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

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;

— 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.

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.

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.]

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.]

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

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.]

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.

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.]

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
$P_{LIM\ max}$
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.

[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'.

[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.

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]

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.

[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]

3.76
usability engineering
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and tasks to achieve adequate *usability*

Note 1 to entry: Achieving adequate *usability* can result in acceptable *risk* related to use.

[SOURCE: IEC 62366-1:2015, 3.17]

3.77
usability engineering file
set of records and other documents that are produced by the *usability engineering process*

[SOURCE: IEC 62366-1:2015, 3.18]

3.78
user
person interacting with (i.e. operating or handling) the medical device

Note 1 to entry: There can be more than one *user* of a medical device.

Note 2 to entry: Common *users* include clinicians, *patients*, cleaners, maintenance and service personnel.

[SOURCE: IEC 62366-1:2015, 3.24]

3.79
user-powered resuscitator
resuscitator with which *ventilation* of the *lungs* is produced by the *user* squeezing its *compressible unit*

[SOURCE: ISO 4135:2022, 3.4.1.8.2, modified — replaced 'compressing' by 'squeezing'.]

3.80
ventilator-dependent
<*patient*> dependent upon *artificial ventilation* in order to prevent serious deterioration of health or death

Note 1 to entry: A *ventilator-dependent patient* cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood. For the purposes of this document, dependent means the loss of therapy can require immediate medical intervention.

EXAMPLE *Patients* with Duchenne muscular dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

[SOURCE: ISO 80601-2-12:2020, 201.3.211]

4 General requirements for testing of a *resuscitator*

4.1 *Risk management process*

a) A *risk management process* complying with ISO 14971 shall be performed. For compliance with this document, all elements of the ISO 14971:2019 *risk management process* shall be applied except:

   1) the planning for and execution of production and post-production monitoring [ISO 14971:2019, 4.1, fourth dash of 4.4, item g) and Clause 10]; and

2) periodic reviews of the suitability of the *risk management process* (ISO 14971:2019, third paragraph of 4.2).

b) The combination of simultaneous independent faults that could result in a *hazardous situation* shall be documented in the *risk management file*.

1) When testing is necessary to demonstrate that the ventilatory requirements of Clause 8 are maintained under such simultaneous independent faults, the related testing may be limited to worst case situations.

NOTE The test results can necessitate a revision of the *risk analysis*.

c) Where this document specifies requirements addressing particular *hazards* or *hazardous situations*, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the *residual risks* have been reduced to acceptable levels unless there is *objective evidence* to the contrary.

d) Where this document specifies requirements addressing particular *hazards* or *hazardous situations* but does not provide specific acceptance criteria, the *manufacturer* shall provide the acceptance criteria defined in the *risk management* plan. These acceptance criteria shall ensure that the *residual risk* is acceptable according to the criteria for *risk* acceptability recorded in the *risk management* plan.

e) Check compliance by:

1) inspection of the *manufacturer's* policy for determining criteria for *risk* acceptability;

2) inspection of the *risk management* plan for the *resuscitator* under consideration;

3) confirming that the *records* in the *risk management file* demonstrate that, after applying the specific requirements of this standard, the acceptance criteria determined by the *manufacturer* are satisfied;

i) Only the relevant parts of the *risk management file* need to be reviewed (e.g. the *manufacturer's* calculations or test results, or the determination of *risk* acceptability).

4) confirming that the *records* in the *risk management file* demonstrate that the *residual risk* is acceptable using the criteria for *risk* acceptability recorded in the *risk management* plan (i.e. no unacceptable *risk* remains); and.

i) Only the relevant parts of the *risk management file* need to be reviewed (e.g. the *manufacturer's* calculations or test results, or the determination of risk acceptability).

5) confirming that the *manufacturer* has prepared a *risk management file* containing the *risk management records* and other documentation required by this document for the *resuscitator* under consideration.

4.2 *Type tests*

The tests described in this document are *type tests*.

4.3 Test conditions

a) Unless otherwise specified in this document

1) all tests are performed within the operating range of environmental conditions of *normal use*;

2) all test performance requirements in this document shall be satisfied when the *resuscitator* is used by one person in its *normal use* position;

3) the *user* shall only use one hand for squeezing the *compressible unit.*

b) Unless otherwise specified in this document, the *resuscitator* and its *accessories* are to be tested under the least favourable working conditions of *normal use*.

1) The least favourable working conditions shall be documented for every test where they apply.

c) A *resuscitator* and its *accessories* having operating values that can be adjusted or controlled shall be adjusted as part of the tests to values that are the least favourable for the relevant test, but in accordance with *normal use*.

d) If the test results are influenced by the inlet pressure and flowrate or chemical composition of the gases supplied to the *resuscitator*, the test is performed at the worst case within the *rated* limits for these characteristics.

e) For testing, the *resuscitator* and its *accessories*

1) shall be connected to gas supplies of *normal use,*

2) except that industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

f) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

4.4 Gas flowrate, volume and leakage specifications

All requirements for gas flowrate, volume and leakage in this document,

a) are expressed at *ATP*,

b) except for those related to gas flowrate from a source of medical gas, which are expressed at *STPD*.

Correct all test measurements to *ATP* or *STPD*, as appropriate.

4.5 Testing errors

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) For the purposes of this document, acceptance criteria for testing declared tolerances shall use:

1) procedure 1 (calculation of uncertainty of measurement) from IEC Guide 115:2021, 4.4.2; or

2) procedure 2 (accuracy method) from IEC Guide 115:2021, 4.4.3.

b) Test equipment and methods shall be selected and controlled to ensure that the uncertainty (with coverage factor k = 2, for confidence of ~ 95 %) is no more than 30 % of the disclosed tolerance for the parameter being tested.

EXAMPLE If the *manufacturer* wishes to claim a tolerance for delivered volume of ±(10 ml +10 % of set volume) then the uncertainty of the measurement cannot exceed ±(3 ml +3 % of set volume).

c) The *manufacturer* shall disclose the measurement uncertainty for each disclosed tolerance in the *technical description*.

Check conformance by inspection of the *IFU* and the *technical description*.

4.6 Environmental conditions in the end user environment

4.6.1 Transport and storage conditions

a) Unless otherwise indicated in the *IFU*, the permissible transport and storage conditions in the end user environment shall be the following:

EXAMPLE In the ambulance, *patient's* car, next to a ventilator as a backup.

1) temperature range of -40 °C to +5 °C without relative humidity control;

2) temperature range of +5 °C to +35 °C at a relative humidity up to 90 %, non-condensing; and

3) temperature range of >+35 °C to +70 °C at a water vapour pressure up to 50 hPa.

b) If the *IFU* state a more restricted range of transport and storage conditions in the end user environment, these environmental conditions shall be:

1) justified in the *risk management file*; and

2) *marked* on the *resuscitator* and *accessory*, and

i) unless such *marking* is not practicable, in which case the more restricted range need only be disclosed in the *IFU*.

3) *labelled* on the point of use packaging.

c) The temperature range may be *marked* with:

1) *Symbol* ISO 7000-0534 or *symbol* 5.3.5 of ISO 15223-1:2021 (see Table C.1, *symbol* 1);

2) *Symbol* ISO 7000-0533 or *symbol* 5.3.6 of ISO 15223-1:2021 (see Table C.1, *symbol* 2); or

3) *Symbol* ISO 7000-0632 or *symbol* 5.3.7 of ISO 15223-1:2021 (see Table C.1, *symbol* 3).

d) The humidity range may be *marked* with *symbol* ISO 7000-2620 or *symbol* 5.3.8 of ISO 15223-1:2021 (see Table C.1, *symbol* 6).

e) The atmospheric pressure range may be *marked* with *symbol* ISO 7000-2621 or *symbol* 5.3.9 of ISO 15223-1:2021 (see Table C.1, *symbol* 7).

f) Check conformance by the following test and when a more restricted range is stated in the *IFU*, inspection of the *risk management file*.

1) Prepare the *resuscitator* and its *accessories* for transport or storage in accordance with the *IFU*.

2) Expose the *resuscitator* and its *accessories* at its lowest specified environmental transport and storage conditions (temperature $^{0}_{-4}$ °C) for at least 48 h.

3) Then expose the *resuscitator* and its *accessories* to 34 °C ± 4 °C and 93 % ± 3 % relative humidity until the test chamber reaches equilibrium. The transition from low to high conditions should be made slowly enough to provide a non-condensing environment. Hold for at least 48 h.

4) Then expose the *resuscitator* and its *accessories* at its highest specified environmental transport and storage conditions, but not requiring a water vapour partial pressure greater than 50 hPa, (temperature $^{+4}_{0}$ °C) for at least 16 h.

NOTE The intent of specifying a minimum duration of the exposure to both the low and high temperature conditions is to ensure that the entire *resuscitator* and its *accessories* reaches the stated conditions.

5) At the end of this conditioning period, allow the *resuscitator* and its *accessories* to return and stabilize at room ambient.

6) Confirm that the *resuscitator* and its *accessories* conform to Clause 8.

4.6.2 Operating conditions

a) Unless otherwise indicated in the *IFU*, the permissible environmental operating conditions of the *resuscitator* and its *accessories* shall be the following:

1) temperature range of –18 °C to +50 °C;

2) a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and

3) an atmospheric pressure range of 620 hPa to 1 060 hPa.

b) If readings or performance vary, a table of correcting values shall be disclosed in the *IFU.*

1) This correction table shall indicate the extent of the variation between the actual values and the values indicated or set.

c) If the *IFU* state a more restricted continuous environmental operating conditions, these conditions shall be:

1) justified in the *risk management file*; and

2) *marked* on the *resuscitator* and *accessory*,

i) unless such *marking* is not practicable, in which case the more restricted conditions need only be disclosed in the *IFU.*

d) The temperature conditions may be *marked* with one the of following:

1) *symbol* ISO 7000-0534 or *symbol* 5.3.5 of ISO 15223-1:2021 (see Table C.1, *symbol* 1);

2) *symbol* ISO 7000-0533 or *symbol* 5.3.6 of ISO 15223-1:2021 (see Table C.1, *symbol* 2); or

3) *symbol* ISO 7000-0632 or *symbol* 5.3.7 of ISO 15223-1:2021 (see Table C.1, *symbol* 3).

e) The humidity conditions may be *marked* with:

1) *symbol* ISO 7000-2620; or

2) *symbol* 5.3.8 of ISO 15223-1:2021 (see Table C.1, *symbol* 6).

f) The atmospheric pressure conditions may be *marked* with:

1) *symbol* ISO 7000-2621; or

2) *symbol* 5.3.9 of ISO 15223-1:2021 (see Table C.1, *symbol* 7).

g) Check conformance by the following test. If a more restricted range of environmental conditions is stated in the *IFU*, inspect of the *risk management file* for the rationale.

1) Set up the *resuscitator* and its *accessories* for operation in accordance with the *IFU.*

2) Expose the *resuscitator* and its *accessories* to 20 °C ± 4 °C for at least 6 h.

3) Cool the *resuscitator* and its *accessories* to its lowest specified continuous environmental operating conditions (temperature $^{0}_{-4}$ °C and relative humidity less than or equal to 15 %) and hold for at least 6 h.

4) Evaluate the *resuscitator* and its *accessories* to its specifications and confirm that they conform to 8.1.1, 8.1.2, 8.2, 8.3, 8.4, 8.6.1, and 8.6.4 under the conditions of 3).

NOTE There is guidance or rationale for this list element contained in Clause A.2.

5) Warm the *resuscitator* and its *accessories* to its highest specified continuous environmental operating conditions, but not requiring a water vapour partial pressure greater than 50 hPa, (temperature $^{+4}_{0}$ °C) and hold for at least 6 h.

6) Evaluate the *resuscitator* and its *accessories* to its specifications and confirm that they conform to Clause 8 under the conditions of 5).

4.6.3 *Shelf-life*

a) The *IFU* shall indicate the *shelf-life* of the *resuscitator* and its *accessories*.

1) The *shelf-life* should not be less than 3 years.

b) The *resuscitator* and its *accessories* shall conform with the specifications as indicated in the *instructions for use* and all the requirements of this document for their entire *shelf-life*.

1) Simulated accelerated storage or ageing may be performed based for example on a room temperature of 23 °C.

NOTE Additional information is found in ISO 2578, ASTM 1980[21], and ASTM D3045[22] for accelerated testing.

EXAMPLE Using the Arrhenius formula for materials with aging factor 2 (every 10 °C increase in storage temperature doubles the ageing speed), an accelerated aging temperature of 53 °C (30 °C increase) and a desired real time of 3 years (e.g. desired *shelf-life*), the accelerated aging test time is calculated to be 19,6 weeks (2 cubed, an 8 times reduction in test time)..

2) The test temperature should be chosen so that the maximum temperature of the *resuscitator's* materials stability is not exceeded.

c) Check conformance by the following.

1) Store the *resuscitator* and *accessories* for their maximum specified *shelf-life*. Accelerated storage conditions may be used.

2) Following the period of storage, confirm that the *resuscitator* and its *accessories* conform to Clause 8.

4.6.4 *Expected lifetime*

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

a) The *expected lifetime* in operation of a *single use resuscitator* shall not be less than 24 h of operation for:

NOTE 2 *Patients* being treated with a *resuscitator* can be *ventilator-dependent* and require intermittent use over a period of treatment.

1) a *resuscitator*; and

2) its *accessories*.

b) The *expected lifetime* in operation of a reusable *resuscitator* shall be not less than 1 h for each of the number of *processing* cycles specified in the *IFU* plus 24 h.

EXAMPLE 1 For a *resuscitator* indicated for 20 *processing* cycles, the minimum *expected lifetime* is 44 h.

c) The *IFU* shall indicate the *expected lifetime* in operation for:

1) a *resuscitator*; and

2) its *accessories*.

d) The *IFU* shall indicate, if reuse is limited, the limitation on reuse for:

EXAMPLE 2 The maximum number of allowable reuses or *processing* cycles.

1) a *resuscitator*; and

2) its *accessories*.

e) Check conformance by the following.

1) Set up the *resuscitator* in accordance with the *IFU* and the row from Table 1 that is selected by the largest intended *patient* ideal body mass.

2) Operate the *resuscitator* for the cumulative period of operation of its *expected lifetime*.

i) Mechanical squeezing of the compressible unit may be used.

3) Confirm that the *resuscitator* and its *accessories* conform to 7.4, 8.1.1, 8.2, 8.3, 8.6.1 and 8.6.4.

Table 1 — Test conditions for ventilatory performance

Test number	*Patient* ideal body mass *B* [a] kg	Test lung		Ventilatory parameters		
		Compliance ml/hPa ±10 %	Resistance [27][30][31] hPa(l/s)$^{-1}$ ±10 %	*Inspiratory time* s ±20 %	*Set rate* breaths/min ±10 %	Minimum guaranteed *tidal volume* (V_T) ml
1	$B \leq 2{,}5$ [b]	0,5	200[c]	0,5	60	10
2	$B \leq 2{,}5$	1,0	200[c]	0,5	60	20
3	$2{,}5 \leq B \leq 5$ [b]	0,5	200[c]	0,5	60	10
4	$2{,}5 \leq B \leq 5$ [b]	1,0	50[c]	0,5	60	30
5	$2{,}5 \leq B \leq 5$	3	20[d]	0,7	40	75
6	$5 \leq B \leq 10$	10	20[d]	0,8	25	150
7	$10 < B \leq 40$	20	20[d]	1,0	20	15 • *B* [a]
8	$B \geq 40$	20	20[d]	1,0	20	600

NOTE There is guidance or rationale for this table contained in Clause A.2.

[a] *B* is the ideal body mass, in kg, as specified in the *IFU*.

[b] During newborn first breath resuscitation.

[c] At a flowrate of 6,25 l/min.

[d] At a flowrate of 45 l/min.

5 *Information supplied by the manufacturer*

5.1 General

a) The *information supplied by the manufacturer* of a *resuscitator* and its *accessories* shall conform with ISO 20417:2021.

b) The form of the *accompanying information* should be such that they are readily available to the intended *user* for the *expected lifetime* of the *resuscitator*.

EXAMPLE 1 Enclosed with the *resuscitator*.

EXAMPLE 2 Attached to the *resuscitator* container.

EXAMPLE 3 Provided as *e-documentation*.

Check conformance by inspection of the *accompanying information*.

5.2 Additional *marking* requirements

a) A *resuscitator* shall be *marked* with the intended *patient* ideal body mass range in [kg].

   1) The *symbol* of IEC 60417-5390 (see Table C.1, *symbol* 7) should be used in combination with the ideal body mass range.

b) A *resuscitator* intended to be used in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014, shall be *marked* with:

   1) *symbol* 7.3.1-1 (Table C.1, *symbol* 7) or *symbol* 7.3.1-2 (Table C.1, *symbol* 8) of IEC 62570 for an 'MR Safe' *resuscitator*, or

   2) *symbol* 7.3.2 of IEC 62570 (Table C.1, *symbol* 9) for an 'MR Conditional' *resuscitator* conforming with IEC 62570:2014.

c) A *resuscitator* not intended for use in the magnetic resonance (MR) environment, in accordance with IEC 62570:2014, shall be *marked* with *symbol* 7.3.3 (Table C.1, *symbol* 10) for an 'MR Unsafe' *resuscitator.*

Check conformance by inspection of the *marking* and by application of the *clearly legible* tests of ISO 20417:2021, Annex B for all the *markings* required by this document.

5.3 Additional *instructions for use* requirements

The *IFU* shall include the following information.

a) The intended *user* needs to be trained in resuscitation using a *user-powered resuscitator.*

b) The specifications for the *resuscitator.*

c) The specifications for the *accessories* recommended in the *IFU.*

d) The intended *patient* ideal body mass range in [kg]; and

e) For a self-inflating bag *resuscitator*, the specification for the *resuscitator* including its *accessories* recommended in the *IFU* of:

   1) the deadspace;

   2) the expiratory resistance and test flowrate; and

   3) the inspiratory resistance and test flowrate.

f) The list of *user*-replaceable parts.

g) Guidance regarding use in hazardous or explosive atmospheres, including a warning to the effect that if the *resuscitator* entrains or permits the *patient* to inhale gas from the atmosphere, its use in contaminated environments can be hazardous unless entrainment is prevented.

   1) If applicable, a description of how to prevent such entrainment or inhalation, (e.g. by using a filter).

h) A warning statement to the effect that "WARNING: Use the correct size resuscitator for the ideal body mass of the patient to avoid the risk of hypoventilation or barotrauma."

i) A warning statement to the effect that “WARNING: To avoid the risk of barotrauma, do not override the mechanical pressure relief unless it clinically justified. Care needs to be taken to immediately restore the pressure relief function after the clinical need is resolved.”

j) A warning statement to the effect that “WARNING: To avoid the risk of barotrauma, do not use abrupt and forceful compressions unless it is clinically justified because they can cause high airway pressures.”

k) A warning statement to the effect that “WARNING: Open flames during resuscitation with oxygen are dangerous and are likely to result in fire or death. Do not allow open flames or sparks within 2 m of the resuscitator or any oxygen-carrying accessories.”

l) A warning statement to the effect that “WARNING: Do not lubricate fittings, connections, tubing, or other accessories of the resuscitator to avoid the risk of fire and burns.”

m) A warning statement to the effect that “WARNING: Avoid using an oxygen concentration more than that which is clinically required by the patient. Delivering excessive oxygen can increase the risk of oxygen toxicity e.g. pulmonary damage, retinopathy of prematurity.”

n) A warning statement to the effect that “WARNING: Patient expired gas is potentially infectious. Breathing filters can reduce but not eliminate contamination risk.”

o) For a flow-inflating bag resuscitator, a warning statement to the effect that “WARNING – Incorrect use of this device can lead to excessive patient rebreathing and death".

Check conformance by inspection of the *IFU*.

6 Connectors and ports

6.1 General

Ports or connectors shall not be capable of being inadvertently blocked with a hand or flat surface if that can lead to a *hazardous situation*.

Check conformance by functional testing.

6.2 *Patient-connection port*

The *patient-connection port* of the *resuscitator* shall be one of the following:

a) a 15 mm socket connector conforming with ISO 5356-1:2015; or

b) a coaxial 15 mm socket / 22 mm cone connector conforming with ISO 5356-1:2015.

Check conformance by application of the tests of ISO 5356-1:2015.

6.3 Expiratory *port* connector for breathing gases

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) If an expiratory *port* connector is provided, it shall be one of the following:

   1) a 30 mm conical cone connector conforming with ISO 5356-1:2015;

   2) a permanent connection; or

   3) a proprietary connector incompatible with any other of the connectors in ISO 5356-1:2015.

b) Means shall be provided to prevent connection with the internal lumen of the connector to any breathing attachment indicated in the *IFU*.

Check conformance by inspection and by application of the tests of ISO 5356-1:2015.

6.4 *Face mask* connectors

a) If provided with the *resuscitator*, face *masks* with connectors of metal or hard plastic materials shall have either:

   1) a 22 mm socket connector conforming with ISO 5356-1:2015; or

   2) a 15 mm cone connector conforming with ISO 5356-1:2015.

b) *Face masks* with connectors of soft or high-friction materials shall

   1) be suitable for connection with the corresponding connectors specified in ISO 5356-1:2015;

   2) have security of engagement.

c) Check conformance by application of the tests of ISO 5356-1:2015 or the following test.

   1) Condition a connector of soft or high-friction materials for 1 h at a temperature of (35 ± 3) °C and relative humidity of at least 80 % and carry out the following test under the same conditions.

   2) Engage the face *mask* connector with the mating connector compliant with ISO 5356-1:2015 in accordance with the face *mask IFU*.

   3) After 1 min of engagement without activation of any disengagement mechanism, apply for 10 s an axial separation force of (5 ± 1) N.

   4) Confirm that the assembled connectors do not become disconnected.

6.5 *Intake* connectors

a) Connectors for the *intake* shall not be compatible with connectors dimensioned in accordance with:

   1) ISO 5356-1:2015; and

   2) the ISO 80369 series.

b) An *intake* connector for the *bag inlet valve* should be designed to minimize the *risk* of unintentional connection of breathing attachments that are specified in the *IFU* which might block the *intake*.

Check conformance by inspection and by functional testing.

6.6 *Bag refill valve* connector

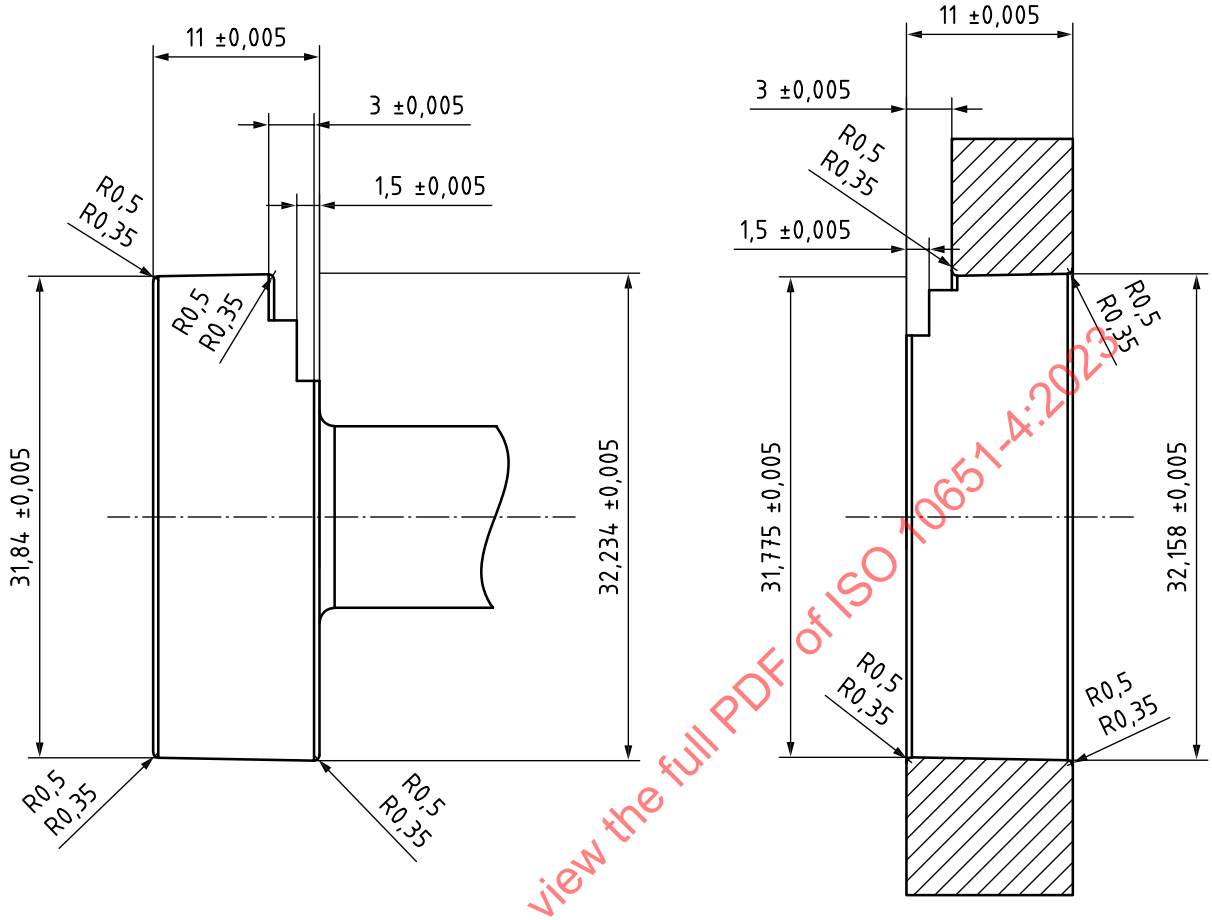
NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

If a conical connector is provided for attachment of a *bag refill valve*, it shall be a 32 mm socket connector with a 1:28 taper.

Check conformance by engaging the plug gauge of Figure 1 to the socket connector while applying an axial force of (50 ± 5) N and simultaneously rotating the connector (20 ± 5)°. Confirm that the leading edge of the connector lies between the minimum and maximum diameter steps of the plug test gauge.

NOTE 2 The ring gauge of Figure 1 can be similarly used to check the cone connector of a *bag refill valve.*

Dimensions in millimetres



NOTE 1 Basic taper is 1:28 on diameter.

NOTE 2 Engagement is 9,5 *nominal*.

Figure 1 — 32 mm plug and ring gauges

6.7 Oxygen inlet connection

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

a) An oxygen input *port* connector intended for connection to oxygen supply tubing that is *user*-detachable without the use of a *tool* shall conform with the R2 socket connector of ISO 80369-2:—.

NOTE 2 Oxygen supplies can include a flowmeter connected to a medical gas pipeline system or oxygen cylinder, oxygen concentrator[16] or *stand-alone gas mixer*.

b) The end of an oxygen tube intended to connect to a flow-controlled oxygen supply, if provided, shall conform with:

1) EN 13544-2:2002+AMD1:2009, 5.1.2; or

2) 9/16-18 UNF-2A-RH socket fitting.

Check conformance by inspection.

6.8 Pressure monitor connector

a) Any pressure monitor connector of the *resuscitator* shall:

   1) not be compatible with the R2 connector of ISO 80369-2:—;

   2) not be compatible with a connector fitting EN 13544-2:2002+AMD1:2009, 5.1.2;

   3) be provided with a means to secure the pressure gauge in position; and

   4) be provided with a means, attached to the *resuscitator,* to secure closure when the pressure gauge is not in use.

b) A pressure gauge connector may conform with the R1 cone connector of ISO 80369-2:—.

Check conformance by inspection.

7 Operational requirements

7.1 Dismantling and reassembly

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) A *resuscitator* intended to be dismantled by the *user*, (e.g. for *processing*, etc.) shall be designed to minimize the *risk* of incorrect reassembly.

b) Parts that are intended to be separated from the *resuscitator* should be *marked* so that they can be re-identified for correct reassembly.

7.2 *Resuscitator* performance after contamination with vomitus

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

a) The *IFU* shall include instructions for the removal of vomitus from the *resuscitator* and its *accessories* during emergency use, including, where necessary:

   1) disassembly;

   2) reassembly; and

      i) Reassembly instructions should include a diagram.

   3) a functional test of operation to be carried out after reassembly.

b) In an emergency situation when the *resuscitator* is soiled with vomitus and cleared in accordance with the *IFU*, the *resuscitator* shall meet the requirements specified in:

   1) 8.2;

   2) 8.3;

   3) 8.6.1; and

   4) 8.6.4.

c) The *patient valve* housing should be constructed so that proper operation of the mechanism can be observed by the *user* (e.g. through a transparent housing).

   NOTE 2 Observation of the functioning mechanism of the *patient valve* can assist the *user* in detecting abnormal operation, particularly following contamination with vomitus.

d) Check conformance with the following test.

1) Prepare simulated vomitus by mixing two parts of baby meal beef with vegetable and one part water.

2) Warm the simulated vomitus to (37 ± 3) °C.

3) Pour 175 ml into the *patient-connection port*.

4) Connect the *resuscitator* to the test lung as specified in Figure 2 as specified for the row in Table 1 selected by the largest intended *patient* ideal body mass.

i) An alternative test apparatus may be used.

5) Cycle the *resuscitator* as specified for the row in Table 1 selected by the largest intended *patient* ideal body mass.

6) Continue to cycle the *resuscitator* for 30 s.

7) Perform emergency cleaning in accordance with the *IFU*.

8) Confirm that the *resuscitator* conforms with 8.2, 8.3, 8.6.1 and 8.6.4.

7.3 Mechanical strength

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) A *resuscitator* and its parts, excluding the face *mask* and attached *accessories*, shall have adequate mechanical strength when subjected to mechanical stress caused by *normal use*, impact, dropping and rough handling.

b) After the following test, the *resuscitator* shall conform with the requirements of:

1) 8.2;

2) 8.3;

3) 8.6.1; and

4) 8.6.4.

c) Check conformance with the following test:

1) Free fall in conformance with IEC 60068-2-31:2008, using Procedure 1 and the following conditions:

i) fall height: 1,0 m; and

ii) number of falls: 2 in each attitude.

2) Confirm that the *resuscitator* conforms with:

i) 8.2;

ii) 8.3;

iii) 8.6.1; and

iv) 8.6.4.

7.4 Resistance to separation from an axial load

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

7.4.1 *Multiple patient multiple use resuscitators*

a) A *multiple patient multiple use resuscitator* shall have adequate mechanical strength to avoid unintentional separation of parts when subjected to mechanical stress caused by *normal use*.

b) All component attachment points from *patient valve* housing to *inlet valve* housing shall withstand:

   1) an axial tensile force of at least 30 N for 10 s without separation; and

   2) a tensile force at an angle of 45° of at least 30 N for 10 s without separation.

c) Check conformance with the following test.

   1) Apply a 30 N axial force at a rate of approximately 10 N/s until 30 N is reached in the direction away from each connection.

   2) Hold the axial force for 10 s and then release the force.

   3) Confirm that the *resuscitator* parts have not separated.

   4) Confirm that the *resuscitator* conforms with 8.6.1. for the largest tidal volume selected by intended *patient* body mass.

   5) Apply a 30 N axial force at an angle of 45° at a at a rate of approximately 10 N/s until 30 N is reached in the direction away from each connection.

   6) Hold the force for 10 s and then release the force.

   7) Confirm that the *resuscitator* parts have not separated.

   8) Confirm that the *resuscitator* conforms with 8.6.1. for the largest tidal volume selected by intended *patient* body mass.

7.4.2 *Single use* and *single patient multiple use resuscitators*

a) A *single use* or *single patient multiple use resuscitator* shall have adequate mechanical strength to avoid unintentional separation of parts when subjected to mechanical stress caused by *normal use*.

b) All component attachment points from *patient valve* housing to *inlet valve* housing shall withstand:

   1) an axial tensile force of at least 100 N for 10 s without separation; and

   2) a tensile force at an angle of 45° of at least 100 N for 10 s without separation.

c) Check conformance with the following test.

   1) Apply a 100 N axial force at a rate of approximately 10 N/s until 100 N is reached in the direction away from each connection.

   2) Hold the axial force for 10 s and then release the force.

   3) Confirm that the *resuscitator* parts have not separated.

   4) Confirm that the *resuscitator* conforms with 8.6.1. for the largest tidal volume selected by intended *patient* body mass.

   5) Apply a 100 N axial force at an angle of 45° at a at a rate of approximately 10 N/s until 100 N is reached in the direction away from each connection.

   6) Hold the force for 10 s and then release the force.

   7) Confirm that the *resuscitator* parts have not separated.

8) Confirm that the *resuscitator* conforms with 8.6.1 for the largest tidal volume selected by intended *patient* body mass.

7.5 Immersion in water

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) A self-inflating bag *resuscitator* and its parts, including the face *mask* and attached *accessories*, shall withstand temporary immersion in water.

b) After the following test, the *resuscitator* shall conform with the requirements of:

1) 8.2;

2) 8.3;

3) 8.6.1; and

4) 8.6.4.

c) Check conformance with the following test:

1) Fully immerse the *resuscitator* with its *accessories* in its ready-for-use condition as indicated in the *IFU* so that the following conditions are satisfied:

2) the highest point of the *resuscitator* is located at least 150 mm below the surface of the water; and

3) the temperature of the water does not differ from that of the *resuscitator* by more than 5 °C.

4) Wait 30 s and then remove the *resuscitator* from the water reservoir.

5) Remove the water by shaking or squeezing for not more than 20 s.

6) Connect the *resuscitator* to the test lung as specified in Figure 2 as specified for the row in Table 1 selected by the largest intended *patient* ideal body mass.

i) An alternative test apparatus may be used.

7) Cycle the *resuscitator* as specified for the row in Table 1 selected by the largest intended *patient* ideal body mass.

8) Continue to cycle the *resuscitator* for 30 s.

9) Confirm that the *resuscitator* conforms with 8.2, 8.3, 8.6.1 and 8.6.4.

7.6 *Bag refill valve*

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

A *bag refill valve* for use with a *resuscitator* shall not have provision for manual operation.

Check conformance by inspection.

7.7 Compatibility with substances

a) All *gas pathways* shall be constructed from materials selected to take into account the chemical and physical properties of any substances (e.g. volatile anaesthetic agents or medications) with which the *resuscitator's gas pathway* can come into contact in *normal use*.

b) The *IFU* shall disclose the medicinal or biological substances considered in the evaluation of material compatibility of the *resuscitator*.

NOTE It is reasonably foreseeable that a *resuscitator* intended for use in the operating room will encounter *patient*-expired volatile anaesthetic agents.

Check conformance by inspection of the *risk management file*.

8 Ventilatory requirements

8.1 *Delivered oxygen concentration*

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

8.1.1 Non-spontaneously breathing *patient*

a) A self-inflating bag *resuscitator* with its *accessories* shall be capable of providing a *delivered oxygen concentration* of at least 85 % (V/V) when connected to an oxygen source supplying not more than 15 l/min under the conditions of the applicable rows of Table 1 (selected by intended *patient* ideal body mass).

   1) The *IFU* shall disclose *resuscitator's* configuration for achieving this oxygen concentration.

b) The *IFU* shall disclose:

   1) the *rated* range of input oxygen source concentration; and

   2) effects of the *rated* range of input oxygen concentration on the *delivered oxygen concentration.*

      NOTE 1 When the input oxygen source is from an oxygen concentrator or a medical gas pipeline supplied by an oxygen concentrator, the input oxygen concentration can vary from 90 % (V/V) to 99,5 % (V/V). When the input oxygen source is from a *stand-alone gas mixer*, the input oxygen concentration can vary from 21 % (V/V) to 99,5 % (V/V).

   3) effects of the oxygen source flowrate on the *delivered oxygen concentration.*

      NOTE 2 A *resuscitator* can draw in ambient air and dilute the delivered oxygen concentration depending on the oxygen source flowrate.

c) A *resuscitator* need not conform to a) to b), if the *resuscitator* is not provided with a connection for oxygen gas and is thus intended for delivering only ambient air.

d) Check conformance by inspection of the *IFU* and with the following test.

   1) Connect the *resuscitator* to the test lung as specified in Figure 2 configured in accordance with the first applicable row of Table 1 (selected by intended *patient* ideal body mass).

      i) Utilize an oxygen source of at least 99 %.

      ii) An alternative test apparatus may be used.

   2) Introduce input oxygen flows of no more than 15 l/min.

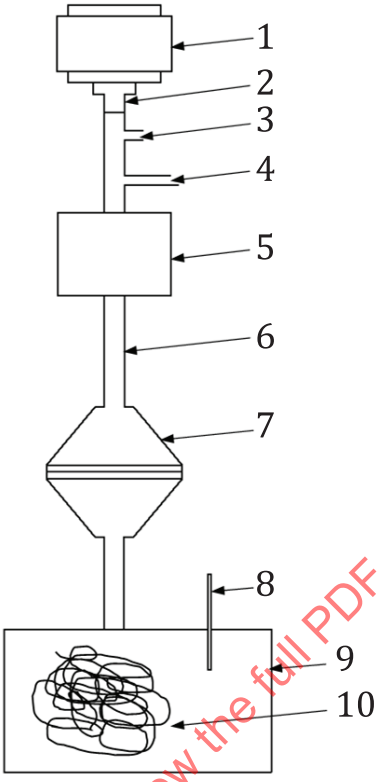
      i) Temporarily ventilating with a larger *tidal volume* to decrease the time to reach a stable value for oxygen concentration may be used.

   3) Ventilate the test lung by squeezing the *compressible unit* using only one hand with maximum allowable hand dimensions as given in Figure 4 or comparable mechanical squeezing in accordance with the applicable row of Table 1 (selected by intended *patient* ideal body mass). Allow the *compressible unit* to recoil on its own.

   4) Continue until a stable value for oxygen concentration is achieved.

   5) Confirm the delivered oxygen concentration.

6) Repeat 2) to 5) with each applicable row of Table 1 (selected by intended *patient* ideal body mass).



Key

1 *resuscitator* under test
2 *patient-connection port* connector
3 oxygen sensor
4 pressure tapping *port* (can be part of flowmeter)
5 flowmeter to determine *tidal volume*
6 non-compliant tubing (Ø 22 mm)
7 resistance
8 thermometer
9 rigid test lung
10 copper wire to maintain isothermal compression

Figure 2 — Example non-spontaneous breathing ventilatory performance test setup

8.1.2 Spontaneously breathing *patient*

A self-inflating bag *resuscitator,* intended for use during spontaneous breathing without any *accessories* other than an oxygen reservoir bag, shall be capable of providing a *delivered oxygen concentration* of at least 85 % of the input oxygen concentration when connected to an oxygen source supplying not more than 15 l/min to a spontaneously breathing *patient* without *squeezing* the *compressible unit* under the conditions of the applicable rows of Table 2 (selected by intended *patient* ideal body mass).

Check conformance with the following test.

a) Connect the *resuscitator* to the test lung as specified in Figure 3 configured in accordance with the first applicable row of Table 2 (selected by intended *patient* ideal body mass) and initiate active test lung to breathing mode.

   1) An alternative test apparatus may be used.

b) Introduce input oxygen flows of no more than 15 l/min.

c) Do not squeeze the *compressible unit*.

d) Continue until a stable value for oxygen concentration is achieved.

e) Confirm the delivered oxygen concentration.

f) Repeat a) to e) with each applicable row of Table 2 (selected by intended *patient* ideal body mass).

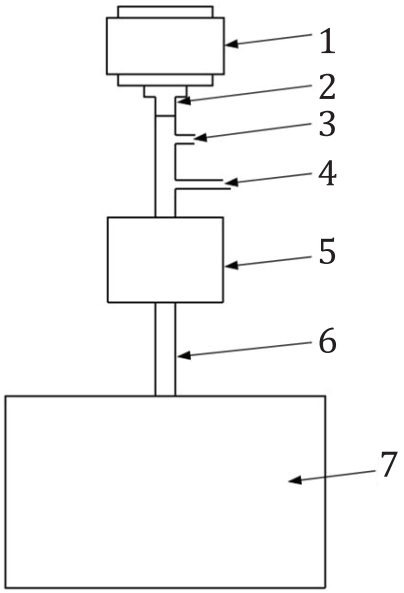
Table 2 — Example test conditions for spontaneous breathing ventilatory performance

Test number	***Patient* ideal body mass, *B*[a]** kg	**Inspiratory *tidal volume*** ml	***Set rate*** breaths/min ±10 %	***Inspiratory time*** S ±20 %
1	B ≤ 2,5 [b]	10	45	0,4
2	2,5 ≤ B ≤ 5	20	32	0,5
3	5 ≤ B ≤ 10	50	30	0,5
4	10 < B ≤ 40	200	20	1,0
5	B ≥ 40	400	15	1,0
6	B ≥ 40	1 000	8	1,5

NOTE There is guidance or rationale for this Table contained in Clause A.2.

[a] *B* = Ideal body mass, in kg, as specified in the *IFU*.

[b] During newborn first breath resuscitation.



Key

1 *resuscitator* under test
2 *patient-connection port* connector
3 oxygen sensor
4 pressure tapping *port* (can be part of flowmeter)
5 flowmeter to determine *tidal volume*
6 non-compliant tubing (Ø 22 mm)
7 active test lung

Figure 3 — Spontaneous breathing ventilatory performance test setup

8.2 Expiratory resistance

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) Unless the *resuscitator* is equipped with a *PEEP accessory*, the expiratory pressure drop measured at the *patient-connection port* with all recommended *accessories* in place, other than any *user-removable breathing system filter*, shall not exceed 5 hPa (5 cmH_2O) at a flowrate of:

   1) 5 l/min for a *resuscitator* for an intended *patient* ideal body mass less than or equal to 5 kg;

   2) 25 l/min for a *resuscitator* for an intended *patient* ideal body mass greater than or equal to 5 kg and less than or equal to 40 kg; or

   3) 50 l/min for a *resuscitator* for an intended *patient* ideal body mass greater than or equal to 40 kg.

b) Check conformance with the following test.

   1) Connect the *patient-connection port* of the *resuscitator* to a flow source of 5 l/min ± 5 %, 25 l/min ± 5 % or 50 l/min ± 5 %, as appropriate.

   2) Orient the *resuscitator* in the position of *normal use*.

   3) For a flow-inflating bag *resuscitator*, close the adjustable *exhaust port* to its most closed position.

   4) Measure the pressure at the *patient-connection port*.

5) Confirm that pressure measured does not exceed ambient pressure by more than 5 hPa (5 cmH_2O).

6) Slowly reduce the flowrate to zero.

7) Confirm that pressure drop does not exceed 5 hPa (5 cmH_2O) while the flowrate drops.

8.3 Inspiratory resistance

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) The inspiratory pressure drop measured at the *patient-connection port* with all recommended *accessories* in place, other than any *user*-removable *breathing system filter*, shall not exceed 5 hPa (5 cmH_2O) at a flowrate of:

1) 5 l/min for a *resuscitator* for an intended *patient* ideal body mass less than or equal to 5 kg;

2) 25 l/min for a *resuscitator* for an intended *patient* ideal body mass greater than or equal to 5 kg and less than or equal to 40 kg; or

3) 50 l/min for a *resuscitator* for an intended *patient* ideal body mass greater than or equal to 40 kg;

b) Check conformance with the following test.

1) Block or cap all gas input ports.

2) Connect the *patient-connection port* of the *resuscitator* to a vacuum source of 5 l/min ± 5 %, 25 l/min ± 5 % or 50 l/min ± 5 %, as appropriate.

3) Orient the *resuscitator* in the position of *normal use*.

4) Measure the pressure at the *patient-connection port*.

5) Confirm that pressure measured does not fall below ambient pressure by more than 5 hPa (5 cmH_2O).

8.4 Gas source excessive flow

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

Unless the *resuscitator* is equipped with a *PEEP accessory*, *PEEP* greater than 6 hPa (6 cmH_2O) shall not be created with an input flowrate of 30 l/min at the oxygen input *port* connector for a resuscitator provided with a connection for oxygen gas.

Check conformance by inspection of the *IFU* and with the following test.

a) Set up the *resuscitator* in accordance with the *IFU* and the row from Table 1 that is the smallest intended *patient* ideal body mass.

b) Operate the *resuscitator*.

1) Mechanical squeezing of the *compressible unit* may be used.

c) Add air or oxygen at 30 l/min to the oxygen input *port* connector.

d) For a flow-inflating bag *resuscitator*, open the adjustable *exhaust port* to its most open position.

e) Confirm that the *PEEP* does not exceed 6 hPa (6 cmH_2O).

8.5 *Resuscitator deadspace*

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) For an intended *patient* ideal body mass less than or equal to 5 kg, the *resuscitator deadspace* shall not exceed 7 ml for a self-inflating bag *resuscitator*.

b) For a self-inflating bag *resuscitator* for an intended *patient* body mass greater than to 5 kg, the *resuscitator deadspace* shall not exceed 5 ml +10 % of the minimum guaranteed *tidal volume* specified by the applicable row of Table 1 (selected by intended *patient* ideal body mass).

c) Check conformance with the following test.

   1) Measure the deadspace of the *resuscitator*. The deadspace is the internal volume of the *patient-connection port* connector and the volume of the *patient valve* housing, limited by the valve position when the expiratory *port* is closed by the valve.

   2) For a *resuscitator* for an intended *patient* body mass less than or equal to 5 kg, subtract the overlapping volume of the 15 mm cone connector of a provided face *mask* (mating with the *patient-connection port* connector of the *resuscitator* conforming with ISO 5356-1:2015) from the *resuscitator's* deadspace.

   3) Confirm that the *resuscitator* deadspace conforms to the requirement.

8.6 Ventilation performance

8.6.1 Minimum guaranteed *tidal volume* (V_T) — one hand

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

a) The minimum guaranteed *tidal volume* of the *resuscitator*, including any combination of *accessories* other than any *user*-removable *PEEP accessory* indicated in the *IFU*, shall be greater than the minimum guaranteed *tidal volume* specified by the applicable row of Table 1 (selected by intended *patient* ideal body mass).

b) The minimum guaranteed *tidal volume* shall be disclosed in the *IFU*.

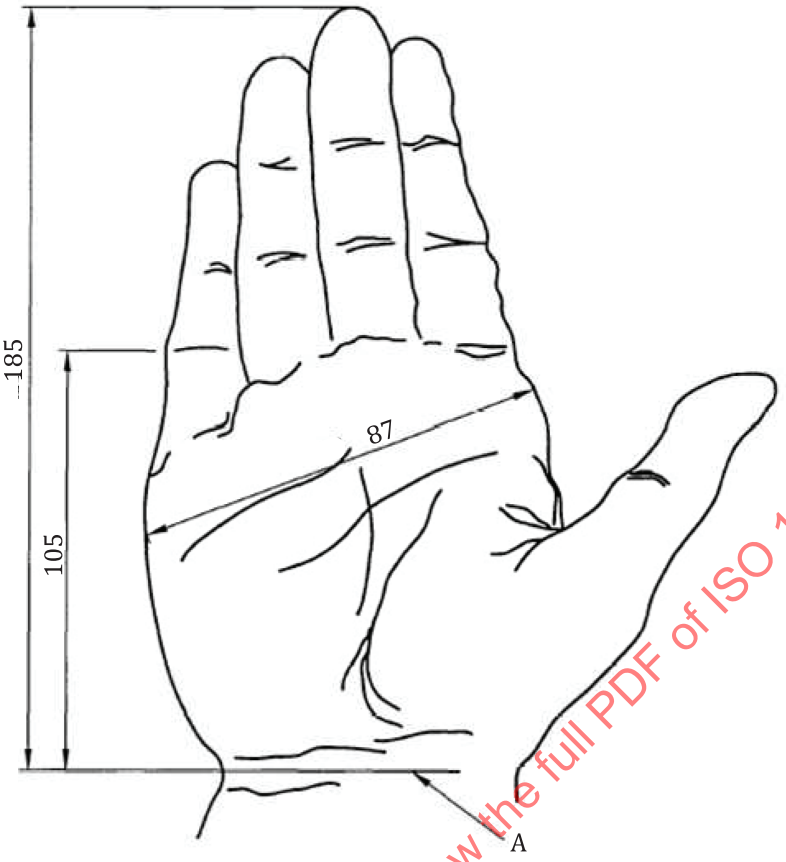
c) Check conformance by inspection, inspection of the *IFU* and with the following test.

   1) Connect the *resuscitator* to a test lung using the resistance and compliance of the first applicable row of Table 1.

   2) Perform this test with the means to limit *airway pressure* enabled and at the lowest *BAP* of a non-*user*-removable *PEEP accessory*.

   3) Ventilate the test lung at a *set rate* and *inspiratory time* as indicated in Table 1 by using only one hand with maximum allowable hand dimensions as given in Figure 4 to squeeze the *compressible unit*.

Dimensions in millimetres



Key

A distal skin crease

Figure 4 — Maximum hand dimensions

1) Measure the volume delivered through the *patient-connection port*.

2) Confirm that the *tidal volume* is greater than or equal to the minimum guaranteed *tidal volume* indicated in the *IFU*.

3) Repeat 1) to 5) for each applicable row of Table 1.

NOTE 2 In the absence of leaks (which is the case in the testing conditions) V_T has the same value as the simulated V_T.

8.6.2 Minimum guaranteed *tidal volume* for *B* < 2,5 kg

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

a) The minimum guaranteed *tidal volume* of the *resuscitator*, including the worst-case combination of *accessories* without any *user*-removable *PEEP accessory* indicated in the *IFU*, shall be greater than 2,5 ml for a resuscitator intended for a *patient* ideal body mass less than to 2,5 kg when the *compressible unit* is squeezed no more than 30 mm.

b) Check conformance with the following test.

1) Connect the *resuscitator* to a test lung using with a resistance of 50 hPa(l/s)$^{-1}$ ± 10 % and a compliance 0,5 ml/hPa ± 10 %.

2) Perform this test with the means to limit *airway pressure* enabled and at the lowest *BAP* of a non-*user*-removable *PEEP accessory*.

3) Ventilate the test lung at a *set rate* of 60 breaths/min ± 10 % with an *inspiratory time* of 0,5 s ± 10 % by squeezing, using only two fingers of one hand with maximum allowable hand dimensions as given in Figure 4, the *compressible unit* at a constant speed to a total compression distance of no more than 30 mm.

4) Mechanical squeezing of the *compressible unit* may be used.

5) Measure the volume delivered through the *patient-connection port*.

6) Confirm that the *tidal volume* is greater than 2,5 ml.

NOTE 2 In the absence of leaks (which is the case in the testing conditions) V_T has the same value as the simulated V_T.

8.6.3 Maximum deliverable *tidal volume* — two hands

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) The maximum deliverable *tidal volume* of the *resuscitator*, including any combination of *accessories* other than any *user*-removable *PEEP accessory* indicated in the *IFU*, shall be greater than the maximum deliverable *tidal volume* disclosed in the *IFU*.

b) The maximum deliverable *tidal volume* using two hands shall be disclosed in the *IFU*.

c) Check conformance by inspection, inspection of the *IFU* and with the following test.

1) Connect the *resuscitator* to a test lung using the resistance and compliance of the last applicable row of Table 3 for the largest intended *patient* ideal body mass.

2) Disable the means to the to limit *airway pressure*, if one is provided.

3) Ventilate the test lung at a *set rate* and *inspiratory time* as indicated in Table 3 by using two hands with maximum allowable hand dimensions as given in Figure 4 to squeeze the *compressible unit*.

4) Measure the volume delivered through the *patient-connection port*.

5) Confirm that the *tidal volume* is greater than or equal to the maximum deliverable *tidal volume* indicated in the *IFU*.

Table 3 — Test conditions for maximum deliverable *tidal volume* —-2 hands

Test number	*Patient* ideal body mass *B* [a] kg	Test lung		Ventilatory parameters	
		Compliance ml/hPa ±10 %	Resistance[b] [27][30][31] hPa(l/s)$^{-1}$ ±10 %	*Inspiratory time* s ±20 %	*Set rate* breaths/min ±10 %
1	$B \leq 2,5$	20	5	0,5	60
2	$2,5 \leq B \leq 5$	20	5	0,5	60
3	$5 \leq B \leq 10$	20	5	0,8	25
4	$10 < B \leq 40$	50	5	1,0	20

[a] *B* = Ideal body mass, in kg, as specified in the *IFU*.

[b] At a flowrate of range of 0 l/min to 120 l/min.

Table 3 *(continued)*

Test number	*Patient* ideal body mass *B* [a]	Test lung		Ventilatory parameters	
		Compliance	Resistance[b] [27][30][31]	*Inspiratory time*	*Set rate*
	kg	ml/hPa ±10 %	hPa(l/s)$^{-1}$ ±10 %	s ±20 %	breaths/min ±10 %
5	$B \geq 40$	50	5	1,0	20

[a] *B* = Ideal body mass, in kg, as specified in the *IFU*.

[b] At a flowrate of range of 0 l/min to 120 l/min.

8.6.4 *Maximum limited pressure*

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

a) A means shall be provided to prevent the *airway pressure* from exceeding the *maximum limited pressure* for more than 200 ms for

   1) a new (i.e. never been operated) *resuscitator*; and

   2) a newly *processed* (i.e. never been operated since being *processed*) *resuscitator*.

b) The *maximum limited pressure* in *normal condition* shall be disclosed in the *IFU*.

   1) The units of measurement of pressure shall be:

      i) cmH_2O; or

      ii) hPa.

c) If the *maximum limited pressure* is set at one fixed pressure, its *nominal* pressure setting in *normal condition* shall be *marked* on the *resuscitator*, rounded down to the nearest 5 hPa (5 cm H_2O).

   1) The accuracy of the *nominal maximum limited pressure* setting shall be disclosed in the *IFU*.

d) For a *resuscitator* designated for use with a *patient* ideal body mass less than or equal to 10 kg, the *maximum limited pressure* shall not exceed for more than 200 ms:

   1) 45 hPa (45 cmH_2O) in *normal condition*; and

   2) the value indicated in the *IFU* in *single fault condition*.

   3) A mechanism may be provided to disable the means to limit *airway pressure*.

      EXAMPLE A disabling mechanism can be the *user* pressing a finger onto the *exhaust port* to prevent the pressure limiting function from operating or engaging a mechanical lock that prevents the pressure limiting function from operating until the lock is disengaged.

e) For a *resuscitator* designated for use with a *patient* ideal body mass greater than or equal to 10 kg, the *maximum limited pressure* shall not exceed for more than 200 ms:

   1) the value indicated in the *IFU*; or

      i) Any *maximum limited pressure protection device* that limits pressure to below 60 hPa (60 cmH_2O) shall be equipped with a disabling mechanism for the means to limit *airway pressure*.

   2) 125 hPa (125 cmH_2O).

f) If the means to limit *airway pressure* is provided with a lock, it shall be so designed that the operating mode (i.e. whether it is on or off), is readily apparent to the *user* by obvious control position, flag, etc.

g) If the means to limit *airway pressure* is not provided with a lock, it shall be so designed that so that a *user* using one hand with maximum dimensions as described in Figure 4, can block it while simultaneously providing ventilations with pressure that exceeds 30 hPa.

h) However, the means to limit *airway pressure* shall always permit the generation an *airway pressure* of at least 30 hPa (30 cmH_2O).

i) Check conformance by inspection, inspection of the *IFU* and with the following test.

   1) Using a *resuscitator* which has not been operated (i.e. either new or since being *processed*).

   2) Separate the *patient valve* housing from the *compressible unit* to allow for connection of a flow source directly into the *patient valve* housing.

j) Inactivate any means to limit airway pressure. Block any port other than the patient-connection port and the maximum limited pressure exhaust port.

   3) Connect the *resuscitator* to a flow source of:

      i) 15 l/min ± 5 % for ideal body mass of less than or equal to 10 kg; or

      ii) 60 l/min ± 5 % for ideal body mass of greater than or equal to 10 kg allowing all the supplied flow to flow out of the *patient-connection port*.

   NOTE 2 125 ml (2 x 62,5) delivered in 0,5 s is 15 l/min.

   NOTE 3 1 000 ml delivered in 1 s is 60 l/min.

   4) Record the pressure at the *patient-connection port* with a sampling rate of at least 200 samples/s.

   5) Abruptly occlude the *patient-connection port* for at least 5 s.

   6) Average the *patient-connection port* pressure measurements following the occlusion.

      i) The first 200 ms of measurements may be omitted.

   7) Confirm that average measured inspiratory pressure for any 200 ms is less than *maximum limited pressure* indicated in the *IFU*.

9 Additional requirements for *resuscitator* parts and *accessories*

9.1 General

All *resuscitator* parts and *accessories* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *resuscitator* or by another entity (“third-party manufacturer”).

Check conformance by the tests of this document.

9.2 Labelling

a) The *accompanying information* provided with each *resuscitator* part or *accessory* shall include *model or type reference* of at least one compatible *resuscitator*.

b) Statements shall be included in the *accompanying information* of each *resuscitator* part or *accessory* to the effect that:

   1) resuscitator parts and accessories are validated for use with specific resuscitators;

   2) incompatible parts can result in degraded performance; and

   3) the responsible organization is responsible for ensuring the compatibility of the resuscitator and all of the parts used to connect to the patient before use.

Check conformance by inspection of the *accompanying information*.

9.3 *Breathing system filters*

Any *breathing system filter*, either incorporated into the *resuscitator* or recommended for use with the *resuscitator*, shall conform with the relevant requirements of:

a) ISO 23328-1:2003; and

b) ISO 23328-2:2002.

Check conformance by inspection of the *IFU* or application of the tests of ISO 23328-1:2003 and ISO 23328-2:2002.

9.4 *Stand-alone gas mixer*

Any *stand-alone gas mixer* recommended in the *IFU* shall conform with ISO 11195:2018.

Check conformance by inspection of the *IFU*.

10 *Processing* requirements for a *resuscitator* and its *accessories* that are reusable

a) A reusable *resuscitator* and its reusable *accessories* shall be capable of withstanding, without damage or deterioration of *safety* provisions or performance:

   1) the *cleaning* and *disinfection processes* as specified in the *IFU*; and

   2) the *cleaning* and *sterilization processes* as specified in the *IFU*.

b) The *manufacturer* shall evaluate the effects of multiple *processing* cycles as indicated in the *IFU* during the *expected lifetime* of the *resuscitator* and its *accessories.*

c) *Gas pathways* through the *resuscitator* and its *accessories* that can become contaminated with body fluids or by contaminants carried by expired gases during *normal condition* or *single fault condition* shall be designed to allow dismantling:

   1) for *cleaning* and *disinfection*; or

2) for *cleaning* and *sterilization*.

d) *Processing* instructions for the *gas pathways* of the *resuscitator* and its *accessories* that can become contaminated shall:

1) conform with ISO 17664-1:2021 and ISO 14937:2009; and

2) be disclosed in the *IFU*.

e) The *user* accessible surfaces of the *resuscitator* and its *accessories* shall be designed to allow for surface *cleaning* and *disinfection* to reduce to acceptable levels the *risk* of cross infection of the next *patient* or *user*.

f) *Processing* instructions for the *user* accessible surfaces of the *resuscitator* and its *accessories* shall:

1) conform with ISO 17664-2:2021 and ISO 14937:2009; and

2) be disclosed in the *IFU*.

g) Check conformance by the following.

1) Perform the *processing* for the number of cycles and with the methods indicated in the *IFU*, including any cooling or drying period.

2) Confirm that the *resuscitator* and its *accessories* conform to Clause 7 and Clause 8.

3) Confirm that the *manufacturer* has evaluated the effects of multiple *processing* cycles and the effectiveness of those cycles.

4) If multiple *processing* methods are specified in the *IFU*, a separate *resuscitator* sample may be used for each *processing* method specified in the *IFU*.

11 *Biocompatibility*

a) A *resuscitator* and its *accessories* intended to come into direct with the *patient* shall be evaluated for *biocompatibility* for surface contact in accordance with ISO 10993-1:2018.

b) The *manufacturer* of a *resuscitator* and its *accessories* shall address in the *risk management process* the *risks* associated with

1) the leaching or leaking of substances into the *gas pathway*; and

2) subsequent to exposure to any substances (e.g. volatile anaesthetic agents or medications) the leaching or leaking of substances into the *gas pathway*.

c) The *gas pathways* shall be evaluated for *biocompatibility* in accordance with ISO 18562-1:2017.

Check conformance by inspection of the *risk management file*, application of ISO 18562-1:2017 and where appropriate application of ISO 10993-1:2018.

12 *Usability*

a) A *resuscitator* and its *accessories* shall designed using the *usability engineering process* of IEC 62366-1:2015+AMD1:2020.

b) For a *resuscitator* and its *accessories*, the following shall be considered *primary operating functions*:

1) for other than *single use resuscitators*, *processing* the *resuscitator* and its *accessories* between *patient* uses;

2) choosing and connection of the detachable parts to the *resuscitator;*

3) choosing and configuring the detachable parts and *resuscitator* to create the intended *tidal volume*;

4) choosing and configuring the detachable parts and *resuscitator* to create the intended *delivered oxygen concentration*; and

5) emergency *cleaning* of vomitus.

c) The following functions, if available, also shall be considered *primary operating functions*:

1) setting the *user*-adjustable controls;

2) engaging the means to limit *airway pressure*;

3) disengaging the means to limit *airway pressure*;

4) observing the state of the means to limit *airway pressure*; and

5) configuring the detachable parts to create the intended pressure.

Check conformance by inspection of the *usability engineering file*.

Annex A
(informative)

Particular guidance and rationale

A.1 General guidance

This Annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this document, with clause and subclause numbers parallel to those in the body of the document.

The clauses and subclauses in this annex have been so numbered to correspond to the clauses and subclauses in this document to which they refer. The numbering is, therefore, not consecutive

— **4.5 – Testing errors**

When testing *resuscitator* performance, several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows.

Because of the relative significance of these uncertainties, it is important that *manufacturers* allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester to recognize the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a *manufacturer* determines that a parameter has an intended tolerance of ±10 %, but the measurement uncertainty is ±3 %, then the test results are acceptable if given the uncertainty band for the measured value, the probability of the measured values being within the limit is at least 50 %. In almost all cases, measurement uncertainty has a symmetrical distribution, and the 50 % likelihood criterion is met if the measured value is within the disclosed limit, in this example, within ±10 % of the setting. If a third party is testing to this document, they also need to include measurement uncertainty in their testing. The third-party testing organization needs to control measurement uncertainty to the same as that disclosed for type testing, in this example ±3 %.

Note that a third party testing organization obtaining a measured value outside the limit does not necessarily invalidate the claim – the deviation from the limit is required to be compared to the uncertainty of the measurement to establish the probability of the data representing a true deviation from specification.

See IEC Guide 115 for more information regarding measurement uncertainty.

Furthermore, the *manufacturer* is required to disclose the measurement uncertainty for each declared value in order to provide both information to the *responsible organization* and guidance for a third-party tester as to the needed measurement accuracy when testing to this document

— **4.6.2 – Operating conditions**

g) 4)

During the test, normal operation of the *resuscitator* will enrich the ambient oxygen inside the environmental chamber if the gas output is in the environmental chamber. An external air source can be needed to compensate for this enrichment and monitoring of the oxygen concentration inside the chamber can be needed.

— **4.6.4 – *Expected lifetime***

Use of a *resuscitator* on a *patient* can be for as little as few minutes, but it can also during emergency conditions extend over many hours. Intermittent ventilatory support of a *ventilator-dependent patient* can accumulate to several hours of use. As a worst case, a *single patient use resuscitator* should be fatigue tested for at least 24 h of accumulated use without a *resuscitator* failure causing it not to meet its specifications.

A reusable *resuscitator* should be tested for 24 h plus 1 h more for each *processing* cycle specified in the *IFU*.

EXAMPLE A *resuscitator* specified for 20 *processing* cycles should be fatigue tested for 44 h of use.

The additional hours should be applied at the end of the *processing* life.

— **Table 1**

The respiratory settings for neonates ($B \leq 2{,}5$ kg and $2{,}5\ \text{kg} \leq B \leq 5$ kg) each consist of two rows. The first of these rows reflect the initial one to twenty ventilations of the newborn child, where the *lungs* are initially liquid-filled, and the functional residual capacity is not yet established. While the second of these rows reflect the conditions after establishment of *lung* capacity and the later neonatal.

During this transition the *lung* volume, and thus its compliance, increases for each breath. The requirement for the compliance of 0,5 ml/hPa reflecting the initial ventilations derives from a balance achieved between data from an observational study of more than 800 near-term/term neonates being ventilated with *user-powered resuscitators* and showing compliance around 0,3 ml/hPa in near-term and term infants at birth[28] and commercially available test lungs which come with compliance adjustments no less than 0,5 ml/hPa.

The requirement for the minimum guaranteed *tidal volume* of 10 ml is a little lower than recommended by clinical guidelines for neonates following initial recovery (i.e. 4 ml/kg to 6 ml/kg)[29] and is also lower than seen in the observational study.[28] The requirement reflects the limitations of the test set up with a rigid compliance vessel having a constant volume (and compliance), as opposed to the infant *lung* where the *lung* volume increases for each of the initial given breaths. The requirement takes into account the maximum possible *tidal volume* that can be delivered by a typical *resuscitator* before the means to limit *airway pressure* is activated, as well as considerations regarding requirements of the previous edition of this document[7].

The compliance chosen for large infants, children and adults of 10 ml/hPa and 20 ml/hPa does not challenge the rigid test lung as does the small infant set up. The required minimum guaranteed *tidal volume* for these ideal body weights reflect worst-case scenarios when compared to clinical guidelines that recommend *tidal volumes* of 6 ml/kg to 7 ml/kg[35] for adults and 5 ml/kg to 8 ml/kg for children[33].

The breath *set rates* reflect the worst-case use situation where the *resuscitator* is challenged with regard to recoil and *tidal volume*. For comparison, current clinical guidelines for resuscitation recommend ventilation at 10 breaths/min in adults,[34][35] (12 to 24) breaths/min according to age normal values in children with return of spontaneous circulation,[32] and 30 breaths/min in neonates.[36] Further, the previously mentioned 800 neonatal *patient* observational study showed an average ventilation rate of 50 breaths/min for establishment of functional residual capacity at birth[28].

— **6.3 – Expiratory *port* connector for breathing gases**

The exhaust connection described is that used for connection to *PEEP accessories* or the transfer tubes of anaesthetic gas scavenging systems. It is essential that breathing system conical connectors are not compatible with this *port*. It is also important that the *exhaust port* be designed such that it cannot be confused with the inspiratory *port* during use of the *resuscitator*.

— **6.6 – *Bag refill valve* connector**

The size of the *bag refill valve* connector is chosen to prevent the accidental fitting of demand valves with manual controls.

— **6.7 – Oxygen inlet connection**

Whilst there are many anecdotal reports of misconnections, published evidence of serious incidents is scarce. Many clinicians openly admit that misconnections are commonplace but go unreported either because the mistake was rectified in time or because serious *harm* did not arise from the event. Discussions with *authorities having jurisdiction* reveal that commonplace but potentially serious events are not reported because *users* consider them as normal events.

In the *risk assessment* of the *gas pathways* of a *resuscitator*, it can be summarised that there are fundamentally three main routes of delivery to the body: intravascular, enteral and respiratory. Some medical devices are intended to be connected to one of these routes depending upon their application or function. Misconnections, which result in the delivery of a substance inappropriately to the body, create *risks* to the *patient*.

The assessment of the *risk* associated with the inadvertent cross connection between these three systems identifies the application of respiratory gases to the delivery route intervascular as "immediate fatal risk to patient".

Considering *usability*, a review of the role of *usability* in accident areas such as aviation, nuclear power and marine transportation exists.[26] The review makes the point that all human beings, without any exceptions whatsoever, make *use errors* and that such *use errors* are a completely normal and an expected part of human cognitive function. The review goes on to say that whilst many accidents are regarded as human error (which is synonymous with *use error*) the guilty party can often be someone else, for example the trainer, the equipment designer, the equipment purchaser etc. Well-designed equipment can prevent or at least ameliorate the effects of *use error*. The review states that one must expect *users* to misconnect devices which are provided with compatible connectors, and recognise that the potential for misconnection rises as the number of devices with similar connectors increases.

Considering further that medical devices have for very many years followed the established principle of *safety* under *single fault condition*, which means that a *single fault condition* should not result in an unacceptable *risk*. This principle is also embodied in IEC 60601 family of standards. Extending this principle to the application of Luer connectors is a logical step (i.e. that misconnection should not result in an unacceptable *risk*).

The widespread use of Luer connectors on a multitude of medical devices can result in connections which have serious, or even fatal, consequences for the *patient*. Fundamentally, the problem results from the application of a single connector design to several incompatible applications.

Claims of a lack of recorded misconnection occurrence indicate a lack of understanding *risk* and *usability*. It's known that most of the actual occurrences are recorded not as medical device failures and if anything, are seen as wrong route of delivery issues – not as misconnections. Human beings without exceptions make errors. We therefore expect *operators* to misconnect medical devices that are provided with compatible connectors. The *safety* concept of the ISO 80369 series is based on the principle that the different applications protect each other by an inherent design of the connectors dedicated to their field of application (i.e. the *safety* concept of the ISO 80369 series is to prevent *users* from misconnecting medical devices of different applications).

— **7.1 – Dismantling and reassembly**

Wrongly assembling a *resuscitator* so that it causes incorrect operation or complete malfunction is a serious *hazard* which can result in inadequate ventilation of the *patient*.

— **7.2 – *Resuscitator* performance after contamination with vomitus**

It is important that vomitus can be quickly and effectively cleared from a *resuscitator* so that resuscitation can be continued with a minimum of interruption.

— **7.3 – Mechanical strength**

It is important that *resuscitators* can withstand severe shock caused by falls from ambulances, hospital beds, etc.

— **7.4 –Resistance to separation from an axial load**

Single use resuscitators need to be stronger than reusable *resuscitators* because paramedics treat them roughly and they break, rather than disconnecting into pieces.

— **7.5 – Immersion in water**

Resuscitators are often used in areas where the *resuscitator* might be inadvertently dropped into water during the resuscitation. If the *resuscitator* is recovered quickly from the water, it should still function.

— **7.6 – *Bag refill valve***

It is imperative that a demand valve with manual controls is not accidentally substituted for a *bag refill valve*. Such valves are capable of high gas flows that can cause *resuscitator patient valves* to jam.

— **8.1 –*Delivered oxygen concentration***

Although 35 % (V/V) oxygen concentration is adequate, under some circumstances 85 % (V/V) or higher oxygen concentrations are preferable for the treatment of severely hypoxaemic *patients* during resuscitation. This concentration should be achievable at supplementary oxygen flows of 15 l/min or less because to specify greater than 15 l/min would exceed the normal calibration of standard, clinically used flowmeters for adult use and could potentially lead to inaccurate control of oxygen flows and jamming of the *patient valve* in the inspiratory position.

For a newborn infant that is not breathing, an initial oxygen concentration in the range of 21 % to 30 % is recommended. Oxygen concentrations above 65 % delivered to a preterm infant can cause severe *harm*.

— **Table 2 — Example test conditions for spontaneous breathing ventilatory performance**

A *resuscitator's* valves might not move to their intended positions at very low inspiratory flowrates. During spontaneous breathing, ambient air can inadvertently be drawn in from the *exhaust port*, thereby diluting the *delivered oxygen concentration*. The intent of the lower *tidal volumes* and higher *inspiratory times* in Table 2 is to test *delivered oxygen concentration* while the flowrate is low.

— **8.2 – Expiratory resistance**

To facilitate exhalation, expiratory resistance should be minimized unless there are special clinical indications to impose such resistance.

— **8.3 – Inspiratory resistance**

The design of a *resuscitator* should be such that it is possible for the *patient* to breathe spontaneously without excessive subatmospheric pressure when the *resuscitator* is applied to the *patient's* airway but is not activated by the *user*.

— **8.4 – Gas source excessive flow**

The subclause was intentionally included to ensure the *resuscitator* does not create excessive *PEEP* if connected to a pressurized gas source that delivers an inappropriately large gas flowrate.

The use of a *resuscitator* with supplementary oxygen flow is common. The gas source often is a flowmeter attached to either a pressurized oxygen cylinder or a medical gas pipeline terminal unit. It is reasonably foreseeable that the *resuscitator* is connected to a flowmeter with an inappropriately high setting. An oxygen flowrate of 15 l/min is common and appropriate. A fully open flowmeter can deliver flowrates in excess of 30 l/min. The test is used to determine that *PEEP* does not increase inappropriately under these conditions. The worst case for this situation is when small volumes are being delivered. Therefore, the test is performed with the settings chosen from the row from Table 1 with the smallest intended minimum guaranteed *tidal volume*.

Valve malfunction or jamming in the inspiratory position at a high supplementary oxygen flow can lead to failure of the *resuscitator* and transmission of excessive pressures to the *patient*. *Resuscitators* are commonly used at oxygen input flows of 15 l/min, but flowmeter valves can be capable of permitting flows of over 30 l/min. It is essential to follow the *IFU* and to use only attachments recommended for use with the *resuscitator*.

— **8.5 – *Resuscitator deadspace***

It is essential to minimize apparatus deadspace in order to limit rebreathing of expired gases.

Self-inflating bag *resuscitators* include *patient valves* with a one-way valve that channels *patient*-expired gases to the expiratory *port*. The inner volume between the end of the *patient-port connector* and the one-way valve in its functional sealing position, is dead-space that is ventilated back to the *patient's lungs*, but is supplemented with fresh input gas (i.e. *user*-set mixture of oxygen and air) when the *compressible unit* is squeezed. The deadspace should be minimized but cannot be smaller than the space required by the inner lumen of the *patient-connection port* and for accommodating the one-way valve.

Flow-inflating bag *resuscitators* do not have a one-way valve that channels expired gases to a dedicated *exhaust port*. Instead they have an open orifice that bleeds out excessive gas when the *compressible unit* has been refilled with a mixture of *patient*-expired gas and input gas flow. The concentration of carbon dioxide and oxygen in the flow-inflating bag *resuscitator* is highly dependent on the *user's* setting of input gas flow, input gas oxygen concentration, the delivered *tidal volume* and the *patient*-expired gas volume. Flow-inflating bag *resuscitators* are primarily used by specialist healthcare *users* within healthcare facilities, and the *patient* is typically monitored by pulse oximetry to ensure that ventilation is effective. The operation and settings that influence the flow-inflating bag *resuscitator's* performance regarding rebreathing, is subject to clinical judgement by the competent *user*, and cannot be specified by this document.

If a flow-inflating bag *resuscitator* does not have dedicated means to channel expired gas away from the *compressible unit*, the *IFU* of a flow-inflating bag *resuscitator*, is required to include a warning to the effect of: WARNING – Incorrect use of this device can lead to excessive patient rebreathing and death.

The test fixture and methods specified in the previous edition of this document are considered ineffective for several reasons. The measurement uncertainty associated with the test method specified in the previous edition was unacceptably large even with state-of-the-art measurement equipment. This is especially true for *resuscitators* intended for use with low ideal body mass *patients* where expanded measurement uncertainty from the measurement equipment alone would be close to 50 % of the allowed *resuscitator deadspace*. In addition, variation of bag compression technique from person to person and choice of one-way valves can impact the test results.

Furthermore, the test method of the previous edition favours *resuscitators* with large *forward leakage*, since the oxygen is diluted more by the *forward leakage* air flow in such *resuscitators*, which leads to lower values of the estimated deadspace.

— **8.6.1 – Minimum guaranteed *tidal volume* (V_T) — one hand**

For adult ventilation a typical *tidal volume* is approximately 600 ml. The compliances and resistances listed in Table 1 are representative of those found in adults and children needing resuscitation. The *tidal volume* requirements of 15 ml/kg are higher than normal and are commonly used during resuscitation to allow for leakage between the face *mask* and the *patient's* face. The ventilatory settings are typical values used in paediatric and adult resuscitation.

Experience shows that, due to leaks and changing compliance during resuscitation of neonates, *tidal volumes* of the order of 20 ml to 30 ml are needed to achieve a *tidal volume* of 20 ml or less.

— **8.6.2 – Minimum guaranteed *tidal volume* for B < 2,5 kg**

For preterm resuscitation it is important for the *tidal volume* to be delivered with limited compression. This ensures that there is not excessive *forward leakage* in the *resuscitator* thereby ensuring that the *patient* can be ventilated. Some resuscitators currently on the market at the time of the writing of this document have clinically unacceptable *forward leakage*[36].

— **8.6.3 – Maximum deliverable *tidal volume* — two hands**

When ventilating a *patient*, the delivered *tidal volume* can be severely reduced due to leakages, particularly in cases with low *lung* compliance or high airway resistance. Activation of the *resuscitator's* pressure release system can bleed gas to ambient in order to limit the gas pressure, while face *mask* ventilation is associated with *risk* of significant leakages. *Resuscitators* should have excess volume capacity to enable *users* to compensate for such leakages. The *user* can, depending on the situation, use either one hand or two hands to squeeze the bag.

Since the compliance and resistance experienced by the *resuscitator* would be less severe when there are such simultaneous leakages, the maximum delivered *tidal volume* is measured with a test lung with less severe compliance and resistance settings, as defined in Table 2.

The minimum guaranteed *tidal volume* (tested under conservative test lung settings with one hand) and the maximum deliverable *tidal volume* (tested with test lung settings which are more compliant, with one or two hands) are required to be disclosed in the *IFU*.

— **8.6.4 – *Maximum limited pressure***

Experience with infant resuscitation suggests that a maximum inspiratory pressure of 45 hPa (45 cmH_2O) will not produce *lung* damage and will permit adequate *tidal volumes* in most *patients* weighing under 10 kg.

A specific *maximum limited pressure* is not specified for *user-powered resuscitators* designated for use with *patients* weighing over 10 kg. However, it is essential that *resuscitators* with such systems satisfy the minimum guaranteed *tidal volume* requirements specified in this document (see Table 1) without disabling the means to limit *airway pressure*. When *airway pressure* is limited to below 60 hPa (60 cmH_2O), the committee considers that the means to limit *airway pressure* is essential in order to ventilate those *patients* with low *lung* compliance or high airway resistance.

Resuscitators with a *maximum limited pressure* less than 30 hPa (30 cmH_2O) might not be able to deliver adequate volume to children with a body weight below 10 kg in case of high airway resistance or reduced *lung* compliance.

A *resuscitator's maximum limited protection device* is typically designed using a spring-loaded valve which opens and closes at a threshold pressure, and bleeds off gas as the mechanism for limiting pressure. The *maximum limited pressure* observed during ventilations would be comprised of the threshold pressure plus the effect of flow resistance through the valve. This flow resistance can typically be approximately constant but at some point, progressively increases with increasing flow through the valve. Abrupt ventilations that cause high bleed flow through the valve's mechanism can therefore cause higher valve flow resistance and therefore higher *airway pressure*. Abrupt compression is considered abnormal use since *users* are trained to properly, slowly squeeze the *compressible unit*.

Annex B
(informative)

Guide to *marking* and labelling requirements for *resuscitators* and their *accessories*

B.1 *Marking* on the outside of the *resuscitator* and its *accessories*

The requirements for *marking* on the outside of a *resuscitator* and its *accessories* are found in 5.2. Additional requirements for *marking* on the outside of a *resuscitator* and its *accessories* are found in the subclauses listed in Table B.1. *Symbols* used in *marking* the outside of *resuscitator* and its *accessories* are found in Annex C.

Table B.1 — *Marking* on the outside of the *resuscitator* and its *accessories*

Description of *marking*	Subclause
For a fixed value *maximum limited pressure protection device*, the *nominal maximum limited pressure* in cmH_2O or hPa	8.6.4 c)
For a *resuscitator* intended for the magnetic resonance (MR) environment, MR safe, if applicable	5.2 b) 1)
For a *resuscitator* intended for the magnetic resonance (MR) environment, MR conditional, if applicable	5.2 b) 2)
For a *resuscitator* not intended for the magnetic resonance (MR) environment, MR unsafe, if applicable	5.2 c)
Intended *patient* ideal body mass range in [kg]	5.2 a)
More restricted range of environmental conditions of operation	4.6.2 c) 2)
More restricted range of environmental transport and storage conditions between uses	4.6.1 b) 2)
More restricted range of environmental transport and storage conditions between uses *labelled* on the point of use packaging	4.6.1 b) 3)
Requirements of ISO 20417	5.1 a)

B.2 *Accompanying information* of the *resuscitator* and its *accessories*

Additional requirements for the *accompanying information* of a *resuscitator* and its *accessories* are found in the subclauses listed in Table B.2.

Table B.2 — *Accompanying information* of the *resuscitator* and its *accessories*

Description of requirement	Subclause
For a *resuscitator* part or *accessory*, at least *model or type reference* of at least one compatible *resuscitator*	9.2 a)
Form of accompanying information is readily available	5.1 b)
Requirements of ISO 20417	5.1 a)
Statement to the affect that incompatible parts can result in degraded performance	9.2 b) 2)
Statement to the affect that resuscitator parts and accessories are validated for use with specific resuscitators	9.2 b) 1)

Table B.2 *(continued)*

Description of requirement	Subclause
Statement to the affect that the responsible organization is responsible for ensuring the compatibility of the resuscitator and all of the parts used to connect to the patient before use	9.2 b) 3)

B.3 *Instructions for use* of the *resuscitator* and its *accessories*

The requirements for the *instructions for use* of a *resuscitator* and its *accessories* are found in 5.3. Additional requirements for the *instructions for use* of a *resuscitator* and its *accessories* are found in the subclauses listed in Table B.3.

Table B.3 — *Instructions for use* of the *resuscitator* and its *accessories*

Description of requirement	Subclause
Any reuse limitation of the *accessories*	4.6.4 d) 2)
Any reuse limitation of the *resuscitator*	4.6.4 d) 1)
Effects of the oxygen source flowrate on the *delivered oxygen concentration*	8.1.1 b) 3)
Effects of the *rated* range of input oxygen concentration on the *delivered oxygen concentration*	8.1.1 b) 2)
Expected lifetime of the *accessories*	4.6.4 c) 2)
Expected lifetime of the *resuscitator*	4.6.4 c) 1)
For a fixed value *maximum limited pressure protection device*, the accuracy of *nominal* value of the *maximum limited pressure*	8.6.4 c) 2)
For a flow-inflating bag resuscitator, a warning statement to the effect that “WARNING – Incorrect use of this device can lead to excessive patient rebreathing and death".	5.3 o)
For a reusable *resuscitator* and its reusable *accessories*, *processing* instructions for *gas pathways*	10 a)
For a self-inflating bag *resuscitator*, the deadspace	5.3 e) 1)
For a self-inflating bag *resuscitator,* the expiratory resistance and test flowrate	5.3 e) 2)
For a self-inflating bag *resuscitator*, the inspiratory resistance and test flowrate	5.3 e) 3)
For self-inflating bag *resuscitator*, the *resuscitator's* configuration and settings for achieving 85 5 oxygen concentration	8.1.1 a) 1)
Guidance regarding use in hazardous or explosive atmospheres, including a warning to the effect that if the resuscitator entrains or permits the patient to inhale gas from the atmosphere, its use in contaminated environments can be hazardous unless entrainment is prevented	5.3 g)
Instructions for the removal of vomitus from the *resuscitator* and its *accessories* during emergency use	7.2 a)
Intended *patient* ideal body mass range in [kg]	5.3 d)
Intended *user* needs to be trained in resuscitation	5.3 a)
List of *user*-replaceable parts	5.3 f)
Maximum limited pressure in *normal condition*	8.6.4 b)
Maximum limited pressure in *single fault condition*	8.6.4 d) 2)
Medicinal or biological substances considered in the evaluation of material compatibility of the *resuscitator*	7.7 b)
Minimum *tidal volume* using one hand	8.6.1 b)
Minimum *tidal volume* using two hands	8.6.3

Table B.3 *(continued)*

Description of requirement	Subclause
Processing instructions for the *user* accessible surfaces of the *resuscitator* and its *accessories*	10 f) 2)
Rated range of input oxygen source concentration	8.1.1 b) 1)
Requirements of ISO 20417	5.1 a)
Shelf-life	4.6.3 a)
Specifications for the *accessories* recommended in the *IFU*	5.3 c)
Specifications for the *resuscitator*	5.3 b)
Table of correcting values, If readings or performance vary over the range of environmental conditions of operation	4.6.2 b)
Warning statement to the effect that “WARNING: Avoid using an oxygen concentration more than that which is clinically required by the patient. Delivering excessive oxygen can increase the risk of oxygen toxicity e.g. pulmonary damage, retinopathy of prematurity.”	5.3 m)
Warning statement to the effect that “WARNING: Do not lubricate fittings, connections, tubing, or other accessories of the resuscitator to avoid the risk of fire and burns.”	5.3 l)
Warning statement to the effect that “WARNING: Open flames during resuscitation with oxygen are dangerous and are likely to result in fire or death. Do not allow open flames or sparks within 2 m of the resuscitator or any oxygen-carrying accessories.”	5.3 k)
Warning statement to the effect that “WARNING: Patient expired gas is potentially infectious. Breathing filters can reduce but not eliminate contamination risk".	5.3 n)
Warning statement to the effect that “WARNING: To avoid the risk of barotrauma, do not override the mechanical pressure relief unless it clinically justified. Care needs to be taken to immediately restore the pressure relief function after the clinical need is resolved.”	5.3 i)
Warning statement to the effect that “WARNING: To avoid the risk of barotrauma, do not use abrupt and forceful compressions unless it is clinically justified because they can cause high airway pressures.”	5.3 j)
Warning statement to the effect that “WARNING: Use the correct size resuscitator for the ideal body mass of the patient to avoid the risk of hypoventilation or barotrauma.”	5.3 h)
Where *marking* is not practicable, the more restricted range of environmental transport and storage conditions between uses	4.6.1 c) 2) i)
Where *marking* is not practicable, the more restricted range of environmental conditions of operation	4.6.2 c) 2) i)

B.4 *Technical description* of the *resuscitator* and its *accessories*

Additional requirements for the *technical description* of a *resuscitator* and its *accessories* are found in the subclauses listed in Table B.4.

Table B.4 — *Technical description* of the *resuscitator* and its *accessories*

Description of requirement	Subclause
Disclosure of the measurement uncertainty for each disclosed tolerance	4.5 c)
Requirements of ISO 20417	5.1 a)

Annex C
(informative)

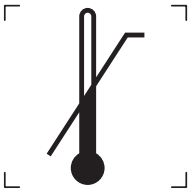
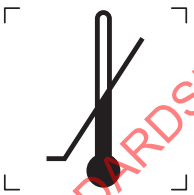
Symbols on *marking*

Symbols are frequently used on medical devices in preference to words with the intention of obviating language differences and permitting easier comprehension of a *marking* or indication, sometimes in a restricted space. New and improved *symbols* and *safety signs* have been introduced since the publication of the first edition of ISO 10651-4. This Annex summarizes the *symbols* and *safety signs* specified in this document.

Consistent use of these *symbols* and *safety signs* in all fields of use (e.g. medical, consumer products, and general transportation) will help *users* to become familiar with their meaning. Conversely, any inconsistent use will lead to confusion and mistakes and jeopardize *safety*.

In Table C.1, the *symbol* graphic and title are provided for information for the convenience of the readers of this document.

Table C.1 — *Symbols* on *marking*

No	*Symbol*	Reference	Title and description
1		ISO 7000-0533 *Symbol* 5.3.6 ISO 15223-1:2021 IEC/TR 60878:2015	Upper limit of temperature To identify the maximum temperature limit. The temperature value may be shown adjacent to the *symbol*. NOTE Indicates the upper limit of temperature to which the medical device can be safely exposed. The upper limit of temperature shall be indicated adjacent to the upper horizontal line.
2		ISO 7000-0534 *Symbol* 5.3.5 ISO 15223-1:2021 IEC/TR 60878:2015	Lower limit of temperature To identify the minimum temperature limit. The temperature value may be shown adjacent to the *symbol*. NOTE Indicates the lower limit of temperature to which the medical device can be safely exposed. The lower limit of temperature shall be indicated adjacent to the lower horizontal line.
3		ISO 7000-0632 *Symbol* 5.3.7 ISO 15223-1:2021 IEC/TR 60878:2015	Temperature limit To identify the temperature limits, for example on transport packaging to indicate limits within which the package has to be kept and handled. The temperature values may be shown adjacent to the *symbol*. NOTE Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.