National Standards Authority of Ireland
Údarás um Chaighdeáin Náisiúnta na hÉireann

IRISH STANDARD

I.S. EN 45502-2-2:2008

ICS 11.040.40

ACTIVE IMPLANTABLE MEDICAL DEVICES -- PART 2-2: PARTICULAR REQUIREMENTS FOR ACTIVE IMPLANTABLE MEDICAL DEVICES INTENDED TO TREAT TACHYARRHYTHMIA (INCLUDES IMPLANTABLE DEFIBRILLATORS)

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This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:
16 May 2008

Price Code AB

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I.S. EN 45502-2-2:2008

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 45502-2-2

March 2008

ICS 11.040.40

Partially supersedes EN 50061:1988 + A1:1995

English version

Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)

Dispositifs médicaux implantables actifs - Partie 2-2: Exigences particulières pour les dispositifs médicaux implantables actifs destinés au traitement des tachyarythmies (y compris les défibrillateurs implantables)

Aktive implantierbare Medizingeräte - Teil 2-2: Besondere Festlegungen für aktive implantierbare medizinische Produkte zur Behandlung von Tachyarrhythmie (einschließlich implantierbaren Defibrillatoren)

This European Standard was approved by CENELEC on 2007-05-01. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 45502-2-2:2008 E

Foreword

This European Standard was prepared by the CEN/CENELEC Joint Working Group on ACTIVE IMPLANTABLE MEDICAL DEVICES (CEN/CLC JWG AIMD).

The text of the draft was submitted to the formal vote and was approved by CENELEC as EN 45502-2-2 on 2007-05-01.

This European Standard, together with EN 45502-2-1:2003, supersedes EN 50061:1988 + A1:1995 (+ corrigendum October 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)	2008-10-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-05-01

The requirements of this Particular Standard 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.

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 members of either CEN or CENELEC.

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 the essential requirements of Directive 90/385/EEC Council Directive of June 1990 on the approximation of the laws of the Member states relating to active implantable medical devices.

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

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Contents

Introduction

This Particular Standard specifies particular requirements for IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia, to provide basic assurance of safety for both patients and users.

An external defibrillator is a MEDICAL DEVICE used, in the emergency setting, to deliver a high-energy shock to the heart, by means of ELECTRODES applied to the external chest wall, in patients suffering ventricular fibrillation (a rapid, disorganized and potentially lethal heart rhythm abnormality), to restore normal heart action. External defibrillators may also be used, in emergency or elective settings, to terminate other ventricular or atrial tachyarrhythmias by delivery of a high-energy shock, synchronised to the intrinsic cardiac rhythm, a procedure known as CARDIOVERSION. In patients known to be at risk of such arrhythmias, due to the occurrence of previous episodes or the presence of specific pre-disposing cardiac conditions, an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR may be implanted to perform similar functions. The implantable device, which is much smaller than an external defibrillator, is contained within a sealed, encapsulating enclosure. It generates high voltage PULSES from an enclosed, miniature, electrical battery. The PULSES are transmitted to the heart by means of implanted, insulated conductors with ELECTRODES (LEADS) The IMPLANTABLE CARDIOVERTER DEFIBRILLATOR may also incorporate other sensing and pacing functions, such as rate support for bradycardia and ANTITACHYCARDIA PACING (ATP) to terminate certain tachyarrhythmias without the need of a high-energy shock. The defibrillator may be adjusted non-invasively by means of an electronic device, known as a programmer.

This Particular Standard is relevant to all parts of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia other than pacing functions to control bradyarrhythmia. Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, ACCESSORIES, programmers and the related software. (Bradyarrhythmia pacing functions are dealt with in EN 45502-2-1).

The requirements of this Particular Standard supplement or modify those of EN 45502-1:1997, *Active Implantable Medical Devices – Part 1: General requirements for safety, marking and for the information to be provided by the manufacturer*, hereinafter referred to as the General Standard. The requirements of this particular standard take priority over those of the General Standard.

Figures or tables that are additional to those of the General Standard are numbered starting from 101; additional annexes are lettered AA, BB, etc.

Annex DD describes a coding system that may be used to designate tachyarrhythmia therapy modes. Annex EE defines the tissue equivalent interface circuits and low pass filter required for some compliance tests. Annex FF describes a method for selecting the filter capacitor used in the tissue equivalent interface circuits defined by Annex EE. Annex GG defines the method of calibrating the injection network defined by Annex EE. All annexes except Annex EE and Annex GG are informative.

1 Scope

This Part 2-2 of EN 45502 specifies requirements that are applicable to IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia.

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 of EN 45502 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 particular standard or by any other method demonstrated to have accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this Particular Standard shall apply.

Any aspect of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias is covered by EN 45502–2-1 *Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (Pacemakers).*

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.

NOTE 4 Particular requirements for congestive heart failure devices are under consideration. These types of devices are not covered by this standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

This clause of the General Standard aplies except as follows:

Additional references:

Publication	Year	Title
EN 980		Graphical symbols for use in the labelling of medical devices
EN 28601		Data elements and interchange formats – Information interchange – Representation of dates and times (ISO 8601 + technical corrigendum 1)
EN 45502-1		Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1		Active implantable medical devices – Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)

EN 60068-2-27	Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock (IEC 60068–2–27)
EN 60068-2-47	Environmental testing – Part 2-47: Tests – Mounting of specimens for vibration, impact and similar dynamic tests (IEC 60068-2-47)
EN 60068-2-64	Environmental testing – Part 2: Test methods – Test Fh: Vibration, broad-band random (digital control) and guidance (IEC 60068-2-64)
IEC 60878	Graphical symbols for electrical equipment in medical practice
ISO 5841-3 + corr. 1	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
ISO 11318	Cardiac defibrillators – Connector assembly DF-1 for implantable defibrillators – Dimensions and test requirements
ANSI/AAMI PC69	Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

3 Definitions

This clause of the General Standard applies except as follows:

Additional definitions:

3.3.1
adaptor
special connector used between an otherwise incompatible IMPLANTABLE PULSE GENERATOR and a LEAD

3.3.2
implantable cardioverter defibrillator (ICD)
ACTIVE IMPLANTABLE MEDICAL DEVICE comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S) that is intended to detect and correct tachycardias and fibrillation by application of CARDIOVERSION/-DEFIBRILLATION PULSE(S) to the heart

3.3.3
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 Particular Standard, the term IMPLANTABLE PULSE GENERATOR describes any ACTIVE IMPLANTABLE MEDICAL DEVICE that incorporates functions intended to treat tachyarrhythmias.

3.3.4
sensitivity (sensing threshold)
minimum signal required to control consistently the function of the IMPLANTABLE PULSE GENERATOR [see 6.1.5]

3.3.5
sensor
special part of an IMPLANTABLE PULSE GENERATOR that is designed to detect signals for the purpose of RATE MODULATION or other control purposes

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