



DPC: 25/30500279 DC

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Date: 23 October 2025

Origin: International

Latest date for receipt of comments: 16 December 2025

Project No. 2024/02621

Responsible committee: CH/150/2 Cardiovascular implants

Interested committees:

Title: Draft BS ISO 10974 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 10974

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*

ICS: 11.040.40

ISO/TC 150/SC 6

Secretariat: **ANSI**

Voting begins on:
2025-10-23

Voting terminates on:
2026-01-15

This document has not been edited by the ISO Central Secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

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Reference number
ISO/DIS 10974:2025(en)

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Published in Switzerland

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91 Foreword

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

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

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

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

108 For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions
109 related to conformity assessment, as well as information about ISO's adherence to the World Trade
110 Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL:
111 www.iso.org/iso/foreword.html.

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

116 This first edition International Standard cancels and replaces the 2018 edition of ISO/TS 10974 and has been
117 technically revised and extended.

118 Changes with respect to the previous edition (ISO/TS 10974:2018) can be found in 7.5 of this document.

119

120 Introduction

121 The first edition (2012) of this document came about following a joint meeting between ISO/TC 150, *Implants*
122 *for surgery*, and IEC/SC 62B/MT 40, *Magnetic resonance equipment for medical diagnosis*, in Vienna, Austria,
123 in September 2006. An agreement was reached to coordinate efforts on the development of a new Technical
124 Specification for the safety of patients with active implantable medical devices (AIMD) undergoing an MRI
125 exam and related further development of IEC 60601-2-33.

126 The second edition (2018) represented experience gained from the first edition of its use in practice and
127 from an understanding of relevant issues and concerns at 1,5 T, the most common MR field strength.

128 This first International Standard edition represents a decade of continued evolution of the state of art since
129 the first Technical Specification was published and close collaboration between medical device
130 manufacturers, MR scanner manufacturers, regulators, and independent experts. It is the product of
131 countless hours of research, development, modelling, testing, and field experience devoted to enabling the
132 safe scanning of patients with AIMDs.

133 Test methods have been expanded to include 3 T and consider advances in MRI technology, such as more
134 complex gradient and RF waveform designs. The methods were streamlined and refined based on extensive
135 field experience. Recognizing that these methods are of potential benefit for passive implants, some
136 considerations for those devices are included.

137 IEC 60601-2-33 provides supporting information and it behooves the readers of this document to be
138 thoroughly familiar with its contents. By mutual agreement between the Joint Working Group (JWG) and
139 MT 40, any and all MR scanner-related requirements will be considered by IEC/SC 62B/MT 40 and will be
140 released through future amendments and editions of IEC 60601-2-33.

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

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

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

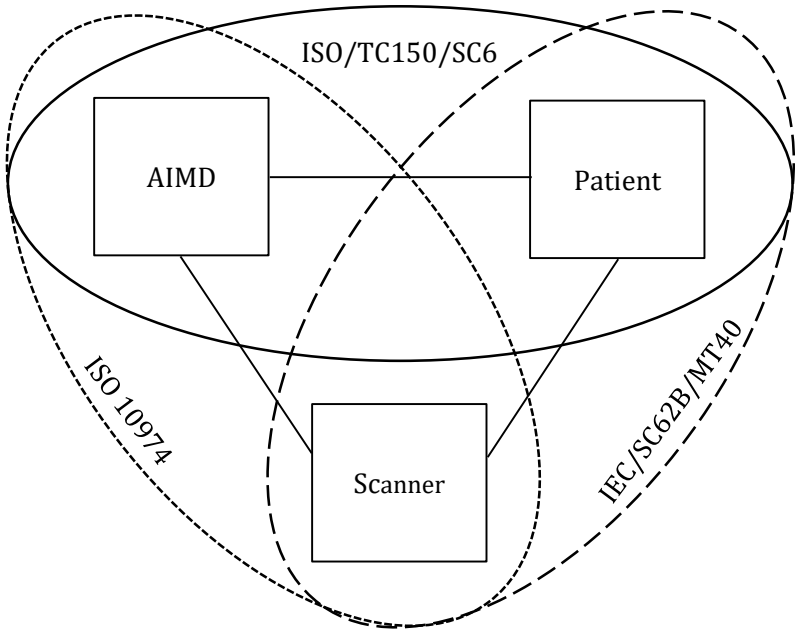


Figure 1 — Responsibilities of product committees illustrating the extent of the scope of this document in terms of the effects between AIMDs and MR scanners

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 acceptance 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 acceptance 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 identified hazards to patients with an AIMD undergoing an MR scan. These hazards give rise to specific test methods as shown in Table 1. Accompanying documentation is also included for consistency between manufacturers and because inadequate labelling can result in a hazard.

Table 1 — Identified patient hazards, corresponding test methods, and accompanying documentation

Patient hazard	Test method and accompanying documentation	Clause
Heat	RF field-induced heating of the AIMD	8
	RF and gradient fields-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
Inadequate labelling	Accompanying documentation	18

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.

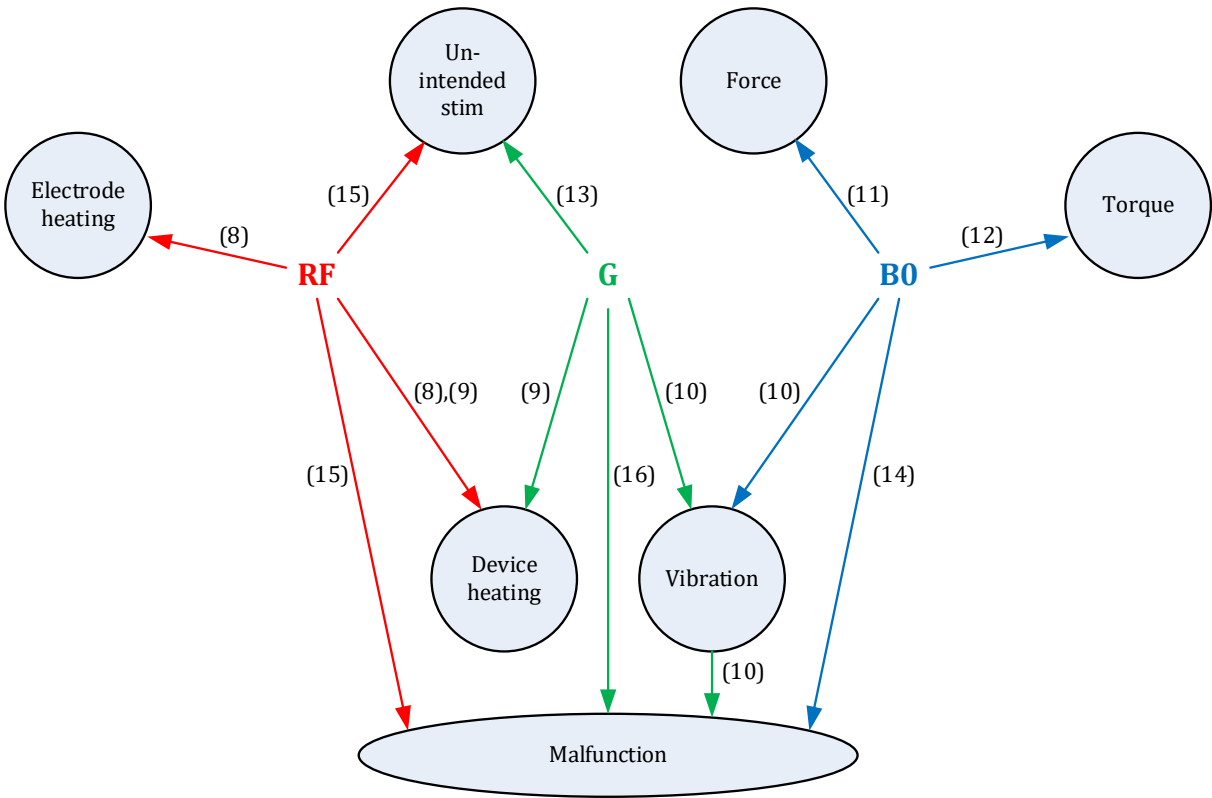


Figure 2 — Relationship between MR scanner output fields (RF, gradient, B_0) and hazards (test method clause numbers in parentheses)

Evaluation of the AIMD for these hazards involves some combination of physical testing and modelling. Tests in Clauses 8 through 16 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 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 are 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 a consequence of the design of the AIMD and is not considered a device failure or malfunction, per se.

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Malfunction is meant to capture a wide range of performance issues, including degradation of performance, loss of function, and unintentional responses 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.

Physical 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 and 3 T scanners (the exceptions are Clause 10, Clause 11, Clause 12, and Clause 17). For all other clauses if a clinical scanner is used the AIMD manufacturer assumes the burden for development and validation of the scanner-based test method. 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. Doing so might result in scanner damage. No scanner operation beyond commercially released clinical performance is required from the MR Manufacturer.

Clause 11 and Clause 12 rely on test methods from ASTM that utilize MR scanners.

The combined fields test (Clause 17) 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 Clause 8 through Clause 16, the combined fields test exposes the AIMD to typical levels and temporal patterns of all three MR scanner magnetic field outputs simultaneously. The combined fields test alone does not constitute a comprehensive assessment of device performance and should be considered as one part of the overall assessment process.

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:

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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 a 1,5 T (64 MHz) or 3 T (128 MHz), whole body cylindrical MR system, using the fixed (integrated) whole body coil.

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

NOTE 2 The scope is fixed (integrated) whole body coil designs and associated RF exposure limits. However, the generalized methods described in this document are equally applicable for evaluating detachable head or extremity RF transmit coils if justification for the RF exposure levels is provided.

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 3 Modification of these tests for particular device types and confirmation of suitability is left to particular product committees.

NOTE 4 Other interested parties, such as device manufacturers, regulatory agencies, and particular product committees, are responsible for setting specific assessment criteria and the determination of risk.

NOTE 5 Safety requirements for MR scanners can be found in IEC 60601-2-33. It provides valuable information regarding the outputs of an MR scanner relevant to AIMDs.

NOTE 6 No consideration has been given to the testing of sensing functionality that might be a part of the intended use of an AIMD. The scope is therefore limited to AIMDs that do not use sensing functions and to AIMDs that have the ability to disable a sensing function during MR scanning that would otherwise be used to affect therapy delivery.

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 60601-2-33:2022, *Medical electrical equipment — Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis*

ASTM F2052-21, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM-F2182-19e2, *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*

ASTM F2213-21, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*

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263 ASTM F2503-23e1, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic*
 264 *Resonance Environment*

265 3 Terms and definitions

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

267 3.1

268 active implantable medical device

269 AIMD

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

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

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

276 3.2

277 active medical device

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

280 [SOURCE: ISO 14708-1:2014, 3.1] [1]

281 3.3

282 B_0

283 static magnetic field of the MR scanner, taken as 1,5 T or 3 T in this document, unless otherwise stated

284 3.4

285 B_{1+rms}

286 root mean square (rms) of B_{1+} , which represents the highest average value for any 10 s period, evaluated
 287 over the duration of the sequence:

$$288 \quad B_{1+rms} = \sqrt{\frac{\int_0^{t_x} [B_{1+}(t)]^2 dt}{t_x}}$$

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

290 Note 1 to entry: When a sequence is shorter than 10 s, the integration time equals the sequence duration, unless sliding
 291 window continuous integration across sequences is used.

292 [SOURCE: IEC 60601-2-33:2022, 201.3.205]

293 3.5

294 B_{1+}

295 component of the RF magnetic field in the rotating frame that is effective for tilting of the nuclear
 296 magnetization

297 [SOURCE: IEC 60601-2-33:2022, 3.203]

298 **3.6**299 B_{1+peak} 300 maximum value of B_{1+}

301 [SOURCE: IEC 60601-2-33:2022, 201.3.204]

302 **3.7**303 **birdcage coil**

304 radiator which generates the RF portion of the magnetic field

305 Note 1 to entry: This usually refers to a bench-top coil used to simulate the operation of a scanner's volume RF transmit
306 coil.307 **3.8**308 **compliance volume**

309 space in which compliance of gradient output is inspected

310 Note 1 to entry: In cylindrical MR equipment with a whole body magnet, the compliance volume is a cylinder with its
311 axis coinciding with the patient's axis and with a radius of 0,20 m and with a length equal to the length of the gradient
312 coil.313 Note 2 to entry: In MR equipment with a transverse field magnet and a whole body gradient system, the compliance
314 volume is a cylinder aligned with the patient's axis, of length equal to the gradient coil diameter, and a radius of 0,20 m
315 or equal to half the distance between the poles of the magnet, whichever is less.316 Note 3 to entry: In all other MR systems, the compliance volume is the volume where any part of a patient
317 body can be properly located according to the intended use of the MR equipment. [SOURCE:
318 IEC 60601-2-33:2022, 201.3.209]319 **3.9**320 $|dB/dt|$ rms

321 root mean square (rms) of the magnitude of the time rate of change of the gradient magnetic field

$$322 \quad \left| \frac{dB}{dt} \right|_{\text{rms}} = \sqrt{\frac{\int_0^{t_x} \left| \frac{dB}{dt} \right|^2 dt}{t_x}}$$

323 where t is time, and t_x is the integration time.324 **3.10**325 **first level controlled operating mode**326 mode of operation of MR equipment where medical supervision mitigates risks associated with biophysical
327 effects induced by exposure to electromagnetic fields328 Note 1 to entry: The electromagnetic fields essential to the operation of MR equipment are the main magnetic field, the
329 spatial encoding gradients, and RF. The operating mode for each field is independently assessed and reported.330 Note 2 to entry: Indirect effects like displacement forces, acoustic noise, or interference with other medical devices are
331 not considered when identifying threshold exposure values.

332 [SOURCE: IEC 60601-2-33:2022, 201.3.216]

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333 **3.11**334 **G**

335 magnetic field gradient expressed in units of T/m

336 Note 1 to entry: G_x introduces a spatial variation of B_0 (or B_z) along the X-axis of the gradient/magnet coordinate system;
 337 it has a non-linear spatial behaviour with significant B_x and B_y components when moving away from isocentre.

338 [SOURCE: IEC 60601-2-33:2022, Table 201.AA.101]

339 **3.12**340 **gradient output**

341 parameter characterizing the gradient performance, such as rate of change of the magnitude of the magnetic
 342 field, or electric field induced by one or more gradient units under specified conditions and at a specified
 343 position

344 [SOURCE: IEC 60601-2-33:2022, 201.3.217]

345 **3.13**346 **gradient unit**

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

349 [SOURCE: IEC 60601-2-33:2022, 201.3.218]

350 **3.14**351 **head SAR**

352 SAR averaged over the mass of the head

353 Note 1 to entry: The lower extent of the head is generally considered to be a line drawn from the foramen magnum
 354 anteriorly along the inferior border of the body of the mandible in closed mouth position.

355 [SOURCE: IEC 60601-2-33:2022, 201.3.219]

356 **3.15**357 **intended use**358 **intended purpose**

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

361 [SOURCE: ISO 14971:2019, 3.6] [2]

362 **3.16**363 **lead**

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

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

367 **3.17**368 **lead port**

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

371 **3.18**
 372 **local SAR**
 373 SAR averaged over any 10 g of tissue of the body

374 [SOURCE: IEC 60601-2-33:2022, 201.3.222]

375 **3.19**
 376 **magnetic resonance equipment**
 377 **MR equipment**
 378 medical electrical equipment for the magnetic resonance examination of a patient

379 Note 1 to entry: The MR equipment is a programmable electrical medical system (PEMS).

380 [SOURCE: IEC 60601-2-33:2022, 201.3.225]

381 **3.20**
 382 **magnetic resonance isocentre**
 383 **MR isocentre**
 384 null point of the spatially encoding gradients

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

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

387 [SOURCE: IEC 60601-2-33:2022, 201.3.228]

388 **3.21**
 389 **magnetic resonance scanner**
 390 **MR scanner**
 391 see 3.18

392 Note 1 to entry: In this document, the term “MR scanner” is often used instead of “MR equipment” to distinguish between
 393 equipment used for testing to the requirements of this document.

394 **3.22**
 395 **maximum gradient slew rate**
 396 rate of change of the gradient obtained by switching one gradient unit between its maximum specified
 397 gradient strengths $G_{+\max}$ and $G_{-\max}$ in the shortest possible ramp time

398 [SOURCE: IEC 60601-2-33:2022, 201.3.231]

399 **3.23**
 400 **MR Conditional**
 401 an item with demonstrated safety in the MR environment within defined conditions, including conditions for
 402 the static magnetic field, the time-varying gradient magnetic field and the radiofrequency fields

403 [SOURCE: ASTM F2503-23e1, 3.1.9]

404 **3.24**
 405 **normal operating mode**
 406 mode of operation of MR equipment where the biophysical effect induced by a specific electromagnetic field typically
 407 presents negligible risk
 Note 1 to entry: The electromagnetic fields essential to the operation of MR equipment are the

ISO 10974:xxxx(E) (draft CDV N 040)

408 main magnetic field, the spatial encoding gradients, and RF. The operating mode for each field is independently assessed
409 and reported.

410 Note 2 to entry: Indirect effects like displacement forces, acoustic noise, or interference with other medical devices are
411 not considered when identifying threshold exposure values.

412 [SOURCE: IEC 60601-2-33:2022, 201.3.235]

413 **3.25**414 **partial body SAR**

415 SAR averaged over the region of the body that receives 95 % of the deposited RF power

416 [SOURCE: IEC 60601-2-33:201.3.237]

417 **3.26**418 **search coil**

419 small diameter coil used in a compliance test to measure B_{1+} or gradient output

420 [SOURCE: IEC 60601-2-33:2022, 201.3.241]

421 **3.27**422 **specific absorption rate**423 **SAR**

424 radio frequency power absorbed per unit of mass (W/kg)

425 [SOURCE: IEC 60601-2-33:2022, 201.3.245]

426 **3.28**427 **time rate of change of the magnetic field**428 **dB/dt**

429 rate of change of the magnitude of the magnetic field (T/s)

430 Note 1 to entry: The dB/dt generated by the gradient units is assumed to be evaluated in a suitably low frequency range
431 (e.g. < 5 kHz) to disregard effects of switching amplifier ripple.

432 Note 2 to entry: Motion in the static magnetic field also causes dB/dt .

433 [SOURCE: IEC 60601-2-33:2022, 201.3.246]

434 **3.29**435 **volume RF transmit coil**

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

438 Note 1 to entry: A volume RF transmit coil is typically a whole body RF transmit coil, or an RF transmit coil designed for
439 homogeneous exposure of a specific part of the body.

440 [SOURCE: IEC 60601-2-33:2022, 201.3.248]

441 **3.30**442 **whole body gradient system**

443 gradient system of sufficient size to perform an MR examination on the torso of adult patients

444 [SOURCE: IEC 60601-2-33:2022, 201.3.249]

445 3.31

446 **whole body SAR**

447 SAR averaged over the total mass of the body

448 [SOURCE: IEC 60601-2-33:2022, 201.3.252]

449 **4 Symbols and abbreviated terms**

B_g	gradient magnetic field magnitude
DBS	deep brain stimulation
EPI	echo planar imaging
DUT	device under test
ESR	equivalent series resistance
FSE	fast spin echo
HPM	high permittivity medium
LPM	low permittivity medium
MR	magnetic resonance
MROC	MR equipment output conditioning
RF	radio frequency
rms	root-mean-square
SAR	specific absorption rate
SE	spin echo
SSFP	steady state free precession
TEM	transverse electromagnetic
TSE	turbo spin echo
TSM	tissue simulating medium

450 **5 General requirements for non-implantable parts**

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

453 **6 Requirements for particular AIMDs**

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

7 General considerations for application of the tests of this document

7.1 Acceptance criteria

This document does not contain requirements for specific acceptance criteria for the test methods listed in Table 1. Specific acceptance criteria and the determination of risk resulting from device behavioural responses, when subjected to the test methods listed in Table 1, are outside the scope of this document. However, specific acceptance criteria are necessary to demonstrate safety in the MR environment in order to label a device MR Conditional.

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

7.2 Use of tiers

Several clauses include the concept of tiers where each tier represents an alternative test method. The lowest numbered tier in each clause 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 can reduce the need for excess design margin because the test result is closer to clinical reality.

Clause 8, Clause 9, and Clause 15 utilize the same tiered methods (Tier 2, Tier 3, Tier 4(-), and Tier 4). Clause 13 and Clause 16 utilize the same tiered methods (Tier 1, Tier 2, Tier 3). Note that tiered methods are not all the same, even though they have the same nomenclature (e.g. Clause 8, Tier 2 is not the same as Clause 13, Tier 2). 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;

- 492 b) description, and photographs or diagrams of each test set-up, including all test and measuring
493 equipment, simulators, configuration, and placement of AIMD components, and phantom placement
494 within coils or MR scanner relative to isocentre;
- 495 c) when used, the phantom dimensions and composition of tissue simulating material and electrical
496 properties;
- 497 d) when applicable, AIMD settings and mode(s) of operation;
- 498 e) when applicable, detailed description of each pulse sequence or waveform used in these tests;
- 499 f) when the test system is an MR scanner (e.g. combined fields test) the manufacturer, model number, and
500 software version of the MR scanner;
- 501 g) test results and test method deviations;
- 502 h) when applicable, a description of preconditioning used to ensure that the AIMD is evaluated in a
503 configuration appropriate for the intended clinical use. For example, soaking to hydrate permeable
504 materials and/or to allow anticipated fluid ingress. Not all interactions are influenced by
505 preconditioning, magnetic force and torque, for example. See Annex Q for details on AIMD test
506 configurations;
- 507 i) when applicable, RF exposure levels or scanner operating modes used for testing;
- 508 j) acceptance criteria applied for each test and supporting rationale;

509 7.4 General test requirements

510 RF exposure levels may be defined in terms of B_{1+rms} and SAR, or by limiting scanning to an operating mode.
511 If the RF exposure level is defined by a SAR value, or an operating mode, then all SAR controls specified in
512 IEC 60601-2-33:2022, including short duration SAR, shall be evaluated.

513 NOTE IEC 60601-2-33:2002 (edition 2), allows a short duration SAR of up to 3 times the 6-minute average. In
514 edition 3, it was reduced to 2 times the 6-minute average.

515 7.5 Legacy testing

516 7.5.1 Clause 8

517 Since the publication of ISO/TS 10974:2018, 3 T RF heating test methods have been added to Clause 8.

518 The changes made to 1,5 T RF heating were to add clarification to the existing methods as well as allow
519 additional methods. The inclusion of Tier 4(-) does not impact testing previously performed using Tier 2,
520 Tier 3 or Tier 4 in accordance with ISO/TS 10974:2018. Methods added to evaluate temperature rise in
521 addition to power deposition do not impact power deposition testing in accordance with
522 ISO/TS 10974:2018. The addition of TSM determination Method 2 and Method 3 do not impact TSM
523 determination testing performed using Method 1 since Method 1 is identical to Method 1 in
524 ISO/TS 10974:2018. The clarifications made to the spatial distribution determination and integration
525 methods do not impact testing in accordance with ISO/TS 10974:2018. The relocation of the validation
526 acceptance criteria Formula (3) in ISO/TS 10974:2018 to Annex U, does not impact validation testing in
527 accordance with ISO/TS 10974:2018. Therefore, tests performed in accordance with ISO/TS 10974:2018,
528 that have demonstrated safety, are still valid in relation to this document. Therefore, no new tests are
529 required of such devices.

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530 7.5.2 Clause 9

531 Since the publication of ISO/TS 10974:2018, RF induced device heating test methods have been added to
 532 Clause 9. These methods are intended to ensure AIMD have been evaluated for potential thermal injury risk
 533 from RF induced case heating.

534 Changes made to the gradient induced device heating malfunction sections of Clause 9 from
 535 ISO/TS 10974:2018 are intended to standardize and streamline the test method without altering its
 536 objectives. A new gradient dB/dt test waveform has been specified to standardize the method. Devices tested
 537 in accordance with ISO/TS 10974:2018 for gradient induced device heating are still valid in relation to this
 538 standard if applicability of the waveform used can be established.

539 7.5.3 Clause 10

540 Since the publication of ISO/TS 10974:2018, a tissue injury section has been added to Clause 10. This section
 541 is intended to ensure AIMDs have been evaluated for the risk of tissue injury due to gradient field induced
 542 vibration. Vibration induced tissue injury may be addressed in particular standards (example AAMI PC76)
 543 and, depending on the manufacture evaluation, testing may not be required.

544 Changes made to the gradient vibration induced device malfunction sections of Clause 10 from
 545 ISO/TS 10974:2018 are editorial in nature intended to add clarification to the test method without altering
 546 its objectives. Accordingly, devices tested for gradient vibration induced device malfunction in accordance
 547 with ISO/TS 10974:2018 that have demonstrated safety are still valid in relation to this standard. Therefore,
 548 no new malfunction testing is required of such devices.

549 7.5.4 Clause 11

550 No new hazards related to B_0 -induced force have been identified since the publication of ISO/TS 10974:2018.
 551 Changes made to Clause 11 are editorial in nature intended to add clarification to the test method without
 552 altering its objectives. Accordingly, devices tested in accordance with ISO/TS 10974:2018 that have
 553 demonstrated safety are still valid in relation to this standard. Therefore, no new tests are required of such
 554 devices.

555 7.5.5 Clause 12

556 No new hazards related to B_0 -induced torque have been identified since the publication of
 557 ISO/TS 10974:2018. Changes made to Clause 12 are editorial in nature intended to add clarification to the
 558 test method without altering its objectives. Accordingly, devices tested in accordance with
 559 ISO/TS 10974:2018 that have demonstrated safety are still valid in relation to this standard. Therefore, no
 560 new tests are required of such devices.

561 7.5.6 Clause 13

562 No new hazards related to gradient-induced extrinsic electrical potential have been identified since the
 563 publication of ISO/TS 10974:2018. Changes made to Clause 13 are editorial in nature intended to add
 564 clarification to the test method without altering its objectives. Accordingly, devices tested in accordance with
 565 ISO/TS 10974:2018 that have demonstrated safety are still valid in relation to this standard. Therefore, no
 566 new tests are required of such devices.

567 7.5.7 Clause 14

568 No new hazards related to B_0 -induced malfunction have been identified and none of the test methods have
 569 been withdrawn since the publication of ISO/TS 10974:2018. Changes made to Clause 14 were to add

clarification to the device class definition and their relevant test methods without altering their objectives. Accordingly, devices tested in accordance with ISO/TS 10974:2018 that have demonstrated safety are still valid in relation to this document. Therefore, no new tests are required of such devices.

7.5.8 Clause 15

Since the publication of ISO/TS 10974:2018, 3 T RF-induced malfunction and RF rectification test methods have been added to Clause 15.

The changes made to 1,5 T RF-induced malfunction and RF rectification are mostly to correct and elaborate the existing methods. Accordingly, devices tested for 1,5 T per ISO/TS 10974:2018 that have demonstrated safety are still valid in relation to this standard. Therefore, no new tests are required of such devices.

The correction made to the sinc modulation pulse period (Formula (16)) testing in accordance with ISO/TS 10974:2018 is conservative. Therefore, this correction does not impact testing executed in accordance with ISO/TS 10974:2018. Elaboration was added to the Tier 2 method in the context of $E_{peakmax}$ definition which does not impact test executed per ISO/TS 10974:2018. Elaboration was added to the RF EMC test method selection in relation to injection of the antenna port. Devices tested in accordance with ISO/TS 10974:2018 are still valid in relation to this standard if the simultaneous injection of the antenna port can be established.

7.5.9 Clause 16

No new hazards related to gradient-induced malfunction have been identified since the publication of ISO/TS 10974:2018. Changes made to Clause 16 are intended to streamline the test method without altering its objectives. Accordingly, devices tested in accordance with ISO/TS 10974:2018 that have demonstrated safety are still valid in relation to this standard. Therefore, no new tests are required of such devices.

7.5.10 Clause 17

No new hazards related to combined fields malfunction have been identified since the publication of ISO/TS 10974:2018. Changes made to Clause 17 are intended to streamline the test method without altering its objectives. Accordingly, devices tested at 1,5 T in accordance with ISO/TS 10974:2018 that have demonstrated safety are still valid in relation to this standard. Therefore, no new tests are required of such devices. Devices tested at 3 T using the ISO/TS 10974:2018 methods may also be considered valid, provided manufacturer justification that the test method could be extended at 3 T.

7.6 Understanding relevant provisions of MR scanners

A complete understanding of this document requires an understanding of IEC 60601-2-33:2022.

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

8.1 Introduction

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

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

NOTE 2 When the MR Conditional labelling does not specify a B_{1+rms} limit, a rationale for applicability of the RF heating test results to potential elevated short duration SAR should be provided. The MR scanner operating mode SAR limits in IEC 60601-2-33:2022 are specified as a 6-minute average value and any 10-second period average value.

During MRI, RF-induced heating of tissues surrounding an AIMD can result in tissue damage or a reduction in the ability of the implanted device to deliver therapy. Tissue heating 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. In addition, the configuration of the implanted AIMD (e.g. soak condition as described in 7.3.3) can also impact the resulting tissue heating. A comprehensive assessment of the safety of RF-induced heating is composed of the two stages summarized below. Stage 2 contains device specific acceptance criteria and is outside the scope of this standard.

Stage 1 Determine the dissipated RF power or local tissue temperature rise at hot spots around the AIMD using one of three tiered approaches described in 8.2 at the RF exposure levels consistent with the MR Conditional labelling. The three tiers are arranged in order of increasing complexity of evaluation method as well as increased accuracy of estimation. A Tiered approach is designed to accommodate the diversity of AIMDs;

Stage 2 Assess tissue changes or damage due to the in vivo RF power deposition or resulting temperature rise. Thermal tissue damage thresholds and risk factors for the determined temperature rise and duration are application-specific and are assessed on an individual AIMD basis.

8.2 Structure of the tiered test methods

Tiered test methods may be used to evaluate RF heating of AIMDs during MRI. The complexity of the test method increases, and conservative margin decreases, with increasing tier number. The output of all tiered test methods is either the total dissipated RF power or in vitro temperature rise at defined hot spots (such as electrodes). Both dissipated RF power and temperature rise methods require additional analysis beyond the scope of this standard to determine the risk of patient harm (Stage 2 activities). The RF heating tiers are illustrated in Figure 3 and summarized below.

NOTE 1 The detailed requirements for the tiers are described in 8.8.

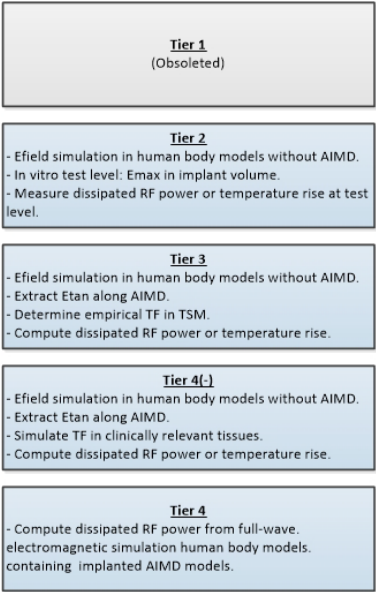
NOTE 2 Tier 1 from ISO/TS 10974:2018 has been removed because it is a subset of Tier 2 as explained in Annex S.

— Tier 2: RF heating is evaluated in vitro by measuring the dissipated power or temperature rise in tissue simulating medium when the AIMD is exposed to a conservative estimate of the electric field induced in the tissues near the implant. The electric field exposure level is determined from human body electromagnetic simulations in the absence of the AIMD. Tier 2 is applicable only to AIMDs that are shorter than resonant length in tissue simulating medium as defined in 8.5;

— Tier 3: AIMD RF heating is evaluated using a validated transfer function (TF) AIMD model that predicts the dissipated RF power or temperature rise in tissue simulating medium as a function of the electric field tangent to the AIMD determined from human body electromagnetic simulations in the absence of the AIMD. Tier 3 TF models are typically measured directly using the piece-wise excitation method or derived based on measured transmission line properties. Less conservative margin than Tier 2;

- 643 — Tier 4(-): A similar approach as Tier 3, but the AIMD TF model is derived numerically in clinically
644 relevant tissues. This can result in less conservative margin or uncertainty than Tier 3 due to the use of
645 clinically relevant tissues in derivation of the TF model;
- 646 — Tier 4: AIMD RF heating is evaluated by full-wave electromagnetic simulations using human body
647 models containing detailed 3-dimensional AIMD models at the clinically relevant anatomical location.
648 Less conservative margin than Tier 4(-).

649

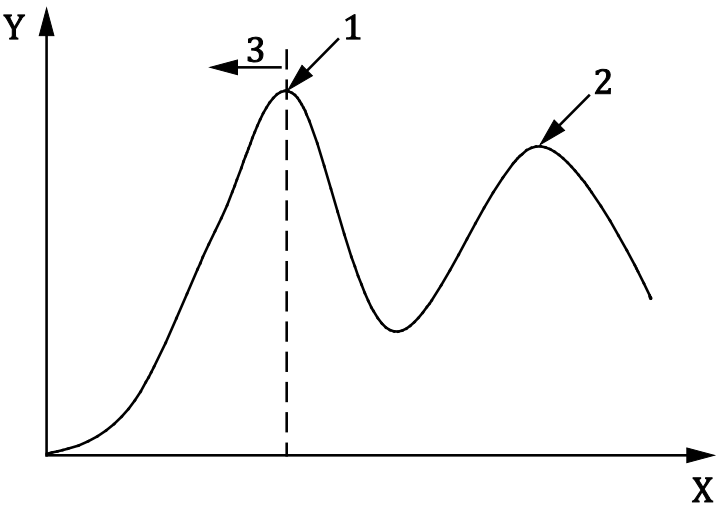


650 **Figure 3 — Tiered test methods for determining deposited RF power or temperature rise at AIMD**
651 **hot spots when exposed to MR scanner incident RF fields**

652 Tiers 3 and 4 apply to all AIMDs. Tier 2 is restricted to AIMDs that are shorter than the resonant length in
653 tissue simulating medium (1/2 wavelength) because the influence of the phase of the incident electric field
654 and induced current on AIMD heating is not considered (see Annex K for details). Examples of AIMDs that
655 might be shorter than resonant length and appropriate for Tier 2 evaluation include cochlear implants,
656 pressure sensors, implantable monitors, and leadless pacemakers.

657 For systems with elongated leads, the length requirement may be demonstrated by showing that the device
658 is shorter than the first resonance determined by measuring the dissipated power or temperature at the
659 hot spot as a function of device length as illustrated in Figure 4. AIMDs without leads are appropriate for a
660 Tier 2 RF heating analysis if the length of the conductive portion of the AIMD is less than the RF wavelength
661 in the surrounding tissue simulating medium divided by 2π [3]. Alternatively, electromagnetic simulations
662 may be used to demonstrate that the device is below resonant length.

663 NOTE 3 Any AIMD that is less than resonant length (electrical length shorter than $\frac{1}{2}$ wavelength in tissue simulating
664 medium) can be evaluated using Tier 2. For AIMDs with lead wires, the electrical length can be determined empirically
665 or by electromagnetic simulation. However, determining the electrical length of a small leadless device such as a
666 leadless pacemaker may be challenging. Such devices conservatively meet the less than $\frac{1}{2}$ wavelength electrical length
667 criterion if the physical length of the AIMD is less than or equal to wavelength divided by 2π in the tissue simulating
668 medium (electrically short). Other computational methods for determining the electrical length of leadless AIMD
669 devices are acceptable with supporting rationale.



Key

- 1 first resonance
- 2 second resonance
- 3 below resonance
- X AIMD length
- Y deposited power at hot spot

Figure 4 — An AIMD with elongated leads is appropriate for a Tier 2 analysis if the length is less than that which produces the first resonance (less than 1/2 wavelength)

8.3 Electromagnetic Modelling requirements for all tiers

8.3.1 General

The electromagnetic fields that an implanted AIMD is exposed to during MR scanning is determined using numerical simulation. The incident fields are determined using validated electromagnetic simulation codes and human body models. The following steps outline the electromagnetic simulation workflow.

- Step 1 Select human body models that span the patient population with respect to gender, height, weight, and BMI.
- Step 2 Validate electromagnetic simulation results and the RF exposure system with measurements in tissue simulating phantom. See ASME V&V 40 [4] for additional guidance on code verification and validating computational models.
- Step 3 Simulate RF electric and magnetic fields as a function of the following:
 - MR whole body transmit coil design;
 - RF coil length and diameter;
 - Clockwise and counterclockwise B_{1+} polarizations (See Annex J);
 - Applicable RF polarization consistent with MR Conditional labelling;
 - The RF exposure limits consistent with the MR Conditional labelling. SAR and B_{1+rms} are defined according to IEC 60601-2-33:2022;
 - Patient population;

- Axial body locations (landmarks) in the RF coil and body postures consistent with the MR Conditional labelling (prone, supine, etc.);
- AIMD locations, orientations and lead pathways (including lead length, if applicable).

8.3.2 Requirements for 2-channel transmit excitation

8.3.2.1 General

At fields higher than 1,5 T, EM wavelengths in tissue can be similar to or less than the scale of the imaging region-of-interest. Traditional circularly polarized excitation might not produce a uniform B_{1+} distribution inside the imaging region-of-interest due to EM wave interference effects, both constructive and destructive.

Most modern 3 T clinical MR scanners are equipped with two or more transmit channels (MC-2 or MC-N) that can be controlled independently to tailor the B_1 transmit field distribution inside the region-of-interest. The act of controlling the relative magnitude and phase of the transmit channels to achieve a desired transmit field distribution is generally called “multi-transmit” or “RF shimming”. During an MR scan session, a 3 T MR scan can use several MC-2 shim modes to meet the needs of scan sequences. Therefore, an analysis of the shim space shall be performed when the AIMD manufacturer seeks MC-2 MR Conditional labelling.

For an AIMD to be labelled for MC-2 excitation at 3 T, both Clause 8 (RF heating) and Clause 15 (EMI/EMC) evaluations shall account for RF shimming as described in 8.3.2.2. MC-N with more than two transmit channels is out of scope of this standard.

8.3.2.2 MC-2 simulation space

Step 1 Generate coil models spanning MC-2 shim mode settings

The geometry and RF drive configuration of the coil models shall reflect clinical 3 T RF coil designs. (See IEC 60601-2-33:2022, 201.12.4.106 for details on MC-2 drive configuration.) Shimming adjusts the relative magnitude and phase at the ports of the transmit coil. The minimum shim space to be evaluated is defined by a -9 dB to +9 dB difference in RF magnitude between coil ports in increments of 3 dB and a difference in phase from -180 to +180 degrees in 30-degree increments. Both clockwise (CW) and counterclockwise (CCW) polarizations shall be considered. If it can be shown that one polarization (CW or CCW) is conservative with respect to AIMD heating, then the shim space may be limited to that polarization only.

Step 2 Apply shim coil models to subject population

Calculate EM-field distributions in the subject population appropriate to the AIMD (such as body model, scan location) for all shim mode settings described in Step 1. For a given shim setting, the larger B_1 component in either CW or CCW directions shall be used to scale the EM-field distributions to the RF exposure levels consistent with the MR Conditional labelling.

Step 3 Predict Temperature or dissipated power increase

Following the Tier 2 – Tier 4 process, use the shimmed EM-field distributions with the validated AIMD hot spot model to predict temperature or dissipated power.

Step 4 Determine the impact of MC-2 shim space on AIMD model prediction

Safety assessment criteria are left to the manufacturer. Note that both constructive and destructive wave effects are possible in the shimmed EM-field distributions. For a particular implant scenario or scan location, the shim mode settings specified in Step 1 might increase or decrease the predicted temperature/SAR or induced voltage relative to that of circular polarization.

8.4 RF field source specifications for all tiers

The following subclauses describe test methods where the AIMD is exposed to controlled RF fields while immersed in tissue simulating medium (TSM). Typically, the test RF fields are generated using conventional 'birdcage' type MRI coils (see Annex J for coil characteristics). Examples of phantoms to hold the TSM are in Annex M. Minimum RF field specifications for the test system are listed in Table 2.

Table 2 — Minimal requirements for the incident electrical field for 1,5 T and 3,0 T test setups

Parameter	Requirement
Incident RF field frequency	63,9 MHz $\pm$ 5 % 127,7 MHz $\pm$ 5 %
Drift of incident field magnitude during assessment	<0,25 dB

NOTE Testing at multiple 1,5 T and 3 T RF test frequencies is not required. The test frequencies are single values within the operational ranges specified in Table 2 (Annex S).

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 is performed at sufficient signal to noise ratio and linearity within the range of instrumentation is demonstrated. If lower magnitudes are used, the measurements shall be scaled (ΔT or SAR) to a value that corresponds to the required amplitude.

8.5 Tissue simulating medium (TSM)

8.5.1 General

The RF power deposition or in vitro temperature rise at an AIMD hot spot with a specific incident tangential electric field 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 body fluids such as blood and cerebrospinal fluid.

Dielectric properties of the tissue simulating medium (TSM) are chosen to represent the relevant in vivo tissue properties. If the AIMD pathway is predominantly in high permittivity tissues such as muscle and blood, the test shall be conducted in an 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 an LPM.

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.

8.5.2 Determination of tissue simulating medium

The manufacturer shall demonstrate that the TSM formulation (conductivity and permittivity) used to develop and validate RF heating (or voltage per Clause 15) models is appropriate for AIMD under test by one of the following methods. Only one method is required; for example, it is not necessary to also justify the TSM based on design considerations if Method 1 or 2 is used.

769 — Method 1: Historical formulations

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

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

774 If the AIMD pathway spans more than 10 % of its cumulative physical length in different tissue
775 conductivities (conductivity of tissues as shown in Table 3 varies by at least 50 %), the AIMD shall be
776 evaluated in HPM using several tissue-appropriate conductivities. This also applies to AIMDs that are
777 implanted at the interface between two or more tissue types (e.g. tunnelled subcutaneously).

778 If the AIMD pathway spans more than 10 % of its cumulative physical length in different tissue
779 permittivities (permittivity of tissues as shown in Table 3 varies by at least 5×), the AIMD shall be
780 evaluated in both HPM (with tissue-appropriate conductivity) and LPM. This also applies to AIMDs that
781 are implanted at the interface between two or more tissue types (e.g. tunnelled subcutaneously).

782 **Table 3 — Electrical properties of phantom liquid and gel materials**

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 F2182-19e2: $\sigma = 0,47$ S/m (global average of biological tissues); — High-conductivity: $\sigma = 0,65$ S/m (average of conductivities of muscle, liver, kidney, brain); — Very high conductivity: $\sigma = 1,2$ S/m (average conductivity of blood).		

783

784 — Method 2: In vivo determination

785 The average electrical properties of the tissues in contact with the AIMD or other use condition rationale
786 can be used to determine the TSM formulation if the resulting lead heating models are verified in vivo.
787 An animal study to verify TSM formulation is composed of the following elements:

- 788 a) AIMD hot spots are instrumented with MR compatible temperature sensors;
- 789 b) Instrumented AIMDs are implanted in animal subjects in clinically relevant anatomical locations;
- 790 c) Identify 3D computational electromagnetic models of the animal subjects. Appropriate models
791 might be commercially available or developed ad hoc by segmenting full-body CT and/or MR images
792 and assigning conductivity and permittivity values to the tissues. It is also acceptable to use one
793 numerical model to represent multiple nominally matched experimental animals;
- 794 d) Monitor the temperature rise at the AIMD hot spots for multiple of landmark positions and body
795 habitus when the animals are scanned at known B_{1+rms} ;

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- e) Determine the electric fields induced in the animal subjects for the specific scan configurations using an appropriate computational method (i.e. FDTD), the 3D animal tissue models, and a scanner RF coil model;
 - f) Compute the hot spot temperature rise for each scan configuration using the RF lead electrical model developed using the TSM being evaluated and the tangential electric fields computed from the numerical animal models and lead paths extracted from imaging data;
 - g) Demonstrate that RF lead electrical model predicts the measured AIMD hot spot temperature.
- Method 3: AIMD design considerations
- In leads that are located predominantly in high permittivity media, the magnitude of the RF power deposition or temperature rise is influenced by the conductivity of the medium surrounding the lead as a whole due to the proximity of the TSM to the conductors of the lead.
- A homogeneous TSM used for the purpose of lead electrode model generation in a Tier 3 procedure shall have a conductivity that approximates the average conductivity of all tissues that are expected to be in intimate contact with the lead at the frequency of interest.
- For the specific case of leads with effectively thick insulation, the RF power deposition and resulting temperature rise at the lead electrode is predominantly influenced by the conductivity of the medium in contact with the electrode. A lead is defined as having effectively thick insulation if the RF power deposition at the electrode changes negligibly (relative to the overall uncertainty assessment) over a clinically relevant range of TSM conductivities. This is because effectively thick insulation reduces capacitive coupling between lead conductors and surrounding tissue such that energy loss along the lead body is negligible. If the thick insulation criterion is met, the conductivity of the homogeneous TSM shall approximate the conductivity of the tissue in contact with the hot spot.

8.6 Electric field exposure and measurement system qualification**8.6.1 General**

Measurement equipment and test methods used for any of the three RF heating tiers shall be qualified by demonstrating performance characteristics and suitability for the intended use. Examples include electric field or SAR measurement, temperature probes, and positioning systems. Qualification of RF exposure and transfer function systems are described in the following subclauses.

8.6.2 RF exposure system qualification

Measurements of SAR or temperature at one or multiple spatial locations around the hot spot while the AIMD is exposed to a known incident electric field are required for all tiers. The RF field exposure test system (such as a RF birdcage coil and TSM containing phantom) shall be qualified by demonstrating that the electric fields generated in the TSM agrees with the results of electromagnetic simulation within characterized uncertainty. Examples of suitable qualification activities include comparing simulated and measured local electric field, SAR, or temperature, comparing simulated total power deposition with measured power deposition using calorimetry, or by measuring electric field, SAR, or temperature at the tip of a standard implant (see Annex I for details).

8.6.3 Transfer function measurement system qualification

A transfer function measurement system (such as piecewise excitation apparatus and TSM containing phantom) may be validated by measuring a test article, such as a solid wire, where the transfer function can be computed numerically (see Annex U for representative examples). The transfer function measurement system is qualified by demonstrating that the measured transfer function agrees with the known transfer

function within the characterized uncertainty of the measurement system or other justifiable acceptance criterion established by the AIMD manufacturer. The computed and measured complex transfer functions are compared either point wise or by comparing the transfer function predictions for defined tangential electric fields.

8.7 Identifying AIMD hot spots

Hot spots are identified by placing the AIMD in TSM within the RF heating measurement system and scanning the AIMD (temperature rise or SAR) in response to multiple electric field exposures. Hot spots are defined as locations where the SAR or temperature rise is within 6 dB of the maximum value measured for all electric field exposures. Electrodes, and tissue contacting conductive material are likely sources of hot spots. Hot spots might be a function of the amplitude and phase of the tangential electric field, particularly for AIMDs with elongated leads. Therefore, care should be taken to ensure that AIMDs with leads are exposed to a diverse set of tangential electric fields when identifying hot spots. For example, using multiple lead paths in phantom/RF coil test system. Justification shall be provided demonstrating that the incident electric field exposures used for the test are appropriate for identifying hot spots. Hot spots can be excluded from further analysis with justification.

8.8 Tier descriptions

8.8.1 General

Select an appropriate tiered test method 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.

The output of Tier 2 is a single deposited RF power or maximum in vitro temperature rise for any patient. The output of Tier 3 and Tier 4 are distributions of body model specific deposited RF powers or in vitro temperatures. The output of any selected test method tier is used to assess the probability of tissue damage and patient safety. However, these activities are outside the scope of this standard.

The safety evaluation for AIMDs that specify a SAR limit will consider the 2x short duration SAR provision in IEC 60601-2-33:2022. Accounting for the potential 2x increase in SAR for short durations compared to the scanner reported 6-minute average value shall be justified by the manufacturer. These considerations do not apply to AIMDs that specify a $B_{1+\text{rms}}$ limit.

8.8.2 Tier 2

The RF-induced power deposition or maximum temperature rise due to the presence of the AIMD is determined from electromagnetic simulations of human body models. The test level is determined from an evaluation of maximum 10 g averaged electric field or SAR in the human body in which the AIMD system is to be implanted (implant region) in the absence of the AIMD. The Tier 2 Clause 8 heating test level is defined either in terms of electric field magnitude or SAR. In addition, the electric field procedure is used to define the Tier 2 Clause 15 RF-induced malfunction electric field test level.

Step 1 Determine the in vitro RF heating electric field test level. Perform the electromagnetic simulations in human body models at the RF exposure levels consistent with the MR Conditional labelling and the clinically relevant conditions specified in 8.3. For each simulation, identify the maximum 10 g average E_{rms} electric field magnitude in the AIMD implant region [5]. If the RF heating test level is specified by SAR, also identify the maximum 10 g average SAR in the AIMD implant region [5].

In case the implant trajectory is confined to a specific one- or two-dimensional surface or interface (e.g. conformal to a bone surface, such as flat electrode arrays along the skull, subcutaneous wire

sensors, rolled stimulator cuffs along a nerve, etc.) the same dimensions of the 10 g cube shall be applied in one or two dimensions to compute the relevant E_{rms} average incident field. For example, a 10 g cube of muscle ($\rho \approx 1 \text{ g/ml}$) measures roughly $(21,5 \text{ mm})^3$ while a 10 g cube of cortical bone ($\rho \approx 1,9 \text{ g/ml}$) measures roughly $(17,4 \text{ mm})^3$. For a two-dimensional implant embedded in muscle, for example, the incident electric field shall be computed over an averaging area of $(21,5 \text{ mm})^2 = 462 \text{ mm}^2$. For these trajectories confined to a surface which are at an interface of two tissues, the higher density tissue, which results in the smallest (and therefore conservative) averaging area, tissue is used to calculate the relevant E_{rms} average incident field. For example, for an implant between the surface of muscle and bone, the averaging area for E_{rms} shall be that of bone: $(17,4 \text{ mm})^2 = 303 \text{ mm}^2$.

Construct a distribution of the maximum 10 g average E_{rms} values in the implant region for all human body simulations (body models, landmark locations, RF coils, relevant implant locations, etc.). If a SAR based RF heating test level is desired, construct a distribution of the maximum 10 g average SAR values in the implant region. The Tier 2 in vitro electric field or SAR AIMD RF heating test levels, E_{rmsmax} , or SAR_{max} , respectively are the 95th percentile values of the 10 g averaged E_{rms} or SAR distributions at the RF exposure conditions consistent with the MR Conditional labelling.

Step 2 Expose the AIMD to the E_{rmsmax} , or SAR_{max} test levels determined in Step 1 and measure the power or temperature deposited at the hot spot(s) in the tissue simulating medium.

NOTE Annex P offers a worked example for a Tier 2 application, where the averaging is conducted on the implant region and across the whole body of the patient.

8.8.3 Tier 3

A validated electromagnetic AIMD model is used to transform the incident electric field tangent to the AIMD, computed in the absence of the AIMD, into the dissipated RF power or temperature rise at AIMD hot spots as shown in Formula (1). $S_{\text{hotspot}}(z)$ is a complex computed or measured transfer function, $E_{\text{tan}}(z)$ is the complex incident electric field and 'A' is a scalar calibration term that is typically determined by measuring the dissipated RF power or temperature rise for multiple known tangential electric field exposures.

The incident tangential electric fields are simulated in human body models in whole body MRI transmit coils at RF exposure levels consistent with the MR Conditional labelling and the clinically relevant conditions specified in 8.3. The Tier 3 model is called a transfer function model (TF) and is typically measured or computed using piece-wise electric field excitation.

Transfer functions may be derived numerically [6] [7] [8] or experimentally [7] [8] and are unique to the AIMD's hot spot, or conducted RF entry point (Clause 15), for the selected tissue environment and frequency. The 'piecewise excitation' method is one commonly used approach for determining a transfer function experimentally. Briefly, the AIMD is immersed in tissue simulating medium and exposed to localized RF electric field generated by a suitable antenna at the desired MRI frequency, and the AIMD response (electric field, voltage, or current) is measured at the hot spot or RF entry point as the exciting antenna is swept along the length of the AIMD. The incident field to which the implant is exposed piecewise is held constant as the exciting antenna is moved along the length of the device, so that the relative magnitude and phase of the AIMD response is accurately measured for each segment.

An alternative approach [8] utilizes the principle of reciprocity together with the Huygens Principle to invert the system, placing the current source at the lead tip and measuring the current distribution along the AIMD length.

The TF lead model methodology may also be used to define the tissue simulating medium (8.5.2).

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

927 if the worst-case configuration cannot be justified. Rationale shall be provided to justify the configuration(s)
928 that have been modelled.

929 The following are the general steps for developing and validating a Tier 3 AIMD RF heating model:

930 Step 1 Develop an equivalent electromagnetic model(s) of the AIMD and the associated confidence
931 interval (uncertainty budget). Analytical, numerical or experimental methods may be used to
932 develop the model. The input to the AIMD model is a series of piece-wise incident field
933 components (amplitude and phase of the incident tangential electric field averaged over an
934 incremental length). The output of the model is an estimate of the local in vivo power deposition
935 or temperature rise at each hot spot of AIMD with a known uncertainty.

$$P \text{ or } \Delta T = A \left| \int_0^l S_{hotspot}(z) E_{tan(z)} dz \right|^2 \quad (1)$$

936 where

P is the in vivo power deposition at the AIMD hot spot;
 ΔT is the in vitro temperature rise at the AIMD hot spot;
 A is a constant;
 l is the length of the AIMD;
 z is the position along the AIMD;
 $S_{hot spot}$ is the complex transfer function model of the AIMD;
 E_{tan} is the local in vivo electric field determined in Step 3.

937 NOTE 1 For an AIMD with multiple leads, power deposition can change when leads follow pathways
938 as described in 8.11.

939 Step 2 The electromagnetic model of the AIMD is validated in homogeneous media/tissue by satisfying
940 the requirements specified in 8.12. For non-homogeneous tissue distribution, additional
941 validation steps might be needed, the methodology of which is not part of this edition.

942 Step 3 The in vivo incident tangential electric fields (magnitude and phase) along all clinically relevant
943 AIMD pathways are determined in accordance with 8.3. The tangential electric field shall be
944 averaged at intervals of 5 mm or less when the AIMD can be approximated by pathways (e.g. thin
945 elongated wires or leads).

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

949 Step 4 The distribution of in vivo local power deposition or temperature rise is computed for each hot
950 spot (see definition in 8.7) and incident tangential electric field (Step 3) using the validated
951 heating model (Step 1). The in vivo local power deposition is computed using Formula (1) of
952 Step 1 or the equivalent (e.g. the integration may be approximated by discrete summation).

953 NOTE 2 Clause 15 defines test methods for evaluating the RF-induced malfunction and RF rectification hazards.
954 Modelling similar to this subclause is required and as described in 15.5.2 and 15.5.3.

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955 **8.8.4 Tier 4**

956 The in vivo power deposition around the implant shall be determined by performing computer simulations
 957 of human bodies with a validated electromagnetic AIMD model placed within the human body models at the
 958 RF exposure levels consistent with the MR Conditional labelling and the clinically relevant conditions
 959 specified in 8.3. Examples of suitable models are CAD-based models without simplifications, lumped element
 960 models that are valid for all tissue distributions surrounding the AIMD, and mixed CAD-based and lumped
 961 element models. The AIMD model must be implanted in the body models realistically according to the clinical
 962 guidelines, with a sufficient range of trajectories and in a sufficient range of human models to represent the
 963 implanted population. Likewise, the simulated exposure conditions (location and type of RF transmit coils)
 964 must be sufficient to capture the exposure conditions experienced by patients undergoing MR scans.

965 **8.8.5 Tier 4 (-)**

966 A modification to Tier 3, referred to as Tier 4(-), uses an electromagnetic AIMD model to numerically derive
 967 transfer functions in the tissue environment of the implant. The method is validated by comparison of
 968 numerically derived transfer functions in homogeneous tissue simulating media to measurements, with a
 969 known uncertainty.

970 Step 1 Develop a tissue block model composed of the dielectric medium representing the tissues around
 971 a set of AIMD trajectories. The approximation of the tissue environment over the set of trajectories
 972 by tissue blocks shall be justified with a corresponding confidence interval, including a sensitivity
 973 analysis of the variation in tissue block size and dielectric properties. If the in vivo temperature
 974 rise is determined, then the block model shall be of sufficiently high detail at each hot spot to
 975 correctly represent the temperature rise in vivo [9].

976 Step 2 Determine the wavelength of the incident field to the implant within each tissue block. Define two
 977 homogeneous tissue simulating media (hTSM) with wavelengths bracketing those of the tissue
 978 blocks in the model. If the wavelength in all tissue block models is within the accepted variation
 979 of homogeneous tissue simulating medium recipes ($\pm 20\%$), a single average hTSM can be
 980 selected.

981 Step 3 Develop equivalent transfer functions of the AIMD valid for the hTSM. The output of the transfer
 982 function is an estimate of the in vivo power deposition or temperature increase around each hot
 983 spot, P_{hotspot} or T_{hotspot} , or terminal voltage in a channel, V_{channel} , of the AIMD in the environment(s)
 984 defined in Step 1. Determine the associated confidence interval (uncertainty budget) of the
 985 prediction.

986 Step 4 Experimentally validate the transfer functions in the selected hTSM including the associated
 987 confidence interval (uncertainty budget) of the prediction for the selected experimental
 988 environment. When two hTSM are tested, a single device configuration and lead state is sufficient
 989 for validation of the transfer function in the hTSM with the longer wavelength.

990 Step 5 Apply the same method as Step 3 to develop the transfer function of the AIMD valid for the tissue
 991 block model in Step 1.

992 Step 6 Define the simulation set comprising anatomical phantoms under EM exposure conditions
 993 representative of patient population, AIMD routings, scan positions, coil types and polarizations.

994 Step 7 Compute the distribution of in vivo local power deposition or temperature rise around each hot
 995 spot (see definition in 8.7) of the AIMD (e.g. around conductive electrodes, device housing), or the
 996 terminal voltage, by exciting the simulation set defined in Step 6 at the RF exposure levels
 997 consistent with the MR Conditional labelling and the clinically relevant conditions specified in 8.3.
 998 The resulting distribution is a prediction of the in vivo power deposition, temperature rise, or
 999 terminal voltage with a characterized uncertainty (8.13).

1000 8.9 Hot spot dissipated RF power measurement in TSM

1001 8.9.1 General

1002 The power dissipated in TSM by an AIMD hot spot due to RF exposure can be determined either by spatial
1003 integration of 3D power measurements (8.9.2) or by calibrated RF injection (8.9.3).

1004 8.9.2 Hot spot dissipated power by spatial integration of 3D SAR measurements

1005 The RF power dissipated from an AIMD hot spot is the volume integral of the local 3D SAR distribution. The
1006 spatially localized SAR around an AIMD hot spot may be measured directly using electric field (SAR) probes
1007 or computed from the spatially localized initial temperature rise rate ($\lim_{t \rightarrow 0} \frac{\Delta T}{\Delta t}$) and the heat capacity (c) of the
1008 TSM as shown in Formula (2). The local temperature rise or SAR due to RF power dissipated by the AIMD
1009 hot spot(s) is the total temperature rise or SAR (ΔT_{total} or SAR_{total}) measured in the TSM with the AIMD, minus
1010 the TSM background temperature rise or SAR ($\Delta T_{\text{backgnd}}$ or SAR_{backgnd}) measured in TSM in the absence of the
1011 AIMD.

$$P = \int^V \rho * \Delta SAR_{\text{total-backgnd}} dV = \int^V \sigma [E_{\text{total}}^2 - E_{\text{backgnd}}^2] dV \quad (2)$$

$$= \int^V \rho * \left[\lim_{t \rightarrow 0} \frac{c \Delta T_{\text{total}}}{\Delta t} - \lim_{t \rightarrow 0} \frac{c \Delta T_{\text{backgnd}}}{\Delta t} \right] dV$$

1012 where

P	is the power deposition at the AIMD hot spot;
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 hot spot by the AIMD;
t	is time;
<i>backgnd</i>	is the measured value in the absence of the AIMD;
<i>total</i>	is the measured value with the AIMD present.

1013 8.9.3 Hot spot dissipated power by calibrated RF injection

1014 The local temperature rise (ΔT) or SAR at a point location near an AIMD hot spot can be related to the total
1015 power deposition using a calibrated RF power injection method. The ΔT or SAR measured at a specific spatial
1016 location is calibrated to the total power dissipated at the hot spot. The AIMD may be modified to facilitate RF
1017 power calibration provided that the power distribution at the hot spot is equivalent to that produced by the
1018 unmodified AIMD. For either unmodified or modified AIMDs, the total dissipated RF power, P_{inject} , shall be
1019 determined.

1020 For each AIMD hot spot, a conversion factor, m , between ΔT or SAR at the hot spot and injected power is
1021 experimentally determined (i.e. $\Delta T = m P_{\text{inject}}$ or $SAR = m P_{\text{inject}}$) by injecting RF power in vitro (using the same
1022 tissue simulating media and test fixtures as would be used for radiated in vitro testing), and measuring ΔT
1023 or SAR at the hot spot for multiple values of P_{inject} .

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- 1024 Step 1 Verify that the injected RF power produces an equivalent normalized spatial SAR or ΔT
 1025 distribution as the radiated case. The SAR or ΔT shall be mapped spatially in minimum of two
 1026 orthogonal directions (axial and radial) relative to the hot spot. The number of measurements in
 1027 each orthogonal direction shall at least include the location of the maximum SAR or ΔT and values
 1028 where the SAR or ΔT is approximately 50 % and 25 % of the maximum value. The injected and
 1029 radiated spatial distributions are considered equivalent if the measured differences are within the
 1030 previously established measurement uncertainty.
- 1031 Step 2 Inject an appropriate range of power levels, P_{inject} , into the unmodified or modified AIMD. Measure
 1032 ΔT or SAR at the hot spot at a fixed high SNR monitoring point. The location of the monitoring
 1033 point and measurement time shall be the same as that used for the measurement of ΔT or SAR for
 1034 the radiated in vitro testing of the actual AIMD. The amplitude range of ΔT or SAR shall be
 1035 determined based on the intended use of the AIMD while ensuring the thermal response of the
 1036 tissue-simulating medium is linear.
- 1037 Step 3 Plot ΔT or SAR vs P_{inject} and fit to a linear model. Determine the conversion factor, m (slope), and
 1038 associated uncertainty from the fitted model.
- 1039 Step 4 The total RF power dissipated at the hot spot for an arbitrary AIMD radiated electric field
 1040 exposure can now be computed from a point SAR or ΔT measurement at a specified spatial
 1041 location relative to the hot spot when the ΔT or SAR is within the range for which the conversion
 1042 factor was determined.

1043 **8.10 Quantitative evaluation of AIMD heating in TSM**1044 **8.10.1 General**

1045 MRI induced AIMD RF hot spots can be evaluated by considering either the total RF power dissipated at the
 1046 hot spot, or the local temperature measured at the AIMD hot spot. The RF heating exposure system (8.4) and
 1047 tissue simulating medium (8.5) are used to characterize AIMD hot spots for all tiers, however the results are
 1048 used differently depending on the Tier:

- 1049 — Tier 2: The electric fields simulated in human body models at the RF exposure levels consistent with the
 1050 MR Conditional labelling are used to define a conservative exposure level (8.8.2). Therefore, the total
 1051 dissipated RF power measured in TSM using one of the methods defined in 8.9 is an estimate of the
 1052 power dissipated in vivo. Similarly, the temperature rise at the hot spot is related to the local dissipated
 1053 power. For Tier 2, the results of the TSM dissipated power or temperature rise measurements are direct
 1054 inputs into the Stage 2 in vivo heating evaluation that is outside the scope of this standard assessment
 1055 (8.14).
- 1056 — Tiers 3, 4 and 4(-): RF heating models are used to predict the RF power dissipated or temperature rise
 1057 from the electric fields simulated in human body models at the RF exposure levels consistent with the
 1058 MR Conditional labelling. For these tiers, the results of the dissipated RF power or temperature rise
 1059 measurements in TSM (8.9) are used to calibrate and/or validate the RF heating models.

1060 **8.10.2 Tier 3, 4, and 4(-): total dissipated RF power evaluation**

1061 The total RF power dissipated at the AIMD hot spot in TSM (8.9) is determined from the incident electric field
 1062 computed from numerical human body simulations (in the absence of the AIMD) using a TF model (8.8.3 and
 1063 8.8.5). The TF model is calibrated to output total dissipated RF power using one of two methods:

1064 — Option 1

1065 The power dissipated at the AIMD hot spot is determined by spatial integration of the normalized 3D
 1066 simulated SAR distribution around the hot spot. The normalized spatial distribution of RF power
 1067 deposition near AIMD hot spot(s) is a function of the hot spot geometry (i.e. electrode size, design, and

geometry), and medium properties. The total dissipated power is the spatial integral of this distribution, and the magnitude is a function of the incident electric field and the characteristics of the AIMD. The normalized spatial RF power dissipation can be determined using full-wave or quasi-static simulations when the dimensions of the hot spot(s) satisfy the quasi-static criterion. Once the normalized and validated (8.10.3) spatial distribution of RF power deposition and normalized total deposited power is known for a specific AIMD hot spot geometry, then the total dissipated power for a radiated exposure is computed from one (or multiple) reference temperature or SAR measurements by spatially integrating the appropriately scaled dissipated power distribution (8.9.2).

— Option 2

The total dissipated RF power is determined using the RF injection method (8.9.3).

NOTE There is no RF power calibration required for Tier 4 evaluations because the dissipated RF power is a direct output of the model.

8.10.3 Validating spatial RF power dissipation simulations

Power distribution simulations (full-wave, or quasi-static) of AIMD hot spots(s) are validated by comparing the simulated dissipated power values at multiple spatial locations around the hot spot(s) to corresponding measured values. Local SAR may be measured using electric field probes or by measuring the initial rate of temperature increase (8.9.2). Alternatively, thermal simulation may be used to transform the computed dissipated power into the temperature rise distribution around the AIMD hot spot. Successful validation of the simulated spatial and temporal temperature rise distribution validates both the dissipated power and the thermal simulations.

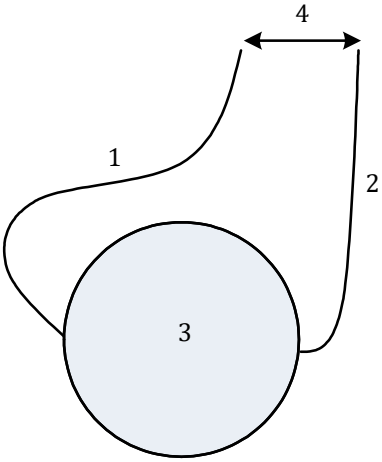
8.10.4 Tier 3 and 4(-): Local temperature rise evaluation

The temperature rise at the AIMD hot spot in TSM is computed from incident electric fields computed from numerical human body simulations (in the absence of the AIMD) using a TF model (8.8.3 and 8.8.5). The TF model is calibrated to output the maximum temperature rise in TSM at the AIMD hot spot at a fixed measurement time.

8.11 Proximity effect for closely spaced electrodes from multiple leads

Devices with multiple leads intended to be closely spaced (i.e. stimulators with multiple leads in the same anatomical target) might exhibit proximity effects with respect to RF heating due to superposition of scattered fields near closely placed electrodes (Figure 5). If electrodes on separate leads are less than 20 mm apart then the proximity effect on RF heating shall be evaluated using numerical modelling or in vitro measurements. The proximity effect for multiple leads might increase or decrease the dissipated RF power or temperature rise relative to a single lead configuration depending upon the specific implementation (for example leads closely coupled along their entire length or only in close proximity near the lead electrodes).

NOTE Multiple lead interactions are therapy and device specific and standardized methods to evaluate proximity effects on RF electrode heating is outside the scope of this document.



Key

- 1 lead 1
- 2 lead 2
- 3 AIMD case
- 4 electrodes, <20 mm apart

Figure 5 — Proximity enhancement factor

8.12 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 or temperature rise around the AIMD when exposed to a well-defined and repeatable radiated electromagnetic field test environment as described in 8.6. 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 of manufacturer selected shape, containing tissue simulating media with characteristics defined in 8.5 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 insure 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 or temperature rise determined using the radiated electromagnetic test apparatus shall be quantified. The in vitro test uncertainty, u_{exp} , represents the total uncertainty of 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 Subclause 8.13 and Annex V 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, or experimental methods used to derive and implement the AIMD model.

- 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 or corresponding temperature rise measured in Step 4 and the deposited RF power or corresponding temperature rise 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} .

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- 1174 Step 7 Evaluate validation criteria and compute the combined in vitro prediction uncertainty.
- 1175 The purpose of model validation is to show that the model is acceptable for the intended use. Transfer
- 1176 function measurement system validation examples are provided in Annex U and transfer function model
- 1177 validation and uncertainty assessment guidance is provided in Annex V.
- 1178 **8.13 Uncertainty analysis requirements**
- 1179 **8.13.1 General**
- 1180 Uncertainty shall be estimated for the AIMD hot spot dissipated RF power or temperature rise values as
- 1181 specified in this clause.
- 1182 **8.13.2 Requirements for all tiers**
- 1183 — The uncertainty (u_{exp}) of the radiated test system defined in 8.6;
- 1184 — All tiers require human body electromagnetic simulations to determine AIMD electric field exposures.
- 1185 The simulation space should represent the relevant patient population, and transmit RF coils,
- 1186 polarizations, landmarks, and patient postures consistent with the MR Conditional labelling (see 8.3). If
- 1187 a reduced set of simulations is used with limited variation of a particular parameter(s), additional
- 1188 uncertainty analysis may be used to account for the expected variation in the simulation space.
- 1189 **8.13.3 Requirements for Tiers 3, 4, and 4(-)**
- 1190 — AIMD RF heating model prediction uncertainty (u_{predict}).
- 1191 NOTE The influence of device location, orientation, and lead pathway, as appropriate for the intended clinical use
- 1192 conditions for the AIMD, is part of a Tier 3, 4, or 4(-) RF heating evaluation. Uncertainty analysis does not apply to these
- 1193 parameters.
- 1194 **8.14 In vivo AIMD RF heating**
- 1195 **8.14.1 General**
- 1196 The output of Clause 8 is the dissipated RF power or temperature rise at a specified measurement time in
- 1197 TSM. Predicting in vivo heating from these results (Stage 2 analysis) is beyond the scope of this standard
- 1198 (8.1). However, general guidance for designing a RF heating risk assessment based on the Clause 8 test
- 1199 methods is outlined in the following subclauses.
- 1200 **8.14.2 Dissipated RF power methods**
- 1201 The dissipated RF power measured (Tier 2) or simulated (Tier 3, Tier 4, Tier 4(-)) can be directly transferred
- 1202 to the in vivo environment and therefore represent the power dissipated in human patients. Options for
- 1203 characterizing risk include, but are not limited to, thermal modeling to compute the temperature distribution
- 1204 near the hot spot, or injected RF power studies in a suitable animal model to correlate dissipated RF power
- 1205 to physiologic response.
- 1206 **8.14.3 Tier 3 and 4(-) local temperature rise methods**
- 1207 The local AIMD hot spot temperature rise measured in vivo is related to the temperature rise measured in
- 1208 TSM through an in vitro to in vivo conversion factor [7]. Options for determining the conversion factor
- 1209 between the maximum temperature rise measured at a specified time in TSM using the Clause 8 methods,

- 1210 and the in vivo temperature rise at a measurement time specified in the AIMD MR Conditional labelling
1211 include but are not limited to:
- 1212 — Predict the in vivo temperature rise in a suitable animal model at a desired evaluation time using the
1213 Tier 3 or Tier 4(-) models calibrated and validated in TSM. The difference between the mean predicted,
1214 and measured temperatures is the in vitro to in vivo conversion factor that is then applied to the TF RF
1215 heating model (see 8.5.2 for an example of this approach);
 - 1216 — The TSM temperature rise predicted by the validated TF model is calibrated to dissipated RF power
1217 using the injected RF power method (8.9.3). The in vitro to in vivo temperature rise conversion factor is
1218 determined by comparing the temperature rise in TSM (at a specified measurement time) with the
1219 temperature rise measured in a suitable animal model at the same dissipated RF power (at the
1220 measurement time specified in the labelling);
 - 1221 — Depending on the tissue thermal properties and the influence of perfusion at the AIMD hot spot, the
1222 validated TF model TSM temperature rise predictions might be shown to be conservative with respect
1223 to the in vivo temperature rise.
- 1224
1225

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

9.1 Introduction

This clause provides an evaluation of potential AIMD case heating due to the effects of the MR scanner's gradient field and RF field. The evaluation of device heating due to gradient-induced fields is covered in 9.2, and the evaluation of device heating due to RF-induced fields is covered in 9.3.

9.2 Gradient-induced device heating

9.2.1 Introduction

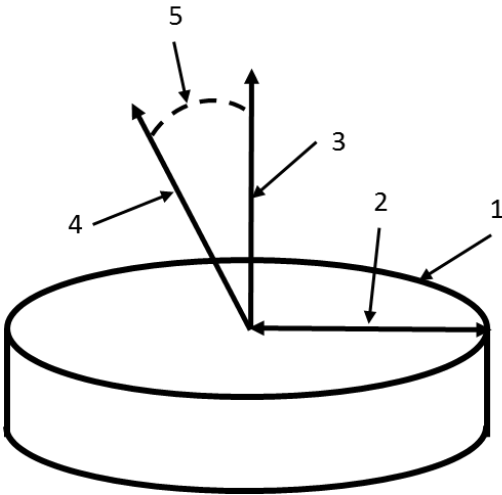
The imaging gradient dB/dt field induces eddy currents on conductive AIMD enclosures and on other conductive internal surfaces, such as battery components, resulting in device heating. For AIMDs with extended leads (e.g. cardiac leads or neuromodulation leads) that do not contain planar conductive surfaces, 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 (3) and shown in Figure 6.

$$Power = \sigma T \pi \frac{R^4}{8} \left(\frac{dB}{dt_{rms}} \cos \beta \right)^2 \quad (3)$$

where

$Power$	is instantaneous deposited power;
R	is the radius;
T	is the material thickness of disk (number 1 in Figure 6);
σ	is the electrical conductivity;
β	is the angle of the dB/dt vector with respect to the normal to the disk plane;
dB/dt_{rms}	is the time rate of change of the magnetic field.



Key

- 1 AIMD enclosure with conductivity, σ , and material thickness of disk, 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 6 — 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.

9.2.2 Testing considerations

9.2.2.1 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.

9.2.2.2 Test exposure level

The AIMD shall be tested at an exposure level of 42 T/s rms (for an AIMD radial position of 20 cm) for a 15-minute duration. See Annex D for test exposure level and duration rationale.

The heating test results shall be reviewed using risk management analysis recognizing that MR scanners can transiently output $|dB/dt|$ rms values exceeding the test exposure in a limited number of use cases. If the risk profile for the AIMD requires mitigation to a level greater than 99,9 %, further analysis should be conducted by the device manufacturer or particular standards to determine the appropriate test exposure level and duration.

For devices with other radial positions, the $|dB/dt|$ rms test exposure values as a function of radial position within the scanner bore is shown in Table 4. Determine the $|dB/dt|$ rms test value using Table 4 and the radius that contains the AIMD for the relevant patient population.

Table 4 — 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 dBy/dt peak in Table A.2. This scaling method can also be applied for radial positions not listed above.

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

9.2.3 Test requirements

9.2.3.1 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 recommended.

NOTE The use of a clinical MR scanner is not recommended due to the likelihood of damage to the MR scanner.

It is not necessary to expose the device to the clinical exposure limits of 9.2.2.2 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 or the dB/dt rms of the test is at least 50 % of the exposure value per Table 4 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 (4)).

$$\Delta T_{\text{clinical exposure}} = \Delta T_{\text{measured}} \left[\frac{\left| \frac{dB}{dt} \right|_{\text{rms}} (\text{requirement})}{\left| \frac{dB}{dt} \right|_{\text{rms}} (\text{test})} \right]^2 \quad (4)$$

1289 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.

1290

1291 9.2.3.2 In vitro test phantom or another suitable container

1292 Position the DUT at the radial centre of a phantom filled with gelled solution or another appropriate test
1293 container. Position and orient the phantom or container with device as required for exposure to the test
1294 condition gradient field magnitude and vector direction in laboratory test equipment capable of producing a
1295 simulated MR gradient field.

1296 When using a phantom within a laboratory gradient field coil, there are often practical limitations to the
1297 phantom container size, and the boundary conditions of the phantom can affect temperature measurements.
1298 It is preferable to hold the phantom container boundary temperature constant for the test duration. If the
1299 boundary temperatures cannot be held constant, then thermal loss to the environment shall be accounted
1300 for in the final temperature rise.

1301 9.2.3.3 Gelled solution

1302 For a device heating test using a phantom, refer to the gelled high permittivity material, defined in Annex L,
1303 for an appropriate test media.

1304 9.2.3.4 Temperature survey to determine orientation and hot spots

1305 Device heating will depend upon orientation of the device relative to the vector of the applied field. For
1306 devices with a large conductive plane (or multiple parallel conductive planes), maximum power deposition
1307 will occur when the dB/dt vector is perpendicular to the largest conductive plane. For devices without a
1308 major conductive plane or devices with internal components that might contribute to heating in other
1309 orientations, a survey shall be conducted to determine the orientation relative to the applied dB/dt vector
1310 that produces the largest heating.

1311 The device will have localized hot spots due to the case shape or heating contributed by power dissipated in
1312 internal components. The device shall be surveyed for hot spots due to gradient-induced heating. The hot
1313 spot survey shall be conducted using the device orientation that produced maximum heating.

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9.2.3.5 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.

9.2.3.6 Definition of dB/dt test waveform

The test waveform to be applied to the AIMD shall be a sine waveform of 1750 Hz. See Annex D for test waveform and frequency rationale.

9.2.3.7 Characterization of applied dB/dt

Using an off-the-shelf 3-axis search coil or a custom-built search coil, measure the dB/dt generated along the axis of the test coil. The search coil should be approximately the same size as the AIMD enclosure or its internal electrically conductive components, ensuring the AIMD is adequately exposed. For a custom-built search coil, the methods described in IEC 60601-2-33:2022, 201.12.4.105.2.2, method b) may be used to monitor the gradient output. Place the search coil in the region of the homogeneous field.

The AIMD shall be oriented with major conductive planes orthogonal to the test coil field. 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 (see Formula (5)).

$$\left| \frac{dB}{dt} \right|_{rms} = \sqrt{\frac{\left(\int_0^{t_x} \left| \frac{dB}{dt} \right|^2 dt \right)}{t_x}} \quad (5)$$

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 dB/dt measurement may be performed independently of the heating test, provided the applied waveforms will be identical for each test.

9.2.4 Lab testing using simulated MR gradient field

Step 1 Place the device in the gelled phantom or other suitable container with temperature probes attached as defined in 9.2.3.5 and placed in a laboratory coil that applies the time-varying magnetic field.

Step 2 Apply the required $|dB/dt|$ rms and duration determined in accordance with 9.2.2.2, with the waveform as specified in 9.2.3.6 and measured in 9.2.3.7. 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 9.2.3.1.

1349 Step 3 Measure the gradient-induced device heating with the temperature probes for the duration of the
1350 test.

1351 **9.3 RF-Induced device heating**

1352 **9.3.1 General**

1353 There are two sources of RF case heating. The first source is RF case heating resulting from a B_1 induced
1354 electric field SAR concentration effect in tissue caused by the electrically conductive device case. The RF
1355 charge concentrates at the edges of the device case, this concentration increases the SAR at the tissue close
1356 to the case. It is important to note that the RF field does not directly heat the device, instead the tissue nearby
1357 the case heats. For AIMDs with implantable leads the second source of RF-related case heating consists of RF
1358 energy injected from the implanted leads into the device case.

1359 **9.3.2 Tissue simulating media**

1360 Select the appropriate TSM to represent the in vivo tissue around the AIMD case in accordance with 8.5,
1361 Method 1. If the AIMD case is predominantly located in LPM, testing in HPM may be acceptable if the selected
1362 scaling method can be shown to conservatively predict the expected in-vivo heating.

1363 **9.3.3 RF-induced case heating from local electric field**

1364 **9.3.3.1 General**

1365 An AIMD with deployed dimensions of less than 2 cm in all directions and at least 3 cm from another
1366 metallic medical device does not need to be tested with respect to RF induced heating at 3 T or less.

1367 The RF case heating test is a radiated test using an RF field source in accordance with 8.4 and a phantom
1368 filled with a gelled TSM. The magnitude and direction of the electric field in the phantom shall be mapped to
1369 aid in determining the test location.

1370 **9.3.3.2 Measurement procedure**

1371 To measure the temperature rise in this test scenario use the following procedure:

1372 Step 1 Identify the electric field or averaged SAR exposure value at the case for the labelled RF exposure
1373 condition. Refer to 9.3.3.3 and 9.3.3.4 for electric field determination methods or 9.3.3.3 for the
1374 background SAR exposure determination method.

1375 Step 2 Identify a location in the phantom that produces the following:

- 1376 a) an electric field or SAR with a signal to noise ratio of 10:1 or an exposure of at least 50 % of
1377 the determined exposure value in Step 1, and
- 1378 b) electric field lines parallel to the device's maximum heating response orientation described
1379 in 9.3.3.5 and graphically illustrated in Figure 7.

1380 Step 3 Measure the electric field or SAR at the identified location without the AIMD present.

1381 Step 4 Measure the background temperature rise for a duration of 15 minutes at the identified location
1382 without the AIMD present or at a reference location with equivalent local SAR.

1383 Step 5 Place the AIMD at the identified location. Temperature probes shall be placed adjacent to the case
1384 (approximately 1 mm above device surface) at maximum heating locations defined in 9.3.3.5.

1385 Step 6 Measure the temperature rise for a duration of 15 minutes.

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1386 Step 7 Subtract the temperature rise of background ($\Delta T_{\text{backgnd}}$) from the temperature rise of the AIMD
1387 max heating locations, (ΔT_{total})

1388 Step 8 Scale ($\Delta T \propto \text{SAR}$ or E_{rms}^2) to the determined electric field or SAR value for the labelled RF exposure
1389 condition.

1390 If labelling for both 1,5 T and 3 T and the device length is shorter than resonant length at 128 MHz as defined
1391 in (Clause 8) Figure 4, the AIMD manufacturer may measure the temperature rise per unit background
1392 exposure (SAR or electric field) at one frequency (e.g. 64 MHz) and scale the temperature rise by the SAR or
1393 electric field determined in Step 1. However, the electric field and SAR can be somewhat higher nearby the
1394 device at 128 MHz. Therefore, when scaling 64 MHz the practitioner shall use appropriate SAR estimates to
1395 ensure conservative scaling for 128 MHz.

1396 9.3.3.3 Tier 2 electric field or SAR determination

1397 Clause 8 Tier 2 can be used to determine the 10 g average electric field or SAR (E_{max} or SAR_{max}) impinging on
1398 the device case (AIMD enclosure not including lead) during the RF temperature measurements. Clause 8
1399 Tier 2 requires defining a volume that encompasses clinically valid locations of the AIMD. For RF case heating
1400 this includes the case and not the leads for leaded systems. The highest magnitude of the electric field in the
1401 volume that defines the device case location is the test amplitude $|E_{\text{max}}|$ or $|\text{SAR}_{\text{max}}|$. Use a percentile defined
1402 by AIMD particular standards or by the AIMD manufacturer's risk management system.

1403 9.3.3.4 Tier 3 electric field determination

1404 Clause 8 Tier 3 can be used to determine the tangential electric field (E_{tan}) impinging on the device case (AIMD
1405 enclosure not including lead) during the RF temperature measurements. Follow the guidance of Clause 8
1406 Tier 3 of the E_{tan} obtained through simulations using a percentile defined by AIMD particular standards or by
1407 the AIMD manufacturer's risk management system.

1408 9.3.3.5 Highest RF heating locations

1409 Figure 7 illustrates an example AIMD case shape typical of a simple cardiac pacemaker. The highest heating
1410 locations, hot spots A and B occur when line AB is aligned with the local RF electric field in the vicinity of the
1411 case. For some AIMDs, Line AB is the longest line through the device or the longest line through the device
1412 that includes a sharp corner. For devices like these the two lines are one and the same and is the maximum
1413 heating response orientation. These AIMDs require only one device orientation and two hot spots be tested.

1414 For more complex AIMDs, for example having case shapes with more angularity, insulated metallic case
1415 regions, and case mounted electrodes will require simulation or evaluation testing to determine hot spot
1416 location(s) and associated device orientation(s).

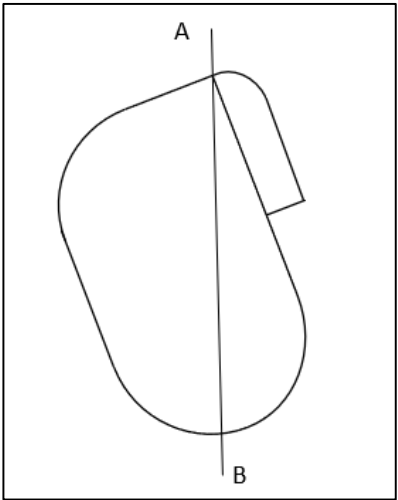


Figure 7 — Line Defining the Worst-Case RF Heating Locations

9.3.4 RF-induced case heating from injected RF from leads

For AIMDs with implanted leads, there is an additional source for RF induced case heating due to injected RF from the leads in a radiated test environment. To measure the temperature rise in this test scenario use the following procedure:

Step 1 Place the AIMD with connected leads in a gelled phantom such that the lead pathway generates a known RF injection level from an electric field with a signal to noise ratio of 10:1 or an injection level of at least 50 % of the modelled value. The AIMD should be placed such that the electric field at the case is negligible (e.g. the corners or center of the ASTM phantom).

Step 2 Measure the injected RF level at each RF entry point using equipment such as that described in 15.7.4 or use a validated model to predict the injected RF level.

Step 3 A hot spot (RF_{inject}) determination step is required to determine probe placement. Temperature probes shall be placed at the location of maximum heating.

NOTE The source and location of injected RF induced heating can vary depending on the lead interface electronics. A common source of heating can be the filtered feed through capacitors depending on the equivalent series resistance (ESR).

Step 4 Measure the temperature rise for a duration of 15 minutes.

Step 5 If the found hot spot is associated with the position of a single RF entry port, scale the measured temperature rise at RF_{inject} hot spot to the rms power level, $RF_{max-rms}$, in accordance with 15.4.5. Use the $RF_{max-rms}$ percentile defined by AIMD particular standards or by the AIMD manufacturer's risk management system for that particular RF entry port. However, if the hot spot can't be associated with the position of a single RF entry point, scale the measured temperature rise at RF_{inject} hot spot to the appropriate percentile rms RF injection level averaged across all the RF entry ports.

Step 6 Scale the temperature rise by using Formula (6), Formula (7), or Formula (8).

$$\Delta T_{in vivo} = \frac{(I_{rms, in vivo})^2}{(I_{rms, test})^2} * \Delta T_{test} \tag{6}$$

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$$\Delta T_{invivo} = \frac{(V_{rms,invivo})^2}{(V_{rms,test})^2} * \Delta T_{test} \quad (7)$$

$$\Delta T_{invivo} = \frac{P_{rms,invivo}}{P_{rms,test}} * \Delta T_{test} \quad (8)$$

where

ΔT_{invivo}	is the calculated in vivo tissue temperature rise
ΔT_{test}	is the measured temperature rise from the test
$I_{rms,invivo}$	is the maximum in vivo rms current for the RF entry port
$I_{rms,test}$	is the applied rms current test level
$V_{rms,invivo}$	is the maximum in vivo rms voltage for the RF entry port
$V_{rms,test}$	is the applied rms voltage test level
$P_{rms,invivo}$	is the maximum in vivo rms power for the RF entry port
$P_{rms,test}$	is the applied rms power test level

For devices with the same external dimensions as a previously tested device, this test may be omitted if the manufacturer provides justification that the component that is the source of heating (due to injected RF) has been identified and has previously demonstrated the heating of the device with that component to be acceptable at the expected in vivo rms exposure level. This test may also be omitted if the identified component that was previously demonstrated to be acceptable at the expected in vivo rms exposure level has been modified where the new component has electrical properties that will result in reduced heating. An example of this might include a filtered feedthrough component near the lead input of the device that experiences heating due to parasitic ESR.

9.4 Reporting temperature rise from gradient, local electric field RF, and injected RF

The AIMD manufacturer shall report the temperature rise due to gradient, local electric field RF, and injected RF separately. See Annex D for additional information and rationale.