INTERNATIONAL STANDARD

ISO 5356-1

Third edition
2004-05-15

Anaesthetic and respiratory equipment — Conical connectors —

Part 1: Cones and sockets

Matériel d'anesthésie et de réanimation respiratoire — Raccords coniques —

Partie 1: Raccords mâles et femelles

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This third edition cancels and replaces the second edition (ISO 5356-1:1996), which has been technically revised. The major differences are the inclusion of 8,5 mm size connectors and some minor corrections to the figures and tables.

ISO 5356 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Conical connectors*:

— *Part 1: Cones and sockets*

— *Part 2: Screw-threaded weight-bearing connectors*

Introduction

In clinical practice, several breathing attachments used in anaesthetic and respiratory equipment may have to be joined together to provide a suitable breathing system. Items of medical equipment, such as a humidifier or a spirometer, are often incorporated into the breathing system which may also be connected to an anaesthetic-gas scavenging system. Connections for these purposes are usually cone and socket joints, and a lack of standardization of these connections has given rise to problems of interchangeability when connecting equipment made by different manufacturers. This part of ISO 5356 specifies the requirements and dimensions for conical connectors used in anaesthetic and respiratory equipment.

An important consideration is that conical connections need to be secure but nevertheless disconnectable by the operator. The use of connectors meeting the requirements of this part of ISO 5356 will not necessarily prevent them being disconnected accidentally. To minimize the risk of 22 mm connectors being accidentally disconnected, latching connectors can be used.

Annex A includes a figure and a table detailing plug and ring test gauges that are used to check conical connectors made of materials other than metal. Annexes B, C and D provide test methods for latching connectors, Annex E includes a figure and table detailing plug and ring test gauges that may be used to check metal conical connectors, and Annex F contains recommendations for testing security of latching connectors.

Figure 1, detailing the dimensions and tolerances of metal conical connectors, has been prepared in accordance with ISO 3040.

Anaesthetic and respiratory equipment — Conical connectors —

Part 1: Cones and sockets

1 Scope

This part of ISO 5356 specifies dimensional and gauging requirements for cones and sockets intended for connecting anaesthetic and respiratory equipment, e.g. in breathing systems, anaesthetic-gas scavenging systems and vaporizers.

This part of ISO 5356 gives requirements for the following conical connectors:

— 8,5 mm size intended for use in paediatric breathing systems;

— 15 mm and 22 mm sizes intended for general use in breathing systems;

— 22 mm latching connectors (including performance requirements);

— 23 mm size intended for use with vaporizers, but not for use in breathing systems;

— 30 mm size intended for the connection of a breathing system to an anaesthetic gas scavenging system.

This part of ISO 5356 does not specify the medical devices and accessories on which these connections are to be provided.

Requirements for the application of conical connectors are not included in this part of ISO 5356, but are or will be given in the relevant International Standards for specific medical devices and accessories.

NOTE Requirements for screw-threaded weight-bearing conical connectors are specified in ISO 5356-2.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*, including Amendment 1:1991 and Amendment 2:1995

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and the following apply.

3.1
22 mm latching connector
female connector for engagement with a male conical connector of 22 mm size complying with this part of ISO 5356, and which has a feature to reduce the possibility of accidental disconnection

4 Conical connectors made of metal

4.1 General requirements

The dimensions of conical connectors made of metal, including those made of composite materials in which the mating surfaces are metal, shall be as shown in Figures 1 and 2 and Table 1.

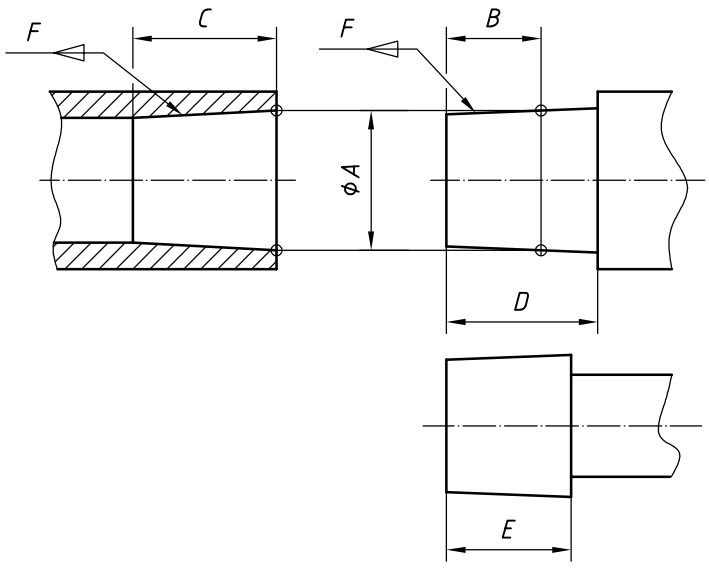
NOTE See Annex E for dimensions of plug and ring gauges for the connectors.

4.2 Additional requirements for male conical connectors of 22 mm size

4.2.1 Male conical connectors of 22 mm size, with the exception of those intended for connection to a face mask, shall incorporate the recess as shown in Figure 2 a).

4.2.2 Male conical connectors of 22 mm size to which it is intended to attach a face mask shall incorporate a shoulder or equivalent construction as shown in Figure 2 b).

4.2.3 If a circumferential groove or grooves are incorporated in the surface of a male conical connector of 22 mm size, the total width of the groove or grooves at the surface shall not exceed 8 mm.



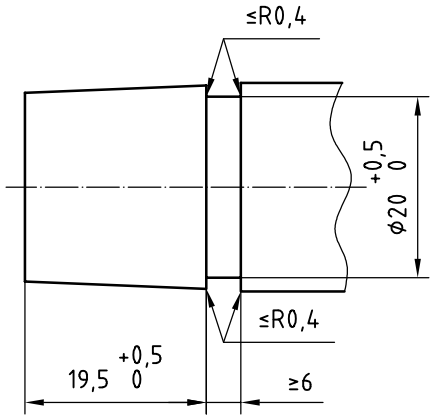
The radius on the entrance to the female connector and on the leading edge of the male cone should be not less than 0,5 mm and not more than 0,8 mm.

Figure 1 — Conical connectors made of metal

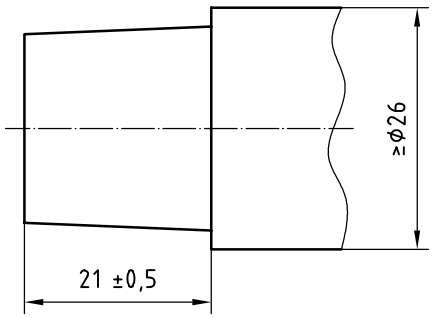
Table 1 — Conical connectors made of metal — Dimensions (see Figure 1)

Connector size mm	*A* mm	*B* mm	**Taper length** min. *C* mm	**Clearance to shoulder** (if present) *D* mm	**Length to taper** min. *E* mm	**Taper ratio** *F*
8,5	8,45 ± 0,04	6	6,4	8,9 min.	8	1:19
15	15,47 ± 0,04	10	16	16 min.	14,5	1:40
22	22,37 ± 0,04	15	21	See Figure 2	See Figure 2	1:40
23	23,175 ± 0,02	13	18	18 min.	15	1:36
30	30,9 ± 0,05	14	18	18 min.	14	1:20

Dimensions in millimetres



a) Connector intended for breathing attachment (with recess)



b) Connector intended for face mask (with shoulder)

Circumferential grooves may be incorporated on the surface of the male cone, if required (see 4.2.3).

Figure 2 — Conical connectors of 22 mm size made of metal — Supplementary dimensions

4.3 Additional requirements for conical connectors of 8,5 mm size

The male conical connector shall have a minimum inside diameter of 6 mm extending inward for at least 6 mm from the end of the connector.

5 Conical connectors made of materials other than metal

5.1 General requirements

Conical connectors made of materials other than metal shall meet the following requirements when they are type-tested with gauges having dimensions as shown in Figure A.1 and Table A.1.

a) Conical connectors made of materials other than metal shall meet the dimensional requirements in Figure 1 and Table 1, with the exception than dimensions A and B and ratio F may vary from those shown.

b) When the connector is engaged in the appropriate plug or ring test gauge shown in Figure A.1 and Table A.1, by applying an axial force of (35 ± 3,5) N for 8,5 mm and 15 mm connectors and (50 ± 5) N for 22 mm and 30 mm connectors and, while maintaining the same force, rotating the connector up to 20°, its leading edge shall lie between the minimum and maximum diameter steps of the gauge. The connectors and gauges shall be maintained at a temperature of (20 ± 3) °C during the test.

NOTE Because connectors made from plastics materials, for example polyamide, polyacetal, polycarbonate, polysulfone, etc., can vary greatly in their physical characteristics, it is not considered practicable to specify their dimensions; for this reason, gauging requirements have been included. It is also considered impracticable to generalize on matters such as cold flow and thermal instability, as well as possible changes in physical characteristics, contact with solvents, etc.

It is the responsibility of the manufacturer to ensure that adequate tests have been carried out to prove as far as possible that the particular materials chosen for the connectors are suitable.

5.2 Additional requirements for conical connectors of 22 mm size

The requirements given in 4.2 apply.

5.3 Additional requirements for conical connectors of 8,5 mm size

The requirements given in 4.3 apply.

6 22 mm latching connectors

6.1 22 mm latching connectors shall engage with the 22 mm male connector with a recess as specified in Figure 2 a).

6.2 When tested in accordance with Annex B, the engaged connection shall not become disconnected.

6.3 When tested in accordance with Annex C, the leakage rate from the engaged connectors shall not exceed 5 ml/min (corrected to 20 °C and 101,3 kPa).

6.4 After being subjected to the procedure described in Annex D, the 22 mm latching connector shall still meet the requirements in 6.1, 6.2 and 6.3.

6.5 22 mm latching connectors intended for re-use shall meet the requirements in 6.1, 6.2, 6.3 and 6.4 after being subjected to the cleaning, disinfection or sterilization procedures specified in IEC 60601-1:1998, 44.7.

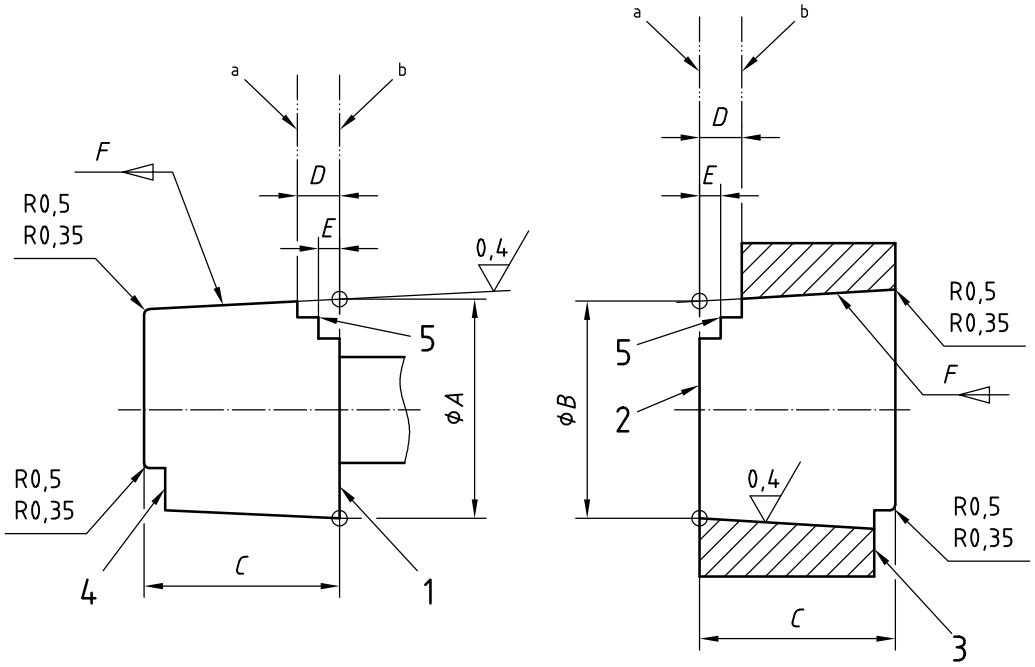
Annex A
(normative)

Plug and ring test gauges for conical connectors made of materials other than metal

Figure A.1 and Table A.1 give details of plug and ring gauges for use in checking conical connectors made of materials other than metals.

Dimensions in millimetres

Surface roughness values in micrometres



Key

1 face A
2 face B
3 step to check mating gauges ground flush to face A
4 step to check mating gauges ground flush to face B
5 basic steps

a Position max.
b Position min.

NOTE Basic and mating gauge steps are optional.

Figure A.1 — Plug and ring test gauges for conical connectors made of materials other than metal

Table A.1 — Plug and ring test gauges for conical connectors made of materials other than metal — Dimensions (see Figure A.1)

Dimensions in millimetres

Connector size	*A*	*B*	*C*	*D*	*E*	*F*	Tolerance on taper per unit of length on diameter
8,5	8,50 ± 0,005	8,09 ± 0,005	8,4 ± 0,005	1,31 ± 0,005	See NOTE	1:19	0,053 ± 0,000 2
15	15,525 ± 0,005	15,165 ± 0,005	14,5 ± 0,005	4,3 ± 0,005	2,2 ± 0,005	1:40	0,025 ± 0,000 2
22	22,425 ± 0,005	21,94 ± 0,005	19,5 ± 0,005	5,2 ± 0,005	2,2 ± 0,005	1:40	0,025 ± 0,000 2
30	30,98 ± 0,005	30,12 ± 0,005	17,2 ± 0,005	3,1 ± 0,005	1,6 ± 0,005	1:20	0,050 ± 0,000 2

NOTE Gauge for 8,5 mm connector has only one mating step.

Annex B
(normative)

Test for security of engagement of 22 mm latching connector to male conical connector

B.1 Condition the male 22 mm conical connector complying with Figure 2 a) and the 22 mm latching connector for 1 h at a temperature of (35 ± 3) °C and relative humidity of at least 80 %, and carry out the test under the same conditions.

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

B.3 After 1 min of engagement without activation of any disengagement mechanism, apply for 10 s an axial separation force of (50 ± 5) N and, unless the 22 mm latching connector permits free radial rotation, also apply a torque of (25 ± 5) N·cm at a rate not exceeding 20 $N \cdot s^{-1}$.

B.4 Observe whether the assembled connectors become disconnected.

NOTE Examples of suitable apparatus that can be used to test security of engagement, together with a more detailed test procedure, are given for information in Annex F.

Annex C
(normative)

Test for leakage from 22 mm latching connectors

C.1 Take the engaged male conical connector and 22 mm latching connector that have been tested as described in Annex B and condition them at (35 ± 3) °C.

C.2 Using air, apply an internal static pressure of (8 ± 0,5) kPa above ambient to the assembly and determine the leakage rate from the assembly, e.g. by pressure drop or volumetric method.

Annex D
(normative)

Drop procedure for 22 mm latching connectors

D.1 Condition a male conical connector complying with Figure 2 a) and the 22 mm latching connector for 1 h at a temperature of (20 ± 3) °C and relative humidity of at least 80 %, and carry out the test under the same conditions.

D.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.

D.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).

D.4 Raise the engaged connectors to a point 1 m above the board and 2 m distant from the other end of the breathing tube and release them so that they fall onto the hardwood board. Repeat this five times.

D.5 Proceed with desired test.

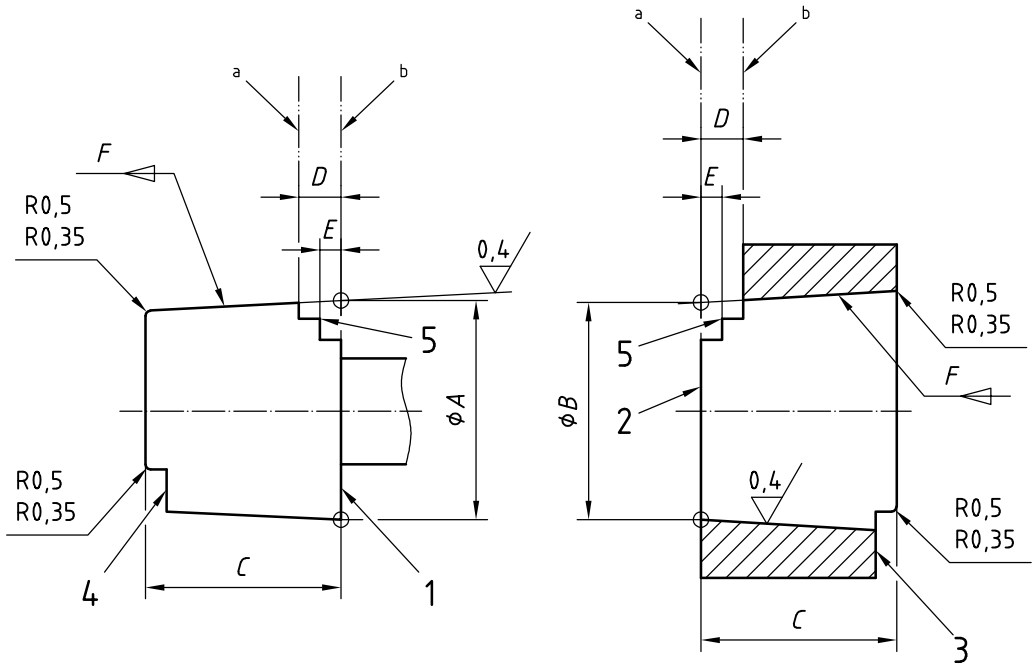
Annex E
(informative)

Plug and ring test gauges for conical connectors made of metal

Figure E.1 and Table E.1 give, for information, details of plug and ring test gauges that may be used to check metal conical connectors.

Dimensions in millimetres

Surface roughness values in micrometres



Key

1 face A
2 face B
3 step to check mating gauges ground flush to face A
4 step to check mating gauges ground flush to face B
5 basic steps

a Position max.
b Position min.

NOTE Basic and mating gauge steps are optional.

Figure E.1 — Plug and ring test gauges for conical connectors made of metal

Table E.1 — Plug and ring test gauges for conical connectors made of metal — Dimensions (see Figure E.1)

Dimensions in millimetres

Connector size	*A*	*B*	*C*	*D*	*E*	Taper ratio *F*	Tolerance on taper per unit of length on diameter
8,5	8,49 ± 0,005	8,094 ± 0,005	8,4 ± 0,005	1,52 ± 0,005	See NOTE	1:19	0,053 ± 0,000 2
15	15,51 ± 0,005	15,18 ± 0,005	14,5 ± 0,005	3 ± 0,005	1,6 ± 0,005	1:40	0,025 ± 0,000 2
22	22,41 ± 0,005	21,955 ± 0,005	19,5 ± 0,005	3 ± 0,005	1,6 ± 0,005	1:40	0,025 ± 0,000 2
23	23,195 ± 0,003	22,794 ± 0,003	16 ± 0,005	1,33 ± 0,005	0,72 ± 0,005	1:36	0,0278 ± 0,000 2
30	30,95 ± 0,005	30,15 ± 0,005	17 ± 0,005	1,9 ± 0,005	1 ± 0,005	1:20	0,050 ± 0,000 2

NOTE Gauge for 8,5 mm connector has only one mating step.

Annex F
(informative)

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

F.1 Method 1 — Bench-mounted test equipment

F.1.1 Apparatus

A typical bench-mounted apparatus for testing the security of engagement of 22 mm latching connectors is shown in Figure F.1. The male test piece should be a 22 mm male conical connector dimensioned as shown in Figure 2 a) but with all the tolerances reduced to ± 0,005 mm and a surface finish of 0,4 µm.

NOTE There are a number of methods for applying the test forces, and Figure F.1 is illustrative of only one approach. Other methods include the use of gravity loading by weights or liquid containers.

The essential features of the apparatus should 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 friction of the apparatus, the tensile force should be measured directly between the 22 mm latching connector and the male test piece.

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 22 mm latching connector does not deform the section(s) that are intended to engage with the male test piece.

F.1.2.2 Condition the 22 mm latching connector and the apparatus at a temperature of (35 ± 3) °C and a relative humidity of at least 80 % for 1 h.

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 again for at least 5 min after being secured to the apparatus.

F.1.2.3 Engage the 22 mm latching connector with the male test piece 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 $N \cdot s^{-1}$ until a force of (50 ± 5) 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 test piece become disconnected.

F.1.2.5 Without reducing the tensile load and without activation of any disengagement mechanism, apply a torque of (25 ± 5) N·cm or rotate the male test piece 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 test piece become disconnected.

F.2 Method 2 — Hand-held test equipment

F.2.1 Apparatus

A typical hand-held apparatus for testing the security of engagement of 22 mm latching connectors is shown in Figure F.2.

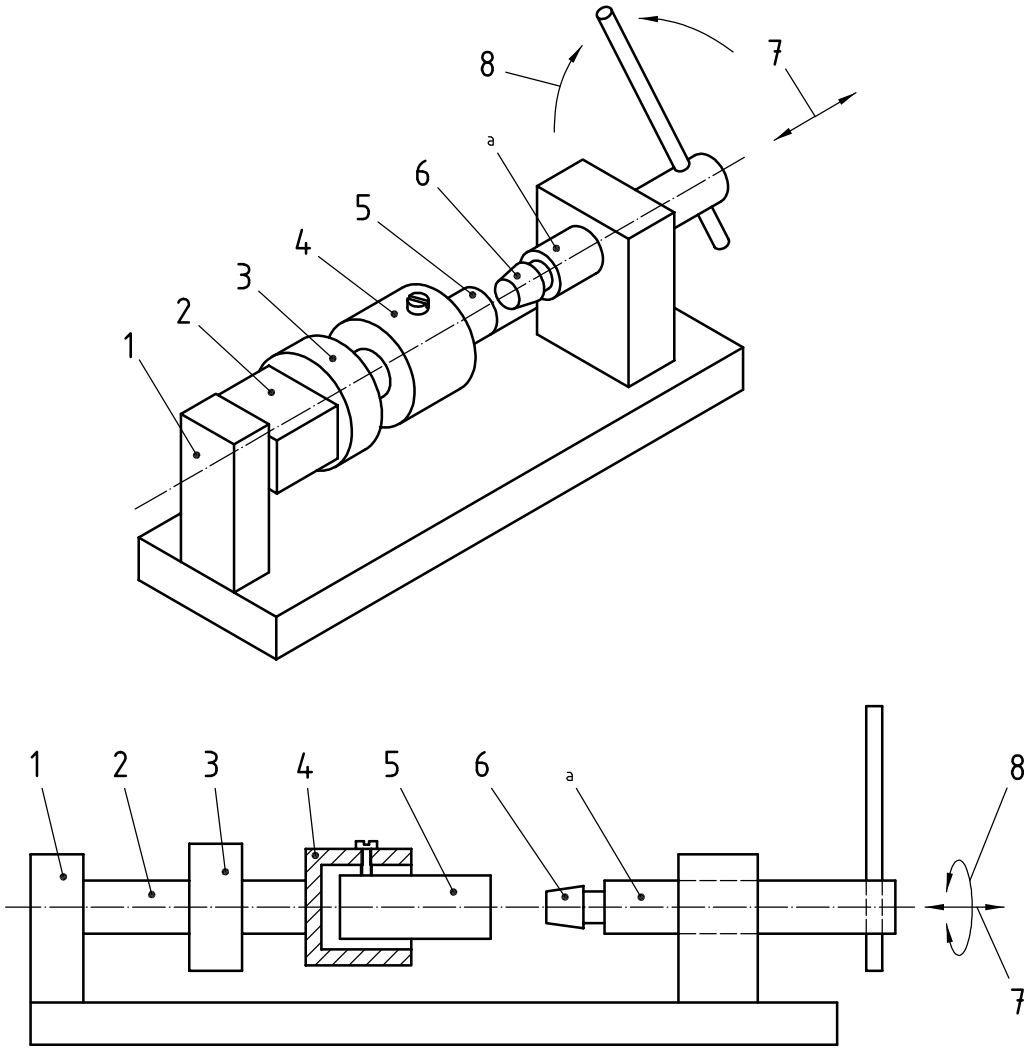
F.2.2 Procedure

F.2.2.1 Condition the 22 mm latching connector and the apparatus (F.2.1) at a temperature of (35 ± 3) °C and a relative humidity of at least 80 % for 1 h.

F.2.2.2 Engage the 22 mm latching connector with the male test piece on the apparatus.

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

F.2.2.4 Without reducing the tensile load and without activation of any disengagement mechanism, apply a torque of (25 ± 5) N·cm or rotate the male test piece 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 test piece become disconnected.

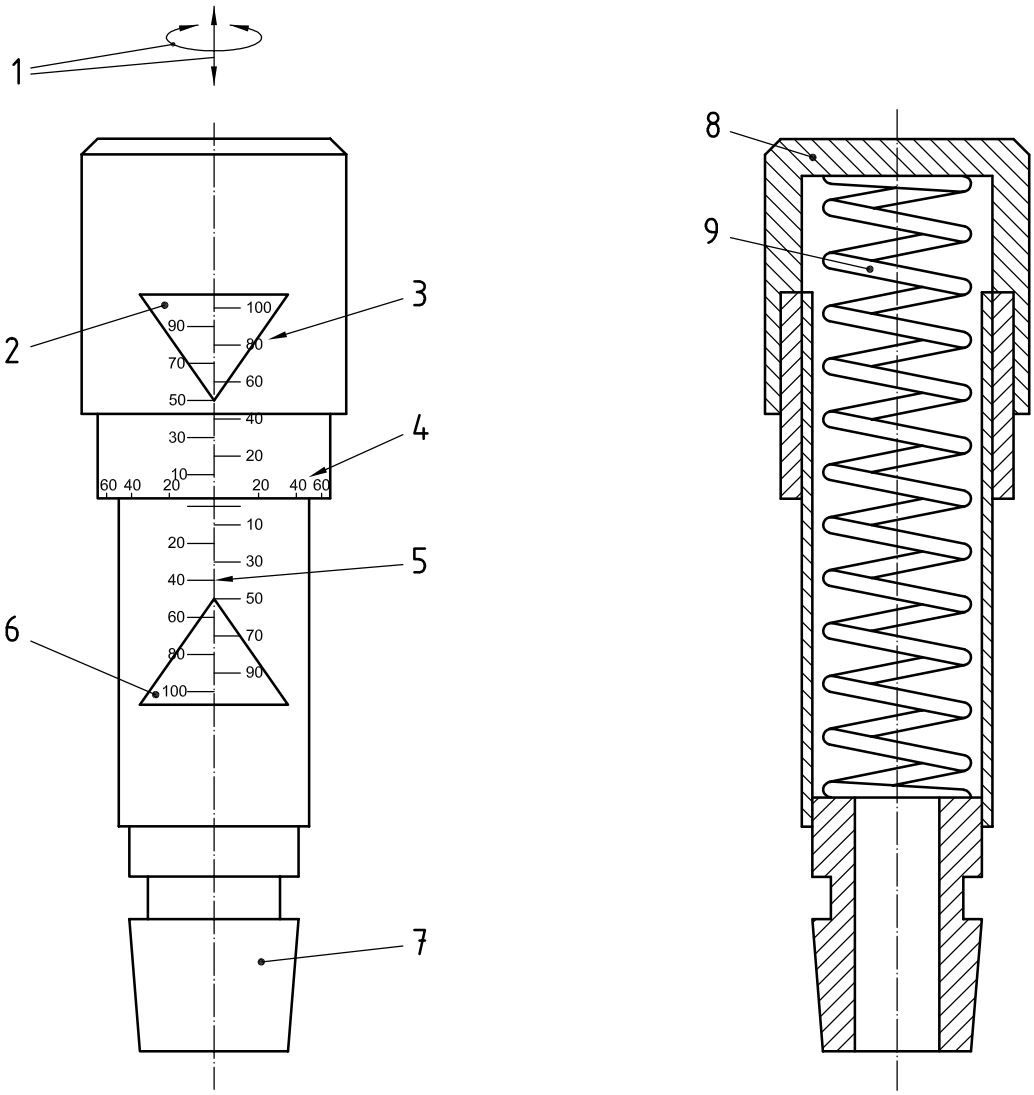


Key

1 rigid support
2 axial load meter
3 torque meter
4 holder
5 22 mm latching connector under test
6 22 mm male test piece
7 application of adjustable axial force
8 application of adjustable torque

a Free to slide and rotate.

Figure F.1 — Apparatus for testing the security of engagement of 22 mm latching connectors (Method 1 — Bench-mounted)



a) External view **b) Sectional view**

Key

1 application of torque or push or pull by hand
2 area of scale indicating acceptable pull and twist forces
3 pull-force scale
4 torque scale
5 push-force scale
6 area of scale indicating acceptable push and twist forces
7 22 mm male test piece
8 knob
9 coil spring fixed at both ends

Torque and force scales should be precalibrated using apparatus in Figure F.1.

Figure F.2 — Apparatus for testing the security of engagement of 22 mm latching connectors (Method 2 — Hand-held)

Bibliography

[1] ISO 3040:1990, *Technical drawings — Dimensioning and tolerancing — Cones*

ICS 11.040.10

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