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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

Reference number
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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*

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.

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.

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.

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.

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.

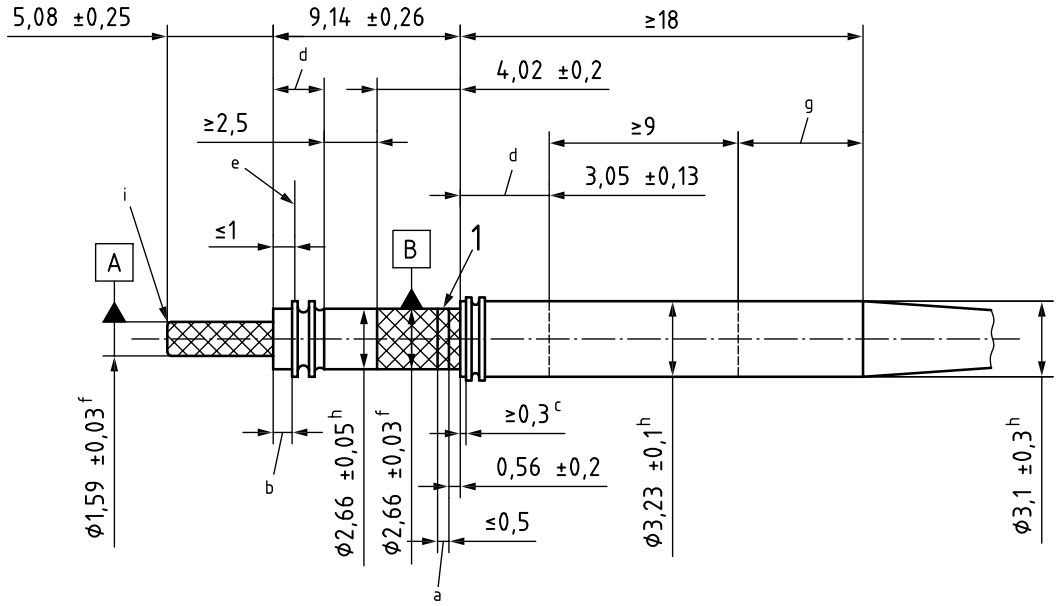
4.2 Lead connector

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 located as specified in Figure 1.

Dimensions in millimetres



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 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.

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.

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.

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

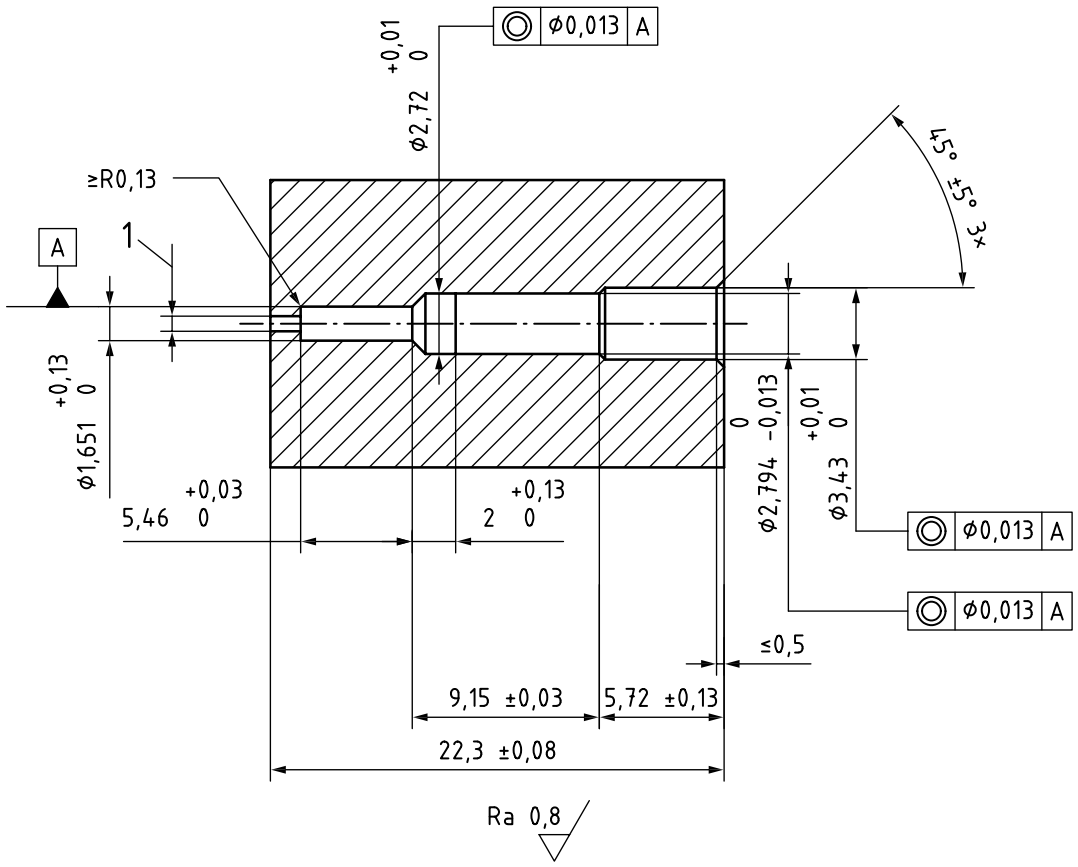
In the zone designated as 5 in Figure 3, the cavity shall accept a gauge pin with a diameter of $\left(2{,}7\ ^{0}_{-0{,}007}\right)$ mm, with a finish not exceeding 0,4 µm. The force required to insert the gauge pin shall not exceed 9 N.

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



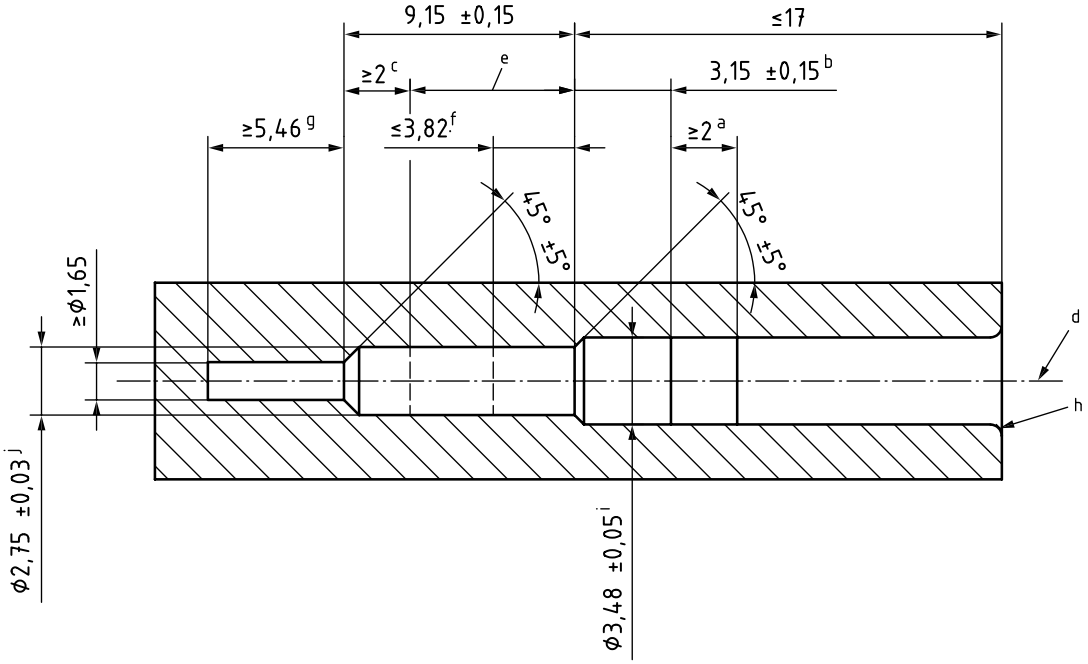
Key

1 vent hole

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

Figure 2 — Lead connector GO gauge

Dimensions in millimetres



Key

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.

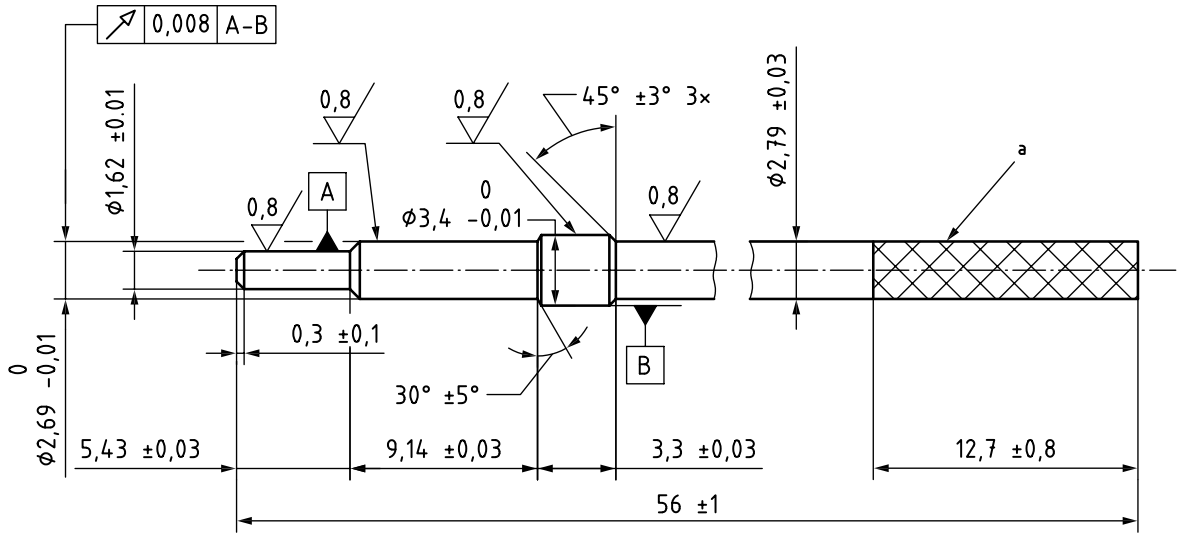
NOTE 2 The minimum cavity depth of 5 mm occurs when zone 2 is at the minimum tolerance and zone 1 is 2 mm.

Figure 3 — Connector cavity

IS-1
UNI
BI

Figure 4 — Symbols/letters for designating connector assembly parts

Dimensions in millimetres



Key

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 °C ± 5 °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 mm^2.

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 10 days.

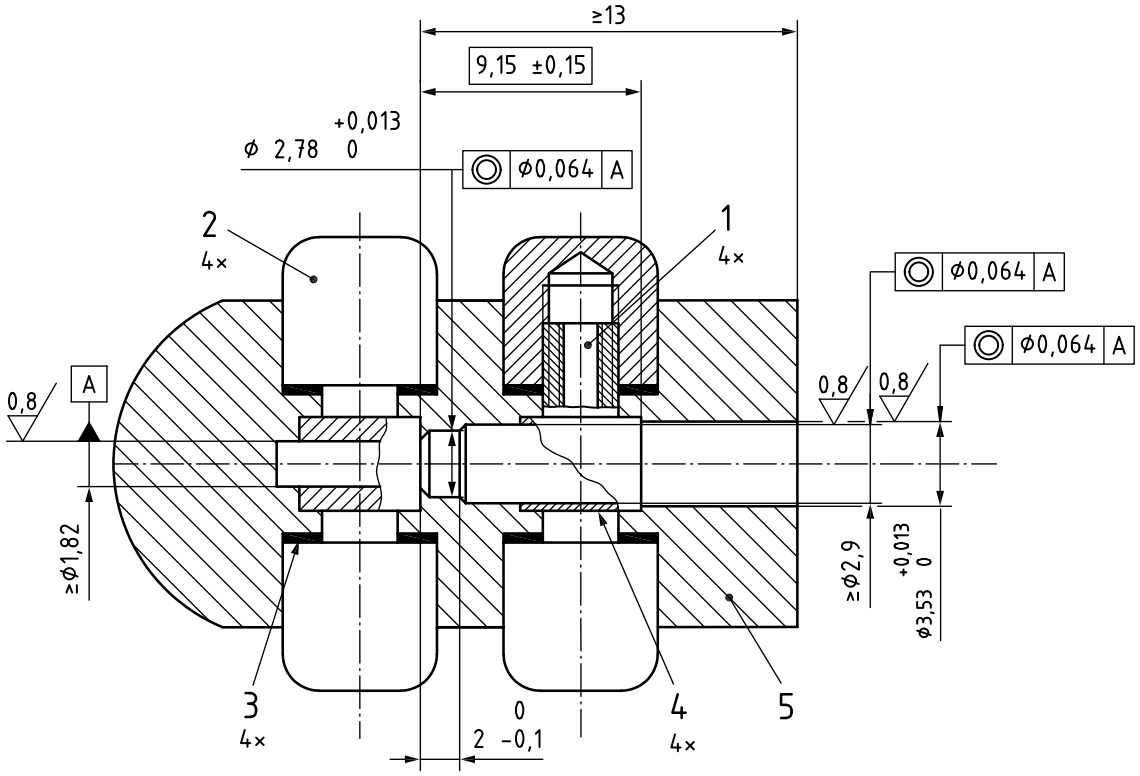
A.4.4 Impedance shall exceed the requirement in 4.2.2.2 between the:

a) pin and ring;

b) pin and saline solution;

c) ring and saline solution (bipolar only).

Dimensions in millimetres



Key

1 set screw, M2 (stainless steel)
2 cap screw (polyacetal)
3 seal (silicone)
4 connector block (stainless steel)
5 housing (epoxy)

Figure A.1 — Lead connector impedance test cavity

Annex B
(informative)

Rationale

B.1 Need for connector standard

NOTE This annex provides a historic rationale for this part of ISO 5841, including reasons for specific requirements.

Clinicians have observed that the constructional differences between connector assemblies that are apparently similar may lead to pulse generators and leads being connected which do not seal properly and, therefore, form an unreliable pacemaker. A standard connector assembly reduces the likelihood of the connection of incompatible leads and pulse generators. The development of smaller pacemakers has led to the need for low-profile connector assemblies. By including both terminals in one connector assembly, a substantial reduction in the size of the pulse generator is accomplished, particularly in dual-chamber models. With faulty or damaged sealing, the sensing of intracardiac signals may be impaired, the output pulse amplitude may be reduced, the pulse generator battery may discharge more rapidly due to the shunting effect of leakage and, in the case of dual-chamber pacemakers, may result in voltage signals from one connector assembly inhibiting the function of the other (i.e. cross-talk).

Adaptors have been supplied for many years to allow connection between dissimilar styles of connector assemblies. However, adaptors add complexity to the clinical procedure, as well as another component in the system with the potential to fail, and therefore the need for them should be minimized.

During the time of transition to full use of the IS-1 connector assembly, the number of leads currently implanted in patients which do not conform to this part of ISO 5841 will gradually decrease over a period of several years, as clinicians should be aware. These leads may require either pulse generators of different dimensions or with seals in the connector cavity, or it will be necessary to adapt a connector cavity complying with this part of ISO 5841 to the implanted lead. The adaptor requires an IS-1 lead connector at one end and an appropriately-configured connector cavity on the other end.

B.2 Selection of basic design concept

The decision on a basic design concept has focused on the sealing mechanism. The sealing elements are installed on the lead connector. Provision of seals on the lead permits a smaller connector cavity and, therefore, a smaller pulse generator than would be possible with seals in the connector cavity.

To allow manufacturers options with regard to the specific sealing ring design, no requirements are provided regarding the specific configuration or material of the seals.

The provision for inclusion of seals within the connector cavity was considered as a means of allowing for backward compatibility with already existing lead connector designs. This was ultimately rejected because of the effort that would be required to specify fully a system with backward compatibility. It is recognized that such backward-compatibility designs will be left to the manufacturer.

B.3 Rationale for specific clauses

Clause 1 Scope

Functional compatibility between leads and pulse generators is also determined by other aspects of the pacemaker, such as electrode area and the nature of its contact with tissue. Fastening methods are not specified in this part of ISO 5841, so as to allow manufacturers to explore new methods of ensuring contact

between connector-cavity terminals and lead-connector terminals. Thus, no restriction has been placed on lead connectors to accommodate fastening methods other than set screws. The IS-1 connector is intended for pacing functions and may be incorporated in leads and/or pulse generators that provide other functions (e.g. defibrillation), provided that all the requirements of this part of ISO 5841 are met in such use.

Whichever fastening method is used, it is considered to be the responsibility of the manufacturer to ensure adequate retention of the lead, and that the lead has adequate proximal strength between the anode and cathode to withstand the largest-value insertion and withdrawal forces allowed by this part of ISO 5841 without compromising the lead integrity or the ability to meet the dimensional or electrical requirements of this part of ISO 5841.

Clause 4 Requirements

B.3.1.1 Subclauses 4.2.1 and 4.3.1: Design requirements

Unipolar and bipolar versions of the connector assembly are specified to be completely interchangeable due to the now wide availability of programmable and automatic bipolar to unipolar features. The possibility of damage to a unipolar lead when fastened in a bipolar pulse generator is addressed by a performance test.

The connector cavity in Figure 3 has a 12 mm long zone in which the diameter is not mandated. This zone allows manufacturers the option to incorporate design features such as chamfers, counterbores, etc. in order to minimize seal distortion when inserting the lead connector into the connector cavity. Seal distortion can result in seal damage and/or increased insertion force.

B.3.1.2 Subclauses 4.2.2 and 4.3.2: Performance requirements

The use of GO gauges permits the assessment of the fit between connector elements without requiring design-restrictive specifications regarding the sealing dimensions and materials. The GO gauge maximum insertion and withdrawal forces specified will result in acceptable clinical handling conditions.

B.3.1.3 Subclauses 4.2.2.1 and 4.3.2.2: Insertion and withdrawal force requirements

This requirement ensures that the lead connector can be engaged and disengaged in the clinical setting without undue force that may complicate the procedure and damage the lead.

B.3.1.4 Subclause 4.2.2.2: Resistance between electrical contacts

A minimum of 50 kΩ is required to ensure that signals from the heart are not shunted, causing sensing to be compromised. In general, 50 kΩ is in excess of 10 times the maximum source impedance of intracardiac signals seen by the pacemaker. Shunt paths due to other features of a connector assembly reduce the overall resistance. These have not been considered in the requirement. The test method given in Annex A provides a worst-case test by having the test cavity sealing areas at maximum dimension and a 0,1 mm offset of the lead connector axis, a condition that minimizes the sealing capability of the lead connector under test.

B.3.1.5 Subclause 4.2.2.3: Deformation of lead connector due to set screw force

This test demonstrates that adequate strength exists in the lead connector terminals so that the lead is not damaged.

B.3.1.6 Subclause 4.2.2.4: Protection of unipolar lead in bipolar pulse generator

When a unipolar lead is inserted into a bipolar pulse generator, a set screw in the lead connector-ring contact zone may damage the lead if it is tightened due to the absence of a lead connector ring on the unipolar lead connector. This is a performance rather than a design requirement, so that a manufacturer may choose the method of protection to be used.

In practice, a higher torque than that specified in these test procedures (4.2.2.3 and 4.2.2.4) could be applied by the operator that may result in damage to the lead connector. Manufacturers should provide warnings to this effect in the accompanying documentation.

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