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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*