camfil FARR

bio-pharma

Camfil Farr	Segment brochure
Bio-Pharma	
Camfil Farr – clean air solutions	

camfil farr world leader

CONTENTS

Camfil Farr is a world leader in clean air technology and air filter production. Our organisation specialises in the field of air filtration solutions. We are focused on research and development, state-of-the-art manufacturing, and marketing of air filtration products and services on a global basis.

The Camfil Farr group of companies is the world's largest designer and manufacturer of air filters with 24 manufacturing facilities around the globe.

Camfil Farr takes great pride in the fact that our products are of the highest quality, offering our customers air filters with the longest life, and lowest operating and maintenance costs.

For the past forty years we have been a leading supplier of air filtration products and services to the Bio-Pharma Industry. Many of our clients have multiple facilities located around the world, Camfil Farr is viewed by many of the largest Pharmaceutical manufacturers as a partner and well positioned to support their air filtration demands on a local and global basis.

Major investments have been made in our R&D departments located around the world to develop products specifically for the Pharmaceutical industry. It is common for us to 'partner' with our customers to meet and often exceed their most demanding air filtration requirements.

Our efforts are driven by the need to offer our clients an extensive range of products and services, catering to many diverse requirements, whether based on technical or commercial criteria.

Strength factors

As the global leader in air filtration, Camfil Farr offer our customers the security of a long-term partnership, backed by a documented capability to analyse needs and supply total air filtration solutions.

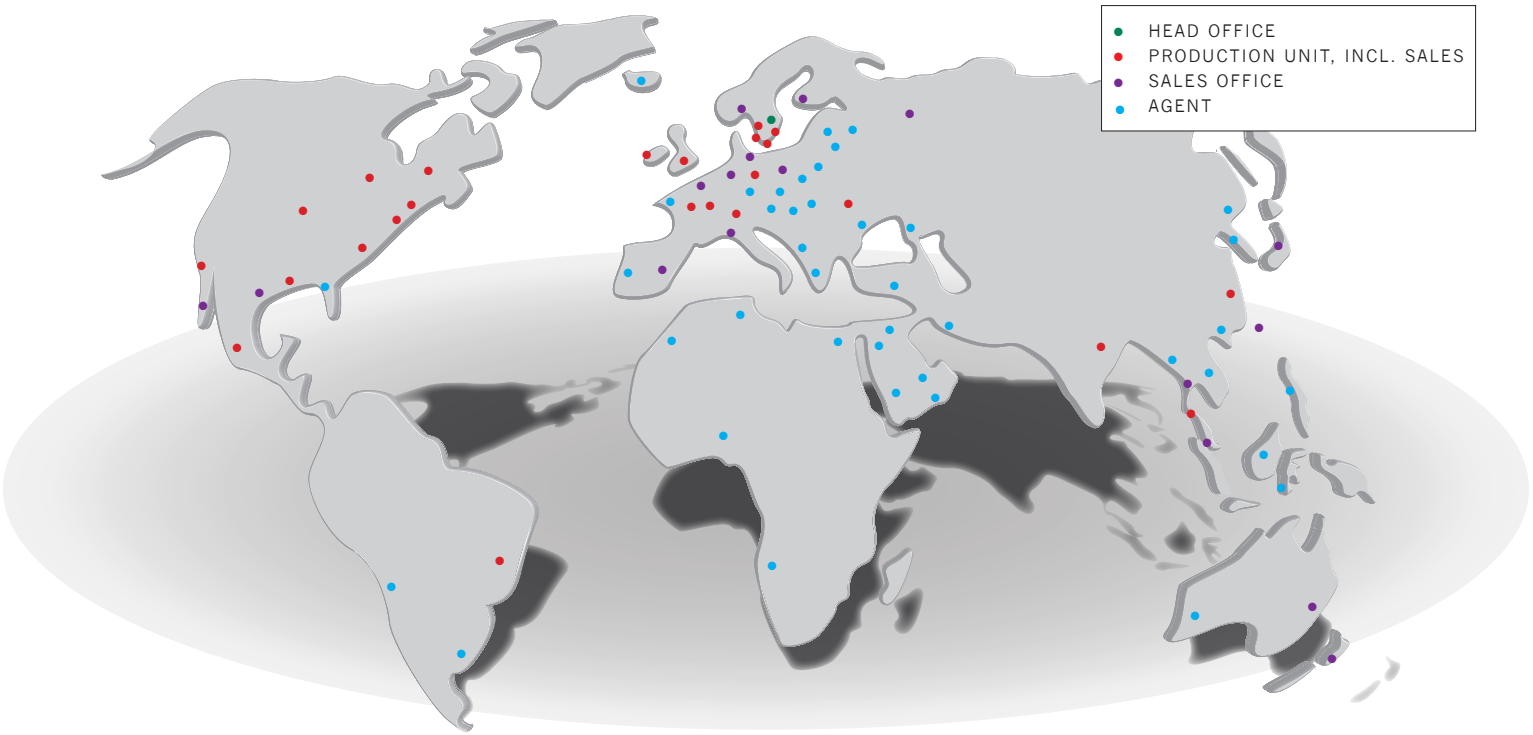
We provide the best possible clean air solutions, customised and optimised for price and performance. We are a driver and standard setter in the filter industry's major trade groups and organisations.

Camfil Farr production plants

In our major plants, filters are produced in controlled environments. As added security for our key customers, we can produce the same type of filters at multiple manufacturing sites.

Camfil Farr is recognised as the number one supplier of high efficiency filtration products for the Bio-Pharma industry.

All our plants are of course ISO 9000 certified.



In the USA Camfil Farr has more than 80 representatives and distributors. In Asia and the rest of Europe more than 50 agents.

In our major plants, filters are produced in controlled environments.

examples of filter testing protocols

EU GGMP

1. EN 1822 High efficiency air filters (HEPA & ULPA) classification and test of filters.

Eurovent 4/4 (replaced by EN 1822), however it is still used in Europe and often misunderstood, especially when specifying filter efficiency, Eurovent uses NaCl (0.65 micrometer diameter) whereas EN 1822 uses the most penetrating particle size (typically 0.15-0.2 micrometer diameter). The resulting efficiency can be in the range of 99.997 for 0.65 micrometer particles and 99.95 for MPPS for the same filter.

Eurovent 4/4 is a volumetric test and may not detect pinhole leaks within the filter, whereas EN 1822 involves a full media scan test, on the higher grades of HEPA filters. This test standard would be the natural choice for pharmaceutical use.

In the United States the term 'bleedthru' is commonly used, Camfil Farr's recommends a H14 grade filter, i.e. 99.995 at MPPS.

Using HEPA filters with 99.99 at 0.3 micrometer when tested with a thermal generator in the field at higher than recommended velocities often leads the 'bleedthru' phenomenon. More detailed information is available on www.camfilfarr.info.

Other testing protocols include:

2. IEST-RP-CC001.4-2005 HEPA & ULPA filters (2005)

3. IEST-RP-CC006.3-2004 Testing Cleanrooms (2004)

4. IEST-RP-C0021.2 Testing HEPA & ULPA filter media (1993)

5. IEST-RP-CC034.2 HEPA & ULPA filter leak test (1999)

Specifying the desired filter efficiency at the required design velocities with Camfil Farr, the end user, A&E firm & M&E contractor by 'pooling' the collective knowledge before a detailed specification is written for the project will eliminate costly mistakes.

Table 1: Standards applicable to the American & European markets

	Classification & Particle Counting in The Room	Filter Classes	Testing Filters
FDA/USA	US FED STD-209 E	IEST-RP-CC001.4	IEST-RP-CC006.3 IEST-RP-CC0021.2 IEST-RP-CC0034.2
GMP/Europe	ISO-14644	EN 1822	EN 1822

Standards International & National:

Today we are getting closer and closer to having one standard for cleanroom classification meeting the requirements of GMP for Europe, the US and Asia. They generally follow the aforementioned standards. Many countries in Asia will use their own national standards. For example, in Japan the JACA and in Australia AS1386. These standards are generally applied to manufacturers located within the borders of the region. However, if an American or European manufacturer invests in Asia and intends to ship product to their home country/ continent, they will generally follow their standards (i.e. GMP, or FDA).

Examples of cleanroom classification standards:

1. ISO 14644 (1-9), introduced in 1999

2. US FED STD 209D 1992 – FDA's Cleanroom classification (edition D was replaced by Edition E in 1998)

3. US FED STD-209E, 1998 – FDA's Cleanroom classification

4. GGMP PIC/EEC ANNEX 1 (January 1997) Cleanroom classifications

Below is a general comparison of these standards

FED STD-209D	FED STD-209E	ISO 14644-1	GGMP PIC/EEC
1	M 1.5	Class 3	
10	M 2.5	Class 4	
100	M 3.5	Class 5	A
1000	M 4.5	Class 6	
10,000	M 5.5	Class 7	C
100,000	M 6.5	Class 8	D

HEPA/ULPA cleanroom filter testing

Protocols Utilized in Camfil Farr Facilities Filter Classifications

Quite a few inaccuracies and erroneous "jargon" are commonplace in the high efficiency filtration industry. One of the key issues pertains to nomenclature (i.e., HEPA, ULPA, VLSI, SULPA, etc.). This issue involves misconceptions regarding a filters efficiency and the relationship to particle size.

CEN Classification: HEPA/ULPA Filters EN 1822-1:1998

Filter Class	Overall value (%)		Local value (%)	
	Efficiency	Penetration	Efficiency	Penetration
H10	85	15	–	–
H11	95	5	–	–
H12	99.5	0.5	–	–
H13	99.95	0.05	99.75	0.25
H14	99.995	0.005	99.975	0.025
U15	99.9995	0.0005	99.9975	0.0025
U16	99.99995	0.00005	99.99975	0.00025
U17	99.999995	0.000005	99.999975	0.000025

CEN, the Comite European de Normalization, has developed a Standard, EN 1822-1:1998, based on particle counting at the Most Penetrating Particle Size (MPPS). This European Standard applies to High Efficiency Particulate Air (HEPA) and Ultra Low Penetration Air (ULPA) filters used in the field of ventilation and for technical processes (e.g., for clean room technology or applications in the nuclear and pharmaceutical industries).

Key definitions from this Standard include:

- Penetration – The ratio of the particle count downstream of the filter to the particle count upstream.
- Efficiency – the ratio of the number of particles captured by the filter to the number of the particles challenging the filter.
- Overall Efficiency/Penetration – the efficiency/penetration averaged over the "superficial/useable" face area of a filter element under given operating conditions of the filter.
- Useable Face Area – the cross-sectional area of the filter element, through which the air passes.
- Local Efficiency/Penetration – the efficiency/penetration at a specific point on the superficial/useable face area of the filter element under given operating conditions of the filter.
- Leak Threshold – Local penetration greater than or equal to five (5) times the filters overall penetration.

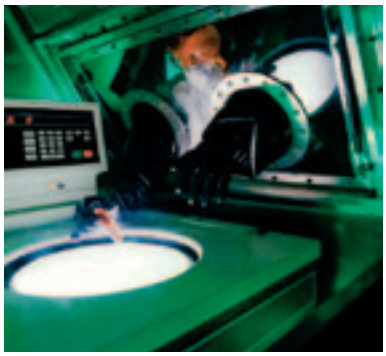
This Standard allows a classification of filters in terms of efficiency and is, therefore, useful for both buyer and seller.

IEST RP 1.4

Suggested nomenclature is based on penetration at a given particle size. Examples below:

- A Filter Efficiency of 99.97 at 0.3 micrometer is classified as a penetration of 300 ppm at 0.3 micrometer.
- A Filter Efficiency of 99.995 at MPPS (H14-EN1822) is classified as a penetration of 50 ppm at MPPS.

mini environments



Glovebox. This is a gas-tight chamber operated through sealed gloves.

The glovebox is maintained under negative pressure.

The Class III cabinet is defined as a ventilated glovebox.

Providing localized control in critical environments

Critical processes in mini environments require a high level of localized control. Laminar Air Flow (LAF) workstations are typically used for this purpose.

In manufacturing environments, many different processing areas require sterile, particle-free air, such as the assembly of electronics products and sterile packaging areas in pharmaceutical plants. Contaminants present in the surrounding air have to be removed to prevent them from negatively impacting processes and products. A filtered laminar air flow in work stations is the most effective way to create and maintain a clean working area.

Ambient air enters into the top of the LAF unit under negative pressure and a pre-filter removes large dust and dirt particles. The pre-filtered air is then blown under positive pressure through a HEPA filter with 99.99% efficiency to provide sterile, ultraclean air in a unidirectional air flow across the entire working area. The speed of the air flow is calculated at a certain velocity to prevent unfiltered room air from penetrating the working area. Particles originating from movements in the LAF workstation are also removed.

HEPA filters – the most cost-effective solution

HEPA filters used in class 100 unidirectional workstations usually have an efficiency of 99.99% or higher to remove particulates that are 0.3 micron in size and are even more effective for particulates bigger and smaller than 0.3 µm. An LAF work station requires high volumes of clean air and the solution for this application is to use pleated filter media, which have a larger surface area than filters with non-pleated media. When used in combination with the right pre-filters, the service life of a HEPA filter is usually three to six years, making it the most dependable and cost-effective solution for LAF applications.

Bio-safety cabinets for three-way protection

Originally designed for the handling of hazardous materials, Class II laminar flow bio-safety cabinets provide the ultimate protection in three ways – for products, operators and the working environment. To protect the operator, a bio-safety cabinet functions like a traditional fume hood, except that it also protects the work process and the environment.

Class II laminar flow bio-safety cabinets (type A and B) are commonly used today to protect personnel, products and the working area. These units employ a negative pressure to protect personnel, a downflow of clean air filtered through HEPA filters to protect the product, and HEPA-filtered exhaust air to protect the environment. Because of their ability to also protect products, Class II cabinets have virtually made the Class I bio-safety cabinet obsolete since it can only protect operators and the environment.

The Class III cabinet, offering the highest possible protection, is basically a ventilated glovebox maintained under negative pressure with supply air filtered through HEPA filters. Exhaust air from the cabinet is filtered twice through HEPA filters. An operator works through sealed gloves in a gas-tight chamber and is effectively sealed off and protected from the hazardous material he works with in the glovebox.

Camfil Farr has developed partnerships with the leading, Biosafety and laminar flow cabinet manufacturers for many years. We are very familiar the technical requirements for this industry, the HEPA filter of choice for the industry is the MEGALAM.

MEGALAM

Our renowned MEGALAM filter allows the OEM to maximize airflow, reduce pressure drop, therefore reducing significant energy costs depending on the filter pack depth selected.

When unidirectional airflow is a must:

Safety Cabinets are known for their high requirements in terms of laminarity. Some of our OEM customers have demanded as low as 0.45 m/s / 90 fpm ± 10%. Due to our Controlled Media Spacing (CMS) pleating technology and optional 'laminator' applied to the filter pack during production, meeting these exacting demands can be readily achieved.

Complete Range of HEPA Filters

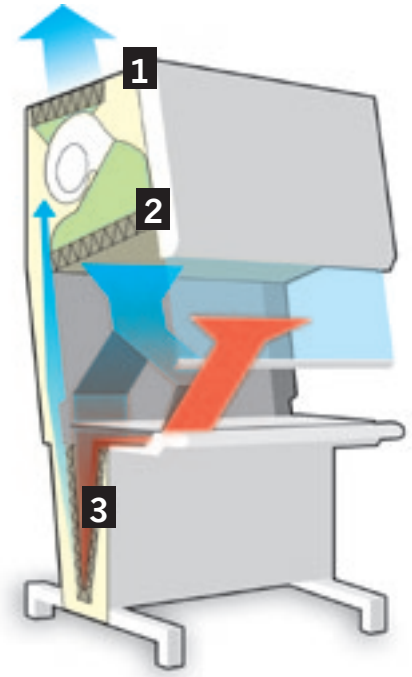
The MEGALAM filters manufactured in 3 standard depths 45, 68 and 90 mm (nominal 2, 3 and 4" packs). All filters supplied are individually tested with full traceability to consistently deliver the cleanest and cost effective air for the most demanding environments.

For more information regarding Safety Cabinet standard, refer to DIN-12950, DIN-12980, EN 12469, NSF-49, BS-5729 and NFX-44-201. (European Standard)

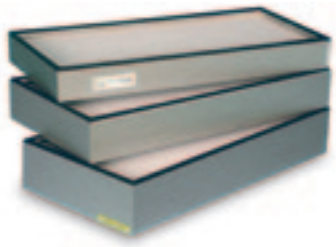
Other available Camfil Farr products for Mini Environments

Close pleat filter model TRSA.

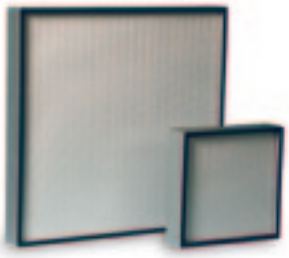
HEPA filters for LAF benches



1 **Megalam MX filter.**

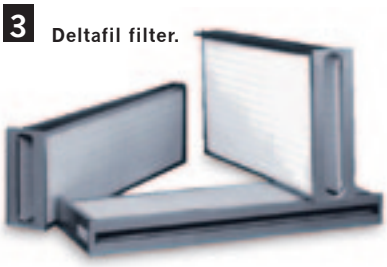


2 **Megalam MD filter.**



Clean Air
Contaminated Air
Negative Pressure
Positive Pressure

3 **Deltafil filter.**



the ‘hottest’ range of filters in the world

Silicon Filter

Absolute FRSI (Europe model)/Absolute K series (US model).

Ceramic Filter

Absolute FRK (Europe model)/Absolute F series (US model).

Sofilair HT (Europe model)/Sofilair HT (US model).

Termikfil 2000 (Europe model)/Termikfil (US model).

Endotoxins are poisonous substances that are produced in bacteria, and continue to exist after the bacteria has been destroyed. Therefore, a sterile surface may still retain dangerous endotoxins.

21CFR Part 211.94 states: “Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.”

Depyrogenation and sterilization processes are used to eliminate viable matter and reduce the amount of endotoxin on vials or other containers used in pharmaceutical processing and distribution. These processes utilize dry heat at a prescribed temperature and duration. It is up to the pharmaceutical manufacturer to decide what cleaning, sterilization, and depyrogenation is appropriate for their given process.

Camfil Farr-High-Temperature HEPA Global Spec & Technical Performance

	FRSI (6"/12") FRSI (150/292 mm)	FRK (6"/12") FRSI (150/292 mm)	Sofilair (high-temp)	Termikfil	K Series (standard & high-capacity)	F Series (standard & high-capacity)
Performance & Features	**1FRSI-600 1FRK-1000**	**1FRK-600 1FRK-1000**	**1506.23.04**	**6P6**	**24 x 24 x 12 610 x 610 x 292**	**24 x2 4 x 12 610 x 610 x 292**
Airflow (24” x 24”) (610 x 610)	730/1200 cfm 1240/2050 m^3/h	730/1200 cfm 1240/2050 m^3/h	1765 cfm 3000 m^3/h	700 cfm 1200 m^3/h	1040 cfm 1770 m^3/h	1000 cfm 1770 m^3/h
Efficiency at Nominal Airflow	99.99% at 0.3 µm or 99.95 % at MPPS	99.99% at 0.3 µm or 99.95 % at MPPS	99995% at 0.3µ	99.99% at 0.3µ	99.97% or 99.99% at 0.3µ	99.97% at 0.3µ
Pressure Drop at Nominal Airflow	1" w.g. 250 Pa	1" w.g. 250 Pa	1.1" w.g. 275 Pa	1" w.g. 250 Pa	1" w.g. 250 Pa	1" w.g. 250 Pa
Standard Frame 304 stainless steel		stainless steel	stainless steel	stainless steel	ceramic	304 stainless steel
Frame Height	6” & $11^{1/2}$” 150 & 292 mm	6” & $11^{1/2}$” 150 & 292 mm	$11^{1/2}$” 292 mm	3.3” 84 mm	6” &$11^{1/2}$” 150 & 292 mm	$11^{1/2}$” 292 mm
Standard Gasket minum & fiberglass		fiber glass	fiber glass	silicon	rolled fiber glass	silicon alu-
Alternate Gasket gasket		no gasket	no gasket	no gasket	no gasket	no gasket no
Sealant	silicone	ceramic	silicon	ceramic	silicon	ceramic
Standard Separator	aluminum	aluminum	fiber glass	fiber glass thread	aluminum	aluminum
Standard Face Grid (protective)	no grid	no grid	no grid	2 pieces of stainless steel		1 piece 304 stainless steel
Alternate Face Grid (protective)				no grid		
Media Type	fiber glass	fiber glass	fiber glass	fiber glass	fiber glass	fiber glass
Media Area (24” x 24”) (610 x 610)	123/242 sq. ft. 11.4/22.5 m^2	123/242 sq. ft. 11.4/22.5 m^2	431 sq. ft. 40.0 m^2	130 sq. ft. 12.1 m^2	186 sq. ft. 17.3 m^2	180 sq ft 16.7 m^2
Mini-pleat			Yes	Yes		
Deep-pleat	Yes	Yes			Yes	Yes
Size Availability 7 standard sizes		12 standard sizes	10 standard sizes	2 sizes	7 standard sizes	7 standard sizes
Leak Rate (%)	0.05%	0.05%	0.10%	0.01%	0.03% (99.97) or 0.01% guaranteed (99.99%)	0.03% (99.97%)
Leak Test Conditions	at 68°F/ 20°C before thermal treatment	at 68°F/ 20°C before thermal treatment	at 68°F/ 20°C	100% individual after thermal treatment	at 68°F/ 20°C before thermal treatment	at 68°F/ 20°C before thermal treatment
Maximum Operating Temperature	482° F 250° C	662° F 350° C	446° F 230° C	662° F 350° C	500° F 260° C	750° F 400° C
Weight	32 lbs. & 46 lbs. 14.5 & 20.9 kg	32 lbs. & 46 lbs. 14.5 & 20.9 kg	67 lbs. 30.4 kg	5 lbs. 5.0 kg	42 lbs. 19.1 kg	59 lbs. 26.8 kg
Handling				Camfil Farr ‘special’ Absolute packaging	Camfil Farr Absolute packaging	Camfil Farr Absolute packaging
Mechanical Resistance	high	high	high	medium	high	high
Burst Pressure	2” w.g. 500 Pa	2” w.g. 500 Pa		1.4” w.g. 350 Pa	2” w.g. 500 Pa	2” w.g. 500 Pa

1 MPPS – Most penetrating particle size **µ- Micron** **F – Fahrenheit** **C – Celsius**

Depyrogenation tunnels and continuous ovens are continuous systems that are used to reduce the amount of endotoxin to an acceptable level on glass or metal vials or other process containers and accessories.

Depyrogenation ovens are batch systems used to reduce the amount of endotoxin to an acceptable level on glass or metal vials or other process containers and accessories.

The items being subjected to the depyrogenation process must remain at the specified temperature for the specified time period for the process to be successful. Reduced heat-up and cool down periods as well as increased maximum temperature can increase the total throughput of the equipment.

In the past, the duration of batch depyrogenation processes has been determined by the ability of the HEPA filters to maintain the cleanliness class required (normally ISO Class 5). Failure of the HEPA filters was a likely event during the heat-up and cool-down cycles. More recently, advances in HEPA filter technology have helped to reduce the negative impact HEPA filters have on the duration of the process.

For many years we have produced 'traditional' HT filters with Silicone & Ceramic based seals. The F and K series filters produced by Camfil Farr in the USA and Europe have long been the 'filter of choice' for our Bio-Pharma and original equipment manufacturers (OEM) customers.

Camfil Farr's Termikfil is an example of a new high-temperature HEPA filtration technology. Specifically designed for use in depyrogenation ovens and tunnels for sterilization purposes, Camfil Farr's Termikfil is the only HEPA filter guaranteed to operate for a minimum of one year at a temperature of 350°C/662°F) while maintaining the leakfree integrity required to pass FDA validations.

The Termikfil is pre-treated, and pre-qualified, during the manufacturing process, with an exclusive heat preparation cycle (300°C/572°F).

New high-temperature air filtration technologies have allowed equipment manufacturers to focus on other process related issues, maximize equipment performance, and reduce the cost of equipment operation. The leading OEM's globally choose Camfil Farr as their vendor of choice for critical applications, the range of filters we produce allows them to deliver equipment to their biopharma customers for the most demanding applications:

Our OEM Customers Globally Include	Country
Bausch & Strobel	Germany
NIRO	Denmark
Icos	Italy
Federgari	Italy
TPS	USA
Despatch	USA
Lytzen	Denmark

bag in/bag out BIBO

Today we are concerned about contaminants that may be introduced into a building through unconventional sources. Whether contaminants are introduced through an outside air intake or released inside of a building, Camfil Farr has the air filtration technology to remove them. Camfil Farr is the world leader in applied technology for the protection of buildings from chemical, biological or radiological (CBR) attacks. As an air filtration leader in cleanrooms, hospital operating suites, nuclear power facilities, isolation rooms and bio-safety facilities, our experience helps us address the security of your building's air quality in our changing world.

Purpose

The purpose of a containment system is to filter dangerous chemical, biological, or carcinogenic contaminants from air. Containment systems, as their name infers, are also designed to contain the filtered contaminants in a sealed housing until such time as the filter media needs replacement or regeneration. Containment systems can filter out particulates, gases, or both.

Containment systems can include a combination of several components, depending on the nature of the contaminant and application. These components can include pre-filtration, test, high-efficiency or final filtration, and adsorber sections mounted in series. The capacity of the system can be increased by adding multiple sections to the system in parallel. Containment systems can also include an option called bag-in/bag-out to facilitate the safe change-out of air filters.

BIBO

Bag-in/Bag-out systems are containment systems with the added option of including a PVC bag which includes integral gloves. The bags are used to seal the containment housing while changing filters that are contaminated with dangerous matter. Utilization of very specific procedures is required for the safe use of bag-in/bag-out systems. Camfil Farr publishes a bag-in/bag-out filter change instruction manual for the use of our customers. The bag is sealed to a flange located at the door opening of the containment section with a shock cord. Used filters are removed from their mount in the housing by reaching into the PVC gloves and sliding the filter into the bag. The bag is then sealed and removed and a new bag is mounted to the flange. The door is then closed and sealed and the unit placed back into service.

Camfil Farr BIBO solutions:

FB Series housings

GB Series housings

Camsafe

Camfil Farr FB Series housings, GB Series housings and Camsafe are designed for use in critical processes where hazardous airborne materials must be prevented from escaping to the atmosphere. Air filters may be replaced using a control barrier to protect change-out personnel from contaminants within the housing or contaminants captured by the filters.

The Camfil Farr FB Series housings, GB Series housings and Camsafe minimize exposure to harmful contaminants during filter service through the use of a PVC bag enclosure system. The entire filter changing process isolates personnel from the hazardous materials. Although the Camfil Farr FB Series housings, GB Series housings and Camsafe are available in a basic configuration, various options specific to the application are available.

These housings are typically used in facilities that incorporate hazardous materials in their processes.

These contaminants may include biomedical, radiological, carcinogenic or other materials of concern.

Containment system

Camfil Farr Self-Contained Isolation Systems can provide a complete solution to applications where hazardous airborne contaminants may present risk to facility personnel or visitors.

These systems can be custom designed to remove airborne particulate, gaseous contaminants, or a combination thereof.

Typical applications include hospital isolation rooms/wards and Intensive Care Units (ICUs).

Camfil Farr Self-Contained Isolation Systems are ideal for the control of airborne pathogens, viral contaminants and infectious organisms.

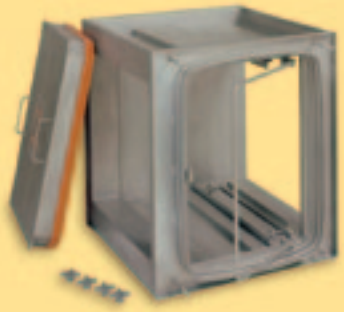
In applications where individuals may come into the proximity of individuals with mycobacteriu tuberculosis, the Centers for Disease Control (CDC) in USA has specified certain air quality control parameters.

For new projects, or renovations, a minimum of 12 air changes per hour of clean air are required. For existing systems the minimum air change requirement is 6 air changes per hour. In both cases the Guideline is specific to the protection of employees and visitors to the facility.

Camfil Farr's Self-Contained Isolation Systems can assist your facility in meeting or exceeding these guidelines. For a copy of these guidelines contact your local Camfil Farr Representative or Camfil Farr.

Available in various customizable configurations, each unit is reviewed by our engineering team and tested as a complete system to ensure suitability to task. Mechanical components are matched to filtration stages to assure deliverance of rated airflow. Optional components such as magnehelic gages, test ports, dampers and control mechanisms are available.

Camfil Farr has the ability to supply the system and the filters. Component compatibility and overall system quality are assured from a single-source manufacturer.



FB Housings.

FB Housings. Camfil Farr Prefilter Housings mate directly to Camfil Farr GB, FB, GN, and FN Seriescontainment housings.

GB Housings.

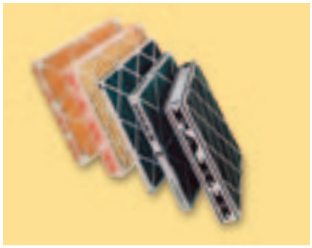
FB-r round bag-in/bag-out housing.

Camsafe.

Self-Contained Air Filtration Systems for Hazardous Contaminant Removal.

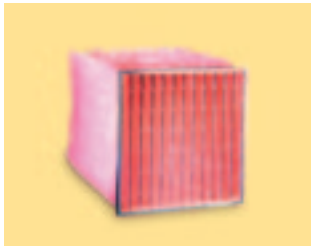
camfil farr clea

for the bio-ph



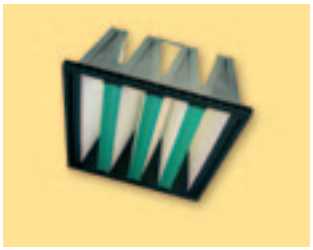
1 30/30

Medium efficiency pleated panel filter. The original pleated filter – today's industry standard. Contains up to 16 pleats per linear foot/ 305 mm. Radial pleat construction for minimum pressure drop and maximum service life. Available in U.L. Class 2 or 1, in 1", 2" and 4"/25, 50 and 75 mm depths. Nonwoven cotton/ synthetic blend media. Rated as a MERV 7 filter according to ASHRAE 52.2 or G4 per EN 779.



2 hi-flo

Use a high performance fine fibre filter with a large media surface area. A bagfilter with a large area (Hi-Flo M-type) is recommended. Rated as a MERV 13/14 filter according to ASHRAE 52.2 or F8/F9 per EN 779:2002.

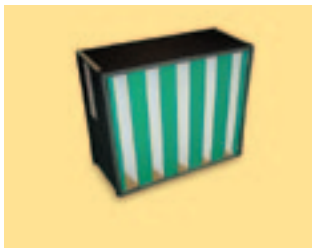


3 opakfil green/ durafil

Multiple close-pleat panels contain maximum media area. Excellent for low external static pressure systems. Minimum energy consumption. Available with header frame. Offered in MERV 11, 13, and 14, per ASHRAE Standard 52.2. or F6, F7 and F8/F9 per EN 779:2002.

4 camcarb/ camsorb

In carbon filtration, Camfil Farr has a number of different solutions. Camcarb/Camsorb activated carbon filters consist of a galvanised/ stainless steel base plate and cylinders of galvanised/stainless steel containing activated carbon. The cylinders are also available in an environmental, green, version, produced in plastic. Filter type: Camcarb 2600-16/CM07 for SO_2 gas.



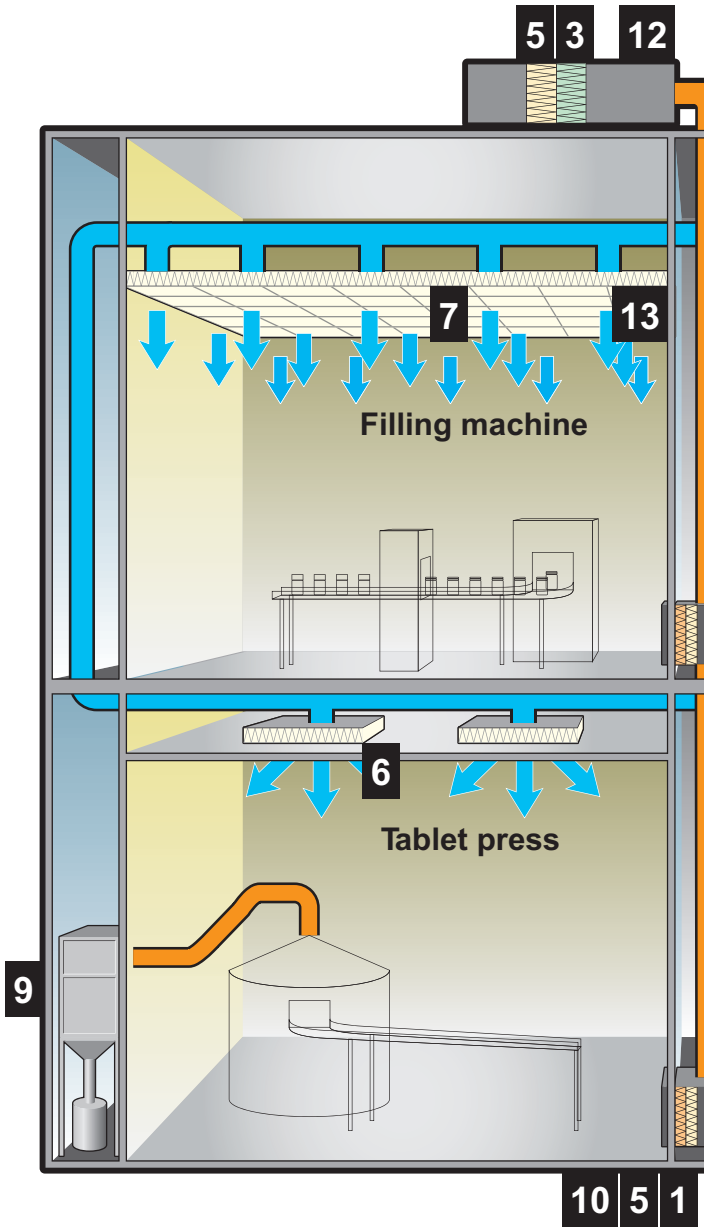
5 filtra 2000®/ sofilair

High capacity HEPA filter 2400 cfm at 1" pd/4000 m^3/h at 250 Pa. Available in extruded aluminum, galvanised, plastic or stainless steel frame with gel or gasket seal. Individually tested to the latest international standards.

6 pharmaseal®

Roomside replaceable HEPA/ULPA ducted ceiling module with all-welded construction eliminating leakage into the clean space. Accepts gel seal filters in efficiencies from 95% at 0.3 micron to 99.9995% at most penetrating particle size.

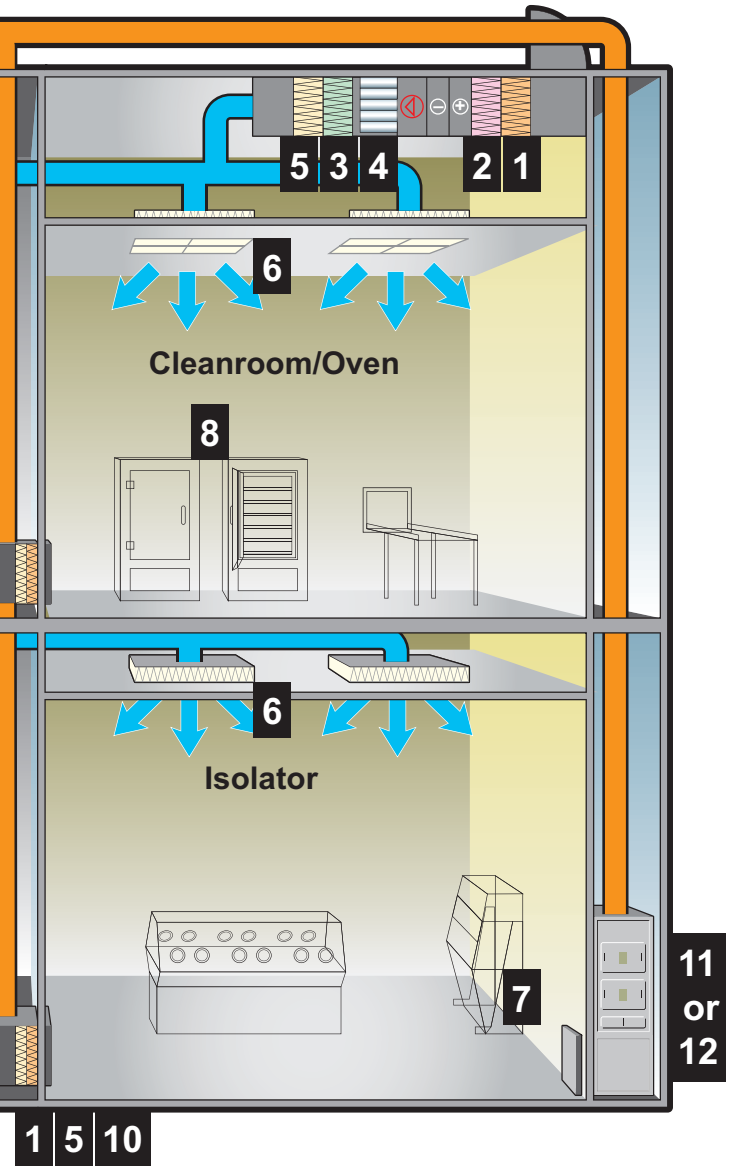
May be installed in a T-bar ceiling or flush mounted in plaster or sheet rock ceilings. Includes aerosol injection/diffusion system for uniform challenge distribution. Available with bubble tight, guillotine or butterfly dampers. Available in 00.63 aluminum or 16 gauge 304 stainless steel.



9 bibo dust collector

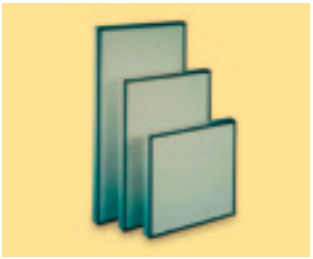
The Gold Series (GS) dust collector can be used in a variety of pharmaceutical dust collection applications such as pill presses, tablet coating, fluid bed dryers, spray dryers, and general room ventilation. The GS is perfect for high efficiency filtration in pharmaceutical manufacturing.

an air solutions
arma industry



10 wm pharmaseal

The wall mounted Pharmaseal is available with 30/30 pre filter and Sofilair/ Filtra 2000 and Megalam panels. The test shroud allows for an overall efficiency test from within the room.



7 megalam® panel filters

Patented close-pleat manufacturing technology ensures low pressure drop, uniform airflow and minimal configuration losses. Available in efficiencies from 95% at 0.3 micron to 99.9999995% at most penetrating particle size. Anodized aluminum frame ensures a rigid and durable pack. Various frame configurations, sealing options and media options available, consult factory. Each unit individually tested and certified.

11 bag-in/bag-out housing

Wall mounted BIBO/Safe Change housing, available with pre, HEPA and scan sections, bubble tight damper, cover panel doors etc. Typically utilized where potent or toxic compounds are in use, minimizes the need to decontaminate ductwork.

8 termikfil 2000®

Close-pleated panel resistant to temperatures up to 662°F/350°C in continuous operation. Unique construction assures maximum dependability and leakfree performance. The composite ceramic frame reduces the thermal expansion to a minimum.

Upstream and downstream diamond point stainless steel grids protects the filters while handling. Efficiency >99.99% at 0.3 micron particles. Individually tested, certified and recorded. Applications include sterilization tunnels and ovans.

12 camsafe

High security Safe change filter housing. Contact free BIBO. Automatic tension-regulating filter clamping device. Fast, secure filter installation, lever operated. Optional filter seal seating test as per DIN 1946, Part 4. Sealed, welded, solid design. Tightness class B as per EN 1866 at 5000 Pa. Camsafe connecting pieces can be supplied in various designs.

13 camgrid dry/camgrid gel

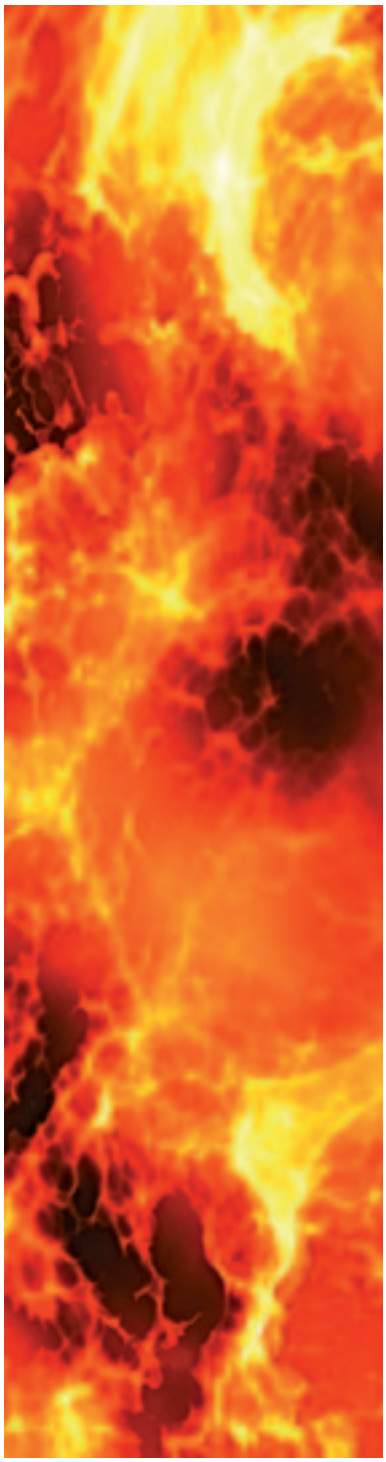
is a modular grid system for mounting in ceilings or walls in Bio-Pharma cleanrooms.

Camgrid system can equip:

- Clean areas down to ISO 5
- Local Unidirectional Airflow Protection
- Complete Unidirectional Airflow Cleanroom
- Non-unidirectional Airflow Cleanroom (with blank panels)

Camgrid system modularity is ideal to optimise filtration coverage and reach maximum effective filtration area with minimising turbulences.

potentially explosive atmospheres regulation



Two important new safety directives become fully operational across Europe. These new regulations are known as the ATEX Directives and apply to manufacturers, suppliers and users of equipment designed for use in potentially explosive atmospheres (also known as hazardous areas).

An explosive atmosphere is defined as a mixture with air, under atmospheric conditions, of dangerous substances in the form of gases, vapours, mist or dust in which after ignition has occurred, combustion spreads to the entire unburned mixture.

Directives 99/92/EC (ATEX 137), "USE" directives, requires employers to protect workers from the risk of explosive atmospheres.

Directives 94/9/EC (ATEX 95 or ATEX 100A) "Equipment and Protective Systems for use in potentially explosive atmospheres" covers electrical and non-electrical products intended for use in hazardous areas (gas, vapours or dust atmospheres).

Compliance with both ATEX directives are a legal requirement in all European Union Members States from 1 July 2003.

In Bio-Pharmaceutical applications, some processes are required to have ATEX classified filters in certain zones (see table).

Camfil Farr in Europe have developed ATEX approved HEPA filters and housings for use in Bio-Pharmaceutical facilities in order to avoid any electrostatic hazards from gas or dust in the ATEX zone.

Camfil Farr has developed ATEX specifically designed versions of most of filters and filter housings generally used in Bio-Pharmaceutical facilities in order to avoid any electrostatic hazards in ATEX zones Gas or Dust.

Camfil Farr ATEX solutions are fully certified according to ATEX Directive requirements with the appropriate "Ex" marking, the "ATEX Declaration of Conformity" and "Instruction for use".

Table legend:
ATEX user Zoning and Product Categories correspondence

Zoning Definitions			Categories	
Zones Gas	Zones Dust	Definitions	ATEX Cat.	Typical Zone Suitability
EN 60079-10	EN 50281-3			
0	20	A place in which an explosive atmosphere is continually present	1G 1D	Equip. suitable for zone 0 Equip. suitable for zone 20
1	21	A place in which an explosive atmosphere is likely to occur in normal operation occasionally	2G 2D	Equip. suitable for zone 1 Equip. suitable for zone 21
2	22	A place in which an explosive atmosphere is not likely to occur in normal operation, but if it does only occurs for short periods.	3G 3D	Equip. suitable for zone 2 Equip. suitable for zone 22

bibo – gold series camtain™

The Only Potent Compound Surrogate Tested Dust Collector

The Gold Series Camtain BIBO door and BIBO dust discharge system has been personnel exposure tested with lactose as the surrogate dust for the potent pharmaceutical compound. Over 75 air qualiity and swab test points were taken during multiple change outs of the dust and filters. This was perfored by an independent testing firm (Broadspire) who IS certified by a major pharmaceutical company for potent compound sample testing. The GS Camtain is the only potent compound tested dust collector on the market today, and can handle your toughest applications. Full test report data is available upon request.

Gold Series CamtainTM on Pharmaceutical Applications

Bag In Bag Out (BIBO) safe change containment systems are available on both the cartridge access doors and dust discharge system underneath the collector. Farr has BIBO dust collectors on pharmaceutical applications in the USA, Canada and Europe, Farr has named its BIBO dust collection system the Gold Series Camtain.

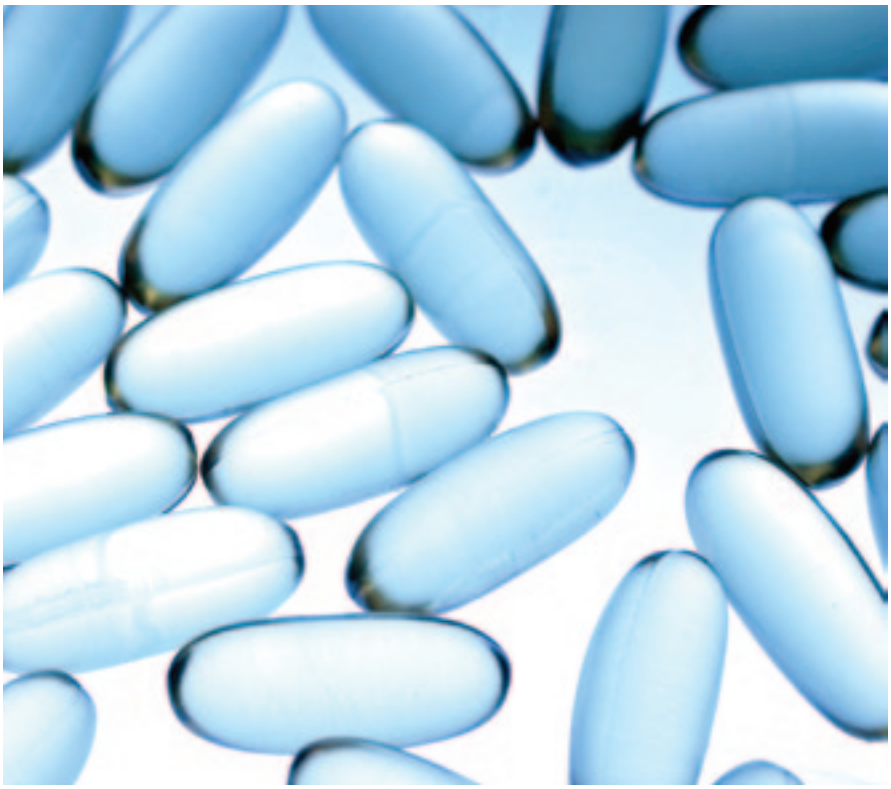
Gold Seriers on Pharmaceutical Company Applications

The Gold Series (GS) dust collector can be used in a variety of pharmaceutical dust collection applications such as pill presses, tablet coating, fluid bed dryers, spray dryers, and general room ventilation. The GS is perfect for high efficiency filtration in pharmaceutical manufacturing.

GS4 8180 camtain self-cleaning dust collector for pharmaceutical applications.

"The Gold Series BIBO Camtain is a winner for our pharmaceutical applications. It is way ahead of the curve of anyone in the dust collection industry. The results from the potent compound surrogate test are very positive. Nice work!"

Project Engineer,
Major Pharmaceutical Company



pharmaseal terminal housing

Bubble-tight damper.

Guillotine damper.

Butterfly damper.

Guillotine or BT damper control damper position indicator and set screw.

Aerosol dispersion system with QD (Quick Disconnect ports) and damper control mechanism.

The Camfil Farr Pharmaseal provides cleanroom level air filtration for pharmaceutical or biotechnology facilities as well as any other facility where clean space is a manufacturing or health-related requirement.

Its unique room side replacement filter design minimizes downtime and ensures repeatable room air cleanliness following filter service.

The Camfil Farr Pharmaseal:

- Has joints and penetrations in the "filter-to-hood" interface that are of welded component construction. Leaks into the cleanroom are eliminated.
- The housing is visually inspected, tested for filter fit, and then leak tested at 3.0" w.g./750 Pa to ensure the housing will not leak under normal operating conditions.
- Is manufactured in various configurations of 0.063 aluminum or 16 gauge/2.8 mm 304 stainless steel.
- May be installed in a heavy-duty T-bar ceiling or flush mounted in a plaster or sheet rock ceiling.
- Damper options:
  – **A Bubble Tight damper** to isolate the room during filter change out or decontamination. The Bubble Tight damper also acts as a volume control damper with the same adjustment mechanism from within the housing in the room.
  – **A Guillotine damper** with heavy-duty room side adjustable linkage for precise airflow adjustment and room air balance.
  – **A Butterfly damper** for easy adjustment of airflow to fine-tune the balancing from within the room.
- Includes an air/aerosol distribution system for uniform dispersion of test challenge across the entire face of the filter.
- Includes a raised-rib inlet collar for easy connection to flexible HVAC air duct supply.
- Housing can be insulated with 2"/50 mm foiled back fiberglass or 1"/25 mm armaflex as standard.
- **Each housing is labeled with a serial number for full traceability of pressure tests and soap bubble welded joints test to ensure a leak free housing.**

Two versions are available;
A seal-welded version on modules with guillotine dampers to ensure leak free performance, or a mechanically connected version on modules with butterfly dampers, both offering a sturdy module connection.

- Includes a flush-mounted face grille to accommodate easy filter change or unit service. The grille has a 40% open area optimized to promote uniform airflow. Various grille fastener types are available. The grille is also available with a hinge.
- Accepts gel seal filters that are available in pack depths of 2, 3 or 4"/53, 70 or 100 mm. Recommended filter efficiency for the Pharmaseal module is H14 (99.995 at MPPS) in accordance with EN-1822.

Camfil Farr's flexible fabrication capabilities can supply a PharmaSeal for virtually any cleanroom requirement. Custom sizes can be manufactured with special trims, and built up banks with single inlet collars for multiple units where horizontal or vertical airflow is required.

The PharmaSeal is available with a bubbletight damper, a guillotine damper or a butterfly damper.

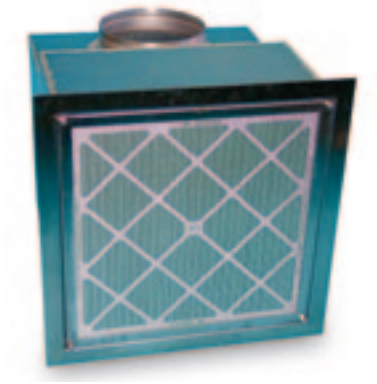
pharmaseal exhaust housing

Wall Mount Exhaust Housing with a HEPA and a Prefilter Option

The Pharmaseal exhaust housing is a simple, yet highly effective solution for exhaust and recirculation applications in pharmaceutical and biotechnology facilities, hospitals, surgical suites and animal labs.

The CamfilFarr Pharmaseal room side replaceable exhaust housing:

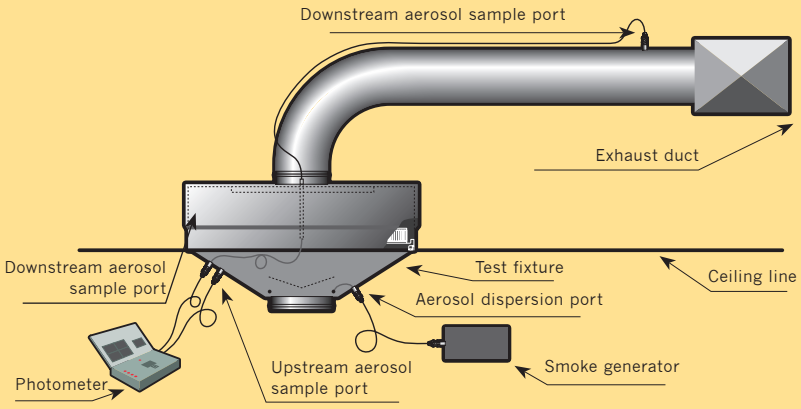
- Allows a maintenance-friendly filter change from within the room, through a removable stainless steel filter face grille, ensuring contaminant containment, the clean space remains uncompromised.
- Enclosure is manufactured from 0.063 aluminum or 316/316L stainless steel. All units includes 304 stainless steel grille and trim.
- Is bubble leak tested to 3.0" w.g./750 Pa to ensure that the housing will not leak under normal operating conditions. The housing is also visually inspected at the factory and tested for filter fit before shipment. **Each unit includes a label which allows for full traceability of the testing procedure.**
- Includes all mounting hardware and a choice of an inward-turned flange, an outward-turned flange or an integral plenum with 10" or 12"/ 250 or 300 mm round flex duct connection.
- The unit includes integral flush perimeter trim. Unit may be mounted in sheet rock walls, plaster, or conventional aluminum or stainless steel honeycomb panels.
- Is available in four standard filter configurations, a 4"/100 mm filter with prefilter, a 4"/100 mm filter without prefilter, a Filtra 2000 filter with prefilter and a Filtra 2000 filter without a prefilter.
- Includes integral filters guides that ensure proper filter fit within the gel to knife edge alignment with the filter.
- Includes a static pressure port and quick-disconnect ports for convenient room side filter evaluation
- Optional test shroud and sampling ports allow all efficiency measurements from the room side.



Pharmaseal Exhaust Housing installed in a cleanroom wall offers an astheticaly pleasing roomside appearance.

Same unit with testing shroud mounted on the Pharmaseal frame for overall filter efficiency testing from within the room.

Pharmaseal Exhaust Hood Test Procedure



1. **Remove grille from Pharmaseal.**
2. **Install test fixture to hood, Note: The flexible hose of the downstream aerosol sample port in the test fixture must be attached to the quick disconnect fitting in the hood just before actually attaching test fixture to hood.**
3. **Connect photometer to test fixture upstream aerosol sample port and the downstream aerosol sample port.**
4. **Connect smoke generator to aerosol injection port.**
5. **Conduct test of filter.**
6. **If result is acceptable, remove test instruments and test fixture.**
7. **Replace grille on Pharmaseal.**

energy saving software programs

LCC Software

The Life Cycle Cost (LCC) software is a tool we have used successfully for many years in the Bio-Pharma industry.

The volatile oil and energy markets and the ever increasing cost of supplying clean air are critical for this industry.

The LCC software allows us to simulate different combinations of filter types with the desired efficiency to maximize lifetime, reduce energy costs and number of filter changes which can save the Pharmaceutical manufacturer valuable resources. An additional benefit is the positive effect reduced motor power and disposal has on the environment.

After filter survey's are carried out at the manufacturing facility, we can input the existing filter set up in the air handling units and optimize the selection of the lowest LCC filter combination for the facility in question.

Parameters the software includes are:

Type of filters in use:

- Outside air condition (environmental condition in the plants location)
- Airflow
- Current change out conditions (we can select filters being changed on time or pressure drop)
- Number of filters in the air-handling units
- Current energy cost

$$E = \frac{q \times \Delta p \times h}{\eta \times 1000}$$

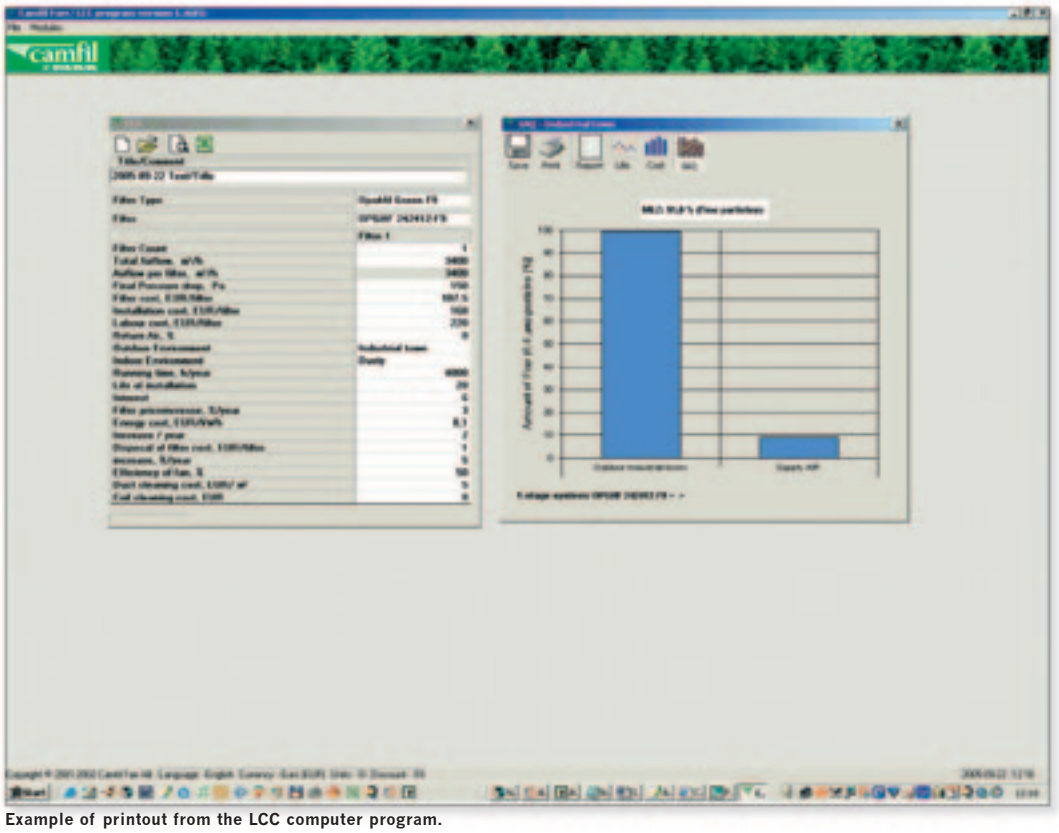
Where:

E = energy output/year
q = airflow m^3/s
Δp = differnece in pressure drop
h = operating time hours/year (year round operation 8,760 h)
η = fan efficiency

- Installation cost
- Disposal and cleaning costs

Camfil Farr filters have proven to be the top filter in several independent tests and competitions about the lowest Life Cycle Cost.

The energy consumption is easily calculated with the formula stated above.



Example of printout from the LCC computer program.

Cleanroom design software

Camfil Farr has designed a software program which allows us to simulate the actual operating conditions when multiple parameters are selected:

Selection options include:

- Particle size of interest, 0.1, 0.3 or 0.5 micron
- Particles generated from the process and activity from people in the room
- Dimensions of the room
- No. of air changes/airflow
- Ventilation effectiveness
- Amount of recirculated air from 0 – 100%
- Pre and terminal filter efficiencies

Example of printout from the Clean Room computer program.

EN 1822 software program

The Camfil Farr EN 1822, former PQ program, allows engineers/end users the opportunity to "maximise" HEPA/ULPA selection.

By simply inputting the actual filter dimension, desired efficiency and airflow/face velocity, the program automatically shows you the actual efficiency at 0.3 µm and MPPS (Most Penetrating Particle Size), the typical and maximum air resistance across the selected media pleat depth and the MPPS particle size.

Protocol from EN 1822 computer program showing penetration vs size of a Megalar H14 filter.

Chemical/carbon filter software program

The Camfil Farr chemical/carbon selection program is designed to help users and design engineers to estimate lifetime and efficiency of chemical/carbon filters against specific target gases at given concentrations.

The software program clearly demonstrates Camfil Farr's continuing commitment to serve our customers and optimise filter selection for the Bio-Pharma segment.

Interface from Chemical/Carbon computer program.

camfil farr testing capacities

ASHRAE test rig.

SEM (Scanning Electron Microscope)

Camfil Farr has several test rigs around the world

Camfil Farr maintain a strong commitment to quality control and R&D.

We have rigorous in-house and ongoing field trials to ensure all products are compliant with specification.

ASHRAE test rig

We were the first air filtration company in Europe to invest in our own Eurovent 4/9 & EN 779:2002 test rigs.

The test rigs have undergone rigorous 'round robin' tests to ensure consistency of filter evaluation with independent test laboratories. Camfil Farr USA was also the first air filtration company to install our own ASHRAE 52.21.1999 test rig. Both rigs can now offer the 'discharging' step of 'electrostratically charged media's' (commonly known as synthetic media's) already adopted in Europe and soon to be adopted in the USA.

By having a number of our own test rigs we can test new filters as well as used filters from the field to build up our own database of how filters work and perform in real life. Standards have so far been concentrating on finding fast, economical methods to classify filters.

SEM

The scanning electron microscope with EDAX capability is another example of our commitment and investment to R&D. This unique tool, allows us to identify and quantify contaminants in the air and in used filters in order to further improve and understand how filters perform in real life. The SEM is situated in our corporate R&D facility in Trosa, Sweden.

Molecular filter test rig.

Media test rig.

Media test rig

The Media test rig allows raw chemical medias to be evaluated under a wide range of conditions and challenged with a wide variety of gases and vapours. Multiple parallel test lines allow simultaneous evaluation of medias for development and quality assurance purposes.

Molecular Filter test rig

The molecular media test rig and the unique full-scale chemical filter test rig at our corporate head-quarters in Trosa, Sweden are examples of the significant investment made in the field of molecular filtration.

In this unique facility, full size gas filters can be operated in the rig under a wide range of temperature and humidity conditions and challenged with different gases. The efficiency and life aredetermined using an array of sophisticated gas detection equipment.

Full scale test device

One of Camfil Farr's latest investments is our full scale test device used to evaluate filtration needs under extreme continuous conditions.

Using this apparatus, we can modify all of the important parameters such as airflow, relative humidity, temperature and salt content. The device can be used with air or other gases and will allow rapid prototyping, product validation, evaluation of competitive products and for research and development testing.

HEPA testing protocol

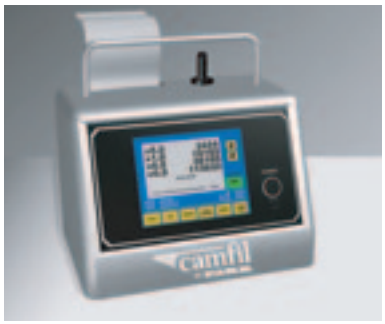
All Camfil Farr Absolute filters are scanned and tested in the factory using a laser particle counter. After gaining approval, each filter receives an inspection label stating its serial number, efficiency for MPPS particles as well ass pressure drop at the test flow rate.

EN 1822 test rig.

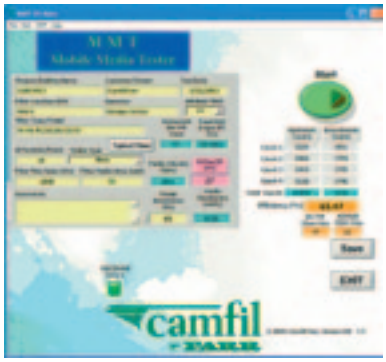
Strategy

We continually seek to develop existing materials and identify new medias. We maintain strategic relationships with key suppliers to ensure we secure premium materials tailored to our specific requirements.

external testing capabilities



Eurovent (EU 4/10) in-Situ Filter testing.



Mobile media test results.

Camfield laboratory inside view.

Camfield laboratory outside view.

Eurovent (EU 4/10) in-Situ Filter Testing

How can filter users differentiate manufacturers claims and make intelligent decisions as to what products are applicable to meet their needs?

Historically, many depended upon test reports. Unfortunately, today's testing laboratory methodologies may not give a true barometer of a filters performance over time as these filters are not tested under real life conditions.

Camfil Farr addresses these concerns by performing actual on-site filter performance evaluations using industry defined procedures.

The final report includes a particle size versus efficiency analysis detailing the filters ability to capture large particles, down to sub-micron size respirable particles that may affect health or processes. Pressure drop data, relative to a filters actual life within a system, and its overall effect on system airflow and use of energy is also detailed.

Mobile media tester

Microfine media fibres, coarse media fibres, synthetics, polyesters, which filter media will provide the efficiency required to ensure that you are protecting the health of your building's occupants or ensure that your process is as clean as it needs to be?

Camfil Farr now offers our Mobile Media Tester to answer your filter performance questions and demonstrate that you are obtaining the particle removal efficiency you are paying for.

This portable testing system can evaluate any high-efficiency flat-sheet filter media including samples obtained directly from your filter stock, existing air handlers or samples as you request from your filter distributor.

Contact your Camfil Farr distributor for a media evaluation at your facility today.

Airaudit service

The airaudit service of Camfil Farr has as our main objective to verify, maintain or improve the quality of filtration of your installation.

Sampling of air is made before and after the filter house or individual filter stages and a qualitative and/or quantitative analysis of the air will be reported.

Qualitative analysis is an electronic microscope analysis of particles collected in the air.

Quantitative analysis is a counting of individual particles per volume of air. Camfil Farr's report will include recommendations and advise on possible solutions to reduce operating cost by improving the efficiency and reliability of your installation.

Mobile test rig

Another new investments is Camfil Farr's mobile approach to filter tests consists of a mobile test rig installed in standard 20-foot container.

Tests can be performed on eight different filters simultaneously in four different air ducts. The mobile test laboratory documents the actual performance of filters in the application they are intended for, with complete control over the operating parameters.

Customers see, right on their site, what the most cost efficient and effective filtration solution will be for their air handling system, building or process. Customers can also participate in monitoring the results.

Accelerated tests are also possible to test filters at a higher airflow with the exact same dust load, to shorten the test period and simulate a long-term test.

Accessories

Camfil Farr provides the suitably designed accessories in order to install and achieve perfect working of filtration solutions as:

– Ceiling grids:
  like Camgrid the ceiling grid solution
– Frame and clamping devices:
  like Magna-Grid
– Safety accessories like Bubble-tight Isolation dampers round or rectangular

Camgrid dry/Camgrid gel

Camfil Farr Camgrid modular ceiling grid system combined with Camfil Farr HEPA/ULPA Megalam panel filters is specifically designed to supply highly filtered air into Bio-Pharma cleanrooms via a pressurised plenum.

Camgrid system can equip:

– Clean areas down to ISO 5
– Local Unidirectional Airflow Protection
– Complete Unidirectional Airflow Cleanroom
– Non-unidirectional Airflow Cleanroom (with blank panels)

Camgrid system modularity is ideal to optimise filtration coverage and reach maximum effective filtration area with minimising turbulences.

HEPA frame

The Camfil Farr HEPA frame Magna-Grid is an factory assembled Absolute filter support module designed to ensure that the system efficiency equals the filter efficiency. It incorporates swing bolt filter fastening assemblies with equibearing clamps to provide uniform filter sealing pressure.

Round Low-Leak or Bubble-Tight Isolation Dampers

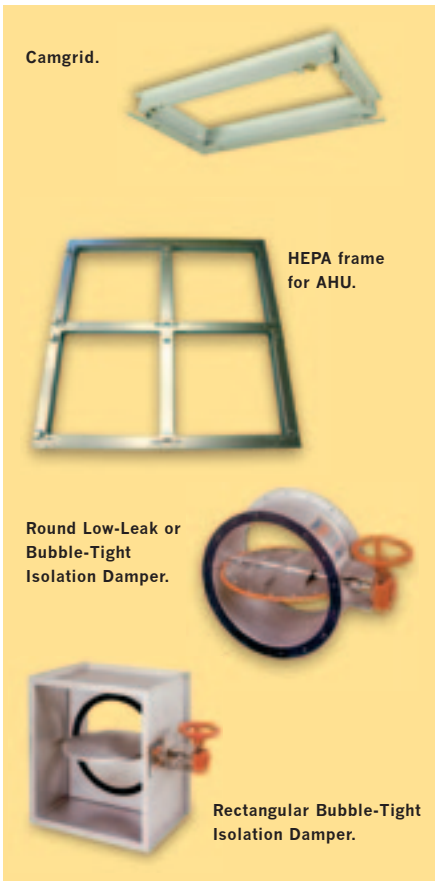
Camfil Farr Round Isolation Dampers create a barrier between hazardous contaminants and the filter change out components typical to a containment system. The Camfil Farr round isolation damper is available in either a low leak 1 or bubble-tight 2 model.

Rectangular Bubble-Tight Isolation Dampers

Camfil Farr rectangular isolation dampers are bubble-tight when tested to 10" w.g./2500 Pa.

1. Low-leak isolation dampers are tested in the closed position at + 10" w.g./2500 Pa by the pressure decay method per applicable sections of ASME N510-1995.

2. Bubble-tight dampers are tested in the closed position at + 10" w.g./2500 Pa to bubble-tight specification per applicable sections of ASME N510-1980.



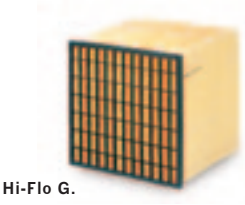
Camgrid.

HEPA frame for AHU.

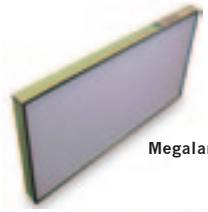
Round Low-Leak or Bubble-Tight Isolation Damper.

Rectangular Bubble-Tight Isolation Damper.

Environmental friendly products



Hi-Flo G.



Megalam Green.

Sofilair Green.

A major cornerstone of our philosophy is our commitment to the environment. In all our product categories we manufacture products to obtain the lowest life cycle cost (LCC). These filters are the lowest energy consuming filters in the market place, therefore good for the environment.

We constantly strive to develop filters that have the longest lifetime during operation and to minimize the cost of disposal.

In certain markets in Europe the local laws dictate we incinerate filters after use. Today it is common for us to supply filters with 'no metal parts'. Our renowned Hi-Flo Bag Filter and Opakfil/Durafil and Riga-Flo ASHRAE filters have long been produced which allows for incineration.

We have now added HEPA filters to our 'eco friendly' product pallet. The Sofilair & Megalam filters are now available in totally insinerable versions.

Manufacturing and supplying filters that protect the environment and deliver the lowest LCC will continue to be the number one factor in our research & development departments.

camfil FARR

On world standards...

...Camfil Farr is the global leader in clean air technology and energy efficient air filter solutions with product development, R&D and local representation in the Americas, Europe and Asia-Pacific region.

We supply high quality products and services with the aim of making our customers operations more sustainable, energy efficient and productive.

Our own vision of sustainability is a global approach combining consideration for people, environmental protection and business performance.

Camfil Farr is a member of the United Nations Global Compact programme and follows the GRI sustainability reporting framework.

www.camfilfarr.com

FOR FURTHER INFORMATION PLEASE CONTACT YOUR NEAREST CAMFIL FARR OFFICE.
YOU WILL FIND THEM ON OUR WEBSITE.

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