SLOVENSKI STANDARD
SIST EN 45502-2-3:2010

01-april-2010

Aktivni medicinski vsadki (za implantacijo) - 2-3. del: Posebne zahteve za sisteme s polžkovim vsadkom

Active implantable medical devices - Part 2-3: Particular requirements for cochlear implant systems

Aktive implantierbare Medizingeräte - Teil 2-3: Besondere Festlegungen für Cochlea-Implantate

Dispositifs médicaux implantables actifs - Partie 2-3: Exigences particulières pour les systèmes d'implant cochléaire

Ta slovenski standard je istoveten z: **EN 45502-2-3:2010**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN 45502-2-3:2010 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 45502-2-3

February 2010

ICS 13.320

English version

Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems

Dispositifs médicaux implantables actifs - Partie 2-3: Exigences particulières pour les systèmes d'implant cochléaire et les systèmes d'implant auditif du tronc cérébral

Aktive implantierbare Medizingeräte - Teil 2-3: Besondere Festlegungen für Cochlea-Implantatsysteme und auditorische Hirnstammimplantatsysteme

This European Standard was approved by CEN and CENELEC on 2010-02-01. CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CEN/CENELEC

CEN-CENELEC Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 45502-2-3:2010 E

Foreword

This European Standard was prepared by the CEN/CENELEC Joint Working Group AIMD, Active Implantable Medical Devices. Members of the Joint Working Group were nominated by one of the members of either CEN or CENELEC. The lead has been given to CENELEC.

The text of the draft was submitted to a second formal vote and was approved by CEN and CENELEC as EN 45502-2-3 on 2010-02-01.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-02-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-02-01

The requirements of this particular standard supplement or modify those of the General Standard EN 45502-1:1997, *Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer*.

This European Standard has been prepared under a mandate given to CEN and CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 90/385/EEC. See Annexes AA and BB.

Although both this European Standard and the Directive deal with the same range of products, the structure and purpose of the two documents are different. Annex AA, BB, CC are rationales, providing some further explanation of particular subclauses of this European Standard. All three annexes are informative.

Contents

Figures

Tables

Introduction

This European Standard specifies particular requirements for those ACTIVE IMPLANTABLE MEDICAL DEVICES that are intended 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 European Standard is relevant to all parts of IMPLANT SYSTEMS, including accessories.

The requirements of this European Standard supplement or modify those of EN 45502–1:1997*, Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer*, hereinafter referred to as Part 1. The requirements of this European Standard take priority over those of Part 1.

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

1 Scope

This Part 2-3 of EN 45502 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 European Standard.

The tests that are specified in EN 45502 are type tests and are to be carried out on samples of a device to show compliance.

This Part of EN 45502 is also applicable to NON-IMPLANTABLE PARTS and accessories of the devices (see NOTE 1).

The electrical characteristics of the IMPLANTABLE PART shall be determined by either the appropriate method detailed in this particular standard 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 particular standard shall apply.

NOTE 1 The 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.

NOTE 2 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

NOTE 3 In this European Standard, 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.

2 Normative references

This clause of Part 1 applies except as follows:

Additional references:

EN ISO 14971 [1)]	2007	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN 1593	1999	Non-destructive testing - Leak testing - Bubble emission techniques
EN 13185	2001	Non-destructive testing - Leak testing – Tracer gas method
EN 45502-1	1997	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 55011 + A2	2007 2007	Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement (CISPR 11:2003, mod. + A1:2004, mod. + A2:2006)
EN 60068-2-27 [2)]	1993	Basic environmental testing procedures - Part 2: Tests - Test Ea and guidance: Shock (IEC 60068-2-27:1987)
EN 60068-2-31 [3)]	2008	Basic environmental testing procedures - Part 2: Tests - Test Ec: Drop and topple, primarily for equipment-type specimens (IEC 60068-2-31:1969 + A1:1982)

---

1) Superseded by EN ISO 14971:2009 "*Medical devices - Application of risk management to medical devices*" (ISO 14971:2007).

2) Will be superseded by EN 60068-2-27:2009 "*Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock*" (IEC 60068-2-27:2008) at the dow of the latter, i.e. 2012-05-01.

EN 60068-2-47	2005	Environmental testing - Part 2-47: Tests - Mounting of specimens for vibration, impact and similar dynamic tests (IEC 60068-2-47:2005)
EN 60068-2-64	2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008)
EN 60068-2-75	1997	Environmental testing - Part 2-75: Tests - Test Eh: Hammer tests (IEC 60068-2-75:1997)
EN 60118-6	1999	Hearing aids - Part 6: Characteristics of electrical input circuits for hearing aids (IEC 60118-6:1999)
EN 60601-1	2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN 60601-1-2	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, mod.)
EN 60801-2 [4)]	1993	Electromagnetic compatibility for industrial-process measurement and control equipment - Part 2: Electrostatic discharge requirements (IEC 60801-2:1991)

3 Definitions

This clause of Part 1 applies except as follows:

Additional definitions:

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 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) Will be superseded by EN 60068-2-31:2008 "*Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens*" (IEC 60068-2-31:2008) at the dow of the latter, i.e. 2011-07-01.

4) Superseded by EN 61000-4-2:1995, "*Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test*" (IEC 61000-4-2:1995).

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 (optional)

NOTE There are no requirements specified in this Part of EN 45502. 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 part 1 applies.*

5.2 *Replacement*

The IMPLANT SYSTEM shall meet the requirements of EN 60601-1-2:2007 for Group 1 equipment as specified in EN 55011:2007.

Compliance shall be checked by review of the test results and documentation provided by the manufacturer.

6 Inspection and measurement

If this standard refers to inspection of design analysis documentation provided by the manufacturer it shall include an inspection of the risk management file as required by EN ISO 14971.

6.1 Measurement of output signal characteristics

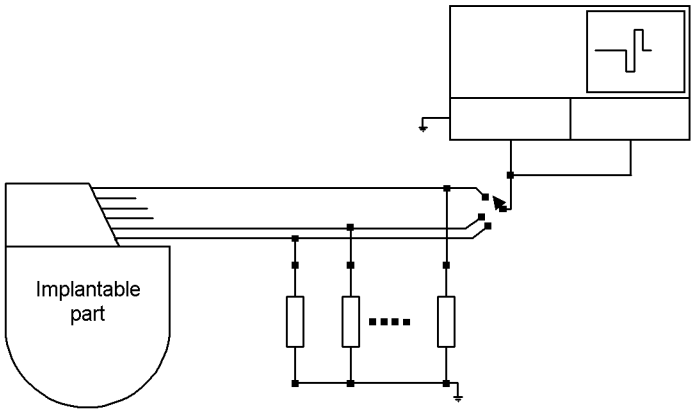
The measurement shall be performed with the implantable part of the IMPLANT SYSTEM at a temperature of (37 ± 2) °C. The IMPLANT SYSTEM shall be configured to use its maximum number of outputs and each output shall be programmed to its maximum value (amplitude and pulse width). An input signal equivalent 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 Part 1 applies.*

7.2 *This subclause of Part 1 applies.*

8 General markings for active implantable medical devices

8.1 *This subclause of Part 1 applies.*

8.2 *This subclause of Part 1 applies.*

9 Markings on the SALES PACKAGING

9.1 *This subclause of Part 1 applies*.

9.2 *This subclause of Part 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 *This subclause of Part 1 applies.*

9.4 *This subclause of Part 1 applies.*

9.5 *This subclause of Part 1 applies.*

9.6 *This subclause of Part 1 applies.*

9.7 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 Part 1 applies.*

9.9 *This subclause of Part 1 applies.*

9.10 *This subclause of Part 1 applies.*

9.11 *This subclause of Part 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 Part 1 applies*

10.2 *This subclause of Part 1 applies.*

10.3 *This subclause of Part 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 Part 1 applies.*

11 Markings on the sterile pack

11.1 *This subclause of Part 1 applies.*

11.2 *This subclause of Part 1 applies.*

11.3 *This subclause of Part 1 applies.*

11.4 *This subclause of Part 1 applies.*

11.5 *This subclause of Part 1 applies.*

11.6 *This subclause of Part 1 applies.*

11.7 *This subclause of Part 1 applies.*

11.8 *This subclause of Part 1 applies.*