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Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases

Matériel d'anesthésie et de réanimation respiratoire — Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux

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Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **2**

3 Terms and definitions ... **2**

4 General requirements ... **6**
4.1 Risk management ... 6
4.2 Usability ... 6
4.3 Clinical investigation ... 6
4.4 Safety ... 6
4.5 Materials ... 7
4.6 Design requirements ... 7
4.7 Constructional requirements ... 10

5 Test methods ... **11**
5.1 General ... 11
5.2 Test method for pressure drop ... 11
5.3 Test method for leakage ... 11
5.4 Test method for gas specificity ... 11
5.5 Test method for mechanical strength ... 11
5.6 Test method for deformation under pressure ... 12
5.7 Test method for resistance to occlusion ... 12
5.8 Test method for durability of markings and colour coding ... 13

6 Marking, colour coding and packaging ... **13**
6.1 Marking ... 13
6.2 Colour coding ... 14
6.3 Packaging ... 15

7 Information to be supplied by the manufacturer ... **15**

Annex A (informative) **Rationale** ... **17**

Annex B (informative) **Environmental aspects** ... **18**

Annex C (informative) **Reported regional and national deviations of colour coding and nomenclature for medical gases** ... **19**

Bibliography ... **21**

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

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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 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This fourth edition cancels and replaces the third edition (ISO 5359:2008) and the Amendment ISO 5359:2008/Amd 1:2011, which has been technically revised as follows:

— deletion of the requirements on the dimensions and allocation of connectors (see ISO 18082);

— addition of definitions of terms;

— addition of requirements on risk management, usability, clinical investigation and leaching of substances;

— amendment of the marking requirements and requirements for information to be provided by the manufacturer.

Introduction

This International Standard has been prepared in response to the need for a safe method of connecting medical equipment to a fixed medical gas pipeline system or other medical gas supply system such that hose assemblies carrying different gases, or the same gas at different pressures, cannot be interchanged. Fixed medical gas pipelines, once installed, are rarely disturbed and are subjected to commissioning procedures to avoid the possibility of cross-connections or contamination of the medical gas conveyed. However, hose assemblies are subjected to wear and tear, misuse and abuse throughout their relatively short service life and are frequently connected to, and disconnected from, the medical equipment and the fixed pipeline.

While recognizing that no system is absolutely safe, this International Standard includes those requirements considered necessary to prevent foreseeable hazards arising from the use of hose assemblies. Operators should be continually alert to the possibility of damage being caused by external factors. Therefore regular inspection and repair should be undertaken to ensure that hose assemblies continue to meet the requirements of this International Standard.

This International Standard pays particular attention to

— suitability of materials,

— gas specificity,

— prevention of cross-connections,

— cleanliness,

— testing,

— identification, and

— information supplied.

Requirements on respiratory therapy tubing are covered by ISO 17256, which refers to ISO 80369-2 on small bore connectors for breathing systems and driving gases.

While the desirability of achieving agreement on a single International Standard for screw-threaded connectors has never been in doubt, the present pattern of usage has made such agreement impossible.

Nevertheless, fears that proliferation of individual national standards or practices will eventually result in potentially dangerous cross-connection between components for different gases have led to the choice of three screw-threaded connector systems, and one gas-specific quick connector system for use on low pressure hose assemblies. The three systems of non-interchangeable screw-threaded connectors are the diameter index safety system (DISS), the non-interchangeable screw-threaded (NIST) system and the sleeve indexed system (SIS). Dimensions and allocation of these connectors to medical gases are not specified in this International Standard.

Rationales for some of the requirements of this International Standard are given in Annex A. Such requirements are indicated by the asterisk (*) after the clause number in the main text.