

Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets (ISO 5356-1:2015)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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English Version

**Anaesthetic and respiratory equipment - Conical connectors -
Part 1: Cones and sockets (ISO 5356-1:2015)**

Matériel d'anesthésie et de réanimation respiratoire -
Raccords coniques - Partie 1: Raccords mâles et femelles
(ISO 5356-1:2015)

Anästhesie- und Beatmungsgeräte - Konische Konnektoren
- Teil 1: Männliche und weibliche Konen (ISO 5356-1:2015)

This European Standard was approved by CEN on 10 January 2015.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 5356-1:2015) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by September 2015, and conflicting national standards shall be withdrawn at the latest by September 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 5356-1:2004.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5356-1:2015 has been approved by CEN as EN ISO 5356-1:2015 without any modification.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This fourth edition cancels and replaces the third edition (ISO 5356-1:2004), which has been technically revised with the following changes:

- harmonizing the terminology used in the text with the title of this part of ISO 5356;
- deleting the definition of 22 mm latching connector because the content is covered by the text of this part of ISO 5356;
- including 11,5 mm cones and sockets;
- adding the minimum internal diameter for the 30 mm cone and changing the minimum internal diameter of the 8,5 mm cone from 6,0 mm to 6,25 mm;
- deleting the requirements on reuse of 22 mm latching sockets and cones because this is covered by the standards for the specific medical devices and accessories;
- making the recess and the shoulder for the 22 mm cone conditional;
- correcting the dimension *D* for the plug and ring test gauges for 8,5 mm cones and sockets made of materials other than metal in [Annex A](#) of this part of ISO 5356;
- restructuring the document for clarity.

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 might 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 cones and sockets 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 cones and sockets 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 sockets can be used.

[Annex A](#) includes a figure and a table detailing plug and ring test gauges that are used to check cones and sockets made of materials other than metal. [Annex B](#), [Annex C](#), and [Annex D](#) provide test methods for latching sockets, [Annex E](#) includes a figure and table detailing plug and ring test gauges that can be used to check metal cones and sockets, and [Annex F](#) contains recommendations for testing the security of latching sockets.

[Figure 1](#), detailing the dimensions and tolerances of cones and sockets, has been prepared in accordance with ISO 3040.

In this document, the following print types are used:

- requirements, compliance with which can be verified, and definitions: roman type;
- notes and examples: smaller roman type;
- test methods: *italic type*.

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. The cones and sockets are therefore not regarded as devices in their own right.

This part of ISO 5356 gives requirements for the following cones and sockets:

- 8,5 mm and 11,5 mm sizes intended for use in neonatal and paediatric breathing systems;
- 15 mm and 22 mm sizes intended for general use in breathing systems;
- 22 mm latching sockets (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 cones and sockets are to be provided.

Requirements for the application of cones and sockets 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 connectors are specified in ISO 5356-2.

2 Normative references

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

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

3 Dimensional requirements

3.1 General requirements

3.1.1 Cones and sockets made of metal shall comply with [Figure 1](#) and the dimensions given in [Table 1](#) as appropriate.

Check compliance by functional testing.

NOTE [Annex E](#) includes a figure and table detailing plug and ring test gauges that can be used to check metal cones and sockets.