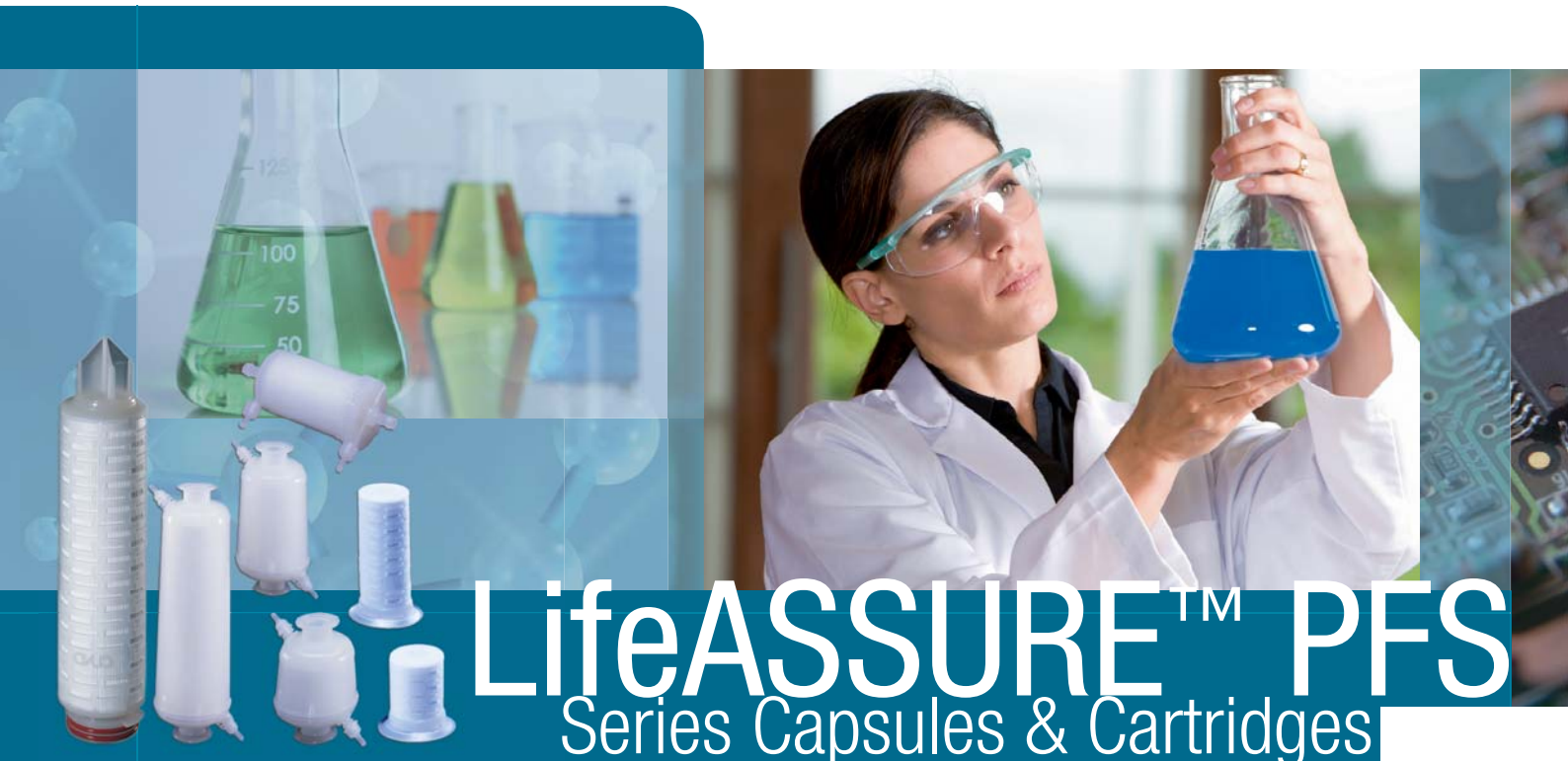


3M Purification

Product brochure



# LifeASSURE™ PFS

Series Capsules & Cartridges

Sterilising Grade PTFE Membrane Filters

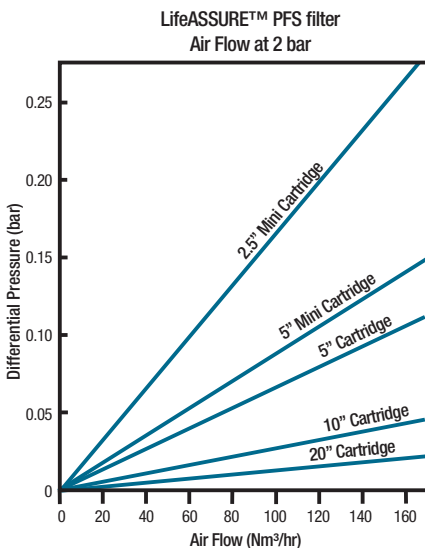
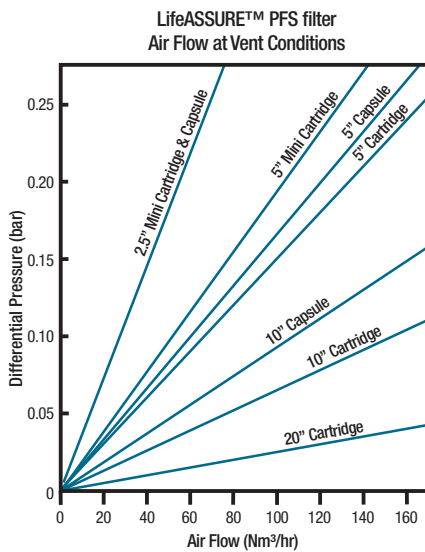
- Hydrophobic PTFE filter medium provides exceptionally high air flow rates at low differential pressures
- Reliable sterilising performance based on liquid and aerosol validated organism retention
- Full range of cartridge and capsule configurations available to meet all process conditions

**3M**



Flow enhanced cartridge and capsule filter construction provides lower differential pressure than competitive filters

Figure 1: LifeASSURE™ PFS Air Flow vs. Differential Pressure



## LifeASSURE™ PFS critical sterilising-grade PTFE cartridge and capsule membrane filters

**LifeASSURE PFS PTFE membrane filters offer the ultimate in microorganism retention for air and gas streams without sacrificing air flow capacity.**

- LifeASSURE PFS PTFE membrane filters with flow enhanced construction allow the use of smaller, more economical air filter assemblies compared to competitors.
- LifeASSURE PFS filters provide validated microorganism retention based on liquid bacteria challenge and aerosol bacteriophage challenge.
- LifeASSURE PFS filters are available in a wide range of cartridge and capsule configurations to provide the most economical solution to air, gas and aggressive liquid filtration applications.

### Cartridge and capsule configurations to meet any process requirement

LifeASSURE PFS membrane filter are available in 5 to 40 inch cartridges, 2.5 and 5 inch mini cartridges and 2.5, 5, 10, 20 and 30 inch capsules. With the exceptionally high LifeASSURE PFS flow rates, smaller and more economical assemblies can provide the same air flow as larger, more costly competitive PTFE filters.

## Features and Benefits

### High air flow at low pressure drop

- Higher air flow for fermenter aeration and economical vent filter assemblies.

### Liquid validation of *B. diminuta* retention

- Reliable sterilising performance in wet or dry conditions.

### Hydrophobic PTFE membrane

- Membrane will not become blocked with moisture.

### 21 CFR materials of construction, USP Class VI Biological Safety Test, Validation Guide and Drug Master File listing

- Eases validation and regulatory submissions.

## LifeASSURE PFS cartridge and capsule applications

LifeASSURE PFS filters are optimised for applications requiring sterilisation of air, gas, or aggressive solvents and chemicals. The hydrophobic PTFE filter membrane prevents wetting with aqueous liquids or moisture that can block free air flow. Some applications, however, may require filtration of aggressive fluids such as acids or bases. Depending on compatibility, LifeASSURE PFS filters can be used to provide sterile filtration of these fluids by pre-wetting the membrane with a low surface tension fluid, such as alcohol. A list of LifeASSURE PFS filter applications includes:

- Sterile venting of process tanks
- Sterile filtration of process air
- Sterile venting of lyophilisers
- Sterile venting of autoclaves
- Sterile air filtration on blow, fill and seal machines
- Sterilising filtration of fermentation inlet and exhaust air
- Sterile filtration of aggressive liquids

LifeASSURE™ PFS filters have been designed to provide exceptionally high flow rates at low differential pressures (figure 1). LifeASSURE PFS filters are available in a range of cartridge and capsule filter configurations to meet any process requirement. Shown in Figure 1 are flow curves for cartridge and capsule filter assemblies at atmospheric (vent) and compressed air conditions.

## The LifeASSURE PFS membrane advantage

LifeASSURE PFS filter cartridges and capsules combine high flow with a liquid validated, bacteria retentive, hydrophobic PTFE filter membrane. Capsule and cartridge filter structural components are polypropylene, optimised for long on-stream air service. The most important characteristics for a sterilising grade air/liquid filter include:

### Validated PTFE membrane

LifeASSURE PFS filters are validated by a liquid bacteria challenge test for complete retention. Liquid bacteria challenge represents the most severe test of filter performance and provides the highest assurance level of reliable sterilising performance. In addition, LifeASSURE PFS filters have been validated for aerosol retention of bacteriophage ( $\Phi$  X-174). For complete details, request the LifeASSURE PFS Validation Guide. The scanning electron micrograph (picture 1) shows the structure of the PTFE membrane with a tortuous pore pathway of flow channels.

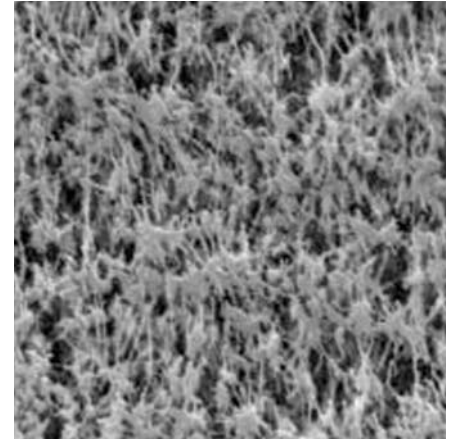
### Hydrophobicity

Free air flow with little resistance requires that the filter does not wet with water or moisture. Membrane wetting can result in filter pore blockage, which in turn prevents free air flow and can cause filter failure. In order to prevent pore blockage, an extremely hydrophobic PTFE membrane is used which prevents wetting with water or moisture. Graph 1 shows the relative hydrophobicity of filter media used in air filters. As can be seen, PTFE offers the highest level of hydrophobicity ensuring optimum air flow service.

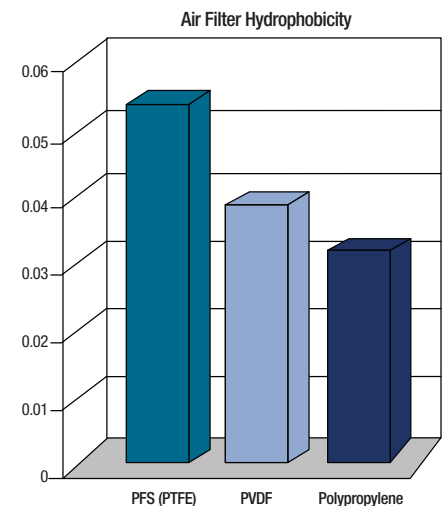
### High air flow

Efficient performance requires maximum air flow at minimum pressure drop. LifeASSURE PFS air filters utilise a construction to achieve a higher air flow vs. pressure drop when compared to competitive air filters. This 3M Purification development involves the use of a specially designed PTFE filter membrane with polypropylene flow enhancing layers. This construction is applied to LifeASSURE PFS cartridge and capsule filters. Picture 2 shows how each layer is positioned in cartridge and capsule filters.

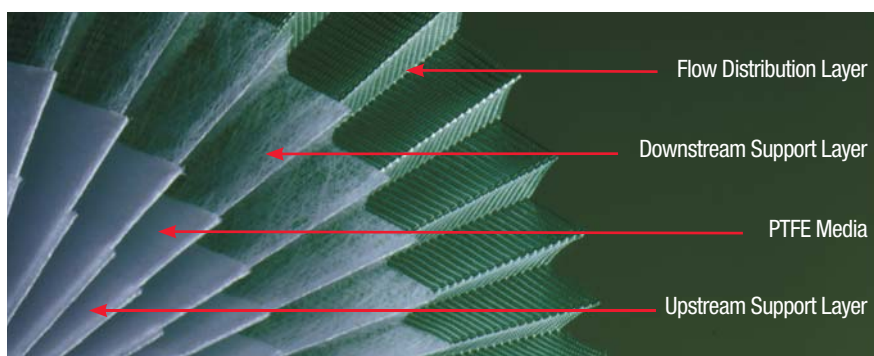
Picture 1: SEM of LifeASSURE™ PFS PTFE membrane



Graph 1: Comparative hydrophobicity



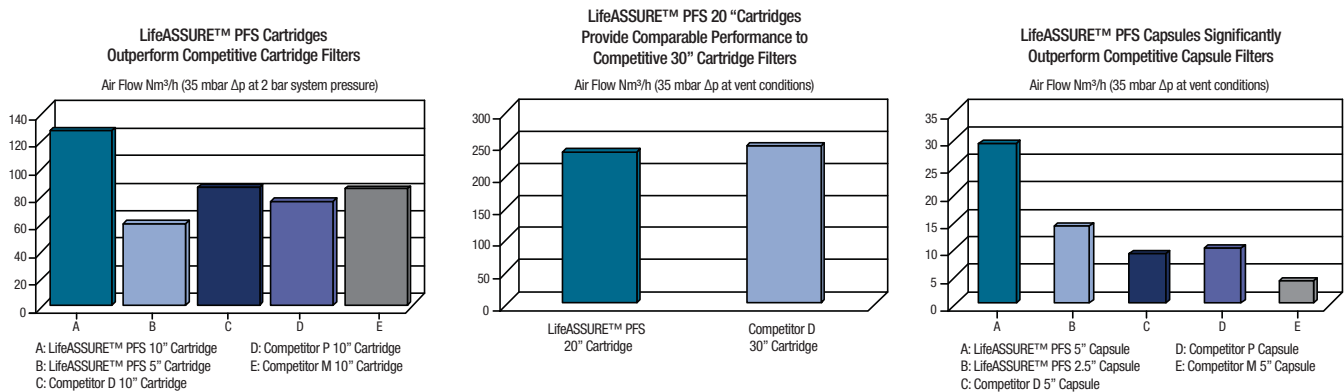
Picture 2: LifeASSURE™ PFS filter construction



## Superior flow rate performance

LifeASSURE™ PFS filter cartridges and capsules offer outstanding flow rate performance at low differential pressures. Whether used for tank venting or autoclave vacuum breaking, fermentation air sterilisation or blow, fill and seal machines, the filter flow rate is a critical parameter. Using the design enhancements described, LifeASSURE PFS filters provide maximum flow performance. Graph 2 presents the comparison of LifeASSURE PFS cartridge and capsule filter performance to competitive air filters.

Graph 2: Air flow rate comparisons



## Reliable microorganism retention performance

LifeASSURE PFS filters are validated for sterilising performance using a liquid bacteria (*B. diminuta*) challenge test method. Liquid bacteria retention testing is the most critical test of sterilising filter performance and provides the user with the utmost assurance that critical product or fermentation broth will be protected from contamination. In addition to demonstrating sterilising performance in liquid, LifeASSURE PFS filters were validated for bacteriophage retention using aerosol challenge test methods. Aerosol retention performance assures users that LifeASSURE PFS filters will provide reliable air and gas sterilisation. Aerosol challenge testing was performed using Φ X-174 bacteriophage, which are small organisms that infect bacterial cells and can ruin bacteria fermentation processes. Complete retention of bacteriophage was observed, as shown in table 1. For complete details, request the 3M Purification LifeASSURE PFS Validation Guide.

Test method	Test organism	Test result
Liquid bacteria challenge	<i>B. diminuta</i>	Sterile
Aerosol virus test	ΦX-174 Bacteriophage	0 plaque forming units



## Robust filter construction

Many applications for air filtration require steam sterilisation of filter cartridges. In vent or fermentation air service applications, filters may be steam sterilised multiple times. For fermentation processes, air sterilising filters may be used for up to two years and if sterilisation is performed weekly, this results in exposure to over 100 steam cycles. LifeASSURE™ PFS air filters were tested for ability to withstand multiple forward and reverse steam cycles and were demonstrated to retain integrity for 200 steam cycles at 145 °C. For complete details, request the LifeASSURE PFS Validation Guide.

### LifeASSURE PFS cartridge and capsule filter configurations

#### Cartridge filters

LifeASSURE PFS filters are available in 5 to 40 inch cartridge filters with a variety of end fittings and O-ring options to meet hardware and process requirements.

#### Mini-cartridges

3M Purification 2.5" and 5" LifeASSURE PFS mini-cartridges can be installed in existing competitors' housings or 3M Purification mini cartridge housings.

#### Capsule Filters

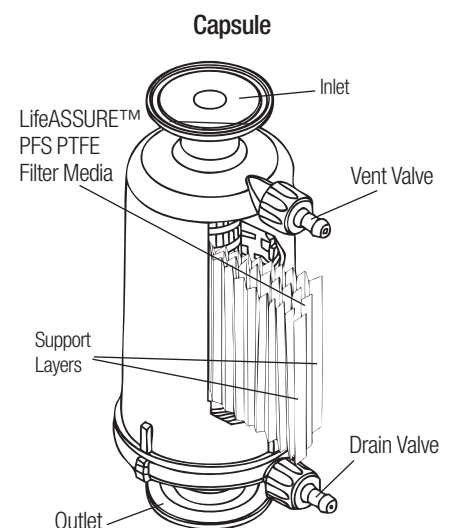
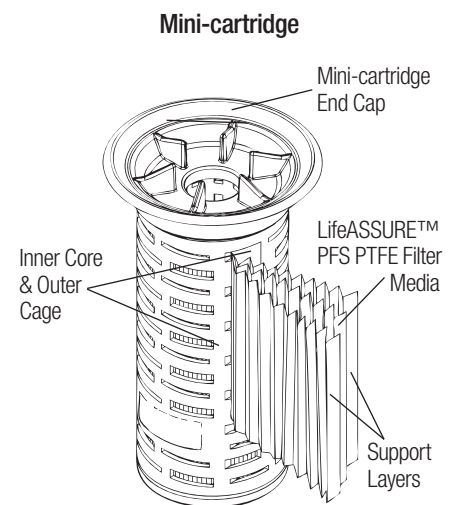
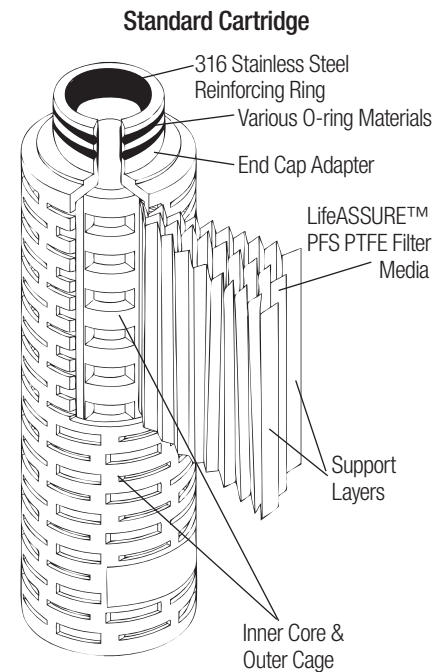
LifeASSURE PFS filters are available in 2.5, 5, 10, 20 and 30 inch capsule filter configurations. Capsule filters may be autoclave sterilised and offer a convenient, easy to use format for air sterilisation. As with LifeASSURE PFS cartridge filters, the capsule filters have been specially designed to provide optimum air flow. Capsules are not recommended for continuous compressed gas service.

## Quality and Reliability

LifeASSURE PFS filters are manufactured to an ISO registered quality system and are 100 % diffusion flow tested prior to shipment. All materials of construction are 21 CFR listed and cartridge and capsule filter components have been tested in accordance with United States Pharmacopoeia (USP) Class VI Biological Safety for Plastics. All LifeASSURE PFS cartridge and capsule filters are shipped with a Certificate of Quality affirming compliance with rigid manufacturing quality specifications. Supporting Drug Master File (DMF) documentation is on file with the United States Food and Drug Administration (FDA). A complete LifeASSURE PFS Validation Guide is available upon request.

## Scientific Applications Support Services (SASS)

3M Purification's 95+ years of experience are synonymous with quality, performance and high-level technical support. The cornerstone of 3M Purification's philosophy is service to customers, not only in product quality and prompt delivery, but also in validation assistance, applications support and in the sharing of scientific information. 3M Purification's Scientific Applications Support Services group works closely with customers to solve difficult separations problems and to recommend the most economical and efficient filter system. SASS Specialists are skilled in performing on-site testing and relating test results to full-scale manufacturing operations.





Operating Parameters and Specifications									
Filter configuration	Cartridges		Mini-cartridges		Capsules**				
	5 to 40"		2.5"	5"	2.5"	5"	10"	20"	30"
Filter rating	0.2 µm								
<b>Material of construction</b>									
Membrane	PTFE								
Membrane support layer	polypropylene								
Core, cage, end caps and adaptors	polypropylene								
End cap reinforcing ring	stainless steel	N/A							
Filtration surface area (m <sup>2</sup> )	1.02*	0.17	0.34	0.26	0.51	1.02	2.04	3.06	
<b>Cartridges operating parameters</b>									
Maximum differential pressure									
Forward pressure		5.5 bar at 25 °C 1.7 bar at 80 °C (Also max. operating pressure)			5.2 bar at 40 °C				
Reverse pressure		4.5 bar at 25 °C			4.5 bar at 25 °C				
Maximum operating temperature		80 °C			40 °C				
<b>Integrity test parameters - Diffusion flow test at 1.11 bar ***</b>									
25% / 75% (v/v) TBA / Water at 20 °C and 1 atm: ml/min		≤ 8.7*	≤ 1.4	≤ 2.9	≤ 2.2	≤ 4.4	≤ 8.7	≤ 17.4	≤ 26.1
60% / 40% (v/v) IPA / Water at 25 °C and 1 atm: ml/min		≤ 35.5*	≤ 5.8	≤ 11.9	≤ 9.0	≤ 17.8	≤ 35.5	≤ 71.0	≤ 106.5
70% / 30% (v/v) IPA / Water at 25 °C and 1 atm: ml/min		≤ 54.0*	≤ 8.8	≤ 18.2	≤ 13.7	≤ 27.0	≤ 54.0	≤ 108.0	≤ 162.0
Water intrusion test maximum Allowable flow at 2.76 bar at 20 °C and 1 atm: ml/min.		0.59*	0.10	0.20	0.15	0.30	0.59	1.18	1.77
Autoclave conditions		126 °C for 30 minutes							
<i>In situ</i> steam		145 °C for 30 minutes			Do not <i>in situ</i> steam				
*per 10 inch element - ** not for continuous compressed gas service *** <b>NOTE:</b> Wetting fluid should be maintained within +/- 2% v/v concentration and +/- 2 °C temperature.									

## 3M Purification filter housings

A complete line of sanitary design, stainless steel filter housings is available for LifeASSURE™ PFS cartridge filters. Options are available for heat traced (electrical and steam jacketed) housings where condensate is a concern. Specialised configurations and housing designs are also available for high flow, fermentation air filtration applications.

For more information on our filter housings, please contact your local 3M Purification representative.

## LifeASSURE™ PFS cartridges - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	O-ring material*
PFS 020	A	50 : 5" 01 : 10" 02 : 20" 03 : 30" 04 : 40"	B : 226 O-ring & Spear C : 222 O-ring & Spear F : 222 O-ring & Flat Cap J : 226 O-ring & Flat Cap	A : silicone (MVQ) B : fluorocarbon (FPM) C : EPR (EPDM) D : nitrile (NBR) K : PTFE-encapsulated fluorocarbon

\* ISO Designation

## LifeASSURE™ PFS mini-cartridges - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	Package quantity
PFS 020	R	01 : 2.5" 02 : 5"	AN	06 : 6 per pack

\* ISO Designation

## LifeASSURE™ PFS capsules - Ordering guide

Grade designation	Configuration	Height (inches)	End modification	O-ring material*	Package quantity
PFS 020	J	25 : 2.5" 50 : 5" 01 : 10" 02 : 20" 03 : 30"	A : Sanitary fitting	A : silicone (MVQ) B : fluorocarbon (FPM) C : EPR (EPDM)	01 : 1 per pack

\* ISO Designation

**NOTE:** LifeASSURE PFS is new name for CUNO Microfluor II.



### Important Notice

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