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

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 60601-2-12:2006 sisaldab Euroopa standardi EN 60601-2-12:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 22.09.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 60601-2-12:2006 consists of the English text of the European standard EN 60601-2-12:2006. This document is endorsed on 22.09.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Specifies the safety requirements for ventilators, as defined below, intended for use in critical care settings. Ventilator: automatic equipment that is intended to augment or provide ventilation of the lungs of the patient when connected to the airway of the patient.	**Scope:** Specifies the safety requirements for ventilators, as defined below, intended for use in critical care settings. Ventilator: automatic equipment that is intended to augment or provide ventilation of the lungs of the patient when connected to the airway of the patient.

ICS 11.040.10

Võtmesõnad:

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.

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*.

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.

INTERNATIONAL STANDARD

IEC 60601-2-12

[ISO 10651-1]

Second edition
2001-10

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-12:
Règles particulières de sécurité pour ventilateurs pulmonaires – Ventilateurs pour utilisation en soins intensifs

Reference number
IEC 60601-2-12:2001(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Further information on IEC publications

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology. Information relating to this publication, including its validity, is available in the IEC Catalogue of publications (see below) in addition to new editions, amendments and corrigenda. Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is also available from the following:

- **IEC Web Site (www.iec.ch)**

- **Catalogue of IEC publications**

  The on-line catalogue on the IEC web site (www.iec.ch/catlg-e.htm) enables you to search by a variety of criteria including text searches, technical committees and date of publication. On-line information is also available on recently issued publications, withdrawn and replaced publications, as well as corrigenda.

- **IEC Just Published**

  This summary of recently issued publications (www.iec.ch/JP.htm) is also available by email. Please contact the Customer Service Centre (see below) for further information.

- **Customer Service Centre**

  If you have any questions regarding this publication or need further assistance, please contact the Customer Service Centre:

  Email: custserv@iec.ch
  Tel: +41 22 919 02 11
  Fax: +41 22 919 03 00

INTERNATIONAL STANDARD

IEC 60601-2-12

[ISO 10651-1]

Second edition
2001-10

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-12:
Règles particulières de sécurité pour ventilateurs pulmonaires – Ventilateurs pour utilisation en soins intensifs

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

PRICE CODE X

For price, see current catalogue

CONTENTS

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.

INTRODUCTION

Critical care VENTILATORS are an essential medical device in every intensive care unit (ICU). Approximately half of all PATIENTS in ICUs receive partial to full ventilatory support with this EQUIPMENT. Given the vulnerable status of these PATIENTS, EQUIPMENT safety is of fundamental importance. Accordingly, this Particular Standard, by building on other standards and specifically on IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety*, herein referred to as the "General Standard", sets the minimum requirements that should be met by every critical care VENTILATOR that is designed after the publication of this Particular Standard.

A rationale for the most important requirements is given in Annex AA.

Continuous positive airway pressure (CPAP) devices, sleep apnea therapy devices, support-care VENTILATORs, anaesthesia, emergency and transport VENTILATORs, jet and high frequency VENTILATOR and oscillators are not covered by this Particular Standard, nor are devices that may be used within hospitals, intended solely to augment the ventilation of spontaneously breathing PATIENTS.

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*