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Safety, Setup, Devices

Mark Westwood,
Consultant Cardiologist



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Conflict of interest

I am a founder/director of MycardiumAI (for corelab work)



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Safety, Setup, Devices

Safety

Devices

Setup

Changing World



General advice



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Safety, Setup, Devices



<http://www.ismrm.org/smrt/files/con2033065.pdf>





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Setup



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1.2. Safety/setup/device

1/ MRI setup

- Main magnet
- Radio frequency transmit/receive systems
- Magnetic field gradients systems
- Computer systems

Is MRI 'safe'?



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Yes

- MRI has an excellent safety record
- No ionising radiation
- Eliminates hazard to patients and staff
- Repeat imaging not problematic
- Fewer ethical problems imaging volunteers

BUT

• Deaths in MR scanners

- Pacemakers
- Ferromagnetic aneurysm clips
- Impact of ferromagnetic oxygen cylinder
- Tools
- Contrast agent reaction

• Injuries in MR scanners

- Burns
- Impact of ferromagnetic objects
- Metallic foreign bodies



Components of an MRI scanner



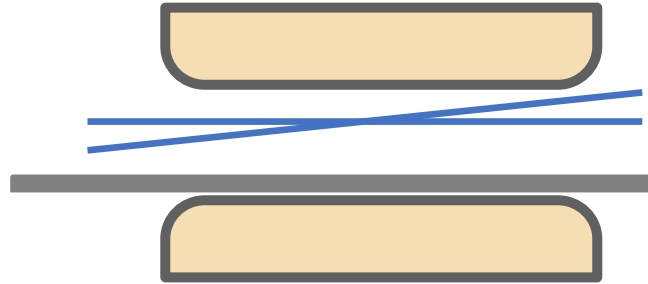
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Static main magnetic field B_0



- Magnetic fields $\sim 50,000 - 100,000 \times$ stronger than the earth's
- Superconducting = **Liquid Helium (-269°C)**
- **Always on!**

Time-varying magnetic field gradients

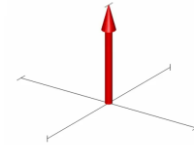


- Linear magnetic field gradients are used to encode the MR signal

Radiofrequency (RF) pulses



Transmit coil
Body or T/R local coil



Perturbed net spin
magnetisation



Receive coil
Body or local coil



Overview of Source of Dangers

Source	Safety risks
Static Magnetic field B_0 field (1T, 1.5T, 3T, ...)	<ul style="list-style-type: none">- Projectile or “missile” effect- Displacement and torque effects- Device disruption- Bioeffects
Radiofrequency (RF) waves B_1 field ($\sim \mu\text{T}$), MHz frequency range	<ul style="list-style-type: none">- Tissue heating, Burns- Medical device heating and disruption- Interference with equipment (monitoring systems)
Time varying Gradient Magnetic Field $G_{x,y,z}$ gradients. Strength in mT/m and slew rate in mT/m/ms	<ul style="list-style-type: none">- Peripheral nerve stimulation (PNS)- Acoustic noise- Interference with equipment
Cryogenics Liquid Helium at $-269\text{ }^\circ\text{C}$ (4 K)	<ul style="list-style-type: none">- Burns- Asphyxia- Hypothermia
Gadolinium Based Contrast Agents	<ul style="list-style-type: none">- Nephrogenic Systemic Fibrosis (NSF)

Safety Regulations

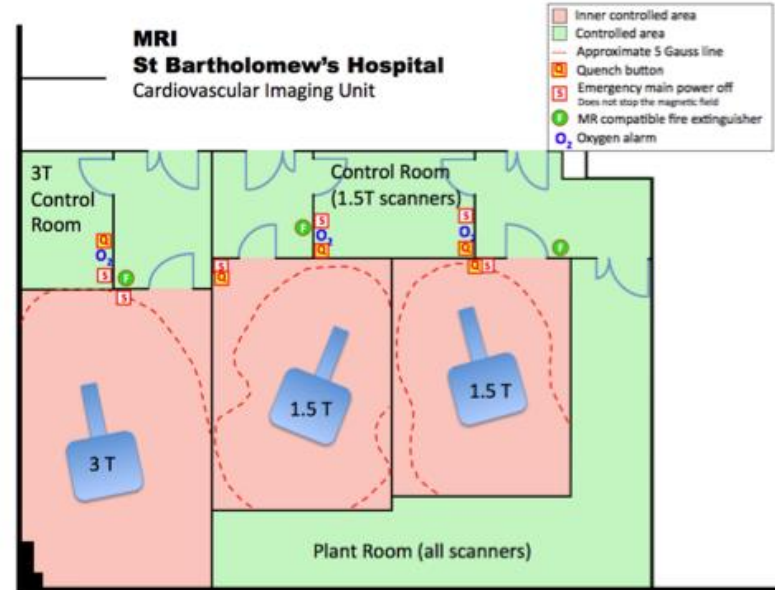
Local Rules



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- Responsibility ultimately lies with the employer
- Delegated to 'responsible person' – usually head of department or other senior professional
- Policies and procedures laid down in local rules

Read and Sign the Local Rules!



MRI safety hazards, Unit layout,
Controlled area, Use of equipment,
Emergency procedures



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Staff Categories



- Only authorised persons allowed unsupervised access, and must satisfy themselves that they meet the requirements of screening
- Unauthorised Persons
 - Are not considered to have the knowledge required to be safe within the Magnet Room.
- Restricted Worker
 - Have received basic training in MR safety such that they are considered responsible for their own safety within the Magnet Room
- Authorised Persons
 - Have received a recent training in MR Safety to a suitable level such that they can take on additional responsibilities including the safety of other people within the Magnet Room
- Fill-in a Worker declaration form and get it signed by a Responsible person

H. Declaration

Section A: Restricted Workers

To be signed by all persons requiring regular access to the MRI unit(s) at Barts Health NHS Trust as a Restricted Worker.

I have read and understood the General Rules within the Local Rules, and agree to comply with these whilst working within the MRI unit(s) at Barts Health NHS Trust.

Name	
Signature	
Date	
Department/Organisation	
Classification granted by (authorised worker)	

Section B: Authorised Workers

To be signed by all persons requiring regular access to the MRI unit(s) at Barts Health NHS Trust as an Authorised Person.

I have read and understood the Local Rules, and agree to comply with these whilst working within the MRI unit(s) at Barts Health NHS Trust.

Name	
Signature	
Date	
Department/Organisation	
Classification granted by (Responsible Person)	

What to look out for?



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- Pacemakers, ICDs
- Implants
- Previous surgery
- Metal (e.g. shrapnel)
- Kidney problems
- Pregnancy
- Epilepsy



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Safety



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2/ MRI safety

- Static field biological effects
- Safety zones for MRI facility, I-IV (USA)
- Radiofrequency field biological effects
 - Sequence-related patient heating
 - Factors affecting SAR & how to reduce it
- Gradient fields biological effects
 - Acoustic noise during MRI scanning
 - Peripheral nerve stimulation

Safety, Setup, Devices

- Precautions prior and during an MRI examination
- Cryogen safety
- Pregnancy
- Emergency procedures
- Contrast agents: families of contrast agents, effect on relaxation times, contraindications (renal failure-NSF, allergy, pregnancy) and main applications

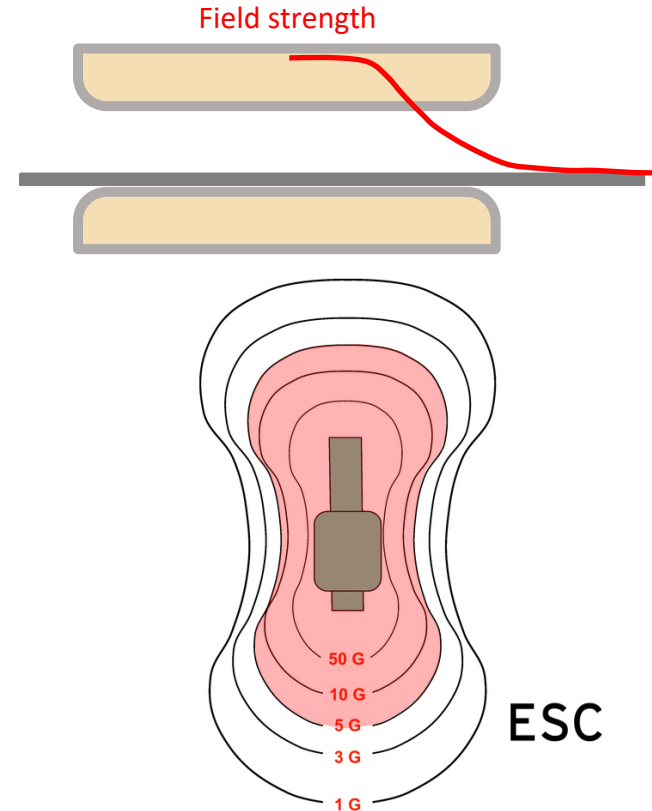
Static Magnetic Field

Static Magnetic Field



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- 0.2-3T in clinical use, up to 11T research systems
- Stray magnetic field extends beyond magnet bore: **Fringe Field**
- Extent of fringe field depends on magnet type and design
- Modern superconducting magnets require both active magnet and room shieldings
- Cardiac pacemaker safety limit defined as the **5 Gauss (0.5 mT)** field line



Static Magnetic Field



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- There is some evidence for some mild effects of static fields:
 - Vertigo and nausea might be associated with movement within the field
 - Probability of clinically relevant physiological effects or of significant changes in cognitive functions in fields of up to 4T seems low
 - “Current information does not indicate any serious health effects resulting from acute exposure to static magnetic fields up to 8T” ICNIRP 2009
 - Human epidemiological studies showed no effect on pregnancies
- These effects might increase with B_0 but cease with the exposure
 - No cumulative exposure risk

Displacement Effects



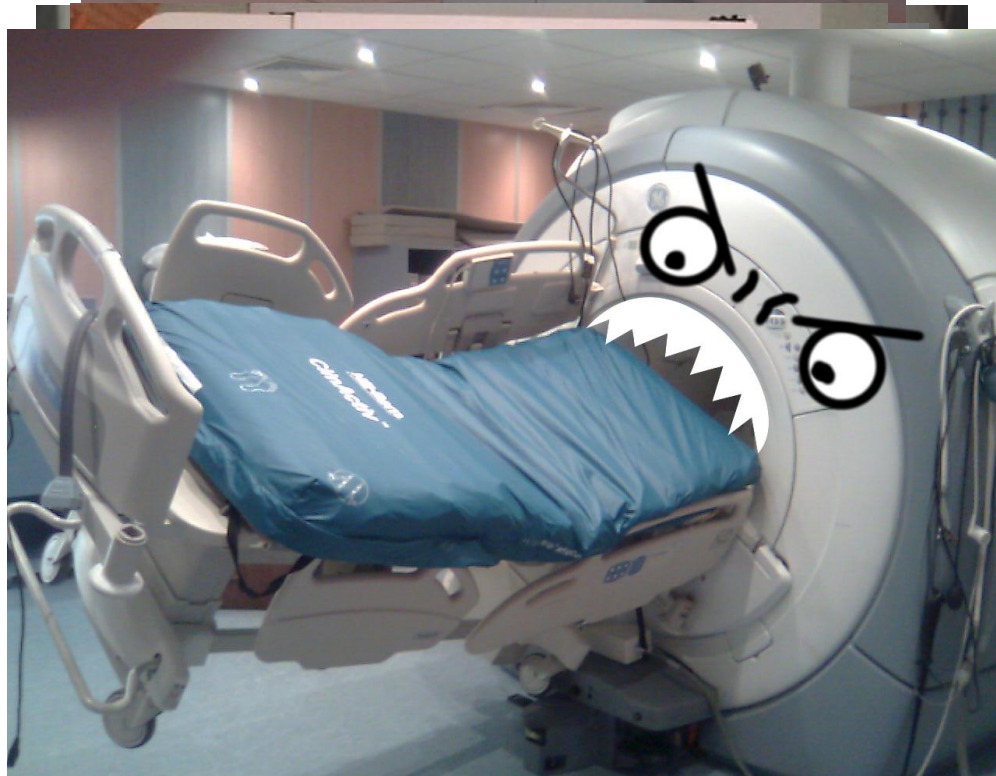
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- A superconducting magnet is always switched on!
- Static field generates an attractive force near the magnet
- Depends on:
 - Field strength B_0
 - Magnetic field gradient
 - Object properties
- Small objects can reach **40 mph (65 kph)** in a 1.5T magnet

Missile effect



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Missile Effect



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Demonstration of the powerful magnetic field of a clinical 1.5 Tesla MR scanner

Part II - Oxygen bottle



by
G. Starck, B. Vikhoff-Baaz, K. Lagerstrand,
E. Forsell-Aronsson och S. Ekholm



SAHLGRENKA
UNIVERSITY HOSPITAL

2004

Demonstration of the powerful magnetic field of a clinical 1.5 Tesla MR scanner

Part IV - Patient bed



by
G. Starck, B. Vikhoff-Baaz, K. Lagerstrand,
E. Forsell-Aronsson och S. Ekholm



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UNIVERSITY HOSPITAL

2004

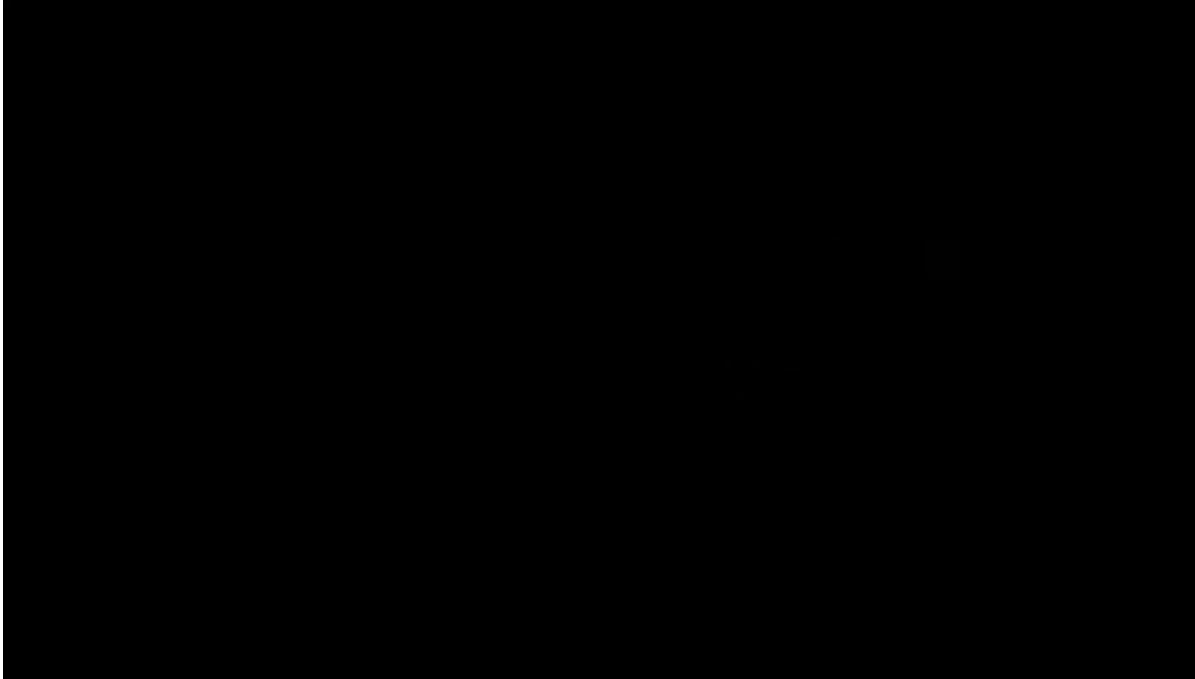


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Missile Effect



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Missile Effect



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TWO STUCK TO MRI MACHINE FOR 4 HRS

By Lata Mishra, Mumbai Mirror | Nov 11, 2014, 12.00 AM IST



The ward boy fractures his arm, while his colleague sustains serious injuries, including a punctured urinary bladder and severe internal bleeding.

Two employees of the Tata Memorial Hospital's treatment and research centre in Khargar in Navi Mumbai suffered grievous injuries on Saturday evening when one of them walked into the centre's MRI room holding an oxygen cylinder, activating the machine's monstrous magnetic field.



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Missile Effect



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Home > India > UP: Weapon of minister's security guard gets stuck in MRI machine, repair to cost Rs 50 lakh

UP: Weapon of minister's security guard gets stuck in MRI machine, repair to cost Rs 50 lakh

Unaware of the machine's capability of producing magnetic pull, his security personnel also entered the room carrying his service pistol.



The pistol got stuck to the MRI machine after it was pulled from UP minister's security officer's gun holster. (Source:ANI)



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Missile Effect



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Kirsty Wynn Kirsty Wynn is a senior reporter at the Herald on Sunday.

Man stabbed in eye during brain scan

5:00 AM Sunday Nov 16, 2014

NHS staff stunned after oxygen tank flies "like a rocket" into £2million MRI scanner

00:00, 15 NOV 2013 | **UPDATED 15:39, 15 NOV 2013** | BY JEREMY ARMSTRONG

Recommended In UK News



MRI Related Deaths



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NEWS

Family: 79-year-old Dan Mahony died after accident involving metal walker at Zwanger-Pesiri Radiology in Medford

Updated January 20, 2014 7:53 PM

Dan Mahony, 79, was at Zwanger-Pesiri Radiology in Medford in 2009 to get an MRI. His son says his father was told to remove all metal from his body before the MRI, but he was never told anything about leaving behind the metal walker he used. Upon entering the room, the magnetic field was so strong his son says the walker was yanked out from under Mahony and he fell and hit his head on the floor.

Mahony suffered a stroke two days after the accident and died two months after that.



Displacements Effects



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- Rotational forces (torques)
 - Strongest in the centre of the magnet (uniform field)
 - Tend to twist objects to align them with the static field
- Pose hazards for ferromagnetic implants (clips, coils, stents, etc.)
- **MRI-Related Deaths of Patients With Aneurysm Clip**

1992 “FDA has learned of a fatal injury sustained by a patient with a cerebral aneurysm clip while she was being prepared for an MRI procedure. upon exposure to the magnetic field in the room, the clip moved and lacerated the patient’s middle cerebral artery. The explanted device was subsequently shown to be magnetically active.”

Aug 2016, San Diego, USA A patient with an aneurysm clip (1982) had an MRI scan but forgot to mention it to the radiographers and he claimed that he had no foreign body implants. When inside the scanner, patient had spasms and was not responsive. He died the following day from brain laceration.



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Radio Frequency (RF)

RF Effects



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- Radio Frequency (RF) waves are used to excite the spins of the imaged object
- Energy of the RF waves is absorbed by the patient (and implants) and turned into heat
 - Tissue heating leads to possible physiological effects, burns
- RF effects are a great cause for concern in term of bio-effects: **under the operator's control**
- Effects on staff
 - Confined to magnet and immediate vicinity
- If body temperature increases so does:
 - Blood pressure
 - Heart rate, stress, anxiety
 - Intolerance to claustrophobic conditions
 - Burn risks
- Sensitivity to heat varies
 - Eye lenses: lack blood supply, tends to accumulate damage
- Have to make sure that temperature doesn't increase:
 - By 1°C (core temperature)
 - Over 38 °C (head), 39 °C (trunk) and 40 °C (extremities)



RF Effects



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- In practise, heating is monitored using the **SAR: Specific Absorption Rate**
- The SAR is a measure of the RF exposure. It is defined as the total power (Watts) per kilogram of tissue (W/kg)
- SAR limits on scanners set by International Electrotechnical Commission
- SAR limits set assuming certain temperature (<24°C) and humidity (between 40% and 60%)
- The SAR is based on mathematical models of human body (weight, tissue type, vascularity, blood flow, etc.)
- SAR increases with:
 - The square of B0: For the same sequence, SAR at 3T is 4 times higher than at 1.5T
 - **The square of flip angle**
 - The patient size
 - The number of RF pulses in a given time
- SAR changes when you change the sequence
- Need to monitor SAR for whole body and body parts



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Time Varying Magnetic Field Gradients

Varying Magnetic Field Gradients



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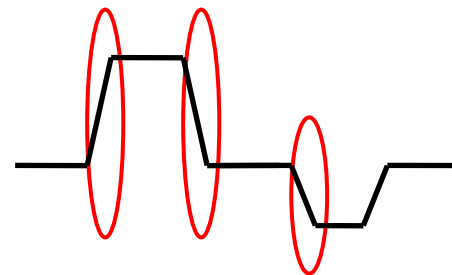
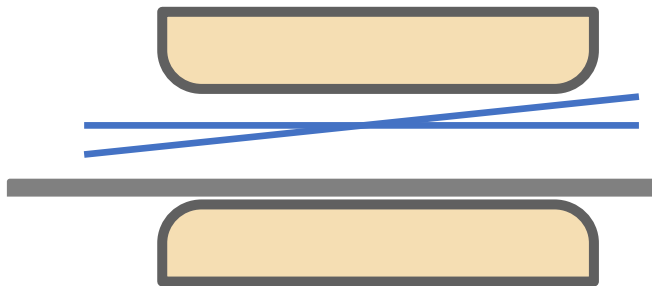
- Electromagnetic fields at 100-1000Hz used for spatial image encoding
- Two hazards are associated with the use of fast switching gradient fields (dB/dt)
 - Nerve and muscle stimulation effects
 - Acoustic noise
- Effects on staff
 - Confined to magnet and immediate vicinity

Varying Magnetic Field Gradients



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- The fast switching gradients induce electrical currents in conducting tissues



- In modern EPI-capable MR systems, this can generate a current that exceeds the nerve depolarisation threshold and cause stimulation

Peripheral Nerve Stimulation



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- PSN is not harmful but can be painful and effect is not acceptable:
 - Tingling or tapping sensation at low levels (< 50%)
 - Patient become uncomfortable and could feel pain (50%-100%)
 - Great variability between individuals
 - Expressed as a % of the median perception threshold
- Current safety standards (gradient strength and slew rates) provide adequate protection from cardiac stimulation
- Conductive implants may increase likelihood of stimulation
- Another effect: magnetophosphenes (sensation of flashes of light)



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Contact Burns



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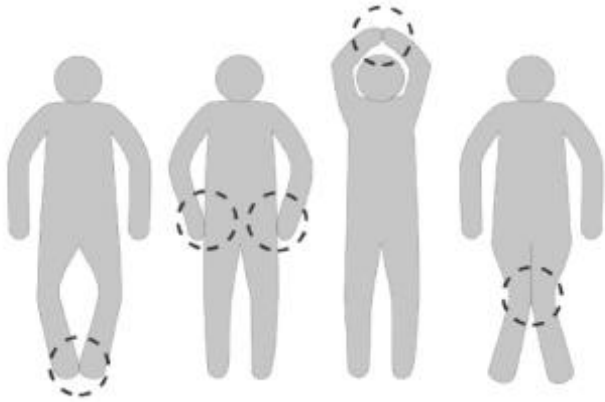
- Electrical currents can be induced in conducting wires and other objects due to RF
- Converted into concentrated heat: can cause severe burns
- Conductive doesn't mean ferromagnetic
- Conductive materials include:
 - Coils, ECG leads, cables, patches, rings, glasses, makeup, tattoos, implants, body parts
- **Sources of danger**
 - Badly placed ECG leads
 - The patient's skin touching the bore of the magnet
 - Unused coils, ECG leads, cables on the MRI table
- Place insulating pads between leads and subject's skin
- Use high impedance, if possible fibre optic leads
- Wireless ECG systems are now standard
- Bring leads straight out along the centre of the bore



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Contact Burns

Avoid loops and crossings of
cables and body parts!



X



fig. 1 The ulcerations were symmetrically observed on the bilateral calves with areola on the right calves with brown-coloured crust (15×5 mm in diameter).



Contact Burns



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Published March 1, 2012 as 10.3174/ajnr.A2827

TECHNICAL NOTE

J.A. Pietryga
M.A. Fonder
J.M. Rogg
D.L. North
L.G. Bercovitch

Invisible Metallic Microfiber in Clothing Presents Unrecognized MRI Risk for Cutaneous Burn

SUMMARY: We report a case of a thermal burn that occurred during MR imaging likely caused by invisible silver-embedded microfibers in the fabric of an undershirt. As the prevalence of fabric containing nondetectable metallic microfiber increases in athletic and “tech” clothing, the importance of having patients change into safe facility-provided garments before MR imaging is emphasized.

ABBREVIATIONS: ACR = American College of Radiology; SAR = specific absorption rate; SMF = silver microfiber



Fig 1. A linear erythematous blistering eruption is noted on the patient's right flank minutes after completion of the MR imaging of her brain and spine.

SC

Contact Burns



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MRI accident leads to loss of thumb for French boy

By Eric Barnes, AuntMinnieEurope.com staff writer



August 11, 2015 -- A 13-year-old French boy lost his thumb during a routine MRI examination of the pancreas, according to a report in the *Courrier Picard* newspaper.

An apparent error at the CHU hospital in Amiens, France, left patient Florian Barreiros in the scanner with a monitoring device attached to his thumb, which the report said was "burned through to the bone."

The boy was under anesthesia during the scan and did not notice the burning until it was too late, when he started screaming in pain, according to his mother. She claims that the medical staff failed to inform her of the accident, and that her son, who has Down syndrome, spent several tortured hours screaming in the emergency room, according to the article published on 4 August.

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Contact Burns



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Radiology. 2017 Aug 31;162921. doi: 10.1148/radiol.2017162921. [Epub ahead of print]

A New Fire Hazard for MR Imaging Systems: Blankets-Case Report.

Bertrand A¹, Brunel S¹, Habert MO¹, Soret M¹, Jaffre S¹, Capeau N¹, Bourseul L¹, Dufour-Claude I¹, Kas A¹, Dormont D¹.

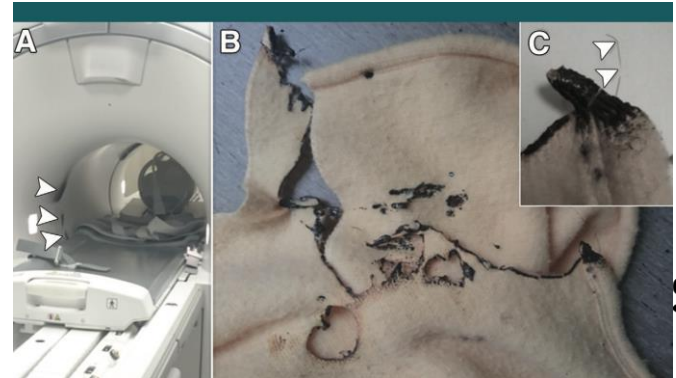
+ Author information

Open/close author information list

Abstract

In this report, a case of fire in a positron emission tomography (PET)/magnetic resonance (MR) imaging system due to blanket combustion is discussed. Manufacturing companies routinely use copper fibers for blanket fabrication, and these fibers may remain within the blanket hem. By folding a blanket with these copper fibers within an MR imaging system, one can create an electrical current loop with a major risk of local excessive heating, burn injury, and fire. This hazard applies to all MR imaging systems. Hybrid PET/MR imaging systems may be particularly vulnerable to this situation, because blankets are commonly used for fluorodeoxyglucose PET to maintain a normal body temperature and to avoid fluorodeoxyglucose uptake in brown adipose tissue. © RSNA, 2017.

PMID: 28858565 DOI: [10.1148/radiol.2017162921](https://doi.org/10.1148/radiol.2017162921)



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Acoustic Noise

Acoustic Noise



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- Sound generated by vibration of current-carrying gradient coils in main magnetic field
 - Can exceed 100 dB in magnet bore
- Very loud noises > 140 dB
 - Acoustic trauma: instantaneous irreversible damage to cochlea
- Noise exposure < 140 dB
 - Temporary raised hearing threshold (> 80-85 dB)
 - Increased stress, anxiety
 - Discomfort (normal pain threshold 120 dB(A))
 - Gradual hearing loss due to damage to hair cells of cochlea can be caused by long-term noise exposure
- Staff are at a greater risk than patients if not properly protected (cumulative risk)




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Acoustic Noise



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- Hearing protection mandatory above 90 dB time averaged
 - Should offer about 20 dB(A) attenuation
- All patients provided with ear defenders and/or ear plugs
 - Ear plugs can offer 10-30 dB attenuation
 - Temporary shifts in hearing thresholds in 43% of the patients scanned without ear protection or with improperly fitted earplugs
- There may be a risk of foetal hearing damage
- Anyone remaining in room during scanning should also use  ESC hearing protection

Cryogen: Liquid Helium

Cryogen Quench



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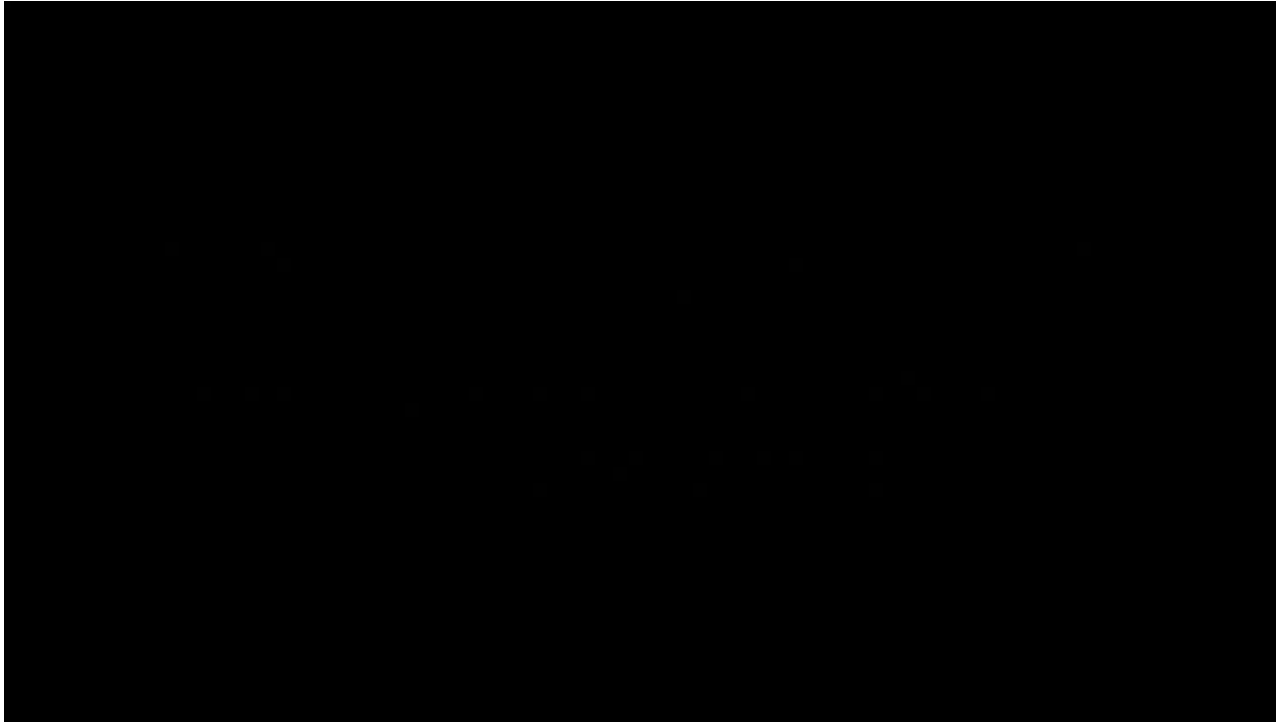
- The superconducting magnet coils are cooled with a cryogen (liquid Helium at $-269\text{ }^{\circ}\text{C}$ or 4 K)
- Quench: Sudden liquid Helium boil-off due to loss of superconductivity
 - Could be spontaneous or by pressing the Emergency quench button
 - Helium should be evacuated outside the scanner and building through a venting pipe
- Risks:
 - Asphyxia, hypothermia
 - Frostbites
 - Ruptured eardrums if pressure builds-up in the scanner room



Cryogen Quench



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Pregnancy

Pregnancy and MR exposure



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- NRPB conclusion on clinical exposure during pregnancy:

“Although there is no good evidence that mammalian embryos are sensitive to the magnetic fields encountered in MR systems, it is prudent, until further information becomes available, to exclude pregnant women during the first three months of pregnancy”

The MHRA recommends that, where possible, the decision to scan should be made at the time by the referring clinician, an MR radiologist and the patient, based on the information above about risks weighed against the clinical benefit to the patient. This decision should be recorded in the patient's notes.



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Contrast Agents

Contrast Agents



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- MRI contrast agents are used to improve the visibility of internal body structures
- The most commonly used compounds for contrast enhancement are **gadolinium**-based
- Gadolinium MRI contrast agents are administered by injection into the blood stream
- Gadolinium MRI contrast agents have proved safer than the iodinated contrast agents used in X-ray or CT
- Anaphylactic reactions are rare, occurring in approx. 0.03–0.1% of patients



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Nephrogenic Systemic Fibrosis (NSF)



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- As a free ion, gadolinium is toxic
- Chelated compound used for contrast are safe and excreted
- However, in persons with impaired renal function a rare but severe (and occasionally fatal) complication (NSF) can occur
- All patients requiring MRI contrast must be questioned closely to determine if they have any history of renal disease, and their most recent blood results checked (if available)
- If a patient has acute renal failure, are on dialysis or have chronic kidney disease, with a glomerular filtration rate (GFR) below 30, then contrast will only be given if agreed by a named consultant

Contrast agents safety



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Contrast Agent Risk

Brands

Recommendations

High	Optimark, Omniscan[†] , Magnevist[†] , Magnegita and Gado-MRT ratiopharm	<ul style="list-style-type: none"> • Contraindicated in: <ul style="list-style-type: none"> - Patients with severe kidney problems - Patients scheduled for or have recently received a liver transplant - Newborn babies up to four weeks of age • Women should discontinue breastfeeding for at least 24 hours after a scan
Medium	Vasovist, Primovist[‡] and MultiHance[‡]	Add new warnings in the prescribing information concerning use in patients with severe kidney problems and patients receiving a liver transplant
Low	<i>Dotarem</i> , ProHance and Gadovist	Add new warnings in the prescribing information concerning use in patients with severe kidney problems and patients receiving a liver transplant

Risk classification of gadolinium contrast agents by the European Medicines Agency (EMA)



[†]: Licences suspended in UK from 1st Feb 2018. [‡]: Use limited to delayed phase liver imaging only.

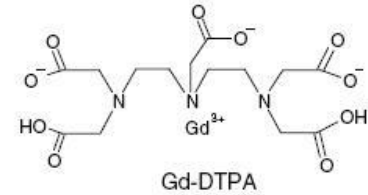
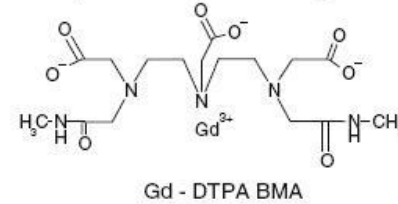
Contrast agents safety



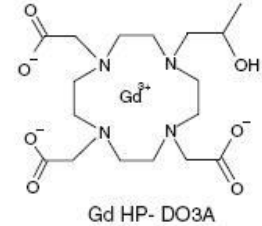
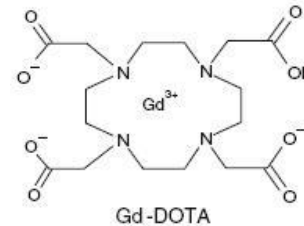
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- In 2013, several reports showed traces of gadolinium in the brain in patients who had a contrast enhanced MRI scan
- Patients had a higher signal intensity in some brain tissues caused by an accumulation of gadolinium
- This prompted a review of gadolinium based contrast agents safety in Europe (EMA) and the US (FDA)
- Linear contrast agents were found to be more prone to deposition in the brain compared to macrocyclic agents

Examples of linear chelates: gadodiamide and gadopentetate dimeglumine



Examples of macrocyclic chelates: gadoterate meglumine and gadoteridol



Contrast agents safety



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- Recently (March 2017), the European Medicines Agency (EMA) restricted the use of linear contrast agent in body scans
- “There is currently *no evidence* that gadolinium deposition in the brain has caused any harm to patients; however EMA has *recommended restrictions for some intravenous linear agents* in order to prevent any risks that could potentially be associated with gadolinium brain deposition”
- FDA investigation still ongoing

Product	Type (formulation)	Recommendation
Artirem / Dotarem (<i>gadoteric acid</i>)	macrocylic (i.v.)	maintain
Artirem / Dotarem (<i>gadoteric acid</i>)	macrocylic (intra-articular)	maintain
Gadovist (<i>gadobutrol</i>)	macrocylic (i.v.)	maintain
Magnevist (<i>gadopentetic acid</i>)	linear (intra-articular)	maintain
Magnevist (<i>gadopentetic acid</i>)	linear (i.v.)	suspend
Multihance (<i>gadobenic acid</i>)	linear (i.v.)	restrict use to liver scans
Omniscan (<i>gadodiamide</i>)	linear (i.v.)	suspend
Optimark (<i>gadoversetamide</i>)	linear (i.v.)	suspend
Primovist (<i>gadoxeticacid</i>)	linear (i.v.)	maintain
Prohance (<i>gadoteridol</i>)	macrocylic (i.v.)	maintain

Claustrophobia

Claustrophobia



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- Limited space in an MRI scanner (60-70cm)
- Patients who are not normally claustrophobic may find it unpleasant
- An accompanying relative or attendant appropriately screened, checked and authorised, may be allowed to remain in the scan room in verbal and, if necessary, physical contact with the patient



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Devices



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Safety, Setup, Devices

3/ MRI device

- MRI device safety classifications
- Passive implants and devices: valve repairs, stents, coils, aneurysm clips and other implants and devices
- Active devices: implantable loop recorders, implantable cardioverter defibrillator (ICD), pacemakers, abandoned leads
 - Safe, conditional and unsafe devices
 - Precautions post and post scans
 - Safety at 1.5T and 3T

Devices: MR Compatibility



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MR safe



Pose no known
hazards *in all MRI
environments*

MR conditional



Pose no known
hazards *in a specified
MRI environment* with
specified conditions of
use

MR unsafe



Pose hazards *in all MRI
environments*



Implants and Foreign Bodies



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- Many implanted devices are safe to image
 - Some are wholly or partly ferromagnetic
 - Some are conducting and subject to heating
- In some cases exposure compromises function
- Lists available at ***<http://www.mrisafety.com/>***
 - US website – no equivalent UK source of information
- **It is critical to check the MRI safety of devices before referring**
- **If in doubt do not scan**



Implants and Foreign Bodies



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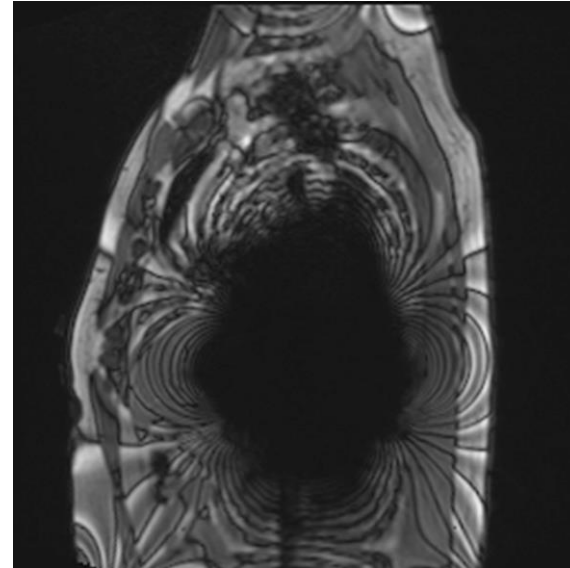
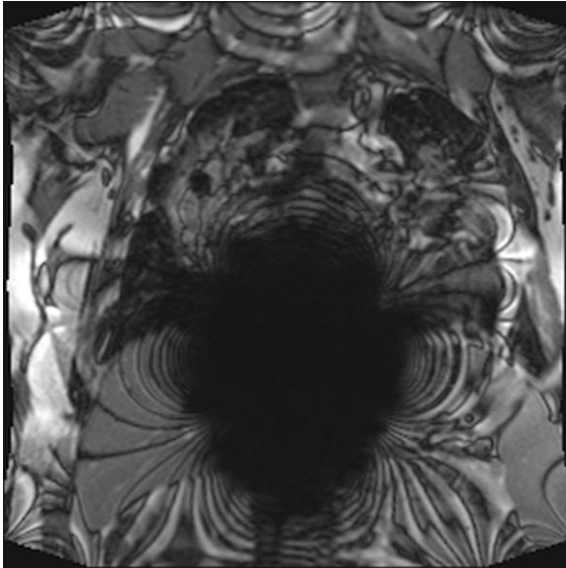
Device	MR Safety Category
Cochlear Implant	MRI Unsafe 
Pacemaker	MRI Unsafe / Conditional at 1.5T  
Implantable Loop-recorder (Reveal device)	MRI Conditional at 1.5T & 3T 
Heart Valves and Annuloplasty Rings	MR conditional: "Considered safe" at 1.5T & 3T 
Intravascular stents, filters, coils and Grafts	MR Conditional: "Considered safe" at 1.5T & 3T 
Brain aneurysm clips	MRI Unsafe / Conditional at 1.5T, 3T  
Cerebrospinal Fluid (CSF) Shunt Valves and Accessories	MRI Unsafe / Conditional at 1.5T  
Jewelry & Body Piercings	MR Conditional: Movement or displacement, heating and burning risks. Should be removed if possible 
Hearing Aid	MRI Unsafe 

Implants and Foreign Bodies



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1.5T cardiac scan localisers



Bomb shrapnel artefact

Patient did not inform staff about a metallic foreign object in his abdomen (bomb shrapnel).

No harm to the patient

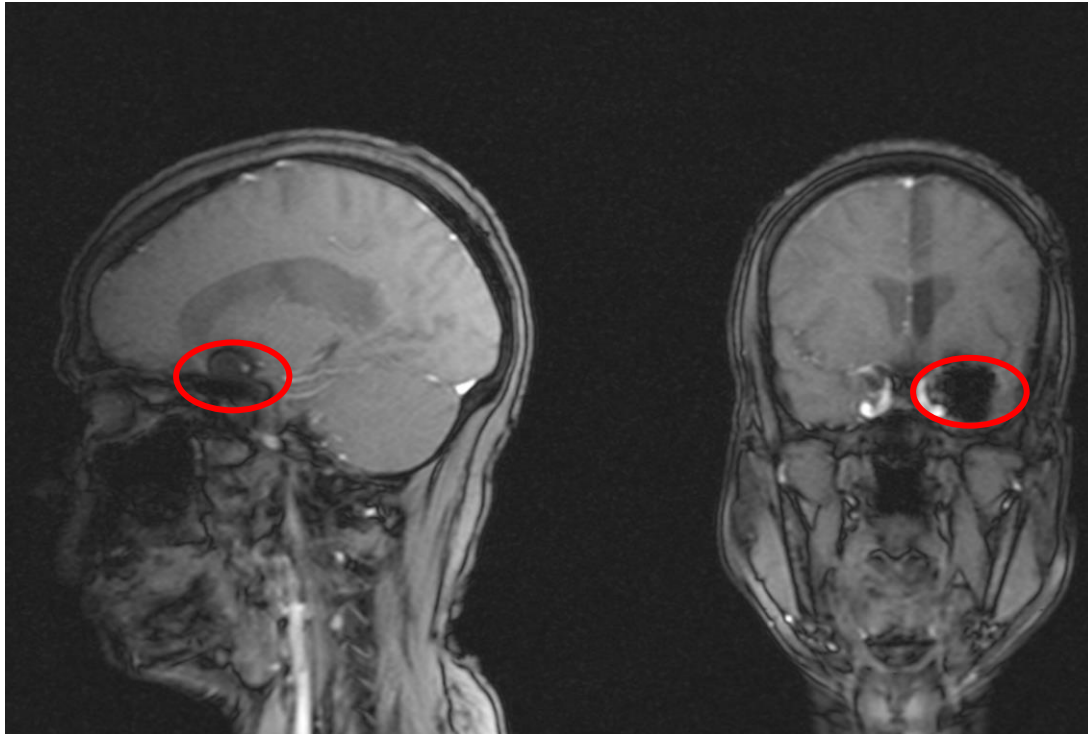


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3T brain scan



Implants and Foreign Bodies



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Brain aneurysm clip

Scan was started without
checking nature of the
patient's brain operation



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Devices Changing World



ESC
European Society
of Cardiology

MRI and Cardiac Implantable Electronic Devices

- Number of patients fitted with cardiac implantable electronic devices (CIED) is growing
- Large percentage will require an MRI scan over their lifetime
- In the past, CIEDs have been considered an absolute contraindication to MRI



MRI and Cardiac Implantable Electronic Devices



- Development of MRI conditional devices
- And, recent studies show that, if strict screening, safety and monitoring procedures are followed, legacy / non MR Conditional CIEDs can be scanned with minimal risks to the patient

Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator

Robert J. Russo, M.D., Ph.D., Heather S. Costa, Ph.D., Patricia D. Silva, M.S., Jeffrey L. Anderson, M.D., Aysha Arshad, M.D., Robert W.W. Biederman, M.D.,

New England Journal of Medicine, 2017

Safety of Magnetic Resonance Imaging in Patients with Cardiac Devices

Saman Nazarian, M.D., Ph.D., Rozann Hansford, R.N., M.P.H., Amir A. Rahsepar, M.D., Valeria Weltin, M.S., Diana McVeigh, B.S.,

New England Journal of Medicine, 2017

2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices

Julia H. Indik, MD, PhD, FHRS, FACC, FAHA (Chair),¹ J. Rod Gimbel, MD (Vice-Chair),² Haruhiko Abe, MD,^{3,*} Ricardo Alkmim-Teixeira, MD, PhD,^{4,†}

Heart Rhythm, 2017

Safe use of MRI in people with cardiac implantable electronic devices








Martin D Lowe,¹ Christopher J Plummer,² Charlotte H Manisty,³ Nicholas J Linker⁴ ;

Heart, 2015

MRI Safety Terminology for Implants and Devices

- Any device/implant falls into one of these three categories
- **No** CIED is classified as **MR Safe**
- An **MR Conditional** device can be safely scanned if **conditions** defined by the manufacturer are met
- Older terminology (MR Compatible) no longer in use

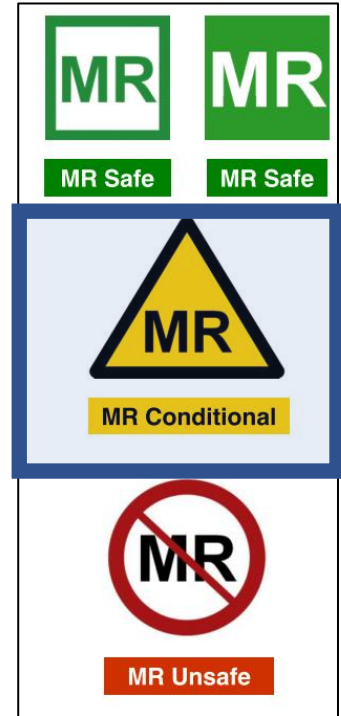
Table 1 Definitions from ASTM international standard F2503-13

MR SAFE 'an item that poses no known hazards resulting from exposure to any MR environment. <u>MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic</u> ' *	  
MR CONDITIONAL 'an item with demonstrated safety in the MR environment within defined conditions. <u>At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.</u> '	 
MR UNSAFE 'an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.'	 

MRI Safety Terminology for Implants and Devices

European Association of
Cardiovascular Imaging

- The development of **MR Conditional CIEDs** (2008 in EU) has made MRI scans safer
- Condition of use include:
 - **The type of device**
 - **Generator + Leads from same manufacturer**
 - Programming modes and parameters,
 - Time since implantation,...
 - **The MRI environment**
 - Type of magnet, maximum value of field strength
 - Spatial magnetic field gradient
 - Time varying magnetic field gradients
 - Type of imaging sequence, induced heating
 - Imaged body part (exclusion zones)
 - Type of imaging coils used, ...





Summary of Potential Risks

	Static Magnetic field B0	Time-varying gradients	RF pulses	Risk mitigation
Force, Torque Patient discomfort, surrounding tissue damage, device malfunction	✓			<ul style="list-style-type: none">• Reduced ferromagnetic content• Limited static field strength (1.5T or 3T)
Vibration Patient discomfort, device malfunction		✓		<ul style="list-style-type: none">• Reduced ferromagnetic content
Induced currents/voltages Induced VT, arrhythmia, pacing inhibition		✓	✓	<ul style="list-style-type: none">• Modified lead design• Gradient slew rate limits• Circuitry shielding
Heating Tissue damage, impedance and threshold changes, loss of sensing and/or pacing capture			✓	<ul style="list-style-type: none">• Modified lead composition• Limited SAR mode
Device malfunction Device reset, mode changes, loss of therapy, patient shocks	✓	✓	✓	<ul style="list-style-type: none">• Solid-state Hall effect switches

Conclusions

Scanning of **MR Conditional** cardiac devices is safe if specific conditions are followed

- Knowledge of device specifications
- Scanning protocols are relatively straightforward
- Can be done at any MRI centre
- No reason to deny a patient MRI when indicated

- Strong evidence from registries and clinical trials that **non-MR Conditional** CIEDs can be scanned safely if specific protocols are observed

Specialized centres

Unlikely to be scanning
Specialized centres to be asked

Conclusion

Safety

Devices

Setup

Changing World