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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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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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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.

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

3.37
transportable
term referring to equipment that, once installed and placed into service, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

EXAMPLE *Mobile* equipment and *portable* equipment.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.130]

3.38
ultra-low penetration air filter
ULPA filter
filter meeting the requirements for ISO 29463-1 Group U

4 General requirements

All pressures in this document are positive gauge pressures, including a descriptor relative to local atmospheric pressure, and are measured in kPa (see Annex E).

EXAMPLE 1 15 kPa pressure means 15 kPa above local atmospheric pressure.

EXAMPLE 2 15 kPa vacuum means 15 kPa below local atmospheric pressure.

4.1 Components

4.1.1 *PESs* shall comprise the following:

a) a *capture device*;

b) a *filtration subsystem*;

c) a control subsystem;

d) a *flow-generator*, except for a *passive PES*.

4.1.2 *PESs* may include the following:

a) a *terminal unit*;

b) *transfer tubing*;

c) an exhaust subsystem.

NOTE The arrangement of these components can vary and a single device can incorporate multiple functions.

4.2 Systems

4.2.1 A *PES* shall, when installed, extended, modified, commissioned, operated, and maintained in accordance with the instructions of the *manufacturer* or *designer*, present no risks that are not reduced to an acceptable level using risk management procedures in accordance with ISO 14971 and which are connected with their intended application, in normal condition and in *single fault condition*.

NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations can remain undetected over a period of time and as a consequence can lead to an unacceptable risk. In that case, a subsequent detected fault condition needs to be considered as a *single fault condition*. Specific risk control measures need to be determined within the risk management process to deal with such situations.

Check conformity by inspection of the risk management file.

4.2.2 Type tests different from those described in this document can be used, if an equivalent degree of compliance can be demonstrated. However, in the event of dispute, the test arrangements and methods described in this document shall be used as the reference methods.

4.2.3 Medical gas connections (see A.1 for rationale).

4.2.3.1 *PES* shall not be connected to medical vacuum. Only *active PES* may be connected to medical vacuum pipeline systems. See 7.1 for additional *active PES* requirements.

4.2.3.2 *PES* components may only be connected to dedicated *plume* evacuation pipeline systems when applicable.

4.2.3.3 *PES's* shall not be connected to AGSS or general room ventilation systems.

4.2.3.4 If venturis are used to generate the *PES* airflow, they shall not be driven with any medical gas.

4.2.4 IEC 62366-1 applies to any *medical device* components of the *PES*

Check conformity by inspection of the usability engineering file.

4.2.5 Means should be provided to minimize the risk of liquids and solids from entering the filtration system and *flow-generator* (see A.2 for rationale)

4.2.6 The resolution and accuracy of all measuring devices used for testing shall be appropriate for the values to be measured. All measuring devices used for certification shall be calibrated at appropriate intervals.

4.3 Capture device

4.3.1 *Capture device plume* removal efficiency shall be at least 90 % when tested according to Annex C (see A.3 for rationale). Any *manufacturer* claiming compliance shall provide the following operating test conditions in the instructions for use (see E.1.2):

a) *capture device* distance and orientation with respect to the operative site;

b) *capture device* settings, if adjustable;

c) minimum flow rate through the *capture device*, or description of the *plume evacuation system* required to generate sufficient flow, including

   i) *transfer tubing* diameter, length and style (or manufacturer's part number)

   ii) quantity and style of connectors

   iii) prefilters, *ULPA* filters and *adsorbers*

   iv) *flow-generator* with setting(s)

   v) exhaust port adapters or extension tubing

d) annular cavity sleeve inner diameter and depth to operative site, if applicable (see Figure C.5);

e) details of any other relevant component not listed above.

4.3.2 Capture devices integrated with monopolar electrosurgical handpieces shall be tested for plume removal efficiency as a general capture device, at minimum (see Figure C.1).

4.3.3 Flammability risks shall be considered in *capture device* material selection.

Check conformity by inspection of the risk management file.

4.3.4 The *capture device* should include a means to prevent attachment to intact tissue or a means to break the vacuum (see A.4 for rationale).

4.4 Transfer tubing

Tubing design shall consider restriction and occlusion risk (see A.5 for rationale).

Check conformity by inspection of the risk management file.

4.5 Filtration subsystem

4.5.1 The *filtration subsystem* shall comprise a particulate filter assembly that provides *ultra-low penetration air* (*ULPA*) *filter* efficiency per ISO 29463-1:—[3], Table 1 as a minimum, and can include a *pre-filter* and/or an *adsorber*.

Check conformity by visual inspection and inspection of the technical file.

4.5.2 Means shall be provided to indicate when a *filtration subsystem* change is required. If *filtration subsystems* lose effectiveness over time, the *PES* shall indicate when *filtration subsystem* components should be replaced through either markings or audio or visual indications.

Check conformity by visual inspection.

4.5.3 The filtration subsystem shall be designed such that a user is not required to touch a biohazardous surface during filter removal and installation (i.e., the user should not be directly in contact with the contaminated filter components).

Check conformity by visual inspection.

4.5.4 The *filtration subsystem* shall contain an *adsorber* when the outlet flow is into the operating room.

4.6 Control subsystem

Control subsystem:

a) shall include an ON-OFF device;

b) shall enable user-adjustable flow control from zero (OFF) to maximum.

Check conformance by visual inspection.

NOTE A wide range of control devices (e.g. electronic footswitches, pneumatic footswitches, sensor devices, and direct cable connections) can be used with *PESs*. A remote-control feature can be coupled with the activation device of the laser or electrosurgical unit.

4.7 Flow-generator

Provided that unacceptable risk is not introduced, and the *PES* continues to meet the requirements of this document, the flow-generating device can be used to power other systems.

Check conformity by inspection of the risk management file.

NOTE The flow-generating device is usually used only to power the *plume evacuation system*.

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

4.8 Exhaust subsystem

Exhaust subsystem:

a) shall be marked with the symbol ISO 7000-1605, Exhaust gas;

b) should be designed to reduce the risk of blockage;

Check conformity by inspection of the technical and risk management files.

4.9 Colour coding

If colour coding is used, they shall comply with Annex D.

NOTE Markings and/or colour coding can be required based on the *manufacturer's* risk management or usability engineering.

5 Portable and mobile system requirements

5.1 General requirements

Portable and *mobile plume evacuation systems* shall comply with the applicable requirements for basic safety and essential performance specified in IEC 60601-1.

5.2 Acoustic noise test

5.2.1 The intent of this testing is to understand noise from the *flow-generator* with a *filtration subsystem*. Variations in system designs shall be taken into consideration in the design of the test.

5.2.2 Acoustic testing shall be conducted in accordance with ISO 3744:—[4)].

5.2.3 Verify that the time-averaged sound pressure level of the background noise is at least 6 dB below the *PES* under test, per ISO 3744:—, 4.4.1.

5.2.4 Testing shall include at least 10 positions distributed about the hemisphere described in ISO 3744:—, Figure B.1. To avoid near field issues, the measurement radius r shall be twice the characteristic source dimension, d_o, and not less than 1 m. Typically, the reflecting plane for *mobile PES* devices will be the test environment floor. For *portable PES* devices, the reflecting plane shall be the standard test table described in 5.2.6. The 10 positions should be evenly distributed about the hemispherical measurement surface.

5.2.5 The *PES* device shall be operated in the worst case setting for acoustic noise. Further, the measurement duration shall be 30 s and include *PES* device operation through the least favourable condition for a given setting to simulate real-world use cases.

5.2.6 For a mobile PES device, it should be positioned in the centre of the test environment (see Figure 5.1). Attach the most favourable *transfer tubing* size with respect to noise that can be normally applied (e.g. 22 mm × 1,8 m long smooth bore flexible tubing) to the *PES* device. The *transfer tubing* shall be routed such that the noise generated by it is minimized. This should be handled by routing the *transfer tubing* inlet to the outside of the test chamber. A *transfer tubing* extension may be applied to reach outside the test chamber.

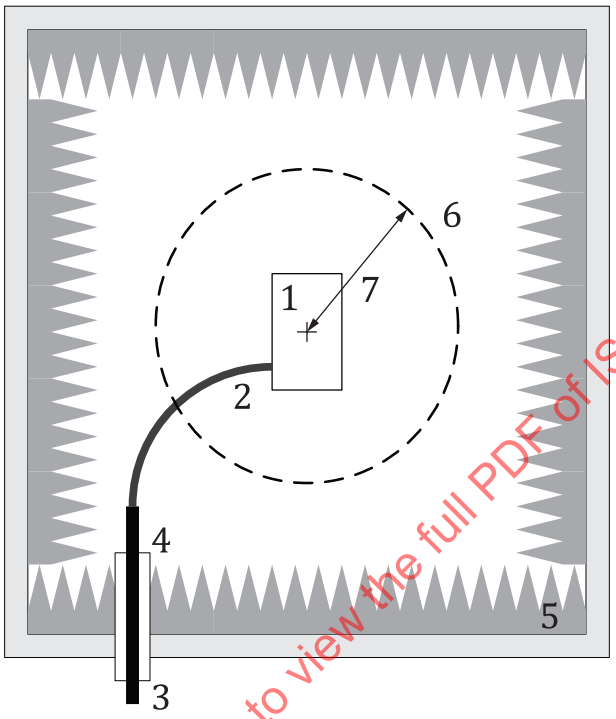
Otherwise, for both laboratory or outdoor testing, the *transfer tubing* inlet may be routed into a muffler as described in Annex F at a minimum distance of 3 m from the geometric centre of the *PES* device.

5.2.7 For a portable PES device, it shall be positioned on a standard test table like that represented in the example shown in Figure 5.2. The standard test table shall conform to ISO 7779:2018, Annex A. This

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

arrangement should then be positioned in the centre of the test environment (see example setup illustration in Figure 5.1). Attach the most favourable *transfer tubing* size with respect to noise that can normally be applied (e.g. 22 mm × 1,8 m long, smooth bore flexible tubing) to the *PES* device. The *transfer tubing* shall be routed such that the noise generated by it is minimized. This should be handled by routing the *transfer tubing* inlet to the outside of the test chamber. A *transfer tubing* extension may be applied to reach outside the test chamber.

Otherwise, for both laboratory or outdoor testing, the *transfer tubing* inlet may be routed into a muffler, as described in Annex F, placed under the test table as shown in the setup example of Figure 5.2.



Key

1	reference box for *PES* device under test	4	sound chamber pass-through
2	*transfer tubing*	5	hemi-anechoic sound chamber
3	*transfer tubing* extension	6	measurement hemisphere perimeter
		7	measurement Radius r

Figure 5.1 — Mobile PES positioned in test environment

a) Example standard test table based on ISO 7779:2018, Annex A

b) Example portable PES positioned in test environment on test table and with a muffler

Figure 5.2 — Example of standard test table set-up

5.2.8 Calculate the A-weighted sound pressure level averaged over the measurement surface according to ISO 3744:—, 8.2.2.

5.2.9 The instructions for use shall state the sound pressure level calculated in 5.2.7 and associated *flow-generator* setting.

5.3 Ingress protection

Enclosures of *portable* and *mobile plume evacuation systems* shall provide at least an IP21 degree of protection (see A.6 for rationale).

Conformity shall be checked per IEC 60529.

6 Stationary and pipeline system requirements

6.1 Stationary plume evacuation systems

6.1.1 Subclause 6.1 shall be applicable to any *plume* system where the *flow-generator(s)* are mounted to or in the building structure or on or in a *medical supply unit*, such that tubing and/or a pipeline and terminal(s) are required to position and allow access to the flow.

6.1.2 A *stationary PES* shall include all the elements of a system defined in Clause 4, with the following additional requirements, which apply only to elements on the source side of the connection to the *transfer tubing*. Elements on the patient side of the connection or integrated into a *control terminal* shall comply with all relevant requirements as for any *PES*.

6.2 Design

6.2.1 *Stationary PES* shall be designed to accommodate the *design flow* of the *PES capture devices* intended for use. The *designer* shall consult with the *manufacturer* of the devices and the healthcare institution, and establish for proper operation of the *capture device*(s):

a) maximum, minimum, and *design flow* required at each terminal;

b) maximum allowable and *design vacuum* level at the terminal.

6.2.2 Each individual *flow-generator* in a multiple *flow-generator* central *supply system* shall be able to provide the design flow at the *design vacuum* or *flow-generators* may be multiplexed following the N+1 rule (the number of *flow-generators* needed for the flow, with one more in reserve). See A.7 for rationale.

6.2.3 The pipeline shall be sized to ensure that the vacuum level at the f*low-generator* is ≤110 % of the vacuum level at the *terminal unit* with full flow at the *capture device*.

6.3 Flow-generators

6.3.1 *Flow-generators* shall be of any type or construction the *manufacturer* considers suitable to the service which is:

a) capable of maintaining the *design flow*;

b) safe for use under continuous operation with no flow (the use of control mechanisms such as air admittance devices, vacuum relief valves and variable speed control is permitted).

6.3.2 *Flow-generators* supplying more than one location (e.g. multiple O.R. or multiple procedure rooms) shall be at least duplexed, with controls which will ensure that should one *flow-generator* fail or be unable to adequately supply the system, the standby *flow-generator* will be brought into operation.

6.3.3 *Flow-generators* supplying only one location (e.g. one O.R. or a single procedure room) may be simplex.

6.3.4 Electrical supply to *flow-generators* shall be from the emergency power supply.

6.3.5 *Flow-generators* shall be isolated from the pipeline to minimize transmission of vibration as necessary.

6.3.6 *Flow-generator* locations shall comply with ISO 7396-2.

6.4 Exhausts

6.4.1 *Flow-generators* that service multiple locations shall have their exhaust(s) piped to the outside of the building as for a medical vacuum exhaust following ISO 7396-1.

6.4.2 *Flow-generators* for a single location may exhaust to outside or into the room as for a *portable* system.

6.5 Flow-generator controls

Flow-generator controls shall provide for the following functions (see A.8 for rationale):

a) Automatic or manual start and stop. This may include manual switches, automatic control by sensor or any other method which will allow the flow-generator to be run when required and stopped when not in use.

NOTE Some flow-generators are continuous operation.

b) Indication of state of operation. This shall indicate to the user when the Flow-generator is in operation and the system is ready for use.

c) Flow-generators serving multiple locations shall have provided in all locations served by the central flow-generator indication of “Flow-Generator Not Operational”, indicating the flow-generator is active [as per 6.5 a)] but is not capable of providing needed flow.

6.6 Pipeline

6.6.1 Pipelines may be constructed of any materials and jointing methods suitable to the vacuum level attainable by the *flow-generators* (see A.9 for rationale).

6.6.2 Flexible hose shall only be used where required to allow for the movement of *medical supply units*. All other piping should be rigid construction and installed following good installation practices as defined by ISO 7396-1.

6.6.3 Shut-off valves shall be provided as needed for maintenance, repair, or planned future extensions and to facilitate periodic testing.

6.6.4 Where used, shut off valves shall follow the operation and labelling requirements of ISO 7396-2.

6.6.5 Pipelines shall be labelled and colour coded as per Annex D and ISO 7396-1.

6.7 Terminal units

6.7.1 All *terminal units* for *stationary PES* shall:

a) be labelled and colour coded as per Annex D;

b) be noninterchangeable with any medical gas or vacuum terminal in use in the same facility;

c) be sized and designed to accommodate the flow and vacuum required by the *capture devices;*

d) prevent flow into the system when off or not connected.

6.7.2 *Terminal units* for *stationary PES* may be *simple terminals* or *control terminals* as suited for the system design.

6.7.2.1 *Simple terminals* shall:

a) comply with 6.7.1;

b) provide for the *design flow* at the *design vacuum* (6.2.1);

c) for *stationary PES*'s serving multiple locations, allow for maintenance of any internal parts without requiring the *PES* system be taken out of service;

d) include a method of retaining the connecting device to ensure it does not unintentionally separate.

6.7.2.2 *Control terminals* shall:

a) comply with 6.7.1;

b) provide for the *design flow* at the *design vacuum* (6.2.1);

c) allow for maintenance of any internal parts without requiring the *PES* system be taken out of service;

d) comply with those portions of this document relevant to the functions which have been integrated into them.

6.8 Commissioning and testing

6.8.1 Measuring accuracy of apparatus used for commissioning and testing shall be appropriate for the values to be measured. All devices should be calibrated before undertaking a testing program or more often if necessary.

6.8.2 *Stationary PES flow-generators* and their associated piping shall be tested before being placed in operation after installation and after any addition or modification, and periodically as determined by the healthcare facility maintenance procedures as follows:

a) cross connection: *Stationary PESs* shall be tested for cross connection with other medical gas, vacuum and AGS systems following procedures as required by ISO 7396-1;

b) leakage: With the *flow-generators* at maximum vacuum (6.2.1), confirm that there are no audible leaks at any pipe joint, connection or terminal;

c) operational test: *Flow-generators* shall be activated and the operation of the reserve (6.3.2) shall be confirmed;

d) indicators test: *Flow-generators* shall be operated and the operation of the indicators [6.5 b) and c)] shall be confirmed;

e) flow test: Each terminal shall be tested for the *design flow* and *design vacuum*. Readings of the static vacuum (no flow), and vacuum at *design flow* shall be demonstrated to be as per the design criteria (6.2.1).

6.8.3 If needed, the system shall be balanced to ensure compliance to design specification at all terminals across the operating range. This shall be demonstrated by performing 6.8.2 e) at each terminal individually with only that one terminal in operation, then again testing each terminal with 100 % of all locations at maximum flow. See A.10 for rationale.

6.8.4 Each *simple terminal* shall be tested to ensure the retention mechanism [6.7.2.1 d)] operates to prevent unintentional disconnection.

6.8.5 Each *control terminal* shall be tested in accordance with *manufacturer's* specifications for the intended functions included in the design.

7 Endoscopic and laparoscopic system requirements

7.1 Active PESs

7.1.1 *Active PESs* shall include the following components:

a) *ULPA filtration*, per 4.5.1

b) Flow controls/restrictions to limit loss of pneumoperitoneum

c) An *adsorber*, except for those utilizing a pipeline vacuum source

d) A fluid trap

e) Luer-lock or other acceptable trocar connections.

7.1.2 *Active PESs* may be self-powered or utilize a *mobile*, *portable*, stationary or pipeline vacuum source. The source shall also comply with the relevant Clauses from 4, 5 and 6. Manufacturers should consider excessive and insufficient peritoneum pressure in their risk management process.

7.2 Passive PESs

Passive PESs shall include the following components:

a) Flow control to limit loss of pneumoperitoneum

b) *ULPA Filtration,* per 4.5.1

c) An *adsorber*

d) Luer-lock or other acceptable trocar connections.

Annex A
(informative)

Rationale

A.1 The use of *anaesthetic gas scavenging systems* for non-*AGSS* applications is prohibited by ISO 7396-2.

A.2 Some *ULPA filters* and *flow-generators* are not tolerant of liquids or solids that can accidentally be suctioned into the *PES*. These events can be difficult to detect, both for users and the devices themselves. They frequently lead to equipment downtime and costly repairs.

A.3 Components of a complete *PES* may be designed, sold, or purchased separately. The most important aspects of a *PES* that determine *plume* removal efficiency are attributes of the *capture device*, along with the flow rate through the *capture device*:

— capture inlet size

— capture inlet shape

— capture inlet location

— capture inlet orientation

— flow rate.

PES users should pay most attention to the *capture device*, how it's used, whether they can locate it close enough to the *plume* source, and whether they can generate enough flow rate through the *capture device* using the *flow-generator* they have or are considering. Description, and ideally pictures, of the use techniques and configurations that enable a system to meet the *plume* removal requirement are essential for users to make that judgment. If a minimum flow rate is specified, users will need to verify using a flow meter and the *PES* they plan to use.

Other than acute irritation, higher severity harm usually results after long term cumulative exposure to *plume*, and no existing published clinical data suggests an evidence-based requirement for *plume* removal efficiency for a *PES*. In lieu of clinical recommendations, the 90 % minimum *plume* removal efficiency requirement and test method serve as a standard basis of comparison between devices.

A.4 High vacuum risk leading to patient tissue trauma was considered during document development. This risk is presumably higher for medical suction devices which are intended to be applied adjacent to or in very close proximity to patient tissue. However, the ISO 10079 series does not limit the maximum vacuum level. Therefore, no maximum vacuum level is specified in this document.

In addition, *capture device* and *transfer tubing* misconnection risk leading to serious adverse events is theoretical at this time. Without evidence, a requirement to prevent possible misconnections was not justified. An informal adverse event audit was performed to determine whether *plume* evacuation tubing misconnections have resulted in patient harm. Publicly available MAUDE FDA datasets were used to search for relevant US reports during the years 2010 to 2020. Zero patient harm reports and zero product field actions related to *plume* evacuation tubing connections were found.

A.5 Reduced or occluded evacuation flow is a hazard that shall be considered in tubing design through risk management and can be difficult or impossible for users to detect or correct. Failure modes leading to this hazard include tubing collapse under normal use conditions, kinking or clogging.

A.6 IP21 was chosen with the understanding that these flow producers will include rotating equipment (fans, regenerative blowers, etc.). Therefore, it is essential that no one be able to insert a finger into the

housing which might be caught or cut by the rotating machinery, requiring a 2 rating for ingress of solids. It is understood that these electrically powered devices will commonly be placed (typically on the floor) in operating theatres. Liquids hanging on stands or set on trays is normal practice in these occupancies. This potentially exposes the device to dripping liquids or in extreme cases to liquids falling onto them. They therefore need a degree of protection against dripping water and require a 1 rating against ingress of liquids.

A.7 The requirement for each *source of supply* to be capable of supplying the system *design flow* is to ensure continuity of supply during a *single fault condition*.

A.8 Continuous-duty *flow-generators* are environmentally unsound, as they will consume energy at all times although there is no usage on the system. For this reason, *flow-generators* should be designed to stop when there is no demand.

A.9 While material compatibility within expected or worst-case use environments are considered by *designers* and *manufacturers*, test methods to evaluate material compatibility with *plume* are lacking. For this reason, no requirement for material compatibility was included in this document.

A.10 The requirement for testing with 100 % of locations helps ensure the system is designed for the worst-case situation.

A.11 The requirement for seven duct diameters from any upstream obstruction or turn helps ensure uniform aerosol mixing and fully developed flow with reduced turbulence at the probe tip to facilitate more consistent measurements.

Gradual flow area changes reduce unpredictable turbulence or unwanted circulation currents in the test chamber that would degrade measurement reproducibility and repeatability. 30° was judged to be sufficient and not overly burdensome.

A.12 DOS/DEHS is a non-soluble, colourless and odourless liquid which is suitable for producing steady aerosols. It's commonly used at aerosol test laboratories, specified within other published test method standards, is cost-effective, and can produce particle size distributions with high concentrations around 200 nm. Specifying an aerosol, rather than allowing many different aerosols, improves the reproducibility of this test method.

The mode (most frequently occurring size) of particle size distributions for monopolar *electrosurgery* surgical *plume* typically falls within 100 nm to 300 nm. Concentrations of larger particles in surgical *plume* are orders of magnitude lower than concentrations found in this range and cannot penetrate human respiratory systems to the depths of smaller particles (see References [79] to [83]).

Quantifying *plume* removal at a single particle size (200 nm) is less burdensome and more reproducible, rather than sweep across a wide particle size range for two main reasons:

a) For a wider size range, many more measurements would be required, which is more costly and more prone to increased repeatability and reproducibility error.

b) For a wider size range, this document would need to specify the required test aerosol particle distribution, rather than only a mode and peak concentration. Each testing facility would need to create and verify that particle distribution, which is very costly.

Besides cost, single size particle measurements are sufficient to enable suitable comparison among *capture devices* and *plume evacuation systems*. This size adequately represents the most dangerous size because surgical *plume* typically contains more particles at this size than others (often by orders of magnitude). It is reasonable to assume that *plume* removal efficiency does not vary much as size gets smaller due to less particle mass/inertia. It is also reasonable to assume that *plume* removal efficiency does not vary much as size gets larger due to development testing that showed measurement insensitivity up through 1,5 µm.

The 2 l/min nominal aerosol flow rate was selected as a balance between competing factors. Lower test aerosol flow rates produced lower orifice exit velocities, similar to the natural convection movement of surgical *plume*. Conversely, higher test aerosol flow rates produce higher concentrations similar to those found in operating theatres. The balance between these competing needs led to 2 for three reasons:

1) Realistic 200 nm particle concentrations were achievable in the test setup.

2) Measurements were more repeatable and reproducible between runs and laboratories.

3) Development test measurements sufficiently corroborated results from a large-scale simulated use study involving several different *capture devices* cutting meat with an electrosurgical generator and monopolar instrument.

The 6,5 mm diameter orifice was selected as a balance between competing factors. A realistic *plume* emission area is desirable to simulate an operative site, which might be closer to 2 mm to 4 mm diameter. However, it is also desirable to emit aerosol at slower speeds that better simulate the effects of natural convection, to which a larger diameter orifice would be more beneficial. Additionally, smoke evacuating pencil *capture devices* often include an *electrosurgery* electrode that will likely be placed at the orifice for realism, but the orifice should never be obstructed to the extent that it affects the intended test aerosol flow. Finally, 6,5 mm was chosen based on sufficient repeatability demonstrated during development testing. The relatively tight diameter tolerance is based on the desired aerosol exit velocity, which is a combination of orifice diameter and flow rate. The 0,25 mm tolerance on diameter translates to a 0,4 l/min tolerance on the aerosol flow rate, which is generally much more difficult to control than orifice diameter.

A.13 During development testing, pulling *transport air* from all four sides of the test chamber ensured sufficient flow uniformity around the aerosol outlet orifice and *capture device*, and improved reproducibility among laboratories. A nominal 375 l/min flow rate was selected due to *plume* removal measurement insensitivity in this range and good corroboration to results from a large-scale simulated use study.

A.14 A diluter is required if the expected aerosol concentration exceeds the limits of the particle counter. Every reasonable effort should be made to avoid use of a diluter to ensure the best measurement precision.

There is no requirement to filter the incoming *transport air* because efficiency calculations correct for it. However, it is best practice to use relatively clean *transport air*. Therefore, there is a maximum background air concentration limit.

Count concentration was selected over mass concentration for a couple reasons. In principle, each particle poses its own hazard, which is correlated to its constituents and not necessarily its mass. Additionally, mass concentration measurements are more heavily influenced by larger particle sizes because mass is a function of particle diameter cubed (for constant density). To control for various test aerosol particle distributions, a focus on count at a specific *mobility diameter* improves measurement system reproducibility and repeatability.

A.15 Primary and secondary research confirmed that 10^5 particles/cm^3 is a reasonable maximum concentration for the mode particle size of monopolar *electrosurgery* tools (less for bipolar tools), and a wide tolerance band is acceptable because the measurement is based on a reduction of particles and not an absolute value (see References [79] to [83]).

A.16 Once activated, strong evacuators may pull enough flow to significantly decrease the *transport air* velocity. This would lead to artificially high *plume* removal efficiency calculations and poor reproducibility. Thus, *transport air* velocity changes should be minimized.

Annex B
(informative)

Plume evacuation system implementation

B.1 General

To ensure the effective application of the requirements specified in this document, the necessary healthcare setting processes need to be established, implemented and maintained. Processes of particular importance in relation to the effective implementation of *PESs* include but are not limited to:

— risk assessment,

— provision of adequate training,

— documentation, including records,

— maintenance controls,

— endoscopic, laparoscopic, and robotic procedural controls,

— assignment of administrative responsibility,

— purchasing

B.2 Risk Assessment

B.2.1 Risk assessment should be conducted prior to selection and/or installation of a *PES* to identify both health, and safety factors to consider in development of a facility policy.

B.2.2 If a facility employs surgical devices or instrumentation that create surgical *plume* (photothermal lasers, electrosurgical units, ultrasound devices, etc.), the facility should have policies to address the findings of the risk assessment, potential hazards and control measures, and are aligned with facility's management systems for quality improvement, occupational health and safety, risk management, infection prevention and control, clinical use, and the environment of care.

B.2.3 The risk of exposure to *plume* for patients should be assessed based on the type of surgical procedure being performed, positioning, duration of exposure, body site being treated, level of anaesthesia and its route of administration, and competency of personnel operating *plume* evacuation devices.

B.2.4 A *PES* should be the primary method of protection against occupational exposure to *plume*, with the use of masks, including particle respirators, laser surgical masks, and eye, face, and respiratory protection used as a secondary line of defence only.

B.2.5 Facility personnel should observe standard (universal) precautions against blood-borne pathogens when entering or working in a zone where infectious material from *plume* could be present in the air or on surfaces, and when handling used *PES*, materials, and supplies.

B.2.6 Policies and procedures should include a requirement for wearing appropriate personal protective equipment when handling these items.

B.3 Education and Training

B.3.1 All surgical team members and ancillary personnel should have education and training, commensurate with their responsibilities, to successfully implement the use of *PES* in their facility, including but not limited to the following:

a) All applicable local, national and international legislation, regulations, and standards related to evacuation of surgical *plume* with a *PES*, and evidence (literature review, research, clinical studies, peer reviewed articles) that informs these regulations and policies;

b) Adherence to all requirements and recommendations in the *manufacturer's* IFU;

c) Only equipment that meets the requirements in this document, and the operational recommendations in the *manufacturers'* IFUs, should be used to evacuate surgical *plume*; and

d) Periodic competency validation related to the use, servicing, and maintenance of *PESs* and all accessories and supplies.

B.3.2 A facility should ensure that everyone working in an environment where *plume* is generated:

a) Has access to current surgical safety information regarding *plume*, including hazard identification, risk assessment, evacuation requirements, and all relevant *manufacturer's* IFUs and instructional and operational materials;

b) Has been appropriately educated and trained on the hazards and risks of exposure to surgical *plume*, its policies and procedures for operating and maintaining the *PES* and all its components; and

c) Periodic competency validation related to the use, servicing, and maintenance of the *PES*.

B.4 Documentation

The facility should maintain the following to ensure continuous successful implementation of *PESs*:

a) Policies and procedures that cover purchasing, installation, testing, use, care and handling, storage, servicing, audit, and regular maintenance of *plume* evacuation equipment and systems (tubing, filters, *capture devices*, etc.);

b) Policies should be reviewed and revised periodically to reflect current knowledge, technology, and facility procedures;

c) Documentation that provides evidence of appropriate audit, employee education, training, and periodic competency evaluation; and

d) Documentation of service, maintenance, filter changes, and clinical use of all *PESs* to include *capture devices* and both re-usable and single-use accessories.

B.5 Maintenance

Appropriate *PES* or approved alternate evacuation systems including filters, *connectors*, tubing and *capture devices* should be checked for proper functioning prior to use, and periodic performance according to the requirements of this document, and positioned in any treatment room or operating room for every clinical procedure where energy-based devices are to be used.

B.6 Endoscopic, Laparoscopic, and Robotic procedural controls

B.6.1 All surgical team members conducting endoscopic, laparoscopic, or robotic procedures with an energy-based device, should have relevant training on the use of *active* or *passive PESs* for evacuation of surgical *plume* during such procedures.

B.6.2 Use of *active* or *passive plume evacuation systems,* designed to prevent the venting of *plume* from the abdominal cavity into the room air during these procedures, should be required and compliance enforced to ensure both staff and patient safety.

B.7 Administrative responsibility

B.7.1 Facility administration should be responsible for implementation of control measures, and compliance with the requirements found in this document.

B.7.2 Facility administration should ensure that policies are established and include a requirement for following the *manufacturer's* IFU.

B.7.3 Facility administration should designate a person who is to be responsible for implementation of *manufacturer's* instructions and recommendations and ensuring that *plume* evacuation requirements are monitored for compliance, reviewed and revised as necessary.

NOTE Personnel who can be designated to oversee compliance with standards and policies, can include but not be limited to: a facility safety officer, health and safety managers, risk managers, laser safety officers, infection prevention and control professionals, biomedical engineers, or anyone in a similar leadership position with authority for all areas of the facility where *plume* can be generated.

B.8 Purchasing

Facility personnel should evaluate *plume evacuation systems* prior to purchase, verifying that it meets the requirements and specifications in this document. The assessment should include, but is not limited to:

a) Types of surgical procedures that generate *plume* and are performed in the facility (ENT, GYN, GI, plastics and dermatology, podiatry, cosmetics and aesthetics, cardiac, etc.);

b) Compatibility of *capture devices* and attachments to be used with energy-based devices in surgery should be assessed;

c) *Manufacturer's* specifications regarding electrical components and recommendations for installation and maintenance;

d) Footprint of the *PES* relative to the size and layout of the operating or treatment room;

e) Potential for flammability, reflectance, or excessive noise;

f) Facility policy on single use or re-usable attachments or *capture devices*; and

g) Filter use life, and frequency and ease of changing filters.

NOTE Facility personnel who would be involved in selecting/purchasing *PES* equipment, *capture devices*, or accessories, can include but not be limited to: users, purchasing agents, clinical educators, biomedical technicians, operating suite managers, health and safety officers, infection prevention and control personnel, and environmental services staff.

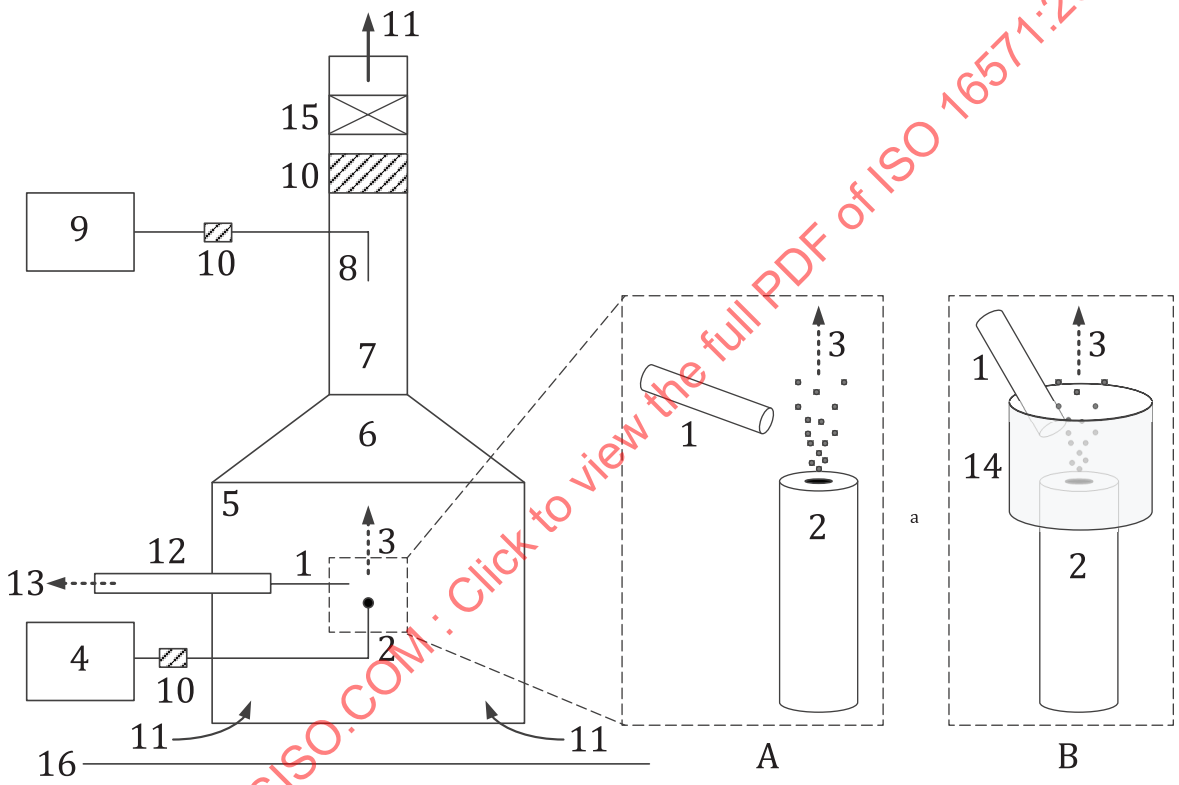
Annex C
(normative)

Plume removal efficiency test method

C.1 Test Setup

C.1.1 General

The essential elements of a *plume* removal efficiency test apparatus are shown in Figure C.1.



Key

1 *capture device* under test
2 aerosol outlet orifice
3 test aerosol
4 DOS/DEHS aerosol source
5 test chamber
6 transition duct
7 sampling duct
8 aerosol sampling probe
9 particle counting meter
10 flow or velocity meter
11 *transport air*
12 *transfer tubing*
13 evacuated aerosol
14 cavity sleeve
15 *transport air* flow-generating device
16 horizontal flat plane
[a] OR.

Figure C.1 — Plume removal efficiency test apparatus for general capture devices (A), and for capture devices intended for plume removal inside surgical cavities (B)

C.1.2 Ductwork

Key dimensional requirements for the test chamber, transition duct, and sampling duct are shown in Figure C.2 (see A.11 for rationale).

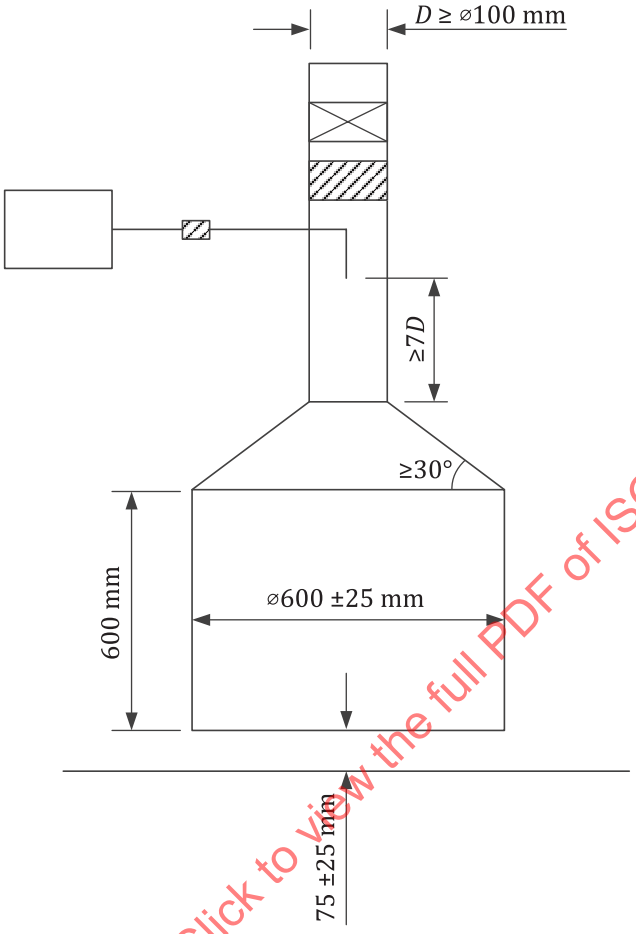


Figure C.2 — Test chamber, transition duct, sampling duct and horizontal flat plane design details

The test chamber shall be prismatic, having internal width and depth measurements of 600 mm ± 25 mm and internal height of at least 600 mm. Top and bottom of the test chamber shall remain open.

The sampling duct shall be cylindrical with a diameter of at least 100 mm. Connect the test chamber and sampling duct with a transition duct having pitch of at least 30° (measured from horizontal) and centred outlet. The sampling duct can include one or more bends, but bends should be minimized.

In the sampling duct, install a flow-generating device configured to pull air up through the test chamber, transition duct, and sampling duct. A calibrated flow or velocity meter shall also be installed in the sampling duct.

NOTE Some flow-generating devices and flow or velocity meters will require upstream filtration to prevent damage due to entrained aerosol.

Install an aerosol sampling probe inside the sampling duct, ensuring that probe inlet is at least seven duct diameters downstream from any change in duct diameter or direction (such as a bend). Connect the sampling probe to a calibrated particle size classifier and counting meter configured to count 200 nm electrical mobility diameter particles (±10 nm) at a known flow rate. The meter shall be a differential electrical mobility analyser compliant with ISO 15900.

Position the test chamber 75 mm ± 25 mm above a horizontal flat plane such that *transport air* can be pulled into the test chamber from all four sides. The flat plane shall extend beyond the test chamber width and

depth as shown in Figure C.2. Supporting structural members should be designed to minimize impact on *transport air* flow.

C.1.3 Aerosol

Key dimensional requirements for the aerosol outlet orifice location within the test chamber are shown in Figure C.3 (see A.12 for rationale).

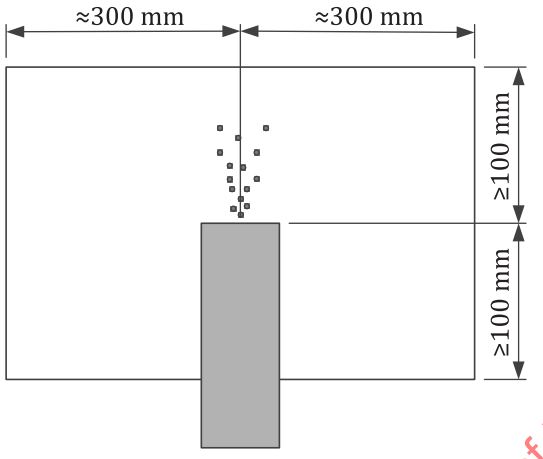
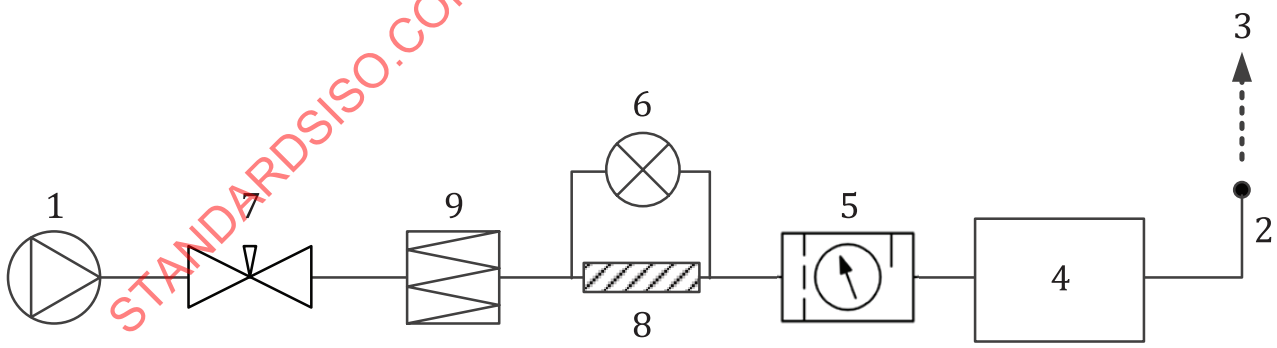


Figure C.3 — Aerosol outlet orifice positioning within the test chamber

An aerosol outlet orifice simulates the *plume* generation operative site and shall be 6,50 mm ± 0,25 mm in diameter facing upward. Centre the aerosol outlet orifice between opposing sides of the test chamber. Vertical position of the aerosol outlet orifice shall be at least 100 mm from the top and bottom horizontal planes of the test chamber, as shown in Figure C.3.

Test aerosol shall be DOS/DEHS [Dioctyl sebacate or di(2-ethylhexyl) sebacate] having particle *mobility diameter* mode of 200 nm ± 100 nm. Aerosol flow rate through outlet orifice into the test chamber shall be 2,0 l/min ± 0,4 l/min (absolute) and shall be measured directly.

Although multiple configurations can produce the correct aerosol concentration and directly measure its flow rate, an example setup is provided in Figure C.4 below.



Key

1	pressurized air source	6	manometer
2	aerosol outlet orifice	7	needle valve
3	test aerosol	8	laminar flow element
4	single jet atomizer	9	particulate filter
5	pressure regulator		

Figure C.4 — Example aerosol generator setup with direct aerosol flow rate measurement.

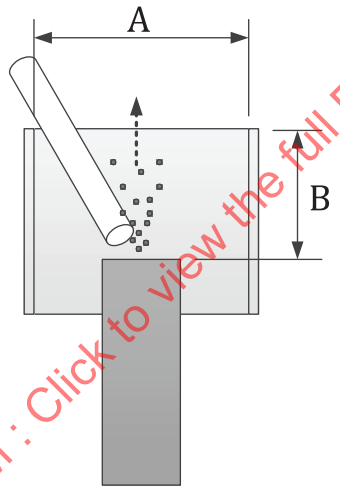
In the example shown, the single jet atomizer is filled with DOS/DEHS. Pressurized air is connected to the generator inlet, using a regulator to maintain fixed input pressure. The circuit's flow rate is directly measured by a manometer across a calibrated laminar flow element protected by a particulate filter. Characteristic pressure drop across the laminar flow element shall be correlated to flow rate, and the flow can be controlled by a needle valve. The generator outlet is connected directly to the aerosol outlet orifice.

C.1.4 Device under test

Capture device shall be tested in the configuration as described in IFU. Position the *capture device* under test at a realistic distance and orientation with respect to the aerosol outlet orifice. Configure the *capture device* using realistic settings, if it has any variable settings. Connect the *capture device* and any associated *transfer tubing* to the desired flow generating device.

NOTE Manufacturers can additionally choose to test alternate capture device configurations. For example, electrosurgical handpiece with alternate electrode.

To demonstrate *plume* removal efficiency for a *capture device* within a surgical cavity, apply an annular cavity sleeve surrounding both the *capture device* and the aerosol outlet orifice. The sleeve's inner diameter represents the cavity width, and the cavity depth is represented by the distance from sleeve top to aerosol outlet orifice, as shown in Figure C.5. The sleeve shall be open at the bottom to allow *transport air* through, and the sleeve top shall at least 100 mm from the top of the test chamber.



Sleeve shall be defined by inner diameter, A, and depth to aerosol outlet orifice, B.

Figure C.5 — Annular cavity sleeve surrounding the capture device and aerosol outlet orifice

C.2 Test execution

C.2.1 General

Activate the *transport air* flow-generating device, inducing *transport air* movement upwards through the test chamber with constant flow rate of 375 l/min ± 75 l/min (absolute). See A.13 for rationale.

C.2.2 Background concentration (initial) $C_{bg\text{-}i}$

Once *transport air* velocity is stable, determine the initial 30 s average background aerosol concentration in the exhaust duct, $C_{bg\text{-}i}$, by the following Formula (C.1), see A.14 for rationale:

$$C = \frac{N_{200} D}{Q \cdot t} \tag{C.1}$$

where

C is the aerosol concentration per cubic centimetre to be calculated

N_{200} is the number of 200 nm *mobility diameter* particles counted during a 30 s period

D is the *dilution ratio* applied to the sample flow, if any

Q is the aerosol sampling probe flow rate, in cm^3/s

t is 30 s.

$C_{bg\text{-}i}$ shall be less than 200 particles/cm^3 to ensure sufficiently clean ambient air.

C.2.3 Evacuator off concentration C_{off}

With evacuator device off, inject DOS/DEHS aerosol through the outlet orifice into the test chamber (see A.15 for rationale).

Once *transport air* flow, aerosol flow, and aerosol concentration are stable, determine the 30 s average of sampling duct aerosol concentration with evacuator off, C_{off}, by Formula (C.1). C_{off} shall be between 10^4 and 10^6 particles/cm^3. Adjust DOS/DEHS aerosol to ensure C_{off} concentration, particle *mobility diameter* mode, and flow rate meet the requirements listed above, if needed.

NOTE Many particle counting meters measure only charged particles, which is typically around one-fifth of all particles at a given *mobility diameter*. Using this type of equipment, actual measurements of 2 000 particles/cm^3 would still meet the minimum C_{off} concentration of 10^4 particles/cm^3.

C.2.4 Evacuator on concentration C_{on}

Activate the evacuator device to induce flow through the *capture device*. This can be a quantified air flow rate, or a specified device configuration and operational settings, per 4.3.1 (see A.16 for rationale).

Transport air flow rate through the test chamber and aerosol flow rate through the orifice shall not change by more than 5 % from step C.2.3. If needed, adjust *transport air* or aerosol flow rates.

Once *transport air* flow, aerosol flow, *capture device* flow, and aerosol concentration are stable, determine the 30 s average of sampling duct aerosol concentration with evacuator on, C_{on}, by Formula (C.1).

C.2.5 Repeat measurements

Repeat C.2.3 and C.2.4 two more times for a total of three runs. During all runs, *transport air* flow rate through the test chamber and aerosol velocity through the orifice shall not change by more than 5 % from step C.2.3. If needed, adjust *transport air* or aerosol flow rates.

C.2.6 Background concentration (final) $C_{bg\text{-}f}$

Deactivate the evacuator device and DOS/DEHS aerosol. *Transport air* flow rate through the test chamber shall not change by more than 5 % from step C.2.2. If needed, adjust *transport air* flow rate.

Once *transport air* flow rate is stable, and residual test aerosol has been exhausted, determine the final 30 s average of background aerosol concentration in the exhaust duct, $C_{bg\text{-}f}$, by Formula (C.1).

$C_{bg\text{-}f}$ shall be less than 200 particles/cm^3 to ensure sufficiently clean ambient air.

Determine the average background aerosol concentration across all three runs as per Formula (C.2):

$$C_{bg} = \frac{C_{bg\text{-}i} + C_{bg\text{-}f}}{2} \quad \text{(C.2)}$$

C.3 Efficiency calculation

Plume removal efficiency for each run shall be calculated by the following Formula (C.3):

$$E_n = \left[1 - \frac{C_{on} - C_{bg}}{C_{off} - C_{bg}}\right] \times 100 \quad \text{(C.3)}$$

where

E_n is the calculated *plume* removal efficiency for *n* run, equal to the percent reduction in aerosol concentration due to the active *capture device* under test;

C_{off} is the average 200 nm particle concentration per cubic centimetre with flow generating device off for a given run;

C_{on} is the average 200 nm particle concentration per cubic centimetre with flow generating device on for a given run; and

C_{bg} is the average 200 nm particle concentration per cubic centimetre of the background air, calculated in C.2.6.

Overall *plume* removal efficiency shall be calculated as the arithmetic mean of efficiency for all three runs as per Formula (C.4):

$$E = \frac{E_1 + E_2 + E_3}{3} \quad \text{(C.4)}$$

where

E_n is the calculated *plume* removal efficiency for *n* run; and

E is the overall *plume* removal efficiency for a given *capture device* with specified operating conditions, which shall meet the requirement specified in 4.3.1 to demonstrate conformity.

Annex D
(normative)

Colour coding

D.1 General

D.1.1 Where colour coding is used, it shall comply with requirements in this Annex, except where national or local rules exist.

D.1.2 Colour coding shall be used in any location where the identity or specificity of *plume* evacuating devices, inlet or outlets to/from these devices and tubing connections is required to be identifiable for the operator.

Check conformity by inspection of the risk management file.

D.1.3 Colour coding and name identification shall be placed so as to allow the user to ensure the identity of the *PES*:

a) at least once on any *plume* evacuating device in a location on the device which will be visible when the unit is in ordinary operation;

b) at any connection point on the *plume* evacuating device, inlet and outlet, where *plume* could be encountered during normal operation (it is optional to colour code a filtered outlet);

c) at any end of the *transfer tubing* provided with end fittings specifically intended to fit the *PES*; and

d) in any other location which would assist the user in identification.

D.1.4 Colour coding shall be removable only with a tool or by appreciable force.

Check conformity by inspection of the risk management file.

D.1.5 Colour coding shall be sufficiently durable to remain capable of being read by a person with normal vision, and adhesive labels are not to have worked loose or become curled at the edges.

Check conformity by inspection after subjecting to the following conditions:

Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96 % and then for 15 s with a cloth rag soaked with isopropyl alcohol.

D.2 Colours

Required colours:

a) Magenta CMYK 12, 100, 11, 0

b) Grey CMYK 26, 20, 20, 0

The colour scheme for *plume* evacuation labelling is formed using the basic graphic design method illustrated in Figure D.1. Labelling in other shapes is permitted provided the colour scheme conforms to this concept.