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Cleanrooms and associated controlled environments —

Part 3: Test methods

*Salles propres et environnements maîtrisés apparentés —
Partie 3: Méthodes d'essai*

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Foreword

序

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有关标准自愿性质的解释、与合格评定相关的国际标准化组织具体术语和表述的含义,以及国际标准化组织在《技术性贸易壁垒》中遵守世界贸易组织(世贸组织)原则的信息,请参见。[org/iso/foreword.html](http://www.iso.org/iso/foreword.html)。

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测试方法

1 Scope

1 范围

This document provides test methods in support of the operation for cleanrooms and clean zones to meet air cleanliness classification, other cleanliness attributes and related controlled conditions.

本文件提供支持洁净室和洁净区操作的测试方法，以满足空气洁净度分类、其他洁净度属性和相关受控条件。

Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional airflow and those with non-unidirectional airflow, in three possible occupancy states: as-built, at-rest and operational.

性能测试规定了两种类型的洁净室和洁净区:单向气流和非单向气流，处于三种可能的占用状态:竣工状态、静止状态和运行状态。

The test methods, recommended test apparatus and test procedures for determining performance parameters are provided. Where the test method is affected by the type of cleanroom or clean zone, alternative procedures are suggested.

提供了用于确定性能参数的测试方法、推荐的测试设备和测试程序。如果试验方法受到洁净室或洁净区类型的影响，建议采用替代程序。

For some of the tests, several different methods and apparatus are recommended to accommodate different end-use considerations. Alternative methods not included in this document can be used by agreement between customer and supplier. Alternative methods do not necessarily provide equivalent measurements.

对于某些测试，建议采用几种不同的方法和设备来适应不同的最终用途。本文件中未包括的替代方法可通过客户和供应商之间的协议使用。替代方法不一定提供等效的测量。

This document is not applicable to the measurement of products or of processes in cleanrooms, clean zones or separative devices.

本文件不适用于洁净室、洁净区或分离装置中产品或工艺的测量。

NOTE This document does not purport to address safety considerations associated with its use (for example, when using hazardous materials, operations and equipment). It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

注意:本文件无意解决与其使用相关的安全问题(例如，当使用危险材料、操作和设备时)。本文档的用户有责任建立适当的安全和健康实践，并在使用前确定法规限制的适用性。

2 Normative references

2 规范性参考

There are no normative references in this document.

本文件中没有规范性参考。

3 术语和定义

就本文件而言，适用以下术语和定义。

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

——国际电工委员会电子媒体:在 <http://www.electropedia.org/>提供

3.1 General terms

3.1 一般条款

3.1.1

3.1.1

cleanroom

洁净室

room within which the number concentration of airborne particles (3.2.1) is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

控制和分类空气中颗粒数量浓度(3.2.1)的房间，其设计、建造和运行方式控制室内颗粒的引入、产生和保留

Note 1 to entry: The class of airborne particle concentration (3.2.4) is specified.

条目注释 1:规定了空气中颗粒浓度的等级(3.2.4)。

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Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

条目注释 2:也可以指定和控制其他清洁度属性的水平，如空气中的化学、活性或纳米级浓度，以及颗粒、纳米级、化学和活性浓度方面的表面清洁度。

Note 3 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

条目注 3:其他相关物理参数也可根据需要进行控制，如温度、湿度、压力、振动和静电。

[SOURCE: ISO 14644-1:2015, 3.1.1]

资料来源:国际标准化组织 14644-1:2015, 3.1.1]

3.1.2

3.1.2

clean zone

清洁区

defined space within which the number concentration of airborne particles (3.2.1) is controlled and classified, and which is constructed and operated in a manner to control the introduction, generation and retention of contaminants inside the space

定义的空间，在该空间内空气传播颗粒(3.2.1)的数量浓度得到控制和分类，其构造和运行方式控制空间内污染物的引入、产生和保留

Note 1 to entry: The class of airborne particle concentration (3.2.4) is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

Note 3 to entry: A clean zone(s) can be a defined space within a cleanroom (3.1.1) or might be achieved by a separative device. Such a device can be located inside or outside a cleanroom.

Note 4 to entry: Other relevant physical parameters might also be controlled as required, e.g. temperature, humidity, pressure, vibration and electrostatic.

equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume

利用结构和动态手段在规定体积的内部和外部之间建立有保证的分离水平的设备

Note 1 to entry: Some industry-specific examples of separative devices are clean air hoods, containment enclosures, glove boxes, isolators and mini-environments.

条目注释 1:一些特定行业的分离装置的例子有清洁空气罩、安全壳、手套箱、隔离器和小型环境。

[SOURCE: ISO 14644-7:2004, 3.17]

资料来源:国际标准化组织 14644-7:2004, 3.17]

3.1.5

3.1.5

resolution

解决

smallest change in a quantity being measured that causes a perceptible change in the corresponding indication

被测量的最小变化，导致相应指示的可察觉变化

Note 1 to entry: Resolution can depend on, for example, noise (internal or external) or friction. It may also depend on the value of a quantity being measured.

条目注释 1:分辨率取决于例如噪声(内部或外部)或摩擦。它也可能取决于被测量的量的值。

[SOURCE: ISO 14644-1:2015, 3.4.1]

资料来源:国际标准化组织 14644-1:2015, 3.4.1]

3.1.6

3.1.6

sensitivity

敏感

quotient of the change in an indication of a measuring system and the corresponding change in a value of the quantity being measured

测量系统指示的变化与被测量的相应变化的商

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3.2 Terms related to airborne particles

3.2 与空气中颗粒相关的术语

3.2.1

3.2.1

airborne particle

空气粒子

solid or liquid object suspended in air, viable or non-viable, sized between 1 nm and 100 m

悬浮在空气中的固体或液体物体，有活力或无活力，尺寸在 1 纳米至 100 米之间

Note 1 to entry: For classification purposes, refer to ISO 14644-1:2015, 3.2.1.

条目注释 1:出于分类目的，请参考国际标准化组织 14644-1:2015，3.2.1。

3.2.2

3.2.2

count median particle diameter

计数中值粒径

median particle diameter based on the number of particles

基于颗粒数量的中值颗粒直径

条目注释 1:对于计数中值,一半的粒子数由小于计数中值大小的粒子贡献,一半由大于计数中值大小的粒子贡献。

3.2.3

质量中值粒径

基于颗粒质量的中值颗粒直径

条目注释 1:对于质量中值,所有颗粒的一半质量由小于质量中值尺寸的颗粒贡献,一半质量由大于质量中值尺寸的颗粒贡献。

3.2.4

粒子浓度

每单位体积空气中单个颗粒的数量

资料来源:国际标准化组织 14644-1:2015, 3.2.3] 3.2.5

粒度

通过给定的颗粒尺寸测量仪器产生响应的球体直径，该响应相当于被测颗粒产生的响应

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Note 1 to entry: For light-scattering airborne-particle instruments, the equivalent optical diameter is used.

challenging of a filter or an installed filter system (3.3.6) by test aerosol (3.2.7)

通过测试气溶胶(3.2.7)对过滤器或已安装的过滤系统(3.3.6)提出挑战

3.3.2

3.3.2

designated leak

指定泄漏

maximum allowable penetration, which is determined by agreement between customer and supplier, through a leak (3.3.8), detectable during scanning (3.3.9) of a filter installation (3.1.3) with light-scattering airborne particle counters (LSAPC) or aerosol photometers (3.6.2)

通过泄漏(3.3.8)由客户和供应商之间的协议确定的最大允许渗透, 可在使用光散射空气微粒计数器 (LSAPC)或气溶胶光度计(3.6.2)扫描(3.3.9)过滤器装置(3.1.3)期间检测到

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3.3.3

3.3.3

dilution system

稀释系统

system wherein aerosol is mixed with particle-free dilution air in a known volumetric ratio to reduce concentration

气溶胶与无颗粒稀释空气以已知的体积比混合以降低浓度的系统

3.3.4

3.3.4

filter system

过滤系统

assembly composed of filter, frame and other support mechanism or other housing

由过滤器、框架和其他支撑机构或其他外壳组成的组件

3.3.5

3.3.5

final filter

终滤器

filter in a final position before the air enters the cleanroom (3.1.1) or clean zone (3.1.2)

在空气进入洁净室(3.1.1)或洁净区(3.1.2)之前，在最终位置进行过滤

3.3.6

3.3.6

installed filter system

安装的过滤系统

filter system (3.3.4) mounted in the ceiling, wall, apparatus or duct

安装在天花板、墙壁、设备或管道中的过滤系统(3.3.4)

3.3.7

3.3.7

installed filter system leakage test

安装的过滤系统泄漏测试

test performed to confirm that the filters are properly installed by verifying that there is absence of bypass leakage of the filter installation (3.1.3), and that the filters and the grid system are free of defects and leaks (3.3.8)

通过验证过滤器安装无旁路泄漏(3.1.3)以及过滤器和电网系统无缺陷和泄漏(3.3.8)，进行测试以确认过滤器安装正确

3.3.8 leak

3.3.8 泄漏

<of air filter system> penetration of contaminants that exceed an expected value of downstream concentration through lack of integrity or defects

<空气过滤系统>由于缺乏完整性或缺陷，污染物渗透超过下游浓度的期望值

3.3.9

3.3.9

scanning

扫描

method for disclosing leaks (3.3.8) in filters and parts of units, whereby the probe inlet of an aerosol photometer (3.6.2) or a light-scattering airborne-particle counter is moved in overlapping strokes across the defined test area

公开过滤器和部件泄漏(3.3.8)的方法，其中气溶胶光度计(3.6.2)或光散射空气粒子计数器的探针入口在规定的测试区域内以重叠的行程移动

3.4 Terms related to airflow and other physical states

3.4 与气流和其他物理状态相关的术语

3.4.1

3.4.1

air change rate air exchange rate

空气交换率

rate expressing number of air changes per unit of time and calculated by dividing the volume of air delivered in the unit of time by the volume of the cleanroom (3.1.1) or clean zone (3.1.2)

表示单位时间内空气变化次数的速率，通过用单位时间内输送的空气量除以洁净室(3.1.1)或洁净区(3.1.2)的体积来计算

3.4.2

3.4.2

measuring plane

测量平面

cross-sectional area for testing or measuring a performance parameter such as the airflow velocity

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3.4.5

3.4.5

total air volume flow rate

总空气体积流量

air volume per unit of time that passes through a section of a cleanroom (3.1.1) or clean zone (3.1.2)

每单位时间通过洁净室(3.1.1)或洁净区(3.1.2)的空气量

3.4.6

3.4.6

unidirectional airflow

单向气流

controlled airflow through the entire cross-section of a cleanroom (3.1.1) or a clean zone (3.1.2) with a steady velocity and airstreams that are considered to be parallel

通过洁净室(3.1.1)或洁净区(3.1.2)的整个横截面的受控气流，具有稳定的速度和被认为平行的气流

[SOURCE: ISO 14644-1:2015, 3.2.7]

资料来源:国际标准化组织 14644-1:2015, 3.2.7]

3.4.7

3.4.7

uniformity of velocity

速度均匀性

unidirectional airflow (3.4.6) pattern in which the point-to-point readings of velocity (speed and direction of airflow) are within a defined percentage of the average airflow velocity

单向气流(3.4.6)模式，其中点对点速度读数(气流速度和方向)在平均气流速度的规定百分比内

3.5 Terms related to electrostatic measurement

3.5 静电测量相关术语

3.5.1

3.5.1

discharge time

放电时间

time required to reduce the voltage to the level, positive or negative, to which an isolated conductive monitoring plate was originally charged

将电压降低到隔离导电监控板最初充电的正或负电平所需的时间

3.5.2

3.5.2

offset voltage

补偿电压

voltage that accumulates on an initially uncharged isolated conductive plate when that plate is exposed to an ionized air environment

当板暴露在电离空气环境中时，最初未充电的隔离导电板上累积的电压

3.5.3

3.5.3

static-dissipative property

静电耗散特性

capability for reducing electrostatic charge on work or product surface, as a result of conduction or other mechanism to a specific value or nominal zero charge level

由于传导或其他机制，将工件或产品表面的静电荷降低到特定值或标称零电荷水平的能力

3.5.4

3.5.4

surface voltage level

表面电压水平

positive or negative voltage level of electrostatic charging on work or product surface, as indicated by use of suitable apparatus

工作或产品表面静电充电的正或负电压水平，如使用合适的设备所示

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3.6.4 LSAPC

3.6.4 LSAPC

light scattering airborne particle counter

光散射空气粒子计数器

apparatus capable of counting and sizing single airborne particles (3.2.1) and reporting size data in terms of equivalent optical diameter

能够计数和测量单个空气传播颗粒(3.2.1)并根据等效光学直径报告尺寸数据的设备

Note 1 to entry: The specifications for a particle counter are given in ISO 21501-4.

条目注释 1:颗粒计数器的规格在国际标准化组织 21501-4 中给出。

[SOURCE: ISO 14644-1:2015, 3.5.1, modified — The term "light scattering discrete airborne particle counter" has been removed.Note 1 to entry has been reworded.]

[资料来源:国际标准化组织 14644-1:2015, 3.5.1, 已修改-术语“光散射离散机载粒子计数器”已被删除。条目注 1 已改写。]

3.6.5

3.6.5

witness plate

见证板

material of defined surface area used in lieu of direct evaluation of a specific surface that is either inaccessible or too sensitive to be handled

定义表面积的材料,用于代替无法接近或太敏感而无法处理的特定表面的直接评估

3.7 Terms related to occupancy states

3.7 与入住状态相关的条款

3.7.1

3.7.1

as-built

竣工

condition where the cleanroom (3.1.1) or clean zone (3.1.2) is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present

洁净室(3.1.1)或洁净区(3.1.2)已完成，所有服务均已连接并运行，但没有设备、家具、材料或人员在场

[SOURCE: ISO 14644-1:2015, 3.3.1]

资料来源:国际标准化组织 14644-1:2015, 3.3.1]

3.7.2

3.7.2

at-rest

休息时

condition where the cleanroom (3.1.1) or clean zone (3.1.2) is complete with equipment installed and operating in a manner agreed upon, but with no personnel present

洁净室(3.1.1)或洁净区(3.1.2)已按约定方式安装和运行设备，但没有人员在场的情况

[SOURCE: ISO 14644-1:2015, 3.3.2]

资料来源:国际标准化组织 14644-1:2015, 3.3.2]

3.7.3

3.7.3

operational

操作的

agreed condition where the cleanroom (3.1.1) or clean zone (3.1.2) is functioning in the specified manner, with equipment operating and with the specified number of personnel present

洁净室(3.1.1)或洁净区(3.1.2)以指定方式运行、设备运行且有指定数量人员在场的商定条件

[SOURCE: ISO 14644-1:2015, 3.3.3]

资料来源:国际标准化组织 14644-1:2015, 3.3.3]

4 Test procedures

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4.1.2 Supporting tests

4.1.2 支持测试

Table 2 lists other appropriate tests that can be used for measuring the performance of a cleanroom or clean zone installation. These tests may be applied in each of the three designated occupancy states; refer to details in Annex B for suggested applications. These tests may not be all-inclusive. Also, they may not all be required for any given project. Tests and test methods should be selected in a manner agreed between the customer and supplier. Selected tests can also be repeated on a regular basis as part of routine monitoring or periodic testing. Guidelines for the selection of tests and a checklist of tests are given in Annex A. Test methods are outlined in Annex B.

表 2 列出了可用于测量洁净室或洁净区安装性能的其他合适测试。这些测试可应用于三种指定占用状态中的每一种；有关建议的应用，请参考附件 B 中的详细信息。这些测试可能不是包罗万象的。此外，对于任何给定的项目，它们可能都不是必需的。测试和测试方法应以客户和供应商同意的方式选择。作为常规监控或定期测试的一部分，也可以定期重复选定的测试。测试选择指南和测试核对表见附件一。测试方法见附件二

NOTE The test methods described in Annex B are in outline form only. Specific methods can be developed to meet the needs of the particular application.

注:附录 B 中描述的试验方法仅是大纲形式。可以开发特定的方法来满足特定应用的需要。

| Supporting tests | Reference in ISO 14644-3 | | |
|------------------------------------------|--------------------------|-----------|-----------|
| | Principle | Procedure | Apparatus |
| Air pressure difference test | 4.2.1 | B.1 | C.2 |
| Airflow test | 4.2.2 | B.2 | C.3 |
| Airflow direction test and visualization | 4.2.3 | B.3 | C.4 |

| | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|------|------|
| Recovery test | 4.2.4 | B.4 | C.5 |
| Temperature test | 4.2.5 | B.5 | C.6 |
| Humidity test | 4.2.6 | B.6 | C.7 |
| Installed filter system leakage test | 4.2.7 | B.7 | C.8 |
| Containment leak test | 4.2.8 | B.8 | C.9 |
| Electrostatic and ion generator tests | 4.2.9 | B.9 | C.10 |
| Particle deposition test ^a | 4.2.10 | B.10 | C.11 |
| Segregation test | 4.2.11 | B.11 | C.12 |
| <p>NOTE These supporting tests are not presented in order of importance or chronological order. The order in which tests are performed can be based on the requirements of a specific document or after agreement between the customer and supplier.</p> <p>a The particle deposition test can also be considered a test for cleanroom performance in the operational state.</p> | | | |

| | | | |
|--------------|----------------------|-----|-----|
| 支持测试 | 国际标准化组织 14644-3 中的参考 | | |
| | 原则 | 程序 | 仪器 |
| 气压差测试 | 4.2.1 | B.1 | C.2 |
| 气流测试 | 4.2.2 | B.2 | C.3 |
| 气流方向测试和可视化 | 4.2.3 | B.3 | C.4 |
| 更新试验 | 4.2.4 | B.4 | C.5 |
| 温度试验 | 4.2.5 | B.5 | C.6 |
| 湿度测试 | 4.2.6 | B.6 | C.7 |
| 已安装的过滤系统泄漏测试 | 4.2.7 | B.7 | C.8 |
| 安全壳泄漏测试 | 4.2.8 | B.8 | C.9 |

速度的均匀性。在这些情况下，可以直接测量空气流量读数，然后用于计算洁净室或洁净区的空气变化率(每小时空气变化)。气流测试的测试程序见 B.2

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4.2.3 Airflow direction test and visualization

4.2.3 气流方向测试和可视化

The purpose of this test is to demonstrate that the airflow direction and its uniformity of velocity conform to the design and performance specifications. The airflow direction test can be conducted in the at-rest state to determine the basic cleanroom airflow patterns and can be repeated in the operational state simulating actual operations. Procedures for this test are given in B.3.

本试验的目的是证明气流方向及其速度均匀性符合设计和性能规范。气流方向测试可以在静止状态下进行，以确定基本洁净室气流模式，并且可以在模拟实际操作的操作状态下重复进行。B.3 给出了该试验的程序

4.2.4 Recovery test

4.2.4 恢复测试

The recovery test is performed to determine whether the cleanroom or clean zone is capable of returning to a specified cleanliness level within a finite time, after being exposed briefly to a source of airborne particulate challenge. This test is not recommended for unidirectional airflow. The procedure for this test is given in B.4. When an artificial aerosol is used, the risk of residue contamination of the cleanroom or clean zone should be considered.

进行恢复试验是为了确定洁净室或洁净区是否能够在短暂暴露于空气中的颗粒挑战源后，在有限的时间内恢复到规定的洁净度水平。不建议单向气流进行此测试。B.4 中给出了该试验的程序。当使用人造气溶胶时，应考虑洁净室或洁净区残留污染的风险。

4.2.5 Temperature test

4.2.5 温度测试

The purpose of this test is to verify the air temperature levels are within the control limits over the time period specified by the customer for the area being tested.Procedures for these tests are given in B.5.

该测试的目的是验证在客户为测试区域指定的时间段内，空气温度水平是否在控制范围内。B.5 给出了这些测试的程序

4.2.6 Humidity test

4.2.6 湿度测试

The purpose of this test is to verify moisture (expressed as relative humidity or dew point) levels are within the control limits over the time period specified by the customer for the area being tested.Procedures for these tests are given in B.6.

该测试的目的是验证在客户为测试区域指定的时间段内，湿度(以相对湿度或露点表示)水平在控制限值内。B.6 给出了这些试验的程序

4.2.7 Installed filter system leakage tests

4.2.7 安装的过滤系统泄漏测试

These tests are performed to confirm that the final high efficiency air filter system is properly installed by verifying the absence of bypass leakage in the air filter installation, and that the filters are free of defects (small holes and other damage in the filter medium, frame, seal and leaks in the filter bank framework).These tests are not used to determine the efficiency of the filter medium.The tests are performed by introducing an aerosol challenge upstream of the filters and scanning downstream of the filters and support frame or sampling in a downstream duct.Leak detection methods are given in B.7.

进行这些测试是为了通过验证空气过滤器安装中没有旁路泄漏，以及过滤器没有缺陷(过滤介质、框架、密封件和过滤器组框架中的小孔和其他损坏)来确认最终高效空气过滤器系统安装正确。这些测试不用于确定过滤介质的效率。通过在过滤器上游引入气溶胶挑战，并在过滤器和支撑框架下游扫描或在下游管道中取样来进行测试。B.7 给出了泄漏检测方法

4.2.8 Containment leak test

4.2.8 安全壳泄漏测试

This test is performed to determine if there is intrusion of unfiltered air into the cleanroom or clean zone(s) from outside the cleanroom or clean zone enclosure(s) through joints, seams, doorways and pressurized ceilings.The procedure for this test is given in B.8.

进行该测试是为了确定未过滤空气是否通过接缝、接缝、门口和加压天花板从洁净室或洁净区外壳外部侵入洁净室或洁净区。B.8 给出了该试验的程序

4.2.9 Electrostatic and ion generator tests

4.2.9 静电和离子发生器测试

The purpose of these tests is to evaluate electrostatic voltage levels on objects, static-dissipative properties of materials and the performance of ion generators (i.e. ionizers) used for electrostatic control in cleanrooms or clean zones. Electrostatic testing is performed to evaluate the electrostatic voltage level on work and product surfaces, and the static dissipative properties of floors, workbench tops, etc. The ion generator test is performed to evaluate the ionizer performance in eliminating static charges on surfaces. Procedures for these tests are given in B.9.

这些测试的目的是评估物体上的静电电压水平、材料的静电耗散特性以及用于洁净室或洁净区静电控制的离子发生器(即离子发生器)的性能。进行静电测试是为了评估工作和产品表面的静电电压水平, 以及地板、工作台顶部等的静电耗散特性。进行离子发生器测试是为了评估离子发生器在消除表面静电方面的性能。B.9 给出了这些试验的程序

4.2.10 Particle deposition test

4.2.10 颗粒沉积试验

The purpose of this test is to verify the quantity and size of particles deposited from the air in the cleanroom onto a surface over an agreed period of time. Procedures for this test are given in B.10.

本试验的目的是验证在一段商定的时间内，洁净室空气中沉积到表面上的颗粒数量和尺寸。B.10 给出了该试验的程序

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4.2.11 Segregation test

4.2.11 离析试验

The purpose of this test is to assess the separation effectiveness achieved by a specific airflow, challenging the lesser classified area with particles and determining the particle concentration in the protected area at the other side of the segregation. Procedures for this test are given in B.11.

本试验的目的是评估特定气流所达到的分离效果，用颗粒挑战较低的分类区域，并确定分离另一侧受保护区域的颗粒浓度。B.11 给出了该试验的程序

5 Test reports

5 份测试报告

The result of each test shall be recorded in a test report, and the test report shall include the following information:

每次试验的结果应记录在试验报告中，试验报告应包括以下信息：

a) the name and address of the testing organization, and the date on which the test was performed;

a)测试组织的名称和地址，以及进行测试的日期；

b) a reference to this document (ISO 14644-3:2019);

对本文件的引用(国际标准化组织 14644-3:2019)；

c)

c)

clear identification of the physical location of the cleanroom or clean zone tested (including reference to adjacent areas if necessary), and specific designations for coordinates of all sampling locations;

明确识别测试洁净室或洁净区的物理位置(如有必要，包括参考相邻区域)，以及所有采样位置坐标的具体名称；

d) the specified designation criteria for the cleanroom or clean zone, including the ISO classification, the relevant occupancy state(s), and the considered particle size(s);

洁净室或洁净区的指定标准，包括国际标准化组织分类、相关占用状态和考虑的颗粒尺寸；

e)

e)

f)

所用试验方法的细节，以及与试验或偏离试验方法相关的任何特殊条件，以及试验设备及其当前校准证书的标识；

测试结果，包括附件 B 相关条款中特别要求报告的数据，以及关于符合要求的指定的声明；

g)针对特定试验定义的与附件 B 条款相关的任何其他具体要求。

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国际标准化组织 14644-3:2019(英)

附件一

(informative)

(信息性)

Choice of supporting tests and checklist

支持测试和检查表的选择

A.1 General

A.1 概述

Special care should be taken when determining the sequence for carrying out tests for cleanroom, clean zone or controlled zone performance.

确定洁净室、洁净区或受控区性能测试的顺序时，应特别小心。

The selection and sequence of tests should be determined between customer and supplier and should detect noncompliance at the earliest stage possible and not compromise other tests in the sequence.

测试的选择和顺序应在客户和供应商之间确定，并应尽可能早地检测不符合项，而不损害顺序中的其他测试。

A.2 Test checklist

A.2 测试清单

Table A.1 provides a checklist of tests and apparatus.

表 a1 提供了测试和仪器清单。

| Selection of test procedure and sequencea | Test procedure | Test procedure reference | Selection of test apparatusb | Test apparatus | Apparatus reference | Comments |
|-------------------------------------------|-------------------------|--------------------------|------------------------------|----------------------------------------|---------------------|----------|
| | Air pressure difference | B.1 | | Electronic micro-manometer | C.2.2 | |
| | | | | Inclined manometer | C.2.3 | |
| | | | | Mechanical differential pressure gauge | C.2.4 | |
| | Airflow | B.2 | | | C.3 | |
| | Uniformity | B.2.2.2 | | Thermal | C.3.1.1 | |

| | | | | | | |
|--|-------------------------------------------------------------------------------------------|---------|--|--------------------------------------------------------|---------|--|
| | of velocity within the cleanroom or clean zone (for unidirectional airflow) | | | anemometer | | |
| | | | | Three-dimensional ultrasonic anemometer, or equivalent | C.3.1.2 | |
| | | | | Vane-type anemometer | C.3.1.3 | |
| | | | | Tube array | C.3.1.5 | |
| | Supply airflow velocity (for unidirectional airflow) | B.2.2.3 | | Thermal anemometer | C.3.1.1 | |
| | | | | Three-dimensional ultrasonic anemometer, or equivalent | C.3.1.2 | |
| | | | | Vane-type anemometer | C.3.1.3 | |
| | | | | Tube array | C.3.1.5 | |
| | Supply air volume flow rate measured by filter face velocity (for unidirectional airflow) | B.2.2.4 | | Thermal anemometer | C.3.1.1 | |
| | | | | Three-dimensional ultrasonic anemometer, or equivalent | C.3.1.2 | |
| | | | | Vane-type anemometer | C.3.1.3 | |
| | | | | Tube array | C.3.1.5 | |

| 测试程序和顺序的选择 a | 检查法 | 测试过程参考 | 测试设备的选择 | 试验装置 | 仪器参考 | 评论 |
|--------------|-----|--------|---------|--------|-------|----|
| | 气压差 | B.1 | | 电子微型压力 | C.2.2 | |

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Table A.1 (continued)

| Selection of test procedure and sequence ^a | Test procedure | Test procedure reference | Selection of test apparatus ^b | Test apparatus | Apparatus reference | Comments |
|-------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------------|------------------------------------------|--------------------------------------------------------|-------------------------|----------|
| | Supply air volume flow rate in air ducts (for unidirectional airflow) | B.2.2.5 | | Orifice meter | C.3.2.3 | |
| | | | | Venturi meter | C.3.2.4 | |
| | | | | Pitot-static tubes and manometer | C.3.1.4 | |
| | | | | Thermal anemometer | C.3.1.1 | |
| | Supply air volume flow rate measured at the inlet (for non-unidirectional airflow installation) | B.2.3.2 | | Airflow capture hood with measuring device | C.3.2.2 | |
| | Supply air volume flow rate calculated from filter face velocity (for non-unidirectional airflow i) | B.2.3.3 | | Thermal anemometer | C.3.1.1 | |
| | | | | Three-dimensional ultrasonic anemometer, or equivalent | C.3.1.2 | |
| | | | | Vane-type anemometer | C.3.1.3 | |
| | Supply air volume flow rate in air ducts (for non-unidirectional airflow) | B.2.3.4 | | Orifice meter | C.3.2.3 | |
| | | | | Venturi meter | C.3.2.4 | |
| | | | | Pitot-static tubes and manometer | C.3.1.4 | |
| | | | | Thermal anemometer | C.3.1.1 | |
| | Airflow direction and visualization | B.3 | | Tracers | C.4.4.1 | |
| | | | | Thermal anemometer | C.4.2 | |
| | | | | Three-dimensional ultrasonic anemometer, or equivalent | C.4.3 | |
| | | | | Aerosol generator | C.4.4 | |
| | | | | Ultrasonic nebulizer | C.4.4.2 | |
| | | | | Fog generator | C.4.4.3 | |
| | Recovery | B.4 | | Light-scattering airborne-particle counter (LSAPC) | C.5.1 | |
| | | | | Aerosol generator | C.5.2 | |
| | | | | Aerosol source substances | C.5.3 | |
| | | | | Dilution system, equipment | C.5.4 | |
| | | | | Thermometer | C.6 | |
| | Temperature | B.5 | | Expansion Thermometer | C.6 a) | |
| | | | | Electrical Thermometer | C.6 b) | |
| | | | | Thermomanometers | C.6 c) | |
| | Humidity | B.6 | | Dewpoint hygrometer | C.7 a) | |
| | | | | Electrical conductivity variation hygrometer | C.7 b) | |

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Table A.1 (continued)

| Selection of test procedure and sequence ^a | Test procedure | Test procedure reference | Selection of test apparatus ^b | Test apparatus | Apparatus reference | Comments |
|-------------------------------------------------------|----------------------------------------------------------------------|--------------------------|------------------------------------------|-----------------------------------------------------|------------------------|----------|
| | Installed filter system leakage | B.7 | | | C.8 | |
| | Installed filter system leakage scan test with an aerosol photometer | B.7.2 | | Aerosol photometer | C.8.1 | |
| | | | | Aerosol generator | C.8.3 | |
| | | | | Test aerosol source substances | C.8.4 | |
| | Installed filter system leakage scan test with a LSAPC | B.7.3 | | Light-scattering airborne- particle counter (LSAPC) | C.8.2 | |
| | | | | Aerosol generator | C.8.3 | |
| | | | | Test aerosol source substances | C.8.4 | |
| | | | | Dilution system, equipment | C.8.5 | |
| | Overall leak test of filters mounted in ducts or air-handling units | B.7.4 | | Aerosol photometer | C.8.1 | |
| | | | | Light-scattering airborne- particle counter (LSAPC) | C.8.2 | |
| | | | | Aerosol generator | C.8.3 | |
| | | | | Test aerosol source substances | C.8.4 | |
| | | | | Dilution system, equipment (LSAPC method only) | C.8.5 | |
| | Containment leak | B.8 | | | C.9 | |
| | Light-scattering airborne-particle counter (LSAPC) method | B.8.2.1 | | Light-scattering airborne-particle counter (LSAPC) | C.9.1 | |
| | | | | Aerosol generator | C.9.2 | |
| | | | | Test aerosol source substances | C.9.3 | |
| | | | | Dilution system, equipment | C.9.4 | |
| | Aerosol photometer method | B.8.2.2 | | Aerosol generator | C.9.2 | |
| | | | | Test aerosol source substances | C.9.3 | |
| | | | | Aerosol photometer | C.9.5 | |
| | Electrostatic and ion generator | B.9 | | | C.10 | |
| | Electrostatic | B.9.2.1 | | Electrostatic voltmeter | C.10.1 | |
| | | | | High resistance ohmmeter | C.10.2 | |
| | | | | Charged plate monitor | C.10.3 | |

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| Selection of test procedure and sequencea | Test procedure | Test procedure reference | Selection of test apparatusb | Test apparatus | Apparatus reference | Comments |
|-------------------------------------------|---------------------|--------------------------|------------------------------|-------------------------------------|---------------------|----------|
| | Ion generator | B.9.2.2 | | Electrostatic voltmeter | C.10.1 | |
| | | | | High resistance ohm-meter | C.10.2 | |
| | | | | Charged plate monitor | C.10.3 | |
| | Particle deposition | B.10 | | Witness plate material | C.11.1 | |
| | | | | Wafer surface scanner | C.11.2 | |
| | | | | Particle fallout aerosol photometer | C.11.3 | |

| | | | | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------|--|----------------------------------------------------|--------|--|
| | | | | | | |
| | | | | Surface particle counter | C.11.4 | |
| | | | | Particle deposition meter | C.11.5 | |
| | | | | Optical particle depo-sition monitor | C.11.6 | |
| | Segregation test | B.11 | | Light-scattering airborne-particle counter (LSAPC) | C.12.1 | |
| | | | | Aerosol generator | C.12.2 | |
| | | | | Test aerosol source substances | C.12.3 | |
| | | | | Dilution system, equipment | C.12.4 | |
| a In the boxes of column 1, test planners can number the selected test methods according to the test sequence.b In the fourth column, test planners can select test apparatus according to the test method selected. | | | | | | |

| 测试程序和顺序的选择 a | 检查法 | 测试过程参考 | 测试设备的选择 | 试验装置 | 仪器参考 | 评论 |
|--------------|-------|---------|---------|---------|--------|----|
| | 离子发生器 | B.9.2.2 | | 静电电压表 | C.10.1 | |
| | | | | 高阻欧姆表 | C.10.2 | |
| | | | | 带电平板监视器 | C.10.3 | |
| | 粒子沉积 | B.10 | | 见证板材料 | C.11.1 | |

| | | | | | | |
|----------------------------------------------------------------------------|------|------|--|-------------|--------|--|
| | | | | | | |
| | | | | 晶片表面扫描仪 | C.11.2 | |
| | | | | 粒子沉降空气溶胶光度计 | C.11.3 | |
| | | | | 表面粒子计数器 | C.11.4 | |
| | | | | 颗粒沉积仪 | C.11.5 | |
| | | | | 光学粒子沉积监视器 | C.11.6 | |
| | 分离试验 | B.11 | | 光散射空气粒子计数器 | C.12.1 | |
| | | | | 气溶胶发生器 | C.12.2 | |
| | | | | 测试气溶胶源物质 | C.12.3 | |
| | | | | 稀释系统、设备 | C.12.4 | |
| <p>在第 1 栏的方框中，测试计划人员可以根据测试顺序对选定的测试方法进行编号。在第四栏中，测试计划者可以根据选择的测试方法选择测试仪器。</p> | | | | | | |

A.3 Planning for testing and verification

A.3 测试和验证计划

As a minimum, testing should be carried out:

至少应进行测试:

- a) in connection with classification according to ISO 14644-1;
- a)根据国际标准化组织 14644-1 进行分类;
- b) at verification during start-up;
- b)启动期间的验证;
- c) at verification after failures have been identified and rectified;

- c)在确认和纠正故障后进行验证；
- d) at verification after modification;
- d)修改后的验证；
- e) during periodic testing.
- e)定期测试期间。

A risk assessment should be performed to establish the appropriate intervals for periodic testing.

应进行风险评估，以建立定期测试的适当间隔。

Monitoring data, trend and test result should be used to confirm and, if appropriate, adjust time intervals for the selected tests.

应使用监控数据、趋势和测试结果来确认并调整所选测试的时间间隔(如果合适)。

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Annex B

附件二

(informative)

(信息性)

Supporting test methods

支持测试方法

B.1 Air pressure difference test

B.1 空气压差测试

B.1.1 General

B.1.1 概述

The purpose of this test is to verify the capability of the complete installation to maintain the specified pressure difference between the cleanroom and its surroundings, and between separate cleanrooms and clean zones within the installation.[] This test is applicable in each of the three designated occupancy states, and can also be repeated on a regular basis as part of a routine facility monitoring program as described in ISO 14644-2[] .

本试验的目的是验证整个装置保持洁净室及其周围环境之间以及独立洁净室和装置内洁净区之间规定压差的能力。[]该测试适用于三种指定占用状态中的每一种，也可以作为国际标准化组织 14644-2[]中描述的常规设施监控计划的一部分定期重复进行。

B.1.2 Procedure for air pressure difference test

B.1.2 空气压差测试程序

It is recommended that the following items are confirmed before starting the measurement of differential pressure between rooms or between rooms and outside areas:

建议在开始测量房间之间或房间与外部区域之间的压差之前，确认以下项目：

— values and acceptable range of differential pressure between rooms should be defined;

—应定义房间间压差的值和可接受范围；

— supply air volume and balancing of the air handling unit supplies are within specifications;

—供气量和空气处理装置供气的平衡符合规范；

— cleanroom components that could impact the differential pressure between rooms such as doors, windows, pass through, etc.should be closed.Permanent openings should be kept open during the test;

—可能影响房间间压差的洁净室组件，如门、窗、通道等。应该关门了。测试期间，永久性开口应保持打开状态；

— the air handling system has been operated and the conditions have been stabilized;

—空气处理系统已经运行，条件已经稳定；

— extraction systems should be operating as agreed and specified.

—提取系统应按照约定和规定运行。

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B.1.4 Test reports

B.1.4 测试报告

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

根据客户和供应商之间的协议，应按照第 5 条所述记录以下信息和数据：

- a) type of tests and measurements, and measuring conditions;
- a)测试和测量的类型以及测量条件；
- b) type designations of each measuring apparatus and apparatus used and its calibration status;
- b)使用的每个测量仪器和仪器的型号名称及其校准状态；
- c) cleanliness classes of the rooms considered;
- c)所考虑房间的清洁等级；
- d) measuring point locations, when required the reference point location;
- d)测量点位置，必要时测量参考点位置；
- e) occupancy state(s).
- e)占用状态。

B.2 Airflow test

B.2 气流测试

B.2.1 General

B.2.1 概述

The purpose of these tests is to measure airflow velocity and uniformity, and supply air volume flow rate in cleanrooms and clean zones. Measurement of velocity distribution is necessary in unidirectional airflow cleanrooms and clean zones, and supply air volume flow rate in non-unidirectional cleanrooms. Measurement of supply air volume flow rate is carried out to ascertain the air volume supplied to the cleanroom or clean zone per unit of time. The supply air volume flow rate is measured either downstream of final filters or in air supply ducts; both methods rely upon measurement of velocity of air passing through a known area, the air volume flow rate being the product of velocity and area. The choice of procedure should be agreed between customer and supplier.

这些测试的目的是测量气流速度和均匀性，并在洁净室和洁净区提供空气体积流量。单向气流洁净室和洁净区需要测量速度分布，非单向洁净室需要提供空气体积流量。进行供应空气体积流量的测量，以确定每单位时间供应到洁净室或洁净区的空气体积。供气量流速在最终过滤器下游或供气管道中测量；这两种方法都依赖于对通过已知区域的空气速度的测量，空气体积流速是速度和面积的乘积。程序的选择应由客户和供应商商定。

When measuring airflow velocity, the following conditions should be considered carefully:

测量气流速度时，应仔细考虑以下条件：

- a) probe direction should be chosen appropriately under the consideration on the airflow velocity;
- a)应在考虑气流速度的情况下适当选择探头方向；
- b) measurement should be conducted during sufficient time for repeatable readings and the average velocity or air volume flow rate should be recorded.
- b)应在足够长的时间内进行测量，以获得可重复的读数，并记录平均速度或空气体积流量。

B.2.2 Procedure for unidirectional airflow testing

B.2.2 单向气流测试程序

B.2.2.1 General

B.2.2.1 概述

The velocity of the unidirectional flow determines the performance of a unidirectional cleanroom. The velocity can be measured close to the face of the terminal supply filters, or within the room. This is done by defining the measuring plane perpendicular to the supply airflow and dividing it into measuring points (grid cells) of equal area. B.2.2.2 Supply airflow velocity

The airflow velocity should be measured at approximately 150 mm to 300 mm from the filter face or entry plane.

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测量点(网格单元)的数量在很大程度上取决于用于进行测量的仪器、房间基础设施的配置、位置或工艺设备以及安装的过滤单元的设计。测量点(网格单元)的最小数量应由公式(B1)确定:

$$N_A = \times 10$$

$$N_A = \times 10$$

(B.1)

(B.1)

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where

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N is the minimum number of measuring points (grid cells;N should be rounded up to a whole number);

n 是测量点的最小数量(网格单元; n 应该四舍五入到整数);

A is the measured area in m.

a 是以 m 为单位的测量面积。

Where the average velocity is required for a zone with unidirectional airflow, the average velocity is calculated from Formula (B.2):

当单向气流区域需要平均速度时，平均速度由公式(B2)计算:

$$V_a = (\sum V_n) / N$$

$$V_a = (\sum V_n) / N$$

(B.2)

(B.2)

where

在哪里

V_a

价值分析

is the average velocity in m/s;

是平均速度，单位为米/秒；

$\sum V_n$ is the sum of all the measured velocities (V_n) in m/s;

$\sum V_n$ 是所有测量速度(V_n)的总和，单位为 m/s。

V_n

越南

is the measured velocity at each of the grid cell centres in m/s;

是每个网格单元中心的测量速度，单位为米/秒；

N

N

is the number of locations at which the velocities (V_n) were measured.

是测量速度(V_n)的位置数量。

At least one point should be measured for each filter outlet or fan-filter unit.

每个过滤器出口或风扇过滤器单元至少应测量一个点。

If the measured data is to be used to determine airflow volume flow rate as in B.2.2.4 or uniformity of velocity as in B.2.2.3, then it can be advantageous to increase the number of measuring points (grid cells).

如果测量数据用于确定气流量(如 B.2.2.4)或速度均匀性(如 B.2.2.3), 则增加测量点(网格单元)的数量可能是有利的。

For smaller areas, it can be necessary to increase the number of measuring points (grid cells) to improve the likelihood of detection of uneven airflow velocities.

对于较小的区域, 可能需要增加测量点(网格单元)的数量, 以提高检测不均匀气流速度的可能性。

The measuring time at each position should be sufficient to ensure a repeatable reading. Time-averaged values of measured velocities should be recorded for multiple locations.

每个位置的测量时间应足以确保读数可重复。应为多个位置记录测量速度的时间平均值。

NOTE 1 If the supply airflow velocity is measured too close to the source, there is a risk of measurement error due to variable airflow distribution. If the supply airflow velocity is measured too far from the filter face, the measurement reading can be compromised.

注 1: 如果送风速度测量得离源头太近, 由于气流分布变化, 存在测量误差的风险。如果送风速度测量得离过滤器表面太远, 测量读数可能会受到影响。

NOTE 2 A temporary barrier can be used to exclude disturbances to the unidirectional airflow.

注 2: 临时屏障可用于排除对单向气流的干扰。

B.2.2.3 Uniformity of velocity within the cleanroom or clean zone

B.2.2.3 洁净室或洁净区内的速度均匀性

The uniformity of velocity can be measured according to B.2.2.2 or as agreed between customer and supplier.

速度的均匀性可以根据 B.2.2.2 或客户和供应商之间的约定进行测量。

NOTE When production apparatus and workbenches are installed, it is important to confirm that significant airflow variations do not occur.

注: 当安装生产设备和工作台时, 重要的是确认不会发生显著的气流变化。

The data to be used to determine the uniformity of velocity and maximum deviation, i.e. the velocity and its variation, should be agreed between customer and supplier.

用于确定速度均匀性和最大偏差的数据，即速度及其变化，应由客户和供应商商定。

The standard deviation and mean average should be calculated from the velocity readings and the uniformity of velocity, UV, obtained with Formula (B.3):

标准偏差和平均应根据速度读数和速度均匀性(紫外线)计算, 速度均匀性由公式(B3)获得:

$$UV = [1 - (\sigma / V_a)] \times 100$$

$$uv = [1(\sigma/va)] \times 100$$

(B.3)

(B.3)

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where

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σ is the standard deviation;

σ 是标准差;

Va is the average velocity.

Va 是平均速度。

The maximum deviation of velocity, Dmax, is calculated with Formula (B.4):

速度的最大偏差 Dmax 用公式(B4)计算:

$$D_{\max} = [(V_d - V_a) / V_a] \times 100$$

$$D_{\max} = [(V_d - V_a) / V_a] \times 100$$

where

在哪里

smax is the maximum deviation in %;

smax 最大偏差，单位为%；

Va is the average velocity;

Va 是平均速度；

Vd is the reading with most variance from the average.

Vd 是与平均值差异最大的读数。

B.2.2.4 Supply air volume flow rate calculated from the velocity measurement

B.2.2.4 供应根据速度测量计算的空气体积流量

(B.4)

(B.4)

The results of the airflow velocity test carried out in accordance with B.2.2.2 can be used to calculate the total supply air volume flow rate with Formula (B.5):

根据 B.2.2.2 进行的气流速度试验的结果可用于计算公式(B.5)中的总供气流量:

$$Q = \sum(V_n \times A_c)$$

$$q = \sum(V_n \times A_c)$$

where

在哪里

(B.5)

(B.5)

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Because of the effect of local airflow turbulence and jet velocities issuing from an outlet, use of an airflow capture hood that captures all of the air issuing from each final filter or supply diffuser is recommended. The supply air volume flow rate is measured using an airflow capture hood with a measuring device, or the air velocity of the air exiting from an airflow capture hood multiplied by the effective area. The opening of airflow capture hood should be placed completely over the entire filter or diffuser, and the face of the hood should be seated against a flat surface to prevent air bypass and inaccurate readings. When an airflow capture hood with measuring device is adopted, the air volume flow rate at each final filter or supply diffuser should be measured directly at the discharge end of the hood.

B.2.3.4 Supply air volume flow rate calculated by velocity measurement in air ducts

B.2.3.4 通过风管中的速度测量计算供应空气体积流量

Supply air volume flow rate in air ducts should be determined in the same way as defined in B.2.2.5.

风管中的送风体积流量应以 B.2.2.5 中定义的相同方式确定

B.2.4 Apparatus for airflow tests

B.2.4 气流测试设备

Descriptions and measurement specifications of apparatus are provided in C.3. For airflow velocity measurements, ultrasonic anemometers, thermal anemometers, vane-type anemometers, or their equivalent, can be used.

设备的描述和测量规范在第 3 节中提供。对于气流速度测量，可以使用超声波风速计、热风速计、叶片式风速计或其等效物。

For supply air volume flow rate measurements, airflow capture hood, orifice meters, Venturi meters, pitot static tubes, averaging tube array and manometers, or their equivalent, can be used.

对于供应空气的体积流量测量，可以使用气流捕获罩、孔板流量计、文丘里流量计、皮托管、平均管阵列和压力计或它们的等同物。

Airflow velocity measurements should be made with apparatus that is not affected by point-to-point velocity variation over small distances, e.g. a thermal anemometer can be used if small grid divisions are

气流速度测量应使用不受小距离点对点速度变化影响的仪器，例如，如果小网格划分为

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selected and additional measuring points (grid cells) are used. On the other hand, a vane anemometer can be used if it is sensitive enough and large enough to measure average air velocity over a range of variation.

使用选定的和附加的测量点(网格单元)。另一方面，如果风速计足够灵敏、足够大，能够测量一系列变化范围内的平均空气速度，则可以使用风速计。

The apparatus chosen should have a valid calibration certificate.

所选仪器应具有有效的校准证书。

B.2.5 Test reports

B.2.5 测试报告

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

根据客户和供应商之间的协议，应按照第 5 条所述记录以下信息和数据：

a) type of tests and measurements, and measuring conditions;

a) 测试和测量的类型以及测量条件；

b) type designations of each measuring apparatus used and its calibration status;

b) 使用的每个测量仪器的型号名称及其校准状态；

c) measuring locations and the distance from the filter face;

c) 测量位置和距过滤面的距离；

d) occupancy state(s);

(d) 占用状态；

e)

e)

f)

f)

result of measurement;

测量结果；

other data relevant for measurement.

与测量相关的其他数据。

B.3 Airflow direction test and visualization

B.3 气流方向测试和可视化

B.3.1 General

B.3.1 概述

The purpose of airflow direction test and visualization is to demonstrate that the airflow direction and its uniformity of velocity conform to the design and performance specifications.

气流方向测试和可视化的目的是证明气流方向及其速度均匀性符合设计和性能规范。

Computational Fluid Dynamics (CFD) used as a predictive or analytical tool is not considered in this

计算流体动力学(计算流体动力学)作为预测或分析工具，在此不考虑

NOTE 1 document.

注 1 文件。

NOTE 2 Tracer thread methods may not give a true indication of the direction of airflow due to the tracer material's characteristics, e.g. weight of the thread.

注释 2 由于示踪材料的特性，例如螺纹的重量，示踪螺纹方法可能不能给出气流方向的真实指示。

B.3.2 Methods

B.3.2 方法

The airflow direction test and visualization can be performed by the following four methods:

气流方向测试和可视化可以通过以下四种方法进行:

a) tracer thread method;

a)示踪螺纹法;

b) tracer injection method;

b)示踪剂注入方法;

c) airflow visualization method by image processing techniques;

c)通过图像处理技术的气流可视化方法;

d) airflow visualization method by the measurement of velocity distribution.

d)通过测量速度分布的气流可视化方法。

By methods a) and b), airflow in the cleanroom or clean zone is actually visualized by the use of fibre tracer thread, or tracer particles. Devices, such as video cameras, record the profiles. The fibre tracer thread or tracer particles should not be a source of contamination and should follow the airflow profile accurately. Other apparatus such as a tracer particle generator, and high intensity light source may be used for these methods.

通过方法 a)和 b)，洁净室或洁净区中的气流实际上通过使用纤维示踪线或示踪粒子来可视化。摄像机等设备会记录这些档案。纤维示踪线或示踪粒子不应成为污染源，应准确跟踪气流分布。这些方法可以使用其他设备，例如示踪粒子发生器和高强度光源。

Method c) is used to demonstrate quantitatively the airflow velocity distributions in the cleanroom or clean zone. The technique is based on tracer particle image processing techniques using computers.

方法 c)用于定量演示洁净室或洁净区的气流速度分布。该技术基于使用计算机的示踪粒子图像处理技术。

Care should be taken to ensure that the personnel undertaking the test do not interfere with the airflow patterns being investigated.

应小心确保进行测试的人员不会干扰正在调查的气流模式。

NOTE 1 The airflow is affected by other parameters such as air pressure difference, air velocity, and temperature.

注 1 气流受其他参数的影响，如空气压差、空气速度和温度。

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NOTE 2 Appropriate airflow visualisation techniques best assess the effectiveness of air distribution in unidirectional airflow cleanrooms, clean zones and controlled zones. However, the method can also be used in non-unidirectional areas.

注 2:适当的气流可视化技术最好地评估单向气流洁净室、洁净区和受控区中气流分布的有效性。然而，该方法也可以用于非单向区域。

B.3.3 Procedures for airflow direction test and visualization

在视频帧或胶片上处理从 B.3.3.2 中描述的方法得到的粒子图像数据，通过该区域的二维空气速度矢量提供气流的定量特征。这种处理技术需要一台具有适当接口和适当软件的数字计算机。为了获得更高的空间分辨率，可以使用激光光源等设备。

B.3.3.4 Evaluation of airflow distribution by measurement of velocity distributions

B.3.3.4 通过测量速度分布评估气流分布

The velocity distributions of airflow can be determined by setting air velocity measuring apparatus, such as thermal or ultrasonic anemometers, at several defined points in the cleanroom or clean zone under investigation. Processing of the measured data provides the information about the airflow distribution.

气流的速度分布可以通过在洁净室或正在研究的洁净区的几个限定点设置空气速度测量装置来确定，例如热或超声波风速计。测量数据的处理提供了关于气流分布的信息。

B.3.4 Apparatus used for airflow direction test and visualization

B.3.4 用于气流方向测试和可视化的设备

The apparatus used for the airflow direction test and visualization is different for each test method. The apparatus suitable for each test method is given in C.4, Table B.1 and B.2.

用于气流方向测试和可视化的设备因每种测试方法而异。C.4、表 B.1 和 B.2 给出了适用于每种试验方法的仪器

Table B.1 — Materials or particles used in tracer thread or injection methods

表 B.1 — 示踪螺纹或注射方法中使用的材料或颗粒

| Item | Description |
|---------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Material used in the tracer thread method | Silk thread, cloth, etc. |
| Particulate method used in the tracer injection method | DI water or other fluid mist of 0,5 m to 50 m in diameter. Bubbles of neutral density in the air at the measuring location. Organic or inorganic test fog. |
| Image recording devices for recording the visualized pictures or images of tracer particles | Various devices, such as photographic cameras, video cameras, including high-speed or strobe or synchronized functions and image recording devices, used in flow visualization procedures. |

| 项目 | 描述 |
|--------------|------------------------------------------------------|
| 示踪螺纹法中使用的材料 | 丝线、布等。 |
| 示踪注入法中使用的微粒法 | 直径为 0.5m 至 50 m 的去离子水或其他流体雾。测量位置空气中中性密度的气泡。有机或无机测试雾。 |

| | |
|--------------------------|----------------------------------------------|
| 用于记录示踪粒子的可视化图片或图像的图像记录设备 | 各种设备，如照相机、摄像机，包括高速或频闪或同步功能和图像记录装置，用于流动可视化程序。 |
|--------------------------|----------------------------------------------|

After flow visualization, it is generally necessary to re-clean the cleanroom or clean zone.

流动可视化后，通常需要重新清洁洁净室或洁净区。

NOTE

注意

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Table B.2 — Illumination light sources for airflow visualization

表 B.2 — 气流可视化照明光源

| Item | Description |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Various illumination light sources for contrasted observation or imaging of airflows | Tungsten lamp, fluorescent lamp, halogen lamp, mercury lamp, laser light sources (He-Ne, argon ion, YAG lasers, etc.) with or without stroboscope or synchronized devices to the recorders. |
| Image-processing technique for quantitative measurement by flow visualization | Laser light sheet method, consisting of high-power laser sources (argon or YAG laser), optics including cylindrical lens, and a controller, where two-dimensional airflows are visualized. |

| 项目 | 描述 |
|--------------------|------------------------------------------------------------|
| 用于气流对比观察或成像的各种照明光源 | 钨灯、荧光灯、卤素灯、汞灯、激光光源(氦氖、氩离子、钕铝石榴石激光器等。)带有或不带有频闪观测仪或记录器的同步装置。 |
| 流动可视化定量测量的图像处理技术 | 激光薄片法，由高功率激光源(氩或钕铝石榴石激光器)、包括柱面透镜的光学器件和控制器组成，其中二维气流被可视化。 |

B.3.5 Test reports

B.3.5 测试报告

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

根据客户和供应商之间的协议，应按照第 5 条所述记录以下信息和数据:

a) type of tests, method of visualization and test conditions;

a)测试类型、可视化方法和测试条件；

b) type designations of each measuring apparatus used and its calibration status;

b)使用的每个测量仪器的型号名称及其校准状态；

c) visualization point locations;

c)可视化点位置；

d) images stored on photographs or any other recording media, or raw data for each measurement,

d)存储在照片或任何其他记录介质上的图像，或每次测量的原始数据，

in the case of the image processing technique or the measurement of velocity distributions, if specified;

在图像处理技术或速度分布测量的情况下，如果指定的话；

e)

e)

f)

f)

a plan of the exact location of all apparatus should accompany the flow visualization report;

流动可视化报告应附有所有设备的准确位置计划；

occupancy state(s).

占用状态。

B.4 Recovery test

B.4 恢复测试

B.4.1 General

B.4.1 概述

This test is performed to determine the ability of the installation to reduce the concentration of airborne particles by dilution. Cleanliness recovery performance after a particle generation event is one of the most important abilities of the installation. This test is only recommended for non-unidirectional airflow systems as the recovery performance is based on the dilution and mixing of the air found in non-unidirectional airflow systems, and not unidirectional airflow systems, where contamination is removed by the unidirectional flow of air. The recovery performance of a non-unidirectional cleanroom is affected by air distribution characteristics such as ventilation effectiveness, thermal conditions, and obstructions. The recovery test can be performed using an LSAPC or an aerosol photometer. When an artificial aerosol is used, the risk of residue contamination of the cleanroom or clean zone should be considered.

进行该试验是为了确定该装置通过稀释降低空气中颗粒浓度的能力。颗粒生成事件后的清洁度恢复性能是安装最重要的能力之一。该试验仅推荐用于非单向气流系统，因为回收性能基于非单向气流系统中发现的空气稀释和混合，而非单向气流系统，单向气流系统中的污染物通过单向气流去除。非单向洁净室的恢复性能受空气分布特征的影响，如通风效率、热条件和障碍物。回收试验可以使用 LSAPC 或气溶胶光度计进行。当使用人造气溶胶时，应考虑洁净室或洁净区残留污染的风险。

B.4.2 Cleanliness recovery performance

B.4.2 清洁度恢复性能

Recovery performance is evaluated by using the 100:1 or 10:1 recovery time and/or the cleanliness recovery rate. The 100:1 or 10:1 recovery time is defined as the time required for decreasing the initial concentration by a factor of 100 times (or 10 times). The cleanliness recovery rate is defined as the rate of change of particle concentration by time. It is possible to estimate both of these from the same particle concentration decreasing curve. The measured concentration levels used should be taken from inside the time range where the decreasing of particle concentration is described by a single exponential, indicated by a straight line on a semi-log chart (concentrations on the ordinate by the logarithmic scale, and the time values on the abscissa by the linear scale). Moreover, the test concentration should not be so high that coincident loss occurs, or so low that counting uncertainty occurs.

通过使用 100:1 或 10:1 的恢复时间和/或清洁度恢复率来评估恢复性能。100:1 或 10:1 回收时间定义为将初始浓度降低 100 倍(或 10 倍)所需的时间。清洁度恢复率定义为颗粒浓度随时间的变化率。从相同的颗粒浓度下降曲线可以估计这两种情况。所用的测量浓度水平应取自时间范围内，在该时间范围内，颗

粒浓度的降低由半对数图上的直线表示(纵坐标上的浓度由对数刻度表示, 横坐标上的时间值由线性刻度表示)。此外, 测试浓度不应高到出现重合损失, 也不应低到出现计数不确定性。

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The purpose of the recovery time test is to evaluate an actual time interval for the concentration to reach target cleanliness level after the particle concentration in the cleanroom or clean zone has temporarily become higher due to planned maintenance shutdown, or unplanned plant failure. The purpose of evaluation by recovery rate is to establish the local ability to recover the cleanliness after the particle concentration around the measuring point has temporarily become higher. The slope of decreasing curve on a semi-log chart indicates this local ability.

恢复时间测试的目的是评估在洁净室或洁净区中的颗粒浓度由于计划维护停机或计划外工厂故障而暂时变高后，浓度达到目标洁净度水平的实际时间间隔。回收率评估的目的是在测量点周围的颗粒浓度暂时变高后，建立恢复清洁度的局部能力。半对数图上递减曲线的斜率表明这种局部能力。

The 100:1 test is not recommended for ISO Classes 8 and 9.

对于国际标准化组织 8 级和 9 级，不建议进行 100:1 测试。

NOTE The measurement of the recovery rate not only gives the recovery rate but the air change rate per unit of time at the location where the measurements were made. If the local air change rate at the location is compared to the overall air change rate in the cleanroom, the effectiveness of the ventilation system in providing clean air at the measuring location can be obtained.

注:回收率的测量不仅给出了回收率,还给出了测量位置单位时间内的空气变化率。如果将该位置的局部空气变化率与洁净室的整体空气变化率进行比较,可以获得通风系统在测量位置提供洁净空气的有效性。

B.4.3 Procedure for recovery test

B.4.3 恢复测试程序

B.4.3.1 Selection of measuring points

B.4.3.1 测量点的选择

Place the LSAPC probe in the working plane at appropriate location(s) (which can include critical locations or suspected worst-case locations). The measuring points and number of measurements should be determined between the customer and supplier. It can be inappropriate to choose measuring locations that give recovery performances not representative of the cleanroom, such as under an air terminal without a diffuser.

将 LSAPC 探头放在工作平面的适当位置(包括关键位置或可疑的最坏情况位置)。测量点和测量次数应由客户和供应商决定。选择恢复性能不代表洁净室的测量位置可能不合适,例如在没有扩散器的空气终端下方。

B.4.3.2 Test method

B.4.3.2 测试方法

Care should be taken to avoid high airborne concentrations of particles that can cause coincidence error and contamination of the LSAPC optics. Before testing, calculate the concentration required to carry out the recovery test. If the concentration exceeds the maximum concentration of the LSAPC, where particle coincidence will occur, use a dilution system. Testing procedure:

应注意避免空气中高浓度的粒子,这些粒子会导致重合误差和 LSAPC 光学器件的污染。测试前,计算进行回收测试所需的浓度。如果浓度超过 LSAPC 的最大浓度,此时会出现颗粒重合,则使用稀释系统。测试程序:

a)

a)

set up the particle counter in accordance with the manufacturer's instructions and the apparatus calibration certificate;

根据制造商的说明和仪器校准证书设置粒子计数器;

b) the particle size used in this test should be less than 1 μm . It is recommended that the size channel used by the LSAPC corresponds to that of the maximum number concentration of the aerosol;

b)本试验中使用的颗粒尺寸应小于 1 μm 。建议 LSAPC 使用的尺寸通道与气溶胶最大数量浓度的通道相对应;

c)

c)

the cleanroom area to be examined should be contaminated with an aerosol while the air-handling units are in operation;

空气处理装置运行时,待检查的洁净室区域应被气溶胶污染;

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B.4.3.3 Evaluation by 10:1 or 100:1 recovery time

B.4.3.3 按照 10:1 或 100:1 的恢复时间进行评估

Evaluation procedure:

评估程序:

a)

a)

note the time when the particle concentration reaches the $10\times$ or $100\times$ target concentration threshold (t_{10n} or t_{100n});

注意颗粒浓度达到 $10\times$ 或 $100\times$ 目标浓度阈值(t_{10n} 或 t_{100n})的时间;

b) note the time when the particle concentration reaches the target cleanliness level, t_n ;

b)记录颗粒浓度达到目标清洁度 t_n 的时间;

c) the 10:1 recovery time is represented by $t_{0,1} = (t_n - t_{10n})$;

c)10:1 恢复时间由 $t_{0,1} = (t_n - t_{10n})$ 表示;

d) the 100:1 recovery time is represented by $t_{0,01} = (t_n - t_{100n})$.

d)100:1 恢复时间由 $t_{0,01} = (t_n - t_{100n})$ 表示。

B.4.3.4 Evaluation by recovery rate

B.4.3.4 回收率评估

Recovery performance can be determined from the slope of the particle concentration decreasing curve, as follows:

从颗粒浓度下降曲线的斜率可以确定回收性能, 如下所示:

a)

a)

commence measurements and record time and concentration continuously. Sampling time should be as short as possible but sampling should be such that the count has statistical relevance. Time intervals between the samplings should be as short as possible;

开始测量并连续记录时间和浓度。采样时间应尽可能短，但采样应使计数具有统计相关性。取样之间的时间间隔应尽可能短；

b) plot the data of decreasing particle concentration on a semi-log chart (concentrations on the ordinate by the logarithmic scale, and the time values on the abscissa by the linear scale);

b) 在半对数图上绘制颗粒浓度降低的数据(纵坐标上的浓度用对数标度, 横坐标上的时间值用线性标度);

c) decide higher and lower concentration limits as to the decreasing curve measured is accepted as almost straight line;

c) 确定较高和较低的浓度极限, 因为测量的下降曲线被接受为几乎直线;

d) cleanliness recovery rate is obtained from the slope of the line between the higher and lower

d) 清洁度恢复率从较高和较低之间的直线斜率获得

concentrations. The cleanliness recovery rate between two measurements is calculated from Formula (B.6):

浓度。两次测量之间的清洁度恢复率由公式(B.6)计算得出:

r

r

tt

tt

C

C

$$C = -\times - \left(\begin{array}{c} | \\ | \\ | \end{array} \right) | 1 \ 0 \ 0, \log \quad (\text{B.6})$$

$$c = \times(| | |) | 1 \ 0 \ 0, \text{对数(B.6)}$$

- / / / / / / / / / / / / / - - / / / / / / / -

" " , , , " " , , - - " " , , , -

- - -

where

在哪里

C0

无着丝粒的

C1

C1

r

r

is the higher concentration at t0;

t0 时浓度较高;

is the lower concentration at t1.

是 t1 时的较低浓度。

is the cleanliness recovery rate;

清洁度回收率;

t1 – t0 is the time between measured concentration crosses C0 and C1;

t1 t0 是测量浓度穿越 C0 和 C1 之间的时间;

NOTE The ventilation effectiveness of a critical location or locations in the cleanroom can be determined by comparing the recovery rate at the location or locations with the overall recovery rate of the cleanroom. When the air and the contamination in the cleanroom are perfectly mixed at the start of the recovery test for the cleanroom, the overall recovery rate of a cleanroom is the same as the air change rate of the cleanroom. Therefore, the ventilation effectiveness can be obtained by comparing the recovery rate at the location or locations with the air change rate of the cleanroom.

注意:洁净室中一个或多个关键位置的通风效率可以通过将该位置或多个位置的回收率与洁净室的总回收率进行比较来确定。当洁净室的空气和污染物在洁净室恢复测试开始时完全混合时, 洁净室的总恢复率与洁净室的空气变化率相同。因此, 可以通过将一个或多个位置的回收率与洁净室的空气变化率进行比较来获得通风效率。

To obtain comparable values of the recovery test, it is necessary to consider the influence of the temperature difference between incoming air and the recovery performance test point, which causes changes to the airflow in the cleanroom. This temperature difference can vary between the at-rest and as-built conditions, due to changes in the heat gains in the cleanroom, and between the different requirements for seasonal warming or cooling. The temperature differential between the incoming air and recovery test point should be measured.

为了获得回收试验的可比值, 有必要考虑进气和回收性能试验点之间温差的影响, 这种温差会导致洁净室气流的变化。由于洁净室中热增益的变化, 静止和竣工条件之间的温差可能不同, 季节性升温或降温的不同要求之间的温差也可能不同。应测量进气和回收测试点之间的温差。

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B.4.4 Apparatus for recovery test

B.4.4 恢复试验设备

The apparatus listed below can be used for a recovery test:

下列设备可用于恢复测试:

— aerosol generator and artificially generated aerosol, which have the same characteristics as those described in C.5;

— 气溶胶发生器和人工产生的气溶胶，其特征与第 5 节中描述的相同；

— light-scattering airborne-particle counter (LSAPC), which has the efficiency described in C.8;

— 光散射空气粒子计数器，其效率如 c8 中所述；

— dilution system, if necessary, as described by C.5.4;

— 如有必要，稀释系统，如 C.5.4 所述；

— thermometer.

温度计。

A recovery test can also be carried out using an aerosol photometer.

回收试验也可以使用气溶胶光度计进行。

NOTE

注意

B.4.5 Test reports

B.4.5 测试报告

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

根据客户和供应商之间的协议，应按照第 5 条所述记录以下信息和数据:

a) type designations of each measuring apparatus used and its calibration status;

a)所用每个测量仪器的型号名称及其校准状态;

b) number and location of measuring points;

b)测量点的数量和位置;

c) occupancy state(s);

c)占用状态;

d) result of measurement.

d)测量结果。

B.5 Temperature test

B.5 温度测试

B.5.1 General

B.5.1 概述

The purpose of this test is to verify the capability of the installation to maintain the air temperature level within the control limits and over the time period agreed between the customer and supplier for the particular area being tested. Refer to ISO 7726[] and other related documents for details of suitable test methods.

该测试的目的是验证安装在控制范围内以及在客户和供应商就测试特定区域商定的时间段内保持空气温度水平的能力。有关合适测试方法的详细信息，请参考国际标准化组织 7726[]和其他相关文件。

B.5.2 Apparatus for temperature test

B.5.2 温度测试设备

The temperature test should be performed using a sensor that has accuracy as defined in ISO 7726, [] for example:

温度测试应使用具有国际标准化组织 7726(I)中定义的精确度的传感器进行，例如:

a) thermometers;

a)温度计;

b) resistance temperature devices;

b)电阻温度装置;

c) thermistors.

c)热敏电阻。

The apparatus should have a valid calibration certificate.

仪器应具有有效的校准证书。

B.6 Humidity test

B.6 湿度测试

B.6.1 General

B.6.1 概述

The purpose of this test is to verify the capability of the installation to maintain the air humidity level (expressed as relative humidity or dew point) within the control limits and over the time period agreed between the customer and the supplier for the area being tested. Refer to ISO 7726[] and other related documents for details of suitable test methods.

本试验的目的是验证装置在客户和供应商就试验区域商定的时间段内将空气湿度水平(以相对湿度或露点表示)保持在控制限值内的能力。有关合适测试方法的详细信息,请参考国际标准化组织 7726[1]和其他相关文件。

— “ ” ” ” ” ” ” ” ” ” ” ” ” ” ” — “ ” ” ” ” ” ” ” ” —

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B.6.2 Apparatus for humidity test

B.6.2 湿度测试设备

Humidity tests should be performed using a sensor that has accuracy appropriate to the measurement as stated in ISO 7726[.].

湿度测试应使用符合国际标准化组织 7726[所述测量精度的传感器进行。

Typical sensors are:

典型的传感器有：

a) dielectric thin film capacitor humidity sensor;

a)电介质薄膜电容器湿度传感器；

b) dew point sensor;

b)露点传感器；

c) psychrometer.

c)干湿表。

B.7 Installed filter system leakage test

B.7 安装的过滤系统泄漏测试

WARNING — The aerosol challenge can provide an unacceptable particulate or molecular contamination within some installations. Some test aerosols can create a safety hazard under certain circumstances. This document does not address any safety issues associated with these methods. It is the responsibility of the user to consult and apply appropriate safety practices, risk assessments and any regulatory limits prior to use of this document.

警告—气溶胶挑战可能会在某些装置中产生不可接受的微粒或分子污染。在某些情况下，一些测试气雾剂会造成安全隐患。本文件不涉及与这些方法相关的任何安全问题。在使用本文件之前，用户有责任咨询和应用适当的安全实践、风险评估和任何监管限制。

B.7.1 General

B.7.1 概述

B.7.1.1 Methods

B.7.1.1 方法

These tests are performed to confirm that installed filter systems with integral efficiency of 99.95 % or higher at most penetrating particle size (MPPS) are properly installed by verifying the absence of bypass leakage in the installation, and that the filters are free of defects (small holes and other damage in the filter medium, frame, seal and leaks in the filter bank framework). Portions of the test methods given in B.7 have been adapted from IEST-RP-CC034.4[1].

进行这些测试是为了通过验证安装中没有旁路泄漏，确认安装的过滤器系统的整体效率在最大穿透粒度 (MPPS) 下为 99.95% 或更高，并且过滤器没有缺陷 (过滤介质、框架、密封件和过滤器组框架中的小孔和其他损坏)。B.7 中给出的部分试验方法已从 IEST-RP-CC034.4 [公司改编而来]。

These tests are not used to determine the efficiency of the filter medium. The leak test establishes the level of leakage, relevant to the cleanliness performance of the installation. The tests are performed by introducing an aerosol challenge upstream of the filters and scanning downstream of the filters and support frame or sampling in a downstream duct. The test is applied to cleanrooms and clean zones in as-built or in at-rest occupational states, and undertaken when commissioning new cleanrooms and clean zones, or when existing installations require re-testing, or after the high-efficiency air filters have been replaced.

这些测试不用于确定过滤介质的效率。泄漏测试确定了与设备清洁性能相关的泄漏水平。通过在过滤器上游引入气溶胶挑战，并在过滤器和支撑框架下游扫描或在下游管道中取样来进行测试。该测试适用于竣工或静止职业状态下的洁净室和洁净区，并在调试新洁净室和洁净区时，或在现有安装需要重新测试时，或在更换高效空气过滤器后进行。

Two procedures for filter systems with ceiling, wall or apparatus mounted filters are described in B.7.2 and B.7.3. A procedure for duct mounted filters is described in B.7.4. The apparatus and methods are different, with the method described in B.7.2 measuring a mass concentration using an aerosol photometer and the method described in B.7.3 measuring numbers of particles using a LSAPC.

B.7.2 和 B.7.3 中描述了天花板、墙壁或设备安装过滤器的过滤系统的两个程序。B.7.4 中描述了管道安装过滤器的程序。设备和方法不同，B.7.2 中描述的方法使用气溶胶光度计测量质量浓度，B.7.3 中描述的方法使用 LSAPC 测量颗粒数量。

B.7.1.2 Aerosol photometer method

B.7.1.2 气溶胶光度计方法

The aerosol photometer method (B.7.2) may be used for testing:

气溶胶光度计方法 (B.7.2) 可用于测试：

- a) cleanrooms and clean zones with all types of air-handling systems;
- a) 带有各种空气处理系统的洁净室和洁净区；
- b) installations where outgassing of oil-based volatile test aerosol deposited on the filters and ducts
- b) 过滤器和管道上沉积的油基挥发性试验气溶胶除气的装置

b)不能容忍沉积在过滤器和管道上的油基挥发性气溶胶放气或建议使用固体气溶胶的装置。

NOTE 1 This method requires a series of calculations to set up the method and can also require the use of a diluter (see C.5.4).The calculations can be manual, through independent computers, instrument linked computers, or within automated adapted LSAPC instruments.

注 1:该方法需要一系列计算来建立该方法,也可能需要使用稀释器(见 C.5.4)。计算可以是手动的,通过独立的计算机、仪器连接的计算机,或者在自动调整的 LSAPC 仪器中进行。

This method can also be used with oil-based aerosol where outgassing can be tolerated.

这种方法也可以用于油基气溶胶，在这种情况下，除气是可以容忍的。

NOTE 2

注2

B.7.2 Procedure for installed filter system leakage scan test with an aerosol photometer

B.7.2 用气溶胶光度计安装过滤系统泄漏扫描测试的程序

B.7.2.1 General

B.7.2.1 概述

Preparatory steps are contained in B.7.2.2, B.7.2.3, B.7.2.5 and B.7.2.6, acceptance criteria in B.7.2.4, the test procedure itself in B.7.2.7, and repair actions are to be found in B.7.6[] [] [].

准备步骤包含在 B.7.2.2、B.7.2.3、B.7.2.5 和 B.7.2.6 中，验收标准包含在 B.7.2.4 中，测试程序本身包含在 B.7.2.7 中，维修措施包含在 B.7.6 中。

B.7.2.2 Determination of probe size

B.7.2.2 探针尺寸的确定

It is desirable to choose a probe which has a rectangular inlet in sizes of $D_p = 1$ cm and $W_p = 8$ cm or a circular probe of diameter $D_p = 3,6$ cm. D_p is the probe dimension parallel to the scan direction, expressed in centimetres; W_p is the probe dimension perpendicular to the scan direction, expressed in centimetres.

最好选择 $D_p = 1$ 厘米、 $W_p = 8$ 厘米的矩形入口或 $D_p = 3,6$ 厘米的圆形探针。 D_p 是平行于扫描方向的探头尺寸，用厘米表示； W_p 是垂直于扫描方向的探头尺寸，用厘米表示。

B.7.2.3 Determination of scan rate

B.7.2.3 扫描速率的确定

The probe traverse scan rate, S_r , should be approximately 5 cm/s[].

探头横向扫描速率 S_r 应约为 5 厘米/秒^[1]。

B.7.2.4 Acceptance criteria

B.7.2.4 验收标准

While scanning, any indication of a leak equal or greater than the limit which characterizes a designated leak should be cause for holding the probe at the leak location. The location of the leak should be identified by the position of the probe that sustains the maximum reading on the aerosol photometer.

扫描时，任何等于或大于指定泄漏极限的泄漏指示都应导致探头保持在泄漏位置。泄漏的位置应通过保持气溶胶光度计最大读数的探头位置来确定。

A leak detected in excess of 0,01 % of the upstream mass concentration is deemed to exceed the maximum allowable penetration. However, for filter systems of an integral efficiency at MPPS $\geq 99,95$ % and less than 99,995 %, the acceptance criterion is 0,1 %.

超过上游质量浓度 0.01% 的泄漏被视为超过最大允许渗透。然而，对于在最大功率点积分效率 $\geq 99.95\%$ 且小于 99.995% 的过滤系统，接受标准为 0.1%。

If filter systems of an integral efficiency lower than 99,95 % at MPPS are to be tested, a different acceptance criterion are necessary, based on agreement between customer and supplier.

如果要测试最大功率点处整体效率低于 99.95% 的过滤系统，根据客户和供应商之间的协议，有必要采用不同的验收标准。

For actions to be taken to eliminate detected leaks, see B.7.6.

如需采取措施消除检测到的泄漏，请参见 B.7.6

B.7.2.5 Choice of upstream aerosol challenge

B.7.2.5 上游气溶胶挑战的选择

An artificially generated aerosol by Laskin nozzle, thermal generator or similar should be introduced into the upstream airflow to achieve the required homogeneous challenge concentration. The mass median particle diameter for this production method is typically between 0,3 μ m to 0,7 μ m with a geometric standard deviation of up to 1,7.

Laskin 喷嘴、热发生器等人工产生的气溶胶应引入上游气流，以达到所需的均匀挑战浓度。这种生产方法的质量中值粒径通常在 0.3 μ m 至 0.7 μ m 之间，几何标准偏差高达 1.7。

A guide to aerosol source substances is given in C.8.4.

C.8.4 给出了气溶胶源物质指南

NOTE

注意

The upstream aerosol concentration measurements taken immediately upstream of the filters should not vary more than 15 % in time about the average measured value. Concentrations lower than the average reduce the sensitivity of the test to small leaks, while higher concentrations increase the

sensitivity to small leaks. Further details as to how to conduct the air-aerosol mixing test should be agreed between customer and supplier.

直接在过滤器上游进行的上游气溶胶浓度测量值在时间上的变化不应超过平均测量值的 15 %。低于平均值的浓度会降低试验对小泄漏的敏感性，而较高的浓度会增加对小泄漏的敏感性。关于如何进行空气-气溶胶混合试验的更多细节应由客户和供应商商定。

B.7.2.7 Procedure for installed filter system leakage scan test

B.7.2.7 安装的过滤系统泄漏扫描测试程序

Prior to performing this procedure, the airflow velocity test (B.2) should be carried out. Where installations are operated at different airflow velocities, the highest level should be selected for the filter system leakage scan test. The test is performed by introducing the specific challenge aerosol upstream of the filter(s) and searching for leaks by scanning the downstream side of the filter(s) and the grid or mounting frame system with the photometer's probe as follows:

在执行该程序之前，应进行气流速度测试(B.2)。当装置以不同的气流速度运行时，应选择最高水平进行过滤系统泄漏扫描测试。通过在过滤器上游引入特定的挑战气溶胶，并使用光度计探头扫描过滤器下游侧和格栅或安装框架系统来搜索泄漏，执行测试，如下所示：

a)

a)

measure the aerosol concentration upstream of the filters according to B.7.2.6. This aerosol concentration should be used as the upstream 100 % reference for the photometer. Downstream measurements is then displayed as percentage penetration of upstream concentration;

根据 B.7.2.6 测量过滤器上游的气溶胶浓度。该气溶胶浓度应用作光度计的上游 100 % 参考。下游测量值显示为上游浓度的渗透百分比；

b) the probe should then be traversed at a scan rate not exceeding 5 cm/s using overlapping strokes

b) 然后应该使用重叠的笔画以不超过 5 厘米/秒的扫描速度穿过探针

(1 cm recommended). The probe should be held in a distance of 3 cm or less from the downstream filter face or the frame structure;

(推荐 1 cm)。探头应保持在距离下游过滤面或框架结构 3 厘米或更短的距离内；

c) scanning should be performed over the entire downstream face of each filter, the perimeter of each filter, the seal between the filter frame and the grid structure, including its joints; d) measurements of the aerosol upstream of the filters should be repeated at reasonable time

c) 应在每个过滤器的整个下游面、每个过滤器的周边、过滤器框架和格栅结构之间的密封(包括其接头)上进行扫描；d) 过滤器上游气溶胶的测量应在合理的时间重复进行

intervals between and after scanning for leaks, to confirm the stability of the challenge aerosol concentration (see B.7.2.6).

扫描泄漏之间和之后的时间间隔，以确认挑战气溶胶浓度的稳定性(见 B.7.2.6)。

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with the LSAPC, detection of more than acceptable count for given test conditions, N_{ar} , in sustained residence time, T_r , indicates the presence of a leak. The determinations of N_{ar} and T_r are described in B.7.3.9.2. The procedure for stage 2 stationary re-measuring is described in B.7.3.9.

对于 LSAPC, 对于给定的测试条件, 检测到超过可接受的计数, 在持续停留时间 T_r 中, N_{ar} 表示存在泄漏。在 B.7.3.9.2 中描述了 N_{ar} 和 T_r 的测定。在 B.7.3.9 中描述了第 2 阶段静态重新测量的程序

B.7.3.2 Determination of probe size

B.7.3.2 探针尺寸的确定

The area of the probe size should ensure that the air velocity into the probe is the same as at the filter face, within a variation of 20 %. The area of the intake probe can be calculated by means of Formula (B.7):

探头尺寸的面积应确保进入探头的空气速度与过滤器表面的速度相同, 在 20 % 的变化范围内。进气探头的面积可以通过公式(B7)计算:

$$D_p \times W_p = Q_{va}/U$$

$$D_p \times W_p = Q_{va}/U$$

where

在哪里

D_p is the probe dimension parallel to the scan direction in cm;

D_p 是平行于扫描方向的探头尺寸, 单位为厘米;

Q_{va} is the sampling rate of the LASPC in cm/s;

Q_{va} 是 LASPC 的采样率, 单位为厘米/秒;

U is the filter face velocity in cm/s.

u 是过滤器表面速度, 单位为厘米/秒。

W_p is the probe dimension perpendicular to the scan direction, in cm;

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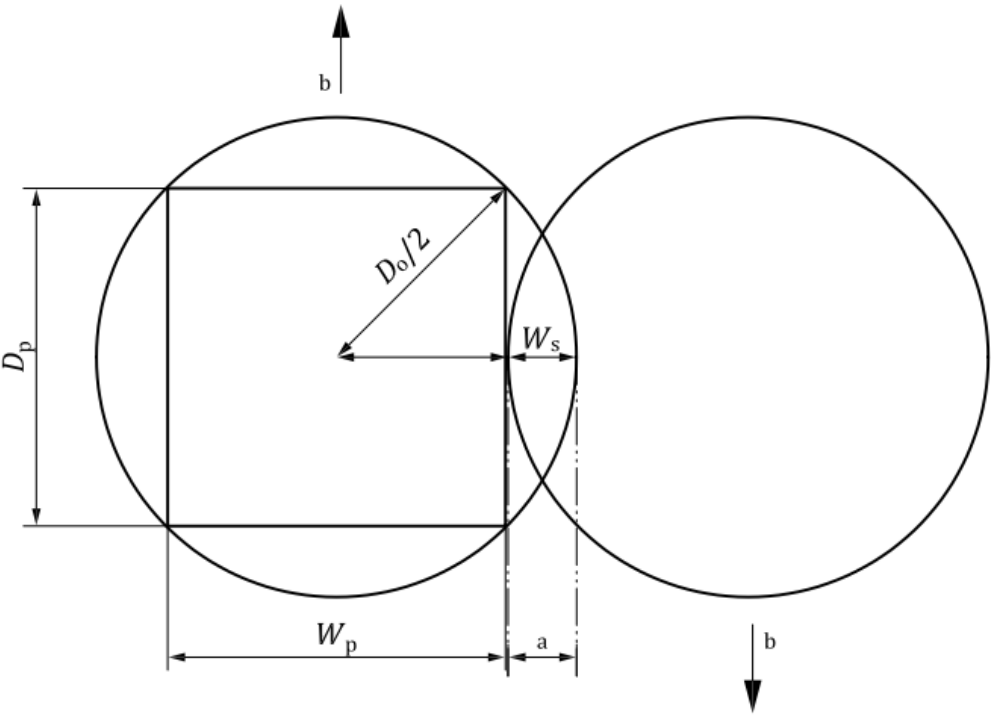
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Key

键



a

a

b

b

Overlap.

重叠。

Scan direction.

扫描方向。

Figure B.1 — Circular probe dimensions diagram

图 B.1 — 圆形探头尺寸图

NOTE In order to scan the target surface area most efficiently, it is necessary to select W_s as D_p becomes equal to W_p . In case of circular probe with a diameter of 3,6 cm, the most efficient D_p is 2,54 cm.

注:为了最有效地扫描目标表面区域,当 D_p 等于 W_p 时,有必要选择 W_s 。对于直径为 3.6 厘米的圆形探头,最有效的 D_p 为 2.54 厘米。

B.7.3.3 Determination of scan rate

B.7.3.3 扫描速率的确定

For a rectangular probe inlet size of $D_p = 1$ cm and $W_p = 8$ cm, the probe scan rate, S_r , is 5 cm/s or less.

对于 $D_p = 1$ cm、 $W_p = 8$ cm 的矩形探头入口,探头扫描速率 S_r 等于或小于 5 cm/s。

For a circular probe inlet diameter of 3,6 cm, the probe scan rate, S_r , is 12 cm/s or less.

对于直径为 3.6 厘米的圆形探头入口,探头扫描速率 S_r 等于或小于 12 厘米/秒。

Where the upstream aerosol concentrations cannot be achieved, it is necessary to change the scan rate. The scan rate, S_r , in cm/s can be determined by assuming the sampling rate of the LSAPC is 0,000 472 m/s and use Formula (B.9).

当上游气溶胶浓度无法达到时,有必要改变扫描速率。扫描速率 S_r , 以厘米/秒为单位,可以通过假设 LSAPC 的采样速率为 0,000±472 米/秒并使用公式(B9)来确定。

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A leak detected in excess of 0,01 % of the upstream number concentration is deemed to exceed the maximum allowable penetration. However, for filter systems of an integral efficiency at MPPS $\geq 99,95$ % and less than 99,995 %, the acceptance criterion is 0,1 %.

超过上游数量浓度 0.01% 的泄漏被视为超过最大允许渗透。然而，对于在最大功率点积分效率 $\geq 99.95\%$ 且小于 99.995% 的过滤系统，接受标准为 0.1%。

If filter systems of an integral efficiency lower than 99,95 % at MPPS are to be tested, a different acceptance criterion is necessary, based on agreement between customer and supplier.

如果要测试 MPPS 处整体效率低于 99.95% 的过滤系统，则需要根据客户和供应商之间的协议，采用不同的验收标准。

B.7.3.5 Expected number of particle counts

B.7.3.5 预期粒子数

The acceptable number of particle counts during the scanning (Stage 1) is N_a and it is desirable to select a N_a value of 0 or 1.

扫描(阶段 1)期间粒子计数的可接受数量是钠，并且希望选择 0 或 1 的钠值。

The lower confidence limit will determine N_a . It can be calculated with Formula (B.10).

置信下限将决定钠。它可以用公式(b10)计算。

$$N N a p N p = -$$

$$N N a p N p = -$$

(B.10)

(B.10)

where N_p is the expected median of particle counts that characterize a designated leak of particles.

其中 N_p 是表征指定颗粒泄漏的颗粒计数的预期中值。

It is the value N_p that is carried forward in Formula (B.9), and Formula (B.11) can be used to calculate N_p :

公式(B.9)中结转的是 N_p 值，公式(B.11)可用于计算 N_p :

$$N_p = N_a + 1 + \frac{N_a}{2}$$

$$N_p = N_a + 1 + \frac{N_a}{2}$$

When $N_a = 0$, N_p is 4, and when $N_a = 1$, N_p is 5.83.

当 $N_a = 0$ 时， N_p 为 4，当 $N_a = 1$ 时， N_p 为 5.83。

(B.11)

(B.11)

NOTE Higher values of N_a and N_p can be selected if there are concerns with false positives being caused by a "bleed through" of particles in undamaged filter media.

注意:如果担心未受损过滤介质中的颗粒“渗出”会导致误报，可以选择较高的钠和氮磷值。

B.7.3.6 Choice of upstream aerosol challenge

B.7.3.6 上游气溶胶挑战的选择

An artificially generated polydisperse aerosol should be introduced into the upstream airflow to achieve the required homogeneous challenge concentration. The count median particle diameter for this production method is typically between 0.1 μ m to 0.5 μ m with a geometric standard deviation of up to 1.7. The median particle diameter for this production method is typically between 0.3 μ m and 0.7 μ m with a geometric standard deviation of up to 1.7.

应在上游气流中引入人工生成的多分散气溶胶，以达到所需的均匀挑战浓度。这种生产方法的计数中值粒径通常在 0.1 μ m 至 0.5 μ m 之间，几何标准偏差高达 1.7。这种生产方法的中值粒径通常在 0.3 μ m 和 0.7 μ m 之间，几何标准偏差高达 1.7。

Alternatively, microspheres with an appropriate diameter can be used and an aerosol challenge.

或者，可以使用具有适当直径的微球体，并对气溶胶进行挑战。

Where an artificial aerosol cannot be introduced, atmospheric aerosol should be used as the upstream aerosol challenge.

在不能引入人工气溶胶的地方，大气气溶胶应被用作上游气溶胶挑战。

NOTE

注意

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where

在哪里

C_c

复写的副本

D_p

数据处理

P_l

P_l

is the challenge aerosol concentration upstream of the filter, in particles/m;

过滤器上游的挑战气溶胶浓度，单位为颗粒/米；

is the probe dimension parallel to the scan direction, in cm;

探头尺寸是否平行于扫描方向，单位为厘米；

is the maximum permitted penetration of the filter installation to be tested at 0,3 μ m.

过滤器装置在 0,3 μ m 处的最大允许渗透率

Q_v is the actual sample flow rate of the measuring apparatus, in m/s;

Q_v 是测量仪器的实际样品流速，单位为米/秒；

S_r is the probe traverse scan rate, in cm/s;

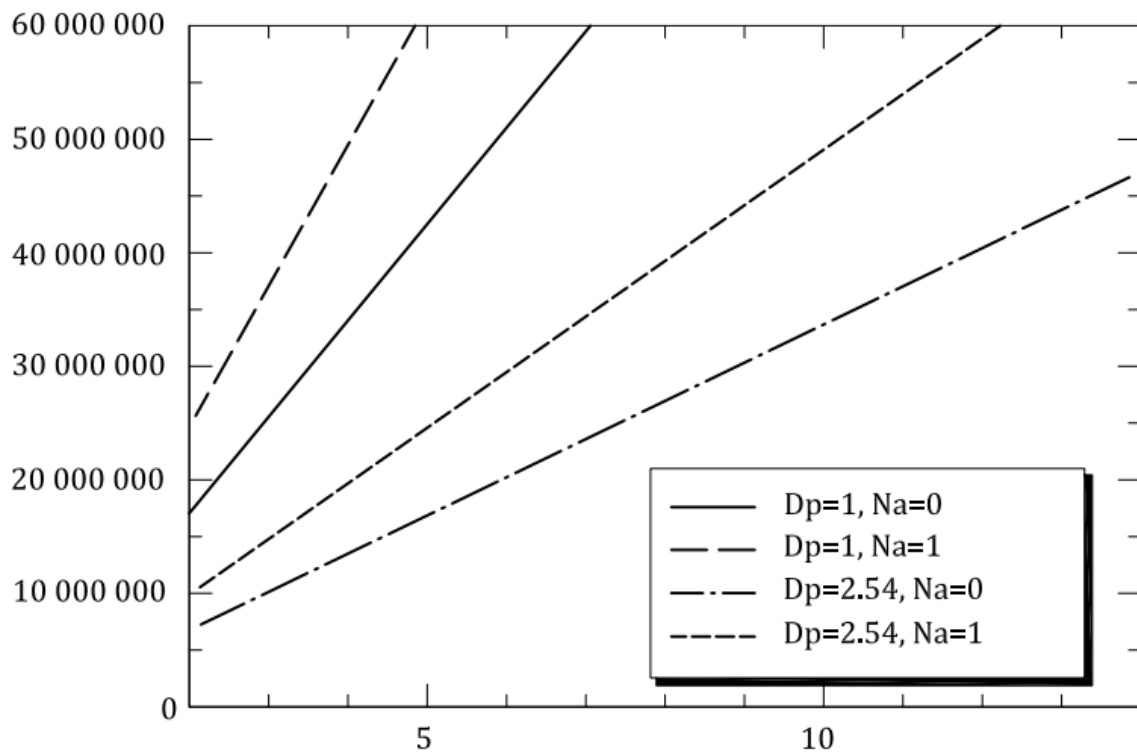
S_r 是探头横向扫描速率，单位为厘米/秒；

Based on the recommend probe size and scan rate as stated in B.7.3.2 and B.7.3.3, the concentration of aerosol challenge upstream of the filter can be selected from Figure B.2:

根据 B.7.3.2 和 B.7.3.3 中规定的推荐探针尺寸和扫描速率，过滤器上游气溶胶激发浓度可从图 B.2 中选择:

Key

键



X

X

Y

Y

probe traverse scan rate, S_r in cm/s challenge aerosol concentration, C_c in particles/m

探针横向扫描速率， S_r (厘米/秒)挑战气溶胶浓度， C_c (颗粒/米)

Figure B.2 — Challenge aerosol concentration, C_c , for various probe traverse scan rate, S_r

图 B.2 不同探头横向扫描速率下的挑战气溶胶浓度

In most cases, generated aerosol should be added to the upstream aerosol challenge to reach the necessary high challenge concentration. To verify such high concentrations, a dilution system can be required to avoid exceeding the concentration tolerance of the LSAPC (coincidence error).

在大多数情况下，生成的气溶胶应添加到上游气溶胶挑战中，以达到必要的高挑战浓度。为了验证如此高的浓度，可能需要一个稀释系统，以避免超过 LSAPC 的浓度公差(重合误差)。

Challenge aerosol concentrations can be adjusted by changing the probe scan rate by use of Formula (B.9).

挑战气溶胶浓度可以通过使用公式(B9)改变探针扫描速率来调节。

Appropriate measurements should be taken for verification of the homogenous mixing of the added aerosol to the supply airflow. The first time a system is tested, it should be determined that sufficient

aerosol mixing is taking place. For such validation, all injection and sampling points should be defined and recorded.

应采取适当的测量来验证添加的气溶胶与供应气流的均匀混合。第一次测试系统时，应确定是否发生了充分的气溶胶混合。对于这种验证，应定义并记录所有注射点和取样点。

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The upstream aerosol concentration measurements taken immediately upstream of the filters should not vary more than 15 % in time from the average measured value. Concentrations lower than the average will reduce the sensitivity of the test to small leaks, while higher concentrations increase the sensitivity to small leaks. Further details as to how to conduct the air-aerosol mixing test should be agreed between customer and supplier.

直接在过滤器上游进行的上游气溶胶浓度测量值与平均测量值的时间偏差不应超过 15 %。低于平均值的浓度会降低试验对小泄漏的敏感性，而较高的浓度会增加对小泄漏的敏感性。关于如何进行空气-气溶胶混合试验的更多细节应由客户和供应商商定。

When upstream aerosol concentrations vary over the time, these measurements should be continued during scanning for leaks in order to gain data for calculations with sequential downstream counts.

当上游气溶胶浓度随时间变化时，应在扫描泄漏期间继续进行这些测量，以便获得数据，用于连续下游计数的计算。

B.7.3.8 Procedure for installed filter system leakage test, stage 1 scan test

B.7.3.8 安装的过滤器系统泄漏测试程序, 第 1 阶段扫描测试

B.7.3.8.1 General

B.7.3.8.1 概述

Prior to performing this procedure, the airflow velocity test (see B.2) should be carried out. Where installations are operated at different airflow velocities, the highest level should be selected for the filter system leakage scan test. The test is performed by introducing the specific challenge aerosol upstream of the filter(s) and searching for leaks by scanning the downstream side of the filter(s) and the grid or mounting frame system with the LSAPC probe as follows:

在执行该程序之前，应进行气流速度测试(见 B.2)。当装置以不同的气流速度运行时，应选择最高水平进行过滤系统泄漏扫描测试。通过在过滤器上游引入特定的挑战气溶胶，并使用 LSAPC 探针扫描过滤器下游侧和格栅或安装框架系统，搜索泄漏，执行测试，如下所示：

a)

a)

measurements of the aerosol upstream of the filters according to B.7.3.7 should be taken first to verify the aerosol concentration;

应首先根据 B.7.3.7 测量过滤器上游的气溶胶，以验证气溶胶浓度；

b) the probe should then be traversed at a scan rate not exceeding the value for S_r stated in B.7.3.3,

b)然后探头应以不超过 B.7.3.3 中规定的 S_r 值的扫描速率通过。

using slightly overlapping strokes. The probe should be held in a distance of approximately 3 cm from the downstream filter face or the frame structure;

使用稍微重叠的笔画。探头应保持在距离下游过滤面或框架结构约 3 厘米的位置；

c)

c)

scanning should be performed over the entire downstream face of each filter, the perimeter of each filter, the seal between the filter frame and the grid structure, including its joints;

应在每个过滤器的整个下游面、每个过滤器的周边、过滤器框架和格栅结构之间的密封(包括其接头)上进行扫描；

d) measurements of the aerosol upstream of the filters should be repeated at reasonable time

d)过滤器上游气溶胶的测量应在合理的时间重复进行

intervals between and after scanning for leaks, to confirm the stability of the challenge aerosol concentration (see B.7.3.7).

扫描泄漏之间和之后的时间间隔，以确认挑战气溶胶浓度的稳定性(见 B.7.3.7)。

B.7.3.8.2 Measuring parameters for two scanning types

B.7.3.8.2 两种扫描类型的测量参数

一般来说, LSAPCs 的设计是为了对特定体积的采样空气中的颗粒进行计数。许多 LSAPCs 不能在非常短的时间内连续测量输出颗粒计数数据。

因此，钠= 0 或钠= 1 的条件(钠对于给定的测试条件是可接受的计数)应在用 LSAPC 安装的过滤器系统泄漏扫描测试中选择。

- / -

选择这种情况，在测试过程中，每次计数或计数之间的周期都会验证泄漏。

如果设备配备为每次计数都发出声音，则可以使用该声音来验证泄漏。

如果仪器能够在非常短的时间内连续测量输出计数，任何钠都适用。如果当时观察到的计数等于或小于钠(Dp / Sr)，则确认无泄漏。

对于合理的测试条件，可以选择以下两种扫描类型：

a)

扫描类型(a):为 0.3m 粒子选择钠= 0;

- 适用于预计静态重新测量的频率非常小的情况;

- type (a) test requires lower concentration for upstream than type (b);

—a 型试验要求上游浓度低于 b 型;

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Cc is the challenge aerosol concentration upstream of the filter in particles/m;

Cc 是过滤器上游的挑战气溶胶浓度，单位为颗粒/米；

Dp is the probe dimension parallel to the scan direction in cm.

Dp 是平行于扫描方向的探头尺寸，单位为厘米。

Nar is acceptable count at stationary re-measuring;

静态重新测量时 Nar 是可接受的计数；

Npr is the number of particle counts which characterize the designated leak;

Npr 是表征指定泄漏的粒子数；

(B.13)

(B.13)

(B.14)

(B.14)

Pl is the maximum permitted penetration of the filter installation to be tested at 0,3 m;

Pl 是在 0.3m 处测试的过滤器装置的最大允许渗透率；

QVS is the actual sample flow rate of the measuring apparatus in m/s;

QVS 是测量仪器的实际样品流速，单位为米/秒；

Tr is the recommended sustained residence time(s);

Tr 是推荐的持续停留时间。

B.7.3.10 Example of an application with evaluation

B.7.3.10 带评估的应用示例

Examples of measuring parameters are shown in Table B.3. These tables give example parameters for $D_p = 1 \text{ cm}$ and $W_p = \text{cm}$ with a scan rate $S_r = \text{cm/s}$, and a circular probe with diameter 3,6 cm and a

测量参数的示例如表 B.3 所示。这些表给出了 $D_p = 1 \text{ cm}$ 和 $W_p = \text{cm}$ 、扫描速率 $S_r = \text{cm/s}$ 以及直径为 3.6cm 和 a 的圆形探针的示例参数

scan rate $S_r = 12 \text{ cm/s}$.

扫描速率 $S_r = 12 \text{ 厘米/秒}$

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Table B.3 — Example of an application with evaluation

表 B.3 —带评估的应用示例

| Measuring parameters Scanning type | | Rectangular probe (1 cm × 8 cm) type (a) type (b) | | Circular probe (diameter 3,6 cm) type (a) type (b) | |
|---------------------------------------|-----------------------------------------------------------------|------------------------------------------------------|------|----------------------------------------------------|------|
| Pl | Maximum allowable penetration of the filter system to be tested | 0,000 1(0,01%) | | 0,000 1(0,01%) | |
| Dp | Nominal probe dimension parallel to the scan direction [cm] | 1 | | 2,54 | |
| Sr | Probe traverse scan rate [cm/s] | 5 | | 12 | |
| Qvs | Sample flow rate of the measuring apparatus [m/s] | 0,000 472 | | 0,000 472 | |
| Np | Expected | 4,0 | 5,83 | 4,0 | 5,83 |

| | | | | | |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|--------------|--------------|--------------|
| | number of particle counts that characterizes the designated leak corresponding to Na [counts] - Stage 1 | | | | |
| Na | Acceptable count during Ts at scan test [counts] - Stage 1 | 0 | 1 | 0 | 1 |
| Cc | Challenge aerosol concentration upstream of the filter [particles/m] | 423 728 814 | 617 584 746 | 400 373 682 | 583 544 642 |
| Npr | Expected number of particle counts during Tr = 10 s in the sustained residence time that characterizes the designated leak corresponding to Nar [counts] - Stage 2 | 200,00 | 291,50 | 188,98 | 275,43 |
| Nar | Acceptable count during Tr = 10 s in the sustained residence time [counts] - Stage 2 (rounded) | 171,72 (171) | 257,35 (257) | 161,48 (161) | 242,24 (242) |

| 测量参数 扫描类型 | | 矩形探头(1 cm × 8 cm) 类型(a)类型(b) | 圆形探针(直径 3.6 厘米)类型(a) 类型(b) |
|--------------|---------|---------------------------------|-------------------------------|
| Pl | 待测试过滤系统 | 0, 000 1(0, 01%) | 0, 000 1(0, 01%) |

| | | | | | |
|---------|-------------------------------------------------------|---------------|---------------|---------------|---------------|
| | 的最大允许渗透率 | | | | |
| 数据处理 | 平行于扫描方向的标称探针尺寸[厘米] | 1 | | 2, 54 | |
| Sr | 探头横向扫描速率[厘米/秒] | 5 | | 12 | |
| Qvs | 测量仪器的样品流速[米/秒] | 0, 000 472 | | 0, 000 472 | |
| 铭牌 | 表征对应于纳[计数的指定泄漏的预期颗粒计数]-阶段 1 | 4, 0 | 5, 83 | 4, 0 | 5, 83 |
| 钠 | 扫描测试时 Ts 期间的可接受计数[计数]-阶段 1 | 0 | 1 | 0 | 1 |
| 复写的副本 | 挑战过滤器上游的气溶胶浓度[粒子/米] | 423 728 814 | 617 584 746 | 400 373 682 | 583 544 642 |
| Npr | 在持续停留时间内, Tr = 10 秒期间的预期颗粒计数, 表征了与纳尔[计数相对应的指定泄漏]-阶段 2 | 200, 00 | 291, 50 | 188, 98 | 275, 43 |
| 一种双浮体小艇 | 在持续停留时间内 Tr = 10 秒期间的可接受计数[计数]-第 2 阶段(四舍五入) | 171, 72 (171) | 257, 35 (257) | 161, 48 (161) | 242, 24 (242) |

B.7.4 Procedure for overall leak test of filters mounted in ducts or air-handling units (AHUs)

B.7.4 安装在管道或空气处理装置(AHu)中的过滤器的整体泄漏测试程序

This procedure may be used for evaluating the overall leakage of duct-mounted filters. This procedure may also be used to determine overall leakage of multistage filter arrays without individual stage tests. It is important to be aware that this procedure is significantly less sensitive at finding leaks than the method described in B.7.2 and B.7.3. The overall leakage test result is affected by the total airflow volume in the system, as the airflow volume increases more dilution of the leak occurs. Therefore, this test method should be used where duct-mounted filter installations serve less critical cleanroom areas and where scan testing of those same filter installations is not practical. If critical, the scan method should be adopted.

该程序可用于评估管道安装过滤器的整体泄漏。该程序也可用于确定多级过滤器阵列的整体泄漏，而无需单独的级测试。需要注意的是，与 B.7.2 和 B.7.3 中描述的方法相比，该程序在发现泄漏方面的灵敏度明显较低。总泄漏测试结果受系统中总空气流量的影响，因为空气流量增加，泄漏会发生更多稀释。因此，当管道安装的过滤器装置服务于不太关键的洁净室区域，并且相同过滤器装置的扫描测试不实用时，应使用该测试方法。如果情况危急，应采用扫描方法。

This test is not designed to cover exhaust HEPA filter systems.

该测试不是为覆盖排气 HEPA 滤波系统而设计的。

NOTE 1

注 1

The test is performed by introducing the challenge aerosol upstream of the filters installed remotely to the cleanroom or clean zone. The upstream particle concentration is first measured. The particle concentration of the filtered air is then measured, and compared to the upstream concentration to determine the total leakage or penetration of the filter installation[7].

测试是通过在远离洁净室或洁净区安装的过滤器上游引入挑战气溶胶来进行的。首先测量上游颗粒浓度。然后测量过滤空气的颗粒浓度，并与上游浓度进行比较，以确定过滤器装置的总泄漏或渗透^[1]。

The airflow velocity test (see B.2) for initial qualification should be done prior to performing this test. Measurements of the upstream aerosol concentration according to B.7.2.6 (aerosol photometer method) or B.7.3.7 (LSAPC method) should be taken first to verify the aerosol concentration and homogeneity.

初始鉴定的气流速度试验(见 B.2)应在进行该试验之前进行。应首先根据 B.7.2.6(气溶胶光度计法)或 b.7.3.7(LSAP 法)测量上游气溶胶浓度,以验证气溶胶浓度和均匀性。

Measurement of downstream aerosol concentration should be carried out at locations where homogeneous mixing has occurred. If homogeneous mixing does not occur, a series of measurements should be taken at equally spaced locations in an agreed plane, between 30 cm and 100 cm downstream of the filter. This is a grid sampling method and the location and number of measurements should be agreed between the customer and the supplier.

下游气溶胶浓度的测量应在发生均匀混合的位置进行。如果没有发生均匀混合，应在过滤器下游 30 厘米至 100 厘米之间的商定平面内等间距位置进行一系列测量。这是一种网格取样方法，测量的位置和数量应由客户和供应商商定。

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Measurements of the total aerosol challenge or particle concentrations upstream of the filters should be repeated at reasonable time intervals to confirm stability of the challenge aerosol source (see B.7.2.6 and B.7.3.7).

过滤器上游总气溶胶激发或颗粒浓度的测量应在合理的时间间隔内重复进行，以确认激发气溶胶源的稳定性(见 B.7.2.6 和 B.7.3.7)。

Using a photometer, from the measured total challenge or concentration, the local penetration is measured as percentage penetration for each downstream location measurement. Using a LSAPC, from the measured particle challenge concentration, the local percentage penetrations should be calculated for each downstream location measurement for the particle size used. Each downstream percentage concentration should be lower than the percentage concentration specified, or as agreed between customer and supplier.

使用光度计，从测量的总挑战或浓度中，局部渗透被测量为每个下游位置测量的渗透百分比。使用 LSAPC，根据测量的颗粒挑战浓度，应为所用颗粒尺寸的每个下游位置测量计算局部渗透百分比。每个下游百分比浓度应低于规定的百分比浓度，或客户和供应商之间商定的浓度。

Repairs or rectification of leaks may be made according to B.7.6 or by procedures agreed between the customer and the supplier.

可以根据 B.7.6 或客户和供应商之间商定的程序进行修补或纠正泄漏。

NOTE 2 For applications, where ducted filters are required to be leak tested by scanning, the methods are described in B.7.2 and B.7.3.

注 2:对于要求管道过滤器通过扫描进行泄漏测试的应用，方法见 B.7.2 和 B.7.3

B.7.5 Apparatus and materials for installed filter system leakage tests

B.7.5 已安装过滤系统泄漏测试的设备和材料

B.7.5.1 Aerosol photometer (see C.8.1), limited to use in instances where the background counts or concentrations are less than 10 % of that which characterizes a designated leak

B.7.5.1 气溶胶光度计(见 C.8.1), 仅限于背景计数或浓度小于指定泄漏特征的 10 %的情况下使用

B.7.5.2 Light-scattering airborne-particle counter (LSAPC) (see C.8.2), limited to use in instances where the background counts or concentrations are less than 10 % of that which characterizes a designated leak.

B.7.5.2 光散射空气粒子计数器(见 C.8.2), 仅限于背景计数或浓度小于指定泄漏特征的 10 %的情况下使用。

B.7.5.3 Suitable pneumatic or thermal aerosol generator(s) to provide appropriate challenge aerosol concentration in the appropriate size range (see C.8.3).

B.7.5.3 合适的气动或热气溶胶发生器, 以在合适的尺寸范围内提供合适的挑战气溶胶浓度(见 C.8.3)。

B.7.5.4 Aerosol dilution system (see C.5.4).

B.7.5.4 气溶胶稀释系统(见 C.5.4)。

B.7.5.5 Aerosol source substances (see C.8.4).

B.7.5.5 气溶胶源物质(见 C.8.4)。

Apparatus specified in B.7.5.1 to B.7.5.3 should have a valid calibration certificate.

B.7.5.1 至 B.7.5.3 中规定的仪器应具有有效的校准证书。

B.7.6 Repairs and repair procedures

B.7.6 修理和修理程序

Leakage repair should only be acceptable by agreement between the customer and the supplier. The method of repair should take into account any instructions from the apparatus manufacturer, or the customer.

只有在客户和供应商同意的情况下, 泄漏修复才是可以接受的。修理方法应考虑仪器制造商或客户的任何说明。

In selecting materials for repair, outgassing and molecular deposition on products and processes should be considered.

在选择维修材料时, 应考虑产品和工艺上的除气和分子沉积。

Detected leakage in filters, the sealant or the grid structure should be repaired. Repairs to filter or the grid support structure may be made using procedures agreed between the customer and supplier.

应修复过滤器、密封剂或格栅结构中检测到的泄漏。过滤器或格栅支撑结构的维修可以使用客户和供应商之间商定的程序进行。

After the repair has been completed and a suitable cure time has been allowed, the leak site should be rescanned for leaks using the defined method.

修复完成并允许合适的固化时间后，应使用规定的方法重新扫描泄漏部位。

— “ ” ” ” ” ” ” ” ” ” ” ” ” ” ” — “ ” ” ” ” ” ” ” ” ” —

[illegible]

B.7.7 Test reports

B.7.7 测试报告

By agreement between the customer and supplier, the following information and data should be recorded as described in Clause 5:

根据客户和供应商之间的协议，应按照第 5 条所述记录以下信息和数据:

a) test method: aerosol photometer or light-scattering airborne-particle counter (LSAPC);

a)试验方法:气溶胶光度计或光散射空气粒子计数器;

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b) type designations of each measuring apparatus used and its calibration status;

b)使用的每个测量仪器的型号名称及其校准状态;

- / -

B.8 Containment leak test

B.8 安全壳泄漏测试

B.8.1 General

B.8.1 概述

This test is performed to determine if there is intrusion of contaminated air into the clean zones from surrounding non-controlled areas and to check pressurized ceiling systems for leaks.

执行该测试是为了确定污染空气是否从周围非控制区域侵入清洁区域，并检查加压天花板系统是否有泄漏。

B.8.2 Procedures for containment leak test

B.8.2 安全壳泄漏测试程序

B.8.2.1 Light-scattering airborne-particle counter (LSAPC) method

B.8.2.1 光散射空气粒子计数器方法

Measure the particle concentration outside the cleanroom enclosure immediately adjacent to the surface or doorway to be evaluated. This concentration should be greater than the cleanroom concentration by a factor of 10, and equal to at least (3.5×10) particles/m at the particle size to be measured. If the concentration is less, generate an aerosol to increase the concentration.

测量紧邻待评估表面或门口的洁净室外壳外的颗粒浓度。该浓度应比洁净室浓度大 10 倍，并且在待测颗粒尺寸下至少等于 (3.5×10) 颗粒/米。如果浓度较低，生成气溶胶以增加浓度。

To check for leakage through construction joints, cracks or service conduits, scan inside the enclosure at a distance of not more than 5 cm from the joint, seal or mating surfaces to be tested at a scan rate of approximately 5 cm/s.

为了检查通过施工缝、裂缝或维修管道的泄漏，以大约 5 厘米/秒的扫描速度，在外壳内距离待测试的接缝、密封或配合面不超过 5 厘米的位置进行扫描。

To check for intrusion at open doorways, flow visualization methods are recommended.

为了检查开放门口是否有入侵，建议使用流动可视化方法。

Record and report all readings greater than 10–2 times the measured external aerosol particle concentration at the appropriate particle size.

记录并报告所有读数，这些读数大于在适当颗粒尺寸下测量的外部气溶胶颗粒浓度的 10-2 倍。

NOTE

注意

supplier.

供应商。

The number and location of test points for this measurement are as agreed between customer and

该测量的测试点的数量和位置由客户和

B.8.2.2 Aerosol photometer method

B.8.2.2 气溶胶光度计方法

Produce an aerosol outside the cleanroom or device in accordance with B.7.2.2 in concentration high enough to cause the aerosol photometer to exceed 0,1 %.

根据 B.7.2.2，在洁净室或设备外产生浓度足以使气溶胶光度计超过 0.1% 的气溶胶。

A reading in excess of 0,01 % indicates a leak.

读数超过 0.01% 表明有泄漏。

To check for leakage through the construction joints, cracks or seams scan inside the enclosure at distance of not more than 5 cm from the joint, or seal surface to be tested, at a scan rate of approximately 5 cm/s.

为了检查通过施工缝的渗漏，裂缝或接缝在外壳内部以大约 5 厘米/秒的扫描速度扫描，扫描距离接缝或待测试密封表面不超过 5 厘米。

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To check for intrusion at open doorways, measure the concentration inside the enclosure at a distance of 0,3 m to 1 m from the open door.

要检查开放式门口是否有入侵，请在距离开放式门 0.3 米至 1 米的地方测量机柜内的浓度。

Record and report all readings in excess of 0,01 % of the photometer scale.

记录并报告超过光度计刻度 0.01%的所有读数。

B.8.3 Apparatus for containment leak test

B.8.3 安全壳泄漏测试设备

B.8.3.1 Artificially generated aerosol source, as described in B.7.5, with a valid calibration certificate;

B.8.3.1 人工生成的气溶胶源，如 B.7.5 中所述，具有有效的校准证书；

B.8.3.2 Light-scattering airborne-particle counter (LSAPC), as specified in C.8.2 (or photometer, as specified in C.8.1) with a valid calibration certificate and a lower particle size discrimination capability of 0,5 μm or smaller.

b . 8 . 3 . 2 c . 8.2 中规定的光散射空气传播颗粒计数器(LSAPC)(或 C.8.1 中规定的光度计)，具有有效的校准证书和 0.5 μm 或更小的较低颗粒尺寸辨别能力。

B.8.4 Test reports

B.8.4 测试报告

By agreement between customer and supplier, the following information and data should be recorded as described in Clause 5:

根据客户和供应商之间的协议，应按照第 5 条所述记录以下信息和数据：

a) type designations of each measuring apparatus used and its calibration status;

a)所用每个测量仪器的型号名称及其校准状态；

b) data collection technique;

b)数据收集技术；

c) measuring point locations;

c)测量点位置；

d) occupancy state(s);

(d)占用状态；

e) result of measurement.

e)测量结果。

B.9 Electrostatic and ion generator tests

B.9 静电和离子发生器测试

B.9.1 General

B.9.1 概述

This test consists of two parts. One is the electrostatic test and the other is the ion generator (ionizer) test. The purpose of the electrostatic test is to evaluate the level of electrostatic charge voltage on work and product surfaces, and the dissipation rate of electrostatic voltage of the floor, workbench top or other cleanroom or clean zone component. The static-dissipative property is evaluated by measuring surface resistance and leakage resistance on the surfaces. The ion generator test is performed to evaluate the performance of ion generators by measuring the discharge time of initially charged monitors, and by determining the offset voltage of isolated monitoring plates. The results of each measurement indicate the efficiency of eliminating (or neutralizing) static charges and the imbalance between the amount of generated positive and negative ions.

该测试由两部分组成。一个是静电测试，另一个是离子发生器测试。静电测试的目的是评估工作和产品表面的静电电压水平，以及地板、工作台顶部或其他洁净室或洁净区组件的静电电压耗散率。静电耗散性能通过测量表面电阻和表面泄漏电阻来评估。进行离子发生器测试是为了通过测量最初充电的监测器的放电时间和确定隔离监测板的偏移电压来评估离子发生器的性能。每次测量的结果表明消除(或中和)静电荷的效率以及产生的正负离子数量之间的不平衡。

B.9.2 Procedures for electrostatic and ion generator tests

B.9.2 静电和离子发生器测试程序

B.9.2.1 Procedure for electrostatic test

B.9.2.1 静电测试程序

B.9.2.1.1 Measurement of surface voltage level

B.9.2.1.1 表面电压水平的测量

The presence of positive or negative electrostatic charges on work and product surfaces is measured using an electrostatic voltmeter or fieldmeter.

使用静电电压表或电场计测量工作和产品表面上正负静电电荷的存在。

Adjust output of the electrostatic voltmeter or fieldmeter to zero by presenting the probe to face a grounded metal plate. The probe should be held such that the sensing aperture is parallel to the plate at a distance according to the manufacturer's instructions. The metal plate utilized for the zero adjustment should be of sufficient surface area for the required probe aperture size and proper probe-to-surface spacing.

将探头朝向接地金属板，将静电电压表或磁场计的输出调节为零。根据制造商的说明，探头应保持在与板平行一定距离的位置。用于调零的金属板应具有足够的表面积，以满足所需的探针孔径大小和适当的探针到表面的间距。

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Surface or leakage resistance is measured using electrodes that have appropriate weight and dimensions. These electrodes should be set at the correct distance from the surface during the measurement of surface resistance.

使用具有适当重量和尺寸的电极测量表面电阻或泄漏电阻。在测量表面电阻时，这些电极应设置在离表面正确的距离。

Specific details of the test conditions should be agreed between customer and supplier.

测试条件的具体细节应由客户和供应商商定。

B.9.2.2 Procedure for ion generator test

B.9.2.2 离子发生器测试程序

B.9.2.2.1 General

B.9.2.2.1 概述

The purpose of this test is to evaluate performance of bipolar ion generators. The test consists of measurements of both discharge time and offset voltage. The measurement of discharge time is performed to evaluate the efficiency of eliminating static charges using ion generators. Measurement of offset voltage is performed to evaluate imbalance of positive and negative ions in the ionized airflow from ion generators. An imbalance of ions can result in undesirable residual voltage.

该测试的目的是评估双极离子发生器的性能。测试包括放电时间和失调电压的测量。放电时间的测量用于评估使用离子发生器消除静电的效率。偏移电压的测量用于评估离子发生器电离气流中正负离子的不平衡。离子不平衡会导致不希望的残余电压。

These measurements are performed using conductive monitoring plates, an electrostatic voltmeter, and a timer and power source. (Sometimes apparatus consisting of those parts is known as a charged plate monitor.)

这些测量使用导电监测板、静电电压表、计时器和电源进行。(有时由这些部件组成的设备被称为充电板监控器。)

B.9.2.2.2 Measurement of discharge time

B.9.2.2.2 排放时间的测量

This measurement is performed using monitoring plates that are (isolated conductive plates) of known capacitance (e.g. 20 pF). Initially the monitoring plate is charged to a known positive or negative voltage from a power source.

使用已知电容(例如 20 pF)的监测板(绝缘导电板)进行测量。最初，监控板从电源充电到已知的正或负电压。

The change of static charge on the plate is measured while exposing the plate to the airflow that is ionized by the bipolar ion generators being evaluated. The change in plate voltage over time should be measured using an electrostatic voltmeter and a timer.

当板暴露在被评估的双极离子发生器电离的气流中时，测量板上静电荷的变化。应使用静电电压表和计时器测量极板电压随时间的变化。

Discharge time is defined as the time that is necessary for the static voltage on the plate to be reduced to 10 % of the initial voltage condition.

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b) type designations of each measuring apparatus used and its calibration status;

b)使用的每个测量仪器的型号名称及其校准状态;

c) temperature, humidity and other environmental data if relevant;

c)温度、湿度和其他相关环境数据;

d) measuring point locations;

d)测量点位置;

e)

e)

f)

f)

occupancy state(s);

占用状态;

result of measurement;

测量结果;

g) other data relevant for measurement.

g)与测量相关的其他数据。

B.10 Particle deposition test

b . 10 颗粒沉积试验

B.10.1 General

B.10.1 概述

This test describes procedures and apparatus for measuring the particle deposition of particles that deposit from the air onto product or other critical work surface in a cleanroom or clean zone. The number of particles that deposit onto a given test surface area such as a witness plate, in a given time, are sized and counted using optical microscopes, electron microscopes, surface scanning apparatus, or real-time particle deposition rate detection device to obtain the particle deposition rate data. Particle deposition rate data should be reported in terms of mass, particle area or number of particles per unit surface area per unit of time.

本试验描述了用于测量从空气中沉积到洁净室或洁净区的产品或其他关键工作表面上的颗粒沉积的程序和设备。使用光学显微镜、电子显微镜、表面扫描设备或实时粒子沉积速率检测设备来确定和计数在给定时间沉积在给定测试表面区域如见证板上的粒子数量，以获得粒子沉积速率数据。颗粒沉积速率数据应以质量、颗粒面积或每单位时间每单位表面积的颗粒数量来报告。

B.10.2 Procedure for particle deposition test

B.10.2 颗粒沉积试验程序

B.10.2.1 Collection of particles on witness plates

B.10.2.1 见证板上颗粒的收集

The witness plate, which should be at the same electrical potential as the test surface, is placed in the same plane, and adjacent to the at-risk surface during the operational state. The at-risk surface is at the

在操作状态下，应与测试表面处于相同电位的见证板放置在同一平面内，并与危险表面相邻。危险表面在

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location of interest. The following procedures and methods should be followed when manipulating and collecting particles on witness plates or another test surface:

感兴趣的位置。操作和收集见证板或另一个测试表面上的颗粒时，应遵循以下程序和方法：

a)

a)

verify that all cleanroom ventilation systems are functioning correctly, in accordance with operational requirements;

根据操作要求，验证所有洁净室通风系统运行正常；

b) identify each witness plate and clean to reduce the surface particle concentration to the lowest

b)识别每个见证板并清洁，以将表面颗粒浓度降至最低

possible level.Determine the background concentration of particles on each witness plate before exposure;

可能的水平。曝光前，确定每个见证板上颗粒的背景浓度；

c)

c)

maintain 10 % of the witness plates as controls.These should be handled in exactly the same manner as the test witness plates;

保持 10 %的见证板作为对照。这些应以与测试见证板完全相同的方式处理；

d) transport all witness plates to the test locations in such a manner as to prevent particle contamination from the air or by surface contact;

d)以防止空气或表面接触造成颗粒污染的方式将所有见证板运输到测试位置；

e)

e)

f)

f)

expose the test witness plate adjacent to an at-risk surface in the cleanroom, such as where the product is exposed to airborne contamination;

暴露洁净室中危险表面附近的测试见证板，例如产品暴露于空气污染的地方；

determine the time intervals for exposure of the test witness plates based upon the cleanroom air cleanliness and the particle counting apparatus.The exposure time should be from approximately one hour to the length of time necessary to obtain sufficient particle deposition to provide statistically valid data;

根据洁净室空气洁净度和颗粒计数设备，确定测试见证板暴露的时间间隔。暴露时间应该从大约一小时到获得足够的颗粒沉积以提供统计上有效的数据所需的时间长度；

g) expose the witness plates during the operational state;it may be necessary to expose them

g)在操作状态下暴露见证板；可能有必要揭露他们

during several manufacturing sessions to ensure that the plates are not used in unoccupied clean conditions where no product is exposed;

在几次生产过程中，确保板材不在没有产品暴露的空闲清洁条件下使用；

h) cover and collect the exposed witness plates after exposure and store in closed containers to protect from further contamination.

h)暴露后覆盖并收集暴露的见证板，并储存在封闭的容器中，以防止进一步污染。

B.10.2.2 Counting and sizing collected particles

B.10.2.2 对收集的颗粒进行计数和分级

Counting and sizing of particles collected on test surfaces should be carried out to obtain reproducible data that can be used to determine the cleanliness of the location being tested.

应对测试表面上收集的颗粒进行计数和测量，以获得可用于确定测试位置清洁度的可再现数据。

When using a witness plate, the number of particles and their sizes can be determined by one of the following means:

当使用见证板时，颗粒的数量及其尺寸可以通过以下方法之一确定：

a) optical light microscope with a calibrated linear or circular graticulate;

a)具有校准的线性或圆形网格的光学光学显微镜；

b) electron microscope with a calibrated grating with known line spacing;

b)电子显微镜，具有已知线间距的校准光栅；

c) surface scanner using size calibration information supplied by the manufacturer.

c)使用制造商提供的尺寸校准信息的表面扫描仪。

When using a witness plate, the PDR can be calculated as follows:

使用见证板时，PDR 可以计算如下：

a)

a)

count and size the particles on the measurement area of the witness plates, including the control plates and categorize them in appropriate particle size ranges, based on the cumulative particle diameters;

对包括控制板在内的见证板测量区域上的颗粒进行计数和尺寸测量，并根据累积颗粒直径将它们分类在适当的颗粒尺寸范围内；

b) subtract the values of the initial cleanliness of the witness plate from each test result;

b)从每个测试结果中减去见证板的初始清洁度值；

c)

calculate the net concentration in a given unit of measurement of surface area, and calculate the number that will deposit in a given time. When appropriate measurement units are used, this calculation yields a PDR in terms of the number of particles deposited per square metre per second.

Where multiple test results are obtained, record the mean PDR value at each location and, if appropriate, its standard deviation.

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B.10.3 颗粒沉积试验设备

各种装置可用于计数和测量沉积在测试表面上的颗粒。这些属于以下类别:

- a) light microscopes (particles larger than or equal to 2 m);
a)光学显微镜(大于或等于 2 m 的颗粒);
- b) electron microscopes (particles larger than or equal to 0,02 m);

b)电子显微镜(大于或等于 0.02 米的颗粒);

c) wafer surface scanner (particles larger than or equal to 0,01 m);

c)晶片表面扫描仪(大于或等于 0.01 米的颗粒);

d)

d)

e)

e)

PDR detection device (particles larger or equal to 5 m);

PDR 检测装置(颗粒大于或等于 5m);

real-time PDR measurement device (particles larger than 15 m).

实时 PDR 测量装置(大于 15 m 的颗粒)。

When choosing the counting and sizing apparatus, consideration should be given to the suitability to detect particles in the relevant size range. Other factors to be considered include the time required for sample collection and analysis. The apparatus used should have a valid calibration certificate.

在选择计数和上浆设备时，应考虑检测相关尺寸范围内颗粒的适用性。需要考虑的其他因素包括样本收集和分析所需的时间。使用的仪器应具有有效的校准证书。

B.10.4 Determination of sampling time and surface area

B.10.4 取样时间和表面积的确

The lower the PDR, the larger the required exposed surface area, A, and exposure time, T. The product of $A \times T$ should be large enough to allow accurate determination of the PDR. A value of 20 is suggested for use with the largest particle of interest [see Formula (B.15)]:

PDR 越低，所需的暴露表面积 a 和暴露时间 t 就越大。 $\times T$ 的乘积应该足够大，以允许 PDR 的精确测定。建议值为 20，用于感兴趣的最大的颗粒[参见公式(b15)]:

$$A \times T \geq 20$$

$$\times T \geq 20$$

(B.15)

(B.15)

where

在哪里

This test describes the procedures and apparatus required for assessment of the protective effect of a specific segregating airflow. Testing can be either across a doorway or across the perimeter of an area with a higher classification or a specific purpose different than the surrounding area. The test is

performed by generating an airborne aerosol in the lesser classified area, measuring this as the reference concentration and counting the particle concentration just across the perimeter in the protected area. The test can be performed at various selected locations along the perimeter under assessment.

本试验描述了评估特定隔离气流保护效果所需的程序和设备。测试可以跨越门口，也可以跨越与周围区域不同的更高等级或特定目的区域的周界。通过在较低分类区域产生空气悬浮微粒，测量其作为参考浓度，并计算保护区周边的微粒浓度来进行测试。该测试可在评估周边的不同选定位置进行。

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This test should be preceded by a classification of air by particles test in the surroundings as well as the protected area to determine the baseline particle concentration level. The challenging particle concentration should be of sufficient level to be able to assess the protection factor.

在此测试之前，应通过环境和保护区中的颗粒测试对空气进行分类，以确定基线颗粒浓度水平。具有挑战性的粒子浓度应足够高，能够评估保护因子。

NOTE Airflow direction test and visualization can be performed to identify the perimeter of the protected area.

注意:可以进行气流方向测试和可视化，以确定受保护区域的周界。

B.11.2 Procedure

B.11.2 程序

B.11.2.1 Generation of reference concentration

B.11.2.1 参考浓度的产生

To challenge the protective airflow in the surroundings, a sufficient number of particles should be generated. Recommended test aerosol particles are described in C.5.3. The mean particle size should be 0.5 μ m and greater unless an alternative size is agreed between customer and supplier.

为了挑战周围的保护气流，应该产生足够数量的颗粒。C.5.3 中描述了推荐的测试气溶胶颗粒。除非客户和供应商同意另一种尺寸，否则平均颗粒尺寸应为 0.5 μ m 或更大。

In order to be sufficient, the following should be considered:

为了做到充分，应考虑以下几点：

a)

a)

verify that all cleanroom systems are functioning correctly, in accordance with an agreed occupancy state;

验证所有洁净室系统是否按照约定的占用状态正常运行；

b) to establish the challenging concentration, the protective effect to be verified should be used to

b) 为了确定具有挑战性的浓度，应使用待验证的保护效果来

calculate the number of challenging particles based on the anticipated particle concentration within the protected zone. This anticipated concentration should at least be 10 times the baseline count in the point to be verified.

根据受保护区域内的预期粒子浓度，计算具有挑战性的粒子数量。该预期浓度至少应为待验证点基线计数的 10 倍。

B.11.2.2 Equipment geometry

B.11.2.2 设备几何形状

Test equipment geometry should be determined. The probe(s) in the protected area should not be more than 0.1 m from the determined air barrier. The challenge concentration probe in the lesser classified area should not be more than 1 m from the determined air barrier (between aerosol generator and air barrier). The aerosol generator should be positioned approximately 1 m to 1.5 m from the challenge concentration probe.

应确定测试设备的几何形状。保护区内的探头距离确定的空气屏障不应超过 0.1m。较低分类区域中的挑战浓度探头距离确定的空气屏障(气溶胶发生器和空气屏障之间)不应超过 1 米。气溶胶发生器应位于距离挑战浓度探针约 1 米至 1.5 米的位置。

NOTE The number of locations where the protected effect is determined depends of the perimeter, the form of the protected area and agreement between the customer and supplier.

注意:确定受保护效果的位置数量取决于周长、受保护区域的形式以及客户和供应商之间的协议。

B.11.2.3 Procedure of measurement

a) The sample times should be determined based on ISO146441:2015, A.4.4. b) Begin the generation of particles in the lesser classified side of the air barrier assuring that the

momentum of the challenge leaving the test apparatus does not overpower the air barrier.c) Record particle concentration in the lesser classified area at each probe(s).A minimum of three 1-minute measurements should be taken.

[illegible][illegible]

d)

注意

测量高浓度时可能需要稀释装置。

record the particle concentration in the protected area at each probe(s). A minimum of three 1-minute measurements should be taken.

记录每个探针保护区的粒子浓度。至少应进行三次 1 分钟的测量。

B.11.2.4 计算保护指数

The protection index is calculated with Formula (B.16):

保护指数用公式(B16)计算:

$$\text{PIX} = -\log (\text{CX}/\text{CRef})$$

PIX =- 日志(CX/CRef)

where

在哪里

(B.16)

(B.16)

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CRef

CRef

CX

CX

PIX

照片

is the reference particle concentration, expressed in p/m, for particles $\geq 0,5 \mu\text{m}$ (challenge concentration) of the nearest reference particle counter, (guidance value: $>5 \times 10/\text{m}$).

是最近的参考粒子计数器的粒子 ≥ 0.5 微米(挑战浓度)的参考粒子浓度，以 p/m 表示，(指导值: $> 5 \times 10/\text{m}$)。

is the average particle concentration at measuring point x, expressed in p/m, for particles $\geq 0,5 \mu\text{m}$;

对于 ≥ 0.5 微米的粒子，测量点 x 处的平均粒子浓度，以 p/m 表示；

is the protection index;

是保护指数；

B.11.3 Test reports

B.11.3 测试报告

By agreement between the customer and supplier, the following information and data should be recorded as described in Clause 5:

根据客户和供应商之间的协议，应按照第 5 条所述记录以下信息和数据:

a) designation of the type of each measuring apparatus used and its calibration status;

a)指定所使用的每个测量仪器的类型及其校准状态;

b) data collection technique;

b)数据收集技术;

c) measuring point locations;

c)测量点位置;

d) occupancy state(s);

(d) 占用状态;

e)

e)

[illegible]

- / / / / / / / / / / / / / / / / - / / / / / / / / / / / / -

result of measurement.

测量结果。

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Annex C

附件三

(informative)

(信息性)

Test apparatus

试验装置

C.1 General

C.1 概述

Annex C describes the measuring apparatus that should be used for the recommended tests given in this document.

附录 C 描述了用于本文件中给出的推荐试验的测量仪器。

Data given in Tables C.1 to C.9 indicate the minimum necessary requirements for each item of apparatus. Items are listed and numbered to correspond with Annex B. Those responsible for planning tests can refer to Annex C for the selection of test apparatus and to Annex A for a checklist of recommended tests of an installation and the sequence in which to carry them out. Measuring apparatus should be chosen subject to agreement between the customer and supplier.

表 C1 至 C9 中给出的数据表明了每种设备的最低必要要求。项目的列出和编号与附件 b 一致。负责计划测试的人员可以参考附件 C 选择测试设备，参考附件 A 选择建议的安装测试清单及其执行顺序。应根据客户和供应商之间的协议选择测量仪器。

This annex does not prevent the use of improved apparatus as it becomes available. Alternative test apparatus can be appropriate and may be used subject to agreement between customer and supplier.

本附件不妨碍使用现有的改进设备。替代测试设备可能是合适的，并且可以根据客户和供应商之间的协议使用。

Test apparatus should be selected with measurement limits and range that are appropriate for its application. The apparatus should also be calibrated with calibration points covering the range of its intended use. All test apparatus sensitivity (3.1.7) should be 1.

测试设备的选择应具有适合其应用的测量极限和范围。仪器还应使用涵盖其预期用途范围的校准点进行校准。所有测试仪器灵敏度(3.1.7)应为 1。

Minimum requirements for test apparatus are given in this annex with a requirement specified for maximum permissible error. Below is an explanation of how the maximum permissible error for an air velocity meter can be estimated.

本附件给出了测试设备的最低要求，并规定了最大允许误差的要求。以下是如何估算空气速度计最大允许误差的说明。

There are at least three contributions to the maximum permissible error:

最大允许误差至少有三个因素:

— the expanded calibration uncertainty (given in the calibration certificate);

— 扩展的校准不确定度(在校准证书中给出);

— the sum of the random errors' absolute values (after correcting for systematic errors, random errors[] still remain. Each of these give rise to variations in repeated observations of the quantity to be measured);

— 随机误差绝对值之和(校正系统误差后, 随机误差[])仍然存在。每种情况都会导致重复观察待测量的变化);

— yearly drift.

— 年漂移。

For the purpose of this example, the expanded calibration uncertainty has been given as 0,025 m/s, the sum of the random errors is 0,03 m/s and the yearly drift is 0,005 m/s.

出于本例的目的, 扩展校准不确定度被给出为 0, 025 米/秒, 随机误差之和为 0, 03 米/秒, 年漂移为 0, 005 米/秒

Adding these three contributions gives 0,06 m/s. Assuming the errors are symmetric around 0, this gives the values for the limits of error (maximum permissible errors) of 0,06 m/s.

将这三个贡献相加得到 0.06 米/秒。假设误差在 0 左右对称, 这给出了 0.06 米/秒的误差极限值(最大允许误差)

NOTE This value of 0,06 m/s is not an uncertainty. Instead, the limits of error indicate the interval inside which the measurement error is permitted to be[].

注:0.06 米/秒的数值不是不确定性。相反, 误差极限表示允许测量误差为[的时间间隔]。

C.2 Air pressure difference test

C.2 空气压差测试

C.2.1 General

C.2.1 概述

表 C1 给出了空气压差测试设备的最低要求

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Table C.1 — Air pressure difference test apparatus

表 C1—气压差测试设备

| | |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Item | Minimum requirements |
| Measuring limits | N/A |
| Resolution | 0,5 Pa (0 Pa-49,9 Pa) 1,0 Pa (≥ 50 Pa) |
| Maximum permissible error | The greater of 2 Pa or 5 % of reading (Mechanical gauges can be used for continuous monitoring reference but not for testing due to potential errors) |

| 项目 | 最低要求 |
|----|------|
|----|------|

| | |
|--------|-------------------------------------------------------|
| 测量极限 | 不适用 |
| 解决 | 0.5 帕(0 帕-49.9 帕)1.0 帕(≥ 50 帕) |
| 最大容许误差 | 2 Pa 或读数 5 %中的较大者 (由于潜在误差, 机械仪表可用于连续监控参考, 但不能用于测试) |

C.2.2 Electronic manometer, to display or output the value of the air pressure difference between a cleanroom or clean zone and its surroundings by detecting the change of electrostatic capacitance or electronic resistance due to the displacement of a diaphragm.

C.2.2 电子压力计, 通过检测由隔膜位移引起的静电电容或电子电阻的变化, 显示或输出洁净室或洁净区与其周围环境之间的气压差值。

C.2.3 Inclined manometer, to measure the air pressure difference between two points, by detecting with the eye amplitude inclined scales which indicate the small pressure head (height) in a gauge tube filled with liquid such as water or alcohol. Care shall be taken when using this type of measuring device. It should be level and used in a fixed position.

C.2.3 倾斜压力计, 通过用眼睛幅度检测倾斜刻度来测量两点之间的空气压力差, 倾斜刻度表示充满液体(如水或酒精)的测量管中的小压头(高度)。使用这种类型的测量装置时应小心。它应该是水平的, 并在固定的位置使用。

C.2.4 Mechanical differential pressure gauge, to measure the air pressure difference between two areas by detecting the movement distance of a needle connected with a mechanical gear or magnetic linkage to the displacement of a diaphragm. Care shall be taken when using this type of measuring device. It should be level and used in a fixed position.

C.2.4 机械压差表, 通过检测与机械齿轮或磁性连杆相连的针相对于隔膜位移的移动距离来测量两个区域之间的空气压差。使用这种类型的测量装置时应小心。它应该是水平的, 并在固定的位置使用。

Careful consideration should be given to selecting the appropriate gauge range when using this apparatus.

使用该仪器时, 应仔细考虑选择合适的量程。

C.3 Airflow test

C.3 气流测试

C.3.1 Air velocity meter

C.3.1 空气速度计

C.3.1.1 General

C.3.1.1 概述

The minimum requirements for the air velocity test apparatus are given in Table C.2.

表 C2 给出了空气速度测试设备的最低要求

| | |
|---------------------------|-------------------------------------------------------------|
| Item | Minimum requirements |
| Measuring limits | N/A |
| Resolution | 0,01 m/s (0,20 m/s-0,99 m/s) 0,1 m/s ($\geq 1,00$ m/s) |
| Maximum permissible error | 0,1 m/s (0,20 m/s-1,00 m/s) 10 % of reading ($> 1,00$ m/s) |

| | |
|--------|--------------------------------------------------------|
| 项目 | 最低要求 |
| 测量极限 | 不适用 |
| 解决 | 0, 01 米/秒(0, 20 米/秒-0, 99 米/秒)0, 1 米/秒 (≥1, 00 米/秒) |
| 最大容许误差 | 读数的 0.1 米/秒(0.20 米/秒-1, 00 米/秒)10 % (大于 1, 00 米/秒) |

C.3.1.2 Thermal anemometer, to calculate air velocity by measurement of the heating power necessary to maintain the electrically heated sensor, exposed to the airflow, at a fixed temperature.

C.3.1.2 热风速计，通过测量将暴露在气流中的电加热传感器保持在固定温度所需的加热功率来计算空气速度。

C.3.1.3 Three-dimensional ultrasonic anemometer, or equivalent, to measure air velocity by sensing the shift of sound frequency (or acoustic velocity) between separated points in the measured airflow.

C.3.1.3 三维超声波风速计或等效物，通过感测测量气流中分离点之间的声音频率(或声速)变化来测量空气速度。

C.3.1.4 Vane-type anemometer, to measure air velocity by counting the revolution rate of the vanes in the airflow.

C.3.1.4 叶片式风速计，通过计算气流中叶片的转速来测量空气速度。

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C.3.1.5 Pitot-static tubes and manometer, to measure air velocity from the difference of total and static pressures at a position in the airflow.

C.3.1.5 皮托管和压力计，根据气流中某一位置的总压和静压差测量空气速度。

C.3.1.6 Tube array, to measure air velocity from the difference of total and static pressures at a position in the airflow. Averaging airflow grids use multiple tube arrays to simultaneously measure airflow on a grid and provide an average velocity, using an electrical multi-meter manometer.

C.3.1.6 管道阵列，根据气流中某一位置的总压和静压差测量空气速度。平均气流网格使用多个管阵列同时测量网格上的气流，并使用多米电子压力计提供平均速度。

C.3.2 Airflow meter

C.3.2 气流计

C.3.2.1 General

C.3.2.1 概述

The minimum requirements for the air volume flow rate test apparatus are given in Table C.3.

表 C3 给出了空气体积流量测试设备的最低要求

| Item | Minimum requirements |
|---------------------------|-----------------------------------------------------|
| Measuring limits | N/A |
| Resolution | 0,001 m/s |
| Maximum permissible error | 0,01 m/s (0 m/s-0,1 m/s) 10 % of reading (>0,1 m/s) |

| | |
|--|--|
| | |
|--|--|

| | |
|--------|---------------------------------------------|
| 项目 | 最低要求 |
| 测量极限 | 不适用 |
| 解决 | 0, 001 米/秒 |
| 最大容许误差 | 读数的 0.01 米/秒(0 米/秒-0.1 米/秒)10 %(大于 0.1 米/秒) |

C.3.2.2 Airflow capture hood with measuring device, to measure air volume flow rate from an area over which there can be variations in airflow, providing an integrated air volume from that area. The total airflow is collected and concentrated so that the velocity at the measuring point represents the cross-sectional average velocity from the total area.

C.3.2.2 带有测量装置的气流捕获罩，用于测量气流可能变化的区域的空气体积流量，提供该区域的综合空气体积。收集并集中总气流，使测量点的速度代表总面积的横截面平均速度。

C.3.2.3 Orifice

C.3.2.3 孔板

C.3.2.4

C.3.2.4

meter, refer to ISO 5167-2[] .

仪表，参考国际标准化组织 5167-2【】。

Venturi meter, refer to ISO 5167-4[] .

文丘里流量计，参考国际标准化组织 5167-4【】。

C.4 Airflow direction test and visualization

C.4 气流方向测试和可视化

C.4.1 Apparatus, materials and accessories for airflow direction test and visualization, see Tables B.1 and B.2.

C.4.1 气流方向测试和可视化的设备、材料和附件，见表 B.1 和 B.2

C.4.2

C.4.2

C.4.3

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邻苯二甲酸二辛酯(2-乙基己基)(DOP1))(例如化学文摘社编号 117-81-72);

e)

e)

f)

f)

food quality mineral oil (e.g. CAS No. 8042-47-5);

食品质量矿物油(如化学文摘社编号 8042-47-5);

paraffin oil (e.g. CAS No. 64742-46-7);

石蜡油(如化学文摘社编号 64742-46-7);

g) microspheres with an appropriate diameter.

g)具有适当直径的微球。

If the required concentration can be achieved, atmospheric aerosol may also be used.

如果能够达到要求的浓度，也可以使用大气气溶胶。

C.5.4 Dilution system, equipment, in which the aerosol is mixed with clean air in a known volumetric ratio to reduce concentration.

C.5.4 稀释系统、设备，其中气溶胶与清洁空气以已知的体积比混合，以降低浓度。

C.6 Temperature test

C.6 温度测试

The temperature test should be performed using a sensor that has accuracy as defined in ISO 7726, [] for example:

温度测试应使用具有国际标准化组织 7726(I)中定义的精确度的传感器进行，例如：

a)

a)

expansion thermometers;

膨胀温度计；

1) liquid expansion thermometer;

1)液体膨胀温度计

2) solid expansion thermometer;

2) 固体膨胀温度计;

b) electrical thermometers;

b) 电温度计;

c)

c)

1) variable resistance thermometer, including;

1) 可变电阻温度计, 包括;

— platinum resistor;

— 铂电阻

— thermistor;

热敏电阻

2) thermometer based on the generation of an electromotive force (thermocouple);

2) 基于电动势产生的温度计(热电偶);

thermomanometers (variation in the pressure of a liquid as a function of temperature).

热压力计(液体压力随温度的变化)。

1) In certain countries, the use of DOP for filter testing is discouraged on safety grounds.

1) 在某些国家, 出于安全考虑, 不鼓励使用 DOP 进行过滤器测试。

2) CAS No., Chemical Abstract Service Registry Number, substances have been registered in Chemical Abstract, issued by American Chemical Society[] .

2) 化学文摘社登记号, 化学文摘社登记号, 物质已在美国化学学会[分会发布的《化学文摘》中登记。

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The minimum measurement resolution requirement for the apparatus is 20 % of the allowable temperature range for the difference between the set point temperature and the permissible range of variation allowed from that set point.

该设备的最小测量分辨率要求是设定点温度和该设定点允许的允许变化范围之差的允许温度范围的 20 %。

NOTE The requirement of range, accuracy, etc., depends on the purpose of the cleanroom or clean zone.ISO 7726[] is for a general purpose.

注意范围、准确度等的要求。，取决于洁净室或洁净区的用途。国际标准化组织 7726[]是通用的。

C.7 Humidity test

C.7 湿度测试

Humidity tests should be performed using a sensor that has accuracy appropriate to the measurement as stated in ISO 7726[.]

湿度测试应使用符合国际标准化组织 7726[所述测量精度的传感器进行。

Typical sensors are:

典型的传感器有：

a) dewpoint hygrometers (e.g. psychrometer);

a)露点湿度计(例如干湿表);

b) electrical conductivity variation hygrometer;

b)电导率变化湿度计;

1) lithium chloride hygrometer;

1)氯化锂湿度计;

2) capacitance hygrometer.

2)电容湿度计。

The minimum measurement resolution for the apparatus should be 20 % of the allowable relative humidity range for the difference between the set point humidity and the permissible range of variation allowed from that set point.

仪器的最小测量分辨率应为设定点湿度和该设定点允许变化范围之差的允许相对湿度范围的 20 %。

NOTE The requirement of range, accuracy, etc., depends on the purpose of the cleanroom or clean zone.ISO 7726 is for a general purpose.

注意范围、准确度等的要求。，取决于洁净室或洁净区的用途。国际标准化组织 7726 是通用的。

C.8 Installed filter system leakage test

C.8 安装的过滤系统泄漏测试

C.8.1 Aerosol photometer, to measure the mass concentration of aerosols in milligrams per cubic meter (mg/m).The aerosol photometer uses a forward scattered-light optical chamber to make this measurement.This apparatus may be used to measure filter leak penetration directly.

C.8.1 气溶胶光度计，用于测量气溶胶的质量浓度，单位为毫克每立方米(毫克/米)。气溶胶光度计使用前向散射光光学室进行测量。该设备可用于直接测量过滤器泄漏渗透率。

The minimum requirements for the aerosol photometer are given in Table C.4.

表 C4 给出了气溶胶光度计的最低要求

Table C.4 — Aerosol photometer

表 C.4 —气溶胶光度计

Item Minimum requirements

项目最低要求

Measuring limits 0,000 1 mg/m to 100 mg/mResolution 0,000 1

测量限值 0, 000 1 毫克/米至 100 毫克/米解决方法 0, 000 1

Maximum permissible error 10 % for the selected range

选定范围的最大允许误差为 10 %

Sample probe tubing dimensions (length and internal diameter) should comply with manufacturer's recommendations.

样本探针管道尺寸(长度和内径)应符合制造商的建议。

NOTE

注意

C.8.2

C.8.2

C.8.3

C.8.3

C.8.4

C.8.4

C.8.5

C.8.5

Sample probe inlet dimensions are detailed in B.7.2.2.

样本探针入口尺寸详见 B.7.2.2

Light-scattering airborne-particle counter (LSAPC), see C.5.1.

光散射空气粒子计数器, 见 C.5.1

Aerosol generator, see C.5.2.

气溶胶发生器, 见 C.5.2

Test aerosol source substances, see C.5.3.

测试气溶胶源物质，见 C.5.3

Dilution system, equipment, see C.5.4.

稀释系统、设备, 见 C.5.4

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C.9 Containment leak test

C.9 安全壳泄漏测试

C.9.1

C.9.1

C.9.2

C.9.2

C.9.3

C.9.3

C.9.4

C.9.4

C.9.5

C.9.5

Light-scattering airborne-particle counter, see C.5.1.

光散射空气粒子计数器, 见 C.5.1

Aerosol generator, see C.5.2

气溶胶发生器, 见 C.5.2

Aerosol source substances, see C.5.3.

气溶胶源物质, 见 C.5.3

Dilution system, see C.5.4.

稀释系统, 见 C.5.4

Aerosol photometer, see C.8.1.

气溶胶光度计, 见 C.8.1

C.10 Electrostatic and ion generator test

C.10 静电和离子发生器测试

C.10.1 Electrostatic voltmeter, to measure the average voltage (potential) in a small area by sensing the intensity of the electrical field at an electrode inside a probe through a small aperture in the probe.

C.10.1 静电电压表，通过探头上的小孔检测探头内电极上的电场强度，测量小面积内的平均电压(电势)。

The minimum requirements for an electrostatic voltmeter are given in Table C.5.

表 C.5 给出了静电电压表的最低要求

Table C.5 — Specification for electrostatic voltmeter

表 C.5 — 静电电压表规范

Item Minimum requirements

项目最低要求

Measuring limits (1-20) kV Resolution 10 V (1 kV-20 kV) Maximum permissible error 10 % of reading

测量极限(1-20 千伏)分辨率 10 伏(1 千伏-20 千伏)最大允许误差 10 %读数

C.10.2 High resistance ohm-meter, to measure the resistance of insulation materials and components by sensing leakage current from a device applying high voltage to a device under test.

C.10.2 高阻欧姆表，通过检测向被测设备施加高压的设备的泄漏电流来测量绝缘材料和部件的电阻。

The minimum requirements for the high resistance ohm-meter are given in Table C.6.

表 C.6 给出了高阻欧姆表的最低要求

Table C.6 — Specifications for high resistance ohm-meter

表 c . 6——高阻欧姆表规范

| Item | Minimum requirements |
|---------------------------|------------------------|
| Measuring limits | 1 000 Ω to 20 GΩ |
| Resolution | 0,01 MΩ |
| Maximum permissible error | 5 % of each full scale |
| Test voltage | DC 100 V to 1 000 V |

C.10.3 Charged plate monitor, to measure the neutralizing properties of an ionizer or ionization system.

C.10.3 带电平板监视器，用于测量电离器或电离系统的中和特性。

The minimum requirements for the charged plate monitor are given in Table C.7.

C.11.1 Witness plate material. Depending on particle size to be detected and means of measurement the following may be used:

C.11.1 见证板材料。根据要检测的颗粒尺寸和测量方法，可以使用以下方法：

a) micro-porous membrane filters;

a)微孔膜过滤器；

b) double-sided adhesive tape;

b)双面胶带；

c) petri dishes;

c)培养皿；

d) petri dishes containing a contrasting colour (black) polymer, such as polyester resin;

d)含有对比色(黑色)聚合物如聚酯树脂的培养皿；

e)

e)

f)

f)

photographic film (sheet);

摄影胶片(片)；

microscope slides (plain or with evaporated metal film coating);

显微镜载玻片(普通或蒸发金属薄膜涂层)；

g) glass or metal mirror plates;

g)玻璃或金属镜板；

h) semiconductor wafer blanks;

h)半导体晶片坯料；

i)

I)

j)

j)

glass photo mask substrates;

玻璃光掩模基板；

transparent plastic plate.

透明塑料板。

The surface smoothness of the witness plate should be appropriate for the size of the particles that are counted to ensure that the particles are easily visible. The selected witness plate material should be electrostatic neutral. The means of measurement employed should be capable of resolving and measuring the smallest particle size to be enumerated. Witness plates that need to be transparent should be free of defects.

见证板的表面光滑度应与被计数颗粒的尺寸相适应，以确保颗粒易于看见。所选的见证板材料应为静电中性。所采用的测量方法应该能够分辨和测量要列举的最小颗粒尺寸。需要透明的见证板应无缺陷。

Particle deposition can be determined by measuring the area coverage of deposited particles or by counting (and sizing) of particles deposited on the witness plate during exposure. Particle deposition measurement can be divided into particle sizes within the air cleanliness level range (0,1 m to 5,0 m) and macro particles (larger than or equal to 5 m).

颗粒沉积可以通过测量沉积颗粒的面积覆盖率或通过对曝光期间沉积在见证板上的颗粒进行计数(和测量尺寸)来确定。颗粒沉积测量可分为空气洁净度水平范围内的颗粒尺寸(0.1m 至 5.0m)和大颗粒尺寸(大于或等于 5 m)。

| Item | Minimum requirements |
|---------------------------|-----------------------------------------------------------------------|
| Measuring limits | Surface number concentration: 1/cmto 10/cmParticle size: 0,1 m to 5 m |
| Resolution | Particle size: 0,1 m |
| Maximum permissible error | Particle size: 1 m |

| 项目 | 最低要求 |
|--------|-----------------------------------|
| 测量极限 | 表面数浓度:1/cmto 10/cm 颗粒度:0.1m 至 5 m |
| 解决 | 粒度:0.1 米 |
| 最大容许误差 | 粒度:1 米 |

Table C.9 — Particle deposition measurement macro particles test apparatus

表 C.9 —颗粒沉积测量宏观颗粒测试设备

| Item | Minimum requirements |
|------|----------------------|
|------|----------------------|

C.12 Segregation test

C.12 离析试验

C.12.1 Light-scattering airborne-particle counter, see C.5.1.

C.12.1 光散射空气粒子计数器，见 C.5.1

C.12.2 Aerosol generator, see C.5.2.

C.12.2 气溶胶发生器，见 C.5.2

C.12.3 Aerosol source substances, see C.5.3.

C.12.3 气溶胶源物质，见 C.5.3

C.12.4 Dilution system, see C.5.4.

C.12.4 稀释系统，见 C.5.4

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Bibliography

文献学

[1]

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ISO 14644-1:2015, Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration

国际标准化组织 14644-1:2015, 洁净室及相关受控环境第 1 部分:空气洁净度的颗粒浓度分类

ISO 14644-2, Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

国际标准化组织 14644-2, 洁净室及相关受控环境第 2 部分:通过颗粒浓度提供洁净室空气洁净度相关性
能证据的监测

ISO 14644-4, Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up

国际标准化组织 14644-4, 洁净室和相关受控环境第 4 部分:设计、施工和启动

ISO 14644-7:2004, Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

国际标准化组织 14644-7:2004, 洁净室和相关受控环境第 7 部分:分离装置(洁净空气罩、手套箱、隔离
器和小型环境)

ISO 14644-8, Cleanrooms and associated controlled environments — Part 8: Classification of air cleanliness by chemical concentration (ACC)

国际标准化组织 14644-8, 洁净室和相关受控环境第 8 部分:按化学浓度对空气洁净度进行分类

ISO 14644-9, Cleanrooms and associated controlled environments — Part 9: Classification of surface cleanliness by particle concentration

国际标准化组织 14644-9, 洁净室和相关受控环境第 9 部分:按颗粒浓度对表面洁净度的分类

ISO 14644-10, Cleanrooms and associated controlled environments — Part 10: Classification of surface cleanliness by chemical concentration

国际标准化组织 14644-10, 洁净室和相关受控环境第 10 部分:按化学浓度对表面洁净度的分类

ISO 14644-12, Cleanrooms and associated controlled environments — Part 12: Specifications for monitoring air cleanliness by nanoscale particle concentration

国际标准化组织 14644-12, “洁净室和相关受控环境” 第 12 部分:用纳米级颗粒浓度监测空气洁净度的规范

ASME N510-1989, Testing of Nuclear Air-Treatment Systems

ASME N510-1989, 核空气处理系统的试验

ASTM F24-00, Standard Method for Measuring and Counting Particulate Contamination on Surfaces

美国材料试验标准 F24-00, 测量和计数表面颗粒污染的标准方法

ASTM F50-92, Standard Practice for Continuous Sizing and Counting of Airborne Particles in Dust-Controlled Areas and Clean Rooms Using Instrument Capable of Detecting Single Sub-Micrometre and Larger Particles

美国材料试验标准 F50-92, 使用能够检测单个亚微米和更大颗粒的仪器在粉尘控制区域和洁净室中连续测量和计数空气中颗粒的标准实施规程

ASTM F312-97, Standard Test Methods for Microscopical Sizing and Counting Particles from Aerospace Fluids on Membrane Filters

美国材料试验学会 F312-97, 薄膜过滤器上航空航天流体微粒显微镜测量和计数的标准试验方法

ASTM F1471-93, Standard Test Method for Air Cleaning Performance of a High-Efficiency Particulate Air-Filter System

美国材料试验标准 F1471-93, 高效微粒空气过滤系统空气净化性能的标准试验方法

Chemical Abstracts Service Registry, Columbus, Ohio, US: American Chemical Society

美国俄亥俄州哥伦布市化学文摘服务登记处:美国化学学会

EN 1822-2, High efficiency air filters (HEPA and ULPA) — Part 2: Aerosol production, measuring equipment, particle counting statistics

欧洲标准 1822-2, 高效空气过滤器(HEPA 和 ULPA)——第 2 部分:气溶胶生产、测量设备、颗粒计数统计

EN 1822-4, High efficiency air filters (HEPA and ULPA) — Part 4: Determining leakage of filter element (scan method)

欧洲标准 1822-4, 高效空气过滤器(HEPA 和 ULPA)-第 4 部分:过滤元件泄漏的测定(扫描法)

IEST-RP-CC001 6:2016, HEPA and ULPA Filters

IEST-RP-CC001 6:2016, HEPA 和 ULPA 过滤器

IEST-RP-CC006 3:2004, Testing Cleanrooms

IEST-RP-CC006 3:2004, 测试洁净室

IEST-RP-CC007 3:2016, Testing ULPA Filters

IEST-RP-CC007 3:2016, 测试 ULPA 过滤器

IEST-RP-CC021 4:2016, Testing HEPA and ULPA Filter Media

IEST-RP-CC021 4:2016, 测试 HEPA 和 ULPA 过滤介质

IEST-RP-CC034 4:2016, HEPA and ULPA Filter Leak Tests

IEST-RP-CC034 4:2016, HEPA 和 ULPA 过滤器泄漏测试

ISO 5167-2, Measurement of fluid flow by means of pressure differential devices inserted in circular cross-section conduits running full — Part 2: Orifice plates

国际标准化组织 5167-2，用插入满负荷运行的圆形横截面导管中的压差装置测量流体流量第 2 部分：孔板

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ISO 5167-4, Measurement of fluid flow by means of pressure differential devices inserted in circular cross-section conduits running full — Part 4: Venturi tubes

国际标准化组织 5167-4，用插入满负荷运行的圆形横截面导管中的压差装置测量流体流量第 4 部分:文丘里管

ISO 5167-5, Measurement of fluid flow by means of pressure differential devices inserted in circular cross-section conduits running full — Part 5: Cone meters

国际标准化组织 5167-5，用插入满负荷运行的圆形横截面导管中的压差装置测量流体流量第 5 部分:锥形流量计

No JACA 24:1989, Standardization and Evaluation of Clean Room Facilities

JACA 24:1989，《洁净室设施的标准化与评价》

JIS B 9921, Light scattering automatic particle counter. Japanese Industrial Standards Committee

JIS B 9921，光散射自动粒子计数器。日本工业标准委员会

SEMI E14-93, Measurement of particle contamination contributed to the product from the process or support tool

SEMI E14-93，颗粒污染的测量有助于工艺或支持工具的产品

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