

BS'D

To Scan or Not to Scan? MR Safety Decision Making & the FPO Mode

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Who will benefit from the information presented in this lecture?

Radiologists, Technologists, and all who are interested in learning more about the Fixed Parameter Option Mode of MR imaging system operation relative to the safe MR scanning of patients with certain active implanted medical devices.

How was a problem determined?

The observation that many patients with certain implanted devices were either not being permitted access to diagnostic MR imaging examinations or were in some cases exposed to MR imaging studies and suffered adverse events/injuries as a result of this exposure.

Examples of how this issue has been addressed:

By creating the Fixed Parameter Option mode for MR imaging system function, it is possible to prospectively design devices meant for human implantation in such a manner to ensure that they can be safely studied in some MR imaging units. This would provide access to these implant patients to one of the more powerful diagnostic imaging tools available today, which is something that many of them have lacked to this point.

What will attendees be able to do differently because of this information?

Understand not only what the FPO imaging mode is, but be able to utilize it in the decision making process as to whether or not to accept a given patient with an active implanted medical device for a clinically requested and indicated MR imaging examination.

The past year has seen a rather remarkable achievement: the emergence of formal definitions and acceptance of Fixed Parameter Option (FPO) mode of operation of clinical and research magnetic resonance imaging systems. When activated, this mode of MR imaging is designed to ensure that the magnetic resonance imaging system will restrict its static and time varying magnetic and electromagnetic fields to prospectively defined specific thresholds. These performance limitations were agreed upon by both magnetic resonance scanner manufacturers as well as industry representatives from the manufacturers of devices that are electromagnetically active and meant to be implanted within humans (e.g., neurostimulators, pacemakers, bone growth stimulators, etc.).

Device/implant manufacturers have not only participated in, but historically have led the call for highlighting the need for a prospectively defined set of thresholds under which the MR imaging units might operate and for which they may be able to design their own implants/devices to be able to safely tolerate. Thus, defining a so-called FPO mode of operation for MR scanners permits implant/device manufacturers to prospectively design and test implants that could safely operate and/or safely tolerate exposure to magnetic resonance imaging examinations whose energies were restricted to the FPO-accepted definitions.

This session is designed predominantly for clinical as well as research radiologists and MR technologists. In this session we introduce the idea of MR imaging of implants that are deemed to be able to safely undergo MR imaging when scanned under the newly defined FPO imaging mode and its concomitant imaging thresholds. A brief overview of the MR safety considerations behind MR scanning of patients with Active Implanted Medical Devices (AIMDs) will be presented, including potential considerations of ferromagnetic concerns (including consideration of translational, rotational/torque, and Lenz forces), the potential for voltages or currents that might be induced not only in the implanted device itself but also possibly the patient's tissues, the concern for possible device/lead heating and secondary thermal safety considerations, and the concern for possible incapacitation or alteration of the functionality of the device itself by virtue of its exposure to both the static as well as the time varying magnetic and electromagnetic fields of the magnetic resonance imaging environment.

This provides the background to enable the attendee to understand the driving forces behind and the history of the development of the FPO mode of operation of MR imaging systems. We will present the presently defined thresholds for FPO operation as they might be applied in clinical MR imaging systems today.

To further illustrate how the availability of the FPO mode of imaging might prove clinically useful as well as how it might be applied in typical imaging settings, we will illustrate various clinical situations. We will introduce the audience to a fictitious Ms. Anne Knowall, an experienced MR technologist, who is presented with a request to perform MR imaging on a patient with an AIMD that is not labeled as MR Conditional under FPO mode. She will take this request to her radiologist, Dr. Clueless, who is the covering radiologist for magnetic resonance services for that day at that site. Dr. Clueless is a radiologist who is not well versed in MR safety considerations in general and certainly not in the potential problems that might arise when a patient with an AIMD might undergo MR imaging. Dr. Clueless will attempt to decide whether to accept or not accept that patient for the requested MR imaging examination. We will then compare and contrast this with how Dr. Clueless and Ms. Knowall might instead react and respond to an otherwise identical clinical situation with a patient in whom there is an AIMD that *is* labeled as MR Conditional under FPO mode.

Finally, the above will be supplemented by illustrating interactions between Ms. Knowall

and Dr. G. Nus, a different radiologist who is well versed in and quite knowledgeable about all matters related to MR safety. We will compare and contrast the decision making process and interactions experienced when Dr. Clueless was covering such a situation to how it might unfold if Dr. G. Nus has been the covering radiologist instead. This will also permit us to demonstrate some of the benefits of the availability of the FPO mode of operation even for sites in which a radiologist experienced and knowledgeable in MR safety is readily available.

By attending this session, the attendee will feel comfortable in understanding what the newly introduced FPO mode represents, why it was created and what problems it was designed to address, and how it can be readily and practically applied in routine clinical and research settings and magnetic resonance environments.