

Utilizing e-PTFE Membrane Media In Cleanroom Applications

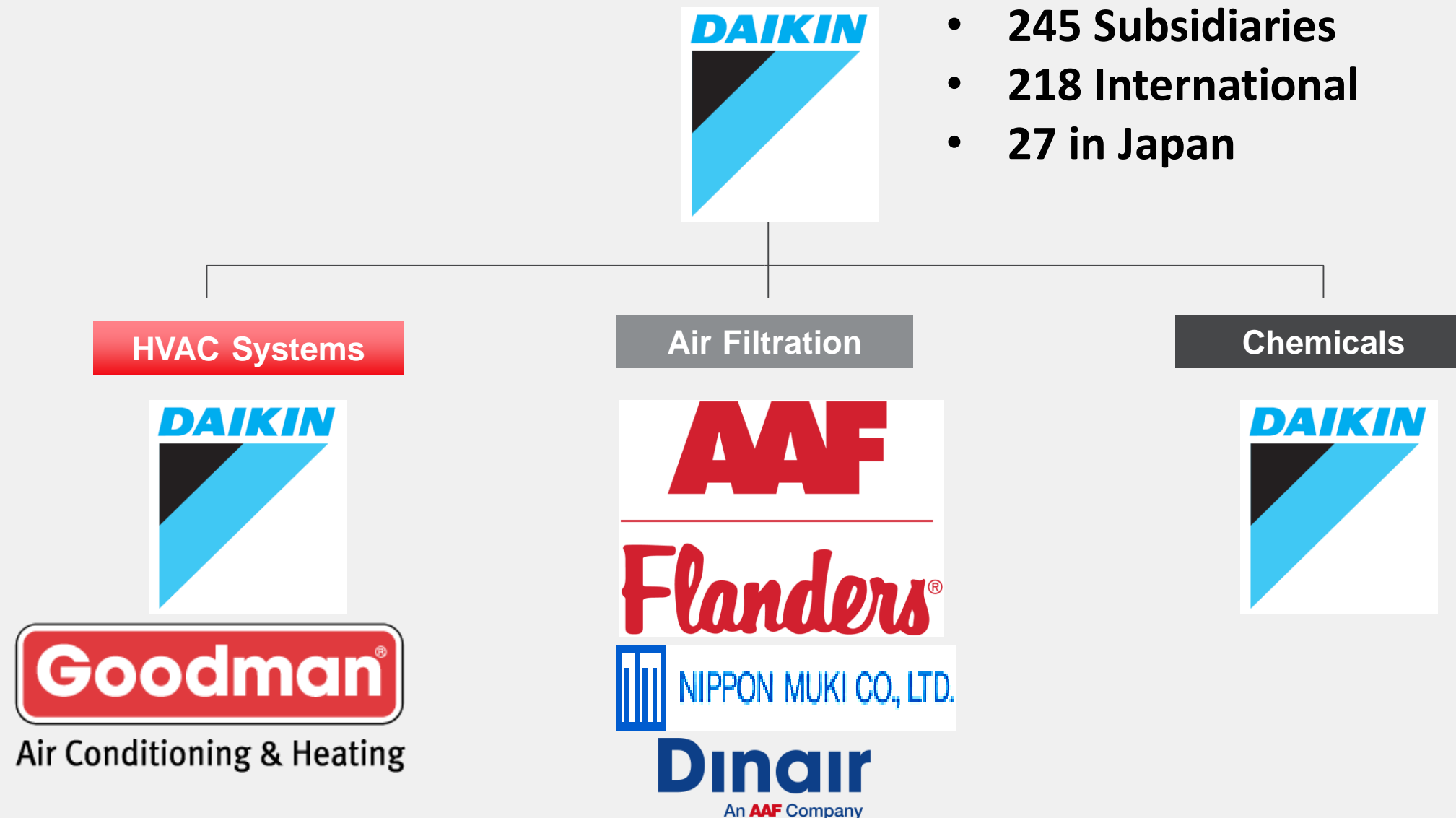
Sean O'Reilly
VP Global Strategic Business Initiatives:
AAF-Flanders
A Daikin Company

Agenda-Not for distribution.

- ▶ HEPA/ULPA Media Options
- ▶ When & Why PTFE membrane was first applied in cleanrooms
- ▶ Factory & Field Testing
- ▶ ePTFE HEPA Filter Media Structure
- ▶ Energy & Cost Savings
- ▶ IoT & Air Filters
- ▶ Cleanroom Design Software



Who We Are:



- 245 Subsidiaries
- 218 International
- 27 in Japan

- World's Leading Air Conditioning and Air Filtration Company
- 2016 sales approximately \$20B USD
- Sold in over 150 countries
- 67,036 Employees
- AAF Founded 1921

Media – The Heart of the Filter and the Cleanroom:

HEPA Filters Types:

Glass Fiber or Micro Glass (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 recipe 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 to filter installation and certifying. Most people involved in the industry know this and it is accepted as the only option available.

Glass Fiber Media:

First developed in the 1940's

- ▶ 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**

Glass Fiber in use 75+ Years

Industry 'standard' for high efficiency filtration



Membrane Media or e-PTFE/e-FRM

- First discovered in 1938, Dr. Roy Plunkett accidentally discovered PTFE while working for DuPont. Polytetrafluoroethylene was abbreviated to Teflon as a registered trademark in 1945. 1958 Jan: W.L. "Bill" Gore (1912-1986) left his job at DuPont to pursue his belief in the untapped potential of PTFE and launched together with his wife W. L. Gore & Assoc. in the basement of their home in Newark, DE. 1969 Oct: Their son Bob Gore accidentally discovered expanded PTFE (ePTFE). **1988 Daikin (AAF Parent) discovered ultrafine fiber structure**
- 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 is in a cleanroom environment.**
- The main benefits of the membrane technology are: **VERY robust media, low pressure drop and chemically inert.**
- The ePTFE membrane media is now the media of choice for Microelectronic applications from the **critical mini-environments to the larger FABS and FPD facilities due to its low energy consumption, lighter weight, and today due to economies of scale lower cost.**
- The eFRM membrane is a relatively new media enjoying rapid adoption in the Life Science/Healthcare industry due to the same benefits but also now 'PAO compatible' which was one of the original challenges with the first generations of ePTFE membranes.

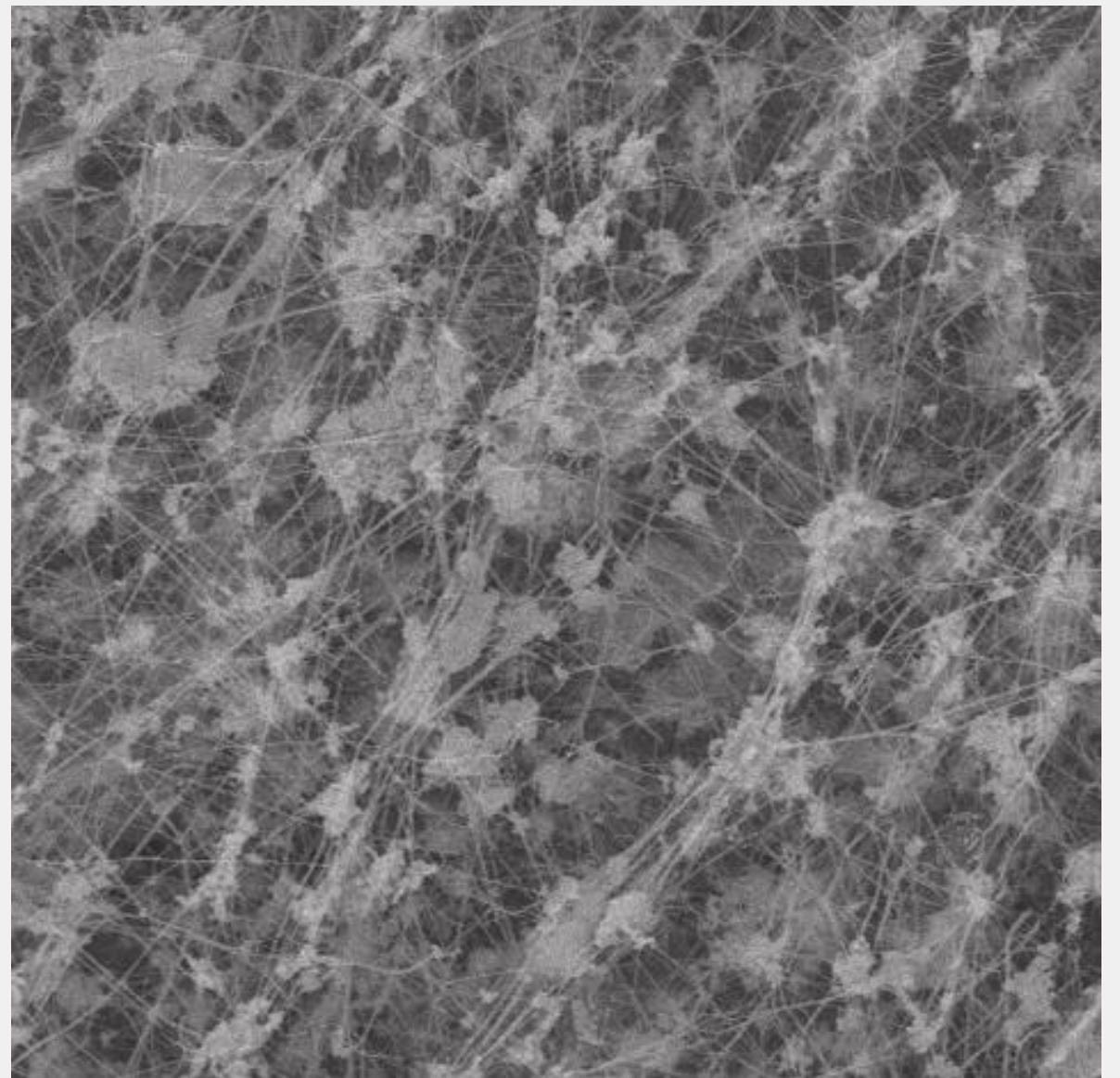
e-PTFE Media:

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.**

e-PTFE approx. 30 years

Semicon application adoption late 1990's



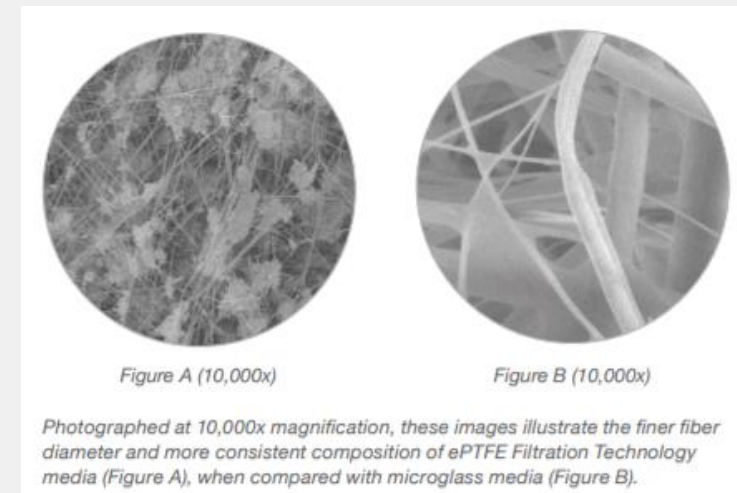
What drove the demand for e-PTFE Media?

- ▶ Semiconductor manufacturing development demanded a cleaner and more stable environment from a particulate and molecular contamination standpoint. Glass Fiber did not meet that need in many cases.
- ▶ Timing, e-PTFE fine fiber structure discovered (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 is 30PA)
- ▶ Gore heavily promotes e-PTFE ULPA applications directly to end users and through filter manufacturers.
- ▶ AMD Dresden Fab wanted to use e-PTFE 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 e-PTFE for 'mega fabs' and early adoption of Life Science applications for media that is PAO compatible.
- ▶ Cost comparable with glass media today with more technical/TCO benefits.

ePTFE Membrane Media:

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

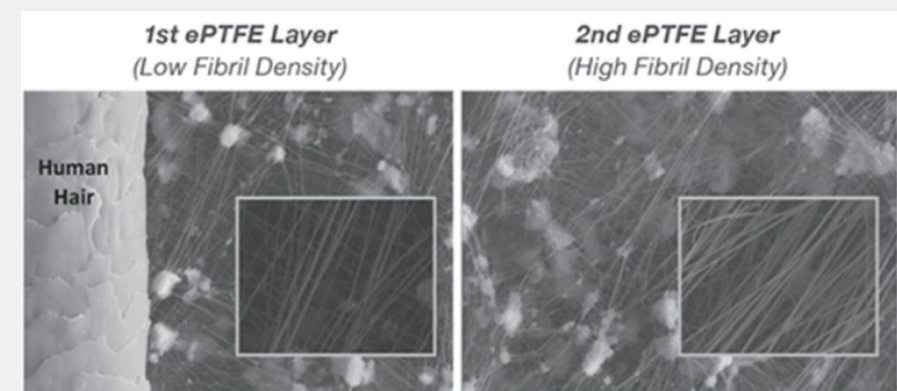
- Available in H13 – U17
- Standard for Microelectronic and Tool Market
- Compatible with Discrete Particle Counters (DPC) testing



eFRM Membrane 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
- High DHC on Oil Based aerosols.
- Compatible with photometric test methods.



ePTFE membrane structure and Cross-section SEM

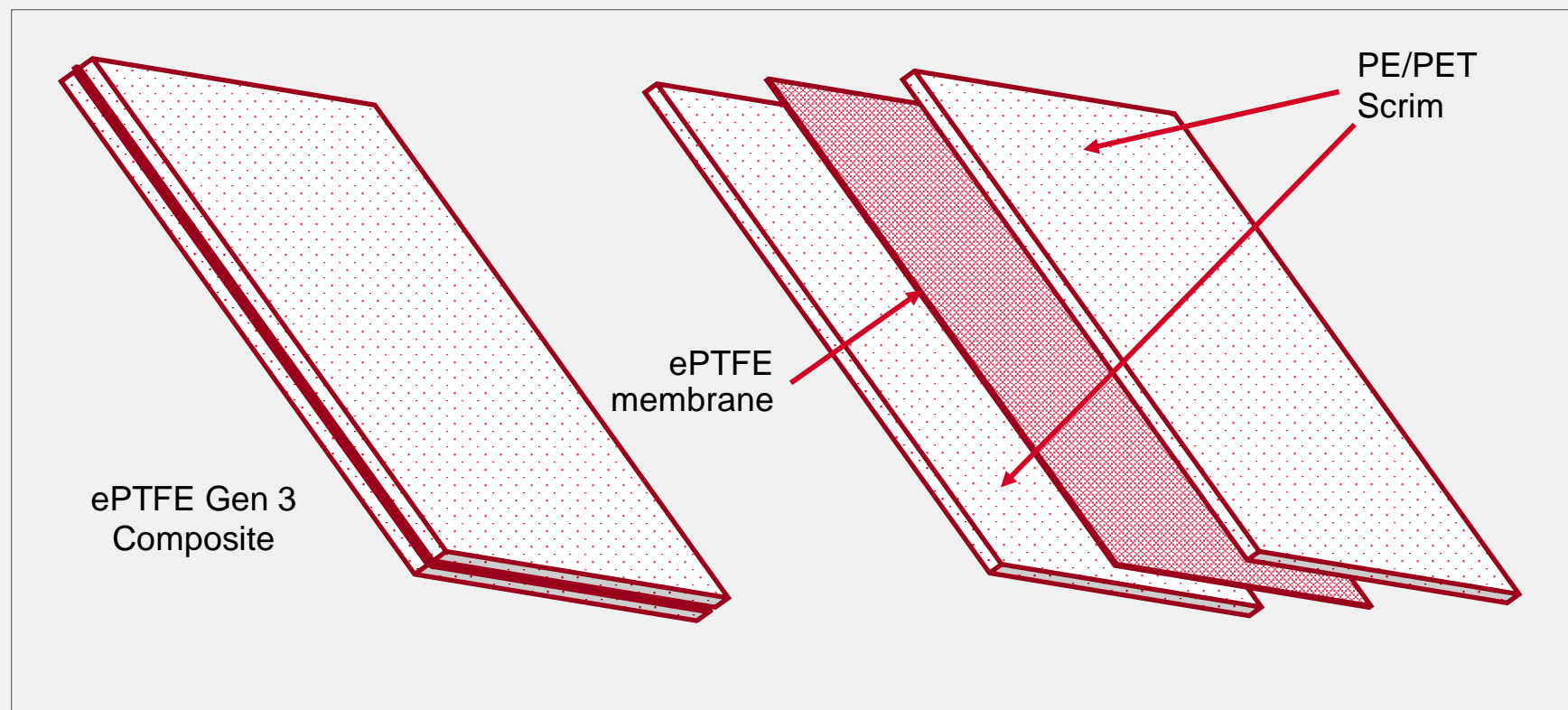


Figure 1: Schematic of ePTFE Gen 3 membrane structure with the 3 different layers

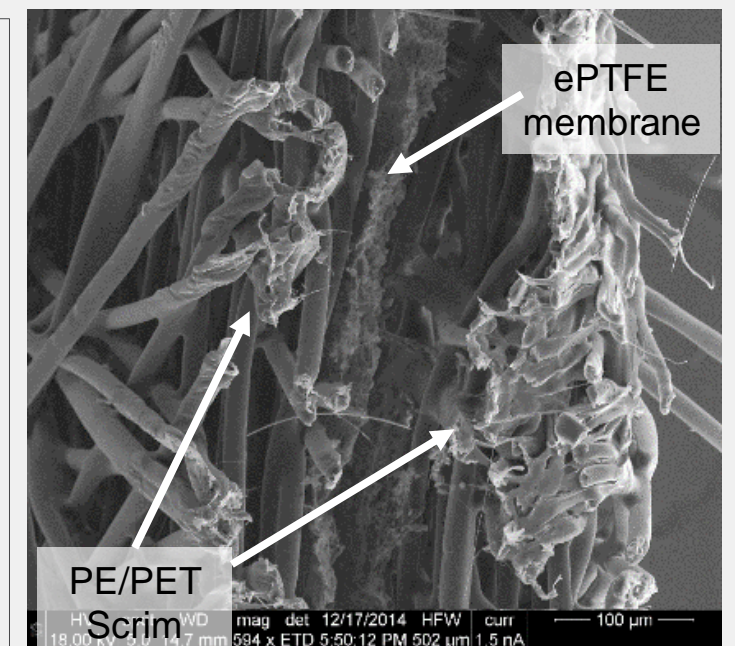


Figure 2: Electron micrograph of ePTFE Gen 3 membrane cross-sectional view showing the 3 layer structure.

- ▶ ePTFE Gen 3 is a 3 layer composite with 2 layers of PE/PET (Polyethylene/Polyethylene Terephthalate) Scrim on both air entering side and air leaving side. Both layers of scrim have a basis weight of 40 gsm with an overall basis weight of 82 gsm. The composite media is uni-directional.

eFRM membrane structure and Cross-section SEM

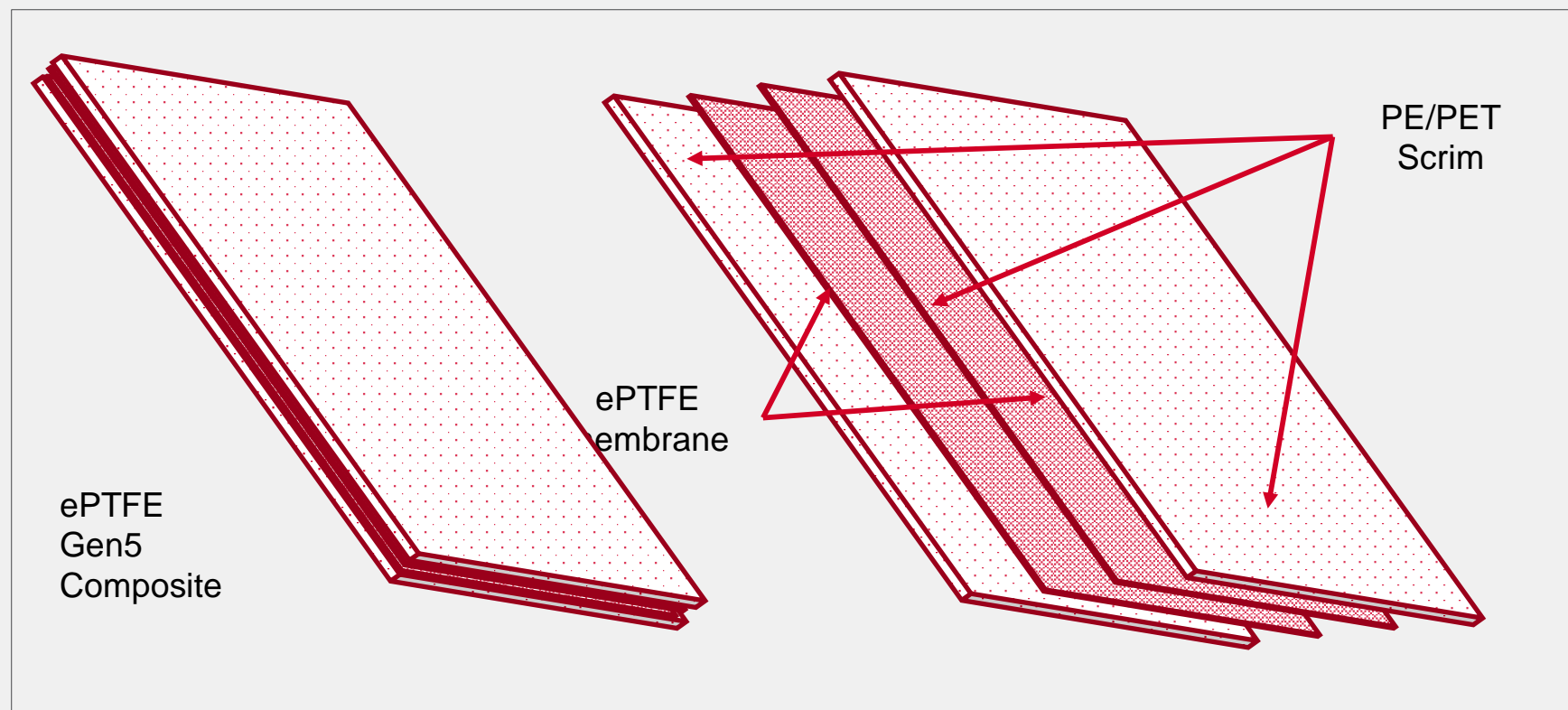


Figure 5: Schematic of ePTFE Gen 4 membrane structure with the 4 different layers

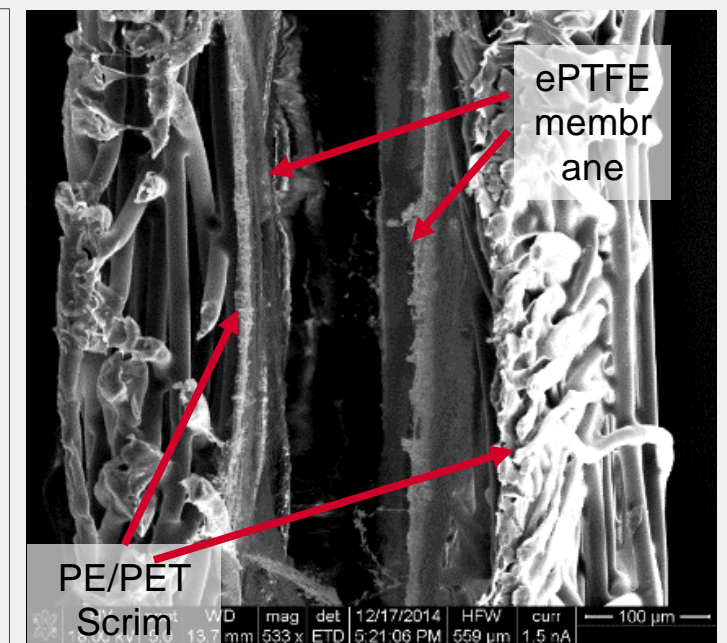


Figure 4: Electron micrograph of ePTFE Gen 5 membrane cross-sectional view showing the 4 layer structure.

- ▶ eFRM is a 4 layer composite with 2 layers of PE/PET (Polyethylene/Polyethylene Terephthalate) Scrim one layer each on air entering side and air leaving and 2 layers of the eFRM membranes in the middle as shown in figure 5. Both layers of scrim have a basis weight of 40 gsm with an overall basis weight of 90 gsm. The composite media is uni-directional. The eFRM membrane on the air entering side is more open giving the media a gradient density.

ePTFE – expanded PTFE

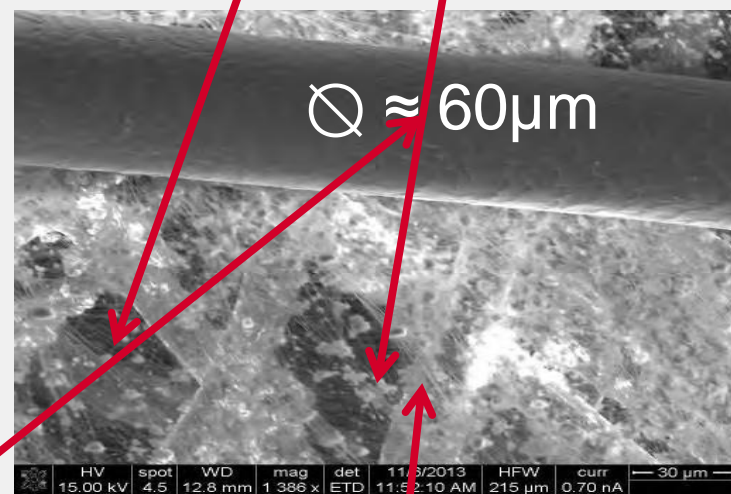
Much finer (nano)
fiber diameters
with slip-flow air
movement
=
HIGHER
efficiency and
LOWER pressure
drop (up to 50%)

PTFE
Nodes
(for structure)

PTFE
Fibrils
(for filtration)

Glass Fiber dia. 0.5 – 1.0 μm

Membrane Fiber dia. 0.02 - 0.2 μm



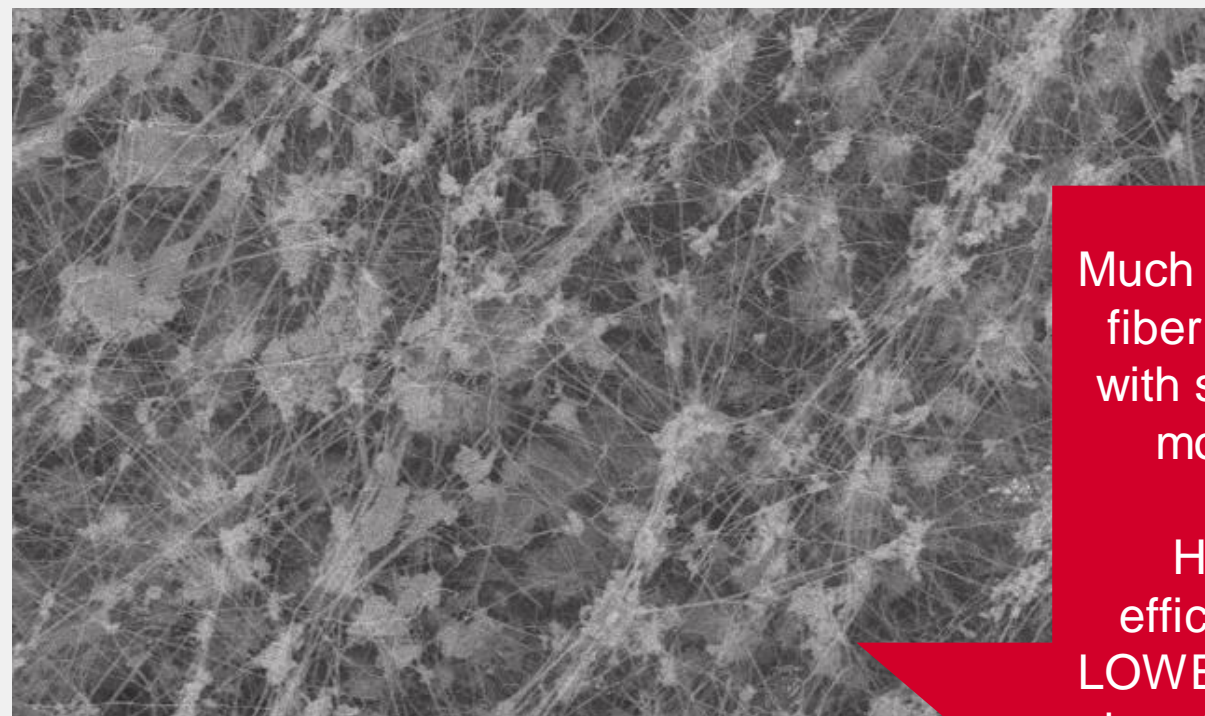
Human Hair
(for comparison)

Nonwoven Support Layer

- ▶ **1988:** Daikin industries (AAF Parent) discovered first ultrafine fiber structure.
- ▶ **1994:** ePTFE membrane HEPA filter for deep filtration revolutionize filtration for microelectronic cleanrooms due to ultralow low emission of volatiles and durability.
- ▶ **2012:** **eFRM** membrane technology developed for high aerosol concentration and high DHC applications

Fiber Comparison

Very thin (nano) fibers – Less energy consumption

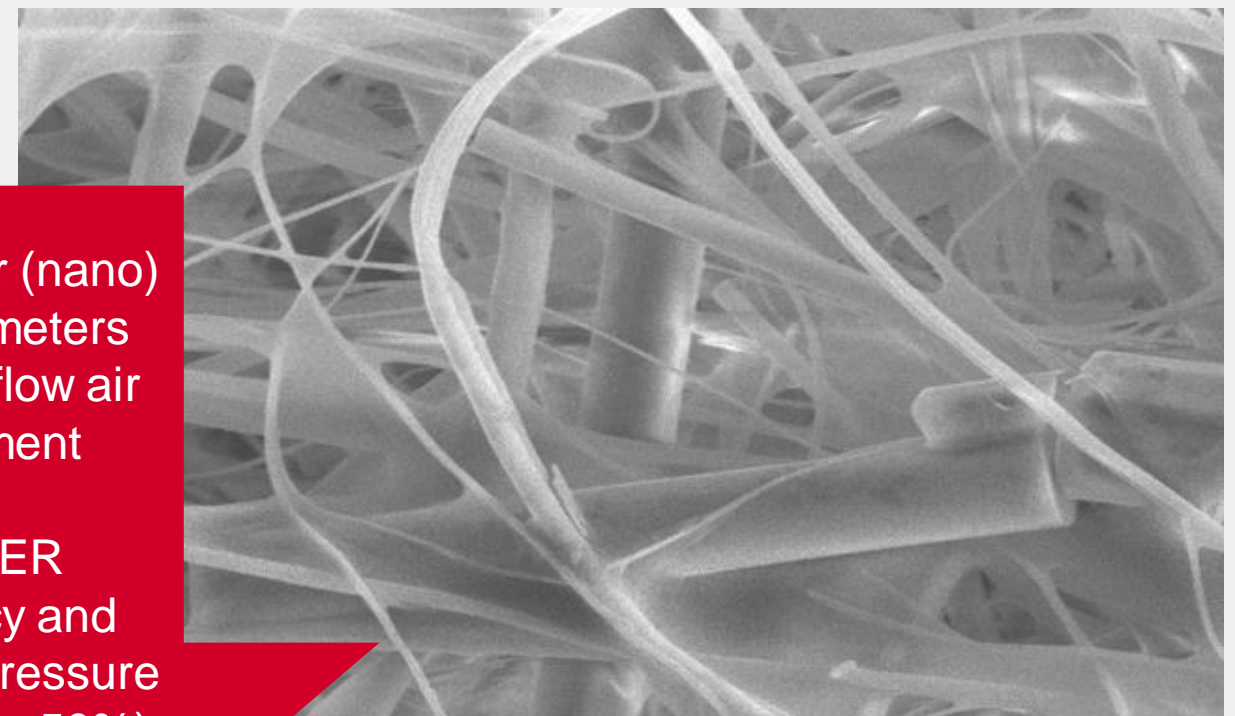


ePTFE membrane

at 10,000x magnification

curr	HV	WD	spot	mag	HFV	det	mode	5 μm
0.16 nA	10.00 kV	6.1 mm	3.5	10 000 x	29.8 μm	TLD	SE	1795-165

Much finer (nano)
fiber diameters
with slip-flow air
movement
=
HIGHER
efficiency and
LOWER pressure
drop (up to 50%)



glass fibers

at 10,000x magnification

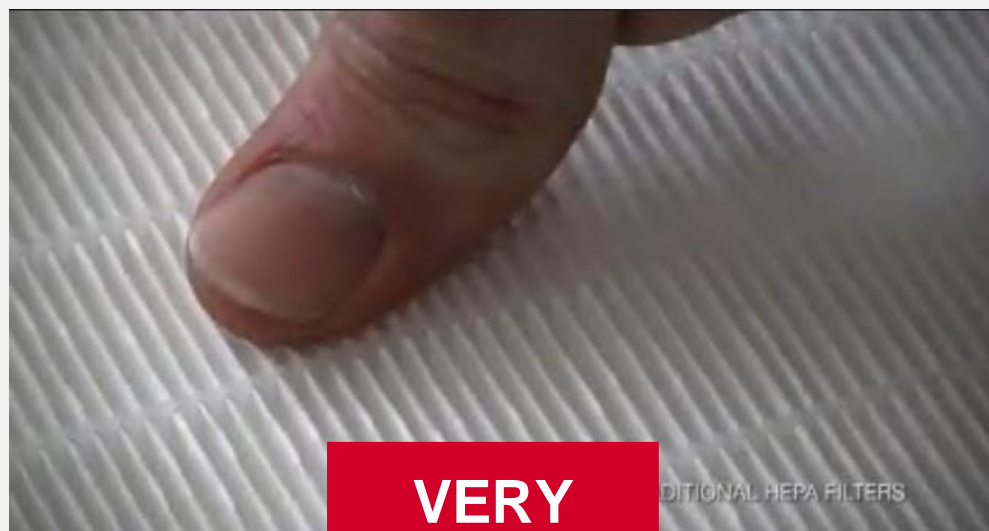
curr	HV	WD	spot	mag	HFV	det	mode	5 μm
0.16 nA	10.00 kV	5.1 mm	3.5	10 000 x	29.8 μm	TLD	BSE	1795-165

0.02 - 0.2 μm

0.5 - 1.0 μm

ePTFE membrane filtration technology provides the
highest efficiency at the lowest operating resistance

Sensitivity of Traditional Glass Media v Membrane



**VERY
FRAGILE**



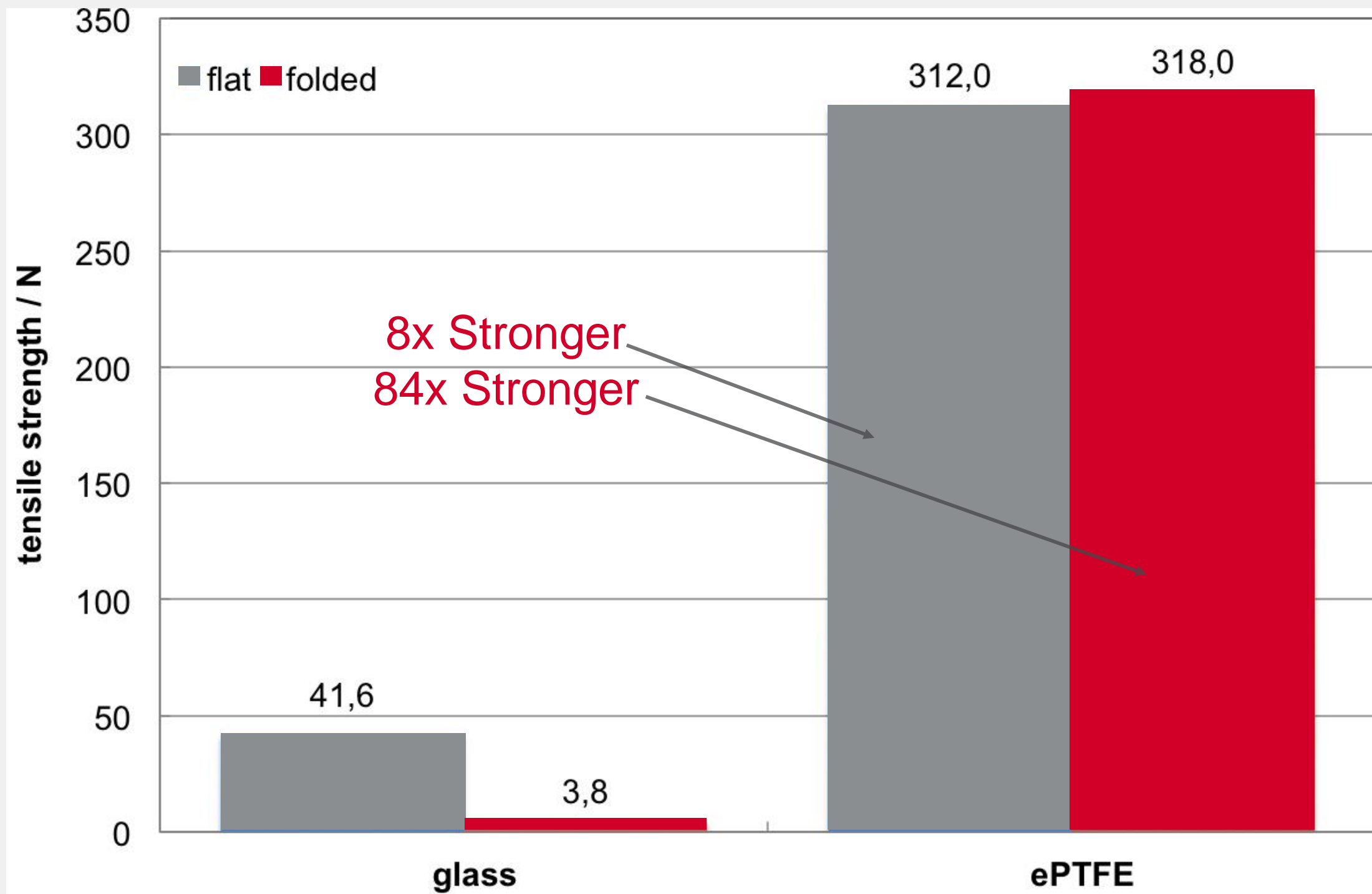
During:

- ▶ filter installation
- ▶ filter validation
- ▶ cleaning of ceiling
- ▶ cleanroom modifications
- ▶ working activities in the cleanroom

Risk of filter damage, resulting in:

- ▶ cleanroom downtime
- ▶ unscheduled replacements
- ▶ costly recovery actions
- ▶ cross contamination
- ▶ uncontrolled release of harmful substances

High Mechanical Stability



Water Resistance-Hydrophobic

MEGAcel® LPD 1220x610x69				
	Before Water Spray	Water Spraying	72h After Water Spray	Comment
Efficiency	99,999952%@0,1µm	500ml deionized water	99,999974%@0,1µm	ok
Pressure Drop	70Pa@0,45m/s		73Pa@0,45m/s	ok
DIN Scan Test	no leak		no leak	ok

MEGAcel® 610x610x65 (Gen3)	Water Resistance			
	Before Exposure (@600m3/h)	Exposure	After Exposure (@600m3/h)	Comment
Visual Appearance	ok	Operation 1h@245Pa while spraying 450ml/min for 1h (total 27l), after that natural drying for 1 week	ok	ok
Efficiency	99,999995%		99,999999%	ok
Pressure Drop	85		85	ok
Leakage	no		no	ok

H₂O₂ Resistance & Common Cleaning-Decon Agents:

Tested Items	Sample	Before Exposure	After 24h Exposure in H ₂ O ₂ Solution	Notes	Result
Efficiency @ 0,1~0,2µm	#1	99,9998%	99,9999%	at 5,3 cm/s	✓
	#2	99,9999%	99,9998%		✓
Pressure Drop	#1	255 Pa	276 Pa	at 5,3 cm/s	✓
	#2	257 Pa	286 Pa		✓
Weight	#1	2,729 g	2,738 g	135x200 mm	✓
	#2	2,603 g	2,609 g		✓

ClO ₂	Before Exposure	After 24h Exposure in 0,2% ClO ₂ Solution	Notes	Result
Efficiency @ 0,3µm PSL	99,9995%	99,9992%	at 5,3 cm/s	✓
Pressure Drop	119 Pa	119 Pa	at 5,3 cm/s	✓
Weight	98 g/m ²	99 g/m ²	-	✓

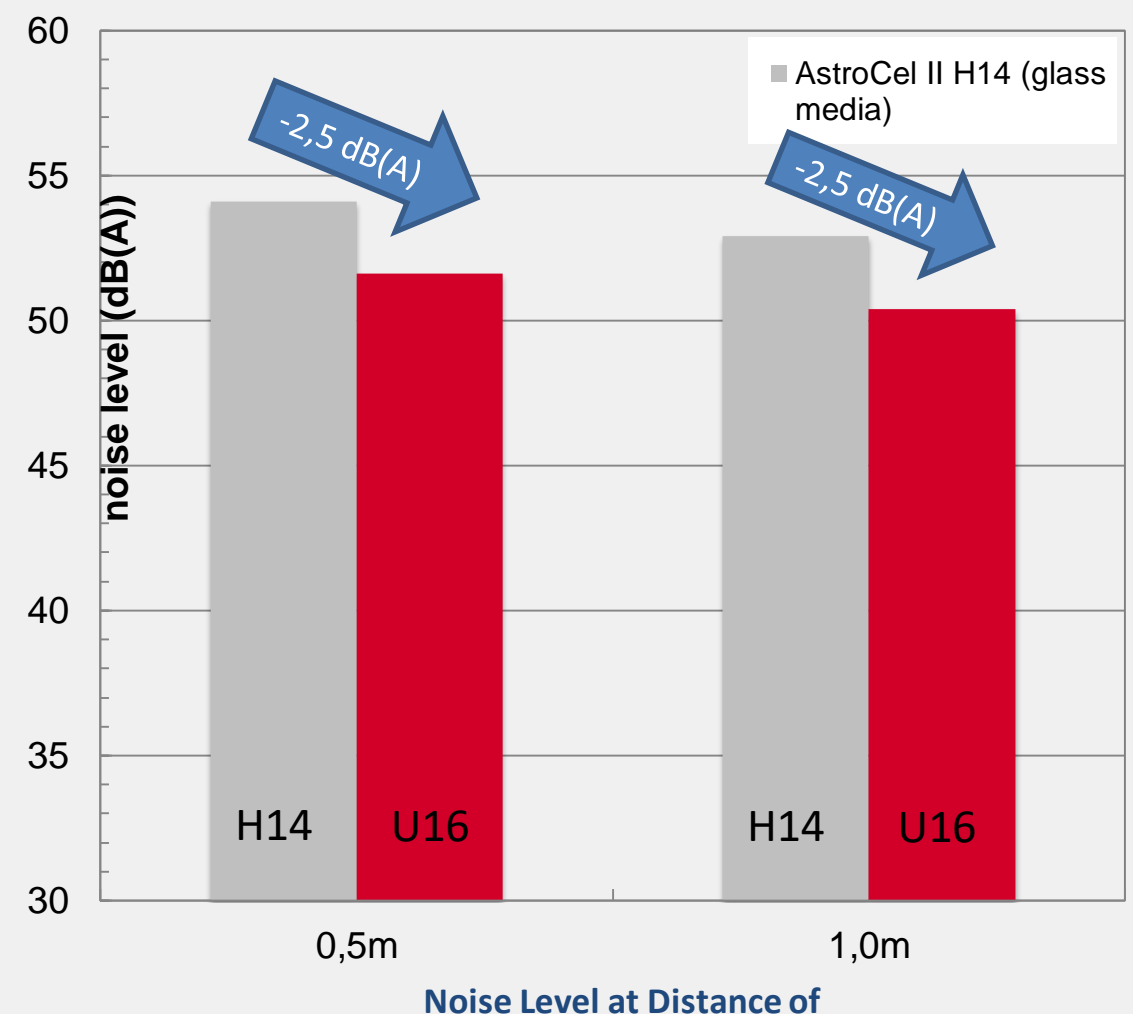
CH ₂ O	Before Exposure	After 24h Exposure in 36% CH ₂ O Solution	Notes	Result
Efficiency @ 0,3µm PSL	99,9998%	99,9996%	at 5,3 cm/s	✓
Pressure Drop	125 Pa	124 Pa	at 5,3 cm/s	✓
Weight	97 g/m ²	101 g/m ²	-	✓

Chemical Resistance

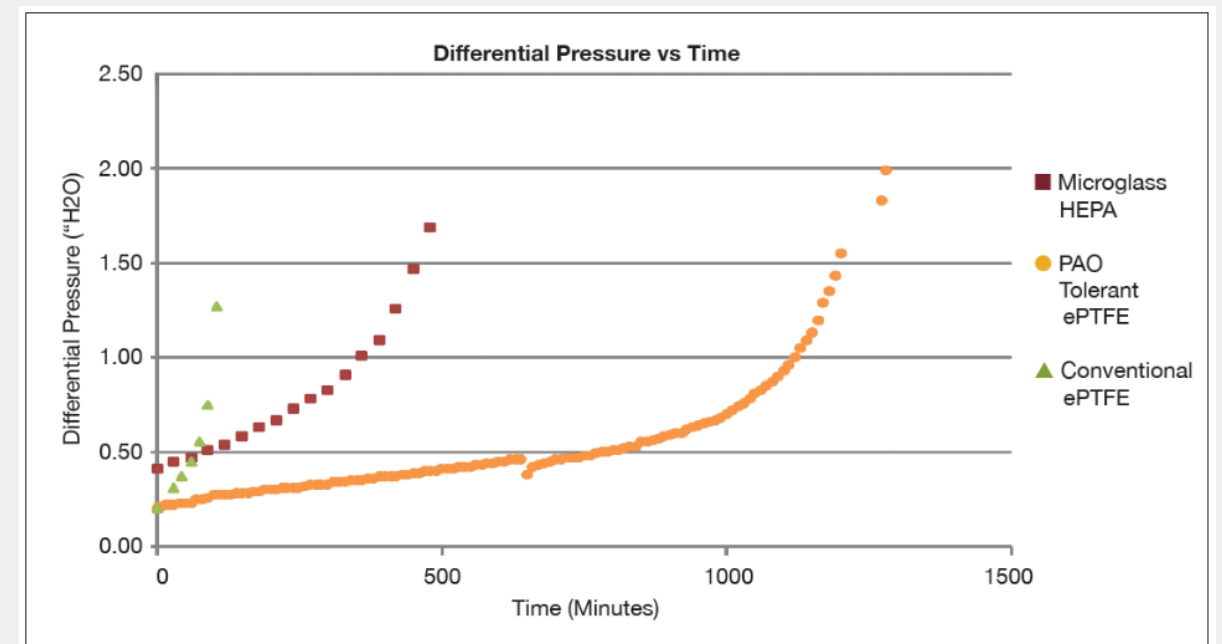
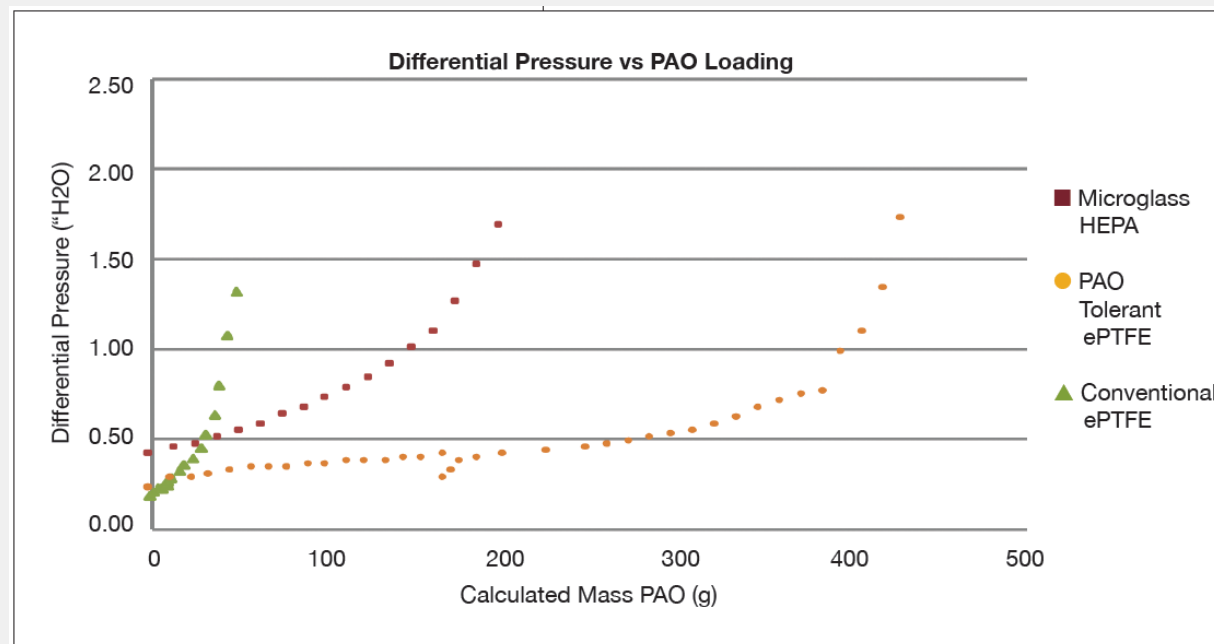
Solvent (dipped in for 24h)		Efficiency	Pressure Drop	Weight
Water	pure water	✓	✓	✓
Acid	conc. hydrochloric acid (35%)	✓	✓	✓
	conc. sulphuric acid (95%)	✓	✓	reduced*
	conc. nitric acid (60%)	✓	✓	✓
	conc. hydrofluoric acid (47%)	✓	✓	✓
Alkalis	ammonia solution (28%)	✓	✓	✓
	sodium hydroxide (10%)	✓	✓	✓
Organic Solvents	isopropyl alcohol	✓	✓	✓
	toluene	✓	✓	✓
	acetone	✓	increased*	✓
	benzene	✓	✓	✓
	xylene	✓	✓	✓
	hexane	✓	✓	✓

Noise Level Reduction

- ▶ Noise level glass fiber H14 HEPA filter vs. U16 PTFE membrane HEPA filter
- ▶ FFU type EC612, filter size 570x1170x84



PAO Loading MEGAcel® II results comparing PTFE v FRM and Microglass HEPA



PAO Loading rate 45µg/l

- ▶ PAO loading tests were carried out in a similar manner to those reported in the article by Roberts et al. to compare the impacts of PAO exposure on FRM, ePTFE, and microglass filter media. Filter loading curves were generated for the three media types by monitoring the differential pressure across the 592mm x 592mm x 69mm filters as they loaded with PAO.

DPC vs. Photometer Leak Testing

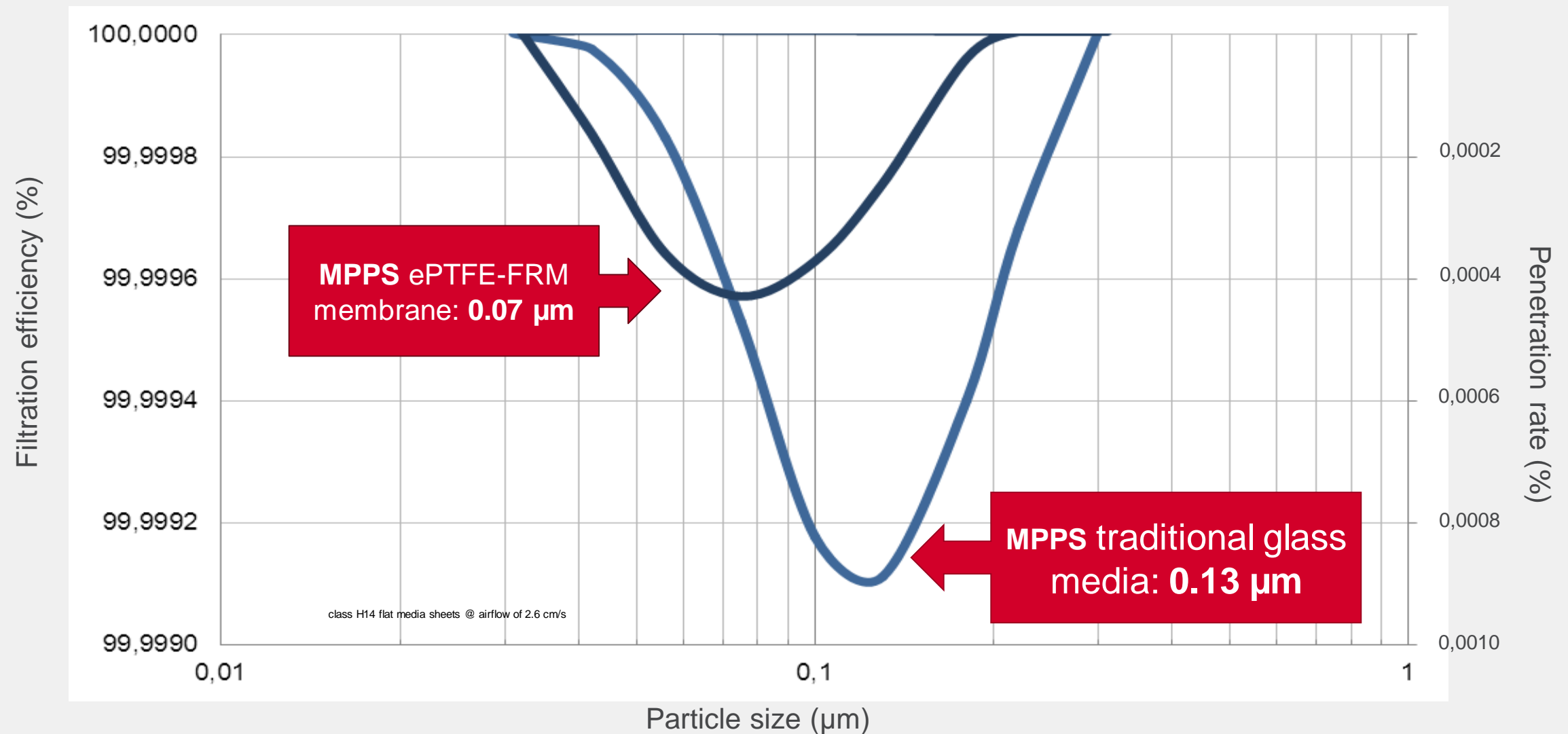
The DPC method is described in numerous international standards like:

- ▶ EN 1822: “High Efficiency Air Filters”
- ▶ ISO 14644-3: “Cleanrooms and associated controlled environments - Test methods”
- ▶ ISO 29463: “High-efficiency filters and filter media for removing particles in air”
- ▶ Institute of Environmental Science and Technology – Recommended Practice: IEST-RP-CC034 “HEPA and ULPA Filter Leak Tests”
- ▶ National Environmental Balancing Bureau (NEBB): “Procedural Standards for Certified Testing of Cleanrooms”

Common aerosols for leak testing:

- ▶ DOP: di-octyl-phthalate ($\text{C}_6\text{H}_4(\text{COOC}_8\text{H}_{17})_2$) (often prohibited as seen as being carcinogenic)
- ▶ PAO: poly-alpha-olefin (Emery 3004: 1-decene tetramer ($\text{C}_{10}\text{H}_{20}$)₄ mixed with 1-decene ($\text{C}_{10}\text{H}_{20}$), viscosity 4 cSt)
- ▶ DEHS: di-2-ethyl-hexyl-sebacate ($\text{C}_{26}\text{H}_{50}\text{O}_4$) (advantage: evaporates residue-free after some time - 0,3µm-particle after 4h)
- ▶ PSL: poly-styrene-latex (suspension, mono disperse sheres (0,13/0,178/0,22/0,33/0,52µm), used in microelectronics)
- ▶ Count Mean Diameter (CMD): 0.1 µm to 0.5 µm

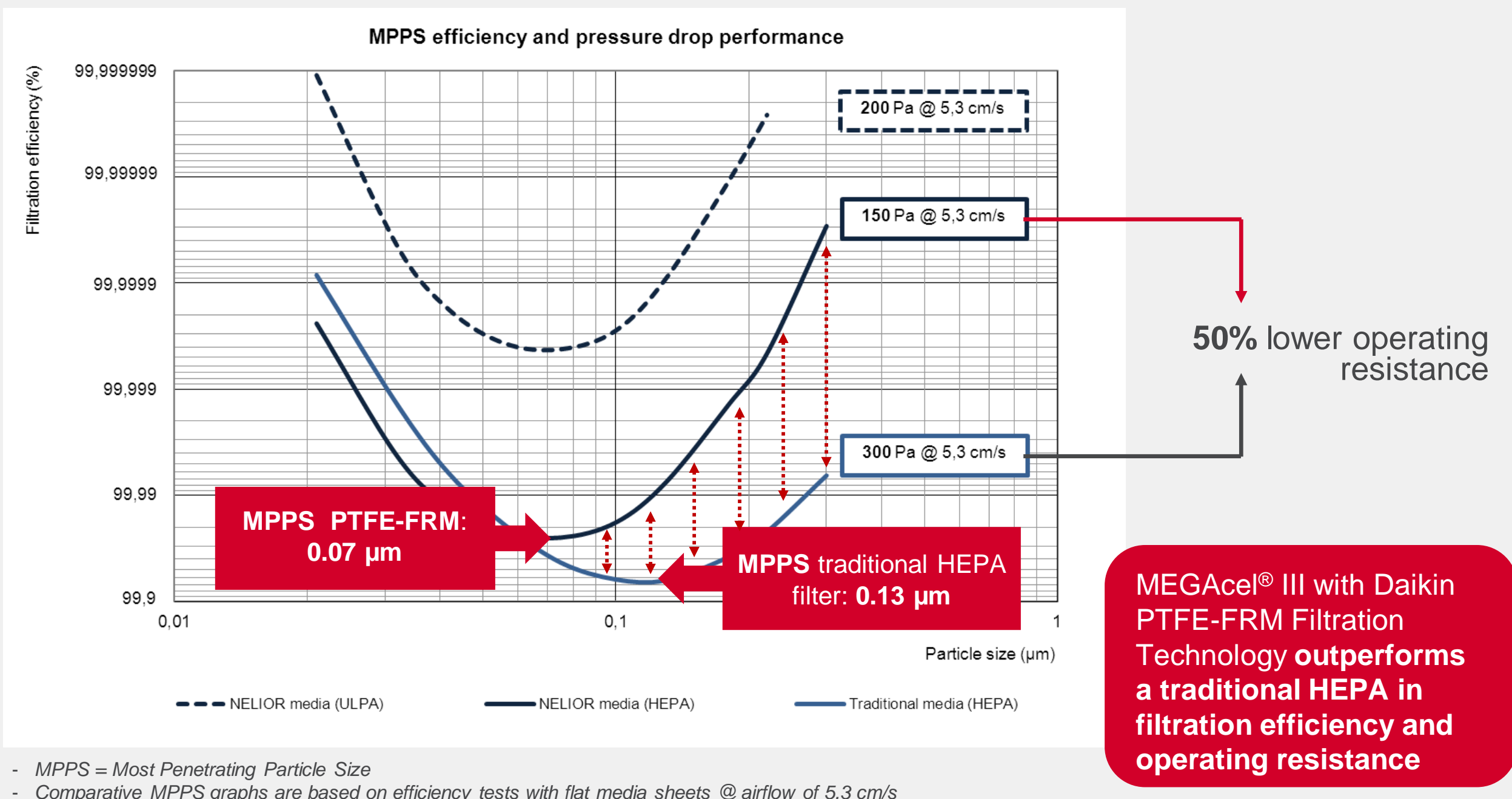
MPPS: Most Penetrating Particle Size



Filtration efficiency @ MPPS determined according to:
 EN1822-5:2009 - Annex A, alternative procedure for membrane media with MPPS < 0,1µm

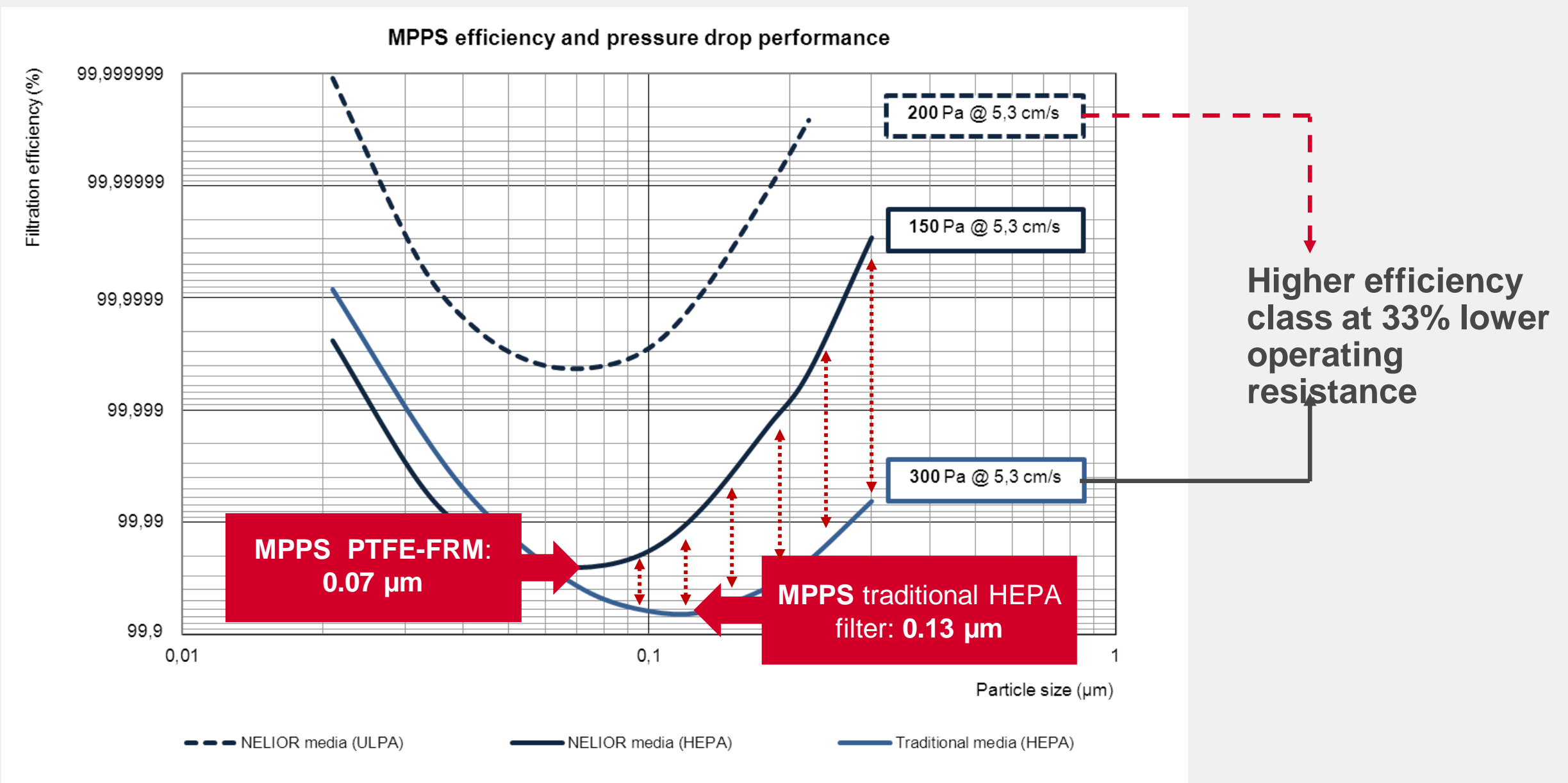
MEGAcel® ePTFE-FRM Membrane Media

High filtration efficiency combined with low operating resistance:



MEGAcel® ePTFE-FRM Membrane Media

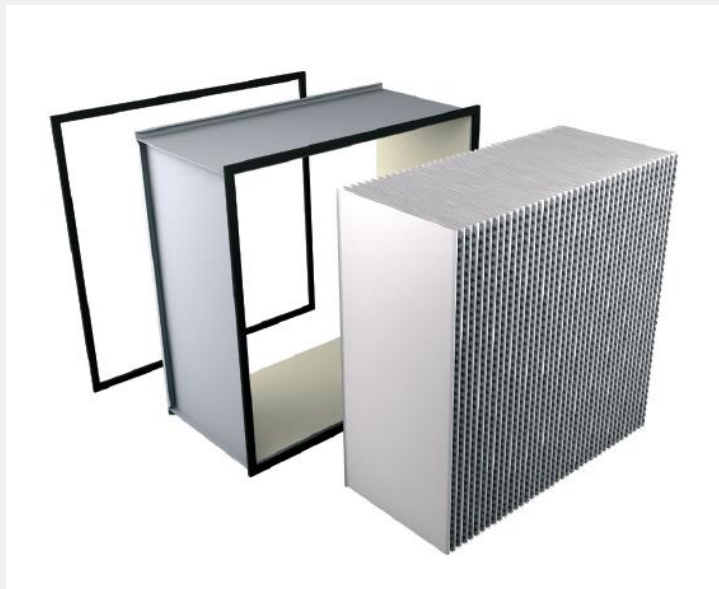
High filtration efficiency combined with low operating resistance:



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

Construction Options:

HEPA Construction Types












Astrocel-MEGAcel I
292mm deep
Deep Pleat design
Dry and gel seal



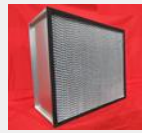
Astrocel-MEGAcel II
20mm-180mm depths
'minipleat/closepleat' design
Dry and gel seals



Astrocel-MEGAcel III
292mm deep
'V' bank design
Dry and gel seals

AstroCel/MEGAcel Series		Construction/Testing Options											
		expanded FluoroResin Membrane	expanded PTFE Membrane	Glassfiber Media	Hot Melt Separators	Ribbon Pleat	Dimple Pleat	String Pleat	Embossed/Close Pleat	Aluminum Separator	Vinyl Coated Aluminum Separator	Plastic Separator	Stainless Steel Separator
	MEGAcel I eFRM	✓							Option	✓	Option	Option	Option
	MEGAcel II eFRM	✓			✓								
	MEGAcel III eFRM	✓			✓								
	MEGAcel I ePTFE*		✓						Option	✓	Option	Option	Option
	MEGAcel II ePTFE*		✓		✓								
	MEGAcel III ePTFE*		✓		✓								
	AstroCel I			✓					Option	✓	Option	Option	Option
	AstroCel II			✓	Option	✓	Option	Option					
	AstroCel III			✓	✓			✓					

AstroCel/MEGAcel Series



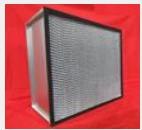
MEGAcel I eFRM



MEGAcel II eFRM



MEGAcel III eFRM



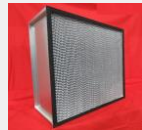
MEGAcel I ePTFE*



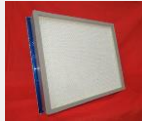
MEGAcel II ePTFE*



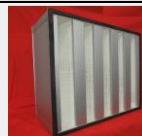
MEGAcel III ePTFE*



AstroCel I



AstroCel II



AstroCel III

Urethane Pack to Frame Sealant	64mm to 292mm frame depths	V-style packs	Gel Seal Filter & Knife Edge	PU-EPDM-Neoprene Gasket	Painted/SS Faceguard	Fabricated Aluminum Frame	Extruded Aluminum Frame	Stainless steel Frame	Galvaneal/Galvanized Frame	Particleboard/Plywood Frame	Plastic Frame	High Temperature (≥65°C)	Factory Testing - Suitable for common test aerosols (Concentration & Equipment Specific) *DOP*, PAO, PSL, DEHS *Nuclear Market Only*	Field testing - Suitable for common test aerosols (PAO and PSL)	EN1822: E10 to U17 (ePTFE H13 to U17only, FRM H13 and H14 only)	IEST-RP-CC001: Type A to Type K	UL-900/ULC-S111	UL-586	FM 4920	Centerboard for PD or Upstream Concentration Measurement
✓	✓		Option	Option	Option	Option	Option	Option	Option	Option	Option		✓	✓	✓	✓	Option			
✓	✓		Option	Option	Option		✓	Option					✓	✓	✓	✓	Option			Option
✓		✓	Option	Option		Option	✓	Option	Option				✓	✓	✓	✓	Option			
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Factory Testing:

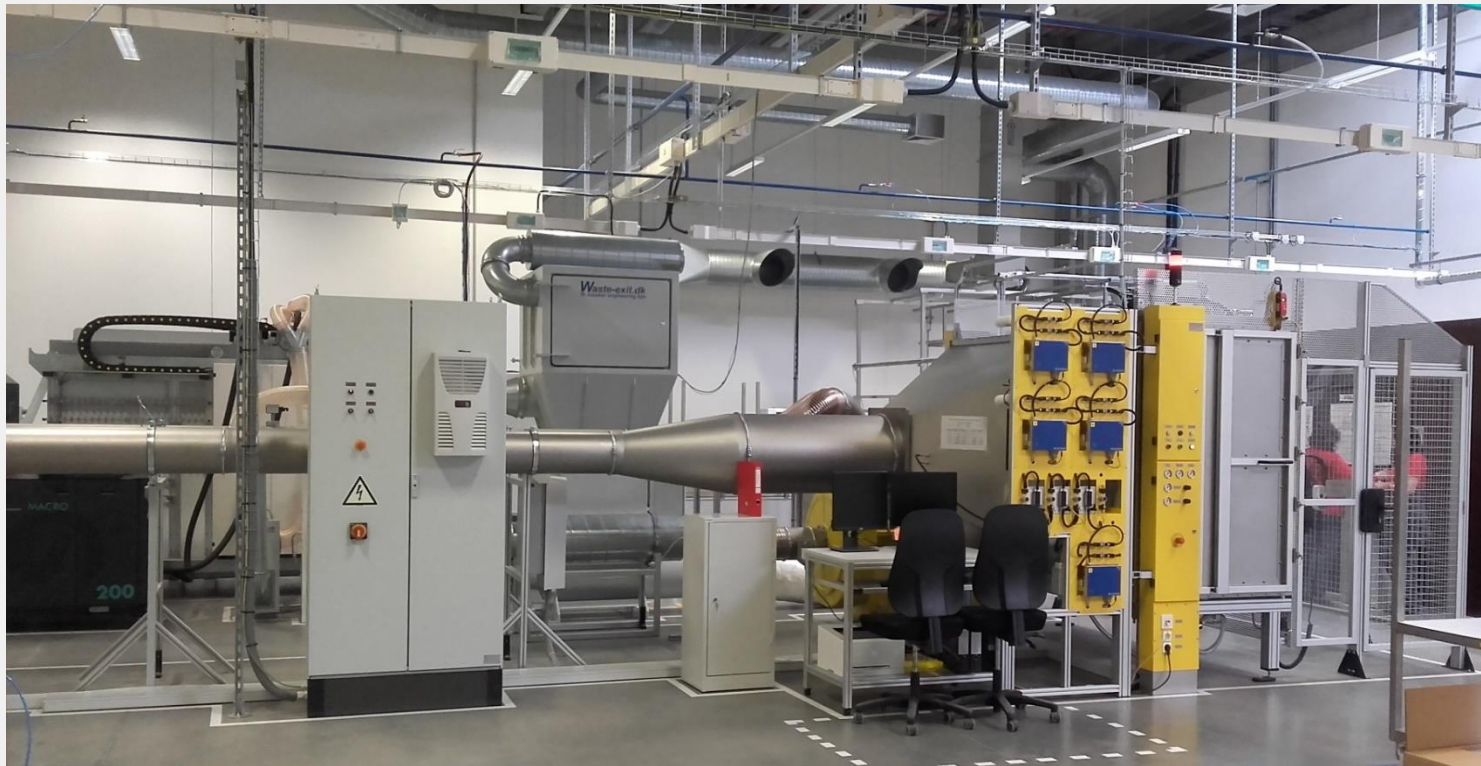
AAF | Flanders® Filter Performance Testing Standards Comparison

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		≥85	≥15			
	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	Overall Value	Local Value
		Efficiency	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	1
J	0.1-0.2 or 0.2-0.3**	≥99.99	1
K	0.1-0.2 or 0.2-0.3**	≥99.995	1,6
D	0.3*	≥99.999	5
F	0.1-0.2 or 0.2-0.3**	≥99.9995	5
G	0.1-0.2 or 0.2-0.3**	≥99.9999	10

*Although the mass median diameter of thermally generated aerosol is approximately 0.3 micron, in practice, the count mean is under 0.2 micron or close to the MPPS.

Important Filter Manufacturers make the necessary investments in the latest fully Automated Factory HEPA Scan Test Technology:



Filter Efficiency v Filter Integrity (aka Global v Local)

Efficiency:

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

EN-1822-5 (Single point measurement fixed)

IEST-RP-CC001

IEST-RP-CC007

Integrity:

Measure of the filters local leakage threshold within specified limits.

EN-1822-1 (Single point measurement during scan test)

EN-1822-4 (Mean value of the local values measured)

IEST-RP-CC001

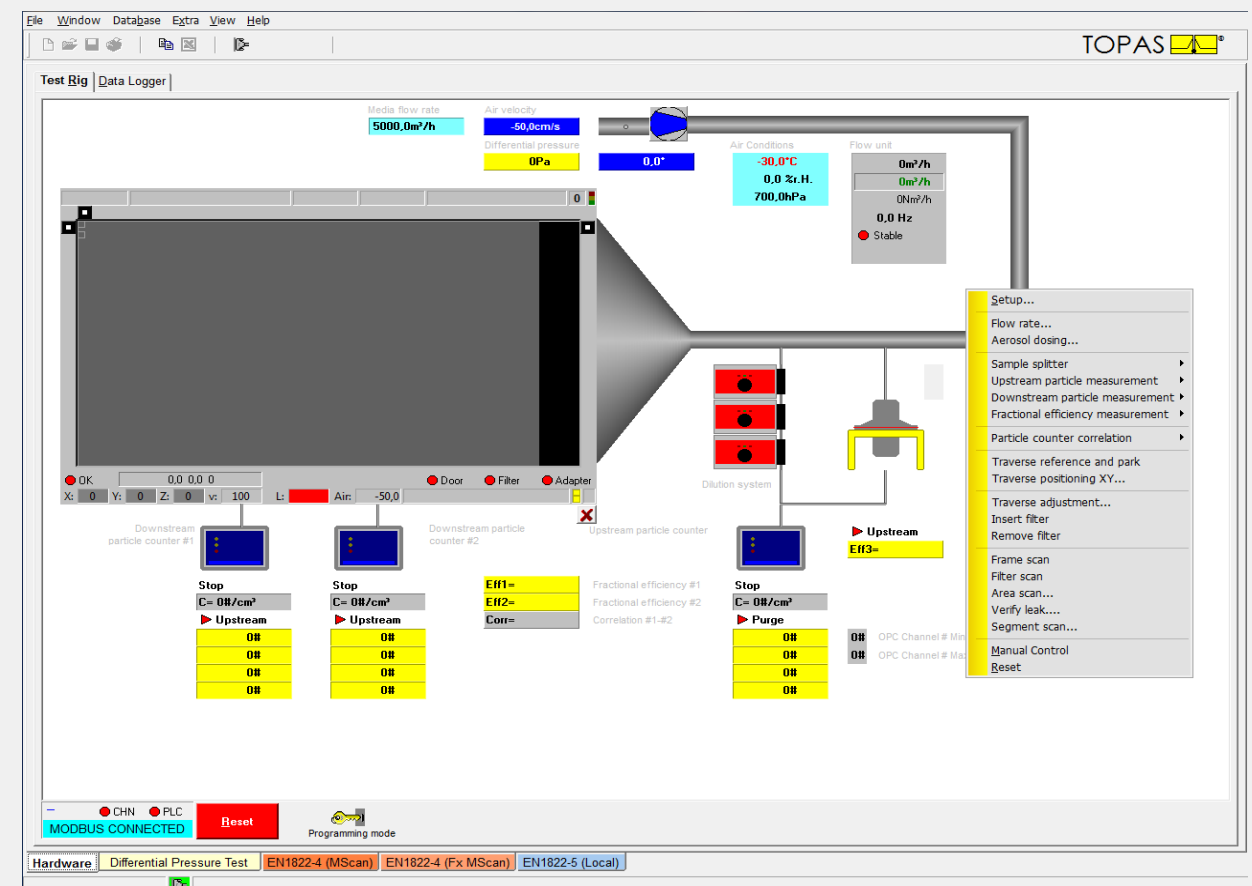
IEST-RP-CC034

**H14 99.995 at
MPPS
(LF 5)**

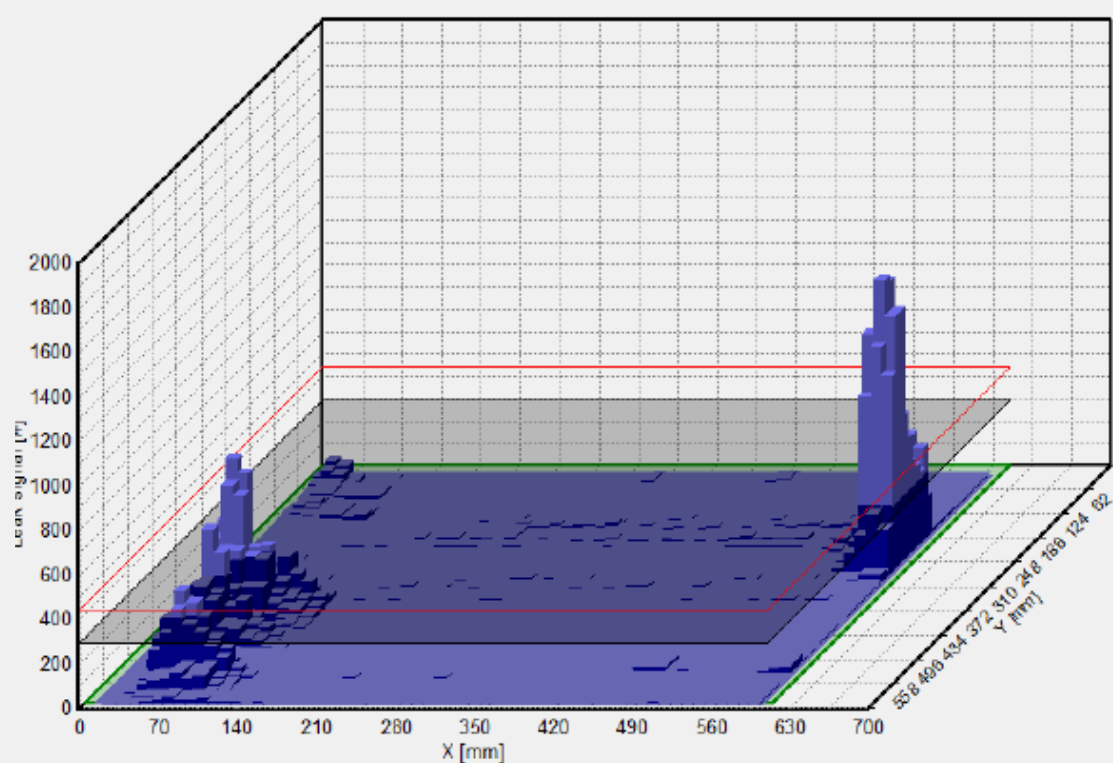
**Type K 99.995 at
0.1-0.2
(LF 1.6)**

**0.005x5=0.025
99.975=Fail
0.01%
Threshold**

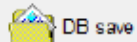
**0.005x1.6=0.008
99.992=Pass
0.01%
Threshold**



Important you request a reliable Scan Test Protocol from the filter manufacturer.



Test Filter			
Length:	610 mm	Classification:	ULPA U16
Width:	610 mm	Part-No.:	123456789
Depth:	90 mm	Serial-No.:	987654321
Frame:	12 mm		
Test Conditions			
Temperature:	24,8 °C	Aerosol:	DEHS
Relative humidity:	45,4 %r.F.	Particle size:	0,10 - 0,30 μm
Barometric pressure:	1015 hPa	Concentration:	1,25E+05 #/cm³
Flow rate:	605,3 m³/h	Signal value:	292 #
		Signal distance:	194 #
		Differential pressure:	120 Pa
Test Results			
Delete not verified leaks			
Flow rate:	605,1 m³/h	Differential pressure:	122 Pa
Integral efficiency:	99,9999560 %		
Minimum efficiency:	99,9983728 %	Leaks:	1
Classification:	-	Leakage test:	FAILED



Pass

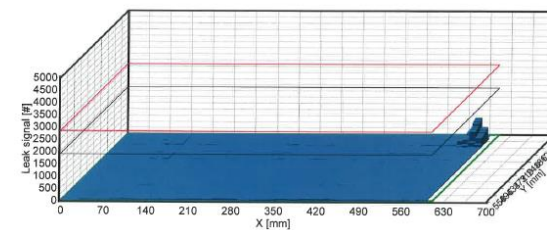
847

Prüfbericht gemäß EN 1822-4
Test report according to EN 1822-4
Rapport de test selon EN 1822-4



Filterdaten / Filter data / Fiches techniques			
Filternummer Part no. Numéro du filtre	Filtertyp Type du filtre	Serial no. Numéro de production	Prüfdatum Date of test Date de test
12-1020-0008	AstroCel II	527430-18	2018-03-29
Filterdimension (L x B x T) Filter dimensions (L x B x T) Dimensions du filtre (L x B x T)	Nennvolumenstrom Nominal flow rate Débit d'air nominal	Anfangsdruckdifferenz Initial pressure drop Pressure de charge initiale	
610 x 610 x 69mm	600m³/h	133Pa	
Filterklasse Filter class Classe de filtration	Minimale integrale Abscheidegrad Minimum integral efficiency Minimum efficacité intégrale	Minimale lokale Abscheidegrad Minimum local efficiency Minimum efficacité locale	Kommentar Comment Commentaire
HEPA H14	99,9950000%	99,9750000%	
Prüfbedingungen / Test Conditions / Conditions de test			
Prüfvolumenstrom Test flow rate Débit de test	Prüfaerosol Test aerosol Aérosol de test	Prüfkonzentration Upstream concentration Concentration amont	Temperatur Temperature Température
598m³/h	DEHS	0,10 - 0,30 μm	21,1°C
Prüfergebnisse / Test results / Résultats de test			
Classifizierung gemäß Testprotokoll Classification to test result Classification selon résultat de test	Integrierte Abscheidegrad Integral efficiency Valeur intégrée d'efficacité	Minimale Abscheidegrad Minimum efficiency Minimum valeur d'efficacité	Druckdifferenz Pressure drop Perte de charge
HEPA H14	99,9953888%	99,9953850%	133Pa
Maximum Leaks Maximum (Leak signal) Maximum (Signal du fuite)	Anzahl der gefundenen Leaks Number of leaks detected Nombre de fuites détectées	Leaktest gemäß EN 1822-4 Leakage test to EN 1822-4 Test de fuite selon EN 1822-4	
1418 (1898)	0	bestanden/passed/accepté	

Id	X	Y	Z	cU	cD	E	P	Class
[#]	[mm]	[mm]	[mm]	[#/cm³]	[#/cm³]	[%]	[%]	Local

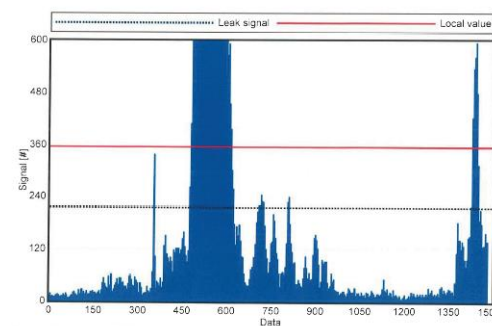


694

Prüfbericht gemäß EN 1822-4
Test report according to EN 1822-4
Rapport de test selon EN 1822-4



Filterdaten / Filter data / Fiches techniques			
Filternummer Part no. Numéro du filtre	Filtertyp Type du filtre	Serial no. Numéro de production	Prüfdatum Date of test Date de test
12-1020-0008	ATMQU-24-Q-FS4HR	527430-18	2018-02-09
Filterdimension (L x B x T) Filter dimensions (L x B x T) Dimensions du filtre (L x B x T)	Nennvolumenstrom Nominal flow rate Débit d'air nominal	Anfangsdruckdifferenz Initial pressure drop Pressure de charge initiale	
610 x 610 x 150mm	1400m³/h	209Pa	
Filterklasse Filter class Classe de filtration	Minimale integrale Abscheidegrad Minimum integral efficiency Minimum efficacité intégrale	Minimale lokale Abscheidegrad Minimum local efficiency Minimum efficacité locale	Kommentar Comment Commentaire
HEPA H13	99,9500000%	99,7500000%	
Prüfbedingungen / Test Conditions / Conditions de test			
Prüfvolumenstrom Test flow rate Débit de test	Prüfaerosol Test aerosol Aérosol de test	Prüfkonzentration Upstream concentration Concentration amont	Temperatur Temperature Température
1389m³/h	DEHS	0,10 - 0,30 μm	22,2°C
Prüfergebnisse / Test results / Résultats de test			
Classifizierung gemäß Testprotokoll Classification to test result Classification selon résultat de test	Integrierte Abscheidegrad Integral efficiency Valeur intégrée d'efficacité	Minimale Abscheidegrad Minimum efficiency Minimum valeur d'efficacité	Druckdifferenz Pressure drop Perte de charge
HEPA H13	99,9617740%	99,9614855%	209Pa
Maximum Leaks Maximum (Leak signal) Maximum (Signal du fuite)	Anzahl der gefundenen Leaks Number of leaks detected Nombre de fuites détectées	Leaktest gemäß EN 1822-4 Leakage test to EN 1822-4 Test de fuite selon EN 1822-4	
1280 (218)	4	nicht bestanden/failed/not accepted	



Fail

Field Testing:

Typical Cleanroom Testing/Monitoring Requirements

Other less critical areas may include the following tests and frequencies:

Test	Frequency
Particle Monitoring in air	Regular – may be 6 monthly
HEPA integrity testing	Yearly-(Grade A/B-6 monthly, D-1-2 Years)
Verification of a/c rates	6 monthly
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.

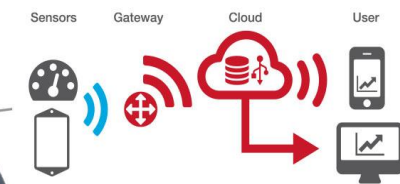
Microelectronic Cleanrooms

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

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

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



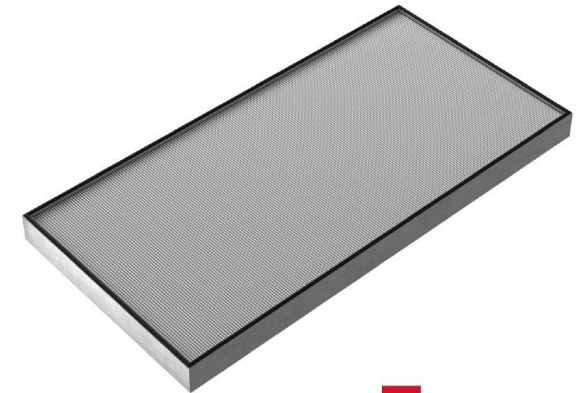
Sensor360®
Cloud-based air quality and pressure drop measurement technology.

AHU Filter Testing

In situ integrity testing of HEPA filter banks is accomplished by injecting an aerosol (PSL) upstream of the filters and manually scanning the downstream side of the filters.

Alternate Overall Efficiency Test

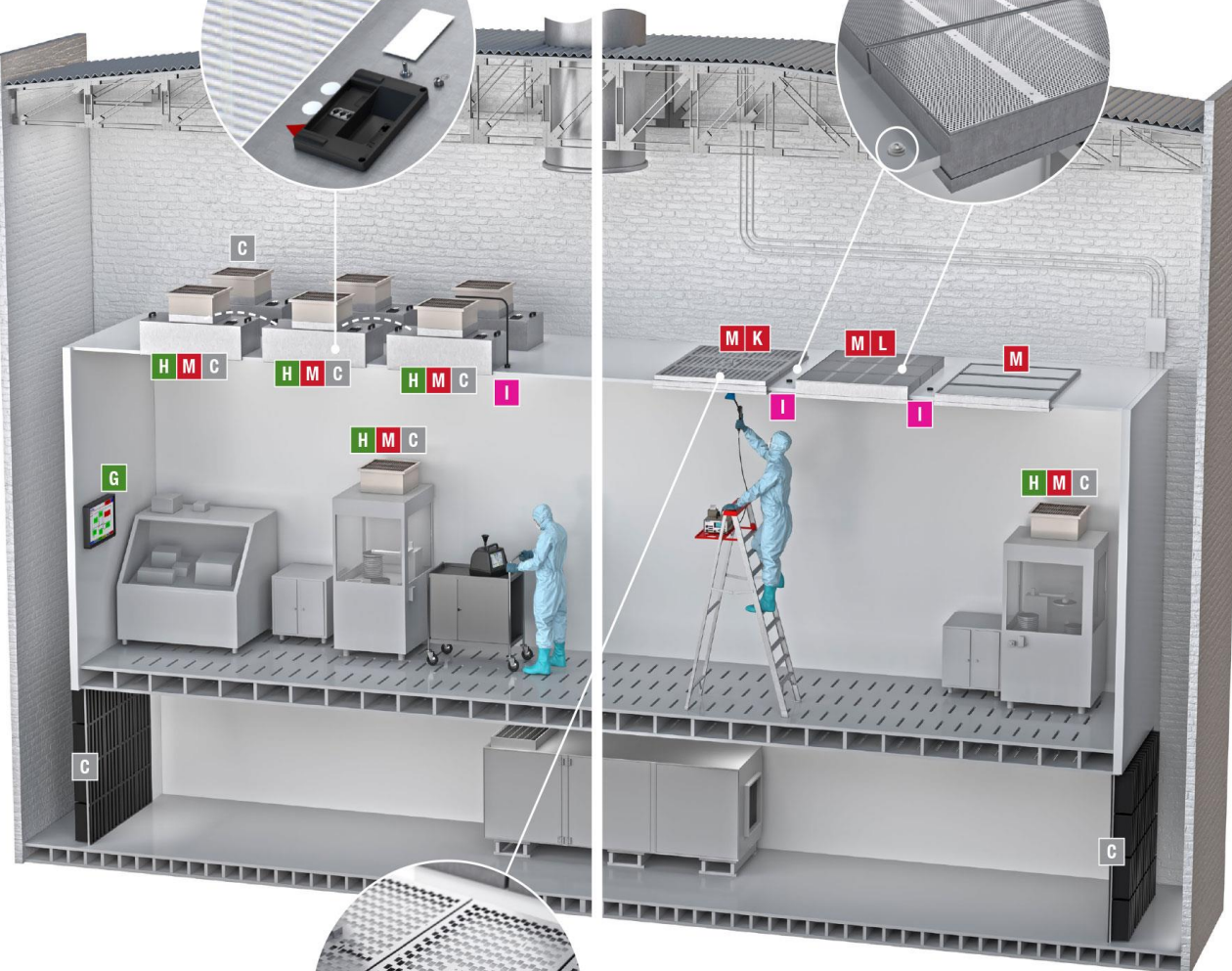
This can be performed by measuring a single point **upstream** **I** and **downstream** **II** of the filter.



MEGAcel® ePTFE **M**
The industry standard with the lowest TCO and durability. The cleanest product for the most sensitive processes.

H J K L N

A	MEGApleat®
B	DriPak® NX
C	VariSorb®
D	VariCel® VXL
E	MEGAcel® III
F	Sensor360®
G	Astro-SCS™
H	AstroFan™ FFU
I	Test Port
J	AstroHood® S-III
K	ESD Damper
L	Walk-on Back Plate
M	MEGAcel® ePTFE
N	In-room HEPA Test Bench



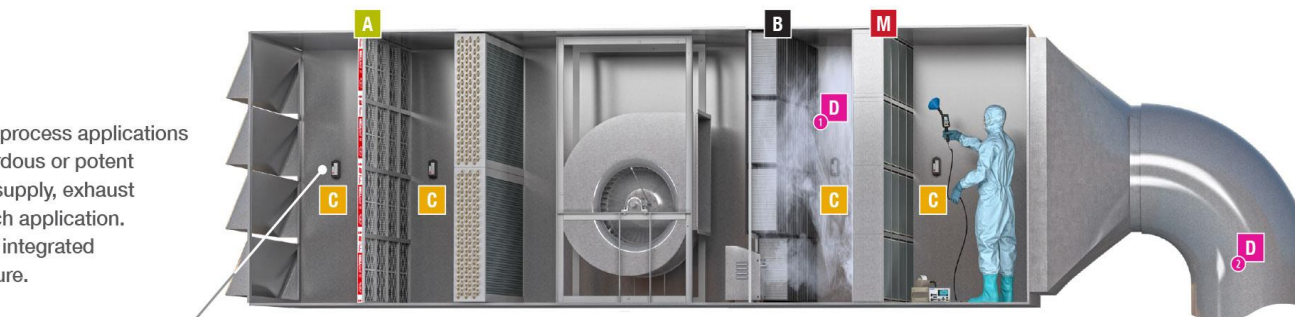
MEGAcel® ePTFE ESD Damper
HEPA/ULPA filter with integrated airflow uniformity Energy Saving Damper.



AstroHood® S-III
Disposable ducted HEPA with integrated centerboard test port and diffusion disc.

Life Science Cleanrooms

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.



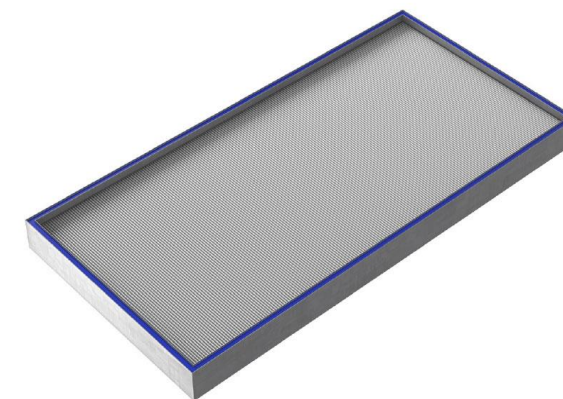
AHU Filter Testing

In situ integrity testing of HEPA filter banks is accomplished by injecting an aerosol (PSL) upstream of the filters and manually scanning the downstream side of the filters.

Alternate Overall Efficiency Test This can be performed by measuring a single point upstream ① and downstream ② of the filter.

MEGAcel® eFRM M
eFRM media exceeds industry requirements from an efficiency and aerosol challenge compatibility standpoint.

E F G H K N P

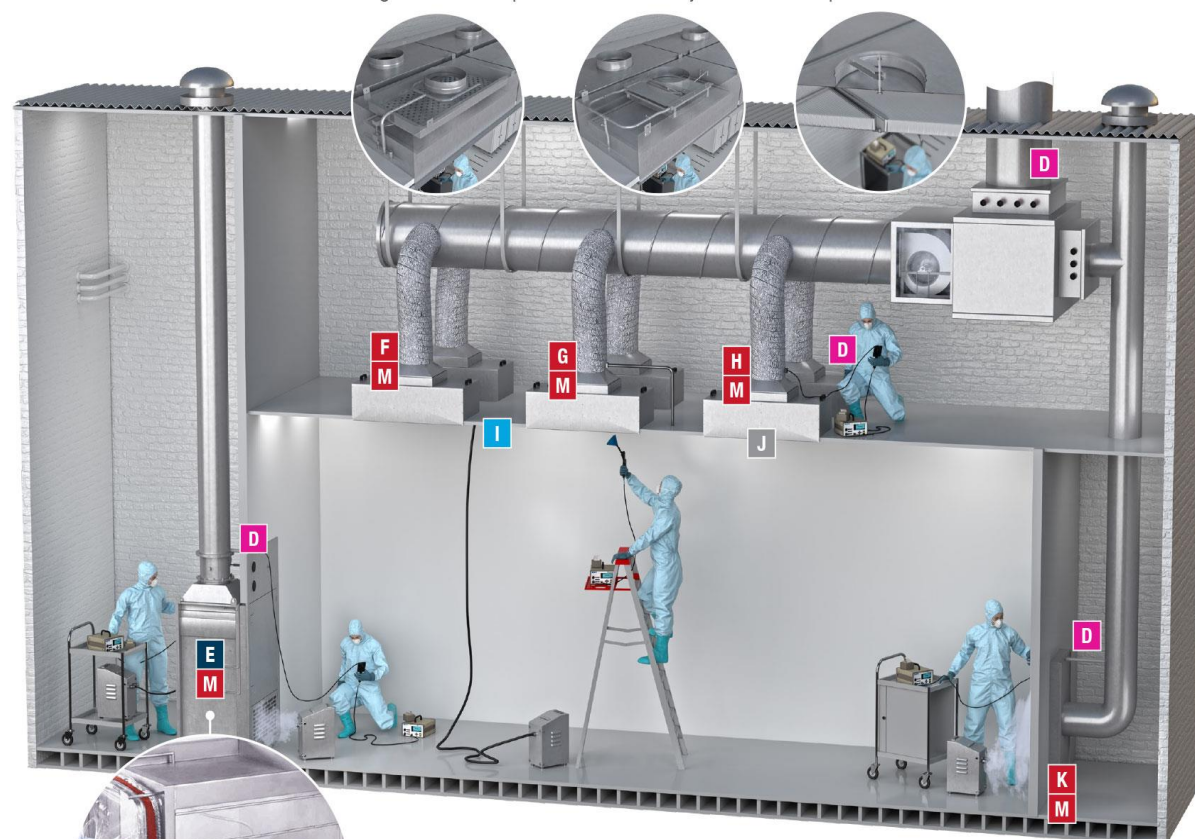


A	MEGApleat®
B	VariCel® VXL/DriPak® NX
C	Sensor360®
D	Test Port
E	AstroSafe® V-BIBO
F	AstroHood® S-I
G	AstroHood® S-II
H	AstroHood® S-III
I	Injection Port
J	Central Test Port
K	AstroHood® E-1
L	AstroHood® Plenum
M	MEGAcel® eFRM
N	AstroFan™
O	Astro-SCS™
P	ESD Damper

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

A 'safe change' or BIBO (Bag-In-Bag-Out) housing with an integrated manual scan section normally utilized when potent or hazardous compounds are in use.

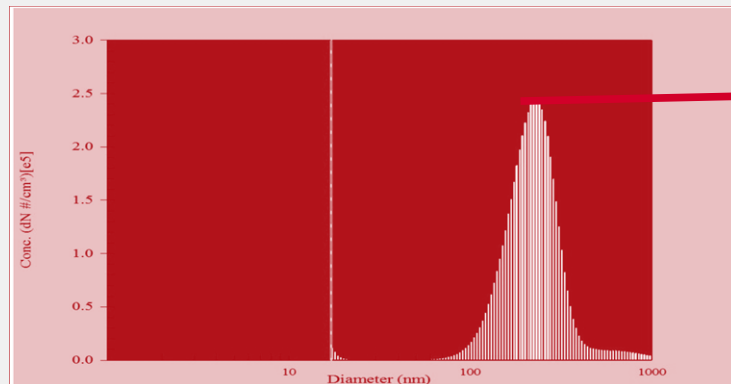


MEGAcel® eFRM ESD Damper
HEPA/ULPA filter with integrated airflow uniformity Energy Saving Damper.

AstroFan™ EC Controls

Intelligent controls gives you continuous motor speed monitoring and modulation, tailoring fan speed to match demand.

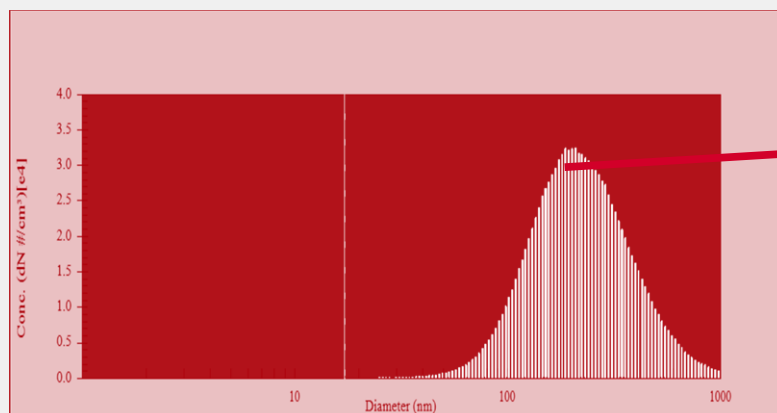
PAO-4 Particle Size Distribution of a Thermal Condensation Generator (ATI-5C)



EN-1822	Number	Surface	Mass	Volume
	Particle Size	Particle Size	Particle Size	Particle Size
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.				

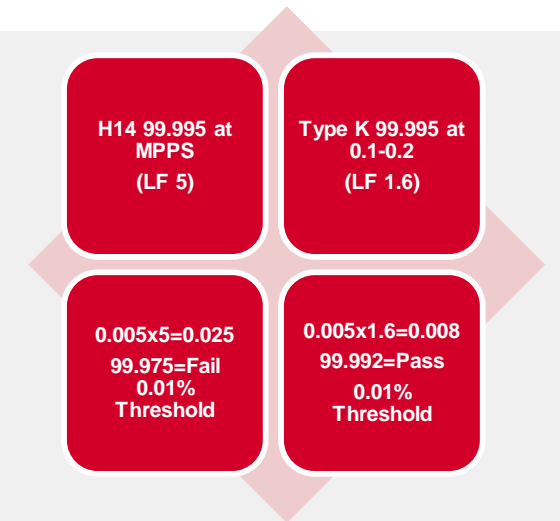
Operating at standard set up parameters of 408 C (765F) with 50psig inert gas supply.

Type 111-Laskin Nozzle at 23 psi using PAO-4



EN-1822	Number	Surface	Mass	Volume
	Particle Size	Particle Size	Particle Size	Particle Size
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

Filter 'Bleedthru'



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)
3. Filter Specification. (The traditional 99.99 at 0.3 micron can 'fail' a scan test when exposed to a thermally generated aerosol especially at higher than design or factory tested velocity in the field)

How to solve the problem:

1. Understand the actual **media** face velocity when selecting/specifying filters. A nominal '4x2 or 1200x600 filter can be as high as 20% smaller when installed in a given housing or ceiling grid therefore increasing the design velocity and risking bleedthru. Most filter manufactures test filers at 120 fpm or 0.6 m/s to minimize risk. Some older facilities are stuck with high velocities. Filters can be 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.
2. Understand where possible how your filters are being tested. A 'hot smoke' (thermal) has a higher penetration than 'cold smoke' (Laskin Nozzle) in the field as stated above.
3. To minimize risk, specify filters with an efficiency of H14 (99.995) at MPPS in accordance with EN-1822 or Type K (99.995) at 0.1-0.2µm 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.

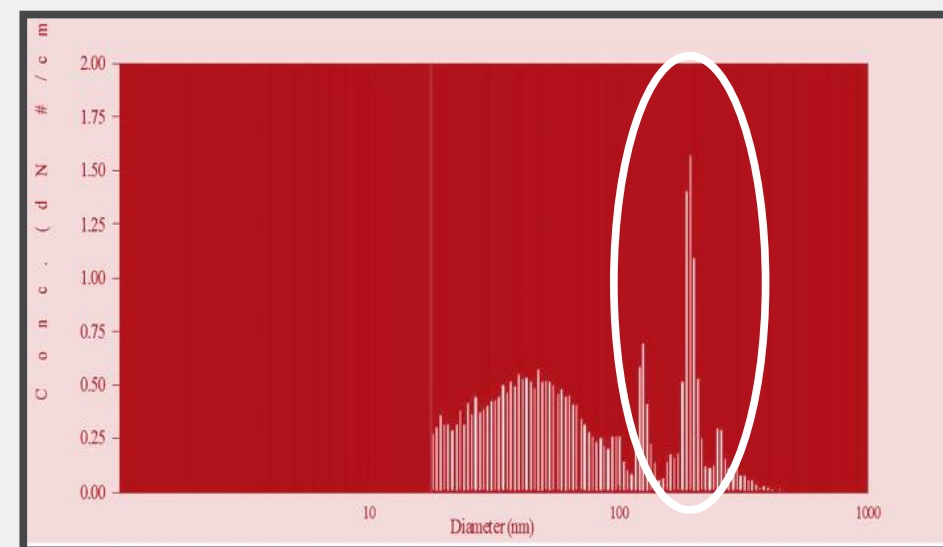
***China is typically running at 1.0 m/s so even more risk.**

PSL Testing:

- Polystyrene Latex spheres are highly accurate, monodisperse, NIST Traceable, particle size standards from **20 nanometers to 160 microns**, suspended in a DI Water solution with a trace surfactant to minimize agglomeration.
- PSL spheres are listed as suitable test materials when using particle counters by both the Institute of Environmental Sciences (**IENT**) and European Norm (**EN**) standards. HEPA-CHECK Filter Challenge Particles are polystyrene latex particles optimized for performance, aerosolization, safety and economy for both HEPA and ULPA filter testing. Unlike traditional oil-based filter test materials such as PAO or DEHS, the PSL spheres do not have carcinogenic health risks associated with atomized oils such as PAO or other oil-based filter test materials.
- PSL microspheres, are also utilized for HEPA and ULPA filter testing, they are manufactured with a consistent, repeatable supply of highly uniform, monodisperse PSL particles that meet or exceed efficiency filter test requirements.

Each 25 mL bottle is to be diluted in one US gallon (3.79 liters) of clean water and then nebulized. Nebulizing can be accomplished by using commercially available ultrasonic PSL Generators, such as a High Output PSL Generator. Single use bottles ensure reproducible test conditions from site to site. The product is available in particle sizes from 0.12µm to 0.3µm, sizes normally associated with testing mean particle penetration size, MPPS, and is sold individually or in convenient packs of 6 or 20 bottles.

Monodispersed 200 nm Aerosol PSL



Challenge Aerosol Types:

Challenge Aerosol	Aerosol Type	Name	Aerosol Generation Method	Industry Type	Plus/Minus
PAO	Liquid	Poly Alpha Olefin	Laskin Nozzle/Thermal	Life Science	Long established synthetic hydrocarbon test aerosol, easy to understand and measure 0.01% of the upstream concentration is allowable downstream. Higher risk of filter contamination due to traditional aerosol generation methods
DEHS	Liquid	Di Ethyl Hexyl Sebacate	Laskin Nozzle/Thermal	Life Science	Proven test aerosols for factory and field testing. It is a no soluble colourless and odourless liquid which is suitable for producing consistent aerosol. The main proportion of droplets generated (ATM) can be stated at MPPS. A droplet with 0.3 micron diameter has a lite time of 4 hours. Long life time, spherical particle, well known optical properties.
PSL	Solid	Polystyrene Latex Spheres	Ultrasonic	Microelectronics	Consistent repeatable, uniform, monodisperse, PSL aerosol utilized by filter manufacturers. No 'oil' contamination and suited well for particle counters. Available from sizes 0.12-3.0 micron.
Silica	Solid	Si O2	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 leaving coatings on surfaces.
DOP*	Liquid	Di Octyl Phthalate	Laskin Nozzle/Thermal	Life Science	Original aerosol of choice. Should not be used today due to *Carcnogenic health risks



Photometer scanning
leak test method



ATI-TDA 5C
'Hot' Generator



ATI-TDA-4B/4B
'Cold' Generator



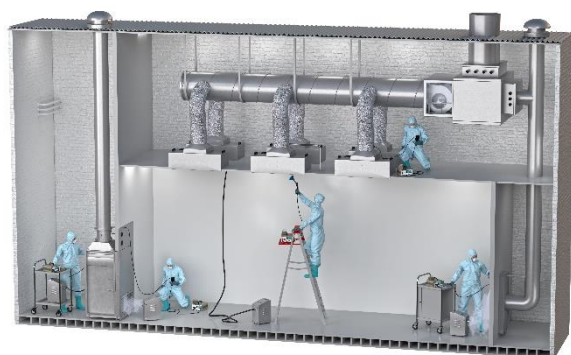
ATI-2i
Aerosol Photometer



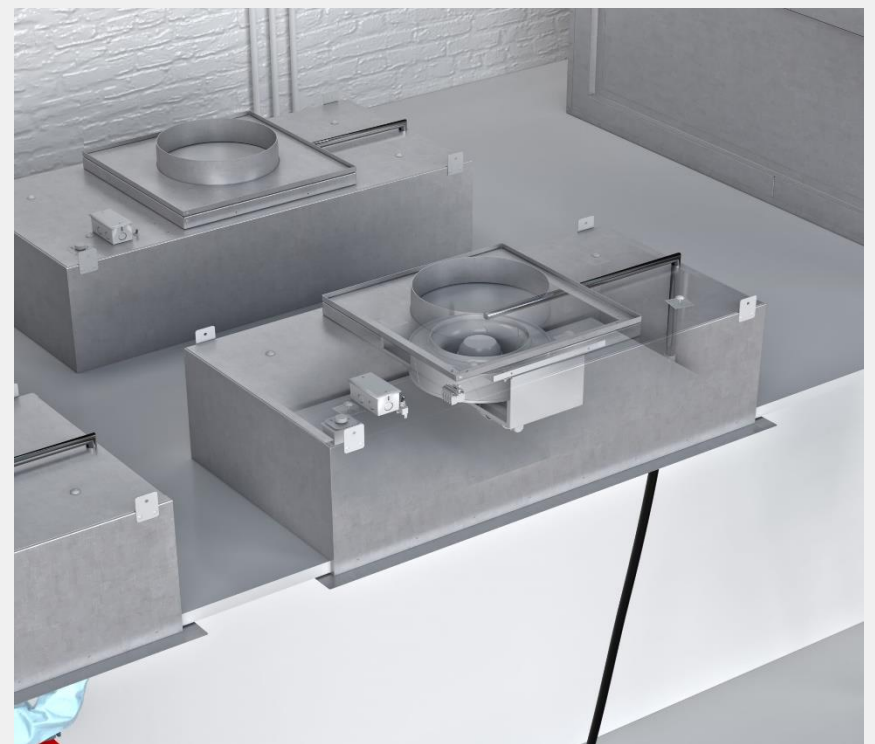
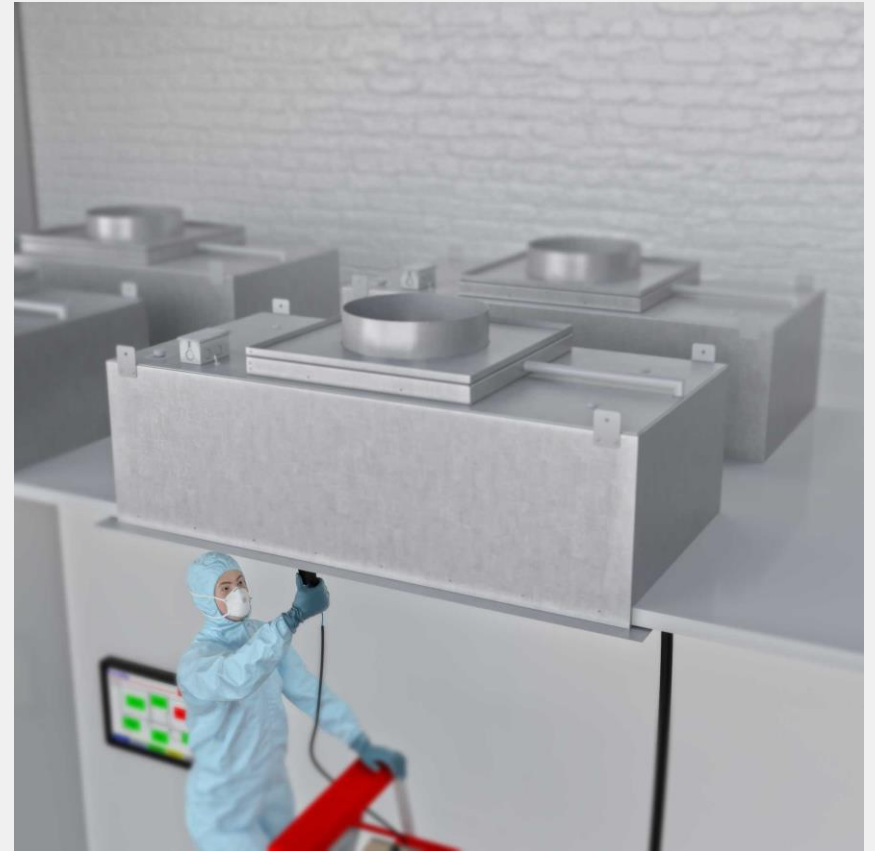
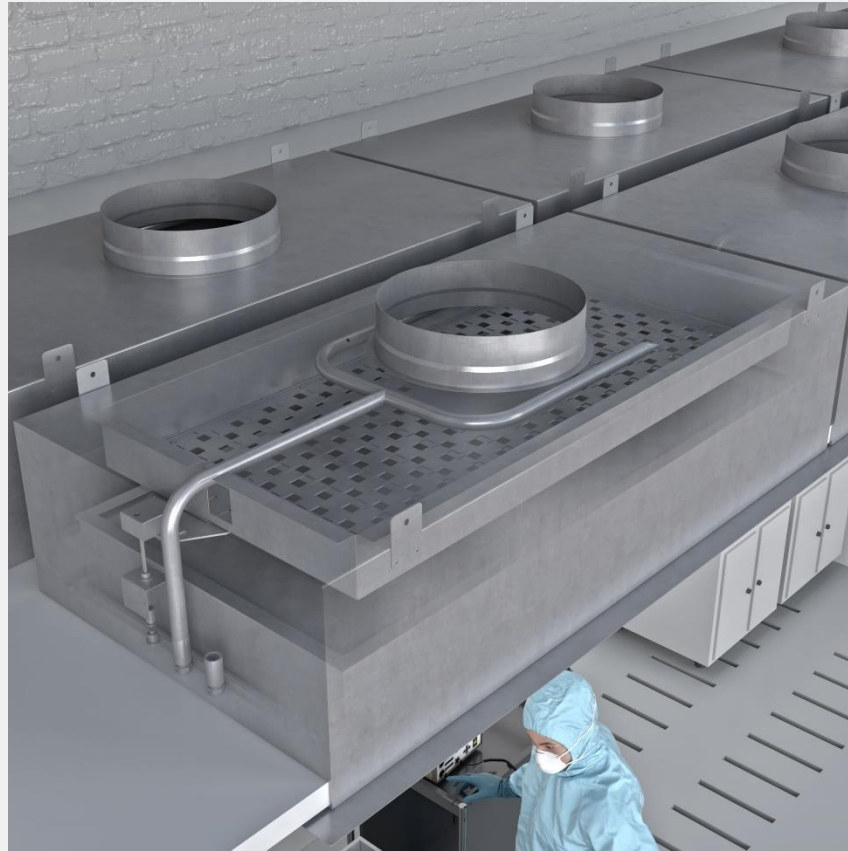
DPC scanning leak test
method





Test Aerosol by Location in the field

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	Excess aerosol exposure, Potential risk of 'bleedthru' if correct filter efficiency is not specified
Supply Duct Work in the Plenum	Laskin Nozzel	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 Nozzel	Minimizes aerosol exposure to multiple filters	Aerosol dispersion ring or 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	Excess aerosol exposure, Potential risk of 'bleedthru' if correct filter efficiency is not specified

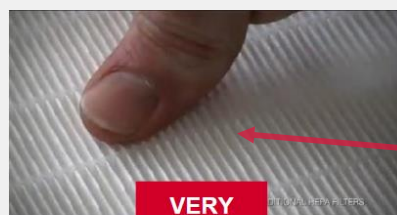


Detailed Animations of Test Locations:



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	IENT-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	IENT-RP-CC034.2	RTV 162 or 108 or Dow 732 is a suitable repair material
Field	No repairs allowed in an Grade A Space. Some will specify no factory repairs for which there is typically a premium from the manufacturer. (Average factory repairs are 5-8%) 95% of end users follow industry norms/repair levels.	End Users	Manufacturers will repair with urethane, media or hot melts used in the production process. 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.

Why should an end user accept a filter that is repaired from the factory?



Fluororesin 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'.



Wet laid Glass fiber HEPA media by nature is very fragile and will fail from a pin hole leak to miss-handling of the filter.

MegaCel & FFU Sales Reference-China

MegaCel	Quantity	Delivery
BOE Hefei	71,698	2009-2017
BOE Fuzhou	41,955	2016
BOE Chongqin	30,000	2014-2015
BOE Chengdu	16,563	2016-2017
Truly Huizhou	11,236	2015-2016
Xiamen Tianma	10,595	2015-2016
yungu	8,421	2017
BOKE Shandong	7,785	2010-2017
Seagate Wuxi	7,300	2001
BOE Ordos	6,944	2013-2016
Royole	6,607	2017
Motorola Tianjing	6,000	1999
SMIC Tianjing	6,000	1999
TSMC Shanghai	5,803	2010
Seagate Suzhou	3,850	2010
Weihai DMS	3,709	2014-2017
Truly Shanwei	3,500	2011-2012
DongMin Shanghai	3,481	2014-2016
Jia Yida Suzhou	3,323	2013-2015
Hefei SinEva	2,074	2015-2017
Hefei changxin	2,042	2017
Qunce Tianjing	2,000	2009-2012
Glory Medical	1,930	2013-2016
Na Mi Suo Suzhou	1,600	2013
Xin Bei Xi Jinan	1,406	2010-2016
Great Wall Suzhou	1,400	2009-2011
Corning Jiangmen	1,300	2009-2012
SAE Donguan	1,272	2009-2012
Newamstar Suzhou	1,260	2008-2017
Hitech Wuxi	1,140	2009-2013
STS	1,138	2013-2016

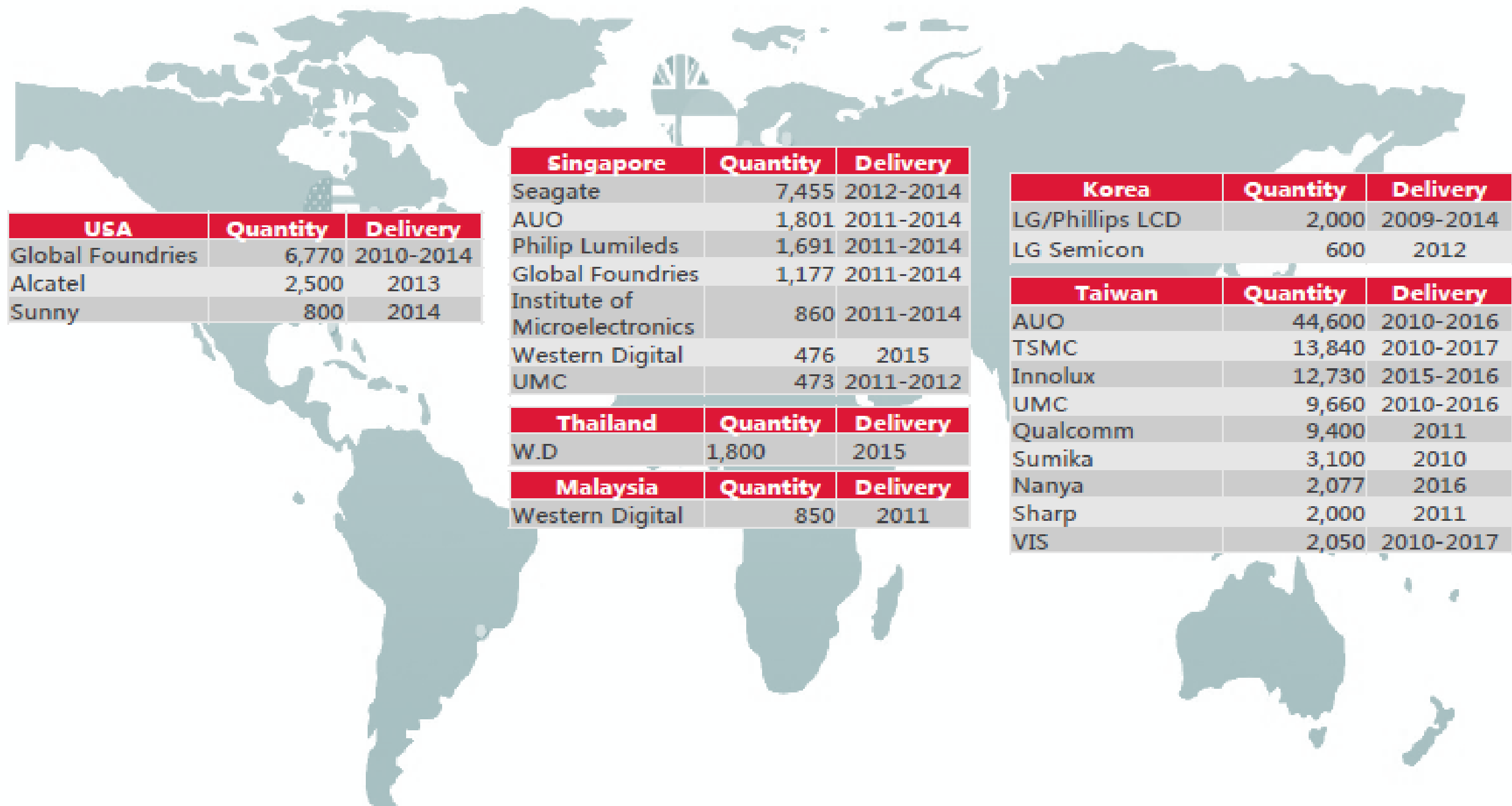
FFU	Quantity	Delivery
Hefei BOE	64,780	2016-2017
Fuzhou BOE	41,376	2016
Chengdu panda	25,840	2017
Chengdu BOE	25,458	2016-2017
Xiamen tianma	14,127	2015-2016
Erdos BOE	11,732	2015-2016
Yungu	10,280	2017
CHOT	6,650	2017
Royole	6,218	2017
Shihlin Electric	2,602	2015-2017

FFU: Yungu 2018 –OELD project
 Royole 624 pcs – AMOLED
 DMS 181pcs for BOE -10.5 gen TFT

EFU	Quantity	Delivery
BOE Hefei	12,330	2017
yungu	9,183	2017
Weihai DMS	7,234	2014-2017
Hefei SinEva	6,442	2014-2016
BOE fuzhou	2,116	2017
BOE chengdu	1,459	2017

EFU: Yungu 4400 –OELD project
 DMS 189pcs for BOE

MegaCel Sales Reference-Overseas



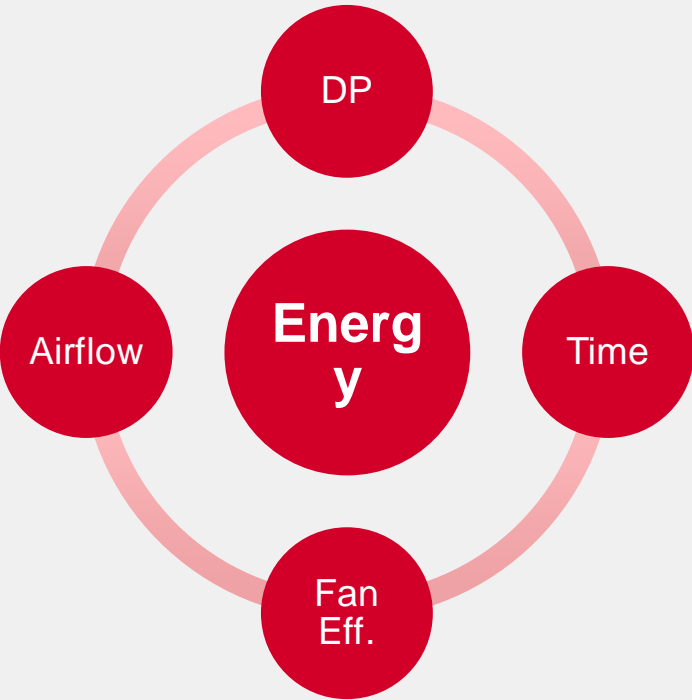
Summary Membrane Pros & Cons:

- ▶ Proven track record in Microelectronic applications.(FFU, Tool & Plenum applications)
 - ▶ High mechanical strength (extreme conditions).
 - ▶ No mechanical degradation (durability).
 - ▶ Chemically Inert.
 - ▶ Very low out-gassing.
 - ▶ Hydrophobic-water repelling.
 - ▶ Lower pressure drop/high energy savings. (33%-50%).
 - ▶ PAO Compatibility ('New') both thermal & Laskin nozzle. (Option for low concentrations with DPC/Dilution)
 - ▶ Improved depth loading for higher DHC.
 - ▶ More scope for future development.
 - ▶ Major suppliers of ePTFE 'fine powder' raw material (Daikin, major international suppliers)
 - ▶ Competitive TCO when compared to Glass Fiber Media
-
- ▶ Relatively new application track record in the Life Science arena. (Changing)
 - ▶ Long term life time testing (although all test data when extrapolated confirms comparable/acceptable lifetime).



Sustainable Facility Opportunities, IoT & Air Filters.

Energy Costs Calculation



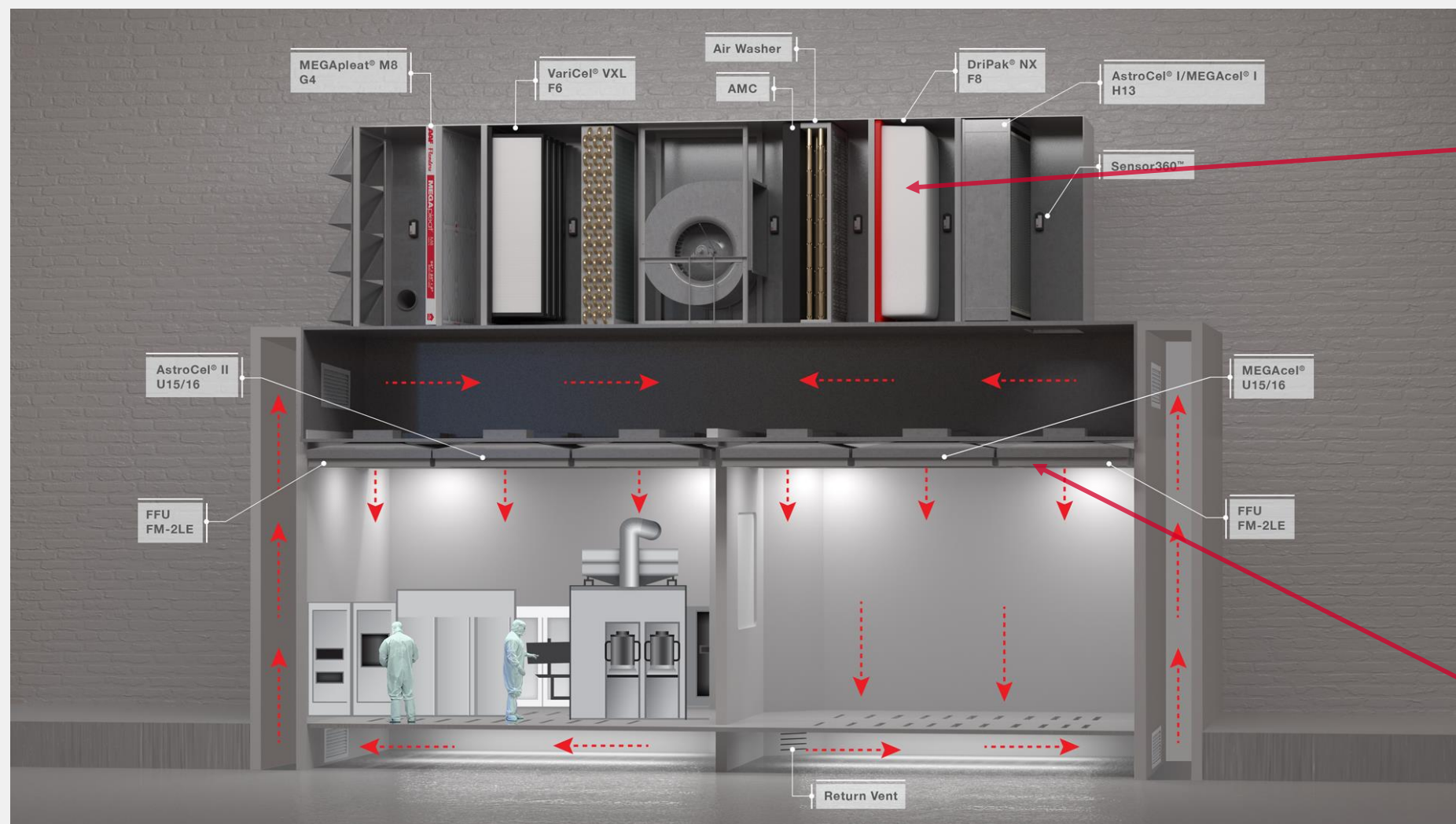
Filtration Energy (kWh) =

(System Airflow (m³/s) x Average Filter Pressure Drop (Pa) x Cycle Time (hrs))
Fan System Fractional Efficiency (0.00) x 1000

WHERE, EQUATION UNITS ARE:

kWh	= kilowatt-hours (yearly energy consumption)	\$0.10 per
m³/s	= cubic meter per second (air volume flow rate)	kWh
Pa	= Pascals (average filter pressure drop)	2.5 m/s
hrs	= Hours (system operating time in a year)	
0.00	= Digital fraction (fan efficiency, to convert digital fraction to %, then multiply by 100)	8760
1000	= Unit conversion factor	0.6

‘Typical’ Microelectronic MUA Application:



- ▶ Important to utilize fine fiber F7 filters for extended life of e-PTFE & Glass media downstream.
- ▶ e-PTFE ULPA filters installed in the FFU's historically has delivered 33%-50% less PD than conventional glass fiber ULPA filters.
- ▶ Lowest pack depth-reduced space & weight

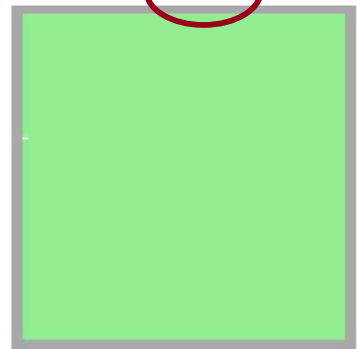
'Low PD Solution'

Autoscan II Report

AAF (Suzhou) Co., Ltd.
No. 116 Changyang Street SIP
Suzhou 215126 PRC

Date and Time 1/4/2017 12:44:07 AM
Room Temperature 21 Degree C
Humidity 65 % RH
Inspector PTFEQC-LGL
Control Number AAFS2M120170104004
Media Number H14
Filter Name MEGAcel-II
Filter Type PTFE(NEUOR)
Serial Number SN17010109
Filter Face Velocity 0.45 m/s
Nominal Air Flow Rate 9.6 m3/min
Counter PMS LASAIR-III-110
Scan Speed 20 mm/s
Filter Pressure Drop 35 Pa

Filter Size 610 x 610 x93 mm		
Upstream Temp.	21	Degree C
Counter	PMS LASAIR-110	
Dilution Ratio	1868	
Upstream Concentration, Particle/Cu.ft		
0.1	136479176	
0.15	61566210	
0.2	36303775	
0.25	22496220	
0.3	16971155	
0.5	605312	
1	11209	
5	0	
Upstream Rate		
10		



Leak Position & Size

Filter Efficiency 99.99995289183 @ 0.3 µm
Final Result Passed

This is a computer generated report and requires no signature. AAF Autoscan system is built in compliance with IEST Standard. AAF (Suzhou) Co. Ltd. No. 116 Changyang Street SIP Suzhou 215126 PRC. Tel: +86-512-62818288 Fax: +86-512-62819645 Website: www.aafchina.com



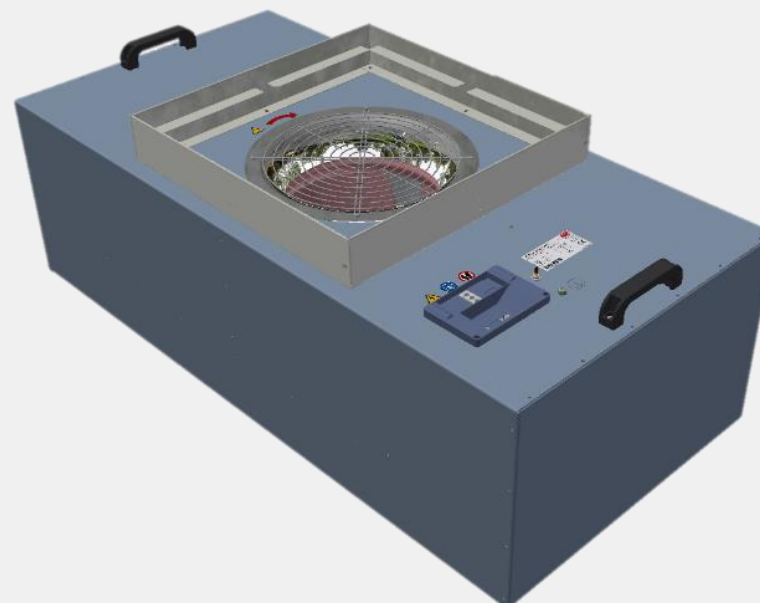
BETTER AIR IS OUR BUSINESS®

35PA @0.45m/s 99.99995 @0.3.

20PA @0.45m/s 99.9995 @MPPS

e-PTFE ULPA filters
Installed in the FFU's deliver
33%- 50% less PD than
conventional glass fiber
ULPA filters.

Additional benefits for fan
selection & reduced noise
level.



AAF HEPA / ULPA Filter Leak Scan Test Report

(According to EN 1822-5)

Measurement Devices: PMS Particle counter Lasair II 110
Velocity meter E87720

Control No: AAFS2M120170906002 Test Date: 9/6/2017 12:00:11 PM

A. Test Details: Filter Name: MEGCel II Filter Type: PTFE Serial No: 1170+1170+69 Style Code: 1170 X 1170 X 69 Filter Class: U15 to EN1822 Media Lot Number: N/A Special Remark: N/A

B. Test Conditions: Challenging Particle Size: 0.1 µm Nominal Air Flow: 2161 cmh Test Air Flow: 2100 cmh Temperature: 21 degree C Rel. Humidity: 65 % Filter Face Velocity: 0.45 m/s Test Particle: silica Upstream Concentration: 1993 pp/cm

C. Test Results:

Filter Height 1170mm X Filter Width 1170mm

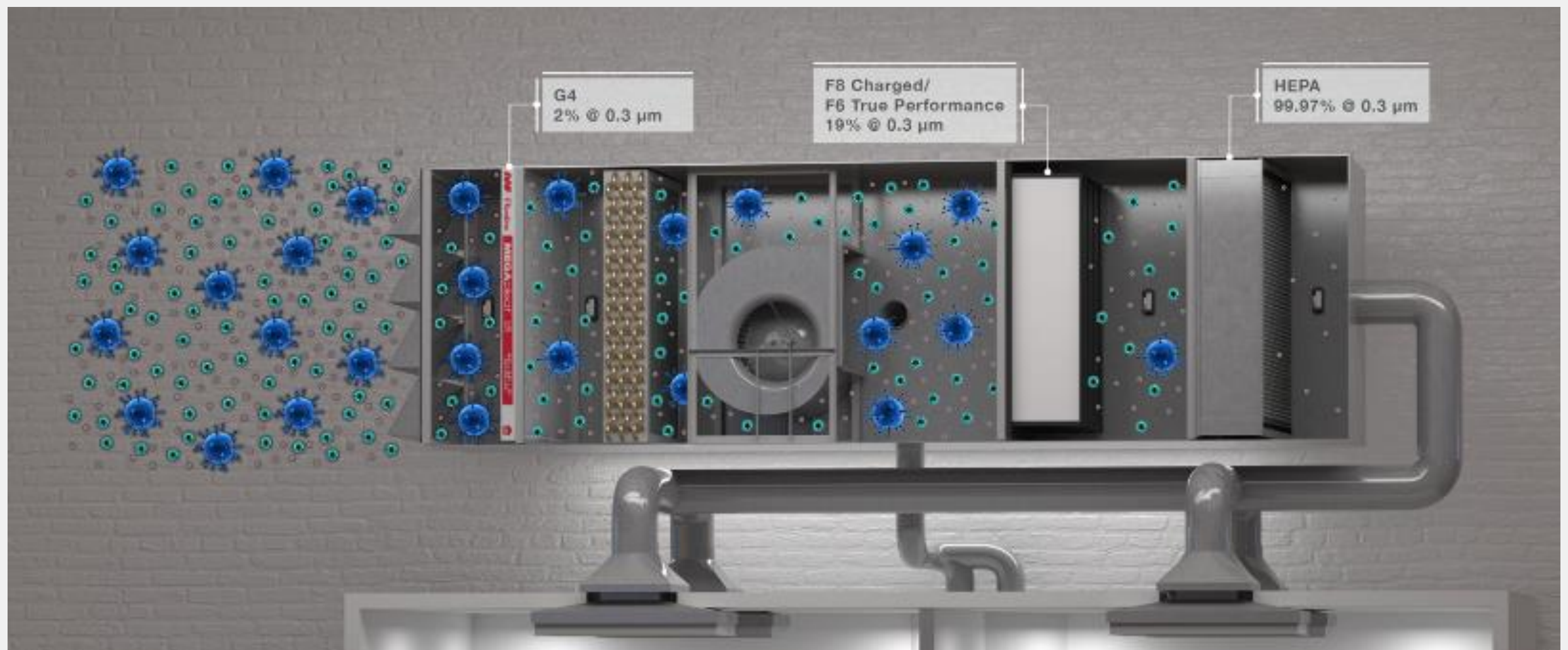
Integral Overall Efficiency: 99.9997785593982 @ MPPS
Minimum Local Efficiency: 99.9988307936222 @ MPPS
Classification to test result: U15 to EN1822
Filter Pressure Drop: 20 Pa
Number of leak found: NO leak detected
Leakage Test: Passed

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AAF BETTER AIR IS OUR BUSINESS®

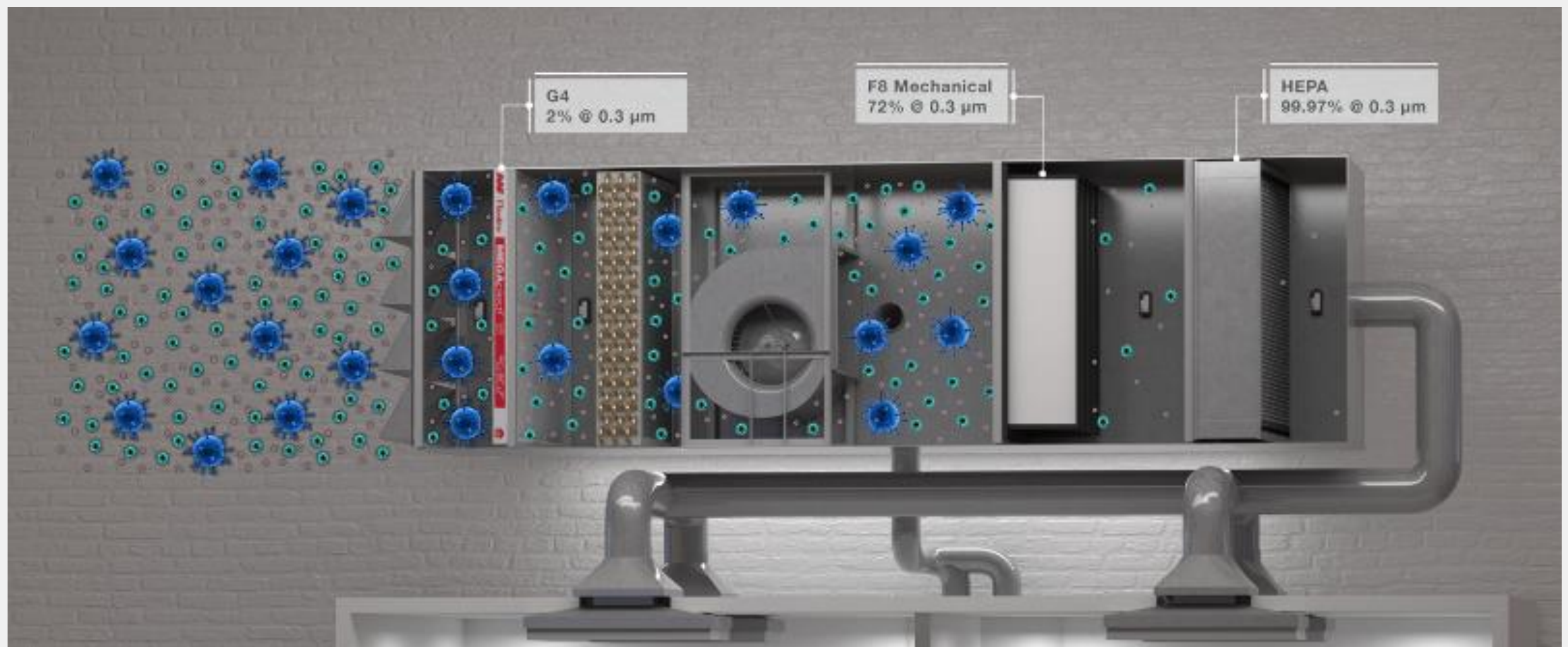
F8 Charged Behaves like an F6 Mechanical (Coarse v Fine Fiber)

A simple 'mathematical' calculation graphic of X particles upstream at a given size, 0.3um in this case (Don't forget 99.9% of all particles airborne by size are less than 1um) you can see logically there is a higher % penetration when coarse fiber (normally synthetic) v fine fibers (normally glass fiber) are in use.

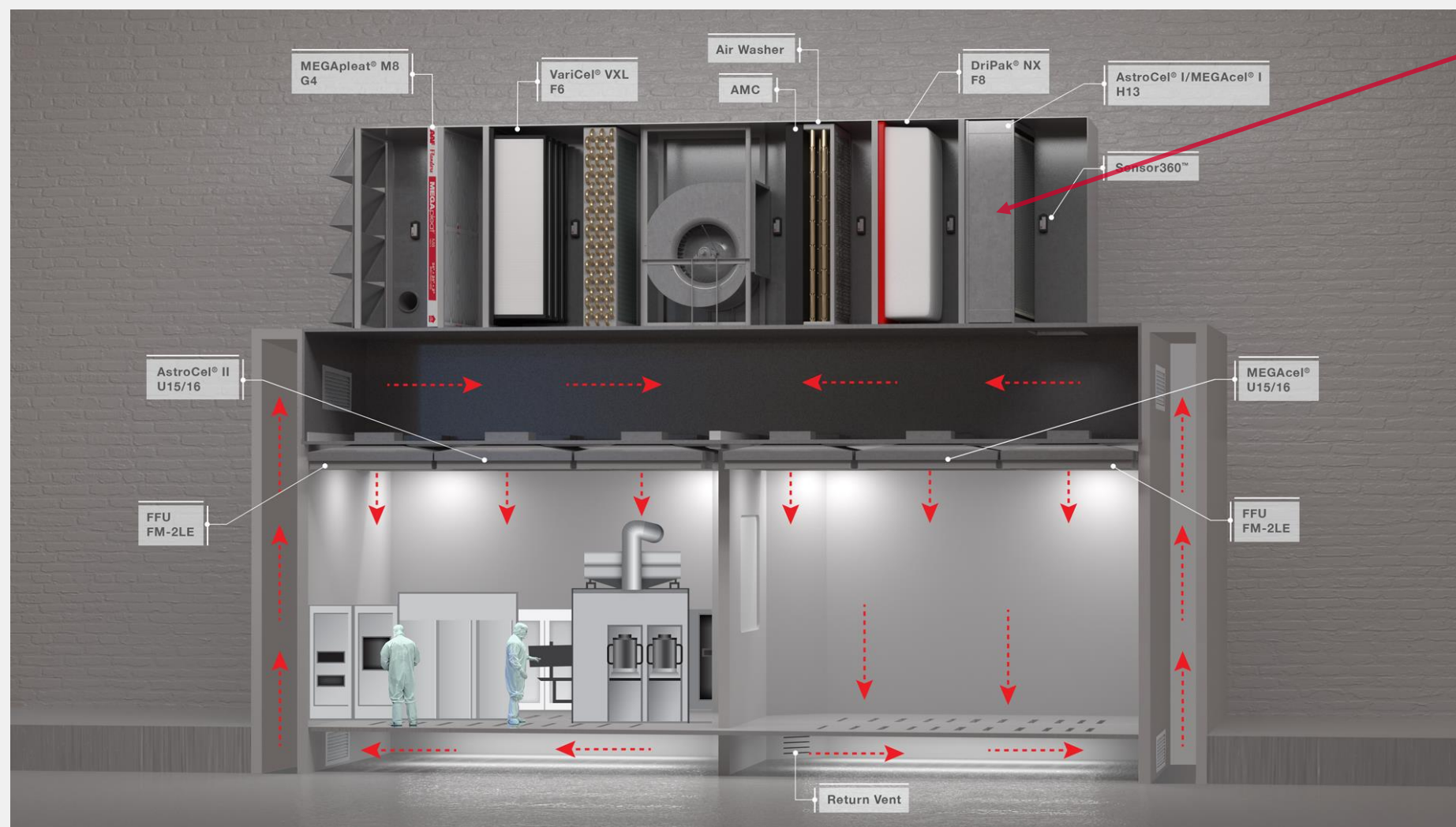


F8 Mechanical

VERY IMPORTANT to state. None of us should be 'anti-synthetic', we should be pro fine fiber, you have seen the higher efficiency achieved with 'finer fibers' when comparing PTFE vs Wet laid Glass on HEPA's from the earlier slides.



‘Typical’ Microelectronic MUA Application:

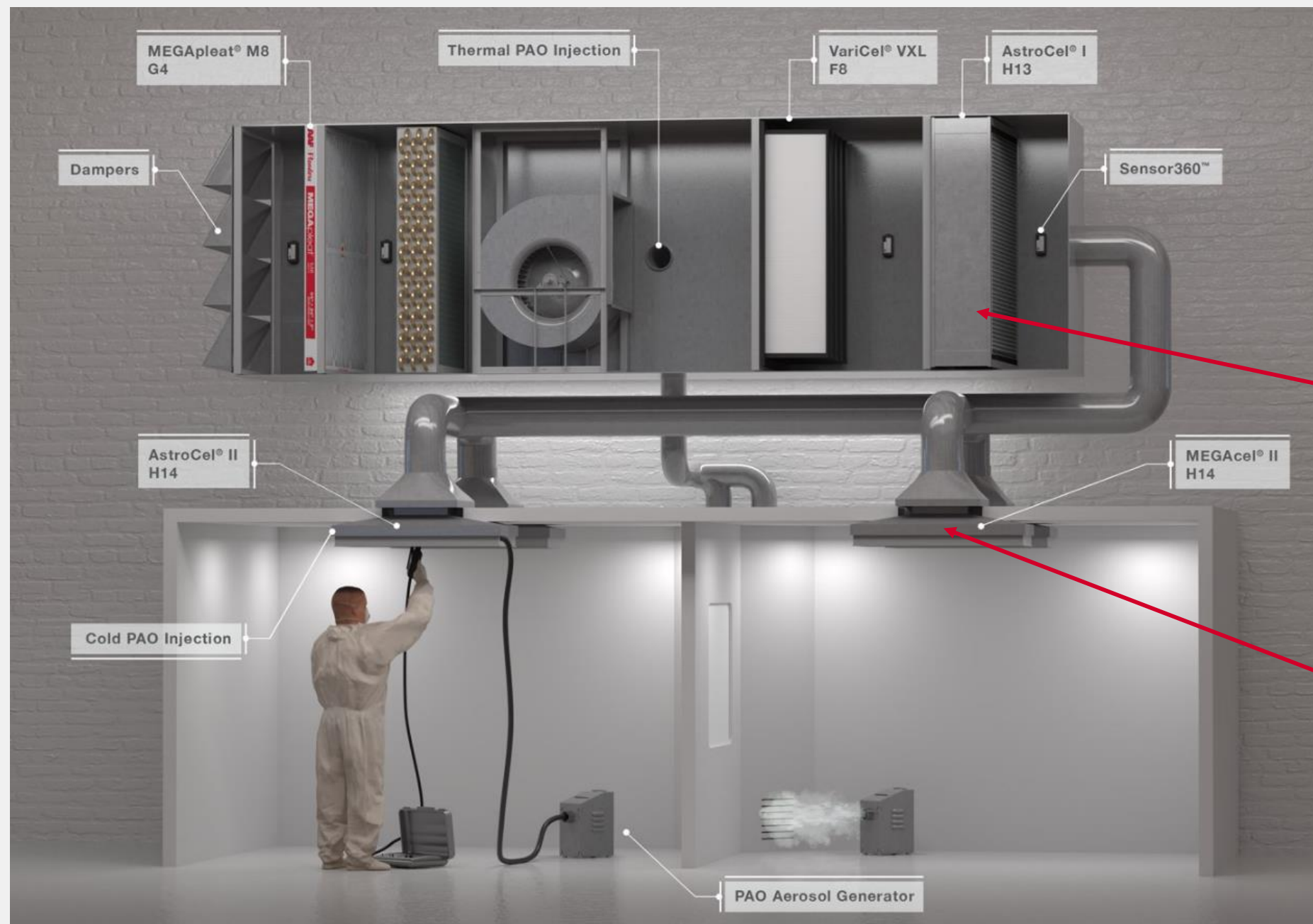


- ▶ Major energy saving opportunity for MUA applications utilizing High Capacity V-Bank e-PTFE HEPA.



- ▶ \$180+ savings per year vs. conventional aluminum separator HEPA filters.
- ▶ ROI < 1 year.
- ▶ Savings are GAURANTEED!

MUA Life Science Application with 'Traditional' HEPA

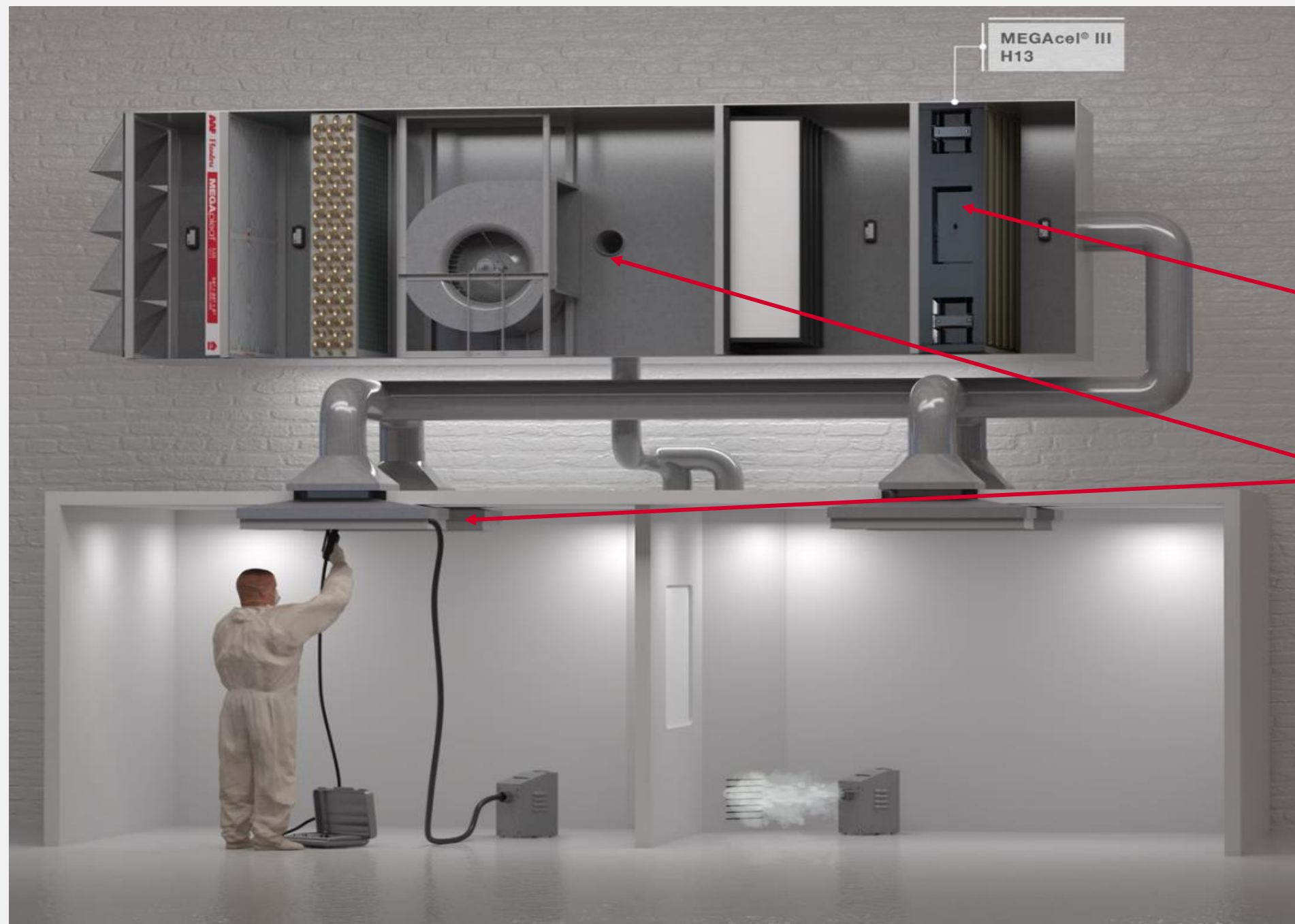


- ▶ Traditional Aluminum separator H13-HEPA filter: 2.5 m/s @ 350PA



- ▶ e-PTFE H14 HEPA Filters 60PA @ 0.45m/s vs. conventional glass @ 125PA.-\$60 per filter savings annually.

MUA Life Science Application with HEPA



- ▶ High Capacity e-PTFE 'mini-pleat' H13-Hepa: 2.5 m/s @ 170PA- \$180 per year per filter

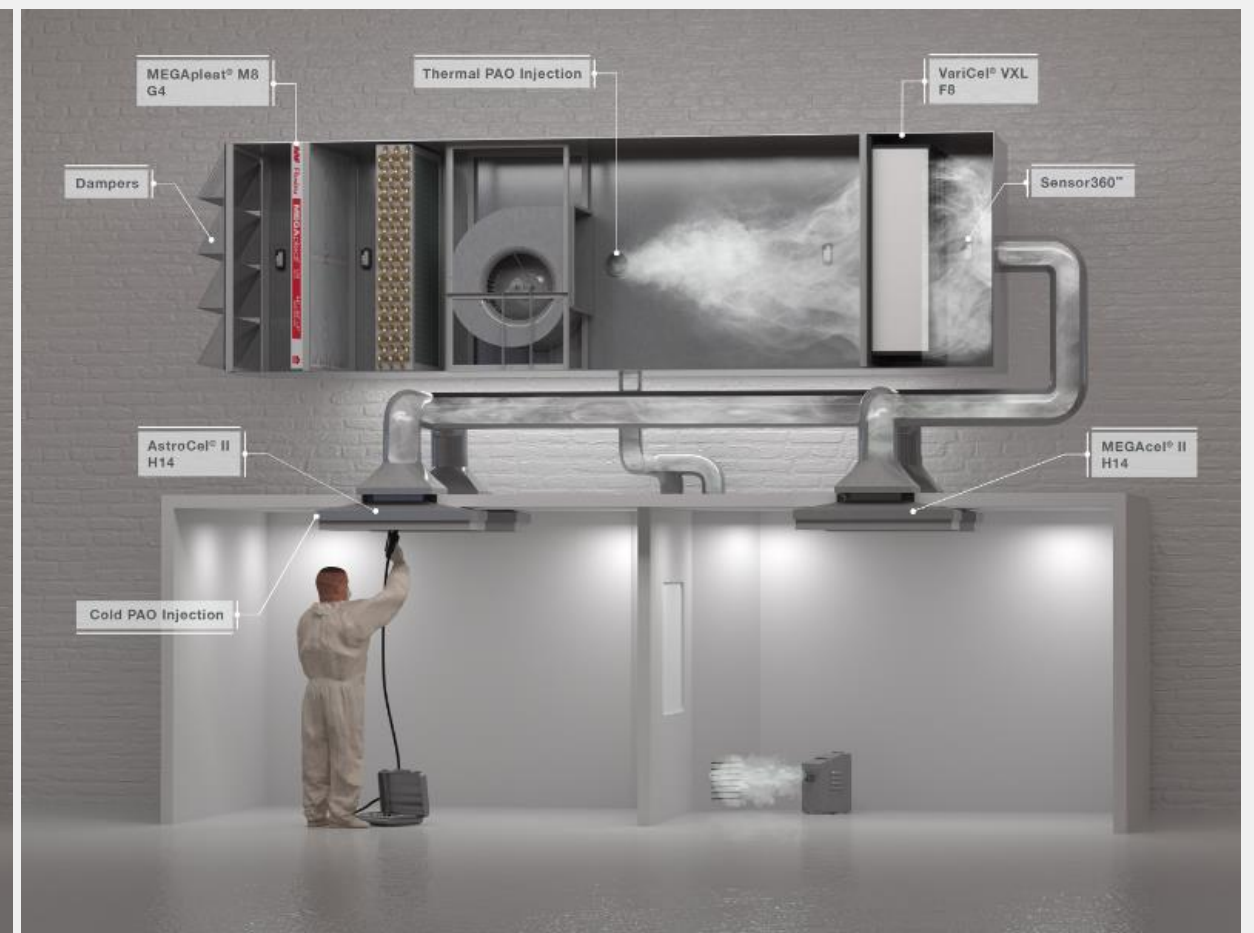
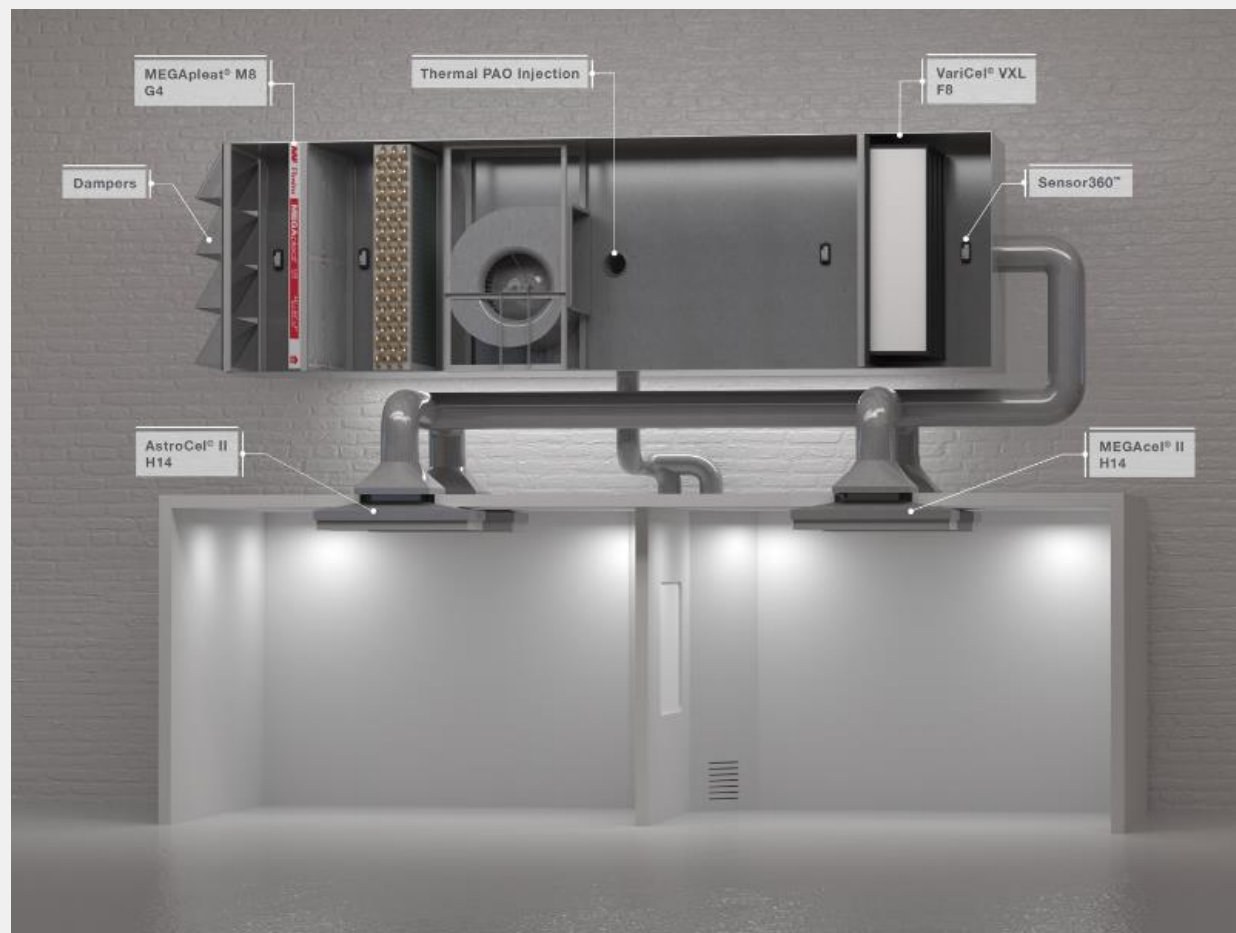


- ▶ Injecting 'hot' aerosol from the ahu at typically 40ug/l vs. 15ug/l with local aerosol injection capability saves significant contamination of the ducts and loading of glass & or e-PTFE filters in Life Science applications.

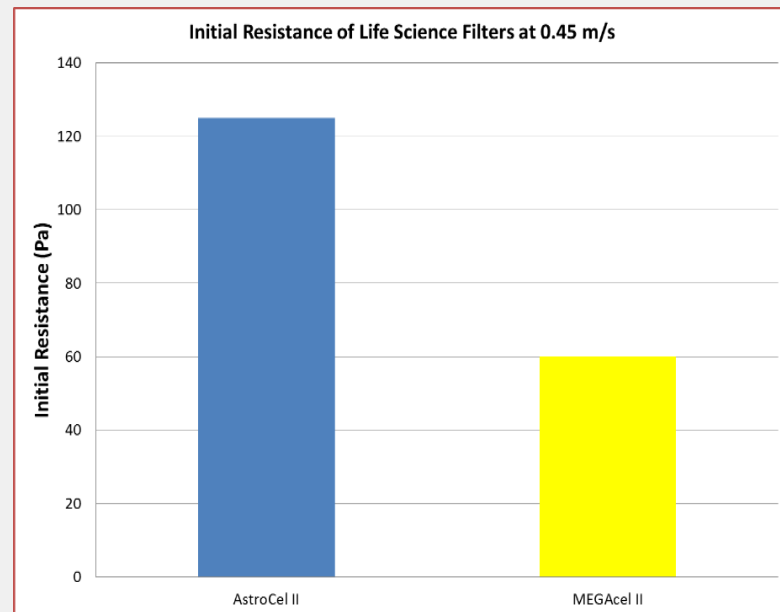
Next page graphic..

2 Stage Filtration in a MUA Life Science Application

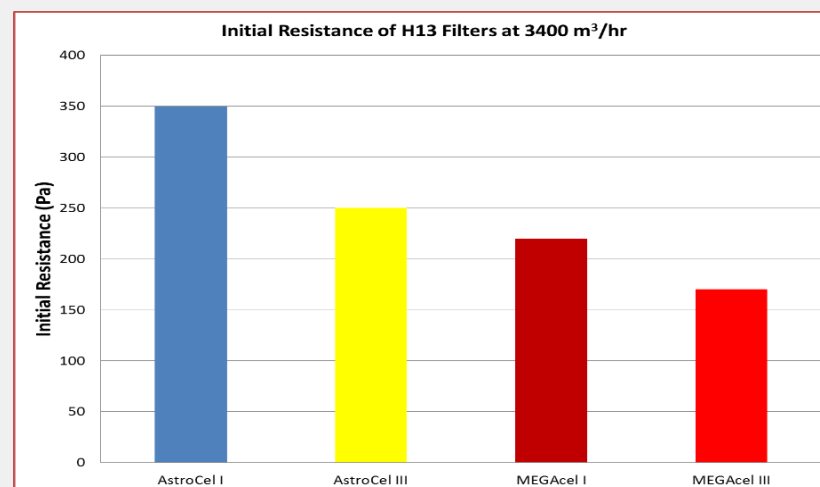
- ▶ When 2 steps of filtration, G4-F8 are installed before terminal housings or ducted modules options to inject PAO locally should be considered. The type of equipment certifiers have available (type of generator, photometer etc.) and ensuring local injection through the housing or ceiling grid as well as access to read upstream concentrations is important.
- ▶ Our goal should always be to keep contamination from any source out and improve cleanliness and minimize MCP's inside the controlled environment.



Energy Comparison-Glass v e-FRM



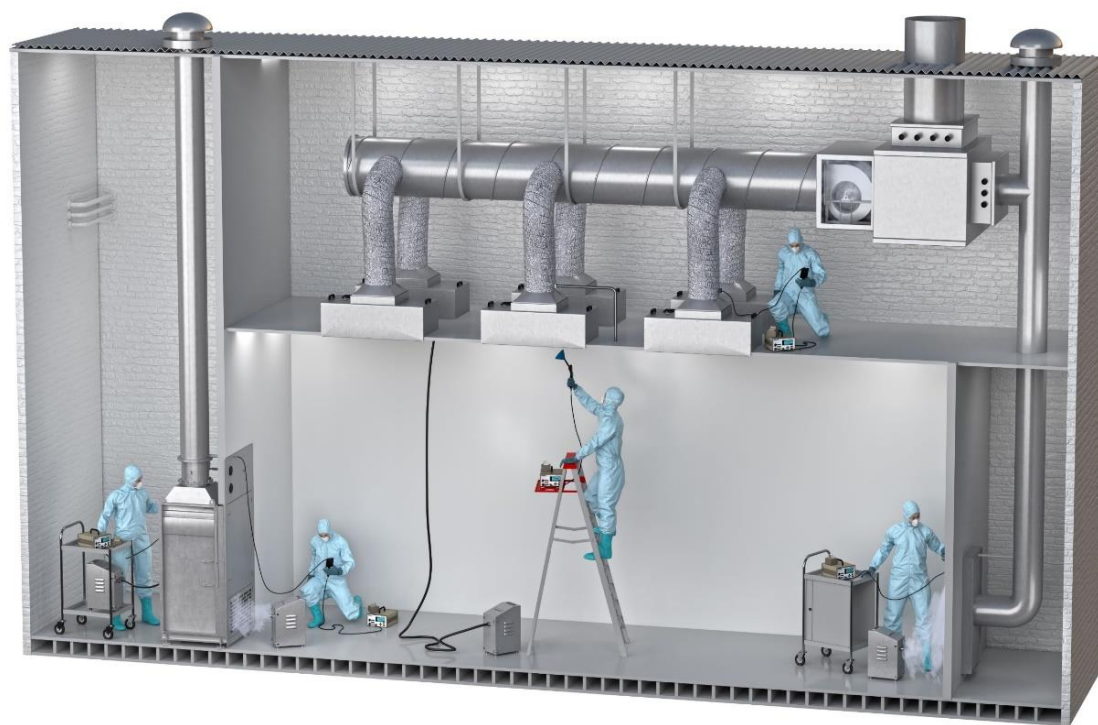
	Astrocel 11	MEGACel 11
Initial Resistance (Pa)	125	60
Air Velocity (m/s)	0.45	0.45
Energy Savings (5 Years) v Glass	\$0	\$100



H13	Astrocel 1	Astrocel 111	MEGACel 1	MEGACel 111
Initial Resistance (Pa)	350	250	220	170
Air Velocity (m/s)	0.94	0.94	0.94	0.94
Energy Savings (5 Years) v Glass	\$0	\$823	\$1,070	\$1,482



Astro-Hood, Astro-Fan Installation & Testing Options

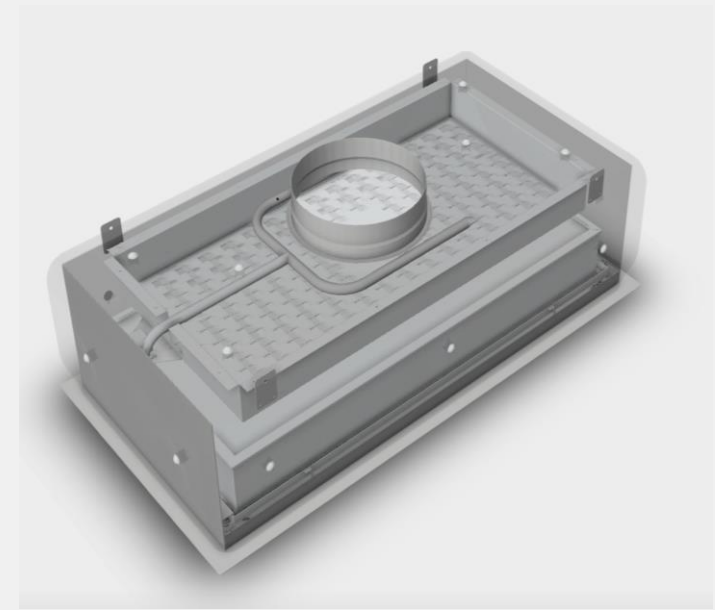
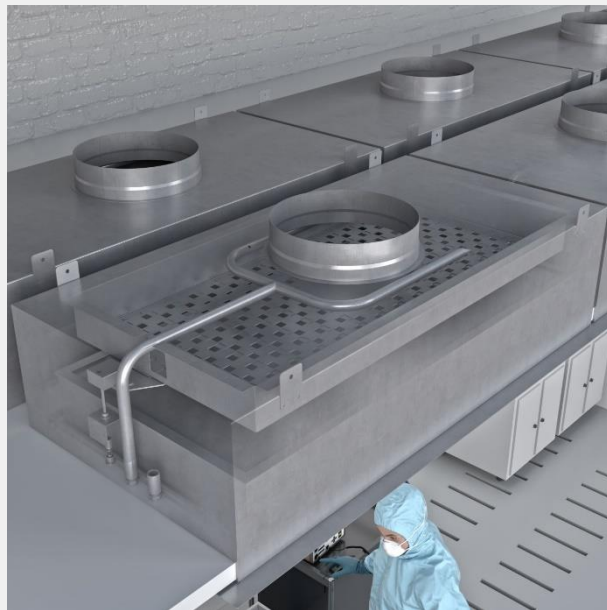


- ▶ We have seen how the membrane technology is superior to glass fiber from a durability standpoint. Excellent mechanical strength and hydrophobic properties.
- ▶ Two types of seal exist. 'Dry' (Gasket, Neoprene, EPDM, PU) and 'Fluid' (Gel, Polyurethane & Silicone) It is important to ensure these sealants are compatible with all common cleaning, testing and decontamination agents.
- ▶ 'The filter only works if the housing or frame it is mounted in works'.
- ▶ **If the housing leaks it does not matter how robust the media is or how tight the seal is?**
- ▶ We need all 3 components to be in harmony and your supplier needs to understand the source of potential failure so you the user or installer minimizes risk and feels safe.

Media + Seal + Housing = System Integrity

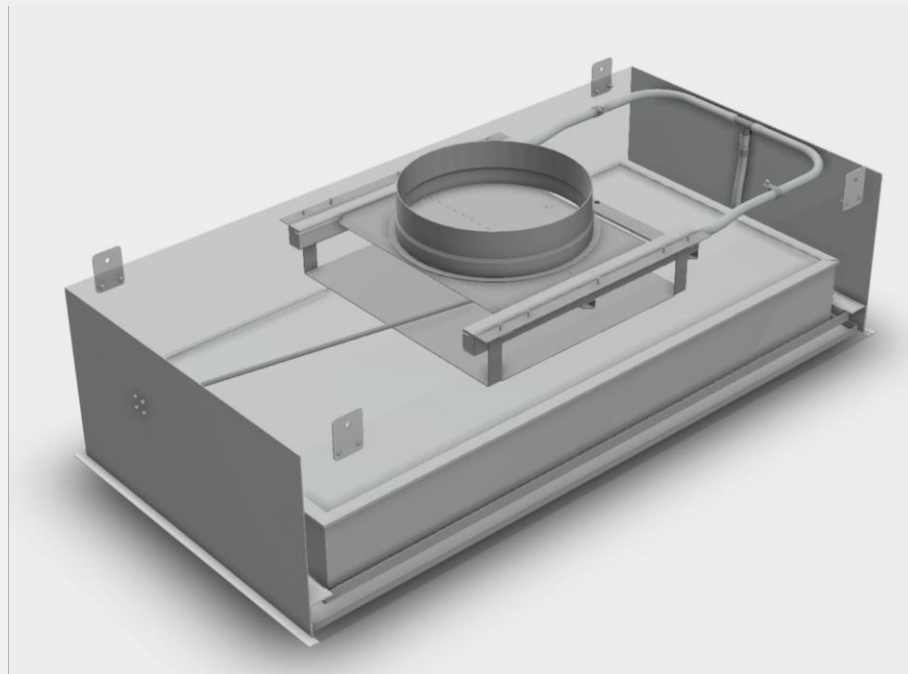
Astro-Hood S-I or E-I

- ▶ Fully welded hood body, pressure tested delivering a guaranteed leak free housing for life.
- ▶ Gel or gasket seal bottom load design ensures a positive seal between the knife-edge or housing plenum.
- ▶ All test ports and damper controls are accessible from the room side fully sealed and pressure tested to ensure no bypass of contaminant.
- ▶ **ESD (Energy Saving Damper)** is standard in the S-1 series ensuring lowest operating costs when combined with the **Megacel e-FRM HEPA filter**.
- ▶ :Fixed or removable trim with 1/4 turn fasteners or acorn nuts and integrated diffuser ensures a flush easy accessible low maintenance solution.



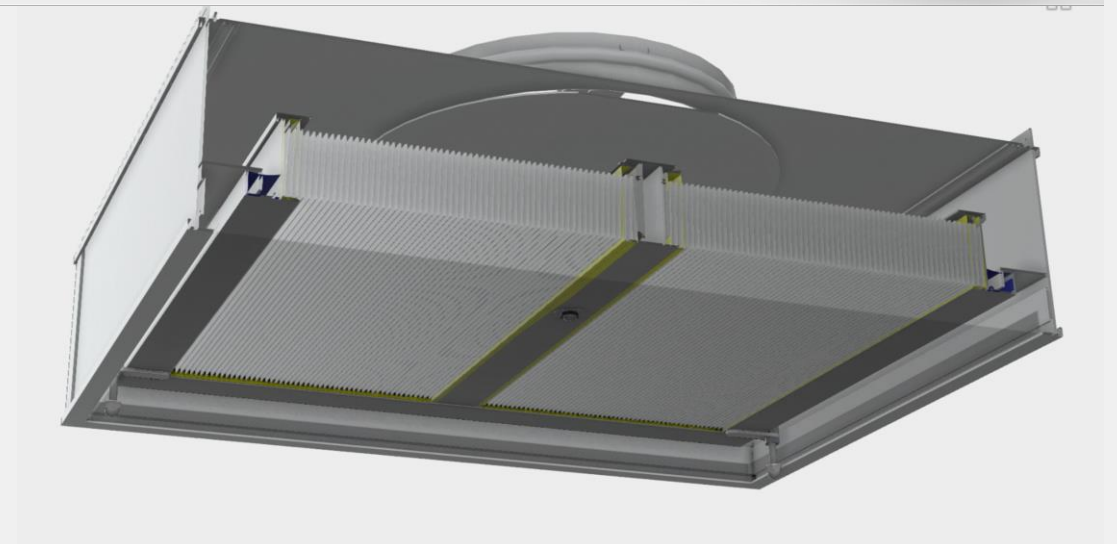
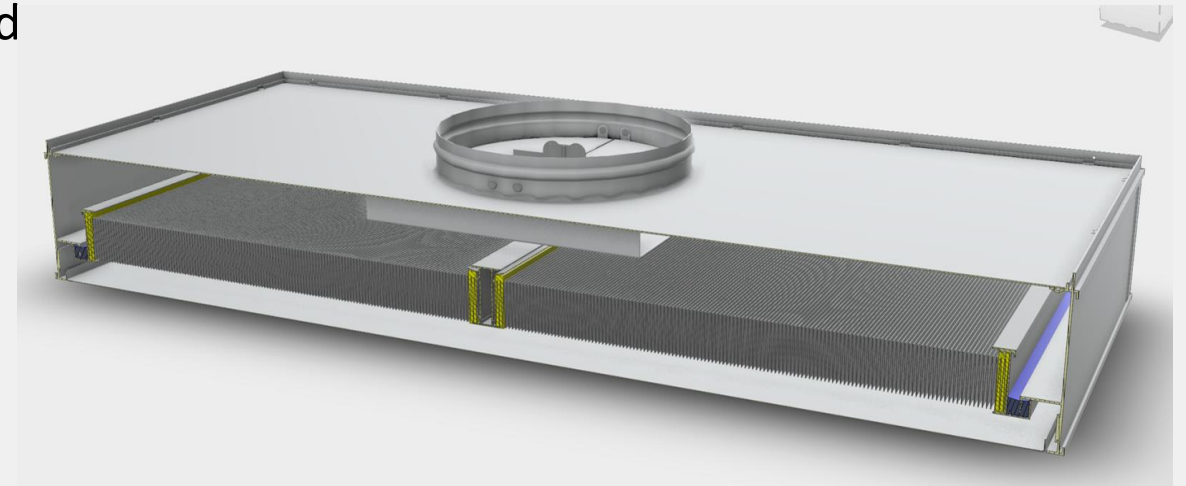
Astro-Hood S-II

- ▶ Welded housing pressure tested to guarantee a leak free housing.
- ▶ Gel or gasket seal bottom load design ensures a positive seal between the knife-edge or housing plenum.
- ▶ All test ports and damper controls are accessible from the room side fully sealed and pressure tested to ensure no bypass of contaminant.
- ▶ Guillotine damper is standard in the S-11 series for 0-100% air volume control.
- ▶ Fixed or removable trim with 1/4 turn fasteners or acorn nuts and integrated diffuser ensures a flush easy accessible low maintenance solution.



Astro-Hood S-III RSR

- ▶ The S-111 RSR has a room side replaceable filter capability combined with an extruded aluminum lightweight slim design housing.
- ▶ Astrocel 11 HEPA as standard, Megacel e-FRM optional for lower operating costs.
- ▶ Perforated diffuser with acorn nuts as standard.
- ▶ Butterfly damper as standard accessible from the room side



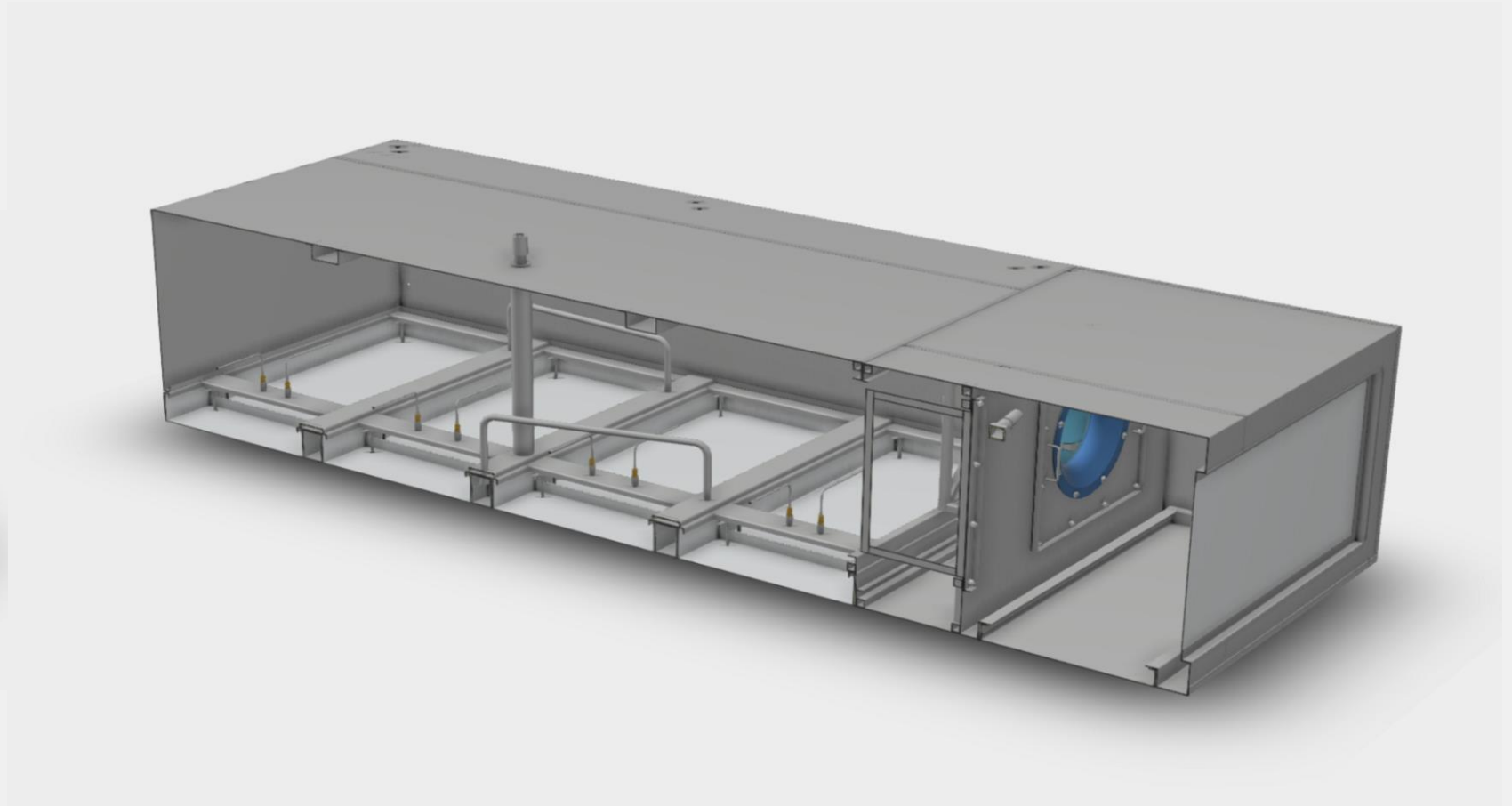
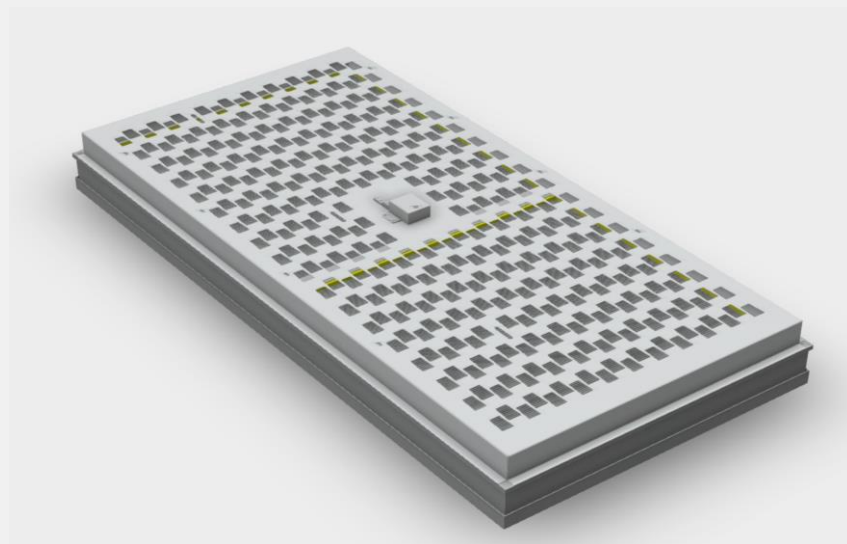
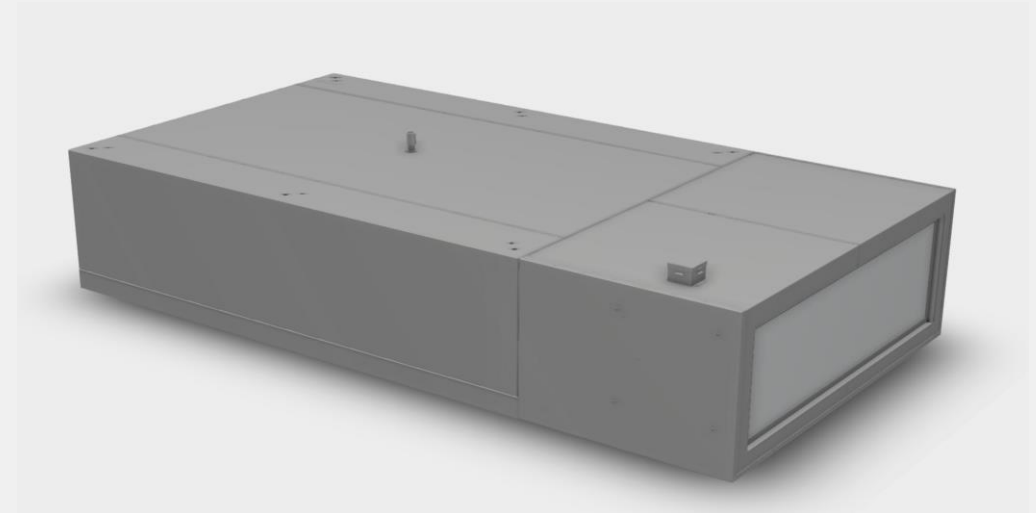
Astro-Hood S-III

- ▶ Light weight disposable HEPA ceiling module.
- ▶ Extruded aluminum housing factory sealed HEPA
- ▶ Adjustable air diffusion disk and test port accessible from the room side.
- ▶ Upstream pressure drop or aerosol concentration measurement possible from the room side.

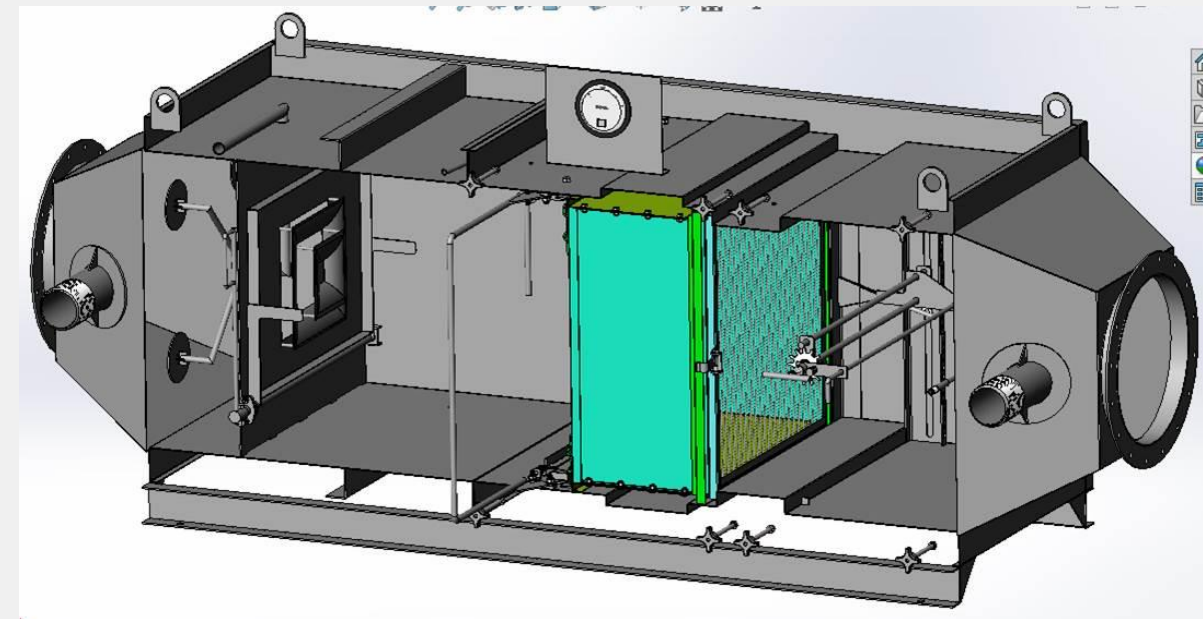
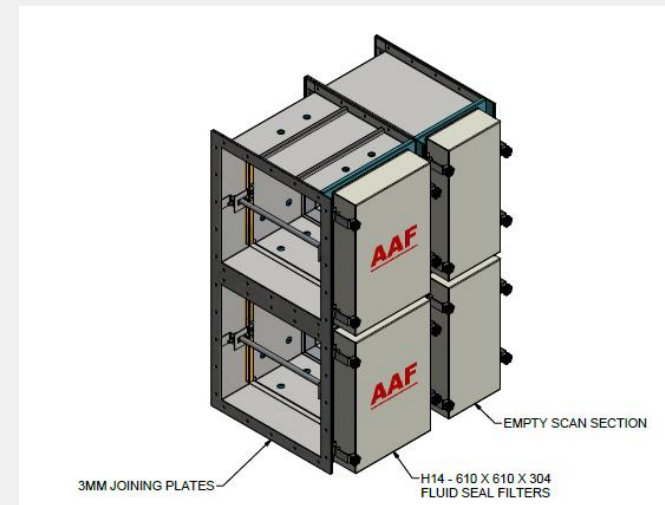
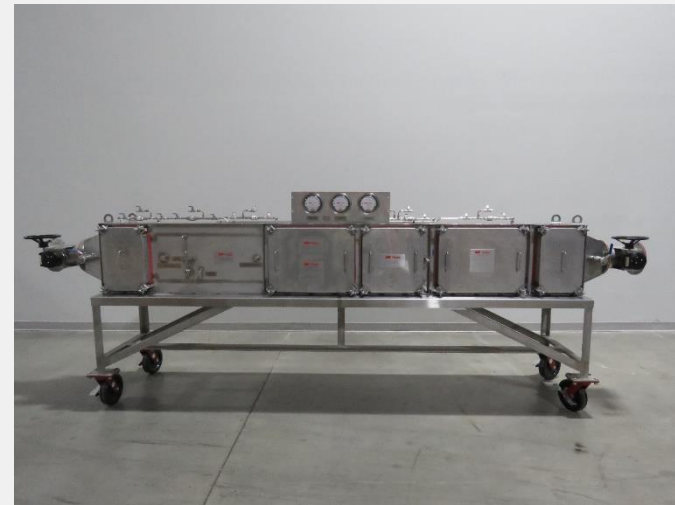


Astro-Hood & Astro-Fan Plenum

- ▶ Portable Clean Spaces
- ▶ 304 and 316 S/SS Const.
- ▶ Sliding Airflow Uniformity Dampers
- ▶ Variety of Fan and Control Options
- ▶ Integrated HEPA & Fan Unit Options



Astro-Hood & Astro-Safe Exhaust Housings:



Industry Trends-Sustainability & CO2 Reduction.

Historic & Changing AC Rate Reduction Levels

Historic design strategy for air-change rates which normally have no technical base					
Big Pharma	Grade A	Grade B	Grade C	Grade D	CNC
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

Facility Type	Opportunity	Potential % Reduction
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 startegy-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%

Real World Room Counts & AC Rates

Medical Device Facility						
Room	Actual-Average Counts 'Operational'	Required ISO Classifications 'At Rest'	Required Counts to achieve ISO-14644-1 Classification			Actual ISO Classification Achieved <i>OPERATIONAL</i>
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
Room 2	41,867	ISO 8 @ 0.5µm	3,520,000	352,000	35,200	ISO 7
Room 3	214,558	ISO 8 @ 0.5µm	3,520,000	352,000	35,200	ISO 7

OSD Facility									
Room	Non-Viable Particle Counts (Only 0.5µm measured)			Allowable Counts			Classification Achieved- <i>OPERATIONAL</i> - SOP cGMP-ISO-14644		Comment
	Condition	0.5µm mean	5µm	Class	0.5µm	5µm	0.5µm	5µm	
AHU 1									
Room 1	Operational	10,800	x	ISO 9	35,200,000	x	ISO 6	x	3,258 x Cleaner- <i>OPERATIONAL</i>
Room 3	Operational	13,965	x	ISO 9	35,200,000	x	ISO 6	x	2,520 x Cleaner- <i>OPERATIONAL</i>
Room 4	Operational	14,679	x	ISO 9	35,200,000	x	ISO 6	x	2,397 x Cleaner <i>OPERATIONAL</i>

Real World Room Counts & A/C Rates:

Sterile Manufacturing							
Room	Activity	Class cGMP ISO	Validated Status	Specified Air Changes/hr	Specified Particle Counts	Actual Particle Counts	Actual at 0.5µm
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 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

Regulatory Position Regarding AC Rates

Organization	Regulatory Position
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 Pharmacopeia	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!

Typical Cleanroom kWh Energy Consumption

Element	Percentage of Total	Function
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

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 dependant 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, especially 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

Conclusions

Life Science facilities generally over-perform therefore wasting valuable energy and money

Compliance and product quality is dependant 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

Simulation Software and IoT, is beginning
beginning to Optimize Air Filtration Selection and
Cleanroom Design.

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 method often results in replacing filters that are still relatively clean, wasting time and money.



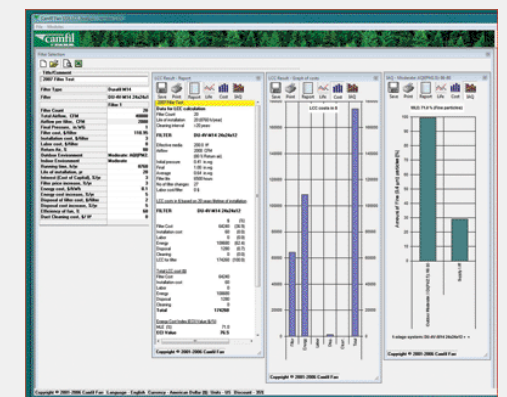
On the Pressure Gauge method requires regular pressure gauge monitoring, frequent gauge maintenance and record-keeping, and adjustments based on airspeed to be effective.

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



	Existing filter system	Viledon® System
1 st Filter stage	glass fibre pocket filter	Viledon® Compact pocket filter F50
2 nd Filter stage	glass fibre pocket filter	Viledon® Compact pocket filter T90
Start of measurement	April 23, 2007 11:00 h	May 14, 2007 11:35 h
End of measurement	May 14, 2007 11:15 h	May 29, 2007 09:40 h
Measured energy consumption	in 504 h = 3,974 kWh	in 358 h = 2,562 kWh
Calculated mean energy consumption	69,072 kWh p.a.	62,690 kWh p.a.



More Scientific Approach for True TCO Analysis.

- ▶ Voltage Sensor Capability should be part of the TCO.
- ▶ Initial power consumption delta brand X 2A. 1 year 6A. (X3 increase in real power)
- ▶ VFD A analysis
- ▶ Real time KW load analysis related to air filters
- ▶ True kWh average cost

$$KW_{\text{saved}} = \frac{(\sqrt{3} * \text{Volt} * \Delta\text{Amp} * \text{PF})}{1,000}$$

$$KW_{\text{saved}} = \frac{(1.73 * 480 * 2 * 0.9)}{1,000}$$

$$KW_{\text{saved}} = 1.5 \text{ KW}$$

$$KWh_{\text{saved}} = KW_{\text{saved}} * \text{Hours}$$

$$KWh_{\text{saved}} = 1.5 \text{ KW} * 8,760 \text{ hours} = 13,140 \text{ KWh per year}$$

$$\text{Energy}_{\text{saved}} = 13,140 \text{ KWh/year} * \$0.12/\text{KWh}$$

$$\text{Energy}_{\text{saved}} = \$1,576/\text{year}$$

$$KW_{\text{saved}} = \frac{(\sqrt{3} * \text{Volt} * \Delta\text{Amp} * \text{PF})}{1,000}$$

$$KW_{\text{saved}} = \frac{(1.73 * 460 * 2 * 0.9)}{1,000}$$

$$KW_{\text{saved}} = 1.434 \text{ KW}$$

$$KWh_{\text{saved}} = KW_{\text{saved}} * \text{Hours}$$

$$KWh_{\text{saved}} = 1.434 \text{ KW} * 8,760 \text{ hours} = 12,561 \text{ KWh per year}$$

$$\text{Energy}_{\text{saved}} = 12,561 \text{ KWh/year} * \$0.12/\text{KWh}$$

$$\text{Energy}_{\text{saved}} = \$1,507/\text{year}$$

$$KW_{\text{saved}} = \frac{(\sqrt{3} * \text{Volt} * \Delta\text{Amp} * \text{PF})}{1,000}$$

$$KW_{\text{saved}} = \frac{(1.73 * 493 * 2 * 0.9)}{1,000}$$

$$KW_{\text{saved}} = 1.535 \text{ KW}$$

$$KWh_{\text{saved}} = KW_{\text{saved}} * \text{Hours}$$

$$KWh_{\text{saved}} = 1.535 \text{ KW} * 8,760 \text{ hours} = 13,448 \text{ KWh per year}$$

$$\text{Energy}_{\text{saved}} = 13,448 \text{ KWh/year} * \$0.12/\text{KWh}$$

$$\text{Energy}_{\text{saved}} = \$1,613/\text{year}$$

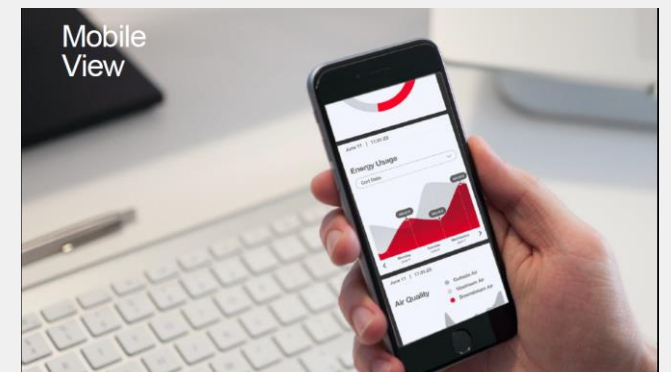
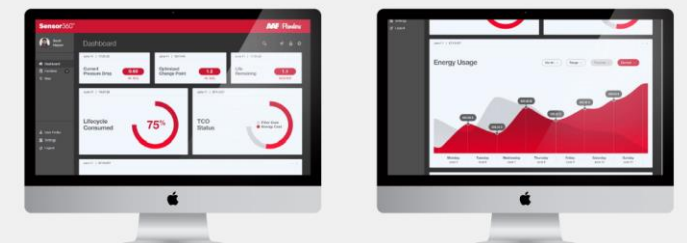
IoT and Air Filtration – Sensor Technology-Current State

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



Desktop View



IoT and Air Filtration – Sensor Technology-Current State

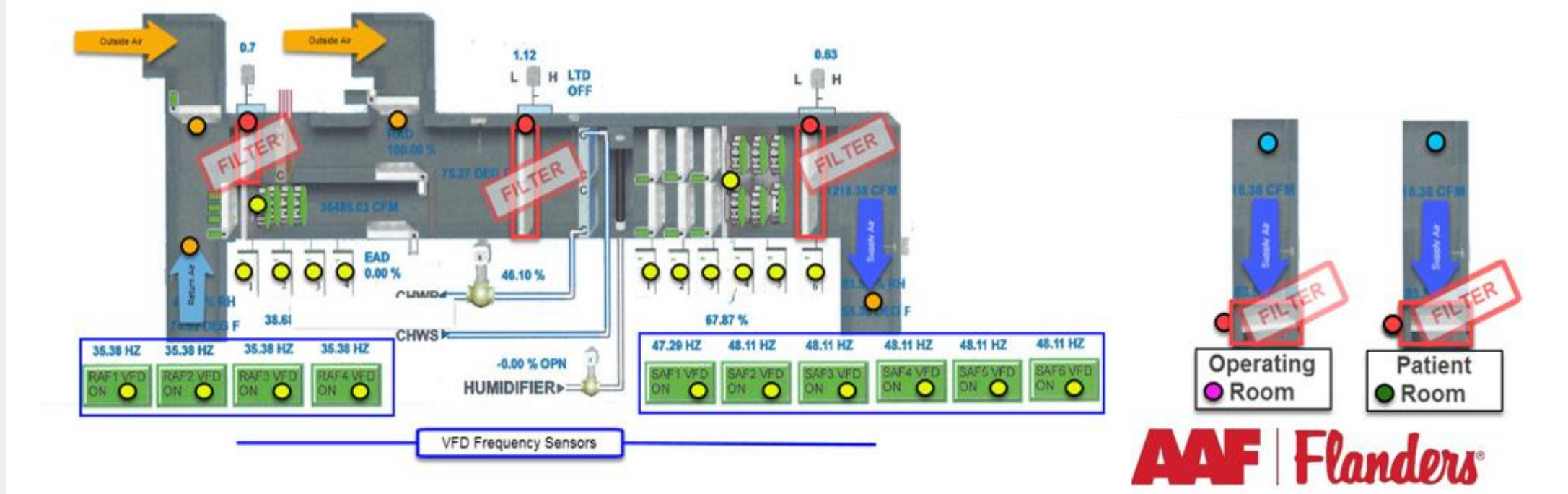
Real-time data that allows optimization of:

- ▶ Intelligent Air filter selection
- ▶ Intelligent Air filter change-outs
- ▶ Indoor air quality (IAQ)
- ▶ Energy usage
- ▶ Filter efficiency

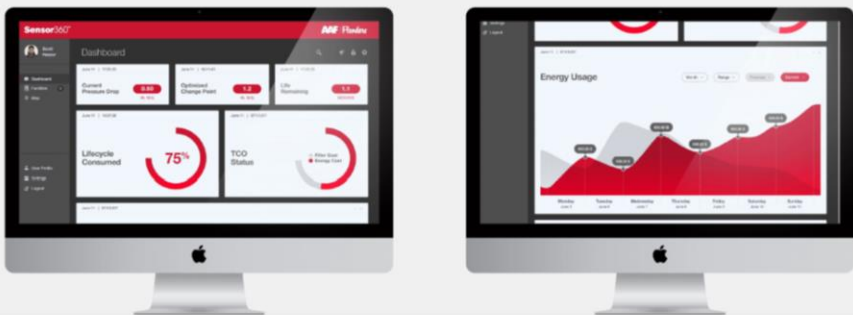


Future Sensor Arrays

Example of Sensor360 Deployed for Complex Hospital Air Handling Unit and Rooms



Desktop View



Mobile View



Sensor Type	Position
Air Flow	OA
Particle Count	OA
Temp / Humidity	OA
Air Pressure	OA
Gas sensor - VOC	OA
Gas sensor - NO2	OA
Gas sensor - CO2	OA
Gas sensor - SO2	OA
Gas sensor - H25	OA
Air Flow	AfterPreFilter
Electricity	BeforeSA
Air Flow	SA
Air Pressure	SA
Temp / Humidity	SA
Particle Count	SA
Temp / Humidity	RA
Electricity	RA
Air Flow	EA
Air Flow	RA

Life Science Cleanrooms

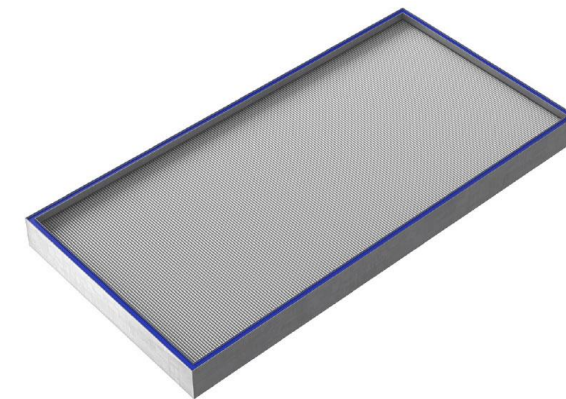
Control of viable and non-viable particles is crucial in many process applications in the Life Science industry. Protection of people from hazardous or potent compounds is equally important. There is a wide variety of supply, exhaust and recirculated air housings and filter types to address each application.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



AHU Filter Testing

In situ integrity testing of HEPA filter banks is accomplished by injecting an aerosol (PSL) upstream of the filters and manually scanning the downstream side of the filters.

Alternate Overall Efficiency Test This can be performed by measuring a single point *upstream* ① and *downstream* ② of the filter.

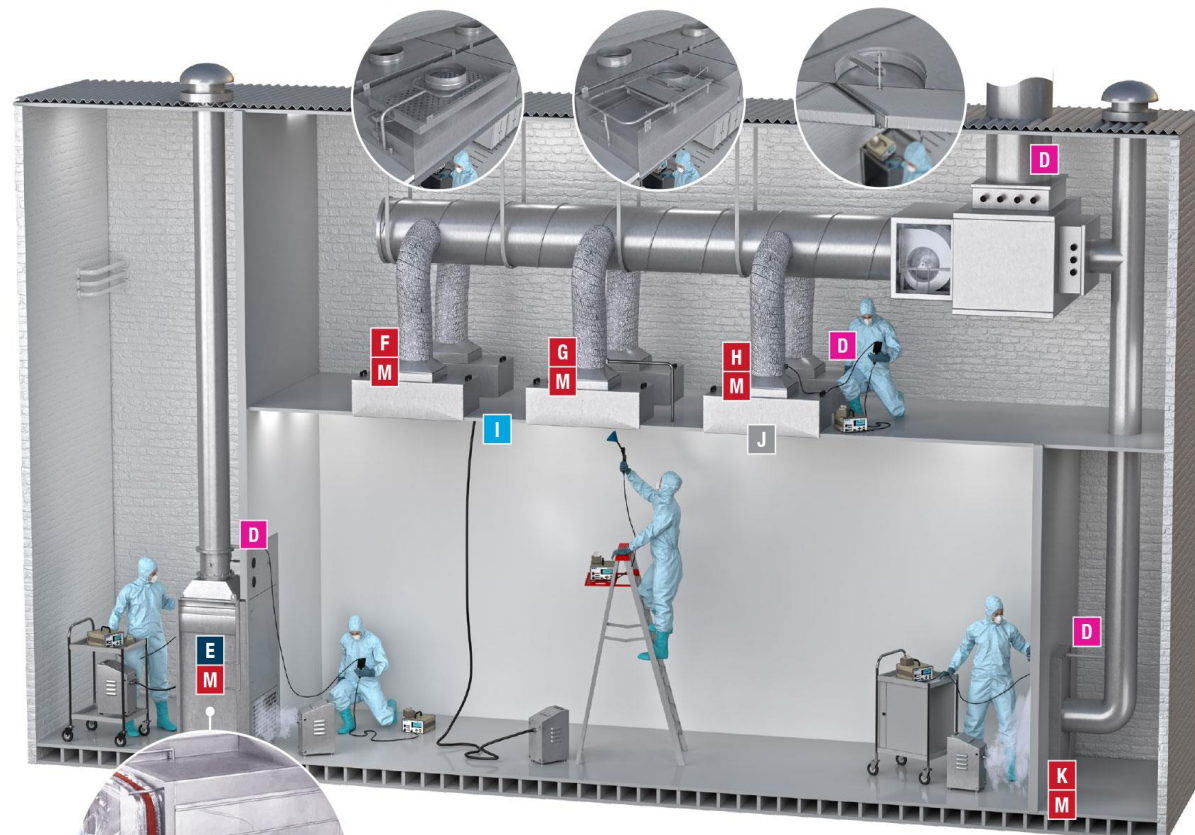


A	MEGApleat®
B	VariCel® VXL/DriPak® NX
C	Sensor360®
D	Test Port
E	AstroSafe® V-BIBO
F	AstroHood® S-I
G	AstroHood® S-II
H	AstroHood® S-III
I	Injection Port
J	Central Test Port
K	AstroHood® E-1
L	AstroHood® Plenum
M	MEGAcel® eFRM
N	AstroFan™
O	Astro-SCS™
P	ESD Damper

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

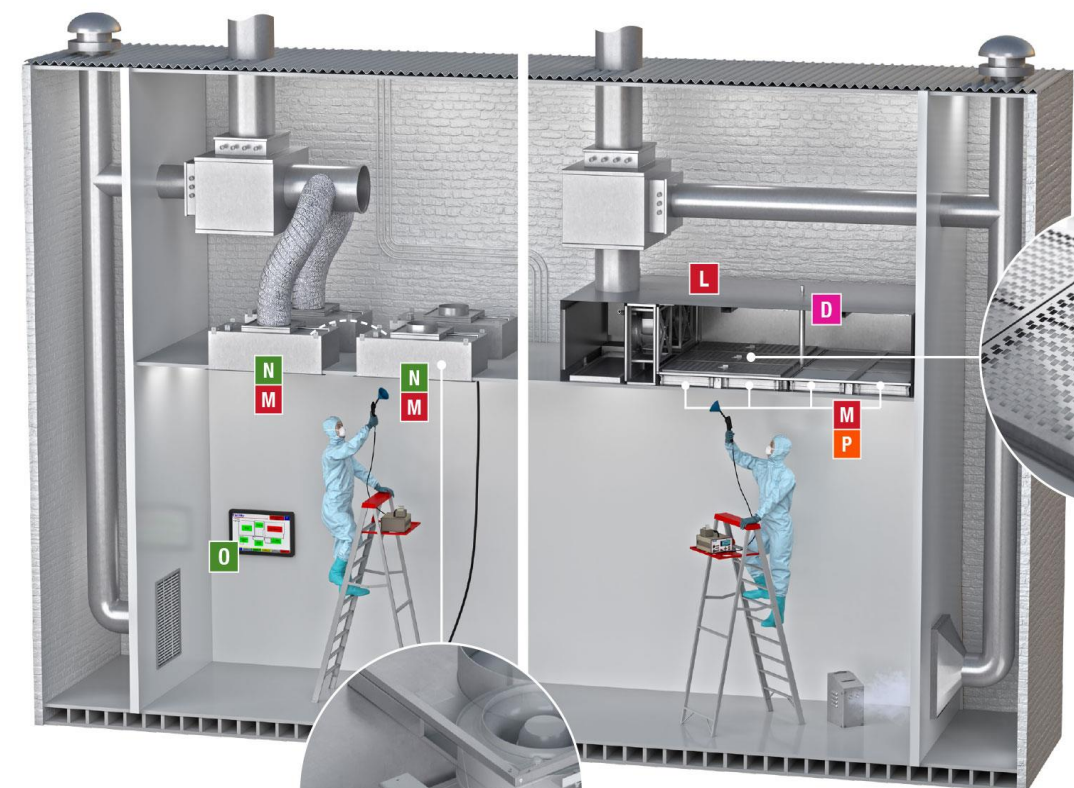
AstroHood® S-II
Guillotine damper and aerosol injection

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



AstroSafe® V-BIBO

A 'safe change' or BIBO (Bag-In-Bag-Out) housing with an integrated manual scan section normally utilized when potent or hazardous compounds are in use.

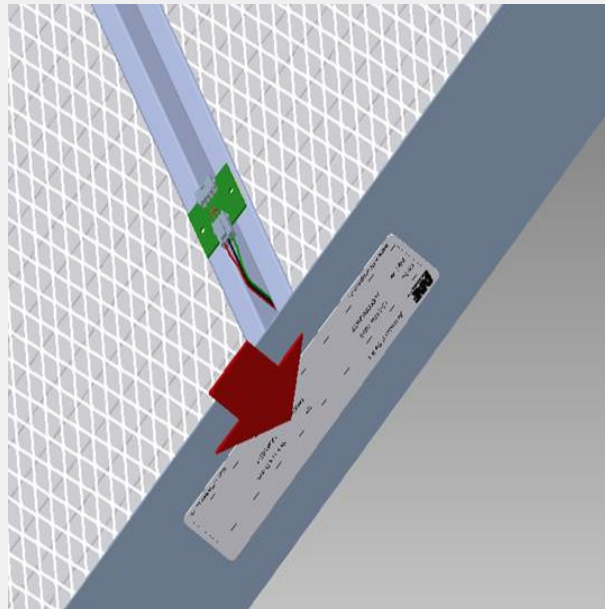


MEGAcel® eFRM ESD Damper
HEPA/ULPA filter with integrated airflow uniformity Energy Saving Damper.

AstroFan™ EC Controls

Intelligent controls gives you continuous motor speed monitoring and modulation, tailoring fan speed to match demand.

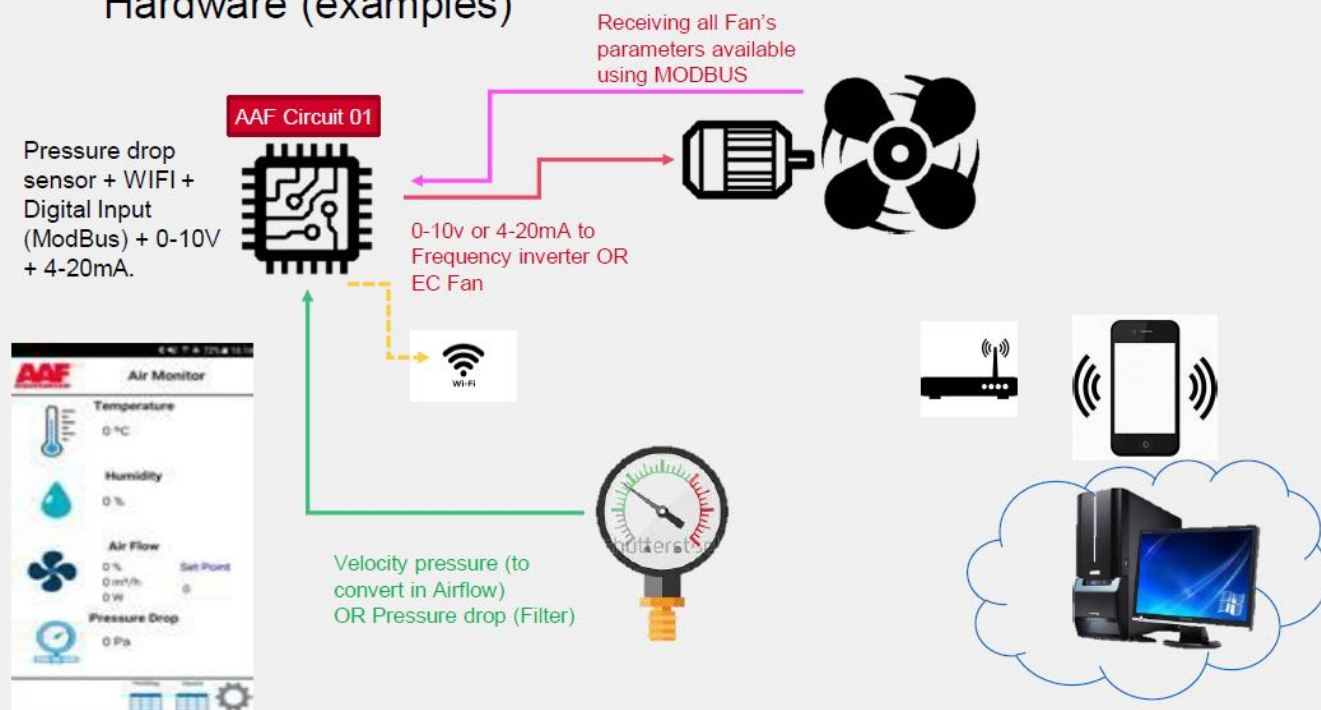
Constant Air Velocity, LED indicator & Aerosol Injection Integrated into the FFU-Current State.



- Local Aerosol Injection Capability:
- 24/7 monitoring of airflow velocity for:
- Pharma monitoring compliance within GMP Grade A environments
- Close control / auto fan speed compensation to overcome increased pressure across the filter
- Optional LED in filter
- Cable set to be selected with motor type being EC or AC
- Red is indication a failure
- Green is correct operation
- No light, no power connection

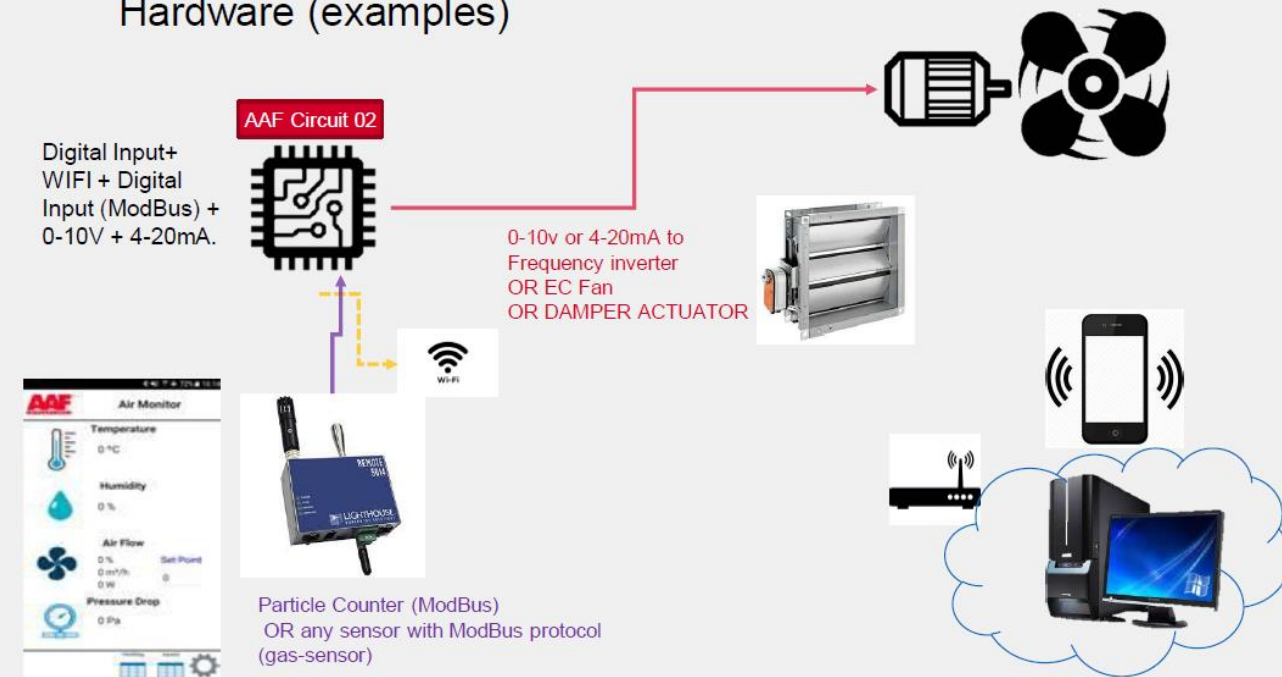
AAF | Flanders® Controlling Air Contamination-Near Future State:

Hardware (examples)



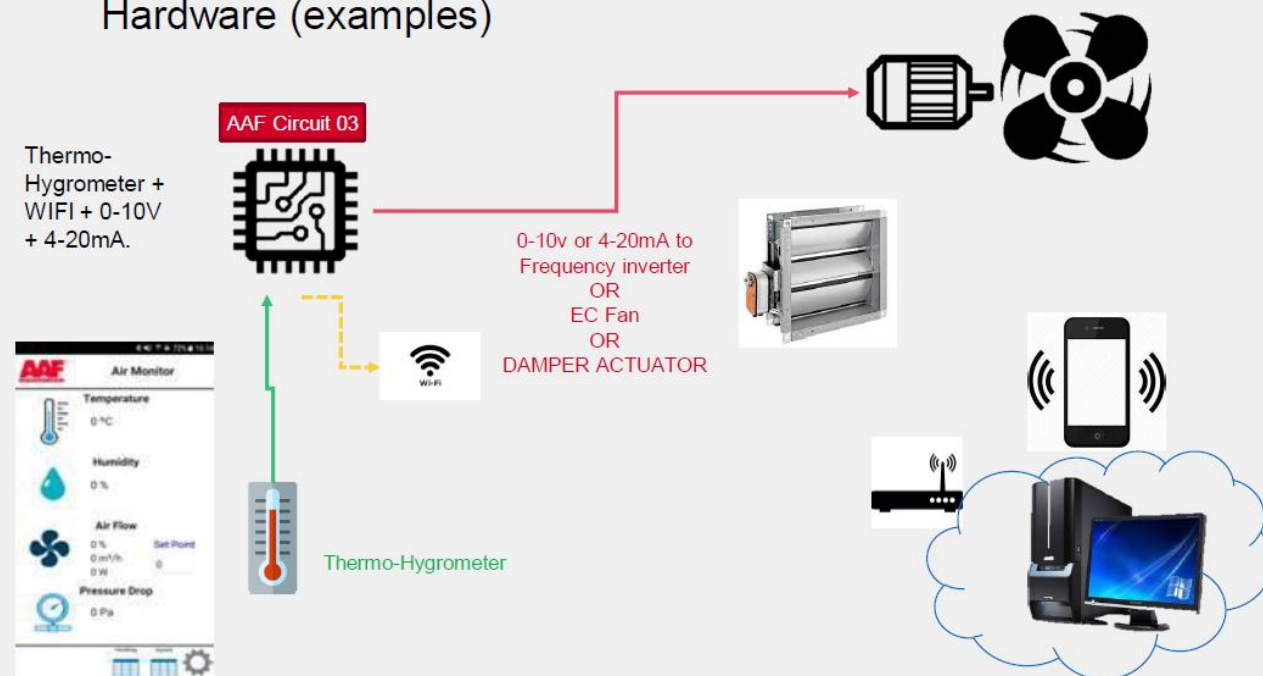
Airflow/Velocity

Hardware (examples)



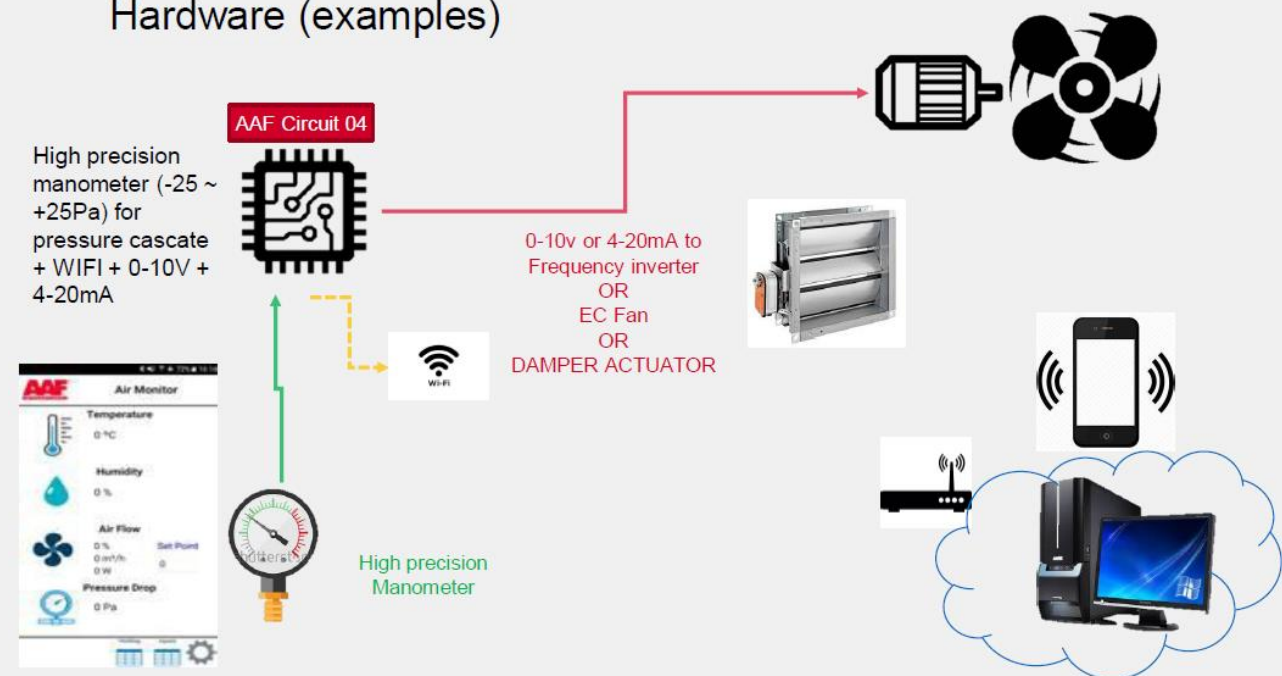
Particle Counter (ModBus Protocol)

Hardware (examples)



Temperature

Hardware (examples)



Pressure

AAF Galaxy

[aaf.advancedsolutions.com/#/filterSelection/490fe0b5-b503-4072-b1da-0fc97f9a7d08](#)

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Project: Test Project Imperial

Last Modified: 2018-04-19T18:58:36

Existing AHU Filters

Stages Filters

Stage 1

MEGApleat MERV 1

Stage 2

VariCel VXL MERV

Stage 3

DriPak NX - 22" 10

Stage 4

No Filter

Stage 5

AstroCel I

Optimized Filters

Stages Filters

Stage 1

MEGApleat MERV

Stage 2

VariCel VXL MERV

Stage 3

DriPak NX - 22" 10

Stage 4

No Filter

Stage 5

MEGAcel III

System Parameters

Operating Hours Per Day:

24

Operating Days Per Week:

7

Total System Air Flow (ft³/m):

80000

Overall Fan System Efficiency:

40

Percent Outside Air in AHU Make Up:

10

Save Filters

Total Cost of Ownership of AHU Filtration System

	Optimized	Existing
Stage 5 Filter	\$2227.86	\$3974.50
Stage 5 Energy	\$17254.29	\$16221.28
Stage 2 Filter	\$3744.74	\$809.07
Stage 2 Energy	\$12570.12	\$9127.45
Stage 1 Filter	\$708.07	\$808.53
Stage 1 Energy	\$5393.62	\$6714.18
Total Cost	\$41898.69	\$37655.01

AAF Galaxy
aaf.advancedsolutions.com/#/roomdetails/490fe0b5-b503-4072-b1da-0fc97f9a7d08/2263b6e0-dc91-44fe-97b6-d3ecc6cb7f56
Task List JIRA Chase Ally reddit Etrade Hacker News Techmeme Techdirt NetSuite ASI Email Sharepoint GoalPOST Other bookmarks

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Project Rooms AHU TCO Model
My Account Logout

Project: Test Project Imperial Last Modified: 2018-04-19T18:58:36

Add New Room

- Room 1 - AHU 1
- Room 2 - AHU 2
- Room 3 - AHU 3

Individual Room Data

Reference	System
Room ID	Room 1 AHU 1
Room Width	43 ft
Room Depth	25 ft
Ceiling Height	10 ft
Room Internal floor area	1075 ft ²
Room Volume	10750 ft ³
% Recirculated From Room	70 %
% Exhausted From Room	25 %
% Leakage From Room	5 %
Terminal Filter	MEGAcel II
Ac/hr	1

Cleanliness Classification

EUGMP	Grade B	2000
ISO14644-1	ISO 5	0
FDA	ISO 5	-

Minimum ac/hr Required

Particle Size	EUGMP	ISO14644-1	FDA
0.1 µm	295	1	-
0.2 µm	420	1	-
0.3 µm	75	1	-
0.5 µm	5	500	-
1 µm	1	1	-
5 µm	11	500	-

Contamination Load

Contamination Chart

Thank you: