



SLOVENSKI STANDARD

SIST EN 50077:1998

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Low-profile connector for implantable cardiac pacemakers

Low-profile connector for implantable cardiac pacemakers

Kleiner Profilstecker für implantierbare Herzschrittmacher

Connecteur à bas profil pour stimulateurs cardiaques implantables

Ta slovenski standard je istoveten z: EN 50077:1993

[SIST EN 50077:1998](https://standards.iteh.ai/catalog/standards/sist/f5ffa57f-4b98-4432-832b-c646ba977290/sist-en-50077-1998)

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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EUROPEAN STANDARD
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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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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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, 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 de Stassart 35, B - 1050 Brussels

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

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 determining 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.

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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

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

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<https://standards.iteh.ai/catalog/standard/standard/sist/59157f4b98-4432-8321-c646ba977290/sist-en-50077-1998>
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.)

3.7 lead connector go-gauge: Tool for assessing the ability of a lead connector to be inserted into a connector cavity of minimum size. (See figure 2.)

3.8 lead connector ring: For a bipolar lead, the outermost conductive element of the lead connector intended to contact the outermost conductive element of the connector cavity.

3.9 lead connector pin:

(1) For a bipolar lead, the innermost conductive element of the lead connector intended to make electrical contact with the innermost conductive element of the connector cavity.

(2) For a unipolar lead, the conductive element of the lead connector intended to contact the innermost (or only) connector cavity conductive element.

3.10 ring set-screw: Set-screw in a bipolar connector cavity which is intended to contact the lead connector ring.

4 Requirements

The test methods provided for the performance requirements are type (qualification) tests. Equivalent test methods may be used. However, in the event of a dispute, the test methods described in this standard shall be used.

4.1 Lead connector

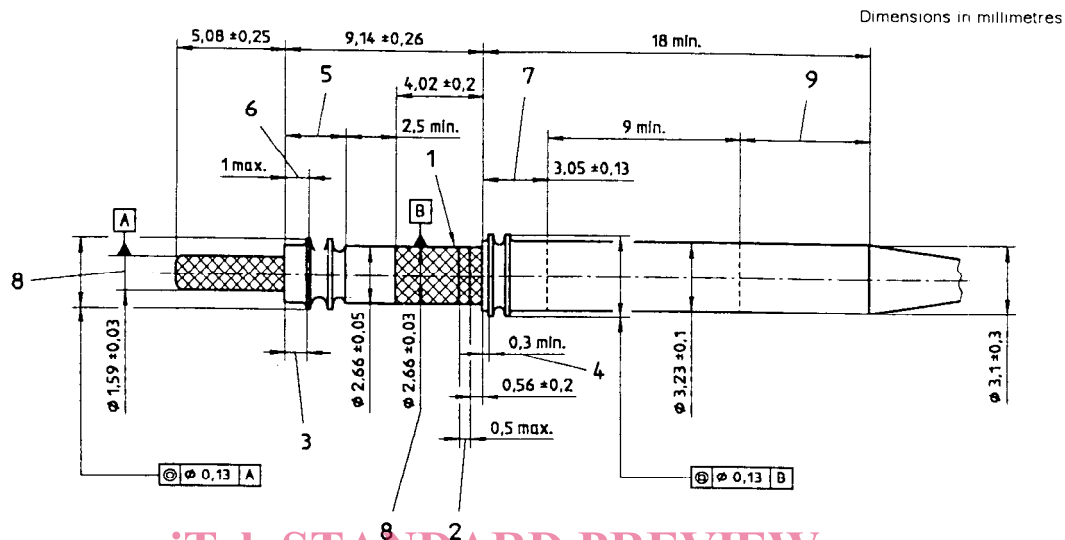
4.1.1 Design requirements

4.1.1.1 Sealing rings

At least one sealing ring shall be provided in each of two sealing ring zones on the lead connector and be located as specified in figure 1.

4.1.1.2 Dimensions

The lead connector shall have the dimensions specified in figure 1.



Key

1 Lead connector ring on bipolar leads.
 2 Optional tooling mark zone.
 3 Optional index mark alignment zone.
 4 Leading edge of first sealing ring.
 5 Sealing ring zone. Sealing rings as shown are for illustration only and are not restricted as to shape, size or number.
 6 Centre-line of first sealing ring in its undeflected position.
 7 Sealing ring zone. Sealing rings as shown are for illustration only and are not restricted as to shape, size or number.
 8 If the section between datum A and datum B is rigid, these two diameters shall be concentric within 0,13 mm.
 9 Zone in which the $3,1 \pm 0,3$ diameter applies.

Figure 1 Lead connector

4.1.1.3 Lead connector / electrode continuity and function

The lead connector pin shall be in electrical continuity with the stimulating electrode of the lead.

The lead connector ring, if utilised, shall be in electrical continuity with an electrode capable of pacing and electrogram-sensing functions other than the electrode which is in electrical continuity with the lead connector pin.

4.1.2 Performance requirements

4.1.2.1 Maximum insertion and withdrawal force of lead connector go-gauge

As shipped, the lead connector shall fit completely into the lead connector go-gauge specified in figure 2 with a maximum insertion and withdrawal force of 14 N.