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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Anaesthetic and respiratory equipment — Conical connectors —

Part 1 : Cones and sockets

Matériel respiratoire et d'anesthésie — 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5356-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Anaesthetic and respiratory equipment — Conical connectors —

Part 1 : Cones and sockets

0 Introduction

0.1 ISO 5356 comprises the following two parts :

Part 1 : Cones and sockets.

Part 2 : Screw-threaded weight-bearing connectors.

0.2 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 ISO 5356 gives requirements for five sizes of conical connector of which only the 15 mm and 22 mm sizes are intended for general use in breathing systems. The 23 mm size is intended for use with vaporizers which are unsuitable for use in the breathing system (see ISO 5358); usually because they impose a high resistance to gas flow. The 19 mm and 30 mm sizes are intended for the connection of a breathing system to an anaesthetic gas scavenging system.¹⁾

An important consideration is that conical connections are secure but are nevertheless disconnectable by the user. The use of connectors meeting the requirements of this part of ISO 5356 will not necessarily prevent their being disconnected accidentally, although accessory devices for this purpose may be incorporated.

It should be noted that compliance with this part of ISO 5356 does not preclude the possibility that some flow direction sensitive components may be mis-connected and it is stressed that the avoidance of this hazard has to remain the responsibility of the user.

0.3 Requirements for the application of conical connectors are not included in this part of ISO 5356 but are given in the

relevant International Standards for devices and items of equipment (see clause 9).

0.4 Figures 1 to 5 detailing the dimensions and tolerances of metal conical connectors have been prepared in accordance with the principles given in ISO 3040.

Annex A gives recommendations for materials and is not an integral part of the standard.

Annex B includes figures detailing plug and ring gauges that may be used to check the sizes of metal conical connectors and is not an integral part of the standard.

1 Scope and field of application

This part of ISO 5356 specifies basic dimensional and gauging requirements for cones and sockets intended for use in breathing systems, anaesthetic gas scavenging systems and vaporizers.

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

2 References

ISO 2878, *Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance.*

ISO 2882, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.*

3 Definitions

For the purposes of this part of ISO 5356, the following definitions apply.

NOTE — Definitions have been taken from ISO 4135.

3.1 **breathing attachments** : Components intended to make up or complete a breathing system.

1) An International Standard on anaesthetic gas scavenging systems is currently being prepared.

3.2 breathing system : Those gas pathways continuously or intermittently in communication with the patient's respiratory tract during any form of ventilation.

NOTES

- 1 In practice a breathing system usually extends from
 - a) the point of supply¹⁾ of a controlled gas mixture, for example the common gas outlet of an anaesthetic machine, or
 - b) the fresh-gas inlet of a circle system, lung ventilator, T-piece, etc., or
 - c) the fresh-gas inlet of a manually-operated resuscitator.
- 2 It usually extends to the point at which gas mixture escapes to atmosphere or a gas scavenging system, for example from an APL valve, the open end of a T-piece, etc.
- 3 Gas pathways exclusively concerned with gas scavenging systems are not regarded as a part of the breathing system.

4 Materials

If components are made of anti-static materials, they shall comply with the requirements given in ISO 2882 when tested by the methods described in ISO 2878.

5 Conical connectors made of metal

NOTES

- 1 Metal connectors include those of composite materials where the mating surfaces are metal.
- 2 Conical connectors of 19 mm, 23 mm and 30 mm size are not breathing system components.
- 3 See annex B for dimensions of plug and ring gauges.

5.1 Conical connectors of 15 mm size

The dimensions of conical connectors of 15 mm size made of metal shall be as shown in figure 1.

5.2 Conical connectors of 19 mm size

The dimensions of conical connectors of 19 mm size made of metal shall be as shown in figure 2.

5.3 Conical connectors of 22 mm size

5.3.1 The dimensions of conical connectors of 22 mm size made of metal, with or without a recess in the male component, shall be as shown in figure 3a) or 3b), as appropriate.

5.3.2 Male conical connectors of 22 mm size, with the exception of those intended for connection with a face mask, shall incorporate the recess as shown in figure 3a).

NOTE — The recess is to accommodate the end of a female connector made of elastomeric material²⁾ or to permit the fitting of other devices

to improve the security of the attachment of the socket to the male conical connector.

5.3.3 All male conical connectors to which it is intended to attach a face mask shall incorporate a shoulder or equivalent construction as shown in figure 3b).

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

NOTE — The design may permit the fitting of a device to ensure the secure attachment of tracheal (or tracheostomy) tube connectors.

5.4 Conical connectors of 23 mm size

The dimensions of conical connectors of 23 mm size made of metal shall be as shown in figure 4.

5.5 Conical connectors of 30 mm size

The dimensions of conical connectors of 30 mm size made of metal shall be as shown in figure 5.

6 Conical connectors made of materials other than metal

6.1 The axial length of conical connectors of 15 mm and 22 mm sizes made of materials other than metal, for example of polyamide, polyacetal, polycarbonate, polysulfone, etc., shall be as shown in figures 1 and 3, respectively. Other dimensions may be varied from those shown in figures 1 and 3 provided that both 15 mm and 22 mm connectors comply with the requirement laid down in 6.2 and that 22 mm connectors comply with the requirement laid down in 5.3.2.

6.2 Conical connectors of 15 mm and 22 mm sizes made of materials other than metal shall comply with the requirements laid down in 6.3 when they are type tested with gauges having dimensions as shown in figures 6 and 7, respectively.

NOTE — Since connectors made from plastics materials may vary enormously 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. Attention is drawn to the fact that some connectors will be used at elevated temperatures, for example those on heated humidifiers, and extra care will be required when selecting suitable materials.

1) In some situations, particularly in lung ventilators, this point may be inside a piece of equipment and should not be confused with a connection port fitted elsewhere, for example on the casing of a ventilator.

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

6.3 When the connector is engaged in the appropriate plug or ring gauge, shown in figures 6 and 7, by applying an axial force of $35 \pm 3,5$ N for 15 mm connectors and 50 ± 5 N for 22 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 this test.

NOTE — A disengagement test for conical connectors made of materials other than metal is currently being prepared. Requirements in this respect will be added in a future revision of this part of ISO 5356.

7 Sockets made of elastomeric material¹⁾

Sockets made of elastomeric material shall mate with the appropriate male connector complying with the requirements laid down in clause 5 or 6.

8 Information to be supplied by the manufacturer

Except for components that are designated for single use, the manufacturer shall state the methods of cleaning and either disinfection or sterilization of the connectors.

9 Bibliography

The following International Standards were used as reference documents in the development of this part of ISO 5356 :

ISO 3040, *Technical drawings — Dimensioning and tolerancing cones.*

ISO 4135, *Anaesthesiology — Vocabulary.*

The following International Standards for devices and items of equipment should be consulted for requirements pertaining to the application of conical connectors :

ISO 5358, *Continuous flow inhalational anaesthetic apparatus (anaesthetic machines) for use with humans.*

ISO 5366-1, *Tracheostomy tubes — Part 1 : Connectors.*

ISO 5367, *Breathing tubes used with anaesthetic apparatus and ventilators.*

ISO 5369, *Breathing machines for medical use — Lung ventilators.*

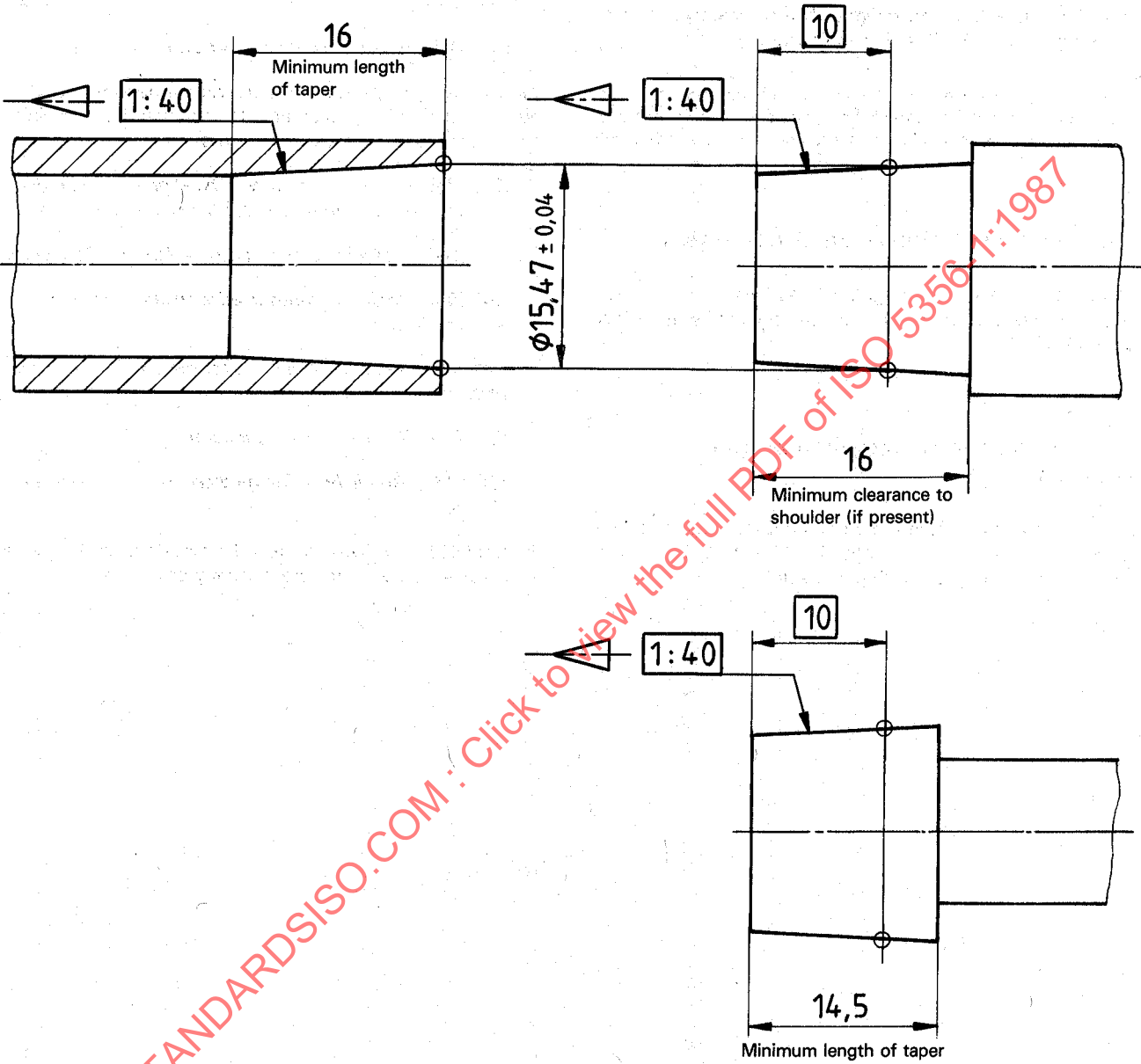
ISO 7228, *Tracheal tube connectors.*

ISO 8185, *Humidifiers for medical use — Safety requirements.*

International Standards on breathing systems and anaesthetic gas scavenging systems are currently being prepared.

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

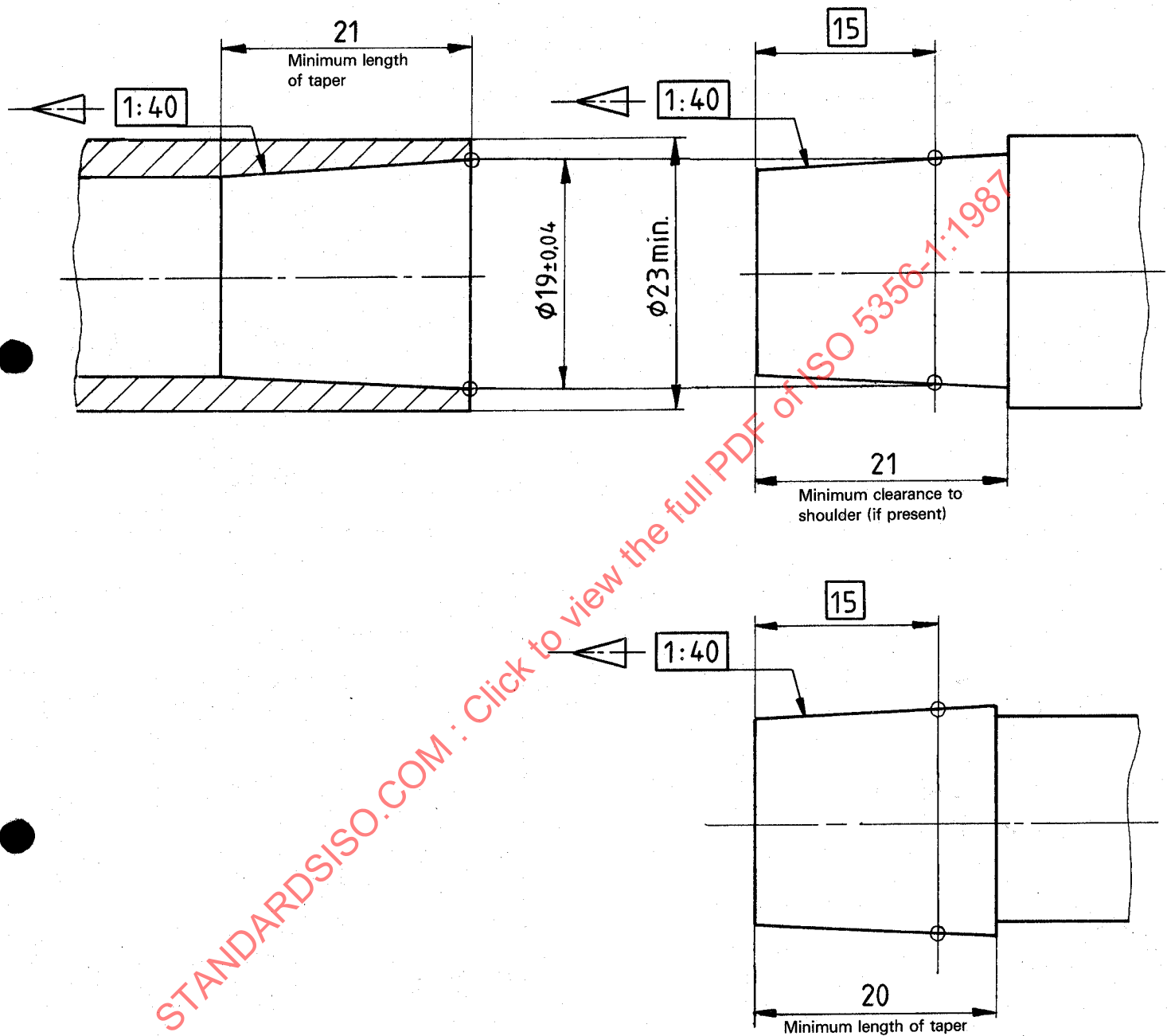
Dimensions in millimetres



NOTE — Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0,5 mm.

Figure 1 — Conical connectors of 15 mm size made of metal

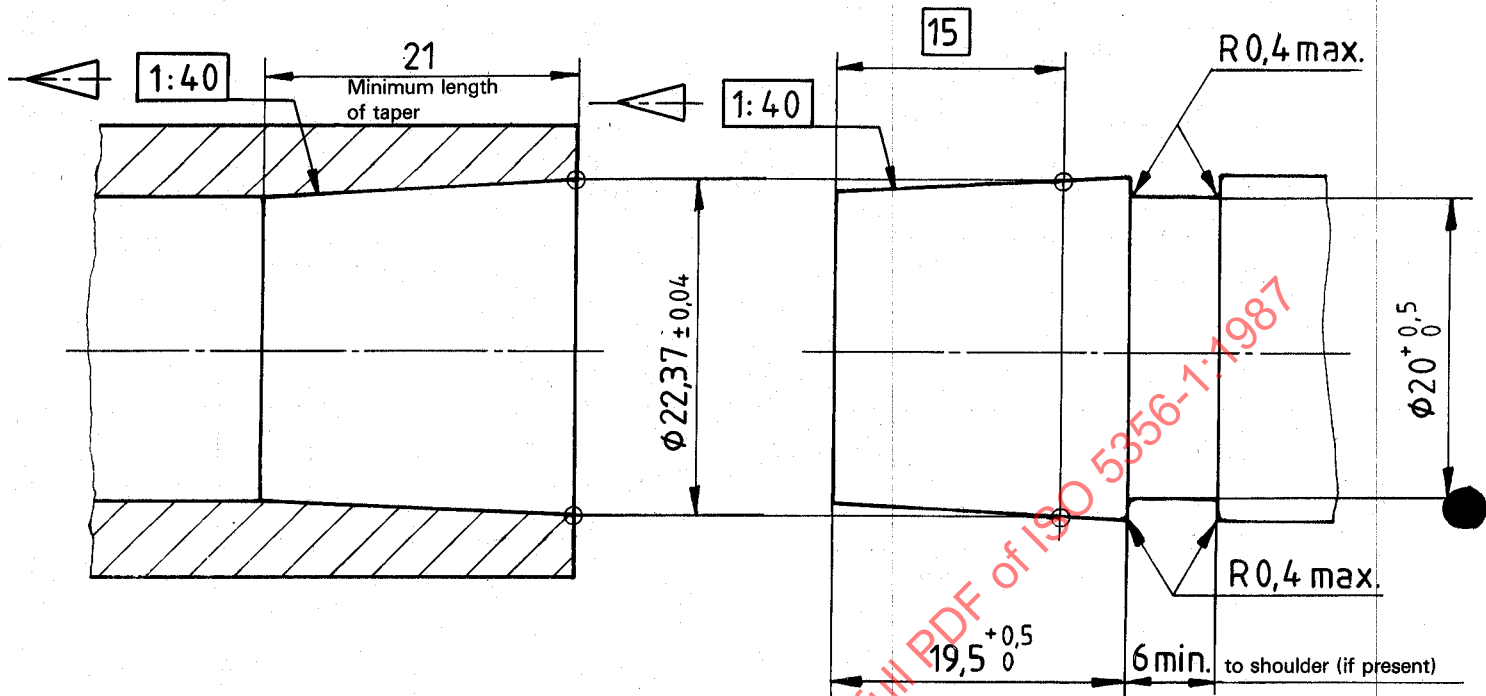
Dimensions in millimetres



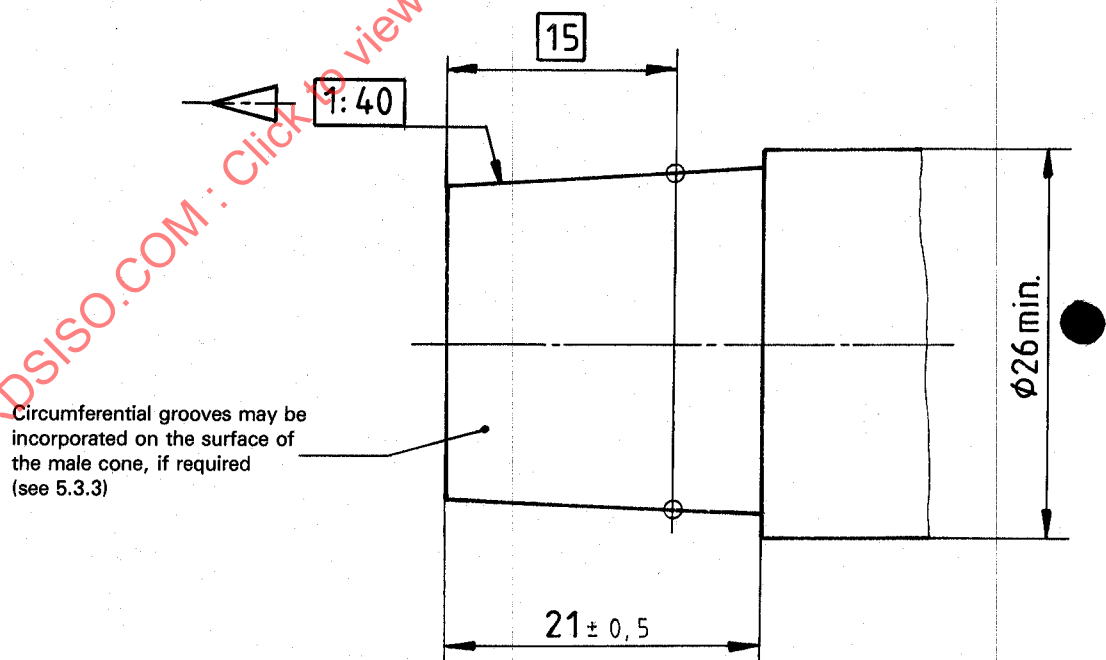
NOTE — Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0,5 mm.

Figure 2 — Conical connectors of 19 mm size made of metal

Dimensions in millimetres



a) Connector intended for breathing attachment (with recess)

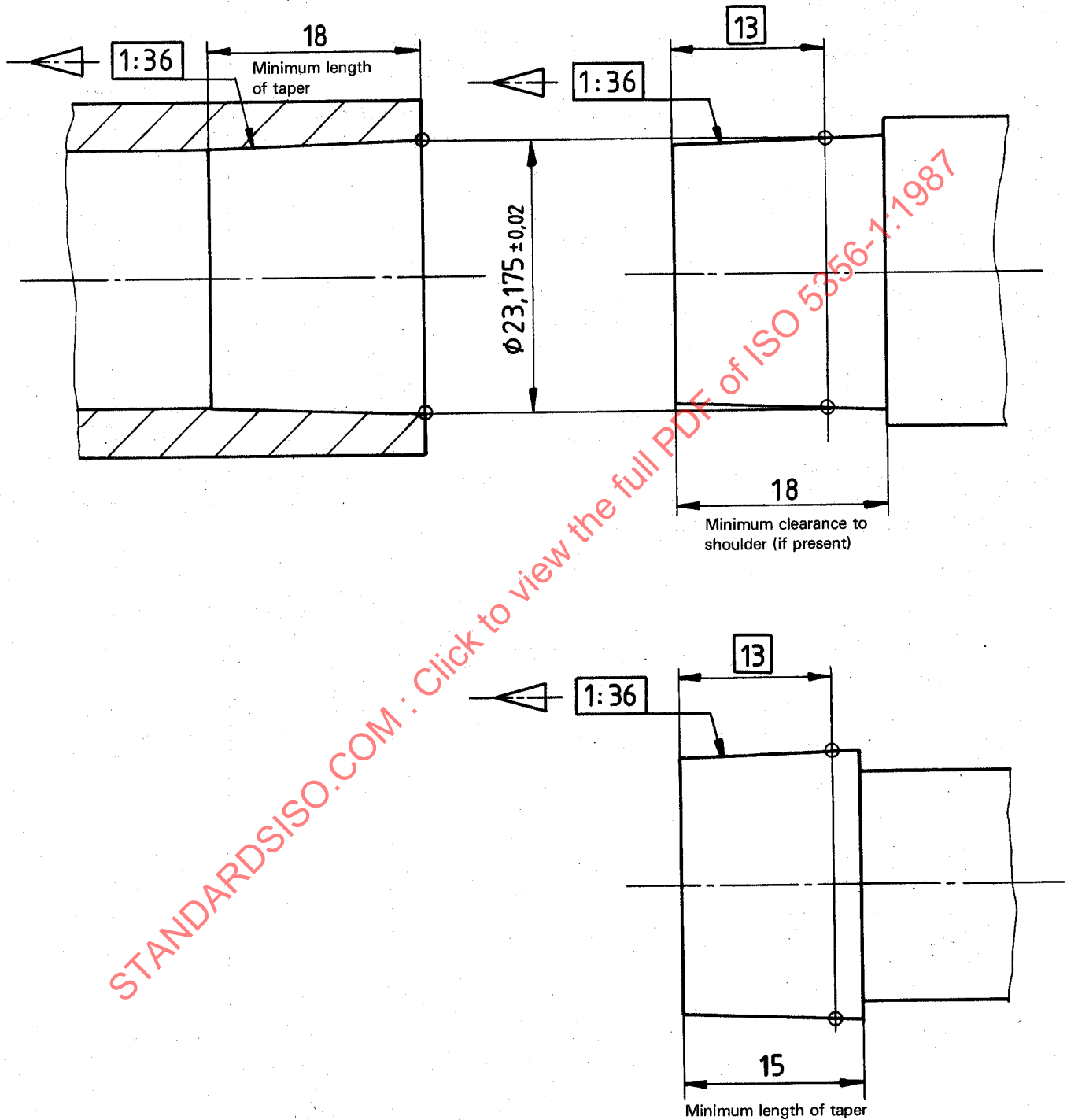


b) Connector intended for face mask (with shoulder)

NOTE — Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0,5 mm.

Figure 3 — Conical connectors of 22 mm size (with or without recess) made of metal

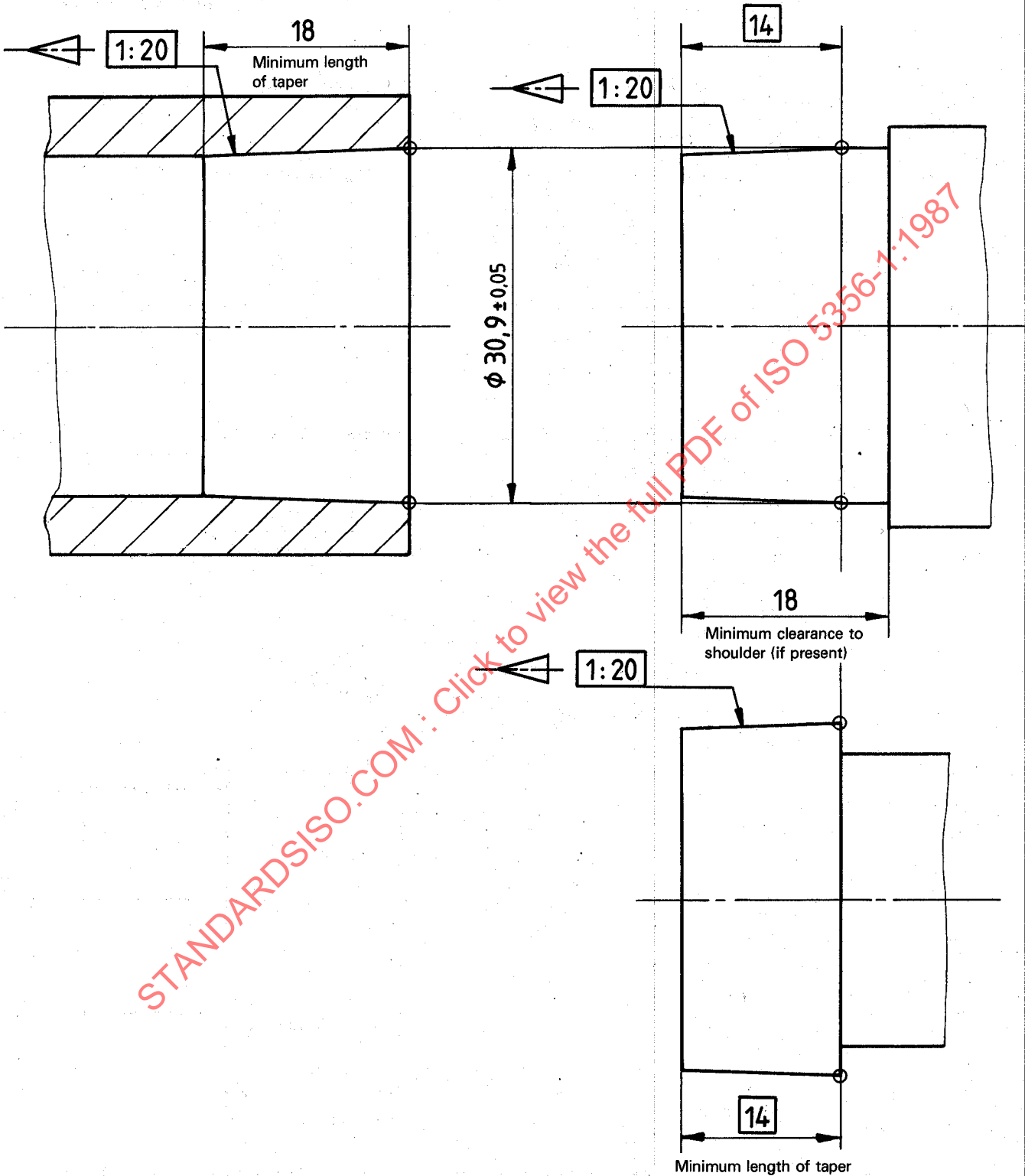
Dimensions in millimetres



NOTE — Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0,5 mm.

Figure 4 — Conical connectors of 23 mm size made of metal

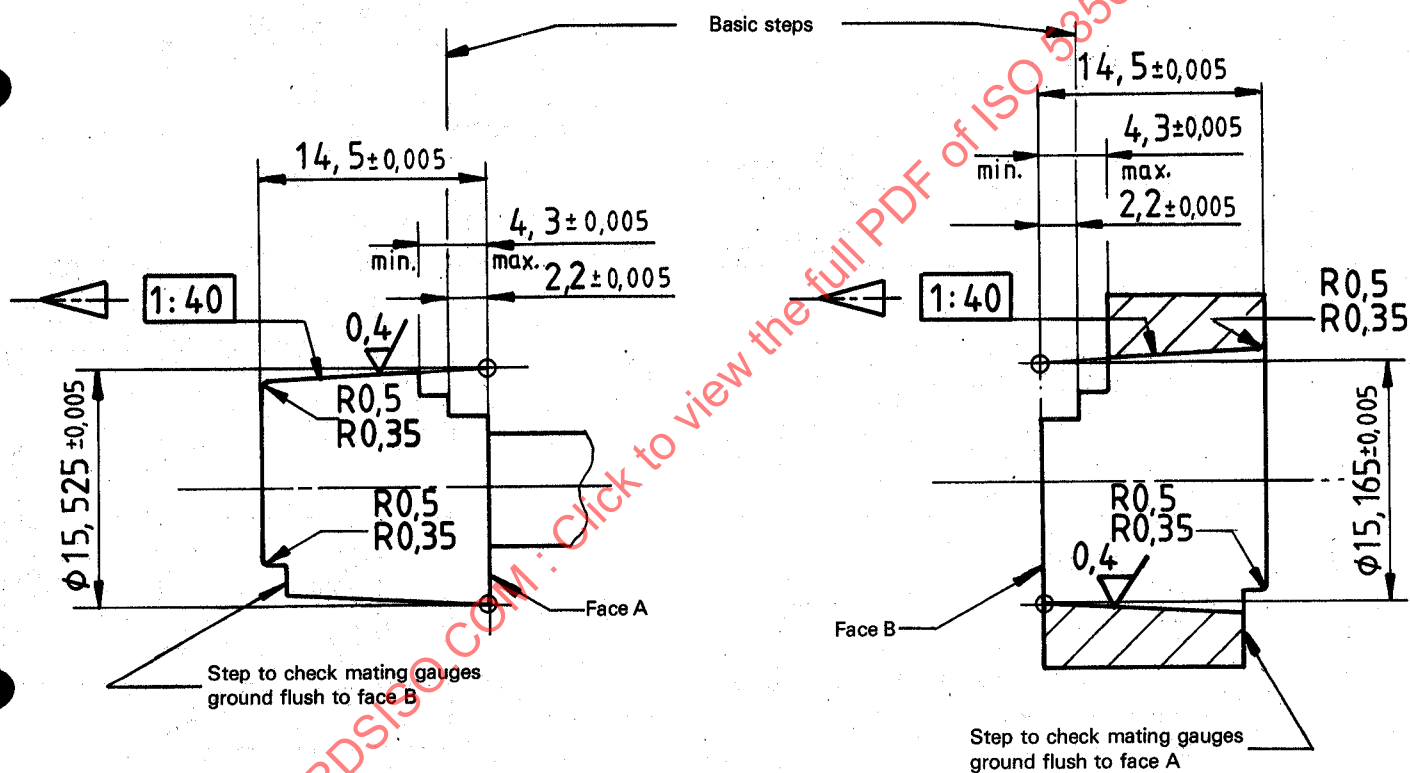
Dimensions in millimetres



NOTE — Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0,5 mm.

Figure 5 — Conical connectors of 30 mm size made of metal

Dimensions in millimetres; surface roughness values in micrometres

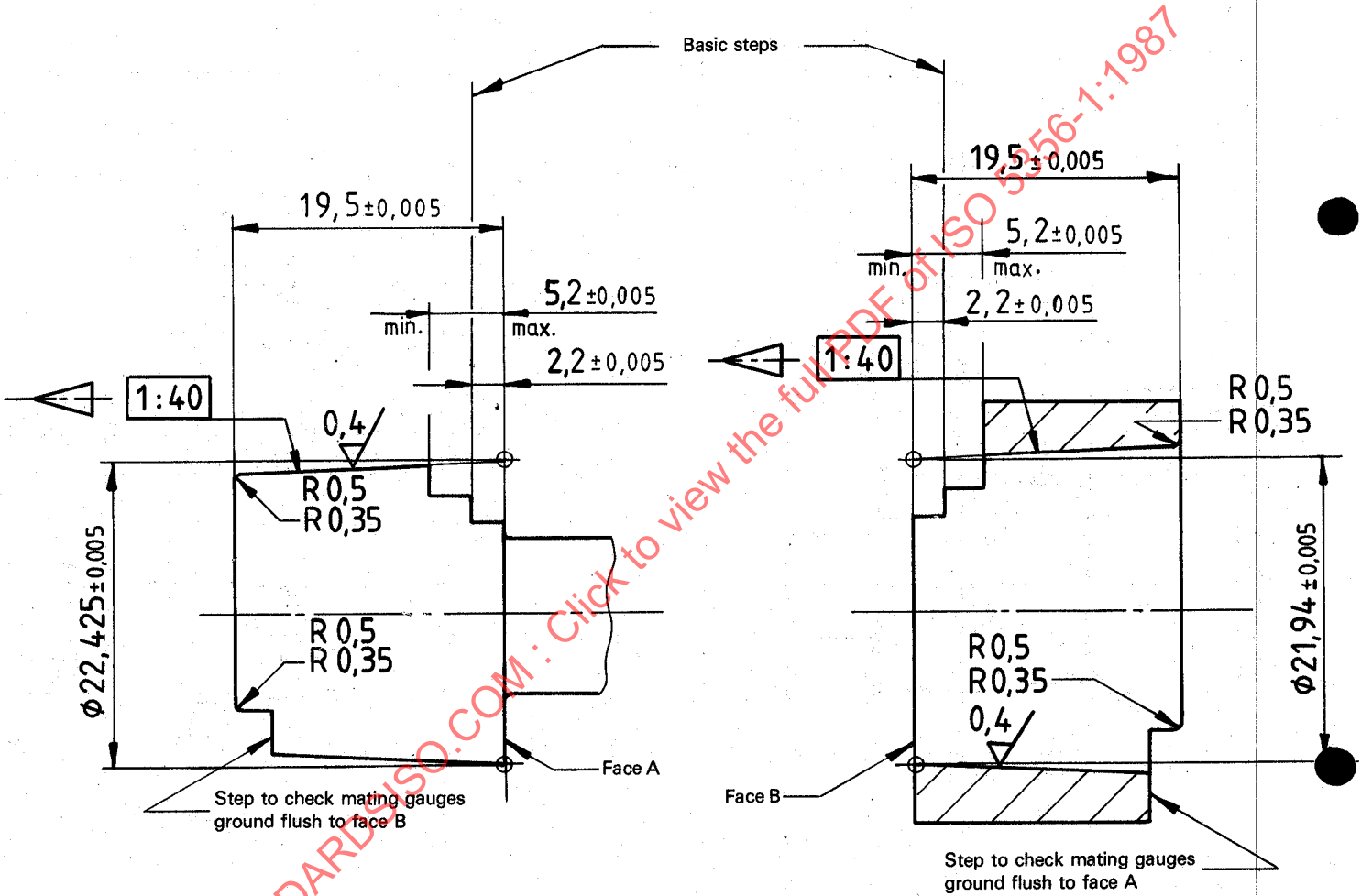


NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : $0,025 \pm 0,000\ 2$ units

Figure 6 — Plug and ring test gauges for conical connectors of 15 mm size made of materials other than metal

Dimensions in millimetres; surface roughness values in micrometres



NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : 0,025 ± 0,000 2 units

Figure 7 — Plug and ring test gauges for conical connectors of 22 mm size made of materials other than metal

Annex A

Recommendations for materials

(This annex does not form an integral part of the standard.)

A.1 General

A.1.1 Except for those connectors intended and labelled only for single use, connectors should withstand accepted methods of steam sterilization.

A.1.2 Male conical connectors should not be made of an elastomeric material¹⁾.

A.2 Freedom from cold welding characteristics

It is essential that conical connectors can be readily disconnected when required. Certain materials have been shown to exhibit the phenomenon of "cold welding" and their use should be avoided.

A.3 Resistance to deformation and to wear

Conical connectors should be resistant to wear in relation to their intended purpose and should be of adequate strength to withstand permanent deformation under conditions of normal use.

A.4 Corrosion resistance

Conical connectors should be resistant to corrosion or other deleterious effects caused by anaesthetic vapours and gases, disinfectants and other agents likely to be employed under conditions of normal use. Resistance to carbon dioxide absorbents, for example soda-lime, is important in the case of absorber canister and related connectors.

A.5 Freedom from risk of spontaneous combustion or incendive sparking

Materials liable to emit pyrophoric particles should not be used.

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

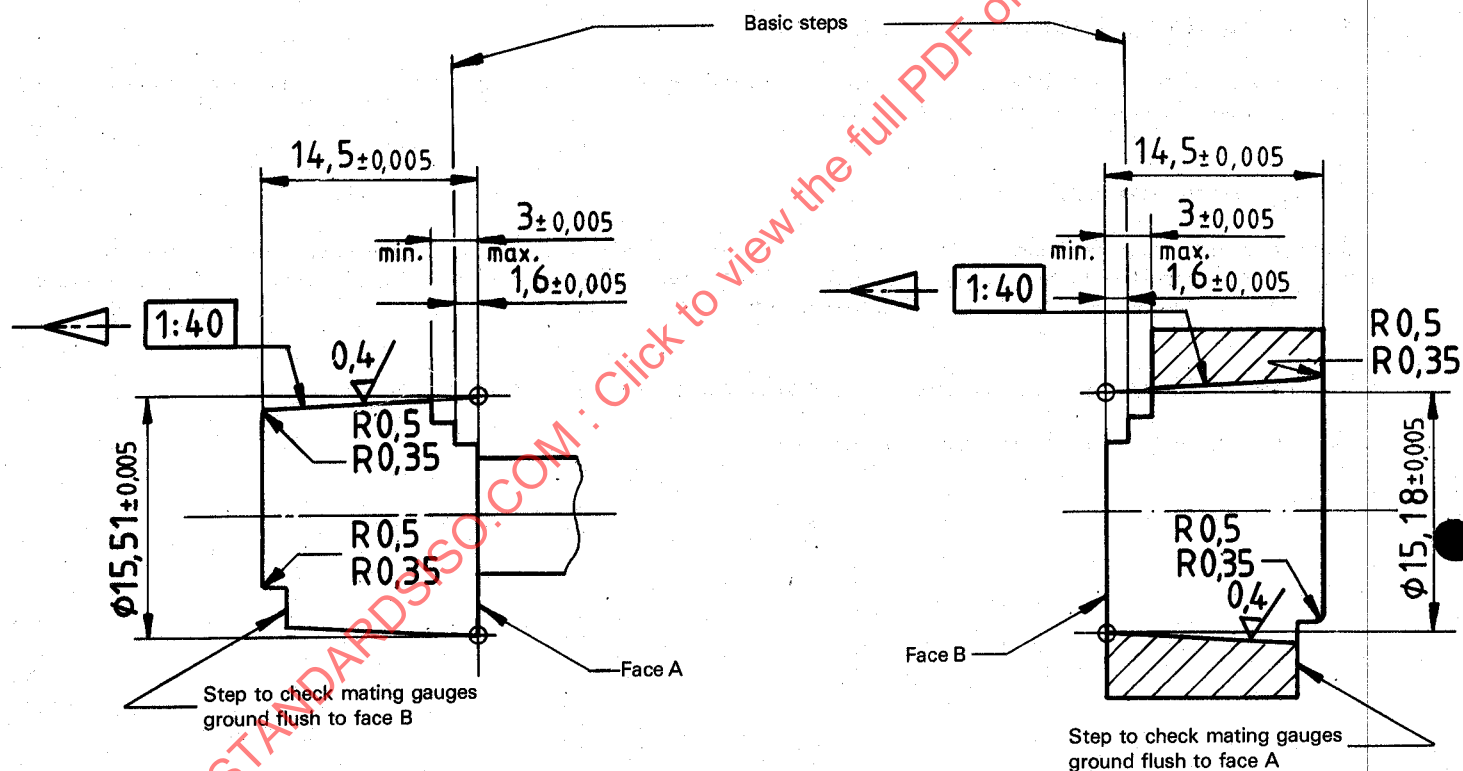
Annex B

Plug and ring gauges

(This annex does not form an integral part of the standard.)

Dimensions of plug and ring gauges that may be used to check the size of 15 mm, 19 mm, 22 mm, 23 mm and 30 mm conical connectors made of metal are given in figures 8, 9, 10, 11 and 12, respectively.

Dimensions in millimetres; surface roughness values in micrometres

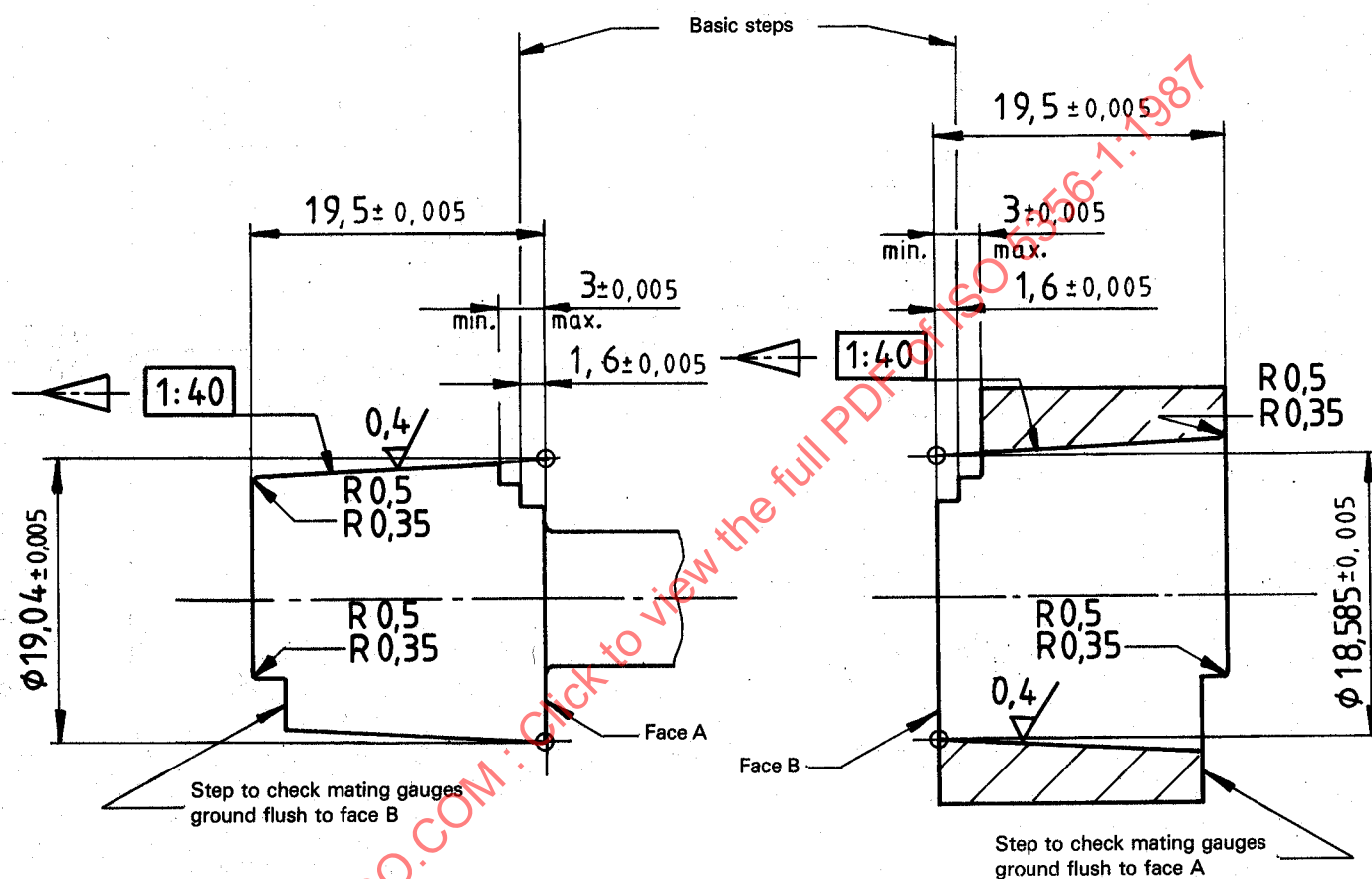


NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : $0,025 \pm 0,0002$ units

Figure 8 — Plug and ring test gauges for conical connectors of 15 mm size made of metal

Dimensions in millimetres; surface roughness values in micrometres

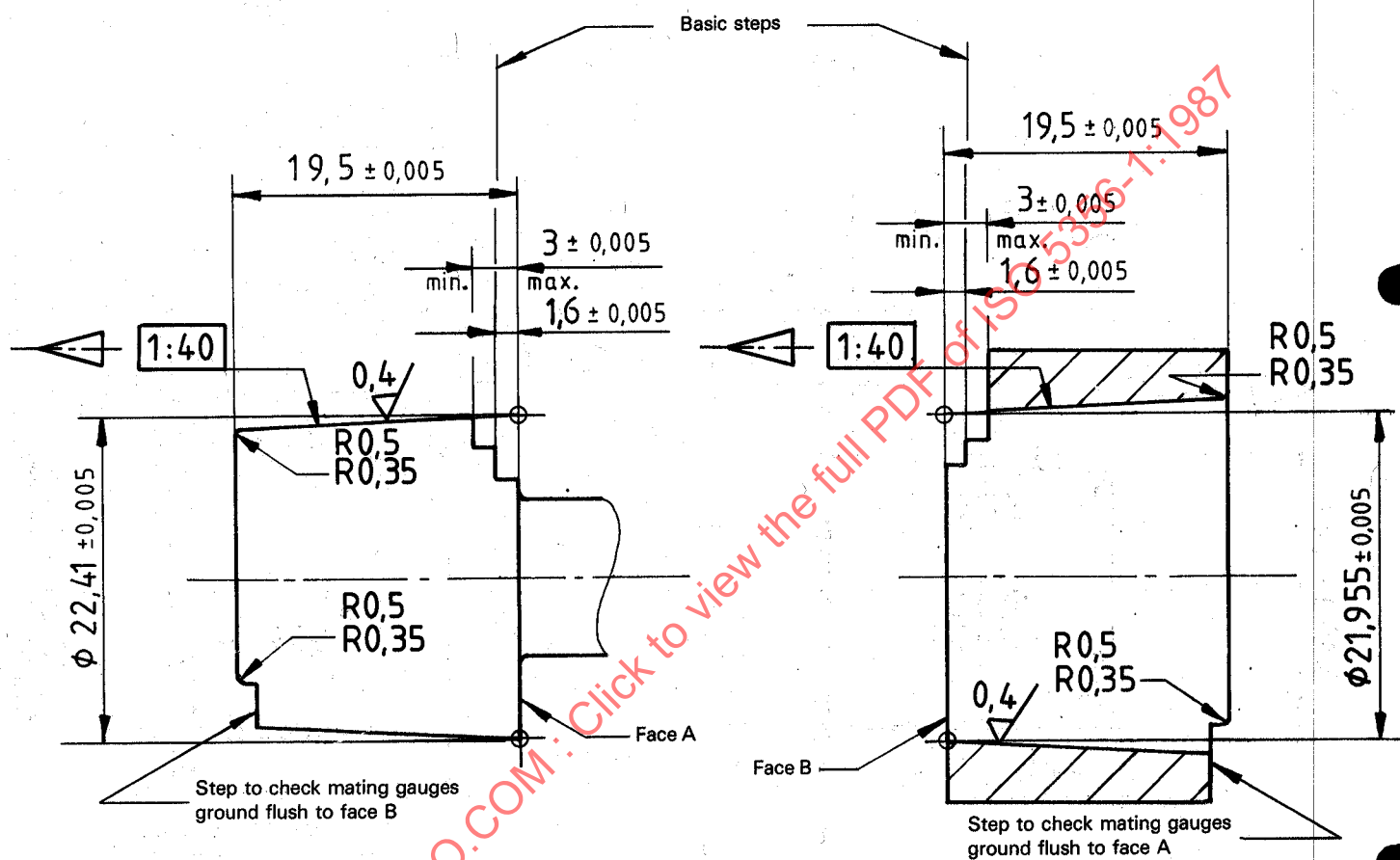


NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : 0,025 ± 0,000 2 units

Figure 9 — Plug and ring test gauges for conical connectors of 19 mm size made of metal

Dimensions in millimetres; surface roughness values in micrometres



NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : $0,025 \pm 0,000\ 2$ units

Figure 10 — Plug and ring test gauges for conical connectors of 22 mm size made of metal