International Standard

ISO 17510

Medical devices — Sleep apnoea breathing therapy — Masks and application accessories

Dispositifs médicaux — Thérapie respiratoire de l'apnée du sommeil — Masques et accessoires d'application

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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 document 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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This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 17510:2015), which has been technically revised.

The main changes are as follows:

— harmonization with IEC 60050-880 sources, where appropriate;

— adding disclosure requirements for magnets in *headgear*;

— updated *processing* requirements;

— updated noise requirements;

— referencing ISO 18562-1, for *biocompatibility* of *gas pathways*;

— harmonization with ISO 20417, where appropriate.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Sleep apnoea is the clinically significant intermittent absences of normal respiration occurring during sleep. The awareness of the *risks* associated with sleep apnoea has grown significantly in recent years. As a result, the use of *sleep apnoea breathing therapy equipment* has become common. This document covers basic safety and essential performance requirements for *masks* and other application *accessories* needed to protect *patients* during use of this equipment.

Sleep apnoea breathing therapy equipment is covered by ISO 80601-2-70. Figure A.1 shows the typical elements of this document together with the *sleep apnoea breathing therapy equipment* of ISO 80601-2-70 that form a sleep apnoea breathing system.

In this document, the following print types are used:

— Requirements and definitions: roman type.

— Informative material appearing outside of tables, such as notes, examples, and references: in smaller type. Normative text of tables is also in a smaller type.

— *Terms defined in Clause 3 in this document or as noted: italics.*

In referring to the structure of this document, the term:

— "clause" means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 5 includes 5.1, 5.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 5.1, 5.2, and 5.3.1 are all subclauses of Clause 5).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission; and

— "can" is used to describe a possibility or capability.

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Medical devices — Sleep apnoea breathing therapy — Masks and application accessories

1 Scope

This document specifies requirements for *masks* and *accessories*, including any connecting element, that are required to connect the *patient-connection port* of *sleep apnoea breathing therapy equipment* to a *patient* for the application of sleep apnoea breathing therapy (e.g. nasal *masks*, *exhaust ports* and *headgear*).

This document applies to *masks* and their *accessories* used to connect *sleep apnoea breathing therapy equipment* to the *patient*.

The requirements in this document take priority over the requirements in ISO 18190.

This document does not cover *oral appliances*.

NOTE This document has been prepared to address the relevant *essential principles*[14] and labelling principles[15] of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex I.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

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

ISO 5356-2:2012, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5356-2:2012/Amd 1:2019, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors — Amendment 1*

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

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

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

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

ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:—[1)], *Medical devices — Information to be supplied by the manufacturer*

1) Under preparation. Stage at the time of publication: ISO/DIS 20417:2025.

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

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

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC Guide 115:2023, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20417:— and the following apply.

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

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

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

NOTE An alphabetical index of defined terms is found in Annex J.

3.1
anti-asphyxia valve
valve used on a breathing *mask* intended to allow spontaneous breathing when the lung ventilator or breathing therapy equipment is not providing adequate pressure or flow

[SOURCE: ISO 4135:2022, 3.6.3.7]

3.2
biocompatibility
ability of a *medical device*, *accessory* or material to perform with an appropriate host response in a specific application

Note 1 to entry: A *medical device* or *accessory* can produce some level of adverse effect, but that level can be determined to be acceptable when considering the *benefit* provided.

[SOURCE: ISO 18562-1:2024, 3.6]

3.3
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in a breathing system

[SOURCE: ISO 4135:2022, 3.6.1.5]

3.4
breathing tube
non-rigid tube used to convey gases or vapours within the *user*-detachable section of a breathing system

[SOURCE: ISO 4135:2022, 3.1.4.4, modified — Deleted Note 1 to entry.]

3.5
cleaning
process to remove contaminants to the extent necessary for further *processing* or for *intended use*

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

Note 2 to entry: *Cleaning* of a new *product* can occur before initial use or during production before release for distribution.

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[SOURCE: ISO 17664-2:2021, 3.1, modified — Replaced “removal of” with “*process* to remove”. In Note 1 to entry, replaced “and/or” with “or” and added “of a used *product*”. Added Note 2 to entry.]

3.6
conformity
fulfilment of a requirement

Note 1 to entry: In English the word “conformance” is synonymous but deprecated. In French the word “compliance” is synonymous but deprecated.

[SOURCE: ISO 9000:2015, 3.6.11, modified — Deleted Note 2 to entry.]

3.7
disinfection
process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-2:2021, 3.5]

3.8
exhaust flow
<airway device> flow from the *mask* 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*, the connecting element and the *mask* or through the *anti-asphyxia valve*.

Note 2 to entry: The *exhaust flow* discharges exhaled gases to atmosphere to reduce *rebreathing* of CO_2.

[SOURCE: ISO 4135:2022, 3.8.1.3]

3.9
exhaust port
port through which gas is discharged to the atmosphere or to an anaesthetic gas scavenging system

[SOURCE: ISO 4135:2022, 3.1.4.11, modified — Deleted notes to entry.]

3.10
gas output port
port of the device through which gas is delivered at respiratory pressures to a *user*-detachable part of a breathing system

[SOURCE: ISO 4135:2022, 3.1.4.22, modified — Deleted Note 1 to entry and deprecated term.]

3.11
gas pathway
interior surfaces over which respiratory gases or liquids pass that can be inspired

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

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

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

Note 1 to entry: The *gas pathway* is bounded by the fluid ports through which gases or liquids enter the *medical device* or *accessory*. This can include the *patient* interface or the interior surfaces of enclosures that are in contact with gases or liquids that can be inspired.

Note 2 to entry: The *gas pathway* can include some surfaces in the expiratory pathway.

Note 3 to entry: The fluids from a *gas pathway* can be ingested.

[SOURCE: ISO 18562-1:2024, 3.11, modified — In the definition, added “respiratory”. In Note 1 to entry, replaced “ports” with “fluid ports”. Replaced Note 3 to entry.]

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3.12
harm
injury or damage to the health of people or animals, or damage to property or the environment

[SOURCE: ISO/IEC Guide 63:2019, 3.1, modified — Added "or animals".]

3.13
headgear
part that is used to fix the *mask* to the *patient*

Note 1 to entry: The *headgear* may be an integral part of the *mask*.

3.14
healthcare professional, adj
appropriately trained, knowledgeable and skilled, providing systematic preventive, curative, promotional or rehabilitative healthcare services

EXAMPLE *Healthcare professional user*, *healthcare professional responsible organization*.

[SOURCE: ISO 80601-2-12:2023, 201.3.247, modified — Deleted "to families or communities". Added example.]

3.15
intended use
use for which a product or *process* is intended according to the specifications, instructions for use and other *information supplied by the manufacturer*

Note 1 to entry: The intended medical indication, *patient* population, part of the body or type of tissue interacted with, *user* profile, use environment, and operating principle are typical elements of the *intended use*.

Note 2 to entry: *Intended use* is different from *normal use*. Both include the concept of use as intended by the *manufacturer*. However, *intended use* focuses on the medical purpose whereas *normal use* incorporates not only the medical purpose, but maintenance, transport, *processing*, etc. as well.

Note 3 to entry: Product includes service.

[SOURCE: ISO/IEC Guide 63:2019, 3.4, modified — Deleted "or service" and replaced "instructions" with "instructions for use", "provided" with "supplied" and added "other". Added Notes 2 and 3 to entry.]

3.16
inspection
conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging

3.17
manufacturer
organization with responsibility for design or manufacture of a *medical device* or *accessory* with the intention of making the *medical device* or *accessory* available for use, under its name; whether such a *medical device* or *accessory* is designed or manufactured by that organization itself or on its behalf by another organization

Note 1 to entry: This organization has ultimate legal responsibility for ensuring compliance with all applicable policies for the *medical device* or *accessory* in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another organization by the authority having jurisdiction.

Note 2 to entry: The *manufacturer's* responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

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

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

Note 5 to entry: Any organization which changes the *intended use* of or modifies a *medical device* or *accessory* without acting on behalf of the original *manufacturer* and which makes it available for use under its own name, is considered the *manufacturer* of the modified *medical device* or *accessory*.

Note 6 to entry: An authorized representative, distributor or importer who only adds their own address and contact details to the *medical device*, *accessory* or the packaging, without covering or changing the existing *information supplied by the manufacturer*, is not considered a *manufacturer*.

Note 7 to entry: To the extent that an *accessory* is subject to the applicable policies of a *medical device*, the organization responsible for the design or manufacture of that *accessory* is considered to be a *manufacturer*.

[SOURCE: ISO/IEC Guide 63:2019, 3.6, modified — Added "or *accessory*", replaced "whether or not" with "whether", "and/or" with "or", "natural or legal person" and "person" with "organization", "regulatory requirements" with "applicable policies", "Regulatory Authority within that jurisdiction" with "authority having jurisdiction", inserted "IMDRF" and replaced "labelling" with "*information supplied by the manufacturer*".]

3.18
mask
device which provides a non-invasive interface between the *patient's* airway and a *patient-connection port* or other connection to a source of respirable gas

[SOURCE: ISO 4135:2022, 3.8.6.4]

3.19
ME equipment
medical electrical equipment
electrical *medical device* having an applied part or transferring energy or substances to or from the *patient* or detecting such energy or substance transfer to or from the *patient*

Note 1 to entry: If *ME equipment* is provided with more than one connection to a particular mains, then the combination of the *ME equipment* and its mains connections is a medical electrical system.

Note 2 to entry: The *ME equipment* includes those *accessories* and detachable parts as defined by the *manufacturer*.

Note 3 to entry: Not all electrical equipment used in medical practice falls within this definition.

Note 4 to entry: The definition of *medical device* is broader than that of *ME equipment*.

Note 5 to entry: The transfer or detecting of energy includes optical radiation, ionising radiation, ultrasound and magnetic resonance.

[SOURCE: IEC 60601-1:2005, 3.63, modified — Replaced "electrical equipment" with "electrical *medical device*" and "supply mains" with "mains", added "or substances", deleted item b), deleted "and which is provided with not more than one connection to a particular mains". Added Notes 1, 2, 4 and 5 to entry.]

3.20
normal condition
condition of a product in which all *risk* control measures are intact

[SOURCE: IEC 60601-1:2005, 3.70, modified — Added "of a product" and replaced "means provided for protection against *hazards*" with "*risk* control measures".]

3.21
oral appliance
device intended to maintain the oral airway by mechanical means and which achieves its purpose independently of *sleep apnoea breathing therapy equipment*

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3.22
patient-connection port
port of a breathing system intended for connection to an airway device

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

Note 2 to entry: The *patient-connection port* is typically a connector suitable for connection to an airway device such as a tracheal tube, tracheostomy tube, face *mask* or supralaryngeal airway.

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, for example, a connector 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, then there is no *patient-connection-port*. Examples include non-invasive ventilation using a face *mask* with an integrated expiratory port, or oxygen therapy using an open *mask*.

[SOURCE: ISO 4135:2022, 3.1.4.41]

3.23
procedure
specified way to carry out an activity or a *process*

Note 1 to entry: *Procedures* can be documented or not.

[SOURCE: ISO 9000:2015, 3.4.5]

3.24
process
set of interrelated or interacting activities that use inputs to deliver an intended result

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

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

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

[SOURCE: ISO 9000:2015, 3.4.1, modified — Deleted Notes 4, 5 and 6 to entry.]

3.25
rated
assigned by the *manufacturer* for a specified operating condition

Note 1 to entry: A *rated* value can have a tolerance.

[SOURCE: IEC 60601-1:2005, 3.97, modified — Deleted "term referring to a value".]

3.26
rebreathing
inhalation of expired gas mixture from which carbon dioxide may or may not have been removed

[SOURCE: ISO 4135:2022, 3.1.5.12]

3.27
risk
combination of the probability of occurrence of *harm* and the severity of that *harm*

Note 1 to entry: The probability of occurrence includes the exposure to a hazardous situation and the possibility to avoid or limit the *harm*.

Note 2 to entry: In French, the term "risqué" also denotes the potential source of *harm*, in English "hazard".

[SOURCE: IEC 60050-903:2013, 903-01-07, modified — Added Note 1 to entry.]

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3.28
risk management
systematic application of management policies, *procedures* and practices to the tasks of analysing, evaluating, controlling and monitoring *risk*

[SOURCE: ISO/IEC Guide 63:2019, 3.15]

3.29
risk management file
set of records and other documents that are produced by *risk management*

[SOURCE: ISO 14971:2019, 3.25]

3.30
single fault condition
condition of a product in which a single *risk* control measure is defective

Note 1 to entry: If a *single fault condition* causes one or more other fault conditions, all shall be considered as one *single fault condition*.

Note 2 to entry: Failure of a component designed to maintain basic safety or essential performance shall be considered a *single fault condition*.

Note 3 to entry: An abnormal external situation is not a *single fault condition*.

[SOURCE: IEC 60601-1:2005, 3.116, and IEC 60601-1:2005/AMD1:2012, 3.116, modified — Replaced "*ME equipment*" with "a *medical device* or *accessory*" and "means for reducing a *risk*" with "*risk* control measure", deleted "or a single abnormal condition is present". Replaced the note with Note 1 to entry. Added Note 2 to entry.]

3.31
sleep apnoea breathing therapy equipment
ME equipment delivering a therapeutic breathing pressure to the *patient* intended to treat obstructive sleep apnoea by keeping the upper airways open

Note 1 to entry: *Sleep apnoea breathing therapy equipment* is primarily used in the *home healthcare environment* by a *lay user* without direct professional supervision.

[SOURCE: ISO 80601-2-70:—, 201.3.257]

3.32
validation
confirmation, through the provision of objective evidence, that the requirements for a specific *intended use* or application have been fulfilled

Note 1 to entry: *Validation* involves a set of activities for gaining confidence that a system is able to accomplish its *intended use*, goals and objectives in its operational environment. In short, *validation* gives the confidence that the correct system was built to fulfil what is required for its intended application.

Note 2 to entry: The use conditions for *validation* can be real or simulated.

Note 3 to entry: The word "*validated*" is used to designate the corresponding status.

Note 4 to entry: In design and development, *validation* concerns the *process* of examining an item to determine *conformity* with *user* needs.

Note 5 to entry: *Validation* is normally performed during the final stage of development, under defined operating conditions, although it may also be performed in earlier stages.

Note 6 to entry: Multiple *validations* may be carried out if there are different *intended uses*.

[SOURCE: IEC 60050-192:2024, 192-01-18, modified — Added Notes 3, 4, 5 and 6 to entry.]

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