TECHNICAL SPECIFICATION

ISO/TS 10974

First edition
2012-05-01

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

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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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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.

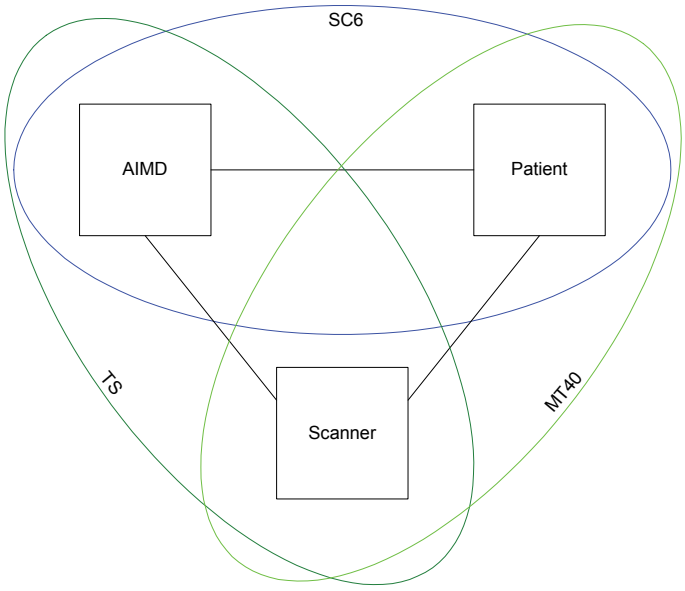
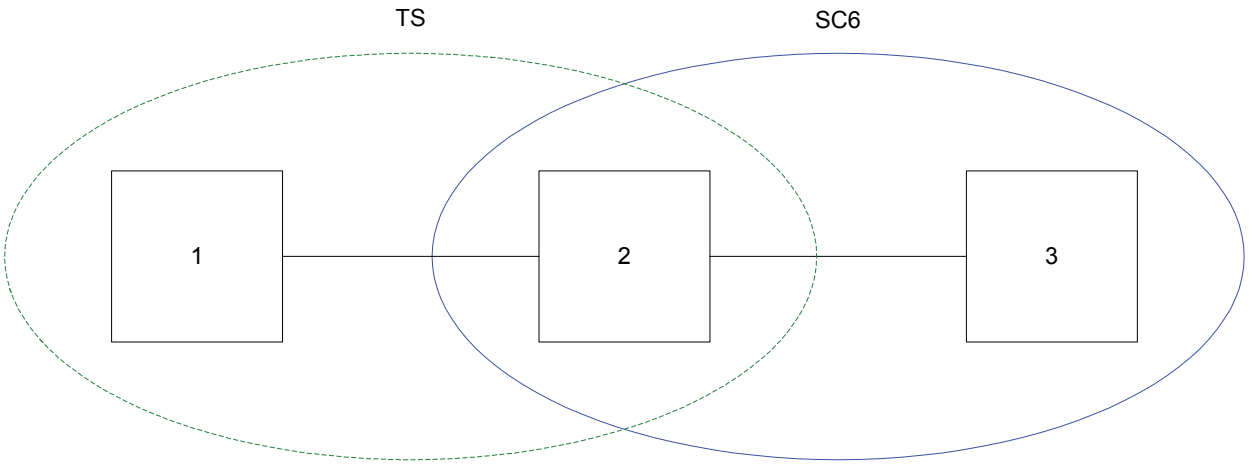


Figure 1 — Diagram showing the responsibilities of product committees and illustrating the extent of the scope of this Technical Specification in terms of the effects between AIMDs and MR scanners

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.

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:

Medtronic, Inc.
Open Innovation and Intellectual Property
8200 Coral Sea St. NE, MVN43
Mounds View, MN 55112
USA

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.

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

IMPORTANT — The electronic file of this document contains colours which are considered to be useful for the correct understanding of the document. Users should therefore consider printing this document using a colour printer.

1 Scope

This Technical Specification is applicable to implantable parts of active implantable medical devices (AIMDs) intended to be used in patients who undergo a magnetic resonance scan in 1,5 T, cylindrical bore, whole body MR scanners for imaging the hydrogen nucleus.

NOTE 1 Requirements for non-implantable parts are outside the scope of this Technical Specification.

The tests that are specified in this Technical Specification are type tests intended to be carried out on samples of a device to characterize interactions with the magnetic and electromagnetic fields associated with an MR scanner. They can be used to demonstrate device operation according to its MR Conditional labelling. The tests are not intended to be used for the routine testing of manufactured products.

This Technical Specification contains test methods that are applicable to a broad class of AIMDs for the purpose of evaluating device operation against several hazards (see Clause 7). Tests for particular device types are not included. Specific compliance criteria and the determination of risk resulting from device behavioural response during these tests are outside the scope of this Technical Specification.

NOTE 2 Modification of these tests for particular device types is left to particular product committees.

NOTE 3 Other interested parties, such as device manufacturers, regulatory agencies, and particular product committees, are responsible for setting specific compliance criteria and determining risk.

NOTE 4 All safety requirements for MRI scanners can be found in IEC 60601-2-33.

2 Normative references

The following referenced documents are indispensable for the application 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.

IEC 60601-2-33:2010, *Medical electrical equipment — Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

ANSI/AAMI PC69:2007, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*

ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM F2213, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*

ASTM F2503-08, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
AIMD
active implantable medical device
active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

[ISO 13485:2003, definition 3.1]

NOTE For the purposes of this Technical Specification, an AIMD is a system consisting of a set of components (e.g. device and leads) and accessories which interact to achieve the performance intended by the manufacturer.

3.2
AIMD configuration
any unique combination or arrangement of AIMD system settings or components, particularly relative geometrical orientations or electrical connections between components (see Annex Q)

3.3
active medical device
medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

[ISO 13485:2003, definition 3.2]

3.4
B_0
static magnetic field of the MR scanner, taken as 1,5 T in this Technical Specification, unless otherwise stated

3.5
B_{1RMS}
root mean square (RMS) of B_1, the radio frequency magnetic induction

$$B_{1RMS} = \sqrt{\frac{\int_0^{t_x} [B_1(t)]^2 \, dt}{t_x}}$$

where t is time, and t_x is the evaluation time, estimated at the RF transmit coil centre

[IEC 60601-2-33:2010, definition 201.3.201]

3.6
birdcage coil
radiator which generates the RF portion of the magnetic field

NOTE This usually refers to a bench-top coil used to simulate the operation of a scanner's volume RF transmit coil.

3.7
compliance volume
patient-accessible space in which compliance of gradient output is inspected

NOTE 1 In MR equipment with a cylindrical whole body magnet, the compliance volume is a cylinder whose axis coincides with the magnet axis, with a radius of 0,20 m and with a length equal to the gradient coil.

NOTE 2 Adapted from IEC 60601-2-33, definition 201.3.202.

3.8
cylindrical bore scanner reference coordinate system
three dimensional Cartesian coordinate system in which the X axis lies in a horizontal plane, the Y axis in a vertical plane, the Z axis is coaxial with the magnet bore, and the origin of the reference coordinate system is located at isocentre

3.9
device
that part of an AIMD that houses a power source and electronic circuit and which produces a stimulation voltage or current pulse

NOTE The complete AIMD includes the device and a means for conveying the output pulse to the stimulation site.

3.10
effective stimulus duration
$t_{s,eff}$
duration of any period of the monotonic increasing or decreasing gradient used to describe its limits for cardiac or peripheral nerve stimulation, defined as the ratio of the peak-to-peak field variation and the maximum value of the time derivative of the gradient in that period

[IEC 60601-2-33:2010, definition 201.3.205]

3.11
extrinsic electric potential
unrectified voltage induced by fields external to the AIMD (i.e. not caused by the device)

3.12
first level controlled operating mode
mode of operation of the MR equipment in which one or more outputs reach a value that can cause physiological stress to patients which needs to be controlled by medical supervision

NOTE Definition and validation of physiological stress is defined in the absence of additional sources that may cause or enhance stress factors (like AIMDs).

[IEC 60601-2-33:2010, definition 201.3.208]

3.13
G
magnetic field gradient in units of T/m

NOTE 1 G_x introduces a spatial gradient along the X axis of the reference coordinate system, G_y introduces a gradient along the Y axis, and G_z introduces a gradient along the Z axis.

NOTE 2 Adapted from IEC 60601-2-33:2010, Table 201.101.

3.14
gradient output
parameter characterizing the gradient performance, such as rate of change of the magnitude of the magnetic field, or E-field induced by one or more gradient units, under specified conditions and at a specified position

[IEC 60601-2-33:2010, definition 201.3.209]

3.15
gradient unit
all gradient coils and amplifiers that together generate a magnetic field gradient along one of the axes of the coordinate system of the MR equipment

[IEC 60601-2-33:2010, definition 201.3.210]

3.16
harm
physical injury or damage to health or property

NOTE Adapted from ISO/IEC Guide 51:1999, definition 3.3.

3.17
hazard
potential source of harm

NOTE Adapted from ISO/IEC Guide 51:1999, definition 3.5.

3.18
implant volume
patient-accessible space

NOTE In MR equipment with a cylindrical whole body magnet, the implant volume is a cylinder whose axis coincides with the magnet axis, with a radius of 0,25 m and with a length equal to the gradient coil

3.19
isocentre
in MR equipment, the null point of the spatially encoding gradients

NOTE 1 Typically, this also corresponds to the region of highest magnet homogeneity.

NOTE 2 Typically, this corresponds to the position in the system targeted for imaging.

[IEC 60601-2-33:2010, definition 201.3.214]

3.20
label
area bearing a marking, affixed to a device or package but not an integral part of the device or package

[ISO 14708-1:2000, definition 3.10]

3.21
lead
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length

[ISO 14708-1:2000, definition 3.5]

3.22
MR equipment
magnetic resonance equipment
medical electrical equipment which is intended for *in vivo* magnetic resonance examination of a patient comprising all parts in hardware and software from the supply mains to the display monitor

[IEC 60601-2-33:2010, definition 201.3.218]

3.23
MR scanner
magnetic resonance scanner
See 3.22

NOTE The term “scanner” is used throughout this Technical Specification in lieu of “equipment”.

3.24
malfunction
device failure causing degradation of performance, loss of function, or unintentional responses

3.25
marking
inscription on a device, package or label

[ISO 14708-1:2000, definition 3.9]

3.26
maximum gradient slew rate
rate of change of the gradient obtained by switching the gradient unit between its maximum specified gradient strengths G_{+max} and G_{-max} in the shortest possible ramp time obtainable under normal scan conditions

[IEC 60601-2-33:2010, definition 201.3.222]

3.27
medical device

article, used alone or in combination, with any accessories or software for its proper functioning, intended by the manufacturer to be used on human beings in the

— diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,

— investigation, replacement or modification of the anatomy or of a physiological process,

— support or sustainment of life

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means

NOTE Adapted from ISO 13485:2003, definition 3.7.

3.28
MR Conditional
item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use

NOTE 1 Field conditions that define the specified MR environment include field strength, spatial gradient, *dB/dt* (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

NOTE 2 Adapted from ASTM F2503, definition 3.1.9.

3.29
normal operating mode
mode of operation of the MR equipment in which none of the outputs have a value that can cause physiological stress to patients

[IEC 60601-2-33:2010, definition 201.3.224]