BRITISH STANDARD

BS EN ISO
17510-2:2009

Sleep apnoea breathing therapy

Part 2: Masks and application accessories (ISO 17510-2:2007)

ICS 11.040.10

BSI
British Standards

National foreword

This British Standard is the UK implementation of EN ISO 17510-2:2009. It is identical to ISO 17510-2:2003. It supersedes BS EN ISO 17510-2:2007 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510-2:2007)

Thérapie respiratoire de l'apnée du sommeil - Partie 2: Masques et accessoires d'application (ISO 17510-2:2007)

Schlafapnoe-Atemtherapie - Teil 2: Masken und Anwendungszubehör (ISO 17510-2:2007)

This European Standard was approved by CEN on 24 February 2009.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 17510-2:2009: E

Foreword

The text of ISO 17510-2:2007 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 17510-2:2009 by 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of an identical text or by endorsement, at the latest by September 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 17510-2:2007.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 17510-2:2007 has been approved by CEN as a EN ISO 17510-2:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 - Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
-	6a	This relevant Essential Requirement is not addressed in this European Standard
4	13.1, 13.6 a)	
4	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
4	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
4	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
4	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard
4.1 a)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
4.1 b)	13.3 b)	

4.1 c)	9.1, 13.6 b) , 13.6 c)	
4.1 d)	9.1, 13.6 b)	
4.1 e)	8.6, 13.6 h)	
4.1 f)	13.3 i)	
4.1 g)	13.3 j)	
4.1 h)	13.3 k)	
4.1 i)	13.3 b), 13.6 i)	
4.1 j)	13.6 k)	
4.1 l)	9.1, 13.6 b)	
4.1 o)	9.1, 13.6 b)	
4.1 m)	13.6 c)	
4.1 n)	13.6 n)	
4.1 q)	13.6 i)	
4.1 r), s)	13.6 d)	
4.2 a)	13.2, 13.3 d), 13.5	
4.2 b)	13.2, 13.3 e), 13.4	
4.2 c)	9.1	
4.2 d)	8.7, 13.2, 13.3 c), 13.3 m)	
4.2 e)	13.6 g)	
5	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5	4, 7.2, 7.5, 7.6	
5.1	12.7.4	
5.2	7.1, 7.3	
5.3	9.2, 12.8.2	
5.4	7.1, 7.3, 8.1, 8.3, 8.4, 8.5	
5.5	9.2, 12.8.1, 12.8.2	
5.6	8.1	
6	12.7.2, 12.7.3	

Warning – Other requirements and other EU Directives may be applicable to the products falling within the scope of this International standard.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 17510-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This second edition cancels and replaces the first edition (ISO 17510-2:2003) which has been technically revised.

ISO 17510 consists of the following parts, under the general title *Sleep apnoea breathing therapy*:

— *Part 1: Sleep apnoea breathing therapy equipment*

— *Part 2: Masks and application accessories*

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 needed to protect patients during use of this equipment.

ISO 17510-2 is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic document for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical electrical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

Throughout this document, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

INTERNATIONAL STANDARD **ISO 17510-2:2007(E)**

Sleep apnoea breathing therapy —

Part 2:
Masks and application accessories

1 Scope

This part of ISO 17510 applies to masks, their fixing and to the accessories used to connect a sleep apnoea breathing therapy equipment to the patient. It 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, and are used for the application of sleep apnoea breathing therapy, e.g. nasal masks, exhaust ports and headgear.

Sleep apnoea breathing therapy equipment is covered by ISO 17510-1. See Figure A.1 for typical elements of the two parts of ISO 17510.

This part of ISO 17510 does not cover oral appliances.

2 Normative references

The following referenced documents are indispensable for the application 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 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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

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

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

ISO 10993 (all parts), *Biological evaluation of medical devices*

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

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17510-1:2007, *Sleep apnoea breathing therapy — Part 1: Sleep apnoea breathing therapy equipment*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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

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

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*; Amendment A1:1991; Amendment A2:1995

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 17510-1, ISO 17664, ISO 23328-2, IEC 60601-1, IEC 60601-1-1 and the following apply.

NOTE For convenience, an alphabetized list of the sources of all defined terms used in this document is given in Annex K.

3.1
anti-asphyxia valve
valve used on a naso-oral mask, which is open to atmosphere when the sleep apnoea breathing therapy equipment is not providing adequate pressure at the mask and that is closed to atmosphere when the sleep apnoea breathing therapy equipment is providing adequate pressure at the mask

3.2
exhaust flow
flow from the mask or application accessories to atmosphere other than the leak due to improper seal to the face

NOTE 1 The exhaust flow can pass through openings in the mask, the connecting element and the mask, or through the anti-asphyxia valve.

NOTE 2 The exhaust flow discharges exhaled gases to atmosphere to reduce rebreathing of CO_2.

3.3
headgear
part that is used to fix the mask to the patient

3.4
mask
part which provides the interface between the patient and the patient connection port

NOTE According to their application, masks are divided into: nasal masks, oral masks or nasal-oral masks.

3.5
multi-patient re-use
capable of being re-used multiple times on multiple patients

3.6
oral appliance
device intended to maintain the oral airway by mechanical means and which achieves its purpose independently of sleep apnoea breathing therapy equipment

3.7
*** patient connection port**
port where the breathing gas pathway connects to the mask

3.8
single-patient reuse
capable of being used multiple times on the same patient

4 Information to be supplied by the manufacturer

NOTE Annex H contains a guide to assist the reader in locating the marking and labelling requirements contained in other clauses of this part of ISO 17510.

4.1 The label of the packaging, marking on the mask or accessory, and/or the accompanying documents shall contain the following information:

a) the name or trade name and address of the manufacturer and the name and address of the person responsible or of the authorized representative of the manufacturer or importer;

b) the identity and intended purpose of the mask and any application accessories;

c) * the pressure-flow curve of the exhaust flow throughout the working pressure range as determined in Annex B;

d) the rated pressure range of the mask including any connecting element;

e) if re-usable:

— the information specified in ISO 17664:2004, 3.9, if sterilizable;

— a warning that frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified in the accompanying documents, or exceeding the number of processing cycles can have an adverse effect on the materials used or performance;

f) any special storage and/or handling conditions;

g) any special operating instructions;

h) any special warnings and/or precautions to be taken;

i) information necessary for correct assembly of the components if the packaging contains more than one component;

j) information to enable the user (prescriber) to inform the patient of any potential contra-indications and any precautions that might need to be taken;

k) a warning statement to the effect that occlusion of any exhaust port should be prevented;

l) * the resistance, derived from pressure drop, between mask and the patient connecting port at flowrates of 50 l/min and 100 l/min, as determined in Annex C;

m) information about the means provided to minimize the risk of rebreathing (see 5.3);

n) a statement on proper disposal at end of life for the mask or accessory;

o) * the inspiratory and expiratory resistance of the mask in combination with the anti-asphyxia valve open to atmosphere, as determined in Annex E;

p) expected service life of any masks and accessories;

q) the details of any further treatment or handling needed before the mask or accessory can be used;

r) the information needed to verify whether the mask or accessory is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that it operates properly and safely at all times;

s) information about the nature and frequency of regular and preventative maintenance of the mask or accessory, including information about the replacement of consumable components of the device during the intended life of the mask or accessory.

Check compliance by inspection of the accompanying documents.

4.2 If appropriate, the label of the packaging, marking on the mask or accessory, and/or the accompanying documents shall contain the following information:

a) a serial number (or symbol 5.16 from ISO 15223-1:2007), or lot identifying number or batch identifying number (or symbol 5.14 from ISO 15223-1:2007);

b) an indication (or symbol 5.12 from ISO 15223-1:2007) of the latest date by which the mask and any application accessories can be used safely, expressed as the year and month;

c) a statement to the effect that combination with other medical devices can alter the performance of the mask, e.g. in combination with a humidifier for medical use, nebulizer, heat and moisture exchanger (HME), filters, bi-level positive airway pressure equipment, self-adjusting equipment, or additional oxygen supply or any exhaust port;

d) symbols 5.20 to 5.24 from ISO 15223-1:2007, if the package is sterile;

e) instructions necessary in the event of damage to the sterile packaging and details of appropriate methods of resterilization.

Check compliance by inspection of the accompanying documents.

5 Construction requirements

5.1 Mask connectors

Mask connectors, if conical, shall be 15 mm or 22 mm size male connectors conforming to ISO 5356-1 or ISO 5356-2.

Non-conical mask connectors shall not engage with conical connectors conforming to ISO 5356-1 or ISO 5356-2, unless they comply with the engagement, disengagement and leakage requirements of ISO 5356-1 or ISO 5356-2.

Check compliance by inspection and functional testing.

5.2 Biocompatibility

Parts and/or materials that are intended to be in contact with the patient or patient gas pathway under normal use shall comply with the ISO 10993 series. For nasal accessories intended to be inserted into the nares or parts of masks intended to be inserted into the mouth, the external materials of the nasal inserts or of the parts of the masks shall be evaluated as mucosal membrane contact. Additionally, for parts or materials not intended to be inserted into nares or mouth, the gas pathway materials shall be evaluated as externally communicating with tissue. For mask materials, including headgear, intended to contact the patient's head, the materials shall be evaluated as skin contacting.

All materials shall be considered as for permanent duration contact as categorized in ISO 10993.

NOTE Permanent duration contact is required because sleep apnoea breathing therapy equipment and accessories have cumulative usage that is greater than 30 days.

Latex shall not be used in the mask and accessories.

Check compliance by application of the ISO 10993 series.

5.3 * Protection against rebreathing

Means shall be provided to minimize the risk of rebreathing during normal condition and single fault condition.

Under normal condition, the relative CO_2 increase shall not exceed 20 % when tested at the minimum rated, 5 hPa (5 cm H_2O), and 10 hPa (10 cm H_2O) pressure.

Under single fault condition, the relative CO_2 increase shall not exceed 60 %.

Check compliance by the tests described in Annex F.

5.4 Cleaning, disinfection and sterilization

The mask and any accessories, whether for single-patient reuse or multi-patient re-use, shall be designed so that contaminant-trapping features are minimized and can be easily cleaned by the operator.

The mask and any accessories and their parts intended for multi-patient re-use shall be so constructed that they can be cleaned and disinfected or cleaned and sterilized.

Processing or (re)processing methods for cleaning and disinfection of a mask shall consist of performing the number of cleaning or cleaning and disinfection cycles that represents the expected lifetime of the mask.

Processing or (re)processing instructions disclosed in the instructions for use for the mask and any accessories and their parts shall comply with ISO 17664 and ISO 14937. The mask and any accessories labelled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937.

Non-sterile device packaging systems shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of contamination.

Check compliance by review of the validation of the processing methods, including the verification that the mask and any accessories and their parts comply with their specifications after re-processing and inspection of instructions for use.

5.5 * Breathing during single fault condition

Means shall be provided to limit inspiratory and expiratory resistance in single fault condition. The resistance to flow shall not exceed 10 hPa (10 cm H_2O) per l/s (measured at the patient connection port) at flowrates of 50 l/min.

If an anti-asphyxia valve is provided, the open-to-atmosphere pressure shall be less than the minimum rated pressure of the mask. The open-to-atmosphere and closed-to-atmosphere pressures shall be disclosed in the instructions for use.

Check compliance by using the tests described in Annexes D and E.

5.6 Breathing system filter

Any breathing system filter shall comply with ISO 23328-1 and ISO 23328-2.

Check compliance by application of the requirements of ISO 23328-1 and ISO 23328-2.

6 Vibration and noise

The A-weighted sound power level caused by the mask and any accessories shall be measured and disclosed in the instructions for use in accordance with ISO 4871 and ISO 3744 using engineering-method grade 2. The A-weighted sound pressure level in accordance with ISO 4871 and ISO 3744 at a distance of 1 m shall also be disclosed in the instructions for use.

NOTE Care is required in the test set-up to ensure that the sound measurement of the mask and any accessories is not interfered with by the noise emitted by the breathing tube or the equipment.

Check compliance by the tests in Annex G.

Annex A
(informative)

Rationale

A.1 Introduction

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

Figure A.1 is a typical example of a series of component arrangements of the ISO 17510 series. It is intended to enhance comprehension of the combination of **sleep apnoea breathing therapy equipment** and **masks** and application **accessories**, as well as to clarify the scope of the parts of ISO 17510 series.

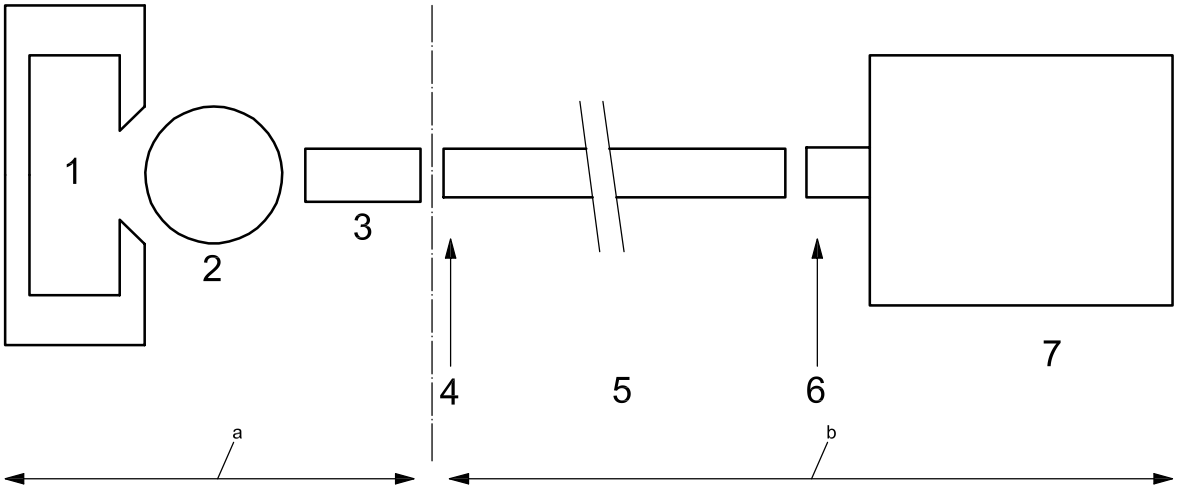
The clauses in this annex have been so numbered to correspond to the clauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

A.2 General

Sleep apnoea breathing therapy equipment is usually combined with a mask and application accessories of different manufacturers. Whereas most sleep apnoea breathing therapy equipment is pressure-adjustable at the patient connection port, all connected accessories and masks are outside the area where pressure is controlled. Therefore, these masks have direct impact on the therapeutic pressure received by the patient. An important mechanism whereby sleep apnoea breathing therapy equipment benefits the patient is by increasing cross-sectional area of the pharynx and decreasing the collapsibility of the upper airway. Sleep apnoea breathing therapy equipment is intended to deliver a therapeutic pressure to the patient by means of masks and/or application accessories.

The resistance of masks and accessories connected to sleep apnoea breathing therapy equipment depends on respiratory flowrate. High inspiratory peak flows, in particular, can cause a substantial pressure drop between the patient connection port and the patient's airway. Consequently, the patient does not receive the required therapeutic pressure, the probability of obstructive apnoea is increased, and the therapeutic objective is not achieved. Furthermore, the sleep apnoea breathing therapy equipment rely on both the design of the sleep apnoea breathing therapy equipment to minimize risk of asphyxia and the defence mechanism of the patient to respond to single fault conditions and arouse the patient from sleep, thereby allowing the patient to remove themselves from potential harm. Therefore, this International Standard deals extensively with the performance standard for sleep apnoea breathing therapy equipment to ensure the delivery of the therapeutic pressure and prevent asphyxia.

The requirements and the test method stated serve to provide guidance to users and operators when selecting appropriate sleep apnoea breathing therapy equipment, masks, accessories and the combination thereof, and to ensure compatibility of the masks and accessories with sleep apnoea breathing therapy equipment.



Key

1 headgear
2 mask
3 connecting element (optional)
4 patient connection port
5 breathing tube
6 gas output port connector
7 sleep apnoea breathing therapy equipment with or without humidifier

[a] Scope of ISO 17510-2.
[b] Scope of ISO 17510-1.

NOTE The exhaust port can be located in the connecting element (3) or the mask (2).

Figure A.1 — Relationship of the components of sleep apnoea breathing therapy equipment and masks and application accessories and the parts of ISO 17510

3.7

The patient connection port of the sleep apnoea breathing therapy equipment breathing gas pathway is the port to which a patient interface (e.g. mask and/or application accessories) or test apparatus can be connected.

4.1 c)

The exhaust flow comprises flow through all orifices in the mask and accessories (including the exhaust port).

Exhaust flow and the derived pressure-flow curve are important characteristics of the mask which assist the clinician in assessing the compatibility of the mask with other equipment. The relationship between the pressure provided to the patient and the exhaust flow is measured and included in the labelling.

The settings chosen for the test were selected to be consistent with ISO 17510-1:2007, Table CC.1.

4.1 l)

The total resistance to flow in sleep apnoea breathing therapy equipment and masks and application accessories comprises the resistance up to the patient connection port, plus the resistance of the mask and application accessories from the patient connection port to the patient.

The resistance up to the patient connection port is addressed in equipment design in ISO 17510-1. The resistance of the mask and application accessories from the patient connection port to the patient is an important characteristic that assists the clinician in assessing the compatibility of the mask and application accessories with other equipment.

The resistance of the mask and application accessories changes with the flow, and this relationship depends on the design. Therefore, a single measurement point is not adequate. The resistance is measured at two typical flows at the patient connection port (50 l/min and 100 l/min).

The pressure drop is provided, rather than the calculated resistance. Pressure drop is more useful to the user (prescriber).

Specifying the resistance to flow of the mask and application accessories allows the clinician to specify compatible sleep apnoea breathing therapy equipment.

4.1 o)

Specifying the inspiratory resistance of the anti-asphyxia valve of the mask at a very low flowrate allows the clinician to specify compatible sleep apnoea breathing therapy equipment so that the valve closes when needed. See also Annex E.

Specifying the expiratory resistance of the anti-asphyxia valve of the mask allows the clinician to specify compatible sleep apnoea breathing therapy equipment so that the valve closes when needed. See also Annex E.

5.3

Masks and other patient interfaces intended for use with sleep apnoea breathing therapy equipment without an active exhalation valve incorporate exhaust ports. The function of the exhaust ports is to allow for passive removal of exhaled gases to minimize rebreathing.

A critical issue to be considered is whether the machine-patient flow through the exhaust port has reduced the residual exhaled CO_2 to acceptable levels.

Most sleep apnoea breathing therapy equipment is equipped with a single-conduit breathing gas pathway with a dual-purpose, inspiratory/expiratory function and an exhaust port. The issue of CO_2 rebreathing will be a function of several variables, such as:

— the type of the breathing attachment — face mask, nasal mask, full face mask or nasal pillows;

— the size and location of the exhaust ports;

— the average flowrate at the minimum CPAP pressure;

NOTE The average flowrate is measured in ISO 17510-1:2007, Annex CC and recorded in Table CC.1, which allows the clinician to assess the potential for rebreathing.

— the duration of the patient's exhalation.

There is the potential for clinically significant CO_2 rebreathing if the exhaust ports are not designed and located appropriately. Therefore the design and configuration of sleep apnoea breathing therapy equipment and its masks and accessories has a major impact on the potential for rebreathing of carbon dioxide and thereby the inspired oxygen concentration.

The maximum recommended time-weighted average for inspired CO_2 in industry is 1 %. An inspired CO_2 fraction of 1 % would add 1 013,25 Pa (7,6 torr) the test model in Annex F and would result in the test end-tidal CO_2 value of 1 013,25 Pa (7,6 torr) + 5 066,25 Pa (38 torr) or 6 079,5 Pa (45,6 torr). This represents a 20 % increase in the CO_2 level. Based on this, the committee chose a 20 % increase in the CO_2 level normal condition limit. Similarly, the 60 % increase in the CO_2 level single fault condition limit represents a time-weighted average for inspired CO_2 of 3 %.

5.5

For patient safety when the sleep apnoea breathing therapy equipment ceases to provide flow, the mask, complete with specified application accessories, is required to have the following features.

— To control rebreathing at an acceptable level by allowing adequate flushing of CO_2 when only patient-generated flow is passing through the mask. See also 5.3.

— To limit the inspiratory and expiratory resistance to an acceptable level.

One method of achieving the above requirement is to provide an anti-asphyxia valve, in parallel with the exhaust port. To ensure that the functioning of this valve does not impair the function of the mask during normal condition it is required to have the following features:

— closing pressure: the anti-asphyxia valve is required to close to atmosphere at an appropriate pressure, to ensure that therapy is provided to the patient;

— opening pressure: the anti-asphyxia valve is required to open at an appropriate pressure, to ensure that the patient is provided with a safe inspiratory and expiratory resistance and a safe level of re-breathing, when therapy is not provided;

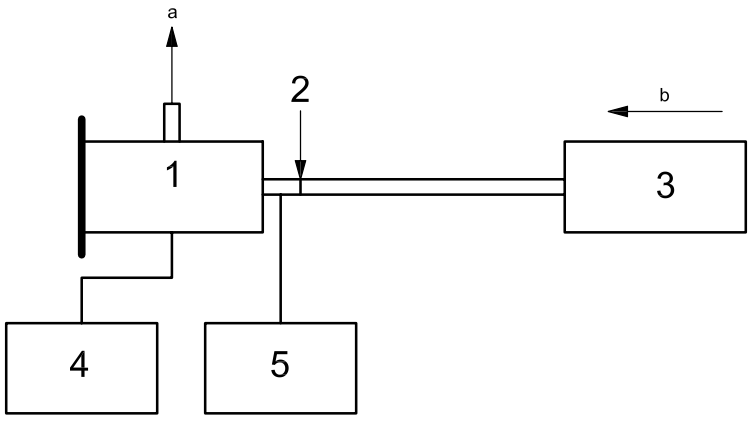
— protection against opening in normal use: to ensure that therapy is provided to the patient, the anti-asphyxia valve is intended to remain closed while the sleep apnoea breathing therapy equipment is operating.

Annex B
(normative)

Exhaust flow test procedure

B.1 Introduction

The objective of this test is to determine the relationship between the pressure provided to the patient and the exhaust flow, which is measured.



Key

1 mask or accessory under test
2 patient connection port
3 flow source
4 pressure meter
5 low meter

[a] Exhaust flow.
[b] Flow.

Figure B.1 — Test set-up for exhaust flow testing

B.2 Procedure

Carry out testing as follows.

a) Set up the mask or accessory and test apparatus as shown in Figure B.1.

b) To measure exhaust flow only, ensure that the test apparatus satisfies the following requirements:

   — exclude flow source (3) (flow between the flow generator and patient connection port) from the measurement (e.g. position the flow meter at the connection port);

   — position the sensor flow meter (5) at the patient connection port (2);

   — exclude flow source (3) (at patient interface) by sealing the patient interface of the mask. Ensure that the patient interface is sealed.

c) To measure the pressure provided to the patient, ensure that the pressure sensor measures the pressure directly adjacent to the patient's nose/mouth.

d) Adjust the flowrate to achieve the minimum pressure in the rated pressure range, and measure the flowrate at this point.

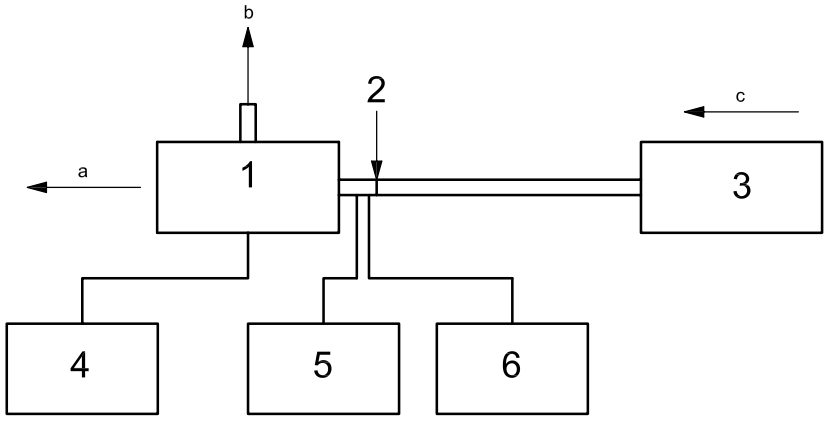
e) Repeat Steps b) to d) for pressures (rounded to the next whole integer) of ¼, ½, ¾ and maximum pressure of the rated pressure range.

Annex C
(normative)

Resistance to flow (pressure drop)

C.1 Introduction

The objective of this test is to measure the pressure drop from the patient connection port to the patient at flowrates of 50 l/min and 100 l/min.



Key

1 mask or accessory under test
2 patient connection port
3 flow source
4 pressure meter 2
5 pressure meter 1
6 flow meter

a Flow to atmosphere.
b Exhaust flow.
c Flow.

Figure C.1 — Test set-up for resistance to flow (pressure drop)

C.2 Procedure

Carry out testing as follows.

a) Set up the mask or accessory (1) and apparatus as shown in Figure C.1. If required, leave the patient interface open to the atmosphere to achieve the specified flowrates.

b) The first point of pressure measurement is at the patient connection port. The second point of pressure measurement is directly adjacent to the patient's nose/mouth, to measure the pressure provided to the patient.

c) Adjust the flowrate to 50 l/min, and measure the pressure drop (pressure metre 1 minus pressure metre 2) in hPa (cm H_2O).

d) Repeat steps b) and c) at 100 l/min flowrate.

Annex D
(normative)

Anti-asphyxia valve pressure testing

D.1 Introduction

The objective of these tests is to:

— determine the pressure at which the anti-asphyxia valve is in the open-to-atmosphere state;

— determine the pressure at which the anti-asphyxia valve is in the closed-to-atmosphere state.

These tests assess the safety means of limiting breathing resistance and to prevent excessive rebreathing when the sleep apnoea breathing therapy equipment has insufficient flow.

The pressure at which the anti-asphyxia valve is open-to-atmosphere shall be below the minimum rated pressure of the sleep apnoea breathing therapy equipment.

NOTE If the pressure at which the anti-asphyxia valve is open-to-atmosphere is not below the minimum rated pressure of the sleep apnoea breathing therapy equipment, the anti-asphyxia valve will not function.

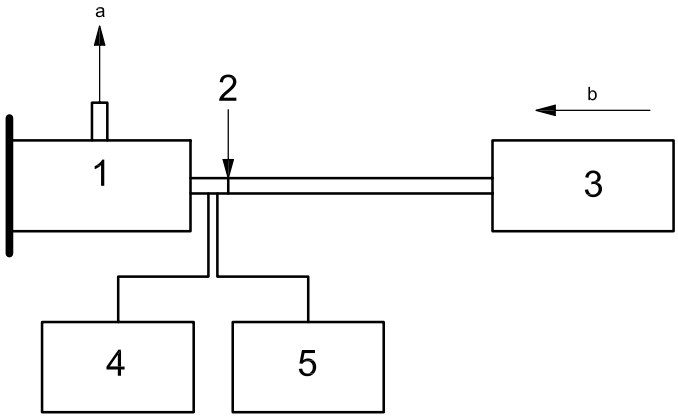
D.2 Opening pressure

Carry out opening testing as follows.

a) Set up the test to generate flow through the breathing gas pathway as indicated in Figure D.1 and ensure that the anti-asphyxia valve is closed to the atmosphere.

b) Slowly decrease the flow from the flow source until the anti-asphyxia valve activates and starts to open to the atmosphere.

c) Record the mask pressure at the point where the anti-asphyxia valve starts to open to the atmosphere.



Key

1 anti-asphyxia valve under test
2 patient connection port
3 flow source
4 pressure meter
5 flow meter

[a] Anti-asphyxia valve flow.
[b] Flow.

Figure D.1 — Determination of the opening and closing pressure of the anti-asphyxia valve

D.3 Closing pressure

Carry out closing testing as follows.

a) Set up the test to generate flow through the breathing gas pathway as indicated in Figure D.1 and assure the anti-asphyxia valve (1) is open to the atmosphere.

b) Slowly increase the flow from the flow source (3) until the anti-asphyxia valve deactivates and completely closes to atmosphere.

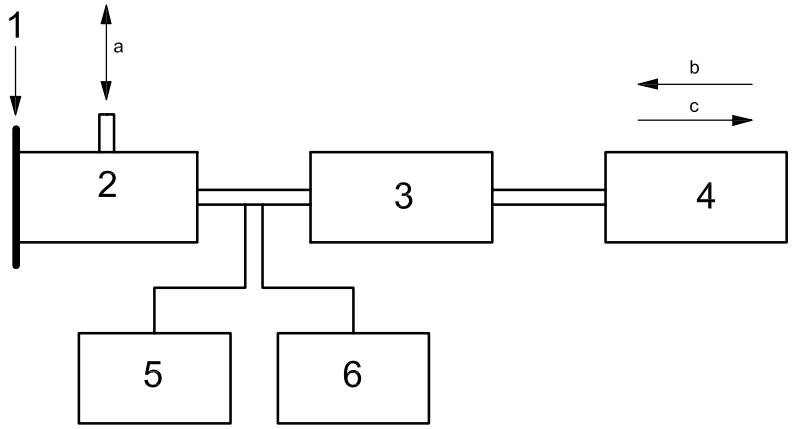
c) Record the mask pressure at the point where the anti-asphyxia valve closes completely.

Annex E
(normative)

Breathing during single fault condition — Determination of the inspiratory and expiratory resistance

E.1 Introduction

The objective of this test is to determine the inspiratory and expiratory resistance at a flow of 50 l/min in the single fault condition, e.g., when the anti-asphyxia valve is activated (open to the atmosphere).



Key

1 patient connection port
2 anti-asphyxia valve under test
3 dummy head with airway
4 flow source
5 pressure meter
6 flow meter

[a] Anti-asphyxia valve flow.
[b] Expiratory flow.
[c] Inspiratory flow.

Figure E.1 — Determination of the inspiratory and expiratory resistance of the anti-asphyxia valve

E.2 Procedure

Carry out testing as follows.

a) Connect a variable pressure source capable of generating subatmospheric pressures to the flowrate-measurement device.

b) Connect the flowrate-measurement device to a dummy head with an artificial airway or other suitable fixture that will seal the mask.

c) Connect the pressure meter to the mask.

d) Occlude the patient connection port on the mask or any other known flow path in the mask that is not normally open during operation (such as pressure ports).

e) Leave open any normally open-air paths.

f) Set the variable flow source to −50 l/min.

g) Read the inspiratory pressure at the pressure meter.

h) Set the variable flow source to +50 l/min.

i) Read the expiratory pressure at the pressure meter.

Annex F
(normative)

CO_2 rebreathing

F.1 Introduction

The objective of the CO_2 rebreathing test is to test the effectiveness of masks or other patient interfaces intended for sleep apnoea breathing therapy with respect to the possibility of rebreathing carbon dioxide (CO_2).

Masks and other patient interfaces intended for use with positive airway pressure equipment without an active exhalation valve incorporate an exhaust port. The function of the exhaust port is to allow for passive removal of exhaled CO_2 to minimize rebreathing. There is the potential for clinically significant CO_2 rebreathing if the exhaust port is not designed and located appropriately. Since the exhaust port location can affect rebreathing, measuring only exhaust port pressure/flow characteristics might not be sufficient to ensure acceptable performance. This test measures CO_2 directly during simulated breathing that allows masks and other patient interfaces to be compared with respect to rebreathing in both normal condition and single fault condition.

F.2 Test Procedure

Carry out testing as follows.

a) Assemble components as shown in Figure F.1.

NOTE 1 In the initial setup, the mask is not attached to the simulated patient head.

NOTE 2 The simulated patient head has approximately 30 ml of internal volume between the gas sampling port and the nose/mouth to simulate a patient airway.

b) Set breathing simulator parameters:

   1) tidal Volume = 0,5 l;

   2) rate = 15 breaths/min;

   3) I:E ratio = 1:2;

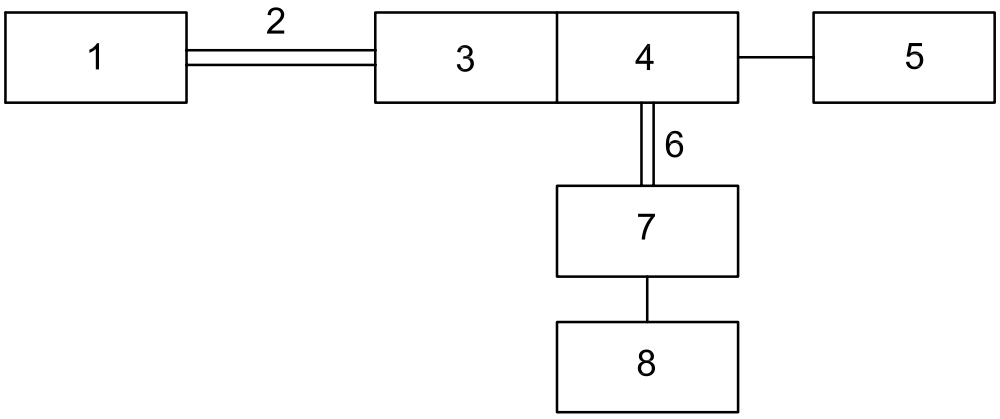
   4) sinusoidal waveform.

c) Connect the CO_2 monitor to the gas sampling port via gas sampling line.

d) Connect the source of gas containing greater than 99 % CO_2 via a flow meter into the lung simulator. Ensure a constant flowrate.

e) Start the lung and breathing simulator and slowly increase gas flow until the end-expiratory peak CO_2 reading is approximately a volume fraction of 5 %. Allow sufficient time for simulation to equilibrate and reading to stabilize.

NOTE A volume fraction of 5 % simulates normal metabolic CO_2 production.



Key

1 flow source
2 1,9 m ± 0,15 m breathing tube
3 mask and, if applicable, connecting element
4 simulated patient head
5 CO_2 monitor
6 dead space of 140 ml ± 5 ml
7 test lung simulator (driving ventilator + breathing simulator)
8 CO_2 constant flow source

NOTE 1 A lung chamber volume of approximately 10 l, with an active mixing fan, is recommended to ensure satisfactory mixing.

NOTE 2 Adapted from reference [3].

Figure F.1 — Apparatus for CO_2 rebreathing testing

f) Record the end-expiratory CO_2 concentration.

NOTE A time greater than three times time constant (i.e. three times the ratio of the volume of the lung chamber and the simulated alveolar ventilation) is sufficient.

g) Secure the test mask to head, simulating normal use. Verify that the mask is completely sealed to face portion of simulated patient head, with no unintentional leaks.

h) Set the pressure source to generate the minimum rated pressure of the mask including any connecting element.

i) Allow sufficient time for the simulation to equilibrate and CO_2 reading to stabilize. Then record the end-expiratory CO_2 concentration.

j) Calculate the relative CO_2 increase by computing the percentage difference between the final and initial end-expiratory CO_2 concentrations, i.e. 100 times [the value in i) minus the value in f)] divided by the value in f).

k) Set the pressure source to generate a pressure of approximately 5 hPa (5 cm H_2O).

l) Repeat steps e) to j).

m) Set the pressure source to generate a pressure of approximately 10 hPa (10 cm H_2O).

n) Repeat steps e) to j).

o) Simulate the following single fault conditions, one at a time.

— blockage of the breathing tube (simulated by occluding the patient connector port);

— failure of the equipment to generate flow (simulated by connecting one end of the breathing tube to the patient connector port with other end open to atmosphere).

p) Repeat steps e) to j).

Annex G
(normative)

Vibration and noise

Carry out testing as follows.

a) Seal the patient interface of the mask or accessory and place the mask and any accessory on the sound-reflecting plane.

b) Fit the breathing tubes and equipment provided or recommended by the manufacturer.

c) If a humidifier is provided with the equipment, include the humidifier in the test.

d) Acoustically insulate the breathing tubes and equipment by a suitable means out of the testing area so that the noise caused by the breathing tube and the gas flow does not interfere with the sound measurement of the mask and any accessory.

NOTE The insulation is intended to ensure that the noise emitted by the breathing tube or the equipment or the noise conducted by the airflow is not interfering with the sound measurement of the mask or accessory.

e) Set the equipment to achieve a continuous pressure of 10 hPa (10 cm H_2O) at the patient connection port.

f) Using the microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672-1, measure the sound pressure levels at 10 positions in a hemisphere with a radius of 1 m to the geometric centre of the mask and any accessories as specified in ISO 3744:1994, 7.2.

g) Calculate the A-weighted sound pressure level averaged over the measurement surface according ISO 3744:1994, 8.1.

h) Calculate the A-weighted sound power level according ISO 3744:1994, 8.6.

i) Ensure that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.

j) Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter in a free field over a reflecting plane as specified in ISO 3744.

Annex H
(informative)

Guide to information to be supplied by the manufacturer

The requirements for information to be supplied by the manufacturer are found in Clause 4. Additional requirements are found in the subclauses listed in Table H.1.

Table H.1 — Marking

Description of information	Subclause
Processing or (re)processing	5.4
If provided, anti-asphyxia valve open-to-atmosphere pressure	5.5
If provided, anti-asphyxia valve closed-to-atmosphere pressure	5.5
Sound power level	6
Sound pressure level	6

Annex I
(informative)

Reference to the essential principles

This part of ISO 17510 has been prepared to support the essential principles of safety and performance of the masks and accessories of sleep apnoea breathing therapy equipment as medical devices according to ISO/TR 16142. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this part of ISO 17510 provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible. Table I.1 maps the clauses and subclauses of this part of ISO 17510 with the essential principles of ISO/TR 16142.

Table I.1 — Correspondence between this document and the essential principles

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/subclause(s) of this part of ISO 17510	Qualifying remarks/Notes
A.1, A.2, A.3	All	
A.4	5	
A.5	—	
A.6	—	
A.7.1	5.2, 5.4	
A.7.2	5	
A.7.3	5.2, 5.4	
A.7.4	—	Not applicable
A.7.5	5	
A.7.6	5	
A.8.1	5.4, 5.6	
A.8.1.1	—	Not applicable
A.8.1.2	—	Not applicable
A.8.2	5.4	
A.8.3	5.4	
A.8.4	5.4	
A.8.5	4.1 e	
A.8.6	4.2 d)	
A.9.1	4.1 c), d), l), o), 4.2 c)	
A.9.2	5.3, 5.5	
A.9.3	—	Not applicable
A.10.1	—	Not applicable
A.10.2	—	Not applicable
A.10.3	—	Not applicable
A.11.1.1	—	Not applicable
A.11.2.1	—	Not applicable

Table I.1 *(continued)*

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/subclause(s) of this part of ISO 17510	Qualifying remarks/Notes
A.11.2.2	—	Not applicable
A.11.3.1	—	Not applicable
A.11.4.1	—	Not applicable
A.11.5.1	—	Not applicable
A.11.5.2	—	Not applicable
A.11.5.3	—	Not applicable
A.12.1	—	Not applicable
A.12.2	—	Not applicable
A.12.3	—	Not applicable
A.12.4	—	Not applicable
A.12.5	—	Not applicable
A.12.6	—	Not applicable
A.12.7.1	—	Not applicable
A.12.7.2	6	
A.12.7.3	6	
A.12.7.4	5.1	
A.12.7.5	—	Not applicable
A.12.8.1	5.5	
A.12.8.2	5.3, 5.5	
A.12.8.3	—	Not applicable
A.13.1	4	
A.14.1	—	

Annex J
(informative)

Environmental aspects

The environmental impact generated by the masks and accessories of sleep apnoea breathing therapy equipment is mainly isolated to the following occurrences:

— impact at local environment during normal use;

— use, cleaning and disposal of consumables during testing and normal use;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this document addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of such masks and accessories.

See Table J.1 for a mapping of the life cycle of masks and accessories of sleep apnoea breathing therapy equipment, to aspects of the environment.

Table J.1 — Environmental aspects addressed by clauses of this part of ISO 17510

	Environmental aspects (inputs and outputs)	**Product life cycle**			
		Production and preproduction **Stage A**	**Distribution (including packaging)** **Stage B**	**Use** **Stage C**	**End of life** **Stage D**
		Addressed in clause			
1	Resource use	—	—	—	—
2	Energy consumption	—	—	—	—
3	Emission to air	—	—	4.1 e) 4.1 n) 4.1 p)	—
4	Emission to water	5.4	—	4.1 e)	4.1 e)
5	Waste	5.4	—	4.1 e) 4.1 n)	4.1 e) 4.1 n)
6	Noise	6	—	6	–
7	Migration of hazardous substances	5.2	—	5.2	5.2
8	Impacts on soil	—	—	—	4.1 n)
9	Risks to the environment from accidents or misuse	—	—	—	4.1 n)

Annex K
(informative)

Terminology — Alphabetized index of defined terms

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[1] ISO/TR 16142, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[2] AAMI TIR No. 12-1994, *Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, A Guide for Device Manufacturers*

[3] ASTM F1246-91:2005, *Standard Specification for Electrically Powered Home Care Ventilators, Part 1: Positive-Pressure Ventilators and Ventilator Circuits*

[4] FARRE, R., MONTSERRAT, J.M., BALLESTER, E. and NAVAJAS, D. *Potential Rebreathing After Continuous Positive Airway Pressure Failure During Sleep*, Chest, **121**, pp 186-200, 2002

[5] GUILHERME, P.P., SCHETTINO, S.C., HESS, D.R. and KACMAREK, R,M. *Position of exhalation port and mask design affect CO_2 rebreathing during non-invasive positive pressure ventilation*, Crit Care Med **31** (8), pp 2178-2182, 2003

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