

Operations Document V260508

Appendix

Safety Policy V230917

Form F1 – Application Form V240405

Form F2 – Screening Form V240808

Form F3 – Scan Information Form V240405

Rush Imaging Research Core Operations Manual for MRI

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1. Overview of RIRC

The Rush Imaging Research Core (RIRC) is a research-only facility that houses a 3 Tesla Siemens Prisma scanner with the XR 80/200 gradient system, a variety of coils including a 64-channel head coil, parallel transmit capabilities, an MR elastography unit for measurements of tissue elasticity, and an extensive list of pulse sequences and packages providing advanced, whole-body imaging capabilities. RIRC houses an array of Nordic Neuro Lab hardware and software for functional MRI stimulus delivery, collecting subject feedback, and eye tracking. A Bracco Empower MR unit is available for studies that require MR contrast.

The RIRC is located adjacent to the diagnostic MR imaging suite on the 5th floor of the Paul and Joan Rubschlager building, a new \$450 million facility at Rush University Medical Center dedicated to cancer and neuroscience care. The facility has a dedicated MR physicist who performs quality checks on RIRC's MRI scanner, supports and guides RIRC users on optimal sequences and experimental approaches, sets up optimized imaging protocols tailored to each project, programs and tests acquisition pulse sequences, and aids users with data management, usage, and interpretation. RIRC also has a dedicated MRI analyst who supports the core users by developing, implementing and applying advanced image processing and analysis tailored to each research project. A full-time certified MR technologist supports the operations of the facility. Access to the collected images is provided via a RIRC-managed data server, with user access available through secure FTP & SSH.

2. Personnel & Contact Information

Konstantinos Arfanakis, Ph.D. (RIRC Director)

Konstantinos_Arfanakis@rush.edu

Christopher Sica, Ph.D. (Technical & Operations Director for MRI)

Christopher_Sica@rush.edu

RAB 5th Floor, Office 5183

Office Phone: 872-318-7685

Mohammad Rakeen Niaz, Ph.D. (Research MRI Analyst)

Mohammad_Niaz@rush.edu

RAB 5th Floor, Office 5181

Kaleb T Gustafson (MRI Technologist)

Kaleb_T_Gustafson@rush.edu

Scanner Phone: 872-318-7688

3. Facility Information

Operating Hours: 9 AM – 5 PM Mon - Fri

Access to the Facility: RIRC is located on the 5th floor of the RAB building at 1520 W. Harrison Street. If you are coming from the Atrium, take the 4th floor corridors through the Tower to the RAB building. If entering the RAB building from the ground entrance, enter through the lobby and take the elevators to the 5th floor.

Parking: Parking is available at both the main Rush parking deck as well as the parking garage adjacent to the RAB building.

Scheduling System: <https://core.bookitlab.com/rush-GMCF/Login.aspx>

4. Equipment & Software

Siemens Prisma 3 Tesla MRI scanner

- Software Revision XA30A
- XR Gradient System
 - 80 mT/m gradients (Vector Sum)
 - 200 mT/m/ms slew rate
 - Three 1st Order Shims & Five 2nd Order Shims
- RF System
 - 2-Channel Parallel Transmit Body Coil (ZOOMit)
 - 64-Channel simultaneous reception
- Receive Coils
 - 1-Ch Tx-Rx Head Coil
 - 64-Ch Head/Neck
 - 20-Ch Head/Neck
 - 32-Ch Spine Coil
 - 18-Ch Body Surface Array
 - 18-Ch UltraFlex Large Surface Array
 - 18-Ch UltraFlex Small Surface Array
 - 16-Ch Shoulder Large
 - 16-Ch Shoulder Small
 - 15-Ch Knee Tx/Rx
- Siemens TIM Application Suite
 - Neuro
 - Angio
 - Cardiac
 - Abdominal
 - Pelvis
 - Oncology
 - Breast
 - Orthopedics
 - Pediatric
 - Spectroscopy
- Siemens Sequences
 - Motion Reduction: 3D PACE & BLADE
 - Metal Artifact Reduction: WARP & SEMAC
 - Accelerated Imaging: Compressed Sense SPACE & Time-Of-Flight
 - Accelerated Imaging: Simultaneous Multi-Slice (BOLD, DTI, TSE)
 - Accelerated Imaging: ZOOMit (Reduced FOV SPACE & EPI)
 - Phase Contrast Flow Quantification (2D & 4D Cardiac)
 - 2D MR Elastography (Liver)
 - MR Spectroscopy: PRESS, MEGA-PRESS, 2D & 3D CSI
 - Diffusion Tensor Imaging: MDDW, QSPACE, and Free
 - 3D Arterial Spin Labeling (Multi – Delay PCASL, GRASE-based)
 - Deep Resolve (Deep Learning Acceleration)
 - T2 Mapping (Multi-Echo Spin Echo)
 - T2* Mapping (mGRE)
 - T1 Mapping (MP2RAGE & VFA)

- Additional Research Sequences
 - Minnesota (CMRR) Multi-band for fMRI BOLD & DTI
 - Minnesota (CMRR) Spectroscopy Package
 - 3D MR Elastography (Brain)
 - 3D PCASL (University of Pennsylvania – Spiral based)
 - 3D Ultrashort Echo Time (UTE) WIP
 - QALAS (Simultaneous T1, T2, PD, Myelin Volume Fraction Mapping)
 - MAPPS (Simultaneous T2 and T1rho Mapping)
 - ME-MPRAGE (Multi-Echo MPRAGE)
 - QDESS (Quantitative DESS)
 - SAGE (Spin & Gradient Echo EPI)
 - vNAV MPRAGE & SPACE

- fMRI equipment (Nordic Neuro Lab)
 - HD Goggles with integrated Eye Tracking Units
 - 40" UHD LCD Display
 - Hand-Held Response Grips
 - Syncbox (Communication between scanner trigger & stimulus presentation)
 - Stimulus Presentation Software (nordicAktiva, Psychtoolbox)

- MR Elastography
 - Resonant Active Driver
 - Circular Paddle Passive Driver [18.5 cm radius]
 - Flexible Foam Small Driver [12.5 x 12.5 x 2 cm]
 - Flexible Foam Large Driver [27.0 x 12.5 x 2 cm]
 - Head Pillow Driver [8.5 x 6.5 x 2 cm]
 - Sequences and analysis software to produce tissue stiffness maps

- Bracco Empower MR Contrast Delivery Unit
- Hokanson Cuff Inflator
 - Inflation Device: adjustable pressure up to 300 mmHg, rapid inflation or deflation in 1–2 sec
 - Flexible Cuff
- CO2 Delivery Unit
 - CO2 Tank
 - Medtronic CapnoStream 35: respiratory monitoring

Visit our website to see pictures of instrumentation:

<https://www.rushu.rush.edu/research-rush-university/rush-core-laboratories/rush-imaging-research-core/instrumentation>

RIRC Data Storage Server

- FTP Access through vsFTPD (very secure FTP daemon)
- SSH access through OpenSSH

RIRC Image Analysis

- Freesurfer (with manual corrections)
- Brain segmentation and total volumes (i.e. gray matter, white matter, CSF volumes, and ICV)
- Deformation based morphometry
- Diffusion Tensor Imaging (FA, MD, axial & radial diffusivity)
- Free-water diffusion imaging
- White matter tractography
- White matter hyperintensity segmentation
- Segmentation of other lesions, regions, organs, tissues, body parts
- Quantitative Susceptibility Mapping
- Resting-state fMRI
- Task-based fMRI
- Regional quantification (e.g. T2, perfusion, tissue stiffness, etc.)
- T1, T2, PD mapping (via QALAS sequence)
- T2* mapping
- Shape analysis
- GABA quantification (via MEGA-PRESS sequence & Gannet package)
- Proton Density Fat Fraction (PDFF)
- Custom Pipelines
- Voxel-wise linear regression
- Custom voxel-wise or node-wise statistical analysis

5. Services Fee Table

MRI Scans

Users can schedule for minimum of 1 hour, then can add 15-minute intervals. Scheduling research MRI scans are handled through our online scheduling system.

Scan Type	Hourly Rate
Human Scans	\$500
Human Scans (External to Rush Rate) ¹	\$550
Tissue Samples / Phantoms Scans	\$200
Tissue Samples / Phantoms Scans (External to Rush Rate)	\$220
Industry Scans	\$750
Optional Charges	Cost
MR Contrast Agent	\$150
Radiologist Review (Final Report within 24 hrs) ²	\$150
Radiologist Review (Initial Screen + Final Report Within Few Days) ³	\$100
Burning a DVD of a Study	\$10

1. Clinical trials external to Rush, but with an internal Rush PI, will receive the internal rate (\$500 per hour)
2. The final report from the radiologist will be provided within 24 hours (approximately). RIRC collects this fee and forwards the entire amount to the radiologist that performs the review.
3. The radiologist performs an initial screen of the images. Any acute findings will be sent to the study coordinator by e-mail. The final report will be sent within several days. RIRC collects this fee and forwards the entire amount to the radiologist that performs the screen and the review.

Cancellation Policy:

- Any scans cancelled within 24 hours of the scan time will be charged.
- If the subject's weight is 250 pounds or greater, there may be an issue with the subject being able to fit within the MRI scanner bore. We ask that you contact us for a recommendation about scanning. If we recommend against scanning because we feel the subject will not fit within the scanner bore, and you still choose to schedule, you will be charged the scan fee if the subject does not fit and the study is cancelled.
- If the subject has an implant, we ask that you provide via e-mail the manufacturer's documentation or model of the implant prior to the study. We recommend (as a guideline) 7 days prior to the study date. If a scan is cancelled because we determine it is unsafe to scan with the implant, and the documentation or model was not provided, we will still charge the scan fee.

MR Image Processing, Quality Control (QC), and Analysis Costs

RIRC offers **optional** image analysis services. Image analysis charges for a research study are based on the number of analysis pipelines applied per subject and the total number of subjects.

MR Image Processing and Quality Control (QC)	Per-Subject Cost
1. Freesurfer (with manual corrections)	\$150
2. Brain segmentation and total volumes (i.e. gray matter, white matter, CSF volumes, and ICV)	\$120
3. Deformation based morphometry	\$120
4. Diffusion Tensor Imaging (FA, MD, axial & radial diffusivity)	\$120
5. Free-water diffusion imaging	\$120
6. White matter tractography	\$130
7. White matter hyperintensity segmentation	\$120
8. Segmentation of other lesions, regions, organs, tissues, body parts	Pricing to be discussed
9. Quantitative Susceptibility Mapping	\$120
10. Resting-state fMRI	\$120
11. Task-based fMRI	\$120
12. Regional quantification (e.g. T2, perfusion, tissue stiffness, etc.)	\$50
13. T1, T2, PD (QALAS)	\$120
14. T2*	\$120
15. Shape analysis (per structure)	\$150
16. GABA quantification (Gannet)	\$100
17. Custom pipelines	Pricing to be discussed
18. Proton Density Fat Fraction (PDFF)	\$120
Voxel-wise or node-wise statistical analysis	
19. Voxel-wise linear regression (per 100 subjects): \$800 for single model, \$100 for additional models (not requiring additional image registrations)	
20. Custom analyses: pricing to be discussed with investigators	

6. Quality Control Procedures

1) Every week, quality assurance (QA) scans of a vendor-provided spherical water phantom are performed on both the 20 channel and 64 channel head coils. This type of spherical water phantom possesses good long-term stability. These scans include pulse sequences to assess geometric distortion, ghost intensity, temporal stability & tSNR (EPI-based), thermal signal-to-noise ratio (TSE-based), field map and shimming (GRE-based), and transmit coil performance (B1+ mapping). The scans are analyzed in a Matlab-based software analysis package, and the results logged longitudinally. Should any significant changes occur in these measured QA quantities, a ticket will be placed with Siemens to inspect the system and the RF coils.

2) All studies performed at RIRC are checked for any gross acquisition errors, some examples being severe patient motion, failed or sub-optimal shim, or artifacts from any MRI safe or conditional implants. If possible, within a scan session, we will attempt to re-acquire poor quality images. Any adverse scan conditions will be noted on the subject's scan information form.

3) The scanner vendor (Siemens) performs preventative maintenance work on a 12-month cycle as part of our service agreement.

7. Study Startup at RIRC

1) The first step when starting a study at the RIRC is to schedule an initial meeting with Christopher Sica (Technical & Operations Director for MRI, Christopher.Sica@rush.edu). At the meeting, we will discuss the logistics of the study, including (but not limited to):

- General overview of the project
- Desired MRI protocol and sequences
- Image analysis needs
- RIRC image server
- Radiologist Review and MRI contrast
- IRB Status
- Facility Tour
- Online scheduling system
- RIRC Forms
- Any additional logistics or required equipment

2) Following the initial meeting, there are several additional tasks to complete prior to starting a study. These steps can occur in parallel and don't have a required order:

User Tasks

- Complete and Submit the RIRC Application Form
 - A one-page application form must be completed. The application form requests a brief description of the project, IRB information, and contact information.
- MRI Safety Training Course
 - A one-hour safety training course is required prior to the start of the study. This course will cover essential safety information for anyone from your study team working in the MRI environment. We will also cover some workflow logistics in terms of transitioning the study volunteers from the waiting area to the MRI scanner.
 - Currently, the safety training course is scheduled on-demand. Please contact us via e-mail to set up a time.
- IRB Approval with MRI
 - If your research IRB protocol doesn't include MRI yet, approval of the protocol with MRI must be obtained prior to the start of your study. Please contact us if you have any questions about the MRI language for your IRB.

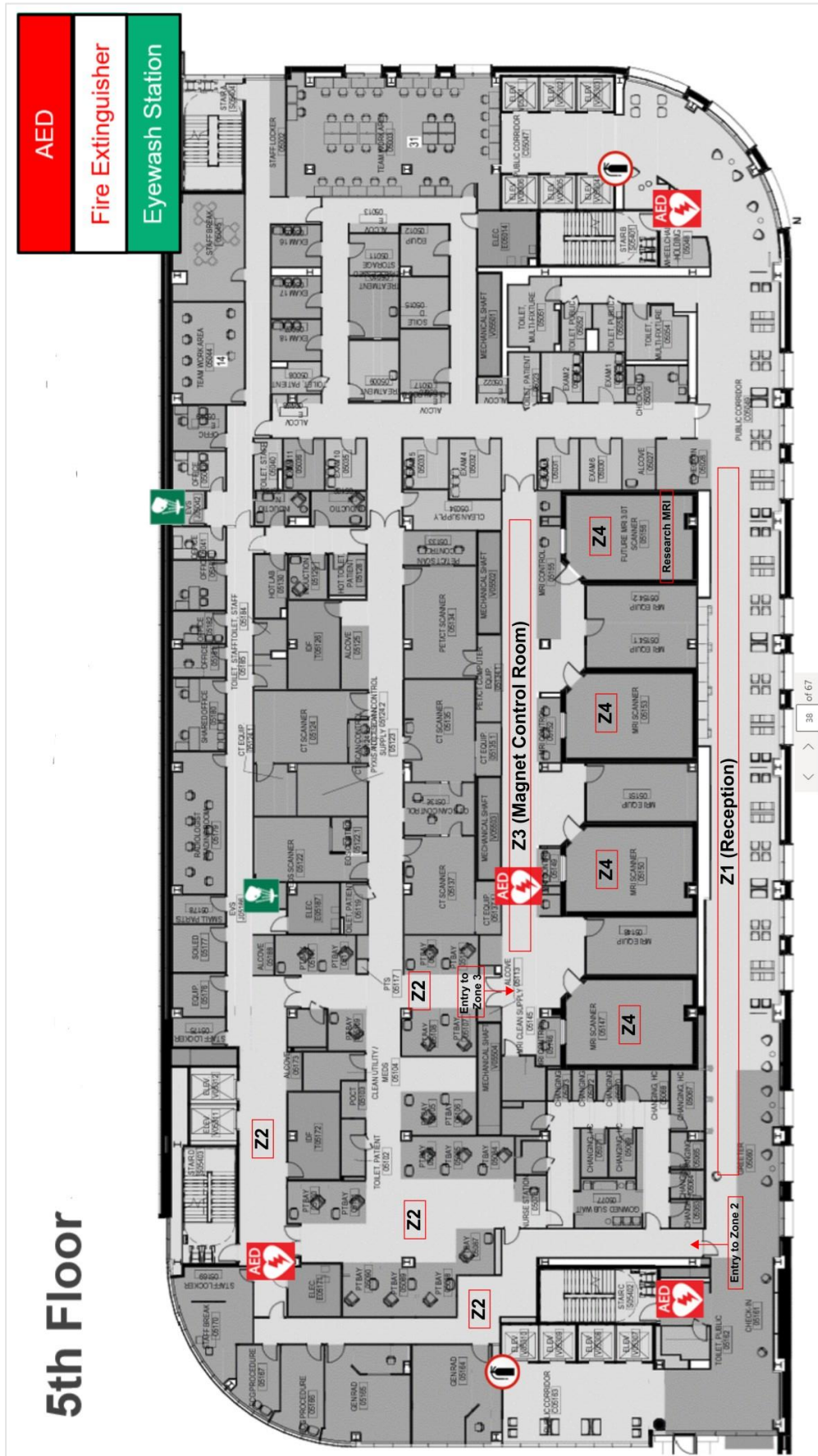
RIRC Tasks

- MRI Protocol Setup
 - Once we have the full details of your desired MRI protocol, the RIRC will implement it on the scanner and perform a test scan on a volunteer (if necessary).
- RIRC Image Server Account Creation
 - The RIRC will create an account on our image server for whomever will be responsible for downloading the images of the study.

8. Study Procedures

- Scheduling your study
 - Please schedule your study on our online scheduling system, located at <https://core.bookitlab.com/rush-GMCF/Login.aspx>
- Prior to the day of the study
 - Complete the RIRC Scan Information Sheet
 - Complete the RIRC Safety Screening Form
 - The screening form should be completed as close to the day of the study as possible. Typically, completing the form within several days of the study will be fine.
 - If any sections of the screening form are checked yes, and/or if you have any questions about possible implants or surgical conditions, please contact Christopher Sica (Technical & Operations Director for MRI) and Kaleb Gustafson (MRI Technologist). Contacting us in advance can help us determine if a cancellation is necessary, which will avoid an unnecessary trip by the participant. If a study is cancelled because we determine it is unsafe to scan with the implant, and the documentation or model was not provided, we will still charge the scan fee.
 - If the subject's weight is 250 pounds or greater, there may be an issue with the subject being able to fit within the MRI scanner bore. We ask that you contact us for a recommendation about scanning.
- On the Day of the Study
 - Bring printed copies of the two completed forms (Scan Information Sheet and Safety Screening Form)
 - When arriving at the diagnostic imaging reception desk on the 5th floor of the RAB building, please inform the person at the front that you are here for a research study on the Prisma and mention the RIRC. They will call back and inform the MRI Technologist, who will give you instructions to either wait in the reception area or proceed to the changing area. Once the technologist is ready, he will come back to accompany you to the MRI scanner.
- After the Study
 - The images from your study will be posted on our image server and available for download via secure FTP or SSH (if requested). They will be posted in your account folder as a single zip file (i.e., one zip file per study), and labeled with the study date.
 - If a radiologist review was requested, we will make the images available to the radiologist. The results will be sent to you via e-mail.
 - If image analysis services were requested, we will post the analysis results in your account folder as an additional zip file.
 - Invoices will be generated monthly by the RIRC and sent to you via e-mail in excel format.

9. Map of the RAB 5th Floor (Including MRI Safety Zones)



10. Appendix - Forms & Safety Policies

Policies

RIRC MRI Safety Policy

Forms

RIRC Study Application Form

RIRC Subject MR Safety Screening Form

RIRC Subject Scan Information Form

Rush Imaging Research Core MRI Safety Policy

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1. Introduction

The purpose of this document is to provide safety guidelines for both employees of the Rush Imaging Research Core (RIRC) and the research staff who access the facility. This document also defines the guidelines to provide a safe environment for study subjects and individuals undergoing MRI examinations at the RIRC. The following guidelines are not comprehensive. If any specific problems or questions arise, the RIRC Technical & Operations Director for MRI should be consulted.

2. Acknowledgements

Certain parts of this document have been adopted from either the *ACR Manual on MR Safety* or the MRI safety policies used by the Rush Radiology department. When a policy has been adapted from either document, there will be a statement noting this.

The below statement, reprinted from the *ACR Manual on MR Safety*, provides a background and overview of the ACR panel on MR safety:

In 2001, the American College of Radiology (ACR) formed a Blue-Ribbon Panel on Magnetic Resonance (MR) Safety in response to various reports in the medical literature and print media detailing MR imaging (MRI) adverse events and incidents involving patients, equipment, and personnel. Initially published in 2002, the ACR MR Safe Practices Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. Subsequently, these guidelines have been reviewed and updated throughout the years to address feedback from the field and installed base as well as changes in the MRI industry since the original publication. The ACR Manual on MR Safety represents the consensus of those representing the Committee on MR Safety of the ACR. The ACR Committee on MR Safety comprises professionals representing diverse fields and backgrounds that include research/academic radiologists, private-practice radiologists, MR/medical physicists, MR safety experts, patient safety experts/researchers, MR technologists, and others. It should be noted that these recommendations are not only appropriate from a scientific point of view but also reasonably applicable in the real world, with consideration given to patient care, throughput, financial pressures, and other considerations.

Additionally, below are links to the current version of the ACR document:

ACR Manual on MR Safety [Current Version]

<https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety>

<https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf>

3. Definitions: MR Zones & Personnel

(This section, in general, has been adopted from the *ACR Manual on MR Safety*)

Zone 1: This region includes all areas that are freely accessible to the general public. This area is outside the MR environment itself and comprises the reception area of the 5th floor of the RAB building.

Zone 2: This area is the interface between the publicly accessible, uncontrolled Zone 1 and the strictly controlled areas of Zones 3 and 4. This includes the subject preparatory and gowning area, locker rooms, bathrooms, and hallways of the 5th floor of the RAB building. Access to this zone is provided by the 5th floor receptionist or a Level 2 MR Personnel.

Zone 3: This area is the region in which free access by unscreened Non-MR Personnel or ferromagnetic objects and equipment can result in serious injury or death due to interactions between the individuals or equipment and the MR scanner's particular environment. This area includes the complete MRI control room bay on the 5th floor of the RAB building. Access is restricted to fully screened subjects, Level 1 and Level 2 MR personnel. Non-MR Personnel will be accompanied by, or under the immediate supervision of and visual contact with a Level 2 MR Personnel. The Zone 3 region is restricted from general public access by a swipe card reader, which only Level 2 MR Personnel will have access enabled. The signage to the right denotes Zone 3.



Zone 4: This area is synonymous with the MR scanner room itself (ie, the physical confines of the room where the scanner is located). Zone 4, by definition, will always be located within Zone 3, as it is the MR magnet and its cryostat that generate the existence of Zone 3. This area includes the four MR scanner rooms on the 5th floor of the RAB building. Access is restricted to fully screened subjects, Level 1 and Level 2 MR personnel. Non-MR Personnel will be accompanied by, or under the immediate supervision of and visual contact with a Level 2 MR Personnel. No loose metal objects or devices are permitted. The signage to the right denotes Zone 4.



The diagram on the next page depicts the 5th floor of the RAB building and the associated zones defined above. Please note that the research magnet shares the space with three other clinical magnets, hence there are four separate Zone 4's on the diagram.

Non-MR Personnel: Research subjects and visitors to the RIRC, and Rush University Medical Center employees who have not taken RIRC MRI safety training, will be referred to as Non-MR Personnel. Non-MR Personnel will be under the supervision of, and in visual contact with, a Level 1 or 2 MR Personnel within Zones 2 and 3, and a Level 2 within Zone 4. Non-MR Personnel must complete a screening form prior to entering Zone 4.

Level 1 MR Personnel: Rush University Medical Center employees who have taken the RIRC MRI safety training course are categorized as Level 1 MR Personnel. Swipe card access to Zone 3 will not be granted to Level 1 MR Personnel. Level 1 MR Personnel can move freely and unaccompanied within Zones 2 & 3. If it is necessary for a Level 1 MR Personnel to enter Zone 4, they will do so under the supervision of a Level 2 MR Personnel.

Level 1 MR Personnel can accompany Non-MR Personnel through Zones 2 & 3.

Level 2 MR Personnel: Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues, including, but not limited to, RF safety, dB/dt-related safety of time-varying imaging gradients, cryogen safety, contrast agent safety, etc, will be referred to as Level 2 MR Personnel. These individuals will have swipe card access to Zone 3. Only Level 2 MR Personnel are permitted to operate the MRI scanner, and are responsible for accompanying all other personnel into and throughout Zone 4.

4. MR Screening Procedure

The purpose of the screening procedure is to determine whether the research MRI can proceed, based on the information provided on the RIRC screening form. Certain types of implants and devices present a risk in the MRI environment and may preclude the subject from receiving a research MRI. For further information on how specific implants, devices and conditions are treated, please see Section 7.

In general, if we feel a device or condition poses an unacceptable risk, or we are not able to determine the level of risk, we will not scan the subject. While a diagnostic MRI presents a risk-benefit opportunity to the person receiving the scan, there typically is no benefit associated with a research MRI to offset any associated risks.

Non-MR Personnel (Research Subjects): The first stage of the screening procedure is to complete the RIRC screening form. If any issues or questions arise while completing the form, or if any section is checked with a Yes, please contact the RIRC Technical & Operations Director for MRI. In particular, please contact us with questions regarding the classification of an implant (MRI safe, MRI conditional, or MRI unsafe/unknown). This will give us time in advance to determine if the MRI needs to be cancelled, and help prevent unnecessary travel by the research subject if the scan is cancelled.

Ideally, the screening form should be completed as close to the scan date as possible (typically within several days of the scan). Please bring the screening form to the MRI scan. After the MR technologist has reviewed the form and determined it is safe to proceed with the research MRI, the next step will be to prepare for the MRI by removing metallic objects.

Research subjects undergoing a MRI must remove all metallic belongings and devices on or in them (watches, jewelry, pagers, cell phone, remove body piercings, contraceptive diaphragms, cosmetics containing metallic particles (such as eye make-up or magnetic eyelashes). For pediatric subjects, toys, pillows, stuffed animals, and other comfort items are not permitted in Zone 4. Clothing items that contain metallic fasteners, hooks, zippers, loose metallic components, metallic threads, glitter, or electrically conductive materials must also be removed. Gowns without metal fasteners are available to change into if needed. A complete list of instructions to follow is listed on the RIRC MR Safety Screening Form. After the research subject has removed all metallic materials, they will then pass through the ferromagnetic detection system (MetraSens) for a final check prior to their MRI scan.

Non-MR Personnel (RUMC employees): Non-MR Personnel should complete a RIRC screening form before entering Zone 4 (this should be completed each time they visit RIRC). As with Level 1 & 2 MR Personnel, all loose metallic objects must be removed before entering Zone 4.

Level 1 & 2 MR Personnel: Level 1 & 2 Personnel must complete a RIRC screening form, which will be kept on file. If any medical changes occur (surgery, injury with metallic fragment, etc), the screening form must be completed again. Level 1 & 2 MR Personnel should remove all loose metallic objects before entering Zone 4.

5. Special Patient Population Considerations

Health care practitioner pregnancies: Pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy. Acceptable activities include, but are not limited to, positioning patients, scanning, archiving, injecting contrast, and entering the MR system room in response to an emergency. Although permitted to work in and around the MR environment, pregnant health care practitioners are requested not to remain within the MR scanner bore or Zone IV during actual data acquisition or scanning. These recommendations are based on the preponderance of data on 3T magnetic fields. **(Section adopted from *ACR Manual on MR Safety*)**

Patient pregnancies: Due to the potential for unknown risks, and the lack of safety data regarding pregnancy at field strengths higher than 1.5T, we do not scan pregnant patients.

Breastfeeding patients: Breastfeeding research subjects will not be scanned using protocols calling for gadolinium-based contrast media but may be scanned with any non-contrast protocol.

Pediatric population: We do scan pediatric research subjects. It is possible for a single accompanying companion to remain in the MRI scanner room during the study, but they must pass the RIRC screening procedure. If sedation is required, it is the responsibility of the RIRC user to obtain IRB approval and services from the anesthesiology department.

Prisoners/Detainees/Parolees: We do not scan participants from this population, due to the presence of ferromagnetic shackles or other metallic prisoner restraining-devices (such as RF identification or tracking bracelets). Accompanying law enforcement officers often carry firearms, which present a severe hazard in the MR environment.

6. MRI Contrast Agents

Studies that use MR contrast agents (Group II, gadolinium-based, macrocyclic) no longer require an estimated glomerular filtration rate (eGFR) measurement. This policy follows the recommendation from the Rush Gadolinium Policy Update. Group II gadolinium agents are not associated with nephrogenic systemic fibrosis (NSF), and a creatine or eGFR measurement is no longer required before the MRI study.

The contrast agent will be used in accordance with the study IRB approved research protocol. If the IRB associated with the study does not have contrast as part of the MRI protocol, RIRC will be unable to use contrast during the scan.

7. Implants, Devices, Conditions, and Objects

Please see the posters on the following pages for definitions of MRI Safe, Conditional and Unsafe devices. A device or implant with **unknown** characteristics should be considered MRI Unsafe and we will not scan subjects with these devices.

7.1 Implants & Devices

a) We will not scan subjects with the following implants or devices present. Additionally, individuals with the following devices may not enter Zone 4:

- Cardiac Pacemaker
- Epicardial Pacer Wire
- Implantable Cardioverter Defibrillators
- Diaphragmatic Pacemakers
- Medication Pumps (IMED, IVAC, morphine, chemotherapy, and others)
- Cochlear Implants
- Metallic Drug Delivery Patch
- Neurostimulators
- Swan-Ganz Catheter
- Foley Catheter
- Dentures
- Shunts
- Holter Monitors
- Artificial Limbs
- Ventilators not designed for MRI usage
- Any other electromechanically activated device
- Any unknown device

b) We will scan subjects with the following devices, if they are labeled MRI safe or MRI conditional and documentation is provided:

- Intracranial Aneurysm Clips
- Arteriovenous Malformation Clips
- Ports for dialysis or IV therapy
- Prosthetic Eyes
- Ear Implants
- Orthopedic implants (joint prosthesis, screws, plates, suture wire. The devices must be firmly attached to the bone).
- Ordinary hemostatic surgical clips
- Feeding Tubes
- Copper-based IUD devices
- Most Dental Devices (fillings, crowns, implants, fixed bridges, permanent retainers, palate expanders. The devices must be firmly attached to the teeth or the bone).
- Intravascular Devices (If the device was implanted six or more weeks prior to the MRI scan)

7.2 Conditions

- a) Eye Surgery or Eye Injury: We will scan subjects in the case of eye surgery or eye injury only if they have a biplanar x-ray demonstrating no metal has been implanted or is residual (in the case of injury).
- b) Other injury involving metallic fragments: A biplanar x-ray will be required to verify no residual metallic fragments are present
- c) Permanent Eyeliner, Lip Liner, Lip Coloring, Tattoos, Skin Staples: Skin staples must not be ferromagnetic, but otherwise we will scan. The subject will be informed of the potential for heating of these superficial objects.
- d) Home-Made Tattoos: The decision to scan will be dependent upon the age and composition of the tattoo.
- e) Unconscious or unresponsive subject: We will not scan a subject that is unconscious or unable to respond verbally, unless they are under an IRB approved sedation protocol.

7.3 Objects

The section has been **adapted from Rush Radiology MRI Sedation Policy (MRI-Safety-13)**.

Sedation Preparation: Sedation subjects who receive oral or IV drugs should be prepared in Zone 2. General anesthesia subjects should be prepared in Zone 3 (drip set-up, intubation and induction of anesthesia with or without ventilation) when using a MR unsafe anesthesia machine. Anesthesia can be prepared within the magnet room with a MR conditional anesthesia machine. **Non-MRI conditional oxygen cylinders should NOT be used in the MRI room.** MR conditional anesthesia machine should be immobilized outside the 200 Gauss lines to avoid being attracted by the magnetic field.

Monitoring Equipment: Only MR safe/conditional monitoring equipment will be allowed within the MRI room. Physiologic monitors that contain microprocessors or other similar components may leak RF, producing electromagnetic interference that can substantially alter MR images. To prevent adverse radiofrequency related interactions between the MR system and physiologic monitors, RF-shielded cables, RF filters, special outer RF-shielded enclosures, or fiber-optic techniques can be utilized to prevent image-related or problems in the MR environment. Routine check and cleaning by Engineer Department is suggested.

Thermal injuries may occur with the use of monitoring equipment and accessories comprised of wires, cables, or components made from conductive materials. It is important to follow closely the instructions and recommendations from the manufacturers regarding the use of these devices in the MR environment. RF padding could be placed upon all necessary electrically conductive material that touches the patient during scanning. MR conditional ECG electrodes should be used. Distortion of the ECG within the magnetic field can make interpretation of the ECG complex unreliable. Routine monitoring of heart rate and rhythm may also be accomplished using pulse oximetry.

Support Devices: Necessary or critical devices that have ferromagnetic components may still be used in Zone 3, but they should be properly labeled with MR safety warning information and should be under the direct supervision of specifically designated level 2 MR personnel who are thoroughly familiar with the device, its function, and the reason supporting its introduction to Zone III. These devices should be placed outside of the pre-defined area to prevent them from being moved too close to the MR magnet room. If users are unsure of the safety of any device, the device should be checked with a hand-held magnet before entering the Zone III.

Only MRI compatible laryngoscopes with MRI compatible batteries should be used in the MRI room. Only MRI compatible stethoscopes that contain no metal and are completely plastic can be brought into the MRI scanners. The regular stethoscopes are **NOT** MRI safe. In an extreme emergency when the regular stethoscope must be used in the MRI scan room, it **MUST be** held securely so that it is not pulled into the scanner.

Understanding MRI Safety Labeling

The MR environment has unique safety hazards for patients with implants, external devices and accessory medical devices. Implants, medical devices and other equipment used in or near the MR

environment should be labeled as **MR Unsafe**, **MR Conditional**, or **MR Safe**.



MR Unsafe items should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned.

MR Conditional items may safely enter the MRI scanner room only under the very specific conditions provided in the labeling. Patients should not be scanned unless the device can be positively identified as MR Conditional AND the conditions for safe use are met.

The conditions for safe use will be different based on the intended use of the device.

For **items intended to enter the bore of the MRI system**, the MRI Safety labeling should be matched with the MRI system for:

- Static field strength
- Maximum spatial field gradient
- dB/dt limitations (usually only applicable to active implants)
- SAR limits
- Any other conditions needed for safe use of the device, for example restrictions on the types of coils that may be used

When present, information about expected temperature rise and artifact extent may inform the risk/benefit decision of whether or not a patient should undergo an MRI examination. Expected temperature rise and artifact extent information are not conditions that must be met.

Items NOT intended to enter the bore of the MRI system usually have gauss line positioning restrictions or requirements to tether or affix the device to an unmovable part of the room.

MR Safe items pose no safety hazards in the MR environment. They may be placed anywhere in the MR environment. Patients with MR Safe devices have no scanning restrictions.



Magnetic Resonance Imaging Tips for Scanning Patients with Implants



- Follow your site's process for screening the patient
- Identify the manufacturer and model of any implanted devices
- Locate the MRI safety information in the device manufacturer's labeling

Look for one of these icons:



MR Safe. Patients with MR Safe devices have no scanning restrictions.



MR Conditional. For patients with MR Conditional devices, implant conditions should be matched with the MR system information.

- Consult your MR system manual for MR system information
- Ensure that the MR system meets all conditions provided in the MR Conditional labeling
- If conditions are not met, the patient should not be scanned



MR Unsafe. Patients with MR Unsafe devices should not be scanned. Assume any unidentified implant is MR Unsafe.

BEFORE



- Document device information in the medical record
 - Consult a physician for any risk/benefit decisions
- For MR Conditional devices:
- Follow all pre-scan conditions, such as special programming modes

DURING

- For MR Conditional devices, follow all scan conditions such as specific absorption rate (SAR) restrictions or patient positioning instructions
- Monitor the patient at all times

AFTER

- Assess the patient for discomfort or injuries
- Follow any post-scan conditions, such as device checks or programming

8. Additional MR Scan Considerations

8.1 Acoustic Noise

Overview (Section adopted from *ACR Manual on MR Safety*): All patients and volunteers should be offered and encouraged to use hearing protection prior to undergoing imaging in MR scanners. The FDA considers MRI systems capable of producing sound pressures that exceed 99 A-weighted decibels (dB(A)) with hearing protection in place as a significant risk. The International Electrotechnical Commission (IEC) standard on this issue (IEC 60601-2-33:2010) also states that, for all equipment capable of producing more than an A-weighted root mean square (rms) sound pressure level of 99 dB(A), hearing protection shall be used for the safety of the patient, and this hearing protection shall be sufficient to reduce the A-weighted rms sound pressure level to below 99 dB(A). Additionally, all patients or volunteers in whom research sequences are to be performed (i.e., MR scan sequences that have not yet been approved by the FDA) should also have hearing protective devices in place prior to initiating any MR sequences. Without hearing protection in place, MRI sequences that are not FDA-approved should not be performed on patients or volunteers.

Procedures: Hearing protection will be provided during the MRI scan, either in the form of MR compatible headphones or ear plugs. The use of hearing protection is required.

8.2 Thermal Considerations

Overview: The radiofrequency (RF) fields used in MRI can cause excessive heating and possibly burns. The following overview is **adapted from the *ACR Manual on MR Safety*** and provides a description of the possible issues associated with RF-related heating.

To avoid potential issues and injuries associated with RF fields, all unnecessary or unused electrically conductive materials external to the patient should be removed from the MR system before the onset of imaging. It is insufficient to merely disconnect and leave unused, unnecessary electrically conductive devices, such as surface coils or EKG leads, in the MR scanner with the patient during imaging. All electrical connections, such as those used for surface coils or patient interfaces used for monitoring systems, must be visually checked by the scanning MR technologist prior to each use to ensure the integrity of the thermal and/or electrical insulation.

Focal heating: Electrical voltages and currents can be induced within electrically conductive materials that are within the bore of the MR scanner during the MRI process. This might result in heating of this material by resistive losses. This heat might be of a caliber sufficient to cause injury to human tissue. As noted below, among the variables that determine the amount of induced voltage or current is the consideration that the larger the diameter of conductive loops, the greater the potentially induced voltages and currents, and thus the greater the potential for resultant thermal injury to adjacent or contiguous patient tissue.

Transmitting coil proximity/contact: To help safeguard against thermal injuries or burns, pads meeting the MR system manufacturer's specifications should be placed between the patient's skin and any transmit RF coil. These pads protect the patient from proximity to the transmit RF coil, to ensure spacing between the transmit coil and the patient's tissues. A single-layer bedsheet is insufficient insulation or spacing. It is also important to recognize that large conducting loops may be created within the patient's own tissues by points of skin-to-skin contact, such as thigh-to-thigh contact. Thus, providing insulation/pads in such areas may also be required to prevent burns. To prevent excessive heating and possible burns in patients in association with MR procedures, the previously published guidelines are recommended.

Large caliber–induced current loops: The greater the caliber of an induced current loop, the greater the amount of current, and therefore potential for heating, that may be induced within that loop. Therefore, it is important to ensure that the patient's tissues, such as their arms and/or legs, do not form large-caliber conductive loops. Examples of large caliber–induced current loops involving the patient's own tissues for which burns have been reported include the inner thighs or the fingers and the outer thighs. Usage of supplied insulation pads to help prevent large caliber–induced current loops is recommended.

Resonant heating: Furthermore, it is possible, with the appropriate configuration, lead length, static magnetic field strength, and other settings, to introduce resonant circuitry between the transmitted RF power and the lead. This could result in very rapid and clinically significant lead heating, especially at the lead tips, in a matter of seconds with a magnitude sufficient to result in tissue thermal injury or burns. This can also theoretically occur with implanted leads or wires even when they are not connected to any other device at either end. It has been demonstrated in vitro that heating of certain implants or wires may be clinically insignificant at 1.5 T but quite significant at 3 T. However, it has also been shown that specific implants might demonstrate no significant thermal issues or heating at 3 T but may heat to clinically significant or very significant levels in seconds at 1.5 T. Thus, it is important to follow established product MR Conditional labeling and safety guidelines carefully and precisely, applying them to and only to the static magnetic field strengths at which they had been tested. MR scanning at either stronger and/or weaker magnetic field strengths than those tested may result in significant heating where none had been observed at the tested field strength(s).

The concern for induced current loops is even greater when electrically conductive wires or leads are involved. When electrically conductive material (wires, leads, implants, etc.) are required to be entirely or partially within the volume undergoing direct RF irradiation during MRI, care should be taken to ensure that no large-caliber electrically conducting loops (including patient tissue) are formed within the MR scanner during imaging. The FDA has noted several reports of serious injury, including coma and permanent neurological impairment, in patients with implanted neurological stimulators who underwent MRI examinations. The injuries in these instances resulted from heating of the electrode tips.

For all the above reasons, exposure of electrically conductive leads or wires to the RF-transmitted power during MR scanning should only be performed with caution and with appropriate steps taken to ensure significant lead or tissue heating does not result.

When any portion of electrically conductive materials external to the patient are required to be within the volume of the transmitting RF coil of the MR scanner during imaging, care should be taken to place thermal insulation (including air, pads, etc.) between the patient and the electrically conductive material, while simultaneously attempting to keep (as much as feasible) the electrical conductor from directly contacting the patient during imaging. It is also appropriate to try to position the leads or wires as far as possible from the inner walls of the MR scanner if the body coil is being used for RF transmission. When it is necessary that electrically conductive leads directly contact the patient during imaging, consideration should be given to prophylactic application of cold compresses or ice packs to such contact areas.

Procedures: The following procedures will be followed to prevent excessive heating and potential burns during MRI scans. These procedures are **adapted from the Rush Radiology MRI Thermal Burns Policy (MRI-Safety-12)**:

1. Prepare the patient for the MR procedure by using insulation material (i.e., appropriate padding) to prevent skin-to-skin contact points and the formation of “closed-loops” from touching body parts.
2. Insulating material (minimum recommended thickness, 1 cm) should be placed between the patient’s skin and transmit RF coil (also known as the **bore**) that is used for the MR procedure (alternatively, the transmit RF coil itself should be padded). There should be no direct contact between the patient’s skin and the transmit RF body coil of the MR system. This may be accomplished by having the patient place his/her arms over his/her head or by using elbow pads or foam padding between the patient’s tissue and the transmit RF body coil of the MR system.
3. Use only electrically conductive devices, equipment, accessories (e.g., ECG leads, electrodes, etc.), and materials that have been thoroughly tested and determined to be safe or otherwise acceptable for MR procedures.
4. Carefully follow the MR Safe or MR Conditional criteria and recommendations for implants and devices made from electrically conductive materials (e.g., bone fusion stimulators, neurostimulation systems, cardiac devices, cochlear implants, etc.).

5. Before using electrical equipment, check the integrity of the insulation and/or housing of all components including surface RF coils, monitoring leads, cables, and wires. Preventive maintenance should be practiced regularly by a MRI technologist for such equipment.
6. Remove all non-essential electrically conductive materials from the MR system prior to the MR procedure (i.e., unused surface RF coils, ECG leads, EEG leads, cables, wires, etc.).
7. Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing thermal and/or electrical insulation between the conductive material and the patient.
8. Keep electrically conductive materials that must remain within the transmit body RF coil or other transmit RF coil from forming conductive loops. Note: The patient's tissue is conductive and, therefore, may be involved in the formation of a conductive loop, which can be circular, U-shaped, or S-shaped.
9. Position electrically conductive materials to prevent "cross points". A cross point is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches either the patient or sides of the transmit RF coil more than once. Even the proximity of conductive materials with each other should be avoided because cables and RF coils can capacitively-couple (without any contact or crossover) when placed close together.
10. Position electrically conductive materials (e.g., cables, wires, etc.) to exit down the center of the MR system, not along the side of the MR system or close to the transmit RF body coil or other transmit RF coil.
11. Do not position electrically conductive materials across an external metallic prosthesis (e.g., external fixation device, cervical fixation device, etc.) or similar device that is in direct contact with the patient.
12. Allow only properly trained individuals to operate devices (e.g., monitoring equipment) in the MR environment.
13. Follow all manufacturer instructions for the proper operation and maintenance of physiologic monitoring or other similar electronic equipment intended for use during MR procedures.
14. Electrical devices that do not appear to be operating properly during the MR procedure should be removed from the patient immediately.
15. RF surface coil decoupling failures can cause localized RF power deposition levels to reach excessive levels. The MR system operator will recognize such a failure as a set of concentric semicircles in the tissue on the associated MR image or as an unusual amount of image non-uniformity related to the position of the transmit RF coil.
16. Closely monitor the patient during the MR procedure. If the patient reports sensations of heating or other unusual sensation, discontinue the MR procedure immediately and perform a thorough assessment of the situation.
17. For patients with extensive, dark, or loop-shaped tattoos or tattooed eyeliner, to decrease the potential for RF heating of the tattooed tissue, place a cold compress or ice pack on the tattooed areas and kept in place throughout the MR process if these tattoos are within the volume in which the body coil is being used for RF transmission.
18. For patients with non-ferromagnetic skin staples or multiple implants in proximity to each other, place a cold compress or ice pack along them.



MRI BURN PREVENTION

Tips for Keeping Patients Safe

Screen patients for implants, devices, and other metallic objects. Assume anything unknown is MR Unsafe.



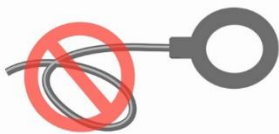
Screen objects to ensure that anything entering the scan room is MR Conditional or MR Safe. Match conditions on MR Conditional devices with your scanner. All metals, even non-ferromagnetic ones, have the potential to heat up and cause burns.

Have patients change out of street clothes whenever possible.



Position patients to avoid skin-to-skin contact (e.g. no hands on hips, no crossed arms, no crossed legs, etc.).

Always use the manufacturer-provided padding to insulate the patient. Sheets and blankets may be added for patient comfort but are not a substitute for manufacturer-provided padding.



Route cables out of the scanner in a straight line. Don't coil cables or allow them to touch the patient.

Use only Normal Operating Mode and the lowest SAR, whenever possible.



Keep your eyes and ears on the patient at all times. Stay in communication with patients to identify warming. Monitor sedated patients using MR Conditional monitoring equipment.



9. Quench, Disaster & Emergency Policy

The following sections have been adapted from the associated Rush Radiology MRI policies:

9.1 Water Damage:	Disaster Policy (MRI-Safety-18)
9.2 Power Outage:	Disaster Policy (MRI-Safety-18)
9.3 Quench:	Disaster Policy (MRI-Safety-18) Quench Policy (MRI-Safety-09)
9.4 Code:	Disaster Policy (MRI-Safety-18) Medical Emergency Code Procedures (MRI-Safety-08)
9.6 Unforeseen Ferrous Objects:	Unforeseen Ferrous Objects in MRI (MRI-Safety-06)

9.1 Water Damage

Water damage can be caused by roof failure, burst pipes, storm surges, or rising water levels. A small quantity of water in contact with an MRI scanner can incapacitate or destroy the equipment. In the event of impending water damage, cover gantries and equipment with sturdy plastic, taped in place. Where possible, electronic components should be raised from the ground. Radiofrequency shields, particularly the floor assembly, may be significantly damaged and may need to be replaced following a flood if not designed to protect against water damage.

9.2 Power Outage

Without electrical power to the vacuum pump/cold head to reliquefy the cryogen within a superconducting MR system, the cryogens will begin to boil off at an accelerated rate. Depending on cryogen vent design and boil-off rate, the additional cryogenic gas discharge may freeze any accumulated water in the cryogen vent, occluding the pipe and increasing the possibility for a cryogen vent breach in the event of a quench. At some point, if power to the vacuum pump is not restored, likely a couple days to perhaps a week after power is lost, the magnet will spontaneously quench, discharging most or all of its remaining cryogenic gases. This poses a safety risk to anyone near the discharge and runs a risk of potentially permanently damaging the magnet coils. However, if power to the vacuum pump/cold head and cryogen levels is restored prior to a quench, there should be no long-term consequences to the magnet's operation from a power interruption. Temporary or backup power electrical should be provided either through on-site or portable emergency generators.

9.3 Quench

Overview: Because of the risks to personnel, equipment, and physical facilities, manual magnet quenches are to be initiated only after careful consideration and preparation. In addition to following those specific recommendations provided by the MRI manufacturer, a facility should initiate a preemptive quench in nonemergent situations only after verifying the function of emergency exhaust systems and verifying or providing means of pressure relief. The facility should check for water leaking from fittings or condensation forming on vent pipe sections as possible signs for water or ice inside the pipe. If/when feasible, a discussion with the device manufacturer regarding an intentional controlled static magnetic field ramp-down may be advisable

Superconductive magnet quenches can potentially create a hazardous environment for patients or any individual in the MRI scanner room due to exposure to cryogenic gas exposure or overpressure generated by cryogen release. The magnet emergency stop button (i.e., Quench button) should ONLY be used in the event of the magnetic field causing patient or personnel injury, and a shutdown of the static field is necessary, or if an

uncontrollable fire or some other unforeseen occurrence requires the quick access of emergency personnel to the examination room.

Definitions

Quench: The term “quench” refers to the release of the cryogenics within the magnet’s cryostat which in turn rapidly reduces the strength of the main magnet field to turn the magnet off. A quench will in general be accompanied by a loud bang or thundering or hissing or rushing sound with the cold gas expulsion. Quenching may cause oxygen deprivation or overpressure in the magnet room if the cryogen evacuation vent malfunctions. Note however, that initiating a quench may not result in total removal of the magnetic field. Some magnets only partially quench and so the field is not completely removed. In such cases care should still be taken when handling ferromagnetic objects near the magnet.

Normal Quench: The escaping cryogenic gases are ducted outside the building to an unoccupied discharge area through the cryogen vent/quench pipe or an emergency exhaust pathway. There is no leak of cryogenic gases observed in the MRI room. The main magnetic field is completely dissipated.

Small Leaks: Small clouds of fog clearly remain above head level and are frequently visibly sucked off by the heating and air conditioning system. They consist of cold air and do not lead to suffocation. In this case, overpressure is not present. There is no risk of suffocation for either patient or personnel. The patient can be removed, either immediately or after a few minutes depending on the patient’s reaction to the situation.

Partial or Complete Failure of Quench Line: The failures of cryogen vent/quench pipe assemblies can lead to considerable quantities of cryogenic gases being inadvertently discharged into the magnet room/Zone IV. Large fog-like clouds including impaired visibility are present. The thermal expansion of the cryogenics, if released into the magnet room, can positively pressurize the magnet room and entrap persons inside until such time that the pressure is equalized. In this case, oxygen deprivation, overpressure in the RF-room, and frostbite become hazards of the environment. Open all doors (the control room door first, and then the MRI room) and evacuate immediately.

Procedures: Quenching may occur by activation of the magnet quench button, or spontaneously, caused by a fault in the magnet itself.

Spontaneous Quench (Uncontrolled Quench)

- Stop scanning or press the stop scan button on the console immediately.
- Remove patient and staff from the MRI scanner room as quickly as possible.
- Do NOT touch a quenched magnet.
- Open the exam room door to prevent a pressure gradient from closing the door.
- If a pressure gradient should occur that prevents escape, the window to the MRI control room should be broken.
- In the event of a cryogen leak, avoid contact with helium cloud and stay low to the ground.
- All individuals should be removed from the MRI suite for 15-20 minutes as the helium cloud dissipates.
- Alert medical center engineering (2-3499), clinical engineering (2-8300), MRI manufacturer, department administrators, and/or in case of a fire, call extension (2-5111) to initiate a “Code Red”.
- Department must remain secure until deemed safe by appropriate personnel.

Initiating a Quench (Controlled Quench)

- This will ONLY be done in a life-threatening emergency triggered by a magnetic event, or if fire or some other unforeseen occurrence requires the quick access of emergency personnel to the examination room.
- A designated MRI technologist in charge can quench the MRI by pressing the quench button after seriously evaluating the situation.
- If a large equipment or object (e.g. oxygen tank) is pinned to the magnet, do NOT try to remove the equipment or object. If/when feasible, a discussion with the device manufacturer regarding an intentional controlled static magnetic field ramp-down is advisable.
- If a person is pinned to the magnet, DO NOT MOVE THE PERSON WITHOUT DIRECTION OF EMERGENCY MEDICAL PERSONNEL UNLESS THERE IS A CRYOGEN LEAK PRECIPITATED BY THE QUENCH. [**See Section 9.6 Unforeseen Ferrous Objects**]
- If a situation arises wherein uncontrolled fire occurs in the MRI room, and firefighters or police need to emergently enter Zones III and/or IV, a decision to quench a superconducting magnet should be seriously considered. A designated Level 2 MR Personnel should verify that the static magnetic field is either no longer detectable or at least sufficiently reduced to prevent a potential hazard to firefighters or others with particular respect to large ferromagnetic objects (e.g., air tanks, pike poles, axes, etc.), communication equipment, and/or helmet cameras. Alert medical center engineering (2-3499), clinical engineering (2-8300), Siemens, department administrators, and/or in case of a fire, call extension (2-5111) to initiate a “Code Red”.
- Department must remain secure until deemed safe by appropriate personnel from the Department of Radiology

MRI Quench Button (Siemens MRI)



9.4 Code

The impulse to respond immediately must be tempered by an orderly and efficient process to minimize risks to subjects, staff, and equipment. This requires specialized training for code teams and, as with fire/police responses, clear lines of authority for screening, access restrictions, and quench. Full resuscitation of patients within Zone 4 is complicated by the inability to accurately interpret electrocardiographic data. Furthermore, this may place at risk of injury all within Zone 4 from ferromagnetic objects that may be on, within, or brought into Zone 4 by emergency response personnel responding to a code.

In case of cardiac or respiratory arrest or other medical emergencies within Zone IV for which emergent medical intervention or resuscitation are required, appropriately trained and certified MR Personnel should immediately initiate basic life support or cardiopulmonary resuscitation as required by the situation while the subject is being emergently removed from Zone 4 to Zone 2, where full resuscitative efforts are to continue. All priorities should be focused on stabilizing (e.g., basic life support with cardiac compressions and manual ventilation) and then evacuating the subject as rapidly and safely as possible from the magnetic environment that might restrict safe resuscitative efforts. If MR personnel with this type of medical training are not available, then the subject should be immediately moved from Zone 4 to Zone 2.

During code procedure, a Code Blue should be initiated. A Level 2 MR Personnel must remain on site prior to the arrival of the emergent responders to ensure that they do not have free access to Zones 3 or 4. The magnet should not be quenched in the event of cardiopulmonary arrest.

9.5 Fire

If a fire occurs within the MRI department and/or scanner, staff must be able to respond appropriately to preserve lives and limit structural damage caused by the fire. MR staff should be familiar with institutional policy regarding fire safety (Fire Plan-Medical Center Response to Fire) including:

- a) Location of nearest fire alarm pull station, and calling (2-5111) to initiate a Code Red.
- b) Location of the nearest MR Safe/Conditional fire extinguisher and its correct method of operation.
Recall the mnemonic P.A.S.S.:

Pull the pin

Aim the hose at the base of the fire

Squeeze the handle of the extinguisher

Sweep from side-to-side while spraying chemical from extinguisher

- c) What to do if they discover a fire. Remember the mnemonic RACE:

Rescue – Rescue patients, staff, students and visitors in the vicinity of the fire

Alarm – Alarm by pulling the closest fire alarm & calling the emergency operator at 2-5111

Confine – Confine the smoke or fire by closing all doors, windows & other sources of airflow

Extinguish – Extinguish the fire using the P.A.S.S. method if it can be done safely.

9.6 Unforeseen Ferrous Objects

Overview: To provide steps if 1) an unforeseen ferrous object is taken into the MR scan room; 2) an MR Conditional device is placed too close to the magnet and is attracted toward the strong magnetic field; or 3) an unexpected implant is found in the patient during the MRI scan.

Definitions

Unforeseen ferrous object: An object that has a magnetic property that produces a strong and powerful attraction between the object and the magnet. It is an item that has mistakenly been taken into the MR environment and is attracted toward the strong static magnetic field.

MR Conditional Device: Portable devices that have been demonstrated to pose no known hazards in an MR environment with specified conditions of use. The device has undergone testing to demonstrate that it is safe or it is made from materials that are considered to be safe if certain separation distance requirements are met.

Unexpected implant or device: An implant or device in the patient's body that is not disclosed during the screening process, but is discovered during the MRI scan.

Procedures

Scenario I: If a person (employee or subject) is pinned by a ferrous object in the scanner, and it is considered to be a harmful or life-threatening situation, quench the MRI magnet and call a Code Blue. For the process of manually initiating a controlled quench, refer to the **Section 9.3 Quench Policy**.

Scenario II: If a ferrous object or MR conditional device is pulled up to or into the magnet and there is NO immediate danger to a person (employee or subject), a quench is not required.

- Do not attempt to remove the object.
- Remove the subject from the MRI room immediately.
- Secure the MRI room to prevent further personal injury or damage.

Scenario III: If an unknown implant or device is discovered in the subject's body during the MRI scan by the MRI technologist, the scan will be stopped and the patient removed from the MRI room. If the subject is under a life-threatening condition, call a Code Blue (also see **Section 9.4 Code**).

I. Approved IRB Protocol & Primary Investigator Information

IRB Study Title:	
IRB Protocol Number:	
IRB Approval & Expiration Date:	

IRB Principal Investigator(s):	
E-Mail Address:	
Position & Department:	

Research Coordinators & Staff		
Name:	E-Mail:	Phone:
Name:	E-Mail:	Phone:
Name:	E-Mail:	Phone:

Project Acronym (A short phrase used to label the project internally at the RIRC)
Name:

II. Financial Information

Projected Scan Usage	
Hours of MRI Scans Needed:	
MR contrast agent required?	<input type="checkbox"/> Y <input type="checkbox"/> N
Radiologist Review of Images required?	<input type="checkbox"/> Y <input type="checkbox"/> N

Funding Information (if available)	
Funding Agency:	
Grant Number(s):	
Project Title (with funding agency):	

III. Documentation & Logistics

Please Provide the following:
1. IRB approval letter, protocol, and consent forms
2. A one paragraph description of the project, providing a basic description.
3. (Optional) Any special considerations you may already know about for your study

Name: _____ DOB: _____ Sex: M F

Height: _____ Weight: _____ Subject Identifier: _____

The following items may be harmful to you during your MR scan and may interfere with the MR examination. Please indicate if you CURRENTLY HAVE or HAVE EVER HAD any of the following. You must provide a "Yes" or "No" answer for every item.

Surgically Implanted Medical Devices	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any type of electronic, mechanical, or magnetic implant (including magnetically-activated implants)
If Y, list type:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Cardiac pacemaker, ICD, defibrillator or other cardiac implant (in place or removed)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Aneurysm Clip
<input type="checkbox"/> Yes <input type="checkbox"/> No	Neurostimulator, diaphragmatic stimulator, deep brain stimulator, vagus nerve stimulator, bone growth/fusion stimulator, spinal cord stimulator, or any biostimulator (in-place or removed)
If Y, list type:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any type of internal electrodes or wires
<input type="checkbox"/> Yes <input type="checkbox"/> No	Cochlear or any other type of ear implant
<input type="checkbox"/> Yes <input type="checkbox"/> No	Implanted drug pump or infusion device (e.g., insulin, baclofen, chemotherapy, pain medicine)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Spinal fixation device
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any type of coil, filter, or stent
If Y, list type:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Artificial heart valve
<input type="checkbox"/> Yes <input type="checkbox"/> No	Artificial eye
<input type="checkbox"/> Yes <input type="checkbox"/> No	Penile implant
<input type="checkbox"/> Yes <input type="checkbox"/> No	Eyelid spring and/or eyelid weight
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any type of implant held in place by a magnet
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any type of surgical clip, staple, or metallic suture
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any IV access port (e.g., Broviac, Port-a-Cath, Hickman, PICC line)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Shunt (including spinal or intraventricular)
If Y, list type:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Artificial limb
If Y, what & where	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Joint Replacement (hip, knee, etc.)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Tissue Expander (e.g., breast)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Surgical or Wire Mesh
If Y, location:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Radiation Seeds
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any other implanted items (e.g., pins, rods, screws, nails, plates, wires)

Removable Medical Devices

<input type="checkbox"/> Yes <input type="checkbox"/> No	Hearing Aid (<i>Remove before entering Zone IV</i>)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Removable drug pump (e.g., insulin, Baclofen, Neulasta)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any type of ear implant
<input type="checkbox"/> Yes <input type="checkbox"/> No	Artificial eye
<input type="checkbox"/> Yes <input type="checkbox"/> No	Triggerfish Contact Lenses (for monitoring intraocular pressure changes)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any type of implant held in place by a magnet
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any type of surgical clip or staple
<input type="checkbox"/> Yes <input type="checkbox"/> No	Medication patch (e.g., nitroglycerine, nicotine)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Artificial limb
If Y, what & where	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Removable dentures, false teeth, or partial plate
<input type="checkbox"/> Yes <input type="checkbox"/> No	IUD, Diaphragm, pessary
If Y, list type:	

Personal Devices

<input type="checkbox"/> Yes <input type="checkbox"/> No	Body piercings
If Y, location:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Wig, hair implants
<input type="checkbox"/> Yes <input type="checkbox"/> No	Tattoos or tattooed liner
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any hair accessories (e.g., bobby pins, barrettes, clips, extensions, weaves)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Jewelry
<input type="checkbox"/> Yes <input type="checkbox"/> No	Metal-containing clothing material and/or underwear
<input type="checkbox"/> Yes <input type="checkbox"/> No	Magnetic cosmetics and hair care (e.g., magnetic eyelashes, magnetic or metallic nail polish)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Electronic monitoring or tagging equipment (e.g., ankle monitor)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Fitness tracker/biometer (e.g., Fitbit)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Any other type of surgically implanted medical devices, removable medical devices or personal items not covered above?
If Y, list type:	

For Female Patients:

<input type="checkbox"/> Yes <input type="checkbox"/> No	Are you pregnant or suspect that you might be?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are you post-menopausal?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are you breast-feeding?

If your study includes MR contrast:

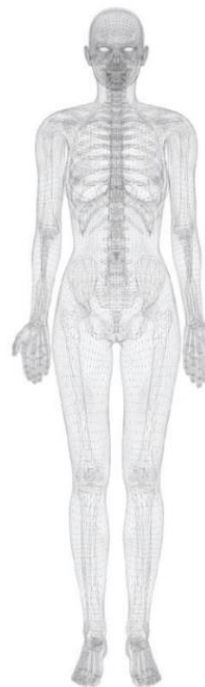
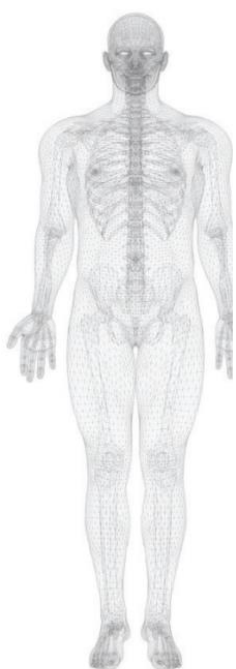
<input type="checkbox"/> Yes <input type="checkbox"/> No	Have you had an allergic reaction to iodinated or gadolinium contrast or a severe reaction to any allergen?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have an acute renal failure or injury?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are you currently on hemodialysis or peritoneal dialysis?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have a condition called Nephrogenic Systemic Fibrosis (NSF)?

Please indicate if you have or have not had any of the following:

<input type="checkbox"/> Yes <input type="checkbox"/> No	Previous MRI examination
<input type="checkbox"/> Yes <input type="checkbox"/> No	Breathing problems, motion disorder, or claustrophobia
<input type="checkbox"/> Yes <input type="checkbox"/> No	Worked as a machinist, grinder, or welder
<input type="checkbox"/> Yes <input type="checkbox"/> No	Injury by a metal object or foreign body (e.g., bullet, BB, shrapnel)
If Y, explain:	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Injury to your eye from a metal object
<input type="checkbox"/> Yes <input type="checkbox"/> No If Y, what was found?	If yes to the above question, did you see medical assistance?
<input type="checkbox"/> Yes <input type="checkbox"/> No If Y, describe what was taken out:	Foreign body removed from eye
<input type="checkbox"/> Yes <input type="checkbox"/> No	Asthma or other allergic respiratory disease
<input type="checkbox"/> Yes <input type="checkbox"/> No	Kidney disease
<input type="checkbox"/> Yes <input type="checkbox"/> No	Diabetes
<input type="checkbox"/> Yes <input type="checkbox"/> No	Hypertension
<input type="checkbox"/> Yes <input type="checkbox"/> No	Previously received contrast agent (dye) for a CT, MRI or other X-ray or study
<input type="checkbox"/> Yes <input type="checkbox"/> No If Y, explain:	Allergic reaction to CT, MRI, X-ray contrast agent (dye)
<input type="checkbox"/> Yes <input type="checkbox"/> No	Spinal fusion procedure
<input type="checkbox"/> Yes <input type="checkbox"/> No	Endoscopy or colonoscopy in last three months
<input type="checkbox"/> Yes <input type="checkbox"/> No	Allergies (including to medication). If yes, list all known allergies:
<input type="checkbox"/> Yes <input type="checkbox"/> No	Surgery or medical procedure of any kind. If yes, list all prior surgeries and approximate dates:

Male:

Female:



MR Hazard Checklist

Please mark the location of any implant, device, or metallic foreign body inside your body or site of surgical operation.

Reference/Source: Kanal's MagnetVision™ app, 2020

Patient Instructions:

1. You will be provided hearing protection during your scan. You will be required to use the earplugs or headphones provided to you during your MR examination, since some patients find the noise levels unacceptable, and the noise levels may affect your hearing if these provided hearing protection devices are not utilized.
2. Remove all jewelry, any body piercings (e.g., necklaces, pins, rings), and cosmetics with magnetic particles
3. Remove all contraceptive diaphragms
4. Remove all hair pins, bobby pins, safety pins, barrettes, clips, etc.
5. Remove all dentures, false teeth, partial dental plates
6. Remove eyeglasses and hearing aids
7. Remove keys, watches, cell phones and pagers
8. Remove all cards with magnetic strips (e.g., credit cards, bank cards, etc.)
9. Remove loose items (paperclips, coins, pens, pocket knife, nail clipper, etc.)
10. Because some clothing may contain metal even when not apparent (i.e. metal threads), the MR technologist may instruct you to remove all clothing and worn/removable items from your body. MR Safe clothing will be provided to you to wear during your MRI scan. This is being done to help ensure your safety during the examination.
11. If you are unable to remove any of the above items please notify the technologist.

I attest that I have answered the above questions accurately, and that I have read and understand the patient instructions. A secure location will be provided for my belongings.

Subject or Legal Guardian Name (Print)

Subject or Legal Guardian Name (Sign)

Date/Time

Reviewed By (Print)

Reviewed By (Sign)

Date/Time

RIRC Use Only

<input type="checkbox"/> Yes <input type="checkbox"/> No	All items on screening form completed?
<input type="checkbox"/> Yes <input type="checkbox"/> No	MetraSens screen passed?
<input type="checkbox"/> Yes <input type="checkbox"/> No	If the participant answered yes to having an implant, was documentation about the implant provided?

Hazard Checklist for Level 2 MR Personnel

<input type="checkbox"/> Yes <input type="checkbox"/> No	Pulse oximetry device
<input type="checkbox"/> Yes <input type="checkbox"/> No	EKG pads/leads
<input type="checkbox"/> Yes <input type="checkbox"/> No	Endotracheal tube
<input type="checkbox"/> Yes <input type="checkbox"/> No	Swan-Ganz catheter
<input type="checkbox"/> Yes <input type="checkbox"/> No	Extra ventricular device
<input type="checkbox"/> Yes <input type="checkbox"/> No	Arterial line transducer
<input type="checkbox"/> Yes <input type="checkbox"/> No	Foley catheter with temperature sensor and/or metal clamp
<input type="checkbox"/> Yes <input type="checkbox"/> No	Rectal probe
<input type="checkbox"/> Yes <input type="checkbox"/> No	Esophageal Probe
<input type="checkbox"/> Yes <input type="checkbox"/> No	Tracheotomy tube
<input type="checkbox"/> Yes <input type="checkbox"/> No	Guidewires
<input type="checkbox"/> Yes <input type="checkbox"/> No	Halo vest

Study Information (For Research Staff to Complete)		
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Project Acronym:		
Subject Identifier:		
Requested Scan Date:		(mm/dd/yyyy)
Requested Scan Start & End Time:		(hh:mm)
Research Staff Completing This Form:		
(Optional) Subject Name:		
(Optional) Date of Birth:		(mm/dd/yyyy)
(Optional) Gender:	<input type="checkbox"/> M <input type="checkbox"/> F	
(Optional) Study Naming Convention:		
Radiologist Review Required:	<input type="checkbox"/> Y <input type="checkbox"/> N	
Contrast Required:	<input type="checkbox"/> Y <input type="checkbox"/> N	

Scanner Information (RIRC Use Only)		
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Siemens Patient Name (Last, First):		
“Study Naming Convention” will be used for the Siemens Patient Name if provided, otherwise we will use as a default ProjectAcronym_SubjectIdentifier (Last_First)		
Siemens Patient ID:		(yyyymmddhhmm)
Actual Scan Start & End Time:		(hh:mm)
Scanner Condition & Image Quality:		
Additional Comments (if needed):		
Contrast Injected: <input type="checkbox"/> Y <input type="checkbox"/> N	If Yes, complete following section:	
Type & Amount:		
Lot Number:		
Expiration Date:		

Scanning Technologist (Signature):	
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