SLOVENSKI STANDARD
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Aktivni medicinski pripomočki za vsaditev - 2-1. del: Posebne zahteve za vsadke, namenjene zdravljenju bradiaritmij (srčni spodbujevalniki)

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

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

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

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

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EUROPEAN STANDARD **EN 45502-2-1**

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English version

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 2003-09-01. 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 Central Secretariat 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

CEN/CENELEC

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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.

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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-grammers 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.

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

3.3.7
pulse amplitude
the time integral over current or voltage, as appropriate, divided by the PULSE DURATION [see 6.1.1]

3.3.8
pulse duration
duration of the PULSE, measured between two reference points specified in Part 2-1 [see 6.1.1]

3.3.9
pulse interval
interval between equivalent points of two consecutive PULSES [see 6.1.1]

3.3.10
basic pulse interval
PULSE INTERVAL in the absence of sensed cardiac or other electrical influence

3.3.11
escape interval
time elapsing between the sensing of a spontaneous BEAT and the succeeding non-triggered PULSE of an IMPLANTABLE PULSE GENERATOR [see 6.1.4]

3.3.12
hysteresis
characteristic of an IMPLANTABLE PULSE GENERATOR defined by the difference between the ESCAPE INTERVAL and the BASIC PULSE INTERVAL

NOTE The ESCAPE INTERVAL is normally longer than the BASIC PULSE INTERVAL — this is “positive” HYSTERESIS.

3.3.13
AV interval; atrioventricular interval
delay between an atrial PULSE or the sensing of an atrial depolarisation and the subsequent ventricular PULSE or the sensing of a ventricular depolarisation [see 6.1.7]

3.3.14
test pulse interval
PULSE INTERVAL of an IMPLANTABLE PULSE GENERATOR when directly influenced by a testing device

3.3.15
pulse rate
number of PULSES per minute [see 6.1.1]

3.3.16
basic rate
PULSE RATE of an IMPLANTABLE PULSE GENERATOR, either atrial or ventricular, unmodified by sensed cardiac or other electrical influence

3.3.17
interference pulse rate
PULSE RATE with which the IMPLANTABLE PULSE GENERATOR responds when it senses electrical activity other than that from the myocardium that it recognises as interference

3.3.18
maximum tracking rate
maximum PULSE RATE at which the IMPLANTABLE PULSE GENERATOR will respond on a 1:1 basis to a triggering signal

3.3.19
rate modulation
altering of the PULSE RATE as a function of a control parameter other than a sensed BEAT

3.3.20
test pulse rate
PULSE RATE of an IMPLANTABLE PULSE GENERATOR when directly influenced by a testing device

3.3.21
input impedance; Z_{in} (of an IMPLANTABLE PULSE GENERATOR)
electrical impedance presented at an input TERMINAL [see 6.1.3] and taken as equal to the electrical loading presented to a sensed BEAT

3.3.22
sensitivity; sensing threshold
minimum signal required to control consistently the function of the IMPLANTABLE PULSE GENERATOR [see 6.1.2]

3.3.23
refractory period
period during which an IMPLANTABLE PULSE GENERATOR will not respond to a BEAT [see 6.1.5 and 6.1.6]

3.5.1
electrode
electrically conducting part (usually the termination of a LEAD) which is designed to form an interface with body tissue or body fluid

3.5.2
unipolar lead
LEAD with one ELECTRODE

3.5.3
bipolar lead
LEAD with two ELECTRODES that are electrically isolated from each other

3.5.4
endocardial lead
LEAD with an ELECTRODE designed to make a contact with the endocardium, or inner surface of the heart. [cf. epicardial lead, a LEAD with an ELECTRODE designed to make a contact with the epicardium, or outer surface of the heart.]

3.5.5
insertion diameter (of a lead)
minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) may be inserted

3.5.6
lead conductor resistance, R_c
ohmic resistance between the ELECTRODE and the corresponding lead connector TERMINAL [see 6.2.1]

3.5.7
lead pacing impedance; Z_p
impedance that is formed by the ratio of a voltage PULSE to the resulting current [see 6.2.2]. The impedance is composed of the ELECTRODE/tissue interface and the LEAD CONDUCTOR RESISTANCE

3.5.8
lead sensing impedance; Z_s
source impedance of a LEAD as seen by an IMPLANTABLE PULSE GENERATOR [see 6.2.3]

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
beginning of service (BOS)
when an individual IMPLANTABLE PULSE GENERATOR is first released by the manufacturer as fit for placing on the market

3.20.2
end of service (EOS)
when the PROLONGED SERVICE PERIOD has elapsed and performance to design specification cannot be assured

3.20.3
projected service life
period from the implantation of the IMPLANTABLE PULSE GENERATOR to the RECOMMENDED REPLACEMENT TIME under defined conditions

3.20.4
prolonged service period (PSP)

period during which the IMPLANTABLE PULSE GENERATOR continues to function as defined by the manufacturer to prolong basic bradyarrhythmia pacing beyond the RECOMMENDED REPLACEMENT TIME

3.20.5
power source indicator
means of indicating the electrical status of the power source during the IMPLANTABLE PULSE GENERATOR's service life

3.20.6
recommended replacement time (RRT)
when the POWER SOURCE INDICATOR reaches the value set by the manufacturer of the IMPLANTABLE PULSE GENERATOR for its recommended replacement. (This indicates entry into the PROLONGED SERVICE PERIOD)

3.20.7
stoichïometric capacity
energy capacity as defined by the content of electro-chemically active materials in the power source

3.20.8
use-before date
date after which the manufacturer recommends that the IMPLANTABLE MEDICAL DEVICE should not be used

3.20.9
usable capacity
portion of the STOICHÏOMETRIC CAPACITY of the power source that can be utilised by the IMPLANTABLE PULSE GENERATOR until END OF SERVICE is reached

3.21.1
beat
ordered spontaneous activity of the heart

3.21.2
transvenous
approach to the heart through the venous system.

3.21.3
dual-chamber
(adj.) relating both to the atrium and ventricle

4 Symbols and abbreviations (optional)

This clause of Part 1 applies.

Additional note:

NOTE See informative Annex EE for optional symbols for use in expressing information so as to reduce the need for the use of multiple languages on packaging and manuals.

5 General requirements for non-implantable parts

This clause of Part 1 applies.

6 (Vacant)

Delete and replace as follows:

6 Measurement of IMPLANTABLE PULSE GENERATOR and LEAD characteristics

6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics

The values of the electrical characteristics for the IMPLANTABLE PULSE GENERATOR measured in accordance with the methods described in this clause shall be within the range of values stated by the manufacturer in the accompanying documentation [see 28.8]

The procedures shall be performed with the IMPLANTABLE PULSE GENERATOR at a temperature of 37 ºC ± 2 ºC, connected to a load of 500 Ω ± 1 % and set to the nominal settings recommended by the manufacturer (the factory recommended settings), unless otherwise stated.