SLOVENSKI STANDARD
SIST EN ISO 10651-4:2023

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Nadomešča:
SIST EN ISO 10651-4:2009

Pljučni ventilatorji - 4. del: Posebne zahteve za naprave za oživljanje, ki jih upravlja uporabnik (ISO 10651-4:2023)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 10651-4:2023**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 10651-4:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10651-4

April 2023

ICS 11.040.10

Supersedes EN ISO 10651-4:2009

English Version

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

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

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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

Ref. No. EN ISO 10651-4:2023 E

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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of an identical text or by endorsement, at the latest by October 2023, and conflicting national standards shall be withdrawn at the latest by October 2023.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.

INTERNATIONAL STANDARD

ISO 10651-4

Second edition
2023-03

Lung ventilators —

Part 4: Particular requirements for user-powered resuscitators

Ventilateurs pulmonaires —

Partie 4: Exigences relatives aux ressuscitateurs actionnés par l'utilisateur

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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;

— 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.

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.

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.