
**Implants for surgery — Cardiac
pacemakers —**

Part 3:
**Low-profile connectors [IS-1] for
implantable pacemakers**

Implants chirurgicaux — Stimulateurs cardiaques —

Partie 3: Connecteurs à bas profil [IS-1] pour stimulateurs implantables



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 5841 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 5841-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

This second edition cancels and replaces the first edition (ISO 5841-3:1992), which has been technically revised.

ISO 5841 consists of the following parts, under the general title *Implants for surgery — Cardiac pacemakers*:

Part 1: Implantable pacemakers

Part 2: Reporting of clinical performance of populations of pulse generators or leads

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

Annex A forms a normative 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 were 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.

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Implants for surgery — Cardiac pacemakers —

Part 3: Low-profile connectors [IS-1] for implantable pacemakers

WARNING — Do not use the connector cavity specified in this part of ISO 5841 if the implantable pulse generator is capable of introducing dangerous nonpacing signals (e.g. defibrillation signals) through an IS-1 connector (see 4.3.3).

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 related to connector fit 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. This part of ISO 5841 is applicable only to the form and fit of the connector assembly, and does not address all aspects of functional compatibility, system performance or reliability of different leads and pulse generator assemblies.

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 requirements in ISO 5841-1.

NOTE 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 normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 5841. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 5841 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

3 Terms and definitions

For the purposes of this part of ISO 5841, the terms and definitions given in ISO 5841-1 and the following 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 3.

3.4

sealing ring

circumferential barrier intended to maintain the electrical insulation between electrically isolated parts of the connector assembly when implanted

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> outermost conductive element of the lead connector intended to contact the outermost conductive element of the connector cavity

3.9

lead connector pin

<for a bipolar lead> innermost conductive element of the lead connector intended to make electrical contact with the innermost conductive element of the connector cavity

3.10

lead connector pin

<for a unipolar lead> conductive element of the lead connector intended to contact the innermost (or only) conductive element of the connector cavity

3.11

ring set screw

set screw in a bipolar connector cavity which is intended to contact the lead connector ring

4 Requirements

4.1 General

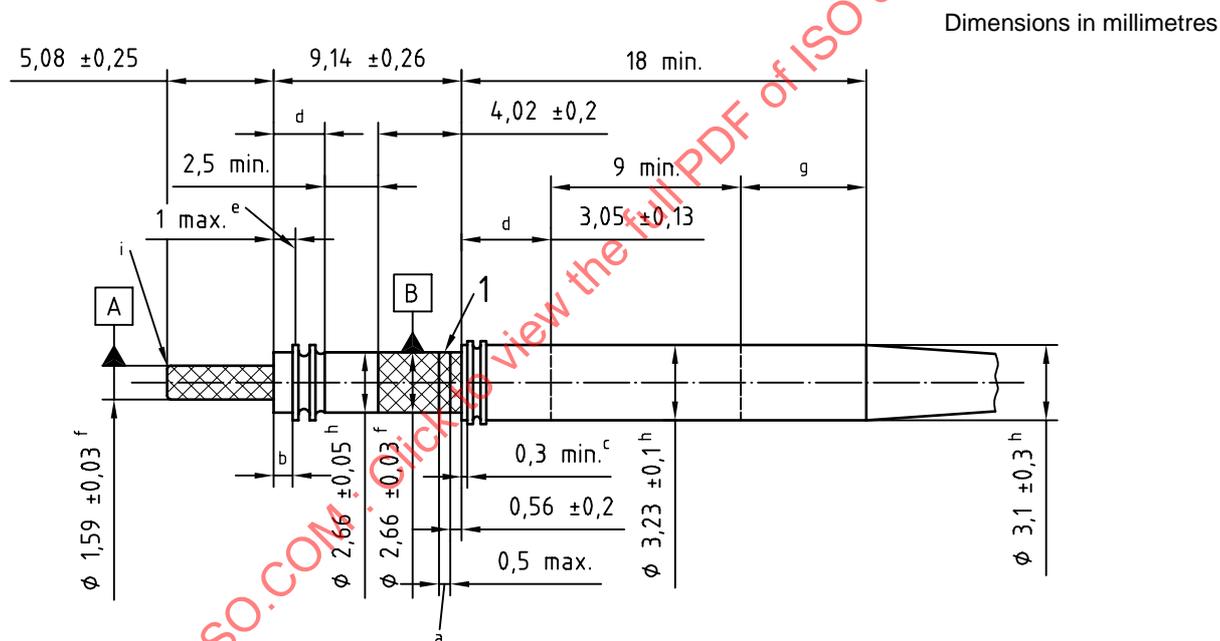
The test methods provided for the performance requirements that follow are type (qualification) tests. Equivalent test methods may be used. However, in the event of a dispute, the test methods described in this part of ISO 5841 shall be used.

4.2 Lead connector

4.2.1 Design requirements

4.2.1.1 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.



Key

- 1 Lead connector ring on bipolar leads.
 - a Optional tooling mark zone.
 - b Optional index mark alignment zone.
 - c Leading edge of first sealing ring.
 - d Sealing ring zone. Sealing rings as shown are for illustration only and are not restricted as to shape, size or number.
 - e Centreline of first sealing ring in its undeflected position.
 - f If the section between datum A and datum B is rigid, these two diameters shall be concentric within 0,13 mm.
 - g Zone in which the (3,1 ± 0,3) mm diameter applies.
 - h The diameter dimensions of the soft sections of the lead may be determined as the mean value of three measurements taken at locations oriented approximately 120° apart around the principal axis of the lead connector.
 - i Break sharp corner.

Figure 1 — Lead connector

4.2.1.2 Dimensions

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

4.2.1.3 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 having pacing and electrogram-sensing functions and which is other than the electrode that is in electrical continuity with the lead connector pin.

4.2.2 Performance requirements

4.2.2.1 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 and shall conform to the requirements of Figure 1.

4.2.2.2 Electrical impedance between conducting parts

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

4.2.2.3 Deformation due to set-screw 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. Insert the lead connector into a connector cavity which conforms to Figure 3. Fasten the lead connector in the centre of zones 6 and 7 (see Figure 3) by two M2 set screws with cup point at a torque of 0,15 N·m \pm 0,01 N·m. Then retract the set screws. The lead connector withdrawal force shall not exceed 14 N and shall comply with the insertion and withdrawal force requirement as specified in 4.2.2.1.

4.2.2.4 Effect on unipolar lead connector of ring set screw of bipolar connector cavity

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

Compliance shall be determined as follows. Carry out the test described in 4.2.2.3 and then check that the electrical function of the lead has not been affected.

4.2.3 Marking

Marking shall be permanent and legible.

The lead connector shall be marked with the symbol "IS-1" as shown in Figure 4, with the size appropriate for the connector assembly part being marked.

For unipolar lead connectors, each connector shall be marked with the letters "UNI"; for bipolar lead connectors, each connector shall be marked with the letters "BI" as shown in Figure 4.

An optional index mark may be provided as an alignment aid. If such a mark is provided, it shall be located in zone 3 as shown in Figure 3.

4.3 Connector cavity

4.3.1 Design requirements

The connector cavity dimensions shall be as specified in Figure 3.

4.3.2 Performance requirements

4.3.2.1 Insertion: connector cavity GO gauge

The connector cavity shall accept the GO gauge specified in Figure 5.

4.3.2.2 Maximum insertion force: gauge pin

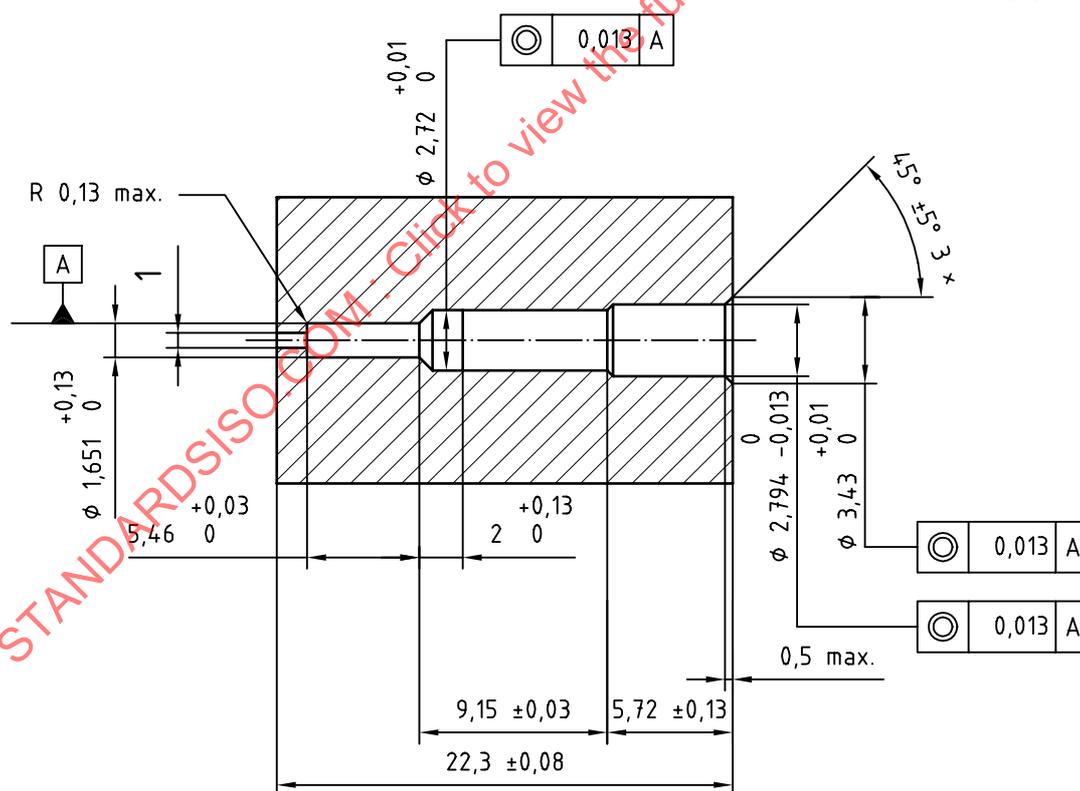
In the zone designated as 5 in Figure 3, the cavity shall accept a gauge pin with a diameter of $(2,7 \begin{smallmatrix} 0 \\ -0,007 \end{smallmatrix})$ mm, with a finish not exceeding $0,4 \mu\text{m}$. The force required to insert the gauge pin shall not exceed 9 N.

4.3.3 Marking

The pulse generator shall be marked with the symbol "IS-1" as shown in Figure 4, with the size appropriate for the connector assembly part being marked.

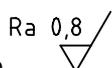
This marking shall not be applied if the pulse generator is capable of introducing dangerous nonpacing signals through an IS-1 lead connector.

Dimensions in millimetres



Key

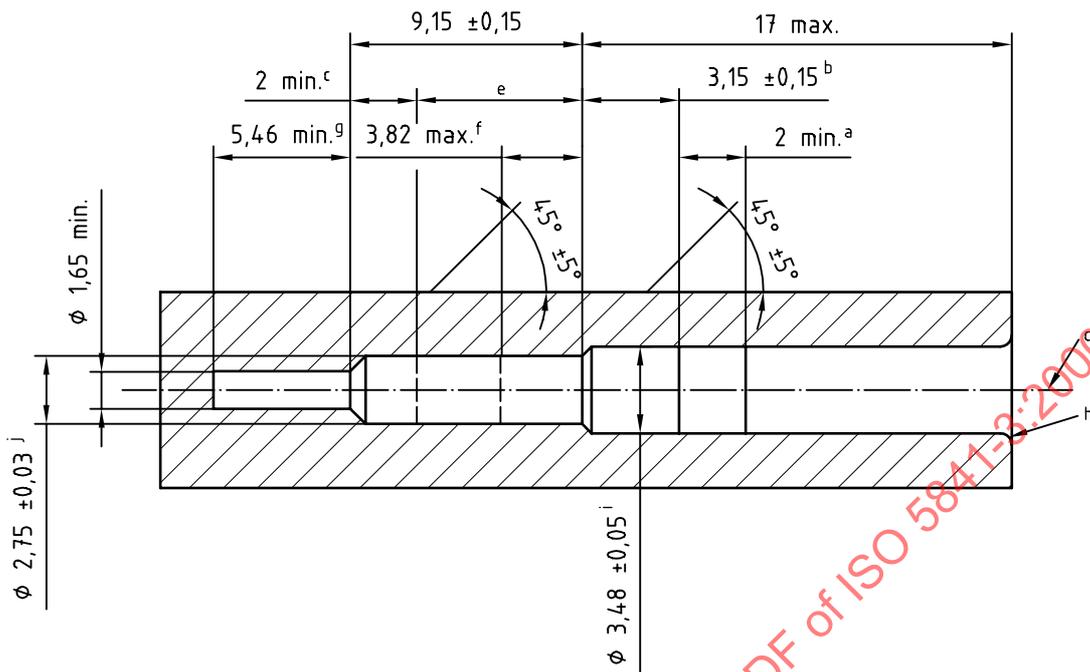
1 Vent hole



Surface roughness on all bore diameters shall be
Material: poly(methyl methacrylate).

Figure 2 — Lead connector GO gauge

Dimensions in millimetres



- a Stabilization zone 1.
- b Seal zone 2 for lead connector sealing rings.
- c Seal zone 3 for lead connector sealing rings.
- d When lead is locked in place, lead axis shall not be displaced from connector cavity centreline by more than 0,10 mm.
- e Zone 5 for gauge pin insertion force requirement.
- f Lead connector ring contact zone 6. (Diameter dimension does not apply to spring contacts.)
- g Lead connector pin contact zone 7. (Diameter dimension does not apply to spring contacts.)
- h Break sharp corner.
- i Zone 2 only.
- j Zone 3 only.

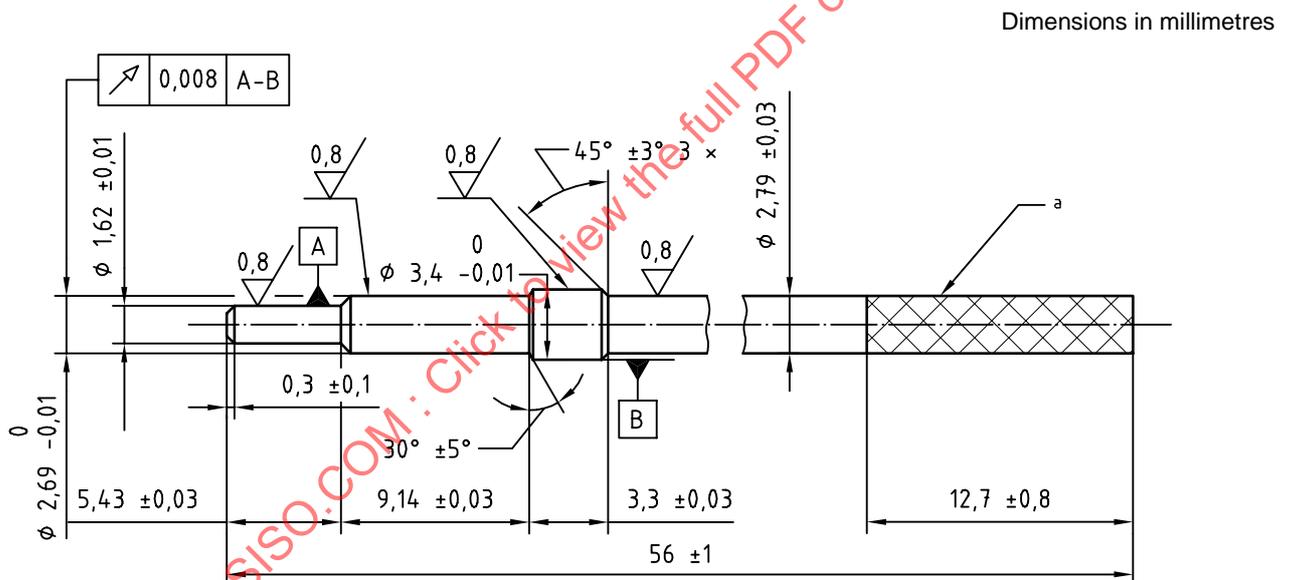
NOTE 1 The entry to the connector cavity should include a transition (i.e. chamfer, counterbore, etc.) in order to minimize seal distortion when inserting the lead connector into the connector cavity.

NOTE 2 The minimum cavity depth of 5 mm occurs when zone 2 is at the minimum tolerance and zone 1 is 2 mm.

Figure 3 — Connector cavity

IS-1 UNI BI

Figure 4 — Symbols/letters for designating connector assembly parts



a Knurled.

Figure 5 — Connector cavity GO gauge

Annex A (normative)

Lead connector electrical impedance test method

A.1 General

This annex describes the test to be employed to determine compliance with 4.2.2.2. This is a type (qualification) test and is not intended to be used as a routine production test. The manufacturer may use equivalent test methods. However, in case of dispute the following test method shall prevail.

A.2 Specimen preparation

Lead connectors for the test shall be in the condition as shipped to the customer.

A.3 Reagent and materials

A.3.1 Test cavity, simulating a connector cavity constructed in compliance with Figure A.1 with provision for offsetting the axis of the lead connector under test by 0,10 mm.

A.3.2 Saline solution, approximately 9 g/l at $37\text{ °C} \pm 5\text{ °C}$.

A.3.3 Test signal.

Frequency: One frequency between 50 Hz and 120 Hz;

Voltage: One voltage between 100 mV RMS and 250 mV RMS.

A.3.4 Electrical impedance-measuring device.

A.3.5 Reference electrode with minimum area of 500 mm².

A.4 Procedure

A.4.1 Immerse the test cavity (A.3.1) in the saline solution (A.3.2). Insert the lead connector (see A.2) into the cavity, ensuring that no air bubbles are trapped and that the lead connector axis is offset 0,10 mm relative to the test cavity axis. Do not immerse distal conducting parts in the saline solution. If a unipolar lead connector is being tested, remove a cap screw (see Figure A.1) from the ring zone of the test cavity.

A.4.2 Immerse the reference electrode (A.3.5) in the saline solution not less than 50 mm from the test cavity.

A.4.3 Measure the electrical impedance at the start of the test and after ten days.

A.4.4 Impedance shall exceed the requirement in 4.2.2.2 between the:

- a) pin and ring;
- b) pin and saline solution;
- c) ring and saline solution (bipolar only).