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Irish Standard
I.S. EN ISO 10651-2:2009

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)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10651-2

April 2009

ICS 11.040.10

Supersedes EN ISO 10651-2:2004

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 essentielles - Partie 2: Ventilateurs pour soins à domicile pour patients dépendants (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)

This European Standard was approved by CEN on 14 March 2009.

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Foreword

The text of ISO 10651-2:2004 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10651-2:2009 by 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 10651-2:2004.

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 EC Directive.

For relationship with EC Directive, 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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 10651-2:2004 has been approved by CEN as a EN ISO 10651-2:2009 without any modification.

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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 on medical devices.

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 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.

Table ZA.1 – Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4 (3.1)	4, 12.1	
4 (3.4)	2	
5.2	12.6	
6.1	2, 13.1	
6.1	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 e)	13.3 a)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 q)	7.1, 7.2, 13.3 k)	
6.1 aa), 6.1 bb)	9.2, 13.2	
6.1 cc)	13.3 i)	
6.1 dd)	13.3 i), 13.6 k)	
6.1 ee)	13.3 e)	
6.1 ff)	13.3 b), 13.3 f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 ff)	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 ff) 2)	13.2	
6.1 ff) 3)	13.3 d), 13.5	
6.1 ff) 4)	13.3 a)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1 ff) 5)	13.3 k)	

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Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.1 ff) 6)	13.3 c)	
6.1 ff) 8)	13.3 m)	
6.1 gg)	8.2, 12, 13.2, 13.3 i)	
6.1 hh)	8.7	
6.3	2, 10, 12.9	
6.6	12.7.4	
6.8.2	2, 9.1, 13	
6.8.2	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2 d)	13.6 a), 13.6 h), 13.6 i)	
6.8.2 aa) 1)	13.4	
6.8.2 aa) 2)	13.6 c)	
6.8.2 aa) 4), 6.8.2 aa) 5), 6.8.2 aa) 6)	12.2, 13.6 d)	
6.8.2 aa) 7), 6.8.2 aa) 8)	12.2, 13.6 a)	
6.8.2 aa) 9)	13.6 p)	
6.8.2 aa) 10)	13.6 l)	
6.8.2 aa) 11)	13.6 b)	
6.8.2 aa) 12), 6.8.2 aa) 13), 6.8.2 aa) 14), 6.8.2 aa) 15), 6.8.2 aa) 16), 6.8.2 aa) 17),	13.6 a)	
6.8.2 aa) 15), 6.8.2 aa) 18)	13.6 d)	
6.8.3	2, 3, 9.1, 13	
6.101	10.2	
7.101	9.1, 12.8.1	
10	4, 5, 9.2	
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36	9.2, 12.5	
43	7.3, 9.3	
44.3	7.6	
44.7	8.1	
44.8	7.1, 7.5	
44.8	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
46	10.2	
49.101	9.2, 12.2, 12.3	
49.102	9.2	
49.103	4, 9.2, 12.1	
49.104	5, 9.2, 12.9	

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Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
51.101	12.8.1. 12.8.2	
51.102	4, 9.2, 12.8.1	
51.103	4, 9.2, 12.8.1	
51.104	6, 10.1, 12.4	
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56.105	9.1, 10	
57.3	2, 4, 12.1, 12.8.1	
201.8.3	12.4, 12.8.2	
201.12	5, 12.4	
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard

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

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For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	EHSR of 2006/42/EC	Qualifying remarks/Notes
-	1.1.4	This relevant EHSR is not addressed in this European Standard
6.1, 56	1.5.4	This relevant EHSR is not fully addressed in this European Standard
-	1.6.1	This relevant EHSR is not addressed in this European Standard
-	1.6.2	This relevant EHSR is not addressed in this European Standard
-	1.6.3	This relevant EHSR is not addressed in this European Standard
-	3.6.2	This relevant EHSR is not addressed in this European Standard

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INTERNATIONAL STANDARD

ISO 10651-2

Second edition
2004-07-01

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
ISO 10651-2:2004(E)

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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.*

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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**.

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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.

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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

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*

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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

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