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Ersatz für
DIN EN ISO 4135:2002-03**Anästhesie- und Beatmungsgeräte –
Begriffe (ISO 4135:2022);
Dreisprachige Fassung EN ISO 4135:2022**Anaesthetic and respiratory equipment –
Vocabulary (ISO 4135:2022);
Trilingual version EN ISO 4135:2022Matériel d'anesthésie et de réanimation respiratoire –
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Version trilingue EN ISO 4135:2022

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DIN-Normenausschuss Rettungsdienst und Krankenhaus (NARK)

Nationales Vorwort

Dieses Dokument (EN ISO 4135:2022) wurde vom Technischen Komitee ISO/TC 121 „Anaesthetic and respiratory equipment“ in Zusammenarbeit mit dem Technischen Komitee CEN/TC 215 „Beatmungs- und Anästhesiegeräte“ erarbeitet, dessen Sekretariat von BSI (Vereinigtes Königreich) gehalten wird.

Das zuständige deutsche Normungsgremium ist der Arbeitsausschuss NA 053-03-04 AA „Terminologie“ im DIN-Normenausschuss Rettungsdienst und Krankenhaus (NARK).

Hinweis zur Übersetzung der Definition von 3.2.2.3 „Verschlussventil der Entnahmestelle“: Die Übersetzung für den englischen Begriff „probe“ ist nach 3.1.4.47 „Stecker“ anstelle von „Messfühler“.

Für die in diesem Dokument zitierten internationalen Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

ISO 5356-1	siehe	DIN EN ISO 5356-1
ISO 5725-1	siehe	DIN ISO 5725-1
ISO 7396-2	siehe	DIN EN ISO 7396-2
ISO 9170-2	siehe	DIN EN ISO 9170-2
ISO 9360-1	siehe	DIN EN ISO 9360-1
ISO 9360-2	siehe	DIN EN ISO 9360-2
ISO 10524-1	siehe	DIN EN ISO 10524-1
ISO 14971	siehe	DIN EN ISO 14971
ISO 17664	siehe	DIN EN ISO 17664
ISO 19223	siehe	DIN EN ISO 19223
ISO 20417	siehe	DIN EN ISO 20417
ISO 23328-1	siehe	DIN EN ISO 23328-1
ISO 23328-2	siehe	DIN EN ISO 23328-2
IEC 60601-1-11	siehe	DIN EN 60601-1-11 (VDE 0750-1-11)

Änderungen

Gegenüber DIN EN ISO 4135:2002-03 wurden folgende Änderungen vorgenommen:

- a) Aktualisierung von Begriffen auf der Grundlage von Neuausgaben von Normen über Anästhesie- und Beatmungsgeräte, über damit verbundene Geräte bzw. Produkte sowie über zugehörige Versorgungssysteme;
- b) Streichung von Begriffen, die für Beatmungsgeräte spezifisch und in ISO 19223:2019 „Lung ventilators and related equipment — Vocabulary and semantics“ erfasst sind;
- c) redaktionelle Überarbeitung.

Frühere Ausgaben

DIN EN ISO 4135: 1996-11, 2002-03
DIN ISO 4135: 1988-11

Nationaler Anhang NA (informativ)

Literaturhinweise

DIN EN 60601-1-11 (VDE 0750-1-11), *Medizinische elektrische Geräte — Teil 1-11: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale — Ergänzungsnorm: Anforderungen an medizinische elektrische Geräte und medizinische elektrische Systeme für die medizinische Versorgung in häuslicher Umgebung*

DIN EN ISO 5356-1, *Anästhesie- und Beatmungsgeräte — Konische Konnektoren — Teil 1: Männliche und weibliche Konen*

DIN EN ISO 7396-2, *Rohrleitungssysteme für medizinische Gase — Teil 2: Entsorgungssysteme von Anästhesiegas-Fortleitungssystemen*

DIN EN ISO 9170-2, *Entnahmestellen für Rohrleitungssysteme für medizinische Gase — Teil 2: Entnahmestellen für Anästhesiegas-Fortleitungssysteme*

DIN EN ISO 9360-1, *Anästhesie- und Beatmungsgeräte — Wärme- und Feuchtigkeitsaustauscher zur Anfeuchtung von Atemgasen beim Menschen — Teil 1: Wärme- und Feuchtigkeitsaustauscher zur Verwendung bei Mindesthubvolumina von 250 ml*

DIN EN ISO 9360-2, *Anästhesie- und Beatmungsgeräte — Wärme- und Feuchtigkeitsaustauscher zur Anfeuchtung von Atemgasen beim Menschen — Teil 2: Wärme- und Feuchtigkeitsaustauscher zur Verwendung bei tracheostomierten Patienten mit Mindesthubvolumina von 250 ml*

DIN EN ISO 10524-1, *Druckminderer zur Verwendung mit medizinischen Gasen — Teil 1: Druckminderer und Druckminderer mit Durchflussmessgeräten*

DIN EN ISO 14971, *Medizinprodukte — Anwendung des Risikomanagements auf Medizinprodukte*

DIN EN ISO 17664, *Aufbereitung von Produkten für die Gesundheitsfürsorge — Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten*

DIN EN ISO 19223, *Beatmungsgeräte und zugehörige Geräte — Terminologie und Semantik*

DIN EN ISO 20417, *Medizinprodukte — Anforderungen an vom Hersteller bereitzustellende Informationen*

DIN EN ISO 23328-1, *Filter für Atemsysteme zur Anwendung bei Anästhesie und Beatmung — Teil 1: Prüfverfahren mit Salzpartikeln zur Bewertung der Filterleistung*

DIN EN ISO 23328-2, *Filter für Atemsysteme zur Anwendung bei Anästhesie und Beatmung — Teil 2: Aspekte, die nicht die Filtration betreffen*

DIN ISO 5725-1, *Genauigkeit (Richtigkeit und Präzision) von Meßverfahren und Meßergebnissen — Teil 1: Allgemeine Grundlagen und Begriffe*

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Deutsche Fassung

Anästhesie- und Beatmungsgeräte — Begriffe (ISO 4135:2022)

Anaesthetic and respiratory equipment —
Vocabulary (ISO 4135:2022)

Matériel d'anesthésie et de réanimation respiratoire —
Vocabulaire (ISO 4135:2022)

Diese Europäische Norm wurde vom CEN am 22. August 2021 angenommen.

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CEN-CENELEC Management-Zentrum: Rue de la Science 23, B-1040 Brüssel

Europäisches Vorwort

Dieses Dokument (EN ISO 4135:2022) wurde vom Technischen Komitee ISO/TC 121 „Anaesthetic and respiratory equipment“ in Zusammenarbeit mit dem Technischen Komitee CEN/TC 215 „Beatmungs- und Anästhesiegeräte“ erarbeitet, dessen Sekretariat von BSI gehalten wird.

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Anerkennungsnotiz

Der Text von ISO 4135:2022 wurde von CEN als EN ISO 4135:2022 ohne irgendeine Abänderung genehmigt.

English Version

Anaesthetic and respiratory equipment - Vocabulary (ISO 4135:2022)

Matériel d'anesthésie et de réanimation respiratoire -
Vocabulaire (ISO 4135:2022)

Anästhesie- und Beatmungsgeräte -
Begriffe (ISO 4135:2022)

This European Standard was approved by CEN on 22 August 2021.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 4135:2022) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2022, and conflicting national standards shall be withdrawn at the latest by August 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 4135:2001.

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Endorsement notice

The text of ISO 4135:2022 has been approved by CEN as EN ISO 4135:2022 without any modification.

Version Française

Matériel d'anesthésie et de réanimation respiratoire - Vocabulaire (ISO 4135:2022)

Anästhesie- und Beatmungsgeräte -
Begriffe (ISO 4135:2022)

Anaesthetic and respiratory equipment -
Vocabulary (ISO 4135:2022)

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EUROPEAN COMMITTEE FOR STANDARDIZATION

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Bruxelles

Avant-propos européen

Le présent document (EN ISO 4135:2022) a été élaboré par le Comité Technique ISO/TC 121 « Matériel d'anesthésie et de réanimation respiratoire » en collaboration avec le Comité Technique CEN/TC 215 « Équipement respiratoire et anesthésique » dont le secrétariat est tenu par BSI.

La présente Norme européenne devra recevoir le statut de norme nationale, soit par publication d'un texte identique, soit par entérinement, au plus tard en août 2022 et les normes nationales en contradiction devront être retirées au plus tard en août 2022.

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Ce document remplace l'EN ISO 4135:2001.

Il convient que l'utilisateur adresse tout retour d'information et toute question concernant le présent document à l'organisme national de normalisation de son pays. Une liste exhaustive desdits organismes se trouve sur le site web du CEN.

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Notice d'entérinement

Le texte de l'ISO 4135:2022 a été approuvé par le CEN en tant que EN ISO 4135:2022 sans aucune modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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 4, *Vocabulary and semantics*, 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 fourth edition cancels and replaces the third edition (ISO 4135:2001), which has been technically revised.

The main changes compared to the previous edition are as follows:

- Deletion of terms that are no longer relevant to International Standards prepared by ISO/TC 121, or that are defined in more widely applicable International Standards, such as ISO 14971.
- Deletion of terms that are specific to lung ventilators and that are covered in ISO 19223.

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

The primary objective for this document has been to facilitate consistent use of terminology across all the standards relevant to manufacturers, test laboratories and regulatory agencies with an interest in equipment for use in anaesthesiology and respiratory care.

Terms defined in ISO 19223 have been included in this document where they have applicability outside the scope of mechanical ventilation.

EXAMPLE 1 *Airway pressure* is included in this document because it has applicability in fields such as pulmonary function testing.

EXAMPLE 2 *Airway resistance* is not included in this document because the only context of use of this term is within standards for lung ventilators, for which ISO 19223 is an appropriate source.

Particular emphasis has been placed on the identification of instances where the same term is used for different concepts, or where the same concept is identified by different terms.

The terms, names and acronyms listed in this document have been described in a manner that formalizes their interpretation to the extent that it minimizes ambiguity and provides a rigid usage discipline for formal data handling and informatics, whilst retaining phraseology that is suitable for user instructions and clinical dialog.

In the application of the vocabulary of this document, the full term should always be used wherever any ambiguity might arise from use of an abbreviated term and where there is no trade-off with conciseness, for example, in the formulation of data bases. However, in many applications the context of use may make some of the parts of a compound preferred term redundant, in which case abbreviations, symbols and permitted terms may be used, as appropriate.

The vocabulary of this document is primarily arranged in a systematic order, with a secondary alphabetical order. An alphabetical index of the terms defined is provided at the end of this document.

For terms that have different definitions in differing contexts, the definition context is specified in <> before the definition.

This document is a “controlled vocabulary”, which includes “pre-coordinated terms”. It is expected that users of this document may also create “post-coordinated terms” by a process of concatenation as appropriate to the field of use. Within the field of terminology standards, a pre-coordinated term is a verbal designation of a concept with more than one root that can be split morphologically into separate components and which is predefined in a controlled vocabulary, for example *minute volume* and *pressure-limiting valve*, while a post-coordinated term is a verbal designation of a concept with more than one root, created by a user by combining terms from controlled vocabularies. An example of this would be *supraglottic airway device*, which can be created by combining the two individually defined terms *supraglottic* and *airway device*.

Anaesthetic and respiratory equipment — Vocabulary

1 Scope

This document establishes a vocabulary of terms used for anaesthetic and respiratory equipment and supplies, related devices and supply systems.

NOTE 1 To avoid multiple definitions of the same term in different categories, this document attempts to ensure consistency by the inclusion of a 'general' category, and by use of domain specifiers and unique pre-coordinated domain-specific term names.

NOTE 2 In addition to terms and definitions used in two of the three official ISO languages (English and French), this document gives the equivalent terms in the German language; these are published under the responsibility of the member body for Germany. However, only the terms and definitions given in the official languages can be considered as ISO terms and definitions.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 General concepts

3.1.1 Properties of gases and materials

3.1.1.1

absolute humidity

mass of water vapour present in a unit volume of gas

Note 1 to entry: In respiratory applications *absolute humidity* is commonly represented in units of milligrams per litre or grams per cubic metre, with volume expressed at BPTS condition.

Note 2 to entry: See also *relative humidity* (3.1.2.4).

3.1.1.2

adiabatic compression

compression process that occurs without transfer of heat into or out of a system

3.1.1.3

aerosol

suspension of liquid or solid particles in a gas

3.1.1.4

air for driving surgical tools

natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, and intended to act as a power source for surgical tools

3.1.1.5

anaesthetic gas

gas, which may be the vapour of a volatile anaesthetic agent, or mixture of gases, used in anaesthesia

Note 1 to entry: In parts of an *anaesthetic breathing system* (3.6.1.8), *anaesthetic gas* includes gases exhaled by the patient.

3.1.1.6

auto-ignition temperature

temperature at which a material will spontaneously ignite under specified conditions

3.1.1.7

body temperature and pressure saturated

BTPS

ambient atmospheric pressure, at a temperature of 37 °C, and at a *relative humidity* (3.1.2.4) of 100 %

3.1.1.8

standard temperature and pressure dry

STPD

pressure of 101,325 kPa at a temperature of 20 °C, dry

3.1.1.9

carrier gas

<respiratory therapy> respirable gas that conveys a substance or substances to the patient

EXAMPLE *Medical air* (3.1.1.18) used to convey a bronchodilatory drug.

3.1.1.10

carrier gas

<anaesthesia> respirable gas that conveys one or more *anaesthetic gases* (3.1.1.5) to the patient

EXAMPLE Ambient air and *oxygen* (3.1.1.21) mixture in a *draw-over vaporiser* (3.3.2.3).

3.1.1.11

combustion

rapid oxidation to produce heat and light

3.1.1.12

compliance

change in volume of gas per unit pressure change within an enclosed space

Note 1 to entry: It is deprecated to include the measurement conditions into the definition of *compliance*; in general *compliance* may be expressed at any specified measurement condition.

Note 2 to entry: ISO 19223 provides definitions for pulmonary *compliance*, respiratory system *compliance*, static *compliance* and dynamic *compliance*, all of which relate to the patient. Various other standards from ISO/TC 121 reference *compliance* with respect to items of equipment such as *breathing tubes* (3.1.4.4) and reservoir bags.

3.1.1.13

delivered gas temperature

temperature of the gas, or *aerosol* (3.1.1.3) or both, being delivered to a patient, referenced to the *patient-connection port* (3.1.4.41)

3.1.1.14

delivered oxygen concentration

concentration of oxygen in the gas delivered at a specified location

EXAMPLE In a closed *anaesthetic breathing system* (3.6.1.8), 100 % oxygen can be added to the *breathing system* (3.6.1.1) to match the patient's oxygen consumption, with the *respiratory gas monitor* (3.11.2.1) at the *patient-connection port* (3.1.4.41) measuring a much lower value for FiO_2 (3.1.1.15).

3.1.1.15

FiO_2

fraction of inspired oxygen

concentration of oxygen in the gas inspired by a patient

Note 1 to entry: The measurement site for FiO_2 should be specified by the equipment manufacturer but should be referenced to the concentration of oxygen in the gas that is intended to be inspired.

EXAMPLE In a closed *anaesthetic breathing system* (3.6.1.8), 100 % oxygen can be added to the *breathing system* (3.6.1.1) to match the patient's oxygen consumption, with the *respiratory gas monitor* (3.11.2.1) at the *patient-connection port* (3.1.4.41) measuring a much lower value for FiO_2 .

3.1.1.16

fresh gas

respirable gas delivered to a *breathing system* (3.6.1.1)

Note 1 to entry: In a *circle breathing system* (3.6.1.8.1), the *fresh gas* is all respirable gas delivered into the *circle breathing system* (including *anaesthetic gases* (3.1.1.5) and vapours). This can include *oxygen* (3.1.1.21) or air delivered into an *anaesthetic vaporiser* (3.3.2.2), and it can also include the vapour generated by an *anaesthetic vaporiser*.

Note 2 to entry: In an open *breathing system* (3.6.1.1), the *fresh gas* is all respirable gas delivered into the *breathing system* (which can be at any point within the *breathing system*).

3.1.1.17

gas for medicinal use

gas or mixture of gases that can be used either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

3.1.1.18

medical air

natural or synthetic mixture of gases, mainly composed of oxygen and nitrogen in specified proportions, with defined limits for the concentration of contaminants, intended for administration to patients

3.1.1.19

medical device gas

gas or mixture of gases intended by the manufacturer to be used as a medical device or as an accessory to a medical device

Note 1 to entry: This encompasses uses for investigation or modification of the anatomy or of a physiological process, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Note 2 to entry: In some countries, *medical device gases* may be regulated as a medical device, a drug or not subject to regulation.

EXAMPLE 1 Liquid gases used for cryoablation.

EXAMPLE 2 Gases used to provide an anaerobic atmosphere.

EXAMPLE 3 Compressed air for hyperbaric chambers.

EXAMPLE 4 Driving gas for surgical tools.

EXAMPLE 5 Inflating gases for laparoscopy.

3.1.1.20

medical gas

any gas or mixture of gases intended for administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes, or as a source of pneumatic power for medical or surgical tools

3.1.1.21

oxygen

gas for medicinal use (3.1.1.17) where the oxygen concentration is at least the minimum specified in the relevant pharmacopoeia monograph

3.1.1.22

oxygen 93

DEPRECATED: oxygen-enriched air

gas for medicinal use (3.1.1.17) where the oxygen concentration is at least the minimum specified in the relevant pharmacopoeial monograph for oxygen 93

Note 1 to entry: *Oxygen 93* is usually manufactured at the healthcare provider site by a pressure-swing adsorption *oxygen concentrator* (3.2.1.3.7).

3.1.1.23

partial pressure

pressure that each gas in a gas mixture would exert if it alone occupied the volume of the mixture at the same temperature

3.1.1.24

saturation vapour pressure

partial pressure (3.1.1.23) of vapour at a given temperature at a liquid-gas interface when a dynamic equilibrium between vaporisation and condensation is reached

3.1.1.25

suction

application of *vacuum* (3.1.1.27) to remove liquid, solid particles, *aerosol* (3.1.1.3) or gas

3.1.1.26

thermal conductivity

rate of heat flow through a unit area, per unit temperature gradient, in the direction perpendicular to the area

3.1.1.27

vacuum

pressure less than ambient pressure

3.1.1.28

volume fraction

volume percent

volume of a gas in a mixture, expressed as a proportion of the total volume

Note 1 to entry: *Volume fraction* can be expressed as a percentage or as a fraction.

Note 2 to entry: The synonym *volume percent* is reserved for the expression of *volume fraction* as a percentage.

3.1.2 Properties of equipment

3.1.2.1

accessible surface temperature

temperature of any surface of the device that can come into contact with any part of the human body during normal use, including during maintenance operations that occur during clinical use

Note 1 to entry: Maintenance operations include refilling a reservoir with water or medication; cleaning and decontamination; and replacement of batteries.

3.1.2.2

antistatic

property of a material or procedure that disperses or inhibits the accumulation of electrostatic charges

3.1.2.3

gas-specific

having characteristics which prevent connections between different gas services, *vacuum* (3.1.1.27) services and *anaesthetic gas scavenging systems* (3.9.1.1).

Note 1 to entry: *Terminal units* (3.2.2.1), *cylinder outlets* (3.1.4.40), *low-pressure hose assemblies* (3.2.3.1), and equipment gas *inlets* (3.1.4.26) and *outlets* (3.1.4.40) are examples of gas services.

3.1.2.4

relative humidity

water vapour pressure, expressed as a percentage of the *saturation vapour pressure* (3.1.1.24), at a particular temperature

Note 1 to entry: See also *absolute humidity* (3.1.1.1).

3.1.3 Metrology concepts

3.1.3.1

accuracy

measurement accuracy

DEPRECATED: accuracy of measurement

closeness of agreement between a measured quantity and a true quantity value of a measurand

Note 1 to entry: The term *accuracy*, when applied to a set of test results, involves a combination of a random component and of a common systematic error or *bias error* (3.1.3.3) component.

Note 2 to entry: In practical terms, a reference value is commonly used with an assumption that it represents the true quantity value.

3.1.3.2

accuracy of flow

difference between the indicated flow and the actual flow

3.1.3.3

bias error

DEPRECATED: bias

difference between the expectation of the test results and an accepted reference value

Note 1 to entry: *Bias error* is the total systematic error as contrasted to random error. There can be one or more systematic error components contributing to the *bias error*. A larger systematic difference from the accepted reference value is reflected by a larger *bias error* value.

Note 2 to entry: Expectation is a statistical term which can be interpreted approximately as the mean of the values that would be obtained if the measurement were made many times.

3.1.3.4

calibration

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

3.1.3.5

calibration range

range of values over which a monitoring device or a control should be tested and verified

3.1.3.6

declared range

DEPRECATED: measurement range

portion of the *displayed range* (3.1.3.10) of measured values over which there is specified *accuracy* (3.1.3.1)

3.1.3.7

display

visual representation of quantitative or qualitative information

3.1.3.8

display update period

duration of time, or number of events (e.g. pulses), between possible changes in the displayed values

3.1.3.9

data update period

duration of time, or number of events (e.g. pulses), between possible changes in the data provided by a *monitoring equipment* (3.11.1.3) algorithm to the *display* (3.1.3.7) or to the signal input/output part

Note 1 to entry: This definition does not refer to any regular refresh period of the *display* (3.1.3.7), but rather to the output of new values of the monitored parameter. The definition encompasses both that the measurement may be taken at asynchronous intervals, and also that the data transmitted to another device may be queued asynchronously due to communication bandwidth or other issues.

Note 2 to entry: A device can have more than one signal input/output part, each with its own specified *data update period*.

3.1.3.10

displayed range

range of values that can be displayed for a specific parameter

Note 1 to entry: The *displayed range* can extend beyond the *declared range* (3.1.3.6).

3.1.3.11

drift

change in the reading of a measuring instrument over a stated period of time, under reference conditions that remain constant, where the quantity or property that is measured remains the same

3.1.3.12

laboratory accuracy

closeness of agreement between the output of a measuring device under laboratory conditions and the true value of the measurand.

Note 1 to entry: *Laboratory accuracy* is a qualitative concept. For a quantitative description, the term 'uncertainty' should be used.

3.1.3.13

long-term automatic mode

mode in which a timer, set by the user, initiates multiple *intermittent* (3.11.1.2) measurements

3.1.3.14

measuring site

part of a patient or equipment where a quantity is measured

EXAMPLE Pulmonary artery, distal oesophagus, sublingual space in the mouth, rectum, ear canal, axilla (armpit), forehead skin, *ventilator breathing system* (3.4.1.9).

Note 1 to entry: See also *reference body site* (3.1.3.17).

3.1.3.15

normalized

displayed at constant amplitude, independent of the actual magnitude of the signal being displayed

3.1.3.16

precision

closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

Note 1 to entry: Measurement *precision* is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.

Note 2 to entry: The ‘specified conditions’ can be, for example, *repeatability* (3.1.3.18) conditions of measurement, intermediate precision conditions of measurement, or reproducibility conditions of measurement (see ISO 5725-1).

Note 3 to entry: Measurement *precision* is used to define measurement *repeatability* (3.1.3.18), intermediate measurement precision, and measurement reproducibility.

Note 4 to entry: Sometimes “measurement *precision*” is erroneously used to mean *measurement accuracy* (3.1.3.1).

Note 5 to entry: *Precision* depends on random errors and does not relate to the true value or the specified value.

Note 6 to entry: “Independent test results” means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. *Repeatability* (3.1.3.18) and reproducibility conditions are particular sets of extreme stipulated conditions.

3.1.3.17

reference body site

part of a patient to which the indicated quantity refers

Note 1 to entry: A clinical measuring device may estimate a parameter such as core temperature based on measurements from a different *measuring site* (3.1.3.14), such as the ear canal.

3.1.3.18

repeatability

precision (3.1.3.16) of the same measurand carried out under the same conditions of measurement

3.1.3.19

self-measurement automatic mode

mode in which a user action initiates a limited number of *intermittent* (3.11.1.2) measurements

3.1.3.20

short-term automatic mode

mode in which a user action initiates a sequence of repetitive automatic *intermittent* (3.11.1.2) measurements within a specified time period

3.1.4 Equipment components

3.1.4.1

adaptor

specialized *connector* (3.1.4.5) to establish functional continuity between otherwise disparate or incompatible components

3.1.4.2

adsorber

device that removes volatile organic compounds or specified gases from a gas stream by a process of adsorption

Note 1 to entry: In specific applications an *adsorber* may be intended to remove a single gas, such as nitrogen from air; or a category of gases, such as odorous volatile organic compounds.

3.1.4.3

blackbody

reference temperature source of infrared radiation made in the shape of a cavity and characterized by precisely known temperature of the cavity walls and having an effective emissivity at the cavity opening as close as practical to unity

3.1.4.4

breathing tube

non-rigid tube used to convey gases or vapours within the *user-detachable* (3.1.4.38) section of a *breathing system* (3.6.1.1)

Note 1 to entry: A *breathing set* (3.6.1.6) typically comprises one or more *breathing tubes*, *connectors* (3.1.4.5) and other components that provide for the functions of the detachable section of a *breathing system* (3.6.1.1).

3.1.4.5

connector

fitting to join two or more components

EXAMPLE *Connectors for low-pressure hose assembly* (3.2.3.1) are any of a range of mating components intended to maintain *gas specificity* (3.1.2.3) by the allocation of a set of different diameters to the mating *connectors* for each particular gas.

3.1.4.6

control system

device or set of devices to manage, command, direct or regulate the behaviour of other device(s) or system(s)

3.1.4.7

cuff

<airway devices> inflatable balloon permanently attached around the *airway device* (3.8.1.2) near the *patient end* (3.1.4.42) to provide a seal between the device and the patient's *airway* (3.8.1.1)

3.1.4.8

cuff

<blood pressure measurement> part of the *automated sphygmomanometer* (3.11.6.1.1) that is wrapped around the limb of the patient

3.1.4.9

equipment mount

component used to attach medical equipment to an *equipment mount holder* (3.1.4.9.1)

3.1.4.9.1

equipment mount holder

component of a *rail system* (3.1.4.50) to which an *equipment mount* (3.1.4.9) can be attached and detached

3.1.4.9.2

equipment mount pin

component of a *rail system* (3.1.4.50) used to attach medical equipment to an *equipment mount pin holder* (3.1.4.9.3)

3.1.4.9.3

equipment mount pin holder

component of a *rail system* (3.1.4.50) to which an *equipment mount pin* (3.1.4.9.2) can be attached and removed

3.1.4.10

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* (3.1.4.5) or designed to not allow connection with any *connector*.

3.1.4.11

exhaust port

port (3.1.4.10) through which gas is discharged to the atmosphere or to an *anaesthetic gas scavenging system* (3.9.1.1)

Note 1 to entry: This definition is intentionally generic. The exhaust gas may be leaving the *breathing system* (3.6.1.1), from an over-pressure relief device, or from other components.

Note 2 to entry: This term encompasses applications in which an exhaust port is connected to the input of an *anaesthetic gas scavenging system* (3.9.1.1).

3.1.4.12

exhaust valve

valve with an *outlet* (3.1.4.40) connected to an *exhaust port* (3.1.4.11)

EXAMPLE An adjustable pressure-limiting valve (3.6.3.5).

3.1.4.13

eye

lateral aperture near the end of a catheter or *airway device* (3.8.1.2)

3.1.4.14

flow outlet

outlet (3.1.4.40) intended to deliver a controlled flow of gas

3.1.4.15

flow-direction-sensitive component

component or accessory through which gas flow has to be in one direction only for proper functioning or patient safety

3.1.4.16

flowgauge

<medical gas supply systems> device that measures pressure and is calibrated in units of flow

Note 1 to entry: The *flowgauge* does not measure flow. It indicates flow by measuring the pressure upstream of a fixed *orifice* (3.1.4.39)

3.1.4.17

flowmeter

equipment that measures and indicates the rate of flow of a specific gas or gas mixture

Note 1 to entry: A *flowmeter* can be calibrated for use within specified conditions for gas temperature, pressure, and composition.

3.1.4.18

flow-metering device

device which controls the flow of gas from an *inlet connector* (3.1.4.26.1) to an *outlet* (3.1.4.40) *connector* (3.1.4.5)

EXAMPLE 1 *Flowmeter* (3.1.4.17) with a flow control valve.

EXAMPLE 2 *Flowgauge* (3.1.4.16) and fixed *orifice* (3.1.4.39) with a flow control valve.

EXAMPLE 3 One or more fixed *orifices* (3.1.4.39) with a means of selection.

3.1.4.19

flow selector

means for selecting the flow and indicating the flow selected

Note 1 to entry: A *flow selector* can be calibrated for use within specified conditions for gas temperature, pressure, and composition.

3.1.4.20

fresh-gas inlet

port (3.1.4.10) through which *fresh gas* (3.1.1.16) enters the *breathing system* (3.6.1.1)

3.1.4.21

gas intake port

port (3.1.4.10) through which gas is drawn for use by the patient

Note 1 to entry: Gas is drawn at a sub-ambient pressure at a *gas intake port*, in apposition to an *inlet* (3.1.4.26), at which gas is provided by a *medical gas supply system* (3.2.1.2).

3.1.4.22

gas output port

DEPRECATED: inspiratory port

port (3.1.4.10) of the device through which gas is delivered at *respiratory pressures* (3.6.1.2) to a *user-detachable* (3.1.4.38) part of a *breathing system* (3.6.1.1)

Note 1 to entry: The *gas output port* of a device is where the *inspiratory port* (3.1.4.10) of the *user-detachable* (3.1.4.38) part of a *breathing system* (3.6.1.1) is attached.

3.1.4.23

gas return port

DEPRECATED: expiratory port

port (3.1.4.10) of the medical electrical equipment or device through which gas is returned at *respiratory pressures* (3.6.1.2) through an *user-detachable* (3.1.4.38) part of a *breathing system* (3.6.1.1), from the *patient-connection port* (3.1.4.41)

Note 1 to entry: The *gas return port* of a device is where the *expiratory port* (3.1.4.10) of the *user-detachable* (3.1.4.38) part of a *breathing system* (3.6.1.1) is attached.

3.1.4.24

high-pressure inlet

DEPRECATED: high-pressure input port

<ventilator; respiratory therapy equipment> *inlet* (3.1.4.26) to which gas is supplied at a pressure exceeding 100 kPa above ambient

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* (3.6.1.1) pressures (typically less than 10 kPa), terminal *outlet* (3.1.4.40) pressures (less than 600 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

3.1.4.25

hose insert

portion of a *connector* (3.1.4.5) which is pushed into and secured within the bore (lumen) of the hose

3.1.4.26

inlet

DEPRECATED: inlet port

DEPRECATED: input port

opening through which gas or other material is pushed by an elevated upstream pressure

Note 1 to entry: An *inlet* is intended for an elevated upstream pressure and therefore necessarily incorporates some form of *connector* (3.1.4.5). The terms *inlet port* and *input port* have historical usage, with no change in meaning. To avoid confusion that can arise when a single concept is represented by multiple terms, these alternates are deprecated.

3.1.4.26.1

inlet connector

connector (3.1.4.5) on an *inlet* (3.1.4.26)

EXAMPLE Connection on a *low-flow nasal cannula* (3.8.6.2) that connects to the *outlet* (3.1.4.40) of *oxygen therapy* (3.1.5.9) tubing.

Note 1 to entry: An *inlet connector* can be *gas-specific* (3.1.2.3), but this should be indicated with the post-coordinated term *gas-specific (3.1.2.3) inlet connector*.

3.1.4.27

intake

DEPRECATED: intake port

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

3.1.4.28

liquid container

part of a vaporiser, *nebulizer* (3.7.3.1) or *humidifier* (3.7.2.1) that holds the liquid

Note 1 to entry: The *liquid container* can be accessible to the breathing gas.

Note 2 to entry: The *liquid container* can also be part of the *humidification chamber* (3.7.2.5).

Note 3 to entry: The *liquid container* can be detachable for filling.

3.1.4.28.1

maximum fill volume

volume of liquid in the *liquid container* (3.1.4.28) when filled to its marked maximum filling level

3.1.4.29

liquid reservoir

reservoir from which the *liquid container* (3.1.4.28) may be replenished or which, in the absence of a *liquid container*, supplies liquid directly to a vaporiser or *aerosol* (3.1.1.3) generator

3.1.4.30

low-pressure inlet

DEPRECATED: low-pressure input port

<ventilator; respiratory therapy equipment> *inlet* (3.1.4.26) to which gas may be supplied at a pressure not exceeding 100 kPa above ambient

Note 1 to entry: *Low-pressure input port* is deprecated as a synonym as *input port* (3.1.4.26) is deprecated as a synonym for an *inlet* (3.1.4.26).

Note 2 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* (3.6.1.1) pressures (typically less than 10 kPa), terminal *outlet* (3.1.4.40) pressures (less than 1 400 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

3.1.4.31

machine end

end of the device or component which is intended to be connected furthest from the patient, and closest to the source of *medical gas* (3.1.1.20) or *vacuum* (3.1.1.27)

Note 1 to entry: The *machine end* of a *tracheal tube* (3.8.3.1) is the end that connects to the *patient-connection port* (3.1.4.41); the *machine end* of a *breathing tube* (3.1.4.4) is the end that is intended to be connected to the *gas output port* (3.1.4.22) of a *ventilator* (3.4.1.1).

3.1.4.32

maximum operating pressure

maximum pressure which a device is intended to be subjected to during normal use

3.1.4.33

medical supply unit

permanently installed medical electrical equipment intended to provide patient care infrastructure to medical areas of a *healthcare facility* (3.1.6.6)

Note 1 to entry: The functions provided can include electric power, telecommunications, lighting, *medical gases* (3.1.1.20), liquids, plume evacuation, or anaesthetic gas scavenging.

3.1.4.34

nominal inlet pressure

upstream pressure specified by the manufacturer for which the *inlet* (3.1.4.26) is intended to be used

3.1.4.35

non-rebreathing valve

valve intended to prevent the inspiration of any expired gas

3.1.4.36

non-return valve

DEPRECATED: unidirectional valve

valve which permits flow in one direction only

3.1.4.37

user control

control that allows the user to cause the device to perform its intended function, without the need for tools

3.1.4.38

user-detachable

detachable without the use of a tool

3.1.4.39

orifice

<medical gas flow control> restriction of known cross-section that delivers a constant flow of gas when supplied with gas at a constant upstream pressure

3.1.4.40

outlet

opening through which gas leaves a device or component

3.1.4.41

patient-connection port

port (3.1.4.10) of a *breathing system* (3.6.1.1) intended for connection to an *airway device* (3.8.1.2)

Note 1 to entry: The *patient-connection port* is the end of the *breathing system* (3.6.1.1) proximal to the patient.

Note 2 to entry: The *patient-connection port* is typically a *connector* (3.1.4.5) suitable for connection to an *airway device* (3.8.1.2) such as a *tracheal tube* (3.8.3.1), *tracheostomy tube* (3.8.5.1), *face mask* (3.8.6.4) or *supralaryngeal airway* (3.8.2.3).

Note 3 to entry: Current product standards typically specify that the *patient-connection port* is required to be in the form of specific standardized *connectors* (3.1.4.5), for example, a *connector* (3.1.4.5) conforming to ISO 5356-1.

Note 4 to entry: In anaesthetic and respiratory equipment where its function is dependent upon a design feature of the component that connects the equipment to the patient's *airway* (3.8.1.1), then there is no *patient-connection-port*. Examples would include non-invasive ventilation using a *face mask* (3.8.6.4) with an integrated expiratory *port* (3.1.4.10), or *oxygen therapy* (3.1.5.9) using an open *mask* (3.8.6.4).

3.1.4.41.1

airway pressure

pressure at the *patient-connection port* (3.1.4.41) or at the distal *outlet* (3.1.4.40) of the equipment where there is no *patient-connection port*

Note 1 to entry: The *airway pressure* can be derived from pressure measurements made anywhere within the equipment.

3.1.4.41.2

mean airway pressure

mean value of the pressure at the *patient-connection port* (3.1.4.41) or at the distal *outlet* (3.1.4.40) of the equipment where there is no *patient-connection port* over a specified period

Note 1 to entry: The mean can be determined over a specified period of time, or over the period of a specified event.

Note 2 to entry: The *mean airway pressure* can be derived from pressure measurements made anywhere within the equipment.

3.1.4.41.3

maximum limited airway pressure

maximum limited pressure

$p_{\text{lim,max}}$

highest *airway pressure* (3.1.4.41.1) that can occur during normal use or under single fault condition

3.1.4.41.4

minimum limited airway pressure

minimum limited pressure

$p_{\text{lim,min}}$

lowest *airway pressure* (3.1.4.41.1) that can occur during normal use or under single fault condition

Note 1 to entry: The *minimum limited pressure* can be sub-atmospheric.

3.1.4.41.5

pressure amplitude

peak-to-trough magnitude of the pressure variation during high-frequency ventilation, as measured at the *patient-connection port* (3.1.4.41)

3.1.4.42

patient end

end of a device which is intended to be closest to or inserted into the patient

3.1.4.43

pressure drop

difference between the pressure measured in a gas stream flowing into a device and the pressure measured in the gas stream flowing out of the device, with a specified constant gas flowrate through the device

3.1.4.44

pressure gauge

device that measures and indicates pressure

3.1.4.45

pressure transducer

component that transforms sensed pressure into an electrical signal

3.1.4.46

pressure-relief device

pressure-relief valve

device intended to relieve excess pressure at a pre-set value

3.1.4.47

probe

connector (3.1.4.5) designed for acceptance by, and retention in, a *socket* (3.1.4.52)

Note 1 to entry: In anaesthesia and respiratory therapy, *probes* for many applications are required to be *gas-specific* (3.1.2.3).

3.1.4.48

protection device

part or function of 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

3.1.4.49

quick connector

pair of type-specific components which can be easily and rapidly joined together by a single action of one or both hands without the use of tools

3.1.4.50

rail system

assembly of components comprising at least a rail, rail supports and rail clamps, and intended to secure medical equipment to a structure or other equipment

3.1.4.51

sensor

transducer

component that transforms a sensed physical or chemical quantity into an electrical signal

3.1.4.52

socket

connector (3.1.4.5) designed with one or more orifices, that accepts a mating *connector* which is retained within the socket's orifice(s)

Note 1 to entry: The means of retention can be a screw thread, a mechanical latch (such as in the case of a *gas-specific* (3.1.2.3) *probe* (3.1.4.47)), an interference fit or other means.

3.1.4.53

Y-piece

adaptor (3.1.4.1) comprising a *patient-connection port* (3.1.4.41) and two *ports* (3.1.4.10) for connection to *breathing tubes* (3.1.4.4)

3.1.5 Physiological terms

3.1.5.1

anatomical airway

natural pathways through which respired gases pass in either direction between the atmosphere and the alveoli

3.1.5.2

blood pressure

pressure in the systemic arterial system of the body

Note 1 to entry: Pressure in the arterial system is not uniform throughout the body. Interpretation requires knowledge of the context of use including the method and site of measurement.

3.1.5.3

diastolic blood pressure

minimum value of the *blood pressure* (3.1.5.2) during a cardiac cycle

3.1.5.4

expiratory phase

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

3.1.5.5

inspiratory phase

interval from the start of inspiratory flow to the start of expiratory flow during an unassisted breath

Note 1 to entry: This term is restricted to the designation of unassisted inspirations because, when used in relation to a breath in natural language, the verb inspire is closely associated with a patient action.

Note 2 to entry: In order to avoid any inference of 'ventilators breathing', the intervals during which inflations are delivered are designated as *inflation phases* (3.1.5.6), see also ISO 19223.

3.1.5.6

inflation phase

interval from the start of the rise in *airway pressure* (3.1.4.41.1) resulting from the initiation of an inflation to the start of the expiratory flow resulting from its termination

3.1.5.7

expired tidal volume

volume of gas leaving a patient or a test apparatus during an *expiratory phase* (3.1.5.4)

3.1.5.8

minute volume

V_M

volume of gas per minute entering or leaving the patient's lungs

3.1.5.9

oxygen therapy

supplemental *oxygen* (3.1.1.21) administered to a patient at atmospheric pressure

3.1.5.10

high flow oxygen therapy

delivery of heated humidified respirable gas at a controlled and greater than atmospheric oxygen concentration and high flow through a *high-flow nasal cannula* (3.8.6.3) set

Note 1 to entry: The respirable gas can be *oxygen* (3.1.1.21), *oxygen 93* (3.1.1.22) or a controlled mixture of air and *oxygen* (3.1.1.21).

Note 2 to entry: The flow is usually intended to exceed the inspiratory flow requirements of the patient.

3.1.5.11

positive end-expiratory pressure

PEEP

positive *airway pressure* (3.1.4.41.1) at the end of an *expiratory phase* (3.1.5.4)

3.1.5.12

rebreathing

inhalation of expired gas mixture from which carbon dioxide may or may not have been removed

3.1.5.13

recruitment manoeuvre

temporary increase in the *mean airway pressure* (3.1.4.41.2) provided during *artificial ventilation* (3.4.1.2), with or without a momentary pause of the *artificial ventilation*, intended to expand the lungs

Note 1 to entry: This definition is differentiated from temporary increase in *mean airway pressure* (3.1.4.41.2) intended to measure static *compliance* (3.1.1.12) of the respiratory system.

3.1.5.14

SaO₂

arterial oxygen saturation

proportion of functional haemoglobin in arterial blood that is saturated with oxygen

Note 1 to entry: *SaO₂* is normally expressed as a percentage (multiplying the fraction by 100).

3.1.5.15

sigh

<ventilator> deliberate increase in delivered volume for one or a few breaths

3.1.5.16

SpO₂

arterial oxygen saturation (3.1.5.14) as estimated by a *pulse oximeter* (3.11.3.1)

Note 1 to entry: *SpO₂* is normally expressed as a percentage (multiplying the fraction by 100).

Note 2 to entry: *SpO₂* may under- or over-estimate *SaO₂* (3.1.5.14) due to the inability to differentiate dysfunctional forms of haemoglobin.

3.1.5.17

systolic blood pressure

maximum value of the *blood pressure* (3.1.5.2) during a cardiac cycle

3.1.5.18

upper airway

anatomical airway (3.1.5.1) above the laryngotracheal junction

3.1.5.19

ventilator-dependent

dependent upon *artificial ventilation* (3.4.1.2) 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.

EXAMPLE Patients with Duchennes Muscular Dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

3.1.6 Use environment and workflow

3.1.6.1

cardiopulmonary resuscitation

combination of rescue breathing and chest compressions delivered to victims thought to be in cardiac arrest

3.1.6.2

healthcare professional

individual with appropriate certification, training, knowledge and skills who provides preventive, curative, promotional or rehabilitative healthcare services in a systematic way to people, families or communities

3.1.6.3

intubation

placement of a *tracheal tube* (3.8.3.1) into the trachea

3.1.6.4

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* (3.1.6.7) between patients.

Note 2 to entry: A *multiple patient multiple use* medical device or accessory may require *processing* (3.1.6.7) between uses on a single patient.

3.1.6.5

oxidant-enriched atmosphere

any atmosphere that contains oxidants (O₂, N₂O) in total concentration greater than 25 % of volume at ambient pressure

3.1.6.6

healthcare facility

facility where professional health services are provided

Note 1 to entry: The requirements for a *healthcare facility* can differ between jurisdictions.

Note 2 to entry: A *healthcare facility* will normally be continuously staffed by suitably trained *healthcare professionals* (3.1.6.2) when patients are present.

Note 3 to entry: Provision of healthcare services within a residential or other building not intended as a *healthcare facility* does not fall within scope of this definition, as the building is not primarily used as a *healthcare facility*.

EXAMPLE Hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical treatment facilities.

3.1.6.7

processing

DEPRECATED: reprocessing

activity to prepare a new or used medical device or accessory for its intended use

Note 1 to entry: *Processing* includes cleaning, disinfection and sterilization (if necessary and applicable).

Note 2 to entry: *Processing* can be applicable to a medical device accessory.

Note 3 to entry: Such activities can occur in *healthcare facilities* (3.1.6.6).

3.1.6.8

single patient multiple use

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* (3.1.6.7) between uses.

Note 2 to entry: See also *single use* (3.1.6.9).

3.1.6.9

single use

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 used again. This includes undergoing *processing* (3.1.6.7).

Note 2 to entry: For an implantable medical device, the duration of a *single use* is from implanting to explanting the medical device.

Note 3 to entry: See also *single patient multiple use* (3.1.6.8).

3.1.6.10

transport use

use during patient transport outside of a *healthcare facility* (3.1.6.6)

EXAMPLE Use in an ambulance or aeroplane.

3.1.6.11

transit-operable

intended for use while being moved

EXAMPLE A medical device that is body-worn, hand-held, attached to a wheelchair, or used in a car, bus, train, boat or plane.

3.2 Medical gas supply systems

3.2.1 Pipeline systems

3.2.1.1

medical gas pipeline system

combination of a *supply system* (3.2.1.2), monitoring and alarm system and a *pipeline distribution system* (3.2.1.6) with *terminal units* (3.2.2.1) for provision of *medical gases* (3.1.1.20) or *vacuum* (3.1.1.27)

3.2.1.2

supply system

medical gas supply system

combination of one or more *sources of supply* (3.2.1.3) that provides *medical gases* (3.1.1.20) to a *pipeline distribution system* (3.2.1.6)

3.2.1.3

source of supply

portion of the *supply system* (3.2.1.2) with associated *control equipment* (3.2.1.5) which supplies the *pipeline distribution system* (3.2.1.6)

Note 1 to entry: The *source of supply* comprises all sources of *medical gas* (3.1.1.20), such as

- a) a system of gas cylinders;
- b) cryogenic or non-cryogenic liquid supply;
- c) air compressors;
- d) proportioning equipment;
- e) *oxygen concentrators* (3.2.1.3.7);
- f) vacuum pumps

3.2.1.3.1

primary source of supply

portion of the *supply system* (3.2.1.2) which is the first to be drawn upon to supply the *pipeline distribution system* (3.2.1.6)

3.2.1.3.2

secondary source of supply

portion of the *supply system* (3.2.1.2) which supplies the *pipeline distribution system* (3.2.1.6) in the event of exhaustion or failure of the *primary source of supply* (3.2.1.3.1)

3.2.1.3.3

reserve source of supply

portion of the *supply system* (3.2.1.2) which supplies the complete, or portion(s) of the *pipeline distribution system* (3.2.1.6) in the event of failure or exhaustion of both the *primary source of supply* (3.2.1.3.1) and *secondary source of supply* (3.2.1.3.2)

3.2.1.3.4

cryogenic liquid system

supply system (3.2.1.2) containing a gas stored in the liquid state in a vessel at temperatures lower than -150 °C

3.2.1.3.5

non-cryogenic liquid system

supply system (3.2.1.2) containing a gas stored under pressure in the liquid state in a vessel at temperatures not lower than -150°C

3.2.1.3.6

air compressor system

supply system (3.2.1.2) with compressor(s) designed to provide *medical air* (3.1.1.18) or *air for driving surgical tools* (3.1.1.4)

3.2.1.3.6.1

booster compressor

compressor used to raise an elevated pressure to a higher pressure

3.2.1.3.7

oxygen concentrator

component of *source of supply* (3.2.1.3) that produces *oxygen 93* (3.1.1.22) from ambient air by extraction of nitrogen

3.2.1.3.7.1

membrane oxygen concentrator

oxygen concentrator (3.2.1.3.7) which functions by selective permeation of oxygen through a membrane

3.2.1.3.7.2

pressure swing adsorption device

PSA

molecular sieve device

oxygen concentrator (3.2.1.3.7) which functions by selective retention and purging of nitrogen during alternate pressurization and passage of ambient air through beds of molecular sieve material

3.2.1.3.8

proportioning unit

component of *source of supply* (3.2.1.3) in which gases are mixed in a fixed ratio

3.2.1.3.9

emergency inlet point

inlet (3.1.4.26) point within a *pipeline distribution system* (3.2.1.6) which allows the connection of an *emergency supply* (3.2.1.3.10)

3.2.1.3.10

emergency supply

source of supply (3.2.1.3) intended to be connected to an *emergency inlet point* (3.2.1.3.9) within a *pipeline distribution system* (3.2.1.6)

3.2.1.3.11

maintenance supply inlet point

DEPRECATED: maintenance supply assembly

inlet (3.1.4.26) which allows the connection of a *maintenance supply* (3.2.1.3.12)

3.2.1.3.12

maintenance supply

source of supply (3.2.1.3) intended to supply the system during maintenance

3.2.1.3.13

supply pressure regulator

pressure regulator (3.2.4.1) fitted within a *source of supply* (3.2.1.3) and intended to regulate the pressure supplied to the *line pressure regulators* (3.2.1.6.2)

3.2.1.4

vacuum source

component of *source of supply* (3.2.1.3) which includes pumps designed to provide flow at less than ambient pressure

Note 1 to entry: See also *vacuum* (3.1.1.27).

3.2.1.5

control equipment

items necessary to maintain the *medical gas* (3.1.1.20) *supply system* (3.2.1.2) within the specified operating parameters

EXAMPLE *Pressure regulators* (3.2.4.1), relief valves, alarm initiators, manual and automatic valves.

3.2.1.6

pipeline distribution system

part of a *medical gas pipeline system* (3.2.1.1) linking the *source of supply* (3.2.1.3) to the *terminal units* (3.2.2.1)

3.2.1.6.1

double-stage pipeline distribution system

pipeline distribution system (3.2.1.6) in which gas is initially distributed from the *supply system* (3.2.1.2) at a pressure higher than the *nominal distribution pressure* (3.2.1.11), and is then reduced to the *nominal distribution pressure* (3.2.1.11) by *line pressure regulators* (3.2.1.6.2)

3.2.1.6.2

line pressure regulator

pressure regulator (3.2.4.1) used in a *double-stage pipeline distribution system* (3.2.1.6.1) to reduce the *nominal supply system* (3.2.1.2) pressure to the *nominal distribution pressure* (3.2.1.11)

3.2.1.6.3

pipeline branch

portion of the *pipeline distribution system* (3.2.1.6) which supplies one or more areas on the same floor of the facility

3.2.1.6.4

shut-off valve

isolating valve

zone valve

valve which prevents flow in both directions when closed

3.2.1.6.5

single-stage pipeline distribution system

pipeline distribution system (3.2.1.6) in which gas is distributed from the *supply system* (3.2.1.2) at the *nominal distribution pressure* (3.2.1.11)

3.2.1.7

commissioning

proof of function to verify that the agreed system specification is met and is accepted by the responsible organization

3.2.1.8

diversity factor

factor which represents the maximum proportion of *terminal units* (3.2.2.1) in a defined clinical area which will be used at the same time, at flowrates defined in agreement with the management of the *healthcare facility* (3.1.6.6)

3.2.1.9

maximum distribution pressure

pressure at any *terminal unit* (3.2.2.1) when the *medical gas* (3.1.1.20) *pipeline distribution system* (3.2.1.6) is operating at zero flow

3.2.1.10

minimum distribution pressure

lowest pressure at any *terminal unit* (3.2.2.1) when the *medical gas* (3.1.1.20) *pipeline distribution system* (3.2.1.6) is operating at the *system design flow* (3.2.1.12)

3.2.1.11

nominal distribution pressure

pressure which the *supply system* (3.2.1.2) is intended to deliver at the *terminal units* (3.2.2.1)

3.2.1.12

system design flow

flow calculated from the maximum flow requirement of the *healthcare facility* (3.1.6.6) and corrected by the *diversity factors* (3.2.1.8)

3.2.2 Terminal units

3.2.2.1

terminal unit

outlet (3.1.4.40) assembly, or *inlet* (3.1.4.26) for *vacuum* (3.1.1.27), joined to a *pipeline distribution system* (3.2.1.6) at which the user makes connections and disconnections

3.2.2.2

terminal unit base block

part of a *terminal unit* (3.2.2.1) which is attached to the *medical gas* (3.1.1.20) or *vacuum* (3.1.1.27) *supply system* (3.2.1.2)

3.2.2.3

terminal unit check valve

valve which remains closed until opened by insertion of an appropriate *probe* (3.1.4.47) and which then permits flow in either direction

3.2.2.4

terminal unit maintenance valve

valve which permits maintenance of that *terminal unit* (3.2.2.1) without shutting down the *medical gas* (3.1.1.20) or *vacuum* (3.1.1.27) *supply system* (3.2.1.2) and other *terminal units* (3.2.2.1)

3.2.2.5

gas-specific connection point

part of a *terminal unit* (3.2.2.1) or pressure *outlet* (3.1.4.40) which is the receptor for a *gas-specific* (3.1.2.3) *probe* (3.1.4.47)

3.2.2.6

gas-specific connector

connector (3.1.4.5) with dimensional characteristics which prevent connections between different gas services

EXAMPLE *Non-interchangeable screw threaded connector* (3.2.3.5); *non-interchangeable quick connectors* (3.1.4.49).

3.2.2.7

terminal unit socket

socket (3.1.4.52) within a *terminal unit* (3.2.2.1) which is either integral or attached to the *terminal unit base block* (3.2.2.2) by a *gas-specific* (3.1.2.3) interface and which contains the *gas-specific connection point* (3.2.2.5)

3.2.2.8

maximum test pressure

maximum pressure to which a *terminal unit* (3.2.2.1) is designed to be subjected during pipeline pressure testing

3.2.3 Low-pressure hose assemblies for use with medical gases

3.2.3.1

low-pressure hose assembly

assembly consisting of a flexible hose with permanently attached *gas-specific* (3.1.2.3) *inlet* (3.1.4.26) and *outlet* (3.1.4.40) *connectors* (3.1.4.5) and designed to conduct a *medical gas* (3.1.1.20) at pressures less than 1 400 kPa

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* (3.6.1.1) pressures (typically less than 10 kPa), terminal *outlet* (3.1.4.40) pressures (less than 1 400 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

3.2.3.2

source connector

gas-specific (3.1.2.3) part of a *low-pressure hose assembly* (3.2.3.1) by means of which it may be connected to the *source of supply* (3.2.1.3)

3.2.3.3

equipment connector

gas-specific (3.1.2.3) part of a *low-pressure hose assembly* (3.2.3.1) by means of which it may be connected to medical equipment

3.2.3.4

diameter-indexed safety system connector

DISS connector

range of threaded *connectors* (3.1.4.5) intended to maintain *gas-specificity* (3.1.2.3) by allocation of a set of different diameters to the mating *connectors* for each particular gas or service

3.2.3.5

non-interchangeable screw-threaded connector

NIST connector

range of threaded *connectors* (3.1.4.5) intended to maintain *gas-specificity* (3.1.2.3) by allocation of a set of different diameters and a left- or right-hand screw thread to mating components for each particular gas or service

3.2.3.6

hose assembly check valve

valve which is normally closed, and which allows flow in either direction when opened by the insertion of an appropriate *gas-specific* (3.1.2.3) *connector* (3.1.4.5)

3.2.4 Pressure regulators

3.2.4.1

pressure regulator

device which, given a variable inlet pressure, provides an outlet pressure within specified limits

3.2.4.1.1

adjustable pressure regulator

pressure regulator (3.2.4.1) which is provided with a means for user adjustment of the outlet pressure

3.2.4.1.2

closure pressure

stabilized outlet pressure, after cessation of the flow, from a *pressure regulator* (3.2.4.1) when the flow has been set to standard discharge

3.2.4.1.3

manifold pressure regulator

pressure regulator (3.2.4.1) intended to be installed within a *source of supply* (3.2.1.3) containing gas cylinders, *cylinder bundles* (3.2.5.2), or *high-pressure reservoirs* (3.2.5.6)

3.2.4.1.4

maximum inlet pressure

maximum upstream pressure specified by the manufacturer for which the *pressure regulator* (3.2.4.1) is intended to be used

3.2.4.1.5

nominal outlet pressure

pressure downstream of the *pressure regulator* (3.2.4.1) under flow conditions specified by the manufacturer

3.2.4.1.6

preset pressure regulator

pressure regulator (3.2.4.1) that is not provided with a means of user adjustment of the outlet pressure

3.2.4.1.7

single-stage pressure regulator

pressure regulator (3.2.4.1) that reduces the inlet pressure to the required pressure in a single stage

3.2.4.1.8

two-stage pressure regulator

pressure regulator (3.2.4.1) that reduces the inlet pressure to the required pressure in two stages

3.2.5 Gas cylinders and accessories

3.2.5.1

content indicator

device that displays the amount of gas remaining in the gas cylinder

Note 1 to entry: The content can be expressed either in percentage of content, volume of gas or cylinder pressure.

3.2.5.2

cylinder bundle

pack or pallet of gas cylinders linked together with one or more *connectors* (3.1.4.5) for filling and emptying

3.2.5.3

filling port

connector (3.1.4.5) on the *VIPR* (3.2.5.8) through which the cylinder is filled

3.2.5.4

filling adaptor

filling tool

means of connecting the *VIPR* (3.2.5.8) *filling port* (3.2.5.3) to the filling system allowing the cylinder fitted with a *VIPR* to be filled or vented

Note 1 to entry: The *filling tool* is typically separate from the *VIPR*.

3.2.5.5

filling port non-return valve

valve which remains closed in normal use thus preventing the flow out of the *VIPR's* (3.2.5.8) *filling port* (3.2.5.3) until opened by insertion of an appropriate means and which then permits flow in either direction

Note 1 to entry: Some *filling port non-return valves* may also be opened by the pressure of the incoming gas.

3.2.5.6

high-pressure reservoir

permanently installed container(s) with nominal working pressures of greater than or equal to 3 000 kPa at 15 °C

Note 1 to entry: The phrases 'low-pressure' and 'high-pressure' are used differently in various contexts, including *breathing system* (3.6.1.1) pressures (typically less than 10 kPa), terminal outlet pressures (less than 1 400 kPa), manifold pressures (typically up to 3 000 kPa) and cylinder pressures (typically less than 30 000 kPa).

3.2.5.7

manifold

device for connecting the *outlets* (3.1.4.40) of one or more gas cylinders, *cylinder bundles* (3.2.5.2) or *high-pressure reservoirs* (3.2.5.6) of the same gas to the pipeline system

3.2.5.8

valve with integrated pressure regulator

VIPR

combination of a *pressure regulator* (3.2.4.1) and cylinder valve intended to be fitted to a *medical gas* (3.1.1.20) cylinder

3.2.5.9

working pressure

settled pressure of a compressed gas at a uniform reference temperature of 15 °C in a full gas cylinder

Note 1 to entry: This definition does not apply to liquefied gases (e.g. carbon dioxide) or dissolved gases (e.g. acetylene).

3.3 Anaesthetic machines and workstations

3.3.1 General terms

3.3.1.1

anaesthetic machine

equipment for dispensing and delivering *medical gases* (3.1.1.20) and *anaesthetic gases* (3.1.1.5) and vapours into a *breathing system* (3.6.1.1)

3.3.1.2

anaesthetic workstation

system for administering inhalational anaesthesia that contains an *anaesthetic gas delivery system* (3.3.2.1), an *anaesthetic breathing system* (3.6.1.8) and any required *monitoring equipment* (3.11.1.3), alarm systems, and *protection devices* (3.1.4.48)

Note 1 to entry: The *anaesthetic workstation* can also include, but is not limited to, one or more of the following: *anaesthetic vapour delivery systems* (3.3.2.2), an *anaesthetic ventilator* (3.4.1.3), parts of an *anaesthetic gas scavenging system* (3.9.1.1), and any associated *monitoring equipment* (3.11.1.3), alarm systems and *protection devices* (3.1.4.48).

3.3.1.3

minimum alveolar concentration

MAC

alveolar concentration of an inhaled anaesthetic agent that, in the absence of other anaesthetic agents and at equilibrium, prevents 50 % of subjects from moving in response to a standard surgical stimulus

Note 1 to entry: For the purposes of this International Standard, *MAC* is calculated from the end-tidal *gas level* (3.11.2.6).

3.3.2 Components

3.3.2.1

anaesthetic gas delivery system

anaesthetic workstation (3.3.1.2) component that receives separate supplies of *medical gases* (3.1.1.20) and delivers mixed gases in concentrations or individual flow rates adjustable by the user

Note 1 to entry: An anaesthetic gas delivery system can include a means of flow rate adjustment control, *flowmeters* (3.1.4.17) or a gas mixer and anaesthetic gas delivery system piping but does not include vaporisers.

3.3.2.2

anaesthetic vapour delivery system

anaesthetic vaporiser

anaesthetic workstation (3.3.1.2) component that provides the vapour of a volatile agent in a controllable concentration

3.3.2.3

draw-over vaporiser

vaporiser from which a sufficient flow of gas vapour mixture is produced by lowering the pressure at the *outlet* (3.1.4.40) of the vaporiser below that at its *inlet* (3.1.4.26) by a patient's inspiratory effort or by a *ventilator* (3.4.1.1)

Note 1 to entry: Air or *oxygen* (3.1.1.21) is commonly used as the *carrier gas* (3.1.1.10).

3.3.2.4

draw-over anaesthetic system

low-resistance system for administering inhalational anaesthesia that can be used in the absence of compressed gas or electricity

3.3.2.5

draw-over valve system

valve, or combination of valves, that controls unidirectional flow to the patient during inspiration and unidirectional flow from the patient during exhalation either during spontaneous breathing or during *artificial ventilation* (3.4.1.2)

3.3.2.6

fresh-gas outlet

DEPRECATED: common gas outlet

port (3.1.4.10) through which *fresh gas* (3.1.1.16) is delivered from the *anaesthetic gas delivery system* (3.3.2.1)

3.3.2.7

agent-specific filling system

functional system of *agent-specific* (3.3.2.8) coded connections between an anaesthetic bottle and an *agent-specific anaesthetic vaporiser* (3.3.2.2)

EXAMPLE An *agent-specific filling system* consisting of a threaded bottle neck with collar, *anaesthetic bottle connector* (3.3.2.11), male *adaptor* (3.1.4.1), and *filler receptacle* (3.3.2.13).

3.3.2.8

agent-specific

having a prescribed configuration and prescribed dimensions which are specific for a prescribed liquid anaesthetic agent

3.3.2.9

anaesthetic bottle adaptor

assembly that is intended to connect a bottle for liquid anaesthetic agent to an *agent-specific* (3.3.2.8) *anaesthetic vaporiser* (3.3.2.2)

3.3.2.10

anaesthetic bottle collar

component on the neck of a bottle causing it to be *agent-specific* (3.3.2.8)

3.3.2.11

anaesthetic bottle connector

agent-specific (3.3.2.8) component that fits the thread on the bottle neck and mates with the *agent-specific anaesthetic bottle collar* (3.3.2.10)

3.3.2.12

anaesthetic bottle neck

external threaded part of the bottle and the adjacent contour over which an *agent-specific* (3.3.2.8) *anaesthetic bottle collar* (3.3.2.10) is fitted

3.3.2.13

filler receptacle

receptacle for a bottle or an *anaesthetic bottle adaptor* (3.3.2.9) on an *agent-specific* (3.3.2.8) *anaesthetic vaporiser* (3.3.2.2)

3.4 Ventilators and resuscitators

3.4.1 General terms

3.4.1.1

ventilator

lung ventilator

medical device or medical electrical equipment intended to provide *artificial ventilation* (3.4.1.2)

Note 1 to entry: In cases of possible ambiguity the full term, *lung ventilator*, should be used.

3.4.1.2

artificial ventilation

intermittent elevation of the pressure in the patient's *airway* (3.8.1.1) relative to that in the lungs by external means with the intention of augmenting or totally controlling the ventilation of a patient

3.4.1.3

anaesthetic ventilator

anaesthetic workstation (3.3.1.2) component that is connected via the *anaesthetic breathing system* (3.6.1.8) to the patient's *airway* (3.8.1.1) and automatically augments or provides ventilation during anaesthesia

3.4.1.4

EMS ventilator

ventilator (3.4.1.1) intended for use in the emergency medical services (EMS) environment

3.4.1.5

high-frequency ventilator

medical device or medical electrical equipment intended to provide ventilation of the lungs of the patient when connected to the *airway* (3.8.1.1) of the patient using a rate greater than 150 inflations/min

3.4.1.6

ventilator for ventilator-dependent patient

medical device or medical electrical equipment intended to augment or provide ventilation of the lungs of a *ventilator-dependent* (3.1.5.19) patient

3.4.1.7

ventilatory support equipment

medical device or medical electrical equipment, suitable for use in the home healthcare environment without continuous professional supervision, intended to augment or provide ventilation of the lungs of a patient who is not *ventilator-dependent* (3.1.5.19)

Note 1 to entry: *Ventilatory support equipment* is a type of *ventilator* (3.4.1.1), but is not a *ventilator for ventilator-dependent patient* (3.4.1.6).

Note 2 to entry: A patient suitable for *ventilatory support equipment* requires a narrow spectrum of ventilation modalities and monitoring for appropriate management.

3.4.1.8

resuscitator

transit-operable (3.1.6.11) 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.

3.4.1.8.1

manually-cycled resuscitator

resuscitator (3.4.1.8) in which the *inflation phase* (3.1.5.6) and *expiratory phase* (3.1.5.4) are controlled by a repeated manual action of the user

Note 1 to entry: A *demand valve* (3.4.1.12) that can be overridden with a manual trigger is classified as a *manually-cycled resuscitator* incorporating a *demand valve* (3.4.1.12) and not as a *demand valve* (3.4.1.12).

3.4.1.8.2

user-powered resuscitator

resuscitator (3.4.1.8) with which ventilation of the lungs is produced by the user squeezing its *compressible unit* (3.4.1.11)

3.4.1.8.3

resuscitator deadspace

volume of previously exhaled gas within the *resuscitator* (3.4.1.8) that is delivered to the patient in the succeeding *inspiratory phase* (3.1.5.5)

3.4.1.8.4

resuscitator set

pack of all the necessary components that enable the *resuscitator* (3.4.1.8) to be carried to the site of a resuscitation emergency and that enable the *resuscitator* to be made ready for immediate use

3.4.1.9

ventilator breathing system

VBS

pathways associated with a *ventilator* (3.4.1.1) through which gas flows to or from the patient at *respiratory pressures* (3.6.1.2), bounded by the *port* (3.1.4.10) through which *fresh gas* (3.1.1.16) enters, the *patient-connection port* (3.1.4.41) and the *exhaust port* (3.1.4.11)

3.4.1.10

driving gas

gas which powers a device and is not delivered to the patient

3.4.1.11

compressible unit

part of a *user-powered resuscitator* (3.4.1.8.2) e.g. a bag or bellows that, when compressed by the user, delivers a volume of gas

3.4.1.12

demand valve

equipment component that delivers a flow of gas related to a reduction of pressure generated by the patient at the *patient-connection port* (3.1.4.41)

3.4.2 Ports

3.4.2.1

driving-gas input port

inlet (3.1.4.26) to which the *driving gas* (3.4.1.10) is applied

3.4.2.2

inflating-gas input port

inlet (3.1.4.26) to which inflating gas is applied

3.4.2.3

emergency intake

DEPRECATED: emergency intake port

DEPRECATED: emergency air intake port

dedicated *gas intake port* (3.1.4.21) through which gas is drawn when the supply of *fresh gas* (3.1.1.16) or inflating gas is insufficient or absent

3.4.2.4

fresh -gas inlet connector

connector (3.1.4.5) on a *ventilator breathing system* (3.4.1.9) to which a *fresh gas* (3.1.1.16) supply is connected

3.4.3 Pressures

3.4.3.1

continuous positive airway pressure

CPAP

positive pressure at a *patient-connection port* (3.1.4.41) which is applied continuously throughout the respiratory cycle

3.4.3.2

maximum working pressure

$P_{w \max}$

highest *airway pressure* (3.1.4.41.1) during the *inspiratory phase* (3.1.5.5) in normal use

3.4.3.3

minimum working pressure

$P_{w \min}$

lowest *airway pressure* (3.1.4.41.1) during normal use

3.4.4 Flowrates

3.4.4.1

bias flow

flow that passes through the *ventilator breathing system* (3.4.1.9) to the *exhaust port* (3.1.4.11) but is not intended to contribute to the work of lung ventilation

3.5 Oxygen therapy delivery systems

3.5.1 Liquid oxygen systems

3.5.1.1

transportable liquid oxygen system

system comprising one or more *liquid oxygen portable units* (3.5.1.3) and compatible *liquid oxygen base units* (3.5.1.2) for *oxygen therapy* (3.1.5.9)

3.5.1.2

liquid oxygen base unit

mobile device that is a vacuum-insulated cryogenic vessel intended to store *oxygen* (3.1.1.21) and maintain it in the liquid state for the purpose of refilling *liquid oxygen portable units* (3.5.1.3) and that can also include an internal vaporiser and a flow control for the direct supply of gaseous oxygen to the patient

3.5.1.3

liquid oxygen portable unit

portable device including a vacuum-insulated cryogenic vessel to maintain liquid oxygen at cryogenic temperatures, an internal vaporiser and a flow control to provide gaseous oxygen to the patient

3.5.1.4

liquid oxygen transfer connector

connector (3.1.4.5) used to transfer liquid oxygen from the *liquid oxygen base unit* (3.5.1.2) to the *liquid oxygen portable unit* (3.5.1.3) or to refill the *liquid oxygen base unit*

3.6 Breathing systems

3.6.1 General terms and classification

3.6.1.1

breathing system

pathways through which gas flows to or from the patient at *respiratory pressures* (3.6.1.2) and continuously or intermittently in fluid communication with the patient's respiratory tract during any form of *artificial ventilation* (3.4.1.2) or respiratory therapy

Note 1 to entry: In practice, a *breathing system* usually extends from

- a) the point of supply of a gas mixture, for example the *fresh-gas outlet* (3.3.2.6) of an *anaesthetic machine* (3.3.1.1).

In some situations, particularly in *lung ventilators* (3.4.1.1), this point may be inside a piece of equipment and should not be confused with a connection *port* (3.1.4.10) fitted elsewhere, for example on the casing of a *ventilator* (3.4.1.1),

- b) the *fresh-gas inlet* (3.1.4.20) of a circle system, *lung ventilator*, T-piece, etc., or

- c) the *fresh-gas inlet* of a *user-powered resuscitator* (3.4.1.8.2).

Note 2 to entry: The *breathing system* usually extends to the point at which the gas mixture escapes to atmosphere or to an *anaesthetic gas scavenging system* (3.9.1.1), for example from an *APL valve* (3.6.3.5) or the open end of a T-piece.

Note 3 to entry: The arrangement of components of any *breathing system* and the method of use affect the composition of the inspired gas mixture.

Note 4 to entry: Gas pathways exclusively concerned with *anaesthetic gas scavenging systems* (3.9.1.1) are not regarded as part of a *breathing system*.

Note 5 to entry: It is not possible to eliminate all ambiguity in defining the term *breathing system*. When this term is used in any standard or document, or other scientific publication in which it could affect the precise interpretation thereof, the limits and configuration of any *breathing system* referred to therein should be clearly defined.

3.6.1.2

respiratory pressure

pressure of the gas in communication with the patient's *airways* (3.8.1.1) during any form of *artificial ventilation* (3.4.1.2) or spontaneous breathing

Note 1 to entry: *Airway pressure* (3.1.4.41.1) is a specific reference to gas pressure at the *patient-connection port* (3.1.4.41) of a *ventilator breathing system* (3.4.1.9).

3.6.1.3

anaesthetic reservoir bag

collapsible gas container which is a component in an *anaesthetic breathing system* (3.6.1.8)

3.6.1.3.1

bag inlet valve

valve activated by the sub-atmospheric pressure in the *compressible unit* (3.4.1.11) of the *resuscitator* (3.4.1.8) to refill the *compressible unit* with gas at ambient pressure

3.6.1.3.2

bag refill valve

valve, with no manual trigger, activated by the sub-atmospheric pressure in the *compressible unit* (3.4.1.11) of the *resuscitator* (3.4.1.8) to refill the *compressible unit* from a pressurized gas source

3.6.1.4

breathing attachment

user-detachable (3.1.4.38) component intended to form part of a *breathing system* (3.6.1.1)

EXAMPLE *Breathing system filter* (3.6.1.5), *humidifier* (3.7.2.1), *closed suction catheter manifold* (3.10.3.3).

3.6.1.5

breathing system filter

BSF

device intended to reduce transmission of particulates, including microorganisms, in a *breathing system* (3.6.1.1)

3.6.1.6

breathing set

assembly of *breathing tubes* (3.1.4.4), *connectors* (3.1.4.5) and components that form the inspiratory and expiratory limbs of the gas pathways of an *anaesthetic breathing system* (3.6.1.8) or *ventilator breathing system* (3.4.1.9) between the *ventilator* (3.4.1.1) and the patient's *airway device* (3.8.1.2)

3.6.1.7

fresh-gas supply tube

tube conveying *fresh gas* (3.1.1.16) to the *fresh-gas inlet* (3.1.4.20) of the *anaesthetic breathing system* (3.6.1.8)

3.6.1.8

anaesthetic breathing system

breathing system (3.6.1.1) intended for use with volatile or gaseous anaesthetic agents

3.6.1.8.1

circle breathing system

anaesthetic circle breathing system

breathing system (3.6.1.1) in which the direction of gas flow through inspiratory and expiratory pathways is unidirectional and in which the two pathways form a loop

Note 1 to entry: In context of anaesthesia, the *breathing system* (3.6.1.1) is often a *circle breathing system*.

3.6.1.8.2

circle absorber assembly

part of a *circle breathing system* (3.6.1.8.1) that comprises one or more carbon-dioxide-absorbent containers, *inspiratory valves* (3.6.3.1) and *expiratory valves* (3.6.3.2) or other means of ensuring unidirectional gas flow, two *ports* (3.1.4.10) for connection to *breathing tubes* (3.1.4.4), a *fresh-gas inlet* (3.1.4.20), and a reservoir bag *port* or an *anaesthetic ventilator* (3.4.1.3) *port* or both

3.6.1.9

air entrainment device

device consisting of a jet orifice adjacent to one or more air entrainment *ports* (3.1.4.10)

3.6.2 Adaptors

3.6.2.1

bag adaptor

adaptor (3.1.4.1) to one end of which the neck of an *anaesthetic reservoir bag* (3.6.1.3) can be attached

3.6.2.2

assembled end

end of a *breathing tube* (3.1.4.4) incorporating a permanently attached *adaptor* (3.1.4.1)

3.6.3 Valves

3.6.3.1

inspiratory valve

valve which, when open, allows gas to pass through it to a patient during the *inspiratory phase* (3.1.5.5) only

3.6.3.2

expiratory valve

valve which, when open, allows gas to pass through it from a patient during the *expiratory phase* (3.1.5.4) only

3.6.3.3

inspiratory-expiratory valve

single valve which performs the function of both an *inspiratory valve* (3.6.3.1) and an *expiratory valve* (3.6.3.2)

3.6.3.4

pressure-limiting device

pressure-limiting valve

means for limiting the maximum pressure within a *breathing system* (3.6.1.1)

3.6.3.5

APL valve

adjustable pressure-limiting valve

pop-off valve

pressure-limiting valve (3.6.3.4) with user-adjustable pressure settings

3.6.3.6

patient valve

valve in the *breathing system* (3.6.1.1) that directs gas to the *patient-connection port* (3.1.4.41) during the *inspiratory phase* (3.1.5.5) and into the atmosphere during the *expiratory phase* (3.1.5.4)

3.6.3.7

anti-asphyxia valve

valve used on a breathing *mask* (3.8.6.4) intended to allow spontaneous breathing when the *lung ventilator* (3.4.1.1) or breathing therapy equipment is not providing adequate pressure or flow

3.7 Humidifiers, nebulizers and moisture exchangers

3.7.1 General terms

3.7.1.1

thermal hazard

hazard resulting from fire, excessive surface temperature or excessive *delivered gas temperature* (3.1.1.13)

3.7.1.2

temperature overshoot

temporary increase in *delivered gas temperature* (3.1.1.13) following a reduction in, or withdrawal of, electrical power or a change in gas flow

3.7.2 Humidifiers

3.7.2.1

humidifier

device that adds water in the form of droplets or vapour, or both, to the inspired gas

Note 1 to entry: This term includes vaporising, bubble-through and ultrasonic *humidifiers* and active *heat and moisture exchangers* (3.7.4.1).

3.7.2.2

active humidifier

humidifier (3.7.2.1) in which energy is added to facilitate vaporisation of water and warming of the respiratory gases

3.7.2.2.1

nebulizing humidifier

humidifier (3.7.2.1) whose output is predominantly in the droplet phase

3.7.2.2.2

vaporising humidifier

humidifier (3.7.2.1) whose output is predominantly in the vapour phase

3.7.2.3

active HME

device where water, water vapour or heat is actively added to the *HME* (3.7.4.1) to increase the humidity level of the gas delivered from the *HME* to the patient

3.7.2.4

passive humidifier

bubble-through or pass-over medical device that creates vapour or droplets from water at room temperature to moisten the inspired gas

Note 1 to entry: The chambers of *passive humidifiers* are at room temperature, so they have a lower *humidification output* (3.7.2.6) than an *active humidifier* (3.7.2.2).

Note 2 to entry: *Passive humidifiers* do not use heat to increase the temperature of either the *humidification chamber* (3.7.2.5) or the *breathing tubes* (3.1.4.4).

3.7.2.5

humidification chamber

part of a *humidifier* (3.7.2.1) in which vaporisation or nebulization takes place

3.7.2.6

humidification output

humidification system output

total mass of water vapour per unit volume of gas at the *patient-connection port* (3.1.4.41)

Note 1 to entry: *Humidification output* is expressed under *body temperature and pressure saturated* (3.1.1.7) conditions.

3.7.3 Nebulizers

3.7.3.1

nebulizer

device that converts a liquid into an *aerosol* (3.1.1.3)

3.7.3.1.1

electrically-powered nebulizer

nebulizer (3.7.3.1) that operates by means of electrical power

3.7.3.1.2

manually-powered nebulizer

nebulizer (3.7.3.1) that operates by means of human power

3.7.3.1.3

gas-powered nebulizer

nebulizer (3.7.3.1) in which the *aerosol* (3.1.1.3) is generated by compressed gas

3.7.3.1.4

ultrasonic nebulizer

nebulizer (3.7.3.1) in which *aerosol* (3.1.1.3) is generated by means of ultrasound

3.7.3.1.5

breath-actuated nebulizer

nebulizer (3.7.3.1) triggered by a respiratory parameter

3.7.3.1.6

continuous nebulizer

nebulizer (3.7.3.1) in which *aerosol* (3.1.1.3) is delivered continuously over multiple inhalation/exhalation breathing cycles or over long periods

3.7.3.2

nebulizing system

system comprising the *nebulizer* (3.7.3.1) and all other components, up to and including the *aerosol outlet* (3.7.3.5), required to make the *aerosol* (3.1.1.3) available for inhalation

3.7.3.3

aerosol output

mass or volume of *aerosol* (3.1.1.3) emitted by the *nebulizing system* (3.7.3.2) at the *aerosol outlet* (3.7.3.5) for the specified fill volume

3.7.3.4

aerosol output rate

mass or volume of *aerosol* (3.1.1.3) emitted by the *nebulizing system* (3.7.3.2) per unit of time

3.7.3.5

aerosol outlet

outlet (3.1.4.40) of the *nebulizing system* (3.7.3.2) through which the *aerosol* (3.1.1.3) is emitted

3.7.4 Heat and moisture exchangers

3.7.4.1

heat and moisture exchanger

HME

device intended to retain a portion of the patient's expired moisture and heat, and return it to the patient's respiratory tract during inspiration

3.7.4.2

HMEF

FHME

heat and moisture exchanger (3.7.4.1) that incorporates the function of a *breathing system filter* (3.6.1.5)

Note 1 to entry: See also ISO 23328-1, ISO 23328-2, ISO 9360-1 and ISO 9360-2.

3.7.4.3

HME patient port

heat and moisture exchanger patient port

port (3.1.4.10) of the *HME* (3.7.4.1) which is intended for connection to an *airway device* (3.8.1.2)

3.7.4.4

HME machine port

heat and moisture exchanger machine port

port (3.1.4.10) of the *HME* (3.7.4.1) which is intended for connection to a *breathing system* (3.6.1.1) *patient-connection port* (3.1.4.41)

3.7.4.5

HME accessory port

heat and moisture exchanger accessory port

port (3.1.4.10) of the *HME* (3.7.4.1) intended for connection to an accessory

EXAMPLE Connection to a *respiratory gas monitor* (3.11.2.1).

3.7.4.6

HME internal volume

heat and moisture exchanger internal volume

compressible volume contained within the *HME* (3.7.4.1)

Note 1 to entry: The internal volume is intended to refer to the compressible volume occupied by breathing gases.

Note 2 to entry: The internal volume is bounded by the internal surfaces of the impermeable material of the *HME* (3.7.4.1), the *ports* (3.1.4.10) of the *HME* (3.7.4.1) and excludes the internal volume of female gas *connectors* (3.1.4.5).

Note 3 to entry: The internal volume excludes the volume of solid elements within the *HME* (3.7.4.1), such as exchange media.

3.8 Airways, tracheal tubes, tracheostomy tubes and intubation equipment

3.8.1 General

3.8.1.1

airway

connected, gas-containing cavities and passages within the respiratory system, that conduct gas between the alveoli and the oral and nasal orifices on the surface of the face, or the *patient-connection port* (3.1.4.41) if an *airway device* (3.8.1.2) is used

Note 1 to entry: This is a well-established term that is commonly used in isolation in references to the *airway* of a patient. Depending on the context, it is sometimes more helpful to use the qualified term, patient's *airway*.

3.8.1.2

airway device

device intended to provide a gas pathway to and from the patient's *airway* (3.8.1.1)

3.8.1.3

exhaust flow

<airway devices> flow from the *mask* (3.8.6.4) or application accessory to atmosphere other than the leak due to improper seal to the face

Note 1 to entry: The *exhaust flow* can pass through openings in the *mask* (3.8.6.4), the connecting element and the *mask*, or through the *anti-asphyxia valve* (3.6.3.7).

Note 2 to entry: The *exhaust flow* discharges exhaled gases to atmosphere to reduce *rebreathing* (3.1.5.12) of CO₂.

3.8.1.4

swivel adaptor

specialized *adaptor* (3.1.4.1) which allows variation in the position of its *ports* (3.1.4.10) relative to each other

3.8.2 Pharyngeal airway

3.8.2.1

nasopharyngeal airway

device intended to provide a gas pathway through the nasal cavity and pharynx

3.8.2.2

oropharyngeal airway

device intended to maintain a gas pathway through the oral cavity and pharynx

3.8.2.3

supralaryngeal airway

device placed through the mouth but not through the vocal cords, which is intended to form an internal seal in the supralaryngeal area to maintain *upper airway* (3.1.5.18) patency

3.8.2.4

flanged end

that end of an *oropharyngeal airway* (3.8.2.2) which is flanged and is intended to be external to the teeth or gums

3.8.2.5

pharyngeal end

end of an *oropharyngeal airway* (3.8.2.2) which is intended to be inserted into a patient's oropharynx

3.8.2.6

supralaryngeal airway connector

tubular component of a *supralaryngeal airway* (3.8.2.3) intended for connection to a *breathing system* (3.6.1.1) or *resuscitator* (3.4.1.8)

3.8.3 Tracheal tubes

3.8.3.1

tracheal tube

DEPRECATED: endotracheal tube

tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

3.8.3.1.1

nasotracheal tube

tracheal tube (3.8.3.1) for insertion through the nose into the trachea

3.8.3.1.2

orotracheal tube

tracheal tube (3.8.3.1) for insertion through the mouth into the trachea

3.8.3.2

bevel

slanted portion at the *patient end* (3.1.4.42) of a *tracheal tube* (3.8.3.1)

3.8.3.2.1

angle of bevel

acute angle between the plane of the *bevel* (3.8.3.2) and the longitudinal axis of a *tracheal tube* (3.8.3.1) at the *patient end* (3.1.4.42)

3.8.3.3

inflating tube

tube through which the *airway device* (3.8.1.2) *cuff* (3.1.4.7) is inflated

3.8.3.3.1

inflation lumen

lumen within the wall of an *airway device* (3.8.1.2) for inflating a *cuff* (3.1.4.7)

3.8.3.4

cuff inflation device

device to inflate an *airway device* (3.8.1.2) *cuff* (3.1.4.7)

EXAMPLE Syringe, hand operated bulb pump, electrically powered pump.

3.8.3.5

cuff pressure indicator

device which indicates to the user the intracuff pressure of an *airway device* (3.8.1.2) *cuff* (3.1.4.7)

3.8.3.5.1

automatic cuff pressure indicator

device used to automatically measure, display and control the intracuff pressure of an *airway device* (3.8.1.2) *cuff* (3.1.4.7)

3.8.3.5.2

integral cuff pressure indicator

cuff pressure indicator (3.8.3.5) that is not detachable from the *airway device* (3.8.1.2)

3.8.3.5.3

pilot balloon

balloon fitted to an *inflating tube* (3.8.3.3) to indicate inflation of the *cuff* (3.1.4.7)

3.8.3.6

reinforced tracheal tube

tracheal tube (3.8.3.1) whose wall incorporates additional material intended to avoid kinking

3.8.3.7

tracheal tube connector

tubular component that fits directly into the *machine end* (3.1.4.31) of a *tracheal tube* (3.8.3.1)

3.8.3.8

Murphy eye

hole through the wall of a *tracheal tube* (3.8.3.1) near the *patient end* (3.1.4.42) and on the side opposite the *bevel* (3.8.3.2)