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YY/T 0866-2024

Total inward leakage (TIL) determination method of protective face masks for medical use

医用防护口罩总泄漏率测试方法

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1 Scope

YY/T 0866 is the test method for total inward leakage of medical protective face masks, the measurement that captures what filtration efficiency alone misses. A respirator that filters well but seals badly protects nobody, because air takes the path of least resistance around the edge rather than through the medium, and total inward leakage is measured on human subjects performing prescribed movements rather than on a bench. It is the method behind the fit performance of the GB 19083 class of medical protective masks. For a manufacturer or an exporter of medical respirators serving the Chinese market, this is the standard the leakage testing follows, and the reference a purchaser can cite when comparing products whose filtration claims look identical.

This document describes the test method for total inward leakage of protective face mask for medical use. This document applies to the total inward leakage test and evaluation of protective face mask for medical use (hereinafter referred to as the mask). The leakage test and evaluation of other biological protective devices for medical use may take this document as a reference.

2 Normative References

This document does not have normative references.

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3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 total inward leakage; TIL Under specified laboratory testing conditions, the ratio of the concentration of simulant leaking into the mask from all parts, including the filter material, during the subjects' inhalation to the concentration of simulant in the test environment. [Source: GB/T 12903-2008, 5.3.7, modified]

4 Test System

4.1 Aerosol Sealed Cabin The design of the aerosol sealed cabin shall meet the following requirements.

a) The cabin size shall ensure that the subjects do not feel constrained while completing all required movements during the test.

b) Aerosol particles shall be continuously transported into the cabin and discharged after filtration. Aerosol particles shall be evenly distributed within the cabin, and the aerosol concentration shall not vary by more than 10% throughout the test.

c) On the premise of ensuring the aerosol concentration in the cabin, when the subjects are standing on the treadmill platform in the center of the cabin, the wind speed at a distance of up to 30 cm above the subjects' head shall be less than

0.2 m/s (without lateral airflow interference).

d) The interior of the cabin shall be visible, allowing test personnel to observe the test progress.

e) Communication facilities shall be provided to ensure unimpeded communication between test personnel outside the cabin and the subjects inside.

f) When testing requires lateral airflow, airflow shall be directed toward the subjects from three directions. in front, behind, and to the side (left or right), with a wind speed of approximately 2 m/s at the subjects' head.

4.2 Treadmill It shall be equipped with an emergency brake function and capable of operating at the specified test speed.

4.3 Sodium Chloride Aerosol Generator

4.3.1 Spray liquid The spray liquid is a sodium chloride solution of a certain concentration, generally 2%. The sodium chloride solution is prepared by dissolving reagent-grade sodium chloride in distilled water.

4.3.2 Compressed air supply system The compressed air supply system is used to provide

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spraying and drying airflows. The compressed air undergoes necessary purification and drying treatment and has sufficient pressure, flow rate and cleanliness. The operating pressure of the aerosol generator is generally approximately

0.7 MPa.

4.3.3 Aerosol generator See Figure 1 for the schematic diagrams of the structure of the aerosol generator. The aerosol is transported to the sealed cabin via a pipeline. The diameter and length of the transportation pipeline shall be large enough to ensure sufficient drying of the aerosol particles, and the radius of the bending parts in the pipeline shall be large enough to reduce particle loss. The air humidity in the sealed cabin shall not exceed 60%. If necessary, the air may be heated or de-humidified. The spray flow rate and pressure of the aerosol generator shall be able to ensure an average mass concentration of sodium chloride aerosol particles within the aerosol sealed cabin of (8 4) mg/m3, with a concentration variation of no more than 10% during the test. The aerodynamic mass median diameter of the sodium chloride aerosol particles shall be between 0.4 m ~ 0.7 m, with a geometric standard deviation of less than 2.0. NOTE. an impactor sampler or particle size spectrometer shall be used to test the aerodynamic diameter of aerosol particles within the cabin.

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4.4 Sampling Device

4.4.1 Sampling probe The sampling probe is used to collect aerosol particles within the mask and can be safely fixed to the mask in a sealed manner. The sampling probe material shall be selected to make the probe lightweight. The connecting pipeline between the sampling probe and the testing device shall be flexible, with an inner diameter of 3 mm ~ 4 mm, and the length should not be too long. In addition, the type and length of the sampling pipeline within the cabin shall be the same as those within the mask. When sampling within a mask, in order to reduce sampling bias, a multi-hole sampling probe is preferred (see Figure 2 and Figure 3). If a single-hole sampling probe is selected, design the entrance of the sampling hole as an inclined plane beveled structure (see Figure 4). The sampling probe shall be installed inside the mask close to the subjects' face (< 10 mm), ideally between the mouth and nose (see Figure 5). If necessary, provide support for the sampling probe to avoid deformation of the mask material in the installation area, which may affect the mask's fitness, thereby increasing the total inward leakage. The sampling probe used to collect particles inside the cabin shall be close to the sampling probe inside the mask but avoid being affected by the exhaled gas from the mask.

4.4.2 Sampling flow rate The sampling flow rate generally ranges from

0.1 L/min ~ 2 L/min, depending on the sampling flow rate of the testing device. Set a low sampling flow rate to avoid interference with the protective effect of the mask when worn. The sampling airflow includes a dry airflow, which is used to reduce particle loss due to

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condensation of sodium chloride particles. This airflow is particularly important for mask products that can generate negative pressure during use. The dry airflow rate is 1 L/min. When the dry airflow is used to dilute the collected particles, the result calculation shall be correspondingly corrected.

4.5.1 Sodium flame photometer

4.5.1.1 Basic principle The sodium flame photometer is a testing device that quantifies the concentration of sodium chloride aerosol particles by testing the intensity of the characteristic combustion spectrum of the element sodium. This method can specifically test sodium chloride particles and is independent of particle size.

4.5.1.2 Parameter requirements The sodium flame photometer must be specifically designed for the testing and analysis of sodium chloride aerosol particles and meet the following requirements.

a) The testing range of sodium chloride aerosol particle concentration shall cover 10 ng/m3 ~ 15 mg/m3;

b) The total sampling flow rate of the photometer shall not exceed 3 L/min;

c) The photometer detector, excluding the sampling module, shall have a full-scale deflection of 10% ~ 90%, and a response time of no more than 500 ms.

4.5.2 Light scattering photometer

4.5.2.1 Basic principle A light scattering photometer is a testing device that irradiates a beam of light onto a particle flow and quantifies aerosol particle concentration by measuring the intensity of the scattered light. This method cannot distinguish between sodium chloride particles and non-sodium chloride particles and has limited detection capabilities for submicron and nanometer-sized particles.

4.5.2.2 Parameter requirements The light scattering photometer shall meet the following requirements.

a) The testing range of sodium chloride aerosol particle concentration shall cover

0.001 mg/m3 ~ 15 mg/m3;

b) The total sampling flow rate of the photometer shall not exceed 4 L/min;

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