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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 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.

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.

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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

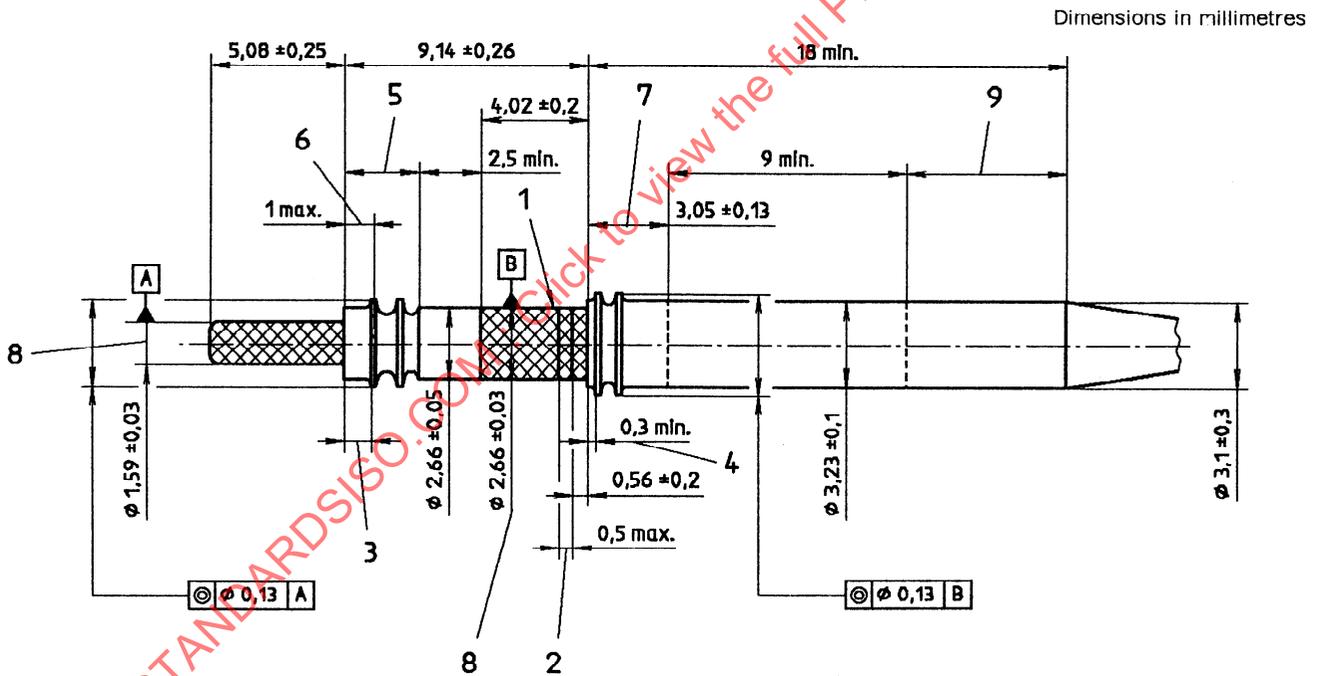
4.1.1 Design requirements

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.



- 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 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 k Ω . 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 \pm 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.

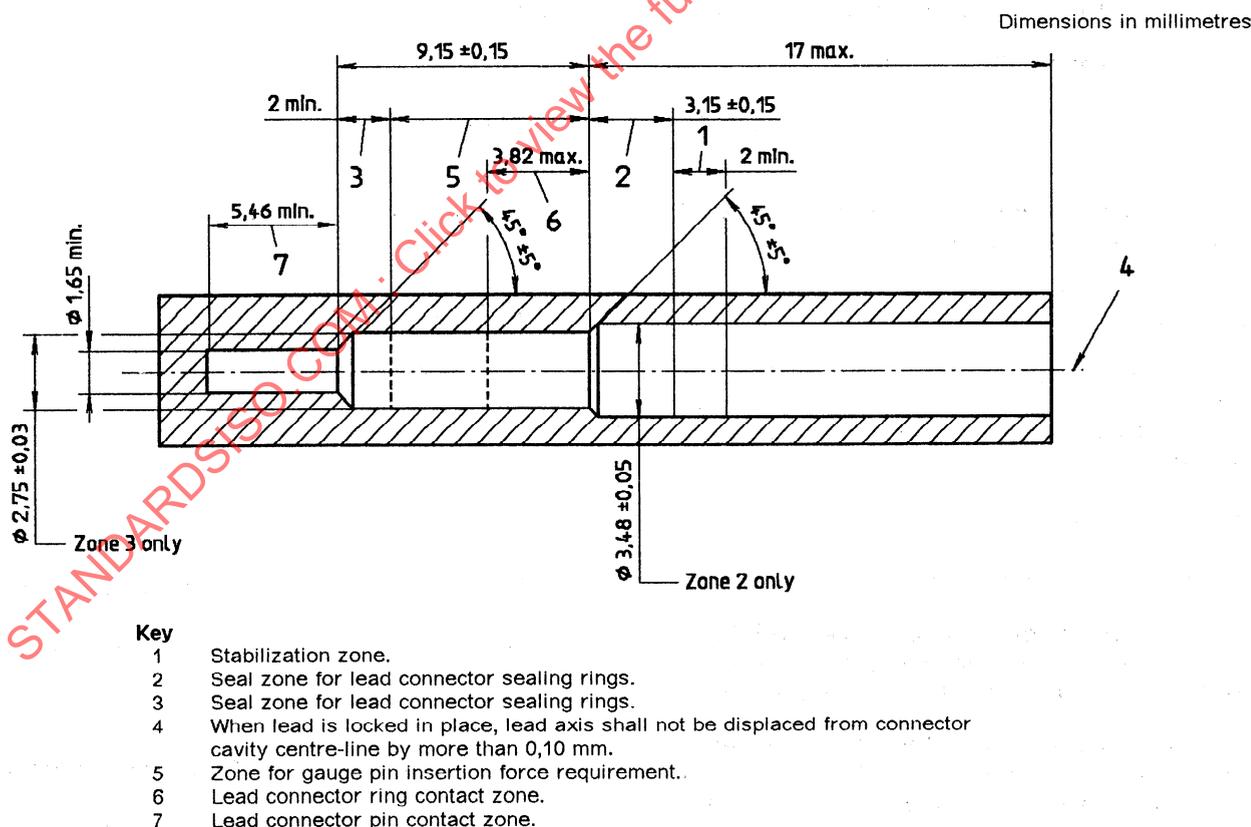
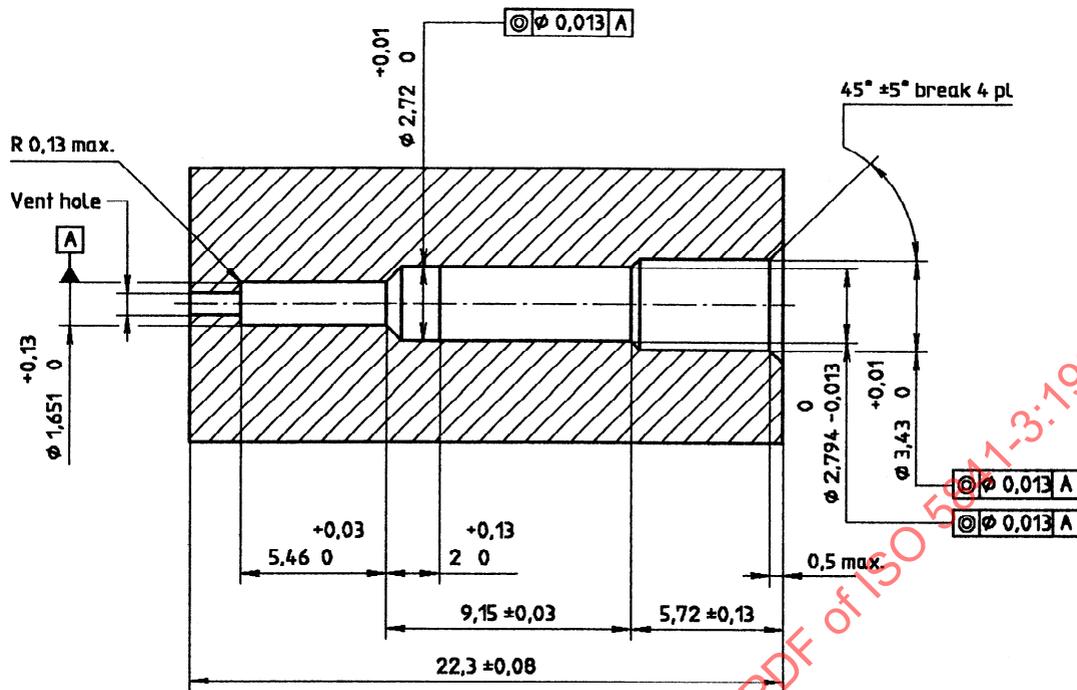


Figure 2 — Connector cavity



NOTE - Surface roughness, R_a , on all bore diameters shall be $\frac{0.8}{\sqrt{\quad}}$.

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 $(2.7 \begin{smallmatrix} 0 \\ -0.007 \end{smallmatrix})$ mm, with a finish not exceeding $0.4 \mu\text{m}$. The force required to insert the gauge pin shall not exceed 9 N.

4.2.3 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

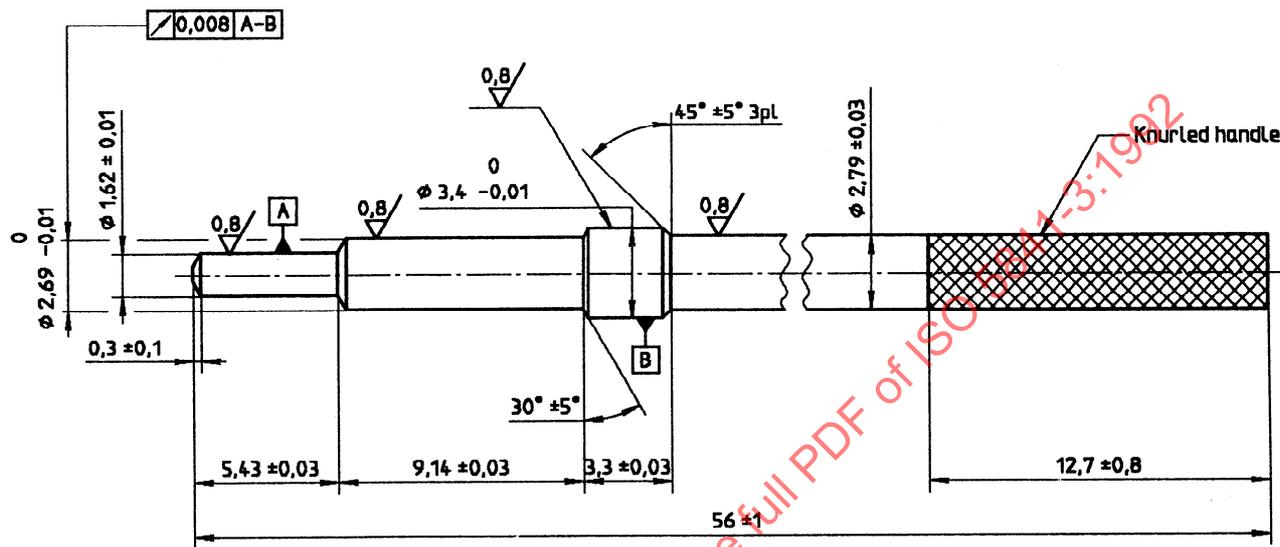


Figure 4 — Connector cavity go gauge

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IS-1
UNI
BI

Figure 5 — Symbols for designating connector assembly parts

Annex A (normative)

Lead connector electrical impedance test method

This annex describes the test to be employed to determine compliance with 4.1.2.2. 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.1 Specimen preparation

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

A.2 Equipment

A.2.1 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.2.2 Saline solution, approximately 9 g/l at $37\text{ °C} \pm 5\text{ °C}$.

A.2.3 Test signal

Frequency: One frequency between 50 Hz and 120 Hz.

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

A.2.4 Electrical impedance-measuring device.

A.2.5 Reference electrode with a minimum area of 500 mm^2 .

A.3 Procedure

A.3.1 Immerse the test cavity (A.2.1) in the saline solution (A.2.2). Insert the lead connector (see A.1) 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 capscrew (see figure A.1) from the ring zone of the test cavity.

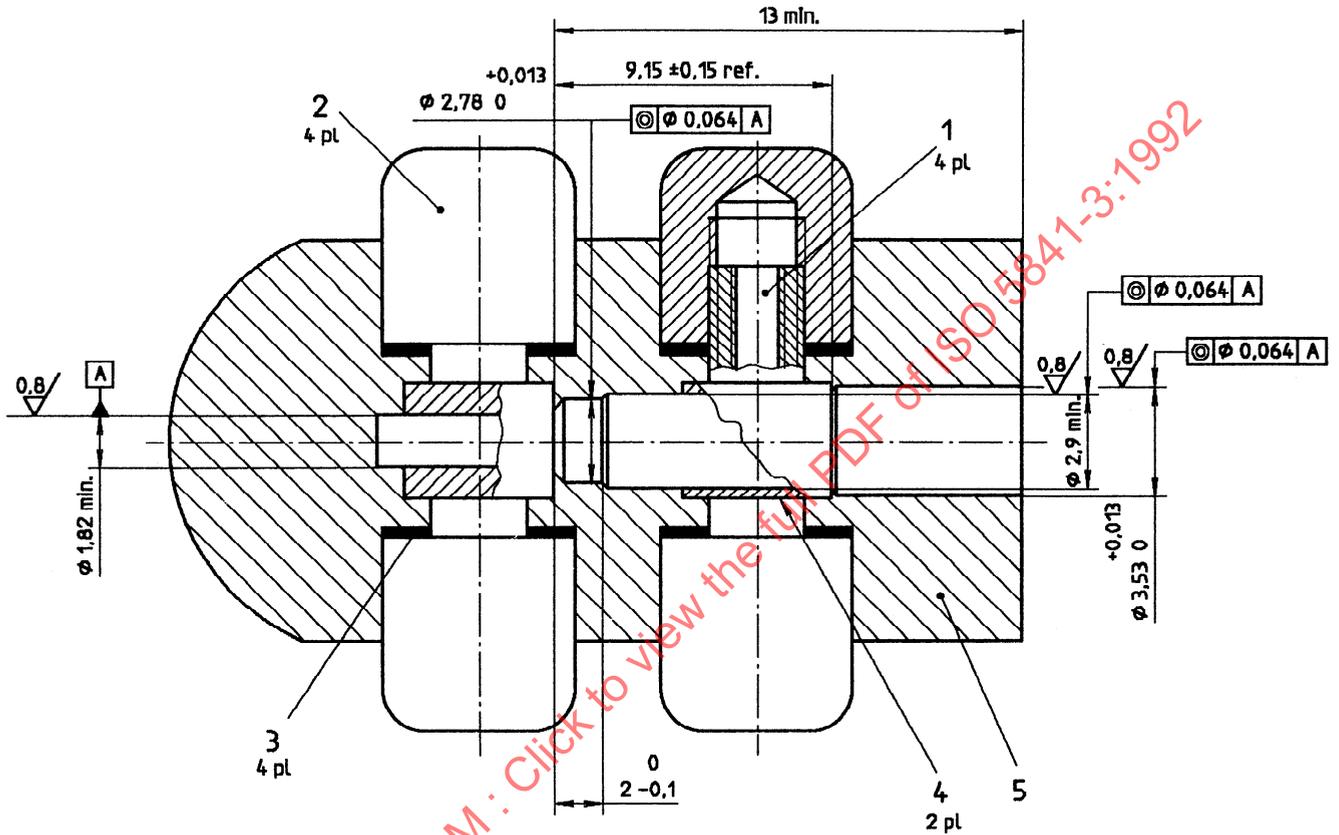
A.3.2 Immerse the reference electrode (A.2.5) in the saline solution not less than 50 mm from the test cavity.

A.3.3 Measure the electrical impedance after ten days.

A.3.4 Impedance throughout the test shall exceed the requirement in 4.1.2.2 between the

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

Dimensions in millimetres



Item	Description	Material
1	Setscrew, M2	SST
2	Cap screw	Polyacetal
3	Seal	Silicone
4	Connector block	SST
5	Housing	Epoxy

Figure A.1 — Lead connector impedance test cavity

Annex B (informative)

Rationale

This annex is provided for information only. It provides a rationale for this part of ISO 5841, including reasons for specific requirements.

B.1 Need for connector standard

Clinicians have observed that the constructional differences between connector assemblies which 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. Recently, 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 procedures and, therefore, the need for them should be minimized.

During the time of transition to full use of the IS-1 connector assembly, clinicians should be aware that 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. 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 will require 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 and approach to standard

The decision on a basic design concept has focused on the sealing mechanism. The sealing elements will be 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 manufacturers.

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 setscrews. The IS-1 connector is intended for pacing functions and may be incorporated in leads and/or pulse generators which 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 that adequate retention of the lead is maintained without damage to the lead.