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Utgåva 1

Aktiva implanterbara medicintekniska produkter –
Del 2-1: Särskilda krav för aktiva implanterbara
medicintekniska produkter avsedda att behandla
bradyarytmier (pacemakers)

Active implantable medical devices –
Part 2-1: Particular requirements for active implantable
medical devices intended to treat bradyarrhythmia
(cardiac pacemakers)

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The European Standard EN 45502-2-1:2004 has the status of a Swedish Standard. This document contains the official English version of EN 45502-2-1:2004.

This standard supersedes the Swedish Standards SS-EN 50061, edition 1 and SS-EN 50061/A1, edition 1, which will be withdrawn at latest by September 2005.

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Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)

Dispositifs médicaux implantables actifs - Partie 2-1:
Règles particulières pour les dispositifs médicaux implantables actifs destinés à traiter la bradyarythmie (stimulateurs cardiaques)

Aktive implantierbare medizinische Geräte - Teil 2-1:
Besondere Festlegungen für aktive implantierbare medizinische Geräte zur Behandlung von Bradyarrhythmie (Herzschrittmacher)

This European Standard was approved by CEN and CENELEC on 1 September 2003.

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 Management Centre or to any CEN or CENELEC member.

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Foreword

This European Standard has been prepared by the CEN/CENELEC Joint Working Group on Active Implantable Medical Devices (CEN/CLC JWG AIMD). Members of the Joint Working Group were nominated by one of the member bodies of either CEN or CENELEC.

The text of the draft was submitted to the formal vote and was approved by CEN and CENELEC as EN 45502-2-1 on 2003-09-01.

This European Standard, together with EN 45502-2-2, supersedes EN 50061:1988 + A1:1995 + A1:1995/corrigendum Oct. 1995.

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) 2004-09-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2005-09-01

This European Standard has been prepared under mandates given to CEN and CENELEC by the Commission of the European Communities and the European Free Trade Association, and supports essential requirements of Directive 90/385/EEC.

EN 45502-2-1:2004 is identical to EN 45502-2-1:2003 issued by CENELEC on 2003-12-19.

Contents

		Page
	Introduction	7
1	Scope	8
2	Normative references	8
3	Definitions	9
4	Symbols and abbreviations (optional).....	13
5	General requirements for non-implantable parts	13
6	Measurement of implantable pulse generator and lead characteristics	13
7	General arrangement of the packaging	28
8	General markings for active implantable medical devices.....	28
9	Markings on the sales packaging	28
10	Construction of the sales packaging.....	29
11	Markings on the sterile pack	29
12	Construction of the non-reusable pack	30
13	Markings on the active implantable medical device.....	31
14	Protection from unintentional biological effects being caused by the active implantable medical device	32
15	Protection from harm to the patient or user caused by external physical features of the active implantable medical device	32
16	Protection from harm to the patient caused by electricity	32
17	Protection from harm to the patient caused by heat.....	33
18	Protection from ionizing radiation released or emitted from the active implantable medical device.....	33
19	Protection from unintended effects caused by the device	34
20	Protection of the device from damage caused by external defibrillators	35
21	Protection of the device from changes caused by high power electrical fields applied directly to the patient.....	35
22	Protection of the active implantable medical device from changes caused by miscellaneous medical treatments	35
23	Protection of the active implantable medical device from mechanical forces.	36
24	Protection of the active implantable medical device from damage caused by electrostatic discharge	40
25	Protection of the active implantable medical device from damage caused by atmospheric pressure changes	40
26	Protection of the active implantable medical device from damage caused by temperature changes.	40

EN 45502-2-1:2004

(issued by CENELEC as EN 45502-2-1:2003)

27	Protection of the active implantable medical device from electromagnetic non-ionizing radiation.....	40
28	Accompanying documentation.....	56
Annex AA (informative)	Table of cross-references from 90/385/EEC to EN 45502-2-1	61
Annex BB (informative)	Relationship between the clauses of EN 45502-2-1 and the essential requirements of 90/385/EEC listed in Annex AA	72
Annex CC (informative)	Notes on EN 45502-2-1	74
Annex DD (informative)	Code for describing modes of implantable pulse generators.....	84
Annex EE (informative)	Symbols.....	88
Annex FF (normative)	Pulse forms.....	89
Annex GG (normative)	Interface circuits	90
Annex HH (informative)	Selection of capacitor C_x	93
Annex II (normative)	Calibration of the injection network, Figure GG.104	94

Figures

Figure 101	- Measurement of pulse amplitude, pulse duration, pulse interval and pulse rate	15
Figure 102	- Sensitivity measurement	16
Figure 103	- Input impedance measurement	16
Figure 104	- Escape interval measurement.....	17
Figure 105	- Initial oscilloscope display, when measuring the escape interval.....	18
Figure 106	- Measurement of escape interval (t_e) in inhibited mode	18
Figure 107	- Measurements of escape interval (t_e) in triggered (synchronised) mode.....	18
Figure 108	- Refractory period measurement.....	19
Figure 109	- Initial oscilloscope display when measuring sensing and pacing refractory period.....	19
Figure 110	- Measurement of sensing refractory period in inhibited mode - A.....	20
Figure 111	- Measurement of sensing refractory period in Inhibited mode - B.....	20
Figure 112	- Measurement of sensing refractory period in triggered (synchronous) mode - A.....	20
Figure 113	- Measurement of sensing refractory period in triggered (synchronous) mode - B	21
Figure 114	- Measurement of pacing refractory period in inhibited mode	21
Figure 115	- Oscilloscope display when measuring AV interval	22
Figure 116	- Post ventricular atrial refractory period (PVARP) measurement.....	23
Figure 117	- Initial oscilloscope display when measuring PVARP.....	23
Figure 118	- Oscilloscope display when measuring PVARP	23
Figure 119	- AV INTERVAL after sensing measurement	24
Figure 120	- Oscilloscope display when measuring the AV interval after sensing	24

Figure 121 - Determination of the lead pacing impedance of a unipolar lead25

Figure 122 - Determination of the lead pacing impedance of a bipolar lead26

Figure 123 - Determination of the lead sensing impedance of a unipolar lead27

Figure 124 - Determination of the lead sensing impedance of a bipolar lead27

Figure 125 - Test set-up for measurement of electrical neutrality33

Figure 126 - Test set-up for proof protection from high frequency currents caused by surgical
equipment35

Figure 127 - Conductor flex test fixture38

Figure 128 - Connector flex test fixture39

Figure 129 - Test signal 242

Figure 130 - Test set-up for measurement of induced current flow42

Figure 131 - Connection to a single channel unipolar pulse generator43

Figure 132 - Connection to a multichannel unipolar pulse generator43

Figure 133 - Common mode connection to single channel bipolar pulse generator43

Figure 134 - Differential mode connection to single channel bipolar pulse generator43

Figure 135 - Common mode connection to multichannel bipolar pulse generator44

Figure 136 - Differential mode connection to multichannel bipolar pulse generator44

Figure 137 - Test set-up to check for induced malfunction45

Figure 138 - Connection to a single channel unipolar pulse generator45

Figure 139 - Connection to a multichannel unipolar pulse generator46

Figure 140 - Common mode connection to a single channel bipolar pulse generator46

Figure 141 - Differential mode connection to a single channel bipolar pulse generator46

Figure 142 - Common mode connection to a multi channel bipolar pulse generator47

Figure 143 - Differential mode connection to a multi channel bipolar pulse generator47

Figure 144 - Test set-up to characterise performance while subject to interference48

Figure 145 - Test signal for frequencies in the range 16,6 Hz - 150 kHz49

Figure 146 - Test signal for frequencies 150 kHz - 450 MHz51

Figure 147 – Test set-up to check for malfunction at high frequency52

Figure 148 - Connection to a unipolar pulse generator52

Figure 149 - Connection to a bipolar pulse generator53

Figure 150 - Test set-up for magnetostatic measurements54

Figure 151 - Loop configuration for varying magnetic field test55

Figure CC.101 - Measurement of x74

Figure CC.102 - Reference test coil78

Figure FF.101 - Measurement of pulse duration89

EN 45502-2-1:2004

(issued by CENELEC as EN 45502-2-1:2003)

Figure FF.102 - Measurement of pulse amplitude.....89

Figure FF.103 - Form of signal from a test signal generator used for the exact determination of sensitivity (sensing threshold)..... 89

Figure GG.101 - Tissue equivalent interface circuit for current measurements.....90

Figure GG.102 - Tissue equivalent interface circuit to check for malfunction90

Figure GG.103 - Low pass filter used to attenuate the 500 kHz component of the test signal91

Figure GG.104 - Injection network.....91

Figure HH.101 - Test to check for spurious low frequency noise and to determine the value of C_x93

Tables

Table 101 - Overall measurement accuracy limits14

Table 102 - Overall measurement accuracy limits25

Table 103 - Settings for determining the projected service life.....34

Table 104 - Spurious injection current limits.....44

Table 105 - Peak to peak amplitudes V_{pp} in the range 16,6 Hz to 150 kHz50

Table 106 - Peak to peak amplitudes V_{pp} in the range 150 kHz to 10 MHz51

Table 107 - Sinusoidally modulated magnetic field strengths55

Table AA.161

Table BB.172

Table DD.101 - Basic mode code scheme84

Table DD.102 - Examples of mode code85

Table EE.101 - Conventional symbols.....88

Table GG.101 - Component values for Figure GG.101.....92

Table GG.102 - Component values for Figure GG.102.....92

Table GG.103 - Component values for Figure GG.103.....92

Table GG.104 - Component values for Figure GG.104.....92

Table II.101 – Calibration signal amplitude.....95

Introduction

This Part 2-1 specifies particular requirements for those ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmias (PACEMAKERS), to provide basic assurance of safety to both patients and users.

An implantable cardiac PACEMAKER is essentially a powered electronic device within a sealed, encapsulating enclosure (an IMPLANTABLE PULSE GENERATOR). The device can stimulate heart beats by generating electrical impulses which are transmitted to the heart along implanted, insulated conductors with ELECTRODES (LEADS). The PACEMAKER may be adjusted non-invasively by an electronic device, known as a programmer.

This Part 2-1 is relevant to all parts of implantable PACEMAKERS, including all accessories. Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, pro-programmers and the related software.

The requirements of this Part 2-1 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 Part 2-1 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.

Although both this Part 2-1 and the Directive 90/385/EEC deal with the same products, the structure and purpose of the two documents are different. Annex AA of this Part 2-1 correlates the requirements of the Directive with the subclauses of EN 45502-1:1997 and this Part 2-1. Annex BB provides reference in the other direction, from this European Standard to the Directive. Annex CC is a rationale providing further explanation of the subclauses of this Part 2-1.

Annex DD describes a coding system that may be used to designate bradyarrhythmia pacing modes. Annex EE provides optional symbols that may be used to reduce the need for translation of MARKINGS and information in the accompanying documentation in multiple languages. Annex FF defines reference points for measurements of PULSE AMPLITUDE and PULSE DURATION, and the form of test signal used to determine SENSITIVITY. Annex GG defines the tissue equivalent interface circuits, signal injection network and low pass filter required for some compliance tests. Annex HH describes a method for selecting the filter capacitor used in the tissue equivalent interface circuits defined by Annex GG. Annex II defines the method of calibrating the injection network defined by Annex GG.

All annexes except Annex FF, GG and II are informative.

EN 45502-2-1:2004

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1 Scope

This Part 2-1 specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat bradyarrhythmias.

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 2-1 is also applicable to some non-implantable parts and accessories of the devices (see Note 1).

The characteristics of the IMPLANTABLE PULSE GENERATOR or LEAD shall be determined by either the appropriate method detailed in this Part 2-1 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 2-1 shall apply.

Any features of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat tachyarrhythmias are covered by EN 45502-2-2.

NOTE 1 The device that is commonly referred to as an active implantable medical device may 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 device.

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 28601:1992	Data elements and interchange formats – Information interchange – Representation of dates and times (ISO 8601:1988 + technical corrigendum 1:1991)
EN 45502-1:1997	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-2 ¹⁾	Active implantable medical devices – Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)
EN 60068-2-27:1993	Basic environmental testing procedures – Part 2: Tests – Test Ea and guidance: Shock (IEC 60068-2-27:1987)

¹⁾ At draft stage.

EN 60068-2-47:1999	Environmental testing – Part 2-47: Test methods – Mounting of components, equipment and other articles for vibration, impact and similar dynamic tests (IEC 60068-2-47:1999)
EN 60068-2-64:1994	Environmental testing – Part 2: Test methods – Test Fh: Vibration, broad-band random (digital control) and guidance (IEC 60068-2-64:1993 + corr. Oct. 1993)
ISO 5841-3:1992	Low profile connectors (IS1) for implantable pacemakers
ISO 11318:1993	Cardiac defibrillators – Connector assembly DF-1 for implantable defibrillators – Dimensions and test requirements
ANSI/AAMI PC69-2000	Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

3 Definitions

This clause of Part 1 applies.

Additional definitions:

3.3.1

implantable pulse generator (IPG)

part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, including the power supply and electronic circuit, that produces an electrical output

NOTE For purposes of this Part 2-1, the term implantable pulse generator describes any ACTIVE IMPLANTABLE MEDICAL DEVICE that incorporates functions intended to treat bradyarrhythmias.

3.3.2

pacemaker

ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias, comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S)

3.3.3

sensor

special part of a PACEMAKER that is designed to detect signals for the purpose of RATE MODULATION or other control purposes

3.3.4

terminal

electrically separate conductive device connection

3.3.5

adaptor

special connector used between an otherwise incompatible IMPLANTABLE PULSE GENERATOR and a LEAD

3.3.6

pulse

electrical output of an IMPLANTABLE PULSE GENERATOR intended to stimulate the myocardium