



SLOVENSKI STANDARD SIST EN 1281-1:2000

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Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets

Anästhesie- und Beatmungsgeräte - Konische Konnektoren - Teil 1: Männliche und weibliche Konen

Matériel respiratoire et d'anesthésie - Raccords coniques - Partie 1: Raccords mâles et femelles

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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EUROPEAN STANDARD

EN 1281-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 1997

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Descriptors: medical equipment, anaesthetic equipment, artificial breathing apparatus, fittings, conical clamping connections, specifications, dimensions, dimensional measurements, standard gauges, junctions, tests, marking

English version

Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets

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Matériel respiratoire et d'anesthésie -
Raccords coniques - Partie 1: Raccords mâles et
femelles

Anästhesie- und Beatmungsgeräte - Konische
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Konen

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This European Standard was approved by CEN on 1996-12-15. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard is based on ISO 5356-1: 1993, prepared by Technical Committee ISO/TC 121 of the International Organization for Standardization (ISO).

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU directives, see informative annex ZA, which is an integral part of this standard.

This European Standard applies to conical connectors for anaesthetic and respiratory equipment and has been prepared in two Parts. This Part addresses cones and sockets: Part 2 addresses screw-threaded weight-bearing connectors.

Annexes B, C, D and E are normative and form Part of this European Standard. Annexes A, F, G and ZA are for information only.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard specifies dimensional requirements for conical connectors used in anaesthetic and respiratory equipment.

The standard comprises two Parts:

- Part 1: Cones and sockets
- Part 2: Screw-threaded weight-bearing connectors.

In clinical practice several breathing attachments 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, though not invariably, 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 the standard gives the requirements for the following conical connectors:

- 8,5 mm sizes intended for use in paediatric breathing systems.¹⁾
- 15 mm and 22 mm sizes intended for general use in breathing systems.²⁾
- 23 mm size intended for use with vaporizers³⁾, which are unsuitable for use in breathing systems.
- 30 mm size intended for the connection of a breathing system to an anaesthetic gas scavenging system.⁴⁾

An important consideration is that conical connections should be secure but nevertheless disconnectable by the operator. The use of connectors meeting the requirements of this Part of the standard will not necessarily prevent them being disconnected accidentally.

¹⁾ See e.g. prEN 1782 and bibliography

²⁾ See e.g. clause 63, 1.7.1 and 66 of prEN 740 : 1992 and bibliography

³⁾ See e.g. clause 64.1.1 of prEN 740 : 1992 and bibliography

⁴⁾ See e.g. clause 70.5 of prEN 740 : 1992 and bibliography

This Part of this European standard specifies the performance of latching connectors of 22 mm size.

Annex A (informative) includes a figure and a table detailing plug and ring test gauges that may be used to check the sizes of metal conical connectors. It is provided for information only and is not a normative part of the standard.

Annex B (normative) includes a figure and a table detailing plug and ring test gauges that are used to check the sizes of conical connectors made of materials other than metal.

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

Requirements and application of conical connectors are not included in this Part of this European standard but are given in particular European Standards for specific medical devices and accessories (see notes and annex G (informative)).

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1 Scope

This Part of this European Standard specifies dimensional and gauging requirements for cones and sockets and performance requirements for latching connectors intended for use in medical devices, e.g. in breathing systems, anaesthetic gas scavenging systems and vaporizers.

This European Standard does not specify the medical devices and accessories on which these connectors are to be provided.

NOTE 1: It is expected that requirements on the use of suitable materials and for the application of this standard will be included in particular standards for specific medical devices and accessories.

NOTE 2: Requirements for screw-threaded weight-bearing conical connectors are specified in Part 2 of this standard.

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2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN ISO 4135	Anaesthesiology vocabulary (ISO 4135 : 1995)
prEN 1041	Terminology, symbols and information provided with medical devices - Information supplied by the manufacturer with medical devices
prEN 12342	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN 60601-1: 1990	Medical electrical equipment Part 1: General requirements for safety (IEC 601-1:1988)

3 Definitions

For the purposes of this European Standard, the following definition applies, in addition to those given in EN ISO 4135.

3.1 latching connector: female connector for engagement with a male conical connector complying with this standard, which has a feature to reduce the possibility of accidental disconnection.

4 Antistatic and electrically conductive connectors

See appropriate device standards for specific requirements.

5 Materials

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See appropriate device standards for specific requirements.

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6 Conical connectors made of metal

6.1 General requirements

The dimensions of conical connectors made of metal shall be as shown in figure 1, figure 2 and table 1.

NOTE 1: See annex A for dimensions of plug and ring gauges.

NOTE 2: Metal connectors include those made of composite materials in which the mating surfaces are metal.

NOTE 3: Conical connectors of 30 mm size are intended for use for the connection of a breathing system to an anaesthetic gas scavenging system.

6.2 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.

6.3 Additional requirements for conical connectors of 22 mm size

6.3.1 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 2a).

NOTE: The recess shown in figure 2a) is to accommodate the end of a female connector made of elastomeric material⁵⁾ or to permit the fitting of other devices to improve the attachment of the socket to the male conical connector e.g. a latching connector (see clause 8).

6.3.2 All male connectors to which it is intended to attach a face mask shall incorporate a shoulder or equivalent construction as in figure 2b).

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

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7 Conical connectors made of materials other than metal

7.1 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 B.1 and table B.1.

a) Conical connectors made of materials other than metal shall meet the dimensional requirements in figure 1 and table 1 with the exception that dimensions A, B and F may be varied from those shown;

⁵⁾ The term "elastomeric material" includes soft rubber (natural or synthetic) and some soft plastic materials, for example polyvinyl chloride, low-density polyethylene and silicone rubber.

b) When the connector is engaged in the appropriate plug or ring test gauge shown in figure B.1 and table B.1, by applying an axial force of $(35 \pm 3,5)$ 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 from polyamide, polyacetal, polycarbonate, polysulfone, etc., may 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, therefore, the responsibility of the manufacturer to ensure that adequate tests have been carried out to prove as far as possible that the particular materials are suitable. See also the note to clause 5.

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

The requirements of 6.2 apply. standards.iteh.ai

7.3 Additional requirements for conical connectors of 22 mm size

The requirements of 6.3 apply. <https://standards.iteh.ai/catalog/standards/sist/9adfed06-4aad-40f5-91ce-881a6c33d918/sist-en-1281-1-2000>

8 Latching connectors of 22 mm size

8.1 The latching connector of 22 mm size shall engage with the 22 mm male connector with a recess as specified in figure 2a).

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

8.3 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).

8.4 After being subjected to the procedure described in annex E the latching connector shall still meet the requirements specified in 8.1, 8.2 and 8.3.