

Cardiac pacemakers —

Part 1: Specification for implantable cardiac pacemakers

This European Standard EN 50061 has the status of a British Standard.

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National foreword

This Part of BS 6902 has been prepared under the direction of the Health Care Standards Policy Committee and is the English language version of EN 50061 “*Safety of implantable cardiac pacemakers*”, published by the European Committee for Electrotechnical Standardization (CENELEC).

BS 6902 is intended to cover the various aspects of cardiac pacemakers, including pulse generators and connecting devices (see Additional Information below), and is published in a number of Parts. BS 6902-2 “*Method of reporting the clinical performance of populations of pulse generators*” was first published in 1987; other Parts are in preparation.

This Part of BS 6902 is closely related to the second edition of ISO 5841-1 “*Implants for surgery — Cardiac pacemakers — Part 1: Implantable pacemakers*” on which EN 50061 was based. This second edition of ISO 5841-1 was published by ISO in 1990 but, because it is not identical to EN 50061, it cannot be implemented as a dual-numbered part of this British Standard.

It has been assumed in the drafting of this British Standard that it will be used and applied by those who are appropriately qualified.

Cross-references. Details of international publications/standards that are quoted in this standard and for which there is an identical or technically equivalent British Standard are given in National appendix Z.

Textual errors. When adopting the text of the European Standard, the textual errors listed below were noted. They have been reported to CENELEC in a proposal to amend the text of the European Standard. These amendments have been incorporated in the second edition of ISO 5841-1.

In 2.4.2, the definition of the term should read:

“**Atrial inhibited mode (AAI):** Mode in which the ventricular functions are disabled or absent. If an atrial BEAT is sensed during the ESCAPE INTERVAL, then the PULSE GENERATOR suppresses atrial pacing. If no atrial BEAT is sensed during the ESCAPE INTERVAL, then the PULSE GENERATOR provides atrial pacing at the BASIC RATE.”

In 2.4.3, the definition of the term should read:

“**Atrial triggered mode (AAT):** Mode in which the ventricular functions are disabled or absent. If an atrial BEAT is sensed during the ESCAPE INTERVAL, then an atrial PULSE is provided immediately in synchrony with the atrial BEAT. If no atrial BEAT is sensed during the ESCAPE INTERVAL, then the PULSE GENERATOR provides atrial pacing at the BASIC RATE.”

In 2.4.5, the definition of the term should read:

“**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 no ventricular BEAT is sensed before the end of the V-A interval. If no ventricular BEAT is sensed during the set A-V interval, a ventricular PULSE is provided at the end of the A-V interval. If at any time a ventricular BEAT is sensed, it starts a new V-A interval.

NOTE If the A-V interval cannot be interrupted by a ventricular beat with a consequent release of a ventricular pulse, the system is said to be “committed”.

In 2.4.6, the definition of the term should read:

“**A-V sequential, ventricular synchronized (triggered) mode (DVT):** Mode in which the atrial sensing function is disabled or absent and the PULSE GENERATOR provides atrial pacing at the BASIC RATE if no ventricular BEAT is sensed before the end of the V-A interval. If no ventricular BEAT is sensed during the set A-V interval, a ventricular PULSE is provided at the end of the A-V interval. If at any time a ventricular BEAT is sensed, a ventricular PULSE is provided immediately and starts a new V-A interval.”

In 2.4.7.1, the definition of the term should read:

“Inhibition in both channels (DDI): Mode in which an atrial BEAT interrupts the PULSE GENERATOR’s atrial ESCAPE INTERVAL and starts a new atrial ESCAPE INTERVAL without release of an atrial PULSE; a ventricular BEAT interrupts a ventricular ESCAPE INTERVAL and starts a new ventricular ESCAPE INTERVAL without release of a ventricular PULSE.”

Additional information. It should be noted that 4.6.1 requires pulse generators to be marked with certain information. Although not stated in 4.6.1, the pulse generator should also be marked with the symbol for the appropriate connector assembly. For example, this symbol could be “IS-1” together with “UNI” or “BI” to indicate respectively, whether the pulse generator requires a monopolar or bipolar connector assembly. The “IS-1” connector assembly has been proposed internationally and is the subject of draft specifications being prepared as Part 3 of ISO 5841 and as an addendum to EN 50061.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 28, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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Descriptors: Medical electrical equipment; surgical implants; pacemakers; definitions; marking; tests; performance tests

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.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CENELEC 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 CENELEC Central Secretariat has the same status as the official versions.

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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

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Brief history

The European Standard 50061 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 50061 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

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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 antitachyarrhythmia 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