

INTERNATIONAL STANDARD

ISO
9360

First edition
1992-10-01

Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans

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



Reference number
ISO 9360:1992(E)
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Contents

	Page
1 Scope	1
2 Normative references	1
3 Definitions	1
4 Symbols and abbreviations	2
5 General requirements and recommendations	2
5.1 Patient port connector	2
5.2 Gas leakage	2
5.3 Pressure drop	2
5.4 Packaging	2
6 Test methods	2
6.1 Temperatures and pressures (see also annex A)	3
6.2 Test gas and apparatus	3
6.3 Measurement of HME moisture output	4
6.4 Calculations	6
6.5 Measurement of compressible volume	6
6.6 Measurement of gas leakage	7
6.7 Measurement of pressure drop	7
7 Marking	7
8 Information to be provided by manufacturer or supplier	7
 Annex	
A Rationale statement	9

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.

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.

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

Annex A of this International Standard is for information only.

Introduction

Heat and moisture exchangers (HMEs) are used to raise the water content and the temperature of gas delivered to the respiratory tract of patients. They are primarily intended for use with tracheotomized or intubated patients, independently or as a part of a breathing system.

The gases generally available for medical use lack sufficient moisture to be physiologically acceptable to the respiratory tract. HMEs capture the exhaled heat and moisture and transfer them to the inspired gases.

Although heat and moisture exchangers have been used for many years, the introduction of HMEs utilizing primarily non-metallic components and hygroscopic additives or hydrophobic material have prompted the development of this International Standard.

Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans

1 Scope

This International Standard specifies minimum performance and safety requirements for heat and moisture exchangers (HMEs) intended for humidification of respired gases in humans, and describes test methods for their evaluation.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 4135:1979, *Anaesthesiology — Vocabulary*.

ISO 5356-1:1987, *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*.

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 4135 and the following definitions apply.

3.1 identification mark; identification number: Symbols, numbers or lettering marked on a device from which the manufacturer/user derives information concerning its production (such as material batch or date of manufacture).

3.2 HME: Device intended to retain a portion of the expired moisture and heat, and return it to the patient's respiratory tract during inspiration.

3.3 HME patient port: That port of the HME which is connected to the patient's respiratory tract.

3.4 HME machine; atmospheric end port: That port of the HME which is connected to the patient connection port of a breathing system or is open to ambient air.

3.5 HME moisture output: Total amount of water, in milligrams per litre, of inspired gas leaving the HME patient port, under specified test conditions.