भारतीय मानक
Indian Standard

IS 17709 : 2022
ISO 11318 : 2002

कार्डियक डिफिब्रिलेटर — इम्प्लांटेबल डिफिब्रिलेटर्स के लिए कनेक्टर असेंबली डी एफ - 1 — आयाम और परीक्षण आवश्यकताएं

Cardiac Defibrillators — Connector Assembly DF-1 for Implantable Defibrillators — Dimensions and Test Requirements

ICS 11.040.40

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NATIONAL FOREWORD

This Indian Standard which is identical with ISO 11318 : 2002 'Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on recommendation of the Thoracic and Cardiovascular Surgery Instruments Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 7436 : 1983 Slotted set screws with cup point	IS 15631 : 2005/ISO 7436 : 1983 Slotted set screws with cup point	Identical

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Introduction

The purpose of this International Standard is to specify a standard connector assembly, DF-1, to provide interchangeability between implantable defibrillator leads and defibrillator pulse generators from different manufacturers. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer.

Defibrillator connector systems not conforming to this International Standard may be safe and reliable, and may have clinical advantages.

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Indian Standard

CARDIAC DEFIBRILLATORS — CONNECTOR ASSEMBLY DF-1 FOR IMPLANTABLE DEFIBRILLATORS — DIMENSIONS AND TEST REQUIREMENTS

1 Scope

This International Standard specifies a unipolar connector assembly, DF-1, intended for use in connecting implantable defibrillator leads to implantable defibrillator generators that do not produce more than 1 kV/50 A peak output. Essential dimensions and performance requirements related to connector fit are specified, along with test methods.

This International Standard does not specify other connector features such as fastening means and material. This International Standard is applicable to the form and fit of the connector assembly, and does not address all aspects of functional compatibility, system performance, or reliability of different implantable defibrillator leads and implantable defibrillator generator assemblies.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, this publication do not apply. However, parties to agreements based on this International Standard 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 7436:1983, *Slotted set screws with cup point*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1
connector assembly
assembly, consisting of a lead connector and a connector cavity, for the electrical and mechanical connection to a defibrillator generator

3.2
lead connector
that part of the connector assembly that is inserted into the connector cavity

3.3
connector cavity
that part of the connector assembly that is part of the defibrillator generator

3.4
sealing mechanism
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 and on the lead connector on which one or more seals are intended to bear

3.6
sealing mechanism zone
portion of the lead connector (and optionally the connector cavity) in which the sealing mechanism is permitted

3.7
connector cavity GO gauge
tool for assessing the ability of a connector cavity to accept a lead connector of maximum size

3.8
lead connector GO gauge
tool for assessing the ability of a lead connector to be inserted into a connector cavity of minimum size

3.9
lead connector pin
conductive element of the lead connector intended to contact the connector cavity conductive element

3.10
defibrillator system
assembly consisting of defibrillator generator and a defibrillator lead(s)

3.11
defibrillator lead
means of electrically connecting a defibrillator generator to the patient

3.12
defibrillator generator
portion of the defibrillator system that includes the power supply and electronic circuits

3.13
grip zone
area of lead connector that is provided for grasping the lead connector during insertion and withdrawal

3.14
connector contact
current-carrying interface between the connector cavity and the lead connector

4 Requirements

4.1 General

The test methods provided for the 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 International Standard shall be used.

The tests shall be conducted at room temperature unless otherwise specified.

4.2 Defibrillator lead connector

4.2.1 Design requirements

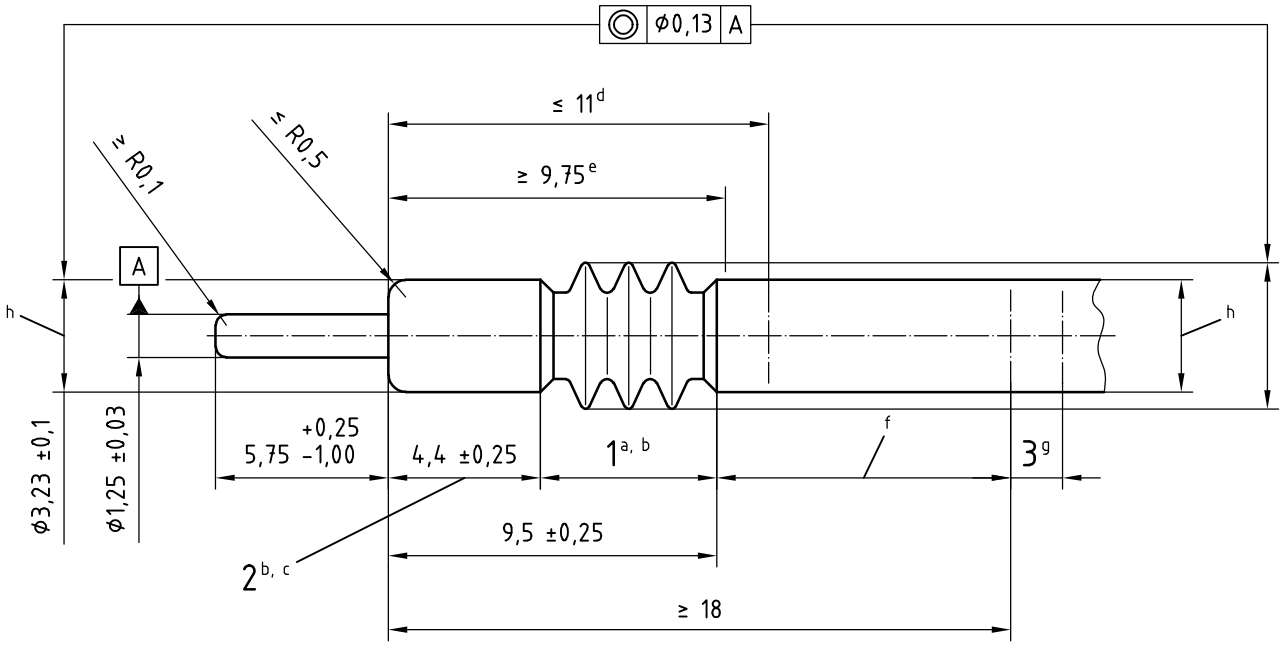
4.2.1.1 Sealing mechanism

At least one seal shall be provided on the lead connector and shall be located as specified in Figure 1.

4.2.1.2 Dimensions

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

Dimensions in millimetres



Key

1 Sealing mechanism zone

2 Seal zone

3 Grip zone

[a] Sealing rings as shown are for illustration only and are not restricted as to shape, size or number.

[b] The two diameters according to zone 1 and 2 shall be concentric within 0,13 mm to datum A.

[c] For optional seal mechanism in connector cavity; ∅ 3,23 ± 0,1 applies to this zone.

[d] Maximum length of rigid area.

[e] Minimum length of rigid area.

[f] $\varnothing\, 3{,}23^{+0{,}1}_{-0{,}2}$ applies to this zone only.

[g] Length at the manufacturer's discretion, max. diameter 4,1 mm.

[h] The diameters 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.

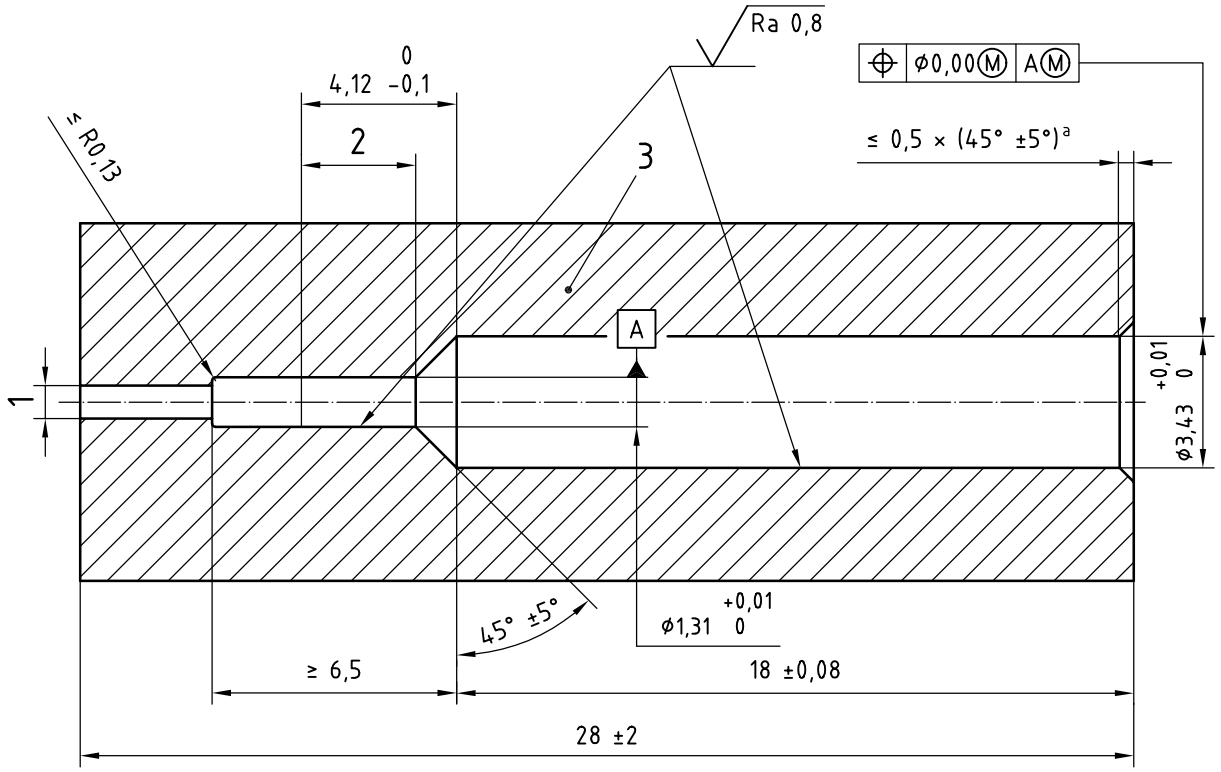
Figure 1 — DF-1 lead connector

4.2.2 Other requirements

4.2.2.1 Insertion and withdrawal forces

As shipped, the lead connector shall fit completely into the lead connector GO gauge specified in Figure 2. Neither the insertion force nor the withdrawal force shall exceed 14 N. After insertion and withdrawal, the lead connector shall comply with Figure 1.

Dimensions in millimetres
Surface roughness in micrometres



Key

1 Vent hole
2 Set-screw contact zone
3 Epoxy material

[a] Break sharp corners.

Figure 2 — DF-1 lead connector GO gauge

4.2.2.2 Deformation due to set-screw and grip zone forces

When tested as described below, the forces imposed by the securing mechanism shall not cause the lead connector to be deformed to the extent that it does not comply with 4.2.2.1.

Compliance shall be determined as follows.

Insert the lead connector into a lead connector GO gauge complying with Figure 2. Fasten the lead connector in the centre of zone 1 (see Figure 2) with an M2 setscrew with cup point complying with ISO 7436, applying a torque of $(0{,}15 \pm 0{,}01)$ N·m. Apply an axial withdrawal force of (15 ± 1) N for (60 ± 10) s to the grip zone and then retract the set-screw. Check that the lead connector still complies with 4.2.2.1.

4.2.2.3 Electrical isolation requirement

The lead connector shall provide electrical isolation between the lead connector pin and the surrounding fluid. Compliance shall be determined as described in annex A.

4.2.3 Marking

Marking shall be permanent and legible.

The lead connector shall be marked with the symbol “DF-1” as depicted in Figure 3.

Figure 3 — Marking for defibrillator lead connector and generator

4.3 Defibrillator connector cavity

4.3.1 Design requirements

4.3.1.1 Optional seal mechanism

If provided, seal(s) shall be located at the zone specified in Figure 4 and shall provide electrical isolation. Compliance shall be determined as described in annex A.

4.3.1.2 Dimensions

The connector cavity dimensions shall be as specified in Figure 4.

4.3.2 Other requirements

4.3.2.1 Insertion and withdrawal forces

As shipped, the connector cavity shall accept the GO gauge specified in Figure 5. Neither the insertion force nor the withdrawal force shall exceed 9 N. After insertion and withdrawal, the connector cavity shall comply with Figure 4.

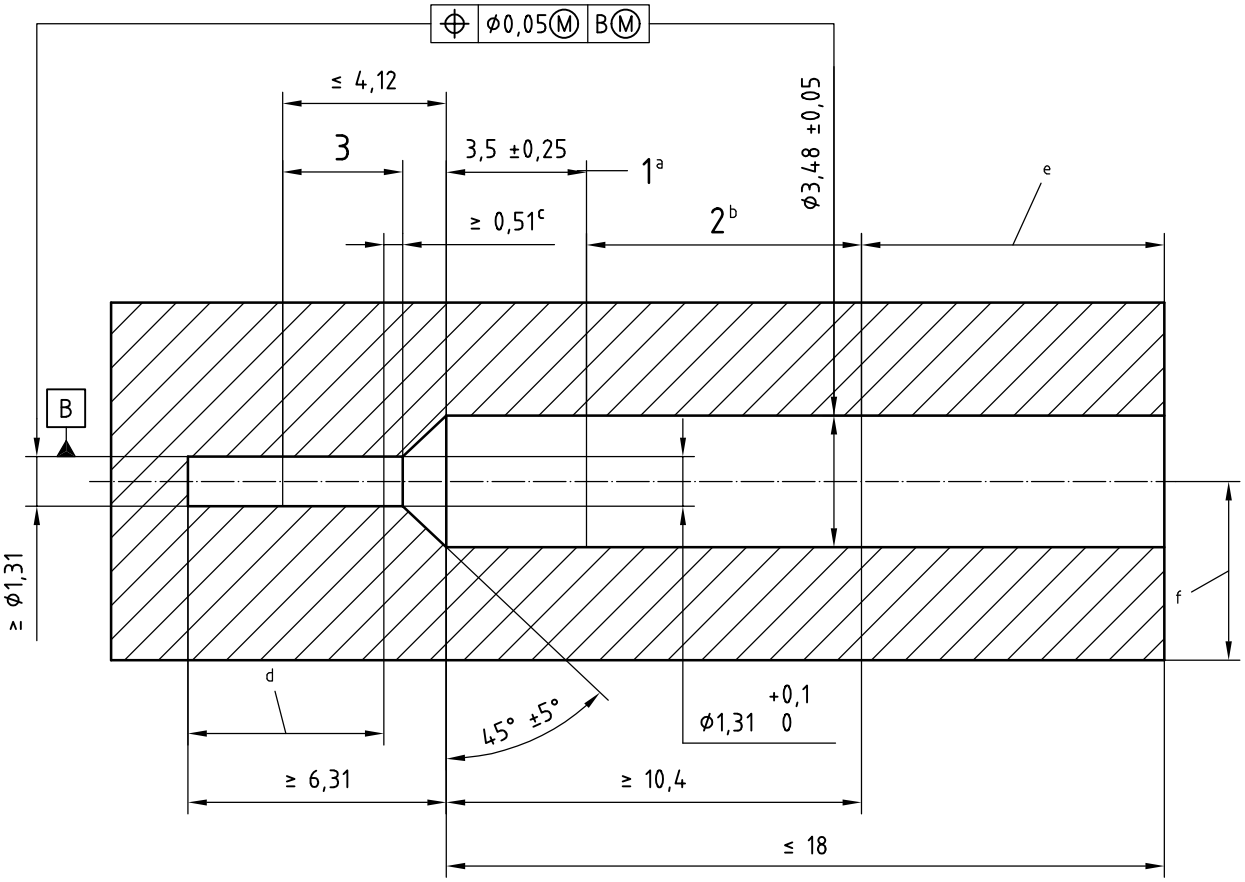
4.3.2.2 Current-carrying requirement

The connector contact shall be capable of carrying current. Compliance shall be determined as described in annex B.

4.3.3 Marking

The defibrillator generator shall be marked with the symbol “DF-1” as depicted in Figure 3.

Dimensions in millimetres unless otherwise indicated



Key

1 Optional sealing mechanism zone

2 Seal zone

3 Lead connector pin contact zone

[a] The diameter of this area shall meet the requirements of 4.3.2.1.

[b] Specified diameter applies to this zone only.

[c] $\varnothing\ 1{,}31^{+0{,}1}_{0}$ applies to this zone only.

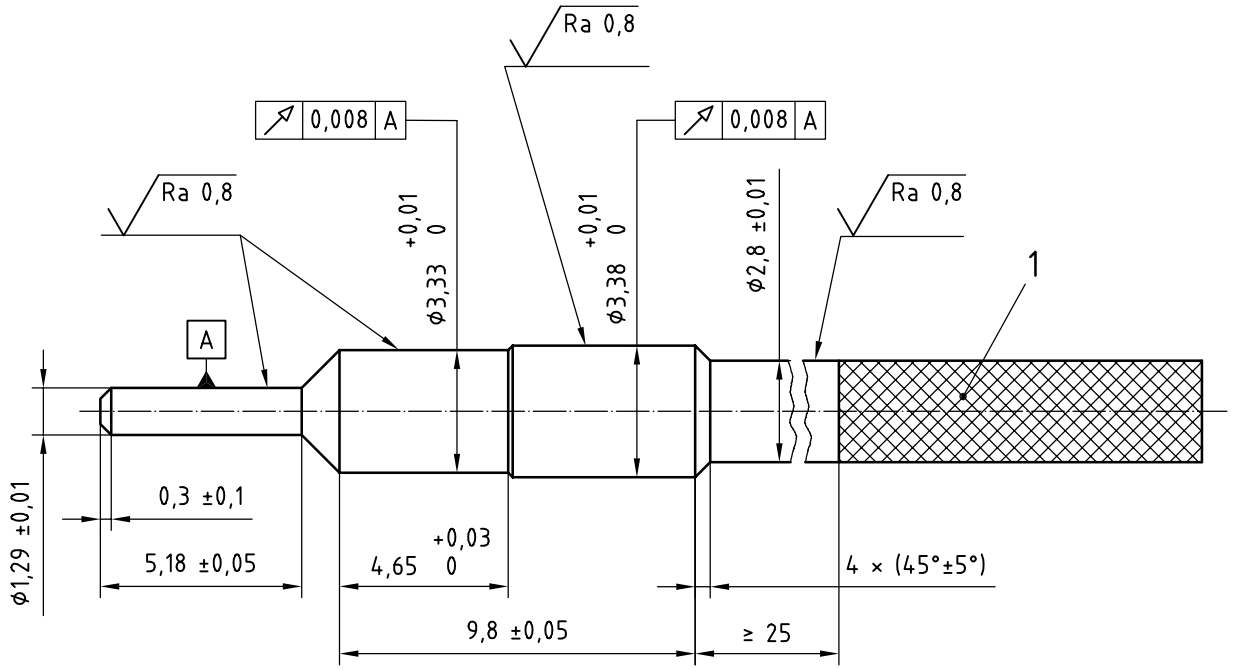
[d] ∅ 1,31 min. applies to this zone only.

[e] ∅ 3,43 min. allowed in this zone.

[f] The bore centreline shall be $\geqslant$ 2,05 mm from the defibrillator generator at any point beyond the open end of the connector cavity.

Figure 4 — DF-1 connector cavity

Dimensions in millimetres
Surface roughness in micrometers



Key

1 Knurled handle

Figure 5 — DF-1 connector cavity GO gauge

Annex A
(normative)

Lead connector electrical isolation test

A.1 General

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 a dispute, this test method shall be used.

A.2 Apparatus

A.2.1 Electrical isolation test arrangement, shown in Figure A.1. The test arrangement shall conform to the following criteria.

a) The test signal shall have a truncated exponential waveform (as an example, see Figure A.2).

b) The test signal shall have a $(1{,}5 \pm 0{,}5)$ μs rise time from $\leqslant$ 10 % to $\geqslant$ 90 % of the peak voltage and the $\mathrm{d}V/\mathrm{d}T$ shall be $\leqslant$ 2 kV/μs.

c) The test signal shall have a duration of $\geqslant$ 18 ms, and there shall be a $\geqslant$ 10 s interval between pulses.

d) The test pulse shall be 1,5 kV $\pm$ 5 % in peak amplitude, and shall be $\geqslant$ 750 V at 18 ms after the peak amplitude.

e) The reference electrode with an area of $\geqslant$ 500 mm^2 shall be immersed in a 9 g/l saline solution at a distance not less than 50 mm, and not more than 200 mm, from the lead connector under test.

A.3 Test samples

The samples intended for test shall be in the condition as shipped to the customer.

A.4 Procedure

A.4.1 For lead connectors

Assemble the lead connector and test cavity (see Figure A.3) while they are submerged in a 9 g/l saline solution, ensuring that the lead connector axis is offset by 0,07 mm and that no bubbles of air are trapped. Allow the assembly to remain immersed in the saline solution at (37 ± 5) °C for a minimum of 10 days prior to the test.

A.4.2 For connector cavities if optional seals are used

Place the impedance test pin (see Figure A.4) in the connector cavity and, using the method recommended by the manufacturer, secure the assembly with it submerged in 9 g/l saline, ensuring that no bubbles of air are trapped. Allow the assembly to remain immersed in the saline solution at (37 ± 5) °C for a minimum of 10 days prior to the test.

A.4.3 Test cycles

WARNING — The following test employs high voltages. Failure to use safe laboratory practices can result in severe electrical shock, causing personal injury or death to persons handling the equipment or conducting the test. Damage to electrical equipment is also possible.

Test either the lead connector or the connector cavity for (500 $\pm$ 50) test cycles by applying the test signal to the assembly.

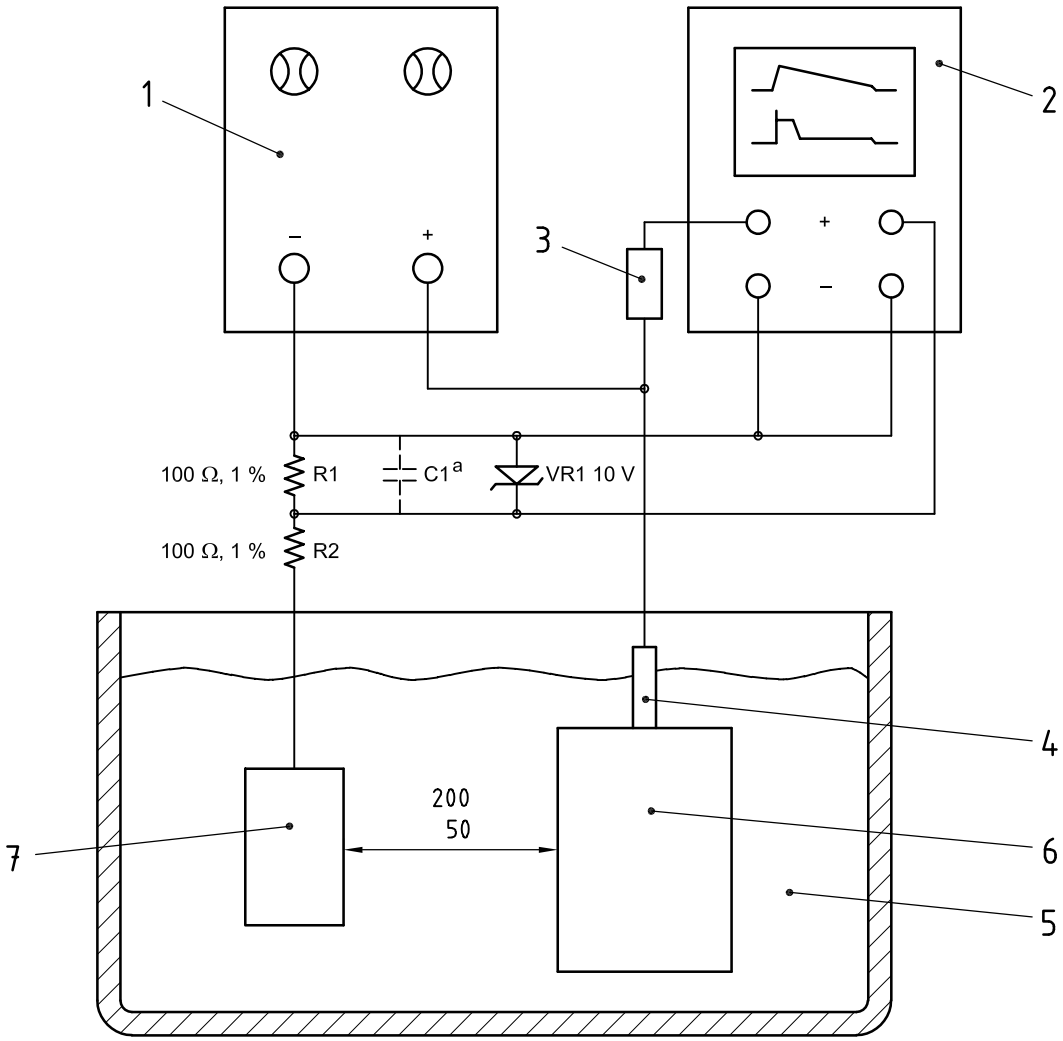
A.5 Test results

Monitor the first 10 and the last 10 test cycles, and check that the current leakage complies with the following criteria (see Figure A.5):

a) from 4 μs to 1 ms, the electrical leakage shall not exceed 100 mA;

b) from 1 ms to the end of the pulse, the electrical leakage shall not exceed 20 mA.

Dimensions in millimetres

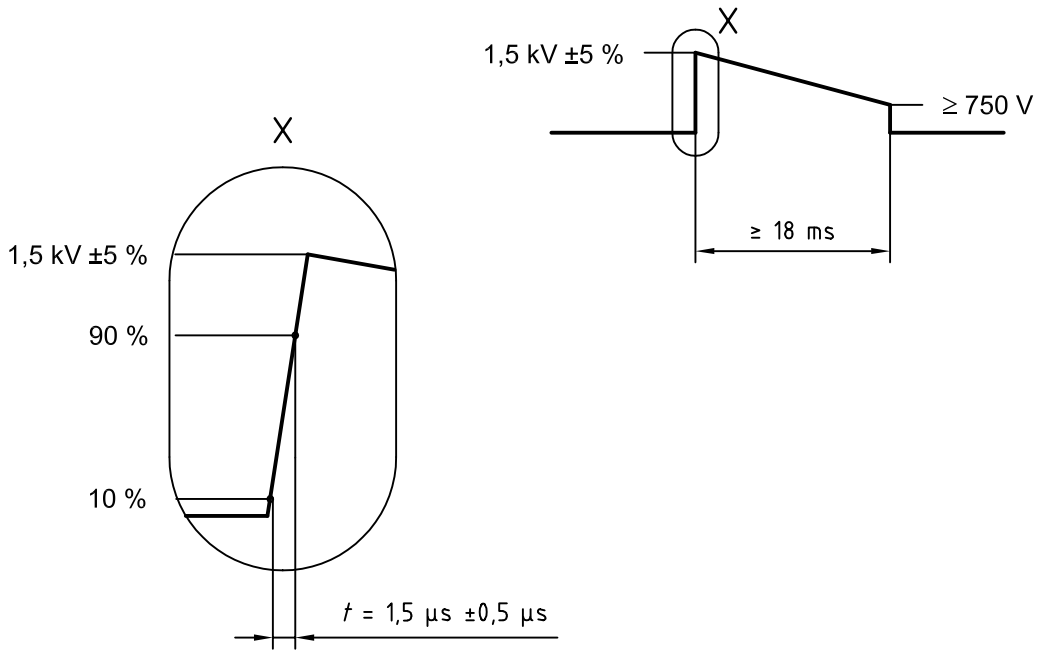


Key

1 Test signal generator
2 Dual channel oscilloscope
3 High-voltage probe
4 Lead connector body
5 Saline solution
6 Test fixture
7 Reference electrode

[a] Optional capacitor maximum value Cl = 1 ηF.

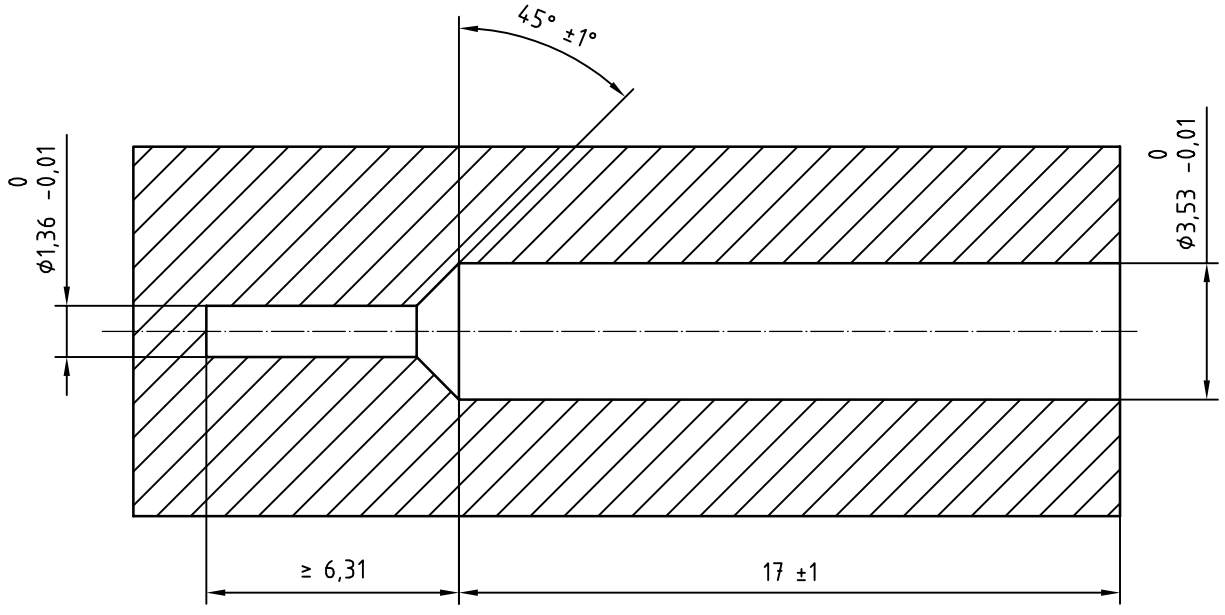
Figure A.1 — Electrical isolation test arrangement



$$\frac{\mathrm{d}V}{\mathrm{d}T} \leqslant 2\ \frac{\mathrm{kV}}{\mu\mathrm{s}}$$

Figure A.2 — Test signal

Dimensions in millimetres

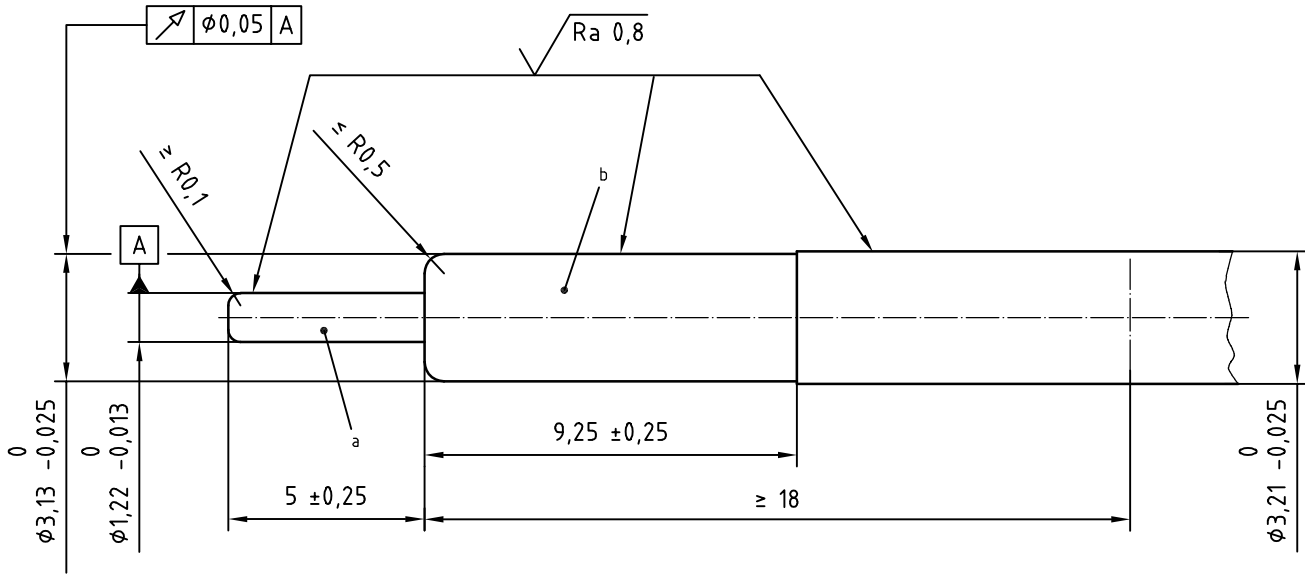


NOTE 1 Material: non-conductive epoxy.

NOTE 2 The provision for 0,07 mm offset is left to the discretion of the tester.

Figure A.3 — Test cavity

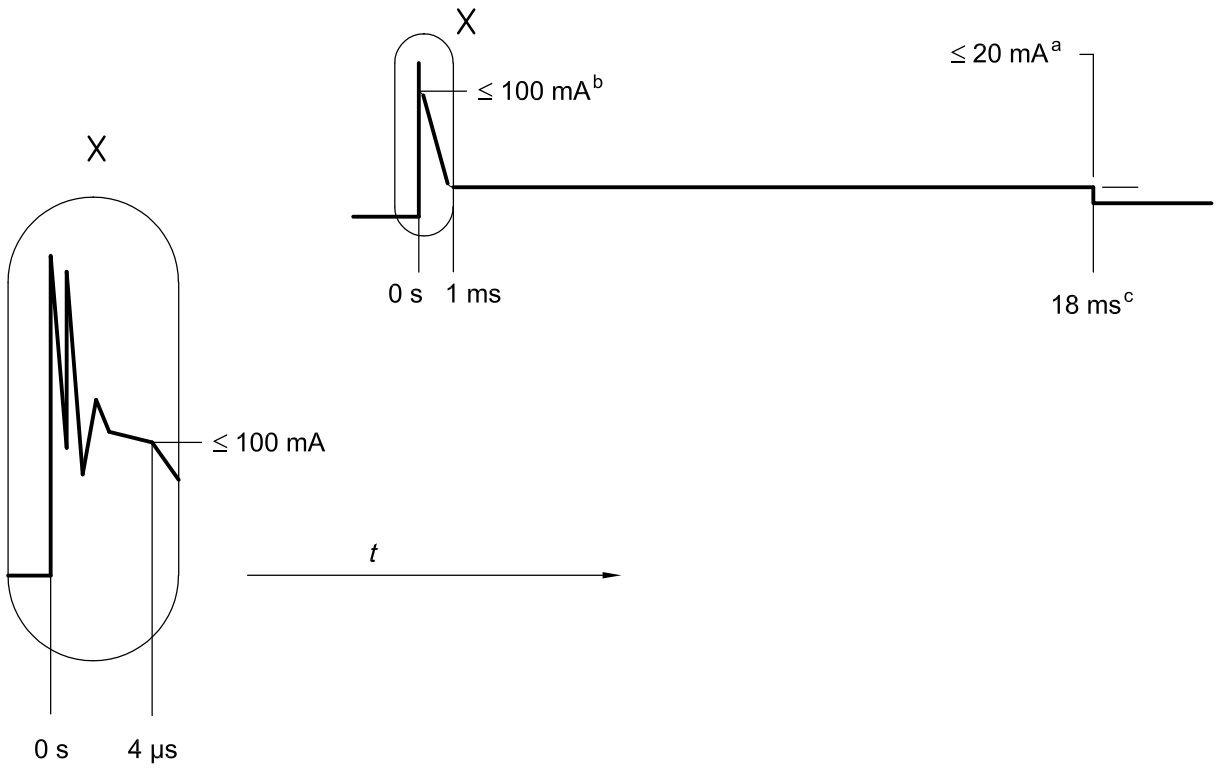
Dimensions in millimetres
Surface roughness in micrometres



[a] Material: stainless steel.

[b] Material: epoxy.

Figure A.4 — Impedance test pin



[a] From 1 ms to end of pulse.

[b] From 4 µs to 1 ms.

[c] Reference time.

Figure A.5 — Current leakage waveform

Annex B
(normative)

Connector cavity current-carrying test

B.1 General

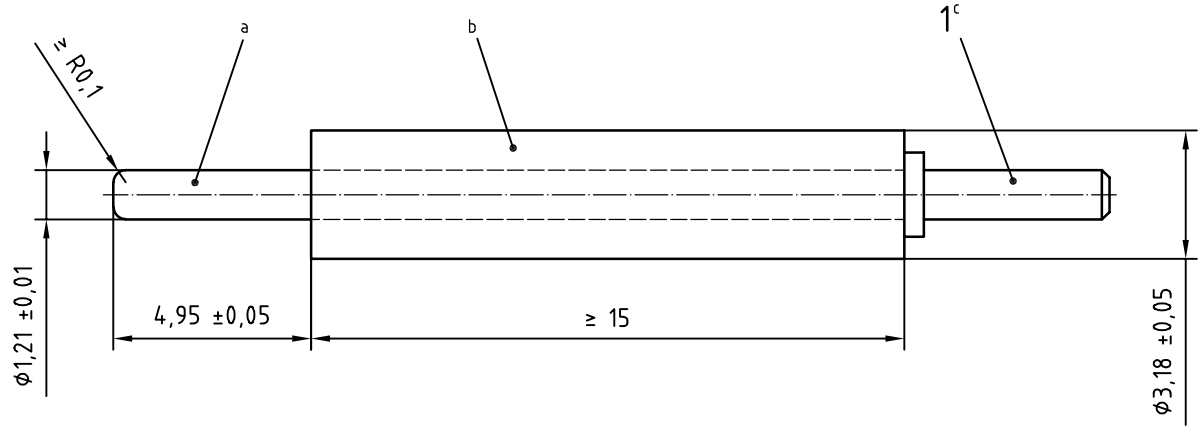
This is a type (qualification) test and is not intended to be used as a routine production test. The manufacturer may use equivalent test methods; however in a dispute, this test method shall be used.

B.2 Apparatus

B.2.1 **Current-carrying test pin** (Figure B.1).

B.2.2 **Current-carrying test arrangement** (Figure B.2).

Dimensions in millimetres



Key

1 Electrical contact

[a] Material: stainless steel.

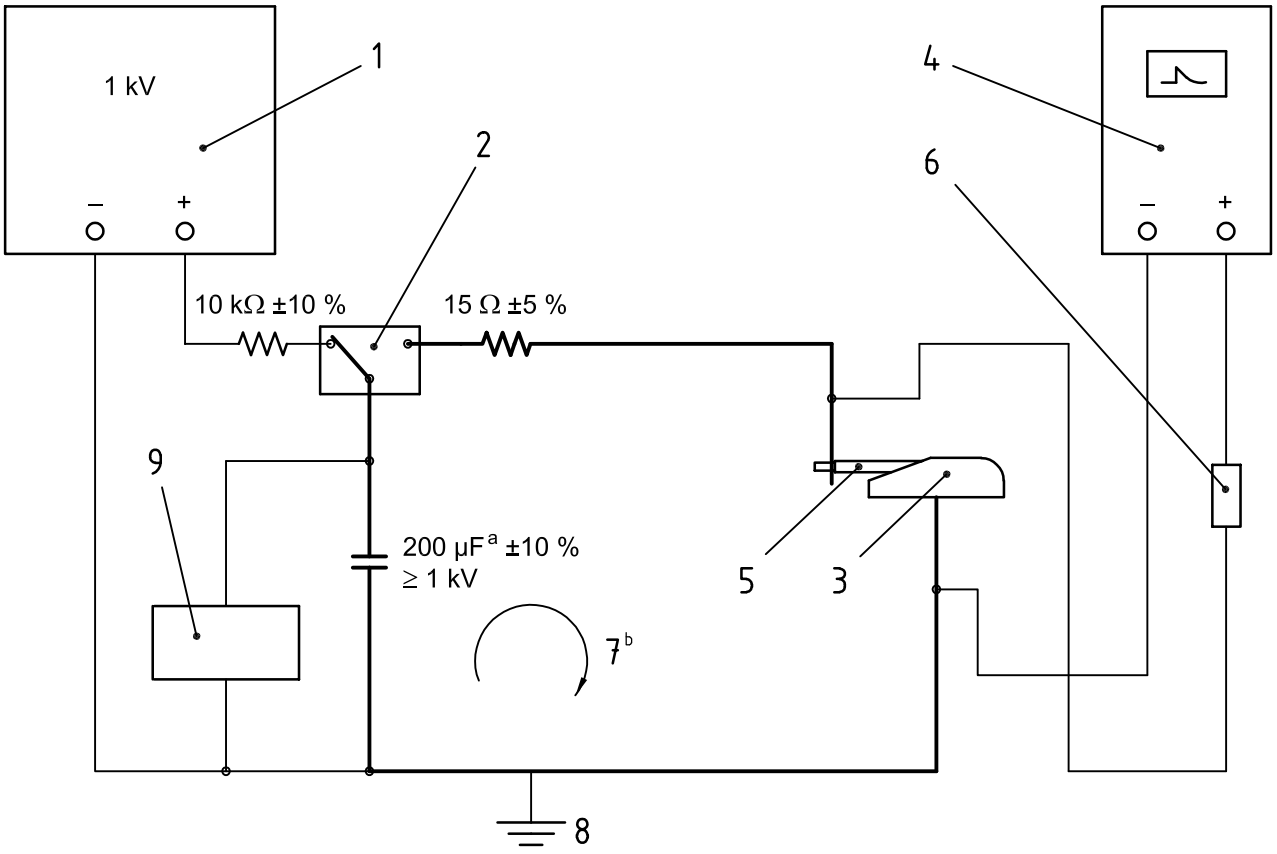
[b] Material: epoxy.

[c] Configuration may vary.

Figure B.1 — Current-carrying test pin

B.3 Specimen preparation

The connector cavity intended for test shall be in the condition as shipped to the customer.



Key

1	Power supply
2	Mercury-wetted high-voltage relay
3	Connector cavity
4	Oscilloscope
5	Current-carrying test pin
6	High-voltage probe
7	High-current loop
8	Single-point ground
9	Voltmeter

[a] The 200 μF capacitance may be a combination of capacitors.

[b] In the boldface high-current loop electrical circuit, use as short and heavy wiring as possible to reduce inductance and resistive losses. Use only soldering, bolting or welding to make electrical contacts in the high-current loop.

Figure B.2 — Current-carrying test arrangement

B.4 Procedure

WARNING — The following test employs high voltages. Failure to use safe laboratory practices may result in severe electrical shock, causing personal injury or death to persons handling the equipment or conducting the test. Damage to electrical equipment is also possible.

Carry out the test as follows.

a) Perform the test at (37 ± 5) °C with the connector cavity dry.

b) Install the current-carrying test pin in the connector cavity using the fastening mechanism that the manufacturer has provided for clinical use (e.g. set-screw, leaf spring, collet). Complete the electrical contact to the current-carrying test pin as shown in Figure B.2 and to the end of the feed-through that enters the defibrillator generator (or the electrical equivalent).

c) Charge the 200 μF ± 10 % capacitor to $(1\,000 \pm 100)$ V (see Figure B.2). After reaching the final voltage, discharge the capacitor through the test assembly via the 15 Ω ± 5 % power resistor for a minimum of 25 ms. Allow a minimum of 10 s to elapse between each successive capacitor discharge.

d) Repeat c) for (500 ± 50) cycles and monitor the voltage across the test assembly using an oscilloscope.

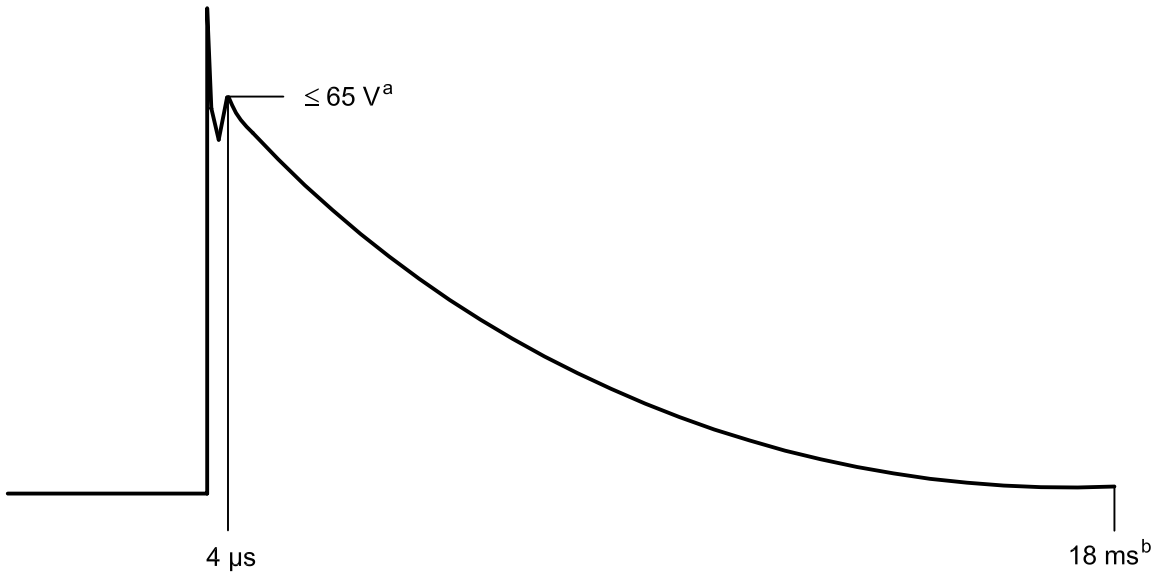
B.5 Test results

Monitor the last 10 test cycles and check that the voltage drop across the test assembly complies with the following criteria (see Figure B.3):

a) the voltage drop waveform shall decay exponentially;

b) the peak voltage measured after the first 4 μs of the waveform shall not exceed 65 V.

At the conclusion of the test, check that the withdrawal force required to remove the current-carrying test pin complies with 4.3.2.1.



[a] After 4 μs.

[b] Reference time.

Figure B.3 — Current-carrying test waveform

Annex C
(informative)

Rationale for lead connector electrical isolation test

C.1 Need for electrical isolation test

The implantable defibrillator system relies on the ability of the lead connector to seal the connector cavity. Failure to seal adequately can lead to current shunting away from the heart, which could make the defibrillation attempt less effective or possibly result in tissue damage in the vicinity of the defibrillator generator.

It is recognized that a lead pin offset of 0,095 mm would be the worst possible theoretical offset. However, in practice with soft materials used in lead construction, a 0,095 mm lead offset will not occur in the seal zone.

C.2 Duration of test

(500 $\pm$ 50) cycles was selected as the number of test cycles because it was considered to exceed usual clinical experience in any one patient.

The test requires that, as a minimum, the leakage current be monitored during the first ten and the last ten test cycles. Experience indicates that most failures occur early in the test procedure. It is possible that an early failure could generate gas inside the cavity by electrolysis and drive out the saline solution. This in turn could increase the isolation resistance and result in “passing” connector by cycles 491 to 500. It seems prudent to monitor the results at the beginning of the test as well as at the end. It is pointless to require the test of an early-failing connector to be run to 500 cycles.

C.3 Test signal

A truncated exponential waveform with a rise time of $(1{,}5 \pm 0{,}5)$ μs was selected because it is similar to the output capabilities of implantable defibrillators that manufacturers expect to employ for the foreseeable future. Furthermore, the comparatively rapid rise time was considered a greater stress than might be exerted by other waveforms such as a damped sinusoid.

The minimum duration of 18 ms was selected as being longer than any value considered clinically useful and the amplitude was selected as being 1,5 times any amplitude currently envisaged by the manufacturers (1 kV as stated in the Scope).

At the time this second edition was prepared, peak operating voltages were in the 700 V to 800 V range. While defibrillation energies were dropping, manufacturers were taking the opportunity to reduce defibrillator size and mass by maintaining the voltage and reducing capacitor size. As a type or qualification test, this procedure is performed on a limited sample. Statistically, some production units may not have as high electrical isolation characteristics as those tested. A safety factor of 1,5:1 between the test and maximum allowed service voltages (approximately 2:1 between the test and the practical service voltages) provides reasonable assurance that all production units will exhibit acceptable electrical isolation.

C.4 Leakage criteria

The current is not measured during the first 4 μs in recognition of the extreme difficulty of accurately monitoring a small current in the presence of a large and rapid voltage step. This was considered acceptable since it is unlikely that a unit under test could produce enough current leakage during the first 4 μs to cause tissue damage, and subsequently meet the specified leakage criteria.

The allowable leakage levels as detailed below were selected to avoid tissue damage and to represent an insignificant loss in output when compared to the many amperes typically required to defibrillate a patient.

$\leqslant$ 100 mA current leakage for the first 1 ms was considered acceptable, and unlikely to cause tissue damage.

$\leqslant$ 20 mA current leakage for the last 17 ms was considered acceptable, and unlikely to cause tissue damage, since it is similar to stimulation levels used clinically.

R2 and VR1 of Figure A.1 were added to the test circuit to provide improved safety for the test equipment and personnel operating the equipment.

Annex D
(informative)

Rationale for connector cavity current-carrying test

D.1 Need for current-carrying test

The implantable defibrillator system relies on the ability of the connector cavity to make sufficiently good electrical contact between the pin on the lead connector and the defibrillator generator to carry the defibrillation current to the patient with minimal resistive losses. If the contact is too resistive, or is unable to handle the current required, sufficient power may be dissipated in the connector assembly causing damage to it, or the defibrillation output may be reduced to the point where it is ineffective.

D.2 Duration of test

(500 $\pm$ 50) cycles was selected as the number of test cycles because it was considered far in excess of what is expected to be experienced clinically in any one patient.

D.3 Test configuration

A capacitor discharge test was selected to provide a means to deliver high peak currents in a repeatable, and easy to implement, fashion. It also represents the waveform that the test assembly is expected to experience clinically.

A 1 000 V source delivered through 15 Ω was selected to represent a very severe, but clinically possible situation.

A 200 μF capacitor was selected to provide 100 J of stored energy, which is far in excess of what the manufacturers contemplate using.

25 ms minimum capacitor discharge time was selected to ensure that the capacitor would be substantially discharged unless there was a gross failure (a borderline failure would take approximately 16 ms substantially to discharge the 200 μF capacitor).

D.4 Peak voltage criterion

The voltage is not measured during the first 4 μs in recognition of the transients that are produced by rapidly switched voltages in the presence of stray inductances. This is not expected to result in any degradation of test results since a test connector assembly having a resistance of 0 Ω will still result in a voltage decay with a time constant of 3 ms. Higher resistance assemblies will have even longer voltage decay time constants.

The peak voltage of 65 V represents a connector assembly resistance of approximately 1 Ω. For two connectors in series with a typical heart load of 40 Ω, this represents a 5 % loss in output voltage from the defibrillator generator. Any greater voltage loss was considered to be highly undesirable.

D.5 Withdrawal force

A withdrawal force requirement at the end of the test is included to check that the connector assembly has not become welded together.

Annex E
(informative)

Rationale for requirements of this International Standard

E.1 Need for a connector standard

Given the recent development and commercial use of implantable defibrillator systems, clinicians and manufacturers alike recognized the need for early development of a standard connector design. Unlike implantable cardiac pacemakers, which were used for many years until a standard connector became an obvious need, it was felt that an early start on the development of a connector standard for implantable defibrillator systems was not only prudent but necessary, if the problems experienced with the use of adapters for cardiac pacemaker connector designs were to be avoided. This International Standard will not eliminate adapters for implantable defibrillator systems, but is intended to minimize their use (and, therefore, their inconvenience and potential functional problems).

E.2 Selection of basic design concept and approach to this International Standard

This International Standard is limited to a unipolar configuration, since implantable defibrillator technology is still relatively limited.

The decision on a basic design concept has focused on the non-interchangeability of existing pacemaker leads (including IS-1 types) with implantable defibrillator systems lead connectors. In particular, it is felt that a conventional pacemaker lead was not to be connectable to a defibrillator pulse generator's high voltage output.

The DF-1 lead connector comprises a pin for electrical contact, a seal zone, a sealing mechanism zone and grip zone. The sealing mechanism on the lead connector is mandatory and provides the fundamental ability of the lead connector assembly to isolate the surrounding fluid from the lead connector pin. The seal zone on the lead provides a bearing surface for optional seals in the connector cavity. The optional seals in the connector cavity are provided to allow the manufacturers design flexibility. In addition, design flexibility is provided as regards the sealing mechanisms; their size, shape and numbers are not specified by this International Standard.

Fastening methods are not specified in this International Standard to allow manufacturers to explore alternative methods of ensuring contact between connector cavity terminals and lead connector terminals. Whatever fastening method is used, it is considered to be the responsibility of the manufacturer to ensure that adequate retention of the lead is maintained.

E.3 Guidance to this second edition

In this second edition, several changes were made to clarify the text and improve the manufacturability of connectors that are intended to meet this International Standard. These changes include:

a) the use of the term “performance requirements” in the scope of the first edition has caused confusion. The scope was revised to clarify that the performance is addressed only as a surrogate for a dimensional requirement, such as using electrical impedance in place of specifying the number and dimensions of the seals;

b) several changes made to Figure 1. These include:

   — a minimum radius of 0,1 mm is specified for the tip of the connector pin in place of “break sharp corner”, which was perceived as being too vague.

   — removal of the concentricity requirement in the seal zone, Zone 1. Placing a concentricity requirement on the sealing rings without specifying the dimensions of the sealing rings does not guarantee that the lead connector will seal properly in the connector cavity. In addition to that, concentricity measurements are costly

without providing any benefit and may result in unnecessary rejection of otherwise good parts. The seal integrity is verified by the isolation test in annex A.

— changing the method for measuring the diameter of the compliant parts for the lead connector from a single measurement to an average of three measurements made around the circumference of the cylinder. This technique is a well-accepted method for measuring the diameter of a cylinder made from compliant material. Further, if the part is too far out-of round, the connector will not be able to pass the requirement in 4.2.2.1.

c) revision upwards of the leakage current limits of the lead connector isolation test (annex A). Almost since the first edition of ISO 11318 was published, this test has been seen as very aggressive, combining a 2:1 over-voltage with a number of test pulses that equals or exceeds the total number of shocks that a lead will see during its implanted lifetime. Such an aggressive test requires fairly “bulky” seals in order to guarantee an acceptable minimum resistance between the lead tip and the surrounding fluid. Manufacturers were not experiencing problems building connectors of the DF-1 form factor that meet this requirement. However, as manufacturers began looking at downsized connectors to work with smaller pulse generators or multi-polar connectors for new applications, this sealing requirement did present a significant technical challenge. Manufacturers of integrated bipolar defibrillation leads where the ring electrode of an IS-1 type connector is electrically connected to the high-voltage coil were the first to experience this problem. This configuration produces a high-voltage potential between the ring electrode and the surrounding fluid every time a shock is delivered. The seals typical of an IS-1 connector may not be able to withstand the DF-1 test pulse. In some cases, this configuration was tested to a lower peak voltage. Yet these connectors were performing satisfactorily in the field. This anomaly prompted the review of the test requirement.

d) several minor editorial and format changes to clarify the text or to align with the requirements of the Part 2 of the ISO/IEC Directives.

e) in Figure A.4, a minimum radius of 0,1 mm was specified for the tip of the impedance test pin in connector pin in place of “break sharp corner.”

f) in Figure B.1, a minimum radius of 0,1 mm was specified for the tip of the connector pin in place of “break sharp corner.”

E.4 Specific requirement elements of this International Standard

E.4.1 Dimensions (4.2.1.2 and 4.3.1.2)

The connector pin cavity aperture depth in Figure 4 of 0,51 mm was established to allow manufacturers the option of using alternative fastening and contact means.

A maximum lead pin length is recommended for optimum visibility of the lead pin.

Only a unipolar version of the connector assembly is specified. Some space is provided to allow for future unknown lead/connector innovations or modification.

The lead connector pin cavity has a diameter smaller than that of previously used pacemaker leads (including IS-1). This will prevent inadvertent connection of such a system to conventional pacing leads, and thus prevent delivery of a high-energy shock through such pacing leads.

This International Standard only ensures physical compatibility between leads and defibrillation generators and does not address the functional compatibility of the defibrillator system.

Moreover, although the DF-1 lead connector can be inserted into an IS-1 connector cavity, the DF-1 connector pin cannot make electrical contact with the IS-1 pin cavity.

E.4.2 Performance (4.2.2 and 4.3.2)

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 maximum GO-gauge insertion and withdrawal forces specified are intended to result in acceptable clinical handling conditions.

Insertion and withdrawal force requirements are intended to provide a lead connector that can be engaged and disengaged without undue force that might damage the lead.

E.4.3 Electrical

The electrical test requirements in annexes A and B ensure that the connector assembly design meets minimum electrical requirements anticipated for an implantable defibrillator generator.

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