SLOVENSKI STANDARD
oSIST prEN ISO 16571:2023

01-april-2023

Sistemi za odsesavanje hlapov, ki nastanejo zaradi uporabe medicinskih pripomočkov (ISO/DIS 16571:2023)

Systems for evacuation of plume generated by medical devices (ISO/DIS 16571:2023)

Rauchgasabsaugsysteme für Medizinprodukte (ISO/DIS 16571:2023)

Systèmes d'évacuation des fumées chirurgicales générées par l'utilisation de dispositifs médicaux (ISO/DIS 16571:2023)

Ta slovenski standard je istoveten z: **prEN ISO 16571**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

oSIST prEN ISO 16571:2023 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 16571

ISO/TC **121**/SC **6** Secretariat: **ANSI**

Voting begins on: **2023-01-31**

Voting terminates on: **2023-04-25**

Systems for evacuation of plume generated by medical devices

Systèmes de gaz médicaux — Systemes d'évacuation des effluents gazeux générés par l'utilisation de dispositifs medicaux

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 16571:2023(E)

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Published in Switzerland

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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This second edition cancels and replaces the first edition (ISO 16571:2014), which has been technically revised. This edition includes significant changes to all clauses of the previous edition and expands scope to include endoscopic systems.

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, ultrasonic instruments, etc. or mechanical surgical tools such as bone saws, high speed drills, and reamers. Energy-based contact with articles such as tubing, swabs, and skin preparation solutions will 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: viable bacteria (including multi-resistant strains), viruses, cellular debris (including DNA), airborne chemicals, particulates, ultrafine particles, aerosols, gases, vapours, and fumes (including fumes from metals). *In vitro* studies of bacterial and viral contamination have found viable *Escherichia coli*, *Staphylococcus aureus*, human papillomavirus (HPV), hepatitis viruses (HVB, HVC), and human immunodeficiency virus (HIV) in *plume*. The gases in *plume* can include toxic substances such as benzene, formaldehyde, and hydrogen cyanide. *Plume* can also contain aerosolized blood (plasma, cells, or fragments of cells) and blood-borne pathogens.

Plume thus poses a hazard to exposed persons. It can transmit infection or have mutagenic or carcinogenic effects. *Plume* can also cause irritation of the mucous membranes, eyes, respiratory system, and skin. 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 seeks to provide readers with the information they need to ensure the capture, filtration, and removal of 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.

Annex A contains rationale statements for some of the requirements of this document. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this document. The clauses and subclauses marked with * after their number have corresponding rationale contained in Annex A. It is considered that knowledge of the

reasons for the requirements will not only facilitate the proper application of this document, but will expedite any subsequent revisions.

Throughout this document the following print types are used:

— Requirements and definitions: roman type;

— *Test specifications: italic type*;

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;

— *Terms defined in clause 3: italics*.

For the purposes of this document, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformance with this document;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” is used to describe permission (e.g., a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3744:2010, *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 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 14971, *Medical devices — Application of risk management to medical devices*

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*

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

EN 1822-1, *High efficiency air filters (EPA, HEPA and ULPA) – Part 1: Classification, performance testing, marking*

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

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

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

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

3 Terms and definitions

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

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 and odours from a gas stream

EXAMPLE Activated carbon filter.

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*

Note 1 to entry: *Flow-generator* may also be known as a vacuum source.

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 himself or on his 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: Detailed information about *medical supply units* can be found in ISO 11197.

[SOURCE: 11197:2016, 201.3.103]

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 Ed. 3.2 en:2020]

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

[SOURCE: amended from ISO 28439:2011, 3.3]

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 Ed. 3.2 en:2020]

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 Ed. 3.2 en:2020]

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]

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]

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

[SOURCE: amended from ISO 9170-1:2017, 3.18 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

[SOURCE: IEC 60601-1 Ed. 3.2 en:2020]

EXAMPLE *Mobile* equipment and *portable* equipment.

3.38
ultra-low penetration air (ULPA) filter
filter meeting the requirements for ISO 29463-1 Group U or EN 1822-1 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 15 kPa pressure means 15 kPa above local atmospheric pressure.

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

4.1 Components

PES's 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*;

PES's 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

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 1 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.

NOTE 2 Regional or national regulations which apply to electrical installations in buildings can exist.

NOTE 3 Regional or national regulations which apply to continuity of earthing across all joints within the same building and to electrical isolation of different buildings from each other can exist.