INTERNATIONAL STANDARD

ISO 10651-2

First edition
1996-08-01

Lung ventilators for medical use —

Part 2:
Particular requirements for home care ventilators

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Ventilateurs pulmonaires à usage médical —

ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4237-a763-33ec63fa4cee/iso-10651-2-1996

Partie 2: Prescriptions particulières pour ventilateurs pour soins domestiques

Reference number
ISO 10651-2:1996(E)

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4237-a763-33ec63fa4cee/iso-10651-2-1996

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

— *Part 1: Particular requirements for critical care ventilators*

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

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

Annexes M, N and P of this part of ISO 10651 are for information only.

© ISO 1996

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Introduction

This part of ISO 10651 specifies requirements for lung ventilators intended mainly for home care use but which could be used elsewhere (in hospitals) for appropriate patients in locations where the use of a ventilator complying with ISO 10651-1 is not required. These devices must meet the definition of a lung ventilator (to automatically augment or provide ventilation of the patient's lungs), but will frequently be used in the home or elsewhere by persons with different levels of training. Devices intended solely to augment the ventilation of spontaneously breathing patients are excluded from the scope of this part of ISO 10651.

A rationale for the most important requirements is given in annex M.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4237-a763-33ec63fa4cee/iso-10651-2-1996

This page intentionally left blank

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4237-a763-33ec63fa4cee/iso-10651-2-1996

Lung ventilators for medical use —

Part 2:
Particular requirements for home care ventilators

Section 1: General

1.1 Scope

NOTE — See the rationale in annex M.

This part of ISO 10651 is one of a series of International Standards based on 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 part of ISO 10651 take precedence over those of IEC 601-1:1988. Where this part of ISO 10651 specifies that a clause of IEC 601-1 applies, it means that the clause applies only if the requirements are relevant to the ventilator under consideration.

This part of ISO 10651 has common requirements with IEC 601-2-12 (see annex P). It also includes requirements from ISO 10651-1.

The scope and object given in clause 1 of IEC 601-1:1988 apply with the following addition:

> This part of ISO 10651 specifies requirements for lung ventilators intended mainly for home care use but which could be used elsewhere (in hospitals) for appropriate patients in locations where the use of a ventilator complying with ISO 10651-1 is not required.
>
> Devices intended solely to augment the ventilation of spontaneously breathing patients are excluded from this part of ISO 10651, as are cuirass ventilators which apply negative pressure to the chest wall.
>
> NOTE — Requirements for ventilators intended for anaesthetic application are given in ISO 8835-1.

This part of ISO 10651 does not cover operator-powered ventilators (i.e. manual resuscitators).

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 listed 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 5356-1:—[1], *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.*

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4237-a763-33ae62fc4aae/iso-10651-2-1996

1) To be published. (Revision of ISO 5356-1:1987)

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

ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

ISO 7767:— [2], *Oxygen monitors 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.*

EN 550:1994, *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization.*

EN 552:1994, *Sterilization of medical devices — Validation and routine control of sterilization by irradiation.*

EN 554:1994, *Sterilization of medical devices — Validation and routine control of steam sterilization.*

EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "Sterile".*

IEC 79-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.*

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

IEC 601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility — Requirements and tests.*

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

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:

2.1.5 applied part: Any part of the ventilator intended to be connected to the patient or to the breathing system.

NOTE — Attention is drawn to the rationale in annex M and to the definitions given in ISO 4135.

The following definitions also apply.

1.3.1 adult: Pertaining to an individual weighing 40 kg or more.

1.3.2 calibrated control: Control with numbered marks on 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 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 and which also may be delivered to the patient.

1.3.6 driving gas port: Driving gas entrance or exit of no particular configuration unless specified.

NOTE — Examples of arrangements of ports are given in annex N.

1.3.7 driving gas input port: Input port to which driving gas is supplied.

NOTE — See annex N.

1.3.8 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.

NOTE — See annex N.

1.3.9 enabling condition: Necessary, but not necessarily sufficient, condition to cause an action.

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

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/481fb56a-93ba-4237-a763-33ec63fa4cee/iso-10651-2-1996

2) To be published. (Revision of ISO 7767:1988)

1.3.12 fresh gas: Gas supplied to the ventilator breathing system, excluding:

a) air drawn through the emergency air intake port;

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

c) gas expired from the patient.

1.3.13 gas exhaust port: Port of the lung ventilator from which gas is discharged to the atmosphere.

NOTE — See annex N, figure N.1 b).

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

NOTES

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

2 See annex N.

1.3.15 high-pressure gas input port: Input port to which gas is supplied at a pressure greater than 100 kPa.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

1.3.16 home care ventilator: Ventilator suitable for domiciliary ventilation of a patient without continuous professional supervision.

ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4237-a763-33ec63fa4cee/iso-10651-2-1996

1.3.17 inflating gas: Fresh gas which powers the ventilator.

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

NOTE — See annex N.

1.3.19 maximum limited pressure (p_{lim} max.): Highest pressure measured at the patient connection port which can be attained in the ventilation breathing system during normal use and under single-fault condition.

1.3.20 minimum limited pressure (p_{lim} min.): Lowest (most negative) pressure measured at the patient connection port which can be attained in the ventilation breathing system during normal use and under single-fault condition.

1.3.21 neonatal: Pertaining to an individual weighing less than 5 kg.

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

1.3.23 paediatric: Pertaining to an individual weighing between 5 kg and 40 kg.

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

1.3.25 respiratory irregularity alarm: Alarm which is activated when a cyclic change in a variable related to the ventilation of the patient does not occur within a specified period of time.

1.3.26 ventilation ($\dot{V}$): Volume of gas per minute entering or leaving the patient's lungs.

1.3.27 ventilator breathing system (VBS): Breathing system bounded by the connector to the inspiratory port, the patient connection port and, if provided, the connector to the expiratory port.

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

1.3.28 maximum working pressure (p_W max.): Highest pressure that 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 — Even if not adjustable, this maximum may be less than the maximum limited pressure.

1.4 General requirements

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

NOTE — All parts of the ventilator should be designed and manufactured to minimize health risks due to substances leached or leaking from the device during use.

3.6 j) Applicable single-fault conditions are

a) short- and open-circuits of components or wiring which can

— cause sparks to occur, or

— increase the energy of sparks, or

— increase the temperature (see section 7);

b) incorrect output resulting from software error.

NOTE — See also 54.1.

3.6 k) An oxidant leak which remains undetected by e.g. an alarm or periodic inspection shall be considered a normal condition and not a single-fault condition.

3.6 l) Illumination of 215 lux shall be provided. Measurement of ambient illumination shall be made from the control panel toward the test subject. Test operator shall have vision of 1, corrected if necessary.

1.5 General requirements for tests

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

1.6 Classification

The requirements given in clause 5 of IEC 601-1:1988 apply.

NOTE — 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, with the following additions and modifications.

6.1 e) Amend existing IEC 601-1:1988 text to read:

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

6.1 j) Amend existing IEC 601-1:1988 text to read:

The power input marking required in 6.1 j) of IEC 601-1:1988 shall be given, as well as the sum of the current ratings for the ventilator and the specific auxiliary mains socket outlets.

After **6.1 z)** add the following:

6.1 aa) All operator-accessible flow-direction-sensitive components of the home care ventilator shall be permanently marked with a clearly legible arrow indicating the direction of flow.

6.1 ab) Any high-pressure gas input port shall be marked with the name or symbol of the intended gas in accordance with ISO 5359, the range of supply pressures and the maximum flow requirement (see 6.8.3 a) 5). The maximum pressure shall be marked in kilopascals (kPa) and the maximum flowrate in litres per minute (l/min).

6.1 ac) If operator-accessible ports are provided, they shall be marked. The following marking 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: the words "DRIVING GAS INPUT";

2) emergency air intake port: the words "WARNING: EMERGENCY AIR INTAKE — DO NOT OBSTRUCT";

3) gas output port: the words "GAS OUTPUT";

4) gas return port: the words "GAS RETURN";

5) gas exhaust port: the words "EXHAUST"

   If the volume of gas discharged from the exhaust port is either more or less than the expired volume, mark additionally the words "NOT FOR SPIROMETER".

6.1 ad) The ventilator shall be durably and legibly marked with the following, as far as applicable:

1) any particular storage and/or handling instructions;

2) any particular instructions for use;

3) any particular warnings and/or precautions relevant to the immediate operation of the ventilator;

4) warning statements to the effect that the ventilator shall:

   — not be covered or located so that the ventilation of the ventilator is impeded, and

   — not be operated immediately following storage or transport outside the recommended operating conditions.

NOTE — If the size of the home care ventilator does not permit the complete marking as specified throughout subclause 6.1, at least the following should be marked on the home care ventilator:

— the name of the manufacturer;

— a serial or lot or batch identifying number;

— symbol 14 in table DI of IEC 601-1:1988.

6.1 ae) Packages containing breathing attachments or other ventilator components intended for single use shall be clearly marked with the following, as far as applicable:

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/0818e56a-03be-4237-a762-33ec63fa4cee/iso-10651-2-1996

1) a description of the contents;

2) the words "SINGLE USE", or the symbol No. 1051 given in ISO 7000;

3) the word "STERILE" or "NON-STERILE";

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

5) an identification reference to the type, batch and serial number;

6) if applicable, packages containing ventilator components made of conductive materials shall be clearly marked with the word "CONDUCTIVE" or "ANTISTATIC".

6.1 af) Packages containing breathing attachments or other ventilator components intended for reuse shall be clearly marked with the following:

1) a description of the contents;

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

3) recommended methods of cleaning, disinfection and sterilization;

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

4) if applicable, packages containing ventilator components made of conductive materials shall be clearly marked with the word "CONDUCTIVE" or "ANTISTATIC".

Packaging containing breathing attachments for single-patient use or which are disposable shall be clearly marked with the recommended duration of use.

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

6.8.2 a) Add the following text:

The instructions for use shall additionally include the following:

1) Expected operating time and conditions therefor.

If the ventilator has an internal power source, a specification of the expected operating time under conditions as stated by the manufacturer. If the ventilator has no internal electrical power source, the manufacturer shall specify a suitable reserve power source which can be connected to the ventilator to provide at least 1 h operating time. The expected operating time shall also be specified under the conditions stated by the manufacturer. The manner of connection to the ventilator shall be described and also how automatic switchover can be achieved when the primary power supply falls below the required level.

Any electrically powered ventilator, whether or not it has an internal reserve battery, should have the capability of operating from an external reserve battery. The expected operating time should be specified under the conditions stated by the manufacturer, the means of connection to the ventilator should be described, as should the manner in which automatic switchover to an internal source can be achieved when the external battery power supply falls below the required level.

2) A method of testing the following prior to connection of the breathing system to the patient.

a) High-pressure alarm/pressure-relief system;

b) respiratory irregularity alarm;

NOTE — Examples of respiratory irregularity which may be detected are leaks or disconnections of breathing system attachments.

c) high and low oxygen concentration alarm (if an oxygen monitor is supplied);

d) power failure alarm;

e) alternative or reserve power supply, if applicable.

3) A check list for each ventilator which summarizes the test procedures recommended by the manufacturer which have to be performed prior to use. The use of an electronic display such as a CRT meets these requirements.

4) The intended use of the ventilator (e.g. adult, neonatal, range of body weights).

5) A recommendation that an alternative means of ventilation be available.

6) A list provided by the manufacturer of the ventilator of the applicable monitoring, alarm and protection devices against hazards from delivery of energy or substances to the patient by the ventilator; e.g. oxygen monitor when the home care ventilator is designed to deliver oxygen concentration(s) above ambient.

7) The statement that the operator will have to ensure that the inspiratory and expiratory resistances, as measured in 56.16, are not exceeded when adding attachments or other components or subassemblies to the breathing system.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4257-a765-33ed63fa4eae/iso-10651-2-1996

8) The manufacturer shall disclose the maximum achievable pressure at the patient connection port under a single-fault condition.

9) A warning statement to the effect that, if class I equipment is used, the protective earth of the domiciliary electrical installation shall be checked for safe and effective operation.

10) Unless the home care ventilator is designed to withstand radiated fields in excess of 10 V/m, the instructions for use shall additionally contain a warning statement to the effect that levels exceeding 10 V/m may compromise equipment safety.

6.8.2 d) Add the following text:

The instructions for use shall contain requirements for cleaning of components, if applicable.

6.8.3 Add the following text to item a):

The technical description shall additionally include disclosure of all information necessary to check that the ventilator is installed correctly and is in safe and correct working order. It shall also specify the nature and frequency of maintenance operations necessary to ensure continuing safety and correct operation. This information should be contained in the instructions for the use of the ventilator and of the accessory components. It shall include the following information, as far as applicable.

1) The following pressure information:

   — maximum limited pressure (p_{lim} max.);
   — range of values to which the maximum working pressure can be set and the means by which the maximum is assured (e.g. pressure cycling, pressure-limiting pressure generation) and a statement whether negative pressure is available in the expiratory phase;
   — minimum (subatmospheric) limited pressure (p_{lim} min.);
   — range of values to which the minimum (subatmospheric) working pressure can be set and the means by which the minimum is assured.

2) Ranges of the following parameters:

   — cycling pressure;
   — end expiratory pressure;
   — delivered concentration of oxygen, if adjustable by controls on the ventilator.

3) Description of the means of triggering.

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) 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 51.9. Unless otherwise specified, parameters shall be assumed to be expressed under ATPD conditions.

6) For alarms used with the ventilator, a statement of their type, capabilities, principle of alarm detection, and, if appropriate, suppression or delay of annunciation.

7) Internal volume of any breathing attachments or other components or subassemblies recommended by the manufacturer to be placed between the patient connection port and the patient. The manufacturer of these components shall disclose the test method on request.

8) Resistance, compliance and volume of the complete ventilator breathing system and/or any breathing attachment or other components or subassemblies, e.g. humidifier or filter recommended by the manufacturer for inclusion in the ventilator breathing system.

   The inspiratory and expiratory resistances, as measured in 56.16, shall be disclosed.

9) Disclosure of the functional characteristics or manufacturer's identification of operator-detachable breathing system components, including particulate filter fitted or recommended.

10) 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.

13) Disclosure of accuracies and ranges of displayed values and calibrated controls.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4237-a763-33ec63fa4cee/iso-10651-2-1996

NOTE — Accuracies should be expressed in the form of maximum zero error (bias), quoted in appropriate units, plus a sensitivity error, quoted e.g. as a percentage of the reading.

1.8 Power input

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-93ba-4237-a763-33ec63fa4cee/iso-10651-2-1996

Section 2: Environmental conditions

2.1 Basic safety categories

The requirements given in clause 8 of IEC 601-1:1988 apply.

2.2 Removable protective means

The requirements given in 6.1 z) of IEC 601-1:1988 apply.

2.3 Environmental conditions

The requirements given in clause 10 of IEC 601-1:1988 apply, with the following additions.

10.2.3 Electrical and pneumatic driving power supplies

The ventilator shall continue to function within the specified tolerances throughout the range of supply variation specified by the manufacturer (see 51.5).

10.3 Operation under extreme conditions

The manufacturer shall declare how the ventilator will respond as the environmental and supply conditions are extended to the following limits, changing one parameter at a time while other parameters are maintained within normal limits:

— ambient temperature range of + 5 °C to + 50 °C;

— ambient relative humidity range of 10 % to 95 %;

— atmospheric pressure range of 60 kPa to 110 kPa (600 mbar to 1 100 mbar);

— supply voltage range of – 20 % to + 10 % of declared nominal value;

— ambient temperature of + 45 °C combined with 75 % relative humidity.

Outside the environmental and supply conditions specified in clause 10.2 of IEC 601-1:1988, but within the limits stated above, the ventilator shall not cause a safety hazard to the patient or operator.

NOTE — The ventilator might continue to function outside the specified tolerances.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 10651-2:1996
https://standards.iteh.ai/catalog/standards/sist/081fa56a-936a-4257-a765-33ec63fa4cee/iso-10651-2-1996