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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).

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

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.