

Fundamentals of Cleanroom

洁净室基本知识



W I N I F R E D

Abstract 概要

- Glossary and definitions
术语和定义
- Cleanroom standards
洁净室相关标准
- The principals of how a cleanroom works
洁净室工作原理
- Contamination control in cleanroom
洁净室的污染控制
- Cleanroom operation
洁净室设备

Glossary and definitions

术语和定义

- **Micron:** More properly, micrometer; a length equal to one millionth of a meter, often written μm .
微米: 长度单位, 等于百万分之一米, 常用 μm 表示。
- **Angstrom (\AA):** Unit of length, $1\text{ \AA}=1\times 10^{-10}\text{m}$, $10000\text{ \AA}=1\text{ }\mu\text{m}$
埃(\AA): 长度单位, $1\text{ 埃}=1\times 10^{-10}\text{米}$, $10000\text{ 埃}=1\text{微米}$
- **HEPA Filter:** Acronym for **H**igh **E**fficiency **P**articulate **A**ir filter, typical filter efficiencies for HEPA filters are 99.997% @ $0.3\text{ }\mu\text{m}$ diameter
高效空气微粒过滤器: 典型过滤效率为99.997% @ $0.3\text{ }\mu\text{m}$ 直径粒子
- **ULPA Filter:** Acronym for **U**ltra-**L**ow **P**articulate **A**ir filter, typical efficiencies for ULPA filters are 99.999997% @ $0.12\text{ }\mu\text{m}$ diameter
超高效空气微粒过滤器: 典型过滤效率为99.999997% @ $0.12\text{ }\mu\text{m}$ 直径粒子
- **Particulate Contaminants:** Solid particles in the 0.01 to $100\text{ }\mu\text{m}$ size range
微粒污染物: 大小在 0.01 to $100\text{ }\mu\text{m}$ 之间的实心微粒。

Glossary and definitions

术语和定义

- **AMC:** Acronym for **A**irborne **M**olecular **C**ontamination, chemical contamination that occurs upon exposure to airborne gases and vapors during product handling, storage and transport.
空气传播分子污染：在产品的搬运、储存和运输过程中暴露在空气传播的气体和蒸气下所造成的化学污染。
- **Ion:** An atom or group of atoms carry a positive or negative charge as a result of having gained or lost one or more electrons.
离子：得到或失去一个或一个以上电子的带正电荷或负电荷的原子或原子群。
- **FFU:** Acronym for **F**an **F**ilter **U**nit, often with an HEPA/ULPA filter underneath.
风机过滤器单元：配合HEPA或ULPA过滤器使用的一种末端送风过滤系统。

Glossary and definitions

术语和定义

- **Class:** As defined in FED STD 209, international Standard ISO 14644 the number of particles found per volume of air.
洁净度等级：如同联邦标准209和国际标准ISO 14644规定的，单位容积空气中发现的粒子的数量。
- **Clean Zoom:** A defined space in which the concentration of airborne particles is controlled to met a specified airborne cleanliness class.
洁净区：空气中微粒的数量控制在规定的洁净度等级范围内的特定区域。
- **Cleanroom:** An enclosed area with control over airborne particles as well as other factors as needed (such as air velocity and direction, temperature, humidity, pressure, molecular contamination)
洁净室：根据需要对空气的传播粒子和其他因素进行控制（例如气流速度和方向、温度、湿度、压力、分子污染等）的一个密闭区域。

Glossary and definitions

术语和定义

- **As-Built Cleanroom:** A cleanroom that is complete and ready for operation, with all services connected and functional, but without equipment of operating personnel in the facility.

空态洁净室：已经建造完成并可以投入使用的洁净室，它具备所有相关的功能，但是室内没有任何生产设备和操作人员。

- **At-Rest Cleanroom:** A cleanroom that is complete with all services connected functioning and with equipment installed and operable or operating, as specified, but without operating personnel in the facility.

静态洁净室：室内各种设备安装完毕，可以随时投入运行的洁净室。但是室内没有操作人员。

- **Operational Cleanroom:** A cleanroom in normal operation with services functioning and with equipment and personnel.

动态洁净室：处于正常使用的洁净室，包括所有的设备和操作人员。

Cleanroom Standards

洁净室相关标准

~~FED STD 209E~~

CANCEL

Cleanroom Standards

洁净室相关标准

ISO TC209

- 14644-1: Cleanrooms and Associated Controlled Environments
Part 1, Classification of air cleanliness.
洁净室与相关的受控环境 第一部分：空气洁净度的分级。
- 14644-2: Cleanrooms and Associated Controlled Environments
Part 2, Specifications for testing and monitoring to prove continued compliance with ISO 14644-1.
洁净室与相关的受控环境 第二部分：保证ISO14644-1持续有效的检测与监测规范。
- 14644-3: Cleanrooms and Associated Controlled Environments
Part 3, Metrology and test methods.
洁净室与相关的受控环境 第三部分：计量与测试方法。

Cleanroom Standards

洁净室相关标准

ISO TC209

- 14644-4: Cleanrooms and Associated Controlled Environments
Part 4, Design, construction and start up.
洁净室与相关的受控环境 第四部分：设计、建造与启动。
- 14644-5: Cleanrooms and Associated Controlled Environments
Part 5, Operations.
洁净室与相关的受控环境 第五部分：运行。
- 14644-6: Cleanrooms and Associated Controlled Environments
Part 6, Terms and definitions.
洁净室与相关的受控环境 第六部分：术语与定义。
- 14644-7: Cleanrooms and Associated Controlled Environments
Part 7, Minienvironments and isolators.
洁净室与相关的受控环境 第七部分：微环境与隔离。

Cleanroom Standards

洁净室相关标准

ISO TC209

- 14698-1: Cleanrooms and Associated Controlled Environments, Biocontamination control Part 1, General principles.
洁净室与相关的受控环境，生物污染控制，第一部分：总则。
- 14698-2: Cleanrooms and Associated Controlled Environments, Biocontamination control Part 2, Evaluation and interpretation of biocontamination data.
洁净室与相关的受控环境，生物污染控制，第二部分：生物污染数据的评估与解释。
- 14698-3: Cleanrooms and Associated Controlled Environments, Biocontamination control Part 3, Metrology for measuring the efficiency of processes of cleaning and disinfection of insert surfaces bearing biocontaminated wet soiling or biofilms.
洁净室与相关的受控环境，生物污染控制，第三部分：评测受到生物污染的湿污染或生物膜清洁和消毒方法的有效性。

Cleanroom Standards

洁净室相关标准

ISO 14644-1

CLASS	Number of Particles per Cubic Meter by Micrometer Size （颗粒数/立方米）					
	0.1 um	0.2 um	0.3 um	0.5 um	1 um	5 um
ISO 1	10	2				
ISO 2	100	24	10	4		
ISO 3	1,000	237	102	35	8	
ISO 4	10,000	2,370	1,020	352	83	
ISO 5	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7				352,000	83,200	2,930
ISO 8				3,520,000	832,000	29,300
ISO 9				35,200,000	8,320,000	293,000

Cleanroom Standards

洁净室相关标准

Compare FED STD 209E to ISO 14644-1

ISO 14644-1	FED STD 209E	
Class	English	Metric
ISO 1		
ISO 2		
ISO 3	1	M1.5
ISO 4	10	M2.5
ISO 5	100	M3.5
ISO 6	1,000	M4.5
ISO 7	10,000	M5.5
ISO 8	100,000	M6.5
ISO 9		

Cleanroom Standards

洁净室相关标准

ISO 14644-2 (Required Test)

Schedule of Tests to Demonstrate Continuing Compliance			
Test Parameter	Class	Maximum Time Interval	Test Procedure
Particle Count Test	<= ISO 5	6 Months	ISO 14644-1 Annex A
	> ISO 5	12 Months	
Air Pressure Difference	All Classes	12 Months	ISO 14644-1 Annex B5
Airflow	All Classes	12 Months	ISO 14644-1 Annex B4

Cleanroom Standards

洁净室相关标准

ISO 14644-2 (Optional Testing)

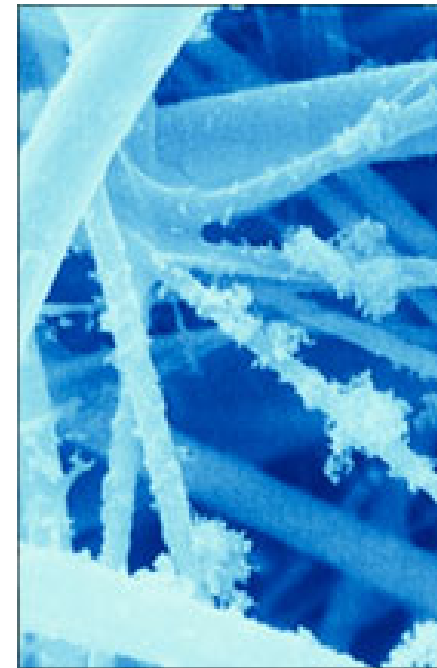
Schedule of Additional Optional Tests			
Test Parameter	Class	Maximum Time Interval	Test Procedure
Installed Filter Leakage	All Classes	24 Months	ISO 14644-3 Annex B6
Containment Leakage	All Classes	24 Months	ISO 14644-3 Annex B4
Recovery	All Classes	24 Months	ISO 14644-3 Annex B13
Airflow Visualization	All Classes	24 Months	ISO 14644-3 Annex B7

The principals of how a cleanroom works

洁净室工作原理

What does it take to make a cleanroom work?
洁净室是如何工作的？

- ➔ Air Filtration
空气过滤
- ➔ Control over airflow
气流组织
 - Laminar flow cleanroom
层流洁净室
 - Conventional (mixed flow) cleanroom
常规（混合流）洁净室



The principals of how a cleanroom works

洁净室工作原理

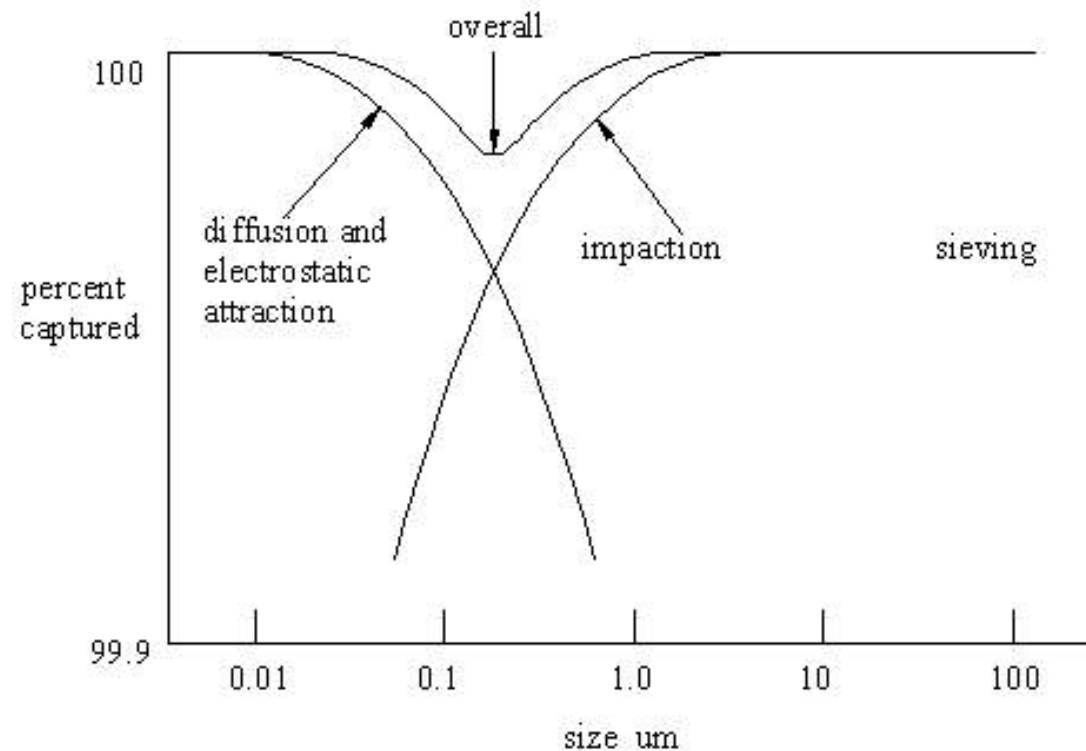
Filtration Mechanisms 过滤机制

- Gravity: large particles simply fall out of the air stream
重力：大微粒直接从空气中掉落。
- Direct interception: A particle follows the upstream flow is collected when it collides with or touches the filter fiber. For very large particles sieving occurs when the collected particles are large than the filter openings.
直接拦截：跟随气流移动的微粒在碰触过滤纤维的时候被收集，当微粒大于过滤器的孔径时，则直接被筛分。
- Inertial impaction: The inertia of the particle caused it to deviate from its initial streamline and collide with the fiber of the filter
惯性撞击：微粒的惯性使它偏离最初的轨迹，与过滤纤维碰触而被收集。
- Diffusion: Particles $< 0.5\mu\text{m}$ have a small enough mass that their trajectories are altered by collision with gas molecules
扩散：小于 $0.5\mu\text{m}$ 的微粒在与气体分子碰撞时改变运动轨迹。（布朗运动）
- Electrostatic mechanisms: Electrical charges on the either the particle or the fiber or both create attractive forces between particle and the filter or particle to particle
静电机制：微粒或过滤纤维上的电荷使两者之间或微粒与微粒之间产生吸引力。

The principals of how a cleanroom works

洁净室工作原理

How do HEPA and ULPA filters work?
HEPA和ULPA过滤器是如何工作的？

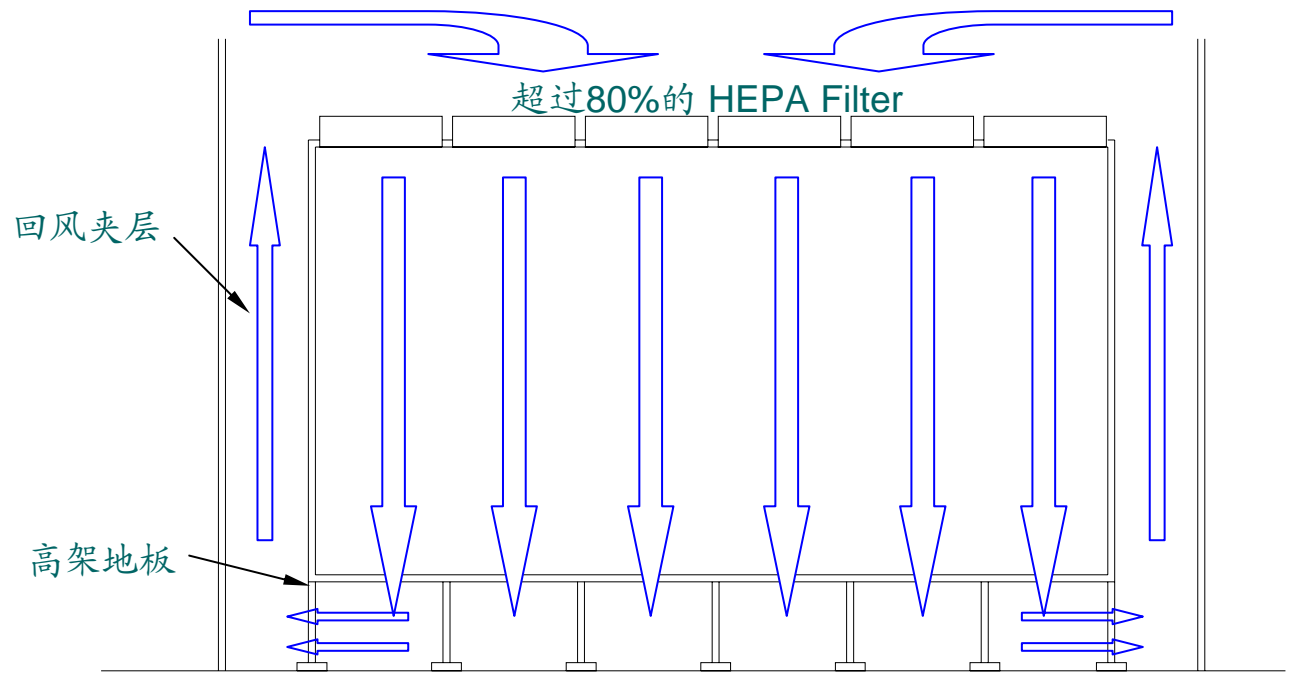


The principals of how a cleanroom works

洁净室工作原理

Laminar flow cleanroom

层流洁净室

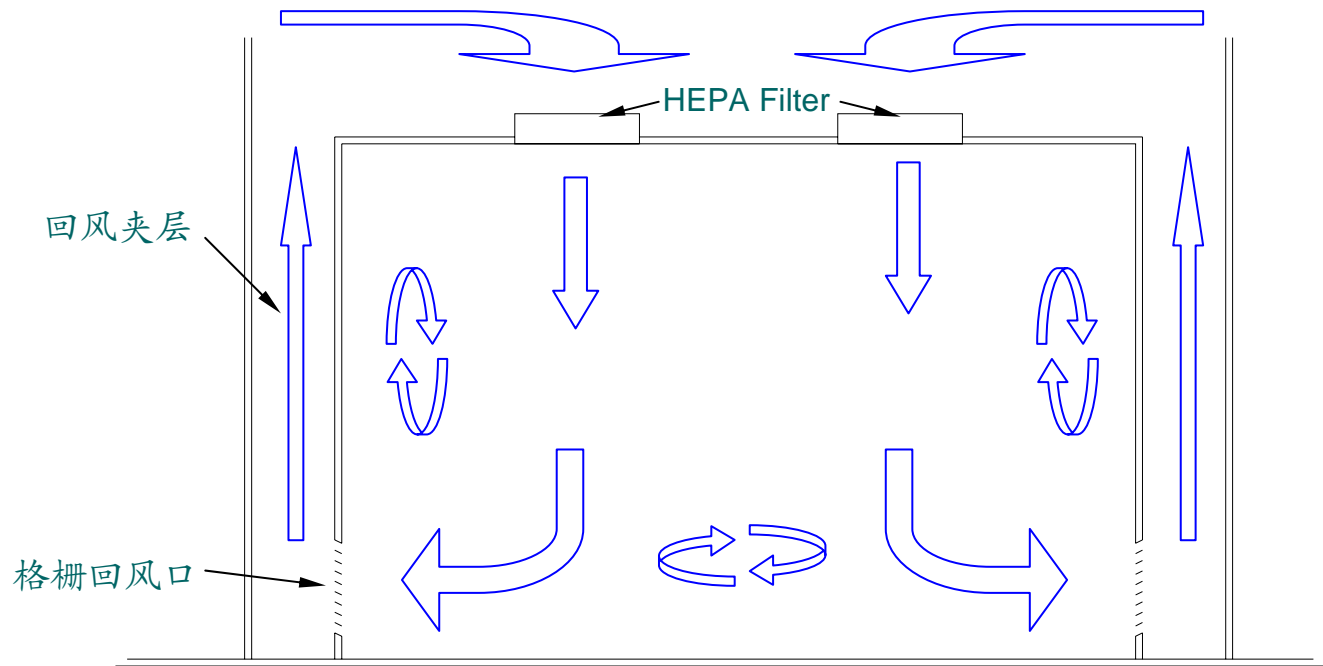


The principals of how a cleanroom works

洁净室工作原理

Conventional (mixed flow) cleanroom

常规（混合流）洁净室



The principals of how a cleanroom works

洁净室工作原理

Cleanroom performance 洁净室性能

- Mixed flow rooms 混合流洁净室
 - Class 100K – less than 20 air changes/hr
十万级洁净室 – 换气次数小于20次/小时
 - Class 10K – 20 to 60 air changes/hr
万级洁净室 – 换气次数20至60次/小时
 - Class 1K – 60 to 150 air changes/hr
千级洁净室 – 换气次数60至150次/小时
- Laminar air flow rooms 层流洁净室
 - Class 100,10,1 – 200 to 600 air changes/hr
100级、10级、1级洁净室换气次数在200到600次之间
 - 80 to 100% ceiling coverage by filters
过滤器的覆盖率不低于80 %
- Mini-environments 微环境
 - Sub-class 1 capable
可提供优于1级的环境



Contamination control in cleanroom

洁净室的污染控制



What is contamination?
什么是污染?

- Definition: Any foreign material or energy that has a detrimental effect on a product or process.
定义：危害产品或工艺的任何外来物质和能量。

Particles

微粒

Ions

离子

Molecular contamination

分子污染

Vibration

微振

Electromagnetic radiation

电磁辐射

Electrostatic charge

静电荷

And more.....

Comparison of particle 空气微粒分布图

Contamination control in cleanroom

洁净室的污染控制

Sources of contamination

污染物的来源

- Personal—Skin, Hair, human oils, skin flakes, bacteria, fibers from clothing.
人员 - 皮肤、毛发、油脂、衣物纤维、代谢产物
- Processes--Ionic contaminants from acids, bases, plating processes. Organic contaminants from photoresist residues, process chambers residues, greases. Spores, viruses. SiO₂ from silicon films.
工艺流程 - 酸、碱、电镀工艺带来的离子污染物，光刻材料污染物、油脂带来的有机污染物，孢子菌、病毒。
- Tools and Materials—Powders and liquids in pharmaceutical environments. Residues in vacuum chambers. Residual contaminants from plating process and equipment. Inorganic contaminants from silicone dust, silicone carbide and nitride.
工具和材料 - 药物环境下的粉末与液体，真空室内的残留物，电镀工艺和设备的残留污染物，硅尘、碳化硅和氧化硅带来的无机污染物。

Contamination control in cleanroom

洁净室的污染控制

Particle adhesion mechanisms

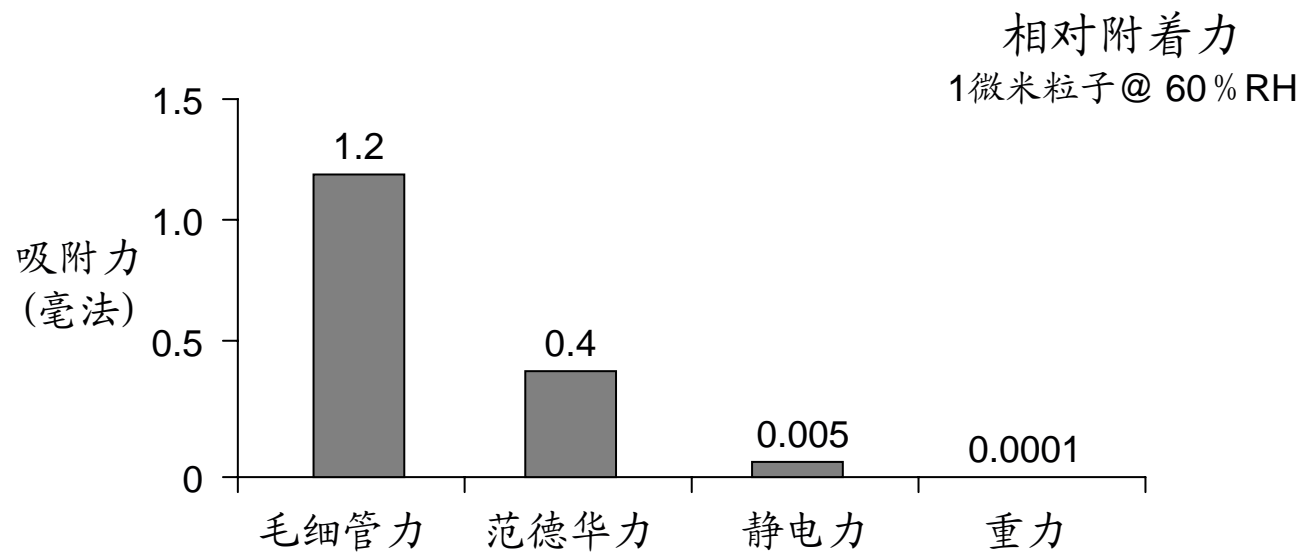
粒子吸附原理

There are four mechanisms that hold particles to a surface:
使粒子附着在表面上的原因有四个：

- Gravity: Adhesion force from gravity depends only on the mass of the particle.
重力：取决于粒子的质量。
- Electrostatic forces: Can both attract and hold a particle forces to a surface.
静电力：通过静电吸引粒子并将粒子吸附在表面。
- Van der waals (atomic) forces: The intermolecular forces come into play when the particle is very near the surface.
范德华力：又称分子间作用力，当粒子表面非常接近时开始起作用。
- Hydroscopic, or capillary force: Caused by thin liquid layer between a particle and a surface. Adhesion increases with humidity and contact area of particle.
毛细管力：由粒子表面薄薄的液层而引起，与湿度和接触面积成正比。

Contamination control in cleanroom

洁净室的污染控制



粒子吸附原理

Contamination control in cleanroom

洁净室的污染控制

Conclusion of adhesion 吸附原理小结

- ➔ Particles are held to surfaces by a variety of forces.
粒子通过各种各样的力附着在表面上。
- ➔ These forces vary according to many factors including particle size and shape and shape, surface texture, and humidity.
这些力与粒子的大小和形状，表面的材质，湿度等因素有关
- ➔ Small particles are more tightly held than large particles.
较小的粒子比较大的粒子吸附的更紧。
- ➔ Removal of small particles requires force greater than that holding the particles.
清除较小的粒子需要用比吸附力更大的力。

Contamination control in cleanroom

洁净室的污染控制

Contaminant removal 污染物的清除

The most common methods used for general cleaning are:
最常用的清洁方法

**The most
effective
method**

- Air blow-off
风吹：用于低级别洁净室，对较大的粒子有效，但是不能防止污染物再沉淀，也不能清除残留物。
- Vacuum
真空吸尘：一般用于清除较大粒子，可防止污染物再沉淀，同样不能清除残留物。
- Tack roller
粘尘滚筒：无法有效清除较小粒子，无法清除残留物，不能完全防止污染物再沉淀。
- Dry wiping
干擦：不能有效清除较小粒子，可以清除部分残留物，不能完全防止污染物再沉淀。
- Wet wiping/mopping
湿擦/拖：有效清除较小粒子和残留物，比干擦效果好，不能完全防止污染物再沉淀。

Contamination control in cleanroom

洁净室的污染控制

The environment to clean 清洁周期

洁净室级别 Cleanroom class	桌子与表面 Tables & surfaces	墙壁 Walls	地板 Floors	设备 Equipment
1级 Class 1	班 Shift	班 Shift	班 Shift	日 Day
10级 Class 10	日 Day	周 Week	日 Day	周 Week
100级 Class 100	日 Day	月 Month	2次/周 2/Week	周 Week
1000级 Class 1000	周 Week	季度 Quarter	月 Month	月 Month
10000级 Class 10000	周 Week	月 Month	月 Month	月 Month
>10000级 >Class 10000	2次/月 2/Month	季度 Quarter	季度 Quarter	周 Week

Contamination control in cleanroom 洁净室的污染控制



Choosing the right tools 选择合适的工具

➤ Vacuum
真空吸尘器

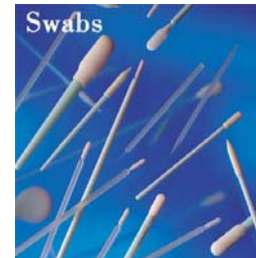
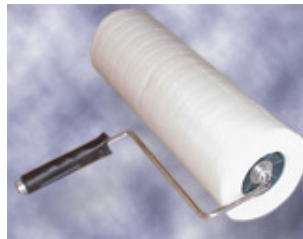
➤ Tack roller
粘尘滚筒

➤ Wipers/Swabs
抹布/棉签

➤ Mopping system
拖洗系统

➤ Solvents/Solutions
溶剂/溶液

➤ Sticky mat
粘尘垫



and more.....

Cleanroom operation

洁净室操作设备



Air Shower
风淋室



Air Shower Tunnel
风淋走道



Pass Through
传递窗

Cleanroom operation

洁净室操作设备



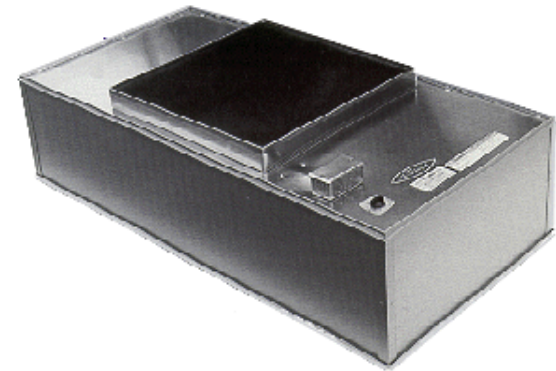
Cleanbooth
净化工作亭

Cleanroom operation

洁净室操作设备



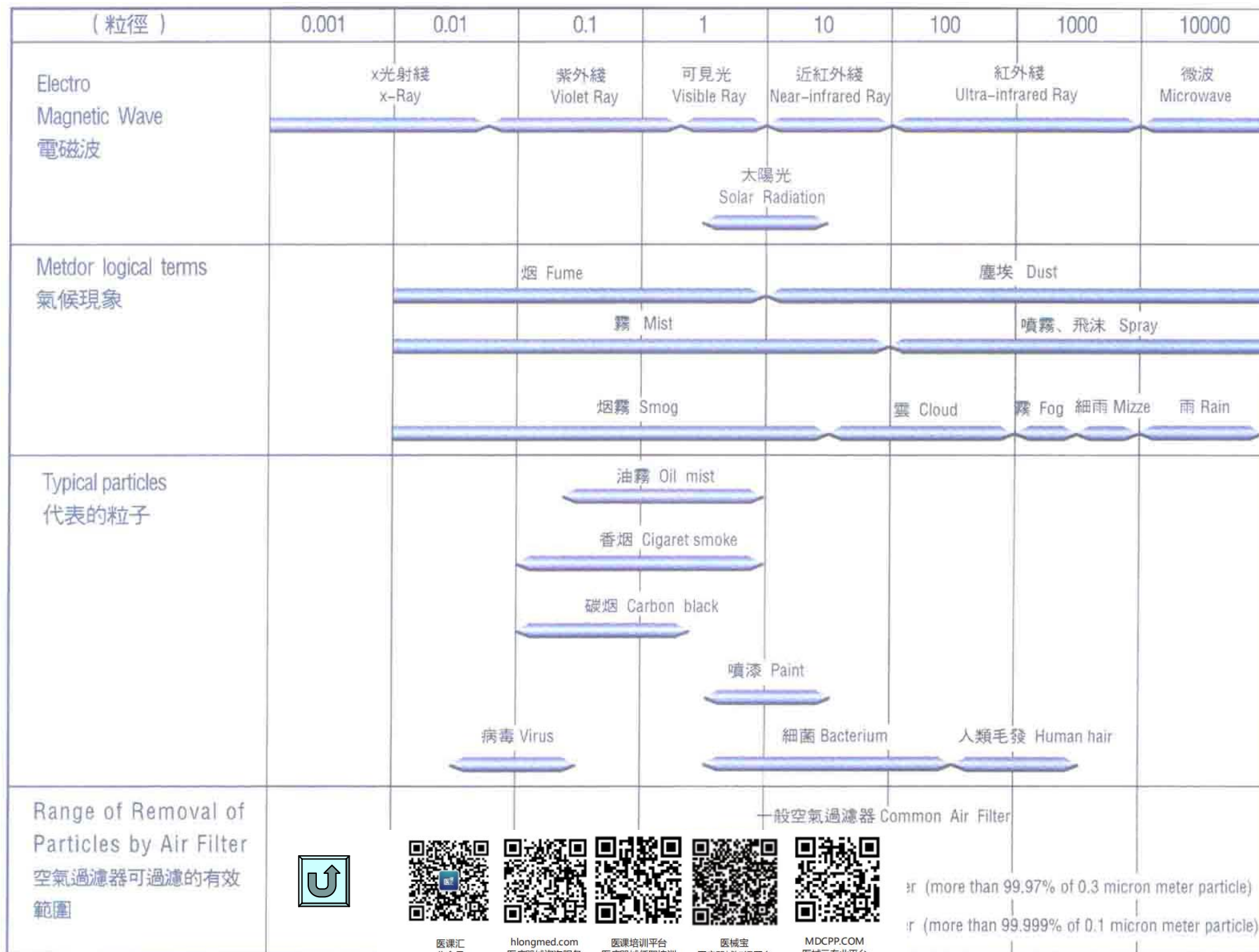
Clean Bench
净化工作台



Fan Filter Unit (FFU)
风机过滤器单元



THE END



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
医械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE

99.97%
(more than 99.97% of 0.3 micron meter particle)

99.99%
(more than 99.999% of 0.1 micron meter particle)