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Anaesthetic and respiratory equipment — Air entrainment devices

Matériel d'anesthésie et de réanimation respiratoire — Dispositifs d'entraînement d'air

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Air entrainment devices, commonly known as venturi masks, are used to provide a known concentration of oxygen to a patient at a known set flow. This is achieved by driving the oxygen through a controlled diameter orifice and entraining room air through side openings These devices are available in various concentrations and can ensure continuity over a long period of time within relatively close limits of accuracy.

However, the use of these devices does not guarantee that the patient receives the designated oxygen concentration as there are physiological factors such as the patient's ventilatory pattern, lung compliance and airway resistance, and physical factors such as the fit of the mask, movement by the patient, etc[2].

Anaesthetic and respiratory equipment — Air entrainment devices

1 Scope

This document specifies minimum performance and safety requirements for *air entrainment devices* used for delivery of designated oxygen concentrations to patients. It provides a test method to check the accuracy of the oxygen concentration in the air/oxygen mixture generated by the *air entrainment devices*. *Air entrainment devices* can be fixed to deliver a single oxygen concentration or adjustable, to deliver a range of oxygen concentration outputs.

This document also specifies marking requirements and recommends an optional system of colour coding to assist the user in identifying the designated oxygen concentration.

This document does not cover *air entrainment devices* which are integral with medical devices specified in other standards (e.g. emergency lung ventilators, humidifiers, nebulizers).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 15002, *Flow-metering devices for connection to terminal units of medical gas pipeline systems*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 80369-2[1)], *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
air entrainment device
device consisting of a jet orifice adjacent to a series of air entrainment ports

1) Under preparation. Stage at the time of publication: ISO/DIS 80369-2:2022.

4 General requirements

The requirements of ISO 18190:2016, Clause 4, shall apply.

5 Materials

5.1 General

The requirements of ISO 18190:2016, Clause 5, shall apply.

5.2 Biocompatibility of breathing gas pathways

Materials used to manufacture *air entrainment devices* shall be tested and evaluated for biocompatibility of the breathing gas pathways as specified in ISO 18562-1.

Check conformance by inspection of the technical file.

6 Design requirements

6.1 General

6.1.1 The requirements of ISO 18190:2016, Clause 6, shall apply.

6.1.2 *Air entrainment devices* shall be designed to operate with an oxygen supply controlled by a flow-control device complying with ISO 15002 and capable of delivering at least 15 l/min when connected to respiratory therapy tubing.

Check conformance by inspection of the technical file.

6.1.3 *Air entrainment devices* shall deliver oxygen within the minimum and maximum concentrations given in Table 1 for their declared, designated oxygen concentrations at the minimum and maximum flows specified by the manufacturer [see 7.3 b)].

Check conformance by the test method given in Annex A.

Table 1 — Delivered oxygen concentrations, colour allocations and colour references

Designated O_2 concentration	Delivered O_2 concentration		Colour	Example of Pantone[a] colour code
	min. (%) volume fraction	max. (%) volume fraction		
24	23	25	Blue	285 C
28	27	29	White	11-0601 TCX
31	30	32	Orange	021 CP
35	33	37	Yellow	12-0633 TCX
40	38	42	Red	Bright red C
50	47	53	Pink	12-1706 TPG
60	56	64	Green	Green CP

[a] Pantone is an example of a suitable colour definition available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO.

6.2 Oxygen inlet connectors

Oxygen inlet connectors shall be an R2 socket small-bore connector complying with ISO 80369-2.

Check conformance by inspection of the technical file.

6.3 Outlet connectors

Outlet connectors shall be a 22 mm socket complying with ISO 5356-1.

Check conformance by inspection of the technical file.

6.4 Air inlet attachments

Any air inlet attachment provided with, or recommended for use with, the *air entrainment device* shall not:

a) affect the safety or the performance of the device;

Check conformance by inspection of the risk management file.

b) obscure any markings on the device, or

Check conformance by functional testing and inspection.

c) become detached when subjected to an axial tensile force of (5 ± 0,5) N for 60 s.

Check conformance by securing the attachment so that it is not distorted and applying an axial tensile force of (5 ± 0,5) N to the oxygen inlet connector of the *air entrainment device* for (60 ± 2) s. Record whether the device separates from the air inlet attachment.

Repeat the test applying the axial force in the opposite direction, i.e. compressing the device into the attachment.

7 Information to be provided by the manufacturer

7.1 General

7.1.1 The requirements of ISO 18190:2016, Clause 9, shall apply.

7.1.2 The information to be provided by the manufacturer shall comply with ISO 20417.

7.2 Marking

7.2.1 *Air entrainment devices* shall be marked with:

a) the appropriate designated oxygen concentration as specified in Table 1 in characters at least 2,5 mm high;

b) the recommended flow in l/min in characters at least 2,5 mm high; and

c) if colour coding is used to differentiate the designated concentrations, the colours shall be those specified in Table 1.

Check conformance by inspection.

7.2.2 *Air entrainment devices* with a means to adjust the delivered oxygen concentrations shall be marked with:

a) each designated oxygen concentration that the *air entrainment device* is designed to deliver, as specified in Table 1, in characters at least 2,5 mm high; and

b) the direction of movement to increase the delivered oxygen concentration.

Check conformance by inspection.

7.3 Instructions for use

Air entrainment devices shall be provided with instructions for use which shall include the following:

a) a table or graph showing the relationship between the oxygen supply flow and the resulting total flow of the delivered air/oxygen mixture;

b) the minimum, and maximum flows of oxygen which enable the *air entrainment device* to achieve the designed performance; and

c) for adjustable *air entrainment devices*, a warning to the effect that means of determining the patient's oxygenation, (e.g. pulse oximeter), and inspired oxygen, (e.g. oxygen monitor), should be used.

Check conformance by inspection.