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Anaesthetic and respiratory equipment — Cuff pressure indication, control and regulation devices

Matériel d'anesthésie et de réanimation respiratoire — Dispositifs d'indication, de contrôle et de régulation de la pression du ballonnet

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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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.

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Introduction

This document provides the essential performance and safety requirements for the design of *cuff* pressure indication and/or regulation devices for use with airway products. *Cuffs* on *tracheal tubes* and *tracheostomy tubes* are intended to seal and protect the trachea from aspiration of secretions and to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation for short or prolonged durations. *Supralaryngeal airways* feature an inflatable *cuff* to provide a guide for insertion and stability of the airway. A variety of *cuff* designs are available to meet particular clinical requirements. *Cuffs* on *tracheal tubes* and *tracheostomy tubes* function by forming a seal between the *airway device* and the epithelial lining of the patient's airway. A pressure will be exerted on the lining of the airway where it makes contact with the *cuff*. Inflation of the airway *cuff* such that the pressure exerted on the epithelium is in excess of the capillary perfusion pressure can result in ischemia of the epithelium. This can result in short or long-term morbidity ranging from mild (e.g. sore throat) to severe (e.g. subglottic stenosis) [1]. Overinflated *cuffs* on *supralaryngeal airways* can cause injuries such as damage to the lingual, hypoglossal or recurrent laryngeal nerves in addition to arytenoid dislocation, haematoma, tongue swelling and cyanosis[2]. Uncontrolled low airway *cuff* pressure can also increase the risk of micro-aspiration and ventilator-associated pneumonia[3,4].

Tracheal tube and *tracheostomy tube cuff* pressures have traditionally been assessed by the clinician at the time of *cuff* inflation. Typically this is done by listening for a leak at the mouth while inflating the *cuff* with positive pressure applied to the airway until the user can no longer appreciate a leak. Evidence suggests that such methods of clinical assessment of airway *cuff* pressure are inaccurate[5]. A number of clinical guidelines now recommend the measurement of cuff pressure using a suitable device[6].

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Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The Normative text of tables is also in smaller type;

— *Terms defined in Clause 3: italic type.*

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Anaesthetic and respiratory equipment — Cuff pressure indication, control and regulation devices

1 Scope

This document specifies essential performance and safety requirements for *cuff pressure indicators* used to indicate the *intracuff pressure* of *airway devices*, such as *supralaryngeal airways*, *tracheal tubes* or *tracheostomy tubes*.

This document is also applicable to devices that combine *intracuff pressure* indication with a method of *cuff* inflation (such as a syringe or pump). The device can also provide a method of automatically maintaining *cuff* inflation at a specific pressure or within a pressure range.

The requirements specified in this document apply to stand-alone *cuff pressure indicators* and those integrated into other medical devices (e.g. ventilators, anaesthesia workstations, etc.).

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 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 80369-7:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

IEC 60601-1-8, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18190 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 device
device that provides a gas pathway to and from the patient's trachea

3.2
automatic cuff pressure regulator
integrated cuff pressure indicator (3.7) able to automatically control the *intracuff pressure* (3.8) of an *airway device* (3.1)

3.3
cuff
inflatable balloon attached to the *airway device* (3.1) near the *patient end* (3.9)

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3.4
cuff inflation device
device to inflate an *airway device* (3.1) *cuff* (3.3)

EXAMPLE Syringe, bulb pump, electrically powered pump.

3.5
cuff pressure indicator
device which indicates to the user the *intracuff pressure* (3.8)

Note 1 to entry: See Figures 1 and 2 for examples

3.6
inflating tube
tube through which the *cuff* (3.3) is inflated

[SOURCE: ISO 4135:2022, 3.8.3.3]

3.7
integrated cuff pressure indicator
cuff pressure indicator (3.5) with an integral *cuff inflation device* (3.4)

3.8
intracuff pressure
pressure exerted within the *cuff* (3.3)

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3.9
patient end
end of an *airway device* (3.1) which is intended to be inserted into the patient's airway

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3.10
supralaryngeal airway
device placed through the mouth but not through the vocal cords, which is intended to form an internal seal in the supralaryngeal area to maintain airway patency

[SOURCE: ISO 11712:2009, 3.10]

3.11
tracheal tube
tube designed for insertion through the larynx into the trachea to convey gases and vapours to and from the trachea

[SOURCE: ISO 4135:2022, 3.8.3.1]

3.12
tracheostomy tube
tube designed for insertion through a tracheostomy into the trachea to convey gases and vapours to and from the trachea

4 General requirements

4.1 General

The requirements of ISO 18190:2016, Clause 4 shall apply.

4.2 Alternative test methods

The manufacturer may use a type test different from those detailed within this document, if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in this document.

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5 Materials

The requirements of ISO 18190:2016, Clause 5 shall apply.

NOTE See Annex A, Clause 5.

6 Design requirements

6.1 General

The requirements of ISO 18190:2016, Clause 6 shall apply.

NOTE See Annex A, Clause 6.

6.2 Metrological requirements

6.2.1 Pressure indication

Cuff pressure indicators shall indicate the *intracuff pressure* by either

a) displaying a numerical value, or

b) a non-numerical visual means.

EXAMPLE Piston gauge using coloured graduation marks.

Check conformity by inspection.

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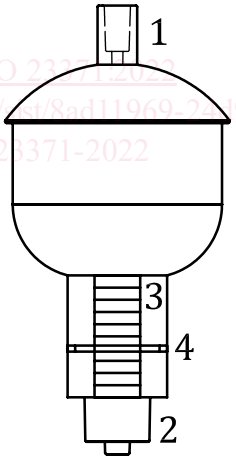

Key

1 female, Luer compatible, connector for connection to a *cuff inflation device*
2 male, Luer compatible, connector for connection to the *airway device cuff inflating tube*
3 scale
4 pointer

Figure 1 — Example of a *cuff pressure indicator* without a *cuff inflation device*

6.2.2 When disconnected from the *inflating tube*, the indicated *intracuff pressure* shall return to zero (atmospheric pressure) for devices that display a numerical value. For devices that use a non-numerical visual means of pressure indication, the reading should correspond to atmospheric pressure.

Check conformity by functional testing.

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6.2.3 Accuracy

For *cuff pressure indicators* that display a numerical value, the indicated value, when measured under steady-state conditions, shall be within ±2 cmH_2O of the actual pressure at the *inflating tube* connector or within ±10 %, whichever is the greater. This value for accuracy should include hysteresis effects when measuring increasing or decreasing *intracuff pressure.*

NOTE Due to the internal volume within the *cuff pressure indicator* a drop in *intracuff pressure* can occur on initial connection to the *inflation tube* which could result in loss of tracheal seal.

Check conformity by inspection of the technical file.

6.3 Connectors

6.3.1 The outlet connector on *cuff pressure indicator* that connects to the *airway device's cuff inflating tube* shall be a male Luer connector complying with ISO 80369-7 but should have a means to prevent connection to female Luer-lock connectors complying with ISO 80369-7.

Check conformity by functional testing.

6.3.2 If present, the inlet connector on a *cuff pressure indicator* that does not have an integrated *cuff inflation device* shall contain a means of sealing with a closure device or inflation valve. The inlet connector shall be compatible with a male Luer connector complying with ISO 80369-7.

Check conformity by functional testing

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6.4 *Integrated cuff pressure indicators*

6.4.1 *Integrated cuff pressure indicators* can be manually (hand) or electrically powered.

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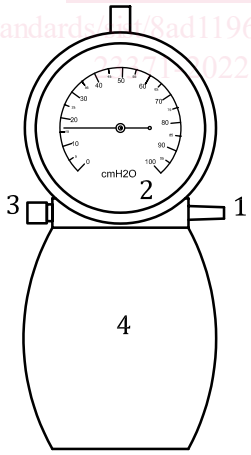

Key

1 male luer connector for connection to the *airway device inflating tube*
2 analogue numerical pressure scale and pointer
3 pressure release valve
4 hand operated bulb pump

Figure 2 — Example of an *integrated cuff pressure indicator* featuring a manually operated *cuff inflation device*

6.4.2 *Automatic cuff pressure regulators*, if fitted with an alarm, shall activate a medium priority visual and audible alarm signal complying with IEC 60601-1-8 if the indicated *intracuff pressure* differs

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