BS EN ISO 10651-4:2023

BSI Standards Publication

Lung ventilators

Part 4: Particular requirements for user-powered resuscitators

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Full document details: BS EN ISO 10651-4:2023

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 It supersedes BS EN ISO 10651-4:2009, which is withdrawn.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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Published by BSI Standards Limited 2023

ISBN 978 0 539 03818 7

ICS 11.040.10

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 April 2023.

Amendments/corrigenda issued since publication

Date	Text affected

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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)

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

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

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

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of an identical text or by endorsement, at the latest by October 2023, and conflicting national standards shall be withdrawn at the latest by October 2023.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

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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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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.

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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*

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 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 62570:2014, *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 terminology databases for use in standardization at the following addresses:

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

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

NOTE For convenience, an alphabetized index of terms and their sources used in this document is found at the end of this document.

1) Under preparation. Stage at the time of publication: ISO/DIS 80369-2:2021.

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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 to 7.]

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

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

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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 4135:2022, 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]

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

[SOURCE: ISO 4135:2022, 3.6.1.5]

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 4135:2022, 3.4.1.11, modified —replaced 'compressed' by 'squeezed'.]

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

[SOURCE: ISO 4135:2022, 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]

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

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

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

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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3.21
gas pathway
interior surfaces, over which gases or liquids that can be inspired, in a medical device bounded by the ports through which gases or liquids enter and leave the medical device including the *patient* interface or the interior surfaces of *enclosures* that are in contact with gases or liquids that can be inspired

Note 1 to entry: *Patient* contact surfaces such as the outer surfaces of a tracheal tube or the cushion of a *mask* are evaluated according to the ISO 10993 series.

EXAMPLE 1 The *ventilator breathing system*, inlet filter, gas mixer, blower and internal piping.

EXAMPLE 2 Enclosed chamber of an incubator including the mattress or the inner surface of an oxygen hood.

EXAMPLE 3 The inner surfaces of breathing tubes, tracheal tubes or *masks* and mouthpieces.

[SOURCE: ISO 18562-1:2017, 3.5]

3.22
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO 14971:2019, 3.3]

3.23
hazard
potential source of *harm*

[SOURCE: ISO 14971:2019, 3.4]

3.24
hazardous situation
circumstance in which people, property or the environment is/are exposed to one or more *hazards*

[SOURCE: ISO 14971:2019, 3.5, modified — deleted note 1.]

3.25
inflation phase
interval from the start of the rise in *airway pressure* resulting from the initiation of an inflation to the start of the expiratory flow resulting from its termination

[SOURCE: ISO 19223:2019, 3.4.10, modified — deleted notes.]

3.26
information supplied by the manufacturer
information related to the identification and use of a *medical device* or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the *medical device* or *accessory*

Note 1 to entry: For the purposes of this document, *e-documentation* is included in *information supplied by the manufacturer.*

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer.* However, some *authorities having jurisdiction* can consider such supplemental information as *information supplied by the manufacturer.*

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the *medical device* and its *manufacturer*, and provide essential information about its *safety*, performance, and appropriate use to the *user* or other relevant persons.

[SOURCE: ISO 20417:2021, 3.10, modified — deleted note 4.]

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3.27
inspiratory time
t_I
duration of an *inflation phase* or inspiratory phase

[SOURCE: ISO 19223:2019, 3.4.8, modified — deleted notes.]

3.28
instructions for use
IFU
portion of the *accompanying information* that is essential for the safe and effective use of a *medical device* or *accessory* directed to the *user* of the *medical device*

Note 1 to entry: For the purposes of this document, a *user* can be either a *lay user* or professional *user* with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the professional *processing* between uses of a *medical device* or *accessory* can be included in the *instructions for use*.

Note 3 to entry: The *instructions for use,* or portions thereof, can be located on the display of a *medical device* or *accessory*.

Note 4 to entry: *Medical devices* or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction.*

[SOURCE: ISO 20417:2021, 3.11, modified —deleted note 5.]

3.29
intake
opening through which gas or other material is drawn by a sub-ambient pressure

[SOURCE: ISO 4135:2022, 3.1.4.27]

3.30
intended use
use for which a product, *process* or service is intended according to the specifications, instructions and information provided by the *manufacturer*

[SOURCE: ISO 14971:2019, 3.6]

3.31
label
<*medical device*, *accessory*> written, printed, or graphic information appearing on the item itself, on the packaging of each item or on the packaging of multiple items

Note 1 to entry: For the purposes of this document, the term *labelled* is used to designate the corresponding act.

Note 2 to entry: *Label* includes the *marking* on the *medical device* or *accessory*.

Note 3 to entry: For the purposes of this document, information indicated on a graphical user interface (GUI) is considered as appearing on the item.

[SOURCE: ISO 20417:2021, 3.12, modified —deleted note 4.]

3.32
lung
each of the pair of compliant organs within the ribcage (thorax), bounded by the terminal bronchiole and the visceral pleura, which during *ventilation* provide gas/blood interfaces that enable oxygen from the gas to pass into the blood and carbon dioxide to be removed

Note 1 to entry: In specific reference to the pair of these organs, in this document the inflection '*lungs*' is used.

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Note 2 to entry: In accordance with what has become common practice in the absence of a more suitable term, this term in its singular form is also used in this document to reference the connected, respiratory-gas containing cavities within the respiratory system, consisting of the airway and the *lungs*. Examples of this common practice in applications that are outside the scope of this document are: *lung* function; *lung* disease; *lung* compliance; *lung* mechanics; test lung. Other established examples are *lung* ventilator; *lung* elastance; *lung* protective strategy.

Note 3 to entry: Although there are no such references in this document, if in the application of this document a need arises to refer to just 'one of the *lungs*' then, in order to avoid any possible ambiguity, it should always be identified as such, or as the 'left *lung*' or 'right *lung*'.

[SOURCE: ISO 19223:2019, 3.1.16, modified —deleted note 4.]

3.33
manufacturer
natural or legal person with responsibility for the design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name, whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: The natural or legal person has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The *manufacturer's* responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture" may include specification development, production, fabrication, assembly, *processing*, packaging, repackaging, labelling, relabelling, *sterilization*, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual *patient*, in accordance with the *instructions for use*, is not the *manufacturer*, provided the assembly or adaptation does not change the *intended use* of the medical device.

Note 5 to entry: Any person who changes the *intended use* of, or modifies, a medical device without acting on behalf of the original *manufacturer* and who makes it available for use under his own name, should be considered the *manufacturer* of the modified medical device.

Note 6 to entry: An authorised representative, distributor or importer who only adds its own address and contact details to the *medical device* or the packaging, without covering or changing the existing labelling, is not considered a *manufacturer*.

Note 7 to entry: To the extent that an *accessory* is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that *accessory* is considered to be a *manufacturer*.

[SOURCE: ISO 14971:2019, 3.9]

3.34
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *medical device* or *accessory*

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from 'direct marking' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct marking' is a type of *marking*.

[SOURCE: ISO 20417:2021, 3.16, modified —deleted note 3.]

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3.35
mask
device which provides a non-invasive interface between the *patient's* airway and a *patient-connection port* or other connection to a source of respirable gas

[SOURCE: ISO 4135:2022, 3.8.6.4]

3.36
maximum limited pressure
$P_{\text{LIM max}}$
highest *airway pressure* that can occur during *normal use* or under *single fault condition*

Note 1 to entry: In addition to its direct reference as a requirement, this term is only used, in context or by qualification, to designate this concept as a set quantity.

Note 2 to entry: As with all unqualified *airway pressures*, this limited pressure is that at the *patient-connection port* and relative to ambient pressure.

Note 3 to entry: As this is the highest-level precaution against excessive pressures being applied to the *patient's* airway this pressure limit is typically preset by the *manufacturer* but can be made adjustable by the *responsible organization* to a lower pressure level.

[SOURCE: ISO 19223:2019, 3.13.3]

3.37
multiple patient multiple use
<*medical device*, *accessory*> intended by the *manufacturer* to be reused on multiple *patients* for multiple uses

Note 1 to entry: A *multiple patient multiple use medical device* or *accessory* typically requires *processing* between *patients*.

Note 2 to entry: A *multiple patient multiple use medical device* or *accessory* may require *processing* between uses on a single *patient*.

[SOURCE: ISO 20417:2021, 3.18]

3.38
nominal
<value> value quoted for reference purposes that is subject to agreed tolerances

[SOURCE: IEC 60601-1:2005, 3.69, modified —deleted example.]

3.39
normal condition
condition in which all means provided for protection against *hazards* are intact

[SOURCE: IEC 60601-1:2005, 3.70]

3.40
normal use
operation, including routine inspection and adjustments by any *user*, and stand-by, according to the *instructions for use* or in accordance with generally accepted practice for those *medical devices* provided without *instructions for use*

Note 1 to entry: *Normal use* should not be confused with *intended use*. while both include the concept of use as intended by the *manufacturer, intended use* focuses on the medical purpose while *normal use* incorporates not only the medical purpose, but maintenance, transport, etc. as well.

Note 2 to entry: *Use error* can occur in *normal use*.

Note 3 to entry: *Medical devices* that can be used safely without *instructions for use* are exempted from having *instructions for use* by some authorities with jurisdiction.

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[SOURCE: IEC 62366-1:2015, 3.9, modified —deleted note 4.]

3.41
objective evidence
data supporting the existence or verity of something

Note 1 to entry: *Objective evidence* can be obtained through observation, measurement, test or by other means.

[SOURCE: ISO 14971:2019, 3.11]

3.42
patient
living being (person or animal) undergoing a medical, surgical or dental *procedure*

Note 1 to entry: A *patient* can be a *user*.

[SOURCE: IEC 60601-1:2005, 3.76, modified — in the note, replaced 'OPERATOR' with '*user*'.]

3.43
patient-connection port
port of a breathing system intended for connection to an airway device

Note 1 to entry: The *patient-connection port* is typically a connector suitable for connection to an airway device such as a tracheal tube, tracheostomy tube, a face *mask*, or a supralaryngeal airway.

Note 2 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the form of a specific standardized connector(s), for example, a connector(s) conforming to ISO 5356-1.

[SOURCE: ISO 4135:2022, 3.1.4.41, modified — deleted notes 1, 4 and 5.]

3.44
patient valve
valve in the breathing system that directs gas to the *patient-connection port* during the inspiratory phase and into the atmosphere during the *expiratory phase*

[SOURCE: ISO 4135:2022, 3.6.3.6]

3.45
PEEP
<actual and measured value> respiratory pressure at the end of an *expiratory phase*

Note 1 to entry: In addition to its direct reference, this term or its acronym, is used in this document to designate this concept as a measured quantity. Without qualification, the quantity is always that at the *patient-connection port* and relative to ambient pressure. When used as part of a post-coordinated term it may be attributed to other measurement sites or reference pressure levels. The term, in its acronym form only, is also an admitted term for the designation of the set value of the baseline airway-pressure level (which encompasses the setting for the end-expiratory pressure), thereby acting as a synonym for *BAP*.

Note 2 to entry: As a *measured* quantity, the qualification 'positive' is not strictly necessary but its use is retained because it places emphasis on one of the main purposes for which *PEEP* is used, that is, retaining at least a minimum 'positive' pressure in the alveoli in order to guard against their collapse.

[SOURCE: ISO 19223:2019, 3.10.4, modified — deleted notes 3, 4, 5 and 6.]

3.46
primary operating function
function that involves *user* interaction that is related to the *safety* of the medical device

Note 1 to entry: Often a *primary operating function* is interacted with by a series of tasks that can be broken down into a series of *user* interactions.

Note 2 to entry: The concept of *safety* includes loss or degradation of performance resulting in an unacceptable *risk* to the *patient*, including *use error* that prevents the *user* from effectively using the medical device to achieve its intended medical purpose. In IEC 60601-1, this is referred to as 'essential performance'.

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[SOURCE: IEC 62366-1:2015, 3.11]

3.47
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the "intended result" of a *process* is called output, product or service depends on the context of the reference.

Note 2 to entry: Inputs to a *process* are generally the outputs of other *processes* and outputs of a *process* are generally the inputs to other *processes*.

Note 3 to entry: Two or more interrelated and interacting *processes* in series can also be referred to as a *process*.

[SOURCE: ISO 14971:2019, 3.14]

3.48
processing
<preparation of *medical device*, *accessory*> activity to prepare a new or used *medical device* or *accessory* for its *intended use*

[SOURCE: ISO 20417:2021, 3.20]

3.49
professional healthcare facility
facility that is continually staffed by suitably trained healthcare professional *users*

Note 1 to entry: A healthcare professional *user* is appropriately trained, knowledgeable, and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services to families or communities.

[SOURCE: ISO 80601-2-12:2020, 201.3.209, modified —deleted example, added note and replaced 'operators' with '*users*'.]

3.50
port
opening(s) for the passage of a fluid through a specified interface

Note 1 to entry: A *port* can be in the form of a specific connector or designed to not allow connection with any connector.

[SOURCE: ISO 4135: 2022, 3.1.4.10]

3.51
protection device
part or function of a *medical device* or *accessory* that, without intervention by the *user*, protects the *patient*, other people or the environment from hazardous output due to incorrect delivery of energy or substances

[SOURCE: ISO 4135: 2022, 3.1.4.48]

3.52
rated
<value> term referring to a value assigned by the *manufacturer* for a specified operation condition

[SOURCE: IEC 60601-1:2005, 3.97]

3.53
record
document stating results achieved or providing evidence of activities performed

Note 1 to entry: *Records* can be used, for example, to formalize traceability and to provide evidence of verification, preventive action and corrective action.

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Note 2 to entry: Generally *records* need not be under revision control.

[SOURCE: ISO 14971:2019, 3.16]

3.54
residual risk
risk remaining after *risk control* measures have been implemented

[SOURCE: ISO 14971:2019, 3.17]

3.55
resuscitator
transit-operable equipment intended for immediate use to provide *lung ventilation* in the resuscitation of individuals who have sudden breathing difficulty

Note 1 to entry: National regulations may restrict this term to manually operated devices.

[SOURCE: ISO 4135:2022, 3.4.1.8]

3.56
resuscitator deadspace
volume of previously exhaled gas within the *resuscitator* that is delivered to the *patient* in the succeeding inspiratory phase

[SOURCE: ISO 4135:2022, 3.4.1.8.3]

3.57
risk
combination of the probability of occurrence of *harm* and the severity of that *harm*

[SOURCE: ISO 14971:2019, 3.18]

3.58
risk analysis
systematic use of available information to identify *hazards* and to estimate the *risk*

[SOURCE: ISO 14971:2019, 3.19]

3.59
risk management
systematic application of management policies, *procedures* and practices to the tasks of analysing, evaluating, controlling and monitoring *risk*

[SOURCE: ISO 14971:2019, 3.24]

3.60
risk management file
set of records and other documents that are produced by *risk management*

[SOURCE: ISO 14971:2019, 3.25]

3.61
safety
freedom from *unacceptable risk*

[SOURCE: ISO 14971:2019, 3.26]

3.62
safety sign
sign giving a general *safety* message, obtained by a combination of a colour and geometric shape and which, by the addition of a graphical *symbol*, gives a particular *safety* message

[SOURCE: ISO 20417:2021, 3.21]

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3.63
set rate
number of assured *inflations* that are set to occur in a specified period of time, expressed as breaths per minute

[SOURCE: ISO 19223:2019, 3.5.1.1, modified — deleted notes and examples.]

3.64
shelf-life
period of time until the expiry date during which a *medical device* or *accessory* in its original packaging maintains its *stability* under the conditions specified in the *information supplied by the manufacturer*

[SOURCE: ISO 20417:2021, 3.24]

3.65
single fault condition
condition of device in which a single means for reducing a *risk* is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005, 3.116, modified — deleted the note and replaced 'ME EQUIPMENT' with 'device'.]

3.66
single patient multiple use
<*medical device*, *accessory*> intended by the *manufacturer* to be reused on an individual *patient* for multiple uses

Note 1 to entry: A *single patient multiple use medical device* or *accessory* may require *processing* between uses.

[SOURCE: ISO 20417:2021, 3.25, modified — deleted note 2.]

3.67
single use
<*medical device*, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use medical device* or *accessory* is not intended by its *manufacturer* to be further processed and used again.

[SOURCE: ISO 20417:2021, 3.26]

3.68
stand-alone gas mixer
non-integrated device that can deliver an adjustable or fixed concentration of medical gas derived from two separate medical gas supplies

[SOURCE: ISO 11195:2018, 3.8]

3.69
standard temperature and pressure, dry
STPD
pressure of 101,325 kPa at an operating temperature of 20 °C, dry

[SOURCE: ISO 4135:2022, 3.1.1.8]

3.70
sterilization
process used to render product free from viable microorganisms

Note 1 to entry: In a *sterilization process*, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

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[SOURCE: ISO 17664-1:2021, 3.17]

3.71
technical description
portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing*, transport or storage for the *expected lifetime* of a *medical device*

Note 1 to entry: The *technical description* may be included in the *instructions for use*.

[SOURCE: ISO 20417:2021, 3.30, modified —deleted note 2.]

3.72
tidal volume
volume of gas that enters and leaves the *lung* during a breath

Note 1 to entry: In addition to its direct reference, this term or its symbol, V_T, displayed in various character styles, may be used, in context or by qualification, to designate this concept as a *set* quantity. As a measured quantity, it is only used to designate this concept when expressed as a compensated value.

Note 2 to entry: In practice, the volumes that enter and leave the *lung* are typically measured as *delivered* (or inspiratory) *volumes* and expired *tidal volumes* because, even without leakage, these two quantities will only be nominally equal due to physical and/or compositional changes of the gas and normal physiological variation in end-expiratory *lung* volume. Leakages between the point at which the flow towards the *patient* is measured and the *lung*, such as occur at the connection to the *patient's* airway, will increase these discrepancies.

Note 3 to entry: Without leakage compensation the measured expired *tidal volume* will be a better representation of the actual *tidal volume* because leakage is less during expiration than during delivery due to the lower mean *airway pressure*. Where leakage compensation is in operation, the actual *delivered* and inspiratory volumes are typically greater than the set *tidal volume*, but the compensated *tidal volume* provides a better representation of the actual *tidal volume*.

Note 4 to entry: With *ventilation* equipment where no inspiratory or expired volume measurements are available the actual *tidal volume* might deviate from the *set* value as a result of the factors referred to in Note 2 to this entry.

[SOURCE: ISO 19223:2019, 3.8.1]

3.73
transit-operable
<adj> term referring to transportable equipment whose *intended use* includes operation while it is being moved

[SOURCE: IEC 60601-1-11:2015, 3.4, modified —deleted note and example.]

3.74
type test
test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this document

[SOURCE: IEC 60601-1:2005, 3.135, modified —replaced 'standard' with 'document'.]

3.75
usability
characteristic of the *user* interface that facilitates use and thereby establishes effectiveness, efficiency and *user* satisfaction in the intended use environment

Note 1 to entry: All aspects of *usability*, including effectiveness, efficiency and *user* satisfaction, can either increase or decrease *safety*.

[SOURCE: IEC 62366-1:2015, 3.16]

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