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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)

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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)

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

Ta slovenski standard je istoveten z: EN ISO 9360-1:2000

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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SIST EN ISO 9360-1:2000 en

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ICS 11.040.00

English version

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This European Standard was approved by CEN on 15 March 2000.

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This European Standard exists 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Foreword

The text of the International Standard ISO 9360-1:2000 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 September 2000, and conflicting national standards shall be withdrawn at the latest by September 2000.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZB, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, 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 Standards are listed in annex ZA (normative).

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Annex ZA (normative)
**Normative references to international publications
with their relevant European publications**

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 4135	1995	Anaesthesiology - Vocabulary	EN ISO 4135	1996

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Annex ZB (informative)

Clauses of this European Standard addressing essential requirements and other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support essential requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA requirements.

Table ZB.1 - Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
4	13.2	
5.1	9.1, 13.6 c)	
5.2	9.1, 13.6 c)	
5.3	8.3	
7.1 a)	9.1, 13.2, 13.3 k), 13.6 c)	
7.1 b)	9.1, 13.2, 13.3 j)	
7.2	13.1	
7.2 a)	13.3 a)	
7.2 b)	13.3 b)	
7.2 c)	8.7, 13.3 c)	
7.2 d)	13.3 i)	
7.2 e)	13.3 l)	
7.2 f)	13.3 e)	
7.3	13.3 f)	
7.4	13.1	
7.4 a)	13.1, 13.6 a), 13.6 b)	
7.4 b)	9.1, 13.3 j)	
7.4 d)	13.6 b)	
7.4 f)	13.6 b)	
7.4 g)	13.6 b)	
7.4 h)	13.3 j), 13.3 k)	
7.4 i)	13.3 m), 13.6 h)	
7.4 j)	13.3 j), 13.3 k)	
7.4 k)	13.6 n)	

**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**

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*Matériel d'anesthésie et de réanimation respiratoire — Échangeurs de
chaleur et d'humidité (ECH) utilisés pour humidifier les gaz respirés par
les êtres humains*

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**Partie 1: ECH pour utilisation avec des volumes courants d'au moins
250 ml**



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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.

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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*:

SIST EN ISO 9360-1:2000

- 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

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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.

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