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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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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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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.

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;