Kopsuventilaatorid. Osa 3: Erinõuded kiirabi- ja transportventilaatoritele

Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators

EESTI STANDARDI EESSÕNA

Käesolev Eesti standard EVS-EN 794-3:1999 sisaldab Euroopa standardi EN 794-3:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 23.11.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 794-3:1999 consists of the English text of the European standard EN 794-3:1998. This document is endorsed on 23.11.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

NATIONAL FOREWORD

Käsitlusala: Standardi käesolev osa esitab nõuded ventilaatoritele, mis on mootorajamiga ning ette nähtud kasutamiseks kiirabi andmisel ja transportimisel. Standard hõlmab tervet rida seadmeid, alates suhteliselt lihtsatest ventilaatoritest, mis on ette nähtud eelkõige kasutamiseks koos näomaskiga ja piiratud aja vältel (nt. gaasitoitel töötavad ventilaatorid), kuni seadmeteni, mis on ette nähtud pikemaajaliseks kasutamiseks.	**Scope:** Standardi käesolev osa esitab nõuded ventilaatoritele, mis on mootorajamiga ning ette nähtud kasutamiseks kiirabi andmisel ja transportimisel. Standard hõlmab tervet rida seadmeid, alates suhteliselt lihtsatest ventilaatoritest, mis on ette nähtud eelkõige kasutamiseks koos näomaskiga ja piiratud aja vältel (nt. gaasitoitel töötavad ventilaatorid), kuni seadmeteni, mis on ette nähtud pikemaajaliseks kasutamiseks.

ICS 11.040.10, 11.160

Võtmesõnad: elektriline meditsiiniaparaat, kaitse elektrilöökide vastu, kaitse mehaaniliste ohtude vastu, kiirguskaitse, klassifikatsioonid, kunstliku hingamise aparaat, maandamine, ohutusnõuded, tulekaitse, õnnetuste vältimine, üksikasjalikud tehnilised andmed

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 794-3

July 1998

ICS 11.040.10; 11.160

Descriptors: Electromedical equipment, lung ventilators, requirements.

English version

Lung ventilators

Part 3: Particular requirements for emergency and transport ventilators

Ventilateurs pulmonaires – Partie 3: Règles particulières pour les ventilateurs d'urgence et de transport

Lungenbeatmungsgeräte – Teil 3: Besondere Anforderungen an Notfall- und Transportbeatmungsgeräte

This European Standard was approved by CEN on 1998-07-01.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

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

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN 794-3 : 1998 E

Contents **Page**

Contents (continued) **Page**

Contents (continued) **Page**

Contents (continued) **Page**

Annexes

Foreword

This European Standard has been prepared 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 January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.

This European Standard 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 standard.

See annex DD for Special National Conditions.

This European Standard applies to lung ventilators and has been prepared in three parts. This Part addresses lung ventilators for emergency and transport use. Parts 1 and 2 address lung ventilators for critical care and lung ventilators for home care respectively.

Annex BB and DD are normative and form part of this Part of this European Standard.

Annexes AA, CC and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard is one of a series based on European Standard EN 60601-1:1990.

In EN 60601-1: 1990 this type of European Standard is referred to as a "Particular Standard". As stated in 1.3 of EN 60601-1: 1990, the requirements of this European Standard take precedence over those of EN 60601-1: 1990.

Clauses and subclauses additonal to those in EN 60601-1: 1990 are numbered beginning '101'. Additional annexes are lettered beginning 'AA'. Additional items in lettered lists are lettered beginning 'aa)'. Additional tables and figures are numbered beginning '101'.

Annex AA contains rationale statements for this Part of this European Standard. The clauses and subclauses which have corresponding rationale statements are marked with **R)** after their number.

Section one. General

1 Scope

The scope given in clause 1 of EN 60601-1: 1990 applies with the following addition :

1.101 R) This part of this European Standard specifies requirements for ventilators, driven by a power source and intended for emergency and transport use.

This covers a range of devices, from relatively simple ventilators intended, primarily, for use with a face mask and for limited periods (e.g. gas powered ventilators) through to devices for pre-planned longer term use.

This part does not cover operator-powered ventilators (i.e. manual resuscitators).

Ventilators aboard aircraft are likely to be subject to additional requirements and national/international regulations.

Additional parts, e.g. concerning lung ventilators for critical care (see EN 794-1), home care ventilators (see EN 794-2), operator powered resuscitators and recent developments such as jet and very high frequency ventilation and oscillation are published or under consideration.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 475	*Medical devices - Electrically generated alarm signals*
EN 550	*Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization*
EN 552	*Sterilization of medical devices - Validation and routine control of sterilization by irradiation*
EN 554	*Sterilization of medical devices - Validation and routine control of sterilization by moist heat*
EN 556	*Sterilization of medical devices - Requirements for medical devices to be labelled "STERILE"*
EN 737-1	*Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum*

prEN 737-3: 1994	*Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum*
prEN 737-6: 1996	*Medical gas pipeline systems - Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum*
EN 738-1	*Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices*
EN 739	*Low-pressure hose assemblies for use with medical gases*
EN 980	*Graphical symbols for use in the labelling of medical devices*
EN 1281-1	*Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets*
EN 1281-2	*Anaesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)*
EN 1820	*Anaesthetic reservoir bags*
EN ISO 4135: 1996	*Anaesthesiology - Vocabulary (ISO 4135:1995)*
EN ISO 8185	*Humidifiers for medical use - General requirements for humidification systems (ISO 8185:1997)*
EN 12342	*Breathing tubes intended for use with anaesthetic apparatus and ventilators*
prEN 12598: 1996	*Oxygen monitors for patient breathing mixtures - Particular requirements*
EN 60601-1: 1998	*Medical electrical equipment - Part 1: General requirements for safety*
EN 60601-1-2	*Medical electrical equipment - Part 1: General requirements for safety - Collateral Standard: Electromagnetic compatibility - Requirements and tests*
IEC 60068-2-6:	*Environmental testing - Tests methods - Test F_c - Vibration (sinusoidal)*
IEC 60068-2-29:	*Environmental testing procedures - Test - Test E_b and guidance - Bump*

IEC 60068-2-32: 1975	*Basic environmental testing procedures - Tests methods - Part 2: Tests - Test E_d: Free fall*
IEC 60068-2-36	*Basic environmental testing procedures - Test methods - Part 2: Tests - Test F_{db}: Random vibration wide band - Reproducibility medium*
IEC 60079-4	*Electrical apparatus for explosive gas atmospheres - Part 4: Method of test for ignition temperature*
IEC 61000-4-2	***Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test – Basic EMC publication***
ISO 32: 1977	*Gas cylinders for medical use - Marking for identification of content*
ISO 9360: 1992	*Anaesthetic and respiratory equipment - Heat and moisture exchangers for use in humidifying respired gases in humans*