TECHNICAL REPORT

ISO/TR 21900

First edition
2018-09

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

Reference number
ISO/TR 21900:2018(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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.

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/

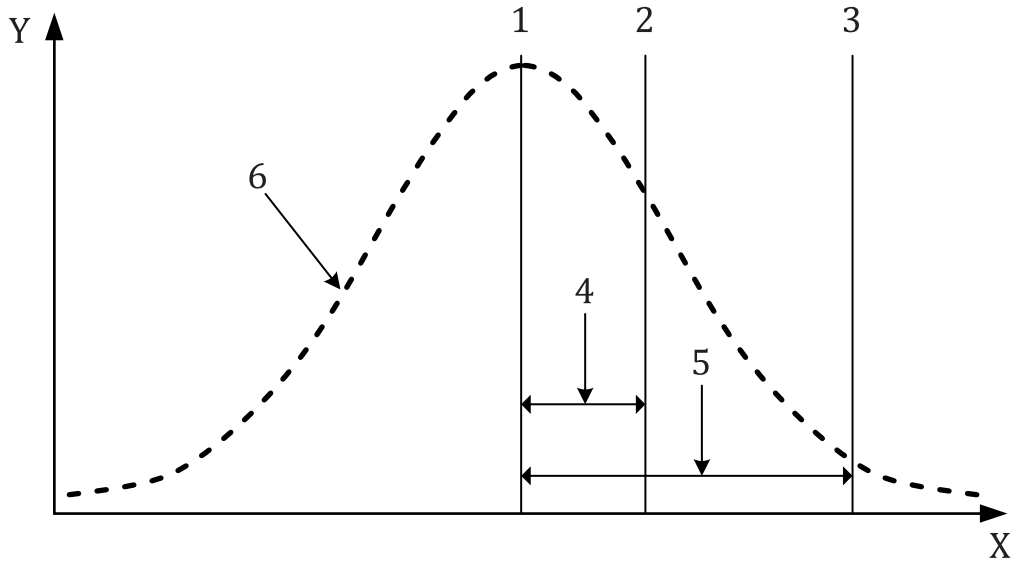
4 Uncertainty background

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.



Key

X	range of values	Y	range of occurrence
1	mean value	4	random error
2	individual value	5	systematic error
3	true value	6	distribution of values

Figure 1 — Relationship of measured, mean, and true values and association of random and systematic errors

Uncertainty assessments of systems such as these can be dominated in magnitude by a small subset of uncertainty sources. When independent uncertainty sources are combined smaller uncertainty sources often contribute negligibly to the overall budget.

A variety of factors contribute to the uncertainty described in Clause 8 of ISO/TS 10974:2018. The dominant sources of uncertainty are specific to the equipment, measurement methods, and numerical simulation tools used for the assessment. Clause 8 of ISO/TS 10974:2018 requires an uncertainty assessment for the measurement system (u_{exp}) and AIMD model ($u_{Predict}$). There are two additional sources of uncertainty being clinical uncertainty (from 8.6 of ISO/TS 10974:2018) and power to temperature uncertainty (8.4.3 of ISO/TS 10974:2018). Techniques for evaluating these uncertainty terms (u_{exp}, $u_{Predict}$, $u_{Clinical}$, u_{Power}) are described. As Clause 8 of ISO/TS 10974:2018 has multiple tiers for evaluation of power deposition, the evaluation of each uncertainty source is specified per tier.

Two methods of uncertainty evaluations are developed in this document. In both methods, the uncertainty of the entire assembly is determined. In one method, many of the components of the assembly are grouped and a single uncertainty determination is made for many of them. In the second, the sources of uncertainty in a system are identified and individually evaluated a priori and the dominant sources are combined to obtain the system uncertainty.

GUM[1] has provided approaches for evaluating the uncertainty of assemblies, regardless of component count, and called their approaches Type A and Type B. Either or both Type A and Type B evaluations for each method is appropriate.

4.2 Method 1 Evaluation

Method 1 determines the uncertainty of a complex measurement system by considering the variability of the system as a whole. Method 1 is based on the assumption that a probability distribution of the random variation of the evaluation results can be deduced from approximation of the measurement or modelling system where the uncertainty is determined for an assembly or collection of many parts of the system. In this approach, multiple elements of the system are assembled or 'lumped' together and

their combined uncertainty is assessed. Estimates of the standard deviation of this distribution are obtained by repeated evaluations and statistical analysis of the obtained values.

4.3 Method 2 Evaluation

Method 2 generally dissects the assembly into its constituent parts, determines the uncertainty of each individually, and then determines the uncertainty of the group by combining the uncertainty of each of the components. Method 2 is based on reasonably assumed probability distributions that account for the available information about the quantities concerned, and the standard deviation of these distributions. This type of evaluation is performed by evaluating the independent sources of uncertainty of the components of the measurement or modelling system. In this approach, the components of the system are separated, and the uncertainty of each component is determined. In a subsequent step, the uncertainty of each is combined together. Techniques for handling the types of distribution of these uncertainties and normalizing to a standard distribution from non-standard distributions (such as rectangular, triangular, and U shaped) are well known[1]. Root sum square (RSS) is a common method for combining individual uncertainty components, however the method assumes that the terms are independent of each other.

In practice, some level of overlap between methods 1 and 2 is likely to exist in uncertainty evaluations.

5 Experiment Uncertainty (u_{exp})

5.1 General

The measurement system of Clause 8 of ISO/TS 10974:2018 is comprised of the RF field source, tissue simulating phantom, and probes for measuring temperature rise, SAR or E-field. It also comprises DUT fixturing to enable accurate positioning of the probe relative to the DUT. The parameter u_{exp} accounts for the combined uncertainty of the RF field source, tissue simulating phantom, the measurement probe, and the positioning of the measurement probe relative to the DUT.

5.2 Measurement tool uncertainty (probe)

For Clause 8 of ISO/TS 10974:2018, measurements of RF hotspots are done using SAR or temperature probes.

For SAR measurements, absolute measurements are necessary and the absolute accuracy is a contributor to the overall uncertainty. The absolute SAR uncertainty is determined from the calibration of the SAR probe. Depending on its use, the probes linearity, isotropy, distortion of the field, and noise level could influence its uncertainty.

For temperature probes, all temperature rise measurements are relative. Temperature probe placement accuracy will likely have a greater impact on measurement uncertainty than the repeatability of the temperature probe due to the spatial distribution of temperature.

5.3 Probe position uncertainty

Temperature or SAR decreases exponentially as a function of distance from the source of the RF hotspot. Therefore, probe positioning is an important contributor to the overall uncertainty.

Assuming a 10 °C peak temperature, a 1 °C temperature change can be observed in less than 250 µm. If ΔT measurements are accurate to within 0,1 °C, this is equivalent to better than 25 µm in probe placement accuracy. Therefore, temperature probe placement accuracy is one of the dominant sources of uncertainty and should be evaluated. When SAR probes are used, probe placement accuracy is equally important.

5.4 Tissue simulating phantom

In order to minimize differences between measurements and model predictions, it is desirable to control the conductivity of the TSM (tissue simulating medium) in addition to the background temperature. Background temperature control is necessary because conductivity and permittivity have large temperature coefficients as described in ISO/TS 10974:2018 Annex H.1.2. Permittivity is relatively insensitive to slight variation in mixing method and similar to conductivity, the variation during experiment can be controlled by limiting the bulk TSM temperature rise. TSM with various conductivity values within the tolerance range as specified in 8.3.2 of ISO/TS 10974:2018 can be used to evaluate the weighting coefficient for its contribution to the uncertainty in the temperature or SAR measurement.

5.5 RF field source

In order to minimize differences between measurements and model predictions, it is important to know the $E_{\tan}$ along the lead pathway matches the exposure assumed for prediction. It is typical to consider and control the RF incident fields along the lead pathway as well as the contribution of phantom position uncertainty to the RF Field uncertainty. Uncertainty of the RF incident fields along the lead pathway is more salient than field error at points in the phantom not near the lead pathways, and hence more useful to control and quantify.

Small changes in the lead pathway can produce a significant change in the measured ΔT, particularly for lead pathways that are producing significant phase cancelation or phase enhancement. The AIMD mounting fixture(s) and probe measurement fixture(s) need to be carefully designed in order to minimize the positional variation of the lead over the entire pathway. Small changes in the position of any section of the lead can change the magnitude or phase of the incident $E_{\tan}$ and result in a change in the measured ΔT or SAR.

The fixturing of the lead pathway on the RF field might distort an idealized simulation of this RF field and lead to uncertainty in the RF field source. Incident field distortion caused by fixturing could be a source of uncertainty, unless accounted for in the simulated incident fields from which $E_{\tan}$ along the lead pathways are derived.

5.6 Phantom position uncertainty

Uncertainty in the phantom position can also cause differences between the measured and simulated $E_{\tan}$ exposures leading to differences in the simulated and actual $E_{\tan}$ along the AIMD. This effect should be closely controlled or quantified as it can be a contributor to the overall uncertainty.

5.7 AIMD influence

The electric field induced in numerical human body models that do not contain AIMDs are used to define RF heating test environment specified in Tiers 2, and 3 of Clause 8. These methods assume that the perturbation of the induced electric field due to the AIMD can be neglected or is accounted for in the RF heating model validation. Care should be taken to ensure that these assumptions are valid for the AIMD being evaluated (particularly when multiple parts of the AIMD are in close proximity).

5.8 Overall $u_{\exp}$ consideration

The above description of a typical power deposition measurement system identified a number of contributors to the overall uncertainty.

In using a Method 2 analysis, the uncertainty of each of the above terms is determined. A specific experiment isolating each of these variables is evaluated, as much as reasonably possible. Then each of these individual contributions are combined using a RSS method to create an overall $u_{\exp}$.

In using a Method 1 analysis, an experiment or series of experiments are devised that combines the equipment or measurement components that are contributors to the overall uncertainty. The measurements from repeated experiments of these assemblies could use the probes (temperature

