AS 16571:2015

Systems for evacuation of plume generated by medical devices (ISO 16571:2014, MOD)

This Australian Standard® was prepared by Committee HE-017, Medical Gas Systems. It was approved on behalf of the Council of Standards Australia on 8 July 2015.
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The following are represented on Committee HE-017:

- Australian and New Zealand College of Anaesthetists
- Australian Chamber of Commerce and Industry
- Australian Industry Group
- Australian Society of Anaesthetists
- Engineers Australia
- Master Plumbers Australia
- Ministry of Consumer Affairs, New Zealand

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Australian Standard®

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-017, Medical Gas Systems.

The objective of this Standard is to specify 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.

This Standard is an adoption with national modifications and has been reproduced from ISO 16571:2014, *Systems for evacuation of plume generated by medical devices* and has been varied as indicated to take account of Australian conditions. The modifications are specified in Appendix ZZ.

NOTE: Users of this Standard should be aware that medical gas systems may be subject to regulatory requirements, e.g. from Therapeutic Goods Administration, WHS Regulatory Authorities or Plumbing Industry Commission. Compliance with this Standard may not fulfil all such requirements.

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian/New Zealand Standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		*Australian Standard*	
ISO		AS	
5359	Anaesthetic and respiratory equipment—Low-pressure hose assemblies for use with medical gases	2902	Medical gas systems—Low pressure flexible hose assemblies
7396	Medical gas pipeline systems	2896	Medical gas systems—Installation and testing of non-flammable medical gas pipeline systems
		AS/NZS	
14971	Medical devices—Application of risk management to medical devices	4810	Medical devices—Risk management
		4810.1	Application of risk analysis
IEC		AS/NZS IEC	
60601	Medical electrical equipment	60601	Medical electrical equipment
60601-1	Part 1: General requirements for basic safety and essential performance.	60601.1	General requirements for basic safety and essential performance
IEC		AS IEC	
61672	Electroacoustics—Sound level meters	61672	Electroacoustics—Sound level meters
61672-1	Part 1: Specifications	61672.1	Part 1: Specifications
13348	Copper and copper alloys—Seamless, round copper tubes for medical gases or vacuum	1423	Copper tubes for plumbing, gas fitting and drainage applications.
		1571	Copper-seamless tubes for air conditioning and refrigeration

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The term ‘normative’ has been used in this Standard to define the application of the appendix to which it applies. A ‘normative’ annex or appendix is an integral part of a Standard.

CONTENTS

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.

AUSTRALIAN STANDARD

Systems for evacuation of plume generated by medical devices (ISO 16571:2014, MOD)

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*