

Aerex™ 2 Hydrophobic Cartridge Filters

LENNTECH

info@lennotech.com Tel. +31-152-610-900
www.lennotech.com Fax. +31-152-616-289

- High performance gas filters for use in industrial fermentation applications



Aerex 2 0.2 µm hydrophobic cartridge filters provide high flow rates at low pressure differentials. Designed to remove bacteria and viruses from moist gas streams, the filters are ideally suited for use in industrial fermentation applications. Aerex 2 cartridge filters are manufactured using PTFE membrane and are 100 % integrity tested to assure optimal sterilizing performance. Each filter lot also must pass rigorous stress testing before release.

Cost Effective

High performance Aerex 2 cartridge filters offer significant savings of operating costs and capital. The combination of high flow rates and low pressure differentials lowers the air compressor loads that are required to achieve the desired flows. This reduction lowers the energy costs of air compressor operation as well as the required frequency of air compressor maintenance. The efficiency of Aerex 2 filters also allows the use of smaller housings, thereby reducing the required capital costs.

Advantages Provided by Aerex 2

- Sterility Assurance
- Improved Process Efficiency
- Long Service Life
- Quality Assurance

Sterility Assurance

Proven Bacterial and Viral Retention

Millipore's qualification of the AereX 2 cartridge filter includes a challenge regimen designed to test viral and bacterial retention by two challenge mechanisms: aerosol and grow-through. Challenge tests are completed on filters that have been exposed to 200 steam-in-place cycles. This challenge test protocol demonstrates organism retention over a long service life, not just when the filter is new.

Bacterial Growththrough Resistance

Millipore's retention test simulates the service challenge of retaining bacteria even after long use. The test entails first exposing AereX 2 filter cartridges to 200 thirty-minute steam-sterilization cycles in the forward direction at 145 °C. The test continues with the exposure of the cartridges to a moist gas stream containing aerosolized bacteria in a concentration $>1 \times 10^7$ cfu/cm². Under these rigorous test conditions, AereX 2 retained all *Brevundimonas diminuta* for 21 days.

Virus (Bacteriophage) Retention

Millipore's bacteriophage retention test performed after steam sterilization simulates the service challenge of retaining virus after long use. The test entails first exposing AereX 2 cartridge filters to 200 thirty-minute steam sterilization cycles in the forward direction at 145 °C. The test continues with the exposure of the filters to a moist gas stream containing the bacteriophage Φ X-174 at a concentration of 10^7 — 10^{10} virus particles per 10-inch cartridge. (The model bacteriophage Φ X-174 is icosahedral, has no tail required for infectivity, and is 29 nm in diameter.) These conditions represent a worst-case service challenge. After these exposures, the cartridges were tested for viral retention. AereX 2 met this challenge, retaining all bacteriophage particles under these extreme conditions.

Improved Process Efficiency

High Flow Rates

AereX 2 filters redesigned core allows for an open structure without compromising strength. This open structure provides superior flow rates, which minimizes the number of filter elements required to achieve a given flow volume, thereby increasing process efficiency. This process efficiency permits the use of smaller cartridge housings and reduces capital costs.

Low Pressure Differentials

AereX 2 filters operates at full efficiency without requiring the high pressure differentials usually needed to achieve high flow volumes. Low pressure differentials reduce air compressor loads, thereby saving energy. Low pressure differentials also preserve filters and air compressors, thereby reducing the need for compressor maintenance.

Long Service Life

The physical stress resulting from high pressure differentials and exposure to steam sterilization can result in the premature failure of hydrophobic

cartridge filters. AereX 2 filters are designed to withstand each of these challenges.

Validated Steam Sterilization

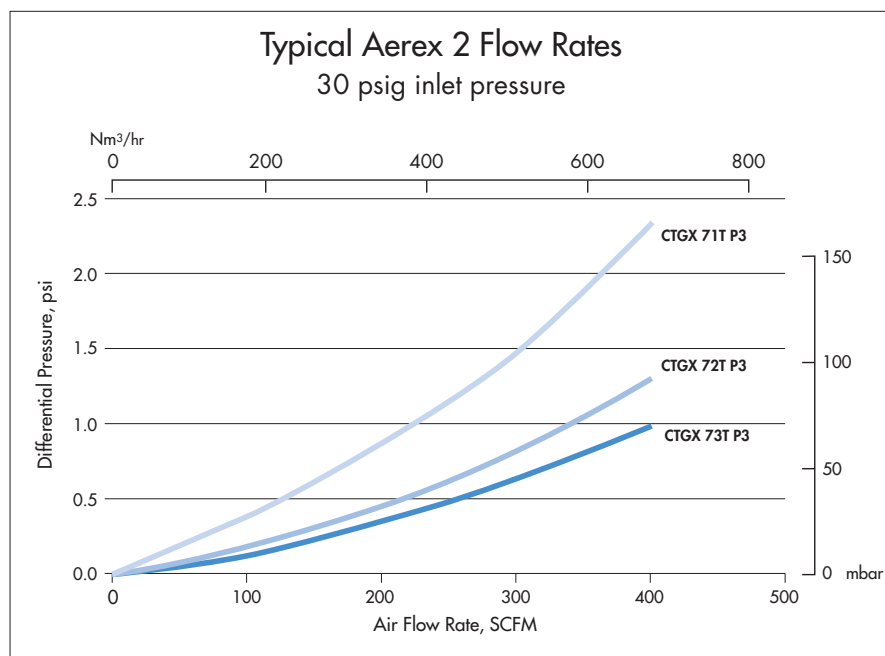
AereX 2 filters have been validated to withstand 200 steam-in-place cycles at 145°C. AereX 2 filters have maintained their integrity even after exposure to 200 steam-in-place cycles.

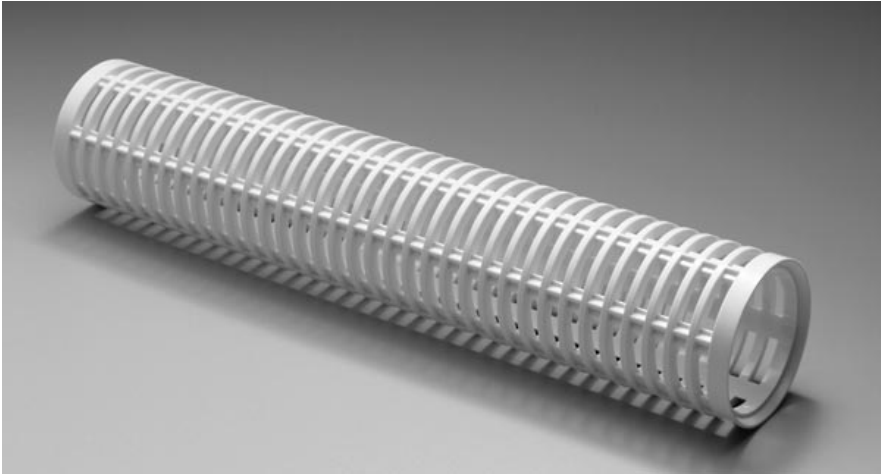
Validated Thermal and Hydraulic Stress Resistance

Millipore has demonstrated the ability of AereX 2 cartridges to resist hydraulically induced failure by validating their integrity against pulsed hydraulic pressure at 4.1 barg (60 psid) in the forward direction and 1.4 barg (20 psid) in the reverse direction.

Withstands Thermal Stress

AereX 2 filters have proved resistant to high levels of thermal stress. The multiple steam-in-place test is designed to demonstrate product resistance to thermally-induced stress. The test entails steaming the cartridges in place for 200 cycles at 145 °C. The test continues as cartridges are integrity tested after 200 steam cycles.





Aerex 2 filters open structured core provides superior flow rates.

Quality Assurance

A Certificate of Quality is provided with every Aerex 2 filter. These certificates record all relevant manufacturing lot-release criteria and accurately record quality test results, ensuring that each filter meets the minimum performance claims as detailed in the certificate. Millipore's Aerex 2 cartridges meet or surpass these claims. Aerex 2 cartridges are designed, developed, and manufactured in accordance with a Quality Management System that meets an ISO® 9000 Quality Systems Standard, as determined by an accredited registering body.

Specifications

Materials	PTFE membrane Spun-bonded polypropylene pleat supports upstream and downstream Polysulfone core Rigid polypropylene outer sleeve, end caps and adapter Silicone O-rings
Connections	Double 2-226 O-rings, bayonet with spear
Pore Size	0.2 µm
Nominal Cartridge Length	10 inch (25 cm) 20 inch (50 cm) 30 inch (75 cm)
Maximum Differential Pressure	<p><i>Forward Pressure:</i> 4.1 bar (60 psid) at 25 °C 340 mbar (5 psid) at 145 °C</p> <p><i>Reverse Pressure:</i> 1.4 bar (20 psid) at 25 °C (Intermittent)</p> <p>Aerex 2 hydrophobic cartridge filters must pass a hydraulic stress test prior to lot release.</p>
Effective Filtration Area	Approximately 0.66 m ² (7.1 ft ²) per 10-inch (25 cm) cartridge
Bacterial Growththrough Resistance	Aerex 2 cartridges resist the grow-through of aerosolized <i>B. diminuta</i> at a concentration of > 1x10 ⁷ cfu/cm ² for 21 days after 200 thirty-minute steam sterilization cycles at 145 °C.
Virus (Bacteriophage) Aerosol Retention	Retention of the model bacteriophage Φ X-174 was complete at exposure levels of 10 ⁷ — 10 ¹⁰ virus particles at 50 scfm (85 Nm ³ /hr) after 200 thirty-minute steam sterilization cycles at 145 °C. This rate of retention under these conditions represents a worst-case challenge for hydrophobic filters meeting these specifications.



Ordering Information

Description		Catalogue No.
Aerex 2, 10" Cartridge	3/pkg	CTGX 71T P3
Aerex 2, 20" Cartridge	3/pkg	CTGX 72T P3
Aerex 2, 30" Cartridge	3/pkg	CTGX 73T P3

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