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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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Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **2**

4 Symbols and abbreviations **3**

5 General requirements for non-implantable parts **3**
5.1 General requirements for non-implantable parts 3
5.2 General requirements for software 3
5.3 Usability of non-implantable parts 3
5.4 Data security and protection from harm caused by unauthorized information tampering 3
5.5 General requirements for risk management 3
5.6 Misconnection of parts of the active implantable medical device 3
5.7 Protection against external electrical hazards for fully implantable systems 3

6 Inspection and measurement **4**
6.1 General 4
6.2 Measurement of output signal characteristics 4
6.3 Measurement of the output signal amplitude and pulse width 4
6.4 Impedance measurement accuracy 4
6.5 Inductive link characterization 4
6.6 Sound processor battery testing 4

7 General arrangement of the packaging **4**

8 General markings for active implantable medical devices **4**

9 Markings on the sales packaging **4**

10 Construction of the sales packaging **5**

11 Markings on the sterile pack **5**

12 Construction of the non-reusable pack **5**

13 Markings on the active implantable medical device **5**

14 Protection from unintentional biological effects being caused by the active implantable medical device **6**

15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device **6**

16 Protection from harm to the patient caused by electricity **6**

17 Protection from harm to the patient caused by heat **7**

18 Protection from ionizing radiation released or emitted from the active implantable medical device **8**

19 Protection from unintended effects caused by the device **8**

20 Protection of the device from damage caused by external defibrillators **9**

21 Protection of the device from changes caused by high power electrical fields applied directly to the patient **9**

22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments **10**

23 Protection of the active implantable medical device from mechanical forces **18**

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24 Protection of the active implantable medical device from damage caused by electrostatic discharge **22**

25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes **22**

26 Protection of the active implantable medical device from damage caused by temperature changes **23**

27 Protection of the active implantable medical device from electromagnetic non-ionising radiation **23**

27.1 Protection from static magnetic fields 23
27.2 Radiated magnetic field test for frequencies 16,6 Hz to 27 MHz 23
27.3 Radiated electric field test for frequencies 10 MHz to 2,7 GHz 25
27.4 General test configuration and setup 25
27.4.1 Test configuration and setup 25
27.4.2 Operating functions, modes and settings 26
27.4.3 Patient physiological simulation 26
27.5 Acceptance Criteria 26

28 Accompanying documentation **27**

Annex A (informative) **General guidance and rationale** **31**

Annex B (informative) **Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this document** **42**

Annex C (informative) **Notes on EN 45502-2-3 (basis for this document)** **61**

Annex D (informative) **Notes on EMI measurements to demonstrate compliance with Clause 27** **62**

Bibliography **66**

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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.

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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.

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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*

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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

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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.

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