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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

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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*.

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.