Safety of implantable cardiac pacemakers

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 50061:2002 sisaldab Euroopa standardi EN 50061:1988+A1:1995 ingliskeelset teksti.	This Estonian standard EVS-EN 50061:2002 consists of the English text of the European standard EN 50061:1988+A1:1995.
Standard on kinnitatud Eesti Standardikeskuse 18.12.2002 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 18.12.2002 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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definitions, marking, medical electrical equipment, pacemakers, performance tests, surgical implants, tests

EUROPEAN STANDARD
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English version

Safety of implantable cardiac pacemakers

Sécurité des stimulateurs cardiaques implantables

Sicherheit implantierbarer Herzschrittmacher

This European Standard was ratified by CENELEC on 1 March 1988. CENELEC members are bound to comply with the requirements of the CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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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 CENELEC Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

Central Secretariat: Rue Bréderode 2, B-1000 Brussels

Brief history

The European Standard 50 061 was prepared by TC 62 of CENELEC; it was submitted to the CENELEC members for formal vote and acceptance as a European Standard (EN) by CENELEC.

Technical text

The text of the European Standard 50 061 was approved by all CENELEC members with the exception of Austria and Norway on 1 March 1988.

The following dates were fixed:

- date of announcement (doa): 1988-09-01
- date of latest publication (dop): 1989-01-01
- date of withdrawal of conflicting national standards (dow): 1989-01-01

CENELEC

Safety of implantable cardiac pacemakers

0 Introduction

This standard was prepared by a working group of CENELEC/TC 62 "Electroradiological and Electromedical Equipment". In preparing this standard for cardiac pacemakers, the working group was faced with a variety of problems.

Pacemakers which are used nowadays differ considerably in their mode of operation and longevity. These medical devices are also subject to frequent and rapid technical development. Because of this, the standard cannot state all the necessary requirements for pacemakers. In addition, a standard for pacemakers which specifies certain constructional requirements would hamper future medical and technical development.

Thus, when stipulating safety requirements for pacemakers, the working group set as its objectives:

* to improve communication between manufacturers and users, as well as among the users themselves, by providing appropriate terminology and documentation, which would lead to easier comparability of different pacemaker makes and models;
* to increase the protection of patients against hazards caused by malfunction or by exogenous influences.

It is not the purpose of this standard to specify the level of quality and reliability of individual products because the working group acknowledged the central role of clinical experience in setting required levels of reliability and performance.

NOTE. This standard covers besides others the mechanical safety and among the electrical hazards the safety during defibrillation. It does not cover safety aspects of electro-magnetic compatibility and high frequency electro-surgery. These aspects are under consideration at the present time.

1 Scope and field of application

This standard specifies safety and other requirements exclusively for all types of wholly implantable cardiac PACEMAKERS.

This standard also establishes basic terminology and definitions and includes requirements for the marking of PACEMAKERS and their packaging. In addition, minimum requirements are specified for the ability of PACEMAKERS to withstand environmental stress conditions. Appropriate test methods are given. This standard specifies the requirements for the reliable operation of PACEMAKERS only insofar as they affect safety.

It does not cover the antitachyarrythmia and defibrillation functions of PACEMAKERS, nor PACEMAKERS operated by isotopic cells.

2 Terminology

The following terms given in this Clause have been established to encourage common usage. Sub-clause **2.4** presents the terminology particular to the modes of PULSE GENERATORS and uses the coding system described in annex A.

2.1 A-V interval (atrio-ventricular interval)
The delay between an atrial PULSE or the sensing of an atrial depolarization and the subsequent ventricular PULSE or the sensing of a ventricular depolarization.

2.2 V-A interval (ventricular-atrial interval)
The delay between a ventricular PULSE or the sensing of a ventricular depolarization and the subsequent atrial PULSE or the sensing of an atrial depolarization.

2.3 Blanking period
Period during which a sensing function of a PULSE GENERATOR is disabled.

2.4 Modes of pulse generators
The definitions that follow describe the mode of operation of PULSE GENERATORS. A system of coding modes is described in annex A.

2.4.1 Atrial asynchronous mode (AOO)
Mode in which an atrial PULSE is provided independent of the activity of the heart. Ventricular functions and atrial sensing are disabled or absent.

2.4.2 Atrial inhibited mode (AAI)
Mode where if during the ESCAPE INTERVAL the atrial sensing function detects a BEAT, then the PULSE GENERATOR suppresses atrial pacing. If the sensed atrial BEAT occurs after the ESCAPE INTERVAL, then the PULSE GENERATOR provides atrial pacing at the BASIC RATE. Ventricular functions are disabled or absent.

2.4.3 Atrial triggered mode (AAT)
Mode where if during the ESCAPE INTERVAL the atrial sensing function detects a BEAT, then an atrial PULSE is produced in synchrony with the atrial BEAT (provided that the MAXIMUM TRACKING RATE is not exceeded). If the sensed atrial BEAT occurs after the ESCAPE INTERVAL, then the PULSE GENERATOR provides atrial pacing at the BASIC RATE. Ventricular functions are disabled or absent.

2.4.4 A-V sequential, asynchronous mode (DOO)
Mode in which the PULSE GENERATOR provides atrial pacing at the BASIC RATE. At the specified A-V interval after each atrial PULSE, a ventricular PULSE is provided independent of the activity of the heart. Atrial and ventricular sensing functions are disabled or absent.

2.4.5 A-V sequential mode with ventricular sense (inhibition) (DVI)
Mode in which the atrial sensing function is disabled or absent, and the PULSE GENERATOR provides atrial pacing at the BASIC RATE. If a spontaneous ventricular BEAT is not sensed during the specified A-V interval after each atrial PULSE, a ventricular PULSE is provided.

2.4.6 A-V sequential, ventricular synchronized (triggered) mode (DVT)
Mode in which the PULSE GENERATOR provides atrial pacing at the BASIC RATE. After each atrial PULSE, during a period equal to the set A-V interval, a ventricular PULSE is provided in synchrony with a spontaneous ventricular BEAT. If no ventricular BEAT is sensed in that period, then a ventricular PULSE is immediately provided. The atrial sensing function is disabled or absent.