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Implants for surgery — Active implantable medical devices —

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

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 7: Exigences particulières pour les systèmes d'implant cochléaire et d'implant auditif du tronc cérébral

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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).

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

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

For an explanation 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 μA/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 ± 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 µA/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:

$$\mathrm{CEM43} \cong \sum_{i=1}^{n} t_{\mathrm{i}} \cdot R^{(43-T_{\mathrm{i}})}$$

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 m^3/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.

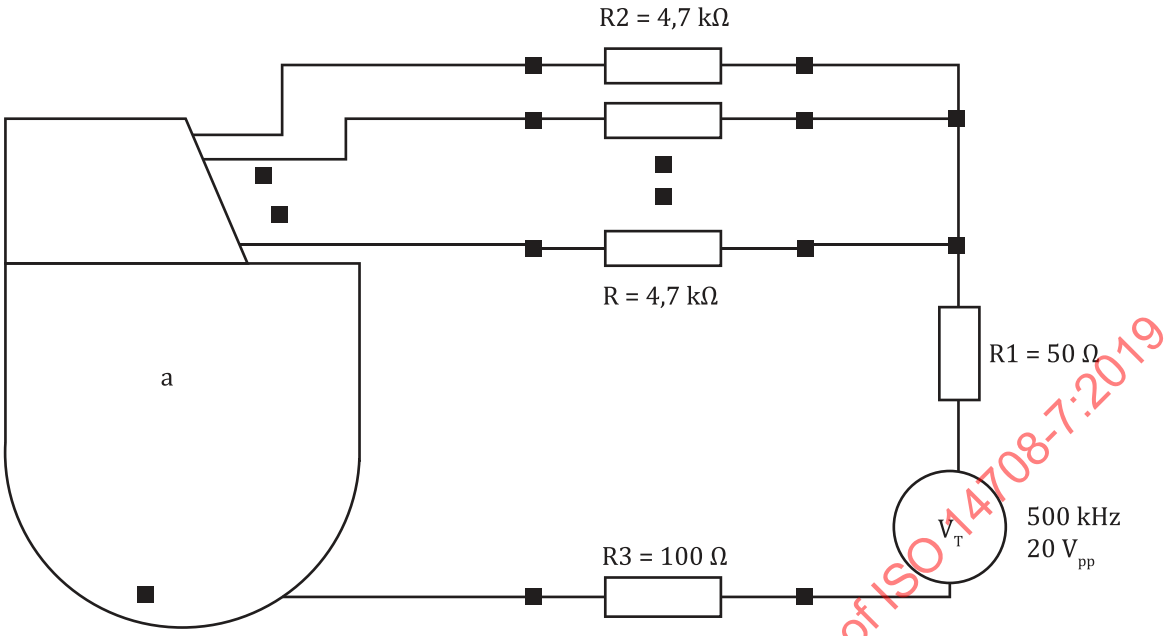
21 Protection of the device from changes caused by high power electrical fields applied directly to the patient

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 kΩ 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 B_0-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.

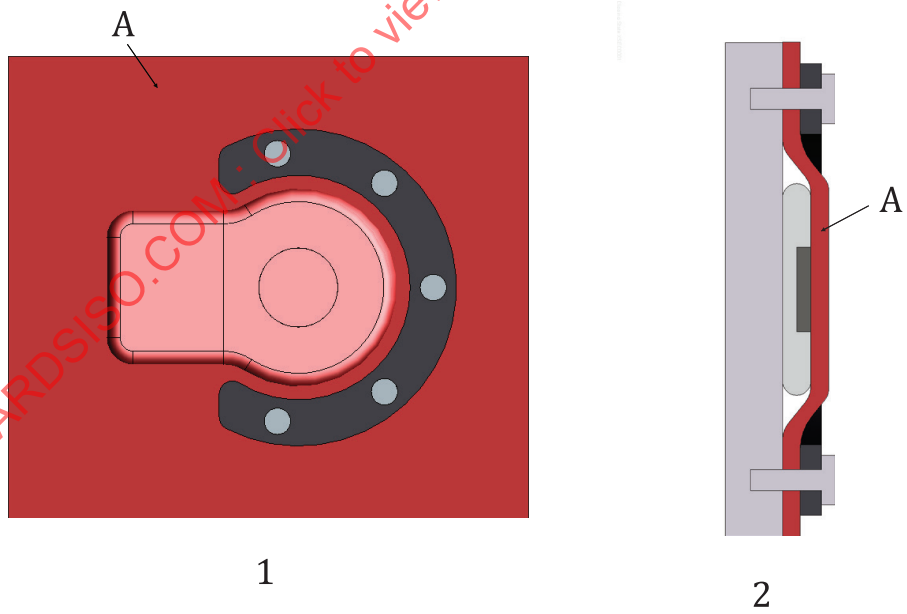
22.2.10 Imaging artifact: The text in ANSI/AAMI CI86:2017, 21.9 applies.

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.



Key

1 top view
2 section view
A skin simulator

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 ±45° 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.

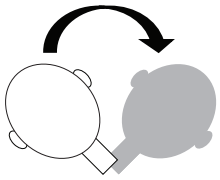


Figure 3 — Roll movement

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.

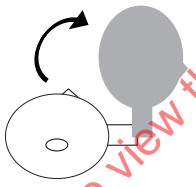


Figure 4 — Pitch movement

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 ±45°.

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 kΩ 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.

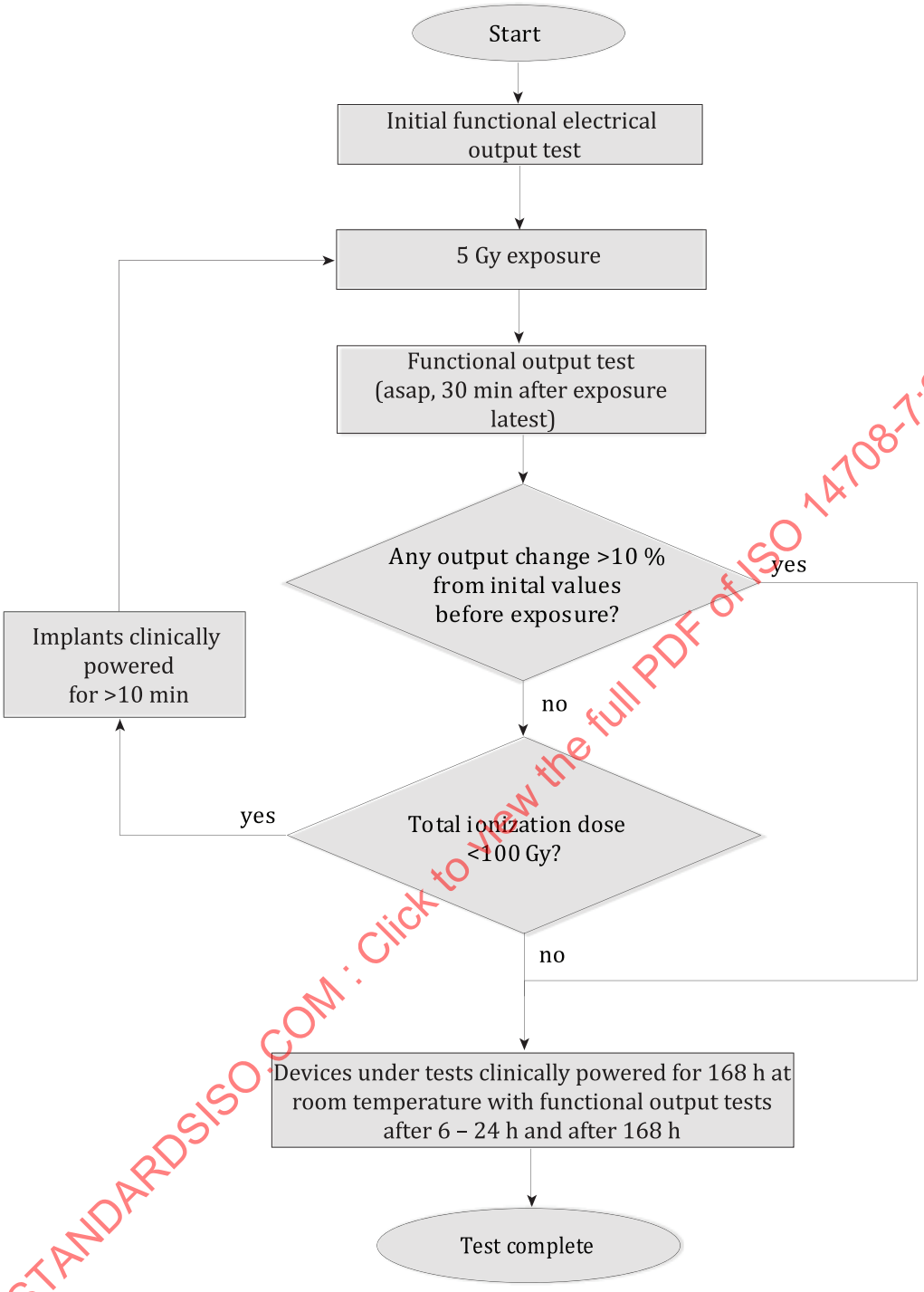
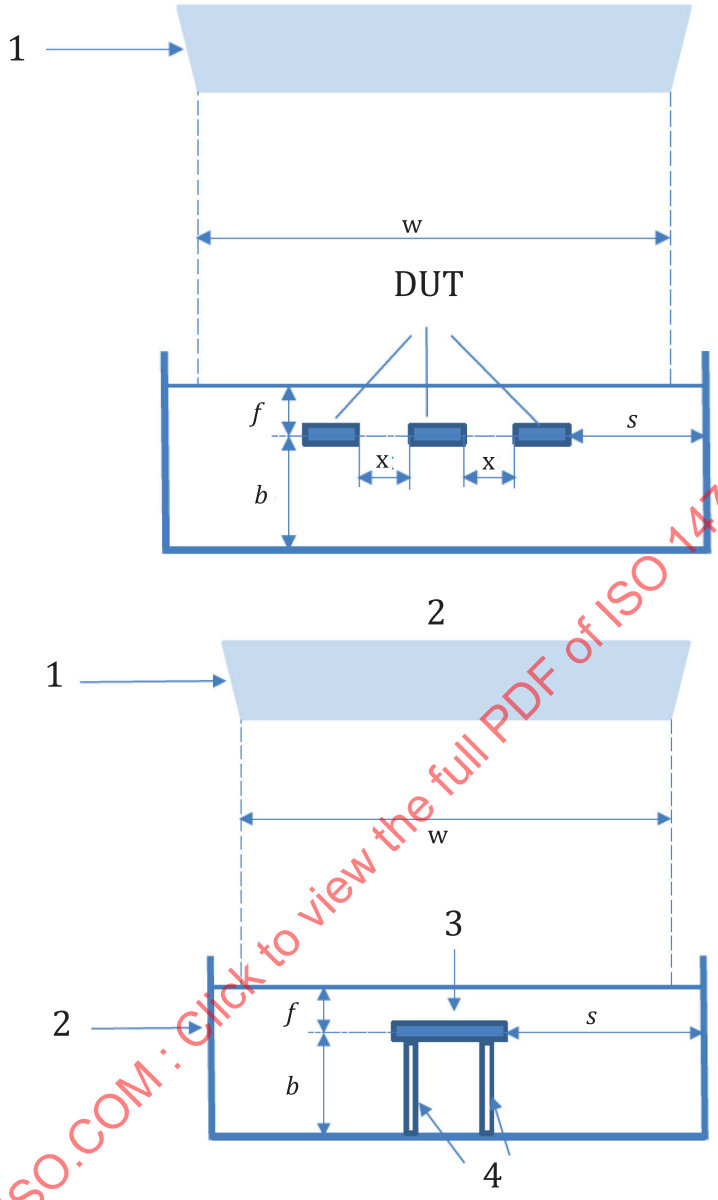


Figure 5 — Flowchart for ionizing radiation robustness test



Key

1 aperture of the linear accelerator

2 non-metallic container filled with water or solid water-equivalent material

3 stimulator as DUT

4 non-metallic pillow blocks for DUT

Dimensions for ionizing radiation test setup for irradiation with 6 MV photons:

DUT devices under test: stimulator of the implantable part of an *implant system*

f submersion depth: 1,5 cm

b backscatter depth: ≥1,5 cm

s distance between DUT and the container wall to each side: ≥3 cm

w width of the radiation beam: shall irradiate an area which exceeds the DUT(s) by at least 1,5 cm on each side

NOTE *b* and *s* double when using 15 MV photons.

Figure 6 — Ionizing radiation test setup for one or three test samples (the latter only for a sufficiently wide radiation beam)

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

23 Protection of the active implantable medical device from mechanical forces

23.1 *Non-implantable parts* of an *implant system* that are either hand-held in normal use, portable or *body-worn* and weigh not more than 10 kg, shall be constructed so that shocks caused by mishandling or dropping while in use do not damage the device.

Test: Hand-held, *body-worn* or portable parts of an *implant system* weighing up to 10 kg shall withstand the free fall test in accordance with IEC 60068-2-31, under the following conditions:

a) test surface: hard wood, density not less than 630 kg/m^3, thickness between 50 mm and 55 mm;

b) height of fall:

   1) hand-held devices: 1 m;

   2) portable devices: 50 mm;

   3) *body-worn* part: 1,5 m or the height of normal use whatever is more severe;

c) attitude from which specimen is dropped: attitude as in normal use.

Compliance shall be confirmed if the dropped part operates as stated in the manufacturer's original specification.

23.2 The implantable part of the *implant system* shall be constructed to withstand the mechanical forces that might occur during normal conditions of use, including the time prior to implantation.

Test: The implantable part of the *implant system*, mounted in accordance with the requirements and guidance given in IEC 60068-2-17, shall withstand a random vibration test in accordance with IEC 60068-2-14, Test Fh, under the following conditions:

a) test frequency range: 5 Hz to 500 Hz;

b) acceleration spectral density: 0,7 $(m/s^2)^2/Hz$;

c) shape of acceleration spectral density curve: flat horizontal, 5 Hz to 500 Hz;

d) duration of testing: 30 min in each of three mutually perpendicular axes.

Compliance shall be confirmed if, after completing the test procedure, the values for the *implant system* characteristics conform with the values stated in the manufacturer's original specification.

23.3 Implantable leads outside the *stimulator* shall withstand the tensile forces that might occur during or after implantation, without fracture of any conductor or deterioration to any functional electrical insulation.

There are two specimens intended for the test:

— specimen A shall be the implantable part in the condition as shipped to the customer; if necessary, the leads shall be attached in accordance with the manufacturer's instruction before the test;

— specimen B shall be the implantable lead without the *stimulator*.

Procedure: Use a saline preconditioning bath of approximately 9 g/l saline at 37 °C ± 5 °C, a tensile load tester and a voltmeter or an oscilloscope.

Both specimens shall be kept in the preconditioning bath for a minimum of 10 days. Immediately prior to testing, the lead shall be rinsed in distilled or deionised water then wiped free of surface water.

The manufacturer shall identify that portion of the lead which, when implanted, might be subject to elongation. The manufacturer shall devise an appropriate method of clamping the lead to include the elongation portion.

a) Test for specimen A

Specimen A shall be clamped at the *stimulator* or at the connector, if applicable. Another clamp shall be firmly attached to the most distal part of the lead subject to elongation. The distance between the clamping points shall be measured.

The lead shall be subjected to an elongation of minimum of 15 mm or a tensile force of minimum 1 N, whichever is reached first. The applied tensile stress shall be sustained for at least one minute then relieved. The tensile load application shall be repeated for each lead. The test specimen(s) shall be returned to the saline bath and shall be immersed again for a minimum of one hour before proceeding.

The electrical continuity of each conduction path (open circuit test) and insulation (short circuit test) between each pair of wires inside the lead (if applicable) shall be verified.

Compliance shall be confirmed if the specimen A exhibits no permanent functional damage (e.g. no open or short circuits).

b) Insulation test for specimen B

Specimen B shall be subjected to the same elongation test as specimen A except both sides of the lead shall be clamped. Following the elongation test the insulation shall be subjected to a test voltage. The test signal shall be a 1 kHz square wave with a peak to peak voltage of twice the maximum peak to peak output voltage of the *implant system*. The test signal shall be applied for a minimum of 15 s between each combination of conducting pairs inside the lead. The impedance between each pair shall be measured.

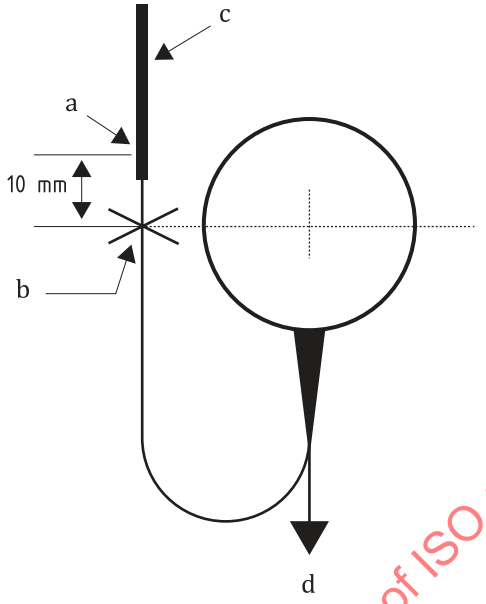
Compliance shall be confirmed if the lead shows no damage as a result of the elongation test and the impedance between each pair of conducting wires exceeds 100 kΩ.

23.4 The text in ISO 14708-1:2014, 23.4 applies.

23.5 Electrode leads shall withstand the flexural stresses that might occur during and after implantation, without fracture of any conductor.

Test 1: The test samples shall be in the condition as shipped to the customer. The tests shall be performed in dry conditions and at room temperature.

For each sample the lead shall be held with a suitable soft clamping mechanism (such that the lead will remain securely clamped during the test) 10 mm ± 2 mm proximal from the most proximal *electrode contact* (see Figure 7). The *stimulator* shall be held at the same height, adjacent to the clamp and released five times.



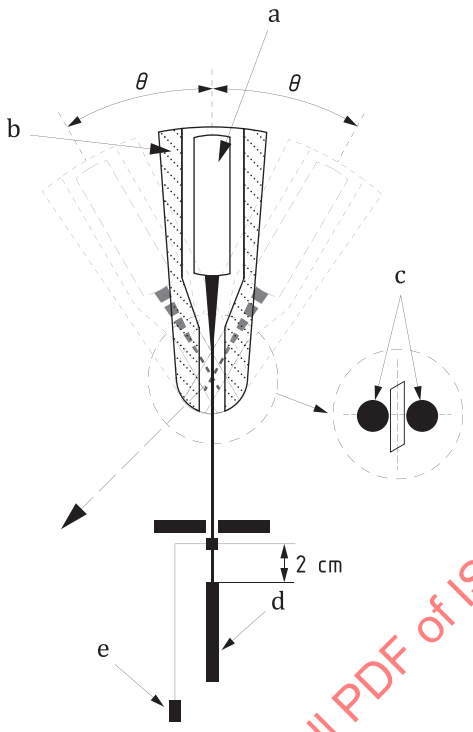
a Most proximal electrode.
b Soft clamp.
c Electrode array.
d Drop.

Figure 7 — Stimulator drop test

Compliance shall be confirmed by each conductor being functionally intact as per the manufacturer's performance specification.

Test 2: The test shall be applied to that region of the lead where, after implantation, flexing can occur due to micro movements. The test samples shall be preconditioned the same way as the fully assembled and shipped product. The tests shall be performed in dry conditions and at room temperature.

Use a holding fixture made of rigid material (see Figure 8) to clamp the *stimulator*.



a Stimulator.
b Holding fixture.
c Cylinders.
d Electrode array.
e Load.

Figure 8 — Flex test fixture

The holding fixture shall be mounted in an oscillating machine that can flex the lead either side from the straight direction. The holding fixture shall allow the lead to be tensioned in the direction it exits the *stimulator*. The lead shall be fed between two cylinders both touching the lead. The pivot point shall be in the middle of the line between the centres of both cylinders. The diameter of the cylinders shall be twice the diameter of the lead at the pivot point between the two cylinders. Where more than one lead exits the *stimulator* each lead shall be tested separately.

The load shall be firmly attached to the lead 2 cm ± 0,2 cm proximal from the most proximal electrode. The total load shall apply 0,03 N ± 0,01 N.

The holding fixture shall be then oscillated through an angle of 15° (or any greater angle specified by the manufacturer) each side at a rate of approximately 2 Hz for a minimum of 100 000 (hundred thousand) cycles.

Alternatively, an equivalent test may be performed where the *stimulator* remains stationary and the lead is oscillated provided all other test conditions remain the same.

Compliance shall be confirmed by each conductor being functionally intact as per the manufacturer's performance specification.

23.6 The text in ISO 14708-1:2014, 23.6 applies.

23.7 The text in ISO 14708-1:2014, 23.7 applies.

23.8 Immunity to mechanical impact stresses during normal use, including trauma.

The implantable part of the *implant system*, excluding the implantable leads, shall be in accordance with ANSI/AAMI CI86:2017, 23.1.3.

23.9 Immunity of implantable antenna coil to mechanical impact stresses.

The implantable part of the *implant system* shall be in accordance with ANSI/AAMI CI86:2017, 23.1.4.

24 Protection of the active implantable medical device from damage caused by electrostatic discharge

24.1 The implantable part and the *non-implantable part* of the *implant system* shall be designed and constructed so that no irreversible change will be caused by an electrostatic discharge, such as might be experienced during normal conditions of use.

The *non-implantable part* of the system shall meet the requirements of IEC 60601-1-2 for all intended use environments.

Test: The implantable part shall be completely immersed in a non-metallic container filled with saline solution of approximately 9 g/l at room temperature. The *non-implantable part* shall be coupled at a distance of 5 ± 1 mm to the implantable part. The *implant system* shall be set to function according to the manufacturer's instructions. The implantable part and the *non-implantable part* of the *implant system* shall withstand the electrostatic discharge test applied to the external components, as specified in IEC 61000-4-2 (with the climatic conditions explicitly defined in IEC 61000-4-2, 8.1.1) with a test voltage of 2 kV in the case of contact discharge to conductive surfaces and 8 kV in the case of air discharge to insulating surfaces. At least 10 discharges at the 2 kV test voltage and 5 discharges at the 8 kV test voltage shall be applied.

Compliance shall be confirmed if the *implant system* operates in a safe mode and if necessary, it can be reset to provide all functions as stated in the manufacturer's specification for the *implant system* when it is checked after performing the test above.

NOTE Resetting can be accomplished by switching the *implant system* off and on.

24.2 The text in ISO 14708-1:2014 applies.

25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes

25.1 The text in ISO 14708-1:2014, 25.1 applies.

25.2 Implantable parts of an *implant system* shall be constructed to withstand foreseeable increases in pressure, which might occur during vocational activities.

Test: The device shall be placed in a suitable water pressure chamber and cycled 20 times from ambient pressure to a maximum pressure, which shall be 1,5 times the pressure specified in the manufacturer's documentation (see 28.21). The rate of pressure change shall be at least 100 kPa/min and the maximum pressure shall be maintained for at least one minute.

Compliance shall be confirmed by inspection of test procedures and results provided by the manufacturer.

26 Protection of the active implantable medical device from damage caused by temperature changes

26.1 The text in ISO 14708-1:2014, 26.1 applies.

26.2 The text in ISO 14708-1:2014, 26.2 applies.

27 Protection of the active implantable medical device from electromagnetic non-ionising radiation

NOTE The tests in this clause apply only to the implantable parts. *Non-implantable parts* are covered by IEC 60601-1-2 (see ISO 14708-1:2014, 5.1).

27.1 Implantable parts of an *implant system* shall not cause unacceptable risk of harm because of susceptibility to interference due to external electromagnetic fields under circumstances likely to be encountered in public access areas, whether through malfunction of the device, damage to the device, heating of the device, or by causing local increase of induced electrical current density within the patient.

Compliance shall be confirmed if the *implant system* meets the requirements of 27.3 to 27.5 with the acceptance criterion B (safety) as described in 27.7.

27.2 The function of an *implant system* shall not be significantly influenced by external electromagnetic fields which commonly might be encountered during normal daily living. No significant influence means that there shall be no long-term discomfort; however, some signal degradation can be tolerated during exposure.

Compliance shall be confirmed if the *implant system* meets the requirements of 27.3 to 27.5 with the acceptance criterion A (performance) as described by 27.7.

This requirement does not apply for the exclusion band (see 27.7).

27.1 Protection from static magnetic fields

Test setup: General test conditions are described in 27.6.

For this test, leads are not required and electrode configuration is not applicable.

Test equipment: A field coil or permanent magnet capable of generating the required magnetic field in the region to be occupied by the DUT. The level is the minimum value to be maintained across the DUT.

Test level for criterion A and B: 50 mT or the strongest magnet used with the CI system shall be subjected to the DUT (whatever is worst case).

Test procedure: The required magnetic field flux density shall be adjusted before placing the DUT in the field. Then the DUT shall be placed into the centre of the field. The permanent magnet is directly placed on the upper side of the implant housing (no field measurement required). Allow enough time for the DUT behavioural response to be observed. The minimum dwell time is 2 s.

Evaluation of test results: The DUT shall meet the immunity pass/fail criteria as determined by the manufacturer and as governed by 27.7.

27.2 Radiated magnetic field test for frequencies 16,6 Hz to 27 MHz

For the test of this chapter, the saline bath will accomplish the cochlear implant termination impedance requirement. Monitoring of the device output stimulation signal is done with two electrodes placed in the saline bath, see D.2 for additional information.

Test equipment: A field coil capable of generating a magnetic field as shown in Table 2 in the region to be occupied by the DUT, see D.3.

Table 2 — Magnetic field test levels *H*

Frequency range *f*	*H* A/m rms		
	Criterion A test level	Criterion B test level	Modulation
16,6 to 40 Hz	240	340	cw
50 Hz to 100 Hz	210	850	cw
200 Hz to 400 Hz	210	540	cw
0,5 to 3 kHz	30	106	cw
4 to 9 kHz	30	106	cw
10 kHz to 150 kHz	30	106	1 kHz, PM
200 kHz to 3 MHz	4	21	1 kHz, PM
4 MHz to 10 MHz	2	21	1 kHz, PM
13,6 MHz	2	12	1 kHz, PM
20 MHz	1	2	1 kHz, PM
27 MHz	0,6	2	1 kHz, PM
rms value before modulation.			

Test procedure: Place the head simulator with DUT within the field coil so that the DUT is centred in the field. All three orientations as defined in D.2 shall be tested.

NOTE 1 Due to the typically short (~10cm) lead length of cochlear implants the lead induced voltage might be uncritical, thus the test can be executed without lead up to 150 kHz.

If the test was performed without lead up to 150 kHz, rationale shall be provided.

The frequency range of the applied radiated magnetic field shall be stepped, pausing to adjust the signal level and to allow enough time for the DUT behavioural response to be observed. The minimum dwell time is 2 s. Incremental steps are indicated in Table 3.

Table 3 — Frequency steps for the radiated magnetic test

Incremental frequency steps											
Hz	16,6	20	30	40	50	60	70	80	90		
Hz	100	120	150	180	200	300	400	500	600	700	
Hz	800	900									
kHz	1	1,66	2	3	4	5	6	7	8	9	10
kHz	16,6	20	30	40	50	58	70	80	90	100	125
kHz	134	150	166	200	300	400	500	600	700	800	900
MHz	1	1,66	2,5	2	3	4	5	5,4	6	6,8	8
MHz	9	10	13,6	20	27						

Over the range of frequencies from 16,6 Hz to 9 kHz, the test signal *H* shall be sinusoidal without modulation.

Over the range of frequencies from 10 kHz to 27 MHz, the test signal *H* shall be sinusoidal carrier, pulse modulated with 1 kHz.

Evaluation of test results: The DUT shall meet the immunity pass/fail criteria as determined by the manufacturer and as governed by 27.7.

27.3 Radiated electric field test for frequencies 10 MHz to 2,7 GHz

For this test, the saline bath will accomplish the cochlear implant termination impedance requirement, see D.2.

Test equipment: (G)TEM cell capable of generating an electric field as shown in Table 4, see D.4.

Table 4 — Electric field test levels *E*

Frequency range *f*	*E* V/m rms		
	Criterion A test level	**Criterion B test level**	**Modulation**
10 MHz	28	141	1 kHz, PM
13,6 MHz	28	141	1 kHz, PM
20 MHz	28	141	1 kHz, PM
27 MHz	28	141	1 kHz, PM
30 MHz to 440 MHz	28	141	1 kHz, PM
450 MHz to 900 MHz	42	141	1 kHz, PM
1 GHz to 1,9 GHz	58	141	1 kHz, PM
2 GHz to 2,7 GHz	61	141	1 kHz, PM
rms value before modulation. Frequency step size: 10 % of last value.			

Test procedure: Place the head simulator with DUT within the field so that the DUT is centred in the field. The two orientations as defined in D.2 shall be tested.

The frequency range of the applied radiated electric field shall be stepped, pausing to adjust the signal level and to allow enough time for the DUT behavioural response to be observed. The minimum dwell time is 2 s. Incremental steps are indicated in Table 4.

The test signal shall be a sinusoidal carrier, pulse modulated with 1 kHz as given in Table 4.

NOTE For a system processing audio data this is considered a worst-case modulation.

Evaluation of test results: The DUT shall meet the immunity pass/fail criteria as determined by the manufacturer and as governed by 27.7.

27.4 General test configuration and setup

27.4.1 Test configuration and setup

The cochlear implant shall be tested in representative configurations, including non-implantable components consistent with intended use that is likely to be the most susceptible to electromagnetic disturbances. This shall be determined using risk analysis, experience, engineering analysis, or pretesting. A full complement of non-implantable components is recommended if possible but not essential as these are covered by IEC 60601-1-2.

Unless specified otherwise in a particular test, the test setup shall include:

— the cochlear implant and electrodes located inside a head simulator as defined in D.2 to simulate normal impedance of the electrode when implanted;

— for devices that have more than one available electrode configuration for stimulation, they shall be tested with the electrode configuration that is the most susceptible to electromagnetic disturbances;

— standalone mode, not in programming mode.

For all tests, provision shall be made to determine the device's behavioural responses during testing including observation of the stimulation waveform. If the operation of the DUT cannot be observed or verified during the test, the manufacturer shall specify an alternative method for determining that the DUT met the required pass/fail criteria during the test. The use of special hardware or software might be necessary.

27.4.2 Operating functions, modes and settings

All requirements in 27.3 to 27.5 shall be met for all settings of the *implant system*. This does not mean that all combinations of settings are considered but at least the following representing the worst case.

— For test levels according to criterion B (safety) in 27.3 to 27.5 the *implant system* shall be configured to continuously produce the maximum value of the *output signal* defined in 6.2 on at least two output electrodes. The microphone sensitivity shall be adjusted to the normal clinical setting, if applicable.

— For test levels according to criterion A (performance) in 27.3 to 27.5 the device shall be configured to continuously produce between 25 % ("threshold level") and 50 % ("comfort level") of the maximum value of the *output signal* defined in 6.2 on at least two output electrodes. The microphone sensitivity shall be adjusted to the normal clinical setting, if applicable. The microphone ports can be blocked acoustically, and any tele-coil can be switched off, if applicable. The device shall be programmed such that an input signal within the input frequency range normally available to the user shall result in a stimulation of the electrodes.

— In case criterion A requirements (performance) can be shown with criterion B test levels (safety levels), the test with criterion A test levels can be omitted.

The manufacturer shall specify the configuration including programming settings used for the implant and the sound processor. Default settings consistent with the intended use shall be used.

27.4.3 Patient physiological simulation

If simulation of the patient is required to verify normal operation of the DUT, it shall be provided during immunity testing. Physiological simulation shall not provide an intentional conductive or capacitive connection to earth other than that required by 27.6.2.

27.5 Acceptance Criteria

During testing of all clauses, the acceptance criteria (pass/fail criteria) shall be based on the manufacturer's intended use and on a risk assessment, as follows.

The manufacturer shall define the details of the acceptable performance and basic safety requirements for the implant both during and after the tests. Prior to testing, risks shall be identified, taking into account the reasonably foreseeable electromagnetic (EM) environment that is likely to occur during its intended use. Immunity test levels in Clause 27 are based on the reasonably foreseeable maximum levels found in the general public electromagnetic environment. Each risk shall be evaluated through a design analysis that takes account of any risk control, according to ISO 14708-1:2014, 5.5.4.

The risk assessment process, performed in accordance with ISO 14971, could result in hazardous situations being identified (see ISO 14971:2007, Figure E.1). Since actual risk cannot be observed during testing, it will be necessary to observe the performance of the device to see if any hazardous situations occur.

Pass/fail criteria shall be defined prior to testing for both criterion A and B. Ideally, these criteria can be measurable or observable during testing. If not, the manufacturer shall specify an alternative method for determining that the DUT met the required pass/fail criteria during the test. The use of special hardware or software might be necessary.

If the pass/fail acceptance criteria are not met during and after testing, the manufacturer shall substantiate DUT behavioural responses and explain why the overall risk(s) are acceptable. In no cases are irreversible changes in performance, outside of specification, allowed.

EXCLUSION BAND: This is the frequency band where the cochlear implant receives energy and data needed to accomplish the intended use. The manufacturer shall declare this frequency range (28.22.1).

Criterion A (performance requirements):

During and after the tests the system shall operate within the performance criteria specified by the manufacturer and continue to function without user intervention. The device shall be in accordance with its basic safety requirements and there shall be no hazards that could result in an unacceptable risk of harm to the user.

During the exposure, the stimulation signal shall remain below "comfort level". The *implant system* might occasionally drop out stimulation signals. In case that the device completely stops stimulation prior to reaching the specified levels, the manufacturer shall declare the level at which this happens (see 28.22.1). Compliance shall be confirmed according to test results and may be supplemented by theoretical modelling provided by the manufacturer, supported by the manufacturer's calculation and data from test studies as appropriate.

This criterion does not apply within the exclusion band.

Criterion B (safety requirements):

During the tests, the system might stop functioning without damage to the device. After the tests, the device shall operate normally. User intervention is acceptable to restore operation after the tests. The device shall be in accordance with its basic safety requirements and there shall be no hazards that could result in an unacceptable risk of harm to the user.

Compliance shall be confirmed according to test results and may be supplemented by theoretical modelling provided by the manufacturer, supported by the manufacturer's calculation and data from test studies as appropriate. In case the output current cannot be measured directly or indirectly while the interference signal is present an additional design analysis of the electronic circuit shall demonstrate that the *implant system* cannot deliver higher *output signals* than defined in 6.2.

Basic safety	No unacceptable risk of harm.	No unacceptable risk of harm.	Undefined
Performance	Operates without user intervention, some temporary degradation of performance is acceptable.	Might stop functioning but recovers after exposure. User intervention is acceptable.	Undefined
Acceptance criteria	A	B	Undefined

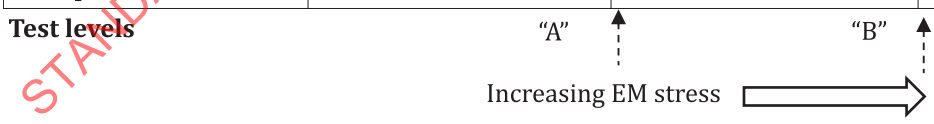


Figure 9 — Acceptance criterion vs electrical or magnetic stress

28 Accompanying documentation

28.1 The accompanying documentation shall include the name and address of the manufacturer, the address being the postal address and telephone number, or the name and address of the authorized representative, where the manufacturer does not have a registered place of business in the community.

Compliance shall be confirmed by inspection.

28.2 The text in ISO 14708-1:2014, 28.2 applies.

28.3 The text in ISO 14708-1:2014, 28.3 applies.

28.4 The text in ISO 14708-1:2014, 28.4 applies.

28.5 The text in ISO 14708-1:2014, 28.5 applies.

28.6 The text in ISO 14708-1:2014, 28.6 applies.

28.7 The text in ISO 14708-1:2014, 28.7 applies.

28.8 The text in ISO 14708-1:2014, 28.8 applies.

The accompanying documentation shall include the following information for the implantable part of the *implant system*, as appropriate.

a) Device description:

   1) a general description, brief explanation of function, available stimulation modes;

   2) a listing and brief description of other functions (e.g. impedance measurement);

   3) the mass (in grams);

   4) the principal dimensions (in millimetres);

   5) the volume without lead (in cubic centimetres);

   6) a listing of the materials which will come into contact with human tissue.

b) Performance characteristics:

   1) amplitude and pulse width of the *output signal* on a 1 kΩ resistor (as specified in 6.3);

   2) impedance measurement accuracy (as specified in 6.4);

   3) MRI Safety Information indicating that the device is either MR Unsafe or MR Conditional; for MR Conditional components, this shall include the conditions for safe use in the MR environment as determined by the assessments specified in 22.2.1;

   4) the default factory settings of the *implant system*, if applicable;

   5) recommended methods for determining that the implantable part of the *implant system* is functioning properly (e.g. impedance measurement).

c) The specification and characteristics for each lead and the electrode array:

   1) the electrical configurations (e.g. monopolar and number of electrically independent *electrode contacts*);

   2) the shape and other characteristics (e.g. perimodiolar and drug delivering);

   3) a listing of the materials used for the conductors, *electrode contacts*, and insulation of the lead;

   4) a statement advising whether the lead contains a medicinal substance as an integral component, giving the identity of the medicinal substance;

   5) the physical dimensions, including (nominal value):

      i) the length of the lead (in millimetres);

ii) the cross-sectional dimensions of the electrode array at the proximal and the distal ends (in millimetres);

iii) the geometric surface area of the smallest and largest stimulating *electrode contacts* (in square millimetres);

iv) the distance(s) between *electrode contacts* and the distance between the most proximal and most distal stimulating *electrode contacts* (in millimetres);

6) the connector geometry, if applicable (lengths and diameters in millimetres), or a reference to published connector standards including any designations or markings.

Compliance shall be confirmed by inspection.

28.9 The text in ISO 14708-1:2014, 28.9 applies.

28.10 the text in ISO 14708-1:2014, 28.10 applies.

28.11 The text in ISO 14708-1:2014, 28.11 applies.

28.12 The accompanying documentation shall contain warning notices appropriate to the intended use and normal function of the device, including information about the risk due to interference either from or to the implantable device during other clinical procedures or medical treatments. Examples of such treatments are those referred to in (but not limited to) 20.2, 21.1 NOTE, 22.2, 22.3 and Clause 27. Where restrictions are required during treatments (e.g. proximity, energy power levels), the manufacturer will also need to declare in labelling and/or instructions those circumstances and limits beyond which risk might exist for the patient.

Compliance shall be checked by inspection.

28.13 The text in ISO 14708-1:2014, 28.13 applies.

28.14 The text in ISO 14708-1:2014, 28.14 applies.

28.15 The text in ISO 14708-1:2014, 28.15 applies. Also refer to 28.12.

28.16 The text in ISO 14708-1:2014, 28.16 applies.

28.17 The text in ISO 14708-1:2014, 28.17 applies.

28.18 The text in ISO 14708-1:2014, 28.18 applies.

28.19 If the *implant system* has an implanted energy source, the accompanying documentation shall include information about the lifetime of the energy source, both when the *implant system* is adjusted to the nominal clinical settings specified by the manufacturer and when adjusted to the worst-case conditions.

Compliance shall be checked by inspection.

28.20 The text in ISO 14708-1:2014, 28.20 applies.

28.21 The text in ISO 14708-1:2014, 28.21 applies.

28.22 The text in ISO 14708-1:2014, 28.22 applies.

The results from 27.2 shall be made available to the clinician.

28.23 The text in ISO 14708-1:2014, 28.23 applies.

28.24 The text in ISO 14708-1:2014, 28.24 applies.

28.25 The text in ISO 14708-1:2014, 28.25 applies.

28.26 The text in ISO 14708-1:2014, 28.26 applies.

28.27 The text in ISO 14708-1:2014, 28.27 applies.

28.28 The text in ISO 14708-1:2014, 28.28 applies.

28.29 The text in ISO 14708-1:2014, 28.29 applies.

28.30 The text in ISO 14708-1:2014, 28.30 applies.

Annex A
(informative)

General guidance and rationale

A.1 General

The following notes on some of the provisions of this document are provided as an aid to understanding. The notes in this annex carry the numbers of the relevant clauses of this document, therefore, paragraph numbering in this annex is not consecutive.

A.2 Notes on specific clauses and subclauses

The following notes on some of the provisions of this document are provided as an aid to understanding. This annex is directed towards those who are familiar with the construction or use of active implantable medical devices but have not themselves participated in drafting this document. The notes in this annex carry the numbers of the relevant clauses of this document; therefore, paragraph numbering in the annex is not consecutive.

Apart from Clauses 5, 7, and 8, the clauses of this document are arranged so they can be addressed in sequence proceeding from checking markings on the outside of the sales pack, then the construction of the sales pack, and so on through to tests on the device, and finally to checks of the accompanying documentation.

[3.2], [3.3], [3.4], [3.5] Most currently *non-implantable parts* could become implantable parts in the future.

[3.13] The *use-before-date* is required in ISO 14708-1:2014, 9.7 and 11.5.

[13.3] This subclause addresses the underlying concern expressed by the Directive for any device in use to be identified without performing a surgical operation and without requiring special equipment specific to a manufacturer or model of a device. In practice it might not be possible to add additional markings to *implant systems*. The present state of the art is to identify the manufacturer and model through X-ray outline profile. For *implant systems* which do not contain an internal power source, identification of the year of manufacture is not considered significant. Future technological advances might allow telemetry identification, including the *serial number* or the date of manufacture of a device. Observing the X-ray outline should allow a suitable telemetry device to be selected.

[14.2] As well as the specific requirement that an implant be sterile, the implant should not introduce unnecessary loose particulate matter ("sterile dirt"). The method of compliance assessment is specified so that meaningful quantitative limits can be set for assessing the results of the test. The manufacturer may choose a recognized measurement technique based on the apparatus that is readily available. Particles that have been purposely added (e.g. pharmaceutical agents) to the implant for a therapeutic reason, coating of implants, or elution from implant are not subject to this test.

The number of particles is related to the surface of the device and not its volume. For example, an empty bag (large surface but negligible volume) might present an excessive particle count when soaked in a bath based on the volume of the empty bag. The same bag when filled might pass the test even though the total particle count is the same. The same holds true for devices covered by this document, especially leads that typically have a large surface area but have a small volume. For *implant systems*, this approach would specify a bath that is of the same order of magnitude as the volume approach in ISO 14708-1:2014.

The test limits are based on a standard test for particulate contamination in large-volume parenteral injections given in the European Pharmacopoeia.

[15.2] ISO/TC 150/SC 6 recognized the need to have appropriate tests done in order to confirm that the physical characteristics of the implantable part do not cause excessive inflammatory reactions. The manufacturer should for instance provide data from animal studies or other appropriate records.

[16.2] Sustained small direct currents (DC) from a cochlear implanted system might cause tissue damage or electrode corrosion. The safe limit has been reduced to 0,75 μA/mm^2 at the *electrode contact* opening in accordance with opinion in current literature (see ISO 14708-1:2014).

The DC current limit ensures that large area electrodes that meet the current density limit do not produce a harmful level of DC current.

The test method should be applicable to a device even while stimulating using levels representing normal clinical practice. The device settings including a rationale for their choice should be documented with the test results. Appropriate steps should be taken to ensure that any transcutaneous link should not interfere with the measurement. Use a DC voltmeter fed through a low pass filter with a time constant of at least 1 s. This can for instance be implemented by a four-element low pass RC filter with the elements built from 1 MΩ resistors and 1 μF metallised polyester capacitors. The input resistance of the DC voltmeter should then be ≥400 MΩ.

[17.1] It is generally accepted[45] that a localised temperature of 39 °C does not cause tissue damage. ISO 14708-1:2014 requires <2 °C rise above the normal surrounding body temperature of 37 °C. The committee understands that the actual "normal surrounding body temperature" is influenced by several factors including the location of the implant and the environment and therefore changed to the 39 °C limit. For the purpose of design verification of a device to meet this subclause, the manufacturer can develop a test method and justify the initial starting temperature of the device based on its intended location in the body and other relevant factors.

CEM43 is a generally accepted method to normalise the impact of temperature and time on tissue for temperatures in the range of 39 °C and 57 °C[46]. Reference [33] demonstrates that the CEM43 values that represent the damage thresholds is different depending on the tissue type. Because the research is generally based on the observation of damage, values below these thresholds might be safe but the margin of this safety cannot be determined. Reference [33] therefore concludes that a CEM43 value of <2 is a safe value for any tissue. This is likely to be very conservative and van Rhoon et al recognises this and recommends a higher CEM43 under certain conditions and for various tissue types. The manufacturer is required to provide further analysis for CEM43 values >2 including, for example,

— the margin to the maximum values in Table 1,

— whether the heating events are repeating or a single event,

— medical assessment of the impact of the possible tissue damage and prognosis for the patient, and

— other controls.

The extent of damage to tissue due to heat is dependent on a number of factors including the duration of the exposure and the temperature experienced during the exposure. Reference [34] describes a mathematical model that unifies temperature and the cumulative duration of exposure into a single value equivalent to the Cumulative Equivalent Minutes (CEM) at 43 °C for 1 min. For example, 10CEM43 is equivalent to 10 min of exposure at 43 °C. General consensus is that the units for CEM43 are minutes.

The CEM43 model approximates the non-linear relationship of tissue damage by using two linear relationships with a break point at 43 °C.

The formula for CEM43 for a given temperature profile is calculated by Formula (A.1):

$$\mathrm{CEM43} \cong \sum_{i=1}^{n} t_{\mathrm{i}} . R^{(43-T_{\mathrm{i}})} \qquad \text{(A.1)}$$

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.

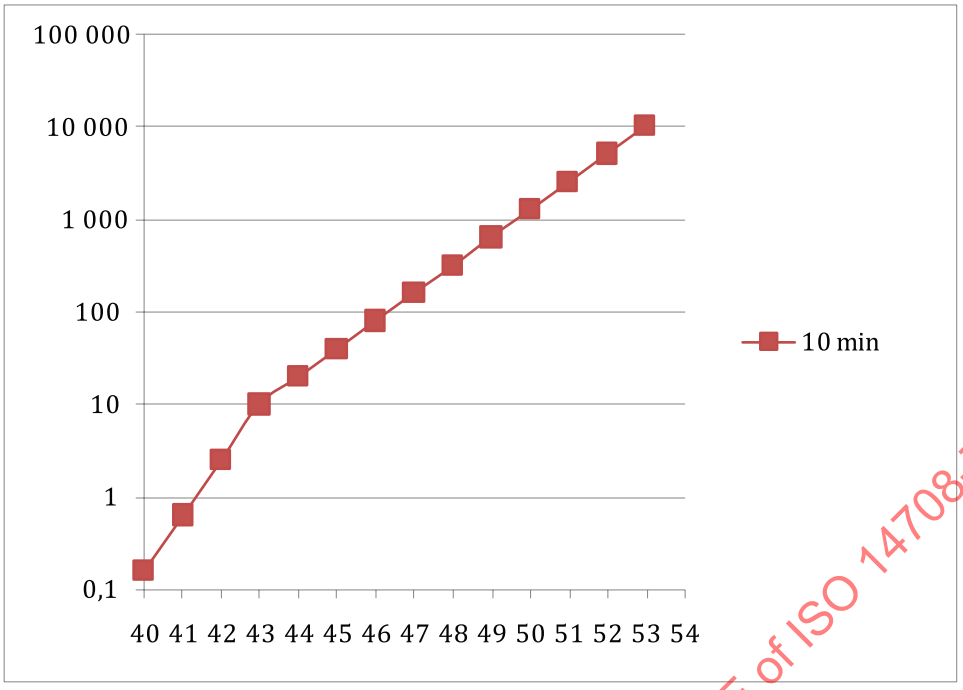
NOTE 2 This method is used in Reference [33].

Formula (A.1) is valid for temperatures between 39 °C and 57 °C.

Evaluating the CEM43 formula at different temperatures and a constant duration yields the values shown in Table A.1.

Table A.1 — Evaluating CEM43 formula at different temperatures

Temperature °C	**Duration** min	**CEM43**
40	10	0,156 25
41	10	0,625
42	10	2,5
43	10	10
44	10	20
45	10	40
46	10	80
47	10	160
48	10	320
49	10	640
50	10	1 280
51	10	2 560
52	10	5 120
53	10	10 240



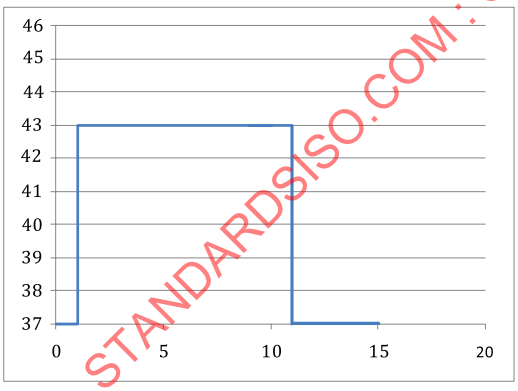
Key

X temperature in °C

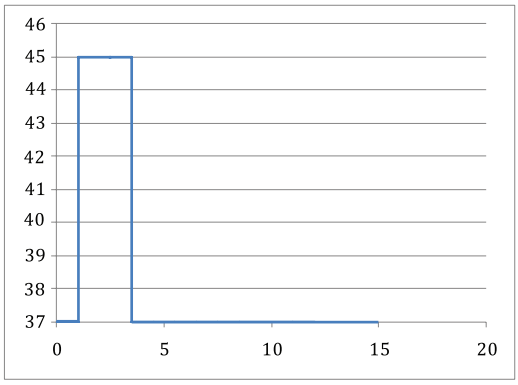
Y CEM43 value

Figure A.1 — CEM43 versus temperature for constant time

Each data point in Figure A.1 assumes that the temperature is fixed to a single value for the duration of the exposure. In this case, a plot of the temperature versus time would be a rectangle and its CEM43 value can be calculated using Formula (A.1).



a)



b)

Key

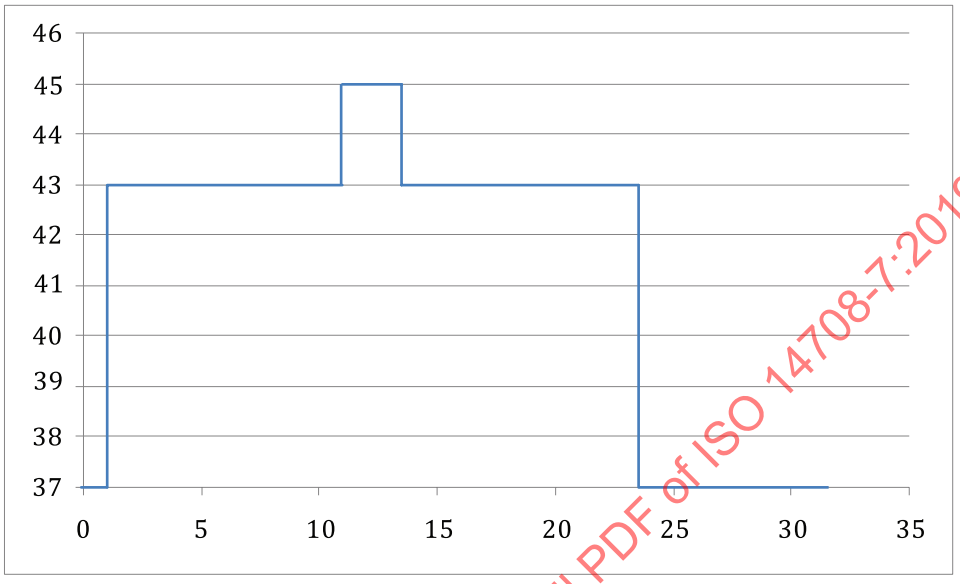
X time in min

Y temperature in °C

Figure A.2 — Two examples of the same CEM43 result with different exposure times

The examples in Figure A.2 both yield a 10CEM43; the first chart shows 10 min exposure at 43 °C while the second is 2,5 min at 45 °C.

In practice, the temperature is likely to vary in value for the duration of exposure. In this case, the CEM43 value can be calculated by the summation of the CEM43 values for a series of rectangles, each with a known duration and temperature. The example in Figure A.3 shows such a profile which results in a 30CEM43. It consists of an initial temperature exposure of 43 °C for 10 min followed by 2,5 min at 45 °C and then another 43 °C for 10 min.



Key

X time in min

Y temperature in °C

Figure A.3 — Example showing a time and temperature profile

The temperature requirements in 17.1 also explicitly apply for single fault conditions.

[20.2] Defibrillators usually apply voltages in the order of 5 000 V across the torso, but present *implant systems* do not have implantable parts in the torso, and the resultant voltage in the area of the implantable part of the *implant system* is not high enough to warrant concern. However, it is conceivable that parts of future devices might be implanted in the torso, for example a battery or a recharging coil. In that case, the test specified in ISO 14708-1:2014 would be necessary. If external parts are touched by the defibrillator electrodes, it is not considered probable that damage will occur because the ESD requirements as outlined in Clause 24 are comparable.

[21.1] The test verifies some immunity from high frequency electrical currents arising from surgical diathermy. The test frequency of 500 kHz was selected as typical of the majority of electro-surgical equipment. The selected amplitude of 20 V pp, to test the protection of the device was adapted from the pacemaker standard, EN 45502-2-3. The load resistor of 4,7 kΩ was chosen to reflect the impedance of the neural tissue interface in the cochlea. During the test, the *implant system* should be switched off. The requirement does not provide complete protection, since the voltages picked up during exposure to surgical diathermy are very dependent upon the distances between the diathermy electrodes and any conductive part of the *implant system* or its electrode array, and the surgeon might not be aware of the positioning of such parts.

[22.1] Note this requirement addresses only exposure to diagnostic ultrasound. In this document, exposure of an *implant system* to therapeutic levels of ultrasound is covered by a requirement for a warning notice (see 28.20).

[22.2] ISO/TC 150/SC 6 recognized the desirability of manufacturers to provide assurance that patients with an *implant system* could undergo MRI testing without compromising the safety of the patient. Due to the large variety of MRI machines currently available and the different transcutaneous link characteristics used by the various *implant systems*, it was determined that where a manufacturer

states a level of MRI safety in the accompanying documentation (see Clause 28), the field strength of the MRI machines for which safety is claimed is to be stated. Regardless of the level of testing, any decision to authorize an MRI scan remains a medical decision balancing the risk of damage against the benefit of information provided by the MRI scan. The test on MRI safety implies that the implant has been placed in accordance with the manufacturer's surgical guidelines and the implant is appropriately stabilized.

The potential demagnetisation of the internal magnet resulting from the MRI scanning was not considered a safety issue. Where there is magnetic degradation expected, labelling should contain the appropriate information (see 28.12).

[22.3] In keeping with good clinical practice, active implants should be shielded during radiation therapy, thereby minimising exposure to harmful radiation.

Literature reports of irradiation testing of some cochlear implants (see References [29] and [32]) indicate that although current designs have a limited degree of "hardness" to the effects of ionising radiation, no device can be designed and manufactured to be totally immune. The group identified the need for manufacturer's designs to demonstrate a level of immunity but agreed that a minimum radiation "hardness" level would result in unfair discrimination. The solution adopted by ISO/TC 150/SC 6 was to agree to a defined irradiation test method, based on common radiation treatment patterns (fractional accumulated dosage). The manufacturer declares the maximum level of accumulated dose after which the device will continue to function normally. Labelling on the basis of this test enables clinicians to judge whether an intended pattern of radiation therapy is likely to permanently affect the functionality of the implanted part.

In the "Testing before and after each irradiation step" section, the committee considered a value of 80 % for the desired output. This was to allow some headroom to capture the case where an implant might produce an erroneous output above 80 %. However, a value from 80 % to 100 % is specified to align with other standards that only specify 100 % and to avoid unnecessary testing.

[23.1] Hand-held programmers and portable device analysers might be subject to severe mechanical shocks during handling by other than the expert user. If such impacts cause damage not immediately apparent to the user, the damaged device might miss-set the implant or give an erroneous analysis, which could subsequently result in an unnecessary explanation.

[23.2] This test is intended to establish minimum requirements for the durability of the implanted part of an *implant system* with respect to mechanical robustness.

Withdrawal of a test originally called by EN 45502-1 has required a new test to be defined.

The replacement text is based on a new part of EN 60068-2-64:2008.

The test severity is determined by the test conditions a) to d). The range of test frequencies is based on experience with the sinusoidal sweep method in common use for a number of years within the pacemaker industry.

The value for the acceleration spectral density was also derived from the sinusoidal sweep method in EN 50061:1988, 8.1.1. That test specifies a peak acceleration of 25 m/s^2. This translates into an r.m.s. value of 1,77 g. An acceleration spectral density of 0,7 $(m/s^2)^2/Hz$ translates into an r.m.s. value of 1,86 g. This last calculation is an approximation that might vary slightly depending on the equipment used to generate the random vibration. However, the level of stress on the *implant system* is comparable to the level in the method in EN 50061.

In general, a short duration test will produce low confidence level results. The duration value for this test is the midpoint of the recommended values in IEC 60068-2-14:2008, 5.5. It should provide reasonable confidence in the reproducibility of the results while producing a test method whose overall time to complete is also reasonable.

Protection of the device during delivery and storage is provided by appropriate design of the packaging, which is evaluated with respect to vibration in ISO 14708-1:2014, 10.1.

[23.3] Reports in literature indicate that paediatrics will be subject to skull growth of 12 mm (standard deviation of 5 mm) from the round window to the sino-dural angle between birth and adulthood (Reference [30]). Leads forming part of an *implant system* need to be designed to withstand elongation, which might be experienced during the skull growth period. In case the lead is not allowing elongation of 15 mm the manufacturer's surgical procedure has to avoid extrusion of the electrode array from the cochlea. ISO/TC 150/SC 6 considered a force of 1 N to be representative of the elongation force acting during bone growth and during implantation. The test method developed in 23.3, for *implant systems* takes into consideration the differing designs of lead geometry. Although the most appropriate method of lead attachment is left to the manufacturer discretion, it is required that the critical lead portion subject to elongation by skull growth is identified in the design and subjected to a standard test.

[23.5] When drafting this document, it was observed that recommended clinical practice was to implant the implantable part of an *implant system* within a bony bed. This provides maximum stability to the implanted part and its associated electrode array and is considered state of the art. Tests 1 and 2 are intended to establish minimum requirements for the flexural durability of implantable leads. Test 1 is designed to simulate any adverse handling conditions, which might be experienced during removal from the sterile pack and handling prior to implantation. Test 2 acknowledges that variation in implantation technique might exist and is designed to simulate micro movement of the lead after implantation especially in the region of the temporalis muscle. However, it is also acknowledged that with the recommended implantation technique, micro movement of the lead can be significantly reduced.

Although the exact conditions are impossible to determine, it is believed that shearing and bending causes similar stress conditions to those experienced by in vivo failures. A weight of 3 g is attached to the test segment to force the test sample to conform to the required angular displacement without providing a significant tensile load. Bending the test sample by ±15° for 100 000 cycles creates a more severe strain at the electrode than is expected in vivo.

[23.6] EN 45502-2-3 leaves the method of providing a secure connection to the manufacturer's specification. Thus, the manufacturer is required to specify compatible connector parts (see ISO 14708-1:2014, 9.9 and 28.9) so that specified parts can be selected for test, ensuring that implanted connector pairs are reliable when subject to tensile force.

[23.8] ISO/TC 150/SC 6 recognized the need for an impact test of the implanted part in order to minimize the risk for failures due to trauma. While adults rarely experience falls which might result in impact damage to the *implant system*, children are particularly vulnerable due to mobility, height, lack of co-ordination of lower limbs. The test has been designed to give assurance that impacts experienced during normal daily living will not compromise the implantable part. Such impacts would include falls or knocks to the head during walking, running or cycling which would not require medical attention or first aid. A project was commissioned by the German Competent Authority (BFARM) to investigate failure modes and develop appropriate test methods. The outcome was published in Reference [34].

Based on the results of that project the committee has chosen an energy of 2,5 J as the goal of protection. This energy will cover a hit to the head (at the location of the implant) of a hard object with the mass of 1 kg and a velocity of about 2,25 m/s. Based on current field experience of several thousand devices using device models identical to those tested by Holtkamp, an energy of (1-1,5) J was deemed sufficient in order to provide an acceptable resistance to environmental impacts. ISO/TC 150/SC 6 concluded that at the time the standard becomes mandatory, an energy of 1,5 J should be applied during the test and three years after the standard becomes mandatory an energy of 2,5 J should be used providing an additional safety margin.

According to the AIMD Directive, the manufacturer can demonstrate compliance with the essential requirements also by not using this document. In that case the manufacturer should demonstrate a comparable level of safety as described in this document. If the *implant system* is provided with an implantable microphone or other transducer these might no longer function after the impact test. This is acceptable provided there is redundancy in the system which does not require replacement of the implantable part of the *implant system*.

[24.1] The test set-up has been chosen to simulate the in vivo situation of an implanted subject wearing the *body-worn* part (e.g. speech processor with coil but without an optional FM unit) The test is applied

to the *non-implantable part*. Any surge affecting the *body-worn* part will also impact the implantable part. The test voltages have been chosen from EN 45502-1:1997, 24.1. Higher test voltages would not be appropriate for the very small external parts (behind-the-ear speech processor) used with *implant systems*.

[25.2] This test simulates in part increased pressure which might occur during particular occupational or recreational activities such as scuba diving. This was included as a result of increased user expectations.

[Clause 27] The intent of this requirement is to cover all currently foreseeable electromagnetic environment the bearer of the *implant systems* might encounter, even those being encountered hardly ever in areas with public access. The requirement is separated into two sub-requirements: One is for protection against harm, damage of tissue or device and pain to the bearer in public areas under every circumstance even those encountered rarely during normal daily living (see 27.1). Other guarantees that the device deliver not significantly influenced function during commonly encountered situations during normal living (see 27.2).

Clause 27 contains requirements in terms of exposure levels (see 27.3, 27.4 and 27.5) and test procedures. It is up to the manufacturer to choose the appropriate means to demonstrate compliance while following the requirements of 27.7. The use of theoretical modelling instead of direct EMI measurements is no longer supported in the normative text of this document.

Annex D gives an example of how to demonstrate compliance by EMI measurements.

[27.1] This requirement guarantees the device will not be damaged and the bearer will not be harmed under electromagnetic exposure. This requirement corresponds to requirement 8, third indent of Directive 90/385/EEC.

The relevant levels for 27.1 (upper levels of the requirements in 27.3, 27.4 and 27.5) are derived from the basic restrictions of Recommendation 1999/519/EC for general public covering reasonable peak and localization factors. Theoretically even higher peak amplitudes and local spots are assumed to provide no risk for persons without implant too, but no known field in the general public really uses such parameters at present. ISO/TC 150/SC 6 decided not to cover such unrealistic values.

The required exposure levels are specified in 27.3, 27.4 and 27.5. These subclauses provide two interference levels: requirement for performance (lower level) and safety requirement (upper level). 27.1 applies at the upper level only and does not require performance of the *implant systems* during exposure.

The settings have been chosen to reflect the highest possible *output signals*. Any significant increase of stimulation signals above the maximum output level might cause harm to the bearer. Therefore, the compliance can be demonstrated by the limitation of the increase of *output signal* level during exposure. Additionally, it is to be demonstrated, that the *implant systems* still function as specified after exposure.

[27.2] The requirement covers commonly encountered electromagnetic environment for the general public and demands for uninfluenced function during exposure. The requirements for 27.2 (lower levels of the requirements in 27.3, 27.4 and 27.5) are derived from various sources including the reference levels of Recommendation 1999/519/EC for general public without taking into account any peak or localization factors. Nevertheless, these lower levels cover almost all known fields too, since these values will be exceeded in very rare situations restricted to short duration and local spots.

The required exposure levels are specified in 27.3, 27.4 and 27.5. These subclauses provide two interference levels, requirement for performance (lower level) and safety requirement (upper level). 27.2 applies at the lower level only and requires uninfluenced function of the *implant systems* during exposure.

The settings have been chosen to reflect typically used *output signals*. Compliance can be demonstrated by the limitation of changes of amplitude and phase of the *output signal* during exposure. The term "performance" does not mean that there should be no detectable changes of amplitude and phase of the *output signal* at all, but the performance defined by the manufacturer should be acceptable to the user.

[27.3] This subclause is intended to check the implant is not adversely affected by static magnetic fields that the patient might encounter. Example sources in the environment would include fridge magnets and toys. The committee noted that most *implant systems* use a magnet to retain non-implantable components and as such the implant is likely to pass this test. The test is included in this document for cases where an implant by design or otherwise might be sensitive to a static magnetic field.

[27.4] This test is intended to cover the most common sources of electromagnetic disturbances in the environment. There are various sources of low frequency magnetic fields in the environment including appliances, hand tools, office equipment, communication equipment, security systems and wireless power transmitters. Please note this test is not intended to cover all electromagnetic disturbances in the environment. If additional test frequencies or test levels are appropriate to address electromagnetic disturbances in the environment, these additional tests should be included for EMC testing. This subclause considers magnetic fields that the patient might be exposed to from sources in the environment such as:

— power grid and transportation systems including power frequency harmonics;

— reasonable proximity fields encountered in the head area (hair drier, shaver);

— interference from EAS systems;

— mobile phones;

— industrial induction heating;

— induction kitchen stoves;

— AM radio transmitters.

The limits shown in Table 2 have been derived from various literature sources including:

— Carried over from ISO 14708-7:2013 with peak converted to RMS;

— ICNIRP limits;

— ISO 14708-3:2017;

— Maximum permissible exposure defined in IEEE C95.1.

Frequency range 16,6 Hz to 10 MHz. The requirements are restricted to pure magnetic fields, because the ratio of acceptable levels for electric and magnetic fields are below Z_0 = 377 V/A. Additionally, at low frequency the shielding of the tissue around the implanted part is much stronger for electric fields than for magnetic.

The strength for the protection requirement (upper level) for frequencies 16,6 Hz and 50 Hz was chosen with respect to the most powerful field sources used in this range, railway systems and power supplies (60 Hz will be covered by 50 Hz test too). At these low frequencies (above 50 Hz and below 1,66 kHz), high field strengths are acceptable for persons without implants, but they are not encountered during everyday life. For frequencies between 1,66 kHz and 100 kHz, the requirement was derived from the basic restrictions of Recommendation 1999/519/EC (which are corresponding to ANSI/IEEE C95.1) supposing a local factor of slightly more than 20, combined with the peak-to-r.m.s. ratio for continuous wave of 1,4. This means, the maximum peak field strength of non-pulsed waves can be about 28 times the reference level (which is r.m.s. value for whole body exposure). The peak factor is 1 for frequencies below 100 kHz. This means, that no exceeded peak values are accepted for pulsed fields. Above 100 kHz, the local factor decreases continuously to factor 5 at 10 MHz and the peak factor increases continuously to about 32 at 10 MHz. This means, that the peak field strength is governed by local factor at low frequencies and by peak factor at high frequencies. 1999/519/EC allows the peak field strength for pulsed fields above 10 MHz to be 32 times the reference levels ($23 \cdot 1{,}4 \cong 32$). The upper levels of 27,3 cover both factors, local and peak, whichever is higher. At present, known fields do not use peak factors of more than about 5. Therefore, peak factors up to about 5 are covered by the upper levels of this document only.

The field strength for the requirement for uninfluenced function (lower level) reflects the reference level of Recommendation 1999/519/EC. This means that locally increased or pulsed field strengths are covered only partially. The lower levels cover all commonly encountered exposures of whole body but do not cover some localized emitters, for example some EAS devices might still influence the function of the implant. The requirement for uninfluenced function at frequencies between 1,66 kHz and 100 kHz is more than 20 times lower than the protection requirement. Since the peak factor covered here increases moderately from 1 at 100 kHz to 5 above 10 MHz, the difference between upper and lower levels decreases slowly at the upper end or the frequency range. Recommendation 1999/519/EC allows at 5 MHz higher magnetic fields than those specified in the Table 2. However, this frequency is used for broadcasting which practically does not provide localized fields. In far field situations (E/H = 377 V/A), the E-field component limits the level of the electromagnetic field.

NOTE 1 “Peak magnetic field strength” describes the maximum amplitude of the magnetic field vector and not the maximum short time r.m.s.-value during a burst.

NOTE 2 Modulation of signals below 10 kHz is not necessary as CIs are processing audio signals.

NOTE 3 For a system processing audio data this is considered a worst-case modulation. Theoretical modelling as well as measurements should demonstrate that compliance is reached for any direction of field vector.

[27.5] considers electric fields that the patient might be exposed to from sources in the environment. The limits shown in Table 4 were derived from the following sources:

Rationale criterion A: Limit harmonized with ISO14708-7:2013 (peak → RMS) and based on ICNIRP and literature on near field measurements.

IEEE C95.1:

10 to 30 MHz: 830/f V/m

30 to 400 MHz: 27,5 V/m

ICNIRP:

10 to 400 MHz: 28 V/m

Both: fM/200 W/m^2 up to 2 GHz

Rationale criterion B: Limit harmonized with ISO14708-7:2013 (peak → RMS). The test levels used since 2010 have demonstrated to be sufficiently high to ensure the required safety.

This safety level is above the IEEE C95.1 or ICNIRP limits at each test frequency.

Frequency range 10 MHz to 2,7 GHz. At frequencies above 10 MHz electric and magnetic component both are relevant. Since most exposures can be covered by far field situations, only the electric field strength is specified.

Theoretically a local factor of 5 and additionally a peak factor of 32 with respect to the reference levels of Recommendation 1999/519/EC would be acceptable for persons without implant. But in real life, no such field sources with public access are known. With respect to known far field sources an overall factor of 5 for frequencies up to 450 MHz was chosen, decreasing to 2,5 at 2 450 MHz. This means that not all possible mobile devices emitting pulsed fields which might be held directly towards the implantation site are covered by the requirement.

The field strengths for the requirement for uninfluenced function (lower level) reflect the reference levels of Recommendation 1999/519/EC supporting neither local factor nor peak factor. This covers most commonly encountered far fields with public access.

NOTE 2 "Peak electric field strength” describes the maximum amplitude of the electric field vector and not the maximum short time r.m.s.-value during a burst.

Above 800 MHz especially near field situations are relevant due to common hand-held cellular phones. Nevertheless, it seems to be sufficient to specify the electric field strength only.

Theoretical modelling as well as measurements should demonstrate that compliance is reached for any direction of field vector.

[27.4] and [27.5] The modulation/pulse shape should reflect two things. It should have the potential to influence the function but, in case of measurements, it should not have the potential to be confused by the test equipment with the stimulation signal of the implant. The amplitude of the interference signal is defined in 27.3 to 27.4.

At 16,6 Hz (some European railway systems) and at 50 Hz (power supply) the fields usually are sinusoidal wave. At all other frequencies various different technical applications exist which use modulated and pulsed fields. Switched carrier signals seam to provide the maximum potential influence on implants.

[28.4] At the time of writing this document, there is no *implant system* currently available using implantable connectors. The intention of this subclause is to ensure that the manufacturer provides the necessary information on appropriate connectors and assembly procedures.

[28.12] While tests have been constructed to demonstrate continued safe performance of the *implant system* either during, or following, the application of certain clinical procedures or medical treatments, warnings might still be required where performance of the *implant system* remains unaffected but where risks might exist to the patient through its presence during the application of clinical procedures or medical treatments.

[28.15] *Implant systems* can withstand specific levels of therapeutic ionizing radiation. According to 28.12 the manufacturer has to provide information on the maximum allowable dosage according to the test described in 22.3.

[28.19] At the time of writing this document, available *implant systems* do not have an implanted energy source. Future *implant systems* are likely to have a rechargeable implanted battery. When estimating the lifetime of the energy source for normal clinical settings and worst-case conditions the manufacturer should take the following parameters into consideration: the battery operating time for a single charge, the total number of recharge cycles and the charging time.

Annex B
(informative)

Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this document

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5 Essential principles		
5.1.1 Implants must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which can be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	(This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708.) 5.3 Requires usability engineering process be applied to *non-implantable parts* of the active implantable medical device. 5.5 Requires parts of an ISO 14971-compliant risk management process to be applied.	* retained
5.1.2 The solutions adopted by the manufacturer for the design and manufacture of the implants must conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the manufacturer must control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer must apply the following principles in the priority order listed: — identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; — eliminate risks as far as reasonably practicable through inherently safe design and manufacture; — reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; — inform users of any residual risks.	(This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. This approach is particularly applicable to the requirements in Clauses 14, 19, and 21.) 5.4 Requires the manufacturer to provide information security when communication with the implantable part is through wireless communication channels 5.5 Requires parts of an ISO 14971-compliant risk management process to be applied.	* retained
5.1.3 Implants must achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.	(This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708.)	* retained

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.1.4 The characteristics and performances referred to in 5.1.1, 5.1.2 and 5.1.3 must not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the implant, as indicated by the manufacturer, when the implant is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	19.2 Requires power source depletion indicator.	* replacement
	19.3 Defines methodology to ensure single fault conditions are not a hazard.	* retained
	23.1 Defines drop test for *non-implantable parts*.	* replacement
	23.2 Defines vibration test for patient carried parts.	* replacement
	23.3 Sets test of tensile strength (e.g. leads).	* replacement
	23.4 Requires strain relief (e.g. leads).	* retained
	23.5 Requires fatigue resistance (e.g. leads).	* replacement
	23.6 Requires connections to be reliable.	* retained
	26.1 Requires protection from heat from powered *non-implantable parts.*	* retained
	28.4 Requires disclosure of maximum proven connector retention strength.	* retained
	28.23 Requires warning against patient entry into hazardous environments.	* retained
5.1.5 Implants must be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (e.g. fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	7.2 Requires sterile pack to be protected by sales packaging.	* retained
	10.1 Requires packaging to be durable.	* retained
	10.2 Requires packaging to be protected against the effects of humidity.	* retained
	10.3 Requires markings on the sales package to be indelible.	* additional note
	10.4 Requires accompanying documentation to be physically associated with the device.	* retained
	12.3 Requires markings on the sterile pack to be indelible.	* retained
	26.2 Requires device to be protected against the effect of temperature changes.	* retained
5.1.6 All known and foreseeable risks, and any undesirable effects, must be minimised and be acceptable when weighed against the benefits of the intended performance of implants during normal conditions of use.	19.3 Defines methodology to ensure single fault conditions are not a hazard.	* retained
	19.4 Requires investigation of unintended effects caused by the device.	* retained 19.7, 19.8 additional requirements
5.2 Specific principles regarding design and construction		
5.2.1 Chemical, physical and biological properties		

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.2.1 The implants must be designed and manufactured in such a way as to ensure the characteristics and performance referred to in 5.1. Particular attention must be paid to: — the choice of materials used, particularly as regards toxicity and where applicable flammability; — the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device; — the choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength.	14.3 Requires investigation of biocompatibility.	* retained
5.2.2 The implants must be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the implants and to patients, taking account of the intended purpose of the implant. Particular attention must be paid to tissues exposed and to the duration and frequency of exposure.	14.2 Defines test for particulate contamination.	* replacement
	14.3 Requires investigation of biocompatibility.	* retained
5.2.3 The implants must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the implants are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	19.5 Demonstrate compatibility with medicinal substances.	* retained
5.2.4 The implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that can leach or leak from the implant. Special attention must be given to substances which are carcinogenic, mutagenic or toxic to reproduction.	25.1 Requires implanted parts to withstand pressure changes.	* retained 25.2 additional requirements
5.2.5 The implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the implant taking into account the implant and the nature of the environment in which it is intended to be used.	25.1 Requires implanted parts to withstand pressure changes.	* retained 25.2 additional requirements
5.2.6 The implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by insufficient cleanliness of the implant. Risks posed by insufficient cleanliness include risks posed by bacterial endotoxins, pyrogens and particulate contaminates.	14.1 Requires device to be supplied sterile.	* retained
5.3 Infection and microbial contamination		

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.3.1 The implants and manufacturing processes must be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design must allow easy handling, and, where necessary: — reduce as far as reasonably practicable and appropriate any microbial leakage from the implant and/or microbial exposure during use; — prevent microbial contamination of the implant, by the patient, user or another person.	14.1 Requires device to be supplied sterile.	* retained
5.3.2 Implants labelled as having a special microbiological state must be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	7.1 Requires device to be supplied in non-reusable pack.	* retained
	7.2 Requires sterile pack to be protected by sales packaging.	* retained
	10.1 Requires packaging to be durable.	* retained
	10.2 Requires packaging to be proof against the effects of humidity.	* retained
	11.7 Requires contents of sterile pack to be declared or visible.	* retained
	11.9 Requires the sterile pack to be marked with the instructions for opening it.	* retained
	12.1 Applies ISO 11607-1 to the reusable pack.	* retained
	12.2 Shall be apparent if sterile pack has been opened.	* retained
	14.1 Requires device to be supplied sterile.	* retained
5.3.2 Implants labelled as having a special microbiological state must be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	(Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile.)	—

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.3.3 Implants delivered in a sterile state must be designed, manufactured and packaged in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.	7.1 Requires device to be supplied in non-reusable pack.	* retained
	7.2 Requires sterile pack to be protected by sales packaging.	* retained
	10.1 Requires packaging to be durable.	* retained
	10.2 Requires packaging to be proof against the effects of humidity.	* retained
	11.7 Requires contents of sterile pack to be declared or visible.	* retained
	11.9 Requires the sterile pack to be marked with the instructions for opening it.	* retained
	12.1 Applies ISO 11607-1 to the reusable pack.	* retained
	12.2 Shall be apparent if sterile pack has been opened.	* retained
	14.1 Requires device to be supplied sterile.	* retained
5.3.4 Implants labelled either as sterile or as having a special microbiological state must have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.	—	—
5.3.5 Implants intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	14.1 Requires device to be supplied sterile.	* retained
	14.2 Defines test for particulate contamination.	* replacement
5.3.6 Packaging systems for non-sterile implants must maintain the integrity and cleanliness of the product and, if the implants are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)	—
5.3.7 The labelling of the implant must distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)	—
5.4 Implants incorporating a substance considered to be a medicinal product/drug		
5.4.1 This subclause is not intended to provide guidance on “combination products” as a whole since definitions have yet to be harmonized and practice varies between different jurisdictions.		
5.4.2 Where an implant incorporates, as an integral part, a substance which, if used separately, might be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and performance of the implant as a whole must be verified, as well as the safety, quality and efficacy of the substance in the specific application.	14.4 Requirement for quality and safety of incorporated medicinal substances.	* retained
5.5 Implants incorporating materials of biological origin		
5.5.1 This subclause is not intended to provide guidance on “combination products” as a whole since definitions have yet to be harmonized and practice varies between different jurisdictions.		

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.5.2 In some jurisdictions, implants incorporating tissues, cells and substances of animal origin might be considered medical devices. In this case, such tissues, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations might require that the manufacturer and/or the Regulatory Authority retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents (e.g. such as prions) must be addressed by the implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	(Not applicable to active implantable medical devices.)	—
5.5.3 In some jurisdictions, implants incorporating human tissues, cells and substances might be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin must be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	(Not applicable to active implantable medical devices.)	—
5.5.4 In some jurisdictions, implants incorporating cells and substances of microbial origin might be considered medical devices. In this case, processing, preservation, testing and handling of cells and substances must be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	(Not applicable to active implantable medical devices.)	—
5.6 Environmental properties		
5.6.1 If the implant is intended for use in combination with other devices or equipment the whole combination, including the connection system must be safe and must not impair the specified performance of the implants. Any restrictions on use applying to such combinations must be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, must be designed and constructed in such a way as to minimize all possible risks from incorrect connection.	9.9 Requires implantable connectors to be identified on sales pack.	* retained
	11.8 Requires implantable connectors to be identified on sterile pack.	* retained
	23.6 Requires connector retention force to be specified.	* retained
	28.4 Requires disclosure of maximum proven connector retention strength.	* retained
	28.5 Requires provision of information on accessories that might be required to facilitate the intended use of the device.	* retained

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.6.2 Implants must be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:		
5.6.2.1 The risk of injury to the patient, user or other persons in connection with their physical and ergonomic features;	15.1 Sets requirement for surfaces of *non-implantable parts*.	* retained
	15.2 Requires implantable parts to have appropriate physical form.	* retained
5.6.2.2 The risk of use error due to the ergonomic features, human factors and the environment in which the implant is intended to be used;	5.3 Requires usability engineering process be applied to *non-implantable parts* of the active implantable medical device.	* retained
	5.5 Requires parts of an ISO 14971-compliant risk management process to be applied.	* retained
5.6.2.3 Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration;	23.1 Defines drop test for *non-implantable parts*.	* replacement
	23.2 Defines vibration test for patient carried parts.	* replacement
	24.1 Defines electrostatic discharge test for *non-implantable parts*.	* replacement
	25.1 Requires implanted parts to be proof against pressure changes.	* retained 25.2 additional requirements
	26.2 Requires implantable devices to be undamaged by extremes of temperature in transit.	* retained
	27.1 Defines requirement for electromagnetic immunity.	* replacement 27.2, 27.3, 27.4, 27.5, 27.6, 27.7 additional requirements
5.6.2.4 The risks associated with the use of the implant when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use;	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
5.6.2.5 The risk associated with the possible negative interaction between software and the environment within which it operates and interacts;	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
5.6.2.6 The risks of accidental penetration of substances into the implant;	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.6.2.7 The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	20.1 Requires defibrillation protection of external ECG leads.	* not applicable to cochlear implants
	20.2 Defines test to prove defibrillation protection of implanted device.	* retained
	21 Requires protection against diathermy, etc.	* replacement
	22 Requires protection against diagnostic ultrasound.	* retained 22.2.1 to 22.3 additional requirements
	28.12 Requirement for warning notices.	* replacement
	28.13 Requires warning about monitoring device in case of diathermy, etc.	* retained
	28.14 Requires warning not to expose device to therapeutic levels of ultrasound.	* retained
	28.15 Requires warning about the effect of therapeutic irradiation on implanted devices.	* retained
5.6.2.8 Risks arising where maintenance or calibration are not possible, including from: — ageing of materials used; — loss of accuracy of any measuring or control mechanism; — excessive increase of leakage currents; — excess heat generated by the implant.	17.1 Requires investigation of local heating caused by faulty implanted device	* replacement
	17.2 Requires that supply heat be investigated.	* does not apply
	19.1 Requires a design analysis.	* retained
	19.2 Requires power source depletion indicator.	* retained
5.6.3 Implants must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to implants whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	5 Applies IEC 60601-1 to the *non-implantable parts* of the active implantable medical device.	* retained 5.7, additional requirements
5.6.4 Implants must be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.	17.1 Requires investigation of local heating caused by the implanted device in normal operation or in any single component failure.	* replacement
	19.1 Requires a design analysis.	* retained
	19.2 Requires power source depletion indicator.	* retained
5.6.5 Implants must be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.	28.29 Requires information on proper disposal of the device.	* retained
5.7 Implants with a diagnostic or measuring function		

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.7.1 Diagnostic implants and implants with a measuring function, must be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for the intended purpose of the implant, based on appropriate scientific and technical methods. The limits of accuracy must be indicated by the manufacturer.	5.1 Applies IEC 60601–1 to the *non-implantable parts* of the active implantable medical device that are connected to or equipped with an electrical power source.	* retained
5.7.2 Any measurement, monitoring or display scale used in association with an implant must be designed in line with ergonomic principles, taking account of the intended purpose of the implant.	5.1 Applies IEC 60601–1 to the *non-implantable parts* of the active implantable medical device that are connected to or equipped with an electrical power source.	* retained
5.7.3 Wherever possible values expressed numerically must be in commonly accepted, standardised units, and understood by the users of the implant.	5.1 Applies IEC 60601–1 to the *non-implantable parts* of the active implantable medical device that are connected to or equipped with an electrical power source.	* retained
5.8 Protection against radiation		
5.8.1 General Implants must be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation must be reduced as far as reasonably practicable and appropriate, compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	(See more particular requirements below.)	
5.8.2 Intended radiation Where implants are designed to emit hazardous, or potentially hazardous, levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such implants must be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.	(Not applicable to active implantable medical devices.)	—
5.8.3 Unintended radiation Implants must be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as reasonably practicable and appropriate.	9.1 Requires markings warning of any radioactive substances.	* retained
	18.1 Requirement for sealed sources.	* retained
	18.2 Requires justification of radiation dose on patient.	* retained
	18.3 Requires radiation dose as low as is possible.	* retained
	28.2 Requires information to be provided about radioactive substances.	* retained
5.8.4 Ionizing radiation	(Not applicable to active implantable medical devices.)	—
5.8.4.1 Implants intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where reasonably practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.	—	—

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.8.4.2 Implants emitting ionizing radiation intended for diagnostic radiology must be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose while minimizing radiation exposure of the patient and user.	—	—
5.8.4.3 Implants emitting ionizing radiation, intended for therapeutic radiology must be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.	—	—
5.9 Implants that incorporate software		
5.9.1 Implants incorporating electronic programmable systems, including software must be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means must be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.	5.2 Requires implants to be designed according to software life cycle process activities compliant with IEC 62304:2006 and validated.	* retained
	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
5.9.2 For implants which incorporate software, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.	5.2 Requires implants to be designed according to software life cycle process activities compliant with IEC 62304:2006 and validated.	* retained
5.10 Active implants and devices connected to them		
5.10.1 For active implants, in the event of a single fault condition, appropriate means must be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.	19.3 Defines methodology to ensure single fault conditions are not a hazard.	* retained
5.10.2 Implants where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	19.2 Requires power source depletion indicator.	* retained
5.10.3 Implants where the safety of the patients depends on an external power supply must include an electronic alarm system to signal any power failure by way of an external device used in association with the implant.	5.1 Applies IEC 60601–1 to the *non-implantable parts* of the active implantable medical device that are connected to or equipped with an electrical power source.	* retained
5.10.4 Implants intended to monitor one or more clinical parameters of a patient must be equipped with appropriate electronic alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health by way of an external device used in association with the implant.	5.1 Applies IEC 60601–1 to the *non-implantable parts* of the active implantable medical device that are connected to or equipped with an electrical power source.	* retained
5.10.5 Implants must be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.	27.1 Defines requirement for electromagnetic immunity.	* replacement

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.10.6 Implants must be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	27.1 Defines requirement for electromagnetic immunity.	* replacement
5.10.7 Implants must be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the implant and in the event of a single fault condition in the implant, provided the implant is installed and maintained as indicated by the manufacturer.	5.1 Applies IEC 60601–1 to the *non-implantable parts* of the active implantable medical device that are connected to or equipped with an electrical power source.	* retained
	16.1 Sets safety limits for leakage currents from *non-implantable parts*.	* replacement
5.11 Protection against mechanical risks		
5.11.1 Implants must be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	5 Applies IEC 60601-1 to the *non-implantable parts* of the active implantable medical device.	* replacement
5.11.2 Implants must be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the implants, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	5 Applies IEC 60601-1 to the *non-implantable parts* of the active implantable medical device.	* retained 5.7, new requirement
5.11.3 Implants must be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	5 Applies IEC 60601-1 to the *non-implantable parts* of the active implantable medical device.	* retained 5.7, new requirement
5.11.4 Implants must be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the implant are intended to be connected or reconnected before or during use.	5.3 Requires usability engineering process be applied to *non-implantable parts* of the active implantable medical device.	* retained
5.11.5 Implant (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal conditions of use.	17.1 Defines requirement for protection from heat.	* replacement
5.11.6 Implant packaging must be designed and manufactured in such a way as to reduce abrasion between packaging and implant to the lowest practicable level.	10.1 Specifies packaging construction.	* retained
5.12 Protection against the risks posed to the patient by energy supplies or substances		
5.12.1 Implants for supplying the patient with energy or substances must be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
	5.1 Applies IEC 60601–1 to the *non-implantable parts* of the active implantable medical device that are connected to or equipped with an electrical power source.	* retained

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
5.12.2 Implants must be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Implants must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.	5.1 Applies IEC 60601–1 to the *non-implantable parts* of the active implantable medical device that are connected to or equipped with an electrical power source.	* retained
5.12.3 The function of the controls and indicators must be clearly specified on the implants or associated devices. Where an implant or associated device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user.	13.4 Specifies on-device markings.	* retained
5.13 Label and instruction for use		
5.13.1 General principles		
This subclause describes the general principles that apply equally to all implants. The primary purpose of labelling is to identify the implant and its manufacturer and communicate safety and performance related information to the user, professional or other person, as appropriate. Such information can appear on the implant itself, on packaging or as instructions for use. The following principles are recommended.		
The medium, format, content, legibility and location of the label and instructions for use must be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use must be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.	4 Allows use of symbols, abbreviations, and identification colours.	* retained
The information required on the label, might be provided on the implant itself. If this is not practicable or appropriate, some or all of the information can appear on the packaging for each unit, and/or on the packaging of multiple implants.	12.3 Requirement that any markings shall be indelible.	* retained
	13.2 Requires implantable parts to be marked with sufficient information to allow for positive identification at the time of implantation.	* retained
Where the manufacturer supplies multiple implants to a single user and/or location, it might be sufficient to provide only a single copy of the instructions for use. In these circumstances, the manufacturer must provide further copies upon request.	—	—
Instructions for use might not be needed or might be abbreviated for implants if they can be used safely and as intended by the manufacturer without any such instructions for use.	—	—
Labels must be provided in a human-readable format but can be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.	—	—

Essential principles	Clauses of ISO 14708-1:2014	Clauses of ISO 14708-7 and aspects covered
Instructions for use can be provided to the user either in paper or non-paper format (e.g. electronic). They can be supplied by various means either with the implant or separate from it. Examples of other means are information downloaded from the manufacturer's website using the internet, and machine-readable sources. The means chosen must be appropriate for, and accessible to, the anticipated user population.	10.4 Requires accompanying documentation to be physically associated with the device.	* retained
Where instructions for use are provided on a medium other than paper, the manufacturer must ensure the user has information on how to: a) view the instructions for use; b) access the correct version of the instructions for use; c) obtain a paper version of the instructions for use.	—	—
Residual risks which are required to be communicated to the user and/or other person must be included as limitations, contraindications, precautions or warnings in the labelling.	8.1 Requires warnings to be prominent.	* retained
The use of internationally recognized symbols must be encouraged provided that implant safety is not compromised by a lack of understanding on the part of the user. Where the meaning of the symbol is not obvious to the implant user, e.g. for a newly introduced symbol, an explanation must be provided within the instructions for use.	4. Allows use of symbols, abbreviations and identification colours.	* retained
Country-specific requirements for the content of the labelling must be kept to the minimum and, where they currently exist, eliminated as the opportunity arises.	—	—
Where national legislation, such as customs statutes, trade agreements and the like, include requirements for additional documentation to accompany the implant, there might be an inconsistency between the additional documentation and the content of implant labelling described in this document. An example is a customs requirement to indicate the "country of origin" of the implant which does not necessarily align with the address of the manufacturer indicated in the labelling according to 5.13.2 c) or 5.13.3 b) of this document.	—	—
Provided that safe and correct use of the implant is ensured, a regulatory authority might authorize labelling to be in one or more language(s) other than its national language(s).	—	—
5.13.2 Content of the label		
The label must contain the following particulars which can appear on the implant itself, or on the packaging of each unit, or on the packaging of multiple devices.		
a) The name or trade name of the implant.	11.1 Requires identification of manufacturer on sterile pack.	* retained