TECHNICAL SPECIFICATION

ISO/TS 10974

Second edition
2018-04

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

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

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Contents

Page

Foreword

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

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

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

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

For an explanation 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.

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.

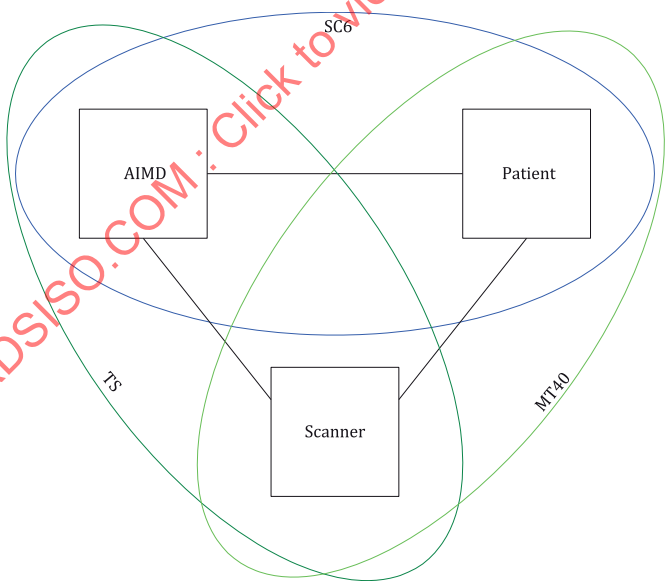

Figure 1 — Responsibilities of product committees illustrating the extent of the scope of this document in terms of the effects between AIMDs and MR scanners

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

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.

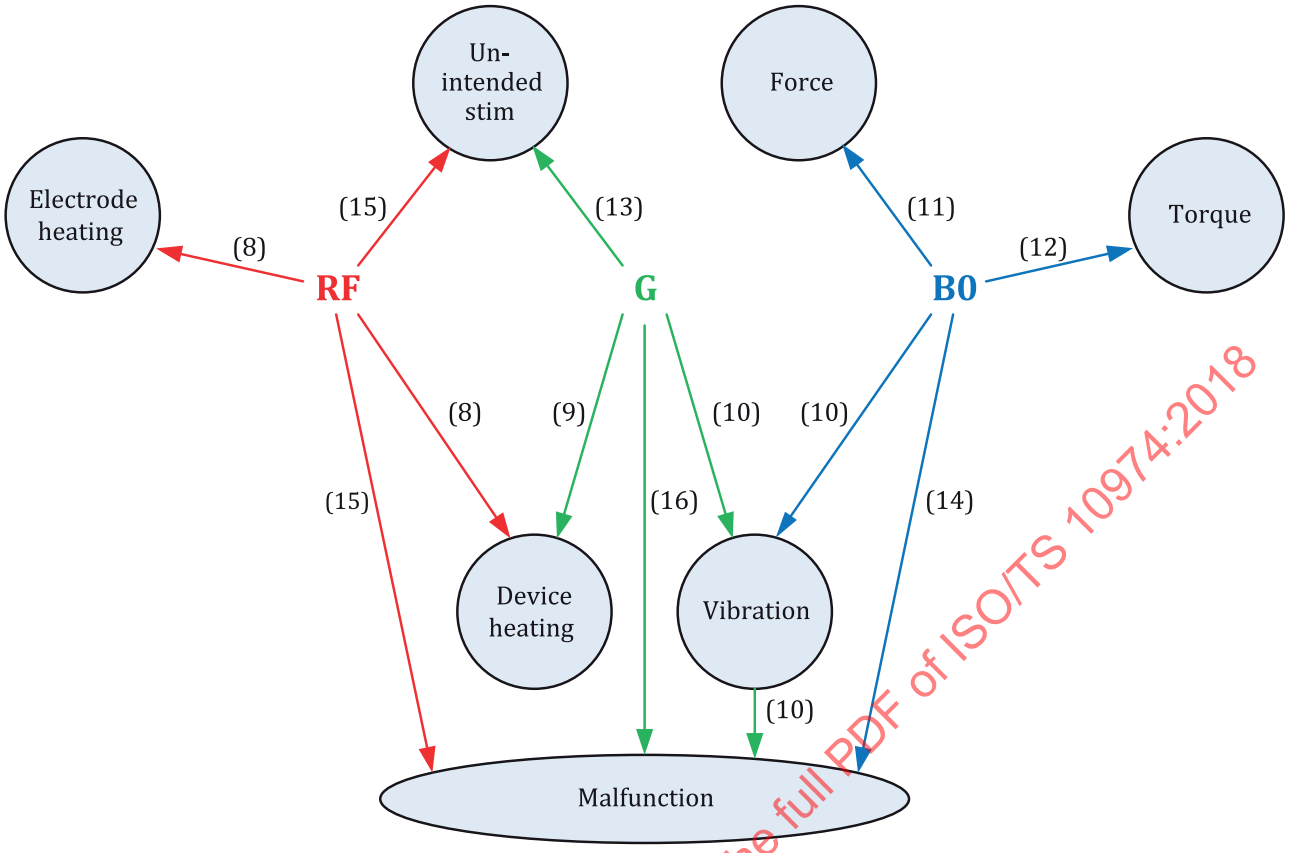

Figure 2 — Relationship between MR scanner output fields (RF, gradient, B_0) and hazards (test method clause numbers in parentheses)

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.

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.
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8200 Coral Sea St. NE, MVN43
Mounds View, MN 55112
USA

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

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

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.

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]

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]

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.]

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]

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.

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.

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.

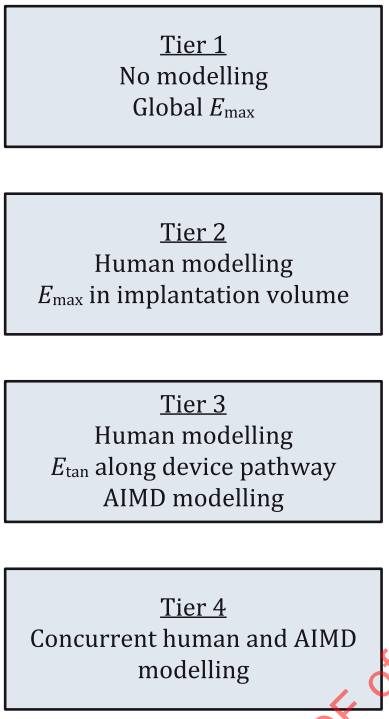
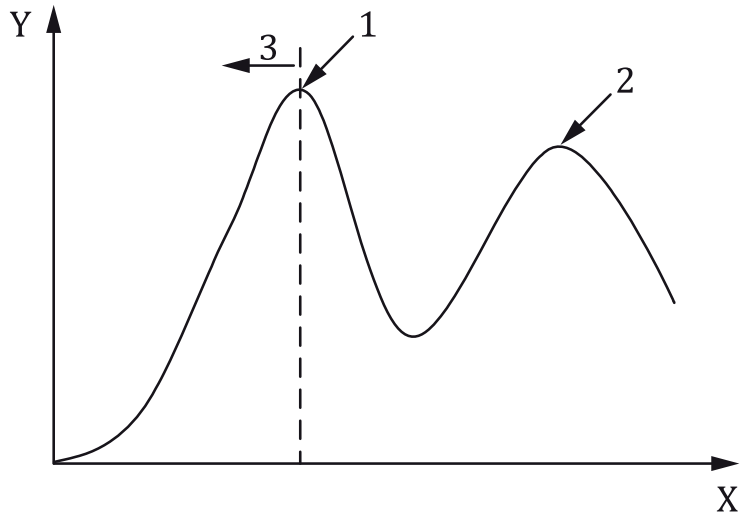


Figure 3 — Four tier approach for determining RF power deposition around an AIMD exposed to MR scanner incident RF fields

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).



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 $E_{\mathrm{rms}}{}^2$) 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,

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).

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 $\Delta T_{backgnd}$ 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.

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

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.

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 (Q);

— 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.

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.

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. $\Delta T = m\ P_{inject}$ or SAR = $m\ P_{inject}$) 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.

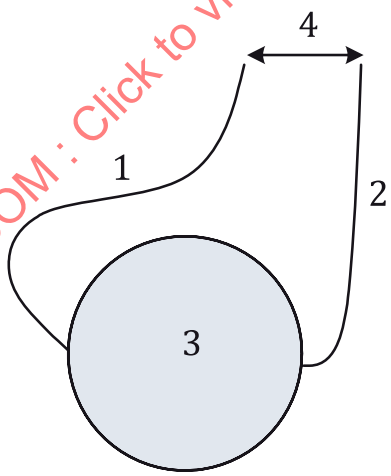
Step 3 Plot ΔT or SAR vs P_{inject} and fit to a linear model. Determine the conversion factor, m (slope), and associated uncertainty from the fitted model.

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);

— SAR or B_{1+rms} excitation amplitude according to labelling and consistent with the SAR and B_{1+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+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.

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.

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].

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

where

P is the power deposition at hotspot of AIMD;

A is a constant;

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.

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.

— 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.

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).

$$e_{total} < \sqrt{u_{predict}^{2} + u_{exp}^{2}} \quad (3)$$

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.

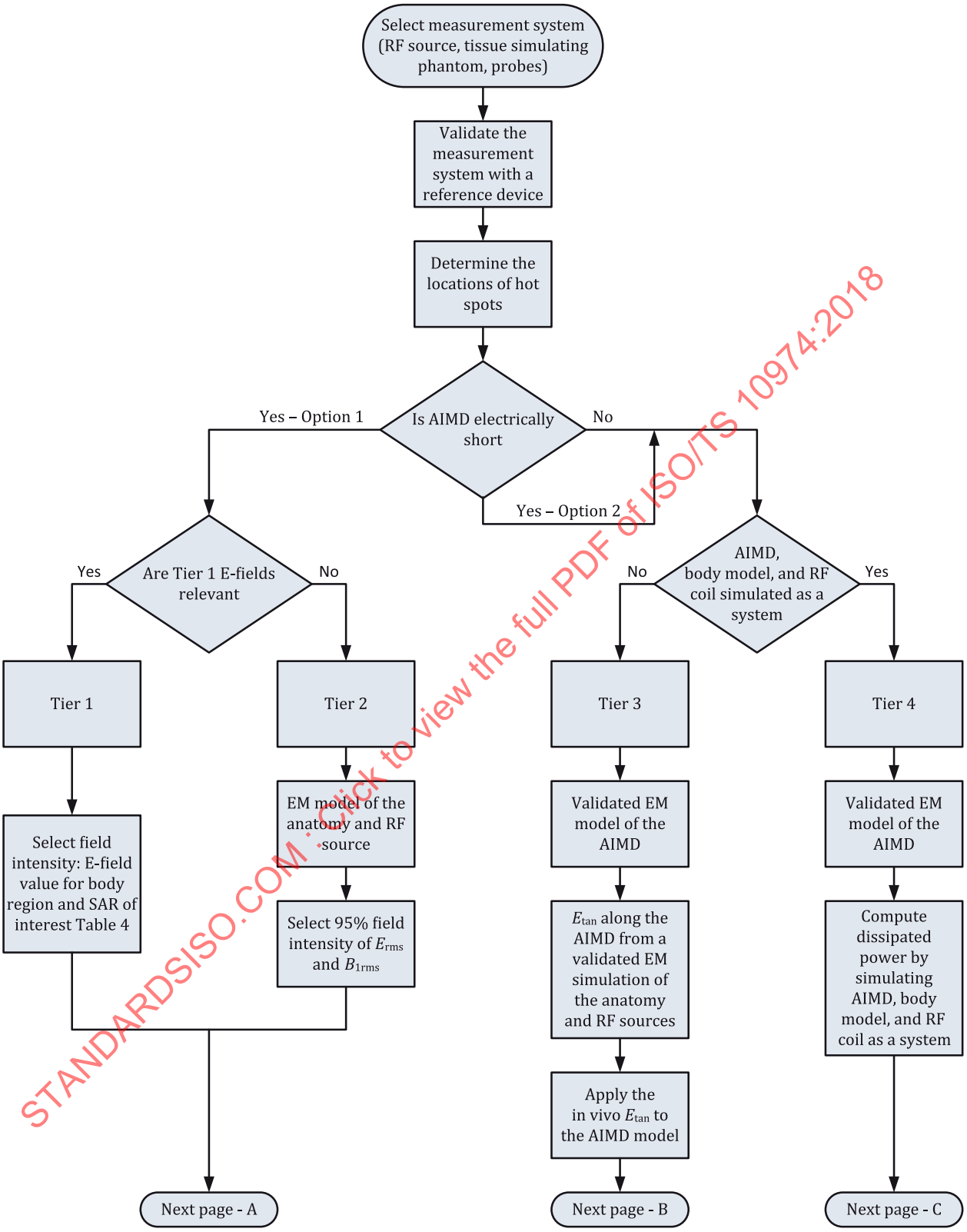
8.10 *In vivo* analysis of power deposition

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 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.



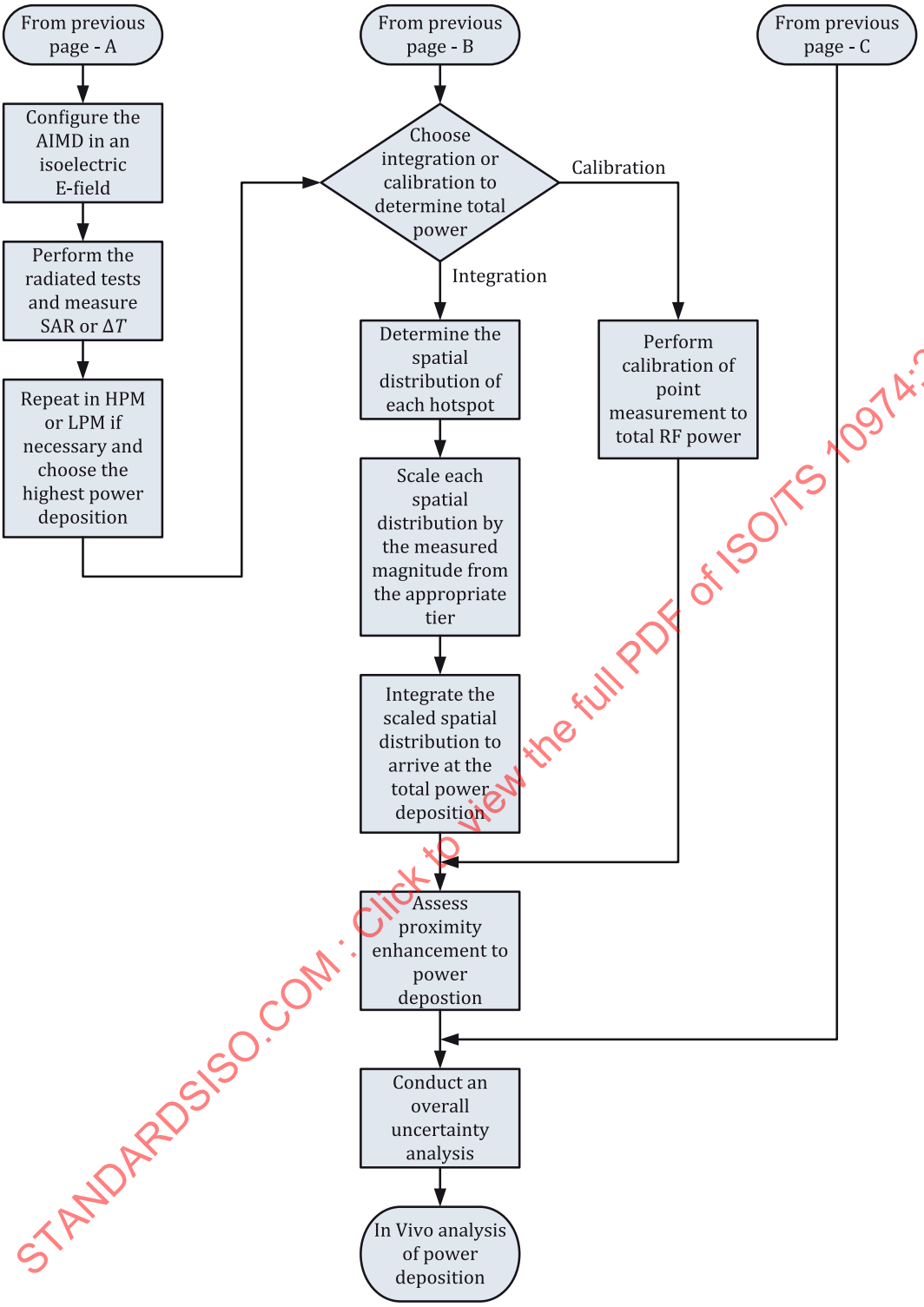


Figure 6 — RF-induced heating assessment process

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;

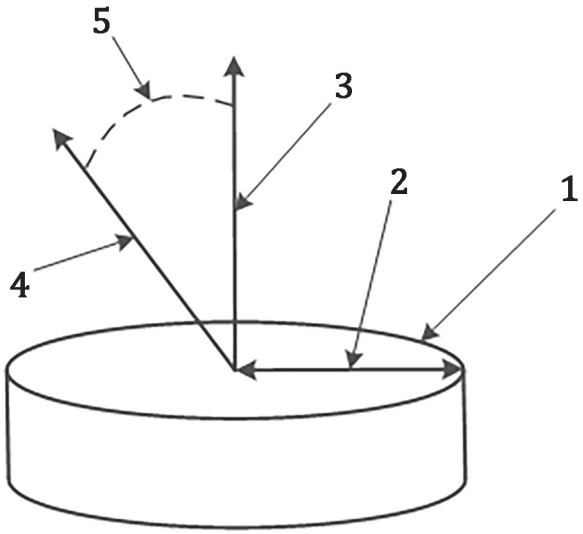
R is the radius;

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.



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.

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

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

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

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.

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

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 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.

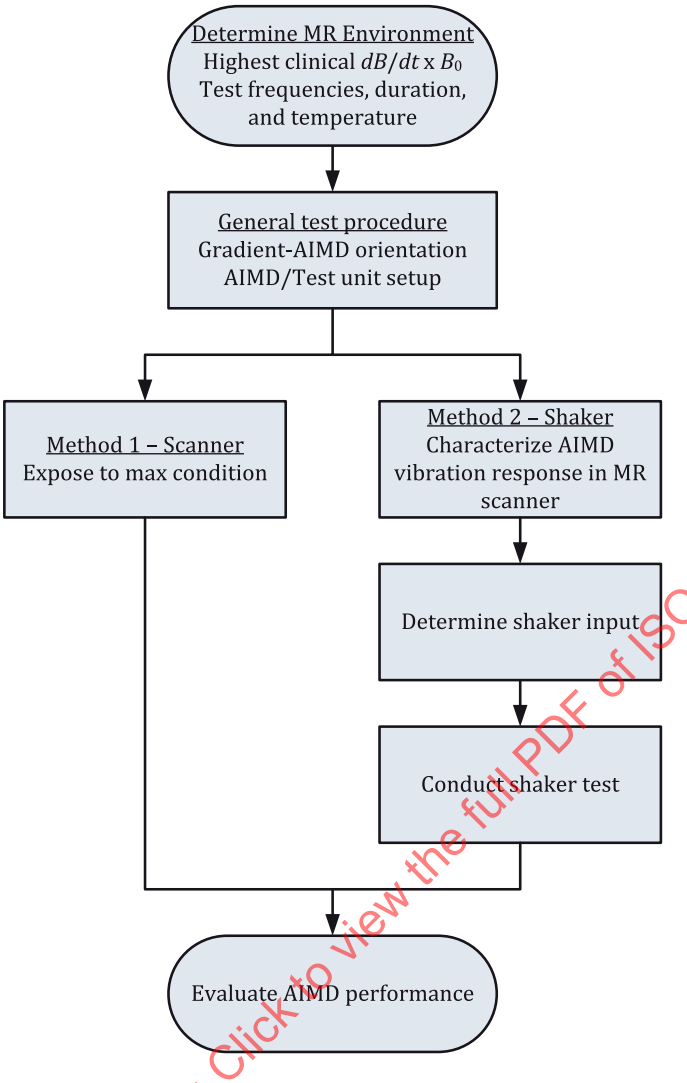


Figure 8 — General test flow for MR-induced vibration

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.

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* × 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* × B_0

The *dB/dt* vector shall be assumed to be perpendicular to the B_0 vector. Therefore, the *dB/dt* × 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* × 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.

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.

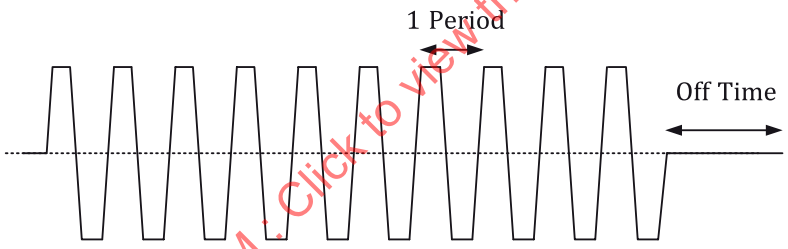


Figure 9 — Example trapezoidal waveform at a specific frequency

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.

10.3.7 Test temperature

10.3.7.1 General

Testing shall be performed at only one of the two following temperature levels.

10.3.7.2 Room temperature

If the AIMD materials have no property change (e.g. reduction of elastic modulus) between room temperature (22 °C) and body temperature (37 °C) that could affect the outcome of the test, testing may be performed at room temperature (18 °C – 25 °C).

If it is unknown whether the AIMD materials experience any property changes between room temperature and body temperature that could affect the outcome of the test, testing shall be performed at body temperature.

10.3.7.3 Body temperature

If the AIMD materials have any properties (relevant to vibration amplitude, frequency, or stress) that might change between room temperature (22 °C) and body temperature (37 °C) in such a way that the test outcome could be affected, the starting temperature of the AIMD under test shall be (37 ± 5) °C. The temperature of the AIMD shall not fall outside this range at any point during vibration exposure.

10.4 General test procedure

10.4.1 Measurement of gradient field and determination of AIMD location

A search coil or equivalent sensor shall be used to measure and record the component of gradient field *dB/dt* perpendicular to the major conductive planes of the AIMD. The following procedure may be used to determine the optimal test location in the scanner.

Step 1 Place the centre of the search coil at the centre of the device test location, run the appropriate scan from 10.3.5, and measure *dB/dt*. The plane of the search coil should be parallel to the major conductive planes of the device.

NOTE If the search coil is not parallel to the plane of the device test location coincident with the major conductive planes of the device under test, the device might be over-exposed.

Step 2 If desired, the search coil may be removed during exposure testing of the device.

10.4.2 AIMD/test unit setup

10.4.2.1 Orientation of AIMD in scanner

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.

If the two outer AIMD dimensions, which comprise the major conductive plane (e.g. the device metal enclosure), are each at least two times greater than the shortest outer dimension, only one orientation is required for test.

For example, an AIMD that is intended to be parallel to the patient table in the clinical scenario may be oriented such that the major conductive planes are perpendicular to the gradient y-coil (*dBy/dt*), as shown in Figure 10.

For AIMDs in which major conductive components are not planar and parallel to one another, the AIMD manufacturer shall determine the orientation that results in maximum stress on internal components.

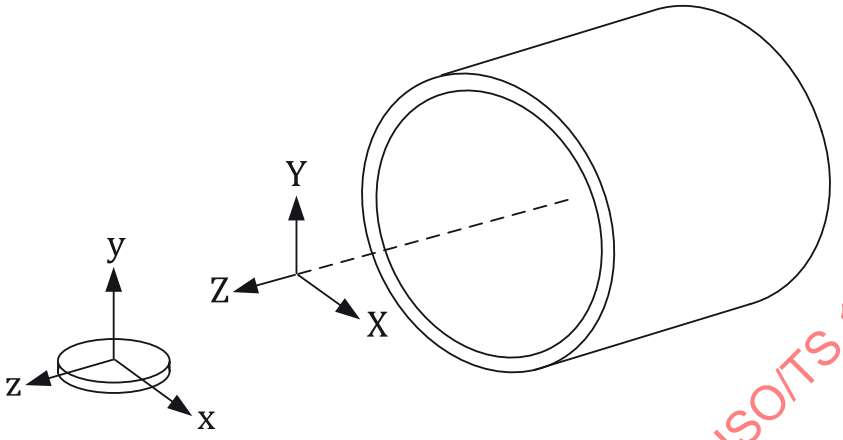


Figure 10 — AIMD orientation in MR scanner

Multiple devices may be tested simultaneously, provided the exposure for each meets the minimum exposure requirement.

The manufacturer shall assess whether the AIMD needs to be tested in multiple orientations about the AIMD y-axis, in order to test internal component rocking. If the assessment is negative, only one test orientation is required. If the assessment determines that multiple orientations are required, the device shall be tested in two different orientations about the AIMD y-axis, the second of which is rotated 90° from the first.

10.4.2.2 Mounting

The AIMD shall be mounted such that non restricted movement of at least 0,5 mm in each direction is allowed. The following are examples for mounting methods:

— Polymer ballistic gel;

— Closed-cell foam;

— Double-sided tape.

Other types of mounting are allowed if the above requirement is met. Tissue-simulating medium does not always ensure a conservative environment and is not required.

10.5 Method 1 — MR scanner

The general test procedure described in 10.4 shall be applied. The vector product of gradient field *dB/dt* and B_0 used to conduct AIMD functional testing shall be greater than or equal to the maximum vector product the AIMD might be exposed to during clinical MRI examinations (from 10.3.4) when the MR Conditional labelling conditions of use are observed.

NOTE A scanner with a field strength greater than 1,5 T can be used to achieve the $dB/dt \times B_0$ from 10.3.4.

Across the frequency range in 10.3.5, the manufacturer shall either allocate the same number of excitations (cycles) to each frequency step such that the total required test duration is achieved, or allocate the same amount of time to each frequency step such that the total required test duration is achieved.

If a clinical scan sequence is used, the manufacturer shall determine that the sequences used cover the range of gradient-intensive clinically relevant sequences such that the *dB/dt* requirement is met.

Apply test conditions from 10.3. For compliance criteria see 7.1.

10.6 Method 2 — Shaker table

10.6.1 General

This procedure describes the functional testing of the AIMD using a shaker table or other vibration test equipment capable of simulating vibration caused by MR gradient and static magnetic fields. Figure 11 shows the steps in this procedure.

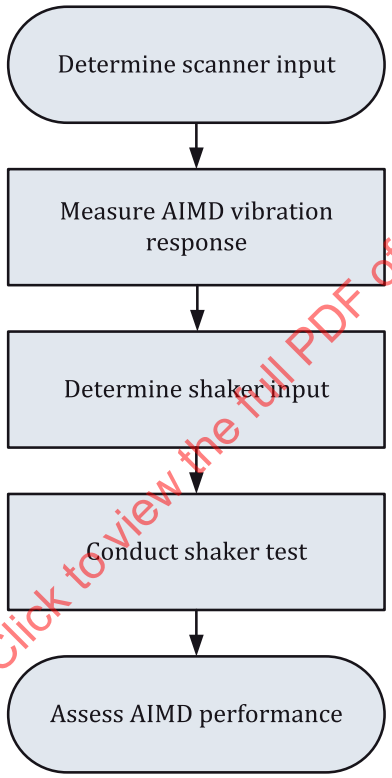


Figure 11 — Flow diagram of shaker table test procedure

10.6.2 Determine scanner input

The manufacturer shall select the scanner excitation from 10.3.5 and an appropriate AIMD orientation to generate a *dB/dt* that results in a vector product that is at least 20 % of the maximum clinical $dB/dt \times B_0$, as determined in 10.3.4. Generating the exact *dB/dt* value derived from the AIMD labelling is not required if the measured vibration response is scaled to the required *dB/dt* as input to the shaker table excitation.

10.6.3 AIMD vibration response

10.6.3.1 Measurement equipment

Sensors shall be used to measure the AIMD vibration response (displacement, velocity, or acceleration). The selected displacement, velocity, or acceleration sensor shall have a minimum bandwidth of 20 Hz to 3 000 Hz. Examples include non-contact light measurements (e.g. laser Doppler vibrometry, interferometry, digital image correlation) and some accelerometers.

10.6.3.2 Measure the AIMD vibration response

Using the requirements given in 10.3, the manufacturer shall excite the AIMD in the scanner and measure the *dB/dt* field and the vibration response of the AIMD. The vibration response shall be measured at the locations of the AIMD known to produce the highest magnitude. The recorded waveform shall have a sampling rate sufficient to capture the details of the motion waveform and prevent aliasing of the signal. The recorded waveform shall also have sufficient length to fully characterize the pulse sequence.

10.6.4 Determine shaker table amplitude (*dB/dt* scaling)

The magnitude of the AIMD vibration response measured in 10.6.3 shall be scaled by the ratio of the target *dB/dt* (derived from AIMD labelling as described in 10.3.2) to the actual *dB/dt* measured in 10.6.3 [see Formula (8)].

$$Scale\ factor = \frac{\left(\frac{dB}{dt}\right)_{\text{labelled}}}{\left(\frac{dB}{dt}\right)_{\text{measured}}} \tag{8}$$

where

$Scale\ factor$ is the scalar applied to the amplitude response of the AIMD in the scanner;

$\left(\frac{dB}{dt}\right)_{\text{labelled}}$ is the target *dB/dt* derived from the maximum slew rate specified in the AIMD labelling;

$\left(\frac{dB}{dt}\right)_{\text{measured}}$ is the *dB/dt* measured when characterizing the AIMD vibration response in the scanner.

10.6.5 Perform vibration exposure using a shaker table

10.6.5.1 General

The scaled shaker table amplitude determined in 10.6.4 shall be used as the input to drive a programmable shaker table, using only one of the waveforms described below.

The shaker table shall be able to generate vibrations at the magnitude and frequency characteristics specified in its driving input. Single or multi-point control strategies may be used to control the vibration of the shaker table.

The AIMD shall be mounted rigidly on the shaker table to allow vibration along the relevant axes.

For compliance criteria see 7.1.

10.6.5.2 Random vibration

The AIMD shall be subjected to a random vibration profile using the appropriate scaled amplitude from 10.6.4. The frequency range shall be 20 Hz to 3 000 Hz for the total test duration from 10.3.6.

10.6.5.3 Profile-driven vibration

Obtain a real-time recorded vibration profile from the AIMD during scanner exposure in 10.6.3.2. Scale the amplitude of vibration in accordance with 10.6.4 and use this as direct input to a shaker table. The appropriate frequency range is embedded in the profile. The total test duration shall be from 10.3.6.

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

Displacement force produced by the static magnetic field (B_0) has the potential to cause unwanted movement of a device containing magnetic materials. AIMDs generally contain paramagnetic, diamagnetic, and ferromagnetic materials. For a paramagnetic, diamagnetic, or ferromagnetic material below saturation, the location of maximum displacement force is at the point where the product of the magnitudes of the magnetic field (B_0) and the spatial gradient of the magnetic field (∇B_0) is at a maximum. The same is true for paramagnetic material above saturation. For ferromagnetic material above the magnetic saturation point, the maximum displacement force will occur at the location where ∇B_0 is a maximum. These locations are off the central axis of the bore of an MR scanner.

Test the device in accordance with ASTM F2052. The manufacturer shall establish and justify acceptance criteria for the magnetically induced deflection force.

Observe all reporting requirements in ASTM F2052.

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

Magnetically induced torque produced by the static magnetic field (B_0) has the potential to cause unwanted movement of a device containing magnetic materials. The magnetically induced torque is a function of B_0 and should be measured at a location where the static magnetic field is homogeneous (e.g. the isocentre of an MR scanner).

Test the device in accordance with ASTM F2213. The manufacturer shall establish and justify acceptance criteria for the magnetically induced torque.

Observe all reporting requirements in ASTM F2213.

13 Protection from harm to the patient caused by gradient-induced extrinsic electric potential

13.1 Introduction

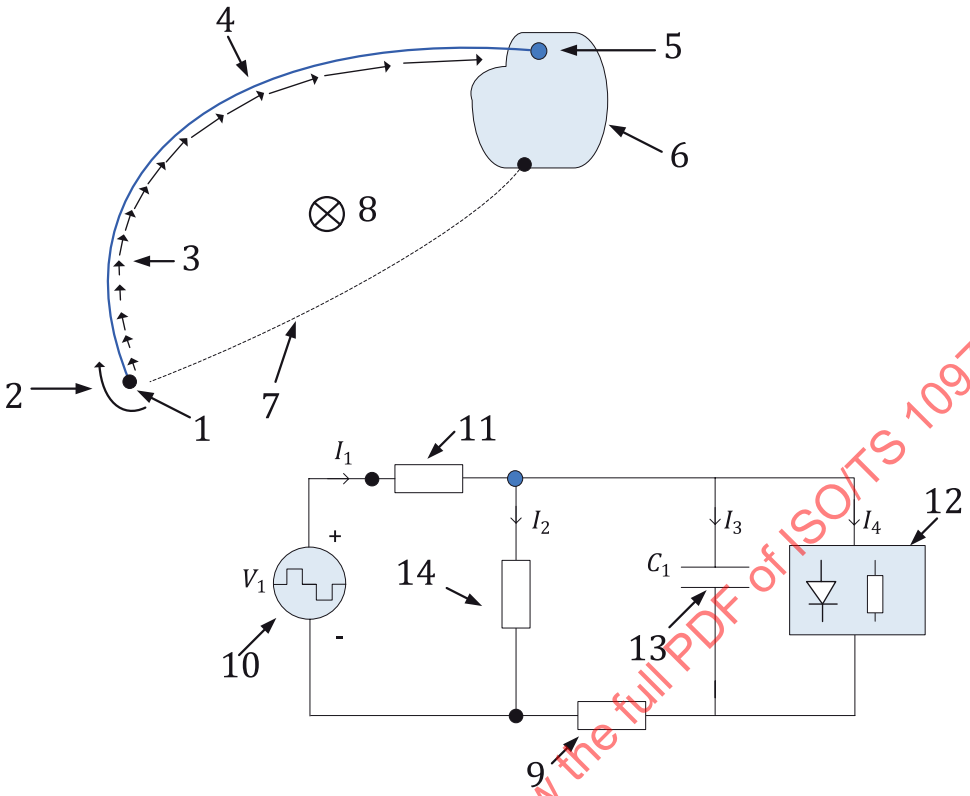
Extrinsic electric potential is gradient field induced voltage that develops between spatially separated electrodes within a single AIMD lead (intra-lead), between electrodes of a multi-lead AIMD (inter-lead), or between electrodes and a conductive AIMD enclosure in contact with tissue. MR gradient field coupling for an example AIMD circuit and extended lead is shown in Figure 12. The time rate of change of the gradient field induces a voltage that can drive current through the AIMD electrical ports and conductive enclosure. If AIMD intra-lead or inter-lead electrode impedance, or electrode to conductive enclosure impedance (e.g. lead sealing system, EMI capacitor, internal AIMD circuits) is too low, the resulting current flow through the device could cause unintended stimulation (US) to tissue in contact with the electrodes. The AIMD internal circuit depicted in Figure 12 is a generalized example; AIMD electronic designs vary depending on AIMD type and manufacturer. If present, nonlinear AIMD input impedance can rectify the gradient pulse train extending the effective pulse width of the stimulus beyond the individual gradient pulse output slew time. In addition, gradient-induced voltage could modify AIMD output therapy significantly due to superposition.

While these effects might not otherwise cause device failure or malfunction, the results of these electromagnetic interactions between the MR scanner pulsed gradient fields and the AIMD can cause patient harm of varying severity depending on AIMD type. The tests of this clause measure the amount of unintended charge, current flow, or therapy output distortion due to the pulsed gradient field.

Gradient-induced current flow through the AIMD lead interface is measured using injected test methods.

NOTE 1 Using a radiated field to test extrinsic potential effects might not be practical due to the large uniform field area required for a device with leads attached, difficulty in controlling electrode voltage, and the possibility of induced noise in the measurement system. Using a radiated field is not recommended for the testing in this clause.

NOTE 2 The sealing system for AIMDs containing lead port connectors can contribute significantly to gradient-induced lead electrode conduction. Test methods for sealing system evaluation can be found in other more specific specifications such as ISO 5841-3 (IS-1 connector)[5] and ISO 27186 (IS-4 connector)[6].



Key

1 tissue contacting electrode
2 gradient-induced AIMD current, I_1
3 tangential electric field (E_{tan})
4 AIMD extended lead body (insulated)
5 lead port connector seals
6 AIMD enclosure
7 gradient-induced current return path
8 gradient magnetic field
9 conductive AIMD enclosure tissue contact impedance
10 gradient-induced voltage, V_1
11 lead electrode tissue contact impedance and current, I_1
12 AIMD internal circuits containing linear and nonlinear components and associated current I_4
13 AIMD EMC filter capacitor, C1, and current, I_3
14 Lead connector seal leakage impedance and current, I_2

Figure 12 — Example AIMD circuit and gradient-induced voltage and current

13.2 General requirements

The tests of this clause apply to AIMDs with two or more tissue contacting electrodes. Leads with electrical contacts to tissue (electrodes), conductive AIMD enclosure surfaces in contact with tissue, and externally mounted electrodes on the AIMD enclosure are examples of tissue contacting electrodes.

Testing shall be performed with the AIMD programmed according to its intended use.

The AIMD is tested using standard bench equipment and connection to the AIMD through a tissue interface network (see Figure 34). The injected methods use voltage levels, V_{emf}, as determined by Annex A.

AIMDs with detachable leads are tested with leads removed and the AIMD lead port connected to the tissue interface network using a suitable connector(s).

NOTE 1 AIMDs with non-detachable leads or enclosure mounted electrodes might require a custom fixture or leads to complete connections between AIMD electrical contacts and the tissue interface network.

Three tests are performed to evaluate gradient-induced effects:

— The first test, defined by two alternative tiered methods, measures gradient-induced charge and current associated with individual gradient pulses;

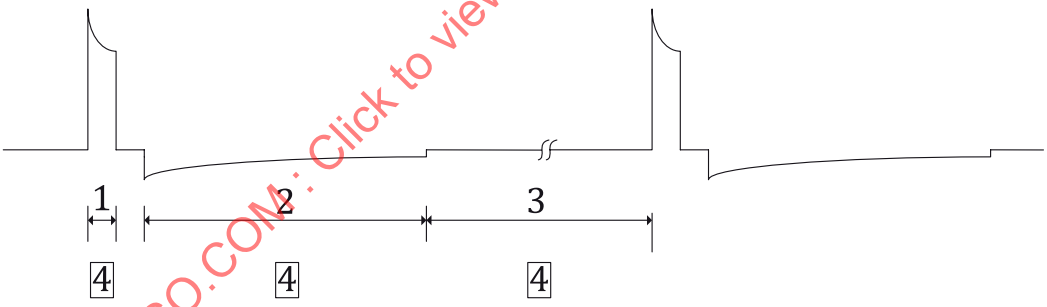
— The second test measures the average rectified current when the AIMD is exposed to a long gradient pulse train;

— The third test evaluates gradient pulse distortion of AIMD output therapy for devices with output therapy enabled during scanning.

Gradient-induced charge and current tests and the rectified current test are required regardless of whether AIMD device output therapy is turned on or off during the MR scan.

For AIMDs with electrode interface circuits that change impedance as a function of time, each impedance state shall be evaluated.

Figure 13 depicts an example AIMD output voltage stimulation sequence with associated dynamic electrode circuit impedance state changes. Gradient test signal application and measurement times for each of the AIMD output impedance state are shown.



Key

1 AIMD therapy voltage or current stimulation pulse
2 AIMD tissue charge balance pulse
3 t_{off} (time between therapy pulses)
4 gradient test signal application and induced current measurement times

Figure 13 — Gradient test pulse timing relative to AIMD dynamic electrode circuit impedance

If AIMD output therapy is enabled during scanning, according to the manufacturer's MR Conditional labelling, the manufacturer should consider the relevance of gradient pulse test application within and outside therapy delivery window and provide justification for excluding either.

If defined as part of the AIMD MR Conditional operation, turning electrical output off shall be considered part of the AIMD operating range and be tested.

For multi-lead AIMDs, testing of the AIMD shall be repeated with a sufficient set of injected voltages to subject the device to the maximum common mode (e.g. with respect to the AIMD conductive enclosure) and differential mode voltages expected during clinical use. These should consider induced voltage

amplitude and polarity variations due to lead path and patient electrode location. Both intra-lead and inter-lead electrode voltages shall be tested, unless justification for not doing so is provided.

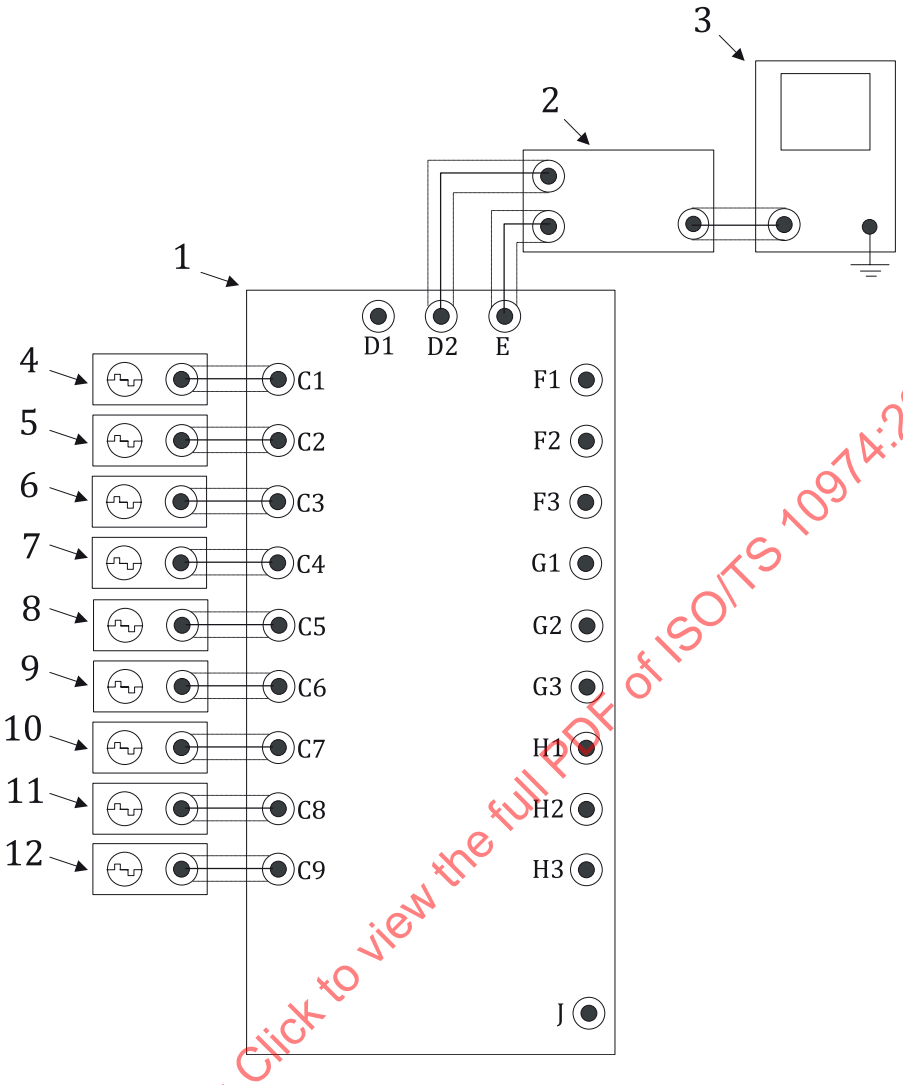
The gradient pulse distortion test is not required for devices that do not provide output therapy during the MR scan according to their MR Conditional labelling. The gradient pulse distortion test may be omitted by the manufacturer, if it can be shown that the amount of distortion possible is insignificant or the gradient-induced voltages will not prevent the AIMD from meetings its intended use.

Insulated antennas are not able to pass gradient current and are excluded from injected testing.

Where use of an oscilloscope is specified, a multichannel digital data acquisition system may be used.

For compliance criteria see 7.1.

NOTE 2 Absolute tissue stimulation charge and current thresholds and associated AIMD limits depend on AIMD electrode design and the specific tissue characteristics which are beyond the scope of this document. These can be found in literature, more specific standards if they exist, or manufacturer's specifications. Annex R contains an introductory summary on electrically excitable tissue charge and current stimulation thresholds and associated unintended stimulation hazard assessment.



Key

1 gradient tissue interface network (see Figure 34)
2 differential amplifier
3 oscilloscope
4 EMF test signal 1
5 EMF test signal 2
6 EMF test signal 3
7 EMF test signal 4
8 EMF test signal 5
9 EMF test signal 6
10 EMF test signal 7
11 EMF test signal 8
12 EMF test signal 9

Figure 14 — Test setup to measure gradient-induced AIMD charge, current injection, and rectification

13.3 Gradient pulse leakage test

13.3.1 General

This test measures gradient-induced current flow through the AIMD electrodes for individual positive and negative gradient pulses. A two tiered test method is provided for gradient pulse leakage:

— Tier 1 requires measurement of the total integrated charge conducted through the AIMD electrodes. It is the simpler and more conservative of the two methods.

NOTE 1 The method is conservative because the total charge measurement can be compared to the minimum tissue charge stimulation threshold.

— Tier 2 requires two measurements. The first measures the initial transient charge associated with AIMD internal electrical circuit component charging at the onset of the gradient voltage change. The second measures the steady-state current flow through the AIMD electrode while the induced voltage is applied after the initial charge transient has subsided.

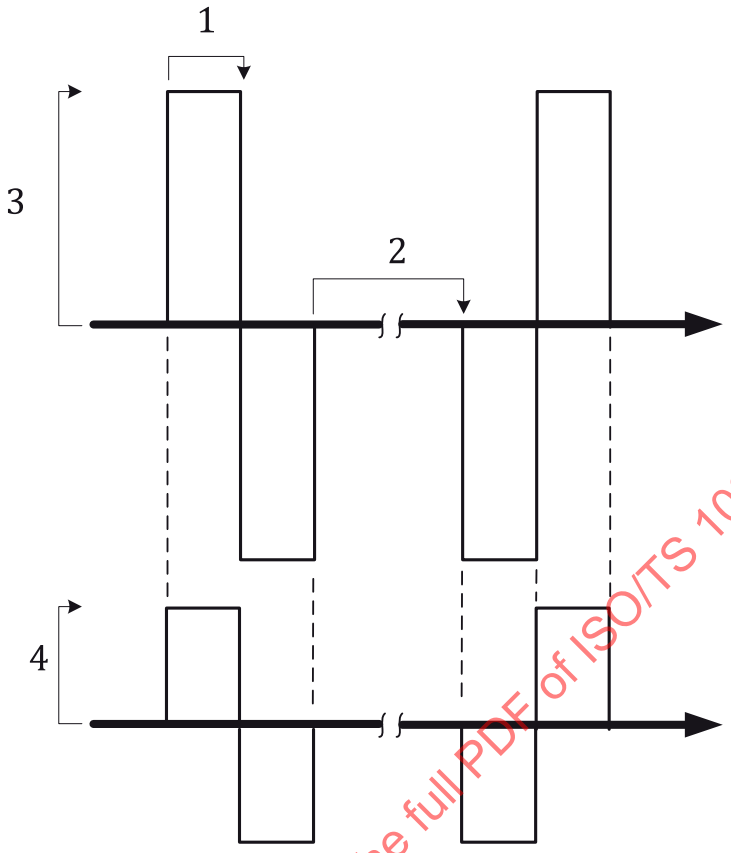
NOTE 2 The first measurement, charge, can be compared to the minimum threshold (e.g. Q_{min}) taken from a tissue charge-duration simulation curve. The second measurement, current, can be compared to the tissue current strength duration curve.

13.3.2 Test equipment

Use the test setup in Figure 14 and tissue interface network shown in Figure 34. AIMD test configurations and connections are defined in 16.5.5.

13.3.3 Test signal

Use the gradient test signal shown in Figure 15 with the timing and voltages specified in Table 7. The AIMD is tested using two test cases. The first test case corresponds to a minimum gradient t_{slew} = 0,2 ms, at the maximum MR scanner slew rate and *dB/dt* exposure. The second test case uses a 1,0 ms pulse width at a reduced MR scanner slew rate and *dB/dt* exposure. Use the injected test levels, V_{emf}, determined from Annex A. Individual V_{emf} levels are referred to as V_{C1}, V_{C2}, etc., when applied to Port C1, Port C2, etc., respectively.



Key

1 pulse width (in ms)

2 t_{off} (time between pulses)

3 V_{C1}, amplitude (Volts peak) of the injected test signal to Port C1

4 V_{C2}, amplitude (Volts peak) of the injected test signal to Port C2

Figure 15 — Simulated gradient-induced voltage pulse waveform

Table 7 — Gradient pulse test signal parameters

Test case	Pulse width[d] ms[a]	Injected electrode voltage V_{peak}[e]
Test 1	0,2	V_{emf} (t_{slew} = 0,2 ms)[b]
Test 2	1,0	V_{emf} (t_{slew} = 1,0 ms)[c]

NOTE V_{emf} (t_{slew} = 1,0 ms) scaling is based on IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.12.4.102.3.3b), *dB/dt* PNS formula. Scale = L12 (1,0 ms)/L12 (0,1 ms) = 0,296, where L12 is the First Level Controlled Operating Mode in whole body gradients.

[a] The tolerance for pulse width is ±5 %.

[b] V_{emf} for pulse width = 0,2 ms is the maximum electrode voltage with respect to the AIMD conductive enclosure. It is determined from the maximum scanner slew rate specified in the AIMD MR Conditional labelling and the injection voltage determination methods defined in Annex A.

[c] V_{emf} (t_{slew} = 1,0 ms) is 0,296 × V_{emf} (t_{slew} = 0,1 ms).

[d] Rise and fall time of the pulses shall be ≤7 µs.

[e] Pulse amplitude ≥V_{emf}.

V_{C1} represents the gradient-induced voltage between an AIMD electrode, such as an electrode on an AIMD lead, and its conductive enclosure. V_{C1} is applied to Port C1 of the tissue interface network shown in Figure 34.

V_{C2} represents the gradient-induced voltage at a second AIMD electrode, such as an electrode on another lead of a multi-lead AIMD and its conductive enclosure. V_{C2} is applied to Port C2 of the tissue interface network shown in Figure 34.

V_{C1}, V_{C2}, ...V_{Cn} transition times are coincident. At MR gradient frequencies phase delays due to propagation are negligible, but, depending on AIMD type and deployment in the body, it is possible for electrode voltages to be of opposite polarity.

Voltage pulse width of 0,2 ms represents the minimum slew time for the MR scanner gradient output to change from maximum gradient output to the maximum gradient output of the opposite polarity.

Electrode voltages for Test 1, 0,2 ms pulse width are determined from the maximum scanner slew rate specified in the AIMD MR Conditional labelling and the injection voltage determination methods defined in Annex A. Electrode voltages for Test 2, 1,0 ms pulse width are determined from the Test 1 electrode voltages, as shown in Table 7.

The inter-pulse delay; t_{off}, as shown in Figure 15 is at least 2 s. The inter-pulse delay should be increased if charging effects from the previous applied pulse(s) have not dissipated before the next pulse is applied.

13.3.4 Tier 1 — Combined gradient-induced charge measurement test procedure

The following procedure shall be used for Tier 1 measurements.

Step 1 Connect the test signal generator(s) to the appropriate input port C (C1 — Cn) of the tissue interface network, Figure 34, as shown in Figure 14.

Step 2 Connect the AIMD to the tissue interface network in accordance with 16.5.5. (AIMD test configurations and tissue interface network connections for Clause 13 are the same as for Clause 16.)

Step 3 Apply the test voltage waveform of Figure 15 and measure the test signal at Port D2 using an oscilloscope. Adjust the test injection voltage amplitude as necessary to achieve the proper level as determined from Annex A.

Step 4 Measure the total positive and negative charge passing through the AIMD lead electrode ports (see Figure 16) using an oscilloscope and differential amplifier. Select the voltage monitoring points and compute charge appropriately as defined below depending on whether the optional Cx capacitor is used for the measurement.

If Cx is not used, measure the voltage between test Port D2 and test Port E and compute the AIMD input charge using Formula (9) and Formula (10). R_{Rx} is the value of the AIMD lead port series input coupling resistor, Rx. (Rx corresponds to R3 for Port C1, R4 for Port C2, etc., as shown in Figure 34.)

If Cx is used measure the voltage between test Port D1 and test Port D2 and compute the AIMD input charge as the product of the voltage change and the Cx capacitor value using Formula (11) and Formula (12).

Integration intervals and measurement times, t_1, t_2, t_3, and t_4, are shown in Figure 16.

$$Positive\ charge = \frac{1}{R_{Rx}} \int_{t_3}^{t_4} V_{D2}(t) - V_E(t)\, dt \tag{9}$$

$$Negative\ charge = \frac{1}{R_{Rx}} \int_{t_1}^{t_2} V_{D2}(t) - V_E(t)\, dt \tag{10}$$

where

R_{Rx} is the value of the series input coupling resistor, Rx;

$V_{D2}(t)$ is the measured voltage on test Port D2 as a function of time;

$V_E(t)$ is the measured voltage on test Port E as a function of time;

t_1, t_2 is the integration time interval for the negative charge measurement;

t_3, t_4 is the integration time interval for the positive charge measurement.

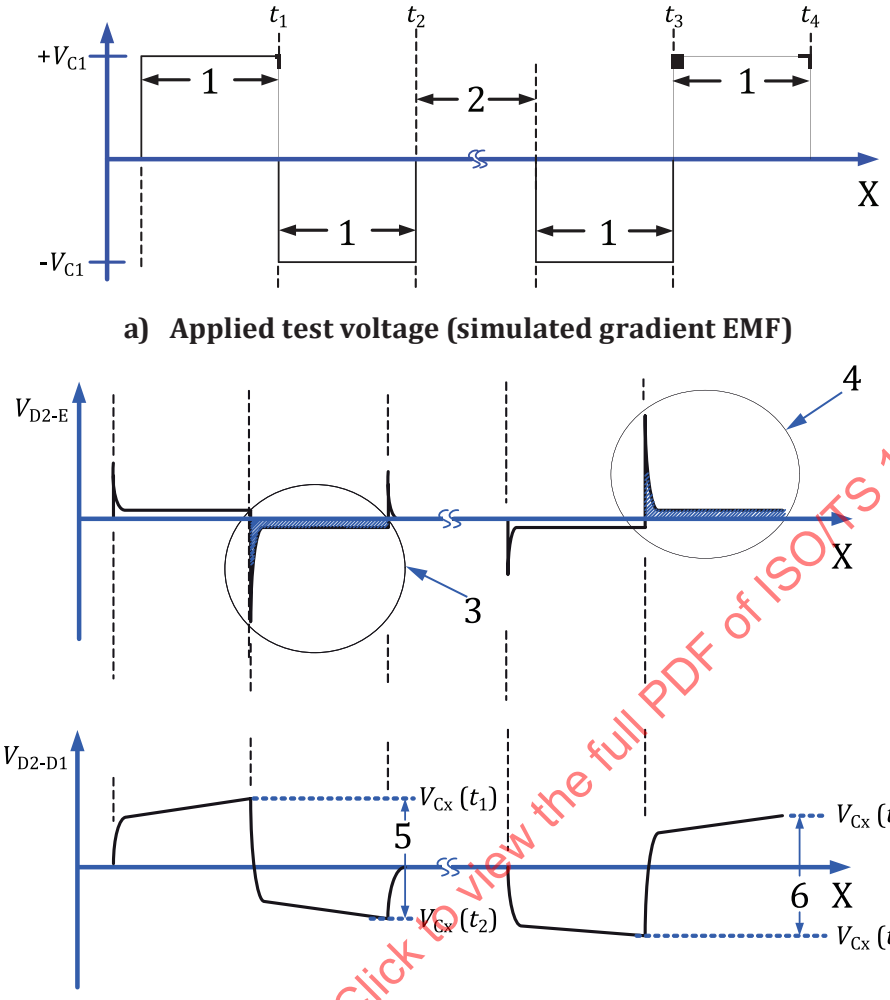
$$Positive\ charge = C_{Cx} \times \left[V_{Cx}\left(t_4\right) - V_{Cx}\left(t_3\right) \right] \quad (11)$$

$$Negative\ charge = C_{Cx} \times \left[V_{Cx}\left(t_2\right) - V_{Cx}\left(t_1\right) \right] \quad (12)$$

where

C_{Cx} is the value of the charge integration capacitor, Cx;

V_{Cx} is the measured voltage across capacitor Cx at times t_1, t_2, t_3, and t_4, respectively.



a) Applied test voltage (simulated gradient EMF)

b) Voltage measurement for AIMD current (Tier 1 AIMD charge measurement integration intervals)

Key

1 pulse width corresponding to gradient slew time duration (t_{slew})
2 t_{off} (time between pulses)
3 Tier 1 (-) AIMD injected charge measurement, using oscilloscope integration function
4 Tier 1 (+) AIMD injected charge measurement, using oscilloscope integration function
5 Tier 1 (-) AIMD injected charge measurement, using integration capacitor, Cx
6 Tier 1 (+) AIMD injected charge measurement, using integration capacitor, Cx
X time
t_1 negative going test voltage transition
t_2 end of first biphasic test pulse
t_3 positive going test voltage transition
t_4 end of second biphasic test pulse

NOTE Actual AIMD voltage response waveforms can differ from the example waveforms shown in the figure. For example, AIMD response might exhibit polarity asymmetry.

Figure 16 — Combined gradient-induced AIMD charge measurement

13.3.5 Tier 2 — Separate transient gradient-induced charge and steady-state current measurement test procedure

13.3.5.1 Gradient-induced charge measurement test procedure

The following procedure shall be used for Tier 2 charge measurements.

Apply the procedure from 13.3.4, Step 1 through Step 4 with the following modifications for Step 4:

— Use Figure 17 instead of Figure 16;

— In the case where Cx is not used the charge measurement integration interval begins at the leading edge of the applied voltage pulse and ends when the measured waveform settles to within 5 % of its final asymptotic step response value.

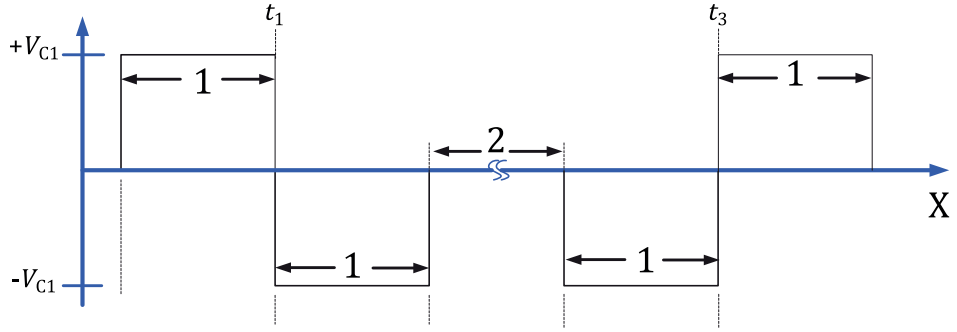
13.3.5.2 Gradient-induced current measurement test procedure

The following procedure shall be used for Tier 2 current measurements.

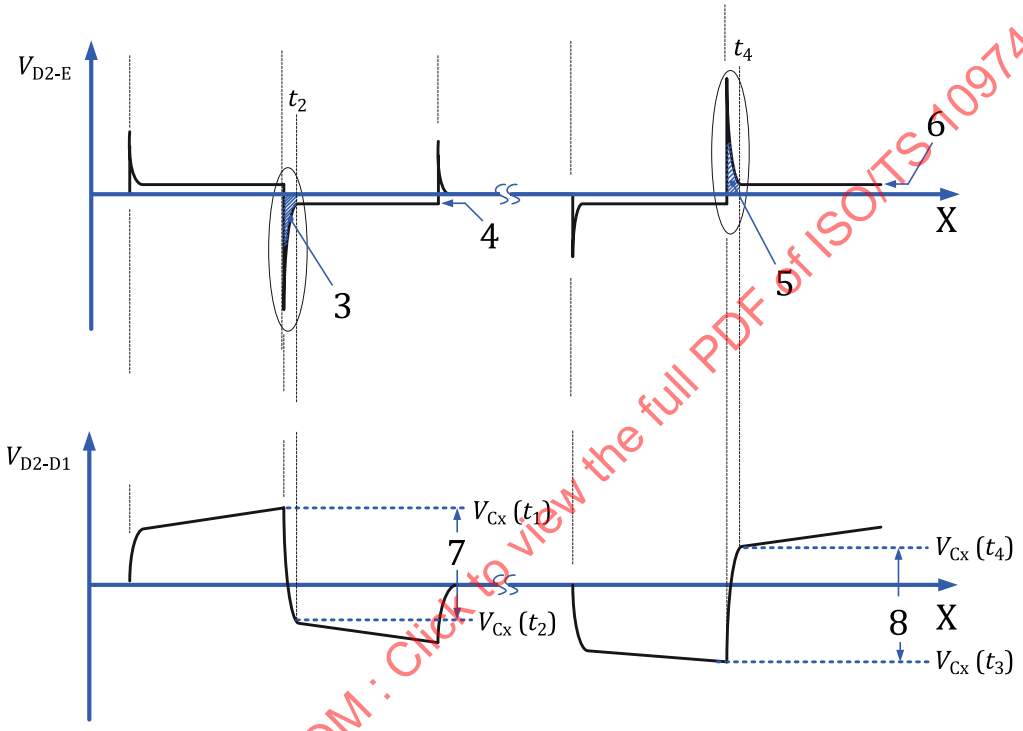
Apply the procedure from 13.3.4, Step 1 through Step 3. Step 4 is replaced, as follows:

Step 4 Using an oscilloscope connected to a differential amplifier measure the voltage between test Port D2 and test Port E during the two time intervals shown in Figure 17 (following t_2 and following t_4). Compute the AIMD lead electrode port current as the average differential voltage measurement divided by the lead port series input coupling resistance (e.g. R3 for Port C1, and R4 for Port C2, etc., as shown in Figure 34).

The start of the averaging time interval begins after any leading edge pulse transient of the measured AIMD input current waveform has settled to within 5 % of its asymptotic step response value. The end of the averaging time interval occurs at the trailing edge of the gradient test voltage pulse.



a) Applied test voltage (simulated gradient EMF)



b) Voltage measurement for AIMD current
(Tier 2 AIMD charge measurement integration intervals)

Key

1 pulse width corresponding to gradient slew time duration (t_{slew})
2 t_{off} (time between pulses)
3 Tier 2 (-) AIMD injected charge measurement, using oscilloscope integration function
4 Tier 2 (-) AIMD injected current measurement
5 Tier 2 (+) AIMD injected charge measurement, using oscilloscope integration function
6 Tier 2 (+) AIMD injected current measurement
7 Tier 2 (-) AIMD injected charge measurement, using integration capacitor, Cx
8 Tier 2 (+) AIMD injected charge measurement, using integration capacitor, Cx
X time
t_1 negative going test voltage transition
t_2 negative current waveform is within 5 % of asymptotic value
t_3 positive going test voltage transition

t_4 positive current waveform is within 5 % of asymptotic value

NOTE Actual AIMD voltage response waveforms can differ from the example waveforms shown in the figure.

Figure 17 — Separate gradient-induced AIMD charge and current measurement

13.4 Gradient rectification test

13.4.1 General

If present, nonlinearity in AIMD input impedance can rectify the gradient pulse train extending the effective pulse width of unintended tissue stimulation beyond the individual gradient pulse output slew time. AIMD nonlinearity can be temperature dependent.

This test measures the average rectified current generated by the AIMD at the tissue contacting electrode interface when exposed to long gradient pulse trains.

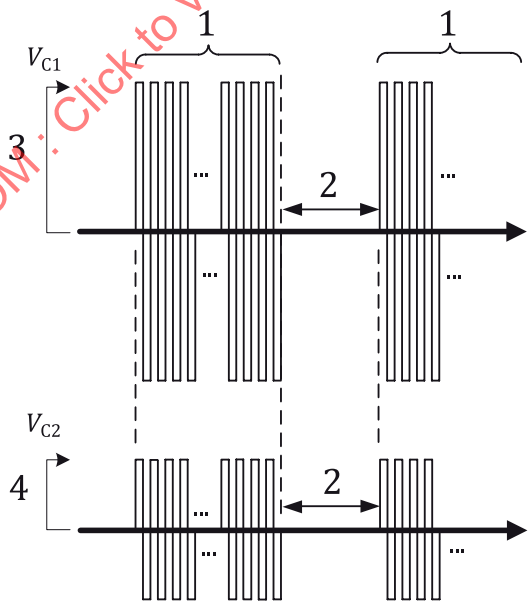
13.4.2 Test equipment

Use the test setup in Figure 14 and tissue interface network shown in Figure 34. AIMD test configurations and connections to the test setup are defined in 16.5.5.

13.4.3 Test signal

Use the gradient test signal shown in Figure 18.

Use the injected test levels, V_{emf}, determined from Annex A. Individual V_{emf} levels are referred to as V_{C1}, V_{C2}, etc., when applied to Port C1, Port C2, etc., respectively.



Key

1 test signal burst length (n = 128, f = 2,5 kHz)
2 burst delay (2 s)
3 V_{C1}, amplitude (Volts peak) of the injected test signal to Port C1
4 V_{C2}, amplitude (Volts peak) of the injected test signal to Port C2

Figure 18 — Example simulated gradient-induced voltage pulse train for rectification test

V_{C1} represents the gradient-induced voltage between an AIMD electrode, such as an electrode on an AIMD lead, and its conductive enclosure. V_{C1} is applied to Port C1 of the tissue interface network shown in Figure 34.

V_{C2} represents the gradient-induced voltage at a second AIMD electrode, such as an electrode on another lead of a multi-lead AIMD and its conductive enclosure. V_{C2} is applied to Port C2 of the tissue interface network shown in Figure 34.

V_{C1}, V_{C2}, ...V_{Cn} transition times are coincident. At MR gradient frequencies phase delays due to propagation are negligible, but depending on AIMD type and deployment in the body, it is possible for electrode voltages to be of opposite polarity.

The pulse width of individual pulses is 0,2 ms, the minimum slew time for a maximum *dB/dt* exposure for long bursts, e.g. n = 128. The time duration of the n = 128 burst is 51,2 ms.

The inter-burst delay is nominally 2,0 s but longer delay might be required depending on the presence of AIMD internal storage elements that can be charged by circuit rectification. To prevent masking of rectification the burst delay should be lengthened, as needed, to ensure storage elements discharge between burst applications.

13.4.4 Gradient-induced rectification measurement test procedure

The following procedure shall be used for rectification measurements.

Step 1 Connect the test signal generator(s) to input Port C of the tissue interface network, Figure 34, as shown in Figure 14.

Step 2 Connect the AIMD to the tissue interface network in accordance with 16.5.5. (AIMD test configurations and tissue interface network connections for Clause 13 are the same as for Clause 16.) If optional Cx capacitors have been included in the tissue interface network (Figure 34), close the switches across all Cx capacitors to remove them from the circuit.

NOTE 1 Short circuiting Cx prevents the capacitors from blocking the flow of rectified current components from the AIMD.

Step 3 Apply the test voltage waveform of Figure 18 and measure the test signal at Port D2 using an oscilloscope. Adjust the test injection voltage amplitude as necessary to achieve the proper level as determined from Annex A.

Step 4 Using an oscilloscope connected to a differential amplifier measure the voltage between test Port D2 and test Port E (see Figure 14) and compute the rectified current through the AIMD lead electrode port using Formula (13). R_{Rx} is the value of the lead port series input coupling resistor, Rx. (Rx corresponds to R3 for Port C1, R4 for Port C2, etc., as shown in Figure 34.)

The integration interval begins at the leading edge of the applied voltage pulse train, t_0, and ends at the trailing edge of the applied voltage pulse train, $t_0 + t_{pw}$.

Test the AIMD while applying injected voltages V_{C1}, V_{C2}, ...V_{Cn} set at the maximum common mode voltage with respect to the conductive AIMD enclosure.

Repeat the test as required to apply the clinically relevant voltage combinations maximizing the voltage differences between electrodes located on separate leads.

Repeat the test as required applying the clinically relevant voltage combinations maximizing the intra-electrode voltage differences on the same lead or AIMD case mounted electrodes.

NOTE 2 An AIMD can rectify gradient-induced differential voltages that develop between electrodes of patient leads, or between electrodes and the AIMD conductive enclosure. It is important to test the AIMD with test voltage cases covering the clinically relevant maximum gradient-induced electrode voltage differences. For example, for a multi-lead AIMD, test cases covering maximum induced voltage on a first lead with a second lead in a routing that might have very little induced voltage or opposite voltage polarity. Testing at intermediate pulse voltage amplitudes can aid in determining and characterizing AIMD nonlinearity.

The applied gradient burst length, t_{pw}, is long compared to the chronaxie time of electrically excitable tissues. If the AIMD rectified current response level varies significantly over the pulse train burst length, the AIMD rectified current response should be evaluated over narrower time interval(s) to avoid underestimating transient "peak" rectification level(s).

$$\textit{Rectified current} = \frac{1}{t_{pw} \times R_{Rx}} \int_{t_0}^{t_0 + t_{pw}} V_{D2}(t) - V_E(t)\, dt \tag{13}$$

where

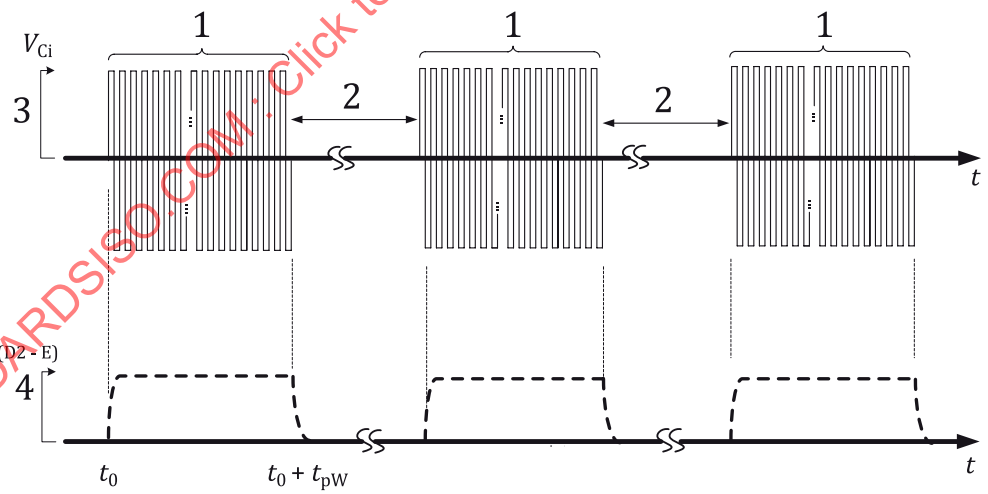
R_{Rx} is the value of the series input coupling resistor, Rx;

$V_{D2}(t)$ is the measured voltage on test Port D2 as a function of time;

$V_E(t)$ is the measured voltage on test Port E as a function of time;

t_0 is the leading edge of the applied voltage pulse train;

t_{pw} is the applied voltage pulse train burst length.



Key

1 test signal burst length (n = 128, t_{pw} = 51,2 ms, f = 2,5 kHz)

2 burst delay = 2 s

3 peak amplitude (Volts) of the injected test signal to Port C1, Port C2, …Port Cn, etc.

4 averaged rectified voltage across the AIMD lead port series coupling resistor (Rx)

Figure 19 — AIMD gradient pulse train rectified current measurement

13.5 Gradient pulse distortion of AIMD output test

13.5.1 General

The gradient pulse distortion test is not required for devices that do not provide output therapy during the MR scan according to its MR Conditional labelling. The distortion test may also be omitted if the manufacture provides as rationale an analysis showing that the intended use will be met when MR gradient field induced lead voltage(s) are superimposed. The analysis shall consider the effects of common mode, intra-lead differential, and inter-lead differential voltage induced between the AIMD lead electrodes and AIMD enclosure.

13.5.2 Test equipment

Use the test setup in Figure 14 and tissue interface network shown in Figure 34. AIMD test configurations and connections to the test setup are defined in 16.5.5.

13.5.3 Test signal

Use the gradient test signal shown in Figure 15.

Use the injected test levels, V_{emf}, determined from Annex A. Individual V_{emf} levels are referred to as V_{C1}, V_{C2}, etc., when applied to Port C1, Port C2, etc., respectively.

13.5.4 Gradient-induced AIMD output distortion test procedure

The following procedure shall be used for observations of therapy output distortion.

Step 1 Connect the test signal generator(s) to input Port C of the tissue interface network, Figure 34, as shown in Figure 14.

Step 2 Connect the AIMD to the tissue interface network in accordance with 16.5.5. (AIMD test configurations and tissue interface network connections for Clause 13 are the same as for Clause 16.)

Step 3 Apply the test voltage waveform of Figure 15 and measure the test signal at Port D2 using an oscilloscope. Adjust the test injection voltage amplitude as necessary to achieve the proper level as determined from Annex A.

Step 4 Observe AIMD therapy output waveforms by connecting an oscilloscope and differential amplifier between test Port D2 and test Port E. With the gradient test signal off, perform baseline observations of the AIMD output therapy waveforms. Repeat for all relevant AIMD lead port connections.

Synchronously apply the gradient test signal so that the first of the two square wave pulses coincides with the AIMD therapy output. Repeat so that the second of the two square wave pulses coincides with the AIMD therapy output. Repeat for all relevant AIMD lead port connections.

If the AIMD electrical output is not continuous but pulsatile, gradient test signal pulse application shall be synchronised so that the gradient test signal overlaps the AIMD output time.

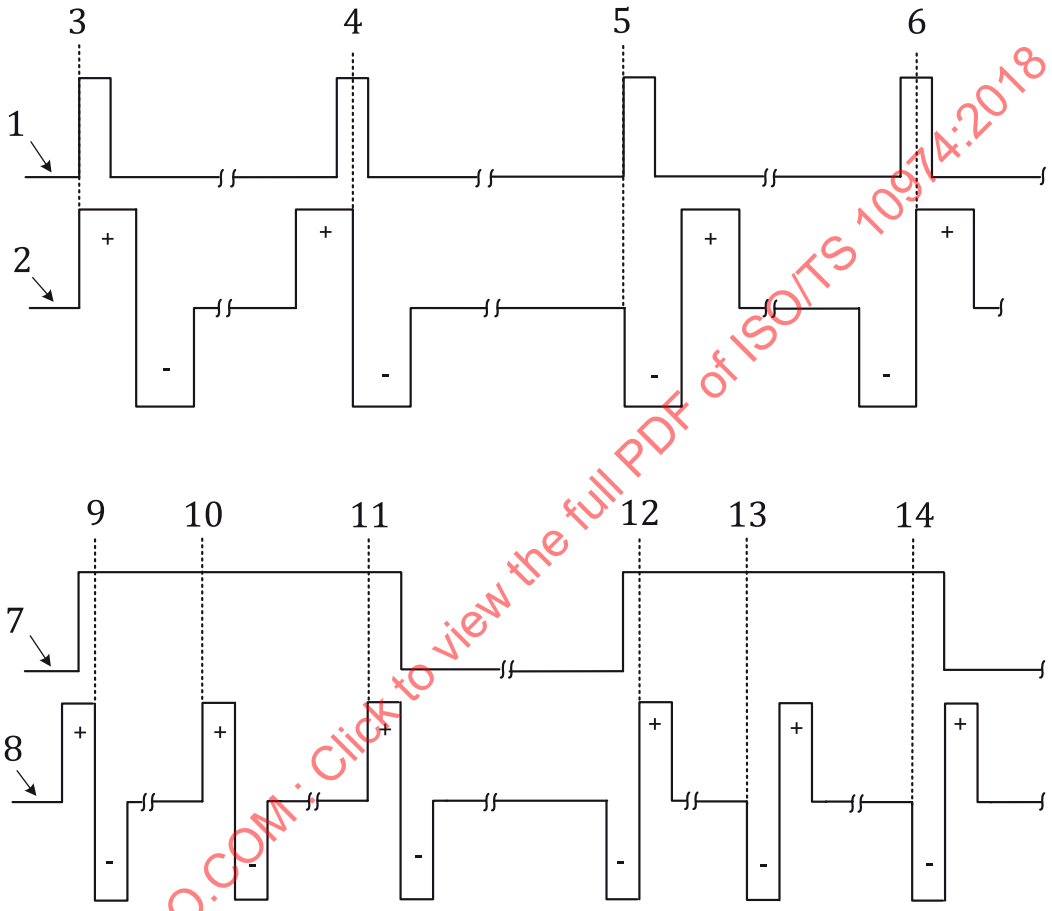
Test the AIMD while applying injected voltages V_{C1}, V_{C2}, ...V_{Cn} set at the maximum common mode voltage with respect to the conductive AIMD enclosure.

Repeat the test as required to apply the clinically relevant voltage combinations maximizing the voltage differences between electrodes located on separate leads.

Repeat the test as required applying the clinically relevant voltage combinations maximizing the intra-electrode voltage differences on the same lead or AIMD case mounted electrodes.

The exact synchronization timing used to apply the test waveform can depend on the AIMD therapy output signal waveform, duration, and consideration of the AIMD output circuit susceptibility to induced gradient voltage. The rationale for the synchronization timing selected shall be documented by the AIMD manufacturer.

Example test signal synchronization timing with respect to AIMD output are shown in Figure 20. Synchronization timing for the case where AIMD output duration is shorter than the gradient test signal is shown in the top two traces of the figure and for the case where AIMD output duration is longer than the gradient test signal is shown in the bottom two traces.



Key

1 AIMD therapy output duration less than gradient test signal duration
2 gradient injection voltage test signal
3 positive going gradient test signal synchronised to leading edge of AIMD output
4 negative going double-sided gradient test signal slew synchronised to middle of AIMD output
5 negative going gradient test signal synchronised to leading edge of AIMD outpu
6 positive going double-sided gradient test signal slew synchronised to middle of AIMD output
7 AIMD therapy output duration greater than gradient test signal duration
8 gradient injection voltage test signal
9 negative going double-sided gradient test signal slew synchronised to beginning of AIMD output
10 positive going gradient test signal synchronised to middle of AIMD output
11 positive going gradient test signal synchronised to end of AIMD output
12 positive going double-sided gradient test signal slew synchronised to beginning of AIMD output
13 negative going gradient test signal synchronised to middle of AIMD output
14 negative going gradient test signal synchronised to end of AIMD output

Figure 20 — Example test signal synchronization timing with respect to AIMD output

14 Protection from harm to the patient caused by B_0-induced malfunction

14.1 Introduction

Exposure to the B_0 field of the MR scanner could produce effects on the function of the AIMD including device reset, re-programming, magnetic remanence, battery drain, and permanent damage. This clause focuses on assessing these potential effects through appropriate testing based on the classification of the potential vulnerabilities of the AIMD to the large static magnetic fields associated with 1,5 T MR scanners. The device is tested for malfunction following exposure.

The electrical performance of semiconductor integrated circuits, transistors, diodes, resistors, capacitors, and interconnect components is not impacted by the MR static field. Some of these components contain ferromagnetic nickel plating for solderability, but the quantity is insignificant and the impact of any ferromagnetic content is evaluated by the force test (Clause 11). A voltage will be induced on coils from movement through the static magnetic field, however, a much higher voltage will be induced on a coil by the time-varying gradient magnetic fields. Therefore, the impact of induced voltage is evaluated during gradient malfunction testing.

The table below describes AIMD components that will be impacted by the static magnetic field. Additional testing will not be required if the component is not used during an MR scan. This can be achieved by disabling or bypassing the portion of the AIMD circuit containing these components.

The appropriate test is based on the class of device. The following table identifies three classes of devices based on expected component behaviour. All devices should be tested soon afterward to establish any potential effect of remanence. The manufacturer shall declare in the test report the appropriate AIMD device classification.

Table 8 — Device test classes

Class	Applicable devices	Concern	Test approach
Class 0	Components that rely on ferrite materials for functionality, but are deactivated for the scan. Devices with a magnetic sensor are included if the sensor 1) cannot impact AIMD operation during MR scanning and 2) is a non-mechanical sensor (e.g. not a reed switch).	Remanence in surrounding components can affect a magnetic sensor for a temporary period after the scan.	Combined fields test, Clause 17 is sufficient to meet the test requirement with no specific B_0 susceptibility orientations required. Monitoring in accordance with combined field requirement.
Class 1	Components that rely on ferrite materials for functionality, but are deactivated for the scan, and — has a magnetic sensor that impacts AIMD operation during MR scanning (e.g. a static-field auto-detect sensor), or — has a mechanical magnetic sensor (e.g. a reed switch). NOTE 1 A sensor with only one possible state regardless of the B_0 field orientation is a Class 0 device for purposes of this test.	Either magnetic sensor activation or lack of activation can occur. Either or both states of the sensor could result in unintended behaviour of the device in the B_0 field. Magnetic sensors using a mechanical switch might be susceptible to permanent malfunction (for example deformation of a mechanical switch such as reed switch). This permanent malfunction might occur in only the activated or de-activated state (e.g. a reed switch wherein the contacts are closed or open), so both states shall be tested.	Test the AIMD in the B_0 magnetic field in at least one orientation that results in activation of the magnetic sensor, and one orientation that does not cause activation of the magnetic sensor. The device shall be tested for at least one minute in each orientation. Can rely on combined fields test methods for monitoring during scan. NOTE 2 AIMDs using non-mechanical magnetic sensors (e.g. Hall Effect sensors) might have only narrow angular windows of orientation wherein the sensor is not activated by the B_0 field, such that testing in this orientation is not practical. These devices can be tested by emulating the logical off-state of the sensor (e.g. by setting device software or hardware state before entering the B_0 field).
Class 2	Components that rely on ferromagnetic materials for functionality and will remain active, or that will be unintentionally rendered active (including any device with a permanent magnet).	Intended functionality could be affected, and unintended functionality could be triggered that results in potential harm.	Class 2 test procedures are not within the scope of this edition. It is incumbent on the manufacturer to define appropriate tests to address B_0 safety.

14.2 Static field testing

14.2.1 B_0 general requirements for static field testing

Testing shall be performed with the AIMD programmed according to its intended use.

Evaluation of potential transient malfunction conditions of the AIMD should be completed in a sufficiently short time after testing such that malfunctions can be detected. Times of AIMD exposure and post-test assessment of performance should be included in the test report.

For compliance criteria see 7.1.

14.2.2 B_0 field generation

The AIMD manufacturer may use either a single MR scanner or a custom magnet. If a custom magnet is used it shall have a known B_0 orientation over at least the AIMD volume with a static field strength of at least 1,5 T. If an MR scanner is used it shall be labelled to at least 1,5 T and the active portion of the AIMD under test shall be located within the range of isocentre ±10 cm.

This test may be performed with or without a phantom.

14.2.3 Test conditions

The AIMD shall be exposed to a static magnetic field as defined in 14.2.2. All parts of the device that contain elements susceptible to magnetic fields shall be exposed. Exposure duration to the static magnetic field shall be sufficient to assess device functionality and the effects of residual magnetism.

14.3 Test procedures

14.3.1 General

The manufacturer shall follow the test procedure for the defined class of the device under test.

14.3.2 Class 0 test procedure

The following test procedure shall be used for Class 0 devices. Testing performed during the Combined Fields test (Clause 17) is sufficient to demonstrate static field malfunction conditional safety provided all the requirements of this subclause are met during that Combined Fields test.

Step 1 Program the DUT according to its intended MR Conditional mode and set of parameters as specified by the device labelling.

Step 2 Expose the DUT to the required B_0 vector field in at least one clinically relevant orientation. Exposure shall be at least one minute.

Assess the DUT for malfunction in accordance with 14.2.1.

14.3.3 Class 1 test procedure

The following test procedure shall be used for Class 1 devices.

Magnetic sensors and mechanical reed switches will be either open or closed depending on the angle between B_0 and the sensitive axis of the sensor or reed switch.

If the device operation is affected by the state of the reed switch during exposure to the MR environment, or the device incorporates a mechanical magnetic sensor that might potentially be damaged by exposure to the B_0 field, then the device shall be tested in at least two orientations: one in which the switch is open and one in which it is closed.

Step 1 Select at least two orientations in the B_0 such that at least one orientation results in activation of the magnetic sensor and at least one orientation does not cause activation of the magnetic sensor.

NOTE AIMDs using non-mechanical magnetic sensors (e.g. Hall effect sensors) might have only narrow angular windows of orientation wherein the sensor is not activated by the B_0 field, such that testing in this orientation is not practical. These devices can be tested by emulating the logical off-state of the sensor during the test, e.g. by setting the device software or hardware state before entering the B_0 field.

Step 2 Program the DUT according to its intended MR Conditional mode and set of parameters as specified by the device labelling.

Step 3 For each orientation verify the sensor state and expose the AIMD to the required B_0 vector field for at least one minute.

Assess the DUT for malfunction in accordance with 14.2.1.

14.3.4 Class 2 test procedure

Class 2 test procedures are not within the scope of this edition. See Table 8.

15 Protection from harm to the patient caused by RF-induced malfunction and RF rectification

15.1 Introduction

This clause provides EMC evaluation of potential AIMD malfunction due to effects of the MR scanner's RF Field on the AIMD. Exposure to the RF field (B_1) of an MR scanner could have certain effects on an AIMD such as, but not limited to, a failure to deliver the intended therapy, re-programming, device reset, permanent damage, and tissue stimulation due to RF rectification. These effects can be transient or permanent and might create a safety hazard that impacts the AIMD patient.

This clause uses RF level determination methods defined in Clause 8.

15.2 General requirements

Testing shall be performed with the AIMD programmed according to its intended use.

Evaluation of potential transient malfunction conditions of the AIMD should be completed in a sufficiently short time after testing such that malfunctions can be detected. Times of AIMD exposure and post-test assessment of performance should be included in the test report.

For compliance criteria see 7.1.

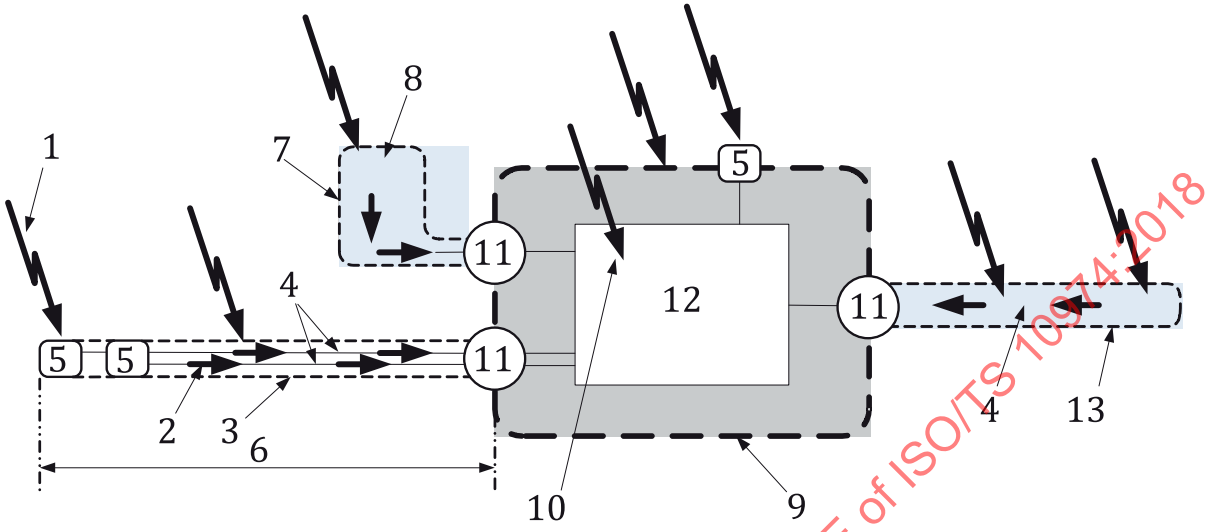
15.3 Mechanisms for RF interaction with an AIMD

Figure 21 illustrates an MR scanner-induced RF field impinging on a generic AIMD. The RF field might interact directly with active electronics within an unshielded enclosure as well as interacting with external conductors such as leads, resulting in RF energy entering into the enclosure via conductive paths. The enclosure might or might not include a shield that attenuates the RF field. The RF field interacts with the AIMD through two primary mechanisms:

— Interaction with internal circuits of the AIMD when RF field penetrates device enclosures containing active electronic circuits. The levels of induced voltages and currents in the interior circuits are dependent on the amplitude of the incident RF field, shielding effectiveness of the device enclosure, and physical and electronic configuration of the interior circuits. Shielding effectiveness might be

reduced by openings in the enclosure, such as an opening for a drug delivery catheter or optical transmission opening;

— Interaction with external components such as leads for therapy delivery or biological signal sensing, or with external antennas.



Key

1 radiated RF interactions
2 induced conducted RF sources
3 insulated lead containing one or more unshielded elongated conductors and tissue contacting electrodes
4 unshielded elongated conductors (e.g. wires)
5 tissue contacting conducting electrodes
6 lead conductor physical length
7 unshielded insulating enclosure
8 active electronic components (e.g. inductive or RF telemetry antenna, charging coil)
9 shielded (conductive) or unshielded (insulating) enclosure (could contain tissue contacting electrodes)
10 radiated RF interacts directly with active electronics with unshielded enclosures
11 enclosure RF conducted entry points
12 active electronic circuits
13 lead containing one or more unshielded elongated conductors and insulated sensor(s)

Figure 21 — RF interaction mechanisms with example AIMD

For RF energy coupling to external conductors and entering through a device enclosure, RF energy can appear with both common mode and differential mode components. Radiated and injected test techniques are included in this clause to evaluate the EMC effects in the presence of differential as well as common mode RF components.

Common mode RF energy components are equal in amplitude and phase for all conductive paths into the enclosure. For an AIMD with a shielded enclosure and similar RF input impedances at all RF entry points into the enclosure, and with elongated conductors of similar construction and length following a common trajectory in the body, and similar tissue impedances, the RF field entering the device enclosure is expected to be primarily common mode with respect to the shielded enclosure.

Differential RF energy components vary in amplitude and phase between conductive paths into the enclosure. If the external conductors include structures of different construction or trajectory in the body, or if device RF input impedances at the RF entry points or electrode impedances vary substantially, then significant differential mode components are expected to be present between the RF entry points.

For some AIMDs there might be insufficient shielding to prevent RF energy from interacting with active electronics within the enclosure. In this case, RF energy entering from external conductors as well as RF voltages and currents induced within the enclosure can contribute to total RF levels present in the interior electronic circuits. These total RF levels will be affected by the magnitudes and relative phase between RF energy conducted into the enclosure and the radiated field impinging on the enclosure.

15.4 Selecting radiated vs injected test methods

15.4.1 General

The testing approach for RF-induced malfunction will include radiated or injected RF exposure, depending on the type of the AIMD system under test.

15.4.2 AIMD type designation for test method selection

Table 9 designates which methods are applicable for various AIMD system types. To select the AIMD system type, use the following designations:

— Shielding of active electronics: For the purposes of Table 9 EMC test method determination, AIMDs for which the active electronics are contained within a metallic conductive enclosure are considered to be effectively shielded such that MR RF radiation incident on the enclosure does not directly interact with electronic circuits within the enclosure. For example, titanium casings used to enclose AIMDs such as pacemakers, defibrillators, or neurostimulators are considered to be shielded enclosures with respect to impinging incident RF fields from the MR environment for the purposes of Table 9. For AIMDs not constructed in a metallic enclosure, to be treated as a shielded device in Table 9, the manufacturer shall show that the active electronics are shielded sufficiently to prevent RF interaction with the internal electronics with respect to RF EMC malfunctions. Enclosures not meeting this shielding criterion shall be treated as "unshielded." The shielding evaluation shall include both shielding materials properties and the effects of any apertures in the shield (e.g. to allow connection to external conductors);

— Tissue contacting electrodes: If the AIMD includes electrodes which contact tissue that can be electrically stimulated, the effects of current flow in these electrodes due to RF rectification shall be considered in determining the AIMD test condition. At the present time, measurement methods have not been demonstrated that are capable of monitoring for tissue stimulation current levels within an RF radiated environment representative of the MR scanner. Because of this limitation, injected testing is required for evaluation of RF rectification currents when the AIMD includes electrodes which could potentially stimulate tissue;

— AIMD electrical length: defined in 8.2.

  a) AIMDs with short electrical length: These AIMDs can be evaluated with uniform phase radiated exposure, as phase variation will be limited to less than 90° in the *in vivo* environment such that additive phase effects cannot occur. However, if the AIMD includes tissue contacting electrodes which could result in hazardous stimulation of electrically excitable tissue, then an injected test shall be performed to evaluate stimulation current levels.

  b) AIMDs exceeding short electrical length: A computational or empirical RF model of the AIMD (using computational techniques or physical measurements) in combination with an injected test is required to account for the effects of *in vivo* RF phase and amplitude variation on AIMD conductors that exceed the short electrical length as set forth in 8.2. In general, a radiated test alone is insufficient to correctly represent the effects of *in vivo* RF amplitude and phase variation along conductors with length exceeding the short electrical length, as large numbers of cases should be considered to make a complete assessment, and arbitrary RF field phase and amplitude profiles have generally been very difficult to obtain. Because of this limitation, an injected test is required to evaluate RF EMC effects for AIMDs exceeding the short electrical length;

— Limitation for testing unshielded AIMDs with electrodes capable of electrically stimulating tissue: From the preceding discussion, unshielded AIMDs require a radiated test. If the AIMD also includes

electrodes that can potentially stimulate tissue, then injected testing is required since measurement techniques for tissue stimulation current have not yet been demonstrated in a radiated RF environment representative of the MR scanner. Therefore, this clause does not designate an RF EMC test method for AIMDs of this type.

Table 9 — RF EMC test method selection

AIMD type	Example AIMDs	Required test method	Test rationale
Has tissue contacting electrodes. Active electronics are shielded. AIMD elongated conductor length exceeds short electrical length.	Pacemakers, defibrillators, neurostimulators, shielded cochlear implants.	Injected test	MR induced malfunctions can include intermittent degradations of the device under test (DUT) as well as RF rectification that could potentially result in tissue stimulation. The injected test method provides measurement of RF rectification voltage/current levels in tissue contacting electrodes as well as assessment of the EMC effects entering the AIMD enclosure via conductive paths. Radiated MR RF EMC testing for this AIMD type is not an option at the present time as radiated test methods have not been demonstrated that: — Allow adequate RF rectification current measurements to be performed; — Correctly represent phase shifts on elongated conductors exceeding short electrical length.
Has tissue contacting electrodes. Active electronics are shielded. Any elongated conductors have short electrical length.	Loop recorders and leadless pacemakers with metallic enclosures.	Injected test is required if unintended stimulation presents a potentially hazardous condition; otherwise test may be either radiated or injected.	If electrodes are implanted such that excitable tissue might be stimulated, then RF rectification shall be assessed using an injected test. Radiated testing is applicable for short electrical length.
No tissue contacting electrodes. AIMD with short electrical length. Active electronics are unshielded	Pressure sensors, pill cameras	Radiated test	Radiated test method is used for AIMDs having short electrical length; no rectification current measurement needed for an AIMD without tissue contacting electrodes that could potentially stimulate tissue.
Has tissue contacting electrodes. Active electronics are unshielded. AIMD could be any length.	Retinal stimulators, unshielded pacemakers, unshielded neurostimulators	No RF EMC test method designated in this edition	Radiated test is required for unshielded AIMD. However, an adequate test method is not available at this time to measure RF rectification levels on tissue contacting electrodes in MR radiated RF environment.

15.4.3 RF antenna type designation for test method selection

RF telemetry/communication antennas that are part of the AIMD under test shall be evaluated. This subclause applies to evaluation of RF telemetry/communication antennas not located within a shielded enclosure.

EXAMPLE Close-range magnetically coupled telemetry loop antennas placed within a shielded enclosure do not require any MR RF testing as they are shielded. Magnetically coupled antennas placed external to a shielded enclosure will require evaluation.

The manufacturer shall select one method from the following three options for evaluating RF antennas not located within a shielded enclosure:

— Option 1, Radiated test: Use a test with the AIMD including leads, if applicable, that considers the lead trajectory while also placing the antenna in a high RF field location. Expose AIMD to a radiated field according to 15.6;

— Option 2, Injected test: Direct connection can be made to inject RF into the communication circuits. For this option treat the RF antenna port as another input port and excite simultaneously to the other ports. This might require a custom device different from the AIMD where access to the RF port is facilitated. If the antenna is insulated the device under test can be modified to provide a direct galvanic connection to the antenna. Perform injected testing according to 15.5. The injection level can be determined by analysis or by measurement of the RF level injected from the antenna into the AIMD enclosure during a radiated test;

— Option 3, Analysis: Perform analysis to demonstrate that the device performs as intended with the RF level induced into the device by the antenna. The RF field levels (B and E) surrounding the antenna shall be scaled to the MR scanner peak B_{1+} level of 30 μT averaged over the adjustment volume (see 3.3, Note 1 to entry).

15.4.4 RF EMC tier selection

Subclauses 8.2 and 8.7 provide definitions of tiers to determine exposure conditions for evaluation of RF-induced AIMD malfunction. Each tier provides an increasing level of refinement for determining the RF exposure level to the AIMD. Higher tiers require greater effort to determine the RF exposure level, but could provide lower RF exposure values. A manufacturer will typically complete tests using a single tier; however it is allowable to use different tiers for different tests.

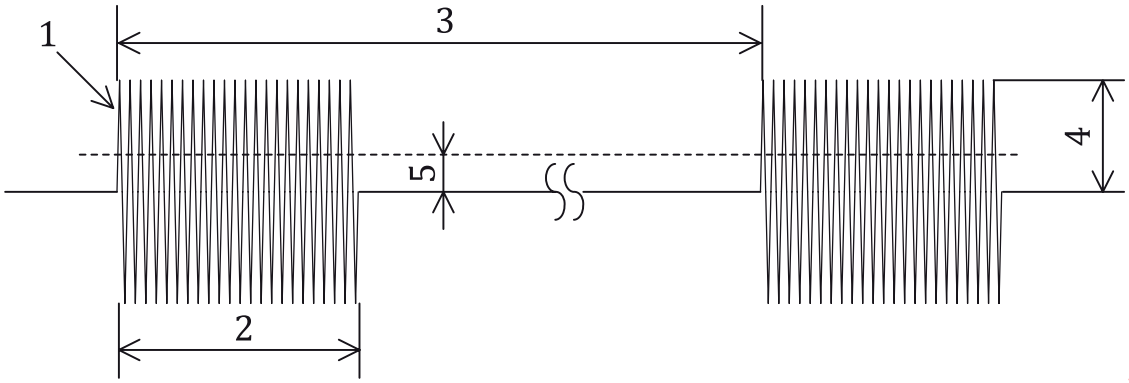
15.4.5 RF test conditions

The following pulse amplitude and timing test conditions are applicable to both radiated and injected testing:

— RF testing shall be performed using rectangular function or sinc function [(sin x) / x] modulation waveforms as shown in Figure 22 and Figure 23 respectively;

— RF_{maxpeak} is defined as the maximum instantaneous RF test level;

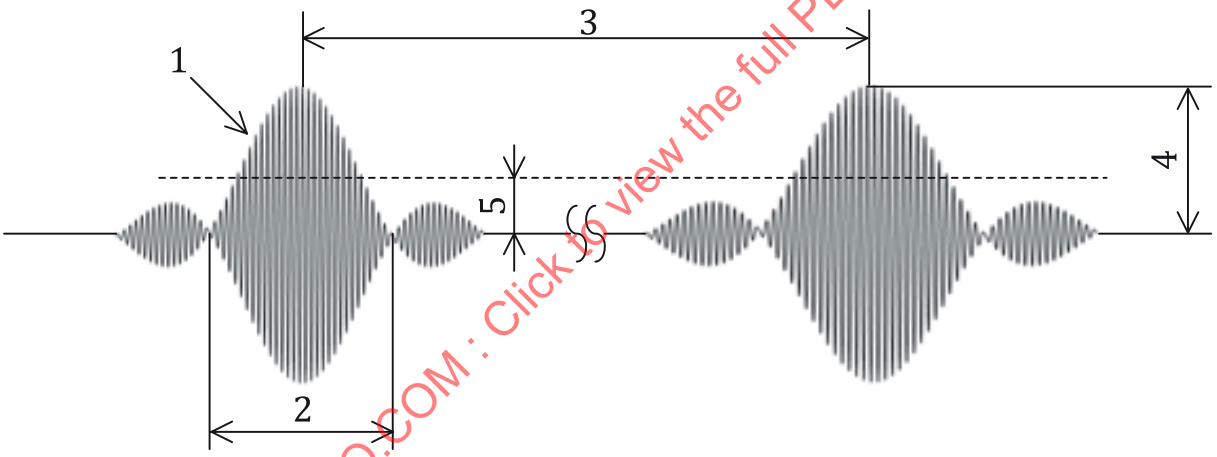
— RF_{maxrms} is defined as the maximum rms RF test level, wherein the rms averaging interval includes the pulse period, see example RF_{maxrms} level shown in Figures 22;



Key

1 rectangular pulse modulation
2 pulse width
3 period
4 $RF_{maxpeak}$
5 RF_{maxrms} (example shown level; will be dependent on period)

Figure 22 — RF rectangular modulation pulse waveform



Key

1 Sinc pulse modulation, sinc(x) = sin(x)/x
2 main lobe pulse width
3 period
4 $RF_{maxpeak}$
5 RF_{maxrms} (example shown level; will be dependent on period)

Figure 23 — RF sinc modulation pulse waveform

— RF frequency for RF EMC radiated and injected tests are defined in Table 2;

— Maximum peak ($RF_{maxpeak}$) and maximum rms (RF_{maxrms}) RF test levels are determined using the selected Tier from 8.7 for Tier 1 and Tier 2 and from 15.5.3 for Tier 3 and Tier 4. For radiated testing, these RF test levels are specified as electric field levels (V/m). For injected testing, these are specified as an RF injection level that can be expressed as either voltage, current, or square root of power.

As defined in IEC 60601-2-33, head SAR and whole body SAR are calculated over a six minute averaging interval. Over a shorter 10 s averaging 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. The 2× SAR multiplier affects the maximum rms (RF_{maxrms}) RF test level, but not the maximum peak ($RF_{maxpeak}$) RF test level. This 2× SAR level shall be taken into account for Test Condition 2 evaluation. 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+rms} or FPO:B do not need to account for the 2× multiplier;

— Both Test Condition 1 and Test Condition 2 are required to be performed.

Test Condition 1: (This test condition defines a pulse width and pulse period that is sufficient for an RF rectification evaluation. Rationale and additional pulse widths and pulse periods might need to be evaluated if RF rectification is observed during the test.)

a) Use the maximum peak RF test level, $RF_{maxpeak}$;

b) Use a rectangular modulation RF pulse [see Formula (14)] or sinc modulation RF pulse [see Formula (15)] with 1 ms (main lobe) pulse width;

c) Select pulse period to achieve a duty cycle yielding an rms level of 25 % of RF_{maxrms};

d) Test the AIMD for a period of time sufficient to observe device malfunction and (if applicable) tissue stimulation current due to RF rectification in order to assess device response to peak RF levels. Monitoring of AIMD performance and behaviour shall continue after the termination of the RF injection or radiated exposure for a period of time sufficient to observe device malfunction.

Rectangular Modulation Pulse:

$$Pulse\ period = 1\,\text{ms} \times \left(\frac{0{,}707 \times RF_{maxpeak}}{0{,}25 \times RF_{maxrms}} \right)^2 = 8\,\text{ms} \times \left(\frac{RF_{maxpeak}}{RF_{maxrms}} \right)^2 \quad (14)$$

where

Pulse period is the test pulse period as shown in Figure 22;

$RF_{maxpeak}$ is the applied RF test level for Test Condition 1;

RF_{maxrms} is the maximum rms RF test level.

Sinc Modulation Pulse:

$$Pulse\ period = 2\,\text{ms} \times \left(\frac{0{,}344\,6 \times RF_{maxpeak}}{0{,}25 \times RF_{maxrms}} \right)^2 = 3{,}8\,\text{ms} \times \left(\frac{RF_{maxpeak}}{RF_{maxrms}} \right)^2 \quad (15)$$

where

Pulse period is the test pulse period as shown in Figure 23;

$RF_{maxpeak}$ is the applied RF test level for Test Condition 1;

RF_{maxrms} is the maximum rms RF test level.

NOTE 1 ms rectangular pulse or sinc pulse width at full amplitude is sufficient to activate EMC responses (catastrophic breakdown or rectification); these are not pulse width dependent.

Test Condition 2:

a) Use the maximum rms RF test level, RF_{maxrms};

b) Use a rectangular modulation RF pulse [Formula (16)] with 10 ms pulse width;

c) Use a 50 ms pulse period (20 % duty cycle);

d) Select a peak RF level (RF_{peak}) to achieve the maximum rms RF test level, RF_{maxrms}, given the pulse duty cycle of 20 %;

e) Test the AIMD for 30 min in order to assess potential device damage, for example, due to internal component heating.

$$RF_{peak} = 1{,}414 \times \frac{RF_{maxrms}}{\sqrt{duty\ cycle}} = 3{,}162 \times RF_{maxrms} \quad (16)$$

where

RF_{peak} is the applied RF test level for Test Condition 2;

RF_{maxrms} is the maximum rms RF test level;

duty cycle is the duty cycle of the test pulse.

15.4.6 B_0 considerations

If the B_0 field is not applied during the test, the manufacturer shall demonstrate, through testing or design analysis, that device performance and behaviour, according to its MR Conditional labelling, is not affected by simultaneous application of a static magnetic field equivalent to B_0 field strength during RF EMC testing. One way to do this is to demonstrate that there are no ferromagnetic components used in the construction of AIMD RF rejection circuits or filters.

15.5 Injected immunity test

15.5.1 General

The test flow alternatives for the injected RF immunity test are determined by the selection of RF Tier. Prior to performing the test the RF injection level shall be determined for the Tier that has been selected. Tier 1 and Tier 2 test flows use an empirical approach for determining the induced RF level. Tier 3 and Tier 4 test flows require calculation of the induced RF level rather than measurement.

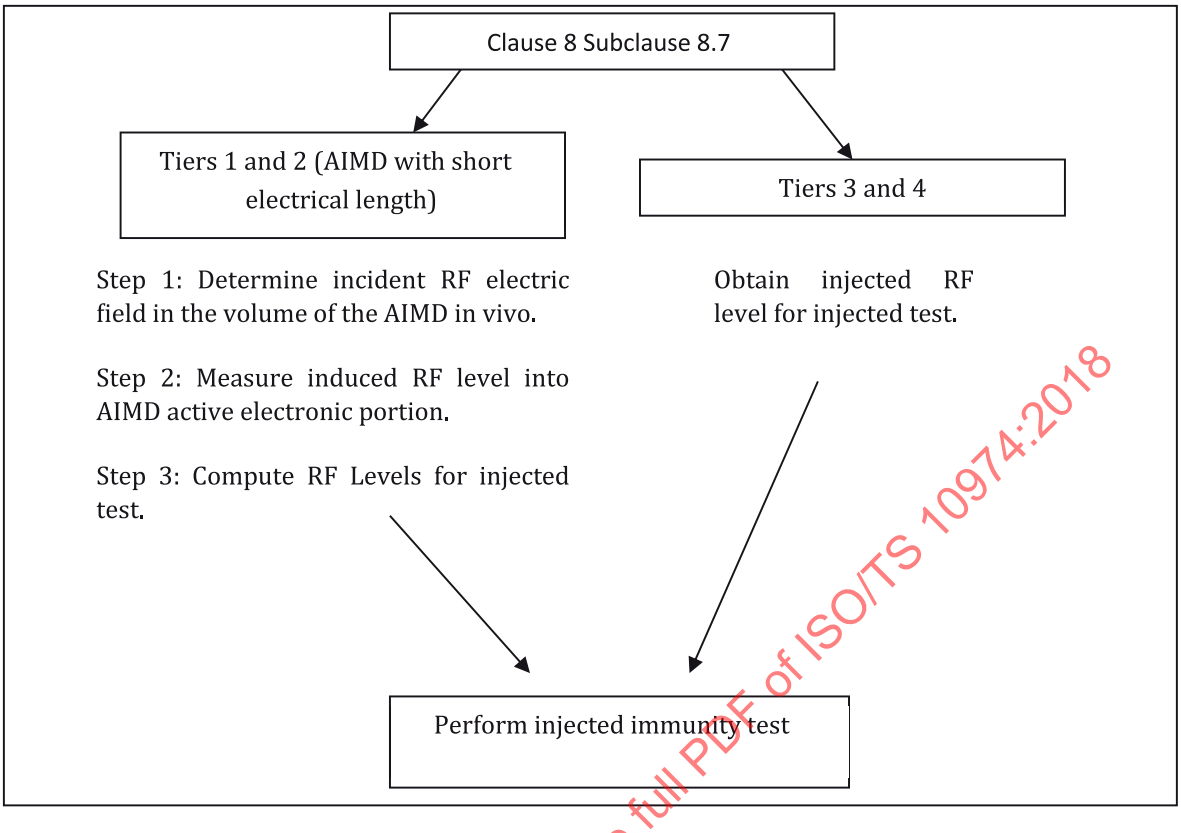


Figure 24 — Flow alternatives for RF immunity test

15.5.2 Determination of peak and rms injected levels for Tier 1 and Tier 2 — AIMD with short electrical length

The following procedure shall be used to determine injected test levels for Tier 1 and Tier 2.

Step 1 Use Table 4 (for Tier 1) or anatomical modelling results from 8.7.3, Steps 1a and 1b (for Tier 2) to determine the incident peak and rms electric field in the anatomical volume containing the AIMD.

Step 2 Expose RF level measuring device and leads to an RF electric field with spatially uniform magnitude and phase. The phantom media (conductivity and permittivity) shall be selected according to 8.3.2. A lower RF electric field level than the Step 1 incident field may be used. Measure the RF levels on all conductive paths into the active electronics. See 15.7.4 for details on the RF level measuring device. See 15.8 for details on the measurement procedure.

Step 3 Compute maximum RF peak, $RF_{maxpeak}$, and maximum rms, RF_{maxrms}, levels for injected test at all RF entry points on conductive paths through which RF energy can enter into the active electronics. Computing $RF_{maxpeak}$ can be done by scaling the measured RF level from Step 2 to the required electric field from Step 1 to determine level for injected test.

Step 4 Perform injected immunity test using RF test waveforms as defined in 15.4.5.

15.5.3 Determination of peak and rms injected levels for Tier 3 and Tier 4

For the purposes of this subclause, RF level distribution refers to the probability distribution of the RF level at the proximal end of the lead.

Tier 3 (8.7.4) and Tier 4 (8.7.5) describe two modelling techniques that can be used to estimate RF AIMD heating. These modelling methods predict the RF power at the hotspots that typically occur

at the distal end for leaded systems. Using a lead model for the proximal end of the lead the same modelling framework can be used to determine the induced rms and peak RF levels at RF entry points on all conductive paths into an enclosure containing active electronics. These rms and peak RF levels may be expressed in units of power, voltage, or current. The optimum test method depends on the characteristic impedance of the lead, the device input impedance, test fixture design, and the choice is left to the user's discretion. The descriptions in this subclause are described in terms of voltage, but current or power are also acceptable.

Annex Q provides examples of many different types of AIMD configurations, some of which could significantly impact RF level impinging on the AIMD active electronics portion, and others that have minimal or no effect. For each conductive path into the device, a model shall be developed and validated for the AIMD configuration resulting in the highest RF level for that conductive path. It might be necessary to develop and validate models for more than one configuration if the worst case configuration cannot be defined a priori. Rationale shall be provided to justify the configuration(s) that have been modelled.

Step 1a (For using Tier 3.) Develop an electromagnetic model(s) of the AIMD for *in vivo* prediction of the RF level on all conductive paths into the active electronics. 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 *in vivo* RF level at the RF entry points into the active electronics with a known uncertainty. Formula (17) determines the RF voltage into an RF entry point into the AIMD active electronics portion; this could also be formulated as an RF current at the user's discretion.

$$V = A\int_0^l S\left(z\right)E_{\tan}\left(z\right)dz \tag{17}$$

where

V is the incident RF voltage on an RF entry point into the active electronics;

A is a constant;

l is the length of the AIMD elongated portion or lead;

S is the complex validated model of the AIMD;

$E_{\tan}$ is the local *in vivo* electric field;

z is the position along the AIMD lead.

Step 1b (For using Tier 4.) Develop an electromagnetic model of the AIMD for *in vivo* prediction. The *in vivo* RF level at all RF entry points into the active electronics shall be determined by performing computer simulations of human bodies with an integrated electromagnetic model of the AIMD. The AIMD electromagnetic model(s) predicts the RF level at the entry points to the active electronics. Examples of suitable models are full-wave RF models, lumped element models, mixed full-wave and lumped element models. Methods of developing the model are left up to the user. The output of the model is an estimate of the *in vivo* RF level at RF entry points into the AIMD device with a known uncertainty.

Step 2 The model(s) developed in Step 1 shall be validated. Use the methodology defined in 8.8, with the following modifications. The model validation described in 8.8 evaluates the difference between measurements of RF deposited power and AIMD model computed RF deposited power. The model validation for this step shall compare the measurements of the induced RF level at a device entry point and AIMD model computed RF levels at the same entry point.

Step 3a (For using Tier 3.) Determine the clinically relevant fields incident on the AIMD. 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 incident tangential electric fields are obtained from electromagnetic modelling of the RF-human interactions under appropriate exposure from an MR scanner RF transmit coil. The tangential electric field will be averaged at intervals of 5 mm or less over the defined AIMD pathways.

NOTE 1 The tangential electric fields used in this step are the same as those determined in Step 3 of 8.7.4.

Step 3b (For using Tier 4.) Determine the clinically relevant fields incident on the AIMD. Create the simulation set, which consists of all combinations of clinically relevant parameters in 8.6.

NOTE 2 The number of incident fields on the AIMD in Step 3a or 3b is equal to the number of human body models utilized, 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 Determine the *in vivo* RF level at the device entry points by applying the simulation conditions defined in Step 3 to the validated electromagnetic model of the AIMD from Step 2. The peak voltage (V_{peak}) is derived by scaling the simulation results to a B_{1+peak} level of 30 μT averaged over the adjustment volume. The rms voltage (V_{rms}) shall be derived by performing the simulations at a B_{1+rms} level consistent with the AIMD MR Conditional labelling (e.g. Normal Operating Mode, First Level Controlled Operating Mode, FPO:B, etc.) as defined by IEC 60601-2-33. The resulting distributions are a prediction of the *in vivo* RF level (peak and rms) impinging on the AIMD device entry point.

Values for the maximum RF peak ($RF_{maxpeak}$) and maximum rms (RF_{maxrms}) levels shall be selected from the RF level distributions based on a risk assessment for this hazard.

15.5.4 Injected immunity test procedure

Use an RF injection network in accordance with 15.7.5 to inject RF signals at RF entry points into the AIMD enclosure containing active electronic elements.

NOTE This is a bench test in air that does not use a phantom or any tissue simulating medium in contact with the AIMD.

The manufacturer shall verify the RF level injected at all RF entry points into the AIMD enclosure.

The RF level measuring device described in 15.7.4 could be used to verify the RF level injected at all RF entry points into the AIMD enclosure. Alternative methods are also acceptable with rationale from the manufacturer.

Perform separate RF injection tests using Test Condition 1 and Test Condition 2 in 15.4.5.

15.5.5 RF phase test conditions

For AIMDs with lead systems including multiple leads or multiple conductors within a lead, RF phase differences can occur at the device RF entry points. Test conditions shall be included to assess the effects of RF phase differences among all AIMD RF entry points. Using Test Condition 1 in 15.4.5 test with a set of phase conditions between RF entry points using one of the following two options:

— Option 1: Worst case phase conditions determined by the manufacturer with accompanying rationale. The modelling methods defined in Clause 8, Tier 3 and Tier 4 provide peak and rms RF magnitude distributions for the testing described in this clause. These modelling methods are also capable of evaluating the phase difference between the RF entry points for the range of different clinical use conditions provided the model is validated for determining phase differences. For many AIMDs the phase difference between RF entry points can be quite small, e.g. single lead multiple electrode DBS systems based on co-radial or parallel conductor lead designs. For other AIMDs the phase difference between RF entry points might be larger but the range of phase difference could

still be quite small. The use of modelling allows the AIMD manufacturer to limit the phase difference analysis to values consistent with clinical use conditions;

— Option 2: If the manufacturer does not provide worst case conditions with rationale, test using the following conditions: 0, 90, 180, and 270 degree phase shift to each RF entry point, one conductor at a time, while injecting RF energy into the remaining conductors at zero degrees phase shift.

15.5.6 AIMD monitoring during the test

Performance and behaviour of the AIMD shall be monitored during the RF injection test. AIMD monitoring equipment is described in 15.7.3.

If the AIMD has electrodes that are in contact with and could potentially stimulate tissue, the AIMD shall be monitored for the presence of rectification products during Test Condition 1 in 15.4.5. Monitoring can be accomplished at the RF entry points to the active electronic portion. These are defined as the points of the AIMD that are connected to the electrodes via the external conductors. Use of an RF injection network to monitor for rectification products at RF entry points to the active electronic portion of the AIMD is described in 15.7. The allowed magnitude of the rectification products is beyond the scope of this document and is application specific.

15.6 Radiated immunity test

15.6.1 General

The purpose of this test is evaluation of device malfunction due to the MR scanner RF field only. This test is performed using RF test equipment as defined in 15.7. The test is intended to represent worst case RF field exposure achievable during an MR scan. It is not specified to be performed using a clinical MR scanner because it is not generally possible to control a given clinical MR scanner to achieve the specified test conditions.

15.6.2 Determining the RF radiated field level

Radiated immunity testing uses the peak and rms RF electric field level as determined using Tier 1, Tier 2, or Tier 3 from Clause 8.

For Tier 1, use Table 4 to determine the maximum RF peak ($RF_{maxpeak}$) and maximum rms (RF_{maxrms}) electric field levels for the anatomical area containing the AIMD. If the AIMD spans multiple anatomical areas use the highest values from the areas spanned.

For Tier 2, use 8.7.3, Step 1a and Step 1b to determine the maximum RF peak ($RF_{maxpeak}$) and maximum rms (RF_{maxrms}) electric field levels within the volume containing the AIMD.

For Tier 3, use 8.7.3, Step 3 to determine the maximum RF peak ($RF_{maxpeak}$) and maximum rms (RF_{maxrms}) electric field levels along the AIMD.

15.6.3 Radiated test procedure

Radiated RF EMC testing shall be performed using an RF field generator as described in 15.7.1 and phantom and tissue simulating medium as described in 8.3.2. For external conductors, the AIMD shall be tested when oriented so that the conductors are aligned with the tangential electric field in the phantom. This might require radiated testing in multiple orientations if the AIMD is constructed with long axes of external conductors that are oriented in multiple directions and cannot be simultaneously aligned with the electric field.

After immersing the AIMD in the tissue simulating medium perform radiated immunity testing as separate tests in accordance with Test Condition 1 and Test Condition 2 as specified in 15.4.5.

15.6.4 AIMD monitoring during the test

It is not possible, with presently available test capabilities, to monitor for RF rectification products at tissue-contacting electrodes during the radiated test. Instead, an injected test as described in 15.5 shall be performed for this purpose.

AIMD monitoring apparatus are described in 15.7.3.

15.7 Test equipment

15.7.1 Generating the RF electric field for radiated testing (AIMD with short electrical length)

The following methods may be used for generating the electric field for radiated testing:

— Radiated RF EMC testing for AIMDs with short electrical length: for an AIMD configured without external conductors or with external conductors with short electrical length, the area of uniform field can be small because modern AIMD device size (without external conductors attached) is small. For these devices, a parallel plate TEM plane or other suitable method for generating large fields may be used in combination with a suitable phantom. See Annex C;

— Radiated RF EMC testing for AIMDs with length exceeding the short electrical length: Methods have not yet been demonstrated that control spatial distributions of RF field magnitude and phase to achieve worst case conditions in general for AIMDs with elongated external conductors that exceed the short electrical length. This clause does not designate a test method for RF EMC radiated testing for these AIMDs; injected RF EMC methods are provided instead as described in 15.5;

— Radiated RF testing to determine RF injection levels: use methods described in 8.3.1 to generate a uniform magnitude and phase electric field.

15.7.2 Phantom and tissue simulating medium for radiated testing

Use phantom and tissue simulating medium as described in 8.3.2.

15.7.3 AIMD monitoring apparatus

To accomplish the required monitoring of device behavioural responses during testing, monitoring apparatus may be placed within the AIMD enclosure, or external to the enclosure, or both at the manufacturer's discretion in accordance with the following:

— Internal monitoring apparatus: Apparatus, including circuitry or other means for monitoring purposes, may be placed inside the AIMD enclosure. The manufacturer shall provide evidence that the inclusion of monitoring apparatus does not invalidate the test outcome. For example, a monitoring signal could be communicated outside the device using a non-conducting transmission medium (e.g. fibre optic). Alternatively, data can be stored within the device or other monitoring circuitry for retrieval following the exposure. Transmission of the monitoring signal via inductive or radiating means is not recommended unless it can be ensured that the transmission and transmitting device do not interfere with the radiated fields and that the transmitted data are not corrupted by the radiated fields. A preferred method of monitoring AIMD internal signals is to convert these to optical signals and use fibre optic cable;

— External monitoring apparatus: If monitoring apparatus are located outside the AIMD an analysis shall be performed to account for any changes in field distribution caused by the monitoring apparatus. It should be expected that external monitoring equipment, or a shielded twisted pair cable, or bud light in a metal can might have an effect on the local field distribution. However, if the manufacturer can demonstrate and account for how induced RF levels are affected then this method is acceptable.

15.7.4 RF level measuring device

When the incident RF field to the AIMD is determined from Tier 1 or Tier 2 and an injected test is to be performed, an RF level measuring device shall be used to determine the RF level to be injected into all RF entry points into the AIMD enclosure containing active electronic circuits. Additionally, an RF level measuring device may be used to validate the Tier 3 or Tier 4 model in 15.5.2, Step 2.

As an example, this can be accomplished using an RF level measuring device constructed within an enclosure with similar RF electrical characteristics to the AIMD enclosure.

If the enclosure includes a shield the RF level measurements can be made using a shielding enclosure as the ground or reference node. Other RF level measuring techniques are also acceptable subject to the considerations listed below in this subclause.

The input impedances for both common and differential mode of the RF level measuring device at each RF entry point shall match the corresponding input impedances for the RF entry points into the AIMD enclosure constituting the device under test within a tolerance of ±20 % impedance magnitude and ±30 degrees impedance phase at the MR RF operating frequency.

Where identical materials or components of the AIMD under test are used in the measurement device, the RF level measurement uncertainty due to these factors could be reduced. This strategy can in turn reduce the required RF injection level. Factors that could affect test uncertainty include:

— Differences between external dimensions and conductive surfaces of the RF level measurement device and the AIMD enclosure. Minimizing these differences helps ensure that the interfacing impedance from the enclosures to the surrounding media is similar;

— Resolution, accuracy, monotonicity, and stability of data conversion processes;

— The effects of data storage or transmission means. Ordinary cables can pick up RF energy and distort the applied field; hence they should not be used. The measurement system shall be chosen to minimize the impact of both effects. Recommended techniques for handling measurement data include:

  a) Optically coupled data transmission;

  b) Data storage for subsequent retrieval.

— Differences in electrical connections made to the measurement device versus the AIMD enclosure in its clinical usage.

15.7.5 RF injection network

The RF injection network is used to simultaneously apply RF energy to the RF entry points, defined as conductive paths or ports through an AIMD enclosure containing active electronics, for the purpose of performing injected RF EMC testing. The RF injection network shall be constructed to provide known RF amplitude and phase at each injection point to achieve amplitude and phase test conditions as defined in 15.5.3 (Tier 3 and Tier 4).

For all test conditions, the required injection levels shall be present at the device under test.

If the AIMD enclosure includes a shield, the RF injection network may use the shielding enclosure as a ground or reference node.

The RF injection network along with its RF source or sources shall be capable of delivering at least the maximum peak injected RF levels simultaneously to all RF entry points into the AIMD enclosure of the device under test as required in 15.5.2 (Tier 1 and Tier 2).

If the AIMD has electrodes that are capable of stimulating tissue then the RF injection network shall provide ports for monitoring for rectification products at the RF entry points corresponding to these electrodes.

An example multiport RF injection network is shown in Annex E. Other injection networks meeting the above requirements are also acceptable for use for testing according to Clause 15.

15.8 Determining the peak RF injected level using a radiated test

In this subclause, RF levels can be expressed in units of power, voltage, or current.

Tier 1 and Tier 2 provide a maximum electric field level that can impinge on the AIMD system. To determine the RF level to be injected for each RF entry point into the AIMD enclosure containing active electronics using Tier 1 or Tier 2, measure the induced RF level at the RF entry point during radiated exposure to an electric field of uniform magnitude and phase (see Table 2).

This clause provides the following method of determining the RF injection levels using a radiated test. This method is applicable when all external conductors provide an RF source impedance of greater than 50 ohms as seen from the RF level measuring device (see 15.7.4). The overall test flow for determining the RF injection levels is illustrated in Figure 25.

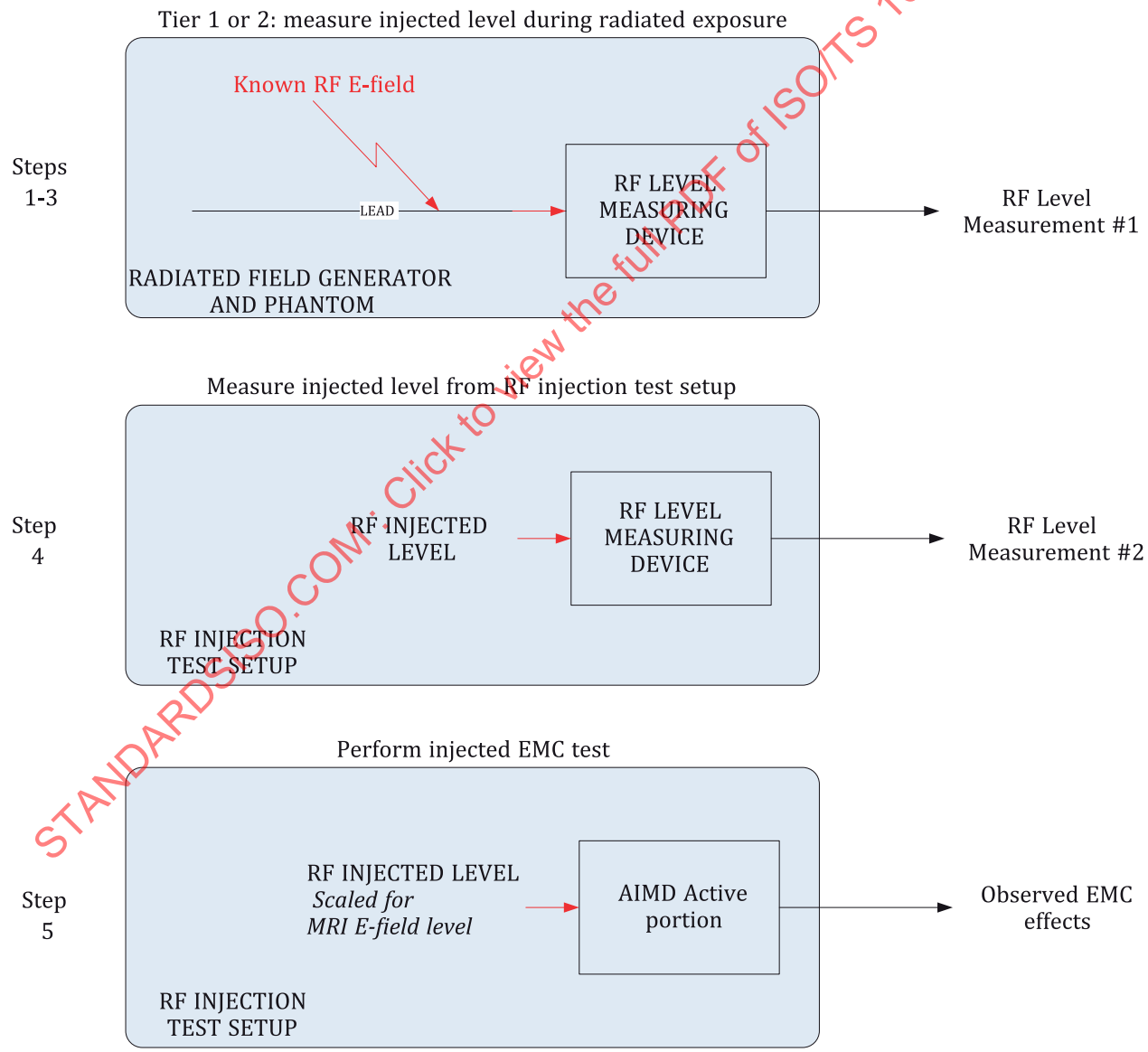


Figure 25 — Determining the peak RF injection levels using a radiated test for Tier 1 and Tier 2

Step 1 Connect all external conductors to an RF measurement device as described in 15.7.4.

Step 2 Place the assembly from Step 1 into a phantom and medium as described in 8.3.2. The assembly is within the phantom so as to provide a uniform magnitude and phase exposure of the electric field.

Step 3 Expose the assembly in the phantom from Step 2 to an RF electric field of uniform magnitude and phase using an RF field generator as described in 15.7.1. During the exposure, use the RF level measuring device to determine the induced RF level at all RF entry points into the AIMD enclosure. The RF field level may be adjusted so that the measured induced RF levels are within the dynamic range of the measurement device. Record the RF field levels used to obtain the induced RF levels.

Step 4 Remove the assembly from the phantom. Connect the RF level measuring device to an RF injection network as described in 15.7.5. This network interfaces the device under test to an RF power source. Increase the RF input level from the power source until the RF level measured at all RF entry points into the AIMD enclosure is greater than or equal to the induced RF levels measured in Step 3. Record the RF input level to the RF injection network at which this condition is met.

Step 5 To determine the RF injection level for the injected testing of the AIMD, scale the RF input level recorded in Step 4 to represent the required peak electric field level as determined using 15.5.2. For example, if the radiated test was performed using a 420 V/m peak electric field and the required test level is 4 200 V/m, then the RF input level to the RF injection network is increased by a factor of 10. The resulting scaled RF input level will be used as the RF injection level to the RF injection network when testing according to 15.5. For example, for RF voltage or current levels, the scaling formula is shown in Formula (18).

$$Scaled\ RF\ input\ level = RF\ input\ level \times \frac{RF\ E\text{-}field}{Test\ RF\ E\text{-}field\ level} \tag{18}$$

where

Scaled RF input level is the required RF injection level;

RF input level is the value determined from Step 4;

RF E-field is the electric field level determined from 15.5.2, Step 1;

Test RF E-field level is the electric field level applied in Step 3.

16 Protection from harm to the patient caused by gradient-induced malfunction

16.1 Introduction

The MR scanner gradient magnetic field could induce adverse effects on AIMD operation or performance, such as failure to deliver intended therapy, memory corruption, or temporary or permanent loss of device programmed settings. These unwanted effects can be caused by voltage induced in AIMD internal circuitry as the gradient magnetic field penetrates the device enclosure or external voltage induced in patient leads for AIMDs having leads. These effects can be transient or permanent and might create a safety hazard that impacts the AIMD patient.

16.2 General requirements

The AIMD shall be tested for MR gradient field induced transient or permanent malfunction and damage.

Testing shall be performed with the AIMD programmed according to its intended use.

If output therapy is enabled during the MR scan the AIMD shall be tested over its programmable therapy output operating range or at representative therapy settings consistent with its MR Conditional labelling. This applies especially to output current, voltage, and polarity settings. If disabling output therapy during scanning is an option, then radiated field and injected voltage malfunction and damage testing shall also be conducted with output therapy disabled.

Where use of an oscilloscope is specified, a multichannel digital data acquisition system may be used.

Evaluation of potential transient malfunction conditions of the AIMD should be completed in a sufficiently short time after testing such that malfunctions can be detected. Times of AIMD exposure and post-test assessment of performance should be included in the test report.

For compliance criteria see 7.1.

16.3 Selecting radiated and injected test methods

Separate radiated and injected malfunction tests are defined to verify absence of device malfunction and interference of intended device output. The AIMD is tested by radiated field exposure, and depending on AIMD type, by additional injected voltage testing.

The radiated test is required for all AIMD device types and shall be performed with patient leads (or appropriate lead simulators) attached, if leads are part of the AIMD.

The injected test shall be performed for AIMDs having extended lead electrodes or containing multiple, externally mounted electrodes on the AIMD enclosure unless the radiated test can be shown to be complete.

The injected test may be omitted if the radiated test can be shown to be complete. Generally, it will be difficult to test multi-lead and multi-electrode AIMDs sufficiently using just the radiated test because of difficulty in controlling electrode voltages or observing AIMD output in the radiated field. The radiated test is complete only if it imparts conservative, common and differential voltage amplitude, and polarity combinations covering the range of *in vivo* MR exposure and output behaviour can be monitored and verified.

Table 10 defines which test methods are applicable for various AIMD types.

Table 10 — Gradient malfunction test method selection

AIMD type	Example AIMDs	Required test method	Test rationale
No tissue contacting electrodes	Pressure sensors, pill cameras	Radiated test	At MR scanner gradient operating frequencies, the AIMD enclosure does not shield or protect internal electronics from the gradient field.
Has no elongated conductors and enclosure mounted tissue contacting electrodes	Implantable loop recorders, leadless pacemakers, retinal stimulators	Radiated test	Radiated only testing is feasible for AIMDs without leads, if the test can replicate the gradient-induced DUT electrode voltage(s) experienced *in vivo* by the implanted device.
Has elongated conductors and has tissue contacting electrodes	Pacemakers, defibrillators, neurostimulators, cochlear implants	Radiated test and injected test	Radiated test required to assess malfunction due to magnetic field coupling to internal circuits of the device under test (DUT). Injected test will usually be needed to complete malfunction assessment of gradient-induced voltage/current conducted through tissue contacting electrodes.

16.4 Radiated immunity test

16.4.1 General

The AIMD enclosure does not shield or protect internal electronics from the MR gradient magnetic field. The radiated test is required for all devices to assess the influence of gradient-induced voltages on internal circuits and components caused by exposure to the MR scanner gradient fields.

For AIMDs that have external tissue contacting electrodes, the test shall be performed with leads (in conductive media), or with lead or electrode simulators (in air) to provide the same external circuit pathways as when the AIMD is implanted.

The test shall be performed with electrode and enclosure impedances representative of the *in vivo* condition. If lead or electrode simulators in air are used, the manufacturer shall justify that the simulators represent the *in vivo* condition.

The selected lead path, or alternative lead or electrode simulator, shall result in gradient-induced voltages between electrodes and AIMD enclosure typically encountered *in vivo*. Thorough testing of inter-electrode gradient-induced voltage differences for multi electrode AIMDs using radiated test methods is beyond the scope of the TS.

NOTE 1 The rationale for testing with leads is that certain AIMD malfunction susceptibilities might depend on simultaneous radiated magnetic field coupling to internal circuitry and gradient-induced voltage or current flow through AIMD external patient connections. The inclusion of leads deployed to evoke typical gradient-induced electrode voltages and currents are presumed to make it more likely that the radiated test will reveal such AIMD susceptibility than to mask it.

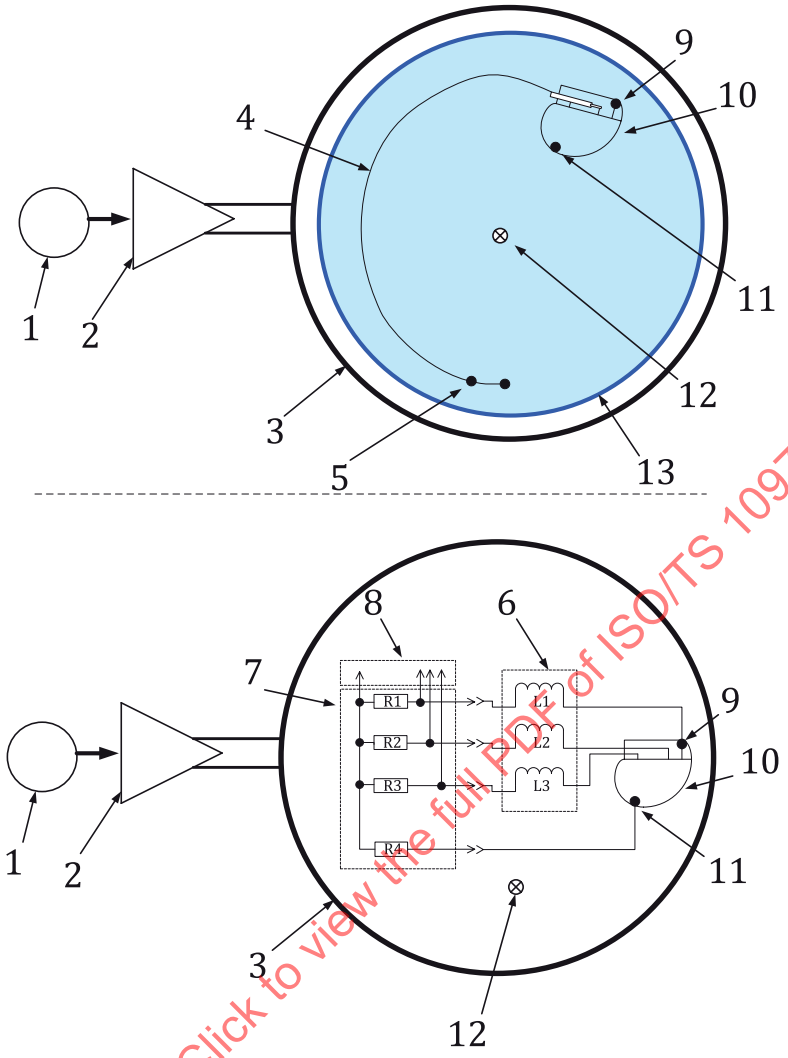
NOTE 2 For AIMDs containing internal or external magnetic loop antennas the potential exists for damage to occur to associated telemetry circuits from radiated field exposure during test.

16.4.2 Test equipment

Use a single axis laboratory bench magnetic test system, Figure 26 capable of generating the radiated gradient field test exposure (dB/dt, t_{slew}) defined in Annex A.

For AIMDs that do not have leads or enclosure mounted patient electrodes the test may be performed in air and without additional test connections.

For AIMDs with leads or enclosure mounted electrodes the test shall be performed with leads in conductive saline as shown in the top pane of Figure 26, or alternatively with lead/electrode simulators in air as shown in the bottom pane of Figure 26.



Key

1 arbitrary waveform generator
2 transconductance amplifier
3 custom electromagnet
4 AIMD lead
5 AIMD lead electrode(s)
6 lead/electrode simulator
7 simulated electrode impedance
8 test measurement port (optional)
9 AIMD enclosure mounted electrode
10 AIMD
11 AIMD conductive enclosure
12 direction of magnetic field
13 conductive saline solution

Figure 26 — Radiated magnetic field test setup for gradient-induced malfunction

16.4.3 Radiated test signal

For AIMDs with leads or tissue contacting electrodes use Annex A to determine typical *in vivo* V_{emf} electrode voltages with respect to the AIMD enclosure. Select AIMD test lead path(s) or lead/electrode

simulator(s) to achieve these typical voltages at the AIMD patient electrode interface for the *dB/dt* radiated test level.

AIMDs with enclosure mounted electrodes shall be tested in air using electrode simulator(s) if typical electrode voltage with respect to AIMD enclosure cannot be achieved using the conductive saline phantom.

NOTE 1 When testing an AIMD with enclosure mounted electrodes in a conductive phantom, typical electrode voltages with respect to AIMD enclosure cannot be achieved without exposing the AIMD enclosure to typical *in vivo* electric fields. The electric field that can be achieved is limited by the radius of a circular phantom as shown in Formula (19).

$$E = \frac{1}{2} \times \frac{dB}{dt} \times r \tag{19}$$

where

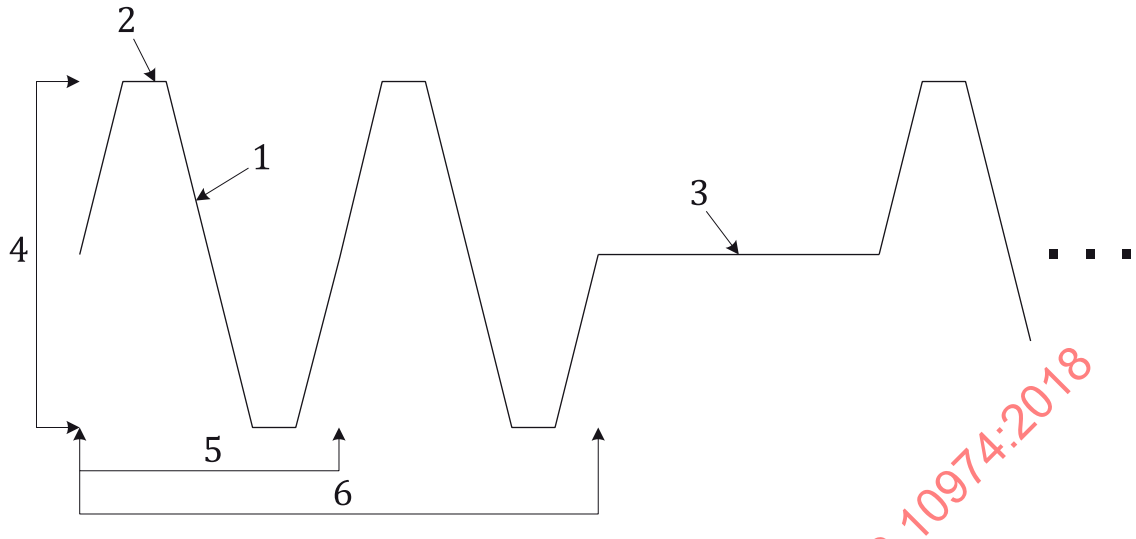
dB/dt is the time rate of change of the magnetic flux density;

r is the radius of the electromagnet coil.

NOTE 2 When testing an AIMD with lead(s) in a conductive saline phantom, a custom lead (e.g. longer length) might be needed if typical *in vivo* V_{emf} cannot be achieved using a standard patient lead.

The trapezoidal waveform used to simulate the gradient field is shown in Figure 27. It is defined by three variable parameters: peak-to-peak amplitude (B_g), peak-to-peak rise/fall time (t_{slew}), and dwell-time (t_{dwell}). Figure 27 presents an example of a test signal consisting of a burst of two waveform cycles followed by the "off-time" before the next burst. The combination of waveform parameters plus burst length and off-time defines a single sequence.

The complete test sequence consists of all combinations of parameters shown in Table 11. (t_{slew} and *dB/dt* are paired dependent parameters that are not independently permuted.) The AIMD shall be tested using all combinations unless appropriate rationale and documentation is provided by the AIMD manufacturer.



Key

1 t_{slew} (min to max rise/fall time in ms)
2 t_{dwell}
3 t_{off} (time between bursts)
4 B_g (magnetic field strength produced by gradient, min to max amplitude in mT)
5 one cycle
6 burst length (two cycles in this example)

Figure 27 — Radiated gradient test signal

Table 11 — Radiated gradient test signal parameters

Sequences				
Parameter[a]	**Values**			
t_{slew} (ms)	0,2[b]	1,0[c]	—	—
t_{dwell} (ms)	0,0	1,0	5,0	20
Number of cycles (burst length)	128	—	—	—
t_{off} (ms)	0,0	5,0	100	500
B_g (mT)	Determined from t_{slew} and *dB/dt*			

NOTE 1 Scaling for *dB/dt* (t_{slew} = 1,0 ms) is based on IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.12.4.102.3.3b), *dB/dt* PNS formula. Scale = L12 (1,0 ms)/L12 (0,1 ms) = 0,296, where L12 is the First Level Controlled Operating Mode in whole body gradients.

NOTE 2 The single axis bench test coil is capable of producing a magnetic field strength of $B_g \geq 0{,}5 \times t_{slew} \times dB/dt$.

NOTE 3 Gradient amplifiers have a limited bandwidth and therefore gradient profiles are not strictly trapezoidal or triangular depending on the particular selection of parameters. An amplifier 3 dB bandwidth ≥ 10 kHz is sufficient for the test.

NOTE 4 CAUTION: Sequences with small t_{dwell} and t_{off} could exceed clinically relevant MR scanner |*dB/dt*| rms levels, e.g. 42 T/s rms. These have the potential to cause excessive AIMD heating if applied for longer than the 15 s minimum. Carefully consider |*dB/dt*| rms level, duration, and sequence application order during test development to avoid overheating.

[a] The tolerance for time value entries is ±5 %.

[b] *dB/dt* (t_{slew} = 0,2 ms) is determined from the maximum slew rate (SR-max) identified in the AIMD MR Conditional labelling using the method defined in Annex A.

[c] *dB/dt* (t_{slew} = 1,0 ms) is 0,296 × *dB/dt* (t_{slew} = 0,1 ms).

16.4.4 Test procedure

The following procedure shall be used for gradient radiated immunity tests.

Step 1 If tested in saline, select the saline conductivity so that AIMD electrode impedances are approximately equal to those of the AIMD when implanted (see Annex N). If tested using lead/electrode simulators, select the electrode simulator resistances to match those of the implanted AIMD.

Step 2 Place and mount the AIMD in the test coil such that the AIMD internal circuit planes, components, and any lead(s) or lead simulator(s) are orthogonal to the test coil magnetic field. If the AIMD internal electrical components and circuit layout design is oriented in multiple planes then the AIMD shall be tested with gradient magnetic field exposure orthogonal to each of the AIMD component or circuit layout planes.

If internal component orientation cannot be determined, then the AIMD shall be tested in three orthogonal axes using a *dB/dt* test level greater than or equal to 1,73 times determined from Annex A.

NOTE A multiplier of 1,73 is required to achieve the target *dB/dt* along the maximum susceptibility axis of the component or circuit if angularly misaligned by 45 degrees in both azimuth angle (Θ) and polar angle (Ø) to the test axes.

Independent of AIMD enclosure orientation, lead or lead simulator orientation should be maintained orthogonal to the test coil magnetic field. Single and multi-lead AIMDs shall be tested with lead (or lead simulator) circuit loop closure such that induced gradient voltages are typical of those experienced by the device during clinical use.

Step 3 Apply each gradient test signal sequence for a minimum of 15 s, or longer if necessary to observe potential device effects.

If the injected malfunction test is to be omitted, the radiated test for the single or multi-lead AIMD shall be repeated with a sufficient set of lead path cases to subject the device to the maximum common and differential mode voltages expected to be experienced during clinical use. For multi-lead AIMDs voltage amplitude and polarity differences between leads due to lead length and lead path should be considered.

16.5 Injected immunity test

16.5.1 General

Injected testing is performed by applying simulated MR gradient-induced EMF voltage to the AIMD tissue contacting electrodes.

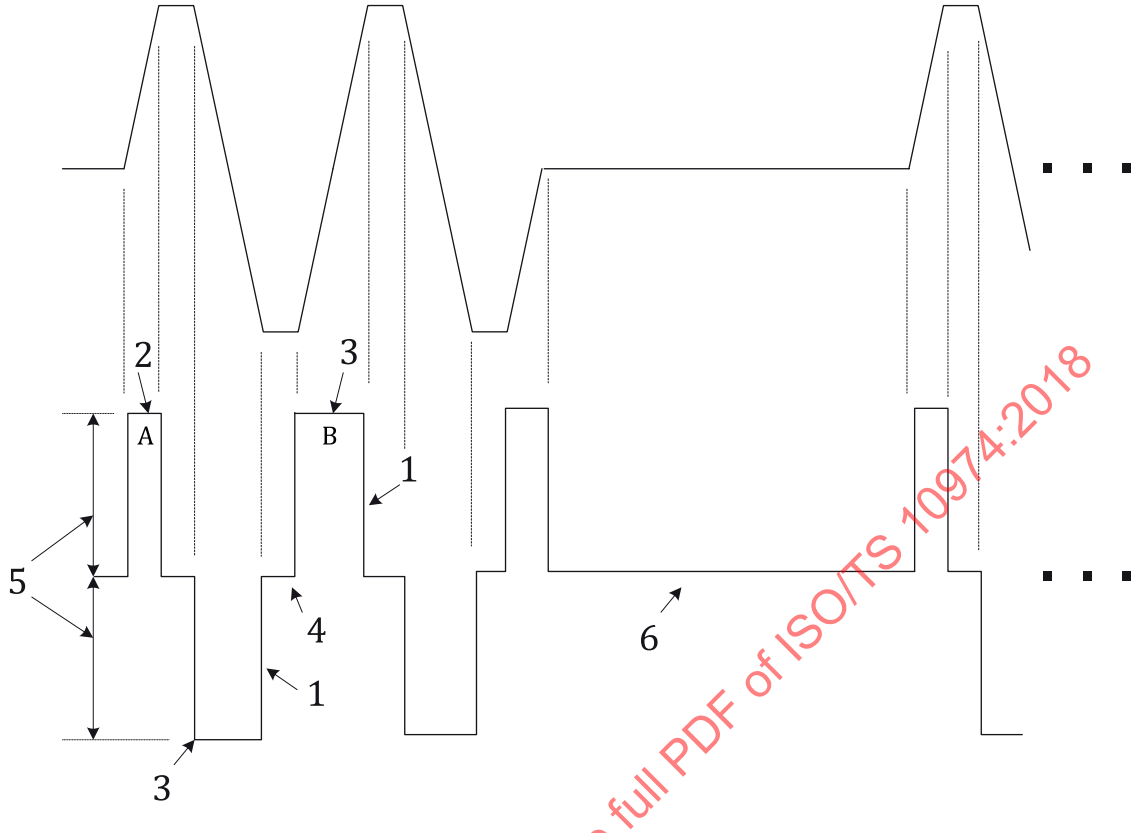
NOTE Insulated antennas not able to pass low frequency gradient current are excluded from injected immunity testing.

16.5.2 Test equipment

Use the test setup in Figure 29 including the tissue interface network defined by Figure 34.

16.5.3 Injected test signal

For injected testing, the time derivative of Figure 27 is required as shown in Figure 28. Table 12 lists the resulting injected voltage test signal parameters. Use the V_{emf} voltage test levels determined from Annex A.



Key

1 t_{edge} (maximum 10 % to 90 % rise or fall time in µs)
2 t_{spw} (Pulse A — single sided slew pulse width)
3 t_{dpw} (Pulse B — double sided slew pulse width)
4 equal to t_{dwell}
5 V_{emf} (Pulse A and B amplitude in volts)
6 t_{off}

Figure 28 — Injected gradient test signal

Table 12 — Injected gradient test signal parameters

Sequences				
Parameter[a]	**Values**			
V_{emf} (volts)	See Annex A			
t_{dpw} (ms)	0,2[b]	1,0[c]	—	—
t_{spw} (ms)	0,1	0,5	—	—
t_{edge} (µs)	7 (maximum)			

NOTE 1 Scaling for V_{emf} (t_{dpw} = 1,0 ms) is based on IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.12.4.102.3.3b), *dB/dt* PNS formula. Scale = L12 (1,0 ms)/L12 (0,1 ms) = 0,296, where L12 is the First Level Controlled Operating Mode in whole body gradients.

NOTE 2 V_{emf} 10 % to 90 % rise time, t_{edge} approximately 2,2 τ. For a maximum gradient amplifier –3 dB bandwidth cutoff frequency f_{co} = 50 kHz; therefore $\tau = 1/(2\pi f_{co})$ = 3,2 µs and t_{edge} = 7 µs.

[a] The tolerance for time value entries is ±5 %.

[b] V_{emf} (t_{dpw} = 0,2 ms) is determined from the maximum slew rate (SR-max) identified in the AIMD MR Conditional labelling using any of the three tiered methods defined in Annex A.

[c] V_{emf} (t_{dpw} = 1,0 ms) is 0,296 × V_{emf} (t_{dpw} = 0,1 ms).

Table 12 *(continued)*

Sequences				
Parameter[a]	**Values**			
t_{dwell} (ms)	0,0	1,0	5,0	20
Number of cycles (burst length)	128	—	—	—
t_{off} (ms)	0,0	5,0	100	500

NOTE 1 Scaling for V_{emf} (t_{dpw} = 1,0 ms) is based on IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, 201.12.4.102.3.3b), *dB/dt* PNS formula. Scale = L12 (1,0 ms)/L12 (0,1 ms) = 0,296, where L12 is the First Level Controlled Operating Mode in whole body gradients.

NOTE 2 V_{emf} 10 % to 90 % rise time, t_{edge} approximately 2,2 τ. For a maximum gradient amplifier –3 dB bandwidth cutoff frequency f_{co} = 50 kHz; therefore $\tau = 1/(2\pi f_{co})$ = 3,2 µs and t_{edge} = 7 µs.

[a] The tolerance for time value entries is ±5 %.

[b] V_{emf} (t_{dpw} = 0,2 ms) is determined from the maximum slew rate (SR-max) identified in the AIMD MR Conditional labelling using any of the three tiered methods defined in Annex A.

[c] V_{emf} (t_{dpw} = 1,0 ms) is 0,296 × V_{emf} (t_{dpw} = 0,1 ms).

16.5.4 Test procedure

The following procedure shall be used for gradient injected immunity tests.

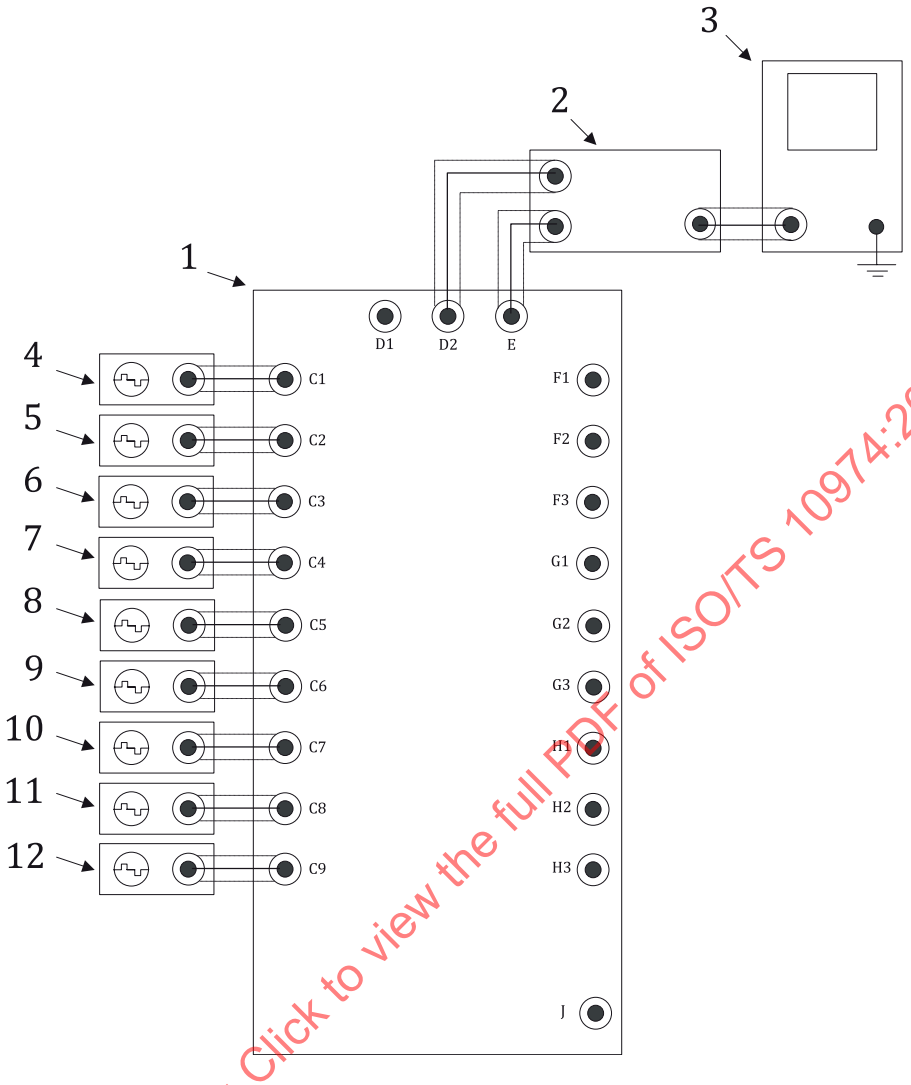
Step 1 Connect the test signal generator(s) to input Port C of the tissue interface network, Figure 34, as shown in Figure 29. All AIMD ports and electrodes shall be simultaneously driven unless appropriate justification for limited testing is provided.

Step 2 Connect the AIMD to the tissue interface network in accordance with 16.5.5. Close the switches across all Cx capacitors to remove them from the circuit.

Step 3 Apply the test voltage waveform of Figure 28 and measure the test signal at Port D2 using an oscilloscope. Adjust the test injection voltage amplitude as necessary to achieve the proper level as determined from Annex A.

Step 4 If AIMD output therapy is enabled during MRI, observe AIMD therapy output waveforms by connecting an oscilloscope and differential amplifier between test Port D2 and test Port E. Apply the test signal for each gradient sequence for a minimum of 15 s, or longer if necessary to observe potential device effects.

For AIMDs having multiple leads or leads with multiple electrodes, testing of the AIMD shall be repeated with a sufficient set of injected voltage test cases to subject the device to the maximum common and differential mode voltages expected to be experienced during clinical use. Electrode voltage amplitude and polarity differences due to electrode spatial separation and lead paths should be considered.



Key

1 gradient tissue interface network (see Figure 34)
2 differential amplifier
3 oscilloscope
4 EMF voltage test signal 1
5 EMF voltage test signal 2
6 EMF voltage test signal 3
7 EMF voltage test signal 4
8 EMF voltage test signal 5
9 EMF voltage test signal 6
10 EMF voltage test signal 7
11 EMF voltage test signal 8
12 EMF voltage test signal 9

Figure 29 — Test setup for gradient-induced malfunction

16.5.5 AIMD test configuration

16.5.5.1 General

The AIMD shall be categorised into one, or both of two groups, as appropriate:

— Single-lead devices or devices having tissue contacting electrodes mounted exclusively on its enclosure shall be Group a);

— Multi-lead devices shall be Group b).

Single lead AIMDs shall be tested in the common mode test configuration.

Multi lead AIMDs shall be tested in common and differential mode test configurations.

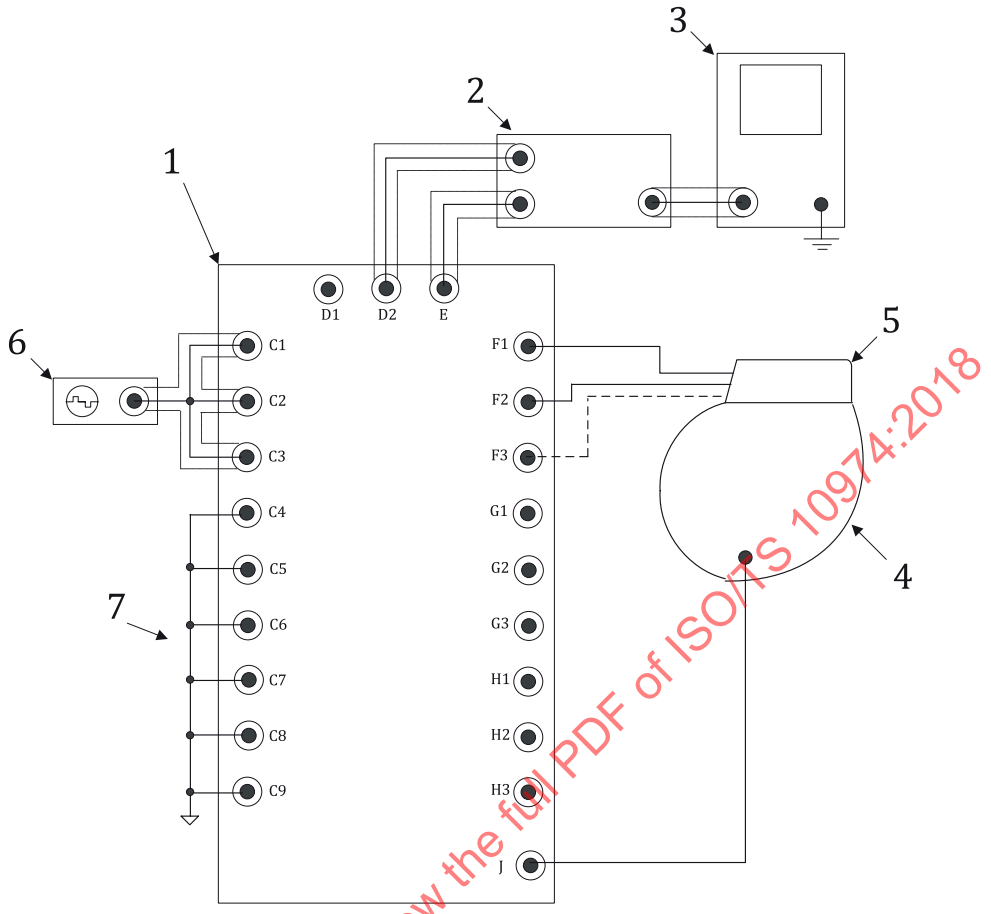
AIMDs that can be implanted in either a single, or in a multiple lead configurations, shall be tested in both single and multi-lead AIMD configurations unless the manufacturer can show that one case is always worse than the other. In this case, only testing in the worst case is required.

Additional differential testing is required for single or multi lead AIMDs having leads that contain spatially separated electrodes such that gradient-induced electrode voltage differences within the lead are significant.

16.5.5.2 Group a)

The tissue interface network connections for a single lead AIMD with negligible gradient-induced intra-lead electrode voltage differences are shown in Figure 30. Connect Port F to the AIMD lead port, and Port J to the AIMD conductive enclosure. For AIMDs containing a multi-electrode lead port, connect the electrodes individually to Port F1, Port F2, through Port Fn.

The AIMD shall be tested by applying a common test signal voltage, V_{emf}, at Port C greater than or equal to the maximum gradient-induced *in vivo* voltage expected to develop between the AIMD lead electrodes and enclosure.



Key

1 gradient tissue interface network (see Figure 34)
2 differential amplifier
3 oscilloscope
4 AIMD
5 AIMD lead port or enclosure mounted electrodes
6 EMF test signal
7 spare inputs terminated to ground

Figure 30 — Test setup, single lead AIMD with negligible gradient-induced intra-electrode voltage

The tissue interface network connections for a single lead AIMD with significant gradient-induced intra-lead electrode voltage differences are shown in Figure 31. Connect Port F to the AIMD lead port, and Port J to the AIMD conductive enclosure. For AIMDs containing a multi-electrode lead port, connect the electrodes individually to Port F1, Port F2, through Port Fn.

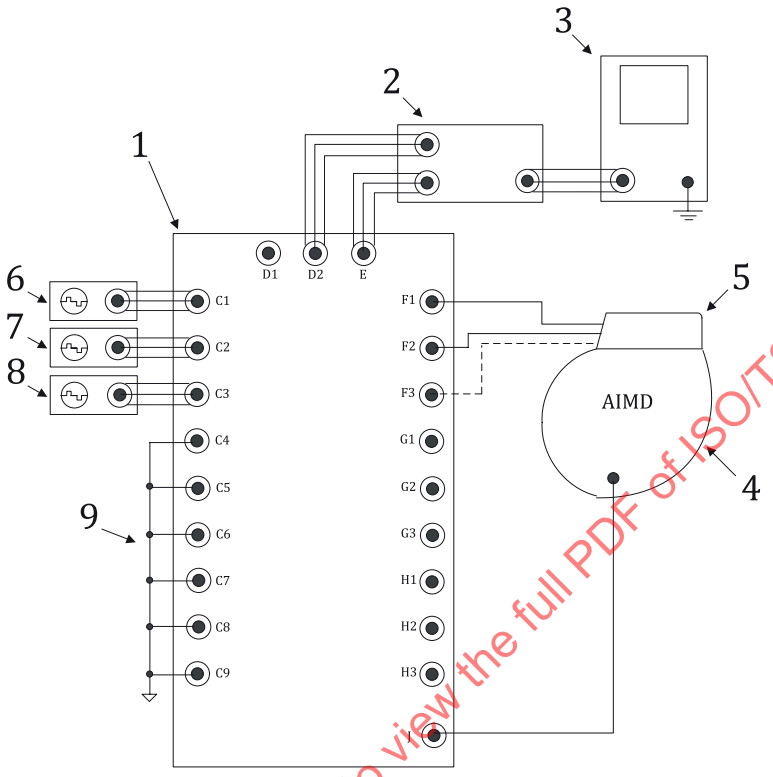
Connect separate Port C voltage generators as required to apply the V_{emf} test voltage at each AIMD lead port. Lead electrode voltages are driven independently as shown in Figure 31 and the AIMD tested using electrode voltage combinations that maximize electrode to enclosure voltages (common mode) and electrode to electrode difference voltages (differential mode).

Common Mode: The AIMD shall be tested by applying test signal voltages greater than or equal to the maximum *in vivo* gradient-induced common mode voltage expected to develop between the AIMD lead or case mounted electrodes and enclosure during maximum gradient *dB/dt* exposure at each lead port. For example Port C1 through Port C3 (see Figure 30).

Differential Mode: The AIMD shall be tested by applying the maximum gradient-induced differential voltage expected to develop between lead or enclosure mounted electrodes during maximum gradient

dB/dt exposure. Identify the maximum electrode voltage differences between each electrode pairing during maximum *dB/dt* exposure considering patient anatomical and AIMD implant variation. Test the AIMD by applying the combinations of maximum electrode voltage differences (see Figure 31).

NOTE Spatially separated electrodes within the same lead can result in significantly different gradient-induced electrode voltages.



Key

1 gradient tissue interface network (see Figure 34)
2 differential amplifier
3 oscilloscope
4 AIMD
5 AIMD lead port or enclosure mounted electrodes
6 EMF test signal 1
7 EMF test signal 2
8 EMF test signal 3
9 spare inputs terminated to ground

Figure 31 — Test setup, single lead AIMD with significant gradient-induced intra-electrode voltage

16.5.5.3 Group b)

The tissue interface network connections for a multi-lead AIMD with negligible gradient-induced intra-lead electrode voltage differences within each lead port are shown in Figure 32. Connect Port F to AIMD lead Port 1, Port G to AIMD lead Port 2, etc., and Port J to the AIMD conductive enclosure. For AIMDs containing a multi-electrode lead port, connect the electrodes individually to the corresponding tissue interface network port, for example AIMD lead Port 1 to Port F1, Port F2, through Port Fn.

Connect separate voltage generators at Port C as required to apply the V_{emf} test voltage at each AIMD lead port independently as shown in Figure 32. The AIMD is tested using electrode voltage combinations

that maximize electrode to enclosure voltages (common mode) and electrode to electrode difference voltages (differential mode).

Common Mode: The AIMD shall be tested by applying test signal voltages greater than, or equal to the maximum *in vivo* gradient-induced common mode voltage expected to develop between the AIMD lead electrodes and enclosure during maximum gradient *dB/dt* exposure at each lead port. For example Port C1 through Port C3 (AIMD lead Port 1), and Port C4 through Port C6 (AIMD lead Port 2) (see Figure 32).

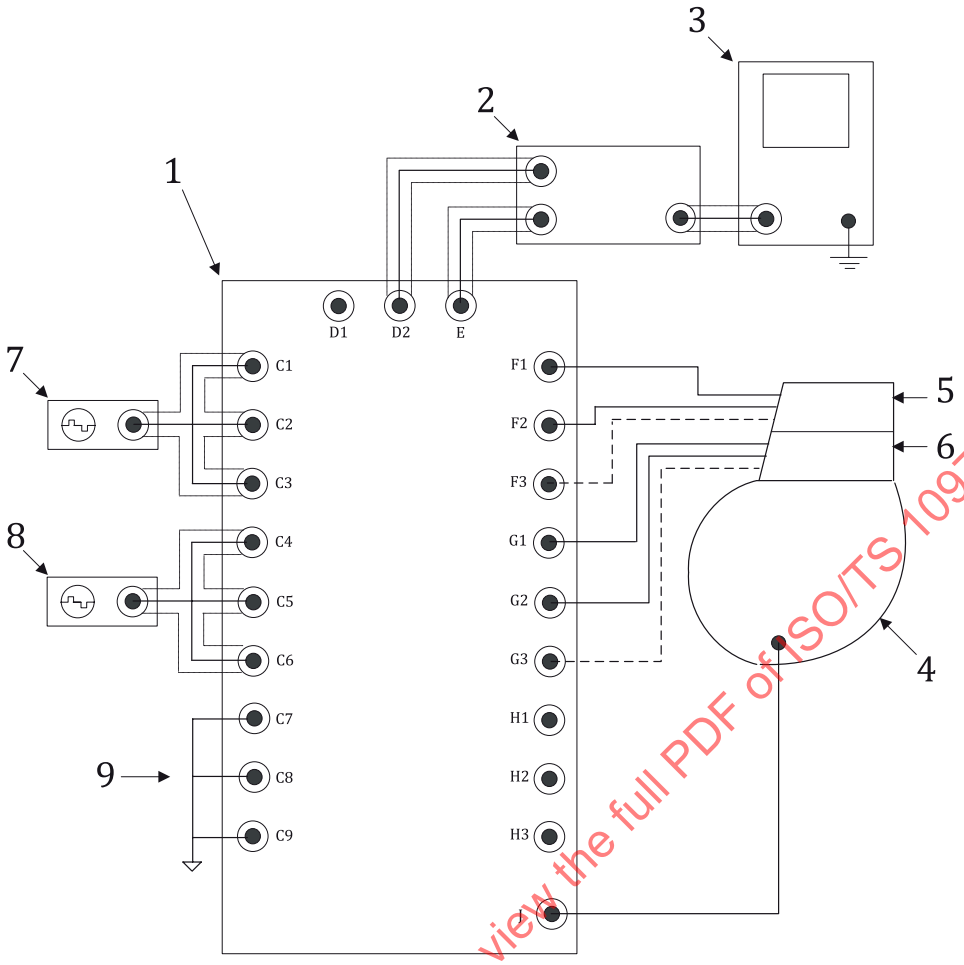
Differential Mode: The AIMD shall be tested by applying the maximum gradient-induced differential voltage expected to develop between AIMD lead ports during maximum gradient *dB/dt* exposure. Identify maximum and minimum induced voltage for each lead port or electrode during maximum *dB/dt* exposure considering patient anatomical and AIMD implant variation. Test the AIMD by applying all possible combinations of maximum and minimum voltages for the AIMD lead ports (see Figure 32).

For the two lead port AIMD example illustrated in Figure 32 the AIMD is tested by applying at least three test voltage cases as shown in Table 13.

Table 13 — Example multi-lead AIMD malfunction voltage test cases

Test cases	Test voltage applied to AIMD lead port 1[a] (Port C1, Port C2, Port C3)	Test voltage applied to AIMD lead port 2[a] (Port C4, Port C5, Port C6)	Mode
Test 1	*Max*	*Max*	Common mode
Test 2	*Max*	*Min*	Differential mode
Test 3	*Min*	*Max*	Differential mode

[a] *Min* can represent either negative voltage, small positive voltage, or zero voltage.



Key

1 gradient tissue interface network (see Figure 34)
2 differential amplifier
3 oscilloscope
4 AIMD
5 AIMD lead port 1
6 AIMD lead port 2
7 EMF test signal 1
8 EMF test signal 2
9 spare inputs terminated to ground

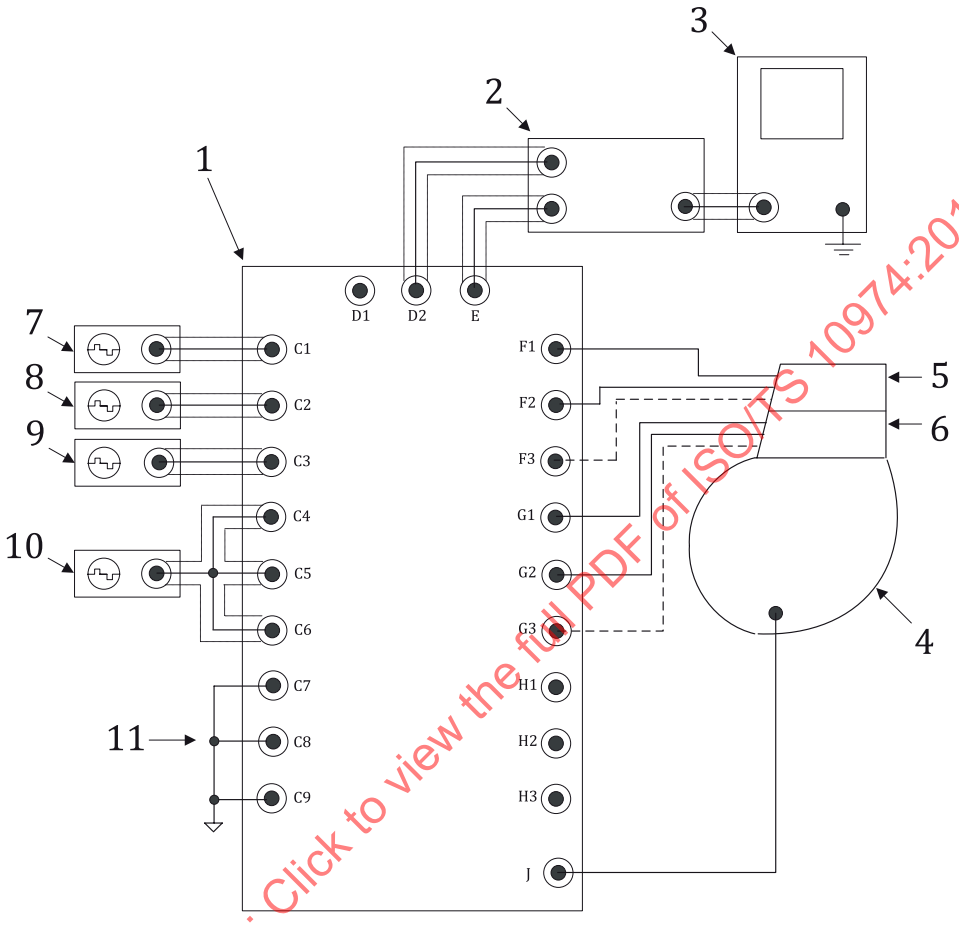
Figure 32 — Test setup, multi-lead AIMD with negligible gradient-induced intra-electrode voltage

The tissue interface network connections for a multi-lead AIMD with significant gradient-induced intra-lead electrode voltage differences within the same lead port, e.g. Port 1, are shown in Figure 33. Connect Port F to AIMD lead Port 1, Port G to AIMD lead Port 2, etc., and Port J to the AIMD conductive enclosure. For AIMDs containing a multi-electrode lead port, connect the electrodes individually to the corresponding tissue interface network port. For example, connect AIMD lead Port 1, electrode 1 to test box Port F1, AIMD lead Port 1 electrode 2 to test box Port F2, AIMD lead Port 2 electrodes to Port G, etc., and Port J to the AIMD conductive enclosure.

Connect separate Port C voltage generators as required to apply the V_{emf} test voltage at each AIMD lead port. Lead electrode voltages are driven independently as shown in Figure 33 and the AIMD tested using electrode voltage combinations that maximize electrode to enclosure voltages (common mode)

and electrode to electrode difference voltages (differential mode) as shown in Table 13. Additional differential mode test cases might be needed to cover intra-electrode voltage difference combinations.

NOTE Spatially separated electrodes within the same lead might result in significantly different gradient-induced electrode voltages.



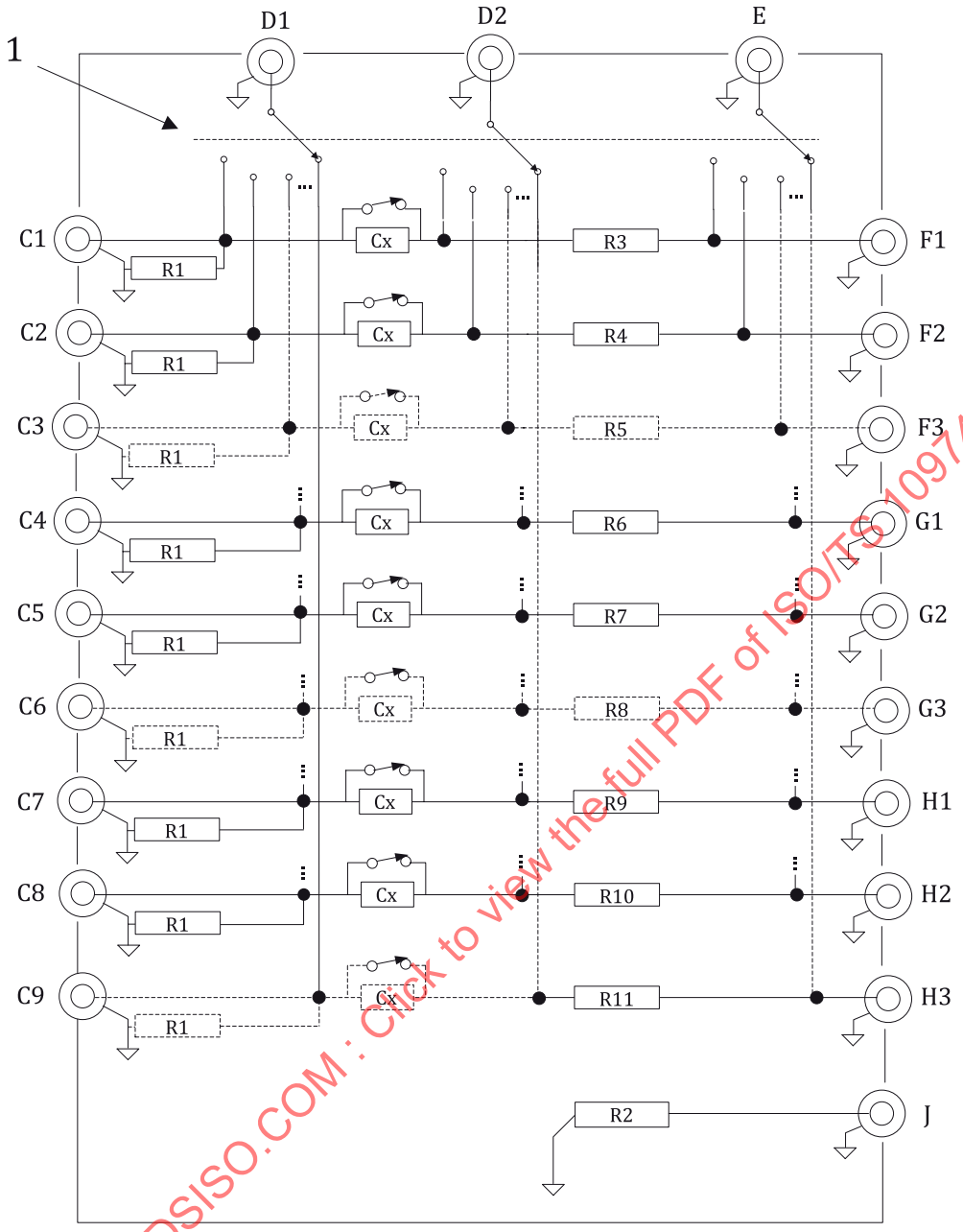
Key

1 gradient tissue interface network (see Figure 34)
2 differential amplifier
3 oscilloscope
4 AIMD
5 AIMD lead port 1
6 AIMD lead port 2
7 EMF test signal 1
8 EMF test signal 2
9 EMF test signal 3
10 EMF test signal 4
11 spare inputs terminated to ground

Figure 33 — Test setup, multi-lead AIMD with significant intra-lead electrode voltage

16.5.5.4 Tissue interface network

Figure 34 is a tissue interface network for observing the AIMD while the simulated gradient-induced pulse voltage is applied during the injected voltage tests of Clause 13 and Clause 16.



Key

1	multi-pole, multi-throw switch, e.g. 3P9T, or equivalent electrical function
C1 – C9	injected test voltage input ports
F1 – F3	AIMD lead port 1
G1 – G3	AIMD lead port 2
H1 – H3	AIMD lead port 3
J	AIMD enclosure port contact
D1, D2, E	measurement points
R1	signal generator impedance matching resistor
R2	AIMD enclosure port impedance matching resistor
R2 – R11	lead port series coupling resistor
Cx	charge integration capacitor

NOTE 1 Port F, Port G, and Port H connect to individual lead ports of a multi-lead AIMD. Port F1 is connected to the first electrode, Port F2 to the second electrode, etc. The AIMD conductive enclosure is terminated to Port J.

NOTE 2 Dashed lines in the figure indicate expansion to accommodate AIMDs with more lead ports or additional lead electrodes.

NOTE 3 Test voltages representing the gradient-induced voltages that develop between the lead electrodes and AIMD enclosure or between other lead electrodes are applied at the Port C inputs. Port C inputs can be driven in parallel in order to minimize the number of EMF test signal generators required if the electrode voltage differences on a multi-electrode lead port are negligible. In this case, a single R1 resistor is sufficient to terminate Port C inputs driven in common.

NOTE 4 D2 is a test point for monitoring the injected signal.

NOTE 5 The operation of the DUT is observed using an oscilloscope connected to a differential amplifier connected to Port D2 and Port E. The multi-pole multi-throw switch shown selects one of n resistors, i.e. R3 – R11, to enable observation at Port D2 and Port E.

NOTE 6 Cx charge integration capacitor and switch are optional components for Clause 13, and are not used for Clause 16 malfunction testing. When used in Clause 13, the voltage across Cx is monitored using Port D1 and Port D2. If Cx is present, the associated switches are closed for Clause 16 malfunction testing.

Figure 34 — Tissue interface network, injected immunity tests

Annex O or an alternate measurement method may be used to determine AIMD electrode tissue interface impedance.

Table 14 component values are for an example multi-chamber pacemaker; other AIMD types might require alternate value selection.

An analysis should be performed to show that the gradient test signal level in combination with the tissue interface network provides a conservative test when the real source impedance of the AIMD electrode tissue interface is taken into account.

Table 14 — Example component values for Figure 34

Component	Value ohms	Component	Value ohms
R1	50 (2 W)	R7	250
R2	20	R8	250
R3	250	R9	250
R4	250	R10	250
R5	250	R11	250
R6	250	Cx (see note)	Not applicable
NOTE Experience has shown that Cx greater than 10x the AIMD electrode port input capacitance (to conductive AIMD enclosure) is appropriate.			

17 Combined fields test

17.1 Introduction

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 individual tests in accordance with Clause 8 through Clause 16, the Combined Fields Test exposes the AIMD to representative levels and temporal patterns of all three MR magnetic fields simultaneously.

The Combined Fields Test is performed using an AIMD positioned in a tissue-simulating media phantom and placed inside an MR scanner. The AIMD is exposed to a series of MR imaging sequences performed at different positions relative to the MR scanner's isocentre.

For compliance criteria see 7.1.

NOTE Failure of the AIMD to meet the compliance criteria according to 7.1, as a result of the Combined Fields Test, indicates that the AIMD has a temporal sensitivity to the combined MR fields.

17.2 Test setup

An ASTM phantom[1] with AIMD inside shall be placed on the MR scanner patient table and positioned within the scanner bore as indicated in Figure 35 and Table 15 for each specified scan protocol listed in Table 16. Alternatively, the manufacturer can determine and provide rationale for the selection of landmarks and sequences used for the test. In this case, the general guidelines described below shall be considered.

For AIMDs generally implanted in anatomic regions not represented by the ASTM torso phantom (e.g. the legs or arms) more representative limb phantoms can be developed and may be used or the ASTM torso phantom may be used.

NOTE 1 Landmarks and sequences applicable to specific categories of devices might also be defined in product specific standards.

The Combined Fields Test provides field exposures typically encountered in clinical MR examinations. Guidance for the selection of protocols is provided in Annex S based on a literature survey of current clinical practice. Additional imaging protocols may be added to extend test coverage.

NOTE 2 Expect variation in design parameters between MR vendors and system types, e.g. with respect to the MR centre frequency, filter characteristics of the gradient signal, and RF peak power.

NOTE 3 IEC 60601-2-33 requires MR Vendors to provide compatibility protocols for a purpose similar to the Combined Fields Test, i.e. type tests of the combination of auxiliary equipment near the MR scanner. A test of the AIMD using these compatibility protocols might be considered. The justification of using compatibility protocols is beyond the scope of this document and is therefore up to the manufacturer.

The following steps shall be followed when implementing the MR imaging protocols described in Table 16 on a particular MR scanner:

— Set up each protocol to image the clinical planes typical for the anatomic target region specified (see examples provided in Annex S);

— Incorporate a localizer scan before each imaging protocol (unless the targeted Field of View remains unchanged from the previous protocol);

— Allow the scanner to perform all regular clinical calibration and pre-scan operations;

— Image with the whole body coil (other volume transmit coils shall be considered only if allowed in AIMD MR Conditional labelling and if the RF coupling would exceed the coupling from the whole body coil);

— Cardiac protocols should be ECG triggered at 60 bpm, either through MR scanner software or external hardware (pulse generator, cardiac waveform generator, etc.);

— Position the Field of View such that:

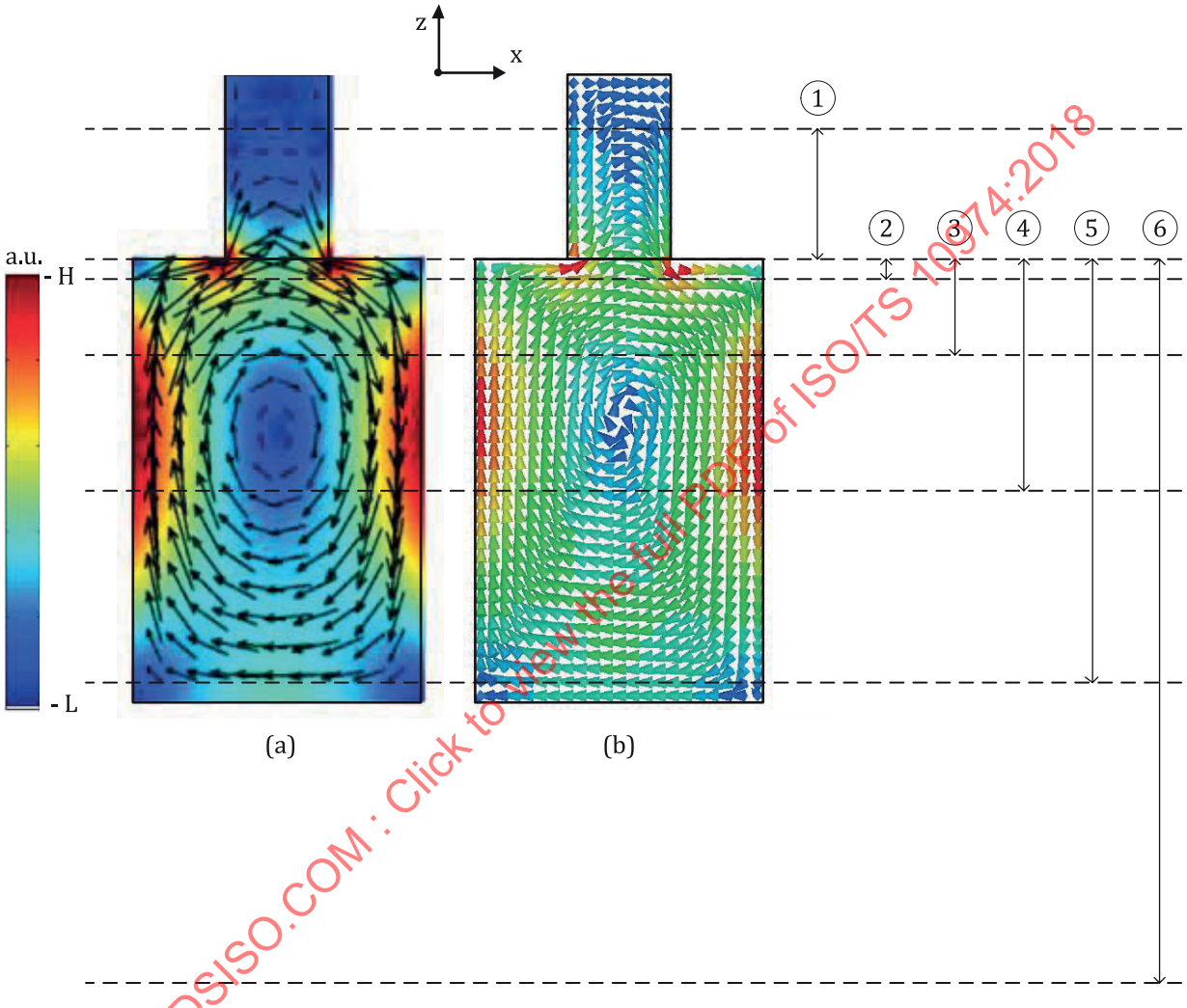
  1) x-axis is centred at the phantom centre;

  2) y-axis is centred at the phantom centre;

  3) z-axis is centred at the current landmark position according to the protocol to run.

Landmarks may be excluded if not relevant for the AIMD under evaluation (e.g. in the case of implanted location according to MR Conditional labelling). In this case, the protocols associated with the excluded landmarks shall be run with the nearest landmark that is consistent with the implant location.

Care should be taken to properly load the MR scanner, particularly for landmarks where the majority of the phantom is outside the MR scanner bore. Proper loading can be achieved by placing additional saline bottles on the patient table within the MR scanner bore as necessary.



Key

dotted lines	represent the locations of the scanner isocentre (landmark location) with respect to the ASTM phantom [1]. The corresponding distance values are shown in Table 15
① – ⑥	represent different landmark positions; see Table 15
(a)	simulated electric field pattern (arbitrary units) in the phantom centred at the scanner isocentre induced by a vertical (y-) axis gradient coil
(b)	simulated RF-induced electric field pattern (arbitrary units) in the phantom centred at the scanner isocentre
a.u.	colour bar arbitrary units
L	low field intensity
H	high field intensity

Figure 35 — Locations of isocentre landmarks

Table 15 — Locations of the MR scanner isocentre (landmark position)

Landmark	Position[a] cm
1	–19
2	3
3	14
4	34
5	62
6	106

[a] See Figure 35.

Table 16 — Scan protocols, with corresponding landmark position

Protocol target region	Landmark	Minimum duration min
Neurological examinations		
Brain	1[a]	6
Lumbar spine	5	4
Thoracic examinations		
Liver	4	4
Kidney	4	2
MRCP	4	2
Enterography	4	2
Breast	3	2
Cardiac	3	5
Upper limb examinations		
Hand	5	3
Shoulder	2	3
Hip examinations		
Prostate	5	3
Vulva and vagina	5	5
Lower limb examinations		
Knee	6	2
Thigh	6	5

NOTE Minimum duration for each MR scan protocol is based on literature data presented in Annex S. Such durations are representative and can vary.

[a] In case the rectangular ASTM phantom is used, Landmark 1 testing shall be completed at Landmark 2.

17.3 AIMD fixation

The AIMD system including all implanted components shall be placed in the phantom before testing.

To avoid MR scanner RF polarization dependence the AIMD system shall be placed with its largest dimensions, generally within a coronal imaging plane, at the central depth in the phantom tissue simulating media.

The AIMD should be located within the coronal plane in such a way as to maximize RF and Gradient field interaction (see Annex S for an example). In order to achieve that, more than one AIMD position might be necessary.

Fixtures may be used to facilitate the positioning of the AIMD inside the phantom provided they are made of nonconductive material.

17.4 Test procedure

17.4.1 General

Repeat the procedures in 17.4.2 to 17.4.4 for all the AIMD configurations selected for testing (See Annex S for an example of AIMD configurations).

17.4.2 Before MR exposure

Step 1 Set the AIMD to its intended MR Conditional mode or operating parameters as specified by the device MR Conditional labelling.

Step 2 Place the AIMD in the phantom along with any required monitoring apparatus.

17.4.3 During MR exposure

Step 1 Prior to each imaging protocol specified in Table 16 move the phantom to the landmark position defined in Table 15.

Step 2 Position the MR Field of View according to guidelines in 17.2.

Step 3 Run the MR protocol.

Step 4 If relevant, monitor the AIMD outputs during exposure. For monitoring system see 17.5.3.

Step 5 Repeat Step 1 to Step 4 for all imaging protocols selected for this test.

17.4.4 After MR exposure

Step 1 Remove the phantom from the MR scanner bore. The AIMD may be removed from the phantom for further testing.

Step 2 Verify that the AIMD functions in accordance with its intended use within 30 min of the MR exposure.

Step 3 A full evaluation of the AIMD for permanent damage, malfunction, and intended use shall be performed within 14 days following the date of the test.

17.5 Test equipment

17.5.1 Field generation

Use a 1,5 T, cylindrical bore, whole body clinical scanner.

17.5.2 Phantom and tissue simulating medium

Use either one of the two ASTM phantoms as defined in Reference [1].

The tissue simulating media shall be chosen according to Annex L and based on the conductivity and permittivity that surrounds the majority of the AIMD.

17.5.3 AIMD monitoring apparatus

In case AIMD monitoring during the Combined Fields Test is required, the AIMD monitoring system shall have the following characteristics:

— The monitoring system shall allow for continuous monitoring of AIMD activity during the test;

— The monitoring system shall not perturb the AIMD activity to a degree that prevents the qualitative observation of the AIMD;

— The MR fields shall not perturb the monitoring system itself to a degree that prevents the qualitative observation of the AIMD;

— The impact of the monitoring system on the incident fields along the AIMD should be minimized.

18 Markings and accompanying documentation

18.1 Definitions

This clause applies to the AIMD accompanying documentation as defined below. The terms below are used for the purpose of this document, and may be referred to by other names by a given manufacturer:

— Patient Card: Issued to the patient by the AIMD manufacturer that identifies the implanted system;

— Patient Manual: Instructional/informative document issued to the patient by the AIMD manufacturer;

— Implant Manual: Instructions for use issued by the AIMD manufacturer for implantation of the AIMD;

— MR Procedure Manual: Instructions for MR scanning issued by the AIMD manufacturer.

18.2 Applicability of labelling requirements

Table 17 designates the subclauses (requirements) that apply to each accompanying document. All devices do not have all of these pieces of documentation. Some of this information may be combined into a single document.

Table 17 — Cross-reference of subclause requirements and document type

Accompanying document type	Audience	Applicable subclause requirements			
Patient Card	Patient Radiologist/MR Technologist	18.3.1[a]	18.3.4	18.3.5	—
Patient Manual	Patient	18.3.1	18.3.2	18.3.3	—
Implant Manual	Implanting physician	18.3.1	18.3.2	18.3.4	18.3.6
MR Procedure Manual	Referring physician (prescribes MR scan) Radiologist/MR Technologist	18.3.1	18.3.2	18.3.3	18.3.4
		18.3.6	18.3.7	18.3.8	18.3.9

NOTE It is recommended that the Patient Manual and the MR Procedure Manual be made as accessible as practical (e.g. manufacturer's website or upon request).

[a] Applicable only to Patient Cards containing patient information issued directly to the patient by the manufacturer.

18.3 Labelling requirements

18.3.1 The term "MR Conditional" together with the corresponding icon shall be used as specified in ASTM F2503.

Compliance is checked by inspection.

18.3.2 The accompanying documentation shall contain general warnings regarding the hazards that could be caused by performing an MR procedure on a patient with an AIMD.

Compliance is checked by inspection.

18.3.3 The accompanying documentation shall direct the patient to consult with the AIMD treating physician prior to an MR scan.

Compliance is checked by inspection.

18.3.4 The accompanying documentation shall contain a statement directing users to the current MR Conditional labelling (e.g. URL and phone number).

EXAMPLE "Refer to [insert URL and phone number] for current MR Conditional labelling and instructions for this device in the MR environment."

Compliance is checked by inspection.

18.3.5 The accompanying documentation shall unambiguously identify the AIMD and all of the MR Conditional AIMD system components (e.g. leads, pulse generator).

NOTE This information is needed in order for the clinician to obtain the proper MR Conditional labelling.

Compliance is checked by inspection.

18.3.6 The conditions under which a patient with an AIMD can be scanned safely shall be provided.

Compliance is checked by inspection.

18.3.7 The accompanying documentation shall include instructions for safely performing the MR procedure on the patient. This might include patient preparation, procedural instructions, special AIMD operating modes, peripheral equipment needed, necessary patient monitoring or intervention during and after scanning, or other similar instructions to ensure safety.

Compliance is checked by inspection.

18.3.8 The accompanying documentation shall describe all intended and expected AIMD operation during an MR scan.

Compliance is checked by inspection.

18.3.9 The AIMD can interfere with the acquisition of MR data, resulting in artefacts that can compromise MR images. The accompanying documentation shall contain a statement concerning AIMD-induced MR image artefacts.

NOTE ASTM F2119[7] specifies a test method for evaluating MR image distortion artefacts from passive implants and could be used to evaluate the MR image distortion artefacts from an AIMD.

Compliance is checked by inspection.

18.3.10 Positive System Identification (PSID)

PSID may be achieved through multiple means. Radiopaque markers are ineffective for PSID purposes, and therefore are not required.

Annex A
(normative)

Pulsed gradient exposure for Clause 10, Clause 13, and Clause 16

A.1 Pulsed gradient exposure for Clauses 10, 13, and 16

This normative annex defines the methods to determine the radiated *dB/dt* and injected voltage levels required to perform Clause 10 (Vibration), Clause 13 (Extrinsic Potential), and Clause 16 (Malfunction). (The *dB/dt* exposure level for gradient heating is defined separately within Clause 9.) Table A.1 summarizes the gradient field exposures that shall be determined.

Table A.1 — Gradient field exposure types determined

Clause	Gradient field induced hazard	Exposure to be determined	
		Type	Units
10	Vibration	Radiated field	*dB/dt* (peak)
13	Extrinsic lead voltage	Injected voltage	V_{emf} (peak)
16	Device malfunction	Radiated field	*dB/dt* (peak)
		Injected voltage	V_{emf} (peak)

A single method is provided for determining AIMD radiated gradient *dB/dt* peak exposure levels for Clause 10 and Clause 16.

Three tiers are provided to determine the gradient-induced AIMD electrode voltage levels for Clause 13 and Clause 16 bench injection tests.

Tier 1 through Tier 3 are applicable methods to determine the gradient induced lead electrode voltages for AIMDs with leads. Tier1 and Tier3 are applicable gradient induced voltage determination methods for AIMD enclosure mounted tissue contacting electrodes, e.g. leadless pacemaker.

Tier 1 requires the least amount of analysis and computation but results in the most conservative injected voltage level. Tier 2 and Tier 3 require additional analysis but result in more accurate and lower injected test levels:

— Tier 1, Lead Length Factor Method: Injection voltage is determined by multiplying AIMD lead length by a conservative voltage conversion factor (V/cm);

— Tier 2, Specific AIMD Lead Loop Area Method: Injection voltage is determined using Faraday's Law of Induction, multiplying the radiated *dB/dt* (T/s) exposure level by AIMD specific implant lead loop area(s);

— Tier 3, Electromagnetic Simulation Method: Injected voltage is determined through electromagnetic modelling and simulation of the gradient magnetic fields, the electric fields induced in the conductive tissues of the body, and the resulting potential developed along the AIMD and leads.

A.2 Determination of *dB/dt* for AIMD electronics module, electrodes, and extended leads

A.2.1 AIMD labelled for Fixed Parameter Option

AIMDs labelled for Fixed Parameter Option (FPO:B) shall use *dB/dt* = 100 T/s peak.

A.2.2 AIMD labelled for maximum gradient slew rate

The patient positions, postures and max gradient slew rate (T/m/s) specified in the AIMD MR Conditional labelling, as well as AIMD implant location and lead routing(s) determine the AIMD gradient *dB/dt* exposure.

Table A.2 contains AIMD system dB/dt exposure factors for cylindrical bore 1,5 T MR scanners. Figure A.2 shows the direction of the various *dB/dt* factors in relation to the MR scanner bore (green) and the gradient coil volume (grey). B_x, B_y, B_z are in the x, y, z directions respectively which can be generated from any single gradient coil. B_m is the magnitude of the vector sum, and is of arbitrary direction.

The tables contain the maximum calculated *dB/dt* factors from the 3-D vector sum of simultaneously energised G_x, G_y, G_z gradient outputs on the cylindrical surface at a radial distance, r, from the z-axis. Table entries (units T/s) are for whole body gradient systems with gradient slew rate specification ≤200 T/m/s per axis; 346 T/m/s effective. See Annex T.

The *dB/dt* determination steps that follow are illustrated in Figure A.1.

Step 1 From the patient positions (e.g. landmarks) and postures (e.g. prone, supine) specified in the AIMD MR Conditional labelling, determine the AIMD location and orientation within the MR scanner bore. Variations in AIMD implant location, patient anatomy, position, and postures on the scanner bed shall be considered. Determine the radius *r* (cm) from the MR scanner z-axis of the cylindrical volume containing the entire AIMD.

NOTE 1 The patient's body axis might be laterally offset from centreline of the MR scanner bed, especially for wider bore machines.

If the radius of the cylindrical volume containing the AIMD electronic module(s) is smaller than the radius of the cylinder containing the AIMD and leads, the smaller radius may be used to determine the radiated exposure of the AIMD electronics module for gradient-induced vibration (Clause 10) and malfunction (Clause 16).

NOTE 2 When performing Clause 16 radiated malfunction test of an AIMD with leads, adjustment of the lead paths or lead simulators might be required to obtain a proper value of induced V_{emf}.

Step 2 Identify the *dB/dt* exposure factor(s) that apply.

For Clause 10 (Vibration), gradient magnetic field components orthogonal to the AIMD's major conductive surfaces and internal components, e.g. metal enclosure and battery, are of primary importance.

For Clause 13 (Extrinsic lead voltage) and Clause 16 (Malfunction) injected voltage tests, the gradient magnetic field components orthogonal to the plane(s) containing AIMD enclosure mounted electrodes and leads are of primary importance.

For Clause 16 (Malfunction) radiated test, the gradient magnetic field components orthogonal to the AIMD's conductive surfaces, internal electronic components, modules, and circuit layout are of primary importance.

For example, the dB_y/dt factor applies for AIMDs with internal circuitry parallel to the patient coronal plane, e.g. pacemakers, transvenous implantable cardioverter defibrillators (ICD), and many neuromodulator devices if the AIMD MR Conditional labelling restricts the patient posture on the scanner patient bed prone or supine. Use the appropriate alternative *dB/dt* factor for other AIMD types or implant orientations. For example, use the B_x or B_z *dB/dt* factors for AIMDs implanted when major conductive surfaces are in the sagittal and axial planes, respectively, or use B_m for AIMD implant orientations not aligned with the anatomical planes of the body.

Step 3 Using the radius, *r*, determined in Step 1, look up the *dB/dt* factor for the AIMD from Table A.2.

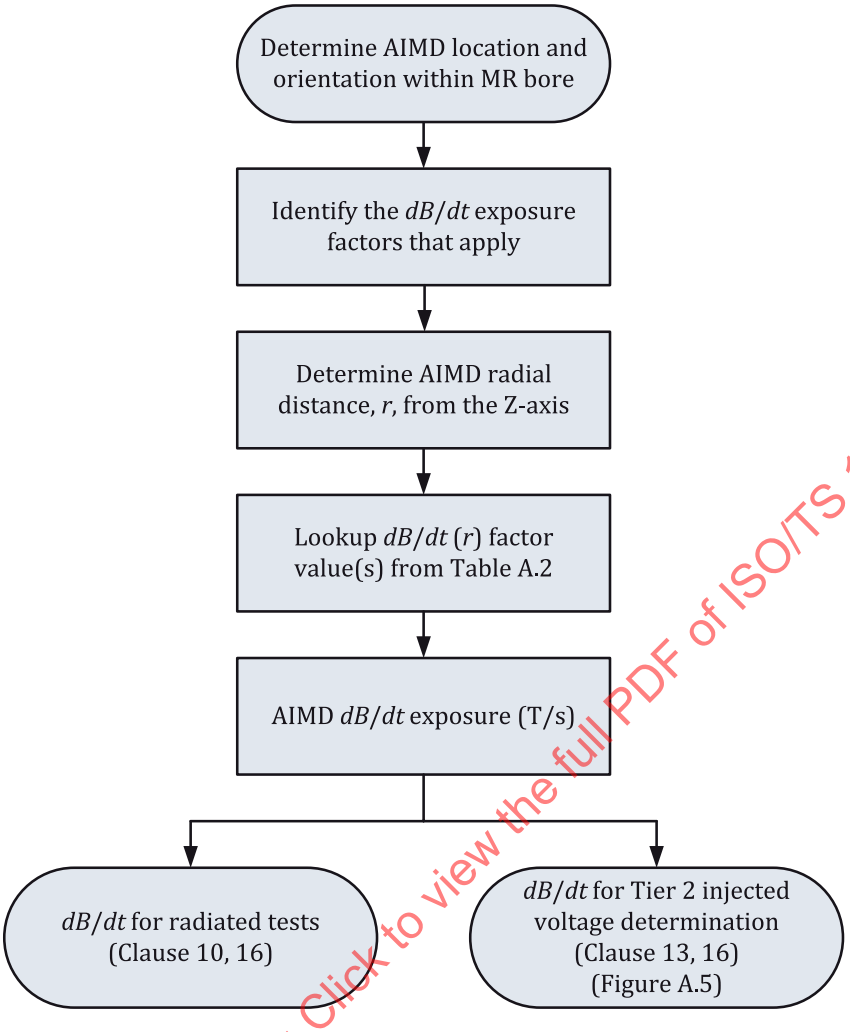
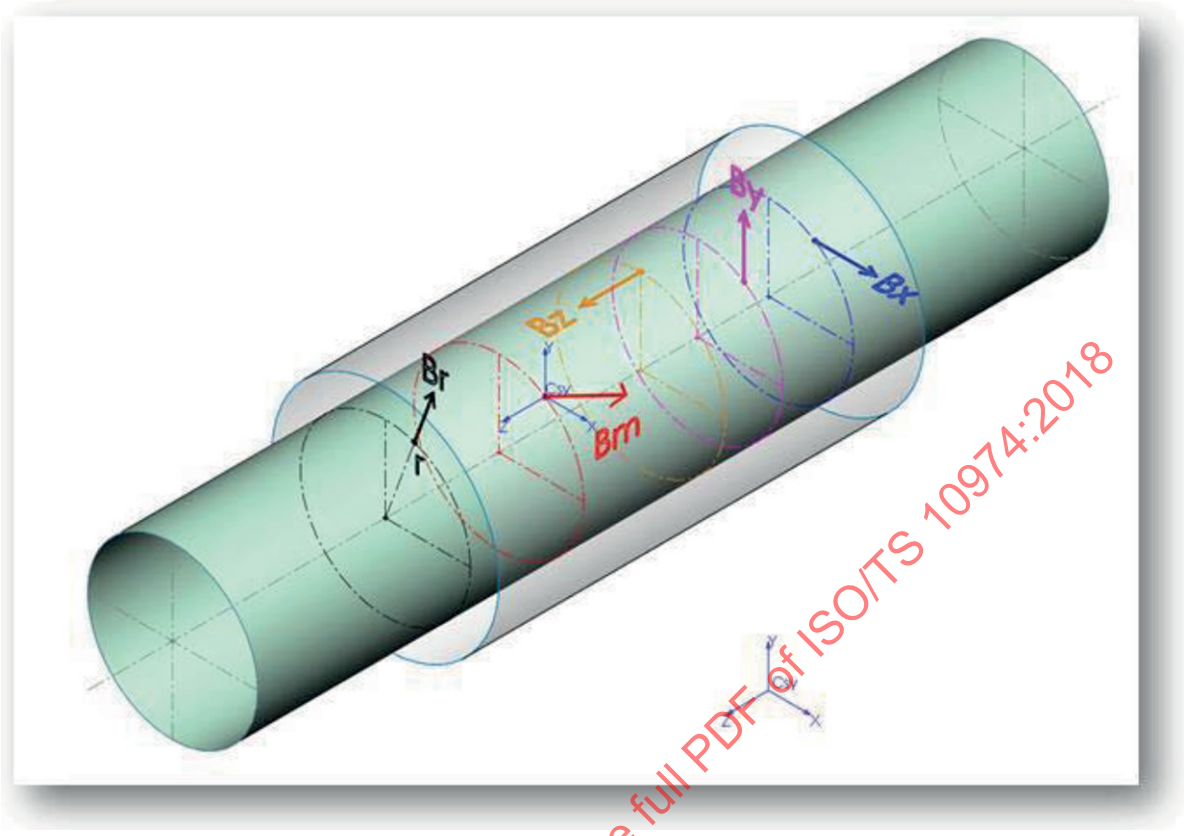


Figure A.1 — *dB/dt* determination



Key

B_x gradient magnetic field in the X direction

B_y gradient magnetic field in the Y direction

B_z gradient magnetic field in the Z direction

B_m magnitude of the vector sum of the gradient magnetic field

Figure A.2 — *dB/dt* exposure factor directional components

Table A.2 — AIMD *dB/dt* exposure factor as a function of radial distance from z-axis

XYZ *dB/dt* factors[a,b,c]			
Radial distance cm	dB_x/dt, dB_y/dt[d] T/s	dB_z/dt T/s	dB_m/dt T/s
5	58,0	65,7	101,6
6	59,0	68,5	102,9
7	59,7	70,1	103,7
8	61,0	73,4	105,3
9	62,4	75,6	106,7
10	63,7	79,3	108,7
11	65,2	81,7	110,5
12	66,9	84,2	112,4
13	69,3	88,7	115,8
14	71,3	91,9	118,5
15	73,5	96,7	122,3
16	76,0	100,1	125,3
17	78,8	105,9	130,2
18	81,9	109,6	133,5
19	86,2	114,0	137,7
20	89,8	120,4	143,4
21	93,8	125,2	148,1
22	98,3	132,7	155,2
23	103,0	137,9	160,4
24	108,2	144,1	166,8
25	115,7	153,3	176,0
26	122,4	159,2	182,3
27	129,4	169,3	192,8
28	137,2	176,7	200,9
29	146,0	188,7	214,1
30	156,8	196,8	223,5

[a] dB_x/dt, dB_y/dt, dB_z/dt are in the x, y, z directions respectively. See Figure A.2.

Key table:

B_x is the gradient magnetic field in the X direction

B_y is the gradient magnetic field in the Y direction

B_z is the gradient magnetic field in the Z direction

B_m is the magnitude of the vector sum of the gradient magnetic field

dB_m/dt is the rate of change of the magnitude of the vector sum and is of unspecified direction.

[b] Table entries are for a gradient slew rate of 200 T/m/s per axis; 346 T/m/s effective. If the AIMD MR Conditional labelling specifies a slew rate other than 200 T/m/s per axis, *dB/dt* factor table entries may be scaled:

$$\text{scaled}\ \frac{dB}{dt}\ \text{factor} = \frac{\text{Labelled SR-per axis}}{200} \times \text{Table A.2}\ \frac{dB}{dt}\ \text{factor}$$

[c] The *dB/dt* directional factors tabulated in each row (radius) are generally from different x, y, and z coil models and occur at different z locations. Therefore, these are not paired data. For example, the vector sum of x, y, and z component is not B_m.

[d] For areas less than 16 cm^2, values up to 15 % higher have been reported. This increase is not applicable to the Tier 2 lead loop area induced voltage method.

A.3 Injected voltage determination

A.3.1 General

The injected voltage tests of Clause 13 and Clause 16 require the gradient-induced voltages between patient lead electrodes and the AIMD conductive enclosure be determined. In addition, inter-lead electrode difference voltages (between electrodes on different leads), or intra-electrode difference voltages (between electrodes on the same lead) need to be determined and tested if significant.

Care should be taken in determining gradient-induced electrode voltages. Intra-electrode voltage differences should be considered for leads with electrode separation greater than 10 cm. Differential voltages between leads for multi lead systems should be determined, especially AIMDs with leads with divergent routings in the body as these can produce induced voltages of opposite polarity. If a differential voltage analysis is not practical, a conservative test condition for the differential voltage is acceptable.

Determining common and differential mode electrode voltage using the Tiers:

— Determining common mode voltage for each lead to the AIMD enclosure can be accomplished using the conservative lead-length factor (Tier 1), the lead loop area method (Tier 2), or gradient coil and human body model electromagnetic simulation (Tier 3);

— Determining intra-electrode voltage can be accomplished using Tier 1 or Tier 3. Tier 1 and Tier 3 may also be used to determine injection voltage for enclosure mounted electrodes;

— Determining voltage differences between electrodes on separate leads (inter-lead) can most accurately be determined using Tier 3. Estimates using Tier 1 or Tier 2 methods, especially for divergent lead routings, can result in significant error requiring the test voltage(s) to be set conservatively to compensate.

NOTE More precise Tier 1 or Tier 2 inter- and intra-lead differential voltage methods that apply generally to all AIMDs are beyond the scope of this document. Improvement to Tier 1 or Tier 2 methods for determining inter- or intra-lead differential voltage might be accomplished in the vertical standards where more specific and applicable assumptions can be made by AIMD type.

A.3.2 Tier 1, Lead length multiplication factor method

This method may be applied to determine the voltage that develops between the AIMD conductive enclosure and other tissue contacting electrodes on extended leads or on other portions of the enclosure.

It assumes the gradient-induced E-field is tangential to conductive elements at every point of the extended lead or electrode. This tier will produce the highest induced voltage, and hence, the highest injected test voltages of any method in this annex. It does not require any electromagnetic computational analysis.

The Tier 1 injected voltage determination steps follow and are illustrated in Figure A.3.

Step 1 Determine the lead length voltage factor from Table A.3 using the length, l, of the external electrode or extended lead.

Step 2 Calculate the injected test voltage (gradient-induced V_{emf}) by multiplying the lead length factor from Step 1.

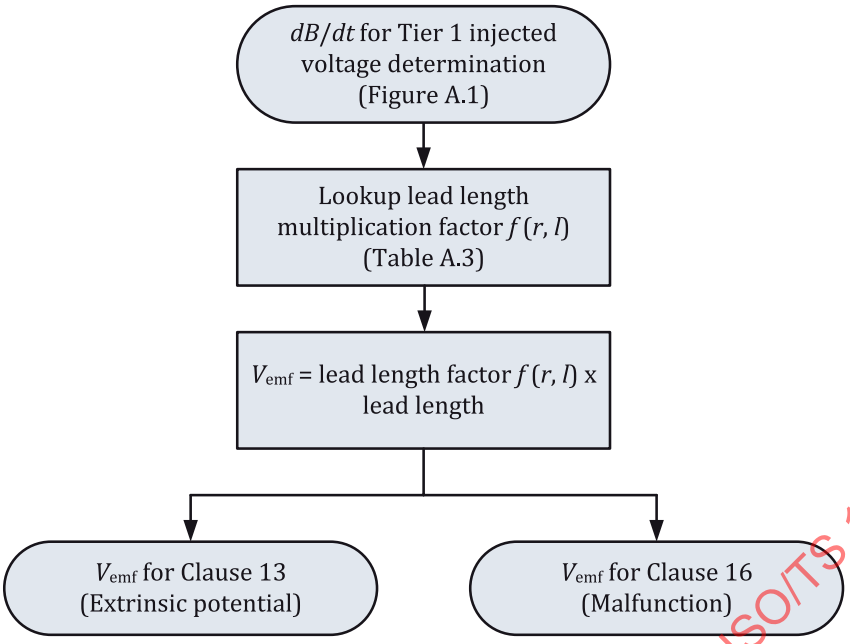


Figure A.3 — Tier 1 injected voltage determination method

Table A.3 — Lead length factor $L_x = f(r, l)$[a,b]

Length cm	$L_x = f(r, l)$[d] volts	**Basis of calculation**
$l \leq 10$	= 16,0 E-2 × l	L_x computed as $E \times l$ EM simulation of human at 100 T/s, E_{max} = 16 V/m (see Annex B)
$10 < l < 63$	= 8,87 E-2 × l + 7,13 E-1	L_x computed as $E \times l$ EM simulation of human at 100 T/s, interpolated between E_{max} = 16 V/m at 10 cm and E_{ave} = 10 V/m at 63 cm (see Annex B)

$63 \leq l \leq 200$[c]	If $l \leq \pi r$ cm then
	= $l^2/2\pi \times 1$ E+2
	else
	= 0,5 × π × a × r × 1E+2
		Lead path assumed to follow the perimeter of a semi-circle or semi-ellipse
		L_x computed as area of a semi-circle
		L_x computed as area of a semi-ellipse

[a] Units for l, a, b lengths are in cm.

[b] r is the radial distance from the MR z-axis defining the cylindrical surface containing the AIMD and extended lead(s).

[c] For lead lengths, $l \geq 63$ cm, a semi-circular or semi-elliptical lead path is assumed with both proximal and distal ends of the lead located on the z-axis. L_x is computed as the area of the semi-circle for $l \leq \pi \times r$. Lead lengths $l \geq \pi \times r$, can't follow a circular path without the circle's radius exceeding r and therefore L_x is computed as the area of a semi-ellipse.

The area of an ellipse is $\pi \times a \times b$, where a is the major axis and b (= r) is the minor axis.

Major axis a is determined by solving;

$$Lead\ length = 2a\int_0^{\pi/2} \sqrt{1-\left(\frac{a^2-b^2}{a}\right)}\left[\sin(\theta)\right]^2 d\theta$$

(see Annex B for computation method).

[d] L_x is continuous at 10 cm and again at 63 cm (corresponding to a circle radius 20 cm, $E \times l = dB/dt \times$ area).

A.3.3 Tier 2, Specific AIMD lead loop area method

This method may be used to determine the voltage that develops along AIMD extended leads ≥35 cm utilizing knowledge of the maximum specific AIMD lead loop area (m^2). If it can be demonstrated that the maximum lead loop area is less than the basis for Tier 1, it is then possible to perform the injected immunity test using smaller values of injected voltages.

The Tier 2 injected voltage determination steps follow and are illustrated in Figure A.5.

Step 1 Determine the *dB/dt* exposure for the AIMD and extended lead using the method defined in A.2.

Step 2 Determine the maximum AIMD specific implant lead loop area by anthropometric analysis, fluoroscopy, or X-ray of human implanted AIMD systems. The analysis should consider variation in anatomy, AIMD implant location, and lead deployment resulting from the implant procedure.

Step 3 For the largest loop area lead path(s) from Step 2, measure the lead path rise height (H = short axis) and run length (K = long axis) as shown in Figure A.4 and compute the aspect ratio as H/K. If $H/K < 0{,}30$ replace the measured loop area from Step 2 with that of a semicircle, area = lead-length$^2/(2\pi)$.

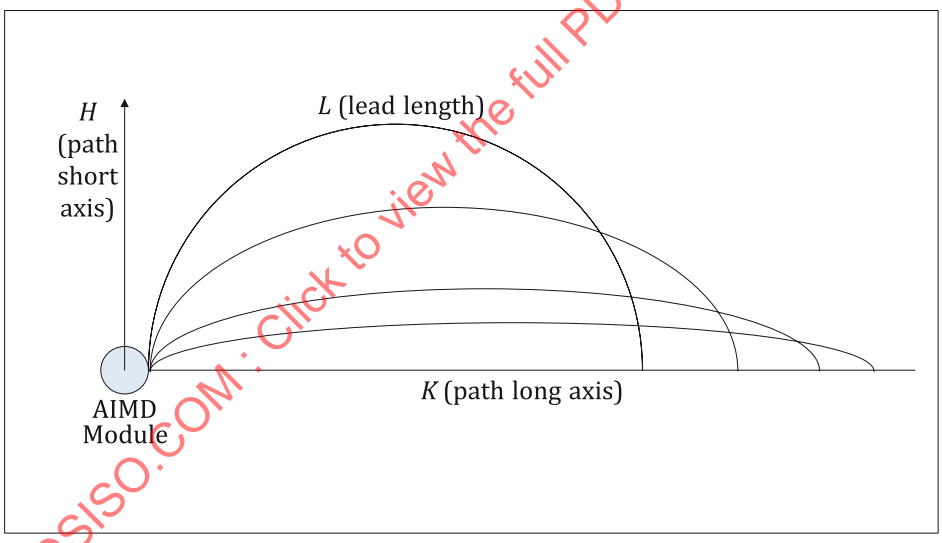


Figure A.4 — Tier 2 lead path aspect ratio measurement

Step 4 Calculate the injected test voltage (gradient-induced V_{emf}) by multiplying the *dB/dt* exposure in Step 1 by the AIMD specific lead loop area from Step 2 or Step 3.

NOTE This method utilizes Faraday's Law of Induction to calculate the voltage induced on a closed loop of wire in a changing magnetic field. Loop area calculated V_{emf} for lead paths approximated by a semi-ellipse with $H/K \geq 0{,}30$, is conservative compared to the $E \cdot dl$ method for $r \leq 20$ cm from z-axis in an ASTM phantom. The more a lead path departs from a closed loop (such as a long, straight, spinal stimulator lead path), the more inaccurate this estimate becomes. Using Faraday's Law of Induction for AIMD systems that use straight lead routings with minimal effective loop areas can result in a significant underestimation of the actual induced voltage. For these types of AIMDs, a minimum loop area of $l^2/(2\pi)$ (the loop area of a lead of length l when formed into a perfect semi-circle) is used to ensure a conservative estimate of induced voltage.

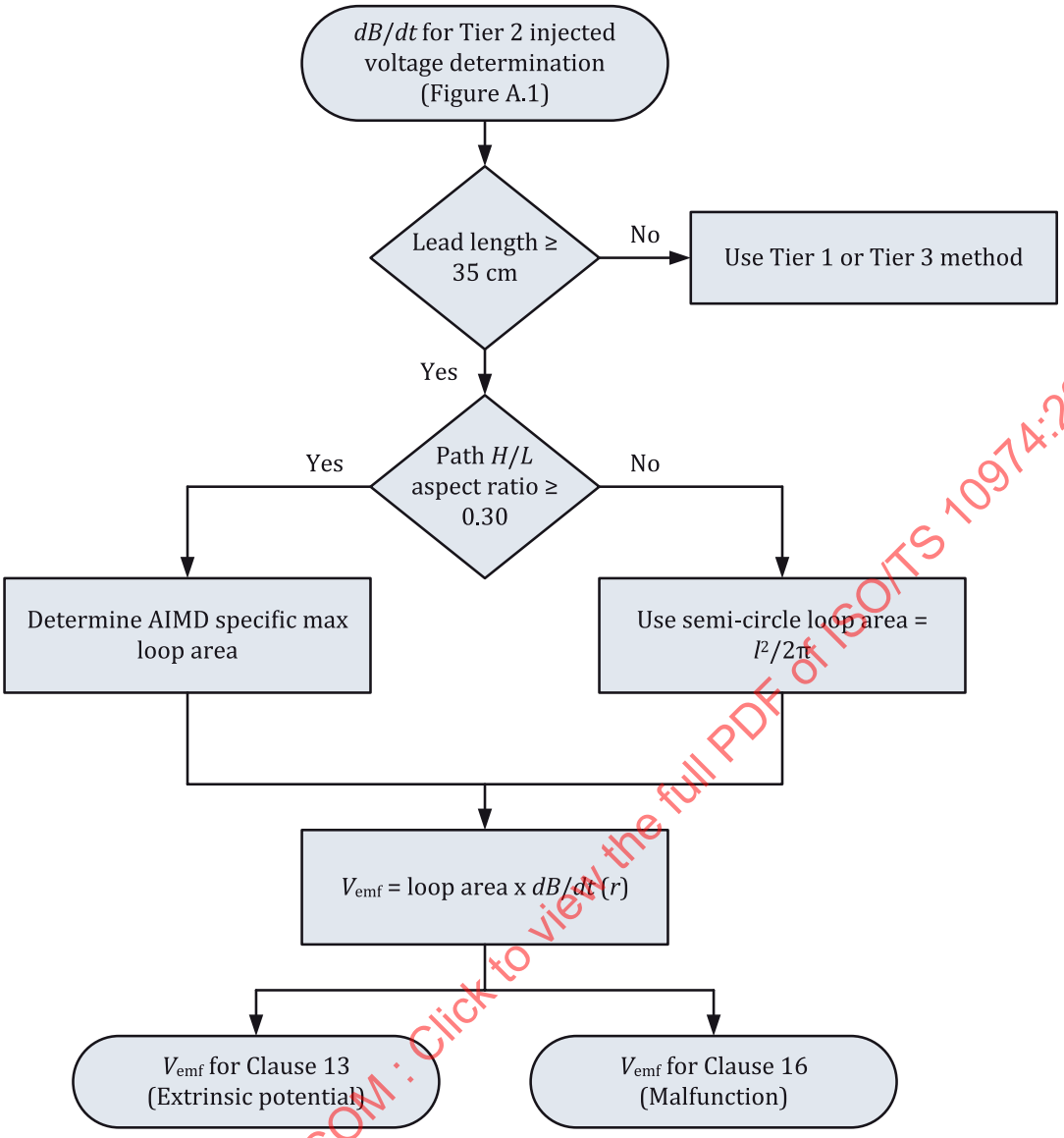


Figure A.5 — Tier 2 injected voltage determination method

A.3.4 Tier 3, Electromagnetic simulation method

Tier 3 is intended to be the most accurate method to determine the gradient-induced voltage for extended tissue contacting electrodes such as leads. It requires electromagnetic computational analysis and has the potential to predict the *in vivo* E-field most accurately and produce the lowest injected voltage test levels.

The Tier 3 injected voltage determination steps follow and are illustrated in Figure A.6.

Step 1 Use an appropriate low frequency electromagnetic simulation tool suitable for modelling the changing magnetic fields produced by the MR gradient coil(s) and the resulting electric fields induced in the conductive tissues of the human body.

Step 2 Develop or select an MR gradient coil model that produces a gradient magnetic field distribution representative of the clinical MR scanner that will be used for model validation.

Step 3 Validate the electromagnetic simulation tool and the gradient coil design. Perform an appropriate uncertainty analysis based on the model validation results (see A.3.5).

Step 4 Develop or select human body models suitably annotated with conductivity and permittivity electrical properties by tissue and organ type.

Step 5 Define AIMD implant site and associated lead trajectories considering variation in AIMD implant location and lead deployment.

Step 6 Simulate the gradient-induced electric fields in the human body models for various exposure conditions including various gradient coil designs, excitations (including the x, y, and z gradient coils) and various landmark locations throughout the MR scanner bore as defined in device labelling.

NOTE Analysis of various gradient coil designs and excitations via modelling can be limited if it can be demonstrated through sensitivity analysis that a particular gradient coil design and excitation provides conservative or worst case induced voltages.

Step 7 Compute the gradient-induced lead voltage as the integral of the tangential electric field along the lead trajectory. Apply an appropriate error factor derived from model validation that bounds the error between measurement and simulation.

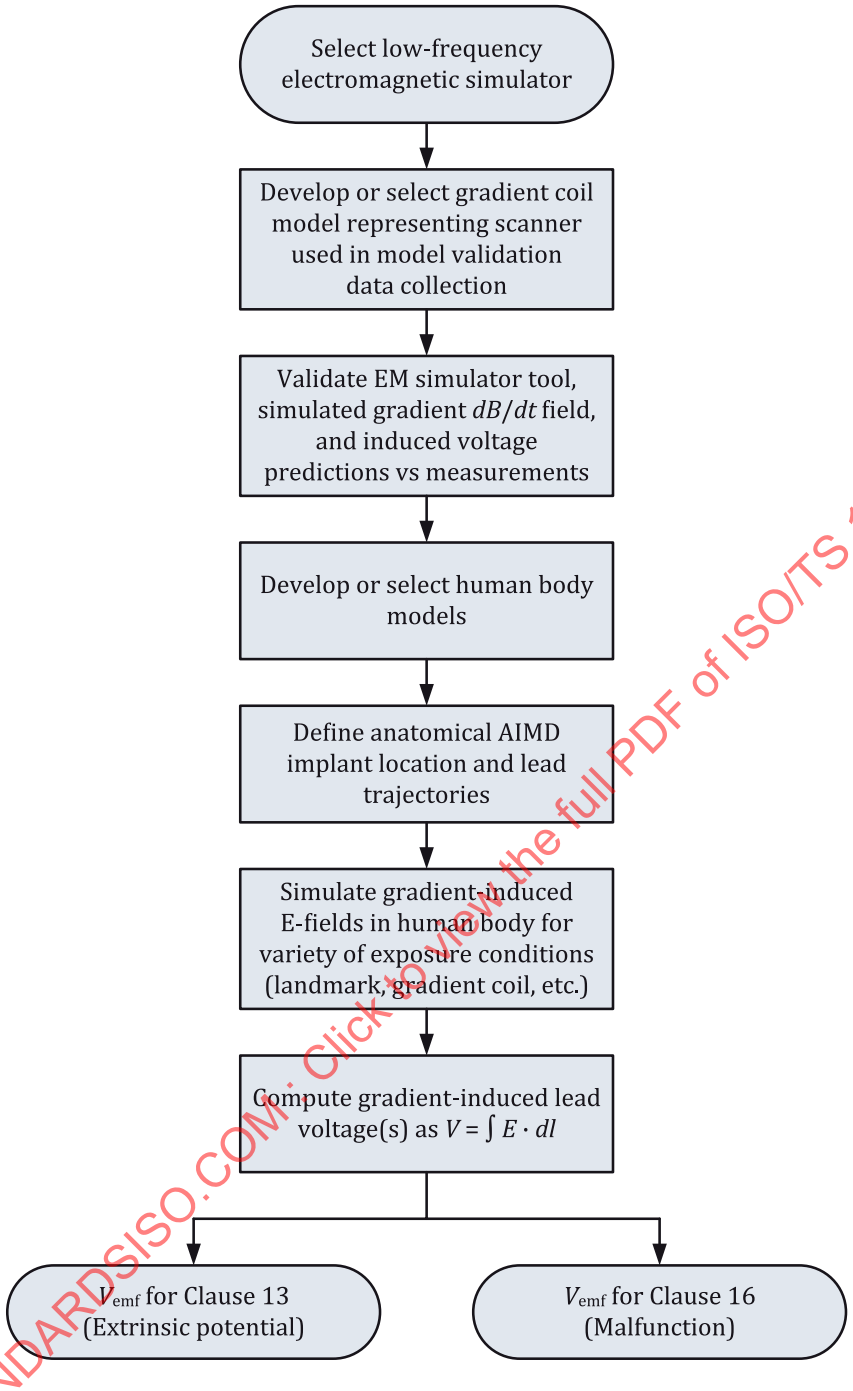


Figure A.6 — Tier 3 injected voltage determination method

A.3.5 Model validation for Tier 3

Prior to acceptance of results, a thorough model validation shall be executed that validates the low frequency electromagnetic simulation tool and the gradient coil design used in the simulations for Tier 3.

For validation of the injected voltage determined by Tier 3 the following shall be demonstrated:

— The selected gradient coil design and simulation tool, model a gradient magnetic field distribution that represents the field distribution measured in a clinical MR scanner;

— The absolute amplitudes of the measured gradient-induced voltage and the simulated gradient-induced voltage are correlated, providing confidence that the tool is appropriately simulating the electric field distribution that results from the gradient magnetic field.

Validation steps follow.

Step 1 Use a *dB/dt* search coil similar to that specified in IEC 60601-2-33 to map the 3D gradient magnetic field distribution throughout the bore of the clinical MR scanner. Demonstrate that the simulated gradient magnetic field distribution throughout the scanner bore appropriately represents the measured *dB/dt* distribution in the clinical MR scanner.

Step 2 Setup a phantom with an appropriate tissue simulating media (TSM) in the MR scanner system. A set of *in vitro* incident electric field test conditions shall be defined that exercises the model through a range a phantom positions and lead trajectories. A custom device with connections between the lead terminals and the device case shall be used to measure the gradient-induced voltage developed along a lead trajectory when the gradients are slewing. Coax or twisted pair cabling can be used to bring the lead terminal connections out of the MR scanner bore and control room to an oscilloscope with low pass filters to filter out the RF energy and gradient switching amplifier noise picked up by the leads and cabling. Measure the gradient-induced voltage for an identifiable gradient pulse such as the slice select gradient for all test conditions. Also, measure the *dB/dt* using the search coil used in Step 1 to provide the *dB/dt* amplitude of the identifiable gradient pulse that was used for induced voltage measurements.

Step 3 Model the phantom with the appropriate TSM in the gradient coil scaled to provide the measured *dB/dt* used during induced voltage measurements. Integrate the simulated tangential electric field along the tested lead trajectories to calculate the voltage. Verify that the measurements and the simulation results are correlated.

Annex B
(informative)

Derivation of lead length factor for injected voltage test levels for Clause 13 and Clause 16

This annex provides rationale for the equations found in the Tier 1 method of Annex A.

Time dependent magnetic fields are known to induce electromagnetic forces, EMF, in electrically conductive materials. The calculation of the EMF, Formula (B.1), is performed by considering the time dependent magnetic field or the associated electric field given by Maxwell's Formula (B.2).

$$EMF = -\int \frac{\partial \vec{B}}{\partial t} \cdot d\vec{a} = \int \vec{\nabla} \times \vec{E} \cdot d\vec{a} = \oint \vec{E} \cdot d\vec{l} \tag{B.1}$$

$$\vec{\nabla} \times \vec{E} = -\partial \vec{B} / \partial t \tag{B.2}$$

where

B is the magnetic field vector;

t is the duration;

E is the electric field vector.

For simplicity and to ensure a reasonably conservative value for the EMF from Formula (B.1) the following assumptions were made to calculate the lead length factor (Table A.3):

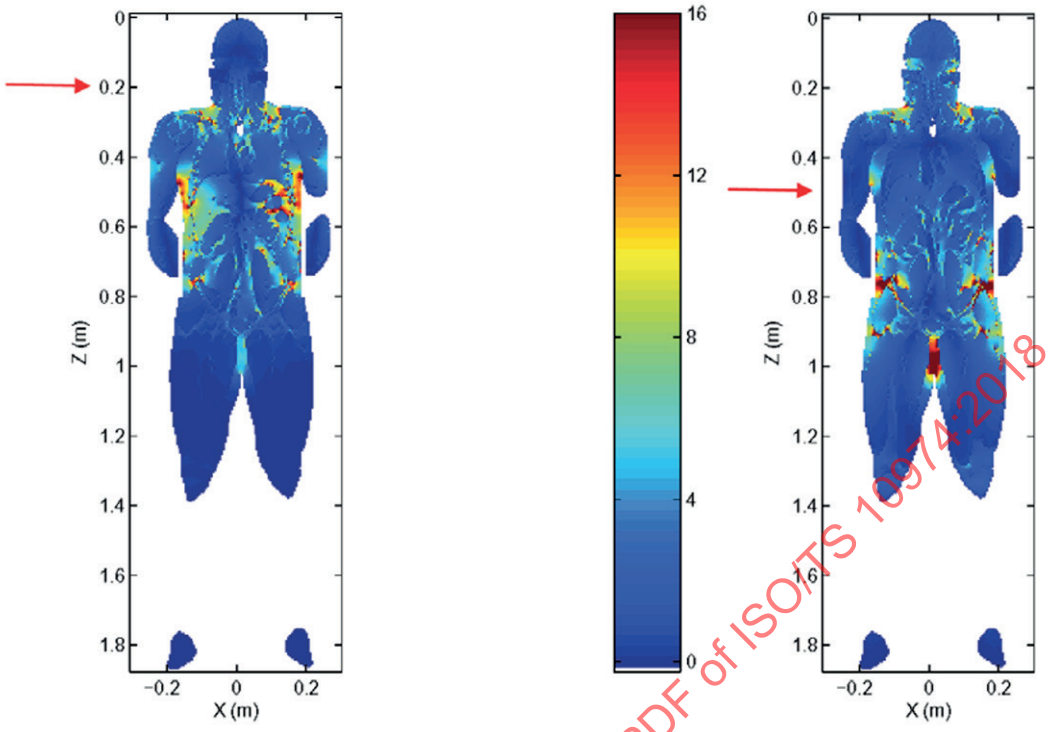
— The magnitudes of the magnetic and electric vector fields are spatially uniform;

— When considering the electric field vector, the electric field is in the same direction as the integration path and hence the lead path;

— When considering the magnetic field vector, the magnetic field is normal to the surface area defined by the integrand's area and hence the area defined by the lead path.

NOTE When making these assumptions the authors recognize and acknowledge that these constraints would not be typically realized in an MR environment.

From Formula (B.1), one can consider either the magnetic field or the electric field when calculating the EMF. In order to better understand the relationship between the magnetic and the electric fields due to gradient fields of an MR scanner simulations were performed for a gradient field from a typical MR scan, Figure B.1 and Figure B.2. The simulations were performed with a maximum *dB/dt* of 100 T/s at a cylinder radius of 20 cm. These simulations demonstrate that for a *dB/dt* of 100 T/s the electric field values have a peak of 16 V/m, and 10 V/m is a conservative average for lead lengths of 10 cm and greater.

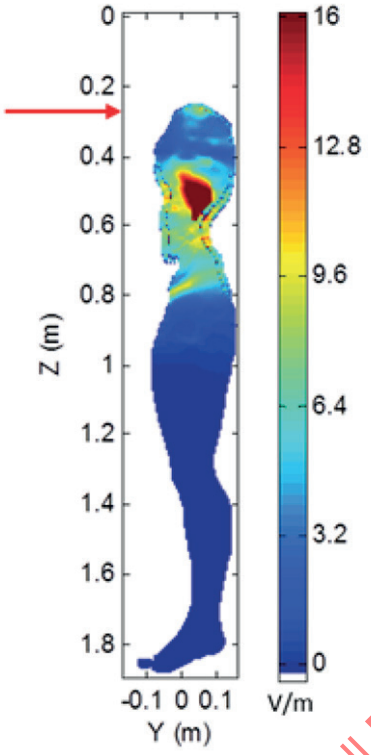


Key

1 landmarks (centre of RF coil) are indicated by the arrows

2 maximal *dB/dt* on a cylinder of 20 cm radius is 100 T/s; colour bar is in V/m

Figure B.1 — Calculated electric field intensity in human model in a y-gradient coil in a coronal slice through the vertical centre of the patient



Key

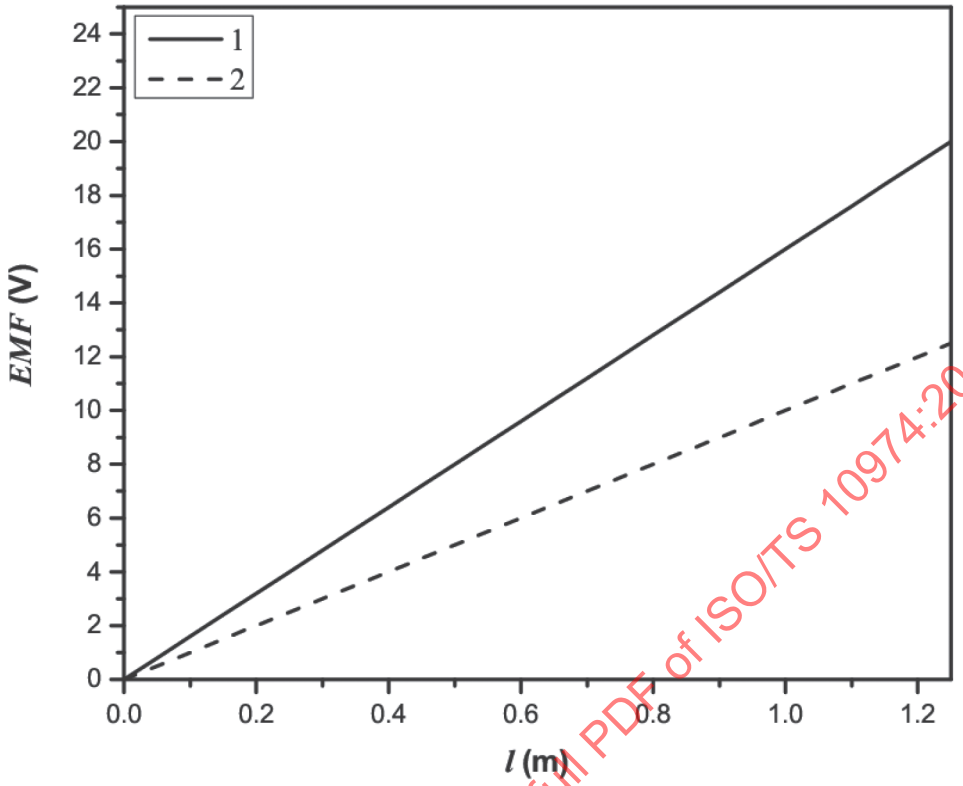
1 landmarks (centre of RF coil) are indicated by the arrows

2 maximal *dB/dt* on a cylinder of 20 cm radius is 100 T/s; colour bar is in V/m

Figure B.2 — Calculated electric field intensity in human model in a y-gradient coil in a sagittal slice through the left side of the patient

While Formula (B.1) demonstrates that the integration methods of the magnetic field and the electric field are equivalent, the assumptions used for simplification result in different EMF values for the two integration methods. Therefore, it is necessary to further consider whether the EMF due to integration of the magnetic field or the electric field is more conservative.

The integration of the electric field is a line integral. When a constant electric field magnitude in the direction of the integration path is assumed, the EMF is a linear function of the length of the integration path (Figure B.3). The previous simulations from Figure B.1 and Figure B.2 demonstrated that the peak electric field is significantly larger than the average value, further they show that the peak could exist over regions spanning a linear dimension of up to 0,10 m. Therefore, it is prudent to assume that the peak value could be applied to structures up to 0,10 m and that for larger structures the average value is more applicable. These two electric field value integration results are shown in Figure B.3.



Key

1 integration result of electric field of 16 V/m

2 integration result of electric field of 10 V/m

Figure B.3 — Electric field integration results for EMF

When considering the integrand for the magnetic field it is most convenient to use a simplified circular lead path geometry. When considering a circular lead path with a fixed lead length, such as an implantable lead, the radius of the circular path is constrained by Formula (B.3). The area of the circular path, when its end points are connected by a straight line, is calculated using Formula (B.5). The lead length constraint of Formula (B.4) results in circular paths with swept angles that are inversely proportional to the radius of the path (Figure B.4). Figure B.5 is the plot of the area of the paths from Figure B.4 that demonstrates that a swept angle of π (a semi-circle) maximizes the area of the loop when the path length is constant.

$$l = r\theta \tag{B.3}$$

$$\theta = \frac{l}{r} \tag{B.4}$$

$$A = \frac{1}{2}\left(\frac{l}{\theta}\right)^2 (\theta - \sin\theta) \tag{B.5}$$

where

l is the path length;

r is the radius of the circular path;

θ is the angle the path sweeps in cylindrical coordinates;

A is the area the circular path sweeps when the end points of the path are connected by a straight line.

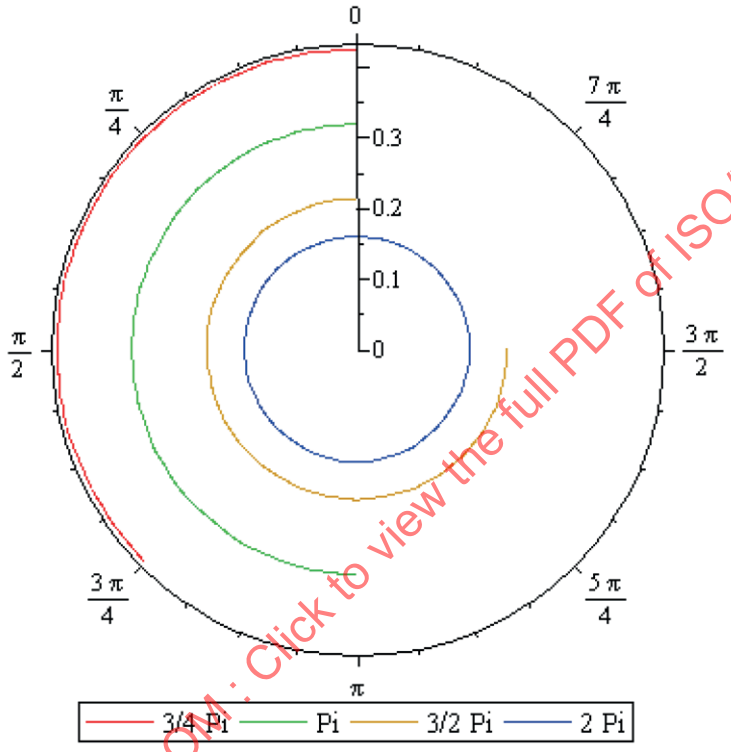


Figure B.4 — Circular paths, with a constrained path length of 1 m, for different swept angles, θ

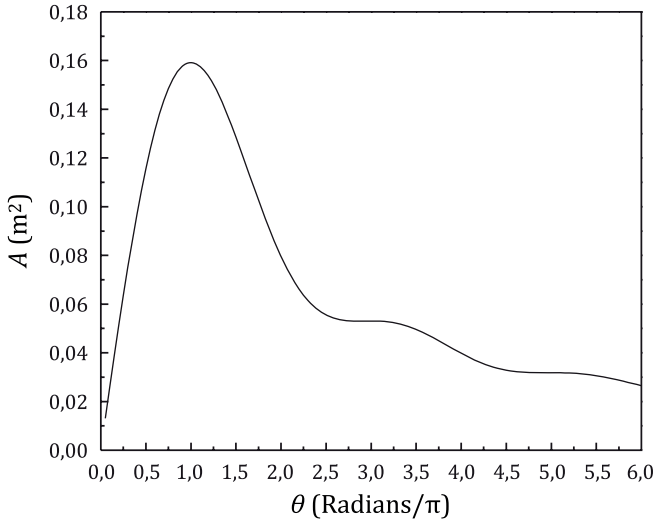
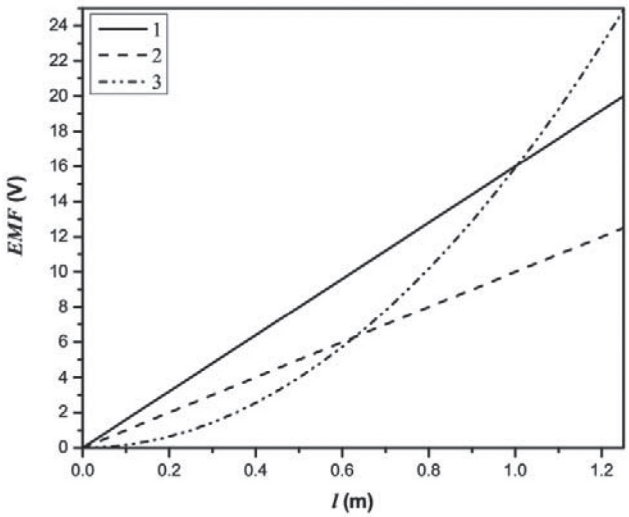


Figure B.5 — Area a circular path sweeps, from Figure B.4, when the end points of the path are connected by a straight line, for a constrained path length of 1 m

Figure B.6 compares the EMF integration results of the magnetic field and the integration results of the electric field as shown in Formula (B.1), where the mentioned simplifications are applied. Figure B.6 is the basis for the lead length factor (Table A.3). In Figure B.6, the 16 V/m electric field line integration produces the maximum EMF for tissue path lengths up to 0,10 m. For tissue path lengths greater than 0,10 m the conservative, average 10 V/m electric field line integration is shown. For path lengths greater than 0,10 m, the 10 V/m electric field EMF exceeds the integration results of magnetic field EMF for lengths up to 0,63 m, where they intersect. Therefore, for path lengths between 0,10 m and 0,63 m it is more applicable to consider the electric field integration results of the 10 V/m electric field line integration. To prevent a discontinuity in the EMF solution at 0,10 m Table A.3 uses a linear interpolation between the 16 V/m solution at 0,10 m and the 10 V/m solution at 0,63 m which results in a line with a slope of 8,86 V/m.

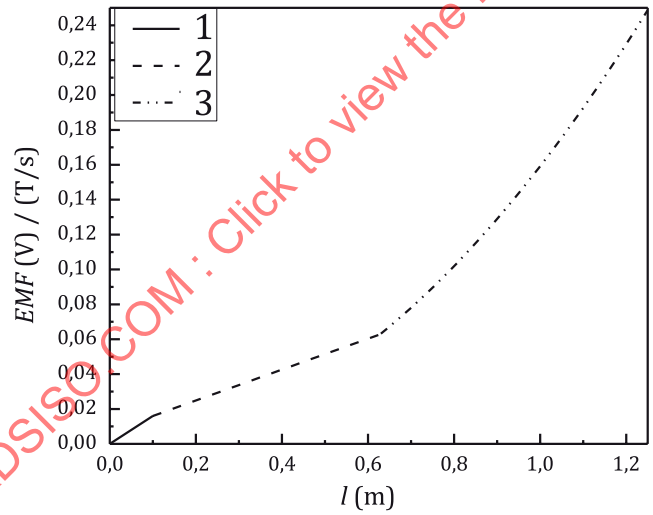
Figure B.7 is the scaled EMF for Table A.3 by combining the EMF results of the 16 V/m electric field line integral from 0,0 m to 0,1 m, the linear interpolation between the electric field integration results of 16 V/m to 0,1 m and 10 V/m to 0,63 m, and the magnetic field area integration for 0,63 m and larger path lengths.



Key

1 integration result of electric field of 16 V/m
2 integration result of electric field of 10 V/m
3 integration result of dB/dt = 100 T/s

Figure B.6 — Comparison of EMF integration results using the magnetic field and electric field



Key

1 integration result of electric field of 16 V/m
2 integration result of electric field of 10 V/m
3 integration result of dB/dt = 100 T/s

Figure B.7 — Scaled results of the combination of the 16 V/m electric field line integral from 0,00 m to 0,1 m, linear interpolation between the electric field integration results of 16 V/m to 0,1 m and 10 V/m to 0,63 m, and magnetic field area integration for 0,63 m and larger path lengths for lead length factor Table A.3

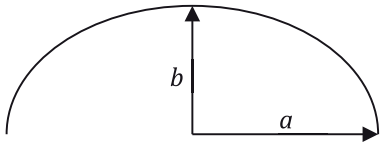


Figure B.8 — Semi-ellipse path with radii labelled

For certain lead lengths the radius of the semi-circle path, with a swept angle of π radians, from Formula (B.3) might exceed either the MR bore diameter or the contour of the patient's body. Therefore, to accommodate lead lengths that would exceed these conditions a semi-ellipse path is included in Figure B.8 and Table A.3. To calculate the path length, *l*, of a semi-ellipse, the elliptical integral in Formula (B.6) is calculated. This can be performed numerically or using the Ramanujan Approximation shown in Formula (B.7). The use of Formula (B.7) requires an iterative method; an example method is shown in Figure B.9. The area of a semi-ellipse is given in Formula (B.8).

$$l = 2a\int_0^{\pi/2} \sqrt{1-\left(\frac{a^2-b^2}{a^2}\right)\left[\sin(\theta)\right]^2}\, d\theta \tag{B.6}$$

$$l \approx \frac{\pi}{2}(a+b)\left(1+\frac{3\lambda^2}{10+\sqrt{4-3\lambda^2}}\right) \tag{B.7}$$

$$A = \frac{1}{2}\cdot\pi\cdot a\cdot b \tag{B.8}$$

where

l is the path length;

a is the semi-major axis length;

b is the semi-minor axis length;

θ is the angle the path sweeps in cylindrical coordinates, $\theta = \pi$ for semi-ellipse;

λ is equal to $(a - b)/(a + b)$;

A is the area the circular path sweeps when the end points of the path are connected by a straight line.

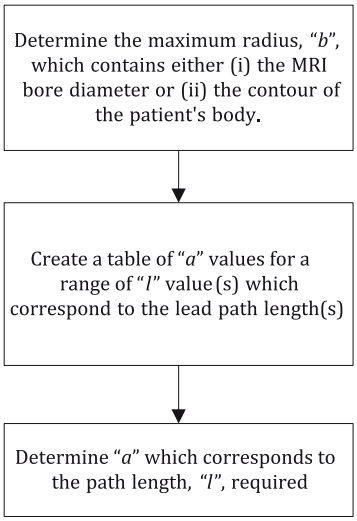


Figure B.9 — Example flow chart for the iterative calculation of *l* using Ramanujan Approximation, Formula (B.6)

Annex C
(informative)

Tier 1 high tangential E-field trough line resonator

C.1 Background

Tier 1 of the technical specification makes conservative worst case rms E-field estimates for head, trunk and extremities to which an AIMD should be exposed to. The requirement for using Tier 1 is that the implant is electrically short such that phase enhancement factors are unimportant. For 30 µT peak B_{1+} field the resulting peak E-fields required in Table 4 are; 3 860 V/m, 6 000 V/m and 7 285 V/m for head, trunk and extremities, respectively. It is not practical to generate these high field strengths within a birdcage coil, therefore a different approach is necessary.

For Tier 1 to be applicable for an implant, its overall dimensions are necessarily short compared to a wavelength. It is suggested that 100 mm is a reasonable upper bound on these dimensions, therefore the size of the exposure phantom should exceed 120 mm such that the discontinuity at the ends is not a significant factor. Furthermore, the phantom should have sufficient cross sectional area such that the tissue simulating media extends around the implant.

C.2 Design Example

One solution for the generation of high field strengths is using a resonator structure. For 64 MHz a trough line resonator with direct coupling where the line is resonated using a parallel plate capacitor with tissue simulating media as the dielectric. The parallel plate capacitor forms the phantom for device exposure and is therefore chosen to have dimensions appropriate to implant exposure. This lossy capacitor has very low Q and a capacitance value that can be approximated by C = εA/d. The equivalent circuit for the resonator is given in Figure C.1. Where C1 is the exposure phantom or cell which has 100 mm × 100 mm cross sectional area and a length chosen such that the trough line is both resonant at 64 MHz and can be impedance matched. The resonator is a copper strip 20 mm wide and 2 mm thick, Figure C.2. The trough should be made from a good conductor (e.g. Al, Cu). Material for the walls is polyethylene.

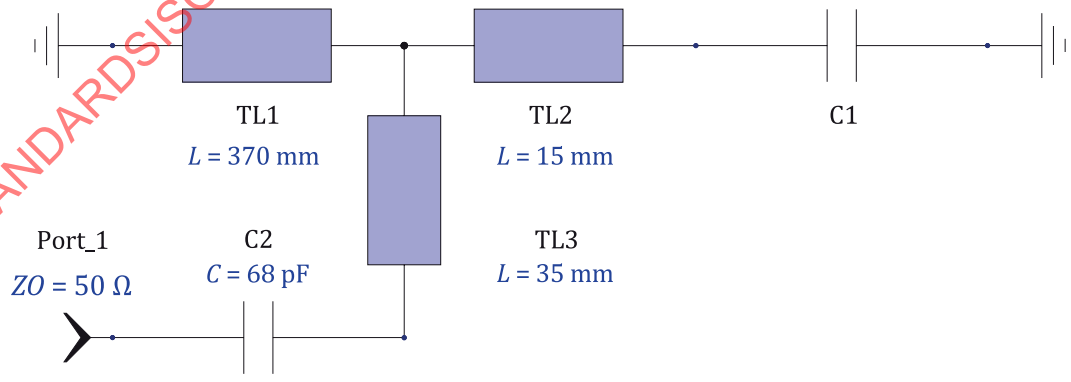


Figure C.1 — Resonator equivalent circuit

Caution — The example equipment described in this annex has surface potentials exceeding 1 000 V and high power RF fields. RF burns from the high power fields and arcing at locations of high voltages are some of the associated hazardous situations that an operator should be aware of and which should be mitigated during use. This prototype equipment description does not

include safety interlocks, access covers, operating procedures, operator training or other safety mechanisms that should be included in a practical exposure system to avoid serious injury.

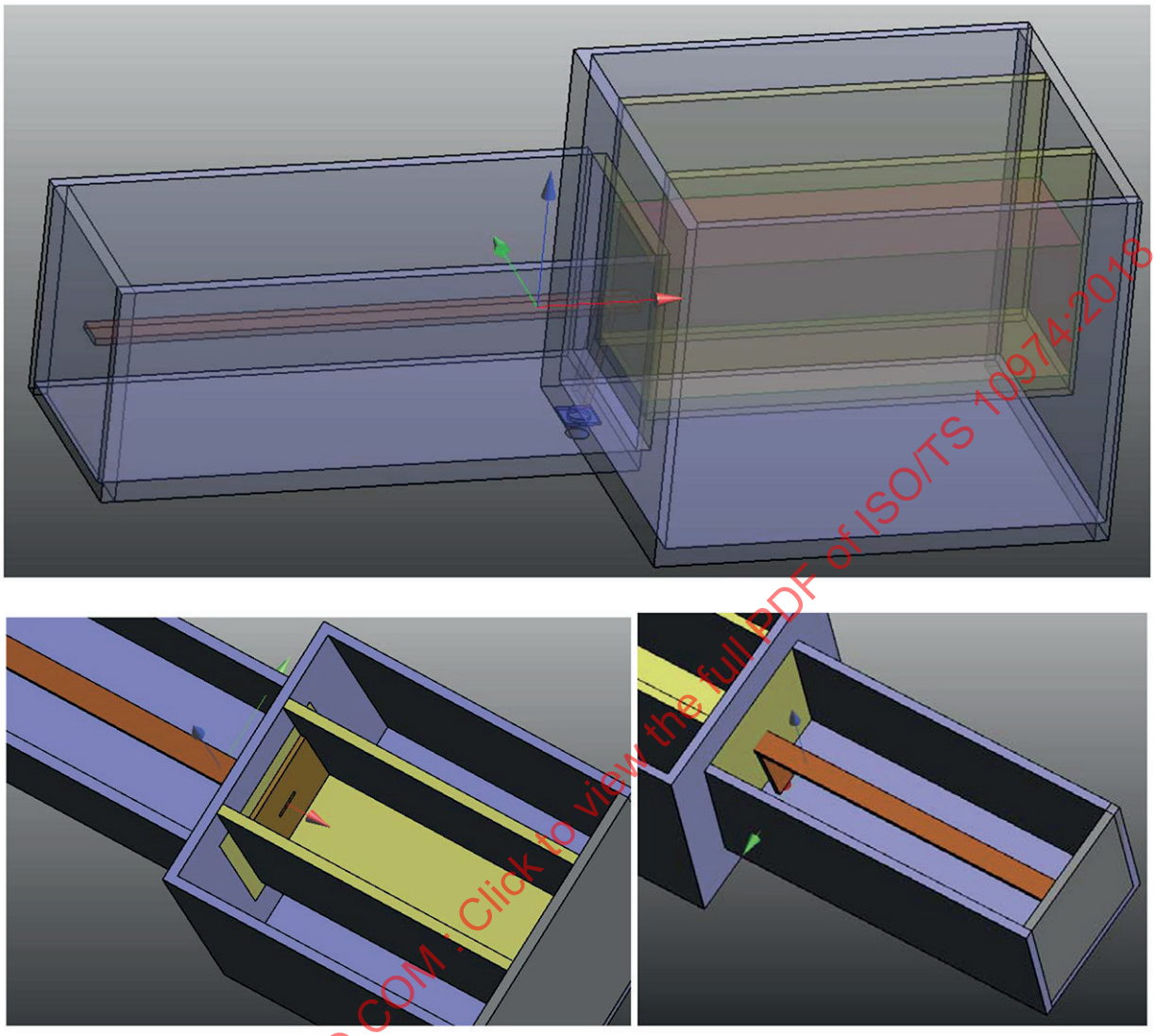


Figure C.2 — 3D view of the trough line resonator with capacitive phantom

The phantom has dimensions 300 mm × 100 mm × 100 mm, where the end wall of the trough forms the earthed end of the capacitor and a 100 mm × 100 mm electrode forms the hot end connected to the strip line. Though a shorter phantom would be sufficient for the sizes of devices to be exposed, the increase in capacitance would result in a shorted strip line and difficultly in achieving an impedance match. Therefore, theoretically, implants up to a maximum length of 250 mm could be accommodated, though the short implant requirement might be exceeded. The resulting resonator length is 385 mm for operation at 64 MHz, resulting in a total internal length of 685 mm. The trough line around the strip line has internal cross section 150 mm × 150 mm but around the phantom it is increased to 250 mm × 250 mm which results in an improved homogeneity of the field along the length, if a constant cross section is used then the field lines tend to bend towards the closest ground rather than running along the length of the phantom. The resonator should be directly coupled as close as possible to the hot end of capacitor C1 using a broad conductive strip. The input impedance is inductive, therefore a series capacitance C2 should be incorporated (see Figure Figure C.3). To make the impedance purely real, 68 pF has been found to be a suitable value. The capacitor should be a high quality, high power porcelain capacitor of size 4040 and 3 600 VDC or higher rating".

Figure C.3 — Matching capacitor connection

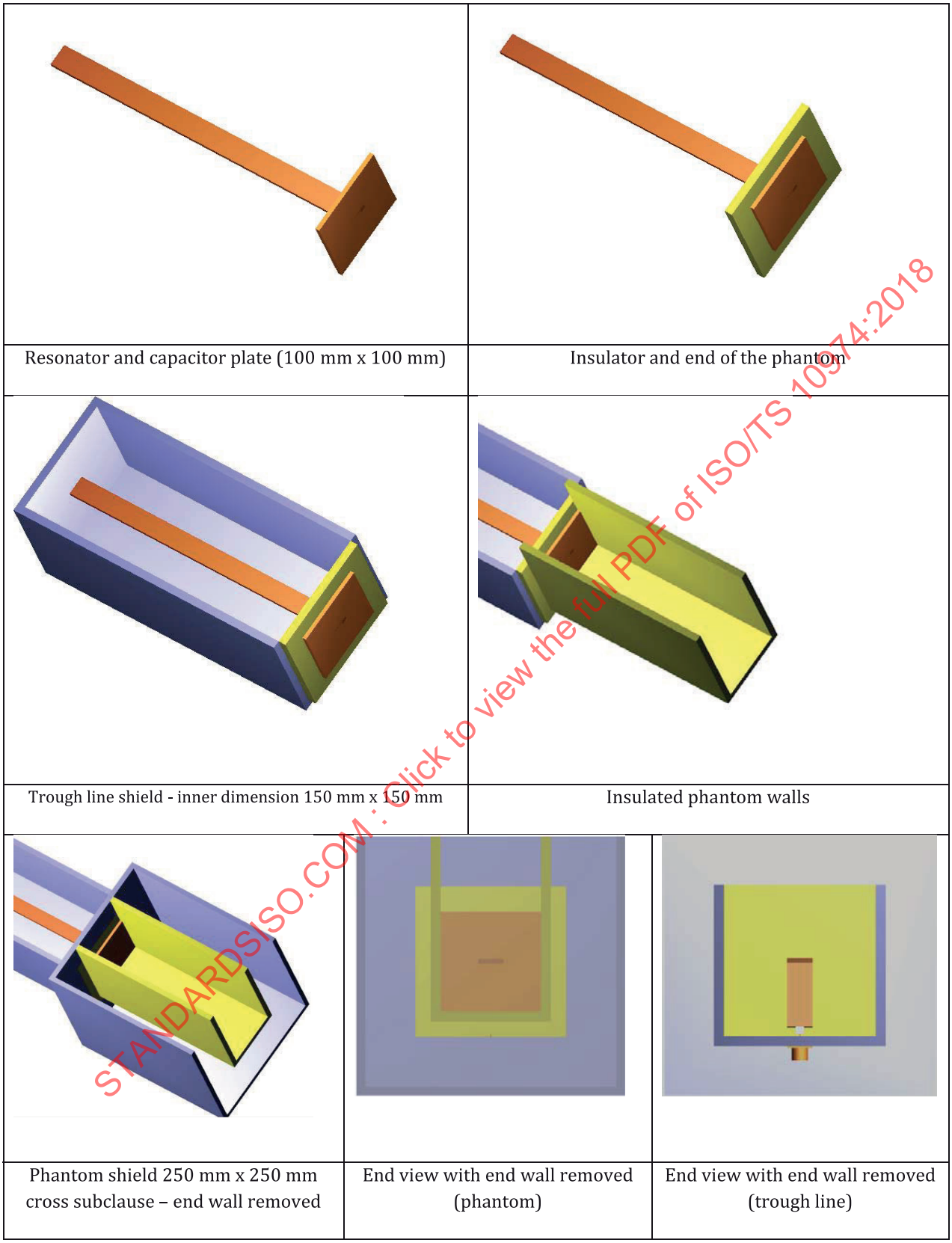


Figure C.4 — Tier 1 high tangential E-field trough line resonator, build up and construction detail

C.3 Performance

With tissue simulating media of σ = 0,47 S/m and ε_r = 78 the following performance was measured:

Some comments on further calculations that can be performed to improve the calculation of the induced EMF are as follows:

— S11~–13 dB into 50 ohms;

— Zin = 32 – j5 ohms @64 MHz;

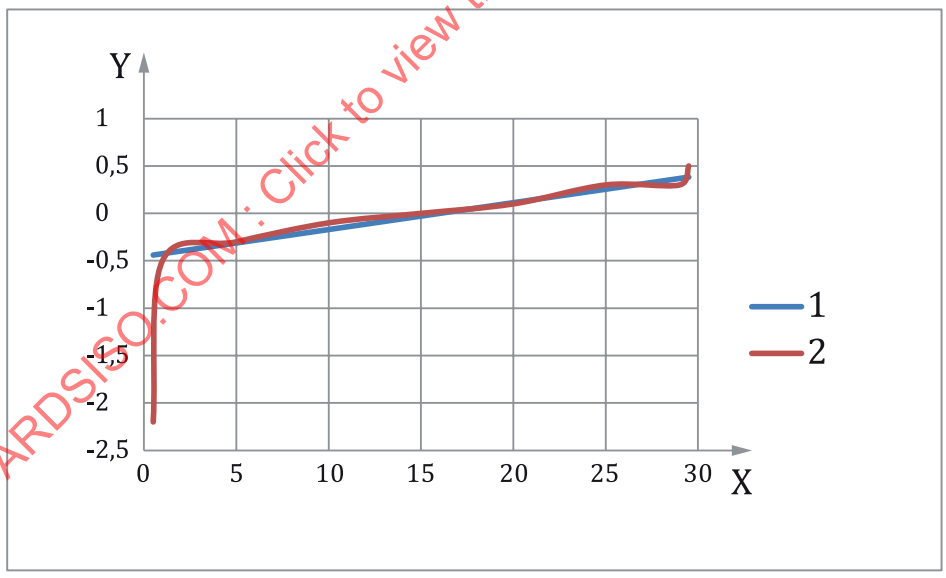
where the E-field for 1 W is 23,9 V/m rms, 33,9 V/m peak.

A typical configuration with 18 kW peak power produces the electric field values shown in Table C.1.

Table C.1 — Measured field strengths

Peak field	Approximate peak power	
V/m	W	dBm
1 000	885	59,47
2 200	4 284	66,32
4 500	17 923	72,53

Figure C.5 and Figure C.6 show the measured performance in terms of amplitude and phase variation respectively along the centre line of the phantom. Figure C.7 shows the expected performance for an implant of given length placed at the centre position of the phantom, therefore, for a short implant of 100 mm the amplitude and phase will be within ±0,14 dB and ±1,5° respectively.



Key

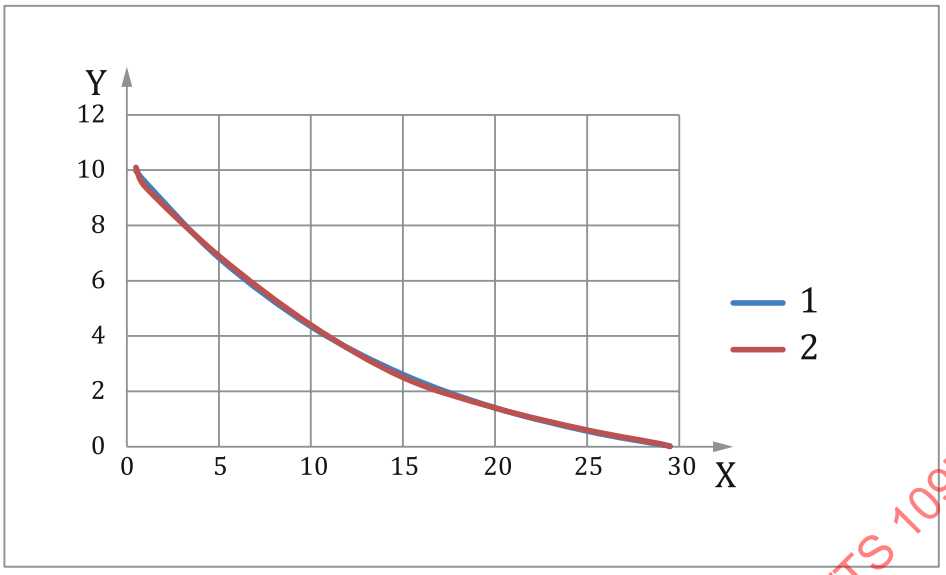
1 fit

2 delta mag

X distance, cm

Y relative magnitude, dB

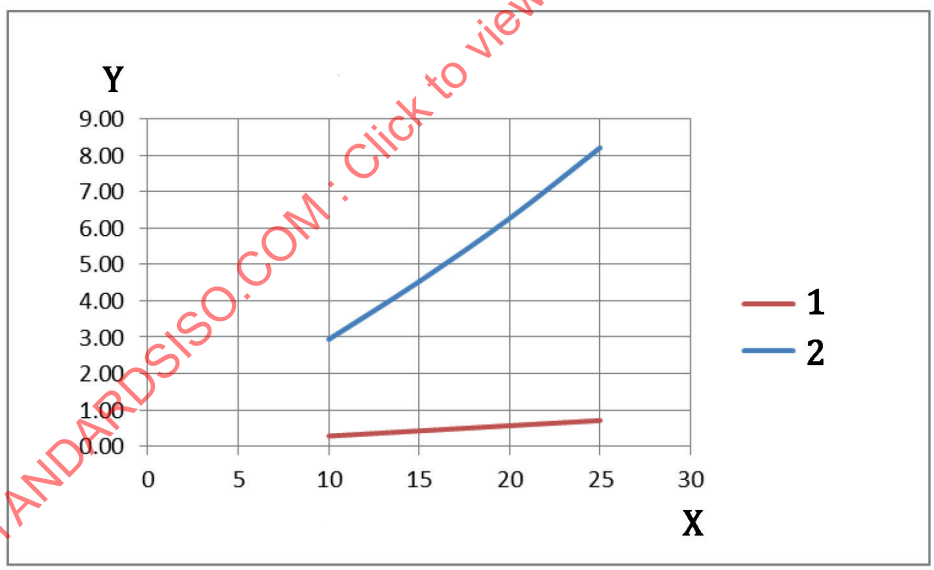
Figure C.5 — E-field magnitude variation along the length of the phantom



Key

1 fit
2 delta phase
X distance, cm
Y relative phase, degrees

Figure C.6 — E-field phase variation along the length of the phantom



Key

1 delta mag
2 delta phi
X implant length, cm
Y dB or degrees

Figure C.7 — Total variation as a function of implant length

In the human body, different conductivity tissues have different induced E-field strengths for a given incident B_{1+} field. In a similar way, filling the trough line resonator phantom with different conductivity liquids will also result in different field strengths for a given input power level (see Table C.2).

Table C.2 — Peak E-fields for different conductivity liquids

Sigma	E_{peak} V/m **for 1 W**	E_{max} V/m **for 18 kW peak power**
0,47	65,3	4 500
0,65	55,2	3 805
0,78	50,4	3 473
1,2	40,4	2 784

The higher conductivity required by some AIMD applications will result in the need to increase the input power in order to achieve the required peak E-field levels. In addition, it should be noted that the match to 50 Ω degrades as the conductivity is increased and an impedance transformer should be included; quarter wavelength of 35 Ω coax would be appropriate.

NOTE The majority of the input power is dissipated heating the saline solution, which can result in fairly rapid solution heating. The conductivity of the saline solution will change approximately 2 %/°C of temperature rise, therefore it is important to monitor and control the allowed temperature increase. 8.3.2 specifies a ±10 % tolerance on the saline solution conductivity; therefore the maximum allowed temperature increase is 5 °C.

Annex D
(informative)

Supporting information and rationale for gradient-induced device heating

D.1 Rationale for gradient heating |*dB/dt*| rms

D.1.1 General

This annex contains the rationale and supporting data for the *dB/dt* exposure and test waveform that is found in 9.2.2.

D.1.2 Data survey of clinical MR scanners

AIMD manufacturers conducted a survey of clinical MR scanners to collect data of the maximum |*dB/dt*| rms that could be achieved on several MR scanners utilizing a variety of pulse sequences. These pulse sequences were typically modified to try to achieve the maximum |*dB/dt*| rms that the system would permit before exceeding the First Level Control PNS thresholds or gradient hardware limitations that would prevent the sequence from executing. The |*dB/dt*| rms is the root mean square of the measured *dB/dt* during the test sequence for a single TR period. The collected data are shown in Table D.1.

Table D.1 — Survey of measured |*dB/dt*| rms exposure values

Scanner details			**Pulse sequence details**			**Search coil position and *dB/dt***				
Scanner make/ model	**Max. slew rate per axis** T/m/s	**Max. gradient amplitude** mT/m	**Pulse sequence type**	**Slice plane**	**Read out direction**	**X** cm	**Y** cm	**Z** cm	**Radial distance** cm	|*dB/dt*| rms (T/s rms) **per TR period**
GE Signa (Twinspeed)	120	33	FIESTA	Gy		16	16	30	22,6	34,5
GE Signa (Twinspeed)	120	33	FIESTA	Gz		16	16	30	22,6	32,4
Siemens Avanto (SQ)	200	45	True FISP	Gz		23	0	30	23,0	38,8
Siemens Avanto (SQ)	200	45	ep2d-diff_ orth	Gy	Gx	25	0	35	25,0	37,95
Siemens Avanto (SQ)	200	45	ep2d-diff_ orth	Gy	Gx	24	0	35	24,0	35,21
Siemens Avanto (SQ)	200	45	ep2d-diff_ orth	Gx	Gy	0	25	35	25,0	37,31
Siemens Avanto (SQ)	200	45	ep2d-diff_ orth	Gx	Gy	0	24	35	24,0	34,65
Siemens Avanto (SQ)	200	45	ep2d-diff_ oblique	Gx Gy (45°)	Gx Gy (45°)	18	18	35	25,5	33,19
Siemens Avanto (SQ)	200	45	ep2d_dif- f_3scan_ trace_p2	Gz	Gx	0	20	35	20,0	21,4

Table D.1 *(continued)*

Scanner details			Pulse sequence details			Search coil position and *dB/dt*				
Scanner make/ model	**Max. slew rate per axis** T/m/s	**Max. gradient amplitude** mT/m	**Pulse sequence type**	**Slice plane**	**Read out direction**	**X** cm	**Y** cm	**Z** cm	**Radial distance** cm	|*dB/dt*| rms (T/s rms) **per TR period**
Siemens Avanto (SQ)	200	45	ep2d_diff_3scan_trace_p2	Gz	Gx	20	0	35	20,0	32,3
Siemens Avanto (SQ)	200	45	ep2d_diff_3scan_trace_p2	Gz	Gy	0	20	35	20,0	25,8
Siemens Avanto (SQ)	200	45	ep2d_diff_3scan_trace_p2	Gz	Gy	20	0	35	20,0	16,5
Siemens Avanto (SQ)	200	45	ep2d_perf_p2_basic	Gz	Gx	0	20	35	20,0	26,3
Siemens Avanto (SQ)	200	45	ep2d_perf_p2_basic	Gz	Gx	20	0	35	20,0	38,6
Siemens Avanto (SQ)	200	45	ep2d_perf_p2_basic	Gz	Gy	0	20	35	20,0	34
Siemens Avanto (SQ)	200	45	ep2d_perf_p2_basic	Gz	Gy	20	0	35	20,0	21,8
Siemens Avanto (SQ)	200	45	t2_psif_sag_diff_r_69_lumbar	Gx	Gz	0	20	35	20,0	9,4
Siemens Avanto (SQ)	200	45	t2_psif_sag_diff_r_69_lumbar	Gx	Gy	20	0	35	20,0	8,8
Siemens Avanto (SQ)	200	45	IV_ep2d_diff_thorax_free_b	Gz	Gx	0	20	35	20,0	21,5
Siemens Avanto (SQ)	200	45	IV_ep2d_diff_thorax_free_b	Gz	Gx	20	0	35	20,0	31,4
Siemens Avanto (SQ)	200	45	IV_ep2d_diff_thorax_free_b	Gz	Gy	0	20	35	20,0	28,1
Siemens Avanto (SQ)	200	45	IV_ep2d_diff_thorax_free_b	Gz	Gy	20	0	35	20,0	18,1
Siemens Avanto (SQ)	200	45	ep2d-diff_oblique	Gx Gy (45°)	Gx Gy (45°)	17	17	35	24,0	31,42
Siemens Avanto (SQ)	200	45	True FISP	Gx		23	0	40	23,0	32,2
Siemens Espree (DZ)	170	33	True FISP	Gz		20	20	20	28,3	27,4

Table D.1 *(continued)*

Scanner details			Pulse sequence details			Search coil position and *dB/dt*				
Scanner make/ model	**Max. slew rate per axis** T/m/s	**Max. gradient amplitude** mT/m	**Pulse sequence type**	**Slice plane**	**Read out direction**	**X** cm	**Y** cm	**Z** cm	**Radial distance** cm	|*dB/dt*| rms (T/s rms) **per TR period**
Siemens Espree (DZ)	170	33	True FISP	Gx		20	20	40	28,3	25,6
Philips Achieva (Master)	150	30	Perfusion	Gy		12	16	30	20,0	23,6
Philips Achieva (Master)	150	30	EPI	Gz		12	16	40	20,0	20,9

D.1.3 Determination of clinical *dB/dt* exposure limits

From the collected data in Table D.1, the maximum value within the compliance volume with a radius of 20 cm was taken and conservatively scaled up approximately 10 %. This resulted in a |*dB/dt*| rms of 42 T/s at the radius of 20 cm. The 42 T/s rms was then scaled to appropriate values for a variety of radii given the ratio between the *dB/dt* at the new radius versus the value at a radius of 20 cm from the *dBy/dt* component in Table A.2. The results of scaling the |*dB/dt*| rms to various specified radial locations within the scanner bore is shown within Table D.2.

Table D.2 — AIMD |*dB/dt*| rms exposure values as a function of radial distance from z-axis

Radius cm	|*dBm/dt*| rms T/s
5	27,1
10	29,8
15	34,4
20	42,0
25	54,1
30[a]	73,3

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

D.2 Gradient heating Tier 1 waveform rationale

D.2.1 General

This subclause contains the rationale and derivation of the Tier 1 waveform found in 9.3.6.2, using the |*dB/dt*| rms of 42 T/s at a radius of 20 cm.

D.2.2 Waveform type

A wide range of gradient waveforms are utilized for MR imaging. Most common waveforms include trapezoidal, triangular, and sinusoidal. MR gradient heating depends on the time derivative of the gradient waveform and on device shape, size, and conductivity of its conductive elements and applied gradient frequency content. Experiments have been performed using simple structures, e.g. cylindrical disk, showing that a critical frequency can be identified over which heating becomes less due to inductive effects. In order to maximize the amount of power deposited, a low frequency sine waveform is proposed to evaluate device heating when exposed to gradient fields present in an MR scanner. A sine waveform does not contain higher order harmonics present in triangle or trapezoidal waveforms.

Because of this all of the power induced on a test article will be focused at the frequencies not attenuated by device inductive effects.

D.2.3 Magnitude of |*dB/dt*| rms

A gradient field rms value of at least 42 T/s rms is applied to the test article for the duration of the test. From scanner survey data collected by multiple AIMD manufacturers using MR scan sequences intended to produce the largest measurable |*dB/dt*| rms value, it was determined that 42 T/s rms is appropriate for the waveform definition. It should be noted that because the amount of device heating is proportional to the square of the |*dB/dt*| rms value, testing can be done at lower |*dB/dt*| rms values and scaled appropriately.

D.2.4 Magnitude of B_G

To determine a clinically relevant low frequency at which to drive the gradient coil during testing, the magnitude of the AIMD gradient exposure, B_G, is considered. Since the time rate of change of a sinusoidal gradient is proportional to frequency × B_G, considering higher B_G allows the 42 T/s rms target exposure to be achieved at lower frequency minimizing potential inductive effects.

An estimate of the maximum clinically relevant B_G exposure at the compliance volume radius (r = 20 cm) can be determined from the information provided in some of the MR scanner manufacturer's IEC 60601-2-33 compliance data sheets. For scanners that this data are not available B_G might be calculated approximately from the scanner's gradient strength G mT/m-per-axis if the scanner's maximum field of view (FOV) capability is known as $B_G \geq \sqrt{3} \cdot G \cdot FOV$ then scaling the result back to the compliance radius if needed. For the purposes of this discussion, the maximum B_G value is set fairly conservatively to 35 mT; higher B_G might be considered in order to lower sinusoidal drive frequency further, but it is undesired to needlessly increase B_G to the point where it becomes too difficult or expensive to achieve using the single axis bench gradient test coil.

D.2.5 Waveform frequency

It is known that frequency dependence exists related to gradient-induced device heating. As frequency decreases below a certain critical frequency, device heating might be maximized. Thus, it is desired to determine the lowest possible clinically relevant frequency which a device might experience in an MR scanner assuming a sine wave gradient signal. Using a sine wave test signal, the $B_G(t)$ function can be described as follows:

$$B_G(t) = B_G \times \sin(2\pi \times f \times t)$$

where

B_G is the magnitude of the gradient field in the MR scanner and bench test coil, in T;

f is the frequency, in Hz;

t is time, in s.

By differentiating the formula above with respect to time, the following formula is produced:

$$\frac{dB_G(t)}{dt} = 2\pi \times f \times B_G \times \cos(2\pi \times f \times t)$$

From this formula, the *dB/dt*_rms value can be determined as:

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

From the values previously discussed, we have:

$$42\frac{\text{T}}{\text{s}} = \frac{2\pi \times f \times (35\ \text{mT})}{\sqrt{2}}$$

Solving for frequency produces the following result:

$$f = \frac{\left(42\frac{\text{T}}{\text{s}}\right) \times \sqrt{2}}{2\pi \times (0{,}035\ \text{T})} = 270\ \text{Hz}$$

The sine wave frequency for alternative values are shown in Table D.3.

Table D.3 — Sine wave frequency for alternative B_G values

B_G mT	**Frequency** Hz
60	158
50	189
40	236
35	270
30	315
20	473

Due to test system B_G limitations, it might not be possible to test at the required $\left(\frac{dB_G(t)}{dt}\right)_{\text{rms}}$ value. In this case, it is acceptable to apply a B_G waveform of the same frequency with lower peak and $\left(\frac{dB_G(t)}{dt}\right)_{\text{rms}}$ value and scale the results proportional to the square of the applied $\left(\frac{dB_G(t)}{dt}\right)_{\text{rms}}$.

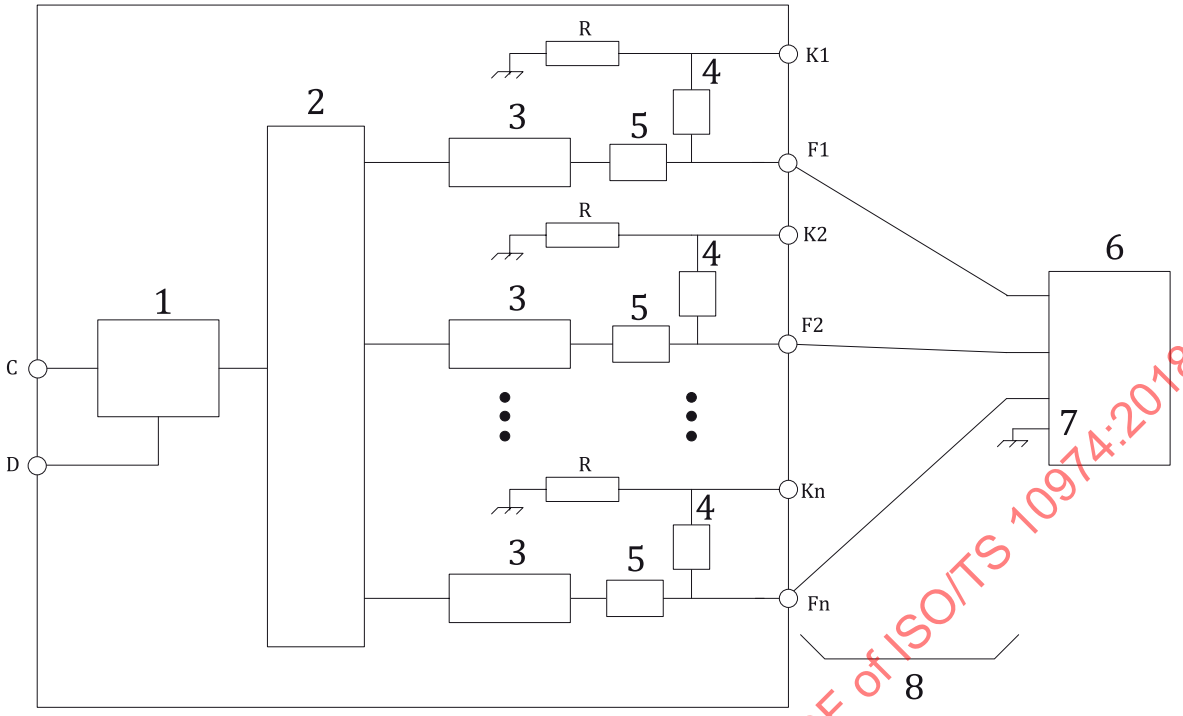
Annex E
(informative)

Example RF injection network

This annex provides an example multiport RF injection network as shown in Figure E.1. Other injection networks meeting the requirements of 15.7.5 are also acceptable. RF power is delivered into the network at point C. Point D provides the forward output of a directional coupler for the purpose of monitoring RF forward level. Points F1 through Fn are RF outputs to RF entry points of the device under test. Points K1 through Kn are provided for the purpose of monitoring for rectification products at the RF entry points.

As an example, RF phase differences between RF entry points can be obtained by substituting a connection cable of sufficiently increased length between the RF power splitter and the isolator with the injection network. Other techniques can be used to obtain the required phase shifts, e.g. with phase locked multiple RF sources.

NOTE The isolator is used to stabilize the impedance loading for the 1:N splitter to achieve equal distribution of RF power between channels, as well as to absorb reflected power from the device under test. As examples, the isolator might be comprised of an attenuator (e.g. –6 dB), an RF isolator, or an RF circulator. The RF path through the high pass filter preserves 50 ohm impedance in this example.



Key

Components		Connections	
1	directional coupler	C	RF power delivery point
2	1:N splitter	D	forward output of directional coupler monitoring point
3	isolator	K1 to Kn	rectification monitoring point
4	low-pass filter	F1 to Fn	RF output to RF entry points of device under test
5	high-pass filter		
6	device under test		
7	case		
8	controlled impedance; equal length for phase matching		
R	resistor		

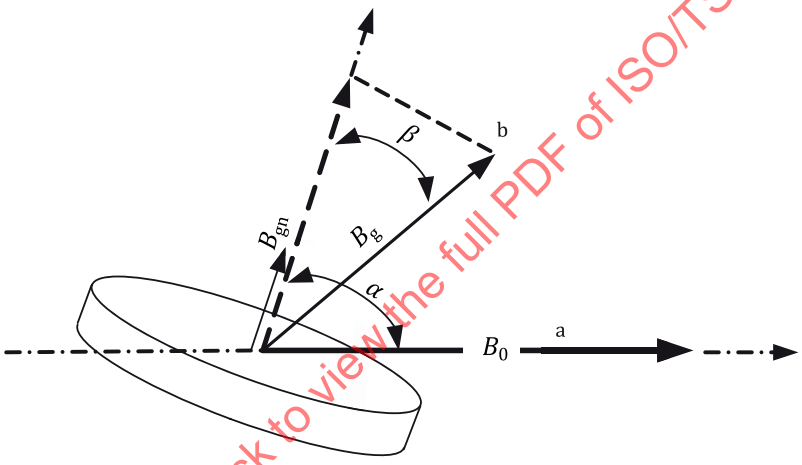
Figure E.1 — Example multiport RF injection network

Annex F
(informative)

Supporting information and rationale for MR-induced vibration

F.1 Explanation of MR-induced vibration

This annex provides supporting information and rationale for Clause 10. The time-varying forces and torques exerted on the AIMD and its components are proportional to the cross product of the transient AIMD-induced magnetic moment and the B_0 field. These forces and torques are therefore maximized when the AIMD conductive planes are oriented parallel to the B_0 field vector and perpendicular to the strongest *dB/dt* vector. Figure F.1 illustrates this for a simple conductive disk.



a Static field.

b Gradient field.

Figure F.1 — Torque due to MR-induced eddy current and static B_0 field

Formula (F.1) is the torque due to *dB/dt* and B_0 fields:

$$Torque = \frac{1}{8}\sigma t \pi r^4 \left[B_0 \frac{dB_g}{dt} \sin(a)\cos(\beta) \right] \quad \text{(F.1)}$$

where

r is the radius (m);

t is the thickness of the conductive plane (m);

σ is the material conductivity of the conductive plane (S/m);

B_g is the incident pulsed gradient field;

β is the angle between the normal to conductive plane and the incident pulsed gradient field;

a is the angle between the eddy current-induced magnetic moment B_{gn} and the static B_0 field.

For a typical AIMD implanted such that the major conductive plane is parallel to the patient table during an MR scan, the clinically maximum exposure occurs when B_0 is parallel to the AIMD major conductive plane, and dB/dt is orthogonal to the major conductive plane (and therefore orthogonal to B_0).

In some AIMDs, this situation might not be clinically relevant. In those cases, Formula (F.1) can be used to determine the appropriate $dB/dt \times B_0$.

F.2 Tiers: MR scanner vs shaker table

Testing in an MR scanner is the closest match to actual use conditions only if the maximum clinical $dB/dt \times B_0$ is achieved for the entire duration of the test. This is extremely difficult to achieve in a clinical scanner, and is better achieved in a research scanner. MR scanners are capable of exciting differential modes that might result in more relative motion between various components than would be caused by a shaker table.

The use of a shaker table can offer advantages for MR vibration AIMD functional testing. Note that the use of a shaker table for MR vibration testing still requires some use of an MR scanner in order to characterize the AIMD's vibration response.

F.3 Clinical scanner vs research scanner

A clinical MR scanner (i.e. a scanner used in clinical practice for imaging the human body) can be used for vibration testing. Clinical scanners might be more readily available than research scanners.

The research MR scanner as defined here refers to non-clinical MR scanners used for research purposes. It does not refer to a clinical scanner operated in research or second level controlled operating mode.

When a clinical scanner is used for Clause 10, Tier 1 testing, it might be possible to achieve the required clinical exposure vector product of $dB/dt \times B_0$ by using one or more of the following techniques:

— Conduct the test using B_0 greater than clinical worst case. For example, if the MR Conditional labelling restricts MR scanning to 1,5 T scanners, testing in a 3 T scanner using clinical worst-case dB/dt will give a higher $dB/dt \times B_0$;

— Test in a location that is not clinically relevant for the AIMD but produces a larger vector product of $dB/dt \times B_0$ (and consequently larger vibration forces). For example, testing the AIMD at a location very close to the inner wall of the scanner bore in a region of very high dB/dt that the AIMD would not be exposed to clinically, might provide a useful test margin;

— Test using an AIMD orientation that is not clinically relevant but produces a larger vector product of $dB/dt \times B_0$ (and consequently larger vibration forces). AIMD vibration will typically be at a maximum when dB/dt is orthogonal to the largest conductive AIMD surfaces. This orientation might not be clinically relevant for some AIMDs.

F.4 Potential for AIMD resonance

This document does not require identification of, nor testing at, the mechanical resonant frequencies of an AIMD for the following reasons:

— Q values for mechanical resonance frequencies measured in AIMDs have generally been low. Given that this document includes a requirement for testing across a full range of relevant gradient frequencies, it is very likely that the defined testing will overlap the AIMD mechanical resonance frequencies that are relevant to the MR gradient fields;

— Given the great difficulty in measuring vibration in various parts of the AIMDs, particularly when installed in a scanner, it would be very difficult to ensure that all frequencies of possible interest are identified;

— Scanners generally have one or more exclusion zones to prevent operation at frequencies that could damage the scanner. So, there is potential that frequencies could be identified that are not able to be tested within the MR scanner.

Considering these factors, the burden of requiring testing at mechanical resonance frequencies is not warranted.

F.5 Supporting rationales

F.5.1 Gradient switch mode noise ("Ripple")

Switch mode gradient ripple will not be included in requirements because it is much higher frequency and much lower amplitude than the fundamental gradient frequencies. Therefore, the gradient frequencies identified in Clause 10 represent the dominant frequencies at which any potential hazard might exist.

F.5.2 Discussion of location for max $dB/dt \times B_0$

The magnitude and orientation of gradient field *dB/dt* varies as a function of location in and around the MR scanner. For the 1,5 T cylindrical bore class of scanner, using whole body gradient coils, maximum levels of *dB/dt* are found near the inner wall of the bore and approximately 0,35 m along the z axis on either side of isocentre. Note that the typical implant location of any AIMD prevents it from coming within 5 cm of the bore wall.

F.5.3 Rationale for test frequencies

For MR-induced vibration of an AIMD caused by clinical imaging sequences, the relevant range of vibration frequency content is 16 Hz to 3 000 Hz based on characterization in MR scanners from multiple manufacturers. Achieving this frequency content requires the gradient to be driven at maximum slew rate, which is only achieved in the approximate frequency range of 300 Hz to 1 150 Hz for most MR scanners evaluated.

Gradient *dB/dt* spectral power decreases rapidly below ~300 Hz, below which the maximum *dB/dt* spectral power can no longer be achieved. Gradient switching frequencies above ~1 150 Hz to 1 300 Hz are outside the usable range for imaging, and therefore the maximum slew rate is often limited by scanner software. Whereas other clauses might need to account for a few pulses in the PNS range (e.g. gradient-induced extrinsic electric potential), the potential harm from MR-induced vibration is dependent on longer durations of pulses, in which the scanner is incapable or prohibited from maintaining continuous pulses in the PNS range. At higher frequencies (near 1 150 Hz to 1 300 Hz), while B_G is less, the maximum slew rate and therefore torque is still maximized and results in more pulses.

F.5.4 Rationale for scan duration

Cumulative scan duration is based on statistical analysis of observed cumulative lifetime MR scans. The test durations in Table F.1 were derived based on a Kaplan-Meier analysis of a manufacturer's database of clinical MR scans performed over a number of years. The analysis looked at the number of scans per patient and was used to identify the cumulative scan time that could occur over the lifetime of a typical AIMD. Determination of the test duration assumes a conservative 30-min active scan time. For example, 99,99 % of patients will have 15 or fewer MR scans, and these scans typically last 30 min or less, or an equivalent of 7,5 h of scan time.

Table F.1 — Cumulative scan duration based on population percentile

Population percentile	Number of scans	Test duration
99,2 %	5	2,5 h
99,9 %	9	4,5 h
99,99 %	15	7,5 h

F.5.5 Rationale for test temperature

AIMDs can have elastic moduli that are temperature dependent. It is known that some materials used in AIMDs have elastic moduli that decrease by 12 % to 86 % between 25 °C and 37 °C. Reduction in modulus can allow larger displacement of components, leading to larger stress on some components. Reduction in modulus can also lower the resonant frequency of assemblies, which could change the failure mode(s), depending on test temperature.

F.6 Vibration measurement equipment consideration

The sensors used to measure the AIMD vibration response (displacement, velocity, or acceleration) should ideally have the following characteristics:

— Low conductivity material;

— Attachable sensors should be relatively small in size for better spatial resolution and to not impact MR induced torque or AIMD mechanical response;

— Relatively insensitive to currents generated by gradient and RF fields;

— Able to accurately measure frequency range of interest.

The selected displacement, velocity, or acceleration sensor should have a minimum bandwidth of 16 Hz to 3 000 Hz. Systems which typically meet these requirements include non-contact light measurements (laser Doppler vibrometry, interferometry, digital image correlation, etc.) and some accelerometers.

Annex G
(informative)

Gradient vibration patent declaration form

Patent Statement and Licensing Declaration Form for ITU-T/ITU-R Recommendation | ISO/IEC Deliverable

Patent Statement and Licensing Declaration for ITU-T/ITU-R Recommendation | ISO/IEC Deliverable

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(*)Number	ISO/TS 10974
(*)Title	Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device

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Signature	
Place, Date	11 November 2010

Annex H
(informative)

Assessment of dielectric and thermal parameters

H.1 Introduction

H.1.1 General

Annex L describes the formulations for HPM (high permittivity medium) and LPM (low permittivity medium). This annex describes suitable measurement methods for determining the dielectric properties ($\boldsymbol{\varepsilon}_r = \boldsymbol{\varepsilon}_{r'} - j\sigma/\omega\boldsymbol{\varepsilon}_0$) that are also a function of temperature. The parameter values for the operating temperature range should be validated. In addition, evaluations based on temperature measurements in non-aqueous medium require well-characterized thermal properties to enable the determination of the bounds of the confidence interval of the measurement.

H.1.2 HPM Considerations

The HPM formulations are water based and contain salt (saline), salt and hydroxyethyl cellulose (HEC gelled solution), and salt and polyacrylic acid (PAA gelled solution). The water content of HPM solutions ranges from 97 % to 99 % of the total solution. Therefore, the relative permittivity ε_r, heat capacity, and thermal conductivity of the solution are that of water and need not be measured.

HPM solutions are relatively stable over time provided steps are taken to minimize the evaporation of water. The conductivity of an HPM solution is very sensitive to the amount of salt, making it necessary to titrate the solution by adding small amounts of salt while actively monitoring with a conductivity meter. The HPM solution conductivity has a temperature coefficient of approximately 2 %/°C and relative permittivity (ε_r) temperature coefficient of approximately 0,5 %/°C [see Formula (H.2)]. Therefore, the practitioner should maintain the HPM solution within a small temperature range to minimize these thermal effects.

After temperature control, evaporation has the next most profound effect on the solution properties. The phantom should be covered when practical, in order to minimize the evaporation rate. In addition, an increase in conductivity (at a constant temperature) is a strong indication that evaporation has occurred and should be remedied by adding water or mixing a new batch of HPM.

H.1.3 LPM Considerations

LPM contains several liquids that have different evaporation rates, different ε_r, heat capacity, and thermal conductivity. The electrical and thermal properties of the solution are a combination of the electrical and thermal properties of the individual components and their relative percentage of the solution. Differing evaporation rates can cause the solution electrical and thermal properties to change in unpredictable ways. Therefore, periodic measurement of the LPM solution is recommended in order to establish reasonable working practices relative to the expected solution longevity.

H.2 Dielectric parameters

H.2.1 General

This subclause describes three methods to determine the frequency dependent dielectric parameters of tissue simulating media used for implant testing. Methods 1 and 2 (open coaxial probe and slotted line) are applicable to all media and Method 3 (static conductivity meter) is limited to HPM solutions.

H.2.2 Method 1

The open coaxial probe method is a general method that is well suited for lossy liquid and gel materials[8]. It is based on a S_{11} measurement of an open end of the coaxial line in contact with the liquid using a Vector Network Analyser (VNA) or equivalent commercially available instrumentation. The open coaxial probe is calibrated for its specified frequency and dielectric parameter range.

H.2.3 Method 2

The slotted TEM transmission line method[8] is another suitable method based on measuring the complex transmission coefficient (S_{21}) in a TEM-mode coaxial transmission line filled with the medium under test. The magnitude and phase as a function of distance are measured inside the slot in the liquid or gel filled slotted TEM line using a VNA. The parameters are most accurately assessed when the reflections can be neglected (i.e. when the transmission line is sufficiently long).

H.2.4 Method 3

For HPM solutions, the permittivity is dominated by water and the frequency dependent dielectric parameters can be determined by the combined use of static conductivity meters and Formulae (H.1) and (H.2). The saline solutions with different conductivities specified in Clause 8 can be accurately mixed using the recipes as described in Reference [9].

A modified Debye model can be used to calculate the complex dielectric parameters:

$$\varepsilon^*(f) = \varepsilon_\infty + \frac{\varepsilon_s - \varepsilon_\infty}{1 + i \cdot 2\pi f \cdot \tau} + \frac{\sigma_i}{i \cdot 2\pi f \cdot \varepsilon_0} \tag{H.1}$$

where the parameters are defined in Table H.1.

All parameters exhibit linear dependence on concentration and temperature in the relevant range and can be fit with simple Formula (H.2).

$$p(c, T) = A + B \times T + C \times c \tag{H.2}$$

where

p can be any of the four parameters (ε_∞, ε_S, τ, σ_i);

c is the concentration of NaCl (mol/l);

T is the temperature in °C;

f is the frequency in Hz;

A, B, C are summarized in Table H.1.

Table H.1 — Parameters for constructing dielectric curves using Method 3

Parameter (p)	A	B	C
ε_∞	10,367	−0,218	3,533
ε_S	86,887	−0,348	−15,973
τ (* 10^{-12} s)	13,973	−0,227	−1,013
σ_i (S/m)	−0,217	0,010	10,336
NOTE Evaluating these parameters in combination with Method 1 and Method 2 results in a conductivity temperature coefficient of approximately 2 %/°C and relative permittivity (ε_r) temperature coefficient of approximately 0,5 %/°C.			

H.2.5 Good measurement practices to achieve precise dielectric measurements

H.2.5.1 General

Several factors influence the quality and reliability of dielectric measurements. The influencing factors are listed and shortly commented for each of the three measurement methods. The factors can vary for probe type, material parameters, and frequency. Calibration documents associated with the dielectric measurement equipment usually provide figures for the measurement precision.

H.2.5.2 Method 1 (open coaxial probe)

The following influencing factors should be considered for Method 1:

— The probe's geometry (diameters) and bead material dielectric properties can deviate from the specifications. Large deviations of the actual probe parameters from specifications that are applied in the data processing algorithm influence the measurement results;

— The probe is connected to a VNA and the complex reflection coefficient, S_{11}, is measured. The S_{11} measurement itself has a certain accuracy, which is related to the VNA. This accuracy of the VNA influences the amplitude and the phase of the measured S_{11};

— System (probe + VNA) calibration should be performed with great care. At this stage the operator can influence the measurement results. Open coaxial probe calibration is based on three standards: Open – Short – Load. Each of the calibration standards should be measured with high confidence and repeatability;

— The applied numerical algorithms can influence the measurement results. Errors or instabilities in the algorithms can lead to questionable dielectric measurements;

— The probe is positioned in the material under test in such a way that the boundaries do not cause extra reflections. With finite sample size volumes, there can be reflections from the container walls. The probe position can influence the reflections. If the container is larger than 1 000 cm^3 the effect of the reflection can be neglected for both HPM and LPM;

— A good contact between the probe flange and the material under test should be established. The presence of air bubbles or surface roughness in planar solids or surface contamination influences the contact quality. If the mentioned items are removed prior to the measurement, this factor can be neglected;

— Temperature dependency of the dielectric parameters should be properly assessed. Errors in the measured temperature of the material under test can lead to less precise dielectric measurement results.

Specific details are described in References [9] and [10].

H.2.5.3 Method 2 (slotted line)

The following influencing factors should be considered for Method 2:

— Deviations in the slotted line geometry (impedance of the line) from specifications can result in false input data for the transmission coefficient calculations;

— The slotted line is connected to a VNA and the complex transmission coefficient, S21, is measured. The accuracy of the VNA influences the amplitude and the phase of the measured S21;

— System (line + VNA) calibration (2-port calibration with the empty line) should be performed. Each of the calibration standards should be measured and the repeatability of the measurements should be checked;

— Temperature dependency of the dielectric parameters should be assessed. Impedance mismatch introduced by the presence of the media in the line (deviation from calibrated condition, i.e. empty

line) can lead to reflections. If not considered, the extra reflections caused by the impedance mismatch of the finite line can lead to inaccurate measurements. Broader frequency sweep and averaging of the dielectric parameter curves can minimize this influence;

— Homogeneity of the material in the line should be maintained and potential air bubbles or separation of emulsion should be avoided. Wrong assumptions regarding homogeneity can lead to erroneous measurement results.

H.2.5.4 Method 3 (static conductivity meter)

The following influencing factors should be considered for Method 3:

— A static conductivity meter works at a very low but finite frequency (in the kHz range), which is a good approximation of the static conductivity;

— Deviations in the geometry of the electrodes from the specifications (mechanical accuracy, cell constant, electrode polarization) can result in false input data for the calculations;

— Resistance measurement and resolution of the static conductivity meter: The method is based on resistivity measurement; the electronics has its own accuracy (residual resistivity and linearity) which affects the conductivity results;

— The static conductivity meter is calibrated with a known reference liquid. The concentration accuracy of the reference solution and the precision of its temperature influence the calibration;

— Temperature of the material under test should be measured to calculate frequency dependent dielectric parameters based on Formula (H.1) and Formula (H.2);

— Homogeneity of the material in the measuring cell should be established for accurate measurements. Shaking of the sample container (e.g. in ultrasonic bath) can remove the inhomogeneity.

In general, for all types of measurements further notes of good measurement practices can be found in documents published by Reference [11].

H.3 Thermal parameters

H.3.1 General considerations

In general, for suitable tissue simulating materials, thermal properties are not a function of the dielectric parameters. However, for a given recipe set, the parameters and the validity of the above assumption should be assessed and demonstrated at least once.

Reliable temperature measurements can only be conducted if the Grashof number is sufficiently large, i.e. the viscosity of the medium or gel should be much larger than 1 Pa·s. An appropriate method for measuring the viscosity should be selected, e.g. rheometers. The viscosity should be determined for the entire temperature range, of which the lowest number should be used.

H.3.2 Methods

H.3.2.1 Introduction

The direct assessment of SAR with temperature probes requires the value of the heat capacity. This subclause describes two methods to determine the heat capacity of tissue simulating media used for implant testing. Furthermore, it is necessary to demonstrate either by simulation or by experiment that the effect of heat conduction and convection are negligible in the assessment of SAR for the maximum spatial gradient, temperature difference and duration of heating. The simulation approach can be used when the thermal conductivity and the Grashof number are known. It can also be demonstrated by experiment for the conditions of maximum spatial temperature gradient ∇T, temperature difference (ΔT) and duration of assessment (Δt). The demonstration of negligible effects related to conduction

and convection is not required for HPM formulations that contain greater than 95 % water and the properties of water can be used.

H.3.2.2 Method to determine heat capacity

The most common way of determining the specific heat capacity is differential scanning calorimetry. It can be used to determine specific heat capacity as a function of temperature as well as the location of phase transition temperatures (relevant for gels). The temperature of the unknown sample and of a reference material is changed on the same way according to a predefined curve with constant cooling and heating rates. At a constant rate the temperature difference observed between the reference material and its surroundings is the result of the different heat capacities of the reference material and the surrounding material. The time dependence of the temperature difference is measured. The differential scanning calorimeter is calibrated with the known reference material, any temperature difference can be directly converted into heat flow. In such a way the heat capacity is determined as a function of the temperature.

H.3.2.3 Method to determine thermal conductivity

The hot wire method is appropriate for determining thermal conductivity. A thin wire is embedded into the sample to be investigated, simultaneously serving as a heating element and a temperature sensor. During the experiment, the wire is heated with a constant electrical power source. The temporal development of the increase in temperature at the hot wire is calculated from the resistance of the wire. This temperature increase is primarily dependent on the thermal conductivity of the sample. The thermal conductivity is determined by considering both the thermal contact resistance between the sample and the wire and the axial heat losses to the temporal temperature development.

Annex I
(informative)

RF exposure system validation method

I.1 Objective

An RF exposure system as described in Clause 8 consists of a tissue simulating media filled phantom and an RF field source. There are a variety of techniques which can be used for validating the RF exposure system and its associated measurement equipment. The objective of this annex is to provide a detailed explanation of one possible general validation method which provides a basic verification that all components of the RF exposure system are functioning properly. The validation method involves comparing measurements of temperature rise, electric field, or SAR around a well-defined test object placed in the RF exposure system to target values derived from numerical simulation of the test object in a representative electromagnetic model of the RF exposure system.

As there are many possible RF exposure systems which meet the needs of Clause 8, this annex demonstrates how to apply the validation method using target values derived from an example ideal RF exposure configuration. This ideal exposure configuration provides nearly uniform tangential electric field incident along the test object. The example RF source configuration does not represent a physically realizable RF exposure system as it incorporates ideal mathematical RF source models with precise locations and orientations. To reduce differences between measurement results and simulation results, the target values for the example exposure configuration provided in this annex can be replaced with more appropriate values obtained from simulation of an RF exposure configuration better representing the physical RF exposure environment being validated (e.g. by including the physical models of the RF field source and media filled phantom). The validation method provided can be adapted for use with alternative test objects or at different measurement locations around test objects by generating new target values from simulation of the test object's RF exposure. The validation method can be repeated at different locations within a tissue simulating media filled phantom to verify the expected field distribution within the phantom from the RF field source is as expected.

I.2 Validation procedure

Perform the following steps to validate an RF exposure system using a test object:

Step 1 Either use one of the pre-defined test objects (called "standard AIMD test objects" or SAIMDs) with the example exposure temperature rise, electric field or SAR target values provided in this annex or complete electromagnetic (and thermal if using temperature measurement) numerical simulations to derive alternative target values specific to an RF exposure configuration of a test object in the RF exposure system to be validated by:

- Simulating a given test object at a given position in a representative model of the RF exposure test system to get temperature rise during RF exposure time, |Electric Field|^2 or SAR results at each desired validation location around the test object;
- Repeating the simulation without the test object present to determine the Incident Field. The incident field is the average electric field component tangential to the test object;
- Calculate normalized target values by dividing the temperature rise during RF exposure time, |Electric Field|^2 or SAR for each location around the test object by the square of the incident field.

Step 2 Execute the RF exposure measurement procedure for specific locations around the test object.

— Measure the temperature rise during RF exposure time, |Electric Field|^2 or SAR at desired validation locations around the test object;

— Determine the measurement incident field on the test object. The measurement incident field is the average electric field component tangential to the test object during RF exposure;

— Normalized measurement values are obtained by dividing the temperature rise during RF exposure time, |Electric Field|^2 or SAR for each measurement location around the test object, by the square of the incident field.

Step 3 Compare the normalized measurement results to the target values from simulation.

— Calculate the difference between the normalized measurement results and simulation target values relative to the target value at each validation location measured around the test object;

— If the difference is within the combined uncertainties of the target value simulations, the RF field source, the tissue simulating phantom and the measurements then the RF exposure system is considered validated.

I.3 Standard test object definitions

An RF exposure system can be validated using either of two standard test objects (SAIMD-1 and SAIMD-2):

— SAIMD-1: A straight AISI 316L Stainless Steel (GoodFellow 502-716-12, McMaster-Carr 92705K17 or equivalent) wire of 1,6 mm diameter and 200 mm length with a 0,5 mm thick polyolefin heat shrink tubing insulation (Alpha Wire FIT-221-3/32, 3M VFP-876-3/32 or equivalent) as shown in Figure I.1[3][12]. At both ends of the rod 10 mm are left un-insulated.

Dimensions in millimetre

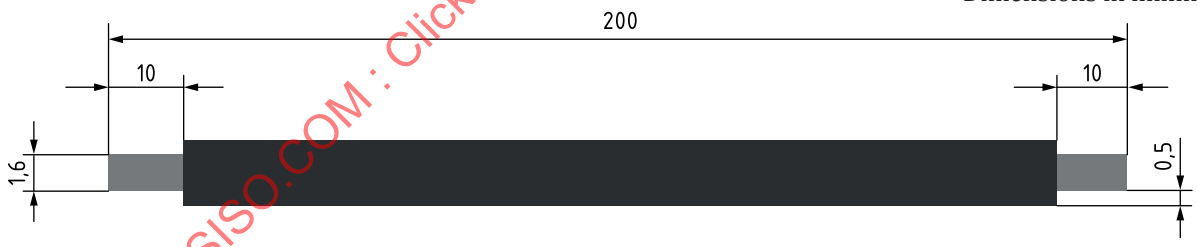


Figure I.1 — SAIMD-1 Polyolefin insulated stainless steel wire (not to scale)[3][12]

— SAIMD-2: An ASTM B348-5 Grade 5 Titanium alloy rod (GoodFellow 030-337-40, McMaster-Carr 89055K313 or equivalent) of 3,175 mm diameter and 100 mm length with 1 mm diameter holes drilled through the rod such that the centre of the holes is 1 mm from each end as shown in Figure I.2[13][14][15]. The 1 mm diameter holes are included to allow placement of temperature measurement probes inside them during use. The use of SAIMD-2 for determination of local SAR is described in ASTM F2182-11a[1].

Dimensions in millimetre

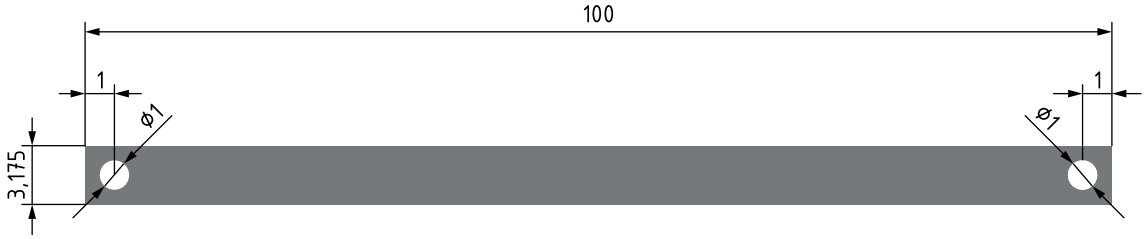


Figure I.2 — SAIMD-2 Uninsulated titanium rod with temperature monitoring holes near ends (not to scale)[13][14][15]

I.4 Example SAIMD exposure simulation target values

I.4.1 General

Numerical electromagnetic simulations of an example ideal SAIMD RF exposure were performed using multiple software tools based on different Merlot solution methods such as finite-difference time-domain (FDTD) and finite element (FEM). Each SAIMD was simulated in 0,47 S/m HPM lossy background dielectric material as defined in Annex L. The electric and thermal material properties of the SAIMD and surrounding background dielectric used for the simulations are given in Table I.1. Differences between the properties of actual SAIMD materials used for measurements from the properties used in simulation to generate target values might increase error in the validation assessment.

To generate the example ideal uniform RF exposure (defined as <±1 dB variation in magnitude and <±20 % variation in phase at 64 MHz ±5 % by Table 2 in Clause 8) along the SAIMD in simulation, each SAIMD was placed in the centre of opposing counter-propagating ideal plane-wave sources with its long axis aligned with the electric field of the sources as illustrated in Figure I.3. The source size was [Sx, Sy, Sz] as given in Table I.2. Using this simple ideal source configuration, the magnetic fields cancel and the incident tangential electric field along the SAIMD has nearly constant amplitude and phase.

To reduce the overall simulation processing time, the spatial resolution of the numerical computations away from the SAIMD was coarser than the resolution within the SAIMD and its nearby high electric field spatial gradient regions. The spatial resolution was adequate when further reductions in simulation resolution had negligible effect on the simulation results. Perfectly matched layer absorbing boundary conditions were used at the electromagnetic simulation boundary extents [Bx, By, Bz] given in Table I.2 for each simulation.

Table I.1 — Simulation dielectric and thermal material properties

Simulation material	Relative permittivity ε_r	Electrical conductivity (σ) S/m	Specific heat (Cp) J/kg/K	Thermal conductivity (k) W/m/K	Density (ρ) kg/m^3
SAIMD-1 AISI 316L Stainless Steel[a]	n/a	∞ (Perfect Electrical Conductor)	500	16	8 000
SAIMD-1 Polyolefin Insulation[b]	4	0 (Perfect Electrical Insulator)	1 000	0,2	1 350
SAIMD-2 Grade 5 Titanium[a]	n/a	∞ (Perfect Electrical Conductor)	526,3	6,7	4 430
HPM[c]	78	0,47	4 181	0,6	1 001

[a] Metal properties from www.matweb.com, www.goodfellowusa.com or www.mcmaster.com accessed 11/3/2014.

[b] Properties of typical wire/cable grade cross-linked polyolefin from www.matweb.com, www.efunda.com, www.plastics.ulprospector.com accessed 11/3/2014.

[c] HPM gel properties match HEC defined in Annex L with the thermal conductivity approximated as that of the main constituent water.

Table I.2 — Simulation sizes in Cartesian X-, Y- and Z-directions when the SAIMD long axis is aligned along the Z-direction

SAIMD	Counter-propagating plane-wave sources S			Simulation boundary extents B		
	Sx mm	Sy mm	Sz mm	Bx mm	By mm	Bz mm
1	100	100	300	160	160	360
2	100	100	200	160	160	260

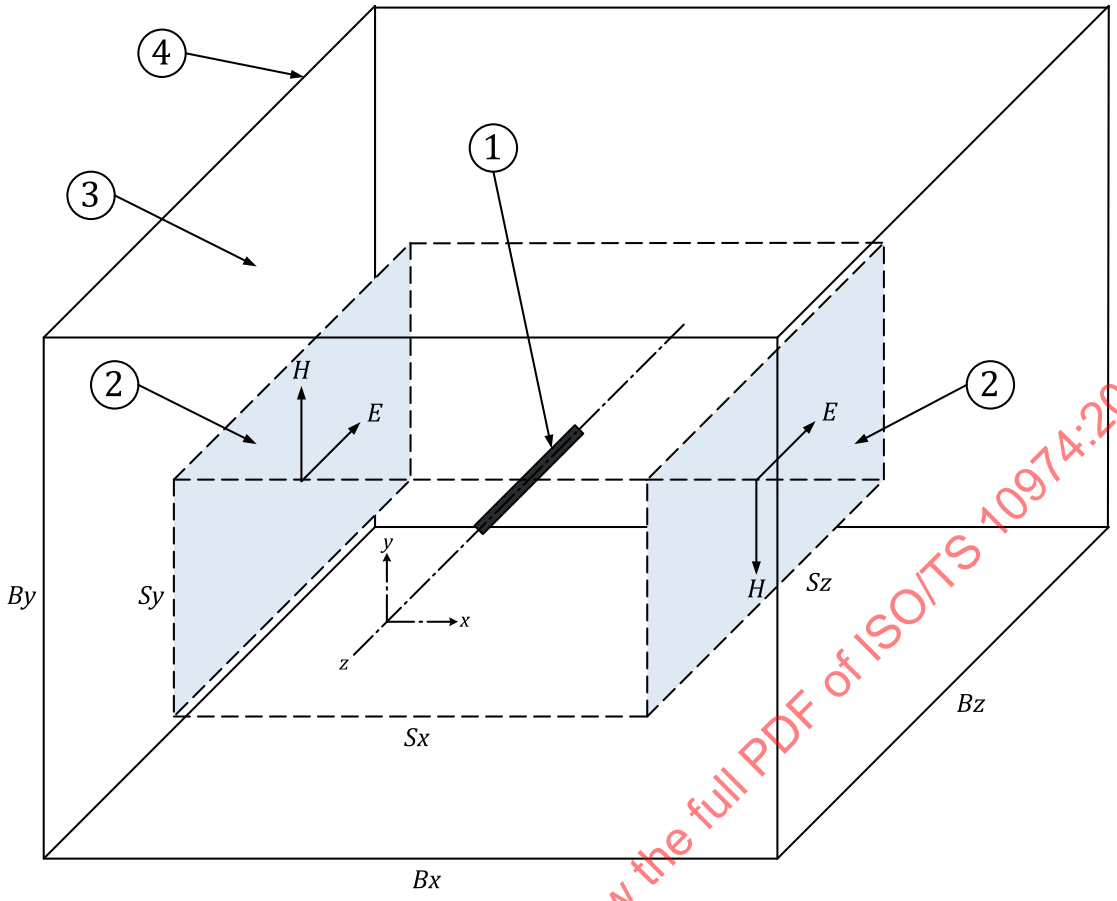


Figure I.3 — Simulation boundary extents [*Bx*, *By*, *Bz*] (4) showing the two counter-propagating sources (2) of size [*Sx*, *Sy*, *Sz*] in homogenous dielectric material (3) with a centred SAIMD (1) (not to scale)

The rms |total electric field| and point SAR values were extracted from the electromagnetic simulation results at specific locations on lines extending along the axis of the SAIMD and radially away from the SAIMD as shown in Figure I.4. All values were from the approximate central plane of the SAIMD long axis.

The electric field distribution around the SAIMD obtained after convergence of the electromagnetic simulation was used as a constant in time input source for thermal simulation. The thermal simulation computation spatial resolution was adequate when further reductions in simulation resolution had negligible effect on the simulation results. The thermal properties used in the simulations are given in Table I.1. The thermal exposure was calculated for 6 min and 15 min constant electromagnetic field exposure durations consistent with durations specified in IEC 60601-2-33 and ASTM F2182-11a[1] respectively. The temperature rise values from the simulation results were calculated on lines extending along the axis of each SAIMD, radially away from each SAIMD, and in the centre of the 1 mm diameter hole near the end of SAIMD-2 as shown in Figure I.4.

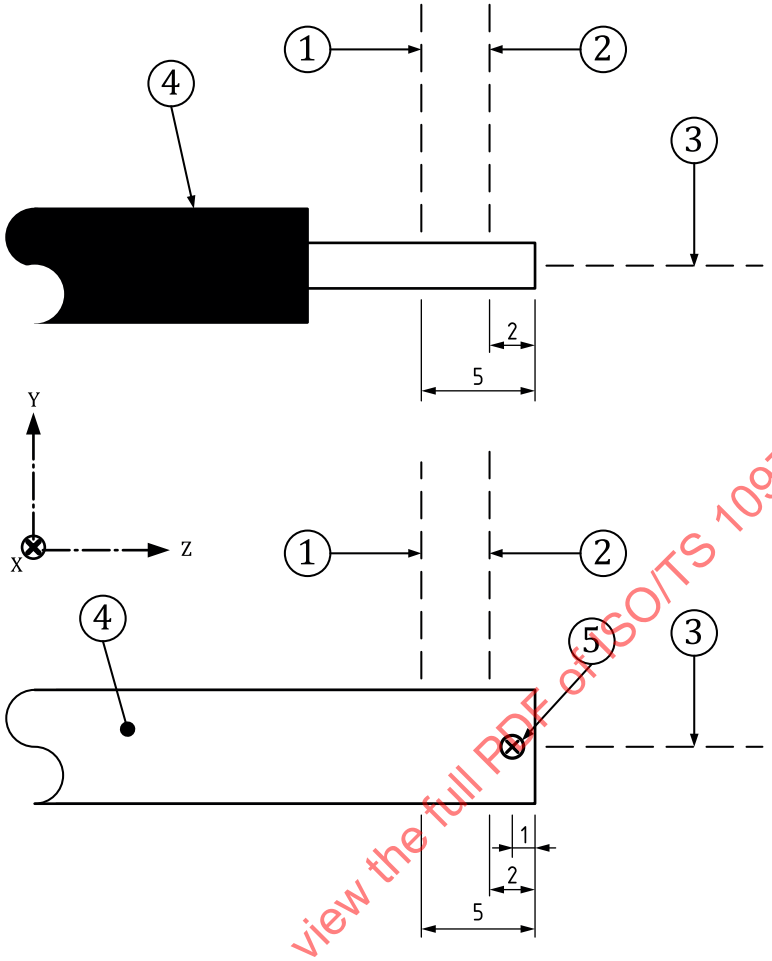


Figure I.4 — Illustration of the 5 mm radial (1), 2 mm radial (2) and axial (3) locations around the two SAIMDs (4) for the simulation electric field, SAR and temperature target results (not to scale). Temperature results are also calculated at the centre of the 1 mm hole in SAIMD-2 (5)

The electromagnetic simulations were repeated without the SAIMD present to get the incident field. The incident field represents the average electric field component tangential to the long axis of the SAIMD. The incident field was calculated as the average of tangential rms electric field values at all simulation points along the SAIMD location.

The normalized target values were calculated at each specific location around the SAIMD by dividing the temperature rise, rms |total electric field|^2 and point SAR, by the square of the incident field.

The simulation results neglect thermal convection, practical disturbances due to fixtures and measurement probes[14] and variation of dielectric parameters with temperature. The temperature rise values depend on the properties of the material (e.g. the temperature rise will be less for a higher HPM specific heat.)

I.4.2 Example SAIMD-1 target values

The temperature rise, rms |total electric field|^2 and point SAR results normalized to the square of the incident exposure from SAIMD-1 simulations are given in Table I.3. These quantities are the median values for the ideal uniform incident electric field along the length of the SAMD reported by four or more independent simulation groups during development of this annex. The individual target values from each of the independent simulations deviated a minimum of −22 % to a maximum of 34 % in electric field and SAR and −5 % to 15 % in temperature rise from the median values in Table I.3. The variation among independent simulation groups does not represent the expected uncertainty for any one particular simulation but rather provides an example of the differences that can occur between

even well-defined simulations and illustrates the need for simulation convergence verification and validation.

Simulated and measured values for temperature rise, electric field, and SAR for real RF exposure systems with actual phantom tanks where there is non-uniform incident tangential electric field and scattering from the phantom boundaries will differ from these target values. The values in the table will be most closely reproduced in a phantom by placing the SAIMD 5 cm or more from all boundaries and in a location that maximizes uniformity of electric field along its length.

Table I.3 — Normalized target values for SAIMD-1 induced rms |total electric field|^2, point SAR, 6 min and 15 min temperature rise at locations along the Z-direction for axial and along the Y-direction for 2 mm, 5 mm radial lines from the SAIMD

Dist. from SAIMD [mm]	|Total electric field|^2 / |Incident electric field|^2 [V/m/(V/m)]^2			Point SAR / |Incident electric field|^2 [mW/kg/(V/m)^2]			6 min. temp. rise / |Incident electric field|^2 [mK/(V/m)^2]			15 min. temp. rise / |Incident electric field|^2 [mK/(V/m)^2]		
	Axial	2 mm radial	5 mm radial	Axial	2 mm radial	5 mm radial	Axial	2 mm radial	5 mm radial	Axial	2 mm radial	5 mm radial
0,5	2 051,71	1 053,12	832,00	968,4	492,65	390,65	3,25	3,19	2,96	3,75	3,70	3,47
1	933,22	536,12	442,63	438,18	251,96	204,84	2,86	2,93	2,77	3,35	3,45	3,28
1,5	429,62	309,11	266,52	201,72	147,30	125,26	2,47	2,66	2,55	2,96	3,17	3,06
2	222,51	194,81	174,75	104,48	93,03	83,03	2,14	2,40	2,33	2,62	2,91	2,84
2,5	127,37	125,92	117,55	59,80	58,75	54,08	1,86	2,13	2,10	2,34	2,64	2,60
3	83,54	87,51	84,03	39,23	41,28	38,91	1,63	1,92	1,91	2,10	2,42	2,41
3,5	57,09	63,87	62,08	27,02	30,02	29,15	1,44	1,73	1,73	1,90	2,23	2,23
4	41,34	48,38	47,48	19,41	22,74	22,32	1,28	1,57	1,57	1,73	2,06	2,06
4,5	30,77	37,46	36,94	14,48	17,36	17,16	1,14	1,42	1,43	1,59	1,90	1,91
5	23,96	28,33	28,20	11,27	13,43	12,96	1,03	1,28	1,29	1,47	1,76	1,77
5,5	19,00	22,55	22,39	8,92	10,68	10,28	0,92	1,15	1,16	1,35	1,62	1,63
6	15,48	18,24	18,02	7,33	8,64	8,27	0,82	1,05	1,06	1,25	1,51	1,52
6,5	12,83	14,98	14,70	6,02	7,08	6,74	0,75	0,95	0,96	1,17	1,40	1,41
7	10,95	12,46	12,14	5,16	5,88	5,56	0,68	0,86	0,87	1,08	1,30	1,31
7,5	9,44	10,48	10,14	4,34	4,89	4,64	0,61	0,79	0,79	1,01	1,22	1,23
8	8,17	8,92	8,57	3,84	4,21	3,92	0,56	0,71	0,72	0,95	1,14	1,14
8,5	7,25	7,67	7,31	3,40	3,61	3,35	0,51	0,64	0,65	0,89	1,06	1,06
9	6,47	6,66	6,31	3,00	3,10	2,88	0,46	0,59	0,59	0,83	1,00	1,00
9,5	5,73	5,83	5,49	2,70	2,74	2,51	0,43	0,53	0,54	0,79	0,93	0,93
10	5,25	5,15	4,82	2,46	2,42	2,21	0,39	0,49	0,49	0,74	0,87	0,87
10,5	4,80	4,59	4,27	2,25	2,15	1,96	0,35	0,45	0,45	0,69	0,82	0,82
11	4,41	4,11	3,82	2,05	1,93	1,75	0,33	0,40	0,40	0,66	0,77	0,77
11,5	4,03	3,72	3,41	1,90	1,74	1,57	0,30	0,37	0,37	0,62	0,72	0,72
12	3,79	3,38	3,11	1,77	1,58	1,43	0,27	0,34	0,34	0,58	0,69	0,69
12,5	3,54	3,09	2,83	1,66	1,45	1,30	0,25	0,31	0,30	0,56	0,64	0,64
13	3,32	2,84	2,61	1,55	1,33	1,20	0,23	0,28	0,28	0,52	0,60	0,60
13,5	3,13	2,63	2,42	1,46	1,23	1,11	0,22	0,26	0,26	0,50	0,58	0,57
14	2,94	2,45	2,24	1,38	1,14	1,03	0,20	0,24	0,23	0,48	0,54	0,54
14,5	2,81	2,29	2,10	1,32	1,07	0,96	0,19	0,22	0,21	0,45	0,51	0,51
15	2,67	2,15	1,97	1,25	1,00	0,91	0,17	0,20	0,20	0,43	0,49	0,48

I.4.3 Example SAIMD-2 target values

The temperature rise, rms |total electric field|^2 and point SAR results normalized to the square of the incident exposure from SAIMD-2 simulations are given in Table I.4 and Table I.5 for an SAIMD oriented with the 1 mm diameter hole axis along the X-direction. These quantities are the median values for the ideal uniform incident electric field along the length of the SAIMD reported by four or more independent simulation groups during development of this annex. The individual target values from each of the independent simulations deviated a minimum of −14 % to a maximum of 14 % in electric field and SAR and −7 % to 19 % in temperature rise from the median values in Table I.4 and Table I.5. The variation among independent simulation groups does not represent the expected uncertainty for any one particular simulation but rather provides an example of the differences that can occur between even well-defined simulations and illustrates the need for simulation convergence verification and validation.

Simulated and measured values for temperature rise, electric field, and SAR for real RF exposure systems with actual phantom tanks where there is non-uniform incident tangential electric field and scattering from the phantom boundaries will differ from these target values. The values in the table will be most closely reproduced in a phantom by placing the SAIMD 5 cm or more from all boundaries and in a location that maximizes uniformity of electric field along its length.

Table I.4 — Normalized target values for SAIMD-2 induced temperature rise at the centre of the 1 mm holes near each SAIMD end

Time min	**Temp. rise** **|Incident field|^2** [mK/(V/m)^2]
6	0,621
15	0,809

Table I.5 — Normalized target values for SAIMD-2 induced rms |total electric field|^2, point SAR, 6 min and 15 min temperature rise at locations along the Z-direction for axial and along the Y-direction for 2 mm, 5 mm radial lines from the SAIMD

Dist. from SAIMD [mm]	**|Total electric field|^2** **|Incident electric field|^2** [V/m/(V/m)]^2			**Point SAR** **|Incident electric field|^2** [mW/kg/(V/m)^2]			**6 min. temp. rise** **|Incident electric field|^2** [mK/(V/m)^2]			**15 min. temp. rise** **|Incident electric field|^2** [mK/(V/m)^2]		
	Axial	**2 mm radial**	**5 mm radial**	**Axial**	**2 mm radial**	**5 mm radial**	**Axial**	**2 mm radial**	**5 mm radial**	**Axial**	**2 mm radial**	**5 mm radial**
0,5	212,44	126,83	79,55	101,19	58,19	36,27	0,660	0,594	0,524	0,841	0,780	0,709
1	149,96	81,26	52,98	72,31	38,24	24,83	0,637	0,569	0,503	0,820	0,751	0,689
1,5	100,22	53,65	36,93	47,70	25,15	17,29	0,596	0,531	0,480	0,780	0,714	0,660
2	66,29	37,52	27,24	31,50	17,45	12,69	0,547	0,493	0,451	0,731	0,678	0,631
2,5	45,20	27,28	20,79	21,37	12,66	9,68	0,504	0,459	0,422	0,687	0,640	0,601
3	31,99	20,54	16,33	15,10	9,54	7,61	0,457	0,422	0,393	0,640	0,603	0,577
3,5	23,71	15,92	13,10	11,17	7,43	6,13	0,420	0,391	0,370	0,600	0,570	0,548
4	18,27	12,41	10,55	8,60	5,64	4,78	0,385	0,360	0,341	0,566	0,540	0,519
4,5	14,72	10,18	8,83	7,07	4,61	3,98	0,355	0,333	0,320	0,530	0,511	0,498
5	11,93	8,38	7,41	5,73	3,84	3,37	0,325	0,308	0,297	0,500	0,483	0,470
5,5	10,05	7,17	6,41	4,86	3,25	2,90	0,303	0,287	0,277	0,478	0,460	0,449
6	8,46	6,09	5,52	4,06	2,80	2,52	0,279	0,265	0,256	0,449	0,439	0,429
6,5	7,22	5,36	4,89	3,45	2,44	2,22	0,258	0,249	0,241	0,428	0,418	0,409
7	6,43	4,71	4,33	3,09	2,16	1,97	0,242	0,229	0,226	0,409	0,399	0,389

Table I.5 *(continued)*

Dist. from SAIMD [mm]	|Total electric field|^2 / |Incident electric field|^2 [V/m/(V/m)]^2			Point SAR / |Incident electric field|^2 [mW/kg/(V/m)^2]			6 min. temp. rise / |Incident electric field|^2 [mK/(V/m)^2]			15 min. temp. rise / |Incident electric field|^2 [mK/(V/m)^2]		
	Axial	2 mm radial	5 mm radial	Axial	2 mm radial	5 mm radial	Axial	2 mm radial	5 mm radial	Axial	2 mm radial	5 mm radial
7,5	5,60	4,19	3,87	2,68	1,92	1,76	0,228	0,210	0,207	0,389	0,379	0,371
8	5,00	3,79	3,51	2,37	1,73	1,60	0,209	0,200	0,198	0,370	0,361	0,358
8,5	4,61	3,43	3,19	2,21	1,57	1,45	0,200	0,187	0,180	0,358	0,344	0,340
9	4,15	3,13	2,92	1,98	1,44	1,33	0,187	0,171	0,168	0,340	0,331	0,328
9,5	3,79	2,90	2,71	1,79	1,32	1,23	0,171	0,162	0,160	0,328	0,318	0,311
10	3,57	2,68	2,51	1,70	1,23	1,14	0,163	0,150	0,149	0,313	0,302	0,299
10,5	3,30	2,49	2,33	1,56	1,14	1,07	0,153	0,141	0,139	0,301	0,291	0,289
11	3,04	2,34	2,19	1,44	1,07	1,00	0,147	0,134	0,131	0,290	0,280	0,275
11,5	2,91	2,21	2,07	1,39	1,01	0,95	0,140	0,128	0,122	0,281	0,269	0,263
12	2,74	2,08	1,96	1,29	0,96	0,90	0,130	0,119	0,117	0,270	0,259	0,253
12,5	2,59	1,97	1,85	1,21	0,91	0,85	0,122	0,112	0,110	0,260	0,250	0,245
13	2,48	1,88	1,77	1,18	0,87	0,81	0,119	0,108	0,103	0,253	0,240	0,235
13,5	2,36	1,80	1,70	1,12	0,83	0,78	0,112	0,100	0,098	0,244	0,231	0,229
14	2,26	1,74	1,63	1,06	0,81	0,75	0,108	0,095	0,093	0,238	0,224	0,220
14,5	2,19	1,67	1,57	1,04	0,77	0,72	0,102	0,090	0,089	0,231	0,215	0,212
15	2,10	1,61	1,51	0,99	0,74	0,70	0,099	0,088	0,083	0,223	0,208	0,204

I.5 Test object measurement

Operation of the RF exposure system can be quantified using measured 6 min or 15 min temperature rise, electric field, or SAR around the test object. Validation measurement locations should be chosen to be reproducible, provide significant measured signal above the incident fields and have minimum measured signal spatial gradient to reduce position sensitivity. Example locations for measurements along lines extending from the SAIMD as shown in Figure I.4 are given in Table I.3, Table I.4 and Table I.5. Although multiple target value examples are provided at a number of locations around the SAIMD, the RF exposure system validation can be completed using measured results of as few as one of these parameter values at a single location. Completing the validation assessment at both ends of a symmetrical test object is recommended to add confidence in the results.

The measured incident field is the nominal rms electric field component tangential to the long axis of the test object during RF exposure and can be determined by:

— Averaging electric field probe measurements taken along the test object mounting location during the equivalent RF exposure without test object present;

— Extrapolation from measurements at other locations during the test object exposure;

— Measurements of the total vector electric field if the vector field orientation is known (e.g. the tangential field component is approximately equal to the total field component in a region where the incident field is predominantly oriented along the test object long axis);

— Thermal measurement calculations.

The conductivity of HPM phantom tissue simulating media surrounding the test object during measurements should be verified to be within specification.

For each validation measurement location around the test object, the normalized measured values are calculated by dividing the temperature rise, total rms |electric field|^2 or point SAR when the test object is present by the square of the measured incident field.

I.6 Compare simulation target values to measured results

The difference between simulated and measured values at a specific validation location, $Diff_{Point}$, around the SAIMD is defined relative to the simulated value as:

$$Diff_{Point} = \frac{|Measurement - Target|}{Target}$$

where

Target is the normalized simulation target value;

Measurement is the normalized measured value.

For multiple measurements along a given axial or radial line, a similar difference metric, $Diff_{Line}$, for the line of measurements can be computed for all measurement locations along the line as:

$$Diff_{Line} = \sqrt{\frac{\sum_{n=1}^{N}(Measurement_n - Target_n)^2}{\sum_{n=1}^{N}(Target_n)^2}}$$

where

n is the measurement location index for N distinct locations;

$Target_n$ is the normalized target value at each location n along the radial or axial line;

$Measurement_n$ is the normalized measured value at each location n along the radial or axial line.

The RF exposure system is considered validated if the calculated validation difference metric(s) are within the combined uncertainties of the target value simulations, the RF field source, the tissue simulating phantom and the measurements.

Alternatively, the difference can be assessed using a statistical analysis of the calculated $Diff_{Point}$ values for multiple measurement locations. In this case, the RF exposure system is considered validated if the distribution of the $Diff_{Point}$ values is within the combined uncertainties. For example, if the standard (k = 1) combined uncertainty of the target value simulations, RF field source, tissue simulating phantom, and the measurements is ±30 % and 100 measurements were collected, then the system is considered validated if at least 68 of the calculated $Diff_{Point}$ values are within ±30 % of the corresponding target values.

Annex J
(informative)

MR scanner RF transmit coil

The ideal MR scanner transmit (TX) coil generates a uniform circularly polarized RF magnetic field (B_{1+}) at the Larmor frequency perpendicular to the static field over the desired imaging volume. TX coil designs are generally based on the fact that an ideal longitudinal current density in an infinitely long cylindrical surface having a sinusoidal dependence around the surface perimeter creates a uniform radial magnetic field inside the cylinder[16]. This ideal current density is approximated using a number of discrete RF current-carrying elements (rungs) to produce a transverse RF magnetic field distribution in the imaging volume of a birdcage-style resonator TX coil[17]. The number of current-carrying elements necessary to produce magnetic field uniformity sufficient for imaging is typically 8 to 32.

When developing models to be used in numerical simulations, additional considerations such as RF power source location and connection to the birdcage structure (e.g. two quadrature sources or idealised current distributions from sources in each element) can affect the resulting RF TX coil fields, particularly for partially implanted AIMDs[18]. TX Coils in MR scanners with quadrature sources are tuned to a representative clinical load (~80 kg male). Such TX coil models used in numerical simulations should use this (single) tuned value for all evaluations.

MR scanners adhere to well defined patient exposure temperature and SAR limits as described in IEC 60601-2-33 however the design of the RF TX coils used in MR scanners varies. Table J.1 describes example design parameters for the common birdcage-style resonator used as a whole-body RF TX coil in 1,5 T clinical MR scanners. This example RF TX coil information is useful for development of RF TX coil simulation models and radiated RF exposure test systems as described in Clause 8 and Clause 15.

Table J.1 — Clinical 1,5 T MR scanner whole-body RF TX birdcage-style resonator design parameters

Design parameter	Typical value	Information
RF Frequency	64 MHz	Typical value for 1,5 T MR scanner.
Resonator shape	Cylindrical	Typical for horizontal bore 1,5 T MR scanner, including scanners with elliptical patient accessible apertures.
Resonator size	60 cm to 70 cm Patient accessible aperture diameter	Typical MR scanner patient accessible apertures have been nominally 60 to 70 cm for the smallest cross section width with the RF birdcage resonator inner surface immediately inside the MR scanner bore wall. Wider aperture birdcage resonators are being introduced to accommodate larger patients with patient aperture width dimensions as large as 74 cm for the major axis of an elliptical coil. To minimize end-ring effects at the birdcage centre, RF Birdcage coils typically have a physical length to minimum diameter aspect ratio close to 1 to 1. Longer RF birdcage coils can provide larger regions of uniform RF magnetic fields for imaging however they expose a greater amount of the patient to the RF fields and thus their field level is generally limited by the whole body SAR exposure levels of IEC 60601-2-33. Shorter RF birdcage coils can be used at higher RF field levels because less of the patient is exposed however their RF field levels become limited by partial body SAR rather than whole body SAR exposure levels from IEC 60601-2-33. Birdcage coils as short as 38 cm have been used in clinical MR scanners.
	55 cm to 70 cm Birdcage length	

Table J.1 *(continued)*

Design parameter	Typical value	Information
Resonator type	High-pass	Birdcage resonators can be designed as low-pass (capacitors in the rungs), high-pass (capacitors in the end rings) or band-pass (capacitors in both locations.)
RF shield	Diameter and length	The birdcage resonator is surrounded by a conductive RF shield to reduce RF coupling to other parts of the MR scanner. The shield diameter will be slightly larger than the birdcage resonator diameter. The shield will typically be within 2 cm of the resonator. The shield length extends beyond the resonator length and can be approximated by the length of the patient accessible MR scanner bore.
Magnetic field polarization	Circular	To reduce patient RF exposure, clinical MR scanners are designed to operate birdcage resonators with clockwise or counter-clockwise circular polarization of the transverse magnetic field (B_{1+}) when loaded and linear polarization operation is considered a serious fault condition. For non-clinical use, linear polarization operation of a birdcage resonator can be useful in providing known and repeatable AIMD RF field exposures.

Annex K
(informative)

Current distribution on the AIMD as a function of the phase distribution of the incident field

K.1 Background

In general, the energy picked up by an antenna is maximum at resonance condition. This condition results in high electrical field strength at the tip. In a similar fashion this holds true for elongated AIMDs (i.e. leads) embedded in a tissue simulant, and gives rise to a high SAR and temperature at its ends. These conditions are generally evaluated assuming a constant phase distribution of the tangential component of the incident E-field along the AIMD. However, it has been shown that the local energy deposition near the ends of the AIMD can be further increased if the phase distribution of the tangential component of the incident electrical field is not uniform [see Formula (K.1)]. Therefore, the worst-case conditions of the tangential incident E-field depend not only on the length of the AIMD but also the phase distribution along the AIMD.

A change of the phase of the tangential component of the incident electrical field along the AIMD leads to an asymmetrical current distribution, which causes a comparatively steep gradient of the current at the exposed end of AIMD. This entails a concentration of charges at the end and, consequently, the electric flux and deposited power near the end will be increased. The conditions under which the deposited power is maximized can be approximated by a constant gradient of the phase of the incident field along the AIMD while keeping the amplitude of its tangential component constant [see Formula (K.1) and Formula (K.2)].

The following subclauses discuss these incident E-field conditions in lossy medium and theoretically demonstrate the effect of the phase on the temperature rise/deposited energy near the end of the AIMD.

K.2 Phase gradients in lossy dielectrics

In a homogeneous lossy dielectric, a constant phase gradient with constant amplitude of the tangential component of the incident field can only be fulfilled for inhomogeneous waves [see Formula (K.3)]. The electric and magnetic field vectors of the inhomogeneous waves can be written as:

$$\begin{Bmatrix} \vec{E} \\ \vec{H} \end{Bmatrix} \propto e^{-jk\vec{n}\cdot\vec{r}} \tag{K.1}$$

where

k is the wave number of the dielectric ;

$\vec{r}$ is the position vector.

In order to satisfy the scalar wave Formula (K.2),

$$\Delta\Phi + k^2\Phi = 0 \tag{K.2}$$

the complex vector $\vec{n}$ should fulfil the following conditions:

$$\begin{aligned} &\mathrm{Re}\left\{\vec{n}\right\}^2 - \mathrm{Im}\left\{\vec{n}\right\}^2 = 1 \\ &\mathrm{Re}\left\{\vec{n}\right\} \cdot \mathrm{Im}\left\{\vec{n}\right\} = 0 \end{aligned} \tag{K.3}$$

which require that the real and the imaginary part of $\vec{n}$ be orthogonal. For constant amplitude and constant phase gradient of the E_y component in the y-direction, $\vec{n}$ can be written as:

$$\begin{aligned} \mathrm{Re}\left\{\vec{n}\right\} &= \begin{pmatrix} \cosh\beta \\ 0 \\ 0 \end{pmatrix} \\ \mathrm{Im}\left\{\vec{n}\right\} &= \begin{pmatrix} 0 \\ -\sinh\beta \\ 0 \end{pmatrix} \end{aligned} \tag{K.4}$$

β is an arbitrary real number, which determines the angle between the direction of maximum attenuation and the direction of the phase gradient. The phase gradient is a function of β.

The exposure of a lead to a field with constant phase gradient can cause a significant increase of the E-field at one of its tips in comparison to, for example, exposure at its resonance length with constant phase. The worst-case phase gradient depends on the dielectric properties of the environment and on the electrical characteristics of the wire. Among these are, for example, insulation properties, wire diameter, and pitch. Therefore, the worst-case phase gradient needs to be determined for each lead in particular. At phase gradients other than the worst case, the E-fields at the tips can be lower than for exposure with constant phase.

Phase characteristics as those described above usually occur in the reactive near field of sources. Due to the nature of inhomogeneous waves, they decay rapidly when the distance from the source is increased. In lossy dielectrics, such as body tissue or tissue simulant, the attenuation of their amplitudes is even more pronounced. In the high field regions of homogeneous phantoms, the phase distribution of the tangential incident E-field is rather constant. It appears therefore difficult to generate a field distribution that is appropriate to account for the effects described above.

The phase gradients which lead to worst-case heating are a function of the electric lead characteristics and have to be determined for each lead.

K.3 Transfer function to determine induced heating

The temperature rise of the tissue surrounding the electrode at the end of an AIMD arises from an E-field induced by an MR RF magnetic field and can be expressed as:

$$\Delta T = A\left|\int_0^L S(z)E_{\tan}(z)dz\right|^2 \tag{K.5}$$

where

A is a constant;

S is the E-field sensitivity function of the lead;

$E_{\tan}$ is the tangential component of the incident E-field;

z is the distance along the lead, which has a length, L, and $z = 0$ is at the electrode (see Reference [3]).

In Formula (K.5), $S(z)$ is a function of AIMD designs and electrical properties of surrounding tissues. $S(z)$ and $E_{\tan}(z)$ are complex quantities and thus can be written as $|S(z)|e^{i\omega\phi s(z)}$ and $|E_{\tan}(z)|e^{i\omega\phi E(z)}$, respectively.

Then, Formula (K.5) becomes:

$$\Delta T = A\left|\int_0^L \left|S(z)\right|\left|E_{\tan}(z)\right|e^{i\omega\left[\phi_S(z)+\phi_E(z)\right]}dz\right|^2 \tag{K.6}$$

From Formula (K.6), it is apparent the temperature rise at the electrode will depend on both magnitude and phase distributions of the incident field. Therefore, depending on $\phi_S(z)$ and $\phi_E(z)$, they can constructively or destructively add to each other. Furthermore, the worst case occurs when phase distributions of $S(z)$ and $E_{\tan}(z)$ are cancelling each other, or in other words, $\phi_S(z) = -\phi_E(z)$. Then, the worst-case temperature rise becomes:

$$\Delta T_{\text{worst}} = A\left|\int_0^L \left|S(z)\right|\left|E_{\tan}(z)\right|dz\right|^2 \tag{K.7}$$

In the worst case, if the condition $\phi_S(z) = -\phi_E(z)$ is achieved, there is no resonance associated with a length of AIMD system.

As shown in Figure 6 of Reference [3], 80 cm capped wire in the worst-case phase distribution can heat more than twice that of the resonant length heating in the uniform phase distribution. Thus, *in vitro* heating testing of an AIMD system that consists of a long lead should properly account for this effect.

Annex L
(informative)

Tissue simulating medium formulations

L.1 Rationale

The following simulated tissue formulations approximate the electrical properties (conductivity and permittivity) of tissues commonly associated with AIMDs. Suggested formulations are provided that simulate high permittivity lossy tissues such as muscle, high permittivity and high conductivity body fluids such as blood, and low loss, low permittivity fatty tissue. Practical considerations for the choice of high permittivity medium (HPM) and low permittivity medium (LPM) formulations include:

— Easily available as a liquid or gel;

— Easy to use;

— Stable over time and with temperature;

— Easy to adjust target conductivity and permittivity values;

— Non-toxic.

NOTE The medium formulations and physical properties listed in the following tables have been evaluated by a limited number of laboratories. It is important to verify critical parameters. Methods for measuring the thermal and electrical properties of tissue simulating media are summarized in Annex H.

L.2 HPM and LPM Recipes

Table L.1 through Table L.4 provide examples of HPM and LPM formulations suitable for characterizing AIMDs labelled for use on 1,5 T MR scanners. The recipes are chosen to produce media with reliable electrical and thermal properties at 25 °C however there can be small differences between ingredient lots so verification of conductivity after preparation is required. To avoid evaporation of water and contamination that can lead to changes in media properties, the media should be sealed in an airtight container when not in use and covered during use whenever possible.

Table L.1 — Hydroxyethyl Cellulose gel recipes for HPM at 64 Mhz and 25 °C

Physical parameters	High permittivity medium (HPM) Hydroxyethyl Cellulose (HEC) Gel		
Contents by % weight	96,85 % water 3 % HEC 0,15 % NaCl	97,71 % water 2 % HEC 0,294 % NaCl	97,37 % water 2 % HEC 0,632 % NaCl
Relative dielectric permittivity	78	78	78
Conductivity [S/m]	0,47	0,65	1,2
Density [kg/m^3]	1 001	993	993
Specific Heat [J/kg/K]	4 181	4 181	4 181
Thermal conductivity [W/m/K]	NA	NA	NA
Viscosity [Pa·s]	4,1	NA	NA
NOTE 0,47 S/m gel is from ASTM F2182-11a, a 2 % 0,47 S/m HEC-based recipe has also been demonstrated. HEC is Sigma-Aldrich product number 09368 (Fluka), CAS no. 9004-62-0.			

Table L.2 — Polyacrylic Acid gel recipes for HPM at 64 Mhz and 25 °C

Physical parameters	High permittivity medium (HPM) Polyacrylic Acid (PAA) Gel	
Contents by % weight	98,9 % water 0,99 % PAA 0,13 % NaCl	98,629 % water 0,838 % PAA 0,533 % NaCl
Relative dielectric permittivity	78	78
Conductivity [S/m]	0,47	1,2
Density [kg/m^3]	NA	NA
Specific Heat [J/kg/K]	4 159	NA
Thermal conductivity [W/m/K]	NA	NA
Viscosity [Pa·s]	NA	NA
NOTE High salt concentrations can affect viscosity of PAA gels. 0,47 S/m gel is from ASTM F2182-11a. PAA is Sigma-Aldrich product number 436364, CAS no. 76774-25-9.		

Table L.3 — Saline recipes for HPM at 64 Mhz and 25 °C

Physical parameters	High permittivity medium (HPM) Saline		
Contents by % weight	99,75 % water 0,25 % NaCl	99,636 % water 0,364 % NaCl	99,315 % water 0,685 % NaCl
Relative dielectric permittivity	78	78	78
Conductivity [S/m]	0,47	0,65	1,2

Table L.4 — Emulsion recipes for LPM at 64 Mhz and 25 °C

Physical parameters	Low permittivity medium Emulsion	
Contents by % weight	55 % Triton 30 % Castor Oil 13,5 % water 1,5 % NaCl	55 % Triton 30 % Canola Oil 13,5 % water 1,5 % NaCl
Relative dielectric permittivity	15,1	11,5
Conductivity [S/m]	0,054	0,045
Density [kg/m^3]	1 033	NA
Specific Heat [J/kg/K]	2 290	NA
Thermal conductivity [W/m/K]	0,189	NA
Viscosity [Pa·s]	0,51	NA
NOTE Castor Oil emulsion is from Annex L of ISO/TS 10974 edition 1. Triton® X-100 is Sigma-Aldrich product number x100, CAS no. 9002-93-1. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO or IEC of the product named. Equivalent products may be used if they can be shown to lead to the same results.		

L.3 Example preparation methods

L.3.1 General

This subclause provides example detailed steps in preparing 0,054 S/m LPM and 0,47 S/m PAA HPM. All steps are done at typical room temperature (20 °C to 25 °C) unless otherwise noted.

L.3.2 LPM formulation

Ingredients [percentage by weight] of Triton®-based low-permittivity medium (LPM) from ISO/TS 10974:2012, Annex L:

— Water [13,5 %] — deionised or distilled water, conductivity less than 1 mS/m;

— NaCl [1,5 %] — reagent grade, >99 % pure;

— Castor Oil [30 %];

— Triton® X-100 [55 %] — Sigma-Aldrich product number X100.

Synonym: p-tertiary-Octylphenoxy polyethyl alcohol, CAS no. 9002-93-1.

Chemical formula: $(C_2H_{40})nC_{14}H_{22O}$.

The steps to follow for the preparation of Triton®-based low-permittivity medium (LPM) are:

Step 1 Add NaCl to water and stir to dissolve completely. Optional: water can be warmed to facilitate dissolving.

Step 2 Add water/NaCl solution to Triton® (be sure Triton® is well-mixed/shaken).

Step 3 Blend vigorously with pail mixer or immersion blender for approximately 5 min.

Step 4 Add Castor Oil to Triton®/water/NaCl solution.

Step 5 Continue to blend vigorously for approximately 20 min.

Step 6 The resulting emulsion is ready to use within 8 h or after bubbles, due to mixing, dissipate. The appearance is semi-transparent.

Step 7 Verify dielectric properties match those given in Table L.4 before use.

NOTE Triton® X-100 is a known irritant.

L.3.3 PAA HPM formulation

Ingredients [percentage by weight] of PAA gelled saline medium (HPM) with conductivity of 0,47 S/m based on ASTM F2182-11a[1]:

— Water [98,9 %] — deionised or distilled water, conductivity less than 1 mS/m;

— NaCl [0,13 %] — reagent grade, >99 % pure;

— Polyacrylic Acid [0,99 %] — Sigma-Aldrich product number 436364.

Synonym: Polyacrylic acid partial sodium salt, CAS no. 76774-25-9.6

NOTE Different PAA can have different gelling properties and the conductivity can vary slightly between PAA lots.

The steps to follow for the preparation of PAA gelled saline high-permittivity medium (HPM) are:

Step 1 Add NaCl to water and stir to dissolve completely. Optional: water can be warmed to facilitate dissolving.

Step 2 Verify the water/NaCl solution conductivity is 0,26 S/m at 25 °C.

Step 3 Add PAA to water/NaCl solution, stir to suspend completely.

Step 4 After one hour, blend the suspension into a slurry. A commercial grade immersion blender with a blade has been found to be satisfactory. The blender is used intermittently for at least 20 min in order to remove all lumps of discernible size.

Step 5 The slurry is ready to use after 24 h. Stir, but do not shake, occasionally. The appearance of the slurry should be semi-transparent, free of bubbles, and free of lumps of discernible size.

Step 6 Verify conductivity matches Table L.2 before use.

Annex M
(informative)

Generation of incident fields

M.1 General

The first objective of this annex is to show example coil-phantom configurations and pathways that generate a relatively uniform tangential E-field for E-field coupling and relatively uniform B-field for inductive coupling. The second objective is to show example coil-phantom configurations and pathways that generate practically achievable non-uniform *in vitro* incident tangential E-fields which can be used for AIMD model validation.

NOTE 1 The fields induced in the phantom are considerably different from the fields induced in the human. However, the phantoms are well suited to generate a well-controlled test environment that can be correlated to human situations.

NOTE 2 Since the E-field can vary with excitation source, phantom, polarization, and pathway, the coil configurations and pathways shown are simulation examples only and are not meant to be used directly. The E-fields generated with a particular system can be determined through characterization.

NOTE 3 The polarization of the coil (linear or quadrature) influences the E-fields generated. Several examples use linear polarization which is typically not achievable in clinical scanners[22] but can be useful in generating model validation excitations.

M.2 Background

Tier 1 and Tier 2 of Clause 8 and Clause 15 rely on uniform tangential E-fields to estimate the energy deposition of the AIMD.

Tier 3 and Tier 4 of Clause 8 and Clause 15 rely on an AIMD model to estimate the energy deposition of the AIMD. The general requirement of AIMD model validation is covered in 8.8.

Since most models and most *in vivo* exposures will both have non-trivial phase behaviour, non-uniform in vitro pathways that vary both phase and magnitude are needed to validate the AIMD model and demonstrate applicability of a model for *in vivo* exposure conditions.

M.3 Uniform incident field distributions

Relatively uniform incident field distributions can be achieved using the ASTM F2182-11a[1], circular or oval phantoms in a birdcage coil. Example phantom placement with respect to the coil, pathways, E-field magnitude maps, and tangential E-fields are shown in Figure M.2 through Figure M.5 for circular polarization (CP) and linear polarization (LP). The relative fields are plotted according to the scale bar in Figure M.1, where yellow is maximum.

Figure M.1 — Scale bar for relative E-field magnitude plots

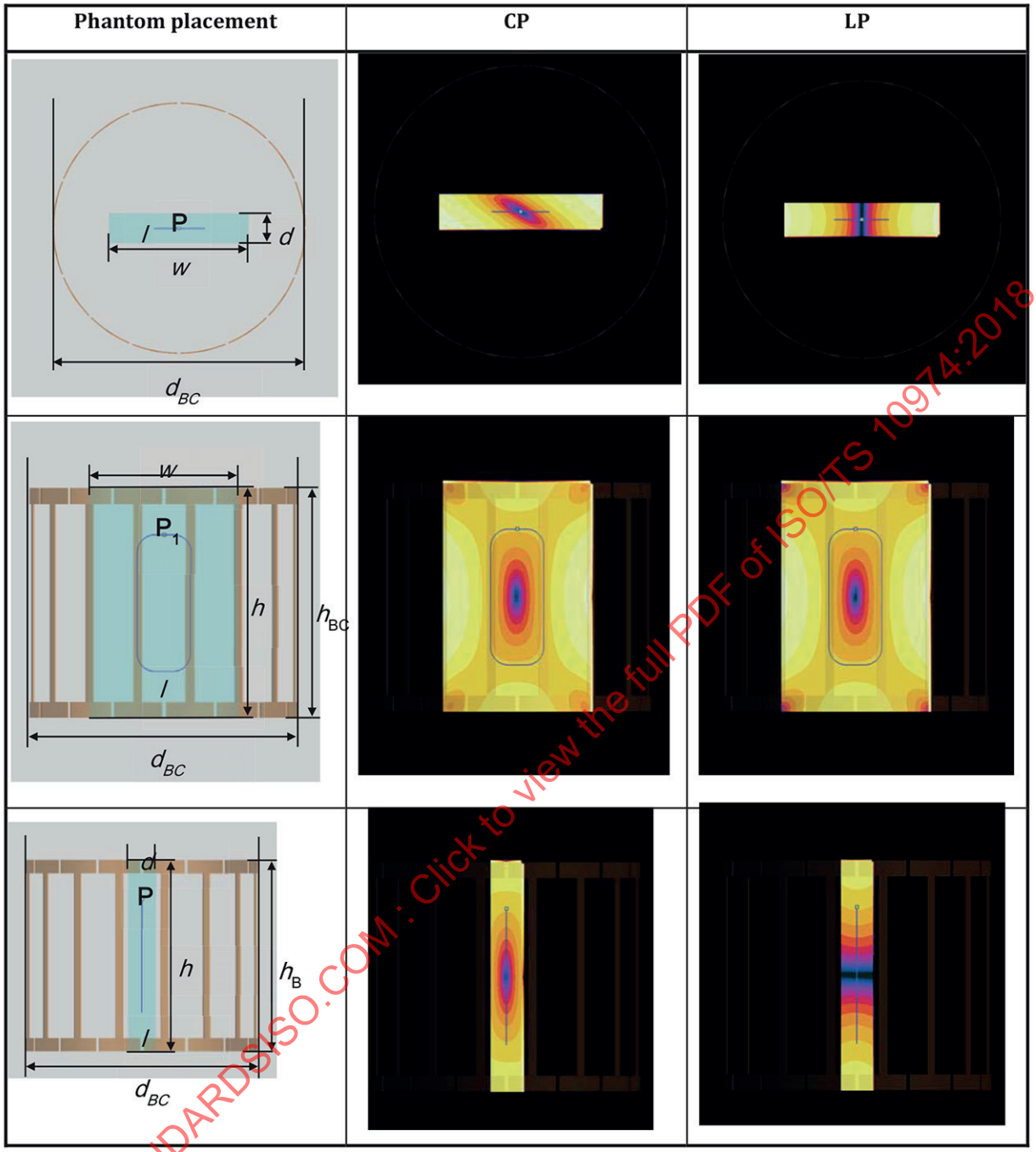


Figure M.2 — Coil and ASTM F2182-11a phantom (phantom placement), E-field magnitude for circular polarization (CP), E-field magnitude for linear polarization (LP)

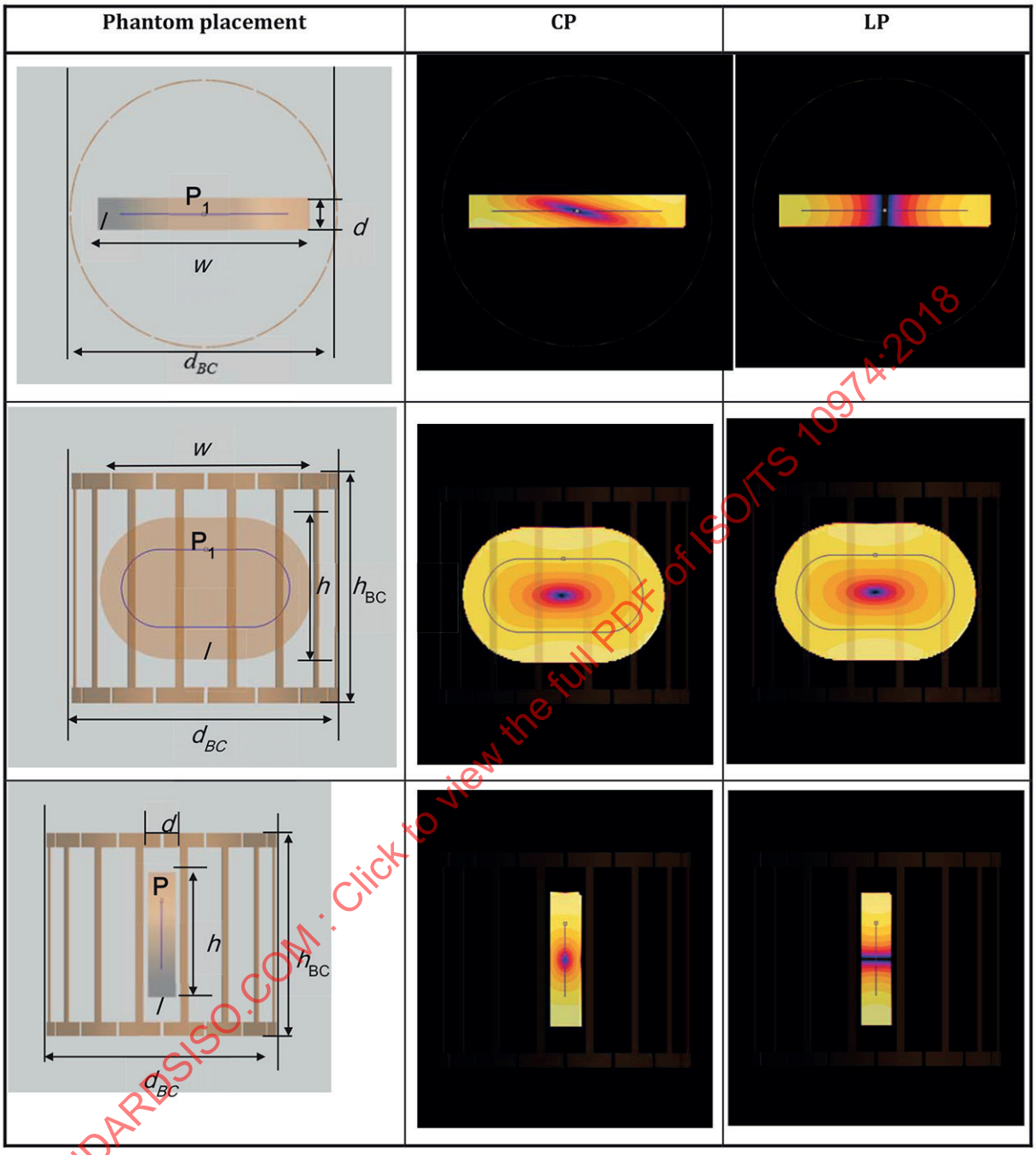


Figure M.3 — Coil and oval phantom (phantom placement), E-field magnitude for circular polarization (CP), E-field magnitude for linear polarization (LP)

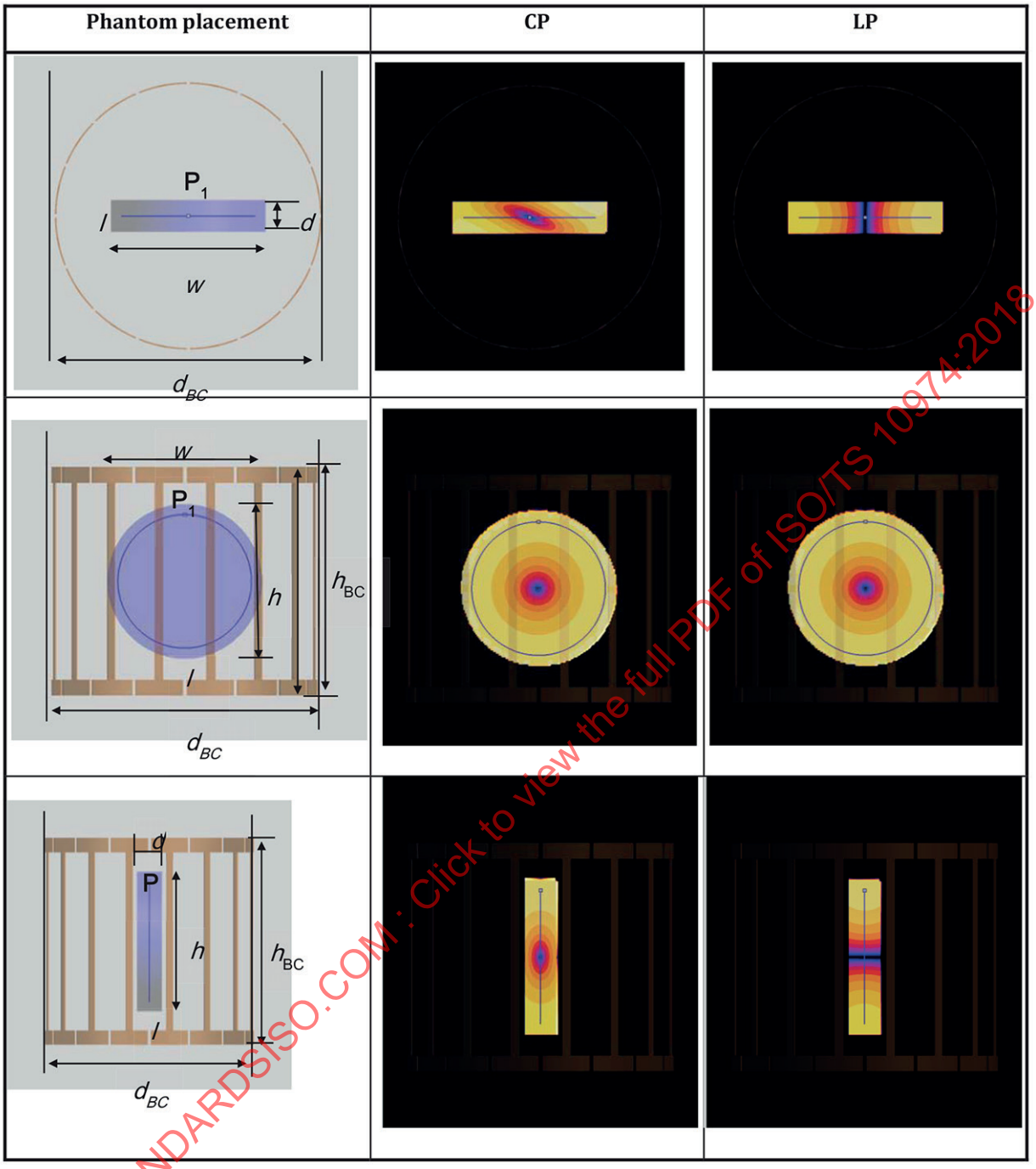
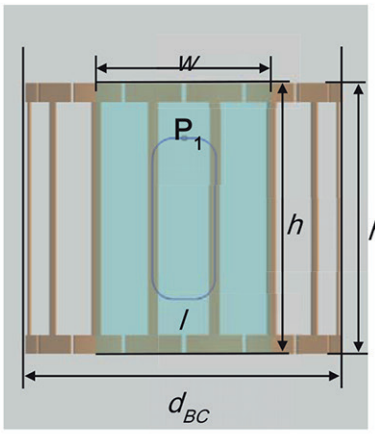
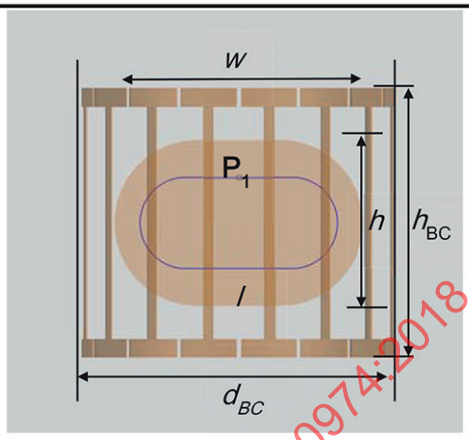
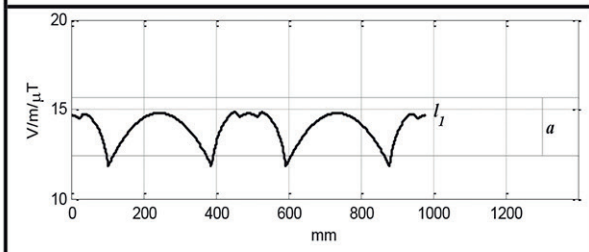
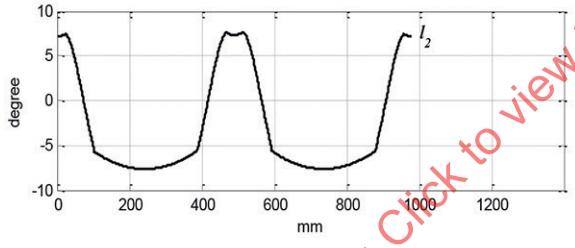
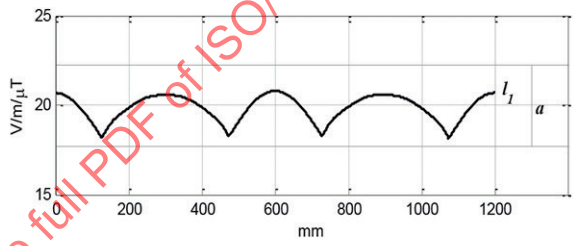
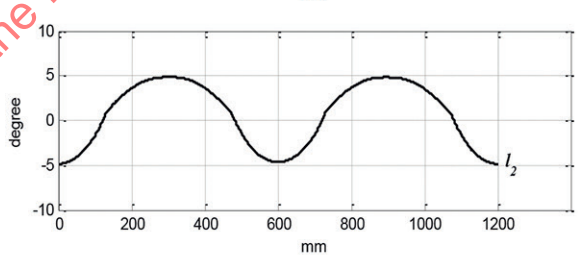
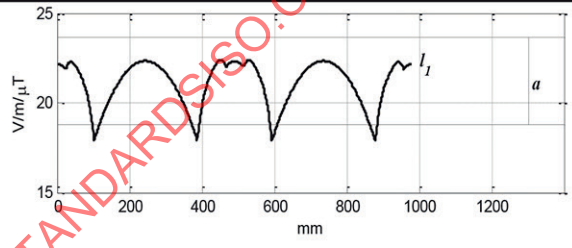
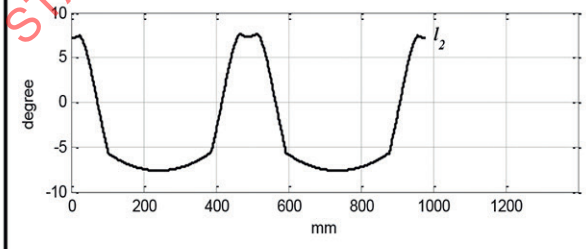
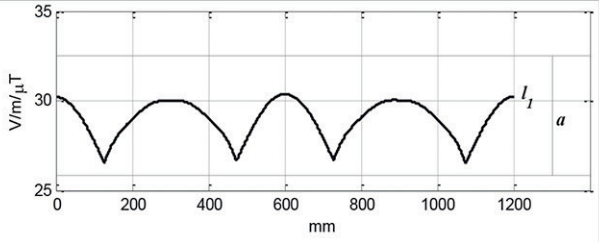
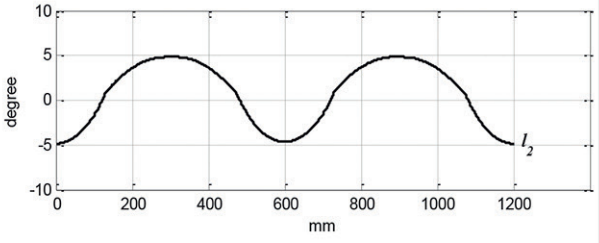


Figure M.4 — Coil and circular phantom (phantom placement), E-field magnitude for circular polarization (CP), E-field magnitude for linear polarization (LP)

ASTM F2182-11a [1]	Oval
	
CP	**CP**
 	 
LP	**LP**
 	 

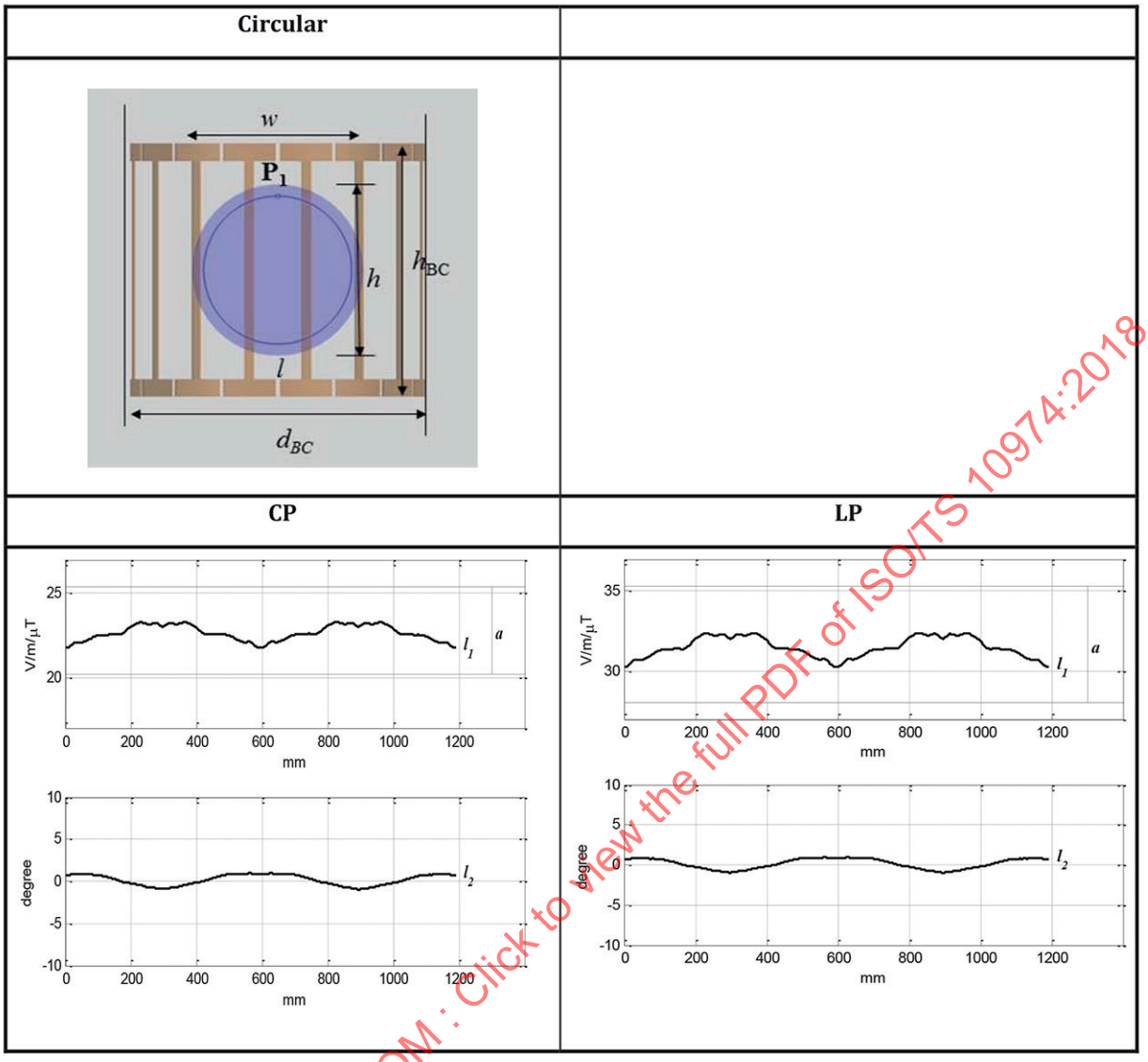


Figure M.5 — Tangential E-field magnitude (V/m/µT) and phase (degree) extracted from the ASTM F2182-11a, oval and circular phantoms for circular polarization (CP) and linear polarization (LP)

Key for Figure M.1 through Figure M.5

w,h,d	extent of phantoms in three dimensions
h_{BC}	length of body coil
d_{BC}	diameter of body coil
l	iso-electric pathway
l_1	magnitude of E_{tan} along *l*
l_2	phase of E_{tan} along *l*
a	average E_{tan} ±1 dB
P_1	spatial location of 0-mm reference