



SLOVENSKI STANDARD SIST EN ISO 23371:2022

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Anestezijska in dihalna oprema - Naprave za merjenje, kontrolo in regulacijo pritiska v balončku (ISO 23371:2022)

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

Anästhesie- und Beatmungsgeräte - Cuffdruckanzeiger und Cuffdruckregulierungsvorrichtungen (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)

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents	Page
European foreword.....	3

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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of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

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INTERNATIONAL
STANDARD

ISO
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First edition
2022-05

**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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Contents

	Page
Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 General requirements.....	2
4.1 General.....	2
4.2 Alternative test methods.....	2
5 Materials.....	3
6 Design requirements.....	3
6.1 General.....	3
6.2 Metrological requirements.....	3
6.3 Connectors.....	4
6.4 <i>Integrated cuff pressure indicators</i>	4
6.5 Mechanical strength.....	5
7 Requirements for Cuff pressure indication, control and regulation devices supplied sterile.....	5
8 Packaging.....	6
9 Information supplied by the manufacturer.....	6
9.1 General.....	6
9.2 Marking.....	6
9.2.1 General.....	6
9.2.2 Markings.....	6
9.3 Instructions for use.....	6
Annex A (Informative) Rationale.....	8
Bibliography.....	9

ISO 23371:2022(E)

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.