

Implanted Devices Evaluation

Anshuman Panda, PhD

AAPM Annual Meeting 2019
San Antonio, TX

No Conflict of Interest to Declare

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Advanced Concepts in MRI Safety for Physicians: MRI Safety of Devices in the MR Environment

R. Jason Stafford, PhD
Department of Imaging Physics



THE UNIVERSITY OF TEXAS

MDAnderson
Cancer Center



AAPM Spring Clinical Meeting 2019



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2019 AAPM Spring Clinical Meeting - Session: MR Safety and Quality Troubleshooting

with 2 requesting, average satisfaction with this presentation (higher is better)

5.00

How satisfied are you with this presentation?

(5 Very Satisfied)

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Device Safety Testing in the MR Environment
R. Jason Stafford, UT MD Anderson Cancer Center
jstafford@mdanderson.org

Handout(s) 144-41907-475666-142046-1401532735.pdf

When you have finished the video, you may watch again, browse/search all videos, go back to the previous page, or watch another video in this session (see below).

All videos in this session:

Image Data

Device Safety Testing in the MR Environment - R. Jason Stafford, UT MD Anderson Cancer Center

Watching -->

List of Active and Passive Devices

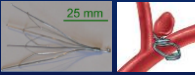
Active Implanted Medical Devices

- Cardiac (pacemakers, ICD, CRT-D, loop recorders)
- Stimulators (deep brain, vagal nerve, spinal, bone and bladder)
- Programmable Shunts and Pumps (pain, drug, insulin)
- Cochlear implants



Passive implanted devices & foreign objects

- Neurological (aneurysm clips, deep brain stimulators)
- Orthopedic and Dental (plates, rods, screws, braces)
- Cardiovascular (valves, stents, coils & filters)
- GI (gastric band, tube, Pill Cam, magnetic sphincter)
- Tissue expanders
- Foreign objects (metal in orbits, BBs, bullet fragments)



External objects and devices

- Medication patches, Glucose Monitor, Hearing aids
- Permanent makeup, tattoos, piercings
- Immobilization, temporary fixation, patient comfort (blankets)



Implanted Devices MR Safety Labeling



MR Safe: The item is safe for use in MRI under all conditions.



MR Unsafe: The item is not safe for use in MRI under any conditions.



MR Conditional: The item is safe for use in MRI only under certain conditions.



NO Label: The item has not been evaluated for MR safety.

Absolute Contraindication Implants for MRI?

10 years ago – most active implanted device and many passive

- Cardiac (pacemakers, ICD, CRT-D, loop recorders)
- Stimulators (deep brain, vagal nerve, spinal, bone and bladder)
- Pain Pumps
- Cochlear implants

5 years ago – majority active implanted devices

- Stimulators (deep brain)
- Pain Pumps
- Cochlear implants

Today

- ?

Typical Implanted Device Evaluation Call

- Patient is in the waiting room
- Does not have any information on implanted device
- Claims had MR at another site (most likely it was CT)
- There is no prior history or images in PACS
- Can we safely scan this patient?
 - Also can you please give me an YES and NO answer in 5 mins, we are running 30 minutes behind schedule
- Hmm...it Depends!



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Implants in MRI: Challenges

- Rapid growth of patients with implants
 - Increased number of MR conditional implants
 - Multiple implants and retained implants
 - Poor documentation in patient EMR
 - Direct vendor patient marketing as "MRI conditional"
 - Evolving and retroactive MR conditional labeling
- Rapid growth of MRI systems
 - High field (7T) and Low Field (<1T MR-Linac)
 - Hybrid Systems (PET-MR, Hybrid MR-OR)
 - Advanced procedures with high end hardware (fast gradients, multichannel transmit, scan parameter complexity)



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Complexity vs Clarity

- Opportunity for physicists to step in and assert our role in clinical practice as MRSE
- Radiation safety framework
 - Leverage Radiation Safety model as a analogy
 - Radiation Safety Committee
- We are all in the same boat – lean on each other
 - Interpersonal – Call a friend
 - Departmental – MR Safety Task Force
 - Institutional/Enterprise – MR Safety Committee
 - Professional Communities – AAPM and ISMRM Safety Committees



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Objectives

- How to operationalize implanted device evaluation and expand scope of our practice as MR Safety Experts
 1. Operational framework for device evaluation (evolving)
 2. Review relevant resources and guidelines (evolving)
 3. MRSE device evaluator starter guide (evolving)



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Safety Concerns – MR Conditional Devices

- Static Field (B0)
 - Time-Varying Gradient Slew Rate
- Radio Frequency Field
 - SAR
 - B1+ rms
 - Duration of single series or entire scanning session
 - Acoustic Noise
 - Positioning/Landmarking/Centering
- Type of coil
 - Patient height, weight
 - Location of device implantation
 - Immobilization: external, comfort
- Spatial Gradient
 - Patient monitoring
 - Additional implants
- Identify
 - Artifacts
- Find vendor guidance



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Operationalize Implanted Devices Evaluation

Evaluation Checks Pre/During

- Verbal, visual, physical screening
 - Evaluation; interpretation and communication plan
 - Escalation process (MRSO, MRSE, MRMD)
- Scan coordination
 - Inter/Intra departmental
 - Vendors
- Safe execution
 - Positioning; coils selection; monitoring;
 - Pulse sequences and parameters (Ultra low SAR protocols)



Evaluation Checks Before

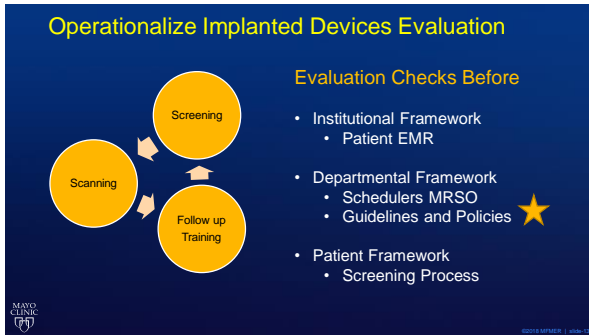
- Institutional Framework
 - Patient EMR
- Departmental Framework
 - Schedulers MRSO
 - Guidelines and Policies
- Patient Framework
 - Screening Form

Post Scan

- Reporting
 - Internal and external (FDA MAUDE)
- Education and Training
 - Safety committee review
 - Guidelines and policy update



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Institutional Framework – Patient EMR

Dr. Watson – Mayo Enterprise MR Safety Committee Chair

Departmental Framework – Schedulers, MRSOs

Flow diagram of MRI labeling process. (MRI) electronic medical record. (MR) registered nurse.

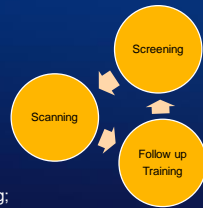
Kanal's MR Safety Implant Risk Assessment app for the iOS platform

<https://www.nwforums.com/appsupport/>

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Screening: Verbal, Visual, Physical



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Escalation Process: MRSO → MRSE → MRMD

MRI Safety Assessment Strategy

| Know what device is in your patient | Search for device safety information | Assess risk and benefit with Radiologist |
|--|--|---|
| Need to know <ul style="list-style-type: none"> Manufacturer Model Serial Number Ways to find out <ul style="list-style-type: none"> Patient info card Talk to pt., care provider, manufacturers' rep Medical note | Use internet search: <ul style="list-style-type: none"> MagResource.com MRISafety.com Information from the manufacturer Google search device name + "MRI safety" | Assess your device against MRI safety considerations: <ul style="list-style-type: none"> B₁ (force, torque) dB/dt (PKS) RF (heating) Acoustic Talk to other techs and Radiologists and Physicists to ensure everyone is in agreement <ul style="list-style-type: none"> Review plan with Radiologist – implement their prescription |

- MRSE clearly communicate technical nuance on risks in MRI environment to aid in making effective patient management decisions
 - Low SAR scanning protocols; off-label scanning; positioning; monitoring; coils; pulse sequences and parameters
- Does not make medical decisions
 - Does advise on technical conditions for scanning on label
 - May be asked to advise on approaches to scanning off label and associated risks



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| Safety Concerns - Evaluation | Device | | Field | |
|---|---|--------|-------|----|
| | Impact | Static | Grad | RF |
| Lead Heating Conductive lead acts as an antenna, picking up RF energy. A portion of this energy is dissipated as heat in cardiac tissue near tip of the electrode. | Heat and electrical shock by concentrating RF energy; myocardial stimulation; tissue damage may affect therapy. | | | ● |
| Unintended Stimulation/heating Gradient and RF fields induce voltages in leads that will be applied to the lead electrodes. Large voltage pulses may directly stimulate the heart. Electrical currents may be induced on the conductive surface of the case. | May lead to a single or intermittent stimulation from oversensing or undersensing; sustained tachycardia; thermal tissue damage near the case | | ● | ● |
| Device Interactions/Vibration Static field will act on ferromagnetic material producing a translation or rotation of the device or lead. Gradient and RF fields can induce electrical currents on conductive surfaces of device components. Interaction with static field may result in components to vibrate. | Pacemaker or defibrillator movement, patient discomfort, malfunction or failure (asynchronous pacing). | ● | ● | ● |

Adapted from: <http://www.medtronic.com/>

| | | |
|---|---|---|
| Safety Plan Communication EXAMPLE PROCEDURE FOR PATIENT SCANNING Medtronic SureScan™ Pacing (ICD or CRT-P) Transvenous Implant | Equipment Specifications: Requires MRI compatible scanner or RCG monitoring devices for use in scan room (pacemaker) or for use of SureScan™ Transvenous Implant (ICD or CRT-P) device. External defibrillator should be accessible in emergency. | CHECKLIST FORM FOR MRI Pacemaker/ICD/CRT (CRT-D and CRT-P) Systems |
| | Procedure for Approval of Exam: Before the patient is scheduled for MRI exam, the following must occur: • Interacting physician (radiologist) approves appropriateness of exam ordered to answer the clinical question. • Pacemaker/ICD/CRT Systems Checklist form, attachment A, is sent for the patient. This form ensures all screening requirements and steps in the procedure are followed. • The patient is not otherwise contraindicated for an MRI. MRI safety screening should be completed per center's protocol. • Patient's Cardiologist approval and order for pacemaker (Attachment B). Procedure: Ensure availability of staff to be present during the exam. This should include the MRI Technologist and a health professional (not a Medtronic employee) trained to monitor the patient. • Standard MRI screening questionnaire and consent are obtained. • MRI Technologist will discuss scan parameters with interacting physician. Any modifications to sequence will be done, when possible, before the patient enters scan room. Special attention will be made to ensure all RF fields are not exceeded. | Pre-scan Day (if exam): Ensure availability of staff to be present during the exam. This should include the MRI Technologist and a health professional (not a Medtronic employee) trained to monitor the patient. • Standard MRI screening questionnaire and consent are obtained. • MRI Technologist will discuss scan parameters with interacting physician. Any modifications to sequence will be done, when possible, before the patient enters scan room. Special attention will be made to ensure all RF fields are not exceeded. |

Safe Scan Execution: Pulse Sequence Changes

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RESOURCES

The following resources are available for you:

- 1T Labeling - BI - MRI scanner** (1/17/18)
- 1T Scan Tips - GE Specific** (1/17/18)
- 1T Scan Tips - Philips Specific** (1/17/18)
- 1T Scan Tips - Siemens Specific** (1/17/18)
- SAR White Paper** (1/17/18)
- Managing Metallic Artifacts in MRI** (1/17/18)

<https://www.medtronic.com/resources/implantable-c>

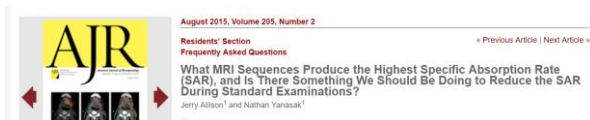
Siemens 1T MR Systems

On the Siemens system, B_{1max} is displayed on the SAR information dialog box (Figure 1). The yellow box in Figure 1 displays the B_{1max} as a percentage of an arbitrary maximum B_{1max} defined by the system. This percentage of limit does not correspond to the B_{1max} limit per the Medtronic labeling. To display a bar graph with the absolute B_{1max} value in a T1 field (see Figure 1), click in the B_{1max} field. It is important to note that the B_{1max} value is not updated in real time as scan parameters are changed. The predicted value for the scan will not be displayed until after the measurement phase. Therefore, the series should be configured so that the scan pauses after the measurement phase. This will allow the operator to verify the B_{1max} value prior to manually initiating the scan.

Specifics Examples for Modifying B_{1max} on Siemens 1T Systems

Reducing the number of slices without increasing the TR or increasing the TR without increasing the number of slices will reduce the B_{1max} . Reducing the number of slices to often not practical for increasing the TR, the more likely choice between the two. Depending on other parameters, you may have to significantly increase the TR. Besides the impact on scan time, significant increases in TR are also not practical when T1-weighted spin echo sequences are desired.

Turbo spin echo series consist of a 90-degree pulse followed by a "train" of refocusing pulses. Generally said to be 180-degree pulses. In reality these are rarely 180-degree pulses but rather 170-degrees or even less. The number of echoes generated by the refocusing pulses is referred to as the Turbo factor. To reduce the B_{1max} you can reduce the Turbo factor (keeping all other parameters unchanged). Figure 4 shows the selection for Turbo factor.



There are several approaches for managing SAR. Most SAR reduction approaches have associated imaging consequences. These approaches are as follows:

- ↑ Increase the TR, which can lead to longer scanning times.
- Reduce flip angles (for FSE sequences, use 60°–130° refocusing pulses rather than 180° refocusing pulses), which can alter image contrast-to-noise ratio or signal-to-noise ratio.
- Reduce the number of slices in an acquisition, which can lead to longer scanning times.
- Reduce the number of echoes in multiecho sequences, which can lead to longer scanning times.
- Control the scanning room temperature and humidity (follow manufacturer specifications), which may affect comfort for lightweight patients.
- Dress the patient in light clothing, which may affect patient modesty.
- Take breaks between high SAR acquisitions or interleave high SAR and low SAR acquisitions to allow patient cooling, which can lead to longer scanning times.
- Be sure the patient ventilation system in the scanner is turned on.

Cardiac MRI Exams with Very Low SAR (0.1 W/kg) for Patients with Active Implantable Medical Devices

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¹Department of Biomedical Engineering, University of California Los Angeles, CA, USA
²Department of Radiological Sciences, University of California Los Angeles, CA, USA
³Radiological Sciences Lab, Department of Radiology, Stanford University, Stanford, CA, USA

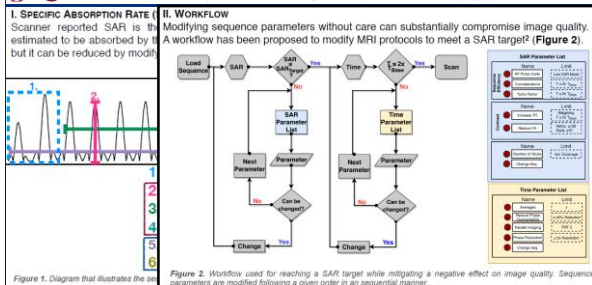
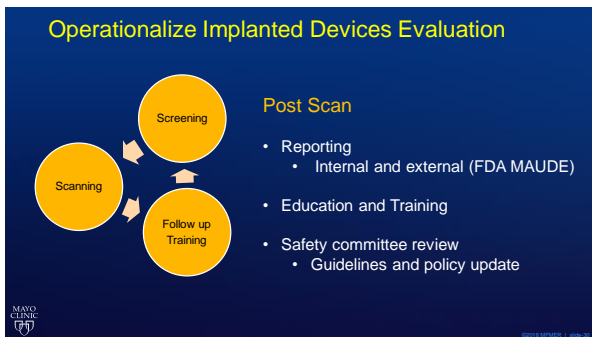



Figure 1. Diagram that illustrates the SAR target.

Figure 2. Workflow used for reaching a SAR target while mitigating a negative effect on image quality. Sequence parameters are modified following a given order in an sequential manner.





Safety

SERF

SAFETY – EVENT – REPORTING – FORM

[SERF Reporting \(Patient\)](#)
[How to Incident Report \(Patient\)](#)
[Incident Reporting \(Employee\)](#)
[Security Audit](#)

Resources

- 1. [Description Template:](#)
- 2. [The "Yellow, White, & What"](#)
- 3. [The "Yellow, White & What"](#)
- 4. [Event/Incident & Data Information](#)
- 5. [Incident Reporting](#)
- 6. [Incident Reporting](#)
- 7. [Hazardous Info](#)
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Reporting – Internal

| Event Information | |
|---|--|
| Event Type & Date | ACCIDENTAL INJURY & 07/14/2017 1:00:00 AM |
| Event Level, Group, Location & Where Occurred | ACTUAL EVENT, MR. MCH & EXAM ROOM |
| Severity, Triage & Sentinel | 2, NO & NO |
| Event Documents | |
| Body Part Imaged | ABDOMEN & PELVIS |
| Department Involved | RADIOLOGY |
| Division Flag | IMR BODY |
| Event Description Summary | <p>1. 1ST DEGREE BURN POST. PATIENT HAD A MR ABDOMEN/PELVIS WITHOUT INCIDENT. THE NEXT MORNING, SHE WOKE UP AND NOTICED REDNESS AROUND HER LOWER ABDOMEN/PELVIS. DESCRIBED IT AS A SUN BURN & DIME SHAPED AREA AND A COUPLE STRIPED AREAS OF REDNESS. WHEN SHE CALLED, THE REDNESS HAD GONE AWAY. SHE THOUGHT IT MIGHT BE RELATED TO HER UNDERWEAR. THE LABEL STAYS 60% POLYESTER, 2% SPANDEX, 2% OTHER FIBER. SHE WILL FOLLOW UP WITH HER PROVIDER AS NEEDED.</p> |
| Injury & Description | <p>YES. AREA OF REDNESS ACROSS LOWER ABDOMEN/PELVIS. 1 DIME SHAPED AND 2 OR 3 STRIPE-LIKE AREAS.</p> |

[illegible]

Reporting – External FDA MAUDE

Medical device reports of the plastic tubing government recall on October 1, 2014

FDA U.S. FOOD & DRUG ADMINISTRATION

Home / Medical Devices / Medical Device Safety / Medical Device Reporting (MDR): How to Report Medical Device Problems

Medical Device Reporting (MDR): How to Report Medical Device Problems

File Track Learn

Medical Device Reporting (MDR): How to Report Medical Device Problems

Manufacturer, Importer, and Device User Facilities: This page is designed to provide you with information on mandatory reporting requirements and procedures.

Manufacturer Mobile App

Search Medical Device Reports (Device)

Report a Medical Device Problem (Manufacturer/Importer)

Report a Medical Device Problem (Health Care Provider)

https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

FOOD & DRUG ADMINISTRATION U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

8/20/2014 10:04 AM

FDA MAUDE Database Search

FDA U.S. FOOD & DRUG ADMINISTRATION

MAUDE - Manufacturer and User Device Experience

100% View | Medical Devices | Databases

The MAUDE database provides medical device reports submitted to the FDA by mandatory reporters,¹ manufacturers, importers and device user facilities; and voluntary reporters such as health care professionals, patients and consumers.

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Search Database

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Product Problem

Product Class

Event Type

Manufacturer

Model Number

Report Number

Brand Name

Product Code

Inc

Case Report Number

MAJ (maudej2009)

01/01/2019

14

06/30/2019

Go to Simple Search

Records per Report Page

Clear Entry

Search

- Product Codes LNH (Nuclear Magnetic Resonance systems, 892.1000)
- MOS (coil Magnetic Resonance, 892.1000).

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>

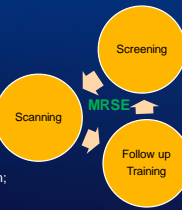
MAYO CLINIC (R)

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Tools of Trade – Start as MRSE Device Evaluator

Tools of Trade – Start as MRSE Device Evaluator

Sample of MR implant safety standards & guidance

- IEC 60601-2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- ASTM F2052: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2213: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2162: Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2119: Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2503-05: Standard practice for marking medical devices and other items for safety in the magnetic resonance environment
- FDA: Establishing Safety and Competibility of Passive Implants in the Magnetic Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff
- FDA: Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices
- ISO 19:2017: Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device
- ACR: Guidance Document on MR Safe Practices

Dr. Jason Stafford

MR Safety Reference Documents

- [A Closer Look at the Thresholds of Thermal Damage](#), Workshoe Report by an ICRP Task Group (2016) (pdf)
- [ACR Addresses FDA Gadolinium Safety Concerns](#) (2016)
- [ACR contrast media manual](#) (2018)
 - American College of Radiologists guidelines for contrast media
- [ACR Guidance Document on MR Safe Practices](#), 2013 (2013)
 - American College of Radiologists' MR guidelines
- [AHRA: Emergency Preparedness for Imaging Service Providers](#)
- [British Heart Rhythm Society, Safe use of MRI in people with cardiac implantable electronic devices](#) (2015)
 - British Cardiology guidance document on the use of Pacemakers in MR scanners
- [CAIR Standard for Magnetic Resonance Imaging](#) (2011)
 - Canadian Association of Radiologists MR guidelines
- [EU Directives on MR safety](#) (2013)
 - European Union MR safety guidelines
- [FDA Guidance on "Assessment of RF-Induced Heating in the MR Environment for Multi-Configuration Passive Medical Devices"](#) (2016) (pdf)
- [FDA site for reporting adverse events](#) (website last updated 2016)
 - A link to the Federal Drug Administration's data base for reporting all adverse events
- [FDA MR Safety Alert](#) (2014)
 - MRI Safety: FDA Safety Communication
- [FDA Safety Alert on Gadolinium](#) (2015)
 - Gadolinium-based Contrast Agents for Magnetic Resonance Imaging (MRI): Drug Safety Communication - FDA Evaluating the Risk of Brain Deposits With Repeated Use
- [Gadolinium Retention Updates & Resources](#) (2016)
 - Compiled for the SMRT by Greg Brown, A.Dip.Rad.Tech.
- [GE Healthcare: Class I Recall](#) (2015)
 - MRI Systems with Magnet Rndown Unit by GE Healthcare: Class I Recall - Potential Disabling of the Magnet Rndown Unit

Where to Start? 1 **Sponsored by**

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For patients

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Magnetic Resonance Imaging (MRI) Safety

What is MRI and how does it work?
What is MRI used for?
How safe is MRI?
How should I prepare for my MRI?

MRI Safety During Pregnancy

Magnetic resonance imaging (MRI)
Why do you need an MRI?
Alternatives to MRI

MRI risks during pregnancy
Contrast material
MRI during pregnancy

MRI during Pregnancy

Susan M.D., Ph.D.
Medical Director

<https://www.radiologyinfo.org/en/info.cfm?pg=safety-mr>
<https://www.radiologyinfo.org/en/info.cfm?pg=safety-mri-pregnancy>

ACR RADIOLOGY 2

Clinical Resources Accuracy and Efficiency

MR Safety

The ACR created a multidisciplinary MR Safe Practices 2017 address numerous MR safety issues.

- Static magnetic field-related issues such as
- Time-varying magnetic field-related issues
- Personnel qualifications and training
- Site access restrictions
- Pregnancy-related issues
- Guidelines on identification, screening and

General MR Safety

- [International Sentinel Event Alert #18](#)
- [Institute for Magnetic Resonance Safety, Education, and](#)
- [MRI Safety Wiki](#)
- [Safety Screening Form for MR Procedures](#)
- [MR Safety Courses](#)
- [MR Safety Training Videos](#)
- [MR Terminology Glossary](#)

MR Contrast Agents

- [Manual on Contrast Media](#)
- [FDA Information on Gadolinium-Based Contrast Agents](#)
- [The International Center for Nephrogenic Fibrosis Dis](#)

FDA Resources

- [FDA Drug Safety Communication: FDA Warns that Gadolin](#)
- [MRI Safety and Burn Prevention Poster](#)
- [Safety Concerns with Implantable Infusion Pumps in the](#)

MR Round 1 Checklist

Please mark on the drawings provided the location of any metal inside your body on site of targeted operation.

Right Left Left Right

The following items may be harmful to you during your MR scan or may interact with the MR magnetism. You must provide a "yes" or "no" for every item. Please indicate if you have or have had any of the following:

YES NO

Any type of electronic, mechanical, or magnetic implant

Type _____

Cardiac pacemaker _____

Respirator _____

Implanted cardiac defibrillator _____

Neurostimulator _____

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

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Non-CAMPF Programs

Medical Physics

Residency

Application Program (APF APT)

Online Learning

Center

AAAP

Virtual Library

Education Resources

Guide

Virtual Library presentation: **On "MR safety"** (the session IDE)

2019 AM
 Virtual Library presentation: **On "MR safety"** (the session IDE)
 Presented by: Jason Salafsky, PhD, Medical Center, Carle
 This presentation has an average satisfaction 5.0 (higher is better), with 1 responding.

2018 AM
 International and non-invasive MRI
 Presented by: Jason Salafsky, PhD, Medical Center, Carle
 This presentation has an average satisfaction 5.0 (higher is better), with 1 responding.

2018 AM
 MRI case
 Presented by: Anthony Dwyer, MD, Henry Ford Health System
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2019 SCM
 Integration of MRI in Radiation Therapy: Practical Safety Considerations
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 This presentation has an average satisfaction 5.0 (higher is better), with 1 responding.

2017 AM
 Practical Clinical MR Safety for the Therapeutic Medical Physicist
 Presented by: Michael Anderson, PhD, University of Wisconsin
 This presentation has an average satisfaction 4.0 (higher is better), with 1 responding.

ISMRM ONE

WELCOME TO ISMRM & SMRT'S MR SAFETY RESOURCES

Welcome to ISMRM & SMRT's MR Safety Resources

SMRT & ISMRM: Your Primary Source for MR Safety Resources, Support & Education

NEWS & EVENTS

- 2nd Annual MR Safety Day with Rush University Medical Center, Chicago, IL, USA
- 2018 MR Safety Week was 22-27 July. Check out our videos and other content produced for the event week.
- MR Safety Level 2 now available in the new MR Collections in the Learning Center.
- Download these suggestions to [globalaccess.org](#)

MR SAFETY EDUCATION

Home Study 2A: MR Safe: A Practical Guide for Non-Stroke Use

Level 1: MR Safety for ALL staff, with OUTPATIENT

- Includes downloadable certificate of participation
- Consent form for the Basic MR Safety Level 1 course

Level 2: MR Safety for Technologists, Radiographers and MR Operators

MR SAFETY RESOURCES

Incident Reporting Guidance - New!

ISMRM MR Safety Articles & Reports

International and National Guidelines

Guideline: Retention: A Research Roadmap from the 2018 NIH/NINDS/NINDS Workshop on Gadolinium Chelates

<https://www.ismrm.org/mr-safety-links/>

ISMRM ONE

WELCOME TO ISMRM & SMRT'S MR SAFETY RESOURCES

Welcome to ISMRM & SMRT's MR Safety Resources


MR Safety Reference Documents

- A Close Look at the Theophylline of Ther
- ACR Addressing FDA Gadolinium Safety c
- ACR Contrast media manual (2018)
- American College of Radiologists g
- ACR Guidance Document on MR Safe Ty
- American College of Radiologists v
- AHA Emergency Preparedness for MR
- British Heart Rhythm Society Safe use o
- British Cardiology guidance docum
- CAT Standard for Magnetic Resonance R
- Canadian Association of Radiologis
- EU Directive on MR Safety (2013)
- European Union MR safety guidel
- FDA Guidance on Disposition of 2nd
- FDA site for reporting adverse events w
- A link to the Federal Drug Administ
- FDA MR Safety Day (2018)
- FDA Safety FDA Safety Communica
- FDA Safety Alert on Gadolinium (2015)
- Gadolinium-based Contrast Agents With Repeated Use
- Gadolinium Retention: A Research Roadmap from the 2018 NIH/NINDS/NINDS Workshop on Gadolinium Chelates
- GL Healthcare Class Recall (2013)
- MR Systems with Magnet Runover
- Guidelines for documentation and consent for nonclinical, nonresearch MRI in human subjects. (2017)
- Guidelines for the Management of Patients with Contrast-Induced Nephropathy (CIN) (2017)
- Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Procedures* (2017)
- Guidelines for the safe acquisition of anaesthesia in magnetic resonance units (2013)
- Guidelines from the Association of Anaesthetists and the Neuro Anaesthesia and Critical Care Society of Great Britain and Ireland
- ISM Safety statement (2013)
- Institute of Physics and Engineering in Medicine: MR Safety Guidelines
- The Joint Commission Related Requirements for Diagnostic Imaging Services (2015)
- Joint Commission: 2015 MR guidelines
- MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (2015)
- Medicines and Healthcare Products Regulatory Agency MR guidance document
- MR Procedures Screening Form for Patients and Other Individuals (2009)
- MR system operator recommended minimum requirements for performing MRI in human subjects in a research setting. (2015)
- MRSafety.com (website updated 2018)
- A comprehensive list of implants and devices with conditional information; MRI safety topics; MRI screening policies and screening forms
- Patient and individual Screening information (website last updated 2017)
- RANZCR MR Safety Guidelines (2017)
- The Royal Australian and New Zealand College of Radiologists MR Safety Guidelines
- Safety Concerns with Implanted Infusion Pumps in the Magnetic Resonance MRI Environment: FDA Safety Communication (2017)
- U.S. Federal Safety Standards, Guidelines and Regulations for MRI Systems: An Overview (2016)
- FDA's MR safety guidelines
- Using MRI Safety - Practical Rules for Employees (2008)
- Dutch guidelines on MR Safety

ISMRM-SMRT-FDA MR Safety Posters

Understanding MRI Safety Labeling

The MR environment has unique safety hazards for patients with implants, external devices and various 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 means the safety hazards are so high that MR scanning is contraindicated. MR Unsafe devices should be removed from the MR environment before MR scanning. MR Unsafe devices should not be used in the MR environment.

MR Conditional means the safety hazards are moderate. MR Conditional devices should be scanned only under specific conditions. MR Conditional devices should be scanned only under specific conditions. MR Conditional devices should be scanned only under specific conditions.

MR Safe means the safety hazards are so low that MR scanning is not contraindicated. MR Safe devices can be scanned without restrictions. MR Safe devices can be scanned without restrictions. MR Safe devices can be scanned without restrictions.

Magnetic Resonance Imaging Tips for Scanning Patients with Implants

BEFORE

- Follow your clinic's protocol for screening for patients with implants.
- Obtain patient information and identify any implanted devices.
- Consult the MR safety information for the device.
- Verify the device is MR Safe, MR Conditional, or MR Unsafe.

MR Conditional means the safety hazards are moderate. MR Conditional devices should be scanned only under specific conditions. MR Conditional devices should be scanned only under specific conditions. MR Conditional devices should be scanned only under specific conditions.

MR Safe means the safety hazards are so low that MR scanning is not contraindicated. MR Safe devices can be scanned without restrictions. MR Safe devices can be scanned without restrictions. MR Safe devices can be scanned without restrictions.

AFTER

- Monitor the patient at all times.
- Assess the patient for discomfort or injury.
- Follow any post-scan conditions, such as device checks or programming.

SMRT Active Implants Safety

Visit the SMRT MR Safety Website for more information: www.ismrm.org/smart

Active Implants Biomedical Devices

From your patient's back, implanted devices that are electronic, programmable, or provide active therapy. Most require the following information:

- Manufacturer name
- Model name and/or number
- Serial number

From the other implanted device have MR safety information:

- MR Conditional?
- MR Safe?
- MR Unsafe?
- Not tested or labeled for MR?
- Other warning

Best source: Device label is controlled by the MR Physician.

Other the device requires special programming or monitoring?

- Any warning restrictions?
- Any device-specific safety?
- Any other safety information?

From the device label, the physician and necessary equipment to label the MR Conditional warning requirements of the device?

- Any other safety information?
- Any other safety information?
- Any other safety information?

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