

Tuimasti- ja hingamisseadmed. Soojus- ja niiskusvahetid (HME'd) niisutavatele respireeritud gaasidele inimestes. Osa 2: Minimaalselt 250 ml hingamismahuga HME-d kasutamiseks trahhetoomiapatsientidel

Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 9360-2:2003 sisaldab Euroopa standardi EN ISO 9360-2:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 19.03.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 9360-2:2003 consists of the English text of the European standard EN ISO 9360-2:2002. This document is endorsed on 19.03.2003 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.
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Käsitlusala: This part of ISO 9360 is based on ISO 9360-1:2000 and specifies certain requirements and test methods for heat and moisture exchangers (HMEs) without machine connector ports, including those incorporating breathing system filters	Scope: This part of ISO 9360 is based on ISO 9360-1:2000 and specifies certain requirements and test methods for heat and moisture exchangers (HMEs) without machine connector ports, including those incorporating breathing system filters
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ICS 11.040.10

Võtmesõnad: anaesthesiology, breathing equipment, definition, definitions, determination of moisture, documentations, exchangers, heat exchangers, inhaled air, marking, medical equipment, moisture control, mould growth tests, people, testing, tracheotomy, wetting, volume

English version

Anaesthetic and respiratory equipment – Heat and moisture exchangers (HMEs) for humidifying respired gases in humans

**Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml
(ISO 9360-2 : 2001)**

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 2: ECH pour utilisation avec des patients trachéotomisés ayant des volumes courants d'au moins 250 ml (ISO 9360-2 : 2001)

Anästhesie- und Beatmungsgeräte – Wärme- und Feuchtigkeitsaustauscher zur Anfeuchtung von Atemgasen beim Menschen – Teil 2: Wärme- und Feuchtigkeitsaustauscher zur Verwendung bei tracheostomierten Patienten mit Mindesthubvolumina von 250 ml (ISO 9360-2 : 2001)

This European Standard was approved by CEN on 2002-09-23.

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 Management Centre 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 Management Centre has the same status as the official versions.

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CEN

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

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Foreword

International Standard

ISO 9360-2 : 2001 Anaesthetic and respiratory equipment – Heat and moisture exchangers (HMEs) for humidifying respired gases in humans – Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2 : 2001),

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 May 2003 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, Malta, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 9360-2 : 2001 was approved by CEN as a European Standard without any modification.

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

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1 Scope

This part of ISO 9360 is based on ISO 9360-1:2000 and specifies certain requirements and test methods for heat and moisture exchangers (HMEs) without machine connector ports, including those incorporating breathing system filters. These devices are intended for the humidification of respired gases for tracheostomized patients having a tidal volume of 250 ml or greater.

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, *Anaesthetic and respiratory equipment — Vocabulary.*

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

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

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.*

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

3 Terms and definitions

For the purposes of this part of ISO 9360, the terms and definitions given in ISO 4135 and ISO 9360-1 apply, except as follows.

3.1 (R)

HME internal volume

volume contained within the HME, when not pressurized, consisting of the internal surface of the impermeable material of the HME and a hypothetical boundary surface which consists of the minimum surface area which encloses the active element of the HME, minus the volume of all solid elements within the HME, minus the volume inside all the female connectors