A SCIENCE-BASED APPROACH TO SELECTING AIR FILTERS

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This article provides an overview of science-based factors to consider when selecting HEPA filters.

INTRODUCTION

Understanding the Total Cost of Ownership (TCO) and the material compatibility of HEPA filters is essential for engineers and end users seeking to optimize filter selection for performance reliability and sustainability. In order to give the reader a basic understanding of how filters work, it is essential that the principles of filtration are clearly defined.

Air filters are physically simple, yet technically complicated devices. Whether particulate or gas phase filters, they rely on a complicated set of mechanisms to perform their function. In many cases, more than one of these mechanisms comes into play. Many new technologies have been employed in the effort to improve on the quality and performance of air filters, and in some cases to reduce their cost. The most notable areas where advancement has been pursued are reduction in pressure drop and elimination of biological contaminants in the filter media. It is important to consider whether applying new technologies to air filter products is necessary and functional. In many cases it is, in some cases, it isn't. Certain technologies, like ionic air cleaners, may generate by-products that may be harmful to the environment. Air filters are physically simple, yet technically complicated devices. Whether particulate or gas phase filters, they rely on a complicated set of mechanisms to perform their function. In many cases, more than one of these mechanisms comes into play. Many new technologies have been employed in the effort to improve on the quality and performance of air filters, and in some cases to reduce their cost. The most notable areas where advancement has been pursued are reduction in pressure drop and elimination of biological contaminants in the filter media. It is important to consider whether applying new technologies to air filter products is necessary and functional. In many cases it is, in some cases, it isn't. Certain technologies, like ionic air cleaners, may generate by-products that may be harmful to the environment.

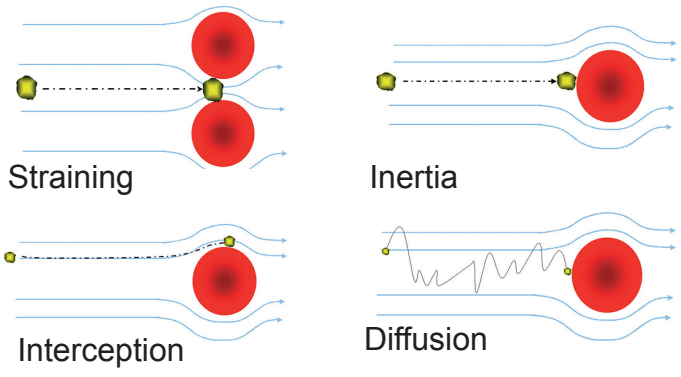

Figure 1. Principles of air filtration

Each mechanism is responsible for filtration of particles in a certain size range:

Impaction: larger particles are filtered due to the impaction mechanism. Larger particles have higher mass and are harder to turn than smaller particles due to inertia. Because of this inertial effect, the particles continue to travel in a somewhat straight line even though the airstream is turning to move past the fiber. Once the particle comes in contact with the fiber, it becomes attached and is "filtered" from the airstream.

Interception: in order to be intercepted, a particle must come within a distance from a fiber of one radius of itself. Thus, the particle makes contact with the fiber and becomes attached. The interception mechanism can be contrasted with the impaction mechanism in that a particle which is intercepted is smaller and its inertia is not strong enough to cause the particle to continue in a straight line. Therefore, it follows the airstream until it comes in contact with a fiber.

Diffusion: is the most difficult air filtration mechanism to imagine or explain. Very small particles come in contact with fibers due to diffusive effects. The particles collide with air molecules and are "pushed around." This effect is called Brownian motion. Because of Brownian motion, small particles don't precisely follow the airstream, but instead "vibrate" or move erratically. This erratic movement increases the probability of the particles coming in contact with filter fibers.

Straining: is the air filtration mechanism in which the particle is larger in all dimensions than the distance between adjoining filter fibers. The particle gets stuck and can't make its way through the filter media. Straining is the mechanism of capture for large particles.

Electrostatic Attraction: filters utilizing large diameter fiber media (coarse fibers) may rely on electrostatic charges to increase their efficiency of fine particle removal. Large diameter fiber media is normally chosen due to low cost and resistance to airflow; however, these filters often lose their electrostatic charge over time because the particles captured on their surface occupy charged sites, neutralizing their electrostatic charge and the filters' real life efficiency.

A perfect air filter would operate at 100% efficiency on the target contaminants, require zero energy input, and last forever; however, no filter of this type has been invented. Filter efficiency, dust holding capacity, and differential pressure can be measured in many ways, and the performance of an air filter changes over time. The challenge imposed on air filters changes as the environment inside and outside of a building changes. Many air filter testing methods have been developed by various organizations for predicting the in-use performance of filters and for comparing the performance of air filters of different designs. It is important to understand the complexity of differentiating air filters. Many variables impact the results of a comparison study, some of which are obvious and some of which aren't. Most air filters will be in a system for months or even years; however, testing of these filters often occurs in a few minutes or hours. During its life, an air filter will see dozens or hundreds of environmental changes such as temperature, humidity, airflow velocity, and particle load. However, testing of filters often occurs in a controlled environment. Add to this the imperfect design of testing methods and the various motivations of the people developing test methods and you can conclude that you must fully understand how to interpret the results of any air filter test prior to using these results to make important decisions.

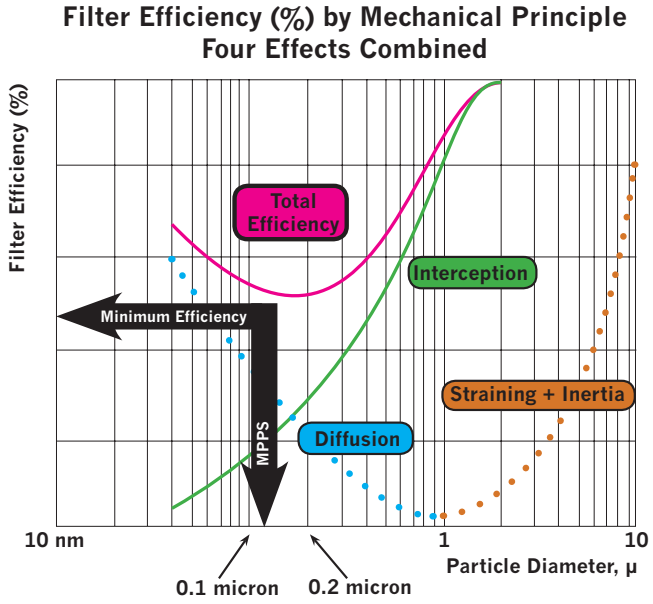

Figure 2. Air filtration mechanisms combined

Organizations involved in setting filter standards and testing methods include:

- American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE)
- Institute of Environmental Sciences and Technology (IEST)
- Underwriters Laboratories (UL)
- Central European Norms (CEN)
- International Organization for Standardization (ISO)

Each of these organizations has an area of focus, but their standards and testing methods may overlap in some cases. Manufacturers have also developed several additional methods for predicting in-use performance, determining the performance of air filters in-use (in-situ), and comparing the performance of air filters of different designs.

The life science industry has additional challenges when it comes to selecting air filters. Sustainability cannot be ignored. Once the correct filter is selected for performance, the design should be optimized to maximize lifetime and reduce energy consumption, ideally based on real life data.[1] Compatibility of HEPA filter construction materials and how they perform and or react with common cleaning agents, decontamination agents, and how test aerosols are applied will be explained in detail using a combination of laboratory and real life data. Membrane HEPA media (PTFE) is an interesting material with application possibilities, but also not without challenges; scientific study and test results will be reviewed with specific discussion on factory versus field testing. Specifying the correct filter efficiency and test procedure, and understanding aerosol generation techniques as well as HEPA filter repair limitations adds a level of complexity to the recipe for selecting air filters for the life science industry.

USING LIFE CYCLE COST (LCC) ANALYSIS IN THE AIR FILTRATION INDUSTRY

Using Life Cycle Cost (LCC) analysis as a tool to calculate the Total Cost of Ownership (TCO) and then selecting the air filter with the lowest TCO is an excellent method for determining the most cost-effective filtration solution to meet user needs. The current industry "standard" for calculating LCC was published by Eurovent in 1999[1] and specifically addressed the role of air filtration based upon life cycle cost. It outlined the calculation methods and formulas used when computing the LCC of an air filtration system. A proper LCC calculation allows owners to identify filtration solutions to help minimize system cleaning, reduce filter disposal costs, reduce labor costs, count the savings as "cost avoidance" with extended filter life, and utilize personnel for other activities.

There are different modeling software products available today. It's imperative when modeling a given application that the data be based upon science and real life testing, not hypothetical data or artificial loading. The use of real life testing is a very time consuming and costly way of evaluating filtration performance, but it provides the data needed to program modeling tools with the most accurate data and thus empowers end users with the confidence that the results are valid.

There are several key factors for selecting air filters to optimize energy consumption. The most important to remember is why was the air filter installed. The primary reason for the filter being installed was not to save money on energy. The air filter is there to remove particulate and contaminants from the air stream to protect the processes. If the filter can do that and use less energy, the air filter has added value.

We must always start with understanding what particle removal efficiency is required by the owner to protect the process, environment, or people. Unfortunately, there is a paradoxical relationship between energy savings and a filter's efficiency; generally, the higher the particle removal efficiency, the higher the energy consumption. Once the required particle removal efficiency requirement has been established, the filter selection can then be based upon additional criteria including:

1. Meeting this particle removal requirement throughout the service life.
2. Optimizing the resistance to airflow for the air filter to reduce energy consumption.
3. Minimizing the TCO of the air filter.

PARTICLE REMOVAL EFFICIENCY

The goal of LCC is to optimize the total cost of the filtration, while maintaining the minimum level of efficiency established by the owner or cognizant authorities. Unfortunately, a large number of commercially available filtration products use a filtration media that will show high particle removal efficiency in laboratory testing, but will decrease in efficiency during actual service. If these products were promoted at the lower performance level where they perform for most of their service life, there would be no confusion; however, they are typically marketed at the higher "test report" efficiency.

Field data from real-life filter installations reveals some interesting facts about the relative performance of electrostatically charged media filters vs. non-charged media filters. Numerous studies have documented the real-life losses in filtration efficiency commonly encountered with charged media. Figure 3 shows the field performance data from the SINTEF[2] filter field test report showing the loss in efficiency over time for an ASHRAE 52.22 MERV 13 (F7 per EN-7793) filter. This study, in actual in-place testing exposed the drop in particle capture efficiency of synthetic or charged media. Table A shows the relative comparison of the industry laboratory test methods for air filters and their efficiency nomenclature.

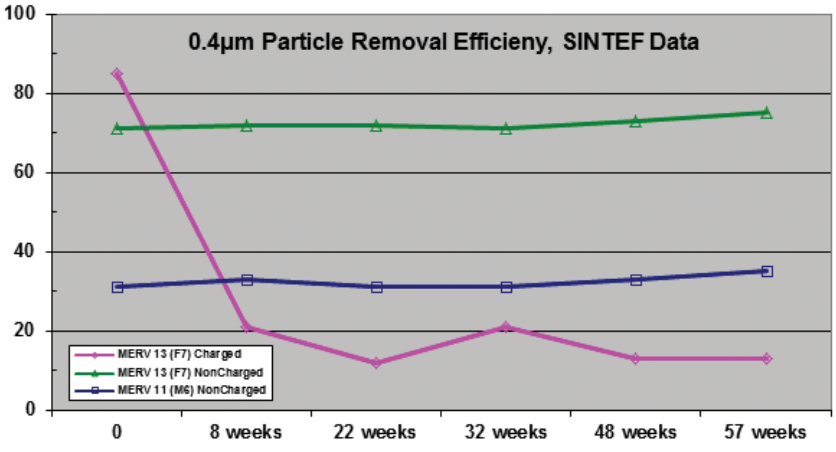

Figure 3. SINTEF air filter performance study

As shown in the data, the coarse fiber charged media of the MERV 13 (F7) filter really performs at a level below that of a MERV 11 (M6) filter. Thus, to properly run an LCC comparison on this charged filter, it should be compared to other MERV 11 (M6) filters. The MERV 13 (F7) non-charged filter performs according to expectations by maintaining a minimum efficiency very close to the initial efficiency throughout its life.

The point to be learned from this field data is that filters carrying the same laboratory test report designations may behave very differently in real life. To obtain an "apples to apples" LCC analysis, filters of the same true efficiency must be

compared. To better assist with this, ASHRAE 52.2-2007B has an optional Appendix J test method that gives the user the conditioned MERV-A value designed to simulate the efficiency loss experienced by some filters in actual application. Likewise, EN-779 requires that the manufacturer report the discharged efficiency at 0.4 µm.

RESISTANCE TO AIRFLOW

Once the actual particle removal efficiency is determined, the resistance to airflow for the product over the time in service must be evaluated. Some simple methods use initial pressure drop versus final pressure drop averaging, not a very scientific methodology and highly inaccurate. This laboratory testing is performed with synthetic dust of large particle size, not the much smaller sized contaminants typically found in the airstream. The purpose of that test is to expedite the filters' loading process so two filters of the same relative construction may be compared under controlled laboratory conditions. The test was never designed to simulate real filter life. Filters of an engineered design have long loading curves with 80% of their average pressure drop well below this averaging. The proper way to establish filter life for product comparison is to take advantage of accumulated real life data performance.

USING LIFE CYCLE COST AND TOTAL COST OF OWNERSHIP

For accurate LCC filter performance data, the best approach is to model current filter performance using typical operating conditions over a set time frame. Usually the owner has data relating to the filter change-out schedule, airflow rates, and airflow resistance values. When this information is input into LCC modeling software, average particle concentration loads may be determined. From there, how that specific system will perform if energy efficient filtration is utilized can be demonstrated. Once the owner accepts the proposed solution, the real fun begins. The new filters are installed and monitored for a period of time. Using standard energy measurement and verification practices, the performance data can be monitored and recorded to determine the associated cost avoidance or energy savings. This can then be included in the LCC calculations to evaluate the TCO for the air filtration systems. The LCC calculations include the cost of the filters, the energy cost, maintenance cost, disposal cost, and any associated cost to clean parts of the system. The TCO can add the additional costs to process orders, inventory materials, and any other costs associated with the purchase, installation, and operation of the system. The difference in TCO of replacing one filtration system with another system is the avoided cost for the owner and can be reported as a savings. Table A shows a typical LCC and TCO data set for comparing two

TCO Elements	Current AHU[1]	Proposed Filter Solution	Comments	Calculation Component
Energy Cost	$25,935	$17,574	The main component of air filter cost is the ENERGY required to move air through the filter, often many times of the cost of the filter itself.	LCC
Filter Cost	$6,372	$3,168	The cost of the initial filter and the replacement filters over the service time of the calculations.	LCC
Labor Cost	$792	$312	The labor cost to replace used filters.	LCC
Waste Cost	$312	$72	The disposal costs of the used filters.	LCC
Mean Life Filter Efficiency (MLE)	71%	77%	The average calculated particle removal efficiency at 0.4 um over the life of the filter.	TCO
Energy Cost Index (ECI)	7.65 USD/%	4.75 USD/%	The Energy Cost Index (ECI) is a method of relating the most important parameter of an air filter (particle removal efficiency) and the largest expense element; energy cost. The lower the ECI, the better the filter value.	TCO
CO2 Impact	343,117 pounds	232,494 pounds	For this calculation the carbon footprint only considers energy usage. A more complete analysis would be required to get the full sustainability impact.	TCO
Landfill Impact	15.81 cubic yards	5.49 cubic yards	Landfill impact is another part of the sustainability equation for filter consideration. Fewer filter changes and/or lower volume (smaller size) filters can help here.	TCO
Period of Evaluation	3.0 years	3.0 years	Service time of this analysis.	LCC
Total Cost of Ownership	**$33,411**	**$21,126**	**The New Filter solution will save this owner approximately $4,000 per year in total cost.**	**TCO**

[1] AHU - Air Handling Unit
[2] MLE - Filter efficiency at 0.4-micron, at the graph high point for number of particles in common airstreams, of a size that can enter the lungs and cause damage.

Table A. Sample output from air filtration total cost of ownership analysis.

filtration systems of the same particle removal efficiency. Not all of the possible TCO costs and system impacts have been included. Particle removal efficiency, based upon the applications demands, should always be the driving force behind filter selection. Energy and sustainability factors when presented, allow facilities to apply total performance solutions.

SUMMARY

Optimizing the filter selection is crucial to maximizing filter life and energy savings. Filter selection and optimization software allows facility operators to select filters based on scientific data. The result is verified savings in the hundreds of thousands of dollars per year on HVAC filters with little or no capital investment.

FACTORY VS. FIELD TESTING OF HEPA FILTERS

Cleanroom HEPA filters utilized in the life sciences require the end user to specify key parameters to ensure the proper installation and performance of their cleanroom. These parameters include, but are not limited to the following:

1. The size, including length, width, and maximum height, and frame configuration to properly fit the installation
2. A minimum global efficiency or maximum global penetration level at a specified particle size and flow-rate
3. A maximum local leakage penetration
4. A pressure drop target at a specified flow-rate
5. The required operational volume flow-rate or filter face velocity

The determination of the appropriate global filter efficiency specification is determined based on the final cleanroom cleanliness classification requirements. The traditional HEPA filter performance level specified within the Life Science industry has been:

- 99.99 efficiency vs. a mass median particle size of 0.3 µm (Type C per IEST-RP-CC001)
- 0.01% maximum local leakage penetration

The cleanroom HEPA filter, as installed, is typically required to meet a maximum leakage specification of 0.01%. This value is identical to the traditional filter factory leakage requirement. This has been cause for concern, as differences in equipment calibration and particle size could result in a filter failure in-situ after already passing factory test. Although this is a concern, it has not been identified as a significant issue, as border-line leaks are not very common.

Two common causes of in-situ failure of HEPA filters, not including physical/handling damage, originate in a difference in factory and field testing criteria. These are:

- Filter face velocity differences
- Test particle size differences

Any of these issues can result in the global filter penetration exceeding the 0.01% specification. This results in in-situ leak test failure of the filter after passing the factory test. The resulting failure typically appears as if the entire filter is leaking. This is known as "Excessive Non-Site Specific Penetration" (Bleed-Thru) and can be defined as: the measurement of background filter penetration exceeding the leakage specification during field certification.

Let's look at these common issues in more detail.

FILTER FACE VELOCITY

Filter manufacturers typically rate filters at a face velocity of 90-100 FPM in life science applications. The actual velocities in-situ can be significantly higher. Unfortunately, end user specifications do not typically indicate the maximum application velocity that the filter design may be applied. It is not unheard of to see filter face velocities from 120-150 FPM and even as high as 180 FPM. This upward shift

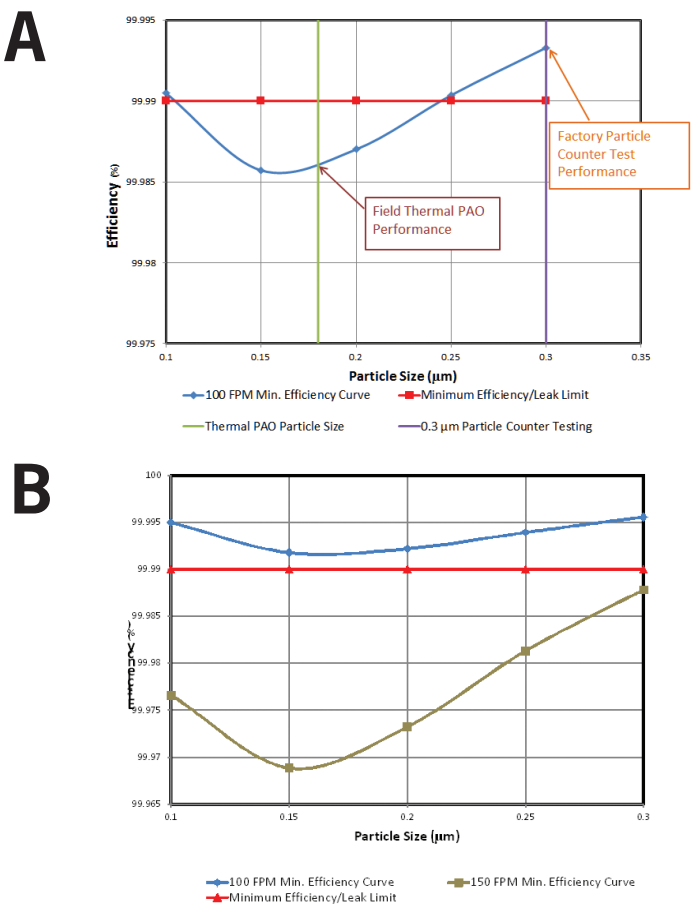

Figure 4. Typical cleanroom HEPA filter efficiency curves.

in velocity has a dramatic negative impact on filter efficiency. Therefore, a filter that passes efficiency and leak testing at 100 fpm in the factory may fail in-situ leak testing at a higher velocity. Figure 4b below demonstrates this downward shift in efficiency, with increased velocity for a typical clean room HEPA filter.

TEST PARTICLE SIZE

Historically, life science facilities typically specified an IEST-RP-CC001[1] "Type C" or performance indicative of a "Type C" filter. The "Type C" requirements specify photometric efficiency testing using near mono-dispersed 0.3 micron diameter (mass median) thermal dioctly-phthalate (DOP) aerosol. Over the last 20 years, DOP testing has been discontinued in the field and by most filter manufactures due to potential health-related issues. It has been replaced with Poly Alpha Olefin (PAO). In this case, filter manufacturers are generating a polydispersed aerosol and using particle counters looking at 0.2-0.3 µm particles. In-situ, however, they are utilizing photometers. In Class A areas (fully filtered ceilings), field certifiers utilize portable thermal generators in order to achieve sufficient upstream concentrations. These generators produce an aerosol in a size range at or very close to a typical cleanroom filter's Most Penetrating Particle Size (MPPS). If a factory tested filter just meets the 99.99% @ 0.3 micron efficiency specification and is then tested with thermal aerosol in the field, it will likely exhibit "Excessive Non-Site Specific Penetration," since the in-situ efficiency will be lower when tested at or near the filter's MPPS. Figure 4a demonstrates this effect.

For those end users that utilize the traditional HEPA filter specification identified in the FDA sterile guide, the solution is to properly specify the filter. This requires that the maximum velocity be specified for the particular filter design. The other option would be to have different filter models for high velocity areas. This is typically frowned upon, as the end-user prefers to stock or specify one model. It also requires that the filters' particle removal and leakage criteria be better specified. The end user will typically rely on using industry standards as a basis. The standards/practices utilized to specify cleanroom filters are IEST-RP-CC001[1] (HEPA and ULPA Filters), EN-1822[3] (high efficiency air filters (EPA, HEPA and ULPA)) and newly published ISO 29463[4] (high efficiency filters and filter media for removing particles from air). Tables B to D show the filter classifications contained within each of these standards/practices.

Filter Class	Particle Size for Testing	Global Values		Local/Leak Values		
		Collection Efficiency (%)	Penetration (%)	Collection Efficiency (%)	Penetration (%)	Multiple of Global Efficiency (%)
E10		≥ 85	≤ 15	-	-	-
E11		≥ 95	≤ 5	-	-	-
E12		≥ 99.5	≤ 0.5	-	-	-
H13	MPPS[a]	≥ 99.95	≤ 0.05	≥ 99.75	≤ 0.25	5
H14	MPPS[a]	≥ 99.995	≤ 0.005	≥ 99.975	≤ 0.025	5
U15	MPPS[a]	≥ 99.9995	≤ 0.0005	≥ 99.9975	≤ 0.0025	5
U16	MPPS[a]	≥ 99.99995	≤ 0.00005	≥ 99.99975	≤ 0.00025	5
U17	MPPS[a]	≥ 99.999995	≤ 0.000005	≥ 99.9999	≤ 0.0001	20
[a] MPPS = Most Penetrating Particle Size						
This European standard is based on particle counting methods that actually cover most needs for different applications. EN 1822:2009 differs from its previous edition (EN: 1822; 1998) by including the following; an alternative method for leakage testing of Group H filters with shapes other than panels; an alternative test method for using a solid, instead of a liquid, test aerosol; a method for testing and classifying of filters made out of membrane-type medial and a method for testing and classifying filters made out of synthetic fiber media. The main difference is related to the classification for the filter classes H10 - H12, which has now been changes to E10 - E12.						

Table B. EN 1822 classifications

Filter Class (Group)	Particle Size for Testing	Global Values		Local/Leak Values		
		Collection Efficiency (%)	Penetration (%)	Collection Efficiency (%)	Penetration (%)	Multiple of Global Efficiency (%)
ISO 15 E	MPPS	≥ 95	≤ 5	-	-	-
ISO 20 E	MPPS	≥ 99	≤ 1	-	-	-
ISO 25 E	MPPS	≥ 99.5	≤ 0.5	-	-	-
ISO 30 E	MPPS	≥ 99.9	≤ 0.1	-	-	-
ISO 35 E	MPPS	≥ 99.95	≤ 0.05	≥ 99.75	≤ 0.25	5
ISO 40 E	MPPS	≥ 99.99	≤ 0.01	≥ 99.5	≤ 0.5	5
ISO 45 E	MPPS	≥ 99.995	≤ 0.005	≥ 99.975	≤ 0.025	5
ISO 50 E	MPPS	≥ 99.999	≤ 0.001	≥ 99.995	≤ 0.005	5
ISO 55 E	MPPS	≥ 99.9995	≤ 0.0005	≥ 99.9975	≤ 0.0025	5
ISO 60 E	MPPS	≥ 99.9999	≤ 0.0001	≥ 99.9995	≤ 0.0005	5
ISO 65 E	MPPS	≥ 99.99995	≤ 0.00005	≥ 99.99975	≤ 0.00025	5
ISO 70 E	MPPS	≥ 99.99999	≤ 0.00001	≥ 99.9999	≤ 0.0001	10
ISO 75 E	MPPS	≥ 99.999995	≤ 0.000005	≥ 99.9999	≤ 0.0001	20
ISO 29463-1:2011 establishes a classification of filters based on their performance, as determined in accordance with ISO 29463-3, ISO 29463-4 and ISO 29463-5. It also provides an overview of the test procedures, and specifies general requirements for assesing and making the filters, as well as for documenting the test results. It is intended for use in conjunction with ISO 29463-2, ISO 29463-3, ISO 29463-4 and ISO 29463-5.						

Table C. ISO 29463 classifications

When considering the previous discussions concerning particle size and the in-situ leak requirements, HEPA filters specified using both EN1822[3] and ISO 29463[4] can result in field failure after passing factory testing when utilized in the life science industry. Both standards typically specify a leak value that is five times the minimum specified global efficiency. Selecting an appropriate filter that has a slightly higher minimum global efficiency than the field requirement results in the selection of an H14 filter according to EN1822[3] and an ISO 45 E filter according to ISO 29463.[4] Both of these filters have a global efficiency of 99.995% at the MPPS; however, the leakage criteria specified by both is 0.025% (5 times the minimum efficiency requirement). This value is 2.5 times the maximum 0.01% typical in-situ requirement. Again, as previously indicated, failure for pin-point leaks that are greater than 0.01%, but less than 0.025% are not very common. With that in mind, since both the EN1822 & ISO 29463 standards test at the MPPS, they would solve the issue of failure due to "Excessive Non-Site Specific Penetration." IEST-RP-CC001[1] has added a specific filter type for the life science industry. The IEST-RP-CC001[1] Type K filter also has a minimum global efficiency of 99.995% and maximum leakage criteria of 0.008% (1.8 times the minimum efficiency requirement). This is less than the 0.01% in-situ requirement, providing a safety factor that minimizes any possibility of rare border-line leaks causing failures in the field. This does not exclude the use of EN1822[3] or ISO 29463[4]; however, the end user needs to consider specifying a local leakage value to help ensure that filters that pass factory testing also will pass the in-situ testing.

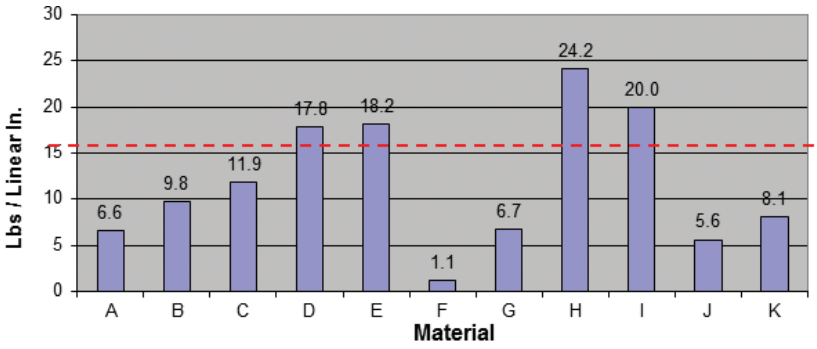

Figure 5. T-Peel resuts.

COMPATIBILITY OF CONSTRUCTION MATERIALS FOR HEPA FILTERS

A variety of polymer materials are used to manufacture HEPA filters. The most common is the sealant or "potting compound" that forms the leak-free bond between the filter media pack and the filter frame. The material of choice for this application is polyurethane. Polyurethane sealant is comprised of two liquid components (a polyol resin, and a diisocyanate hardener) that when mixed, create a solid cross-linked rubber-like polymer. Since these materials will not melt when heated, they are called thermoset polymers.

The filter gasket system is made using polymer foams including neoprene and polyurethane or gels made from soft polyurethane or silicone. Often a thermoplastic "hot melt" material is used to control and maintain regular separation between the pleats in the filter pack. While polymer materials have been used for many years to provide adhesion and flexibility, understanding their compatibility with other agents and their limitations is critical to achieving long and trouble-free filter service. HEPA filter manufacturers should qualify the materials they use by testing, and test results should be shared with end users upon request.

Filter Type	Particle Size for Testing	Global Values		Local Leak Values		
		Collection Efficiency (%)	Penetration (%)	Collection Efficiency (%)	Penetration (%)	Multiple of Global Efficiency
A	0.3[a]	≥ 99.97	≤ 0.03			
B	0.3[a]	≥ 99.97	≤ 0.03	Two-Flow Leak Test		
E	0.3[a]	≥ 99.97	≤ 0.03	Two-Flow Leak Test		
H	0.1-0.2 or 0.2-0.3[b]	≥ 99.97	≤ 0.03			
I	0.1-0.2 or 0.2-0.3[b]	≥ 99.97	≤ 0.03	Two-Flow Leak Test		
C	0.3[a]	≥ 99.99	≤ 0.01	≥ 99.99	≤ 0.01	1
J	0.1-0.2 or 0.2-0.3[b]	≥ 99.99	≤ 0.01	≥ 99.99	≤ 0.01	1
K	0.1-0.2 or 0.2-0.3[b]	≥ 99.995	≤ 0.005	≥ 99.992	≤ 0.008	1.6
D	0.3[a]	≥ 99.999	≤ 0.001	≥ 99.99	≤ 0.005	5
F	0.1-0.2 or 0.2-0.3[b]	≥ 99.9995	≤ 0.0005	≥ 99.995	≤ 0.0025	5
G	0.1-0.2	≥ 99.9999	≤ 0.0001	≥ 99.999	≤ 0.001	10

[a] Mass median diameter particles (or with a count median diameter typically smaller that 0.2µm as noted above).
[b] Use the particle size range that yields the lowest efficiency.

This Recommended Practice (RP), IEST-RP-CC001.5, covers basic provisions for HEPA (high efficiency particulate air) and ULPA (ultra-low penetration air) filter units as a basis for agreement between customers and suppliers. HEPA filters and ULPA filters that meet the requirements of this RP are suitable for use in clean air devices and cleanrooms that fall within the scope of ISO 14644 and for use in supply air and contaminated exhaust systems that require extremely high filter efficiency (99.97% or higher) for sub micrometer (µm) particles. This RP describes 11 levels of filter performance and six grades of filter construction. The customer's purchase order should specify the level of performance and grade of construction required. The customer should also specify the filter efficiency required if it is not covered by the performance levels specified in this RP.

Table D. IEST-RP-CC001

POLYURETHANE POTTING

The polyurethane potting compound is a high-performance material capable of maintaining flexibility and adhesion over a wide range of temperatures. It is 100% solid, meaning there are no liquid plasticizers that could exude to the surface or evaporate over time causing the material to shrink, become brittle or "dry out."

Before being approved for use in a filter, the polyurethane is fully characterized and undergoes 14 rigorous performance evaluation tests, including outgassing analysis, adhesion, temperature cycling and accelerated aging. The polyurethane is checked carefully to ensure it does not contain known compounds that could interfere with cleanroom processes.

GEL

The filter gel seal is a two-component, lightly cross-linked material made of polysiloxane or polyurethane. Like the potting compound, gel materials also are fully characterized and undergo a battery of tests to ensure quality and fitness for use. In addition to physical property testing, such as hardness (penetration), both silicone and polyurethane gels are exposed to decontamination agents and cleaning agents. They are also exposed to common filter test aerosols like Poly Alpha Olefins (PAO) to ensure that the effect of these oils on the gel is understood and does not cause the gel to fail.

Silicone gels are generally considered robust and offer very good resistance to chemical attack, but not all gels are equal. Some gel systems contain significantly more free liquid material. In certain circumstances and over time, this liquid material may be forced out of the gel by a process that is not yet fully understood.

Generally speaking, silicone gels with greater than 30% free liquid are associated with field issues of "dripping gel" after years of installation. Recent investigations have determined the free liquid content of many commercially available grades of gel by Soxhlet extraction and wide variability of free liquid content between different grades and suppliers. Extraction results correlate directly with "blot-plot" results, which express the migration rate of the unbound phase and with gel softness. The softer the gel, the higher the extractable content and the faster rate of migration.

While some believe there may be a link to PAO exposure, this has not been clearly demonstrated and has not been experimentally proven in the laboratory. In numerous experiments where gel has been exposed or immersed in an excess of PAO, liquefaction has not been observed. Measurements indicate that silicone gel can swell up to about 5% when immersed in PAO; however, no loss in gel integrity was observed.

COMPATIBILITY WITH CLEANING AGENTS

High Efficiency Particulate Absolute (HEPA) filters are widely used to provide clean air to facilities where microorganisms cannot be tolerated and to filter the air leaving laboratories where pathogens may be present. In these situations, facilities are routinely cleaned and decontaminated, and HEPA filter are often exposed to antimicrobial agents.

Recent research has considered the likely exposure of HEPA filters to decontamination agents. Laboratory testing and field experience indicates that the compatibility between HEPA filter materials and cleaning agents is good to excellent. Naturally, there is always interaction between decontamination agents and the materials they contact; indeed, that is how microorganisms are controlled. Under normal conditions, HEPA filters manufactured with qualified materials can withstand these effects without loss of performance.

Test Results	Supplier A		Supplier B	
	High Viscosity	Low Viscosity	High Viscosity	Low Viscosity
Characteristic Parameter				
Total Outgassing by TD-GC-MS at 50°C / 30 minutes (ppmw)	0.56	3.5	2.7	1.6
Trace Element Analysis by ICP-AES, ICP-FID (EPA 200.7, EPA 200.8) (mg/Kg) Total of 11 elements	2.33	2.83	6	4.15
Linear Shrinkage (ASTM D 2566) (%)	0.593	0.282	0.25	0.22
T-Peel (ASTM D 1876) (Lbs/Lin. inch)	20	24.2	11	11.3
Lab Shear (ASTM D 3163; ASTM D 5868)	358.4	240.4	297.9	361.3
Hardness Shore A (ASTM D 2240)	90	96	89	92
Hardness Shore D (ASTM D 2240)	47	57	47	55
Weight loss (Cured Sample, 107°C, 7 days) (%)	0.177	0.282	0.211	0.787
Flame Retardancy (Time to self-extinguish) (Sec.)	1	1	2	2
Dry Aging (Observe for exudation) (Pass / Fail)	Pass	Pass	Pass	Pass
Wet Aging (Observe for reversion)	Pass	Pass	Pass	Pass
Deep Pour Crack Resistance	Pass	Pass	Pass	Pass
Reaction Stability	Stable	Stable	Stable	Stable
Adhesion to Anodized Aluminum Frame	Pass	Pass	Pass	Pass
Final Evaluation	Pass	Pass	Pass	Pass

Table E. Sealant summary test results

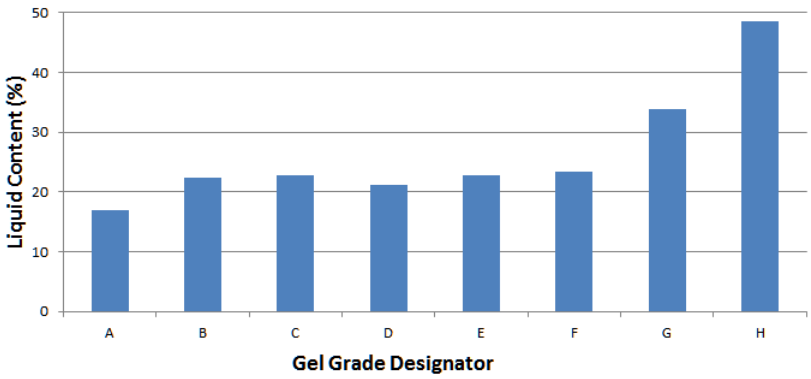

Figure 6. Liquid content of gel

In a recent year-long study where silicone gels were exposed to concentrated vapors generated by a variety of cleaning agents, the results indicated that these agents did not cause failure or “liquefaction” of silicone gel materials tested. The tests were conducted at elevated temperature to promote accelerated aging. Silicone gel was exposed to common antimicrobial cleaning agents, including one containing quaternary ammonium compounds, one containing sodium hypochlorite (bleach), and a third containing a blend of hydrogen peroxide and per acetic acid. There was no observed failure of the gel as defined by the formation of a liquid or oily substance on the surface; however, in cases following significant exposure, the blue pigment present in the gel sometimes faded and the gel became lighter in color or clear.

Exposure of silicone gel to very strong acids (like concentrated hydrochloric acid solution) or bases (like concentrated sodium hydroxide solution) should be avoided since these are strong enough to attack the partially ionic Si-O bonds in the polymer backbone.

Polyurethane gels are slightly less resistant to oxidative attack than silicone gels; however, polyurethane gels perform well to seal filter modules in clea room applications, and there may be other reasons to choose a polyurethane gel over a silicone gel.

Where silicone materials must be avoided due to their potential effect on a process or product downstream, polyurethane gels are often specified. A classic example is microelectronics cleanrooms, where trace molecular contamination by silicone can interfere with wafer etching processes and final product quality. Sometimes, polyurethane gel is selected because it is slightly less expensive. Prior experience with a silicone gel issue or process incompatibility may also persuade the user to select polyurethane gel. Polyurethane gel contains substantially more unbound liquid component in the form of plasticizer than silicone gel. Over a period of several years, a small amount of the plasticizer may evaporate from the gel surface, causing the formation of a light “skin.” Some cutting of the gel by the knife edge and some micro-cracks form normally on the surface of the gel adjacent to the knife edge due to the tensile forces present.

Although the initial assumption upon removal of a filter that has been installed for some time is that there is a problem with the gel, in reality these phenomena are normal. Since these small cracks do not threaten to extend down to or completely around the tip of the knife edge, bypass of air around the filter media pack is prevented. However, it is best not to re-install a gel seal filter that shows extensive skinning or splits unless the gel is removed and replaced. Often the most cost-effective solution is to simply replace an old filter with a new one. The expected life time of a gel filter that has been removed is about five years. When undisturbed, gel filters often provide leak-free service well beyond five years.

COMPATIBILITY WITH SPACE DECONTAMINATION AGENTS

In addition to cleaning agents, HEPA filter materials, including silicone gel, were exposed to common space decontamination agents, including formaldehyde, hydrogen peroxide vapor, and chlorine dioxide. The exposure routines simulated what would be expected during normal decontamination procedures during the 10 year service life of the filter.

Laboratory testing and field experience both indicate that when qualified materials are used to construct HEPA filters, they provide good to excellent chemical compatibility with formaldehyde, hydrogen peroxide, and chlorine dioxide when used for typical decontamination processes.

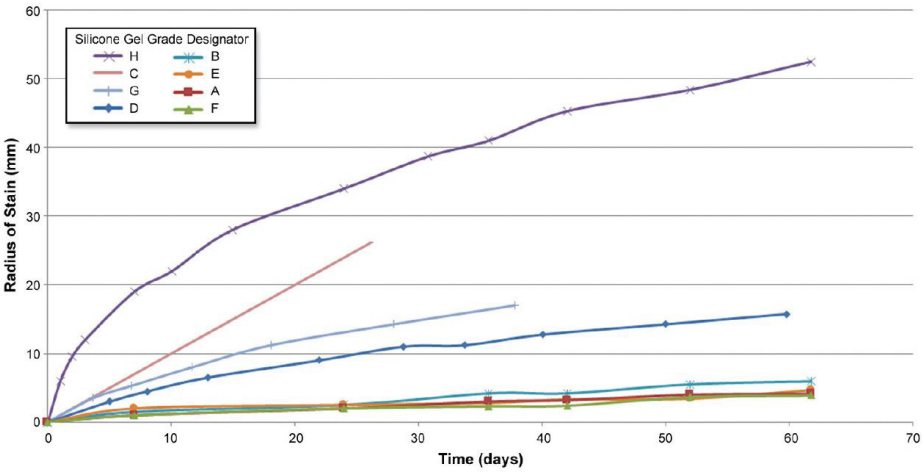

Figure 7. Gel plot blot at 30°C

HEPA filters show excellent chemical compatibility with hydrogen peroxide under typical decontamination cycles. It is known that, over time, hydrogen peroxide adsorbs onto exposed surfaces; during aeration (or ventilation) it desorbs over time. Laboratory testing and field monitoring indicate that the presence of a HEPA filter in a system may delay the attainment of peak concentration levels downstream of the HEPA filter, due to the enormous surface area of the filtration media.

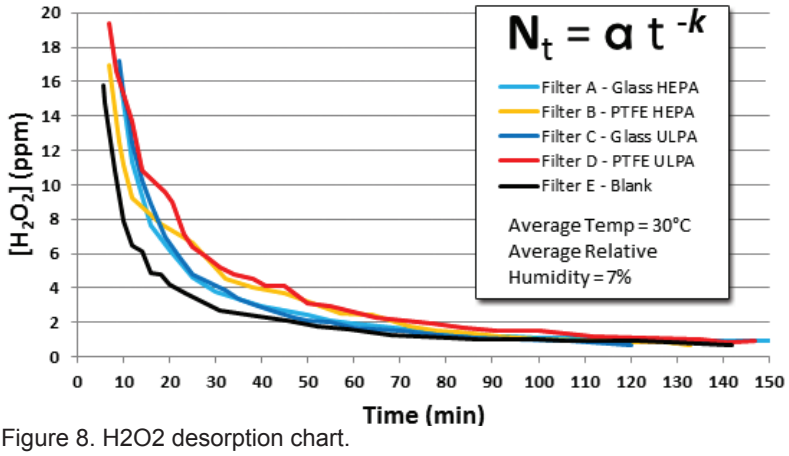

Figure 8. H2O2 desorption chart.

The HEPA filter also will capture droplets of aerosol in the air steam, if present. Hydrogen peroxide in the vapor phase will pass through the HEPA filter, and downstream concentrations will rise accordingly, approaching levels similar to upstream concentration levels once adsorption has occurred. After exposure, during the aeration phase, the opposite effect is observed. Downstream hydrogen peroxide levels will momentarily peak at the start of aeration due to rapid desorption from the filter media. Reduction in downstream concentration levels will initially lag that of the upstream level.

The overall aeration time may or may not be extended due to the presence of the HEPA filter, depending upon the type and area of other surfaces present in the system. Studies have shown that the use of expanded Polytetrafluoroethylene (PTFE) membrane filter media offered no advantages in terms of more rapid aeration compared to micro-fiberglass filter media when the aeration endpoint was <1 ppm H_2O_2. More rapid aeration can be achieved by using warm dry air for aeration.

HEPA filters also exhibited good compatibility with the chlorine dioxide process used for decontamination. It is recommended that welded stainless steel filter housings be treated by pickling prior to exposure to chlorine dioxide. HEPA filter potting compound made of polyurethane will show a characteristic yellowing following exposure to chlorine dioxide; however tests indicate no measurable change to the bulk properties and no loss in performance of the exposed polyurethane. Fraction negative decontamination studies using biological indicators inoculated with 10^6 spores of a target organism demonstrate the effectiveness of all three agents in decontamination of HEPA filters.

MEMBRANE HEPA FILTERS IN THE LIFE SCIENCE INDUSTRY

In recent years, there has been a push by some media and filter manufacturers to promote PTFE media technology to the life science industry. The application of this technology has been difficult due to its limited loading capacity. Although air supplied to these final filters is typically very clean, annual/biannual testing can substantially increase the pressure drop of these filters. Figure 9 below demonstrates the substantial difference in loading characteristic between traditional micro-glass media and PTFE media filters. Both filters were loading with Laskin nozzle generated PAO aerosol.

As you can see in Figure 9, even though the initial pressure drop of the e-PTFE filter is lower than the micro-glass

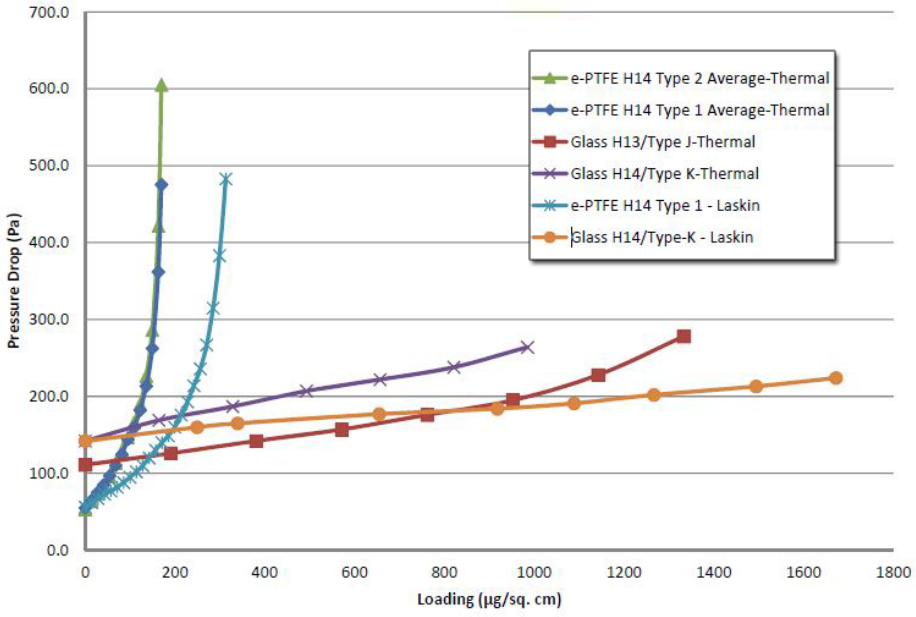

Figure 9. PTFE vs glass grades loading curves.

media filter, the rate of increase in pressure drop per unit mass of PAO loaded is substantially higher for the e-PTFE media.[8]

Over the last two years, there has been an attempt to implement e-PTFE filters in the life science industry. The basis of this implementation was testing these filters with very low concentrations of PAO aerosol along with the utilization of a discrete particle counter. This equates to a concentration < 0.1 µg/l as compared to > 10 µg/l when using a photometer.[3]

The microelectronics industry has tested PTFE filters with low concentration aerosol for over a decade. In this case, the aerosol used is microspheres (PSL microspheres) and the technology to generate this aerosol is well-established. The technology to generate ultra-low concentrations of PAO aerosol is not. This is evident based on the issues experienced.[3] In addition, in-situ testing of HEPA filters with discrete particle counters adds a substantial level of complexity compared to a photometer and PAO.

The "pros" are lower pressure drop and extreme durability. The "cons" are a cost approximately twice that of micro-glass fiber media (so even with lower pressure drop, the TCO is questionable), acceptable test methods, stable uniformity and airflow distribution, and readily available equipment to field test as outlined above. These obstacles, along with a reliable source of supply, remain a concern.

In summary, e-PTFE or membrane HEPA and ULPA filters have been manufactured since the 1990s. The industry needs to keep an open mind to applying this type of product. As technology continues to advance, discrete particle counter operation more closely simulates a photometer's operation, and reliable ultra-low concentration PAO aerosol generation equipment becomes available, e-PTFE media filters may have a place for specific applications within the life science industry.

CONCLUSION

There is a science to manufacturing, testing, supplying, and selecting air filters. Just like in the life science industry, raw material safety, material compatibility, longevity, reliability, consistency, and now more than ever, sustainability are absolute requirements if companies want to compete in this arena. Filters should be selected based on TCO for all applications, and buyers should ensure that air filter suppliers have the support, depth of knowledge, and experience necessary to deliver product consistently on a global basis.

REFERENCES

1. Institute of Environmental Sciences and Technology (IEST): IEST-RP-CC001, "HEPA and ULPA Filters."
2. EUROVENT: "Recommendation Concerning Calculating of Life Cycle Cost for Air Filters." Paris, 1999.
3. European Committee for Standardization (CEN): EN-1822, "High efficiency air filters (EPA, HEPA and ULPA)."
4. International Standardization Organization (ISO): ISO 29463, "High-efficiency filters and filter media for removing particles from air."
5. ASHRAE: "ANSI/ASHRAE Standard 52.2-2007B: Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size," ASHRAE, Atlanta, 2008.
6. CEN: EN-779: 2012 E, "Particulate Air Filters for General Ventilation, Determination of the Filtration Performance," CEN, Brussels, Belgium, 2012.
7. SINTEF: "Long-term Tests of Filters in a Real Environment," SINTEF Refrigeration and Air Conditioning, STF11 A95052, Trondheim, Norway, 1995.
8. "The Effect of PAO Aerosol Challenge on the Differential Pressure of a PTFE media ULPA (Experimental) Filter," *IEST Journal*.

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50 YEARS OF CLEAN AIR SOLUTIONS