SLOVENSKI STANDARD
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Pljuļ ni ventilatorji - 1. del: Posebne zahteve za ventilatorje za intenzivno nego

Lung ventilators - Part 1: Particular requirements for critical care ventilators

Lungenbeatmungsgeräte - Teil 1: Besondere Anforderungen an Beat-mungsgeräte für die Intensivpflege

Ventilateurs pulmonaires - Partie 1: Prescriptions particulières des ventilateurs pour soins critiques

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This European Standard was approved by CEN on 5 March 1997 and includes Amendment 1 approved by CEN on 20 October 2000 and Amendment 2 approved by CEN on 24 February 2009.

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Foreword

This document (EN 794-1:1997+A2:2009) has been prepared by Technical Committee 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2000-10-20 and Amendment 2, approved by CEN on 2009-02-24.

This document supersedes EN 794-1:1997.

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 Directives, see informative annex ZA, which is an integral part of this standard.

See Annex FF for Special National Conditions.

This European Standard applies to lung ventilators and has been prepared in three parts. This Part addresses lung ventilators for critical care; Parts 2 and 3 address respectively lung ventilators for home care and lung ventilators for emergency and transport use.

Annexes BB and FF are normative and form part of this Part of this European Standard.

Annexes AA, CC, DD, EE 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 sub-clauses 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 sub-clauses which have corresponding rationale statements are marked with R) after their number.

Section one. General

1 Scope

The scope given in clause 1 of the EN 60601-1:1989 applies except that 1.1 is replaced by the following.

1.1 This Part of this European Standard specifies requirements for lung ventilators intended for medical use. Additional Parts, e.g. concerning emergency and transport ventilators, home care ventilators, and recent developments such as jet and very high frequency ventilation and oscillation are under consideration. Requirements for ventilators intended for anaesthetic applications are given in prEN 740.

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.

Appendix L of EN 60601-1:1990 applies with the following additions:

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"*

prEN 737-1, *Medical gas pipeline systems – Part 1: Terminal units for compressed medical gases and vacuum*

prEN 737-2, *Medical gas pipeline systems – Part 2: Anaesthetic gas scavenging disposal systems – Basic requirements*

prEN 737-3, *Medical gas pipeline systems – Part 3: Pipelines for compressed medical gases and vacuum – Basic requirements*

prEN 737-6, *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*

prEN 739, *Low pressure flexible connecting assemblies (hose assemblies) for use with medical gas supply systems*[1)]

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)*

prEN 1820, *Anaesthetic reservoir bags*

prEN 12342, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

EN 60601-1:1990, *Medical electrical equipment – Part 1: General requirements for safety (IEC 601-1:1988)*

EN 60601-1-2, *Medical electrical equipment – Part 1: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (IEC 601-1-2:1993)*

prEN ISO 8185-1, *Humidifiers for medical use – Part 1: General requirements for humidification systems (ISO/DIS 8185-1:1995)*

ISO 32, *Gas cylinders for medical use – Marking for identification of content*

ISO/DIS 7767, *Oxygen monitors for monitoring patient breathing mixtures – Safety requirements*

ISO 9360, *Anaesthetic and respiratory equipment – Heat and moisture exchangers for use in humidifying respired gases in humans*[1)]

IEC 79-4, *Electrical apparatus for explosive gas atmospheres – Part 4: Method of test for ignition temperature*

EN 60801-2, *Electromagnetic compatibility for industrial-process measurement and control equipment – Part 2: Electrostatic discharge requirements (IEC 801-2:1991)*

3 Terminology and definitions

Clause 2 of EN 60601-1:1990 applies with the following additions:

2.1.5 R) applied part. Add the following item:

— all parts of the ventilator intended to be connected to the breathing system.

1) See also Annex AA (in this European Standard).

3.1
cycling pressure
pressure in the ventilator breathing system which initiates an inspiratory or expiratory phase

3.2
driving gas
gas which powers the ventilator but is not delivered to the patient

3.3
driving gas input port
gas input port to which driving gas is supplied

NOTE An input port is a port to which gas is supplied under positive pressure and through which the gas is driven by this pressure. The gas may be supplied either at a controlled pressure or at a controlled flow.

3.4
emergency air intake port
dedicated gas intake port through which ambient air may be drawn by the patient when the supply of fresh and/or inflating gas is insufficient.

NOTE A gas intake port is a port through which gas is drawn into the ventilator breathing system by the ventilator or the patient. Gas may be supplied to the port at or about ambient atmospheric or end-expiratory pressure, or the port may simply be left open to the atmosphere. In a ventilator breathing system, energy is required to reduce the pressure below that of the atmosphere.

Therefore, when gas is supplied at or about atmospheric pressure to a gas intake port, work is done, either by the ventilator (using energy from, for example, an electrical supply and/or a driving gas supply) or by the patient in order to lower the breathing system pressure sufficiently for gas to flow in through the gas intake port. In this sense, gas is "drawn" into the breathing system. A similar argument applies, even if gas is supplied to the gas intake port at a small positive pressure to compensate for the use of positive end-expiratory pressure.

3.5
fresh gas
gas supplied to the ventilator breathing system
It excludes the following:

a) Air drawn through the emergency air intake port;

b) Air drawn through leaks in the ventilator breathing system;

c) Expired gas from the patient.

3.6
fresh gas intake port
gas intake port, other than the emergency air intake port, through which fresh gas may be drawn into the ventilator breathing system by the ventilator or the patient (see note to 3.4)

3.7
fresh gas input port
gas input port to which fresh gas is supplied (see note to 3.3)

NOTE There can be more than one fresh gas input port.

3.8
gas exhaust port
the port of the ventilator from which gas is discharged to the atmosphere under normal operating conditions either directly or via an anaesthetic gas scavenging system

3.9
gas output port
the port of the ventilator through which gas is delivered at respiratory pressures through an operator-detachable part of the breathing system to the patient connection port

3.10
gas return port
the port of the ventilator through which gas is returned at respiratory pressures through an operator-detachable part of the breathing system from the patient connection port

3.11
high pressure gas input port
gas input port to which gas is supplied at a pressure greater than 100 kPa (see note to 3.3)

3.12
inflating gas
fresh gas which powers the ventilator and is supplied to the patient

3.13
inflating gas input port
gas input port to which inflating gas is supplied (see note to 3.3)

3.14
label
all printed information applied to a medical device or any of its containers or wrappers

3.15
low pressure gas input port
gas input port to which gas is supplied at a pressure not exceeding 100 kPa

3.16
lung ventilator
automatic device which is intended to augment or provide ventilation of the patient's lungs when connected to the patient's airway

3.17
manual ventilation port
the port of the ventilator to which a device may be connected for manual inflation of the lungs

3.18
marking
an inscription in writing or as a symbol applied on a medical device from which the inscription is not dissociable

3.19
maximum limited pressure ($P_{lim, max}$)
highest pressure measured at the patient connection port which can be attained in the ventilator breathing system during malfunction of the ventilator but which functioning safety mechanism

NOTE Components of a ventilator are operating normally when individually they operate as the manufacturer intended, even though particular combinations or settings of controls and of the compliance and resistance of the patient's respiratory tract may lead to an inappropriate pattern of ventilation.

3.20
maximum working pressure ($P_{w, max}$)
highest pressure which can be attained at the patient connection port during the inspiratory phase, irrespective of the setting of controls other than any control intended to adjust this pressure, with the ventilator working normally

NOTE Even if not adjustable, this maximum may be less than the maximum limited pressure.

3.21
microbial filter
device intended to reduce bacteria content and particulate matter content of the gas stream

3.22
minimum limited pressure ($P_{lim, min}$)
lowest (most negative) pressure measured at the patient connection port, which can be attained in the ventilator breathing system during malfunction of the lung ventilator but with functioning safety mechanism

NOTE See the note to 3.19

3.23
patient connection port (of the ventilator breathing system)
the port of the ventilator breathing system to which the patient can be connected

3.24
ventilation (V)
volume of gas per minute entering or leaving the patient's lungs

3.25
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 inlet and exhaust port(s), if these are provided. (See annex CC).

NOTE Valves can be placed anywhere in relation to ports and, indeed, anywhere in the ventilator breathing system, provided the requirements of this standard are met.

4 General requirements and general requirements for test

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.

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.

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 6060-1:1990 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 authorised 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 k):

The requirement for marking of auxiliary mains socket-outlets shall apply to each auxiliary mains socket-outlet and the maximum allowed output shall be marked in amperes.

In 6.1 add the following additional 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 prEN 739, with the range of supply pressures in kPa and with the maximum flow requirement in l/min.

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

— Driving gas input port: "DRIVING GAS INPUT"

— Inflating gas input port: "INFLATING GAS INPUT"

— Fresh gas input port: "FRESH GAS"

— Fresh gas intake port: "FRESH GAS INTAKE"

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

— Manual ventilation port: "BAG"

— Gas output port: "GAS OUTPUT"

— Gas return port: "GAS RETURN"

— Gas exhaust port: "EXHAUST"

If the volume of gas discharged from the exhaust port is either more or less than the expired volume, additionally: "NOT FOR SPIROMETER".

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

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

The labelling 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.

— The name or trade name and address of the manufacturer. For attachments imported into the EU, 6.1 e) of this European Standard applies.

— 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 single use;

NOTE Symbol ISO 7000-1051 can be used (see also EN 980).

— Any special storage and/or handling conditions;

— Any warning and/or precaution to take (see also 6.8.2 aa) 8th dash).

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

NOTE This indication can be included in the batch code or serial number.

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

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

ee) Each ventilator shall be provided with a check list that summarises the test procedures recommended by the manufacturer which have to be performed prior to use. The use of electronic displays e.g. a CRT (Cathode Ray Tube) is permitted.

ff) If auxiliary mains socket-outlet(s) can accept a mains plug, the auxiliary mains socket-outlet(s) shall be marked with symbol 14 given in table D.1 in appendix D of EN 60601-1:1990.

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

In 6.8.2 add the following items:

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

— **R)** A statement to the effect that antistatic or electrically conductive hoses or tubing should not be used.

— **R)** If the ventilator has an internal electrical power source, a specification of the operating time under conditions stated by the manufacturer.

If the ventilator is pneumatically powered, the range of supply pressures shall be stated (see 10.2).