



National Standards Authority of Ireland

STANDARD

I.S. EN 45502-2-1:2004

ICS 11.040.40

**ACTIVE IMPLANTABLE MEDICAL DEVICES -
PART 2-1: PARTICULAR REQUIREMENTS
FOR ACTIVE IMPLANTABLE MEDICAL
DEVICES INTENDED TO TREAT
BRADYARRHYTHMIA (CARDIAC
PACEMAKERS)**

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*This Irish Standard was
published under the
authority of the National
Standards Authority of
Ireland
and comes into effect on:
November 12, 2004*

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Údarás um Chaighdeán Náisiúnta na hÉireann

EUROPEAN STANDARD

EN 45502-2-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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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EN 45502-2-1:2004

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

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 (dop) 2004-09-01
at national level by publication of an identical national
standard or by endorsement
- latest date by which the national standards (dow) 2005-09-01
conflicting with the EN have to be withdrawn

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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