FINAL
DRAFT

AMENDMENT

ISO 5360:1993 FDAM 1

ISO/TC **121**/SC **1**

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Anaesthetic vaporizers — Agent-specific filling systems

AMENDMENT 1

Évaporateurs d'anesthésie — Systèmes de remplissage spécifiques à l'agent

AMENDEMENT 1

Reference number
ISO 5360:1993/FDAM 1:2005(E)

Foreword

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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.

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.

Amendment 1 to ISO 5360:1993 (including Technical Corrigendum 1:1998) was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*, and introduces additional requirements for information to be supplied by the manufacturer and additional labelling requirements.

Anaesthetic vaporizers — Agent-specific filling systems

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Page 14, Clause 12

Replace Clause 12 with the following:

12 Information provided by the manufacturer

12.1 Marking

Agent-specific filling systems or bottle collars or bottle adaptors supplied individually shall be marked with

a) the manufacturer's name and/or trademark,

b) the batch code, or the serial number, and

c) the name of the anaesthetic agent with which it is intended to be used.

The use of the generic names of anaesthetic agents according to Table 2 is recommended.

12.2 Labelling

12.2.1 Agent-specific filling systems or components supplied individually shall provide the following information on the device itself or on the unit pack or on a leaflet accompanying the device:

a) the name and address of the manufacturer/supplier;

b) the information necessary to identify the device or the contents of the package;

c) the anaesthetic agent with which the device is to be used;

d) if appropriate, an indication of the time limit for using the device safely, expressed as year/month;

e) an indication if the device is for single use only;

f) any relevant particular storage and/or handling requirements.

12.2.2 The bottle adaptor package shall have a leaflet enclosed with the device giving statements to the following effect:

CAUTION — Agent-specific filling cannot be assured when bottles without collars are used.

CAUTION — Any handling of anaesthetic agent during filling, emptying or disposal should be carried out so that leakage of agent to the atmosphere is minimized. High concentrations of anaesthetic agent in the working area may cause a health risk to the operator.

12.3 Instructions for use

Instructions for use of the agent-specific filling systems shall include:

a) the details referred to in 12.2.1 with the exception of those in points c) and d);

b) the warning given in 12.2.2;

c) the information necessary to ensure that the agent-specific filling system is in safe and correct working order;

d) if appropriate, details on the nature and frequency of maintenance operations to ensure safe and correct operation at all times;

e) a statement indicating compliance of the agent-specific filling system with this International Standard.

ICS 11.040.10

Price based on 2 pages