



BSI Standards Publication

Implants for surgery — Active implantable medical devices

Part 7: Particular requirements for cochlear and auditory brainstem implant systems

National foreword

This British Standard is the UK implementation of EN ISO 14708-7:2022. It is identical to ISO 14708-7:2019.

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

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

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Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear and auditory brainstem implant systems (ISO 14708-7:2019)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 7: Exigences particulières pour les systèmes d'implant cochléaire et d'implant auditif du tronc cérébral (ISO 14708-7:2019)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 7: Besondere Anforderungen an Cochlea-Implantat Systeme (ISO 14708-7:2019)

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European foreword

This document (EN ISO 14708-7:2022) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN-CENELEC/ JTC 16 "Active Implantable Medical Devices" the secretariat of which is held by DKE.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN-CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

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Endorsement notice

The text of ISO 14708-7:2019 has been approved by CEN-CENELEC as EN ISO 14708-7:2022 without any modification.

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Foreword

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

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

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

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

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

This second edition cancels and replaces the first edition (ISO 14708-7:2013), which has been technically revised. The main changes compared to the previous edition are as follows:

- alignment to the revised ISO 14708-1:2014;
- significant changes to [Clauses 17, 22 and 27](#);
- many clauses have been replaced by references to ANSI/AAMI CI86:2017.

A list of all part in the ISO 14708 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This corrected version of ISO 7063:2018 incorporates the following correction: in [16.2](#), the word "direct" was added in the following sentence: "The maximum direct current density at the *electrode contact* opening shall be no more than 0,75 $\mu\text{A}/\text{mm}^2$ ".

Introduction

This document specifies particular requirements for active implantable medical devices used to treat hearing impairment via electrical stimulation (for example, *cochlear implant systems* or *auditory brainstem implant systems*), to provide basic assurance of safety for both patients and users.

A *cochlear implant system* or *auditory brainstem implant system* is an active implantable medical device comprising implantable and *non-implantable parts* (external parts). The power source can be externally derived or from an internal battery. The *implant system* is designed to restore hearing via electrical stimulation of the auditory pathways. Externally or internally processed acoustic information is converted to electrical stimulation signals which are delivered via one or more electrodes. The working parameters of the device may be adjusted via a non-implantable accessory.

This document is relevant to all parts of *implant systems*, including accessories.

The requirements of this document supplement or modify those of ISO 14708-1:2014.

In this document, terms printed in italic letters are used as defined in [Clause 3](#). Where a defined term is used as a qualifier in another term, it is not printed in italic letters unless the concept thus qualified is also defined.

Information is also provided in [Annex B](#) that explains the relationship between [ISO/TR 14283](#), ISO 14708-1:2014 and this document.

Notes on [EN 45502-2-3](#) (basis for this document) is provided in [Annex C](#) for information.

Implants for surgery — Active implantable medical devices —

Part 7: Particular requirements for cochlear and auditory brainstem implant systems

1 Scope

This document specifies requirements that are applicable to those active implantable medical devices that are intended to treat hearing impairment via electrical stimulation of the auditory pathways. Devices which treat hearing impairment via means other than electrical stimulation are not covered by this document.

The tests that are specified in this document are type tests and are to be carried out on samples of a device to show compliance.

This document is also applicable to *non-implantable parts* and accessories of the devices (see NOTE).

The electrical characteristics of the implantable part are determined by either the appropriate method detailed in this document or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this document applies.

NOTE A device that is commonly referred to as an active implantable medical device can in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, this document specifies those requirements of *non-implantable parts* and accessories which could affect the safety or performance of the implantable part.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 10974, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*

ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

[IEC 60068-2-31](#), *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

[IEC 60601-1-2](#), *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

[IEC 61000-4-2](#), *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

[EN 1593](#), *Non-destructive testing — Leak testing — Bubble emission techniques*

[EN 13185](#), *Non-destructive testing — Leak testing — Tracer gas method*

ANSI/AAMI CI86:2017, *Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1:2014 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 cochlear implant system

CIS

active implantable medical device, comprising implantable and *non-implantable parts* (3.4), intended to treat hearing impairment via electrical stimulation of the cochlea

3.2 auditory brainstem implant system

ABIS

active implantable medical device, comprising implantable and *non-implantable parts* (3.4), intended to treat hearing impairment via electrical stimulation of the auditory brainstem

3.3 implant system

either *cochlear implant system* (3.1) or *auditory brainstem implant system* (3.2)

3.4 non-implantable part

external part of the *implant system* (3.3)

Note 1 to entry: Examples would include, but are not limited to, sound processor, microphone, coil or power source.

3.5 stimulator

implantable part of the *implant system* (3.3) containing electronic circuitry required to produce electrical stimulation

3.6 body-worn

non-implantable part (3.4) of the *implant system* (3.3) and worn on the body (e.g. belt or ear level)

3.7 electrode contact

electrically conducting part which is designed to form an interface with body tissue or body fluid

3.8 electrode array

distal part of a lead containing more than one *electrode contact* (3.7)

3.9 reference electrode

electrically conducting part designed as return path for electrical stimulation current

3.10 model designation

name and/or a combination of letters and numbers used by a manufacturer to distinguish, by function or type, one device from another

3.11

serial number

unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a device from other devices with the same *model designation* ([3.10](#))

3.12

output signal

electrical output, either pulsatile or analogue, of an *implant system* ([3.3](#)) intended to stimulate the auditory pathways

3.13

use-before-date

date after which the manufacturer recommends that the *implant system* ([3.3](#)) should not be implanted

4 Symbols and abbreviations

There are no requirements specified in this document. However, this does not preclude the use of symbols defined in other standards nor special symbols defined in the accompanying documentation.

5 General requirements for non-implantable parts

5.1 General requirements for non-implantable parts

The text in ISO 14708-1:2014, 5.1 applies.

5.2 General requirements for software

The text in ISO 14708-1:2014, 5.2 applies.

5.3 Usability of non-implantable parts

The text in ISO 14708-1:2014, 5.3 applies.

5.4 Data security and protection from harm caused by unauthorized information tampering

The text in ISO 14708-1:2014, 5.4 applies.

5.5 General requirements for risk management

The text in ISO 14708-1:2014, 5.5 applies.

5.6 Misconnection of parts of the active implantable medical device

The text in ISO 14708-1:2014, 5.6 applies.

5.7 Protection against external electrical hazards for fully implantable systems

The text in ANSI/AAMI CI86:2017, 5.7 applies.

6 Inspection and measurement

6.1 General

If this document refers to inspection of design analysis documentation provided by the manufacturer, it shall include an inspection of the risk management file as required by [ISO 14971](#).

6.2 Measurement of output signal characteristics

The text in ANSI/AAMI CI86:2017, 8.1 applies.

NOTE This ANSI/AAMI CI86 subclause is not a measurement step but describes the test configuration for the measurement steps in [6.3](#) to [6.5](#).

6.3 Measurement of the output signal amplitude and pulse width

The text in ANSI/AAMI CI86:2017, 8.2 applies.

6.4 Impedance measurement accuracy

The text in ANSI/AAMI CI86:2017, 8.3 applies.

6.5 Inductive link characterization

The text in ANSI/AAMI CI86:2017, 8.4 applies.

6.6 Sound processor battery testing

The text in ANSI/AAMI CI86:2017, 8.5 applies.

7 General arrangement of the packaging

The text in ISO 14708-1:2014, Clause 7 applies.

8 General markings for active implantable medical devices

The text in ISO 14708-1:2014, Clause 8 applies.

9 Markings on the sales packaging

9.1 The text in ISO 14708-1:2014, 9.1 applies.

9.2 The sales packaging shall bear the name and full address of the manufacturer.

The sales packaging shall also bear the name and address of the authorized representative, if the manufacturer does not have a registered place of business in the European Community.

Compliance is checked by inspection.

9.3 Where an *implant system* is supplied in separate sub-assembly packaging, each individual sales packaging shall bear a description of the contents of the packaging, the *model designation* or part number and, if applicable the batch number or the *serial number*.

Compliance is checked by inspection.

9.4 The text in ISO 14708-1:2014, 9.4 applies.

9.5 The text in ISO 14708-1:2014, 9.5 applies.

9.6 The text in ISO 14708-1:2014, 9.6 applies.

9.7 The text in ISO 14708-1:2014, 9.7 applies.

10 Construction of the sales packaging

10.1 The text in ISO 14708-1:2014, 10.1 applies.

10.2 The text in ISO 14708-1:2014, 10.2 applies.

10.3 The text in ISO 14708-1:2014, 10.3 applies.

NOTE Removable stickers, which provide supplementary information exceeding the information specified in [Clause 9](#), need not be subjected to the test specified in [10.3](#).

11 Markings on the sterile pack

11.1 The text in ISO 14708-1:2014, 11.1 applies.

11.2 The text in ISO 14708-1:2014, 11.2 applies.

12 Construction of the non-reusable pack

12.1 The text in ISO 14708-1:2014, 12.1 applies.

12.2 The text in ISO 14708-1:2014, 12.2 applies.

12.3 The text in ISO 14708-1:2014, 12.3 applies.

13 Markings on the active implantable medical device

13.1 The text in ISO 14708-1:2014, 13.1 applies.

13.2 The text in ISO 14708-1:2014, 13.2 applies.

13.3 Implantable parts of an *implant system* shall be unequivocally identifiable (particularly with regard to the *model designation* of the device), when necessary, without the need for a surgical intervention.

Compliance shall be confirmed by inspection of the procedure defined by the manufacturer in the instructions for use (see [28.6](#)).

NOTE [Annex A](#) provides additional context for this and other subclauses.

13.4 The text in ISO 14708-1:2014, 13.4 applies.

14 Protection from unintentional biological effects being caused by the active implantable medical device

14.1 The text in ISO 14708-1:2014, 14.1 applies.

14.2 Any implantable part of the active implantable medical device, intended in normal use to be in contact with body fluids, shall cause no unacceptable release of particulate matter when the device is used as intended by the manufacturer.

Test: The implantable part of the *implant system* shall be removed aseptically from the non-reusable pack. The implantable part shall be immersed in a bath of saline solution, approximately 9 g/l and suitable for injection in a neutral glass container. The volume of the saline in millilitres (ml) shall be $5 \pm 0,5$ times the numerical value of the surface area of the implantable part expressed in cm^2 . The container shall be covered with a glass lid and maintained at 37 ± 2 °C for between 8 h and 18 h, the bath being agitated throughout the period. A reference sample of similar volume shall be prepared from the same batch of saline, maintained and agitated in a similar way to the specimen. A sample of liquid from the specimen bath and from the reference bath shall be compared using apparatus suitable for measurement of particle size, such as apparatus operating on the light blockage principle (see method V.5.7.1 of the European Pharmacopoeia) or the electrical zone sensing principle (the Coulter principle, see Appendix XIII of the British Pharmacopoeia).

Compliance shall be confirmed if the excess average count of unintentional particles from the specimen compared to the reference sample does not exceed 100 per ml greater than 5,0 μm and does not exceed 5 per ml greater than 25 μm .

14.3 The text in ISO 14708-1:2014, 14.3 applies.

14.4 The text in ISO 14708-1:2014, 14.4 applies.

15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device

15.1 The text in ISO 14708-1:2014, 15.1 applies.

15.2 The text in ANSI/AAMI CI86:2017, 6.4 applies.

16 Protection from harm to the patient caused by electricity

16.1 The text in ANSI/AAMI CI86:2017, 17.1 applies.

16.2 Except for its intended function, a *cochlear implant system* pulse generator, when in use, shall be electrically neutral.

The maximum direct current density at the *electrode contact* opening shall be no more than 0,75 $\mu\text{A}/\text{mm}^2$.

In addition, the net direct current shall not exceed 0,1 μA .

NOTE The electrode contact opening is the area exposed to tissue and is not covered by insulation. In the case of recessed electrodes, the *electrode contact* opening is the opening in the outer surface of the insulating part of the electrode that might expose the tissue to the electric current.

16.3 The text in ISO 14708-1:2014, 16.3 applies.

16.4 Charge and charge density limits for biphasic, charge-balanced pulses

The text in ANSI/AAMI CI86:2017, 17.3 applies.

16.5 Phase duration requirements

The text in ANSI/AAMI CI86:2017, 17.4 applies.

16.6 Stimulation waveform requirements

The text in ANSI/AAMI CI86:2017, 17.5 applies.

17 Protection from harm to the patient caused by heat

17.1 In the absence of external influence, an implantable part of the *implant system*, not intended to supply heat to the patient, shall be in accordance with at least one of the following conditions [a), b) or c)] when implanted, and whether in normal operation, including recharge:

NOTE Examples of external influences include exposure to MRI, electrosurgery, external defibrillation, ultrasound and electromagnetic fields.

- a) no outer surface greater than 39 °C,
- b) no tissue receives a thermal dose greater than the CEM43 dose thresholds in [Table 1](#), or
- c) manufacturer's evidence that a transient higher temperature rise is justified for a particular application based upon an analysis of the risk.

Because the values in [Table 1](#) represent tissue dose thresholds, the manufacturer's risk assessment shall include an analysis of any effects to the patient due to the time/temperature relationship.

Table 1 — CEM43 dose thresholds for various tissues

Tissue	CEM43 dose threshold
muscle	40
fat	40
peripheral nerve	40
skin	21
bone	16
brain	2
BBB (blood brain barrier)	15

The CEM43 value is calculated using the following formula:

$$\text{CEM43} \cong \sum_{i=1}^n t_i \cdot R^{(43-T_i)}$$

where

- t_i is the i-th time interval in minutes;
- T_i is the average temperature of the tissue in degrees Celsius during the interval t_i ;
- R is 0,25 for $T < 43$ °C and 0,5 for $T \geq 43$ °C;
- n is the number of samples taken during the heating duration.

NOTE 1 The above CEM43 formula is an approximation of the integral form.

This formula is valid for temperatures between 39 °C and 57 °C.

Compliance is checked by inspection of a design analysis provided by the manufacturer, supported by the manufacturer's calculations and data from test studies as appropriate.

NOTE 2 For the purpose of design verification, a body temperature of 37 °C can be assumed.

NOTE 3 A future edition of this document might include examples of acceptable calculations, analyses and/or test methods.

17.2 The text in ISO 14708-1:2014, 17.2 does not apply.

18 Protection from ionizing radiation released or emitted from the active implantable medical device

18.1 The text in ISO 14708-1:2014, 18.1 applies.

18.2 The text in ISO 14708-1:2014, 18.2 applies.

18.3 The text in ISO 14708-1:2014, 18.3 applies.

19 Protection from unintended effects caused by the device

NOTE See also [28.20](#).

19.1 The text in ISO 14708-1:2014, 19.1 applies.

19.2 The text in ISO 14708-1:2014, 19.2 applies.

19.3 The text in ISO 14708-1:2014, 19.3 applies.

19.4 The text in ISO 14708-1:2014, 19.4 applies.

19.5 The text in ISO 14708-1:2014, 19.5 applies.

19.6 The text in ISO 14708-1:2014, 19.6 applies.

19.7 The physical, biological and geometric properties of the implantable parts of an *implant system* shall, as far as necessary, be designed to ensure that device removal and replacement with a device from the same manufacturer is not compromised.

Compliance shall be confirmed by inspection of a design analysis provided by the manufacturer and where available supported by appropriate test and clinical data, for example, post market surveillance data relating to device replacement.

19.8 The implantable *stimulator* case of an *implant system* intended in normal use to be in contact with body fluids shall provide sufficient hermeticity so that no fluid can infiltrate the *stimulator* case.

Tests: Fine and gross leak tests shall be conducted on the hermetic casing of the *stimulator* of an *implant system* in accordance with [EN 13185](#) and [EN 1593](#). Alternatively, testing may be conducted as specified in MIL STD 883 Method 1014. If a group A technique is used from [EN 13185](#) then a gross leak test is not required; if a group B technique is used then the gross leak test shall follow the fine leak test.

NOTE The manufacturer can include adequate hermeticity testing in their manufacturing process.

Compliance shall be confirmed by inspection of test procedures and results provided by the manufacturer and by the device leak rate not exceeding 5×10^{-9} Pa m³/s for the fine leak test and no definite stream of bubbles, or two or more large bubbles, originating from the same point of the *stimulator* case for the gross leak test.

19.9 Implantable device internal moisture content

The text in ANSI/AAMI CI86:2017, 20.7 applies.

20 Protection of the device from damage caused by external defibrillators

NOTE See also [28.12](#).

20.1 The text in ISO 14708-1:2014, 20.1 is not applicable to this document.

20.2 The text in ISO 14708-1:2014, 20.2 applies.

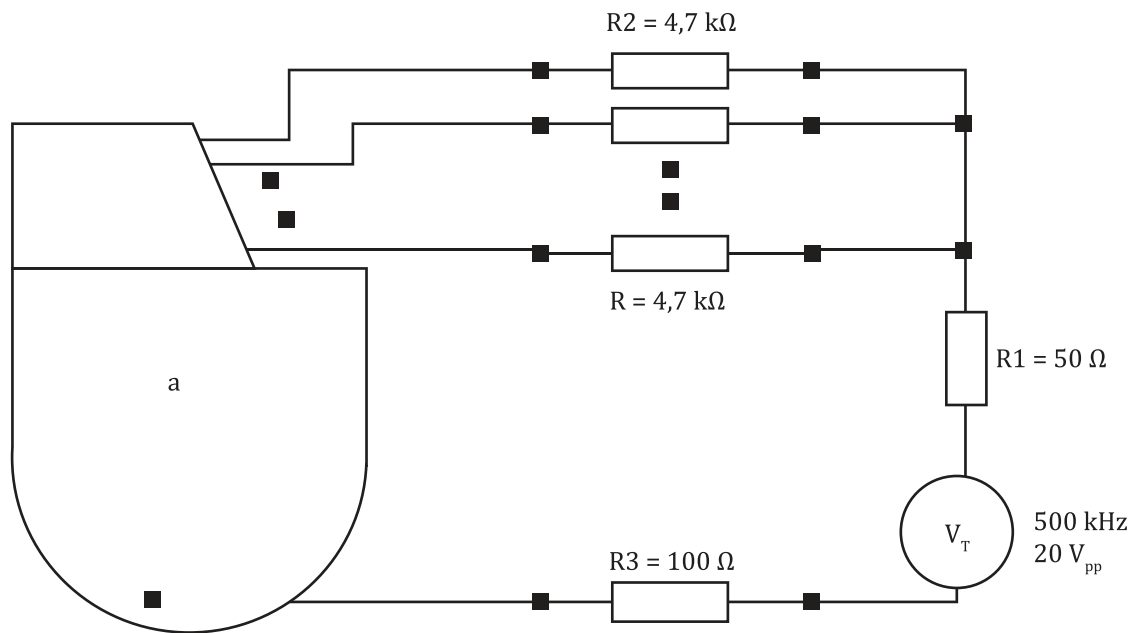
21 Protection of the device from changes caused by high power electrical fields applied directly to the patient

NOTE See also [28.12](#) and [28.13](#).

21.1 The implantable part of an *implant system* shall be designed so that stray, high frequency current from surgical equipment (surgical diathermy) flowing through the patient shall not permanently affect the device provided the *implant system* does not lie directly in the path between cutting and return [radio frequency (RF) earth] electrodes (see also requirement for warning advice, [28.13](#)).

Test: Use a signal generator with an output impedance of 50 Ω (R1). The test signal frequency shall be 500 kHz sinusoid and the open loop test signal amplitude 20 V_{pp}.

The *implant system* shall be switched off. Each output of the implantable part of the *implant system* shall be connected via a resistor (R) of 4,7 k Ω to a common point which shall be connected to the output of the signal generator (see [Figure 1](#)). The *reference electrode* of the implantable part of the *implant system* shall be connected via a 100 Ω resistor (R3) to the ground of the signal generator.



a Cochlear or brainstem implant.

Figure 1 — Test set-up for proof of protection from high frequency currents caused by surgical equipment

Apply the test signal in 10 bursts each for a duration of 1 s, allowing a recovery period of 5 s between bursts.

Compliance shall be confirmed if, after completing the test procedure and reactivating, the *implant system* characteristics conform with the manufacturer's original specification.

21.2 The text in ISO 14708-1:2014, 21.2 applies.

22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments

NOTE See also [28.12](#), [28.14](#) and [28.15](#).

22.1 The text in ISO 14708-1:2014, 22.1 applies.

22.2 The text in ISO 14708-1:2014, 22.2 applies.

22.2.1 All parts of an *implant system* shall be assessed for safety in the MR environment (see [28.8](#)) and labelled as either MR Unsafe or MR Conditional as required in [28.12](#).

The manufacturer shall declare (see [28.12](#)) the conditions (including the specific field strengths) under which the safety of MRI testing has been verified.

The declaration shall include the risk for demagnetisation, image distortion and instructions for safe performance of MRI examinations, where applicable.

The risks to a subject implanted with an *implant system* entering an MRI machine can be grouped under the following areas:

- 1) magnetically induced torque;
- 2) magnetically induced displacement force;
- 3) gradient-induced vibration;
- 4) radio frequency induced heating;
- 5) gradient-induced heating;
- 6) unintentional device output;
- 7) implant magnet weakening;
- 8) loss of implant functionality;
- 9) imaging artefact;
- 10) magnet dislocation.

Each of these factors shall be tested in accordance with [22.2.2](#) to [22.2.11](#).

22.2.2 Magnetically induced torque: Torque is exerted on the implant magnet, aiming to align the magnet so that its magnetization is parallel to the static magnetic field B_0 .

Test method: Measure the B_0 -induced torque acting on the implantable parts of an *implant system* according to the method described in ASTM F2213 or an equivalent method.

Acceptance criteria: Magnetically induced (B_0 -induced) torque shall be less than the worst-case gravity-induced torque which is defined as the product of the weight of the device and the longest linear dimension or less than a greater specified value supported by a scientific based rationale.

The implantable part of an *implant system* shall not produce any unacceptable risk to the patient arising from mechanical loads that can occur during MRI scanning. A rationale shall be given as to why the induced torque during MRI does not produce unacceptable risk.

22.2.3 Magnetically induced displacement force: A magnetically induced displacement force acts to pull ferromagnetic and paramagnetic elements of the implant into the bore of the MRI system.

Test method: Magnetically induced forces acting on the implant shall be measured according to the method described in ASTM F2052 or any equivalent method.

Acceptance criteria: Magnetically induced force shall be less than the weight of the device or less than a greater specified value that is supported by a scientifically based rationale. The implantable part of an implant system shall not produce any unacceptable risk to the patient as arising from mechanical forces that can occur during MRI scanning. A rationale shall be given why the forces arising from the displacement force during the MRI do not produce an unacceptable risk.

22.2.4 Gradient-induced vibration: Gradient fields of MR scanners induce eddy currents in the AIMD. The magnetic moments of these eddy currents interact with the MR scanner static magnetic field resulting in vibration of the AIMD. Therefore, tests need to be performed with the worst case clinically relevant gradient fields acting orthogonal to the different surfaces of the AIMD in clinically relevant orientations of the implant.

Test method: Gradient-induced vibrations shall be tested according to the methods described in the protection from harm to the patient caused by gradient-induced vibration clause of ISO/TS 10974 or an equivalent method.

Acceptance criteria: Unacceptable risk to the patient shall not result from gradient-induced vibrations of the implantable part of an *implant system*. The potential of unacceptable risk to the patient by gradient-induced vibrations of the implantable part of an *implant system* shall be assessed based on a scientific rationale. One possibility is to compare the intensity of gradient-induced vibrations to that of middle-ear hearing implants or bone conduction hearing implants.

The implantable part of an *implant system* shall not be damaged through mechanical forces arising from gradient-induced vibrations. The implantable part of the *implant system* shall be fully functional according to the manufacturer's specification after the MRI exposure.

22.2.5 Radio frequency induced heating: The implantable part of the *implant system* shall not generate excessive heat during MRI scanning.

Test method: The test shall be performed according to the protection from harm to the patient caused by RF induced heating clause of ISO/TS 10974, or an equivalent method.

Acceptance criteria: RF induced heating of adjacent tissue shall not cause unacceptable risk. The heating of tissue shall be below a limit supported by scientific rationale linked to clinical significance for the adjacent tissue. If the temperature rise is ≤ 2 °C, no further scientific rationale is needed.

If the maximum modelled and/or measured specific absorption rate (SAR) value permissible to avoid unacceptable risk due to the heating of the device electrodes is lower than the maximum SAR value possible with an MRI scanner, this safe maximum SAR value shall be labelled.

22.2.6 Gradient-induced heating: The implantable part of the *implant system* shall not generate excessive heat during MRI scanning.

Test method: The test shall be performed according to the protection from harm to the patient caused by gradient-induced device heating clause of ISO/TS 10974, or an equivalent method.

Gradient-induced heating of adjacent tissue shall not cause unacceptable risk. This heating value shall be below a limit supported by scientific rationale linked to clinical significance for the adjacent tissue. If the temperature rise is ≤ 2 °C, no further scientific rationale is needed.

22.2.7 Unintentional device output: The implantable part of the *implant system* shall be in accordance with ANSI/AAMI CI86:2017, 21.6.

22.2.8 Implant magnet weakening: The text in ANSI/AAMI CI86:2017, 21.7 applies.

When selecting the worst-case magnet angles for test, the following influencing factors shall be considered and a rationale provided as to how the selected test angle covers:

- Variation in skull size (e.g. child vs adult);
- Variation in device positioning, as allowed by the manufacturer's labelling;
- MRI bore polarity;
- Rotation of the head away from the supine (typical) position.

22.2.9 Loss of implant functionality: The implantable part of an *implant system* shall operate as intended according to the MR Conditional functionality specified in the MR Conditional labelling and shall not be damaged during MRI scanning.

Test method: Implant malfunction may be tested according to the protection from harm to the patient caused by B₀-induced malfunction, the protection from harm to the patient caused by RF induced malfunction and RF rectification, and the protection from harm to the patient caused by gradient-induced malfunction clauses of ISO/TS 10974, or an equivalent method.

Acceptance criteria: The implant shall be fully functional according to the manufacturer's specification both during (if labelled) and after exposure to the MRI environment. As soon as possible after each MRI test exposure, the implant output characteristics (RF link, pulse amplitude, pulse duration) shall be checked. The device shall later be tested by the manufacturer comprehensively to ensure that the device has not been damaged by the MRI exposure.

For magnet weakening acceptance criteria, see [22.2.8](#).

Compliance shall be checked by review of the test results and documentation provided by the manufacturer.

22.2.10 Imaging artifact: The text in ANSI/AAMI CI86:2017, 21.9 applies.

22.2.11 Magnet dislocation:

a) Test setup

The implantable part of the *implant system* shall be mounted on a fixture consisting of a non-metallic bottom plane on the side of the implant which would face towards the human skull and a skin simulator with fixture on the side which would face towards the skin flap. An example with a C-shaped non-metallic fixture on the side towards the skin flap which does not clamp the coil part of the implant itself is shown in [Figure 2](#). The skin simulator shall mimic the mechanical properties of the skin in the temporal bone region. An appropriate skin simulator or an artificial skin model shall be used, with justification of mechanical properties to be provided by the manufacturer.

A supportive head bandage may be additionally applied over the implant and skin simulator if needed. The bottom plate of the fixture may be curved like a real skull to enable better support by a head bandage.

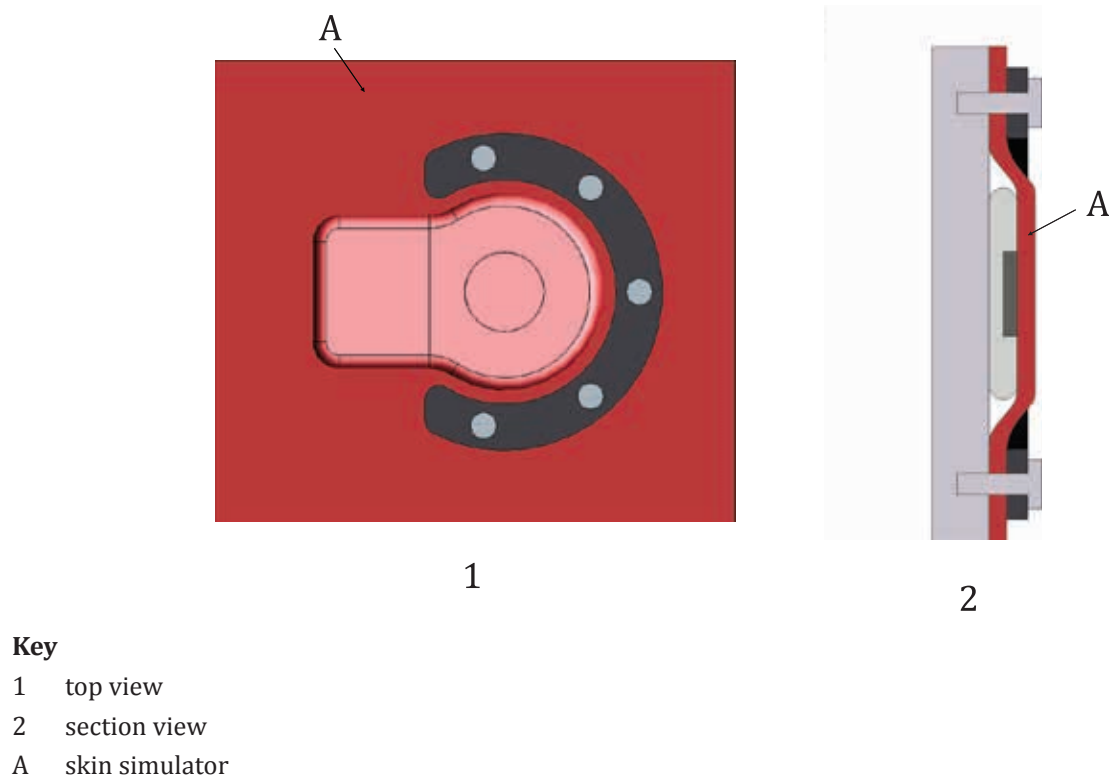


Figure 2 — Example of the implant fastening

b) Performing the test

The test fixture shall be positioned in the MRI scanner with the implant being oriented in a vertical plane parallel to the MRI scanner axis. This represents a clinically relevant orientation in which the patient, for example, is in supine position with the head kept straight.

The test fixture shall be placed in the isocentre of the scanner and shall then undergo a rotational movement of $\pm 45^\circ$ according to [Figure 3](#). Afterwards, the test items shall be inspected for damage in the magnet encapsulation or magnet dislodgement. The extent of rotation should cover the range possible for a recipient within the MRI bore and should also cover situations where the implant is not implanted in a plane exactly parallel to the long body axis of the patient.

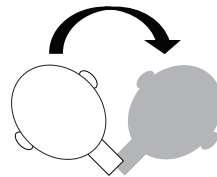


Figure 3 — Roll movement

This dynamic motion test shall be repeated at the entrance of the scanner tube with a rotational movement from 0° to 90° according to [Figure 4](#), mimicking the head movement when the patient leaves the examination table outside the scanner tube.

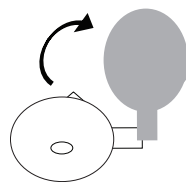


Figure 4 — Pitch movement

Afterwards, the test items shall be inspected for damage in the magnet encapsulation or magnet dislodgement.

Each test shall be performed with three representative samples of the implantable part of the *implant system* with magnetization according to specification. If in one or more test samples the implant magnet can remain in its position only at a reduced rotation angle, this safe maximum rotation angle shall be documented.

Acceptance criteria for correct implant magnet position:

The implant might not show any signs of damage in the magnet area that impacts the functionality of the implant. Magnet dislodgement is not acceptable.

The labelling shall contain the maximum safe head inclination at the isocentre if the acceptance criteria can be met only at a smaller angle than $\pm 45^\circ$.

The labelling shall also contain the specification for a head bandage if it is needed to prevent magnet dislocation or implant damage in the magnet area.

Any limitation on head rotation angle and/or any additional means of implant or magnet fixation needed to prevent damage to the implant or unacceptable risk to the patient shall be described and specified in the manufacturer's labelling.

22.3 The implantable part of an *implant system* shall be tested against therapeutic ionizing radiation as specified by the implant manufacturer.

Test: At least three samples of the implantable part of the *implant system* shall be irradiated using a linear accelerator for photon or electron irradiation with energies greater than or equal to 6 MV. After irradiation, the *stimulator* output levels shall be checked to assess any changes caused by ionizing irradiation.

Test sample modification: The test samples may be modified to allow direct connection to *stimulator* outputs or to a resistor network. The test samples can be modified by having each output connected to a 1 k Ω load resistor, which allows precise measurement of the *output signal*.

Test setup: Irradiation shall be performed with the test samples submerged in a container filled with water and placed at the depth of maximum dose intensity; 1,5 cm for 6 MV linear accelerators, 3 cm for 15 MV linear accelerators. Water shall surround the test sample to ensure scatter radiation equilibrium (see [Figure 6](#)). Alternatively, instead of using a water-filled container, testing can also be performed using a plastic material with the same density as water.

The size of the radiation beam shall be wide enough to irradiate an area which exceeds all *stimulator* bodies of the test samples on each side by at least 1,5 cm or 3 cm (for irradiation with 6 MV and 15 MV photons, respectively).

The complete test can be done at room temperature.

Irradiation scheme: Irradiation is to be delivered in fractions of 5 Gy using clinically relevant dose rates (e.g. 3 Gy/min) until a cumulative dose of 100 Gy is reached or until the output has changed by more than 10 % of its value before initial exposure. As soon as possible after each irradiation step, the implant output characteristics (pulse amplitude and pulse duration) shall be checked and then the implant shall be powered under typical clinical conditions for at least 10 min. For details, see flowchart in [Figure 5](#). After all irradiation steps have been applied, a final annealing (implants powered under typical clinical conditions for 168 h), with measuring the output characteristics is being measured after 6 h to 24 h and finally after 168 h of operation (plus eventual additional resting time where the implants under test are not powered).

Testing before and after each irradiation step: For measuring the output characteristics, the test samples shall be operated on all output channels with a constant output level. The “test signal” should apply clinically relevant pulse durations using stimulation amplitudes adjusted on all output channels to a value between 80 % and 100 % of their maximum output amplitude.

Measurement of the *output signals* amplitudes and pulse durations shall be performed before the initial irradiation and as soon as possible after each irradiation step. The output characteristics of an implant could potentially be affected only for a relatively short period of time after irradiation. Therefore, the time span between each irradiation step and the consecutive *output signal* measurement shall be kept as short as possible and, and the time gap shall be documented. This could be the basis for a recommended waiting period after irradiation before the audio processor can be safely worn again.

Operating the implants between the irradiation steps: Between irradiation steps the test samples shall be kept operating as in a typical clinical setting (pulse durations and amplitudes). Alternatively, they can be operated with the test signal defined above.

Accompanying documents: The accompanying documents (see [28.12](#)) shall declare the cumulative dose given, in Gy, and the associated *output signal* change (mean value and standard deviation of pulse amplitude and duration overall output channels of that test sample which showed the biggest change) compared to its baseline value prior to receiving any radiation. Additionally, the time span between irradiation and output measurement, in min, for a potential waiting period for safe use of the processor after irradiation, and the photon energy, in MV, shall be declared. Information shall be provided that audiological re-fitting of the *implant system* may be considered. If no ionizing irradiation test has been performed the accompanying documents (see [28.12](#)) shall state this.

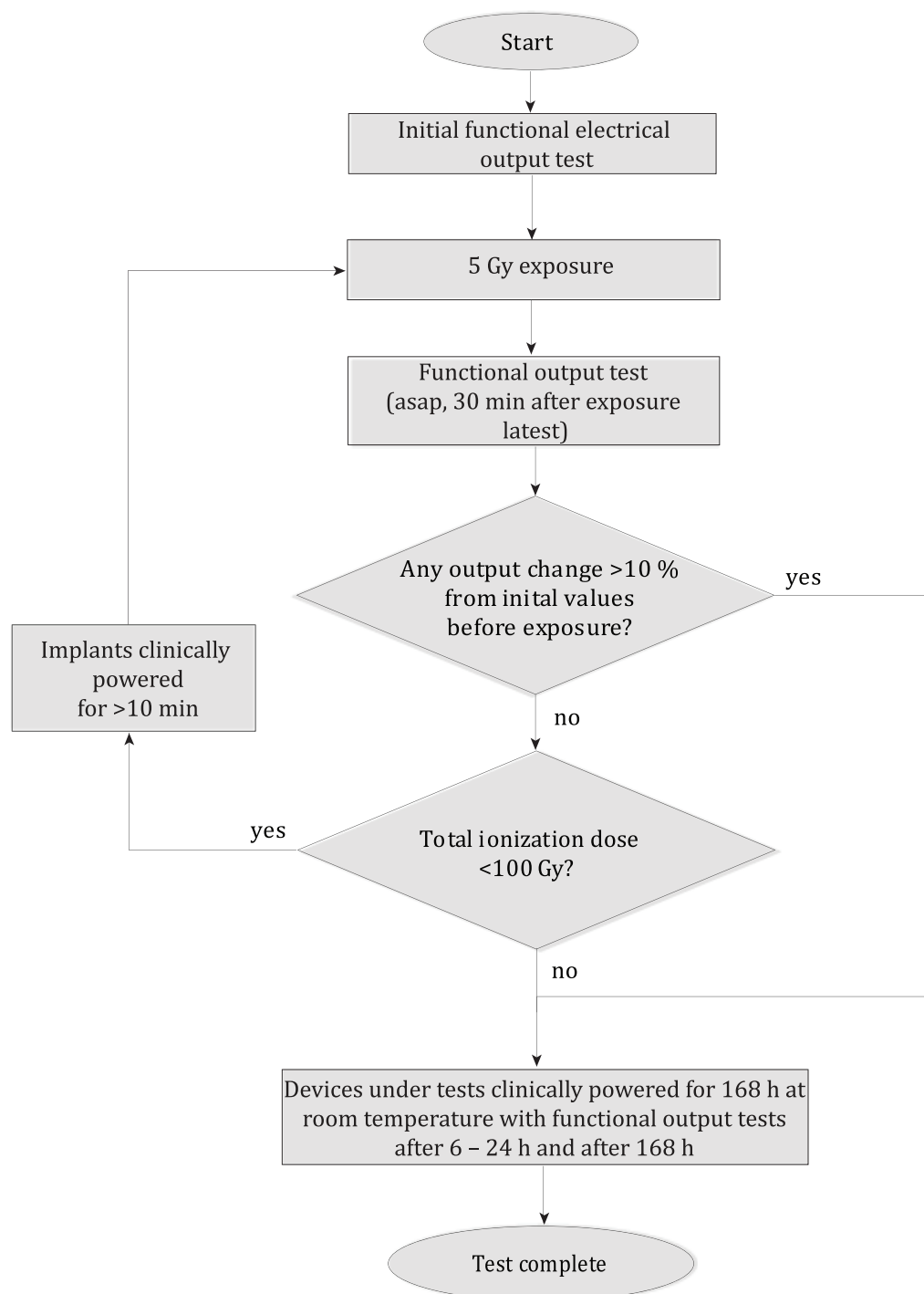


Figure 5 — Flowchart for ionizing radiation robustness test