INTERNATIONAL STANDARD

ISO 8185

Third edition
2007-07-01

Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems

Humidificateurs respiratoires médicaux — Exigences spécifiques des systèmes d'humidification respiratoires

Reference number
ISO 8185:2007(E)

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.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword v
Introduction vi
1 Scope 1
2 Normative references 2
3 Terms and definitions 2
4 General requirements and general requirements for tests 4
5 Classification 4
6 Identification, marking and documents 5
7 Power input 7
8 Basic safety categories 7
9 Removable protective means 7
10 Environmental conditions 7
11 Not used 8
12 Not used 8
13 General 8
14 Requirements related to classification 8
15 Limitation of voltage and/or energy 8
16 Enclosures and protective covers 8
17 Separation 8
18 Protective earthing, functional earthing and potential equalization 8
19 Continuous leakage currents and patient auxiliary currents 8
20 Dielectric strength 9
21 Mechanical strength 9
22 Moving parts 9
23 Surface, corners and edges 9
24 Stability in normal use 9
25 Expelled parts 9
26 Vibration and noise 9
27 Pneumatic and hydraulic power 9
28 Suspended masses 9
29 X-Radiation 10
30 Alpha, beta, gamma, neutron radiation and other particle radiation 10
31 Microwave radiation 10
32 Light radiation (including lasers) 10
33 Infra-red radiation 10
34 Ultraviolet energy 10
35 Acoustical energy (including ultrasonics) 10

36 Electromagnetic compatibility **11**
37 Locations and basic requirements **11**
38 Marking, accompanying documents **11**
39 Common requirements for category AP and category APG equipment **11**
40 Requirements and tests for category AP equipment, parts and components thereof **11**
41 Requirements and tests for category APG equipment, parts and components thereof **11**
42 Excessive temperatures **11**
43 * Fire prevention **12**
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection **12**
45 Pressure vessels and parts subject to pressure **13**
46 Human error **13**
47 Electrostatic charges **13**
48 Biocompatibility **13**
49 Interruption of power supply **13**
50 Accuracy of operating data **14**
51 * Protection against hazardous output **14**
52 Abnormal operation and fault conditions **15**
53 Environmental tests **16**
54 General **16**
55 Enclosure and covers **16**
56 Components and general assembly **16**
57 Mains parts, components and layout **17**
58 Protective earthing — Terminals and connections **17**
59 Construction and layout **18**
101 * Humidification system output **18**
102 Liquid container **18**
103 Alarm systems **18**
Annex AA (informative) **Rationale** **20**
Annex BB (normative) *** Determination of the accuracy of the displayed temperature** **27**
Annex CC (informative) **Specific enthalpy calculations** **29**
Annex DD (normative) **Temperature sensors and mating ports** **35**
Annex EE (normative) *** Determination of humidification system output** **36**
Annex FF (normative) *** Standard temperature sensor** **39**
Annex GG (informative) **Environmental aspects** **41**
Annex HH (informative) **Reference to the essential principals of safety and performance** **44**
Annex II (informative) **Terminology — Index of defined terms** **46**
Bibliography **48**

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8185 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This third edition cancels and replaces the second edition (ISO 8185:1997), which has been technically revised. It also incorporates the Technical Corrigendum, ISO 8185:1997/Cor. 1:2001.

Introduction

This International Standard is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all **medical electrical equipment** used by, or under the supervision of, qualified personnel in the general medical and **patient** environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable **equipment**, such as medical systems, EMC, radiation protection in diagnostic X-ray **equipment**, software, etc. The Particular Standards apply to specific **equipment** types, such as medical electron accelerators, high frequency surgical **equipment**, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard are found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

This International Standard uses the same main Clause titles and numbering as the General Standard, to facilitate cross-referencing of the requirements. The changes to the text of the General Standard are specified by the use of the following words.

— "Replacement" means that the indicated Clause or Subclause of the General Standard is replaced completely by the text of this International Standard.

— "Addition" means that the relevant text of this International Standard is supplementary to the requirements of the General Standard.

— "Amendment" means that existing text of the General Standard is modified as indicated by the text of this International Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this International Standard, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— description of type of document change and test methods: *italic type*;

— terms defined in the General Standard IEC 60601-1**:**1988, Clause 2 or in this International Standard: **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

Humidifiers are used to raise the water content of gases delivered to **patients**. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of **patients** whose upper airways have been bypassed. Reduction of the **relative humidity** at the **patient connection port** can cause desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, and consequently may cause narrowing or even obstruction of the airway [19]. Heat can be employed to increase the water output of the **humidifier**.

In addition, many **humidifiers** utilise heated **breathing tubes** in order to increase operating efficiency and reduce water and heat loss. Ventilator and anaesthesia **breathing tubes** in common use might not withstand the heat generated by **humidifiers** and heated **breathing tube** mechanisms.

Many **humidifier** manufacturers use off-the-shelf electrical connectors for their electrically-heated **breathing tubes**. However, since different manufacturers have used the same electrical connector for different power outputs, electrically-heated **breathing tubes** can be physically, but not electrically, interchangeable. Use of improper electrically-heated **breathing tubes** has caused overheating, circuit melting, **patient** and **operator** burns, and fires. It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between **humidifiers** and **breathing tubes** produced by different manufacturers.

Since the safe use of a **humidifier** depends on the interaction of the **humidifier** with its many **accessories**, this International Standard sets total-system performance requirements, applicable to **accessories** such as **breathing tubes** (both heated and non-heated), temperature sensors, and devices intended to control the environment within these **breathing tubes**.

Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems

1 Scope

IEC 60601-1:1988, Clause 1, applies, except as follows:

Amendment (add at the end of 1.1):

This International Standard includes requirements for the basic safety and essential performance of **humidification systems**, as defined in 3.6. This International Standard also includes requirements for individual devices specified for use in **humidification systems** such as heated **breathing tubes** (heated-wire **breathing tubes**) and devices intended to control these heated **breathing tubes** (**heated breathing tube controllers**). ISO 5367 specifies other safety and performance requirements for **breathing tubes**.

NOTE Heated **breathing tubes** are **medical electrical equipment** and are subject to the requirements of IEC 60601-1.

***** This International Standard also includes requirements for **active HME** (heat and moisture exchanger) devices, which actively add heat and moisture to increase the humidity level of the gas delivered from the HME to the **patient**. This International Standard is not applicable to passive HMEs, which return a portion of the **patient's** expired moisture and heat to the respiratory tract during inspiration without adding heat and moisture. ISO 9360-1 and ISO 9360-2 specify safety and performance requirements for passive HMEs and describe methods for testing performance.

Respiratory tract **humidifiers** can be gas-powered, electrically-powered, or both. However, this International Standard has been prepared as a Particular Standard based on IEC 60601-1, which gives general requirements for all aspects of safety, not only electrical safety, and many of the requirements are therefore applicable to **humidifiers** not powered by electricity. Where this International Standard specifies that a Clause of IEC 60601-1 applies, it means that the Clause applies only if the requirement is relevant to the **humidification system** under consideration.

This International Standard is not applicable to devices commonly referred to as "room humidifiers" or humidifiers used in heating, ventilation and air conditioning systems, or humidifiers incorporated into infant incubators.

This International Standard is not applicable to nebulizers used for the delivery of drugs to **patients**.

In the planning and design of products within the scope of this International Standard, it is advisable to give due consideration to the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex GG.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7396-1:2002, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

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 9360-2:2001, *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*

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety, and its Amendment 1:1991 and Amendment 2:1995*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2004, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability*

IEC 60601-1-8:2003, *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*

IEC 60601-2-19:1990, *Medical electrical equipment — Part 2: Particular requirements for safety of baby incubators*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in Clause 2 of IEC 60601-1:1988, IEC 60601-1-8:2003, ISO 4135:2001, and the following apply.

NOTE For convenience, the sources of all defined terms used in this International Standard are given in Annex II.

3.1
accessible surface temperature
temperature of any surface which can be touched by a hand or finger during **normal use**, which includes filling and refilling of the **humidifier**

3.2
active HME
device where water, water vapour or heat is actively added to the heat and moisture exchanger (HME) to increase the humidity level of the gas delivered from the HME to the **patient**

3.3
delivered gas temperature
temperature of the gas, or aerosol, or both, at the **patient connection port**

3.4
heated breathing tube controller
device which controls the temperature or the heating of a **breathing tube**

NOTE The controller can be either stand-alone or part of the **humidifier**.

3.5
humidification chamber
part of the **humidifier** in which vaporization or nebulization takes place

3.6
humidification system
complete system that comprises a **humidifier** and **accessories**

NOTE **Accessories** can include a **breathing tube** (heated or unheated), **breathing tube** heater, **heated breathing tube controller,** and temperature sensor.

3.7
humidification system output
total mass of water (in the form of liquid and vapour) per unit volume of gas normalized to body temperature, atmospheric pressure and saturated (BTPS), i.e. at 37 °C, 101,3 kPa (760 mmHg) and saturated with water vapour at the **patient connection port**

3.8
humidifier
device that adds water in the form of droplets or vapour, or both, to the inspired gas

NOTE This term includes vaporizing, bubble-through and ultrasonic **humidifiers** and **active heat and moisture exchangers (HMEs)**.

3.9
liquid container
part of the **humidifier** which holds the liquid

NOTE 1 The **liquid container** can be accessible to the breathing gas.

NOTE 2 The **liquid container** can also be part of the **humidification chamber**.

NOTE 3 The **liquid container** can be detachable for filling.

3.10
liquid reservoir
part of the **humidifier** which replenishes the **liquid container**

3.11
maximum operating pressure
maximum **pressure** in the **humidification chamber**

3.12
measured gas temperature
temperature of the gas, or aerosol, or both, that the **humidification system** is measuring and, if applicable, displaying

3.13
relative humidity
water vapour **pressure**, expressed as a percentage of the saturation vapour **pressure,** at a particular temperature

3.14
set temperature
temperature at which the **humidification system** attempts to maintain **measured gas temperature**

NOTE The **set temperature** can be **operator**-adjustable.

4 General requirements and general requirements for tests

IEC 60601-1:1988, Clauses 3 and 4, apply, except as follows:

3.6

Addition:

aa) Operation of the **humidifier** without any liquid.

bb) If the **humidifier** includes a temperature sensor, any **single fault condition** with the temperature sensor. For example:

- temperature sensor single open-circuit;
- temperature sensor single short-circuit;
- temperature sensor disconnected from the **humidifier** control system; or
- temperature sensor disconnected from **breathing tube** or **humidifier**.

cc) A **safety hazard** (e.g. thermal injury to the **patient**) resulting from software error.

4.6 Other conditions

Addition:

aa) The test gas shall be medical-grade air, medical-grade oxygen, or a mixture of the two.

NOTE Reference test gas to BTPS (37 °C, RH = 100 %, 101 kPa)

bb) Unless otherwise specified, the **liquid container** and **liquid reservoir**, if provided, shall be filled to maximum capacity, as indicated in the instructions for use, at the beginning of a test with distilled water at the ambient test temperature.

cc) For the purpose of checking compliance with requirements of this International Standard, the **delivered gas temperature** shall be sensed in the **breathing tube** no more than 50 mm from the **patient connection port** (see Annex BB).

5 Classification

IEC 60601-1:1988, Clause 5, applies.

6 Identification, marking and documents

IEC 60601-1:1988, Clause 6, applies, except as follows:

6.1 Markings on the outside of equipment or equipment parts

Amendment:

*g) * Connection to the supply*

NOTE A heated **breathing tube** connector to the **humidifier** or **heated breathing tube controller** is a connection to the supply that can need this marking.

Amendment (add at end of item):

p) Output

NOTE The **applied part** electrical connector of a **humidifier** for heated **breathing tubes** is an output that needs this marking.

Addition:

aa) The marking on the outside shall also include the following:

1) the maximum and minimum liquid levels, if these are necessary for the correct operation of the **humidifier**;

2) the direction of flow, for a **humidifier** or **humidification system** with **flow-direction-sensitive components**;

3) if a **pressure**-relief mechanism is provided, the **pressure** at which it opens. This marking shall be on or near the **pressure**-relief device;

4) ***** if the **humidifier** is driven by compressed gas, the ranges of the supply flowrates and **pressures** that are required;

5) the **humidification system** and its parts shall be marked with regard to proper disposal, as appropriate.

6.8.2 Instruction for use

a) General Information

Amendment (add after the last bullet):

— The instructions for use shall also include the following information:

1) ***** For a **humidifier,** identification of at least one set of **accessories** and, if applicable, a ventilator necessary for its intended use, and a warning to the effect that it is potentially unsafe to configure a **humidifier** with **breathing tubes** or **accessories** and a ventilator that are not specified for use with the **humidifier.**

2) For **breathing tubes** or other **accessories** intended to be used within **humidification systems**, identification of at least one **humidifier** that, when used with the **breathing tube** or **accessories**, will meet the requirements of this International Standard.

3) * A warning to the effect that it is potentially unsafe to configure **breathing tubes** or **accessories** with any **humidifier** and ventilator that are not specified for use with these **breathing tubes** or **accessories**.

4) * If the **humidifier** entrains air for the purpose of diluting oxygen, the following shall be provided:

   i) a statement to the effect that the oxygen concentration can be affected by a partial obstruction downstream of the **humidifier**, e.g. when using **accessory equipment**;

   ii) a recommendation that the oxygen concentration be measured at the point of delivery to the **patient**.

5) The intended use of the **humidification system**, and whether or not the **humidification system** is intended for use with a **patient** whose upper airways have been bypassed.

6) * If the **humidifier** is intended for use with **patients** whose upper airways are bypassed, the operating range of gas flowrates and settings which provide a **humidification system output** of at least 33 mg/l.

7) The maximum volume of water, expressed in millilitres, available for vaporization contained in the **liquid container** and, if provided, in the **liquid reservoir**.

8) If the **humidifier** is powered by pressurized gas, the **rated** ranges of flowrates and supply **pressures** and method(s) of connection.

9) The **maximum operating pressure** of the **humidifier**.

10) * The inspiratory and expiratory **pressure** drop, as a function of flowrate, across the **humidification system** or individual components, as appropriate. The pressure drop should be determined in accordance with ISO 5367 or an equivalent method. The pressure drop for **active HMEs** should be determined in accordance with ISO 9360-1 and ISO 9360-2.

11) The gas leakage of the **humidification system** or individual components, as appropriate, at the **maximum operating pressure**. The gas leakage should be determined in accordance with ISO 5367 or an equivalent method. The gas leakage for **active HMEs** should be determined in accordance with ISO 9360-1 and ISO 9360-2.

12) * The internal compliance of the **humidification system** or individual components, as appropriate. If this internal compliance can be affected by the depletion of the liquid, the minimum and maximum compliance values shall be disclosed. The internal compliance should be determined in accordance with ISO 5367 or an equivalent method. The internal compliance for **active HMEs** should be determined in accordance with ISO 9360-1 and ISO 9360-2.

13) The **humidification system output** and **relative humidity** over the recommended operating range of gas flowrates and settings.

14) The time required (warm-up time) for the **measured gas temperature** to reach the **set temperature** from a starting temperature of (23 ± 2) °C when operated in accordance with the **accompanying documents**.

15) The maximum **delivered gas temperature**, if the **humidification system** is not provided with a means of continuously indicating the **measured gas temperature.**

16) Appropriate warning about operation of the **breathing tubes** if they can be affected by normal clinical procedures (e.g. tubes covered with a blanket or heated in an incubator or overhead heater for a neonate).

17) The operating ambient temperature range and the operating gas inlet temperature range.

18) A warning if humidity performance of the device can be compromised when used outside the specified ambient temperature range or humidity range.

19) Known adverse effects on the performance of the **humidification system** when exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference.

20) Information concerning the disposal of the **humidification system** or components thereof.

21) * The location in the **humidification system** to which the displayed gas temperature is referenced.

Replacement:

d) For components specified for reuse, which come into contact with the **patient** or breathing gases during **normal use**, the instructions for use shall contain:

— any details about cleaning and disinfection or cleaning and sterilisation methods that can be used (see 44.7);

— the list of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such **humidification system**, parts or **accessories** can tolerate.

For non-**patient** contact parts, a list of cleaning solutions suitable for cleaning those parts.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies, except as follows:

10.2.1 Environment

Replacement:

a) An operating ambient temperature range as specified in the **accompanying documents**.

Addition:

10.2.101 Pneumatic power supply

If the **humidifier** is intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with ISO 7396-1 or a pressure regulator complying with ISO 10524-1) it shall operate and meet the requirements of this International Standard for a pneumatic power supply range of 280 kPa to 600 kPa and shall not cause a **safety hazard** under the **single fault condition** when the medical gas supply inlet pressure is 1000 kPa.

11 Not used

12 Not used

13 General

IEC 60601-1:1988, Clause 13 applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies, except as follows:

14.6 Types B, BF and CF equipment

Amendment [add at the end of the list element c)]:

Applied parts of **humidifier** shall be **type BF** or **type CF applied parts**.

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

17 Separation

IEC 60601-1:1988, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies, except as follows:

19.4 Tests

h) *Measurement of the **patient leakage current***

Replacement:

9) The **humidifier** connected to the **breathing tube** and other necessary **accessories** shall be tested using metal foil as described in 19.4 g) 5). Wrap the metal foil around the **patient connection port**.

See also Figure 25 of IEC 60601-1:1988.

20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies.

21 Mechanical strength

IEC 60601-1:1988, Clause 21 applies.

22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

23 Surface, corners and edges

IEC 60601-1:1988, Clause 23 applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.

26 Vibration and noise

IEC 60601-1:1988, Clause 26 applies.

27 Pneumatic and hydraulic power

IEC 60601-1:1988, Clause 27 applies.

28 Suspended masses

IEC 60601-1:1988, Clause 28 applies.

29 X-Radiation

IEC 60601-1:1988, Clause 29 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

IEC 60601-1:1988, Clause 30 applies.

31 Microwave radiation

IEC 60601-1:1988, Clause 31 applies.

32 Light radiation (including lasers)

IEC 60601-1:1988, Clause 32 applies.

33 Infra-red radiation

IEC 60601-1:1988, Clause 33 applies.

34 Ultraviolet energy

IEC 60601-1:1988, Clause 34 applies.

35 Acoustical energy (including ultrasonics)

IEC 60601-1:1988, Clause 35 applies, except as follows:

Addition:

35.101 * Noise measurement

35.101.1 Steady-state noise for all humidifiers

The steady-state noise generated by a **humidifier** or **humidification system** shall not exceed 50 dB (A-weighted) at any point 1 m from the **humidifier**.

Check compliance with the tests of ISO 3744.

35.101.2 Steady-state noise for humidifiers for use with incubators

A **humidifier** or **humidification system** intended for use with an incubator shall comply with the sound pressure level requirements in IEC 60601-2-19:1990, 102.1.

Check compliance with the tests of IEC 60601-2-19.

36 Electromagnetic compatibility

IEC 60601-1:1988, Clause 36 applies, except as follows:

Addition:

A **humidifier** or **humidification system** shall not be considered **life-supporting equipment** or **systems** as defined in IEC 60601-1-2:2001. A **humidifier** or **humidification system** shall meet the appropriate requirements of IEC 60601-1-2:2001.

IEC 60601-1-2:2001, applies, except as follows:

36.202.1 General

j) Compliance criteria

Replacement:

j) Under the test conditions specified in 36.202, the **humidifier** or **humidification system** shall provide essential performance and not create a **safety hazard**. If an anomaly occurs, such as display interruption, **false positive** or **negative alarm condition**, or loss of function without the integrity of the associative protective device being compromised, this shall not be considered a **safety hazard**, provided it is possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance.

37 Locations and basic requirements

IEC 60601-1:1988, Clause 37 applies.

38 Marking, accompanying documents

IEC 60601-1:1988, Clause 38 applies.

39 Common requirements for category AP and category APG equipment

IEC 60601-1:1988, Clause 39 applies.

40 Requirements and tests for category AP equipment, parts and components thereof

IEC 60601-1:1988, Clause 40 applies.

41 Requirements and tests for category APG equipment, parts and components thereof

IEC 60601-1:1988, Clause 41 applies.

42 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies, except as follows:

Addition:

42.101 * The **accessible surface temperature** within 25 cm of the **patient connection port** shall not exceed 44 °C.

43 * Fire prevention

IEC 60601-1:1988, Clause 43 applies, except as follows:

Addition:

43.101 Humidifier used in conjunction with oxidants

a) In order to reduce the risk of fire for **patients**, for other persons and for the surroundings, ignitable material, under **normal** and **single fault condition**, shall not, at the same time, be subjected to conditions in which

   — the temperature of the material is raised to its minimum ignition temperature, and

   — an oxidant is present.

   EXAMPLE Nitrous oxide.

NOTE For partial pressures of oxygen up to 27,5 kPa, when no other oxidants are present, the requirements in the IEC 60601-1:1988 are considered to be sufficient.

The minimum ignition temperature is determined in accordance with IEC 60079-4 using the oxidizing conditions present under **normal** and **single fault condition**.

*Check compliance by determining the temperature to which the material is raised under **normal** and **single fault condition**.*

b) If sparking can occur under **normal** or **single fault condition**, the material subjected the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

*Check compliance by observing if ignition occurs under the most unfavourable combination of **normal conditions** with a single fault.*

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

IEC 60601-1:1988, Clause 44 applies, except as follows:

Replacement:

44.2 * Overflow

Amendment (replace second sentence with):

When the **humidifier** is tilted through 20° in any direction from its normal operating position, and for an **active HME** in its least favourable orientation, there shall be no spillage of water from the **liquid container** or **liquid reservoir** into the **breathing system** when operated at the maximum flowrate stated in the **accompanying documents**.

Amendment (replace second paragraph of the compliance test with):

*Subsequently tilt the **humidifier** through an angle of 20° in the least favourable direction(s) and for an **active HME** in its least favourable orientation, (if necessary with refilling) starting from the position of **normal use** while it is operating at the maximum flowrate. Verify that no liquid spills into the **breathing system**.*

44.7 Cleaning, sterilization and disinfection

Amendment:

All components specified for reuse in the instructions for use, which come into contact with the **patient** or breathing gases in **normal use** shall be capable of being cleaned and disinfected or cleaned and sterilized.

*Check compliance by reviewing the **accompanying documents** for methods of cleaning and disinfection or sterilization [see 6.8.2 d)] and by inspection of the relevant validation reports.*

44.8 Compatibility with substances used with the equipment

Addition:

The **humidification system** and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the **humidification system** or its components during **normal use**.

Particular attention should be paid to the biocompatibility of materials and their compatibility with substances and gases with which they enter into contact during **normal use** or routine procedures.

Check compliance by inspection of the relevant validation reports.

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45 applies.

46 Human error

IEC 60601-1:1988, Clause 46 applies except as follows.

Replacement:

IEC 60601-1-6:2004 applies.

Check compliance with the tests of IEC 60601-1-6.

47 Electrostatic charges

Not used.

48 Biocompatibility

IEC 60601-1:1988, Clause 48 applies.

49 Interruption of power supply

IEC 60601-1:1988, Clause 49 applies.

50 Accuracy of operating data

IEC 60601-1:1988, Clause 50 applies, except as follows.

50.1 * Marking of controls and instruments

Replacement:

If the **humidification system** includes a means of continuously indicating the **measured gas temperature**, then the displayed **measured gas temperature** shall have a range of at least 25 °C to 45 °C. See also 6.3.

Check compliance by inspection.

50.2 * Accuracy of controls and instruments

Replacement:

aa) If provided, the displayed **measured gas temperature** shall be accurate to ± 2 °C.

Check compliance by the test given in Annex BB.

bb) If the **humidifier** entrains air for the purpose of diluting oxygen or other gas mixtures, the **nominal** oxygen concentration value shall not differ by more than ± 10 % of the control setting.

Check compliance by functional testing.

cc) The following requirements do not apply during the period the **humidification system** is in transition to a new state of thermal equilibrium following a change in gas flowrate and/or change in **set temperature**; however, no thermal hazard shall exist during this period.

— * Under the operating conditions specified in the **accompanying documents**, the displayed **measured gas temperature** averaged during any period of 5 min shall not differ by more than ± 2 °C from the **set temperature** after the warm-up period specified in the **accompanying documents**. See also 6.8.2 a) 14).

— * If the displayed **measured gas temperature** differs from the **set gas temperature** by more than the range that is specified in the **accompanying documents**, the **humidifier** shall have a means to detect a temperature out-of-range **alarm condition**. The temperature out-of-range **alarm condition** shall be at least **medium priority**.

Check compliance by functional testing and the test given in Annex BB.

51 * Protection against hazardous output

IEC 60601-1:1988, Clause 51 applies, except as follows.

Addition:

51.101 Under **normal condition** and any **single fault condition** the volume of liquid exiting the **humidification chamber** outlet shall not exceed:

— 1,0 ml in 1 min or 2,0 ml in 1 h when intended for use with neonates; and

— 5 ml in 1 min or 20 ml in 1 h for all other applications.

Check compliance by functional testing.

51.102 If the **delivered gas temperature** is capable of exceeding 43 °C under **normal** or **single fault condition,** then the **humidification system** shall have a means to detect an extreme over-temperature **alarm condition** and shall automatically interrupt heating whenever the **delivered gas temperature** exceeds 43 °C. The extreme over-temperature **alarm condition** shall be at least **medium priority**. See also 201.8.3.

Check compliance by functional testing.

51.103 Under **normal** and **single fault conditions**, a thermal overshoot at the **patient connection port** shall not exceed an energy equivalent to 43 °C and 100 % **relative humidity** (a specific enthalpy not to exceed 194 kJ/kg dry gas) when averaged over 30 s. See Table 101 for examples of combinations of temperature and **relative humidity** with such a specific enthalpy.

Table 101 — Examples of permissible combinations of temperature and relative humidity

Temperature	Relative humidity
°C	%
43	100
44	95
45	90
48	76
50	68

*Check compliance by inspection and measurement of energy (as specified in Annex CC) during **normal use** and under the following conditions:*

a) ***Humidification system** turned on with no gas flow for an extended time, then sudden increase in flowrate.*

Precondition the **humidification system** by turning it on with no (zero) gas flow and waiting 30 min. Adjust the flow of gas to the minimum continuous flowrate indicated in the **accompanying documents**. Repeat this test using the maximum continuous flowrate indicated in the **accompanying documents**.

b) ***Humidification system** stable, gas flow interrupted for a short period, while the **humidification system** is left on.*

Precondition the **humidification system** by turning it on and operating it at the minimum recommended flowrate indicated in the **accompanying documents** until the **measured gas temperature** reaches the **set temperature** (warm-up). Turn the gas flow off for 3 min. Adjust the flowrate to the minimum continuous flowrate indicated in the **accompanying documents**. Repeat this test using the average and maximum continuous flowrates.

c) *Large changes in flowrate within the recommended limits indicated in the **accompanying documents**.*

Precondition the **humidification system** by turning it on and operating it at the minimum recommended flowrate indicated in the **accompanying documents** until the **measured gas temperature** reaches the **set temperature** (warm-up). Adjust the flow of gas to the maximum continuous flowrate indicated in the **accompanying documents**. Repeat this test, stabilizing at the maximum continuous flowrate and then adjusting to the minimum continuous flowrate.

52 Abnormal operation and fault conditions

IEC 60601-1:1988, Clause 52 applies.

53 Environmental tests

IEC 60601-1:1988, Clause 53 applies.

54 General

IEC 60601-1:1988, Clause 54 applies.

55 Enclosure and covers

IEC 60601-1:1988, Clause 55 applies.

56 Components and general assembly

IEC 60601-1:1988, Clause 56 applies, except as follows:

56.3 Connections — General

Addition:

aa) If a **humidification system** is intended to be placed in a **breathing system** fitted with conical **breathing system** connectors, the conical connectors shall be in accordance with ISO 5356-1.

Check compliance by functional testing.

bb) If the **humidifier** is fitted with any other type of connector, these connectors shall mate with **breathing tubes** that comply with ISO 5367, and shall not accept or permit connection with either the 15 mm or 22 mm conical connectors complying with ISO 5356-1.

Check compliance by inspection.

cc) If the **humidifier** incorporates an independent filling or **accessory** orifice (e.g. an air entrainment or a heater orifice), that orifice shall not accept any of the connectors specified in ISO 5356-1.

Check compliance by inspection.

Addition:

56.101 * Breathing tubes

56.101.1 Breathing tubes used in conjunction with anaesthetic machines and/or some ventilators should meet the requirements of ISO 5367.

The machine end of **breathing tubes** used in conjunction with anaesthetic machines and/or some ventilators should either

— meet the requirements of ISO 5367, or

— be a proprietary fitting that does not permit connection to **breathing tubes** complying with ISO 5367 or any of the conical connectors complying with ISO 5356-1.

Check compliance by inspection and testing in accordance with ISO 5367.

56.101.2 Breathing tubes and associated connectors specified for use in a **humidification system** shall not collapse on bending, occlude or otherwise cause a **safety hazard** at the maximum output of the **humidification system**.

*Check compliance by inspection and testing in accordance with ISO 5367:2000, Annex D and Annex E, while connected to the specified **humidification system** operated at its maximum **rated** output.*

56.101.3 Breathing tubes which are heated shall not collapse on bending, occlude or otherwise cause a **safety hazard** when the **breathing tubes** are subject to the maximum **rated** output power of the specified **heated breathing tube controller,** including under conditions of no flow. See also 6.8.2 a).

Check compliance by inspection and testing:

— *in accordance with ISO 5367:2000, Annex D and Annex E, while applying the **rated** output of the specified **heated breathing tube controller** and while connected to the specified **humidification system** operated at its maximum **rated** output;*

— *under conditions of no flow while applying the maximum **rated** output of the specified **heated breathing tube controller**.*

56.102 Temperature sensors and temperature sensor ports

56.102.1 Dimensional requirements

Temperature sensors shall meet the dimensional requirements in Annex DD or shall be sufficiently different that they cannot be interchanged with those that do.

Check compliance by testing in accordance with Annex DD or by inspection and functional testing.

56.102.2 Security of engagement

When the temperature sensors or mating ports are engaged as indicated in the **accompanying documents**, the connection shall not become disconnected under the conditions of no flow or maximum **rated** flow.

*Check compliance by inspection and testing in accordance with Annex DD while applying the constant maximum output power of the **heated breathing tube controller** and under the worst-case condition of no flow.*

56.102.3 Leakage

The leakage from an engaged temperature sensor or mating port shall not exceed 5 ml/min.

Check compliance by functional testing.

57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57 applies.

58 Protective earthing — Terminals and connections

IEC 60601-1:1988, Clause 58 applies.

59 Construction and layout

IEC 60601-1:1988, Clause 59 applies.

Addition:

101* Humidification system output

All **humidification systems** shall be capable of producing a **humidification system output** of at least 10 mg/l throughout the operating range of flowrates.

Humidification systems intended for use in **patients** whose upper airways have been bypassed shall be capable of producing a **humidification system output** of at least 33 mg/l over the range of flowrates, settings, ambient temperature, and gas inlet temperature indicated in the **accompanying documents**.

*Check compliance for **humidifiers** other than **active HMEs** by inspection of the **accompanying documents** and by testing in accordance with Annex EE, and for **active HMEs** by performing the tests indicated in the technical description.*

102 Liquid container

102.1 Filling

The method of filling the **liquid container**, and if provided, the **liquid reservoir**, shall be subject to the usability testing requirements of IEC 60601-1-6.

Check compliance using the methods specified in IEC 60601-1-6.

102.2 Liquid level

Means shall be provided to permit the **operator** to determine the liquid level in the **liquid container** and, if provided, the **liquid reservoir**, without dismantling the **humidifier**.

Check compliance by inspection.

102.3 Filling cap

Reusable filling caps, if provided, shall be tethered to part of the **humidification system**.

Check compliance by inspection.

103 Alarm systems

The requirements of IEC 60601-1-8:2003 apply, except as follows:

201.1.2 Alarm condition priority

Amendment (add after the note):

See also 50.2 cc) and 51.102.

201.8 Alarm signal inactivation states

201.8.3 Indication and access

Amendment (add at the end of third paragraph):

The maximum duration of **audio paused** or **alarm paused** for the extreme over-temperature **alarm condition** shall not exceed 120 s. See also 51.102.

Annexes

IEC 60601-1:1988, Appendices apply, except as follows:

Addition:

Annex AA
(informative)

Rationale

This Annex provides a rationale for certain requirements of this International Standard and is intended for those who are familiar with the design and use of **humidifiers** but who have not participated in their development. An understanding of the reasons for these requirements is provided to aid in the application of this International Standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate a revision of this International Standard.

The clauses in this annex have been so numbered to correspond to the clauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

AA.1 Scope

Active HMEs are also electrically-powered devices that contain heater elements to vaporize liquid water that is added into the device. This water vapour augments that delivered to the respiratory tract of the **patient** from the HME. Most requirements of this International Standard therefore apply. Those requirements that do not apply are clearly indicated.

AA.6.1 g) Connection to supply

The **heated breathing tube controller** manufacturer needs to mark the maximum amount of energy that the **breathing tube** could ever experience. This is necessary to permit manufacturers of **breathing tubes** to be able to completely test their components in order to meet the requirements of 6.8.2 a) 1) and 56.12.3. Since many of the **breathing tube** manufacturers "reverse-engineer" the **breathing tube**, the worst-case, maximum energy output of the controller would not otherwise always be known.

AA.6.1 aa) 4) Gas supply pressures used in different parts of the world vary considerably. Also **humidifiers** of similar appearance can have different supply requirements. Therefore it is important that the **rated** range of supply pressures and flowrates are marked on the **humidifier**.

AA.6.8.2 a) 1) The safe use of a **humidifier** is dependent on the interaction of the **humidifier** with its many **accessories**, such as **breathing tubes** (both heated and non-heated), temperature sensors and **heated breathing tube controllers**. The committee felt that the best way to address the problems created by the proliferation of components that were physically, but not functionally, interchangeable was to consider the whole **humidification system** in which all of the components operate and set total **humidification system** performance requirements.

The committee recognized that there are many more **breathing tube** manufacturers than **humidifier** manufacturers. It was the committee's intent that **humidifier** manufacturers list the **accessories** (e.g. **breathing tubes**) that have been tested together and meet the requirements of this International Standard, so that **users** can choose the most appropriate **accessories**. Moreover, the committee intended that **accessory** manufacturers, such as **breathing tube** manufacturers, test their **accessories** with **humidifiers**, so that **users** can configure the **humidification system** appropriately.

In addition, the **operator** and **user** are required to be warned that a **humidification system** that has components that have not been tested together to meet the requirements of this International Standard might not be safe.

AA.6.8.2 a) 3) Advances in respiratory humidification technology have provided **humidification systems** that can minimize **breathing tube** condensate.

Inspiratory **breathing tubes** deliver humidified gases to the **patient** while expiratory **breathing tubes** deliver the **patient's** exhaled breath to the ventilator gas return port.

Expiratory **breathing tubes** can be heated or unheated. Unheated expiratory **breathing tubes** allow the **patient's** exhaled breath to cool towards room temperature thereby causing condensation that can be drained into a water trap. Heated expiratory **breathing tubes** may prevent the **patient's** exhaled breath from condensing and deliver this humid gas to the ventilator exhalation port. If the ventilator exhalation pathway allows the gas to cool, then condensate can develop and can adversely affect ventilator expiratory sensors.

When using heated expiratory **breathing tubes** the **operator** and **user** should confirm that the ventilator is capable of accepting high temperature and high humidity gases prior to using this combination with **patients**.

AA.6.8.2 a) 4) The amount of air entrained by a device, e.g. by a Venturi mechanism, is a function of gas velocity. Changes in gas velocity, e.g. as a result of a partial obstruction of the ventilation circuit, will directly affect the oxygen concentration.

AA.6.8.2 a) 6) To prevent desiccation (or drying out) of airway secretions in **patients** whose upper airways have been bypassed, a **humidification system output** of more than 33 mg/l should be considered. [25]

AA.6.8.2 a) 10) Resistance to flow can increase the work of breathing. It can also interfere with the effectiveness of intermittent mandatory ventilation (IMV) or triggering mechanisms in lung ventilators.

AA.6.8.2 a) 12) The internal compliance of the ventilator **breathing system**, which includes the **humidifier**, needs to be known in order to accurately determine the tidal volume settings of volume-controlled ventilators.

AA.6.8.2 a) 21) **Humidification systems** can incorporate temperature sensors that measure and display the temperature of the gas at various locations. Many different **humidification systems** exist. Displaying the temperature of the gas at the **patient connection port** is not always the most clinically useful temperature to display, for example:

EXAMPLE 1 Humidifier with heated wire breathing tube.

Water is heated in a chamber until the **measured gas temperature** in the chamber reaches 37 °C. The gas is then heated in the **breathing tube** to 40 °C at the **patient connection port** to prevent condensation. The **relative humidity** exiting the chamber is approximately 100 % and approximately 85 % at the **patient connection port**. In addition, because the total heat content (or energy content) of the gas is primarily due to the water vapour content, the total heat content of the gas at the **patient connection port** is only slightly higher (due to the increased temperature) than that of the gas exiting the chamber. This means that once the gas leaves the **patient connection port** rapid cooling will occur until the gas returns to 100 % **relative humidity** and therefore has cooled back to the chamber temperature (the saturated gas temperature). Following this rapid cooling, the gas will more slowly equilibrate to the temperature of the **patient**.

In Example 1, the **measured gas temperature** in the chamber is the best indication of the humidity being delivered to the **patient** because it represents the saturated gas temperature. The **measured gas temperature** at the **patient connection port** represents a gas temperature that has a **relative humidity** of less than 100 % and is therefore not a good indication of the humidity the **patient** receives.

EXAMPLE 2 Humidifier with non-heated breathing tube.

Water is heated in a chamber and the resultant vapour is carried by gas flowing through the **humidifier** to an unheated **breathing tube.** As the gas travels through the **breathing tube** it cools until it reaches 37 °C at the **patient connection port**. The **relative humidity** at the **patient connection port** is approximately 100 %. To achieve this temperature, the **measured gas temperature** in the chamber can be as high as 55 °C with 100 % **relative humidity**.

In Example 2, the **measured gas temperature** at the **patient connection port** is the appropriate indication of the humidity being delivered to the **patient**.

Therefore, in order to encompass different technologies, it is not appropriate for this International Standard to require a temperature display to show only the temperature delivered at the **patient connection port** or at any specific point in the humidification system. The manufacturer is required to clearly state in the instructions for use the site to which the displayed gas temperature is referenced.

Safety in both examples is maintained as both devices meet the requirements of this International Standard (e.g. Clause 101, **Humidification system output** at the **patient connection port**, and 51.102, protection against hazardous output) despite the fact that they are displaying temperatures from different locations.

AA.35.101 Noise measurement

The noise levels generated by **humidifiers** can contribute significantly to ambient noise levels. **Humidifiers** are often positioned close to the **patient**. In special environments, such as adjacent to infant incubators, the effect is more pronounced and can lead to permanent injury. Excessive noise can hinder voice communications, mask audio signals, cause stress and contribute to sociocusis in **patients**.

AA.42.101 The objective of this Subclause is to protect the **patient** from skin burns due to contact with the external surface of the **breathing tube**. See rationale to Clause 51 for selecting 44 °C.

AA.43 Fire protection

Reports of fire caused by medical devices are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements that are necessary in order to start a fire:

— ignitable material (fuel);

— a temperature equal to or above the minimum ignition temperature of the material, or sparks with energy dissipation equal to or above the minimum ignition energy of the materials;

— an oxidant.

Therefore, following the basic safety concepts of IEC 60601-1, the objective in the design of the **equipment** is to ensure that under both **normal** and **single fault conditions** the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition can occur provided it is self-limiting so that no hazard is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established and published in the literature, although normally only for ambient air and pure oxygen environments. The minimum ignition temperature can be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or oxygen concentrations are required, these can be determined using the methods and apparatus described in IEC 60079-4.

In considering the ignitable materials, particular attention should be paid to materials that can accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The risk of fire directly caused by sparking of electrical circuits is generally considered insignificant in **equipment**, as temperature rise resulting from the power dissipation caused by a spark will not normally reach the ignition temperature of the solid materials generally used when following good design practice.

However, if materials with a low ignition temperature and a very low thermal capacity, e.g. cotton wool, paper or organic fibre accumulations, are present then it might not be possible to determine the surface temperatures attained during exposure to spark energy, and specific tests, e.g. ignition tests, can be necessary to assure safety under these conditions.

In certain standards currently in use, the requirements to minimize fire are based on a limitation on temperature and electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire-retardant cotton in 100 % oxygen which is given in the NFPA publication 53M as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in **equipment** with oxygen-enriched atmospheres.

The origin of the electrical energy values is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards. However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power can be dissipated and the proximity and type of any "fuel" present.

It is now generally accepted that there are no single or universally applicable ranges of temperatures, energy and concentration of oxidant that can ensure safety under all circumstances. Ultimately, electrical energy is only significant in its ability to raise the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under **single fault conditions** in a typical electrical circuit, the possible number of failure modes is very high. In this case, full assurance of safety can only be possible by using appropriate hazard and safety analysis **procedures**, taking into consideration the three basic elements, i.e. material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under **normal condition**, and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a **single fault condition.**

Alternatively, it can be appropriate to limit the electric energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under **single fault conditions**.

The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

AA.44.2 Overflow

Humidifiers are often mounted on poles. However, these **humidifiers** are often not mounted exactly horizontally. The committee felt that a 20° tilt could be construed as mounted correctly, and therefore required that the **humidifier** should operate normally, which includes not spilling any liquid, when operated at this position. **Active HMEs** are located proximal to the **patient** and can be in any orientation. The least favourable orientation needs to be determined for the overflow test.

AA.50.1 Marking of controls and instruments

For a **humidification system** that displays the **measured gas temperature**, the committee concluded that a range of 25 °C to 45 °C was the minimum that an **operator** needed to operate the **humidification system**. It should be very clear to the **operator** if the displayed **measured gas temperature** is higher than 45 °C or lower than 25 °C.

AA.50.2 Accuracy of controls and instruments

The displayed **measured gas temperature** needs to be as accurate as possible. The committee considered that an inaccuracy of less than 2°C of the displayed **measured gas temperature** does not compromise the clinical condition or the safety of the **patient**.

AA.50.2 cc) first dash A **humidifier** controller, by its nature, continuously adjusts the components of the **humidification system** that affects the temperature of the humidified gas delivered to the **patient**. It is normal, therefore, for the **measured gas temperature** to cycle about the **set temperature** but this is not considered to be clinically significant providing the temperature is within ± 2 °C of the **set temperature** when averaged over 5 min.

AA.50.2 cc) second dash It is important that the **operator** is made aware, promptly, when the **measured gas temperature** has exceeded the **set temperature** by more than an acceptable amount. The committee agreed that what constituted an acceptable amount could be left to the manufacturer.

AA.51 Protection against hazardous output

Excessive liquid output could cause **patient** injury and an accumulation of water in the **breathing tube**.

Sustained **delivered gas temperatures** above 41 °C represent a potential thermal hazard to the **patient**. Although it is rarely needed for **patient** care, a sustained **delivered gas temperature** of 41 °C at any level of saturation is not a thermal hazard to the **patient**. **Delivered gas temperatures** above 41 °C, depending on the combination of gas temperature, level of saturation and **patient** exposure time, can be hazardous.

Studies to measure the relative importance of exposure time and temperature in causing cutaneous burns determined that surface temperatures of at least 44 °C and 6 h exposure were required to cause irreversible damage to epidermal cells. [20] This is confirmed by studies conducted by the U.S. Navy Medical Research and Development Command [7], which concluded that fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.

Gas at body temperature and fully saturated (37 °C and 100 % RH) will not transfer thermal energy to or from the **patient** with a normal body temperature of 37 °C. Dry gas at body temperature (37 °C and 0 % RH) will draw heat away through evaporation. Gas at 41 °C and fully saturated has the capacity to deliver less than 130 kJ/kg of dry gas breathed by the **patient**. To protect the **patient** from thermal injury, heating of the **humidification system** is interrupted if the **delivered gas temperature** exceeds 43 °C. A thermal overshoot, not to exceed energy equal to 43 °C and 100 % RH averaged over 30 s (194 kJ/kg of dry gas), is inconsequential to the **patient** and is permitted to simplify construction of the **humidifier**.

It is therefore important that the **operator** be provided with a continuous display of the **measured gas temperature,** and that the **humidifier** automatically interrupts heating and activates the extreme over-temperature **alarm condition** when the **measured gas temperature** exceeds 43 °C.

The testing conditions listed in 51.7 a), b) and c) are important to ensure that large shifts in flowrates do not result in excessive overshoots of high-energy gases being delivered to the **patient**.

AA.56.101 Breathing tubes

Breathing tubes have been reported to collapse on bending, occlude and perforate due to the heat generated by **humidifiers** and supplemental electrical heating. It is believed that a **breathing tube** which is tested to meet the requirements of this International Standard, and which does not kink, occlude and perforate during these tests, will not be a **safety hazard** in clinical use.

AA.101 Humidification system output

Humidifiers can be used with **patients** whose upper airways have been bypassed by a tracheostomy or tracheal tube. The upper airway provides 75 % of the heat and moisture supplied to the alveoli. When the upper airways are bypassed, the **humidifier** needs to supply this missing heat and moisture. Since the total required moisture input is 44 mg/l, the portion that is supplied by the **humidifier** is $0{,}75 \times 44$ mg/l = 33 mg/l.

The humidity in the trachea in normal respiration can range from 36 mg/l to 40 mg/l. Since the optimal required moisture below the carina is 44 mg/l (100 % RH at 37 °C), more than 33 mg/l, and up to 44 mg/l at the **patient connection port**, is required to prevent the drying out of secretions in the artificial airway.

For **active HMEs** the **humidification system output** cannot be determined with the tests described in this clause. The moisture loss test specified in ISO 9360-1 and ISO 9360-2 is more appropriate and can provide an indication of performance for **active HMEs**. Since an **active HME** adds water, the tests of ISO 9360-1 and ISO 9360-2 might not indicate a moisture loss, but an addition of moisture. The moisture loss value and **humidification system output** are not directly comparable.

AA.Annex BB Determination of the accuracy of the displayed temperature

It is difficult to measure temperature at precisely the same location as the device's temperature sensor without modifying the gas flowrate, and hence the thermal transfer characteristics from the gas to the sensor. The object of the test is to measure temperature on either side of the sensor and interpolate the temperature to the site under test. Temperature drop in the circuit can be non-linear. Hence the objective is to place the standard sensors as close as possible to the device under test, but with minimal disruption of gas flow patterns.

AA.Annex EE Determination of humidification system output

A gravimetric technique was selected as the simplest, most consistent method to give a measure of **humidification system output**. Hygrometers will not provide consistent and correct results when operated in the non-isothermal environment of the **breathing system**. Attention is drawn to the definition of **humidification system output**, which is defined as milligrams of water vapour per unit of moist gas at 37 °C. This was considered to be physically and physiologically more appropriate than other definitions, e.g. mg/l dry gas.

The calculation of the **humidification system output,** n, is as follows:

$$n = \frac{m_{\mathrm{w}}}{V_{\mathrm{da,37\,°C}} + V_{\mathrm{w,37\,°C,sat}}} \qquad \text{(EE.1)}$$

where

m_{w} is the mass of water;

$V_{\mathrm{w,37\,°C,sat}}$ is the volume of water at 37 °C, saturated;

$V_{\mathrm{da,37\,°C}}$ is the volume of dry air at 37 °C which can be obtained from the volume measured at 23 °C.

Correcting for the volume measured at 23 °C, this becomes:

$$n = \frac{m_{\mathrm{w}}}{V_1\left[1 + y(37 - T_1)\right] + V_{\mathrm{w,\,37\,°C,\,sat}}} \qquad \text{(EE.2)}$$

where $V_{\mathrm{da,37\,°C}}$ has been substituted by

$$V_{\mathrm{da,37\,°C}} = V_1[1 + y(37 - T_1)]$$

where

V_1 is the volume of dry air at temperature, T_1;

T_1 is the temperature at which the measure is made and is equal to 23 °C;

y is the expansion coefficient for dry air from 23 °C to 37 °C, which is calculated as follows:

$$y = \frac{\dfrac{v_{\mathrm{da,37\,°C}}}{v_{\mathrm{da,23\,°C}}} - 1}{\Delta T} = \frac{\dfrac{0{,}878\,4}{0{,}838\,7} - 1}{37 - 23} = \frac{0{,}047\,34}{14} = 0{,}003\,38 \qquad \text{(EE.3)}$$

where

$v_{\text{da,37 °C}}$ is the specific volume of dry air at 37 °C, equal to 0,878 4;

$v_{\text{da,23 °C}}$ is the specific volume of dry air at 23 °C, equal to 0,838 7;

ΔT is the difference in temperature from 23 °C to 37 °C.

$V_{\text{w,37 °C,sat}}$ is calculated as follows:

$$V_{\text{w, 37 °C, sat}} = V_{\text{da, 37 °C}} \frac{v_{\text{wv, 37 °C}}}{v_{\text{da, 37 °C}}} \quad \text{(EE.4)}$$

where

$v_{\text{wv,37 °C}}$ is the specific volume of water vapour at 37 °C;

$v_{\text{da,37 °C}}$ is the specific volume of dry air at 37 °C.

Sustitituting $V_1[1+y(37 - T_1)]$ for $V_{\text{da,37 °C}}$, this gives:

$$V_{\text{w, 37 °C,sat}} = V_1\left[1+y(37-T_1)\right]\frac{0{,}936\,2-0{,}878\,4}{0{,}878\,4} = 0{,}065\,8V_1\left[1+y(37-T_1)\right] \quad \text{(EE.5)}$$

Substituting Equation (EE.5) and the value from Equation (EE.3) into Equation (EE.2), rationalizing units and rearranging:

$$n = \frac{1\,000m_{\text{w}}}{1{,}065\,8V_1\left[1+0{,}003\,4(37-T_1)\right]}$$

AA.Annex FF Standard temperature sensor

The standard temperature sensor includes an additional copper thermal mass to effect an averaging of temperature across the circuit, to minimize effects of condensation forming on the sensor, to reduce effects of precise positioning of the sensor, to increase thermal transfer to the sensor, and to ensure a stable temperature measurement.

NOTE The copper sleeve is most easily manufactured from standard copper tube, diameter 3,18 mm (1/8 in). The temperature bead can be a YSI series 400 bead (Yellow Springs Instruments, Inc., P.O. Box 279, Yellow Springs OH 45387, USA; this information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named; equivalent products may be used if they can be shown to lead to the same results) or equivalent, e.g. Fenwal 192-222LET-DO1. Dimensions are not critical within reason. The simplest dimension check on the copper sleeve is by mass. The sleeve is 0,23 g **nominal** mass. A tolerance of ± 0,05 mm on all dimensions equates to ± 0,03 g.

Annex BB
(normative)

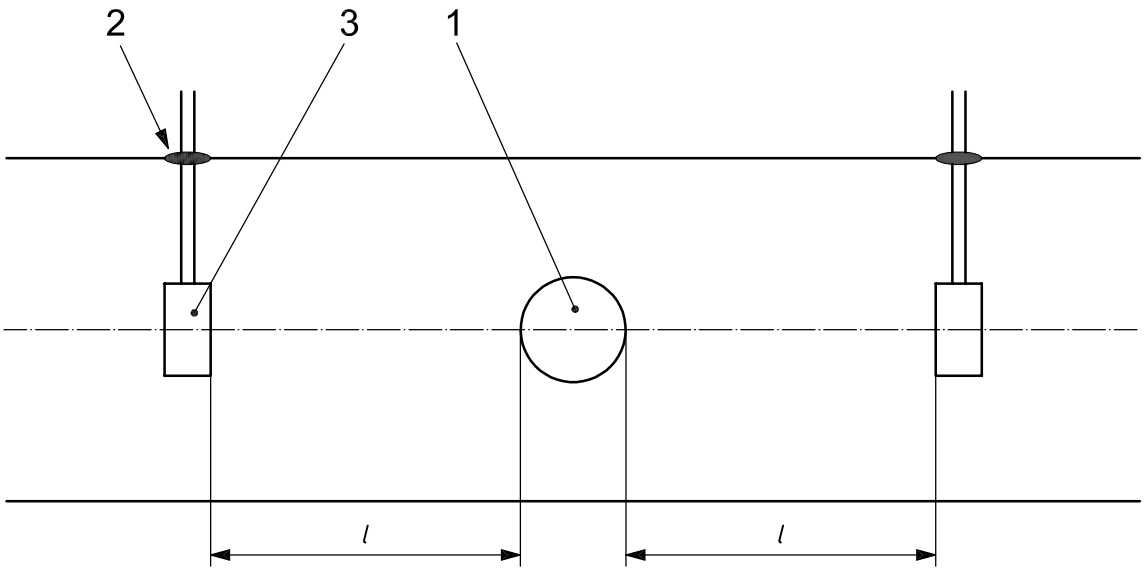
* Determination of the accuracy of the displayed temperature

BB.1 Test preparation

Confirm the accuracy of the displayed temperature by introducing two standard temperature sensors, as defined in Annex FF, into the **humidification system** that is configured in accordance with the **accompanying documents.** The configuration of the sensors is shown in Figure BB.1.

If necessary, add extension tubing so that ambient drafts and temperatures do not unduly influence the sensors. Such tubing should be of the same diameter as the **breathing tubes** and long enough so that all sensors are located at a distance from ambient drafts equal to at least ten times the **breathing tube** diameter.

The distances from the normal location of the **humidification system's** temperature sensor to the location of the standard temperature sensors (distance *l* in Figure BB.1) shall be equal, and shall measure from 20 mm to 30 mm.



Key

1 normal location
2 seal
3 standard temperature sensor

Figure BB.1 — Configuration for displayed temperature accuracy test

BB.2 Test procedure

Carry out testing as follows.

a) Sample temperature at least every 2 s.

*b) Operate the **humidification system** over the flowrate range indicated in the **accompanying documents**.*

*c) Set the minimum **set temperature** and confirm that the **measured gas temperature** is within ± 2 °C of the arithmetic mean of the two standard temperature sensors in a steady-state condition.*

*d) Quickly change the **set temperature** from the minimum to the maximum setting. This change should simulate a step function from minimum to maximum to the extent that it is practical.*

*e) Confirm that the **measured gas temperature** is within ± 2 °C of the arithmetic mean of the two standard temperature sensors in a steady-state condition for the maximum **set temperature**.*

Annex CC
(informative)

Specific enthalpy calculations

CC.1 Calculation of specific enthalpy

Specific enthalpy is calculated using the equations given below (see References [6], [7] and [12]). Measurement of the temperature at the **humidification chamber** outlet and of the **delivered gas temperature** is made with the standard temperature sensor, as defined in Annex FF, and should be sampled at least every 2 s.

NOTE 1 The equations given in this annex do not account for the enthalpy contribution of water in droplet form, nor do they apply to nebulizing **humidifiers**.

The temperatures, t_d and t_h, are measured:

t_d is the temperature, expressed in degrees Celsius, of the delivered gas;

t_h is the temperature, expressed in degrees Celsius, of the delivered gas or of the humidification chamber outlet, whichever is lower.

NOTE 2 $t_h = t_d$ when the **humidification chamber** outlet is the **patient connection port**.

The vapour pressure, p_v, expressed in kilopascals, is calculated as follows:

$$p_v = 10^{30,590\,51 - 8,2 \lg T_h + 2,480\,4 \times 10^{-3} \times T_h - \left(\frac{3\,142,31}{T_h}\right)}$$

For each measurement of the temperatures, calculate p_v, w (humidity ratio), and h (specific enthalpy) as follows.

The absolute temperature, T, expressed in kelvins, is calculated as follows:

$$T_h = 273,15 + t_h$$

$$T_d = 273,15 + t_d$$

The humidity ratio, w, expressed as a mass fraction (kg/kg), is calculated as follows (assuming the total gas pressure is equal to 101,325 kPa):

$$w = 0,625 \times \frac{p_v}{101,325 - 1,005 p_v}$$

The specific enthalpy, h, is calculated as follows:

$$h = 1,006\,7 t_d + w(2\,501,82 + 1,8 t_d)$$

Then, for any 30 s period, calculate the average specific enthalpy, $\bar{h}$, as follows:

Error! Objects cannot be created from editing field codes.

where

$h(t)$ is the specific enthalpy h at time t;

Δt < 2 s;

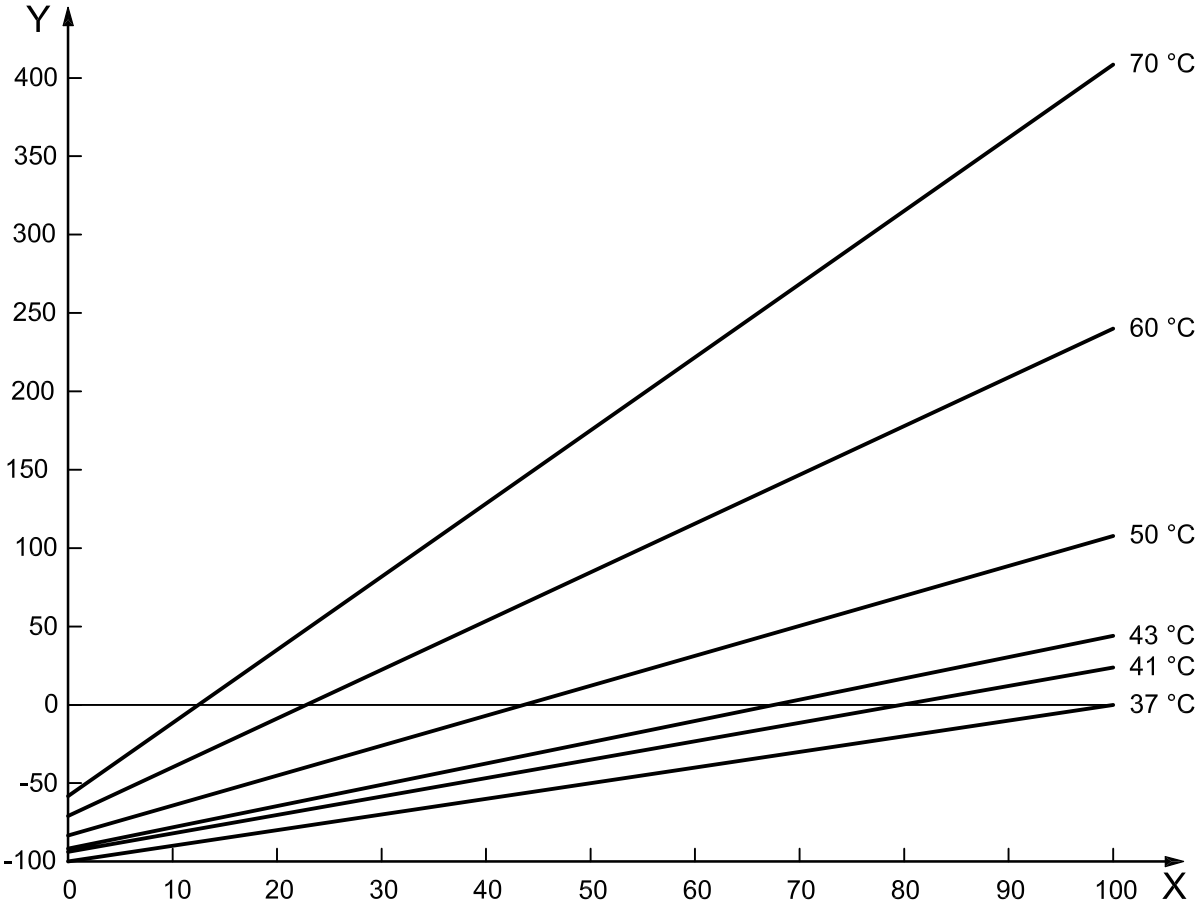
$N\Delta t$ is the time interval of 30 s;

t' is any time after warm-up period.

CC.2 Heat transfer calculations

Energy content or specific enthalpy is not directly measurable; however, it can be determined from the temperature and water vapour content of the gas. The gas exiting the **humidifier** is assumed to be at 100 % RH to give a worst-case energy content via the maximum water vapour content. However, if it can be demonstrated or measured otherwise, this would be a more appropriate figure to use. At the time of publication of this International Standard, no commercially available humidity measuring devices with adequate response time or appropriate thermal characteristics were known to exist.

Temperature alone does not determine whether a humidified gas presents a thermal hazard to a **patient**. The degree of saturation also needs to be known in order to determine the thermal energy of the humidified gas (see Figure CC.1).



Key

X relative humidity, %

Y Q, total energy, J

Figure CC.1 — Heat transfer, relative to 37 °C, saturated

The total energy transferred, Q_{total}, is calculated as follows:

$$Q_{total} = Q_a + Q_w + Q_{wv} + Q_{lhv}$$

where

Q_a is the heat transferred by air and

$$Q_a = c_{p,a} \times m_a \times T_a$$

where

$c_{p,a}$ is the specific heat capacity at constant pressure of air;

m_a is the mass of air;

T_a is the temperature of air;

Q_w is the heat transferred by water, and

$$Q_{\mathrm{w}} = c_{p,\mathrm{w}} \times m_{\mathrm{w}} \times T_{\mathrm{w}}$$

where

$c_{p,\mathrm{w}}$ is the specific heat capacity at constant pressure of water;

m_{w} is the mass of water;

T_{w} is the temperature of water;

Q_{wv} is the heat transferred by water vapour, and

$$Q_{\mathrm{wv}} = c_{p,\mathrm{wv}} \times m_{\mathrm{wv}} \times T_{\mathrm{wv}}$$

where

$c_{p,\mathrm{wv}}$ is the specific heat capacity at constant pressure of water vapour;

m_{wv} is the mass of the water vapour;

T_{wv} is the temperature of water vapour;

Q_{lhv} is the latent heat of vaporization, and

$$Q_{\mathrm{lhv}} = 2\,410\ \mathrm{J/g} \times m_{\mathrm{wv}} \times T$$

CC.3 Example of specific enthalpy calculation

Heat capacity of 1 l of saturated air at 50 °C and when cooled to 37 °C with the characteristics given in Table CC.1.

Table CC.1 — Thermal characteristics for saturated air

Quantity	Temperature 50 °C	Temperature 37 °C
Absolute humidity	83 mg/l	44 mg/l
Density of air	1,089 0 g/l	1,138 4 g/l
c_p of dry air	1,008 0 J/g °C	1,006 7 J/g °C
c_p of water	4,179 J/g °C	4,179 J/g °C
c_p of water vapour	1,884 J/g °C	1,884 J/g °C
Latent heat	2,382 J/g	2,413 J/g

Using the values given in Table CC.1, the heat capacity is calculated as given in Table CC.2.

Table CC.2 — Calculation of heat capacity of 1 litre of saturated air at 50 °C and when cooled to 37 °C

Heat	Heat calculation at	
	50 °C	37 °C
Q_a	1,008 0 J/g °C × (1 l × 1,089 0 g/l) × 50 °C = 54,89 J	1,006 7 J/g °C × (1 l × 1,138 4 g/l) × 37 °C = 42,40 J
Q_w	4,179 J/g °C × (1 l × (0) × 10^{-3} g/l) × 50 °C = 0 J	4,179 J/g °C × (1 l × (83 – 44) × 10^{-3} g/l) × 37 °C = 6,03 J
Q_{wv}	1,884 J/g °C × (83 × 10^{-3} g/l) × 50 °C = 7,82 J	1,884 J/g °C × (44 x 10^{-3} g/l) × 37 °C = 3,07 J
Q_{lhv}	2,382 J/g × (1 l × (83 × 10^{-3} g/l) = 197,71 J	2,413 J/g × (1 l × (83-44) × 10^{-3} g/l) = 94,11 J
Q_{total}	54,89 +0 +7,82 + 197,71 = 260,42 J	42,40 + 6,03 +3,07 + 94,11 = 145,61 J
$\Delta Q_{(50\ ^\circ C\text{-}37\ ^\circ C)}$	260,42 – 145,61 = **114,81 J**	

CC.4 Expression in terms of thermodynamic properties

The thermal energy of the humidified gas can be expressed in terms of its thermodynamic properties. Applying the first law of thermodynamics for the transfer of thermal energy under an isobaric (constant **pressure**) condition yields:

$$\mathrm{d}Q = \mathrm{d}U + \mathrm{d}W$$

Calculating work under an isobaric condition:

$$\mathrm{d}W = p\mathrm{d}V$$

Therefore

$$\mathrm{d}Q = \mathrm{d}U + p\mathrm{d}V$$

and as cited from Reference [18]:

"We find that in this very restricted case (constant **pressure**), the heat transfer during the **process** is given in terms of the change in the quantity $U + pV$ between initial and final states. Inasmuch as all of these quantities are thermodynamic properties, functions only of the state of the system, their combination has these same characteristics. Therefore, we find it convenient to define a new extensive property called enthalpy, H:

$$H = U + pV$$"

By "extensive property" is meant one that cannot be directly measured but needs to be calculated (e.g. enthalpy), in contrast to an intensive property, which can be directly measured (e.g. temperature).

Differentiating

$$\mathrm{d}H = \mathrm{d}U + p\mathrm{d}V + V\mathrm{d}p$$

Substituting

$$\mathrm{d}Q = \mathrm{d}U + p\mathrm{d}V$$

Therefore

$$\mathrm{d}H = \mathrm{d}Q + V\mathrm{d}p$$

Under isobaric conditions, dp = 0, therefore:

$$dH = dQ$$

The value of specific enthalpy of 194 kJ/kg (dry gas) represents a safe level delivered in any 30 s period. This specific enthalpy level is based on References [20] and [22].

Annex DD
(normative)

Temperature sensors and mating ports

DD.1 Dimensional requirements for temperature sensors

Check dimensional accuracy as follows:

a) Maintain the temperature sensor and gauge at ambient air temperature.

b) Ensure that the axial length of the taper of temperature sensors is at least 10,5 mm.

c) Engage the temperature sensor with the ring gauge shown in Figure DD.1, by applying an axial force of (35,0 ± 3,5) N and while maintaining the same force rotating the sensor up to 20°.

d) Ensure that leading edge is within the minimum and maximum steps of the gauge.

Dimensions in millimetres
Surface roughness values in micrometres

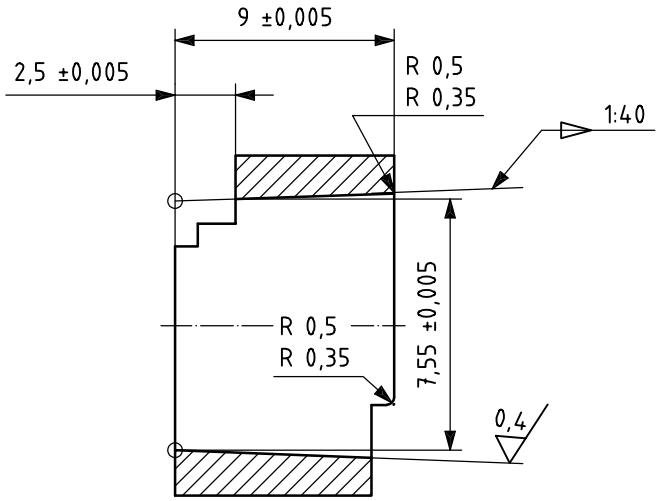


Figure DD.1 — Temperature sensor gauge

DD.2 Test method for security of engagement of temperature sensors to mating ports

Carry out security of engagement testing as follows:

a) Condition temperature sensors and mating ports at (41 ± 2) °C and (95 ± 5) % RH for at least 1 h.

b) Engage the temperature sensor with the mating port in accordance with the ***accompanying documents****.*

c) Condition the engaged components, without activation of any disengagement mechanism, for at least 1 h at the conditions specified in a).

d) Apply an axial separation force of (25 ± 2,5) N for 10 s at a rate not exceeding 20 N/s.

Annex EE
(normative)

* Determination of humidification system output

EE.1 General

*Carry out measurements over the flowrates, the operating ambient temperature range, and the operating gas inlet temperature range as indicated in the **accompanying documents** and **operator** control settings, as stated in 6.8.2 a) 6).*

EE.2 Test preparation

Perform the following test preparation at the specified test settings, with measurement apparatus and for sufficient duration such that a total measurement accuracy of $\pm$ 1 mg/l is achieved.

a) *Configure the humidification system in accordance with the accompanying documents.*

b) *Mount the entire test set-up on a set of scales so that mass measurements can be made simply and accurately.*

c) *If necessary, add extension tubing such that ambient drafts and temperatures do not unduly influence sensors. Ensure that the extension tubing is of equal diameter to the **breathing tube** and of length such that all sensors are located at a distance from ambient drafts equal to at least ten times the **breathing tube** diameter.*

d) *Arrange relative elevations of the **humidifier**, **breathing tube** and **humidification chamber**, as applicable, such that:*

   — *Condensation that does not represent humidification reaching the **patient** (e.g. condensation in the inspiratory limb) does not leave the **humidification system** and is included in m_1 [the mass of the humidifier, its contents and the recommended breathing tube as defined in EE.3 d)].*

   — *Condensation that represents humidification reaching the **patient** (e.g. condensation occurring in the instrumental dead space) leaves the **humidification system** and is not included in m_1 [see EE.3 d)].*

e) *Install a temperature sensor as defined in Annex FF in the air stream at a site representing the **delivered gas temperature**. Call this temperature T_2 (°C).*

f) *Connect the **humidifier** to a medical grade dry gas source. Perform this test with the temperature of this dry gas entering the **humidification chamber** within $\pm$1 °C of the minimum and maximum gas inlet temperature specified in the **accompanying documents**. Call this temperature T_1 (°C).*

g) *If the **humidifier** or its **breathing tube** is heated and the test is being carried out in the heated mode, allow the temperature to stabilize for the recommended warm-up time.*

h) *Turn off the **humidifier**; disconnect all **accessories**, including the air supply, electrical connections and any extension tubing to remove any extraneous influences on the mass measurement. Weigh only the **humidifier**, its contents and the recommended **breathing tube**; record this mass as m_0. This is the initial mass of the **humidification system**.*

i) *Express the **humidification system output** in milligrams per litre of moist gas [normalized to body temperature, standard pressure, saturated (BTPS)].*

j) Repeat steps f) to h) under the following conditions:

— the minimum gas inlet temperature, the minimum operating ambient temperature and the minimum flowrate,

— the minimum gas inlet temperature, the minimum operating ambient temperature and the maximum flowrate,·

— the minimum gas inlet temperature, the maximum operating ambient temperature and the minimum flowrate,·

— the minimum gas inlet temperature, the maximum operating ambient temperature and the maximum flowrate,·

— the maximum gas inlet temperature, the minimum operating ambient temperature and the minimum flowrate,·

— the maximum gas inlet temperature, the minimum operating ambient temperature and the maximum flowrate,·

— the maximum gas inlet temperature, the maximum operating ambient temperature and the minimum flowrate,·

— the maximum gas inlet temperature, the maximum operating ambient temperature and the maximum flowrate, specified in the **accompanying documents.**

EE.3 Test procedure

*Perform the following test **procedure** at the specified test settings, with measurement apparatus and for sufficient duration such that a total measurement accuracy of ± 1 mg/l is achieved.*

a) Reconnect all **accessories**. Turn the **humidifier** back on to begin the test (record time as t_0) and maintain **operator** control settings throughout the test. Monitor the dry gas flowrate and temperature to ensure compatibility with the objective of a total measurement accuracy of 1 mg/l.

b) Stop the test when the measurement of the following quantities maintains a total measurement accuracy of ± 1 mg/l:

— *the **humidifier** has used a sufficient quantity of the usable capacity of the **liquid container**; and*

— *the test is of sufficient duration.*

c) Record the time as t_1 and record the duration of the test ($t_1 - t_0$).

Special attention is drawn to the objective of a total measurement error of less than ± 1 mg/l. Measurement of time, temperature, especially flowrate and mass used, should be sufficiently accurate relative to the value of the quantity to maintain that objective. In practice, the mass and estimated output of the **humidifier** will give a guide as to the minimum duration of the test to maintain overall accuracy. An error analysis of the measurement apparatus and estimated results is strongly recommended as a guide.

d) Make a mass measurement as for m_0 above; record this mass as m_1. The difference $m_0 - m_1$ represents the total moisture reaching the **patient** over the test duration.

The **humidification system output**, n_{BTPS}, expressed in milligrams per litre of moist gas normalized to BTPS (body temperature, standard pressure, saturated) is given by the following equation:

$$n_{BTPS} = \frac{1000 m_w}{1{,}065\ 8\ V_1[1 + 0{,}003\ 4(37 - T_1)]} n_{BTPS}$$

where

m_w is the mass, in grams, of water used and

$m_w = (m_0 - m_1)$

where

m_0 is the mass, in grams, at time t_0;

m_1 is the mass, in grams, at time t_1;

V_1 is the volume in litres of dry gas normalized to standard temperature and pressure (STP) (i.e. the product of flowrate and the duration of test);

T_1 is the temperature of dry gas, in degrees Celsius.

Annex FF
(normative)

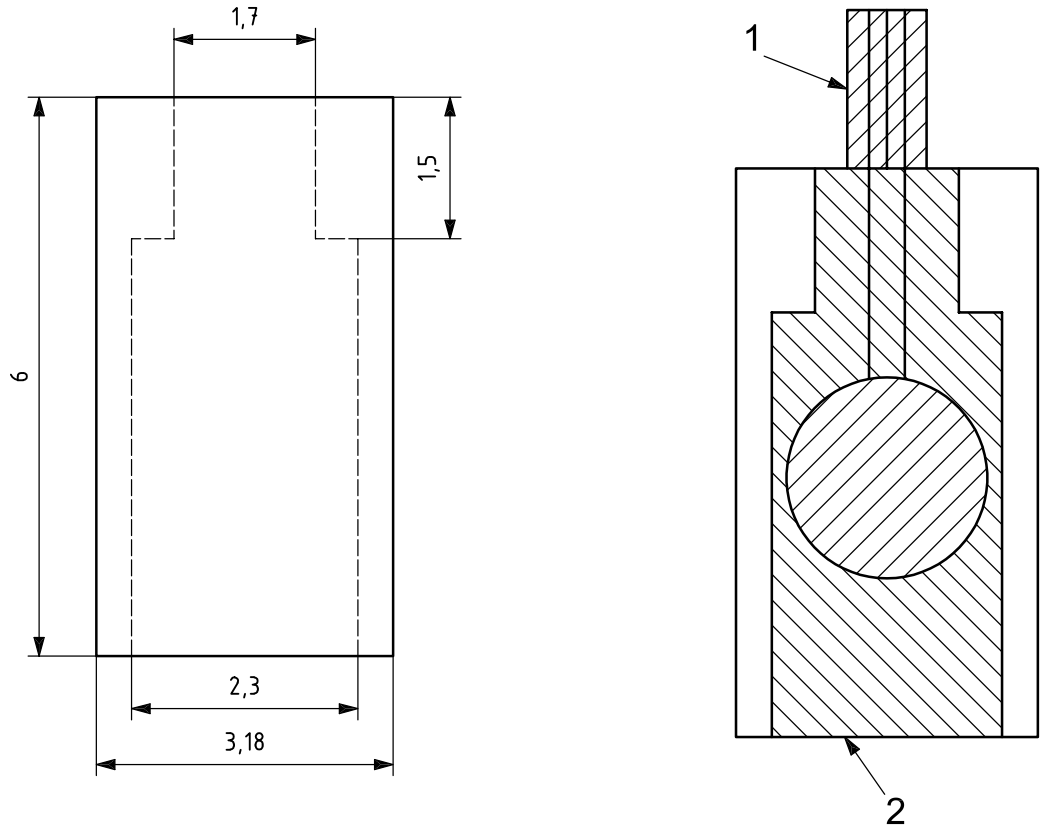
* Standard temperature sensor

The standard temperature sensor shall meet the requirements indicated below. See also Figure FF.1. A properly assembled standard temperature sensor shall have the following performance characteristics:

a) time constant > 0,5 s and < 1,0 s for a step change of 22 °C to 37 °C in water at a flowrate of 1 m/s;

b) influenced by changes in ambient temperature of < 0,01 °C per 1 °C.

Dimensions in millimetres



a) Sheath for standard temperature sensor **b) Standard temperature sensor construction**

Key

1 electrical insulation
2 epoxy casing

Figure FF.1 — Standard temperature sensor

An example of the construction characteristics of such a sensor is as follows.

— A sheath with thermal conductivity > 386 W/(m · K) with the dimensions given in Figure FF.1; e.g. a piece of solid 1/8 inch copper rod with appropriate drilled spaces;

— A thermistor with an accuracy of ± 0,1 °C from 25 °C to 45 °C in isothermal stirred air or water, e.g. YSI series 400 bead, Fenwal 192-222LET-D01[1)] ;

— Epoxy the thermistor into the copper sheath, as in Figure FF.1 b). The epoxy has a thermal conductivity > 0,183 W/(m · K), e.g. Creative Materials Inc. (CMI) 108-50 thermally conductive, low-stress epoxy[1)].

— The electrical leads have a conductivity < 180 W/(m · K) (i.e. copper alloy). The leads have a minimum length of 60 mm. The electrical insulation has a thermal conductivity < 0,02 W/(m · K), e.g. polyvinylchloride (PVC).

1) This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Annex GG
(informative)

Environmental aspects

The environmental impact generated by a **humidification system** performing humidification of respiratory tracts is mainly isolated to the following occurrences:

— impact at local environment during **normal use**;

— disposal of contaminated biologic fluids during **normal use**;

— use, cleaning and disposal of consumables during testing and **normal use**;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this International Standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during the different stages of the **humidification system**.

See Table GG.1 for a mapping of the life cycle of a **humidification system** to aspects of the environment.

Table GG.1 — Environmental aspects addressed by clauses of this International Standard

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stade A	Distribution (including packaging) Stade B	Use Stade C	End of life Stade D
		Addressed in Clause	Addressed in Clause	Addressed in Clause	Addressed in Clause
1	Resource use	1	1	1	1
2	Energy consumption	1	1	1 42	—
3	Emission to air	1	1	1 6.1 6.8.2 29 36 42 43 44 45 56.7 56.101 57 59	1
4	Emission to water	1	1	1 6.8.2 44	1
5	Waste	1	1 10.1	1 6.1 6.8.2 44 56.7	1 6.1 6.8.2
6	Noise	—	—	1 35	—

Table GG.1 *(continued)*

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stade A	Distribution (including packaging) Stade B	Use Stade C	End of life Stade D
		Addressed in Clause	Addressed in Clause	Addressed in Clause	Addressed in Clause
7	Migration of hazardous substances	1	—	1 6.1 6.8.2 25 44 45 48 56.7	1
8	Impacts on soil	—	—	—	1 6.8.2
9	Risks to the environment from accidents or misuse	1	—	1 6.8.2 44 45 56 57	1

Annex HH
(informative)

Reference to the essential principals of safety and performance

This International Standard has been prepared to support the essential principles of safety and performance of **humidifiers** as medical devices in accordance with ISO/TR 16142. This International Standard is intended to be acceptable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2006, Table A.1. Other means are possible.

Table HH.1 — Correspondence between the essential principles and this International Standard

Essential principal of ISO/TR 16142:2006, Table A.1	Corresponding Clause/Subclause of this International Standard	Comments
A.1	All	
A.2	All, 6.8.2 a), 50.2 aa), 50.2 bb), 50.2 cc), 51.101, 51.102, 51.103, 103, 201	
A.3	All, 101, 102	
A.4	10.2, 21, 23, 24, 35.101, 36, 42.101, 49, 51, 101	And via IEC 60601-1, Clauses 21, 23, 24, 49
A.5	10.1, 21	And via IEC 60601-1, Subclause 10.1 and Clause 21
A.6	13.1	And via IEC 60601-1, Clause 6
A.7.1	43, 43.101, 44.8, 48	And via IEC 60601-1, Clauses 43, 48
A.7.2	44, 44.2, 44.8, 52, 56.101	And via IEC 60601-1, Clause 52
A.7.3	43.101, 44.8, 56.101	
A.7.4	—	
A.7.5	44, 44.2, 44.4, 56.102	
A.7.6	44, 44.3, 44.6, 52	Via IEC 60601-1, Clause 52
A.8.1	44.7	And via IEC 60601-1, Clause 44.7
A.8.1.1	—	
A.8.1.2	—	
A.8.2	—	
A.8.3		
A.8.4	44.7	
A.8.5	44.7	
A.8.6	—	
A.9.1	6.6, 56, 56.3, 56.101, 56.102, 103	And via IEC 60601-1, Subclause 6.6, Clause 56 and IEC 60601-1-8

Essential principal of ISO/TR 16142:2006, Table A.1	Corresponding Clause/Subclause of this International Standard	Comments
A.9.2	21, 23, 36, 36.202.1, 45, 49, 52	And via IEC 60601-1, Clauses 21, 23, 36, 45, 49, 52
A.9.3	37, 38, 39, 40, 41, 43, 52, 56.7, 59	And via IEC 60601-1, Clauses 52, 59
A.10.1	6.3, 50, 50.2	And via IEC 60601-1, Subclause 6.3, Clause 51
A.10.2	46, 50.2, 102	And via IEC 60601-1, Clause 46
A.10.3	6.3	And via IEC 60601-1, Subclause 6.3
A.11.1	—	
A.11.2.1	—	
A.11.2.2	—	
A.11.3	29	Via IEC 60601-1, Clause 29
A.11.4	—	
A.11.5.1	—	
A.11.5.2	—	
A.11.5.3	—	
A.12.1	4 [3.6 cc)]	Via IEC 60601-1-8
A.12.2	—	Via IEC 60601-1, Subclause 56.7
A.12.3	—	
A.12.4	—	
A.12.5	36	Via IEC 60601-1, Clause 36
A.12.6	15, 16, 17, 18, 19, 20, 56, 57, 58, 59	Via IEC 60601-1, Clauses 15, 16, 17, 18, 19, 20, 56, 57, 58, 59
A.12.7.1	21, 22, 23, 24, 25, 28, 52	Via IEC 60601-1, Clauses 21, 22, 23, 24, 25, 28, 52
A.12.7.2	26	Via IEC 60601-1, Clause 26
A.12.7.3	35, 35.101, 103	And via IEC 60601-1, Clause 35 and IEC 60601-1-8
A.12.7.4	10.2.101, 57	And via IEC 60601-1, Clause 57
A.12.7.5	42, 42.101, 51, 56, 56.3	And via IEC 60601-1, Clauses 42, 56
A.12.8.1	42.101, 50, 50.2 aa), 50.2 bb), 51, 56.101	
A.12.8.2	50.2 cc), 56.101	
A.12.8.3	6.3, 6.7, 50.1, 103	And via IEC 60601-1, Subclauses 6.3, 6.7 and IEC 60601-1-8
A.13.1	6, 103	Via IEC 60601-1, Clause 6 and IEC 60601-1-8
A.14.1	—	

Annex II
(informative)

Terminology — Index of defined terms

accessible surface temperature 3.1

accessory ..... IEC 60601-1:1988, 2.1.3

accompanying documents ..... IEC 60601-1:1988, 2.1.4

active HME 3.2

alarm condition ..... IEC 60601-1-8:2003, 2.201

alarm paused ..... IEC 60601-1-8:2003, 2.205

alarm signal ..... IEC 60601-1-8:2003, 2.209

alarm system ..... IEC 60601-1-8:2003, 2.211

audio paused ..... IEC 60601-1-8:2003, 2.213

breathing system ..... ISO 4135:2001, 4.1.1

breathing tube ..... ISO 4135:2001, 4.1.2

delivered gas temperature 3.3

equipment ..... IEC 60601-1:1988, 2.2.11

false negative alarm condition ..... IEC 60601-1-8:2003, 2.220

false positive alarm condition ..... IEC 60601-1-8:2003, 2.221

flow-direction-sensitive component ..... ISO 4135:2001, 4.3.11

heated breathing tube controller 3.4

humidification chamber 3.5

humidification system 3.6

humidification system output 3.7

humidifier 3.8

life-supporting equipment ..... IEC 60601-1-2:2001, 2.2.19

liquid container 3.9

liquid reservoir 3.10

maximum operating pressure 3.11

measured gas temperature 3.12

medium priority ..... IEC 60601-1-8:2003, 2.228

nominal ..... IEC 60601-1:1988, 2.12.3

normal condition ..... IEC 60601-1:1988, 2.10.7

normal use ..... IEC 60601-1:1988, 2.10.8

operator ..... IEC 60601-1:1988, 2.12.17

patient ..... IEC 60601-1:1988, 2.12.4

patient connection port ..... ISO 4135:2001, 4.2.1.2

patient leakage current ..... IEC 60601-1:1988, 2.5.6

rated ..... IEC 60601-1:1988, 2.12.8

relative humidity 3.13

safety hazard ..... IEC 60601-1:1988, 2.12.18

set temperature 3.14

single fault condition ..... IEC 60601-1:1988, 2.10.11

user ..... IEC 60601-1:1988, 2.12.13

Bibliography

[1] ISO 14971, *Medical devices — Application of risk management to medical devices*

[2] ISO/TR 16142:2006, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[3] IEC 60601-2-12:2001, *Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators*

[4] ANSI/AAMI HE48-1993, *Human factors engineering guidelines and preferred practices for the design of medical devices*

[5] ASTM F1690-96, *Standard specification for humidifiers for medical use — Part 1: General requirements for active humidification systems*

[6] Report from SWG 17 of IEC 60Sc 62A on Thermal Hazards, draft, 62A (Brighton, WG 17), 9 July 1989

[7] Report of the Naval Medical Research and Development Command, Physiological Design Goals for Thermal Protection for Divers, Conference report of 5 September 1980

[8] CHALON, J., LOEW, D., MALEBRANCHE, J. Effect of dry anesthetic gases on tracheobronchial ciliated epithelium. *Anesthesiology*, **37**(3), pp. 338-343, 1972

[9] DERY, R., PELLETIER, J., JACQUES, A., CLAVET, M., HOUDE, J.J. (1997). Humidity in anaesthesiology. III. Heat and moisture patterns in the respiratory tract during anaesthesia with the semi-closed system, *Can. Anaes. Soc. J.*, **14**(4) pp. 287-298

[10] DERY, R. (1973). The evolution of heat and moisture in the respiratory tract during anaesthesia with a non-rebreathing system. *Can. Anaes. Soc. J.*, **20**(3), pp. 296-309

[11] FONKALSRUD, E.W., SANCHEZ, M., HIGASHIJIMA, I., ARIMA, E. (1975). A comparative study of the effects of dry vs. humidified ventilation on canine lungs, *Surgery*, **78**(3), pp. 373-380,

[12] GOFF, J.A. and GRATCH, S. Thermodynamic properties of moist air. *Trans ASHVE*, **51**, pp. 125-164, 1945

[13] GOFF, J.A. and GRATCH, S. (1945). Low pressure properties of water from -160 to 212 F. *Trans ASHVE*, **52**, pp. 92-122

[14] GOFF, J.A. Standardization of thermodynamic properties of moist air. *Trans ASHVE*, **55**, pp. 59-484

[15] HEIRONIMUS, T. and BAGEANT, R.A. *Mechanical Artificial Ventilation, a Manual for Students and Practitioners. Chapter 6, Airway Humidification — Vapor and Aerosol Therapy*, pp. 387-401. Springfield, IL, Charles C. Thomas Publishing Co. 1977

[16] HORSTMANN, G., IRAVANI, J., NORRIS, M.G., RICHTER, H.G. (1977). Influence of temperature and decreased water content of inspired air on the ciliated bronchial epithelium. A physiological and electron microscopical study, *Acta. Otolaryngol.*, **84**(1-2), pp. 124-31

[17] LELLOUCHE, F., TAILLE, S., MAGGIORE, S.M., QADER, S., Il'HER, E., DEYE, N., BROCHARD, L. (2004). Influence of ambient and ventilator output temperatures on performance of heated-wire humidifiers. *Am. J. Respir Crit. Care. Med.*, **170**(10), pp. 1073-1079; Epub 2004 Jul 21

[18] MIYAO, H., MIYASAKA, K., HIROKAWA, T., KAWAZOE, T. (1996). Consideration of the International Standard for airway humidification using simulated secretions in an artificial airway, *Respiratory Care*, **41**(1), pp. 43-49

[19] MIYAO, H., HIROKAWA, T., MIYASAKA, K., KAWAZOE, T. (1996). Relative humidity, not absolute humidity, is of great importance when using a humidifier with a heating wire. *Crit. Care. Med*., **20**(5), pp. 674-679

[20] MORITZ, A.R. and HENRIQUES, F.C., JR. (1974). Studies of thermal injury I. The relative importance of time and surface temperature in the causation of cutaneous burns. *Am. J. Pathol*., **23**, pp. 695-720

[21] SANDERS, M.S. and MCCORMICK, E.J., Eds. *Human Factors in Engineering and Design*, 7th edition, New York: McGraw Hill, 1993

[22] STOLL, A.M., GREENE, L.C. (1959). Relationship Between Pain and Tissue Damage Due to Thermal Radiation. *J. Appl. Physiol*. **14**(3), pp. 373-82

[23] VAN WYLEN, G.J. and SONNTAG, R.E. *Fundamentals of Classical Thermodynamics*, New York, John Wiley and Sons, 1985, p. 94.

[24] WALKER and WELLS, Jr. (1961). Heat and water exchange in the respiratory tract. *Am. J. Med.* **30**(2), pp. 259-267

[25] WILLIAMS, R., RANKIN, N., SMITH, T., GALLER, D., SEAKINS, P. (1996). Relationship between the humidity and temperature of inspired gas and the function of the airway mucosa. *Crit. Care. Med*. **24**(11), pp. 1920-1929

ICS 11.040.10

Price based on 49 pages