

GPPI

General Processing Platform Isolator

Introduction

The Esco General Processing Platform Isolator (GPPI) is a highly adaptable, unidirectional airflow isolator that can be used for sterility testing or other processes that require an ISO Class 5 (Grade A) aseptic environment. The GPPI's advanced control system allows the operator to select either positive or negative chamber pressure as well as single pass or recirculating airflow patterns. These features, along with the ability to perform safe change procedures on the supply and return ULPA filters, make the GPPI a highly versatile isolator that can be used for potent or non-potent aseptic materials.

In addition, the Esco GPPI's design offers over 20 standard options and configurations ensuring that Esco can provide a standard solution to fit your specific process and facility requirements. Should a standard option not fit your requirements Escos can offer customized solutions as well.

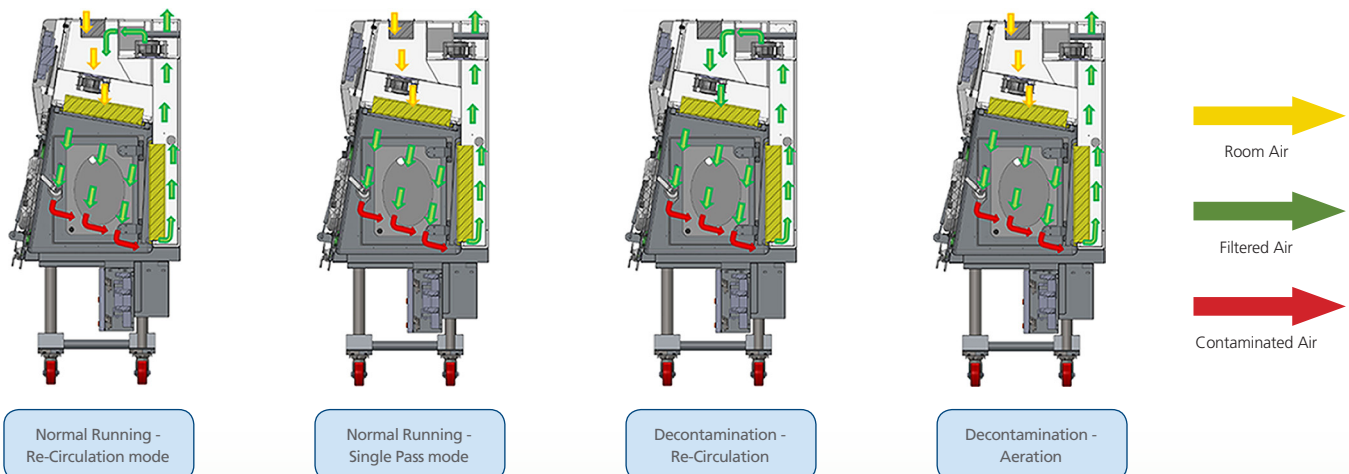
Basic Features

- Unidirectional airflow
- User selectable positive or negative chamber pressures and single pass or recirculating airflow regimes
- Multiple standard VHP bio-decontamination options providing 6 log reduction in viable contaminants
- Low Contamination Change Filter design allows for the handling of potent and non-potent aseptic products

Applications

- Pharmaceutical Compounding (Chemotherapy/TPN)
- Small Batch Sterility Testing
- Small-scale Potent Material Handling
- Cell Processing
- Aseptic Processing
- Research and Development

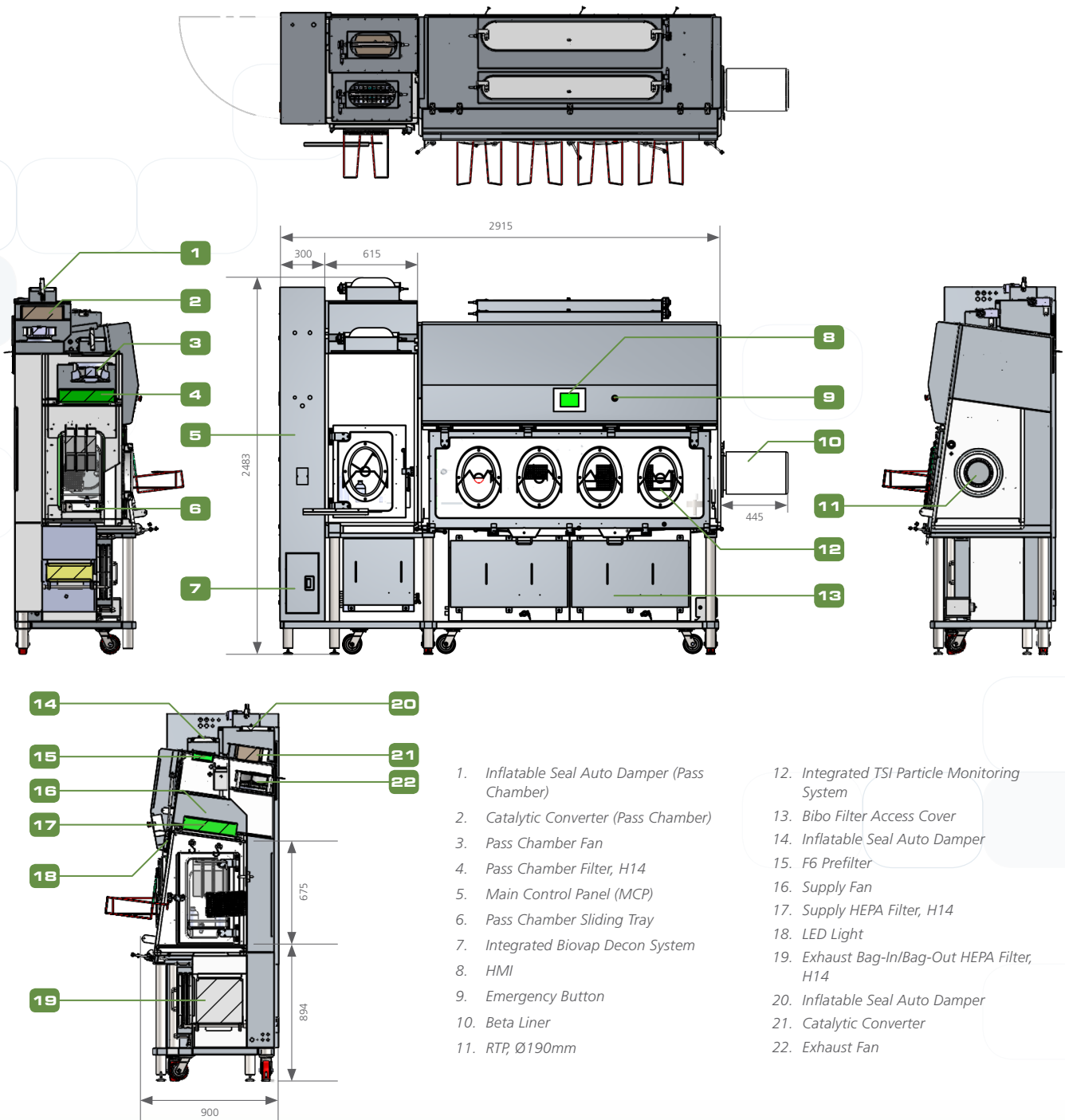
Airflow Regimes



Standard Features

- Fully welded SS316L internal chambers with rounded covered corners
- Optional on-board exhaust catalytic convertor allows exhaust into the surrounding room without modifications to the facility and fitted with an interlocked external H₂O₂ sensor for safety
- Optional on-board air compressor eliminates the requirement for a site supplied compressed air connection, which allows for the installation of a simple plug-in of electrical power.
- Product is designed with FDA-approved hydraulic liquid that not only allows the user to raise and lower for optimal ergonomics but also enables ease of transport through a variety of doorway and ceiling heights.
- Self-contained design of control system & electrics allow for simple, plug-in installation
- Integrated particle monitoring connections and optional inclusion of the viable and non-viable monitoring equipment
- Automated pressure hold test
- Pre-Programmed system to function with multiple H₂O₂ system options
- Standard design incorporates cGMP compliant features; with the inclusion of an optional chart recorder or printer the GPPI will meet the data handling requirements for 21 CFR Part 11 requirements.
- Safe change glove system allows the changing of gloves while maintaining aseptic conditions inside of the chambers

ENGINEERING DRAWING (MODEL: GPPI-4G)



GENERAL SPECIFICATIONS

GENERAL PROCESSING PLATFORM ISOLATOR (GPPI)

				GPPI-2G	GPPI-3G	GPPI-4G
Nominal Size main Chamber (Width)				1200 mm	1600 mm	2000 mm
Internal Dimensions (W x D x H)		1200 mm x 610 mm x 720 mm		✓	✓	✓
		1200 mm x 720 mm x 720 mm		✓	✓	✓
External Dimensions (W x D x H)		With Adjustable Base Stand (Min)		1920 mm x 1030 mm x 2200 mm	2320 mm x 920 mm x 2200 mm	2720 mm x 900 mm x 2200 mm
		With Adjustable Based Stand (Max)		1920 mm x 1030 mm x 2500 mm	2320 mm x 920 mm x 2500 mm	2720 mm x 920 mm x 2500 mm
Glove Port Height (Min)				1055 mm		
Glove Port Height (Max)				1355 mm		
Chamber Environment				ISO Class 5 (Grade A)		
Chamber Seal	Static (-S)	Recirculating Airflow	Filter in Rear	With BIBO		
				Without BIBO	✓	
		Filter in Bottom	With BIBO	✓		
			Without BIBO	✓		
		Total Exhaust Airflow	Filter in Rear	With BIBO	✓	
			Without BIBO	✓		
	Filter in Bottom	With BIBO	✓			
		Without BIBO	✓			
	Inflatable Seal (-IS)	Recirculating Airflow	Filter in Rear	With BIBO	✓	
			Filter in Bottom	Without BIBO	✓	
		Total Exhaust Airflow	Filter in Rear	With BIBO	✓	
			Filter in Bottom	Without BIBO	✓	
		Recirculating/Total Exhaust Airflow	Filter in Rear	With BIBO	✓	
			Filter in Bottom	Without BIBO	✓	
Filtration	Prefilter		Washable non-woven polyester fibers with 85% arrestance and 20% efficiency			
	Chamber Supply	Filter Type	ULPA (U15) with Knife Edge Gel Seal			
		Filter Efficiency	99.999% at 0.3 microns			
	Chamber Exhaust	Filter Type	HEPA (H14) with Gasket Seal and Integral Mesh Guard			
Filter Efficiency		99.99% at 0.3 microns				
Lighting Level				≥ 600 Lux		
Sound Level				68 dBA		
Isolator Construction		Chamber		SS 316L		
		Service Housing		SS 304L		
		Support Frame		SS 304L		
Isolator Finish		Internal Chamber		≤ 0.4 Ra		
		External Chamber		≤ 0.6 Ra		
		External Service Housing		≤ 0.6 Ra		
		Support Frame		≤ 1.0 Ra		
Electrical Requirements		220-240V, AC, 50Hz, 1Ø		✓		
		110-120V, AC, 60Hz, 1Ø		✓		
		220-240V, AC, 60Hz, 1Ø		✓		
Compressed Air Requirement (By Client) (If no on-board compressor)		2 Bar-g Pressure at 5Ltr/sec		✓		
Exhaust Duct Requirements (By Client) (Unless Integral Catalytic Convertor is Included)				10" Duct from Isolator to Outside		

Options	Pass Chamber	✓
	Biodecontamination System (other brands)	✓
	Non-viable Air Sampler	✓
	Viable Air Sampler	✓
	Sterility Test Pump	✓
	Glove Tester	✓
	Waste Bag Grommet	✓
	Sterile Continuous Liner	✓
	Bag Welder with Table	✓
	RTPØ105, 190, 270, 350, 460 - Alpha	✓
	RTPØ105, 190, 270, 350, 460 - Beta Canister	✓
	RTPØ105, 190, 270, 350, 460 - Beta Liner	✓
	Weighing Scale	✓
	Spray Gun	✓
	Temperature and RH Monitoring System	✓
	H2O2 Monitoring System	✓
	Product Waste Entry/Exit Ports	✓
	Liquid Water Entry/Exit Ports	✓
Integral Catalytic Converter	✓	
On-board Air Compressor	✓	

BUILDING EXHAUST REQUIREMENTS		2G-GPPI	3G-GPPI	4G-GPPI
Recirculating	Process Chamber	Pa 30 ,hr/m3 198	Pa 30 ,hr/m3 264	Pa 30 ,hr/m3 330
	Pass-thru chamber	Pa 50 ,hr/510m3	Pa 50 ,hr/510m3	Pa 50 ,hr/510m3
(Total Exhaust (Single Pass	Process Chamber	80 ,hr/991m3	Pa 140 ,hr/1322m3	Pa 200 ,hr/1652m3
	Pass-thru chamber	Pa 50 ,hr/510m3	Pa 50 ,hr/510m3	Pa 50 ,hr/510m3

*Each PTC has an individual exhaust duct

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