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ISO 10651-1

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Lung ventilators for medical use —

Part 1:
Requirements

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Ventilateurs pulmonaires à usage médical —

Partie 1: Prescriptions

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Foreword

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

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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International Standard ISO 10651-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 3, *Lung ventilators and related equipment*.

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This first edition of ISO 10651-1 cancels and replaces the first edition of of ISO 5369, published in 1988, and IEC 601-2-12:1988, of both of which it constitutes a technical revision and amplification.

ISO 10651 consists of the following parts, under the general title *Lung ventilators for medical use*:

— *Part 1: Requirements*

— *Part 2: Particular requirements for home care ventilators*

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

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Lung ventilators for medical use —

Part 1:
Requirements

Section 1: General

1.1 Scope

ISO 10651 is one of a series of International Standards based on IEC 601-1:1988. In IEC 601-1:1988 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1:1988.

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This International Standard is a revision and amplification of IEC 601-2-12:1988, *Medical electrical equipment — Part 2: Particular requirements for the safety of lung ventilators for medical use*. It includes requirements from ISO 5369:1988 and replaces both documents.

The scope and object given in clause 1 of IEC 601-1:1988 applies except that **1.1** shall be replaced by the following:

This part of ISO 10651 specifies requirements for lung ventilators intended for medical use, excluding ventilators primarily intended for anaesthesia, home care, transport, and other devices such as jet and high-frequency ventilators.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10651. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10651 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 4135:1979, *Anaesthesiology — Vocabulary.*

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

ISO 5356-2:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors.*

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

ISO 5362:1986, *Anaesthetic reservoir bags.*

ISO 5367:1991, *Breathing tubes intended for use with anaesthetic apparatus and ventilators.*

ISO 7767:1988, *Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements.*

ISO 8185:1988, *Humidifiers for medical use — Safety requirements.*

ISO 9360:1992, *Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans.*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

IEC 65:1985, *Safety requirements for mains operated electronic and related apparatus for household and similar general use.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements.*

IEC 801-2:1991, *Electromagnetic compatibility for industrial-process measurement and control equipment — Part 2: Electrostatic discharge requirements.*

1.3 Definitions

For the purposes of this part of ISO 10651, the definitions given in clause 2 of IEC 601-1:1988 apply except that the definition given in 2.1.5 shall be replaced by the following[1].

[2.1.5] **applied part:**[1] All parts of the ventilator intended to be connected to the patient or to the breathing system.

For the purposes of this part of ISO 10651, the following additional definitions also apply.

1.3.1 bacterial filter: Device intended to reduce bacteria content and particulate matter content of the gas stream.

1.3.2 calibrated control: Control with numbered marks in which the numbers purport to indicate the value of the parameter being controlled, whether or not the control has been individually calibrated.

1.3.3 clearly legible: Visual attribute of information displayed by the equipment that allows the operator to discern (or identify) qualitative or quantitative values or functions under a specific set of environmental conditions.

1.3.4 cycling pressure: Pressure in the ventilator breathing system which initiates an inspiratory or expiratory phase.

1.3.5 driving gas: Gas which powers the lung ventilator but is not necessarily delivered to the patient.

1.3.6 driving gas input port: Gas input port to which driving gas is supplied.

1.3.7 emergency air intake port: Dedicated gas intake port through which ambient air may be drawn when the supply of fresh and/or inflating gas is insufficient.

1.3.8 expired tidal volume: Volume of gas leaving the patient's lungs during an expiratory phase.

1.3.9 expiratory phase: Interval from the start of expiratory flow to the start of inspiratory flow.

1.3.10 flow-direction-sensitive component: Component through which the gas flow has to be in one direction only for its proper functioning and/or patient safety.

1.3.11 fresh gas: Gas supplied to the lung ventilator breathing system. It excludes the following:

a) air drawn through the emergency air intake port;

b) air drawn through leaks in the ventilator breathing system;

c) expired gas from the patient.

1.3.12 fresh gas input port: Gas input port to which fresh gas is supplied.

NOTE 1 There may be more than one fresh gas input port.

1.3.13 fresh gas intake port: Gas intake port, other than the emergency air intake port, through which fresh gas may be drawn into the ventilator breathing system by the lung ventilator or the patient.

1.3.14 gas exhaust port: Port of the lung ventilator from which gas is discharged to the atmosphere either directly or via an anaesthetic gas scavenging system.

1.3.15 gas input port: Port to which gas is supplied under positive pressure and through which the gas is driven by this pressure.

NOTES

2 The gas may be supplied either at a controlled pressure and/or at a controlled flow.

3 c.f. gas intake port.

1.3.16 gas intake port: The port through which gas is drawn into the ventilator breathing system by the lung ventilator or the patient.

NOTES

4 Gas may be supplied to the port at or about ambient atmosphere or end-expiratory pressure, or the port may simply be left open to the atmosphere.

5 In a ventilator breathing system, energy is required to reduce the pressure below that of the atmosphere. Therefore, when gas is supplied at or about atmospheric pressure to a gas intake port, work has to be done, either by the lung ventilator (using energy from, for example, an electrical supply or a driving gas supply) or by the patient in order to lower the breathing system pressure suf-

1) See also annex L in this part of ISO 10651.

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ficiently for gas to flow in through the gas intake port. In this sense, gas is "drawn" into the breathing system. A similar argument applies, even if gas is supplied to the gas intake port at a small positive pressure to compensate for the use of positive end-expiratory pressure.

1.3.17 gas output port: Port of a lung ventilator through which gas is delivered through a tube to the patient connection port.

1.3.18 gas return port: Port of the lung ventilator through which gas is returned at respiratory pressures through a tube from the patient connection port.

1.3.19 high pressure gas input port: Gas input port to which gas is supplied at a pressure greater than 100 kPa.

1.3.20 inflating gas: Fresh gas which powers the lung ventilator and is supplied to the patient.

1.3.21 inflating gas input port: Gas input port to which inflating gas is supplied.

1.3.22 inspiratory phase: Interval from the start of inspiratory flow to the start of expiratory flow.

1.3.23 low pressure gas input port: Gas input port to which gas is supplied at a pressure not exceeding 100 kPa.

1.3.24 lung ventilator: Any device which is intended to augment automatically or provide ventilation of the patient's lungs when connected to the patient's airway, referred to as a ventilator throughout this document.

1.3.25 manual ventilation port: Port of the ventilator to which a device may be connected for manual inflation of the lungs.

1.3.26 maximum limited pressure, $P_{lim,max}$: Highest pressure measured at the patient connection port which can be attained in the ventilation breathing system during malfunction of the ventilator but with a functioning safety mechanism.

NOTE 6 Components of a ventilator are operating normally when individually they operate as the manufacturer intended, even though particular combinations of settings of controls and of the compliance and resistance of the patient's respiratory tract may lead to an inappropriate pattern of ventilation.

1.3.27 maximum working pressure, $P_{w,max}$: Highest pressure which can be attained at the patient connection port during the inspiratory phase, irrespective of the setting of controls other than any control intended to adjust this pressure, with the ventilator working normally.

NOTE 7 Even if not adjustable, this maximum may be less than the maximum limited pressure.

1.3.28 minimum limited pressure, $P_{lim,min}$: Lowest (most negative) pressure measured at the patient connection port, which can be attained in the ventilator breathing system during malfunction of the ventilator but with a functioning safety mechanism.

NOTE 8 See note 6.

1.3.29 minimum working pressure, $P_{w,min}$: Lowest (most negative) pressure which can be attained at the patient connection port during the expiratory phase, irrespective of the setting of controls other than any control intended to adjust this pressure, with the ventilator working normally.

1.3.30 operator's position: Intended orientation of the operator with respect to the equipment for normal use according to the instructions for use.

1.3.31 patient connection port (of the ventilator breathing system): Port of the ventilator breathing system to which the patient may be connected.

1.3.32 triggering: Initiation of the inspiratory phase of the lung ventilator by the inspiratory effort of the patient.

1.3.33 ventilation, V: Volume of gas per minute entering or leaving the patient's lungs.

1.3.34 ventilator breathing system (VBS): Breathing system bounded by the low pressure gas input port(s), the gas intake port(s) and the patient connection port together with the fresh gas inlet and exhaust port(s), if these are provided.

NOTES

9 Attention is drawn to the definition of a breathing system in ISO 4135.

10 Gas supplied to the ventilator at any gas input port may enter the ventilator breathing system at any point.

11 Valves may be placed anywhere in relation to ports and, indeed, anywhere in the ventilator breathing system, provided the requirements of this part of ISO 10651 are met.

1.4 General requirements

The general requirements given in clause 3 of IEC 601-1:1988 apply with the following addition:

3.6 j) Applicable single fault conditions are short- and open-circuits of components of wiring which can

— cause sparks to occur, or

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— increase the energy of sparks, or

— increase temperatures.

A single fault condition shall not cause a monitoring and/or alarm device as in 8.2 and 11.1, and the corresponding ventilation control function shall not fail in such a way that the monitoring function becomes simultaneously ineffective, and thus fails to detect the loss of the monitored ventilator function.

Test for compliance by simulation of a single fault condition or by visual inspection.

1.5 General requirements for tests

The requirements given in clause 4 of IEC 601-1:1988 apply.

1.6 Classification

The classification given in clause 5 of IEC 601-1:1988 applies.

NOTE 12 A ventilator may have applied parts of different types.

1.7 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1:1988 apply except for the following additions and modifications.

a) Amend **6.1 e)** as follows:

The address of the manufacturer and/or authorized representative, as applicable, shall also be marked.

b) Amend **6.1 j)** as follows:

The power input marking shall be given in amperes for the ventilator and for the sum of the current ratings for the ventilator and auxiliary mains socket outlets.

c) Amend **6.1 k)** as follows:

The requirement for marking of auxiliary mains socket outlets shall apply to each auxiliary mains socket outlet and the maximum allowed output shall be marked in amperes.

d) In **6.1**, add the following items:

aa) All operator-accessible flow-direction-sensitive components, unless non-interchangeable, shall be permanently marked with a clearly legible arrow indicating the direction of flow.

ab) Any high pressure gas input port shall be marked in accordance with ISO 5359.

ac) If parts are marked, the following terms shall be used at least in the national language or English. Alternatively, symbols may be used and explained in the instructions for use:

1 Driving gas input port: "driving gas input"

2 Inflating gas input port: "inflating gas input" or "driving and fresh gas input", as appropriate

3 Fresh gas input port: "fresh gas"

4 Fresh gas intake port: "fresh gas intake"

5 Emergency air intake port: "WARNING: emergency air intake — do not obstruct"

6 Manual ventilation port: "bag"

7 Gas output port: "gas output"

8 Gas return port: "gas return"

9 Gas exhaust port: "exhaust". If the volume of gas discharged from the exhaust port is either more or less than the expired volume, additionally: "not for spirometer"

ad) A checklist indicating the procedures to be carried out by the user immediately before use shall be permanently attached to the ventilator. The use of electronic displays, e.g. a CRT, is permitted.

ae) If auxiliary mains socket outlet(s) can accept a mains plug, the auxiliary mains socket outlet(s) shall be marked with symbol 14 given in table D1 in Appendix D of IEC 601-1:1988.

af) If gas-specific colour coding of flow controls and flexible hoses is provided, it shall be in accordance with ISO 32.

ag) Packages containing breathing attachments intended for single use shall be clearly marked with the following:

a) a description of the contents;

b) the words "single patient use";

NOTE 13 Symbol No. 1051 given in ISO 7000 may additionally be used.

c) the words "sterile" or "non-sterile", as applicable;

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d) the name and/or trademark of the manufacturer and/or supplier;

e) an identification reference to the type, batch, serial number or date of manufacture.

ah) Packages containing breathing attachments intended for re-use shall be clearly marked with the following:

a) a description of the contents;

b) the name and/or trademark of the manufacturer and/or supplier;

c) recommended methods of cleaning, disinfection and sterilization;

NOTE 14 Some breathing attachments may contain these recommended methods in the instructions for use.

ai) Packages containing breathing attachments made of conductive materials shall be clearly marked with the word “conductive” or “antistatic”.

e) In **6.8.2 a)**, add the following:

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1 a statement to the effect that antistatic (conductive) hoses or tubing should not be used,[2)]

2 if the ventilator has an internal electrical power source, a specification of the operating time under conditions stated by the manufacturer,

3 the manufacturer shall disclose what electromagnetic compatibility standard or test method the ventilator was tested to at the time the accompanying documents were prepared,

4 a method of testing the following alarms prior to connection of the breathing system to the patient:

a) high pressure alarm,

b) low volume alarm,

c) high and low oxygen concentration alarm,

d) breathing circuit integrity alarm,

NOTE 15 Examples may be leaks or disconnects of breathing system components.

e) power failure alarm;

5 if auxiliary mains socket outlet(s) accept a standard mains plug, a warning related to the symbol required in item ac) of 6.1 to the effect that the connection of equipment to the auxiliary mains socket outlet(s) may increase the patient leakage currents to values exceeding the allowable limits in the event of a defective earth conductor,

6 the intended use of the ventilator (e.g. intensive therapy, adult, paediatric, neonatal),

7 if the lung ventilator is fitted with a gas mixing system, the manufacturer shall disclose the following:

a) the recommended range of flows from the mixing system,

b) the leakage from one gas system to the other,

c) the design pressure and any pressure differential,

f) In **6.8.3**, add the following to item a):

The technical description shall additionally include disclosure of all information necessary to check that the lung ventilator is installed correctly and is in safe and correct working order, and on the nature and frequency of maintenance operations necessary to ensure continuing safety and correct operation, as listed below, as far as applicable.

1 a listing of the following pressures:

— maximum limited pressure, $P_{\text{lim,max}}$,

— range of values to which the maximum working pressure can be set and the means by which the maximum is ensured (e.g. pressure cycling, pressure limiting, pressure generation) and a statement whether negative pressure is available in the expiratory phase,

— minimum (most negative) limited pressure,

— range of values to which the minimum (most negative) working pressure can be set and the means by which the minimum is ensured;

2 a listing of the ranges of the following parameters, if applicable:

— cycling pressure,

— end-expiratory pressure,

2) See also annex L in this part of ISO 10651.

— delivered concentration of oxygen, if adjustable by controls on the ventilator.

If there is a facility for negative pressure in the expiratory phase, the limiting pressure and generated pressure, if applicable, shall be listed for the expiratory phase and the inspiratory phase.

3 a technical description of the means of triggering shall be provided, if applicable;

4 the purpose, type, range and sensing position of all measuring and display devices either incorporated into the ventilator or recommended by the manufacturer for use with the ventilator;

5 the conditions under which any measured or displayed flow, volume or ventilation is to be expressed (e.g. ATPD, BTPS) and the condition and composition of gas in the corresponding sensor so that the display complies with the accuracy requirements specified in 51.10;

6 for alarms either supplied with or fitted to the ventilator or recommended for use with the ventilator, a statement of their type, capabilities, principle of the alarm detection and, if appropriate, suppression or delay of annunciation, estimated battery life and suitable replacement batteries;

7 size and type of the battery and criteria for the need for replacement and any special precautions;

8 the internal volume of any breathing attachments or other components or sub-assemblies recommended by the manufacturer to be placed between the patient connection port and the patient. The manufacturer shall disclose the test method on request;

9 the resistance and compliance of the complete ventilator breathing system and/or any breathing attachment or other components or sub-assemblies, e.g. humidifier or bacterial filter recommended by the manufacturer for inclusion in the ventilator breathing system shall be disclosed in the instructions for use.

Inspiratory and expiratory resistances shall be disclosed for flows of 60 l/min for adult use, 30 l/min for paediatric use and 5 l/min for neonatal use.

The instructions for use shall state that the operator will have to ensure (as stated in 56.16) that these values are not exceeded when adding attachments or other components or sub-assemblies to the breathing system.

10 a pneumatic diagram of the ventilator and a diagram for each ventilator breathing system either supplied or recommended by the manufacturer;

11 details of any restrictions on the sequence of components within the ventilator breathing system, e.g. where such components are flow-direction-sensitive;

12 interdependence of controls, if applicable.[3)]

If a display, or a calibrated scale or control, measures or controls a parameter within the ventilator, either

1 the display or scale shall be marked to indicate that it refers to a machine parameter and not a patient parameter, or

2 if the indicated value agrees with the value of a patient parameter to within the accuracy specified in 10.2.4 and under the conditions specified in those clauses, the display or scale shall be marked to indicate that it refers to a machine parameter or patient parameter.

Compliance shall be determined by inspection of marking and instructions for use.

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1.8 Power point

The requirements given in clause 7 of IEC 601-1:1988 apply.

3) See also annex L in this part of ISO 10651.