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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)

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Foreword

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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.*

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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.

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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.

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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;

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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:

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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.

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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.