MR Safety Week 2019



Day 1 - Active implants

Introduction

Many patients who come for an MRI scan have some kind of implanted medical device. Before the patient can have a scan the MRI safety of the device needs to be assessed. Implants can be broadly categorised as either active or passive devices. Active devices have a power source in order to provide some sort of therapy or function for the patient. The interactions of active devices with the static, gradient and RF fields of an MRI scanner can be complex, and the conditions for *MR Conditional* devices can be more difficult to attain that for many passive devices. During MRI safety week, the BIR will issue a series of information sheets aimed at raising awareness of the typical conditions associated with scanning active devices.

Interactions with MRI

For active devices the same considerations as for passive devices are relevant. Devices are tested for attraction and torque forces in the static field of the scanner and for heating resulting from RF power deposition. However, exposures outside of the stated MR conditions could lead to unintended functional interactions of the devices (such as unintended stimulation effects). Therefore, it is important to follow ALL MR conditions for the device.

Common MR conditions

Just as with passive devices, MR conditions for active devices are designed so that the exposure to the static, gradient and RF fields of the scanner are within safe limits identified by testing. Often these limits will be more exacting than those for passive devices. It is common, for example, to have SAR limits that are substantially lower than the limit imposed by the scanner's *Normal Mode* of operation. Therefore, it may be necessary to develop modified protocols in order to meet these requirements. Note that all components of the scan session should stay within the implant limits. A thorough audit of the protocol should be performed and any additional scans monitored carefully.

It is also important to be aware of additional MR conditions that do not directly relate to exposure within the scanner. For example, there may be detailed instructions for how to put a device into the correct mode prior to the subject entering the *MR Environment*, or there may be requirements for certain staff members to be present during a scan. Always read the manufacturer instructions and ensure that ALL conditions can be met. Your local MR Safety Expert can advise on whether and how the conditions can be met.

Things to be aware of

MR conditions vary by device. Often individual manufacturers will make different models of a device type and the MR Conditions may be different for different models. Furthermore, the same manufacturer may have current or legacy devices that are labelled as *MR Unsafe* rather than *MR Conditional*. Devices will also often have more than one component. For example, neuro-stimulator devices are comprised of both the stimulator unit and the leads that deliver the stimulation to the target location. Therefore:

Always positively identify the Make and Model of ALL device components

Positive identification will take information from a primary source such as a patient implant ID card, a copy of the relevant section of the operation notes (with device stickers), manufacturer device eligibility forms completed by the patient's clinical team or, in some circumstances, a formal letter from the patient's clinical team. Information that is verbally delivered, or copied into an email, may not be sufficient to positively identify the device.

Manufacturers may update the MR conditions relating to specific devices as a result of additional device testing. Therefore:

Always obtain up-to-date details of MR conditions from the manufacturer

If information is not available from the manufacturer's website, contact a representative by email, or phone.

Many devices have detailed instructions for assessing device eligibility. It may be the case that a device requires up-to-date information on its integrity in order to establish its eligibility for MRI. For example, for devices with leads it is often required that the lead impedance is measured to ensure that no open or short circuits are present that could change the heating response to the RF field of the scanner. Remember:

Establish eligibility for EVERY scan. Previous MRI scans do not guarantee eligibility for future scans.

MRI scanning of patients with active devices is perfectly feasible. The development of *MR Conditional* devices means that more patients with these devices are eligible for MRI. By obtaining and following detailed safety instructions from manufacturers, these scans can be performed safely, and patients can have access to the diagnostic tests that they require.

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