
**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**

*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*



Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

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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 9360-2 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 9360-2 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*

Annex A of this part of ISO 9360 is for information only.

Clauses and subclauses to which there is a rationale are marked with (R). These rationales are found in annex A.

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*.

3 Terms and definitions

For the purposes of this part of ISO 9360, the terms and definitions given in ISO 4135 and ISO 9360-1 apply, except as follows.

3.1 (R)

HME internal volume

volume contained within the HME, when not pressurized, consisting of the internal surface of the impermeable material of the HME and a hypothetical boundary surface which consists of the minimum surface area which encloses the active element of the HME, minus the volume of all solid elements within the HME, minus the volume inside all the female connectors

4 Symbols and abbreviated terms

The symbols and abbreviated terms given in ISO 9360-1 apply.

5 General requirements and recommendations

5.1 (R) HME patient port connector

The patient port connector shall mate with a 15 mm male 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 relative humidity of $50\% \pm 20\%$, and an atmospheric pressure of 86 kPa to 106 kPa.

6.2 (R) 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 (see Figure 1 in ISO 9360-1:2000) 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 (see Figure 2 in ISO 9360-1:2000) through which air is bubbled in both directions;
- b) a rigid cylindrical reservoir (see Figure 3 in ISO 9360-1:2000) 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 (see Figure 4 in ISO 9360-1:2000), which contains the water bath, the reservoir and a heat source.

6.2.2.3 Air delivery system, to supply dry air that is directed into the chamber (see Figure 1 of this part of ISO 9360).

6.2.2.4 Test chamber (see Figure 1 of this part of ISO 9360) which allows the delivery of dry air to the HME.

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

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

6.2.2.7 Calibration HME (see Figure 6 in ISO 9360-1:2000) 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 of ISO 9360-1:2000.

6.2.3 Test conditions

6.2.3.1 The air delivered to the test chamber by the air delivery system shall be at a temperature of $23\text{ °C} \pm 1\text{ °C}$ and shall have humidity not exceeding 1 g/m^3 .

6.2.3.2 The HME shall be tested at those conditions specified in Table 2 of ISO 9360-1:2000 which are within the range specified for the HME by the manufacturer, at the maximum tidal volume recommended by the manufacturer if this value is greater than 1 l, at a frequency of $10\text{ breaths min}^{-1}$, and at an I:E ratio of 1:1.

6.2.3.3 For HME that can be used to provide supplemental oxygen, the test specified in 6.2.3.2 shall be repeated with the maximum oxygen flowrate recommended by the manufacturer, or 10 l/min if a maximum flowrate is not recommended.

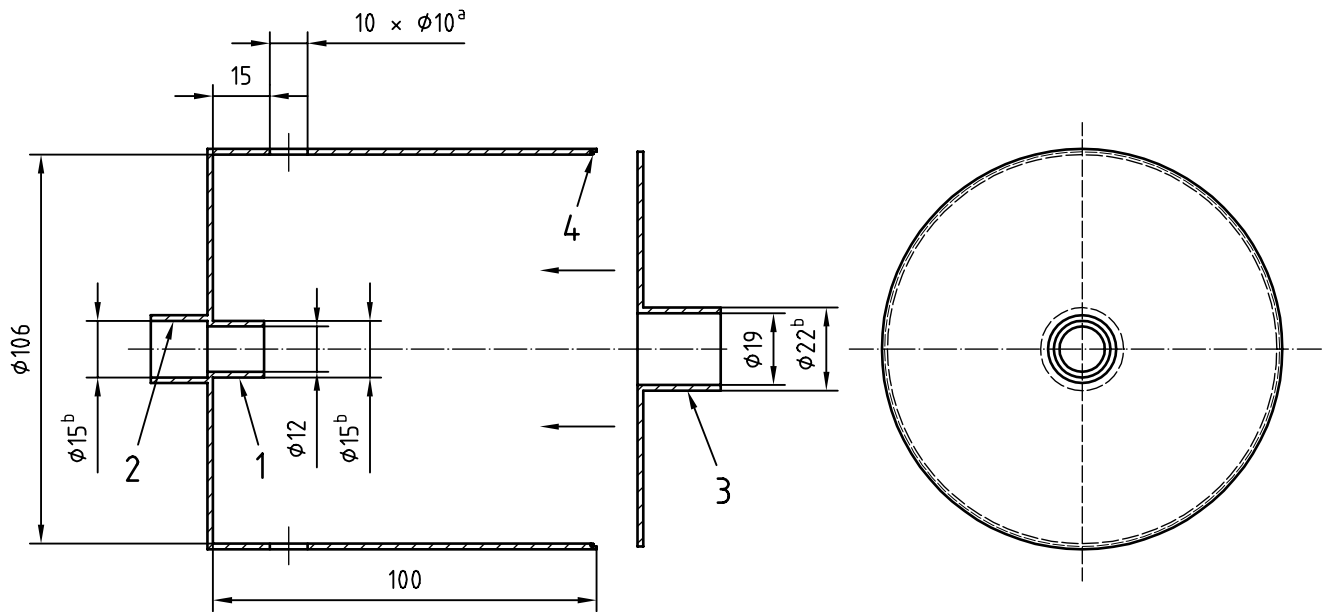
6.2.4 Procedure

6.2.4.1 Connect the HG to the bidirectional flow generator.

6.2.4.2 Adjust the bidirectional flow generator to give one of the test conditions in Table 2 of ISO 9360-1:2000, measured at the HME connector of the test apparatus, within the operating range of the HME as specified by the manufacturer. Adjust the flowrate of air delivered by the air delivery system to be between 1 and 1,5 times the peak flowrate of air drawn into HME connector of the test apparatus. The peak flowrate is stated in Table 2 of ISO 9360-1:2000.

6.2.4.3 Operate the test apparatus with an HME of the same type that is to be tested, placed within the test chamber, for a minimum of 1 h, with the water bath at a temperature of $37\text{ °C} \pm 0,5\text{ °C}$, and the air within the insulated chamber at temperature of $37\text{ °C} \pm 1\text{ °C}$. Maintain this temperature for the duration of the test procedure.

6.2.4.4 With the HME and test chamber connected to the test apparatus, confirm that the volume of air leaving the HME connector is that required for the test condition chosen from Table 2 of ISO 9360-1:2000.



Key

- 1 HME connector, 15 mm male conical (ISO 5356)
- 2 Test apparatus connector, 15 mm female conical (ISO 5356)
- 3 Air delivery system connector, 22 mm male conical (ISO 5356)
- 4 O-ring

- a Vent holes equally spaced around the periphery of the container.
- b In accordance with ISO 5356.

Figure 1 — Test chamber

- 6.2.4.5** Record the mass of the humidity generator (HG) only (i.e. not including the HME and test chamber) (m_0).
- 6.2.4.6** Replace the HME with the one to be tested and operate the test apparatus for (60 ± 5) min.
- 6.2.4.7** Record the mass of the HG only (i.e. not including the HME and test chamber) (m_1).
- 6.2.4.8** Continue to operate the test apparatus up to the maximum time of use recommended by the manufacturer.
- 6.2.4.9** Record the mass of the HG only (i.e. not including the HME and test chamber) (m_2).
- 6.2.4.10** With the HME and test chamber connected to the test apparatus, confirm that the volume of air leaving the HME connector is that required for the test condition chosen from Table 2 of ISO 9360-1:2000.
- 6.2.4.11** Calculate the HME moisture loss for the first hour, M_1 , using the formula

$$M_1 = (m_0 - m_1) / V_1$$

where

- m_0 is the initial mass of the HG;
- m_1 is the mass of the HG after 1 h;
- V_1 is the total volume of air leaving the HME connector during the first hour of the test.

6.2.4.12 Calculate the HME moisture loss for the entire duration, M_{\max} , using the formula

$$M_{\max} = (m_0 - m_2) / V_2$$

where

m_0 is the initial mass of the HG;

m_2 is the mass of the HG after the maximum time of use as recommended by the manufacturer;

V_2 is the total volume of air leaving the HME connector during the entire test period.

6.2.4.13 Repeat the procedures in 6.2.4.2 to 6.2.4.12 for all the test conditions given in Table 2 of ISO 9360-1:2000 which are within the operating range of the HME as specified by the manufacturer.

When the apparatus has been constructed and operated as specified in 6.2.4, the moisture loss from the humidity generator with the calibration HME attached should be as shown in Table 3 of ISO 9360-1:2000. This shall be confirmed for the specific test apparatus by conditioning the test apparatus for at least 2 h (see 6.2.4.3), and then operating the test apparatus for a period of 2 h with the calibration HME, and measuring the mass loss over that period (all mass measurements shall be made without the HME attached to the test apparatus).

6.3 Measurement of pressure drop

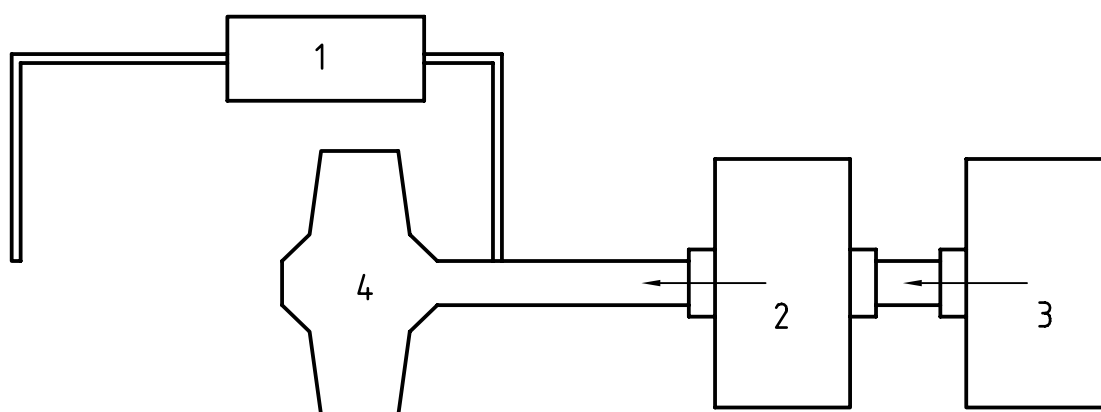
6.3.1 Using the apparatus shown in Figure 2 below, connect the differential pressure gauge across the HME and connect the flow meter.

6.3.2 Determine the pressure drop at the flowrates specified in Table 4 of ISO 9360-1:2000, within 5 s of initiating flow through the HME, using dry medical air or oxygen. The temperature of the gas shall be $23\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$.

6.3.3 Remove the HME, reconnect the flow generator to the flow meter, and determine the pressure drop at the same flowrate. Subtract this value from that obtained in 6.3.2. This is the pressure drop attributable to the HME.

6.3.4 Repeat steps 6.3.1 through 6.3.3 after preconditioning the HME with the test apparatus specified in 6.2.1 for the recommended maximum time of use at the conditions appropriate for the intended application of the device as specified in Table 2 of ISO 9360-1:2000.

For recording purposes, the use of an electronic measuring device is recommended.



Key

- 1 Differential pressure gauge
- 2 Flow meter
- 3 Flow generator
- 4 HME

Figure 2 — Arrangement of apparatus to measure pressure drop

7 Marking, labelling and packaging

7.1 The HME shall be marked with:

- a) the direction of orientation towards the patient in the case of orientation-sensitive HME;
- b) the letters APG (explained in IEC 60601-1) if the manufacturer states that the HME is safe for use with flammable anaesthetics.

7.2 The HME package shall be marked with:

- a) the trade mark or trade name of the manufacturer;
- b) the intended use of the HME;
- c) the word "STERILE" (or the equivalent), if applicable;
- d) storage instructions;
- e) date of manufacture;
- f) expiry date, if the HME is sensitive to storage or shelf-life.

7.3 For HMEs intended for single use, the HME or the package shall be marked either with the words "SINGLE USE" (or the equivalent) or with symbol No. 1051 of ISO 7000.

7.4 The following information shall be provided by the manufacturer or supplier:

- a) instructions for use of the HME;
- b) the recommended range of tidal volumes;
- c) the moisture loss, in milligrams water per litre of air and expressed to the nearest milligram, at the test conditions given in Table 2 of ISO 9360-1:2000 which are within the operating range of the HME as specified by the manufacturer, and at the minimum and maximum tidal volumes recommended by the manufacturer, when tested in accordance with 6.2;
- d) the pressure drop at the flowrates in Table 4 of ISO 9360-1:2000, measured as specified in 6.3 before use and after use on the test system specified in 6.2.2 for the maximum time of use recommended by the manufacturer;
- e) the internal volume of the HME;
- f) if the HME or any of its parts are re-usable, instructions for the maintenance and cleaning, disinfection and/or sterilization;
- g) recommended maximum time of use for each unit before either disposal or cleaning;
- h) instructions for the safe disposal of the HME after use.

Annex A (informative)

Rationale

The subclause numbers below refer to the main body of this part of ISO 9360, and thus are not consecutive.

3.5 HME internal volume

The surface of some HME consists, in part, of the active element of the HME. This surface may be highly convoluted. It was considered that the internal volume of the HME includes, in this case, the air-filled spaces contained between these convolutions on the outside of the surface. The periphery of this type of HME was therefore defined to include the air in these spaces.

5.1 A connector which mates with a 15 mm male connector complying with ISO 5356-1 can be shorter in length than a 15 mm female connector complying with ISO 5356-1. A shorter length of connector, while perhaps conferring less resistance to disconnection, increases patient comfort and acceptability of the HME, especially as disconnection of this type of HME is not hazardous to a patient with a tracheostomy.

6.2 The absence of a machine connection port prevents the direct connection of the air delivery system. The HME is placed in a closed, but vented chamber (test chamber) which has three connectors:

- HME connector (item 1 in Figure 1);
- test apparatus connector (item 2 in Figure 1);
- air delivery system connector (item 3 in Figure 1).

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Price based on 7 pages

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