PD ISO/TS 10974:2018

BSI Standards Publication

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

Documents
Document Sharing Hub

Full document details: PD ISO/TS 10974:2018

National foreword

This Published Document is the UK implementation of ISO/TS 10974:2018. It supersedes PD ISO/TS 10974:2012, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2018
Published by BSI Standards Limited 2018

ISBN 978 0 580 95455 9

ICS 11.040.40

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 April 2018.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: PD ISO/TS 10974:2018

TECHNICAL SPECIFICATION

ISO/TS 10974

Second edition
2018-04-23

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 10974:2018(E)

Documents
Document Sharing Hub

© ISO 2018

Full document details: PD ISO/TS 10974:2018

COPYRIGHT PROTECTED DOCUMENT

© ISO 2018, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub

Full document details: PD ISO/TS 10974:2018

Contents

Page

Foreword ... **vii**
Introduction ... **viii**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Symbols and abbreviated terms ... **6**
5 General requirements for non-implantable parts ... **6**
6 Requirements for particular AIMDs ... **6**
7 General considerations for application of the tests of this document ... **6**
7.1 Compliance criteria ... 6
7.2 Use of tiers ... 7
7.3 Test reports ... 7
7.3.1 General ... 7
7.3.2 Description of the AIMD under test ... 7
7.3.3 Test methods and results ... 7
8 Protection from harm to the patient caused by RF-induced heating ... **8**
8.1 Introduction ... 8
8.2 Outline of the Stage 1 four-tier approach ... 8
8.3 Measurement system prerequisites for all tiers ... 10
8.3.1 RF field source ... 10
8.3.2 Tissue simulating phantom ... 10
8.3.3 Definition of power deposition ... 12
8.3.4 Measurement system validation ... 12
8.4 Determination of RF-induced power deposition in a tissue simulating medium ... 12
8.4.1 General ... 12
8.4.2 Determine location of hot spots around the AIMD ... 13
8.4.3 Determination of spatial (3D) distribution of power deposition for each hot spot ... 13
8.4.4 Determine the final power deposition ... 14
8.5 Proximity effect of electrodes from multiple leads ... 16
8.6 Modelling prerequisites for Tier 2, Tier 3, and Tier 4 ... 16
8.7 Tier selection for RF-induced power deposition ... 17
8.7.1 General ... 17
8.7.2 Tier 1 ... 17
8.7.3 Tier 2 ... 18
8.7.4 Tier 3 ... 19
8.7.5 Tier 4 ... 20
8.8 *In vitro* model validation ... 21
8.9 Overall uncertainty analysis ... 23
8.10 *In vivo* analysis of power deposition ... 23
8.11 RF-induced heating assessment flow chart ... 24
9 Protection from harm to the patient caused by gradient-induced device heating ... **27**
9.1 Introduction ... 27
9.2 Testing considerations ... 28
9.2.1 General ... 28
9.2.2 Determination of $|dB/dt|$ rms exposure limits ... 29
9.2.3 Determination of test duration ... 29
9.3 Test requirements ... 29
9.3.1 General ... 29
9.3.2 *In vitro* test phantom or other suitable container ... 30
9.3.3 Gelled solution ... 30

AVA Documents
Document Sharing Hub

© ISO 2018 – All rights reserved

Full document details: PD ISO/TS 10974:2018

9.3.4 Temperature survey to determine orientation and hot spots ... 30
9.3.5 Minimum temperature instrumentation ... 31
9.3.6 Definition of *dB/dt* test waveform ... 31
9.3.7 Characterization of applied *dB/dt* ... 32
9.4 Lab testing using simulated MR gradient field ... 32
9.5 MR scanner testing ... 32
9.6 Analysis of gradient heating test ... 33

10 Protection from harm to the patient caused by gradient-induced vibration ... 33
10.1 Introduction ... 33
10.2 Overview of tiers ... 34
10.3 MR environmental conditions ... 35
10.3.1 General ... 35
10.3.2 Determination of maximum clinical *dB/dt* ... 35
10.3.3 Determination of clinical B_0 ... 35
10.3.4 Determination of clinical $dB/dt \times B_0$ ... 35
10.3.5 Test frequencies ... 35
10.3.6 Test duration ... 36
10.3.7 Test temperature ... 37
10.4 General test procedure ... 37
10.4.1 Measurement of gradient field and determination of AIMD location ... 37
10.4.2 AIMD/test unit setup ... 37
10.5 Method 1 — MR scanner ... 38
10.6 Method 2 — Shaker table ... 39
10.6.1 General ... 39
10.6.2 Determine scanner input ... 39
10.6.3 AIMD vibration response ... 39
10.6.4 Determine shaker table amplitude (*dB/dt* scaling) ... 40
10.6.5 Perform vibration exposure using a shaker table ... 40

11 Protection from harm to the patient caused by B_0-induced force ... 40

12 Protection from harm to the patient caused by B_0-induced torque ... 41

13 Protection from harm to the patient caused by gradient-induced extrinsic electric potential ... 41
13.1 Introduction ... 41
13.2 General requirements ... 42
13.3 Gradient pulse leakage test ... 46
13.3.1 General ... 46
13.3.2 Test equipment ... 46
13.3.3 Test signal ... 46
13.3.4 Tier 1 — Combined gradient-induced charge measurement test procedure ... 48
13.3.5 Tier 2 — Separate transient gradient-induced charge and steady-state current measurement test procedure ... 51
13.4 Gradient rectification test ... 52
13.4.1 General ... 52
13.4.2 Test equipment ... 53
13.4.3 Test signal ... 53
13.4.4 Gradient-induced rectification measurement test procedure ... 54
13.5 Gradient pulse distortion of AIMD output test ... 55
13.5.1 General ... 55
13.5.2 Test equipment ... 55
13.5.3 Test signal ... 55
13.5.4 Gradient-induced AIMD output distortion test procedure ... 56

14 Protection from harm to the patient caused by B_0-induced malfunction ... 57
14.1 Introduction ... 57
14.2 Static field testing ... 59
14.2.1 B_0 general requirements for static field testing ... 59
14.2.2 B_0 field generation ... 59

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

14.2.3 Test conditions ... 59
14.3 Test procedures ... 59
14.3.1 General ... 59
14.3.2 Class 0 test procedure ... 59
14.3.3 Class 1 test procedure ... 60
14.3.4 Class 2 test procedure ... 60

15 Protection from harm to the patient caused by RF-induced malfunction and RF rectification ... 60
15.1 Introduction ... 60
15.2 General requirements ... 60
15.3 Mechanisms for RF interaction with an AIMD ... 61
15.4 Selecting radiated vs injected test methods ... 62
15.4.1 General ... 62
15.4.2 AIMD type designation for test method selection ... 62
15.4.3 RF antenna type designation for test method selection ... 64
15.4.4 RF EMC tier selection ... 64
15.4.5 RF test conditions ... 65
15.4.6 B_0 considerations ... 68
15.5 Injected immunity test ... 68
15.5.1 General ... 68
15.5.2 Determination of peak and rms injected levels for Tier 1 and Tier 2 — AIMD with short electrical length ... 68
15.5.3 Determination of peak and rms injected levels for Tier 3 and Tier 4 ... 69
15.5.4 Injected immunity test procedure ... 70
15.5.5 RF phase test conditions ... 71
15.5.6 AIMD monitoring during the test ... 71
15.6 Radiated immunity test ... 71
15.6.1 General ... 71
15.6.2 Determining the RF radiated field level ... 71
15.6.3 Radiated test procedure ... 72
15.6.4 AIMD monitoring during the test ... 72
15.7 Test equipment ... 72
15.7.1 Generating the RF electric field for radiated testing (AIMD with short electrical length) ... 72
15.7.2 Phantom and tissue simulating medium for radiated testing ... 72
15.7.3 AIMD monitoring apparatus ... 72
15.7.4 RF level measuring device ... 73
15.7.5 RF injection network ... 73
15.8 Determining the peak RF injected level using a radiated test ... 74

16 Protection from harm to the patient caused by gradient-induced malfunction ... 76
16.1 Introduction ... 76
16.2 General requirements ... 76
16.3 Selecting radiated and injected test methods ... 77
16.4 Radiated immunity test ... 77
16.4.1 General ... 77
16.4.2 Test equipment ... 78
16.4.3 Radiated test signal ... 79
16.4.4 Test procedure ... 81
16.5 Injected immunity test ... 82
16.5.1 General ... 82
16.5.2 Test equipment ... 82
16.5.3 Injected test signal ... 82
16.5.4 Test procedure ... 84
16.5.5 AIMD test configuration ... 86

17 Combined fields test ... 93
17.1 Introduction ... 93
17.2 Test setup ... 94

AVA Documents
Document Sharing Hub

© ISO 2018 – All rights reserved

Full document details: PD ISO/TS 10974:2018

17.3 AIMD fixation ... 96
17.4 Test procedure ... 97
17.4.1 General ... 97
17.4.2 Before MR exposure ... 97
17.4.3 During MR exposure ... 97
17.4.4 After MR exposure ... 97
17.5 Test equipment ... 97
17.5.1 Field generation ... 97
17.5.2 Phantom and tissue simulating medium ... 97
17.5.3 AIMD monitoring apparatus ... 98

18 Markings and accompanying documentation ... 98
18.1 Definitions ... 98
18.2 Applicability of labelling requirements ... 98
18.3 Labelling requirements ... 98

Bibliography ... 100

Annex A (normative) **Pulsed gradient exposure for Clause 10, Clause 13, and Clause 16 ... 103**

Annex B (informative) **Derivation of lead length factor for injected voltage test levels for Clause 13 and Clause 16 ... 115**

Annex C (informative) **Tier 1 high tangential E-field trough line resonator ... 124**

Annex D (informative) **Supporting information and rationale for gradient-induced device heating ... 131**

Annex E (informative) **Example RF injection network ... 136**

Annex F (informative) **Supporting information and rationale for MR-induced vibration ... 138**

Annex G (informative) **Gradient vibration patent declaration form ... 142**

Annex H (informative) **Assessment of dielectric and thermal parameters ... 144**

Annex I (informative) **RF exposure system validation method ... 149**

Annex J (informative) **MR scanner RF transmit coil ... 159**

Annex K (informative) **Current distribution on the AIMD as a function of the phase distribution of the incident field ... 161**

Annex L (informative) **Tissue simulating medium formulations ... 164**

Annex M (informative) **Generation of incident fields ... 168**

Annex O (informative) **Gradient field injected testing — AIMD electrode tissue impedance determination method ... 187**

Annex P (informative) **Estimation of conservative B_1 and 10 g averaged E-field values for Tier 1 for RF-induced heating and RF malfunction ... 192**

Annex Q (informative) **AIMD configuration ... 200**

Annex R (informative) **Electrically excitable tissue stimulation, terms and definitions ... 201**

Annex S (informative) **Combined fields test ... 203**

Annex T (informative) **General methods for modelling *dB/dt* levels in MR gradient coils ... 209**

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*, and Technical Committee IEC TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62B, *Diagnostic imaging equipment.* The draft was circulated for voting to the national bodies of both ISO and IEC.

This second edition cancels and replaces the first edition (ISO/TS 10974:2012) which has been technically revised.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

Introduction

The first edition (2012) of this document 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 second edition represents experience gained from the first edition of its use in practice and 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 document (ISO/TC 150/SC 6/JWG 2 and IEC/SC 62B/JWG 1) releases this edition to promote further developments in this area. The JWG anticipates the possibility that an International Standard might result from this work.

IEC 60601-2-33 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.

No requirements contained within this document, including the use of clinical scanners, construe or imply any obligation for compliance on the part of MR scanner manufacturers. Any statement to the contrary is strictly unintentional.

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.

The JWG is concerned with effects on the AIMD caused by the scanner. ISO/TC 150/SC 6 is concerned with resulting potential hazards to the patient caused by the AIMD. IEC 62B/MT40 is concerned with potential hazards to the patient caused by the MR scanner.

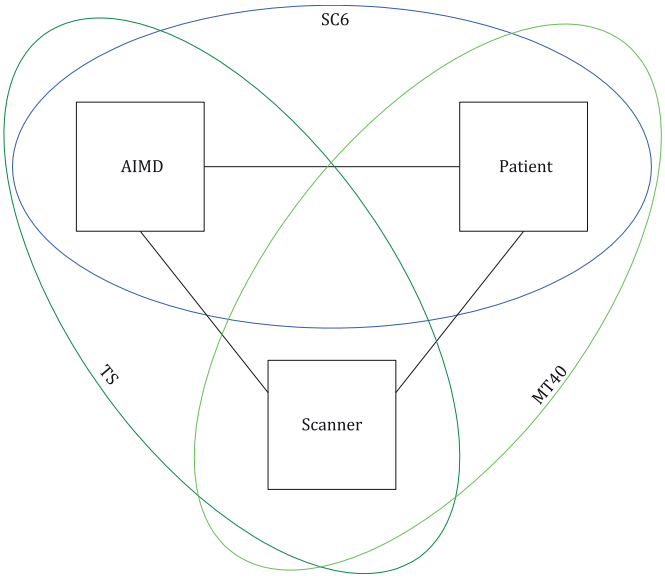


Figure 1 — Responsibilities of product committees illustrating the extent of the scope of this document in terms of the effects between AIMDs and MR scanners

The test methods contained in this document for evaluating device operation against several hazards are applicable to a broad class of AIMDs. Tests for particular device types are not included. Specific

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

compliance criteria and the determination of risk resulting from device behavioural responses during these tests are outside the scope of this document.

NOTE The device manufacturer, regulatory agencies and particular product committees, are responsible for setting specific compliance criteria and the determination of risk. For example, ISO/TC 150/SC 6 might turn the general provisions of this document into product-specific requirements.

The test methods in this document were derived from six known or foreseeable potential hazards to patients with an AIMD undergoing an MR scan. These general hazards give rise to specific test methods as shown in Table 1.

Table 1 — Potential patient hazards and corresponding test methods

General hazard	Test method	Clause
Heat	RF field-induced heating of the AIMD	8
	Gradient field-induced device heating	9
Vibration	Gradient field-induced vibration	10
Force	B_0-induced force	11
Torque	B_0-induced torque	12
Unintended stimulation	Gradient field-induced lead voltage (extrinsic electric potential)	13
	RF field-induced rectified lead voltage	15
Malfunction	B_0 field-induced device malfunction	14
	RF field-induced device malfunction	15
	Gradient field-induced device malfunction	16
	Combined fields test	17

Figure 2 depicts the relationship between the three output fields of an MR scanner (RF, gradient, and B_0) and the hazards considered by this document. In the figure, extrinsic electric potential and RF rectification are represented as Unintended Stimulation and heat is shown as occurring from two sources, Electrode Heating and Device Heating. Numbers in parentheses indicate clause numbers. For example, RF field-induced heating of electrodes is evaluated according to the test method in Clause 8.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

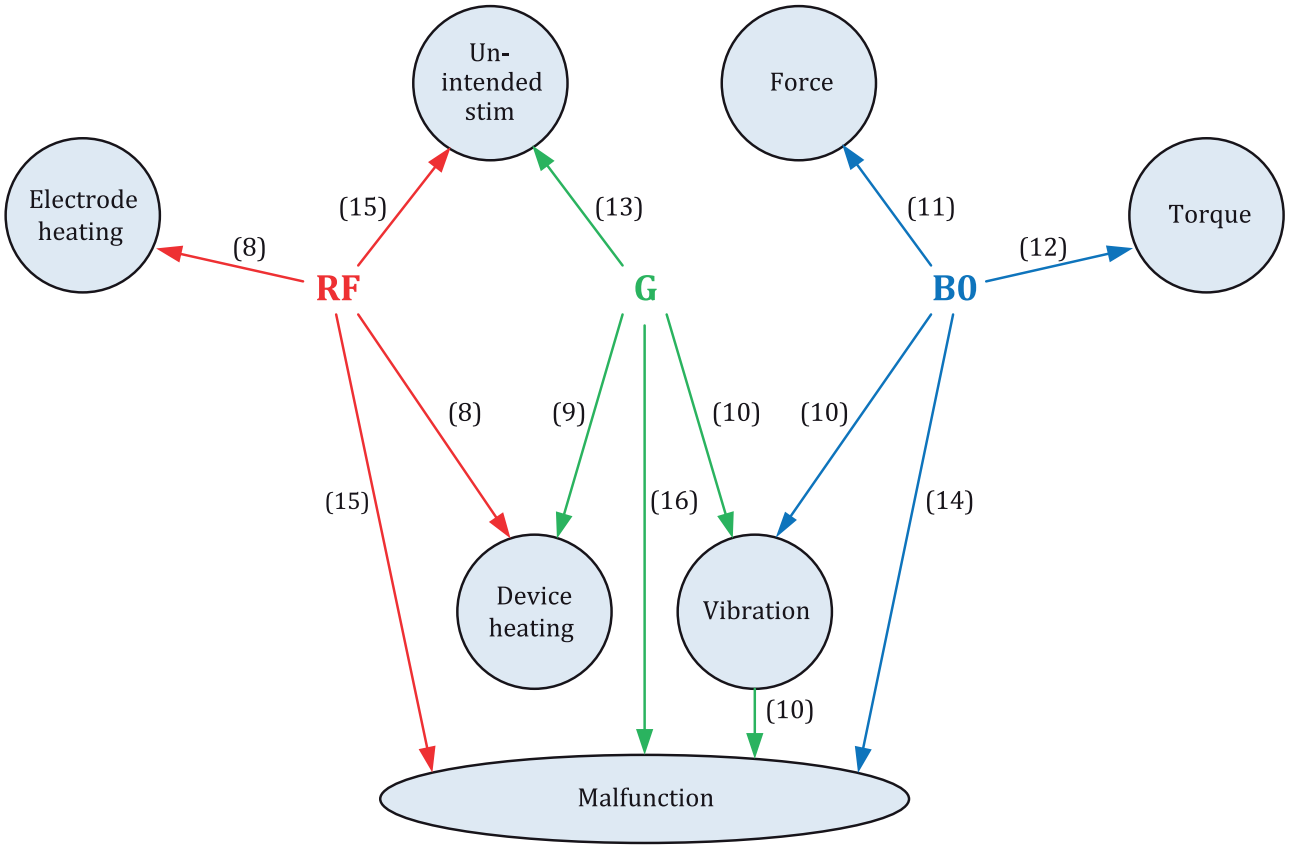


Figure 2 — Relationship between MR scanner output fields (RF, gradient, B_0) and hazards (test method clause numbers in parentheses)

Evaluation of the AIMD for these hazards involves some combination of testing and modelling. Tests in Clauses 8 through 16 may use bench-top testing, modelling, MR scanners, or a combination of these approaches. The test in Clause 17 uses an MR scanner. Devices are subjected to radiated fields or injected voltages in order to witness behavioural responses. Modelling may be employed to determine appropriate test signal voltage levels or to estimate tissue heating, for example. Within this document device immunity to the B_0, RF, and gradient fields is evaluated separately, except for Clause 17.

In addition to the tests listed in Table 1, this document contains requirements for markings and accompanying documentation (Clause 18).

RF-induced heating of tissues surrounding an AIMD is caused by elevated local SAR and associated component heating that arises from induced currents.

Gradient-induced device heating is caused by eddy currents.

Device vibration is due to the combined effect of the B_0 (static) and gradient fields.

Force and torque is caused by B_0 (static) interaction with magnetic materials.

Extrinsic electric potential is meant to imply that the induced voltage comes from outside the device as in the case of gradient-induced stimulation or modification of output pulses due to superposition. The result involves voltages not caused by a device malfunction.

Rectification of induced voltages can occur if the induced voltage is high enough to cause nonlinear circuit elements to conduct, for example, an input protection diode. Rectification might result in voltage pulses occurring at a distal electrode. The resulting rectified voltage is an unintended consequence of the reaction of the AIMD and is not considered a device failure or malfunction, per se.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

Malfunction is meant to capture a wide range of performance issues, such as degradation of performance, loss of function, unintentional responses, etc., due to device failure caused by, for example, the improper operation of a circuit element or motor. Since malfunctions are highly device-specific, and unknown in a general sense for all AIMD types, they remain undefined in this document.

This document applies to AIMDs that are intended to be introduced into certain MR environments. It applies only to AIMDs that do not use sensing functions or to AIMDs that are programmed not to use sensing functions to affect therapy delivery during an MR scan.

The Combined Fields Test establishes an *in vitro* evaluation of the AIMD functioning under simultaneous exposure to the static, gradient, and RF magnetic field conditions. Unlike the maximal exposures required in the tests for Clauses 8 through 16, the Combined Fields Test exposes the AIMD to levels and temporal patterns of all three MR scanner magnetic field outputs simultaneously. The Combined Field Test alone does not constitute a comprehensive assessment of device performance and should be considered as one part of the overall assessment process.

Test methods described in this document are primarily designed and intended as bench-top tests using equipment and techniques producing effects (B_0 static, gradient, and RF) representative of those generated by MR 1,5 T scanners. The exception being Clause 17. 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 document for bench-top testing are not being encouraged or recommended for use on clinical scanners and to do so might result in scanner damage. No scanner operation beyond commercially released clinical performance is required from the MR Manufacturer.

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 document may involve the use of a patent concerning gradient vibration given in Clause 10.

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 (an example of the patent declaration is shown in Annex G). 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.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

This page deliberately left blank

Documents
Document Sharing Hub

Full document details: PD ISO/TS 10974:2018

TECHNICAL SPECIFICATION **ISO/TS 10974:2018**

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

1 Scope

This document 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 (circular or elliptical cross-section) bore, whole body MR scanners operating at approximately 64 MHz with whole body coil excitation.

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

The tests that are specified in this document are type tests that characterize interactions with the magnetic and electromagnetic fields associated with an MR scanner. The tests 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.

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 Safety requirements for MR scanners can be found in IEC 60601-2-33.

NOTE 5 The scope is limited to AIMDs that do not use sensing functions or to AIMDs that are programmed not to use sensing functions to affect therapy delivery during an MR scan.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Medical electrical equipment — Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*

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, *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.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

3.1
active implantable medical device
AIMD
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

Note 1 to entry: For the purposes of this document, an AIMD is a system consisting of a set of one or more implantable components (e.g. device and leads).

[SOURCE: ISO 14708-1:2014, 3.2]

3.2
B_0
static magnetic field of the MR scanner, taken as 1,5 T in this document, unless otherwise stated

3.3
$B_{1+\mathrm{rms}}$
root mean square (rms) of B_{1+}

$$B_{1+\mathrm{rms}} = \sqrt{\frac{\int_0^{t_x} \left[B_{1+}(t)\right]^2 dt}{t_x}}$$

where t is time, and t_x is the integration time, which shall be any 10 s period over the duration of the entire sequence

Note 1 to entry: B_{1+} is derived from the flip angle averaged over an adjustment volume, which is typically represented by the axial central slab wherein MR signal is generated.

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.201]

3.4
B_{1+}
component of the RF field in the rotating frame that is effective for tilting of the nuclear magnetization

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.244]

3.5
$B_{1+\mathrm{peak}}$
peak amplitude of B_{1+}

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.245]

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

Note 1 to entry: 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 to entry: In MR equipment with a cylindrical whole body magnet, the compliance volume is a cylinder with its axis coinciding with the magnet axis and with a radius of 0,20 m and with a length equal to the gradient coil. In all other MR equipment the compliance volume is the volume where any part of a patient body can be properly located according to the intended use of the MR equipment.

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.202]

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

3.8
|*dB/dt*| rms
root mean square (rms) of the magnitude of the time rate of change of the gradient magnetic field

$$\left|\frac{dB}{dt}\right|\text{rms} = \sqrt{\frac{\int_0^{t_x}\left|\frac{dB}{dt}\right|^2 dt}{t_x}}$$

where t is time, and t_x is the integration time.

3.9
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 1 to entry: Definition and validation of physiological stress is defined in the absence of additional sources that can cause or enhance stress factors (like AIMDs).

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.208, modified — the term "may" in Note 1 to entry has been replaced to "can".]

3.10
fixed parameter option
FPO
option within existing modes (normal operating mode or first level controlled operating mode), which specifies a set of operational limit values for the allowable RF field and gradient output and the specified B_0 of the MR equipment in a MR examination

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.242]

3.11
fixed parameter option:basic
FPO:B
"basic" denotes a specific implementation of FPO, exclusively for 1,5 T MR systems

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.243]

3.12
G
magnetic field gradient expressed in units of T/m

Note 1 to entry: 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.

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, Table 201.101]

3.13
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

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.209]

3.14
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

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.210]

Documents
Document Sharing Hub

© ISO 2018 – All rights reserved

Full document details: PD ISO/TS 10974:2018

3.15
intended use
intended purpose
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

[SOURCE: ISO 14971:2007, 2.5]

3.16
isocentre
<MR equipment> null point of the spatially encoding gradients

Note 1 to entry: Typically, this also corresponds to the region of highest magnet homogeneity.

Note 2 to entry: Typically, this corresponds to the position in the system targeted for imaging.

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.214, modified.]

3.17
lead
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length

[SOURCE: ISO 14708-1:2014, 3.13]

3.18
lead port
insulated AIMD receptacle or port providing electrical and mechanical connection between an AIMD and a lead

3.19
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

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.218]

3.20
MR scanner
magnetic resonance scanner
see 3.19

Note 1 to entry: In this document, the term “MR scanner” is often used instead of “MR equipment”.

3.21
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

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.222, modified.]

3.22
MR Conditional
item with demonstrated safety in the MR environment within defined conditions, including conditions for the static magnetic field, the switched gradient magnetic field and the radiofrequency fields

Note 1 to entry: Additional conditions, including specific configurations of the item, may be required.

[SOURCE: ASTM F2503, 3.1.11, modified — The first and second sentences have been merged.]

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

3.23
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

Note 1 to entry: Definition and validation of physiological stress is defined in the absence of additional sources that can cause or enhance stress factors (like AIMDs).

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.224, modified — The term "may" in Note 1 to entry has been replaced to "can".]

3.24
search coil
small diameter coil used in a compliance test to measure gradient output

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.230]

3.25
SAR
specific absorption rate
radio frequency power absorbed per unit of mass (W/kg)

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.233]

3.26
dB/dt
time rate of change of the magnetic field
rate of change of the magnetic flux density with time (T/s)

Note 1 to entry: The time rate of change of the magnetic field *dB/dt* is assumed to be evaluated in a suitably low frequency range (e.g. <5 kHz) to disregard effects of switching amplifier ripple.

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.234]

3.27
volume RF transmit coil
RF transmit coil suitable for use in MR equipment that produces a homogeneous RF field over an extended volume encompassed by the coil

Note 1 to entry: The volume RF transmit coil can be a whole body RF transmit coil, a head RF transmit coil or an RF transmit coil designed for homogeneous exposure of a specific part of the body. A single-loop coil enclosing the body or a part of the body is considered to be a volume RF transmit coil (e.g. single-loop wrist coil).

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.236]

3.28
whole body gradient system
gradient system suitable for use in whole body MR equipment

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.237]

3.29
whole body MR equipment
whole body magnetic resonance equipment
MR equipment of sufficient size to allow whole body MR examination and partial body MR examination of adult patients. It can be equipped with volume RF transmit coils, local RF transmit coils and with a special purpose gradient system

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.239]

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

3.30
whole body SAR
SAR averaged over the total mass of the body and over a specified time

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.241]

3.31
partial body SAR
SAR averaged over the mass of the body that is exposed by the volume RF transmit coil and over a specified time

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.225]

3.32
local SAR
SAR averaged over any 10 g of tissue of the body and over a specified time

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.216]

3.33
head SAR
SAR averaged over the mass of the head and over a specified time

[SOURCE: IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.3.212]

4 Symbols and abbreviated terms

B_G gradient magnetic field magnitude

DUT device under test

MR magnetic resonance

RF radio frequency

rms root-mean-square

TEM transverse electromagnetic

5 General requirements for non-implantable parts

Requirements for non-implantable parts of an AIMD are outside the scope of this document. They might be specified in a future edition.

6 Requirements for particular AIMDs

Requirements for particular AIMDs are not specified in this document. They might be specified in a future edition or in particular product standards.

7 General considerations for application of the tests of this document

7.1 Compliance criteria

Compliance criteria and the determination of risk resulting from device behavioural responses, when subjected to the tests listed in Table 1, are outside the scope of this document.

NOTE 1 This subclause does not apply to Clause 18.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

NOTE 2 The DUT is expected to operate in accordance with its intended use (see 3.15) and not create an unacceptable risk to the patient.

NOTE 3 The device manufacturer, regulatory agencies and particular product committees, are responsible for setting specific compliance criteria and the determination of risk.

7.2 Use of tiers

Several clauses include the concept of Tiers (e.g. Tier 1, Tier 2, …, Tier n) where each Tier represents an alternative test method. The lowest numbered Tier (Tier 1) represents the least complex test method, produces the least accurate result, but is conservative to ensure safety. AIMDs using the lower tiers require considerable margin to be able to accommodate the conservative assumptions.

As the tier number increases, the test method becomes more complex and is more difficult to implement, but provides a more accurate result. The use of the higher tiers reduces the need for excess design margin because the test result is closer to clinical reality.

Several clauses (8, 9, 10, 13, 15 and 16) use the Tier concept. The manufacturer may select an appropriate tier for each test and different tiers may be used for different tests. It is not required to use more than one tier for each test.

7.3 Test reports

7.3.1 General

Every test requires a report of the results. Each report shall include the information in 7.3.2 and 7.3.3. A single test report may include the results from multiple tests. See individual test clauses for any additional requirements.

7.3.2 Description of the AIMD under test

For the AIMD under test, provide at least the following information:

a) device model number(s) and product description of the configuration tested (include all system components, e.g. devices, leads);

b) photograph or drawing of the AIMD.

7.3.3 Test methods and results

For the test method and results, provide at least the following information:

a) complete description of all tests performed, including name and location of test facility and date(s) of testing;

b) description, and photographs or diagrams of each test set-up, including all test and measuring equipment, simulators, configuration, and placement of AIMD components, and phantom placement within coils or MR scanner relative to isocentre;

c) when used, the phantom dimensions and composition of tissue simulating material and electrical properties;

d) AIMD settings and mode(s) of operation;

e) detailed description of each pulse sequence or waveform used in these tests;

f) if the test system is an MR scanner (e.g. combined fields test) the manufacturer, model number, and software version of the MR scanner;

g) test results and test method deviations.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

8 Protection from harm to the patient caused by RF-induced heating

8.1 Introduction

This RF-induced heating assessment is applicable to the implantable parts of AIMDs.

NOTE For information on RF heating near passive implants, see ASTM F2182[1].

Patient harm due to RF-induced heating is a function of absolute temperature, duration of the temperature, and individual implant considerations. RF-induced heating of tissues surrounding an AIMD can result in local tissue temperature rises, leading to tissue damage or a reduction in the ability of the implanted device to deliver therapy. Determining the rise in local tissue temperature due to interaction of an AIMD with the RF field of an MR scanner is a complex process that depends on AIMD design, MR scanner technology (RF coil and pulse sequence design), patient size, anatomy, position, AIMD location and orientation, and tissue properties. When specifying SAR limits in AIMD MR Conditional labelling the definitions listed in Table 201.105 of IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, apply.

A comprehensive assessment of the safety of RF-induced heating requires two stages that are to be performed in a progressive manner:

Stage 1 Determine an estimate of the RF power deposition around the AIMD using one of four tiered approaches described in 8.2. The four tiers are arranged in order of increasing complexity of evaluation method as well as increased accuracy of estimation. This tiered approach is designed to accommodate the diversity of AIMD applications;

Stage 2 Assess tissue changes or damage due to the *in vivo* RF power deposition or resulting temperature rise. The thermogenic tissue damage threshold values and risk factors for the determined temperature rise and duration are application-specific and shall be assessed on an individual AIMD basis.

Only Stage 1, an assessment of the AIMD generated RF-induced power deposition, is included in Clause 8 of this document. Requirements for Stage 2 are outside the scope of this document.

8.2 Outline of the Stage 1 four-tier approach

Four approaches for determining RF power deposition around an AIMD exposed to incident RF fields are illustrated in Figure 3 and described below in order of increasing complexity:

— Tier 1 is the most conservative approach to determine power deposition and requires no electromagnetic modelling;

— Tier 2 relies on electromagnetic modelling of human RF exposures to determine the electric field in the implant volume of interest;

— Tier 3 involves electromagnetic modelling to determine the tangential electric field along a device pathway and the development and validation of an AIMD model;

— Tier 4 provides the least overestimation and requires the most extensive electromagnetic computational modelling by assessing the AIMD model within anatomical models, for relevant RF exposure conditions.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

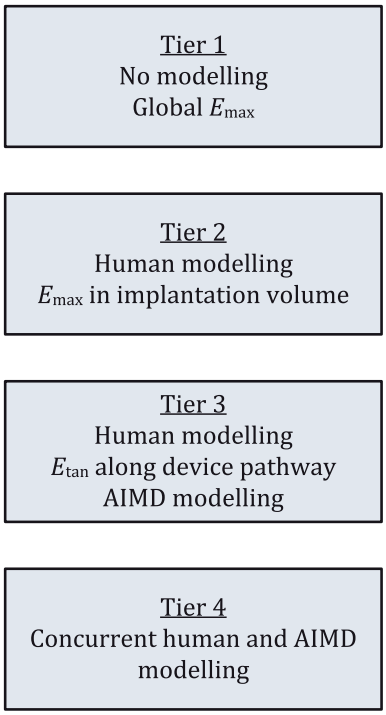


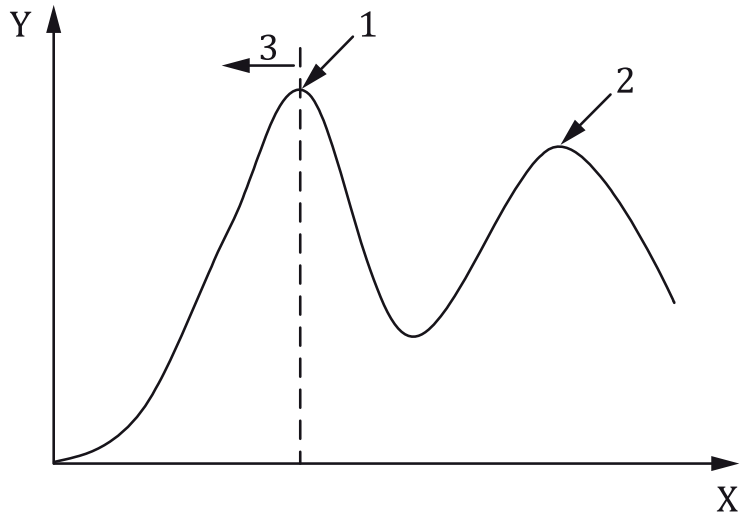
Figure 3 — Four tier approach for determining RF power deposition around an AIMD exposed to MR scanner incident RF fields

There are some restrictions to using the four tiered approaches for determining RF power deposition around an AIMD exposed to incident MR scanner RF fields. Tiers 1 and 2 can only be used for electrically short AIMDs due to phase effects that are described in Annex K. Due to highly conservative assumptions used for Tiers 1 and 2, longer structures will result in impractically high power estimation. Examples of small AIMDs that may be appropriate for evaluation using these tiers include cochlear implants, pressure sensors, implantable monitors and leadless pacemakers. Tiers 3 and 4 are applicable for any AIMD.

An AIMD is considered to be electrically short if it can be demonstrated to be much less than resonant length in terms of both the power dissipated at hotspots and the induced voltage at points of entry to active device electronics when exposed to a uniform E_{tan} excitation. This shall be demonstrated by appropriate means, e.g. simulations, monotonic decline of power deposition with reduced length of the AIMD (see Figure 4), local response model (see Tier 3).

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018



Key

1 first resonance
2 second resonance
3 below resonance
X AIMD length
Y deposited power at hotspot

Figure 4 — The AIMD is electrically short if the length is less than that which produces the first resonance

8.3 Measurement system prerequisites for all tiers

8.3.1 RF field source

Testing conditions can be generated with various RF field sources (see Table 2 for 1,5 T minimum requirements). Typical characteristics of MR scanner RF birdcage coil systems are given in Annex J.

Table 2 — Minimal requirements for the incident electrical field for 1,5 T-test setups

Parameter	Requirement
Incident RF field frequency	64 MHz ± 5 %
Incident field variation (relative to targeted field) over entire AIMD pathway	<±1 dB in magnitude or <±20 degrees in phase
Drift of incident field magnitude during assessment	<0,25 dB

If the incident field magnitude as determined by the selected tier (described later) is beyond the capability of the test system, a lower amplitude incident field can be used, provided the AIMD measurement signal to noise ratio is 10:1 and linearity within the range of instrumentation is demonstrated. If lower magnitudes are used, the measurements shall be scaled ($\Delta T \propto$ SAR or E_{rms}^2) to a value that corresponds to the required amplitude.

An evaluation of the radiated electromagnetic field test environment uncertainty is required.

8.3.2 Tissue simulating phantom

The power deposition due to an implant for a given incident field distribution is a function of the physical properties of the implant, the wavelength inside the surrounding media (which is a function of permittivity and conductivity) and the losses per unit length (dominated by conductivity). Therefore,

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

the implant is tested in an appropriate phantom filled with media that simulates the tissues that dominate the immediate surroundings of the implant. These include low loss tissues (such as fat and bone), lossy solid tissues (such as liver and kidney) and ion loaded tissue fluids such as blood and cerebrospinal fluid.

Dielectric properties of the phantoms are chosen to be generally representative of *in vivo* tissue properties listed in Table N.1. The dielectric properties of representative tissue simulating media are provided in Table 3. The maximum acceptable tolerance for high permittivity medium (HPM) relative permittivity and conductivity is ±10 %. The maximum acceptable tolerance for low permittivity medium (LPM) relative permittivity and conductivity is ±20 %. Example tissue simulating media (TSM) formulations are provided in Annex L and electrical and thermal TSM measurement methods are provided in Annex H. Phantom examples are provided in Annex M.

Table 3 — Electrical properties of phantom liquid and gel materials at 64 MHz

Tissue simulating medium	Relative permittivity, ε_r	Electrical Conductivity, σ S/m
High permittivity medium (HPM) appropriate for all tissues except for bone and fat	78	0,47
		0,65
		1,2
Low permittivity medium (LPM) appropriate for bone and fat tissues	11,5 or 15,1	0,045

NOTE 1 The dielectric and thermal properties of the media change as water evaporates. The dielectric properties are a function of temperature. Therefore, it is recommended to check the dielectric properties of the phantom material regularly to ensure they remain within tolerance, particularly if the phantom is stored for an extended period of time (e.g. one week or more).

NOTE 2 The rationale for HPM conductivities is:

— ASTM F2182: σ = 0,47 S/m (global average of biological tissues, λ (wavelength) ≅ 0,44 m);

— High-conductivity: σ = 0,65 S/m (average of conductivities of muscle, liver, kidney, brain; λ ≅ 0,40 m);

— Very high conductivity: σ = 1,2 S/m (average conductivity of blood, λ ≅ 0,32 m).

If the AIMD pathway is predominantly in high permittivity tissues such as muscle and blood, the test shall be conducted in a HPM with tissue-appropriate conductivity.

If the AIMD pathway is predominantly in low permittivity tissues such as bone and fat, the test shall be performed in a LPM.

If the AIMD pathway spans more than 10 % of its cumulative physical length in different tissue conductivities (conductivity of tissues as shown in Table N.1 varies by at least 50 %), the AIMD shall be evaluated in HPM using several tissue-appropriate conductivities. This also applies to AIMDs that are implanted at the interface between two or more tissue types (e.g. tunnelled subcutaneously).

If the AIMD pathway spans more than 10 % of its cumulative physical length in different tissue permittivity's (permittivity of tissues as shown in Table N.1 varies by at least 5×), the AIMD shall be evaluated in both HPM (with tissue-appropriate conductivity) and LPM. This also applies to AIMDs that are implanted at the interface between two or more tissue types (e.g. tunnelled subcutaneously).

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

8.3.3 Definition of power deposition

Power deposition can be quantified by measuring temperature rise or SAR. The measured SAR_{total} or ΔT_{total} with the AIMD includes the background rise $\Delta T_{\text{backgnd}}$ or SAR_{backgnd} without the AIMD. SAR or ΔT are defined as the net temperature increase or power deposition, above background, due to the presence of AIMD.

$$P = \int^{v} \Delta SAR_{\text{total}-\text{backgnd}} dV = \int^{v} \frac{\sigma\left[E^2_{\text{total}} - E^2_{\text{backgnd}}\right]}{\rho} dV = \int^{v} \left[\lim_{t \to o} \frac{c\Delta T_{\text{total}}}{\Delta t} - \lim_{t \to o} \frac{c\Delta T_{\text{backgnd}}}{\Delta t}\right] dV \qquad (1)$$

where

P	is the power deposition at the AIMD hotspot;
E	is the local rms value of the induced electric field;
σ	is the local electric conductivity;
ρ	is the local tissue density;
c	is the local heat capacity;
ΔT	is the local temperature rise;
V	is the volume that includes the deposited power at the hotspot by the AIMD;
t	is time;
backgnd	is the fields or temperature induced at the location of the measurement without the AIMD present;
total	is the fields or temperature induced at the location of the measurement with the AIMD present.

The SAR, temperature, or incident fields on the AIMD shall be monitored by calibrated probe(s). This allows the monitoring of the incident field strength. For ΔT measurements, it is recommended to use a reference probe to monitor the incident fields at a location that provides equivalent or consistent SAR.

8.3.4 Measurement system validation

The measurement system shall be validated for accurate measurement of SAR or temperature. This can be accomplished by using calorimetry or one of the standard implants as described in Annex I.

8.4 Determination of RF-induced power deposition in a tissue simulating medium

8.4.1 General

The *in vivo* effect of RF-induced heating requires the assessment of the AIMD generated RF-induced power deposition. The goal of this subclause is to determine the power deposition, due to the AIMD. The power deposition is conserved between the *in vitro* and *in vivo* environments if the *in vitro* termination impedance matches the termination impedance of the target tissue. Therefore, the power deposition determined here is also the *in vivo* power deposition due to the AIMD. Power deposition has a spatial distribution and magnitude. The spatial distribution can be a function of the local geometric properties of the AIMD and surrounding tissues. The magnitude is a function of the capability of the AIMD to collect RF energy. Therefore, the spatial distribution of the power deposition and the magnitude of the deposition may be determined separately. When spatial distribution is established in a given medium, power deposition induced by the AIMD can be obtained via magnitude measurements of one or only a few points at or around the locations with highest ΔT or SAR.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

One of the following two methods shall be used to determine power deposition.

— Option 1:

  Three elements are required to determine power deposition:

  — Find the points of high power deposition (hot spots);

  — Find the spatial distribution for each hot spot;

  — Find the final power deposition by measuring the magnitude of power deposition and then scaling the spatial distribution by the measured magnitude. The spatial integral of the final power deposition is total power deposited by the AIMD and is defined by Formula (1);

— Option 2:

  — Find the points of high power deposition (hot spots);

  — Use the direct calibration procedure of 8.4.4.4.

8.4.2 Determine location of hot spots around the AIMD

The following procedure shall be used to determine the location of hot spots around the AIMD.

Step 1 Select the test conditions as defined by the applied tier.

Step 2 Scan the entire length of the AIMD for any high power deposition. Hot spots are defined as any location that is within 6 dB of the highest measured SAR or greater than 0,25× of the highest ΔT across a diversity of pathways. Electrodes, conductive material, and lumped elements have a greater probability of meeting the hotspot definition. Justification shall be provided for the pathways included in the analysis. Hot spots can be excluded from further analysis if justification is provided.

Step 3 The positional accuracy of the hot spot shall be within ±10 mm.

Step 4 Justify that you have identified and tested all hotspots in relevant configurations of the AIMD according to the guidance provided in Annex Q.

8.4.3 Determination of spatial (3D) distribution of power deposition for each hot spot

8.4.3.1 General

The spatial power distribution for each hot spot can be determined from numerical simulation or full 3D experimental measurement. One of the four following procedures for determining the 3D relative distribution of local power deposition shall be used. However, this 8.4.3 and associated procedures is not required if using Procedure 3 in 8.4.4.

8.4.3.2 Procedure 1: Numerical assessment with thermal validation

Step 1 Conduct quasi-static or full-wave electromagnetic SAR (EM) modelling of the AIMD local geometry to generate spatial distribution of hot spot for the tissue simulating medium.

NOTE Quasi static modelling might not be appropriate for all AIMDs.

Step 2 Conduct thermal modelling of the power deposition of Step 1 to derive a temperature distribution in the tissue simulating medium.

Step 3 Based on the distribution, determine the most suitable points for validating the distribution, i.e. the points resulting in the largest signal.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

Step 4 Measure ΔT at the selected points to verify the distribution pattern.

Step 5 Compare measured and predicted temperature rise. If the deviation is less than the combined thermal modelling and measurement uncertainty, the thermal model has been successfully validated. Validation of the thermal model also validates the SAR (EM) model in Step 1, the final output of this procedure.

8.4.3.3 Procedure 2: Numerical assessment with SAR validation

Step 1 Conduct quasi-static or full-wave electromagnetic SAR (EM) modelling of the AIMD local geometry to generate spatial distribution of hot spot for the tissue simulating medium.

NOTE Quasi static modelling might not be appropriate for all AIMDs.

Step 2 Based on the spatial distribution from Step 1, determine the most suitable points for validating the distribution, i.e. the points resulting in the largest signal.

Step 3 Measure SAR (e.g. using a SAR probe) at the selected points to verify the distribution.

Step 4 Compare measured and predicted SAR. If the deviation is less than the combined modelling and measurement uncertainty, the model has been successfully validated.

8.4.3.4 Procedure 3: Full 3D SAR measurements

Step 1 Position the AIMD in the test setup to maximize the power deposition.

Step 2 Conduct the full 3D SAR measurements to determine the spatial distribution by interpolation and extrapolation. At minimum, positioning accuracy of 0,25 mm with respect to the hot spot is recommended to minimize uncertainty.

8.4.3.5 Procedure 4: Full 3D ΔT measurements

Step 1 Position the AIMD in the test setup to maximize the power deposition.

Step 2 Measure 3D ΔT using temperature probes. A minimal positioning accuracy of 0,5 mm with respect to the hot spot is recommended to minimize uncertainty.

8.4.4 Determine the final power deposition

8.4.4.1 General

The final power deposition is found by scaling the spatial distribution by the measured hot spot magnitude. Measure the magnitude of power deposition for each hot spot generated by the test configuration(s) (AIMD positioning within test phantom) specified in each tier, which also defines the appropriate tissue simulating media. The final power deposition shall be determined by using one of the following three procedures. The RF power dissipated by the AIMD shall be determined by numerically integrating the scaled power distribution using Procedure 1 or Procedure 2 or by using the direct calibration method described in Procedure 3 below.

8.4.4.2 Procedure 1: Temperature increase ΔT (if using Procedure 4 from 8.4.3)

Step 1 Select the test conditions as defined by the applied tier.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

Step 2 Determine the magnitude by measuring the temperature rise ΔT as a function of time at one or several points near the hot spot, which correspond to measurement locations from 8.4.3.5. A minimal positioning accuracy of 0,5 mm with respect to the hot spot is recommended to minimize sources of error. However, less accuracy may be usable as long as it is accounted for in the analysis.

Step 3 Scale the temperature distribution determined in 8.4.3.5 by the temperature values measured in Step 2.

Step 4 Transform the scaled spatial distribution of temperature increase from Step 3 to a spatial distribution of the power deposition, by calculating the initial slope of the temperature rise multiplied by the specific heat capacity to arrive at the final power deposition.

8.4.4.3 Procedure 2: SAR (if using Procedure 1, Procedure 2, or Procedure 3 from 8.4.3)

Step 1 Select the test conditions as defined by the applied tier.

Step 2 Determine the magnitude by measuring the SAR at one or several points near the hot spot, which correspond to measurement locations from 8.4.3. A minimal positioning accuracy of 0,25 mm with respect to the hot spot is recommended to minimize sources of error. However, less accuracy may be usable as long as it is accounted for in the analysis.

Step 3 Scale the spatial distribution determined from 8.4.3 to the magnitude measured in Step 2 to arrive at the final power deposition.

8.4.4.4 Procedure 3: Calibration of point temperature or SAR measurements to total dissipated RF power

The local temperature rise (ΔT) or SAR at a point location in a hot spot produced by the AIMD can be related to the total power deposition using a calibrated RF power injection method. The objective of this method is to calibrate ΔT or SAR measured at a specific spatial location to the total RF power dissipated at or near the AIMD hot spot. For example, the ΔT or SAR at a specified location with respect to a lead electrode can be related to the total dissipated RF power. The AIMD may be modified to facilitate RF power calibration provided that the power distribution at the hot spot is equivalent to that produced by the unmodified AIMD. For either unmodified or modified AIMDs, the total dissipated RF power, P_{inject}, shall be determined with established uncertainty.

For each AIMD hot spot, a conversion factor, m, between ΔT or SAR at the hot spot and injected power is experimentally determined (i.e. $\Delta T = m\ P_{\text{inject}}$ or SAR = $m\ P_{\text{inject}}$) by injecting RF power *in vitro* (using the same tissue simulating media and test fixtures as would be used for radiated *in vitro* testing), and measuring ΔT or SAR at the hot spot for multiple values of P_{inject}.

Step 1 Verify that injected RF power produces an equivalent normalized spatial SAR or ΔT distribution as the radiated case. SAR or ΔT measurements shall be made at several locations in the axial and radial directions. The measurement locations for each direction shall be chosen to include the maximum and to encompass the 50 % of maximum and 25 % of maximum locations. The injected and radiated spatial distributions are considered equivalent if the measured differences are within the previously established measurement uncertainty.

Step 2 Inject an appropriate range of power levels, P_{inject}, *in vitro* into the AIMD or specialized version of the AIMD. Measure ΔT or SAR at one specified location near the hot spot. The location and time duration shall be the same as that used for the measurement of ΔT or SAR for radiated *in vitro* testing (see 8.4.3, Procedure 3 and Procedure 4) of the actual AIMD. The amplitude range of ΔT or SAR shall be determined based on intended use of the AIMD while ensuring the thermal response of the tissue-simulating medium is linear.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

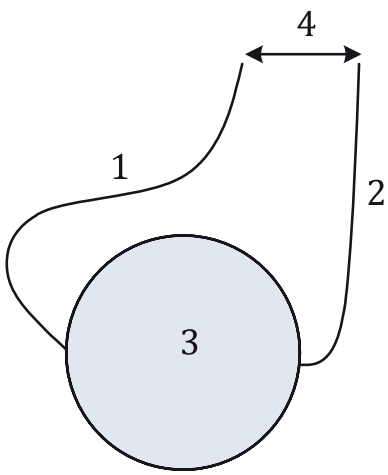
Step 3 Plot ΔT or SAR vs P_{inject} and fit to a linear model. Determine the conversion factor, m (slope), and associated uncertainty from the fitted model.

Step 4 The conversion factor from Step 3 can be used to convert any measured ΔT or SAR values (at the same location as Step 1) to P_{inject}, provided ΔT or SAR is within the amplitude range for which the conversion factor was determined.

8.5 Proximity effect of electrodes from multiple leads

A proximity enhancement due to coupling can occur if multiple electrodes from leads traversing different pathways are in close proximity (see Figure 5). An assessment of this enhancement factor shall be performed when the electrodes are separated by less than 20 mm. The results of the assessment shall be documented in the test report.

NOTE A specific method for evaluating this enhancement effect has not been developed for this edition.



Key

1 lead 1

2 lead 2

3 AIMD case

4 electrodes, <20 mm apart

Figure 5 — Proximity enhancement factor

8.6 Modelling prerequisites for Tier 2, Tier 3, and Tier 4

This subclause is not applicable to Tier 1. For Tier 2, Tier 3 and Tier 4, electromagnetic simulations will be performed to quantify the electromagnetic fields that the AIMD will be exposed to *in vivo*. The incident fields shall be determined by the following procedure using validated electromagnetic simulation packages and human models.

Step 1 Identify the intended patient population with respect to anatomical properties such as length, body mass index (BMI), age, and tissue properties.

Step 2 The electromagnetic simulation tools and the RF source shall be validated by comparing measurements and simulations, in a tissue simulating phantom.

Step 3 Simulate the electric and magnetic field as a function of the following:

— MR scanner technology (transmit RF coil and both clockwise and counter-clockwise B_{1+} polarization);

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

— SAR or $B_{1+\mathrm{rms}}$ excitation amplitude according to labelling and consistent with the SAR and $B_{1+\mathrm{rms}}$ definitions defined in IEC 60601-2-33;

— Patient population;

— Position in RF coil, including posture if applicable;

— AIMD location, orientation and lead pathway (including lead length, if applicable).

8.7 Tier selection for RF-induced power deposition

8.7.1 General

Select one of the four tiers for determining *in vivo* RF power deposition around an AIMD exposed to incident RF fields. The tiers are ordered by increasing complexity. RF fields expressed as rms levels are required for RF-induced power deposition assessment. Peak field levels and rms field levels are required as an input to RF-induced malfunction and RF rectification, which are described in Clause 15.

Tier 1 and Tier 2 produce a single RF power deposition level, and Tier 3 and Tier 4 produce a distribution of RF power deposition levels, which will be used to assess the probability of tissue damage and patient safety. However, tissue damage and patient safety assessment are outside the scope of this document.

As defined in IEC 60601-2-33, head SAR and whole body SAR are calculated over a six minute averaging interval. Over a shorter time interval the SAR level can increase by a factor of two. In the worst case, the SAR level can double for a 3 min interval, if preceded and followed by a 3 min RF off interval, while meeting the 6 min average definition. This 2× SAR level shall be taken into account during the RF heating analysis. For Tier 1, the values in the Normal Operating Mode column and the First Level Controlled Operating Mode column in Table 4 shall be multiplied by $\sqrt{2}$. For the remaining tiers, the 2× SAR shall also be taken into account. There are several methods to do this, with the actual implementation to be justified by the manufacturer. The 2× SAR multiplier only applies for AIMDs that are labelled using SAR. AIMDs that are labelled to $B_{1+\mathrm{rms}}$ or FPO:B do not need to account for the 2× multiplier.

8.7.2 Tier 1

The user can assess RF-induced power deposition without requiring electromagnetic modelling of the RF-human interactions. The user shall determine the AIMD power deposition at the hot spots in phantom media using the predetermined electric field values in Table 4. Phase enhancement can occur for AIMDs that are not electrically short and at present there is no defined method for determining the enhancement factor. Therefore, Tier 1 can only be used for AIMDs that are electrically short.

Step 1a Determine the incident rms electric field for AIMD *in vitro* testing. Select the E_{rmsmax} electric field value from Table 4 consistent with the product labelling and the body region occupied by the AIMD. If the AIMD spans multiple body regions (head, trunk, extremities) the highest regional electric field shall be used. The E_{rmsmax} electric field value is also used in Clause 15 for RF-induced malfunction testing.

Step 1b Determine the incident peak field for Clause 15*in vitro* testing. The Peak electric field column in Table 4 provides the peak electric field value for use in Clause 15*in vitro* testing. If the AIMD spans multiple body regions (head, trunk, extremities) the highest regional electric field shall be used.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

Table 4 — Overall worst-case electric field values

Body region	Maximum induced field (normalized to B_1 averaged over the adjustment volume) $E_{rmsmax}/B_{1rms\text{-}max}$ V/m/μT	Peak electric field (scaled to 30 μT peak B_{1+}) E_{peak} V/m	Normal Operating Mode E_{rmsmax} V/m	First Level Controlled Operating Mode E_{rmsmax} V/m	FPO:B Fixed Parameter Option:Basic E_{rmsmax} V/m
Head	90	3 860	450	470	419
Trunk	140	6 000	500	710	667
Extremities	170	7 285	600	840	802

NOTE 1 E_{rmsmax} values are simulated. E_{rmsmax} values for the head are normalized to whole head average SAR values of 3,2 W/kg for both Normal Mode and First Level Mode. E_{rmsmax} values for the trunk and extremities are normalized to whole body average SAR values of 2 W/kg for normal mode and 4 W/kg for First Level Mode.

NOTE 2 The values in the table have been computed using human body models with RF exposure levels consistent with Normal Operating Mode, First Level Controlled Operating Mode, and Fixed Parameter Option:Basic (FPO:B) as defined in IEC 60601-2-33. Details of the analysis and rationale are provided for reference in Annex P.

Step 2 Determine the RF-induced power deposition by immersing the AIMD in the appropriate tissue simulating medium. The tissue simulating medium shall be selected from Table 3. The AIMD shall be exposed to a tangential uniform electric field (magnitude and phase) in accordance with the conditions specified in Table 2 and Table 4. Measure the RF-induced power deposition along the entire AIMD system in accordance with 8.4.

Step 3 Assess the enhancement from differential mode coupling. For an AIMD with multiple leads, power deposition can change when leads follow pathways as described in 8.5 and shall be evaluated.

Step 4 Assess the maximum power deposition from the electric field in alternate tissue simulating medium, if necessary. This step is required for AIMDs that are to be tested separately in both LPM and HPM as defined in 8.3.2. Step 2 through Step 4 shall be repeated with the other material properties. The final power deposition shall be the higher of the two results from the LPM and HPM tests.

8.7.3 Tier 2

The RF-induced power deposited by the AIMD is determined from electromagnetic simulations of human body models. The user shall determine the fields over the area of the human body in which the AIMD system is to be implanted (implant region). For AIMDs labelled using SAR-based limits and considering the short-term SAR increase of 2× permitted by IEC 60601-2-33, the field values determined shall include the effects of short-term SAR.

The user shall measure the AIMD power deposition in tissue simulating media using the fields determined by the electromagnetic model. Phase enhancement can occur for AIMDs that are not electrically short, and at present there is no defined method for determining the enhancement factor. Therefore, Tier 2 can only be used for AIMDs that are electrically short.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

Step 1a Determine the incident rms electric field for AIMD *in vitro* testing. Perform the electromagnetic simulations using all relevant parameters in 8.6. For each simulation, identify the maximum 10 g average E_{rms} electric field magnitude in the AIMD implant region[2]. In addition, for each simulation, identify the B_{1+rms} magnitude averaged over the adjustment volume.

Construct the distribution of E_{rms} for all simulations. Construct the distribution of the normalized electric field, defined as E_{rms}/B_{1+rms}.

The *in vitro* electric field test level, E_{rmsmax}, is the 95th percentile value of E_{rms} computed in the human body electromagnetic simulations. This test level is also used for the RF-induced malfunction testing described in Clause 15.

Step 1b Determine the incident peak field for Clause 15*in vitro* testing. A conservative incident B_{1+peak} field value is 30 µT averaged over the adjustment volume. The final peak incident field amplitude, E_{peak}, is determined by the 95th percentile of E_{rms}/B_{1+rms} scaled to 30 µT.

Step 2 Assess the maximum power deposition from the electric field in a homogeneous tissue simulating medium. Same as Step 2 in Tier 1, except the final incident electric field amplitude is from Step 1a of Tier 2.

Step 3 Assess the enhancement from differential mode coupling. Same as Step 3 in Tier 1.

Step 4 Assess the maximum power deposition from the electric field in alternate tissue simulating medium if necessary. Same as Step 4 in Tier 1.

8.7.4 Tier 3

The *in vivo* power deposition around the implant shall be determined by applying incident electromagnetic field distributions (magnitude and phase) to a validated electromagnetic model of the AIMD. The incident fields are obtained from electromagnetic modelling of the RF-human interactions under appropriate exposure from MR scanner RF transmit coil. The AIMD model is an approximation of the electromagnetic physics and its departure from the true answer is quantified by the $u_{predict}$ component described in 8.8, *in vitro* model validation.

Annex Q describes many different types of AIMD configurations, some of which could significantly impact RF heating, and others that have minimal or no effect. A model shall be developed and validated for the highest heating AIMD configuration. It is necessary to develop and validate models for more than one configuration if the worst case configuration cannot be justified. Rationale shall be provided to justify the configuration(s) that have been modelled.

The development, validation, and utilization of a Tier 3-compliant AIMD model to estimate the *in vivo* power deposition of the AIMD is specified in the following procedure.

Step 1 Develop an equivalent electromagnetic model(s) of the AIMD and the associated confidence interval (uncertainty budget). Analytical, numerical or experimental methods may be used to develop the model. The input to the AIMD model is a series of piece-wise incident field components (amplitude and phase of the incident tangential electric field averaged over an incremental length). The output of the model is an estimate of the local *in vivo* power deposition at each hotspot along the AIMD with a known uncertainty[3].

$$P = A\left|\int_0^l S_{hotspot}(z)\,E_{tan}(z)\,dz\right|^2 \tag{2}$$

where

P is the power deposition at hotspot of AIMD;

A is a constant;

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

l is the length of the AIMD;

z is the position along the AIMD;

S_{hotspot} is the complex validated model of the AIMD;

E_{tan} is the local in vivo electric field determined in Step 3.

NOTE 1 For an AIMD with multiple leads, power deposition can change when leads follow pathways as described in 8.5.

Step 2 The electromagnetic model of the AIMD is validated for prediction of power deposition in homogeneous media/tissue by satisfying the requirements defined in 8.8. For non-homogeneous tissue distribution, additional validation steps might be needed, the methodology of which is not part of this edition.

Step 3 The expected *in vivo* incident tangential electric fields (magnitude and phase) along all clinically relevant AIMD pathways are determined in accordance with 8.6. The tangential electric field shall be averaged at intervals of 5 mm or less over the defined AIMD pathways.

NOTE 2 Averaging intervals of 5 mm or less are defined for regions of AIMD that are approximately one-dimensional (e.g. over thin elongated wires or leads).

Wherever the AIMD can represent a two- or three- dimensional structure, with respect to the *in vivo* incident field, e.g. over device housing or over multiple adjacent leads, the user shall determine, justify, apply, and document their averaging scheme and results.

Step 4 The distribution of *in vivo* local power deposition is computed at each hotspot (see definition in 8.4.2) along the AIMD (e.g. around conductive electrodes, device housing) by exciting the validated model of Step 1 with the incident fields of Step 3. The *in vivo* local power deposition is computed according to Formula (2) of Step 1 or its equivalence (e.g. the integration may be approximated by discrete summation). The resulting distribution is a prediction of the *in vivo* power deposition.

NOTE 3 Clause 15 defines test methods for evaluating the RF-induced malfunction and RF rectification hazards. Modelling similar to this subclause is required and as described in 15.5.3.

8.7.5 Tier 4

The *in vivo* power deposition around the implant shall be determined by performing computer simulations of human bodies with an electromagnetic AIMD model placed within the human body models. Examples of suitable models are full-wave RF models, lumped element models, and mixed full-wave and lumped element models. The human simulations shall be performed under appropriate exposure from an MR scanner RF transmit coil using a validated electromagnetic model of the AIMD. The AIMD model is an approximation of the electromagnetic physics and its departure from the true answer is quantified by the u_{predict} component described in 8.8, *in vitro* model validation.

Annex Q describes many different types of AIMD configurations, some of which could significantly impact RF heating, and others that have minimal or no effect. A model shall be developed and validated for the highest heating AIMD configuration. It is necessary to develop and validate models for more than one configuration if the worst case configuration cannot be justified. Rationale shall be provided to justify the configuration(s) that have been modelled.

The development, validation, and utilization of a Tier 4-compliant AIMD model to estimate the *in vivo* power deposition of the AIMD is specified in the following procedure.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

Step 1 Develop an equivalent electromagnetic model(s) of the AIMD and the associated confidence interval (uncertainty budget). Methods of developing the model are the responsibility of the implant manufacturer. The output of the model is an estimate of the local spatial integral of the local *in vivo* power deposition at each hotspot, $P_{hotspot}$, along the AIMD with a known uncertainty.

Step 2 The electromagnetic model of the AIMD is validated for prediction of power deposition in homogeneous media/tissue by satisfying the requirements defined in 8.8. For non-homogeneous tissue distribution, additional validation steps might be needed, the methodology of which is not part of this edition.

Step 3 Create the simulation set, which consists of all combinations of clinically relevant parameters in 8.6. Therefore the size of the simulation set is equal to the number of human bodies multiplied by the number of clinically relevant AIMD pathways, multiplied by the number of positions in the coil, multiplied by the number of transmit coil types and polarization.

Step 4 The distribution of *in vivo* local power deposition is computed at each hotspot (see definition in 8.4.2) along the AIMD (e.g. around conductive electrodes, device housing) by exciting the simulation set defined in Step 3 with the MR Scanner field conditions defined in 8.6. The resulting distribution is a prediction of the *in vivo* power deposition.

NOTE Clause 15 defines test methods for evaluating the RF-induced malfunction and RF rectification hazards. Modelling similar to this subclause is required and as described in 15.5.2.

8.8 *In vitro* model validation

The AIMD model for homogeneous tissue/media shall be validated *in vitro* by comparing model predictions to measurements of power deposition around the AIMD when exposed to a well-defined and repeatable radiated electromagnetic field test environment described in 8.3. The model validation procedure shall include the following:

— A radiated electromagnetic field test environment producing known and repeatable variations in electric field magnitude and phase tangent to the AIMD;

— An evaluation of the radiated electromagnetic field test environment uncertainty;

— An evaluation of the AIMD model uncertainty;

— A quantification of the AIMD model error.

Step 1 The AIMD shall be immersed in a phantom containing tissue simulating media with characteristics defined in 8.3.2 and exposed to a set of tangential electric fields that are unique relative to the excitation fields used to generate the model. Depending on the application, more than one formulation of tissue simulating media might be required. The spatial locations (pathways) in the phantom containing tissue simulating medium that produce the desired validation electric fields, phantom characteristics (size and shape), and tissue simulating media properties (such as permittivity, conductivity, and depth), are referred to as the model validation set. A justification shall be provided as to the appropriateness of the model validation set relative to the AIMD. The selected incident fields for the validation shall be sufficiently different than the incident field(s) used for generating the AIMD model, and the difference shall be justified.

The tangential electric field exposures used for AIMD model validation shall be defined using one of the following two methods.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

— Option 1: Incident electric field exposures based on clinically relevant exposure characteristics.

  Electric fields tangentially incident to the AIMD shall be extracted from simulations of clinically relevant human exposures. An analysis of these extracted electric fields shall be used to define *in vitro* test conditions that span the range of anticipated *in vivo* electric field exposure characteristics. As it is generally not feasible to replicate complex *in vivo* electric field distributions *in vitro*, the *in vitro* test environment shall produce incident fields with characteristics representative of the clinically relevant *in vivo* exposures. Example characteristics can include the following: regions of high and low incident electric field magnitude, regions of rapidly changing electric field magnitude and phase, and regions where the incident electric field phase changes along the AIMD at an approximately uniform rate. Justification shall be provided for the applicability of the selected exposure conditions to the clinically relevant human exposures.

— Option 2: Incident electric field exposures based on model response characteristics.

  A set of tangential electric field exposures shall be used for AIMD model validation (see Annex M for examples). The set shall include changes in magnitude, phase or combinations of magnitude and phase, at different locations spanning the length of the AIMD. The exposures shall ensure that both high and low power depositions are generated. For example, the amplitude ramps, linear phase and phase reversal fields in Annex M provide sufficient variation of power deposition and incident field to validate the model.

Step 2 The uncertainty of the AIMD local deposited power determined using the radiated electromagnetic test apparatus shall be quantified. The *in vitro* test uncertainty, u_{exp}, represents the total uncertainty in the AIMD local deposited power due to variations in the test and measurement system including but not limited to the uncertainty of the incident tangential electric field, tissue simulating medium properties, AIMD placement, and deposited power measurement method (e.g. SAR or temperature).

NOTE 1 The level of uncertainty is specified according to the desired confidence level. The radiated test uncertainty, u_{exp}, represents the root-sum-square (rss) combination of all significant and appropriately normalized sources of uncertainty associated with the test environment and power deposition measurement. 8.9 provides additional information on uncertainty.

Step 3 Determine the AIMD model uncertainty, $u_{predict}$. This represents the uncertainty and variability associated with the numerical, analytical, and/or experimental methods used to derive and implement the AIMD model.

NOTE 2 The level of uncertainty is specified according to the desired confidence level. The AIMD model prediction uncertainty, $u_{predict}$, represents the root-sum-square (rss) combination of all significant and appropriately normalized sources of uncertainty associated with the derivation and implementation of the AIMD model. 8.9 provides additional information on uncertainty.

Step 4 Measure the RF power deposited or corresponding temperature rise by the AIMD for the model validation set developed in Step 1.

Step 5 Compute the RF power deposited or corresponding temperature rise using the AIMD model for the model validation set developed in Step 1.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

Step 6 Compute the error between the deposited RF power measured in Step 4 and the deposited RF power computed in Step 5.

The total error, e_{total}, is computed from the difference between the predicted and measured deposited power values from the model validation data set using appropriate statistical methods. When replicate measurements corresponding to a single model prediction are included, the total error can be composed into two components, e_{model} and e_{random}. The e_{random} error term represents random measurement error relative to the mean value of all replicate measurements. The e_{model} error term relates the mean value of replicate measurements to the model predicted value and therefore provides an estimate of the model lack of fit or prediction error. Since the total error, e_{total}, includes both random error (e_{random}) and prediction error (e_{model}) contributions, it may be used as a conservative estimation of model prediction error, e_{model}.

Step 7 Evaluate validation criteria and compute the combined *in vitro* prediction uncertainty.

The AIMD model is validated if the total error, e_{total}, is less than the root-sum-square (rss) combination of the radiated test uncertainty, u_{exp}, and the AIMD model prediction uncertainty, $u_{predict}$, as shown in Formula (3).

$$e_{total} < \sqrt{u_{predict}^{2} + u_{exp}^{2}} \tag{3}$$

where

e_{total} is the total error;

$u_{predict}$ is the model prediction uncertainty;

u_{exp} is the radiated test uncertainty.

8.9 Overall uncertainty analysis

The output of Clause 8 is an expected power deposition that will have a tolerance that reflects the uncertainty of the final answer. A thorough uncertainty analysis is required for the following (see Reference [4] for additional detail relative to uncertainty topics):

— All tiers produce either SAR or temperature measurements of the AIMD hotspots in a phantom. Uncertainty of the measurement system, as defined in 8.3.1, shall be evaluated;

  a) Tier 1 and Tier 2 require an analysis of the absolute accuracy of the radiated test and its variability, u_{exp}, because absolute error directly impacts the power deposition;

  b) Tier 3 and Tier 4 derive an AIMD model that is validated in a measurement system. Both require an uncertainty assessment by determination of $u_{predict}$ and u_{exp}, respectively;

— Tier 2, Tier3, and Tier 4 all rely on human body simulations to determine the electric field that the AIMD is exposed to in subsequent steps of the analysis. The simulations should include the patient population, transmit RF coils, polarizations and positions in RF coil, as described in 8.6. If a reduced set of simulations is done with limited variation of a particular parameter(s), an additional uncertainty analysis may be used to include those variations of that particular parameter(s) not considered in the simulations;

— Tier 3 and Tier 4 require AIMD location, orientation, and lead pathways that shall include the clinical use cases. Uncertainty analysis does not apply for these parameters.

8.10 *In vivo* analysis of power deposition

The AIMD hotspots are analysed using one of the tiers described in 8.7 using SAR or temperature measurements and some level of human body RF simulations. Independent of the measurement method

AVA Documents
Document Sharing Hub

© ISO 2018 – All rights reserved

Full document details: PD ISO/TS 10974:2018

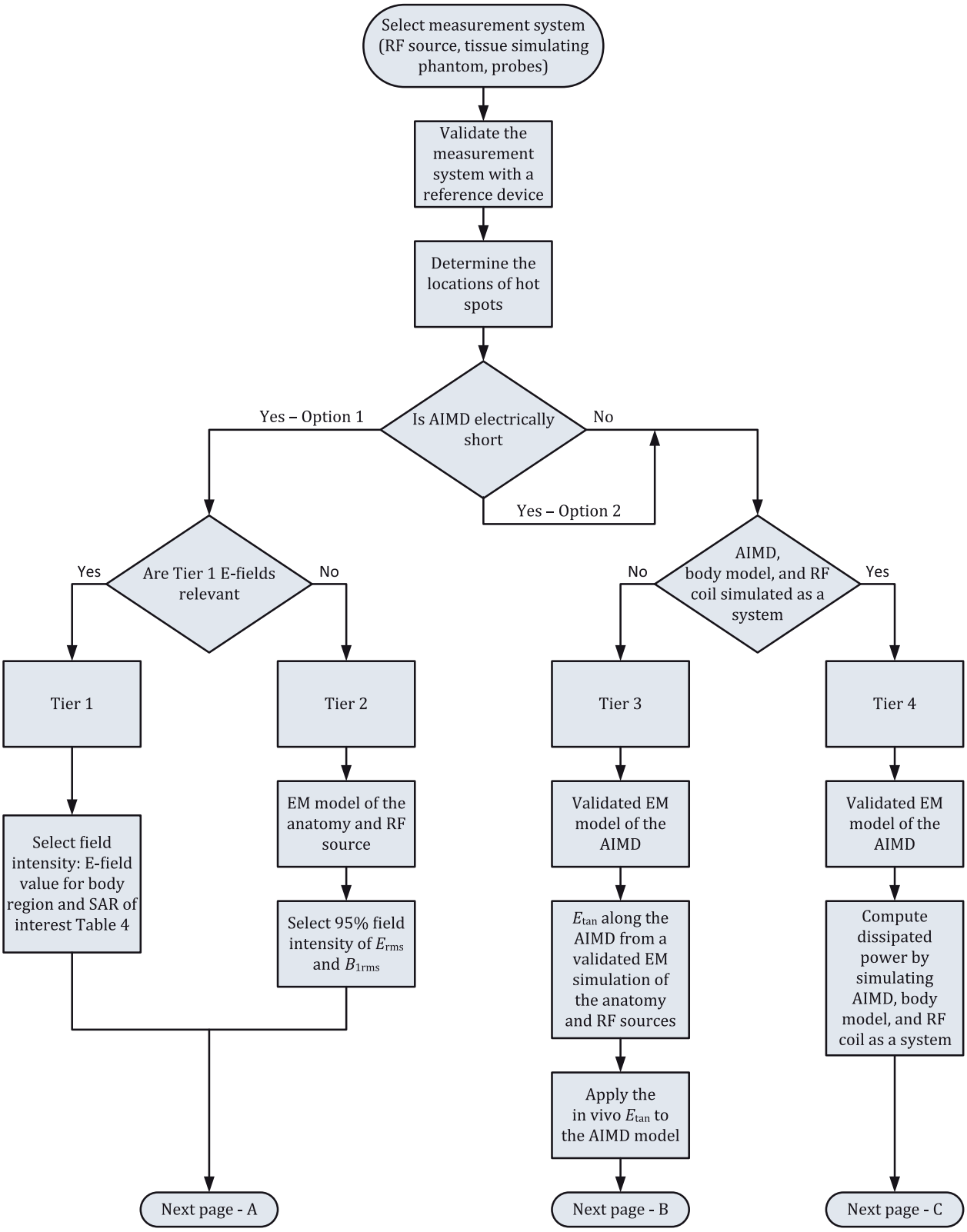
and tier, the final result is always expressed in deposited power because deposited power can be directly transferred to the *in vivo* environment.

The analysis of the impact of the deposited power on the tissue, local to the hotspot, is extremely complex and beyond the scope of this document (see 7.1).

8.11 RF-induced heating assessment flow chart

Figure 6 provides an overview of the RF-induced heating assessment process described in Clause 8.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018



© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

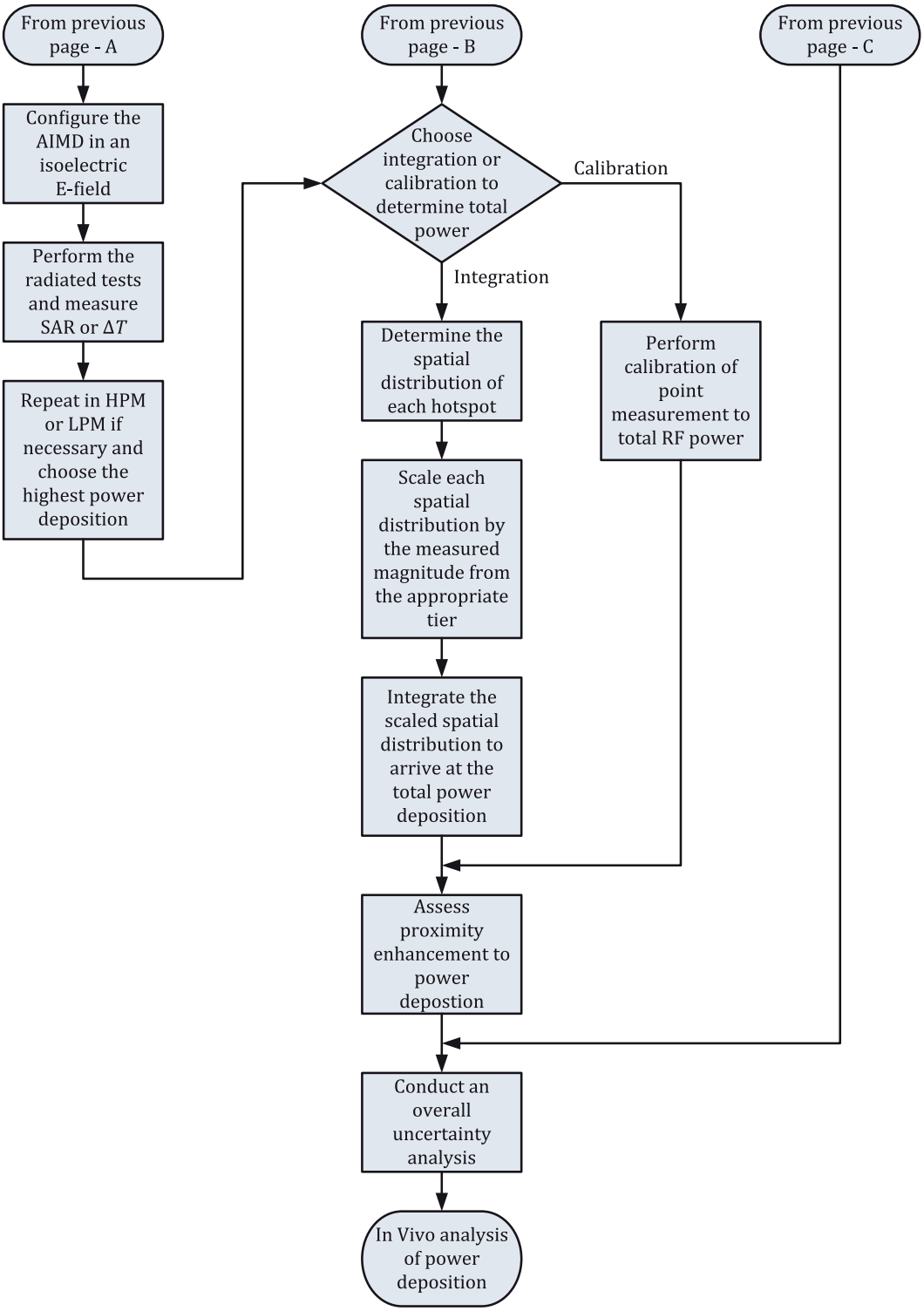


Figure 6 — RF-induced heating assessment process

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

9 Protection from harm to the patient caused by gradient-induced device heating

9.1 Introduction

The imaging gradient *dB/dt* field induces eddy currents on conductive AIMD enclosures and other conductive internal surfaces such as battery components and circuit traces resulting in device heating. For AIMDs with extended leads (e.g. cardiac leads or neuromodulation leads) that do not contain planar conductive surfaces, there is no mechanism for MR-induced eddy current heating to occur in the leads. These leads do not require an evaluation of MR-induced eddy current heating.

The instantaneous power deposited by eddy currents induced in a cylindrical conductive disk by a time varying magnetic field can partially be represented by Formula (4) and shown in Figure 7.

$$P = \sigma T \pi \frac{R^4}{8} \left(\frac{dB}{dt} \cos\beta \right)^2 \tag{4}$$

where

P is instantaneous deposited power;

R is the radius;

T is the material thickness;

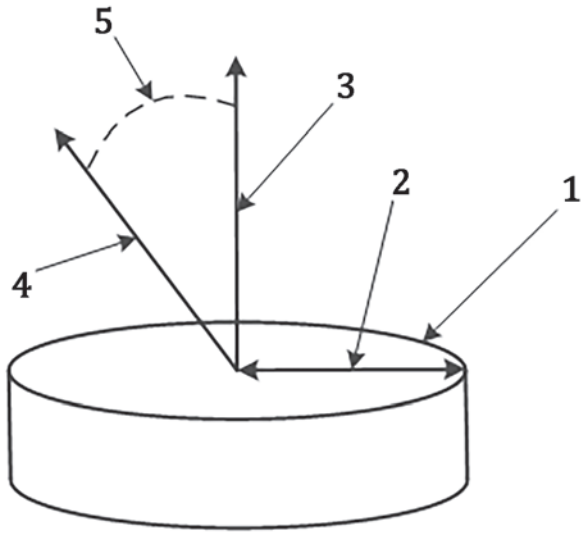
σ is the conductivity;

β is the angle of the *dB/dt* vector with respect to the normal to the disk plane;

dB/dt is the time rate of change of the magnetic field.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018



Key

1 AIMD enclosure with conductivity, σ, and material thickness, T

2 radius, R, of the AIMD enclosure

3 vector normal to the plane of the AIMD

4 dB/dt vector of the time rate of change of the magnetic field

5 angle, β, of the dB/dt vector with respect to the normal to the plane of the device

Figure 7 — Illustration of a cylindrical conductive disk and the relevant parameters that affect gradient-induced heating

When determining the average power deposited in the device and associated surrounding tissue, the mean value of the square of dB/dt for the particular MR pulse sequence(s), as well as the time integral of the exposure and incident angle across all conducting material of the device should be considered. The heating will be greatest for implants with a large surface area and high electrical conductivity.

NOTE Device heating caused by gradient field induced eddy currents is proportional to the square of $|dB/dt|$ rms.

9.2 Testing considerations

9.2.1 General

The magnitude and orientation of the pulsed gradient magnetic field vectors vary throughout the scanner bore. Device heating is greatest when the device is located where the gradient field $|dB/dt|$ rms is maximum. In addition, heating is typically greatest when the device is oriented so that the gradient field vector is orthogonal to the AIMD surface(s) with the largest conductive area. However there might be exceptions where maximum heating occurs at a different orientation. For example, devices with unusual case designs or devices where substantial power is deposited in internal components might heat maximally at a non-obvious orientation with respect to the dB/dt vector. Evaluation of gradient-induced device heating shall be conducted under test conditions sufficient to represent all gradient system exposures allowed by the AIMD MR Conditional labelling.

Device heating could also depend on the gradient waveform characteristics. The gradient-induced device heating test may be conducted using one of two tiers for the gradient waveform shape. Tier 1 is a conservative waveform shape, and Tier 2 allows the characterization and use of a clinically relevant waveform.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

9.2.2 Determination of |*dB/dt*| rms exposure limits

The maximum Normal Operating Mode |*dB/dt*| rms as a function of radial position within the scanner bore is shown in Table 5. Determine the |*dB/dt*| rms test value using Table 5 and the radius that contains the AIMD for the relevant patient population.

Table 5 — AIMD |*dB/dt*| rms exposure values as a function of radial distance from z-axis

Maximum AIMD radial position cm	Exposure value |*dB/dt*| rms [T/s]
5	27,1
10	29,8
15	34,4
20	42,0
25	54,1
30[a]	73,3

NOTE Based on scaling 42 T/s rms at a radius of 20 cm using ratios derived from the *dB/dt* peak in Table A.2. The 42 T/s rms at a radius of 20 cm was derived based on scanner survey data collected by multiple AIMD manufacturers where the MR scanner sequences were optimised to produce the largest measureable |*dB/dt*| rms while complying with gradient hardware limitations. See Annex D for additional information.

[a] 30 cm radius is only applicable for 70 cm bore systems.

9.2.3 Determination of test duration

The device under test shall be evaluated with a gradient field |*dB/dt*| rms duration corresponding to conservative clinical use conditions. The duration may be based on the maximum allowed scan duration as specified by the AIMD MR Conditional labelling, or 30 min.

9.3 Test requirements

9.3.1 General

Evaluation of device heating involves exposing the AIMD device to the specified gradient field *dB/dt* (rms value and vector orientation) and measuring the resulting temperature rise. Testing shall be conducted in an environment that minimizes thermal convection and is dominated by thermal conduction (e.g. gel solution or insulated container).

Use of a laboratory coil, amplifier and function generator that can simulate clinical gradient field exposure is preferred. This type of equipment has the benefit of being able to easily generate arbitrary pulse sequences that can be consistently reproduced. The use of this type of apparatus may be applied to Tier 1 and to Tier 2 test waveforms (see 9.3.6).

Alternatively, testing may be conducted using a clinical MR scanner. If a scanner is used, care should be taken that the device location, device orientation and scanner set-up are well controlled. This is a difficult task and specialized knowledge is required in order to operate the MR scanner. In addition, use of the clinical MR scanner might not be possible for the Tier 1 test waveform (see 9.3.6.2).

It is not necessary to expose the device to the clinical exposure limits of 9.2.2 during temperature testing to determine device heating. If the applied field generates a temperature rise large enough to achieve a signal to noise ratio of at least 10:1, and linearity within the range of instrumentation is

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

demonstrated, it is permitted to evaluate the device using temperature scaling and the rms value of *dB/dt* [see Formula (5)].

$$\Delta T_{\text{clinical exposure}} = \Delta T_{\text{measured}} \left[\frac{\left| \frac{dB}{dt} \right|_{\text{rms}} (\text{requirement})}{\left| \frac{dB}{dt} \right|_{\text{rms}} (\text{test})} \right]^2 \tag{5}$$

where

$\Delta T_{\text{clinical exposure}}$ is the calculated temperature rise at the time averaged *dB/dt* required for evaluation;

$\Delta T_{\text{measured}}$ is the measured temperature rise from the test;

$\left| \frac{dB}{dt} \right|_{\text{rms}} (\text{requirement})$ is the time averaged *dB/dt* required for evaluation;

$\left| \frac{dB}{dt} \right|_{\text{rms}} (\text{test})$ is the time averaged *dB/dt* used for the test.

9.3.2 *In vitro* test phantom or other suitable container

Position the DUT at the radial centre of a phantom filled with gelled solution or other appropriate test container. Position and orient the phantom or container with device as required for exposure to the test condition gradient field magnitude and vector direction in either laboratory test equipment capable of producing a simulated MR gradient field or a clinical MR scanner.

When using a phantom within a laboratory gradient field coil, there are often practical limitations to the phantom container size, and the boundary conditions of the phantom can affect temperature measurements. It is preferable to hold the phantom container boundary temperature constant for the test duration. If the boundary temperatures cannot be held constant, then thermal loss to the environment shall be accounted for in the final temperature rise.

9.3.3 Gelled solution

For a device heating test using a phantom, refer to the gelled high permittivity material, defined in Annex L, for an appropriate test media.

9.3.4 Temperature survey to determine orientation and hot spots

Device heating will depend upon orientation of the device relative to the vector of the applied field. For devices with a large conductive plane (or multiple parallel conductive planes), maximum power deposition will occur when the *dB/dt* vector is perpendicular to the largest conductive plane. For devices without a major conductive plane or devices with internal components that might contribute to heating in other orientations, a survey shall be conducted to determine the orientation relative to the applied *dB/dt* vector that produces the largest heating.

The device will have localized hot spots due to the case shape or heating contributed by power dissipated in internal components. The device shall also be surveyed for hot spots due to gradient-induced heating. The hot spot survey shall be conducted using the device orientation that produced maximum heating.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

9.3.5 Minimum temperature instrumentation

An appropriate temperature probe shall be used to measure device temperature by placing the probe at the highest temperature spot determined from the survey. Additional probes may be used as needed for repeatability. At least one additional probe shall be placed such that it can monitor the ambient temperature of the test media. Measured device temperature data may be corrected if the ambient temperature changes more than the error of the probe measurements. The ambient probe shall be placed in the test media near the edge of the container to isolate it from device heating.

9.3.6 Definition of *dB/dt* test waveform

9.3.6.1 General

The test waveform to be applied to the AIMD shall be determined by one of the following two tiers. Tier 1 applies a conservative *dB/dt* waveform that has been configured with the understanding that there is a frequency dependent variable for device heating that is due to the self-inductance of the AIMD conductive planes or surfaces (see Annex D for additional information). However this waveform is not clinically representative of actual *dB/dt* waveforms experienced during MR pulse sequences. Alternatively, Tier 2 may be utilized where the AIMD manufacturer is responsible for characterizing and determining a conservative clinically representative waveform. Whichever tier is utilized, the heating shall be evaluated at the |*dB/dt*| rms level determined in 9.2.2.

9.3.6.2 Tier 1

The radiated *B* field waveform is defined as shown in Formula (6).

$$B_G(t) = \left(\frac{dB_G}{dt}\right)_{rms} \times \left(\frac{\sqrt{2}}{2\pi f}\right)\sin(2\pi f t) \tag{6}$$

where

$B_G(t)$ is the time varying magnetic field magnitude;

t is time;

f is the frequency set to 270 Hz;

$\left(\frac{dB_G}{dt}\right)_{rms}$ is the rms value of the time varying gradient field (determined in 9.2.2).

NOTE 1 The Tier 1 test waveform was defined with a $|B_G|_{peak}$ value of 35 mT and a $\left(\frac{dB_G}{dt}\right)_{rms}$ value of 42 T/s rms. These selected values resulted in a nominal frequency of 270 Hz. A sine wave is used for the Tier 1 test waveform to limit the spectral power to the specified frequency to reduce the potential for gradient field energy to be stored in self-inductance of the AIMD enclosure and components, rather than dissipated in eddy current heating.

NOTE 2 The use if a Tier 1 test waveform is only applicable to a single axis laboratory coil and not to a clinical MR scanner.

9.3.6.3 Tier 2

Use of the Tier 1 radiated *B* field waveform is not clinically realistic. Consequently, the AIMD manufacturer may determine a clinically relevant test waveform with specific properties such as waveform shape and spectral content that produces the required rms value of *dB/dt* and can be demonstrated to be clinically representative. If the Tier 1 test waveform is not used, the AIMD manufacturer shall provide a rationale

AVA Documents
Document Sharing Hub

© ISO 2018 – All rights reserved

Full document details: PD ISO/TS 10974:2018

for the *dB/dt* test waveform and conditions used to evaluate eddy current heating. The rationale shall indicate the source of gradient field *dB/dt* waveform information. For example, gradient field *dB/dt* waveform information may come from measurement and characterization of clinical sequences.

If measurement is the method used to determine the clinically relevant test waveform shape, the 3-axis search coil and methods described in IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.12.4.105.2.2, method b) may be used to monitor the MR pulse sequence. Another method if possible may include direct monitoring of the gradient amplifier outputs to determine waveform shape using a gradient amplifier sample port.

Whatever measurement method is chosen for characterizing clinically relevant test waveforms, care should be taken to ensure that the test system used to conduct the characterization is not adversely affecting the results due to limitations of the test system; for example, one such limitation might be the bandwidth of the test system.

9.3.7 Characterization of applied *dB/dt*

Place a search coil in the region of the homogeneous field. The AIMD shall be oriented with major conductive planes parallel to the scanner z axis. The *dB/dt* vector orthogonal to the major conductive planes of the AIMD shall be measured. Record the applied *dB/dt* waveform used for the heating test at the location corresponding to the minimum *dB/dt* exposure applied to the AIMD. The waveform shall be sampled at a rate sufficient to capture the details of the *dB/dt* waveform and prevent aliasing of the signal. The recorded waveform shall have sufficient length to allow determination of mean values. If mean square or |*dB/dt*| rms is not directly recorded, the gradient field exposure recording shall be such that it can be post-processed to calculate mean square or |*dB/dt*| rms. The *dB/dt* measurement may be performed independently of the heating test, provided the applied waveforms will be identical for each test.

If utilizing a clinical MR scanner the vector direction of the applied *dB/dt* can vary with time. To prevent under-estimation of the AIMD heating, only the *dB/dt* component that is perpendicular to the planar conductive surface of the AIMD should be used in determination of the applied |*dB/dt*| rms.

9.4 Lab testing using simulated MR gradient field

Case heating in the bench-top test is measured using the following procedure:

Step 1 Place the device in the gelled phantom or other suitable container with temperature probes attached as defined in 9.3.5 and placed in a laboratory coil that applies the time-varying magnetic field.

Step 2 Apply the required |*dB/dt*| rms determined in accordance with 9.2.2 with a selected waveform from either Tier 1 or Tier 2 as specified in 9.3.6 and measured in 9.3.7. If the laboratory test system is not capable of producing the specified |*dB/dt*| rms with the associated waveform, then testing may be conducted at a lower |*dB/dt*| rms and then scaled to the specified |*dB/dt*| rms using the formula shown in 9.3.1.

Step 3 Measure the gradient-induced device heating with the temperature probes for the duration of the test as determined in 9.2.3.

9.5 MR scanner testing

Most of the discussion regarding laboratory testing could be adapted to testing conducted using a clinical scanner. If a clinical scanner is used, accurate and repeatable fixtures will be needed to locate and orient the phantom and device under test. Selecting, controlling, and repeating the scanner clinical pulse sequence used for testing is also important. Measurement in a clinical MR scanner is accomplished using the procedure in 9.4 by utilizing a clinical MR scanner in place of the laboratory coil.

The gradient output used for this test shall be consistent with intended AIMD labelling, taking into consideration variables between scanners and sequences. Pulse sequence characteristics and the

© ISO 2018 – All rights reserved
AVA Documents Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

magnitude of *dB/dt* are both important parameters to be considered because device heating will be proportional to the mean square (averaged over time) of gradient field *dB/dt*. It might not be practical to apply the gradient field exposure requirements defined in 9.2.2 when testing is conducted using a clinical MR scanner.

At a minimum, gradient heating should be tested and evaluated using gradient intense compatibility protocol information provided by MR scanner manufacturers (see IEC 60601-2-33 :2010+AMD1:2013+AMD2:2015, 201.7.9.3.101).

9.6 Analysis of gradient heating test

From the recorded *dB/dt* waveform taken from the search coil, determine the value of |*dB/dt*| rms, orthogonal to the plane of the search coil (and AIMD surface), from Formula (7).

$$\left|\frac{dB}{dt}\right| \text{rms} = \sqrt{\frac{\int_0^{t_x} \left|\frac{dB}{dt}\right|^2 dt}{t_x}} \tag{7}$$

where

|*dB/dt*| rms is the root mean square of *dB/dt*;

t_x is a suitable averaging time for the *dB/dt* pulse sequence.

The heating result may be scaled according to Formula (5).

For compliance criteria see 7.1.

10 Protection from harm to the patient caused by gradient-induced vibration

10.1 Introduction

Pulsed magnetic field gradients from an MR scanner induce eddy currents on the conductive surfaces of an AIMD. These eddy currents produce a time varying magnetic moment that interacts with the static magnetic field (B_0) causing vibration of the conductive surfaces and, subsequently, the device.

MR-induced vibration differs from typical AIMD vibration (e.g. transportation, patient activity) where the applied forces and torques are external to the device. MR-induced vibration also occurs at higher frequencies than traditional tests. A detailed description is found in Annex F. The potential for patient harm arises from malfunction of the device, resulting in reduced functionality or lack of therapy.

Because of this unique nature, evaluating the potential for harm requires use of an MR scanner. Figure 8 shows the general test flow and two tiers for evaluating MR-induced vibration. One tier provides higher accuracy with an increase in test burden, while the other tier uses conservative approximations to reduce test burden.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

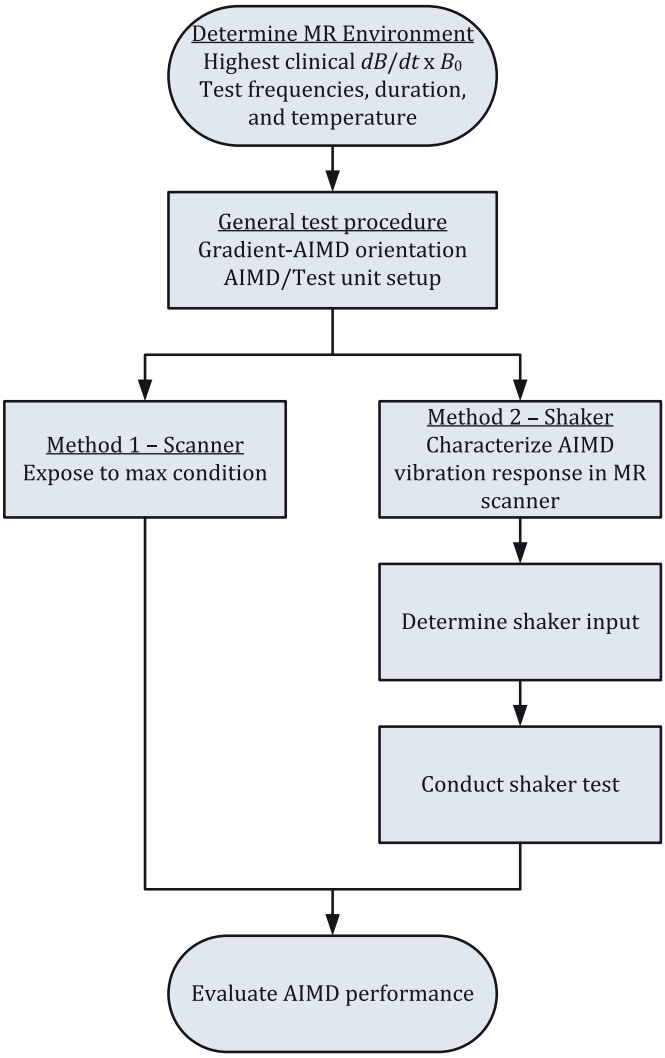


Figure 8 — General test flow for MR-induced vibration

For AIMDs with extended leads (e.g. cardiac leads or neuromodulation leads) that do not contain planar conductive surfaces, there is no mechanism for MR-induced vibration to occur in the leads. These leads do not require an evaluation of MR-induced vibration.

This clause provides a method for evaluating AIMD malfunction due to MR-induced vibration. It also provides a method for measuring the extent of vibration generated within the AIMD, which may subsequently be used to assess tissue damage if applicable; such assessment is outside the scope of this document. In addition, the potential for MR-induced vibration resulting in patient discomfort is acknowledged, but not considered a hazard; no assessment is required.

10.2 Overview of tiers

When an MR scanner is used (Method 1), the vector product of gradient field dB/dt and B_0 to which the AIMD is exposed shall be greater than or equal to the maximum exposure allowed by the AIMD manufacturer's MR Conditional labelling.

If a shaker table is used (Method 2), the AIMD manufacturer shall demonstrate that the mechanical stresses on affected components and their interconnections, and relative motion between components, are equal to or greater than those experienced during an MR scan at the maximum dB/dt allowed in accordance with the AIMD MR Conditional labelling. The AIMD manufacturer shall also demonstrate that the shaker table appropriately replicates the frequencies of vibration experienced by the AIMD during an MR scan at the maximum dB/dt allowed in accordance with the AIMD MR Conditional labelling.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

For AIMD characterization in a scanner (Method 2) it is not necessary to use the maximum vector product of gradient field *dB/dt* and static field B_0 as the test environment. The test conditions shall be determined by characterizing the vibration response at a less-than-maximum gradient field *dB/dt* and static field B_0 vector product and scaling the result to the maximum $dB/dt \times B_0$ vector product allowed in accordance with the AIMD MR Conditional labelling.

10.3 MR environmental conditions

10.3.1 General

MR-induced AIMD vibration shall be evaluated at the maximum acceleration that the AIMD or its components would experience in MR scanners, with gradient output set in accordance with its MR Conditional labelling. Pulse sequence waveform characteristics and the magnitude of *dB/dt* are both important parameters to be considered. The following subclauses define use conditions that are relevant for scanners.

10.3.2 Determination of maximum clinical *dB/dt*

The *dB/dt* magnitude shall be determined from Annex A, based on the maximum value for the gradient slew rate (T/m/s) and applicable patient positions and postures specified in the AIMD MR Conditional labelling.

For AIMDs labelled for Fixed Parameter Option (FPO:B), the *dB/dt* magnitude shall be 100 T/s peak.

For AIMDs not using Fixed Parameter Option:B (FPO:B), dB_y/dt or dB_x/dt magnitude shall be used. Use the *dB/dt* magnitude that represents the primary orthogonal vector to the AIMD's major conductive planes during this test.

10.3.3 Determination of clinical B_0

The B_0 vector used to determine the product of *dB/dt* and B_0 shall be 1,5 T with a direction parallel to the magnet bore axis (z) (see Figure 10).

10.3.4 Determination of clinical $dB/dt \times B_0$

The *dB/dt* vector shall be assumed to be perpendicular to the B_0 vector. Therefore, the $dB/dt \times B_0$ vector product is defined as the scalar product of the *dB/dt* and B_0 magnitudes respectively. This is the maximum achievable cross product of the clinical *dB/dt* and B_0, and thus provides a conservative condition for AIMD evaluation.

NOTE For some types of AIMDs, the orthogonal orientation of B_0 and *dB/dt* might not be clinically relevant. Refer to Annex F to determine the result of $dB/dt \times B_0$ based on the clinically relevant orientation of the AIMD relative to *dB/dt* and B_0.

10.3.5 Test frequencies

10.3.5.1 General

For MR scanning sequences using a trapezoidal gradient waveform (via clinical sequence or driving signal), the driving frequency shall range from ≤300 Hz to at least 1 150 Hz. Frequency steps shall be no greater than 300 Hz, and specific frequency ranges may be excluded if they would damage the MR scanner due to mechanical resonances of the MR gradient coils. This driving frequency range will result in vibration frequency content up to at least 3 000 Hz, which shall be used for Method 2 (shaker table). See Annex F for further rationale.

NOTE Driving the gradient amplifier directly can void the manufacturer's warranty and can cause scanner damage.

© ISO 2018 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018

The following subclauses describe methods and examples for achieving exposure at multiple frequencies within this range. Only one method is required; it is not necessary to use both.

10.3.5.2 Using a clinical MR scan sequence

Clinical imaging sequences such as Echo Planar Imaging (EPI) may be used for mechanical vibration testing. If this method is used, the AIMD manufacturer shall measure, by means of a pickup coil, the frequencies, amplitudes, and number of pulses of *dB/dt* that are generated.

Devices shall be tested in the frequency range and frequency steps as given in 10.3.5.1 using an EPI sequence that results in at least 16 sequential gradient pulses (32 phase encode steps).

NOTE By changing MR imaging parameters, such as bandwidth and field of view, it is possible to induce gradient pulse trains at specific frequencies. Due to the variations in design between scanner manufacturers the AIMD manufacturer is responsible for determining the appropriate imaging sequence and parameters that will generate the desired field.

10.3.5.3 Using an arbitrary gradient waveform

The gradients of an MR scanner may also be driven using a trapezoidal waveform as shown in Figure 9. Devices shall be tested in the frequency range and frequency steps given in 10.3.5.1.

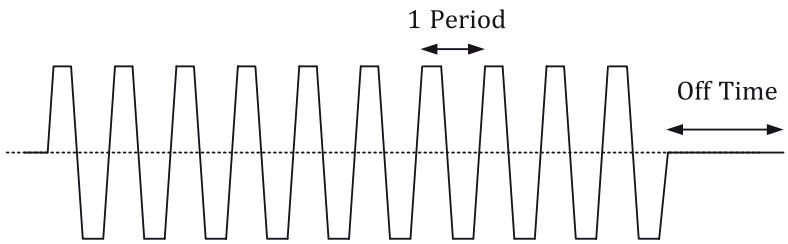


Figure 9 — Example trapezoidal waveform at a specific frequency

10.3.6 Test duration

Table 6 provides the test duration that represents the cumulative scan time over the lifetime of a typical AIMD for a given percentile of the patient population. This is the total duration for the entire test, including all frequencies to be tested. The manufacturer may select an appropriate test duration based on the risk profile of the AIMD. Test durations are based on a 50 % duty cycle (e.g. using a 100 % duty cycle during test reduces the test duration by half).

Table 6 — Test duration based on population percentile

Population percentile %	Test duration h
99,2	2,5
99,9	4,5
99,99	7,5

Test duration is not required to be continuous. Periods of cool down for the scanner or other breaks in continuity are allowed, provided the test setup is not changed and the total exposure time requirements are met.

NOTE Further elaboration can be found in Annex F.

© ISO 2018 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD ISO/TS 10974:2018