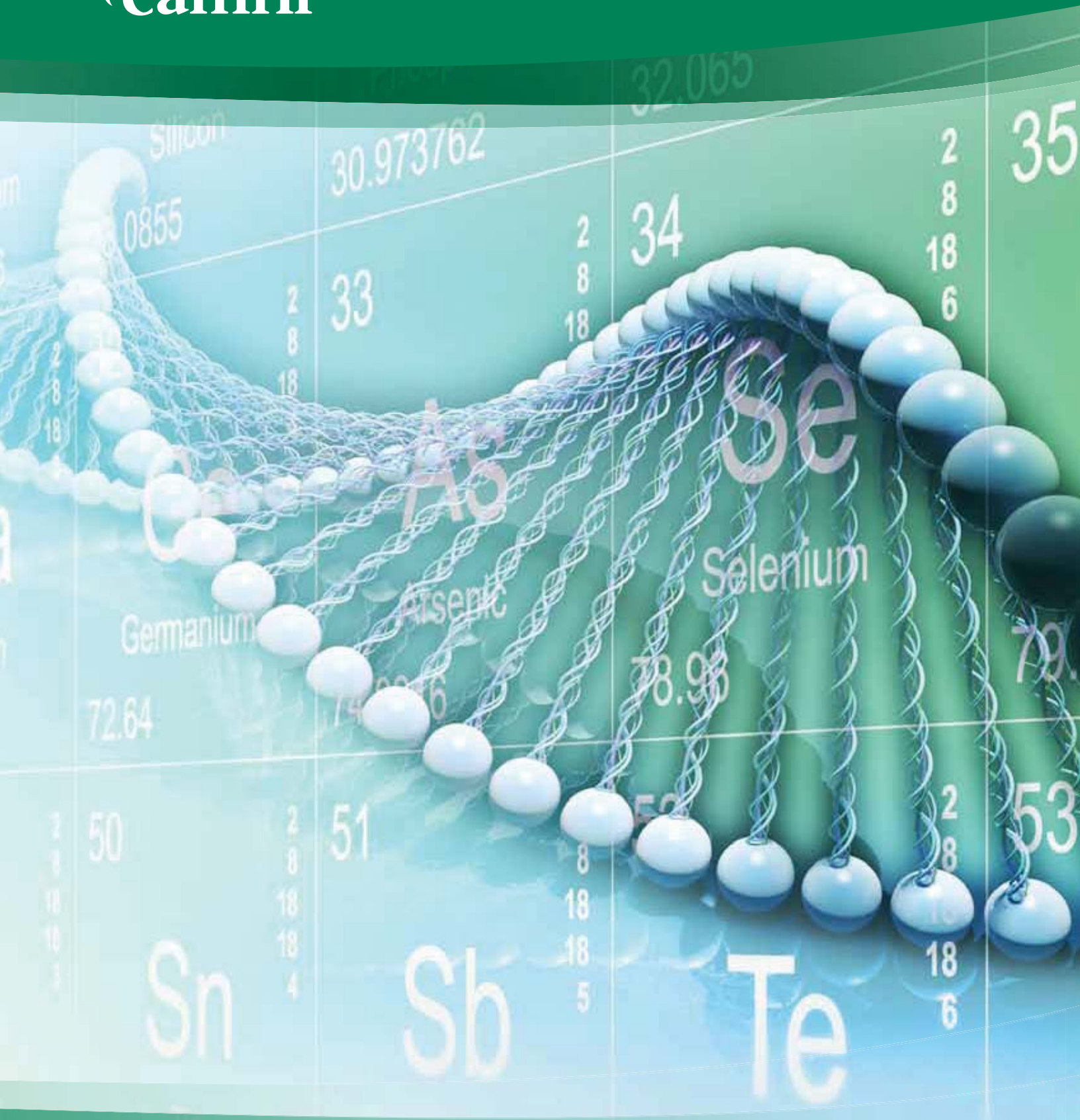
camfil

LIFE SCIENCE INDUSTRY



Clean air solutions

SUSTAINABILITY
ENERGY SAVINGS

For over 50 years, the Camfil group have been developing the air filtration solutions to help customer's improve indoor air quality at lowest possible energy costs. By doing so our customers can protect people, processes and the environment from air pollution, while reducing their carbon footprint, in a profitable way.

According to the US EPA Agency, sustainable buildings shall reduce the overall impact of the built environment on human health and the natural environment by:

- Efficiently using energy, water, and other resources
- Protecting occupant health and improving employee productivity
- Reducing waste, pollution and environmental degradation

Energy efficiency becomes a tool to achieve global financial performance involving business controlers and finance departments, whereas it was delegated to maintenance departments so far.

Sustainable air filtration solutions, can provide concrete answers to new requirements from authorities regarding climate change mitigation and energy efficiency policies implementation, without compromising indoor air quality.

It is all about finding the right balance between energy conservation and people health or environment protection. Without a global approach, people health and environment protection will be trade off.

Today priority is given to energy efficiency and indoor air quality is overlooked, most of the time considered as an additional feature for good comfort of buildings occupants. However, scientific evidences has shown the direct impact of indoor air pollution on peoples health. Optimizing ventilation and air filtration in buildings lead to unsuspected cost savings and enhanced productivity.

Camfil was the first air filter manufacturer to produce and publish a sustainability report. This was the year 2009.

ENERGY IMPACT

THE COST OF VENTILATION
It is well known that building ventilation costs are significant. The "typical" energy cost of filters as a percentage of the total system is approximately 30%.

A bad filter construction could add 50 Pascal (0.2" wg) compared to a "good" construction, even when the same filter class is used.

LCC – LIFE CYCLE COST
From a long-term perspective, it is evident that the energy consumption is the major overall cost cost in operating a filter.

Camfil has developed software to determine precise LCC costs for a particular filter, in any given system, with its unique conditions and requirements. Our Camfil Sales Team will help you optimise your system.

70% OF THE COST IS ENERGY!
Calculations reveal that energy normally accounts for **70% of the total life cycle cost** of the system. The energy consumption is directly proportional to the average pressure drop over the filter.

Q: *Air flow, m3/s (cfm)*
ΔP: *Average filter pressure loss, Pa (in WG)*
T: *Operation time, hr*
η: *Fan efficiency, %*
Pc: *Cost of Power, $/kWh*
Co: *Constant, 1000 in SI units, 8515 in IP units*

$$Energy\ (E) = [(Q \cdot \Delta P \cdot T)/(\eta \cdot Co)] \cdot Pc$$

TOTAL COST OF OWNERSHIP

It is important to focus on the right things when choosing a filter. Using the initial resistance to airflow can be a bad indicator of the **Total Cost of Ownership (TCO)** for a filter selection. The way the filter loads in real life applications is vital to determining the true cost.

Many believe that adding prefilters will extend the life of the final filter and save the user money. In some extreme cases this can work out, but multiple stages of filtration will rarely reduce the TCO. Generally multiple filtration stages are used to achieve a higher level of particle removal efficiency or to provide a safety factor with filter redundancy.

The **Camfil LCC Green Software** program can calculate the total cost of ownership for filters in actual usage and will be used by our local representative to calculate the total cost for specific systems, upon request. This is an excellent tool for evaluating the performance of air filters under various conditions such as evaluating the effect of running at a higher or lower airflow rate.

The data utilized by the LCC Green Software is generated using multiple methods, including the CamField Labs. However, one of the premises of comparing total cost of ownership calculations is the calculations have to be run on equivalent particle removal efficiency filtration systems.

Thus, if one filter drops in efficiency to a level below the minimum specified by the customer or application the comparison of the TCO is not the same as we are not comparing 'apples to apples' with filter efficiency.

SUMMARY EXAMPLE OF COMPARING VARIOUS STAGES AND TYPES OF FILTERS BASED ON TCO

Filter(s)	Filter Price ($/filter)	Changes per year	Average Rest. For 1 year (inWG)	Energy Cost ($/Filter/yr)	Labor & Waste ($/filter/yr)	Total TCO ($/filter/yr)	Total TCO for AHU ($/AHU/yr)
Camfil, Hi-Flo ES	$80	1	0.60	$246	$7	$333	$6,658
Competitor Pleat	$3.50	5	1.24	$508	$20	$582	$11,645
Competitor Pocket	$30	1	1.24	$508	$7	$582	$11,645
Competitor, 4V	$80	1	0.90	$371	$7	$458	$9,157

- **Total TCO** = [(Filter Price · Changes) + (Energy Cost) + (Labor & Waste)] · Number of Filters
- **Labor & Waste** = [Labor & waste cost * Changes]
- **Energy Cost** = [(Resistance * Airflow * Time) / (Fan Eff)] * Cost of Energy

- Air Handle Unit size – (20) 24x24 filters
- Fan operation – 8,760 hrs/yr
- Fan Efficiency – 55%
- Filter Air flow rate – 2,000 cfm per 24x24 filter
- Pre-filter labor rate (including waste cost) – $4/filter
- Final Filter labor rate (including waste cost) – $7/filter
- Cost of Energy – $0.11 per kWh

AIR FILTRATION
INTERNATIONAL STANDARDS

HVAC AIR FILTER STANDARDS

The filtration industry is inundated with multiple filtration standards to classify, identify, and evaluate various performance characteristics of an air filter.

In the USA, the organization known as ASHRAE (American Society of Heating, efrigerating, and Air-Conditioning Engineers) was founded in 1894 and is currently an international organization of 50,000 persons. ASHRAE has published a laboratory filtration performance standard for testing air filters since 1968 and all have been accredited by the American National Standards Institute (ANSI) to define minimum values or acceptable performance.

In Europe, the history of the filtration standards mimics the ASHRAE standard path. The European Committee for Standardization (CEN) formalized their filtration standard in 1993 with the publication of EN 779:1993. This document was very similar to ASHRAE 52.1-1992 and with only minor differences, used the same equipment and test method of the ASHRAE standard. In 2002 CEN followed the ASHRAE lead by revising EN-779 into a particle removal efficiency standard similar to ASHRAE 52.2. However, this new document EN-779:2002 had some striking differences, both good and bad. In 2002 CEN released the version of the European EN-779 standard.

As with the 1999 revision to the ASHRAE document, this new procedure converted from Dust Spot efficiency to a particle removal test method. The actual test method and equipment used is different between the two standards in a number of ways with the most important variations listed below:

Particle size range measured – Since 99% of all the particulate found in atmospheric air is below 1.0 micron it is important to know the filtration performance below that point. ASHRAE went with a higher upper limit to be able to provide particle removal efficiency for lower end pre-filters.

The EN 779 standard was revised in 2012. EN779:2012 now classifies fine air filters according to their lowest filtration efficiency, referred to as "Minimum Efficiency" (ME). The introduction of the new criteria for F7 to F9 filter classes secures the air cleaning ability of air filters over time, regardless of the type of filtration media that the filters are made of. This will have a beneficial impact on indoor air quality.

To support the selection of energy-efficient air filters, EUROVENT, the trade association for the European HVAC industry, has developed guidelines, Eurovent 4/11 Document,to classify air filters according to their performance and energy consumption during the usage phase.

As a result, air filters offering the same air cleaning performance can be compared on the basis of their annual energy consumption. This tool now allows the selection of efficient filters according to EN 779 while keeping energy consumption as low as possible.

AIR FILTERS TESTING STANDARDS COMPARISON

ASHRAE Standard 52.2-2012				ASHRAE 52.1-1992		EN 779 2012				
Minimum Efficiency Reporting Value	Composite Average Particle Size Efficiency, % in Size Range, microns			Average Arrestance	Average Dust Spot Efficiency	Class	Group	Average Efficiency at 0.4 micron[1]	Average Arrestance of synthetic dust	Minimum Efficiency at 0.4 micron[1]
	Range 1	Range 2	Range 3							
MERV	0.30 - 1.0	1.0 - 3.0	3.0 - 10.0	%	%			%	%	%
1	n/a	n/a	E_3 < 20	A_{avg} ≥ 65	< 20	G1	Coarse	-	50≤ A < 65	-
2	n/a	n/a	E_3 < 20	A_{avg} ≥ 65	< 20	G2		-	65 ≤ A < 80	-
3	n/a	n/a	E_3 < 20	A_{avg} ≥ 70	< 20					
4	n/a	n/a	E_3 < 20	A_{avg} ≥ 75	< 20					
5	n/a	n/a	E_3 ≥ 20	80	20	G3		-	80≤ A < 90	-
6	n/a	n/a	E_3 ≥ 35	85	20-25					
7	n/a	n/a	E_3 ≥ 50	90	25-30	G4		-	90≤ A	-
8	n/a	n/a	E_3 ≥ 70	92	30-35					
9	n/a	n/a	E_3 ≥ 85	95	40-45	M5	Medium	40< E ≤60	-	-
10	n/a	E_2 ≥ 50	E_3 ≥ 85	96	50-55					
11	n/a	E_2 ≥ 65	E_3 ≥ 85	97	60-65	M6		60< E ≤80	-	-
12	n/a	E_2 ≥ 80	E_3 ≥ 90	98	70-75					
13	n/a	E_2 ≥ 90	E_3 ≥ 90	98	80-85	F7	Fine	80< E ≤90	-	35
14	E_1 ≥ 75	E_2 ≥ 90	E_3 ≥ 90	99	90-95	F8		90< E ≤95	-	55
15	E_1 ≥ 85	E_2 ≥ 90	E_3 ≥ 90	99	95	F9		95≤ E	-	70
16	E_1 ≥ 95	E_2 ≥ 95	E_3 ≥ 95	100	99	NA	NA		-	-

Notes:
The final MERV value is the highest MERV where the filter data meets all requirements of that MERV.
The characteristics of atmospheric dust vary widely in comparison with those of synthetic dust used in the tests. Because of this the test results do not provide a basis for predicting either operational performance or life. Loss of media charge or shedding of particles or fibers can also adversely affect efficiency.
[1]Minimum efficiency is the lowest efficiency among the initial efficiencies, discharged efficiency and the lowest efficiency throughout the test procedure.

ISO 29463 CLASSIFICATIONS

Filter Class (Group)	Particle Size for Testing	Global Values		Local/Leak Values		
		Collection Efficiency (%)	Penetration (%)	Collection Efficiency (%)	Penetration (%)	Multiple of Global Efficiency (%)
ISO 15 E	MPPS	≥95	≤5	-	-	-
ISO 20 E	MPPS	≥99	≤1	-	-	-
ISO 25 E	MPPS	≥99.5	≤0.5	-	-	-
ISO 30 E	MPPS	≥99.9	≤0.1	-	-	-
ISO 35 E	MPPS	≥99.95	≤0.05	≥99.75	≤0.25	5
ISO 40 E	MPPS	≥99.99	≤0.01	≥99.5	≤0.5	5
ISO 45 E	MPPS	≥99.995	≤0.005	≥99.975	≤0.025	5
ISO 50 E	MPPS	≥99.999	≤0.001	≥99.995	≤0.005	5
ISO 55 E	MPPS	≥99.9995	≤0.0005	≥99.9975	≤0.0025	5
ISO 60 E	MPPS	≥99.9999	≤0.0001	≥99.9995	≤0.0005	5
ISO 65 E	MPPS	≥99.99995	≤0.00005	≥99.99975	≤0.00025	5
ISO 70 E	MPPS	≥99.99999	≤0.00001	≥99.9999	≤0.0001	10
ISO 75 E	MPPS	≥≤99.999995	≤0.000005	≥99.9999	≤0.0001	20

EN1822 CLASSIFICATION

Filter Class	Particle Size for Testing	Global Values		Local Leak Values		
		Collection Efficiency (%)	Penetration (%)	Collection Efficiency (%)	Penetration (%)	Multiple of Global Efficiency (%)
E10		≥ 85	≤ 15			
E11		≥ 95	≤ 5			
E12		≥ 99.5	≤ 0.5			
H13	MPPS[a]	≥ 99.95	≤ 0.05	≥ 99.75	≤ 0.25	5
H14	MPPS[a]	≥ 99.995	≤ 0.005	≥ 99.975	≤ 0.025	5
U15	MPPS[a]	≥ 99.9995	≤ 0.0005	≥ 99.9975	≤ 0.0025	5
U16	MPPS[a]	≥ 99.99995	≤ 0.00005	≥ 99.99975	≤ 0.00025	5
U17	MPPS[a]	≥ 99.999995	≤ 0.000005	≥ 99.9999	≤ 0.0001	20

[a] MPPS - Most Penetrating Particle Size

IEST-RP-CC001

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

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

ISO 29463-1:2011 establishes a classifcation of filters based on their performance, as determined in accordance with ISO 29463-3, ISO 29463-4 and ISO 29463-5. It also provides an overview of the test procedures, and specifies general requirements for assessing and marking the filters, as well as for documenting the test results. It is intended for use in conjunction with ISO 29463 2, ISO 29463 3, ISO 29463-4 and ISO 29463-5.

EN-1822

This European standard is based on particle counting methods that actually cover most needs for different applications. EN 1822:2009 differs from its previous edition (EN 1822:1998) by including the following:

- An alternative method for leakage testing of Group H filters with shapes other than panels
- An alternative test method for using a solid, instead of a liquid, test aerosol
- A method for testing and classifying of filters made out of membrane-type media
- A method for testing and classifying filters made out of synthetic fiber media
- The main difference is related to the classifica tion for the filter classes H10 - H12, which has now been changed to E10 - E12.

IEST –RP-CC-001

This Recommended Practice (RP), IEST-RP-CC001.5, covers basic provisions for HEPA (high efficiency particulate air) and ULPA (ultra-low penetration air) filter units as a basis for agreement between customers and suppliers.

HEPA filters and ULPA filters that meet the requirements of this RP are suitable for use in clean air devices and cleanrooms that fall within the scope of ISO 14644 and for use in supply air and contaminated exhaust systems that require extremely high filter efficiency (99.97% or higher) for sub micrometer (µm) particles.

This RP describes 11 levels of filter performance and six grades of filter construction. The customer's purchase order should specify the level of performance and grade of construction required. The customer should also specify the filter efficiency required if it is not covered by the performance levels specified in this RP.

ENGINEERING TOOLS

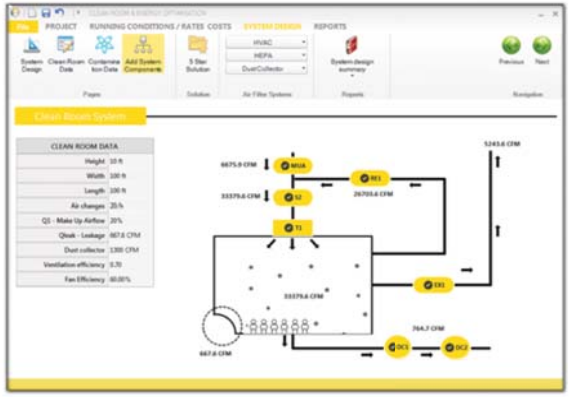
CREO SOFTWARE

The **Clean Room and Energy Optimization** software enables the user to create a customized clean room application. The software allows the user to calculate the Life Cycle Cost and cleanliness class for different Clean room designs.

Different Cleanroom configurations can be analyzed ranging from ventilating to unidirectional (Laminar flow) installations.

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



Wide ranges of reports are available, including Cleanroom classifications as well as specifications for selected products. Additional information such as CO_2-emissions and efficiency of the filter system is also available.

LCC SOFTWARE

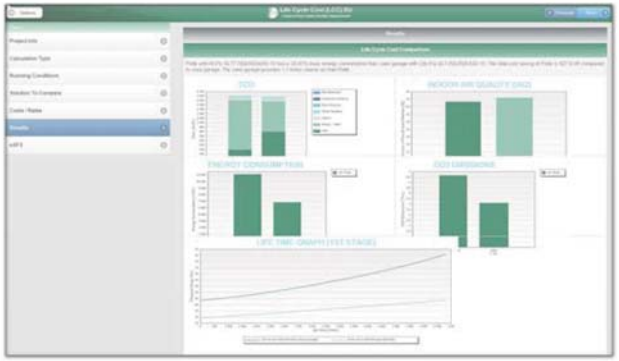
The **LCC (Life Cycle Cost)** software is a tool we have used successfully for many years in the Life Science industry. The volatile oil and energy markets and the ever increasing cost of supplying clean air are critical for this industry.

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.

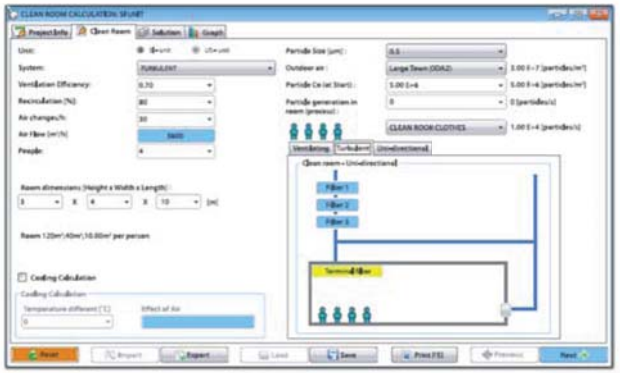
After filter survey's are carried out at the manufacturing facility, we can input the existing filter set up in the air handling units and optimize the selection of the lowest LCC filter combination for the facility in question.

Parameters the software includes:
Type of filters in use:

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



CLEAN SOFTWARE

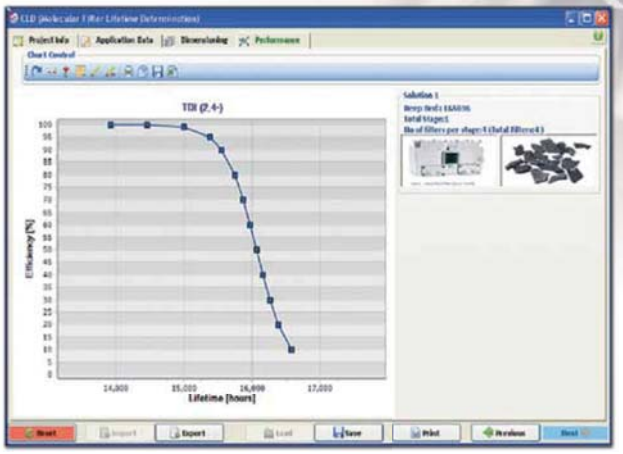


Before we developed **CREO**, the original cleanroom design software **CLEAN** was developed in the early 1990's and is still a useful software utilized today.

The software is perfect for a simple quick overview to calculate the desired cleanroom class and recovery time.

CARBON SOFTWARE

Camfil has developed a powerful sofware called **CLD (Carbon Lifetime Determination)** to simulate the efficiency and lifetime of molecular filtration solutions under application real conditions. The software provides the opportunity to input data relating to the application, e.g flow rate, contaminant gas(es), gas concentration(s), temperature and relative humidity. The performance of different molecular filtration products and adsorbent medias can then be compared. The output from the software is a an efficiency/lifetime chart, together with relevant data such as the application details, product selection, pressure loss and contact time.



The software has been developed using data from 3 sources:

1) Physical and chemical characteristics of the contaminant molecule, adsorption theory and adsorption isotherms.

2) The results from thousands of test reports generated in the Camfil molecular filtration test rigs. In these rigs, different products have been evaluated against a range of gases at different temperature and relative humidity values.

3) The results of on-site measurements and the observation of filter performance in the real world.

For optimal data, it is essential that the Camfil molecular filtration test rigs and CLD software can take account of the gas, gas concentration, temperature and relative humidity since these parameters directly influence the performance of a molecular filtration solution.

PHARMASEAL FOR
PRODUCTIVITY AND COMPLIANCE

PHARMASEAL:
Room side replaceable all welded terminal housing designed specifically for use in the Life Science Industry

LONG TERM SECURITY:
Pharmaseal is a fully welded terminal housing that is pressure tested to 750 PA (3"WG) as standard in addition to all penetrations through the housings having a visual soap bubble test on the welds selds

REDUCTION OF OPERATING COSTS AND INCREASED PRODUCTIVITY:
Regulatory requirements from bodies such as the EMA & FDA expect end users to periodically certify the HEPA filters installed in the Pharmaseal.

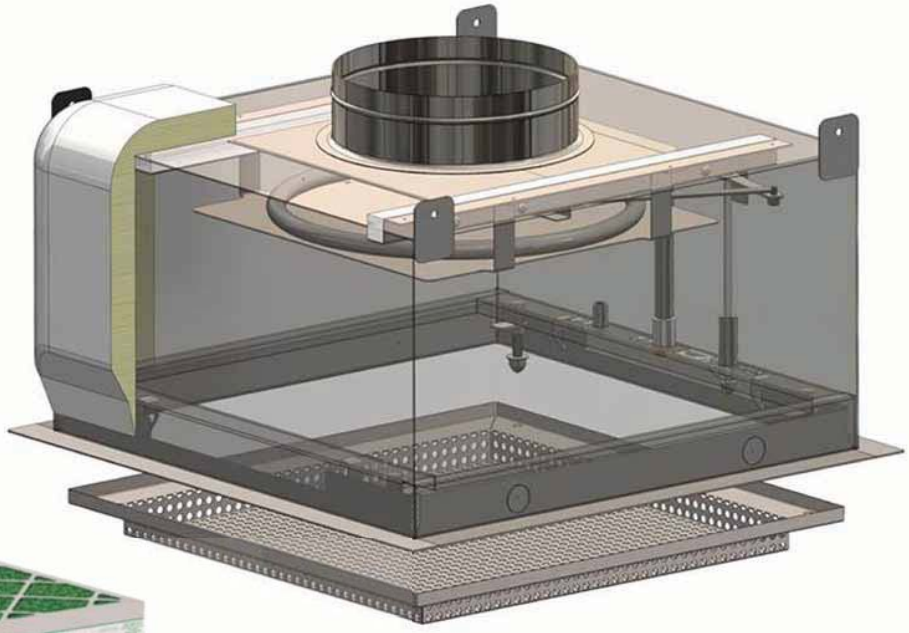
An integrated aerosol dispersion system fully compliant with IEST or similar standard requirements is installed in the Pharmaseal.

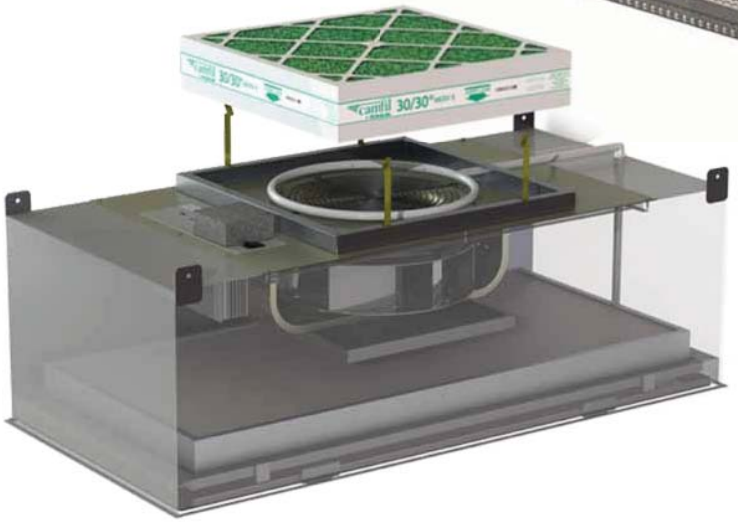
It's crucial to achieve sufficient upstream aerosol distribution which allows our customers the option to test each filter locally, while minimizing PAO or DEHS test aerosol contamination as well as decreasing test set up time.

ISOLATION OR VOLUME CONTROL DAMPERS OPTIONAL:
Being able to control the Pharmaseal Guillotine volume damper that can act as a 'full balancing damper' all controlled from the room side in addition to improving productivity and accuracy during the commissioning phase makes this device the damper of choice.

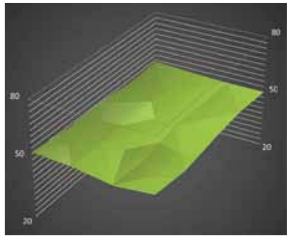
The Pharmaseal Isolation damper has been utilized in multiple vaccine or P3/BSL3 type applications where the need for decontamination of the space is required. The damper is integrated into the terminal housing with a memory stop to return the damper to the balanced position after decon. Possibility to integrate both isolation & volume control dampers into one housing with separate controls is optional.

FILTER OPTIONS:
The Camfil Pharmaseal can be installed with a Gel or Gasket seal HEPA filter depending on which region and preferences are required. Pack depths from a nominal 2"-4" (45mm-90mm) are also optional depending on air volume requirements.





UNIFORM AEROSOL DISTRIBUTION



VORTEL AIR DIFFUSER:
A revolutionary new air diffuser specifically designed for cleanroom applications. The Vortel diffuser is delivered as standard with the Pharmaseal housing.

TWO PRIMARY FUNCTIONS:

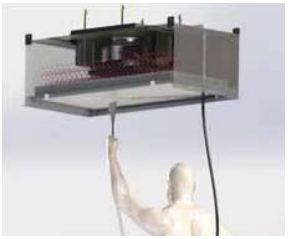
1 New construction Projects:
The Vortels superior air distribution and ventilation effectivness allows the designer to deliver the same or more amount of air with less terminal housings.

2 Retrofit Applications:
The Vortel can deliver improved ventilation effectiveness with less air or reduced air change rates saving substantial operating costs.

PHARMASEAL FFU
The Pharmaseal FFU is the first product designed and tested to meet the Life Science industry certification factory & field aerosol testing requirements.

It's unique room side replaceable HEPA and aerosol injection system minimizes downtime and delivers consistent repeatable test results while still maintaining the construction characteristics and features of the Pharmaseal.

TESTING
Testing may be performed on site using the standard features of the Camfil Pharmaseal FFU module. Airflow during testing can be controlled from the room side.



MINI ENVIRONMENTS

RABS
(Restricted Access Barrier system):
A barrier system with a rigid wall enclosure, undirectional airflow providing an ISO 5 environment, glove ports with sterilizable (preferably sterilizable-in-place or CIP) surfaces, and are typically surrounded by an ISO 7 or lower environment.

Three types of RABs exist:

- Active
- Passive
- Closed

RABS are not airtight and are not sterilizable using vaporized hydrogen peroxide like isolators. c.RABS can operate as "doors closed" for processing with very low risk of contamination similar to isolators, or permit rare "open door interventions" provided appropriate measures are taken.

ISOLATOR:
A leak tight enclosure designed to protect operators from hazardous/potent processes or protect processes from people or detrimental external environments or both.

A basic enclosure consists of a shell, viewing window, glove/sleeve assemblies, supply and exhaust filters, light (s), gauge (s), Input and Output openings (equipment door airlocks, Rapid Transfer Ports (RTPs), etc.), and various other penetrations. Sterile filtration and filling are performed under positive-pressure and can be completely decontaminated. Areas of application include syringe lines and many other fill/finish operations.

The Isolator or RABS acts as the primary barrier within the classified space. In more recent applications the need has arisen to install a secondary barrier as close to the primary barrier as possible.

The Camfil Pharmatain BIBO or safe change room mounted housing was developed specifically for such applications.

There is a trend towards small facilities similar to what happened to the semiconductor industry from large ballrooms to mini-environments or SMIF technology:

- ISO 5 is the standard inside the Isolator with an ISO 7 or 8 background.
- Both aseptic and containment facilities opportunities apply. There is a growing acceptance and even preference by regulatory agencies with these systems

Camfil is partnering with RABS-Isolator companies to customize air filtration and latest housing technology such as our Camsafe auto scan system.

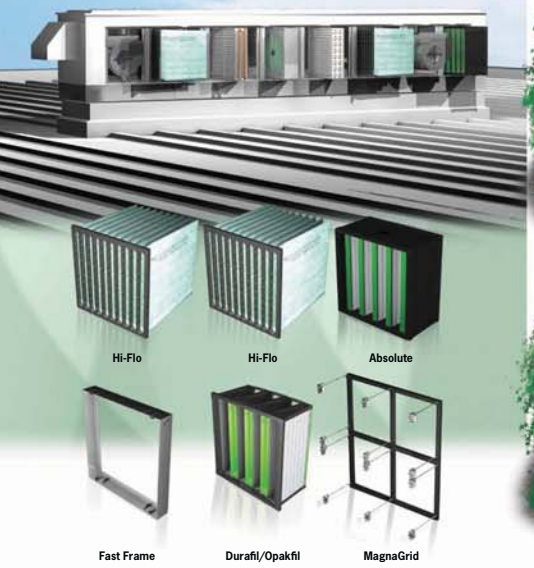
We are well positioned to offer our customers all of their air filtration needs from the outside air through to the most critical applications found in these critical processes.

RABS

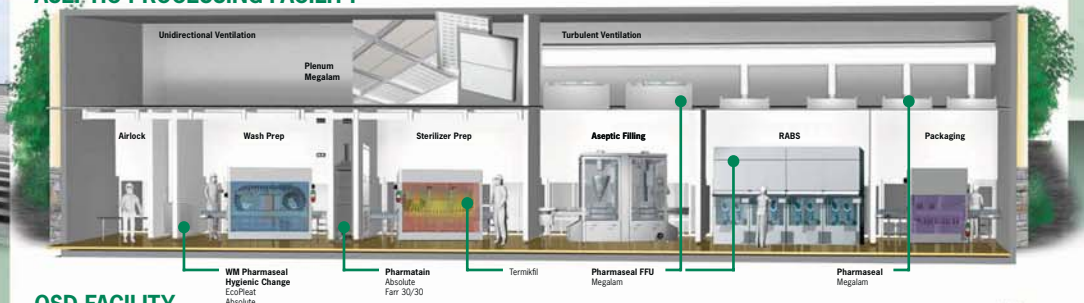
ISOLATOR


...AND OUR
APPLICATION
KNOW HOW!
YOU CAN
COUNT ON
CAMFIL
PRODUCTS...
EU
ISO
CFR
GMP
EMA
FDA
IEST

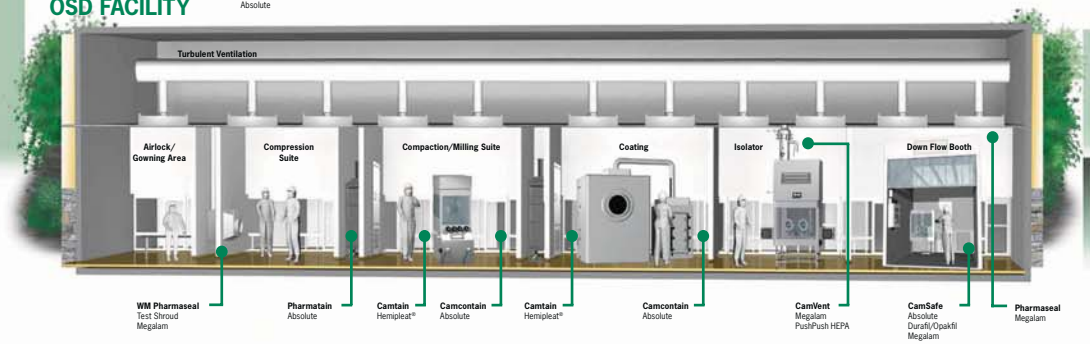
OUTSIDE AIR



ASEPTIC PROCESSING FACILITY



OSD FACILITY



SUPPLY, EXHAUST & RECIRCULATING AIR

HIGH TEMPERATURE FILTERS

HEPA filters, when exposed to elevated temperatures, present multiple challenges for filter integrity testing. It is one of the few areas of air filtration where there are simply no black or white answers.

To summarize Camfil's experience on this subject, the following are some recommendations and answers related to high temperature filters.

WHAT IS THE PRIMARY APPLICATION OF HEPA FILTERS AT ELEVATED TEMPERATURES?

These filters are used in ovens and tunnels designed for use in the Life Science and Microelectronics industries. This equipment may be performing sterilization and depyrogenation of instruments or glassware (vials) in Life Science and die-bond curing or other semiconductor packaging processes. Applications can range in temperature from 212° to 752° F (100° to 400° C) and require ramprates (burn-in) from steady state to as much as 60° F + per minute (15° C/min). These variations create tremendous stress and challenge to the filter's construction and therefore filter performance integrity.

CAMFIL 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 m³/h	730/1200 cfm 1240/2050 m³/h	1765 cfm 3000 m³/h	700 cfm 1200 m³/h	1040 cfm 1770 m³/h	1000 cfm 1770 m³/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" & 11½" 150 & 292 mm	6" & 11½" 150 & 292 mm	11½" 292 mm	3.3" 84 mm	6" &11½" 150 & 292 mm	11½" 292 mm
Standard Gasket aluminum & fiberglass		fiber glass	fiber glass	silicon	rolled fiber glass	silicon
Alternate Gasket no gasket		no gasket	no gasket	no gasket	no gasket	no gasket
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 m²	123/242 sq. ft. 11.4/22.5 m²	431 sq. ft. 40.0 m²	130 sq. ft. 12.1 m²	186 sq. ft. 17.3 m²	180 sq ft 16.7 m²
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**

WHAT ARE THE OPTIONS FOR CONVENTIONAL HIGH TEMPERATURE FILTERS?

There are two common types of high temperature HEPA filters, in simple terms, silicone and ceramic sealed filters. For the silicin type, one is for moderately high temperature and is often used in the supply and exhaust ("cool" zone) of an oven in addition to the recirculated HEPA filters and for a variety of other applications. The distinguishing characteristic of this filter is the red high temperature silicone potting compound used to seal the metal-separated media pack to the metal fiilter frame. There are sometimes slight manufacturing differences, with different location within Camfil.

European (EU) manufatured filters in this class are rated at 482° F (250° C), in the United States (US) they are rated at 500° F (260° C).

The other high temperature HEPA filter type has a white ceramic sealant, and is most commonly used in the "hot" zone of a tunnel and for other very high temperature applications. These filters incorporate a ceramic material to seal the metal-separated filter pack to the metal frame. Again there are slight differences in temperature ratings due to some specific design criteria, EU is rated to 662° F (350° C) and the F series in the US is rated to 750° F (398° C).

TERMIKFIL

F-SERIES/FRK

SOFILAIR HT/FRSI

HEPA/ULPA
APPLICATIONS

Hepa filters are used in a wide variety of applications, different components are utilized in the filters construction as well as the test methods employed to optimize the filters life while still delivering the desired filter efficiency.

HEPA FILTERS
Camfil's Megalam & Absolute brands are specified daily and chosen by our customers worldwide for the most critical applications, these filters are used to protect the process from contamination, they often must be resistant to a wide range of cleaning and decon agents as well as the test aerosol used periodically during the filters working life.

HEPA filters used on the exhaust air are used to protect the people and our environment from any harmful or dangerous compound or virus being generated in the classified space.

FILTER CONSTRUCTION
There are 5 main components of materials utilized in a HEPA filter.

Frame:
Produced in aluminum, electro galvanized, MDF, Stainless and steel and plastic as standard.

Media:
Glass fiber as standard for 99% of applications, PTFE media historically supplied to the Microelectronics industry has potential but unproven applications in Life Science today.

Sealant:
Thixotropic Urethanes, High temperature ceramics and silicone sealants are used widely in HEPA filters.

Gaskets:
This can be a liquid such as Gel which can be delivered in Silicone & Polyurethane, Neoprene, poron & one piece PU gaskets also apply.

Media separator:
Hot melt, aluminum & glass thread are 3 common methods delivered by Camfil globally depending on the application.

TEST METHODS
Being the world's largest supplier of HEPA filters with production plants in all corners of the globe, we need to manufacture specific grades of filters to meet local, regional and international standards. We manufacture in-house all major scanning and pleating machines to ensure consistency of product quality and construction throughout the world.

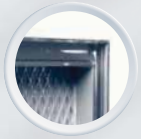
We primarily manufacture filters in accordance with EN-1822 part 5, IEST CC 034 & ISO 29463.

Applications that require shake table testing, high airflow, burst pressure tests, High temperature tempering are often used subject to demand.

PLEATING
Proprietary pleating technology allows us to produce and optimize pleat height to maximize performance.

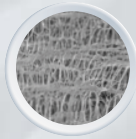
GASKET
Installations mainly utilize a Gel or PU endless gasket system as seen below.

PU endless Gasket

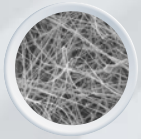


Gel

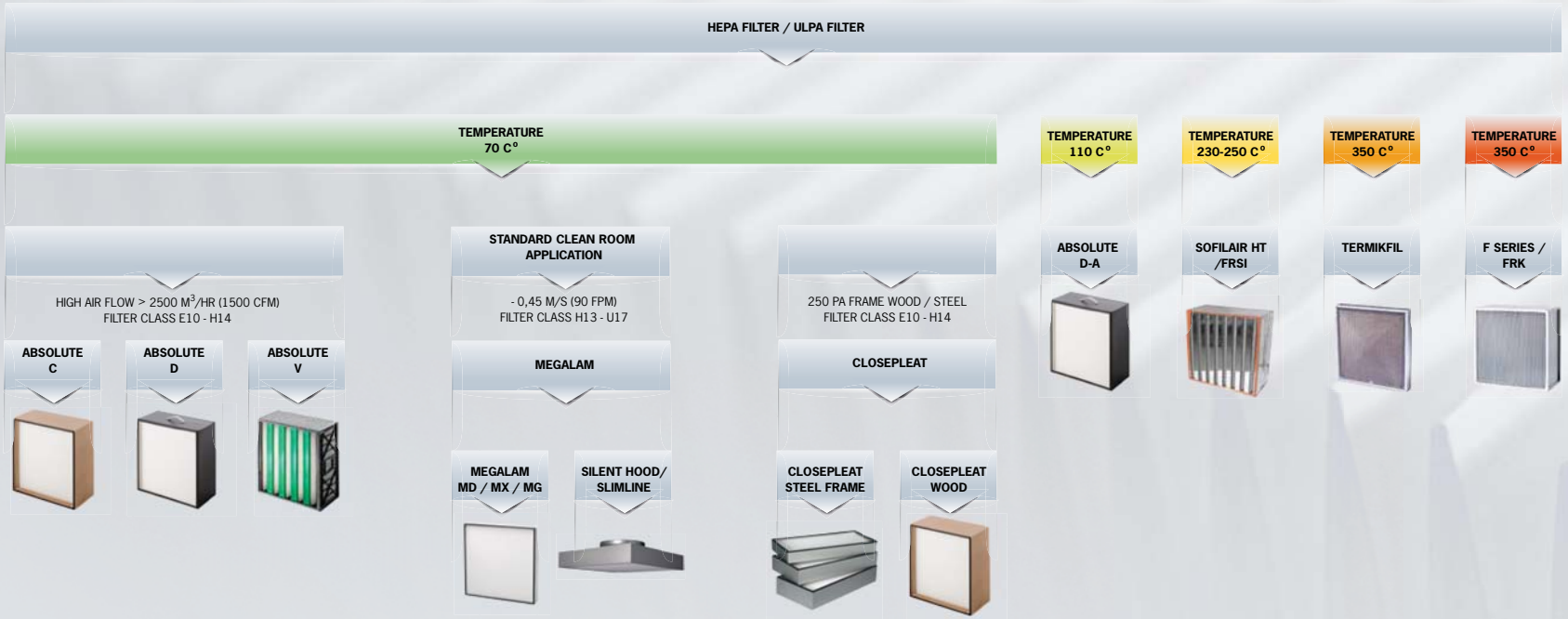
MEDIA



Other



Glass fibre



CONTAINING YOUR PROCESS
BIOSAFETY & CONTAINMENT

CONTAINMENT IN LIFE SCIENCE APPLICATIONS:

A methodology for Performance based control banding of specific compounds was first developed in the late 1980's by a pharmaceutical industry safety group which included companies then named as Merck & Co, Abbott Labs, Syntex, Eli Lilly & Upjohn.

The banding system adopted was essentially based on the Bio-Safety levels BSL-1-BLS-4. It became known as the 'Merck model' published in AIHA Journal in 1996.

There has been different terminology used, the high potency of some pharmaceutical compounds required the use of alternatives to setting numerical occupational exposure limits (OEL's).

Performance-Based Exposure Control Levels (PB-ECL) or occupational exposure bands (OEB's) were adopted especially for early development compounds where information was limited.

PB-ECL can define a exposure control strategy based on substance specific properties linked to a concentration limit and placed in a banding system of 1 of 4 hazard "bands". These bands define practices of containment such as:

- Level of containment
- LEV (Local Exhaust Ventilation) requirements
- General ventilation requirements
- Respiratory protection/PPE use
- Exposure assessment practices

Of the 4 categories established, they can be broadly defined as follows:

- Category 1 Low toxicity
- Category 2 Intermediate toxicity
- Category 3 Toxic (potent/hazardous)
- Category 4 Highly toxic (highly potent/hazardous)

Most major Pharma companies have used this categorization as a base to establish their own specific internal guidelines driven by a combination of internal and external Toxicologist, EHS&S & Engineering. One such expanded banding system along with exposure control limit is shown below.

THERE ARE BASICALLY 3 TYPES OF CONTAINMENT TECHNOLOGIES for control of potent Active Pharmaceutical Ingredients (API's) & liquids utilized today. The traditional cleanroom, a RABS (Restricted Access Barrier System) or a fully isolated system, all have pros and cons when it comes to operating cost, risk and capital investment.

What is consistent and necessary in all of the equipment mentioned and to minimize the risk is the use of HEPA filters and containment housings.

Camfil is a global supplier to many of the leading equipment providers as well as supplying and developing housings, containment, and testing apparatuses (CamScan) to optimize the effective functionality of the equipment utilized today and meet and exceed the demands of the future.

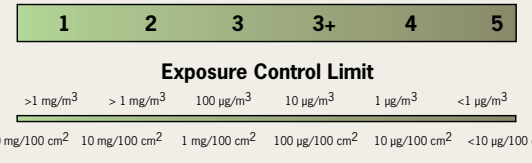
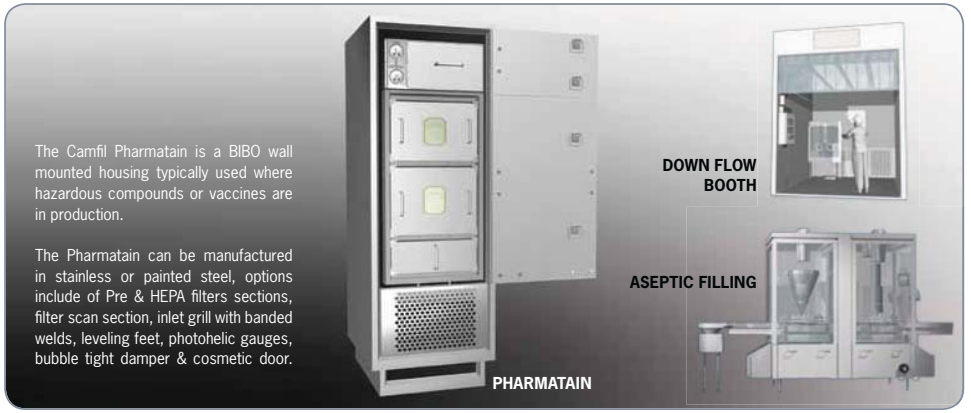


TABLE III Comparison of HSE Hazard Categories and PB-ECL Categories

Control Bank	HSE Hazard Group	Merck PB-ECL Category
>1 - 10 mg/m³	**A** - Use good industrial hygiene practise	**1** - Good manufacturing practises
>0.1 - 1 mg/m³	**B** - Use local exhaist ventilation	**2** - Good manufacturing practises (with local exhaust ventilation)
>0.01 - 0.1 mg/m³	**C** - Enclose process	**3** - Essentially no open handling (ventilated enclosure required)
>0.001 - 0.01 mg/m³	**D** - Seek specialist advise	**3+** - Virtually no open handling (containment systems required)
≤0.001 mg/m³	**D** - Seek specialist advise	**4** - No open handling (closed systems required)
≤0.001 mg/m³	**D** - Seek specialist advise	**5** - No manual operations/human intervention (robotids or remote operations required)

Some examples of equipment utilized for various process steps and hazardous compound band levels



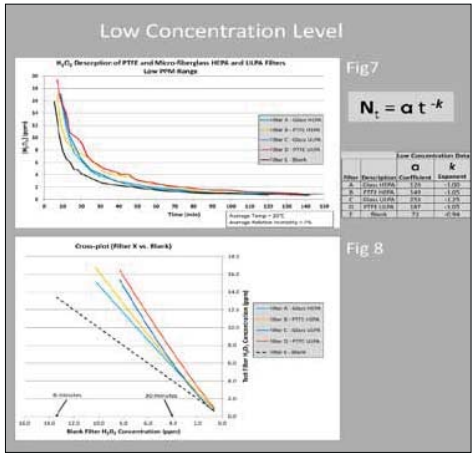
CAMFIL R&D CAPABILITIES:

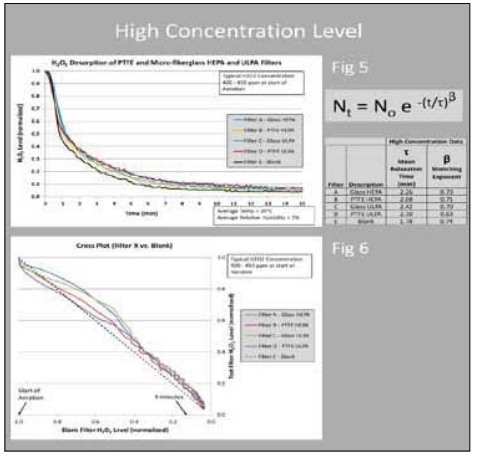
The study of how HEPA filters behave with different media types and how media, gel, frames etc reacts to common cleaning and decon agents has been studied extensively within our R&D departments globally. One such study result is outlined below.

Adsorption characteristics of micro-fiberglass and PTFE HEPA filter media to vaporized hydrogen peroxide Vaporized hydrogen peroxide is commonly used to decontaminate a variety of enclosures including bio-safety cabinets and labs, filling and sterility-test isolators, animal holding and clean rooms, decontamination chambers and pass-throughs.

In some cases peroxide vapor is introduced via a HEPA filter and in others HEPA filters are part of systems used to re-circulate and distribute the vapor. In some instances the aeration phase of a decontamination cycle is the longest. Initially a rapid decline in concentration can be observed that directly correlates with the rate of peroxide-free air introduced. This is followed by a much more gradual decline following the first few air exchanges where eliminating peroxide from an enclosure becomes a function of desorption.

Because the surface area of a HEPA filter typically exceeds the total surface area of the enclosure by several orders of magnitude, it is likely that steps taken to minimize aeration times for HEPA filters will have a direct impact on shortening cycle times.
(*Full report available upon request.)





PROTECTING THE ENVIRONMENT
FROM HARMFUL DUST

Gold Series Camtain GSC2 Safe change filters and continous liner dust discharge system.

CAMFIL HANDLING EXPLOSION PROTECTION

Most solid substances used in the pharmaceutical industry if they occur in powder form are potentially explosive.

Typical processes are tablet manufacturing and mixing of substances in powder form. In addition to this comes solvent use, these solvents are sometimes used in the process or for cleaning process equipment. This makes explosion safety an important issue for the industry. Over the years there has been several big accidents and the present state of safety on equipment is often lacking.

GOLD SERIES CAMTAIN™ DUST COLLECTOR FOR PHARMACEUTICAL AND CONTAINMENT APPLICATIONS

The Gold Series® Camtain™ is used in a wide range of pharmaceutical applications including tablet presses, coating, fluid bed and spray drying, blending, granulation and general ventilation.

Safe-change (BIBO) containment systems are available for both the filter cartridges and discharge system underneath the collector.

The cartridge change utilizes the safe change filter replacement method while the discharge uses continuous liner technology.

The Gold Series Camtain is perfect for high efficiency filtration in pharmaceutical manufacturing processes where recovery of the product is not required.

The only dust collector that is potent compound surrogate tested for validated performance verification. Test report available upon request.

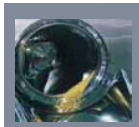
Camfil use various technologies to protect our Equipment and Pharmaceutical workers in these circumstances .We can help and provide advice on a case by case basis.

In Europe The ATEX rules set the basic framework, but this is not sufficient as the reality is often too complex for detailed rules, in these areas experienced suppliers and advisors are equally important.

Relevant solutions designed with safety in mind and not only the simple rule compliance will give you a sound basis of safety.

Camfil APC experts have the industry experience and knowledge to help Pharmaceutical plants comply with legislation, make workplaces safe for operators and maintenance people and be environmentally friendly on emission limit's whilst still insuring low Total Cost of Ownership of our equipment at your facility.

Camfil have developed ATEX approved Hepa housings and Filters for use in the life science industry in order to avoid any electrostatic hazards from gas or dust in ATEX zones.


Coater application


Blending application


Granulation application


Tablet press application

PROCESSES INVOLVING PHARMACEUTICAL DUST

- Tablet presses
- Tablet coating
- Fluid bed drying
- Spray drying
- Blending
- Granulation
- General room ventilation

Gold Series Camtain units in various configurations available for custom applications.

Scan to see video about safe change

Surrogate tested bag-in/bag-out safe change option available.

Scan to learn more or go to www.camfilfarrapc.com/pharma

Gold Series Camtain GSC6
for process room exhaust ventilation.

High efficiency **Gold Cone® HemiPleat®** filters up to MERV 16 stop 99.99% of the dust at 0.5 microns!

We carry out research so you can breathe clean air.

RESEARCH FOR THE LIFE SCIENCE INDUSTRY

Camfil is a family company with an unusually strong interest in technology. Since the earliest days we have invested large amounts of money in research and development. We believe that R&D is one of the most important factors behind our success.

By constantly investing in our business, we have become the world's leading filter manufacturer. And by collaborating with universities, colleges and organisations such as the Karolinska Institute, the Wallenberg Laboratory and the IVL Swedish Environmental Research Institute, we keep ourselves permanently up-to-date. We also have representatives within a number of international organisations, including Eurovent, CEN, ISO and ASHRAE.

We are continuously working to ensure that our end-products are the best on the market. And by staying at the leading edge, we can meet the requirements of the future.

Constant new investment
The most recent expansion of our corporate R&D facility is the latest in a series of major investments. We now have four completely new labs – a particle lab, a molecular lab, an IAQ (Indoor Air Quality) lab and a gas turbine lab – all complete with the latest technical equipment. Our high-efficiency particle and comfort filter lab can carry out tests in accordance with EN 779 for Europe and ASHRAE for the USA.

The ultramodern technical centre covers an area of 2,500 m2 and acts as an innovation hub for product and process solutions. It includes the air filter industry's largest and most advanced laboratory for research into indoor air quality, with gas chromatography systems and a scanning electron microscope.

Air quality analysis
We have been using a proprierity air quality analysis method for more than 10 years. This method is unique within the industry and involves collecting particles from the air and studying them using a scanning electron microscope and accompanying X-ray analysis system.

The analysis shows the particle content of the air and the size and appearance of the particles. This provides useful information about the efficiency of the ventilation system. Using this method, we can carry out air, gas and dust analyses which show the actual benefits of our high efficiency air filters.

Our own innovations
Chemists, engineers and air quality specialists work at our technical centre. Their expertise ensures that we stay up-to-date on the latest developments. We use one area of the centre to develop our own processes, including designing machinery, creating new concepts and optimising industrial processes for filter production.

Our filters are known for maintaining their high efficiency over long periods, their low pressure drop and minimal servicing requirements. And their lower energy consumption also reduces overall operating costs.

By always setting high standards and not buying in standard solutions, we have maintained our position as the global market leader.

1. Molecular Lab
- Development of molecular filters
- Climate controlled test rigs for carbon media and full-size molecular filters
- Gas chromatography

2. GT/APC Lab
- Development of filter solutions for dust collection and gas turbines
- High-Speed filter rig for gas turbines
- Climate simulation

3. Process Development Workshop
- Development of process equipment for manufacturing filters
- Fully equipped machine shop
- 3D printer for prototyping

4. Particle Lab 1
- Development of comfort and HEPA filters
- Aerosol research
- Test rig for full-scale filters and smaller filters
- Nano particle measurements using an electrostatic classifier with CPC
- Filter media testing and development

5. Particle Lab 2
- Classification of filters according to EN 779:2012 and ASHRAE 52.2
- Energy classification of filters
- Classification rig and IPA discharge rig
- Remote-controled mobile laboratories for testing air filters in the field

6. IAQ Lab
- Quantitative and qualitative air quality analysis
- Media and fibre development
- Air quality research
- Scanning Electron Microscope, SEM

FIELD SERVICE CAPABILITIES

CAMTESTER 11
An easy to maneuver mobile test unit that can instantly identify pre filters performance and quantify the TCO when filters are newly installed or in use.

The CamTester delivers the following:

- Verifies initial resistance to airflow as published in manufacturers literature.
- Examine pressure drops of various types of prefilters to establish a product specification.
- Compare different brands and construction types from V-bank to Bag Filters and determine the best operating value for your installation.
- Provide data to identify filter replacement specifications.

CAMFIELD LAB
The Camfield Lab is a portable full scale laboratory for testing air filters. It contains four separate test ducts each with its own independent fan and control system.

The airflow for each test duct is manually set at the start of the test. The control system monitors resistance to airflow across the calibrated orifice plate installed in each duct. The VFD on each motor maintains the airflow of each test duct to the set point.

All air intakes are located together at the back of the lab so the sample air is as homogenous as possible for each duct.

The Camfield Lab is designed so the actual site conditions can be mimicked to see how our and competitors filter behave during real life. Airflow, pressure drop, filter efficiency, temperature and relative humidity can all be measured remotely trough cell phone technology.

CAMFIL CERTIFICATION SERVICES PROGRAM

Camfil has developed a wide range of on-site services depending on the location of our office or representative to monitor real life performance of pre filters and periodically verify filter life, efficiency and construction functionality.

PRE-FILTER ON SITE VERIFICATION:
Camfil CFIS (Camfil Field In Situ) test system has proved to be a valuable tool to verify real life performance of our own and our competitors filters. This real life data is loaded into our LCC (Life Cycle Cost) Green Software, another tool to simulate very quickly the TCO for a given facility.

This test method follows a prescribed protocol for field testing first developed by Eurovent (4/10-1996). ASHRAE updated the method and used the Eurovent document as the basis for Guideline 26-2008 (revised to 2012). The ASHRAE document was the basis for the latest ISO Standard for In Situ testing ISO-29462 published in 2013.

HEPA CERTIFICATION:
In some markets and countries our clients demand that Camfil supplies, installs & tests HEPA filters. These services can be offered by our own experienced technicians in-house or with chosen partners Camfil has approved and is fully compliant and familiar with the latest factory & field testing requirements.

End users and contractors favor the idea in many cases of the 'one stop shop' approach especially for these critical filters and applications.

SEM (Scanning Electron Microscope)
Measurement of IAQ and source contamination is a common request from Life Science customers. Camfil was the first and we believe only air filtration company who can offer these services with our in-house SEM.

Utilizing our own method developed by our R&D staff corporately, particles down to 0.1 micron in size can be captured and then studied in an SEM and associated with EDAX X-ray spectrometer. The SEM allows the study of particles and their surface structure, size, shape and composition of the particles captured.

Measurement of AMC or Gas contamination along with studies of Virus & Bacteria contamination helps compliemnt a wide range of field servies to support the supply of our products and ensure the best back up and technical competency in the industry.

CAMFIL is the world leader in air filters and clean air solutions.

Camfil is the global industry leader in clean air solutions with 50+ years of experience. Our solutions protect people, processes and the environment to benefit human health, increase performance, and reduce and manage energy consumption. Twenty-three manufacturing plants, six R&D sites and over 65 local sales offices worldwide provide service and support to our customers. The Camfil Group is headquartered in Sweden but more than 95% of sales are international. The Group has around 3,500 employees and sales in the range of SEK 4.9 billion.

www.camfil.com/Industries/Life-Science

For further information please contact your nearest Camfil office.