INTERNATIONAL STANDARD

ISO 10651-2

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

Part 2: Home care ventilators for ventilator-dependent patients

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

Partie 2: Ventilateurs pour soins à domicile pour patients dépendants

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

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Contents

Page

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 10651-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This second edition of ISO 10651-2, together with ISO 10651-6, cancels and replaces the first edition (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 lung **ventilators** intended mainly for home care use but which could be used elsewhere (in healthcare facilities or other locations) for **patients** dependent on ventilatory support i.e. where the **ventilator** is considered to be **life-supporting equipment**. These **ventilators** will frequently be used in locations where driving power is not reliable. These **ventilators** will often be 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 Standard 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 existing text 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 International Standard: 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 Particular Standard: **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 2: Home care ventilators for ventilator-dependent patients

1 Scope

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

Amendment:

This part of ISO 10651 specifies requirements for lung **ventilators** intended for home applications for those **patients** who are dependent on ventilatory support. Such **ventilators** are considered **life-supporting equipment**, are frequently used in locations where driving power is not reliable, and are often supervised by non-healthcare personnel with different levels of training.

This part of ISO 10651 is not applicable to cuirass and “iron-lung” **ventilators**.

This part of ISO 10651 is not applicable to **ventilators** intended only to augment the ventilation of spontaneously breathing **patients**.

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 8185, *Humidifiers for medical use — General requirements for humidification systems,* and *Technical Corrigendum 1:2001*

ISO 9360-1, *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, *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 9919, *Pulse oximeters for medical use — Requirements*

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 14971, *Medical devices — Application of risk management to medical devices*

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*

ISO 21647, *Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors*

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, *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*

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, IEC 60601-1:1988, IEC 60601-1-8 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
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 1 As this **ventilator** is intended to be applied to **patients** who are dependent on this ventilation, it is considered to be **life-supporting equipment**.

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

3.5
home care ventilatory support device for non-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 not dependent on this ventilation

NOTE This **ventilatory 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.

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** during **normal use** of the **equipment**

3.8
reserve electrical power source
part of the **equipment** that temporarily provides electrical power in the event of interruption of the primary supply

4 General requirements and 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

Amendment (add at the end of the subclause):

NOTE A **ventilator** can 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) 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) 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.

bb) **operator**-accessible ports shall be marked. If symbols are used, they shall be explained in the instructions for use and validated according to 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 Those relevant 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 intended for single use 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 the 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

g)

Amendment (add at the end of the list item):

Airway pressures shall be marked in both SI units and centimetres water column (cmH_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) 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.

Addition:

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, flowrate);

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, expressed in appropriate units, plus a sensitivity error, expressed, 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 pressures 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) a statement to the effect that it is of vital importance to provide supervision of ventilation. In addition, it should be assured that the person taking care of the **patient** is capable of taking the necessary corrective actions in the event of a **ventilator alarm condition** or a malfunction of the **ventilator**;

18) 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,

— the means by which the continuing pressure **alarm condition** is detected and the structure of the detection algorithm,

— 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 sub-atmospheric pressure can be used, the limiting pressure for the inspiratory and expiratory phases;

— the means of triggering;

— 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* $\pm$ *10 % at a light level of (215* $\pm$ *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:

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

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

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

d) 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

a)

Replacement (third dashed list item):

— a 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 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 conditions**. 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:

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 which 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 Ultraviolet 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 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 An air mixture with a volume fraction of less than 25 % oxygen is 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 conditions**,*

— *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** system 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 second 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 of the **accompanying documents** for methods of sterilization and disinfection and comparison 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.

Additions:

49.101 * Internal electrical power source

The **ventilator** shall be equipped with an **internal electrical power source** capable of powering the **ventilator** for at least 1 h. The **ventilator** shall be equipped with a means of determining the state of this power source.

NOTE Ways to evaluate the state include, for example, determination of the time remaining, the percent charged, or via a fuel gauge.

As the **internal electrical power source** depletes, but prior to the loss of all power, the **ventilator** shall be equipped with a means to detect an impending supply failure **alarm condition.** It shall be of at least **medium priority**. The impending supply failure **alarm condition** priority may escalate to **high priority** as the **internal electrical power source** depletes. The instructions for use shall state the time between loss of all power and the generation of **alarm signals** for the impending supply failure warning **alarm condition**.

The **operator** needs sufficient time “prior to the loss of all power” to take action to ensure that alternative arrangements can be made to continue the life-supporting function.

Compliance is checked by reducing the power source(s) to values below the minimum value(s) specified by the manufacturer as required for the intended use.

49.102 Additional external backup power source

The **ventilator** shall have a means of connection to an additional external backup power source. A description of the means of connection shall be given in the instructions for use.

NOTE A means of connection to an automotive vehicle power source can be provided.

Compliance is checked by inspection and inspection of the instructions for use.

49.103 Spontaneous breathing during power failure

The **ventilator** shall be designed to allow spontaneous breathing when normal ventilation is compromised as a result of electrical or pneumatic supply power being outside the values specified by the manufacturer [see 6.8.2 aa) 3)]. Resistance values during **single fault condition** shall be disclosed in the **accompanying documents** [see 6.8.2 aa) 11)].

NOTE The purpose of 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**, measuring flowrate, pressure and resistance at the **patient connection port** and comparing them to the values in the **accompanying documents**.*

49.104 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 means of hardware or software.

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.

Additions:

51.101 Failure of air and oxygen supply systems

The **ventilator** shall be equipped with a means to detect a gas failure **alarm condition** to indicate a failure of the air supply system or oxygen supply. If a loss of the oxygen supply occurs, the **ventilator** shall continue to ventilate with air.

Not delivering the set gas mixture within the manufacturer's tolerance for the composition of the mixture is considered a failure.

Compliance is checked by inspection and functional testing.

51.102 Adjustable ventilator breathing system pressure limitation

A means shall be provided to prevent pressure in the **ventilator breathing system** in excess of the active limit value(s).

NOTE Depending on the types of breaths being delivered by the **ventilator**, there can be more than one active pressure limit (e.g. during SIMV ventilation, volume control and pressure support can both coexist, each with its own high-pressure limit).

Pressure limits shall be **operator**-adjustable or specified by (within) an active breathing algorithm or a combination of both. If pressure limits are not directly adjustable by the **operator**, the algorithm(s) that determines the limit value(s) shall be described in the instructions for use.

Each time an active limit value is reached, the **ventilator** shall act to reduce the pressure in the **ventilator breathing system**. The interval from the moment that the **ventilator breathing system** pressure equals the limit until the pressure starts to decline shall not exceed 200 ms.

Compliance is checked by inspection and functional testing.

51.103 Maximum ventilator breathing system pressure limitation

The pressure at the **patient connection port** shall not exceed 60 hPa (60 cmH_2O) in **normal condition** and **single fault 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 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.

51.105 * High-inspiratory pressure alarm condition

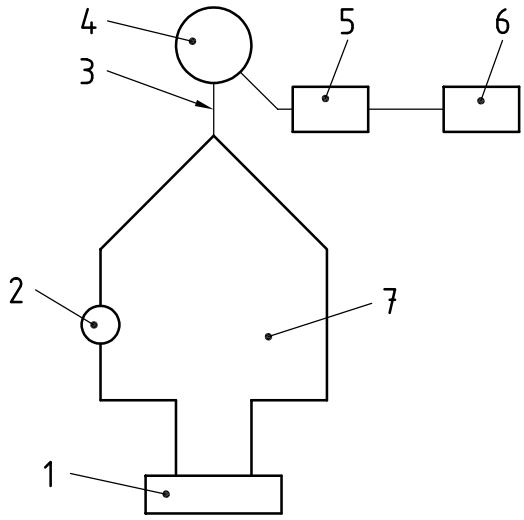
The **ventilator** shall be equipped with a means to detect a high-inspiratory pressure **alarm condition**. The maximum **alarm condition delay** of the high-inspiratory pressure **alarm condition** shall be three consecutive breaths.

If this **alarm condition** exists for longer than ten consecutive breaths, the priority of this **alarm condition** shall escalate. See also Clause 101.

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

Means shall be provided to prevent the **alarm limit** from being set above the **maximum steady limiting pressure** as described in 51.103.

*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.*



Key

1 **ventilator**
2 volume measurement device (part of **ventilator**) to be tested
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

51.106 Expiratory monitoring

The **ventilator** shall be provided with a means of expiratory monitoring by

a) expiratory tidal volume with a means to detect both a low-expiratory and a high-expiratory tidal volume **alarm condition** of at least **medium priority**, or

b) expiratory **minute volume** with a means to detect both a low-expiratory and a high-expiratory **minute volume alarm condition** of at least **medium priority**, or

c) expiratory end-tidal CO_2 with a means to detect both a low-expiratory and a high-expiratory end-tidal CO_2 gas level **alarm condition** of at least **medium priority** (see 56.103).

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.

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.		

51.107 Hypoventilation alarm condition

The **ventilator** shall be equipped with a means to detect a hypoventilation **alarm condition**.

NOTE The hypoventilation **alarm condition** can be determined by the measurement of the variables specified in 51.104 or 51.106 but possibly requires additional detection means. The hypoventilation **alarm condition** can also be determined by an **intelligent alarm system** utilizing one or more variables.

Compliance is checked by inspection.

51.108 Continuing pressure alarm condition

The **ventilator** shall be equipped with a means to detect a continuing positive-pressure **alarm condition**. The maximum **alarm signal generation delay** shall be 17 s.

Compliance is checked by using the method described in the technical description.

51.109 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**. It may also be equipped with a means to detect a high respiratory frequency **alarm condition**.

Compliance is checked by inspection.

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

Additions:

aa) * Gas leakage from gas supply connections

1) Reverse gas flowrate 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**. Under **single fault conditions**, the cross-flowrate of gases from one to another 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, **gas return port**, and **patient connection port** connectors

The gas output, **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.

56.102 Humidifiers and heat and moisture exchangers

Any humidifier or heat and moisture exchanger, either incorporated into the **ventilator** or recommended for use with the **ventilator**, shall comply with ISO 8185, ISO 9360-1 or ISO 9360-2 respectively.

Compliance is checked by inspection.

56.103 Pulse oximeters and capnometers

Any pulse oximeter or capnometer, either incorporated into the **ventilator** or recommended for use with the **ventilator**, shall comply with ISO 9919 or ISO 21647, respectively.

NOTE See ISO 21647.

Compliance is checked by inspection.

56.104 Oxygen monitor and alarm condition

If the **ventilator** is intended for use with a fractionally inspired oxygen concentration greater than ambient, then the **ventilator** shall be provided with an oxygen monitor for the measurement of inspired oxygen concentration, e.g. in the inspiratory limb or at the **patient connection port**. The oxygen monitor shall comply with ISO 21647 and shall, in addition, be provided with a means to detect a high-oxygen-concentration **alarm condition**. The high-oxygen-concentration **alarm condition** shall be at least **medium priority**.

The **alarm limits** can be set by the **operator** or can be derived from the set oxygen concentration or a combination of both. If limit values are not directly adjustable by the **operator**, the algorithm that determines the **alarm limit** values should be disclosed in the technical description.

Compliance is checked by inspection.

56.105 Integrated monitoring equipment

Any monitoring **equipment** integrated into the **ventilator** that is not referenced in this part of ISO 10651 shall comply with the relevant Particular Standard for that monitoring **equipment**.

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

Amendment (add an additional dashed list item):

— 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 of 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, except as follows.

201.8.3 Indication and access

Amendment: (add at the end of the third paragraph)

The maximum duration of the **alarm paused** interval for any **alarm condition** required by this part of ISO 10651 shall not exceed 120 s.

201.12 Alarm condition logging

Amendment (replace the first sentence with the following):

The **ventilator alarm system** shall be provided with:

Replacement [list items a), b) and c)]:

a) the **alarm system** shall log the occurrence, identity and **alarm limits** of all **high priority alarm conditions**;

The **alarm system** should log

— the time of occurrence,

— **alarm signal** inactivation states,

— **physiological alarm conditions**,

— **technical alarm conditions**.

b) the contents of the log

— shall be stored for a specified period of time not less than 72 h or until deleted by **user** action,

— shall not be lost by losses of power of less than 72 h,

— shall not be erasable by the **operator**, and

— should be available for review by the **operator**.

c) the manufacturer shall disclose what happens to the contents of the log after the **alarm system** has experienced a total loss of power (**supply mains** and/or **internal electrical power source**) for a duration greater than 72 h in the instructions for use.

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.

Annex AA
(informative)

Rationale

This annex provides a rationale for some requirements of this part of ISO 10651, and is intended for those who are familiar with the subject of this part of ISO 10651 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 10651 necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 10651. The numbering is, therefore, not consecutive.

AA.3.2

The definition of **applied part** in this part of ISO 10651 is the basis for clarification of requirements for, and measurement of, **patient leakage current**.

It is possible that antistatic tubing or other tubing that is conductive could be used in the **ventilator breathing system** in error.

It is not possible, however, to include in this part of ISO 10651 any requirements on leakage currents from electrically operated attachments, such as humidifiers and heating elements, that can be connected in the **ventilator breathing system**, because the types of such attachments that will be used in clinical work with a type of **ventilator** cannot be anticipated by a manufacturer or a test house.

However, parts integrated with the **ventilators**, such as temperature and carbon dioxide sensors, that are intended to come into contact with the **patient** and that are connected to the **ventilator**, are considered as parts for which requirements for leakage currents can be specified in this part of ISO 10651. Such parts are therefore included in the definition of **applied part**.

AA.4 (3.1)

Software errors, should they occur, should not cause a safety hazard to the **patient**, **operator**, or the **user**.

This requirement, however, is equivalent to that of IEC 60601-1:1988, 3.1 that effectively states that all devices shall cause no safety hazard under **normal conditions** and a **single fault condition**.

It is, therefore, not only logical but also prudent to handle an undetected software defect that leads to a hazardous condition as a **normal condition** in order to amply accommodate software-controlled devices within the framework of IEC 60601-1 and IEC 60601-1-4.

This approach is advisable, especially with respect to a failure mode effect analysis, to prove compliance with IEC 60601-1:1988, 3.1.

A fault that is not detected can exist for a long time. Under these circumstances it is not acceptable to regard a further fault as a second fault that can be disregarded. Such a first fault is regarded as a **normal condition**.

An undetected oxygen leak is an important example. It should be considered as a **normal condition** if it is not detected by an **alarm system** or by periodic inspection or unless the system is considered infallible.

AA.6.1 dd)

Immediate implies the ability to be used quickly enough to prevent serious **patient** injury.

AA.6.8.2 aa) 7)

The operating time can vary considerably and be affected by temperature and both the charge and the discharge rate of the battery.

AA.6.8.2 aa) 10)

IEC 60601-1 specifies a set of ambient conditions (temperature, relative humidity, barometric pressure, power supply, etc.) under which **equipment** shall comply with the requirements of the General Standard. These conditions represent the typical environment within a healthcare facility, but the manufacturer can specify an extension of these conditions.

If the manufacturer specifies that the **equipment** is permitted to be used in a wider range of conditions than those specified in 10.2.1 of this part of ISO 10651, then that **equipment** shall not cause a safety hazard to the **patient** or **operator** if used outside the environmental conditions, i.e. all safety mechanisms shall remain functional, but the performance parameters can degrade below their specified values.

AA.6.8.2 aa) 13)

The use of antistatic and/or electrically conductive materials in the **ventilator breathing system** was not considered as contributing to any higher degree of safety. On the contrary, the use of such material increases the hazard of electrical shock to the **patient**.

AA.6.8.3 aa) Third dashed list item

Some changes in the conditions and composition of the gas at the sensor can alter the flowrate or volume-sensitivity of some types of sensor. Also, changes in the conditions in the sensor can alter the correction required to express the flowrate, volume or ventilation under some standard conditions. For example, a volume-displacement-type meter, whenever it is operating normally, will indicate the volume that has passed through it, expressed in terms of the conditions within it, irrespective of those conditions or of the composition of the gas. However, if a pneumotachograph sensor at the expiratory port is used to drive a display of "expired tidal volume" expressed at BTPS on the assumption that typical expired air, saturated at 30 °C, is passing through the pneumotachograph, then, if the temperature of the gas is less than 30 °C, the indicated volume will be less than the true expired volume at BTPS.

Also, if the composition of the gas changes, the indicated volume will change in proportion to the viscosity of the mixture [−8 % for a change from a mixture consisting of 50 % (volume fraction) of nitrogen and 50 % (volume fraction) of oxygen to 50 % (volume fraction) of nitrous oxide and 50 % (volume fraction) of oxygen]. Conversely, if a display of volume is derived from an inherently mass-flow-sensitive device, the indicated volume will change in proportion to the density of the mixture in the sensor [+27 % for a change from a mixture consisting of 50 % (volume fraction) of nitrogen and 50 % (volume fraction) of oxygen to 50 % (volume fraction) of nitrous oxide and 50 % (volume fraction) of oxygen].

AA.14.2 Class II Equipment

The **ventilator** should be Class II **equipment**. In many parts of the world and in many older homes as well, there is NO earth ground available. This is the case even though some **fixed mains socket outlets** appear as though they are earthed.

AA.19.4 h) Tests

See AA.3.2.

AA.43.2 Oxygen-enriched atmospheres

Reports of fire caused by **ventilator** are unusual. However, when such fires occur 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);

— 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; and

— an oxidizer

Therefore, following the basic safety concepts of IEC 60601-1, the objective in the design of the **ventilator** is to ensure that under both **normal** and **single fault conditions** and under the oxidizing conditions to which the material can be exposed, 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, to the **patient**, other persons or the surroundings, because its effect is limited by the supply of oxidizer or fuel or by the use of fire-extinguishing materials, and that the **patient** is not exposed to any toxic products resulting from the ignition.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although usually only for ambient air and pure oxygen environments. The minimum ignition temperature can be critically dependent upon the concentration of oxidizer present. If ignition temperatures for other materials or different 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 effect of sparks in environments containing oxidizers is quite different from that in explosive gas mixtures. Spark energy is the most potent form of energy in igniting explosive gas mixtures, while in environments containing oxidizers thermal energy is more fundamental. It is possible that at higher power levels sufficient spark energy can be dissipated in the interface between sparking conductors to allow their temperature to be raised above the minimum ignition temperatures of the conductors or their surroundings, so that sustained burning occurs, but there is at present no documented evidence as to the power level at which this might occur for different materials and environments. Where the potential spark power dissipation deviates from well established safe practice, therefore, specific spark tests should be conducted simulating the most unfavorable environment that can be reasonably foreseen.

The accumulating materials mentioned above are particularly susceptible to ignition by spark energy because of their low ignition temperatures and very low thermal capacity coupled with poor conductance.

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

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

The origin of the electrical energy values that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards. IEC 60601-2-13 introduced a 10 V·A power limitation, along with other requirements, and to the knowledge of this committee, no fires have occurred with **equipment** designed to conform to these standards. However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either overly 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 oxidizer that can ensure safety under all circumstances. Ultimately, electrical energy is only significant with respect to 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 the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidizer.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air-ignition temperature under **normal conditions** 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 electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under a **single fault condition**.

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

AA.49.101 Internal electrical power source

One hour was chosen as the minimum acceptable time necessary to ensure that alternative arrangements could be made to continue the life-supporting function. Climatic, traffic and other conditions require at least this period before restoration of power or arrangement for other supplies.

AA.51.105 High-inspiratory-pressure alarm condition

Recurring high-pressure **alarm conditions** during the mechanical ventilation of a **patient** can be an indication of serious lung problems.

AA.52.5 Arrangement of functions

This subclause prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

AA.56.3 aa) Gas leakage from gas supply connections

These requirements are necessary to maintain **patient** safety by protecting the gas supply system from contamination.

AA.56.3 dd) 7) Manual ventilation port

Although provision for the manual ventilation of the **patient** in cases of emergency is strongly encouraged, it was decided that this should be by means of a connection into the detachable part of the **ventilator breathing system** or at the **patient connection port**. It was decided that the use of a connection port on the **ventilator** could lead to misuse or confusion, with no compensating advantage.

AA.57 3) Power supply cords

Accidental disconnection of a **detachable power supply cord** can be hazardous for the **patient**.

Annex BB
(informative)

Reference to the essential principles

This part of ISO 10651 has been prepared to support the essential principles of safety and performance of **home care ventilators for ventilator-dependent patients** as medical devices in accordance with ISO/TR 16142. This part of ISO 10651 is intended to be acceptable for conformity assessment purposes.

Compliance with this part of ISO 10651 provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible.

Table BB.1 — Correspondence between this part of ISO 10651 and the essential principles of ISO/TR 16142

Clause(s)/subclause(s) of this part of ISO 10651	Corresponding essential principle of ISO/TR 16142:1999	Qualifying remarks/Notes
All	1, 2, 3	
4 (3.1)	4, 12.1	
4 (3.4)	3	
5.2	12.6	
6.1	2	
6.1 hh)	8.7	
6.3	2, 10, 12.9	
6.6	12.7.4	
6.8.2	2, 9.1, 13	
6.8.3	2, 9.1, 13	
6.101	10.2	
7.101	9.1, 12.8.1	
10	4, 5, 9.2	
19.4	12.6	
36	9.2, 12.5	
43	7.3, 9.3	
44.3	7.6	
44.7	8.1	
44.8	7.1, 7.5	
46	10.2	
49.101	9.2, 12.2, 12.3	
49.102	9.2	
49.103	9.2, 12.1	
49.104	5, 9.2, 12.9	

Table BB.1 (*continued*)

Clause(s)/subclause(s) of this part of ISO 10651	Corresponding essential principle of ISO/TR 16142:1999	Qualifying remarks/Notes
51.101	12.8.1, 12.8.2	
51.102	4, 9.2	
51.103	4, 9.2	
51.104	6, 10.1	
51.105	12.4	
51.106	10.1, 12.4, 12.8.2	
51.107	12.4, 12.8.2	
51.108	12.4, 12.8.2	
51.109	10.1, 12.4, 12.8.2	
52.5	2, 12.1	
54.3	5, 9.2, 12.9	
56.3	12.7.4	
56.101	9.1, 12.8.1	
56.102	9.1, 12.7.5	
56.103	9.1, 10.1, 10.2	
56.104	9.1, 10.1, 10.2	
56.105	9.1, 10	
57.3	2, 12.1	
201.8.3	12.4, 12.8.2	
201.12	5, 12.4	

Bibliography

[1] ISO 31 (all parts), *Quantities and units*

[2] ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

[3] ISO 690, *Documentation — Bibliographic references — Content, form and structure*

[4] ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*

[5] ISO 8359, *Oxygen concentrators for medical use — Safety requirements*

[6] ISO 8835-5, *Inhalational anaesthesia systems — Part 5: Requirements for anaesthetic ventilators*

[7] ISO 9703-1, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals*

[8] ISO 9703-2, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals*

[9] ISO 9703-3, *Anaesthesia and respiratory care alarm signals — Part 3: Guidance on application of alarms*

[10] ISO 10241, *International terminology standards — Preparation and layout*

[11] ISO 10524-2, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

[12] ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

[13] ISO 11195, *Gas mixers for medical use — Stand-alone gas mixers*

[14] ISO 15002, *Flow-metering devices for connection to terminal units of medical gas pipeline systems*

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

[16] ISO 18777, *Transportable liquid oxygen vessel systems for medical use*

[17] ISO 18779, *Devices for conserving oxygen and oxygen mixtures — Particular requirements*

[18] ISO 23328-2, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

[19] IEC 60027 (all parts), *Letter symbols to be used in electrical technology*

[20] IEC/TR 60513, *Fundamental aspects of safety standards for medical electrical equipment*

[21] IEC 60601-1-1, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

[22] IEC 60601-1-4, *Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems*

[23] IEC 60601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

[24] IEC/TR 60878, *Graphical symbols for electrical equipment in medical practice*

[25] IEC 80416-1, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of symbol originals*

[26] ISO/IEC TR 10000-1, *Information technology — Framework and taxonomy of International Standardized Profiles — Part 1: General principles and documentation framework*

[27] ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards, 1997*

[28] EN 550, *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization*

[29] EN 552, *Sterilization of medical devices — Validation and routine control of sterilization by irradiation*

[30] EN 554, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat*

[31] EN 556 (all parts), *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile"*

[32] EN 1041, *Information supplied by the manufacturer with medical devices*

[33] EN 13014, *Connections for gas sampling tubes to anaesthetic and respiratory equipment*

[34] ASTM F 1100-90, *Standard Specification for Ventilators Intended for Use in Critical Care*

[35] IEEE P1073, *Standard for medical device communications*

[36] NFPA Publication 53, *Recommended Practice on Materials, Equipment, and Systems Used in Oxygen-Enriched Atmospheres* [1)]

1) Available from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, USA.

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