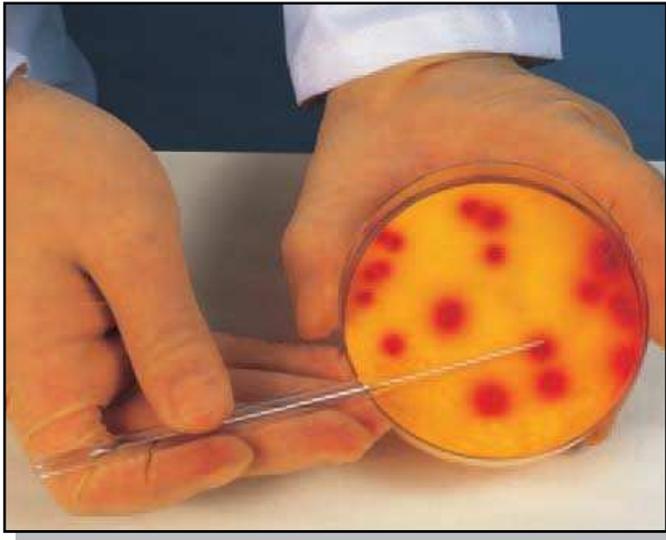


PROCESS FILTERS

for Compressed Air & Gas



Sterile Air : The Problem



THE PROBLEM

As the term micro-organisms suggests, these are extremely small and cover organisms such as bacteria, viruses and bacteriophage. Typically bacteria can reach a size of up 0.2 to 4 micron. Viruses are smaller than 0.3 micron and bacteriophage can be as small as 0.01 micron.

Notwithstanding their size, micro-organisms present a genuine problem in production processes that require sterile compressed air or other sterile gasses. As a "living organism" they are capable of multiplying at any speed, given the right conditions.

Even if only very few organisms capable of surviving enter a clean environment, a sterile process or production system, enormous damage can be caused that not only diminishes product quality but may even render the product entirely unfit for use.

Where sterile compressed air or other sterile gasses are required, there is no alternative to the use of sterile filters.

THE SOLUTION

A large variety of filters are available for the removal of oil, water and dirt from compressed air and other compressed gasses, but these filters do not remove micro-organisms effectively.

ZANDER Sterile Filters are specially designed to remove all micro-organisms and thus produce 100% sterile compressed air. This air can then be used in those processes in which sterility is crucial.

The **ZANDER** Sterile Filter Series covers a whole range of models, from filters for low air volumes in laboratories or pilot plants to filters for large scale industrial process applications.

THE APPLICATION

In a large number of processes sterile air and other sterile gasses are required for yeast cultures, filling, storage, packaging, etc.

Sterile filters have a wide range of applications with varying demands on the filter medium. Initial conditions are very different if a filter is used in a compressed air system with effective prefiltration as compared to a vent filter on a storage tank.

Filtration : Difficult Choices

OPERATION

When filtering air or gas by depth media filtration, three principal filtration mechanisms apply:-

- a) **Direct Interception**
With direct interception, particles impinge upon the surface of the filtration medium and are caught there. This mechanism applies to particles of 1 micron and larger.
- b) **Inertial Impaction**
With inertial impaction, particles cannot follow the winding open channels in the filter medium. They directly impinge upon the filter matrix and adhere to it. This filtration mechanism is restricted to particles of 0.3 to 1 micron.
- c) **Diffusion / Brownian's Molecular Motion**
With diffusion or Brownian's molecular motion, particles, with their own energy, can move independently within the gas flow. Thus, they inevitably collide with the filter material and are stuck deep in the filter medium. Particles of 0.3 micron or smaller are subject to diffusion.

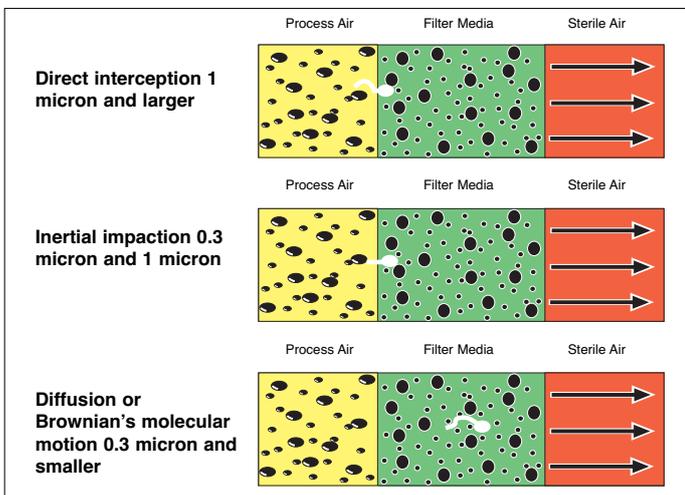


Fig. 1: Filtration mechanisms

These classical three filtration mechanisms for particles within the sub-micron range have been examined in many years of industrial and research studies. They all agree that certain particles have a higher filter penetration probability than others. With sterile gas filters these so-called MPPS particles (most penetrating particle size) are in the range of 0.1 to 0.3 micron.

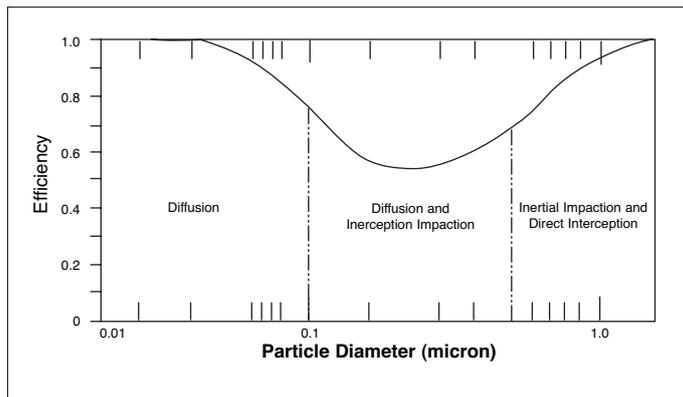


Fig. 2: Filter efficiency

Within this particle size range, inertial impaction and diffusion cannot wholly complement each other. On the one hand the particles are too small to flow inertly and straight within the gas; on the other hand, they are too big to develop sufficient self-motion for diffusion.

Therefore the penetration probability of this particle size is highest for one filter medium or, in other words, the removal of particles of 0.1 to 0.3 micron from an air or gas flow is most difficult.

For this reason a sterile filter must be capable of even removing this most critical particle size form the air/gas.

With their wide range of products **ZANDER** offer various filter assemblies and housings as individual solutions in nearly all areas of production and research.

Exact knowledge of individual process parameters and objectives is essential in this. Total filter reliability - even after prolonged operational use - is imperative in very critical processes.

The Process Housing Series



In addition to their size the fact that micro-organisms as “living organisms” are capable of multiplying very rapidly given the right conditions makes special demands on the sterile filter element as well as on the sterile filter housing.

Therefore the new **ZANDER** filter housing range is designed for the most critical application. 1.4301 (optional 1.4571) high-quality stainless steel, high-polished surfaces and the elimination of edges and corners offer a high degree of biological safety when sterilising air and other compressed gasses.

Special attention has been paid to the location of the element. Unlike traditional plug-in adapters with a single internal ‘O’ ring or two external ‘O’ rings, a special “Click Lock” system was developed for the new housing series.

Two external ‘O’ Rings together with bayonet ensure that the element is safely fixed. Thus the risk of bypass formation around the ‘O’ Ring could be minimised.

The design of the new housing series guides the air/gas flow into the filter element without any turbulence. The result is minimal pressure loss across the filter housing and filter elements and therefore a considerable reduction of operating costs.

With the deep-medium filter series HB and the steam filter SERIES D and DS nearly all requirements for modern, safe and cost-effective filtration can be met.

TECHNICAL DATA

Features

- “Click-Lock” system for locating the element with double ‘O’ Ring and bayonet. Elimination of bypass potential ‘O’ Ring and therefore greater filtration safety.
- High-polished housing surface without edges or corners for greater biological safety.
- Made from high-quality 1.4301 (optional 1.4571) stainless steel - no fouling or corrosion.
- Plenum chamber design improves drainage from the filter housing
- To be used with depth media filter SERIES HB and steam filter SERIES D and DS and universally useable for all applications.
- Available in common connection sizes and types.

Technical Specification

Construction material - Stainless steel 1.4301 (optional 1.4571)

Surface finish high-polished

Max. permissible operating pressure 16 bar g

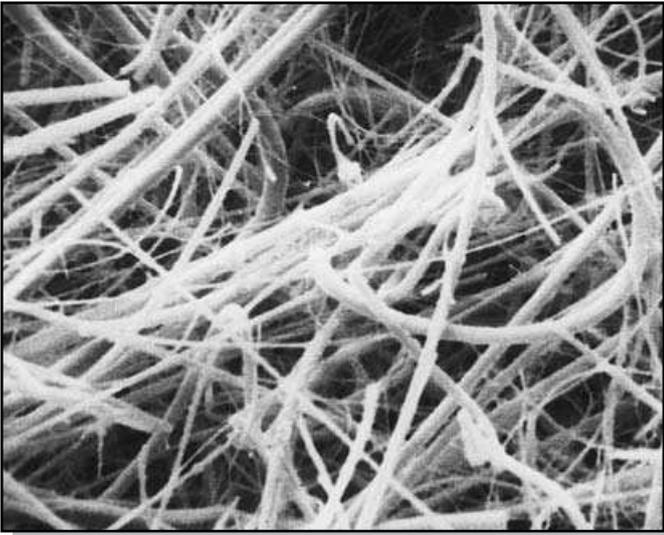
Max. permissible operating temperature 200°C

Aseptic EPDM housing seal

Available as connection type: BSP, NPT, Clamp, Milk Pipe, welded edge, flange, SMS



Filtration : Depth Media Filters



Pure depth media filters should be used where, at a high air/gas throughput, a sterile filtrate is required after condensate removal. If these requirements are not met, a depth media filter that has been made water-repellent must be used.

The **ZANDER** filter range for air sterilisation includes special depth media filters from water-repellent PTFE-impregnated microfibre web. (See filter SERIES HB)

ZANDER Depth media filter series: SERIES ST-R and SERIES HB

Selecting the correct filter type and construction (pleated or wrapped) is of crucial importance.

Not every type of filter is suitable for a specific application. The wide product range of **ZANDER** guarantees the use of the “correct” filter in any given sterile process.

The expression depth media or media filter not only relates to the “relative depth” or “thickness” of the filter material but also to the method with which micro-organisms are removed.

Irregularly arranged fibres with a diameter of 0.5 to 100 micron are formed into several layers.

Filtration takes place in the depth of the filter media. The gaps form winding channels through which the air or gas must pass. Any micro-organisms are completely separated by the fibres.

Depth media filters feature particularly high flow rates. By utilising the depth of the media even dirt particles can be removed from the gas flow.

The integrity of a depth media filter is highly affected by insufficiently filtered condensate in the process air or after sterilisation has taken place. If the filter medium is wet by this condensate, the filter can no longer provide a sterile filtrate. Its integrity is no longer ensured.



SERIE ST-R : At the Heart of Problem Solving



Three layers of the microfibre filter medium between Nomex* supporting material prevent the penetration of micro-organisms and ensure added filter stability.

Between the stainless steel support cylinders the filter layer is secured with epoxy resin to the stainless steel end caps. This results in a SERIES ST-R filter element of exceptional stability and highest possible efficiency for total safety under critical process conditions.

SERIES ST-R filter elements are particularly suited to high temperature applications. They also meet the requirements for sterile compressed air/gas in dairies, breweries and other food industries.

Filter elements of the ST-R SERIES are available for existing **ZANDER** filter housings and also as filter elements for housings of other manufacturers.

*Nomex is a registered trademark of E.I. du Pont de Nemours and Co. Inc.

TECHNICAL DATA

Features

- Stainless steel construction
- 3 layers of microfibre media between Nomex* supporting material
- Bonding of end caps with epoxy resin
- Large voids volume of 95%
- Can be repeatedly steam sterilised
- High operating temperatures
- High particle retaining capacity
- Can be integrity tested with FILTEGRITY

MAXIMUM PERMISSIBLE OPERATING TEMPERATURE (HOT AIR)

200°C intermittently

170°C continuously

STEAM STERILISATION (see page 9 Steam Filters)

Can be sterilised in-line with purified, saturated steam up to 100 times at 121°C (1.1 barg) for 30 minutes.

REPLACEMENT ELEMENTS FOR ULTRAFILTER LTD HOUSINGS

Ultrafilter Ltd Type	ZANDER Type	Ultrafilter Ltd Type	ZANDER Type
SRF 3/1	ST-R 3/1	SRF 10/30	ST-R 10/30
SRF 3/1,5	ST-R 3/1,5	SRF 15/30	ST-R 15/30
SRF 4/1,5	ST-R 4/1,5	SRF 15/30	ST-R 15/30
SRF 4/2,5	ST-R 4/2,5	SRF 20/30	ST-R 20/30
SRF 5/2,5	ST-R 5/2,5	SRF 30/30	ST-R 30/30
SRF 5/3	ST-R 5/3	SRF 30/50	ST-R 30/50
SRF 10/3	ST-R 10/3	P-SRF 02/05	PST-R 02/05
SRF 15/3	ST-R 15/3	P-SRF 02/10	PST-R 02/10
SRF 20/3	ST-R 20/3	P-SRF 03/05	PST-R 03/05
SRF 30/3	ST-R 30/3	P-SRF 03/10	PST-R 03/10
SRF 30/5	ST-R 30/5	P-SRF 04/10	PST-R 04/10
SRF 02/05	ST-R 02/05	P-SRF 04/20	PST-R 04/20
SRF 02/10	ST-R 02/10	P-SRF 05/20	PST-R 05/20
SRF 03/05	ST-R 03/05	P-SRF 05/25	PST-R 05/25
SRF 03/10	ST-R 03/10	P-SRF 07/25	PST-R 07/25
SRF 04/10	ST-R 04/10	P-SRF 07/30	PST-R 07/30
SRF 04/20	ST-R 04/20	P-SRF 10/30	PST-R 10/30
SRF 05/20	ST-R 05/20	P-SRF 15/30	PST-R 15/30
SRF 05/25	ST-R 05/25	P-SRF 20/30	PST-R 20/30
SRF 07/25	ST-R 07/25	P-SRF 30/30	PST-R 30/30
SRF 07/30	ST-R 07/30	P-SRF 30/50	PST-R 30/50

SERIE HB : The Filtration Revolution



Demands for the sterilisation of compressed air and gas in the food industry, dairies and breweries are continuously increasing. Complete retention of micro-organisms such as bacteria, viruses and bacteriophages, the largest possible filter area, low differential pressure and cost effectiveness are standard requirements that a filter must meet.

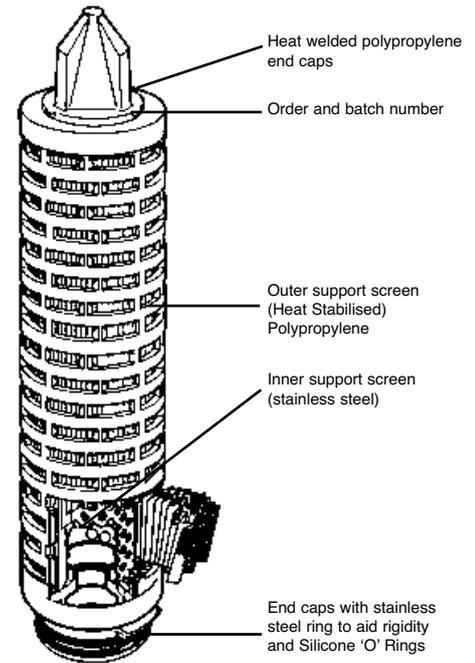
As a solution for this application range **ZANDER** specially developed the SERIES HB filter element with an absolute retention rate of 0.01 micron in gas and compressed air. With the help of the pleated depth media with a voids volume of 95% (PTFE: 85%; PVDF: 67%) the flow rate could be increased several times while maintaining a low differential pressure.

The high particle absorption capacity increases the life of the SERIES HB filter element while at the same time reducing filtration costs. Heat-stabilised polypropylene together with an internal stainless steel core result in high mechanical stability. The PTFE-impregnated filter medium protects against the wetting of the filter medium with water/condensate on the inlet side of the filter.

SERIES HB filter elements revolutionise sterile air filtration. They offer the user the best opportunity for cost-effective and reliable filtration.

FEATURES

- Rugged element construction with internal stainless steel core.
- PTFE-impregnated hydrophobic microfibre media with a voids volume of 95%.
- Absolute retention rate of 0.01 micron in compressed air and gasses.
- Larger internal diameter and pleated medium for markedly improved flow characteristic.
- Validated to aerosol bacteria challenge test.
- Can be integrity tested with FILTEGRITY
- Heat-welded construction



FILTRATION AREA FOR STANDARD FILTER ELEMENTS

	Length		Filter Area m ²
	mm	inch	
HB09T	65	2,5	0,09
HB13T	125	5	0,18
HB14T	250	10	0,40
HB18T	500	20	0,80
HB19T	750	30	1,20

MAX. RECOMMENDED OPERATING TEMPERATURE (HOT AIR)

80°C continuous

STEAM STERILISATION (See page 9 steam filters)

Maximum 142°C (2.8 bar g) for 15 minutes

BIOLOGICAL SAFETY

All construction materials meet the safety requirements of USP Plastics Class VI and BS 5736

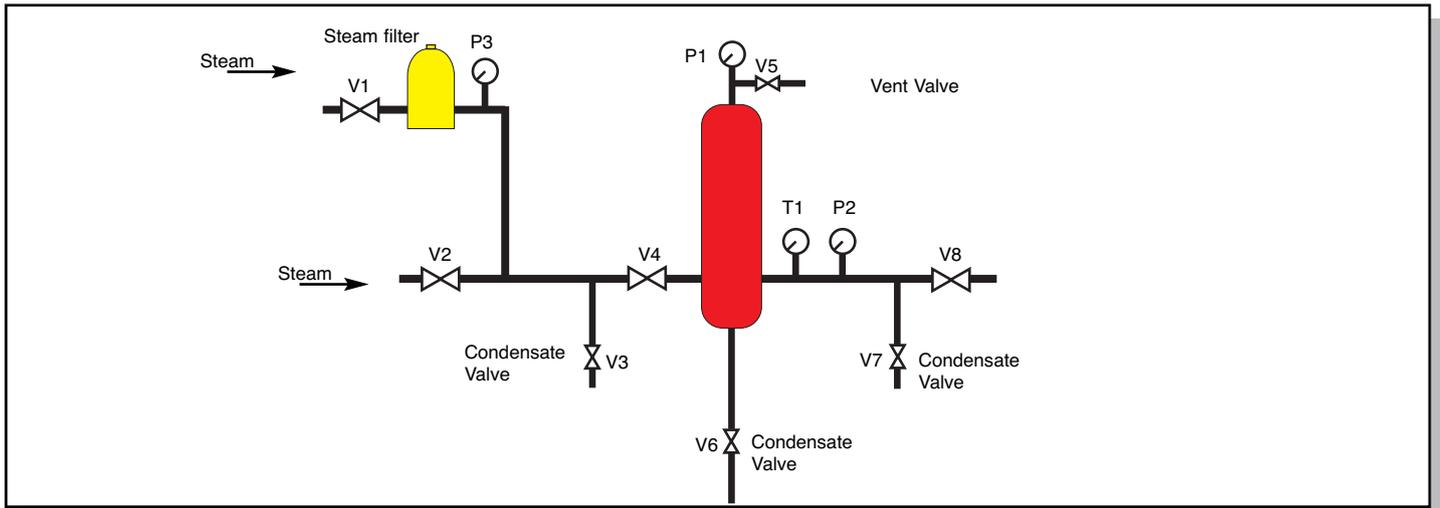
VALIDATION

SERIES HB filter elements are validated by the Aerosol Bacteria Challenge Test. Titre reductions of >10¹² were established.

ORDERING INFORMATION FOR STERILE FILTERS SERIES HB

Housing Type	Connection	Element Type
S 02 HB	1/4"	HB 09T
S 05 HB	3/8"	HB 09T
S 07 HB	1/2"	HB 09T
S 09 HB	3/4"	HB 09T
S 11 HB	1"	HB 13T
S 12 HB	1 1/4"	HB 13T
S 13 HB	1 1/2"	HB 13T
S 14 HB	2"	HB 14T
S 15 HB	2"	HB 18T
S 18 HB	2 1/2"	HB 18T
S 19 HB	3"	HB 19T

Steam Sterilisation of Sterile Filters



Steam sterilisation is the most effective form of sterilisation. Saturated water steam in conjunction with appropriate dwell times results in the complete destruction of micro-organisms that are capable of multiplying. Due to the continuous balance between steam and water as a condensate an effective heat transfer to the components to be sterilised is ensured.

The biggest advantage of steam sterilisation as compared to other sterilisation methods is the complete co-sterilisation of elbows, connecting pipework and transition pieces within the filtration system. But the disadvantage on this sterilisation method is the high thermal and mechanical stress of the sterile filter element. High differential pressures in conjunction with high temperatures (up to 142°C) may cause damage to the filter medium or to its component parts

In-line sterilisation (i.e. sterilisation of the filter element within the production housing) normally takes place at 121°C, 1.1 bar g for 30 minutes. Dwell times and steam temperature must be maintained for the sterile filter to be sterilised thoroughly and safely on the sterile and on the non-sterile side.

Steam sterilisation should always use purified (pre-filtered by steam filters up to 1micron) saturated steam. Unsaturated steam, recognisable by excessive steam pressure, does not condense completely and thus provides much lower heat transfer to piping, housing walls and filter element. Therefore, there must always be sufficient liquid phase in the steam (and must be fed in during sterilisation) to maintain the thermodynamic balance between steam and water.

The time it takes to heat the entire filtration system to sterilisation temperature depends on the steam velocity and on the size of the system. Likewise, sterilisation temperature will only be reached if all the air within the filtration system has been completely replaced by steam and if the emerging condensate may exit via drain valves.

MINIMISING DIFFERENTIAL PRESSURE

During sterilisation the various system components expand at a different rate. The polypropylene component of the filter element also expands. Thus the element must not be subjected to great mechanical stress by high differential pressures. During sterilisation the maximum permissible differential pressure should not exceed 0.3 bar. Steaming through the filter would inevitably lead to its deformation and therefore to the destruction of the filter medium.

NOTES ON SAFE STERILISATION

- Larger filtration systems should only be steamed gradually.
- Any emerging condensate should be drained unrestrictedly via drain valves or condensate valves.
- Sterile filters should never be steamed through with large amounts of steam.
- Measuring of dwell time should only start when the coldest point of the system has been brought to sterilisation temperature.
- During sterilisation the vent valve on the filter housing should be slightly opened so that a sufficient amount of saturated steam can be fed in.
- Before commencing production ensure that the filter has completely cooled down and that the system is free of condensate.

SERIE D and DS : Clean Steam



In many areas of the food and pharmaceutical industries vessels, piping and filter systems are sterilised by steam. The steam required to sterilise these systems may contain a considerable amount of rust or other pipe-scale. The resulting contaminated steam may cause serious faults in the system. If the steam is contaminated, the life of valves, filters and other ancillary equipment is shortened.

ZANDER SERIES D and DS steam filters prevent the systems being contaminated and thus increase the life of adjoining equipment.

ZANDER SERIES D and DS steam filters consist of porously sintered stainless steel that ensures the effective separation of particles. The filter elements show excellent chemical resistance and mechanical stability due to their special design. Using **ZANDER** SERIES D and DS steam filters can considerably reduce the post-filtration costs of your system.

TECHNICAL DATA

Features

- Porously sintered stainless steel construction
- High flow rate with low differential pressure
- High mechanical stability
- High temperature range
- Separation rates to 1 micron
- Construction with welded end caps optional

ORDERING INFORMATION FOR STEAM FILTERS SERIES D

Housing Type	Connection	Element Type
S 02 D	1/4"	D 09 T
S 05 D	3/8"	D 09 T
S 07 D	1/2"	D 09 T
S 09 D	3/4"	D 09 T
S 11 D	1"	D 13 T
S 12 D	1 1/4"	D 13 T
S 13 D	1 1/2"	D 13 T
S 14 D	2"	D 14 T
S 15 D	2"	D 18 T
S 18 D	2 1/2"	D 18 T
S 19 D	3"	D 19 T

Option: Models with welded elements (SERIES DS).

REPLACEMENT ELEMENTS FOR ULTRAFILTER LTD HOUSING

Ultrafilter Ltd Type	ZANDER Type	Ultrafilter Ltd Type	ZANDER Type
D-SS 3/1	D-R 3/1		
D-SS 3/1,5	D-R 3/1,5	D-SS 10/30	D-R 10/30
D-SS 4/1,5	D-R 4/1,5	D-SS 15/30	D-R 15/30
D-SS 4/2,5	D-R 4/2,5	D-SS 20/30	D-R 20/30
D-SS 5/2,5	D-R 5/2,5	D-SS 30/30	D-R 30/30
D-SS 5/3	D-R 5/3	D-SS 30/50	D-R 30/50
D-SS 10/3	D-R 10/3	P-GS 02/05	PD-R 02/05
D-SS 15/3	D-R 15/3	P-GS 02/10	PD-R 02/10
D-SS 20/3	D-R 20/3	P-GS 03/05	PD-R 03/05
D-SS 30/3	D-R 30/3	P-GS 03/10	PD-R 03/10
D-SS 30/5	D-R 30/5	P-GS 04/10	PD-R 04/10
D-SS 02/05	D-R 02/05	P-GS 04/20	PD-R 04/20
D-SS 02/10	D-R 02/10	P-GS 05/20	PD-R 05/20
D-SS 03/05	D-R 03/05	P-GS 05/25	PD-R 05/25
D-SS 03/10	D-R 03/10	P-GS 07/25	PD-R 07/25
D-SS 04/10	D-R 04/10	P-GS 07/30	PD-R 07/30
D-SS 04/20	D-R 04/20	P-GS 10/30	PD-R 10/30
D-SS 05/20	D-R 05/20	P-GS 15/30	PD-R 15/30
D-SS 05/25	D-R 05/25	P-GS 20/30	PD-R 20/30
D-SS 07/25	D-R 07/25	P-GS 30/30	PD-R 30/30
D-SS 07/30	D-R 07/30	P-GS 30/50	PD-R 30/50

FILTEGRITY



After a sterile filter is produced the manufacturer will subject it to a series of quality tests to ensure that a high-quality product leaves the factory.

Based on experience and tests under laboratory conditions the manufacturer can provide the physical limits (e.g. max. number of possible sterilisation cycles, etc.) of each filter element. Upon request the manufacturer will supply these data as validation documents. Yet each sterile process and each sterile application makes different demands to a sterile filter element and these cannot all be considered under laboratory conditions. It is therefore extremely difficult and even dangerous to state the serviceable life of any filter. It would be preferable if every user was able to individually test the integrity of their sterile filters in order to ensure controlled filter replacement.

For membrane filter elements liquid-based integrity tests such as the Bubble Point Test, pressure decay tests, etc. have been in use for several years. These serve to test a filter element by wetting it with suitable solvents (usually an IPA/ Water mixture). These test methods only check the membrane surface for homogeneity and pore size distribution or any existing defects. Membrane filters used in gas sterilisation typically have a pore size of 0.2 micron. However, for sterilisation a quantitative reduction of 0.01 micron particles from the gas flow is required. Liquid tests are only capable of testing the filter elements as a 0.2 micron liquid filter. These tests take into account neither the behaviour of micro-organisms within the carrier gas (mobility, etc.) nor the filtration mechanisms that apply to gas sterilisation.

Up to now depth media filters could only be checked for their integrity by the so-called DOP or smoke test. The disadvantage of this test method is that an organic solvent was used as a test particle whose harmful effects have been known for some time. DOP or smoke tests are not

suitable for testing membrane filters since the admitted DOP concentration leads to a blockage of the filter membrane.

In order to allow fast and reliable checking of a sterile gas filter in practice, **ZANDER** offer the test system FILTEGRITY.

Unlike the above test methods this system does not require any wetting of the filter media. The filter element is directly subjected to test particles (aerosols) in the air flow. Whereas a liquid-based test can take up to 3 hours, FILTEGRITY tests a filter element in less than one minute (test time depends on filter size). FILTEGRITY is simple and fast to use and does not require any special knowledge or skills.

SELECTING THE AEROSOL CONCENTRATION

An integrity test should check the filter element under absolute worst case conditions. Only then can the state of the filter be assessed safely and reliably. Another important criteria for determining worst case conditions is the maximum possible filter contamination with micro-organisms or particles.

Assuming a microbiological air contamination of 200 cfu/m³ (the average contamination in a biotechnology plant is 120 to 700 cfu/m³), the following maximum annual micro-organism contamination results at 24 hours operation for a 10 inch filter element: -

2000	cfu/m ³	Conc. of micro-organisms in gas flow
x 240	m ³ /h	Throughput of a 10" filter element
x 24	h/day	Operating hours per day
x 365	days	Working days per year
<hr/>		
4,2 x 10 ⁹	cfu	max. possible filter contamination per year.

A sterile gas filter serves to completely remove the entire microbiological contamination from the air or gas flow while maintaining the maximum flow rate of the element. Therefore, the required retention rate for a 10 inch sterile filter element should be at least 4.2 x 10⁹ cfu.

FILTEGRITY'S MODE OF OPERATION

The basic principle is the admission of high concentrations (up to 3.3×10^{11} particles for a 10 inch filter element per test) of an aerosol of the critical particle size of 0.1 micron to 0.3 micron.

As a test aerosol Shell Ondina EL (FDA Approved, Number: 178-3620(a)) is used. The test aerosol is produced at a constant overpressure of 1.4 bar through a nozzle (Laskin nozzle) in the aerosol chamber.

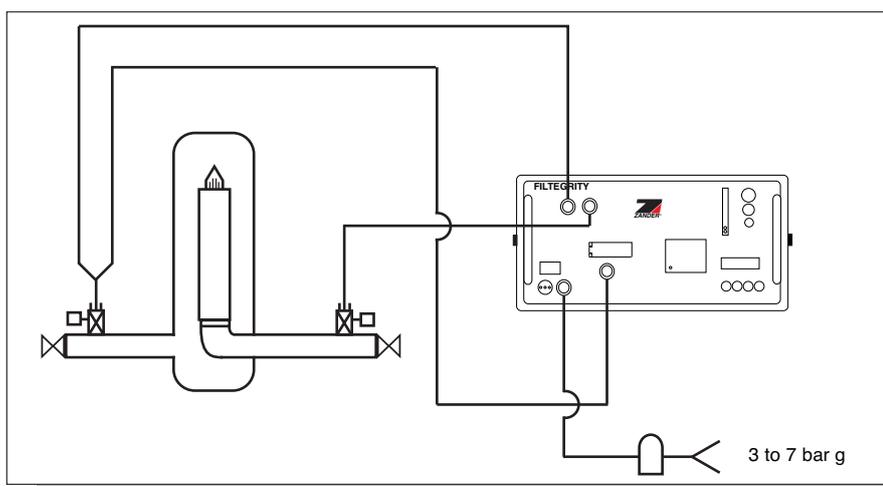


Fig. FILTEGRITY connection

A constant air flow through a small, exactly defined opening ensures the consistent test aerosol size distribution. The aerosol is then fed into the filter housing via pipes and is directly applied to the discharge side of the filter element under test.

The tubing on the sterile side of the filter leads from the filter housing back into the FILTEGRITY photometer chamber. Here, those aerosol particles that passed through the filter matrix are registered by a scattered-light diode detector and converted into readable values on the display screen.

The admissible aerosol volume depends on the size and thus on the filter area of the element under test. Aerosol concentration can be con-

trolled by the freely selectable test time. There is no blocking of filter membranes.

The operation of FILTEGRITY was correlated with the aerosol bacteria challenge test by the independent institution PHLS Center for Applied Microbiology and Research in Porton Down.

In the course of these studies various sterile air filter elements were subjected to the micro-organisms *Pseudomonas diminuta* (NCTC 11091), *Bacillus subtilis* (NCTCC 10073) and MS-2 Coliphage (NCIMB 10108) in the gas flow.

The results showed that FILTEGRITY can reliably and safely assess the integrity of a sterile filter. Its extreme sensitivity permits the identification of filter defects that cannot be detected by liquid-based integrity tests.

The findings were published in the Pharmaceutical Technology Europe magazine in April 1995 and can be obtained from **ZANDER** upon request.

FEATURES

- No wetting/drying of filter elements required
- Test time of only a few seconds
- No organic solvents required
- Testing of filter under absolute worst case conditions
- Testing of depth media and membrane filters
- In-line testing is possible
- No further accessories required

Successful in Germany Successful throughout the World



Clear Concept in Function and Form

This is the result of quality, innovation and continuity. This is what the name **ZANDER** stands for.

The company developed continually upwards into one of the most important and world-leading specialists in the field of filtration, adsorption, condensate, and sewage technology. In Germany, expert engineers offer qualified consultation and sales. Subsidiaries in the USA, France, UK and Italy as well as numerous exclusive agencies in Europe, Asia, South America and Africa ensure the presence of the company around the globe.

We reserve the right to change design and dimensions.