

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

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

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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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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

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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.

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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 use¹⁾ 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	<i>Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization</i>
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EN 552	<i>Sterilization of medical devices — Validation and routine control of sterilization by irradiation</i>
EN 554	<i>Sterilization of medical devices — Validation and routine control of sterilization by moist heat</i>
EN 556	<i>Sterilization of medical devices — Requirements for medical devices to be labelled ‘STERILE’</i>
prEN 737-1	<i>Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum</i>
prEN 737-3	<i>Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum — Basic requirements</i>
prEN 737-6	<i>Medical gas pipeline systems — Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum</i>
EN 738-1	<i>Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices</i>
prEN 739	<i>Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas supply systems</i>
EN 980	<i>Graphical symbols for use in the labelling of medical devices</i>
EN 1281-1	<i>Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets</i>
EN 1281-2	<i>Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2 : 1987 modified)</i>
prEN 1820	<i>Anaesthetic reservoir bags</i>
prEN 12342	<i>Breathing tubes intended for use with anaesthetic apparatus and ventilators</i>
EN 60601-1: 1990	<i>Medical electrical equipment — Part 1: General requirements for safety (IEC 601-1 : 1988)</i>

¹⁾ Called hereafter ‘ventilator’.

EN 60601-1-2	<i>Medical electrical equipment — Part 1: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 601-1-2 : 1993)</i>
EN 60801-2	<i>Electromagnetic compatibility for industrial-process measurement and control equipment — Part 2: Electrostatic discharge requirements (IEC 801-2 : 1991)</i>
prEN ISO 8185-1	<i>Humidifiers for medical use — Part 1: General requirements for humidification systems (ISO/DIS 8185-1 : 1995)</i>
ISO 32	<i>Gas cylinders for medical use — Marking for identification of content</i>
ISO/DIS 7767	<i>Oxygen monitors for monitoring patient breathing mixtures — Safety requirements</i>
ISO 9360	<i>Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans</i>
IEC 79-4	<i>Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature</i>

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:

- air drawn through the emergency air intake port;
- air drawn through leaks in the ventilator breathing system;
- 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).