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SPECIFICATION

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10974

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**Assessment of the safety of magnetic
resonance imaging for patients with an
active implantable medical device**

*Évaluation de la sécurité de l'imagerie par résonance magnétique pour
les patients avec un dispositif médical implantable actif*



Reference number
ISO/TS 10974:2012(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

ISO/TS 10974 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

Introduction

This Technical Specification came about following a joint meeting between ISO/TC 150, *Implants for surgery*, and IEC/SC 62B/MT 40, *Magnetic resonance equipment for medical diagnosis*, in Vienna, Austria, in September 2006. An agreement was reached to coordinate efforts on the development of a new Technical Specification for the safety of patients with active implantable medical devices (AIMD) undergoing an MRI exam and related further development of IEC 60601-2-33.

This Technical Specification represents a broad-based effort to capture the current understanding of relevant issues and concerns at 1,5 T, the most common MR field strength. The Joint Working Group (JWG) responsible for this Technical Specification (ISO TC150/SC6/JWG2 and IEC SC62B/JWG1) recognizes its incomplete understanding and coverage of relevant details. The JWG releases this edition to promote developments in this area.

The JWG plans to refine this first edition with the intention of publishing a second edition in the time frame allowed by the ISO/IEC Directives and seeks input from interested parties. At this time, the JWG anticipates the possibility that eventually an International Standard might result from this work.

IEC 60601-2-33:2010 provides supporting information. By mutual agreement between the JWG and MT 40, any and all MR scanner-related requirements will be considered by IEC/SC 62B/MT 40 and will be released through future amendments and editions of IEC 60601-2-33.

The relationship between product committees is shown in Figure 1. Straight lines represent the relationship and not necessarily a physical connection. Ellipses represent scope, i.e. the effects between patient and scanner, patient and AIMD, and AIMD and scanner.

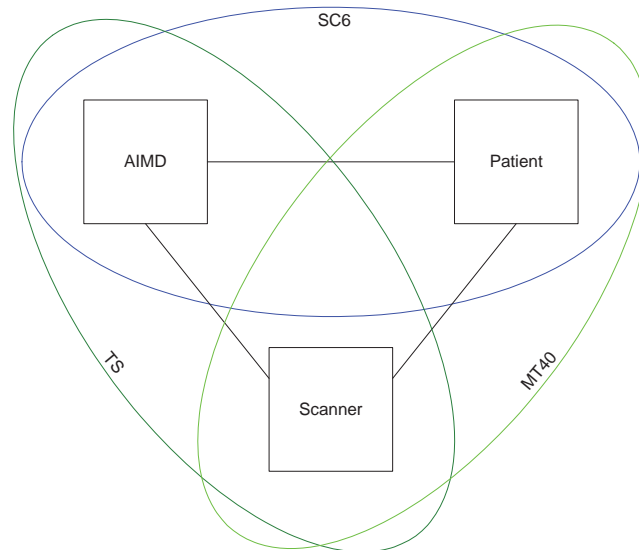
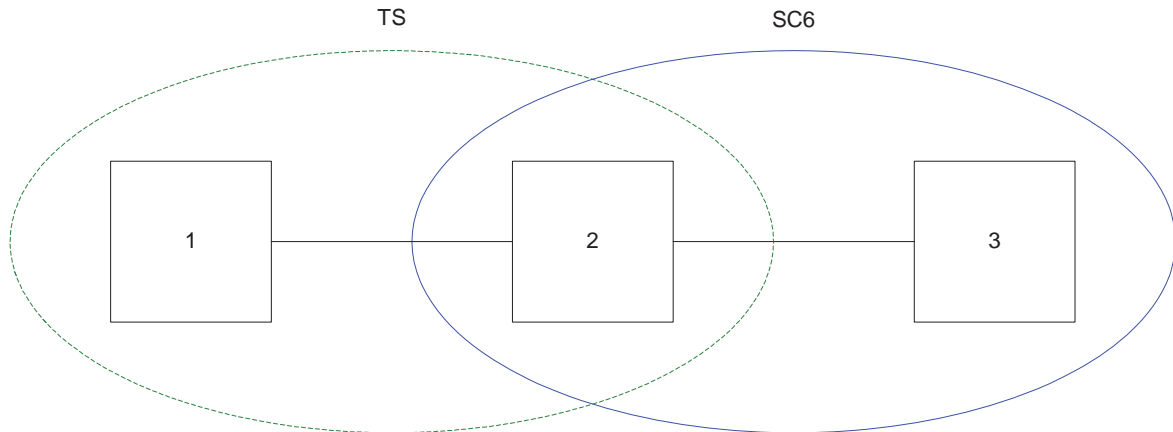


Figure 1 — Diagram showing the responsibilities of product committees and illustrating the extent of the scope of this Technical Specification in terms of the effects between AIMDs and MR scanners

This Technical Specification is concerned with interactions on the AIMD caused by the scanner. ISO/TC 150/SC 6 product committees are concerned with how those interactions affect patient safety.

This Technical Specification is general for all AIMD types, while ISO/TC 150/SC 6 product committees deal with specific types. ISO/TC 150/SC 6 will turn the general provisions of this Technical Specification into product-specific requirements, if necessary.



1. Hazardous situation/mechanism/phenomenon: Interactions between the AIMD and scanner and resulting phenomenon, e.g. induced voltage.
2. Hazard: Potential source of harm, e.g. heating or malfunction. A knowledge of known or foreseeable hazards resulting from physical interactions will guide comprehension, selection and development of TS test methods.
3. Risk: Probability of occurrence of harm x severity of harm.

Figure 2 — Responsibilities of product committees illustrating the extent of the scope of this Technical Specification in terms of the delineation between hazards and harms

Test methods described in this Technical Specification are primarily designed and intended as bench-top tests using equipment and techniques to simulate the fields (B_0 static, gradient, and RF) found in MR 1,5 T scanners. Although, in a few cases, clinical scanner tests are implied, in all others, the AIMD manufacturer assumes the burden for development and validation of clinical scanner-based test methods. Furthermore, the test signals and parameters specifically described within this Technical Specification for bench-top testing (e.g. Clause 8) are not being encouraged or recommended for use on clinical scanners and to do so might result in scanner damage.

No requirements contained within this Technical Specification, including the use of clinical scanners, construe or imply any burden or obligation on the part of MR equipment manufacturers. Any statement to the contrary is strictly unintentional.

The requirements contained within this Technical Specification are based on specific potential hazards that have been identified as applicable to a general class of AIMDs (see Clause 7). Risks associated with these specific hazards, and any additional hazards and risks that might occur for any specific AIMD type (e.g. implantable neurostimulators), are outside the scope of this Technical Specification.

NOTE 1 Other interested parties, such as device manufacturers, regulatory agencies and particular product committees, are responsible for setting specific compliance criteria and determining risk.

NOTE 2 The discussion of risk and, in some cases, test methods in some of the informative annexes (e.g. Annex S, Annex T and Annex V) serves to provide additional information and a rationale that might assist readers in their comprehension of this material. The information provided in these annexes is supplementary and subordinate to the normative requirements in this Technical Specification.

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The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) draw attention to the fact that it is claimed that compliance with this Technical Specification may involve the use of a patent concerning gradient vibration given in Clause 12.

ISO and IEC take no position concerning the evidence, validity and scope of this patent right.

The holder of this patent right has assured ISO and IEC that he or she is willing to negotiate licences under reasonable and non-discriminatory terms and conditions with applicants throughout the world. In this respect, the statement of the holder of this patent right is registered with ISO and IEC (a copy of the patent declaration is shown in Annex A). Further information may be obtained from:

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Open Innovation and Intellectual Property
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Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those identified above. ISO and IEC shall not be held responsible for identifying any or all such patent rights.