SWEDISH STANDARDS INSTITUTE

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SS-EN 45502-2-1:2004

Fastställd 2004-10-01

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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Denna standard ersätter SS-EN 50061, utgåva 1 och SS-EN 50061/A1, utgåva 1 som kommer att upphävas senast i september 2005.

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This standard supersedes the Swedish Standards SS-EN 50061, edition 1 and SS-EN 50061/A1, edition 1, which will be withdrawn at latest by September 2005.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 45502-2-1

September 2004

ICS 11.040.40

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 1 September 2003.

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Ref. No. EN 45502-2-1:2004 E

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.

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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