DRAFT INTERNATIONAL STANDARD

ISO/DIS 18190

ISO/TC **121**/SC **2**	Secretariat: **ANSI**
Voting begins on: **2015-05-04**	Voting terminates on: **2015-08-04**

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

ICS: 11.040.10

Reference number
ISO/DIS 18190:2015(E)

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Published in Switzerland

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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. www.iso.org/directives

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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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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

Introduction

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

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

NOTE General requirements contained in this 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.

European Commission Medical Device Directive, *Essential Requirements of Directive 93/42/EEC*

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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

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

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-2:2005, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: 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*

ISO 11607-1:2006/Amd.1:2014, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2:2006/Amd.1:2014, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

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

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

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

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

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ISO/DIS 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*

IEC 60417, *Graphical symbols for use on equipment*

IEC 60601-1, *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 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

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*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

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

EN 1041, *Terminology, symbols and information provided with medical devices: Information supplied by the manufacturer with medical devices*

EN 15986:2011, *Symbols for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

ASTM D3002-2007, *Standard guide for evaluation of coatings applied to plastics*

ASTM F640-2007, *Standard test methods for radiopacity for medical use*

3 Terms and definitions

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
a 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]

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

[SOURCE: ISO 14971:2007]

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 and a RISK EVALUATION

[SOURCE: ISO 14971:2007]

3.7
RISK EVALUATION
process of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO 14971:2007]

3.8
RISK MANAGEMENT
systematic application of MANAGEMENT policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring RISK

[SOURCE: ISO 14971:2007]

3.9
RISK MANAGEMENT FILE
set of records and other documents that are produced by RISK MANAGEMENT

[SOURCE: ISO 14971:2007]

3.10
SINGLE FAULT CONDITION
a condition in which a single means for reducing a RISK is defective or a single abnormal condition is present

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

3.11
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 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).

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, or

— 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 — mathematical, computer, physical, cell and tissue culture, and animal — in a complementary and interactive manner to simulate the performance of medical devices.[1]

Check compliance by inspection of the technical documentation.

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

The RISKS associated with AIRWAYS AND RELATED EQUIPMENT made of materials that incorporate phthalates shall be assessed. If such AIRWAYS AND RELATED EQUIPMENT are used for the treatment of children or pregnant or nursing women, the residual **RISK** shall be identified and stated on the labelling if required by a competent authority or national regulatory body.

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

5.6 Natural rubber (latex)

The RISKS associated with AIRWAYS AND RELATED EQUIPMENT made of materials that incorporate natural rubber (latex) shall be assessed.

NOTE See 10.3 n).

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

5.7 Gas compatibility

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

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.*

5.7.2 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, Clause 4.

5.7.3 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.).