SLOVENSKI STANDARD
oSIST prEN ISO 24072:2022

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Preskusna metoda za zadrževanje bakterij v aerosolu pri napravah za vnos zraka (ISO/DIS 24072:2021)

Aerosol bacterial retention test method for air-inlet on administration devices (ISO/DIS 24072:2021)

Prüfverfahren für die Aerosol-Bakterienrückhaltung beim Lufteinlass an Verabreichungsgeräten (ISO/DIS 24072:2021)

Méthode d'essai de rétention bactérienne dans les aérosols pour l'admission d'air sur les dispositifs d'administration (ISO/DIS 24072:2021)

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Foreword

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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

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

Several methods are used to assess the retention ability of filter membranes, including the liquid bacterial retention test, the aerosol bacterial retention test and the aerosol virus retention test (e.g. ASTM-F-1671-07 for viral retention for membranes, ASTM-F-2101-19 for bacterial retention of membranes). Though the aerosol bacterial retention test is not as rigorous as the liquid bacterial retention test, it can represent the clinical application of air-inlet filters.

This document proposes a method to assess aerosol bacterial retention efficiency / capability of air-inlet filters for medical infusion and transfusion equipment through their simulation in clinical practice. *Staphylococcus aureus* is used as the challenging bacterial strain and test parameters are set more strictly than in typical clinical practice. The test follows general requirements on bacterial retention ability of air-inlet filters for medical infusion and transfusion sets.

Since the aerosol bacterial retention test is a destructive test and more complicate that other methods, generally it is not applicable to regular quality control, and it has higher requirements for test conditions and personnel operation.

Aerosol bacterial retention test method for air-inlet on administration devices

1 Scope

This document specifies a test method which is applicable for the assessment on bacterial retention ability of finished air-inlet filters for infusion and transfusion sets.

Assessment on bacterial retention ability of air filtration membrane materials for infusion and transfusion sets may refer to this document.

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.

There are no normative references in this document.

3 Terms and definitions

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

No terms and definitions are listed in this document.

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

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

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

3.1
aerosol
suspension of solid or liquid particles in a gas

3.2
bacterial retention ability
effectiveness of an air filter to prevent the ingress of microorganisms into the container into which the device is to be inserted

3.3
collecting fluid
fluid contained in the liquid impact sampler which is used to collect the challenging bacteria for subsequent bacteria counting analysis

4 Test system

4.1 Overview

The test system utilizes a test device as shown in Figure 1, a bacterial challenging suspension and a collecting fluid. The test device includes multiple pipelines for sample testing and at least one for a positive control.

The bacterial challenging suspension of specified concentration (as determined during system validation according Clause 7) is used to generate bacterial aerosol under the function of aerosol generator, which is then sprayed to the aerosol chamber. The vacuum suction system enables air-inlet filters for test in sample challenging sets to go through challenge of bacterial aerosol at a specified flow. Bacteria passing through the samples are collected with the aids of liquid impact sampler filled with collecting fluid. Then, bacteria counting analysis is conducted over the collecting fluid, so as to assess the aerosol bacterial retention ability of air-inlet filters for test.

4.2 Aerosol generator

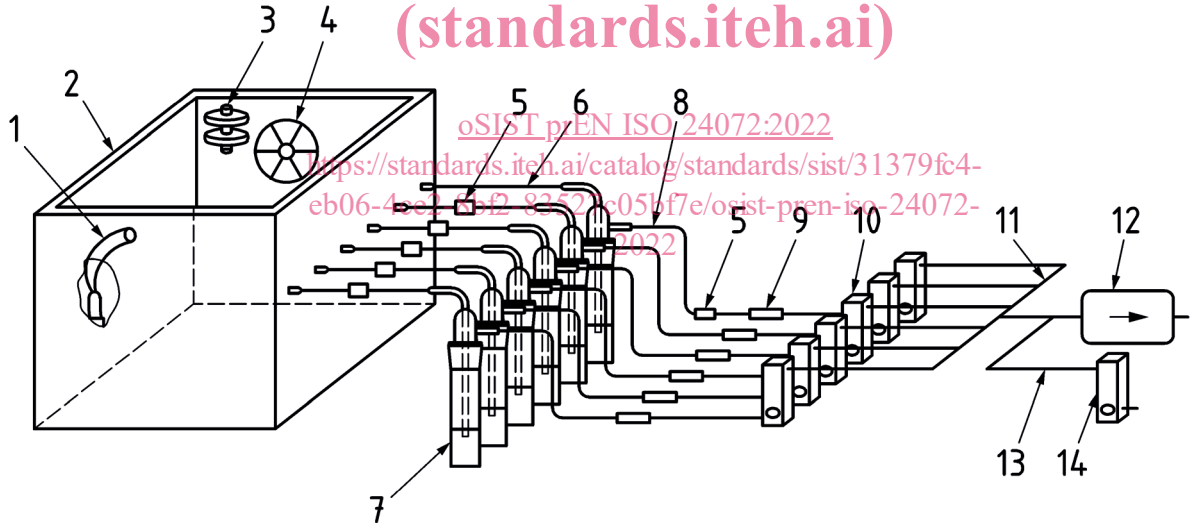
The bacterial challenging suspension is aerosolized to produce aerosol particles with a mass medium diameter of (2,5 to 3,3) µm.

4.3 Aerosol chamber

The aerosol chamber and the included fan shall allow uniform dispersing of the aerosol. A possible design is shown in Figure 1. It should be designed with transparent materials so as to observe aerosol formation and must withstand disinfection treatment. The aerosol chamber is also set with an air vent equipped with air-inlet filters for balancing indoor pressure, as well as a fan for uniformly dispersing aerosol.

4.4 Sample challenging sets

Sample challenging sets (as shown in Figures 2 and 3) are used to load air filters for test so that air filters stand challenge from one side in exposure to the intended use environment to the other side.



Key

1 microbial aerosol generator
2 aerosol chamber
3 air vent equipped with air-inlet filters
4 fan
5 sample challenging sets (see Figures 2 and 3)
6 positive control line
7 liquid impact sampler (see Figure 4)
8 suction route
9 terminal filter
10 float flowmeter with regulating valve (to regulate and indicate flow of all pipelines)
11 six pipelines
12 vacuum pump
13 gas balance pipeline
14 float flowmeter with regulating valve (to regulate total flow)

Figure 1 — Example for test device (schematic)