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Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 2: Tests for emissions of particulate matter

Évaluation de la biocompatibilité des chemins de gaz respiratoire utilisés dans le domaine de la santé —

Partie 2: Essais concernant les émissions de matières particulaires

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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 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 3, *Lung ventilators and related equipment*, 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 18562-2:2017), which has been technically revised.

The main changes are as follows:

- added informative mapping annexes to relevant regulatory requirements;
- clarified terms and definitions used in the document.

A list of all parts in the ISO 18562 series can be found on the ISO website.

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

This document is intended to protect *patients* connected to *medical devices* from excessive amounts of *particulate matter* that arises from within *gas pathways* of *medical devices*.

This document is intended to cover the biological evaluation of *gas pathways* of *medical devices* within a *risk management process*, as part of the overall *medical device* evaluation and development. This approach combines the review and evaluation of existing data from all sources with, where necessary, the selection and application of additional tests.

In general, the ISO 10993 series^[2] is intended to cover the biological evaluation of *medical devices*. However, the ISO 10993 series does not appropriately address the biological evaluation of the *gas pathways* of *medical devices*. For example, the ISO 10993 tests do not evaluate inspired *particulate matter*.

It is not within the scope of this document to address contamination arising from the source of the breathing gases entering such *medical devices*, but rather to address only the potential contamination generated from within the *medical device* itself. This contamination might be from the original manufacturing *process* or be generated by the *medical device* itself during use.

This document is concerned with *particulate matter* that could be conveyed to the *patient* by the breathing gases. The smaller the particle, the deeper into the lungs it can penetrate and the longer it takes the body to eliminate it. Originally, the main health concerns with regard to *particulate matter* were focused on respiratory health, but now there is emerging evidence of effects on the cardiovascular system as well.

The tests for the presence of *particulate matter* generated by respiratory *medical devices* are based on standard laboratory practice and require no advanced techniques or equipment.

The acceptable levels of contamination are based on worldwide published health data for *particulates*. It is accepted that there is no point in setting a level that is lower than that found in air that people might breathe every day of their lives.

This document has been prepared in consideration of:

- the *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*, IMDRF/GRRP WG/N47:2018^[5] as indicated in [Annex B](#);
- the *Labelling Principles for Medical Devices and IVD Medical Devices*, IMDRF/GRRP WG/N52:2019^[6] as indicated in [Annex B](#);
- the *essential principles of safety and performance on the information supplied by the manufacturer of a medical device* according to ISO 16142-1:2016^[3] as indicated in [Annex C](#); and
- the general safety and performance requirements of a *medical device* according to regulation (EU) 2017/745^[2].

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or capability.

Biocompatibility evaluation of breathing gas pathways in healthcare — applications —

Part 2: Tests for emissions of particulate matter

1 Scope

NOTE There is guidance or rationale for this Clause contained in [Clause A.2](#).

This document specifies tests for the emissions of *particulate matter* from the *gas pathways* of a *medical device*, its parts or *accessories*, which are intended to provide respiratory care or supply substances via the respiratory tract to a *patient* in all environments. The tests of this document are intended to quantify particles from 0,25 μm *diameter* to 10 μm *diameter* that are emitted by the *medical device*, its parts or *accessories* into the respirable gas stream. This document establishes acceptance criteria for these tests.

This document does not address nanoparticles. Insufficient data exist to establish exposure limits for particles less than 0,25 μm *diameter*.

This document does not address particles larger than 10 μm *diameter*. These particles are deposited in the nasal cavity. Additional information can be needed for *medical devices* or *accessories* that bypass the nose. This is outside the scope of this document but can be required by some *authorities having jurisdiction*.

This document therefore adopts the same approach as the US Environmental Protection Agency (EPA) in setting limits based solely on particle size and not their chemistry.

This document addresses potential contamination of the gas stream arising from the *gas pathways*, which is then conducted to the *patient*.

This document applies over the *expected lifetime* of the *medical device* in *normal use* and takes into account the effects of any intended *processing*.

This document does not address biological evaluation of the particles that are deliberately released by a nebulizer (i.e. the therapeutic agent).

This document does not address biological evaluation of the surfaces of *gas pathways* that have direct contact with the *patient*. The requirements for direct contact surfaces are found in the ISO 10993 series.

Medical devices, parts or *accessories*, containing *gas pathways* that are addressed by this document, include, but are not limited to, ventilators, anaesthesia workstations (including gas mixers), breathing systems, oxygen conserving devices, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, medical respiratory personal protective equipment, mouth pieces, resuscitators, breathing tubes, breathing systems filters, Y-pieces, and any breathing *accessories* intended to be used with such devices. The enclosed chamber of an incubator, including the mattress, and the inner surface of an oxygen hood are considered to be *gas pathways* and are also addressed by this document.

This document does not address contamination already present in the gas supplied from the gas sources while *medical devices* are in *normal use*.

EXAMPLE Contamination arriving at the *medical device* from gas sources such as *medical gas pipeline systems* (including the non-return valves in the pipeline outlets), outlets of pressure regulators connected or integral to a medical gas cylinder or room air taken into the *medical device* is not addressed by ISO 18562 (all parts).

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 18562-1:~~2024~~:¹, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18562-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— IEC Electropedia: available at <https://www.electropedia.org/>

— ISO Online browsing platform: available at <https://www.iso.org/obp>

NOTE For convenience, an alphabetized index of terms and their sources used in this document is found in [Annex D](#).

3.1

diameter

aerodynamic diameter

diameter of a sphere of density 1 g/cm³ with the same terminal velocity due to gravitational force in calm air as the particle of interest, regardless of its geometric size, shape and true density, under the prevailing conditions of temperature, pressure and relative humidity

[SOURCE: ISO 7708:1995, 2.2, modified — added “of interest, regardless of its geometric size, shape and true density”]

4 General principles

All *gas pathways of medical devices or accessories* shall be evaluated using the strategy detailed in ISO 18562-1.

5 Particulate matter emissions

NOTE There is guidance or rationale for this Clause contained in [Clause A.2](#).

5.1 General

a) During its *expected lifetime*, a *medical device*, part or *accessory* shall not add to the gas that could be inspired by the *patient* levels of *particulate matter*:

1) less than or equal to 2,5 µm *diameter*, in excess of 12 µg/m³;

2) less than or equal to 10 µm *diameter*, in excess of 150 µg/m³.

NOTE 1 The allowable limits are taken from the US EPA 40 § CFR Part 50^[8].

NOTE 2 These limit values are for continuous exposure to that concentration of *particulate matter*.

¹ Under preparation. Stage at the time of publication: ISO/FDIS 18562-1:2023.

- b) All *gas pathways* of *medical devices* or *accessories* shall be evaluated for *particulate matter* emissions. The evaluation shall use the *risk management process* to assess if testing is required.

NOTE 23 The evaluation of some components, which are identical in *formulation*, *processing* and preparation for use to an existing component of a *medical device* that has been previously tested, might conclude that no further testing is required. Refer to ISO 18562-1:2024, [Figure 2](#).

- c) Evaluation and, if required, testing shall take in to account:

- 1) the *expected lifetime*;
- 2) the effects of any intended manufacturing *processes*;

NOTE 3 Manufacturing *processes* include *processing* (e.g., cleaning/disinfection/sterilization during manufacturing).

- 3) the effects of transportation and storage prior to and during use; and
- 4) the effects of any intended application *processes*;

NOTE 4 Application *processes* include *processing* (e.g., cleaning/disinfection/sterilization either prior to use or between uses).

- 5) the worst-case *patient* exposure.

- d) The report shall document this evaluation as well as the criteria for selection of test articles and methodologies, including component parts to be tested and the duration of testing in relation to the intended duration of clinical use.

- e) If the *risk management process* determines that testing is required, testing shall be performed according to:

- 1) [5.5](#);

- i) For testing according to [5.5](#), use the setup according to either [5.3](#) or [5.4](#).
- ii) The *manufacturer* may choose the appropriate test method.

- 2) [5.6](#); or

- 3) [5.7](#).

Conformity is checked by examining the *report* and *risk management file*.

5.2 Testing methods overview

NOTE 1 There is guidance or rationale for this subclause contained in [Clause A.2](#).

- a) There is a great variety of components and *medical devices* within the scope of this document, and so several different methods are proposed. The most appropriate method should be selected for the particular application. A simple component such as a connector with minimal area exposed to the *patient* breathing gas stream is very unlikely to need testing for *particulate matter*, while a mechanical *medical device* with moving parts such as a ventilator could well require thorough testing.
- b) The simplest method (described in [5.3](#)) is to use a single particle filter to trap everything with a *diameter* over 0,25 μm , and consider the limit to be 12 $\mu\text{g}/\text{m}^3$ for all trapped particles. This is a quick simple test that does not differentiate particle sizes.

NOTE 2 There is guidance or rationale for this list item contained in [Clause A.2](#).

- 1) It may be sufficient for simple *medical devices*.
- 2) It is very difficult to measure very small amounts of *particulate matter* captured using a barrier filter test method since the mass of the filter is substantially more than that of the *particulate matter*. The volume of gas used in the test should therefore be large enough to capture a sufficiently large amount of *particulate matter* to be able to measure it or prove that the total mass of *particulate matter* is below the allowed amount.
- c) If testing for the different particle sizes is used, with the different limits, then a full test using inertial particle separators and filters is required. This is described in more detail in [5.6](#).
- d) A third alternative is to use a particle counter. The particle count measured by these instruments needs to be converted into an estimate of $\mu\text{g}/\text{m}^3$. A method is suggested in [5.7](#).

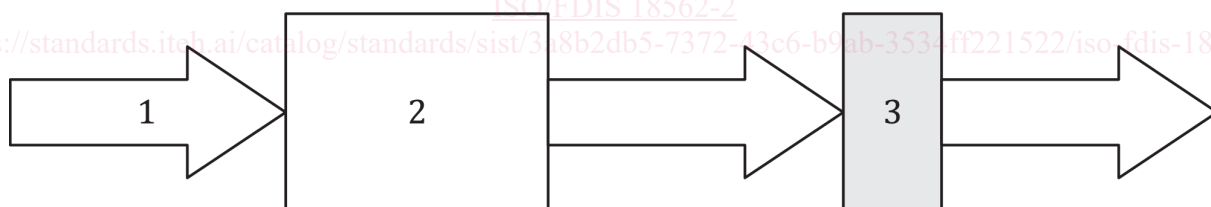
5.3 Single filter test setup

This is a simple method suitable for suspected low levels of *particulate matter*.

- a) In principle, if sufficiently clean input gas is available, then a single measurement of *particulate matter* contamination in the output gas stream is sufficient. All of the *particulate matter* measured is considered to have come from the *medical device* itself as indicated in [Figure 1](#). For a simple, low-flow *medical device*, this may be sufficient.

NOTE It is important to ensure that the filter is validated for filtration of particles in airstreams, and that it is suitable for the airflow being used.

- b) The input gas stream may be cleaned by passing all the input air through a $0,25 \mu\text{m} \pm 0,05 \mu\text{m}$ filter before the *medical device*. Then the measuring filter on the output only measures *particulate matter* that originates from the *medical device* itself.



Key

- 1 clean input airstream, filtered if necessary
- 2 one or more *medical devices* under test
- 3 $0,25 \mu\text{m} \pm 0,05 \mu\text{m}$ filter

To produce a meaningful result, more than one *medical device* may be required to be placed in series or measured sequentially.

Figure 1 — Example test setup for full flow

- c) If the *medical device* operates with a flowrate, in excess of that which reasonably dimensioned filters can handle, then a different approach may be utilized.
 - 1) For these flowrates, it is not feasible to have the full flow pass through the $0,25 \mu\text{m} \pm 0,05 \mu\text{m}$ filter, so a fractional sampling method is used as shown in [Figure 2](#).
 - 2) A subatmospheric pressure (partial vacuum) source may be used to draw the sample volume through the measurement filter.