INTERNATIONAL STANDARD

ISO 16571

First edition
2014-03-15

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

Reference number
ISO 16571:2014(E)

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Published in Switzerland

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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 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).

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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*.

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, electrosurgical generators, broadband light sources, ultrasonic instruments, etc. or mechanical surgical tools such as bone saws, high speed drills, and reamers. New technologies in cutting and sealing can result in less plume generation (see Reference[85]) but plume remains a hazard. Energy-based contact with articles such as tubing, swabs, and skin preparation solutions will produce additional chemicals. This International Standard 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 International Standard 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 International Standard.

This International Standard seeks to ensure that plume generated in healthcare facilities is not evacuated through the medical vacuum or anaesthetic gas scavenging systems. For this reason, type-specific components are specified for terminal units and for other connectors which are intended to be used by the operator.

The objectives of this International Standard are to ensure the following:

a) non-interchangeability with other products or pipeline systems by design;

b) continuous extraction at specified pressures and flows;

c) use of suitable materials for all components of the system;

d) provision of monitoring indicators and alarm systems;

e) correct rating of filtration systems;

f) correct indication of filter life;

g) correct marking and labelling;

h) electrical and environmental testing;

i) correct installation;

j) testing, commissioning, and certification;

k) provision of guidance on operational management;

l) appropriate manufacturer's instructions for use, training, service, and maintenance.

Annex F contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this International Standard. The clauses and subclauses marked with * after their number have corresponding rationale contained in Annex F. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

Systems for evacuation of plume generated by medical devices

1 Scope

1.1 This International Standard specifies requirements and guidelines for the design, manufacture, installation, function, performance, maintenance, servicing, documentation, testing, and commissioning of equipment for evacuation of plume generated by medical devices.

NOTE A plume evacuation system (PES) can be a functionally independent component of a medical device that has other functions.

1.2 This International Standard is applicable to

a) portable and mobile plume evacuation systems,

b) local stationary plume evacuation systems,

c) dedicated central pipeline systems for plume evacuation systems, and

d) plume evacuation systems integrated into other equipment (e.g. laser equipment).

1.3* This International Standard does not apply to active and passive devices used to evacuate plume generated during invasive (e.g. laparoscopic or endoscopic) procedures.

1.4 This International Standard 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;

NOTE Some other aspects of laser safety are covered by IEC 60825 (see Reference[7]).

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 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

ISO 11197, *Medical supply units*

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 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 1822-1, *High efficiency air filters (HEPA and ULPA) — Classification, performance testing, marking*

EN 13348, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

3 Terms and definitions

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

3.1
adsorber
device that removes volatile organic compounds and odours from a gas stream

EXAMPLE Activated carbon filter.

3.2
capture device
hose, tube, funnel, or other accessory that provides the inlet to the plume evacuation system at the site of plume generation

3.3
central plume evacuation system
permanently installed PES which includes a supply system, a pipeline system, and terminal unit(s), and that conveys the plume to the outside of the building

3.4
diversity factor
factor which represents the maximum proportion of terminal units in a defined clinical area which will be used at the same time, at flow rates defined in agreement with the management of the healthcare facility and according to this International Standard

3.5
electrocautery
surgical technique that uses an electrically heated device 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.

3.6
electrosurgery
surgical technique that uses a radiofrequency electric current passing through the patient to cut, ablate, or coagulate tissue for therapeutic purposes

3.7
flow-generating device
part of a plume evacuation system that provides flow and vacuum for evacuating plume

3.8
junction point
connection point between the inlet tubing to the flow-generating device and the PES pipeline

Note 1 to entry: See Figure A.3.

3.9
local stationary plume evacuation system
permanently installed PES that includes a flow-generating device and terminal unit and that vents the filtered plume inside the room

3.10
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 his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.11
medical device
any instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, and intended by the manufacturer to be used for human beings for the purpose of

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

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

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

— control of conception,

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

3.12
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.

3.13
mobile
referring to transportable equipment intended to be moved from one location to another while supported by its own wheels or equivalent means

3.14
pipeline system
portion of a central PES between the terminal unit(s) and the supply system

3.15
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.

3.16
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).

Note 2 to entry: Diagrams of typical PESs are found in Annex A.

3.17
portable
referring to transportable equipment intended to be moved from one location to another while being carried by one or more persons

3.18
pre-filter
device intended to protect filtration equipment from damage by preventing the intake of large particles and/or moisture

3.19
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

3.20
single use
referring to a product intended to be used once and then discarded

3.21
source of supply
portion of the supply system with associated control equipment which supplies the pipeline system

[SOURCE: ISO 7396-1]

3.22
supply system
assembly which supplies the pipeline system and which includes all sources of supply

[SOURCE: ISO 7396-1]

3.23
system design flow
flow calculated from the maximum flow requirement of the healthcare facility and corrected by the diversity factor(s)

[SOURCE: ISO 7396-1]

3.25
terminal unit
inlet assembly in a plume evacuation system at which the operator makes connections and disconnections

Note 1 to entry: See Figure 1.

3.26
transfer tubing
tubing between the capture device and the filtration system

3.27
transportable
referring to equipment that is intended to be moved from one place to another, whether or not connected to a supply and without any appreciable restriction of range

EXAMPLE Mobile equipment and portable equipment.

3.28
ultra-low penetration (or particulate) air (ULPA) filter
filter with an overall particulate efficiency of not less than 99,999 5 % as determined by EN 1822-1

3.29
ultrasonic surgical device
surgical device that utilizes high frequency vibration to enable hemostatic cutting or cautery, created by thermal effects, coupled with fragmentation of tissue

4 General requirements

All pressures in this International Standard are gauge pressures (i.e. relative to local atmospheric pressure) and are measured in kPa.

4.1 PESs shall, when installed, extended, modified, commissioned, operated, and maintained in accordance with the instructions of the manufacturer, 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 Typical safety hazards are listed in Annex D.

4.2 The manufacturer can use type tests different from those described in this International Standard, if an equivalent degree of compliance can be demonstrated. However, in the event of dispute, the test arrangements and methods described in this International Standard shall be used as the reference methods.

4.3 When used in accordance with the manufacturer's instructions, the efficiency of plume removal shall be at least 90 %.

Evidence shall be provided by the manufacturer.

4.4* A PES shall not be connected to any pipeline system for medical gases and/or vacuum, an anaesthetic gas scavenging system (AGSS), or a heating and recirculating ventilation system.

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

NOTE National or regional regulations can specify additional requirements.

4.6 The sound pressure level emitted by the PES shall be measured in accordance with 12.2 and shall be disclosed in the instructions for use.

NOTE National and regional regulations concerning noise levels within the medical environment can exist.

4.7* Enclosures of portable and mobile plume evacuation systems shall provide at least an IP31 degree of protection when tested according to 12.4.1.

4.8 The manufacturer shall evaluate usability in accordance with IEC 62366. Check compliance by inspection of the usability engineering file.