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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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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Contents

Page

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;

k) training;

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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
active PES
PES whose evacuation is accomplished through endoscopic or laparoscopic ports by external vacuum source or a closed loop filtration system

3.2
adsorber
device that removes volatile organic compounds or specified gases from a gas stream by a process of adsorption

EXAMPLE Activated carbon filter.

[SOURCE: ISO 4135:2022, 3.1.4.2]

3.3
anaesthetic gas scavenging system
AGSS
complete system which is connected to the exhaust port(s) of a breathing system or to other equipment for the purpose of conveying expired and/or excess anaesthetic gases and vapours to an appropriate place of discharge

[SOURCE: ISO 7396-2:2007, 3.11]

3.4
capture device
accessory that captures the *plume* near the site of generation and passes it into the *transfer tubing*. A *capture device* can be *single use* or reusable

3.5
connector
fitting to join two or more components

[SOURCE: ISO 4135:2022, 3.1.4.5]

3.6
control terminal
PES pipeline end point which includes elements of the systems such as filters, flow controls, etc. integrated into the terminal

3.7
design flow
specified as the flow which the *PES* is intended to deliver at the *terminal units*

3.8
design vacuum
specified as the vacuum which the *PES* is intended to deliver at the *terminal units*

3.9
designer
natural or legal person who lays out, sizes and specifies the constituent parts of the pipeline *PES* as they will be installed

3.10
dilution ratio
amount of aerosol dilution applied to a sample flow to avoid particle meter saturation

3.11
electrocautery
surgical technique to cauterize tissue by means of an instrument heated by an electric current for therapeutic purposes

3.12
electrosurgery
surgical technique that uses a radiofrequency electric current passing through the patient to cut, ablate, or coagulate tissue for therapeutic purposes

Note 1 to entry: *Electrosurgery* is also known as high frequency (HF) surgery or surgical diathermy.

3.13
filtration subsystem
part of the overall *plume evacuation system* which separates the *plume* from the air

3.14
flow-generator
part of a *plume evacuation system* that provides flow and vacuum for evacuating *plume*

3.15
installer
natural or legal person with responsibility for the on-site assembly of pipeline *PES*

3.16
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, and labelling of a device before it is placed on the market under their own name, regardless of whether these operations are carried out by that person or on their behalf by a third party

3.17
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of *medical devices*,

— providing information by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

Note 1 to entry: Products which can be considered to be *medical devices* in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO 14971:2019, 3.10]

3.18
medical supply unit
permanently installed medical electrical equipment intended to supply electric power, lighting, and/or medical gases and/or liquids, *plume evacuation systems*, and *anaesthetic gas scavenging systems* to medical areas of a healthcare facility

Note 1 to entry: *Medical supply units* can include medical electrical equipment or medical electrical systems or parts thereof. *Medical supply units* can also consist of modular sections for electrical supply, lighting for therapy or illumination, communication, supply of medical gases and liquids, *plume evacuation systems*, and *anaesthetic gas scavenging systems*. Some typical examples of *medical supply units* are bed head services modules, ceiling pendants, beams, booms, columns, pillars, cabinetry, concealed compartments on or in a wall, and prefabricated walls.

Note 2 to entry: Examples of configurations are given in ISO 11197:2019, Figures 201.103, 201.104 and 201.105.

[SOURCE: ISO 11197:2019, 201.3.201]

3.19
mobile
term referring to *transportable* equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.65]

3.20
mobility diameter
diameter of a spherical particle with the same electrical mobility as the (potentially non-spherical) particle in question

[SOURCE: ISO 28439:2011, 3.3 — modified]

3.21
operations management
process for infrastructure maintenance, monitoring and event management

[SOURCE: ISO/IEC TS 22237-7:2018, 3.1.14]

3.22
passive PES
PES whose *plume* evacuation is accomplished through endoscopic or laparoscopic ports by internal pressure

3.23
pipeline system
portion of a centralised *PES* between the *terminal unit(s)* and the *supply system*

3.24
plume
noxious airborne contaminants generated as by-products, particularly by procedures that rely on the ablation, cauterization, mechanical manipulation, or thermal desiccation of target tissue by devices such as lasers, electrosurgical or *electrocautery* devices, broadband light sources, ultrasonic instruments, or surgical tools such as bone saws, high speed drills, and reamers

Note 1 to entry: *Plume* can include visible or invisible aerosol particles, smoke, or gases.

3.25
plume evacuation system
PES
device for capturing, transporting, and filtering *plume* and exhausting the filtered product

Note 1 to entry: *Plume evacuation systems* can also be called smoke evacuators, laser *plume* evacuators, *plume* scavengers, and local exhaust ventilators (LEVs).

3.26
portable
term referring to *transportable* equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.85]

3.27
pre-filter
device intended to protect filtration equipment from damage by preventing the intake of large particles and/or moisture

3.28
simple terminal
PES pipeline end points to which other devices (filters, flow controls, etc.) will connect. They are typically valves which are open when connected and closed when disconnected

3.29
single fault condition
condition of equipment in which a single means for reducing a risk is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.116]

3.30
single use
referring to a product intended to be used once and then discarded

3.31
source of supply
portion of the *supply system* with associated control equipment which supplies the *pipeline system*

[SOURCE: ISO 7396-1:2016, 3.62]

3.32
stationary plume evacuation system
PES

permanently installed *PES* which is part of the infrastructure of the building and includes a *supply system*, a *pipeline system*, and *terminal unit(s)*, and that conveys the *plume* to the outside of the building

3.33
supply system
assembly which supplies the *pipeline system* and which includes all sources of supply

[SOURCE: ISO 7396-1:2016, 3.64]

3.34
terminal unit
inlet assembly in a *plume* evacuation *pipeline system* at which the operator makes connections and disconnections

[SOURCE: ISO 9170-1:2017, 3.18 — modified: adapted for *plume evacuation systems*]

3.35
transfer tubing
tubing or hose connecting the *capture device* to the *filtration subsystem*. Where no other device is used, the transfer tube may also act as the *capture device*

3.36
transport air
air moving through a test apparatus intended to carry test aerosol past a sampling probe