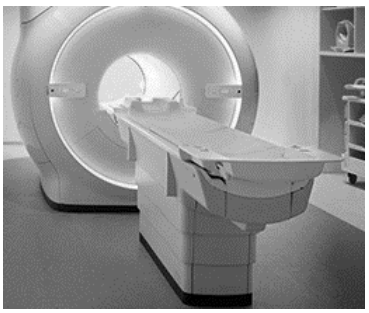
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Information Notice

Medical Devices

MR Imaging of Patients with Implanted Medical Devices



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ISSUE

Magnetic Resonance (MR) Imaging is considered to be a safe modality once the appropriate precautions are taken. There is however an underlying potential for injury due to the strong electromagnetic (EM) fields created. EM fields can interact with any metal objects in their vicinity to cause displacement of the object and injury (eg. wheelchairs).

This effect is particularly relevant for patients with medical implants who are referred for MR imaging. The potential for interaction between metallic implants and the EM fields generated by MRI machines raises additional considerations in relation to MR safety. Medical implants include active implantable devices where functionality is dependent on an energy source (such as pacemakers, defibrillators, neurostimulators, programmable shunts, cochlear implants and drug infusion pumps), and non active implants which require no power source (such as joint replacements, heart valves, occlusive clips / staples, coronary stents, coils, ocular implants, penile implants, and tissue expanders). Potential effects on these implanted devices include internal displacement of the device, interference with the device operation, malfunction of the device, heating and vibration of the device, and unexpected programming changes in the device.

There have been a small number of deaths following MR scanning of patients with implanted devices where either appropriate precautions were not taken, or the presence of the implanted device went undetected. The HPRA have also been informed of a small number of near fatalities where implanted devices were mistakenly understood to be MR Conditional.

The HRPA would like to emphasise that MRI continues to be a valuable diagnostic tool. However precaution in relation to the imaging of patients with implanted medical devices is advised and it is important to be aware of the MR safety status of all implanted devices.

RECOMMENDATIONS

The HPRA would like to emphasise:

1. Patients should be appropriately assessed for the presence of implants prior to MR imaging. An up-to-date radiograph may be useful in this regard.
2. MR safety information in relation to implanted medical devices should be acquired before the patient attends for MRI to allow sufficient time to plan.
3. Healthcare professionals referring a patient for MRI should aim to provide information sufficient to clearly identify any medical implants (such as device name, manufacturer and model).
4. The MR safety of implanted devices should be assessed by appropriately qualified personnel and in accordance with the advice and recommendations issued by the implant manufacturer.
5. The MR safety for each implanted device should be considered. This includes all accessories and inactive hardware from previous implants (such as cardiac leads etc.).
6. Any device with an unknown MR safety status should be assumed to be MR Unsafe.
7. An MR Conditional device is only safe within the MR environment that matches its conditions of safe use.
8. MRI safety websites should be referred to as appropriate, for example www.mrisafety.com
9. The cognitive status of the patient may also need to be taken into consideration.
10. Electronic implants should be placed in the appropriate MR compatible mode prior to scanning, and should be re-set immediately after the scan by a suitably trained person.
11. Electronic implants should be checked at the next scheduled patient check-up following MR imaging to ensure they are working correctly, as deemed necessary.
12. A scan should be terminated where the patient experiences adverse symptoms.
13. In exceptional circumstances, and under the guidance of appropriately qualified personnel, MR conditions may vary from those indicated by the manufacturer. This is a decision for the local MRI centre.
14. Any device related issues should be reported to the HPRA.
15. This notice follows up on the previous HPRA Safety Notice SN2014(33) on Magnetic Resonance Imaging Safety.

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