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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~~ 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~~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.

Field Code Changed

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 ~~compared to the previous edition~~ 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 ~~updated from ENs to current ISO standards;~~

— ~~updated~~and defined terms ~~to be consistent with current ISO standards~~;

— specified test conditions;

— specified calculation and disclosure of measurement uncertainty;

— harmonized storage and operating environmental conditions ~~with current ISO standards~~;

— 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;

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— 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.

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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~~Annex A contains rationale or guidance to some of the requirements in this document.

~~Annex B~~Annex B contains a guide to the *marking* and *labelling* requirements in this document.

~~Annex C~~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][24] and labelling[25][25] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in ~~Annex D.~~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.~~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][23] as indicated in ~~Annex F.~~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.

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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ISO 11195:2018, *Gas mixers for medical use — Stand-alone gas mixers*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562–1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2021, *Medical devices — Information to be provided supplied by the manufacturer*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-2:—, [1], *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases applications*

IEC 60068-2-31:2008, *Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62570:20152014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

IEC Guide 115:2021, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

EN 13544-2:2002+AMD1:2009, *Respiratory therapy equipment - Part 2: Tubing and connectors*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminologicalterminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obphttps://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/https://www.electropedia.org/

NOTE See Annex G for the alphabetized index of defined terms.

[1] Under preparation. Stage at the time of publication: ISO/FDISDIS 80369-2:20222021.

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3.1
accessory
item, intended specifically by its *manufacturer*, to be used together with one or more *medical devices* to specifically enable or assist those *medical devices* to be used in accordance with their *intended use*

Note 1 to entry: An *accessory* is typically a consumable or separate item for use with one or more *medical devices*.

Note 2 to entry: Some *authorities having jurisdiction* consider an *accessory* to be a *medical device*.

Note 3 to entry: Some *authorities having jurisdiction* have a different definition of *accessory*.

[SOURCE: ISO 20417:2021, 3.1]

3.2
accompanying information
information accompanying or *marked* on a *medical device* or *accessory* for the *user* or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the *medical device* or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the *medical device* or *accessory.*

Note 2 to entry: The *accompanying information* can consist of the *label*, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g., CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified —deleted notes 4 ~~to7~~to 7.]

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3.3
airway pressure
pressure at the *patient-connection port*, relative to ambient pressure unless otherwise specified

Note 1 to entry: In addition to its direct reference, this term or its symbol P_{aw}, displayed in various character styles, is only used, in context or by qualification, to designate this concept as a measured quantity.

Note 2 to entry: The site(s) of actual measurement(s) may be anywhere in the *ventilator breathing system*, providing that the indicated value is referenced to that at the *patient-connection port*.

Note 3 to entry: This is the generic term for this fundamental concept. Post-coordinated terms, for example, peak inspiratory pressure and baseline *airway pressure*, are used in particular contexts.

Note 4 to entry: Although providing no explicit indication as to where along the *patient's* airway this pressure is measured, this term, along with its symbol, has become widely adopted as referencing the pressure at the point at which *artificial ventilation* equipment is connected to the *patient's* airway or to an *airway device*. This is the final site where a common and replicable pressure can be continuously monitored, conveniently, before breathing gas enters the *patient*.

Note 5 to entry: A pressure measured in the *patient's* airway at a site other than at the *patient-connection port* is referred to in this document as a respiratory pressure.

[SOURCE: ISO 19223:2019, 3.6.1 modified — deleted notes 6 and 7.]

3.4
atmospheric temperature and pressure
ATP
expressed at ambient atmospheric pressure and temperature

3.5
bag inlet valve
<self-inflating bag *resuscitator*> valve activated by the sub-atmospheric pressure in the *compressible unit* of the *resuscitator* to refill the *compressible unit* with gas at ambient pressure

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[SOURCE: ISO 4135:~~2021~~2022, 3.6.1.3.1, modified — added context.]

3.6
bag refill valve
<self-inflating bag *resuscitator*> *accessory* valve activated by the sub-atmospheric pressure in the *compressible unit* of the *resuscitator* to refill the *compressible unit* from a pressurized oxygen source

[SOURCE: ISO 4135:~~2021~~2022, 3.6.1.3.2, modified — added context and *accessory,* replaced 'gas' with 'oxygen' and deleted 'with no manual trigger'.]

3.7
BAP
quantity by which the baseline *airway pressure* is set to be positively offset from the ambient pressure

[SOURCE: ISO 19223:2019, 3.10.2, modified — deleted notes.]

3.8
biocompatibility
ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: Medical devices may produce some level of adverse effect, but that level may be determined to be acceptable when considering the benefits provided by the medical device.

[SOURCE: ISO 18562-1:2017, 3.2]

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3.9
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in a breathing system

[SOURCE: ISO 4135:~~2021~~2022, 3.6.1.5]

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3.10
cleaning
removal of contaminants to the extent necessary for further *processing* or for *intended use*

Note 1 to entry: *Cleaning* consists of the removal, usually with detergent and water, of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a *medical device* by a manual or automated *process* that prepares the items for safe handling or further *processing*.

[SOURCE: ISO 17664-1:2021, 3.1]

3.11
clearly legible
capable of being read by a person with normal vision

[SOURCE: ISO 20417:2021, 3.4]

3.12
compressible unit
part of a *user-powered resuscitator* e.g. a bag or bellows that, when squeezed by the *user*, delivers a volume of gas

[SOURCE: ISO 4135:~~2021~~2022, 3.4.1.11, modified —replaced 'compressed' by ~~'squeezed''~~'squeezed'.]

3.13
delivered oxygen concentration
concentration of oxygen in the gas delivered to a *patient*

[SOURCE: ISO 4135:~~2021~~2022, 3.1.1.14, modified —deleted example.]

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3.14
disinfection
process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-1:2021, 3.3]

3.15
e-documentation
any form of electronically accessible *information supplied by the manufacturer* related to a *medical device* or *accessory*

EXAMPLE CD/DVD-ROM, USB stick, website.

[SOURCE: ISO 20417:2021, 3.6, modified —deleted note 1.]

3.16
essential principles
essential principles of safety and performance
fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

[SOURCE: ISO 16142-1:2016, 3.3]

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3.17
exhaust port
port of the medical equipment or device from which gas is discharged to the atmosphere during *normal use*, either directly or via an anaesthetic gas scavenging system

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Note 1 to entry: A *resuscitator* may have more than one *exhaust port*.

[SOURCE: ISO 19223:2019, 3.14.2, modified —added note.]

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3.18
expected lifetime
time period specified by the *manufacturer* during which the *medical device* or *accessory* is expected to remain safe and effective for use

Note 1 to entry: The *expected lifetime* can be affected by the *stability*.

Note 2 to entry: Maintenance, repairs or upgrades (e.g. *safety* or cybersecurity modifications) can be necessary during the *expected lifetime*.

Note 3 to entry: Some *medical devices* have an absolute lifetime (e.g. 5 years), whereas other *medical devices* (e.g. software) have a relative lifetime (e.g., the time between two major releases).

[SOURCE: ISO 20417:2021, 3.7]

3.19
expiratory phase
interval from the start of expiratory flow to the start of inspiratory flow within a respiratory cycle

[SOURCE: ISO 19223:2019, 3.4.2, modified — deleted notes.]

3.20
forward leakage
volume of gas produced by the *resuscitator* during the *inflation phase* which does not pass through the *patient-connection port* to the *patient* but passes to the atmosphere

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