



MALAYSIAN STANDARD

MS ISO 9360-1:2008

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, IDT)

ISO 9360-1:2000 is endorsed as Malaysian Standard with the reference number MS ISO 9360-1:2008.

ICS: 11.040.10

Descriptors: anaesthetic, respiratory equipment, heat and moisture exchangers, humidifying, respired gases, HMEs

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Century Square, Level 1 & 2
Block 2300, Jalan Usahawan
63000 Cyberjaya, Selangor
MALAYSIA

Tel: 60 3 8318 0002
Fax: 60 3 8318 1455

<http://www.standardsmalaysia.gov.my>

E-mail: central@standardsmalaysia.gov.my

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1, Persiaran Dato' Menteri
P.O. Box 7035, Section 2
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Committee representation

The Medical Devices and Facilities for Healthcare Industry Standards Committee (ISC R) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Association of Malaysian Medical Industries
Association of Private Hospitals of Malaysia
Biomedical Engineering Association Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Jabatan Standard Malaysia
Lembaga Perlesenan Tenaga Atom
Malaysian Association of Standards Users
Malaysian Medical Association
Malaysian Medical Devices Association
Malaysian Nuclear Agency
Malaysian Organization of Pharmaceutical Industry
Malaysian Rubber Board
Malaysian Rubber Export Promotion Council
Ministry of Health Malaysia
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Universiti Kebangsaan Malaysia (Faculty of Allied Health Sciences)
Universiti Teknologi Malaysia (Faculty of Science)

The Technical Committee on Anaesthetic/Respiratory and Electromechanical Devices which recommends adoption of the ISO Standard consists of representatives from the following organisations:

Academy of Medicine of Malaysia (College of Anaesthesiologists)
Association of Private Hospitals of Malaysia
Biomedical Engineers Association of Malaysia
Malaysian Medical Association
Malaysian Medical Devices Association
Ministry of Health Malaysia (Mechanical Engineering Section)
Ministry of Health Malaysia (Medical Device Bureau)
SIRIM Berhad (Secretariat)
Universiti Malaya (Biomedical Engineering Department)
Universiti Teknologi Malaysia (Faculty of Science)
Universiti Teknologi MARA (Electrical Engineering Faculty)

MS ISO 9360-1:2008

NATIONAL FOREWORD

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Technical Committee on Anaesthetic/Respiratory and Electromechanical Devices under the authority of the Medical Devices Industry Standards Committee.

This Malaysian Standard is identical with 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*, published by the International Organization for Standardization (ISO). However, for the purposes of this Malaysian Standard, the following apply:

- a) in the source text, "this International Standard" should read "this Malaysian Standard";
- b) the comma which is used as a decimal sign (if any), to read as a point; and
- c) references to International Standards should be replaced by equivalent Malaysian Standards as follows:

<u>Referenced International Standards</u>	<u>Corresponding Malaysian Standards</u>
ISO 4135: 1995, <i>Anaesthesiology - Vocabulary</i>	MS ISO 4135: 2006, <i>Anaesthesiology - Vocabulary</i>
ISO 5356-1:1996, <i>Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets</i>	MS ISO 5356-1:2007, <i>Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets</i>
ISO 5356-2:1987, <i>Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weightbearing connectors</i>	MS ISO 5356-2:2007, <i>Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weightbearing connectors</i>
IEC 60601-1:1988, <i>Medical electrical equipment - Part 1: General requirements for safety</i>	MS IEC 60601-1-8:2006, <i>Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems</i>

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.

**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**

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



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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

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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.

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.