## Specialty Area: MR Imaging of Patients with Implanted Devices


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| Speaker Name | Niels Kuster kuster@itis.ethz.ch |
| Organization/employer | IT'IS Foundation & ETH Zurich |
| Address | Zeughausstrasse 43<br>8004 Zurich, SWITZERLAND |


## Highlights

- Current safety standards for implants during MR exposure
- Why are the current ASTM standards on the safety assessment of passive implants during MR exposure inadequate for active implantable medical devices (AIMD)?
- Fundamental assumptions and solutions developed for the Technical Specifications ISO/TS10974 "Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device"
- Four-tier safety assessment method and uncertainty budgets for AIMD RF-induced heating of ISO/TS10974
- Three-tier safety assessment method and uncertainty budgets for AIMD pulsed gradient-induced malfunction of ISO/TS10974
- Open issues and scientific gaps to fill

## MR Safety Considerations for Patients with Implanted Devices

### Target audience

Researchers, developers, and regulators of MR safe implants

### Objectives

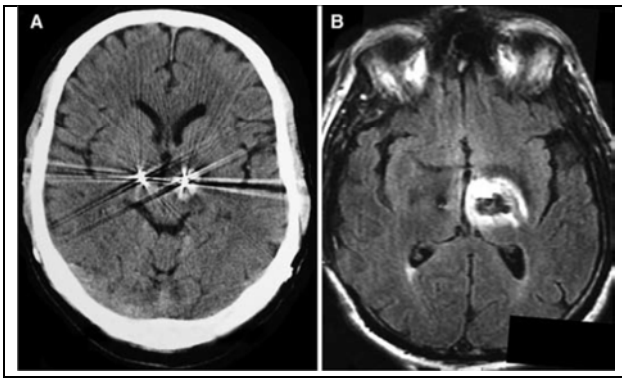
- To provide the latest update in current research and regulatory perspectives with respect to the safety considerations of patients with implanted devices undergoing MRI examination
- To describe the solutions for and challenges of developing MR-safe active implantable medical devices (AIMD) and demonstrating the MR safety of these devices
- To identify the scientific gaps in MR safety assessments of patients with implanted devices that have yet to be addressed.

### Interaction of MR fields with Active Implants

RF heating is one of the potential hazards for patients undergoing MRI examination. Recent studies [1,2] have shown that local SAR enhancements can reach much higher levels than previously assumed, i.e., >80 W/kg, while the safety limits for public and occupational exposures are 2 and 10 W/kg, respectively. When a moderate thermoregulation model, such as that applied in [1], is used to translate the local SAR exposure to temperature, the maximum exposure of the first level operating mode can result in peak temperatures of > 42°C, resulting in scan times of considerably less than one hour [3]. Much more severe damage is expected in

patients with severely impaired or dysfunctional local thermoregulation [3]. These current established safety limits do not take into account the presence of any medical implants.

Patients with metallic medical implants face an increased risk of local tissue damage at the vicinity of the implants due to RF heating. As a metallic implant embedded within the human body behaves as an antenna in lossy media, it can receive and locally deposit the received RF power (e.g., at the electrodes). Large common passive implants, such as hip or bone implants, lead to slightly elevated tissue temperature near the implants (< 1°C) [4]. Unfortunately, local RF heating caused by elongated active implants (e.g., cardiac pacemakers [5] and deep-brain stimulators [6]) can be several orders of magnitude higher than that of passive implants. Furthermore, the current standard for RF heating risk assessments, which is applicable to passive implants [7], does not sufficiently address the risk of active implantable medical devices (AIMDs). In this part of the talk, the RF-AIMD interaction mechanisms will be explained in detail and the various design measures to reduce the receiver performance of the AIMD will be described (e.g., increase of the RF impedance and filters).




**A computed tomography scan performed immediately after the lumbar spine MRI scan revealed evidence of a hemorrhage surrounding the left DBS electrode. B, T2-weighted MRI scan of the brain showing edema around the left DBS electrode. Illustration and caption extracted from [6].**

**Procedures for Demonstrating the MR Safety of AIMDs (ISO/TS10974)**

During the last eight years, an ISO/IEC working group composed of implant and MR manufacturers, regulators, and academics, has developed procedures for demonstrating the MR safety of implants. The ISO/TS 10974:2012 addresses the following potential hazards caused by AIMD interactions with the MR scanner [8]:

1. $B_0$ field: force & torque
2. Gradient field: local heating & malfunction
3. RF field: local heating & malfunction.

The technical specification identifies the deficiencies of the current standards for passive implants in addressing the risks for AIMDs. The application of the specification is illustrated by specific examples that focus on two specific hazards: RF-induced heating and gradient-induced voltage (malfunction). The proposed multi-tier methods vary in complexity, and more importantly, each tier is not appropriate for all AIMDs and the selection of the suitable tier may not be straightforward. In this part of the presentation, Based on several case studies of commonly used AIMDs, I will demonstrate how a specific tier that is successfully applied to a

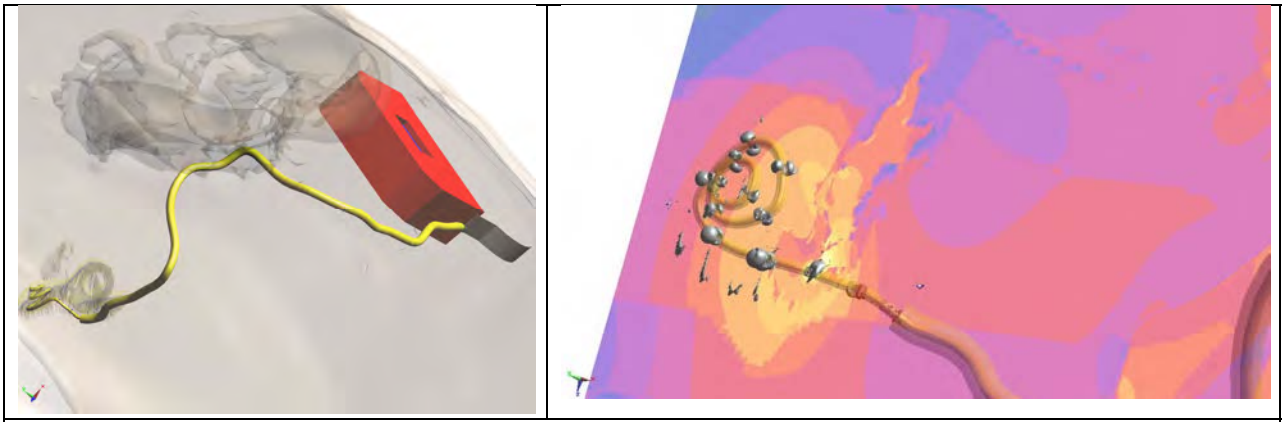
particular AIMD may fail to address the hazards for different AIMDs. The multi-tier approach for these two specific hazards are outlined as follows:

**A. RF-induced heating of an AIMD during MR exposure**

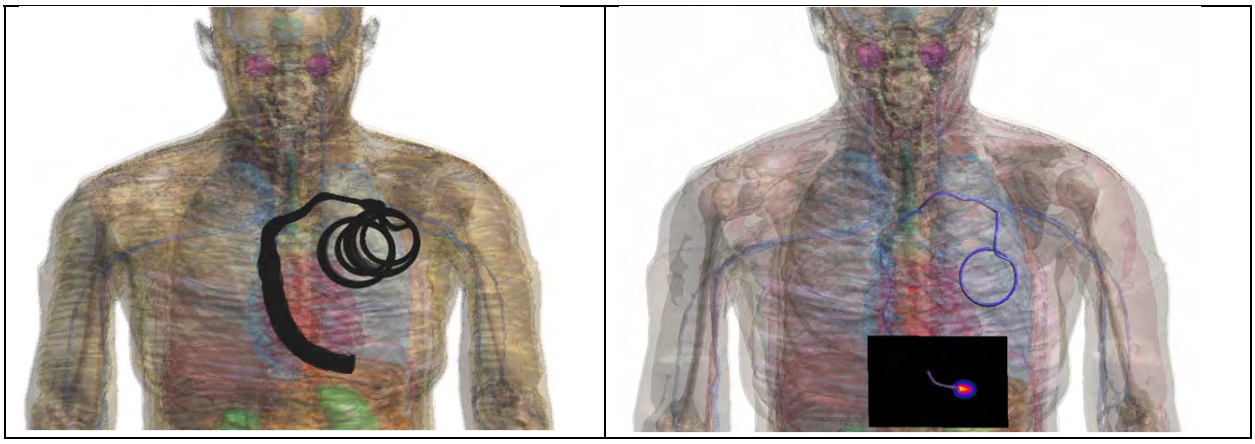
- Overview of the four-tier method and applications
- Tier 4: The gold standard and its (in)feasibility
- Tier 3: Synergistic and practical
  - Uncertainty budget of method
  - Piecewise excitation technique
  - *in vitro* validation
  - Estimating *in vivo* heating
- Tiers 1 & 2: Overestimate RF heating, applicable for certain AIMDs

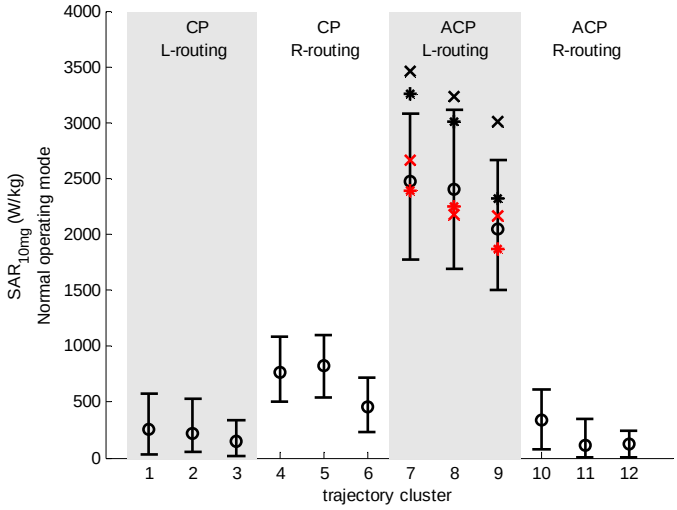
**B. Gradient-induced malfunction of an AIMD during MR exposure**

- The gradient fields, slew-rate, and Faraday's Law
- Overview of the three-tier method and applications
- Tiers 1 – 2: Assumptions, current implementation, and applicable situations
- Tier 3: Assumptions, current implementation, and computational costs



**Case study: Tier 4 evaluation of RF-induced heating of Cochlear implant. (Left) Tier 4 modeling. (Right) Local RF-induced tissue temperature.**






**Case study: Tiers 3 & 4 evaluations of RF-induced heating of cardiac pacemaker. (Top-left) Tier 3 modeling. (Top-right) Tier 4 modeling. (Bottom) Evaluated *in vivo* local power deposition of Tier 3 vs. Tier 4. Illustration extracted from [9].**

## Scientific Gaps to Fill

The Tier 3 approach for RF-induced heating safety assessment is based on separating the induced fields and the response of the leads to the induced fields [10]. The preconditions allowing these simplifications are generally violated, the consequences of which have not been fully assessed yet. The latest progress will be discussed in this talk.

For the emerging field of interventional MR, the exposure safety assessment for leads and catheters, such as ablation catheters, cannot be fully addressed with the proposed method of ISO/TS 10974. The complex exposure scenario of these devices requires special considerations. Similar considerations must be applied to body-mount devices, such as EEG/ECG leads. Potential solutions will also be discussed in this section.

Recent studies have shown that in addition to improving the AIMD design, MR exposure may also be modified to further reduce RF-induced heating risks to benefit the patient [11,12]. A combination of the two may further increase the safety of MR diagnostics for every patient, irrespective of his/her pre-existing condition.

## References

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