SLOVENSKI STANDARD
SIST EN ISO 16571:2024

01-junij-2024

Sistemi za odsesavanje hlapov, ki nastanejo zaradi uporabe medicinskih pripomočkov (ISO 16571:2024)

Systems for evacuation of plume generated by medical devices (ISO 16571:2024)

Rauchgasabsaugsysteme für Medizinprodukte (ISO 16571:2024)

Systèmes d'évacuation des fumées chirurgicales générées par l'utilisation de dispositifs médicaux (ISO 16571:2024)

Ta slovenski standard je istoveten z: **EN ISO 16571:2024**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 16571:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16571

April 2024

ICS 11.040.10

English Version

Systems for evacuation of plume generated by medical devices (ISO 16571:2024)

Systèmes d'évacuation des fumées chirurgicales générées par l'utilisation de dispositifs médicaux (ISO 16571:2024)

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This European Standard was approved by CEN on 1 March 2024.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 16571:2024) 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of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.

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 16571:2024 has been approved by CEN as EN ISO 16571:2024 without any modification.

International Standard

ISO 16571

Systems for evacuation of plume generated by medical devices

Systèmes d'évacuation des fumées chirurgicales générées par l'utilisation de dispositifs médicaux

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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 document 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 6, *Medical gas systems*, 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).

This second edition cancels and replaces the first edition (ISO 16571:2014), which has been technically revised.

The main changes are as follows:

— the scope has been expanded to include endoscopic systems and there are therefore significant changes throughout.

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

Certain surgical, diagnostic, and therapeutic techniques can generate noxious airborne contaminants (*plume*) as by-products, particularly from procedures that include the cutting, ablation, cauterization, or mechanical manipulation of target tissue by energy-based devices such as lasers, *electrosurgery* generators, broadband light sources, and ultrasonic instruments. Energy-based contact with articles such as tubing, swabs, and skin preparation solutions can produce additional chemicals. This document was developed in response to awareness of the potential hazards to patients and staff of *plume* generated by these techniques in healthcare settings.

Plume can contain a variety of contaminants: airborne chemicals, particulates, ultrafine particles, aerosols, gases, vapours, volatile organic compounds, tissue fragments, cellular material and blood-borne pathogens, posing a hazard to exposed persons. Additionally, *plume* reduces the clinician's ability to clearly see the operative field, resulting in unsafe operating conditions.

This document specifies requirements for systems for evacuation of *plume* generated in healthcare facilities. It is intended for those persons involved in the design, construction, inspection, and operation of healthcare facilities. Those persons involved in the design, manufacture, installation, testing, and use of equipment and components for *plume evacuation systems* should also be aware of the contents of this document.

This document provides the information needed to capture, filter, and remove surgical plume.

The objectives of this document are to ensure the following:

a) continuous extraction at specified pressures and flows;

b) use of suitable materials for all components of the system;

c) provision of monitoring indicators and alarm systems;

d) correct rating of filtration systems;

e) correct indication of filter life;

f) correct marking and labelling;

g) electrical and environmental testing;

h) correct installation;

i) testing, commissioning, and certification;

j) provision of guidance on operational management;

k) appropriate *manufacturer's* instructions for use, training, service, and maintenance.