

TECHNICAL BULLETIN

FAQ: HEPA & ULPA Air Filters



This information pertains to HEPA filters manufactured by Camfil Farr only. It should not be assumed that this information is accurate for products manufactured by other companies.

What is the recommended shelf life of a HEPA Filter?

Camfil Farr agrees with the recommendations of Werner Berman in Appendix C of the Nuclear Air Cleaning Handbook, a 10 year shelf life. This assumes that filters are stored in the original packaging, in a dry climate controlled area and not subjected to extremes in temperature or humidity.

How long will a HEPA Filter last?

Filter life depends upon the operating conditions. A general recommendation is that, at minimum, the filter be replaced when the pressure drop reaches two times the initial pressure drop (assuming 'normal' design airflows).

HEPA filters that are not subject to high contaminant concentrations may have an indefinite life, depending on the operating conditions. Generally speaking, 10 years is the recommended life. Camfil Farr has experience with HEPA filters that have been in operation in excess of 15 plus years without problems. In Bio-Pharma applications, especially in 'critical' zones (Grade A space for example), we have seen certain major Pharma companies establishing a time period and not pressure drop as the guideline for change. One guideline suggests five years for the Grade A space and seven years for less critical spaces. Factors that may influence filter service life



Sofilair® and Megalam® Green panels are Camfil Farr's latest HEPA filters that now include plastic frames to address sustainability.

include: volume of outdoor air filtered, volume of re-circulated air filtered, aerosol challenge exposure frequency and duration, the total amount of challenge aerosol impingement on the filter, the method of aerosol introduction to the system and the filter efficiency of pre filtration. The use of coarse fiber (i.e. charged synthetic media filters) as prefilters may shorten HEPA filter life due to prefilter drop in efficiency over time due to inherent charge dissipation of the media. Wet filters should be replaced as soon as possible and the conditions that caused the filter to become wet should be corrected. Filters that are allowed to remain wet for 48-hours or more could be subject to mold growth within the media. The construction components of the filter are inert to contaminant amplification. Filters that are allowed to dry after being wet may have a higher pressure drop when compared to their pressure drop before they were wet.

What is the recommended final pressure drop for a terminal and air handling unit (AHU) or Exhaust mounted HEPA to be changed?

The 'rule of thumb' in our industry has been double the initial assuming 'normal' design airflows. For example, a Camfil Farr Megalam® panel applied in a terminal filter housing or plenum will have a clean pressure drop of approximately 100 Pa or 0.4" w.g. at 0.45 M/s or 90 fpm. Doubling the pressure drop as a change target to 200 Pa or 0.8" w.g. is reasonable and prudent for filter performance and energy use considerations. For an AHU mounted, exhaust, or Bag-in/Bag-out (BIBO) HEPA filter the clean pressure drop is normally targeted at around 250 Pa or 1" w.g. using double the clean pressure drop at 2.5 M/s or 500 fpm then the change out point would be 500 Pa or 2" w.g. respectively. Filter pack depth, filter efficiency and velocity can vary depending upon filter design so be sure to consult with your nearest Camfil Farr office for technical assistance.

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What is the gel seal filter life expectancy?

Both urethane and silicone gels are acceptable for the Life Sciences Industry applications. When using Gel we recommend a specific grade of Silicone gel, it is recommended for Life Science industry applications. Undisturbed gel will last the life of the filter. Camfil Farr has carried out multiple studies how the common decon and cleaning agents such as VHP, Formaldehyde, Chlorine Dioxide, Spor-Klenz & Vaprox etc has affected urethane & silicone gel. Historically, some HEPA filter manufacturers used certain formulations of silicone gel that, over time, can break down in the field. Detailed reports are available on request. Specifying the correct type of gel is as critical as the filter efficiency and pressure drop requirements.

What aerosol should I use when testing HEPA Filters?

Polystyrene latex spheres (PSL) are most commonly used in microelectronic applications, PAO in Life Sciences.

Related definitions; Aerosol: a gaseous suspension of fine solid or liquid particles. Challenge Aerosol: an aerosol derived from the selected source material and used as the leak test challenge for filter medium testing.

Aerosol Generation Methods

Laskin Nozzle Generator - ('cold PAO') (average 0.5-0.7 micron)

Thermal Generator - ('hot PAO') (average particle between the MPPS range)

Ultrasonic Generator - (PSL)

Measuring Equipment

Photometer or discrete particle counter (DPC) dilution system is required when testing with an oil based aerosol.

Aerosol Concentrations

10-20 mg/m³ - (IEST-RP-CC034)

10-100 mg/m³ - (ISO-14644-3)

What is the correct definition of a HEPA or an ULPA Filter?

HEPA - 99.97 efficiency at 0.3 micron

ULPA - 99.999 efficiency at 0.12 micron

What is MPPS?

MPPS; Most Penetrating Particle Size.

MPPS is 'typically' between 0.1 and 0.2 micron. It will vary with velocity but at 'normal' design for a terminal filter this range is accurate 80% of the time with a H14 filter at 90 fpm/0.45m/s it is 0.17/0.18 micron. The MPPS is always identified in Camfil Farr's factory scan test and noted on the HEPA filter label.



The Photometer is normally used for in-situ scan testing of HEPA filters.

What is the correct Filter Efficiency to select?

H14 in accordance with EN1822 (leakage factor should be 0.008%) to avoid 'bleed-through'

Type K in accordance with IEST RP-CC-034

ISO 45 E in accordance with ISO 29463

What is bleed-through?

Filter 'failure' or bleed-through' (a term adopted in the USA), has been attributed to a number of factors.

The 'failure' of HEPA filters can sometimes be attributed to the selection of the wrong filter efficiency, type & concentration of the selected aerosol, how it is generated (hot or cold), excessive filter velocities and a misunderstanding of calculated upstream concentrations. An article on bleed-through is available upon request as well as a HEPA specification written to the latest international industry requirements.

Challenge Aerosols Frequently Used for HEPA Testing	
DEHS (DOS), a liquid	Di-ethyl hexyl sebacarte
DOP, liquid	Di-octyl phthalate
Emery 3004, liquid	Product name for a type of PAO
PAO, liquid	Poly-alpha olefin
PSL	Poly-styrene latex spheres
Shell Ondina EL, liquid	Refined mineral oil
Total Finaveston A80B, liquid	Refined mineral oil



Typical aerosol generation equipment used in the field.

What is a leak?

A leak is local, but efficiency is global! A leak is generally 5-10 times the average penetration at a specific local point.

Local Leak is = 0.01% of penetration.

Global (also known as Overall or Volumetric test) is 0.01% (0.005% is utilized by some end users when testing with photometers).

Five times MPPS is the volumetric acceptance criteria when testing with a discrete particle counter.

What is the difference between local and global (overall or volumetric) efficiency?

Efficiency is the measure of the entire filter product and is the average of variations in the performance of the media.

The local leak is the measurement under a probe (scan head) that scans for the possible defects, not local variations.

What standard(s) should I follow when testing HEPA filters?

IEST RP-CC-001 HEPA and ULPA Filters

IEST RP-CC-034 HEPA and ULPA Filter Leak Tests

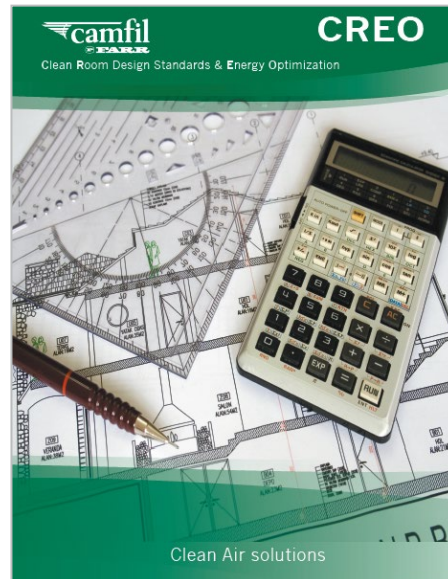
ISO 14644 Part 3 Test Methods

EN1822 PART 5

Cross references charts and cleanroom standards publications by Camfil Farr are available upon request. (**Life Sciences Industry Insights** and **CREO** publications)

Should I use a gasket seal or a gel seal on a HEPA filter?

In general, the United States has used gel, Europe/Asia have used gaskets for Life Sciences applications. Microelectronics is about a 50/50 split globally depending upon the design (fan filter units (FFU), recirculating units, etc.). It has been common in the past



Useful technical guides recently published by Camfil Farr available from www.camfilfarr.com

for gel to be poured into the ceiling grid and to use a top-load knife-edge filter. Today, it is more common to have a bottom-load gel seal filter. Gasket seal is most common for FFU applications.

Like gel, there are different gasket technologies. Camfil introduced the 'one piece' seamless poured-in-place gasket that minimizes potential corner leaks that are typical with traditional neoprene 'dove-tail corner' type gaskets. Gaskets need more study, like we have done with gel, on common cleaning and decon agents but the technology is proven when applied correctly.

Housing 'planarity' tests should be standard when employing a gasket. Consideration to the filter clamping system is equally important for a solid filter to housing seal.

A note to remember when selecting filters and housings.....'The filter seal is only as good as the housing/grid in to which it is installed'. We can have the most studied gel/gasket seal and tested HEPA filter, but if the housing or clamping system has a flawed design, the 'filters will leak' and the system will be compromised.



What is the temperature limit of the gel material?

USA Silicone Gel: Useful temperature range -58° to 400° F (-50° to 204° C).

Europe / Asia Silicone Gel: Useful temperature range -40° to 392° F (-40° to 200° C).

Global – Polyurethane Gel: Useful temperature range -9° to 150° F (-23° to 65° C).

Does PAO affect gel performance?

The simple answer is "no". Many studies by Camfil and significant end users have been presented at global organizational meeting including ISPE, NEBB, IEST and other industry forums. Additional support information is available upon request.

Is there a recommended practice for mixing and pouring gel in the field and in the factory?

Camfil has specific computer-optimized controls implemented with production mixing and pouring equipment utilized to dispense gel in our plant. Temperature and humidity is controlled precisely. Guidelines for field installation are available upon request.

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What type of filter media is used in a HEPA Filter?

Glass fiber is the industry standard. Polytetrafluoroethylene (PTFE) membrane media is also available and is commonly used in the microelectronics industry where specific outgassing demands may be a concern.

PTFE is not suitable or accepted as of yet in the Life Sciences industry due to the current accepted testing procedures. (Refer to Camfil Farr's Life Sciences Industry Insight Publication for more detailed information).

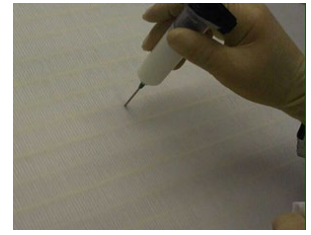
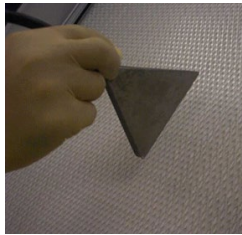
What is your recommended factory and field-patching procedure?

Camfil Farr follows the recommended practice of IEST RP-CC001.5 Section 8.3.2 and IEST RP-CC034.4 Section 6.2.2 e) 2) or EN 1822-4 for filters requiring patching at the factory. This is dependent upon customer requirements and Standard practices in effect at the filter manufacturing location.

IEST RP-CC001.5 Section 8.3.2 states: "Unless otherwise specified, the medium of filter units to be used in cleanroom or clean air device applications may be patched with medium or adhesive, not to exceed an area of 13 cm² (2 in²) in any one patch, or a total of 1% of the area being patched."

EN 1822-4, Section 8.5.4 states: "A filter may be repaired if necessary and shall then be retested" and further notes: "All repairs together (including those made by the filter manufacturer) shall not block or restrict more than 0.5% of the filter face area (not including the frame) and the maximum length of each single repair shall not exceed 3.0 cm. Alternative repair criteria may be otherwise agreed between buyer and seller."

Camfil Farr recommends adherence to IEST RP-CC034.4 for field repairs.



Leaks are identified through a prescribed procedure, marked for repair and repaired.

IEST RP-CC034.4 in various sections states: "Field repair should not block or restrict more than an additional 3.0% of the filter face area, and no single repair should have a lesser dimension exceeding 3.8 cm (1.5 in.)."

ISO 14644-3, Section B. 6.6 allows for repairs and repair procedures "by agreement between the customer and supplier."

FDA - Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice, Section 4.D.2 allows HEPA filters to be repaired in (undefined) limited areas when appropriate.

For field repairs, Camfil Farr recommends the use of a tool similar to EFD's DispensGun (Syringe type).

We recommend using a good quality viscous Silicone caulking like RTV 162, RTV 108, Dow 732, Hot-Melt (same as the pleat separator) or other suitable alternative.

Always test the filter after performing repairs both in the factory and in the field.

What is the industry stating about patches in HEPA filters (repairs)?

Camfil Farr follows the recommended practice by IEST and EN for Factory and field repair. There are a handful of companies globally that request 'patchless' filters. 99.9% of the filters Camfil Farr produce for Life Science applications are not requested to be

patch free. The typical price premium for patch free filters is a 20-25% premium, depending on the filter specification.

Recently we have noted that more end users specify that no field repairs allowed in their Grade A space.

Does patching shorten the life of a filter?

Factory patches do not shorten filter life. Field repairs should be performed by trained personnel using recommended methods and materials. Repairs should meet IEST-RP-CC001 Section 8.3.2 or be approved by the end user. Filters should be retested after being repaired.

What is the recommended filter patching material?

A mixture of RTV160 and RTV162 cleanroom grade silicone caulk is used at the factory for media repairs. Dow Corning 732 silicone caulk is used for field repairs. Camfil Farr has field repair kits available upon request. Some of our plants will also use the hot-melt separator solution as the repair material. Camfil Farr does not use filter media for patches.

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