
**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* 2000

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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.

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.

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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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

1 Scope

This part of ISO 9360 specifies certain requirements for heat and moisture exchangers (HMEs), including those incorporating breathing system filters, intended for the humidification of respired gases for use primarily with patients with a tidal volume equal to or greater than 250 ml, and incorporating at least one machine port, and describes test methods for their evaluation.

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: 1995, *Anaesthesiology — Vocabulary*.

ISO 5356-1:1996, *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*.

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

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

3 Terms and definitions

For the purposes of this part of ISO 9360, the terms and definitions given in ISO 4135 and the following apply.

3.1

heat and moisture exchanger

HME

device intended to retain a portion of the patient's expired moisture and heat, and return it to the respiratory tract during inspiration

3.2

HME machine port

that port of the HME which is connected to the patient connection port of a breathing system

3.3

HME patient port

that port of the HME which is connected to the patient's respiratory tract

3.4

HME accessory port

that port of the HME which can be connected to an accessory device

EXAMPLE An accessory device may be e.g. a gas sampling line.

3.5

HME internal volume

volume contained within the HME, when unpressurized, minus the volume of all solid elements within the HME, minus the volume inside all female connectors

3.6

HME moisture loss

total amount of water lost from the test apparatus when tested as specified in 6.2

NOTE It is expressed in milligrams water per litre of air.

3.7

pressure drop

difference between the pressure measured in a gas stream flowing into a device and the pressure measured in the gas stream flowing out of the device, with a given continuous gas flowrate through the device

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4 Symbols and abbreviated terms

The principal symbols and abbreviations used in this part of ISO 9360 are given in Table 1. Other symbols and abbreviations are explained in the relevant context.

Table 1 — Symbols and abbreviations

Symbol	Term	Unit
V_T	Tidal volume	ml
f	Frequency	min ⁻¹
I:E ratio	Inspiratory:expiratory ratio	—
RH	Relative humidity	%

5 General requirements and recommendations

5.1 HME patient port connector

The connector at the patient port shall be either a 15 mm female conical connector or a 15 mm female/22 mm male coaxial connector complying with ISO 5356-1.

5.2 Additional ports

The connectors at other ports intended to accept breathing attachments, for example a Y-piece, if present, shall be 15 mm male and/or 22 mm conical connectors as specified in ISO 5356-1.

If the HME incorporates an accessory port, that port shall not accept the 15 mm or 22 mm connectors specified in ISO 5356-1 or ISO 5356-2.

5.3 Packaging of sterile HME

HME supplied sterile shall comply with the requirements specified in ISO 11607.

6 Test methods

6.1 General

The apparatus and test methods specified in 6.2 to 6.5 are not intended to exclude the use of other measuring devices or methods yielding results of an accuracy equal to or greater than those specified. In the case of a dispute, the methods given in this part of ISO 9360 shall be the reference methods.

The tests shall be performed at a temperature of $23\text{ °C} \pm 2\text{ °C}$, a RH of $50\% \pm 20\%$, and an atmospheric pressure of 86 kPa to 106 kPa.

6.2 Measurement of moisture loss

6.2.1 Principle

The performance of an HME shall be measured by recording the mass of water lost from the test apparatus specified in 6.2.2.

6.2.2 Test apparatus

The test apparatus (Figure 1) shall comprise the following components.

6.2.2.1 Bidirectional flow generator.

This is a mechanically-driven piston used to produce a flow having sinusoidal waveform.

6.2.2.2 Humidity generator (HG), consisting of

- a) a heated water bath (Figure 2) through which air is bubbled in both directions;
- b) a rigid cylindrical reservoir (Figure 3) with a maximum volume of 7 l and a diameter of approximately 150 mm, containing a 2 l reservoir bag;
- c) a thermally insulated chamber (Figure 4), which contains the water bath, the reservoir and a heat source.

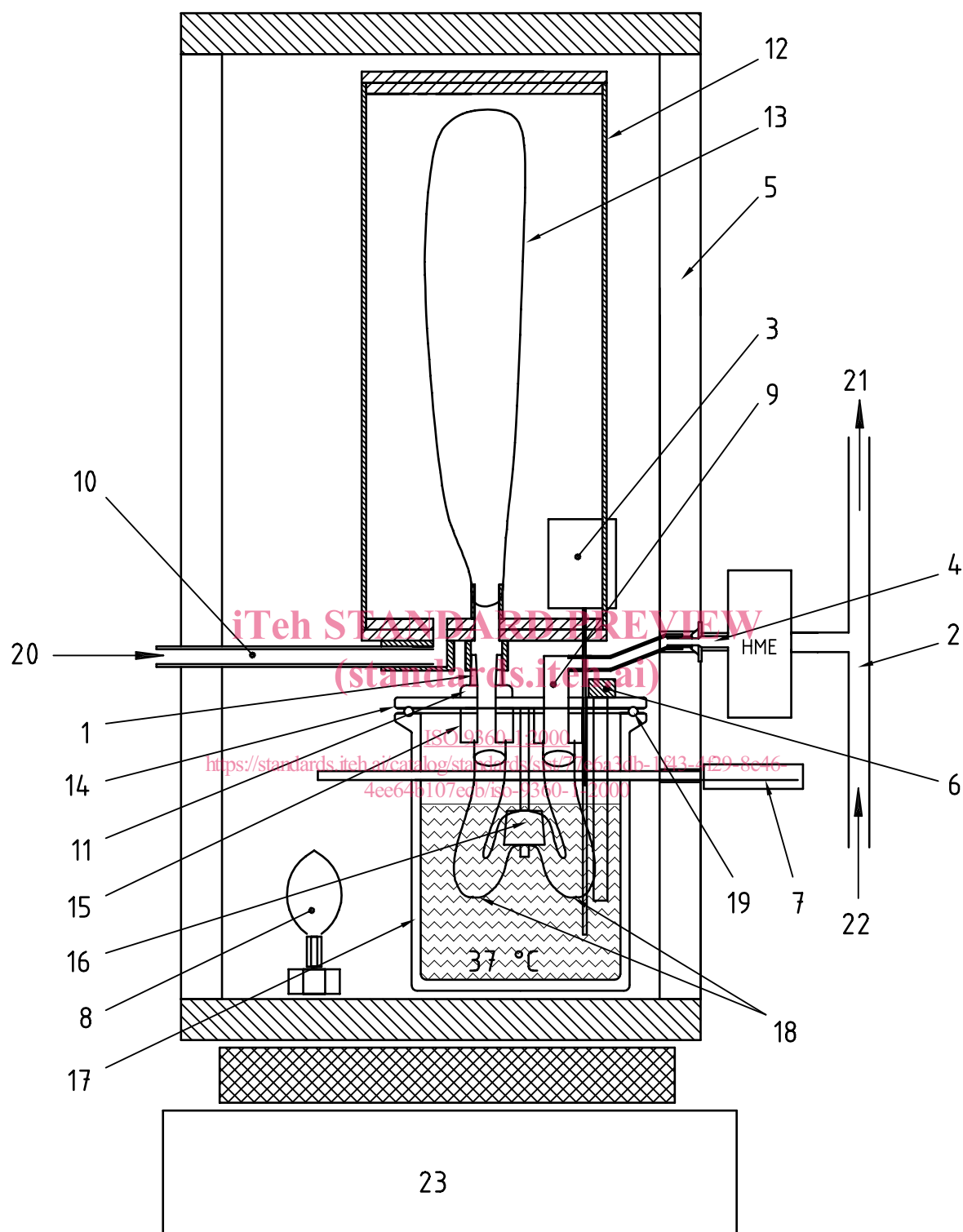
6.2.2.3 Air delivery system (Figure 5), consisting of a T-piece with an internal diameter greater than 15 mm, and an exhaust tube at least 200 mm in length.

6.2.2.4 Weighing equipment, with an accuracy of $\pm 0,1\text{ g}$ or better in the range of the mass to be measured.

6.2.2.5 Flowrate measuring equipment, with an accuracy of at least 5 % of the reading.

6.2.2.6 Calibration HME (Figure 6) consisting of a housing containing 81 polyvinyl chloride (PVC) tubes arranged in a 9×9 array, each with an internal diameter of 2 mm, an external diameter of 4 mm, and a length of 50 mm.

When the apparatus has been constructed and operated as specified in 6.2.2, the moisture loss from the humidity generator with the calibration HME will be as shown in Table 3.

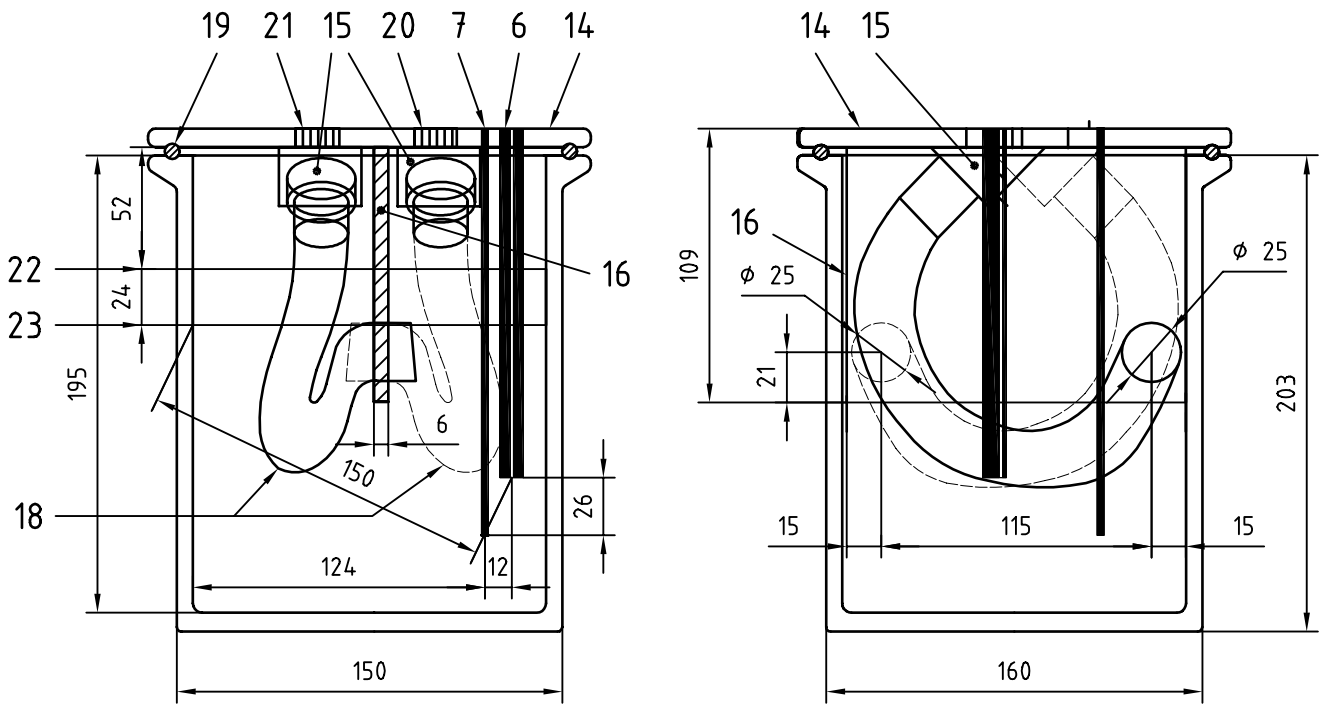


Key

- 1 to 19 see annex A
- 20 Sinewave generator inlet
- 21 Air outlet
- 22 Dry air supply (23 ± 1) °C, < 1 mg H₂O per litre air
- 23 Weighing equipment

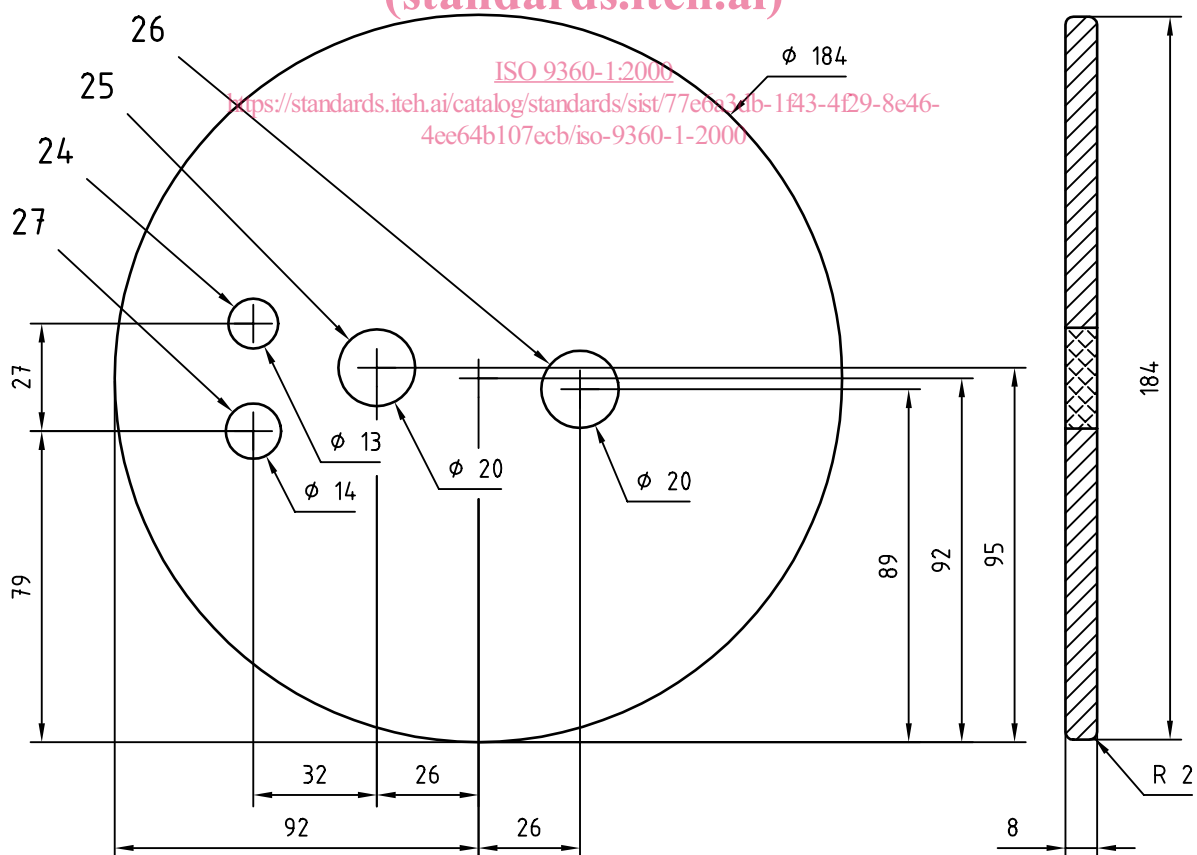
Figure 1 — Test apparatus side view

Dimensions in millimetres



2 a) Heated water bath — Front view

2 b) Heated water bath — Side view



2 c) Cover of heated water bath