

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 9360-2:2009 sisaldab Euroopa standardi EN ISO 9360-2:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 29.05.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

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Standard on kättesaadav Eesti standardiorganisatsioonist.

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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 - Échangeurs 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 28 March 2009.

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Foreword

The text of ISO 9360-2:2001 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 9360-2:2009 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 9360-2:2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 9360-2:2001 has been approved by CEN as a EN ISO 9360-2:2009 without any modification.

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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

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.*