SLOVENSKI STANDARD
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Oprema za zdravljenje motenj dihanja: Vhodne naprave za zrak (ISO/DIS 23372:2019)

Respiratory therapy equipment: Air entrainment devices (ISO/DIS 23372:2019)

Appareils de thérapie respiratoire - Dispositifs d'entraînement d'air (ISO/DIS 23372:2019)

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

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Respiratory therapy equipment — Air entrainment devices

Appareils de thérapie respiratoire — Dispositifs d'entraînement d'air

ICS: 11.040.10

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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. 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. www.iso.org/patents

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/SC2.

This is the first edition which is based on the European standard EN 13544-3:2005 Amd 1:2009 and aligns with ISO 18190:2016 the General standard for airway devices.

Throughout this International Standard the following print types are used:

- Requirements and definitions: roman type;
- *Compliance tests: italic type;*
- Informative material appearing outside of tables, such as notes, examples and references: smaller type. The Normative text of tables is also in smaller type;
- *terms defined in clause 3: green italic.*

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

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. They achieve this by driving the oxygen through a controlled diameter orifice and entraining room air through side openings. [1] 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 ventilator pattern, lung compliance and airway resistance and physical factors such as the fit of the mask, movement by the patient etc. [2]

Respiratory therapy equipment – Air entrainment devices

1 Scope

ISO 18190:2016 Clause 1 is replaced by:

This document specifies minimum performance and safety requirements for *air entrainment devices* used for delivery of designated oxygen concentrations to patients and includes 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 a fixed to deliver a single oxygen concentration or adjustable, to deliver a range of oxygen concentration outputs.

It 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, etc.

2 Normative references

ISO 18190 Clause 2 is replaced by:

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 15002:2008 + amd 1:2017, *Flow-metering devices for connection to terminal units of medical gas pipeline systems*

ISO 17256, *Anaesthetic and respiratory equipment — Respiratory therapy equipment — Tubing and connectors* [1]

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

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 18562-2:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter*

ISO 18562-3:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —: Part 3: Tests for emissions of volatile organic compounds (VOCs)*

ISO 18562-4:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —Part 4: Tests for leachables in condensate*

ISO 80369-2:20XX, *Small bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications* [2]

EN 1041:2008+A1:2013, *Information supplied by the manufacturer with medical devices*

[1] Under development
[2] Under development

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:
— IEC Electropedia: available at http://www.electropedia.org/
— ISO Online browsing platform: available at https://www.iso.org/obp

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

4 General requirements

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

5 Materials

The applicable requirements of ISO 18190:2016, clause 5, apply.

In addition:

Materials used to manufacture *air entrainment devices* shall be tested and evaluated for biocompatibility of the breathing gas pathways as specified in ISO18562:2017, parts 1, 2, 3 and 4, as appropriate.

Check compliance by inspection of the technical file.

6 Design requirements

The applicable requirements of ISO 18190:2016, clause 6, apply.

In addition:

6.1 General

6.1.1 *Air entrainment devices* shall be designed to operate with an oxygen supply controlled by a flow-metering device complying with ISO 15002:2008 +Amd 1:2017 and capable of delivering at least 15 L/min and connected using respiratory therapy tubing complying with ISO 17256.

Check compliance by inspection of the technical file.

6.1.2 *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 7.2b)].

Check compliance by the test method given in Annex A.

Table 1 – Delivered oxygen concentrations, colour allocation and colour references

Designated O_2 concentration	Delivered O_2 concentration		Colour	Example of Pantone colour code
	min (%) $^{v}/_{v}$	max (%)$^{v}/_{v}$		