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Anaesthetic and respiratory equipment — General requirements for airway devices 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 document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airway devices and related equipment*.

This second edition cancels and replaces the first edition (ISO 18190:2016), which has been technically revised.

The main changes are as follows:

— Title altered from airways to airway devices.

— The introduction has been changed to clarify that this standard can be used in the absence of a device specific standard.

— Definitions for *clinical evaluation* and *clinical investigation* added.

— Risk management process and *clinical evaluation* now mandated.

— A new requirement recommending that manufacturers consider the environmental impact of their device and its packaging during its lifetime has been added.

— A requirement for the biological evaluation for devices with breathing gas pathways has been added.

— Information provided by the manufacturer, including marking, now refers to ISO 20417 for the common requirements and only lists those requirements specific to *airway devices and related equipment.*

— Devices that are safe, conditionally safe or unsafe to be used in an MR environment are now to be marked accordingly.

— The requirements for positioning of controls and protection against inadvertent adjustments have been deleted as they were deemed not applicable to airway devices.

— A new requirement for shelf life has been added.

— All requirements relating to sterility have been condensed into one clause.

— A new requirement has been added for cleanliness and disinfection and combined with sterility.

— A new requirement to disclose the transport and environmental conditions that the airway device can withstand has been added.

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

Introduction

This document provides the general requirements for basic safety and performance for the design, materials, packaging, marking and labelling that are generally applicable to all *airway devices and related equipment.*

This document is intended to consolidate the general requirements that are common among the set of standards within the category of *airway devices and related equipment* and serve as a reference for these common requirements, allowing each device-specific standard to focus on the unique safety and essential requirements more concisely for that device.

This document should be used in conjunction with device-specific *airway devices and related equipment* standards.

The requirements in a device-specific standard take priority over any conflicting requirements in this document.

If there is no airway device-specific standard, then this document can be referenced for all the applicable requirements.

NOTE The terms defined in Clause 3 are denoted throughout the document in *italic font.*

Anaesthetic and respiratory equipment — General requirements for airway devices and related equipment

1 Scope

This document specifies the general requirements common to *airway devices and related equipment.*

2 Normative references

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

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

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

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

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

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 14155:2020, *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 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

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

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

ISO 17665, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

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

ISO 18601, *Packaging and the environment — General requirements for the use of ISO standards in the field of packaging and the environment*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 22441, *Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014+AMD1:2020, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, *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 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

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

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 14971, ISO 20417 and the following apply.

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

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

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

3.1
airway devices 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
clinical evaluation
assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

[SOURCE: ISO 13485:2016, 3.3]

3.3
clinical investigation
systematic investigation in one or more human subjects undertaken to assess the clinical performance, effectiveness or safety of a medical device

Note 1 to entry: For the purpose of this document, "clinical trial" or "clinical study" are synonymous with "*clinical investigation*".

[SOURCE: ISO 14155:2020, 3.8]

3.4
biophysical or modelling research
application of validated physical methods and theories to biological problems

EXAMPLE 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.

4 General requirements

4.1 Risk management

Manufacturers shall apply an established risk management process to the design and manufacture of *airway devices and related equipment*. The risk management process shall include the following elements:

a) risk analysis;

b) risk evaluation;

c) risk control; and

d) production and post-production information.

NOTE 1 See Annex B for a list of hazards that can be used as guidance in the risk management process.

NOTE 2 A risk management process compliant with ISO 14971 is considered to meet this requirement.

NOTE 3 Conformity with ISO/TR 20416 is considered to compliment the requirements in ISO 14971 for production and post-production activities.

NOTE 4 There is rationale for this subclause in A.2.

Check conformance by inspection of the *risk management file.*

4.2 Alternative test methods

The manufacturer may use type tests different from those detailed within this document, if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall be used as the reference methods.

4.3 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.

NOTE A usability process compliant with IEC 60601-1-6 or IEC 62366-1 is considered to meet this requirement.

Check conformance by inspection of the usability engineering file.

4.4 *Clinical evaluation* and *clinical investigations*

4.4.1 Manufacturers shall carry out a *clinical evaluation* under the conditions for which performance is claimed.

NOTE *Clinical evaluation* carried out according to ISO 18969[1)] is considered to meet this requirement.

4.4.2 *Clinical investigations* shall conform with the requirements of ISO 14155.

NOTE Clinical data can be sourced from:

a) *clinical investigation*(s) of the device concerned;

b) *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

c) 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 conformance by inspection of the technical file.

4.5 *Biophysical or modelling research*

Where appropriate, validated *biophysical or modelling research* shall be performed under the conditions for which performance is claimed.

Check conformance by inspection of the technical file.

5 Materials

5.1 Environmental impact

5.1.1 Manufacturers should consider when developing *airway devices and related equipment* the environmental impact throughout the lifetime of the device.

NOTE ISO 14001 can be used to assess the environmental impact.

5.1.2 Manufacturers shall assess the environmental impact of packaging used for *airway devices and related equipment.*

Check conformance by the tests given in ISO 18601.

5.2 Biological evaluation

5.2.1 *Airway devices and related equipment* that come into direct or indirect contact with the patient's body, shall, after any preparation for use recommended by the manufacturer, satisfy appropriate biological evaluation according to ISO 10993-1.

Check conformance by inspection of the technical file.

5.2.2 *Airway devices and related equipment* that provide a gas pathway to the patient shall, after any preparation for use recommended by the manufacturer, satisfy appropriate biological evaluation according to ISO 18562-1.

Check conformance by inspection of the technical file.

1) Under preparation. Stage at the time of publication: ISO/WD 18969:2024.

5.3 Intended use and environmental conditions

Airway devices and related equipment shall be made of materials suitable for their intended use and the environmental conditions that they can be subjected to during transport, storage or when in use.

Check conformance by inspection of the technical file.

5.4 Materials of concern

Manufacturers shall identify the applicable regulations which control the use of substances in the *airway device and related equipment* and its packaging. The manufacturer shall provide evidence to demonstrate conformance to the regulations within each region the device is sold.

NOTE Conformance can include applying warnings or providing a justification for the continued use of a restricted substance.

Check conformance by inspection of the technical file.

5.5 Gas compatibility

5.5.1 Any known incompatibility risks associated with those gases and vapours used in anaesthesia and respiratory care, shall be justified in the risk management file and disclosed in the instructions for use [see 8.3.3 b)].

Check conformance by inspection of the risk management file and the instructions for use.

5.5.2 *Airway devices and related equipment* and components thereof, which can come into contact with oxygen at gas pressures greater than 50 kPa under normal or single fault condition, shall conform with the cleanliness requirements of ISO 15001:2010, Clause 4.

5.5.3 The risks associated with ignition by a flame, electrocautery, electrostatic discharge or laser beam in an oxygen-enriched atmosphere in *airway devices and related equipment* shall be identified in the risk management file.

Check conformance by inspection of the risk management *file*.

5.6 Magnetic resonance (MR) environment safety

NOTE There is rationale for this subclause in A.3.

Airway devices and related equipment at risk of being used in an MR environment shall be:

a) assessed as safe, unsafe or conditional for use in an MR environment; and

b) be labelled according to IEC 62570 [(see 8.2 b)].

Check conformance by inspection and inspection of the risk management file and the label.

6 Design requirements for *airway devices and related equipment*

6.1 Mechanical safety

6.1.1 The mechanical design of *airway devices 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 conformance by inspection of the risk management file.

6.1.2 Connectors for inflating cuffs shall:

a) be compatible with the L1 cone slip connector specified in ISO 80369-7; and

b) have a captive means of sealing.

For example, tethered cap or plug, integrated self-sealing valve.

NOTE There is rationale for this subclause in A.4.

Check conformance by functional testing.

6.1.3 A*irway devices and related equipment* labelled as radiopaque shall be radiographically identifiable when compared to a 1 mm x 1 mm x 10 mm aluminium sample.

NOTE There is rationale for this subclause in A.5.

Check conformance by functional testing specified in ASTM F640.

6.2 Medical electrical equipment safety

Airway devices and related equipment defined as medical electrical equipment (see IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.63) shall, in addition to the requirements given in this document, conform with the requirements given in IEC 60601-1:2005+AMD1:2012+AMD2:2020.

Check conformance by inspection of the technical file.

6.3 Prevention of electrostatic charges

Antistatic *airway devices 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 MΩ and not more than 1 000 MΩ when tested in accordance with the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020, G.4.3.

NOTE There is rationale for this subclause see A.6

Check conformance by inspection of the technical file.

6.4 Expected device lifetime

Airway devices and related equipment shall conform with the performance requirements specified in the device-specific standard or by the manufacturer throughout the expected device lifetime.

Check conformance by inspection of the technical file.

6.5 Shelf life

Airway devices and related equipment shall conform with the performance requirements specified in the device-specific standard or by the manufacturer throughout the intended shelf life.

Check conformance by inspection of the technical file.

6.6 Transport and storage

Airway devices and related equipment shall conform with the performance requirements specified in the device-specific standard or by the manufacturer after being subjected to the transport and storage conditions specified in the instructions for use.

NOTE ISO 20417 specifies the requirement to include, in the instructions for use, any special transport or storage conditions.

Check conformance by inspection of the technical file.

6.7 Interoperability

Airway devices and related equipment, intended to be operated together with other devices, shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

EXAMPLE A 3rd party heated breathing tube, according to ISO 5367, intended to be used with a humidifier will likely affect the basic safety and essential performance so the relevant clauses of ISO 80601-2-74 will need to be evaluated such as humidification output, maximum surface temperature, electromagnetic compatibility, patient leakage.

Check conformance by inspection of the technical file.

7 Cleaning, disinfection and sterilization

7.1 Cleaning and disinfection

Unless intended for single use, *airway devices and related equipment* that can become contaminated with body fluids or expired gases during normal condition or single fault condition, shall be designed to allow for cleaning and disinfection or cleaning and sterilization. Instructions for processing the *airway devices and related equipment* shall comply with ISO 17664-1 or ISO 17664-2 and shall be disclosed in the instructions for use [see 8.3.2 b)].

Check conformance by inspection of the technical file.

7.2 Sterility assurance

Airway devices and related equipment supplied sterile shall satisfy the requirements of EN 556-1 and, if applicable, ISO 11135 or ISO 11137-1, ISO 17665, ISO 20857, ISO 25424 or ISO 22441.

Check conformance by inspection of the technical file.

7.3 Sterile packaging

Packaging of *airway devices and related equipment* supplied sterile shall conform with ISO 11607-1 and ISO 11607-2.

Check conformance by inspection of the technical file.

8 Information to be supplied by the manufacturer

8.1 General

Information to be supplied by the manufacturer shall conform with ISO 20417 and the following:

8.2 Marking on the device

Airway devices and related equipment shall be marked with the following. If it is not practicable to mark the actual device the required information shall be given on a label, insert or in the instructions for use.

a) An indication that antistatic *airway devices and related equipment* are suitable for use with flammable anaesthetic agents/gases [e.g. symbol “AP” (IEC 60417-5331) or “APG” (IEC 60417-5332)] and the word ‘antistatic’.

NOTE *Airway devices and related equipment* can also bear a continuous indelible, yellow-coloured marking throughout their length.

b) Where applicable, an indication that the device is safe, unsafe or conditionally safe for use in an MR environment. For the appropriate symbol see IEC 62570:2014, Table 201.D.2.101.

c) Any warnings or precautions to take.

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

EXAMPLE 2 Use that deviates from the currently accepted medical practice.

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

d) The expected lifetime.

e) Use by date.

f) With the symbol "contains phthalates" given in EN 15986, if applicable.

g) With the symbol "contains natural rubber", given in ISO 15223-1:2021, (5.4.5), if applicable.

Check conformance by inspection.

8.3 Instructions for use

8.3.1 General

Airway devices and related equipment shall be provided with instructions for use unless the *airway devices and related equipment* can be used safely without any such instructions.

Check conformance by inspection of the instructions for use or the risk management file.

8.3.2 Information to be provided

Instructions for use shall include the information required in 8.2 and the following, as applicable:

a) information on residual risks regarding the use of phthalates;

b) cleaning and disinfection instructions.

Check conformance by inspection.

8.3.3 Materials compatibility information

Information on the compatibility of materials shall include the following where applicable:

a) Information about any precautions to be taken if there is a residual risk associated with the compatibility between the materials of *airway devices and related equipment* and any dispensed liquids.

b) Known incompatibility risks with anaesthetic gases and vapours.

c) Warning statements to the effect that:

i) "Do not use near sparks or open flames".

ii) "Smoking during oxygen therapy is dangerous and is likely to result in serious injury from fire".

iii) "Use only lotions or salves that are labelled as oxygen-compatible to avoid the risk of fire and burns".

iv) "Do not lubricate fittings, connections, tubing or other accessories to avoid the risk of fire and burns".

v) "This device shall not be used with nitric oxide (NO). Such use can cause serious deterioration of health".

NOTE There is rationale for this subclause in A.7 and A.8.

8.3.4 Dismantling and reassembling information

If the manufacturer recommends disassembly for maintenance or cleaning, then the instructions for use shall include:

a) procedures for the dismantling and reassembly of the *airway device and related equipment;*

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

c) a warning to the effect that "the *airway device and related equipment* must be disconnected from the power source (electrical or pneumatic), prior to dismantling and reassembling".

8.3.5 Monitoring alarm and protection devices

The instructions for use shall include the following:

a) information required by IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 5.2.1; and

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

EXAMPLE 1 Opening pressure.

EXAMPLE 2 Leakage rate.

8.3.6 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 60601-1-2:2014+AMD1:2020".

8.3.7 Device disposal information

Information about any precautions to be taken if there are any residual risks associated with disposal of *airway devices and related equipment*.

8.3.8 Parts not integral to the *airway devices and related equipment*

A list of the parts that are not integral parts of the *airway device and related equipment* but are necessary for correct use shall be included in the instructions for use.

Check conformance of 8.3.3 to 8.3.8 by inspection of the instructions for use.

Annex A
(informative)

Rationale

A.1 General

This Annex provides a concise rationale for the important requirements of this document and is intended for use by 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 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 document necessitated by those developments.

A.2 General requirements for *airway devices and related equipment* (4.1)

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.3 Magnetic resonance environmental safety (5.6)

Rather than require testing for all *airway devices and related equipment*, this requirement requires evaluation per IEC 62570, which defines the three states of MR Compatibility as MR Safe, MR Conditional, and MR Unsafe. As stated in IEC 62570, *airway devices and related equipment* components manufactured entirely of electrically non-conductive, non-metallic and non-magnetic materials may be determined to be MR Safe by providing a scientifically based rationale rather than test data. IEC 62570 requires that testing, sufficient to characterize the behaviour of the item in the MR environment, be conducted and lists relevant test methods for such characterization.

A.4 Cuff inflation (6.1.2)

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 residual risk associated with a requirement for special inflation devices that employ these unique connectors is greater than the risk of misconnection.

A.5 Radiopacity (6.1.3)

The requirement for radiopaque markers is intended to allow visualization of certain *airway devices and related equipment* when verification of the depth of intubation is required.

A.6 Prevention of electrostatic charges (6.3)

Antistatic airway devices 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:

a) conductive – i.e. able to conduct significant amounts of current; or

b) *antistatic* – i.e. able to dissipate charge over time to prevent static build-up.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 8.7.3 c) defines a limit of the touch current 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.7 Material compatibility, fire safety warnings [8.3.3 b) and c)]

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.

This document 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, woodstoves 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.

Some jurisdictions have restricted oxygen therapy to those who continue to smoke cigarettes as there is an increased fire risk and the probability of a poorer prognosis that may offset any benefits of the treatment.

Fire activated oxygen shut-off devices such as those specified in ISO 19211 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).

A.8 Nitric oxide (8.3.3 c) v)

Nitric oxide is typically used with intubated and ventilated patients with pulmonary hypertension.

Annex B
(informative)

Hazard identification for risk assessment

B.1 General

This list is not intended to be comprehensive for all devices within the scope of this document, but it provides guidance for risk assessment. Not all hazards will apply to all types of *airway devices and related equipment.* Additional information may be found in Reference [1].

B.2 Patient harm associated with the use of *airway devices and related equipment*

B.2.1 Trauma — Mechanical or physiologic trauma to the upper airway and surrounding tissue:

a) Minor abrasions, oedema and inflammation (naso/oropharynx, periglottic area, trachea, bronchus).

b) Sore throat (temporary or prolonged).

c) Bleeding and hematoma (naso/oropharynx, periglottic area, trachea, bronchus).

d) Changes in cerebral blood flow and increased intracranial pressure.

e) Dental damage.

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

g) Infection (cellulitis, abscess, naso/oropharynx, periglottic area, trachea, bronchus).

h) Neuropathy, temporary or permanent, cranial or peripheral nerves.

i) Arytenoid injury or dislocation.

j) Salivary gland swelling or inflammation.

k) Epiglottic entrapment or inflammation.

l) Injury to cervical spine or spinal cord: paralysis, paresis, neuropathy.

m) Tracheal damage (ulcers, web, necrosis, granuloma, scar, fibrosis, erosions, burns, perforation, stenosis).

n) Fistula formation (vascular, oesophageal).

o) Dermal ischaemia.

p) Necrosis.

q) Upper oesophageal sphincter injury.

r) Trapping, avulsing or injury of intra-nasal tissue and/or pharyngeal tissue.

s) Failing to conform to transition from “nasal angle” to “pharyngeal angle” thereby impacting/injuring/penetrating posterior pharyngeal wall tissue.

t) Excessive adhesion of airway device material to:

   i) another device (e.g. nasopharyngeal catheter); or

ii) airway tissue.

B.2.2 Inadequate oxygenation and/or ventilation resulting in hypoxia and/or hypercarbia due to the following:

a) leakage of respiratory gases due to inadequate seal;

b) obstruction, kinking, foreign body, secretions;

c) bronchospasm, laryngospasm, stridor, hiccup, coughing, breath-holding;

d) pulmonary oedema (due to negative intrathoracic pressure in the presence of obstruction);

e) rebreathing due to excessive deadspace;

f) increased work of breathing;

g) increased intrathoracic pressure;

h) barotrauma leading to pneumothorax, emphysema;

i) endobronchial intubation;

j) oesophageal intubation;

k) inadequate oxygen flow;

l) low oxygen concentration;

m) inadequate spontaneous ventilation; and

n) thickened secretions, mucus plugs impacting/injuring/penetrating the posterior pharyngeal wall tissue.

B.2.3 Aspiration or regurgitation due to the following:

a) excessive supralaryngeal airway pressure;

b) gastric insufflations, secondary to oesophageal ventilation;

c) inability to evacuate gastric contents secondary to obstruction;

d) aspiration of debris or bulk solutions, water, saline; and

e) dislodgement of the bacterial biofilm into the lower airway.

B.2.4 Lung injury

a) Barotrauma, volutrauma, stretch injury.

b) Decrease in dynamic lung compliance and functional residual capacity.

c) Atelectasis.

d) Hypoxia/hypoxemia.

e) Trauma to the tracheal and/or bronchial mucosa.

f) Bronchoconstriction/bronchospasm.

g) Increased microbial colonization of lower airway.

h) Hypertension.

i) Hypotension.