TECHNICAL SPECIFICATION

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Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment

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

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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 18835 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

Introduction

The continuous-flow anaesthetic system described in ISO 8835-2 to ISO 8835-5 relies upon supplies of compressed medical gases and an uninterrupted electricity supply. These in turn depend upon a highly developed infrastructure of transport facilities, power generation and technical service.

The World Federation of Anaesthesiologists (WFSA) has requested ISO to ensure that the needs for safe anaesthesia for people in the populous and developing countries of the world are also addressed in ISO standards for anaesthetic equipment. This should include a practical standard for draw-over vaporizers and associated equipment.

In accordance with this request, this Technical Specification deals with such a system that is not dependent on compressed gas and electrical power.

It is based on the use of ambient air, preferably with the addition of supplementary oxygen, as the carrier gas to convey anaesthetic vapour to a patient from a draw-over vaporizer.

Attention is drawn to IEC 60601-2-13 and the ISO 8835 series of standards relating to other devices used for inhalational anaesthesia.

Throughout this Technical Specification, text for which a rationale is provided in Annex C is indicated by an asterisk (*).

Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment

1 Scope

This Technical Specification specifies safety and performance requirements for draw-over vaporizers and associated equipment to provide draw-over anaesthetic systems for patients weighing greater than 15 kg using both non-flammable and, in places where regulations permit their use, flammable anaesthetic agents.

No requirements for monitoring the equipment are given in this Technical Specification.

2 Normative references

The following referenced documents are indispensable for the application 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 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, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 8835-2:1999, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems for adults*

ISO 8835-4:2004, *Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices*

IEC 60601-1:1988 + A1:1991 + A2:1995 and corrigendum 1995 mod, *Medical electrical equipment — Part 1: General requirements for safety*

IEC/SC62A/389/CDV; 2002, *Medical electrical equipment — Part 1: General requirements for safety and performance (revision of IEC 60601-1:1988)*

EN 13544-2, *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 and the following apply.