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Implants for surgery — Active implantable medical devices —

Part 7: Particular requirements for cochlear implant systems

Implants chirurgicaux — Dispositifs médicaux implantables actifs — Partie 7: Exigences particulières pour les systèmes d'implant cochléaire

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14708-7 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

ISO 14708 consists of the following parts, under the general title *Implants for surgery — Active implantable medical devices*:

— *Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

— *Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

— *Part 7: Particular requirements for cochlear implant systems*

Introduction

This International Standard 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 may 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 International Standard is relevant to all parts of IMPLANT SYSTEMS, including accessories.

The requirements of this International Standard supplement or modify those of ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*.

Figures or tables that are additional to those of Part 1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

In this part of ISO 14708, terms printed in small capital 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 small capital letters unless the concept thus qualified is also defined.

Implants for surgery — Active implantable medical devices —

Part 7:
Particular requirements for cochlear implant systems

1 Scope

This part of ISO 14708 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 part of ISO 14708.

The tests that are specified in this part of ISO 14708 are type tests and are to be carried out on samples of a device to show compliance.

This part of ISO 14708 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 part of ISO 14708 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 part of ISO 14708 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, but there is a need to specify some requirements of NON-IMPLANTABLE PARTS and accessories if they could affect the safety or performance of the implantable part.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

This clause of ISO 14708-1 applies except as follows:

Additional references:

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

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

IEC 60068-2-47, *Environmental testing — Part 2-47: Test — Mounting of specimens for vibration, impact and similar dynamic tests*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60068-2-75, *Environmental testing — Part 2-75: Tests — Test Eh: Hammer tests*

IEC 60118-6, *Hearing aids — Part 6: Characteristics of electrical input circuits for hearing aids*

IEC 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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*

IEC 62304, *Medical device software — Software life cycle processes*

EN 1593, *Non-destructive testing — Leak testing — Bubble emission techniques*

EN 13185, *Non-destructive testing — Leak testing — Tracer gas method*

3 Terms and definitions

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

3.3.1
cochlear implant system
CIS
active implantable medical device, comprising implantable and NON-IMPLANTABLE PARTS, intended to treat hearing impairment via electrical stimulation of the cochlea

3.3.2
auditory brainstem implant system
BIS
ACTIVE IMPLANTABLE MEDICAL DEVICE, comprising implantable and NON-IMPLANTABLE PARTS, intended to treat hearing impairment via electrical stimulation of the auditory brainstem

3.3.3
implant system
either COCHLEAR IMPLANT SYSTEM or AUDITORY BRAINSTEM IMPLANT SYSTEM

3.3.4
non-implantable part
external part of the IMPLANT SYSTEM

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

3.3.5
stimulator
implantable part of the IMPLANT SYSTEM containing electronic circuitry required to produce electrical stimulation

3.3.6
body-worn
NON-IMPLANTABLE PART of the IMPLANT SYSTEM and worn on the body (e.g. belt or ear level)

3.5.1
electrode contact
electrically conducting part which is designed to form an interface with body tissue or body fluid

3.5.2
electrode array
DISTAL part of a LEAD containing more than one ELECTRODE CONTACT

3.5.3
reference electrode
electrically conducting part designed as return path for electrical stimulation current

3.5.4
distal
located away from the point of attachment to the STIMULATOR

3.5.5
proximal
located closest to the point of attachment to the STIMULATOR

3.9.1
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

3.9.2
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

3.20.1
output signal
electrical output, either pulsatile or analogue, of an IMPLANT SYSTEM intended to stimulate the auditory pathways

3.20.2
pulse
specified electrical OUTPUT SIGNAL (voltage or current) of a specified amplitude and duration

3.20.3
biphasic pulse
PULSE which has both negative and positive going phases

3.22.1
use-before-date
date after which the manufacturer recommends that the IMPLANT SYSTEM should not be implanted

3.22.2
magnet
component producing an external magnetic flux

4 Symbols and abbreviations

There are no requirements specified in this part of ISO 14708. 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 This subclause of ISO 14708-1 applies.

5.2 *Replacement*

Software of an ACTIVE IMPLANTABLE MEDICAL DEVICE or software that falls within the definition of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be designed according to software life cycle process activities compliant with IEC 62304 and validated.

6 Inspection and measurement

If this part of ISO 14708 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.

6.1 Measurement of output signal characteristics

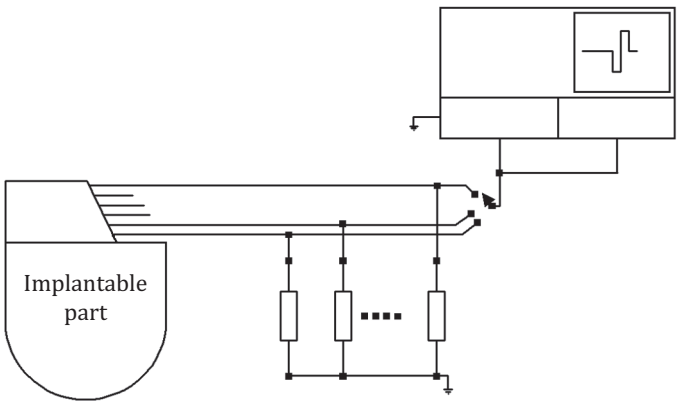
The measurement shall be performed with the implantable part of the IMPLANT SYSTEM at a temperature of (37 ± 2) °C. The IMPLANT SYSTEM shall be configured to use its maximum number of outputs and each output shall be programmed to its maximum value (amplitude and pulse width). An input signal equivalent to 70dB SPL shall be applied to the microphone. Where applicable, the transcutaneous link shall operate over a distance of (5 ± 1) mm. Where the IMPLANT SYSTEM provides alternative OUTPUT SIGNALS each shall be measured and listed separately. To facilitate connection the test sample may be unfinished. The accuracy of the amplitude measurement shall be better than ± 5 % taking all errors into consideration.

6.2 Measurement of the output SIGNAL amplitude and pulse width

A representative sample of the IMPLANT SYSTEM shall have each output connected to a 1 kΩ (±1 %) load resistor (see Figure 101) and configured per 6.1. An oscilloscope shall be adjusted to display the full output at its maximum resolution. The measurement shall be made in the peak of the OUTPUT SIGNAL. Each output shall be in turn connected to the oscilloscope and the amplitude and pulse width shall be measured. The median of the amplitudes and pulse widths and their range shall be recorded and the result shall be expressed in µA and µs.

6.3 Impedance measurement accuracy

Where the IMPLANT SYSTEM allows an impedance measurement (either by telemetry or direct measurement) the manufacturer shall specify the accuracy of the impedance measurement for a 10 kΩ load resistor. The measurement conditions shall be chosen to reflect normal clinical practice. The measurement shall be repeated on every output (see Figure 101). The accuracy of the impedance measurement shall be expressed as a percentage.



NOTE Ground is connected to the external reference electrode, if available.

Figure 101 — Measurement of output signal amplitude and load impedance

7 General arrangement of the packaging

7.1 This subclause of ISO 14708-1 applies.

7.2 This subclause of ISO 14708-1 applies.

8 General markings for active implantable medical devices

8.1 This subclause of ISO 14708-1 applies.

8.2 This subclause of ISO 14708-1 applies.

9 Markings on the SALES PACKAGING

9.1 This subclause of ISO 14708-1 applies.

9.2 This subclause of ISO 14708-1 applies except as follows:

Replacement:

The SALES PACKAGING shall bear the name and address of the manufacturer, the address including at least the city and country. The SALES PACKAGING shall 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 *Replacement*

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 This subclause of ISO 14708-1 applies.

9.5 This subclause of ISO 14708-1 applies.

9.6 This subclause of ISO 14708-1 applies.

9.7 *Replacement*

The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear the USE-BEFORE-DATE, as expressed in 9.6.

Compliance shall be checked by inspection.

9.8 This subclause of ISO 14708-1 applies.

9.9 This subclause of ISO 14708-1 applies.

9.10 This subclause of ISO 14708-1 applies.

9.11 This subclause of ISO 14708-1 applies.

9.12 *Additional subclause*

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 shall be checked by inspection.

10 Construction of the SALES PACKAGING

10.1 This subclause of ISO 14708-1 applies.

10.2 This subclause of ISO 14708-1 applies.

10.3 This subclause of ISO 14708-1 applies.

Additional note:

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

10.4 This subclause of ISO 14708-1 applies.

11 Markings on the sterile pack

11.1 This subclause of ISO 14708-1 applies.

11.2 This subclause of ISO 14708-1 applies.

11.3 This subclause of ISO 14708-1 applies.

11.4 This subclause of ISO 14708-1 applies.

11.5 This subclause of ISO 14708-1 applies.

11.6 This subclause of ISO 14708-1 applies.

11.7 This subclause of ISO 14708-1 applies.

11.8 This subclause of ISO 14708-1 applies.

11.9 This subclause of ISO 14708-1 applies.

11.10 This subclause of ISO 14708-1 applies.

NOTE This subclause can be fulfilled using an unambiguous symbol.

12 Construction of the non-reusable pack

12.1 This subclause of ISO 14708-1 applies. except as follows:

Replacement:

The NON-REUSABLE PACK shall comply with ISO 11607-1.

Compliance shall be checked by inspection and by review of records provided by the manufacturer.

12.2 This subclause of ISO 14708-1 applies.

12.3 This subclause of ISO 14708-1 applies.

13 Markings on the active implantable medical device

13.1 This subclause of ISO 14708-1 applies.

13.2 This subclause of ISO 14708-1 applies.

13.3 *Replacement*

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).

13.4 This subclause of ISO 14708-1 applies.

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

14.1 This subclause of ISO 14708-1 applies.

14.2 *Replacement*

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 *Replacement*

This subclause of ISO 14708-1 applies with the addition that ISO 10993-1 shall be used.

14.4 This subclause of ISO 14708-1 applies.

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

15.1 This subclause of ISO 14708-1 applies.

15.2 *Replacement*

Implantable parts of an IMPLANT SYSTEM shall have no surface features, such as sharp corners or edges that could cause excessive reaction or inflammation beyond that caused by the implanting procedure, or rough surfaces which are not required for the correct functioning of the device.

Compliance shall be confirmed if records provided by the manufacturer establish that the safety of the physical characteristics has been verified with appropriate methods.

16 Protection from harm to the patient caused by electricity

16.1 *Replacement*

Electrical audio inputs into NON-IMPLANTABLE PARTS of an IMPLANT SYSTEM shall comply with the requirements for electrical safety of the hearing aid standard IEC 60118-6. Other electrical inputs or outputs of NON-IMPLANTABLE PARTS of an IMPLANT SYSTEM that allow the NON-IMPLANTABLE PART to be connected to supply mains or mains powered devices which do not meet the insulation requirements of IEC 60601-1 shall either contain or be provided with a separation device which complies with the applicable clauses regarding insulation of IEC 60601-1 (separation device as defined in IEC 60601-1:2006, 16.5.).

NOTE A separation device is not required for battery powered devices when used alone.

Compliance shall be checked as specified in IEC 60601-1 (if applicable) and by review of the documentation provided by the manufacturer.

16.2 *Replacement*

Except for its intended function, implantable parts of an IMPLANT SYSTEM shall be electrically neutral when in contact with the body. No leakage current (direct current) of more than 0,1 µA shall be sustained in any of the current pathways when the device is in use.

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

16.3 This subclause of ISO 14708-1 applies.

17 Protection from harm to the patient caused by heat

17.1 This subclause of ISO 14708-1 applies.

17.2 This subclause is to be left vacant for future editions.

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

18.1 This subclause of ISO 14708-1 applies.

18.2 This subclause of ISO 14708-1 applies.

18.3 This subclause of ISO 14708-1 applies.

19 Protection from unintended effects caused by the device

NOTE See also 28.20.

19.1 This subclause of ISO 14708-1 applies.

19.2 *Replacement*

If the implantable part of an IMPLANT SYSTEM contains within it a source of power, such as a battery, the IMPLANT SYSTEM shall include an 'indicator' that gives advance notice of energy source depletion to the clinician and user.

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

19.3 This subclause of ISO 14708-1 applies.

19.4 This subclause of ISO 14708-1 applies except as follows:

Replacement of the assessment:

Side effects and benefits from the intended use of the device shall be identified either by reference to current medical practice and demonstrated by analogy, or by reference to clinical investigations conducted according to ISO 14155.

Additional subclauses:

19.5 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 e.g. post market surveillance data relating to device replacement.

19.6 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. If a group A technique is used from the EN 13185 standard 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 should 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.

20 Protection of the device from damage caused by external defibrillators

NOTE See also 28.12.