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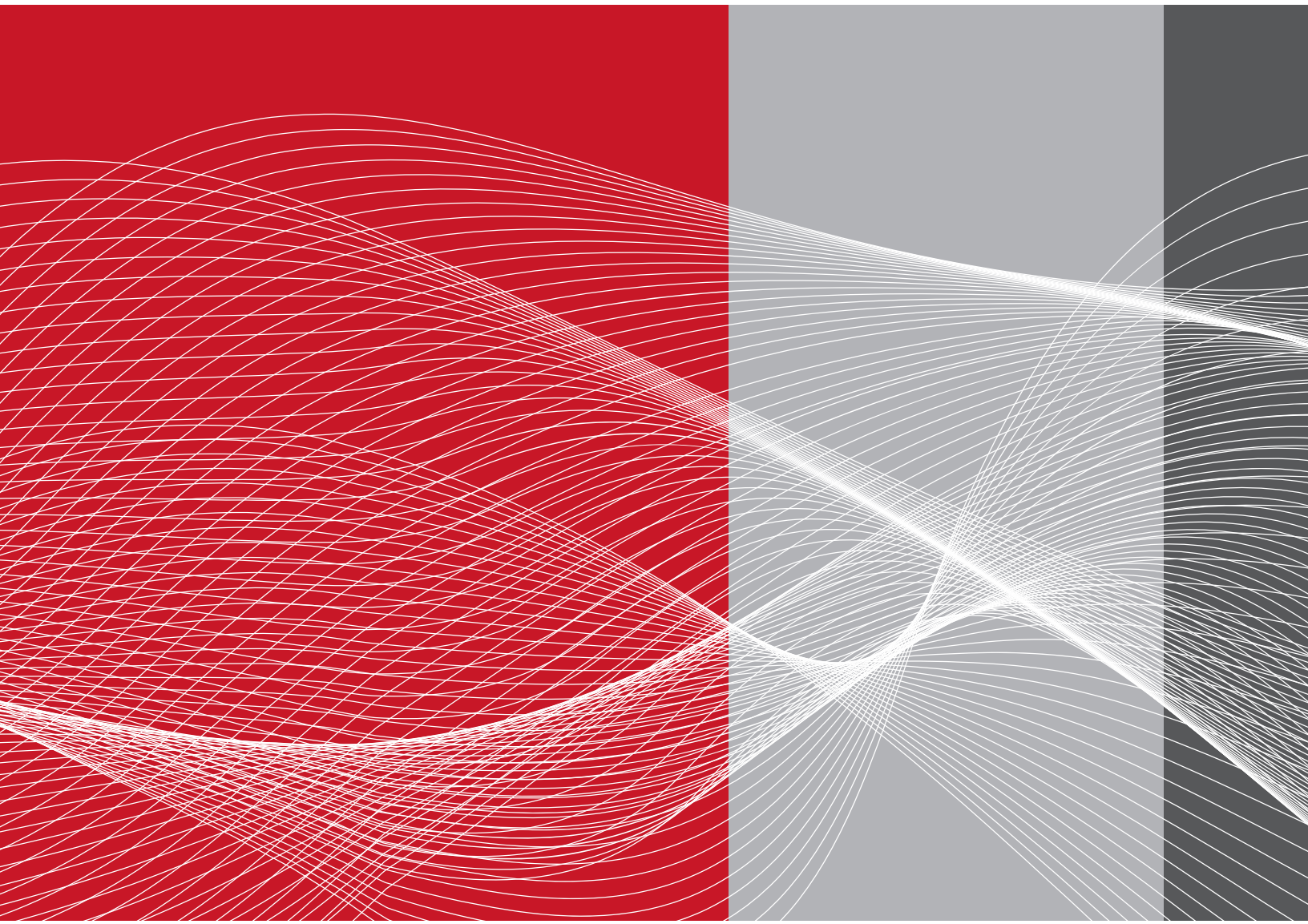
High Purity Air Filtration Guide



This book is for guidance value only and is meant as a ‘quick and easy’ reference for those involved in specifying, using, and testing filters.

The most widely utilized standards and guidelines in the high efficiency air filtration and cleanroom industry are:

- EN-1822 Parts 1-5
- IEST-RP-CC001, 007, 021, 034
- ISO-29463 Parts 1-5
- ISO-14644
- FDA Guidelines
- EMA-EU GMP Annex1

High Purity Air Filtration Guide

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International Cleanroom Standards Summary

		Country and Standards								
		USA 209D	USA 209E	Britain BS 5295	France AFNOR	Germany VDI 2083	Japan JISB 9920	Australia AS 1386	EU GMP Annex 1	ISO 14644
Particles per m^3 0.5 µm	1									
	3.5									
	10		M1				2			
	35.3	1	M1.5	C		1	3	0.035		3
	352	10	M2.5	D		2	4	0.35		4
	3,520	100	M3.5	E or F	4,000	3	5	3.5	A	5
	35,200	1000	M4.5	G or H		4	6	35	B	6
	352,000	10,000	M5.5	J	400,000	5	7	350	C	7
	3,520,000	100,000	M6.5	K	4,000,000	6	8	3500	D	8

EN-ISO 14644-1 2015: Classification by Particles

		Maximum Concentration Limits (Particles/m^3)					
		0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
ISO 14644-1 Classification Number (N)	1	10					
	2	100	24	10			
	3	1,000	237	102	35		
	4	10,000	2,370	1,020	352	83	
	5	100,000	23,700	10,200	3,520	832	
	6	1,000,000	237,000	102,000	35,200	8,320	293
	7				352,000	83,200	2,930
	8				3,520,000	832,000	29,300
	9				35,200,000	8,320,000	293,000

Major change from 1999 is the elimination of the max concentration limit of 29 particles at 0.5 µm in the ISO 5 space.
This **does not replace EU GMP requirements. 0.5 and 5.0 µm need to be assessed for monitoring.*

Room Count Sample Locations

Area (m^2) Less than or equal to:	Minimum Number of Sample Locations
2	1
4	2
6	3
8	4
10	5
24	6
28	7
32	8
36	9
52	10
56	11
64	12
68	13
72	14
76	15
104	16
108	17
116	18
148	19
156	20
192	21
232	22
276	23
352	24
436	25
636	26
1000	27

- Simplify the classification process and remove the need to evaluate the 95% UCL for 2-9 sample locations.
- Made it more applicable to rooms in operation.
- Limited any radical changes from the older classification.

ISO-14644 Overview

ISO-14644	Description
1	Classification of Air Cleanliness by Particle Concentration
2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
3	Test Methods
4	Design & Construction
5	Cleanroom Operations
6	Withdrawn (Definitions in each standard)
7	Separative Devices
8	Air Cleanliness Classification by Chemicals
9	Surface Cleanliness Classification by Particles
10	Surface Cleanliness Classification by Chemicals
12	Air Cleanliness (Monitoring) by Nano Particles
13	Cleaning of Surfaces
14	Suitability by airborne particle concentration of equipment
15	Suitability by airborne chemical concentration of equipment and materials
16	Energy efficiency in cleanrooms and separative devices

**The above table was updated in August 2025.*

Comparison of Regulatory Requirements

			EU; PIC/S; WHO; ANVISA; TGA; HCA; S-FDA							
			In Operation (particles/m³)	Microbiological Active Air Action Levels (cfu/m³)		In Operation (particles/m³)		At Rest (particles/m³)		Microbiological Active Air Action Levels (cfu/m³)
FDA	ISO	USP	1	Limits	EU, WHO, PIC/S Grade	0.5µm	5.0µm	0.5µm	5.0µm	Limits
	5	100	3,520	1	A	3,520	not specified	3,520	not specified	<1
	6	1,000	35,200	7						
	7	10,000	352,000	10	B	352,000	2,930	3,520	not specified	10
	8	100,000	3,520,000	100	C	3,520,000	29,300	352,000	2,930	100
					D			3,520,000	29,300	
	9	1,000,000	35,200,000	100						

- All values are averages
- Samples from Grade A areas should normally show no viable organisms
- Recovery from the "In-Operation" to the "At-Rest" state should be verified to occur within 15-20 minutes. The recovery test as defined in ISO 14644-3
- (20) 5.0µ particles is equivalent to ISO 4.8, not ISO 5

Measurement of MCP's. *An active air sampler draws a fixed flow of air over agar plates. These plates are incubated over 5-7 days, any viable organisms grow and are counted. Limits are given in FDA and EU regulatory docs.*

FDA Sterile Guide 2004

CDER-21-CFR-210 & 211

Clean Area Classification (0.5 µm particles/ft³)	ISO Designation[b]	≥0.5 µm particles/m³	Microbiological Active Air Action Levels[c] (cfu/m³)	Microbiological Settling Plates Action Levels[c,d] (diam. 90mm; cfu/4 hours)
100	5	3,520	1[e]	1[e]
1,000	6	35,200	7	3
10,000	7	352,000	10	5
100,000	8	3,520,000	100	50

a- All classifications based on data measured in the vicinity of exposed materials/articles during periods of activity
b- ISO-14644-1 designations provide uniform particle concentration values for cleanroom in multiple industries. An ISO 5 particle concentration is equal to Class 100 and approximately equals EU Grade A.
c- Values represent recommended levels of environmental quality. You may find it appropriate to establish alternate microbiological action levels due to the nature of the operation or methods of analysis.
d- The additional use of settling plates is optional.
e- Samples from Class 100 (ISO 5) environments normally yield no microbiological contaminants.
CDER The Center for Drug Evaluation and Research (CDER, pronounced "see'-der") is a division of the U.S. Food and Drug Administration (FDA) that monitors most drugs as defined in the Food, Drug, and Cosmetic Act.

FDA Guideline for Aseptic Processing GMP

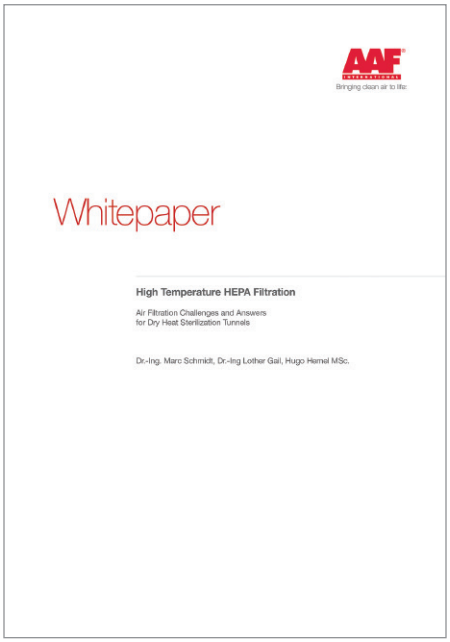
Section IV (Buildings & Facilities) item D (Air Filtration) includes a section on HEPA filters require:

- Leak testing at installation.
- Thereafter at suitable intervals (provides example of 2x per year) for aseptic processing room.
- Also specifies leak testing for HEPAs in depyrogenation tunnels but allows alternate methods for hot zone filters.
- Indicates DOP and PAO as appropriate leak testing aerosols.
- References the use of aerosol photometer.
- Specifies 0.01% as significant leak.
- Indicates that velocity uniformity across a filter and relative to adjacent filters should be monitored periodically.

The FDA actually states where justified alternate methods can be employed to test HEPA filters in the hot zone of ovens and tunnels. Most end users test filters ‘cold’ to ensure there is no mechanical damage to the filter and sealing surface, then ‘burn in’ or ‘ramp up’ the filter to the operating temperature, cool down and re-test. It would not be unusual to find a ‘leak’ at the sealing surface between the media pack and frame, or frame and sealing surface, while still maintaining the desired cleanliness level of ISO 5 in the critical zone protecting the process. Most end users follow the OEM recommended SOP yet many will contact the filter manufacturer for advice and recommendations on why filters have ‘failed’ after burn in. Unfortunately there is no black or white answer to why and how these filters ‘fail’ when exposed to extreme temperatures and heat cycles. The equipment manufacturers have validated specific filters in their ovens/tunnels and often push the limits of filter performance especially when it comes to speeding up where possible the burn in or ramp rate. Many equipment manufactures also create a negative seal to minimize downstream contamination from particulate shedding with specific frame and clamping mechanisms employed.

The traditional ‘High Temp’ filters of red silicone sealant and white ceramic sealant are still in use after many years in successful operation. There are filters that require no burn in and have no sealant which look interesting but the cost to the end user can be 3-5 times traditional HT solutions and the end user should really look carefully at the risk/benefit when selecting HT filters of any kind.

This publication gives a good summary of the application of filters in these environments. Copy available on request.

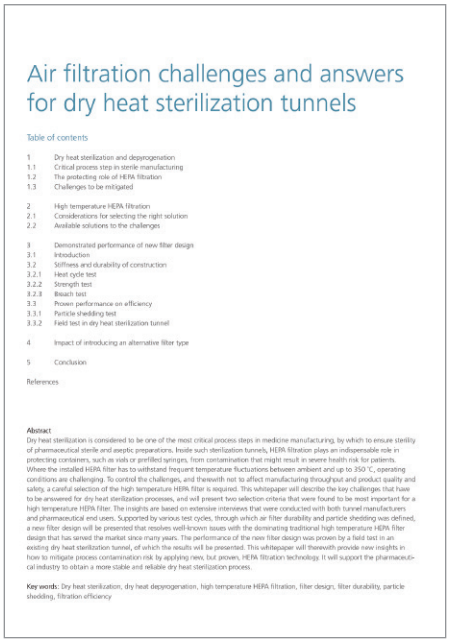

Bringing clean air to life

Whitepaper

High Temperature HEPA Filtration

Air Filtration Challenges and Answers
for Dry Heat Sterilization Tunnels

Dr.-Ing. Marc Schmidt, Dr.-Ing Lother Gail, Hugo Hemal MSc.


Air filtration challenges and answers for dry heat sterilization tunnels

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Abstract

Dry heat sterilization is considered to be one of the most critical process steps in medicine manufacturing, by which to ensure sterility of pharmaceutical sterile and aseptic preparations. Inside such sterilization tunnels, HEPA filtration plays an indispensable role in protecting containers, such as vials or prefilled syringes, from contamination that might result in severe health risk for patients. Where the installed HEPA filter has to withstand frequent temperature fluctuations between ambient and up to 350 °C, operating conditions are challenging. To control the challenges, and therewith not to affect manufacturing throughput and product quality and safety, a careful selection of the high temperature HEPA filter is required. This whitepaper will describe the key challenges that have to be answered for dry heat sterilization processes, and will present two selection criteria that were found to be most important for a high temperature HEPA filter. The insights are based on extensive interviews that were conducted with both tunnel manufacturers and pharmaceutical end users. Supported by various test cycles, through which air filter durability and particle shedding was defined, a new filter design will be presented that resolves well-known issues with the dominating traditional high temperature HEPA filter design that has served the market since many years. The performance of the new filter design was proven by a field test in an existing dry heat sterilization tunnel, of which the results will be presented. This whitepaper will therewith provide new insights in how to mitigate process contamination risk by applying new, but proven, HEPA filtration technology. It will support the pharmaceutical industry to obtain a more stable and reliable dry heat sterilization process.

Key words: Dry heat sterilization, dry heat depyrogenation, high temperature HEPA filtration, filter design, filter durability, particle shedding, filtration efficiency

1 Dry heat sterilization and depyrogenation

1.1 Critical process step in sterile manufacturing

The pharmaceutical production of sterile medicine is subject to special requirements to minimize risks of particulate and microbial contamination. Stringent FDA and GMP guidelines are in place to limit exposure to such contamination, therewith preventing severe harm or life-threatening health risks to the patient.

Dry heat sterilization and depyrogenation are applied to ensure sterility of pharmaceutical aseptic preparations, as imposed by FDA regulation 21 CFR-211.94. For aseptic preparations, such as vials, ampoules, cartridges or prefilled syringes, terminal sterilization of the final container is not possible. The glassware therefore has to be rendered free from harmful contaminants that might affect the medicine, before filling.

Depending on the process, either dry heat sterilization or depyrogenation is applied. Sterilization is typically applied in the 160 - 180 °C temperature range, to render a product free from living microorganisms. Depyrogenation aims to remove or inactivate endotoxins for which higher temperatures are required in the bandwidth of 200 - 350 °C, taking place in either static ovens or in tunnels for automatized, continuous processes. Because of the increasing demand for pyrogen-free sterile packaging and for fast, safe and efficient processing, dry heat depyrogenation nowadays represents one of the most critical steps in the sterile medicine manufacturing process[1].

Pyrogen-free packaging material was originally demanded merely for the filling of large volume containers; meanwhile it became a standard for the whole field of sterile filling [1]. Modern demands on sterilization processes, layed down by the FDA, require temperature programs which demonstrate “that the endotoxic substance has been inactivated to not more than 1/1000 of the original amount (3 log cycle reduction)” [2]. This demand contributed decisively to the development of safe, fast and efficient dry heat sterilization processes including unidirectional airflow with HEPA filtration.

1.2 The protecting role of HEPA filtration

For protecting dry heat sterilized containers against particulate and microbial contamination, HEPA filtration has been introduced to such processing. Despite that the cleanliness in the environment of sterilized containers was considerably improved, a certain risk caused by released particles on the clean side of HEPA filters still has to be considered.

“The identification of dry heat sterilization with depyrogenation imposed much more stringent demands on dry heat sterilization of glassware.”

Dr.-Ing. Lothar Gail - VDI

“Defined and homogenous conditions regarding particle concentration, airflow and temperature distribution are crucial for safe and reliable operation of sterilization tunnels. High temperature HEPA filters are playing a vital role for that.”

Dr.-Ing. Gerardo Fumagalli - General Manager, Steriline s.r.l.

[1] The remainder of the whitepaper will speak about dry heat sterilization as an umbrella term for both dry heat sterilization and dry heat depyrogenation.

EU CGMP

		Maximum Permitted No of Particles per cubic meter equal to or above			
		At Rest[2]		In Operation	
		0.5µm	5µm	0.5µm	5µm
Grade	A	3,520	not specified	3,520	not specified
	B[1]	35,200	29	352,000	2,930
	C[1]	352,000	2,930	3,520,000	29,300
	D[1]	3,520,000	29,300	Not Defined[3]	Not Defined[3]

		Limits for Microbial Contamination During Qualification		
		Air sample cfu/m³	Settle plate (dia. 90mm) cfu/4 hours	Contact plates (dia. 55mm) cfu/plate
Grade	A	No Growth		
	B	10	5	5
	C	100	50	25
	D	200	100	50

		Minimum Test Requirements for the Requalification of Cleanrooms				
		Determination of the concentration of airborne viable and non-viable particles	Integrity test of terminal filters	Airflow volume measurement	Verification of air pressure difference between rooms	Air velocity test
Grade	A	Yes	Yes	Yes	Yes	Yes
	B	Yes	Yes	Yes	Yes	*
	C	Yes	Yes	Yes	Yes	*
	D	Yes	Yes	Yes	Yes	*

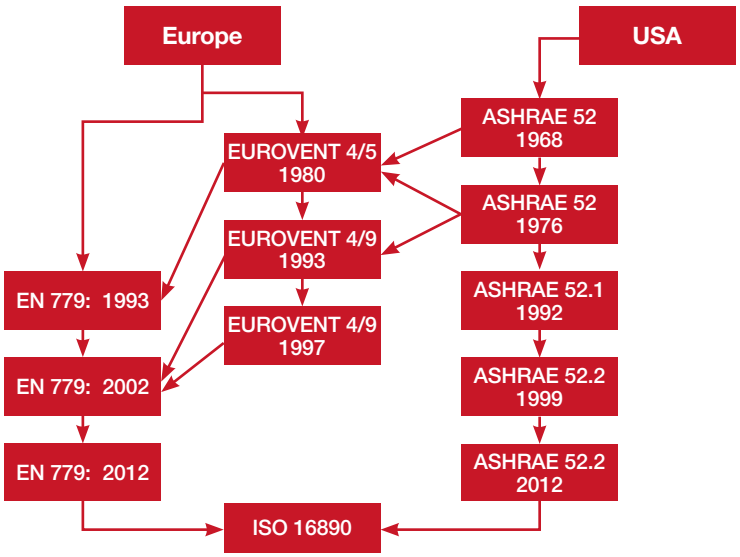
Recommended limits for microbiological monitoring during operation.

1. *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 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.*
2. *The guidance given for the maximum permitted number of particles in the 'at rest' condition corresponds approximately to the ISO classification as follows: Grades A and B correspond with ISO 5, Grade C with ISO 7 and Grade D with ISO 8.*
3. *The requirement and limit for this area will depend on the nature of the operation carried out.*

The particulate conditions given in the table for the 'at rest' state should be achieved in the unmanned state after a short 'clean up' period of 15-20 minutes (guidance value) after completion of operations. The particle conditions for Grade A in operation given in the table should be maintained in the zone immediately surrounding product whenever the product or open container is exposed to the environment. It is accepted that it may not always be possible to demonstrate conformity and particulate standards at the point of fill when filling is in progress, due to the generation of particles or droplets from the product itself.

**Performed according to a risk assessment documented as part of the CCS. However, required for filling zones (e.g. when filling terminally sterilized products) and background to Grade A RABS.*

History of HVAC Air Filter Standards

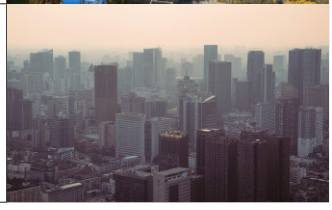


- In 1968, ASHRAE published the first unified standard which measured the arrestance, as well as the dust-spot efficiency with artificial test dust.
- In 1976, ASHRAE Standard 52-76 was published introducing the atmosphere dust-spot efficiency.
  - dust spot efficiency
  - arrestance
  - dust holding capacity
- Initial efficiency as a function of a particle size (MERV: Minimum Efficiency Reporting Value).
- This standard had many improvements over time. Some of the improvements found in the ANSI/ASHRAE 52.2 standard. The improvement of the 52.2 standard allowed for the 52.1 standard to be retired.

Comparison of Standards

		ASHRAE 52.2: 2017	ISO 16890	EN 779: 2012
Standard	Aerosol	KCl	DEHS/KCL	DEHS
	Aerosol Range	0.3 to 10.0 µm	DEHS: 0.3 to 1.0 µm KCL: 1.0 – 10 µm	0.4 µm
	Particle Sizes for Rating	E1: 0.3 – 1.0 µm E2: 1.0 – 3.0 µm E3: 3.0 – 10.0 µm	PM1: 0.3 – 1.0 µm PM2.5: 0.3 – 2.5 µm PM10: 0.3 – 10 µm	0.4 µm
	Loading Dust	ASHRAE 52.2 Dust	ISO Fine	ASHRAE 52.2 Dust
	Conditioning	Optional: Appendix J (whole filter)	Mandatory: IPA Vapor (whole filter)	Mandatory: IPA Liquid (flat sheet)
	Conditioning Substance	<0.3 µm KCl	IPA Vapor	IPA Liquid
	Conditioning Time	Efficiency measured after minimum increments of $6.4x10^7$ particles/cm^3 min. Conditioning stops after no further significant drop in efficiency.	24 h	2 min soak
	Classification	MERV 4 – MERV 16	ePM1, ePM2.5, ePM10	G1 – G4, M5 – M6, F7 – F9
	Rating	Worst case	Average of initial and discharged condition	Worst case

Outdoor Air Quality (OAQ) Categories

		Description	Typical Environment
Category	OAQ1	**Outdoor air, which may be only temporarily dusty** Applies where the World Health Organization WHO (2005) guidelines are fulfilled (annual mean for PM2.5 ≤ 10 µg/m3 and PM10 ≤ 20 µg/m3).	
	OAQ2	**Outdoor air with high concentrations of particulate matter** Applies where PM concentrations exceed the WHO guidelines by a factor of up to 1.5 (annual mean for PM2.5 ≤ 15 µg/m3 and PM10 ≤ 30 µg/m3).	
	OAQ3	**Outdoor air with very high concentrations of particulate matter** Applies where PM concentrations exceed the WHO guidelines by a factor of greater than 1.5 (annual mean for PM2.5 > 15 µg/m3 and PM10 > 30 µg/m3).	

Supply (SUP) Air Categories

Category	Description	General Ventilation	Industrial Ventilation
SUP1	Refers to supply air with concentrations of particulate matter which fulfilled the WHO (2005) guidelines limit values multiplied by a factor x 0.25 (annual mean for PM2.5 ≤ 2.5 µg/m3 and PM10 ≤ 5 µg/m3).		**Applications with high hygienic demands** Hospitals, pharmaceutics, electronic and optical industry, supply air to cleanrooms.
SUP2	Refers to supply air with concentrations of particulate matter which fulfilled the WHO (2005) guidelines limit values multiplied by a factor x 0.5 (annual mean for PM2.5 ≤ 5 µg/m3 and PM10 ≤ 10 µg/m3).	**Rooms for permanent occupation** Kindergartens, offices, hotels, residential buildings, meeting rooms, exhibition halls, conference halls, theaters, cinemas, concert halls.	**Applications with medium hygienic demands** Food and beverage production.
SUP3	Refers to supply air with concentrations of particulate matter which fulfilled the WHO (2005) guidelines limit values multiplied by a factor x 0.75 (annual mean for PM2.5 ≤ 7.5 µg/m3 and PM10 ≤ 15 µg/m3).	**Rooms with temporary occupation** Storage, shopping centers, washing rooms, server rooms, copier rooms.	**Applications with basic hygienic demands** Food and beverages production with a basic hygienic demand
SUP4	Refers to supply air with concentrations of particulate matter which fulfilled the WHO (2005) guidelines limit values multiplied by a factor x 1.0 (annual mean for PM2.5 ≤ 10 µg/m3 and PM10 ≤ 20 µg/m3).	**Rooms with short-term occupation** Restrooms, storage rooms stairways.	**Applications without hygienic demands** General production areas in the automotive industry.
SUP5	Refers to supply air with concentrations of particulate matter which fulfilled the WHO (2005) guidelines limit values multiplied by factor x 1.5 (annual mean for PM2.5 ≤ 15 µg/m3 and PM10 ≤ 30 µg/m3).	**Rooms without occupation** Garbage room, data centers, underground car parks.	**Production areas of the heavy industry.** Steel mill, smelters, welding plants.

Determining Recommended Filter Efficiency by Application & Typical Outdoor Air Quality

The table below helps you select air filters that ensure you meet requirements for the air inside your facilities based upon a combination of factors. By cross-referencing **your application** with the **typical quality levels of outdoor air**, you can determine the recommended minimum MERV rating for air filters in your application.

Application		Typical Outdoor Air Quality		
Commercial	**General Ventilation**	**GOOD** PM 2.5 ≤ 10 PM 10 ≤ 20	**MODERATE** PM 2.5 ≤ 15 PM 10 ≤ 30	**UNHEALTHY** PM 2.5 ≥ 15 PM 10 ≥ 30
High Hygenic Demand (pharma, hospitals, electronic industry, supply air in facilities with cleanrooms)	N/A	**MERV 14**	**MERV 15**	**MERV 16**
Medium Hygenic Demand (food and beverage production, etc.)	**Permanently Occupied** (schools, offices, hotels, residences, conference/exhibition halls, theaters)	**MERV 13**	**MERV 14**	**MERV 15**
Basic Hygenic Demand (less critical food and beverage production)	**Temporarily Occupied** (storage, server rooms, copier rooms)	**MERV 11**	**MERV 12**	**MERV 13**
No Hygenic Demand (automotive general production)	**Short-Term Occupancy** (restroom, stairways)	**MERV 8**	**MERV 11**	**MERV 12**
Heavy Industry Production Areas (steel mill, smelting, welding plants)	**Unoccupied** (garbage room, parking garage)	**MERV 7**	**MERV 8**	**MERV 11**

Given the speed at which Outdoor Air Quality can worsen due to wildfires and other unexpected events, we recommend exceeding the above efficiencies when feasible to ensure adequate protections if conditions worsen.

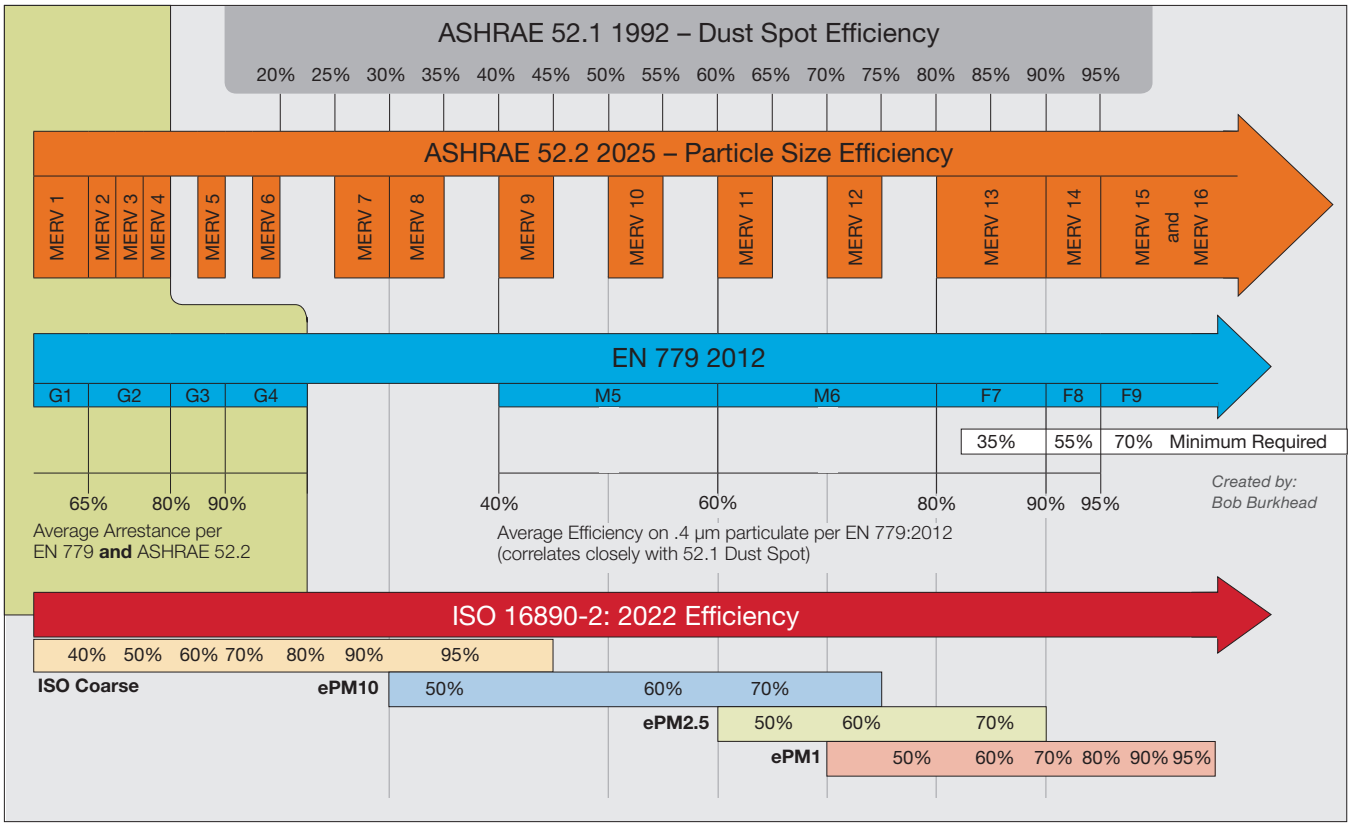
Minimum recommended filtration requirements above refer to final stage of filtration, ensure prefiltration is used as-recommended for the final filter chosen.

Based in part on EUROVENT 4/23/2017 "Selection of EN ISO 16890-rated air filter classes for general filtration applications" 1st Edition, published Jan. 9th, 2019.

Some countries may have national guidelines or industry-specific requirements that vary from the above.

HVAC Filter Designations

Test Standard Correlations



The test standard correlations above are approximations based on results obtained on a sampling of products. Actual results on products may differ somewhat from these correlations, and a product tested to one standard that needs to meet the requirements of another standard should be tested in accordance with the specified standard.

HVAC Filter Examples

HVAC filters filter supply air and may be used either in a stand-alone configuration for less critical spaces or as prefilters located upstream of HEPA/ULPA filters.

MEGApleat® Prefilter - Available in MERV 9 efficiency

DriPak® GX Bag Filter - Galvanized header, available in MERV 13 and MERV 15 efficiencies

VariCel® VXL RC V-Bank Filter - Available in MERV 11, 13, 14, and 15 efficiencies

Comparison of EN 779 and EN ISO 16890 Rated Filter Classes

The direct conversion of EN 779 and EN ISO 16890 classes is not possible. To facilitate an indicative comparison, particularly for the purpose of replacing existing filters, the Eurovent Association has developed a table matching both EN 779 and EN ISO 16890 classes tested for the same filters.

The comparison shows the actual overlapping of EN 779 and EN ISO 16890 classes and was developed based on real test data of 91 filters provided by Eurovent Certita Certification.

ASHRAE 52.2	EN 779 2012	EN ISO 16890 – Range of Actual Measured Average Efficiencies		
Filter Class		ePM_1	$ePM_{2.5}$	ePM_{10}
MERV 10	M5	5% – 35%	10% – 45%	40% – 70%
MERV 11	M6	10% – 40%	20% – 50%	60% – 80%
MERV 13	F7	40% – 65%	65% – 75%	80% – 90%
MERV 14	F8	65% – 90%	75% – 95%	90% – 100%
MERV 15	F9	80% – 90%	85% – 95%	90% – 100%

EN 779 – EN ISO 16890 comparison

Relevance of Fine Particulate Matter

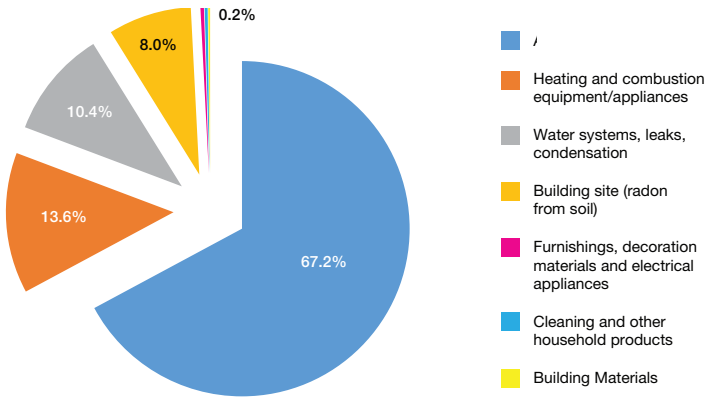
Outdoor air pollution plays a significant role in indoor air exposures. Due to ventilation providing continuous air exchange in buildings, the indoor air exposure to fine PM originates mostly from outdoor air, especially in areas affected by heavy traffic. The second most important source of exposure comes from the indoor combustion of solid fuels for cooking and heating (if present).

The outdoor air fine PM originates mostly from combustion sources, local and distant, in particular where the levels exceed rural background.

What is often not acknowledged is that in strongly polluted areas (e.g. heavy industry zones, city centres with heavy traffic) without air filtration, over 90% of ambient PM levels monitored outdoors, occurs indoors.

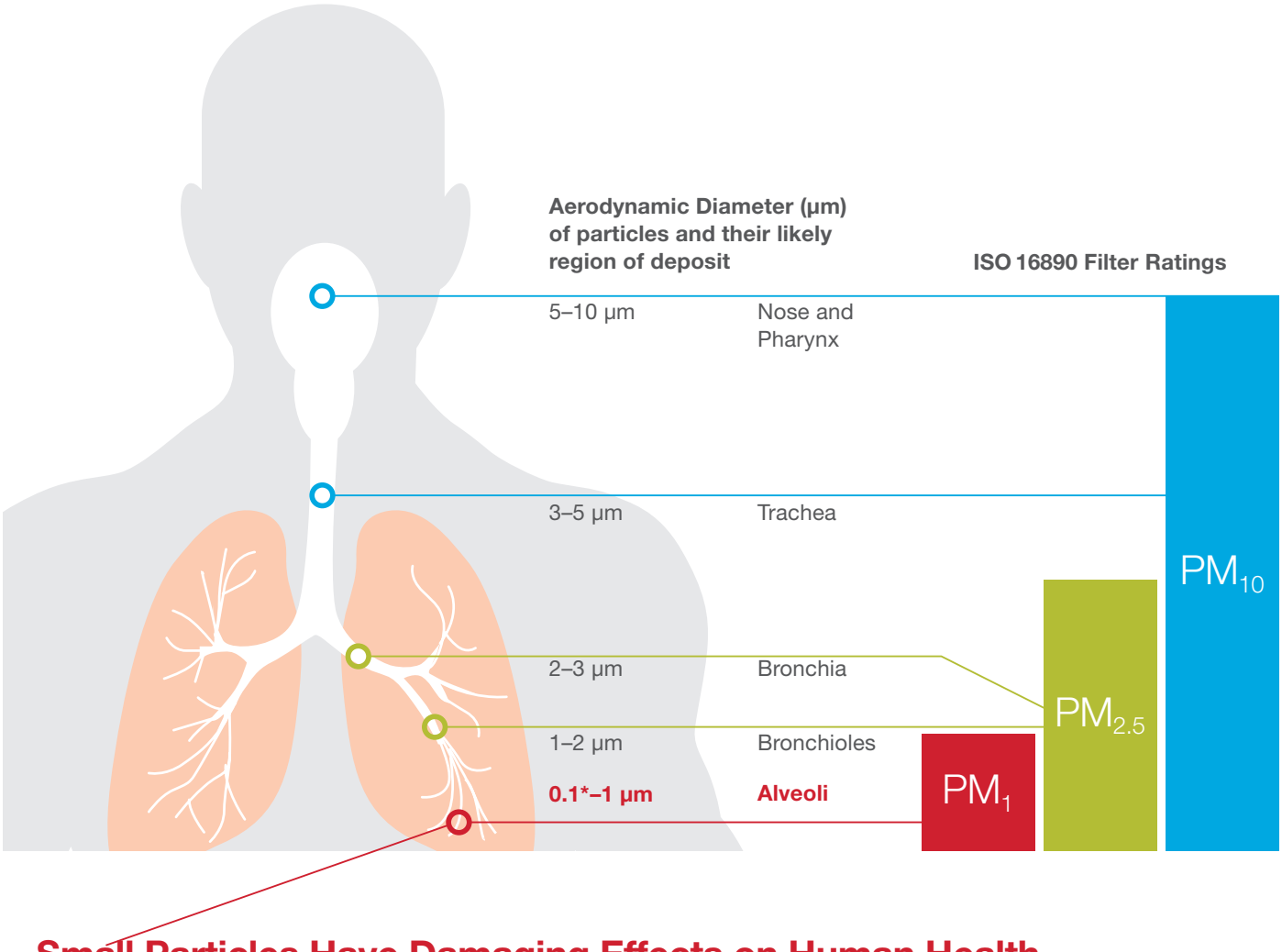
Applying correctly selected, efficient air filters in ventilation systems can significantly reduce the impact of PM exposure on the Burden of Disease (BoD).

Bad Ambient Air Quality Most Affects the Burden of Diseases (BoD)



Source: Eurovent 4/23-2017

Burden of Diseases (BoD)



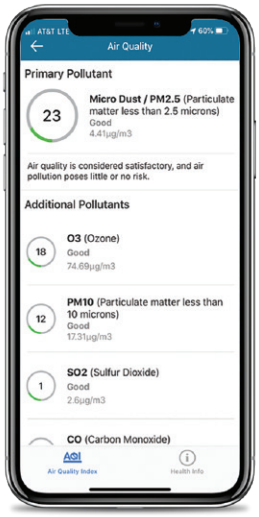
Small Particles Have Damaging Effects on Human Health

A variety of studies focus on the negative health impact of small particle pollution.

Conducted research determined an impact of IAQ on the burden of diseases (BoD). The burden of diseases is measured by the means of a so-called disability-adjusted-life-year (DALY). This time-based measure combines years of life lost due to premature mortality and years of life lost due to time lived in states of less than full health and was originally developed in 1990.

The total estimated burden of disease attributable to IAQ in the European Union is approximately 2 million DALYs per year, which means that two million years of healthy life is lost annually. It is worth noticing that, according to latest estimation carried out by French economists, the cost of 1 DALY can amount up to 100.000 EUR. On a global scale, losses resulting from an inadequate IAQ are large.

Source: Eurovent 4/23-2017



Information on small particle pollution is included in the air quality data of most weather apps.

Relevant/Useful Documents Specific to the Life Science Industry

Publisher	International Guideline Documents for the Life Science Industry	
	Description	**Reference Document**
EN 1822	European Norm for Classification & Testing of HEPA/ULPA Filters	EN-1822 Parts 1-5
EN 779	European Norm for Air Filters for General Ventilation	CSN EN-779 2012
PICS	Pharmaceutical Inspection Convention & Co-operation Scheme	Improve co-operation with GMP between regulatory authorities and the Pharmaceutical industry
ANVISA	Brazilian Health Regulatory Agency	
FDA	Federal Drug Agency	Section 1V Bldgs & Facilities D (Air Filtration)
CFDA (SFDA)	China Federal Drug Agency	
TGA	Therapeutic Goods Administration	
HCA	Hospital Corporation of America	
NOM	Norma Official Mexicana	SSA1 164, SSA1 059, SSA1 241
ISPE	International Society of Pharmaceutical Engineers	HVAC & Industry Guidelines
WHO	WHO Expert Committee for Pharmaceutical Preparations	TRS-961
ASHP	Pharmaceutical Compounding Sterile Preparations	USP 797, USP 800
US DOH	USA Department of Health	CGMP
Eurovent	In Situ HVAC Testing	4 10
ISO	International Standards Organization	14644, 16890, 29463, 29462, 12249
IEST	Institute of Environmental Sciences	IEST-RP-CC001-007,021,034
ASHRAE	American Society Heating, Refrigeration, A/C Engineers	Standard 52.2, Standard 180 HVAC Equipment Maintenance, Standard 170 Hospitals

Typical Cleanroom Testing/Monitoring Requirements

Critical areas may include the following tests and frequencies

Test	Frequency
Particle Monitoring in Air	Annually or every 6 months, depending on application
HEPA Integrity Testing	Yearly— (Grade A/B: every 6 months, D: 1-2 Years)
Verification of A/C Rates	Every 6 months
Air Pressure Differentials	Continuous / Daily
Temperature & Humidity	Continuous / Daily
Microbial Monitoring	Regularly— Daily / Weekly / Monthly
Smoke Visualization	3 - 5 Year Cycle Smoke Visualization

As determined by HACCP

Hazard Analysis and Critical Control Points. This is a preventative food safety system in which every step in the manufacture, storage and distribution of a food product is scientifically analyzed for microbiological, physical and chemical hazards.

HEPA Filter Classification Comparison EN-1822 & ISO-29463

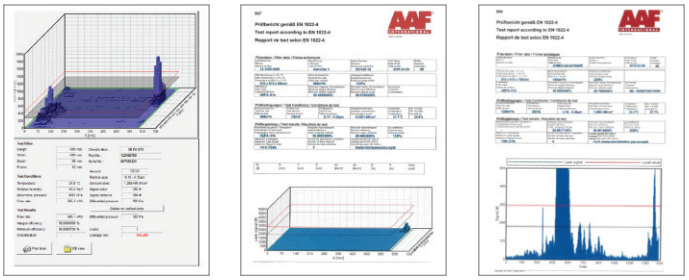
Group		EN-1822	ISO 29463	Integral Value		Local Value		Leakage Factor
				Efficiency at MPPS%	Penetration at MPPS%	Efficiency at MPPS%	Penetration at MPPS%	
	EPA	E10	ISO 05 E	≥85	≤15			
			ISO 10 E	>90	<10			
		E11	ISO 15 E	≥95	≤5			
			ISO 20 E	≥99	≤1			
		E12	ISO 25 E	≥99.5	≤0.5			
			ISO 30 E	≥99.9	≤0.1			
	HEPA	H13	ISO 35 H	≥99.95	≤0.05	≥99.75	≥0.25	5
			ISO 40 H	≥99.99	≤0.01	≥99.95	≥0.05	5
		H14	ISO 45 H	≥99.995	≤0.005	≥99.975	≥0.025	5
			ISO 50 H	≥99.999	≤0.001	≥99.995	≥0.005	5
	ULPA	U15	ISO 55 U	≥99.9995	≤0.0005	≥99.9975	≥0.0025	5
			ISO 60 U	≥99.9999	≤0.0001	≥99.9995	≥0.0005	5
		U16	ISO 65 U	≥99.99995	≤0.00005	≥99.99975	≥0.00025	5
			ISO 70 U	≥99.99999	≤0.00001	≥99.9999	≥0.0001	10
		U17	ISO 75 U	≥99.999995	≤0.000005	≥99.9999	≥0.0001	20

IEST RP-CC001 Classification

Filter Type	Particle Size for Testing µm	Overall Value Efficiency %	Local Value Leakage %
A	0.3*	≥99.97	
B	0.3*	≥99.97	
E	0.3*	≥99.97	
H	0.1-0.2 or 0.2-0.3**	≥99.97	
I	0.1-0.2 or 0.2-0.3**	≥99.97	
C	0.3*	≥99.99	0.01
J	0.1-0.2 or 0.2-0.3**	≥99.99	0.01
K	0.1-0.2 or 0.2-0.3**	≥99.995	0.008
D	0.3*	≥99.999	0.005
F	0.1-0.2 or 0.2-0.3**	≥99.9995	0.0025
G	0.1-0.2 or 0.2-0.3**	≥99.9999	0.001

**Although the mass median diameter of thermally generated particles are approximately 0.3 micron when efficiency testing per IEST/MILStd-282, the count mean is ~ 0.18 micron, near the MPPS.*
***Overall efficiency value based on the lower efficiency of the two particle ranges, typically 0.1-0.2 range.*

Typical HEPA/ULPA Auto-Scan Equipment



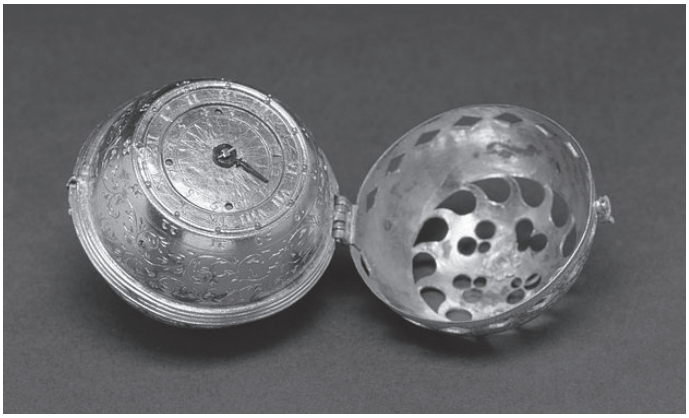
Typical Scan Test Protocol

PASS

FAIL

History of High Purity Filtration

How Did the Cleanroom Industry Evolve?



Vintage Swiss timepiece

It is said the first controlled environment dates back to the late 1800s. Swiss watch makers would prevent particles from settling on their precious merchandise by covering them with small bell jars. About 150 years ago, surgeons started to become increasingly aware of contamination from bacteria causing infection in healthcare environments. Even in today's era of "modern medicine," an average of 1.7 million people in the United States alone develop hospital-related infections each year. Approximately 100,000 of these infected patients die annually, due at least in part to inadequate contamination control procedures.

In the early 20th century, a ball bearing producer allegedly recognized that particle contamination affected its manufacturing process. As a result, it made a major investment to introduce air filtration into their existing facility. Their next new facility had dedicated "white rooms" strategically located according to the criticality of the processes that took place in those spaces. In effect, this manufacturer had created the first clean zones within its building.

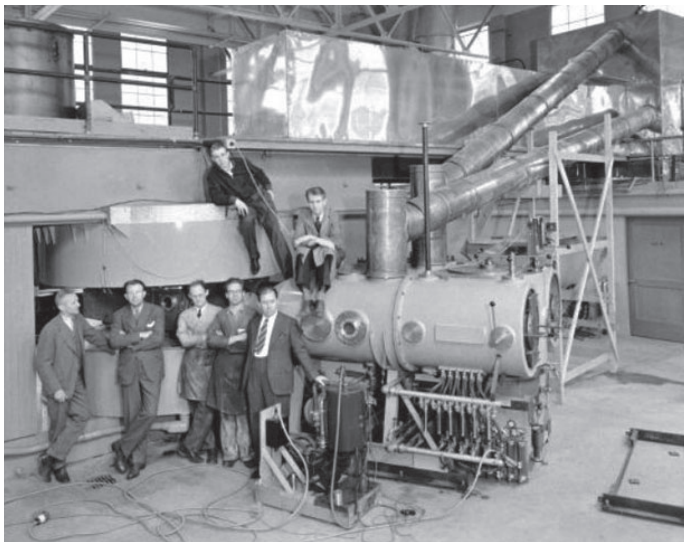
Willis Whitfield from Sandia National Labs invented the first true cleanroom in 1962. A revolution at the time, the design schematics for the first "ultra-clean room" actually has a patent: US3158457 A. In a recorded interview in 1993, Whitfield explained that before his design, most "cleanroom contamination control" was managed by sealing all potential leak paths and vacuuming constantly. He and his team designed a room that recirculated the air through HEPA filters, completely replacing the air in the room 600 times per hour!

Air changes per hour (ACPH) or air change rate (ACR) represents the number of times a cleanroom can completely replace its air volume within one hour. The higher the air change rate, the more effective it will be at removing contamination, therefore achieving a higher cleanroom class. We will point out later in this guide why and how the ACR has been reduced dramatically over a period of decades, driven mainly by the need to conserve energy and the availability of improved cleanroom contamination control protocols and equipment.

When Were HEPA Filters First Commercially Available?

At the heart of the modern cleanroom is either a high-efficiency particulate air (HEPA) filter or an ultra-low particulate air (ULPA) filter, which emerged later. The first major breakthrough in air filtration contamination control occurred when the HEPA was developed around the middle of the 20th century in or near 1940.

The R&D firm Arthur D. Little designed the HEPA filter under a classified government assignment as part of the larger Manhattan Project. The firm originally developed this new class of air filter for the Atomic Energy Commission to isolate deadly nuclear particles from recirculated air in process areas.

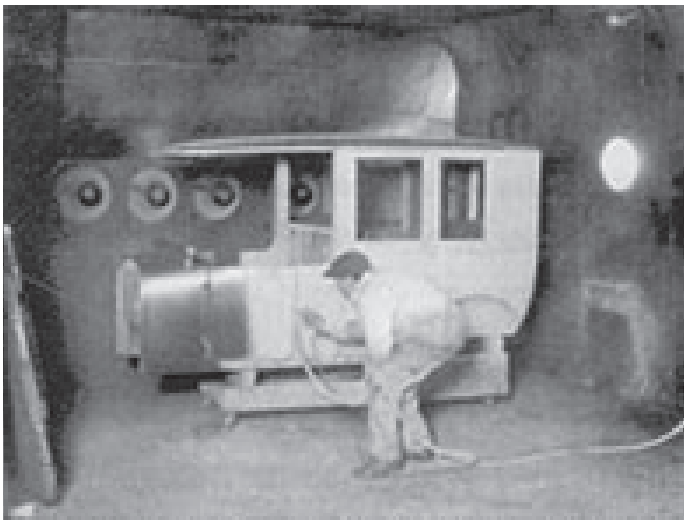


Manhattan Project development team

The Manhattan Project, which resulted in the development of the atomic bomb, began modestly in 1939 but eventually employed more than 130,000 people and cost nearly U.S. $2 billion at the time. Research and production took place at more than 30 sites across the United States, the United Kingdom, and Canada.

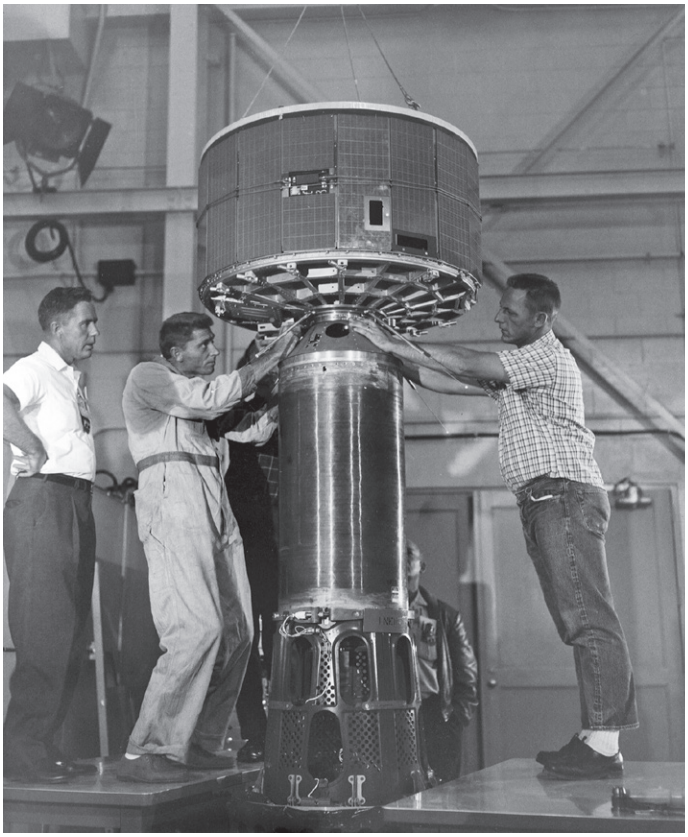
Carrier Corporation is believed to have been the first commercial entity to gain access to, or show initial interest in, the HEPA filter when the product was essentially demilitarized at the end of World War II. For unknown reasons, they did not commercialize the product, but maybe they did not forecast a significant market for these filters. In 1950, the Cambridge Filter Corporation of Syracuse, NY gained access to the technology and started to produce HEPA filters commercially. Upon its founding in 1950, the **Flanders Filters** Corporation also started production of HEPA filters at their New York facility. The majority of the filters sold in this era functioned as safety devices in ventilating systems of atomic power reactors and nuclear fuel manufacturing facilities, where they helped prevent small particles carrying radiation from being released into the atmosphere.

The industry started to spread into the world regions where nuclear power was produced. Camfil started their business in 1963 in these same regions as a licensee of Cambridge Filters, at first supplying HEPA filters for nuclear applications in northern Europe. Cambridge also partnered with Kondoh Industries Japan in 1968, while **Nippon Muki** Japan (an **AAF** sister company) had started manufacturing HEPA filters in the 1950s, soon after its foundation in 1939. AAF Flanders, originally known as "American Air Filter" and then as "AAF," traces its roots back to 1921, when it started producing the first air filters for protection of overspray in the automotive industry. AAF Flanders produced its first commercial HEPA filters in 1964 at one



Circa 1935 - 1940: Prefabricated automotive paint spray booth

of their production facilities in Shelbyville, KY. Also worth noting, the company that would go on to be the future parent of AAF and largest air conditioning equipment manufacturer in the world today, **Daikin Industries,** was founded in Japan in 1924.



Assembly of the Television Infrared Observation Satellite (TIROS) in a clean environment, April 1960

Cleanroom Construction Boomed

The modern cleanroom evolved rapidly in the 1960s and 1970s when the need for increasingly clean environments for industrial manufacturing of everything from instrumentation to weapons accelerated. During this period, the National Aeronautics and Space Administration (NASA)'s space travel program was in full swing, and the concept of "laminar flow" for the assembly of optics, electronics, and sub-assembly for satellites marked a turning point in cleanroom technology.

In the 1970s and 1980s, the mass production of the microprocessor demanded significantly cleaner and larger cleanrooms, which were frequently the size of football fields. In 1965 Gordon Moore, one of the founding members of Intel, made a bold statement for the time by predicting that processor speeds or overall processing power for computers would double every 18 months. This incredible foresight has held true for over 50 years. Although many say Moore's law will come to an end in the coming years, today's processor holds more than 2 billion times as much data as the first memory chip did in 1965.

With geometries shrinking every 18-24 months, the quest for continued contamination control reduction drove product development from multiple vendors and created a worldwide network of local and global suppliers. Cleanroom garments

History of High Purity Filtration

continually improved as operators recognized that people were the main source of contamination in these spaces. During this same period in the 1970s and 1980s, contamination control also improved in terms of construction materials (walls, floors, and ceiling) generally, in terms of protection against particle shedding and outgassing within Microelectronic applications, and in terms of flush finishes within Life Science applications.

Building “rooms within a room” or mini-environments to further isolate or minimize cross-contamination became the norm. Room pressurization regimes and controls for temperature and humidity all advanced as technology evolved and specialized HVAC, controls, and cleanroom vendors developed standards. Around this same time, researchers sought to introduce sealants and media separators used in the construction of HEPA filters that would minimize outgassing and contamination. Airborne molecular contamination **(AMC)** filtration and polytetrafluoroethylene **(PTFE)** ULPA membrane media product development accelerated in the 1990s and continued to evolve to protect the most critical process steps for the most state-of-the-art manufacturing facilities.

Membrane Media Revolution

HEPA product development, mainly in the area of improved media performance over the traditional glass fiber media with **PTFE** and fluororesin media **(FRM)** membrane technology has gained more attention in the last decade or so in a number of regions and applications. Optimizing the design of the filter pack (configuration) in combination with the membrane technology offers the lowest resistance and highest efficiency at the most penetrating particle size (MPPS), therefore delivering the lowest possible total cost of ownership (TCO) over the filter’s useful lifetime.

At a minimum, end users expect that HEPA and ULPA filter manufacturers will deliver as clean a product as possible, i.e., less outgassing and particle shedding, that is manufactured “cradle to grave” in a controlled environment to reduce the risk of cross-contamination. Further, end users have long desired a more durable media than glass fiber to minimize the risk and downtime associated with their HEPA filters. The discovery of the ultra-fine fiber PTFE technology in 1988 by Daikin Japan (AAF's parent) ushered in a new area in high efficiency ULPA media manufacturing.

The Microelectronic industry almost immediately recognized the major advantages of PTFE membrane technology, leading to its rapid adoption. This membrane media’s superior durability over glass fiber, low outgassing (essentially chemically inert), and lower energy consumption won over the industry, where it is ubiquitous today. From the same family as PTFE membrane, the more recent media option FRM earns rave reviews in the Life Science arena because it adds compatibility with oil-based aerosol polyalphaolefin (PAO) to these same advantages of PTFE. PAO is most commonly utilized for field testing HEPA filters in industries outside of Microelectronics.

Containment Applications Require Negative Pressure Rooms

In applications such as Bio-Safety Level (BSL-3 and BSL-4) spaces, operators maintain negative room pressurization. One of the critical containment protocols utilizes the concept of cascading differential pressure, meaning that air in a bio containment facility flows from cleaner to dirtier adjacent spaces. Air follows the desired path by maintaining slightly lower (more negative) room pressures between each adjacent space, with the dirtiest space featuring the most negative pressure and exhaust filters. This delicate process might sound simple in concept but proves difficult to accomplish. Complications include different sizes of adjacent rooms, dampers of different sizes and with different characteristic curves, and so on. Other than door openings and closings associated with scientist access to a space, the change in Δp associated with the HEPA filter represents the biggest cause for room pressure gradient fluctuation. Adoption of the FRM membrane technology from AAF can help achieve significant benefits in this area due to its significant reduction in resistance and longer loading characteristics.

The housings that these filters are installed in vary by the combination of components, such as upstream and downstream test sections, HEGA (high-efficiency gas absorbers) bubble-tight dampers, integrated spark arrestors, automated scanning, pre and HEPA sections, decontamination ports, and multiple gauges and measurement devices. The housing construction can also vary depending on the application and geographic region of the world where it is installed. The “standard” for these high-risk applications can start with a 316 stainless steel 100% welded #4 finish and pressure decay tested to 6000PA. In “less critical” applications (more on the topic of “less critical” follows), one might see a painted steel box, spot welded and caulked, or maybe a sealed housing with a plastic bag masquerading as a “safe-change” housing, especially in cases involving a limited budget.

Zero Tolerance for Risk

If consulting engineers and end users take the time to write a specification for a containment housing, then they should ensure what is provided by the supplier meets that specification. Of equal importance, the specification as written must suit the application. If the decision is made to install a containment housing to minimize risks to the production process, such as cross-contamination, long-term research disruption, or product-to-personnel contact in a given facility, then the selected product must addresses this combination of risks. Of course, the selected containment housing should feature reliable, functioning components that stand the test of time.

AAF's next generation containment housing **AstroSafe®-**

AstroSafe™ containment unit with AstroScan™ M manual scanning system installed

AstroScan® allows for filter testing, decontamination, and aerosol injection with no or minimal downtime, minimizing risk and extending service life.

If a housing leaks, or the seal on the safe-change bag fails, (or, even worse, if no bag is installed in the housing, which is far too common) and the contaminant captured in the filter is released, people's lives could be at risk. DO NOT cut corners in this area, regardless of budget concerns. Qualified, certified master welders cost money for good reason. Work with internationally recognized manufacturers who have a robust quality control system and, more importantly, have a history of delivering product successfully over a long period. The user and specifier may also wish to ensure that the supplier of the housing also manufactures the filters, since this manufacturer knows how all the components function together from a performance and certification standpoint.

Internal application expertise and a proven track record of product development further separates the pack, especially in the areas of media development, housing development, and testing capabilities. Take advantage of this expertise when developing specifications for your application. More information about the governing agencies and guidelines used in the industry, as well as info on product applications requiring bag in-bag out (BIBO) or safe-change housings and filters, can be found later in the guide.

Industry Regulation

Standards and regulations started to play a more influential role in the construction and classification of rooms as the industry grew. The Microelectronics industry remains essentially self-regulated, although working groups and bodies such as Semiconductor Equipment and Materials International **(SEMI)** and International Roadmap for Devices and Systems **(IRDS)** have formed. These groups function mainly to provide guidance for AMC controls in Microelectronics facilities, thereby protecting equipment and processes.

Those who are new to the industry may be unfamiliar with the age-old rule of thumb of 100fpm (0.5m/s) room air velocity to create "laminar flow." Originally published by the father of cleanroom design Dr. Willis Whitfield of Sandia National Labs, operators of mammoth energy-consuming cleanrooms began challenging this concept decades ago. More than 20 years ago, these operators reduced air speed, and therefore filter resistance and energy consumption, to as low as 60fpm or 0.3m/s. According to a separate rule of thumb regarding filters, for every 1Pa one saves in resistance, one saves approximately U.S. $1 in energy per filter. As a result, 20Pa, 30Pa, or 50Pa becomes very interesting to the end user in terms of reduced operating costs. Because **PTFE** delivers consistently reduced filter resistance over glass for similar pack heights and media efficiency, this media makes a lot of sense from a TCO perspective.

Dr. Willis Whitfield of Sandia National Laboratories

The airflow uniformity in these room designs can be influenced substantially by (1) how the air is delivered into the terminal device, and (2) how the air is exhausted or recirculated. Some Microelectronics designs have integrated dampers in the raised floor to control or improve the airflow direction. Most established filter manufacturers optimize the pleating or configuration of HEPA filters to improve airflow uniformity. Some manufacturers add a laminar flow scrim or screen, which are sometimes referred to as the "CG screen," first promoted by Luwa in Switzerland. Typically one mounts the scrim or screen about 50mm downstream of the filter, which creates a back pressure and evens up the airflow distribution. Other airflow diffusion devices exist as part of the grid system itself, or dampers can be mounted on the back of a HEPA filter in the plenum to improve airflow distribution.

History of High Purity Filtration

The Life Science industry faces much more regulation due to the nature of the products they produce. The Centers for Disease Control (CDC) and Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe regulate Life Science manufacturers and have global counterparts, especially in advanced markets such as China and India. Most of the global agencies from around the world that influence the industry are listed later in the guide.

A document published by the FDA in 1987 defined two main areas:

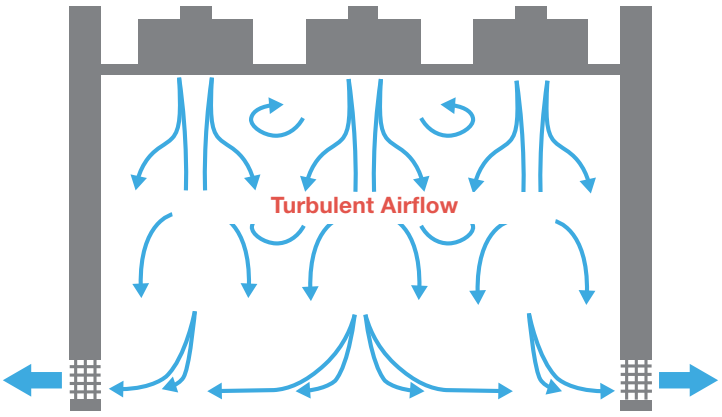
- A critical area where the sterilized dosage form, containers, and closures are exposed to the environment.
  - Air in critical areas should be supplied at the point of use as HEPA-filtered laminar flow air, having a velocity sufficient to sweep particle matter away from the filling/closing area. Normally a velocity of 90 feet per minute (fpm) or 0.45 meters per second (m/s) plus or minus 20% is adequate.
- A controlled area where unsterilized product, in-process materials, and container closures are prepared.
  - In controlled areas, it is important to achieve a sufficient air flow of 20 to 60 ACPH and a positive pressure differential of 10-15Pa relative to adjacent uncontrolled areas. When doors are open, outward airflow should be sufficient to minimize ingress of contamination.

Within the Life Science arena, two schools of thought have emerged as to how air ought to be delivered into the room – either via displacement (uni-directional/laminar flow) or dilution (turbulent flow). The most common delivery method for cleanrooms that don't face a laminar flow or uni-directional requirement involves a terminal housing or box delivering a turbulent flow, depending on world region. A typical Grade A space generally does not have any such requirement, so it utilizes a fan filter unit (FFU) or plenum with recirculation fans.

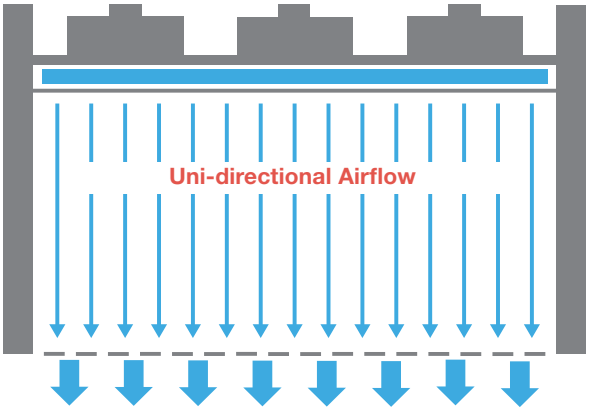
The housings and filters delivered to the Life Science industry have essentially remained the same over recent years. The industry adopted traditional commercial grade room air diffusers in Europe, but in Asia a swirl or 4-way throw diffuser is preferred. These diffusers operate on a dilution or turbulent design principle. The United States generally standardized on a perforated style diffuser, which behaves more like a displacement device.

Recently a true cleanroom supply diffuser has been engineered for the first time. In simple terms, it looks like a perforated diffuser but behaves like an improved swirl diffuser and delivers an umbrella air distribution effect. There are multiple advantages with this design, such as enhanced ventilation effectiveness, lower air change rates, reduced number of housings required, improved ease of cleaning, and decreased costs stemming from less installation and certification. Even in spaces that have been built out previously, operators find that they are able to retrofit them easily to enjoy the benefits of improved airflow distribution and eliminating/minimizing dead zones.

Traditional Dilution or Turbulent Flow



Typical Displacement or Laminar Flow



Cleanroom Standards

In 1963 the Institute of Environmental Science and Technology (IEST) published Federal Standard 209 (FS 209), which became the first internationally recognized standard for cleanroom classifications. Many countries adopted or made their own versions of the standard, primarily to account for conversion to the metric system. Australia (AS 1386), France (AFNOR X44101), Germany (VDI 2083:3), Holland (VCCN 1), Japan (JIS-B-9920), Russia (Gost-R 50766), and the United Kingdom (BS 5295) are among the major countries that established standards that referenced FS 209.

International Cleanroom Standards Summary

		Country and Standards								
		USA 209D	USA 209E	Britain BS 5295	France AFNOR	Germany VDI 2083	Japan JISB 9920	Australia AS 1386	EU GMP Annex 1	ISO 14644
Particles per m^3 0.5 µm	1									
	3.5									
	10		M1				2			
	35.3	1	M1.5	C		1	3	0.035		3
	353	10	M2.5	D		2	4	0.35		4
	3,530	100	M3.5	E or F	4,000	3	5	3.5	A	5
	35,300	1000	M4.5	G or H		4	6	35	B	6
	353,000	10,000	M5.5	J	400,000	5	7	350	C	7
	3,530,000	100,000	M6.5	K	4,000,000	6	8	3500	D	8

Occasionally veterans of the cleanroom industry still quote “Class 100” from the old Federal Standard 209D. As a multitude of applications and industries evolved over the last decades, it has taken quite a while to settle on an internationally acceptable cleanroom standard that suited them all. The ISO Technical Committee ISO/TCO209 on “clean rooms and other associated controlled environments” started in 1993 and has effectively rendered FS 209 obsolete.

This committee introduced new standards within the first draft of ISO-14644, which continues to evolve. Within ISO-14644 currently, 16 different standards exist. Of these, ISO-14644-1 and -3 have the most bearing on air filtration, with ISO-14644-1 “Classification of Air Cleanliness” becoming mandatory in the EU in 1999. ISO-14644-1 Clause 2.1.1 defines cleanrooms thusly:

> 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 parameters, e.g., temperature, humidity, and pressure are controlled as necessary.

One of the latest additions to the standard, ISO-14644-16 focuses on optimizing energy in cleanrooms and clean air devices.

VisionAir Clean™ (VAC) software from AAF identifies opportunities to minimize energy consumption within a clean environment, especially in the area of air change rate optimization. For more information, refer to the VisionAir Clean section in this guide. Latter portions of this guide expound on the concepts of **system economy** and **system integrity.** The importance of these ideas stands out when one confronts the fact that the dampers in supply and exhaust housings frequently generate more resistance within a system than do the filters. This point often gets missed or downplayed during the design selection of these housings, but the consequences can have a significant impact on energy costs.

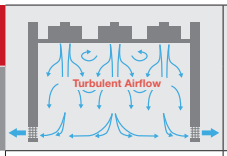
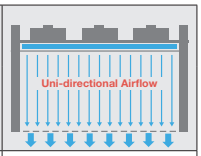
ISO-14644 Overview

		Description
ISO-14644	1	Classification of Air Cleanliness by Particle Concentration
	2	Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
	3	Test Methods - In Revision DIS Out for Comment
	4	Design & Construction
	5	Cleanroom Operations (Current)
	6	Withdrawn (Definitions in each standard)
	7	Separative Devices (Current)
	8	Air Cleanliness Classification by Chemicals (Current)
	9	Surface Cleanliness Classification by Particles (Current)
	10	Surface Cleanliness Classification by Chemicals (Current)
	12	Air Cleanliness (Monitoring) by Nano Particles
	13	Cleaning of Surfaces
	14 & 15	Equipment Stability - Part 14 New DIS Passed Vote
	16	• New work started 2015, based on BS 8568:2013, Cleanroom energy. • Code of practice for improving energy efficiency in cleanrooms and clean air devices
	1 & 2	The 14698 standards are still in place
	104	New standard in ISO TC209 WG2, work stopped - Air and surface cleanliness by variables. Work taken up by CEN TC243

The above table was updated in November 2020.

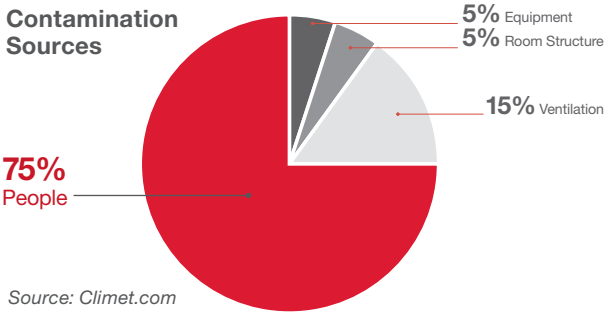
History of High Purity Filtration

Typical Cleanroom ISO-14644-1 Cleanliness Classification by Segment

Selected airborne particulate cleanliness classes for cleanrooms and cleanzones											
Industry	ISO Class 1	ISO Class 2	ISO Class 3	ISO Class 4	ISO Class 5	ISO Class 6	ISO Class 7	ISO Class 8	ISO Class 9		
Microelectronics	•	•	•	•	•	•	•	•	•		•
Pharmaceuticals			•	•	•	•	•	•	•	•	•
Aerospace			•	•	•	•	•	•	•	•	•
Medical Devices					•	•	•	•	•	•	
F&B and Healthcare						•	•	•	•	•	

Internet of Things and Cleanrooms

With the explosion of the Internet of things (IoT), sensor technology has the potential to connect all these control and contamination monitoring devices. Users can view real-time data such as particle and molecular contamination counts, as well as temperature, pressure, and humidity levels. Through artificial intelligence (AI) and automated machine learning of the demands of the plant and building, precise forecasting and optimization of energy demand becomes possible. In fact, such technology may even be possible to predict points of failure for individual components. As a final point, sensors that detect human movement are being used more frequently for ventilation-on-demand applications, which can save 20 percent or more of the costs associated with moving air through systems.



Source: Climet.com

For more information, refer to the Contamination Sources Section in the guide.

AAF's sensor technology is monitoring key parameters in air filtration to optimize system economy and system integrity

Definition:
Machine-to-machine communication that is built on cloud computing and networks of data-gathering sensors with mobile, virtual, and instantaneous connection.

For more information, refer to the Sensors and Internet of Things (IoT) Section in this guide.

Future Industry Trends

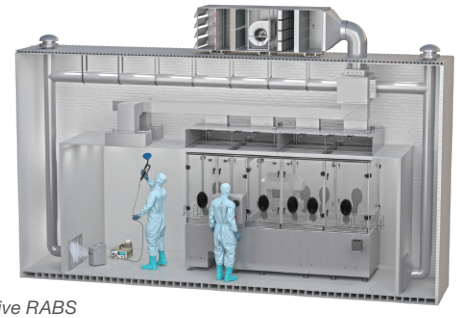
Looking at where the cleanroom and bio-safety industry is today and where it is going in the future, a number of trends start to emerge.

Microelectronics Industry

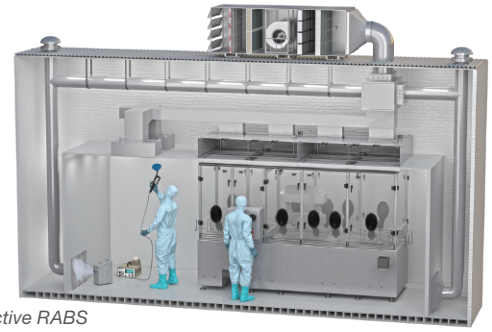
- MEGA cleanroom facilities constructed primarily for the flat panel display (FPD) market and foundries to a lesser extent, 80% of which are owned and operated by Asian firms.
- Days of "fully filtered" ceilings essentially over, giving way to an ISO 5 background with clean zones or mini-environments to control contamination.
- Open plenum or ducted HEPA designs rare by comparison with scenarios involving FFUs, which are the standard due to their flexibility on many fronts, but especially for the smaller footprint required of the facility (see the FFU Section in this guide).
- Increased need for control of airborne molecular contamination (AMC) with chemical filters coupled with the lowest contaminant-generating ULPA (PTFE) filters.
- Expectations for major developments in the next 5-10 years of IoT-driven solutions to control and monitor the most critical process steps.
- Energy cost at the forefront of product selection, with contamination control a close second, due to the huge costs associated with operating these facilities (100MW in annual energy consumption in these larger facilities not unusual).
- Further consolidation of the major manufacturing base in Asia, primarily China, Korea, and Taiwan, with 80% of today's capacity coming from homegrown talent of TSMC, UMC, and SMIC in the top tier, and Samsung and Global Foundries rounding out the top 5.

Life Science Industry

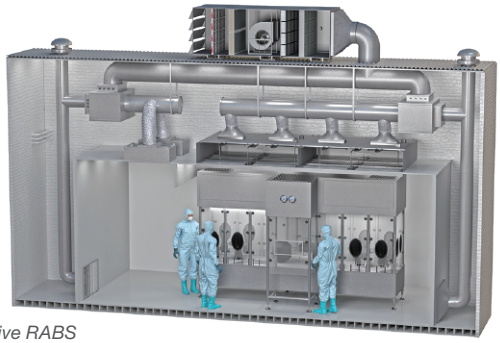
- Continued pressure within Big Pharma to reduce their cost base, driving further consolidation and outsourcing, but market expects major brands to be localized.
- Continued growth in Generic and Biosimilar drugs as R&D budgets shrink and worldwide political pressure on healthcare costs escalates.
- Wider adoption of Open, Active, and Passive Random Access Barrier Systems (RABS) while Isolator Technology will decrease in cost due to economies of scale.
- Shift to modular or POD cleanroom assembly to speed up construction time and offset rising validation costs.
- Decisions on production equipment and processes dominated by sustainability focus, driving demand for system economy for reduced energy consumption and system integrity for risk minimization.
- Increased challenges to historic design parameters established 30+ years ago as regulators dictate reduction of Air Changes per Hour (ACPH) and Room Velocities (Grade A space), as well as introduce new certification/validation norms.
- Rapid adoption of IoT-driven solutions by manufacturers, and acceptance of this development by regulatory agencies.



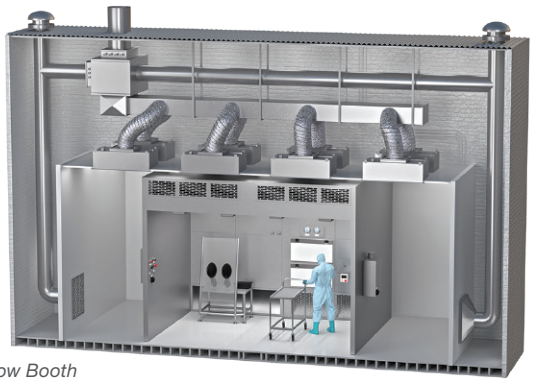
Open Passive RABS



Closed Active RABS



Open Active RABS



Downflow Booth

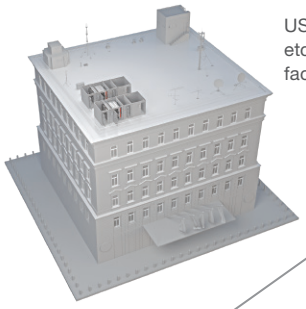
For more information, refer to the RABS Section in this guide.

History of High Purity Filtration

Bio-Safety

- Further discussion of HEPA filter efficiency and breakthrough as viruses and bacteria evolve different structures or mutate into different organisms.
- Intensified study on how airflow uniformity or distribution within a containment housing affects the MPPS in terms of media penetration.
- More attention focused on how containment BIBO or Safe-Change housings are assembled, tested, and certified in the factory and the field, leading to discussion of system economy and system integrity.
- Improvements in HEPA filter scanning, controlling airflow through automated bubble- or gas-tight dampers, and real-time monitoring of system integrity driven by automation and IoT.
- Major investment growth in high containment labs globally, but especially in China and India.

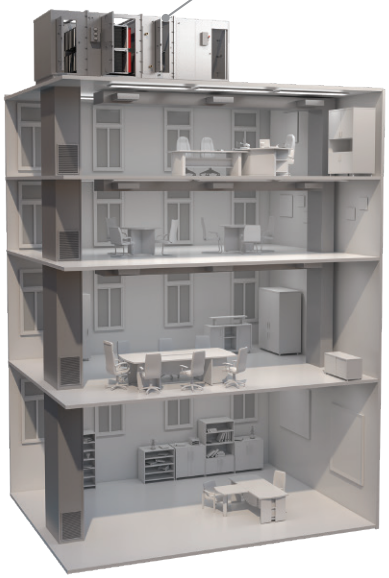
Homeland Security

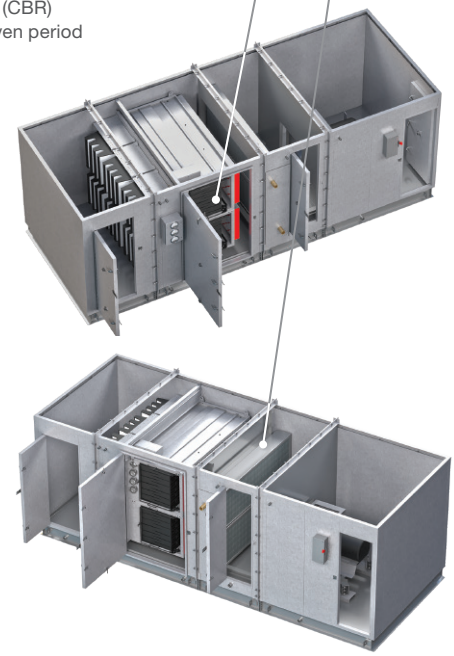


US Embassy, DOD, DOE, etc. Protection of critical facilities globally

Custom AHU with integrated air filtration system primarily to prevent a Chemical, Biological, and Radiological (CBR) attack for given period

Multiple steps of filtration and framing system with custom designed HEGA & HEPA filters



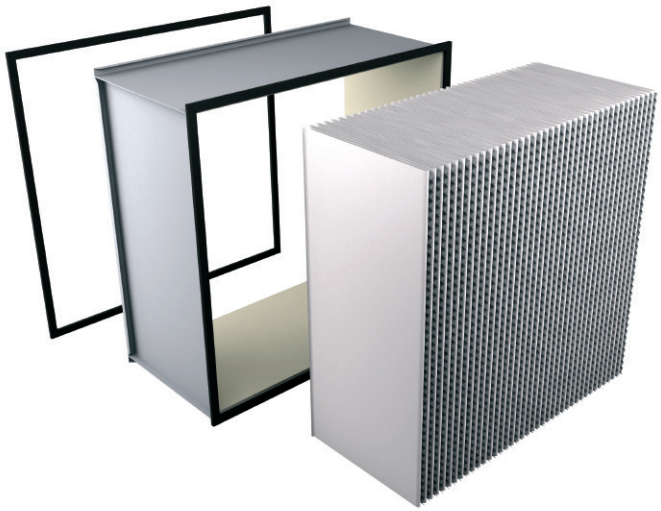


BIBO 'Safe Change' Housings

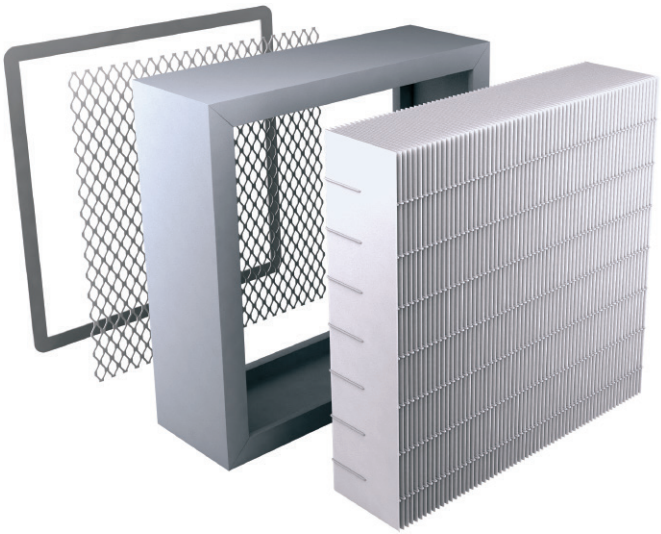
For more information, refer to the BioSafety/BIBO Section in this guide.

AstroSafe®/AstroScan® M

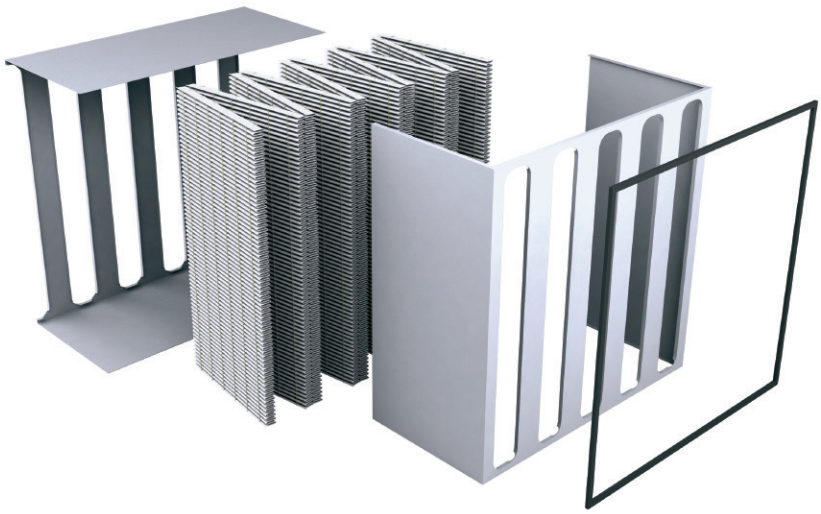
HEPA Construction Types



AstroCel® I and MEGAcel® I
- 292mm (11-½") deep
- Deep pleat design
- Dry and fluid/gel seal



AstroCel® II and MEGAcel® II
- 35mm-100mm (1.5"- 4" nominal) depths
- 'Minipleat/closepleat' design
- Dry and fluid/gel seals



AstroCel® III and MEGAcel® III
- 292mm (11-½") deep
- 'V' bank design
- Dry and fluid/gel seals

HEPA Media Types

Glass Fiber or Microglass (wet laid) Media:

First developed in the 1940's

The manufacturing process starts with a slurry of glass fibers in water with binder, it's then poured on a moving screen conveyor, water vacuumed from below, baked dry in an oven, media rolls shipped to filter manufacturer, pleated into packs, potted in urethane in filter frames, tested and packed.

The basic process and recipes have has remained the same for 75+ years, the biggest exception being the introduction of a low Boron Media for specific semiconductor applications.

There is a wide range of filter efficiencies available and has been the industry standard for high efficiency filtration.

The fact remains, the media is delicate and vulnerable at every stage of the manufacturing and assembly process, filter installation, certification, and shipping or transportation process.

- Slurry of glass fibers in water with binder
- Poured on a moving screen conveyor
- Water vacuumed from below
- Baked dry in an oven
- Pleated into packs
- Potted in urethane in filter frames
- **Media is delicate and vulnerable at every stage of manufacturing, filter installation to testing**
- **Media is extremely fragile**

HEPA Membrane Media or PTFE/MEGAcel

In 1938, Dr. Roy Plunkett of DuPont accidentally discovered polytetrafluoroethylene (PTFE), later trademarked as Teflon in 1945. A decade later, in January 1958, W.L. "Bill" Gore left DuPont to pursue the material's potential and, together with his wife, founded W.L. Gore & Associates in the basement of their Newark, Delaware home. In October 1969, their son Bob Gore advanced this legacy when he accidentally discovered expanded PTFE (ePTFE), opening new possibilities for applications across industries. Building on this foundation, Daikin, which would later become the parent company of AAF, discovered the ultrafine fiber structure in 1988, marking another milestone in the continuing evolution of PTFE technology.

The manufacturing process starts with a 'fine powder' recipe, there is then a process of mixing and pre-forming a paste, then a paste extrusion, then stretching/drying/calendering, then stretching-scoring, laminating/pleating/assembly testing. The whole manufacturing and assemble process occurs in a cleanroom environment.

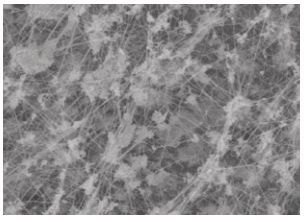
The main benefits of the membrane technology are: VERY robust media, low pressure drop and chemically inert.

PTFE/MEGAcel ME membrane media has become the preferred choice for microelectronic applications—from critical minienvironments to large FABS and FPD facilities—because of its low energy consumption, lighter weight, and, today, its cost efficiency driven by economies of scale.

MEGAcel media is a relatively new technology that is rapidly being adopted in the Life Science and Healthcare industries, offering the same benefits as earlier PTFE membranes while overcoming a key limitation: it is fully PAO-compatible, unlike the first generations of PTFE membranes.

1988 Daikin discovered ultrafine fiber structure

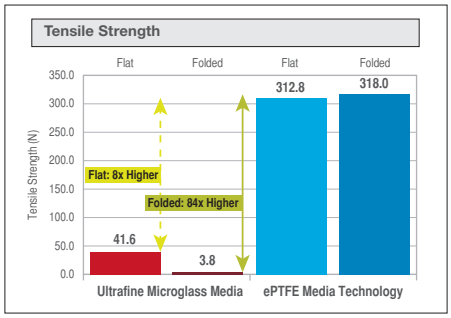
- Starts with 'fine powder' depending on grade/layers
- Mixing & pre-forming paste
- Paste extrusion
- Stretching/drying/calendering
- Stretching-Scoring
- Laminating/Pleating
- **Whole process controlled in a cleanroom environment**
- **Media is VERY robust.**



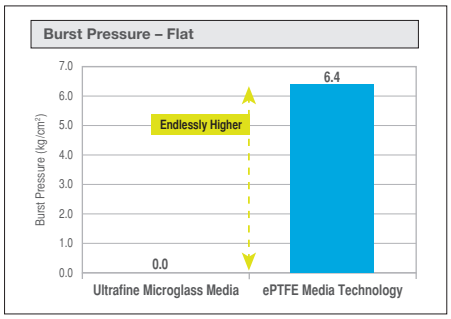
Evolution of PTFE Media in Microelectronic Applications

- The microelectronics industry's product development required a cleaner and more stable environment from a particulate and Airborne Molecular Contamination (AMC) standpoint. ME exceeded Glass fiber medias performance in many applications especially where boron was a concern.
- Timing, ME fine fiber structure discovery (1988 Daikin) led to commercialization of ULPA filters in mid 1990's.
- 1999, Motorola installs 6000+ filters in MOS 17 Tianjin China (mainly driven by 'handling benefits'– 2017 Fab is now SMIC, filter PD increase in 20 years is approximately only an additional 50 PA.)
- Gore heavily promotes ME ULPA applications directly to end users and through filter manufacturers.
- AMD Dresden Fab wanted to use ME but Gore had no production know-how/capacity, PO placed for LB filters.
- Glass Fiber manufacturers 'fight back' with Low Boron media development + lower cost.
- 'The whole world' does not change to PTFE but the tools/mini-environments adopt quickly combining with AMC filtration.
- Steady increase of installations in Asia (Taiwan-China) as media availability and manufacturing expertise/costs improves during the 2000's.
- Today– Standard product in mini-environments. Wide spread adoption of ME for 'mega fabs' and early adoption of Life Science applications for MEGAcel media that is PAO compatible.
- Today– Cost comparable with glass media with more technical/TCO benefits.

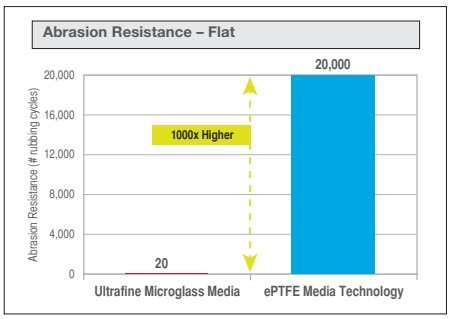
Proven Durability— 84x the Pleated Strength of Microglass



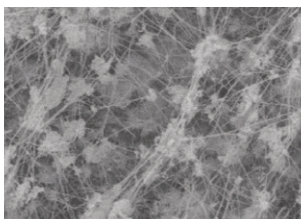
Results based on Test Standard DIN EN 29073-3.

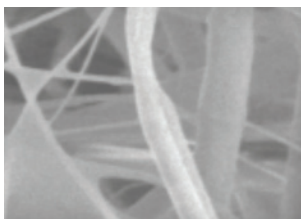


Results based on Test Standard DIN EN 13938-2.



Results based on Test Standard DIN EN 12947-2.

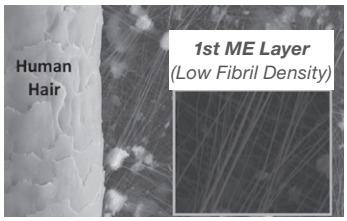


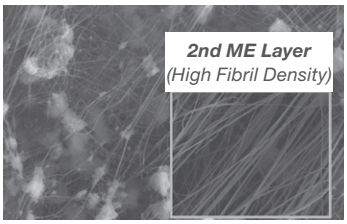


PTFE/MEGAcel ME Media

Single layer of expanded PTFE supported by a layer of spun bonded synthetic media on the upstream and downstream side.

- Available in H13 – U17
- Standard for Microelectronic and Tool Market
- Compatible with Discrete Particle Counters (DPC) testing





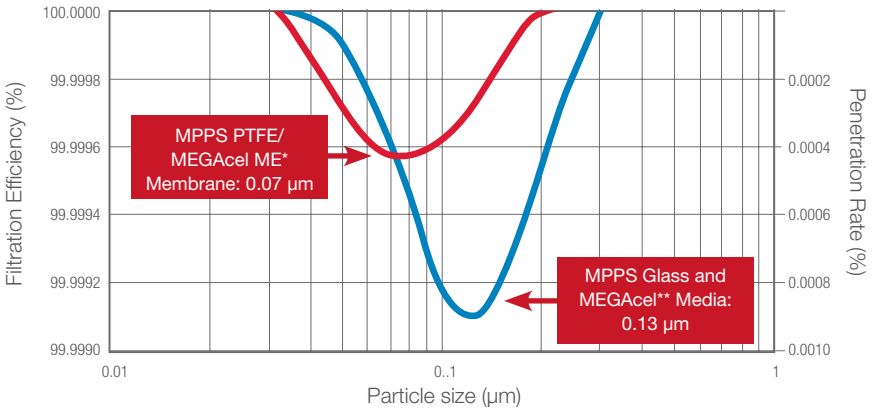
MEGAcel Media

Dual layers of expanded Fluororesin supported by a layer of spun bonded synthetic media on the upstream and downstream side.

- Available in H13 – H14
- Suitable for Life Science Applications
- Compatible with photometric test methods

Filter Efficiency

MPPS Filter Designations Microglass and Membrane Media



**MEGAcel ME - traditional single layer expanded PTFE membrane utilized primarily in SemiCon, Micro Electronic, and aerospace applications.*

***MEGAcel for Life Science applications is a discrete, two-layer, ePTFE membrane technology designed specifically for Life Science and general duty applications.*

Filtration efficiency @MPPS determined according to:
EN1822-5-2009 - Annex A, alternative procedure for testing membrane media with MPPS < 0.1µm

EPA	Efficiency Particulate Air Filter
HEPA	High Efficiency Particulate Air Filter
ULPA	Ultra Low Penetration Air Filter

IEST designation for a HEPA: 99.97% @ 0.3um to 99.995% @ MPPS

IEST designation for an ULPA: ≥99.999 @ 0.12µm

EN1822/ISO-29463 designation is MPPS E10-U17: XX.X5 @ MPPS

(Most Penetrating Particle Size)

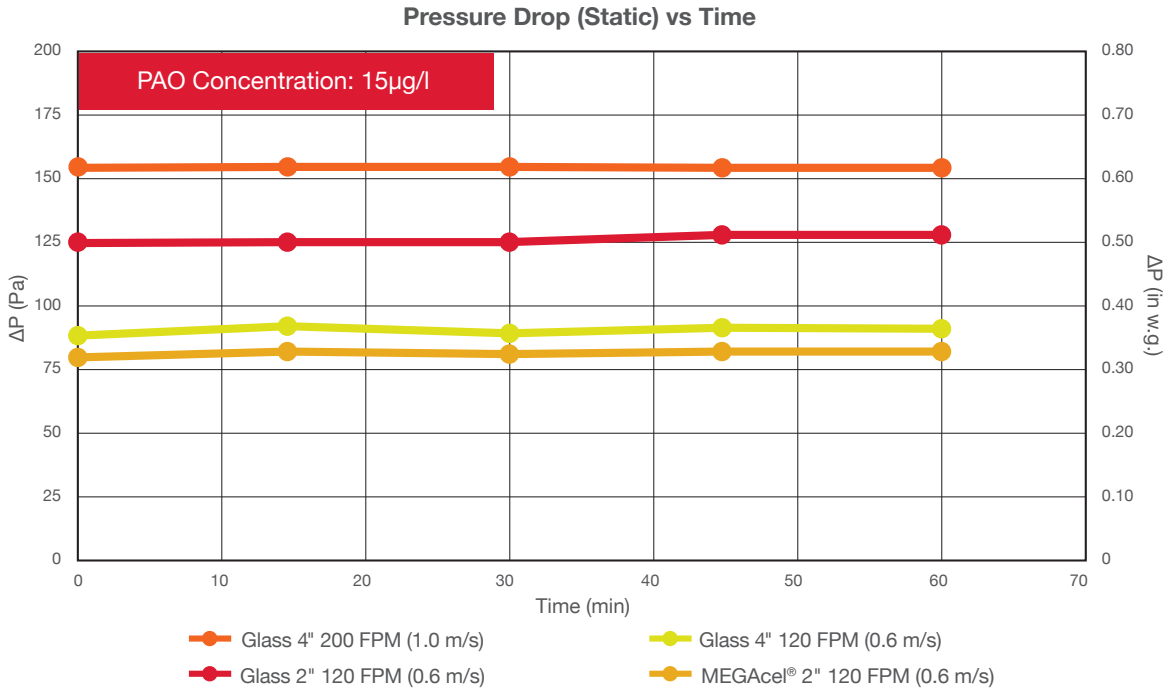
See Filter Classification in prior pages.

MEGAcel Media Oil Aerosol Exposure

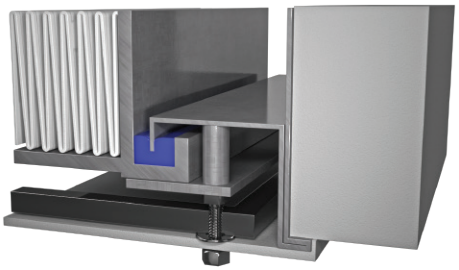
Laskin Nozzle 'Cold' PAO Pressure Drop Data

- Stable pressure development for 1 hour with local injection

Average PAO Concentration: 15µg/l

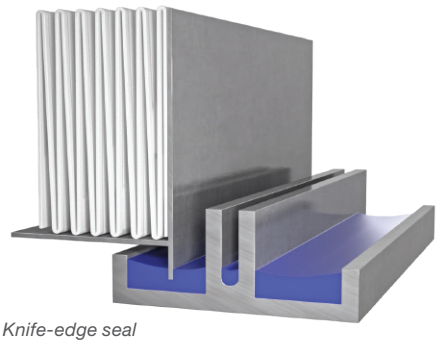


HEPA Filter Seals



Bottom load fluid seal

Top load fluid seal



Knife-edge seal

Gasket PU applied in a bottom load extruded channel.

Fluid/Gel Seal

Gel or fluid seal materials have been used as an easy and reliable method of sealing HEPA filters to housings, holding frames, ceiling grids, and terminal hoods for over thirty years and continue to gain in popularity over other sealing methods. Gel materials are much softer and more forgiving than typical gaskets, requiring near-zero clamping pressure.

Polydimethylsiloxane (Silicone) vs. Polyurethane

Both silicone and polyurethane allow for easy, reliable air-tight sealing of HEPA filters to housings, holding frames, ceiling grids, and terminal hoods, creating a leak free connection to supply or exhaust air. Both silicon and polyurethane gels exhibit comparable external properties in hardness/softness, surface tack, and elasticity; however, there are significant differences in specific applications as well as usage and availability outside of filtration.

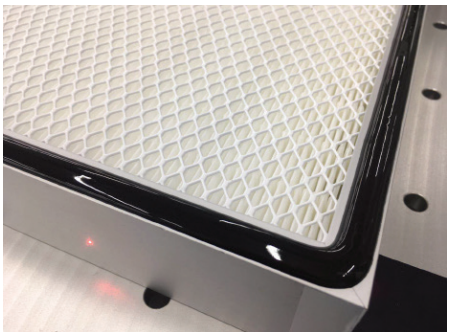
Testing

Very important to ensure the filter manufacturer has the necessary understanding and testing capability to verify fluid/gel seal material compatibility with common cleaning, decontamination and field certification test aerosols such as VHP, ClO_2, CH_20, Spor-Klenz®, Vaprox®, PAO or application defined by the user.

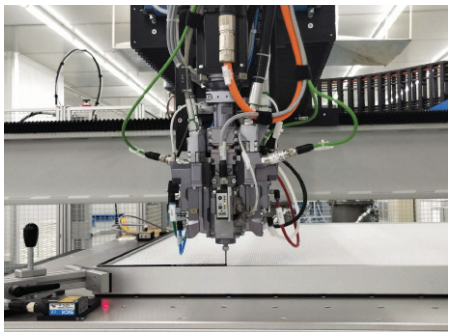
Dry Seal

The original mechanism utilized to seal a HEPA filter sealing face to the framework of a housing such as an AHU, a Bio-Safety Cabinet (BSC) or Terminal Housing has been a gasket.

There are different materials used today from a closed cell sponge type normally neoprene with a ‘dove tail’ or interlocking adhesion on each corner and to the frame. Ethylene Propylene Diene Monomer, or more commonly known as EPDM can be adhered to the HEPA filter surface in a one-piece mold with a double sealing surface ‘U’ shape in certain regions. There is a growing adoption of polyurethane or ‘PU’ gaskets with the advancement of robotic application technology. This ‘one-piece poured’ gasket minimizes any potential leak paths especially on corners. Commonly used on FFU’s and is more cost effective than the gel material historically used in these cleanroom applications.



PU poured gasket on the HEPA sealing surface.



Automated PU application during assembly.

HEPA Filter Seals

HEPA Seal Chemical Compatibility Testing

HEPA seal materials are evaluated to ensure material compatibility with common cleaning, decontamination and field certification test aerosols. The filter manufacturer must have an in-depth understanding and the necessary testing capability to verify material compatibility against common cleaning, decontamination and test aerosols or agents, especially in the Life Science application arena. Equal importance should be given to how the sealing materials utilized in filters are controlled in the factory from a storage, pouring and curing standpoint.

Common cleaning, decontamination, and testing agents that have been tested by AAF on various fluid and dry seal applications.

	Cleaning	Decontamination	Filtration Testing
Acetone	●		
IPA (70%)	●		
Sodium Hypochlorite (NaOCl/NaClO)	●		
Spor-Klenz®	●		
Vaprox®	●		
Vesphane™ IIse	●		
Vesphane™ LpH st	●		
Veltek Hypo-Chlor©	●		
Chlorine Dioxide (ClO_2)		●	
Formaldehyde (CH_2O)		●	
Vaporized Hydrogen Peroxide (H_2O_2)		●	
Di-Ethyl-Hexyl-Sebacate (DEHS)			●
Dioctyl Phthalate (DOP)			●
Poly Alpha Olefin (PAO)			●
PSL Spheres			●

Advanced Testing:

Due to the sensitive nature of some applications, HEPA seal materials are tested for their attributes to ensure a long, successful service life.

Fluid Seal gels are tested for hardness, tack, elasticity, and other physical properties to guarantee performance at the knife-edge interface. As a result of a gel's soft properties, gel formulations can vary in makeup and, therefore, performance. One of the properties affecting performance is the percentage of extractable materials. Variations in the percent extractables in HEPA Fluid Seal Gels can vary from 30% down to 5%, the latter being the most desirable. These extractables have been historically qualified using an industry 'Blot Plot' test and have been quantified by AAF using multiple extraction techniques. Purity of these formulations is also evaluated and quantified using Nuclear Magnetic Resonance (NMR). NMR identifies all materials in the Fluid Seal gel formulation to quantify gel purity and determine what impurities may be present.

Dry Seal Gasket materials are also tested for physical properties significant to fielded performance. Gaskets are tested for hardness, durometer, porosity, and compressibility. Dry seal gaskets must compress with adequate force between the sealing surface of the HEPA filter and the mating surface of the Housing or Frame along the entire gasket length. Many materials, once deformed will relax and may exhibit memory (i.e. stay deformed). This relaxing and memory can have a detrimental impact on the sealing capability.

Note:

This piece is specifically focused on the HEPA sealing options. It should be noted that of at least equal importance is how the seal itself is mated to the frame or housing and by extension how the frame or housing is mated to the ceiling or wall.

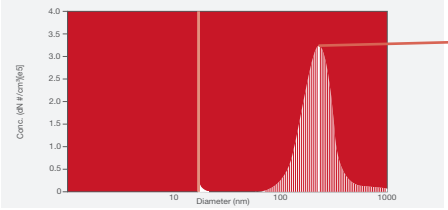
This is what is known as 'system Integrity'. In other words, if the housing or frame leaks, or the housing to ceiling has bypass then the seal on the HEPA filter becomes moot.

Further information on Filter & Housing System Integrity (and economy) is available in AAF's High Purity Guide.

Contact your nearest AAF office for further explanation.

Aerosol Distribution for ‘Hot’ (Thermal) and ‘Cold’ (Laskin Nozzle) Generators

PAO-4 Particulate Size Distribution of a Thermal Condensation Generator (ATI-5C)

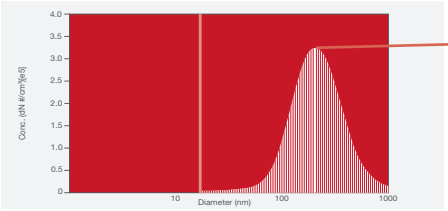


	Particle Size			
	Number	Surface	Mass	Volume
Median (nm)	221	282	373	373
Mean (nm)	237	364	488	488
Geo. Mean (nm)	219	317	421	421
Mode (nm)	225	269	479	479
Geo. Std. Dev.	1.5	1.65	1.73	1.73

The ATI-5C aerosol distribution listed above is characteristic of the operating conditions and settings present at the time of testing. Particle size distributions generated during field usage will change depending upon ambient temperature, humidity and equipment settings in use.

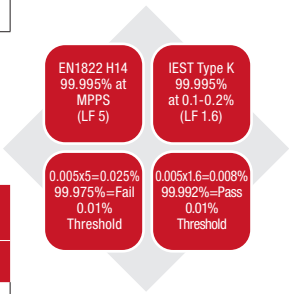
Operating at standard set up parameters of 408ºC (765ºF) with 50 psig inert gas supply.

Type 111-Laskin Nozzle at 23 psi using PAO-4 (Cold)



	Particle Size			
	Number	Surface	Mass	Volume
Median (nm)	215	392	513	513
Mean (nm)	252	434	536	536
Geo. Mean (nm)	218	383	487	487
Mode (nm)	209	414	615	615
Geo. Std. Dev.	1.72	1.67	1.59	1.59

**Important to note that particle size distribution will vary in the field and is very much dependent on ambient temperature, humidity and equipment settings while in use.*



Impact of the factory leak scan Leakage Factor (LF) on penetration

Filter ‘Bleedthru’

The term bleedthru is a phrase coined by industry professionals when multiple filters (normally installed in a Grade A space) are exposed to a thermal (‘hot smoke’) challenge aerosol and an excessive media penetration phenomena manifests, hence the term ‘bleedthru’.

A lot has been written about mitigating this topic from "use thicker media" to ‘replace with ULPA filters’, but the issue and ‘fix’ can be summerized below.

The three main factors to be aware of are:

1. Higher than expected or design velocity. (We should look at effective filter area not the nominal frame size.)
2. Challenge aerosol type. (‘Hot’ smoke mean particle size can be close to the MPPS, particularly at low output/system flow rates.)
3. 'Hot' (Thermal) aerosol generators used for smaller systems will produce smaller particles. Aerosol size changes with output concentrations and can approach MPPS.

How to solve the problem:

1. Understand the actual media face velocity when selecting/specifying filters. A nominal ‘2x4’ or 600x1200mm filter can be as high as 20% smaller when installed in a given housing or ceiling grid, therefore increasing the actual face velocity which can contribute to higher penetration values. Most filter manufacturers test filters at 120 fpm or 0.6 m/s to minimize risk. Some older facilities due to the specific site design have higher than recommended filter face velocities. Filters can be designed and manufactured to perform at elevated velocities if known ahead of time. The only negative of course is the penalty paid in a higher energy cost due to the increased pressure drop. (MEGAcel media can reduce pressure drop substantially in these applications)
2. Understand where possible how your filters are being tested. A ‘hot smoke’ (thermal) aerosol can have a higher penetration than ‘cold smoke’ (Laskin Nozzle) in the field as stated above.
3. Increase concentration output of thermal generator and/or use a hose adaptor kit (from generator manufacturer) to grow the aerosol size.
4. Specify filters with an efficiency of H14 (99.995%) at MPPS in accordance with EN-1822 or Type K (99.995%) in accordance with IEST CC001. The leakage factor for the H14 filter should be 1.6 (Type K) instead of 5, therefore giving a maximum penetration of 0.008% assuming a standard velocity of 120 fpm or 0.6 m/s.

It’s important all parties involved from the end user, specifier, certifier and filter vendor understand the site specific variables. Again, filter efficiency specified, actual on site HEPA media velocity, and the equipment and specification of how filters are tested both in the factory and field are key parameters.

Challenge Aerosol Types

	Aerosol Type	Name	Aerosol Generation Method	Industry Type	Plus/Minus
Challenge Aerosol	**PAO**	Liquid	Poly Alpha Olefin	Laskin Nozzle/ Thermal	Life Science	Long established synthetic hydrocarbon test aerosol, easy to understand and measure. The leak threshold limit is 0.01% of the upstream concentration allowable downstream. Can be used with aerosol photometer or optical particle counter.
	DEHS	Liquid	Di-ethyl-hexyl-sebacate	Laskin Nozzle/ Thermal	Life Science	Proven test aerosol for factory and field testing. It is a non soluble colorless and odorless liquid which is suitable for producing a consistent aerosol. Can be used with aerosol photometer or optical particle counter.
	PSL	Solid	Polystyrene Latex Spheres	Ultrasonic	Microelectronics	Size traceable, monodispersed, aerosol utilized by filter manufacturers. No 'oil' contamination and suited well for particle counters. Available in discreet sizes 0.12-3.0 micron. Can be costly where large concentrations of aerosols are required in semiconductor, microelectronic, and aerospace applications.
	Silica	Solid	$Si0_2$	Gravity Feed-Compressed Air	Microelectronics	Not commonly used Non toxic, has a size distribution of 0.08-0.15 micron. Has a tendancy to 'float' and can leave coatings on surfaces.
	DOP*	Liquid	Dioctyl Phthalate	Laskin Nozzle/ Thermal	Life Science	Original industry test reagent. Rarely used today (Nuclear applications can still apply) due to possible carcinogenic health risks.

ATI's 2i Photometer Detects Leaks in HEPA Filters

ATI's iProbe, Paired with a Photometer, Scans HEPA Filters to Detect Leaks

Filling a Laskin Nozzle Generator with an Oil Reagent to Create a Challenge Aerosol

ATI's 4B Laskin Nozzle Aerosol Generator

ATI's 5D Thermal Aerosol Generator

Efficiency:
Measure of the filter's overall (global) value as a % of 100.

EN-1822-5

ISO-29463-5

IEST-RP-CC001

IEST-RP-CC007

Integrity:
Measure of the filters local leakage threshold within specified limits. (Penetration through the filter that falls under sample probe) Factory Integrity testing can be either at/near MPPS (i.e. autosan using same aerosol as efficiency test) to mitigate defects such as pin hole leaks as well as variation within the media or simply simulate Field Integrity testing using a Laskin Nozzle aerosol.

EN-1822-4 (Factory)

IISO-26493-4 (Factory)

ISO-14644-3 (Field)

IEST-RP-CC034 (Factory and Field)

How big is a leak?

Probe area = 0.011ft^2

0.01% of 0.011ft^2 = 1.1E-6 ft^2 or 102,000µm^2

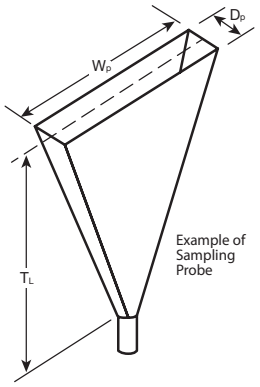
This equates to a round leak (i.e. hole) with a diameter of 360µm! That's HUGE when compared to the test aerosol size. It does not matter if you look at 0.1µm,0.3µm or 0.5µm particles, they will pass freely through the defect.

Summary

Leak % or standard local penetration basics apply to photometers and particles counters.

A 0.01% leak is LARGE compared to the particles being used to size the leak.

Scanning is used for leak detection and not to size leaks.



Probe Design and Isokinetic Sampling

$$W_p D_p V_{filter} = F_a$$

W_P = *probe dimension perpendicular to the scan direction in cm (or in.)*

D_P = *probe dimension parallel to the scan direction in cm (or in.)*

V_{filter} = *average exit airflow velocity of the filter*

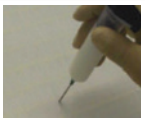
F_a = *flow rate of the instrument*

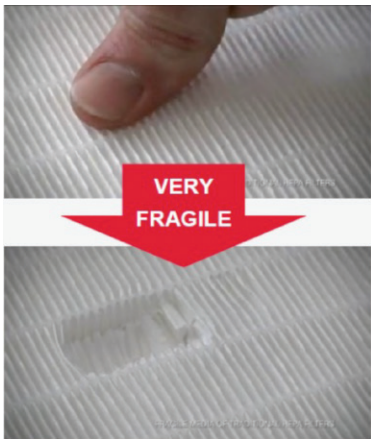
Source: DMA

Where and How is the Test Aerosol Generated?

Aerosol Generator Location	How Aerosol is Typically Generated	Positive	Negative
Supply Air AHU	Thermal	Good aerosol distribution, dispersed over multiple filters simultaneously which saves time	Potential excessive aerosol exposure; potential risk of 'bleedthru'
Supply Duct Work in the Plenum	Laskin Nozzle	Good aerosol distribution, dispersed over multiple filters simultaneously which saves time	Access to the plenum-ability to measure upstream concentrations
Locally through Aerosol Dispersion Ring in the Housing	Laskin Nozzle	Minimizes aerosol exposure to discrete filter of interest, avoiding potential aerosol infiltration from surrounding area. Concentration can be calculated if an upstream measurement isn't possib	Aerosol distribution needs to be validated to ensure adequate upstream challenge
Low Wall Return Air Ductwork	Thermal	Good aerosol distribution, dispersed over multiple filters simultaneously which saves time	Potential excessive aerosol exposure; potential risk of 'bleedthru'

Guidelines for Factory and Field Repairs

Location	Repair Limits	Guideline	Repair Equipment
Factory	Up to 13 cm^2 (2sq in) in any one patch or a total of 1% on the area of the face being patched	IEST-RP-CC001.6	EFD Dispense Gun 
Factory	Up to 0.5% of the face area. No single repair larger than 1.2" (30mm) in any dimension	EN-1822-4	EFD Dispense Gun 
Field	Up to an additional 3% of the face area. No single repair larger than 1.5" (38mm) in any dimension	IEST-RP-CC034.5	RTV 162 or 108 or Dow 732 is a suitable repair material
Field	No repairs allowed in a Grade A Space. Some will specify no factory repairs for which there is typically a premium from the manufacturer. 95% of end users follow industry norms/repair levels.	End Users	Repairs should be recorded on the scan test reports for a given filter. Filters should always be re-scanned after repair in the factory and re-tested in the field.
Field	Less is more 	Experience 	Covering filters with more silicone does not mean you will 'seal the leak'. Leaks 'travel' and you will end up chasing leaks. Leave repairs to professionals.



Wet laid glass fiber HEPA media by nature is very fragile and will fail from a pinhole leak due to mishandling of the filter.

MEGAcel membrane technology utilizing Daikin's unique recipe and manufactured by AAF is the filter of choice if your facility is concerned or has a history of HEPA filter "failures".

High Temperature Filter Applications

The destruction process of microorganisms is a function of time and temperature. The rate of destruction is linear, meaning in a given time interval and at a given temperature, the same percentage of the bacterial population will be destroyed.

The Forced Conventional Dry Heat Sterilizer consist of

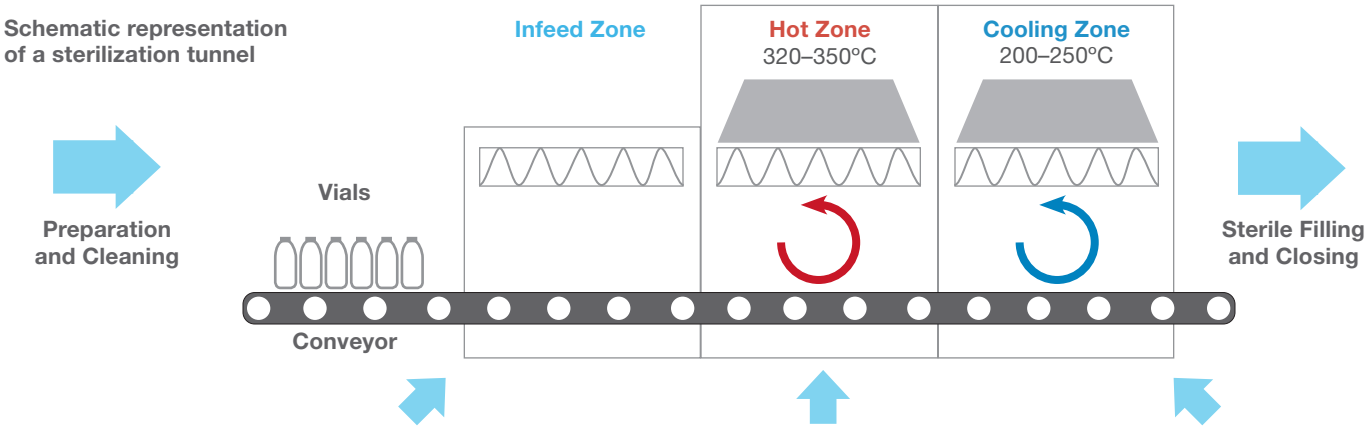
- **Drying/Pre-Heat Zone** **Typical filters: F7 & H13 HEPA filters**
- **Sterilization Zone** **Typical filters: H13 HEPA filters**
- **Cooling/Stabilization Zone** **Typical filters: F7 & H13 HEPA filters**

Dry heat sterilization is considered one of the most critical process steps in the Life Science industry. The process is either in an oven or a tunnel. HEPA filters play a crucial role in protecting the equipment such as vials or prefilled syringes from contamination which could result in product failure or even worse a health risk to patients if compromised. These filters can be exposed to extreme variability in frequent temperature fluctuations between ambient and as high as 350°C.

Understanding what these variables are, how often they occur as well as addressing some industry FAQ's will help the user understand the application and product availability from AAF.

Total Life Science Solution

AAF Filtration System for Dry Heat Sterilization and Depyrogenation Tunnels



VariCel® II HT

- M6, F8 to EN779:2012
- 350°C continuous (480°C Peak)
- Max. 1340 m³/h (790 CFM) for 610 x 610 x 84mm

Nippon Muki ATMCU

- ≥ 99.97% at ≥ 0.3µm
- 350°C continuous (400°C Peak)
- Max. 2100 m³/h (1236 CFM) for 610 x 610 x 290mm

Nippon Muki HEATMOS

- ≥ 99.995% at MPPS (H14 per EN1822-1)
- 350°C continuous (400°C Peak)
- Max. 2100 m³/h (1236 CFM) for 610 x 610 x 292mm

AstroCel® I HT-500

- ≥ 99.995% at MPPS
- 260°C continuous (260°C Peak)
- Max. 1700 m³/h (1000 CFM) for 610 x 610 x 292mm

High Temperature Filter Applications

AAF Standard Range of HT HEPA Filters

	Nippon Muki HEATMOS	Nippon Muki ATMCU	AstroCel® I HT-500	AstroCel® I HT-750
Airflow (24" x 24")	847 CFM/1236 CFM	847 CFM/1236 CFM	500 CFM/1000 CFM	1000 CFM
Efficiency at Nominal Airflow	99.995% on MPPS (H14)	99.99% @ 0.3 um	99.99% @ 0.3 um	99.97% @ 0.3 um
Pressure Drop at Nominal Airflow	1.1 in w.g.	1.0 in w.g.	1.0 in w.g.	1.0 in w.g.
Standard Frame Material	430 SS	430 SS	304 SS	304 SS
Alternate Frame Materials	304 SS	304 SS	316 SS	316 SS
Frame Depth	5.875"/11.5"	5.875"/11.5"	5.875"/11.5"	11.5"
Standard Gasket	glass	glass	red silicone	ceramic fiber
Sealant	glass fiber + ceramic	glass packing	silicone	refractory cement
Standard Separator	SS	SS	aluminum	aluminum
Standard Face Screen	none	none	none	none
Media Type	glass	glass	glass	glass
Standard Size Availability	many	many	many	24 x 24, 24 x 30
Max. Overall Penetration	0.005% on MPPS	0.01%	0.01%	0.03%
Leak Test Conditions	ambient	ambient	ambient	ambient
Max. Operation Temperature	350°C continuous/ 400°C for 1 hour	350°C continuous/ 400°C for 1 hour	500°F (260°C)	750°F (399°C)
Packaging	fiberboard carton	fiberboard carton	fiberboard carton	fiberboard carton

Product

FAQ HT HEPAs

1. What guideline exists for testing HT HEPA filters in tunnels or ovens?

This is one of the few variables in the Life Science industry and is often down to interpretation of a guideline or historical practice of the need to test HEPA filters in all applications to a 0.01% threshold of the upstream concentration. The FDA does state that alternate methods can be used to test HEPA filters in the hot zones of tunnels and ovens.

2. Do I test the filter before or after burn in, or both?

You can only leak test HEPA filters at normal temperatures and this should be done first when the filter is installed before burn in. You can test after burn in but the chances of the filter passing a 0.01% penetration are slim due to the tremendous stress and strain or expansion and contraction of the filter when it is exposed to these elevated temperatures and cycles.

The most important test is the cleanliness classification test. This is a particle count test at multiple locations and it should meet ISO 5 conditions in operation in accordance with ISO 14644-1. This test can only be carried out in the hot zone. The critical point is the transient condition when particles are shed.

High temperature air sampling requires cooling of the sample. An air or water cooled probe can be used. (Ensure you apply the ideal gas equation to determine the count per cubic meter)

Particle losses in a long cooled probe may make evaluation of >= 5 micron particles for compliance a challenge due to settlement of particles in the sampling tube so the shorter the better but ensure adequate cooling.

3. Where do I take the samples?

Sampling at high temperature in a tunnel is relatively straight forward as there is normally adequate access at the front of the tunnel. Batch ovens normally need a sample probe through the oven wall with a multi-probe device.

4. Are the fumes from the filters toxic during burn in?

The smoke generated is from the acrylic binder and is not considered toxic. That said, we would always recommend precautions and the room is well ventilated during the burn in process. There have been specific studies on the gases generated from the binder and are available upon request.

Note:
LOI (Loss of Ignition) testing shows burning off of organic material including PAO so no issue with burn in procedure. Be sure to avoid igniting the oil residue (PAO) in the filter by holding the temperature below the flash point for a few hours before increasing the ramp rate.

5. Is there any data on shedding of particulate from these filters?

There are multiple filter construction types available in the market. The gasket (ceramic, PTFE, silicone) the media (glass fiber, some dual layer medias are used). The separators (aluminum, stainless steel, glass fiber) have been used depending on the temperature rating and application. There are some studies which show the effect of shedding as the temperature increases and decreases. Modern demands on the sterilization process also are set down by the US FDA & EU requiring temperature programs which demonstrate for example, 'that the endotoxin in substance has be inactivated to not more than 1/1000 of the original amount'.

6. What causes filters to 'fail' so often in this application?

Let's define what an acceptable test is first, when and how the filters are tested?

If we test cold, ramp up and leak test again the chances are the filters will 'fail'. This is not the filter, it's the SOP. It is common to leak test when cold to ensure a 'tight' installation (some equipment manufacturers create a negative pressure at the sealing surface to minimize leaks) and then carry out the particle cleanliness test as described earlier after burn in.

Vibration of the tunnel or oven can cause a filter to fail over time considering all the binder and seals are essentially burned off and the media in particular is extremely fragile.

7. What is the recommended burn in cycle time?

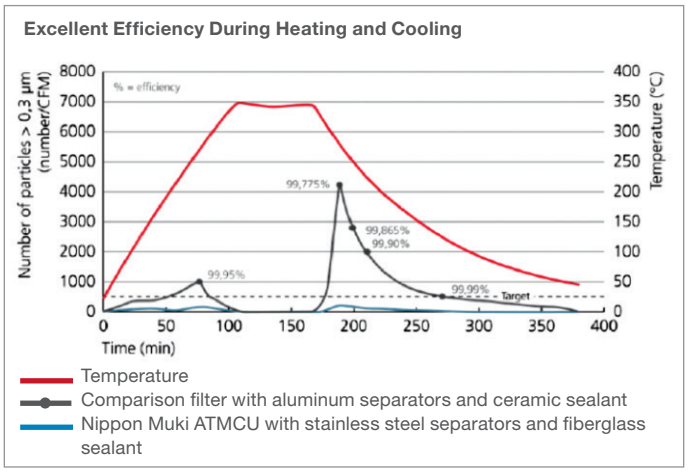
Different filters and tunnels have preferred or recommended burn in times varying from 1.5°C per minute to 10°C per minute. The best advice is to follow the O&M manuals provided by the equipment providers. They have often validated different filters beyond the manufacturer's recommended limits who are conservative by nature especially for this type application.

8. How important is filter efficiency for these applications?

Historically 99.99% at 0.3 micron or H13 grade which is 99.95% at MPPS is acceptable. Building filters with higher efficiency when the main criteria is to achieve an ISO 5 condition has little impact on the cleanliness level downstream of the filter due to the air delivery system. What is most important is meeting the cleanliness classification test.

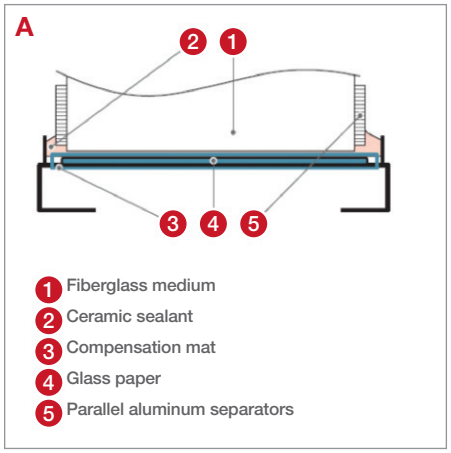
Improved Process Performance

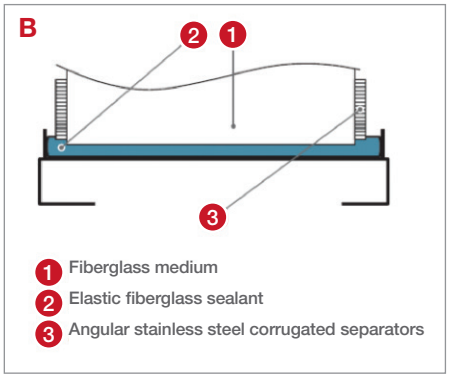
Limited risk of particle shedding during elevated temperatures

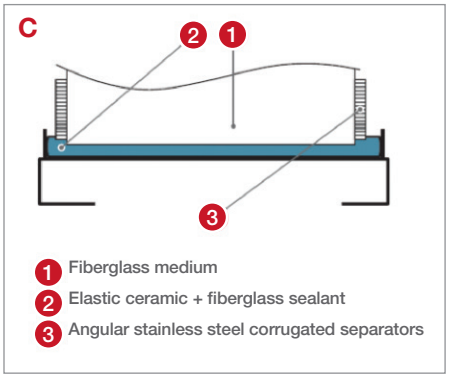


Superior Performance of Nippon Muki ATMCU

- Significant difference in particle shedding properties and potential process contamination.
- Meeting ≥ 99.99% at 0.3 um ≥ 99.95% at MPPS during efficiency test.







Filter A is a typical competitive filter.
Filter B is the Nippon Muki ATMCU, which provides superior performance.
Filter C is the Nippon Muki HEATMOS, which offers true H14 performance.

High Temperature Filter Applications

Test results showing cleanliness level downstream of a HEPA filter in a tunnel (Nippon Muki ATMCU).

Challanged with 17 Million PAO Particles/ft³

			Measured Particle Concentration (particles/cf of air)			
			0.3 µm	0.5 µm	1.0 µm	5.0 µm
Location	Hot Zone	A-1	34	4	1	
	Hot Zone	A-2	61	8	1	
	Hot Zone	A-3	137	29	2	
	Hot Zone	B-1	73	14	2	
	Hot Zone	B-2	58	7	2	
	Hot Zone	B-3	135	35	5	
	Hot Zone	C-1	30	6		
	Hot Zone	C-2	36	7		
	Hot Zone	C-3	80	20	4	
			Particle Limits According to ISO 14644-1:1999			
	ISO Class 5 Limit		289	100	24	≤1

Sample Location in the Hot Zone of the Sterilization Tunnel.

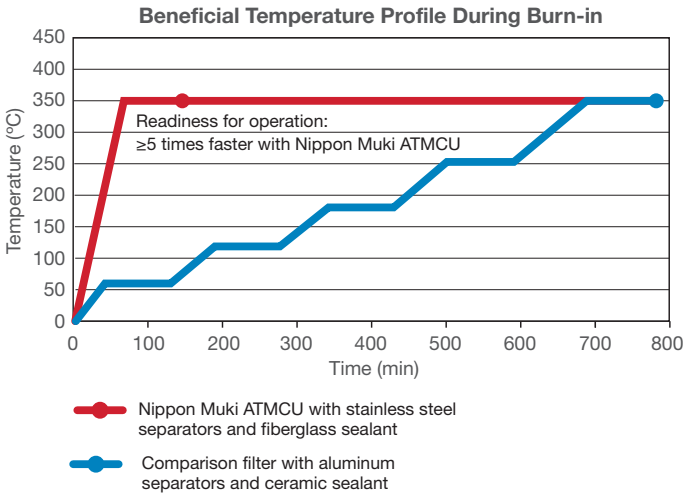
Conveyor Direction			
↓	A-1	B-1	C-1
↓	A-2	B-2	C-2
↓	A-3	B-3	C-3

Superior Performance of Nippon Muki ATMCU

- High airflow rate of 1236 CFM-2100 m³/h for 610 x 610 x 292 mm, 850 CFM-1440 m³/h for 610 x 610 x 150 mm, 514-CFM 870 m³/h for 610 x 610 x 84 mm.
- Possibility for heating up to 350ºC with 10ºC/min versus 1.5ºC/min.
- Note: actual burn-in procedure is subject to instructions of the equipment manufacturer.

Beneficial TCO

Speedy Temperature Control for Improved Operational Readiness



HEATMOS vs. ATMCU: Filters for Extreme Requirements

Item	Nippon Muki	
Model	**ATMCU** (ATMCU - * - * - FS4HR)	**HEATMOS** (H14CU - * - * - FS4CS)
Remarks	Current	Current
Size for this Comparison (mm)	610 x 610 x 290	610 x 610 x 292
Alternative Depths (mm)	84, 150, 290	150, 292
Frame	stainless steel (430), 2 support bars	
Design Filter Media Pack	deep pleats w/ separators	
Media	glass paper	
Separator	stainless steel	
Sealant Media Pack/Frame	fiberglass	glass fiber cotton + ceramic
Gasket Frame/Tunnel	laminated glass fiber, needs to be attached by customer	
Faceguard	-	
Temperature (°C)	350	
Max. Temperature (1h/°C)	400	
Heating Max. (°C/min)	10	5
Tempering Media After Installation Necessary	NEED	
Rated Air Volume (CMH/CMM)	2,100/35	
Pressure Drop (initial/final, Pa)	250/500	≤ 270/500
Average Efficiency	99.99% @ 0.3µm	≥99.995% @ MPPS
Local Penetration Resp. Leaks	Yes	No
Scan Test	Failed	Passed
Efficiency Rating by EN1822	like H13	Real H14

Cycle time or ramp speed is an important consideration in sterilization and depryogenation applications. Faster ramp speeds lead to quicker time to reach the required temperature for tunnels and faster throughput for batch-style ovens. In conventional high-temperature HEPA filters, higher ramp speeds can result in higher particulate levels due to thermal expansion and contraction of filter materials. The ATMCU HEPA filters minimizes cycle time, which is important for batch operations.

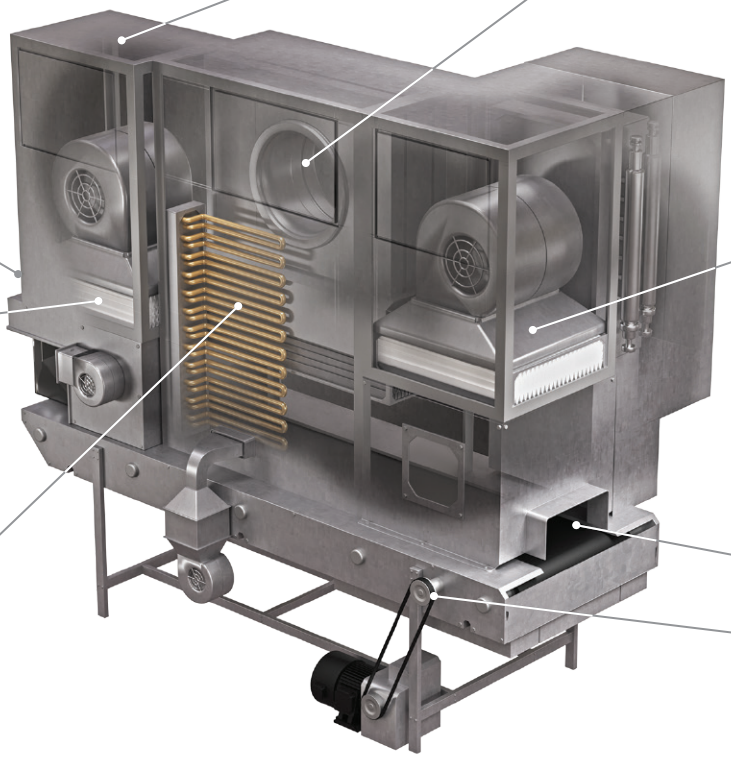
Max. Ramp Rate (°C/min)		
Conventional HT HEPA	**ATMCU**	**HEATMOS**
1.5	10	5

Highest Air Purity

High air quality is required in the oven Hot Zone. The HEATMOS HEPA is a good combination of fast ramp speed and high filter efficiency for tunnel applications. The HEATMOS gives true H14 performance (≥99.995% with ≤ 0.025% scan) for the best air quality.

Depyrogenation Tunnel

Tunnel sterilization chamber is typically 350°C with non-silicone sealant HEPA filter, such as ATMCU or HEATMOS from Nippon Muki



Depyrogenation Batch Oven

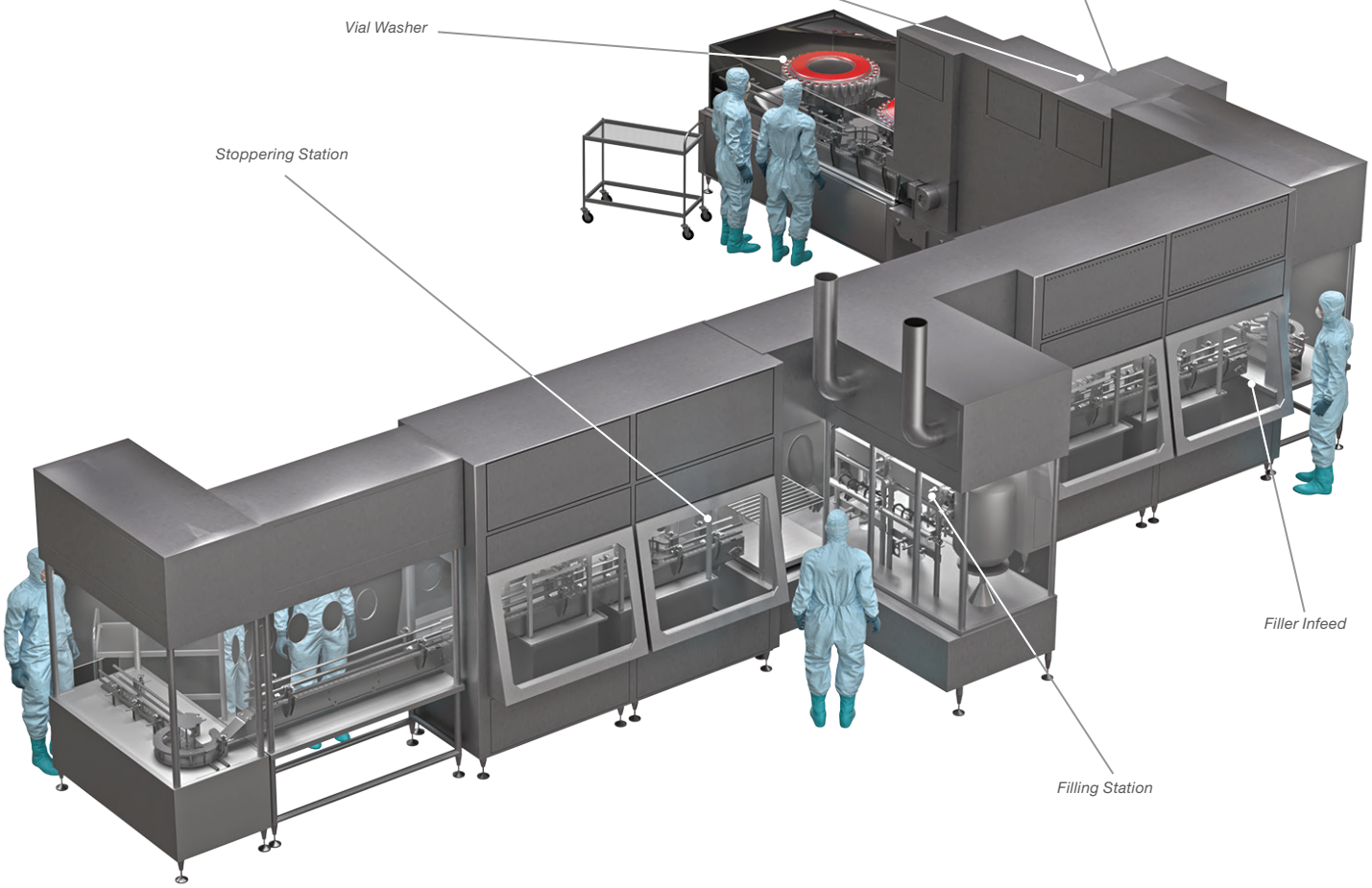
350°C Hot Zone HEATMOS or ATMCU from Nippon Muki

Complete elimination of micro-organisms
The Depyrogenation oven for dry heat sterilization provides complete destruction of micro-organisms and endotoxins by means of a controlled temperature for a controlled period of time.

Heat is applied by baking in a dry heat oven that is designed specifically for the depyrogenation process. Although endotoxins are relatively thermally stable, sufficient heating (250°C for 30 min.) results in a 3-log reduction of endotoxin levels.

Isolator Technology Overview

- Drying/Pre-Heat Zone-
  F7 and H13 HEPA Filters
- Sterilization Zone-
  H13 HEPA Filters
- Cooling/Stabilization Zone-
  F7 & H13 HEPA Filters



Internally the isolator must assure a Grade A environment. The leak tight structure allows the surrounding production area to be classified as Grade C.

Understanding Fire Safety Classifications for HEPA Filtration

There are three primary agencies that affect the Air Filtration Industry as it applies to fire events in the US and often applied around the world; United Laboratories (UL), the National Fire Protection Association (NFPA), and Factory Mutual (FM). Each agency provides guidance and states requirements for Air Filtration in the interest of public safety. UL specifies the requirements and provides testing and listing services of discrete commercial products - air filters as it relates to this document. NFPA specifies the requirements regarding fire prevention and retardation for air moving systems of commercial and residential building construction. FM, as an insurance underwriter, specifies and performs testing to meet their underwriting requirements.

Underwriters Laboratories (UL):

Underwriters Laboratories (UL) is the world's largest product safety testing and certification organization. Founded in 1894 in the United States, it permits the use of its listing mark (the UL mark) as its stamp of approval on goods and materials after standardized and stringent testing. Thereafter its inspectors regularly visit the producer to audit compliance with its certification requirements. UL has some 46 laboratories and 200 inspection centers in over 70 countries and applies its 750 standards to more than 18 thousand types of products manufactured by about 60 thousand firms. The UL mark, however, guarantees only the safety of the item in use, not its performance or quality.

UL 900 - Standard for Safety for Air Filters

In the United States filter industry, UL 900 is generally accepted as a fundamental requirement as it relates to air filters. The UL 900 classification assures design and construction engineers as well as end users these air filters will meet local requirements for most applications.

UL 900 specifies the allowable combustibility and smoke generated for air filters, both washable and throwaway, used for removal of dust and other airborne particulates from mechanically circulated air. This is in accordance with National Fire Protection Association, NFPA 90A - Installation of Air Conditioning and Ventilating Systems, of Other Than Residence Type, and NFPA 90B, Installation of Residence Type Warm Air Heating and Air Conditioning Systems.

The requirements of UL 900 apply only to air filters in a clean, like-new condition. It is important to note, once fielded and after a period of service, the combustibility and quantity of smoke generated will depend upon the nature and quantity of the material collected by the filter. When filters are susceptible to the accumulation of combustible deposits, maintenance and inspection practices should be followed as proposed in Appendix B of NFPA 90A.

A UL 900 Classified Filter is an air filter which, when clean, will burn moderately when attacked by flame, or emit moderate amounts of smoke, or both. The air filter unit shall not produce flame or extensive sparks, which are sustained beyond the discharge end of the test duct when subjected to the flame-exposure test and shall not cause the development of an area of more than 9 square inches (58 cm^2) as measured below the smoke-density time curve, all of which is specified within the standard. It is important to note, UL 900 does not provide requirements or guidance with respect to the toxicity of materials as a result of combustion.

Additionally, any adhesive material used for coating the filtering medium or other part of an air filter unit shall have a flash point of not less than 325°F (163°C) as determined by ASTM D92, Standard Test Method for Flash and Fire Points by Cleveland Open Cup.

UL 900 provides a uniform test protocol as well as a follow-up auditing program to ensure air filter units meet a specific level of quality as it relates to fire safety. Upon submission of a product for evaluation by UL, a unique product file number is given to which the technical aspects of the product are documented. The product is tested in accordance with UL 900 and must meet the stated requirements:

- No flame beyond the end of the test duct.
- Less than 25 sparks sustained beyond the end of the test duct.
- Less than 9 square inches of smoke measured below the smoke density time curve.

Once a product is listed, to be UL Marked, it must be incorporated into the Follow-Up Service (FUS) auditing program for routine inspections at each manufacturing location. Inspections compare current product production with the UL file, identifying variations in either construction process or materials of construction. Material designation, material vendor, and the amount of material utilized must match with the UL file. Material measurement instrumentation calibration certifications can also be inspected.

The UL 900 standard has seen numerous changes since inception. It is now in its eighth revision. The most notable change was the removal of references to Class 1 and Class 2 in 2010, dictating that all air filter units adhere to the Class 2 requirements by May 2012.

UL 586- Standard for Safety – High-Efficiency Particulate Air Filter Units

While technically not a fire rating, UL 586, Standard for Safety – High-Efficiency Particulate Air Filter Units, is an Underwriters' Laboratories standard that applies to HEPA filter construction and filtration performance, most notably when subjected to various environmental extremes.

The construction of the frame shall be made of metal or other inorganic material, or of wood treated to reduce combustibility by pressure impregnation or the equivalent. The filter medium shall be glass fiber or other equivalent inorganic material and may include an organic binder material; it shall not contain un-bonded asbestos fiber materials. The gasket, when provided, shall be securely attached to the frame and shall provide a continuous seal about the face.

Aerosol Penetration tests are performed after the filter unit is subjected each of a Heated Air Test, Moist Air Test, and Low Temperature Test. Additionally, a Spot Flame Test is performed to ensure the filter will self-extinguish.

The Heated Air Test subjects the HEPA filter unit to heated air at 700°F (371°C) for 5 minutes at a test flow rate no less than 40% of rated flow. The Moist Air Test subjects the HEPA filter unit to static atmosphere at a relative humidity of 90 +/- 5% at 77°F (25°C) for 24 hours. The Low Temperature Test subjects the HEPA filter unit first to a static atmosphere at a relative humidity of 50 +/- 5% at 77°F (25°C) for 24 hours, then transferred to a static atmosphere of 27 +/-4°F (minus 3 +/- 2°C) for an additional 24 hours, then the sample is allowed to warm up to room temperature 77°F (25°C) prior to aerosol penetration testing.

The Spot Flame Test utilizes a Bunsen burner applied to the corner of the filter, where the media and adhesive meet, and, once removed, the filter is required to self-extinguish within two seconds.

The U.S. Department of Defense and U.S. Department of Energy have adopted UL 586 as a requirement for ASME AG-1, Code on Nuclear Gas and Air Treatment, qualified HEPA filters.

Glass fiber is the traditional media of choice for these type applications. HEPA membrane media will adhere to all but the 700°F Heated Air Requirement of UL 586. Applications such as Biological, Radiological, and Nuclear Containment may specify UL 586; however, the features and benefits of membrane technology vs. traditional glass filter media products should be considered where appropriate.

A listing of product Certifications, for all manufacturers is available on the UL website at http://www.ul.com.

National Fire Protection Association (NFPA):

NFPA is a United States trade association, with some international membership, that creates and maintains private, copyrighted standards and codes for usage and adoption by local governments. The NFPA 90A standard dates from 1899, when committee attention was first given to blower and exhaust systems. Since 1955, the two parts of NFPA 90 have been published separately as NFPA 90A, Standard for the Installation of Air-Conditioning and Ventilating Systems, and NFPA 90B, Standard for the Installation of Warm Air Heating and Air Conditioning Systems. The former of which is addressed in this document.

NFPA 90A specifically addresses HVAC Systems, how these systems are integrated with Building Construction, the Controls associated with these systems, and the Acceptance Testing necessary to adhere to this standard. Filters are considered an HVAC system component and are defined as ”A device used to reduce or remove airborne solids from heating, ventilating, and air-conditioning systems”. With respect to Air Filters, whether pleated, box, terminal, or any other classification, NFPA 90A Section 4.2.2.2 states they shall comply with UL 900, Standard for Safety Air Filter Units.

NFPA 90A also offers general Air Filter Maintenance guidance. Annex B specifies air filters should be kept free of excess dust and combustible material, unit filters should be renewed or cleaned when the resistance to airflow has increased to two times the original resistance or when the resistance has reached a value of recommended replacement by the manufacturer, and that a suitable gauge should be provided for that purpose. Furthermore, when filters are replaced, care should be taken to use the proper type and size and to avoid gaps between filter sections, mounting frames, or hardware. And that damaged filter sections or media should not be used and throw away filters should never be cleaned and reused.

In the United States, all AAF HEPA Membrane Media and Glass HEPA/ULPA air filtration products are UL 900 classified. UL 900 is necessary to comply with National Fire Prevention Association (NFPA) standard 90A and 90B, both of which specify UL 900 with respect to air filters. NFPA 90 is the basis for nearly all building fire codes in the USA.

In summary, when asked whether an air filter is NFPA 90 compliant, you can rest assured in knowing that if the filters utilized are UL 900 compliant they will, by definition, comply with NFPA 90 requirements.

Factory Mutual (FM):

Factory Mutual (FM) Approvals is the independent testing arm of international insurance carrier, FM Global. FM Approvals use scientific research and testing to make sure products conform to the highest standards for safety and property loss prevention. Products that pass the requirements set by FM Approvals can use the “FM APPROVED” mark and are preapproved for FM Global underwriting.

FM Approvals Standard 4920 states the requirements for filter assemblies used in cleanroom facilities; final stage wall and ceiling filters and prefiltration filters. The requirements may include performance and marking, examination of manufacturing facilities, audit of quality assurance procedures, and a follow-up program.

In 2014, FM radically changed FM Approvals Standard 4920. Historically, filters were mounted horizontally in a ceiling grid and a pan containing 90% isopropyl alcohol (IPA) was placed a few feet below the filters and ignited. If the filters or grid were not considered a fuel source, and never were under these conditions, the filter passed and was listed in the FM Approvals Guide.

The 2014 revision states testing of the cleanroom filter assembly shall be in accordance with FM Approvals Clean Room Materials Flammability Test Method for the Parallel Panel Test, Class 4910, FM Approvals, LLC. In this test, two vertical parallel panels (i.e. filter assemblies) are separated by 1ft. (0.31m) and an ignition source consisting of a 2ft. (0.61m) long, 1ft. (0.31m) wide, and 1ft. (0.31m) high 57 BTU/s (60kW) propane sand burner is located at the bottom of and between the filter panels. The ignition source is applied for 12 minutes and the Conditions of Acceptance for this Fire Exposure Test are:

1. The visual flame height shall not exceed 6ft. (1.83m).
2. The heat release rate, measured 2 minutes after the burner is shut off is to be at or below 25% of the maximum heat release rate observed up to 10 seconds before the burner is shut down.
3. The cumulative smoke generation shall be less than or equal to 0.13lb. (60g).
4. The smoke generation rate shall be less than or equal to 0.0005lb/s (0.23g/s).
5. The smoke generation rate at 12 minutes shall be less or equal to 0.0002lb/s (0.07g/s).

It is AAF's position that the FM Standard 4920 test methodology adds little value unless the filters are wall mounted. Since the vast majority of cleanroom applications utilize ceiling mounted HEPA filters, this testing methodology does not adequately represent real world conditions. However, since Factory Mutual is both an insurance underwriter and testing organization, they often require their test specification for any facility they underwrite.

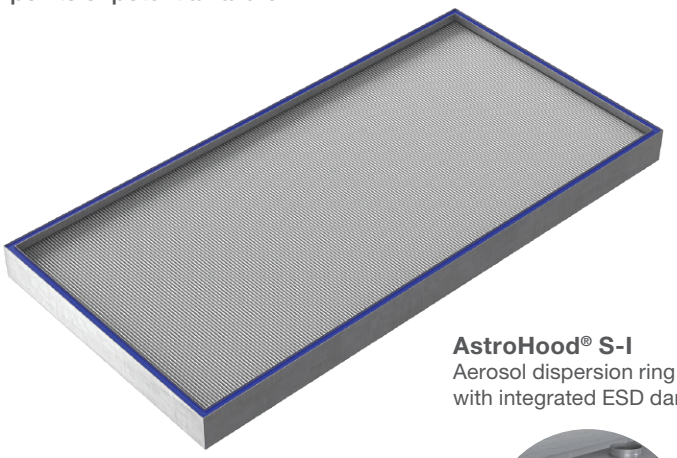
Standard Glass fiber media HEPA filters can pass the FM test. No commercially available membrane filter from ANY manufacturer can meet the current FM Standard 4920 test methodology.

Source, UL, FM, NFPA

Illustration of Equipment and Test Protocol in the Life Science Industry

Control of viable and non-viable particles is crucial in many process applications in the Life Science industry. Protection of people from hazardous or potent compounds is equally important. There is a wide variety of supply, exhaust and recirculated air housings and filter types to address each application. It is important to utilize a manufacturer who can offer a fully integrated solution in order to minimize risk and points of potential failure.

A	MEGApleat®
B	VariCel® VXL/DriPak® NX
C	Test Port
D	AstroSafe® V-BIBO
E	AstroHood® S-I
F	AstroHood® S-II
G	AstroHood® S-III
H	Injection Port
I	Central Test Port
J	AstroHood® E-I
K	AstroHood® Plenum
L1	MEGAcel® I
L2	MEGAcel® II
M	AstroFan®
N	AstroDrive™
O	ESD Damper



MEGAcel® L

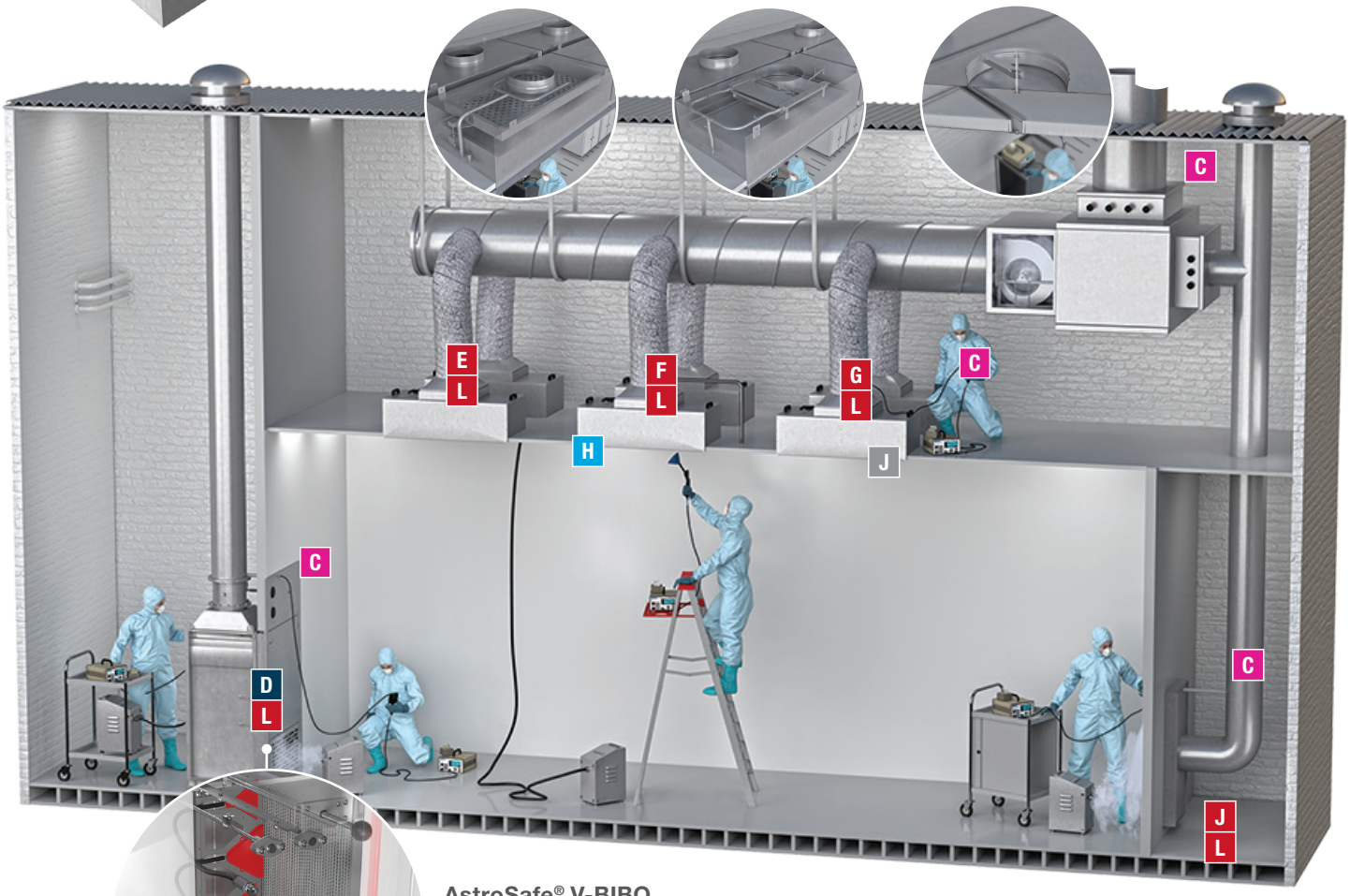
Membrane media exceeds industry requirements from an efficiency and aerosol challenge compatibility standpoint.

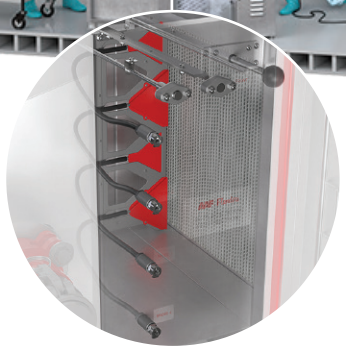
D E F G J M O

AstroHood® S-I
Aerosol dispersion ring with integrated ESD damper

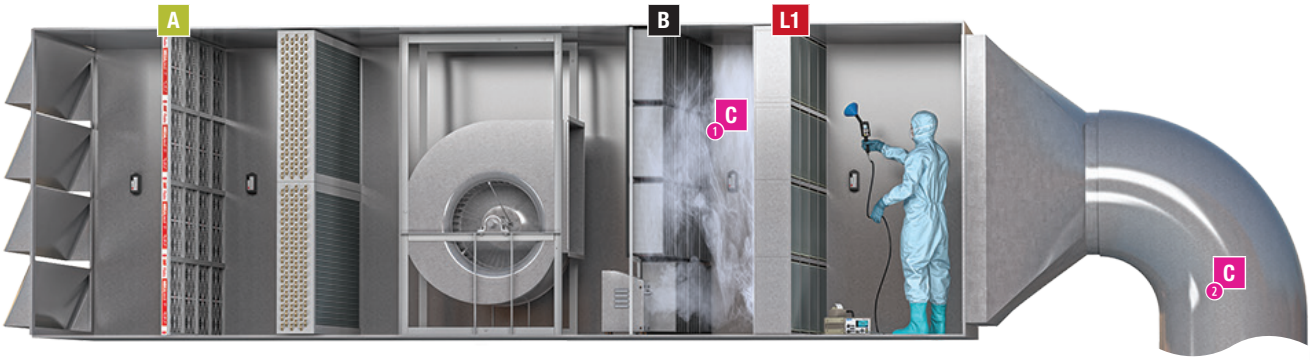
AstroHood® S-II
Guillotine damper and aerosol injection

AstroHood® S-III
Integrated centerboard test port and diffusion disc



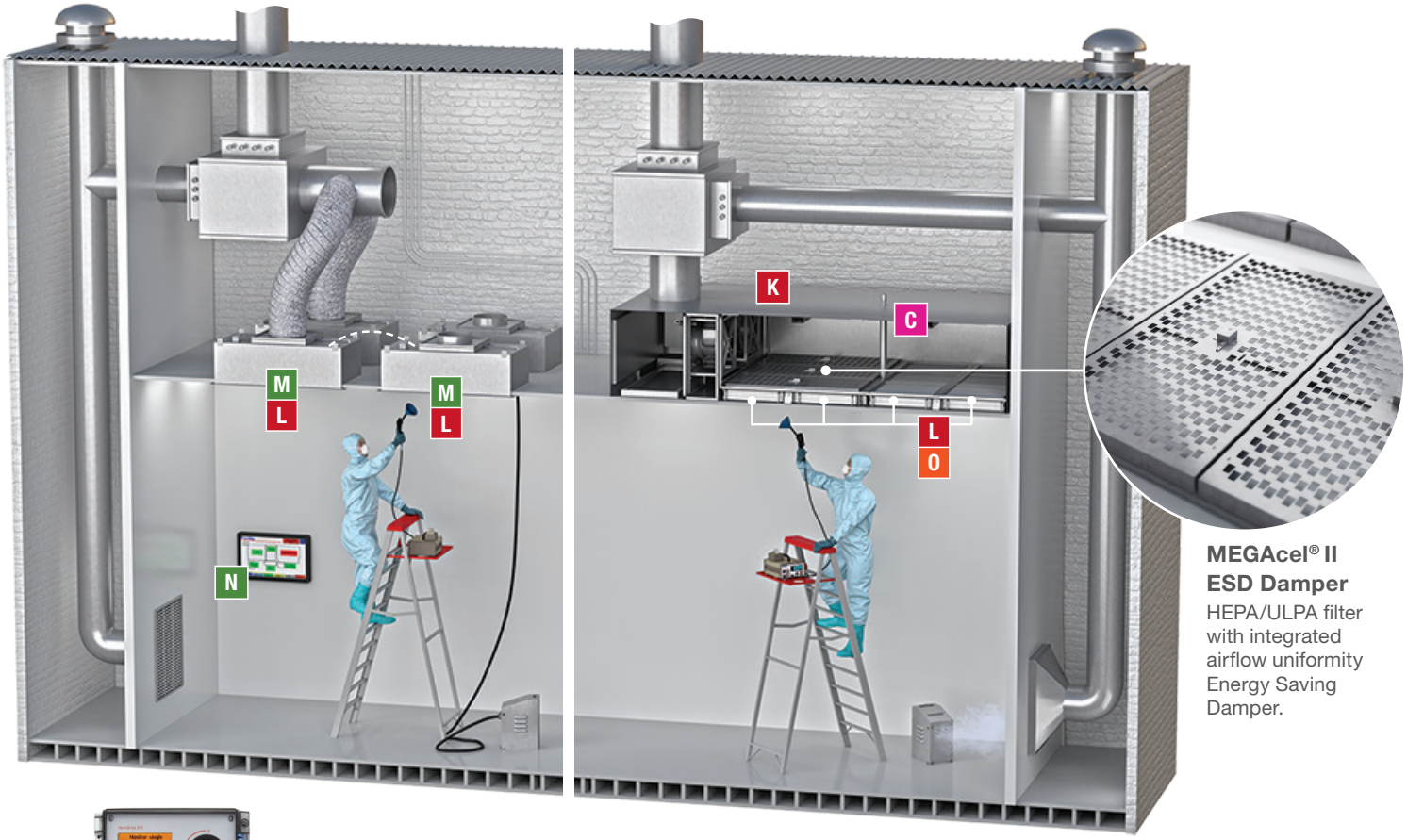


AstroSafe® V-BIBO
The AstroSafe V low-wall containment system is a “safe change” (Bag-In/Bag-Out) housing with an integrated **AstroScan® M** manual scan system. It enables in-situ scanning for potential leaks while fully protecting employees and the environment. The design ensures that potentially hazardous contaminants within the housing remain contained, completely eliminating the risk of exposure.



AHU Filter Testing
In situ integrity testing of HEPA filter banks is accomplished by injecting an aerosol upstream of the filters and manually scanning the downstream side of the filters.

Alternate Overall Leak Test
This can be performed by measuring a single point *upstream* ❶ and *downstream* ❷ of the filter.



MEGAcel® II ESD Damper
HEPA/ULPA filter with integrated airflow uniformity Energy Saving Damper.

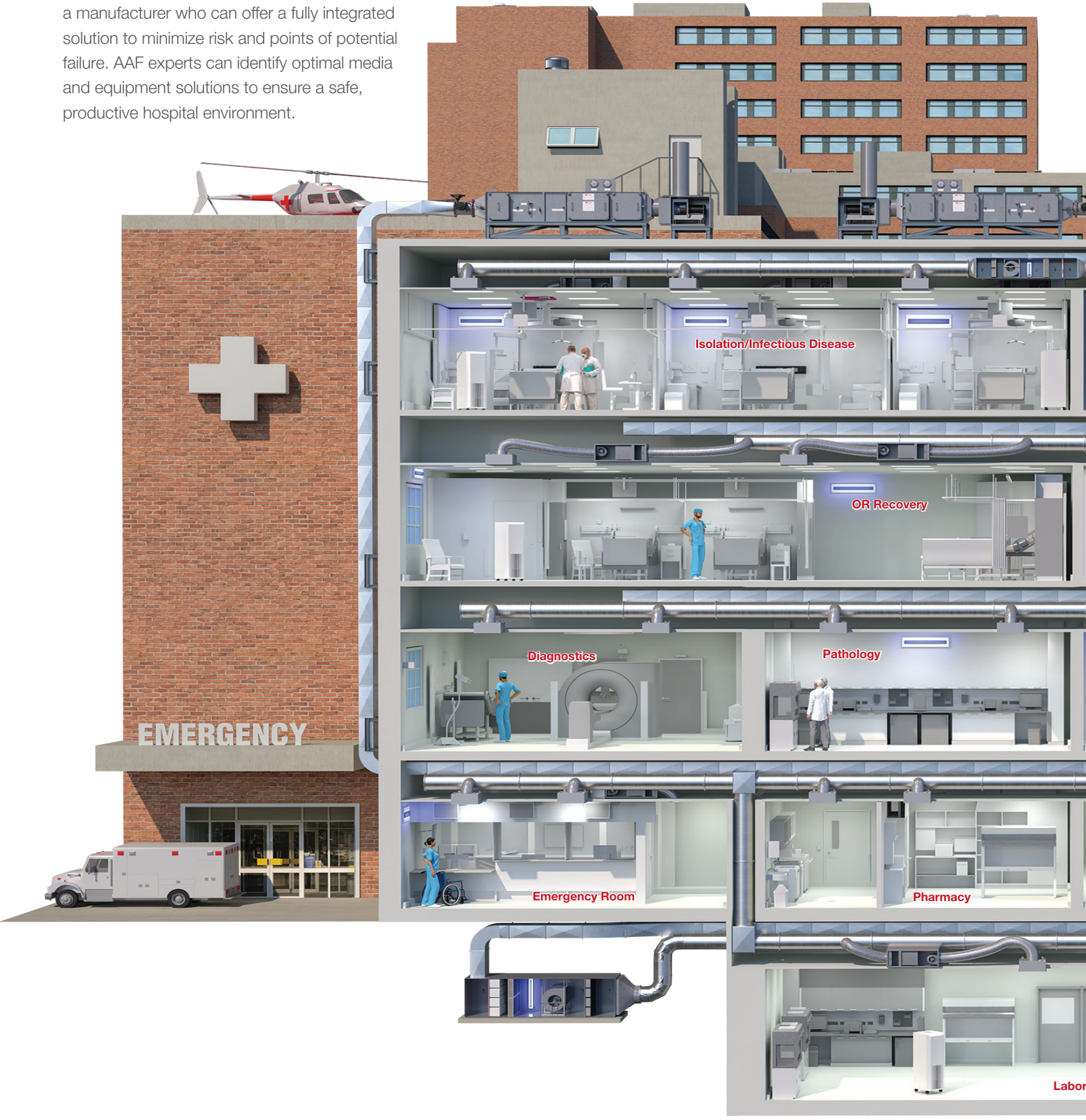
AstroDrive 200 – Wall-Mount Control

AstroDrive 100 – Handheld Control

AstroDrive™ Controls
Intelligent control options for AstroFan™ units gives you continuous motor speed monitoring and modulation, tailoring fan speed to match demand.

Healthcare Integrated Solutions

This comprehensive illustration represents the various levels of air filtration required in a hospital application. There is a wide variety of supply, exhaust, and recirculated air housings and filter types to address each specific area for maintaining effective air quality and controlling contamination. It is essential to utilize a manufacturer who can offer a fully integrated solution to minimize risk and points of potential failure. AAF experts can identify optimal media and equipment solutions to ensure a safe, productive hospital environment.



High Purity Air Filtration

- **MEGAcel® II**
  High Performance HEPA Membrane Media Filter
- **AstroCel®**
  High Efficiency HEPA Microglass Filter
- **VariSorb® XL15 RC**
  Chemical Filter
- **AstroHood®**
  Air Supply Housing
- **AstroFan™ EC**
  Fan Filter Unit
- **AstroPure™**
  Portable Air Purification System
- **UVGI Light**
  Ultraviolet Germicidal Irradiation Disinfectant Device
- **AstroSafe®**
  Containment System

HVAC Air Filtration

- **MEGApleat® M9**
  Pleated Prefilter
- **DriPak® GX**
  Medium Efficiency Bag Filter
- **VariCel® VXLE**
  Medium Efficiency Compact Filter
- **BioCel® VXL RC**
  Bioaerosol Particulate Filter
- **AstroFlow™**
  Displacement Air Diffuser

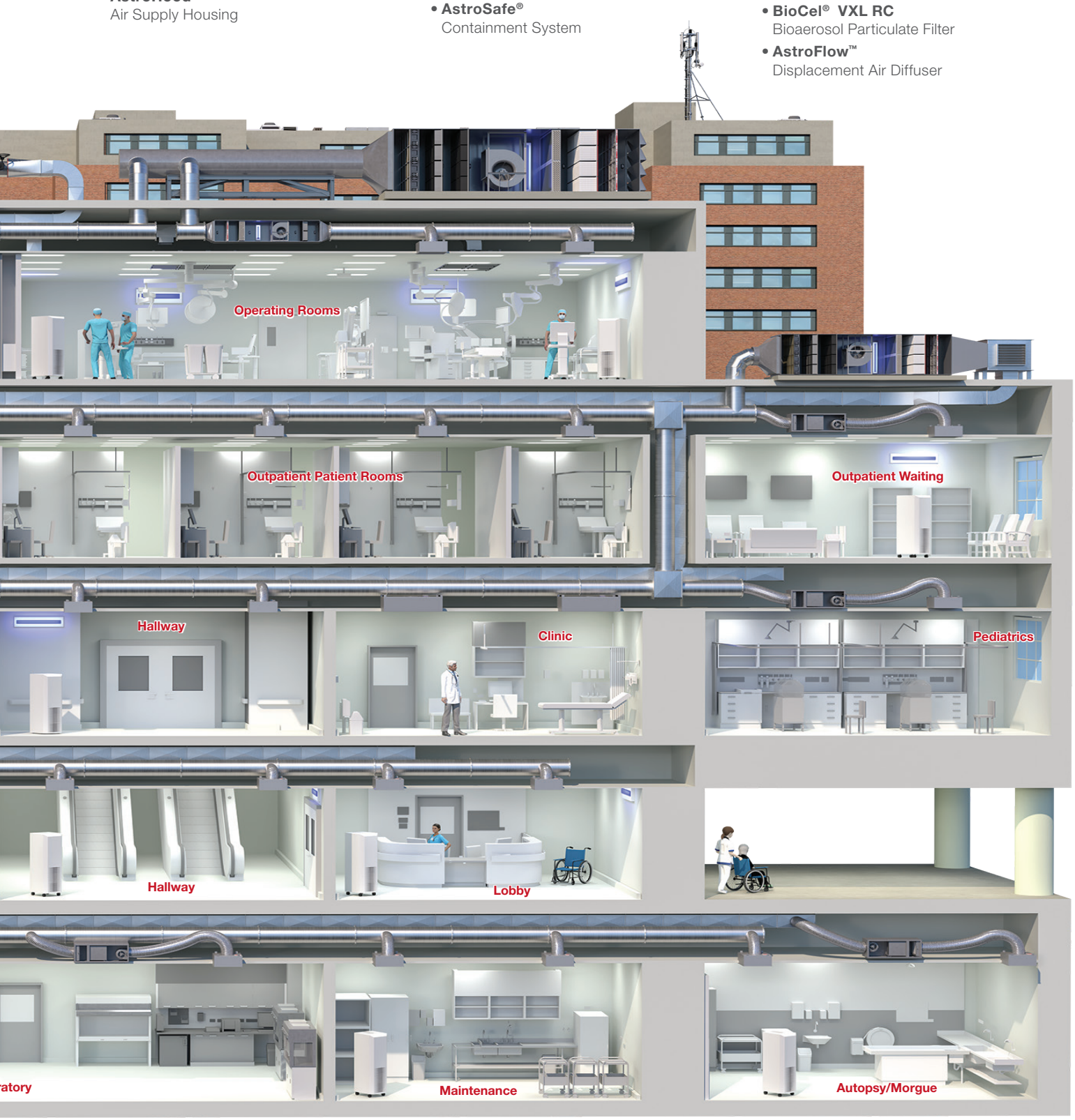


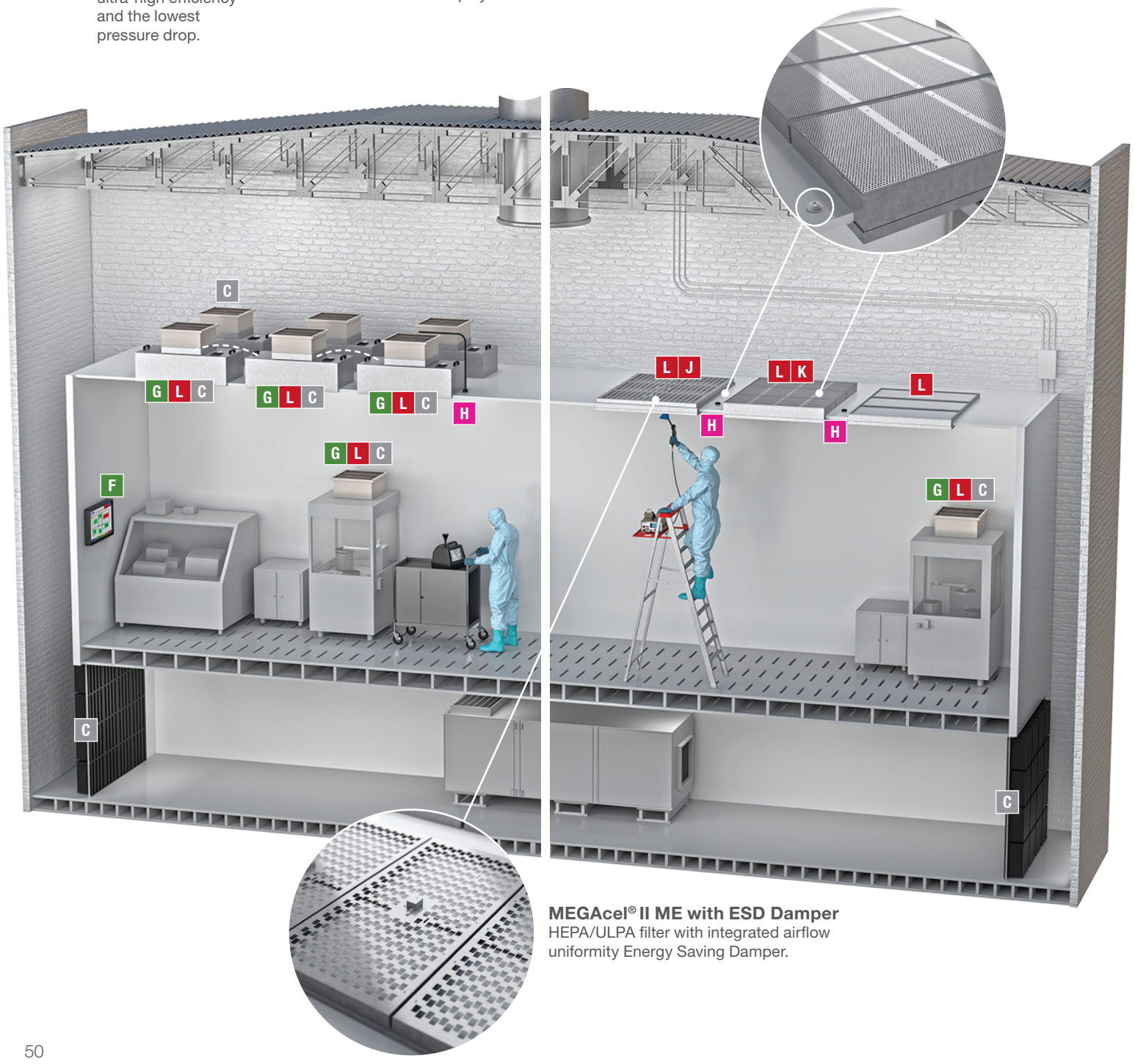
Illustration of Equipment and Test Protocol in the Microelectronics Industry

Historically the need to control particulate in semiconductor applications has been addressed with conventional HEPA/ULPA filtration. In the last decades the need to control AMC (Airborne Molecular Contamination) has increased where specific grades of chemical filters and membrane ULPA filters have been deployed. Reduction of energy consumption by optimizing construction and media types has become 'the norm' as the industries thirst for lower operating costs and increased yields continues to drive our product development and technical leadership in this segment.

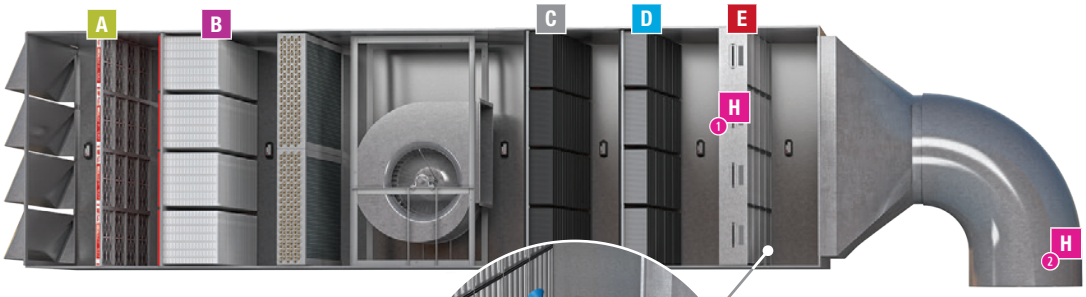
MEGAcel®II ME HEPA/ULPA Filter
High tensile strength, boron-free media with ultra-high efficiency and the lowest pressure drop.

AstroDrive™
Control options range from 0-10 V potentiometers to fully customizable PLCs and PC displays.

MEGAcel® II ME Walk-on Back Plate
For open plenum applications, HEPA/ULPA filters can be supplied with walk-on back plates to facilitate ease of maintenance.



MEGAcel® II ME with ESD Damper
HEPA/ULPA filter with integrated airflow uniformity Energy Saving Damper.



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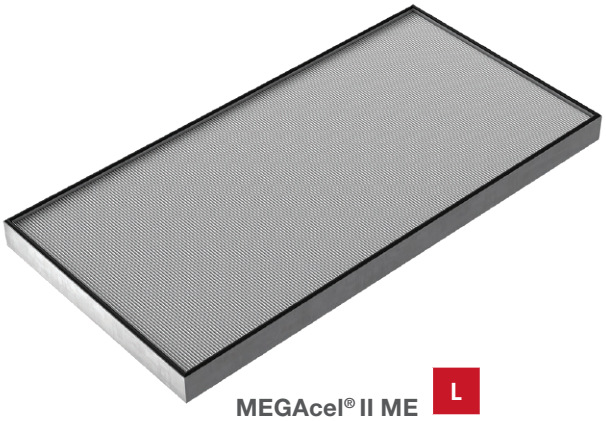


MEGAcel® II ME L

The industry standard with the lowest TCO and durability. The cleanest product for the most sensitive processes.

G I J K M

A	MEGApleat® M9
B	DriPak® GX
C	AstroSorb®
D	VariCel® VXLE
E	MEGAcel® I
F	AstroDrive™
G	AstroFan® FFU
H	Test Port
I	AstroHood® S-III
J	ESD Damper
K	Walk-on Back Plate
L	MEGAcel® II ME
M	In-room HEPA Test Bench

AstroHood® S-III

Disposable ducted HEPA with integrated centerboard test port and diffusion disc.

System Integrity and System Economy

Filter integrity matters—but system integrity defines performance

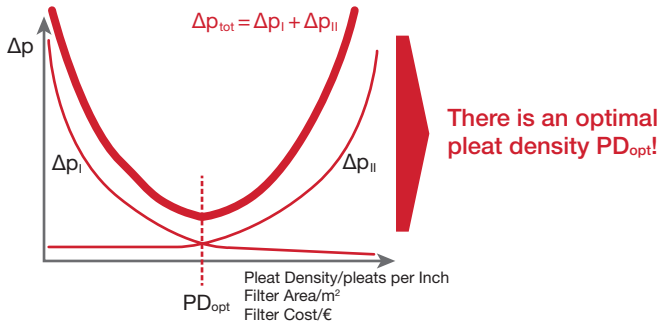
Leaks can originate from many different points in a system—sometimes in the filter media itself, but often at the frame, the seal, or the housing. It might occur at the housing-to-filter seal, the housing-to-ceiling seal, or the media-to-frame interface. Just as often, the problem is at the gasket seal or the gel seal. In some cases, the leak has nothing to do with the filter at all. Particles may be entrained from another area, escaping from an adjacent housing or filter, through a nearby door, or even from a light fixture. Anyone who has spent time in this field has encountered their share of "traveling leak" scenarios. The essential point is that a filter is only as effective as the housing or frame it sits in, and in turn, that housing or frame is only as reliable as the ceiling or unit in which it is mounted. In short, integrity must be considered at the system level.

Filter + Housing + Seal = SYSTEM INTEGRITY.

Understanding system integrity is only part of the equation; the other part is system economy. The "ideal" filter would deliver 100% efficiency, zero resistance, and unlimited service life. In reality, no such filter exists. What is possible, however, is to minimize resistance in finished filters, most often by refining configuration or construction. While this is an important area of focus, it has inherent limits. Current commercially available media impose constraints—though emerging membrane technologies show promise—and there are practical boundaries to how much effective media can be incorporated in a way that balances both technical and commercial considerations. The emphasis is on effective media because more media does not necessarily equate to lower resistance, slower media velocity, or higher efficiency. The key lies in the optimum use of media within defined boundaries such as pack depth, density, and outer frame.

Filter design and construction play a critical role. Depending on type and design—whether thoughtfully engineered or poorly executed—factors such as pleat geometry, pocket shaping, or frame style can account for a significant share of resistance. In fact, construction-related resistance can reach 60–70% of the initial pressure drop, leaving only 30% attributable to the flat sheet media itself. More typically, the split is closer to 50/50, which underscores that there is equal opportunity to optimize both through filter design (configuration) and media specification.

Pressure Drop as Function of Pleat Density



English Units

Product Type	Pressure Drop Attributed to the Filtration Media (in w.g.)	Filter Pressure Drop (in w.g.)	Structure Dp (in w.g.)	Structure Contribution to Dp (%)	Media Contribution to Dp (%)
AstroCel I HCX (99.99%/H13)	1.01	1.45	0.44	30	70
AstroCel II - 2" (99.99%/H13)	0.45	0.53	0.08	15	85
AstroCel III (99.99%/H13)	0.47	0.85	0.38	45	55
MEGAcel I (99.99%/H13)	0.56	0.7	0.14	20	80
MEGAcel II (99.995%/H14)	0.23	0.27	0.04	15	85

SI Units

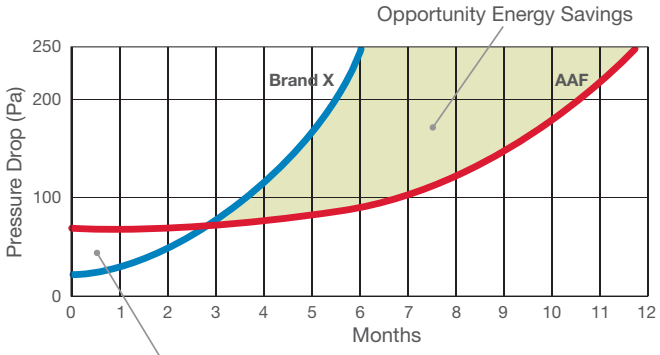
Product Type	Pressure Drop Attributed to the Filtration Media (in w.g.)	Filter Pressure Drop (Pa)	Structure Dp (Pa)	Structure Contribution to Dp (%)	Media Contribution to Dp (%)
AstroCel I HCX (99.99%/H13)	251	361	109	30	70
AstroCel II - 2" (99.99%/H13)	112	132	20	15	85
AstroCel III (99.99%/H13)	117	212	95	45	55
MEGAcel I (99.99%/H13)	139	174	35	20	80
MEGAcel II (99.99%/H14)	57	67	10	15	85

The filter industry has seen no real change or paradigm shift in how filters are constructed in the last 50+ years. The design is essentially the same. From filter manufacturers globally, it is either a Box, V-bank, Pockets or Minipleats. The majority of manufacturers try to improve filter performance over the other by squeezing another 10-20Pa from the media suppliers and/or re-shaping a frame or pleat density to get another 20Pa from the filter design. Where is the limit? Have we already reached the limit on current design? Is there a revolutionary new media that has 100% efficiency and zero resistance? Never say never but not yet.

We are not minimizing the quest for lower resistance. Pressure drop = money. For every Pa we save equates to approximately $1 in energy saving ($100 for every 0.4" of static) which is worth pursuing especially when there are multiple stages and large volumes of high efficiency filters in advanced facilities.

% Reduction in Resistance is Proportional to % Reduction in Energy

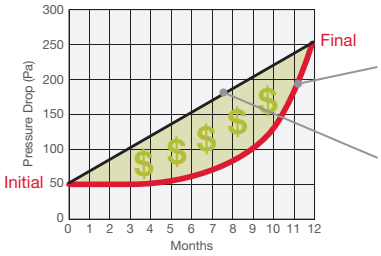
While on this topic it's important to remember that the configuration of the filter has a significant influence on how the filter loads over time. Some filters that start off with a low initial resistance might not maintain this advantage due to inferior construction of the filter and will see an accelerated loading curve and ultimately a much higher total cost of ownership (TCO) over the filters working life. Equally important when benchmarking pressure development over the filters life we ensure we are comparing apples to apples with efficiency.



Although Brand X had a lower initial resistance the AAF 'equivalent' filter demonstrated a longer life and lower energy cost due to the superior configuration of the media and frame even at the same efficiency

How is average pressure drop calculated?

There is the simple straight line average calculation which means Δ Initial + Δ Final / 2 = Average. This is not how a well-constructed filter loads. The loading has a parabolic trajectory (as shown in the next column) which means the true average is much lower than the simple straight line calculation and more reflective of real life. These calculations are important when it comes to calculating energy through TCOD (Total Cost of Ownership Diagnostics) simulation software in order to optimize design and the economy of an installation.



A well-constructed filter will have a parabolic loading curve (shown in red) where the actual true average pressure drop is approximately 25% lower than the straight line calculation (shown in black).

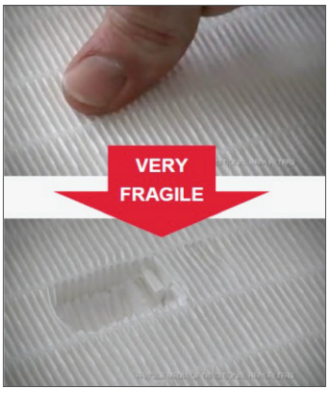
This 25% reduction in average resistance results in approximately the same reduction in energy consumption.

HEPA filter construction pressure drop has less influence from the pleating or configuration and more from the media selection itself. For cleanroom ceiling applications the options are limited from a construction or pleat pack type standpoint.

The 'mini-pleat' design is utilized by most of the major manufacturers. There are different separator types. Hot melt separators are probably the most common globally, string, ribbon, aluminum, embossed are others. Glass fiber is by far the most common media in use today and has been around for 75+ years, well established and reliable although the media itself is susceptible to damage due to the nature of the wet laid glass construction. A pin hole can cause failure, as well as damage from transport is common in the form of media shear, which is when the pack splits vertically across the pleats.

- The media that has grabbed the most attention over the last decade or so has been the membrane technology expanded **P**oly**T**etra**F**luoro**E**thylene (**ePTFE**) **Expanded**

Expanded PolyTetraFluoroEthylene (ePTFE) has some really interesting characteristics especially with durability, almost impossible to damage and has a very low resistance due to its unique structure. The resistance of glass media is 30-50% higher than ePTFE for the same pack depth and construction type. This can have significant benefits in energy consumption for major cleanroom operators especially in the microelectronics world where the media has been widely deployed in the form of FFU's (Fan Filter Units).



Very Fragile During:

- Filter Installation
- Filter Validation
- Cleaning of Ceiling
- Cleanroom Modifications
- Working Activities in the Cleanroom

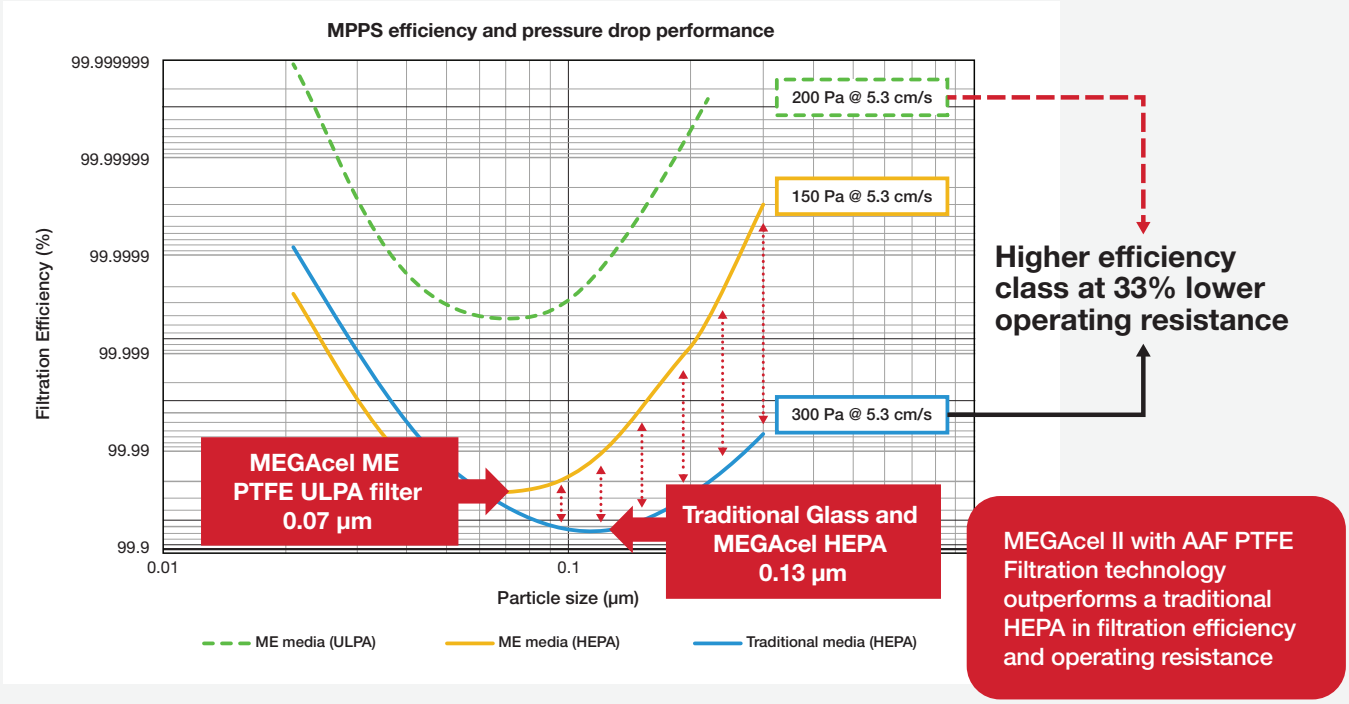
Risks of Filter Damage, Resulting In:

- Cleanroom Downtime
- Unscheduled Replacements
- Costly Recovery Actions
- Cross Contamination
- Uncontrolled Release of Harmful Substances

System Integrity and System Economy

MEGAcel® ME Membrane Media

High Filtration Efficiency Combined with Low Operating Resistance:



– MPPS = Most Penetration Particle Size
– Comparative MPPS graphs are based on efficiency tests with flat media sheets @ airflow of 5.3 cm/s

So, the media pressure drop is important, construction pressure drop has less influence on the combined factors of configuration and media in a HEPA filter. It has an approximate 30/70 split (the opposite is true with ME due to the low PD) in favor of the media. Adoption of the membrane technology will continue to accelerate as availability and cost has comes closer to glass. The well-known durability benefits of MEGAcel PTFE and/or MEGAcel (PAO testable media) along with the reduced energy costs will ensure more wide spread adoption in the future.

Many engineers focus on specifying the lowest pressure drop HEPA or ULPA filter in order to minimize energy consumption and the total static in the system. Most engineers will calculate with the tried and tested ‘double the initial’ pressure drop as a rule of thumb for the dirty condition. In reality, assuming good pre-filtration and ‘normal’ cleanroom operating conditions these filters rarely meet the projected ‘double the initial’ as the change out point.

In Microelectronic applications the vast majority of the air is recirculated. Installations with 20+ years of service will see only a nominal increase in pressure drop. It is not unusual to see a 20% to 50% increase over this 20 year period in this environment. Life Science applications can be more challenging and varied from a load standpoint depending on the product being produced (tablets, powders, liquids) and environment (cleaning, decontamination, test aerosols etc) but again these filters are rarely changed because they have reached their final resistance, it’s mainly because of an internal protocol or SOP.

The ‘dirty’ additional static is in fact often absorbed by miscalculated, forgotten or simply unknown resistance within the housing itself.

Where does this static come from?

The common denominator is the damper.

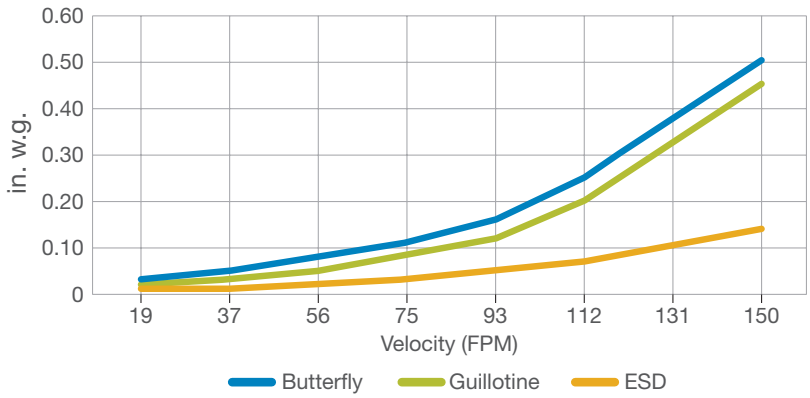
Supply housings in Life Science applications in particular are commonly installed with a balancing or sometimes full volume control damper in the form of a Guillotine or Butterfly design. There are dampers known as ESD or slide plate style designs now utilized that have significantly lower pressure drops (normally 50% less) than the aforementioned dampers. FFU's by the way have low static through the housing itself (excluding coils or additional features for specialized applications). Typical static is about 25Pa.

You can see in the table and graph the actual inlet velocity nec essary through the collar to deliver the desired CFM and the resulting resistance generated through the common dampers utilized today.

	Filter Velocity (CFM)		Inlet Velocities (FPM)		
	2x2	2x4	10"	12"	14"
100	43	18	183	127	94
200	87	36	367	255	187
230	**100**	42	**422**	293	215
300	130	55	550	382	281
400	174	73	733	509	374
500	217	91	917	637	468
550	239	**100**	1008	**700**	514
600	261	109	1100	764	561
700	-	127	1283	891	655
800	-	**145**	1467	**1019**	748
900	-	164	1650	1146	842
1000	-	182	1833	1273	935

Filter face velocity is often more than expected due to the effective filter area being smaller than the nominal housing size.

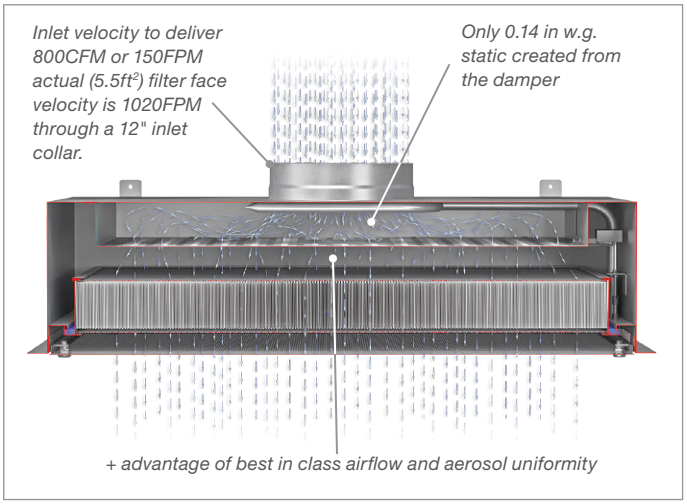
Nominal Inlet Velocity measured at unit inlet collar.

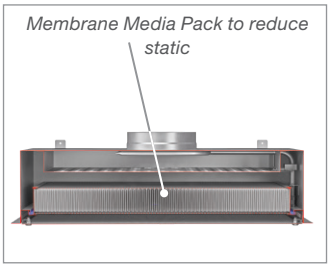


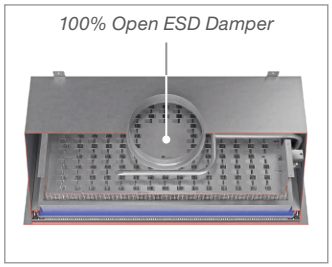
Damper design can have a significant impact on overall system resistance, this affect is amplified as flow rate increases.

System Integrity and System Economy

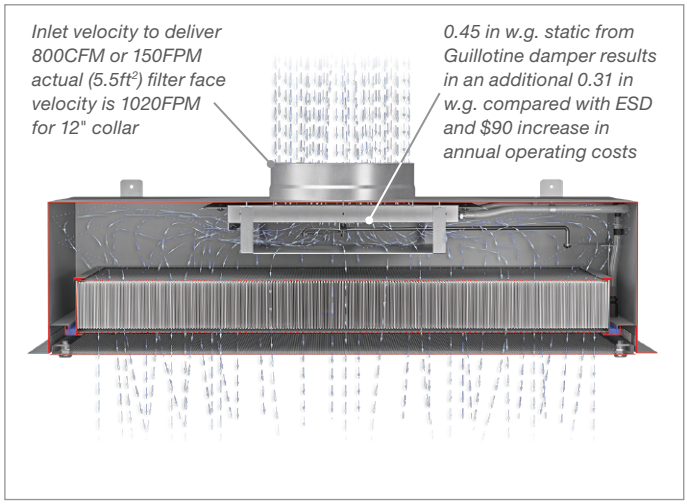
AstroHood S-I ESD Damper Static:

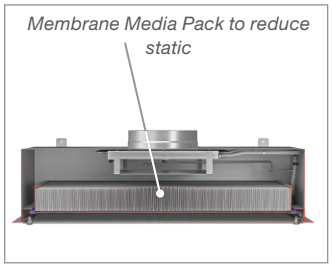


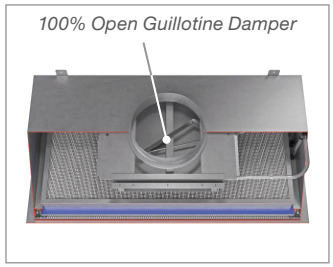




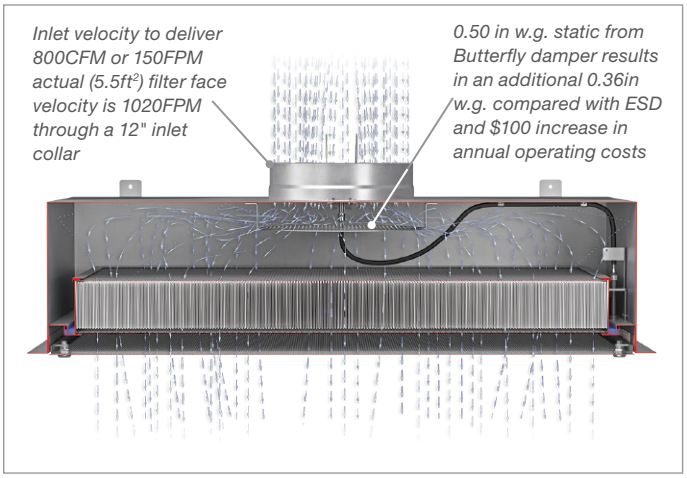
AstroHood S-II Guillotine Damper Static:

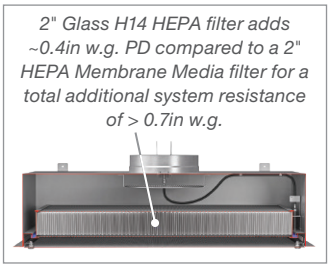


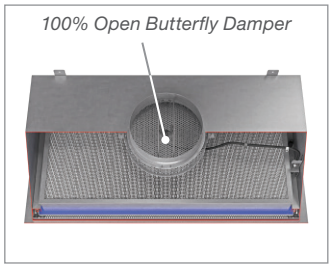




AstroHood S-II Butterfly Damper Static:







BIBO or safe change housings are the biggest culprits with some linear style bubble tight dampers exceeding 250Pa in static in the fully open position. These dampers are sometimes specified on the inlet of a supply housing used to minimize migration of decontamination agents or contamination back into the HVAC system and when specified for their original design are necessary. There have been misapplication of these dampers and unnecessary static of 0.5 in w.g.+ (125Pa) is absorbed for what could be an avoided operating expense.

In addition to the housing or damper resistance there is an additional resistance again often not taken into account from the supply diffuser. In the U.S. a Perforated diffuser with a nominal pressure drop is the most common solution. In Europe and Asia however a Swirl or 4-Way diffuser is the diffuser of choice. Static pressure of 50Pa+ is common especially at the elevated velocities of 1m/s+ (200 FPM) in these regions.

System Economy Calculations

Imperial

System Airflow	Filter Face Velocity		Collar Inlet Velocity			Damper PD			Damper PD			Diffuser PD			Filter PD (H14)			
	2x2	2x4	10"	12"	14"	2x2 ESD	2x2 Gu*	2x2 Bu**	2x4 ESD	2x4 Gu*	2x4 Bu**	Perf	Swirl	4-Way	2x2 Glass	2x2 FRM	2x4 Glass	2x4 FRM
cfm	fpm	fpm	fpm	fpm	fpm	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.	"w.g.
100	43	18	183	127	94	0.01	0.02	0.04	0.01	0.02	0.03	0.002	0.02	0.003	0.21	0.18	0.09	0.08
200	87	36	367	255	187	0.03	0.05	0.08	0.01	0.03	0.05	0.004	0.05	0.005	0.45	0.28	0.20	0.12
230	**100**	42	**422**	293	215	0.04	0.08	0.11	0.02	0.05	0.07	0.004	0.06	0.007	**0.57**	**0.33**	0.25	0.14
300	130	55	550	382	281	0.07	0.15	0.19	0.02	0.07	0.10	0.005	0.08	0.01	0.69	0.38	0.29	0.16
400	174	73	733	509	374	0.11	0.28	0.33	0.03	0.09	0.12	0.01	0.18	0.02	0.97	0.48	0.4	0.20
500	217	91	917	637	468	0.15	0.46	0.52	0.05	0.12	0.16	0.02	0.27	0.03	1.23	0.60	0.51	0.25
550	239	**100**	1008	**700**	514	0.18	0.51	0.57	0.06	0.18	0.22	0.03	0.31	0.04	1.47	0.71	**0.56**	**0.27**
600	261	109	1100	764	561	0.22	0.71	0.78	0.08	0.25	0.29	0.03	0.36	0.05	1.63	0.80	0.61	0.30
700	-	127	1283	891	655	-	-	-	0.11	0.34	0.39	0.05	0.45	0.09	-	-	0.72	0.36
800	-	145	1467	1019	748	-	-	-	0.14	0.45	0.50	0.07	0.55	0.14	-	-	0.85	0.43
900	-	164	1650	1146	842	-	-	-	0.18	0.59	0.64	0.10	0.60	0.19	-	-	0.96	0.51
1000	-	182	1833	1273	935	-	-	-	0.22	0.75	0.80	0.13	0.67	0.26	-	-	1.09	0.60

* Gu = Guillotine
** Bu = Butterfly

Typical Design Airflow (US) — *ESD Damper PD* — *Diffuser PD* — *FRM PD*

Housing (Damper) + Diffuser + Filter (HEPA Membrane Media) = REAL System Static

Metric

System Airflow	Filter Face Velocity		Collar Inlet Velocity			Damper PD (610x610)			Damper PD (1220x610)			Diffuser PD			Filter PD (H14) (610x610)		Filter PD (H14) (1220x610)	
	610x 610	1220x 610	250mm	300mm	350mm	ESD	Gu*	Bu**	ESD	Gu*	But**	Perf	Swirl	4-Way	Glass	FRM	Glass	FRM
m^3/hr	m/s	m/s	m/s	m/s	m/s	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa	Pa
169	0.21	.09	0.92	0.64	0.47	2.48	4.9	9.9	2.4	4.9	7.4	0.5	5	0.8	52.2	44.7	22.3	19.9
340	0.44	0.18	1.86	1.29	0.94	7.46	12.4	19.9	2.4	7.4	12.4	1.0	13	1.3	111.9	69.6	49.7	29.8
390	**0.5**	0.21	**2.14**	1.48	1.09	9.95	19.9	27.3	4.9	12.4	17.4	1.0	15	1.7	**141.8**	**82.1**	62.2	34.8
510	0.66	0.27	2.79	1.94	1.42	17.41	37.3	47.2	4.9	17.4	24.8	1.3	21	2.5	171.7	94.5	72.1	39.8
680	0.88	0.37	3.72	2.58	1.89	27.37	69.6	82.1	7.4	22.3	29.8	2.5	44	5.0	241.3	119.4	99.5	49.7
850	1.1	0.46	4.65	3.23	2.37	37.32	114.4	129.3	12.4	29.8	39.8	5.0	68	7.5	306.0	149.3	126.9	62.2
934	1.2	**0.5**	5.12	**3.55**	2.61	44.79	126.9	141.8	14.9	44.7	54.7	7.4	77	9.9	365.7	176.6	**139.3**	**67.1**
1020	1.3	0.55	5.58	3.88	2.84	54.74	176.6	194.0	19.9	62.2	72.1	7.5	90	12.5	405.6	199.0	151.7	74.6
1189	-	0.64	6.51	4.52	3.32	-	-	-	27.3	84.6	97.0	12.5	113	22.5	-	-	179.1	89.5
1359	-	0.73	7.45	5.17	3.79	-	-	-	34.8	111.9	124.4	17.5	138	35.0	-	-	211.5	107.0
1529	-	0.83	8.38	5.82	4.27	-	-	-	44.7	146.8	159.2	25.0	150	47.5	-	-	238.8	126.9
1700	-	0.92	9.31	6.46	4.74	-	-	-	54.7	186.6	199.0	32.5	168	65.0	-	-	271.2	149.3

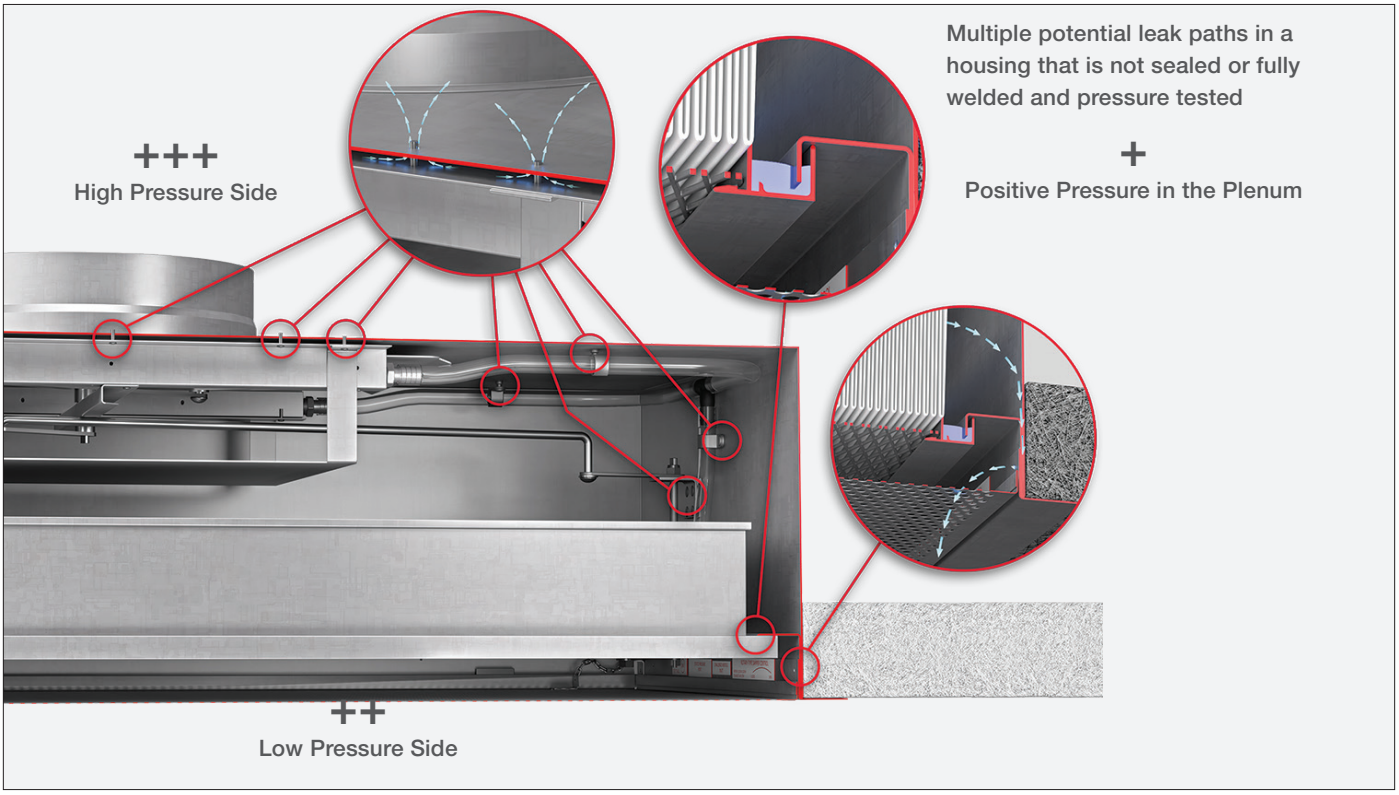
* Gu = Guillotine
** Bu = Butterfly

In summary, yes, we should focus on optimizing initial pressure drop of the HEPA filter ideally by utilizing membrane technology which is 30-50% less than traditional glass fiber media. Take care with the additional static from the housing (damper) and diffuser (Swirl) when calculating the necessary system static.

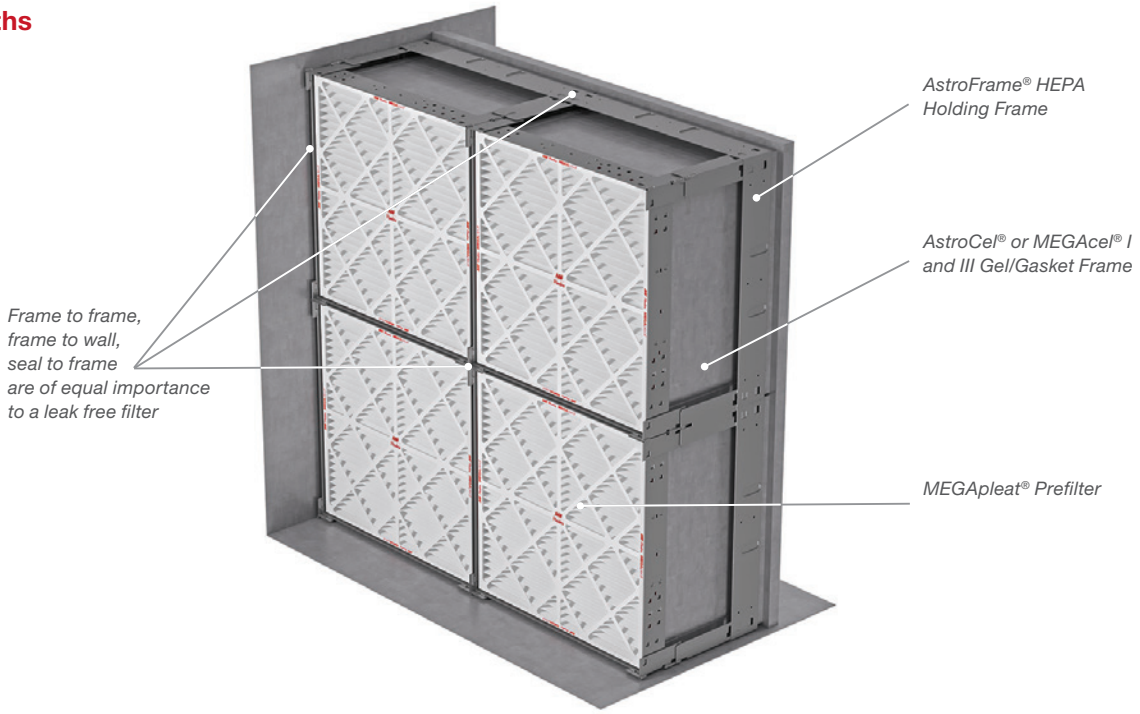
System Integrity and System Economy

It is clear there are opportunities to first understand and then optimize the system static by utilizing energy efficient dampers (ESD) and HEPA filters (MEGAcel) but the system economy will always come second to the system integrity. We mentioned at the beginning of this section that the filter is only as good as the housing or frame it is housed and installed in.

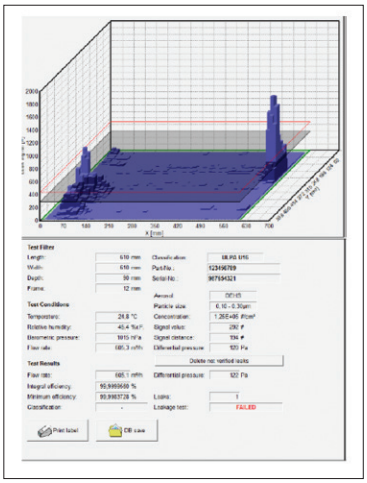
Riveted, Stitch-welded, and Caulked Supply Housing



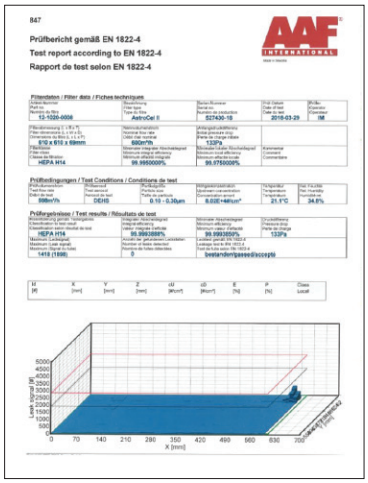
AHU Leak Paths



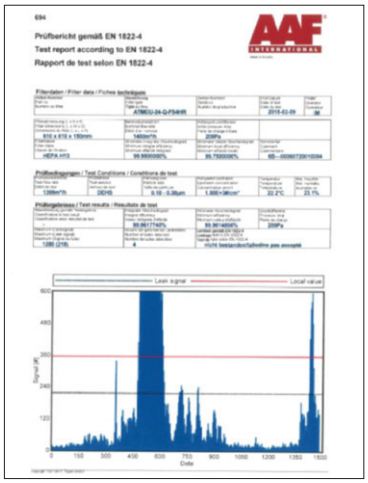
As a user or specifier of filters and housings it is common knowledge to expect a test certificate for the HEPA filter as shown below.



Typical Scan Test Protocol



PASS

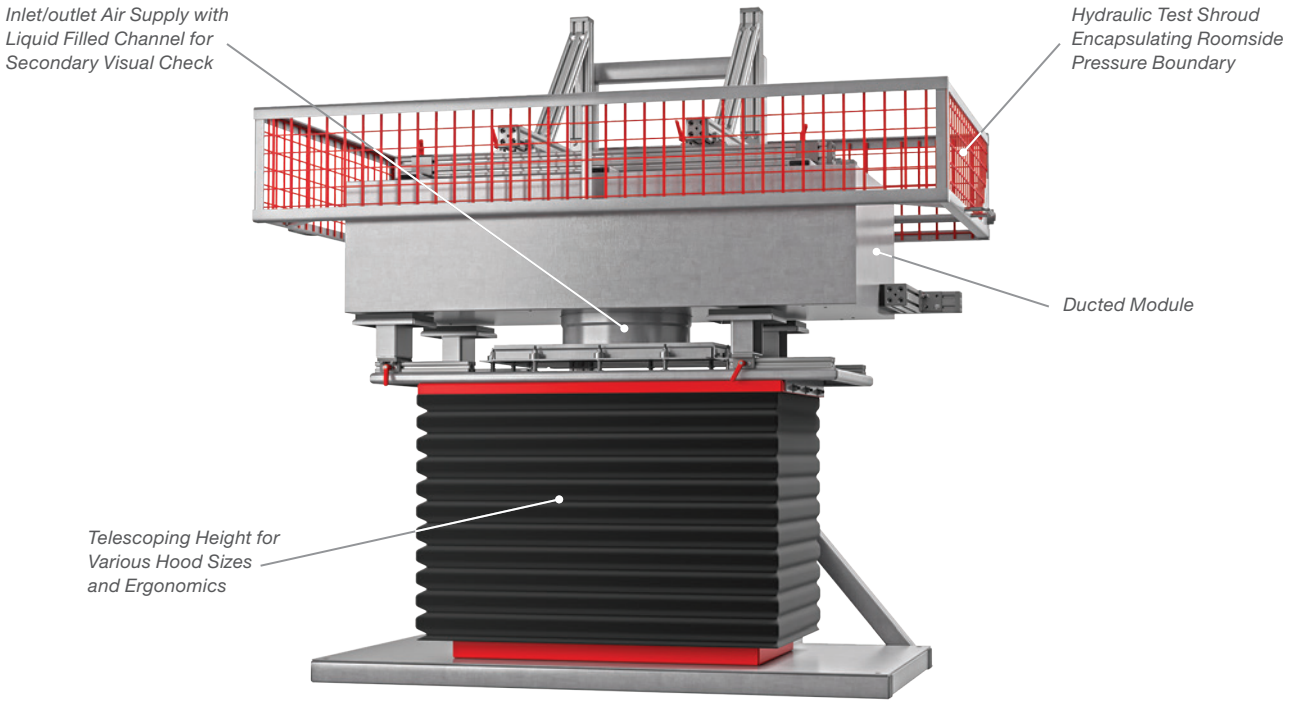


FAIL

We should treat the housing as we should treat the filter by performing a leak test (essentially a pressure decay test) to ensure there are no leaks in the body of the housing and all penetrations through the pressure boundary. Some manufacturers use caulk which will increase the risk of failure over time if applied in the critical leak paths identified in the schematic on the previous page.

Even though all these penetrations are on the dirty side or above the filter, these penetrations if not properly sealed are all potential leak paths into the plenum and then through the housing to trim penetration of trim to ceiling penetration.

Pressure Decay Housing Test Rig



Room and Air Pressure Guidelines

Air always moves from areas of high pressure to areas of low pressure. Pressure differential can be positive, negative or neutral.

Air filter requirements for negative pressure rooms:

The most common types of negative pressure cleanrooms or zones are isolation rooms in healthcare facilities along with BSL 3-4 facilities used for research of infectious diseases and or hazardous compounds in life science facilities.

For negative pressure rooms, air should be exhausted to the outside through HEPA filters and not be recirculated except to the same area, and provided that an additional HEPA filter stage is in place in the return air. Some facilities prefer where possible a single-pass air-handling systems with no recirculation should be provided. The exhausted air or return air should be filtered through a safe-change or bag-in-bag-out filter housing. The filter housing should contain prefilters and HEPA filters, both of which should be removable within a reliable bagging system.

We have seen both recirculated and once through air for the exact same hazardous compound facilities in different parts of the world for the same manufacturer. Local regulations and the sites EHS teams often drive the decision for the M&E teams.

Room Pressurization Levels:

Some examples of room differential pressures outlined below

Airborne Infection Isolation Rooms:

- -0.01 in w.g. minimum differential
- Permanent monitoring device required

Protective Environment Rooms:

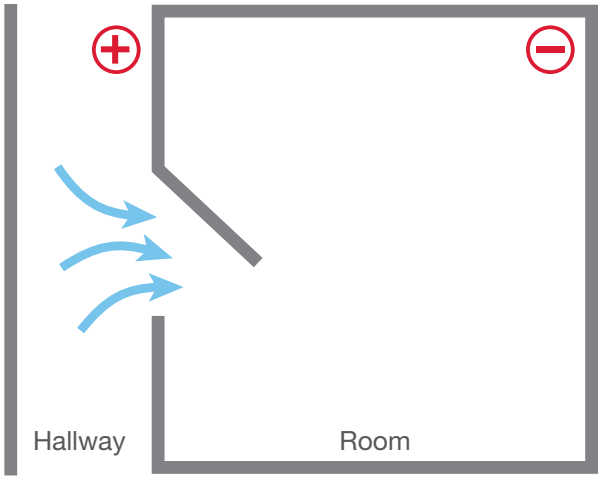
- +0.01 in w.g. minimum differential
- Permanent monitoring device required

USP 797 Compliant Pharmacy:

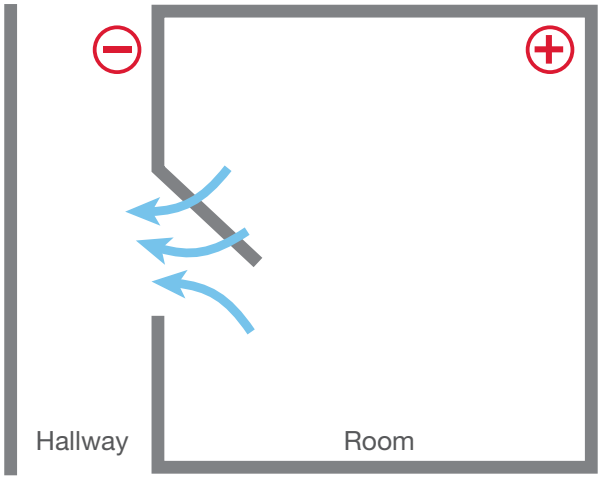
- 0.02 - 0.05 in w.g. range
- Permanent monitoring device required

Operating Rooms:

- +0.01 in w.g. minimum differential
- Monitoring devices not required



Negative room pressures are present when air flows from the hallway to the room.



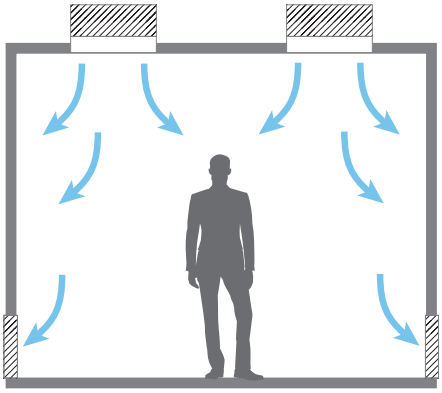
Positive room pressures are present when air flows from the room to the hallway.

Positive pressure is a pressure within a system that is greater than the environment that surrounds that system. Consequently, if there is any leak from the positively pressured system it will egress into the surrounding environment.

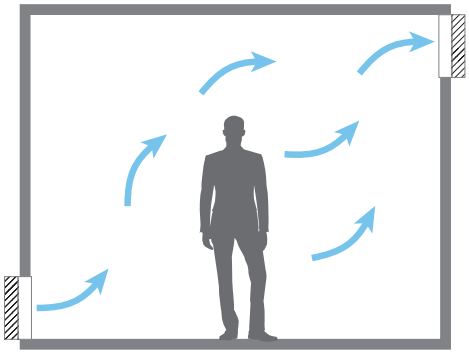
Positive pressure cleanrooms are used primarily for industries where the cleanroom functions to keep the product clean and safe from particulates and in some applications AMC (Airborne Molecular Contamination) and MCP's (Microbial Carrying Particles) seen in the Life Science and Microelectronic industry.

Cleanrooms are designed to maintain positive pressure, preventing "unclean" (contaminated) air from flowing inside and less-clean air from flowing into clean areas. A differential air pressure of 0.03 (7Pa) to 0.05 (12Pa) inches water gauge is typically recommended between spaces.

Negative pressure is generated and maintained by a ventilation system that removes more exhaust air from the room than air is allowed into the room. Air is allowed into the room through a gap under the door (typically about one half-inch high). Except for this gap, the room should be as airtight as possible, allowing no air in through cracks and gaps, such as those around windows, light fixtures and electrical outlets. Leakage from these sources can compromise or eliminate room negative pressure. Negative air pressure cleanrooms are used in industries that manufacture pharmaceutical products (potent compounds), Bio Safety Level (BSL) 3 & 4 Rooms, and also in hospitals to quarantine seriously contagious patients. Any air that flows out of the room has to first flow through a HEPA filter, ensuring that no contaminants can escape.



Positive Pressure



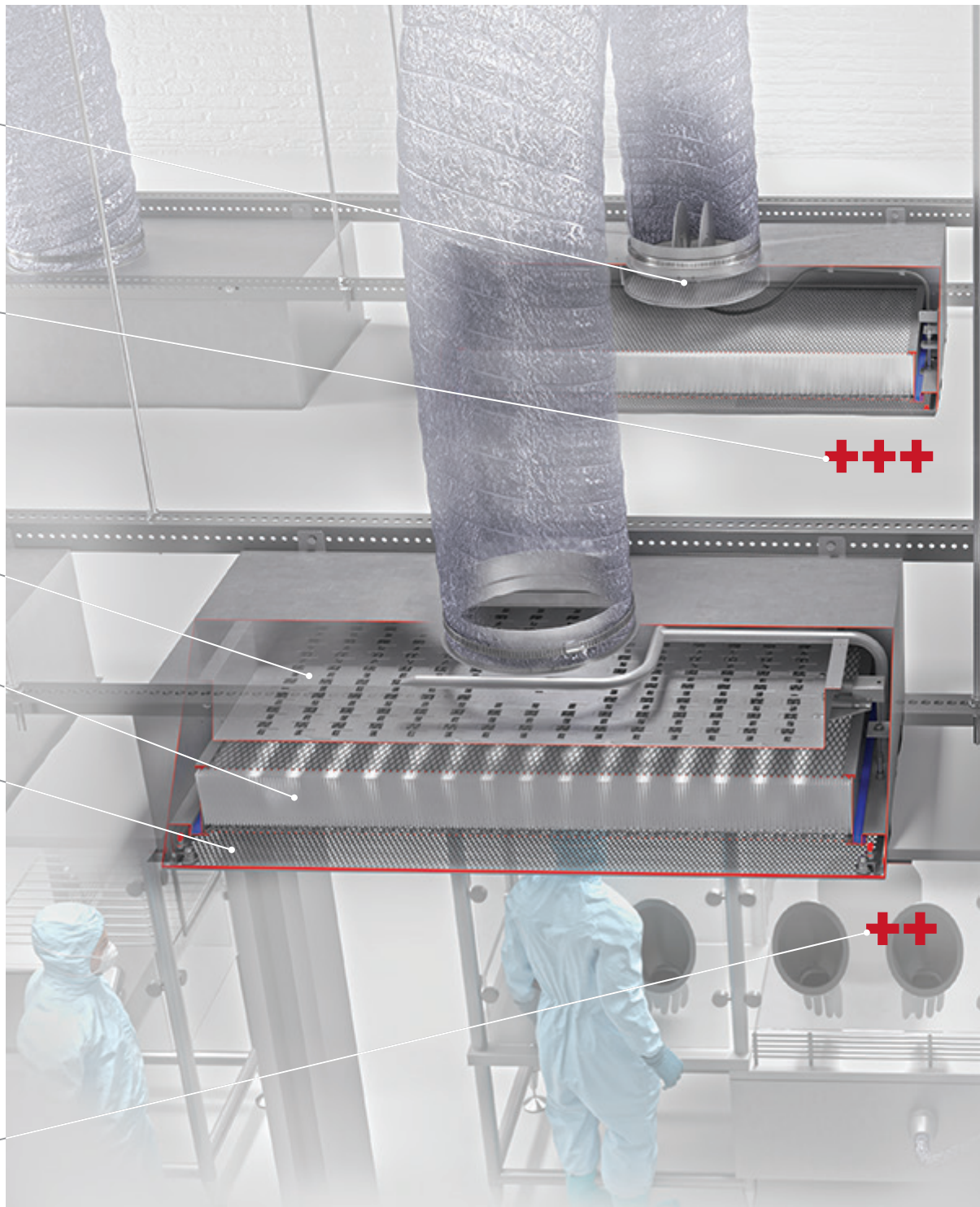
Positive Pressure

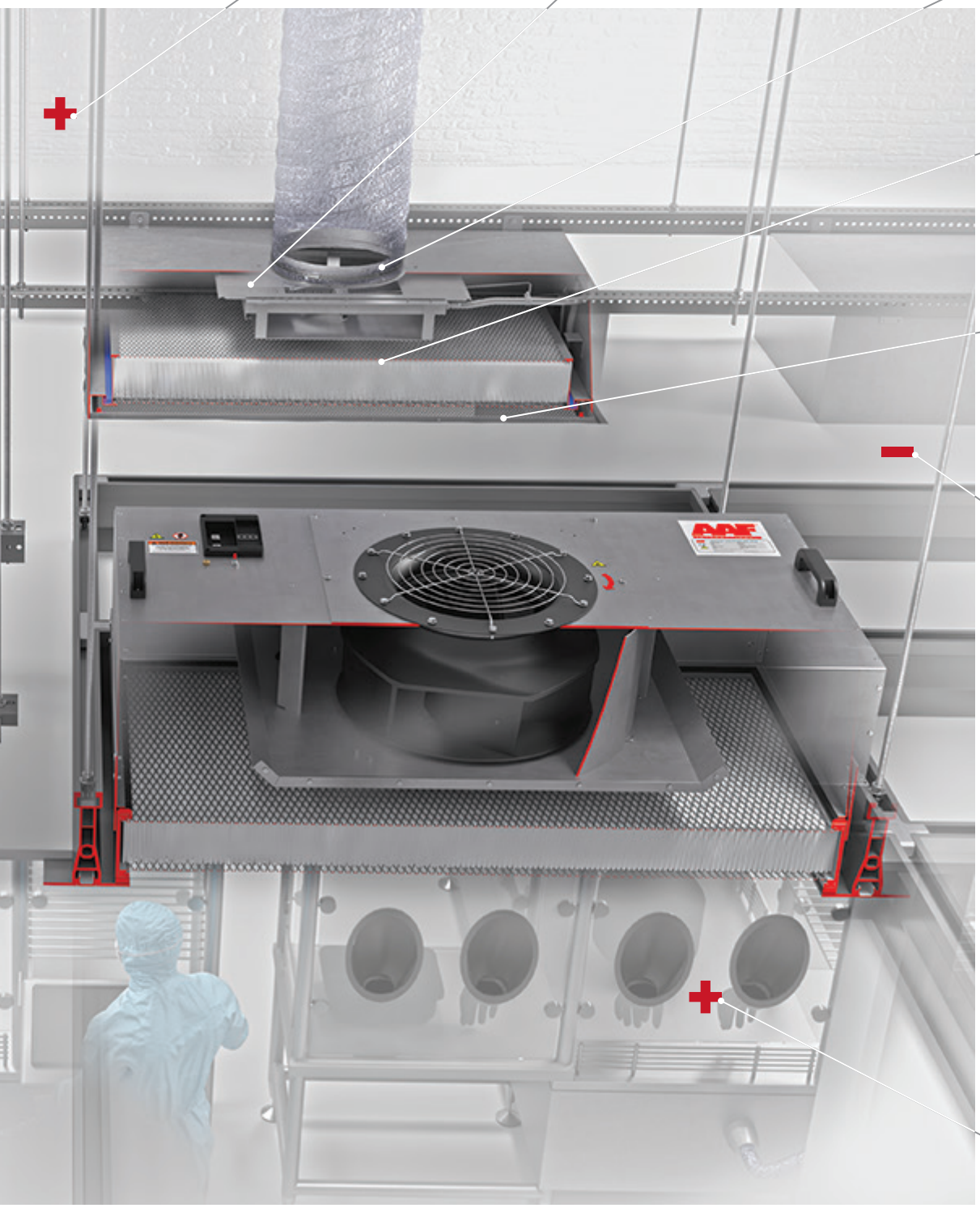
Space Function	Pressure Relationship to Adjacent Space	Recirculated Air
Operating Room	Positive	Yes
Infectious Isolation Room	Negative	Yes
BSL 1	Positive	Yes
BSL 2	Negative*	Yes
BSL 3	Negative	Yes
BSL 4	Negative	Yes
Grade A	Positive	Yes
Grade B	Positive	Yes
Grade C	Positive	Yes
Grade D	Positive	Yes
ISO 1-9	Positive**	Yes

** Not specified but recommended*
*** Plenum is negative when FFU's are installed*

Terminal Device Installations

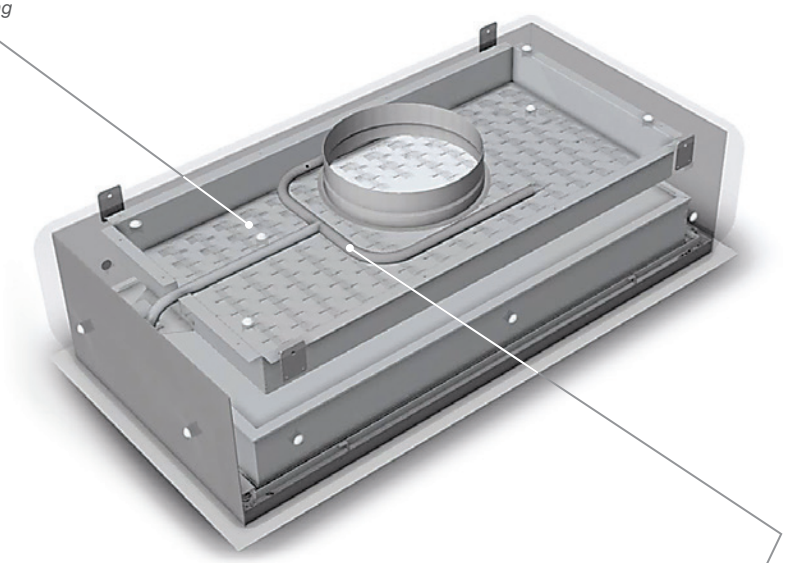
We will see a Housing 0.2-0.4 in.w.g. (50-100Pa) + Filter 0.4 in. w.g. (100Pa) + Diffuser 0.12-0.28 in. w.g (30-70Pa) which could equate to an average CLEAN static pressure drop above 1.0 in. w.g. (250Pa), more than double the filter static we focus on during design discussions.




Typically positive in the plenum for direct ducted HEPA housings
Guillotine damper resistance 0.4-0.6 in w.g. depending on airflow
High inlet collar velocity 800-1200 FPM depending on airflow and collar size
HEPA filter initial resistance can vary from 0.15 to 0.5 in w.g. depending on pack depth and media type (Glass or Membrane) and efficiency selected.
Diffuser pressure drop can vary from 5Pa-75Pa depending on type selected (Perf, 4-Way, Swirl)
Negative Pressure Plenum
Using FFU's in an open negative pressure plenum design helps prevent leakage or by-pass of contaminants into the room.
Another advantage to the FFU design is the reduction in size of the AHU's as the FFU's handle more of the recirculated air requirements that can save space and cost.
Positive Pressure Room

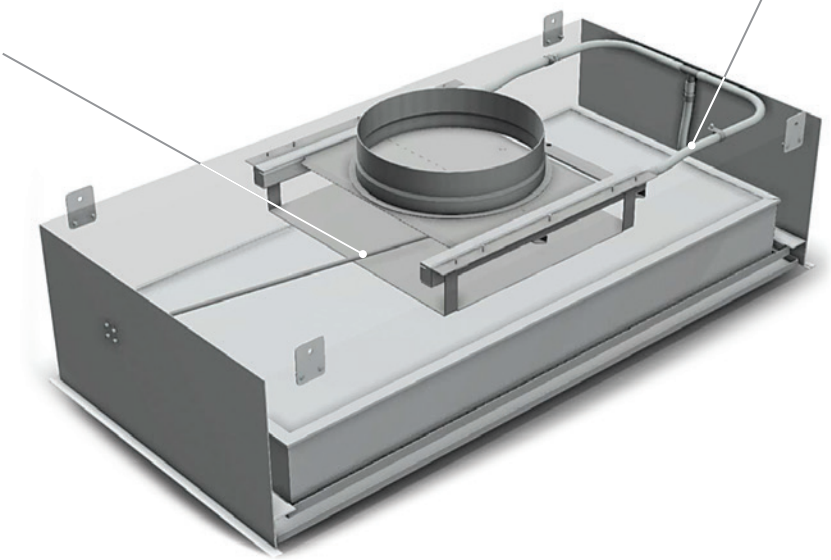
AstroHood® S-I and S-II

ESD (Energy Saving Damper) is standard in the S-I series ensuring lowest operating costs when combined with the MEGAcel® II HEPA filter



Fully certified aerosol dispersion system to ensure homogeneous mix of a suitable upstream challenge injected from the roomside

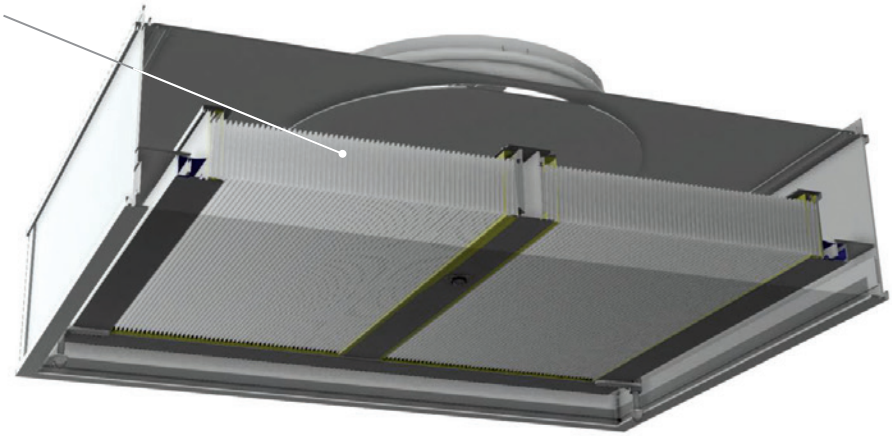
Guillotine damper is standard in the S-II series for air volume control and balancing



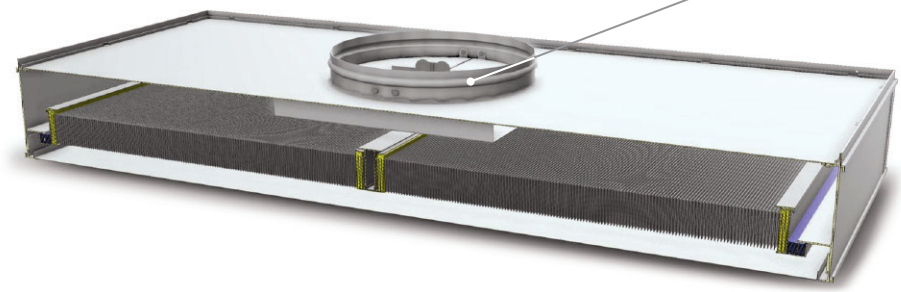
AstroHood® S-III and S-III RSR

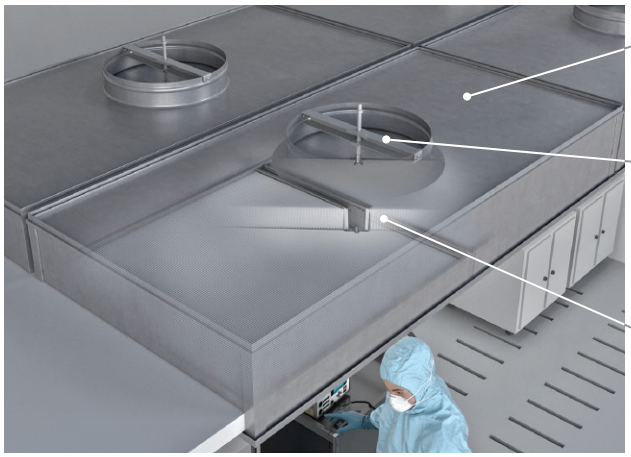
The S-III RSR has a roomside replaceable filter capability combined with an extruded aluminum lightweight housing

AstroCel® II Fluid seal HEPA as standard



Butterfly damper as standard, accessible from the roomside





Light weight disposable HEPA ceiling module

Adjustable air diffusion disk and test port accessible from the roomside as an option through a centerboard

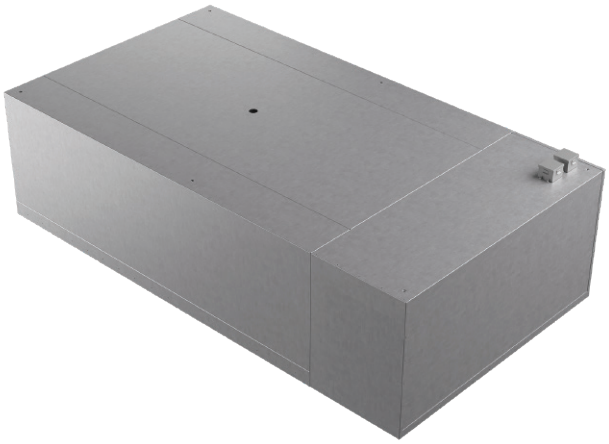
Upstream pressure drop or aerosol concentration measurement possible from the roomside

AstroClean™ Module

A self-contained uni-directional flow module, the AstroClean™ is designed to meet requirements for cleanliness levels of ISO Class 5 or better. These modules are used to supply clean air to processes and equipment including freeze dryers, autoclaves, vial filling, vial filling with powders, research and development work, cell culturing, and ovens. The AstroClean can be supplied with or without EC fans, as well as with standard options such as aerosol injection, flush LED lighting, and sprinkler pass-throughs.

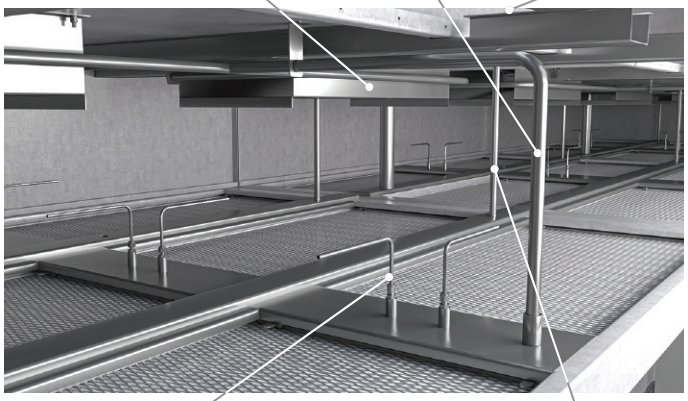
The AstroClean flow module can be used in many applications, including:

- Pharmaceutical
- Biomedical
- Bioresearch
- Microelectronics
- Hospitals
- Universities
- Food Processing

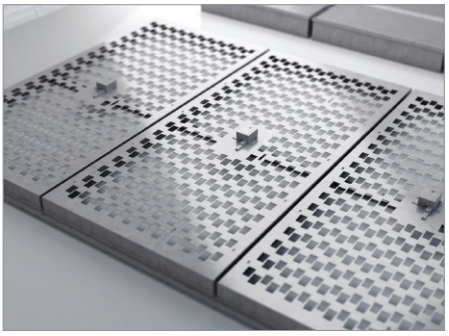


The AstroClean is constructed of an 11-gauge stainless steel grid section and a 14-gauge stainless steel plenum section. It is available with an integrated fan section (side or top) for stand-alone applications, or with duct connections for supply-air entry from an AHU. Top mounted fan option provides n+1 redundancy for further risk mitigation. It also comes with several different standard and optional features:

- Roomside Aerosol Injection
- Stainless Steel Trim Package
- LED Lighting
- Sprinkler Pass-throughs
- Pressure Differental Gauges
- Manual or Digital Controls
- 40% Open Perforated Stainless Steel Grilles
- Insulation



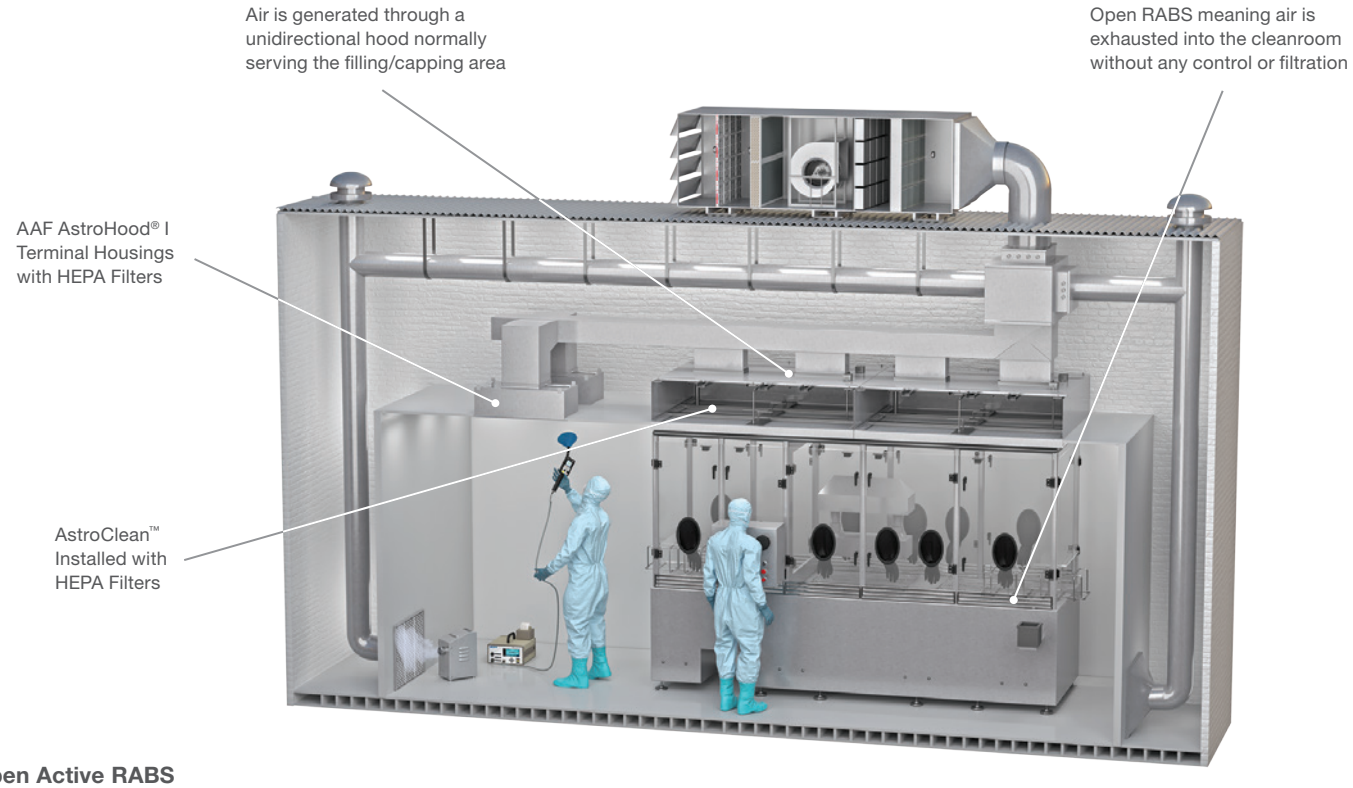
The AstoClean offers the lowest pressure drop on the market when used in conjunction with AAF HEPA/ULPA filters made with membrane media. There is also an option to integrate the AAF energy-saving damper (ESD) with the filters if volume control is desired.



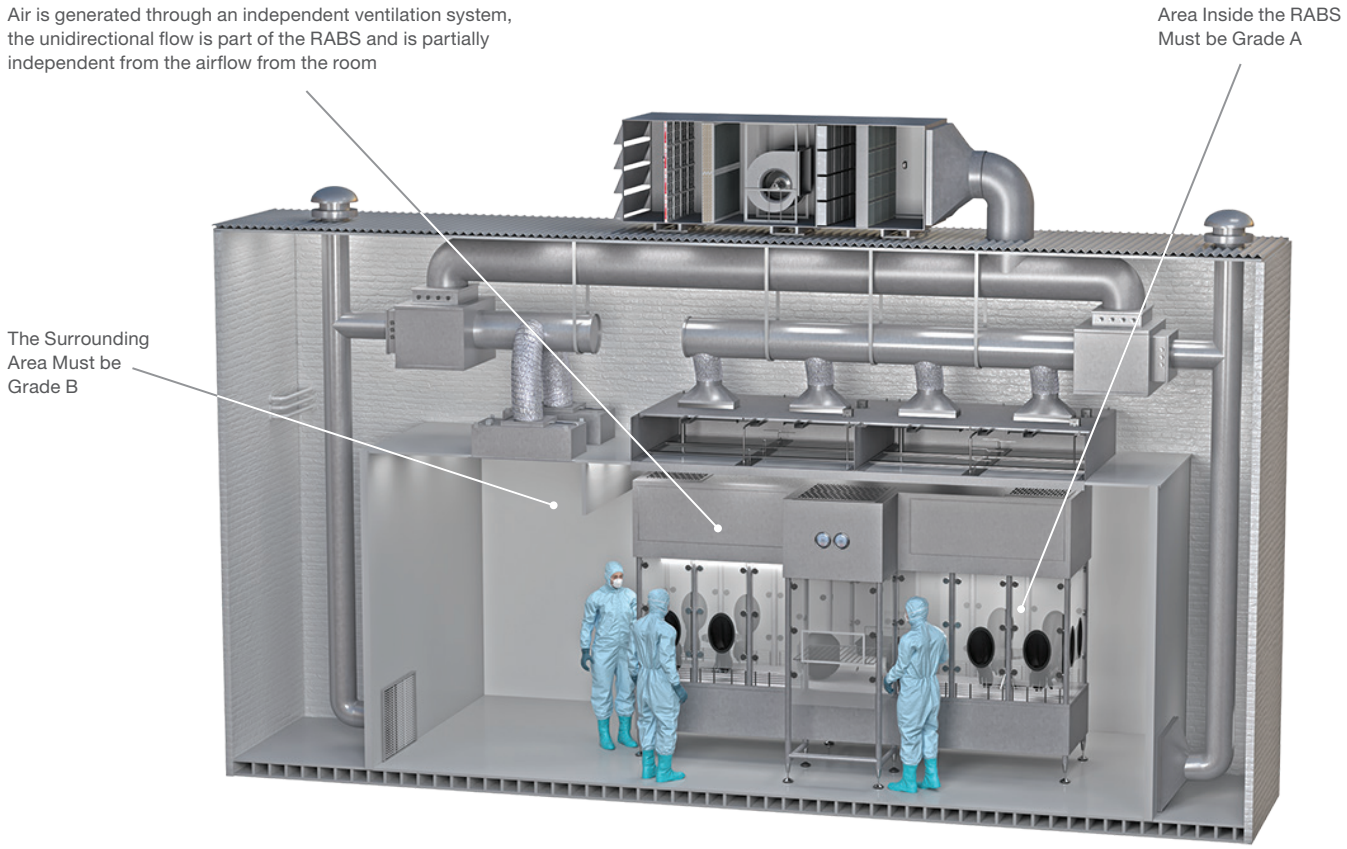
Integrated HEPA/ULPA media with ESD damper option

Examples of AstroClean™ Units Used Above RABs

Open Passive RABS



Open Active RABS



Gas-Phase Filtration

History of Gas-Phase Filtration

The first documented use of activated carbon (commonly known as charcoal) can be traced back to around 3750 B.C., when it was first used by the Egyptians for smelting ores to create bronze. By 1500 B.C., the Egyptians had expanded its use to healing intestinal ailments, absorbing unpleasant odors, and for writing on papyrus. By 400 B.C., the Ancient Hindus and Phoenicians recognized the antiseptic properties of activated charcoal and began using it to purify their water.

Between 400 B.C. and the 1800s, activated charcoal was used to remove odors from wounds, preserve water during ocean voyages, and by the military to treat battle wounds by removing toxins.

The earliest use of activated carbon for gas-phase contaminant removal dates back to 1854, when a Scottish chemist invented the first mask that utilized activated carbon to remove noxious gases. Wood was originally used as the base material for gas masks, since it was good at capturing poisonous gases when converted to activated carbon. By 1918, it was determined that shells and nuts converted to activated carbon performed even better than wood.

Around this same time, activated carbon began to be produced on a large scale, and its use spread to decolorization in the chemical and food industries. In the later 1900s, other industries such as corn and sugar refining, gas adsorption, alcoholic beverage production, and wastewater treatment plants began to use activated carbon.

Today, activated carbon is available in many different shapes and sizes, and its applications are growing every day. For air filtration, the most common types of activated carbon are granular activated carbon (GAC), pelletized activated carbon (PAC), and structured activated carbon. In addition, other substrates such as alumina and zeolite are used in lieu of activated carbon due to their tremendous pore structures. The most common applications of these different media types include corrosion control, odor control, and protection from toxic gases.

AAF's SAAFCarb™ Chemical Media

AAF's SAAFBlend™ GP Chemical Media

What are Gaseous Contaminants?

Gaseous contaminants are undesirable airborne molecules mixed with the normal molecular oxygen and nitrogen in the atmosphere. Because of their molecular size, in the sub-nano range, they are not visible. Also not visible, but present in the air, is desirable molecular water, which is referred to as humidity. Some common offensive undesirable gaseous contaminants are hydrogen sulfide, the rotten egg smell, or skatole, the dirty diaper smell. Many gases that evolve from combustion are considered to be contaminants, such as carbon monoxide, oxides of nitrogen, oxides of sulfur, and polyaromatic hydrocarbons.

Size – Gaseous and Particulate Contaminants

The graphic in Figure 1 illustrates the relative size differences of airborne contaminants. Some particulate contaminants, such as viruses and bacteria, although not visible, have a mass size large enough to be filtered with specialized particulate filters. Gaseous contaminants can only be effectively removed using molecular gas-phase filtration technologies.

Types and Sources of Gaseous Contaminants

Gaseous contaminants are generally classified as Odorous, Corrosive, or Harmful/Toxic. Examples of their sources are shown in Figure 2.

Control of Gaseous Contaminants

The principle of specialized gas-phase filtrations systems, as seen in Figure 3, most often in combination with particulate filters, are used to remove molecular gaseous contaminants.

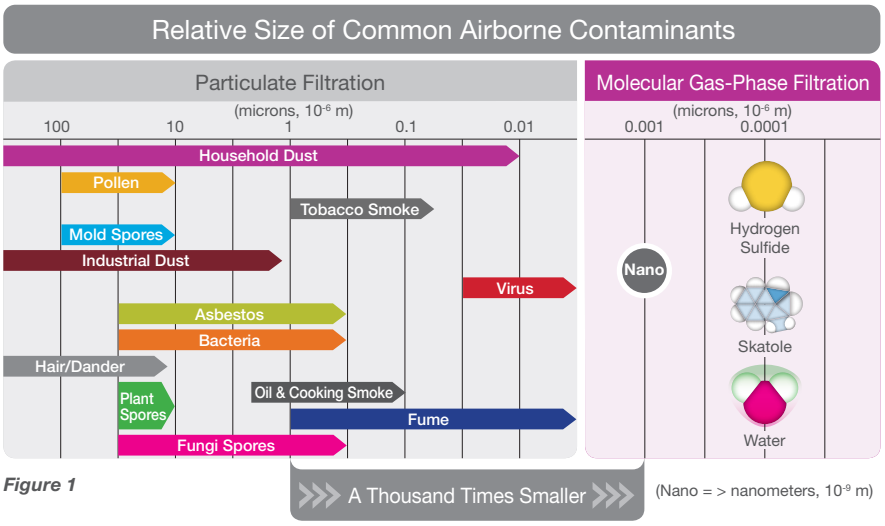


Figure 1

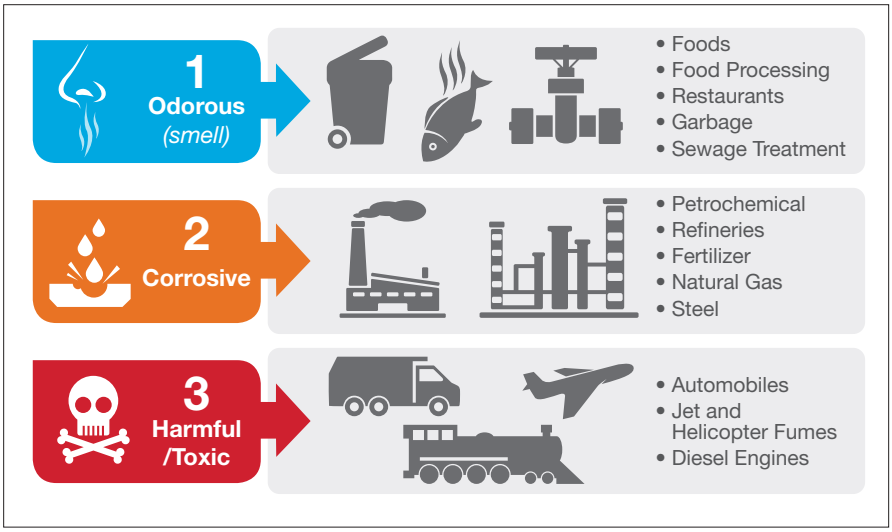


Figure 2

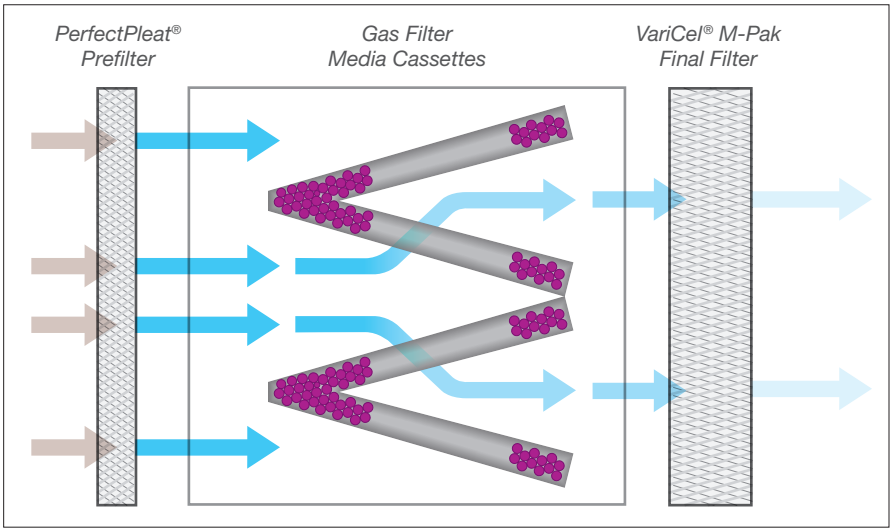


Figure 3

Gas-Phase Filtration

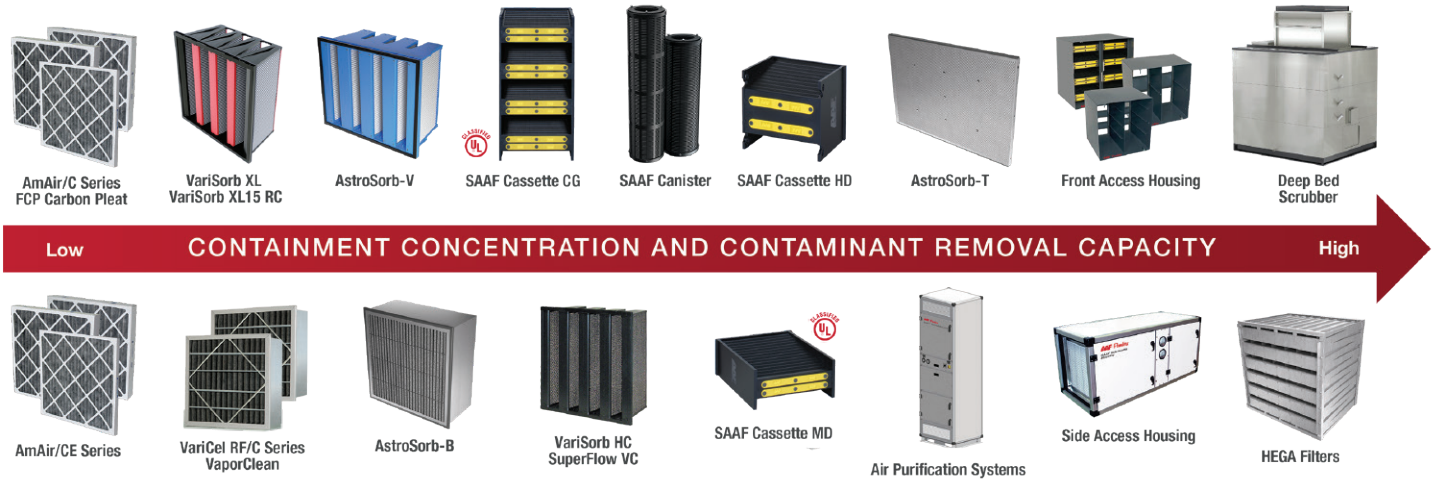
Industry Segments and Applications

Segments	Airborne Molecular Contamination (AMC)	Commercial Indoor Air Quality (IAQ)	Corrosion Control	Odor Control		HEGA / Warfare	Nuclear
Applications	Semiconductor, Microelectronics, Photovoltaic Manufacturing	Airports	Petro Chemical (Control Rooms, Safety Valves, Compressors)	Food / Kitchen	Emergency Ventilation	Embassies	Nuclear Power Plants
	Pharmaceuticals / Biotechnology / IVF Lab	Schools, Homes / Offices	Pulp & Paper (Control Rooms, Compressors)	Frangrance	Cannabis	Shelter in Place (SIP) and Collective Protection	Hospitals
	Process Tools	Hospitals	Data Center (Emergency Power, Server)	Wastewater	Lab		
Gases	Acids, Bases, VOCs, Oxidants, Dopants, Ozone	Acids, Bases, VOCs, Ozone, Formaldehyde	Acids, Bases, Ozone, Sulfer Compounds, Oxidants (Cl)	Bases, Ozone, Sulfur Compounds, VOCs, Amines, NOx	Acids, Bases, Ozone, Sulfer Compounds, Oxidants, VOCs, Flammable	Phosphorous Compounds, Oxidants, VOCs, Bio Contaminants	Radioactive Compounds (Iodine, F-18, Ga-68)
Attributes	Very High Requirements, Low Concentrations, High Product Value	Safety, Moderate Requirements	Moderate Requirements, Low / Medium Concentrations	Moderate Requirements, Low /Medium / High Concentrations	Typically, Big Projects, Safety, High Concentrations	Safety, Testing, Low / Medium Concentrations	Safety, Testing, Low / Medium Concentrations
Products	Pleated / Loose Fill (VariSorb, VariCel, SAAF Cassettes)	Pleated / Loose Fill (AmAir/C, Carbon Tray (Carbon tray, SAAF VariCel, VariSorb)	Loose Fill (Carbon Tray, SAAF Cassettes, SAH, DBS)	Pleated / Loose Fill (Carbon Tray, SAAF Cassetes, AmAir/C VariCel, VariSorb)	Loose Fill (Carbon Tray, SAAF Cassettes, SAH, DBS)	Loose Fill (HEGA)	Loose Fill (HEGA)

When Is Gas-Phase Filtration Required?

Just like particulate filtration, gas-phase filtration is required in a wide variety of industries and applications. The table above is a list of most of the more common industry segments and their specific applications that require gas-phase filtration. These applications predominantly require gas-phase filtration to protect personnel, processes, and sensitive electronics that are exposed to harmful contaminants in the air.

Product Offering Overview



*The **AstroSorb**® line of filters are optimized for the control of airborne molecular contaminants (AMC) in microelectronics and EV battery manufacturing applications.*

What Gas-Phase Products are Available?

There are a wide variety of products that are available to remove gas-phase contaminants from the air. These products are typically categorized as low, medium, or high removal capacity products. On the low end are products such as two-inch pleated filters containing chemical media to remove gas-phase contaminants. In the middle are 12"-18" deep filters and cassettes to remove moderate challenge levels. On the high end is equipment with loose-fill chemical media specifically designed to eliminate high concentrations of gas-phase contaminants.

Selecting Gas-Phase Air Filters

Choosing the correct chemical media type and the correct chemical media delivery product is a daunting task. There is a lot of information that must be gathered first, such as the contaminants of concern (COC), the concentrations of the COC, the air volume, the desired media life, and the space available as examples. A good starting point is to complete an application questionnaire like the one below to document as much of this information as possible.

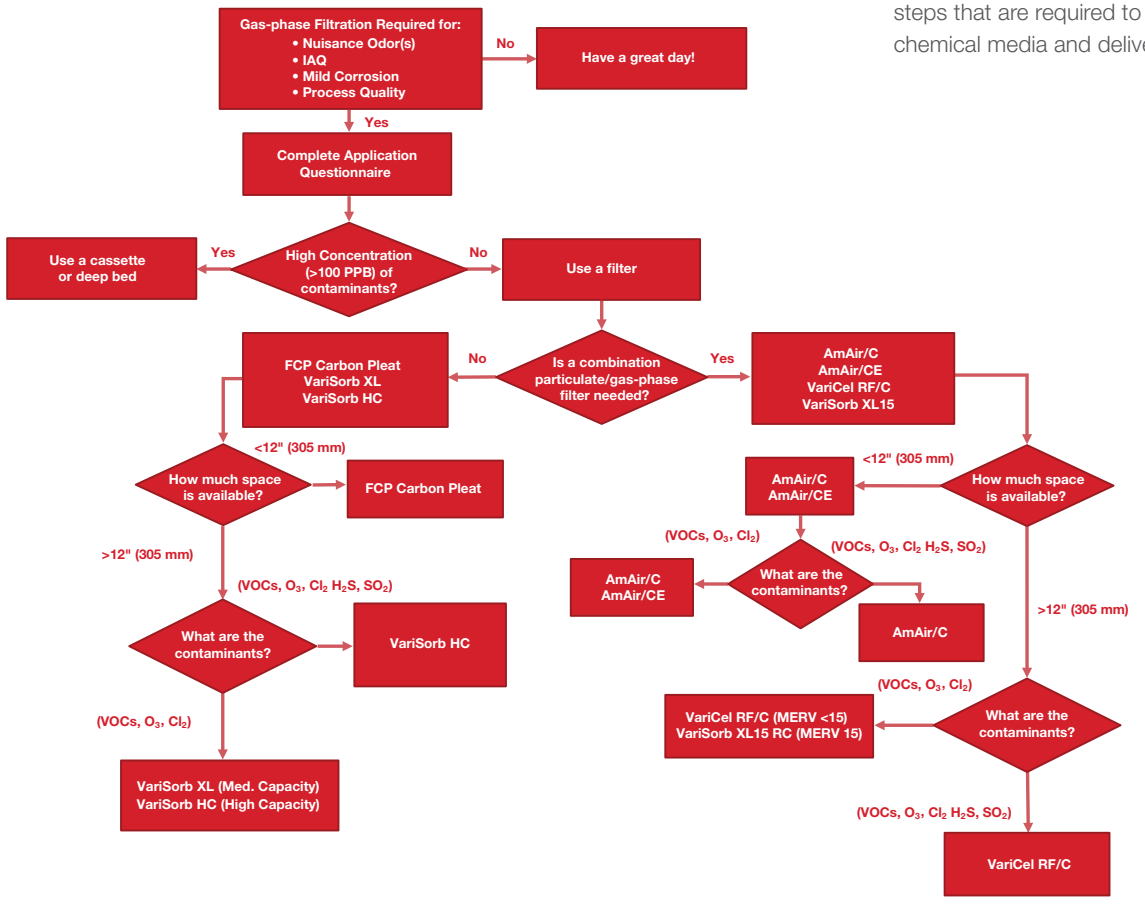
Gas-Phase Product Application Questionnaire

1	What is the size of the space to be protected?	Height (ft)	10	Width (ft)	15	Length (ft)	20	Volume (ft^3) 3000
2	What is the airflow that is required?	Airflow (ft^3/min)	2000					
3	What contaminants are present and in what concentration?							

Contaminant	Peak Concentration (ppb)	Average Concentration (ppb)
acetaldehyde	25	1
formaldehyde	125	5
nitric acid	300	12
nitrogen dioxide	575	23
sulfur dioxide	125	5
voc	525	21

4	What are the operation times?		Hours/Day	Days/Week	Weeks/Year
		Average	23.5	7	52
		Peak	0.5	7	52
5	Are there any dimensional constraints?	Max Height (ft)	10	Max Width (ft)	10	Max Length (ft)	10
6	How many passes of media can be used (1, 2, 3 or 4)?	2					
7	What is the desired media life in months?	6					
8	What are the performance requirements? (electrical/electronic corrosion protection, ISA G1 environment, odor control, etc.)	Odor Control					

Notes



This gathering of the data is the first step in determining the correct type of media. In most applications, there is one chemical media type that will work best. There are times, however, when more than one media type will work. In other cases, more than one media type is required as part of a comprehensive solution due to the list of contaminants that need to be removed.

To further complicate matters, there are multiple chemical media delivery devices available, and most of the time, more than one of those devices will work. The amount of space that is available, along with the number of media types required, are the two main factors that determine which delivery device will best serve the application at hand.

Due to this complexity, it is recommended that you reach out to your local AAF representative to assist you with making the proper selection. The sample flowchart below shows the various decision points and steps that are required to select the best chemical media and delivery device.

Gas-Phase Standards

As the methods and uses of gas-phase air-cleaning grew and diversified, the air filtration industry recognized the need to establish standards for measuring performance and efficiency within gas-phase applications. The table below provides at-a-glance information on some of these standards that are commonly used.

STANDARD	PURPOSE	CONDITIONS
ASHRAE Standard 145.1-2024 Laboratory Test Method for Assessing the Performance of Gas-Phase Air Cleaning Systems: Loose Granular Media (ANSI Approved)	Compare gas-phase media options	Elevated gas challenge concentrations that exceed those in typical applications
ASHRAE Standard 145.2-2025 Laboratory Test Method for Assessing the Performance of Gas-Phase Air Cleaning Systems: Air Cleaning Devices	Compare gas-phase device options	Elevated gas challenge concentrations that exceed those in typical applications but mimic the mix of contaminants and/or gases in these applications
ASHRAE Guideline 27-2019 Measurement Procedures for Gaseous Contaminants in Commercial Buildings	Plan and implement measurement and sampling of gaseous contaminants	Actual conditions in live commercial building applications
ASTM-D6646-03-2022 Standard Test Method for Determination of the Accelerated Hydrogen Sulfide Breakthrough Capacity of Granular and Pelletized Activated Carbon	Establish relative breakthrough performance of activated carbon in granular or pelletized form in terms of removal of hydrogen sulfide	Elevated challenge concentration and humidified gas stream that does not simulate actual conditions in typical applications
ISO 10121-2:2013 Test methods for assessing the performance of gas-phase air cleaning media and devices for general ventilation — Part 2: Gas-phase air cleaning devices (GPACD)	Compare gas-phase device options	An objective test method to estimate the performance of any full size gas filtration device (GPACD) for general filtration regardless of media or technique used in the device
ISO 10121-1:2014 Test Method for Assessing the Performance of Gas-Phase Air Cleaning Media and Devices for General Ventilation – Part 1: Gas-Phase Air Cleaning Media	Compare gas-phase media options	Elevated gas challenge concentrations that exceed those in typical applications
ISO 10121-3:2022 Test Method for Assessing the Performance of Gas-Phase Air Cleaning Media and Devices for General Ventilation – Part 1: Gas-Phase Air Cleaning Media	Establishes a classification system for GPACDs	This classification system is intended to aid in assessing molecular contamination.
IEST-RP-CC008 High-Efficiency Gas-Phase Adsorber Cells	Specify suggested design and testing of modular gas-phase adsorber cells in single-pass or recirculating air cleaning systems	Applications that require high-efficiency removal of gaseous contaminants
IEST-G-CC035 Design Considerations for Airborne Molecular Contamination Filtration Systems in Cleanrooms and Other Controlled Environments	Describes areas of concern when considering filtration systems that will be effective in eliminating trace amounts of airborne molecular contamination (AMC)	Establishes the types of information required to design and implement an effective AMC filtration system

Please refer to the Gas-Phase Testing information in the next section for additional details.

Gas-Phase Testing

ASHRAE Standard 145.1-2024

Laboratory Test Method for Assessing the Performance of Gas-Phase Air Cleaning Systems: Loose Granular Media (ANSI Approved)

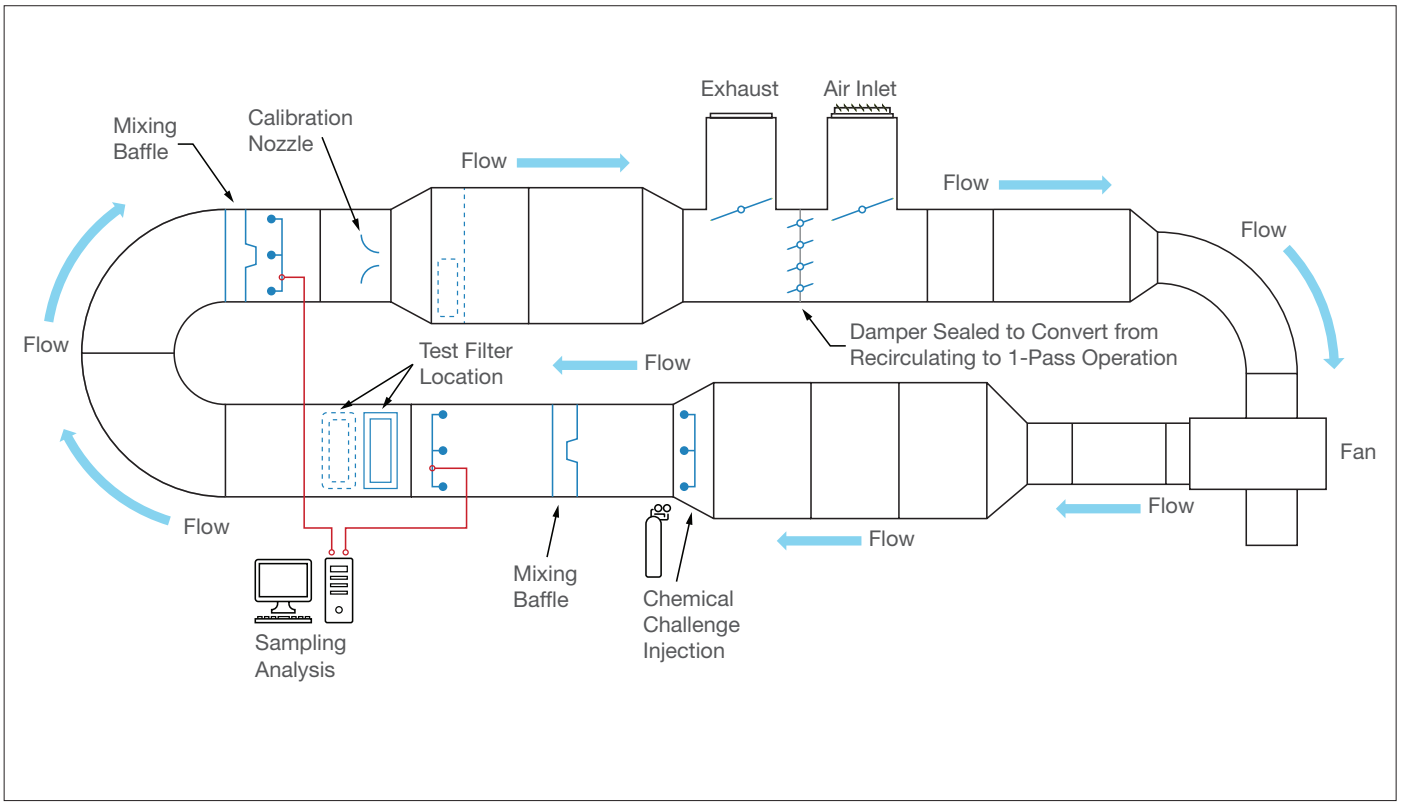
The purpose of this standard is to provide a standard laboratory test method for assessing the performance of loose granular media used in gas-phase air-cleaning systems. The standard details a small-scale laboratory test method for measuring the contaminant removal efficiency of loose granular sorptive media used in gas-phase air-cleaning equipment as installed in a test apparatus in an airstream challenged with test gases under steady-state conditions. The testing is conducted at elevated gas challenge concentrations relative to actual applications, and this testing should therefore be used to compare media rather than directly predict the performance in a particular application.

ASHRAE Standard 145.2-2025

Laboratory Test Method for Assessing the Performance of Gas-Phase Air Cleaning Systems: Air Cleaning Devices

The purpose of this standard is to provide a standard laboratory test method for assessing the performance of in-duct sorptive media gas-phase air-cleaning devices. The standard details a small-scale laboratory test method for measuring the contaminant removal efficiency of loose granular sorptive media used in gas-phase air-cleaning equipment as installed in a test apparatus in an airstream challenged with test gases under steady-state conditions. The testing is conducted at elevated gas challenge concentrations relative to actual applications, and therefore this testing should be used to quantify the performance of air cleaning devices for removing one or more specified gaseous contaminants or gas mixtures intended to simulate operation during service life.

Laboratory Test Method for Assessing the Performance of Gas-Phase Air-Cleaning Systems: Air Cleaning Devices

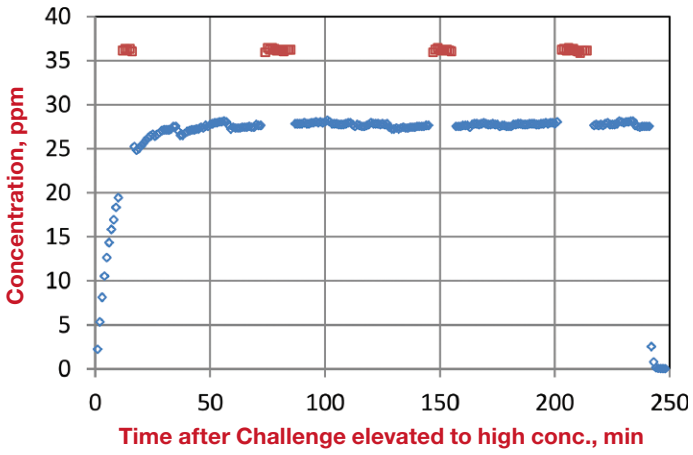


Source: ASHRAE

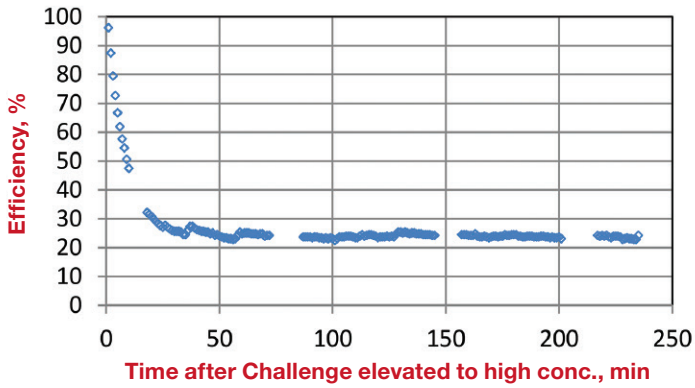
Gas-Phase Testing

Example of Test Report: Capacity Test Results

Concentrations



Efficiency



ASHRAE Guideline 27-2019

Measurement Procedures for Gaseous Contaminants in Commercial Buildings

The purpose of this guideline is to assist engineers and other professionals with planning and implementing the measurement and sampling of gaseous contaminants in commercial buildings.

ASTM-D6646-03-2022

Standard Test Method for Determination of the Accelerated Hydrogen Sulfide Breakthrough Capacity of Granular and Pelletized Activated Carbon

This test method is intended to evaluate the performance of virgin, newly impregnated or in-service, granular or pelletized activated carbon for the removal of hydrogen sulfide from an air stream, under laboratory test conditions. The method determines the relative breakthrough performance of activated carbon for removing hydrogen sulfide from a humidified gas stream. This test does not simulate actual conditions encountered in an odor control application, and it therefore is meant only to compare the hydrogen sulfide breakthrough capacities of different carbons under the conditions of the laboratory test.

ISO 10121-1:2014

Test Method for Assessing the Performance of Gas-Phase Air Cleaning Media and Devices for General Ventilation -- Part 1: Gas-Phase Air Cleaning Media

This standard provides an objective laboratory test method, a suggested apparatus, normative test sections, and normative tests for evaluation of three different solid gas-phase air cleaning media (GPACM) or GPACM configurations for use in gas-phase air cleaning devices intended for general filtration applications.

IEST-RP-CC008

High-Efficiency Gas-Phase Adsorber Cells

This Recommended Practice (RP) covers the design and testing of modular gas-phase adsorber cells in single-pass or recirculating air-cleaning systems where the need for high-efficiency removal of gaseous contaminants is a requirement.

IEST-G-CC035

High-Efficiency Gas-Phase Adsorber Cells

This Guideline describes areas of concern when considering filtration systems that will be effective in eliminating trace amounts of airborne molecular contamination (AMC), here defined as less than 1 part per million by volume (ppmv), from the air supplied to cleanrooms and other controlled environments.

Gas-Phase Filtration: HEGA Filters

HEGA Filters

Originally developed to protect the military from toxic gases, High Efficiency Gas Adsorbers (HEGA) are to gas-phase filtration as HEPA filters are to particulate filtration. These adsorbers are typically used in containment systems where high removal efficiency of dangerous gaseous contaminants is required.

To be called a HEGA, an adsorber must exhibit a minimum contaminant removal efficiency of 99.9% when tested in accordance with the Recommended Practice (RP) of the Institute of Environmental Sciences and Technology (IEST) as outlined in IEST-RP-CC008.2. In addition, the adsorber must be designed, built, and packaged in accordance with the intent of the standard.

It is highly recommended that a HEGA be installed in a housing from the same manufacturer that is specifically designed for sealing and servicing them. Depending on the contaminants that the HEGA will be adsorbing, careful consideration should also be given to whether the housing containing the HEGA is required to be a bag-in/bag-out type of housing to protect personnel when replacing the HEGA.

HEGA Filter Type IV CineSorb

HEGA Filter Type IV-Stainless Steel

Gas-Phase Filtration: AMC Filters

AstroSorb® AMC Filters

The AstroSorb line of chemical filters are designed to remove airborne molecular contamination (AMC) in makeup air units (MAUs), outside air conditioning (OAC) units, fan filter units (FFUs) upstream of HEPA/ULPA filters, in cleanroom ceilings, reticle and wafer stockers, minienvironments, and process equipment. Available in all standard sizes, the AstroSorb filters use proprietary chemical filtration media to target specific AMC or multiple AMC in semiconductor and microelectronic manufacturing cleanrooms.

Product Overview

- Removal of airborne molecular contamination in cleanroom environments
- **Target gases:** ammonia and amines, acids (HF, HCl, Cl_2, NOx, SOx, H_2S), VOCs (toluene, PGME, PGMEA, siloxanes), ozone, and others
- High adsorption capacity and high removal efficiency
- Single or multi-sorbent filters are available
- Constructed of cleanroom-compatible materials that do not emit dopants, metals, organics, or other molecular contaminants at levels that would pose a risk to cleanroom processes
- No particle generation
- Frame options of anodized aluminum, stainless steel, galvanized steel, or corrosion-free, non-metal construction (specific filters)
- Low-pressure drop, energy efficient
- Industry-standard dimensions

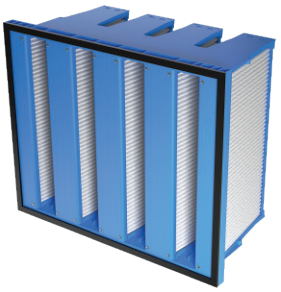
Typical Applications

- Wafer manufacturing
- Semiconductor device fabrication
- Microelectronics component assembly
- TFT/LCD manufacturing
- LTPS OLED manufacturing
- Hard disk drive manufacturing
- Biopharmaceuticals
- Genetic engineering

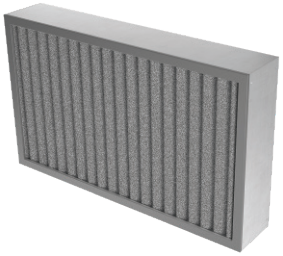
Additional Features

AstroSorb filters are suitable for retrofit into existing installations, for specification into new construction projects, or for direct replacements of competitive AMC filters. Each filter is individually sealed in a polybag to prevent exposure to fugitive gaseous contaminants prior to installation at customer's site.

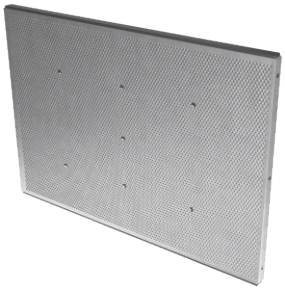
AstroSorb-B
The AstroSorb-B is a box-style chemical filter designed to remove AMC in makeup air units (MAUs) and outside air conditioning (OAC) units.



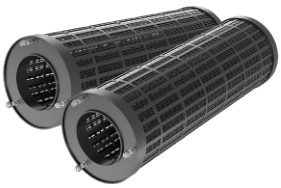
AstroSorb-V
The AstroSorb-V is a V-Bank chemical filter designed to remove AMC in makeup air units (MAUs), recirculating air units (RAUs), or outside air conditioning (OAC) units.



AstroSorb-P
The AstroSorb-P is a panel-style chemical filter designed to remove AMC in fan-filter units (FFUs) upstream of HEPA/ULPA filters, in cleanroom ceilings, reticle and wafer stockers, minienvironments, and process equipment.



AstroSorb-T
The AstroSorb-T is a Tray-type chemical filter designed to remove AMC in makeup air units (MAUs), and outside air conditioning (OAC) units.



AstroSorb-C
The AstroSorb-C is a canister-style chemical filter designed to remove AMC in makeup air units (MAUs) and outside air conditioning (OAC) units.

HEPA & AMC Filtration Utilized in the Microelectronic Industry

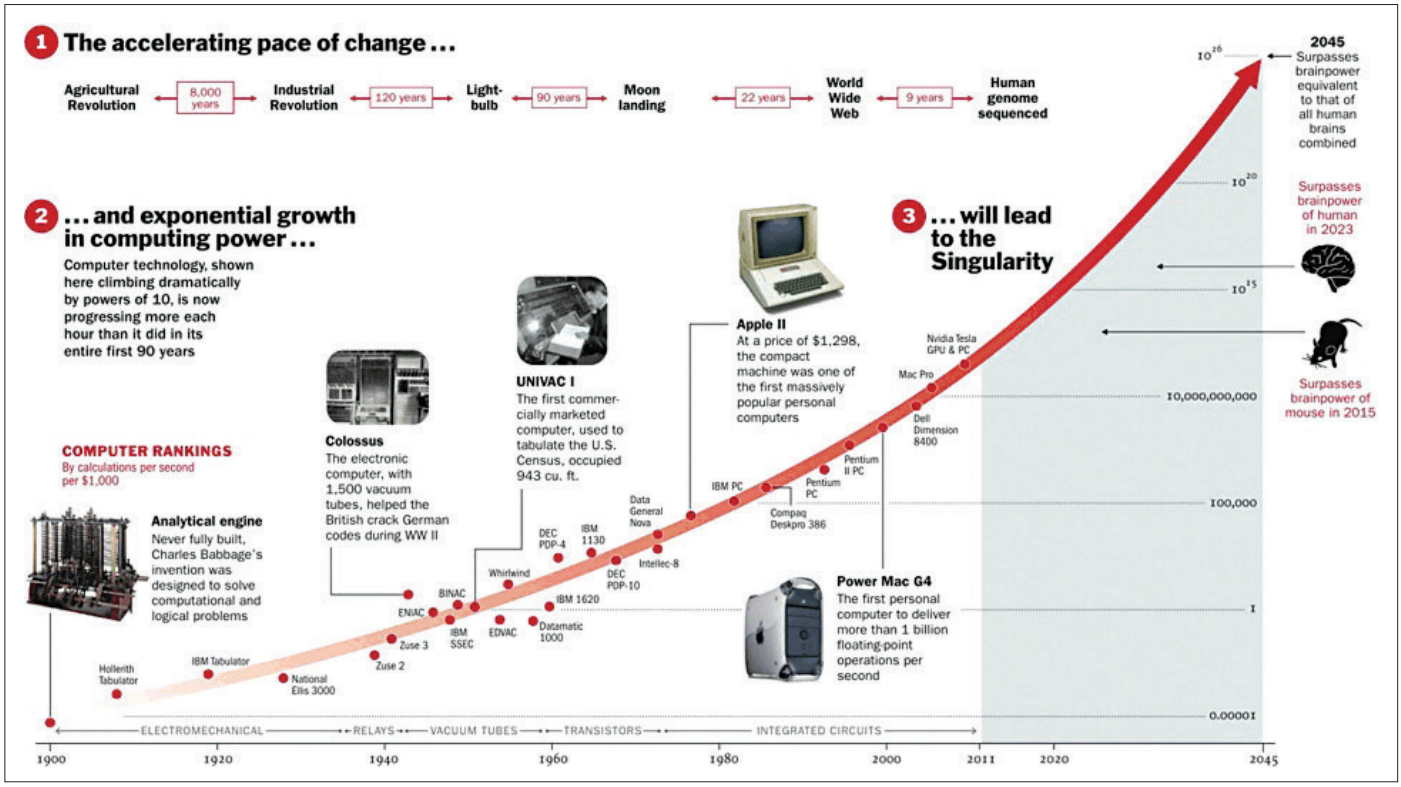
Short history of the Microelectronics Industry and how it has evolved specific to HEPA & AMC Filtration:

During the mid-1990's there was a marked increase in semiconductor demand due to a booming global economy. Increased chip prices, shortened product life cycle for MPUs (Microprocessors), which led Intel among others, the largest manufacturer to introduce chips more frequently to the market. Product innovation had also accelerated, made possible by an increase in Moore's Law, a stylized description of technology that stated the number of electrical components on a chip will double every eighteen months.

As the geometries of the integrated circuits decreased, there was a marked increase in awareness and therefore, demand to reduce not only particulate contamination but Airborne Molecular Contamination (AMC) in the cleanroom. Glass fiber filters, the traditional media utilized in the industry, did not measure up in many applications and the door opened for wider adoption of the PTFE membrane technology.

Motorola (now a SMIC facility) was an early adopter installing over 6000 PTFE filters at their facility in Tianjin, China in 1998. Ironically, the driving factor for the decision to use the membrane technology at the time was the filters excellent mechanical stability and durability.

The End of Moore's Law?



"Moore's law refers to an observation made by Intel co-founder Gordon Moore in 1965. He noticed that the number of transistors per square inch on integrated circuits had doubled every year since their invention. Moore's law predicts that this trend will continue into the foreseeable future."

I think the end of Moore's Law, as I have defined the end, will bring about a golden new era of computer architecture. No longer will architects need to cower at the relentless improvements that they know others will get due to Moore's Law. They will be able to take the time to try new ideas out in silicon, now safe in the knowledge that a conventional computer architecture will not be able to do the same thing in just two or four years in software. And the new things they do may not be about speed. They might be about making computation better in other ways.

Source Unknown

HEPA & AMC Filtration Utilized in the Microelectronic Industry

Protecting and Improving Yield

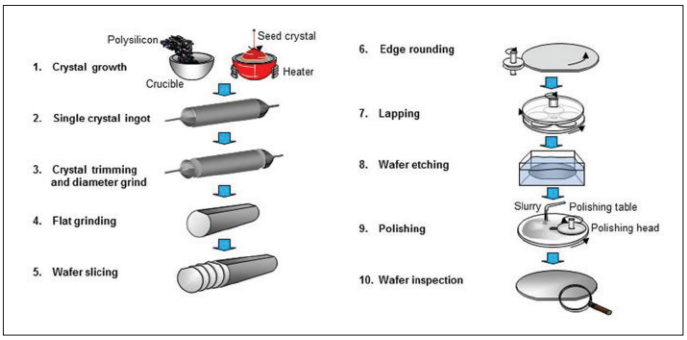
Product yield in simple terms relates to the proportion of finished product compared to the total of products that were scrapped and therefore, contributes to yield loss. Due to the multiple process steps, the risk of contamination and by default increased scrap rate, many of the Wafer manufacturers demanded 'No Boron filters' or a heavily reduced Boron content in traditional glass fiber media. Borosilicate glass fiber will actually increase the contamination in these particular applications when acids from certain process steps (Diffusion) are found to accelerate the release of B3 from the glass fiber filters into the cleanroom.

The traditional glass fiber media paper suppliers quickly developed a 'low Boron media' (LB, typically 8% Boron content by weight) to 'compete' with the membrane technology. Some end users at the time made the cost benefit analysis and chose the lower cost LB glass fiber media often coupled with chemical filters to address their specific applications. AMD in Dresden was one of the first facilities to install low Boron media. Although their original choice was to use the PTFE membrane filters, availability along with manufacturing capability and capacity was low, as demand far outweighed capacity for these filters at the time (circa 1997).

Industry Cleanroom Design Change

The design of cleanrooms for semiconductor facilities also started to change in this period from the traditional ballroom/plenum design to an FFU design. The mass adoption of the FFU (Fan Filter Unit) design which has proven to deliver specific flexibility benefits from an equipment support standpoint, low operating cost with advancement in the EC fan and smart controls technology, and the added benefit a negative plenum delivers from a contamination control standpoint.

Simultaneously, an increase in the use of mini-environments and/or SMIF (Standard Mechanical Interface) took place where widespread installations of the PTFE membrane filters was well underway. The PTFE filters were often combined with multi-layer AMC (Chemical/Carbon) filtration for the most critical process applications.



Wafer Process

Protecting wafers within their own mini-environments or pods/FOUPS (Front Opening Unified Pod) against a growing list of potential contaminants during the manufacturing process vastly improved the yield rate, but also increased operating costs. The PTFE membrane technology became the product of choice, coupled with the Fan Unit due to the lower initial resistance than glass fiber filters and very high filter efficiency at the MPPS. (MPPS of PTFE is typically 70nm). PTFE is installed in the most critical environments while the 'background' contamination level in the cleanroom, although less critical, still has the economic benefits of lower operating costs when utilizing PTFE.

In the 2000's there was a rapid acceptance and increase of installations of PTFE membrane media mainly for the newer manufacturing hubs in Taiwan, Singapore and China. The major investments continued to migrate from the EU/US to the Asia region. The home grown foundries such as TSMC, UMC, and SMIC were now dominating the global manufacturing capacity landscape. Samsung and Global Foundries can be added to the 'Top five' which shows 80% of today's capacity has its origins in Asia.

The early adopters of PTFE who had specific application needs from an AMC or durability standpoint were willing to pay a premium over glass fiber media. The industry in general (Microelectronic Cleanrooms) who were at the more competitive end of the business continued to utilize traditional or low Boron glass fiber technology while continuing to utilize PTFE membrane media for the tools.

The TFT-LCD industry recognized very quickly the benefits outlined associated with the PTFE membrane but were primarily driven by the advantages of lower pressure drop and therefore, lower operating costs due to their extremely high energy consumption.

As the feature size decreased and the wafer size increased, the cost of equipment to support these facilities sky rocketed during this period. A brand new Chip factory could cost over $10 Billion USD and yet have an expected ROI of 3 years. The operating costs were and are huge and the need for flexibility within the production space is vital as the technology is constantly evolving. The constant pressure to reduce cost, improve yield AND develop the next generation technologies drove many suppliers to be at their innovative best especially in the field of improved efficiency and lowest Total Cost of Ownership (TCO). PTFE filters was one of those innovations as pleating and testing capability vastly improved in this decade.

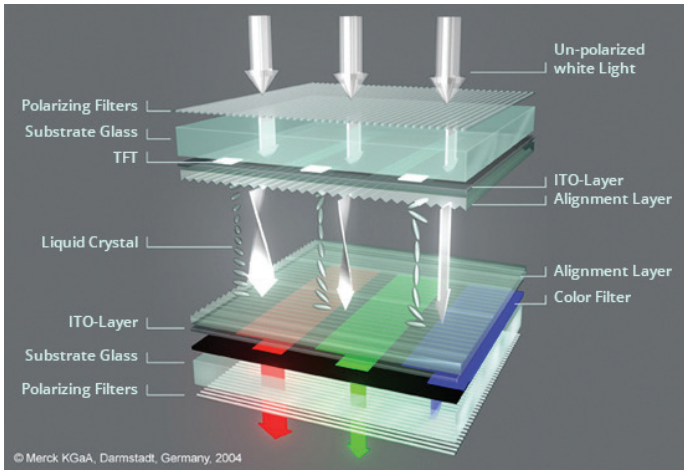
Sustainability and Energy Focus

The energy consumed by some of the larger semiconductor or FPD (Flat Panel Display) facilities is staggering. A typical fab will consume as much power on average of approximately 50,000 homes. The MEGA Fabs or facilities will consume over 100MW or more than an automotive or refinery facility.

Flat Panel Display Assembly

A facility that is producing LCD (Liquid Crystal Display), PDP (Plasma Display Panel), LED (Light Emitting Diode), OLED (Organic Light Emitting Diode) or FED (Field Emission Display) need to maintain critical cleanroom cleanliness levels due to the high risk of contamination during multiple process steps.

Thin Film Transistor, (TFT-LCD) facilities need vast cleanrooms due to the size of the screens now being produced with a typical air cleanliness requirement of ISO 5 with IS0 4 in controlled zones. The large amount of air movement has made the manufacturers pay attention to optimization of the FFU/Controls and filters for these MEGA facilities.



Display Functionality

The initial resistance to airflow for a PTFE membrane filter vs. a Borosilicate glass fiber filter is typically 50% less when comparing the same filter efficiency and filter pack depth. This can represent hundreds of thousands of dollars in reduced operating costs. An additional benefit of the very low resistance of PTFE to airflow is the reduction in pack depth or media area when compared to glass fiber that has added reduced weight benefits and reduction of fan size in certain instances.

A Flat Panel Display (FPD) facility can have ceiling heights of between 10m and 15m. They also normally have much larger areas under filter coverage > 200,000m^2 is not unusual. They typically operate in the ISO 5 to ISO 7 range.

The good news is there is no regulatory requirement driving cleanliness classes or ACH therefore factory owners have aggressively reduced the typical air change rates and average room velocity as mentioned previously during the past twenty years. There are limits to decreases in ACH, filter coverage, and average room velocity based on risk evaluation to exposed product, recovery time, and ability to maintain temperature control.

Cooling

With high internal heat loads (up to 1000 w/m^2) from the process equipment, the equipment must be cooled with sufficient cleanroom ACH or by other sources. The average across the entire space is typically 200-250 W/m^2

Dehumidification

The source of moisture is fresh air and adjacent spaces with no humidity control. Fresh air requirements are based upon minimum requirements to meet building codes, process exhaust, and pressurization.

Economies of Scale

Economies of scale driven by an ever increasing demand for the PTFE membrane filters has reduced the manufacturing cost significantly, allowing the end user to make an easy decision when faced with choosing PTFE or glass fiber especially in microelectronic applications due to the three main benefits previously mentioned.

- Lowest Contamination (When compared to Glass Fiber Media)
- Lowest Operating Cost (When compared to Glass Fiber Media)
- Highest Durability (When compared to Glass Fiber Media)

AMC– ‘the norm’

The control of Airborne Molecular Contamination (AMC) is now the norm in advanced Wafer or FPD facilities. The PTFE membrane technology is also ‘now the norm’ in the most critical process areas.

Most products have a product life cycle. The PTFE membrane technology is no different. Widespread acceptance of the product has reduced manufacturing and sales cost. The last 10 years has seen the price decrease by as much as 50%. PTFE combined with a robust AMC management from the front to the back end of a facility is ‘now the norm’.

The PTFE membrane technology makes excellent technical and commercial sense and is ideally suited to work very effectively in the environmental conditions demanded from the microelectronic industry.

HEPA/ULPA Filter Construction and Testing Options

This table provides a thorough overview of the options available for each of our HEPA and ULPA filters, allowing you to make informed decisions for a given application and configuration. Each feature is denoted as standard (•), optional (Option), or not available ( ).

	MEGAcel® I ME*	MEGAcel® II ME*	MEGAcel® III ME*	MEGAcel® I	MEGAcel® II	MEGAcel® III	AstroCel® I	AstroCel® II
Expanded Membrane Media (ME)	•	•	•					
Expanded Fluororesin Membrane				•	•	•		
Glass Fiber Media							•	•
Hot Melt Separators		•	•		•	•		Option
Dimple Pleat								Option
String Pleat								
Embossed/Close Pleat							Option	
Aluminum Separator	•			•			•	
Vinyl Coated Aluminum Separator	Option			Option			Option	
Plastic Separator	Option			Option			Option	
Stainless Steel Separator	Option			Option			Option	
Urethane Pack to Frame Sealant	•	•	•	•	•	•	•	•
Silicone Sealant							Option	
64 mm to 149 mm Frame Depths		•			•			•
V-Style Packs			•			•		
Gel Seal Filter & Knife Edge	Option	Option	Option	Option	Option	Option	Option	Option
PU-EPDM-Neoprene Gasket	Option	Option	Option	Option	Option	Option	Option	Option
Silicone Gasket							Option	
Painted/Stainless Steel Faceguard	Option	Option		Option	Option		Option	Option
Fabricated Aluminum Frame	Option		Option	Option		Option	Option	Option
Extruded Aluminum Frame	Option	•	Option	Option	•	Option	Option	•
Stainless Steel Frame	Option	Option	Option	Option	Option	Option	Option	Option
Galvaneal/Galvanized Frame	Option		Option	Option		Option	Option	
Particleboard/Plywood Frame	Option			Option			Option	
Plastic Frame	Option			Option			Option	
High Temperature (≥65°C / 149°F)							Option	Option
Factory Testing - Suitable for Common Test Aerosols (Concentration & Equipment Specific) *DOP*, PAO, PSL, DEHS *Nuclear Market Only*	•	•	•	•	•	•	•	•
Field Testing - Suitable for Common Test Aerosols (Concentration & Equipment Specific) PAO, PSL	•	•	•	•	•	•	•	•
EN1822: E10 to U17 (ME H13 to U17 only, Membrane Media H13 and H14 only)	•	•	•	•	•	•	•	•
IEST-RP-CC001: Type A-E, H-K	•	•	•	•	•	•	•	•
IEST-RP-CC001: Type F-G		•						•
UL-900	•	•	•	•	•	•	•	•
ULC-S111	Option	Option	Option	Option	Option	Option	Option	Option
UL-586							Option	Option
FM 4920								Option
Centerboard for PD or Upstream Concentration Measurement		Option			Option			Option

Microelectronic Industry

It has been a long time since the main concern of contamination in a semiconductor cleanroom were from particles. Airborne Molecular Contamination (or AMC) has been one of the major sources of contamination in advanced manufacturing facilities as the geometries on the integrated circuit has continued to shrink.

AMC (Airborne Molecular Contamination) Standards

Definition of the contamination source of AMC (Airborne Molecular Contaminants)

- **SEMI F21-1016**

Semiconductor Equipment and Materials International (SEMI) officially released SEMI F21-95 Standard (1996 Edition), and the revised version of the SEMI F21-1016 Standard (2016 Edition) for Classification of Airborne Molecular Contaminant Levels in Clean Environments. The purpose of this standard is to classify microelectronics clean environments with respect to their molecular (non-particulate) contaminant levels. In the standard, the AMCs are classified into five categories: acids, bases, condensable materials, dopants, and metals.

The magnitude combination of each category produces a classification of the description environment. The name of each category begins with the letter "M", followed by the first capital letter of the category name, A, B, C, D, and M.

		Concentration Grade				
	Material Category	1[#1]	10[#1]	100[#1]	1,000[#1]	10000[#1]
AMC Classification	Acids	MA-1	MA-10	MA-100	MA-1,000	MA-10,000
	Bases	MB-1	MB-10	MB-100	MB-1,000	MB-10,000
	Condensables	MC-1	MC-10	MC-100	MC-1,000	MC-10,000
	Dopants	MD-1	MD-10	MD-100	MD-1,000	MD-10,000
	Metals	MM-1	MM-10	MM-100	MM-1,000	MM-10,000

#1 Concentration, in parts per trillion

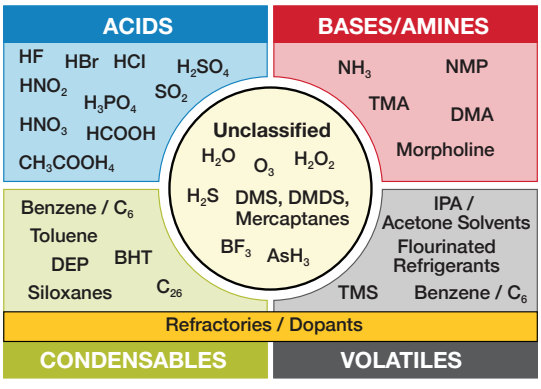
Acid AMC (MA), alkaline AMC (MB), condensable AMC (MC) and dopant AMC (MD)

- **MA:** molecular acids mainly comprise of hydrofluoric acid, hydrochloric acid, sulfuric acid and nitric acids. Acids in clean environment have detrimental effects in semiconductor manufacturing such as thin film defects, high contact resistance, corrosion of metallic films etc
- **MB:** molecular bases mainly comprise of ammonia, amines and amides. Bases in clean environment also have similar negative effects as molecular acids.
- **MC:** molecular condensables include plasticizers, antioxidants, phosphates and silicones. Condensables can cause gate oxide integrity problems, delamination of thin films, and hazing of optics and masks used in lithography tools.
- **MD:** molecular dopants in cleanroom air are a result of reaction of acids with borosilicate glass used in HEPA and ULPA filters. They also originate from the flame retardants such as TEP (triethylphosphate) used in filtration systems.
- **MM:** molecular metals comprise of elements such as Al, W, Mn, etc. that may be by products of reaction chemistries utilized in semiconductor manufacturing. Increasing use of organometallic precursors in processes such as atomic layer deposition (ALD) will likely contribute to increased presence of molecular metals in clean environments.

The name of each category should represent the maximum gas phase concentration, which is expressed as an integer of pptM (pptM $1x10^{-12}$).

- **ISO Standard 14644-8:2022**

This purpose of the ISO 14644-8:2022 Standard is to define and classify cleanrooms and controlled environments based on airborne chemical contaminants that can affect sensitive products and processes. The standard groups these contaminants—such as acids, bases, organics, dopants, and other molecular species—into categories and provides a consistent system for specifying and measuring chemical cleanliness across industries.



Categories of chemical contamination and typical compounds

Airborne - transport pathway of the contamination from the source to the product by convective or diffusive processes in air

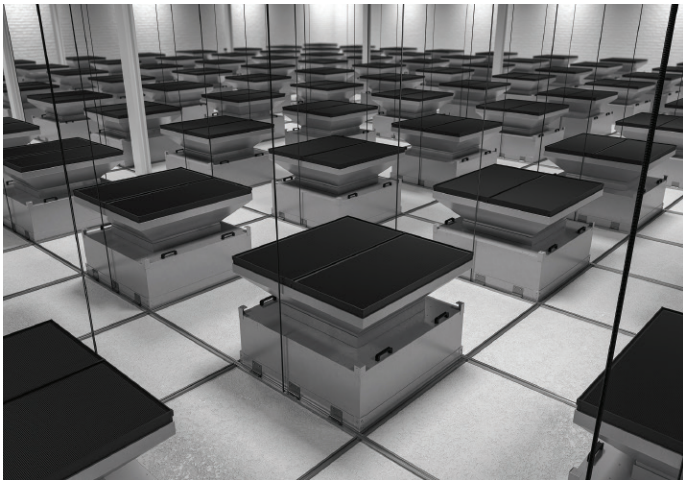
Molecular - contaminant is highly diluted in the air and has no agglomerate characteristic as particles

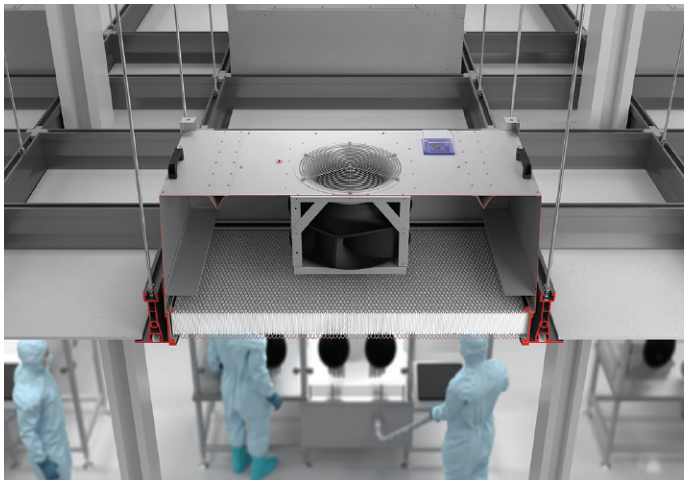
Contamination - compound is of potential damage to the product or production tool in contact with the molecular compound

Source: IONICON

Microelectronic Industry

Category	Contaminant	Source	Adverse Effect	Bad Results	Countermeasure
MA	Acid gas (HF, HCl, H_2SO_4, H_3PO_4, -Cl_2, NOx, SOx)	External air, chemicals in dust-free room, etc.	Commonly contaminated metals, hard disks, wafer surface contamination, chemical photoresist resolution of bad salt particles, Haze phenomenon	Abnormal welding of aluminum/copper wiring, element impedance anomaly	Installation of acid removing chemical filter
MB	Base gas (NH_3, organic amines, ammonia	NH_4OH-H_2O_2 can easily hydrolyze and separate out	Easy to have neutralization reaction with H+ in chemical photoresist	Bad lithography	Installation of alkali removing chemical filter
MC	Condensables: VOCS, Siloxane Gas	Sealant, polymer	Easy to attach to the CVD film on the surface of wafer/ glass, and the occurrence of Haze phenomenon	Abnormal LCD display, foreign body, and defective Gate oxide film with poor voltage withstanding	Installation of VOC removing chemical filter, sealing reagent-free operation outside the dust-free room
MD	Dopant (B, P) boron particle (B_2O_3), BF_3 Gas	Release of boron and HF reaction in the glass fiber filter, release of reaction between BPSG related materials and HF	Wafer surface contamination, impedance change	Abnormal critical voltage	Use an activated carbon filter, or a boron-free HEPA filter





IRDS-International Roadmap for Devices and Systems

IRDS was initiated by five main chip manufacturing areas, Europe, Japan, Korea, Taiwan and the United States. The purpose of IRDS is to ensure the performance improvement of integrated circuit (IC) and IC products based on cost effectiveness, so as to sustain the health and success of the semiconductor industry.

Critical AMC Concentration for the Individual Processes

	Acids		Bases	Sulphur Compounds	Refractory Compounds	Other Corrosive Species	Metals	Dopants	Organics	
IRDS recommended AMC concentrations for advanced technology nodes (update 2017)	**Total Organic Acids**	**Total Inorganic Acids**	**Total Bases**	**Total Sulphur Compounds (organic, inorganic)**	**Total Refractory Compounds**	**Total Corrosive Species**	**Total Metals**	**Total Dopants**	**Volatile Organics with GC MS retention time >= Benzene calibrated to Hexadecane**	**Condensable Organics (boiling point > 150 deg. C)**
AMC examples	Acetic acid, Formic acid, Oxalic acid	HCl, HF, HBr, HNO_3, SO_2, H_2S	Ammonia, NMP, TMAH, Trimethyl-amine	DMS, DMSO, H_2S, Mercaptanes	Siloxanes, Silanol, HMDS, HMDSO, S- and P organic compounds	Cl_2, O_3, F_2, H_2O_2	Cu, Fe, Mg, Na, Ca	BF_3, BCl_3, AsH_3, PH_3, TEP	PGMEA, Ethyllactate, etc	DOP, BHT, etc
AMC sensitive process area/wafer surfaces	**All contaminant concentration in air. Units in ppbV**									
Cleanroom lithography wafer stage & reticle library	2	5	20*	Unrelated	2	Unrelated	Unrelated	Unrelated	26*	Unrelated
Cleanroom lithography - inspection tools stage	2	2	2	Unrelated	TBD	Unrelated	Unrelated	Unrelated	Unrelated	1
Reticle storage inside stocker, inside inspection tool, inside pod, inside exposure tool library	<0.2	<0.2	<0.2	Unrelated	TBD	Unrelated	Unrelated	Unrelated	Unrelated	<0.1
Salicidation (wafer environment, FOUP inside)	5	2	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated
Gate/Furnace area (wafer environment)	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	2	Unrelated
Exposed copper (wafer environment)	0.5	TBD	2	2.5 (1 for H_2S)	Unrelated	1	Unrelated	Unrelated	Unrelated	Unrelated
Exposed copper (inside FOUP)	0.1	0.2(HCl), 5(HF), HBr(TBD), HNO_3(TBD)	TBD	5 (H_2S TBD)	Unrelated	TBD	Unrelated	Unrelated	Unrelated	Unrelated
Exposed aluminum wafer environment (FOUP inside)	TBD	0.1 for HCl, 0.2 for HF, HBr TBD, HNO_3 TBD, total inorganic acids TBD	Unrelated	Unrelated	Unrelated	TBD	Unrelated	Unrelated	Unrelated	Unrelated
AMC sensitive process area/wafer surfaces	**Surface analysis SEMI E45-1101. Units in E+10 atoms/cm2/day**									
Gate/Furnace area (wafer environment)	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	Unrelated	0.5	0.5	Unrelated	Unrelated

**Process tool filter with 99% removal efficiency required.*

TBD = to be determined

Note: AAF recommends to keep cleanroom AMC level on lowest possible level due to area pressure differences.

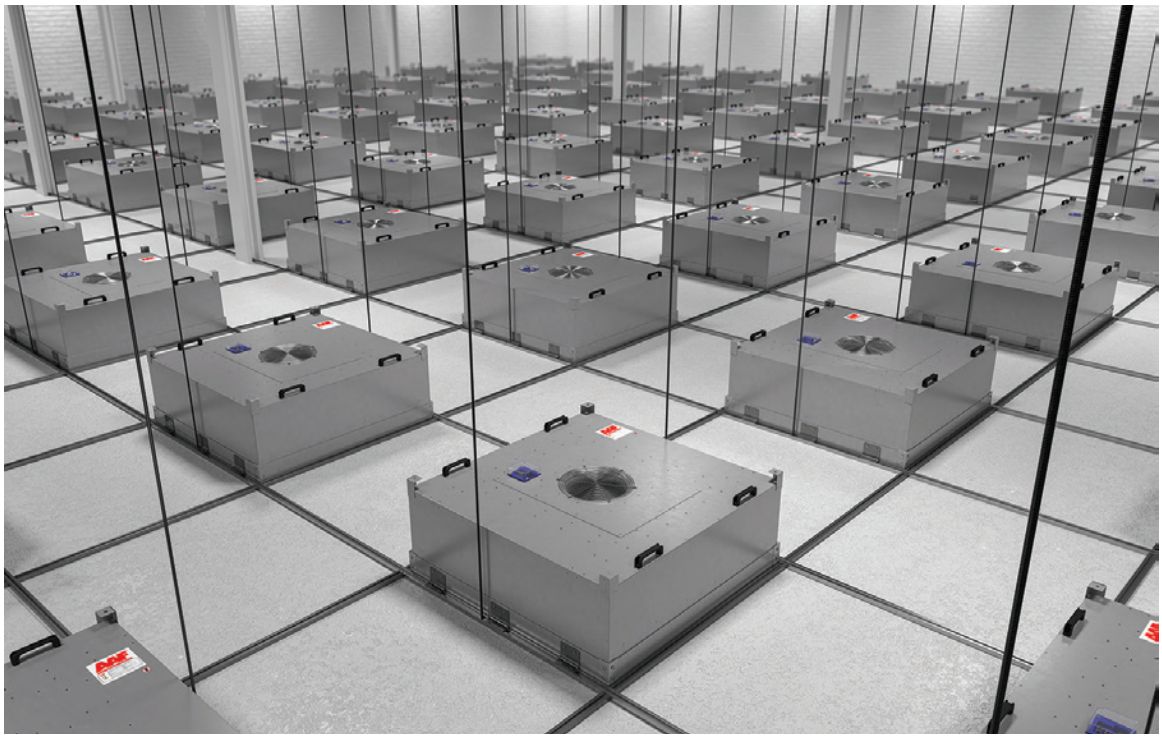
IRDS-International Roadmap for Devices and Systems

Critical AMC, Sources, Effect and Measurement Method

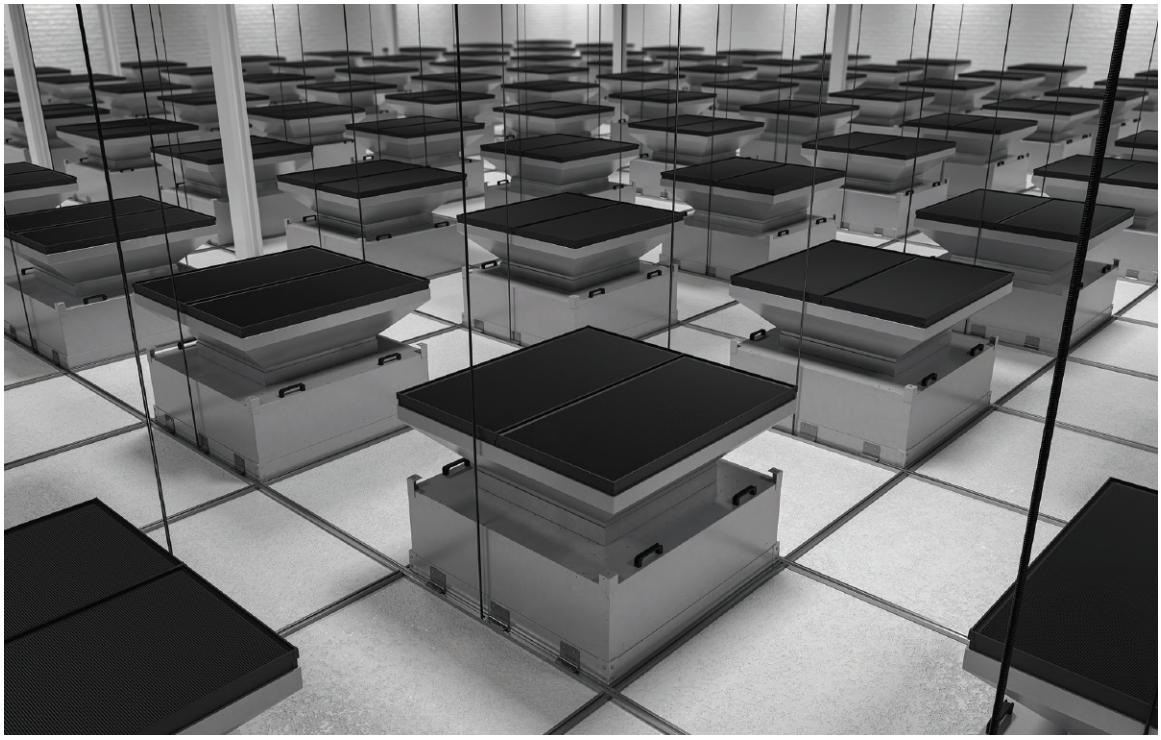
Category	Examples	Source	Adverse Effect	Bad Results	Countermeasure	Analysis Method
Acids	HF, HCl, SO2, CH3COOH, (COOH)2	Process chemical, exhaust cross contamination, outside air	Lens and mask hazing, surface corrosion, haze/particle formation from surface deposited contamination	Yield loss, line corrosion, device failure over time, reliability issues	AMC filter, good exhaust design, proper site selection, proper tool maintenance procedures	Impinger sampling + IC, online monitoring, passive sampling + IC
Bases	Ammonia, Amines, NMP	Process chemical, exhaust cross contamination, outside air, agriculture	Resist issues, surface corrosion, haze/particle formation from surface deposited contamination	Yield loss, line corrosion, device failure over time, reliability issues	AMC filter, good exhaust design, proper site selection, proper tool maintenance procedures	Impinger sampling + IC, online monitoring, passive sampling + IC
Sulfur Compounds	H2S, SO2, Mercaptanes, DMS	Process chemical, exhaust cross contamination, outside air, agriculture	Surface corrosion, hazing	Yield loss, line corrosion, device failure over time, reliability issues, high maintenance and replacement cost	AMC filter, good exhaust design, proper site selection, proper tool maintenance procedures	"UV Fluorescence IMS PTR-MS"
Refractory Compounds	Silanol, Siloxanes, Mercaptanes, HMDS, HMDSO	Process chemical, outside air	Hazing, SiO2, P and S compound deposition	Yield loss, high maintenance and replacement cost	Proper cleanroom system material selection, AMC filter, proper site selection	TD-GC MS, PTR-MS
Other Corrosive Species	Cl2, F2, O3	Process chemical, exhaust cross contamination, outside air	Corrosion	Yield loss, surface and line corrosion, equipment corrosion	AMC filter, proper site selection, proper tool maintenance procedure	IMS / online devices, impinger + IC (some), passive sampling + IC (some)
Metals	Ca, Mg, Na, Cu	Particles, process chemicals	Changing electrical properties, short between lines	Yield loss, line damage, reliability issues	Particle filters, AMC filters, proper tool maintenance procedures	Witness wafer + ICP MS (SEMI E45-1101)
Dopants	BCl3, BF3, PH3, B2H6, AsH3	Process chemicals, by-products from reaction between HF and glass fiber filters	Changing electrical properties, short between lines, surface corrosion	Yield loss, line damage, reliability issues	PTFE filter, AMC filter, proper tool maintenance procedure	PTR-MS, Witness wafer + ICP MS (SEMI E45-1101)
Organics	PGMEA, Ethyllactate, DOP, BHT	Process chemicals, outside air, exhaust cross contamination	Surface deposition of carbon particles, hazing	Yield loss, high maintenance and replacement cost	AMC filter, proper tool maintenance procedure, proper cleanroom system material selection	PTR-MS, TD-GC MS

AstroFan® FFU

Fan Filter Units

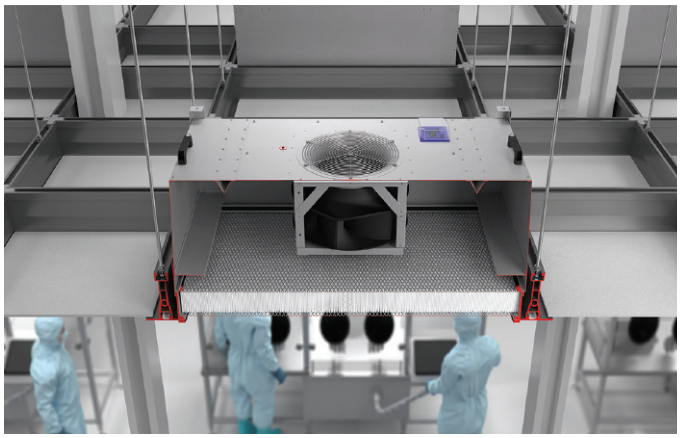


Fan Filter Units with AMC Filtration



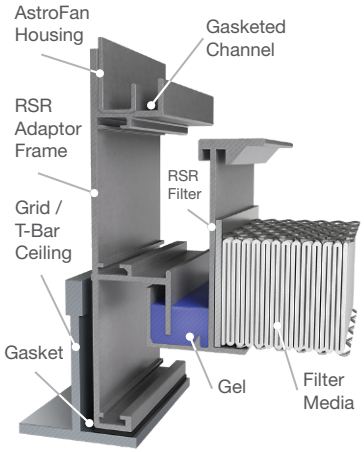
AstroFan® Product Options

AstroFan® FFU



Top or Roomside Access

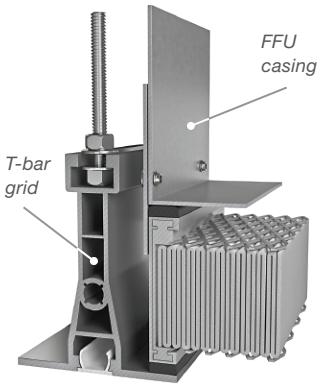
(North America)



Top Side

Top or Roomside Access

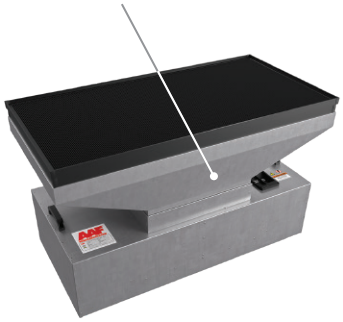
(Asia, China, and Europe)



Top side

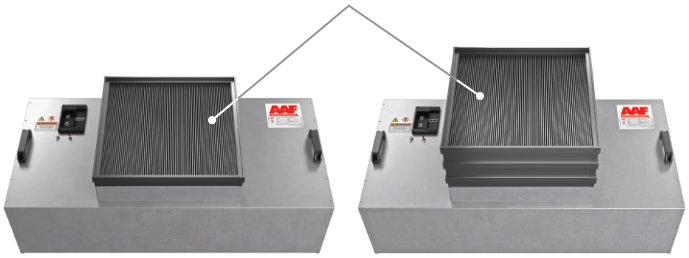
Fan Filter Units with AMC Filtration

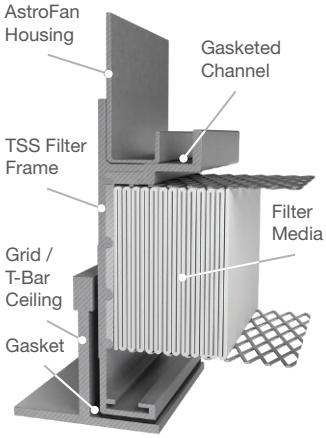
Adaptor plenum for larger AMC filters



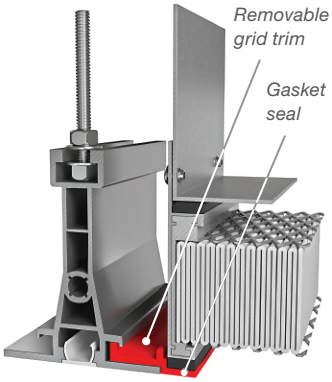
Multiple layer AMC filters

Single/multiple layer standard inlet AMC filters

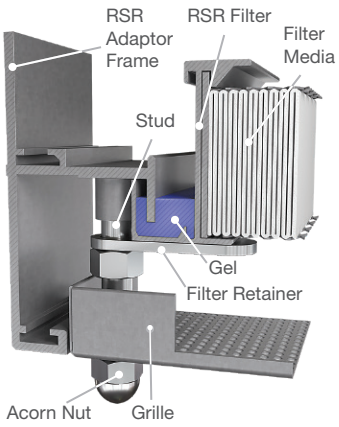




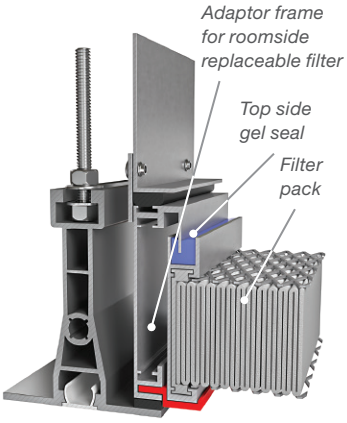
Roomside Change Grid



Roomside Change Grid



Roomside Change Frame



Roomside Change Frame

AstroFan® Product Features

	Product Type	AstroFan A/C	AstroFan E/C	Specification	FAB's
Product Features	Roomside Change (RSC) Filter/Fan	X	Option	Extruded frame & filter with roomside fan adjustment	Ease of maintenance, Limited Height availability
	Top-side Change (TSC) Filter/Fan	√	√	Unit 'lid' guides with gasket/knife-edge filter design	Economical Solution
	MEGAcel ME ULPA	X	Option	Boron free Membrane media	Low Energy Consumption, Boron Free Media, Durability
	MEGAcel ME HEPA	X	√	Boron free Membrane media	Low Energy Consumption, Boron Free, Durability
	MEGAcel	X	Option	Boron free membrane media, PAO compatible aerosol challenge	Low Energy Consumption, PAO Compatible
	AstroCel II HEPA	√	Option	Borosilicate glass media	Traditional established technology
	AstroCel II ULPA	√	Option	Borosilicate glass media	Traditional established technology
	Dry seal filter	√	√	PU, EPDM, Neporene options	Proven solution, lowest cost
	Gel grid ceiling adaptor/filter	X	Option	Urethane/Silicone options	Proven solution, low compression
	Aerosol Injection	X	Option	Validated aerosol distribution steel or tygon design	Point of use testing, minimizes exposure
	Quick disconnect for SP & DOP	X	Option		Secure. Speed of connection
	Prefilter frame	Option	Option	Optimized aluminum frame	Secures prefilter position
	AMC filter frame/adaptor	X	Option	Optimized aluminum frame	Secures AMC filter position
	Particulate prefilter	Option	Option	Pleated design suitable for application	Protects HEPA/ULPA
	Acoustic insulation	X	Option	Rockwool	Decrease sound level
	Stainless Steel Construction	X	Option	Fully welded 304/316 design	No corrosion
	Aluminum Construction	√	√	1.2-2mm design options	Lightweight, cost effective design
	4-way diffuser	X	Option	Extruded painted aluminum	Air distribution by dilution
	Swirl diffuser	X	Option	Extruded painted aluminum	Air distribution by dilution
	Perforated Plate diffuser	X	Option	Stainless Steel/Painted diffuser	Air distribution by displacement
	Filter SP monitoring	√	√	Pressure test port	Ease of PD & integrity measurement
	Direct duct connection spigots	X	Option	Aluminum flanged connection	Ease of installation

AstroDrive™ Control Matrix

	Interfaces and FFU Capability					Most Popular Features					Remote and Auto Control			Extended Features								Advanced Features		
AstroFan®/AstroDrive™ Controls Matrix	Serial Interfaces - LAN Ports	Max # of FFUs	No. of Groups of FFUs	Ethernet	Addressing Capability	Alarm Outputs	Individual / Global Set Speed Control	Communication Alarm	RPM Monitoring	Fan Performance Alarm	Remote Shutdown	Remote Night Setback	Clock Calendar Control	Door Interlocking	Graphical Ceiling Grid Displays	Pressure Switch	UPS	Particle Counter Interface	Constant Air Volume Control	Lighting Control	Exhaust Air Control	Data Logging	BMS Inputs & Outputs	Closed Loop Auto Controls
AstroDrive-PLC-3.5-6-12	1 or 2	1 to 400 per PCL	1 to 50	√	Manual	√	√	√	√	√	√	√	√	Option	6-12 Only	Option	Option	Option	Option	Option	Option	√	√	√
AstroDrive-PC (Using Ethernet Switch & Gateways)		62992	254	√	Automatic	√	√	√	√	√	√	√	√	X	√	Option	Option	X	X	X	X	√	Output Only	√
AstroDrive-I (Sensor based controls approach)		Unlimited	Unlimited	√	Automatic	√	√	√	√	√	√	√	√	√	√	Option	Option	√	√	√	√	√	√	√
AstroDrive-PLC-3.5	1	80	1 to 4	X	Manual	√	√	√	√	√	√	√	√	X	X	Option	X	X	Option	X	X	X	√	√
AstroDrive-MC		1 to 124	1 to 4	X	Manual	X	X	X	X	X	X	X	X	X	X	Option	X	X	X	X	X	X	X	X
AstroDrive-100 (AD-100) Handheld Tool for EBM BUS & MODBUS		1 to 100		√	Manual	X	√	X	√	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
AstroDrive-200 (AD-200) Wall-Mounted Controller for EBM BUS & MODBUS		1 to 100 x 2	1 to 4	√	Manual	√	√	√	√	X	√	X	√	X	X	X	X	X	X	X	X	X	√	√

Biological Safety Levels (BSL)

Biological Safety Levels (BSL) are a series of protections relegated to autoclave-related activities that take place in particular biological labs. They are individual safeguards designed to protect laboratory personnel, as well as the surrounding environment and community.

These levels, which are ranked from one to four, are selected based on the agents or organisms that are being researched or worked on in any given laboratory setting. For example, a basic lab setting specializing in the research of nonlethal agents that pose a minimal potential threat to lab workers and the environment are generally considered **BSL-1**—the lowest biosafety lab level. A specialized research laboratory that deals with potentially deadly infectious agents like Ebola would be designated as **BSL-4**—the highest and most stringent level.

The Centers for Disease Control and Prevention (CDC) sets BSL lab levels as a way of exhibiting specific controls for the containment of microbes and biological agents. Each BSL lab level builds on the previous level—thereby creating layer upon layer of constraints and barriers. These lab levels are determined by the following:

- Risks related to containment
- Severity of infection
- Transmissibility
- Nature of the work conducted
- Origin of the microbe
- Agent in question
- Route of exposure

BSL-1

As the lowest of the four, biosafety level 1 applies to laboratory settings in which personnel work with low-risk microbes that pose little to no threat of infection in healthy adults. An example of a microbe that is typically worked with at a BSL-1 is a nonpathogenic strain of E. coli.

BSL-1 labs also requires immediate decontamination after spills. Infection materials are also decontaminated prior to disposal, generally through the use of an autoclave.

BSL-2

This biosafety level covers laboratories that work with agents associated with human diseases (i.e. pathogenic or infections organisms) that pose a moderate health hazard. Examples of agents typically worked with in a BSL-2 include equine encephalitis viruses and HIV, as well as Staphylococcus aureus (staph infections).

BSL-2 laboratories maintain the same standard microbial practices as BSL-1 labs, but also includes enhanced measures due to the potential risk of the aforementioned microbes. Personnel working in BSL-2 labs are expected to take even greater care to prevent injuries such as cuts and other breaches of the skin, as well as ingestion and mucous membrane exposures.

BSL-3

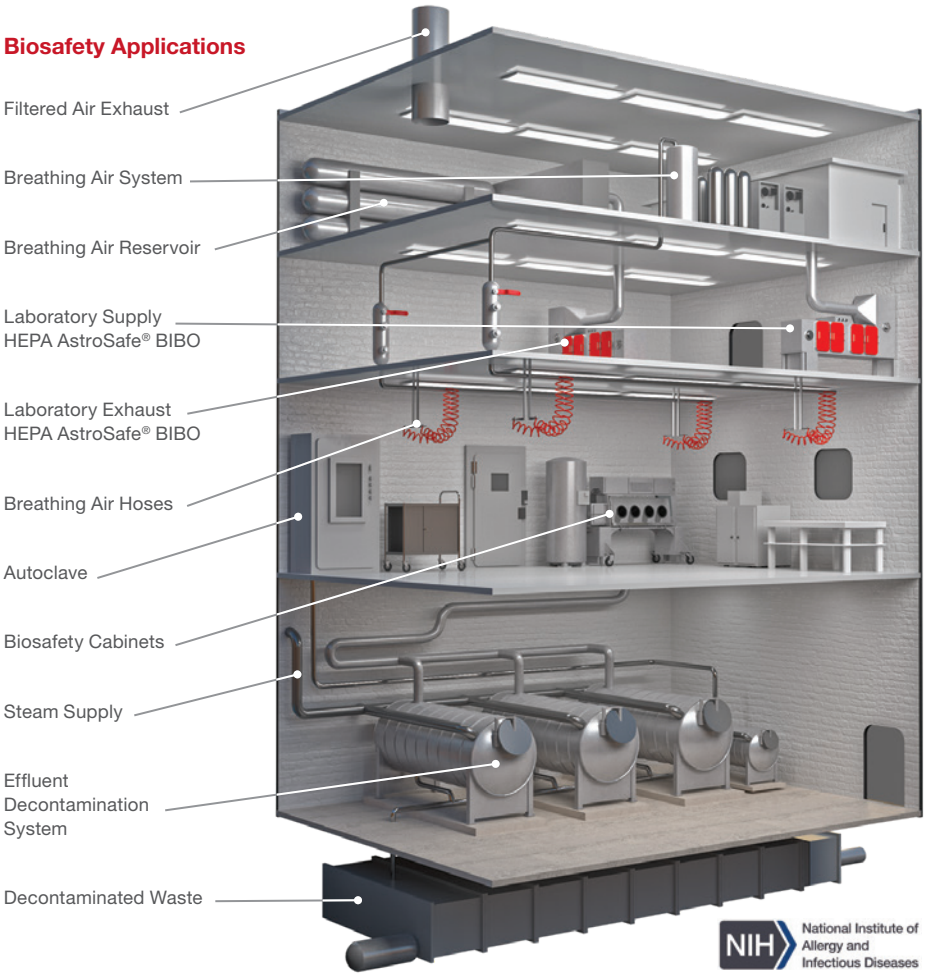
Again building upon the two prior biosafety levels, a BSL-3 laboratory typically includes work on microbes that are either indigenous or exotic, and can cause serious or potentially lethal disease through inhalation. Examples of microbes worked with in a BSL-3 includes; yellow fever, West Nile virus, and the bacteria that causes tuberculosis.

The microbes are so serious that the work is often strictly controlled and registered with the appropriate government agencies. Laboratory personnel are also under medical surveillance and could receive immunizations for microbes they work with. Access to a BSL-3 laboratory is restricted and controlled at all times.

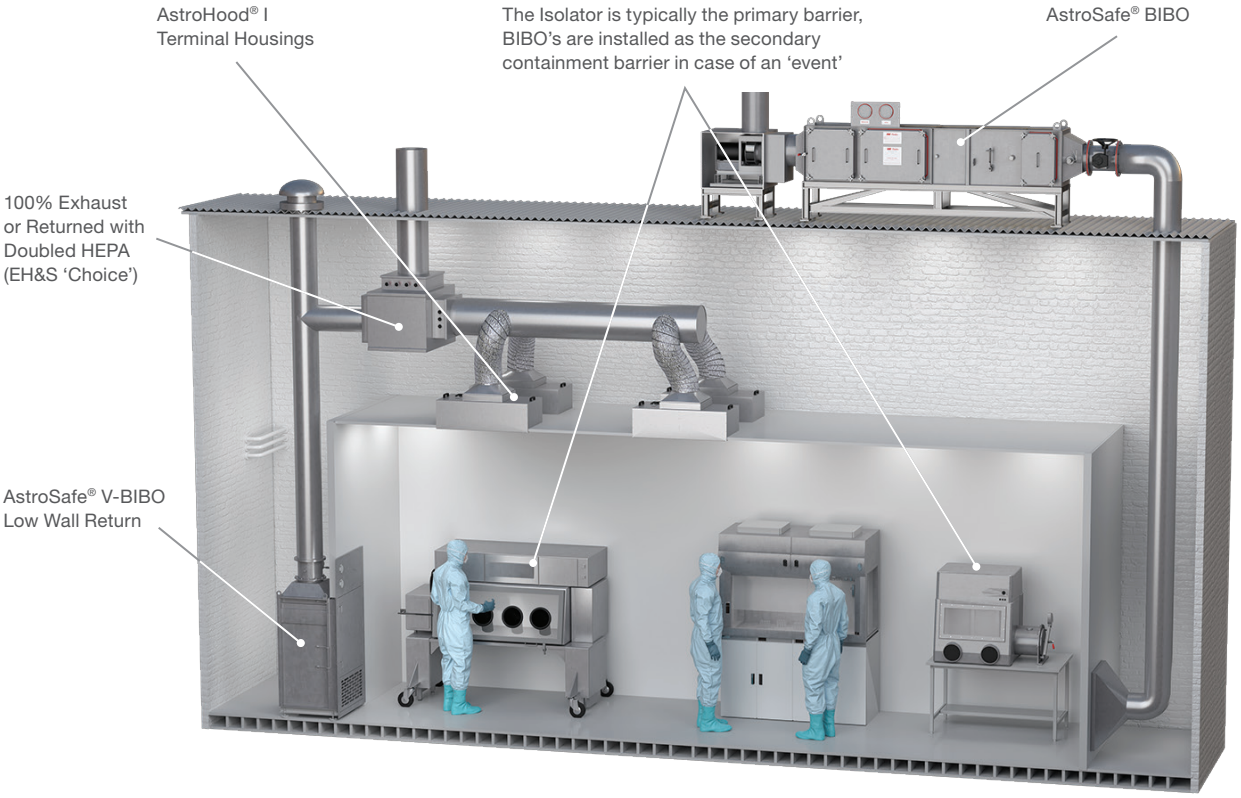
BSL-4

BSL-4 labs are rare. However some do exist in a small number of places in the U.S. and around the world. As the highest level of biological safety, a BSL-4 lab consists of work with highly dangerous and exotic microbes. Infections caused by these types of microbes are frequently fatal, and come without treatment or vaccines. Two examples of such microbes include Ebola and Marburg viruses.

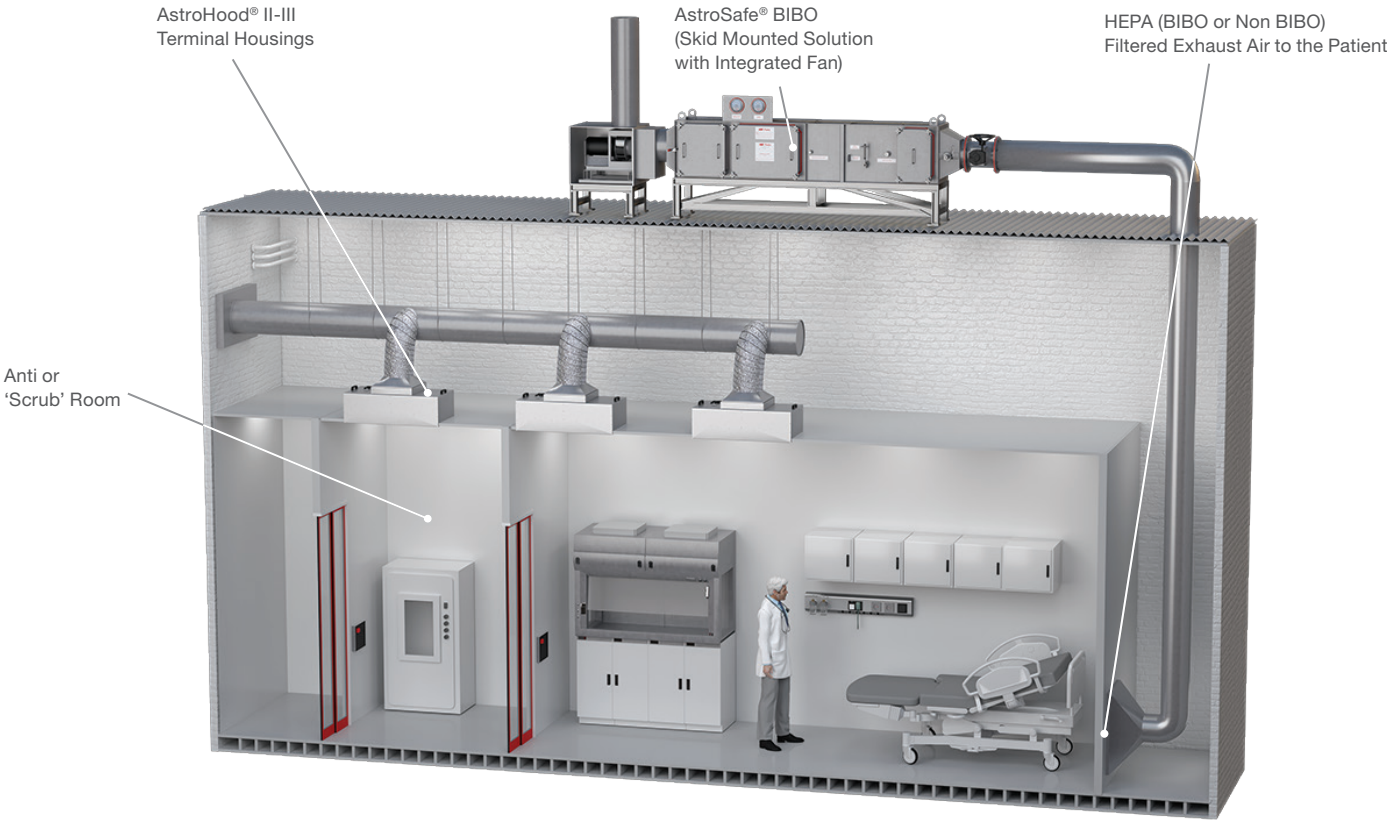
A BSL-4 laboratory is extremely isolated—often located in a separate building or in an isolated and restricted zone of the building. The laboratory also features a dedicated supply and exhaust air, as well as vacuum lines and decontamination systems.



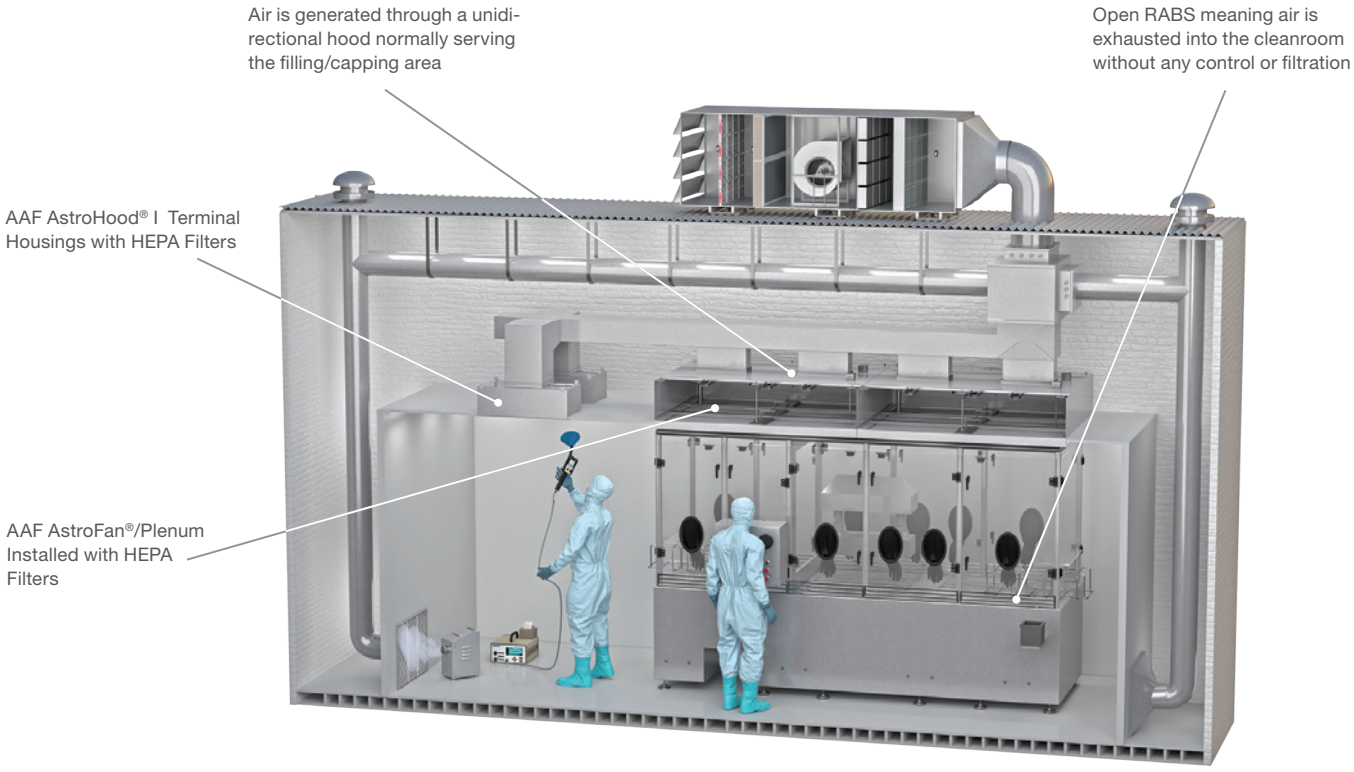
Biosafety: Life Science Applications



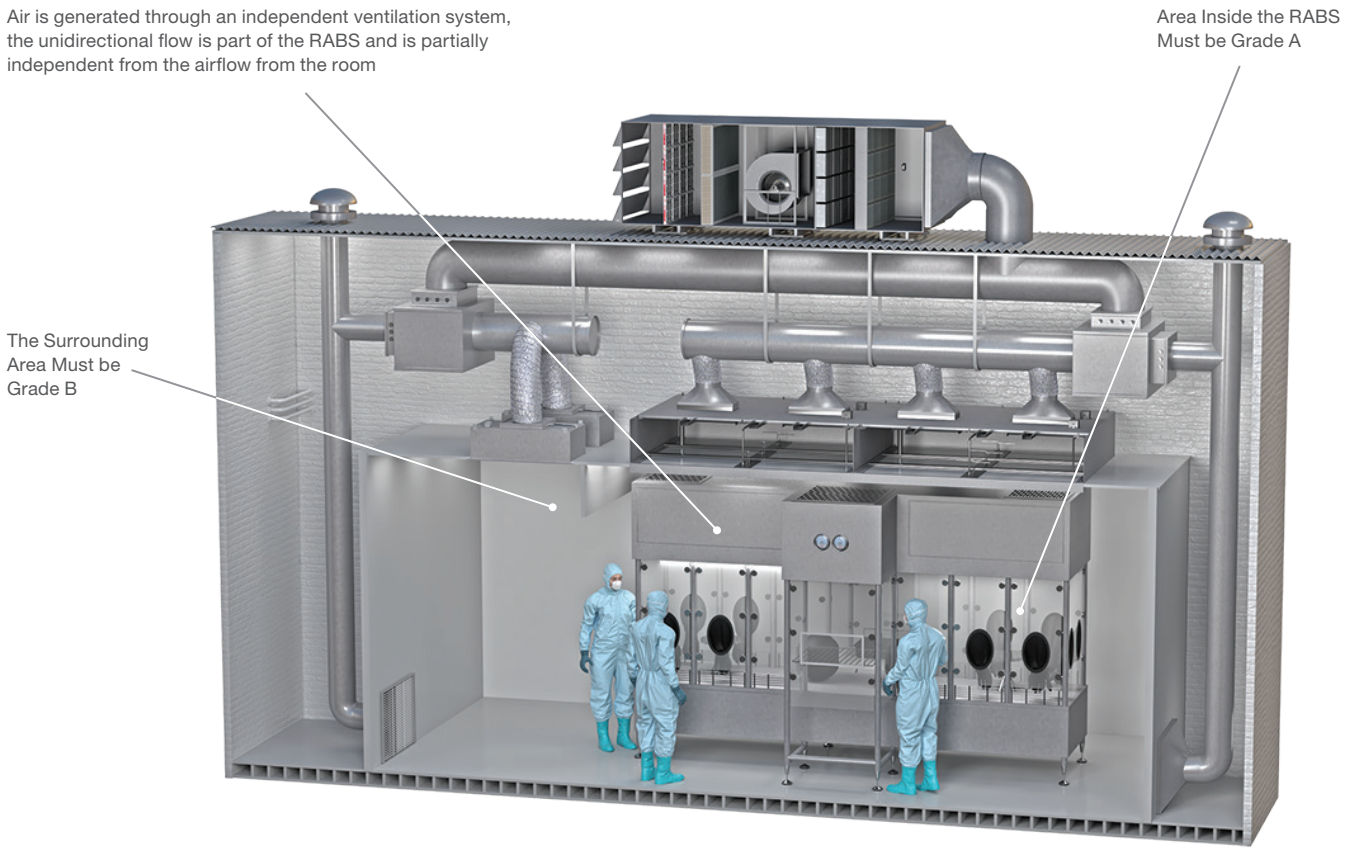
Biosafety: TB Isolation Room



Open Passive RABS



Open Active RABS

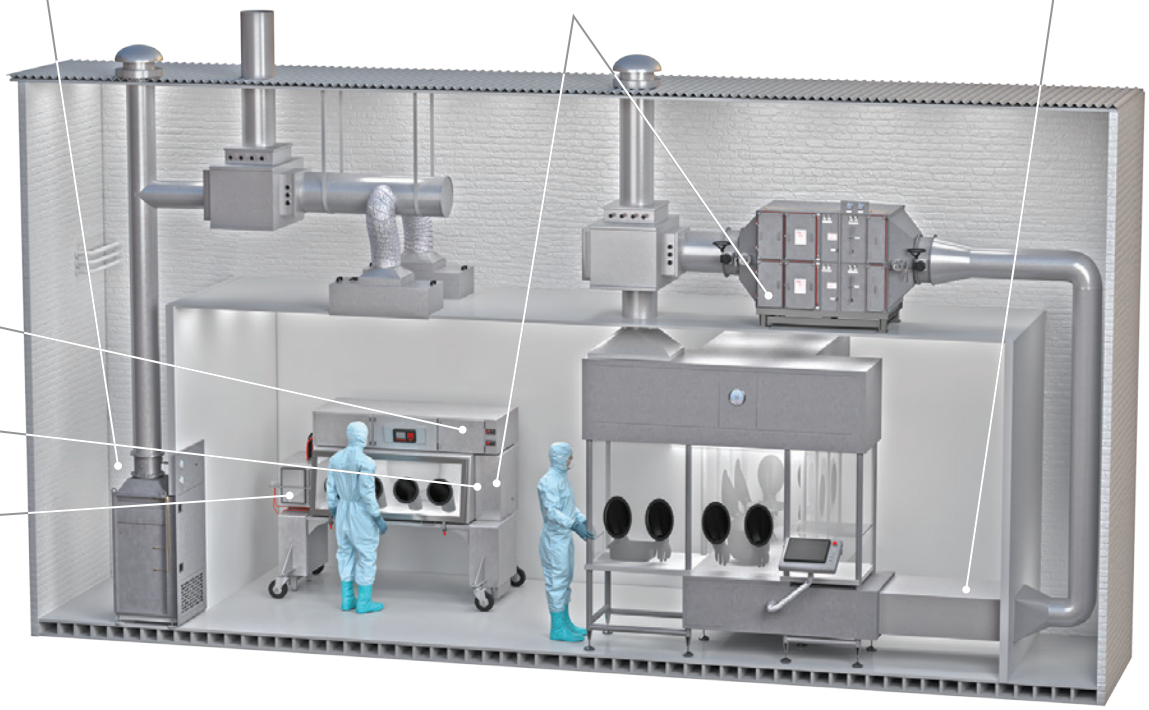


Closed Active RABS

Isolator technology is normally installed in a Grade C area as the primary barrier with AstroSafe® V-BIBO mounted on the low wall returns

The system controls the full airflow (inlet and outlet). It allows for correct pressure control inside the system and therefore could be used for slightly toxic products where AstroSafe® BIBO technology can be utilized in the equipment, plenum, or room

Air is not exhausted into the cleanroom but through recirculated and/or exhausted via a controlled channel



Isolator

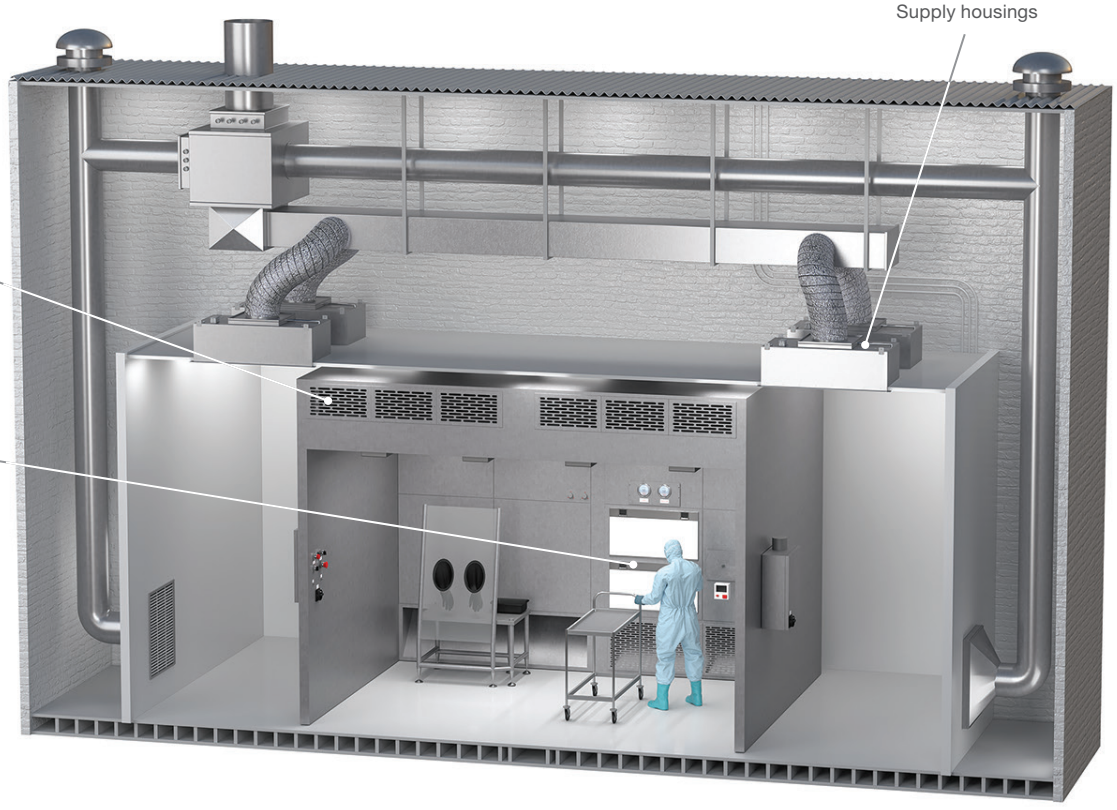
MEGAcel®
HEPA Filters
Improve Aeration
Time

BIBO MEGAcel®
HEPA Filter

Rapid Transfer
Port (RTP)

Downflow Booth

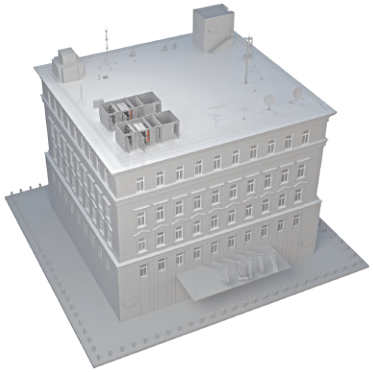
AstroHood® I
Supply housings



Prefilter
inlet before
supply
HEPA Membrar
Media filters

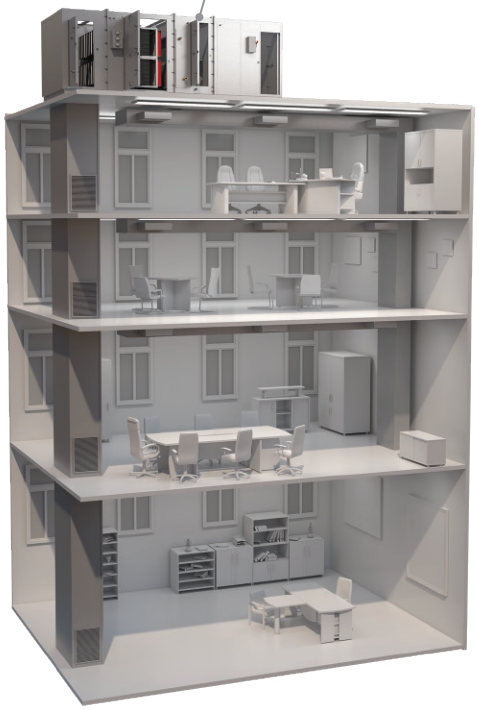
AstroSafe®
BIBO Housing
for recirculating
or exhaust air

Biosafety: Homeland Security



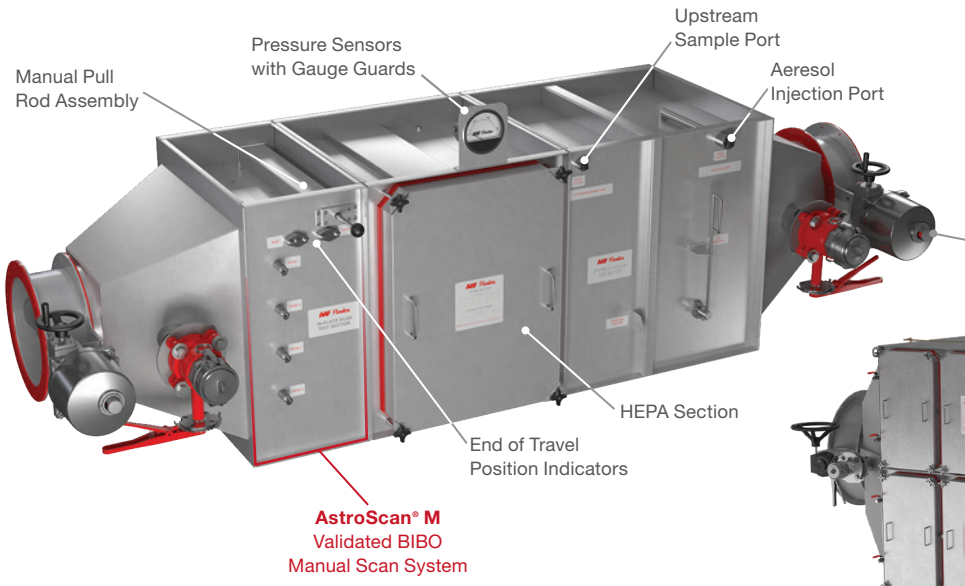
US Embassy, DOD, DOE, etc.
Protection of critical facilities globally

Custom AHU with integrated air filtration system primarily to prevent a Chemical, Biological, and Radiological (CBR) attack for given period



Multiple steps of filtration and framing system with custom designed HEGA & HEPA filters

Biosafety: BIBO ‘Safe Change’ Housings and Scan Systems



AstroSafe™ Containment Units

Containment Filtration

All AAF products are designed, developed, and maintained to exact standards for control of dangerous, toxic, or noxious contaminants. We provide equipment and services for the Department of Energy; the Department of Defense; hospitals; pharmaceutical, genetics, and biotech facilities; universities; and nuclear power and materials processing facilities. We also provide filtration equipment for customers with general ventilation requirements.

Containment systems are high-quality, high-efficiency systems used to filter and contain dangerous particulate and/or gaseous contaminants. In addition to manufacturing standard components, AAF specializes in the design, manufacturing, and testing of complete custom filtration systems. Detailed engineering ensures compatibility and maximum operating efficiency of housings, blower/motor assemblies, dampers, transitions, plenums, test ports, instrumentation, and other equipment.

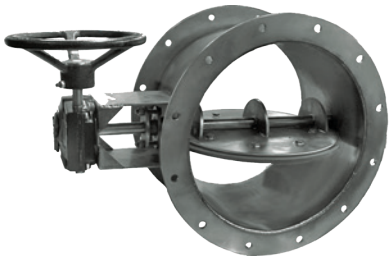
Customized manufacturing of total filtration systems allows AAF to match components accurately to airflow rate and capacity, residence time, and other technical requirements. Installation of the system is also simplified, since a single manufacturer has responsibility from the inlet to the outlet of the system.

AAF manufactures new adsorbers and refills spent adsorbers to meet original equipment specifications. We can also provide in-place testing and radioiodine testing services.

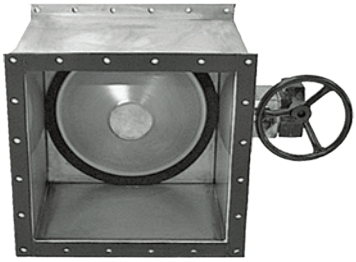
Most AAF customers prefer this single-source, total-systems approach. We are responsible for each component in the system, and can therefore guarantee a reliable, efficient system.

Isolation Dampers

The bubble-tight isolation dampers are our top-of-the-line dampers. These dampers are specifically designed to provide cost-effective isolation of filter banks with high volumes of air. Each bubble-tight damper is leak tested at the factory to ensure a “bubble-tight” seal at a differential pressure of 10 inches water gage. Isolation dampers are available with the standard manual actuator or optional electric or pneumatic actuators.



Round Bubble-Tight Dampers – *Used for isolation of a filter or a filter bank.*



Square Bubble-Tight Damper – *Used for isolation of a filter or filter bank primarily during the filter change-out process.*

In-Place Overall Efficiency Testing

Many filter systems are associated with critical applications. A critical application is one that uses materials that could be harmful to the health of personnel. Regulatory agencies often mandate in-place testing as a prerequisite before the critical filter system becomes operational.

Most installed filter systems are in-place tested per ASME-N510 – Testing of Nuclear Air Treatment Systems and/or AG-1 – Code on Nuclear Air & Gas Treatment. In-place testing determines if there is bypass around the HEPA filters or carbon adsorbers. These in-place testing procedures require that the filter system meets a series of pretests to ensure testability.

Procedures are as follows:

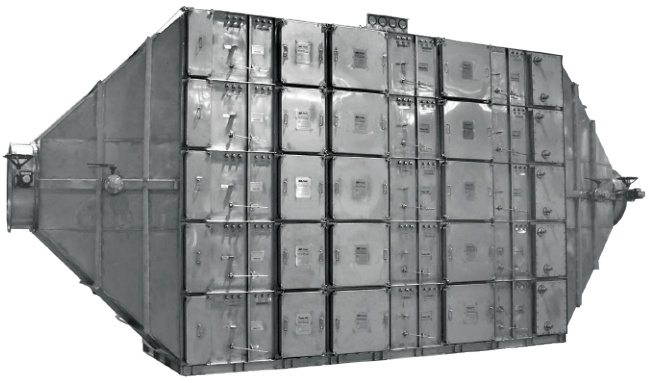
1. After the pretests are completed, a challenge agent is injected upstream of the HEPA filter(s) or carbon adsorber(s).
2. Upstream and downstream concentrations are determined, and a system penetration is calculated.
3. The penetration is compared to the acceptance criteria.

The system either passes and is operational, or it fails and requires corrective action.

AAF manufactures in-place test sections that allow testing to ASME N510 and AG-1 standards when there are space restrictions, or when isolation of a leaking filter is required.

Three types of efficiency test sections are available:

- **Inlet –** Upstream of filter banks to introduce, mix, and sample aerosol or vapor challenge in the airstream for the first bank of filters.
- **Combination –** Middle test sections are designed for systems that have multiple banks of filters. In this location between banks of filters, the test sections will sample the penetrant in the air for the upstream bank of filters and introduce challenge for the downstream bank of filters. Single point sampling is provided for both incoming and exiting air.
- **Outlet –** Downstream test sections provide for single point sampling of penetration of the preceding filter bank.



BF1 System with Prefilters, Test Sections, HEPA Filters, Transitions, Carbon Adsorbers, and Dampers

In-Place Manual Scan

In-place acceptance or surveillance testing of standard HEPA filters, after the filters have been installed, is a common requirement of for users of HEPA filter systems. This in-place testing is necessary to ensure that an installed filtration system meets minimum specified filtering efficiencies.

Many HEPA filter systems are associated with critical applications. However, a filter system can have some penetration and still meet the system acceptance criteria. This penetration may be due to a “pinhole” in the filter media, for example. If a leak is a large one, the filter will have unacceptable gross penetration. But if the leak is small enough, any penetration will be diluted by surrounding clean air, and the leak will remain undetected.

The materials handled in certain laboratories are so hazardous that relying solely on the overall efficiency in-place leak test method may not be sufficient. In such cases, every leak, regardless of size, is unacceptable. The ability to both detect and pinpoint pinhole leaks is therefore essential. Scan testing, utilizing the AstroScan® M validated scan system, can identify pinhole leaks in filters installed within side access filter housings.

***AstroScan M** BIBO Validated Manual Scan System*

Summary of Recommended Biosafety Levels for Infectious Agents

Biological Safety Levels (BSL)	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in healthy adults	Standard microbiological practices	• No primary barriers required • PPE: laboratory coats and gloves; eye, face protection, as needed	Laboratory bench and sink required
2	• Agents associated with human disease • Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure	**BSL-1 practice plus:** • Limited access • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies	**Primary barriers:** • BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials • PPE: laboratory coats, gloves, face and eye protection, as needed	**BSL-1 plus:** Autoclave available
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	**BSL-2 practice plus:** • Controlled access • Decontamination of all waste • Decontamination of laboratory clothing before laundering	**Primary barriers:** • BSCs or other physical containment devices used for all open manipulations of agents • PPE: Protective laboratory clothing, gloves, face, eye and respiratory protection, as needed	**BSL-2 plus:** • Physical separation from access corridors • Self-closing, double-door access • Exhausted air not recirculated • Negative airflow into laboratory • Entry through airlock or anteroom • Hand washing sink near laboratory exit
4	• Dangerous/exotic agents which post high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments • Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level • Related agents with unknown risk of transmission	**BSL-3 practices plus:** • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	**Primary barriers:** All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure suit	**BSL-3 plus:** • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination systems • Other requirements outlined in the text

BSL-4 Positive Pressure Protective Suit (PPPS)

Number of U.S. scientists authorized to work with deadly pathogens: **15,000**

Federal agencies that fund, operate, or work with Biosafety Level-3 or Level-4 labs: **12**

Federal agencies charged with tracking the number and assessing the risks of all Level-3 and Level-4 labs: **0**

AstroSafe® BIBO (Safe Change) Housing with AstroScan M Manual Scan System

NIOSH Occupancy Exposure Levels (OEL)

NIOSH has a banding classification in terms of Occupancy Exposure Levels (OEL). Each of the five occupational exposure bands (OEBs) define a range of exposures expected to protect worker health. Band A has the highest exposure range for the least severe hazards, while Band E has the lowest exposure range.

	Occupational Exposure Band				
	A	**B**	**C**	**D**	**E**
Airborne Target Range for Particulate Concentration (mg/m^3)	> 10 mg/m^3	> 1 to 10 mg/m^3	> 0.1 to 1 mg/m^3	> 0.01 to 0.1 mg/m^3	≤ 0.01 mg/m^3
Airborne Target Range for Gas or Vapor Concentration (ppm)	> 100 ppm	> 10 to 100 ppm	> 1 to 10 ppm	> 0.1 to 1 ppm	≤ 0.1 ppm

Control of Substances Hazardous to Health (COSHH) Classification

Classification of biological agent USUALLY determines minimum containment level required:

Hazard Group 1	Hazard Group 2	Hazard Group 3	Hazard Group 4
Containment Level 1	Containment Level 2	Containment Level 3	Containment Level 4

HG 1: *Unlikely to cause human disease.*

HG 2: *Can cause human disease and may be a risk to employees, but usually has effective prophylaxis or treatment available.*

HG 3: *Can cause severe disease and is a serious hazard, but effective prophylaxis or treatment is typically available.*

HG 4: *Presents the greatest risk to health and the community, with no effective prophylaxis or treatment.*

Health Agency Guidelines

CDC & NIH	NIH	OSHA	DOT, ICAO, and IATA	WHO
• Guidance for designing work areas and labs to the proper Biosafety level	• Research involving Genetically Modified Materials (i.e., Recombinant DNA)	• Bloodborne Pathogen Standards	• Transportation of Hazardous Materials • DOT regulates ALL shipments in the U.S. • ICAO/IATA regulates all International air shipments	• Laboratory Safety Guidelines

CDC: Centers for Disease Control and Prevention
DOT: U.S. Department of Transportation
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
NIH: National Institutes of Health
OSHA: Occupational Safety and Health Administration
WHO: World Health Organization

Occupational Exposure Bands (OEB)

		OEB 1	OEB 2	OEB 3	OEB 4	OEB 5
Property	**Potency (mg)**	> 500	50 – 500	5 – 50	5 – 0.5	< 0.5
	Significant Adverse Effects	**Lowest Concerns** →				**Highest Concerns**
	Acute Oral Toxicity (mg/kg)	> 2000	300 – 2000	50 – 300	5 – 50	< 5
	Repeat-dose Tox (NOAEL: mg/kg/day					
	Rat (28 Day)	> 500	50 – 500	5 – 50	5 – 0.5	< 0.5
	Dog (28 Day)	> 300	30 – 300	3 – 30	3 – 0.3	< 0.3
	Rat (90 Day)	> 200	20 – 200	2 – 20	2 – 0.2	< 0.2
	Dog (90 Day)	> 100	10 – 100	1 – 10	1 – 0.1	< 0.1
	Monkey	> 100	10 – 100	1 – 10	1 – 0.1	< 0.1
	Genotoxicity	Negative	Negative	Ames or Other Single in vitro Geneotox Positive	Cat 3 (R68) Cat 2 (R46)	Cat 1(R46)
	Carcinogenicity	Negative	Negative	Negative	Cat 3 (R40) Cat 2 (R45)	Cat 1(R45)
	Reproductive Toxicity	Negative	Negative	Negative	Cat 3 (R62/63) Cat 2 (R60/61)	Cat 1(R60/61)

		Occupational Exposure Level (OEL)	Occupational Exposure Band (OEB)	Biotherapeutics Occupational Exposure Band (B-OEB) based on ADI
Type	**Potent Compound**	< 10 µg/m³ (0.01 mg/m³)	OEB 4	B-OEB 4 (10-100 ug/day)
	High Potent Compound	< 1 µg/m³ (0.001 mg/m³)	OEB 5	B-OEB 5 (< 10 ug/day)

- Compounds handled within a research environment are "born" as unclassified from an occupational toxicology perspective unless data indicates otherwise. Unclassified compounds are handled as Occupational Exposure Band 4 (OEB 4s).
- This requirement applies to all Laboratories, Vivarium and Clinical Manufacturing activities.

ADI – Allowable Daily Intake

Engineering Features of Biosafety Levels

		BSL-2 Laboratory	BSL-3 Laboratory	ABSL-3 Animal Facility	BSL-3 AG	ABSL-4 Animal Facility
Engineering Features of Biosafety Levels	**Directional Airflow**	●	●	●	●	●
	Double Door Entry		●	●	●	●
	Autoclave Available	●				
	Pass-through Autoclave		●	●	●	●
	Seamless Floors		●	●	●	●
	Monolithic Ceilings		●	●	●	●
	HEPA Filtered Exhaust			●	●	●
	HEPA Filtered Supply				●	●
	Supply/Exhaust Interlock				●	●
	Personnel Shower			●	●	●
	Airlock Entry				●	●
	Pressure Differential				●	●
	HEPA Plumbing Vents				●	●
	Effluent Decontamination				●	●
	Pressure Decay Testing				●	●
	Breathing Air System					●

Source: CUH2A Inc. and Smith Carter Architects & Engineers, Inc.

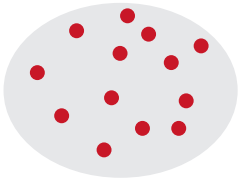
Disinfectant and Sterilization Methods

Antisepsis	A process involving the destruction or inhibition of microorganisms in living tissue thereby limiting or preventing the harmful effects of infection.
Antiseptic	Typically an antiseptic is a chemical agent that is applied to living tissue to kill microbes. Note that not all disinfectants are antiseptics because an antiseptic additionally must not be so harsh that it damages living tissue. Antiseptics are less toxic than disinfectants used on inanimate objects. Due to the lower toxicity, antiseptics can be less active in the destruction of normal and any pathogenic flora present.
Autoclave	An autoclave is a high pressure device used to allow the application of moist heat above the normal-atmosphere boiling point of water.
Biocidal	Active substances and preparations which serve to repel, render harmless or destroy chemically or biologically harmful organisms.
Biocide	Substance or chemical that kills biological organisms.
Decontamination	The killing of organisms or removal of contamination after use, with no quantitative implication, generally referring to procedures for making items safe before disposal.
Disinfectant	A germicide that inactivates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms. They may not be effective against bacterial spores.
Disinfection	A procedure of treatment that eliminates many or all pathogenic microorganisms with the exception of bacterial spores.
Germicide	An agent that destroys microorganisms, particularly pathogenic microorganisms.
Pathogenic	A microbe or other organism that causes disease.
Sanitization	The process of reducing microbial contamination to an acceptable “safe” level. The process of cleaning objects without necessarily going through sterilization.
Steam Sterilization	Autoclave, the process of sterilization by the use of heated steam under pressure to kill vegetative microorganisms and directly exposed spores. Common temperature and pressure for being effective is 121°C (250°F) at 15 psi (pounds per square inch) over pressure for 15 minutes. Special cases may require a variation of the steam temperature and pressure used.
Sterilization	The complete elimination or destruction of all forms of life by a chemical or physical means. This is an absolute not a relative term.

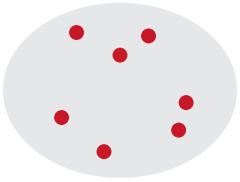
Decontamination Levels and Methods

	Levels
Sterilization	Uses a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.
Disinfection	Uses a liquid chemical to eliminate virtually all pathogenic microorganisms, with the exception of bacterial spores, on work surfaces and equipment. Effectiveness is influenced by the kinds and numbers of organisms, the amount of organic matter, the object to be disinfected, and chemical exposure time, temperature, and concentration.
Antisepsis	Is the application of a liquid antimicrobial chemical to skin or living tissue to inhibit or destroy microorganisms. It includes swabbing an injection site on a person or animal and hand washing with germicidal solutions. Manufacturer recommendations for appropriate use of germicides should always be followed.
Cleaning	Uses water, detergent, and some mechanical action such as scrubbing with a gloved hand or brush. Cleaning is often a required step before sterilization or disinfection of inanimate objects because it removes all material such as soil or organic material and reduces the number of microorganisms on an object.
	Methods
Heat	**Wet heat** is the most dependable method of sterilization. Autoclaving, sometimes called steam sterilization, is the most convenient method of rapidly achieving destruction of all forms of microbial life. Autoclaves use saturated steam under pressure of approximately 15 pounds per square inch to achieve a chamber temperature of at least 250°F (121°C) for a prescribed time—usually 30–60 minutes. Typical uses: Autoclaving is a dependable method of sterilizing laboratory equipment and decontaminating biohazard wastes. **Dry heat** is less efficient than wet heat and requires longer times and/or higher temperatures to achieve sterilization. It is suitable for the destruction of viable organisms on impermeable non-organic surfaces such as glass, but it is not reliable in the presence of shallow layers of organic or inorganic materials which may act as insulation. Typical uses: Sterilization of glassware by dry heat can usually be accomplished at 160°–170°C for periods of 2 to 4 hours. Precautions: Monitor wet and dry heat sterilizers on a regular basis using appropriate biological indicators [spore strips].
Liquid Disinfection	Liquid disinfectants can be generally classified as halogens, acids, alkalis, heavy metal salts, quaternary ammonium compounds, phenolic compounds, aldehydes, ketones, alcohols, and amines. Liquid disinfectant effectiveness varies with the organism, concentration, contact time, and other conditions of use. Select only liquid disinfectants that are confirmed to be effective against the organism(s) present. No liquid disinfectant is equally useful or effective under all conditions and for all viable agents. Typical uses: Liquid disinfectants are used for surface decontamination and, when used in sufficient concentration, as a decontaminate for liquid wastes prior to final disposal in the sanitary sewer. Precautions: The more chemically reactive a compound is, the more likely it is to be toxic and corrosive.
Vapors & Gases	Vapors and gases, when used in closed systems and under controlled conditions of temperature and humidity, provide excellent disinfection. Agents in this category include the aerosol, vapor, or gas phase of **chlorine dioxide**, glutaraldehyde, **paraformaldehyde**, ethylene oxide, peracetic acid, and **hydrogen peroxide**. Typical uses: Vapors and gases are primarily used to decontaminate biosafety cabinets, animal rooms, and their associated systems, bulky or stationary equipment not suited to liquid disinfectants, instruments or optics that might be damaged by other decontamination methods, and rooms, buildings, and associated air-handling systems. **Caution:** Due to their hazardous nature, contact EH&S Biosafety, for special monitoring requirements if these compounds will be used.
Radiation	**Ionizing radiation** will destroy microorganisms but is not a practical tool for laboratory use. **Non-Ionizing:** The UV-C band of ultraviolet (UV) radiation contains wavelengths (250-270 nm, 265 is optimum) that effectively destroy most microorganisms in air and water and on surfaces. Organisms must be directly exposed to the UV light; dirt, dust, and shadows can shield organisms, limiting UV lamp effectiveness. Typical uses: Ultraviolet radiation is typically used to reduce levels of airborne microorganisms and maintain good air hygiene in air locks, animal holding areas, ventilated cabinets, and laboratory rooms. UV is also used in biological safety cabinets (BSC) and in some laboratory rooms to reduce surface contamination. EH&S Biosafety strongly discourages UV lamps in BSCs. See Biosafety Cabinets: Usage Guidelines. Precautions: UV can cause burns to the eyes (photokeratitis) and skin of people exposed for even a short period of time.

Levels of Biological Decontamination



SANITIZATION
Two log – 10^{-2}



DISINFECTION
Five log – 10^{-5}

STERILIZATION
Six log – 10^{-6}

I LOG KILL 90%	2 LOG KILL 99%	3 LOG KILL 99.9%	4 LOG KILL 99.99%	5 LOG KILL 99.999%	6 LOG KILL 99.9999%
100,000 Microorganisms Remain	10,000 Microorganisms Remain	1,000 Microorganisms Remain	100 Microorganisms Remain	10 Microorganisms Remain	≤1 Microorganisms Remain

Aspect	Formalin Vapor	Chlorine Dioxide	Hydrogen Peroxide
Is it Carcinogenic	Yes	No	No
Is it a Genotoxin	Yes	No	No
Permissible Exposure Level (PEL)	0.75 ppm	0.1 ppm	1 ppm
Immediately Damaging to Life & Health (IDLH)	2 ppm	5 ppm	75 ppm
Sealing of the Device (BSC)	Must be airtight	Must be airtight	Some small gaps are OK
Need for People to Leave the Lab	Yes, due to leakage risk	Yes, due to leakage risk	No, people can still work in the lab
Is Room Humidity Control Required	Yes, above 60%	Yes, between 60-80%	No
Residue	Substantial, needs extensive cleaning	Minimal, in the form of NaCl	No residue
Decontamination Time (BSC)	11-17 hours	3-4 hours	3-10 hours

Difference between sterilization & disinfection:

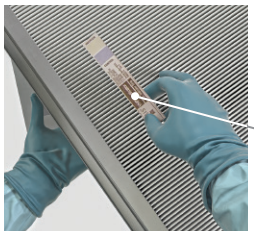
Sterilization: is defined as the process where all the living microorganisms, including bacterial spores are killed.

Disinfection: is the process or elimination of most pathogenic microorganism (excluding bacterial spores) on inanimate (non-living) objects.

Sterilization is an absolute condition while disinfection is not.

Chemical and Biological Indicators

	Biological Indicators (BIs)
Biological Indicators for Sterilization	Sterilization indicators, such as spore strips and indicator tape, enable routine monitoring, qualification, and load monitoring of the steam sterilization process. They indicate whether the conditions during a steam autoclave cycle were adequate to achieve a defined level of microbial inactivation. **Bacterial Spores: Bacillus atrophaeus (BA)- Geobacillus stearothermophilus (GS)**
BI's Use & Applications	Biological Indicators are test systems that contain viable microorganisms with a defined resistance to a specific sterilization process. They help monitor whether the necessary conditions were met to kill a specified number of microorganisms for a given sterilization process. Bacterial spores are some of the toughest microorganisms to kill. Since Geobacillus stearothermophilus spores demonstrate a high resistance toward steam and vaporized hydrogen peroxide, they're used in biological indicators that monitor these sterilization processes, while BIs with Bacillus atrophaeus are used for ethylene oxide (EO) and dry heat applications. A passing result for the BI demonstrates that the sterilizer is effective in killing a large number of highly resistant bacterial spores, providing users with a level of assurance in their sterilization process.
	Chemical Indicators
Chemical Indicators for Sterilization	Chemical indicators are designed to respond to one or more of the physical conditions within the sterilizing chamber. Use them to routinely monitor the process parameters of your sterilization process to ensure that they meet your quality assurance goals. Prevacuum sterilizers. Dry heat sterilization Steam sterilization processes Ethylene oxide (EO) sterilization processes VHP Biodecontamination Units.
CI's Use & Applications	Indicators containing chemicals that are affected by high heat are used to confirm if an item has been subjected to the sterilization process. The indicators contain one or more chemicals that visibly change in color when effectively exposed to specific sterilizing parameters. There are two basic types of chemical indicators. Single-parameter, temperature-specific indicators, which are affected only by heat, and multi-parameter chemical indicators that respond to a combination of conditions, such as time, temperature, moisture, gas concentration, and humidity. Chemical indicators provide immediate verification that items have been processed as soon as they're removed from the sterilizer, making them a key part of any sterility assurance program.

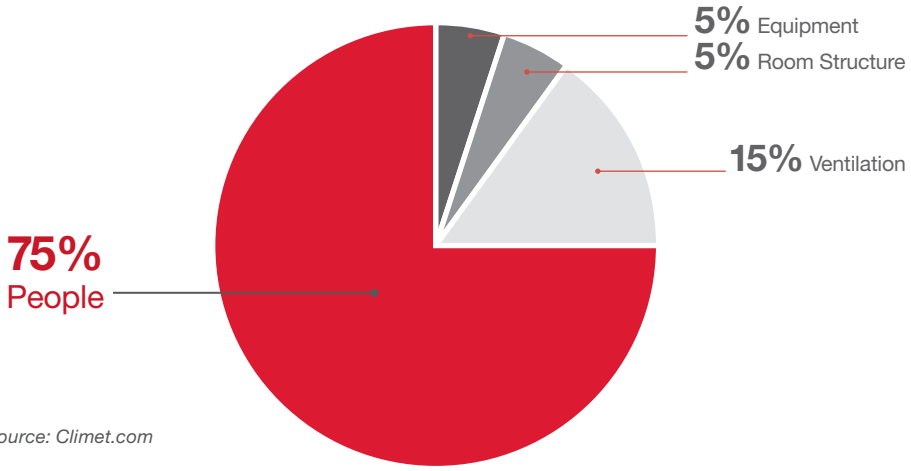


Biological indicators can be placed in multiple area's of the chosen equipment or filter medium

Detergents and Cleaners

Pharmaceutical Detergents and Cleaners	For pharmaceutical, biotechnology, cosmetic, dietary supplement, medical device, and regulated industries. Alkaline-, acidic- and neutral based detergents are available for routine cleaning, derouging, passivation, and removal of organic and inorganic residues.
Glassware Washing and Detergents	Detergents remove particulate and scale, as well as other organic and inorganic residues from laboratory glassware. Mild- to high alkaline formulas are available in addition to phosphoric acid, citric acid and chelate-based detergents.
Cage Washing Detergents	Cage-Klenz® research laboratory detergents remove hard water scale, urine scale, animal fats, oily proteinaceous soils, metal oxides and organic residues. They're available in alkaline and acidic formulas for many animal cage materials, including metals, plastics and glass.
Surface Disinfectants and Cleaners	Sporicides and sterilants for the removal of spores from hard surfaces.

Contamination Sources



Source: Climet.com

Contamination Risk: Particles Created by Movement of People

		Particle/min (>0.5µm)
Type of Movement	**Sitting without moving**	100,000
	Moving hands, arms, head	500,000
	Active hand/arm movement. Fast turning of the head	1,000,000
	Standing up from a sitting position or vice versa	2,500,000
	Rapid movement, climbing stairs, etc.	110,000,000

Source: JJ Napi Liberty Industries 1985

Contamination Risk: Microorganisms

		Potential Contamination Risk
Source	**Outer layer of human skin**	Can host up to $1x10^6$ microorganisms per cm^2
	Human saliva	Can contain up to $1x10^9$ microorganisms per ml
	Nasal wash (healthy person)	Can contain up to $1x10^6$ microorganisms per ml
	Aerosol produced by sneezing (if no barrier, ex. handkerchief is used)	Can contain 1x100,000 microorganisms

Source: Matts Randstorp CCCT

Particle Release Testing

HELMKE Drum Test -IEST RP-CC-003.4

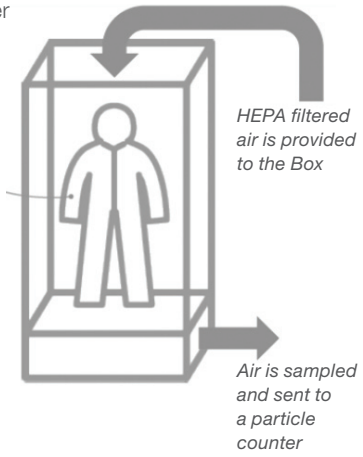
Garment is tumbled in a rotating drum called Helmke Drum. Concentration of particles are counted over a given period by a DPC.

Limitation: Does not simulate real wear conditions, garments may not tumble properly due to stiffness, size or other factors, so fabric swatches are used.

BODYBOX Test -IEST RP-CC-003.4

Simulates particle release under real wear conditions. Test person performs a series of defined movements in a cabin. Concentration of particles are counted by a DPC.

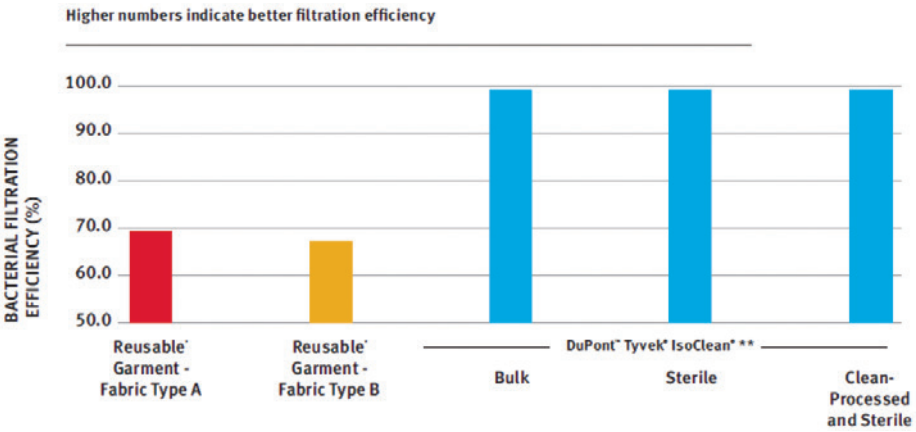
Limitation: Due to high variation in particle generation between individuals, one can only compare relative performance of garment systems if the test person and test parameters are identical.



Source: Dupont Lab Test

Bacterial Efficiency Test

Average Bacterial Filtration Efficiency (%)



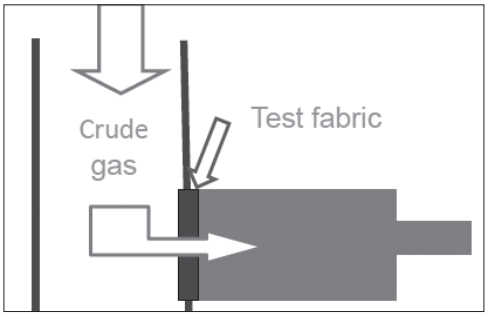
The more operators move (e.g. during cleaning operations), the higher the risk of contamination with microorganisms, the better the bacterial efficiency should be.

Bacterial Filtration Efficiency- ASTM F2101

Measures the ability of the fabric to filter out bacteria (staphylococcus aureus) from a standard aerosol challenge

Particles: Sodium Chloride (NaCl)
Flow Rate: 2.3 l/min

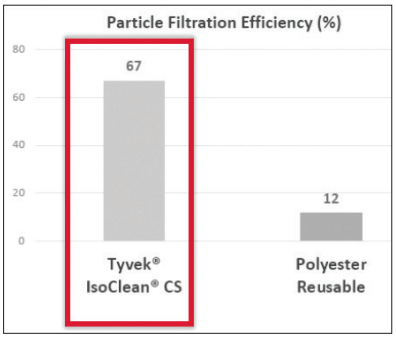
Simulates Filtration of Cleanroom Clothing Fabric



Source: Dupont Lab Test

"Transmitting Factor" is defined for every measured particle size:
(particle concentration of clean gas/particle concentration of crude gas) x 100%

Air is pulled through the test fabric-



Environmental Monitoring

Environmental monitoring and **microbiological** testing play a critical role in ensuring the safety of patients and the efficacy of drugs and biologics by preventing their contamination with microbes. Microbiological testing alone does not provide complete or absolute assurance of absence of microbial contamination.

Bioburden is normally defined as the number of bacteria living on a surface that has not been sterilized. The term is most often used in the context of bioburden testing, also known as microbial limit testing, which is performed on pharmaceutical products and medical products for quality control purposes.

Recommended average limits for microbiological monitoring during operation:

		Air sample cfu/m3	Settle plate (dia. 90mm) cfu/4 hours	Contact plates (dia. 55mm) cfu/plate
Grade	A	<1	<1	<1
	B	10	5	5
	C	100	50	25
	D	200	100	50

Source: EU GMP, Annex A

Microbial Air Sampling

There are two primary methods for microbial air sampling**: Active** and **Passive monitoring**. In **active monitoring**, a microbial **air sampler** is used to force **air** into, or onto its collection medium (e.g., Petri Dish with nutrient agar based test media) over a specified period of time.

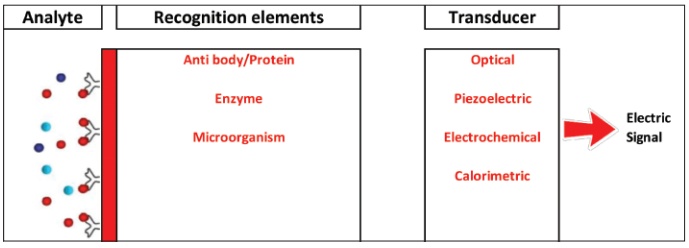
Passive air monitoring is usually performed with **settle plates** (also known as sedimentation plates or settling plates) – standard Petri dishes containing culture media that are exposed to the air for a given time and then incubated to allow visible colonies to develop and be counted.

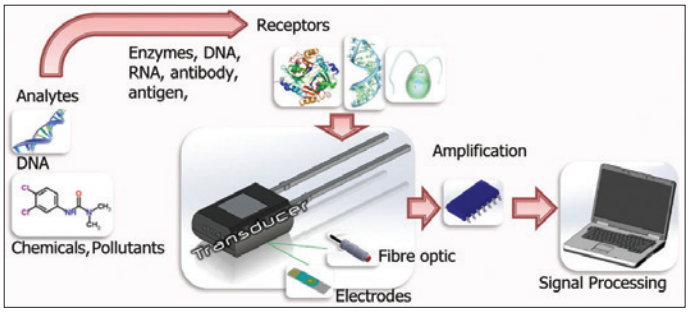
Airborne gases and vapors are collected by a physical process such as diffusion through a static **air** layer or permeation through a membrane. Most **passive samplers** used by health and safety professionals operate on the principle of diffusion; therefore, they are referred to as diffusive **samplers**.

		Type of Data Collected	Data Availability	Typical Averaging Time	Typical Cost $
Instrument Type	Passive Sampler	Manual	After lab analysis	1-30 days	10
	Active Sampler	Manual/Semi-automatic	After lab analysis	24 hrs	1,000
	Continuous Monitors	Automatic continuous	Directly on-line	5 min to 1 hr	10,000
	Remote Monitors	Automatic continuous Path Integrated	Directly on-line	1 min	75,000

Biosensors can give 'instant' results of EM breakthrough in critical spaces.

Biosensors are analytical tools for the analysis of **bio material** samples to gain an understanding of their **bio-composition**, structure and function by converting a biological response into a measurable response.





Industry Trends– Sustainability

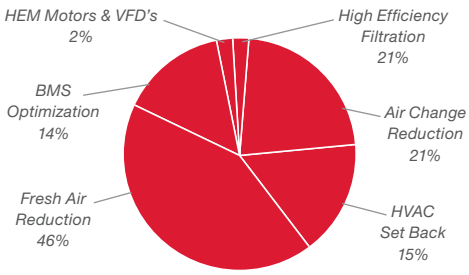
Historic Design Strategy for Air Change Rates

		Grade A	Grade B	Grade C	Grade D	CNC
Big Pharma	A	0.5 m/s (100fpm)	30 acph	20 acph	15 acph	12-20 acph
	B	0.5 m/s (100fpm)	45 acph	25 acph	15 acph	15 acph
	C	0.5 m/s (100fpm)	60 acph	40 acph	25 acph	15-20 acph
	D	0.5 m/s (100fpm)	More than 20 acph	More than 20 acph	More than 10 acph	More than 10 acph
	E	0.45 m/s (90fpm)	40 acph min	20 acph min	20 acph min	
	F	0.45 m/s (90fpm)	40 acph min	25 acph	15-20 acph	10-15 acph
	Trial Work Operational	0.25-0.35 m/s	10 acph	5 acph	5 acph	<5 acph
	Trial Work at Rest	0.15 m/s	10 acph	5 acph	~0 acph	~0 acph

		Opportunity	Potential % Reduction
Facility Type	All	Lower air change rates, fresh air make up reduction, decreased velocity (Grade A) recirc in lieu of once through air	30-45%
	Labs	Reduce fume cupboard capture face velocity, introduce system diversity, convert CAV to VAV	20-30%
	All	Night/Weekend setback	15-20%
	Offices/non-GMP Areas	Night/Weekend shutdown of non-GMP areas	12-18%
	All	Chilled water temperature management and control upgrades	13-15%
	All	Voltage Optimization, Seamless UPS, Energy Storage (Frequency balancing, Peak shaving)	8-12%
	All	Remove obsolete plant due to product changes-BIBO, dehumidifiers, heating, cooling, etc.	10-15%
	Manufacturing/Packaging	Reduction of manufacturing spacial requirements, i.e. enclose temperature/humidty vulnerable products to reduce space volumes	10-15%
	All	Improvement in BMS control strategy-set point control	8-12%
	Manufacturing/Packaging	Improvement in dehumidifier heat recuperation	7-12%
	All	Installation of air filters based on TCOD. Optimize filter efficiency from G4-U15, Selection housings to optimize maintenance efficiency from a replacement and testing standpoint	5-7%
	Warehouses	Air destratification, ventilation improvements, control linked to temperature mapping, eliminate fresh air	5-7%

**Courtesy of EECO2 UK.*

		kWh	$	T.CO2
Description	Air Change Reduction	21%	1,542,011	124,889	1,420
	HVAC Set Back	15%	1,064,285	46,256	134
	Fresh Air Reduction	46%	3,269,197	128,784	131
	BMS Optimization	14%	1,030,960	83,499	950
	HEM Motors & VFD's	2%	126,889	10,277	117
	High Efficiency Filtration	2%	149,150	12,080	137
	Totals	**100%**	**7,182,492**	**405,785**	**2889**
	% of HVAC Totals		42%	40%	46%



What barriers exist today to reducing energy/costs?

- No finance/budget available
- Lack of confidence in savings/cost predictions-Proven M&V
- QA will not agree to any change
- Finding the relevant expertise
- Plant availability/downtime
- 'Too busy'-Lack of focused resource for projects

Real World Room Counts and A/C Rates

Sterile Manufacturing

		Activity	Class CGMP ISO	Validated Status	Specified Air Changes/hr	Specified Particle Counts	Actual Particle Counts	Actual at 0.5µm
Room	1	Airlock	D/8	At Rest	>12/h	0.5µm=3,520,000/m3 5µm=29,000/m3	0.5µm=10,465/m3 5µm=508/m3	Good C/7
	2	Filling	C/7	At Rest	Min 20/h	0.5µm=352,000/m3 5µm=2,900/m3	0.5µm=283/m3 5µm=132/m3	>B/4
	3	Filling	B/5	At Rest	Min 20/h	0.5µm=3,520/m3 5µm=29/m3	0.5µm=218/m3 5µm=0/m3	>B/4
	4	Cleaner Prep Room	B/5	At Rest	Min 20/h	0.5µm=3,520/m3 5µm=29/m3	0.5µm=848/m3 5µm=6/m3	B/5
	5	Exit Airlock	C/7	At Rest	Min 20/h	0.5µm=352,000/m3 5µm=2,900/m3	0.5µm=12768/m3 5µm=102/m3	Good C/6
	6	Entry Airlock	B/5	At Rest	Min 20/h	0.5µm=3,520/m3 5µm=29/m3	0.5µm=19/m3 5µm=0/m3	>B/3
	7	Change Rooms	C/7	At Rest	Min 20/h	0.5µm=352,000/m3 5µm=2,900/m3	0.5µm=7909/m3 5µm=306/m3	Good C/6
	8	Male Store	D/8	At Rest	>12/h	0.5µm=3,520,000/m3 5µm=29,000/m3	0.5µm=12,178/m3 5µm=283/m3	Good C/6
	9	Female Store	D/8	At Rest	>12/h	0.5µm=3,520,000/m3 5µm=29,000/m3	0.5µm=5447/m3 5µm=224/m3	Good C/6
	10	Sterile Corridor	B/5	At Rest	Min 20/h	0.5µm=3,520/m3 5µm=29/m3	0.5µm=2,315/m3 5µm=0/m3	B/5

Medical Device Facility

		Actual-Average Counts 'Operational'	Required ISO Classifications 'At Rest'	Required Counts to Achieve ISO-14644-1 Classification			Actual ISO Classification Achieved OPERATIONAL
	Supply Air AHU	0.5µm		ISO 8	ISO 7	ISO 6	
Room	1	189,747	ISO 8 @ 0.5µm	3,520,000	352,000	35,200	ISO 7
	2	41,867	ISO 8 @ 0.5µm	3,520,000	352,000	35,200	ISO 7
	3	214,558	ISO 8 @ 0.5µm	3,520,000	352,000	35,200	ISO 7

OSD Facility

		Non-Viable Particle Counts (Only 0.5µm measured)			Allowable Counts			Classification Achieved-OPERATIONAL- SOP CGMP-ISO-14644		Comment
	AHU 1	Condition	0.5µm mean	5µm	Class	0.5µm	5µm	0.5µm	5µm	
Room	1	Operational	10,800	X	ISO 9	35,200,000	X	ISO 6	X	3,258 x Cleaner-OPERATIONAL
	2	Operational	13,965	X	ISO 9	35,200,000	X	ISO 6	X	2,520 x Cleaner-OPERATIONAL
	3	Operational	14,679	X	ISO 9	35,200,000	X	ISO 6	X	2,397 x Cleaner-OPERATIONAL

Examples of ‘Big Pharma’ Energy Optimization

		Class	GMP Impact	Optimization Solution						
				Switch-Off HVAC	Reduce AC/HR	Set-back Airflow Out of Hours	Reduce Room Pressure	Temp & % RH Control	$ Saving	Simple Payback
Company	A	CNC & Grade D	Low		Yes	Yes	Yes	Yes	$130k	<1 Year
		New Sterile Facility	High		Yes		Yes		$600k	Capital
	B	Grade D	Low		Yes			Yes	$170k	<6 mths
	C	CNC	Low	Yes					$60k	<6 mths
	D	CNC & Grade D	Low			Yes			$30k	<6 mths
	E	Grade D	Low		Yes		Yes		$25k	<6 mths

**Courtesy of Energy & Carbon UK.*

Load Split on a Typical Life Science Facility

Typical Cleanroom kWh Energy Consumption

		Percentage of Total	Function
Element	Ventilation Fans	60%	Airflow Rate (AC/HR) & Pressurization
	Chillers	5%	Cooling
	Pumps	2.50%	Heating & Cooling
	Air Filtration	30% (F7+HEPA)	Supply Air Quality/Dust Control
	Compressed Air		Pneumatics
	House VAC	2.50%	Cleaning
	Lighting & Small Power		Luminance & Equipment Power

Ventilation/Cooling & Filtration= 97.5% + Associated Heating (Gas/other) / Dehumidification & Humidification= HVAC

WHY?-Large Airflow/Air-Changes/Close Temp & %RH Control

Industry SME's (Subject Matter Experts)

Experience from Industry SME's

- Cleanliness levels within well run and controlled Life Science facilities are generally better than internal or regulatory requirements
- Cleanliness is dependent on multiple factors, containment utilizing applicable clothing, competent operatives, and robust cleaning procedures and practices are often the primary control measures-ventilation becomes a secondary measure
- Airflows and resulting air change rates are generally higher than required
- Number of Supply housings and HEPA filters therefore are often excessive
- Fan power is a high cost and can be significantly reduced
- Risks to product and compliance due to airflow reduction do exist, however with good management and stakeholder support
- QA, these can be resolved or control measures developed to mitigate
- Effective ventilation is key to successful contamination dilution and ventilation effectiveness must be considered as part of any airflow reduction project
- Need to consider the type of environment and risk turbulence may have
- There are still traditional/cultural barriers that exist in the industry
- The regulatory guidance can be misinterpreted both within the regulatory bodies themselves and within the manufacturing facility

Regulatory Position in Life Science Applications

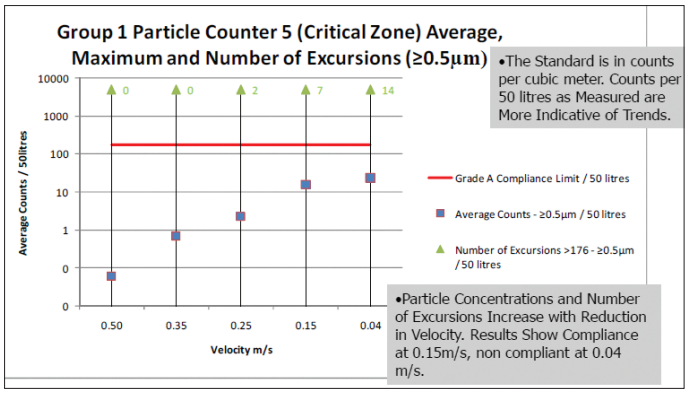
		Regulatory Position
Organization	US FDA	"For Class 100k (ISO 8) supporting rooms, airflow sufficient to achieve at least 20 AC/hr is typically acceptable" "Significantly higher air change rates are normally needed for Class 10k (ISO 7) and Class 100 (ISO 5)
	US Pharmacopea	USP-797-30 AC/hr for compounding-ISO 7, CETA suggests 20 AC/hr for ISO 8, US-1116 (Optional) ISO 5-100 AC/hr, ISO 7-50 AC/hr, ISO 8-20 AC/hr
	EU GMP Annex 1	Air changes not applicable for Grade A UDAF-Velocity and Uniformity applies: Air changes are not specified for non-UDAF zones. Clean up or recovery time is defined: The particle limits given in the table for the 'at rest' state should be achieved after a short 'clean up' period of 15-20 minutes (guidance value) in an unmanned state after completion of operations: This will generally require 20-35 AC/hr depending on the effectiveness of the mixing and dilution. A recovery time test is required to qualify this performance.
	Summary Position	A risk based approach can be taken where key components are validated to ensure product quality and compliance are achieved: Air change rates are not cast in stone!

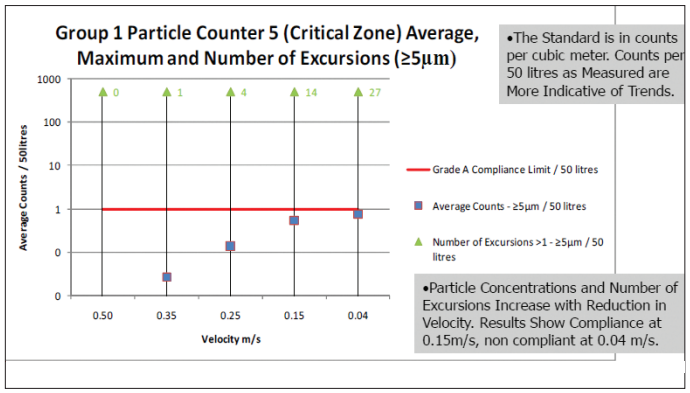
Conclusions

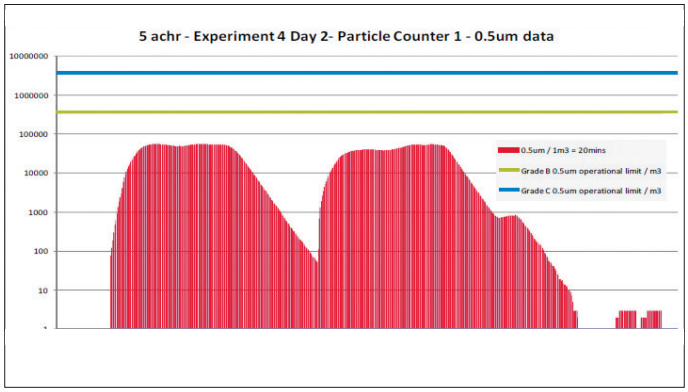
- Life Science facilities generally over-perform therefore wasting valuable energy and money
- Compliance and product quality is dependent on many factors beyond ventilation– people, gowning, cleaning
- Substantial $$$ and CO2 reductions can be achieved by optimizing the cleanroom design from a ventilation standpoint
- Engage all stakeholders from the A&E to Facility Managers, QA of course from the start of the project
- Use vendors who have the experience and understanding, and help optimize the design with minimum risk

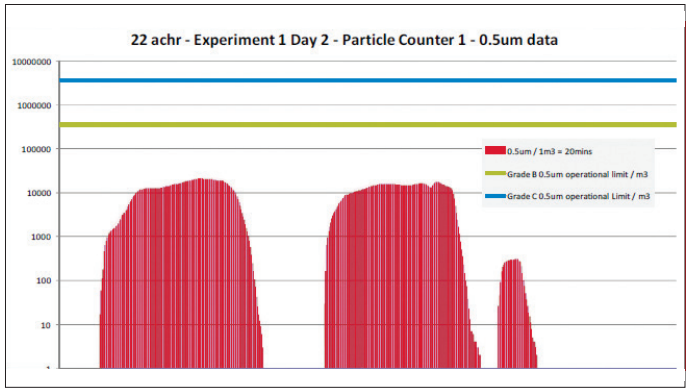
Source: Energy & Carbon UK

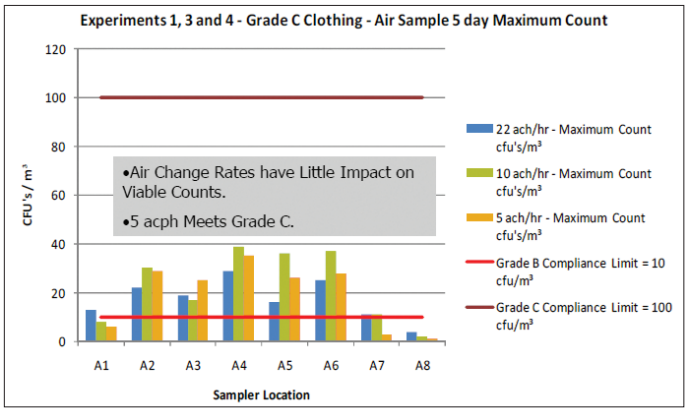
ISPE Case Study

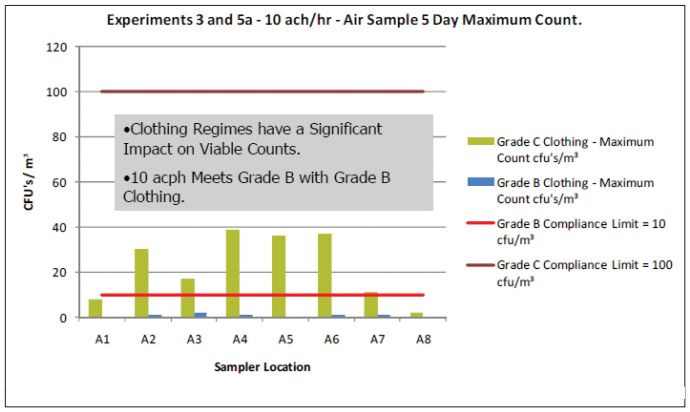


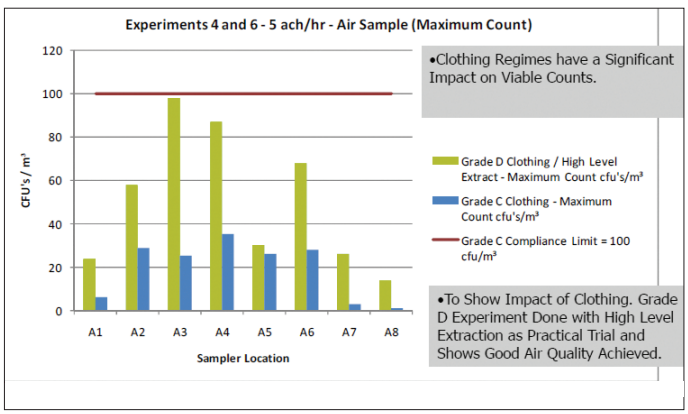












Conclusions

- Air changes have an impact on particle levels but compliance can be achieved at levels significantly below the current norms.
- Clothing standards have a far more significant impact on room cleanliness than Air Change Rates.
- The experiments showed that compliance could be achieved with Grade A at air velocities down to 0.15m/s.
- The trends in particle levels showed that there would be notable Quality concerns at velocities below 0.25m/s.

Source: Stanway/Third ISPE Dallas 2011

AAF VisionAir™ Clean with TCO Diagnostics® Software

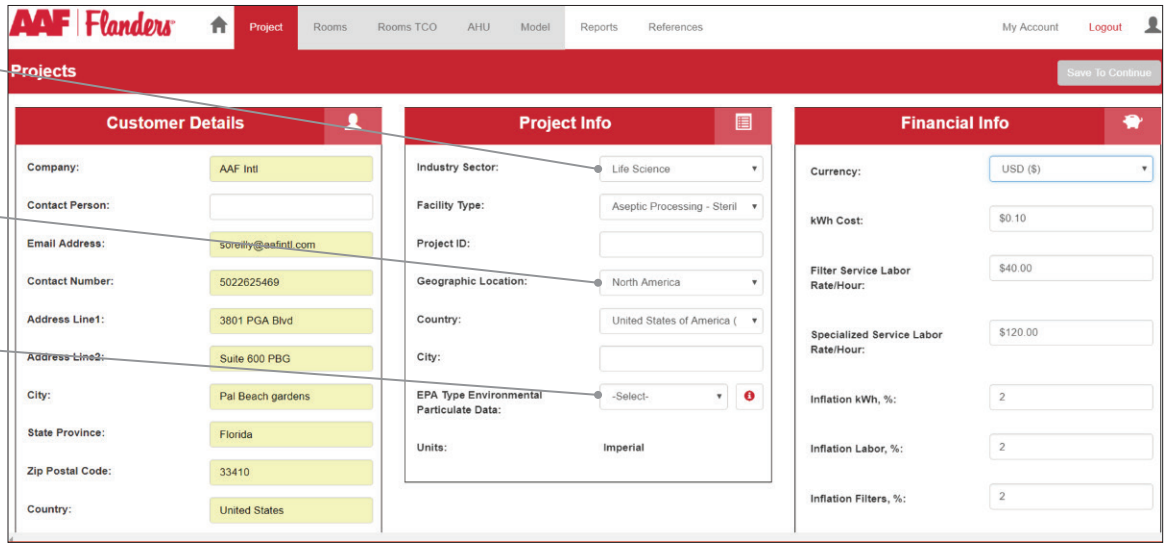
A revolutionary new cleanroom design and air filter selection program designed specifically with energy optimization in mind.

- High Purity Filtration Selection and Design Software for multiple market segment applications
- Air Change Rate Selection– make science based decisions to deliver optimum cleanroom efficiency
- Calculate multiple rooms for a cross functional facility. Greenfield and existing facility design considerations built into the software
- TCO Calculations for ALL stages of filtration and housing selection reports
- Generate detailed recovery time and air change rate optimization reports
- Generate latest industry specifications with Revit drawings for BIM Models
- Technical library– access latest industry standards and International guidelines

Industry sector options for Life Science (14 different cleanroom applications per ISPE HVAC Guidelines)

Global regions selection, languages, currency and units (metric/imperial)

EPA-ISO 16890 referenced outside air contamination concentrations data



Filter class selection to see impact on downstream cleanliness levels/recovery time

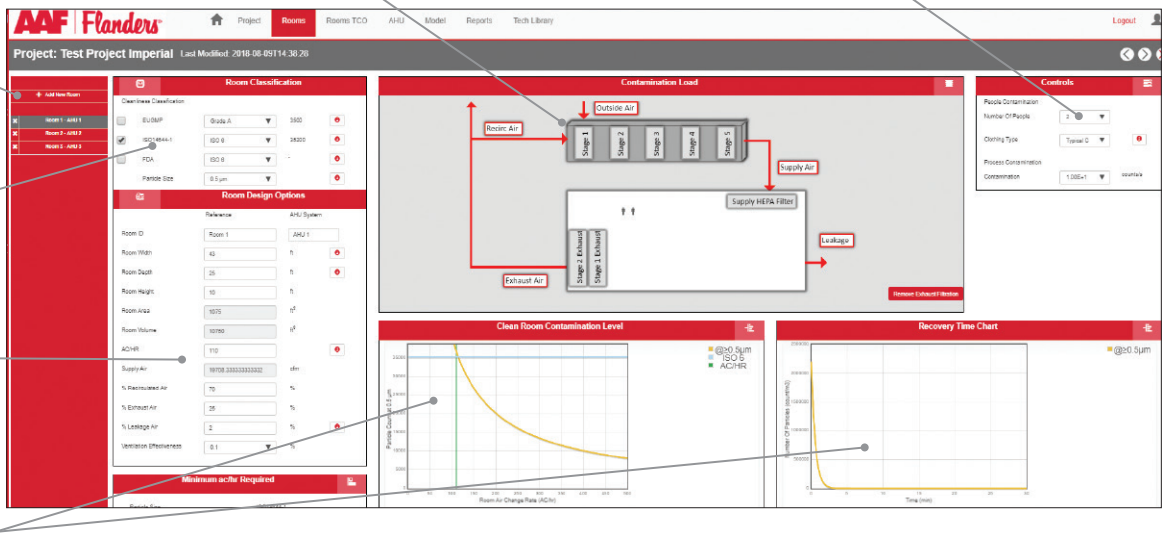
Contamination source inputs from people and the process

Multiple room calculation options (First time, add rooms off 1 AHU)

Cleanroom classification options, EU GMP, ISO, FDA

Contamination levels and A/C rate minimum calculations to meet target room classification and optimized design comparison

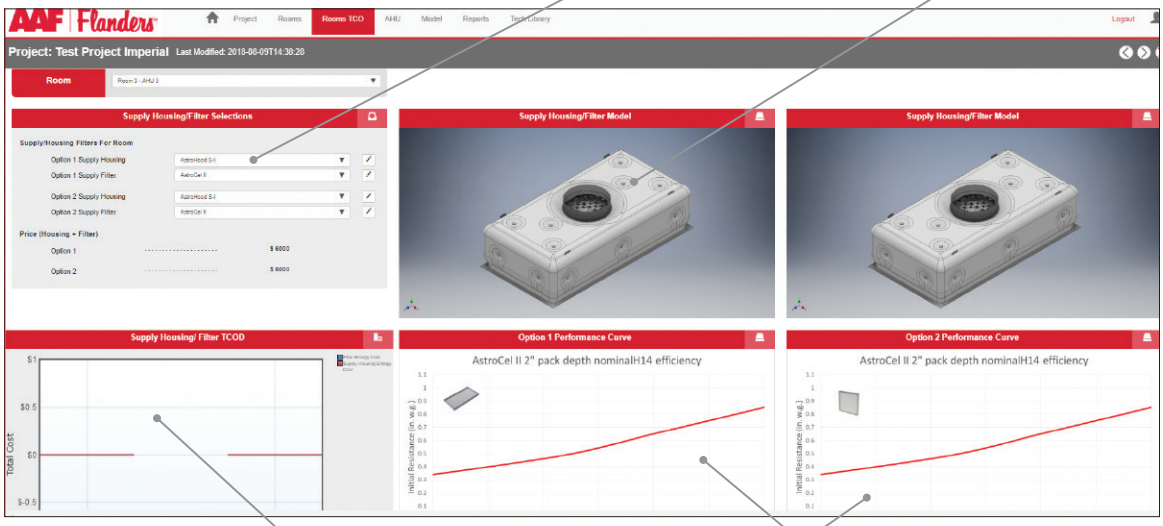
Room recovery calculation-contamination level vs. time



AAF VisionAir™ Clean with TCO Diagnostics® Software

Housing (AstroHood® I-III) and Filter (Membrane vs. Glass) comparison selection options

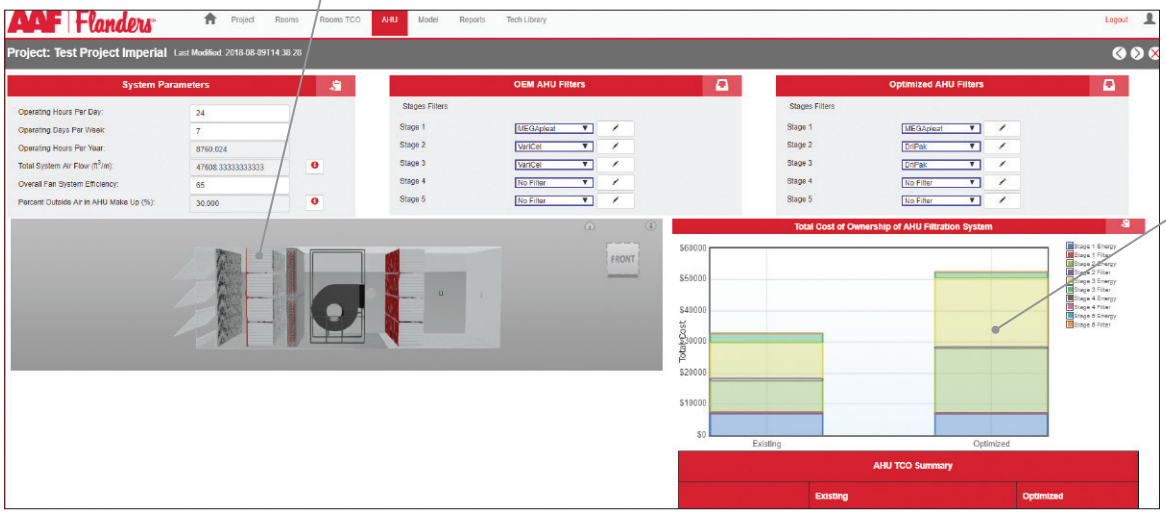
3D dynamic image of product selection



TCO calculation on Housing and Filter (damper/'system' resistance)

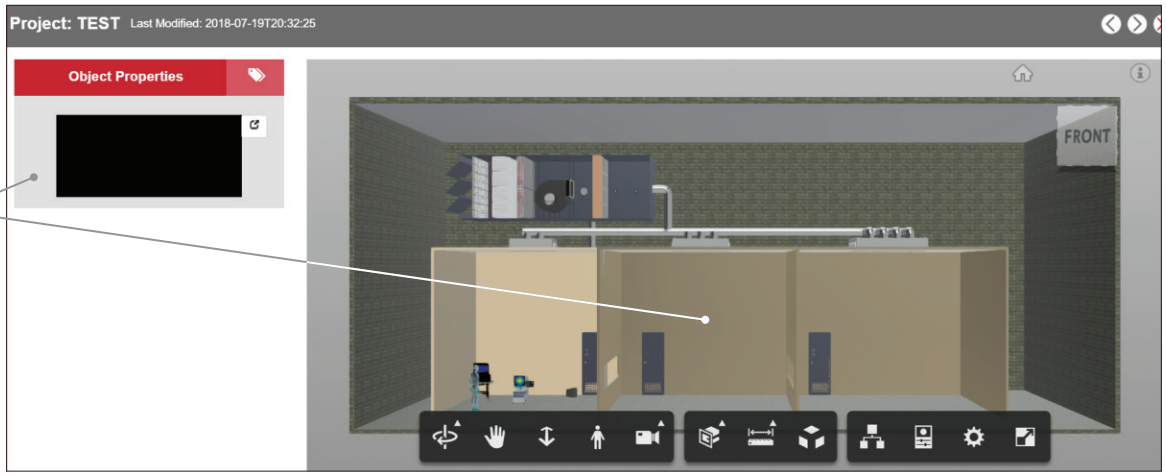
HEPA performance curve comparisons

3D dynamic animation of filter selection

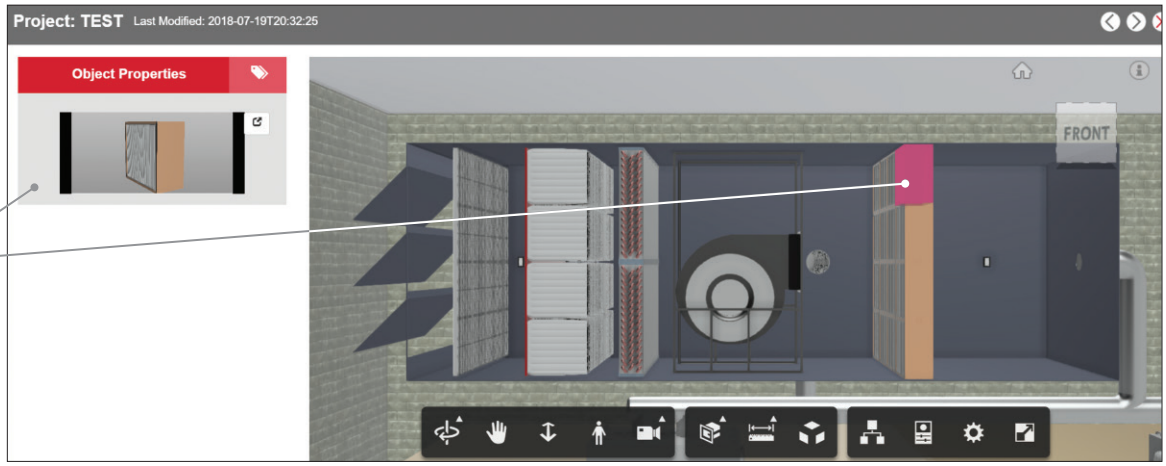


TCOD optimized design calculations for AHU filters

AHU/Cleanroom (multiple) design layout with ‘zoom in/out’ capability and CAD view of product features/benefits/ functionality

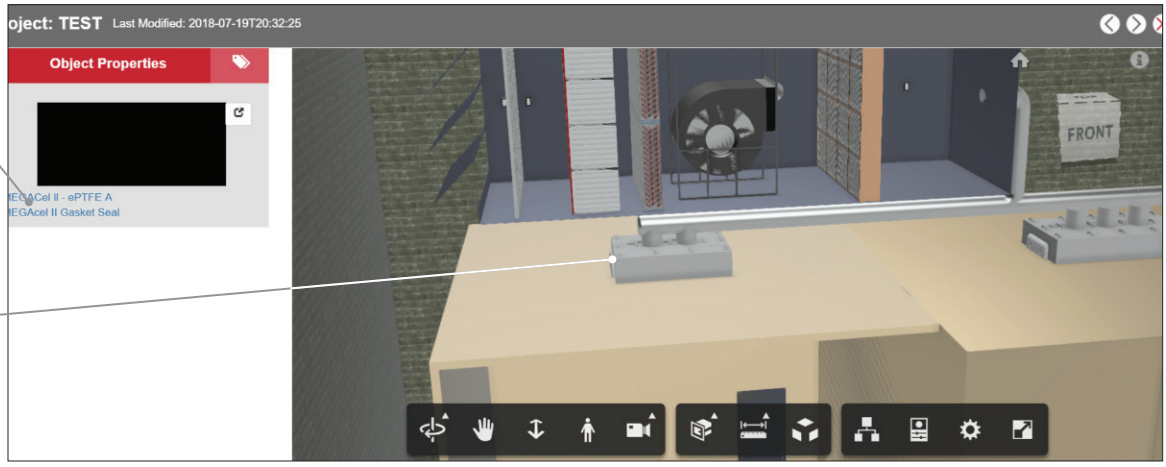


Product selection 3D 360° view

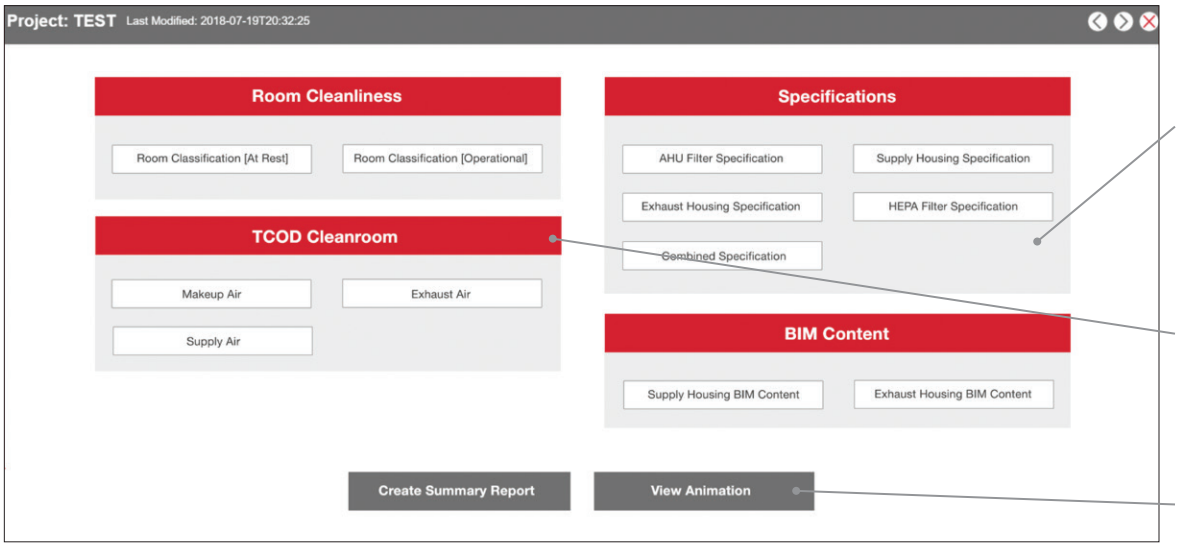


Revit, full specification and 2D product drawing auto generated from product/design selection

Terminal housing/filter selection view



AAF VisionAir™ Clean with TCO Diagnostics® Software



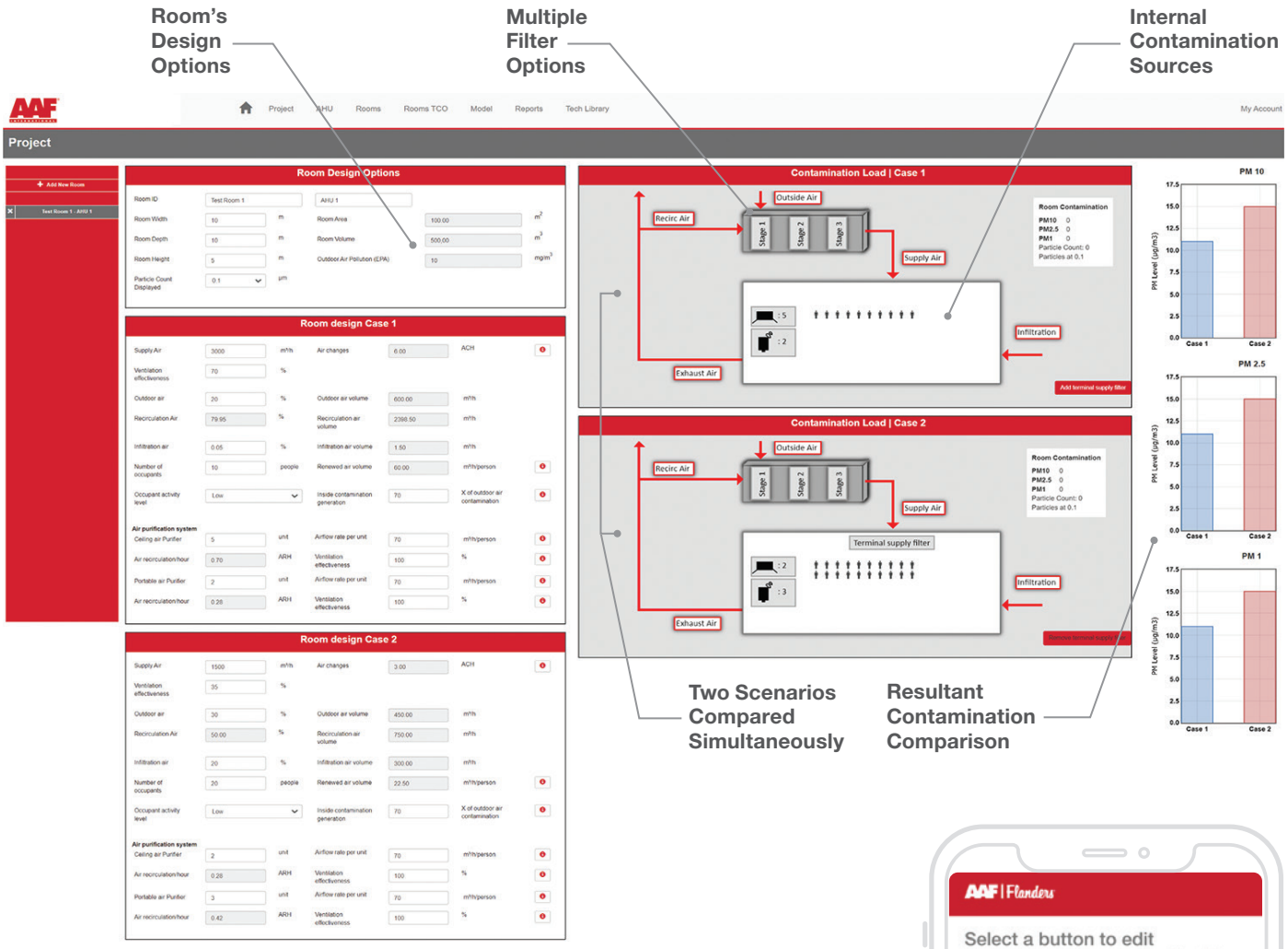
Product specification selection options for ALL filter, frame and housing types (consolidated FULL specification) auto selection option

Room contamination levels, a/c rate, recovery time report options. TCOD calculations per product group or system design standard and optimized designs

3D animation walk through capability of the room design from AHU to supply-exhaust devices

Tech library access for HP Guide (80+ pages), white papers and cleanroom calculation formulas

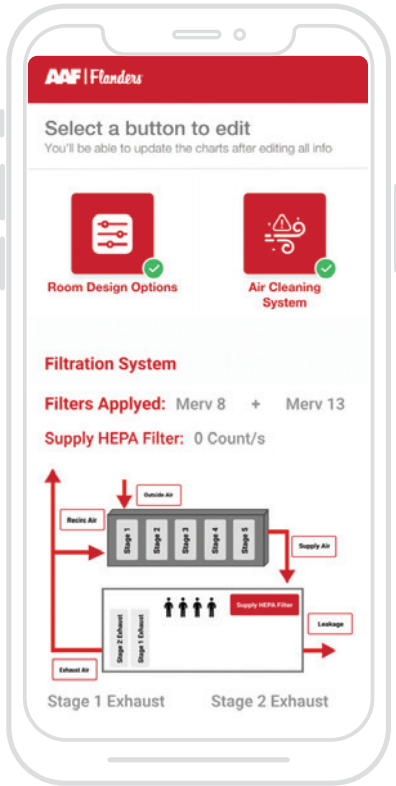
VisionAir™ IEQ



VisionAir™ IEQ

VisionAir IEQ is a software that is designed to simulate the PM level reduction impact with and without an air purifier while also seeing the impact of upgrading your supply air filtration from MERV 8 to MERV 13 for example, as recommended by ASHRAE due to COVID-19 pandemic. This software can be applied to almost any application but is primarily focused on commercial buildings, schools, and medical clinics to mitigate risks associated with viral load.

This powerful tool allows users to present virtually the targeted space PM level based on the present or future state of the environment.This allows the user to showcase the impact of the current and improved air quality in each application quickly and effectively. A mobile application has also been developed for both **VisionAir Clean** and **VisionAir IEQ** allowing for a quick and easy to use demonstration of findings and the resulting indoor air quality levels.



Mobile version available in your Apple App Store and Google Play Store.

Available on the App Store

ANDROID APP ON Google Play

TCO Diagnostics®

The High Cost of Deferred Maintenance

Today's competitive business landscape is becoming increasingly complex and competitive, which means everyone must do "more with less." Unfortunately, this culture is wreaking havoc on facilities in the form of deferred maintenance. By reacting to issues, rather than preventing them, even the smallest delays can add up to exorbitant costs due to:

- Equipment failure
- Safety risks and insurance claims
- Facility disrepair
- Energy overspending

88% of facility managers say that deferred maintenance is an issue.

HVAC—The System Most Affected by Deferred Maintenance

When HVAC systems are not maintained on time or as planned, they do not perform as they should, costing you time and money. Energy costs are up to 81% higher in facilities with deferred maintenance. 71% of this increase is HVAC-related. With half of a facility's energy costs attributed to heating, cooling, and moving air, proper filter maintenance is essential to keeping HVAC systems operating effectively and efficiently. The proper selection of air filters is critical to a system's performance and can extend the life of components, decrease energy spend, and reduce labor costs.

50% of a facility's energy costs are attributed to heating, cooling, and moving air.

TCO Diagnostics®

Optimize Preventative Maintenance Schedules & Total Cost of Ownership

Filters play an important role in reducing your deferred maintenance backlog, so having a program for optimizing filter maintenance and replacement is vital to a facility's operations. TCO Diagnostic® is an HVAC filtration system analysis program that helps reduce deferred maintenance backlogs and decrease reactive time by analyzing each facility's HVAC data, optimizing preventative maintenance schedules, and extending changeout cycles at the lowest total cost of ownership. This tool provides a complete optimization of your filtration system to determine the most effective and efficient filter selection based on your facility's needs, saving you time and money while reducing risk.

The Most Accurate Methodology and Data Sources

TCO Diagnostic® is more than the typical software program that calculates total cost of ownership using generalized data and user assumptions, which by extension "assumes" the answer. The basis of TCO Diagnostic® is to use the real-life, local filter performance information from your air handlers in their current state. This information is then benchmarked against standard dust-loading test results for the specific class of filters you use. It is the statistical information from your facility's systems that provides the basis for determining total cost of ownership for your current filters and their maintenance and replacement protocols.

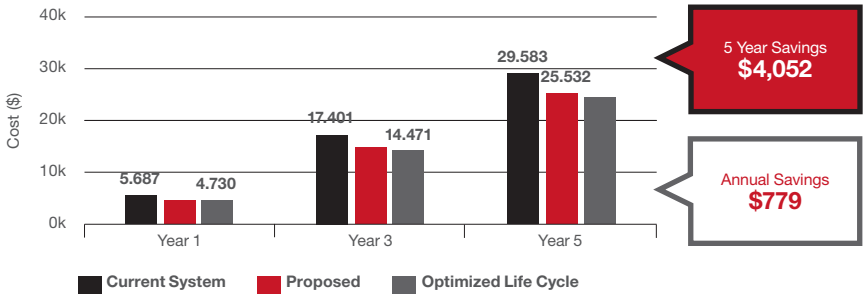
Optimizing for your facility results in a Proposed Solution that takes into account your current operating requirements and constraints. This Proposed Solution identifies the filter best suited for each stage of your system. As an end user, you receive a report providing reliable, verifiable analyses:

- System Comparison Overview and Breakout
- Total Cost of Ownership Assessment
- Performance Analysis
- Annual Cost Savings
- Environmental Impact Improvement
- Expected Returns

Results

Business Case

Investment in AAF's Proposed Solution versus Current System results in a **0.8 month** payback period and a **1,511%** ROI



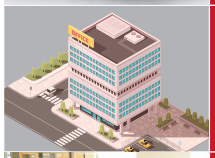
Sensors and Internet of Things (IoT)

Definition:

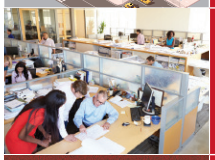
Machine-to-machine communication that is built on cloud computing and networks of data-gathering sensors with mobile, virtual, and instantaneous connection.

4th Generation

1G: Protection of HVAC Equipment



2G: Protection of Downstream Assets



3G: Protection of People (IAQ)

4G: Making the Invisible Visible® (IoT)

How to Optimize Your Change-Out Cycle?

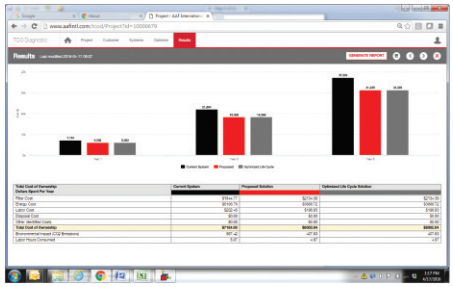
On the Clock/Calendar
method often results in replacing filters that are still relatively clean, wasting time and money.

On the Pressure Gauge
method requires regular pressure gauge monitoring, frequent gauge maintenance and record-keeping, and adjustments based on airspeed to be effective.

On the Money
method allows data-driven approach to changeout cycles based upon intelligent, Internet-connected sensors. Change filters only as necessary at the time that offers the lowest possible combination of materials, labor, and energy costs.

Multiple Assumptions Made in Current Calculations of TCO by ALL Filter companies

- Outside Contamination
- Airflow
- Fan Efficiency
- Filter Efficiency
- Change Based on Final PD
- Change Based on PM
- Estimated Average DP
- Voltage



Sensors and Internet of Things (IoT)

Continuously Updated Sensor Data and Analytics Allow a More Scientific Approach

- **Test** assumptions stemming from audit process
- **Refine** recommendations based on audit findings
- **Adjust** for changing conditions

IoT and Air Filtration – Sensor Technology

Placement of sensors, at a minimum, to measure and monitor:

- Outside air quality
- Upstream air quality
- Downstream air quality ➔ IAQ
- Differential pressure ➔ Energy usage
- Dashboard & Mobile View

Clean Air Innovation and Research Center

Clean Air Innovation & Research Center

Opened in September 2016, the AAF Clean Air Innovation and Research Center (Clean AIR Center) represents a significant advancement in research and development efforts for the entire global air filtration industry. For nearly 100 years, AAF and Flanders have been innovating solutions that bring clean air to life, and the Clean AIR Center will help us remain the industry leader for decades to come. This $5.4 million, 39,000-square foot facility offers unrivaled capabilities and technology, ensuring that every filter we produce is backed by advances in each of its components, and in every phase of its design and production. Ultimately, this means that we produce products fine-tuned to deliver the highest quality and lowest total cost of ownership for our customers.

Creating New Possibilities

The way that many organizations approach research and development is a top-down method, where a select few determine the products and product direction. This approach limits the bandwidth of products and ideas. AAF's Global R&D team exercises a bottom-up approach to product development. This approach encourages ideas to flow from customers throughout the product development process, while also spurring collaboration with multiple business units within Daikin to achieve the product goals of the global entity.

The key to continue AAF's forward progress in the industry is to not only retain our current products and development processes, but also to create disruptive technologies for the air filtration industry. The standard industry approach is to take a current product and upgrade it with additional features and benefits. The Clean AIR Center utilizes this approach but also enhances our product lineup by targeting disruptive products and technologies that transform how customers view and incorporate air filtration.

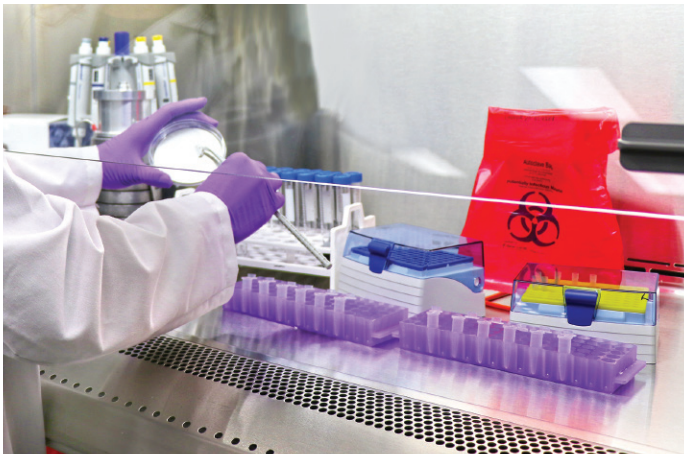
Clean Air Innovation and Research Center

Bringing Clean Air to Life™

AAF's Global R&D team creates open lines of communication to all regions and customers to support an active and fluid product pipeline, and to deliver key innovative products and processes throughout the world. With this seamless and synergistic communication, as well as continued product innovation, our team maintains AAF's position as the number one global air filtration company. The Global R&D team achieves success in every aspect of product formulation, encompassing design, performance, and customer-focused innovation.

Lab Services Offered

- **Filter Testing:** The filter lab has 7 test ducts capable of testing to various industry standards to help ensure product performance and streamline product development.
- **Media/Materials Lab:** The media/materials lab has a variety of analytical test equipment to validate performance of the various components that go into our filters as well as examining environmentally loaded filters to help our end users understand what is in their air and help them develop better solutions for their filtration needs.
- **Biosafety Lab:** AAF's laboratory features biosafety level 2 (BSL-2) requirements with microbiological and molecular biological testing capabilities. This lab allows AAF to perform viral efficacy testing for PRRS, PED, and Influenza A, which is crucial to our customers in the agriculture industry. Our ability to make rapid quantitative assessments for viral load using real-time PCR technology provides our customers with actionable information on, and protection from, the biological and viral agents that threaten their most valuable assets.



Clean Air Innovation and Research Center

COVID-19 Surrogate Testing

AAF filters prove effective at reducing airborne coronaviruses. Previous testing undertaken by a University of Minnesota research team, later replicated by AAF in our biological research laboratory at the Clean AIR Center, demonstrated that air filtration reduced not only airborne particles within the 0.5-1.0 micron size range that viruses tend to travel on, but also the virus particles themselves.

Background

For this study, the university researchers used the Porcine Reproductive Respiratory Syndrome (PRRS) Virus as the test organism for the bioaerosol tests. Because this PRRS virus studied previously is much smaller and behaves differently than the new coronavirus that causes COVID-19, AAF researchers sought answers to the question: **Could a member of the coronavirus family also be filtered out of airstream?**

Because SARS-CoV-2, the coronavirus that causes COVID-19, is highly infectious to humans, our biological research team tested penetration rates for various air filters using the Porcine Epidemic Diarrhea (PED) virus as a surrogate.

Like SARS-CoV-2, the PED virus:

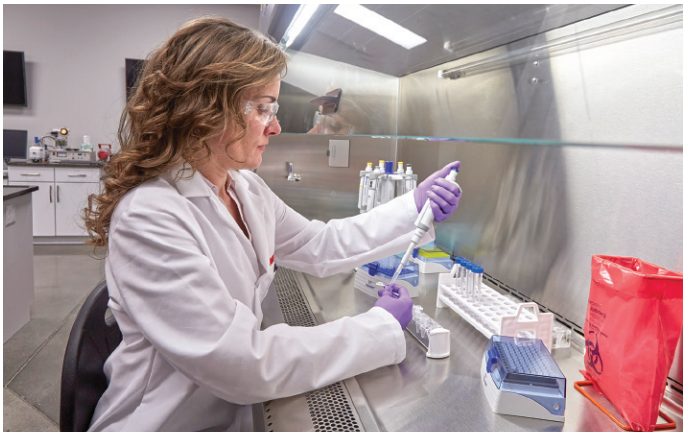
- Is a member of the coronavirus family
- Is of similar size
- Behaves similarly in aerosol

Fortunately, however, the PED virus is not known to infect humans, making it a safe surrogate for the AAF research trial.

Methodology

We used essentially the same methodology as was used with the PRRS-V testing performed previously, but at higher rates of airflow (1968 CFM, as commonly used for ASHRAE 52.2 testing, rather than 650 CFM) and substituted the PED vaccine for the PRRS-V vaccine.

- First, we created an aerosol containing 10% Potassium Chloride (KCl), a fluorescent tracer dye to determine particle distribution by mass, and a PED vaccine with a virus concentration of 10^8 (or 100 million).
- The KCl was generated at particle sizes corresponding to a typical ASHRAE test size range, 0.3-10 micron, along with some larger sizes.
- That aerosol was introduced into an ASHRAE test duct and drawn through individual air filters at 1968 CFM, while keeping temperature, humidity, and other parameters at ASHRAE 52.2-prescribed levels.
- We collected air samples before and after each filter with an Anderson Cascade Impactor, which separates and collects particles by size.
- We then analyzed the collected samples. First, we isolated and purified the virus in each sample. The purified virus in the samples was prepared for testing using Reverse Transcription Polymerase Chain Reaction (RT-PCR) where the data generated was used to determine virus concentration per cubic meter of air. Last, we quantified the overall particle distribution by mass as a positive test control.

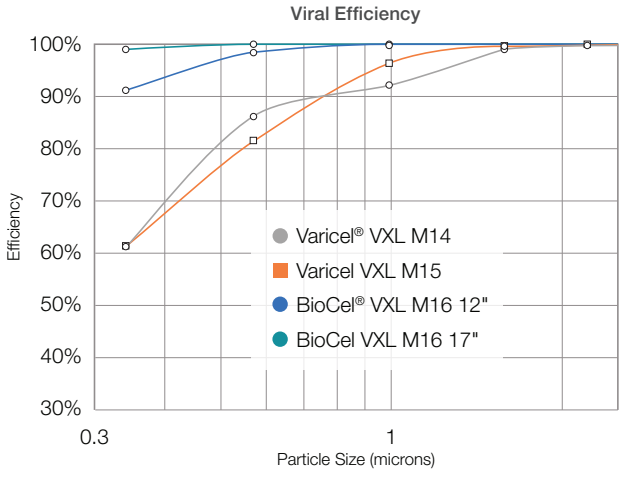


- Using this viral concentration data, we calculated the penetration and viral efficiency rates for each filter vs. individual particle sizes.
- The resulting data is shown on the following tables.

Results

For each air filter tested, the virus carrier removal efficiency closely followed the general particle removal efficiency:

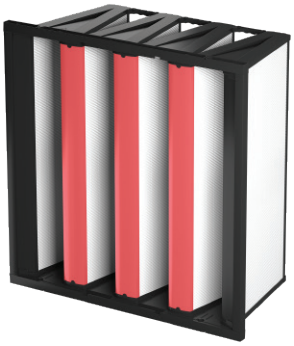
- VariCel® VXL MERV 14 filter
- VariCel VXL MERV 15 filter
- BioCel® VXL MERV 16 (12" depth) filter
- BioCel VXL MERV 16 (17" depth) filter



Clean Air Innovation and Research Center

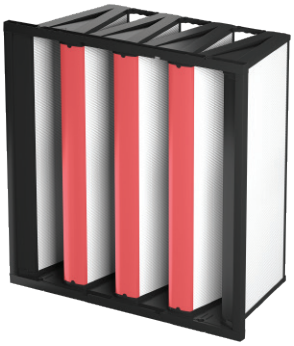
Featured Products

The U.S. Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) recommend at least MERV 13 air filters to protect against airborne pathogens, with a preference for MERV 14 or higher efficiency. Therefore, while we tested numerous air filters, we are highlighting the performance of VariCel® and BioCel® filters of efficiencies ranging from MERV 14 through 16.



VariCel® VXL RC Box Filter Results

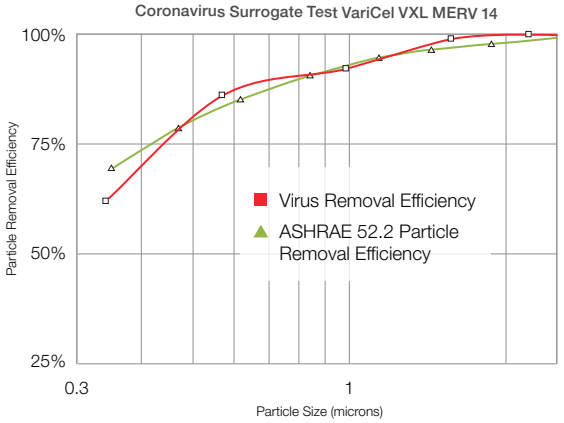
- Optimal media area for greater airflow capacity and low resistance
- Maximum dust holding capacity
- Available in MERV 11-15
- MERV 14-15 available with antimicrobial
- Excellent performance in difficult operating conditions
- Usable in high-velocity systems up to 750 FPM

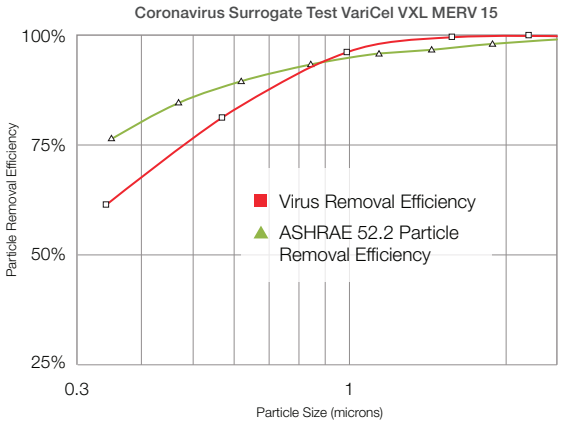


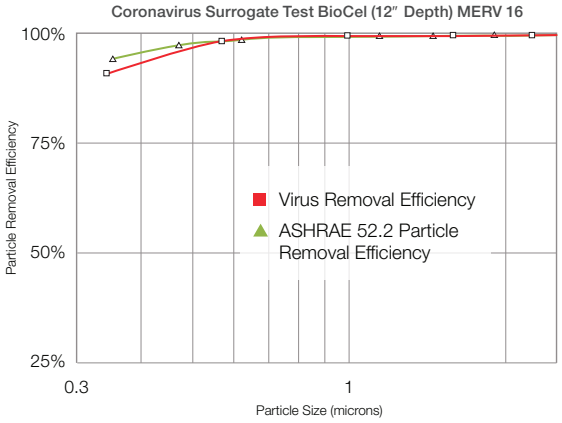
BioCel® VXL RC Box Filter Results

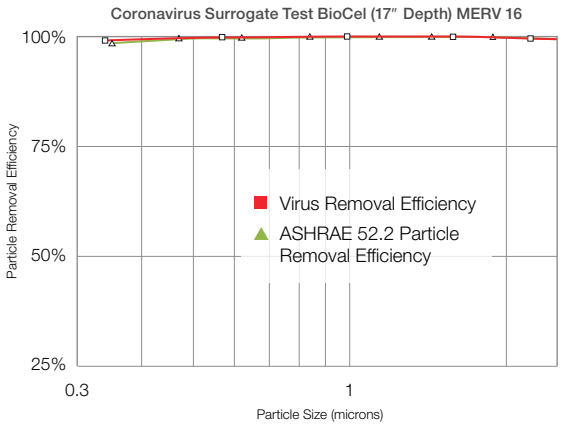
- Meets exacting requirements of precision manufacturing and laboratory operations
- Fills gap between high-efficiency ASHRAE and HEPA filters
- Available in MERV 16, antimicrobial optional
- Optimal media area for greater airflow capacity and low resistance
- Fully incinerable

This methodology is based on previous successful virus capture methodologies utilizing comparisons between standard ASHRAE 52.2 and predictive analysis based on virus carriers. The filter is only one component and the overall system and the test results should be viewed as directional depending on the complete HVAC environment.









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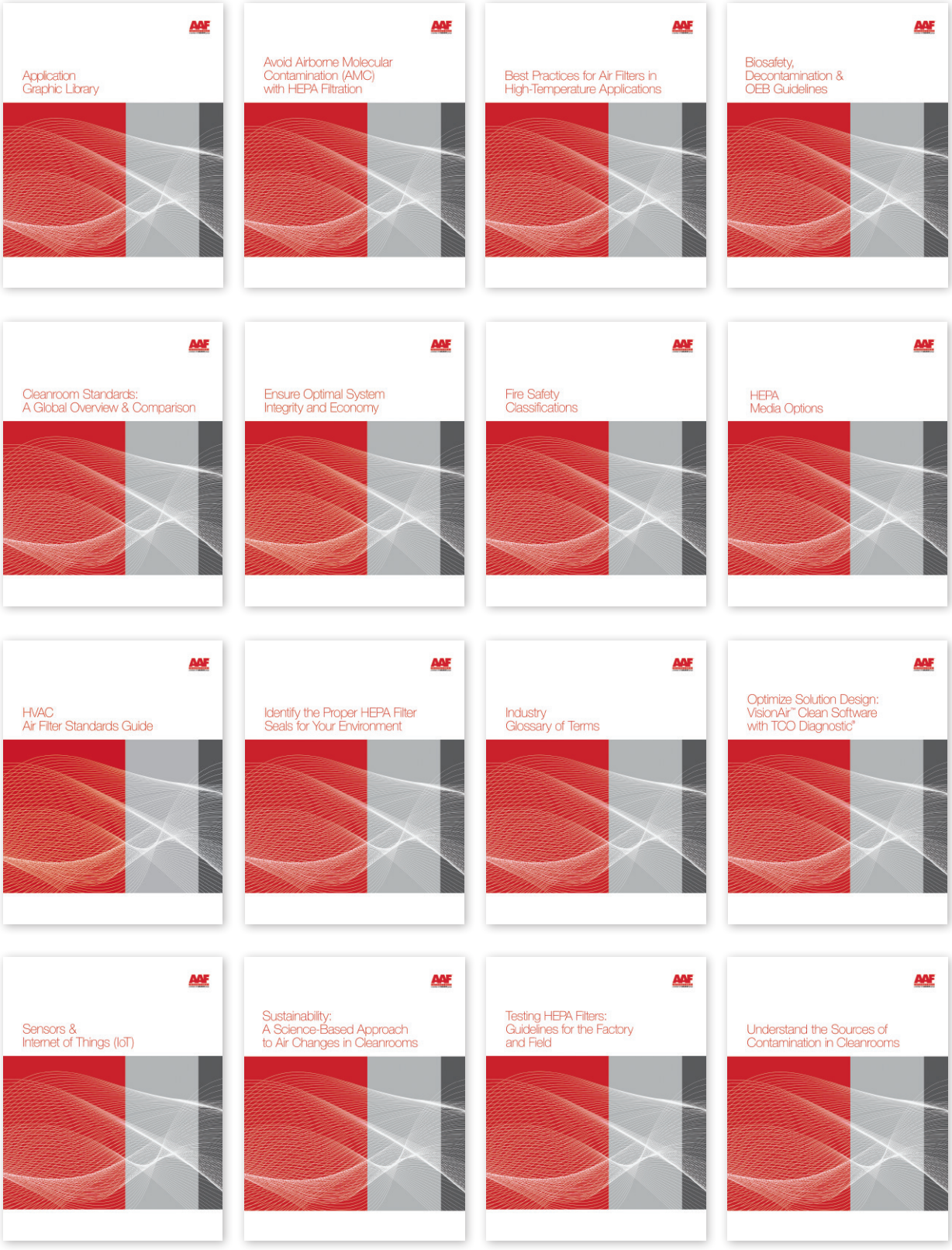

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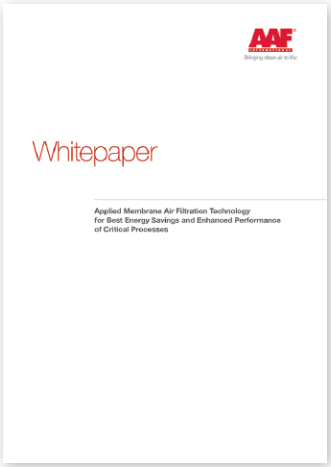
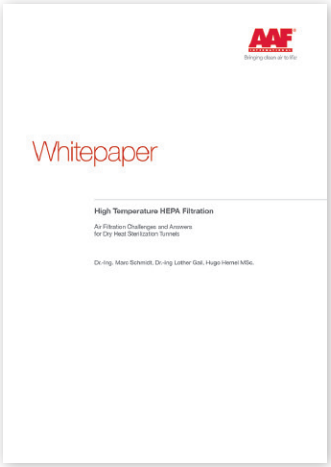


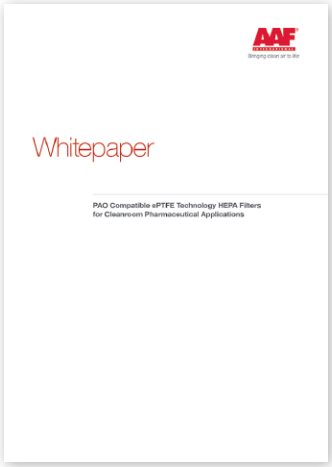
Applied Membrane Air Filtration Technology for Best Energy Savings and Enhanced Performance of Critical Processes

Cleanroom Industry Tech Papers from Global SME's

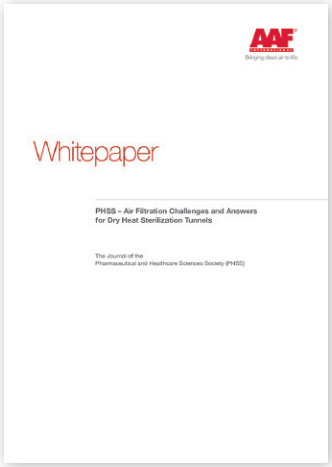
Decontamination and Disinfection Methodologies for Labs



High Temperature HEPA Filtration



PAO Compatible ME Technology HEPA Filters for Cleanroom Pharmaceutical Applications



PHSS – Air Filtration Challenges and Answers for Dry Heat Sterilization Tunnels

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Filtration Industry Glossary of Terms

Organizations

ABNT Brazilian Association of Technical Standards
ABSA American Biological Safety Association
ACS American College of Surgeons
AFNOR French Standardization Association
AIA American Institute of Architects
ANSI American National Standards Institute
ANVISA Brazilian Health Regulatory Agency
APHIS Animal & Plant Health Inspection Services
ARS Agricultural Research Service
AS/NZS Australian New Zealand Standards
ASHP Pharmaceutical Compounding Sterile Preparations
ASHRAE American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc.
ASTM American Society for Testing and Materials

BMBL Biosafety in Microbiological and Biomedical Laboratories
BSI British Standards Institute
Cal/OSHA California Division of Occupational Safety and Health (California OSHA)
CDC Centers for Disease Control and Prevention (a Federal agency)
CDER Center for Drug Evaluation and Research
CFDA China Food and Drug Administration
CITC Curry International Tuberculosis Center
CMC California Mechanical Code

EMA European Medicines Agency
EPA Environmental Protection Agency

FDA US Food and Drug Administration (a Federal agency)

HPRA Health Products Regulatory Authority

ICC International Code Council
ISO International Standards Organization (29463,14644 filter & cleanroom norms)
ISPE International Society of Pharmaceutical Engineers
ITRS International Technology Roadmap for Semiconductors

JACA Japan Air Cleaning Association
JCAHO Joint Commission on Accreditation of Healthcare Organizations
JCI Joint Commission International (accreditation)
JSA Japanese Standards Association

MHRA Medicines and Healthcare Products Regulatory Agency (UK)
MMWR Morbidity and Mortality Weekly Report

NACMCF National Advisory Committee on Microbiological Criteria for Foods
NEBB National Environmental Balancing Bureau
NFPA National Fire Protection Association
NIH National Institute of Health
NIOSH National Institute for Occupational Safety and Health (a Federal agency)
NOM Official Mexican Standards
NSF National Sanitation Foundation

OECA Office of Enforcement and Compliance Assurance (EPA)
OSHA Occupational Safety and Health Administration (a Federal agency)
OSHPD Office of Statewide Health Planning and Development (a California agency)

PDA Parental Drug Association
PHSS Pharmaceutical & Healthcare Sciences Society
PICS Pharmaceutical Inspection Convention & Co-operation Scheme

SEMI Semiconductor Equipment and Materials International

TGA Therapeutic Goods Administration (Australia)
TPD Therapeutic Products Directorate (Canada)

US DOD Department of Defense
US DOE Department of Energy
US DOH Department of Health
USDA United States Department of Agriculture
USP U.S. Pharmacopeia

VDI Association of German Engineers

WHO World Health Organization

Filtration Industry Glossary of Terms

Acronyms

ACH	Air Changes per Hour
AFB	Acid-Fast Bacilli
AHJ	Authority Having Jurisdiction
AHU	Air Handling Unit
AIDS	Acquired Immunodeficiency Syndrome
AIIR	Airborne Infection Isolation Room
AMC	Airborne Molecular Contamination
AMHSs	Automated Material Handling Systems
APC	Aerodynamic Particle Counter
API	Active Pharmaceutical Ingredient
aRABs	Active Restricted Access Barrier System
BACnet	Building Automation Control networking protocol
BAMT	Blood Assay for Mycobacterium Tuberculosis
BAS	Building Automation System
BCG	Bacille Calmette-Guérin (vaccine)
BI	Biological Indicators
BIBO	Bag In Bag Out
BMS	Building Management System
BOD	Basis of Design
BSC	Biological Safety Cabinet
BSL	Bio-Safety Level
C&Q	Commissioning & Qualification
CAV	Constant Air Volume
CFD	Computational Fluid Dynamics
CFM	Cubic Feet per Minute
CFR	Code of Federal Regulation
CFUs	Colony Forming Units
CGMP	Current Good Manufacturing Practice
CHW	Chilled water
CIP	Clean In Place
CMD	Count Mean Diameter
CMMS	Computerized Maintenance Management System
CNC	Controlled Not Classified
COSHH	Control of Substances Hazardous to Health
CPC	Condensation Particle Counter
CPU	Central Processing Unit
cRABs	Closed Restricted Access Barrier System
CRR	Contamination Recovery Rates
CVCM	Collected Volatile Condensable Material
DFW	Downflow Booth
DIW	Deionized Water
DOT	Directly Observed Therapy
DPC	Discrete Particle Counter
DQ	Design Qualification
DRAM	Dynamic Random Access Memory
DUV	Deep Ultraviolet
ECM	Electronically Commutated Motor
EM	Environmental Monitoring
EMI	Electromagnetic Interference
EMS	Energy Management System
EN	1822 European Norm for Air Filter Testing Parts 1-5
ESD	Energy Saving Damper
ESD	Electrostatic Discharge
FAMU	Fresh Air Make Up
FAT	Factory Acceptance Test
FFU	Fan Filter Unit
FOUP	Front Opening Unified Pod
FPD	Flat Panel Display
FPM	Feet Per Minute
FRM	Fluoro-Resin-Media
FRS	Functional Requirement Specification
GCHW	Glycol Chilled Water
GEP	Good Engineering Practice
GIP	Gassing In Place
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points
HCW	Healthcare Worker
HEPA	High Efficiency Particulate Air
HIV	Human Immunodeficiency Virus
HMI	Human Machine Interface
HPC	Highly Potent Compound
HSC	Health & Safety Commission (UK)
HSE	Health & Safety Executive (UK)
HVAC	Heating, Ventilating, and Air Conditioning
IAQ	Indoor Air Quality
IEQ	Indoor Environmental Quality
ICP	Infection Control Plan
IDLH	Immediately Dangerous to Life and Health
IGRA	Interferon Gamma Release Assay
IIoT	Industrial Internet of Things
INH	Isoniazid
IoT	Internet of Things
IQ	Installation Qualification
LAF	Laminar Flow
LCC	Life Cycle Cost
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LEV	Local Exhaust Ventilation
LLF	Light Loss Factor
LTBI	Latent Tuberculosis Infection
LUX	Light (Latin)

Acronyms (continued)

M.tb	Mycobacterium Tuberculosis
MA	Molecular Acids
MALs	Material Air Locks
MB	Molecular Bases
MC	Molecular Condensable (Organic Compounds)
MCP	Microbial Carrying Particles
MD	Molecular Dopants
MDR	Multidrug-Resistant
MPPS	Most Penetrating Particle Size
MTBF	Mean Time Between Failures
MTP	Material Transfer Port
MUA	Make Up Air
NAAT	Nucleic Acid Amplification Test
NTM	Nontuberculous Mycobacteria
NTT	No Touch Transfer
NVR	Non Volatile Residue
OAQ	Outdoor Air Quality
OEB	Occupational Exposure Bands
OEL	Occupational Exposure Limit
OPC	Optical Particle Counter
OPS	Operations Performance Systems
OQ	Operational Qualification
OSD	Oral Solid Dosage
PALs	Personnel Air Locks
PCW	Process Chilled Water
PE	Particle Exhaust
PEH	Heat Exhaust
PEV	VOC Exhaust
PFC	Power Factor Correction
PIN	Policy Intent Notice
PLC	Programmable Logic Control
POG	Point of Generation
POU	Point of Use
PPD	Purified Protein Derivative
PPE	Personal Protection Equipment
PQ	Performance Qualification
PTFE	Poly-Tetra-Fuoro-Ethylene
PUPSIT	Preuse Post Sterilization Integrity Testing
QFT-G	QuantiFERON®-TB Gold blood test
QRM	Quality Risk Management
RABs	Restricted Access Barrier System
RAH	Recirc Air Handling Unit
REL	Recommended Exposure Limits
RFU	Recirc Fan Unit
RIPT	Respiratory Isolation of Pulmonary Tuberculosis
RTMCC	Regional Training and Medical Consultation Center
RTP's	Rapid Transfer Ports
SAL	Sterility Assurance Level
SAT	Site Acceptance Test
SBV's	Split Butterfly Valves
SEM	Scanning Electron Microscope
SIP	Sterilize In Place
SME	Subject Matter Expert
STEL	Short Term Exposure Limit
SUP	Supply Air Categories
TB	Tuberculosis
TCOD	Total Cost of Ownership Diagnostics® Software
TCOD-Clean	Total Cost of Ownership Diagnostics®-Cleanroom Design Software
TFT	Thin Film Transistor
TLV	Threshold Limit Values
TOC	Total Organic Compound
TST	Tuberculin Skin Test
TVOCs	Total Volatile Organic Compounds
UDF	Unidirectional Down-Flow Hood
UPS	Uninterrupted Power Supply
UPW	Ultrapure Water
URS	User Requirement Specification
UV	Ultraviolet
UVGI	Ultraviolet Germicidal Irradiation
VAV	Variable Air Volume
VCM	Volatile Condensable Material
VFD	Variable Frequency Drive
VHP	Vaporized Hydrogen Peroxide (H_2O_2)
VLF	Vertical Laminar Flow
VMP	Validation Master Plan VO-Voltage Optimization
VOC	Volatile Organic Compound
VO	Voltage Optimization
VSD	Variable Speed Drives
VUs	Viable Units
"W.G."	Inches of Water Gauge
XDR	Extensively Drug-Resistant

Industry Definitions

ABSOLUTE – An arbitrary term once used to describe high efficiency particulate air filters, based on minimal penetration of 0.3 micron particles. In air filtration, there are no absolutes.

ABSOLUTE FILTER – This term has been applied to air filters of high efficiency—greater than 95% against submicron particles—but is now less frequently used. Modern terminology prefers the term HEPA filter (High Efficiency Particulate Air).

ABSORB – To intercept, or drink in, as a sponge sucks in water.

ABSORPTION – A physio-chemical process in which one substance associates with another to form a homogeneous mixture that presents the characteristics of a solution.

ACFM – Actual Cubic Feet Per Minute. Airflow measured at operating temperature and pressure.

ACID – Any of a class of substances whose aqueous solutions are characterized by a sour taste, the ability to turn blue litmus to red, and the ability to react with bases and certain metals to form salts. Acids will yield hydrogen ions when dissolved in water.

ACTIVATED ALUMINA – A highly porous and granular form of aluminum oxide having preferential adsorptive capacity for moisture from gases, vapors, and some liquids.

ACTIVATED CARBON – Any form of carbon characterized by high adsorptive capacity for gases, vapors, or colloidal solids. The carbon or charcoal is produced by destructive distillation of wood, peat, lignite, nut shells, bones, vegetable, or other carbonaceous matter, but must be activated by high temperature steam or carbon dioxide, which creates a porous particle structure.

ACTIVATED CHARCOAL – See activated carbon.

ADHESION – Intermolecular forces which hold matter together. Also applied to the sticking together of a particle to a surface, a fiber or another particle. The main factors affecting adhesion of particles are 1) London-van der Waals forces, which are electrical in origin, 2) electrostatic forces, and 3) surface tension, due to films of moisture on particles or on the surface. Other factors influencing adhesion are the nature of the surfaces, surface contaminants, particle size, shape and roughness, and time of contact.

ADSORB – The physio-chemical phenomenon involved to attract and hold a gas, vapor, or liquid on the surface of a solid, particularly on a finely divided material.

ADSORBATE – The material which is adsorbed; i.e., the gas, vapor, or liquid which adheres, or is chemically attracted to, the surface of the solid.

ADSORBENT – The material which adsorbs; i.e., the solid which attracts and holds on its surface the gas, vapor, or liquid. Activated carbon and activated alumina are all adsorbents

ADSORPTION – The natural phenomenon of a gas, vapor, or liquid being attracted to, and held on, the surface of a solid. To some extent, adsorption takes place on any solid surface, but certain materials have sufficient adsorbent capacity because they are finely divided and are therefore useful in such industrial applications as the purification and separation of gases and liquids.

AEROSOL – Liquid or solid particles suspended in air, gas, or vapor.

AHRI – Air-Conditioning, Heating, and Refrigeration Institute.

ALKALI – A term that applies to the type of compounds which have basic properties and will neutralize acids. Some alkaline materials are hydroxides, carbonates, or caustics.

AMBIENT – Of the surrounding area or environment.

AMBIENT AIR – The air surrounding a building. The source of outdoor air brought into a building.

AMINE – A class of organic compounds of nitrogen that may be considered to be derived from ammonia. It may be a gas, liquid, or solid. All amines are basic in nature and will usually combine readily with hydrochloric or other strong acids to form salts.

AMMONIA – A colorless gas with a characteristic pungent odor. Used for refrigeration, fertilizer, chemical manufacturing, and many other uses.

ANGSTROM – A unit of length, 10-10 meter, or one ten thousandth of a micron.

ANSI – American National Standards Institute.

ARRESTANCE – A measure of the ability of an air-cleaning device to remove ASHRAE loading dust from test air. Measurements are made of the weight of loading dust fed and the weight of the dust passing the device during loading. The difference between the weight of dust fed and the weight of dust passing the device is calculated as the dust captured by the device. Arrestance is then calculated as the percentage of the dust fed that was captured by the device.

AROMATIC COMPOUNDS – Compounds related to six-carbon membered rings as benzene or its derivatives.

ASHRAE – American Society of Heating, Refrigerating and Air-Conditioning Engineers.

ASHRAE LOADING DUST – Loading dust for testing air filtration devices composed, by weight, of 72% SAE Standard J726 test dust (fine), 23% powdered carbon, and 5% milled cotton linters.

ASME – American Society of Mechanical Engineers.

ATMOSPHERIC PRESSURE – The pressure of approximately 14.7 pounds per square inch exerted at sea level in all directions by the atmosphere.

BIOAEROSOL – A suspension of airborne particles that contain living organisms or were released from living organisms.

BLEEDTHRU – A phenomena where a leak test aerosol is at/near the MPPS and the leak test pass/fail threshold is less stringent than the factory efficiency test, manifesting in a large leak across the filter face. *(See page 33 for more details.)*

BLIND SPOTS – Places in a medium where no filtering occurs. These places are also referred to as dead areas and are the opposite of the effective area.

BREAKTHROUGH – When the downstream concentration exceeds the allowable concentration.

BRIDGING – Where particles being removed from the air form an arch over the individual openings/pleats in an extended surface filter, blocking the narrow air passages between pleats and reducing the service life of the filter.

BROWNIAN MOTION – The random movement of microscopic particles suspended in a liquid or gas, caused by collisions with molecules of the surrounding medium. Also called Brownian Movement.

Industry Definitions (continued)

BTU (BRITISH THERMAL UNIT) – A standard measure of heat content in a substance that can be burned to provide energy.

BYPASS – Condition resulting from the fluid stream flowing through a housing without flowing through the filtering medium. In air filtration, unfiltered air going around the filter.

CAPACITY – Volume of air expressed in cubic feet per minute (CFM), or similar units that a filter is rated to handle.

CFM – Cubic feet per minute.

CHEMISORPTION – The combined process of adsorption, absorption, and oxidation, where gases trapped in chemisorbant media (adsorbent with an impregnant) are changed from gases into harmless solids.

CHIMNEY EFFECT – The tendency of heated air to rise due to lower density in comparison with ambient, also called thermal, updrafts. In cleanroom areas, heat generating equipment may cause severe upward air currents, resulting in unwanted turbulence.

CLEAN PRESSURE DROP – Differential pressure (drop) across a clean filter, typically measured in inches of water column (water gauge) or pascals.

CLEAN SPACE – A term referring to cleanrooms or work stations within a room.

CLEANING – Removal of soil from objects/surfaces.

CLEANROOM – A specially constructed enclosed area environmentally controlled with respect to airborne particulates, temperature, humidity, air pressure, airflow patterns, air motion, and lighting.

COALESCING – Action of uniting of small droplets of one liquid, preparatory to its being separated from another liquid.

COMPOSITE MEDIA – Media made up of more than one material.

CONTACT TIME – The length of time an absorbent is in contact with a liquid or gas prior to being removed by the filter.

CONTAMINANT – Synthetic or naturally occurring chemical, particle, or microorganism in air that could have adverse effects

NON-LAMINAR FLOW CLEANROOM – A cleanroom with no requirements for uniform airflow patterns and air velocities.

CORROSION – Conversion of metals into oxides, hydrated oxides, carbonates, or other compounds, due to the action of air or water, or both. Salts and Sulphur are also important sources of corrosion.

CRITICAL SURFACE – The surface in a cleanroom or work station to be protected from particulate contamination.

DEAD AREAS – Places in a medium where no filtering occurs. Also referred to as blind spots. The opposite of the effective area.

DECONTAMINATION – Removal of all pathogenic microorganisms from objects to ensure they are safe to handle.

DEGRADATION – The wearing down, or reduction in the efficiency of, the medium.

DELTA (Δ) P – A commonly used symbol denoting the difference in pressure between two points, such as the inlet and outlet of a filter. This difference is often referred to as the pressure drop and is typically measured in inches of water column (water gauge) or pascals.

DEPTH FILTRATION – Filtration accomplished by a progressively denser, deep medium, designed to allow finer particles to penetrate further into the medium, while larger particulates are lodged closer to the surface. A progressive density medium has superior dust holding capacity.

DIFFERENTIAL PRESSURE – Difference in pressure between two points, such as the inlet and outlet of a filter. This difference is often referred to as the pressure drop, and is typically measured in inches of water column (water gauge) or pascals.

DIFFERENTIAL PRESSURE INDICATOR – Indicator that signals the difference in pressure at two points.

DIFFERENTIAL PRESSURE SWITCH – Electrical switch operated by the difference between two pressures and often used to give warning of the end of a filtration cycle.

DIFFUSER – An air distribution outlet specifically designed to mix conditioned air with room air by induction. Mixing is accomplished by venture action, as the high velocity airstream leaving the diffuser aspirates ambient air toward the device.

DIFFUSION – A method of filtration that is effective on particles 0.1 micron and smaller, whose direction and velocity are influenced by molecular collisions (called Brownian Motion). Particulates of this size do not follow the airstream, but behave more like gases than particulate. Their dwell time in the media is longer as they are battered across the direction of flow in a random “helter skelter” fashion. When a particle strikes a fiber, it is retained by the inherent adhesive forces between the particle and fiber (van der Waals forces).

DISINFECTION – Elimination of many or all pathogenic organisms with the exception of bacterial spores.

DISPOSABLE – Describes an expendable component which is to be discarded after use and replaced with an identical component. This means that the component is replaceable, not reusable.

D.O.P. (DIOCTYL PHTHALATE) – An oil-like plasticizer which is readily atomized to form the test aerosol which was once used in the overall penetration and scan tests of HEPA filters. This test aerosol is now rarely used and has been replaced with PAO (poly-alpha-olefin).

DOWNSTREAM – Portion of the system located after a filter. Also, the leaving air or the clean air side of a filter.

DUAL LAYER MEDIA – Media in a filter element that has a coarse layer followed by a fine layer, to enhance dust holding capacity.

DUST HOLDING CAPACITY (DHC) – The total weight of ASHRAE test dust a filter can hold before reaching a given final resistance. This amount will vary, depending on the size and design of the filter and airflow rate. Typically reported in grams, DHC is used to provide a relative measure of filter service life.

EFFECTIVE AREA – Area of the medium exposed to flow and usable for its intended purpose (filtering). This term means the opposite of blind spots or dead area.

EFFICIENCY – Degree to which a filter will perform in removing solids, in accordance with the chosen test method.

Industry Definitions (continued)

EFFICIENCY CURVE – Graph showing the performance of a filter when challenged by specified contaminants under controlled conditions. Usually will be plotted against particle size at a given face velocity.

ELECTRET MEDIA – Filter media containing an electrostatic charge.

ELECTROSTATIC PRECIPITATION – A method of filtration that imparts a positive charge to airborne particulate matter and collects the particles on negatively charged collection plates.

EXFILTRATION – Outward air leakage from a space through openings, caused by pressure differences across these openings.

EXTENDED SURFACE FILTER – A category of filter that is designed with pleats or pockets to increase the amount of media exposed to the airstream within a given face dimension. Greater filter surface area reduces media velocity and increases efficiency and dust holding capacity.

FACE AREA – The area of a filter perpendicular to the flow direction.

FACE LOADING – The phenomenon by which contaminants in the air load up on the surface of the filter, causing an abnormal rise in resistance.

FDA – U.S. Food and Drug Administration, which is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, animal food and feed, and veterinary products. The FDA enforces Current Good Manufacturing Practices (CGMPs).

FIBER – Fundamental unit comprising a textile raw material such as cotton or wool.

FIBERGLASS – A term used to describe a variety of filter media made with glass fibers.

FILTER – A term generally applied to a device used to remove contaminates from the air. A filter may be one of a number of types, such as panel, automatic self-renewable, extended surface, HEPA, electrostatic, or gas phase. The term filter is sometimes erroneously used to describe the media used inside the device.

FILTER MEDIUM – The porous material mounted in the filter through which air is passed to remove the contaminants.

FILTRATION – The process of removing contaminants from liquid or gas by forcing them through a porous medium.

FINAL FILTER – The last and usually most efficient filter in a multi-stage filtration system.

FPM – Feet Per Minute. This term refers to the speed at which air moves through an area.

FRESH AIR – Term used for outdoor air.

GAS – The state of matter in which molecules move freely, causing matter to expand indefinitely, occupying the total volume available.

GAS-PHASE FILTER – Air cleaning device that uses the adsorption and/or chemisorption removal process. Typical filter mediums are activated carbon, alumina, and zeolite, with and without chemical impregnants.

GASKET – Material inserted between contact surfaces of a joint to ensure a seal.

HEPA FILTER – High Efficiency Particulate Air filter, which is capable of removing a minimum of 99.97% of 0.3 micron particles (typically PAO) of other gases from air.

HYDROCARBON – Any one of a large number of compounds composed primarily of the elements carbon and hydrogen. As they increase in molecular weight and boiling point, these compounds may be respectively gases, liquids, or solids.

HYDROPHILIC – Water accepting, or water wetting. Having an affinity for water, the opposite of hydrophobic.

HYDROPHOBIC – Non-water wetting. Having an antagonism for water, the opposite of hydrophilic.

IEST – Institute of Environmental Sciences and Technology, whose mission is "To globally expand and communicate the knowledge of contamination control, nanotechnology facilities, and test reliability. This is accomplished through the development of Recommended Practices and Standards by a community dedicated to professional collaboration, training, and education."

IMPINGEMENT – A method of filtration that is effective on particles with sufficient inertia to cause them to leave the airstream and collide with a fiber. Often referred to as "viscous impingement," when the fibers are coated with an adhesive.

INCHES W.G. – Abbreviation for "inches water column gauge." This is a method of reporting filter resistance (or pressure drop) across a filter.

INFILTRATION – Inward air leakage from a space through openings, caused by pressure differences across these openings.

INITIAL RESISTANCE – Differential pressure (drop) across a clean filter, typically measured in inches of water column (water gauge) or pascals. Synonymous with initial pressure drop, or clean pressure drop.

INTERCEPTION – A special case of the impingement method of filtration that does not depend on the inertia of the particles to bring them in contact with a fiber. Interception occurs when a particle follows the airstream but touches a fiber as it attempts to flow around it. The particle is held by the inherent adhesive forces between the particle and fiber (van der Waals force).

INTERSTICES – Spaces or openings in a medium, such as the spaces between intersecting fibers. Also referred to as pores or voids.

KNIFE-EDGE SEAL – A narrow, pointed ridge on the peripheral sealing surface of a filter or filter frame, which provides a seal by the impression of a sharp edge into a gasket or gel.

LAMINAR AIRFLOW – Airflow in parallel flow lines with uniform velocity and minimum eddies.

LAMINAR FLOW CLEANROOM – A cleanroom with a requirement for laminar airflow. Airflow velocities are usually not greater than 90 FPM.

LIFE EXPECTANCY – The service life or change-out interval of a filter cartridge. Even with known dust holding capacity, the useful life will vary according to the type and size of contaminants entering the filter, particularly on makeup air or 100% outside air systems.

Industry Definitions (continued)

LIFE CYCLE COSTS (FILTER) – Sum of all costs associated with operating a filter system, including product, energy, labor, transportation, and disposal costs.

MAKEUP AIR – Outside air introduced to the HVAC system for ventilation, pressurization, or to replace exhausted air quantities.

MASS TRANSFER ZONE – Area of the adsorbent bed where contaminants are removed from the airstream. The mass transfer zone will move away from the inlet of the bed to the discharge until breakthrough occurs (end of useful life of the medium).

MAXIMUM DIFFERENTIAL PRESSURE – The highest pressure differential which a filter is required to withstand without structural failure or collapse.

MAXIMUM RECOMMENDED PRESSURE DROP – Published final pressure drop by manufacturer.

MEDIA – Plural of medium. This is the material that performs the actual separation of contaminants from the air stream.

MEDIA VELOCITY – Speed of the air flowing perpendicular to the media, calculated by dividing the total airflow through a filter by the effective media area.

MEDIUM – The porous material through which air is passed to remove contaminants (particulates or gases). It is usually confined within a frame or cell sides and is generally referred to as a filter or filter cartridge.

MERV – Minimum Efficiency Reporting Value is a single number that is used, along with the air velocity at which the test was performed, to simplify the extensive data generated by the ASHRAE Standard 52.2, Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size. MERV is expressed on a 16 point scale (MERV 1 through MERV 16) and is derived from the particle size removal efficiency measured in the test.

MICRON OR MICROMETER – A unit of length in the metric system. This term means one millionth of a meter, 10-4 centimeter, 10-3 millimeter, or 0.000039 of one inch. It is commonly used as a measure of particle size or fiber size in filter media. The naked eye can see a particle approximately 10 microns or larger without magnification.

MICROORGANISMS – Living bodies that can be seen only through a microscope.

MIGRATION – Contaminant captured and subsequently released downstream of a filter.

MILLILITER – One thousandth of a liter, equal to one cubic centimeter.

MOORE'S LAW – The amount of information storable on a given amount of silicone doubles every year. (Gordon Moore, 1964, founded Intel)

NET EFFECTIVE MEDIA AREA – The amount of media area in a filter that is exposed to airflow and usable for collecting airborne contaminants. The opposite of blind spots or dead area, this term is synonymous with net effective filtering area.

NEGATIVE PRESSURE – Vacuum or suction.

NON-LAMINAR – As applied to cleanroom airflow, this is less desirable than laminar flow because the air supply is introduced at random, causing turbulence and induction that stir the airborne dust particles and keep them in suspension.

NONWOVEN – A filter cloth or paper that is formed of synthetic fibers that are randomly oriented in the media. It is usually held together with a binder or binder fibers.

NON-SUPPORTED FILTERS – Extended-area filters which rely on the airflow to support the media in the airstream. Filters will generally sag or collapse under low or no airflow conditions.

NVR – **Non Volatile Residue** - refers to the matter that remains after the solvent containing such matter has been filtered and evaporated at a specified temperature.

OFFGASSING – Term used to express the release of a gas from a material that was previously captured by an adsorbent. Preferential off-gassing occurs when an adsorbent releases a lighter molecular weight gas in order to adsorb a heavier molecular weight gas.

ORGANIC – Describes the vast number of chemical substances containing carbon, hydrogen, and oxygen.

OUTDOOR AIR – Ambient air that enters a building through a ventilation system, through intentional openings for natural ventilation, or by infiltration.

OXIDE – Combination of oxygen with another element.

OXIDATION – Any chemical reaction in which a material gives up electrons, as when the material combines with oxygen. Burning is an example of rapid oxidation, while rusting is an example of slow oxidation.

PANEL FILTER – A low efficiency filter, consisting of a flat sheet of media that is usually contained within a cardboard frame. An alternative design has an internal wire frame. Panel filters are typically made with fiberglass or synthetic media and are often referred to as throw-away filters.

PARTICLE COUNT – In a cleanroom, the particulate concentration expressed as particles per cubic foot or particles per cubic meter, by particle size, is used to express the Airborne Particulate Cleanliness Class in accordance with Federal Standard 209E or ISO Standard 14644-1. Depending on the cleanliness class, particles are simultaneously measured from 0.1 micron to 5 microns in size.

PARTICULATE MATTER (PM) – Also known as particle pollution, PM is a complex mixture of extremely small particles and liquid droplets. Particle pollution is made up of a number of components, including acids (such as nitrates and sulfates), organic chemicals, metals, and soil or dust particles.

PENETRATION – The leak rate through the filter, penetration is expressed as a percentage based upon a specific particle size. The percentage of penetration is the reciprocal of the percentage of the efficiency. HEPA filters, for example, have a 0.03% maximum penetration on 0.3 micron (μ) particles.

PLEATED FILTER – A type of extended surface filter where the media is folded back and forth to increase the amount of media exposed to the airstream within a given face dimension. Greater filter surface area reduces media velocity and increases the efficiency and dust holding capacity.

Industry Definitions (continued)

PLEATING – In filters with a paper medium or other sheet material, pleating means the folding processes which provide a large surface area within a given volume of filter.

PREFILTER – A filter placed in front of another filter to remove larger, heavier particles. The primary purpose of this is to extend the life of the final filters. Prefilters are highly recommended in systems requiring high efficiency filtration, especially where a high concentration of lint and larger particles are present.

PRESSURE DIFFERENTIAL – Difference in pressure between two points.

PRESSURE DROP – Difference in pressure between two points, generally at the inlet and outlet of a filter. Pressure drop is typically measured in inches of water column (water gauge) or pascals.

PRESSURE, STATIC – The fan-induced pressure that tends to burst or collapse a duct, which is required to move air through a system. Fans must push or pull air to deliver against resistance from duct friction, filters, coils, and other airflow obstructions.

PRESSURE, TOTAL – The combination of static pressure and velocity pressure within a duct.

PRESSURE, VELOCITY – The pressure required to maintain movement of air through a duct.

RESIDENCE TIME – The theoretical time that a contaminant is within the confines of a media bed.

RETENTIVITY – The ability of an adsorbent to resist the desorption of an adsorbate.

ROOM CLASSIFICATION

As Built - As built testing is carried out when the cleanroom envelope and all mechanical and electrical systems are complete but no production or process equipment is installed.

At Rest - At rest testing is carried out when all the production and process equipment is installed but has no occupancy of personnel.

Operational - Operational testing is carried out when all the production, process and occupants are in place– full working cleanroom.

SAMPLING

Isokinetic - Isokinetic sampling is when the sampling velocity is equal to the system or approach air velocity. Isokinetic sampling produces the most accurate and quantifiable results while leak scan testing.

Hyperkinetic - Hyperkinetic sampling is when the sampling velocity is greater than the system or approach air velocity. Leak scan testing via hyperkinetic sampling (greater than Isokinetic) produces less conservative readings that add the risk of missing leaks.

Hypokinetic - Hypokinetic sampling is when the sampling velocity is lower than the system or approach air velocity. It has been shown through experiment that the measured concentrations are conservative. In other words, leak scan testing via hypokinetic sampling (lower than Isokinetic) produces readings that may indicate a larger leak.

Note: Hypokinetic sampling method may be used qualitatively (not to quantify the reading at the leak) as a more conservative method than Isokinetic sampling to leak scan filters. In other words, this method increases the chances of finding a leak while leak scan testing.

SCAN TEST – Technique for disclosing leaks in HEPA and ULPA filters. Tests are performed by introducing a challenge aerosol upstream of the filters and passing the inlet of a sampling probe of an aerosol photometer or discrete particle in a series of parallel, slightly overlapping strokes across the downstream face of the filter (scanning), to detect any leaks.

SCFM – Standard Cubic Feet per Minute. This term refers to airflow that has been corrected to “standardized” conditions of temperature and pressure.

SKIN LOADING – The condition that occurs when collected particles build up on the surface of the media, plugging the spaces between the fibers. This is also known as blocking or surface loading. As a rule, the finer the media, the more susceptible it is to skin loading by “coarse” particles.

SORBENT – A substance that has the property of collecting molecules of another substance by adsorption or absorption.

STATIC TIP – Device used to measure static pressures in ducts or rooms. These devices are frequently installed upstream and downstream of a filter bank and connected to a pressure gauge to measure the pressure differential across the filter bank.

STERILIZATION – Complete elimination, destruction of all microbial life.

STOKES’ LAW – A physical law which approximates the velocity of a particle falling under the action of gravity through a fluid. The particle accelerates until the frictional drag of the fluid just balances the gravitational acceleration, after which it will continue to fall at a constant velocity known as the terminal or free-settling velocity.

STRAINING – A method of filtration that removes larger particles. Straining occurs when a particle is larger than the space between fibers and cannot pass through them.

SULPA FILTER – Super Low Penetrating Air filter with a minimum efficiency of 99.9999% on 0.12 micron (μ) particles.

SURFACE AREA – The surface area of an adsorbent is determined by the BET method and is usually expressed in square meters per gram of adsorbent.

TCOD – **Total Cost of Ownership Diagnostics®** – AAF Software designed specifically to optimize LCC of HVAC filters.

TERMINAL HEPA MODULE – A HEPA filter module that is connected to the end of a duct, most often mounted in the ceiling of a cleanroom.

TERMINAL VELOCITY – Steady velocity achieved by a falling particle when gravitational forces are balanced by viscous forces. See Stokes’ Law.

Industry Definitions (continued)

TEST AEROSOLS

DEHS: di-2-ethyl-hexyl-sebacate - Frequently used in the factory, occasionally in the field.

DOP: di-octyl-phthalate - Often prohibited, seen as being carcinogenic (Still utilized in Nuclear applications)

PAO: poly-alpha-olefin - Most commonly utilized test aerosol in the field for Life Science applications.

PSL: poly-styrene-latex - mono dispersed spheres, typically used as a challenge aerosol in the HEPA manufacturing facility.

U DESCRIPTOR – method to present the measurement results for ultrafine particle concentration in a cleanroom. The descriptor serves as the upper limit for the location averages or as an Upper Confidence Limit (UCL), or both as appropriate.

UL 586 – Standard for High Efficiency, Particulate Air (HEPA) Filter Units. For this standard, filters are tested for efficiency and penetration and undergo a moisture test, heated air test, a low temperature test, and a spot flame test. A UL 586 label can only be applied to HEPA filters whose designs have been proven to meet the requirements of UL 586 test standard and must be tested for efficiency and resistance.

UL 900 – Standard for Air Filter Units. Filters that are classified to this standard and bear the UL mark meet the requirements of the test for the amount of smoke generated and the combustibility of the air filter unit. Filters meeting the standard are classified as follows: “Air filter units covered by this standard are classified as those that, when clean, burn moderately when attacked by flame or emit moderate amounts of smoke, or both.”

ULPA FILTER – Ultra Low Penetrating Air filter with a minimum efficiency of 99.9995% on 0.12 micron (µm) particles.

UNLOADING – Release downstream of trapped contaminate. This can be due to a change in flow rate, mechanical shock, vibration, excessive pressure build-up, or medium failure.

VAPOR – A substance diffused or suspended in the air, especially one that is normally liquid or solid.

VENTILATION – The movement of air to and from a space by mechanical or natural means, including both the exchange of air to the outside, as well as the circulation of air within a building or space.

VISIONAIR™ CLEAN WITH TCO DIAGNOSTICS® SOFTWARE – An AAF software designed specifically to optimize A/C change rates, HEPA and Housing Selection.

VISIONAIR™ IEQ – An AAF software designed to simulate before and after scenarios of adding an air purifier and/or upgrading supply air filtration, with a focus on the impact on PM level reductions and indoor air quality (IAQ) improvement.

VOLATILE ORGANIC COMPOUNDS (VOCs) – Organic chemicals that have a high vapor pressure/low boiling point at ordinary room temperature, which causes large numbers of molecules to evaporate or sublimate from the liquid or solid form of the compound and enter the surrounding air. The health effects of VOCs in indoor environments vary, depending on the type and concentration of VOCs, along with the length of time a person is exposed.

Notes

Better Together

AAF International became part of the **Daikin Group** in 2006. Though staff from both companies began working together to provide complementary solutions for customers since then, the level of cooperation currently taking place between Daikin and AAF is unprecedented.

Through this collaboration, employees of Daikin and AAF can leverage each company's outstanding reputation, lineup of quality products, and incredible work ethic to enhance brand recognition and build a stronger, more complete answer to challenges faced by customers.

Employees from both organizations coordinate to offer customers the most innovative, long-lasting solutions that ensure clean, comfortable air.

AAF International Plant Locations

AAF, the world's largest manufacturer of air filtration solutions, operates production, warehousing and distribution facilities in 22 countries across four continents. With its global headquarters in Louisville, Kentucky, AAF is committed to protecting people, processes and systems through the development and manufacturing of the highest quality air filters, filtration equipment, and associated housing and hardware available today.

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Contact your local AAF representative for a complete list of AAF Air Filtration Product Solutions.

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