# MRI: Hazards and Safety in Clinical Practice

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8<sup>th</sup> June 2023





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EPAR



- Magnetic Resonance Imaging
- Nearly 100 clinical MRI scanners in Ireland
- In Ireland these clinical scanners are either
   1.5T or 3T



- In Children's Health Ireland we are about to open our 4<sup>th</sup> MRI
- Crumlin: 1.5T Siemens Avanto, 1.5T Siemens Sola
- Temple Street: 1.5T GE HDXT, 3T GE Architecht



# **Benefits of MRI**

- MRI is non-invasive.
- ▶ It does *not* involve exposure to ionising radiation (unlike x-ray/CT/Nuclear Medicine).
- It provides better soft tissue contrast, i.e., it is more useful for differentiating between fat, water, muscle and other soft tissues than other modalities, such as CT.
- MRI can image very small and very large regions of interest.
- > You can obtain images from *any orientation* of the desired anatomy.
- There is a lower incidence of allergic reaction post gadolinium-based contrast medium injection when compared to iodinated contrast medium (0.17% vs 0.48%).
- It can measure biochemical changes in tissues (using spectroscopy).



# The "SAFE" modality?

- There is a misconception that because MRI does not involve ionising radiation, that it is the safest modality.
- MRI has the potential to cause:
  - Burns
  - Hearing damage
  - Implanted device movement/malfunction
  - Projectile related injuries

And even...

• Death

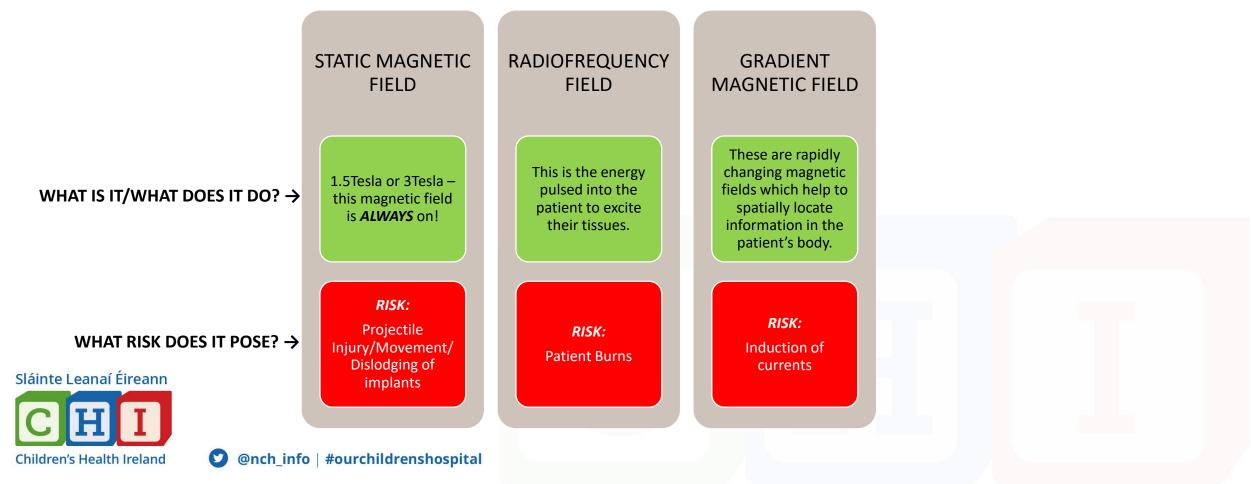






# How is MRI dangerous?

MRIs are superconducting magnets, which utilise 3 different powerful magnetic fields to create diagnostic images:



#### American College of Radiology's Manual on MRI Safety

- First version published in 2002, following the death of Michael Colombini (9yo in NY) which was caused by a projectile.
- This document set industry standards for safe and responsible practices in clinical and research MR environments.
- The MHRA MRI Safety guidelines (UK) are also utilised in Ireland, in combination with the ACR guidelines (US).
- These documents provides safety guidelines on areas such as:
  - Zoning of the MRI Department
  - Defining the roles/responsibilities of staff/patients/referrers
  - Implants
  - Patient screening etc.
  - Staffing



#### **MRI Safety Labelling**



#### **MR SAFE**

MR Safe implants/objects are non-metallic, non-conducting, and non-magnetic objects that pose no known hazards in any MR Environment.

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#### **MR CONDITIONAL**

MR Conditional implants/objects may be safely used in the MR environment, provided the conditions for safe use are met.

These conditions are specific to each implant/object's make and model.



#### **MR UNSAFE**

MRI Unsafe indicates that the implant/object is known to present safety risks in the MR environment. These are primarily ferromagnetic objects.

These items are <u>never</u> to enter the MRI scanning room, and should even be restricted from adjacent rooms, unless deemed totally

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necessary.



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### An out-of-date term

- "MRI Compatible" is a term that is still used in healthcare settings but should no longer be.
- Historically most metallic implants were deemed unsafe in an MRI environment, allowing for the use of only two terms:
  - MRI UNSAFE
  - MRI COMPATIBLE
- > This is not the world we live in now, however, as *most* implants are manufactured to be **MRI Conditional**.
- "Compatible" does not differentiate between Safe and Conditional. One may incorrectly presume a "compatible" implant to be MRI Safe, when in fact there are very strict scanning conditions to be adhered to.
- The MRI Safety community is actively trying to educate health care providers on the importance of the use of proper MRI safety terminology.



### **Conditions? What conditions?**

- Each MRI Conditional device has specific conditions to be adhered to before/during/after scanning.
- If you cannot meet even just one of the listed conditions for a device, you are scanning "off-label" and may cause harm to the patient.

#### These conditions include (but are not limited to):

- What static field strength it can be exposed to (i.e. 1.5T or 3T).
- How much energy can be deposited into the patient/implant, to avoid overheating.
- What equipment (e.g. scanning coils) can be utilised.
- The patient position on the table.
- Interrogation of the implant before/after performing the MRI.
- Turning devices into "MRI Mode".
- Removal of part of the device.
- The patient may be required to be alert/responsive in order to inform MRI staff if an issue during scanning.
- There may be exclusion zones, where specific areas of the body cannot be scanned.



### The 2 clinical scanning modes

- > These two scanning modes are defined based on the risk to the patient.
- Normal Mode: Deemed lowest risk to the patient. Less energy is deposited in to the patient in this mode. Siemens and Phillips default to Normal Mode.
- First Level Controlled Mode: This level is defined as one where certain imaging parameters may cause physiologic stress (such as peripheral nerve stimulation or tissue heating). GE defaults to this mode.

   Volume Transmit Coils

Operating Mode	Volume Transmit Coils			Local Transmit Coils		
	Whole body	Partial body	Head	Head	Trunk	Extremities
Normal	2	2-10 <sup>a</sup>	3.2	10	10	20
1 <sup>st</sup> Level	4	4-10 <sup>b</sup>	3.2	20	20	40

International Electrotechnical Commission. IEC 60601-2-33:2010: Medical Electrical Equipment - Part 2-33: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis. 3rd ed. with amendments. International Electrotechnical Commission; 2015. (accessed July 2020)



## **Example of implant conditions**

- This is (part 1 of) the MRI scanning conditions for MAGEC rods, which are used for the correction of scoliosis.
- The MAGEC system can only be scanned on 1.5T, not on 3T.
- The amount of RF energy deposited needs to be capped at ¼ that of Normal Mode.
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#### **MRI Safety Information:**

Non-clinical testing demonstrated that the MAGEC System is MR Conditional. The following conditions must be followed:

A patient with this device can be scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla (1.5 T)
- Maximum spatial field gradient of 3000 gauss/cm (30T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 0.5 W/kg at 1.5 T

Under the scan conditions defined above, the MAGEC system is expected to produce a maximum temperature rise of no greater than 3.7° C after 15 minutes of continuous scanning. Additional considerations are listed on the following page.

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# Continued...

- Patient cannot roll laterally on the table.
- External devices associated with this system must be left outside the MRI room.
- Warning regarding the diagnostic value of performing an MRI in the region of the implant

#### **MRI Safety Information Continued:**

- Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.
- The patient should not be permitted to roll on the table, as this motion may cause unintended lengthening/shortening of the implant.
- The External Remote Controller, Manual Distractor, and Wand Magnet Locator are MR Unsafe. Do not bring them into the MRI scan room.
- In non-clinical testing, the image artifact caused by the MAGEC® system extends beyond the imaging field of view when imaged with a gradient-echo pulse sequence in a 1.5 T MRI. system. However, imaging in locations approximately 20cm away from the actuator of the MAGEC System may produce images in which anatomical features may be discerned.



### Similar device, different conditions...

- This expandable device (VEPTR) is also used for the treatment of scoliosis.
- This device can be scanned at 1.5T OR 3T.
- The restriction on the amount of RF energy deposited into the patient is 4 times greater than the other implant.
- No patient position restrictions.

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#### MRI Information

Synthes Vertical Expandable Prosthetic Titanium Rib (VEPTR/ VEPTR II) implants are labeled *MR Conditional* according to the terminology specified in ASTM F 2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Non-clinical testing of the VEPTR/VEPTR II demonstrated that the implant is *MR Conditional*. A patient with a VEPTR/VEPTR II implant may be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla and 3.0-Tesla at Normal Operating Mode
- Highest spatial gradient magnetic field of 3,000 Gauss/cm (30 T/m) or less
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for the Normal Operating Mode for 15 minutes of scanning

To minimize heating, the scan time should be as short as possible, and the SAR as low as possible.

**Note:** In non-clinical testing, Synthes shortest, longest, and two intermediate VEPTR/VEPTR II implant construct lengths were assembled and tested for heating and results showed a maximum observed heating of 3.4° C for 1.5T and a maximum observable heating of 4.2° C for 3.0T with a machine reported whole body averaged SAR of 2 W/kg as assessed by calorimetry.

#### Are weaker magnets better for implants?

Not necessarily – it depends on the risks associated with the specific implant...





### **Deep Brain Stimulator Case Report**

- This case report describes the irreversible damage done to a 56-year-old man, who had a deep brain stimulator to help with Parkinson's symptoms.
- The MRI conditions (right) state this implant can only be scanned at **1.5T**.
- In this case the patient was scanned on **1.0T** MRI scanner.
- This report also describes that the choice of scanning coils also does not comply with the manufacturer's instructions for use.
- The RF energy used during this scan caused the leads to heat up to the point of causing an RF burn at the lead tip in the patient's brain.
- This is as a result of the RF wavelength at 1.0T and the coils used did not limit the region of the body exposed to the RF energy.
- The antenna effect is maximized when the length of the conductors or wires is equal to half the RF wavelength.

Henderson, J.M. *et al.* (2005) 'Permanent neurological deficit related to magnetic resonance imaging in a patient with implanted deep brain stimulation electrodes for parkinson's disease: Case report', *Neurosurgery*, 57(5). doi:10.1227/01.neu.0000180810.16964.3e.

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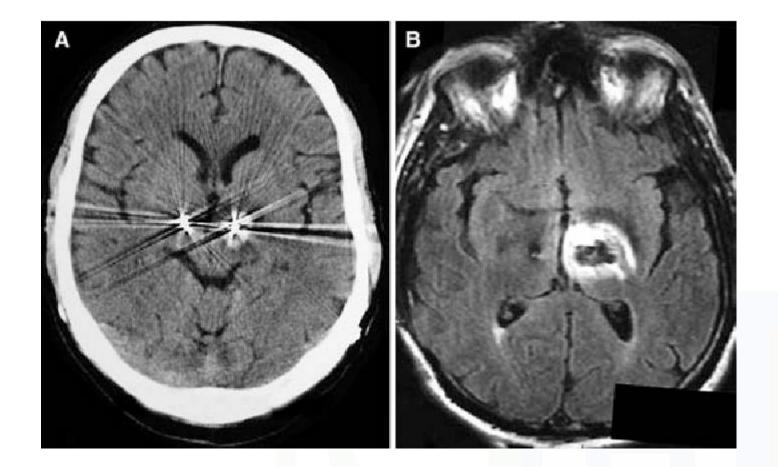
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TABLE 1. Manufacturer's recommendations and guidelines for neurostimulation system used for deep brain stimulation<sup>a</sup>

These recommendations were developed on the basis of experimental and clinical findings obtained for this particular implant (includes Model 7426 Soletra and Model 7424 Itrel II neurostimulators; Model 7482 and Model 7495 extensions; Model 3387 and Model 3389 DBS leads; Product Information, Medtronic, Minneapolis, MN). It is important to follow all safety warnings, precautions, and recommendations as stated in the Product Insert information for this specific neurostimulation system used for DBS. Failure to follow all warnings and guidelines could result in serious and permanent injury.<sup>b,c</sup>

- On the basis of tests to date, some MRI procedures can be performed safely with an implanted Activa system. MRI systems used to safely perform MRI include MRI systems operating at 1.5 T. The safety of other MRI machines used with implanted Activa systems is not known.
- Patients should be informed about potential problems; interrogate the system before and after MRI scanning
- All scans should be supervised carefully by an MRI-trained radiologist or physicist
- Program the system to off and at 0-V setting
- Use only a transmit-and-receive-type RF head coil to minimize the exposure of the lead/neurostimulator system to the MRI RF fields.
- Do not use a whole-body RF coil, a receive-only head coil, or a head transmit coil that extends over the chest area
- Select imaging parameters to perform MRI at an SAR that does not exceed 0.4 W/kg in the head<sup>d</sup>
- After performing the prescan for the MRI examination, the MRI parameters and conditions should not be changed, because this could alter the RF power deposition (i.e., the SAR level)

## The damage...



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#### The role of the referrer

How can referrers help us ensure patient's safety?

#### **MHRA MRI Safety Guidelines**

It is the responsibility of the referrer to identify those patients with implants and/or contraindications to MR before referral...

Healthcare organisations should require referrers to supply sufficient medical data (such as previous diagnostic information or medical records) relevant to the MR examination requested by the referrer to enable the accepting clinician to decide on whether there is a hazard associated with the exam.





### To summarise these guidelines...

- Prior to a request being placed for MRI, find out if the patient has any contraindications to MRI (i.e., implants, accidents with metal etc.).
- Provide all relevant information on the request for assessment by the MRI department.
- For implants, provide make and model information to the department (ideally in the form of surgical notes/traceability).



### "But I've had an MRI before?..."

A common phrase we hear from patients when we say we can't scan them without implant safety information. This is not sufficient evidence of implant safety in an MRI environment, however.

#### Why?

- Not all magnets are created equally.
- They may be mistaking a CT for an MRI.
- If performed in another facility, they may have had access to implant make/model and therefore the implant safety conditions.
- If they were scanned without the implant information being available to the MRI department, they may have just been lucky previously, and may not be so lucky again.



## **Safety Checklist**

- Upon arrival in the MRI department, patients (and any accompanying person, if required) will be asked to complete a safety checklist.
- Checklists should be checked twice with the patient, by a Level 2 MR Personnel in order to ensure the questions are understood and answered accurately.
- These safety checklists vary only slightly between MRI departments. They ask the patient whether:
  - They have any implants?
  - They had any accidents involving metal/they work with metal (e.g., welding)?
  - They have piercings/tattoos?
  - They have any allergies?
  - They have any renal problems?
- Contrast related
- They have a history of any surgeries/procedures?



### **Unknown implant**

- If a patient arrives for an appointment with an implant that was not declared at the time of referral, and no information is readily available, this will result in:
  - The patient's imaging being delayed by days/weeks or even months.
  - Dead time on the scanner.



# Metal orbital foreign body

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- Each department should have a policy regarding patients who potentially have metallic fragment in their eyes.
- Movement of intraorbital metal in the magnetic field could irreversibly damage the patient's eyesight.
- If the patient has orbital x-rays or CT from a time following the injury, these can be used to clear the presence of a foreign body.
- ▶ If no prior imaging is available, the patient should be referred for orbital imaging.
- The clearance of orbital imaging should be performed by a radiologist/radiographer who has undergone specific training.

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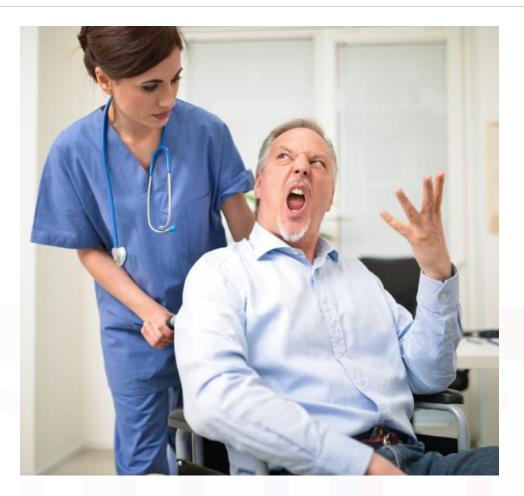
#### **Patient Preparation**

#### **PATIENT:**

"I came prepared, I didn't wear any metal"

#### US:

"Sorry, but we still need you to get changed"







# **Metallic Nanofibers in Clothes**



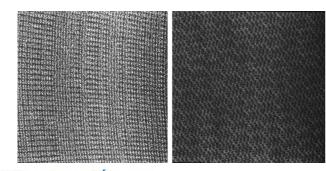
AJNR Am J Neuroradiol. 2013 May; 34(5): E47–E50. doi: 10.3174/ajnr.A2827

PMCID: PMC7964672 | PMID: 22173750

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

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J.A. Pietryga,<sup>a</sup> M.A. Fonder,<sup>b</sup> J.M. Rogg,<sup>a</sup> D.L. North,<sup>c</sup> and L.G. Bercovitch<sup>b</sup>







- Metallic microfibers in clothing, particularly sports clothing marketed as "anti-perspiration"
- Thermal injury due to heating of metallic fibres by the RF field
- It is impossible to identify these items of clothing by looking at them

### More burns...



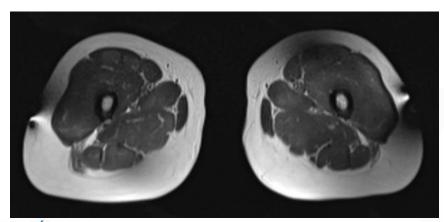
Radiology Case Reports Volume 14, Issue 11, November 2019, Pages 1348-1351



#### Case Report

# Unexpected magnetic resonance imaging burn injuries from jogging pants

Hiroyuki Tokue MD 🝳 🖾 , Azusa Tokue MD 🖾 , Yoshito Tsushima MD 🖾



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The list of materials used in the trousers (shown above) does not mention any metal/metallic nanofibers.

The only way to avoid incidences like this is to get every patient changed prior to undergoing their MRI.

# **Preparing inpatients**

- Inpatients can arrive to the MRI department with a range of MRI Unsafe items on them, hidden from view.
- These include (but not limited to):
  - Unsafe ECG stickers
  - O2 Sats probe
  - Temperature Probes
  - Blankets with metallic fibres

Inpatients need to be thoroughly checked for the presence of MRI Unsafe monitoring/items on them, prior to transferring into the MRI scanning room.



#### **Blanket Fire**

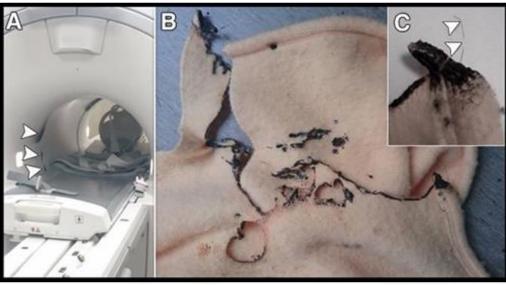
Radiology. 2017 Aug 31:162921. doi: 10.1148/radiol.2017162921. [Epub ahead of print]

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

Bertrand A', Brunel S', Habert MO', Soret M', Jaffre S', Capeau N', Bourseul L', Dufour-Claude I', Kas A', Dormont D'.

#### 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.





#### WARNING

The next slide contains graphic images of burns sustained by a baby during an MRI.







#### **MRI Unsafe O2 sats probe**

#### **Case report**

#### MRI induced fourth-degree burn in an extremity, leading to amputation

Josef Haik<sup>a</sup>, Simon Daniel<sup>b,\*</sup>, Ariel Tessone<sup>a</sup>, Arie Orenstein<sup>a</sup>, Eyal Winkler<sup>a</sup>

<sup>a</sup> Department of Plastic & Reconstructive Surgery and Burn Unit, The Chaim Sheba Medical Center at Tel HaShomer 52600, Israel <sup>b</sup> Sackler School of Medicine, Tel Aviv University, Israel



Fig. 1 - The attached pulse oximeter with exposed wiring.

 $\mathbf{ }$ 



Fig. 2 - Fourth-degree burn of right forearm and wrist immediately after the MRI session.



Fig. 3 - Non-viable forearm and wrist prior to amputation.

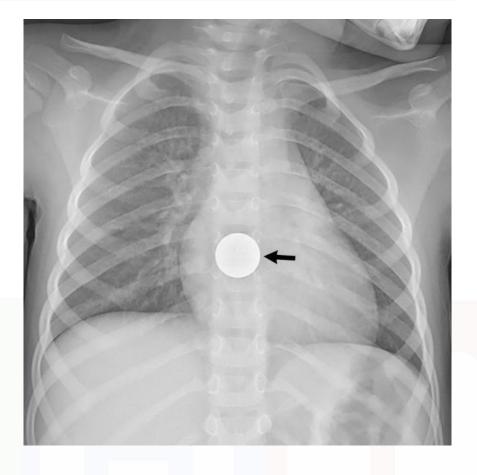




#### What about internal, unknown metals?

If a child swallows a metallic item (e.g., coin) or shoves magnets up their nose and doesn't inform anybody, there is a chance this would not be picked up prior to the MRI.

So how can we endeavour to catch these undeclared metal items?





#### **Ferromagnetic Detectors**





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#### **MRI under GA**

- MRI Conditional ventilators and monitoring equipment is required in order to safely perform an MRI under GA.
- Syringe driver infusion pumps cannot go into the MRI scanning room, unless they can be housed in shielding, to prevent malfunction of pump and/or the pump becoming a projectile.



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# **Hearing protection**

- MRIs are noisy due to the coils within the scanner vibrating.
- All patients should receive hearing protection, to be worn for the duration of the MRI.
- MRI manufacturers provide headphones for entertainment (e.g., music) for the patients to use during the scan. Most (if not all) of these "entertainment" headphones do not provide sufficient dB protection and should be used in conjunction with earplugs.
- Some patients can't/don't want to use earplugs, and so an alternative (e.g., MRI Safe noise cancelling earmuffs) should be available for use.
- If staff/guardian need to remain in the MRI room during scanning, they should also wear hearing protection.



### **Examples of Hearing Protection**



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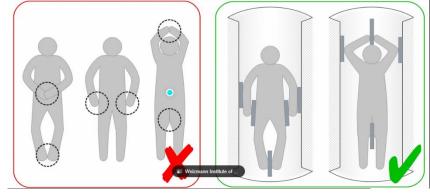




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# Padding

• Padding used in MRI should be made of non conductive materials, and be at least 1cm thick.

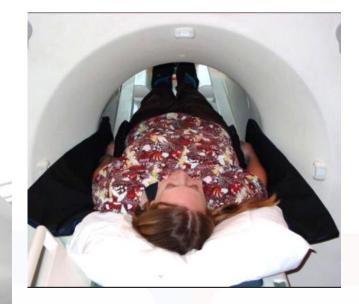


- Anatomy can't touch anatomy
- Cords can't touch anatomy
- Cords can't loop
- Cords can't touch side of scanner

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Children's Health Ireland V @nch\_info | #ourchildrenshospital http://www.appliedradiology.org/courses/3277/PayInteractive/PDF\_Downloads/07\_Burn\_Prevention\_Guidelines.pdf#:~:text=Insulating%20material%20%28minimum%20recommended%20thickness%2C%201-cm%29%20should%20be,transmit%20RF%20body%20coil%20of%20the%20MR%2



### **Patient Call Bell**

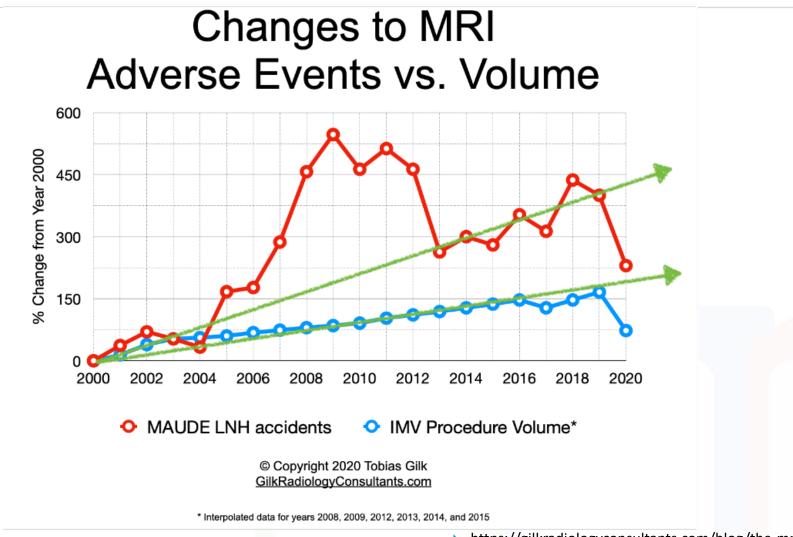
- All patients that are alert should be given the patient call bell. Maintain communication throughout scan
- Its purpose is to alert us to a change in the patient's condition, e.g.,:
  - Overheating
  - Pain
  - Allergic Reaction to Contrast
  - Panic Attack
  - Implant complication
  - Nausea/Vomiting
- If a patient is unable to use the call bell (level of consciousness/physical limitations), they should be connected to monitoring.







#### The Trend of MRI Incidents in USA



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https://gilkradiologyconsultants.com/blog/the-mri-accident-chart-2000-2020/

### Why are so many accidents happening?

- Lack of training.
- Lack of up-to-date departmental policies.
- Reduced staffing!
- MRI is becoming an increasingly popular modality some departments have shortened appointment times to tackle waiting lists. This reduced time per patient can negatively impact the safety checks required to ensure no harm is done.
- New hazards e.g., magnetic fake eyelashes, fitness trackers that look like wedding bands...



### **Take home points**

- MRI can cause serious injury or even death.
- The 3 magnetic fields can vary greatly between MRI scanners, and so...
- Make/model of MRI Conditional implants is required to ensure safe scanning of patients.
- NB An implant that may be safe to scan on one scanner may not be safe to scan on another!
- There are constantly new hazards emerging, e.g., metallic nanofibers.





You can <u>never</u> be too careful in MRI.

Only a Level 2 MR Personnel (e.g., MRI radiographer, Physicist or Radiologist) can deem a patient safe to undergo an MRI.

If you have any concerns regarding the safety of one of your patients in relation to an MRI scan, please reach out to your MRI department.

(We don't bite 🙂 )





# Thank you all for your attention

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- International Electrotechnical Commission. IEC 60601-2-33:2010: Medical Electrical Equipment

   Part 2-33: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis. 3rd ed. with amendments. International Electrotechnical Commission; 2015. (accessed July 2020)
- Health Protection Agency. Protection of patients and volunteers undergoing MRI procedures. Documents of the Health Protection Agency Radiation, Chemical and Environmental Hazards, August 2008.
- Medicines and Healthcare Products Regulatory Agency (MHRA). Safety guidelines for magnetic resonance imaging equipment in clinical use. 2015.



