TIS COCUME

IMPLANTAADID KIRURGIAS. AKTIIVSED IMPLANTEERITAVAD MEDITSIINISEADMED. OSA 1: ÜLDNÕUDED OHUTUSELE, MÄRGISTUSELE JA TOOTJA ANTAVALE INFORMATSIOONILE

Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer



EESTI STANDARDI EESSÕNA NATIONAL FOREWORD

45502-1:2015 This Estonian standard EVS-EN 45502-1:2015 See Eesti standard EVS-EN sisaldab Euroopa standardi EN 45502-1:2015 consists of the English text of the European standard EN 45502-1:2015. ingliskeelset teksti. Standard on jõustunud This standard has been endorsed with a sellekohase teate notification published in the official bulletin of the avaldamisega EVS Teatajas. Estonian Centre for Standardisation. Euroopa standardimisorganisatsioonid on teinud Date of Availability of the European standard is Euroopa standardi rahvuslikele liikmetele 22.05.2015. kättesaadavaks 22.05.2015. Standard kättesaadav Eesti The standard is available from the Estonian Centre on Standardikeskusest. for Standardisation.

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

STOLION

ICS 11.040.01

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud. Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega: Aru 10, 10317 Tallinn, Eesti; koduleht <u>www.evs.ee</u>; telefon 605 5050; e-post <u>info@evs.ee</u> The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Aru 10, 10317 Tallinn, Estonia; homepage <u>www.evs.ee</u>; phone +372 605 5050; e-mail <u>info@evs.ee</u>

EUROPEAN STANDARD NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 45502-1

May 2015

ICS 11.040.01

Supersedes EN 45502-1:1997

English Version

Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Dispositifs médicaux implantables actifs - Partie 1: Règles générales de sécurité, marquage et informations fournies par le fabricant

Aktive implantierbare medizinische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit, Aufschriften und vom Hersteller zur Verfügung zu tellende Informationen

This European Standard was approved by CENELEC on 20 April 2015. 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 CEN and 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 CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre 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, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom



European Committee for Electrotechnical Standardization Comité Européen de Normalisation Electrotechnique Europäisches Komitee für Elektrotechnische Normung

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

Contents

Fore	word	4
Intro	duction	
1	Scope	6
2	Normative references	6
3	Terms and definitions	7
4	Symbols and abbreviations (optional)	12
5	General requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES	12
6	Requirements for particular ACTIVE IMPLANTABLE MEDICAL DEVICES	14
7	General arrangement of the packaging	14
8	General MARKINGS for ACTIVE IMPLANTABLE MEDICAL DEVICES	14
9	MARKINGS on the SALES PACKAGING	15
10	Construction of the SALES PACKAGING	16
11	MARKINGS on the STERILE PACK	17
12	Construction of the NON-REUSABLE PACK	18
13	MARKINGS on the ACTIVE IMPLANTABLE MEDICAL DEVICE	18
14	Protection from unintentional biological effects being caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE	19
15	Protection from HARM to the patient or user caused by external physical features of the ACTIVE IMPLANTABLE MEDICAL DEVICE	21
16	Protection from HARM to the patient caused by electricity	21
17	Protection from HARM to the patient caused by heat	22
18	Protection from ionizing radiation released or emitted from the ACTIVE IMPLANTABLE MEDICAL DEVICE	22
19	Protection from unintended effects caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE	23
20	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by external defibrillators	24
21	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by electrical fields applied directly to the patient	27
22	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by Omiscellaneous medical treatments	28
23	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces	29
24	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by electrostatic discharge	30
25	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by atmospheric pressure changes	
26	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by temperature changes	31
27	Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from electromagnetic non-ionizing radiation	31
28	Accompanying documentation	32

Figures

Figure 1 – Damped sinus defibrillation waveform	25
Figure 2 – Defibrillation test voltage generator	25
Figure 3 – Timing sequence used for Test 1 and Test 2	26
Figure 4 – Test setup for truncated exponential DEFIBRILLATION waveform	26
Figure 5 – Biphasic DEFIBRILLATION waveform for Test 2	27
Figure A.1 – RLC implementation for generating a damped sinus defibrillation waveform	42
Figure A.2 – Positioning and scanning the ultrasound field exposure upon the implantable part	44
Tables	
Table 1 – Timing parameters of test signal for Test 2	26

Foreword

This document (EN 45502-1:2015) has been prepared by CEN/CLC/JWG AIMD "CEN/CENELEC Joint Working Group on Active Implantable Medical Devices".

The following dates are fixed:

- latest date by which this document has (dop) 2016-04-20 to be implemented at national level by publication of an identical national standard or by endorsement
 latest date by which the national (dow) 2018-04-20 down and the second standard or by endorsement
- standards conflicting with this document have to be withdrawn

This document supersedes EN 45502-1:1997.

EN 45502-1:2015 includes the following significant technical changes with respect to EN 45502-1:1997:

- a) update according to the modified AIMD;
- b) update of normative references to the "state of the art";
- c) implementation of usability issues;
- d) implementation of links to information security;
- e) implementation of elements according to EN 14971:2012;
- f) improvement of Clause 14 "Protection from unintentional biological effects being caused by the active implantable medical device";
- g) improvement of Clause 20 "Protection of the active implantable medical device from damage caused by external defibrillators";
- h) improvement of Clause 22 "Protection of the active implantable medical device from changes caused by miscellaneous medical treatments" especially for ultrasonic diagnostic devices.

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

202 172 5

Introduction

This European Standard specifies general requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES to provide basic assurance of safety for both patients and users.

To minimize the likelihood of a device being misused, this European Standard also details comprehensive requirements for MARKINGS and for other information to be supplied as part of the documentation with any ACTIVE IMPLANTABLE MEDICAL DEVICE.

For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICE, the general requirements can be supplemented or modified by the requirements of other parts of EN 45502. A requirement of a particular part of EN 45502 takes priority over the corresponding requirement of this general part of EN 45502. Where particular parts of EN 45502 exist, this general standard of EN 45502 is not intended to be used alone. Special care is required when applying this general standard part of EN 45502 alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular part of EN 45502 has yet been published. e Na Chair an Anna Anna an Anna an

- 5 -

- 6 -

1 Scope

This part of EN 45502 specifies requirements that are generally applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES.

NOTE 1 For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICES, these general requirements are supplemented or modified by the requirements of particular standards which form additional parts of this European Standard.

The tests that are specified in EN 45502 are type tests and are to be carried out on samples of an ACTIVE IMPLANTABLE MEDICAL DEVICE to show compliance.

This part of EN 45502 is applicable not only to ACTIVE IMPLANTABLE MEDICAL DEVICES that are electrically powered but also to those powered by other energy sources (for example by gas pressure or by springs).

This part of EN 45502 is also applicable to some non-implantable parts and accessories of the ACTIVE IMPLANTABLE MEDICAL DEVICES.

NOTE 2 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE can 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 device.

NOTE 3 In this part of EN 45502, 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

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.

EN 60068-2-14:2009, Environmental testing – Part 2 14: Tests – Test N: Change of temperature (IEC 60068-2-14:2009)

EN 60068-2-27:2009, Environmental testing – Part 2 27: Tests – Test Ea and guidance: Shock (IEC 60068-2-27:2008)

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 60601-1:2006, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)

EN 60601-1:2006/A1:2013, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A1:2012)

EN 62304:2006, Medical devices software – Software life-cycle processes (IEC 62304:2006)

EN 62366:2008, Medical devices – Application of usability engineering to medical devices (IEC 62366:2007)

EN ISO 10993-1:2009, Biological testing of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2003)

EN ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)

EN ISO 14155:2011-10, Clinical investigation of medical devices for human subjects -- Good clinical practice (ISO 14155:2011)

EN ISO 14971:2012, Medical devices – Application of risk management to medical devices (ISO 14971:2007)

ISO 8601:2004, Data elements and interchange formats – Information interchange – Representation of dates and times

Terms and definitions 3

For the purposes of this document, the following terms and definitions apply.

3.1

ACTIVE MEDICAL DEVICE

MEDICAL DEVICE relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.2

ACTIVE IMPLANTABLE MEDICAL DEVICE

ACTIVE MEDICAL DEVICE which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

Note 1 to entry: For purposes of this part of EN 45502, an ACTIVE IMPLANTABLE MEDICAL DEVICE can be a single ACTIVE MEDICAL DEVICE, or a system consisting of a set of components and accessories, including software, which interact to achieve the performance intended by the MANUFACTURER. Not all of these components or accessories may be required to be partially or totally implanted.

3.3

AUTHORIZED REPRESENTATIVE

any natural or legal person established in the European Community who, explicitly designated by the MANUFACTURER, acts and can be addressed by authorities and bodies in the Community instead of the MANUFACTURER with regard to the latter's obligations

3.4

BEGINNING OF SERVICE

BOS

when an individual ACTIVE IMPLANTABLE MEDICAL DEVICE is first released by the MANUFACTURER as fit for placing on the market

3.5

CATHETER

flexible tube allowing access to a point within the body at its distal end through a lumen, often for delivering a substance 2 172 .'

Note 1 to entry: A CATHETER CAN be combined with a LEAD.

3.6

CORRECT USE NORMAL USE without USE ERROR

[SOURCE: EN 62366:2008, 3.7]

3.7

END OF SERVICE

EOS

point at which an individual PROLONGED SERVICE PERIOD has elapsed and performance to design specification cannot be assured