

INTERNATIONAL STANDARD

ISO
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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.