



Isoclean[®]

Healthcare Platform Isolator

(Inflatable Seal Model)

Optimized Solution for Sterile/Aseptic Applications



ESCO[®]
PHARMA

Introduction

The Isoclean® Healthcare Platform Isolator – Inflatable Seal Model (HPI-IS) facilitates the isolation of a product/process while providing the required sterile environment. HPI-IS is designed with inflatable seals and automated dampers. The standard unit is fully integrated with auto pressure hold testing and BioVap™ (hydrogen peroxide biodecontamination system with H₂O₂ sensors and catalytic converter).

Integration of Esco BioVap™ allows master biodecon and independent biodecon of main chamber and passthrough chambers.

This improved design facilitates ease of isolation control especially during pressure decay testing and bio-decontamination process. This model can be adjusted on-site to operate in positive or negative pressure regime. It is available in recirculating or total exhaust configuration.

Main Features

- This model is capable of expanding up to 3 modules of 2-glove main chamber with 2 modules of passthrough chamber (left and right).
- Capable of automated pressure hold testing (APHT) and biodecontamination with log 6 reduction
- HEPA (H14) filter (as per EN 1822) with a typical efficiency of > 99.999% at 0.1 to 0.3 microns; provide superior ISO Class 5 air cleanliness as per ISO 14644-1
- Containment enclosure classification: Class 2 as per ISO 10648-2
- Electromagnetic interlocking doors with time delay effect ensures safety and containment during material transfer

* With built-in air compressor to support inflatable seals in the window and dampers, and the BioVap™ biodecontamination system.

Applications

- Aseptic and/or Potent Compounding
- Pharmacy Compounding
- Sterility Testing
- Cell and Gene Therap
- Peptide Production
- Biosafety Facility Level 3 or 4
- Benchtop/Small-scale Aseptic Formulation and Filling
- Small-scale Potent Material Handling
- Cosmeceutical
- R&D and Clinical Trials

Options:

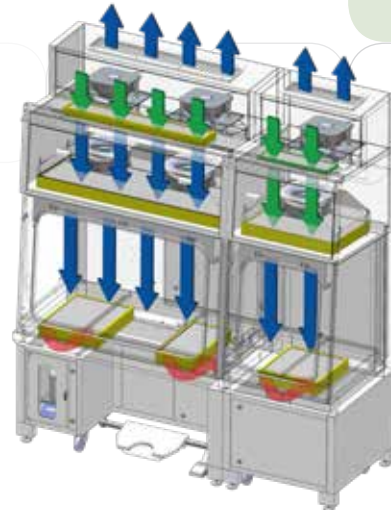
- Available in Recirculating or Total Exhaust Configuration
- Integration of a side-mounted CO2 Incubator
- Glove Leak Tester
- Glove Port Sizes (300 mm or 300 x 200 mm)
- CCTV Integration
- Access to Rear View Monitor
- Addition of Sterility Test Pump
- Mechanical Integration of Viable/Non-viable Particle Monitoring (with separate software)

HPI-IS Airflow Pattern

Total Exhaust Configuration

The main chamber and passthrough chamber are independent systems equipped with its own blower and filter.

Ambient air is pulled through the inlet prefilter and downflow filter placed on top of the isolator. The HEPA (H14) filter provides a laminar airflow providing ISO Class 5 air cleanliness to the main chamber and the passthrough chamber. The exhaust fan pulls the air and passes through the HEPA (H14) filter below the work zone, resulting to the air being pulled to the back plenum. It is then exhausted through the optional HEPA (H14) or carbon filter at the top portion of the isolator.

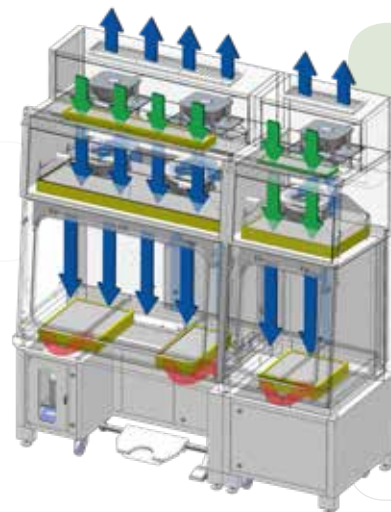


- HEPA-filtered air
- Unfiltered / potentially contaminated air
- Room air / Inflow air

Recirculating Configuration

The main chamber and passthrough chamber are independent systems equipped with its own blower and filter.

Ambient air is pulled through the inlet prefilter and downflow filter placed on top of the isolator. The HEPA (H14) filter provides a laminar airflow providing ISO Class 5 air cleanliness to the main chamber and the passthrough chamber. The exhaust fan pulls the air and passes through the HEPA (H14) filter below the work zone, resulting to the air being pulled to the back plenum. A percentage of the air is recirculated back to the main chamber/passthrough chamber, while a smaller percentage is then exhausted through the optional HEPA (H14)/Carbon Filter filter at the top portion of the isolator.



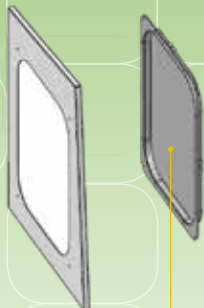
- HEPA-filtered air
- Unfiltered / potentially contaminated air
- Room air / Inflow air

Automated dampers for improved and safer isolation control during pressure decay testing and bio-decontamination process

Esco HMI Control system

supervises all cabinet operations and monitors cabinet performance in real time

Large graphical touch-screen display to illustrate isolator operating parameters



Standard Side Adaptor

Inflatable Seal Flanges allows integration of multiple HPI-IS modules

Inflatable Seals

Hydrogen Peroxide Bottle Compartment – Easy to access H₂O₂ Bottle compartment for refilling procedure

Foldable footrest to provide better working ergonomics

Main Chamber Module

Foot Switch provides hands-free opening of the inner door of the passthrough chamber

Passthrough Chamber Module

Polycarbonate Main Window

300 mm Glove Ports

Pre-filter: F6 (for PTC) and **HEPA H14** (for Main Chamber) extends the HEPA (H14) Downflow Filter

• **Inlet F6 Pre-filter** (for PTC)

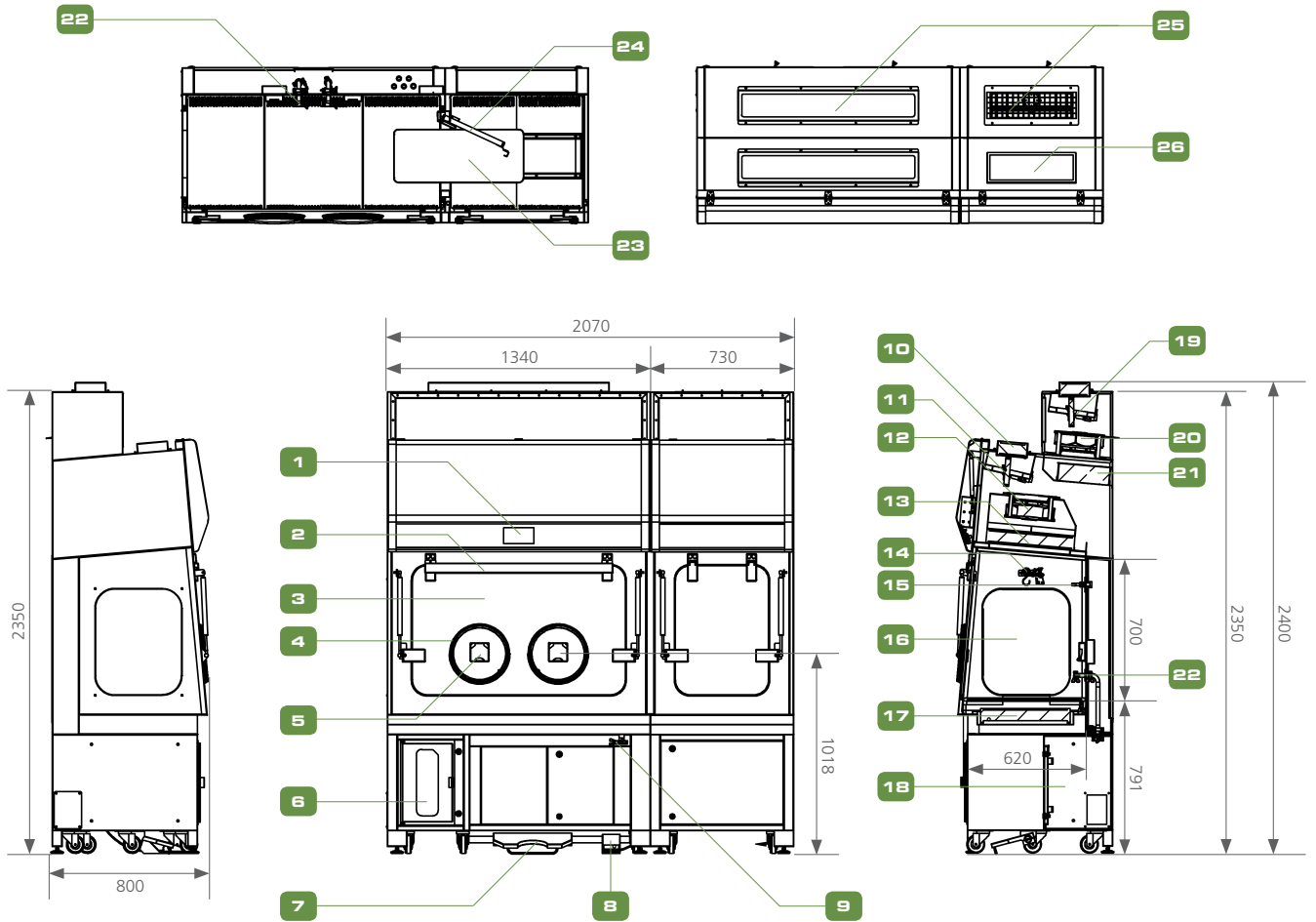
• **Inlet HEPA (H14) Filter** (for Main Chamber)

Electromagnetic interlocking doors with time delay effect ensures safety and containment during material transfer

ISOCLEAN® Healthcare Platform Isolator - Inflatable Seal Model (HPI-IS)

		2-glove Main Chamber	3-glove Main Chamber	4-glove Main Chamber	Passthrough Chamber	3-way Passthrough Chamber
External Dimension (W x D x H)		1340 x 800 x 2350 mm	1645 x 800 x 2350 mm	1950 x 800 x 2350 mm	730 x 800 x 2350 mm	730 x 800 x 2350 mm
Internal Dimension (W x D x H)		1290 x 620 x 700 mm	1595 x 622 x 700 mm	1900 x 622 x 700 mm	680 x 620 x 700 mm	680 x 620 x 700 mm
Passthrough Chamber - Tray Dimension		N/A	N/A	N/A	270 x 660 mm	270 x 660 mm
Isolator Construction	External Body	ISOCIDE™ Powder-coated electrogalvanized steel				
	Internal Chamber	Stainless steel 316L				
Airflow		Unidirectional/Laminar Airflow (Recirculating or Total Exhaust/Single-Pass Airflow Models are available)				
Process Chamber Pressure		+37 Pa			+25 Pa	
Process Chamber Downflow Velocity		Selectable between -60 Pa to +75 Pa				
Process Chamber Downflow Velocity		0.45 m/s +/-20%				
Chamber Lighting	Normal Operating Mode	Warm White, Minimum 500 Lux			no lighting for PTC Module	
	Bio-decontamination Mode	Blue			no lighting for PTC Module	
	Alarm Mode	Red			no lighting for PTC Module	
Aeration Mode		With Integrated Catalytic Converter				
Pressure Hold Test	During FAT and IQOQ	Class 2 Containment as per ISO 10648-2				
	Automated Daily Routine	Class 3 Containment as per ISO 10648-2 (Pressure hold test prior to each biodecontamination)				
Net Weight		525 Kg	650 Kg		328 Kg	
Inflatable Sealed Side Adaptor Plate/ Retrofit Option		RTP for sizes 105 mm, 190 mm, or 270 mm			N/A	
		Up to 4 x 1" Tri-clover connection			N/A	

ENGINEERING DRAWING



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| <ul style="list-style-type: none"> 1. Esco HMI Control 2. LED Light 3. Process Chamber Inflatable Seal 4. Glove Port (ø 300 mm) 5. Electrical Outlet 6. Hydrogen Peroxide Bottle Compartment 7. Foldable Footrest 8. Foot switch 9. Spare Drain (1" Tri-clover) | <ul style="list-style-type: none"> 10. HEPA (H14) Pre-filter 11. Inlet Damper Inflatable Seal 12. Supply Fan 13. Supply HEPA (H14) Filter 14. IV Bar with 6 S-hooks 15. Relative Humidity and Temperature Sensor 16. Side Adaptor Inflatable Seal Flange 17. Exhaust HEPA (H14) Filter 18. Main Control Panel | <ul style="list-style-type: none"> 19. Exhaust Damper Inflatable Seal 20. Exhaust Fan 21. Catalytic Converter 22. Tri-clover Connection for Viable and Non-viable Particle Counter 23. Pass Chamber Sliding Tray 24. Pass Chamber Inner Door Inflatable Seal 25. 2nd Exhaust HEPA (H14) or Carbon Filter (Optional) 26. F6 Prefilter |
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Esco Pharma
 21 Changi South Street 1 Singapore 486777 • Tel: +65 65420833
 Fax: +65 65426920 • Email: csis.pharma@escoglobal.com
Esco Technologies, Inc.
 2512 Metropolitan Drive, Suite 120 B
 Feasterville- Trevoze, PA 19053-6738
 Tel: 215 322 2155 • Email: eti.pharma@escoglobal.com
Esco Gb Ltd
 Unit 2 R-evolution @ Gateway 36, Kestrel Way, Barnsley, S70 5SZ
 Tel: +44 (0) 1226 360 799 • Email: egb.pharma@escoglobal.com

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