SLOVENSKI STANDARD
oSIST prEN ISO 14708-7:2018

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Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 7. del: Posebne zahteve za sisteme s polžkovim vsadkom (ISO/DIS 14708-7:2018)

Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems (ISO/DIS 14708-7:2018)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 7: Exigences particulières pour les systèmes d'implant cochléaire (ISO/DIS 14708-7:2018)

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Implants for surgery — Active implantable medical devices —

Part 7: Particular requirements for cochlear implant systems

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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. 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. 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 on 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 the following URL: 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:

- alignment to the updated ISO 14708-1:2014
- significant changes to clauses 17, 22, 27
- many clauses have been replaced by references to the ANSI/AAMI CI86:2017 standard

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

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 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 document is relevant to all parts of IMPLANT SYSTEMS, including accessories.

The requirements of this document 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, this standard 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.

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 60601-1:2012, *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*

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 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/

3.101
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

3.102
auditory brainstem implant system
ABIS
ACTIVE IMPLANTABLE MEDICAL DEVICE, comprising implantable and NON-IMPLANTABLE PARTS, intended to treat hearing impairment via electrical stimulation of the auditory brainstem

3.103
implant system
either COCHLEAR IMPLANT SYSTEM or AUDITORY BRAINSTEM IMPLANT SYSTEM

3.104
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.

3.105
stimulator
implantable part of the IMPLANT SYSTEM containing electronic circuitry required to produce electrical stimulation

3.106
body-worn
NON-IMPLANTABLE PART of the IMPLANT SYSTEM and worn on the body (e.g. belt or ear level)

3.107
electrode contact
electrically conducting part which is designed to form an interface with body tissue or body fluid

3.108
electrode array
DISTAL part of a LEAD containing more than one ELECTRODE CONTACT

3.109
reference electrode
electrically conducting part designed as return path for electrical stimulation current

3.110
distal
located away from the point of attachment to the STIMULATOR

3.111
proximal
located closest to the point of attachment to the STIMULATOR

3.112
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

3.113
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

3.114
output signal
electrical output, either pulsatile or analogue, of an IMPLANT SYSTEM intended to stimulate the auditory pathways

3.115
pulse
specified electrical OUTPUT SIGNAL (voltage or current) of a specified amplitude and duration

3.116
biphasic pulse
PULSE which has both negative and positive going phases

3.117

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

3.118
magnet
component producing an external magnetic flux

3.119
SAR value
SAR = Specific Absorption Rate

3.120
RF
Radio Frequency

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 This subclause of ISO 14708-1 applies.

5.3 This subclause of ISO 14708-1 applies.

5.4 This subclause of ISO 14708-1 applies.

5.5 This subclause of ISO 14708-1 applies.

5.6 This subclause of ISO 14708-1 applies.

Additional subclauses:

5.7 Protection against external electrical hazards for fully implantable systems

Clause 6.5 of ANSI/AAMI CI86:2017 applies.

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

Clause 8.1 of ANSI/AAMI CI86:2017 applies.

6.2 Measurement of the output SIGNAL amplitude and pulse width

Clause 8.2 of ANSI/AAMI CI86:2017 applies

6.3 Impedance measurement accuracy

Clause 8.3 of ANSI/AAMI CI86:2017 applies.

6.4 Inductive link characterization

Clause 8.4 of ANSI/AAMI CI86:2017 applies.

6.5 Sound processor battery testing

Clause 8.5 of ANSI/AAMI CI86:2017 applies.

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 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 *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 This subclause of ISO 14708-1 applies.

9.13 This subclause of ISO 14708-1 applies.

9.14 This subclause of ISO 14708-1 applies.

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.

12 Construction of the non-reusable pack

12.1 This subclause of ISO 14708-1 applies.

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 This subclause of ISO 14708-1 applies.

14.4 This subclause of ISO 14708-1 applies.