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

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

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Contents

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ISO 11318:1993
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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.

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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*.

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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.

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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.

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ISO 11318:1993
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...iso-11318-1993

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.

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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.

ISO 11318:1993
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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.

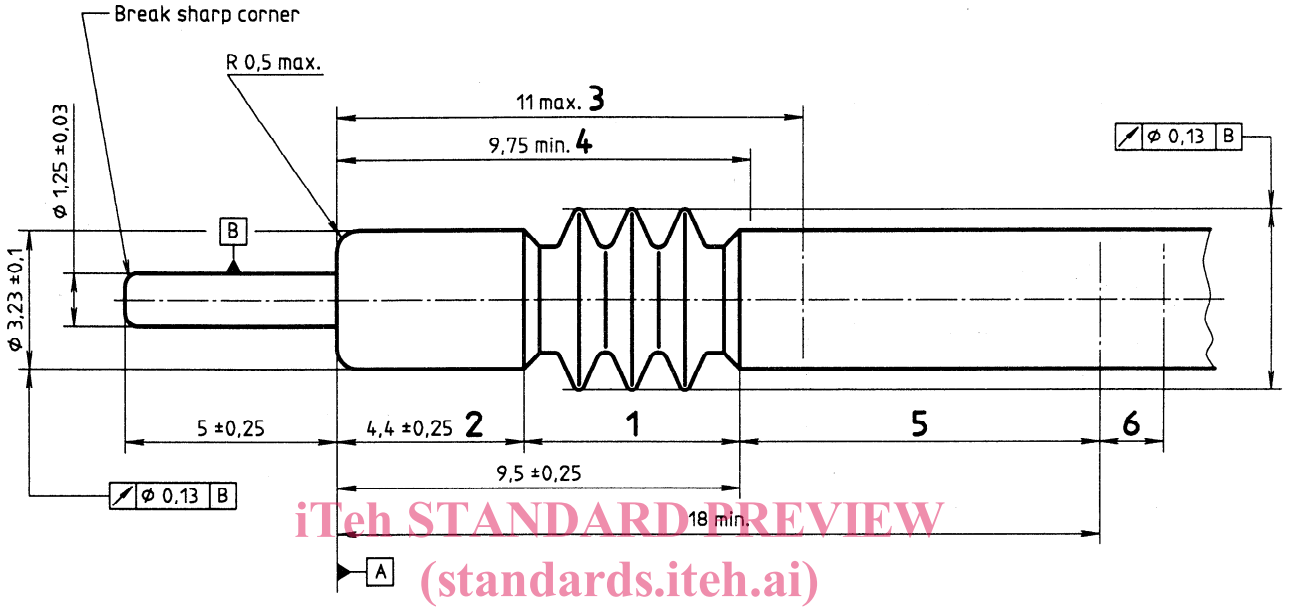
4.2.2.2 Current-carrying requirement

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



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Key

ISO 11318:1993
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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.

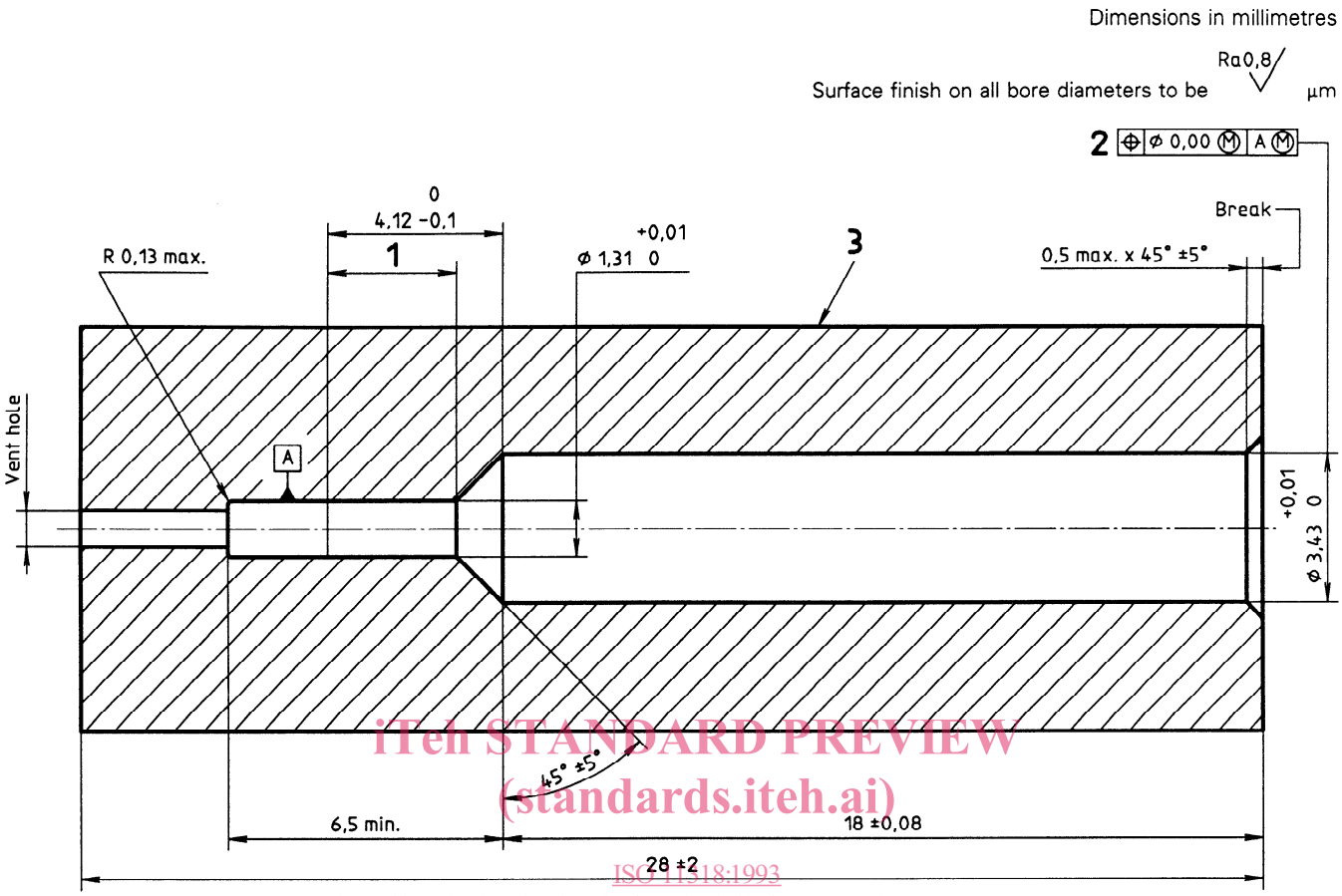
3 Maximum length of rigid area.

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



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ISO 11318:1993
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Key

1 Setscrew contact zone.

2 Ⓜ : indicates maximum material condition.

3 Material: epoxy.

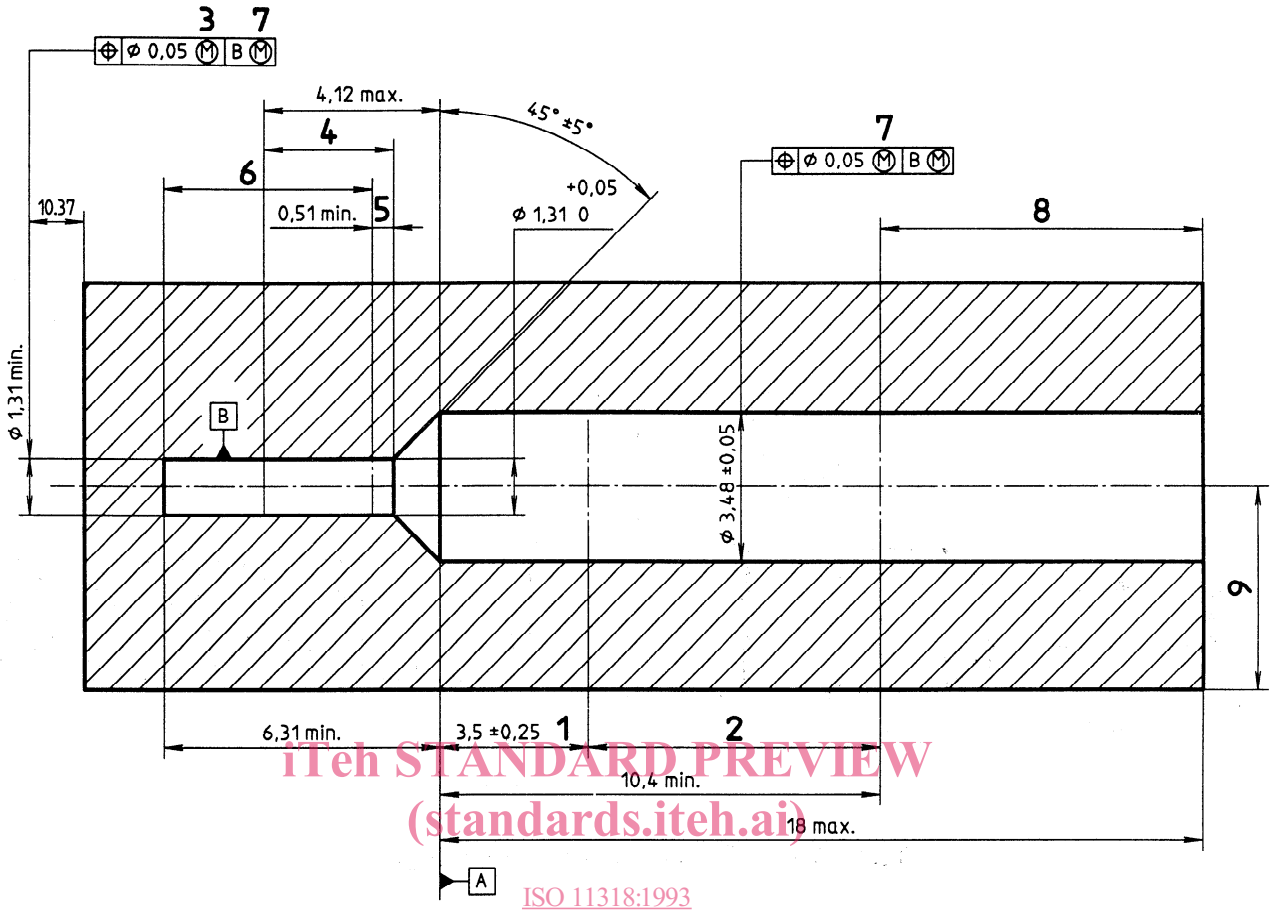
Figure 2 — DF-1 lead connector GO gauge

DF-1

Symbol to be used on the defibrillator lead connector and generator

Figure 3 — Marking

Dimensions in millimetres unless otherwise noted



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ISO 11318:1993
https://standards.iteh.ai/catalog/standards/sist/4232f885-be00-4198-84e3-3287874aa8c6/iso-11318-1993

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

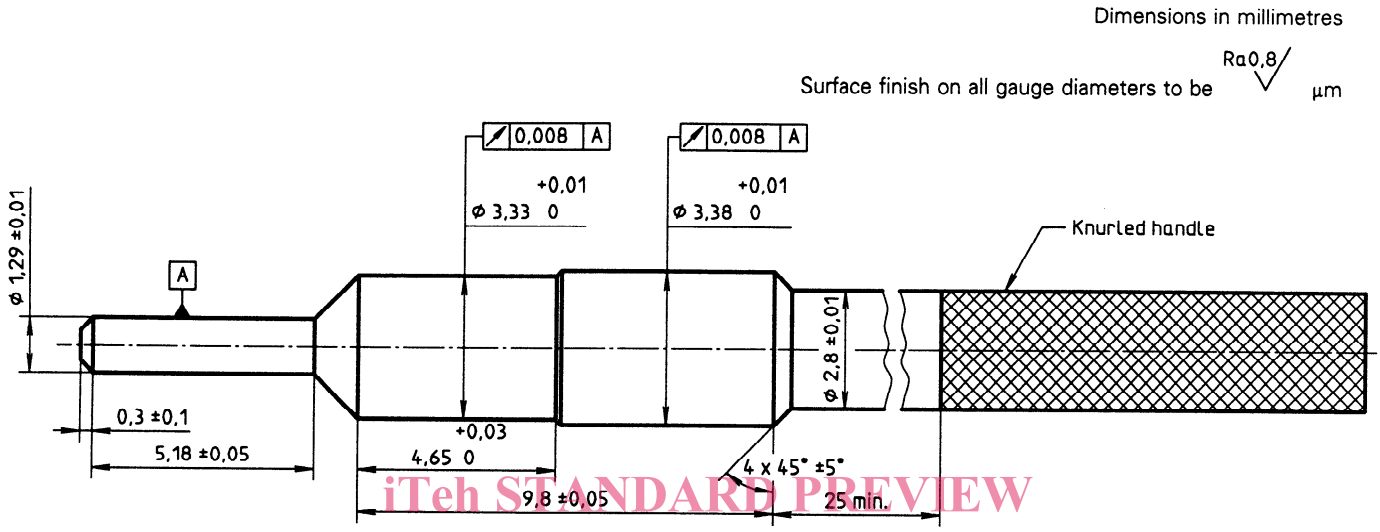

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Figure 5 — DF-1 connector cavity GO gauge

ISO 11318:1993
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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.

iTeh STANDARD PREVIEW
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ISO 11318:1993
https://standards.iteh.ai/catalog/standards/sist/4232f885-be00-4198-84e3-3287874aa8c6/iso-11318-1993

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.