

Containment Barrier Isolator (CBI)



Solpharma
Technologies

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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) $\leq 1.0 \mu\text{g}/\text{m}^3$ during controlled operations
- Levels of $\leq 0.1 \mu\text{g}/\text{m}^3$ 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.

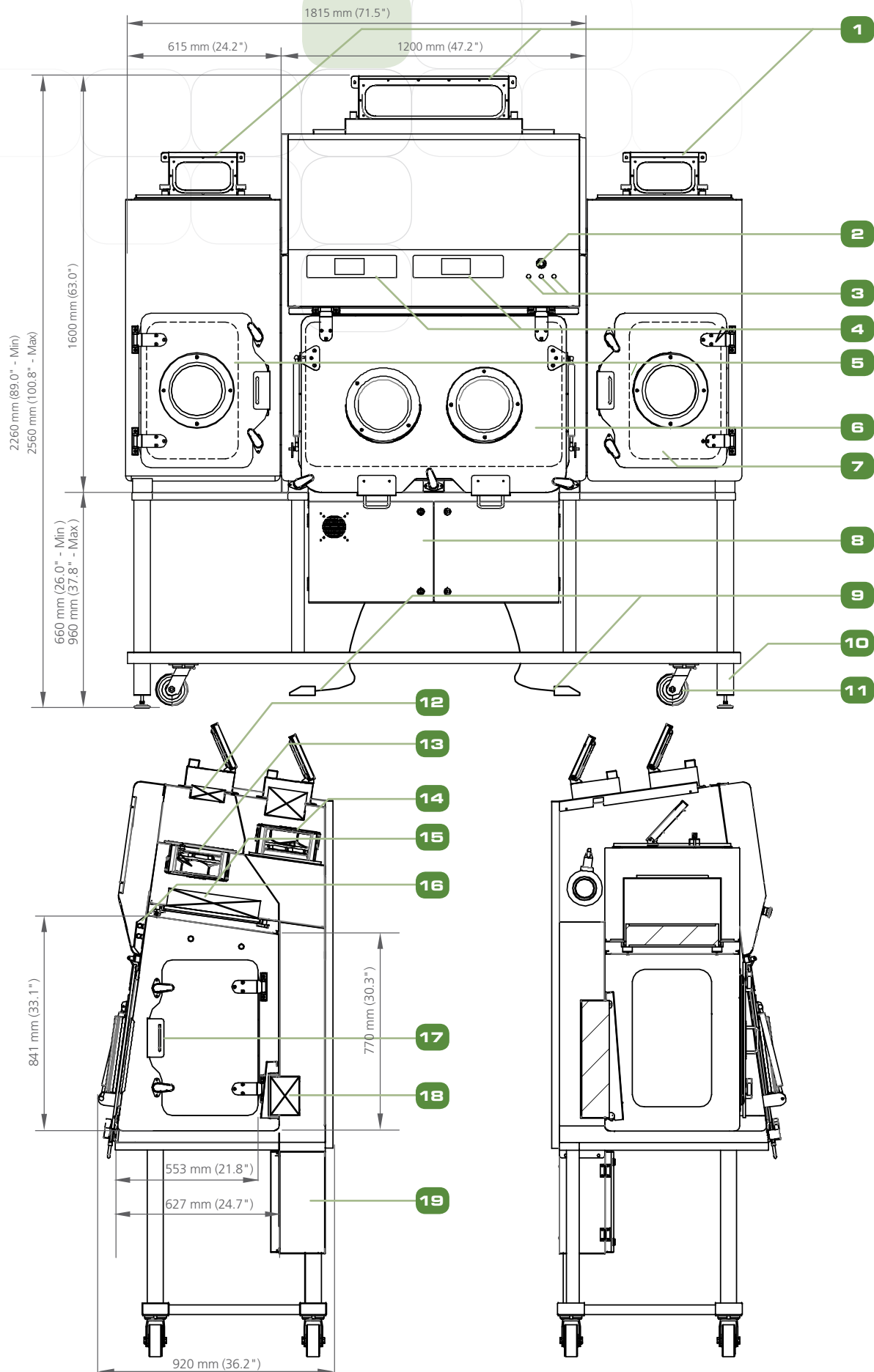
Control System

- 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 unauthorized party other than Esco Service Team will void the warranty of the unit.

ENGINEERING DRAWING



- | | | | |
|---|-----------------------|--------------------------------|---|
| 1. Dampers | 5. Pass Chambers | 10. Leveling Feet | 15. Gel-Sealed U15 Inlet Filter |
| 2. Emergency Stop or E-Stop | 6. Process Chamber | 11. Caster Wheel | 16. T5 Fluorescent Lamp |
| 3. Pressure Injection Buttons | 7. Sliding Tray | 12. F6 Pre-filter | 17. Electromagnetic Interlock |
| 4. Sentinel™ Platinum Microprocessor Control System | 8. Main Control Panel | 13. Inlet EC Centrifugal Fan | 18. Gasket-Sealed H14 Return Filter |
| | 9. Foot Switch | 14. Exhaust EC Centrifugal Fan | 19. Hydraulic Adjustable Support Stand (Optional) |

GENERAL SPECIFICATIONS				
Model		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 x 0.55 x 0.77 m	1.6 x 0.55 x 0.77 m	2.0 x 0.55 x 0.77 m
Working Chamber Dimensions - Max (L x W x H)		1.2 x 0.63 x 0.84 m	1.6 x 0.63 x 0.84 m	2.0 x 0.63 x 0.84 m
External Dimension (with one Pass Chamber) (L x W x H)	With Adjustable Base Stand (Min)	1.82 x 0.92 x 2.26 m	2.22 x 0.92 x 2.26 m	2.62 x 0.92 x 2.26 m
	With Adjustable Base Stand (Max)	1.82 x 0.92 x 2.56 m	2.22 x 0.92 x 2.56 m	2.62 x 0.92 x 2.56 m
Glove Port Height (Min)		1000 mm	1000 mm	1000 mm
Glove Port Height (Max)		1300 mm	1300 mm	1300 mm
Chamber Environment		ISO Class 5 all Chambers (Grade A)		
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%		
Lighting Level		≥ 700 Lux		
Sound Level		<63 dBA	TBA	TBA
Isolator Construction	Chamber	SS316L		
	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, 1Ø	✓	✓	✓
	110-120 VAC, 50/60 Hz, 1Ø	✓	✓	✓
Compressed Air Requirement (by Client) if no on-board compressor	2 Bar-g Pressure at 5 L/sec	✓	✓	✓
Exhaust Duct Requirements (by Client) unless Integral Catalytic Converter 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	✓	✓	✓
	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	✓	✓	✓
	Analytical Balance	✓	✓	✓
	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	✓	✓	✓
	UV Lamp	✓	✓	✓
	Carbon Filter	✓	✓	✓
	Adjustable Hydraulic Stand	✓	✓	✓
	CCTV Camera	✓	✓	✓
	TV Monitor	✓	✓	✓