

Isoclean® Healthcare Platform Isolator (Inflatable Seal Model)

Optimized Solution for Sterile/Aseptic Applications

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™ biodecontamination system (hydrogen peroxide-based system with H₂O₂ sensors and catalytic converter).

The integration of Esco BioVap™ allows master and independent biodecontamination of main chamber and passthrough chambers.

This 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 automated biodecontamination with log⁶ reduction in bioburden.
- HEPA (H14) filter (as per EN 1822) with a typical efficiency of > 99.995% at Most Penetrating Particle Size as per EN1822; provide superior ISO Class 5 air cleanliness as per ISO 14644-1
- Containment enclosure classification: Class 2 as per ISO 10648-2
- Doors with Inflatable Seals configured with electromagnetic interlock ensures safety and containment during material transfer

** Where client-supplied compressed air is not available, HPI-IS-BVP can come with mobile air compressor to support inflatable seals in the window and dampers, and the BioVap™ biodecontamination system.*



Applications

- Aseptic and/or Potent Compounding
- Benchtop/Small-scale Aseptic Formulation and Filling
- Cosmeceutical
- Cell and Gene Therapy
- Peptide Production
- Pharmacy Compounding
- R&D and Clinical Trials
- Small-scale Potent Material Handling
- Sterility Testing

Options:

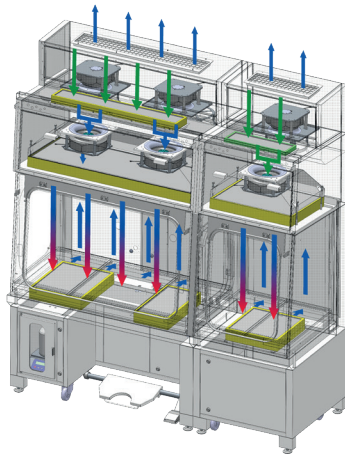
- Aseptic Liquid Transfer Port
- Available in Recirculating or Total Exhaust Configuration
- Integration of a side-mounted CO₂ Incubator
- Glove Leak Tester
- Glove Port Sizes Circular (200 x 200 mm) or Oval (200 x 300 mm)
- CCTV Integration
- Access to Rear View Monitor
- Provision for Tabletop Sterility Test Pump
- Mechanical and controls integration of Viable/Non-viable Particle Monitoring

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 totally exhausted through the optional HEPA (H14) or carbon filter at the top portion of the isolator.

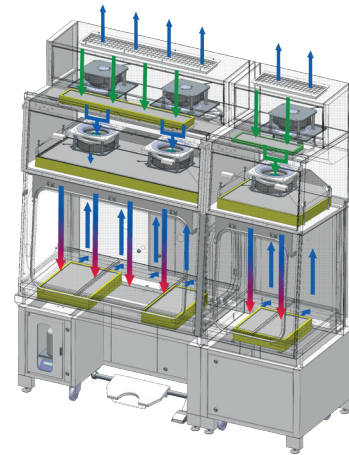


■ HEPA-filtered air ■ Unfiltered / potentially contaminated air ■ Room air / Inflow air

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.



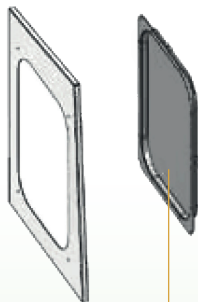
■ HEPA-filtered air ■ Unfiltered / potentially contaminated air ■ Room air / Inflow air

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

Industrial Grade Siemens HMI/PLC Control system supervises all cabinet operations and monitors cabinet performance in real time

7" graphical touch-screen display to illustrate isolator operating parameters

Versatile SS304 frame



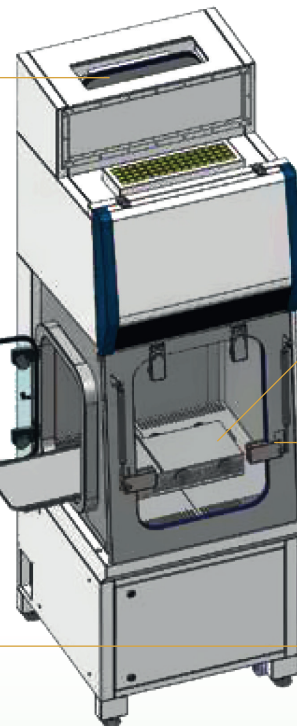
Standard Side Adaptor Inflatable Seal Flanges allows integration of multiple HPI-IS modules

Inflatable Seals 21CFR177.2600 compliant reliable Inflatable Seals

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

Main Chamber Module

Foldable footrest to provide better working ergonomics



Stainless Steel 316L internal provide excellent resistance for product contact internal chamber construction

Doors with Inflatable Seals with time delay effect ensure safety and containment during material transfer

10mm Tempered Glass Main Window

Passthrough Chamber Module

200 x 200 mm Circular Glove Ports (or Optional 200 x 300 mm Oval Glove ports)

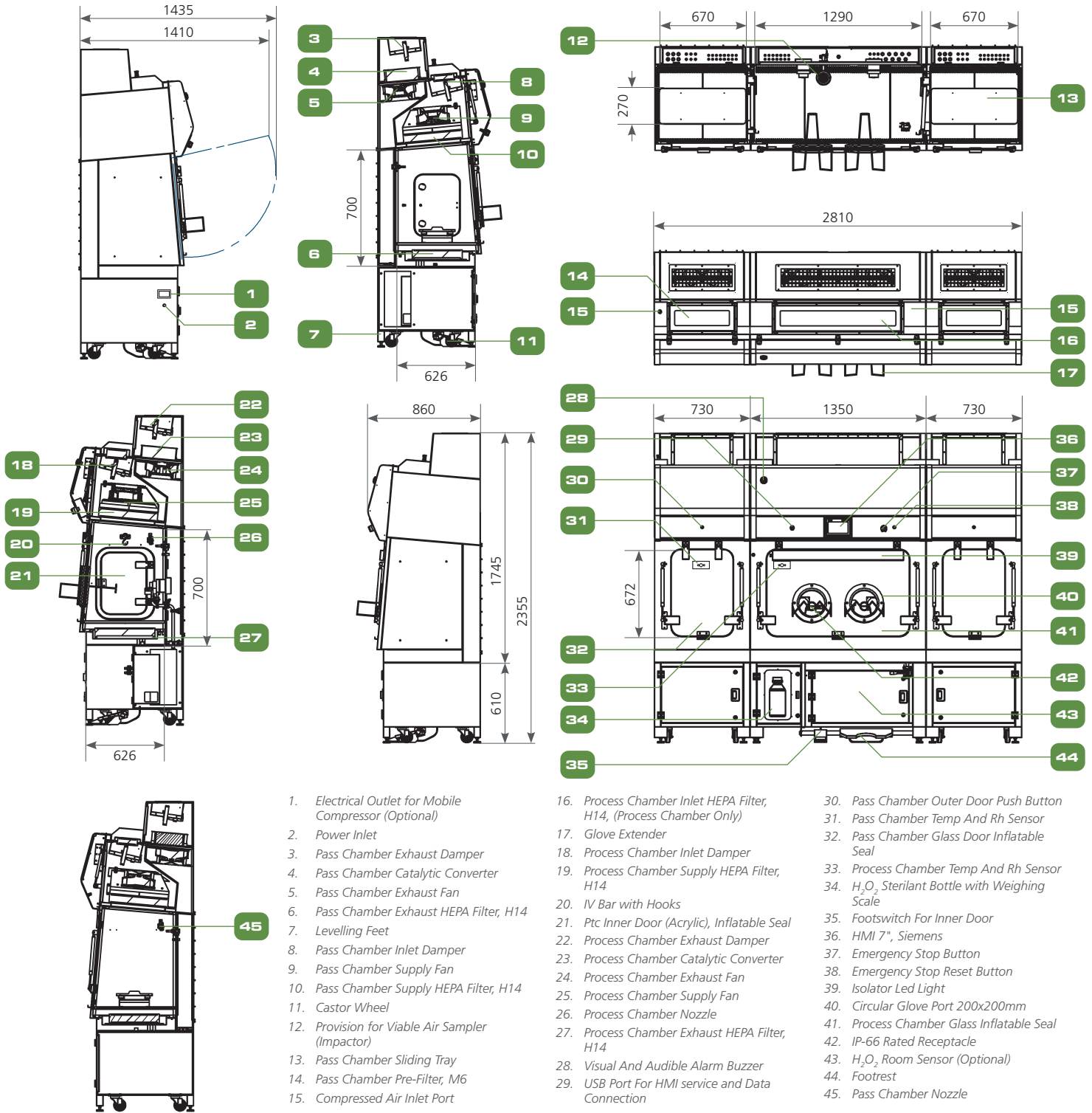
Foot Switch provides hands-free opening of the inner door of the passthrough chamber

ISOCLEAN® Healthcare Platform Isolator - Inflatable Seal Model (HPI-IS)		2-Glove Main Chamber	3-Glove Main Chamber	4-Glove Main Chamber	Pass Chamber	3-way Pass Chamber
External Dimension (W x D x H)*		1350 x 860 x 2355 mm	1645 x 860 x 2355 mm	1950 x 860 x 2355 mm	730 x 860 x 2355 mm	730 x 860 x 2355 mm
Internal Dimension (W x D x H)		1290 x 620 x 700 mm	1595 x 620 x 700 mm	1902 x 620 x 700 mm	670 x 626 x 700 mm	670 x 626 x 700 mm
Isolator Construction	External Body	ISOCIDE™ Powder-coated electrogalvanized steel				
	Internal Chamber	2.0 mm Stainless steel 316L				
	Outer doors	10 mm Tempered Glass				
	Inner doors	25 mm Acrylic				
Airflow Regime		Unidirectional/Laminar Airflow <i>(Recirculating or Total Exhaust/Single-Pass Airflow Models are available)</i>				
Pressure		Positive or Negative, minimum 37 Pa			Positive or Negative, minimum 25 Pa	
Downflow Velocity		0.45 m/s +/-20%			0.30 m/s +/- 20%	
Sound Level		≤ 80 dBA				
Chamber Lighting		Minimum 500 Lux			No lighting for PTC Module	
Biodecontamination		BioVap Biodecontamination System				
Pressure Hold Test	During FAT/IQOQ/SAT	Class 2 Containment as per ISO 10648-2				
	Automated Daily Routine	Class 3 Containment as per ISO 10648-2 (prior to each decontamination)				
Electrical Requirement		220-240 VAC, 50/60 Hz, 1Ø 380-480 VAC, 50/60 Hz, 3Ø				
Compressed Air Requirement		Min 6 Bar-g, max 12 Bar-g with 200 Liter per Minute Flow				
Isolator Surface Finish	Internal Chamber	≤ 0.4 Ra				
HMI Type		HMI Siemens 7" <i>Note: Industrial PC upgrade is available as optional</i>				
Control System		Industrial Grade PLC Siemens				
Exhaust Duct Requirement (by Client)		250 mm (10") Duct from Isolator to Outside <i>Optional: Exhaust Collar for ducted unit</i>				
Net weight		560 kg (1234.6 lbs)	690 kg (1521.2 lbs)	850 kg (1873.9 lbs)	320 kg (705.5 lbs)	Contact Escro office for more details
Shipping weight		725 kg (1598.35 lbs)	1015 kg (2237.7 lbs)	TBA	560 kg (1234.6 lbs)	Contact Escro office for more details
Shipping dimension		1680 x 1300 x 2500mm (66.14 x 51.18 x 98.42")	2200 x 1000 x 2500mm (86.61 x 39.37 x 98.42")	2200 x 1000 x 2500mm (86.61 x 39.37 x 98.42")	1050 x 1100 x 2500mm (41.33 x 43.30 x 98.42")	Contact Escro office for more details

* Without Exhaust Collar

BUILDING EXHAUST REQUIREMENT		2-Glove Main Chamber	3-Glove Main Chamber	4-Glove Main Chamber
Total Exhaust (Single Pass)	Process Chamber	1100 cmh @ 500 Pa	1300 cmh @ 600 Pa	1600 cmh @ 700 Pa
	Pass Chamber	410 cmh		
Recirculating	Process Chamber	550 cmh @ 250 Pa	650 cmh @ 300 Pa	800 cmh @ 350 Pa
	Pass Chamber	205 cmh		

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



1. Electrical Outlet for Mobile Compressor (Optional)
2. Power Inlet
3. Pass Chamber Exhaust Damper
4. Pass Chamber Catalytic Converter
5. Pass Chamber Exhaust Fan
6. Pass Chamber Exhaust HEPA Filter, H14
7. Levelling Feet
8. Pass Chamber Inlet Damper
9. Pass Chamber Supply Fan
10. Pass Chamber Supply HEPA Filter, H14
11. Castor Wheel
12. Provision for Viable Air Sampler (Impactor)
13. Pass Chamber Sliding Tray
14. Pass Chamber Pre-Filter, M6
15. Compressed Air Inlet Port
16. Process Chamber Inlet HEPA Filter, H14, (Process Chamber Only)
17. Glove Extender
18. Process Chamber Inlet Damper
19. Process Chamber Supply HEPA Filter, H14
20. IV Bar with Hooks
21. Ptc Inner Door (Acrylic), Inflatable Seal
22. Process Chamber Exhaust Damper
23. Process Chamber Catalytic Converter
24. Process Chamber Exhaust Fan
25. Process Chamber Supply Fan
26. Process Chamber Nozzle
27. Process Chamber Exhaust HEPA Filter, H14
28. Visual And Audible Alarm Buzzer
29. USB Port For HMI service and Data Connection
30. Pass Chamber Outer Door Push Button
31. Pass Chamber Temp And Rh Sensor
32. Pass Chamber Glass Door Inflatable Seal
33. Process Chamber Temp And Rh Sensor
34. H₂O₂ Sterilant Bottle with Weighing Scale
35. Footswitch For Inner Door
36. HMI 7", Siemens
37. Emergency Stop Button
38. Emergency Stop Reset Button
39. Isolator Led Light
40. Circular Glove Port 200x200mm
41. Process Chamber Glass Inflatable Seal
42. IP-66 Rated Receptacle
43. H₂O₂ Room Sensor (Optional)
44. Footrest
45. Pass Chamber Nozzle



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