
Geregistreeerde Belgische norm

NBN EN ISO 10651-6

1e uitg., september 2004

Normklasse: S 30

Longventilatoren voor medisch gebruik - Bijzondere eisen voor basisveiligheid en essentiële eigenschappen - Deel 6: Ventilatiehulpstukken voor de thuiszorg (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)

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

Toelating tot publicatie: 31 augustus 2004

Deze Europese norm EN ISO 10651-6: 2004 heeft de status van een Belgische norm.

Deze Europese norm bestaat in drie officiële versies (Duits, Engels, Frans).



Belgisch instituut voor normalisatie (BIN), vereniging zonder winstoogmerk
Brabançonnelaan 29 - 1000 BRUSSEL - telefoon: 02 738 01 12 - fax: 02 733 42 64
e-mail: info@bin.be - BIN Online: www.bin.be - prk. 000-0063310-66

***norme belge
enregistrée***

NBN EN ISO 10651-6

1e éd., septembre 2004

Indice de classement: S 30

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)

Longventilatoren voor medisch gebruik - Bijzondere eisen voor basisveiligheid en essentiële eigenschappen - Deel 6: Ventilatiehulpstukken voor de thuiszorg (ISO 10651-6:2004)

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

Autorisation de publication: 31 août 2004

La présente norme européenne EN ISO 10651-6: 2004 a le statut d'une norme belge.

La présente norme européenne existe en trois versions officielles (allemand, anglais, français).



Institut belge de normalisation (IBN), association sans but lucratif
avenue de la Brabançonne 29 - 1000 BRUXELLES - téléphone: 02 738 01 12 - fax: 02 733 42 64
e-mail: info@ibn.be - IBN Online: www.ibn.be - CCP. 000-0063310-66

ICS 11.040.10

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
essentiels - Partie 6: Dispositifs d'assistance respiratoire
à domicile (ISO 10651-6:2004)

This European Standard was approved by CEN on 21 June 2004.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 10651-6:2004 (E)

Foreword

This document (EN ISO 10651-6:2004) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

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

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 10651-6:2004 has been approved by CEN as EN ISO 10651-6:2004 without any modifications.

ANNEX ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42 EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO
10651-6

First edition
2004-07-01

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

Part 6:

Home-care ventilatory support devices

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

Partie 6: Dispositifs d'assistance respiratoire à domicile



Reference number
ISO 10651-6:2004(E)

© ISO 2004

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2004

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements and general requirements for tests	3
5 Classification	3
6 Identification, marking and documents	3
6.1 Marking on the outside of equipment or equipment parts	4
6.3 Marking of controls and instruments	5
6.6 Identification of medical gas cylinders and connections	5
6.101 Test method for legibility	7
7 Power input	8
7.101 Pneumatic power	8
8 Basic safety categories	8
9 Removable protective means	8
10 Environmental conditions	8
10.101 Pneumatic driving power supplies	9
11 Not used	9
12 Not used	9
13 General	9
14 Requirements related to classification	9
14.2 * Class II Equipment	9
15 Limitation of voltage and/or energy	9
16 Enclosures and protective covers	9
17 Separation	9
18 Protective earthing, functional earthing and potential equalization	9
19 Continuous leakage currents and patient auxiliary currents	10
19.4 * Tests	10
20 Dielectric strength	10
21 Mechanical strength	10
22 Moving parts	10
23 Surfaces, corners and edges	10
24 Stability in normal use	10
25 Expelled parts	10

ISO 10651-6:2004(E)

26	Vibration and noise.....	10
27	Pneumatic and hydraulic power.....	10
28	Suspended masses	11
29	X-radiation	11
30	Alpha, beta, gamma, neutron radiation and other particle radiation.....	11
31	Microwave radiation	11
32	Light radiation (including lasers)	11
33	Infra-red-radiation	11
34	Ultra-violet radiation	11
35	Acoustical energy (including ultrasonics)	11
36	Electromagnetic compatibility.....	11
37	Locations and basic requirements.....	11
38	Marking, accompanying documents.....	12
39	Common requirements for category AP and category APG equipment.....	12
40	Requirements and tests for category AP equipment, parts and components thereof.....	12
41	Requirements and tests for category APG equipment, parts and components thereof.....	12
42	Excessive temperatures.....	12
43	Fire prevention	12
43.2	Oxygen enriched atmospheres	12
43.101	Compatibility with pressurized oxygen	13
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	13
44.3	Spillage	13
44.7	Cleaning, sterilization and disinfection	13
44.8	Compatibility with substances used with the equipment.....	13
45	Pressure vessels and parts subject to pressure	13
46	Human errors.....	14
47	Electrostatic charges.....	14
48	Biocompatibility	14
49	Interruption of the power supply.....	14
49.101 *	Internal electrical power source	14
49.102	Spontaneous breathing during power failure	14
49.103	Accidental operation of the on/off-switch	15
50	Accuracy of operating data.....	15
51	Protection against hazardous output	15
51.101	Maximum ventilator breathing system pressure limitation.....	15
51.102	Measurement of airway pressure.....	15
51.103 *	High-inspiratory pressure alarm condition	15
51.104	Expiratory monitoring	15
51.105	Respiration rate alarm condition.....	16

52	Abnormal operation and fault conditions	17
53	Environmental tests	17
54	General.....	17
54.3	Protection against inadvertent adjustments.....	17
55	Enclosures and covers	17
56	Components and general assembly	17
56.3	Connections — General.....	17
56.101	Reservoir bags and breathing tubes	19
57	Mains parts, components and layout	19
57.3 *	Power supply cords.....	19
58	Protective earthing — Terminals and connections.....	19
59	Construction and layout	20
101	Alarm systems	20
102	Appendices of IEC 60601-1:1988	20
Annex AA	(informative) Rationale.....	21
Annex BB	(informative) Reference to the Essential Principles	25
Bibliography	26

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 10651-6 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This first edition of ISO 10651-6, together with the second edition of ISO 10651-2, cancels and replaces the first edition of 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 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**.

ISO 10651-6:2004(E)

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 6: Home-care ventilatory support devices

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*