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Anaesthetic and respiratory equipment — General requirements for airways and related equipment

Matériel d'anesthésie et de réanimation respiratoire — Exigences générales pour canules et équipement connexe

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Foreword

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

Introduction

This International Standard provides the general requirements for basic safety and performance for the design, packaging, marking and labelling that are generally applicable to all AIRWAYS AND RELATED EQUIPMENT.

This International Standard is intended to replace or supplement the often, repetitive general requirements that are common among the set of standards within the category of AIRWAYS AND RELATED EQUIPMENT. The aim of this International Standard is to serve as a central catalogue of these common requirements, allowing each device-specific standard to more concisely focus on the unique safety and essential requirements for the equipment.

For certain types of AIRWAYS AND RELATED EQUIPMENT, these general requirements are either supplemented or modified by the specific requirements of a device-specific standard. Where device-specific standards exist, this International Standard should not be used alone.

For the purposes of clarity, the following conventions have been used:

— DEFINED TERMS APPEAR IN SMALL CAPS TYPE;

— clauses/subclauses for which a rationale is provided in Annex A is indicated by an asterisk (*);

— *compliance checks are given in italics type*.

Anaesthetic and respiratory equipment — General requirements for airways and related equipment

1 Scope

This International Standard specifies the general requirements common to AIRWAYS AND RELATED EQUIPMENT and applicable to those device-specific standards that reference it.

The requirements of a device-specific standard take priority over this International Standard.

NOTE General requirements contained in this International Standard have historically been referenced in more than two other AIRWAYS AND RELATED EQUIPMENT standards.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE See Annex A for information on the use of dated and undated normative references.

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

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

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1:2006/Amd.1:2013, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices/Amendment 1*

ISO 14155:2011/Cor.1:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice/Technical Corrigendum 1*

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 80369-7[1)], *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

1) To be published.

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

ASTM F640, *Standard test methods for determining radiopacity for medical use*

ASTM F2052, *Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment*

ASTM F2213, *Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment*

ASTM F2503, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

3 Terms and definitions

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

3.1
AIRWAYS AND RELATED EQUIPMENT
devices that provide an interface to the patient's airways, either through direct contact, or as an intermediate component to other anaesthetic and respiratory equipment

3.2
ANTISTATIC
property of material or a procedure that disperses or inhibits the accumulation of electrostatic charges

3.3
RISK
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2007, 2.16]

3.4
RISK ANALYSIS
systematic use of available information to identify hazards and to estimate the RISK (3.3)

[SOURCE: ISO 14971:2007, 2.17, modified]

Note 1 to entry: RISK ANALYSIS includes examination of different sequences of events that can produce hazardous situations and harm (see Annex B and ISO 14971:2007, Clause 4).

3.5
RISK ASSESSMENT
overall process comprising a RISK ANALYSIS (3.4) and a RISK EVALUATION (3.6)

[SOURCE: ISO 14971:2007, 2.18]

3.6
RISK EVALUATION
process of comparing the estimated RISK (3.3) against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO 14971:2007, 2.21]

3.7
RISK MANAGEMENT
systematic application of MANAGEMENT policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring RISK (3.3)

[SOURCE: ISO 14971:2007, 2.22]

3.8
RISK MANAGEMENT FILE
set of records and other documents that are produced by RISK MANAGEMENT (3.7)

[SOURCE: ISO 14971:2007, 2.23]

3.9
SINGLE FAULT CONDITION
condition in which a single means for reducing a RISK (3.3) is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005, 3.116]

3.10
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: The term "validated" is used to designate the corresponding status.

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

4 General requirements for AIRWAYS AND RELATED EQUIPMENT

4.1 * RISK MANAGEMENT

4.1.1 This International Standard specifies requirements that are generally applicable to risks associated with AIRWAYS AND RELATED EQUIPMENT. An established RISK MANAGEMENT process shall be applied to the design of AIRWAYS AND RELATED EQUIPMENT. The RISK MANAGEMENT process shall include the following elements:

— RISK ANALYSIS;

— RISK EVALUATION;

— RISK control - production and post-production information.

EXAMPLE ISO 14971.

NOTE See Annex B for a list of hazards that can be used as guidance in the RISK ASSESSMENT.

Check compliance by inspection of the RISK MANAGEMENT FILE.

4.2 Usability

The manufacturer shall apply a usability engineering process to assess and mitigate any RISKS caused by usability problems associated with correct use (i.e. normal use) and use errors (see IEC 60601-1-6 and IEC 62366-1).

Check compliance by inspection of the usability engineering file.

4.3 Clinical evaluation

Where appropriate, clinical studies shall be performed under the conditions for which performance is claimed and documented in the RISK MANAGEMENT FILE. The clinical studies shall comply with the requirements of ISO 14155.

NOTE Clinical data may be sourced from

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, or

— published and/or unpublished reports on other clinical experience with either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

Check compliance by inspection of the RISK MANAGEMENT FILE.

4.4 Biophysical or modelling research

Where appropriate, validated biophysical or modelling research shall be performed under the conditions for which performance is claimed, and documented in the RISK MANAGEMENT FILE.

NOTE Biophysical or modelling research is the application of validated physical methods and theories to biological problems. Examples include the use of a combination of models (i.e. mathematical, computer, physical, cell and tissue culture, and animal) in a complementary and interactive manner to simulate the performance of medical devices.[29]

Check compliance by inspection of the technical file.

5 Materials

5.1 Biological safety testing

AIRWAYS AND RELATED EQUIPMENT, in their ready-to-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing (e.g. ISO 10993-1).

Check compliance by inspection of the technical file.

5.2 Intended use and environmental conditions

AIRWAYS AND RELATED EQUIPMENT shall be made of materials suitable for their intended use and the environmental conditions that they may be subjected to during transport, storage or when in use.

Check compliance by inspection of the technical file.

5.3 Leaching

AIRWAYS AND RELATED EQUIPMENT shall be manufactured to reduce, to a minimum, the RISKS posed by substances leaching from the materials.

NOTE Attention is drawn to substances, which are carcinogenic, mutagenic or toxic to reproduction.

Check compliance by inspection of the RISK MANAGEMENT FILE.

5.4 Cleaning, disinfecting or sterilizing agents

The recommended cleaning, disinfecting or sterilizing agents shall not alter the specified performance of the device throughout the claimed use life.

Check compliance by inspection of the technical file.

5.5 Phthalates

Manufacturers of AIRWAYS AND RELATED EQUIPMENT intended for the treatment of children or pregnant or nursing women and made of materials that incorporate phthalates, which are classified as carcinogenic, mutagenic or toxic to reproduction, shall provide a specific justification for the use of these substances in their technical file. See also 9.1.1.4 m) and 9.2.3 c) for additional marking and instructions for use requirements.

Check compliance by inspection of the manufacturer's RISK MANAGEMENT FILE.

5.6 Natural rubber (latex)

Manufacturers of AIRWAYS AND RELATED EQUIPMENT made of materials that incorporate natural latex shall provide a specific justification for using these substances in their technical file. See also 9.1.1.4 n) for additional marking requirements.

Check compliance by inspection of the manufacturer's RISK MANAGEMENT FILE.

5.7 Gas compatibility

5.7.1 AIRWAYS AND RELATED EQUIPMENT shall be compatible with those medical gases and vapours specified by the manufacturer.

Check compliance by inspection of the manufacturer's RISK MANAGEMENT FILE.

5.7.2 AIRWAYS AND RELATED EQUIPMENT devices in contact with oxygen during normal use shall meet the cleanliness requirements of ISO 15001.

NOTE This requirement is necessary to reduce the RISK of contamination ignition and fire in oxygen-enriched atmospheres.

Check compliance by the tests and requirements in ISO 15001 *and by inspection of the RISK controls described in the RISK ASSESSMENT and associated verification and VALIDATION studies.*

5.7.3 Components of AIRWAYS AND RELATED EQUIPMENT in contact with medical gases during normal use shall meet the cleanliness requirements of ISO 15001.

NOTE This requirement is necessary to reduce the RISK of contamination ignition and fire in oxygen-enriched atmospheres.

Check compliance by the test and requirement in ISO 15001:2010, Clause 4.

5.7.4 The RISKS associated with ignition by a flame, electrocautery, electrostatic discharge or laser beam in an oxygen-enriched atmosphere in AIRWAYS AND RELATED EQUIPMENT shall be identified. Attention is drawn to the following:

a) maintenance of combustion in oxygen-enriched atmospheres;

b) specular reflectance so as to avoid laser injury to non-targeted tissue;

c) heat transfer that may damage adjacent tissue;

d) products of pyrolysis and combustion that satisfy appropriate biological safety testing, as indicated in ISO 10993-1;

e) RISKS associated with electrocautery and lasers in operating room environments;

f) RISKS associated with use in home environments (i.e. cooking, cigarette smoking, etc.).

NOTE See also ISO/TR 11991.

Check compliance by inspection of the RISK MANAGEMENT FILE.

5.8 * Durability of marking

The marking on AIRWAYS AND RELATED EQUIPMENT shall be durable.

Check compliance by the requirements and tests described in IEC 60601-1:2005, 7.1.3.

5.9 Resistance to deterioration

If intended and marked for reuse, materials used for AIRWAYS AND RELATED EQUIPMENT shall be resistant to deterioration by cleaning and disinfection or sterilization methods recommended by the manufacturer. The recommended method or methods of sterilization shall not produce changes in the materials which will compromise the biological safety of the AIRWAYS AND RELATED EQUIPMENT.

Check compliance by inspection of the RISK MANAGEMENT FILE.

5.10 Magnetic resonance imaging (MRI) compatibility

AIRWAYS AND RELATED EQUIPMENT that are marked suitable for use in an MRI environment shall be evaluated according to ASTM F2052 and ASTM F2213.

Check compliance by inspection of the RISK MANAGEMENT FILE.

6 Design requirements for AIRWAYS AND RELATED EQUIPMENT

6.1 Mechanical safety

6.1.1 The mechanical design of AIRWAYS AND RELATED EQUIPMENT shall be such that it does not compromise the clinical condition or safety of the patient, or the safety and health of users and others in the environment.

Check compliance by inspection of the RISK MANAGEMENT FILE.

See ISO 10524-3.

6.1.2 * Connectors for inflating cuffs shall be compatible with a male connector complying with ISO 80369-7 and have a captive means of sealing.

The following are examples of captive means of sealing:

— tethered cap;

— integrated self-sealing valve.

Check compliance by functional testing.

6.1.3 * AIRWAYS AND RELATED EQUIPMENT labelled as radiopaque shall be radiographically identifiable *in vivo*.

Check compliance by functional testing in ASTM F640. *The reference sample shall be a 1 mm by 1 mm by 10 mm piece of aluminium*.

6.1.4 The positioning of controls shall follow usability principles to minimize the RISK of harm to the patient.

Check compliance by inspection of the RISK MANAGEMENT FILE.

6.2 Medical electrical equipment safety

AIRWAYS AND RELATED EQUIPMENT that utilize electrical power shall meet the requirements given in IEC 60601-1, in addition to the requirements given in this International Standard.

Check compliance by application of the tests of IEC 60601-1.

6.3 Pneumatic safety

AIRWAYS AND RELATED EQUIPMENT intended to be connected to a medical gas pipeline system complying with ISO 7396-1 or a pressure regulator complying with ISO 10524-1 or ISO 10524-3, shall reduce, to a minimum, the RISKS posed when subjected to a pressure of 1 MPa (10 bar) inlet pressure.

Check compliance by functional testing.

6.4 Protection against inadvertent adjustments

6.4.1 Means of protection against inadvertent adjustment of controls which can create a hazardous condition shall be provided.

NOTE Mechanical control techniques, such as locks, shielding, friction-loading and detents, are considered suitable. Pressure-sensitive finger pads, capacitive finger switches and microprocessor-oriented "soft" controls or a specific sequence of key or switch operations are also considered suitable.

Check compliance by functional testing following the instructions for use.

6.4.2 Control devices (if fitted) shall be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.

Check compliance by inspection of the usability engineering file.

6.5 * Prevention of electrostatic charges

ANTISTATIC AIRWAYS AND RELATED EQUIPMENT and integrally attached components that are for use with flammable anaesthetic mixtures shall have an end-to-end resistance of not less than 1 megohm (1 MΩ) and not more than 1 000 megohm (1 000 MΩ) when tested in accordance with the requirements of IEC 60601-1:2005, Annex G4.3.

6.6 Device lifetime

AIRWAYS AND RELATED EQUIPMENT shall comply with the requirements of this International Standard throughout the device lifetime marked on the label and instructions for use.

NOTE Device lifetime can include shelf life, time after opening and recommended service life including any cleaning/disinfection/sterilization cycles.

Check compliance by inspection of the technical file.

7 Requirements for AIRWAYS AND RELATED EQUIPMENT supplied sterile

7.1 Sterility assurance

AIRWAYS AND RELATED EQUIPMENT supplied sterile shall satisfy the requirements of EN 556-1:2001, 4.1 and, if applicable, ISO 11135 or ISO 11137-1.

Check compliance by inspection of the technical file.

8 Packaging

8.1 Packaging of AIRWAYS AND RELATED EQUIPMENT supplied sterile

8.1.1 AIRWAYS AND RELATED EQUIPMENT supplied sterile shall be contained in an individual pack.

8.1.2 The pack shall serve as an effective barrier to the penetration of microorganisms and particulates.

8.1.3 The pack shall not be capable of reclosure without clearly revealing that it has been opened.

Check compliance by inspection of the technical file.

9 Information supplied by the manufacturer

9.1 Marking

9.1.1 General

9.1.1.1 Information needed to use the AIRWAYS AND RELATED EQUIPMENT safely should be set out on the AIRWAYS AND RELATED EQUIPMENT itself or, if not practicable, on the unit packaging or on the insert.

9.1.1.2 Symbols shall be used where appropriate.

EXAMPLE ISO 7000, ISO 15223-1, ISO 15223-2 and EN 15986.

9.1.1.3 Packaging and labelling shall differentiate between the same or similar AIRWAYS AND RELATED EQUIPMENT supplied, both sterile and non-sterile, by the same manufacturer.

9.1.1.4 Marking on the AIRWAYS AND RELATED EQUIPMENT, their unit pack, shelf or multi-unit pack or insert shall conform to EN 1041 and shall include the following, if appropriate:

a) the name or trade name and address of the manufacturer or supplier. In addition, where required, the name and address of their authorized representative;

b) the batch code preceded by the word “LOT,” where applicable, or serial number;

c) an indication of the date by which the AIRWAYS AND RELATED EQUIPMENT, or parts thereof, can be used in safety, expressed as the year and month;

d) if appropriate, details necessary for the user to identify the AIRWAYS AND RELATED EQUIPMENT and the contents of the packaging;

e) if appropriate, instructions on preparation for use;

f) if appropriate, the word “STERILE”;

g) if appropriate, an indication that the device, or parts thereof, are for single use—a manufacturer's indication of single use should be consistent;

h) if appropriate, the word "ANTISTATIC";

NOTE The AIRWAYS AND RELATED EQUIPMENT may also bear a continuous indelible yellow-coloured marking throughout their length.

i) if appropriate, with an indication that the AIRWAYS AND RELATED EQUIPMENT are suitable for use with flammable anaesthetic agents/gases (e.g. symbol "AP" or "APG" given in IEC 60417-5331 or IEC 60417-5332);

j) * where required, a statement that the sale, distribution and use of this device is restricted to prescription use;

NOTE This is to fulfil the requirements of US 21 CFR 801.109[30].

k) if appropriate, instructions for cleaning and disinfection or sterilization and the maximum number or period of re-uses;

l) if appropriate, the RISKS associated with reusing the AIRWAYS AND RELATED EQUIPMENT;

m) if appropriate, an indication that phthalates are present in the device;

EXAMPLE Use symbol given in ISO 15986.

n) if appropriate, an indication that natural rubber (latex) is present in the device;

EXAMPLE Use ISO 15223-1:2012, symbol 5.4.5.

o) * the patient category as indicated in Table 1 for the intended delivered volume;

Table 1 — Patient categories

Patient category	Intended delivered volume
Adult	Vt ≥ 300 ml
Paediatric	50 ml < Vt < 300 ml
Neonatal	Vt ≤ 50 ml

p) any special storage or handling conditions;

q) * any warnings or precautions to take;

EXAMPLE 1 Compatibility with the use of gas mixtures or compatibility with administered drugs.

EXAMPLE 2 Use that may deviate from the currently accepted medical practice.

EXAMPLE 3 RISK of fire associated with oxygen equipment and therapy.

r) if appropriate, the maximum pressure the tubing and connectors can withstand at ambient conditions expressed in Pascals;

s) MRI compatibility of AIRWAY AND RELATED EQUIPMENT should be disclosed on the information to be supplied by the manufacturer.

Check compliance by inspection of the manufacturer's risk management file.

t) Labelling of the device shall be in accordance with ASTM F2503.

Check compliance by inspection.

9.1.2 Marking on controls and instruments

9.1.2.1 The marking on controls and instruments shall meet the requirements of IEC 60601-1:2005, 7.4.1 and 7.4.2.

9.1.2.2 The units of measurement shall be as given in Table 2.

Table 2 — Units of measurement

Parameter	Unit of measurement
Pressures - gas supply	kilopascals (kPa)
Pressures - breathing systems	hectopascals (hPa) (cm H_20)
Flows	litres per minute (l/min)
Air entrainment/oxygen dilution controls	percent oxygen (% O_2)

Check compliance of 9.1 by inspection.

9.2 Instructions for use

9.2.1 AIRWAYS AND RELATED EQUIPMENT shall be provided with instructions for use unless the AIRWAYS AND RELATED EQUIPMENT can be used safely without any such instructions.

Check compliance by inspection of the instructions for use or the RISK MANAGEMENT FILE.

9.2.2 Instructions for use shall include the information required in 9.1.1.4 and the following:

a) the date of issue or the date of the latest revision of the instructions for use;

b) the purpose and the intended use of the AIRWAYS AND RELATED EQUIPMENT and parts thereof, including the power or control devices;

c) the interdependence of controls, if applicable;

d) specific instructions and the level of training needed for the safe use of the AIRWAYS AND RELATED EQUIPMENT;

e) for AIRWAYS AND RELATED EQUIPMENT intended to be connected to an electrical power source, the maximum temperature, above ambient, reached in the gas pathways under all operating conditions;

f) for AIRWAYS AND RELATED EQUIPMENT intended to be connected to a power source (electrical or pneumatic), the maximum A-weighted sound pressure level, as derived from the test method in IEC 60601-1:2005, 9.6.2.1.

Check compliance of 9.2.2 by inspection.

9.2.3 Materials compatibility information

Information on the compatibility of materials shall include the following:

a) information about any precautions to be taken if there is a residual RISK associated with the compatibility between the materials of the AIRWAYS AND RELATED EQUIPMENT and any dispensed liquids;

b) if applicable, a statement to the effect that "the materials used in the AIRWAYS AND RELATED EQUIPMENT may not be compatible with anaesthetic or respirable gases, solutions/suspensions/emulsions that have not been evaluated";

c) a statement identifying the residual RISK, if phthalates are incorporated in parts of the AIRWAYS AND RELATED EQUIPMENT coming directly or indirectly into contact with the patient and if the AIRWAYS AND RELATED EQUIPMENT are used in the treatment of children or pregnant or nursing women;

d) * if applicable, a warning statement to the effect that "There is a RISK of fire associated with oxygen equipment and therapy. Do not use near sparks or open flames";

e) * if applicable, a warning statement to the effect that "smoking during oxygen therapy is dangerous and is likely to result in serious injury from fire";

f) * if applicable, a warning statement to the effect that "use only lotions or salves that are labelled as oxygen-compatible to avoid the RISK of fire and burns";

g) * if applicable, a warning statement to the effect that "do not lubricate fittings, connections, tubing or other accessories to avoid the RISK of fire and burns";

9.2.4 Cleaning, disinfection and sterilization information

9.2.4.1 Unless the AIRWAYS AND RELATED EQUIPMENT are intended for single use, the instructions for use shall include the following:

a) if applicable, a warning to the effect that "the AIRWAYS AND RELATED EQUIPMENT must be disconnected from the power source (electrical or pneumatic), prior to cleaning, disinfection and sterilization";

b) for AIRWAYS AND RELATED EQUIPMENT intended for single-patient reuse, the recommended methods of cleaning and, if indicated, disinfection prior to reuse;

c) for AIRWAYS AND RELATED EQUIPMENT intended for multi-patient reuse, the recommended methods of cleaning and either disinfection or sterilization prior to reuse;

d) an indication of the useful life of the AIRWAYS AND RELATED EQUIPMENT if processing, in accordance with the instructions, leads to a degree of degradation in performance;

e) where such degradation is established, the manufacturer shall provide an indication of the number of reprocessing cycles that can be tolerated or some other indication of the end of the device's useful life.

Check compliance by inspection of the RISK MANAGEMENT FILE and accompanying documents.

9.2.4.2 For AIRWAYS AND RELATED EQUIPMENT intended for single use, the instructions for use shall include

— the residual RISKS deemed unacceptable by the RISK MANAGEMENT process specified in 4.1 associated with cleaning and disinfection or sterilization prior to reuse.

Check compliance by inspection of the RISK MANAGEMENT FILE and accompanying documents.

9.2.5 Dismantling and reassembling information

The instructions for use shall include the following:

a) if applicable, procedures for disconnecting the AIRWAYS AND RELATED EQUIPMENT from the power source (electrical or pneumatic) and for dismantling and reassembly;

b) the recommended functional test(s) to be carried out after reassembly and before use;

c) if applicable, a warning to the effect that "the AIRWAYS AND RELATED EQUIPMENT must be disconnected from the power source (electrical or pneumatic), prior to dismantling and reassembling".

9.2.6 Monitoring, alarm and protection devices

The instructions for use shall include the following:

a) information required by IEC 60601-1-8:2006, 5.2.1;

b) details and characteristics of non-return valves and pressure-relief valves, if fitted.

EXAMPLE 1 Opening pressure.

EXAMPLE 2 Leakage rate.

9.2.7 Electromagnetic compatibility information

If applicable, a warning statement to the effect that "the functioning of the device may be affected by electromagnetic interference exceeding the levels specified in IEC 60601-1-2.

9.2.8 Device disposal information

The instructions for use shall include

— information about any precautions to be taken if there are any residual RISKS associated with disposal of AIRWAYS AND RELATED EQUIPMENT.

9.2.9 Parts not integral to the AIRWAYS AND RELATED EQUIPMENT

A list of the parts that are not integral parts of the AIRWAYS AND RELATED EQUIPMENT but are necessary for correct use shall be included in the instructions for use.

Check compliance of 9.2.3 to 9.2.9 *by inspection of the labelling*.

Annex A
(informative)

Rationale

A.1 General

This Annex provides a concise rationale for the important requirements of this International Standard and is intended for use by those who are familiar with the subject of this International Standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered essential for its proper application. Furthermore, as clinical practices and technologies change, it is believed that rationales for the present requirements will facilitate any revisions of this International Standard necessitated by those developments.

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

A.2 Normative references

Use of dated or undated references are in accordance with the following principles.

Dated references are required when

— reference made in text is to a specific edition (or a specific DIS or FDIS) and/or a specific element in the referenced document (obligatory to put the date);

EXAMPLE … in accordance with ISO 6142-1:2015, Clause 7.

NOTE Reference to a term which is recited from the source does not make it a dated normative reference if that normative reference is not cited anywhere else in the document as a requirement.

— subsequent amendments to, or revisions of, dated references will need to be incorporated by amendment of the document referring to them.

Undated references are permitted when

— reference is not to a specific edition nor to any specific element in referenced document (so, reference to a complete document or a part thereof);

— all future changes (Amendments, Technical Corrigenda, new editions) to the referenced document are included.

EXAMPLE "… as specified in ISO/IEC Guide 21-1…" or "… the terms and definitions given in ISO 10414-2 and ISO 15403-1, and the following apply."

So in summary, it is possible to date all the references, but the committee will need to watch that the specific edition has not been revised or amended. If this happens, then the document will need to be revised or amended to reflect the new normative reference. The committee will need to be vigilant to make sure that the dated reference is not cancelled and replaced or amended so that a device no longer complies with this International Standard. Therefore, the committee needs to watch the International Standard referred to and react if it is modified. Otherwise, if all future revisions would apply, then to make sure that the user can always comply with the normative reference.

A.4.1 General requirements for AIRWAYS AND RELATED EQUIPMENT

The need for a RISK MANAGEMENT FILE is a well-recognized process through which the manufacturer of a medical device can identify hazards associated with a medical device, estimate and evaluate the RISKS associated with these hazards, control these RISKS and monitor the effectiveness of that control. Clinical evaluation may also be necessary to confirm the adequacy of the controls (see ISO 14971 for additional information).

A.5.8 Durability of marking

Although material biocompatibility is important for all AIRWAYS AND RELATED EQUIPMENT, it was considered of special importance for airways that might remain *in situ* for weeks. Anaesthetic agents would not be in contact with the tube marking materials for such long periods of time, but these agents might be damaging to marking materials.[26]

A.6.1.3 The subcommittee understood that it is necessary to be able to quickly and safely inflate and deflate the cuff using a means that is readily available to all operators, under all conditions, especially in airway emergencies. The common intravenous syringe with a Luer connector was chosen because it is readily available to all healthcare providers worldwide and this provides a wide margin of safety and usability. The RISKS associated with misconnection was considered and judged to be very low due to low frequency. Use of unique small-bore connectors designed to prevent misconnection was considered, but the subcommittee believed that the residual RISK associated with a requirement for special inflation devices that employ these unique connectors was greater than the RISK of misconnection.

NOTE ISO 594-1 is expected to be replaced by ISO 80369-7 when it is published.

A.6.1.4 The requirement for radiopaque markers is intended to allow visualization of certain AIRWAYS AND RELATED EQUIPMENT when verification of the depth of intubation is required.

A.6.5 Prevention of electrostatic charges

ANTISTATIC AIRWAYS AND RELATED EQUIPMENT should be sufficiently conductive to allow any charge to dissipate, but not conductive enough to allow a potentially harmful current to flow.

There is a need to distinguish between levels of conductivity. A device could be:

— conductive – able to conduct significant amounts of current;

— ANTISTATIC – able to dissipate charge over time to prevent static build-up.

IEC 60601-1:2005, 8.7.3 c) defines a limit of touch current of as a maximum of 500 µA in SINGLE FAULT CONDITION.

The upper limit of 1 000 MΩ is suggested to ensure that sufficient conductivity is present to still allow static charges to dissipate before they can build up and potentially cause a spark.

A.9.1.1.4 o) Patient category, Table 1

The definition for patient category is harmonized with the intended delivered volumes for the requirements and tests in ISO 80601-2-12.

A.9.2.3 d), e), f) and g) Material compatibility, fire safety warnings

Fire safety warnings that are similar to the warnings proposed for oxygen concentrator equipment (see ISO 80601-2-69) have been added to the instructions for use.

See also A.4.1 regarding the rationale for warnings on any use that may deviate from the currently accepted practice.

This International Standard also aims to consider the reported hazardous situation of oxygen fires propagating from oxygen sources, particularly in the home healthcare environment.

In recognition of the RISK of fire, consider adding the following warnings on the package labelling:

— Never smoke in a home where oxygen is used.

— Never use an open flame, such as candles, matches, wood stoves or sparking toys, when oxygen is in use.

— Never smoke or light a match while using oxygen.

— Keep all flames and heat sources away from oxygen containers and oxygen systems.

— Do not allow smoking inside of a home where oxygen is used. Even if it is not being used at a particular moment, the home is still an oxygen-enriched environment and fire can get out of hand quickly.

For healthcare providers, consider instructing the patient about the hazards, and, if patients continue to smoke while receiving oxygen therapy, consider discontinuing the therapy.

Note that the Position Statement of the Thoracic Society of Australia and New Zealand on the subject states:

"Oxygen therapy is not indicated for patients… who continue to smoke cigarettes (owing to the increased fire risk and the probability that the poorer prognosis conferred by smoking will offset treatment benefit)… and who are not sufficiently motivated to undertake the discipline required for oxygen therapy."

Devices are available on the market to prevent the propagation of fire back to the oxygen equipment by stopping the flow of gas towards the patient if the respiratory tubing becomes ignited. The means of protection should be located as close to the patient as practicable, i.e. between the junction of the nasal cannula and the oxygen supply tubing.

Annex B
(informative)

Hazard identification for RISK ASSESSMENT

NOTE This list is not intended to be comprehensive for all devices within the scope of this International Standard, but it provides guidance for RISK ASSESSMENT. Not all hazards will apply to all types of AIRWAYS OR RELATED EQUIPMENT.

Additional information may be found in ASA Practice Guidelines for Management of the Difficult Airway.[27]

B.1 Patient harm associated with the use of AIRWAYS AND RELATED EQUIPMENT

a) Trauma — Mechanical or physiologic trauma to the upper airway and surrounding tissue:

— Minor abrasions, oedema and inflammation (naso/oropharynx, periglottic area, trachea, bronchus);

— Sore throat (temporary or prolonged);

— Bleeding and hematoma (naso/oropharynx, periglottic area, trachea, bronchus);

— Changes in cerebral blood flow and increased intracranial pressure;

— Dental damage;

— Vocal cord damage (trauma, ulceration, web, stenosis, oedema, fibrosis, scar, paralysis, paresis, granuloma, dysphonia, stridor, aspiration, difficulty breathing);

— Infection (cellulitis, abscess, naso/oropharynx, periglottic area, trachea, bronchus);

— Neuropathy, temporary or permanent, cranial or peripheral nerves;

— Arytenoid injury or dislocation;

— Salivary gland swelling or inflammation;

— Epiglottic entrapment or inflammation;

— Injury to cervical spine or spinal cord: paralysis, paresis, neuropathy;

— Tracheal damage (ulcers, web, necrosis, granuloma, scar, fibrosis, erosions, burns, perforation, stenosis);

— Fistula formation (vascular, oesophageal);

— Dermal ischaemia;

— Necrosis;

— Upper oesophageal sphincter injury;

— Trapping, avulsing or injury of intra-nasal tissue and/or pharyngeal tissue;

— Failing to conform to transition from "nasal angle" to "pharyngeal angle" thereby impacting/injuring/penetrating posterior pharyngeal wall tissue;

— Excessive adhesion of airway device material to

  — another device (e.g. nasopharyngeal catheter), or

  — airway tissue.

b) Inadequate oxygenation and/or ventilation resulting in hypoxia and/or hypercarbia due to the following:

— Leakage of respiratory gases due to inadequate seal;

— Obstruction, kinking, foreign body, secretions;

— Bronchospasm, laryngospasm, stridor, hiccup, coughing, breath-holding;

— Pulmonary oedema (due to negative intrathoracic pressure in the presence of obstruction);

— Rebreathing due to excessive deadspace;

— Increased work of breathing;

— Increased intrathoracic pressure;

— Barotrauma leading to pneumothorax, emphysema;

— Endobronchial intubation;

— Oesophageal intubation;

— Inadequate oxygen flow;

— Low oxygen concentration;

— Inadequate spontaneous ventilation;

— Thickened secretions, mucus plugs impacting/injuring/penetrating the posterior pharyngeal wall tissue.

c) Aspiration or regurgitation due to the following:

— Excessive supralaryngeal airway pressure;

— Gastric insufflations, secondary to oesophageal ventilation;

— Inability to evacuate gastric contents secondary to obstruction;

— Aspiration of debris or bulk solutions, water, saline;

— Dislodgement of the bacterial biofilm into the lower airway.

d) Lung injury

— Barotrauma, volutrauma, stretch injury

— Decrease in dynamic lung compliance and functional residual capacity

— Atelectasis

— Hypoxia/hypoxemia

— Trauma to the tracheal and/or bronchial mucosa

— Bronchoconstriction/bronchospasm

— Increased microbial colonization of lower airway

— Hypertension
— Hypotension
— Cardiac dysrhythmias
— Tachycardia
— Excessive coughing
— Pain, anxiety, dyspnoea

e) Fire injury

— Adult respiratory distress syndrome (ARDS) associated with smoke inhalation injury
— Dermal burns
— Thermal airway burns
— Overheating, hyperthermia

f) Toxicity

— Allergy, including allergy to natural rubber latex
— Tissue sensitivity, inflammation, necrosis
— Reactive airways disease
— Systemic absorption of toxic substances
— Pollution, emission of harmful gases
— Leakage of ventilatory gas or anaesthetic gases and vapours
— Smoke inhalation injury
— Oxygen toxicity
— Inhalation of cleaning and/or disinfection solutions
— Radiation toxicity (due to excessive DTPA aerosol administration/contamination)

g) Injury due to excessive/inadequate oxygen or drug aerosol delivery

— Hypoxia
— Tachycardia
— Bradycardia
— Cardiopulmonary failure
— Hypertension/hypotension
— Hypervolemia
— Unconsciousness

h) Death