BRITISH STANDARD

BS EN
794-3:1999

Lung ventilators —

Part 3: Particular requirements for emergency and transport ventilators

The European Standard EN 794-3:1998 has the status of a British Standard

ICS 11.040.10; 11.160

National foreword

This British Standard is the English language version of EN 794-3:1998.

The UK participation in its preparation was entrusted to Technical Committee CH/46, Lung ventilators and related equipment, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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

Summary of pages

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EUROPEAN STANDARD

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Descriptors: electromedical apparatus, artificial breathing apparatus, classifications, safety requirements, detail specifications, accident prevention, protection against electric shocks, earthing, protection against mechanical hazards, radiation protection, fire protection, electromagnetic compatibility, performance evaluation, equipment specifications

English version

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

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

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

This European Standard was approved by CEN on 1st July 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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 CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

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

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Foreword

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

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 1999, and conflicting national standards shall be withdrawn at the latest by January 1999.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

See annex DD for special national conditions.

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

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

Annexes AA, CC and ZA are for information only.

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

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 EN 60601-1:1990, **1.3** the requirements of this European Standard take precedence over those of EN 60601-1:1990.

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

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

Section one. General

1 Scope

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

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

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

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

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

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

2 Normative references

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

EN 475, *Medical devices — Electrically generated alarm signals.*

EN 550, *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization.*

EN 552, *Sterilization of medical devices — Validation and routine control of sterilization by irradiation.*

EN 554, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat.*

EN 556, *Sterilization of medical devices — Requirements for medical devices to be labelled "STERILE".*

EN 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum.*

prEN 737-3:1994, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum.*

prEN 737-6: 1996, *Medical gas pipeline systems — Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum.*

EN 738-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices.*

EN 739, *Low-pressure hose assemblies for use with medical gases.*

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1281-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

EN 1281-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors* (ISO 5356-2:1987 modified).

EN 1820, *Anaesthetic reservoir bags.*

EN ISO 4135:1996, *Anaesthesiology — Vocabulary* (ISO 4135:1995)

EN ISO 8185, *Humidifiers for medical use — General requirements for humidification systems* (ISO 8185:1997).

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

prEN 12598:1996, *Oxygen monitors for patient breathing mixtures — Particular requirements.*

EN 60601-1:1998, *Medical electrical equipment — Part 1: General requirements for safety.*

EN 60601-1-2, *Medical electrical equipment — Part 1: General requirements for safety — Collateral Standard: Electromagnetic compatibility — Requirements and tests.*

IEC 60068-2-6, *Environmental testing — Test methods — Test Fc — Vibration (sinusoidal).*

IEC 60068-2-29, *Environmental testing procedures — Test — Test Eb and guidance — Bump.*

IEC 60068-2-32:1975, *Basic environmental testing procedures — Test methods — Part 2: Tests — Test Ed: Free fall.*

IEC 60068-2-36, *Basic environmental testing procedures — Test methods — Part 2: Tests — Test Fdb: Random vibration wide band — Reproducibility medium.*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.*

IEC 61000-4-2, *Electrostatic discharge immunity test — Basic EMC publication.*

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 9360:1992, *Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans.*

3 Terminology and definitions

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

2.1.5 applied part R): Add the following item:

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

3.1

clearly legible

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

3.2

cycling pressure

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

3.3

emergency and transport ventilator

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

NOTE Hereinafter called "ventilator".

3.4

label

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

3.5

marking

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

3.6

maximum limited pressure ($P_{\text{lim max}}$)

highest pressure, measured at the patient connection port, which can be attained in the ventilator breathing system with a single fault condition of the ventilator

3.7

operator powered resuscitator

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

3.8

operator's position

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

3.9

permanent connection

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

3.10

ventilation ($\dot{V}$)

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

3.11

ventilator breathing system (VBS)

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

4 General requirements and general requirements for tests

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

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

In **3.6** add the following:.

aa) Applicable single fault conditions are:

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

- cause sparks to occur; or
- increase the energy of sparks; or
- increase temperature (see section seven).

— incorrect output resulting from software error.

NOTE See also **54.1**.

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

4.2 Clause 4 of EN 60601-1:1990

Clause **4** of EN 60601-1:1990 applies.

5 Classification

Clause **5** of EN 60601-1:1990 applies.

NOTE A ventilator can have applied parts of different types.

6 Identification, marking and documents

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

In **6.1** add the following to item e):

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

In **6.1** add the following to item j):

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

In **6.1** add the following items:

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

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

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

— Driving gas input port: “DRIVING GAS INPUT”
— Inflating gas input port: “INFLATING GAS INPUT”
— Fresh gas intake port: “FRESH GAS INTAKE”
— Fresh gas input port: “FRESH GAS”
— Emergency air intake port: “WARNING: EMERGENCY AIR INTAKE — DO NOT OBSTRUCT”
— Manual ventilation port: “BAG”
— Gas output port: “GAS OUTPUT”
— Gas return port: “GAS RETURN”
— Gas exhaust port: “EXHAUST”

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

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

The 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 community, **6.1**e) of this European Standard applies.

— Device identification and content information.

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

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

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

— Where appropriate, an indication that the device is for single use.

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

— Any special storage and/or handling conditions.

— Any warning and/or precaution to take.

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

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

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

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

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

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

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

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

In **6.8.2** add the following items:

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

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

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

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

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

- high pressure alarm;
- breathing system integrity alarm, if provided;
- power failure alarm;
- low oxygen concentration alarm, if provided.

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

NOTE Other intended uses can include:

— Emergency:

- in resuscitation at the scene of an accident, drowning, etc.;
- longer-term use in continuing emergency (e.g. fire, mining accident).

— Transport:

- between hospital rooms and departments;
- between hospitals and/or other sites;
- emergency situation;
- long-distance planned transport.

— If the ventilator incorporates a gas mixing system the manufacturer shall disclose the information necessary for safe operation of the mixing system. See **6.8.3**a), 2nd dash, 15th bullet.

— Each ventilator shall be provided with a check list that summarises the test procedure recommended by the manufacturer which has to be performed prior to use. The use of electronic displays, e.g. a cathode ray tube (CRT), is permitted.

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

— A statement that volume-limited ventilators are not to be used on unattended patients.

— The mass of the ventilator and any associated equipment e.g. cylinders, batteries, regulators, carrying cases, etc., and the external dimensions of the ventilator.

— Unless entrainment of air is prevented, recommendations for use in hazardous or explosive atmospheres shall be given, including a warning that if the ventilator will entrain or permit the patient to inhale gas from the atmosphere, its use in contaminated environments can be hazardous. If applicable, the manufacturer shall describe how to prevent or minimize such entrainment or inhalation, for example, by the use of a non-return valve or a filter.

bb) Manufacturers of software controlled devices shall disclose by what means the possibility of hazards arising from errors in the software program is minimized.

In **6.8.2**d) add the following:

R) The instructions for use shall contain:

- instructions for the dismantling and reassembly of components for cleaning and sterilization (if applicable). This shall include an illustration of the parts in their correct relationship. The manufacturer shall recommend a functional test of operation to be carried out after reassembly;
- recommendations for the preferred methods of cleaning and disinfection or sterilization of the ventilator and its components;
- a recommended functional test for operation to be carried out immediately prior to use.

In **6.8.3**a) add the following items:

R) The requirement given applies with the following addition.

— Unless otherwise specified, parameters shall be assumed to be expressed under ATPD[1)] conditions.

— The technical description shall additionally include disclosure of the following information, as far as applicable.

- A listing of the following pressures:

  i) maximum limited pressure ($P_{\text{lim max}}$);

  ii) minimum (sub-atmospheric) limited pressure ($P_{\text{lim min}}$);

  iii) range of values to which the maximum working pressure ($P_{\text{w max}}$) can be set and the means by which the maximum is assured (e.g. pressure cycling, pressure-limiting, pressure generation);

  iv) a statement whether negative pressure (sub-atmospheric) is available in the expiratory phase;

  v) range of values to which the minimum (sub-atmospheric) working pressure ($P_{\text{w min}}$) can be set and the means by which the minimum is assured.

- A listing of the ranges of the following parameters:

  i) delivered ventilation (i.e. minute volume);

  ii) delivered volume (i.e. tidal volume);

  iii) ventilatory frequency;

  iv) I:E ratio or % inspiratory time;

  v) cycling pressure;

  vi) end-expiratory pressure;

  vii) delivered concentration of oxygen, if preset or adjustable by controls on the ventilator.

[1)] ATPD: Ambient temperature and pressure, dry.

• If there is a facility for negative pressure in the expiratory phase, the limiting pressure and generated pressure, if applicable, shall be listed for the expiratory phase and the inspiratory phase.

• A technical description of the means of triggering.

• 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 **50**, **51.102** and **51.106**.

• For alarms used with the ventilator, a statement of their type, capabilities, principle of the alarm detection, and, if appropriate, disabling or delay of annunciation. A statement of the estimated life of the battery and suitable replacement batteries.

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

• The manufacturer shall disclose the test method on request.

• The inspiratory and expiratory resistance, compliance and internal volume of the complete ventilator breathing system and/or any breathing attachment or other components or sub-assemblies recommended by the manufacturer of the ventilator for inclusion in the ventilator breathing system.

• Resistance shall be disclosed for flows of 60 l/min for adult use, 30 l/min for paediatric use and 5 l/min for neonatal use, whichever is applicable.

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

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

• Interdependence of controls, if applicable.

• Disclosure of accuracies and ranges of displayed values and calibrated controls.

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

• Disclosure of how the delivered tidal or minute volumes and oxygen concentrations are affected by pressure at the patient connection port, in particular the maximum deviations from the calibrated or stated settings of these parameters at mean pressures of 0,5 kPa, 1,5 kPa, 3 kPa and 6 kPa (5 cm H_2O, 15 cm H_2O, 30 cm H_2O and 60 cm H_2O).

• The approximate duration of the gas supply, expressed as time per litre of the volume of the cylinder when charged at a typical nominal pressure and when the ventilator is set with typical ventilator settings. The chosen pressure and the ventilator settings shall be declared.

In **6.8.3** add the following:

aa) Extreme conditions

The manufacturer shall declare how the ventilator will respond as the environmental and supply conditions are extended outside the limits given in clause **10**, changing one parameter at a time, whilst the other parameters are maintained within the limits given in clause **10**, as well as combinations given by the manufacturer.

Outside the environmental and supply conditions specified in clause **10** but within the limits declared, 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.

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.

[2)] BTPS: Body temperature and pressure, saturated.

10 Environmental conditions

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

10.2.1 R) Environment

Replace items a), b), and c) with the following:

a) An ambient temperature range of −10 °C to +40 °C.

b) A relative humidity of 15 % r.h. to 95 % r.h.

c) An atmospheric pressure range of 70 kPa to 110 kPa.

In **10.2.2** add the following:

aa) R) The ventilator shall operate and meet the requirements of this European Standard throughout the following internal and/or external electrical power tolerances:

— AC voltage: −25 % + 15 % of nominal value.

— DC voltage: −15 % + 25 % of nominal value.

— AC frequency: − 5 % + 5 % of nominal value.

NOTE DC noise should be considered in the design of a ventilator intended to be powered by an external DC supply.

In clause **10** add the following:

10.101 External pneumatic power

If the ventilator is intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3:1994 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 1 000 kPa inlet pressure. The time-weighted average over 10 s and the steady state 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 Extreme conditions

The ventilator shall function under the extreme conditions and combinations of these as declared by the manufacturer in **6.8.3**aa).

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 those applied parts classified as the same type (see EN 60601:1990, **14.6**). The parts shall be connected together electrically. Parts connected to the protective earth terminal shall be tested separately.

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 with the following additions:

21.101 The ventilator shall be submitted to the following tests:

— Vibration (sinusoidal) according to IEC 60068-2-6, Test Fc, using the following parameters:

Frequency range: 10 Hz – 1 000 Hz

Amplitude/acceleration: 0,35 mm/49 $m \cdot s^{-2}$

Sweep rate: 1 octave/min

Number of sweep cycles: 4 in each axis

— Random vibration wide band — Reproducibility Medium according to IEC 60068-2-36, Test Fdb, using the following parameters:

ASD[3] 10 Hz – 200 Hz: $0{,}01g^2$/Hz

ASD 200 Hz – 500 Hz: $0{,}003g^2$/Hz

Total r.m.s. acceleration: $1{,}7g_{ms}$

Duration/axis/mounting: 30 min

— Bump according to IEC 60068-2-29, Test Eb, using the following parameters:

Peak acceleration: $15g$

Pulse duration: 6 ms

Number of bumps: 4 000

Direction: Vertical, with the ventilator in its normal operating position(s)

During and after the tests, the ventilator shall continue to function within the tolerances specified by the manufacturer.

21.102 The ventilator shall, while functioning, be submitted to the following test:

— Free fall according to IEC 60068-2-32:1975, Procedure 1, using the following parameters:

Height of fall: 0,75 m

Number of falls: 1 on each of the 6 faces

If the ventilator is fixed, as defined in EN 60601-1:1990, **2.2.12** it is exempted from this test.

After the test, the ventilator shall function within the tolerances specified by the manufacturer.

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 ultra-sonics)

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

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[3] Acceleration Spectral Density.

36 Electromagnetic compatibility

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

36.101 General

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 throughout the frequency range of 80 MHz to 2 GHz.

If an anomaly occurs, such as display interruption, false alarm or loss of function, without the integrity of the associated protective system being compromised, 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.

Discharges shall be applied only to accessible parts as defined in IEC 61000-4-2 with a level for contact discharges of ±(2, 4, 6) kV and for air discharges of ±(2, 4, 8) kV.

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

36.102 Transients

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.

If an anomaly occurs, such as display interruption, false alarm or loss of function, without the integrity of the associated protective system being compromised, this shall not be considered a safety hazard provided it is possible to restore normal operation within 30 s after the transients have been applied.

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 applies.

39 Common requirements for Category AP and Category APG equipment

Clause **39** of EN 60601-1:1990 applies.

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

Clause **40** of EN 60601-1:1990 applies.

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

Clause **41** of EN 60601-1:1990 applies.

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 additions:

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 60079-4 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 normal or single fault conditions, 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

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

In **44.6** add the following:

The ventilator shall be splash-proof (i.e PX4: see EN 60601-1:1990, **5.3**).

During and after the test specified in EN 60601-1:1990, **44.6** the ventilator in the condition given in EN 60601-1:1990, **4.6**a) shall continue to function within the tolerances specified by the manufacturer for normal use conditions and shall not cause a safety hazard.

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.

46

Not used.

47

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**) together with the following additions:

49.101 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 at the patient connection port to inspiratory and expiratory flows shall not exceed 0,6 kPa (6 cm H_2O) at 30 l/min for adult use, 0,6 kPa at 15 l/min for paediatric use and 0,6 kPa at 2,5 l/min for neonatal use.

This test is performed without use of attachable accessories which may affect inspiratory and expiratory resistance as declared by the manufacturer in **6.8.3**.

NOTE See **6.8.2**aa), 9th dash.

49.102 Off switch

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

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 of accuracies when tested under the operating conditions given in **10.2.1**, **10.101** and **10.102** 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 R) Electrical or pneumatic driving power

The ventilator shall have a power failure alarm which activates a continuous visual signal or an auditory signal of at least 7 s duration if the internal or external, electrical or pneumatic, power supply falls below the values specified by the manufacturer.

This signal shall not conflict with EN 475.

NOTE 1 Attention is drawn to the benefit of an auditory alarm in some circumstances or places (transport, mines, etc.).

NOTE 2 This requirement provides a means for the operator to determine the state of the internal power supply as well as providing a power failure alarm.

Compliance shall be checked by simulating a drop below the supply power (pneumatic and/or electrical) required for the intended purpose of use with the values specified by the manufacturer.

51.101.2 Reserve power supplies

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

NOTE An example of a reserve power supply is operation of a device with batteries in case of a mains power failure.

51.102 Pressure limitation under normal use

Means shall be provided to reduce the risk of barotrauma under normal use. If a ventilator breathing system (VBS) pressure measuring device is provided for this purpose, its accuracy shall be within $\pm$ (2 % of the full scale reading +8 % of the actual reading) and it shall be in combination with an adjustable setting device having a range including 6,6 kPa (66 cm H_2O), i.e. 6,0 kPa + 10 % or a preset pressure limitation not exceeding 6,6 kPa (66 cm H_2O), i.e. 6,0 kPa + 10 %.

For volume-limited ventilators with no VBS pressure measuring device, the VBS pressure shall be limited to less than 6,6 kPa (66 cm H_2O), i.e. 6,0 kPa + 10 % during normal use and the setting of the pressure limiting device shall be clearly marked as specified in **6.1**hh).

Test for compliance by visual inspection and verification of accuracy.

51.103 R) Pressure limitation under single fault condition

The maximum achievable pressure at the patient connection port under single fault condition shall not exceed 10 kPa (100 cm H_2O).

51.104 High pressure alarm

A high pressure alarm shall be provided. It shall activate an auditory signal when the inspiratory pressure alarm level is reached.

It shall not be possible to set the alarm level above the maximum pressure permitted by the means of pressure limitation referred to in **51.103**.

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 Patient-generated transient pressures (e.g. cough) might not activate the alarm.

51.105 Ventilation monitoring

Means shall be provided to prevent or indicate hypoventilation due to inadvertent reduction in inspiratory flow.

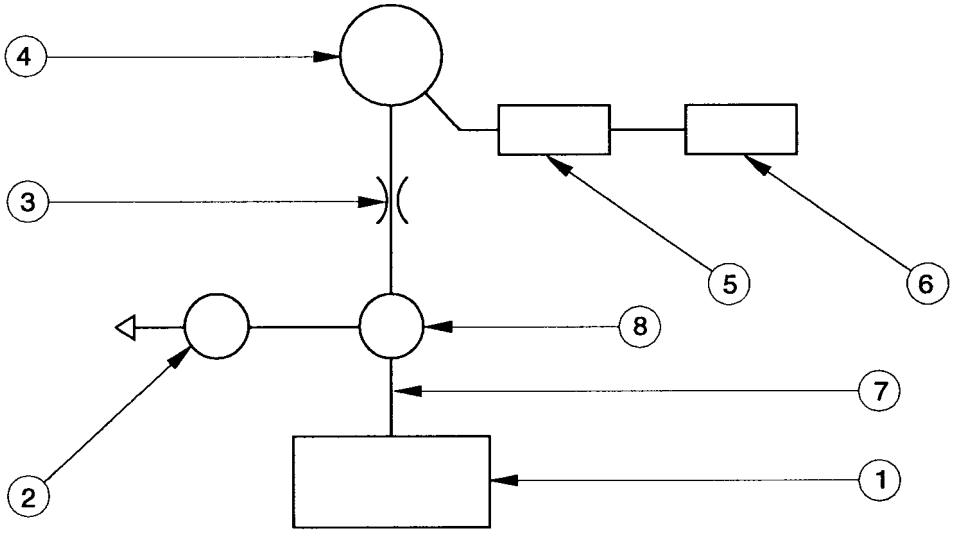
NOTE This can be achieved for example by one or more of the following:

a) monitoring the pressure as described in **51.102**;

b) monitoring the volume as described in **51.106**;

c) monitoring the breathing system (disconnect) as described in **51.107**;

d) monitoring the oxygen concentration as described in **51.108** or the carbon dioxide concentration in the expiratory gases.



1 Ventilator
2 Volume measuring 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 measuring device
7 Breathing system
8 Expiratory valve

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

Table 101 — Test conditions for expiratory volume tests

Adjustable parameter	Test conditions		
	Adult use	Paediatric use	Neonatal use
Tidal volume V_T (ml) as measured by means of pressure sensor on test lung ($V_T = C \times P_{max}$)	500	300	30
Frequency f (min^{-1})	10	20	30
I/E ratio	1/2 or nearest	1/2 or nearest	1/2 or nearest
Resistance R (kPa/l/s)	0,5 kPa/l/s ± 10 %	2 kPa/l/s ± 10 %	5 kPa/l/s ± 10 %
Isothermal compliance C (ml/kPa)	500 ml/kPa ± 5 %	200 ml/kPa ± 5 %	10 ml/kPa ± 5 %

NOTE The accuracies for C and R apply over the ranges of the measured parameters.

51.106 Measuring device for expiratory volume

If a measuring device for the expiratory tidal volume or minute volume is provided, the accuracy shall be within ±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 Table 101.

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

51.107 R) Breathing system integrity alarm (disconnection)

If a ventilator breathing system integrity alarm is provided it shall generate an auditory signal in the case of disconnection of the patient from the ventilator and a means for silencing the alarm shall be provided in accordance with **51.109**.

Compliance shall be checked by disconnecting the patient connection port while performing a controlled ventilation.

The operational apparatus is attached to a test lung and operated in accordance with the instructions for use. The auditory alarm signal shall sound within 20 s following disconnection. In the case of IMV it is permissible to delay the alarm for the period between two IMV strokes but not longer than 45 s.

51.108 Oxygen monitor and alarms

If the ventilator is fitted with an oxygen monitor for measurement of the inspiratory oxygen concentration, it shall be in compliance with prEN 12598:1996 and shall have a low-concentration auditory alarm.

Compliance shall be tested by visual inspection and functional testing by simulating an oxygen concentration below the set alarm limit.

51.109 Alarms

Electrically generated visual alarms, if provided, shall comply with EN 475. If visual alarms are generated by other means, e.g. pneumatically, they shall comply with the colours specified in EN 475.

51.109.1 The characteristics of any auditory alarm shall be disclosed by the manufacturer.

NOTE The auditory level characteristics should be appropriate for the intended application(s), e.g. in a road ambulance, between the departments of a hospital, in a helicopter, etc.

51.109.2 The maximum time for which an auditory alarm signal can be silenced shall be 120 s.

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

51.109.4 If adjustable alarms are provided they shall be indicated continuously or on operator demand.

51.110 Protection against inadvertent adjustments

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

NOTE Mechanical techniques such as locks, shielding, friction-loading and detents are considered 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 together with the following modification and addition:

54.1 Arrangements of functions

Replace **54.1** with the following:

R) 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.

Test for compliance by simulation of a single fault condition and/or visual inspection.

54.101 R) Leaching of substances

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

Documentary evidence shall be held by the manufacturer.

54.102 Delivered oxygen concentration

The ventilator shall be capable of delivering at least 95 % O_2 (*V/V*).

54.103 The ventilator, or its carrying case if applicable, shall be provided with means for lifting and carrying.

55 Enclosures and covers

Clause **55** of EN 60601-1:1990 applies with the following additions:

55.101 Physical dimensions

55.101.1 Size

The external dimensions of the ventilator shall be given [see **6.8.2**aa), 8th dash].

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 items:

aa) If more than one high pressure input port is provided, each port shall be fitted with means to prevent reverse flow either to the atmosphere or to the supply system.

The reverse flow of gases from one to another high pressure input port of the same gas type shall not exceed 100 ml/min (ATPD) under normal conditions.

The reverse flow of gases from one to another high pressure input port of a different gas shall not exceed 100 ml/h (ATPD) under normal and single fault conditions.

Evidence of compliance with these requirements, either by test or other methods, shall be provided by the manufacturer.

bb) High pressure gas input port connectors

If the ventilator is intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with prEN 737-3:1994 or a pressure regulator complying with EN 738-1), each high pressure gas input port connector shall be either the body of a non-interchangeable screw-threaded (NIST) connector complying with EN 739 or a probe complying with EN 737-1 and prEN 737-6:1996. See annex DD for special national conditions.

cc) 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 EN 739. If a hose assembly is permanently connected to the ventilator, the connector to the medical gas supply system shall be a probe complying with EN 737-1.

dd) Ventilator breathing system connectors

Ventilator breathing system connectors, if conical, shall be 8,5 mm, 15 mm or 22 mm size connectors complying with EN 1281-1 and EN 1281-2.

Non-conical connectors shall not engage with conical connectors complying with EN 1281-1 or EN 1281-2 unless they comply with the engagement, disengagement and leakage requirements of EN 1281-1 or EN 1281-2.

ee) Gas exhaust port connector

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

— a 30 mm male conical connector complying with EN 1281-1; or

— a permanent connection or proprietary connector incompatible with EN 1281-1 and EN 737-1.

ff) Emergency air intake port

An emergency air intake port shall be provided and shall not accept any connector complying with EN 1281-1 and 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.

gg) Patient connection port

The patient connection port connector, if conical, shall be either 8,5 mm female or coaxial 15 mm/22 mm complying with EN 1281-1 and EN 1281-2.

hh) Manual ventilation port

If a manual ventilation port is provided, the connector shall be either 22 mm conical female complying with EN 1281-1 or male cylindrical connector that will accept a breathing tube complying with prEN 12342:1996.

ii) Flow direction-sensitive component connectors

Any flow direction-sensitive, operator-detachable component shall be so designed that it cannot be fitted in such a way as to present a hazard to the patient.

jj) Accessory port

If an accessory port is provided, it shall not be compatible with connectors as 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 the introduction of therapeutic aerosols.

kk) Monitoring probe port

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

In clause **56** add the following:

56.101 Reservoir bags and breathing tubes

56.101.1 Any reservoir bags intended for use in the ventilator breathing system shall comply with EN 1820. Breathing tubes with an internal diameter of more than 18 mm, intended for use in the ventilator breathing system, shall comply with prEN 12342:1996.

56.101.2 Respiratory gas-conducting components (packaging and decontamination)

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

56.101.2.2 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.

Evidence about the method(s) used to ensure the intended level of cleanliness of breathing system components during production and supply shall be given by the manufacturer upon request.

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

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

56.102 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 8185:1995 and ISO 9360 respectively.

56.103 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 and 5 l/min for neonatal use.

Compliance shall be checked by measurement of the pressure at the patient connection port at the specified flows.

56.104 Leakage from the complete ventilator breathing system

Leakage from the ventilator breathing system shall not exceed 200 ml/min for adult breathing systems, 100 ml/min for paediatric breathing systems or 50 ml/min for neonatal breathing systems.

Compliance shall be determined by the following test:

Set up the breathing system for the intended application as recommended by the manufacturer. Seal all ports. Connect the pressure measuring device and introduce air into the breathing system until a pressure of 2 kPa is reached for neonatal breathing systems, 4 kPa for paediatric breathing systems or 5 kPa for adult breathing systems Adjust the flow of air to stabilize the pressure and record the leakage flow.

56.105 Tests for compliance

Compliance with **56.3** and **56.101** to **56.104** shall be checked by visual inspection and functional tests, simulating the conditions specified.

57 Mains parts, components and layout

Clause **57** of EN 60601-1:1990 applies together with the following additions:

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

R) Any supply cord of an electrically powered ventilator shall be a non-detachable cord or shall be protected against accidental disconnection from the ventilator.

Compliance shall be checked by inspection and the test described in EN 60601-1:1990, **57.4** respectively.

During the test, the mains connector shall not become disconnected from the appliance inlet.

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 concise rationale for the important 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 the main requirements is considered to be essential for its proper application.

Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements 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.1 The purpose of this European Standard is to establish particular requirements for the safety of emergency and transport ventilators.

Emergency and transport ventilators are often installed in ambulances or other types of rescue equipment, but are also often used outside of them, where they have to be carried by the operator to other persons. It also has to be considered that the operators could have limited training.

AA 1.101 Current Federal Aviation Requirements/Joint Aviation Requirements (FAR/JAR) regulations and EU regulations are likely to impose requirements on these ventilators.

AA.3 The definition of “applied part” in this European Standard is the basis for clarification of requirements for, and measurement of, patient leakage current.

It cannot be excluded that antistatic tubing or other tubing which is considered as electrically conductive may be used in the breathing system of ventilators.

Parts integrated with 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 for leakage currents can be specified in this European Standard. Such parts are therefore included in the definition of the applied part.

AA.4.1[3.6aa), 2nd dash] This requirement, however, is equivalent to EN 60601-1:1990, **3.1** which effectively states that all devices shall cause no safety hazard under normal conditions 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 amply to accommodate software driven devices within the framework of EN 60601-1:1990. This approach is advisable, especially with respect to, e.g. a failure mode effect analysis, to prove compliance with EN 60601-1:1990, **3.1**.

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 to be regarded as a normal condition.

AA.6.8.2aa), 1st dash The available operating time may vary but provides the most important information for a ventilator mostly used outside of a hospital, where no extra power backup is available (see **51.101.1**).

AA.6.8.2d) Wrongly assembling a ventilator so that it causes incorrect operation or complete malfunction is a serious hazard which can result in inadequate ventilation of the patient.

AA.6.8.3 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”. 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; 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.6.8.3, 2nd dash, 6th bullet Some changes in the condition and composition of the gas at the sensor can alter the flow – or volume – sensitivity for 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 conditions. 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 is saturated at 30 °C, the indication will be less than the true expired volume at BTPS.

AA.6.8.3, 2nd dash, 14th 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.10.2.1 The ranges of environmental conditions specified do not cover the extremes that can be experienced in certain severe environments but have been chosen to represent normal use conditions. The manufacturer's declaration required by **6.8.3**e) is intended to allow users to select devices appropriate for use in different operating environments.

AA.10.2.2aa) The electrical power tolerances specified are more severe than those normally used for medical devices, but this is to allow for the fact that emergency devices will often be required to operate from small portable generators, DC to DC converters, battery systems subjected to simultaneous charging and other such poorly regulated power sources.

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

AA.21.101 There are no established generalized test programmes that exactly reproduce the range of vibration and shock conditions that devices might meet when installed in a range of land vehicles and aircraft. The dynamic tests specified in this clause have been chosen on the basis that devices tested to these levels are likely to withstand the normal dynamic disturbances that they will meet when used in the range of vehicles and aircraft (including helicopters) likely to be used for carrying ventilated patients.

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);

— 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 oxidising 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 60079-4.

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 assure safety under these conditions.

In certain standards currently in use the requirements to minimise 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.51.101.1 An emergency and transport ventilator is attended by an operator when in use. The operator is the party responsible for the safety of the patient, whilst the ventilator primarily provides a life support function under the given circumstances. Experience shows that the knowledge of the available operating time (see also **AA.6.8.2**aa), 1st dash) and a power failure alarm is an acceptable means of determining the state of the internal power supply.

AA.51.102 6,6 kPa corresponds to a nominal value of 6 kPa with 10 % positive tolerance. To minimize the risk of pulmonary barotrauma during routine and emergency ventilation, the maximum airway pressure should be limited to 6,0 kPa (60 cm H_2O) (FDAO, European Council for Resuscitation). With a volume-limited ventilator, the flow is set and maintained by the volume/time control of the device. In addition, a pressure relief valve is incorporated to prevent the accidental release of energy to the patient.

AA.51.103 10 kPa may be necessary for patients with high resistance (e.g. asthmatics).

AA.51.107 Typical examples of activation principles for breathing system integrity are as follows:

a) if intended to annunciate loss of pressure, the alarm might be actuated when the pressure falls 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 falls 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 falls 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 % (*V/V*) 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 breathing system integrity alarm can be unreliable when different concentrations of oxygen are used;

e) if intended to annunciate a change in the level of carbon dioxide, the alarm might be activated by failure of the level of carbon dioxide at the patient connection port to fluctuate by 1 % (*V/V*) with an alternation of 3 % (*V/V*) (i.e. failure of the intermittent signal consequent upon breathing or ventilation); failure of the carbon dioxide concentration to return to 0,5 % (*V/V*) might also be considered. The sampling site should be in the return (expiratory) tube of the ventilator breathing system or in the exhaust gas pathway within 5 cm of the patient connection port or in the respiratory tract (e.g. the tracheal tube may have an integral sampling channel). A capnometer complying with EN 864 is suitable for this purpose;

f) if intended to annunciate a change in the peripheral oxygen saturation of the patient, the alarm might be activated if a reduction of 5 % SpO_2 is detected when using a pulse oximeter complying with EN 865.

AA.54.1 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 monitoring failure.

This requirement, however, is equivalent to **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 amply to accommodate software driven devices within the framework of EN 60601-1:1990. This approach is advisable, especially with respect to, e.g. a failure mode effect analysis, to prove compliance with **3.1** of EN 60601-1:1990.

AA.54.101 Such evidence will be provided by the manufacturer e.g. to a Notified Body during CE conformity assessment or to a Competent Authority upon request.

AA.55.101.1 Emergency ventilators can be required to be used where access to patients is difficult, such as in crawl spaces and through manholes.

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

Annex BB (normative)
Legibility and visibility

BB.1 General testing conditions

a) the operator has a visual accuity of 1 (corrected if necessary), and;

b) an illumination of 215 lx shall be provided, and;

c) measurement of ambient illumination shall be made from the control panel towards the subject.

BB.2 Legibility

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

BB.3 Visibility

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)
Bibliography

NFPA publication 53 M, *Fire hazards in oxygen-enriched atmospheres*[5)].

EN 794-1, *Lung ventilators — Part 1: Particular requirements for critical care ventilators.*

EN 794-2, *Lung ventilators — Part 2: Particular requirements for home care use.*

EN 864, *Medical electrical equipment — Capnometers for use with humans — Particular requirements.*

EN 865, *Pulse oximeters — Particular requirements.*

Annex DD (normative)
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.

56.3bb): 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.

56.3bb): Special national condition for all CEN members.

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

6.1ee) and 56.3bb) Special national condition for Austria, Germany and Switzerland.

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

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

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 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.

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	Qualifying remarks
All	1, 2, 3	
8 to **36**	9.2	
21 to **49**	4	
37 to **41**	9.3	
51.104 to **51.109**	12.4	
Section three	12.6	
Section four	12.7.1, 12.7.2, 12.7.3, 12.7.4	
Section nine	12.6	
Section ten	12.6	
6	9.1, 13.1	
6.1	13.3 (except g), h)), 13.4, 13.5	
6.1dd)	7.2, 8.7	
6.8	13.4, 13.6 (except e) j))	
6.8.2	13	
6.8.2aa)	10.1	
6.8.3	13	
6.8.3a)	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	
50	10.1, 12.8.1	
51	12.8.1, 12.8.2	
51.101	12.2, 12.3	
52	4, 7.5	
54.101	7.2, 7.3, 7.5	
56.3	9.1, 12.7.4	
56.101	8.1, 9.1	
56.101.2	8.3	
56.102	9.1	
57.3	12.7.4	
Annex BB	10.2	

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