



BSI Standards Publication

Lung ventilators

Part 4: Particular requirements for user-powered resuscitators

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National foreword

This British Standard is the UK implementation of EN ISO 10651-4:2023. It is identical to ISO 10651-4:2023. It supersedes BS EN ISO 10651-4:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

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

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English Version

Lung ventilators - Part 4: Particular requirements for user-powered resuscitators (ISO 10651-4:2023)

Ventilateurs pulmonaires - Partie 4 : Exigences relatives aux ressuscitateurs actionnés par l'utilisateur (ISO 10651-4:2023)

Beatmungsgeräte - Teil 4: Anforderungen an anwenderbetriebene Wiederbelebungsgерäte (Handbeatmungsgeräte) (ISO 10651-4:2023)

This European Standard was approved by CEN on 17 February 2023.

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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 CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 10651-4:2023) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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of an identical text or by endorsement, at the latest by October 2023, and conflicting national standards shall be withdrawn at the latest by October 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10651-4:2009.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 10651-4:2023 has been approved by CEN as EN ISO 10651-4:2023 without any modification.

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Contents

	Page
Foreword.....	v
Introduction.....	vii
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	2
4 General requirements for testing of a <i>resuscitator</i>.....	15
4.1 <i>Risk management process</i>	15
4.2 <i>Type tests</i>	16
4.3 Test conditions.....	16
4.4 Gas flowrate, volume and leakage specifications.....	17
4.5 Testing errors.....	17
4.6 Environmental conditions in the end user environment.....	18
4.6.1 Transport and storage conditions.....	18
4.6.2 Operating conditions.....	19
4.6.3 <i>Shelf-life</i>	20
4.6.4 <i>Expected lifetime</i>	20
5 Information supplied by the manufacturer.....	21
5.1 General.....	21
5.2 Additional <i>marking</i> requirements.....	22
5.3 Additional <i>instructions for use</i> requirements.....	22
6 Connectors and ports.....	23
6.1 General.....	23
6.2 <i>Patient-connection port</i>	23
6.3 Expiratory <i>port</i> connector for breathing gases.....	23
6.4 <i>Face mask</i> connectors.....	24
6.5 <i>Intake</i> connectors.....	24
6.6 <i>Bag refill valve</i> connector.....	24
6.7 Oxygen inlet connection.....	25
6.8 Pressure monitor connector.....	26
7 Operational requirements.....	26
7.1 Dismantling and reassembly.....	26
7.2 <i>Resuscitator</i> performance after contamination with vomitus.....	26
7.3 Mechanical strength.....	27
7.4 Resistance to separation from an axial load.....	27
7.4.1 <i>Multiple patient multiple use resuscitators</i>	28
7.4.2 <i>Single use and single patient multiple use resuscitators</i>	28
7.5 Immersion in water.....	29
7.6 <i>Bag refill valve</i>	29
7.7 Compatibility with substances.....	29
8 Ventilatory requirements.....	30
8.1 <i>Delivered oxygen concentration</i>	30
8.1.1 Non-spontaneously breathing <i>patient</i>	30
8.1.2 Spontaneously breathing <i>patient</i>	31
8.2 Expiratory resistance.....	33
8.3 Inspiratory resistance.....	34
8.4 Gas source excessive flow.....	34
8.5 <i>Resuscitator deadspace</i>	35
8.6 Ventilation performance.....	35
8.6.1 Minimum guaranteed <i>tidal volume</i> (V_T) — one hand.....	35
8.6.2 Minimum guaranteed <i>tidal volume</i> for $B < 2,5$ kg.....	36
8.6.3 Maximum deliverable <i>tidal volume</i> — two hands.....	37

This is a preview of "BS EN ISO 10651-4:20...". Click here to purchase the full version from the ANSI store.

8.6.4	<i>Maximum limited pressure</i>	38
9	Additional requirements for <i>resuscitator</i> parts and <i>accessories</i>	39
9.1	General.....	39
9.2	Labelling.....	40
9.3	<i>Breathing system filters</i>	40
9.4	<i>Stand-alone gas mixer</i>	40
10	Processing requirements for a <i>resuscitator</i> and its <i>accessories</i> that are reusable	40
11	<i>Biocompatibility</i>	41
12	<i>Usability</i>	41
Annex A	(informative) Particular guidance and rationale	43
Annex B	(informative) Guide to <i>marking</i> and labelling requirements for <i>resuscitators</i> and their <i>accessories</i>	49
Annex C	(informative) <i>Symbols on marking</i>	52
Annex D	(informative) Reference to the <i>IMDRF essential principles</i> and labelling guidances	55
Annex E	(informative) Reference to the <i>essential principles</i>	58
Annex F	(informative) Reference to the general safety and performance requirements	60
Bibliography	63
Terminology — Alphabetized index of defined terms	65

This is a preview of "BS EN ISO 10651-4:20...". Click here to purchase the full version from the ANSI store.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 10651-4:2002), which has been technically revised.

The main changes are as follows:

- clarified scope to include flow-inflating bag and self-inflating bag *resuscitators* and also indicated that the requirements include specified *accessories*;
- updated normative references and defined terms;
- specified test conditions;
- specified calculation and disclosure of measurement uncertainty;
- harmonized storage and operating environmental conditions;
- added requirements for *shelf-life* and *expected lifetime*;
- harmonized *information supplied by the manufacturer* with ISO 20417 and ISO 15223-1;
- added requirements for the oxygen inlet connector;
- clarified ventilatory testing requirements;
- clarified *delivered oxygen concentration* performance requirements;
- added *processing* requirements;

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- added *biocompatibility* requirements; and
- added *usability* requirements.

A list of all parts in the ISO 10651 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

In this document, the following print types are used:

- requirements and definitions: roman type;
- *terms defined in this document: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability;
- “must” indicates an external constraint.

[Annex A](#) contains rationale or guidance to some of the requirements in this document.

[Annex B](#) contains a guide to the *marking* and *labelling* requirements in this document.

[Annex C](#) contains a summary of the *symbols* referenced in this document.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

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Lung ventilators —

Part 4:

Particular requirements for user-powered resuscitators

1 Scope

This document specifies requirements for *user-powered resuscitators* intended for use with all age groups and which are intended to provide *lung* ventilation to *patients* whose breathing is inadequate. *User-powered resuscitators* are designated according to ideal body mass range.

Example *user-powered resuscitators* include:

- self-inflating bag *resuscitators* intended to be squeezed by the *user's* hand and refilled by elastic recoil; and

NOTE 1 Self-inflating bag *resuscitators* are generally *transit-operable* and can be used in a wide range of environmental and emergency situations.

- flow-inflating bag *resuscitators* intended to be squeezed by the *user's* hand and refilled by a flow from a medical gas source.

This document is also applicable to those *accessories* that are intended for use with *resuscitators* where the characteristics of those *accessories* can affect the *safety* of the *user-powered resuscitator*.

Examples of such *accessories* include *face masks*, *PEEP* valves, capnometric indicators, manometers, metronomes, flow restrictors, filters, gas refill valves, oxygen gas mixers, connectors, electronic feedback devices, electronic sensors and transmission of data to other equipment.

This document is also applicable to point-of-use packaging.

This document does not specify the requirements for:

- gas-powered emergency resuscitators, which are given in ISO 10651-5;
- electrically-powered resuscitators;
- gas powered resuscitators for *professional healthcare facilities*; and
- anaesthetic reservoir bags, which are given in ISO 5362.

NOTE 2 This document has been prepared to address the relevant *essential principles*^[24] and labelling^[25] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in [Annex D](#).

NOTE 3 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in [Annex E](#).

NOTE 4 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745^[23] as indicated in [Annex F](#).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.