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Guidance for uncertainty analysis regarding the application of ISO/TS 10974

Lignes directrices pour l'analyse de l'incertitude concernant l'application de l'ISO/TS 10974

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Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Uncertainty background **1**
4.1 General 1
4.2 Method 1 Evaluation 2
4.3 Method 2 Evaluation 3
5 Experiment Uncertainty (u_{exp}) **3**
5.1 General 3
5.2 Measurement tool uncertainty (probe) 3
5.3 Probe position uncertainty 3
5.4 Tissue simulating phantom 4
5.5 RF field source 4
5.6 Phantom position uncertainty 4
5.7 AIMD influence 4
5.8 Overall u_{exp} consideration 4
6 AIMD model uncertainty ($u_{Predict}$) **5**
6.1 Piecewise excitation method for deriving AIMD model 5
6.2 AIMD model uncertainty ($u_{Predict}$): Method 1 6
6.3 AIMD model uncertainty ($u_{Predict}$): Method 2 11
7 Clinical uncertainty ($u_{Clinical}$) **12**
8 Uncertainty in conversion to power (u_{power}) **13**
9 Final uncertainty (combination and application) **13**
Bibliography **14**

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Clause 8 of ISO/TS 10974:2018 describes methods (Tiers) for analyzing the RF power deposition for active implantable medical device (AIMD). EM evaluations in a complex near-field exposure scenario can be difficult and involve many uncertainty sources. Simulations requiring a model of the DUT and clinical incident field have uncertainties that need to be carefully assessed.

The objective of the uncertainty analysis is to determine the confidence interval of the RF-induced power deposition with respect to its true value. The acceptable level of uncertainty for an AIMD model is relative to the safety margin afforded by the AIMD's RF performance. For instance, if the expected MRI RF induced AIMD power deposition *in vivo* is very low, it is less critical to have a highly accurate model and more uncertainty can be tolerated in the model predictions.

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Guidance for uncertainty analysis regarding the application of ISO/TS 10974

1 Scope

This document provides guidance for some methods that could be used to evaluate the sources of uncertainty. It is important to note that there are many legitimate methods for analyzing the overall uncertainty and that the methods in this document are illustrative only.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 10974:2018, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 10974 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Uncertainty background

4.1 General

The uncertainties are divided into random and systematic uncertainties.

Random errors result in measured values being distributed about the mean value. Measurement variations are often well approximated by normal or lognormal distributions. Many of the sources of uncertainty for the measurements described in this document are the result of exponential or r^n functions, e.g., the decay of power levels as a function of distance from the AIMD, and therefore can be approximated by lognormal distributions.

In addition to random errors, systematic errors should also be considered. Systematic error is the error remaining once the random error is removed as shown in Figure 1. Systematic errors should be eliminated wherever possible.

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