LIGHTHOUSE
WORLDWIDE SOLUTIONS

CLEANROOMS EXPLAINED

Lighthouse Worldwide Solutions

What Is A Cleanroom?

A cleanroom is a specifically designed room that controls contamination. Cleanrooms are used in practically every industry where small particles can adversely affect the manufacturing process and product. The main components of a cleanroom are what keeps the cleanroom clean. To control contamination in a cleanroom clean air is required, access is limited and outside contamination is restricted. The main contaminators inside a cleanroom are people. A HVAC system is used to provide air at a define temperature and humidity and HEPA filters are used to provide sterile air into the cleanroom. The internal design and materials of construction inside a cleanroom must be smooth, antistatic, easily sterilized and cleaned and do not cause particle traps where dirt can build up. The number of air changes per hour coupled with the cleanroom design of interior structures and materials define the Cleanroom classification. The key component is the High Efficiency Particulate Air (HEPA) filter that is used to trap particles that are 0.3 micron and larger in size. All of the air delivered to a cleanroom passes through HEPA filters, and in some cases where stringent cleanliness performance is necessary, Ultra Low Particulate Air (ULPA) filters are used.

What is Cleanroom Classification?

A cleanroom is classified or also defined as certified based on the level of air cleanliness. The cleaner the air or particle concentration based on a known sample volume then the higher the cleanroom classification. Particle Counters are used to certify cleanrooms based on cleanroom standards. There are several standards in operation. Cleanrooms are classified by how clean the air is. In the USA the Federal Standard 209 (A to D) the number of particles equal to and greater than 0.5mm is measured in one cubic foot of air, and this count is used to classify the cleanroom. This standard has been surpassed by ISO 14644-1 which came out in 1999 however FS 209 which has been around since 1963 and was published by the Institute of Environmental Sciences and Technology (IEST).

This metric nomenclature is also accepted in the most recent 209E version of the Standard. Federal The cleanroom classification standards FS 209E and ISO 14644-1 require specific particle count measurements and calculations to classify the cleanliness level of a cleanroom or clean area.

CLEANROOM ISO CLASSES

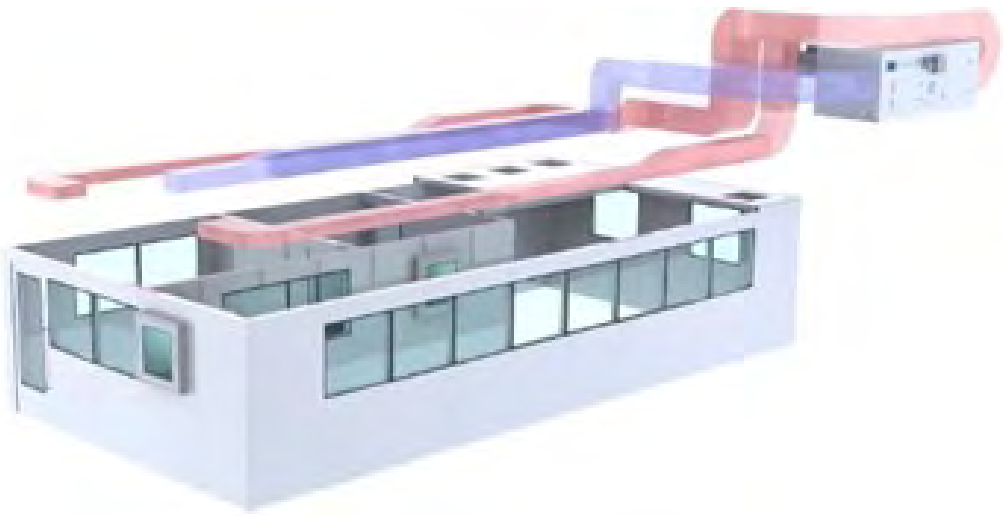
ISO Classification Number (n)	≥0.1µm	≥0.2µm	≥0.3µm	≥0.5µm	≥1.0µm	≥5.0µm	FED STD 209E EQUIVALENT
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		Class 1
ISO 4	10,000	2,370	1,020	352	83		Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7				352,000	83,200	2,930	Class 10,000
ISO 8				3,520,000	832,000	29,300	Class 100,000
ISO 9				35,200,000	8,320,000	293,000	ROOM AIR

Controlling the Cleanroom Environment

Cleanrooms maintain particulate-free air through the use of either HEPA or ULPA filters employing unidirectional or turbulent air flow principles. Unidirectional air flow systems direct filtered air downward in a constant stream. Unidirectional air flow systems are typically employed across 100% of the ceiling to maintain constant, unidirectional flow. Laminar flow criteria is generally stated in portable work stations (LF hoods), and is mandated in ISO-1 through ISO-4 classified cleanrooms.

Cleanrooms need a lot of air. The cleaner the cleanroom needs to be, the more air it will need to use. Air handling systems are designed to circulate air through the room, removing contamination as air is generated and keeping the temperature and humidity stable. The amount of air we put into the room is important as well.

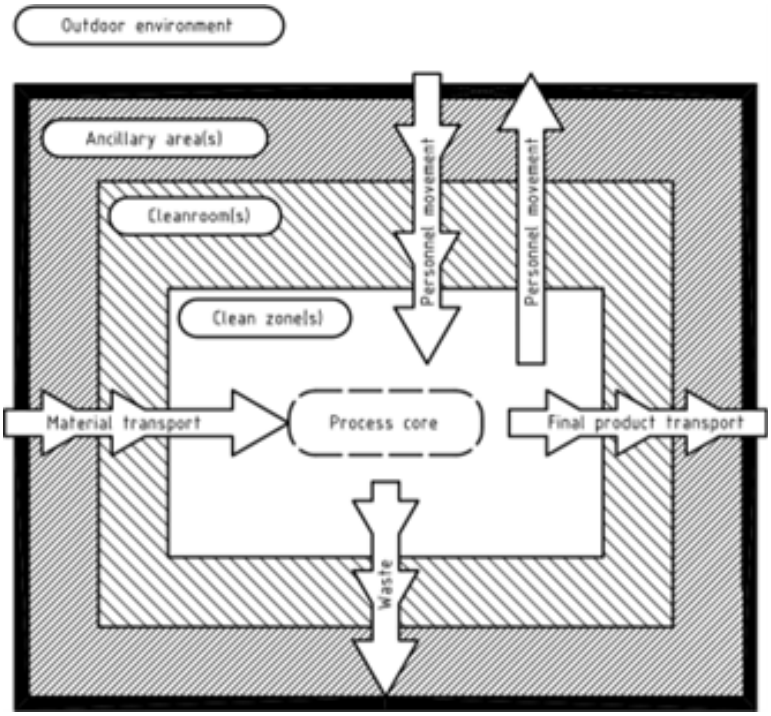
The more air that goes in, the faster the room cleans itself. This can be important for rooms that occasionally experience high amounts of contamination, or something like a sampling room or dispensary where the room needs to be cleaned quickly between operations.



Facility Control

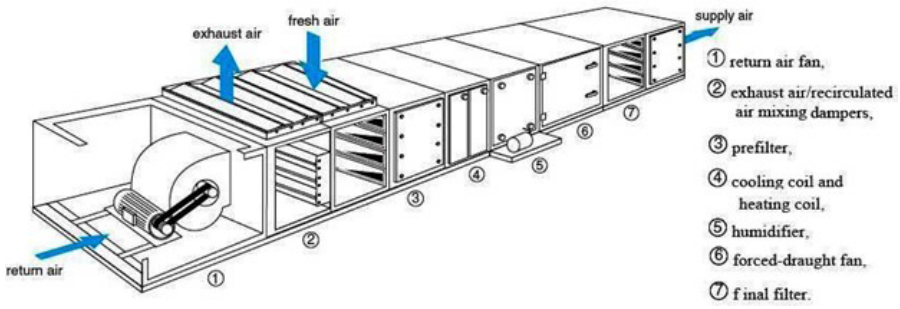
To maintain a cleanroom the whole facility needs to be properly controlled.

- **Access to different areas needs to be tightly controlled.**
- **Room pressure cascades need to be maintained to enable the process core to be sterile.**
- **SOPs should be developed and followed for cleaning the cleanroom.**
- **Continuous monitoring of the filters and air flows and frequent recertification of thecleanroom is required.**
- **In the aseptic core it is critical that the environmental conditions are recorded and monitored during processing for viable and non-viable contamination.**



Air Handling Units (AHU's)

When we think of cars the heart of the car is the engine. With cleanrooms the heart of the cleanroom is the Air Handling Unit. The AHU uses a centrifugal fan to circulate air to various parts of a cleanroom facility. In fact a cleanroom facility would have many AHU's each serving different rooms and parts of the building. Each AHU would have its fan sized to the room(s) requirements. The selection of the fan will depend on the air volume and the static pressure required. For example one or two AHU's would be specified for Grade A/B rooms and another. For Grade C/D rooms as there are less air changes required in the lower grade rooms and environments. The use of variable air volume (VAV) systems is becoming more accepted as this technology enables fan speed variation for different environments.



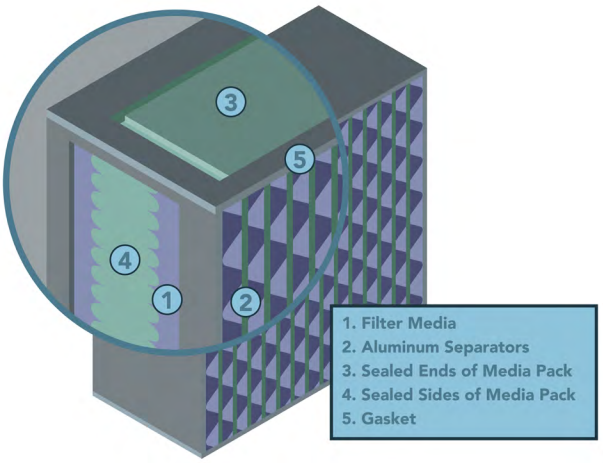
The Cooling Coil is used to cool and dehumidify the air. Both DX (direct expansion) cooling and CW (chilled water) cooling coils are available for use depending on the system design. The coil diameter, no. of rows of copper tubes are calculated on the basis of surface area required for effective heat transfer.

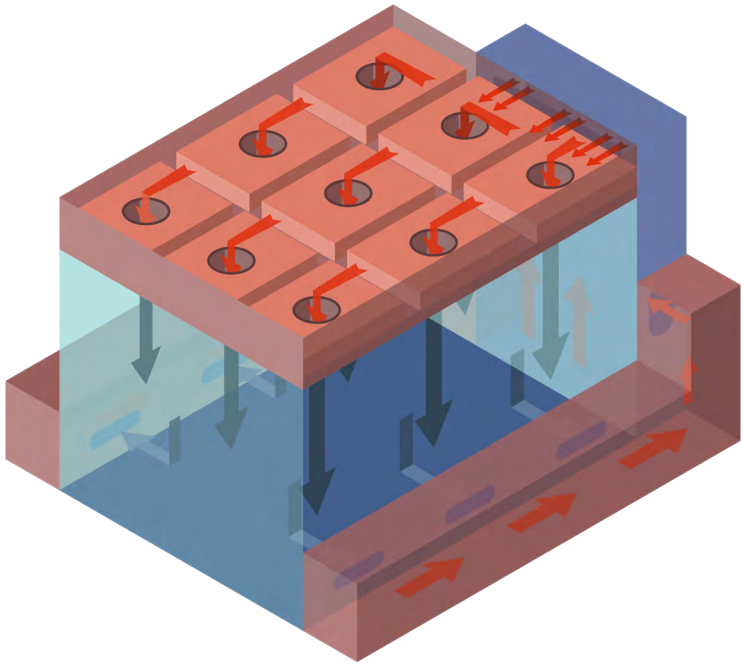
Filters are used to remove particles and contaminants of various sizes from the air. The type of air filter being used will very much depend on the application of the system. In the AHU there are a few filtration stages. The final filter for cleanroom applications would be HEPA and in semiconductor applications HEPA and ULPA filters are used. HEPA Filter is very efficient and is able to achieve efficiencies up to 99.97%, removing minute particles and airborne bacteria from the air.

ISO FILTER CLASS	EFFICIENCY	IEST* FILTER TYPE	EN 1822**	REMARKS
ISO 15 E	≥95%	-	E 11	
ISO 20 E	≥99%	-		
ISO 25 E	≥99.5%	-	E 12	
ISO 30 E	≥99.9%	-		
ISO 35 H	≥99.95%	-	H 13	
-	99.97%	A, B, E, H, I		Type A, B, E are traditional HEPA Filters
ISO 40 H	≥99.99%	C, J, (K)		In current usage, higher performance Type K is prefered over Type J for added safety
ISO 45 H	≥99.995%	K	H 14	
ISO 50 U	≥99.999%	D		
ISO 55 U	≥99.9995%	F	U 15	
ISO 60 U	≥99.9999%	G		
ISO 65 U	≥99.99995%	G	U16	
ISO 70 U	≥99.99999%	G		
ISO 75 U	≥99.999995%	G	U17	

***IEST Filter Types A, B, C, D, E classified per tests using photometers according to Mil Standard 282.**
Filter Types F, G, H, I, J, K are classified per test results using particle counters.

**** EN 1822 Filter Class E 10 not within range of efficiences in the ISO standard.**





Apart from AHU's used in cleanroom FFU's applications, Filter Fan filter units are flexible and economic solutions to remove particles from the recirculated air of turbulent or unidirectional ventilated cleanrooms. Fan filter units are stand-alone units with integrated HEPA-filter, fan and control system. They supply purified air to cleanrooms by removing harmful airborne particles from recirculating air. FFUs create a positive room pressure that reduces the contamination risk. Newly built cleanrooms now use a combination of AHU's and FFU's.

How is a cleanroom Certified?

Cleanrooms are certified to a specific class, based on ISO 14644-1, or similar standards. Cleanroom testing and certification involves checking that the cleanroom is functioning to the specific parameters and ISO classification. The room must perform, according to the standards, to meet or exceed the ISO parameters to maintain compliance. Typically the room is initially certified when construction is completed to ensure it was built to the client's specifications. The room is also then routinely retested (annually or semiannually) to ensure the quality has not changed during operations. The standards which cleanrooms are tested to are ISO14644-1, ISO 144644-2 and ISO 14644-3.

Cleanroom Testing (Annually or Semi Annual based upon specification)

Airflow volume / Velocity Readings	Assures that both unidirectional (velocity preferred) and non- unidirectional flow (airflow volume preferred) areas are properly balanced and unidirectional zones are maintaining proper air patterns.
HEPA Filter Integrity Testing	Test HEPA filters and system for leakage through the filtration system. This test is not required by ISO standards, but many auditing agencies such as the FDA will require it.
Non-Viable Particle Counting	Reports the amount of airborne particulate of a specified size in the clean zone. This test determines cleanliness class.
Room Pressurization Testing	Verifies that room differential pressures are operating according to the design.

Optional Cleanroom Testing

Optional tests are based upon the organization's need for monitoring, industry requirements and internal QA/SOPs.

Air Balancing	Adjusts airflow in the air handling systems to achieve design airflow, room exchange rates and pressure cascade.
Airflow Visualization Testing/ Smoke Testing	Verifies the airflow direction using a source of visible fog.
Viable Environmental Monitoring (EM)	Air and surface sampling for microbe enumerations.
Room Air Exchange Rates	States if the area is meeting its design airflow.
Temperature/Relative Humidity Testing	Examines whether the air HVAC controls are functioning uniformly and properly.
Lighting, Vibration, and Sound Testing	Assures workers comfort.
Humidity Testing	Evaluates moisture in the air that could affect product.
Particle Deposition Testing	Measures the effects of particles deposited upon surfaces and measure the quantity (number or mass).
Recovery Test	Performed to determine if the room is capable of returning to the specified cleanliness level.

What equipment is used to certify a Cleanroom?

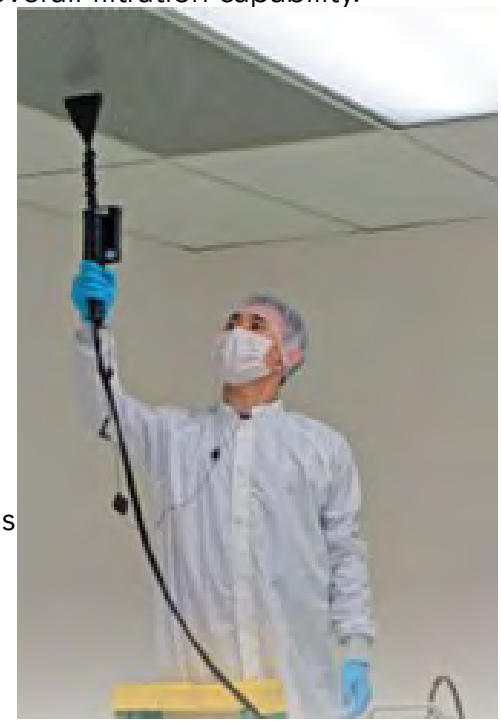
Air Handling Units (AHU's)

Anemometers are used to capture the flow of air entering the cleanroom through the AHU grilles. An airflow capture hood or balometer is used to measure the volume of air coming out of grilles and diffusers in HVAC systems. Most modern balometers also have anemometers built into them.

HEPA Filter Integrity Testing

The HEPA filter integrity test is typically performed on cleanroom supply air HEPA filters using a photometer to scan the filter surface for pinhole leaks that could allow the transmission of contaminant particles that would be unacceptable in a critical application.

HEPA filters are capable of removing 100% of airborne particulate above 5µm. Below that, they are less efficient and typically will remove 95% to 99.9995% in the 0.15µm to 0.25µm particle size range. The grade of the filter chosen for the application determines the overall filtration capability.



Access is required to the relevant air handling unit related to the HEPA filter to be tested. The air system should be operating as normal for the duration of the HEPA test, so the introduced test aerosol will be pulled through the HEPA filter. Access is also required to the air output side of the HEPA filter, so that a technician is able to scan the HEPA filter surface at 25mm from the installation for traces of the test aerosol. A HEPA integrity test certificate is provided upon completion of the test. ISO 14644-2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 outlines the HEPA filter test methods and identifies two methods one using a photometer and another using a particle counter to test the filter integrity.

Photometer filter testing

A photometer is used to scan over the filter face which is downstream of the introduced test aerosol. The tests require that an aerosol challenge be introduced upstream of the filter. This is to ensure that there is actually a challenge present against which we can make a downstream measurement. The common oils for this purpose are:

- **Poly-alpha olefin (PAO) – Emery 3004 or Durasyn 162**
- **Shell ondina (EL) food quality mineral oil**
- **Dioctyl sebacate (DOS)**
- **Di-2-ethyl hexyl sebacate (DEHS)**
- **Dioctyl (2-ethyl hexyl) phthalate (DOP)**
- **Paraffin oil.**

The filter gasket, frame and media are scanned for leaks. The maximum permissible leak is set at 0.01%, although lower limits may be used.

Particle Counter filter testing

A particle counter with the right accessories is a versatile instrument as not only can it perform cleanroom filter integrity testing a particle counter is also used for certification based on ISO 14644-1 and ISO 8573 for gas sampling. A particle counter covers 4 important tests in a cleanroom environment.

- **Cleanroom certification based on ISO 14644-1**
- **Continuous monitoring based on GMP standards for regulation**
- **Gas sampling of gases introduced into the cleanroom**
- **Filter Integrity testing based on ISO 14644-2 and ISO 14644-3**

For filter testing the particle counter method uses a lower concentration of test aerosol using latex particles. Because the particle counter is more sensitive than the photometer less concentrations of test aerosol are used. Which is less likely to shorten the filters life span.

Non-Viable Particle Counting

For cleanroom certification and ongoing continuous monitoring particle counters are widely used to provide Pass/Fail results based on cleanroom standards. Particle counters come with cleanroom standard calculations built into the firmware and once you enter the basic parameters and take your samples the particle counter will verify if the room meets the criteria for cleanliness based on whatever standard is been tested. If the test fails, the operator is alerted.