

Medical electrical equipment —

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

The European Standard EN 60601-2-12:2006 has the status of a
British Standard

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National foreword

This British Standard was published by BSI. It is the UK implementation of EN 60601-2-12: 2006. It is identical with IEC 60601-2-12: 2006. It supersedes BS EN 794-1:1997 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/121, Anaesthetic and respiratory equipment, to Subcommittee CH/121/3, Lung ventilators and related equipment.

A list of organizations represented on CH/121/3 can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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**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)

This European Standard was approved by CENELEC on 2006-05-01. CENELEC 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 CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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

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.

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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*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety*, 4. Collateral standard: *Programmable electrical medical systems*
Amendment 1¹

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).

2 Terminology and definitions

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

* 2.1.5 applied part

Addition:

or any part of the VENTILATOR intended to be connected to the breathing system

¹ There exists a consolidated edition 1.1 (2000) that includes IEC 60601-1-4 (1996) and its amendment 1 (1999).

Additional definitions:

2.1.101**bacterial filter**

device that removes bacteria and particulate matter from the gas stream

[ISO 4135:1995, definition 4.1.7 modified]

2.1.102**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

2.1.103**emergency air intake port**

dedicated intake port through which ambient air may be drawn when the supply of FRESH GAS is insufficient or absent

[ISO 4135:1995, definition 4.2.2 modified]

2.1.104**flow-direction-sensitive component**

VENTILATOR component through which the gas flow has to be in one direction only for its proper functioning and/or PATIENT safety

[ISO 4135:1995, definition 4.1.13]

2.1.105**fresh gas**

gas supplied to the VENTILATOR BREATHING SYSTEM. It excludes the following:

- air drawn through the EMERGENCY AIR INTAKE PORT;
- air drawn through leaks in the VENTILATOR BREATHING SYSTEM;
- expired gas from the PATIENT

2.1.106**fresh gas intake port**

intake port, other than the EMERGENCY AIR INTAKE PORT, through which FRESH GAS may be drawn into the VENTILATOR BREATHING SYSTEM

[ISO 4135:1995, definition 4.2.6 modified]

2.1.107**gas exhaust port**

that port of a VENTILATOR from which gas is discharged to the atmosphere either directly or via a gas scavenging system

[ISO 4135:1995, definition 4.2.7]

2.1.108**gas intake port**

port through which gas is drawn into the VENTILATOR BREATHING SYSTEM

2.1.109

gas output port

port through which gas is delivered at RESPIRATORY PRESSURES via the inspiratory limb to the PATIENT CONNECTION PORT

[ISO 4135:1995, definition 4.2.8 modified]

2.1.110

gas return port

port through which gas is returned at RESPIRATORY PRESSURES via the expiratory limb from the PATIENT CONNECTION PORT

[ISO 4135:1995, definition 4.2.9 modified]

2.1.111

high pressure gas input port

input port to which gas may be supplied at a pressure greater than 100 kPa

[ISO 4135:1995, definition 4.2.10 modified]

2.1.112

inflating gas

FRESH GAS that may also power the VENTILATOR

2.1.113

inflating gas input port

input port to which INFLATING GAS is supplied

[ISO 4135:1995, definition 4.2.11]

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.

2.1.114

inhibition (disabled)

state in which an alarm system or part of an alarm system can not annunciate alarm signals

NOTE 1 INHIBITION may apply to an individual alarm condition, to a group of alarm conditions, or to the entire alarm system of the EQUIPMENT.

NOTE 2 INHIBITION may be invoked by the OPERATOR or by the EQUIPMENT (for instance, in a warm-up mode or when no PATIENT is connected).

NOTE 3 The duration of INHIBITION is always indefinite. Only direct action by the OPERATOR or a change in the EQUIPMENT caused by the OPERATOR (for instance, the end of a warm-up mode or when a PATIENT is connected) will revoke INHIBITION.

2.1.115

low-pressure gas input port

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

[ISO 4135:1995, definition 4.2.14]

2.1.116

manual ventilation port

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

[ISO 4135:1995, definition 4.2.15 modified]

2.1.117

maximum limited pressure (P_{LIM} max)

Highest pressure at the PATIENT CONNECTION PORT during NORMAL USE and under a SINGLE FAULT CONDITION

2.1.118**maximum working pressure ($P_w \text{ max}$)**

highest pressure at the PATIENT CONNECTION PORT during NORMAL USE, irrespective of the setting of controls, other than the control intended to adjust this pressure

NOTE Even if not adjustable, this maximum is equal to or less than the MAXIMUM LIMITED PRESSURE.

2.1.119**minimum limited pressure ($P_{\text{lim}} \text{ min}$)**

lowest pressure at the PATIENT CONNECTION PORT during NORMAL USE and under a SINGLE FAULT CONDITION

NOTE This pressure may be sub-atmospheric.

2.1.120**minute volume ($\dot{V}$)**

volume of gas per minute entering or leaving the lungs of the PATIENT

2.1.121**operator's position**

intended location and orientation of the OPERATOR with respect to the EQUIPMENT for NORMAL USE according to the instructions for use

2.1.122**patient connection port (of the VENTILATOR BREATHING SYSTEM)**

port of the VENTILATOR BREATHING SYSTEM to which the PATIENT can be connected

[ISO 4135:1995, definition 4.2.16]

NOTE Interface between the VENTILATOR BREATHING SYSTEM and the PATIENT.

2.1.123**respiratory pressure**

pressure at the PATIENT CONNECTION PORT

2.1.124**suspended**

state of an alarm system where OPERATOR action has temporarily caused an otherwise enabled alarm system to disable all auditory or all auditory and visual alarm signals for a fixed interval

2.1.125**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

2.1.126**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

[ISO 4135:1995, definition 4.1.6 modified]

3 General requirements

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

* 3.1

Addition:

Any fault that can lead to a hazard and that is not detected by intrinsic means or by periodic inspection (e.g. an oxidant leak, software defect) shall be regarded as a NORMAL CONDITION and not a SINGLE FAULT CONDITION.

3.4

Addition:

An equivalent degree of safety may be demonstrated by means of a risk analysis, in accordance with ISO 14971.

4 General requirements for tests

This clause of the General Standard applies.

5 Classification

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

5.2

Addition:

NOTE A VENTILATOR may have APPLIED PARTS of different types.

6 Identification, marking and documents

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

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

e) *Indication of origin*

Addition (after the existing sentence):

The name and address of the manufacturer or authorized representative, as applicable, shall also be marked.

k) *Mains power output*

Replacement:

If provided, AUXILIARY MAINS SOCKET OUTLET(S) of EQUIPMENT shall be marked with the maximum allowed output in amperes or volt-amperes.

q) *Physiological effects*

Addition (between the first and second paragraphs)

If applicable, a warning that latex is used.

Addition:

- aa) Any HIGH PRESSURE GAS INPUT PORT shall be marked with the name or symbol of gas in accordance with ISO 5359 and with the supply pressure range and the nominal maximum flow requirements. If gas-specific color-coding of flow control or flexible hoses is provided, it shall be in accordance with ISO 32.
- bb) If OPERATOR accessible ports are provided, they shall be marked. The following terms should be used.
- INFLATING GAS INPUT PORT: 'Inflating Gas Input'
 - MANUAL VENTILATION PORT: 'Bag'
 - GAS OUTPUT PORT: 'Gas Output'
 - GAS RETURN PORT: 'Gas Return'
 - GAS EXHAUST PORT: 'Exhaust'

Alternatively, other terms or symbols may be used in the above and explained in the instructions for use.

- EMERGENCY AIR INTAKE PORT: 'WARNING: Emergency Air Intake – Do Not Obstruct'
- cc) Any particular storage and/or handling instructions.
- dd) Any particular warnings and/or precautions relevant to the immediate operation of the VENTILATOR.
- ee) Where appropriate, an indication of the date by which the EQUIPMENT or ACCESSORY shall be used expressed as the year and month.

NOTE Symbol 3.12 from ISO 15223:2000 may be used.

- ff) Packages containing breathing attachments intended for single use shall be clearly marked with the following, as far as applicable:
- A description of the contents.
 - The words "SINGLE USE", "DO NOT REUSE", Symbol 1051 from ISO 7000:1989 or Symbol 3.2 from ISO 15223:2000.
 - The word "STERILE," if applicable, or one of Symbols 3.20 to 3.24 from ISO 15223:2000.
 - The name or trademark and address of the manufacturer, supplier, or authorized representative.
 - An identification reference to the type, or Symbol 3.15 from ISO 15223:2000.
 - An identification reference to the batch or serial number or Symbol 3.14 or 3.16 from ISO 15223:2000.
 - Packages containing latex shall be clearly marked with the word 'LATEX'.
- gg) Packages containing breathing attachments intended for reuse shall be clearly marked with the following:
- A description of the contents.
 - The name or trademark and address of the manufacturer, supplier, or authorized representative.
 - An identification reference to the type, or Symbol 3.13 from ISO 15223:2000.
 - An identification reference to the batch or serial number or Symbols 3.14 or 3.16 from ISO 15223:2000.
 - Recommended methods of cleaning, disinfection and sterilization.

NOTE Some breathing attachments may contain recommended methods for cleaning, disinfection and sterilization in the instructions for use. See also 6.8.2 d).

- Packages containing latex shall be clearly marked with the word 'LATEX'.

- hh) All FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a tool shall be durably marked with a CLEARLY LEGIBLE arrow indicating the direction of the flow.

6.3 g)

Addition:

- Pressure:
 - cm H₂O

6.6 Identification of medical gas cylinders and connections

Replacement:

- a) If gas-specific color-coding is used (e.g., for flow controls, flexible hoses, gas cylinders, etc.) it shall be in accordance with ISO 32. See also 56.3 a).

6.8.2 Instructions for use

6.8.2 d) Cleaning, disinfection and sterilization of parts in contact with the PATIENT

Addition (as a second paragraph):

If applicable, the instructions for use shall contain:

- information about cleaning and sterilization prior to first use;
- information about cleaning, disinfection and sterilization and any restriction concerning re-use;
- instructions which indicate the maximum number of processes for each reusable component or visual functional pass/fail criteria to be used in determining when a component needs replacement.

Device packaging and/or labelling shall differentiate between the same or similar products placed on the market by the same manufacturer, both sterile and non-sterile. See also 6.1 ff) 3.

Addition:

aa) *Additional general information*

The instructions for use shall include the following:

1. * A statement to the effect that antistatic or electrically conductive hoses or tubing shall not be used.
2. * If the VENTILATOR has provisions for an INTERNAL and/or external reserve ELECTRICAL POWER SOURCE, the manufacturer shall disclose in the appropriate documentation at least the following data (see also 49.101 and 49.102):
 - the ampere-hour rating;
 - the voltage requirement;
 - the current requirement;
 - the operational time from the power source after it has become fully charged;
 - the means for determining the status of the reserve power source; and
 - the means by which the reserve power source can be tested.
3. If the VENTILATOR is provided with a reserve power supply, the functioning after a switchover to the reserve power supply shall be described.
4. If the VENTILATOR is designed to operate with high-pressure gas(es), the supply pressure and flow range(s) shall be stated.