
**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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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

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For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

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.

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].

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)

**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)

**3.9
patient end**

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

**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.

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

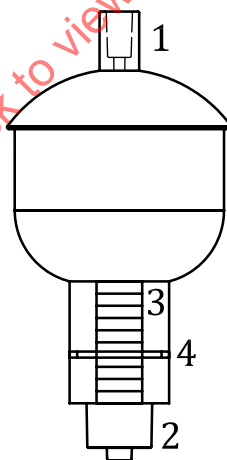
6.2.1 Pressure indication

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.



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.

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 cmH₂O 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.

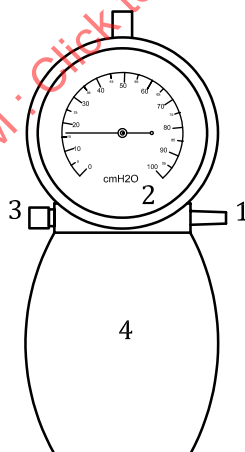
Check conformity by functional testing.

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

6.4 Integrated cuff pressure indicators

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



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

from the intended set pressure by more than $\pm 10\%$ with an additional fixed value tolerance of ± 2 hPa for a period greater than 180 s.

Example The system shall activate an alarm when the cuff pressure exceeds specified limits. For a set pressure of 25 hPa then the threshold for low pressure is no less 20,5 hPa, and the threshold for high pressure no greater than 29,5 hPa. These are calculated as the set value, plus or minus the sum of 2,5 hPa (10 % of setting) and 2,0 hPa (offset tolerance).

Check conformity by functional testing.

6.4.3 Electrically powered *cuff inflation devices* shall have a visual alarm signal to alert the user to failing electricity supply (e.g. battery charge). If they have an audible alarm mechanism this should also activate to alert the user to failing electricity supply.

Check conformity by functional testing.

6.5 Mechanical strength

6.5.1 Handheld *cuff pressure indicators* shall meet the requirements of [Clause 6](#) after being dropped onto a rigid surface from a height of 1 m.

Check conformity by the following test:

The device is allowed to fall freely from three different starting orientations from the height of $(1 \pm 0,1)$ m onto a (50 ± 5) mm thick hardwood board (hardwood > 600 kg/m³) lying flat on a concrete or a similar rigid base.

After the test verify that the device meets the performance requirements of [Clause 6](#) and any damage sustained to the device that results in an unacceptable increase in risk as determined by inspection of the risk management file shall constitute a failure.

6.5.2 Portable *cuff pressure indicators* shall withstand the stress caused by a free fall from the height indicated in [Table 1](#) onto a hard surface.

Check conformity by the following test:

The sample to be tested, with the safe working load in place, is lifted to a height as indicated in [Table 1](#) above a $50 \text{ mm} \pm 5 \text{ mm}$ thick hardwood board (hardwood > 600 kg/m³) that lies flat on a concrete floor or a similar rigid base. The dimensions of the board are at least those of the sample tested. The sample is dropped three times from each orientation in which it can be placed during normal use.

Table 1 — Drop height

Mass (m) of portable <i>cuff pressure indicator</i> or its parts (kg)	Drop height (cm)
$m \leq 10$	5
$10 < m \leq 50$	3
$m > 50$	2

After the test verify that the device meets the performance requirements of [Clause 6](#) and any damage sustained to the device that results in an unacceptable increase in risk as determined by inspection of the risk management file shall constitute a failure.

7 Requirements for Cuff pressure indication, control and regulation devices supplied sterile

The requirements of ISO 18190:2016, Clause 7 shall apply.

8 Packaging

The requirements of ISO 18190:2016, Clause 8 shall apply.

9 Information supplied by the manufacturer

9.1 General

The requirements of ISO 18190:2016, Clause 9 shall apply.

9.2 Marking

9.2.1 General

- a) Markings shall be clearly legible when viewed at $500\text{ mm} \pm 10\text{ mm}$ at a maximum illuminance of $215\text{ lx} \pm 15\text{ lx}$ using normal vision (corrected if necessary).

Check conformity by functional testing.

- b) Numerical scales shall be marked at intervals no greater than 10 hPa / $10\text{ cmH}_2\text{O}$.

Check conformity by inspection.

9.2.2 Markings

Cuff pressure indicators shall be marked with the following:

- a) The intended range of operating pressures;
- b) Numerical pressure measurements shall be displayed in hPa or cmH_2O . Other units of measurement may also be used in addition.

Check conformity by inspection.

9.3 Instructions for use

The instructions for use shall include the information required in [9.1](#), [9.2](#) and the following:

- a) The risks associated with excessive *intracuff pressure*;
- b) The accuracy of the device at its intended operating *intracuff pressure* or across a range of *intracuff pressures*;
- c) A warning that due to the internal volume of the *cuff pressure indicator*, a drop in *intracuff pressure* may occur on initial connection to the *inflation tube*;
- d) For *cuff pressure indicators* with a non-numerical means of pressure display:
- i) the method of interpretation of *intracuff pressure* indication;
 - ii) the pressure (in cmH_2O) that corresponds to the indicated pressure or pressure range;
- e) For *cuff pressure indicators* designed for multi-patient use the manufacturer shall state the method and frequency of inspection and/or calibration to verify the required accuracy in [6.2.3](#);
- f) Whether the *cuff pressure indicator* is suitable for continuous use or if it should be disconnected from the inflation tube between discrete measurements;