INTERNATIONAL STANDARD

ISO 10651-3

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Lung ventilators for medical use —

Part 3:
Particular requirements for emergency and transport ventilators

Ventilateurs pulmonaires à usage médical —

Partie 3: Exigences particulières pour ventilateurs de secours et de transport

Reference number
ISO 10651-3:1997(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.

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

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 and N of this part of ISO 10651 are for information only.

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Introduction

This part of ISO 10651 specifies requirements for portable lung ventilators designed for use in emergency situations and transport. 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 outside the hospital or home by persons with different levels of training.

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

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Lung ventilators for medical use —

Part 3:
Particular requirements for emergency and transport 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 requirement is relevant to the ventilator under consideration.

This part of ISO 10651 has common requirements with IEC 601-2-12. It also includes requirements from ISO 10651-1:1993.

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

> This part of ISO 10651 specifies requirements for portable lung ventilators designed for use in emergency situations and transport. Emergency and transport ventilators, called hereafter "ventilator", are often installed in ambulances or other types of rescue vehicles, but are often used outside this environment, where they have to be carried by the operator or other persons. These devices will frequently be used outside the hospital or home by personnel with different levels of training. This part of ISO 10651 is also applicable to devices permanently mounted in ambulances or aircraft.
>
> 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 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 5356-1:1996, *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 5358:1992, *Anaesthetic machines for use with humans.*

ISO 5359:1989, *Low-pressure flexible connecting 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:— [1], *Oxygen monitors for monitoring patient breathing mixtures — Safety requirements.*

ISO 9170:1990, *Terminal units for use in medical gas pipeline systems.*

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

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals.*

ISO 10651-1:1993, *Lung ventilators for medical use — Part 1: Requirements.*

IEC 68-2-6:1982, *Environmental testing — Part 2: Tests — Test Fc: Vibration (sinusoidal).*

IEC 68-2-29:1987, *Environmental testing — Part 2: Tests — Test Eb and Guidance: Bump.*

IEC 68-2-32:1990, *Environmental testing — Part 2: Tests — Test Ed: Free fall.*

IEC 68-2-36:1983, *Environmental testing — Part 2: Tests — Test Fdb: Random vibration wide band — Reproducibility medium.*

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 — Electromagnetic compatibility — Requirements and tests.*

1.3 Definitions

For the purposes of this part of ISO 10651, the definitions given in ISO 10651-1:1993, 1.3, and in clause 2 of IEC 601-1:1988 apply, with the following exceptions.

The definition given in IEC 601-1:1988, 2.1.5, shall be replaced by the following:

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

NOTE — See also the rationale in annex M.

1) To be published.

The definition given in ISO 10651-1:1993, 1.3.19, shall be replaced by the following:

1.3.19 high-pressure gas input part: Gas input port to which gas is supplied at a pressure greater than 500 kPa.

NOTE — Attention is drawn to the definitions given in ISO 4135.

The following definitions also apply:

1.3.1 emergency ventilator: Portable lung ventilator intended for emergency ventilation and resuscitation use primarily outside hospital facilities.

1.3.2 microbial [bacterial] [particulate] filter: Device intended to reduce bacteria content and particulate matter content of the gas stream.

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

1.3.4 operator-powered resuscitator: Portable non-active medical device used in emergency situation to provide lung ventilation to individual whose breathing is inadequate.

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

1.3.6 transport ventilator: Lung ventilator intended for use during transport to, between, or within hospital facilities.

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 k) Applicable single-fault conditions are

a) short- and open-circuits of components or wiring which can increase temperature (see clause 7);

b) incorrect output resulting from software error(s).

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

NOTE — See also 54.1.

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

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

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

6.1 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.

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.

6.1 ac) If operator-accessible ports are provided, they shall be 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: the words "DRIVING GAS INPUT";
2) fresh gas intake port: the words "FRESH GAS INTAKE";
3) emergency air intake port: the words "WARNING: EMERGENCY AIR INTAKE — DO NOT OBSTRUCT";
4) manual ventilation port: the word "BAG";
5) gas output port: the words "GAS OUTPUT";
6) gas return port: the words "GAS RETURN";
7) gas exhaust port: the word "EXHAUST";
8) pressure gauge port: the words "PRESSURE GAUGE" marked with a clearly legible arrow.

6.1 ad) Each ventilator assembly shall be provided with a permanently attached checklist which summarizes the test procedures recommended by the manufacturer which have to be performed prior to use. The use of electronic displays, e.g. a CRT, is permitted.

6.1 ae) 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) the range of body mass for which use of the ventilator is specified.

6.1 af) Packages containing breathing attachments intended for single-patient use shall be clearly marked with the following:

1) a description of the contents;
2) the words "SINGLE PATIENT USE";

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

3) the word "STERILE" or "NON-STERILE", as applicable;
4) the name and/or trademark or the manufacturer and/or supplier;

5) recommended methods of cleaning, disinfection and sterilization;

6) an identification reference to the type, batch or serial number;

7) the mass of the ventilator and any associated equipment (e.g. cylinder, batteries, regulators, carrying cases, etc.);

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

6.1 ag) Packages containing breathing attachments made of conductive materials shall be clearly marked with the word "CONDUCTIVE" or "ANTISTATIC".

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

6.1 ai) 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.

a) If the ventilator has an internal power source, a specification of the minimum operating time during which the ventilator meets the specifications under normal use as stated by the manufacturer shall be given.

b) If the ventilator is pneumatically powered, the range of supply pressures shall be stated (see 10.2).

c) If the ventilator is provided with a reserve power supply, the functioning after a switchover to the reserve power supply shall be described.

2) Unless entrainment of air is prevented, recommendation for use in hazardous or explosive atmospheres, including a warning that if the ventilator will entrain or permit the patient to inhale gas from the atmosphere, its use in contaminated environments may be hazardous. If applicable, the manufacturer shall describe how to prevent such entrainment or inhalation, for example, by the use of a filter.

3) A method of testing the following alarms prior to connection of the breathing system to the patient:

a) high-pressure alarm;

b) breathing circuit integrity alarm, if provided;

c) power failure alarm;

d) high and low oxygen concentration alarms, if provided.

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

5) If the ventilator is fitted with a gas mixing system, the manufacturer shall disclose the information necessary for safe operation.

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

6.8.2 d) Add the following text:

The instructions for use shall contain information about cleanliness and sterility upon delivery for parts in contact with the patient or the respiratory gases.

6.8.3 a) Add the following text:

The requirement given applies with the following addition:

Unless otherwise specified, parameters shall be assumed to be expressed under ATPD (atmospheric temperature and pressure, dry) conditions. The technical description shall additionally include the following information, as far as applicable.

1) The following pressure information:

   — maximum limited pressure (p_{lim} max.);
   — minimum (subatmospheric) limited pressure (p_{lim} min.);
   — 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);
   — a statement whether negative pressure (subatmospheric) is available in the expiratory phase. 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;
   — 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, if preset or settable to values above ambient:

   — cycling pressure;
   — end-expiratory pressure;
   — delivered concentration of oxygen.

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 ($\dot{V}$) are 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.

6) For alarms used with the emergency 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 battery, criteria for the need for replacement and any special precautions.

8) 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.

9) The instructions for use shall include disclosure of the resistance, compliance, internal volume and other functional characteristics of the complete ventilator breathing system, including any breathing attachment or other components or subassemblies, e.g. humidifier or microbial filter, recommended by the manufacturer, and identification of any operator-detachable breathing system components.

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

   A statement that the operator will have to ensure (in accordance with 56.16) that these values are not exceeded when adding attachments or other components or subassemblies to the breathing system.

10) Disclosure of the characteristics or the microbial filter, if fitted.

11) Pneumatic diagram of the ventilator and a diagram for each ventilator breathing system either supplied or recommended by the manufacturer.

12) Details of any restrictions on the sequence of components within the ventilator breathing system, e.g. where such components are flow-direction-sensitive.

13) Interdependence of controls.

14) Disclosure of accuracies, in terms of precisions and bias and ranges of displayed values and calibrated controls.

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

Rationale: A zero error, together with a sensitivity error, is needed if a variable can pass through zero or can, in any application, cover a range such that the minimum is a small fraction of the maximum.

15) Disclosure of how the delivered tidal or minute volumes and oxygen concentration are affected by pressure at the patient connection port, in particular the maximum deviations from the calibrated or stated settings of these parameters at mean pressures of 0,5 kPa, 1,5 kPa, 3,0 kPa and 6,0 kPa.

16) Approximate duration of the gas supply, expressed as time per litre volume of the cylinder when charged at a typical pressure and when the ventilator is set with typical ventilator settings. The chosen pressure and the ventilator settings shall be disclosed.

After **6.8.3 d)** add the following clause:

6.8.3 e) Extreme conditions

The manufacturer shall declare how the ventilator will respond as the environmental and supply conditions are extended outside the limits given in clause 10, changing one parameter at a time, while the other parameters are maintained within the limits given in clause 10, as well as combinations given by the manufacturer.

Outside the environmental and supply conditions specified in clause 10 but within the limits declared, the ventilator shall not cause a safety hazard to the patient or operator.

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

1.8 Power input

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

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 modifications and additions.

10.2.1 a) An ambient temperature range of – 18 °C to + 50 °C.

10.2.1 b) A relative humidity range of 15 % to 95 %.

10.2.1 c) An atmospheric pressure range of 70 kPa to 110 kPa.

10.2.2 c) The ventilator shall continue to function within the specified tolerances throughout the following ranges of internal and external electrical power tolerances:

— a.c. voltage: – 25 % to + 15 % of nominal value;
— d.c. voltage: – 15 % to + 25 % of nominal value;
— a.c. frequency: – 5 % to + 5 % of nominal value.

NOTE — D.C. noise should be considered in the design of a ventilator intended to be powered by an external d.c. supply.

10.2.3 External pneumatic power

The ventilator shall continue to function within the specified tolerances throughout the range of pressure variations specified by the manufacturer.

If the ventilator is intended to be connected to a medical gas supply (either a medical gas pipeline system complying with prEN 737-3 or a pressure regulator complying with prEN 738-1), it shall operate and meet the requirements of this part of ISO 10651 for a pneumatic power supply throughout a range of 280 kPa to 600 kPa, and shall cause no safety hazard under the single-fault condition of the medical gas supply of up to 1 000 kPa inlet pressure. The time-weighted average over 10 s and the steady-state flowrate of each medical gas required by the ventilator shall not exceed 60 l/min at a pressure of 280 kPa measured at the gas inlet port. The transient flowrate of each medical gas required by the ventilator shall not exceed the equivalent of 200 l/min for 3 s.

10.3 The ventilator shall function under the extreme conditions and combinations of these as declared by the manufacturer in 6.8.3 e).

Section 3: Protection against electric shock hazards

3.1 General

The requirements given in clause 13 of IEC 601-1:1988 apply.

3.2 Requirements related to classification

The requirements given in clause 14 of IEC 601-1:1988 apply.

3.3 Limitation of voltage and/or energy

The requirements given in clause 15 of IEC 601-1:1988 apply.

3.4 Enclosures and protective covers

The requirements given in clause 16 of IEC 601-1:1988 apply.

3.5 Separation

The requirements given in clause 17 of IEC 601-1:1988 apply.

3.6 Protective earthing, functional earthing and potential equalization

The requirements given in clause 18 of IEC 601-1:1988 apply.

3.7 Continuous leakage currents and patient auxiliary currents

The requirements given in clause 19 of IEC 601-1:1988 apply with the following amendment.

19.4 Add the following text to item h).

NOTE — See also annex M in this part of ISO 10651.

The patient leakage current shall be measured from the ventilator inlet(s) and outlet(s) and other parts which are defined as applied parts for the purpose of this part of ISO 10651. 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.

3.8 Dielectric strength

The requirements given in clause 20 of IEC 601-1:1988 apply.

Section 4: Protection against mechanical hazards

4.1 Mechanical strength

The requirements given in clause 21 of IEC 601-1:1988 apply with the following additions and modifications:

21.6 Replace the existing text with the following:

The ventilator while functioning shall withstand the stresses caused by rough handling and shall comply with the tests in 21.6 a) to d).

During and after the tests, the ventilator shall continue to function within the tolerances specified by the manufacturer for normal use conditions.

21.6 a) Vibration (sinusoidal) in accordance with IEC 68-2-6 Test Fc

— Frequency range: 10 Hz-1 000 Hz
— Amplitude/acceleration: 0,35 mm/49 $m \cdot s^{-2}$
— Number of sweep cycles: four on each axis
— Sweep rate: 1 octave/min ± 10 %

21.6 b) Random vibration (wide band) — Reproducibility medium in accordance with IEC 68-2-36, Test Fdb

— ASD 10-200 Hz: 0,01g2/Hz
— ASD 200-500 Hz: 0,003g2/Hz
— Total r.m.s. acceleration: 1,7g (rms)
— Duration/axis/mounting: 30 min

21.6 c) Bump test in accordance with IEC 68-2-29, Test Eb

— Peak acceleration: 15g
— Pulse duration: 6 ms
— Number of bumps: 4 000
— Direction: vertical, with the ventilator in its normal operating positions

21.6 d) Free fall test in accordance with IEC 68-2-32, Procedure 1

— Height of fall: 0,75 m
— Number of falls: one on each of the six surfaces

4.2 Moving parts

The requirements given in clause 22 of IEC 601-1:1988 apply.

4.3 Surfaces, corners and edges

The requirements given in clause 23 of IEC 601-1:1988 apply.

4.4 Stability in normal use

The requirements given in clause 24 of IEC 601-1:1988 apply.

4.5 Expelled parts

The requirements given in clause 25 of IEC 601-1:1988 apply.

4.6 Vibration and noise

The requirements given in clause 26 of IEC 601-1:1988 apply.

4.7 Pneumatic and hydraulic power

The requirements given in clause 27 of IEC 601-1:1988 apply.

4.8 Suspended masses

The requirements given in clause 28 of IEC 601-1:1988 apply.

Section 5: Protection against hazards from unwanted or excessive radiation

5.1 X-radiation

The requirements given in clause 29 of IEC 601-1:1988 apply.

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

The requirements given in clause 30 of IEC 601-1:1988 apply.

5.3 Microwave radiation

The requirements given in clause 31 of IEC 601-1:1988 apply.

5.4 Light radiation (including lasers)

The requirements given in clause 32 of IEC 601-1:1988 apply.

5.5 Infrared radiation

The requirements given in clause 33 of IEC 601-1:1988 apply.

5.6 Ultraviolet radiation

The requirements given in clause 34 of IEC 601-1:1988 apply.

5.7 Acoustical energy (including ultrasonics)

The requirements given in clause 35 of IEC 601-1:1988 apply.

5.8 Electromagnetic compatibility

The requirements given in clause 36 of IEC 601-1:1988 apply.

5.8 a) The ventilator shall continue to function and meet the requirements of this part of ISO 10651 or shall fail without causing a safety hazard when tested in accordance with IEC 601-1-2:1993, with the following modification.

If an anomaly occurs, such as display interruption, alarm activation, etc., it shall be possible to restore normal operation within 30 s after the electromagnetic disturbances have been applied.

NOTE — Silencing of an activated alarm should not be considered as a failure.

5.8 b) The requirements of IEC 601-1-2 apply, with the following modifications:

36.202.1 Replace the test voltages specified to 8 kV for contact discharges and 15 kV for air discharges.

If an anomaly occurs, such as display interrupt, alarm activation or silencing of an activated alarm, it shall not be considered a failure if it is possible to restore normal operation within 30 s.

36.202.2.1 Replace the level of 3 V/m with 30 V/m.

For the purposes of radiated immunity tests, the ventilator shall not be considered as patient-coupled equipment as defined in 2.202 of IEC 601-1-2.

Section 6: Protection against hazards of ignition of flammable anaesthetic mixtures

6.1 Locations and basic requirements

The requirements given in clause 37 of IEC 601-1:1988 apply.

6.2 Marking, accompanying documents

The requirements given in clause 38 of IEC 601-1:1988 apply.

6.3 Common requirements for category AP and category APG equipment

The requirements given in clause 39 of IEC 601-1:1988 apply.

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

The requirements given in clauses 40 and 41 of IEC 601-1:1988 apply.

Section 7: Protection against excessive temperatures and other safety hazards

7.1 Excessive temperatures

The requirements given in clause 42 of IEC 601-1:1988 apply.

7.2 Fire prevention

The requirements given in clause 43 of IEC 601-1:1988 apply, together with the following additions.

43.1 In order to reduce the risk to patients, other persons or 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 oxidant is present.

The minimum ignition temperature shall be determined in accordance with IEC 79-4 using the oxidizing conditions present under normal and single-fault conditions.

Compliance is checked by determining the temperature to which the material is raised under normal and single-fault conditions.

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

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

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

The requirements given in clause 44 of IEC 601-1:1988 apply, with the following modifications.

44.6 Modify as follows.

The ventilator shall be splash-proof. During and after the test as specified in 44.6 of IEC 601-1:1988, the emergency ventilator in the condition given in 4.6. a) shall continue to function within the tolerances specified by the manufacturer for normal use conditions and shall not cause a safety hazard.

44.4 Add the following text.

The emergency ventilator shall be splash-proof.

44.7 Add the following text.

Ventilator breathing system attachments and subassemblies in contact with exhaled gases and intended for reuse shall be so constructed that they can be dismantled for cleaning, disinfection or sterilization.

7.4 Pressure vessels and parts subject to pressure

The requirements given in clause 45 of IEC 601-1:1988 apply.

7.5 Human errors

Not used.

7.6 Electrostatic charges

Not used.

7.7 Materials in applied parts in contact with the body of the patient

The requirements given in clause 48 of IEC 601-1:1988 apply.

7.8 Interruption of the power supply

The requirements given in clause 49 of IEC 601-1:1988 apply, with the following addition.

49.6 Spontaneous breathing during power failure

The ventilator shall be designed so that under conditions of power failure, either electrical or pneumatic, the patient can breathe spontaneously.

During power failure, the resistance at the patient connection port to inspiratory and expiratory gas flows shall not exceed 0,6 kPa (6 cmH_2O) at 30 l/min for adult use, 0,6 kPa at 15 l/min for paediatric use and 0,6 kPa at 2,5 l/min for neonatal use.

This test is performed without use of attachable accessories which may affect inspiratory and expiratory resistance as declared by the manufacturer in 6.8.3 of IEC 601-1:1988.

Means shall be provided to prevent inadvertent operation of the OFF switch.

Ventilators configured for use in hazardous atmospheres are exempt from this requirement. See IEC 601-1:1988 6 (d) 2 for hazardous environment requirements.

Section 8: Accuracy of operating data and protection against hazardous output

8.1 Accuracy of operating data

The requirements given in clause 50 of IEC 601-1:1988 apply, with the following addition.

50.3 Displays of measured variables

While the emergency ventilator is in normal use, all displays of measured variables shall be accurate within the manufacturer's specified range when tested under the operating conditions given in clause 10.

8.2 Protection against hazardous output

The requirements given in clause 51 of IEC 601-1:1988 apply, with the following additions.

51.5 Power-failure alarm

51.5.1 Electrical or pneumatic driving power

The ventilator shall have a power-failure alarm which activates an auditory alarm signal of at least 7 s duration and which shall comply with ISO 9703-2, if the electrical or pneumatic power supply falls below the values specified by the manufacturer.

Compliance shall be checked by simulating a drop below the supply power (pneumatic and/or electrical) required for the specified purpose of use.

51.5.2 Reserve power supplies (if provided)

If a switchover (automatic or manual) to a reserve power supply has occurred, this shall be indicated.

NOTE — Examples of reserve power supplies are:

— operation of a device with accumulators instead of mains power;

— operation of a device with gas cylinders instead of gas supply pipelines;

— use of oxygen as driving power after failure of the air supply.

A means shall be provided to allow the operator to determine the state of the reserve power supply during and prior to use.

51.6 Pressure limitation

The maximum limited pressure at the patient connection port under normal use and single-fault conditions shall not exceed 10 kPa (100 cmH_2O) or 120 % of the maximum working pressure, whichever is greater.

51.7 Device for measuring respiratory pressure

Transport ventilators shall be provided with a device for measuring the respiratory pressure. The value read by the operator shall be accurate within ± (2 % of the full-scale reading + 8 % of the actual reading).

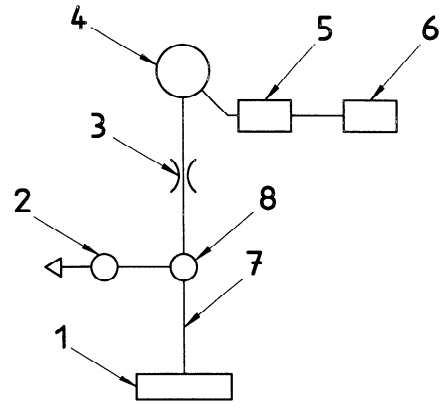
Test for compliance by visual inspection and verification of accuracy.

51.8 High-pressure alarm

A high-pressure alarm shall be provided. It shall activate an auditory signal when the inspiratory-pressure alarm level is reached.

It shall not be possible to set the alarm levels above the maximum pressure permitted by the means of pressure limitation referred to in 51.6.

Test for compliance by creating a respiratory pressure exceeding the upper alarm limit in the breathing system during controlled ventilation of the test lung (see figure 1 and table 1) and while simulating relevant single fault conditions.



Key

1 Ventilator
2 Volume measurement device 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 Breathing system
8 Expiratory valve

NOTE — Location of the volume measurement device (2) is arbitrary; it may be located elsewhere in the breathing system.

Figure 1 — Typical configuration of test apparatus for measurement of expiratory volume

Table 1 — Conditions for expiratory volume measurements

Adjustable parameter	Test conditions		
	Adult use	Paediatric use	Neonatal use
Tidal volume, V_T (ml) as measured by a pressure sensor on the test lung ($V_T = C \times p_W$ max.)	500	300	30
Respiratory cycle frequency, f (min^{-1})	10	20	30
I/E ratio	1/2 or nearest	1/2 or nearest	1/2 or nearest
Resistance to flow, R ($kPa \cdot l^{-1} \cdot s^{-1}$)	0,5 ± 10 %	2 ± 10 %	5 ± 10 %
Isothermal compliance, C (ml/kPa)	500 ± 5 %	200 ± 5 %	10 ± 5 %
NOTE — The accuracies for C and R apply over the entire range of measurements.			

51.9 Device for measuring expiratory volume

If a device for measuring the expiratory tidal volume or the minute volume is provided, the accuracy requirement shall be within ± 20 % of actual reading above 100 ml tidal volume or 2 l/min. Accuracy below 100 ml tidal volume shall be disclosed in the instructions for use.

Test for compliance by visual inspection and verification of accuracy using apparatus as outlined in figure 1.

51.10 Breathing system integrity alarm

If a breathing system integrity alarm is provided, it shall generate an auditory signal in accordance with ISO 9703-2. A means of silencing the alarm shall be provided in accordance with 51.12.

Compliance shall be checked by disconnecting the patient connection port at the patient tube while performing a controlled ventilation.

The operational apparatus is attached to a test lung and operated in accordance with the instructions for use. The auditory alarm shall sound within 20 s following disconnection. In case of IMV ventilation, it is permitted to delay the alarm for the period between two IMV cycles but no longer than 45 s.

51.11 High and low oxygen concentration alarm

If provided, the high and low oxygen concentration alarms shall comply with the requirements of ISO 7767.

Compliance shall be tested by visual inspection and functional testing simulating an oxygen concentration above and below the set alarm limits.

51.12 Alarms

a) The characteristics of any auditory alarm shall be disclosed by the manufacturer.

Visual alarm indication, if provided, shall comply with ISO 9703-1. Auditory alarms shall comply with ISO 9703-2.

NOTE — The characteristics should be appropriate for the intended application(s), e.g. in a road ambulance, between the departments of a hospital, in a helicopter, etc.

b) The maximum time for which an auditory alarm signal can be silenced shall be 120 s.

c) Visual indicators and their associated markings and warnings integral to the ventilator that are intended to be viewed from the operator's position shall be clearly legible when tested as follows:

Place the test operator in the operator's position at a distance of 500 mm from the ventilator. The test is passed if the test operator can correctly identify all controls and indicators, verify all qualitative and quantitative information, and read all warning statements.

51.13 Protection against inadvertent adjustments

Means of protection against inadvertent adjustment of controls which 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 key or switch operations is considered suitable.

Test for compliance by visual inspection following the instructions for use.

Section 9: Abnormal operation and fault conditions; environmental tests

9.1 Abnormal operation and fault conditions

The requirements given in clause 52 of IEC 601-1:1988 apply.

9.2 Environmental tests

The requirements given in clause 53 of IEC 601-1:1988 apply.

Section 10: Constructional requirements

10.1 General

The requirements given in clause 54 of IEC 601-1:1988 apply, with the following additions.

54.1 Arrangements of functions

A single-fault condition shall not cause a monitoring and/or alarm device as per clause 51 and the corresponding ventilation control function to 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 and/or visual inspection.

54.3 Delivered oxygen concentration

The ventilator shall be capable of delivering at least 85 % O_2 (V/V).

10.2 Enclosures and covers

The requirements given in clause 55 of IEC 601-1:1988 apply.

10.3 Components and general assembly

The requirements given in clause 56 of IEC 601-1:1988 apply, with the following additions and modifications.

56.3 Add the following items:

If more than one driving gas input port is provided, each driving gas input port shall be fitted with means, such as unidirectional valves, to prevent reverse gas flow either to the atmosphere or into the pipeline, blender or other supply system. The reverse gas flowrate shall not exceed 5 ml/min under the operating conditions of the lung ventilator specified by the manufacturer [see 6.8.2 a) (5)].

Compliance shall be verified by visual inspection.

56.3 c) High pressure gas input port connectors

If the ventilator is intended to be connected to a medical gas supply system complying with ISO 5359, or a pressure regulator complying with ISO 5358, each high pressure gas inlet connector shall be either the body of a NIST connector complying with ISO 5359 or a probe complying with ISO 9170.

56.3 d) Connection to the medical gas supply system

If a user-detachable hose assembly is provided for connection between the ventilator and the medical gas supply system, it shall comply with ISO 5359. If a hose assembly is permanently connected to the ventilator, the connector to the medical gas supply system shall be a probe complying with ISO 9170.

NOTE — A permanent connection is a connection which can be separated only by the use of a tool.

56.3 e) Ventilator breathing system connectors

Ventilator breathing system connectors, if conical, shall be either 15 mm or 22 mm connectors complying with ISO 5356-1.

56.3 f) Gas exhaust part connector

If an exhaust port connector is provided, it shall be one of the following:

— a 30 mm male conical connector complying with ISO 5356-1, or

— a permanent connection or proprietary connector incompatible with ISO 5356-1 or 5356-2.

56.3 g) Emergency air intake port

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

NOTE — An emergency air intake port should be designed so that it cannot easily be obstructed when the emergency ventilator is in use.

56.3 h) Patient connection port

The patient connection port shall have a coaxial 15 mm/22 mm connector complying with ISO 5356-1.

56.3 i) Manual ventilation port connector

If a manual ventilation port is provided, it shall be either a 22 mm conical connector complying with ISO 5356-1 or a male cylindrical connector that will accept a breathing tube complying with ISO 5367.

56.3 j) Flow-direction-sensitive component connectors

Unless flow-direction-sensitive breathing system components are integral, their connectors, if conical, shall be either 15 mm or 22 mm conical connectors complying with ISO 5356-1 if intended for adult use, or 15 mm conical connectors complying with ISO 5356-1, if intended for neonatal use.

56.3 k) Accessory port

If an accessory port is provided, e.g. for sampling of gases or injection of fluids, it shall not be compatible with connectors as described in ISO 5356-1 or ISO 5356-2 and shall be provided with a means to insure fit-in and closure.

56.3 l) Monitoring probe port

If a port is provided for introduction of a solid sensor, it shall not be compatible with connectors as described in ISO 5356-1 or 5356-2, and shall be provided with a means to secure the sensor in position.

After **56.11** add the following subclauses.

56.12 Reservoir bags and breathing tubes

56.12.1 Reservoir bags and breathing tubes intended for use in the ventilator breathing system, if provided, shall comply with ISO 5362 and ISO 5367.

56.13 Flow-direction-sensitive components

If any component of the ventilator breathing system is a flow-direction-sensitive component, it shall, if user-detachable, be designed such that it cannot be fitted in such a way that it presents a hazard to the patient.

56.14 Inspiratory and expiratory resistances

The inspiratory and expiratory resistances measured at the patient connection port shall, during spontaneous breathing and normal operation, not exceed 0,6 kPa (6 cmH_2O) at flowrates of 60 l/min for adult use, 30 l/min for paediatric use and 5 l/min for neonatal use.

Compliance shall be checked by measurement of the pressure at the patient connection port at the specified flowrates.

56.16.2 Leakage from the ventilator breathing system

Leakage from the ventilator breathing system shall not exceed 200 ml/min for adult circults, 100 ml/min for paediatric, or 50 ml/min for neonatal circuits.

Compliance shall be determined by the following test.

Set up the breathing system for the intended application as recommended by the manufacturer. Seal all ports. Connect the pressure-measuring device and introduce air into the breathing system until a pressure of 5 kPa for adult circuits, or 4 kPa for paediatric circuits, or 2 kPa for neonatal circuits is reached. Adjust the flow of air to stabilize the pressure and record the leakage flowrate.

10.4 Mains parts, components and layout

The requirements given in clause 57 of IEC 601-1:1988 apply, with the following additions.

57.3 Add the following to item a).

The mains supply cord of an electrically powered ventilator shall be a nondetachable cord or, if detachable, shall be protected against accidental disconnection from the ventilator.

Compliance shall be checked by inspection and the test described in 57.4 of IEC 601-1:1988 respectively.

During the test, the mains connector shall not become disconnected from the application inlet.

10.5 Protective earthing — Terminals and connections

The requirements given in clause 58 of IEC 601-1:1988 apply.

10.6 Construction and layout

The requirements given in clause 59 of IEC 601-1:1988 apply.

Annexes

Annexes A to L in IEC 601-1:1988, together with annexes M and N of this part of ISO 10651 apply.

Annex M
(informative)

Rationale

This annex provides a concise rationale for the important 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 reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of this part of ISO 10651 necessitated by those developments.

The clauses in this annex have been so numbered as to correspond to the clauses in this part of ISO 10651 to which they refer. The numbering is, therefore, not consecutive.

1.1 The purpose of this part of ISO 10651 is to establish particular requirements for the safety of emergency ventilators.

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

It should be recognized that antistatic tubing or other tubing which should be considered as electrically conductive may be used in the breathing system of emergency ventilators.

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

1.7 Identification, marking and documents

"6.8.2 a) 2)" The available operating time may vary but presents the most important information for an emergency ventilator mostly used outside a hospital, while no extra power back-up is available.

"6.8.3 a)" No mention of patient parameter or machine parameter is given here, because this distinction exists in IEC 601-1:1988.

Examples of machine parameters are "stroke volume" rather than "tidal volume", "generated pressure" rather than "airway pressure", "set ventilation" rather than "expired ventilation", "return-port pressure" rather than "airway pressure" (as, in this last instance, it is especially important to distinguish between these in some neonatal ventilators).

Some fault conditions, e.g. obstruction or leaks, can cause serious differences between volumes and pressures in the ventilator and the corresponding volumes and pressures in the patient; but other fault conditions, e.g. excessive secretions or the accumulation of condensation in a pressure line, can cause serious errors in directly measured patient parameters.

"6.8.3 a) 5)" Some changes in the conditions and composition of the gas at the sensor can alter the flow- or volume-sensitivity of some types of sensor. Also, changes in the conditions in the sensor may alter the correction required to express the flowrate, volume or ventilation under some standard condition. For example, a volume-displacement-type meter, whenever it is operating normally, will indicate the volume which 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 indication will be less than the true expired volume at BTPS.

3.7 Continuous leakage currents and patient auxiliary currents

"19.4 h)" See the rationale to 1.3.

7.2 Fire prevention

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

The risk of a fire is fundamentally determined by the three elements which 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;

— an oxidant.

Therefore, following the basic safety concepts of IEC 601-1:1988, the objective in the design of the equipment must be to ensure that under both normal and single-fault conditions and under the oxidizing conditions to which the material may 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 may occur provided it is self-limiting so that no hazard is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although usually only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required, these may be determined using the methods and apparatus described in IEC 79-4.

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

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

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

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

The temperature value is based on the minimum hotplate ignition temperature for fire-retardant cotton in 100 % oxygen, which is given in the 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 which 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. 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 may be dissipated and the proximity and type of any "fuel" present.

It is now generally accepted that there are no single or universally applicable ranges of temperatures, energy and concentration of oxidant which 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 may 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 oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal 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 may 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, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

8.2 Protection against hazardous output

"51.11" Typical examples of test criteria for some methods in use are as follows:

a) if intended to annunciate loss of pressure: the alarm might be actuated when the pressure fell by more than, e.g., 20 % from the set or expected peak pressure at the patient connection port;

b) if intended to annunciate reduction of flowrate: the alarm might be actuated when the flowrate fell by, e.g., 20 % from that set or that previously measured at the patient connection port or in the expiratory gas pathway;

c) if intended to annunciate reduction of volume or ventilation: the alarm might be actuated when the volume or ventilation fell by, e.g., 20 % from that set or that previously measured at the patient connection port or in the expiratory gas pathway;

d) if intended to annunciate a change in the level of oxygen: the alarm might be activated by a change of, e.g., 15 % in the mean oxygen concentration. The sensor should be in the return (or expiratory) tube of the ventilator breathing system or in the exhaust gas pathway within 5 cm of the patient connection port. However, the use of an oxygen monitor to activate an alarm is not recommended because of the inherent unreliability of the technique when different concentrations of oxygen are used;

e) if intended to annunciate a change in the level of carbon dioxide, the alarm might be activated by failure of the level of carbon dioxide at the patient connection port to fluctuate by 1 % (*V*/*V*) with an alternation of 3 % (i.e. failure of the intermittent signal consequent upon breathing or ventilation); failure of the carbon dioxide concentration to return to 0,5 % might also be considered. The sampling site should be in the return (expiratory) tube of the ventilator breathing system or in the exhaust gas pathway within 5 cm of the patient connection port or in the respiratory tract (e.g. the tracheal tube may have an integral sampling channel).

10.1 General

"54.1" This clause prevents the use of a monitoring device to control an actuator which would lead to an undetected malfunction of the actuator in case of monitoring failure.

10.4 Mains parts, components and layout

"57.3" Accidental disconnection can be hazardous for the patient.

Annex N
(informative)

Bibliography

[1] IEC 601-2-12:1988, *Medical electrical equipment — Part 2: Particular requirements for the safety of lung ventilators for medical use.*

[2] ISO 4135:1995, *Anaesthesiology — Vocabulary.*

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

[4] prEN 737-3:—[1)], *Medical gas pipeline systems — Part 3: Pipelines for compressed gases and vacuum.*

[5] prEN 738-1:—[1)], *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices.*

1) To be published.

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ICS 11.040.10

Descriptors: medical equipment, electrical equipment, portable equipment, artificial breathing apparatus, ventilators, classification, specifications, safety requirements, tests, marking, instructions for use.

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