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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

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Contents

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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.

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.

4 Symbols and abbreviations

The principal symbols and abbreviations used in this International Standard are given in table 1. Additional symbols are explained in the relevant context.

5 General requirements and recommendations

5.1 Patient port connector

The connector at the patient port shall be a 15 mm female conical connector as specified in ISO 5356-1:1987.

The connector at the patient port may also have a 22 mm male conical connector as specified in ISO 5356-1:1987.

If the HME incorporates an accessory port, that port shall not accept the 15 mm or 22 mm connectors specified in ISO 5356-1:1987 or ISO 5356-2:1987.

Other ports intended to accept breathing attachments, if present, shall be 15 mm male and/or 22 mm female conical connectors as specified in ISO 5356-1:1987.

If the HME incorporates a gas-scavenging port, that port shall be either a 19 mm or 30 mm male conical connector as specified in ISO 5356-1:1987.

5.2 Gas leakage

When tested according to 6.6, the leakage from HMEs intended to be used at elevated intermittent or continuous pressures shall not exceed 25 ml/m at a pressure of 30 hPa (30 cm H_2O). (See also annex A.)

5.3 Pressure drop

When tested according to 6.7, the pressure drop across the HME shall not exceed 5 hPa (5 cm H_2O). (See also annex A.)

5.4 Packaging

5.4.1 HMEs supplied sterile and intended for single use shall be individually packaged.

5.4.2 The type of container used shall be such as to ensure that once opened, the container cannot be easily resealed, and that it shall be obvious that the container has been opened.

Each HME should be packed in a single container, the materials of which should not have detrimental effects on the contents. The material and design of this container should be such as to ensure

— minimal risk of contamination of the contents from opening and removal from the container;

— adequate protection of the contents during normal handling, transit and storage.

6 Test methods

The apparatus and test methods specified in 6.1 to 6.7.5 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 case of dispute, the methods given in this International Standard shall be the reference methods.

Table 1 — Symbols and abbreviations

Symbol	Definition	Unit
HME	Heat and moisture exchanger	
E_w	HME moisture output	mg/l
m_1	Initial mass of the patient model before testing with the HME	g or mg
m_2	Final mass of the patient model after testing with the HME	g or mg
m_3	Initial mass of the patient model before testing without the HME	g or mg
m_4	Final mass of the patient model after testing without the HME	g or mg
f	Frequency	
bpm	breaths per minute	
C	Compliance	ml/hPa
R	Resistance	hPa/l/s
I:E ratio	Inspiratory: expiratory ratio	
r.h.	Relative humidity	per cent
V_t	Tidal volume	ml

6.1 Temperatures and pressures (see also annex A)

6.1.1 The ambient temperatures (defined as temperature t_A in figure 1, zone 1) for the duration of the test shall be 23 °C ± 2 °C. Barometric pressure shall be stated, as shall the temperature at which the measurements were taken.

6.1.2 Temperature t_B in figure 1, zone 3, shall be high enough to eliminate condensation in rubber bags, valves and tubing.

A suggested temperature is 37 °C ± 3 °C.

6.1.3 The water-bath temperature, t_G, in figure 1 shall be regulated to give a maximum temperature t_F measured at the HME patient port of 34 °C ± 1 °C when averaged over 20 expirations.

6.1.4 The temperature in the inspiratory flow, t_H, in figure 1 shall be 23 °C ± 2 °C.

6.1.5 The response time for probes measuring t_A, t_B and t_H in figure 1 shall be 10 s or less for 50 % of the actual value. The response time in flowing air at points E and F shall be 0,1 s or less for 50% of the temperature cycle.

6.2 Test gas and apparatus

6.2.1 The test gas shall be air having a humidity not exceeding 0,88 mg/l, equivalent to a dew point of − 20 °C at atmospheric pressure.

6.2.2 Gas flow measuring equipment shall be calibrated to an accuracy of ± 5 % of the reading in the range 1 l/min to 100 l/min.

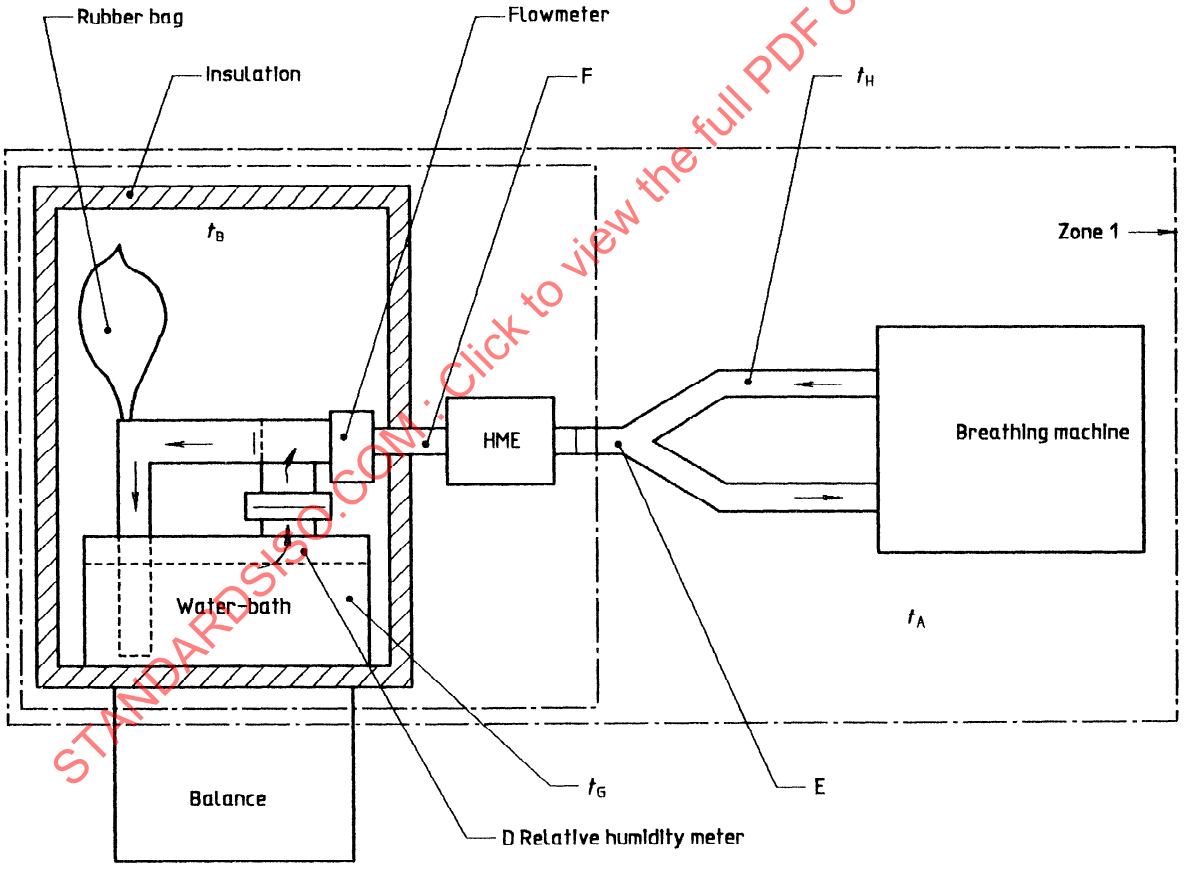

Figure 1 — Test set-up

6.2.3 Test apparatus consisting of a temperature-controlled water-bath with a means of providing compliance and resistance values as specified in table 2 shall be used (see figure 1). The inspiratory and expiratory flows shall be directed via one-way valves into separate pathways. Provision shall be made to measure the flow through the HME. Temperature probes shall be mounted at points A, B, E, F, G and H (where these letters refer also to subscripts of points at which temperature-measuring probes are inserted). The temperatures at these points shall be recorded. The temperature probe at point F shall be connected to a control system in order to regulate the water-bath temperature, t_G. Temperature probes at points E and F shall be mounted within 10 mm of the HME patient port. The length of tubing between the HME and the ventilator shall not exceed 1 m, and the length of tubing between the HME and the point of separation of the inspiratory and expiratory gas flow pathways shall not exceed 10 cm. The inspiratory and expiratory limbs shall be isolated by a uni-directional valve. A relative humidity probe shall be mounted at point D. A flowmeter shall be connected at point F. The capacity of the bag shall be greater than the tidal volumes given in table 2.

6.2.4 The HME shall be connected to the test apparatus and a ventilator.

For HMEs intended only for use during spontaneous breathing, a suitable adaptor with minimal dead space should be used.

6.2.5 The ventilator shall deliver the minute volumes at the frequencies shown in table 2. The flow profile of the ventilator during the measurements shall be stated in the test report.

NOTE 1 It is recognized that the flow profile may influence the efficiency of the HME; it is therefore assumed that the ventilator used in the test apparatus, as shown in figure 1, is capable of delivering as constant a flow as possible during inspiration.

6.2.6 The weighing equipment used shall have an accuracy of $\pm$ 0,1 g or better in the range of mass to be measured.

6.2.7 Pressure drop measuring equipment shall consist of a differential pressure gauge with an accuracy equal to or better than $\pm$ 10 kPa (0,1 cm H_2O) for the test as shown in figure 2.

6.3 Measurement of HME moisture output

6.3.1 Principle

The test apparatus, comprising the patient model and the HME under test, is connected to a flow generator, for example a ventilator. After it has operated for approximately 60 min, a steady state is achieved in the test system. During inspiration, the dry gas at ambient temperature passes through the HME, thereby absorbing accumulated heat and moisture. During expiration, the expired gas, which now is assumed to be saturated with water vapour, passes through the HME, in the reverse direction, so that heat and moisture are retained in the HME.

6.3.2 Procedure

6.3.2.1 Connect the HME to the patient model and the ventilator.

6.3.2.2 Record temperatures t_A, t_B and t_H.

6.3.2.3 Adjust the ventilator to give one of the test conditions in the combinations listed in table 2 within the HME's operating range as specified by the manufacturer.

6.3.2.4 Adjust the water-bath temperature to give a maximum temperature at point F of 34 °C $\pm$ 1 °C during expiration.

6.3.2.5 Verify that the relative humidity at point D is 100 % during the entire breathing cycle.

Care should be taken to choose a humidity-measuring instrument suitable for measurements in the region of 100 % r.h. at the test temperatures.

6.3.2.6 Verify that the humidity at point H is less than 0,88 mg/l (equivalent to a dew point of $-$ 20 °C).

6.3.2.7 Let the equipment run for 60 min $\pm$ 5 min to precondition the HME and stabilize the test system.

6.3.2.8 Disconnect the HME, seal the ports, and weigh the patient model.

6.3.2.9 Connect the HME and operate the test apparatus for 1 h. Record the temperatures at points E and F continuously.

NOTE 2 This temperature will vary, and typical variations are shown in figure 3.

6.3.2.10 Disconnect the HME such that any condensation that has occurred is retained *in situ* within the patient model and then weigh the patient model.

Table 2 — Test conditions

Intended for V_t of	Test conditions	V_t ml	f bpm	Minimum volume l/m	I:E ratio	C	R
> 500 ml	1 2 3	1 000 1 000 500	20 10 20	20 10 20	1:2 1:2 1:2	50 50 50	5 5 5
51 ml to 500 ml	1 2	500 250	20 20	10 5	1:2 1:2	50 10	5 20
< 50 ml	1 2	50 25	40 40	2 1	1:1 1:1	10 10	20 20

Dimensions in millimetres

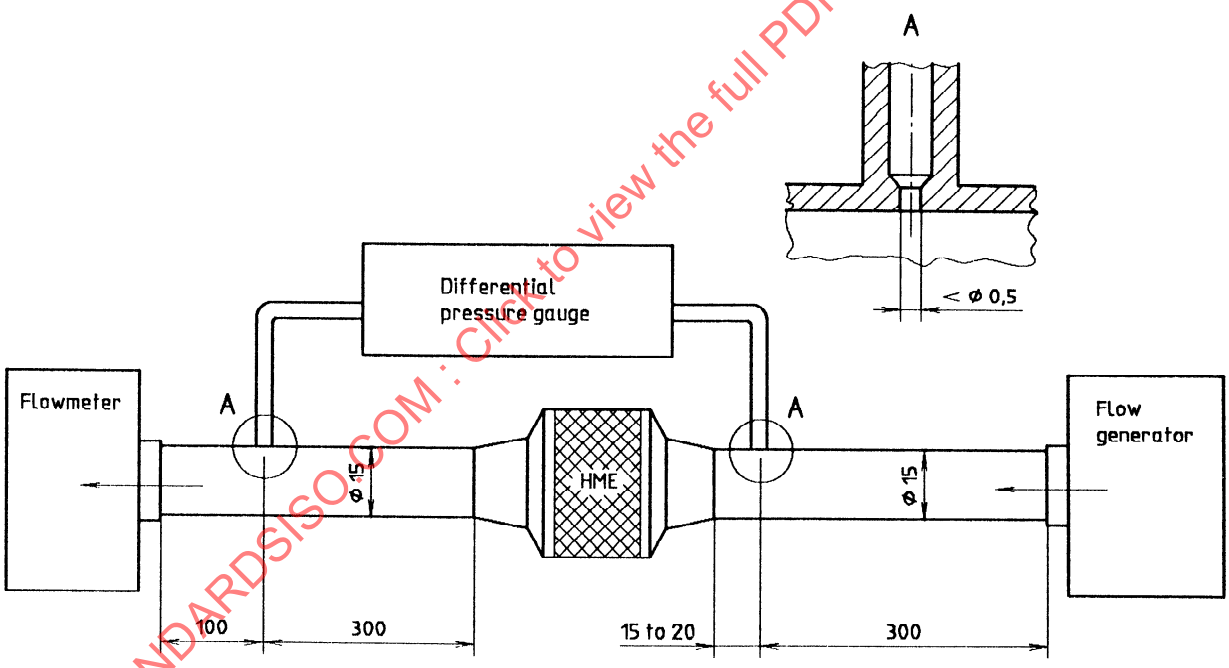

Figure 2 — Pressure drop measuring set-up

6.3.2.11 Reconnect the HME and operate the test apparatus up to the recommended maximum time of use for the HME and record the temperatures at points E and F continuously.

6.3.2.12 Disconnect the HME and weigh the patient model.

6.3.2.13 Repeat the procedures given in 6.3.2.1 to 6.3.2.11 but with the patient model connected directly to the ventilator (i.e. without the HME).

6.3.2.14 Repeat the procedures given in 6.3.2.1 to 6.3.2.13 for all conditions given in table 2 which are within the operating range as specified by the manufacturer.

6.4 Calculations

Calculate the HME moisture output, E_W, using the following formula:

$$E_w = 1 - \left[\frac{(m_1 - m_2)}{(m_3 - m_4)} \times V_2/V_1 \right] \times 37{,}6$$

where

m_1 is the initial mass of the patient model, in grams or milligrams, before testing with the HME;

m_2 is the final mass of the patient model, in grams or milligrams, after testing with the HME;

m_3 is the initial mass of the patient model, in grams or milligrams, before testing without the HME;

m_4 is the final mass of the patient model, in grams or milligrams, after testing without the HME;

V_1 is the total volume of test gas, in litres, transported from the patient model when testing with the HME;

V_2 is the total volume of test gas, in litres, transported from the patient model when testing without the HME.

6.5 Measurement of compressible volume

6.5.1 Occlude all orifices of the HME except one and eliminate all leaks. In the case of female conical connectors complying with ISO 5356-1:1987, this shall be by means of the appropriate plug gauge.

6.5.2 Connect the remaining orifice to one arm of a "T" piece and the other arms to a calibrated, gas-tight syringe and a pressure-monitoring device.

The use of an electronic pressure transducer is recommended.

6.5.3 Record the syringe piston position, as a millilitre mark on the barrel (ml), and the pressure reading, p_1.

6.5.4 Advance the syringe piston sufficiently to increase the pressure reading by 70 hPa (70 cm H_2O) and record the new pressure reading, p_2.

6.5.5 Record the new syringe piston position, "ml", and the change in volume from that in 6.6.3, y ml.

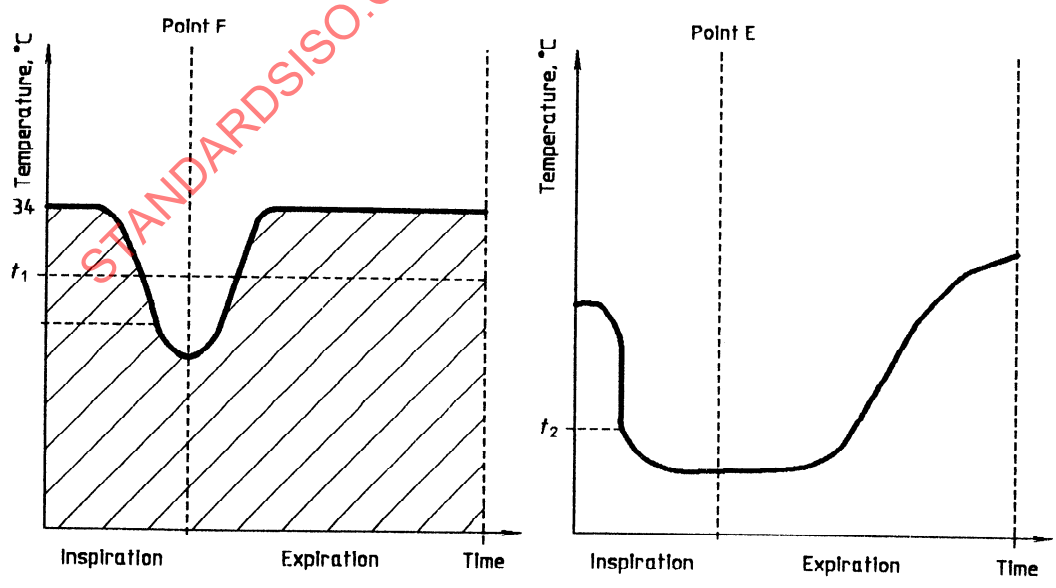

Figure 3 — Temperature variation at points F and E

6.5.6 Remove the HME and insert a suitable plug gauge into the "T" piece and repeat 6.5.3 through 6.5.5. Record the change in volume, x ml.

6.5.7 Calculate the compressible volume, V_c, in millilitres of the device using the following formula:

$$V_c = \frac{p_2(x - y)}{(p_1 - p_2)}$$

6.6 Measurement of gas leakage

6.6.1 Occlude all ports of the HME except one, to which a pressure connection port is attached. Connect this port to a suitable pressure source.

6.6.2 Submerge the HME in a water bath and measure the water depth.

6.6.3 Apply an internal pressure of 30 hPa (30 cm H_2O), compensating for the effect of depth of submersion. Confirm the pressure by a gauge accurate to at least ± 1 % of the reading, and maintain this pressure for a minimum of 5 min.

6.6.4 Collect any air leaking from the HME in a suitable calibrated vessel for a period of 5 min. Record the volume of leakage.

6.7 Measurement of pressure drop

6.7.1 Pre-condition the HME in the patient model for 1 h at the conditions appropriate for the intended application of the device as specified in table 2.

6.7.2 Using the apparatus in figure 2, connect the differential pressure gauge across the HME and connect the flowmeter.

6.7.3 Determine the pressure drop at the flow appropriate for the intended application of the HME, as specified in table 3, within 5 s of initiating flow through the HME.

Table 3 — Flows for measurement of pressure drop

Intended V_t for	Flow l/min
adult use	60
paediatric use	30
neonatal use	15

6.7.4 Remove the HME and determine the pressure drop at the same flow. Subtract this value from that obtained in 6.6.3. This is the pressure drop attributable to the HME.

6.7.5 Repeat steps 6.6.2 through 6.6.4 after preconditioning the HME in the patient model for the recommended maximum time of use at the conditions appropriate for the intended application of the device as specified in table 2.

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

7 Marking

7.1 Re-usable HMEs shall be marked with at least the following information:

a) the trade-mark or -name of the manufacturer, and the identification mark: for HMEs intended for single use, this marking shall be either on the device or on the package;

b) direction of orientation towards the patient in the case of orientation-sensitive HMEs;

c) the letters APG (which is explained in IEC 601-1:1988) if the manufacturer states that the HME is safe for use with flammable anaesthetics.

7.2 The HME package shall be marked with at least the following information:

a) an indication of whether or not the HME is intended to be placed in a breathing system;

b) the word STERILE (or the equivalent), if applicable;

c) the words SINGLE USE (or the equivalent), if applicable, or symbol 1051 as listed in ISO 7000:1989;

d) an indication that maintenance of sterility of the contents requires storage under dry, clean and adequately ventilated conditions, if applicable.

8 Information to be provided by manufacturer or supplier

The manufacturer or supplier of the HME shall provide the following information:

a) the intended use of the HME (for example, in anaesthesia, in respiratory care, at home or in hospital): in particular, whether or not the HME is suitable for use with intubated patients or for inclusion in a ventilator or other positive-pressure breathing systems;

b) the pressure drop in hPa as a function of flow, at flows of 0,5 l/s, 1,0 l/s and 1,5 l/s when tested in accordance with 6.7;

c) the compressible volume of the HME including its components, when tested in accordance with 6.6;

d) if applicable, a statement as to the possible hazards of blockage with certain types of inhalants during inhalational therapy;

e) the temperature and moisture output within the operating range of gas flows given in table 2, when tested in accordance with 6.5;

f) instructions for use of the HME;

g) an indication of whether the HME or parts thereof are re-usable. For single-use HMEs, the instructions for use shall contain a statement as to the possible hazards of re-use, for example, the emission of anaesthetic gas from the HME even after discontinuation of anaesthetic gas flow, and that the user should be aware of possible transmission of infection;

h) if the HME or parts thereof are re-usable, instructions for the maintenance and details of cleaning, disinfection and sterilization techniques;

i) if particular agents, such as anaesthetic gases and vapours, degrade the performance of the HME, a statement to that effect;

j) recommended maximum time of use for each unit;

k) recommended shelf-life;

l) a warning of the potential hazards associated with the use of an HME with the active use of a humidifier or nebulizer (if applicable);

m) the specified operating range expressed in tidal volume.