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Writing and marking instruments — Specification for caps to reduce the risk of asphyxiation

Instruments pour l'écriture et le marquage — Spécifications pour les capuchons afin de réduire le risque d'asphyxie

Reference number
ISO 11540:2014(E)

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Foreword

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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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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 10, *Technical product documentation*.

This second edition cancels and replaces the first edition (ISO 11540:1993), which has been technically revised.

Introduction

If a child inhales a pen cap it might become lodged below the larynx and block the trachea. The risk of asphyxiation can be reduced if the pen cap is ventilated or too large to enter the airway. Children have to be actively discouraged from sucking, chewing, or putting pen caps in their mouths. A way of avoiding the risk of inhalation of caps of writing and marking instruments is to manufacture products without caps whenever possible. However, if caps are essential, the provisions of ISO 11540 minimize risk by specifying the design and performance of ventilated caps which reduce the likelihood of inhalation and delays asphyxiation pending medical intervention.

ISO/TC 10 recognizes that while it is possible to identify the age range of the children who are most at risk, it is not possible to identify with certainty any writing instruments with detachable caps that would never be accessible to children and hence never pose a risk. It is, however, acknowledged that certain products (i.e. writing and marking instruments which are designed or only intended for use by adults, e.g. jewellery pens, expensive fountain pens, professional technical pens) are not intended for use by children and such items have to be clearly labelled to that effect.

Writing and marking instruments — Specification for caps to reduce the risk of asphyxiation

1 Scope

This International Standard specifies requirements to reduce the risk of asphyxiation from caps for writing and marking instruments. It relates to such instruments which in normal or foreseeable circumstances are likely to be used by children up to the age of 14 years.

This International Standard is not applicable to the following:

— writing and marking instruments which are designed or only intended for use by adults, e.g. jewellery pens, expensive fountain pens, professional technical pens;

— transit caps for refills.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
writing and marking instruments
instruments for writing or marking with a detachable cap, including pens with a self-contained reservoir of ink or other marking fluid

2.2
cap
detachable closure designed to cover the writing or marking tip when not in use

3 Requirements

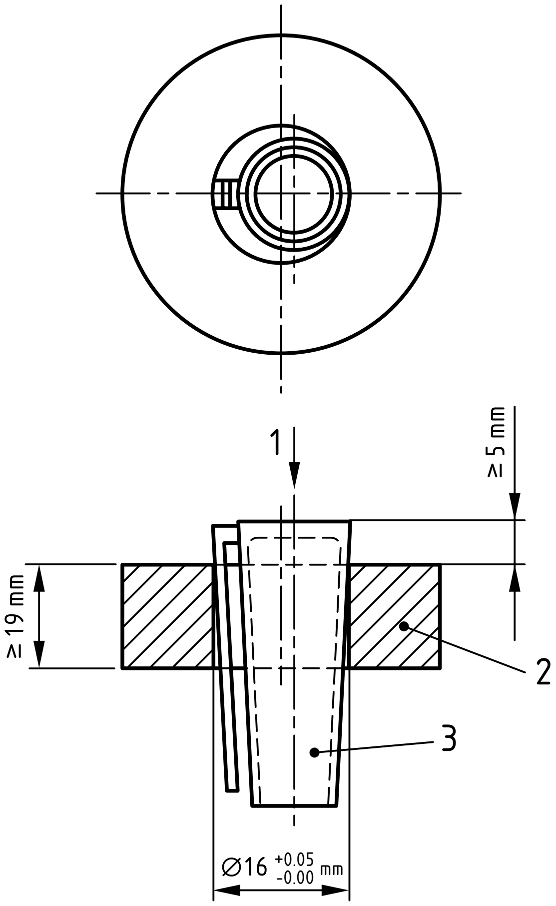
3.1 General

Caps shall conform to at least one of the following: 3.2 or 3.3.

3.2 Cap size

When a cap is introduced with its main axis perpendicular to a $16\,^{+0,05}_{-0,00}$ mm diameter ring gauge of at least 19 mm thickness, and part of the cap enters the gauge, at least 5 mm of the length shall not enter under its own weight, see Figure 1.

NOTE Caps which conform to this subclause are deemed to be too large to present an inhalation hazard.



Key

1 direction of fall

2 ring gauge

3 cap

Figure 1 — Schematic diagram of gauge

3.3 Ventilated caps air flow

When tested in accordance with Annex A, caps shall permit a minimum air flow of 8 l/min, measured at room temperature, with a maximum pressure drop of 1,33 kPa.

NOTE 1 For caps relying on internal ventilation, a singular circular orifice with a cross-sectional area of approximately 3,4 mm^2 can be expected to satisfy this criterion, but multiple small orifices might require a larger total cross-sectional area.

NOTE 2 Guidance is given in Annex B for caps that rely on external ventilation.

NOTE 3 Caps conforming to this subclause are deemed to not present an asphyxiation hazard.

3.4 Test report

The report shall indicate whether the cap conforms to 3.2 or 3.3.

The test report should indicate at least the following information:

a) the size of the tubing used (see A.2.6) and its % relationship to the circumscribing circle of the caps tested;

b) the number of caps tested, the airflow of each cap in both directions, and the minimum air flow recorded.

4 Identification

Writing or marking instruments, or their packaging or accompanying documentation, shall be legibly and indelibly identified with the name, trademark, or other means of identifying the manufacturer and/or supplier.

Annex A
(normative)

Test for air flow

A.1 Principle

The test cap is fully inserted into an elastomeric tube of the appropriate diameter and the air flow through the tube and the pressure drop are measured in both directions.

A.2 Apparatus

A.2.1 **Air supply**, pulse free and with a flow rate of at least 25 l/min within the pressure range of 4 kPa to 50 kPa.

A.2.2 **Flow regulator**, capable of controlling the air flow with an accuracy of ±0,1 l/min.

A.2.3 **Flow gauge**, capable of measuring a flow rate of between 5 l/min and 10 l/min with an accuracy of ±0,2 l/min.

A.2.4 **Pressure gauge**, capable of measuring a pressure of at least 4,00 kPa to an accuracy of ±0,01 kPa.

A.2.5 **Coupling and tubing**, suitable for connecting equipment described above in accordance with Figure A.1.

A.2.6 **Elastomeric tubing**, with an internal diameter of 80 % to 85 % of that of the circumscribing circle of the cap to be tested, measured at its widest point; with a wall thickness of 0,75 mm ± 0,25 mm and shore A hardness of 55 ± 10.

NOTE 1 The apparatus is illustrated in Figure A.1.

NOTE 2 Tubing of diameters appropriate to the cap body might be difficult to obtain and it might be advantageous to manufacture the tubing, as required, by a dip-moulding technique.

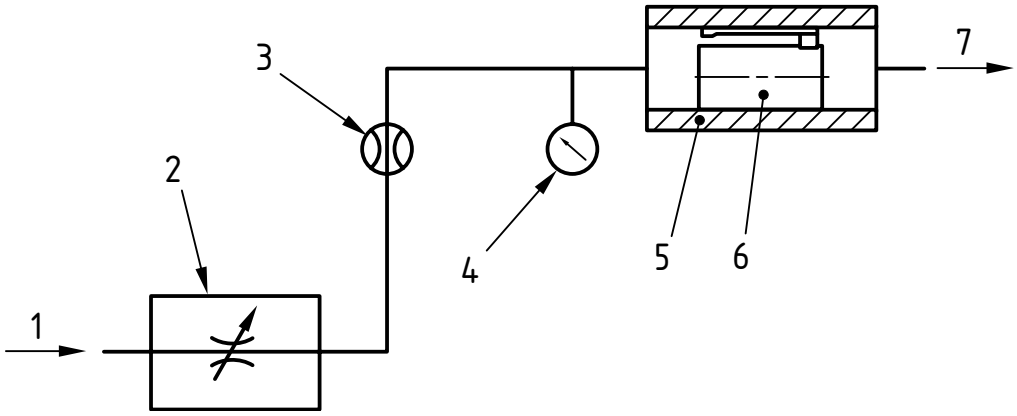
A.3 Procedure

A.3.1 Cut the elastomeric tubing (see A.2.6) into a length such that when the cap is inserted there is a relaxed diameter of tubing at both ends of the cap when connected in the apparatus. Apply a soap solution or other suitable low viscosity lubricant to the full internal area of the tubing. Insert the cap into approximately the centre of the tube length and ensure that, as far as practicable, the cap is parallel to the major axis of the tubing.

A.3.2 Using suitable connectors and tubing, connect the tube/cap assembly (see A.3.3) to the apparatus, in accordance with Figure A.1. Turn on the air supply and adjust the flow until the pressure gauge indicates a pressure difference of 1,33 kPa. Record the flow rate indicated on the flow gauge at this pressure.

A.3.3 Turn off the air supply, remove and reverse the tube/cap assembly and repeat A.3.2. Test the cap, giving the air flow results found in each direction.

A.3.4 Complete the test report (see 3.4).



Key

1 air supply
2 flow control valve
3 flowmeter
4 pressure gauge
5 elastomeric tubing
6 cap
7 air exhaust

Figure A.1 — Schematic diagram of test rig

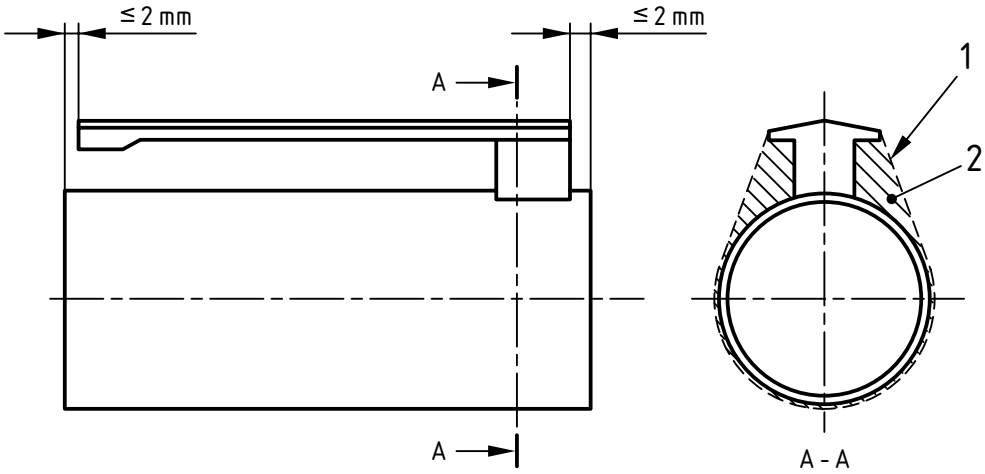
Annex B
(informative)

Design guidance for pen caps vent area

A continuous air passage of a least 6,8 mm^2 should extend for the length of the cap body to within 2 mm of both ends. The cross-sectional area of the continuous air passage, if not entirely enclosed, should be that area that would be enclosed by a thin piece of cotton thread wrapped tautly around any section perpendicular to the main axis or the largest dimension (see Figure B.1). Alternatively, this area can be calculated using a CAD system. Where a clip or other protrusion is the means of providing the air passage it should be securely fixed and it should extend to within at least 2 mm of each end of the cap body.

NOTE 1 The clip can extend any distance beyond the end of the cap body.

NOTE 2 Caps conforming to this annex are unlikely to present an asphyxiation hazard, but need air flow testing to validate. Some caps quite different in configuration from the design described in this annex but which rely on external ventilation might nevertheless satisfy the air flow requirements in 3.3 if tested using elastomeric tubing close to the maximum permitted internal diameter. A wise precaution is to retest such caps using tubing with an internal diameter close to 80 % of the caps circumscribing circle.



Key
1 line of cotton thread
2 included area

NOTE 1 It is essential that measurements are made at each change of section.

NOTE 2 Included area has to be not less than 6,8 mm^2 except within 2 mm of either end of cap body.

Figure B.1 — Sectional view of cap

Bibliography

[1] ISO 1938-1, *Geometrical product specifications (GPS) — Dimensional measuring equipment — Part 1: Plain limit gauges of linear size*

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Price based on 7 pages