

Tuimasti- ja hingamisseadmed. Soojus- ja niiskusvahetid (HME'd) niisutavatele respireeritud gaasidele inimestes. Osa 1: HME-d kasutamiseks minimaalselt 250 ml hingamismahuga

Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 9360-1:2000 sisaldab Euroopa standardi EN ISO 9360-1:2000 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 12.09.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 9360-1:2000 consists of the English text of the European standard EN ISO 9360-1:2000.</p> <p>This document is endorsed on 12.09.2000 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p>Käsitlusala:</p> <p>This Standard specifies certain safety requirements for HMEs, including those incorporating breathing system filters, intended for the humidification of respired gases for use with patients with a tidal volume equal to or greater than 250 ml, and describes test methods for their evaluation.</p>	<p>Scope:</p> <p>This Standard specifies certain safety requirements for HMEs, including those incorporating breathing system filters, intended for the humidification of respired gases for use with patients with a tidal volume equal to or greater than 250 ml, and describes test methods for their evaluation.</p>
---	---

ICS 11.040

Võtmesõnad:

English version

Anaesthetic and respiratory equipment
Heat and moisture exchangers (HMEs) for humidifying
respired gases in humans
Part 1: HMEs for use with minimum tidal volumes of 250 ml
(ISO 9360-1 : 2000)

Matériel d'anesthésie et de réanimation respiratoire – Echangeurs de chaleur et d'humidité (ECH) utilisés pour humidifier les gaz respirés par les êtres humains – Partie 1: ECH pour utilisation avec des volumes courants d'au moins 250 ml (ISO 9360-1 : 2000)

Anästhesie- und Beatmungsgeräte – Wärme- und Feuchtigkeitsaustauscher zur Anfeuchtung von Atemgasen beim Menschen – Teil 1: Wärme- und Feuchtigkeitsaustauscher zur Verwendung bei Mindesthubvolumina von 250 ml (ISO 9360-1 : 2000)

This European Standard was approved by CEN on 2000-03-15.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

International Standard

ISO 9360-1 : 2000 Anaesthetic and respiratory equipment – Heat and moisture exchangers (HMEs) for humidifying respired gases in humans – Part 1: HMEs for use with minimum tidal volumes of 250 ml,

which was prepared by ISO/TC 121 'Anaesthetic and respiratory equipment' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 215 'Respiratory and anaesthetic equipment' as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by September 2000 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 9360-1 : 2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

Contents

	Page
Foreword.....	3
Introduction	3
1 Scope	4
2 Normative references	4
3 Terms and definitions	4
4 Symbols and abbreviated terms	5
5 General requirements and recommendations	5
5.1 HME patient port connector.....	5
5.2 Additional ports	5
5.3 Packaging of sterile HME.....	6
6 Test methods.....	6
6.1 General.....	6
6.2 Measurement of moisture loss.....	6
6.3 Measurement of pressure drop	16
6.4 Test for gas leakage	16
6.5 Test for compliance	16
7 Marking	18
Annex A (informative) Lists of parts and specifications in Figures 1 and 2	20
Annex B (informative) Rationale	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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 part of ISO 9360 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9360-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This first edition of ISO 9360-1 cancels and replaces, in part, the first edition of ISO 9360 (ISO 9360:1992), which has been technically revised.

ISO 9360 consists of the following parts, under the general title *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans*:

- *Part 1: HMEs for use with minimum tidal volumes of 250 ml*
- *Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

Annexes A and B of this part of ISO 9360 are for information only.

Introduction

The gases generally available for medical use lack sufficient moisture to be physiologically acceptable to the respiratory tract of patients. Heat and moisture exchangers are used to raise the water content and the temperature of the gas delivered to the respiratory tract. They are primarily intended for use independently or as part of a breathing system.

1 Scope

This part of ISO 9360 specifies certain requirements for heat and moisture exchangers (HMEs), including those incorporating breathing system filters, intended for the humidification of respired gases for use primarily with patients with a tidal volume equal to or greater than 250 ml, and incorporating at least one machine port, and describes test methods for their evaluation.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 9360. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 9360 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 4135: 1995, *Anaesthesiology — Vocabulary*.

ISO 5356-1:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5356-2:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*.

ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis*.

ISO 11607, *Packaging for terminally sterilized medical devices*.

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

3 Terms and definitions

For the purposes of this part of ISO 9360, the terms and definitions given in ISO 4135 and the following apply.

3.1

heat and moisture exchanger

HME

device intended to retain a portion of the patient's expired moisture and heat, and return it to the respiratory tract during inspiration