

Introduction

Esco Containment Barrier Isolator (CBI) facilitates the isolation of a product or process while providing the required conditions for a sterile/ aseptic environment. It is configured to operate at positive or negative pressure. This equipment provides a comprehensive range of personnel and product protection in addition to protection for the surrounding work areas and the environment.

CBI's design has complete compliance to PIC/s and EU cGMP standards with its 19 mm radius coved internal corners in a single piece chamber (no perforations or grilles for contaminants to be trapped on all 4 corners). Its Rear Return Filter ensures that ducts are not contaminated. The system comes in either recirculatory or single pass airflow.

Applications

- Pharmacy Compounding (Chemotherapy/TPN)
- As a Class III Cabinet for Biosafety Levels (BSL) 3 and 4
- Small Batch Sterility Testing
- Small-scale Potent Material Handling
- Cell Processing
- Aseptic Processing
- Research and Development

Key Features

- Controls exposure/cross-contamination risk to hazardous/aseptic materials for a wide variety of equipment and processes
- Controls false-positive risk for sterility testing
- Provides Operator Exposure Levels (OEL's) ≤1.0 µg/m³ during controlled operations
- Levels of ≤0.1 µg/m³ can be achieved via closed-transfer processes or based on client SOPs
- Enhances cGMP practices
- Quiet, energy-efficient ECM fans auto adjust to compensate for filter blockage
- Standard dimensions available are easily customized to suit process requirements
- Safe glove change and low contamination filter change
- FDA-approved static seals
- Pressure tested class 1 ISO 10648-2 standards
- System comes with a Semi-automated or Automated Pressure Hold Testing

- Pass Chamber comes in 2 sizes:
 - Small, non-gloved
 - Large, non-gloved/gloved

Filtration Package

Process Chamber

- Room Inlet Filter F6 filtration. Panel filter, glass fiber media.
- Chamber Inlet Filter Single U15 ULPA filtration. Panel filter, gel seal, glass fiber media.
- Chamber Return Filter Single H14 HEPA filtration. Panel filter, gasket seal, glass fiber media.
- Chamber Outlet Filter Standard F6 filtration, optional H14 HEPA filtration. Panel filter, gasket seal, glass fiber media.

Note: Hydrogen Peroxide Vapor (HPV) will pass through the filters during the HPV cycle to allow decontamination of the filters and air path.

Pass Chamber

- Room Inlet Filter G4 filtration. Panel filter, polyester media.
- Chamber Inlet Filter Single U15 ULPA filtration. Panel filter, gasket seal, glass fiber media.
- Chamber Exhaust Filter F6 filtration. Panel filter, gel seal, glass fiber media.

Note: HPV will pass through the HEPA filters during the HPV cycle to allow decontamination of the filters and air path.

Basic Principles

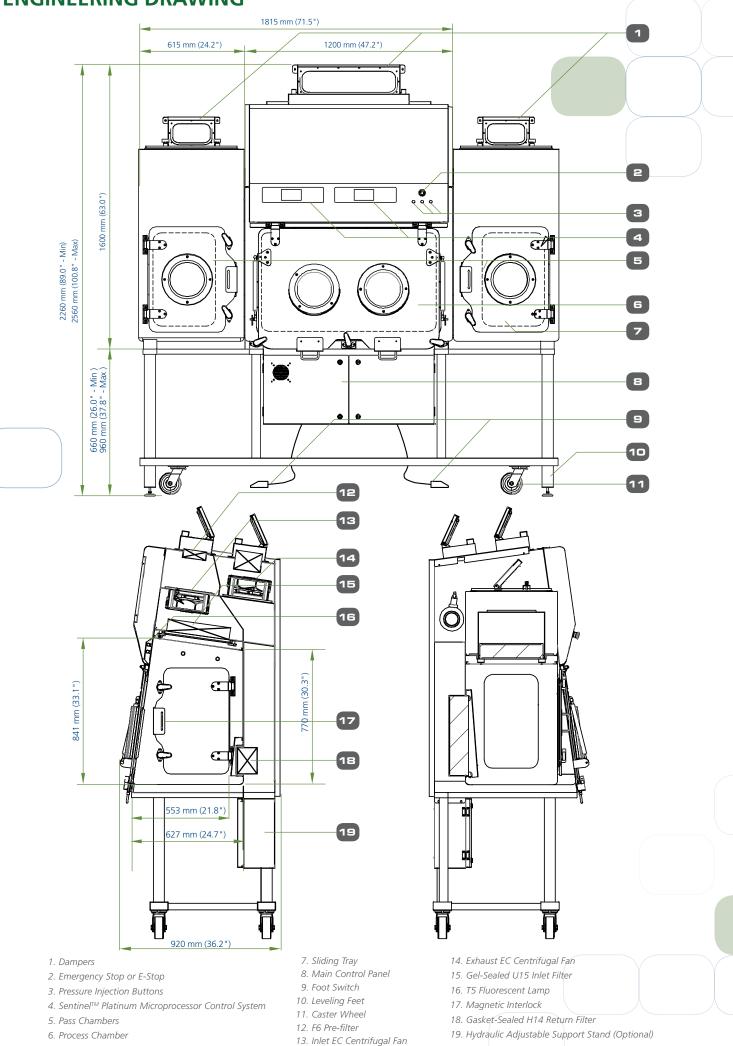
- Equipped with dual Sentinel™ Platinum Microprocessor Control System
- Standard Controls suitable for safe area applications
- Includes two IP66 electrical sockets as standard

Warranty

One year warranty (excluding consumables). Consumables are ballast, fluorescent, and filters. The warranty will cover all other parts including the blower, fan switch, and electrical main board. During the period of warranty, any repair, modification, testing and commissioning performed by any unathorized party other than Esco Service Team will void the warranty of the unit.



ENGINEERING DRAWING



GENERAL SPECIFICATIONS CONTAINMENT BARRIER ISOLATOR (CBI)		CBI-2G	CBI-3G	CBI-4G
Main Chamber Nominal Size (Width)		1.2 m	1.6 m	2.0 m
Working Chamber Dimensions - Min (L x W x H)		1.2 m x 0.55 m x 0.77 m	1.6 m x 0.55 m x 0.77 m	2.0 m x 0.55 m x 0.77 m
Working Chamber Dimens	ions - Max (L x W x H)	1.2 m x 0.63 m x 0.84 m	1.6 m x 0.63 m x 0.84 m	2.0 m x 0.63 m x 0.84 m
External Dimension	With Adjustable Base Stand (Min)	1.82 m x 0.92 m x 2.26 m	2.22 m x 0.92 m x 2.26 m	2.62 m x 0.92 m x 2.26 m
(with one Pass Chamber)	With Adjustable Base Stand (Max)	1.82 m x 0.92 m x 2.56 m	2.22 m x 0.92 m x 2.56 m	2.62 m x 0.92 m x 2.56 m
(L x W x H)				
Glove Port Height (Min)		1000 mm 1300 mm	1000 mm 1300 mm	1000 mm
Glove Port Height (Max) Chamber Environment			Class 5 all Chambers (Grade	
Filter Type - Chamber Inlet		ULPA U15 with Integral Mesh Guard and Knife Edge Gel Seal		
Filter Efficiency - Chamber Inlet		99.9998%		
Filter Type - Chamber Exhaust		HEPA H14 with Integral Mesh Guard and Gasket Seal		
Filter Efficiency - Chamber Exhaust		99.995%		
		≥ 700 Lux		
Sound Level		<63dBA	TBA	ТВА
	Chamber		SS316L	
Isolator Construction	Service Housing	SS304L		
	Support Frame	SS304L		
Isolator Finish	Chamber Internal	≤0.4 Ra		
	Chamber External	≤ 0.6 Ra		
	Service Housing External	≤ 0.6 Ra		
	Support Frame		≤ 1.0 Ra	
Electrical Requirements (by Client)	220-240 VAC, 50/60 Hz, 1 Ø	✓	✓	✓
	110-120 VAC, 50/60 Hz, 1 Ø	✓	✓	✓
Compressed Air Requirement (by Client) if no on-board compressor	2 Bar-g Pressure at 5 L/sec	✓	✓	\checkmark
Exhaust Duct Requirements (by Client) unless Integral Catalytic Convertor is Included		10" Duct from Isolator to Outside		
Options	Pass Chamber (Small, nongloved or Large, nongloved/gloved)		✓	✓
	Bio-Decontamination BIOVAP	✓	✓	✓
	Non-Viable Air Sampler	✓	✓	✓
	Viable Air Sampler	✓	✓	✓
	Sterility Test Pump	✓	✓	√
	Glove Tester	✓	✓ <i>✓</i>	√
	Waste Bag Grommet	, ,	 	· · · · · · · · · · · · · · · · · · ·
	Sterile Continuous Liner	, , , , , , , , , , , , , , , , , , ,	· · · · · · · · · · · · · · · · · · ·	· · ·
	Bag Welder with Table	, , , , , , , , , , , , , , , , , , ,	· · · · · · · · · · · · · · · · · · ·	, ,
	RTPØ105, 190, 270, 350, 460 - Alpha	· · ·	•	· · ·
	RTPØ105, 190, 270, 350, 400 - Alpina RTPØ105, 190, 270, 350, 460 - Beta Canister	· ·	•	
	RTPØ105, 190, 270, 350, 460 - Beta Liner	· · ·	✓ ✓	./
		v	v	v
	Analytical Balance	v	v	v
	Spray Gun	✓ ✓	✓ /	✓ ✓
	Temperature and Humidity Monitor	✓ ✓	✓	✓ ✓
	H ₂ O ₂ Monitoring	✓ ✓	✓	✓
	Product Waste Entry / Exit Ports	✓ 	✓ 	✓
	Liquid Waste Entry / Exit Ports	✓ 	✓	✓
	4" Butterfly Valve	✓ 	✓	✓
	Drain	✓ 	✓	✓
	Liner System	✓	✓	✓
	On-board Air Compressor	✓	\checkmark	✓
	UV Lamp	✓	\checkmark	✓
	Carbon Filter	✓	✓	✓
	Adjustable Hydraulic Stand	✓	✓	✓
	CCTV Camera	✓	✓	✓

ESCO GLOBAL NETWORK



Air Shower Aseptic Containment Isolator (ACTI) **Ceiling Laminar Airflow Units** Containment Barrier Isolator (CBI) Dynamic Pass Box Esco Straddle Unit Single **Evidence Drying Cabinet** Garment Storage Cabinet General Processing Platform Isolator (GPPI) Hard Capsule Laminar Flow Horizontal Trolley Laminar Flow Straddle Units Laminar Flow Vertical Trolley Pass Box Soft Capsule Sputum Booth

Weighing and Dispensing Containment Isolator (WDCI)



Esco Pharma dedicated R&D engineers have a combined 30 years of experience in systems design of a variety of containment and aseptic process equipment. Compared to industry averages, Esco invests a significant percentage of annual revenues in research and development. As a result of our investment, and with continuous feedback and idea evaluation among our research, global sales, marketing, purchasing and manufacturing teams, Esco products reflect the best contemporary designs in performance, ergonomics and customer satisfaction. www.escopharma.com



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