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Inhalational anaesthesia systems — Draw-over anaesthetic systems

Systèmes d'anesthésie par inhalation — Alimentation en vapeur et équipements annexes

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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 (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 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.

This International Standard cancels and replaces ISO/TS 18835:2004, which has been technically revised.

Introduction

The continuous-flow anaesthetic workstations described in ISO 80601-2-13 rely upon an uninterrupted supply of compressed medical gases and electricity. These in turn depend upon a highly developed infrastructure of transport, power generation, and technical services.

The World Health Organization (WHO) and the World Federation of Societies of Anaesthesiologists (WFSA) have requested ISO ensure that the needs for safe anaesthesia for people in populous and low to middle income countries of the world are also addressed in ISO standards for anaesthetic equipment.

In accordance with this request, ISO/TC 121/SC 1 has developed a standard for anaesthetic systems (ISO 8835-7) that can give a safe inhalation anaesthetic without relying on electricity or compressed gas.

To achieve this, it is recognized that the DRAW-OVER ANAESTHETIC SYSTEM is an essential part of this system. A technical specification for DRAW-OVER VAPORIZERS and associated equipment, ISO/TS 18835 has been in publication since 2004 and forms the basis of this International Standard.

Throughout this International Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

In this International Standard, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— test methods: *italic type*;

— terms defined in this document: SMALL CAPS.

Inhalational anaesthesia systems — Draw-over anaesthetic systems

1 * Scope

This International Standard specifies basic safety and essential performance requirements for anaesthetic systems utilizing the draw-over method to provide inhalational anaesthesia.

Requirements are included to allow the use of these systems with both non-flammable and flammable anaesthetic agents.

This International Standard also includes requirements for a bellows-type manual ventilator.

NOTE 1 Requirements for automatic anaesthetic ventilators are covered by ISO 80601-2-13.

NOTE 2 Requirements for operator-powered self-inflating bags are covered by ISO 10651-4.

This International Standard does not specify requirements for monitoring of the equipment or the patient.

2 Normative references

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 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5360, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5367, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 23328-1, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-7[1)], *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

EN 13544-2:2002+A1:2009, *Respiratory therapy equipment — Part 2: Tubing and connectors*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001 and the following apply.

1) This reference will be replaced by ISO 80369-2 once this International Standard has been published.