DISPERSE

Electronics for spatially distributed sensors and transducers arrays

Labeled in PENTA, a EUREKA cluster, Call 1

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	PP	Restricted to other programme participants	
	RE	Restricted to a group specified by the consortium	
	CO	Confidential, only for members of the consortium	

DOCUMENT HISTORY

Release	Date	Reason of change	Status	Distribution
V0.1	30/09/2019	First draft by Philips and discussion at Consortium Meeting in Mechelen	Draft	All DISPERSE partners
V0.3	08/10/2019	Additional input and feedback from Cochlear and GTX Medical.	Concept	Cochlear, GTX Medical, KU Leuven, Philips
V0.3	15/10/2019	Document submitted to FDA (formatted conform FDA guidelines)	Final	FDA
V1.0	15/10/2019	Reformatted in to DISPERSE Deliverable template	Submitted	Public

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Glossary

Abbreviation / acronym	Description
AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
B1+	Effective part of the RF transmit field in MRI
CT	Computed Tomography
FDA	Food and Drug Administration
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MARS	Metal Artifact Reduction Sequences
MR(I)	Magnetic Resonance (Imaging)
RMS	Root Mean Square
SAR	Specific Absorption Rate
TS	Technical Specification
URL	Uniform Resource Locator

1. Executive Summary

This document provides comments and suggestions concerning standardization related to testing and labelling medical devices for safety in the Magnetic Resonance (MR) environment.

2. Introduction

This document provides feedback from the DISPERSE consortium to the standardization bodies. Specifically it refers to FDA's draft guidance on Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment [1].

3. Recommendation

DISPERSE is a research consortium focusing on the requirements for safely scanning patients with multiple MR Conditional implants or devices [2]. In this document, we provide suggestions for improved labeling for single implants and additional concerns and required guidance for situations related to co-existence of implants, both passive and active. Our focus has been on the particular use case of implanted hearing devices and neural stimulator devices (brain or spine). Preliminary data shows that co-existence can increase heating beyond values detected for single/isolated implants. We realize that the full space of potential combined implants cannot be covered by any single manufacturer alone. Nevertheless, we suggest that FDA extends its guidance document with suggestions how users may be informed about additional required pre-cautions in case of multiple implants.

One such approach may be to inform users that the (fractional) SAR (or preferably B1+rms) numbers on the two implants may need to be derated by e.g. 20%, and the MR system controlled by the minimum B1+rms number thus obtained. This suggested approach obviously requires additional research and validation. Also, landmark exclusion zones need to be combined from the individual labels, and possibly extended. There is no scientific data to support any guidance in such cases.

Associated to this comment, we are concerned about the lack of validation of effectiveness of the additional labeling proposed in the draft Guidance. MR radiographers participating in our research consortium have reviewed the proposed tabular format, and want to bring to FDA's attention the following concerns:

- Line 650: Suggest adding another statement to direct users to the current MR conditional labelling (e.g. URL and phone number) as described in ISO/TS 10974:2018 [3]. A suggestion to add contact information to the patient card is already given on line 517, but we suggest to also add another line to the safety sheet.
- Lines 644-645: Suggest expanding the minimum reporting criteria listed here to also include a reference image of the tissue surrounding the device using a worst-case imaging sequence. For cochlear implants, this is already required as per AAMI/ANSI CI86 and we believe this increases the clarity of the resulting MRI safety sheets of a device for post-operative follow-up. For implants where it is common to remove certain implantable components, we recommend putting images of the different configurations, e.g. the removal of cochlear implant retention magnets prior to MRI.
- Lines 644-645: Suggest adding more information when there is a need to visualize the tissue surrounding the implant, for example via the use of metal artefact reducing sequences (MARS) or different imaging modalities like CT imaging.
- Line 633-635: As implant manufacturer, GTX medical recommends to use B1+rms for heating related hazard rather than SAR, especially partial body and head SAR that cannot be accurately quantified. In addition, we suggest to add the maximum permitted B1+peak value to the labeling to prevent rectification.

4. Conclusions

The DISPERSE has jointly informed FDA with respect to their research findings related to scanning patients with multiple active implantable medical devices in MRI. Through FDA, and independent means, this input will be transferred to ISO/IEC as well.

5. References

[1] FDA, “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance Environment, *document number 1500059*, August 2, 2019.
[2] PENTA, “DISPERSE investigates solutions for MRI scanning op patients with multiple implants”, *press release*, January, 2018.
[3] ISO, “Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device”, *ISO/TS 10974:2018*, April, 2018.
[4] AAMI, “Cochlear implant systems: requirements for safety functional verification, labelling and reliability reporting, *ANSI/AAMI CI86:2017*, January 6, 2017.

