
Medicinska električna oprema – 2-12. del: Posebne varnostne zahteve za pljučne ventilatorje – Ventilatorji za kritično oskrbo (IEC 60601-2-12:2001)

Medical electrical equipment – Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators (IEC 60601-2-12:2001)

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English version

**Medical electrical equipment
Part 2-12: Particular requirements
for the safety of lung ventilators –
Critical care ventilators
(IEC 60601-2-12:2001)**

Appareils électromédicaux
Partie 2-12: Règles particulières de
sécurité pour ventilateurs pulmonaires –
Ventilateurs pour utilisation en soins
intensifs
(CEI 60601-2-12:2001)

Medizinische elektrische Geräte
Teil 2-12: Besondere Festlegungen
für die Sicherheit von Beatmungsgeräten
für den medizinischen Gebrauch –
Beatmungsgeräte für die Intensivpflege
(IEC 60601-2-12:2001)

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SIST EN 60601-2-12:2006

This European Standard was approved by CENELEC on 2006-05-01. CENELEC 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 CENELEC 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 CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of 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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of the International Standard IEC 60601-2-12:2001, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and ISO TC 121/SC 3, Lung ventilators and related equipment, was submitted to the Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-12 on 2006-05-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2007-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2009-05-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard replaces EN 794-1:1997, *Lung ventilators - Part 1: Particular requirements for critical care ventilators*, which was prepared by CEN/TC 215 and will be withdrawn by CEN.

Other European Standards which may be of interest relating to lung ventilators prepared by CEN/TC 215 are:

- ITeH STANDARD PREVIEW**
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- EN 794-3:1998, *Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators*
[https://standards.iteh.ai/catalog/standards/sist/7b8f89d-e519-456b-a4a1-45117089e79e/sist/7b8f89d-e519-456b-a4a1-45117089e79e](https://standards.iteh.ai/catalog/standards/sist/7b8f89d-e519-456b-a4a1-45117089e79e/sist/7b8f89d-e519-456b-a4a1-45117089e79e/sist/7b8f89d-e519-456b-a4a1-45117089e79e)
 - EN ISO 10651-2:2004, *Lung ventilators for medical use - Part 2: Home care ventilators for ventilator-dependent patients*
 - EN ISO 10651-4:2002, *Lung ventilators – Part 4: Particular requirements for operator-powered resuscitators*
 - EN ISO 10651-6:2004, *Lung ventilators for medical use - Part 6: Home-care ventilatory support devices.*

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, notes, general statements, exceptions and references: small roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS PARTICULAR STANDARD: SMALL CAPITALS.

Annexes ZA, ZB and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-12:2001 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-13	NOTE	IEC 60601-2-13:2003 is harmonized as EN 60601-2-13:2006 (not modified).
ISO 594-1	NOTE	Harmonized as EN ISO 20594-1:1993 (not modified).
ISO 10651-2	NOTE	Harmonized as EN ISO 10651-2:2004 (not modified).

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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Addition to Annex ZA of EN 60601-1:1990/A2:1995:</i>				
IEC 60079-4 + A1	1975 1995	Electrical apparatus for explosive gas atmospheres Part 4: Method of test for ignition temperature	-	-
+ IEC 60079-4A	1970	First Supplement		
IEC 60601-1 + A1	1988 1991	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July + A1	1990 1994 1993
+ A2 + corr. June	1995 1995		+ corr. July + A2 + A13	1994 1995 1996
<i>Replacement in Annex ZA of EN 60601-1:1990/A2:1995:</i>				
IEC 60417-1 ¹⁾	2000	Graphical symbols for use on equipment Part 1: Overview and application	-	-
IEC 60417-2 ¹⁾ + A1	1998 2000	Graphical symbols for use on equipment Part 2: Symbol originals	-	-
IEC 60601-1-1	2000	Medical electrical equipment Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	2001
IEC 60601-1-2	2001	Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001
IEC 60601-1-4 + A1	1996 1999	Medical electrical equipment Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	EN 60601-1-4 + A1	1996 1999

¹⁾ IEC 60417-1 and 60417-2 were superseded by the IEC 60417 database.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Addition to Annex ZA of EN 60601-1:1990/A2:1995:</i>				
ISO 4135	1995 ²⁾	Anaesthesiology - Vocabulary	-	-
ISO 5356-1	1996	Anaesthetic and respiratory equipment - Conical connectors Part 1: Cones and sockets	-	-
ISO 5356-2	1987	Anaesthetic and respiratory equipment - Conical connectors Part 2: Screw-threaded weight-bearing connectors	-	-
ISO 5359	2000	Low-pressure hose assemblies for use with medical gas systems	-	-
ISO 5362	2000	Anaesthetic reservoir bags	-	-
ISO 5367	2000	Breathing tubes intended for use with anaesthetic apparatus and ventilators	-	-
ISO 7000	1989	Graphical symbols for use on equipment - Index and synopsis	-	-
ISO 7396	1987 ³⁾	Non-flammable medical gas pipeline systems -	-	-
ISO 7767 ⁴⁾	1997	Oxygen monitors for monitoring patient breathing mixtures - Safety requirements	-	-
ISO 8835-3	1997	Inhalational anaesthesia systems Part 3: Anaesthetic gas scavenging systems	-	-
ISO 9360-1	2000	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	2001	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 9703-1 ⁵⁾	1992	Anaesthesia and respiratory care alarm signals Part 1: Visual alarm signals	-	-
ISO 9703-2 ⁵⁾	1994	Anaesthesia and respiratory care alarm signals Part 2: Auditory alarm signals	-	-

²⁾ ISO 4135:1995 is superseded by ISO 4135:2001, *Anaesthetic and respiratory equipment - Vocabulary*

³⁾ ISO 7396:1987 is superseded by ISO 7396-1:2002 and ISO 7396-2:2000, *Medical gas pipeline systems*

⁴⁾ ISO 7767:1997 and ISO 9918:1993 are superseded by ISO 21647:2004, which is harmonized as EN ISO 21647:2004, *Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors.*

⁵⁾ The ISO 9703 series is superseded by IEC 60601-1-8:2003, which is harmonized as EN 60601-1-8:2004.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 9703-3 ⁵⁾	1998	Anaesthesia and respiratory care alarm signals Part 3: Guidance on application of alarms	-	-
ISO 9918 ³⁾	1993	Capnometers for use with humans - Requirements	-	-
ISO 9919	1992 ⁶⁾	Pulse oximeters for medical use - Requirements	-	-
ISO 11134	1994	Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization	-	-
ISO 11135	1994	Medical devices - Validation and routine control of ethylene oxide sterilization	-	-
ISO 11137	1995	Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization	-	-
ISO 11138-1	1994	Sterilization of health care products - Biological indicators Part 1: General	-	-
ISO 11138-2	1994	Sterilization of health care products - Biological indicators Part 2: Biological indicators for ethylene oxide sterilization	-	-
ISO 11138-3	1995	Sterilization of health care products - Biological indicators Part 3: Biological indicators for moist heat sterilization	-	-
ISO 14971	2000	Medical devices - Application of risk management to medical devices	-	-
ISO 15223	2000	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	-	-

Annex ZB (informative)

References to international publications with their corresponding European publications

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Delete the reference to IEC 601-1:1977 from Annex ZB of EN 60601-1:1990/A2:1995</i>				
<i>Replacement in Annex ZB of EN 60601-1:1990/A2:1995:</i>				
ISO 8185	1997	Humidifiers for medical use - General requirements for humidification systems	-	-

⁶⁾ ISO 9919:1992 is superseded by ISO 9919:2005, *Medical electric equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.*

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

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

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IEC 60601-2-12

[ISO 10651-1]

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Part 2-12: Particular requirements for the safety of lung ventilators – Critical care ventilators

iTeh STANDARD PREVIEW

Appareils électromédicaux –

Partie 2-12: EN 60601-2-12:2006

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Règles particulières de sécurité pour ventilateurs
pulmonaires – Ventilateurs pour utilisation en soins intensifs

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-12: Particular requirements for the safety of lung ventilators –
Critical care ventilators**

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization, comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of the IEC on technical matters, express as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides, and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. IEC shall not be held responsible for identifying any such patent rights.

International Standard IEC 60601-2-12 has been prepared by subcommittee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

ISO TC 121/SC 3, Lung ventilators and related equipment, also participated in the preparation of this standard.

This second edition replaces the first edition of IEC 60601-2-12:1988, *Medical electrical equipment – Part 2: Particular requirements for the safety of lung ventilators for medical use*, and ISO 10651-1:1993, *Lung ventilators for medical use – Part 1: Requirements*.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/414/FDIS	62D/440/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

Annex BB forms an integral part of this standard.

Annexes AA and CC are for information only.

In this Particular Standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- notes, explanations, advice, introductions, general statements and references: smaller roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2004. At this date, the publication will be:

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

NOTE IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for safety – Collateral Standard: General requirements and guidelines for the application of alarms in medical electrical equipment* is currently under development. This Standard will require maintenance to conform to that Collateral Standard.

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