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AMENDMENT 1
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Anaesthetic and respiratory equipment – Conical connectors –

Part 1: Cones and sockets

AMENDMENT 1

Matériel respiratoire et d'anesthésie – Raccords coniques –

Partie 1: Raccords mâles et femelles

AMENDEMENT 1



Reference number
ISO 5356-1:1987/Amd.1:1993(E)

Foreword

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Amendment 1 to International Standard ISO 5356-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 1, *Breathing attachments and anaesthetic machines*.

Annexes C, D and E form an integral part of this part of ISO 5356. Annex F is for information only.

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Anaesthetic and respiratory equipment – Conical connectors –

Part 1 : Cones and sockets

AMENDMENT 1

Page 1, 0 Introduction

Add the following to the end of the second paragraph of 0.2.

This part of ISO 5356 also gives requirements for one size (22 mm) of latching connector which is intended to reduce the possibility of accidental disconnection between a 22 mm female latching connector and a 22 mm male conical connector.

Add the following to 0.4.

Annexes C, D and E form normative parts of this International Standard. Annex F is given for information only.

2 References

Change the heading of the clause to "Normative references" and add the following beneath the clause heading.

The following standards contain provisions, which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were 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 editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

Add the following to the list of standards cited:

ISO 5367:1991, *Breathing tubes intended for use with anaesthetic apparatus and ventilators.*

Page 2, 3 Definitions

Add a new definition 3.3 as follows.

3.3: 22 mm latching connector: 22 mm female connector which incorporates a latching mechanism to reduce the possibility of accidental disconnection from a male 22 mm conical connector complying with clauses 5 and 6, and figure 3 a).

Clause 6

Correct the clause heading to read:

Conical connectors made of materials other than metal

Page 3, 8 Information to be supplied by the manufacturer

Delete existing clause 8, and substitute the following.

The following information shall be supplied with the connector:

- technical information (including operating and storage conditions) and instructions for connecting and disconnecting;
- if appropriate, details of a pre-use test to confirm correct operation;
- if appropriate, recommended methods for cleaning and disinfection or sterilization;
- instructions in the event of damage to the packaging of connectors supplied sterile and, if appropriate, methods of re-sterilization;
- any special precautions related to the disposal of the connector.

9 Bibliography

Add to the list of standards cited:

ISO 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*

Delete from the list of standards cited:

ISO 5367.

Add the following new clauses 10 and 11.

10 22 mm latching connectors

10.1 The 22 mm latching connector shall engage with a male 22 mm conical connector as specified in clauses 5 and 6, and figure 3 a).

10.2 When tested as described in annex C, the engaged connection shall not become disconnected.

10.3 When tested as described in annex D, the leakage from the engaged connectors shall not exceed 5 ml/min (corrected to 20 °C and 101,3 kPa).

10.4 After being subjected to the procedure described in annex E, the latching connector shall still meet the requirements specified in 10.1, 10.2 and 10.3.

10.5 22 mm latching connectors intended for re-use shall meet the requirements specified in 10.1, 10.2, 10.3 and 10.4 after being subjected to 20 cycles of cleaning and disinfection or sterilization as recommended by the manufacturer.

11 Marking

The connector and/or its packaging shall be marked, as applicable, with the following information:

- a) a description of the product including its intended use;
- b) the name and/or trademark of the manufacturer and/or supplier;
- c) a differentiation between the packaging and/or labelling of the same or similar products from the same manufacturer supplied sterile and supplied non-sterile, and the word "sterile" if appropriate;
- d) an indication if the connector is for single use, e.g. symbol 1051 of ISO 7000; the words "single patient use";
- e) if not supplied as a permanently attached component of a medical device, and if made of antistatic or conductive materials, the word "antistatic";
- f) the expiry date expressed as year/month;
- g) an identification reference to the type, batch or serial number.

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Following the existing figure 12, add new annexes C, D, E and F, and figures 13 and 14.

Annex C (normative)

Test method for security of engagement of 22 mm latching connectors

NOTE – Examples of suitable apparatus that may be used, together with a more detailed test procedure, are given for information in annex F.

C.1 Precondition a male 22 mm conical connector, complying with clauses 5 and 6 and figure 3 a), and the 22 mm latching connector for 1 h at a temperature of $(37 \pm 3)^\circ\text{C}$ and a relative humidity of at least 80 % RH, and carry out the test under the same conditions.

C.2 Engage the 22 mm latching connector with the male conical connector in accordance with the manufacturer's instructions.

C.3 Apply for 10 s, without activation of any disengagement mechanism, an axial separation force of (50 ± 5) N and, unless the design of the 22 mm latching connector permits free rotation, a torque of (25 ± 5) N·cm first in one direction of rotation and then in the other.

C.4 Observe whether the assembled connectors become disconnected.

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Annex D (normative)

Test method for leakage from 22 mm latching connectors

D.1 Take the engaged male conical connector and 22 mm latching connector that have been tested as described in annex C and maintain them at $(37 \pm 3) ^\circ\text{C}$.

D.2 Using gas, apply an internal static pressure of $(8 \pm 0,5) \text{ kPa}$ above ambient to the assembly and determine the leakage rate from the assembly, for example by pressure drop or volumetric methods.

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Annex E (normative)

Drop procedure for 22 mm latching connectors

E.1 Precondition a male 22 mm conical connector, complying with clauses 5 and 6, and figure 3 a), and the 22 mm latching connector for 1 h at a temperature of $(20 \pm 3) ^\circ\text{C}$ and a relative humidity of at least 80 % RH, and carry out the test under the same conditions.

E.2 Engage the 22 mm latching connector with the male conical connector in accordance with the manufacturer's instructions. Attach the male conical connector to a breathing tube complying with ISO 5367 and having a length of 2 m.

E.3 Attach the opposite end of the breathing tube to a point 1 m above a 50 mm thick hardwood board (e.g. hardwood having a density greater than 700 kg/m^3) standing on a rigid base (e.g. a concrete block).

E.4 Raise the latched male and female connectors to a height of 1 m and release them so that they fall onto the hardwood board. Repeat this five times.

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Annex F (informative)

Suggested apparatus and test methods for security of engagement of 22 mm latching connectors

F.1 Method 1 – Bench-mounted test equipment

F.1.1 Apparatus

An example of an apparatus is shown in figure 13.

NOTE – There are a number of methods of applying the test forces and figure 13 is illustrative of only one approach. Other methods include the use of gravity loading by weights or liquid containers.

The essential purpose of the apparatus is to ensure that the tensile force can be applied in a truly axial direction and that torque can be applied without changing the tensile force. To minimize the effects of the friction of the apparatus, the tensile force should be measured directly between the two halves of the joint under test.

F.1.2 Procedure

F.1.2.1 Secure the 22 mm latching connector to be tested in the self-centring holder of the apparatus (F.1.1), ensuring that the method of securing the latching connector does not deform the section(s) that are intended to engage with the male conical connector.

F.1.2.2 Condition the 22 mm latching connector and the apparatus at a temperature of $(37 \pm 3)^\circ\text{C}$ and a relative humidity of at least 80 % RH for 1 h.

NOTE – If a number of 22 mm latching connectors are to be tested, some may be conditioned at the required temperature and relative humidity without being secured to the apparatus provided that they are conditioned for at least 5 min after being secured to the apparatus.

F.1.2.3 Engage the 22 mm latching connector with the male conical connector in accordance with the manufacturer's instructions.

F.1.2.4 After 1 min, attach the force-measuring device and apply an axial separation force at a rate not exceeding 20 N s^{-1} until a force of $(50 \pm 5)\text{ N}$ is being applied.

Maintain this force for 10 s without activating any disengagement mechanism and observe whether the engaged 22 mm latching connector and male conical connector become disconnected.

F.1.2.5 Without reducing the tensile load and without activation of any disengagement mechanism, apply a torque of $(25 \pm 5)\text{ N}\cdot\text{cm}$ or rotate the male conical connector through an angle of 20° , whichever occurs first. Maintain this torque or position for 10 s and observe whether the engaged 22 mm latching connector and male conical connector become disconnected.

F.1.2.6 Repeat the procedure described in F.1.2.5 with the torque applied in the opposite direction.

NOTE – Consideration is being given to applying air pressure to the test connection to determine whether leakage occurs before disconnection.

F.2 Method 2 – Hand-held test equipment

F.2.1 Apparatus

An example of an apparatus is shown in figure 14.

F.2.2 Procedure

F.2.2.1 Condition the 22 mm latching connector and the apparatus (F.2.1) at a temperature of $(37 \pm 3)^\circ\text{C}$ and a relative humidity of at least 80 % RH for 1 h.

F.2.2.2 Engage the 22 mm latching connector with the male conical connector on the apparatus in accordance with the manufacturer's instructions.

F.2.2.3 After 1 min, manually apply an axial separation force at a rate not exceeding 20 N s^{-1} until a force of $(50 \pm 5)\text{ N}$ is being applied. Maintain this force for 10 s without activating any disengagement mechanism and observe whether the engaged 22 mm latching connector and male conical connector become disconnected.

F.2.2.4 Without reducing the tensile load and without activation of any disengagement mechanism, manually apply a torque of (25 ± 5) N·cm or rotate the male conical connector through an angle of 20° , whichever occurs first. Maintain this torque or position for 10 s and observe

whether the engaged 22 mm latching connector and male conical connector become disconnected.

F.2.2.5 Repeat the procedure described in F.2.2.4 with the torque applied in the opposite direction.

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