INTERNATIONAL STANDARD

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Cardiac defibrillators — Connector assembly for implantable defibrillators — Dimensional and test requirements

Défibrillateurs cardiaques — Ensemble connecteur pour défibrillateurs implantables — Prescriptions dimensionnelles et d'essai

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Contents

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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 11318 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*.

Annexes A and B form an integral part of this International Standard. Annexes C, D and E are for information only.

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.

Cardiac defibrillators — Connector assembly for implantable defibrillators — Dimensional 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 which do not produce more than 1 kV/50 A peak output. Essential dimensions and performance requirements are specified along with test methods.

This International Standard does not specify other connector features such as fastening means and material. Nor does it address all aspects of functional compatibility or reliability of different implantable defibrillator leads and implantable defibrillator generators assembled into an implantable defibrillator system.

NOTE 1 Defibrillator connector systems not conforming to this International Standard 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 International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard 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 7436:1983, *Slotted set screws with cup point.*

3 Definitions

For the purposes of this International Standard, the following 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 which is inserted into the connector cavity.

3.3 connector cavity: That part of the connector assembly which 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 which includes the power supply and electronic circuits.

3.13 grip zone: Area of lead connector which 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

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.

4.1 Defibrillator lead connector

4.1.1 Design requirements

4.1.1.1 Sealing mechanism

At least one seal shall be provided 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.

4.1.2 Other requirements

4.1.2.1 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.

4.1.2.2 Deformation due to setscrew 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 4.1.2.1.

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 ± 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 setscrew. Check that the lead connector still complies with 4.1.2.1.

4.1.2.3 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.

4.1.3 Marking

Marking shall be permanent and legible.

The lead connector shall be marked with the symbol "DF-1" as depicted in figure 3.

4.2 Defibrillator connector cavity

4.2.1 Design requirements

4.2.1.1 Optional seal mechanism

4.2.1.1.1 Location

If provided, seal(s) shall be located at the zone specified in figure 4.

4.2.1.1.2 Electrical isolation requirement

If provided, seal(s) shall provide electrical isolation. Compliance shall be determined as described in annex A.

4.2.1.2 Dimensions

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

4.2.2 Other requirements

4.2.2.1 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.

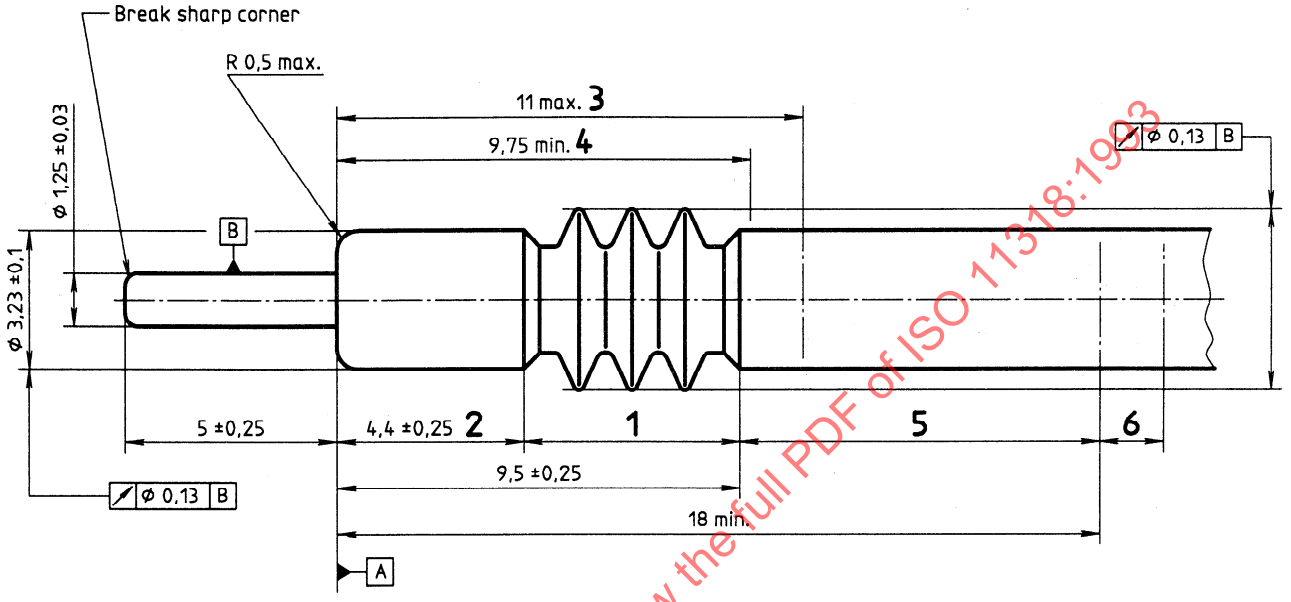
4.2.2.2 Current-carrying requirement

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

4.2.3 Marking

The defibrillator generator shall be marked with the symbol "DF-1" as depicted in figure 3.

Dimensions in millimetres



Key

1 Sealing mechanism zone. Sealing rings as shown are for illustration only and are not restricted as to shape, size or number.

2 Seal zone (for optional seal mechanism in connector cavity), ø 3,23 ± 0,1 applies to this zone.

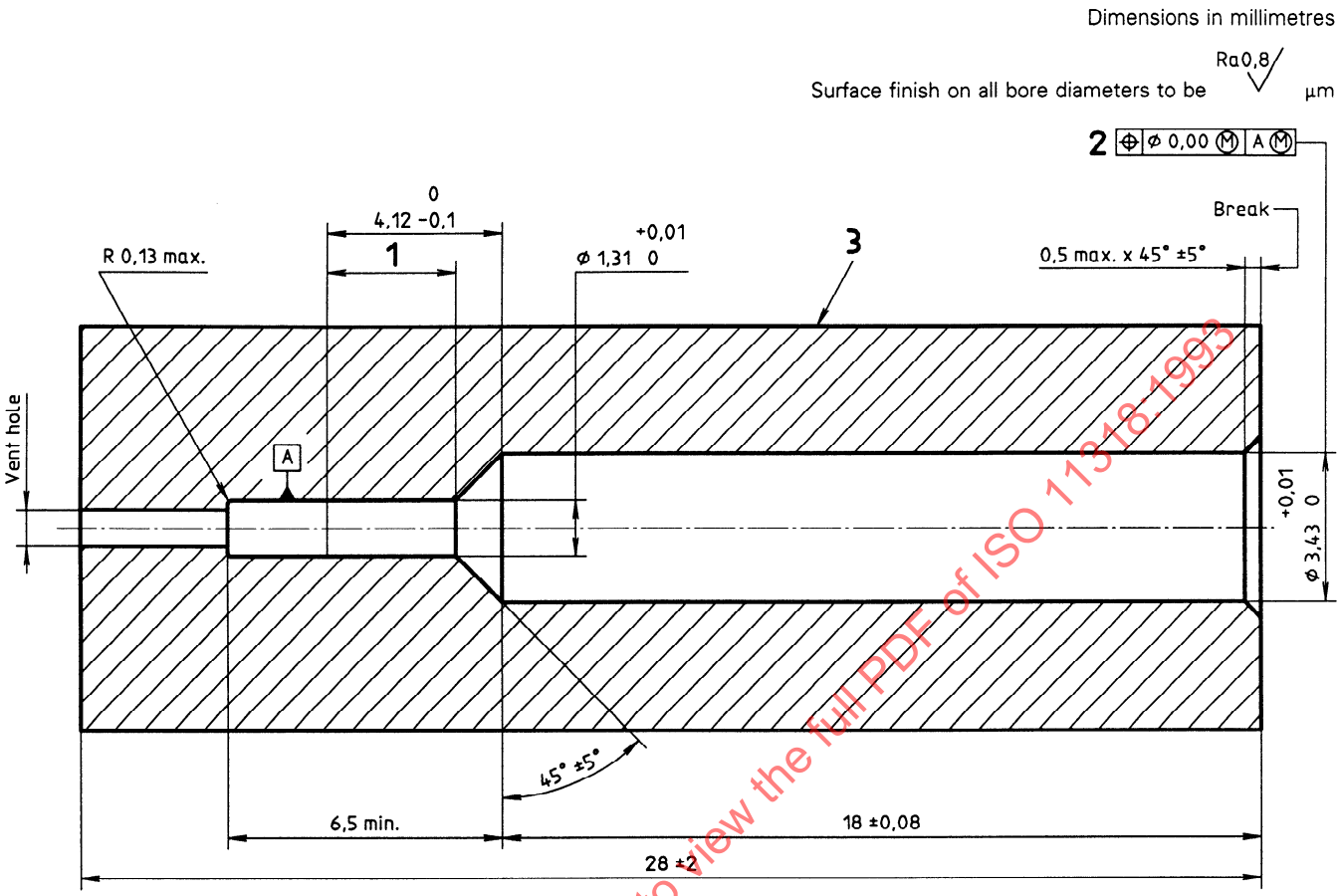
3 Maximum length of rigid area.

4 Minimum length of rigid area.

5 ø $3{,}23\ ^{+0,1}_{-0,2}$ applies to this zone.

6 Grip zone length dimension at the manufacturer's discretion, diameter 4,1 mm max.

Figure 1 — DF-1 lead connector



Key

1 Setscrew contact zone.

2 Ⓜ : indicates maximum material condition.

3 Material: epoxy.

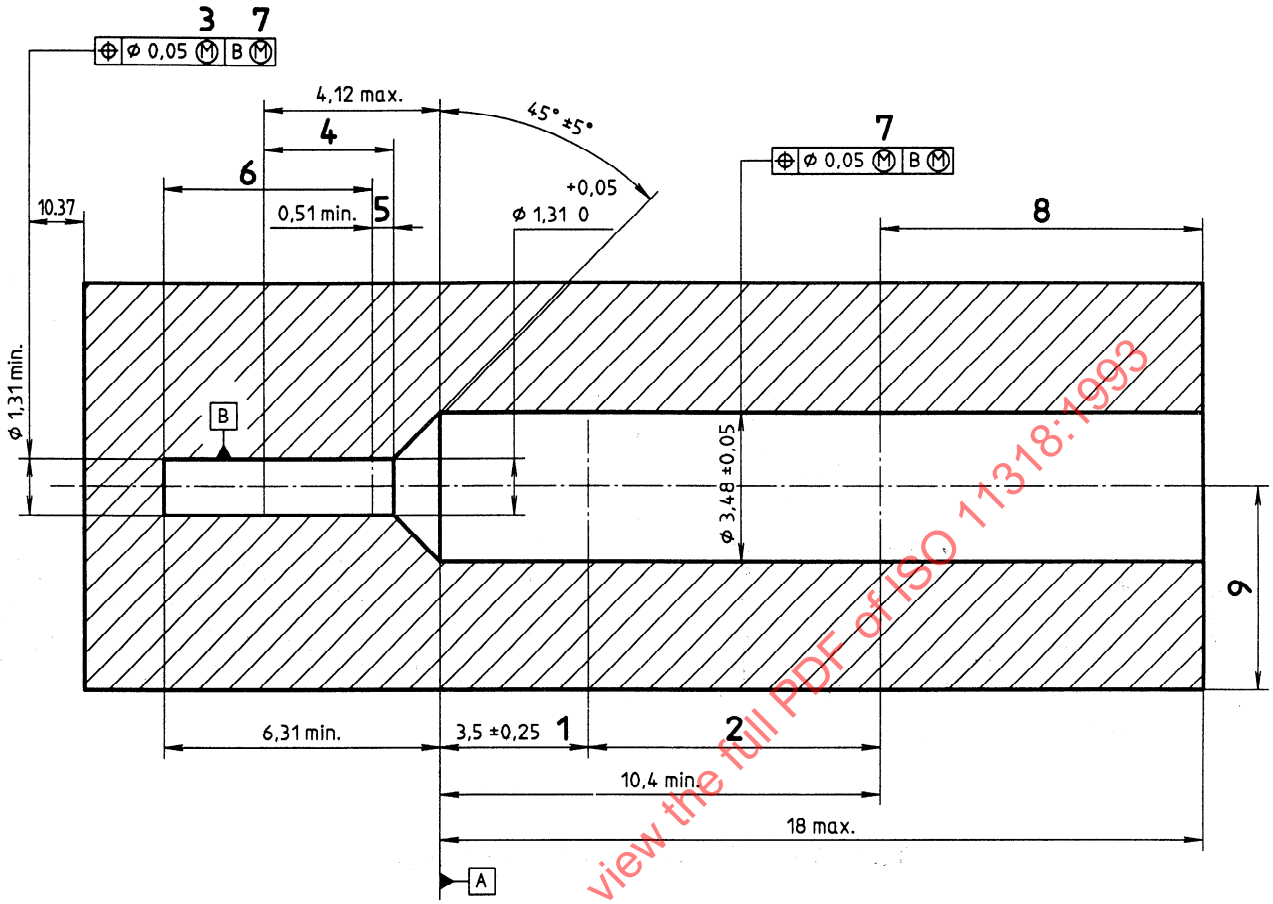
Figure 2 — DF-1 lead connector GO gauge

DF-1

Symbol to be used on the defibrillator lead connector and generator

Figure 3 — Marking

Dimensions in millimetres unless otherwise noted



Key

1 Optional sealing mechanism zone. The diameter in this area is required to meet the requirements of 4.2.2.1.

2 Seal zone. Specified diameter applies to this zone only.

3 When lead is locked in place, lead axis shall not be displaced from connector cavity axis by more than 0,07 mm.

4 Lead connector pin contact zone.

5 ⌀ 1,31 $^{+0,1}_{0}$ applies to this zone only.

6 ⌀ 1,31 min. applies to this zone only.

7 Ⓜ Indicates maximum material condition.

8 ⌀ 3,43 min. applies to this zone only.

9 The bore centreline shall be 2,05 mm min. from the defibrillator generator at any point beyond the open end of the connector cavity.

Figure 4 — DF-1 connector cavity

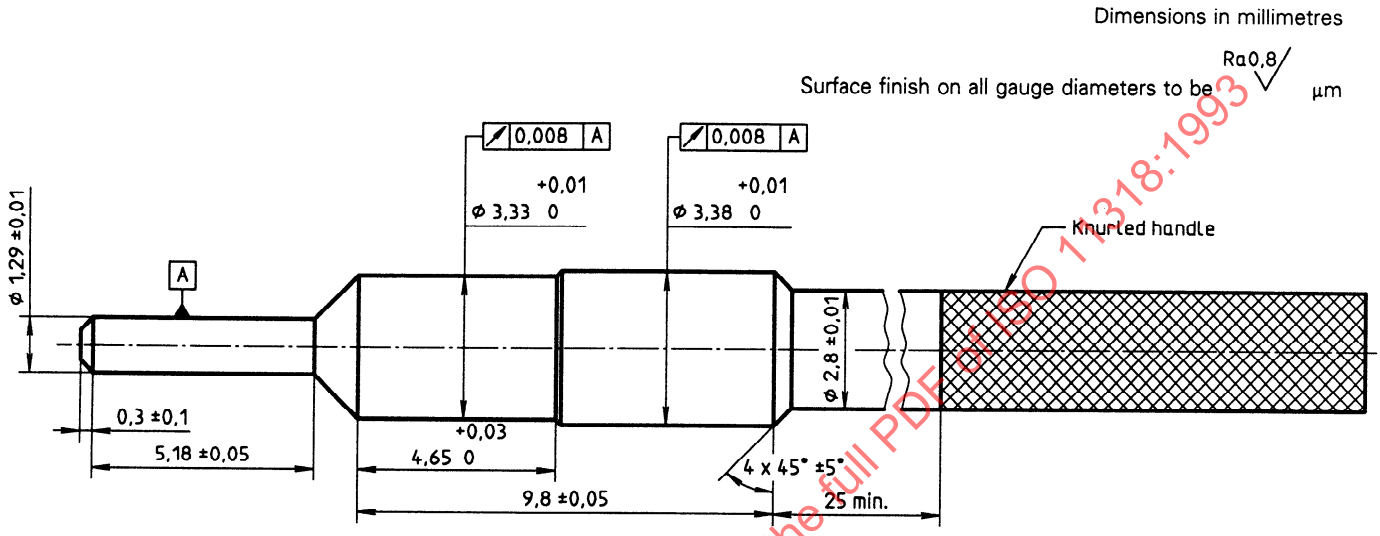


Figure 5 — DF-1 connector cavity GO gauge

Annex A
(normative)

Lead connector electrical isolation test

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.1 Equipment

The test equipment shall be the electrical isolation test arrangement shown in figure A.1. The test arrangement shall conform to the following criteria.

a) Test signal shall be truncated exponential waveform (figure A.2).

b) Test signal shall have a (1,5 ± 0,5) µs rise time from 10 % (maximum) to 90 % (minimum) of the peak voltage and the dV/dT shall be 2 kV/µs maximum.

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

d) Test pulse shall be 1,5 kV ± 5 % in peak amplitude, and shall be 750 V minimum at 18 ms after the peak amplitude.

e) Immerse a reference electrode with a minimum area of 500 mm^2 in a 9 g/l saline solution not less than 50 mm, and not more than 200 mm, from the lead connector under test.

A.2 Test samples

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

A.3 Procedure

A.3.1 For lead connectors

Assemble the lead connector and test cavity (see figure A.3) while submerged in 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.3.2 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 and 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.3.3 Test cycles

CAUTION — The following test employs high voltages. Faillure 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.

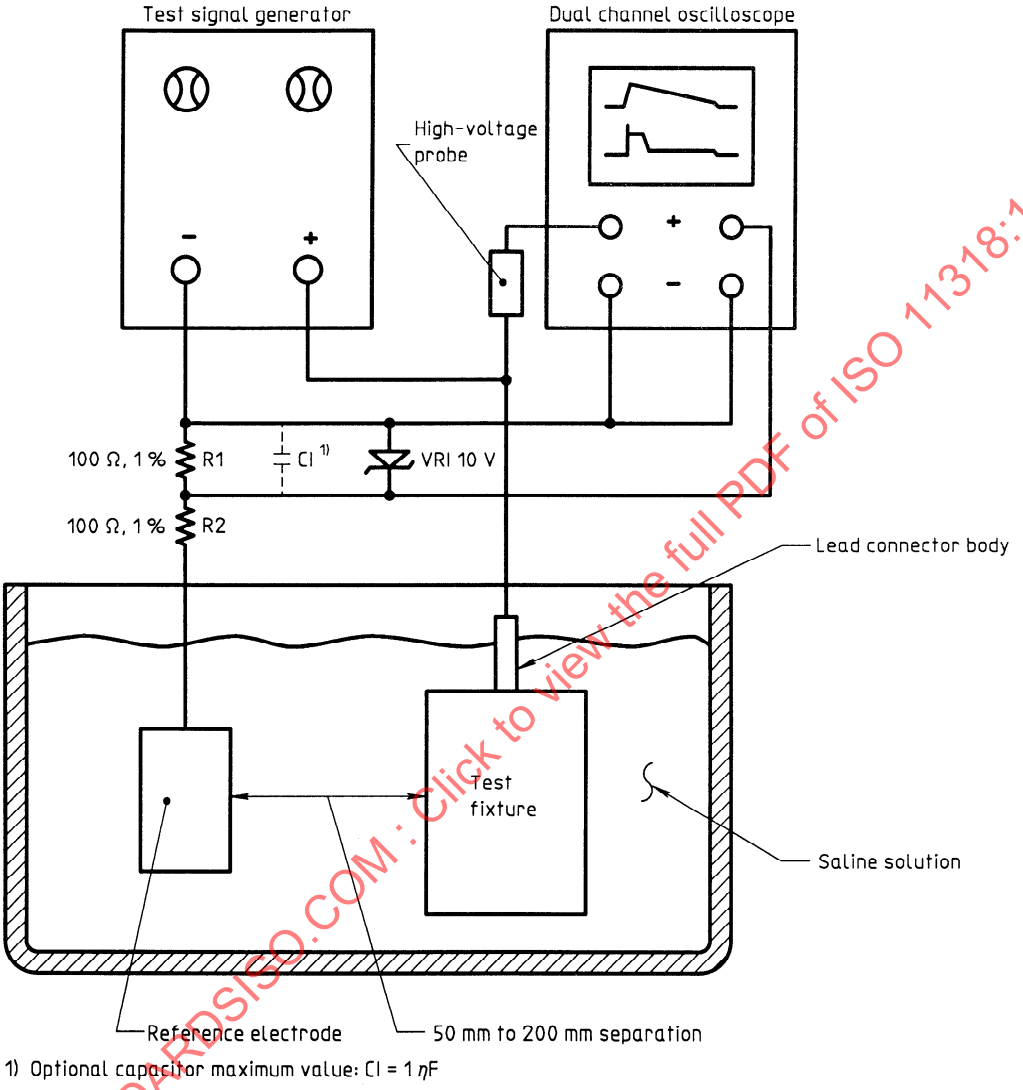
Test either the lead connector or the connector cavity for (500 ± 50) test cycles by applying the test signal to the assembly.

A.4 Test results

Monitor 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 does not exceed 50 mA;

b) from 1 ms to the end of the pulse, the electrical leakage does not exceed 10 mA.



1) Optional capacitor maximum value: Cl = 1 ηF

Figure A.1 — Electrical isolation test arrangement

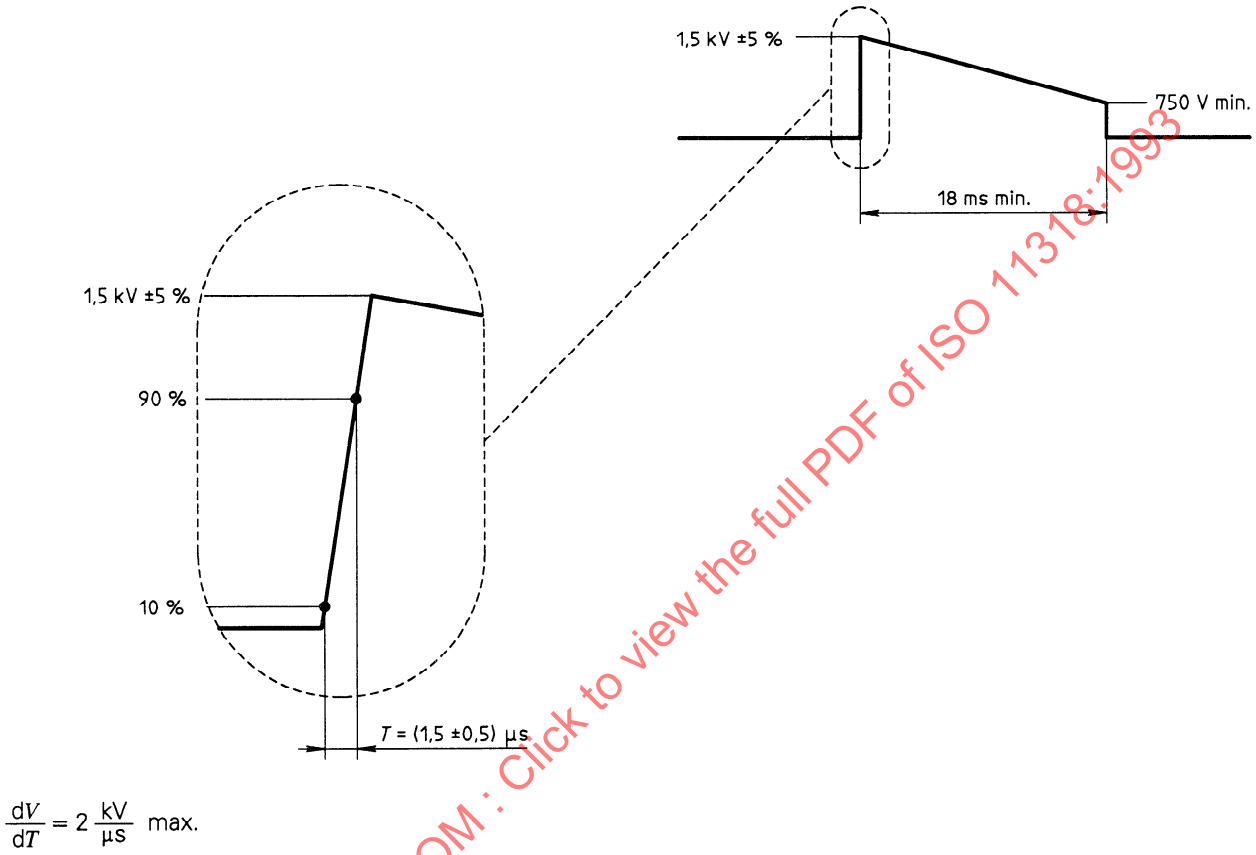
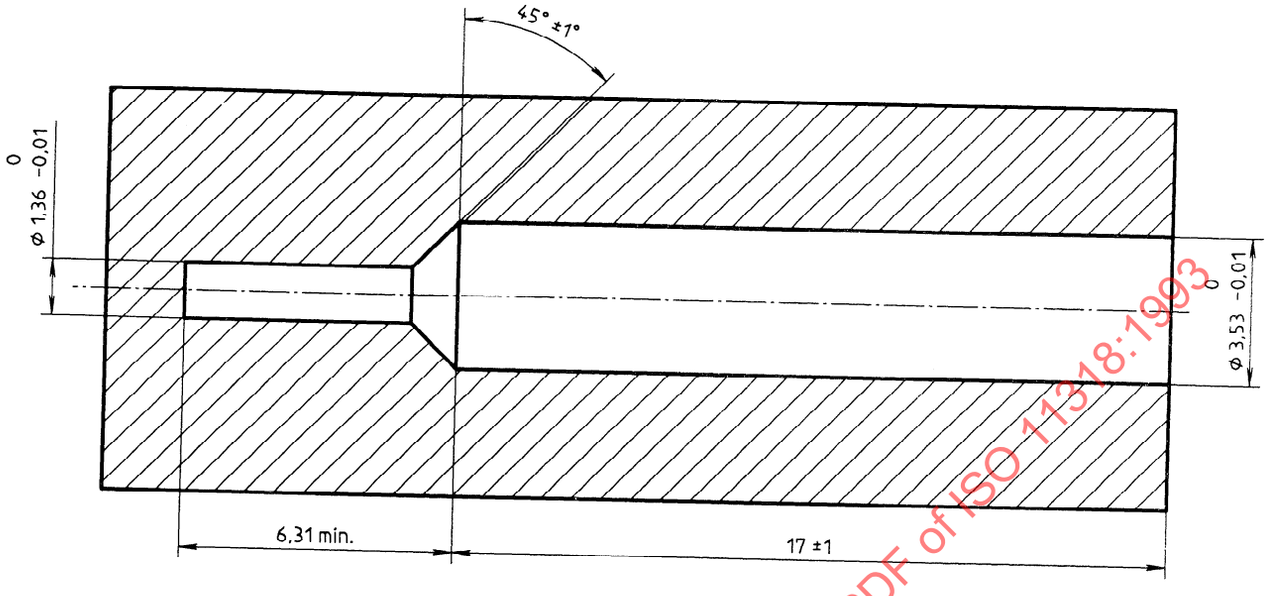


Figure A.2 — Test signal

Dimensions in millimetres



Key

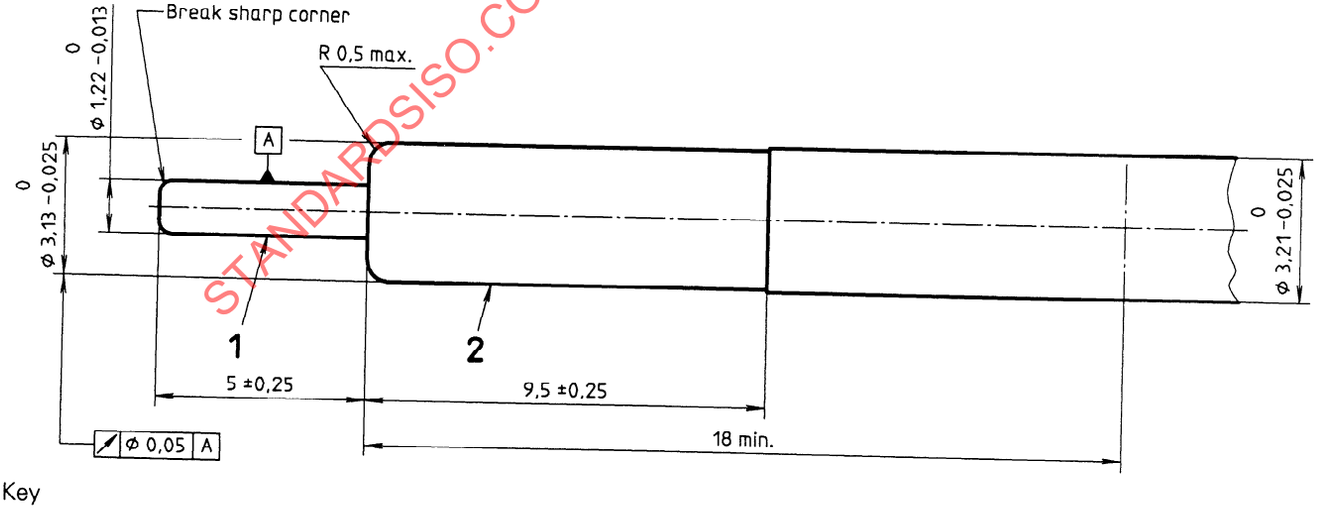
Material: non-conductive epoxy

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

Figure A.3 — Test cavity

Dimensions in millimetres

Surface finish on all pin diameters to be Ra 0,8 µm



Key

1 Material: stainless steel

2 Material: epoxy

Figure A.4 — Impedance test pin

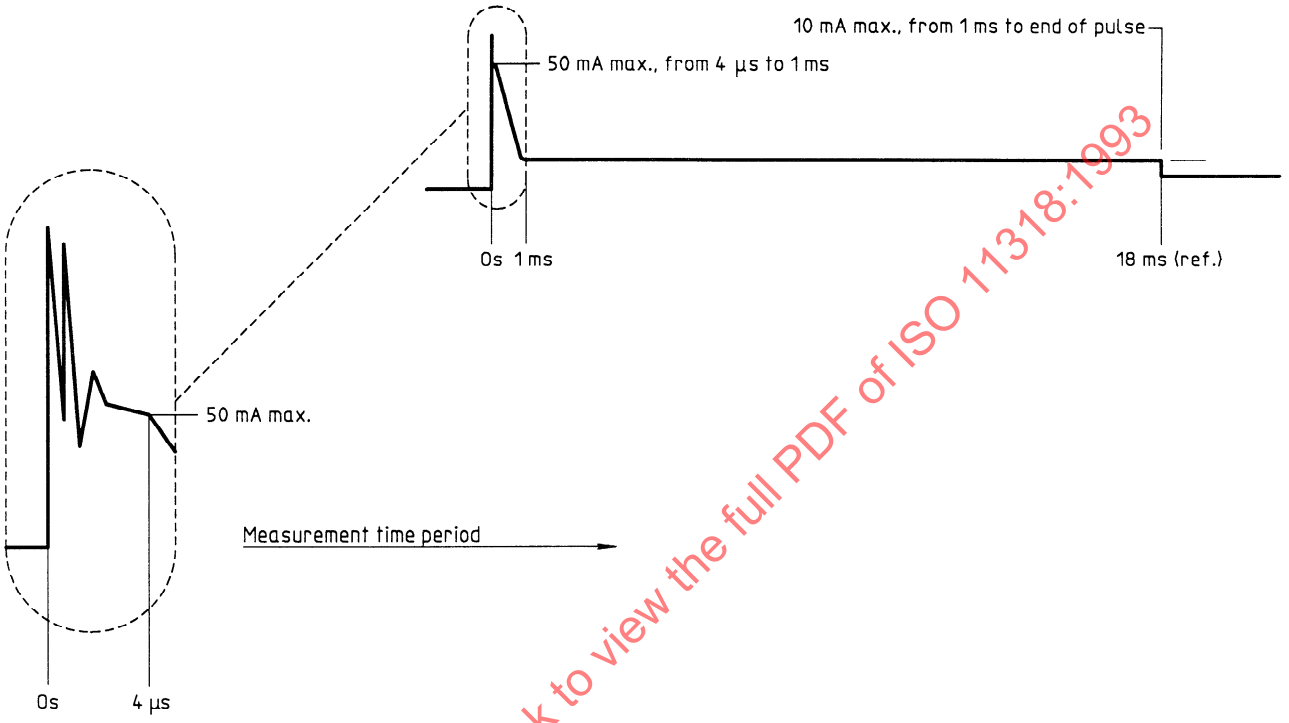


Figure A.5 — Current leakage waveform

Annex B
(normative)

Connector cavity current-carrying test

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.1 Equipment

The test equipment shall consist of the current-carrying test pin (figure B.1) and the current-carrying test arrangement (figure B.2).

B.2 Specimen preparation

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

B.3 Procedure

CAUTION — 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.

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. setscrew, 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 ± 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.4 Test results

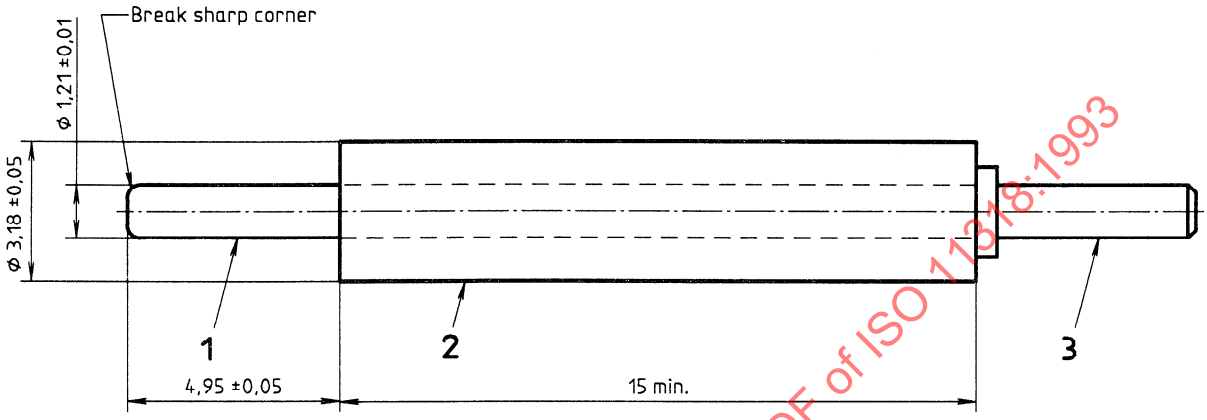
Monitor the last 10 test cycles and check that the voltage drop across the test assembly complies with the following (see figure B.3):

a) that the voltage drop waveform decays exponentially;

b) that the peak voltage measured after the first 4 µs of the waveform does 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 4.2.2.1.

Dimensions in millimetres



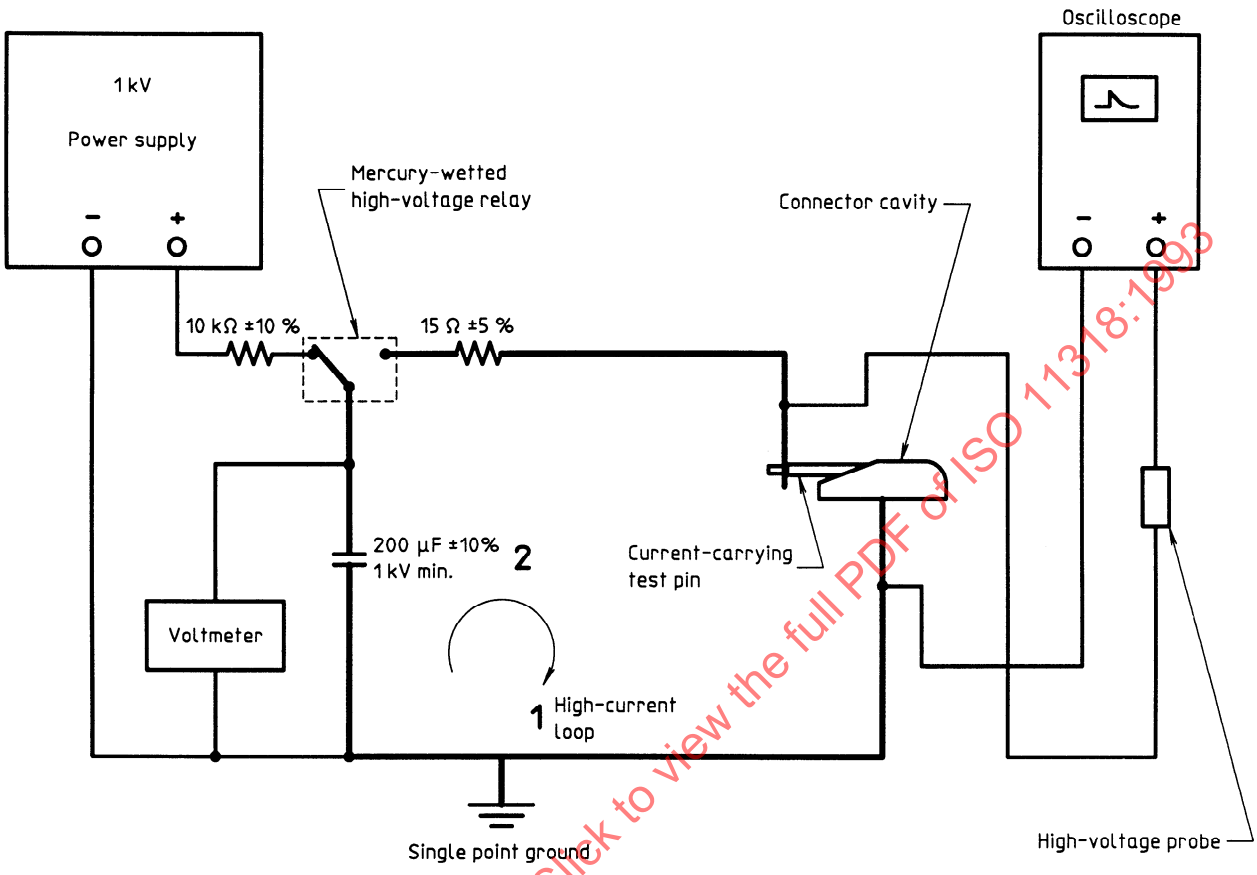
Key

1 Material: stainless steel

2 Material: epoxy

3 Electrical contact; configuration may vary.

Figure B.1 — Current-carrying test pin



Key

1 In the highlighted 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.

2 The 200 µF capacitance may be a combination of capacitors.

Figure B.2 — Current-carrying test arrangement

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.

C.2 Duration of test

(500 ± 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.

C.3 Test signal

A truncated exponential waveform with a rise time of (1,5 ± 0,5) µs was selected because it is similar to the output capabilities of implantable defibrillators that the 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 one and one half times any amplitude currently envisaged by the manufacturers (1 kV as stated in the Scope).

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.

50 mA maximum current leakage for the first 1 ms was considered acceptable, and unlikely to cause tissue damage, since it is similar to stimulation levels used clinically.

10 mA maximum 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 ± 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 thorough 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 Standard

E.1 Need for 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 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 Standard

The DF-1 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 Standard.

Fastening methods are not specified in the 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 manufacterer to ensure that adequate retention of the lead is maintained.

E.3 Specific requirement elements of Standard

E.3.1 Dimensions (4.1.1.2 and 4.2.1.2)

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.

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 smaller diameter 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 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.3.2 Performance (4.1.2 and 4.2.2)

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.