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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/22

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EN ISO 23371

June 2022

ICS 11.040.10

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)

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European foreword

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INTERNATIONAL STANDARD

ISO 23371

First edition
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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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Foreword

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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.*

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INTERNATIONAL STANDARD **ISO 23371:2022(E)**

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

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