Meditsiiniliseks kasutamiseks ettenähtud kopsuventilaatorid. Erinõuded esmasele ohutusele ja olulistele toimimisnäitajatele. Osa 6: Koduseks raviks mõeldud ventilatoorsed abiseadmed

Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10651-6:2004 sisaldab Euroopa standardi EN ISO 10651-6:2004 ingliskeelset teksti. Käesolev dokument on jõustatud 23.09.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 10651-6:2004 consists of the English text of the European standard EN ISO 10651-6:2004. This document is endorsed on 23.09.2004 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of ISO 10651 specifies the basic safety and essential performance requirements for home-care ventilatory support devices, intended mainly for use in home care but which could be used elsewhere (e.g. in healthcare facilities) for appropriate patients for whom the use of a home-care ventilator complying with ISO 10651-2 is not required.	**Scope:** This part of ISO 10651 specifies the basic safety and essential performance requirements for home-care ventilatory support devices, intended mainly for use in home care but which could be used elsewhere (e.g. in healthcare facilities) for appropriate patients for whom the use of a home-care ventilator complying with ISO 10651-2 is not required.

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English version

Lung ventilators for medical use

Particular requirements for basic safety and essential performance
Part 6: Home-care ventilatory support devices
(ISO 10651-6 : 2004)

Ventilateurs pulmonaires à usage médical – Exigences particulières pour la sécurité de base et les performances essentielles – Partie 6: Dispositifs d'assistance respiratoire à domicile (ISO 10651-6 : 2004)

Beatmungsgeräte für die medizinische Anwendung – Besondere Festlegungen für die grundlegende Sicherheit einschließlich der wesentlichen Leistungsmerksmale – Teil 6: Heimbeatmungsgeräte zur Atemunterstützung (ISO 10651-6 : 2004)

This European Standard was approved by CEN on 2004-06-21.

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CEN

European Committee for Standardization
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Foreword

International Standard

ISO 10651-6 : 2004 Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 6: Home-care ventilatory support devices,

which was prepared by ISO/TC 121 'Anaesthetic and respiratory equipment' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 215 'Respiratory and anaesthetic equipment', the Secretariat of which is held by BSI, as a European Standard.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of the relevant EU Directive.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by January 2005 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10651-6 : 2004 was approved by CEN as a European Standard without any modification.

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Introduction

This part of ISO 10651 specifies requirements for ventilatory support devices mainly for home-care use but which could be used elsewhere (in healthcare facilities or other locations) for **patients** not dependent on ventilatory support, i.e. where the **ventilator** is not considered to be **life-supporting equipment**. These **ventilators** are frequently used in locations where driving power is not reliable. These **ventilators** often are 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 Standards 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 an existing element 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 part of ISO 10651: 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 part of ISO 10651: **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.

1 Scope

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

Amendment:

This part of ISO 10651 specifies the basic safety and essential performance requirements for home-care ventilatory support devices, intended mainly for use in home care but which could be used elsewhere (e.g. in healthcare facilities) for appropriate **patients** for whom the use of a home-care **ventilator** complying with ISO 10651-2 is not required.

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 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 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*

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 60601-1-2:2001, *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 (at present Commmittee draft)*

IEC 60601-1-8:2003, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: Alarm systems — Requirements, tests and guidelines — General requirements and guidelines 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 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, 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 As this **ventilator** is intended to be applied to **patients** who are dependent on this ventilation, it is considered to be **life-supporting equipment**.