BRITISH STANDARD

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Lung ventilators

Part 2. Particular requirements for home care use

The European Standard EN 794-2 : 1997 has the status of a British Standard

ICS 11.040.10

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/46, Lung ventilators and related equipment, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health-care Industries
Association of Paediatric Anaesthetists
British Anaesthetic and Respiratory Equipment Manufacturers' Association
Department of Health (Medical Devices Agency)
Electro Medical Trade Association Limited
Institution of Mechanical Engineers
Institution of Physics and Engineering in Medicine and Biology
Intensive Care Society
Royal College of Paediatrics and Child Health
Safety Equipment Association

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National foreword

This British Standard has been prepared by Technical Committee CH/46 and is the English language version of EN 794-2 *Lung ventilators* — Part 2 : 1997 *Particular requirements for home care use*, published by the European Committee for Standardization (CEN). Attention is drawn to BS EN 794-1 which gives requirements for ventilators for critical care use, and to prEN 794-3 which gives requirements for ventilators for transport and emergency use.

Cross-references

Publication referred to	Corresponding British Standard
EN 550	BS EN 550 : 1994 *Sterilization of medical devices. Validation and routine control of ethylene oxide sterilization*
EN 552	BS EN 552 : 1994 *Sterilization of medical devices. Validation and routine control of sterilization by irradiation*
EN 554	BS EN 554 : 1994 *Sterilization of medical devices. Validation and routine control of sterilization by moist heat*
EN 556	BS EN 556 : 1995 *Sterilization of medical devices. Requirements for terminally-sterilized devices to be labelled 'Sterile'*
EN 738-1	BS EN 738-1 *Pressure regulators for use with medical gases* Part 1: *Pressure regulators and pressure regulators with flow metering devices*
EN 980	BS EN 980 : 1997 *Graphical symbols for use in the labelling of medical devices*
EN 1281-1	BS EN 1281 *Anaesthetic and respiratory equipment — Conical connectors* Part 1 : 1997 *Cones and sockets*
EN 1281-2	Part 2 : 1996 *Screw-threaded, weight-bearing connectors*
EN 60601-1 : 1990	BS 5724 *Medical electrical equipment* Part 1 : 1989 *General requirements for safety*
EN 60601-1-2	BS EN 60601 *Medical electrical equipment* Part 1. *General requirements for safety* Section 1.2 : 1993 *Collateral standard. Electromagnetic compatibility*
EN 60801-2	BS EN 60801 *Electromagnetic compatibility for industrial-process measurement and control equipment* Part 2 : 1993 *Electrostastic discharge requirements*

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 24, an inside back cover and a back cover.

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EN 794-2

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ICS 11.040.10

Descriptors: Medical equipment, electric equipment, electromedical apparatus, artificial breathing apparatus, utilization, detail specifications, safety requirements, accident prevention, protection against electric shocks, protection against mechanical hazards, equipment specification, performance evaluation, marking

English version

Lung ventilators — Part 2: Particular requirements for home care use

Ventilateurs pulmonaires — Partie 2: Prescriptions particulières pour l'emploi à domicile

Lungenbeatmungsgeräte — Teil 2: Besondere Anforderungen für Heimbeatmungsgeräte

CEN

European Committee for Standardization
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Europäisches Komitee für Normung

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

Ref. No. EN 794-2 : 1997 E

Foreword

This European Standard has been prepared by Technical Committee TC 215, Respiratory and anaesthetic equipment, the secretariat of which is held by BSI.

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 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 home care use. Parts 1 and 3 address respectively lung ventilators for critical care and lung ventilators for emergency and transport use.

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

Annexes AA, CC, EE and ZA are for information only.

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 1997, and conflicting national standards shall be withdrawn at the latest by the 13th of June 1998.

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

Contents

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 European Standard. The clauses and sub-clauses which have corresponding rationale statements are marked with **R)** after their number.

Section one. General

1 Scope

Clause **1** of EN 60601-1 : 1990 applies except that **1.1** is replaced by the following:

1.1 This Part of this European Standard specifies requirements for lung ventilators intended mainly for home care use[1)] for patients but which could be used elsewhere (hospitals) for appropriate patients in locations where the use of a ventilator complying with Part 1 of this standard is not required. Additional parts, e.g. concerning emergency and transport ventilators, and recent developments such as jet and very high frequency ventilation and oscillation are 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.

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

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 737-3	*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*
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)

[1)] Called hereafter 'ventilator'.

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)
EN 60801-2	*Electromagnetic compatibility for industrial-process measurement and control equipment* — Part 2: *Electrostatic discharge requirements* (IEC 801-2 : 1991)
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*
IEC 79-4	*Electrical apparatus for explosive gas atmospheres* — Part 4: *Method of test for ignition temperature*

3 Terminology and definitions

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

2.1.5 Applied part R): Add the following item:

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

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

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

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

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 home care ventilator

Ventilator suitable for domiciliary ventilation of a patient without continuous professional supervision.

3.13 inflating gas

Fresh gas which powers the ventilator and is supplied to the patient.

3.14 inflating gas input port

Gas input port to which inflating gas is supplied (see note to **3.3**).

3.15 label

Printed or graphic information applied to a medical device or any of its containers or wrappers.

3.16 low pressure gas input port

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

3.17 lung ventilator

Automatic device which is intended to augment or provide ventilation of the patient's lungs when connected to the patient's airway.

3.18 manual ventilation port

Port of the ventilator to which a device may be connected for manual inflation of the lungs.

3.19 marking

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

3.20 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 with 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 patients respiratory tract may lead to an inappropriate pattern of ventilation.

3.21 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.

3.22 microbial filter

Device intended to reduce bacteria content and particulate matter content of the gas stream.

3.23 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 **3.20**.

3.24 patient connection port (of the ventilator breathing system)

Port of the ventilator breathing system to which the patient can be connected.

3.25 ventilation ($\dot{V}$)

Volume of gas per minute entering or leaving the patient's lungs.

3.26 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 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 rated input marking required in **6.1**j of EN 60601-1 : 1990 shall be given in amperes for the ventilator as well as for the sum of the current ratings for the ventilator and the specific auxiliary mains socket outlets.

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'.

– Emergency air intake port: 'WARNING: EMERGENCY AIR INTAKE - DO NOT OBSTRUCT'.

– 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) Marking of devices

The ventilator shall be durably and legibly marked with the following, as far as applicable.

– Any particular storage and/or handling instructions.

– Any particular instructions for use.

– Any particular warnings and/or precautions relevant to the immediate operation of the ventilator.

– Warning statements to the effect that:

• electromagnetic disturbances e.g. mobile phone operation, may affect the ventilator;

• the ventilator shall not be operated in direct sunlight;

• the ventilator shall be not covered or located such that ventilation of the ventilator is impeded;

• the ventilator shall not be operated immediately following storage or transport outside the recommended operations conditions.

ee) R) 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 indentification 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.

– Any special storage and/or handling conditions.

– Any warning and/or precaution to take (see also **6.8.2**aa 7th dash).

– For devices which are considered as active medical devices, year of manufacture, except for those covered by **6.1**ee 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'.

ff) 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.

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 electrical power source, a specification of the expected operating time under conditions stated by the manufacturer.

If the ventilator has no internal electrical power source the manufacturer shall specify a suitable reserve power source which can be connected to the ventilator to provide at least one hour operating time. The expected operating time shall also be specified under the conditions stated by the manufacturer. The manner of connection to the ventilator shall be described and also how automatic switchover can be achieved when the primary power supply falls below the required level.

– A method of testing the following alarms prior to connection of the breathing system to the patient.

a) High pressure alarm/presssure relief.

b) Respiratory irregularity alarm.

NOTE. Examples of respiratory irregularity are leaks or disconnections of breathing system attachements.

c) High and low oxygen concentration alarm (if oxygen monitor is supplied).

d) Power failure alarm.

e) Alternative or reserve power supply, if applicable.

– Each ventilator shall be provided with a check list which summarizes the test procedures recommended by the manufacturer which have to be performed prior to use. The use of an electronic display such as a Cathode Ray Tube (CRT) meets the requirement.

– The manufacturer of the ventilator shall provide a list of the applicable monitoring, alarm and protection devices against hazards from delivery of energy or substances to the patient by the ventilator; e.g. oxygen monitor when the ventilator is designed to deliver oxygen concentration(s) above ambient.

– The intended use of the ventilator, (e.g. adult use, paediatric use).

– A recommendation that an alternative means of ventilation should be available.

– The statement that the operator will have to ensure that the inspiratory and expiratory resistances, as measured in **56.105**, are not exceeded when adding attachments or other components or sub-assemblied to the breathing system.

– If applicable:

• information about cleaning and sterilization prior to first use;

• information about cleaning, disinfection and sterilization and any restriction concerning re-use.

bb) The manufacturer shall disclose the maximum achievable pressure at the patient connection port under a single fault condition (see **51.102**).

cc) A warning statement to the effect that, if class I equipment is used, the protective earth of the domicilary electrical installation shall be checked for safe and effective operation.

dd) A warning statement to the effect that:

The functioning of this ventilator can be adversely affected by electromagnetic interferences exceeding the level of 10 V/m in the test conditions of EN 60601-1-2.

NOTE. If it can be demonstrated that the ventilator is resistant to the levels exceeding those specified in EN 60601-1-2 (with the modification of 10 V/m), the instructions for use can state the appropriate higher levels to which the equipment has been tested.

In **6.8.3**a add the following items.

– **R)** The technical description shall additionally include disclosure of all information necessary to check that the ventilator is installed correctly, that it is compatible with its intended environment (e.g. EMC) and is in safe and correct working order. It shall also specify the nature and frequency of maintenance operations necessary to ensure continuing safety and correct operation. It shall include the following information, as far as applicable.

• A listing of the following pressure information.

i) Maximum limited pressure ($P_{\text{lim,max}}$).

ii) Range of values to which the maximum working pressure can be set and the means by which the maximum is assured (e.g. pressure cycling, pressure-limiting, pressure generation) and a statement whether negative pressure (sub-atmospheric) is available in the expiratory phase.

iii) Minimum (sub-atmospheric) limited pressure.

iv) Range of values to which the minimum (sub-atmospheric) working pressure can be set and the means by which the miniimum is assured.

• A listing of the ranges of the following parameters.

i) Delivered ventilation.

ii) Delivered volume.

iii) Ventilatory frequency.

iv) I/E ratio or % inspiratory time.

v) Cycling pressure.

vi) End-expiratory pressure.

vii) Delivered concentration of oxygen, if adjustable by controls on the ventilator.

• The means of triggering, if provided, shall be described.

• The purpose, type, range and sensing position of all measuring and display devices either incorporated into the ventilator or recommended by the manufacturer for use with the ventilator.

• **R)** The conditions under which any measured or displayed flow, volume or ventilation is to be expressed (e.g. ATPD, BTPS)[2)] and the condition and composition of gas in the corresponding sensor so that the display complies with the accuracy requirements specified in **51.105.** Unless otherwise specified, parameters shall be assumed to be expressed under ATPD conditions.

• For alarms used with, or fitted to, the ventilator, a statement of their type, principle of the alarm detection, methods of testing, and, if appropriate, suppression or delay of annunciation, estimated battery life and suitable replacement batteries.

• The internal volume of any breathing attachments or other components or sub-assemblies supplied or recommended by the manufacturer of the ventilator to be placed between the patient connection port and the patient.

• The resistance, compliance and volume of the complete ventilator breathing system and/or any breathing attachment or other components or sub-assemblies, e.g. humidifier or filter recommended by the manufacturer for inclusion in the ventilator breathing system. The inspiratory and expiratory resistance, as measured in **56.105**, shall be disclosed.

• Disclosure of the functional characteristics or manufacturer's identification of operator detachable breathing system components including microbial filter fitted or recommended.

[2)] ATPD = Ambient temperature and pressure, dry

BTPS = Body temperature and pressure, saturated.

• A diagram of the pneumatic system of the ventilator and a diagram for each ventilator breathing system either supplied or recommended by the manufacturer.

• Details of any restrictions on the sequence of components within the ventilator breathing system, e.g. where such components are flow-direction sensitive.

• Interdependence of controls, if applicable.

• **R)** Disclosure of accuracies and ranges of displayed values and calibrated controls.

NOTE. The accuracies should be expressed in the form of maximum zero error quoted in appropriate units plus a sensitivity error e.g. quoted as a percentage of the reading.

7 Power input

Clause **7** of EN 60601-1 : 1990 applies.

Section two. Environmental conditions

8 Basic safety categories

Clause **8** of EN 60601-1 : 1990 applies.

9 Removable protective means

Not used

10 Environmental conditions

Clause **10** of EN 60601-1 : 1990 applies with the following additions:

10.101 Electrical and pneumatic driving power supplies

The ventilator shall continue to function within the specified tolerances throughout the range of supply variation specified by the manufacturer.

If the ventilator is intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3 or a pressure regulator complying with EN 738-1), it shall operate and meet the requirements of this European Standard for a pneumatic power supply throughout a range of 280 kPa to 600 kPa and shall cause no safety hazard under the single fault condition of the medical gas supply of up to 1000 kPa inlet pressure. The time weighted average over 10 s and the steady flow of each medical gas required by the ventilator shall not exceed 60 l/min at a pressure of 280 kPa measured at the gas input port. The transient flow of each medical gas required by the ventilator shall not exceed the equivalent of 200 l/min for 3 s.

10.102 R) Operation under extreme conditions

The manufactuer shall declare how the ventilator will respond as the environmental and supply conditions are extended to the following limits, changing one parameter at a time whilst other parameters are maintained within normal limits:

– ambient temperature range of +5 °C to 50 °C;

– ambient relative humidity (RH) range of 10 % RH to 95 % RH;

– atmosphere pressure range of 600 mbar to 1100 mbar;

– supply voltage range from −20 % to +10 % of declared nominal value;

as well as the combination of +45 °C and 75 % RH.

Outside the environmental and supply conditions specified in subclause **10.2** of EN 60601-1 : 1990 but within the limits stated above, the ventilator shall not cause a safety hazard to the patient or operator.

NOTE. The ventilator might continue to function but outside the specified tolerances.

11 Not used.

12 Not used.

Section three. Protection against electric shock hazards

13 General

Clause **13** of EN 60601-1 : 1990 applies.

14 Requirements related to classification

Clause **14** of EN 60601-1 : 1990 applies.

15 Limitation of voltage and/or energy

Clause **15** of EN 60601-1 : 1990 applies.

16 Enclosures and protective covers

Clause **16** of EN 60601-1 : 1990 applies.

17 Separation

Clause **17** of EN 60601-1 : 1990 applies.

18 Protective earthing, functional earthing and potential equalization

Clause **18** of EN 60601-1 : 1990 applies.

19 Continuous leakage currents and patient auxiliary currents

Clause **19** of EN 60601-1 : 1990 applies with the following addition.

In **19.4** add the following to item h):

101) R) The patient leakage current shall be measured from the machine outlet(s) and other parts which are defined as applied parts for the purpose of this European Standard. All parts of the same type shall be connected together electrically with the exception of parts connected to the protective earth terminal which shall be tested separately from parts not so connected.

20 Dielectric strength

Clause **20** of EN 60601-1 : 1990 applies.

Section four. Protection against mechanical hazards

21 Mechanical strength

Clause **21** of EN 60601-1 : 1990 applies.

22 Moving parts

Clause **22** of EN 60601-1 : 1990 applies.

23 Surfaces, corners and edges

Clause **23** of EN 60601-1 : 1990 applies.

24 Stability in normal use

Clause **24** of EN 60601-1 : 1990 applies.

25 Expelled parts

Clause **25** of EN 60601-1 : 1990 applies.

26 Vibration and noise

Clause **26** of EN 60601-1 : 1990 applies.

27 Pneumatic and hydraulic power

Clause **27** of EN 60601-1 : 1990 applies.

28 Suspended masses

Clause **28** of EN 60601-1 : 1990 applies.

Section five. Protection against hazards from unwanted or excessive radiation

29 X-radiation

Clause **29** of EN 60601-1 : 1990 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

Clause **30** of EN 60601-1 : 1990 applies.

31 Microwave radiation

Clause **31** of EN 60601-1 : 1990 applies.

32 Light radiation (including lasers)

Clause **32** of EN 60601-1 : 1990 applies.

33 Infra-red radiation

Clause **33** of EN 60601-1 : 1990 applies.

34 Ultra-violet radiation

Clause **34** of EN 60601-1 : 1990 applies.

35 Acoustical energy (including ultrasonics)

Clause **35** of EN 60601-1 : 1990 applies.

36 Electromagnetic compatibility

Clause **36** of EN 60601-1 : 1990 applies with the following additions:

36.101 Electromagnetic compatibility

The ventilator shall continue to function and meet the requirements of this European Standard or shall fail without causing a safety hazard when tested in accordance with EN 60601-1-2 with the level of 3 V/m replaced with 10 V/m.

If an anomaly occurs, such as display interruption, false alarm, loss of function without the integrity of the associated monitoring, alarm and protection device being comprised, this shall not be considered a safety hazard, provided it is possible to restore normal operation within 30 s after the electromagnetic disturbances have been applied.

NOTE. Silencing of an activated alarm should not be considered as a failure.

36.102 Electrostatic discharge

Discharges shall be applied only to accessible parts as defined in EN 60801-2.

Section six. Protection against hazards of ignition of flammable anaesthetic mixtures

37 Locations and basic requirements

Clause **37** of EN 60601-1 : 1990 applies.

38 Marking, accompanying documents

Clause **38** of EN 60601-1 : 1990 does not apply.

39 Common requirements for Category AP and Category APG equipment

Clause **39** of EN 60601-1 : 1990 does not apply.

40 Requirements and tests for Category AP equipment, parts and components thereof

Clause **40** of EN 60601-1 : 1990 does not apply.

41 Requirements and tests for Category APG equipment, parts and components thereof

Clause **41** of EN 60601-1 : 1990 does not apply.

Section seven. Protection against excessive temperatures and other safety hazards

42 Excessive temperatures

Clause **42** of EN 60601-1 : 1990 applies.

43 R) Fire prevention

Clause **43** of EN 60601-1 : 1990 applies together with the following addition.

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault conditions, shall not at the same time be subjected to conditions in which:

– the temperature of the material is raised to its minimum ignition temperature; and

– an oxidant is present.

Determine the minimum ignition temperature in accordance with IEC 79-4 using the oxidizing conditions present under the normal and single fault condition.

Compliance is checked by determining the temperature the material is raised to under the normal and single fault condition.

If sparking can occur under a normal or a single fault condition, the materials subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection and compatibility

Clause **44** of EN 60601-1 : 1990 applies with the following modification.

In **44.3** add the following:

During and after the test as specified in **44.3** of EN 60601-1 : 1990, the ventilator shall continue to function within the tolerances specified by the manufacturer for normal use.

In **44.7** add the following:

Ventilator breathing system attachments and sub-assemblies intended for reuse shall be so constructed that they can be dismantled for cleaning, disinfection or sterilization.

45 Pressure vessels and parts subject to pressure

Clause **45** of EN 60601-1 : 1990 applies with the following addition:

45.101 Clause **45** does not apply to the ventilator breathing system.

46 Not used.

47 Electrostatic charges Not used.

48 Biocompatibility

Clause **48** of EN 60601-1 : 1990 applies.

49 Interruption of the power supply

Clause **49** of EN 60601-1 : 1990 applies (see also **51.101**) with the following additions:

49.101 Means shall be provided to prevent inadvertent operation of the off-switch.

49.102 Spontaneous breathing during power failure

The ventilator shall be designed in such a manner that under conditions of power failure, either electrical or pneumatic, as applicable, the patient can breathe spontaneously.

During failure, the resistance of the ventilator breathing system to inspiratory and expiratory flows shall not exceed the value specified in **56.105**.

NOTE. The design of the ventilator breathing system should be such that, during failure, rebreathing is minimized (i.e. one-way valves may be necessary to prevent inhalation of expired gas).

49.103 The ventilators shall be provided with means for reserve power supply (see also **6.8.2**aa 1st dash).

NOTE. The means could be, for example, an integrated reserve power supply or connectors for an external power supply.

Section eight. Accuracy of operating data and protection against hazardous output

50 Accuracy of operating data

Clause **50** of EN 60601-1 : 1990 applies with the following addition:

50.101 While the ventilator is in normal use, all displays of measured values shall be within the manufacturer's disclosed range when tested under the operating conditions given in **10.2.2** of EN 60601-1 : 1990 and **10.101** of this European Standard.

Annex BB gives requirements and test methods relating to legibility of markings, controls and indicators.

51 Protection against hazardous output

Clause **51** of EN 60601-1 : 1990 applies together with the following additions:

51.101 Power failure alarm

51.101.1 *Electrical or pneumatic driving power*

The ventilator shall have a power failure alarm which activates an audible alarm signal of at least 120 s duration if the electrical or pneumatic power supply falls below the values specified by the manufacturer.

Compliance shall be checked by simulating a drop below the values specified by the manufacturer.

51.101.2 Alternative and reserve power supplies

If the switch-over (automatic or manual) to an alternative or reserve power supply has occurred this shall be indicated.

51.102 Pressure limitation

The maximum achievable pressure at the patient connection port under normal use and single fault condition (see **6.8.2**bb) shall not exceed 8 kPa or 120 % of the maximum adjustable pressure.

51.103 Measuring device for ventilator breathing system pressure

A measuring device shall be provided for the VBS pressure. The value read by the operator shall be accurate within $\pm$ (2 % of the full scale reading + 8 % of the actual reading). Test for compliance by visual inspection and verification of accuracy.

51.104 High pressure alarm

A high pressure alarm shall be provided. It shall activate an auditory signal and provide a visual indication when the inspiratory pressure alarm level is reached on not more than 3 consecutive breaths.

It shall not be possible to set the alarm level above the maximum pressure achieved by the pressure limitation as described in **51.102**.

The alarm is tested during controlled ventilation of the test lung (see figure 101 and table 101) and while simulating relevant single fault conditions. The pressure at the patient connection port is measured.

NOTE. This alarm will not necessarily be activated by patient generated transients.

51.105 Measuring device for expiratory volume

If a measuring device for the expiratory tidal volume or minute volume is provided, the accuracy requirement shall be within $\pm$ 20 % of actual reading for the range specified by the manufacturer.

Test by visual inspection and verification of the accuracy using the apparatus as outlined in figure 101 and described below.

51.106 R) Respriratory irregularity alarm

A respiratory irregularity alarm shall be provided. An audible and visual signal shall be activated when the measured variable deviated from the set breathing pattern:

– during controlled ventilation for more than 15 s; or

– during IMV (intermittent mandatory ventilation) for more than 1 IMV cycle but not longer than 45 s; or

– during spontaneous modes of ventilation for more than the period specified by the manufacturer.

NOTE 1. A means of muting the audible alarm signal should be provided.

NOTE 2. Examples of a respiratory irregularity alarm are:

– Breathing system integrity alarm (disconnection).

Means to generate an alarm in the case of disconnection of the patient from the ventilator or other loss of delivered volume.

– Apnoea alarm.

For intermittently controlled, assisted or spontaneous modes of ventilation, means to generate an alarm when the patient's breathing effort fails to appear within the declared period of time.

51.107 Oxygen monitor and alarm

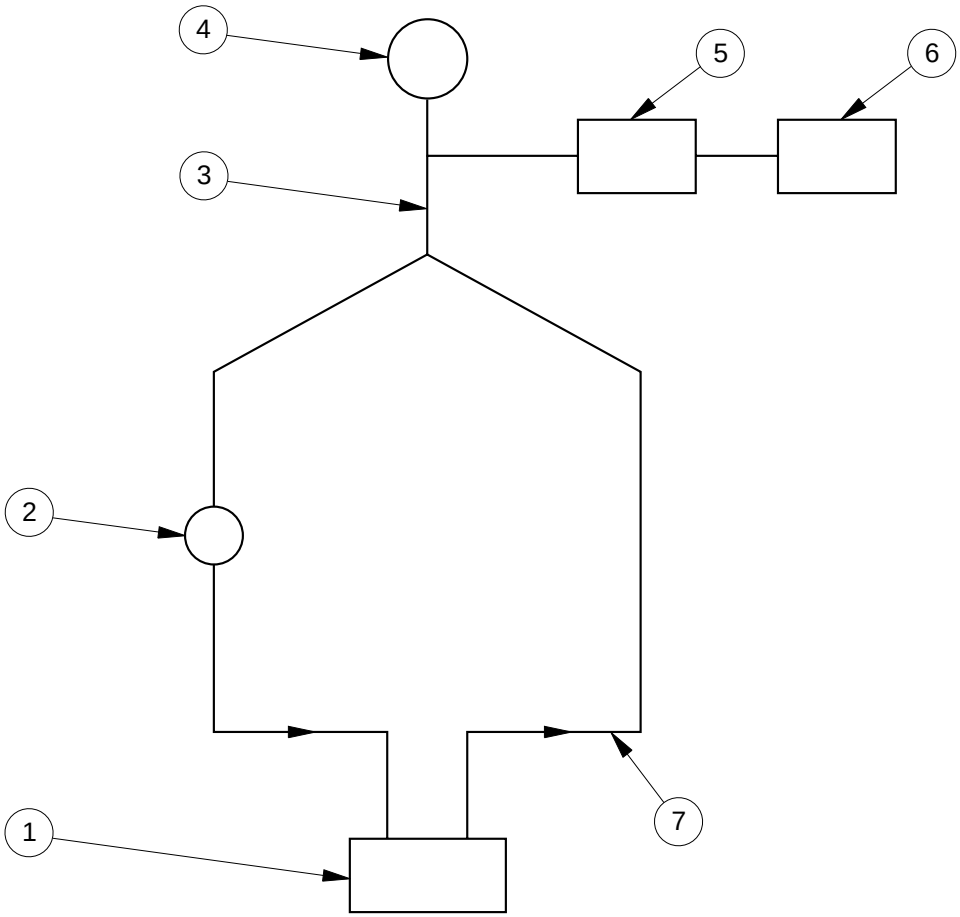
If an oxygen monitor is provided, it shall be in compliance with ISO/DIS 7767 and shall have an oxygen concentration alarm with adjustable high and low alarm limits. An auditory and visual signal shall be generated when the alarm limits are exceeded.

NOTE. If the ventilator permits an inspiratory oxygen concentration above ambient an oxygen monitor may be needed for measurement of the inspiratory oxygen concentration.

Compliance shall be tested by visual inspection and functional testing via simulating an oxygen concentration outside the set alarm limits.

Table 101. Test conditions for expiratory volume tests

Ajustable parameter	Test condition	
	Adult use	Paediatric use
Tidal volume V_T (ml) as measured by means of pressure sensor on test lung ($V_T = C \times P_{max}$)	500	100
Frequency f (min^{-1})	10	30
I/E Ratio	1/2 or nearest	1/2 or nearest
Resistance R (kPa/l/s)	0,5kPa/l/s $\pm$ 10%	1 kPa/l/s $\pm$ 10%
Isothermal compliance C (ml/kPa)	500 ml/kPa $\pm$ 5%	30 ml/kPa $\pm$ 5%
NOTE. The accuracies for C and R apply over the ranges of the measured parameters.		



1 Ventilator

2 Volume measurement device to be tested

3 Resistance

4 Test lung

5 Pressure sensor

6 Recorder p (t) with an accuracy of ± 2 % of actual reading for verification of accuracy of volume measurement device

7 Breathing system

NOTE. Location of the volume measuring device in figure 101 is arbitrary. It may be located elsewhere in the breathing system.

Figure 101. Typical configuration of test apparatus for measurement of expiratory volume

51.108 Alarms

51.108.1 Means shall be provided to indicate the set points of adjustable alarms.

51.108.2 The maximum time an auditory alarm signal can be silenced shall be 120 s.

51.108.3 If an auditory alarm signal(s) can be disabled by the operator there shall be a visual indication that it has been disabled.

51.108.4 When an alarm is activated and when the condition causing the alarm has cleared, the auditory signal shall be cancelled.

51.109 Protection against inadvertent adjustments

Means of protection against inadvertent adjustment of controls which can create a hazardous output shall be provided.

NOTE. Mechanical techniques such as locks, shielding, friction-loading and detents are considered as suitable.

For pressure-sensitive finger pads, capacitive finger switches and microprocessor oriented 'soft' controls, a specific sequence of key or switch operations is considered suitable.

Test for compliance by visual inspection following the instructions for use.

Section nine. Abnormal operation and fault conditions; environmental tests

52 Abnormal operation and fault conditions

Clause **52** of EN 60601-1 : 1990 applies.

53 Environmental tests

Clause **53** of EN 60601-1 : 1990 applies.

Section ten. Constructional requirements

54 General

Clause **54** of EN 60601-1 : 1990 applies, with the following additions:

54.1 R) Arrangements of functions

Replace **54.1** with the following:

A single fault condition shall not cause a monitoring and/or alarm device as specified in clause **51** and the corresponding ventilation control function to fail in such a way that the monitoring function becomes simultaneously ineffective and thus fails to detect the loss of the monitored ventilator function.

54.3 Inadvertent changing of settings

Replace **54.3** with the following:

Means of protection against inadvertent adjustments shall be provided. If grouped pressure-sensitive finger pads, grouped capacitive finger switches and grouped 'soft' (e.g. microprocessor based) controls are used, proper operation of the ventilator shall be selected only as the result of specifc programmed sequences of such key or switch operations.

NOTE. Techniques such as locks, shielding, friction-loading and dentents are recommended.

54.101 To facilitate data transfer capability between different monitoring devices, a BUS system for data transfer may be used.

54.102 R) Leaching of substances

All parts of the ventilator should be designed and manufactured to minimize health risks due to substances leached or leaking from the device during use.

55 Enclosures and covers

Clause **55** of EN 60601-1 : 1990 applies.

56 Components and general assembly

Clause **56** of EN 60601-1 : 1990 applies with the following additions and modifications:

In **56.3** add the following item:

aa) High pressure gas input ports

If the ventilator is intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3 or a pressure regulator complying with EN 738-1), each high pressure gas input connector shall be either the body of a Non-Interchangeable Screw-Threaded (NIST) connector complying with prEN 739 or a probe complying with prEN 737-1 and prEN 737-6. See annex DD for Special National Conditions.

bb) Connection to the medical gas supply system

If a user detachable hose assembly is provided for connection between the ventilator and the medical gas supply system, it shall comply with prEN 739.

cc) Ventilator breathing system connectors

A ventilator breathing system connector, if conical, shall be either a 15 mm or 22 mm connector complying with EN 1281-1 or EN 1281-2.

dd) Gas intake port connector

A gas intake port connector, if provided, shall not be compatible with connectors complying with EN 1281-1 or EN 1281-2.

ee) Emergency air intake port

An emergency air intake port shall be provided and any connector shall not be compatible with connectors complying with EN 1281-1 or EN 1281-2.

NOTE. An emergency air intake port should be designed so that it cannot easily be obstructed when the ventilator is in use.

ff) Gas output and gas return port connectors (inspiratory port connector and expiratory port connector)

The inspiratory and expiratory port connector, shall, if conical, be one of the following.

a) For ventilators intended for adult use, a 22 mm conical connector complying with EN 1281-1 or EN 1281-2.

b) For ventilators intended for paediatric use, a 15 mm conical connector complying with EN 1281-1 and 1281-2.

c) A coaxial 15 mm/22 mm conical connector for both adult and paediatric use, complying with EN 1281-1 or EN 1281-2.

gg) Gas exhaust port

If an exhaust port connector is provided, it shall be one of the following:

a) a 30 mm male conical connector complying with EN 1281-2; or

b) a permanent connection or proprietary connector incompatible with EN 1281-1 and prEN 737-1.

hh) Patient connection port

The patient connection port shall be, if conical, one of the following.

a) For ventilators intended for adult use, a 22 mm conical male connector complying with EN 1281-1 or EN 1281-2.

b) For ventilators intended for paediatric use, a 15 mm conical female connector complying with EN 1281-1 or EN 1281-2;

c) A coaxial 15 mm/22 mm conical connector complying with EN 1281-1 or EN 1281-2.

ii) Manual ventilation port

A manual ventilation port shall not be provided.

jj) Accessory port

If an accessory port is provided, it shall not be compatible with connectors specified in EN 1281-1 or EN 1281-2 and shall be provided with a means to secure engagement and closure.

NOTE. This port is generally used for sampling of gases or for introduction of therapeutic aerosols.

kk) Monitoring probe sensor port

If a port is provided for the introduction of a monitoring probe sensor, it shall not be compatible with connectors as described in EN 1281-1 or EN 1281-2, and shall be provided with a means to secure the sensor in position and a means to secure closure after removal of the sensor.

In clause **56** add the following sub-clauses:

56.101 Reservoir bags and breathing tubes

56.101.1 Reservoir bags intended for use in the ventilator breathing system shall comply with prEN 1820. Breathing tubes intended for use in the ventilator breathing system shall comply with prEN 12342 .

56.101.2 Respiratory gas-conducting components (decontamination and packaging)

56.101.2.1 All parts of the ventilator which are subject to contamination by exhaled gases during any form of ventilation and are intended to be re-used, shall be disinfectable or sterilizable.

The manufacturer shall, upon request, disclose method(s) used to ensure the cleanliness of breathing system components during production and supply.

56.101.2.2 If a claim is made in the labelling that a device is sterile it shall have been sterilized using an appropriate validated method described in EN 550, EN 552, EN 554 or EN 556.

56.101.2.3 Non-sterile device packaging systems shall be designed to maintain products which are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination (see EN 868-1).

56.101.2.4 Device packaging and/or labelling shall differentiate between the same or similar products placed on the market, both sterile and non-sterile.

56.102 Flow direction sensitive components

If any component of the ventilator breathing system is a flow direction sensitive component, it shall, if operator-detachable, be designed such that it cannot be fitted in such a way that it presents a hazard to the patient.

56.103 Humidifiers and heat and moisture exchangers

Any humidifier or heat and moisture exchanger either incorporated into the ventilator or recommended by the manufacturer for use with the ventilator shall comply with prEN ISO 8185-1 and ISO 9360 respectively.

56.104 Microbial filters

Microbial filters, provided or recommended for use in the inspiratory and/or expiratory limbs of the ventilator breathing system, except those intended for single-use, shall withstand sterilization as specified in **44.7** without deterioration.

NOTE. Expiratory filters can be heated.

56.105 Inspiratory and expiratory resistances

The inspiratory and expiratory resistance measured at the patient connection port shall, during spontaneous breathing and normal operation, not exceed 0,6 kPa (6 cm H_2O) at 60 l/min for adult use, 30 l/min for paediatric use.

Compliance shall be checked by functional test and by measurement of flow and pressure at the patient connection port.

57 Mains parts, components and layout

Clause **57** of EN 60601-1 : 1990 applies with the following additional requirements:

In **57.2** add the following:

aa) R) The ventilator and each specific auxiliary mains socket outlet shall be provided with separate fuses or over-current releases, as required for a single equipment in **57.6** of EN 60601-1 : 1990.

Compliance shall be checked by inspection and loading all specific auxiliary mains socket outlets up to the maximum of their rating. Each specific auxiliary mains socket outlet shall in turn additionally be overloaded by a factor between 5 and 10. The ventilator shall maintain its normal function.

In **57.3** add the following item to a):

R) The mains supply cord of an electrically powered ventilator shall be a non-detachable cord or shall be protected against accidental disconnection from the ventilator under a force of 100 N. Compliance shall be checked by inspection and, for a ventilator provided with an appliance coupler, by applying an axial pull force of 100 N during 1 min.

58 Protective earthing – Terminals and connections

Clause **58** of EN 60601-1 : 1990 applies.

59 Construction and layout

Clause **59** of EN 60601-1 : 1990 applies.

Annexes

Annexes A to K of EN 60601-1 : 1990 apply.

Annex AA (informative)
Rationale

This annex provides a rationale for some requirements of this European Standard and is intended for those who are familiar with the subject of this European Standard but who have not participated in its development. An understanding of the reasons for these requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this European Standard necessitated by those developments.

The clauses in this annex have been so numbered to correspond to the clauses in this European Standard to which they refer. The numbering is, therefore, not consecutive.

AA.3 The definition of 'applied part' in this European Standard is the basis for clarification of requirements on the measurement of patient leakage current.

It is not possible, however, to include any requirements in this European Standard on leakage currents from electrically operated attachments, such as humidifiers and heating elements (which may be connected in the breathing system), because the types of such attachments which may be used with a type of ventilator cannot be anticipated by a manufacturer or a test house.

However, parts integrated with the ventilators, such as temperature and carbon dioxide sensors which are intended to come into contact with the patient and which are electrically connected to the ventilator, are considered as parts for which requirements on leakage currents can be specified in this European Standard. Such parts are therefore included in the definition of the applied part.

AA.4.1 (3.6bb**)** A fault condition which is not detected can exist for a long time. Under those circumstances it is not acceptable to regard a further fault as a second which can be disregarded. Such a first fault is regarded as a normal condition.

AA.6.1ee The use of antistatic and/or electrically conductive materials in the breathing systems of ventilators is not considered as contributing to any higher degree of safety. On the contrary, the use of such material increases the hazard of electrical shock in the patient.

AA.6.8.2aa **1st dash** The operating time may vary considerably and be affected by temperature in both the charging and the discharging rate of the battery.

AA.6.8.3a **1st dash** No mention of patient parameter or machine parameter is given here because this distinction exists in EN 60601-1 : 1990.

Examples of machine parameters are 'stroke volume' rather than 'tidal volume', 'generated pressure' rather than 'airway pressure', 'set ventilation' rather than 'expired ventilation', 'return-port pressure' rather than 'airway pressure' (as, in this last instance, it is especially important to distinguish between these in some neonatal ventilators).

Some fault conditions, e.g. obstruction or leaks, can cause serious differences between volumes and pressures in the ventilator and the corresponding volumes and pressures in the patient, but other fault conditions, e.g. excessive secretions or the accumulation of condensation in a pressure line, can cause serious errors in directly measured patient parameters.

AA.6.8.3a **1st dash, 5th bullet** Some changes in the condition and composition of the gas at the sensor can alter the flow or volume-sensitivity of some types of sensor. Also, changes in the conditions in the sensor may alter the correction required to express the flow, volume or ventilation under some standard condition. For example, a volume-displacement-type meter, whenever it is operating normally, will indicate the volume which has passed through it, expressed in terms of the conditions within it, irrespective of those conditions or of the composition of the gas. However, if a pneumotachograph sensor at the gas return port is used to drive a display of 'expired tidal volume' expressed at BTPS on the assumption that typical expired air, saturated at 30 °C, is passing through the pneumotachograph then, if the temperature of the gas is less than 30 °C, the indication will be less than the true expired volume at BTPS.

AA.6.8.3a**, 1st dash, 13th bullet** A zero error together with a sensitivity error is needed, if a variable can pass through zero, or can, in any application, cover a range such that the minimum is a small fraction of the maximum.

AA.10.102 Operation outside specified conditions

Clause **10.2** of EN 60601-1 : 1990 specifies a set of ambient conditions (temperature, relative, humidity, barometric pressure, power supply, etc.) under which medical devices shall comply with the requirements of the standard. These conditions apply to the environment conditions within a hospital.

Some medical devices are, however, used outside hospitals, e.g. home care ventilators, emergency and transport equipment.

These devices are subject to more extreme conditions than those specified in **10.2.1** of EN 60601-1 : 1990, e.g. experts have proposed 5 °C to 50 °C for home care ventilators (instead of 10 °C to 40 °C) and for emergency care ventilators even wider temperature ranges have been suggested.

To meet all the likely extremes, even when considering only the most probable combinations of them, with one type (one design and construction) will undoubtedly lead to quite expensive devices for which there is hardly any place in this market, which anyway has more constraints than that of the hospitals.

It should also be recognized that these extremes only apply to some areas or occur rarely, and that most uses fall well within much narrower limits, the majority of home-care environmental conditions are thus covered by the specifications for hospital environments in **10.2** of EN 60601-1 : 1990.

The consequence of using a device designed according to the requirements of EN 60601-1 : 1990 outside the specified conditions therefore will have to be investigated, especially with regard to the product liability.

There was a consensus that a device ought not to cause a safety hazard to the patient or operator is used outside the environmental conditions specified in **10.2.1** of EN 60601-1 : 1990, e.g. all safety mechanisms ought to remain functional but the performance parameters might degrade below their specified values.

There will nevertheless be a limit when the degradation of performance reaches a level where the risks posed by the continued use of the device will outweigh its benefits. This limit cannot be addressed in absolute unambiguous terms within a standard and would not present a satisfactory solution to the problem from a product liability point of view.

To resolve this, it has been proposed to specify a set of likely extreme conditions for a particular use, e.g. home-care, that are outside those specified in **10.2.1** of EN 60601-1 : 1990.

EN 794-2 requires the manufacturer to declare how the performance of the device is affected when subjected to one of the extreme conditions at the time, whilst maintaining the other parameters within reasonable limits.

If necessary, certain critical combinations of extreme conditions can be specified.

It is felt that information will enable the user to make an appropriate selection of a device to suit his particular situation or to take necessary precautions to correct the conditions, e.g. install an air-conditioner to control the room temperature in extremely hot climates.

This approach is consistent with current product liability case law where any warning statement is to be explained indicating the potential consequences of not abiding by the warning.

AA.19.4h **101)** See the rationale to clause **3**.

AA.43 Reports of fire caused by medical devices are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements which are necessary in order to start a fire:

– ignitable material (fuel);

– a temperature equal to or above the minimum ignition temperature of the material or sparks with energy dissipation equal to or above the minimum ignition energy of the materials;

– an oxidant.

Therefore, following the basic safety concepts of EN 60601-1 : 1990, the objective in the design of the equipment is to ensure that under both normal and single fault conditions and under the oxidizing conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur, provided it is self-limiting so that no hazard is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although usually only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required, these can be determined using the methods and apparatus described in IEC 79-4.

In considering the ignitable materials particular attention should be paid to materials which may accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The risk of fire directly caused by sparking of electrical circuits is generally considered insignificant in medical equipment as temperature rise resulting from the power dissipation, caused by a spark will not normally reach the ignition temperature of the solid materials generally used when following good design practice.

However, if materials with a low ignition temperature and a very low thermal capacity, e.g. cotton wool, paper or organic fibre accumulations, are present then it may not be possible to determine the surface temperatures attained during exposure to spark energy and specific tests, e.g. ignition tests, may be necessary to assume safety under these conditions.

In certain standards currently in use the requirements to minimize fire risk are based on limitation of temperature, electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen which is given in the American NFPA publication 53 M as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical equipment with oxygen enriched atmospheres.

The origin of the electrical energy values which have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from accepted working practices or from tests performed in other environments. However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any 'fuel' present.

It is now generally accepted that there are no single or universally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under single fault conditions in a typical electrical circuit the possible number of failure modes is very high. In this case full assurance of safety may only be possible by the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions, and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a single fault condition.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under a single fault condition.

The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

AA.51.106 Typical examples of test criteria for some methods in use are as follows.

a) If intended to annunciate loss of pressure: the alarm might be actuated when the pressure fell by more than, for example, 20 % from the set or expected peak pressure at the patient connection port.

b) If intended to annunciate reduction of flow: the alarm might be actuated when the flow fell by, for example, 20 % from that set or that previously measured at the patient connection port or in the expiratory gas pathway.

c) If intended to annunciate reduction of volume or ventilation: the alarm might be actuated when the volume or ventilation fell by, for example, 20 % from that set or that previously measured at the patient connection port or in the expiratory gas pathway.

d) If intended to annunciate a change in the level of oxygen: the alarm might be activated by a change of, for example, 15 % in the mean oxygen concentration. The sensor should be in the return (or expiratory) tube of the ventilator breathing system or in the exhaust gas pathway within 5 cm of the patient connection port. However, the use of an oxygen monitor to activate a gas leakage alarm is not recommended on account of the inherent unreliability of the technique when different concentrations of oxygen are used.

AA.54.1 It is important that software errors, should they occur, do not cause a safety hazard to the patient or to the user.

This requirement, however, is equivalent to that of **3.1** of EN 60601-1 : 1990 which effectively states that all devices shall cause no safety hazard under normal condition and a single fault condition.

It is therefore not only logical but also prudent to handle a software programme error as a single fault condition in order to amply accommodate software driven devices within the framework of EN 60601-1 : 1990. This approach is advisable, especially with respect to a failure mode effect analysis, to prove compliance with **3.1** of EN 60601-1 : 1990.

This clause prevents the use of a monitoring device to control an actuator, which would lead to an undetected malfunction of the actuator in case of a monitor failure.

AA.54.102 Such evidence will be provided by the manufacturer e.g. to a Notified Body during CE conformity assessment or to a Competent Authority.

AA.57.2aa It is important that a short circuit of other equipment connected to the auxiliary mains socket-outlet does not affect the normal function of the life-support function of the lung ventilator.

AA.57.3 Accidental disconnection can be hazardous for the patient.

Annex BB (normative)
Legibility and visibility of visual indications

BB.1 Definitions

BB.1.1 clearly legible

The 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.

BB.1.2 operator's position

The intended orientation of the operator with respect to the equipment for normal use according to the instructions for use.

BB.2 General requirements and conditions

Illumination of 215 lx shall be provided. Measurement of ambient illumination shall be made from the control panel toward the test subject. Test operators shall have vision of 1, corrected if necessary.

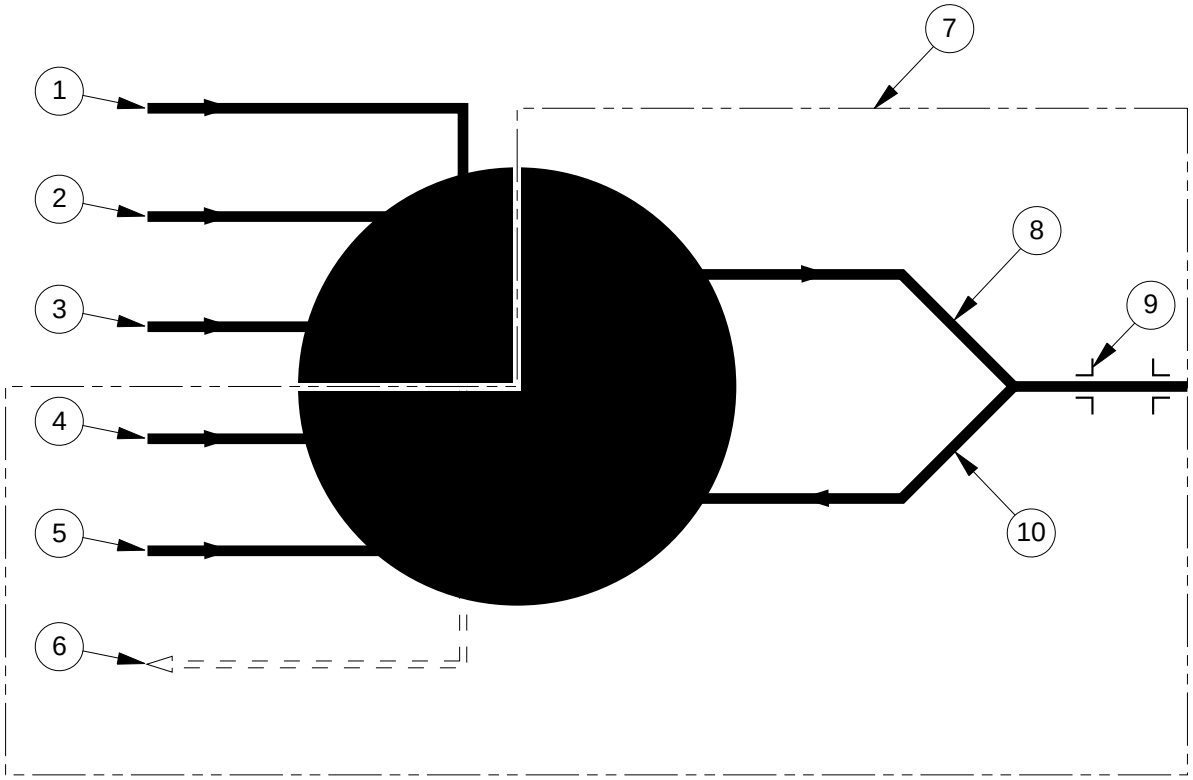
BB.3 Visual indicators and their associated markings and warnings integral to the ventilators that are intended to be viewed from the operator's position shall be clearly legible when tested in accordance with **BB.4**.

BB.4 Place the test operator in the operator's position at a distance of 500 mm from the ventilator. The test is passed if the test operator can correctly identify all controls and indicators, verify all qualitative and quantitative information, and read all warning statements.

Annex CC (informative)
Typical ventilator arrangements

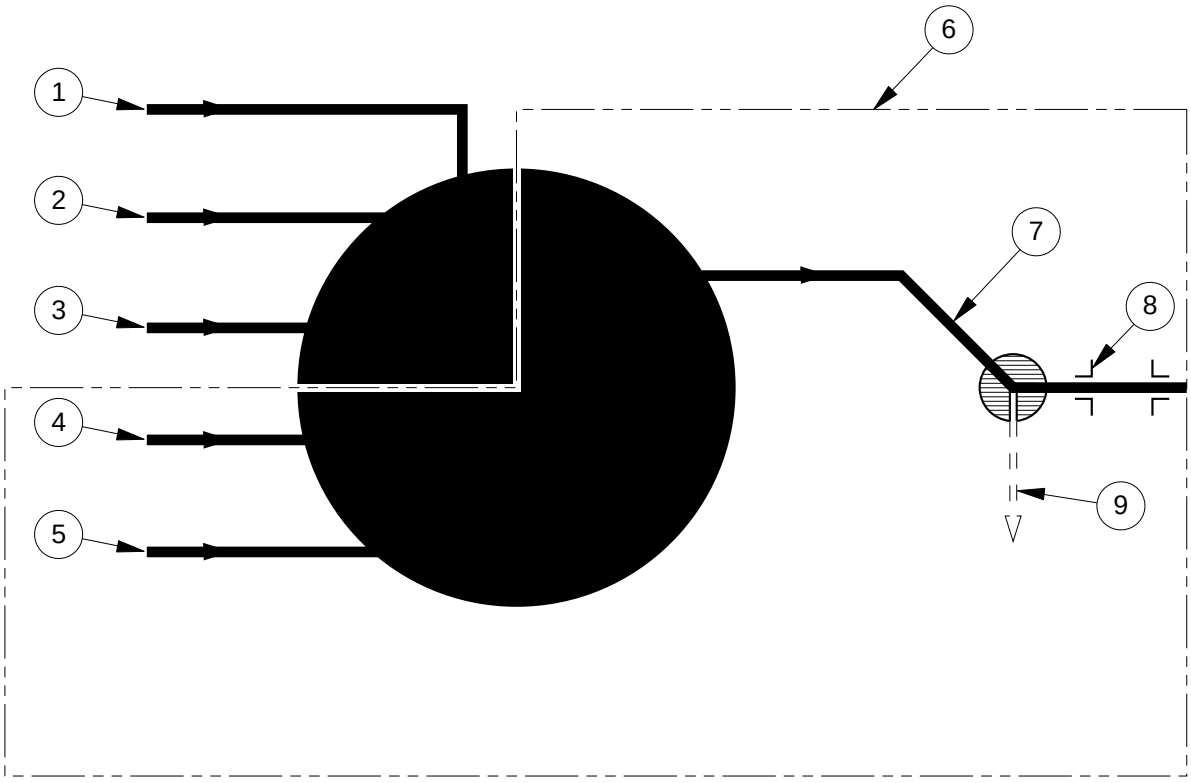
CC.1 General

Typical arrangements of ventilators are shown in figures CC.1 and CC.2.



1 Driving gas input port (optional)
2 Inflating gas input port (optional)
3 Fresh gas input port (optional)
4 Fresh gas intake port (optional)
5 Emergency air intake port (optional)
6 Gas exhaust port
7 Ventilator breathing system
8 Gas output port
9 Patient connection port
10 Gas return port (optional)

Figure CC.1 Typical ventilator arrangement — Example A



1 Driving gas input port (optional)

2 Inflating gas input port (optional)

3 Fresh gas input port (optional)

4 Fresh gas intake port (optional)

5 Emergency air intake port (optional)

6 Ventilator breathing system

7 Gas output port

8 Patient connection port

9 Exhaust port

Figure CC.2 Typical ventilator arrangement — Example B

Annex DD (informative)
Special national conditions

Special national condition: National characteristic or practice that cannot be changed even over a long period, e.g. climatic conditions, electrical earthing conditions. If it affects harmonization, it forms part of the European Standard. In the countries in which the relevant national condition applies these provisions are normative, for other countries they are informative.

Clause 56.3aa: Special national condition for all CEN members utilizing terminal units and probes which comply with the National Standards of Austria (ÖNORM 7387-4), France (NF S 90-116), Germany (DIN 13260 : Part 2), Italy (UNI 9507), Sweden (SS 87 524 30) and United Kingdom (BS 5682).

The requirement to comply with prEN 737-6 does not apply until the latest date of withdrawal of the special national condition (2012-12-01), subject to review taking into account e.g. the results of a forthcoming European study.

Clause 56.3aa Special national condition for all CEN members.

The requirement to use NIST connectors in accordance with prEN 739 does not apply until the latest date of withdrawal of the special national condition (1998-06-13), subject to review taking into account eg. the results of a forthcoming European study.

Clauses 6.1ff **and 56.3**aa Special national condition for Austria, Germany and Switzerland.

The requirement to comply with **6.1**ff and **56.3**aa does not apply until the latest date of withdrawal of the special national condition (2006-07-01), subject to review taking into account eg. the results of a forthcoming European study and the ongoing European Standardization activities of the EN 1089 series.

Annex EE (informative)
Bibliography

EN 868-1	*Packaging materials and systems for medical devices which are to be sterilized* — Part 1: *General requirements and test methods*
prEN 1041	*Terminology, symbols and information provided with medical devices — Information supplied by the manufacturer with medical devices*
ISO 7000 : 1989	*Graphical symbols for use on equipment — Index and synopsis*
NFPA publication 53 M	*Fire hazards in oxygen-enriched atmospheres*[3)]

Annex ZA (informative)
Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING. Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard as given in table ZA.1 are likely to support requirements of Directives 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

[3)] Available from the National Fire Protection Association, 1 Batterymarch Park, PO Box 9101, Quincy MA 02269-9101, USA.

Table ZA.1 Correspondence between this European Standard and EU Directives		
Clause/subclause/annex of this European Standard	**Corresponding Essential Requirement of Directive 93/42/EEC**	**Comments**
All	1, 2, 3	
21 to **49**	4	
37 to **41**	9.3	
51.106 to **51.108**	12.4	
56.101 to **56.104**	9.1	
Section 3	12.6	
Section 4	12.7.1, 12.7.2, 12.7.3, 12.7.4	
Section 9	12.6	
Section 10	12.6	
6	9.1, 12.6, 12.9, 13.1, 13.2	
6.1	13.3 (except g), h)), 13.4, 13.5	
6.1ee	7.2, 8.7	
6.8	13.4, 13.6 (except e) and j))	
6.8.2	9.2	
6.8.2aa 8th dash	8.1	
6.8.3a dash	10.1	
10	4, 5	
36	12.5	
42	7.1, 12.7.5	
43	7.1, 7.3, 7.5, 9.3	
44	7.6, 8.1	
49	12.2, 12.3	
50	10.1, 12.8.1, 12.8.2	
51	12.8.1, 12.8.2	
51.101	12.2, 12.3	
51.102	4	
51.104	12.4	
52	4, 7.5, 9.3	
54.102	7.1, 7.2, 7.3, 7.5,	
56	12.8.1, 12.8.2, 12.9	
56.3	12.7.4	
56.101	8.1	
56.104	8.3	
56.105	9.1	
57	12.7.4	
57.2	9.1	
Annex BB	10.2	
N/A = Not applicable		

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