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.

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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.

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Systems for evacuation of plume generated by medical devices

1 Scope

1.1 This document specifies requirements and guidelines for systems and equipment used to evacuate *plume* generated by *medical devices*.

1.2 This document applies to all types of *plume evacuation systems* (*PES*s), including

a) *portable*;

b) *mobile*;

c) stationary, including dedicated central pipelines;

d) *PES*s integrated into other equipment;

e) *PES*s for endoscopic procedures (e.g., minimally invasive, laparoscopic).

1.3 This document applies to all healthcare facilities where *PES*s are used, including, but not limited to

a) surgical facilities;

b) medical offices;

c) cosmetic treatment facilities;

d) medical teaching facilities;

e) dental clinics;

f) veterinary facilities.

1.4 This document provides guidance on the following aspects of *PES*s:

a) importance;

b) purchasing;

c) design;

d) manufacture;

e) documentation;

f) function;

g) performance;

h) installation;

i) commissioning;

j) testing;

k) training;

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l) use;

m) risk assessment;

n) servicing;

o) maintenance.

1.5 This document does not apply to the following:

a) *anaesthetic gas scavenging systems* (AGSSs) which are covered in ISO 7396-2;

b) medical vacuum systems which are covered in ISO 7396-1;

c) heating, ventilation, and air-conditioning (HVAC) systems;

d) aspects of laser safety other than airborne contamination; and

e) aspects of *electrosurgery*, *electrocautery*, and mechanical surgical tools other than airborne contamination produced by such equipment resulting from interaction with tissue or materials.

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 3744:—[1)], *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 7396-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

ISO 7779:2018, *Acoustics — Measurement of airborne noise emitted by information technology and telecommunications equipment*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15900, *Determination of particle size distribution — Differential electrical mobility analysis for aerosol particles*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 29463-1:—[2)], *High efficiency filters and filter media for removing particles from air — Part 1: Classification, performance, testing and marking*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

1) Under preparation. Stage at the time of publication: ISO/FDIS 3744:2024.

2) Under preparation. Stage at the time of publication: ISO/FDIS 29463-1:2024.

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