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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).

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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.

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

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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*.

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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.

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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*

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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.

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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

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

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[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]

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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.

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4 General requirements for AIRWAYS AND RELATED EQUIPMENT

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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.

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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]

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Check compliance by inspection of the technical file.

5 Materials

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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.

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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.

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

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

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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.).

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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.

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6 Design requirements for AIRWAYS AND RELATED EQUIPMENT

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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*.

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