INTERNATIONAL STANDARD

ISO 10651-2

Second edition
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Lung ventilators for medical use — Particular requirements for basic safety and essential performance —

Part 2: Home care ventilators for ventilator-dependent patients

Ventilateurs pulmonaires à usage médical — Exigences particulières pour la sécurité de base et les performances essentielles —

Partie 2: Ventilateurs pour soins à domicile pour patients dépendants

Reference number
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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition of ISO 10651-2, together with ISO 10651-6, cancels and replaces the first edition (ISO 10651-2:1996), which has been technically revised.

ISO 10651 consists of the following parts, under the general title *Lung ventilators for medical use — Particular requirements for basic safety and essential performance*:

— *Part 2: Home care ventilators for ventilator-dependent patients*

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

— *Part 4: Particular requirements for operator-powered resuscitators*

— *Part 6: Home-care ventilatory support devices*

The following part is under preparation:

— *Part 5: Gas-powered emergency resuscitators*

NOTE ISO 10651-1:1993, *Lung ventilators for medical use — Part 1: Requirements*, was withdrawn in 2001 and has been revised as IEC 60601-2-12:2003, *Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators.*

Introduction

This part of ISO 10651 specifies requirements for lung **ventilators** intended mainly for home care use but which could be used elsewhere (in healthcare facilities or other locations) for **patients** dependent on ventilatory support i.e. where the **ventilator** is considered to be **life-supporting equipment**. These **ventilators** will frequently be used in locations where driving power is not reliable. These **ventilators** will often be supervised by non-healthcare personnel with varying levels of training.

This part of ISO 10651 is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this part of ISO 10651, the following drafting conventions have been applied.

This part of ISO 10651 uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

— “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list item, note, table, figure) additional to the General Standard.

— “Amendment” means that existing text of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this part of ISO 10651, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— description of type of document change, and test methods: *italic type*;

— terms defined in the General Standard IEC 60601-1:1988, Clause 2 and terms defined in this Particular Standard: **bold type**.

Throughout this part of ISO 10651, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

Requirements for **ventilators** intended for anaesthetic applications are given in ISO 8835-5.

Lung ventilators for medical use — Particular requirements for basic safety and essential performance —

Part 2: Home care ventilators for ventilator-dependent patients

1 Scope

IEC 60601-1:1988, Clause 1 applies, except as follows.

Amendment:

This part of ISO 10651 specifies requirements for lung **ventilators** intended for home applications for those **patients** who are dependent on ventilatory support. Such **ventilators** are considered **life-supporting equipment**, are frequently used in locations where driving power is not reliable, and are often supervised by non-healthcare personnel with different levels of training.

This part of ISO 10651 is not applicable to cuirass and "iron-lung" **ventilators**.

This part of ISO 10651 is not applicable to **ventilators** intended only to augment the ventilation of spontaneously breathing **patients**.

The requirements of this part of ISO 10651 which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

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

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 5362, *Anaesthetic reservoir bags*

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

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

ISO 8185, *Humidifiers for medical use — General requirements for humidification systems,* and *Technical Corrigendum 1:2001*

ISO 9360-1, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 9919, *Pulse oximeters for medical use — Requirements*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices,* and *Technical Corrigendum 1:2003*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 21647, *Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety,* and *Amendment 1:1991* and *Amendment 2:1995*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility- Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability*

IEC 60601-1-8:2003, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, IEC 60601-1:1988, IEC 60601-1-8 and the following apply.

3.1
airway pressure
pressure at the **patient connection port**

3.2
*** applied part**
part of the **equipment** which in **normal use**

— necessarily comes into physical contact with the **patient** for the **equipment** to perform its function; or

— can be brought into contact with the **patient**; or

— needs to be touched by the **patient**; or

— all parts of the **ventilator** intended to be connected to the **ventilator breathing system**

NOTE Adapted from IEC 60601-1/A2:1995, 2.1.5.

3.3
clearly legible
capable of being read by the **operator** or other relevant person with normal vision

3.4
home care ventilator for ventilator-dependent patient
ventilator
ventilator, suitable for domiciliary use without continuous professional supervision, intended to augment or provide ventilation of the lungs of a **patient** who is dependent on this ventilation

NOTE 1 As this **ventilator** is intended to be applied to **patients** who are dependent on this ventilation, it is considered to be **life-supporting equipment**.

NOTE 2 This term is hereinafter referred to as “ventilator”.

3.5
home care ventilatory support device for non-ventilator-dependent patient
ventilator, suitable for domiciliary use without continuous professional supervision, intended to augment or provide ventilation of the lungs of a **patient** who is not dependent on this ventilation

NOTE This **ventilatory support device** is intended to be applied to **patients** who are not dependent on this ventilation and will survive without this ventilatory support, without significant degradation in their health.

3.6
minute volume
$\dot{V}$

volume of gas per minute entering or leaving the lungs of the **patient**

3.7
operator's position
intended position of the **operator** during **normal use** of the **equipment**

3.8
reserve electrical power source
part of the **equipment** that temporarily provides electrical power in the event of interruption of the primary supply

4 General requirements and requirements for tests

IEC 60601-1:1988, Clause 3 and Clause 4 apply, except as follows.

3.1 *

Amendment (add at the end of the subclause):

This shall include all displayed values and calibrated controls over the environmental ranges specified in 10.2.1, as well as the combination of all **accessories** specified by the manufacturer in the instructions for use.

Any fault that can lead to a hazard and that is not detected by intrinsic means or by periodic inspection (e.g. an oxidant leak, software defect) shall be regarded as a **normal condition** and not a **single fault condition**.

3.4

Amendment (add at the end of the subclause):

An equivalent degree of safety can be demonstrated by means of a risk analysis, in accordance with ISO 14971.

5 Classification

IEC 60601-1:1988, Clause 5 applies, except as follows.

5.2

Amendment (add at the end of the subclause):

NOTE A **ventilator** can have **applied parts** of different types.

6 Identification, marking and documents

IEC 60601-1:1988, Clause 6, applies, except as follows:

6.1 Marking on the outside of equipment or equipment parts

Replacement:

e) Indication of origin

The name and address of the manufacturer and authorized representative, if applicable.

Amendment (add at the end of the list item):

j) Power input

The **rated** power input marking shall include the maximum **rated** power output available to the **auxiliary mains socket-outlets** with which the **ventilator** is equipped.

Amendment (add at the end of the list item):

q) Physiological effects

If applicable, a warning that latex is used.

Addition:

aa) Any **high-pressure input port** shall be marked with the name or symbol of gas in accordance with ISO 5359 and with the supply pressure range and the maximum flow requirements. If gas-specific colour-coding of flow control or flexible hoses is used, it shall be in accordance with ISO 32.

bb) **operator**-accessible ports shall be marked. If symbols are used, they shall be explained in the instructions for use and validated according to IEC 60601-1-6.

cc) Any particular storage and transport instructions.

dd) * Any particular warnings and/or precautions relevant to the immediate use of the **ventilator**.

EXAMPLE Those relevant after storage or transport outside the environmental conditions specified for use.

ee) Where appropriate, the date after which the safe operation of the **ventilator** or **accessory**, when used for the first time, is not assured, expressed as the year and month. Symbol 3.12 from ISO 15223:2000 may be used.

ff) Packages containing breathing attachments intended for single use shall be clearly marked with the following, as far as applicable:

1) a description of the contents;

2) an identification reference to the type, or Symbol 3.13 from ISO 15223:2000;

3) an identification reference to the batch or serial number, or Symbol 3.14 or 3.16 from ISO 15223:2000;

4) the name or trademark and the address of the manufacturer, supplier and authorized representative;

5) packages containing latex shall be clearly marked with the word “LATEX”;

6) the word “STERILE”, or Symbols 3.20 to 3.24 from ISO 15223:2000;

7) the words “SINGLE USE ONLY”, “DO NOT REUSE”, or Symbol 3.2 from ISO 15223:2000;

gg) All flow-direction-sensitive components that are operator-removable without the use of a tool shall be durably and legibly marked with an arrow indicating the direction of the flow.

hh) Device packaging and/or labelling shall differentiate between sterile and non-sterile versions of the same or similar products placed on the market by the same manufacturer [see 6.1 ff) 6)].

6.3 Marking of controls and instruments

g)

Amendment (add at the end of the list item):

Airway pressures shall be marked in both SI units and centimetres water column (cmH_2O).

Addition:

aa) Visual displays shall be visible and **clearly legible**.

Amendment (add at the end of the compliance test):

and the legibility test of 6.101.

6.6 Identification of medical gas cylinders and connections

Replacement:

If gas-specific colour-coding is used (e.g. for flow controls, flexible hoses, gas cylinders, etc.) it shall be in accordance with ISO 32. See also 56.3 aa).