

# Sartofluor GA – 0.1 µm & 0.2 µm

## Sterilizing Grade Air Filter Cartridges for Bio-Pharmaceutical Applications



### Description

Sartofluor GA filter cartridges, manufactured with permanently hydrophobic PTFE membranes, are specially designed for sterile venting and gas applications where adherence to cGMP's is a must. Due to their permanent hydrophobicity, Sartofluor GA cartridges offer the highest process security, even with high volume gas streams, extreme humidity and stringent in-line steam sterilizations.

### Applications

Sartofluor GA cartridges are ideally suited for applications requiring a sterile, hydrophobic gas filter such as:

- Fermenter and bioreactor inlet gases
- Fermenter and bioreactor vents
- Autoclave vents
- Lyophilizer vents
- Purified water system storage tank vents
- In process storage tank vents
- Filling equipment process air

### Performance

PTFE is the most hydrophobic of all membranes used in sterile filtration of gases. The inherent hydrophobicity of the PTFE membrane remains unaffected by repeated autoclaving or steaming. The sterile filtration of dry or moist gases is guaranteed. The unique single layer design is optimized for high flow rates at low differential pressures with short blow-down times.

### Stability

Sartofluor GA can withstand high differential pressures in either the forward or reverse direction of flow. The mechanical stability and membrane structure are not affected by pulsation or high flow rates.

### Water Intrusion Test (WIT) | Water Flow Test (WFT)

A Sartorius development, the WIT offers the first and only correlated in-situ integrity testing system for hydrophobic vent filters. WIT not only eliminates downstream intervention and preflushing, more importantly, it does not require a single drop of alcohol.

### Quality Control

Each individual element is tested for integrity prior to release, assuring absolute reliability.

### Documentation

Sartofluor GA cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

### Specifications

#### Materials

Membrane:	PTFE
Support Fleece:	Polypropylene
Core:	Polypropylene
End Caps:	Polypropylene
O-Rings:	Silicone (EPDM or Viton optional)

#### Pore Sizes

0.2 µm, 0.1 µm

#### Available Sizes | Filtration Area

##### Standard Cartridges

Size 0	5"	0.38 m <sup>2</sup>   4.0 ft <sup>2</sup>
Size 1	10"	0.75 m <sup>2</sup>   8.1 ft <sup>2</sup>
Size 2	20"	1.5 m <sup>2</sup>   16.1 ft <sup>2</sup>
Size 3	30"	2.25 m <sup>2</sup>   24.2 ft <sup>2</sup>

##### Mini Cartridges

Size 7	0.05 m <sup>2</sup>   0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1.1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup>   2.2 ft <sup>2</sup>

#### Available Adapters Cartridges

14, 15, 25

#### Operating Parameters

Max. Allowable	5 bar   75 psi at 21°C
Differential Pressure:	0.5 bar   7 psi at 140°C
Max. Allow. Back Press.	3 bar   43.5 psi at 21°C

#### Integrity Test Limits

##### Bubble Point\*:

Pore Size	Min. Bubble Point
0.1 µm	1.5 bar   22 psi
0.2 µm	1.0 bar   14.5 psi

##### Diffusion\*:

Pore Size	Size	Max. Diffusion	Test Pressure
0.1 µm	9	5 ml/min	0.9 bar   13 psi
	10"	11 ml/min	0.9 bar   13 psi
	20"	22 ml/min	0.9 bar   13 psi
	30"	33 ml/min	0.9 bar   13 psi
0.2 µm	7	2 ml/min	0.7 bar   10 psi
	8	3 ml/min	0.7 bar   10 psi
	9	4 ml/min	0.7 bar   10 psi
	5"	6 ml/min	0.7 bar   10 psi
	10"	11 ml/min	0.7 bar   10 psi
	20"	22 ml/min	0.7 bar   10 psi
	30"	33 ml/min	0.7 bar   10 psi

\* Wetted with 60:40 IPA|H<sub>2</sub>O

##### Water Intrusion Test:

Pore Size	Size	Max. WIT	Test Pressure
0.1 µm	9	4 ml/10min	3.0 bar   43.5 psi
0.2 µm	8	2 ml/10 min	2.5 bar   36 psi
	9	4 ml/10 min	2.5 bar   36 psi
	5"	7 ml/10 min	2.5 bar   36 psi
	10"	13 ml/10 min	2.5 bar   36 psi
	20"	26 ml/10 min	2.5 bar   36 psi
	30"	39 ml/10 min	2.5 bar   36 psi

# Membrane Filter Cartridges

## Specifications

### Extractables

Sartofluor GA filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

### Regulatory Compliance

100% Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test.

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

## Sterilization

### In-Line Steam Sterilization

134 °C, 20 min. at max differential pressure of 0.5 bar | 7 psi

### Autoclaving

134 °C, 2 bar | 29 psi, 30 min

### Sterilization Cycles

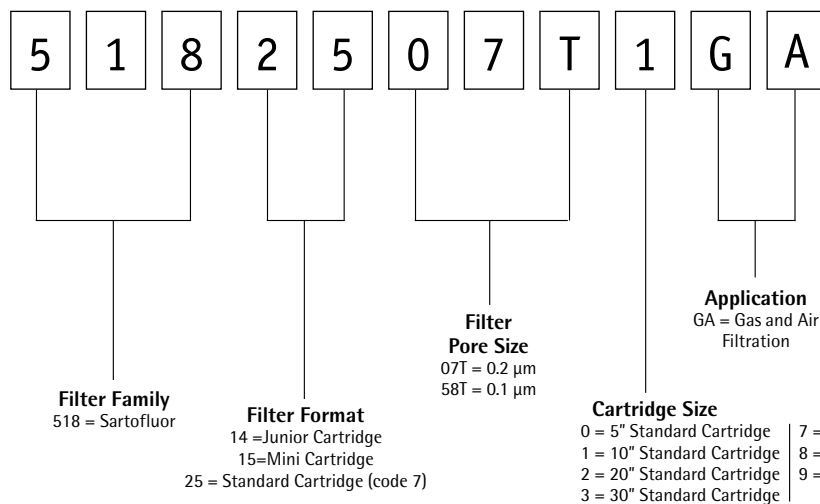
In-Line Sterilization: min 150 (in direction and in reverse direction of filtration)

## Technical References

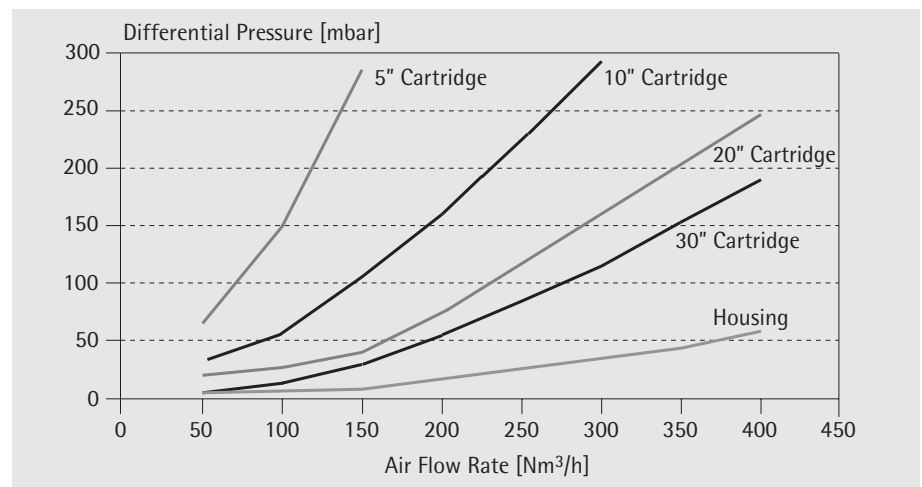
### Validation Guide:

SPK 5711-e  
SPK 5710-e

## Ordering Guide:

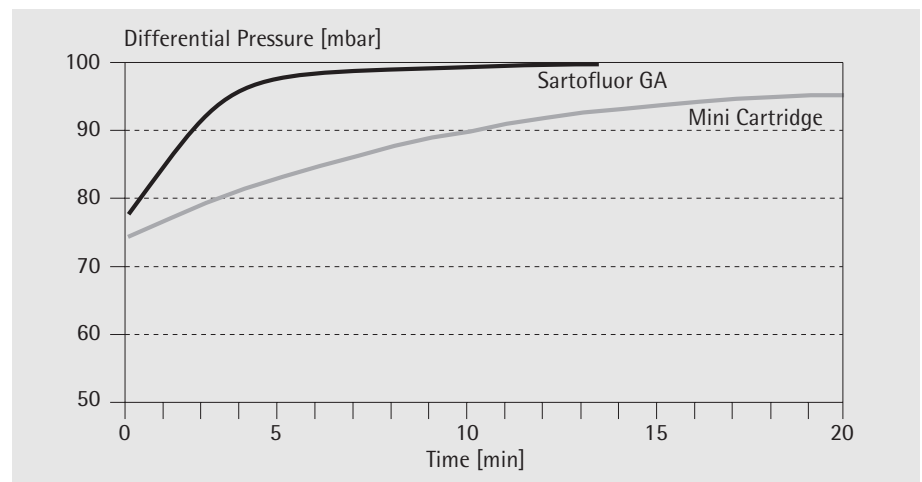


Air Flow Chart Sartofluor GA 0.2 µm



Under atmospheric pressure conditions

Blow-Down Time after WIT



Differential pressure after steam sterilization measured at 200 mbar

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