BRITISH STANDARD

BS EN
45502-2-1:2003

# Active implantable medical devices —

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

The European Standard EN 45502-2-1:2003 has the status of a British Standard

ICS 11.040.40



BSI
British Standards

# National foreword

This British Standard is the official English language version of EN 45502-2-1:2003. It supersedes BS 6902-1:1990 and BS 6902-1:Supplement No. 1:1996 which are withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery, to Subcommittee CH/150/6, Active implants, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

**Cross-references**

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

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

NORME EUROPÉENNE

EUROPÄISCHE NORM December 2003

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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.