INTERNATIONAL STANDARD

ISO 14708-7

Second edition
2019-12

Corrected version
2020-05

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

Reference number
ISO 14708-7:2019(E)

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

Published in Switzerland

Contents

Page

Foreword

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

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

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

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

For an explanation 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.