SVENSK STANDARD SS-EN 60601-2-12

Fastställd	Utgåva	Sida	Ingår i
2007-03-26	1	1 (1+45)	SEK Område 62

Svenska Elektriska Kommissionen, SEK

Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2-12: Särskilda fordringar på lungventilatorer – Intensivvårdsventilatorer

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

Som svensk standard gäller europastandarden EN 60601-2-12:2006. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-12:2006.

Nationellt förord

Europastandarden EN 60601-2-12:2006

består av:

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
- **IEC 60601-2-12, Second edition, 2001 - Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators**

  utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1.

Tidigare fastställd svensk standard SS-IEC 601-2-12, utgåva 1, 1991, SS-EN 794-1, utgåva 1, 1997 och SS-EN 794-1/A1, utgåva 1, 2000, gäller ej fr o m 2009-05-01.

ICS 11.040.10

Denna standard är fastställd av Svenska Elektriska Kommissionen, SEK,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

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SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

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Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

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Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-12

June 2006

ICS 11.040.10

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)

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

Ref. No. EN 60601-2-12:2006 E

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:

– EN 794-3:1998, *Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators*

– EN ISO 10651-2:2004, *Lung ventilators for medical use - Particular requirements for basic safety and essential performance – 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 - Particular requirements for basic safety and essential performance - 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.

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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).

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.

Publication	Year	Title	EN/HD	Year
Addition to Annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60079-4 + A1 + IEC 60079-4A	1975 1995 1970	Electrical apparatus for explosive gas atmospheres Part 4: Method of test for ignition temperature First Supplement	-	-
IEC 60601-1 + A1 + A2 + corr. June	1988 1991 1995 1995	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July + A1 + corr. July + A2 + A13	1990 1994 1993 1994 1995 1996
Replacement in Annex ZA of EN 60601-1:1990/A2:1995:				
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.

Publication	Year	Title	EN/HD	Year
Addition to Annex ZA of EN 60601-1:1990/A2:1995:				
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 - Transfer and receiving 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.

Publication	Year	Title	EN/HD	Year
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

Publication	Year	Title	EN/HD	Year
Delete the reference to IEC 601-1:1977 from Annex ZB of EN 60601-1:1990/A2:1995				
Replacement in Annex ZB of EN 60601-1:1990/A2:1995:				
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*.

CONTENTS

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1 Scope

Addition:

This Particular Standard specifies the safety requirements for VENTILATORS, as defined in 2.1.125, intended for use in critical care settings.

Continuous positive airway pressure (CPAP) devices, sleep apnea therapy devices, support-care VENTILATORs, emergency and transport VENTILATORs, jet and high frequency VENTILATORs and oscillators are outside the scope of this Particular Standard, nor are devices that may be used within hospitals, intended solely to augment the ventilation of spontaneously breathing PATIENTS. Standards for other types of VENTILATORs, e.g. high frequency jet and oscillation ventilators, are under consideration.

Requirements for VENTILATORs intended for anaesthetic applications are given in IEC 60601-2-13.

1.2 Object

Addition:

The object of this standard is to specify particular safety requirements for VENTILATORS intended for use in critical care settings.

1.3 Particular standards

Addition:

This Particular Standard refers to IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995), herein referred to as the “General Standard”.

The General Standard takes into account a set of Collateral Standards:

IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety, Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety, 4. Collateral standard: Programmable electrical medical systems*
Amendment 1[1]

The term “this Standard” covers this Particular Standard, used together with the General Standard and the Collateral Standards.

The numbering of sections, clauses, and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

– “Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.
– “Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.
– “Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures that are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk *. These rationales can be found in an informative Annex AA.

Annexes AA and CC are not normative parts of this Particular Standard and only provide additional information; they can never be the subjects of testing.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or specified Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or a Collateral Standard takes precedence over the corresponding general requirement(s).