INTERNATIONAL STANDARD

ISO 5841-3

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Cardiac pacemakers —

Part 3:
Low-profile connectors (IS-1) for implantable pacemakers

Stimulateurs cardiaques —

Partie 3: Connecteurs à bas profil (IS-1) pour stimulateurs implantabies

Reference number
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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5841-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Sub-Committee SC 2, *Cardiovascular implants*, in collaboration with IEC Sub-Committee 62D, *Electromedical equipment*, which together form the Joint IEC/ISO International Pacemaker Standards Working Group. It is based on the work of an ad hoc group of manufacturers and others. The European Working Group on Cardiac Pacing (EWGCP) of the European Society of Cardiology, the North American Society for Pacing and Electrophysiology (NASPE) and the International Association of Medical Prosthesis Manufacturers (IAPM) provided important encouragement.

ISO 5841 consists of the following parts, under the general title *Cardiac pacemakers*:

— *Part 1: Implantable pacemakers*

— *Part 2: Reporting of the clinical performance of populations of pulse generators*

— *Part 3: Low-profile connectors (IS-1) for implantable pacemakers*

Annex A forms an integral part of this part of ISO 5841. Annex B is for information only.

Introduction

The development of this part of ISO 5841 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 such leads is 3,2 mm, these connectors are frequently referred to as "3,2 mm" leads.) The purpose of this part of ISO 5841 is to specify a standard connector assembly, IS-1, to allow leads and pulse generators from different manufacturers to be interchangeable. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer.

Annex A gives a test method for lead connector impedance.

Annex B provides a rationale: it is recommended that this annex be read before using this part of ISO 5841 so that the user is informed about its limited objectives.

Cardiac pacemakers —

Part 3:
Low-profile connectors (IS-1) for implantable pacemakers

1 Scope

This part of ISO 5841 specifies a connector assembly to be used to connect implantable pacemaker leads to implantable pacemaker pulse generators. Essential dimensions and performance requirements are specified together with appropriate test methods. Other connector features such as fastening means and materials are not specified in this part of ISO 5841. Nor does it address all aspects of functional compatibility or reliability of different leads and pulse generators assembled into a pacemaker system.

WARNING — The connector cavity specified in this part of ISO 5841 is not to be used if the implantable pulse generator is capable of introducing dangerous non-pacing signals (e.g. defibrillation signals) through an IS-1 connector (see 4.2.3).

This part of ISO 5841 supplements ISO 5841-1 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 ISO 5841-1.

NOTE 1 Pacemaker connector assemblies not complying with this part of ISO 5841 may be safe and reliable and may have clinical advantages.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 5841. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5841 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 5841-1:1989, *Cardiac pacemakers — Part 1: Implantable pacemakers*.

3 Definitions

For the purposes of this part of ISO 5841, the definitions given in ISO 5841-1 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 a lead. (See figure 1.)

3.3 connector cavity: That part of the connector assembly attached to the pulse generator. (See figure 2.)

3.4 sealing ring: Circumferential barrier intended to maintain the electrical insulation 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 4.)

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 3.)

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 setscrew: Setscrew in a bipolar connector cavity which is intended to contact the lead connector ring.

4 Requirements

The test methods provided for the performance requirements that follow are type (qualification) tests. Equivalent test methods may be used. However, in the event of a dispute, the test methods described in this part of ISO 5841 shall be used.

4.1 Lead connector

4.1.1 Design requirements

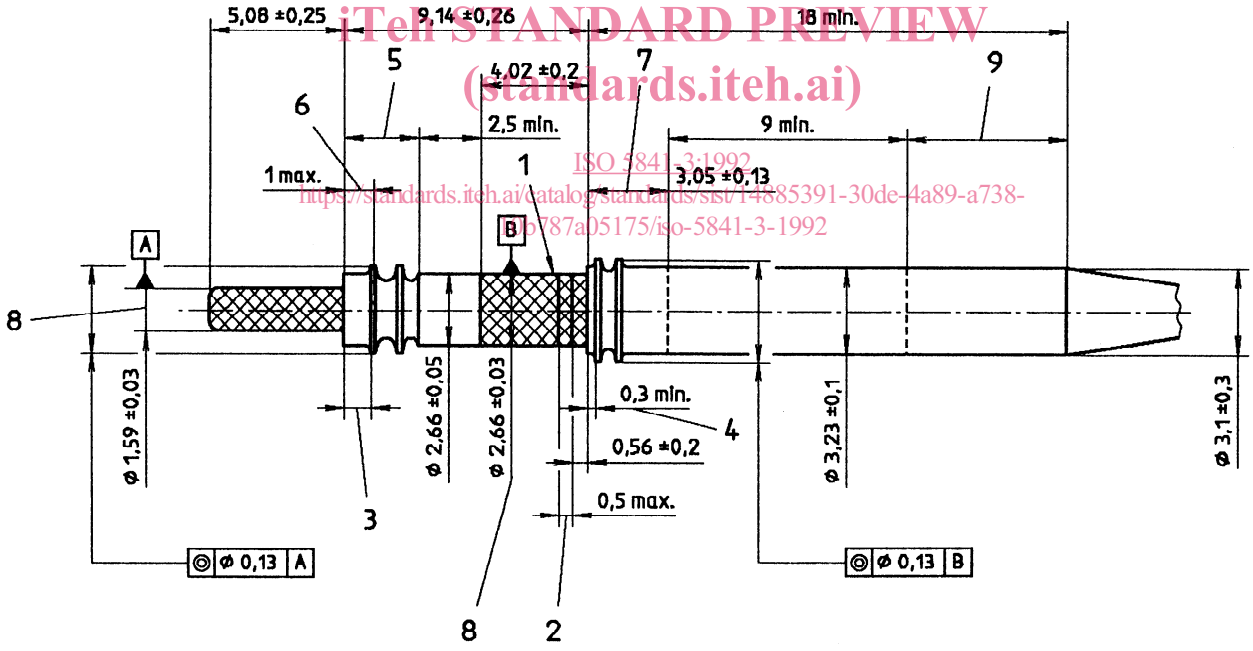
4.1.1.1 Sealing rings

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.

Dimensions in millimetres



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 ± 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 used, 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 3 with a maximum insertion and withdrawal force of 14 N and shall conform to the requirements of figure 1.

4.1.2.2 Electrical impedance between conducting parts

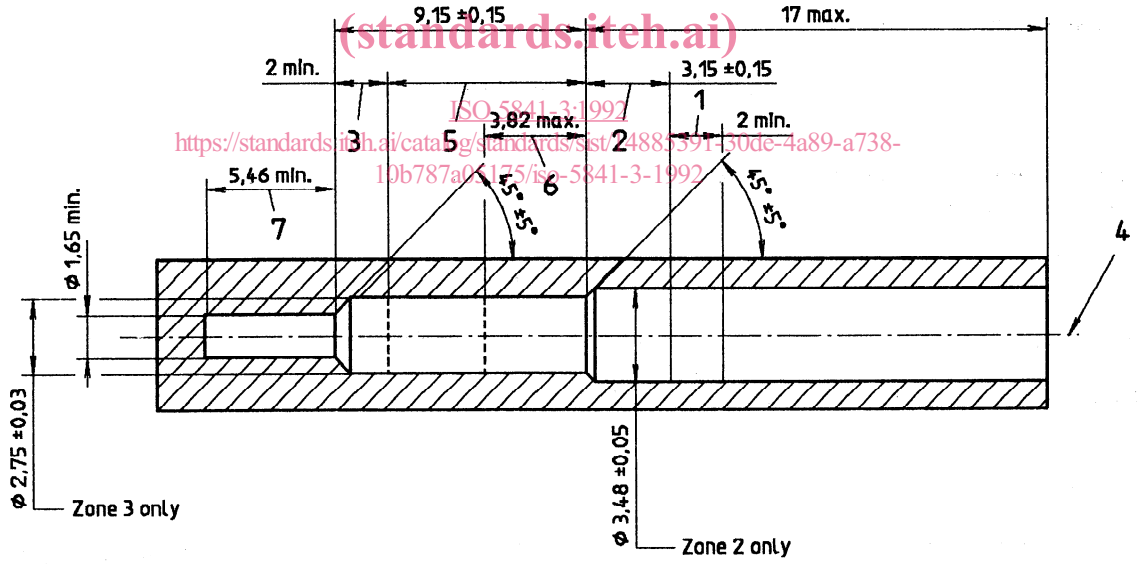
The minimum electrical impedance between conductive elements intended to be electrically insulated by the sealing rings shall be 50 kΩ. Compliance shall be determined by the test method described in annex A.

4.1.2.3 Deformation due to setscrew forces

Securing mechanism forces shall not deform the lead connector to the extent that insertion and withdrawal forces are excessive.

Compliance shall be determined as follows. The lead connector is inserted into a connector cavity which conforms to figure 2. The lead connector is fastened in the centre of zones 6 and 7 (see figure 2) by two M2 setscrews with cup point at a torque of 0,15 N·m ± 0,01 N·m. The setscrews are then retracted. The lead connector withdrawal force shall not exceed 14 N and shall comply with the insertion and withdrawal force requirement as specified in 4.1.2.1.

Dimensions in millimetres

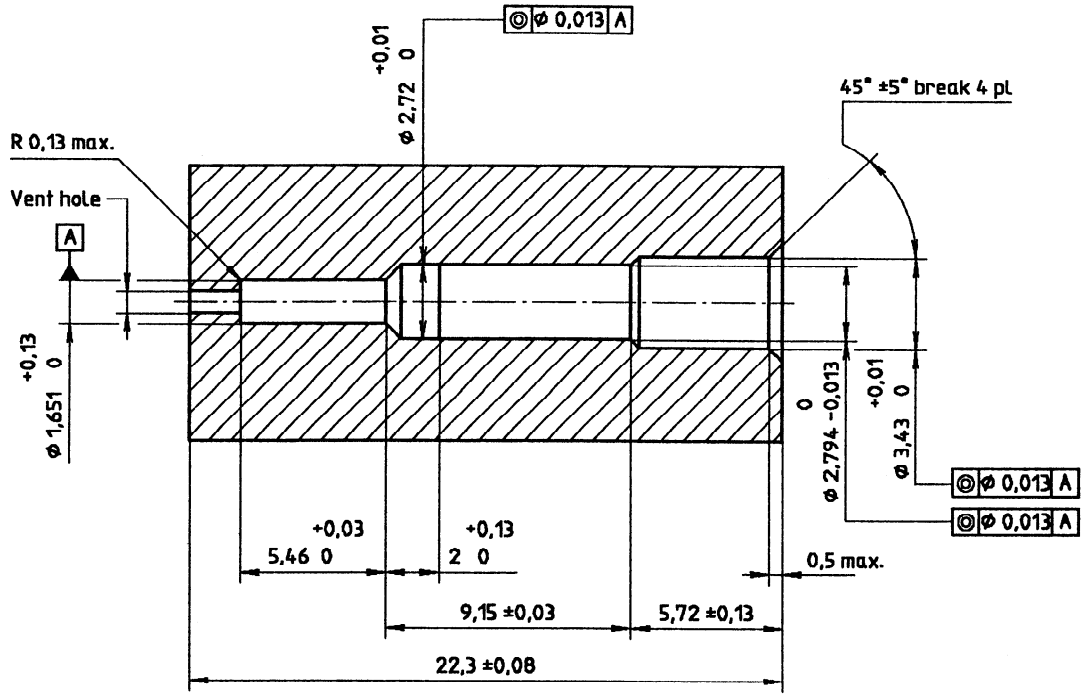


Key

1 Stabilization zone.
2 Seal zone for lead connector sealing rings.
3 Seal zone for lead connector sealing rings.
4 When lead is locked in place, lead axis shall not be displaced from connector cavity centre-line by more than 0,10 mm.
5 Zone for gauge pin insertion force requirement.
6 Lead connector ring contact zone.
7 Lead connector pin contact zone.

Figure 2 — Connector cavity

Dimensions in millimetres



NOTE – Surface roughness, R_a, on all bore diameters shall be 0,8 ▽.

Material : Polymethylmethacrylate.

Figure 3 — Lead connector go gauge

4.1.2.4 Effect on unipolar lead connector of ring setscrew of bipolar connector cavity

The ring setscrew shall not affect the function of a unipolar lead.

Compliance shall be determined as follows. Carry out the test described in 4.1.2.3 and then check that the electrical function of the lead has been unaffected.

4.1.3 Marking

Marking shall be permanent and legible.

The lead connector shall be marked with the symbol "IS-1" as shown in figure 5, with the size appropriate for the connector assembly part being marked.

For unipolar lead connectors, each connector shall be marked with the symbol "UNI"; for bipolar lead connectors, each connector shall be marked with the symbol "BI" as shown in figure 5.

An optional index mark may be provided as an alignment aid. If such a mark is provided, it shall be located as shown at point 3 in figure 1.

4.2 Connector cavity

4.2.1 Design requirements

The connector cavity dimensions shall be as specified in figure 2.

4.2.2 Performance requirements

4.2.2.1 Insertion: connector cavity go gauge

The connector cavity shall accept the go gauge specified in figure 4.

4.2.2.2 Maximum insertion force: gauge pin

In the zone designated as 5 in figure 2, the cavity shall accept a gauge pin with a diameter of $(2{,}7\ ^{0}_{-0{,}007})$ mm, with a finish not exceeding 0,4 µm. The force required to insert the gauge pin shall not exceed 9 N.

4.2.3 Marking

The pulse generator shall be marked with the symbol "IS-1" as shown in figure 5, with the size appropriate for the connector assembly part being marked.

This marking shall not be applied if the pulse generator is capable of introducing dangerous non-pacing signals through an IS-1 lead connector.

Dimensions in millimetres

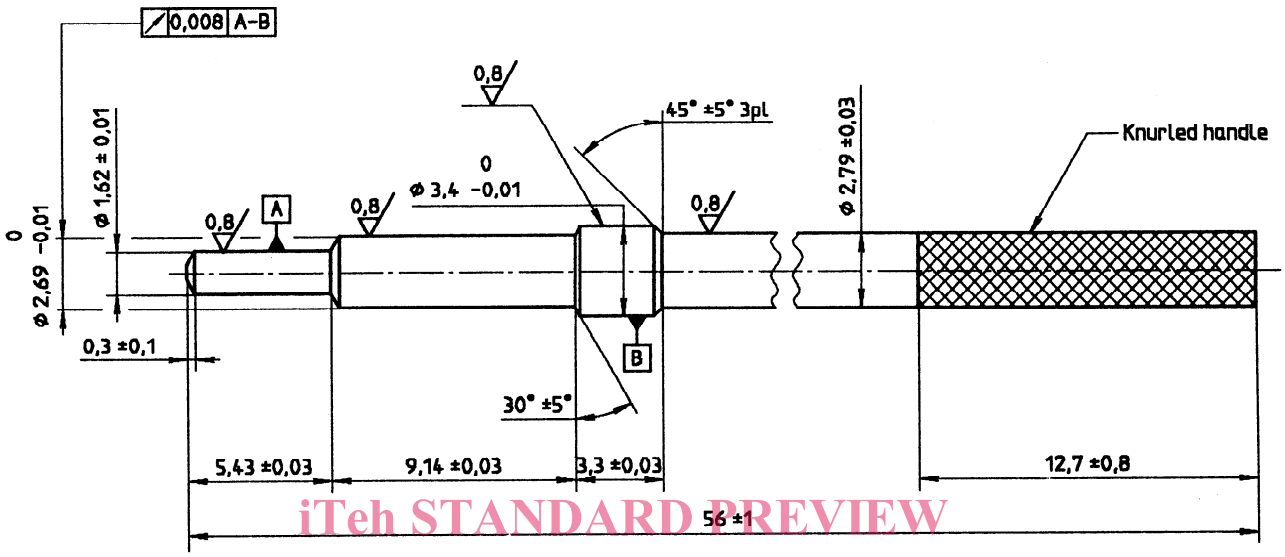


Figure 4 — Connector cavity go gauge

IS-1
UNI
BI

Figure 5 — Symbols for designating connector assembly parts