



# SLOVENSKI STANDARD SIST EN ISO 10651-2:2005

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SIST EN 794-2:2000

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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 (ISO 10651-2:2004)

Beatmungsgeräte für die medizinische Anwendung - Besondere Festlegungen für die grundlegende Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Teil 2: Heimbeatmungsgeräte für vom Gerät abhängige Patienten (ISO 10651-2:2004)

Ventilateurs pulmonaires a usage médical - Exigences particulieres pour la sécurité de base et les performances essentielles - Partie 2: Ventilateurs pour soins a domicile pour patients dépendants (ISO 10651-2:2004)

**Ta slovenski standard je istoveten z: EN ISO 10651-2:2004**

### **ICS:**

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN ISO 10651-2

July 2004

ICS 11.040.10

Supersedes EN 794-2:1997

English version

Lung ventilators for medical use - Particular requirements for  
basic safety and essential performance - Part 2: Home care  
ventilators for ventilator-dependent patients (ISO 10651-2:2004)

Ventilateurs pulmonaires à usage médical - Exigences  
particulières pour la sécurité de base et les performances  
essentiels - Partie 2: Ventilateurs pour soins à domicile  
pour patients dépendants (ISO 10651-2:2004)

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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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

**EN ISO 10651-2:2004 (E)****Foreword**

This document (EN ISO 10651-2:2004) 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 supersedes EN 794-2:1997.

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 10651-2:2004 has been approved by CEN as EN ISO 10651-2:2004 without any modifications.

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## **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.

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STANDARD

ISO  
10651-2

Second edition  
2004-07-01

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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**

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*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*

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# Contents

Page

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

## ISO 10651-2:2004(E)

26	Vibration and noise .....	11
27	Pneumatic and hydraulic power .....	11
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.....	12
34	Ultraviolet radiation.....	12
35	Acoustical energy (including ultrasonics).....	12
36	Electromagnetic compatibility .....	12
37	Locations and basic requirements .....	12
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.....	13
43.2 *	Oxygen-enriched atmospheres .....	13
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 .....	14
45	Pressure vessels and parts subject to pressure .....	14
46	Human errors .....	14
47	Electrostatic charges .....	14
48	Biocompatibility.....	14
49	Interruption of the power supply .....	14
49.101 *	Internal electrical power source .....	15
49.102	Additional external backup power source .....	15
49.103	Spontaneous breathing during power failure .....	15
49.104	Accidental operation of the on/off-switch .....	15
50	Accuracy of operating data .....	15
51	Protection against hazardous output.....	16
51.101	Failure of air and oxygen supply systems.....	16
51.102	Adjustable ventilator breathing system pressure limitation .....	16
51.103	Maximum ventilator breathing system pressure limitation .....	16
51.104	Measurement of airway pressure .....	16
51.105 *	High-inspiratory pressure alarm condition .....	16
51.106	Expiratory monitoring .....	17
51.107	Hypoventilation alarm condition.....	18
51.108	Continuing pressure alarm condition .....	18
51.109	Respiration-rate alarm condition .....	18
52	Abnormal operation and fault conditions .....	18

53	Environmental tests .....	19
54	General .....	19
54.3	Protection against inadvertent adjustments .....	19
55	Enclosures and covers .....	19
56	Components and general assembly .....	19
56.3	Connections — General .....	19
56.101	Reservoir bags and breathing tubes.....	21
56.102	Humidifiers and heat and moisture exchangers.....	21
56.103	Pulse oximeters and capnometers.....	21
56.104	Oxygen monitor and alarm condition .....	21
56.105	Integrated monitoring equipment.....	21
57	Mains parts, components and layout.....	22
57.3 *	Power supply cords .....	22
58	Protective earthing — Terminals and connections .....	22
59	Construction and layout.....	22
101	Alarm systems.....	22
201.8.3	Indication and access .....	22
201.12	Alarm condition logging.....	22
102	Appendices of IEC 60601-1:1988 .....	23
Annex AA	(informative) Rationale.....	24
Annex BB	(informative) Reference to the essential principles .....	28
Bibliography	.....	30

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## ISO 10651-2:2004(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.

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**.