INTERNATIONAL STANDARD

ISO 10651-6

First edition
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Lung ventilators for medical use — Particular requirements for basic safety and essential performance —

Part 6: Home-care ventilatory support devices

Ventilateurs pulmonaires à usage médical — Exigences particulières pour la sécurité de base et les performances essentielles —

Partie 6: Dispositifs d'assistance respiratoire à domicile

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 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 10651-6 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This first edition of ISO 10651-6, together with the second edition of ISO 10651-2, cancels and replaces the first edition of ISO 10651-2:1996, which has been technically revised.

ISO 10651 consists of the following parts, under the general title *Lung ventilators for medical use — Particular requirements for basic safety and essential performance*:

— *Part 2: Home care ventilators for ventilator-dependent patients*

— *Part 3: Particular requirements for emergency and transport ventilators*

— *Part 4: Particular requirements for operator-powered resuscitators*

— *Part 6: Home care ventilatory support devices*

The following part is under preparation:

— *Part 5: Gas-powered emergency resuscitators*

NOTE ISO 10651-1:1993, *Lung ventilators for medical use — Part 1: Requirements,* was withdrawn in 2001 and has been revised as IEC 60601-2-12:2003, *Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators.*

Introduction

This part of ISO 10651 specifies requirements for ventilatory support devices mainly for home-care use but which could be used elsewhere (in healthcare facilities or other locations) for **patients** not dependent on ventilatory support, i.e. where the **ventilator** is not considered to be **life-supporting equipment**. These **ventilators** are frequently used in locations where driving power is not reliable. These **ventilators** often are supervised by non-healthcare personnel with varying levels of training.

This part of ISO 10651 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 Standards can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this part of ISO 10651, the following drafting conventions have been applied.

This part of ISO 10651 uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard, as supplemented by the Collateral Standards, 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 Particular Standard.

— “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list item, note, table, figure) additional to the General Standard.

— “Amendment” means that an existing element of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this part of ISO 10651: clauses, 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 part of ISO 10651, 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 and terms defined in this part of ISO 10651: **bold type**.

Throughout this part of ISO 10651, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

Requirements for ventilators intended for anaesthetic applications are given in ISO 8835-5.

Lung ventilators for medical use — Particular requirements for basic safety and essential performance —

Part 6: Home-care ventilatory support devices

1 Scope

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

Amendment:

This part of ISO 10651 specifies the basic safety and essential performance requirements for home-care ventilatory support devices, intended mainly for use in home care but which could be used elsewhere (e.g. in healthcare facilities) for appropriate **patients** for whom the use of a home-care **ventilator** complying with ISO 10651-2 is not required.

The requirements of this part of ISO 10651 which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

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 32, *Gas cylinders for medical use — Marking for identification of content*

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 5362, *Anaesthetic reservoir bags*

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

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

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices, and Technical Corrigendum 1:2003*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

IEC 60079-4, *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 *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, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability (at present Commmittee draft)*

IEC 60601-1-8:2003, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: Alarm systems — Requirements, tests and guidelines — General requirements and guidelines for alarm systems in medical electrical equipment and medical electrical systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, IEC 60601-1:1988 and the following apply:

3.1
airway pressure
pressure at the **patient connection port**

3.2
*** applied part**
part of the **equipment** which in **normal use**

— necessarily comes into physical contact with the **patient** for the **equipment** to perform its function, or

— can be brought into contact with the **patient**, or

— needs to be touched by the **patient**, or

— all parts of the **ventilator** intended to be connected to the **ventilator breathing system**.

NOTE Adapted from IEC 60601-1/A2:1995, 2.1.5

3.3
clearly legible
capable of being read by the **operator** or other relevant person with normal vision

3.4
home care ventilator for ventilator-dependent patient
ventilator, suitable for domiciliary use without continuous professional supervision, intended to augment or provide ventilation of the lungs of a **patient** who is dependent on this ventilation

NOTE As this **ventilator** is intended to be applied to **patients** who are dependent on this ventilation, it is considered to be **life-supporting equipment**.

3.5
home-care ventilatory support device for non-ventilator-dependent patients
ventilator
ventilator, suitable for domiciliary use without continuous professional supervision, intended to augment or provide ventilation of the lungs of a **patient** who is not dependent on this ventilation

NOTE 1 This **ventilator** support device is intended to be applied to **patients** who are not dependent on this ventilation and will survive without this ventilatory support, without significant degradation in their health.

NOTE 2 This term is hereinafter referred to as “ventilator”.

3.6
minute volume
$\dot{V}$
volume of gas per minute entering or leaving the lungs of the **patient**

3.7
operator's position
intended position of the **operator** in **normal use** of the **equipment**

4 General requirements and general requirements for tests

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

3.1 *

Amendment (add at the end of the subclause):

This shall include all displayed values and calibrated controls over the environmental ranges specified in 10.2.1 as well as the combination of all **accessories** specified by the manufacturer in the instructions for use.

Any fault that can lead to a hazard and that is not detected by intrinsic means or by periodic inspection (e.g. an oxidant leak, software defect) shall be regarded as a **normal condition** and not a **single fault condition**.

3.4

Amendment (add at the end of the subclause):

An equivalent degree of safety can be demonstrated by means of a risk analysis, in accordance with ISO 14971.

5 Classification

IEC 60601-1:1988, Clause 5 applies, except as follows.

5.2

Additon (add at the end of the subclause):

NOTE A **ventilator** may have **applied parts** of different types.

6 Identification, marking and documents

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

6.1 Marking on the outside of equipment or equipment parts

Replacement:

e) Indication of origin

The name and address of the manufacturer and authorized representative, if applicable.

Amendment [add at the end of the list item j)]:

j) Power input

The **rated** power input marking shall include the maximum **rated** power output available to the **auxiliary mains socket-outlets** with which the **ventilator** is equipped.

Amendment [add at the end of the list item q)]:

q) Physiological effects

If applicable, a warning that latex is used.

Addition:

aa) Any **high-pressure input port** shall be marked with the name or symbol of gas in accordance with ISO 5359 and with the supply pressure range and the maximum flow requirements. If gas-specific colour-coding of flow control or flexible hoses is used, it shall be in accordance with ISO 32:1977.

bb) **Operator-**accessible ports shall be marked. If symbols are used, they shall be explained in the instructions for use and validated in accordance with IEC 60601-1-6.

cc) Any particular storage and transport instructions.

dd) * Any particular warnings and/or precautions relevant to the immediate use of the **ventilator**.

EXAMPLE After storage or transport outside the environmental conditions specified for use.

ee) Where appropriate, the date after which the safe operation of the **ventilator** or **accessory**, when used for the first time, is not assured, expressed as the year and month. Symbol 3.12 from ISO 15223:2000 may be used.

ff) Packages containing breathing attachments shall be clearly marked with the following, as far as applicable:

1) a description of the contents;

2) an identification reference to the type, or Symbol 3.13 from ISO 15223:2000;

3) an identification reference to the batch or serial number, or Symbol 3.14 or 3.16 from ISO 15223:2000;

4) the name or trademark and address of the manufacturer, supplier, and authorized representative;

5) packages containing latex shall be clearly marked with the word ‘LATEX’;

6) the word “STERILE”, or Symbols 3.20 to 3.24 from ISO 15223:2000;

7) the words “SINGLE USE ONLY”, “DO NOT REUSE”, or Symbol 3.2 from ISO 15223:2000;

gg) All **flow-direction-sensitive components** that are **operator-**removable without the use of a tool shall be durably and legibly marked with an arrow indicating the direction of the flow.

hh) Device packaging and/or labelling shall differentiate between sterile and non-sterile versions of the same or similar products placed on the market by the same manufacturer [see 6.1 ff) 6].

6.3 Marking of controls and instruments

Amendment [add at the end of the list item g)]:

g)

Airway pressures shall be marked in both an SI unit and centimetre water column (cm H_2O).

Addition:

aa) Visual displays shall be visible and **clearly legible**.

Amendment (add at the end of the compliance test):

and the legibility test of 6.101.

6.6 Identification of medical gas cylinders and connections

Replacement:

If gas-specific colour-coding is used (e.g. for flow controls, flexible hoses, gas cylinders, etc.) it shall be in accordance with ISO 32. See also 56.3 aa).

6.8.2 Instructions for use

Amendment [add at the end of the list item d)]:

d) Cleaning, disinfection and sterilization of parts in contact with the **patient**

If applicable, the instructions for use shall contain

— information about cleaning and sterilization prior to first use,

— information about cleaning, disinfection and sterilization and any restriction concerning re-use,

— instructions which indicate the maximum number of reprocessing cycles of cleaning, disinfection and sterilization before a component can no longer be used, or instructions which indicate the visual or functional pass/fail criteria to be used in determining when a component can no longer be used after reprocessing.

Additions:

aa) Additional general information

The instructions for use shall include the following:

1) the intended use of the **ventilator**;

2) description of **operator-**accessible ports. See also 6.1 bb) and 56.3 dd);

3) the **rated** supply range and consumption that is required for **normal use** of the **ventilator** (see also 49.101 e.g. voltage, current, pressure, flow);

4) information necessary to ensure that the **ventilator** is installed correctly and is in safe and correct working order;

5) a method for testing the function of the **alarm system** for each possible **alarm condition** and a recommendation for the interval of testing;

6) if the **ventilator** is provided with a reserve power supply,

   — how to determine the status of the reserve power source,

   — how the reserve power source can be tested, and

   — the functioning after a switchover to the reserve power supply.

7) * the ampere-hour rating of the **internal electrical power source** and the operational time after it has become fully charged;

8) if the **ventilator** has provision for an external reserve electrical power source (see 49.101 and 49.102),

   — the **rated** voltage range requirement,

   — the **nominal** voltage range, and

   — the maximum current requirement.

9) for each control and measured variable provided on the **ventilator**, a listing of the applicable range, resolution and accuracy (see also Clause 51);

   The accuracy should be expressed in the form of maximum zero error quoted in appropriate units, plus a sensitivity error quoted, e.g., as a percentage of reading.

10) * if the **ventilator** is specified as being suitable for use in environmental conditions which extend beyond those specified in 10.2.1 and performance is affected by this, disclosure of the extended limits and how the **ventilator** will be affected;

11) the inspiratory and expiratory pressure measured at the **patient connection port** at 60 l/min for **ventilators** intended for providing tidal volumes greater than 300 ml, or at 30 l/min for tidal volumes between 300 ml and 30 ml, or at 5 l/min for tidal volumes less than 30 ml, when the recommended **ventilator breathing system** is in use and normal ventilation is compromised by the total or partial loss of power supply (see 49.102);

12) a statement as to whether any portion of the gas supplied to a **high-pressure input port** is used as **fresh gas**;

13) * a statement to the effect that antistatic or electrically conductive hoses or tubing shall not be used;

14) warning statement to the effect that the **ventilator** shall not be covered or positioned in such a way that the operation or performance of the **ventilator** is adversely affected (e.g. positioned next to a curtain that blocks the flow of cooling air, thereby causing the **ventilator** to overheat);

15) a statement to the effect that adding attachments or other components or sub-assemblies to the **ventilator breathing system** can cause the pressure during expiration at the **patient connection port**, to increase;

16) a statement to the effect that, while the **ventilator** is in use, an alternative means of ventilation should always be available;

17) specifications about the nature and frequency of maintenance operations necessary to ensure continuing safe and correct operation. This information also applies to **accessory** components.

6.8.3 Technical description

Addition:

aa) Additional general information

The technical description shall include

— the conditions under which any measured or displayed flow, volume or ventilation is to be expressed, e.g. Ambient Temperature and Pressure Dry (ATPD) or Body Temperature and Pressure Saturated (BTPS) etc.,

— the principle, including a summary of algorithms, by which each **alarm condition** is detected,

— * the performance characteristics of the **ventilator** with any **ventilator breathing system**, breathing attachment, and other component or sub-assembly (e.g., breathing tubes, humidifier, filter, etc.) recommended by the manufacturer for inclusion in the **ventilator breathing system**,

— a pneumatic diagram of the **ventilator**, including each **ventilator breathing system** either supplied or recommended by the manufacturer,

— any restrictions on the sequence and directions of components intended to be placed within the **ventilator breathing system**, e.g. where such components are flow-direction-sensitive,

— interdependence of control functions,

— a listing of the following pressures:

  — **maximum steady limiting pressure** (p_{LSmax});

  — **minimum steady limiting pressure** (p_{LSmin});

  — range of values to which the **maximum working pressure** (p_{Wmax}) can be set and the means by which the maximum is limited (e.g. pressure cycling, pressure limiting, pressure generation);

  — range of values to which the **minimum working pressure** (p_{Wmin}) can be set and the means by which the minimum is achieved.

The technical description shall include, if applicable, the following:

— for all variables displayed or used for control, the filtering and/or smoothing techniques applied;

— if subatmospheric pressure can be used, the limiting pressure for the inspiratory and expiratory phases;

— the means of triggering; and

— the characteristics of the **breathing system filter**, e.g. connector size, dead space, compliance and flow resistance.

6.101 Test method for legibility

Clearly legible *indications are correctly perceived by an* ***operator*** *with a visual acuity of 0 on the log MAR scale or 6-6 (20/20) vision (corrected if necessary) from the* ***operator's position*** *or a distance of 1 m ± 10 % at a light level of (215 ± 65) lx, when viewing the information, markings, etc. perpendicular to and including 15° above, below, left and right of the line of sight of the* ***operator****.*

7 Power input

IEC 60601-1:1988, Clause 7 applies, except as follows.

Addition:

7.101 Pneumatic power

When the **rated** supply pressure range is maintained, the **rated** [see 6.1 aa)] maximum flow requirement, as measured at the **ventilator's high-pressure input port**, shall not be exceeded for more than 0,25 s.

Compliance is checked by inspection.

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:

b) an ambient temperature range of + 5 °C to + 40 °C;

c) an ambient relative humidity range of 10 % to 95 %;

d) an atmospheric pressure range of 600 hPa to 1 100 hPa;

e) an ambient temperature of + 45 °C combined with 75 % relative humidity.

Any extension (widening) of these conditions, as specified by the manufacturer, shall be disclosed in the **accompanying documents**. See also 6.8.2 aa) 10).

10.2.2 Power supply

Replacement:

a) *(third dashed list item):*

— voltage fluctuation not exceeding – 20 % to + 10 % of the **nominal** voltage;

Addition:

10.101 Pneumatic driving power supplies

If the **ventilator** is intended to be connected to a medical gas pipeline system complying with ISO 7396-1, it shall operate and meet the requirements of this part of ISO 10651 throughout a pressure range of 280 kPa to 600 kPa, and shall cause no safety hazard with inlet pressures up to 1 000 kPa. The gas flowrate measured at the **ventilator's high-pressure input port** shall not exceed 60 l/min (time-weighted average over 10 s) at a pressure of 280 kPa under **normal condition**. Further, the transient flow requirement shall not exceed the equivalent of 200 l/min for 3 s.

NOTE Flowrate values are expressed under ATPD conditions.

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

Replace 14.2 title with:

14.2 * Class II Equipment

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**

Addition of sub-item:

101) The **patient leakage current** shall be measured from all parts that are defined as **applied parts**. All parts of the same type shall be connected together electrically, with the exception of parts connected to the protective earth terminal that shall be tested separately from parts not so connected.

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 Surfaces, 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 Ultra-violet radiation

IEC 60601-1:1988, Clause 34 applies.

35 Acoustical energy (including ultrasonics)

IEC 60601-1:1988, Clause 35 applies.

36 Electromagnetic compatibility

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

Amendment (add at the end of the clause):

The **ventilator** shall meet the appropriate requirements of IEC 60601-1-2. The **ventilator** shall be Class B and shall not be considered **life-supporting equipment**.

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.

43 Fire prevention

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

43.2 Oxygen enriched atmospheres

Replacement:

* In order to reduce the risk to **patients**, to other persons or to the surroundings due to fire, ignitable material, under **normal** and **single fault conditions**, 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 oxidizer is present.

NOTE Air mixtures with a volume fraction of less than 25 % oxygen are not considered to be an oxidizer.

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

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

Compliance is checked by

— *determining the temperature to which the material is raised under the **normal** and **single fault condition**,*

— *observing if ignition occurs under the most unfavourable combination of **normal conditions** with a **single fault condition**.*

Addition:

43.101 Compatibility with pressurized oxygen

Components of the **ventilator** which can come in contact with oxygen in **normal condition** or in **single fault condition** at pressures greater than 50 kPa shall meet the requirements of ISO 15001.

Compliance is checked by inspection.

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

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

44.3 Spillage

Amendment (add at the end of the subclause):

The **ventilator** shall be so constructed that the spillage does not cause a safety hazard.

44.7 Cleaning, sterilization and disinfection

Amendment (add at the end of 2nd sentence):

, or be provided with a **breathing system filter**.

Amendment (add before the compliance test):

Ventilators or **accessories** labelled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937.

Non-sterile device packaging systems shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of contamination.

Amendment (add at the end of the compliance test):

*If a sterility claim is made, review the **accompanying documents** for methods of sterilization and disinfection and compare to the relevant validation reports.*

44.8 Compatibility with substances used with the equipment

Replacement:

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

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

Compliance is checked by inspection of the information provided by the manufacturer.

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45 applies, except as follows.

Amendment (add as an additional sentence):

These requirements shall not apply to the **ventilator breathing system**.

46 Human errors

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

Replacement:

IEC 60601-1-6 applies.

47 Electrostatic charges

Not used.

48 Biocompatibility

IEC 60601-1:1988, Clause 48 applies.

49 Interruption of the power supply

IEC 60601-1:1988, Clause 49 applies, except as follows.

Addition:

49.101 * Internal electrical power source

If the **ventilator** is equipped with an **internal electrical power source**, means shall be provided to determine the state of this power source.

EXAMPLE 1 Time remaining.

EXAMPLE 2 Percent charged.

EXAMPLE 3 Fuel gauge.

Compliance is checked by inspection.

49.102 Spontaneous breathing during power failure

The **ventilator** shall be designed such as to allow spontaneous breathing when normal ventilation is compromised as a result of any supply power being outside the values specified by the manufacturer [see 6.8.2 aa) 11)].

NOTE This requirement is to allow the **patient** to breathe spontaneously during “power failure conditions” of the **ventilator**.

*Compliance is checked by simulating supply power conditions outside those specified for **normal conditions** and measuring of flowrate, pressure and resistance at the **patient connection port** and comparing them to the values in the **accompanying documents**.*

49.103 Accidental operation of the on/off-switch

Means shall be provided to prevent accidental operation of the on/off-switch.

NOTE This can be accomplished by hardware or software means.

Compliance is checked by inspection.

50 Accuracy of operating data

IEC 60601-1:1988, Clause 50 applies.

51 Protection against hazardous output

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

Addition:

51.101 Maximum ventilator breathing system pressure limitation

The pressure at the **patient connection port** shall not exceed 60 hPa (60 cm H_2O) in **normal** and **single fault conditions**.

*Compliance is tested during controlled ventilation of a test lung (see Figure 101 and Table 101) while simulating relevant **normal** and **single fault conditions,** including occlusion of the **patient connection port**. The pressure at the **patient connection port** is measured.*

51.102 Measurement of airway pressure

The **airway pressure** shall be indicated. The displayed value shall be accurate within ± (2 % of the full-scale reading + 8 % of the actual reading).

Compliance is checked by visual inspection and verification of accuracy.

51.103 * High-inspiratory pressure alarm condition

If the pressure at the **patient connection port** can exceed 30 hPa (30 cm H_2O) under **normal** and **single fault condition** (see 51.101), the **ventilator** shall be equipped with a means to detect a high-inspiratory pressure **alarm condition**. The maximum **alarm condition delay** shall be three consecutive breaths.

Patient-generated transient pressures (e.g. a cough) should not cause the **alarm condition**.

*Compliance is tested during controlled ventilation of a test lung (see Figure 101 and Table 101) while simulating relevant **normal** and **single fault conditions,** including occlusion of the **patient connection port.** The pressure at the **patient connection port** is measured.*

51.104 Expiratory monitoring

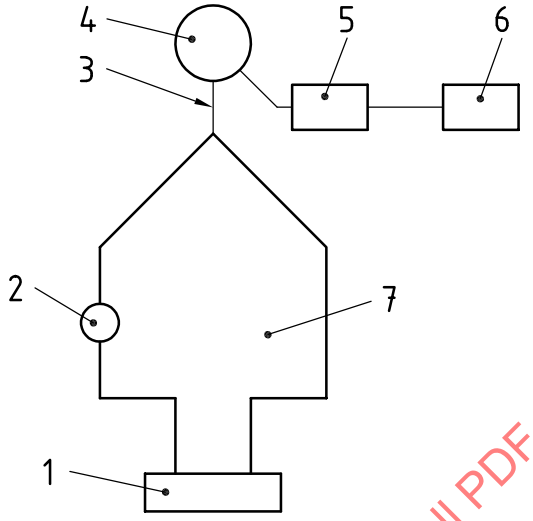
If the **ventilator** is provided with a means of measuring adequacy of ventilation by expiratory tidal volume or expiratory **minute volume**, the accuracy of the measurement for tidal volumes greater than 100 ml or **minute volumes** greater than 3 l/min shall be ± 20 % of the actual value.

Compliance is checked by visual inspection and verification of accuracy using the apparatus shown in Figure 101 and described in Table 101.

51.105 Respiration rate alarm condition

If the **ventilator** is equipped with a means to detect a respiratory frequency **alarm condition**, it shall be equipped with a means to detect a low-level respiratory frequency **alarm condition**.

Compliance is checked by inspection.



Key

1 **ventilator**
2 volume measurement device (part of **ventilator**)
3 resistance to flow
4 test lung
5 pressure sensor
6 recorder (pressure as a function of time) with an accuracy ± 2 % of actual reading for verification of accuracy of volume measurement device
7 **ventilator breathing system** (part of **ventilator**)

NOTE The volume measurement device (2) can be located elsewhere in the **ventilator breathing system** (7).

Figure 101 — Configuration of test apparatus for measurement of expiratory pressure and volume

Table 101 — Conditions for expiratory pressure and volume measurements

Adjustable parameter	Test conditions	
	For ventilators intended to deliver tidal volumes:	
	V_T > 300 ml	$V_T \leqslant$ 300 ml
Tidal volume V_T (ml) as measured by means of pressure sensor on test lung ($V_T = C \times p_{max}$)	500	100
Frequency f (min^{-1})	10	20
I:E ratio	1:2	1:2
Resistance R [kPa (l/s)$^{-1}$]	0,5 ± 0,05	2 ± 0,2
Isothermal compliance C (ml·kPa^{-1})	500 ± 25	200 ± 10
NOTE The accuracy for C and R applies over the ranges of the measured parameters.		

52 Abnormal operation and fault conditions

IEC 60601-1:1988, Clause 52 applies, except as follows.

52.5

Amendment (add following the existing paragraph):

* A **single fault condition** shall not cause a monitoring or **alarm system** and the corresponding ventilation control function to fail in such a way that the monitoring or **alarm system** fails to detect the loss of the monitored **ventilator** control function.

53 Environmental tests

IEC 60601-1:1988, Clause 53 applies.

54 General

IEC 60601-1:1988, Clause 54 applies, except as follows.

54.3 Protection against inadvertent adjustments

Replacement:

A means of protection against accidental adjustments of controls that can create a hazardous output shall be provided.

NOTE Mechanical control techniques such as locks, shielding, friction-loading and detents are considered suitable. For pressure-sensitive finger pads, capacitive finger switches and microprocessor-oriented “soft” controls, a specific sequence of keys or switch operations is considered suitable.

Compliance is tested by visual inspection following the instructions for use.

55 Enclosures 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) * Gas leakage from gas supply connections

1) Reverse gas flow from all gas input ports into the supply system of the same gas shall not exceed 100 ml/min under **normal conditions**.

2) The cross-flowrate of gas from the **high-pressure input port** of one gas to the **high-pressure input port** of a different gas shall not exceed 100 ml/h under **normal use**. If under **single fault conditions**

the cross-flowrate of gases from one to another exceeds 100 ml/h, the **ventilator** shall generate an auditory **alarm signal**. This cross-flowrate shall not exceed 100 ml/min.

Compliance is checked by inspection of the information provided by the manufacturer.

bb) **High-pressure input ports**

High-pressure input port connectors shall be the body of an NIST fitting complying with the requirements of ISO 5359, the male part of a quick connection complying with the requirements of ISO 5359, or a proprietary connector incompatible with the fittings and connectors specified in ISO 5359.

Compliance is checked by inspection.

cc) Connection to the medical gas supply system

If an **operator**-detachable hose assembly is provided for connection between the **ventilator** and the medical gas supply system, it shall comply with ISO 5359.

Compliance is checked by inspection.

dd) Statements specific to named ports

1) fresh-gas intake port

A fresh-gas intake port, if provided, shall not be compatible with connectors complying with ISO 5356-1 or ISO 5356-2.

2) **gas output port, gas return port**, and **patient connection port** connectors

The **gas output port**, **gas return port**, and **patient connection port** shall, if conical [see also 6.1 bb)], be one of the following:

— a 22 mm conical connector complying with ISO 5356-1 or ISO 5356-2;

— a 15 mm conical connector complying with ISO 5356-1;

— a coaxial 15 mm/22 mm conical connector complying with ISO 5356-1 or ISO 5356-2.

Non-conical connectors shall not engage with conical connectors complying with ISO 5356-1 unless they comply with the engagement, disengagement and leakage requirements of that standard.

3) **Emergency air intake port**

An **emergency air intake port** shall be provided. It shall not accept any connector complying with ISO 5356-1 or ISO 5356-2.

The **emergency air intake port** should be designed to prevent obstruction when the **ventilator** is in use.

4) **Flow-direction-sensitive component** connectors

Any **operator**-detachable **flow-direction-sensitive component** of the **ventilator breathing system** shall be so designed that it cannot be fitted in such a way that it presents a hazard to the **patient**.

5) **Accessory** port

If an **accessory** port is provided, it shall not be compatible with connectors specified in ISO 5356-1 or ISO 5356-2 and shall be provided with a means to secure engagement and closure.

NOTE This port is commonly used for sampling of gases or for introduction of therapeutic aerosols.

6) Monitoring probe port

If a port is provided for introduction of a monitoring probe, it shall not be compatible with connectors as specified in ISO 5356-1 or ISO 5356-2, and shall be provided with a means to secure the probe in position and a means to secure closure after removal of the probe.

7) * Manual ventilation port

The **ventilator** shall not be equipped with a **manual ventilation port**.

Compliance is checked by inspection.

Addition:

56.101 Reservoir bags and breathing tubes

a) Any reservoir bags intended for use in the **ventilator breathing system** shall comply with ISO 5362.

b) Breathing tubes intended for use in the **ventilator breathing system** shall comply with ISO 5367.

Compliance is checked by inspection.

57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57 applies, except as follows.

57.3 * Power supply cords

a) Application

Addition (add an additional dash):

— Any **detachable power supply cord** of an electrically powered **ventilator** shall be protected against accidental disconnection from the **ventilator** under a force of 100 N.

Replacement (replace the compliance test):

*Compliance is checked by inspection and, for a **ventilator** when provided with an **appliance coupler**, by the following test:*

*Subject the **detachable power supply cord** for 1 min to an axial pull force of 100 N.*

*During the test, the **mains connector** becoming disconnected from the **appliance inlet** of the **ventilator** is considered a failure.*

58 Protective earthing — Terminals and connections

IEC 60601-1:1988, Clause 58 applies.

59 Construction and layout

IEC 60601-1:1988, Clause 59 applies.

101 Alarm systems

IEC 60601-1-8:2003, Clause 201 applies.

102 Appendices of IEC 60601-1:1988

The Appendices of IEC 60601-1:1988 apply.

Addition: The subsequent annexes form an additional element of this part of ISO 10651.