INTERNATIONAL STANDARD

ISO 5841-3

Third edition
2013-04-15

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

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This third edition cancels and replaces the second edition (ISO 5841-3:2000), which has been technically revised. It also incorporates the Technical Corrigendum ISO 5841-3:2000/Cor 1:2003.

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

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

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

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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 14708-2 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 14708-2.

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

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2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14708-2, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-2 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

Note 1 to entry: See Figure 1.

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3.3
connector cavity
that part of the connector assembly attached to the pulse generator

Note 1 to entry: 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

Note 1 to entry: 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

Note 1 to entry: See Figure 2.

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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

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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.

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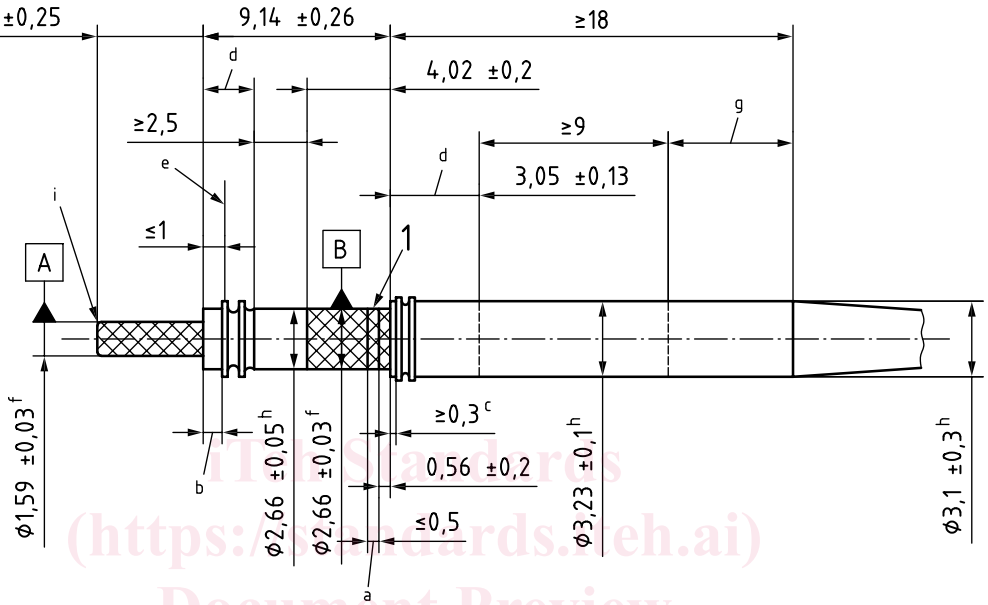
4.2 Lead connector

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 located as specified in Figure 1.

Dimensions in millimetres



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Key

1 lead connector ring on bipolar leads

a Optional tooling mark zone.

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b Optional index mark alignment zone.

c Leading edge of first sealing ring of second seal set.

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 of first seal set 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.

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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 kΩ. 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 ± 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.

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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 by carrying out the tests described in 4.2.1.3 and 4.2.2.2.

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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.

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