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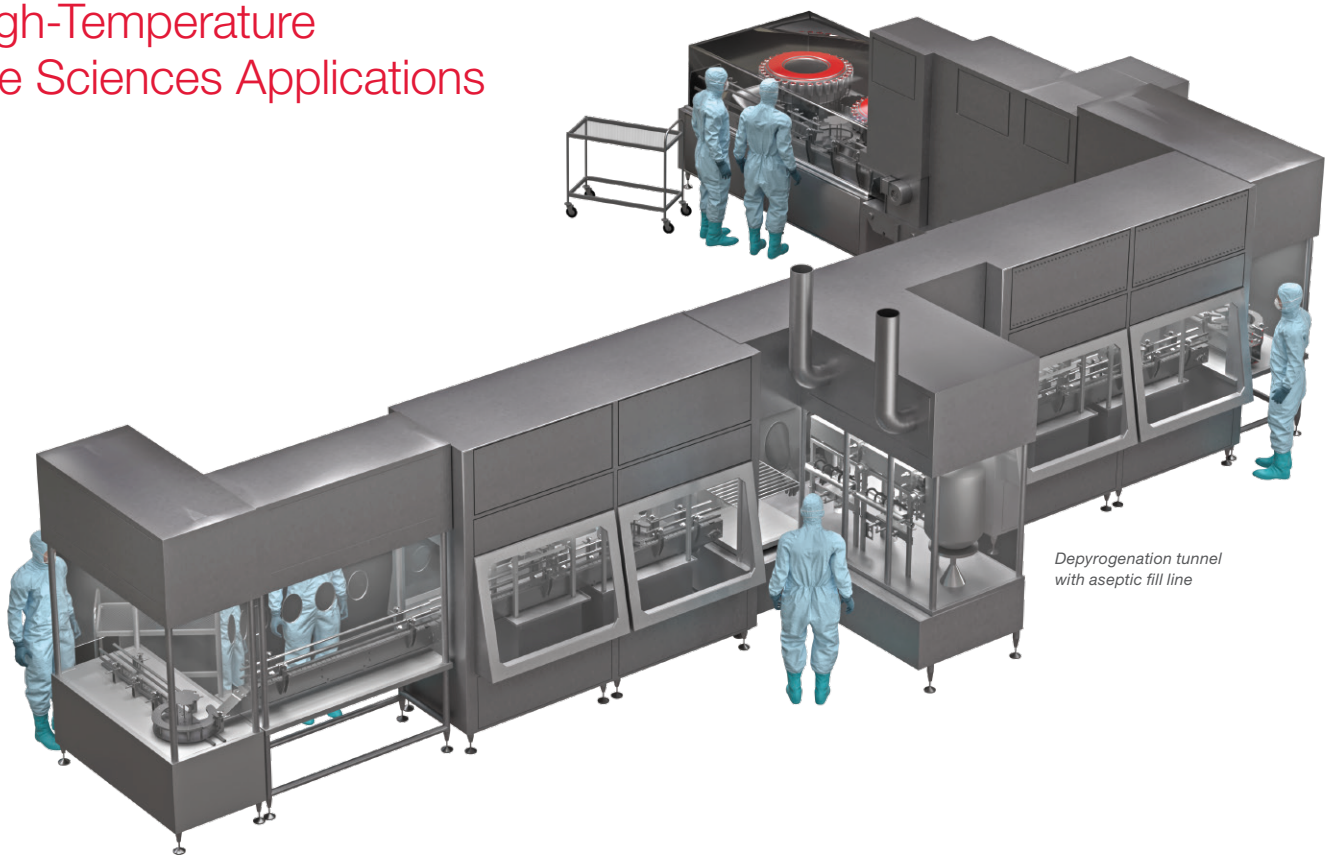
High-Temperature HEPA Filters for High Purity Applications

High-Temperature Life Sciences Applications



Depyrogenation tunnel with aseptic fill line

The Institute of Environmental Sciences and Technology recommended practice IEST-RP-CC001.6 (HEPA and ULPA Filters) defines a HEPA filter as “An extended-medium, dry-type filter in a rigid frame when tested at rated airflow having a minimum particle collection efficiency of 99.97% for 0.3-µm mass mean diameter particles of DOP when tested in accordance with MIL-STD-282.” HEPA filters are used in the most critical applications where particulate-free air is a necessity.

Sterilization and depyrogenation are critical processes used to prepare glassware for parenteral, i.e., injectable, pharmaceutical medicines. HEPA filters utilized in these processes provide ISO 5 or cleaner air to prevent contamination.

Glassware includes:

- Prefilled syringes
- Ampules
- Stoppered vials

Parenteral pharmaceuticals are non-oral medications that are delivered directly into the body by intramuscular, subcutaneous, or intravenous means. These include:

- Vaccines
- Insulin
- Chemotherapy drugs

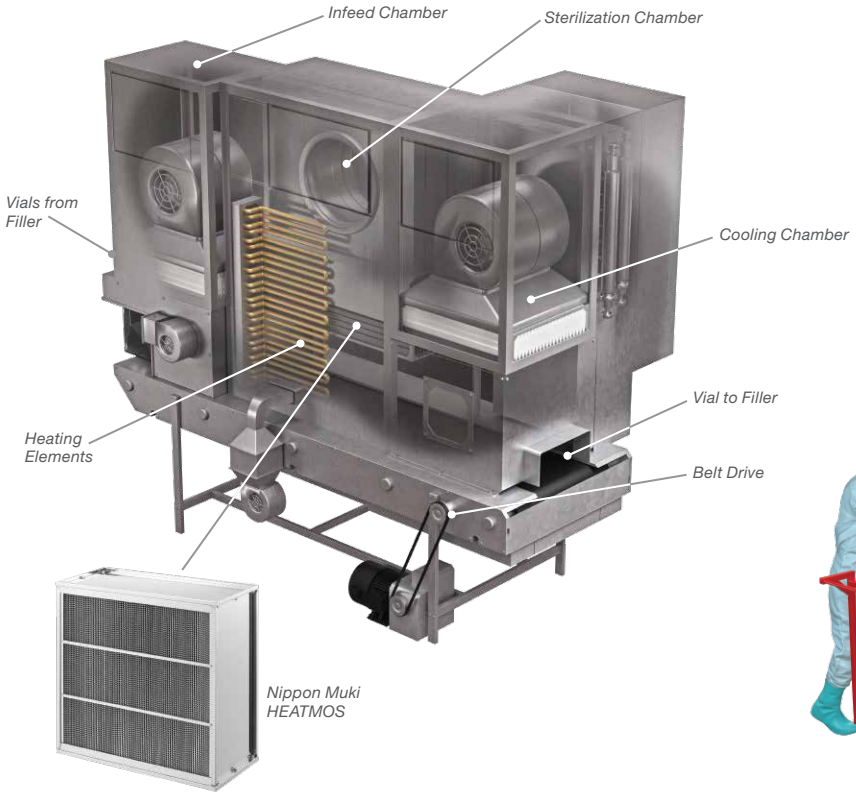
Prior to filling, glassware must be sterilized and depryogenated with clean, dry, heated air. To guarantee proper sterilization and depyrogenation, glassware is subjected to elevated temperatures. HEPA filters in these applications typically operate at temperatures of 260˚C / 500˚F for ovens and 400˚C / 752˚F for tunnels. These processes reduce the risk of contamination by endotoxins and pyrogens.

Sterilization: *The process of making something free from bacteria or other living organisms.*
Depyrogenation: *The removal of fever-producing substances (i.e., pyrogens).*

AAF Typical Life Sciences HT HEPA Filter Offerings

Depyrogenation Tunnel

A tunnel design continuously feeds the glassware into the hot zone via a conveyor system.



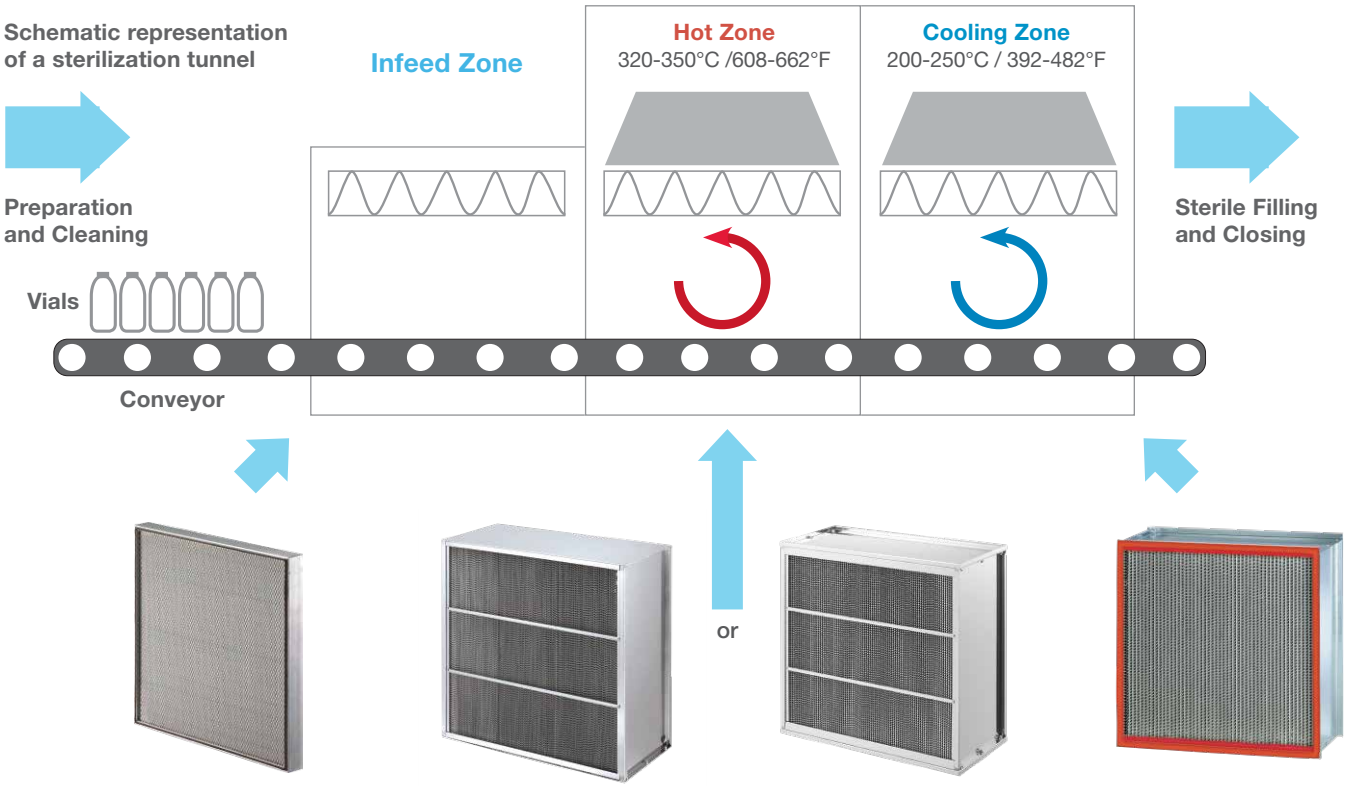
Depyrogenation Batch Oven

A batch oven requires a manual feed of a discrete amount of glassware into and out of the hot zone per cycle.

		Nippon Muki H14CU (HEATMOS)	Nippon Muki ATMCU	AstroCel® I HT-500	AstroCel® I HT-750
Product	Airflow (24" x 24")	847 CFM/1236 CFM	847 CFM/1236 CFM	500 CFM/1000 CFM	1000 CFM
	Efficiency at Nominal Airflow	99.995% on MPPS (H14)	99.99% @ 0.3 um	99.99% @ 0.3 um	99.97% @ 0.3 um
	Pressure Drop at Nominal Airflow	1.1 in w.g.	1.0 in w.g.	1.0 in w.g.	1.0 in w.g.
	Standard Frame Material	430 SS	430 SS	304 SS	304 SS
	Alternate Frame Materials	304 SS	304 SS	316 SS	316 SS
	Frame Depth	5.875"/11.5"	5.875"/11.5"	5.875"/11.5"	11.5"
	Standard Gasket	glass	glass	red silicone	ceramic fiber
	Sealant	glass fiber + ceramic	glass packing	silicone	refractory cement
	Standard Separator	SS	SS	aluminum	aluminum
	Standard Face Screen	none	none	none	none
	Media Type	glass	glass	glass	glass
	Standard Size Availability	many	many	many	24 x 24, 24 x 30
	Max. Overall Penetration	0.005% on MPPS	0.01%	0.01%	0.03%
	Leak Test Conditions	ambient	ambient	ambient	ambient
	Max. Operation Temperature	350°C / 662°F continuous/ 400°C / 752°F for 1 hour	350°C / 662°F continuous/ 400°C / 752°F for 1 hour	260°C / 500°F	400°C / 752°F
	Packaging	fiberboard carton	fiberboard carton	fiberboard carton	fiberboard carton

Total Life Sciences Solution

AAF Filtration System for Dry Heat Sterilization and Depyrogenation Tunnels



VariCel® II HT

- M6, F8 to EN779:2012
- 350°C / 662°F continuous (480°C / 896°F Peak)
- Max. 1340 m³/h (790 CFM) for 610 x 610 x 84mm

Nippon Muki ATMCU

- ≥ 99.99% at ≥ 0.3µm
- 350°C / 662°F continuous (400°C / 752°F Peak)
- Max. 2100 m³/h (1236 CFM) for 610 x 610 x 290mm

Nippon Muki HEATMOS

- ≥ 99.995% at MPPS (H14 per EN1822-1)
- 350°C / 662°F continuous (400°C / 752°F Peak)
- Max. 2100 m³/h (1236 CFM) for 610 x 610 x 292mm

AstroCel® I HT-500

- ≥ 99.995% at MPPS
- 260°C / 500°F continuous (260°C / 500°F Peak)
- Max. 1700 m³/h (1000 CFM) for 610 x 610 x 292mm

AAF offers a variety of HT HEPA filters to meet the demands of every high-temperature application. HT HEPA solutions are manufactured domestically in the U.S. by AAF and in Japan by Nippon Muki, a sister company with expertise and emphasis on high-temperature filters. With a combined history of over 180 years, AAF and Nippon Muki are proud members of the Daikin Group of companies.

HEATMOS & ATMCU: Filters for Extreme Requirements

Item	Nippon Muki	
Model	**ATMCU** (ATMCU - * - * - FS4HR)	**H14CU (HEATMOS)** (H14CU - * - * - FS4CS)
Size for this Comparison (mm)	610 x 610 x 292	610 x 610 x 292
Alternative Depths (mm)	84, 150, 292	150, 292
Frame	stainless steel (430), 2 support bars	
Design Filter Media Pack	deep pleats w/ separators	
Media	glass paper	
Separator	stainless steel	
Sealant Media Pack/Frame	fiberglass	glass fiber cotton + ceramic
Gasket	factory installed laminated glass fiber when ordered	
Temperature (°C)	350	
Max. Temperature (1h/°C)	400	
Temperature Ramp Speed	10°C/min	5°C/min
Tempering Media After Installation Necessary	required (factory tempering optional)	
Rated Air Volume (CMH/CMM)	2,100/35	
Pressure Drop (initial/final, Pa)	250/500	≤ 270/500
Efficiency	99.99% @ 0.3µm	≥99.995% @ MPPS
Scan Tested	No	Yes, per EN1822
Efficiency Rating by EN1822	Approx. H13	H14

Robustness and Ramp Speed

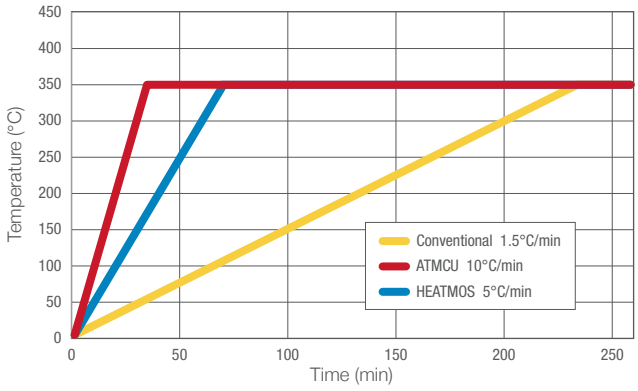
Materials expand when heated and contract when cooled. This movement can cause particle generation. Particles are generated as different materials within the filter slide against each other as they expand and contract. To minimize this particle generation, typically high-temperature (HT) HEPA filters are heated and cooled in a slow, controlled manner. Heating or cooling per unit of time is referred to as **temperature ramp speed.** Ramp speed directly impacts process cycle times for each oven glassware batch and each tunnel production run. Increasing temperature ramp speed will increase the amount of glassware that can be processed in a given period of time.

Guaranteed Filtration Performance

The ATMCU and HEATMOS HT HEPA filters are first-in-class solutions. The ATMCU's exceptional temperature ramp speed is ideal for depyrogenation ovens. The HEATMOS's temperature ramp speed, combined with true H14 performance as required by EN1822, is ideally suited for depyrogenation tunnels.

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

Temperature Ramp Speed Profile



HEATMOS Leak-Free Performance

Leaks in any filter allow air to bypass the media. For the most critical HT applications, AAF offers the NM HEATMOS. It is a EN1822-1, H14-classified filter that is factory scanned. This scanning ensures that no unfiltered air enters your clean zone, ensuring consistent ISO 5 clean space. This HT HEPA filter maintains H14 performance after repeated cycling. Repeated thermal cycling on lesser filters can cause leaks to develop, compromising the quality of air, which in turn can result in failure to maintain an ISO class 5 environment.

Upon request, the HEATMOS is available pre-baked or tempered at the factory, allowing you to place the filter into immediate operation to maximize productivity and minimize downtime required to condition the filter. The HEATMOS has several advantages over a rival product below.

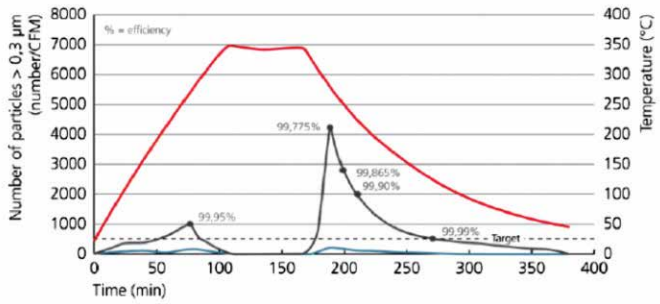
	Nippon Muki HEATMOS™	Camfil Absolute™ D-Pryo
Classification per EN1822-1	H14	H14
Efficiency on MPPS*	≥99.995%	≥99.995%
Pressure Drop (24 x 24 x 11.5)	270 Pa @ 35 CMM	290 Pa @ 32.7 CMM
Separators	Angled Corrugated Stainless Steel	Conventional Corrugated Stainless Steel
Price	$$$	$$$$

**MPPS = Most Penetrating Particle Size*

Improved Process Performance

Limited risk of particle shedding during elevated temperatures

Excellent Efficiency During Heating and Cooling

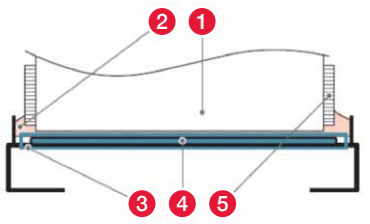


Temperature
Comparison filter with aluminum separators and ceramic sealant
Nippon Muki ATMCU with stainless steel separators and fiberglass sealant

Superior Performance of Nippon Muki ATMCU

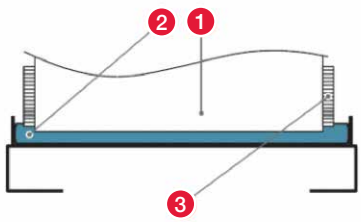
- Significant difference in particle shedding properties and potential process contamination.
- Meeting ≥ 99.99% at 0.3 um ≥ 99.95% at MPPS during efficiency test.

Typical HT HEPA



1. Fiberglass medium
2. Ceramic sealant
3. Compensation mat
4. Glass paper
5. Parallel aluminum separators

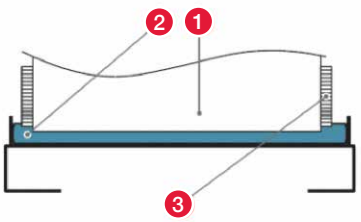
Nippon Muki ATMCU



1. Fiberglass medium
2. Elastic fiberglass sealant
3. Angular stainless steel corrugated separators

The Nippon Muki ATMCU provides superior performance.

Nippon Muki HEATMOS



1. Fiberglass medium
2. Elastic ceramic + fiberglass sealant
3. Angular stainless steel corrugated separators

The Nippon Muki HEATMOS offers true H14 performance.

Other HT HEPA Applications

In addition to the Life Sciences market, AAF have HT HEPA Filters for most any application.

Item	Temperature (ºC)				
	180	250	400	500	600
High Temperature Operating System	Semiconductor/Display (Drying/Baking Process)				
	Medicine (Sterilization Process)				
	Film (Drying Process)				
	Automobile (Painting Process)				

Other HT HEPA filters available include

AstroCel I HT-400

- 200ºC (400ºF) max Op. Temp
- RTV Silicone

Alpha HT/ AstroCel I HT-500

- 260ºC (500ºF) max Op. Temp
- RTV Silicone

AstroCel I HT-750

- 400ºC (750ºF) max Op. Temp
- Black Cement

Alpha HT Exhaust

- 540ºC (1000ºF) max Op. Temp
- Glass Pack
- Exhaust only!

High-Temp HEPAs FAQs

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

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

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

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

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

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

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

3. Where do I take the samples?

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

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

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

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

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

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

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

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

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

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

7. What is the recommended burn in cycle time?

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

8. How important is filter efficiency for these applications?

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

AAF International Plant Locations

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

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

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a member of DAIKIN group

9920 Corporate Campus Drive, Suite 2200, Louisville, KY 40223-5690
888.223.2003 Fax 888.223.6500 I aafintl.com

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