The Need for EMI Risk Management in MRI Systems

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***Abstract*—This paper presents a MAUDE database analysis focusing on MRI systems. It links the adverse reports with electromagnetic interferences, unveiling the need to introduce a risk-based approach and EMI risk management during the life cycle of the system.**

MRI, EMC, EMI, Intended Environment, Rule-based, Risk-based, Install-based Equipment

I. Introduction

Magnetic Resonance Imaging (MRI) has been an available clinical imaging tool for over three decades. Recently, ultra-high-field (i.e., 7 T) MRI has attracted increasing attention because it can provide higher signal-to-noise ratio (SNR), spatial resolution, and contrast than the more known 1.5 T and 3 T systems [1]. Additionally, the use of MR-compatible devices is proliferating in interventional MRI [2]; and there is an increasing trend to use commercially available components (COTS) to develop the system [3-6]. These technological tendencies highlight the importance of electromagnetic compatibility (EMC) during the system's design, implementation, and maintenance.

EMC standards are mostly based on a rule-based approach, which has been demonstrated to have evident shortcomings [7][8]. Taking real-life medical environments, the disturbance levels will vary according to a statistical distribution, and the allowed emission levels can be exceeded in particular circumstances [9][10]. Therefore, being compliant with current medical standards does not ensure a minimum risk for the patient.

Analyses of the MAUDE database [11-12] show that there have been many situations where an MRI or MR-compatible device met the existing standards, but failed to operate safely in line with its intended use. Although, none of these analyses link the adverse reports with electromagnetic interferences (EMI).

This paper presents an updated MAUDE database analysis, following the procedure explained in [11]. Also, it links the adverse reports with EMIs, which shows the need for an EMC risk-based approach and EMI risk management.

II. MRI Accidents due to EMI

The MAUDE database analysis summarizes the MRI adverse reports from January 2017 to December 2021, retrieving 532 results.

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The main causes of the adverse reports, considering the ones related to the functioning of MRIs, are thermal by 45%, followed by acoustic (15%), projectile (11%), mechanical (10%), and image quality (8%).

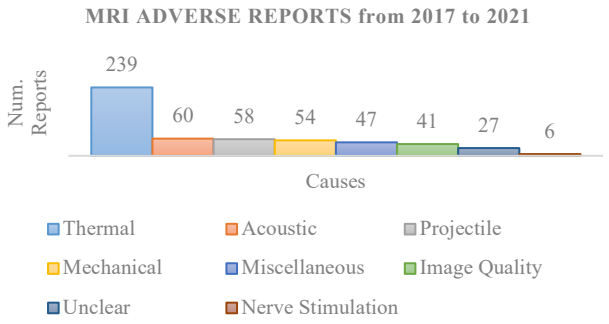

Fig 1. MRI Adverse Reports from 2017 to 2021

Two of these causes can be due to EMI. (1) Thermal causes derive from heating sensations, blisters, and burns on the patient. Those harms can be produced by a Specific Absorption Rate higher than allowed. Although, Laura Tagell [13] states that most burns on patients are due to their body positioning. (2) Image quality can be degraded if the static magnetic field is disturbed or there is an interference in the receiver chain. Those hazards can harm the patient in terms of an incorrect diagnostic. Throughout the reports' analysis, we detected multiple situations where the doctor made a misdiagnose due to a flipped MR image.

The link between EMI and thermal and quality image causes unveils the need to include extra testing in the life cycle of the MRI system. Its resilience needs to be improved in the intended environment. The integration of MRIs typically takes place at the site of the clinical researchers. Due to the collaborative way of working and on-site installation, testing can only occur at the component level or in-situ. It is known that in-situ measurements are cumbersome and often unreliable [10]. Furthermore, this testing will help to introduce new technology without disturbing the install-based equipment, e.g., MRIs.

III. Conclusions

The analysis of the MAUDE database shows that there are still situations where an MRI system or MR-compatible device, due to EMI, does not operate safely in its intended environment. There is a need to tailor the safety requirements defined in the standards to each particular environment. To achieve this, an EMI risk management and an EMC risk-based approach that offers higher levels of safety are needed.

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