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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 voies de gaz respiratoires dans les applications de soins de santé —

Partie 2: Essais concernant les émissions de matières particulaires

Reference number
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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 voluntary nature of ISO 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

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

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 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.

In this document, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— *test specifications: italic type*;

— TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR AS NOTED: SMALL CAPITALS TYPE.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 2:
Tests for emissions of particulate matter

1 Scope

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 0,2 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 0,2 µm in DIAMETER.

NOTE 1 Smaller and larger particles could also present biological HAZARDS, and additional information outside the scope of this document can be needed to meet requirements of 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 SERVICE LIFE of the MEDICAL DEVICE in NORMAL USE and takes into account the effects of any intended processing or reprocessing.

This document does not address biological evaluation of the surfaces of GAS PATHWAYS that are in 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, 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).

NOTE 2 This document has been prepared to address the relevant essential principles of safety and performance as indicated in Annex B.

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 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 18562-1:2017, *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 7396-1, ISO 14971, ISO 18562-1 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

NOTE For convenience, an alphabetized index of all defined terms and their sources used in this document is given in Annex C.

3.1
DIAMETER
AERODYNAMIC DIAMETER
diameter of a sphere of density 1 g/cm^3 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

4.1 TYPE TESTS

The tests described in this document are TYPE TESTS. TYPE TESTS are performed on the final MEDICAL DEVICE, a component of the MEDICAL DEVICE or a representative sample of the MEDICAL DEVICE, part or ACCESSORY being evaluated. If representative samples are used (i.e. manufactured and processed by equivalent methods), consideration should be given to whether or not the differences between the representative sample and the final MEDICAL DEVICE or component could affect the results of the test. Testing of representative samples (manufactured and processed by equivalent methods) instead of the final MEDICAL DEVICE should be supported by a description of any differences between the representative sample and the final MEDICAL DEVICE, and a detailed rationale for why each difference is not expected to impact the BIOCOMPATIBILITY of the final MEDICAL DEVICE.

NOTE Some AUTHORITIES HAVING JURISDICTION evaluate these differences and rationales.

4.2 General

All GAS PATHWAYS from which the PATIENT inspires gas shall be evaluated using the strategy detailed in ISO 18562-1.

5 * PARTICULATE MATTER emissions

5.1 General

A MEDICAL DEVICE, part or ACCESSORY shall not add to the gas that could be inspired by the PATIENT levels of PARTICULATE MATTER:

— less than or equal to 2,5 µm DIAMETER, in excess of 12 µg/m^3;

— less than or equal to 10 µm DIAMETER, in excess of 150 µg/m^3.

NOTE 1 The allowable limits are taken from the US EPA 40 § CFR Part 50[5].

All GAS PATHWAYS from which the PATIENT inspires gas shall be evaluated for PARTICULATE MATTER emissions. The evaluation should use the RISK MANAGEMENT PROCESS to assess if testing is required.

NOTE 2 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 18562-1:2017, Figure 2.

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

— the EXPECTED SERVICE LIFE;

— the effects of any intended processing or reprocessing;

— the worst-case PATIENT exposure.

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

NOTE 3 Some AUTHORITIES HAVING JURISDICTION evaluate these rationales.

If the RISK MANAGEMENT PROCESS determines that testing is required, the testing according to 5.5, 5.6, or 5.7 shall be performed. For testing according to 5.5, use the setup according to either 5.3 or 5.4. The MANUFACTURER may choose the appropriate test method.

Compliance is checked by RISK MANAGEMENT plan and RISK MANAGEMENT FILE.

5.2 Testing methods overview

There is a great variety of components and MEDICAL DEVICES within the scope of this document, and so several different methods are proposed. The MANUFACTURER should select the most appropriate method for their 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.

The simplest method (described in 5.3) is to use a single particle filter to trap everything with a DIAMETER over 0,2 µm, and consider the limit to be 12 µg/m^3 for all trapped particles. This is a quick simple test that does not differentiate particle sizes. It may be sufficient for simple MEDICAL DEVICES. 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.

If the MANUFACTURER wishes to test for the different particle sizes, with the different limits as detailed from the US EPA 40 § CFR Part 50[5], then a full test using inertial particle separators and filters

following the general principles described in 40 § CFR Part 50 is required. This is described in more detail in 5.6.

A third alternative is to use a particle counter. The particle count measured by these instruments needs to be converted into an estimate of $\mu g/m^3$. A method is suggested in 5.7.

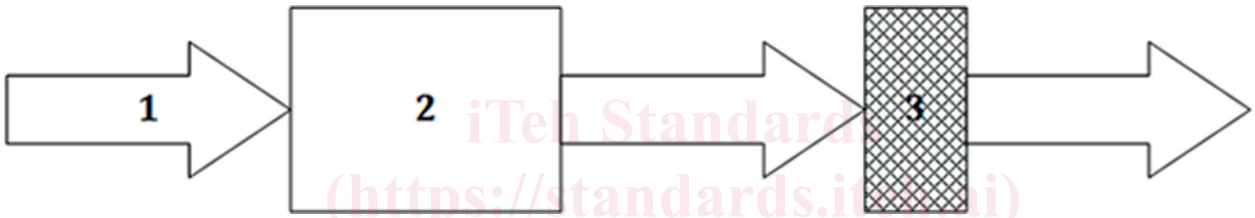
5.3 Single filter test setup

This is a simple method suitable for suspected low levels of PARTICULATE MATTER.

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.

The input gas stream may be cleaned by passing all the input air through a 0,2 µm 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 0,2 µm 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

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. For these flowrates, it is not feasible to have the full flow pass through the 0,2 µm filter, so a fractional sampling method is used as indicated in Figure 2. A subatmospheric pressure (partial vacuum) source may be used to draw the sample volume through the measurement filter.