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Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors

Matériel d'anesthésie et de réanimation respiratoire — Tubulures pour thérapie respiratoire et raccords

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Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 General requirements ... **2**
4.1 General ... 2
4.2 Test methods and conditions ... 2
5 Materials ... **2**
5.1 General ... 2
5.2 Biological assessment of gas pathways ... 2
6 Design requirements ... **2**
6.1 General ... 2
6.2 Specific design requirements ... 3
6.3 Inlet connectors ... 5
6.4 Outlet connectors ... 6
7 Requirements for *respiratory tubing*, *extension tubing* and connectors supplied sterile ... **6**
8 Packaging ... **6**
9 Information supplied by the manufacturer ... **6**
9.1 General ... 6
9.2 Information supplied by the manufacturer ... 6
Annex A (informative) **Rationale** ... **7**
Annex B (normative) **Respiratory therapy equipment tubing connectors** ... **9**
Annex C (informative) **Hazard identification for the purposes of risk assessment** ... **11**
Bibliography ... **12**

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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 document 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 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, *Airway devices and related equipment*.

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.

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Introduction

Respiratory tubing and connectors form the essential conduit between the *patient interface* and the gas supply device. The connectors specified in this document have been selected taking into consideration the risks of misconnection with other medical devices commonly used within the same environment. The requirements in this document were further developed and are to be circulated to all ISO/TC 121 subcommittees as recommendations.

Respiratory tubing and connectors are used extensively in healthcare facilities and increasingly in the home healthcare environment where medically trained personnel are not always in attendance. These environments have been carefully considered throughout the development of this document.

This document recognizes the significant use and the inherent safety of the EN 13544-2[1] specified nipple as the gas outlet on respiratory gas supply devices and therefore specifies a compatible elastomeric (funnel) connector as the inlet of the *respiratory tubing*. This document also recognizes the high risks associated with misconnection of the previously prescribed elastomeric (funnel) connector at the outlet (patient end) of the tubing and has therefore specified the new R2 respiratory small-bore connector as the outlet connector if the *respiratory tubing* is not integrated with the *patient interface* device (e.g. face mask, nasal cannula).

The concept of *extension tubing*, commonly used to provide flexibility of movement for the patient in home-care environments and hospital environments, such as MRI units, toilets and endoscopy units, has now been included in this document with particular emphasis on the connectors.

This document is adapted from EN 13544-2:2009[1] and has been modified as follows:

— the change of outlet from an elastomeric funnel to an R2 respiratory small-bore connector;

— requirements for *extension tubing*;

— requirements for *respiratory tubing* integrated with *patient interface* devices;

— a requirement to assess the biocompatibility of the materials of the devices that provide a gas pathway has been added;

— the dimensions of the nipple have been better defined;

— the option to specify a gas-specific threaded connection at the inlet of the *respiratory tubing* to replace the elastomeric funnel inlet connector has been made clearer;

— the gas-specific threaded inlet connectors now include gasses other than oxygen and air; and

— a hazard identification annex has been added (Annex C).

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Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors

1 Scope

This document specifies requirements for the *respiratory tubing* and connectors used to convey respirable gases to a patient in the healthcare and homecare environments and provide a safe connection between the gas supply device and the *patient interface*. *Respiratory tubing* and connectors are mainly used for delivery of oxygen but can also be used for respirable air or oxygen/air mixtures and breathable medicinal gas mixtures such as oxygen/nitrous oxide or oxygen/helium mixtures. This document also specifies requirements for respiratory therapy *extension tubing*.

NOTE 1 The gas supply devices referred to in this document do not include anaesthetic machines/workstations and ventilators.

NOTE 2 This document does not cover breathing tubes for breathing systems. These are specified in ISO 5367.

This document is written following the format of ISO 18190, *General standard for airways and related equipment*. The requirements in this device-specific standard take precedence over any conflicting requirements in the General standard

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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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 21920-1, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 1: Indication of surface texture*

ISO 80369-2, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Respiratory small-bore connectors*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 18190 and the following 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/

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