
**Cardiac defibrillators — Connector
assembly DF-1 for implantable
defibrillators — Dimensions and test
requirements**

*Défibrillateurs cardiaques — Ensemble connecteur DF-1 pour défibrillateurs
implantables — Dimensions et exigences d'essai*



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11318 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 11318:1993), which has been technically revised.

Annexes A and B form a normative 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.

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

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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

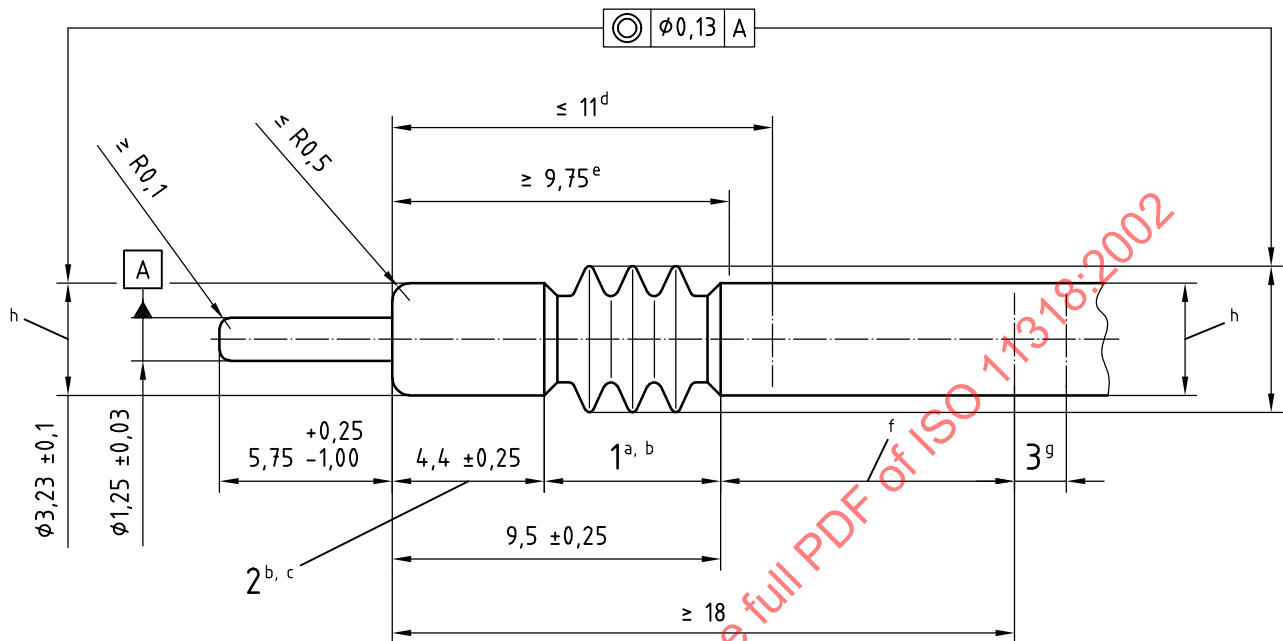
4.2.1.1 Sealing mechanism

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; $\varnothing 3,23 \pm 0,1$ 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.

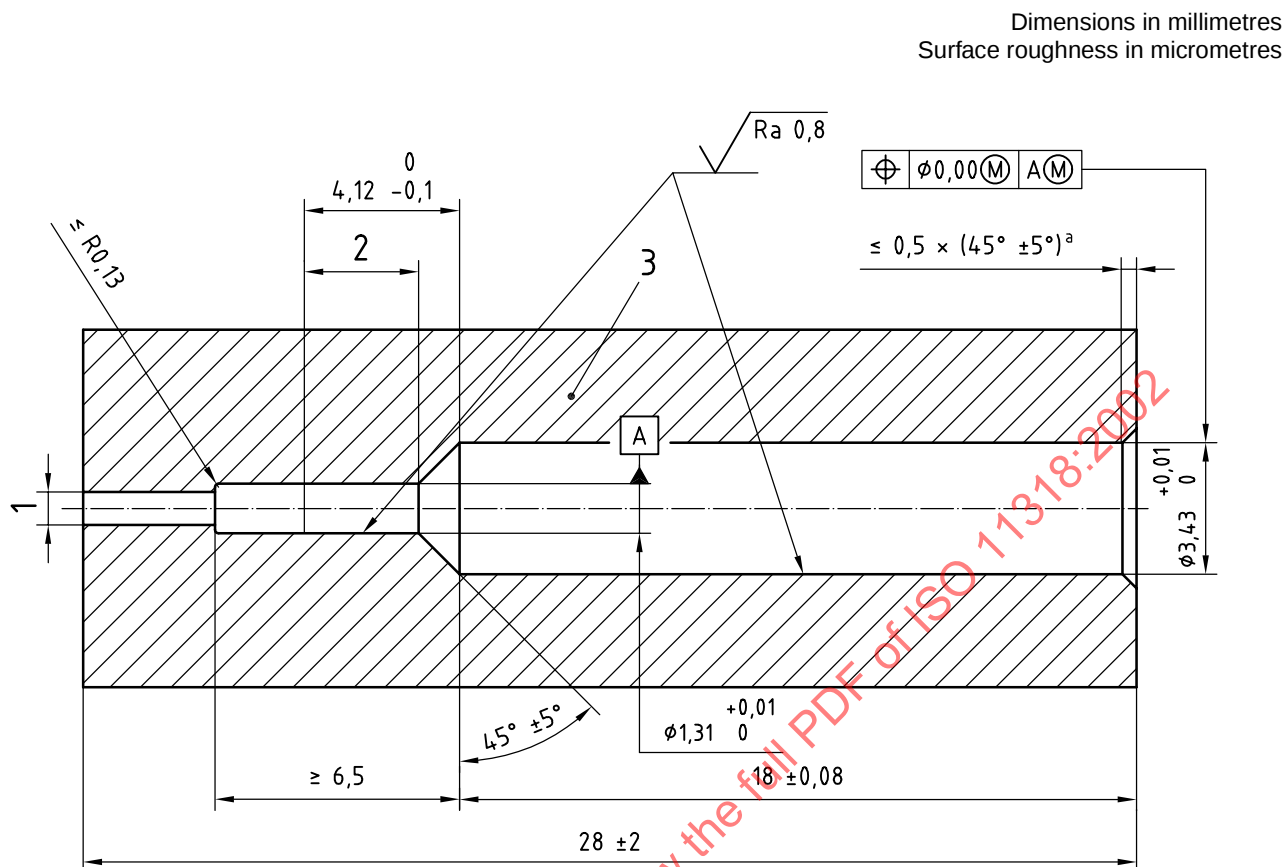
^h The diameters of the soft sections of the lead may be determined as the mean value of three measurements taken at locations oriented approximately 120° apart around the principal axis of the lead connector.

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.



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.

DF-1

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.

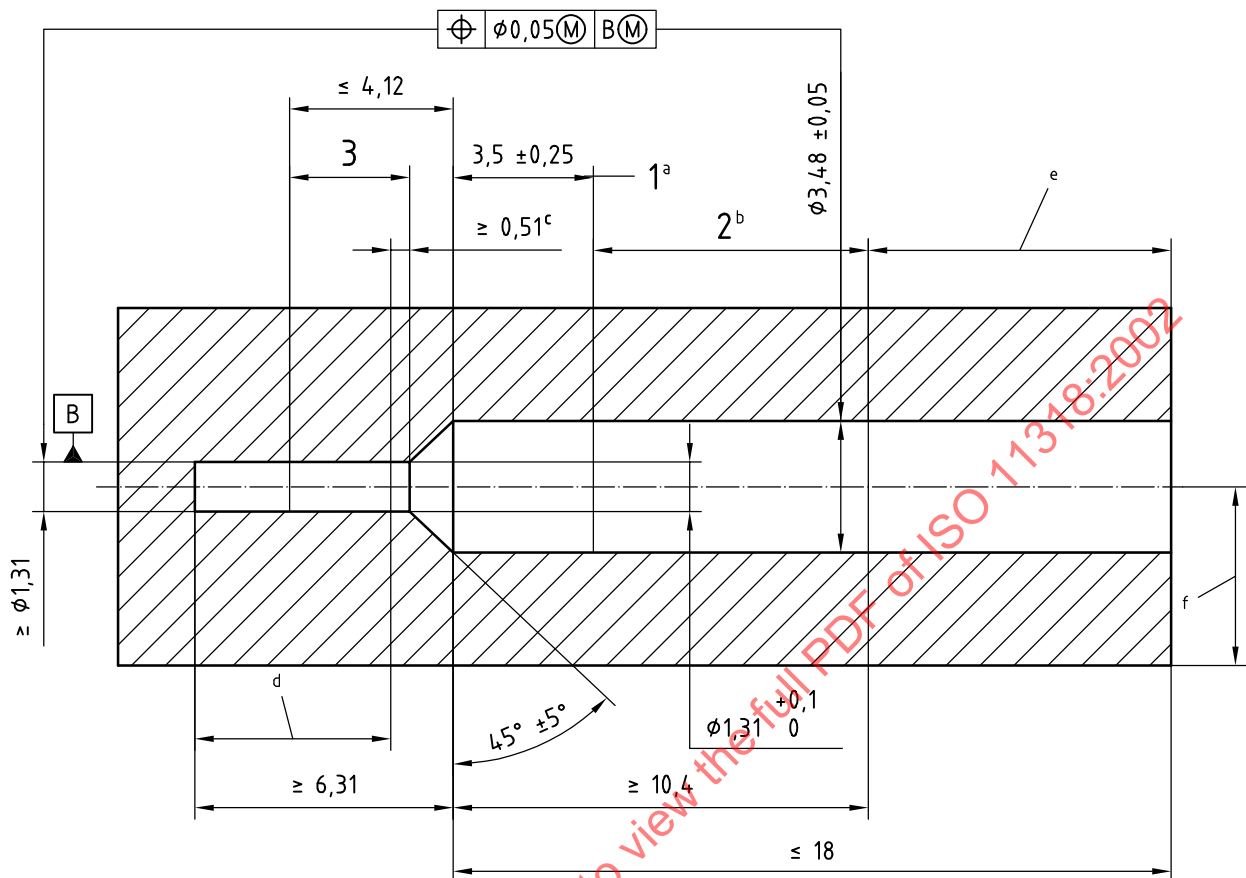
4.3.2.2 Current-carrying requirement

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.

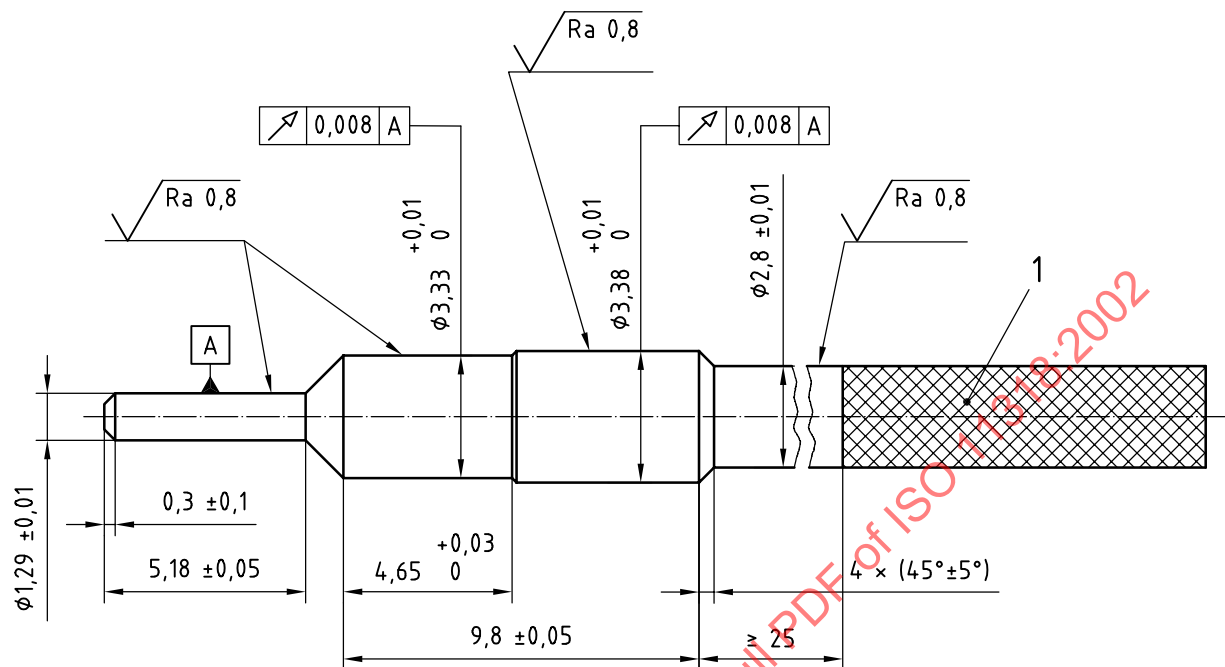
^d $\varnothing 1,31$ min. applies to this zone only.

^e $\varnothing 3,43$ min. allowed in this zone.

^f The bore centreline shall be $\geq 2,05$ 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 $\leq 10\%$ to $\geq 90\%$ of the peak voltage and the dV/dT shall be $\leq 2 \text{ kV}/\mu\text{s}$.
- c) The test signal shall have a duration of $\geq 18 \text{ ms}$, and there shall be a $\geq 10 \text{ s}$ interval between pulses.
- d) The test pulse shall be $1,5 \text{ kV} \pm 5\%$ in peak amplitude, and shall be $\geq 750 \text{ V}$ at 18 ms after the peak amplitude.
- e) The reference electrode with an area of $\geq 500 \text{ mm}^2$ 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 $0,07 \text{ mm}$ and that no bubbles of air are trapped. Allow the assembly to remain immersed in the saline solution at $(37 \pm 5) ^\circ\text{C}$ 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 $(37 \pm 5) ^\circ\text{C}$ 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.

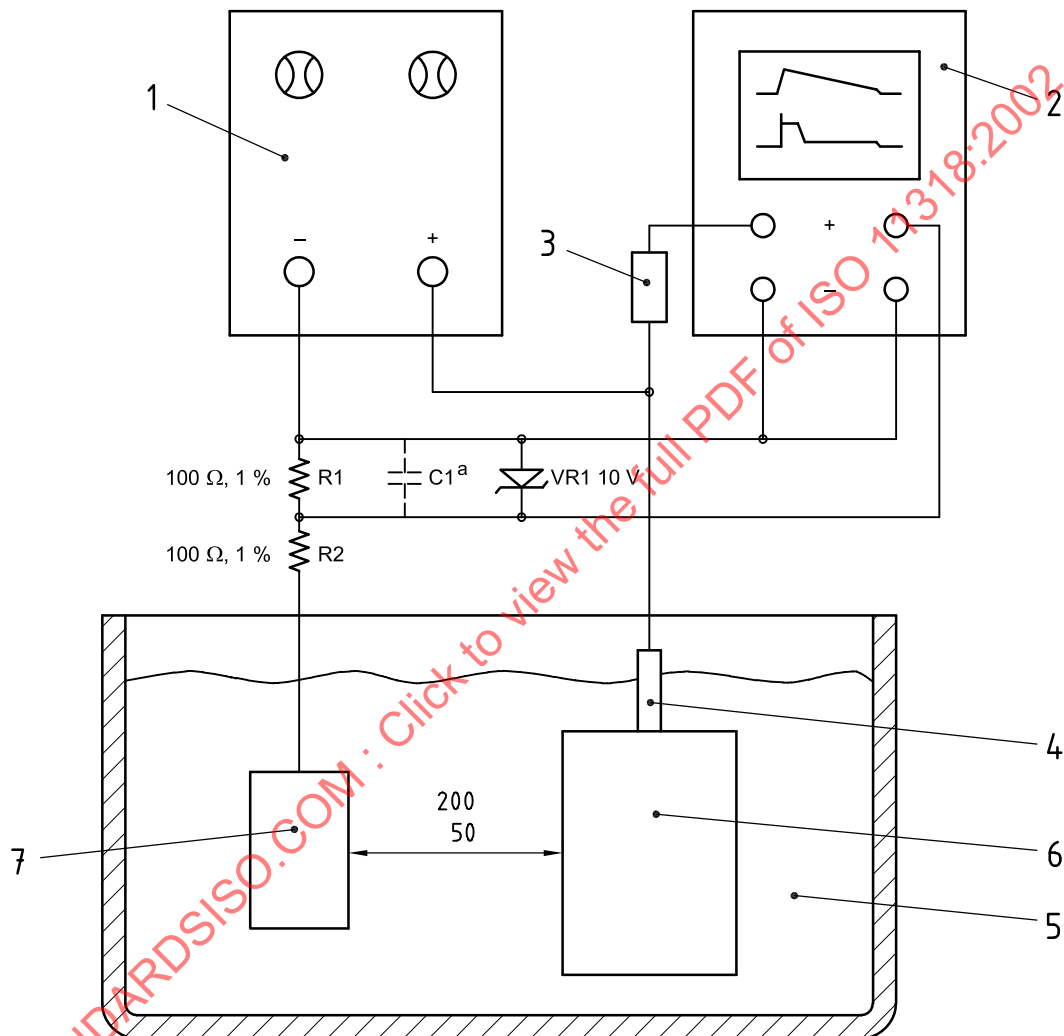
Test either the lead connector or the connector cavity for (500 ± 50) test cycles by applying the test signal to the assembly.

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):

- from $4\ \mu\text{s}$ to $1\ \text{ms}$, the electrical leakage shall not exceed $100\ \text{mA}$;
- from $1\ \text{ms}$ to the end of the pulse, the electrical leakage shall not exceed $20\ \text{mA}$.

Dimensions in millimetres

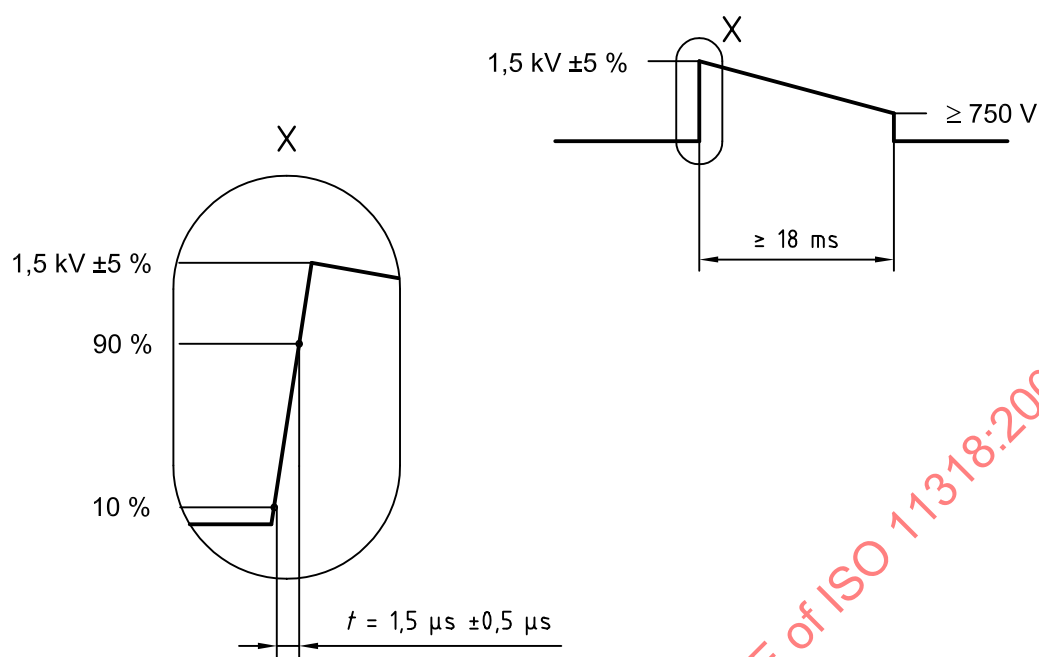


Key

- 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 $C1 = 1\ \mu\text{F}$.

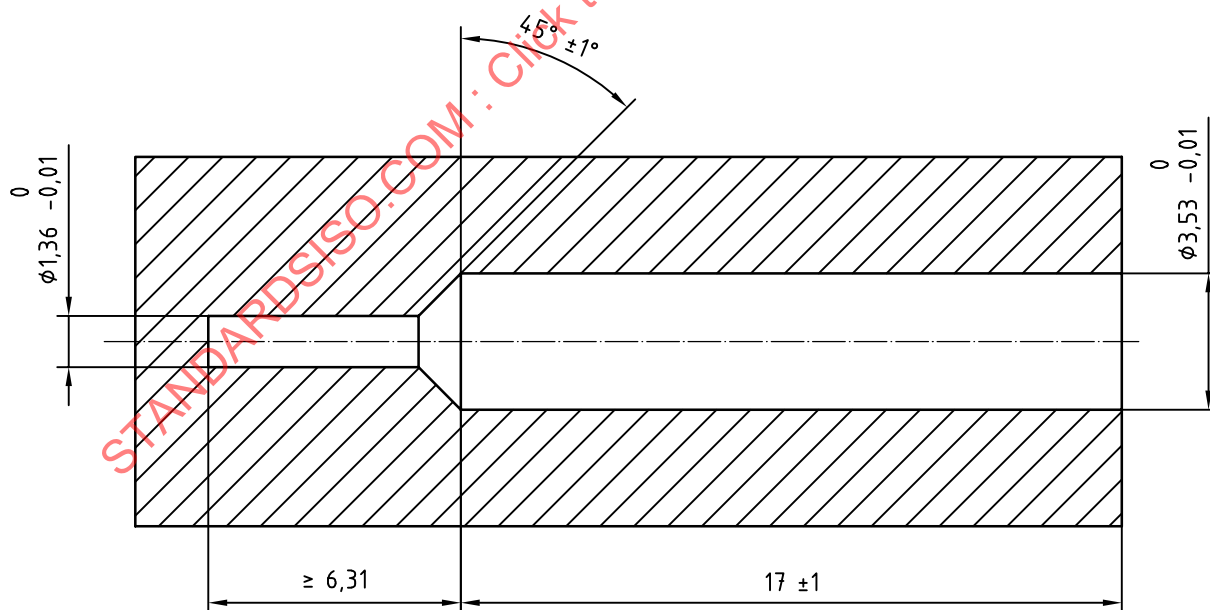
Figure A.1 — Electrical isolation test arrangement



$$\frac{dV}{dT} \leq 2 \frac{\text{kV}}{\mu\text{s}}$$

Figure A.2 — Test signal

Dimensions in millimetres

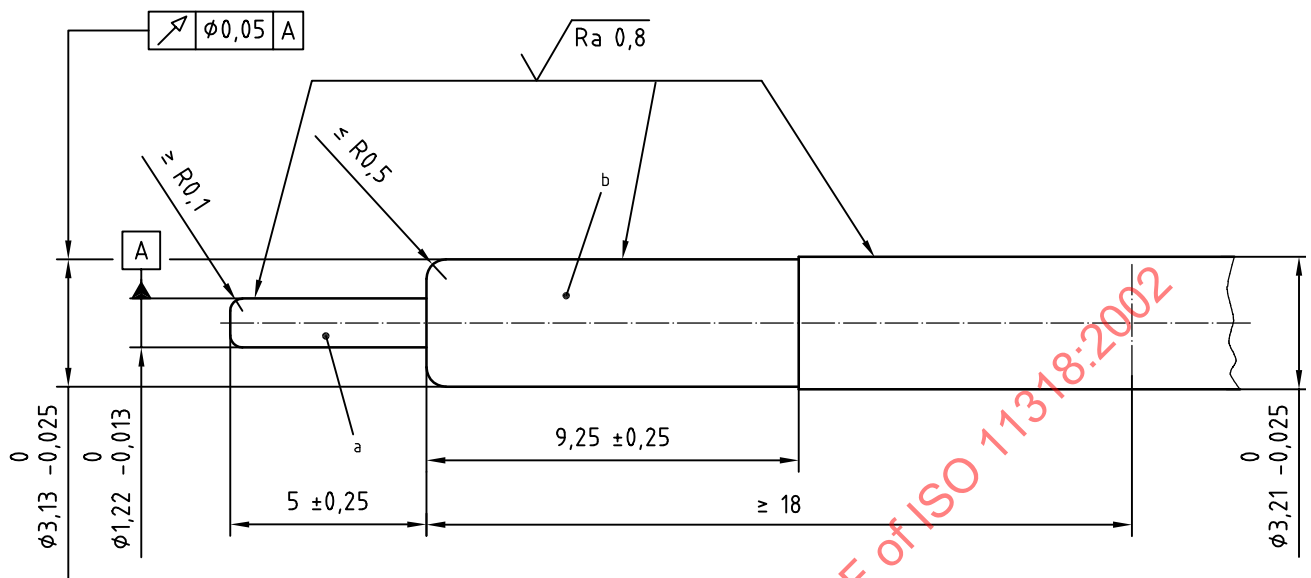


NOTE 1 Material: non-conductive epoxy.

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

Figure A.3 — Test cavity

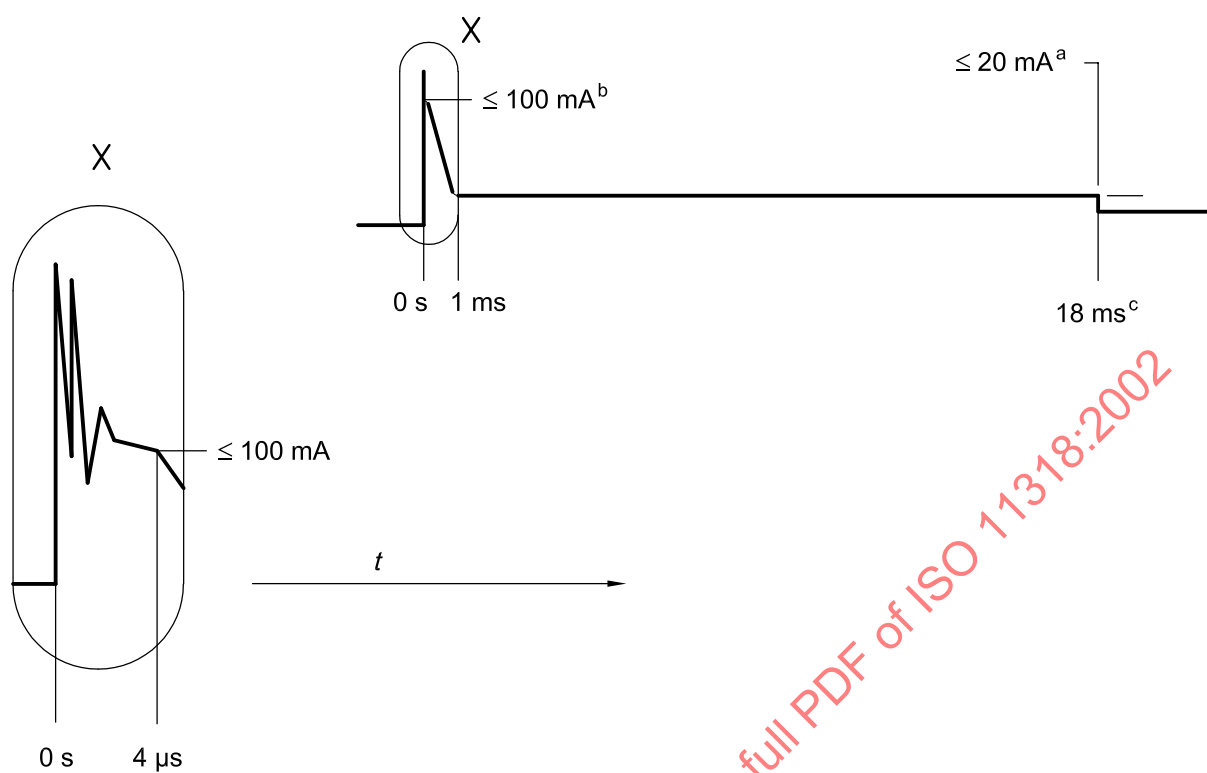
Dimensions in millimetres
Surface roughness in micrometres



a Material: stainless steel.

b Material: epoxy.

Figure A.4 — Impedance test pin



^a From 1 ms to end of pulse.

^b From $4\text{ }\mu\text{s}$ to 1 ms .

^c Reference time.

Figure A.5 — Current leakage waveform

Annex B (normative)

Connector cavity current-carrying test

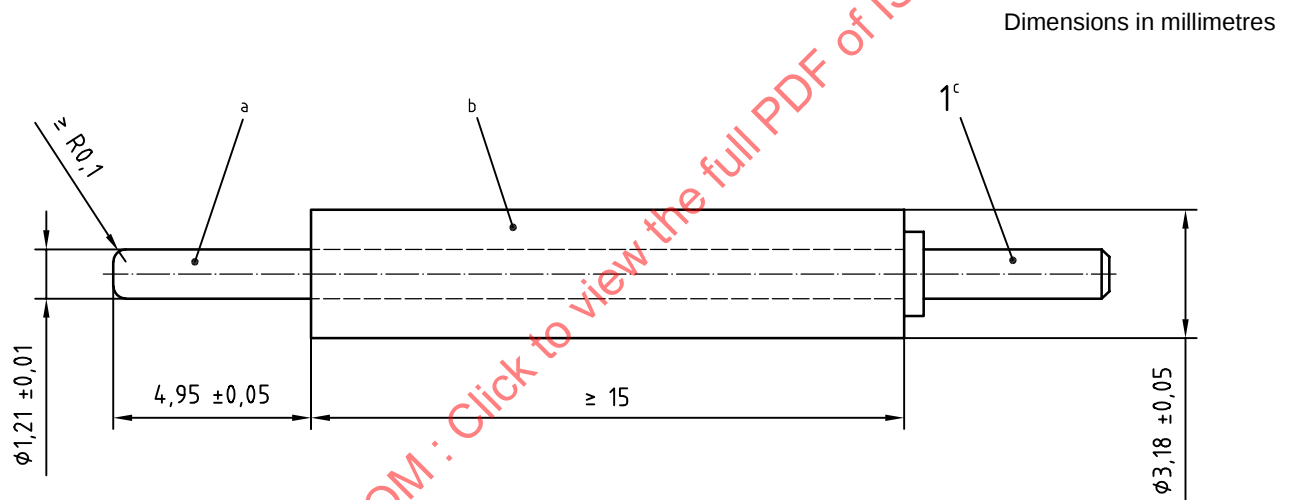
B.1 General

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).



Key

1 Electrical contact

a Material: stainless steel.

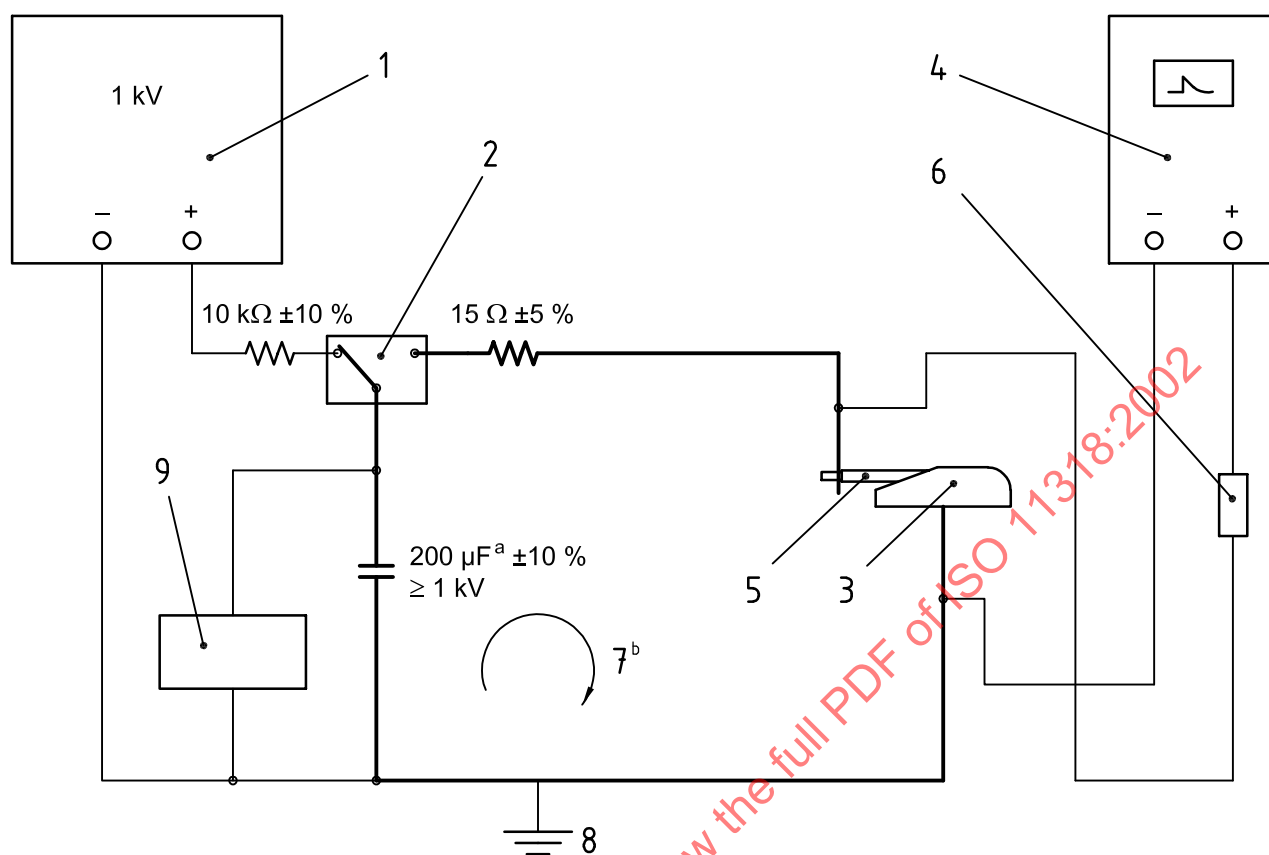
b Material: epoxy.

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.

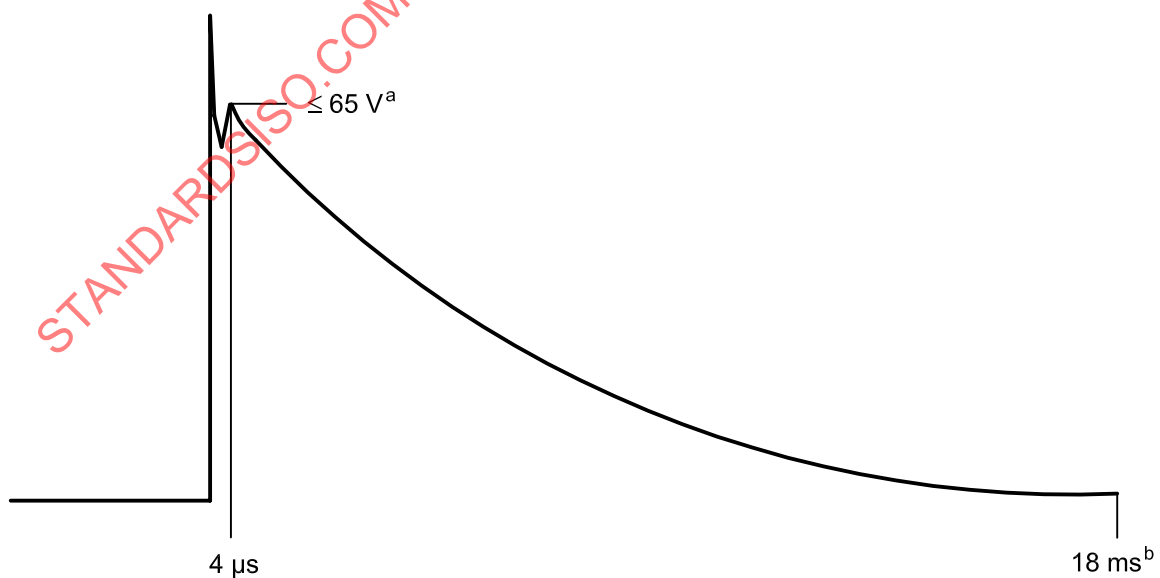
- Perform the test at $(37 \pm 5) ^\circ\text{C}$ with the connector cavity dry.
- Install the current-carrying test pin in the connector cavity using the fastening mechanism that the manufacturer has provided for clinical use (e.g. set-screw, leaf spring, collet). Complete the electrical contact to 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).
- Charge the $200 \mu\text{F} \pm 10 \%$ capacitor to $(1\,000 \pm 100) \text{ V}$ (see Figure B.2). After reaching the final voltage, discharge the capacitor through the test assembly via the $15 \Omega \pm 5 \%$ power resistor for a minimum of 25 ms. Allow a minimum of 10 s to elapse between each successive capacitor discharge.
- 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):

- the voltage drop waveform shall decay exponentially;
- the peak voltage measured after the first $4 \mu\text{s}$ 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 $4 \mu\text{s}$.

^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 ± 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 $(1,5 \pm 0,5) \mu\text{s}$ 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.