Low-profile connector for implantable cardiac pacemakers

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EESTI STANDARDI EESSÕNA

Käesolev Eesti standard EVS-EN 50077:2002 sisaldab Euroopa standardi EN 50077:1993 ingliskeelset teksti. Käesolev dokument on jõustatud 18.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 50077:2002 consists of the English text of the European standard EN 50077:1993. This document is endorsed on 18.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

NATIONAL FOREWORD

Käsitlusala: This European standard specifies a connector assembly to be used to connect implantable pacemaker leads to implantable pulse generators. Essential dimensions and performance requirements are specified, together with appropriate test methods. However, this standard does not address all aspects of the functional compatibility and reliability of different leads and pulse generators assembled into a pacemaker system.	**Scope:** This European standard specifies a connector assembly to be used to connect implantable pacemaker leads to implantable pulse generators. Essential dimensions and performance requirements are specified, together with appropriate test methods. However, this standard does not address all aspects of the functional compatibility and reliability of different leads and pulse generators assembled into a pacemaker system.

ICS 11.040.40

Võtmesõnad: cardiac pacemakers, definitions, design, leads, low-profile connectors, markings, medical electrical equipment, performances, requirements, surgical implants, tests

EUROPEAN STANDARD

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Descriptors: Medical electrical equipment, surgical implants, cardiac pacemakers, leads, low-profile connectors, definitions, design, performances, markings, requirements, tests

English version

Low-profile connector for implantable cardiac pacemakers

Connecteur à bas profil pour stimulateurs cardiaques implantables

Kleiner Profilstecker für implantierbare Herzschrittmacher

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
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Foreword

This standard was prepared by CENELEC TC62 WG Active Implants in parallel with the Joint IEC/ISO International Pacemaker Standards Working Group (ISO TC150/SC2/WG2 and IEC62D/WG6). The document was submitted to the CENELEC members for formal vote in June 1991 and was approved by CENELEC as EN 50077 on 24 March 1992.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1993-12-01
- latest date of withdrawal of conflicting national standards (dow) 1993-12-01

This European Standard is identical to ISO 5841-3 except for minor editorial corrections.

The scope of ISO 5841-3 warns that the standard does not provide a complete specification for a safe working connector pair. In particular, no minimum disconnecting force is specified for the mated connector pair. This, and other essential requirements, are under consideration by the CEN/CENELEC JWG Active Implantable Medical Devices, and will be covered by clauses of EN 46003-1 (in preparation), a harmonised standard relating to the European Council Directive relating to active implantable medical devices of 20 June 1990 (90/385/EEC).

Annex A gives a test method for detemining the electrical separation provided by the mated lead connector, and is an integral part of this standard.

Annex B provides an explanatory rationale for the requirements of this standard, and is an informative annex. It is recommended that this annex be read before using the standard, so that the user may be informed about the limitations in the provisions of this standard.

CONTENTS **Page**

0 Introduction

The development of this standard was prompted by the concern of clinicians over the variety of apparently similar but incompatible pacing leads of the low-profile in-line type. (Because the major diameter of these lead connectors is 3.2 mm, they are generally referred to as "3.2 mm" leads.) The purpose of this European Standard is to specify a standard connector assembly, IS-1, to allow leads and pulse generators from different manufacturers to be interchangeable. The overall safety, reliability and function of particular connector parts remain the responsibility of the manufacturers.

1 Scope

This European standard specifies a connector assembly to be used to connect implantable pacemaker leads to implantable pulse generators. Essential dimensions and performance requirements are specified, together with appropriate test methods. However, this standard does not address all aspects of the functional compatibility and reliability of different leads and pulse generators assembled into a pacemaker system: in particular, this standard does not specify certain essential features, such as the means of fastening the connector assembly, or the materials of construction.

WARNING ***The connector cavity specified in this standard is not to be used with an implantable device if that device is capable of introducing dangerous non-pacing signals (e.g. defibrillation signals) through an IS-1 connector.***

This European standard supplements EN 50061 only for those pacemaker components which are claimed by their labelling to be fitted with an IS-1 connector assembly part. It does not replace any requirement in EN 50061 regarding leads.

2 Normative references

This European standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited

at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

EN 50061	Safety of implantable cardiac pacemakers

NOTE: EN 50061 is technically equivalent to ISO 5840-1: Cardiac Pacemakers - Part 1: Implantable pacemakers.

3 Definitions

For the purposes of this standard, the definitions of EN 50061 and the following definitions apply.

3.1 connector assembly: Assembly consisting of a lead connector and a connector cavity for the electrical and mechanical connection of a lead to a pulse generator.

3.2 lead connector: That part of the connector assembly attached to the lead. (See figure 1.)

3.3 connector cavity: That part of the connector assembly attached to the pulse generator. (See figure 4.)

3.4 sealing ring: Circumferential barrier intended to maintain the electrical separation between electrically isolated parts of the connector assembly.

3.5 seal zone: Surface in the connector cavity on which one or more sealing rings on the lead connector are intended to bear.

3.6 connector cavity go-gauge: Tool for assessing the ability of a connector cavity to accept a lead connector of maximum size. (See figure 5.)