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Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear and auditory brainstem implant systems (ISO 14708-7:2019)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 14708-7:2022 sisaldab Euroopa standardi EN ISO 14708-7:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14708-7:2022 consists of the English text of the European standard EN ISO 14708-7:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 27.07.2022.	Date of Availability of the European standard is 27.07.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear and auditory brainstem implant systems (ISO 14708-7:2019)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 7: Exigences particulières pour les systèmes d'implant cochléaire et d'implant auditif du tronc cérébral (ISO 14708-7:2019)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 7: Besondere Anforderungen an Cochlea-Implantat Systeme (ISO 14708-7:2019)

This European Standard was approved by CEN on 6 July 2022.

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CEN-CENELEC Management Centre:
Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 14708-7:2022) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN-CENELEC/ JTC 16 “Active Implantable Medical Devices” the secretariat of which is held by DKE.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

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Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

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Endorsement notice

The text of ISO 14708-7:2019 has been approved by CEN-CENELEC as EN ISO 14708-7:2022 without any modification.

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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).

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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.

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