Back to Foreword

Editorial

Changes in industrial production have also resulted in changes in the prevailing environmental conditions. The demand for quality has risen and the reduction of costs has now become the essential criterion. Cleanroom production offers considerable potential here – as long as it is used properly.

The more sensitive the item to be produced, the "cleaner" the production method required. Production in cleanrooms or using cleanroom technology has become increasingly popular. However, it is not always immediately obvious what is actually behind it, never mind how it should be used. Even the concepts used to describe it are often difficult to understand and unclear.
Let us start with the concept of the cleanroom. The only possible method of cleanroom comparison is based on the number of airborne particles relative to a volume equivalent. The VDI Guideline 2083 and the US Federal Standard 209E have made a start by defining international standards for cleanliness classes.

One of the main factors that influences air cleanliness is the equipment installed in a cleanroom. As a supplier of automation expertise Festo has been concerned with this subject for over ten years. Back then the number of customers in this specialized area was small. That has since changed. The propagation of high-tech chip development facilities, for example, has resulted in a clear increase in cleanroom production.

The purpose of this manual is to provide solutions to specific problems in the area of cleanroom technology. Our aim was to produce a comprehensive work containing all relevant information to serve as a valuable reference source.

We are grateful to the Institute for Production Technology and Automation (IPA) at the Fraunhofer Institute in Stuttgart for its support in technical matters and Wiley & Sons which kindly allowed us to quote from its reference book "Cleanroom Design" by W. Whyte (ISBN 0 472 94204 9).

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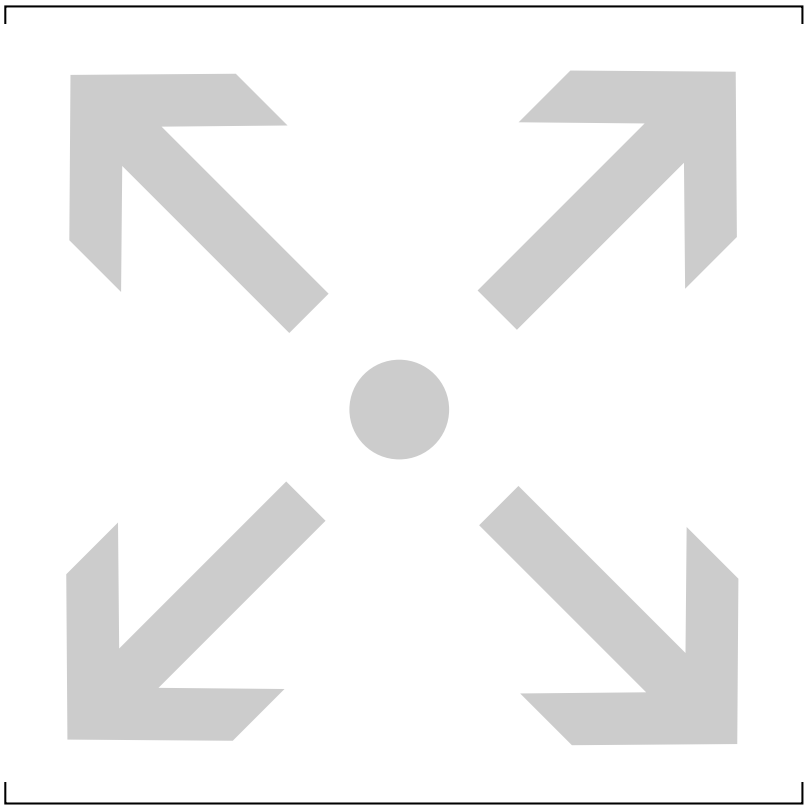
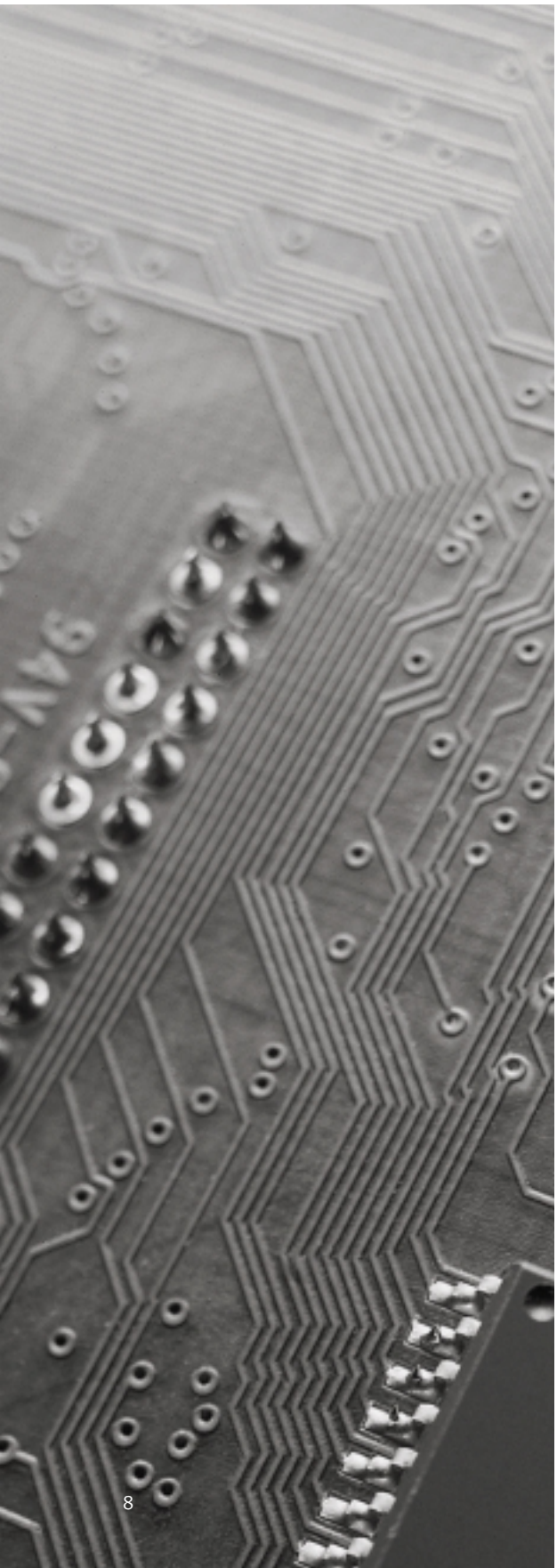


1.1 Introduction of Cleanroom



The term “Cleanroom” is something you associate with in modern industries. However, the roots of cleanroom design goes back more than a century. Think of the need to control contamination in hospitals and you would be able to imagine the first cleanroom.

At present, the need for cleanrooms is a requirement of modern industries. The use of cleanrooms is diverse. Table 1.1 below shows you the needs of different industries.

Electronics	Computers, TV tubes, flat screens, magnetic tape production
Semiconductors	Production of integrated circuits used in computer memory and control
Micromechanics	Gyroscopes, miniature bearings, computer disc players
Optics	Lenses, photographic film, laser equipment
Biotechnology	Antibiotic production, genetic engineering
Pharmacy	Sterile pharmaceuticals
Medical Devices	Heart valves, cardiac by-pass systems
Food and Drink	Disease-free food and drink
Hospital	Immunodeficiency therapy, isolation of contagious patients, operating rooms

Table 1.1

It can be seen that the requirement for cleanrooms can be broadly divided into two areas.

- That in which inanimate particles are a problem and where their presence may prevent a product functioning or reduce its useful life.
- To ensure the absence of microbe carrying particles whose growth could lead to human infection.

The table will be continuously increased to include future innovations requiring cleanrooms. The demand for cleanrooms will definitely grow.

1.2 Definition of Cleanroom

A cleanroom must certainly be “clean”. However, a cleanroom now has a special meaning and it is defined in US Federal Standard 209E as:

“A room in which the concentration of airborne particles is controlled and which contains one or more clean zones.”

And in ISO 14644-1 as:

“A room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation and retention of particles inside the room and in which other relevant particles inside the room and in which other relevant parameters, e.g. temperature, humidity and pressure, are controlled as necessary.”

1.3 Classification of Cleanrooms

Cleanrooms are classified by the cleanliness of their air. The method most easily understood and universally applied is the one suggested in versions of US Federal Standard 209 up to edition “D”.

To classify cleanrooms, the number of particles equal to and greater than 0.5 µm is measured in one cubic foot of air and this count is used to identify the Cleanroom Class.

US Federal Standard 209D Cleanroom Class Limits

Class	Measured Particle Size (µm)				
	0.1	0.2	0.3	0.5	5.0
1	35	7.5	3	1	NA
10	350	75	30	10	NA
100	NA	750	300	100	NA
1000	NA	NA	NA	1000	7
10000	NA	NA	NA	10000	70
100000	NA	NA	NA	100000	7000

Table 1.2

Table 1.2 shows the simplified classification of Cleanroom Class according to the older US Federal Standard 209D. This standard has now been superseded by the metric version; US Federal Standard 209E which was published in 1992.

However, because of the simplicity and universal usage of the US Federal Standard 209D, it is unlikely to be forgotten or removed. It is also likely that the US Federal Standard 209E will not supersede it but by the new International Standard Organization’s (ISO) standard 14644-1.

We will go into details later.

1.3 Classification of Cleanrooms

The basic unit of measurement within a cleanroom is a micron (µm) which is one millionth of a metre. Table 1.3 gives a better understanding of just how small a submicron particle is.

The human eye is capable of seeing particles down to approximately 25 µm. Humans typically emit 100,000 to 300,000 particles per minute sized 0.3 µm and larger.

It should also be noted that the airborne contamination level in cleanrooms is dependent on the particle generating activities going on in these rooms. Which means low particle concentration for an empty room and high particle concentration for a room in full production.

The different conditions for classifying the cleanroom

As built:
Condition where the installation is complete with all services connected and functioning but with no production equipment, materials or personnel present.

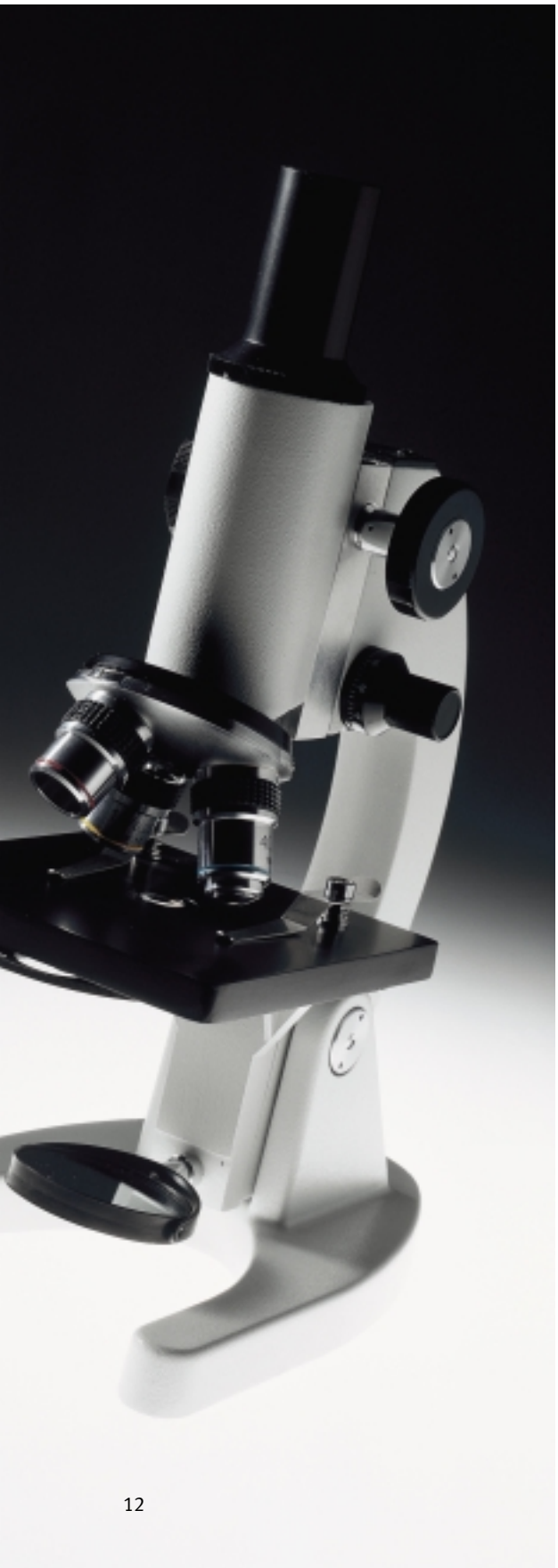
At rest:
Condition where the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present.

Operational:
Condition where the installation is functioning in the specified manner, with the specified number of personnel and working in the manner agreed upon.

Objects	Approximate size (microns)
Human hair	100
Rubbing or abrading an ordinary painted surface	90
Sliding metal surfaces (non-lubricated)	75
Crumpling or folding paper	65
Rubbing an epoxy-painted surface	40
Belt drive (conveyor)	30
Dust	25
Writing with ball pen on ordinary paper	20
Abrading of the skin	0.4
Oil smoke particles	0.1

Table 1.3

1.4 Cleanrooms for Different Industries



The required standard of cleanliness of a room is dependent on the task performed in it; the more susceptible the product is to contamination, the better the standard. Table 1.4 shows the possible cleanroom requirements for various tasks.

Class	
1	Integrated circuit manufacturers manufacturing submicron geometries only use these rooms.
10	Semiconductor manufacturers producing integrated circuits with line widths below 2 µm use these rooms.
100	Used with a bacteria-free or particulate-free environment is required in the manufacture of aseptically produced injectable medicines. Required for implant or transplant surgical operations.
1000	Manufacture of high quality optical equipment. Assembly and testing of precision gyroscopes. Assembly and testing of precision gyroscopes. Assembly of miniaturized bearings.
10000	Assembly of precision of hydraulic or pneumatic equipment, servo-control valves, precision timing devices, high-grade gearing.
100000	General optical work, assembly of electronic components, hydraulic and pneumatic assembly.

Table 1.4

1.5 Types of Clean Areas

Clean areas can be divided into four main types:
- Conventional
- Unidirectional flow
- Mixed flow
- Isolators or minienvironment

1.5.1 Conventionally ventilated cleanrooms

These cleanrooms are also known as turbulently ventilated or non-unidirectional flow and are distinguished by their method of air supply.

As shown in Figure 1.1, air supply diffusers or filters in the ceiling supply the air.

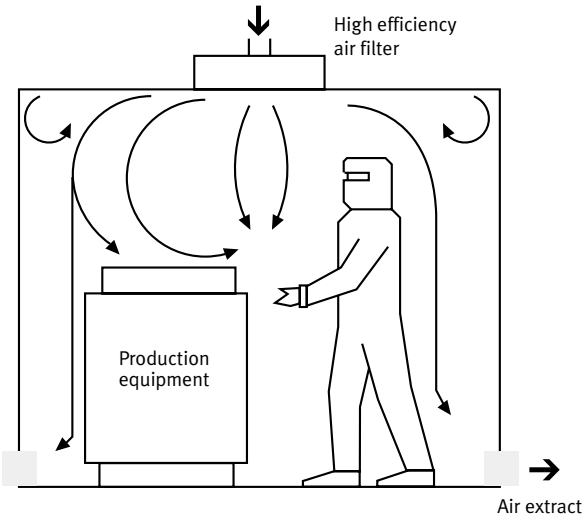


Figure 1.1

Figure 1.2 is a diagram of a simple conventionally ventilated cleanroom. The general method of ventilation used in this type of cleanroom is similar to that found in offices, shops, etc. in that air supplied by an air-conditioning plant through diffusers in the ceiling.

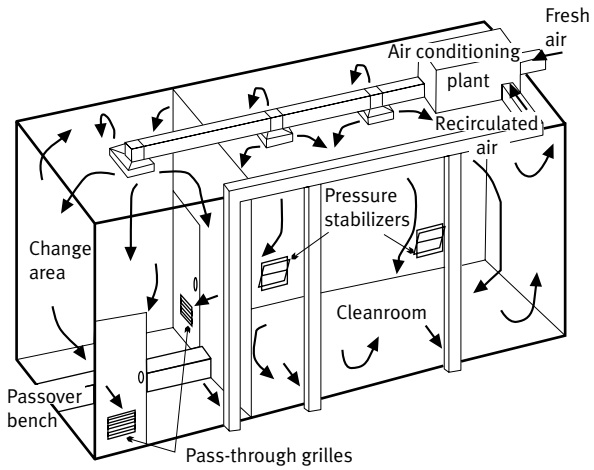


Figure 1.2

1.5 Types of Clean Areas

However, a cleanroom differs from an ordinary ventilated room in a number of ways:

- Increased air supply –
  An office or shop will be supplied with sufficient air to achieve comfort conditions; this may be in the region of 2 to 10 air change per hour.
  A conventionally ventilated cleanroom is likely to have between 20 to 60 air changes per hour. This additional air supply is mainly produced to dilute to an acceptable concentration the contamination produced in the room.
- High-efficiency filters –
  A cleanroom uses filters that are much more efficient. Cleanroom filters would normally be 99.97 % more efficient in removing particles greater than 0.3 mm from the room air supply. These filters are known as High Efficiency Particle Air (HEPA) filters, although Ultra Low Particle Air (ULPA) filters, which have a higher efficiency, are used in microelectronic fabrication areas.
- Terminal air filters –
  The high-efficiency filters used in cleanrooms are installed at the point of discharge into the room. In air conditioning systems used in offices, etc. the filters will be placed directly after the ventilation plant but particles may be induced into the air supply ducts or come off duct surfaces and hence pass into the room.
- Room pressurization and pass-through grilles –
  To ensure that air does not pass from dirtier adjacent areas into the cleanroom is positively pressurized with respect to these dirtier areas to prevent infiltration by wind. This is done by extracting less air from the room that is supplied to it, or by extracting the supplied air in adjacent areas. To achieve the correct pressure and allow a designed movement of air from the cleanest to the less cleanrooms is a suite, pass-through grilles or dampers will usually be seen at a low level on walls or doors.

Another indication that the room is a cleanroom is the type of surface finish in a room. The room will be of materials, which do not generate particles and are easy to clean. Surfaces will be constructed so that they are accessible to cleaning and do not harbour dirt in cracks, e.g. covered flooring and recessed lighting.

The airborne cleanliness of a conventionally ventilated cleanroom is dependent on the amount and quality of air supplied to the room and the efficiency of mixing of the air.

Generally speaking, a cleanroom will have sufficient air supply to achieve good mixing and the air quality of the room will therefore only depend on the air supply quantity and quality. It is important to understand that the cleanliness is dependent on the volume of air supplied per unit of time and not the air change rate.

The cleanliness is also dependent on the generation of contamination with the room, i.e. from machinery and individuals working in the room. The more people in the cleanroom, the greater their activity and the poorer their cleanroom garments the more airborne contamination is generated.

1.5.2 Unidirectional airflow cleanrooms

Unidirectional airflow is used when low airborne concentration of particles of bacteria is required. This type of cleanroom was previously known as “laminar flow”, usually horizontal or vertical, at a uniform speed of between 0.3 and 0.45 m/s and throughout the entire air space.

The air velocity suggested is sufficient to remove relatively large particles before they settle onto surfaces. Any contaminant generated into the air can therefore be immediately be removed by this flow of air, whereas the conventional turbulently ventilated system relies on mixing and dilution to remove contamination.

For these cleanrooms, you must ensure that the velocity is sufficient to overcome obstructions from the machines and people moving about. The disrupted unidirectional flow must be quickly reinstated and the contamination around the obstructions is adequately diluted.

Unidirectional airflow is correctly defined in terms of air velocity, the cleanliness of a unidirectional room being directly proportional to the air velocity. The air volumes supplied to unidirectional flow rooms are many times (10 to 100) greater than those supplied to a conventionally ventilated room. They are therefore very much more expensive in capital and running costs.

There are generally two types of unidirectional flow rooms:
- Horizontal – the air flow is from wall to wall
- Vertical – the airflow is from ceiling to ceiling.

1.5 Types of Clean Areas

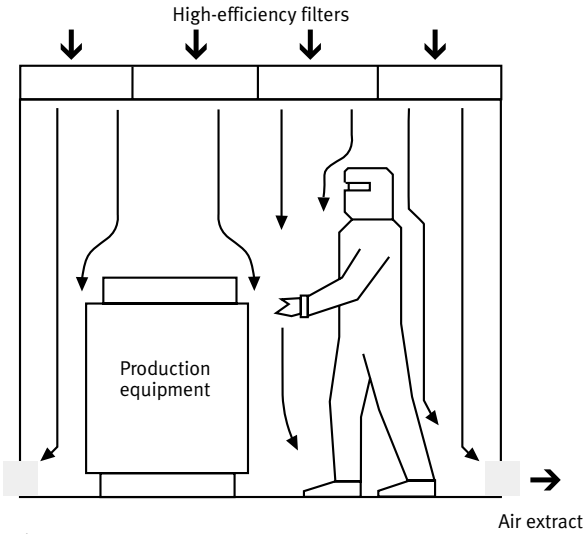


Figure 1.3

Figure 1.3 and 1.4 show a typical vertical flow type of cleanroom. Air is supplied from a complete bank of HEPA filters in the roof and this flows vertically through the room and out though open grilled flooring.

An alternative is to have the airflow out through the lower levels of the floor. The exhaust air is recirculated, mixed with some fresh make-up air, and supplied to the room through the HEPA filters in the ceiling.

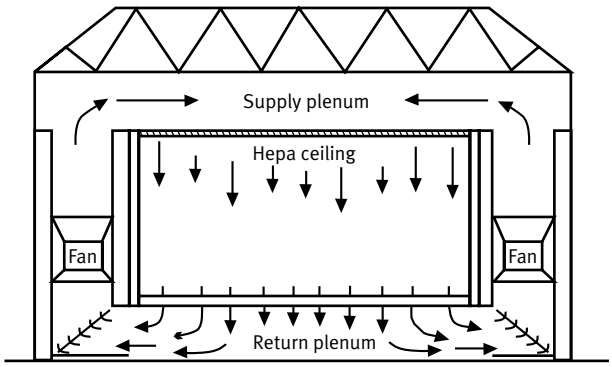


Figure 1.4

Most unidirectional cleanrooms are built in a vertical manner, as particles generated within the room will be quickly swept down and out of the room. Less popular is the horizontal type of cleanroom. Figure 1.5 shows a typical example.

This type is not so popular as any contamination generated close to the filters will be swept down the room and could contaminate work processes downwind. However, as the area of a wall in a room is usually much smaller than the ceiling, the capital and running costs is less.

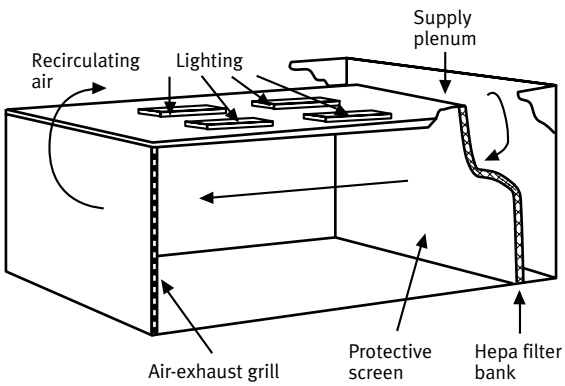


Figure 1.5

1.5.3 Mixed flow cleanrooms

This type of room is a conventional flow room in which the critical manufacturing operations are carried out within a higher quality of air provided by a unidirectional flow system, e.g. bench. This mixed type of system is very popular as the best conditions are provided only where they are needed and considerable cost savings are available for use in this room. (Figure 1.6)

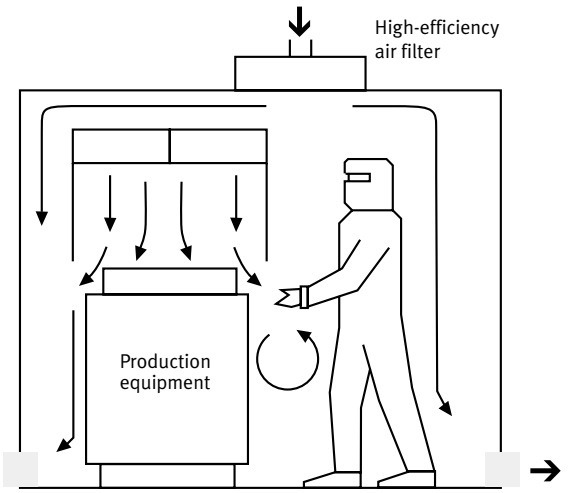


Figure 1.6

Figure 1.7 shows a horizontal flow cabinet, this being one of the simplest and most effective methods of controlling contamination. In this bench the operator's contamination is kept downwind of the critical process.

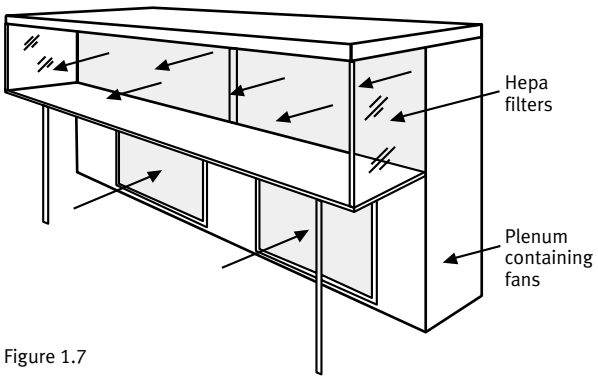


Figure 1.7

1.5 Types of Clean Areas

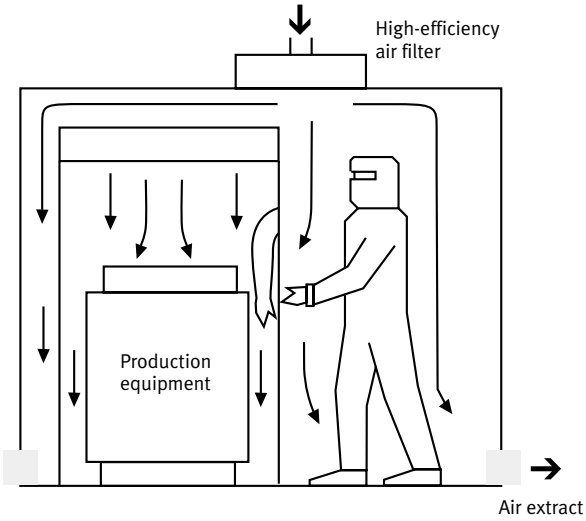


Figure 1.8

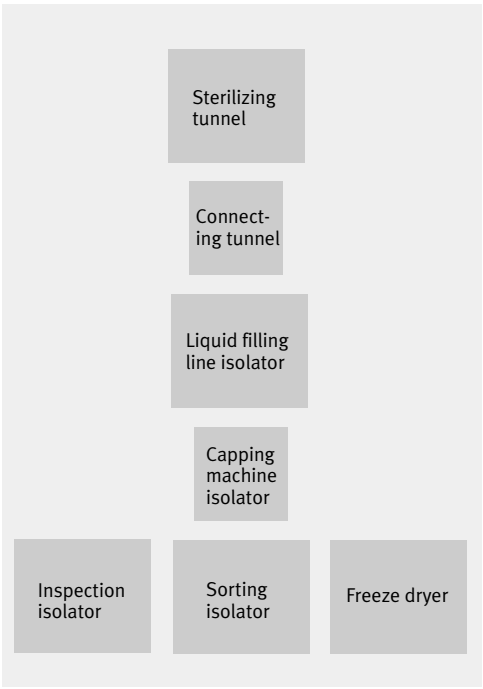


Figure 1.9

1.5.4 Isolator or minienvironment

Hazardous work with toxic chemicals or dangerous bacteria has been carried out for many years in glove boxes. These contaminant-retaining and contaminant-excluding systems do not principally depend on airflow for isolation but uses walls of metal and plastic. This principle of isolation clearly has excellent barrier properties and it has now been developed for use in modern classroom technology. (Figure 1.8)

In the pharmaceutical manufacturing area, this technology is generally known as isolator or barrier technology, whereas in the semiconductor industry it is generally known as minienvironments.

Figure 1.9 shows a system of interlocked plastic film isolators of the type used in pharmaceutical manufacturing. It may be seen that the plastic sheet acts as a barrier to outside contamination, and personnel either enter into half suits or use gauntlets to work at the clean processes within the isolators.

The air within the isolator is sterile and particle-free having been filtered by HEPA and this air is also used to pressurized the system and prevent ingress of outside contamination.

1.5 Types of Clean Areas

In the semiconductor industries, minienvironments are commonly used; they are not called isolators.

Minienvironments are used to isolate the product or operation from contamination. The minienvironment has the capability of delivering clean filtered air in the vertical or horizontal direction. The minienvironment does not have to be fully enclosed like an isolator but could be just an enclosed space in the cleanroom.

The minienvironment rapidly sweeps away all particles from the space surrounding the equipment. A ballroom cleanroom does not flush this critical area nearly as effective or as rapidly. And it is these particles, right next to the equipment and present in high concentrations in a ballroom but largely absent in a minienvironment.

Figure 1.10

Another system, which is used in semiconductor manufacturing, is the SMIF (Standard Mechanical Interface Format) system. In this system, silicon wafers are transported between machines in special containers, which prevent the wafers being contaminated by the air outside (Figure 1.11). These containers which contain the wafers, are slotted into the machine interface, the wafers processes and then loaded onto another container which can be taken to another machine and loaded into its interface.

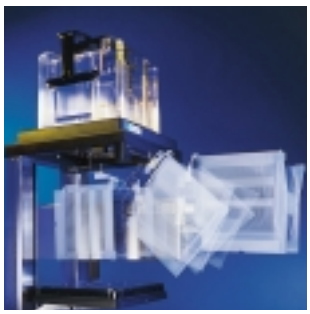
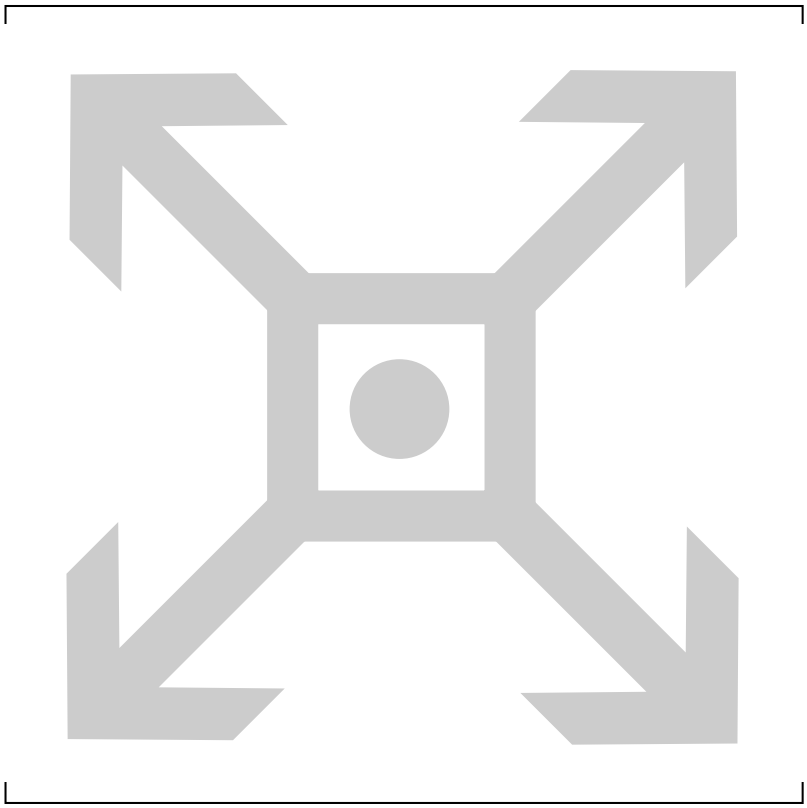


Figure 1.11

2.0 Cleanroom Design and Technology



2.1 Introduction

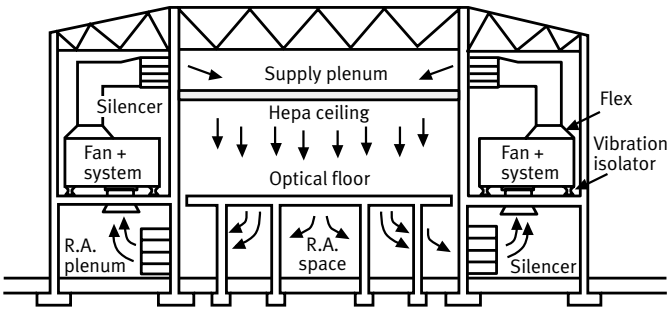
As earlier stated, cleanrooms are a reaction to ever more demanding clean production processes. They have been developed to establish minimum contamination to a defined task whether in the form of pharmaceutical work or in the semiconductor industry.

Contamination can be considered in many ways with one particular definition covering airborne particulate matter. The principles for air treatment design must recognize containment and elimination, to define standards, of airborne contamination.

2.2 Tasks of Cleanroom Technology

Before we start on the design of cleanrooms, we must understand the required tasks of cleanroom technology. There are basically two parts to consider:

- Personnel protection
- Product protection



R.A. = Return air

Figure 2.1

2.2.1 Personnel protection

Personnel must be protected against harmful dust particles or microorganisms.

2.2.2 Product protection

Products must be protected against contamination from the surroundings, production facilities or from personnel.

2.3.1 Layout

The design of semiconductor cleanrooms has evolved over several years. The design of a cleanroom that has been popular for a number of years.

The air flows in an unidirectional way from a complete ceiling of high-efficiency filters down through the floor of the cleanroom. The design shown is often called the “ballroom” type because there is one large cleanroom. Typically it is over 1,000m^2 in floor area. It is expensive to run but it is very adaptable.

In the “ballroom” type of cleanroom, a ceiling of high-efficiency filters provides clean air throughout the whole room irrespective of need. It is clear that the best quality air is necessary where the product is exposed to airborne contamination, but that lesser quality would be acceptable in other areas. (Figure 2.1)

2.3 Design Features

Using this concept, less expensive cleanrooms have been designed in which service chases with lower environmental cleanliness standards are interdispersed with cleanroom tunnels. Figure 2.2 shows this.

It is also in the ballroom type of design to divide up the ballroom with prefabricated walls and provide clean tunnel and service chases; these walls can be dismantled and reassembled with different configuration should the need arise.

Figure 2.3 and 2.4 show two typical designs of tunnel and service chase. These are designs which have been used in the past but are still applicable in manufacturing areas or laboratories where less than state-of-the-art components are produced.

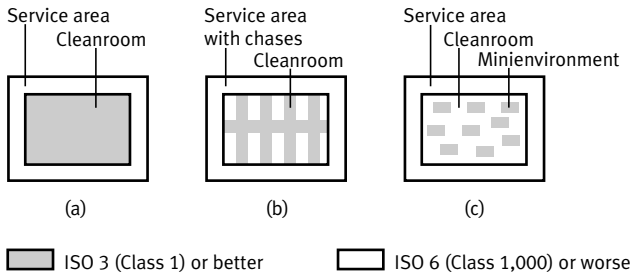


Figure 2.2

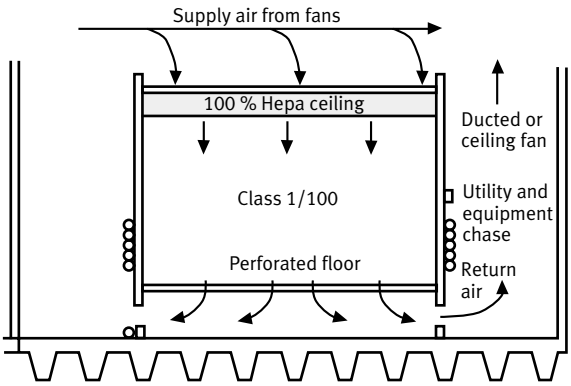


Figure 2.3

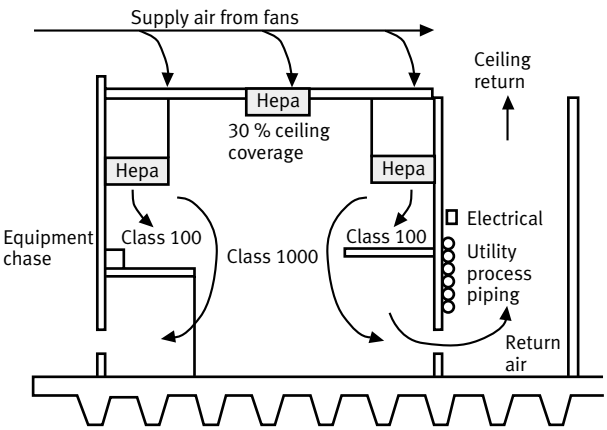


Figure 2.4

2.3 Design Features

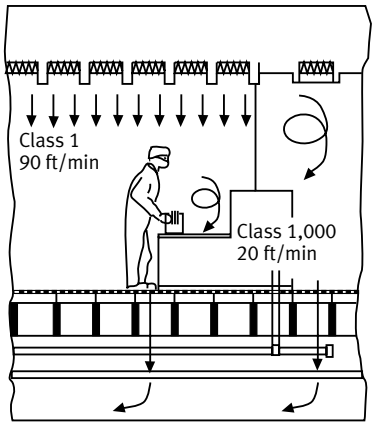
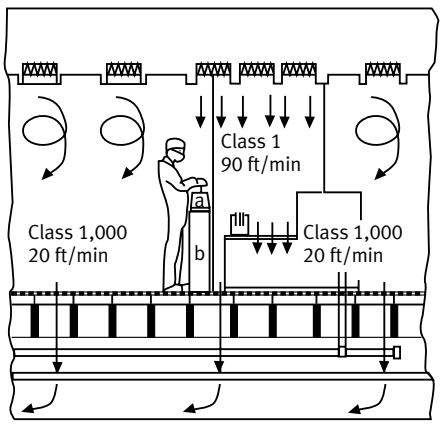


Figure 2.5



a = SMIF Pod b = SMIF Arm

Figure 2.6

Reducing the capital and running costs of a semiconductor cleanroom is always required. There has therefore been much interest in what have been variously called “isolators”, “barrier technology” and “minienvironments”. Minienvironments is the term commonly used in the semiconductor industry.

A minienvironment uses a physical barrier (usually a plastic film, plastic sheet or glass) to isolate the susceptible or critical part of the manufacturing process from the rest of the room. The critical manufacturing area is kept within the minienvironment and provided with large quantities of the very best quality air, the rest of the room being provided with lower quantities of air.

Figure 2.5 shows the traditional way and Figure 2.6 is the design using minienvironments. The total air supply volume can be seen to be much less when minienvironments are used.

As well as using minienvironment to isolate the area where the critical components are exposed, they can also be transported between processing machines in specially designed carriers, which interface, with machines through a Standard Mechanical Interface (SMIF). The components are then laded by a SMIF arm into the processing machine where it is contained within a minienvironment. After processing, the components are loaded back into the carrier and taken to the next machine.

2.3 Design Features

2.3.2 Air flow patterns

The type of air flow pattern employed most often describes cleanroom air flow. Selection of an air flow pattern should be based on cleanliness requirements and layout of the process equipment.

Cleanroom air flow patterns are either:
- Unidirectional
- Nonunidirectional
- Mixed air flow

Air flow patterns for cleanroom class M3.5 (Class 100) or cleaner are typically unidirectional while nonunidirectional are mixed flow are used for Class M4 and M4.5 (Class 1,000) or less cleanrooms.

a) Unidirectional Air flow

Air flow in unidirectional cleanrooms is often vertical. Air flows downwards through HEPA/ULPA filters located in the ceiling and returns through sidewall returns or perforated flooring. (Figure 2.7)

Air flow in unidirectional cleanrooms may also be horizontal when the air flow horizontally through a full wall of filters and flows through sidewall returns located in the opposite wall. Figure 2.8 shows this.

In general, unidirectional air flow has a degree of turbulence of between 5 and 20. It is highly recommended to have laminar airflow in the system. Laminar airflow is much better as the degree of turbulence is less than 5. Mainly used in cleanroom as the most relevant and we must try to achieve this at all times.

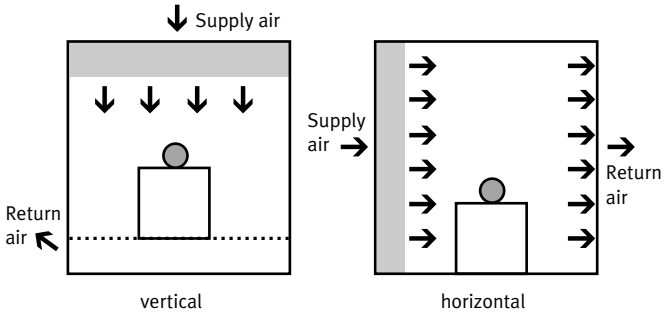


Figure 2.7

Figure 2.8

2.3 Design Features

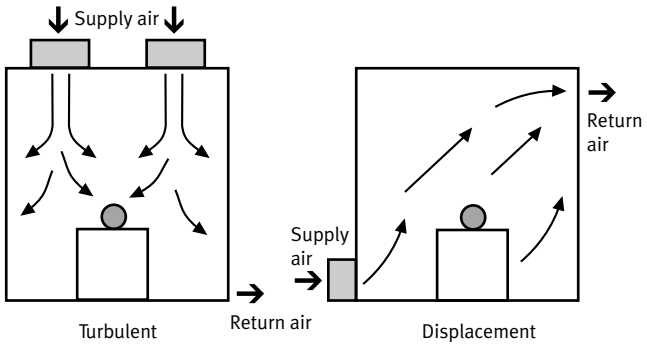


Figure 2.9

b) Nonunidirectional air flow (Figure 2.9)

In nonunidirectional airflow cleanrooms, air flows through HEPA/ULPA filters located in various positions and is returned through opposite locations. Filters may be distributed at equal intervals throughout the cleanroom or grouped over critical process areas. Because of the distribution of the filters, air flow may be turbulent in nature. The degree of turbulence is usually greater than 20.

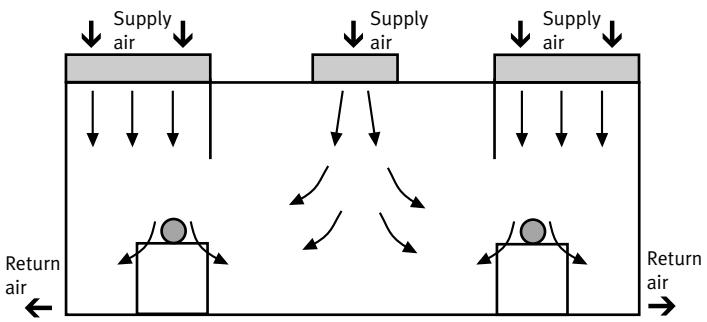


Figure 2.10

c) Mixed air flow (Figure 2.10)

Mixed air flow cleanrooms combine both unidirectional and nonunidirectional air flow in the same room.

2.3.3 Cleanroom layout determines air flow patterns

The layout of the cleanroom can determine the air flow that is needed to maintain a specified level of room cleanliness. For example, it may take less air flow to achieve a desired level of cleanliness if the cleanroom layout has taken into account the uniformity of air flow patterns.

Unidirectional air flow cleanrooms rely on the air flow to move particles in the direction of the air flow. Layouts that would interrupt the path of air flow should be avoided; resulting dead air spaces and zones would be likely to trap particles, creating areas of high particulate concentration.

The layout of mixed air flow cleanrooms should be considered even more carefully. Mixed air flow cleanrooms maintain cleanliness primarily by dilution, rather than by air flow. As a result, areas within the cleanroom that are isolated from the air path are most likely to develop high concentration of contamination.

Internal surfaces, in contact with the air flow, should be smooth and free from cracks, ledges and cavities. Irregular surfaces and similar features that might collect contaminants should be minimized.

In vertical unidirectional air flow cleanrooms, space should be provided to accommodate return air flow. The return air path may be in the service area, duct work, or space adjacent to the cleanroom.

The quantity and resulting velocity of the air supplied by a central system may be restricted by the architectural configuration of the building. As the quantity of centrally supplied air increases, so too do the requirements for mechanical space to house air handling equipment. Typically, the mechanical space allocated for air-handling equipment is placed either on a separate level or adjacent to it.

The flexibility of a cleanroom may be either enhanced or detracted from by additional air flow, depending on how flexibility is defined. If defined as the ability to rearrange and relocate equipment within the cleanroom, flexibility may be enhanced by additional air flow.

The additional air flow makes the cleanroom more capable of recovering from transient episodes of particle generation due to activity within it. If flexibility is defined as the ability to modify the entire cleanroom, then fan hoods or modules capable of being easily rearranged may be used in lieu of a central recirculating system.

2.3 Design Features

2.3.4 Air Velocity

Relating a cleanliness class level to a specific air velocity is a complex task because a number of variables that may be involved. Operating protocol, flow direction, and filter quality all have an impact on the potential cleanliness level for a given velocity. Air velocity is a determining factor in achieving air flow uniformity under unidirectional air flow devices. Air velocities in those cases may vary with the configuration of the equipment downstream of the air filters.

Air velocity can be specified by one of two methods:

- Average air velocity (metres per second or feet per minute)
- Number of air changes per hour.

Table 2.1 provides some general rules for selection of air velocity in cleanrooms. The air velocity shown is based on average room cross-section velocity as opposed to filter-face velocity.

Air velocity in cleanrooms

Class	Air flow Type[1]	Average air flow velocity[2]	Air changes per hour[3]
M7 & M6.5 (Class 100,000)	N M	.005 - .041 m/s (1-8 ft/min)	4 – 48
M6 & M5.5 (Class 10,000)	N M	.051 - .076 m/s (10-15 ft/min)	60 – 90
M5 & M4.5 (Class 1,000)	N M	.127 - .203 m/s (25-40 ft/min)	150 – 240
M4 & M3.5 (Class 100)	U N M	.203 - .406 m/s (40-80 ft/min)	240 – 480
M3 & M2.5 (Class 10)	U	.254 - .457 m/s (50-90 ft/min)	300 – 540
M2 & M1.5 (Class 1)	U	.305 - .457 m/s (60-90 ft/min)	360 – 540
M1 & Cleaner	U	.305 - .508 m/s (60-100 ft/min)	360 – 600

[1] When air flow type is listed, it represents the more common airflow characteristics for cleanrooms of that class: U = unidirectional; N = nonunidirectional; M = mixed

[2] Average air flow velocity is the way that air flow is standard dimension cleanrooms (i.e. those that typically have a ceiling height of 10 feet or 3 metres) usually is specified. This term is commonly used to refer to unidirectional air flow.

[3] Air changes per hour are the way that nonunidirectional and mixed air flow in nonstandard, high bay, or unusually configured cleanrooms usually is specified. Air flow velocity and air changes per hour are mathematically equivalent methods, the conversion formula being:

$$\text{air changes p/hr} = \frac{\text{average air flow velocity x room area x 60 min/hr}}{\text{room volume}}$$

Table 2.1

Selection of the air velocity should be based on such considerations as product cleanliness criteria, the contamination rate expected from the processes and operating equipment, the anticipated use of the cleanroom for processing or storage, and the influence of personnel on the contamination load.

Take note that the selection of air flow patterns and velocities affect the cleanroom capital and operating costs. Higher velocities increase capital cost as a result of the cost of larger fans and air conditioning equipment. Operating costs also increase with high velocities because of the increased costs of energy required for air movement and cooling.

Figure 2.11 shows air flow patterns at air flow velocity of 0.45 m/s.

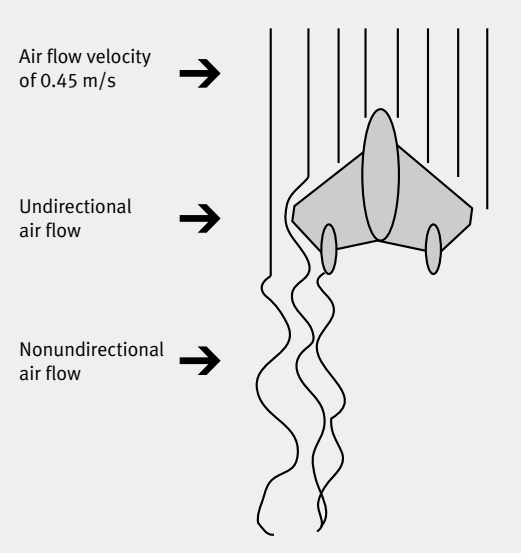


Figure 2.11

2.3 Design Features

2.3.5 Filters

Filters are used to ensure that the supply air is removed of particles that would contaminate the process being carried out in the room. Until the early 1980s, the air was filtered with High Efficiency Particulate Air (HEPA) filters, which were the most efficient air filters available.

Today, HEPA filters are still used in many types of cleanrooms but one cleanroom application, the production of integrated circuits, has evolved to a level where more efficient filters are required. These are known as Ultra Low Penetration Air (ULPA) filters.

In cleanrooms, high-efficiency filters are used for the dual purpose of removing small particles and, in unidirectional flow cleanrooms, straightening the air flow. The arrangement and spacing of high-efficiency filters, as well as the velocity of air, affect both the concentration of airborne particles and the formation of turbulent zones and pathways in which particles can accumulate and migrate throughout the cleanroom. The combination of a high-efficiency filter and a fan only initiates the unidirectional flow process. A balance of the entire air flow path is required to ensure good unidirectional flow.

It is generally accepted that for cleanrooms of ISO 6 (Class 1,000) and higher, HEPA filters are sufficient to meet the room classification, and traditional ventilation techniques, such as the use of terminal filter units or filters installed in the air supply ducting, are adequate.

For ISO 5 (Class 100), HEPA filters should completely cover the ceiling, supplying unidirectional flow down through the cleanroom. For ISO 4 (Class 10) or lower, ULPA filters should be used in a unidirectional flow cleanroom.

Figure 2.11 Samplers of HEPA and ULPA filters Fa. Freuden-

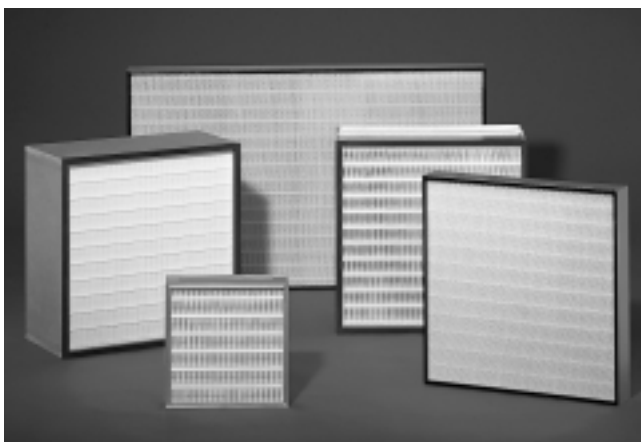


Figure 2.11

a) High-efficiency filters

High-efficiency filters are usually constructed in two ways, i.e. deep pleated or mini-pleated. Both methods are used to ensure that a large surface area of filter paper is compactly and safely assembled into a frame so that there is no leakage of unfiltered air through it.

b) HEPA filters

Its particle removal efficiency and its pressure drop at a rated air flow define a HEPA filter.

A HEPA filter is defined as having a minimum efficiency in removing small particles (approximately equal to 0.3 mm) from air of 99.97 % (i.e. only three out of 10,000 particles, 0.3 mm in size, can penetrate through the filter).

The traditional size of a deep-pleated type of HEPA filter is 2 ft x 2 ft x 12 in. (0.6 m x 0.6 m x 0.3 m), which has a rated flow of 1,000 ft^3/min (0.47 m^3/s). At this rated flow, the air velocity would be between 3.6 ft/min (1.8 cm/s) and 5.9 ft/min (3.0 cm/s). This velocity is important, because it determines the removal efficiency of the filter medium and if the air velocity is increased or decreased the efficiency will change. It is possible, by increasing the amount of filtering medium in a filter, not only to decrease the pressure drop across it but also to increase its efficiency.

2.3 Design Features

c) ULPA filters

The category of ULPA filter was created to define filters that have efficiencies higher than standard HEPA filters.

An ULPA filter will have efficiency greater than 99.999 % against 0.1-0.2 mm particles.

They differ in that the filter medium used has a higher proportion of smaller fibres and the pressure drop is slightly higher. For a filter with the same amount of medium, an ULPA filter will have a higher resistance than a HEPA filter. Because of the higher efficiency of removal of smaller particles, the methods used for testing HEPA filters are not appropriate and other methods using laser optical particle counters or condensation nuclei counters are applied.

d) Filters remove upstream contamination

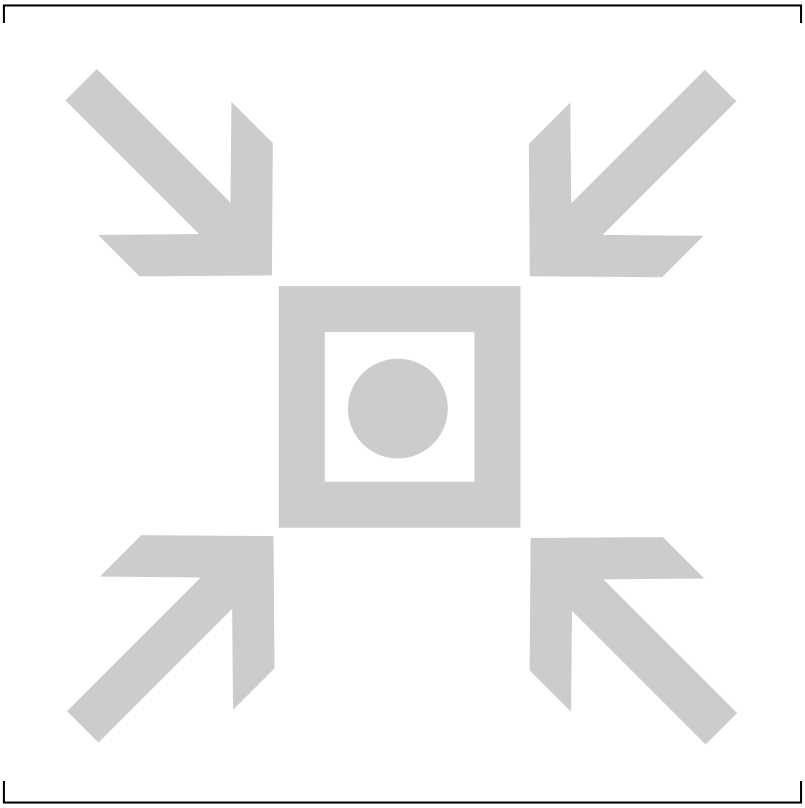
It is important to note that filters can remove a portion of upstream contamination and not reduce the amount of contamination introduced downstream of the filter. Filters ensure that the air coming into the cleanroom is removed of contaminants and we must keep in mind of the internal contamination of the cleanroom.

Recommended ceiling filter coverage:

Class (FS 209E)	Ceiling Coverage
M7 and M6.5 (Class 100,000)	5 – 15%
M6 and M5.5 (Class 10,000)	15 – 20%
M5 and M4.5 (Class 1,000)	25 – 40%
M4 and M3.5 (Class 100)	35 – 70%
M3 and M2.5 (Class 10)	50 – 90%
M2 and M1.5 (Class 1)	60 – 100%
M1 and Cleaner	80 – 100%

Actual average velocity and air changes required may vary depending on application and floor plan.

3.0 Design Principles of Cleanroom Equipment

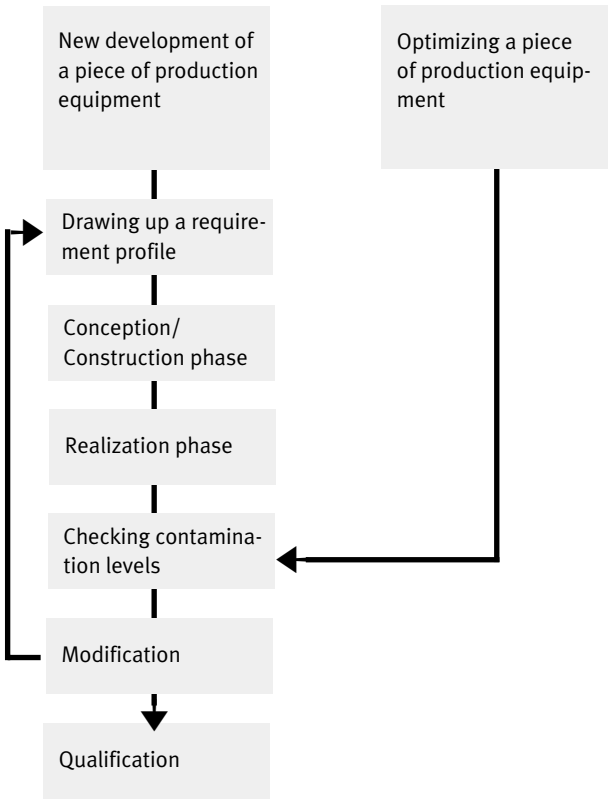


3.1 Introduction

The design of cleanroom equipment plays an important role in cleanroom technology. It would be wasteful to design a state-of-the-art cleanroom and do not place any importance on the equipment used in the cleanroom.

3.2 The Importance of Equipment Design

When designing cleanroom equipment, care must be taken right from the initial stage. The following chart shows a typical equipment development procedure:



When designing cleanroom equipment, we must remember that

- If there is a design fault in one part, it will affect the whole equipment
- If there is a fault in conception stage and it is not taken care of, it will spread and, accumulate down the equipment development procedure. Faults at this stage must be rectified immediately.
- Reworking of existing equipment is expensive and time-consuming.

As can be seen, the importance of equipment design is constantly increasing. This is due to the following reasons:

- Larger substrates
- Smaller structures
- Higher throughput
- Higher costs per substrate
- Higher reject losses

3.3 Influence on air flow pattern

One of the points to note is the way air flow patterns are influenced during the design stage.

3.3.1 Influence of operating materials on air flow patterns

There are some guidelines on how the choice of operating materials affects the air flow patterns. The basic requirements are:

- Air must be able to flow through the operating material.
- Operating materials must ensure well-directed transportation of any contamination generated.
- Wherever possible first air flow should be used.

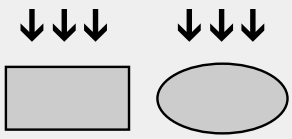
Things to avoid include:

- Counterdrafts
- Stagnant areas
- Areas where air rises
- Turbulent areas
- Cross currents

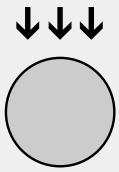
3.3.2 Influence of individual components on air flow patterns

The geometrical profile of the component will affect the air flow pattern and should be considered when designing equipment.

Unsuitable geometric profile



Suitable geometric profile



Ideal geometric profile

3.4 Suitable Materials for Equipment Design

When choosing materials for the equipment, important factors to take into account are friction and combination of materials.

You should keep operating material friction elements to a minimum. If friction is unavoidable:
- Employ lubricants suitable for cleanroom use.
- Encapsulate materials rubbing against each other.
- Extract particles using a vacuum.
- Keep materials rubbing against each other as far apart from the product as possible and place them “downstream”.

With regard to combination of materials, it must be noted that material combination is a deciding factor affecting particle emission concentrations.

Factors to consider are:
- Surface structure/Surface roughness
- Contact pressure between materials

Material overview for equipment design

Material	Treatment	Properties		Application	Usage
		Electro-static	Abrasion		
Stainless steel	electro-polished	good	good	Process chamber tool surface	very often
	polished	good	good	tool surface	very often
Aluminum	eloxed	good	neutral	handling tool	seldom
Steel	coated	neutral	bad	Tool Surface	often
Polypropylene (PP)	–	bad	good	process chamber tool surface means of transp.	very often
Polyvinyl chloride (PVC)	–	bad	neutral	process chamber tool surface	often
Polyethylene (PE)	–	bad	good	process chamber tool surface	often
Polyvenylidene fluoride (PVDF)	–	bad	good	process chamber means of transp.	often
Polyfluoralcoxy (PFA)	–	bad	neutral	process chamber	often
Polytetrafluor-ethylene (PTFE)	–	bad	bad	process chamber	often

3.4 Suitable Materials for Equipment Design

3.4.1 Surface structure/ Surface roughness

- There should be minimal surface roughness of all surfaces. This would equip the surface with easy cleaning properties.
- It has to be resistant to cleaning agents and not change its properties after cleaning.
- Wherever possible, there should be no gaps or edges, this would avoid contamination from collecting in areas, which cannot be cleaned.
- However, the surface should have sufficient roughness for handling equipment such as grippers. There should be adequate adherence achieved between the gripper and the product.

Surface roughness of materials

Technical surface	Surface roughness	
	R_a (µm)	R_{max} (µm)
Stainless steel, electro-polished	0.40	3.46
Stainless steel, polished (V2A)	0.65	5.61
Polypropylene (PP)	0.02	0.24
Silicon Wafer	0.001	0.005

3.4 Suitable Materials for Equipment Design

3.4.2 Treatment of materials

When choosing the suitable materials to be used, there are a few points to note:

- When manufacturing the material, try to have as few cutting and material-abrading processes as possible. The reason for this is that abrasives can be found on the products, which needs to be kept clean. This will also lead to the contamination of the product.
- Ideally, no further processing of the material is made. If further processing is unavoidable, then the material needs to be further cleaned. You can clean by:
  – ultrasonic, megasonic baths
  – ionized, compressed ultrapure air
  – wiping
  – carbon dioxide cleaning
  – laser cleaning

3.4.3 Recommended materials for process tools

Requirements:

- Product fabrication
- Low contamination
  – direct contact with product
  – indirect contact with product

Materials:

- Stainless steel
- Conductive plastic plates
- Ceramics
- Glass
- Plastics (PTFE, PFA, PVDF, PP...)

3.4.4 Recommended materials for handling and transport systems

Requirements:

- Low abrasive behaviour
  – moving parts generate particles
  – no outgassing of such items as transport boxes or lubricants

Materials:

- Stainless steel
  – chemically or electrochemically polished
  – pickled roughness R_a ‹5 µm
- Eloxed aluminum (thickness ›20 µm)
- Stoved finished quartz
- Glass
- Plastics
  – no outgassing of additives
  – no out-diffusion of softener: PTFE, PFA, PVDF, PP

3.5 Cleaning Methods

When cleaning the equipment, care must be taken to ensure the following:

- Avoidance of cross contamination
- Awareness of chemical incompatibility
- Prevention of mechanical destruction

The following are the commonly used cleaning methods:

- Cleaning blasts, e.g. compressed air, CO_2
- Thermal cleaning, e.g. steam cleaning
- Flow technology, e.g. ultrasound, megasound
- Plasma-jet cleaning
- Chemical, solvent cleaning

3.6 Basic Principles of Equipment Design

The following principles are used as a guide for equipment design; these are used to minimize faults in the final equipment.

3.6.1 Using rotary moving elements

Whenever possible rotary movements should be employed, as lesser particles are generated by rotary moving elements. Furthermore, it is easier to seal rotating elements from the clean environment.

3.6.2 Minimizing sliding friction

The design should minimize sliding friction. Do not use sliding tracks, it is better if you could use roller tracking. Lip sealing is also not allowed and tries to avoid unnecessary functional contact.

3.6.3 Principle of arranging task integration

Reduce the number of components used to a minimum, if possible make use of single components which can assume several functions.

3.6.4 Analyzing of ways of gripping products

If you need to use a gripper in the production, avoid gripping in the same direction as the direction of the first air flow. Keep the product contact to a minimum either by the equipment or the operator.

If you grip either from the side or from beneath the product, the gripper does not affect the air flow around the product and the air flow obstruction caused by the gripper is kept to a minimum.

If the gripper can only be used above the product, then keep moving elements next to the product and select the shape of the gripper and its distance away from the product in such a way that stagnant areas do not reach the product

3.6.5 Choice of materials/ Surface finish

With regard to the choice of materials, the following are recommended:

- Use materials with low electrostatic charge properties
- Combination of materials: plastic – metal: avoid insulated partial systems
- Surfaces should be smooth where possible, no sharp edges:
  - easier to clean, minimizing influence on air flow
- In semiconductor industry:
  - no moving elements made of copper of brass
  - better: special steel, aluminum

3.6.6 Secondary measures/ alternatives

The above five principles are required but however, if you are not available to meet these requirements.

The following are some guidelines, which should be considered:

- Encapsulating components
- All moving parts enclosed
- Vacuum suction
- Accurately aimed local air flow direction

3.7 Contamination Control of Cleanroom Equipment

Besides knowing the basic principles behind the designing of cleanroom equipment, we must also know what type of contamination control is required for this equipment.

3.7.1 Types of contamination

Contamination is defined as "Any unwanted substance present in or on a material or any surface within a clean zone". This presumes that one is working in an area where cleanliness is regulated.

Contaminants are particulate, liquid, gaseous, film or biological. Other authorities also include radiation and electromagnetic interference (EMI) as contaminants.

Particles can be solids or liquids and can be solid-solid, solid-liquid, solid-gas, liquid-liquid or liquid-gas as long as they are discrete entities. Films are typically dried liquids containing solids or gasses and are often only molecules thick. A trace amount of gas within another gas may be considered a contaminant.

3.7.2 Reason for contamination control

In all cleanrooms, three parameters influence the production area:

- Cleanroom class
- Personnel
- Equipment

We need to define the three parameters, but here we are concentrating only on the equipment. Contamination characteristics of equipment have major influence on cleanliness level of the production area.

3.7 Contamination Control of Cleanroom Equipment

3.7.3 Sources of contamination

There are many sources of contamination. The atmosphere contains dusts, microorganisms, condensates, and gases. People in clean environments, are the greatest contributors to contamination emitting body vapours, dead skin, microorganisms, skin oils, and, if smoking or wearing cosmetics, the fumes and particles from these materials.

Industrial processes produce the widest variety of contaminants. Wherever there is a process which grinds, corrodes, fumes, heats, sprays, turns, etc., particles and fumes are emitted and will contaminate their surroundings. Finally plants and soils contribute particulate and biological contaminants.

Airborne contaminants may be organic, inorganic, or aerosols, the latter being composites of any number of components. Organic contaminants include hydrocarbons such as hexanes, benzene, alcohol, ketones, and other volatile organic solvents.

Inorganic contaminants are mainly composed of gases such as carbon dioxide, chlorine, hydrogen sulphide, sulphur oxides, ammonia, etc. Aerosols can entrain any of the above into liquid or particle agglomerations containing dusts, pollens, small organisms such as mites, microorganisms, etc.

In addition to dust and other particles, surface contamination can be any one of the following – reaction layers of chemical compounds, absorbed layers of mostly hydrocarbons and moisture, or variable composition contaminants due to preferential diffusion of one component through a substrate.

3.7 Contamination Control of Cleanroom Equipment

a) ESD Behaviour of operating materials

ESD stands for Electrostatic Discharge. It is the rapid transfer from static charged bodies of materials to or from Electrostatic Discharge Sensitive Electronic Devices.

Virtually all electronic devices are ESD sensitive; the sensitivity is based on product and design. ESD occurs when charge is generated, stored on an object and rapidly transferred.

Materials become charged via:
- First air flowing onto them
- Particles generated are not removed by the first air flow
- Contamination adheres to charged materials
- Formation of larger agglomerates
- Sporadic, intermittent detachment of very large forms of contamination

As shown, ESD is harmful to the system and must be removed. Recommended ways of removing of electrostatic charges are:
- Equipping with various ionizers
  – nuclear or x-ray ionizers: ionizing radiation
  – corona discharge: electronic
  – emission of particles (approx. 5 P/cbf, P = 0.03 µm)
- Grounding (earthing) the equipment

b) Magnetic influences

When handling components, which are subject to magnetic influences, care must be taken to ensure that they are shielded from the electromagnetic effects.

Another option would be keeping critical products away from electromotors, permanent magnets, coils and electromagnetic fields.

c) Properties of materials

The properties of the materials used in the equipment affects the level of contamination. If the wrong choice were made there would be more particles emitted and would greatly affect the cleanroom.

Take note of the following points when choosing the right material:

- Know the emission of particles from the material in use
- Constantly
- Sporadically
- Which size of particle, critical/uncritical?
- Which combinations of materials emit particles
- Know the life span of material
- Correlation between the wear and tear of materials used and tool life

d) Outgassing

When the equipment is under extremes of temperature, there is the likely occurrence of "Outgassing" which is simply the release of gases or volatile substances from a material other than a change of state of the material.

Make sure that the emission levels of volatile substances do not exceed limits. They must not be harmful to either the product or the personnel working the area. The materials chosen must pass tests at extremes of temperature.

3.8 Qualification of Cleanroom Equipment

VDI-RICHTLINIEN

VEREIN DEUTSCHER INGENIEURE

Reinraumtechnik

Reinraumtauglichkeit von Betriebsmitteln

VDI 2083

Inhalt

VDI-Handbuch Raumlufttechnik

Qualification tests are carried out to assess the cleanroom suitability of operating materials that include equipment.

It is very important to note here that **“No operating material may be allocated to a cleanroom class”**. It is therefore wrong to say that “Our product has the Cleanroom Class 100”.

The reasons are:

- Cleanroom classes were drawn up only for the acceptance and classification of cleanrooms.
- Operating materials do not fulfil these fundamental conditions.
- Missing of specifications for the classification of operating materials.

It might be easy to say that we could just transfer the cleanroom classifications to operating materials, but there are problems in doing so.

- Correlation of cleanroom classification/air volume
  – air volume
  – defined degree of cleanliness per volume of air
- Procedures for classification standards are related to cleanrooms

A possible solution is to draw up and use standardized procedures for classification of cleanroom products. This is covered in German standard VDI 2083 Part 8. However, it is important to note that the US Federal Standard and ISO standard does not cover this.

3.9 Cleanroom and Cleanliness Suitability

When using operating materials, there is a need to differentiate on the difference between cleanroom suitability and cleanliness suitability.

As shown in Figure 3.1, you would be able to see that the cleanroom suitability of the operating material will depend on the cleanliness suitability and the examination of the airborne particulate contamination.

To summarize, cleanliness suitability would consider all contamination, relevant to the specific product while cleanroom suitability would only consider airborne particulate contamination.

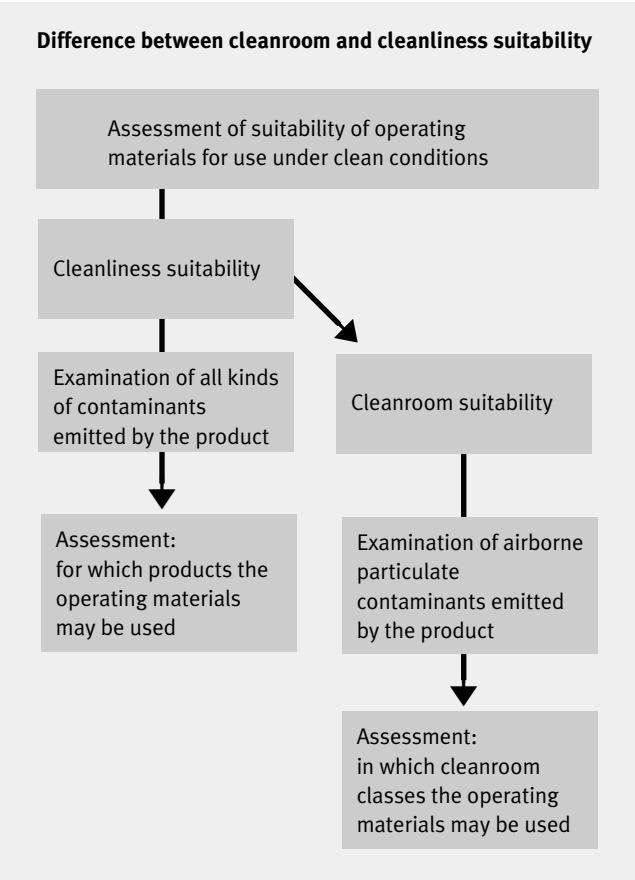


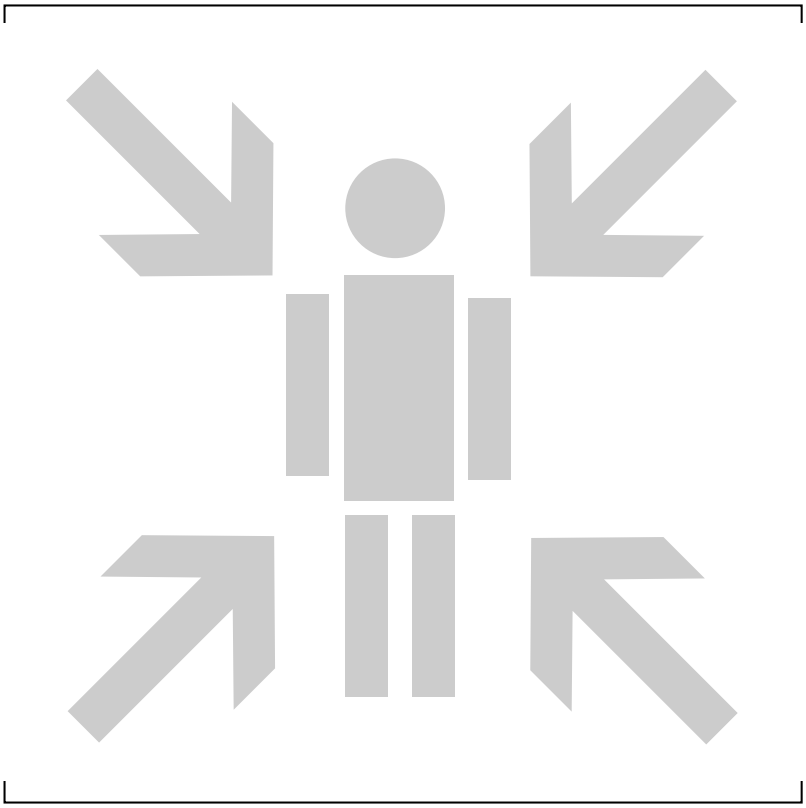
Figure 3.1

3.9.1 Parameters of cleanliness suitability

The following lists out the parameters that affect the cleanliness suitability.

- Airflow patterns
- Airborne particulate contamination
- Finding optimization potentials
- ESD behaviour
- Quality of surfaces
- Sedimented particle emission behaviour
- Cleanroom suitability of material used
- Conception of the operating materials
- Molecular contamination
- Upholding constructional device standards (e.g. SEMI)
- Upholding national and international regulations/ guidelines for cleanliness

4.0 Cleanroom Garment System



4.1 Introduction

The largest cause of contamination in a cleanroom is personnel. To illustrate this, let us look as some statistics:

Action	Particles generated/ minute (0.3 µm or larger)
Standing or sitting with no movement	100,000
Sitting or standing, light head, hand and forearm movements	500,000
Sitting or standing, average body or arm movement, toe tapping	1,000,000
Changing positions, sitting to standing	2,500,000
Slow walking (2 mph)	5,000,000
Average walking (3.5 mph)	7,500,000
Fast walking (5 mph)	10,000,000
Climbing stairs	10,000,000

Personnel working in cleanrooms disperse large quantities of particles from their skin and clothing. It is therefore necessary for personnel working within a cleanroom to use clothing that will minimize this dispersion. Cleanroom clothing is made from fabrics that do not lint or disperse particles and act as a filter against particles dispersed from the person's skin and indoor, or factory, clothing.

The type of clothing used in a cleanroom varies according to the type of cleanroom. In cleanrooms where contamination control is very important, personnel wear clothing that completely envelops them to ensure that particles and bacteria are not dispersed into the air. Whatever the choice of fabric or style of clothing, garments will have to be put on prior to entering the cleanroom. This should be done in such a manner that outside of the clothing is not contaminated.

The majority of cleanrooms require that a garment be used more than once. It is therefore necessary to devise a method that ensures garments are removed and then stored in such a way to ensure that the minimum of contamination is deposited onto them.

4.2 Cleanroom Garments

The garments used in cleanrooms are:

- Coverall or overall
- Hood
- Face mask
- Knee-length boots
- Gloves

In cleanrooms where contamination is not as critical, then a smock, cap and shoe cover may be sufficient.

4.3 Entry and Exit Procedures

4.3.1 Entry procedure

It is necessary to change into cleanroom garments before entering a cleanroom. The method outlined here can be used in a typical cleanroom. It should be noted that there are alternatives to the proposed method and these are quite acceptable as long as they give an appropriate level of contamination control. It is common to find that the change area is divided into three zones, or areas. These zones are prechange zone, changing zone, and cleanroom entrance. Personnel move through the zones carrying out the changing procedure in the following manner:

4.3.2 Prechange zone

Before changing clothing, it is best to go to the bathroom. If it is necessary to come out of the cleanroom to go to the bathroom this is likely to entail changing in and out of cleanroom clothing. In cleanrooms where outdoor shoes are not removed or fully covered, shoe cleaners should be used. These shoe cleaners are specially made for cleanrooms. Cleanroom mats or flooring are often used in the approach route to the prechange room. The shoes should be applied to a mat three times to ensure the removal of practically all footwear contamination. Cleanroom flooring should be of sufficient size for the correct number of steps (a minimum of three). Within the prechange zone, the following tasks may be carried out:

- Personnel should remove sufficient street or factory clothes to feel comfortable in the cleanroom. If the company provides dedicated cleanroom garments for wearing under the cleanroom garments, then all street clothing should be removed and replaced.
- Watches and rings should be removed. Wedding rings that are smooth may be acceptable if the ring (and under the ring) is kept clean. Rings that are not smooth can be taped over. Along with other items, such as cigarettes and lighters, wallets and any other valuables should be securely stored.
- Remove cosmetics and, if required, apply a suitable skin lotion. Don a disposable bouffant hat or hairnet to ensure that hair will not stick out from under the cleanroom hood.
- Put on a pair of disposable footwear coverings, or change into cleanroom-dedicated footwear.
- If a hand washing system is located in this area, then wash the hands, dry and apply a suitable hand lotion. However, it is probably best that the hands be washed within the change area just before the clean garments are put on.
- Cross over from the preentry area into the changing area or zone. The demarcation between these two zones may be a door or a crossover bench, or both. The bench will normally be built between the zones to ensure that personnel cannot walk round it but must cross over it. If a bench is used, it may be best to attend to footwear as one crosses over it. If a bench is not used, then a cleanroom mat or flooring can be used.

4.3 Entry and Exit Procedures

4.3.3 Changing zone

The outer cleanroom garments are put on in this area. Several methods can be used but the following one is used in many cleanrooms. This method assumes that a face mask, hood, coverall and overboots are used but it can be adapted for use with a cap, gown and overshoes. This method requires that the garments be donned from the top down.

- The garments to be worn are selected. If a fresh garment is used then it should be checked for size and the packaging checked to see that it is free from tears and faulty heat seals. The packaging is then opened.
- If a hand washing system is installed in this area, then the hands should now be washed (and disinfected if required). This is probably the best time to wash hands; temporary gloves known as “donning gloves” are sometimes used. Use of these gloves is confined to the highest quality of cleanroom. These should be put on, if required.
- A face mask and hood (or cap) should be put on. It appears to make little difference whether the mask is put under, or over, the hood. However, the mask should not be placed under the nose.
- The coverall (or gown) should be unfolded without touching the floor. The garment should then be put on ensuring that it does not touch the floor.
- The garment should then be zipped all the way up to the top, with the yoke of the hood (if used) being tucked inside the collar.
- If the garment has snaps at the ankles and wrists, then these should be snapped shut.

4.3 Entry and Exit Procedures

4.3.4 Cleanroom entrance

If a crossover bench is available, it should be crossed over now. This bench is used to demarcate the slightly soiled changing zone from the cleaner entrance zone and allows cleanroom footwear (overshoes or overboots) to be correctly put on.

- Personnel should sit on the bench. One leg should be raised, the cleanroom footwear put on, the leg transferred over the bench and placed on the floor of the entrance zone. Footwear should be put on the other foot and the leg taken over the bench. While still sitting on the bench, the legs of the cleanroom garment and the footwear should be adjusted for comfort and security. Personnel should now stand up.
- If donning gloves have been used they can be dispensed with now; if deemed necessary, the hands can again be washed (or disinfected).
- Powder-free cleanroom gloves should now be put on. A method should be employed to prevent the outside of them from becoming contaminated when being put on. This usually entails holding the glove at the cuff.
- Protective eyeglasses, if required, may be put on.
- The garment should be checked in a full-length mirror to see that it is being worn correctly.
- Personnel may now proceed into the cleanroom. This may be over a cleanroom mat.

4.3 Entry and Exit Procedures

4.3.5 Exit changing procedures

When leaving a cleanroom, personnel will either:

- Discard all their garments and disposable items; on reentry they will use a freshly processed set of garments (this method is normally only used in a pharmaceutical cleanroom) or
- Discard their disposable items, such as their mask and gloves, but reuse their garments on reentry. If a complete change of clothing is required on reentry, then the disposable bouffant hat, gloves, face mask and (if disposable) shoe covers will be placed in a container for disposal. The remainder of the garments that are not disposable should be placed in a separate container for dispatch to the cleanroom laundry for processing.

If the garments are to be used again on reentry, they should be removed in such a way that the outside of the garment is contaminated as little as possible. The cleanroom footwear should be removed at the crossover bench, one at a time, and the inner shoe (with or without the covering of a plastic shoe cover) placed in the less clean zone.

The coverall should be unzipped and removed using the hands within the garment to remove it over the shoulder and down to the waist. In a sitting position, one leg is now removed from the garment.

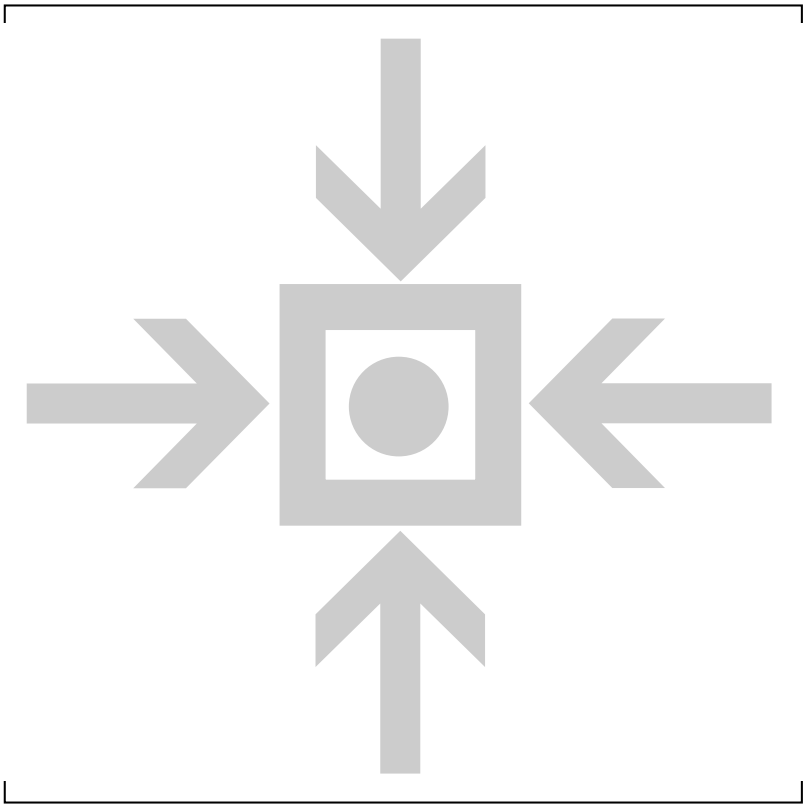
The empty arm and leg of the garment should be held so that they do not touch the floor. The other leg can now be removed. The face mask and hood can now be removed.

Garments to be used again on reentry should be correctly stored. This can be done in several ways. These are as follows:

- Each item of clothing can be rolled up ensuring the inside does not touch the outside. In the case of cleanroom footwear, this should be done so that the dirty soles are to the outside. The footwear can now be placed in one open compartment and the hood and coverall (or cap and gown) in another. If thought necessary, the items of clothing can be placed into bags before being put in an open compartment.
- The hood (or cap) can be attached to the outside of the coverall (or gown) by means of a snap, and hung in a cabinet. The cleanroom footwear can be placed at the bottom of the cabinet. Garments can also be hung up in the room but they should not touch the wall, or each other. In higher-grade cleanrooms, clothing is often hung up in unidirectional flow cabinets (normally vertical flow type), specifically made to ensure that garments are not contaminated.
- Garment bags, which can be hung up, can be used. These will have separate pockets for the various clothing items and should be regularly laundered.

If the entry described above and exit changing methods are used in a cleanroom facility then contamination of garments during donning will be minimized. However, because the layout of particular change areas, it may be necessary to modify the method suggested above. If an alternative method can be devised to minimizing contamination then no harm will be done to the product.

5.0 International Standard for Cleanrooms



5.1 Introduction

The US Federal Standard 209E have long been the only definition of cleanroom classification available from a standard organization. It is from the U.S. General Service Administration and approved for use by all U.S. Agencies. In the absence of an international standard, FS 209E was broadly used internationally.

The need for a new international standard that covered more cleanroom environmental parameters and practices led to the formation of a technical committee of the International Standards Organization. The technical committee is named TC 209 Cleanrooms and Associated Controlled Environments.

The goal of TC 209 is "standardization of equipment, facilities and operational methods for cleanrooms and associated controlled environments. This includes procedural limits and testing procedures to achieve desired attributes to minimize microcontamination."

The ISO committee will produce 10 new standards documents that relate to cleanrooms or clean zones.

National and international standards will be introduced in this chapter with emphasis given to the above two.

5.2 Cleanroom Classes

Cleanroom classification standards can be divided into the following subgroups:

Engineering classes	These originate from Federal Standard 209 and are based on inanimate particles in air.
Biocontamination (pharmacy) classes	These were originally based on Federal Standard 209 but developed to include living microorganisms. These standards are required for hygienic or sterile production.
Containment classes	These are for areas where hazardous contaminants are used or can occur.

Table 5.1

5.3 The Present Engineering Classes

These classes are used mainly in rooms where electronic and engineering items are manufactured. Most of these standards are based on one of the various editions of the US Federal Standard 209. Some countries completely adopted FS 209, while others made their own national version, similar to FS 209. Some made minor changes of the classes to comply with the metric system, but all changed the denomination of the classes.

Major national standards

Country	Standard	Year	Description
Australia	AS 1386	1989	Cleanrooms and clean work stations
France	AFNOR X44101	1981	Definition of cleanroom levels
Germany	VDI 2083.3	1993	Contamination control measuring technique for clean air rooms
Holland	VCCN 1	1992	Dust and microorganism classification of air
Japan	JIS-B-9920	1989	Measuring methods for airborne particles in cleanroom and evaluating methods, etc.
Russia	Gost-R 50766	1995	Cleanroom classification, general requirements
UK	BS 5295	1989	Environmental cleanliness in enclosed spaces
US	FS 209E	1992	Airborne particulate cleanliness classes in cleanrooms and clean zones

A comparison of major engineering cleanroom classes in the world

USA 209E 1992		ISO 14644-1 1997	Japan B 9920 1989	France X44101 1981	Germany VDI 2083 1990	UK BS 5295 1989	Australia AS 1386 1989
		ISO Class 1	1				
		ISO Class 2	2		0		
1	M1	ISO Class 3	3		1	C	0.035
10	M2	ISO Class 4	4		2	D	0.35
100	M3	ISO Class 5	5	4,000	3	E, F	3.5
1,000	M4	ISO Class 6	6	–	4	G, H	35
10,000	M5	ISO Class 7	7	40,0000	5	J	350
100,000	M6	ISO Class 8	8	4,000,000	6	K	3500
	M7	ISO Class 9			7	L	

Note: The M values for FS 209E (and the ISO values) are in metric units. The M figures are therefore elevated above the line of the others, which are given in cubic feet. FS 209E class 100 therefore corresponds to M class 3.5 and ISO 5.

5.4 Federal Standard 209E, and its Four Early Editions

The following table shows a summary of the Federal Standard 209.

Federal Standard	Year	Comments
209	1963	Initial standard
209A	1966	First revision
209B	1973	Mixture of information advises and rules. Helped people enter the new field of contamination control and building cleanrooms.
209C	1987	Revision of 209B but had printing errors
209D	1988	Proper revision of 209C
209E	1992	Present version

Table 5.4

The following table shows the cleanroom classification prior to version 209E.

Federal Standard 209 (A to D) Class Limits

Class	Messured particle size (µm)				
	0.1	0.2	0.3	0.5	5.0
1	35	7.5	3	1	NA
10	350	75	30	10	NA
100	NA	750	300	100	NA
1,000	NA	NA	NA	1,000	7
10,000	NA	NA	NA	10,000	70
100,000	NA	NA	NA	100,000	700

Table 5.5

5.4 Federal Standard 209E, and its Four Early Editions

5.4.1 Federal Standard 209 – Version E

A substantially changed version E was published in 1992, with a more precise title: "Airborne particulate cleanliness classes for cleanrooms and clean zones."

Version E differs from the previous editions as follows:

- The cleanroom classes are metric.
- It has seven classes of cleanliness: M1-M7.
- It gives a method for measuring air cleanliness.
- It demands a plan for monitoring air cleanliness.
- It gives a rational for the statistical rules used.
- Ultrafine particles are considered, i.e. particles ‹0.02 mm.
- It considers iso-anisokinetic sampling.
- It describes sequential sampling for low concentrations of particles.

Table shows the class limits of the classroom in terms of the particle concentration in both metric and the original English units. This table does not necessarily represent the size distribution to be found in any particular situation.

Concentration limits can be calculated for intermediate classes, approximately, from the equation:

$$particles/m^3 = 10M\,(0.5/d)^{2.2}$$

Where "M" is the numerical designation of the class based on SI units and "d" is the

Federal Standard 209E Airborne Particle Cleanliness Classes

Class		Class limits (µm)									
		0.1		0.2		0.3		0.5			
SI	English	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)	(m^3)	(ft^3)
M1		350	9.91	75.7	2.14	30.9	0.875	10.0	0.283		
M1.5	1	1,240	35.0	265	7.50	106	3.00	35.3	1.00		
M2		3,500	99.1	757	21.4	309	8.75	100	2.83		
M2.5	10	12,400	350	2,650	75.0	1,060	30.0	353	10.0		
M3		35,000	991	7,570	214	3,090	87.5	1,000	28.3		
M3.5	100			26,500	750	10,600	300	3,530	100		
M4				75,700	2,140	30,900		10,000	283		
M4.5	1,000							35,300	1,000	247	7.00
M5								100,000	2,830	618	17.5
M5.5	100,000							353,000	10,000	2,470	70.0
M6								1,000,000	28,300	6,180	175
M6.5								3,530,000	100,000	24,700	700
M7								10,000,000	283,000	61,800	

Table 5.6

5.5 German Standard: VDI 2083

The German Engineering Association, known in Germany as Vereinigte Deutsche Ingenieure (VDI), has a group working in the field of contamination control. In 1976, the VDI published VDI 2083 as their "Cleanroom Engineering" standard with a metric system used in the classification. It was then revised from 1987 onwards and consists (in 1998) of eleven parts.

Part 1	Fundamentals, definitions and determination of classes	issued 1991
Part 2	Construction, operation and maintenance	issued 1991
Part 3	Measuring technique for clean air rooms	issued 1993
Part 4	Surface cleanliness	issued 1991
Part 5	Criterion on comfort	issued 1989
Part 6	Personnel in cleanroom work area	issued 1991
Part 7	Cleanliness of process media (liquids, gasses, etc.)	issued 1991
Part 8	Suitability of products for cleanroom	issued 2000
Part 9	Quality, production and distribution of superpure water	issued 1991
Part 10	Media distribution	issued 1998
Part 11	Quality assurance	under development

Table 5.7

VDI 2083: Part 3 gives the German cleanroom classification. It is a metric standard and uses a size ≥1.0 µm as a basis of its nomenclature, instead of the ≥0.5 µm used by FS 209E.

5.6 British Standard: BS 5295

This standard, which is entitled "Environmental cleanliness in enclosed spaces", was first published in 1976 and revised and published in 1989. It is similar to FS 209B in that it gives useful information to those designing and using a cleanroom. It is divided into 5 sections.

Part 0	General introduction, terms and definitions for cleanrooms and clean air devices.
Part 1	Specification for cleanrooms and clean air devices.
Part 2	Methods for specifying the design, construction and commissioning of cleanrooms and clean air devices.
Part 3	Guide to operational procedures and disciplines applicable to cleanrooms and clean air devices.
Part 4	Specification for monitoring cleanrooms and clean air devices.

Table 5.8

BS 5295: Environmental cleanliness classes

Class of environ. cleanliness	Maximum permitted number of particles per m^3				
	0.3 µm	0.5 µm	5 µm	10 µm	25 µm
C	100	35	0	NS	NS
D	1,000	350	0	NS	NS
E	10,000	3,500	0	NS	NS
F	NS	3,500	0	NS	NS
G	100,000	35,000	200	0	NS
H	NS	35,000	200	0	NS
J	NS	350,000	2,000	450	0
K	NS	3,500,000	20,000	4,500	500
L	NS	NS	200,000	45,000	5,000
M	NS	NS	NS	450,000	50,000

NS – No specified limit

Table 5.9

5.7 Japanese Industrial Standard: JIS B 9920

FS 209B to D were translated into Japanese and were used by the Japanese until the late 1980s. The JIS B 9920 was published in 1989 and it deviates from the FS 209E in the following ways:

- It is metric and has a denomination system based on the exponent of particle concentration.
- It uses particles ≥ 0.1 µm as the reference size, instead of ≥ 0.5 µm used in FS 209E.
- It has two cleaner classes than FS 209E.

However, it is similar to the ISO 14644-1, as the ISO cleanroom classification is also based on particles ≥ 0.1 µm, that method being derived from this standard.

5.8 Australian Standard: AS 1386

This was first published in 1976 and is now revised and was republished in 1989. It consists of seven parts. The Australians classify cleanrooms using a metric system.

5.8 French Standard: AFNOR X 44101

In France, the French cleanroom association (ASPEC) has developed many “Recommendations” for cleanrooms since 1972. Their main cleanroom classification was taken over and published in 1981 by the French Organization for Standards (AFNOR) and given the number X 44101.

5.10 Dutch Standard: VCCN-RL-1

In the Netherlands, their cleanroom association, VCCN, has issued contamination control “Guidelines”. They have issued six contamination control standards since then, the first being VCCN-RL-1 that considers the “Particle and microorganism classification” of cleanrooms. VCCN-RL-2 is about “Building and maintenance of cleanrooms”.

5.11 Russian Standard: GOST R 50766-95

In the 1970s, the Soviet Union published a cleanroom classification standard with five classifications. It was based on FS 209E. During the 1980s a similar COMECON standard was published in the Soviet Union. In 1991, a Soviet Cleanroom Association (ASENMCO) was formed acting for international cooperation and standardization. The first Russian classification, GOST R 50766-95, "Cleanroom classifications. Methods of certification. General Requirements", was developed by ASENMCO and approved by Gosstandard in January, 1986.

5.12 ISO Classification Standard

Because of the large number of cleanroom standards produced by individual countries, it is very desirable that one worldwide standard of cleanroom classification is produced. ISO has setup a technical committee (TC 209) and will produce 10 new standards documents that relate to cleanrooms or clean zones. The first two standards have been published: ISO 14644-1 and –2.

Table 5.10 shows the 10 different documents which will make up the cleanroom standards. Many of these documents are at the final voting stage and can be legally used in trade.

ISO Document	Title
ISO 14644-1	Classification of Air Cleanliness
ISO 14644-2	Cleanroom Testing for Compliance
ISO 14644-3	Methods for Evaluating & Measuring Cleanrooms & Associated Controlled Environments
ISO 14644-4	Cleanroom Design & Construction
ISO 14644-5	Cleanroom Operations
ISO 14644-6	Terms, Definitions & Units
ISO 14644-7	Enhanced Clean Devices
ISO 14698-1	Biocontamination: Control General Principles
ISO 14698-2	Biocontamination: Evaluation & Interpretation of Data
ISO 14698-3	Biocontamination: Methodology for Measuring Efficiency of Cleaning Inert Surfaces

Table 5.10

5.12 ISO Classification Standard

5.12.1 ISO 14644-1 classification of air cleanliness

Cleanliness class designations and quantity have changed from FS 209E. Along with the obvious change to metric measure of air volume, ISO 14644-1 adds three additional classes – two cleaner than Class 10 and one dirtier than Class 100,000.

Airborne particulate cleanliness classes

Class	Number of particles per cubic meter by micrometer size					
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm
ISO 1	10	2				
ISO 2	100	24	10	4	8	
ISO 3	1,000	237	102	35	83	
ISO 4	10,000	2,370	1,020	352	832	
ISO 5	100,000	23,700	10,200	3,520	8,320	29
ISO 6	1,000,000	237,000	102,000	35,200	83,200	293
ISO 7				352,000	832,000	2,930
ISO 8				3,520,000	8,320,000	29,300
ISO 9				35,200,000	83,200,000	293,000

Table 5.11

5.12 ISO Classification Standard

5.12.2 ISO 14644-2 cleanroom testing for compliance

ISO 14644-2 determines the type and frequency of testing required conforming to the standard. Table 5.12 indicates which tests are mandatory and Table 5.13 indicates which tests are optional.

Schedule of Tests to Demonstrate Continuing Compliance

Test parameter	Class	Maximum time interval	Test procedure
Particle count test	≤ ISO 5	6 month	ISO 14644-1 Annex A
	› ISO 5	12 month	
Air pressure test	all classes	12 month	ISO 14644-1 Annex A
Air flow	all classes	12 month	ISO 14644-1 Annex B4

Table 5.12

Schedule of additional optional tests

Test Parameter	Class	Maximum time interval	Test procedure
Installed filter leakage	all classes	24 month	ISO 14644-3 Annex B6
Containment leakage	all classes	24 month	ISO 14644-3 Annex B4
Recovery	all classes	24 month	ISO 14644-3 Annex B13
Air flow visualization	all classes	24 month	ISO 14644-3 Annex B7

Table 5.13

5.12.3 Status of other ISO 14644 Standards

The development stages are given the following prefixes:

- WD – Working Draft.
  Circulation of developing within the Working Group setup by the ISO/TC209 committee.
- CD – Committee Draft.
  Circulation of approved Working Draft within ISO/TC209 for approval and/ or comments by the National Technical Bodies of the participating countries.
- DIS – Draft International Standard.
  Circulation of the ISO-approved Committee Draft by ISO for public enquiry in all ISO member countries.
- FDIS – Final Draft International Standard.
  Circulation of approved DIS for final vote.

Status of ISO 14644 Standards

Document	Title	Status
ISO 14644-3	Methods for evaluating & measuring cleanrooms & associated controlled environments	CD 14644-3 DIS in 2001
ISO 14644-4	Cleanroom design & Cconstruction	DIS 14644-4
ISO 14644-5	Cleanroom operations	CD 14644-5
ISO 14644-6	Terms, definitions & units	CD 14644-6 DIS in 2001
ISO 14644-7	Enhanced clean devices	CD 14644-7

Table 5.14

5.13 Summary of FS 209E and ISO 14644-1 and -2

The cleanliness classification levels defined by FS 209E and ISO 14644-1 are approximately equal, except the new ISO Standard uses new class designations, a metric measure of air volume and adds three additional classes – two cleaner than Class 10 and one dirtier than Class 100,000.

The second new ISO Standard, ISO 14644-2, gives requirements for monitoring a cleanroom or clean zone to provide evidence of its continued compliance with ISO 14644-1. The following table compares the FS 209E to the new ISO 14644-1 classifications.

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

Table 5.15

The ISO Standard also requires fewer sample locations, especially as the cleanroom/area size increases; however, the ISO Standard does require minimum one minute samples, whereas the Federal Standard allows shorter samples, especially at smaller particle sizes. For example, to certify an FS Class 10 cleanroom (ISO Class 4), with 250 square feet (7.08 square meters), classified at 0.3 micron with a 1 ft^3/m flow rate particle counter, the required number of sample locations, sample volumes, and sample times would be as follows:

- FS 209E requires 10 sample locations, 19.6 litre minimum sample volume (0.85 ft^3), and a sample time of 51 seconds. This yields a total minimum sample time of 510 seconds and 10 equipment moves.
- ISO 14644-1 requires three sample locations, 19.6 litre minimum sample volume (0.85 cft^3), but also a minimum sample time of one minute yielding three samples of one cubic foot. This yields a total sample time of 180 seconds and three equipment moves.

5.13 Summary of FS 209E and ISO 14644-1 and -2

Comparison between FS 209E and ISO Standard 14644-1

Regarding	FED STD 209E	ISO 14644
Disposition	according to federal regulations	according to ISO
Particle range	0.1 – 10 µm	0.1 – 5 µm
Classification	according to table, equation given	according to equation
Formula for classes	$C = (0.5/D)^{2.2} \times 10^{N}$	$C = (0.1/D)^{2.08} \times 10^{N}$
Reference for particle size	0.5 µm	0.1 = a constant
Number of classes	M1 to M7	ISO 1 to 9 (expandable)
Occupancy states or conditions	at built, at rest, operational	at built, at rest, operational
Occupational states at test	not given	1 or more states
Requirement of particle sizes for classification	1 or more	1 or more, where diameter of one is 1.5 x diameter of next smaller particle
Minimum sample volume	2.83 litres	2 litres
Minimum counts/test	20	20
Sampling locations	according to three given equations	number of locations = V area of room
Number of samples/location	1 or more	1 but 3 if one location
Measurement methods	DPC (=OPC, CNC) + optical microscopy	DPC for 0.1 – 5 mm particles, CNC for ultrafines; optical microscope for macroparticles
Ultrafine particles	considers particles ≤ 0.02 µm	considers particles ≤ 0.1 µm
Macroparticles ≥ 5 µm	not considered	information on particles ≥ 5 µm
Confidence level needed	95 % UCL for ≤ 9 sample locations	95 % UCL for ≤ 9 sample locations
Sequential sampling	included	included
Isokinetic sampling	included	not included

Table 5.16

5.14 Biocontamination and Pharmaceutical Classes

In the early 1960s, the pharmaceutical industry developed cleanroom standards to counteract contamination problems of sterile products which had caused sickness and death in patients.

It had been realized that as only a small sample of drugs could be tested, a final test of sterility could never determine the safety of sterile products. It was necessary therefore to rely on proper manufacturing, i.e. good manufacturing practice (GMP).

These standards are known as Guides to Good Manufacturing Practice (GGMP). They were based on experience of the then new FS 209, BS 5295 and other engineering standards, as well as the experience in the manufacture of pharmaceutical products.

The goal of GGMPs is to carefully specify the proper method of manufacture of sterile products by eliminating microbial and particle contamination and hence creating the correct quality assurance (QA).

The GMP guides deals largely with the methods of good manufacturing but also specify the building design, building material, care of personnel, etc. They also give figures for the cleanliness classes of cleanrooms: particles, microorgan-isms, as well as the type of air filters and number of air changes per hour.

The GMP guides, produced by the various countries, are advisory rather than legal and consider that there is more than one way to achieve the recommended standards. To check that the GMP is being applied correctly, each country has government inspectors. They will interpret the generally expressed statements of the guides. A pharmaceutical manufacturer must also comply with the GMP guides of the countries receiving their products.

5.14 Biocontamination and Pharmaceutical Classes

Some of the produced GMPs

By	Year	Remarks
Food and Drug Administration (FDA)	1963	first GMP
Swedish Regulation	1966	made official
World Health Organization (WHO)	1969	first guide published
European Pharmaceutical Inspection	1972	first published
Convention (PIC)	1983	revised
This guide is accepted in most Western	1989	revised
European countries and a few Eastern	1992	revised
European countries and Australia	1995	revised (document PH 5/92)
EEC Guide to Good Manufacturing	1989	first issue
Practices for Medicinal Products	1992	reprinted with new Annexes
(produced by Commission of the European Communities)		It came into legal use and superseded all other GMP guides produced in EEC countries.
EU GMP Annex 1	1997	revised with a new cleanroom classification method
GMP, LD 64-125-91 from Russia	1992	first GMP issued in Eastern Europe

Table 5.17

Most used GMP Guides

By	Year	Remarks
PIC: GMP and Guidelines	1995	valid in European countries outside the EU and Australia
FDA cGMP	1987	valid for the United States
EU GGMP	1997	valid for the EU area

Table 5.18

5.14 Biocontamination and Pharmaceutical Classes

Table 5.19 shows the comparison of major GMP guides regarding working conditions and classes. Unfortunately, these GMPs are not harmonized. The conditions for testing (at rest, or operational) are different and the letters for the level, or grade do not mean the same in different countries.

A revised classification scheme was developed and issued for use in 1997.

Comparison of Major Pharmacy GMP Guides regarding working conditions and classes

GMP	PIC GMP	EU-GMP 1992	FDA 1987	Transfer of classes, all operational		
Condition	at rest	operational	operational	209D	209E	ISO
Grade A	100	100	critical area	100	M3.5	ISO 5
Grade B	100	10,000	–	100	M3.5	ISO 5
Grade C	10,000	100,000	–	10,000	M5.5	ISO 7
Grade D	100,000	–	controlled area	100,000	M6.5	ISO 8

Table 5.19

EU GMP Guide 1997, air particle classification system for the manufacture of sterile products

Grade	Maximum permitted number of particles per m^3 equal to or above			
	at rest (b)		in operation	
	0.5 µm	5 µm	0.5 µm	5 µm
A	3,500	0	3,500	0
B (a)	3,500	0	350,000	2,000
C (a)	350,000	2,000	3,500,000	20,000
D (a)	3,500,000	20,000	not defined (c)	not defined (c)

Table 5.20

(a) In order to reach the B, C and D air grades, the number of air changes should be related to the size of the room and the equipment and personnel present in the room. The air system should be provided with appropriate filters such as HEPA for grades A, B and C.

(b) At rest should be received in the unmanned state after the 15-20 min "clean-up" period.

(c) Appropriate alert and action limits should be set for the results of particulate and microbiological monitoring. If these limits are exceeded, operating procedures should prescribe corrective action.

5.15 ISO Biocontamination Standards: 14698

Originally, the ISO/TC 209 committee created a package of three standards on biocontamination control. This has been subsequently revised to two standards and one technical report.

5.15.1 ISO 14698-1

a) Title
Cleanrooms and associated controlled environments – Biocontamination control. Part 1 – General Principles and Methods.

b) Scope
Describes the principles and basic methodology for a formal system to assess and control biocontamination in cleanrooms.

c) Status
FDIS (Final Draft International Standard) document is awaiting issue by ISO Geneva for an FDIS vote by all member ISO nations.

d) Remarks
ISO 14698-1 is concerned only with a formal system to address microbiological hazards in cleanrooms. Such a system must have the means to identify potential hazards, determine the resultant likelihood of occurrence, designate risk zones, establish measures of prevention or control, establish control limits, establish monitoring and observation schedules, establish corrective actions, establish training procedures, and provide proper documentation.

It also provides detailed guidance on how to measure airborne biocontamination, how to validate air samples and how to measure biocontamination of surfaces, liquids and textiles used in cleanrooms; it also provides guidance for validating laundering processes and how to provide proper personnel training.

5.15 ISO Biocontamination Standards: 14698

5.15.2 ISO 14698-2

a) Title
Cleanrooms and associated controlled environments – Biocontamination control. Part 2 – Evaluation and Interpretation of Biocontamination Data.

b) Scope
Gives guidance on basic principles and methodology requirements for all microbiological data evaluation obtained from sampling for viable particles in specified risk zones in cleanrooms.

c) Status
FDIS (Final Draft International Standard) document is awaiting issue by ISO Geneva for an FDIS vote by all member ISO nations.

5.15.3 ISO 14698-3

a) Title
Cleanrooms and associated controlled environments – Biocontamination control. Part 3 – Measurement of the Efficiency of Processes of Cleaning and/or Disinfection of Inert Surfaces Bearing Biocontamination Wet Soiling or Biofilms.

b) Scope
Describes guidance for a laboratory method for measuring the efficiency of cleaning an inert surface.

c) Status
Passed an ISO DIS (Draft International Standard) vote in July, 1999. Has been subsequently determined to be too limiting to be issued as an ISO standard.

5.16 The Containment Classes

The handling of toxic or pathogenic material, as well as genetic engineering work, must be performed in special premises using containment equipment. Premises, equipment, and working techniques are regulated by these "Standards".

In the United States, guides on biosafety, which have been developed by the National Institute of Health, are contained DNA research – actions under the Guidelines: Federal Register 56" (1961). In Europe, the designer must meet the standards given in the EC Directive 90/912/EEC of 1990 when designing facilities for genetically modified organisms.

A European standard "EN 1620: Biotechnology – Large-scale processes and production – Plant building according to degree of hazard", was issued in 1997.

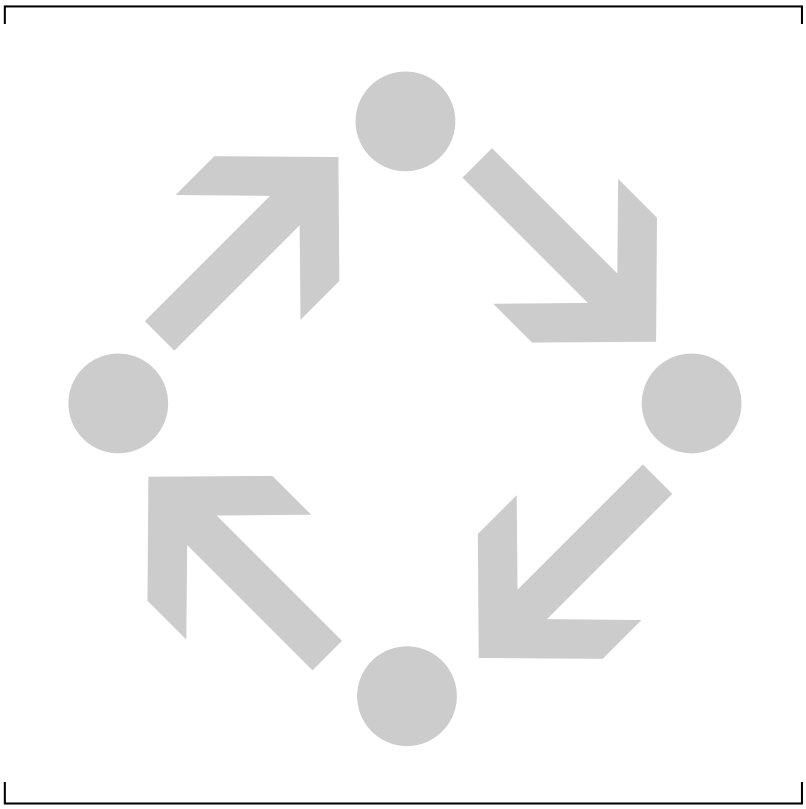
Biological risks, and the measures are directed toward these are classified in four classes. Four laboratories with risks levels of BL1 to BL4 are used.

Four Classes BL1- BL4 of Biosafety Laboratories

Class	Explanation	Example
BL1	Normal laboratory standard	Ordinary biochemistry labs
BL2	Special training and routines to	School and university labs
BL3	prevent lab infections	Diagnostic labs
BL4	Appropriate waste handling	Health labs
	Special lab with negative pressure Air locks for people and material Autoclave in the room All work done in safety cabinet Special decontamination of waste	Special safety labs Tuberculosis labs
	Special labs with total separation between humans and microorganisms in every aspect, negative pressure, sterilization	High-risks labs

Table 5.21

6.0 Airborne Particle Emission Measurements



6.1 Introduction

When we talk about clean-rooms, airborne particle emission measurement is an important factor. In this chapter, we will discuss on the source of particles, the methods for measuring particles and the LASAIR optical particle counter.

6.2 Sources of Particles

As stated in the earlier chapter, one of the sources of contamination is operating materials. Contamination caused by operating materials can be either:

- Chemical
- Physical
- Biological
- Radiological
- Ionic

Particle contamination falls under the umbrella of physical contamination. Particles are caused by:

- Leakage
- Abrasion
- Vibration

6.2.1 Leakage

Leakage from the pneumatic components will lead to particle contamination. The air, which leaks, might bring along particles with it.

6.2.2 Abrasion

When operating materials come into contact with one another, there is bound to be abrasion, make sure that the abrasion is to a minimum as particles are generated.

6.2.3 Vibration

When the pneumatic components move from end to end, there tend to be knocking at the end position, this will lead to minor vibration and also cause particles to be released.

There are a few methods to measure particles. Table 6.1 shows the recommended methods for measuring particles of different sizes.

Methods for measuring particles

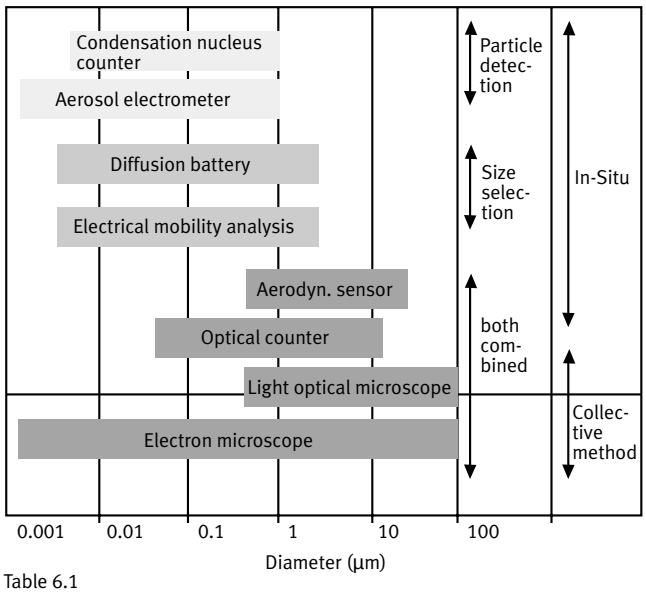


Table 6.1

6.3 Optical Particle Counters

6.3.1 A basic particle counter

Airborne particle counters are sophisticated instruments that measure airborne particles in a number of size ranges which are far too small to be seen, but may have a serious impact on air quality.

Although they come in a wide variety of sizes from heavy bench top units designed for semipermanent installation to hand-held counters weighing less than half a kilogram, all counters have the same basic components of sensor, vacuum source (for sample flow) and control electronics.

Display, printer and data interface is available on many counters as shown in Figure 6.1. The vacuum pump pulls the sample through the sensor where any particles present are detected. The counting electronics collect, report and store the information for use by the operator. The counted particles are trapped in an exhaust filter and not returned to the environment from which the sample was taken.

Counting particles

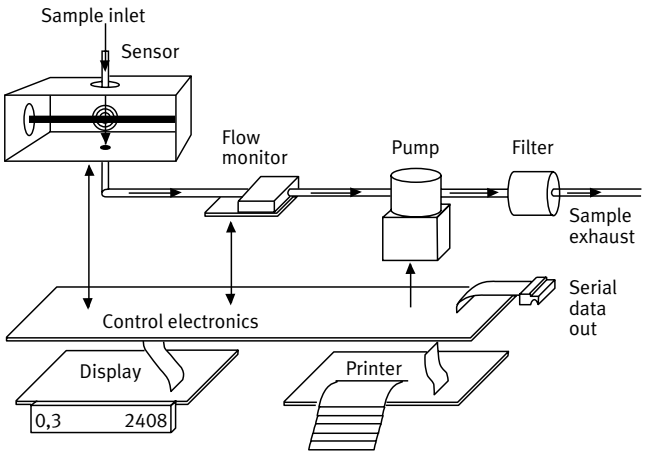


Figure 6.1

The most important part of a particle counter is its sensor, which uses collected light scattered from particles. The sensor contains a laser light source that illuminates an area called the “view volume” with intense light. Particles in the sample pass through the view volume and scatter the laser light; just as dust motes or smoke particles do in a sunbeam.

The light is then collected and focused onto a photo detector. The photo detector converts the light signal to electrical pulses, the height of which is directly proportional to the particle size.

The counting electronics categorize and count the pulses according to size, then stores the count data in a buffer and formats it for use by the display, printer and remote communications. For those counters equipped with an internal pump, sample flow control is achieved by operating a vacuum pump under control of the counting electronics and using a flow meter to monitor for the correct flow rate. Automatic or manual controls are then employed to correct any unacceptable variations.

In addition to discrete particle counters, there are facility-monitoring systems that use remote sensors, external vacuum pumps and PC workstations to complete the basic particle counter concept.

6.3 Optical Particle Counters

6.3.2 Technical characteristics of particle counters

Analyzing unit	Signal processing
Detection volumes – measuring cell	Size and position of registering range (light collector) e.g. 90° or forward area Shape and size of the measuring cell In-situ sensors, volumetric
Sensor-light source	White light Gas laser Solid matter laser
Distribution of intensity of the incoming light ray	Monitors Spectrometers

Table 6.2

6.3.3 General characteristics of particle counters

Individual particle detection	Single particles in motion Statistical statement (sampling range, sample taking techniques)
Indirect measuring method	No recognition of particular material No recognition of the measuring medium No recognition of particle shape (killer particle) Classification of a latex-equivalent, optical particle diameter Limited comparability of different measuring devices
Sample-feeding	Defined volume flow Constant volume flow

Table 6.3

6.4 LASAIR 210 Optical Particle Counter

The LASAIR particle counter is a microprocessor-based instrument that detects airborne particles, analyses and stores the data in eight size classes, and produces reports. It displays real-time data on a 5-inch CRT and contains a printer, which can be used to produce hard copies of reports.

6.4.1 Working Principle

The LASAIR sizes and counts particles by measuring the amount of light scattered from each particle. The source of illumination is a 10-milliwatt HeNe laser. The patented passive optical cavity is defined by the laser output coupler mirror and a mirror-coated quartz which is part of an oscillator.

The vibration of the crystal shifts the wavelength of the reflected light to maximize the transfer of power into the external passive cavity while minimizing reflection of coherent light back into the laser.

The cavity has a resonant Q of approximately 100. When it is driven with 10-milliwatt HeNe laser, a one-watt beam is available to illuminate particles.

The LASAIR flow system (Figure 6.2) provides a sample flow. The system includes a pump, filters, flow meter, inlet jet and outlet jet. The jet tip defines the size, shape, and position of the sample stream in relation to the laser beam. A purge flow is drawn across the sample cavity mirrors to keep the laser optics clean while sampling.

The collecting optics includes four Mangin mirrors and a solid-state photodetector. The mirrors are anti-reflective A-R coated for minimal light loss. One set of mirrors is located on each side of the laser optical bench. The collecting optics provides one-to-one magnification of scattered light to the detector.

The amplified signal from the photodiode is proportional to the size of the particle and the brightness of the illumination. This signal is compared to the reference voltage derived from the laser light leaked through the crystal mirror to provide automatic gain control.

The data system tallies the particles in each size bin, processes and displays the data.

6.4.2 Flow volume

The flow volume for this counter is 1 ft^3/min (cubic foot per minute) or 28.3 litres per minute.

6.4.3 Size range

The counter is able to detect particle size from 0.2 µm to 5.0 µm.

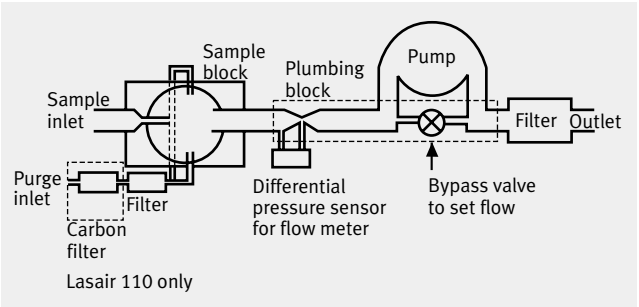


Figure 6.2

6.5 Setting Up of Optical Counters

When setting up an optical counter, there are certain features, which needs to be noted. The following are some of the important ones.

6.5.1 Flow rate

The flow rate through the counters can either is full stream or partial stream. There are of course advantages and disadvantages of both.

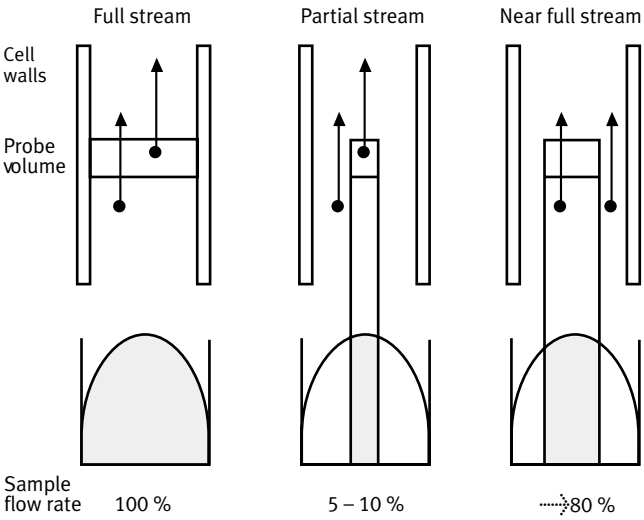


Figure 6.3

a) Full-stream flow rate

- Statistically good as all the air flow passes the probe
- Poor detection of particle sizes

b) Partial stream

- Statistically poor as not all the air flow passes the probe
- Good detection of particle sizes

6.5 Setting Up of Optical Counters

6.5.2 Condition for Sampling

When particles are sampled from a flowing air stream, a difference between the air velocity in the stream and the air velocity entering the probe inlet can cause a change in concentration because of particle inertia. When these velocities are the same, the sampling is isokinetic; otherwise, the sampling is anisokinetic.

a) Anisokinetic

The condition of anisokinetic sampling is when the mean velocity of the flowing air stream differs from the mean velocity of the air entering the inlet of the sampling probe.

Because of particle inertia, anisokinetic sampling can cause the concentration of particles in the sample to differ from the concentration of particles in the air being sampled.

b) Isokinetic

Isokinetic sampling is achieved when the probe inlet is pointed into the direction from which the flow is coming and is parallel with that flow, and when the mean velocity into the inlet matches the mean flow velocity of the air at that location.

6.5.3 OPC parameters

During the airborne particle emission measurements, the operating parameters of the OPC are set as follows:

- Air volume: 1.0 ft^3/min
- Sampling time: 60 seconds
- Delay time: 1 second
- Measurement time: 5 minutes

6.6 Test Environment Measurements

6.6.1 Purpose

In order to get correct particle count results, the test environment, in which the tests are carried out should have little or no influence on the particle measurements. The parameters, which influence the particle count, are the particle count in the:

- Environment
- Air velocity
- Degree of turbulence
- Relative humidity

The purpose of measuring the test environment is to determine whether the given environment is suitable for particle measurement.

Therefore, the “ground contamination level” of the test environment has to be measured for the cleanroom as well as the Minienvironment (MENV). The lower the “ground contamination level”, the more accurate the particle measurements will be.

6.6.2 Zero-count measurement

Before any test is done, a zero-count measurement is made. When doing a zero-count measurement, it is a functional test. For this test, a zero-filter is attached to the OPC and the counter takes measurement for about 3 minutes. The reading obtained should be zero. Then the environment is ready for use.

6.6.3 Base measurement of airborne particulate in MENV (Figure 6.4)

Similar to the zero-count measurement, which is used for the OPC, the base measurement is used for the Mini-environment. The measurement time is 3 minutes, 1.0 ft^3 and at maximum air flow velocity of the MENV. The measurement point used is the centre of MENV on operational level of component.

6.6.4 VTH measurement (Figure 6.5)

Three major environment parameters:
- Air velocity
- Air temperature
- Relative humidity

are measured in the cleanroom and MENV to ensure the meet the requirements. We obtain these readings by using the Kanomax Climomaster. This is a precision measuring instrument, which has velocity, temperature and humidity sensors.

Simultaneous measurements of air velocity air temperature and relative humidity can be obtained with a single probe of this instrument.

The Climomaster is set up as follows:
- Data sampling time: 60 seconds
- Data sampling interval: 1 second
- Number of sampling data: 1
- VTH measurement time: 3 minutes

Upon completion of the test, the readings must be within the parameters:
- First air flow velocity: 0.45 ±0.05 m/s
- Temperature: 20.0 ±2.0 °C
- Relative humidity: 55 ±10 %

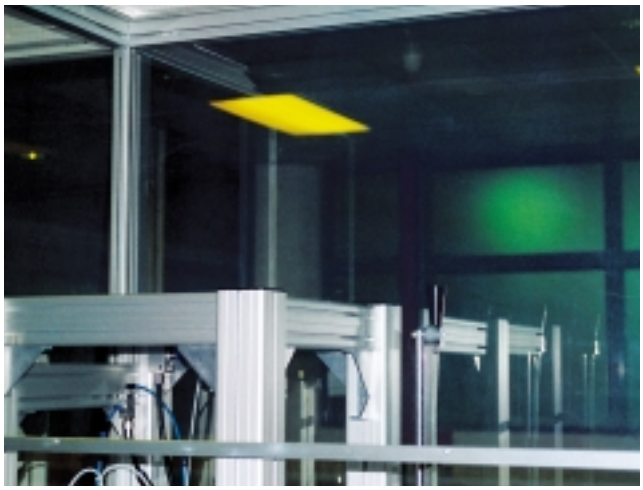


Figure 6.4

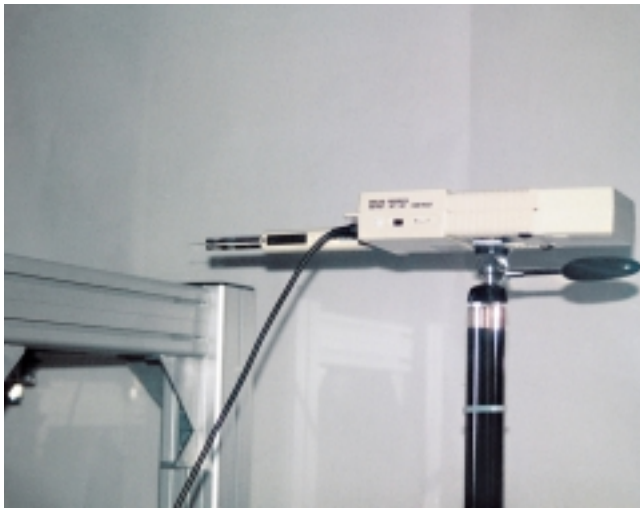
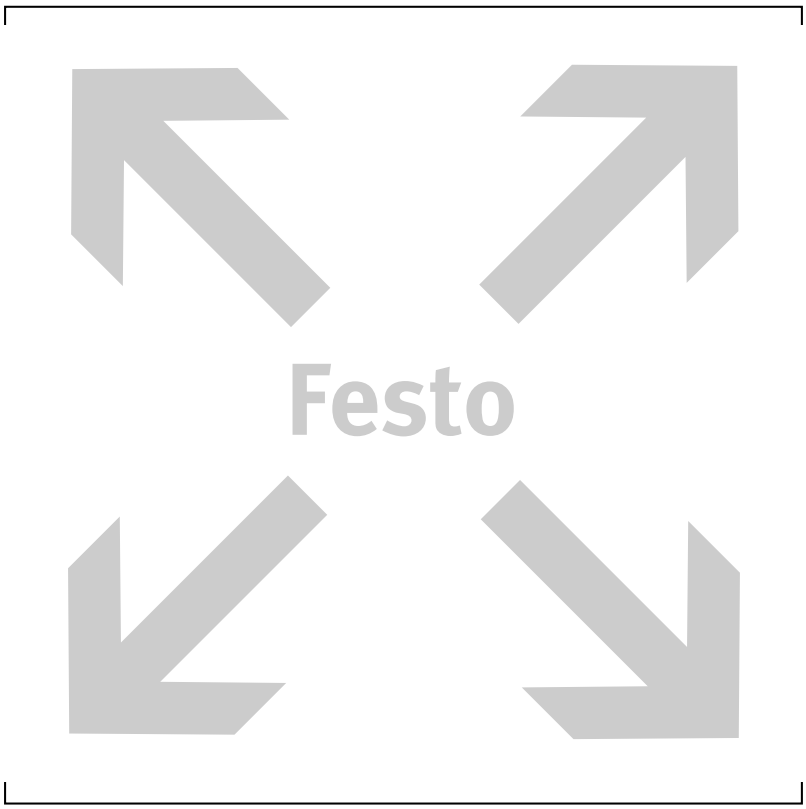


Figure 6.5

7.0 Festo Cleanroom Project

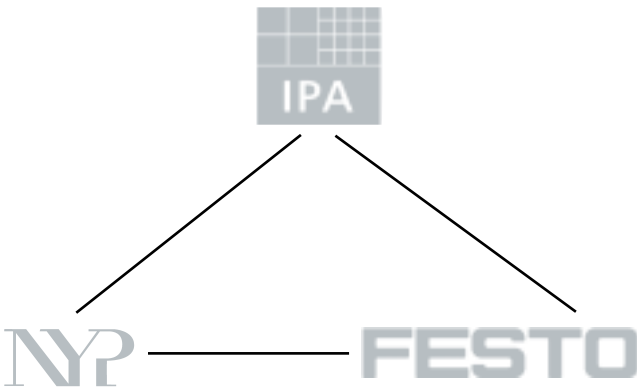


7.1 Introduction

The objective of the project is to accumulate sufficient know-how in the field of cleanroom applications, especially for the electronic industry.

First we had to develop and to set up a suitable test process for the “Cleanroom Products”. With this procedure we were able to define the cleanliness of the pneumatic products.

7.2 Festo's Collaboration with Fraunhofer and Nanyang Polytechnic



The cleanroom project initiated by Festo has a collaboration with Fraunhofer Institute for Manufacturing Engineering and Automation of Germany and Nanyang Polytechnic (NYP) of Singapore.

Festo's objective is to measure the particle emission of its products, in order to establish how far selected products can be used inside of clean rooms. Furthermore, it is Festo's intention to gain experience in the field of particle measurements, contamination control as well as cleanroom applications in general.

Nanyang Polytechnic's objective is to develop capabilities to support the industry's needs in equipment building for use in clean zones. Furthermore, it is NYP's intention to gain experience in the field of particle measurements, contamination control as well as cleanrooms in general.

Fraunhofer Institute for Manufacturing Engineering and Automation department of "Cleanroom Manufacturing" will train Festo and NYP staff on cleanroom technology. They will also help to measure some Festo standard products.

7.2 Festo's Collaboration with Fraunhofer and Nanyang Polytechnic

7.2.1 Scope of cooperation

Festo and NYP will setup a particle test rig inside the cleanroom at NYP. This test rig will be suitable for particle testing according to US FED STD 209E.

To obtain the necessary know-how, the Fraunhofer Institute for Production Technology and Automation will be invited to train NYP and Festo staff on how to do particle measurements on industrial components.

Festo will test several of its products in order to establish their cleanroom class suitability. NYP staff and students are invited to participate in the testing process.

NYP is also allowed to do their own tests and train their staff and students with the equipment.

Festo and NYP will in the future do particle testing for third parties on a commercial basis but not in the area of industrial pneumatics.

7.3 Test Environment and Test Conditions

7.3.1 Cleanroom environment

The cleanroom environment in Nanyang Polytechnic is Class 1,000 cleanroom (according to US FED STD 209E). The design of this cleanroom is shown as Figure 7.1, and the layout is a cleanroom typical layout.

This is a "ballroom" type cleanroom with the area of 120 m^2. The air flows in a unidirectional way from a ceiling of High-Efficiency Particular Air (HEPA) filters down to the floor of the cleanroom. The return air passes through a return air plenum in the Grey Room shown in Figure 7.1. The Grey Room, which is located just beside the cleanroom, is used for service.

Layout of the cleanroom

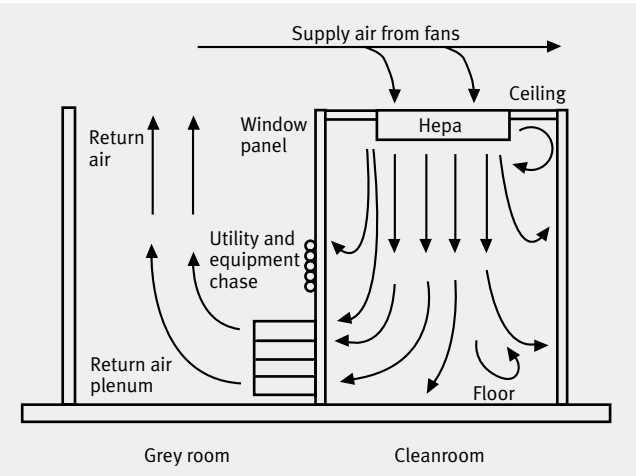


Figure 7.1

7.3.2 Minienvironment

A Class 1 clean Minienvironment (MENV) is used within a cleanroom to provide the high level of protection to products against contamination and ESD events. This MENV is a cleanroom test cabinet with one clear antistatic front panel and three side panels (Figure 7.2). The dimension of MENV is 1.2 m x 0.6 m internal area and with 2.2 m height. In order to achieve high cleanliness class, Ultra-low Penetration Air (ULPA) Fan Filter Unit (99.9995 % efficiency on 0.12 micron) is installed on the ceiling of the MENV. The unidirectional supply of air flows vertically from the Fan Filter Unit (FFU), and the air velocity can be adjusted up from 0.2 m/s to 0.6 m/s.

In accordance with the US FED STD 209E, a cleanroom is classified to be of Class 1 if only one particle of the size of 0.5 µm or larger can be found in a reference volume of 1 cubic foot (ft^3) of the first air (filtered air supplied).

Figure 7.2

7.3 Test Environment and Test Conditions

7.3.3 Test conditions

Before any test is done, the components need to be prepared. The preparation for the cleanroom suitability assessment involves the cleaning of these components according to the Festo-SG guidelines "Operating Conditions for Cleanroom Tests". The cleaning sequence is outlined below:

- Precleaning by blowing component surface with ultrapure compressed dry air.
- Cleaning of component surface using presaturated wipers containing a blend of isopropyl alcohol.
- Final cleaning by blowing component surface with ultrapure compressed dry air.

It is also important to note that each time before the tests are made the required instrument and environment tests are carried out as stated in the earlier chapter.

The component is mounted on a test support fixture as shown in Figure 7.3.

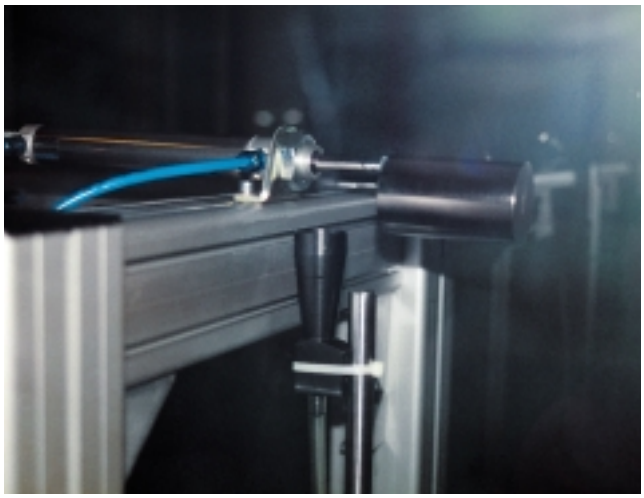


Figure 7.3

7.3.4 Measurement technique

During the test, the airborne particle generated by the component is measured using a discrete particle counter (DPC). The measuring range of particle size is ⇢0.2 µm, ⇢0.7 µm, ⇢1.0 µm, ⇢2.0 µm, ⇢3.0 µm, and ⇢5.0 µm are selected.

Figure 7.4 shows the measuring point used for checking the cylinders. All cylinders are checked at this exact point to ensure that the measurements obtained are consistent.

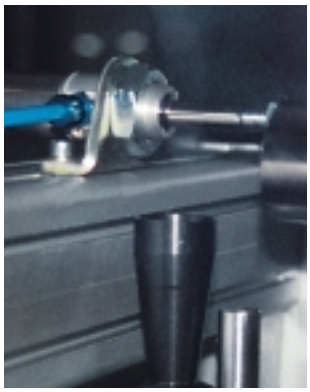


Figure 7.4

7.4 Standard Operating Procedure

7.4.1 Inward transfer of test samples

- Decontamination of test samples (inner and outer parts) with isopropanol saturated wipers and ultra-pure compressed dry air.
  Sequence:
  1st: cleaning with dry compressed air,
  2nd: isopropanol wipers,
  3rd: cleaning with dry compressed air
- Bringing the test samples into the CR environment and MENV
- Arranging the test samples (with gloves, intermediate decontamination, cleaning)

7.4.2 Instrumentation test

Before every measurement checking following items:

- Bringing the test samples into the CR-environment and MENV
- OPC air flow
- OPC laser reference
- OPC zero-particle count (measurement time: 3 minutes, with zero filter attached)
- MENV air flow velocity (maximum power of FFU)
- Relative humidity (measurement time: 3 times for 1 minute with measurement intervals of 1 second)
- Air flow velocity (measurement time: 3 times for 1 minute with measurement intervals of 1 second)
- Temperature (measurement time: 3 times for 1 minute with measurement intervals of 1 second)
- Base measurements of MENV, airborne particulate contamination (measurement time 3 minutes, 1.0 ft^3, at maximum air flow velocity of MENV, measurement point in the centre of MENV on operational level of component).

7.4 Standard Operating Procedure

7.4.3 Adjustment of the operating parameters for the test sample

- Adjustment of operating parameters
- Statement about performed duty cycles at the time of testing
- Documentation of adjustment (sketch or photograph)

7.4.4 Localization measurements

Determination of points of highest concentrations of particle emission (according to VDI 2083 part 8)

- Coarse localization measurement
- Localization measurement

7.4.5 Classification measurements

- Measurement time:
  - standard-classification: 100 minutes (according to VDI 2083 part 8) at the measurement points that were found during the localization measurements
  - lifecycle test: several days, up to months
- Documentation of measurements points (sketch or photograph)

7.4.6 Statistical evaluation

Evaluation according to guideline VDI 2083 part 8

7.4.7 Visual inspection

Visual inspection of tested components (e.g. wear and tear, deposition of lubricants and particles, product failure ...)

7.4.8 Classification

Classification according to statistical evaluation and visual inspection (see guideline VDI 2083 part 8)

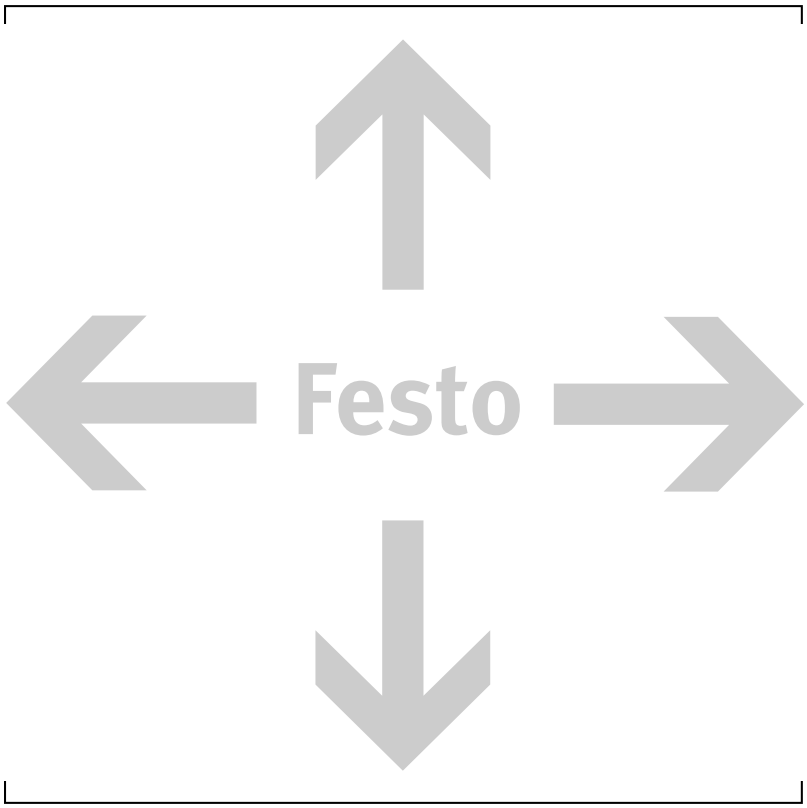
7.4 Standard Operating Procedure

7.4.9 Documentation

Documentation should contain following information:

- Title
- Date
- Place
- Person responsible
- Test environment
  - operating parameters
  - temperature
  - relative humidity
  - air flow velocity
  - particulate concentration in test environment
- Measurement technology
  - type
  - model
  - detection limits
  - air flow
  - description of sample technique
- Sample characteristics
  - type
  - supplier
  - serial number
  - component description
- Operating parameters of components
  - break-in load
  - running-in time
  - mounting position
  - operating frequency
  - attached load
  - supply (air power supply, etc.)
- Description of measurement points
  - sketches or photographs
- References to applied standards and guidelines
- Documentation
  - particle concentration at measurement points
  - graphical visualisation of particle emission
- Interpretation of results and conclusion
  - classification related to applied standards/guidelines
  - general assessment
  - potential for optimization

8.0 Cleanroom Products



8.1 Introduction

Cleanrooms are essential in industries, be it electronics or pharmaceutical manufacturing. Products have to be manufactured to be used in cleanrooms. With the rapid development of electronic industries, more and more pneumatic products are required for cleanrooms.

8.2 Reasons

In all automation processes, pneumatics plays an important role. This is the same for cleanrooms, pneumatics are used in cleanrooms for the following reasons:

- Automation of production sequence with pneumatics
- Lower space requirements with pneumatics
- Lower levels of contamination with pneumatics
- Laminar flow virtually unimpaired by pneumatics

8.2.1 Benefits

- Avoidance or reduction of particle emissions both with stationary components and in an operating sequences
- Minimization of disturbance factors affecting laminar flow
- Counter measures against possible environmental influences (e.g. acids, aggressive media)

8.2.2 Difference in comparison with standard products

The following list is the difference between the standard products and those used in cleanrooms.

- Generally suitable for unlubricated operation
- Cleanroom compatible grease used when necessary
- Cleanroom compatible markings
- Ducted exhaust ports and connections for air breather ports
- Extraction by means of vacuum where necessary

8.3 Basic Principles for Cleanroom Products

It is known that there isn't a standard or guideline for cleanroom product design available.

In order to develop products for cleanroom application, we mainly base on the principle of "avoiding cleanroom contamination by preventing particles generated from the components".

This principle includes the following three aspects:

- Noncontaminant release – very low leakage construction
- Noncontaminant generation – special material, surface treatment and special lubrication specification
- Noncontaminant in production processes – component cleaning and double bag packaging

The above three aspects can be achieved for cleanroom compatibility by modifying our standard products to cleanroom products with some special features. The general principle is to design an additional vacuum suction port so that air leakage during operation can be sucked back and extracted by vacuum.

Products	Noncontaminant releasing	Noncontaminant generating	Noncontaminant in production process
Cylinders	• Air leakage from the piston rod is sucked back and extracted by vacuum via a additional vacuum suction port on the front cap or barrel (housing) • Leak-free design principle	• Piston rod is made of corrosion-resistant steel	• Cleaning individual components by ultrasonic cleaning bath • All components are cleaned and assembled in a clean room • Functional test in a cleanroom • Double-packed in plastic bags in a cleanroom
Valves	• Exhaust air from both main valve and pilot valve are released via common exhaust ports • Breather air from underside of piston is removed via exhaust ports • Leak-free design principle		

Table 8.1

Products	Noncontaminant releasing	Noncontaminant generating	Noncontaminant in production process
Air service units	• Regulator: vent air in the bonnet is sucked through a vacuum connection on an additional ring		• Cleaning individual components by ultrasonic cleaning bath • All components are cleaned and assembled in a cleanroom • Functional test in a cleanroom • Double-packed in plastic bags in a cleanroom
Grippers	• Air filter: drain is discharged from cleanroom via drain guide port • Air leakage is extracted via vacuum suction port		
Vacuum equipment others	• Exhaust air is ported to the outside of cleanroom • Shock absorber: replacement of a new housing with a vacuum port • Fittings & tubing: air leakage is minimized by using the barbed fittings		

Table 8.2

Table 8.1 and 8.2 show the basic principles for pneumatic products in the cleanroom product range.

8.4 Production Sequence for Cleanroom Products

This section describes the sequence, how cleanroom products are designed and produced. Basically, the manufacturing of clean room pneumatics is not any different from the design of any other pneumatic component. It is just, that special care is taken, to avoid any kind of contamination caused by the product.

8.4.1 Design Office

Firstly the design of a standard product is modified with a view to cleanroom compatibility. How this is done, was discussed in Chapter 3 of this textbook already.

8.4.2 Assembly

All products are assembled outside the cleanroom, according to the standard assembly procedures. In very special cases, cleanroom grease is applied instead of the standard lubricant.

8.4.3 Testing

Just as any standard product, cleanroom products are tested, concerning their functionality. There is no particle emission test conducted for every product.

8.4.4 Cleaning

Before packing all products are cleaned under cleanroom condition of Class 10,000 according to US FED STD 209E. The cleaning is done either by means of an ultrasonic bath or with isopropanol wipers.

8.4.5 Packaging

Packaging is done in antistatic plastic bags. Whereby each product is double packed and sealed. Just as the cleaning, the packaging takes place under cleanroom condition of Class 10,000.

8.5 Performance of Cleanroom Products

At present our standard products are suitable to be used in cleanrooms with Cleanroom Class 10.000, with the change or modification on the design, we can achieve Cleanroom Classes up 10 or 100.

8.6 Precautions in Operation

8.6.1 Purification of supply air

For the cleanliness of an application clean dry air is extremely important. To supply clean air, we have set up the air supply as follows:

8.6.2 Piping

Pipes and fitting have a large influence on the cleanliness of an application. Generally barbed fitting should be applied whenever possible. Push-pull fitting are not suitable for cleanroom applications, as they tend to leak. Also, the way, how tubes are laid, is important for clean applications of pneumatics. It should be avoided that tubes rub on any surface.

8.6.3 Notes of set up

The way, how pneumatic components are mounted does not directly influence the particle emission. However, it is an important factor to avoid cross contamination. Meaning, contamination caused by particles, which are carried by the air from a less sensitive location to a sensitive location.

8.6.4 Operating piston speed

Piston speed and thus the impact the piston generates when touching the end cap of a cylinder, is the most crucial parameter concerning particle emission. The piston speed should not exceed 0.2 m/s in order to archive a good cleanliness.

8.6.5 Solenoid valve manifold

Whenever possible valves should not be used in the direct vicinity of any sensitive product, although, valves in general only emits little particle. It is best to install valves directly above the floor.

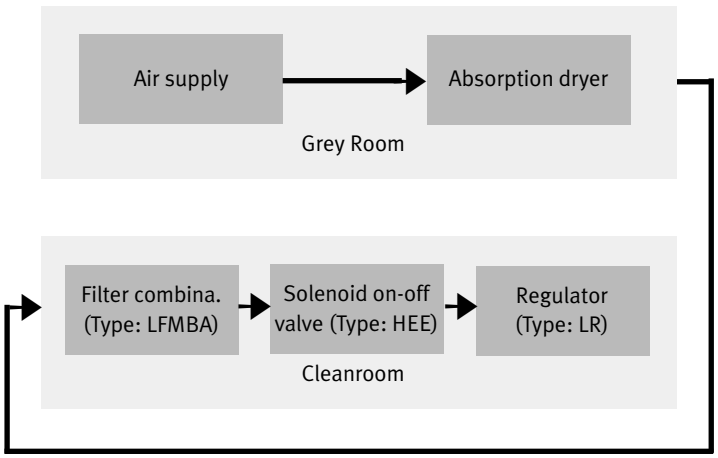


Figure 8.1

Keyword

What are the points to bear in mind when using Festo components?

The specified values for pressures, speeds, loads, lateral forces, actuating forces, voltages, magnetic fields and temperatures should be adhered to at all times and at any operational note observed by the user to ensure the correct functioning of the equipment.

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