

7 Tesla MRI non-significant risk (NSR) device justification

The 7 Tesla MR system to be used in this study is located at the Kennedy Krieger Institute (KKI) and manufactured by Philips Healthcare. While some commercial 7T MRI systems are FDA-approved for marketing (Siemens 7T MAGNETOM Terra, approved 2017), the Philips scanner located at KKI is not FDA-approved.

7 Tesla MRI systems have been classified as non-significant risk (NSR) devices by the FDA, as detailed in the document "Guidance for Industry and FDA Staff --Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices" issued July 14, 2003. A copy of this document has been uploaded in eIRB section 20. This document classifies magnets below 8 Tesla field strength as NSR.

Aside from magnetic field strength, other MRI safety parameters, such as radiofrequency heating specific-absorption rate (SAR), peripheral nerve stimulation (PNS) due to field gradient switching (dB/dt) and acoustic noise limits (dB) on the Philips 7T scanner all are within FDA guidelines for FDA-approved MRI scanners (at any field strength).

Safety of 7T MRI has been reviewed in several publications over the last few years. Currently (2021) there are about 80 7T MR systems installed around the world, and there are no reports of serious adverse medical effects in the literature. The 7T system at KKI has been operating for more than a decade (1st subject scanned spring 2009) now without any reported adverse events.

Magnetic fields do have transient bioeffects on the human body, which increase in intensity with increasing magnetic field strengths. From the participants perspective, the most noticeable is the magnetohydrodynamic effect on the vestibular system, which causes transient nystagmus, as well as possible feelings of vertigo, nausea, dizziness and false feelings of motion (1). In one multi-center study of over 3000 patients imaged using 7T MRI, approximately 20% subjects experienced moderate and 38% experienced mild vertigo during table movement in and out of the magnet (2, 3). Similar effects may be seen in lower field magnets (such as 3T) but with lower intensity and prevalence. In the same large multi-center study, other minor physiological effects reported at 7T include a metallic taste sensation (~5%), and magnetophosphenes (perception of flashing light) in the retina (~1% of cases (2)). All of these effects are temporary and resolve following removal from the magnet field.

Certain medical implants containing metal are unsafe for use with MRI, either because of magnetic forces exerted on them when placed in the magnet, or due to radiofrequency heating. Most medical implants have been extensively tested at the standard MRI field strengths of 1.5 or 3.0T, and are listed as MRI compatible or not. Fewer implants have been tested at 7.0T (4-6); therefore, all patients will be carefully screened for the presence of implants, and patients will only be allowed to participate if it is certain that the implants are 7T safe, as determined by the Kirby Center Chief MRI Technologist and Safety officer.

Literature Cited

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