SLOVENSKI STANDARD
SIST EN 794-3:2000+A2:2009

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Pljuļ ni ventilatorji - 3. del: Posebne zahteve za ventilatorje za nujno medicinsko pomoļ in prevoz

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

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

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

Ta slovenski standard je istoveten z: **EN 794-3:1998+A2:2009**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.160	Prva pomoļ	First aid

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EUROPEAN STANDARD

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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

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Contents

Page

Foreword

This document (EN 794-3:1998+A2:2009) 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of an identical text or by endorsement, at the latest by February 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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 includes Amendment 1, approved by CEN on 2005-05-25 and Amendment 2, approved by CEN on 2009-07-23.

This document supersedes EN 794-3:1998.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩ and ⟨A2⟩ ⟨A2⟩.

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.

Annexes 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, 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 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 additional 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. ⟨A1⟩ This includes gas-powered resuscitators, which are generally used by first responders. ⟨A1⟩

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*

〚A2〛 EN 62304, *Medical device software - Software life-cycle processes* 〚A2〛

IEC 60068-2-6, *Environmental testing – Tests method – 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 – Tests methods – Part 2: Tests – Test F_{db}: Random vibration wide band – Reproducibility medium*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres – Pat 4: Method of test for ignition temperature*

IEC 61000-4-2, *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*

3 Terminology and definitions

Clause 2 of EN 60601-1:1990 applies with the following additions, and the definitions given in EN ISO 4135:1996 apply:

2.1.5 applied part R): Add the following item:

All parts of the ventilator intended to be connected to the patient or to the breathing system.

3.1
clearly legible
visual attribute of information displayed by the equipment that allows the operator to discern (or identify) qualitative or quantitative values or functions under a specific set of environmental conditions

3.2
cyling pressure
pressure in the ventilator breathing system which initiates an inspiratory or expiratory phase

3.3
emergency and transport ventilator
portable active medical device for lung ventilation intended for emergency use and/or transportation

NOTE Hereinafter called 'ventilator'.

3.4
label
printed or graphic information applied to a medical device or any of its containers or wrappers

3.5
marking
inscription in writing or as a symbol applied on a medical device from which the inscription is not dissociable

3.6
maximum limited pressure ($P_{lim\ max}$)
highest pressure, measured at the patient connection port, which can be attained in the ventilator breathing system with a single fault condition of the ventilator

3.7
operator powered resuscitator
resuscitation device in which ventilation of the lungs is produced by the operator compressing the compressible unit of the device

3.8
operator's position
intended orientation of the operator with respect to the equipment for normal use according to the instructions for use

3.9
permanent connection
connection which can be separated only by the use of a tool

3.10
ventilation ($\dot{V}$)
volume of gas per minute entering or leaving the patient's lungs

3.11
ventilator breathing system (VBS)
breathing system bounded by the low pressure gas input port(s), the gas intake port(s) and the patient connection port, together with the fresh-gas intake and exhaust port(s), if these are provided

4 General requirements and general requirements for tests

4.1 Modifications to clause 3 of EN 60601-1:1990

Clause 3 of EN 60601-1:1990 applies with the following additions:

In 3.6 add the following:

aa) Applicable single fault conditions are:

— short and open-circuits of components or wiring which can:

  — cause sparks to occur, or;

  — increase the energy of sparks, or;

  — increase temperature (see section seven).

— Incorrect output resulting from software error.

NOTE See also 54.1.

bb)R) An oxidant leak which is not detected by e.g. an alarm or periodic inspection shall be considered a normal condition and not a single fault condition.

〈A2〉

3.10 Clinical evaluation

A clinical evaluation shall be performed and documented in the risk management file.

Check compliance by inspection of the risk management file. 〈A2〉

4.2 Clause 4 of EN 60601-1:1990

Clause 4 of EN 60601-1:1990 applies.

5 Classification

Clause 5 of EN 60601-1:1990 applies.

NOTE A ventilator can have applied parts of different types.

6 Identification, marking and documents

Clause 6 of EN 60601-1:1990 applies with the following additions and modifications:

In 6.1 add the following to item e):

If imported from outside the EU, the name and address of the person responsible or of the authorized representative of the manufacturer or the importer established within the EU shall be provided with the label or the accompanying documents.

In 6.1 add the following to item j):

The marking(s) for the rated input requirements of the ventilator required in 6.1 j) of EN 60601-1:1990 shall be given in amperes.

In 6.1 add the following items:

aa) All operator-interchangeable flow-direction sensitive components shall be permanently marked with a clearly legible arrow indicating the direction of flow.

bb) Any high pressure gas input port shall be marked on or in the vicinity with the name or symbol of the gas as given in EN 739, with the range of supply pressures in kPa and with the maximum flow requirement in l/min (see 6.8.3a), 2nd dash, 6th bullet).

6.1cc) If operator-accessible ports are provided, they shall be marked. The following terms may be used:

— Driving gas input port: "DRIVING GAS INPUT PORT"

— Inflating gas input port: "INFLATING GAS INPUT"

— Fresh gas intake port: "FRESH GAS INTAKE"

— Fresh gas input port: "FRESH GAS"

— Emergency air intake port: "WARNING: EMERGENCY AIR INTAKE – DO NOT OBSTRUCT"

— Manual ventilation port: "BAG"

— Gas return port: "GAS RETURN"

— Gas exhaust port: "EXHAUST"

Alternatively, other terms, pictograms or symbols may be used, in which case they shall be explained and referred to in the above terms.

dd) Labelling and packaging of the ventilator and accessories (e.g. breathing system attachments)

The labeling and marking of the packages of the devices shall contain the following:

— If the intended purpose of the device is not obvious to the operator, the attachment or its package shall be provided with an instruction leaflet or operating instructions;

— A2 The name or trade name and address of the manufacturer and the name and address of authorized representative. For attachments imported into the community, 6.1e) of this European Standard applies where the manufacturer does not have a registered place of business in the Community; A2

— Device identification and content information;

— Where appropriate, the symbol STERILE in accordance with EN 980 and the method of sterilization;

— Where appropriate, the batch code preceded by the symbol LOT in accordance with EN 980 or serial number;

— Where appropriate, an indication of the date by which the device can be used, expressed as the year and month;

— Where appropriate, an indication that the device is for singe use A2 . For single use devices the manufacturer shall disclose the risks associated with reusing in the instructions for use or upon request A2;

A2 NOTE 1 A2 Symbol ISO 7000 – 1051 can be used (see EN 980).

A2 NOTE 2 Manufacturer's attention is drawn to the regulatory provision for a consistent use of indication for single use devices. A2

— Any special storage and/or handling conditions;

— Any warning and/or precaution to take;

— For devices which are considered as active medical devices, year of manufacture, except for those covered by 6.1 dd) 6th dash;

〈A2〉 NOTE 3 〈A2〉 This indication can be included in the batch code or serial number.

— Where applicable, recommended methods of cleaning, disinfection and sterilization.

〈A2〉

— If phthalates are incorporated in parts of the medical devices coming directly or indirectly into contact with the patient the medical device shall be labelled accordingly. If such devices are used for the treatment of children or treatment of pregnant or nursing women, the residual risk has to be identified and stated in the instructions for use. 〈A2〉

Packages containing breathing attachments made of conductive materials shall be clearly marked with the word "CONDUCTIVE" or "ANTI-STATIC".

ee) If gas-specific colour coding of flow controls and flexible hoses is provided, it shall be in accordance with ISO 32. See annex DD for special national conditions.

ff) If the ventilator is designed to be fixed only, a warning that the ventilators shall be maintained fixed.

gg) A statement that volume-limited ventilators are not to be used on unattended patients (see also 51.102).

hh) For volume-limited ventilators, with no VBS pressure measuring device, marking of the maximum limitation pressure under normal use as specified in 51.102.

In 6.8.2 add the following items:

aa) The instructions for use shall additionally include the following:

— **R)** If the ventilator has an internal power source, a specification of the minimum operating time during which the ventilator meets the specifications under normal use as stated by the manufacturer.

If the ventilator is pneumatically powered, the range of supply pressures and flow requirements (see 10.101).

If the ventilator is provided with a reserve power supply, a description of the functioning after a switchover to the reserve power supply.

— A method of testing the following alarms prior to connection of the breathing system to the patient:

— High pressure alarm;

— Breathing system integrity alarm, if provided;

— Power failure alarm;

— Low oxygen concentration alarm, if provided.

— The intended use of the ventilator (e.g. for adult, paediatric, neonatal, range of body mass).

NOTE Other intended uses can include:

— Emergency: