

**3M** Science.  
Applied to Life.™



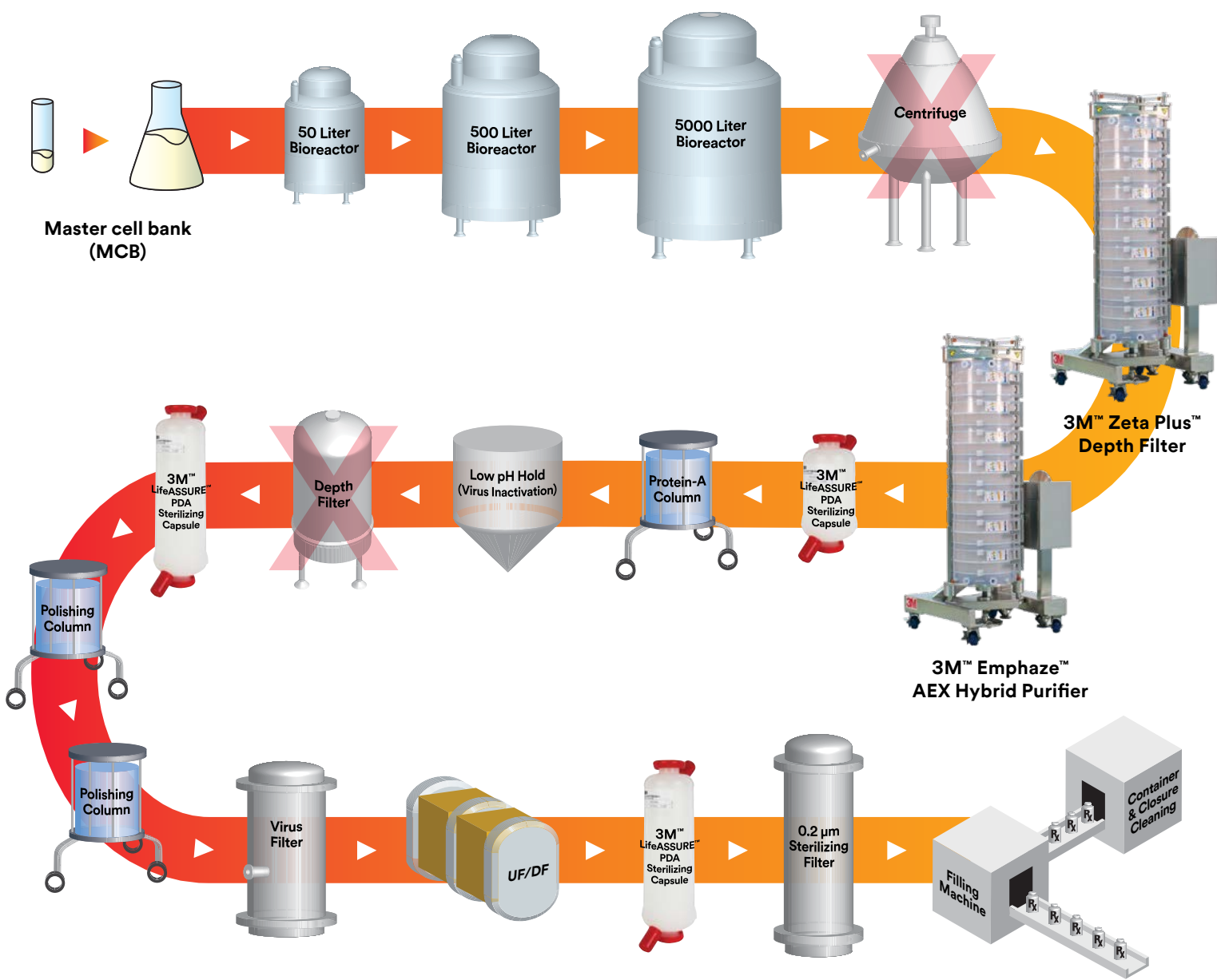
# Biopharmaceutical Innovation. Pure and simple.

3M™ Emphaze™ AEX Hybrid Purifier

# Bioprocessing – reimaged.

## Biopharmaceutical manufacturing process improvements

Biopharmaceutical purification is a complex process, composed of multiple unit operations. The 3M™ Emphaze™ AEX Hybrid Purifier is designed to simplify biopharmaceutical manufacturing, including that of recombinant proteins and monoclonal antibodies (mAb), by providing flow-through chromatographic separation of contaminants.



## Intensified process

3M™ Emphaze™ AEX Hybrid Purifier chromatographically reduces DNA, HCP and endotoxin, improving product purity and yield early in the process.

## Harvest and clarification

The Emphaze AEX Hybrid Purifier's built-in 0.2 micron membrane provides opportunity for reduction of the sterilization-grade membrane surface area and enables the use of 0.1 micron membrane.

### 3M™ LifeASSURE™ PDA Sterile Filter

- ▶ 0.1µm sterilizing membrane
- ▶ Bacteria and mycoplasma removal

### 3M™ Emphaze™ AEX Hybrid Purifier

- ▶ Robust turbidity reduction
- ▶ DNA, HCP and endotoxin reduction

### 3M™ Zeta Plus™ Depth Filter

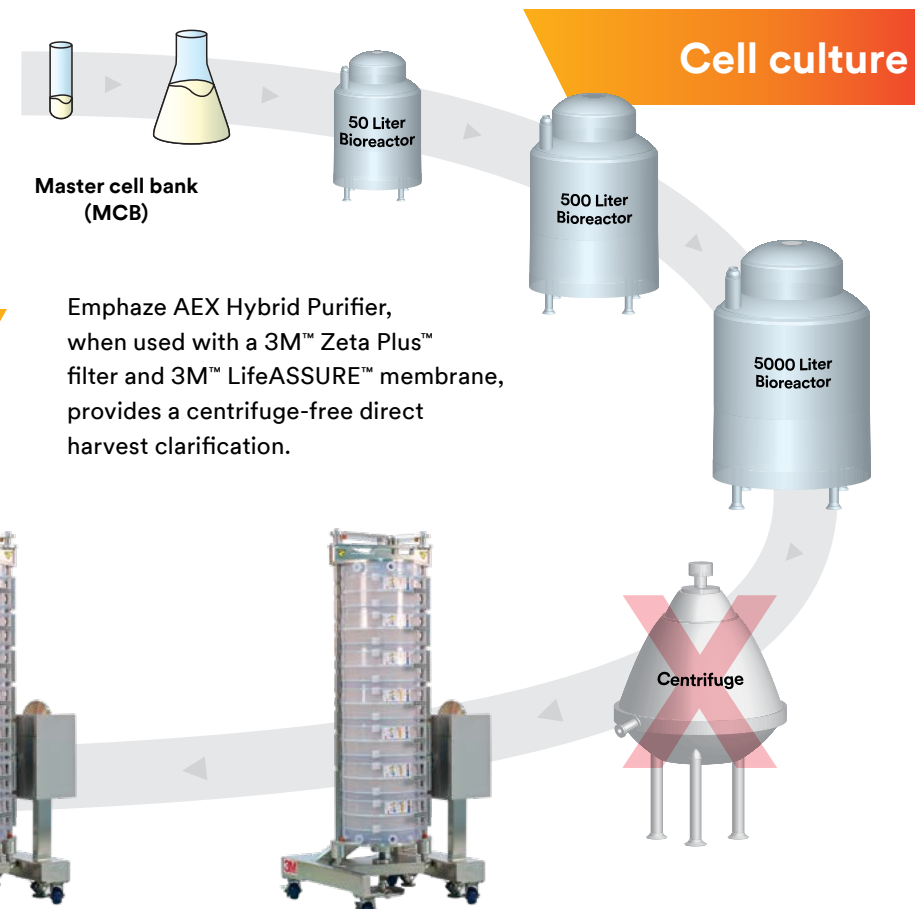
- ▶ Removes whole cells and reduces cell debris
- ▶ Sizes available from benchtop to production scale

## Simpler bioprocessing

## A new way to design bioprocessing

Emphaze AEX Hybrid Purifier delivers consistent, high-purity clarified process fluid by reducing cell debris, DNA, HCP and endotoxin, through a combination of chromatographic and size-exclusion mechanisms. This provides a more efficient process from end to end: product recovery can be substantially increased by reducing the sterilizing membrane surface area pre-Protein A, eliminating the post-viral inactivation depth filter clarification requirement and combining polishing trains into one connected operation.

Integrating Emphaze AEX Hybrid Purifier in the clarification stage may reduce the total cost of ownership for the mAb purification process. Single-use designs reduce time and cost for cleaning validation.





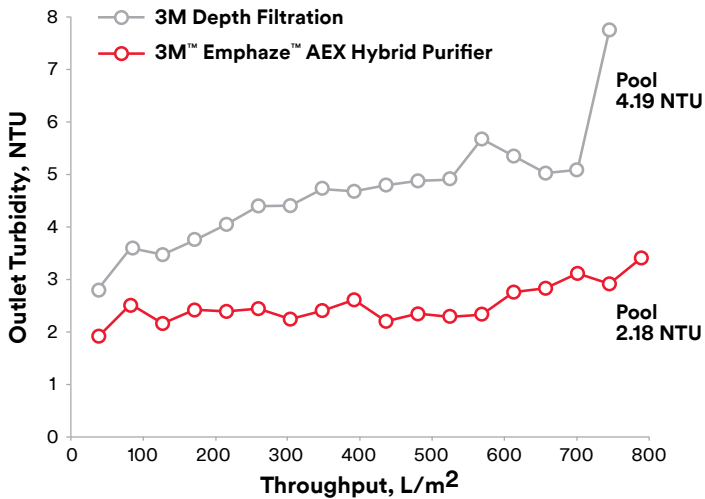
# 3M™ Emphaze™ AEX Hybrid Purifier

## Process features

### Superior turbidity reduction

The 3M™ Emphaze™ AEX Hybrid Purifier provides superior turbidity reduction compared to 3M depth filtration, with typical outlet turbidity less than 5 NTU throughout the entirety of the clarification run, due to high anion exchange capacity.

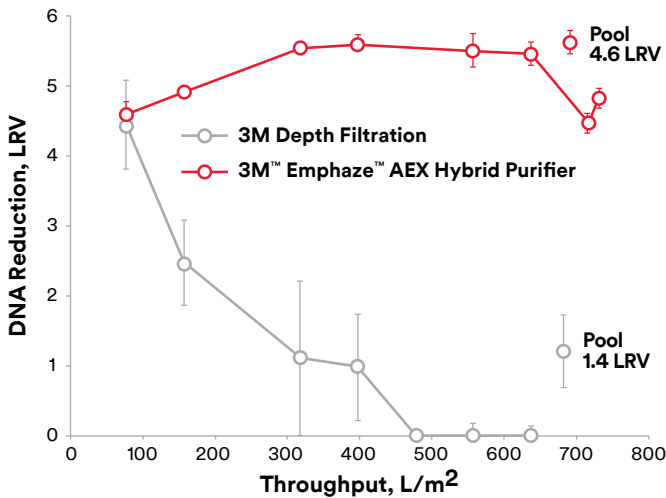
Graph 1: Pressure and turbidity reduction, as a function of throughput, during clarification of a CHO centrate



## DNA reduction

Emphaze AEX Hybrid Purifier has substantially higher DNA binding capacity compared to that of 3M depth filters. The Emphaze AEX Hybrid Purifier generally provides greater than a 4 log reduction (LRV) of DNA from harvest and centrate fluids.

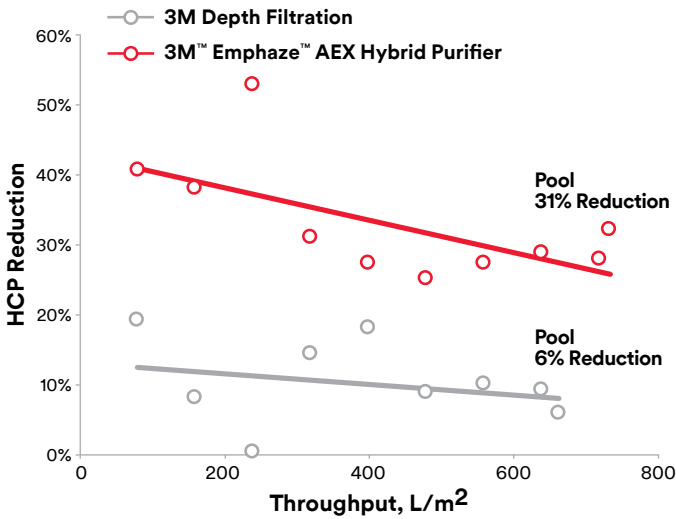
Graph 2: Pressure and DNA reduction, as a function of throughput, during clarification of a CHO centrate



## Host cell protein reduction

The Emphaze AEX Hybrid Purifier typically reduces negatively charged HCP by 20-40% from harvest and centrate fluids.

Graph 3: Pressure and HCP reduction, as a function of throughput, during clarification of a CHO centrate



## Monoclonal antibody process benefits

### Excellent throughput and mAb recovery

While providing superior reduction of turbidity, DNA, HCP and endotoxin, the 3M™ Emphaze™ AEX Hybrid Purifier generally exhibits throughput performance comparable to 3M's fine-grade depth filter (see Graphs 1-3). Also, the Q-functional nonwoven and very low nonspecific binding of the all-synthetic hybrid media provide excellent mAb recovery, typically exceeding the very good mAb recovery achieved by 3M depth filters.

### Enhanced capture column performance

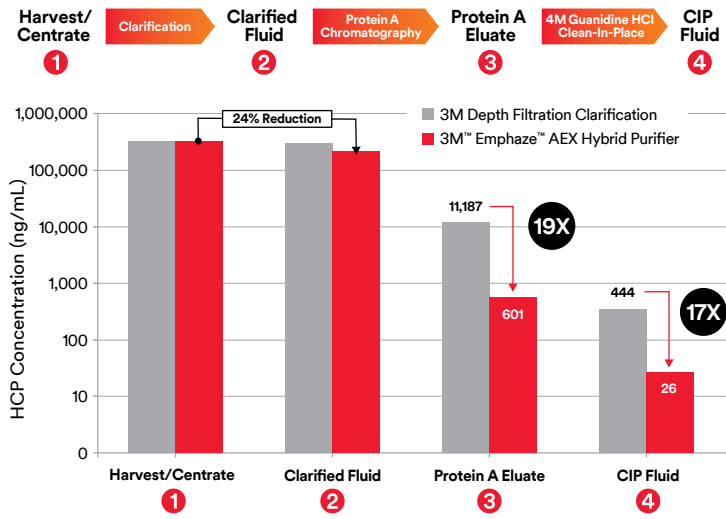
Emphaze AEX Hybrid Purifier can substantially enhance purification performance of the chromatography column by significantly reducing DNA and HCP load when Emphaze AEX Hybrid Purifier is used in the upstream clarification process.

### Enhanced capture column protection

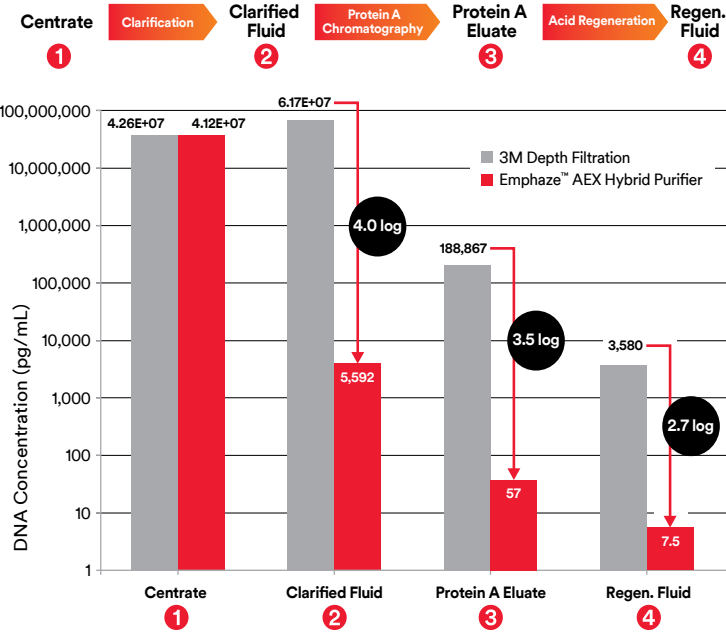
The Emphaze AEX Hybrid Purifier provides protection of the valuable capture chromatography column by decreasing the contaminant load, resulting in measurably fewer column-bound impurities. This has the potential to enable less aggressive column cleaning procedures.



Graph 4: HCP concentrations in CHO harvest or centrate (1), clarified fluid (2), protein A eluate (3), and clean-in-place fluid (4) when CHO harvest/centrate was clarified using either 3M Depth Filtration clarification (grey) or 3M™ Emphaze™ AEX Hybrid Purifier (red).



Graph 5: DNA concentrations in CHO centrate (1), clarified fluid (2), protein A eluate (3), and acid regeneration fluid (4) when CHO centrate was clarified using either a 3M depth filter (grey) or 3M™ Emphaze™ AEX Hybrid Purifier (red).



A more efficient process –  
for increased product recovery.

Enhanced mAb protein purity

In a representative monoclonal antibody (mAb) manufacturing process, the 3M™ Emphaze™ AEX Hybrid Purifier increases process efficiency and protein purity when used in clarification with a 3M depth filter like 3M™ Zeta Plus™ Depth Filters and 3M™ LifeASSURE™ Filters. Customers experience benefits in typical monoclonal antibody purification processes using the Emphaze AEX Hybrid Purifier:

- ▶ Nominal 20-40% HCP and greater than 4 log DNA reduction
- ▶ Consistent output turbidity (<5 NTU)
- ▶ Increase product purity post-protein A
- ▶ Downsizing of the sterilizing grade membrane
- ▶ Reduce turbidity post viral inactivation/neutralization step
- ▶ Reduce impurities load on downstream AEX column



Benefits

(Experienced in a typical mAb harvest-clarification unit operation)

High performance clarification

- ▶ >4 log DNA reduction
- ▶ Consistent output turbidity (<5 NTU)
- ▶ Nominal 20-40% HCP reduction

Enables higher Protein A column performance over 3M depth filtration

- ▶ >10x less HCP post-Protein A
- ▶ >1,000x DNA reduction post-Protein A
- ▶ >10x less residual contaminants on Protein A column

Enables

- ▶ Significant reduction in filter surface area of sterilizing filters

Provides

- ▶ >10x less contaminants entering downstream AEX column

Increased process efficiency

- ▶ Simplify the process by removing multiple types of impurities in a single process step, leading to better process economics.
- ▶ The combination of 3M's Zeta Plus Series Depth Filter, Emphaze AEX Hybrid Purifier and LifeASSURE Filters may be a compelling alternative to a centrifuge-based Harvest-Clarification process.

Increase product purity over traditional harvest-clarification unit operations (centrifuge + depth filter or 2 stage depth filters)

- ▶ Removing more impurities early in the process, the Emphaze AEX Hybrid Purifier provides protection to chromatography columns increasing their purification performance.

3M™ Emphaze™ AEX Hybrid Purifier

Product Selection/Specification (NOTE: R after product and model name indicates the sterilization/sanitization compatible products)										
Product Name		BV0.3R	BV1R	BV8R		BV60R	BV120R	BV360R	BV800R	BV5600R
Model Name		EMP101AEX020R	EMP201AEX020R	EMP301AEX020R	EMP303AEX020R	EMP503AEX020R	EMP513AEX020R	EMP533AEX020R	EMP710AEX020R	EMP770AEX020R
Part Number		70020346857	70020346865	70020346873	70020346881	70020346899	70020346907	70020346915	70020346923	70020346931
Global Part Number		7100179206	7100174193	7100158433	7100158434	7100158416	7100166976	7100158435	7100158436	7100158437
Height x Diameter		4.8 × 4.3 cm (1.9 × 1.7 in.)	5.9 × 4.3 cm (2.3 × 1.7 in.)	4.5 × 7.7cm (1.7 × 3.0 in.)	8.8 × 7.7cm (3.5 × 3.0 in.)	10.3 × 21.6cm (4.1 × 6.5 in.)		15.2 × 21.6cm (6.0 × 6.5 in.)	5.7 × 45.2cm (2.2 × 17.8 in.)	20.3 × 45.2cm (8.0 × 17.8 in.)
Dry Weight		9.0 g	14.5 g	71g	77g	1.0kg	1.1kg	1.6kg	3.4kg	9.5kg
Weight Wet Post Blow Down		9.5 g	16.0 g	80g	85g	1.1kg	1.2kg	2.1kg	4.1kg	14.2kg
Fill Volume¹		2.0 mL	5.5 mL	13mL	16mL	0.55L	0.55L	1.4L	3.4L	10.6L
Hold up Volume Post Blow Down²		0.5 mL	1.5 mL	9mL	9mL	0.10L	0.15L	0.46L	0.70L	4.7L
Capsule Material		Polypropylene		Polypropylene, Glass Filled Polypropylene		Polysulfone, Polypropylene, Thermoplastic Elastomer, Fluorocarbon			Thermoplastic Elastomer, Glass Filled Polypropylene Oxide, Polystyrene, Silicone	
Autoclave Cycle	Sterilization Pre-Use	121°C, 30 min	121°C, 30 min	121°C, 30 min		121°C, 30 min	121°C, 30 min	121°C, 40 min	121°C, 40 min	121°C, 40 min
	Sterilization Post Use	121°C, 40 min	121°C, 40 min	121°C, 40 min		121°C, 40 min	121°C, 40 min	121°C, 40 min	121°C, 40 min	121°C, 40 min
Alkaline Resistance	Pre-Use	1M NaOH soak for 1 hour at ambient temperatures followed by gravity drain to remove excess base; <b>DO NOT BLOW DOWN</b>								
	Post Use	Capsule soak for 1 hour with 1M NaOH or 5% NaClO (bleach)								
Inlet/Outlet Connections		Luer-Lok			3/4 in. Sanitary Connectors				1-1/2 in. Sanitary Connectors	
Maximum Inlet Pressure³		3.4 bar		2.8 bar		3.1 bar			3.4 bar	
Maximum Differential Pressure		2.4 bar		2.4 bar		2.4 bar	2.4 bar	2.4 bar	2.4 bar	2.4 bar
Maximum Temperature		40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)
Required Preconditioning Flush Volume⁴		6.5 mL	22 mL	130mL		0.9L	1.8L	5.5L	12L	85L
Recommended Use Flow Rate		0.4 mL/min	1.4 mL/min	8mL/min		50mL/min	100mL/min	300mL/min	680mL/min	4700mL/min
Storage Conditions		Controlled indoor temperatures: 0–30°C (32–86°F) in original sealed packaging								
Shelf Life		Up to 2 years from date of manufacture @ 30°C maximum storage								

A full support package is available for the 3M™ Emphaze™ AEX Hybrid Purifier. This package includes Installation and Operation Instructions, Certificate of Quality or Certificate of Lot Conformance, and a Regulatory Support File.

1. Capsule Fill Volume is defined as the volume of liquid that is required to fill the capsule.
2. Post Blow-Down Hold-Up Volume is defined as the volume of the residual liquid after air/gas blow down.
3. Do not use this product for continuous service with compressed gasses. The use of compressed gas is permissible for integrity testing and blow down purposes.
4. A Preconditioning Flush is required for the product to be compliant with USP Biological Reactivity Tests, including USP <87> and <88> Class VI. The flush solution can be a buffer or 25–150mM sodium chloride solution. Refer to Installation and Operation Instructions for complete instructions on how to perform the preconditioning flush.



**Intended Use:** Single-use processing of aqueous based biological pharmaceuticals (drugs) and vaccines to remove biological contamination strictly following the product operating instructions and cGMP requirements, where applicable.

**Prohibited Use:** As a component in a medical device that is regulated by any agency, and/or globally exemplary agencies, including but not limited to: a) FDA, b) European Medical Device Directive (MDR), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA); Applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring FDA Food Contact or comparable compliance.

**Product Selection and Use:** Many factors beyond 3M's control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. As a result, end-user is solely responsible for evaluating the product and determining whether it is appropriate and suitable for end-user's application, including completing a risk assessment that considers the product leachable characteristics and its impact on drug safety conducting a workplace hazard assessment and reviewing all applicable regulations and standards (e.g., OSHA, ANSI, etc.). Failure to properly evaluate, select, and use a 3M product and appropriate safety products, or to meet all applicable safety regulations, may result in injury, sickness, death, and/or harm to property.

**Warranty, Limited Remedy, and Disclaimer:** 3M warrants that each 3M product meets the applicable 3M product specification at the time 3M ships the product. 3M MAKES NO OTHER WARRANTIES OR CONDITIONS, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ARISING OUT OF A COURSE OF DEALING, CUSTOM, OR USAGE OF TRADE WITH RESPECT TO THE INFORMATION PROVIDED AND THE PRODUCT THE INFORMATION REFERS TO. If a 3M product does not conform to this warranty, then the sole and exclusive remedy is, at 3M's option, replacement of the 3M product or refund of the purchase price.

**Limitation of Liability:** Except for the limited remedy stated above, and except to the extent prohibited by law, 3M will not be liable for any loss or damage arising from or related to the 3M product, whether direct, indirect, special, incidental, or consequential (including, but not limited to, lost profits or business opportunity), regardless of the legal or equitable theory asserted, including, but not limited to, warranty, contract, negligence, or strict liability.

For more information about the 3M™Emphaze™AEX Hybrid Purifier, contact your local sales rep.



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