

Advanced Concepts in MRI Safety for Physiciats: MRI Safety of Devices in the MR

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Environment











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 age majority active implanted devices
 - Stimulators (deep brain)
 - Pain Pumps
 - Cochlear implants
- Today
- ?

CTIN CPF

Typical Implanted Device Evalution 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! CLINE CPD

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 Clarity

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



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)

Safety Concerns – MR Conditional Devices

- Static Field (B0)
- Radio Frequency Field
 - SAR
 - Duration of single series or
 - entire scanning session
- Type of coil
- Spatial Gradient
- Identify
- Find vendor guidance
- CUINIC CUINIC

- Time-Varying Gradient Slew Rate
- Acoustic Noise
- Positioning/Landmarking/Centering
- Patient height, weight
- Location of device implantation
- · Immbolization: external, comfort
- Patient monitoring
- Additional implants
- Artifacts







Institutiona	I Framework –	Patient EMR	
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Committees	Home = Magnetic Resonance Imaging Safety	I must take Prothese and Acculation Rings
Contact Information		 Internet-split'd Parent/pera 3CP Handker 200
Personnel Directory	Mission Statement: The goal of this committee is to enable the clinical practice to make informed decisions	 Int_Read Control for most tailout
Policies, Procedures & Protocols	with regard to safety issues in MRI, thereby providing a safe environment for our patients and staff. With this is mind, the committee will:	Control and a state and a
Projects	I Organize and distribute MRI safety information	 Mixing Selater Policy and Propelary
Supportions & Questions	a Assess HRI safety information for relevance to our practice	 Bater Codex Stimulator 34CS) December Leads (Buildivide) to online comercian present
Radiology Composes	II Provide MRI safety education to Mayo patients and staff	 Examples (Mr. confident) Description and IEC
me-ARZIFLA[MCHS]RST	I Identify and investigate practices or equipment which can present a safety risk within the MRI environment	 Facing Virgs (Temporary and Permanent) Fada Cannot Be Med
	Where possible suggest changes in practice methods or equipment to assure safety	 Dahles Sustainat Disa Delans Salas Tabeta Heedra Susain Stora Sul San Aracebus
	The intent of this effort is to offer guidance, the final decision is at the Staff Radiologist's discretion.	Emile Incluts Tesconce and Latitie Tesconce and Latitie Testonce incoments Tesconce Incoments Tesconce Incoments
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	Found 48 in MR > MR Safety	Arizona 💌
	MR > MR Safety	Site(s)
	Antimicrobial Dressings Containing Silver MR Imaging Guideline	Arizona, Florida, Rochester, Albert Lea, Austin, Cannon Falla, Decorah, Fairmont, Farbaut, La Crosse, Lake City, Manilato, Owstonna, Red Wing
	Body Piercing MR Imaging Guideline	Arizona, Florida, Rochesler, Abert Lea, Auslin, Cannon Falla, Deconah, Eau Claire, Fairmori, La Crosse, Lake Chy, Mariato, Menomonie, Owatonna, Red Wing
	Breast implants and Tissue Expanders - MR imaging Guideline	Arizona, Florida, Rochester, Albert Lea, Austin, Cannon Faila, Decorah, Fairmont, Faribaut, La Crosse, Lake City, Marikato, Owatonna, Red Wing
	Burn Prevention: Pad Use To Prevent Bore Contact For MR Imaging Guideline	Arizona, Florida, Rochester, Abert Lea, Austin, Cannon Falla, Decorah, Eau Claire, Fairmort, Faribaut, La Crosse, Lake City, Maniata, Menomonie, Overstenen, Red Wite
	Conditional Pacemakers MR Imaging Guideline	Arizona, Florida, Rochester, Decorah, La Crosse
	Foley Catheters with & without Temperature Probe and Central Wire MR Imaging Guideline	Arizona, Florida, Rochester, Albert Lea, Austin, Cannon Falla, Decorah, Fairmont, Faribaut, La Crosse, Lake City, Marikato, Owatonna, Red Wing
	Gastrointestinal (GI) Clips MR Imaging Guideline	Arizona, Florida, Rochester, Albert Lea, Austin, Cannon Falla, Decorah, Fairmont, Faribaut, La Crosse, Lake City, Marikato, Owatonna, Red Wing
	Halo Traction Devices MR Imaging Guidline	Arizona, Florida, Rochester, Decorah, Fairmont, La Crosse, Maniato
CLINIC CUNIC	Heart Valve Prostheses and Annuloplasty Rings MR Imaging Guideline	Arizona, Florida, Rochester, Albert Lea, Austin, Cannon Falls, Fairmont, Faribault, Lake City, Mankato, Owatonna, Red Wing Roose Ministra

Stents MR Imaging Guideline

Scope MR Safety - Rochester, Arizo Menomonie, Owatonna, Red	ľ	Guidance The purpose of this statement is to provide general guidance to the MR practice from the MR Safety Committee. It is ultimately the Radiologist's decision whether or not to scan a particular patient.
Purpose	NA	
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Guideline	N/A	
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adverse events involving any	2.	Strohm O, Kivelitz D, Gross W, Schuiz-Menger J, Liu XM, Hamm B, Dietz R, Friedrich MG. Safety of implantable coronary stents during H-1-magnetic resonance imaging at 1.0 and 1.5 T. Journal of Cardiovasoular Magnetic Resonance. 1999;1:239-246.
 Coronary: Several re coronary stents who a immediate scanning p 	3.	Hug J, Nagel E, Bornstedt A, Schnackenburg B, Oswald H, Fleck E. Coronary arterial stents: safety and artifacts during MR imaging. Radiology. 2000;216:781-7.
+/- 2 days after stent strength is recommen	4.	Nijveldt R, Hitsch A, Hofman MB, Beek AM, Biglienboer AM, Piek JJ, van Rossam AG. 3.0 T cardiovasoular magnetic resonance in patien treated with coronary sterning for myocardial infarction: evaluation of short term safety and image quality. Int J Cardiovasc Imaging. 2008 Mar24(3):283-31.
	5.	Sheliock FG. Reference Manual for MR Safety, Implants, and Devices. 2009. Los Angeles: Biomedical Research Publishing Group.
Peripheral, Biliary, a	6	Hiramoto JS, Relly LM, Schneider DB, Skorobogaty H, Rapp J, Chuter TA. The effect of magnetic resonance imaging on stalniess-steel



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Blanket Policies - "All Stents are Safe"

Use caution when using blanket safety statements in guideline





Multiple overlapping stents represent a potential thermal risk at higher fields due to shorter wavelength

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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)
- MANR T





Escalation Process: MRSO → MRSE → MRMD

		Assess risk and benefit with
Need to know - Manufacturer - Model - Serial Number Ways to find out - Patient info card - Talk to pt., care provider, manufactures' rep - Medical note	Use internet search: - MagResource.com - MRISafety.com - Information from the manufacturer - Google search device name + "MRI safety"	Radiologist Assess your device against MF safety considerations: - Buforce, torque) - dB/dt (PNS) - RF (heating) - Acoustic Talk to other techs and Radiologists, and Physicists to ensure everyone is in agreement 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

- nning protocols itioning; monito scanning; p coils; pulse 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

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 tradition or 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, matfunction or failure (asynchronous pacing).	•	•	•	
Ada V	pted from: http://www.medt	ronic.co	m/	MER LANS	

ç	EXAMPLE PRC FOR PATIENT SCANNING PF MRI SureScan* Pacing ICD, a	Equipment Specifications: Reque MR compatible ownetry or ECG monitoring devices for use in scan room (pacemaker) or for use is SursScan" to programmed DN ICD/CRT-D and CRT- devicel. External definitator should be accessible in control area.	CHECKLIST FORM FOR MRI Page 101 Page 10 Page 10 Page 10 Page 101 Page 101 Page 101 Page 101 P	systems
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lnic	Purpose: To define conditions that will allow a pat	 Interpreting physician (radiologist) approves appropriateness of exam ordered to answer the clinical question 	nal management dat. New Your value investigation of each optimation of the second of t	dia in serana 2014 a Dirini. Ima fo parmine depender patient, ("Incascador, Int
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E Co		procedure are followed. • The patient is not otherwise contraindicated for an MRI_MRIsafety screening should be completed per center's protocol.	PR care in parallelisment in taking menorial status in our trajence? Provide Provi	
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	pacemakers/ICD/CRT systems enter th will be requests for scanning these path can be a conclusive and/or less invasive important diagnostic information.	Ensure availability of staff to be present during the ex This should include the MR Technologist and a health professional not a Meditoric employee) trained to monitor the patient.	Patient TCC or polici servicity will be uniterated by monitored or 37 — HMI reductinguescy IMP parent Pressuest Controlled Concerng Mach CM Named Cysiency Pacie Marcine and the preference of the A Paciety Parent Services	127 - HO addregancy (K) power Pornal Operating Nate • Protectory, and get specific absorption at a 549 matches • 2019/06
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	conditions of use exist for 1.5T versus 3 See the information in Table 1 for the sp of use for either 1.5T or 3T field strengt covered with this protocol	interprising physician. Any modifications to sequen will be done, when possible, before the patient is in tracamoun. Special attention will be made to ensure or ull immits are not exceeded.	Page 1986 at a signs with a later and insumerical Page 13 page 1000 (1) setting " and rups programs bandling" (ording uncert) For CPT patients insure to program 1985 bandling " most to O Theoretic resk (bades programme page) in the Freezowski Freezowski (bades programme page) in the Freezowski Freezowski (bades programme page) in the Freezowski Freezowski (bades programme page)	

Mectronic		Siemens 3T MR Systems On the Siemens system, B _{inders} is displayed on the prediction tab in the SAR information dialog box	Specific Examples for Modifying B _{1+RMS} on Slemens 3T Systems
		Figure 11 The yellow box in Figure 1 displays the B _{sense} as a percentage of an arbitrary maximum B _{sense} defined	Reducing the number of slices without increasing the TR or increasing the TR without increasing the number of slices will reduce the B
	onals 2 MRI Resources 2 Implantable Cardiac Device	such that scanner performance will not be limited due to B_{1-490} . This percentage of limit does not correspond to the B_{1-490} limit per the Medtronic labeling. To display a	of sloes is often not practical so increasing the TR is the more likely choice between the two. Depending on other parameters, you may have to significantly increas the TR. Besides the impact on scient time, significant
RESOUR MRI ACC	3T Labeling - B1-RHS everyles: (pdf) (3 4458)	bar graph with the absolute B_{relev} value in μT (red box in Figure 1), click in the B_{relev} field. ¹ It is important to note that the B_{relev} value is not updated in real time as scan parameters are changed. The predicted value for the	the IK 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.
The following resources SureScan system.	3T Tech Tips - GE Specific (pr/) (3	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.	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
	ST Tech Tips - Philips Specific (pdf) IS	This will allow the operator to verify the $B_{\rm pairs}$ value prior to manually initiating the scan.	The number of echoes generated by the refocusing pulses is referred to as the Turbo factor . To reduce the B _{1,025} you can reduce the Turbo factor (leaving all other
DOWNLOADS	3T Tech Tips - Siemens Specific (po		parameters unchanged. Figure 4 shows the selection for Turbo factor.
SureScan Systems	SAR White Paper (pdf)		And the set of the set
	Menaging Hetallic Artifacta in MRI (per) C 1,198		



August 2015, Volume 205, Number 2 Residents' Section Frequently Asked Qu

What MRI Sequences Produce the Highest Specific Absorption Rate (SAR), and Is There Something We Should Be Doing to Reduce the SAR During Standard Examinations? 1 and Nathan Ya Jerry A

« Previous Article | Next Article »

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 tilp 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.
- comon to ignineegin patients. Dress the patient in light cidning, 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 ^a, Ashley Pros S CRSL UCLA MAGNETIC RESONANCE Research Labs



Figure 2. for reaching a SAR target wi Nowing a given order in an seg

Operationalize Implanted Devices Evaluation



Post Scan

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

Safety	Reporting	– Internal
RadielCBy	Event Information	
SHRH	Event Type & Date	ACCIDENTAL INJURY & 07/14/2017 1:00:00 AM
SAFETY-EVENT-REPORTING-FORM	Event Level, Group, Location & Where Occured	ACTUAL EVENT, MRI, MCH & EXAM ROOM
Midas Incident Reporting (Patient) FLA MCHS. RST	Severity, Triage & Sentinel	2. NO & NO
Incident Reporting (Employee) Soverity Scale	Event Documents	
-	Body Part Imaged	ABDOMEN & PELVIS
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Education Sessions: 1: The "Why, Who, & What"	Division Flag	MR BODY
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	Injury & Description	YES, AREA OF REDNESS ACROSS LOWER ABDOMEN/PELVIS. 1 DIME SHAPED AND 2 OR 3 STRIPE-LIKE AREAS.







MAUDE - Manu	Ifacturer and User Facility Device
MAUDE Advers	e Event Report: GE MEDICAL SYSTEMS,
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Search Alerts/Recalls

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	CRITICAL ELEMENTS	MET	NOT	
	Scansing Tech to verify and sign MR screening form-MUST REVIEW IT ONUME FIRST Henriver all blamens that armse with the patient.			
	3. Patent must be changed to Mayo gown ino street duttes/pagamas permitted	-		
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	 Constantly monitor patient and aix about their control level (communicative (ch)) For non-communicative patient, it is CRUTICAL to reactive that proper models to transmission. Look after convision (The collect has merced) 			
2	 Screen staff individually (provide green badge when possible) Off hours staff screening may be performed with Ferro Guard and/or within hand held obtector in Zone 5 HZWEXER, at personal terms must be strength Zone 2 			

Policy and Guideline Updates

- VNS Brain w/wo
 - Pt scanned at 1:00 pm
 - VNS identified (pt disclosed) and noted in the screening form; VNS turned OFF, set to 0 mA.
 Non TR coil used; TR coil was not identified correctly
 - Pt rescanned at 3:00 pm
 - VNS missed (pt did not disclose)
 - TR coil not used

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Operationalize Implanted Devices Evaluation



MRI Safety Program Assessment	t Checklist	JMRI	FINISH STATE	
The site's written MU safety policy addresses the following Descripted MU makety policy addresses the following Descripted MU makety downlary	g Yes No.565	Commentary d free-Acces	ilities for management of MR safety	
 Sile access submitters (Mt Jones) Decarrented MI Safety education/trains for all persons 	. =		Inities for management of Mix safety	
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 Written policies are present and readily available to facility 2. Written policies are nerviewed and updated on a regular to 	r staft.	Internet Sight Tuesday Internet 2:30 AM - 0:30 AM	TU-AB-221CD-0 - ISMRM-AAMM Joint Tymy V Kinderelf - Hickman and "Hiddmonson"	esia: MR Safety Operatio
 Facility has appropriate MII safety warring signaps and in controlled access. 		du Consider End arrive an		
and a second	ixit Passifail	approved the de- monstrational are The metio	7:30 AM TU AB-221CD-1 Introduction	
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Tools of Trade – Start as MRSE I	Device Evaluator
\$ ample of MR implant safety standards & guidance	MR-CONDITIONAL CARDIAC DEVICE SLIMMARY CHART
IEC 60601-2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	The fact large certain at Hadrone certic data of the periods (MR care adds see the certification for ex-
ASTM F2052: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	1 TOTO -
ASTM F2213: Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	
ASTM F2182: Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging	Martin Brazilian
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 Compatibility 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	1.5T — Mill radiofrequency (RF) preser Normal Operating Mode First Level Controlled Operating Mode or Normal
ISO TS 10974: Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	Which body averaged specific absorption site (SAR) must be 12.0 Wkg (Sarth sector) and the sector of the Hillbore is inferior to the C2 workford and the sector of the Hillbore is inferior to the C2
ACR: Guidance Document on MR Safe Practices Dr. Jason Stafford	Pread Swithsactor Soars can be performed without 8-laws writing when the locenter is at or speciar to the C2 writeballow Pigure 11





MR Safety Reference Documents

- A Closer Look at the Thresholds of Thermal Damage: Workshop Report by an ICNIRP 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 Radiologist's MR guidelines
- American Collegio of Nationologist Mit guidantes
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 Call Standard for Magnetic Resonance Imaging (2011)
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- Construent in Solution (10 Manufacture) and an appendix on parameter
 El Directives and Additional (2015)
 E Langean Union MS selectly guidelines
 F Dia Guidance on <u>Statissisment of Bill Induced Heating in the MI Environment for Multi-Configuration Passive Medical Devices</u> (2016) (pdf)
- EDA site for reporting adverse events (website last updated 2016)
 A link to the Federal Drug Administration's' data base for reporting all adverse events

- a A link to the reveal a unit presentation
 ExpLMS Salety Card (2014)
 But Markety Card (2014)
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 With Repeated Use
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- min Impactance Use Soldhimma Retention (Judates & Resources) (2016) © Compiled for the SMRT by Greg Brown, A.Dp.Rad. Tech. © El Hashbrane: Cassa Readil 2016) © MR Systems with Magnet Rundown Unit by GE Healthcare: Class I Recall Potential Disabiling of the Magnet Run







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- Non-CAMPEP Programs	2019/201	
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European Union MR safety guide FDA Guidance on <u>"Assessment of RF-1</u> EDA site for reporting adverse events	nd • h (w • h	RiSafety co	III (website	updated 2	018)				s.in a research setting. (2015) MRI screening policies and screening form
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