

Anaesthetic and respiratory equipment - Cuff pressure indication, control and regulation devices (ISO 23371:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 23371:2022 sisaldab Euroopa standardi EN ISO 23371:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 23371:2022 consists of the English text of the European standard EN ISO 23371:2022.
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English Version

Anaesthetic and respiratory equipment - Cuff pressure
indication, control and regulation devices (ISO
23371:2022)

Matériel d'anesthésie et de réanimation respiratoire -
Dispositifs d'indication, de contrôle et de régulation de
la pression du ballonnet (ISO 23371:2022)

Anästhesie- und Beatmungsgeräte -
Manschettendruck-Anzeigegeräte (ISO 23371:2022)

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 23371:2022) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 23371:2022 has been approved by CEN as EN ISO 23371:2022 without any modification.

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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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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).

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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].

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.

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)