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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*



Reference number
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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;

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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.