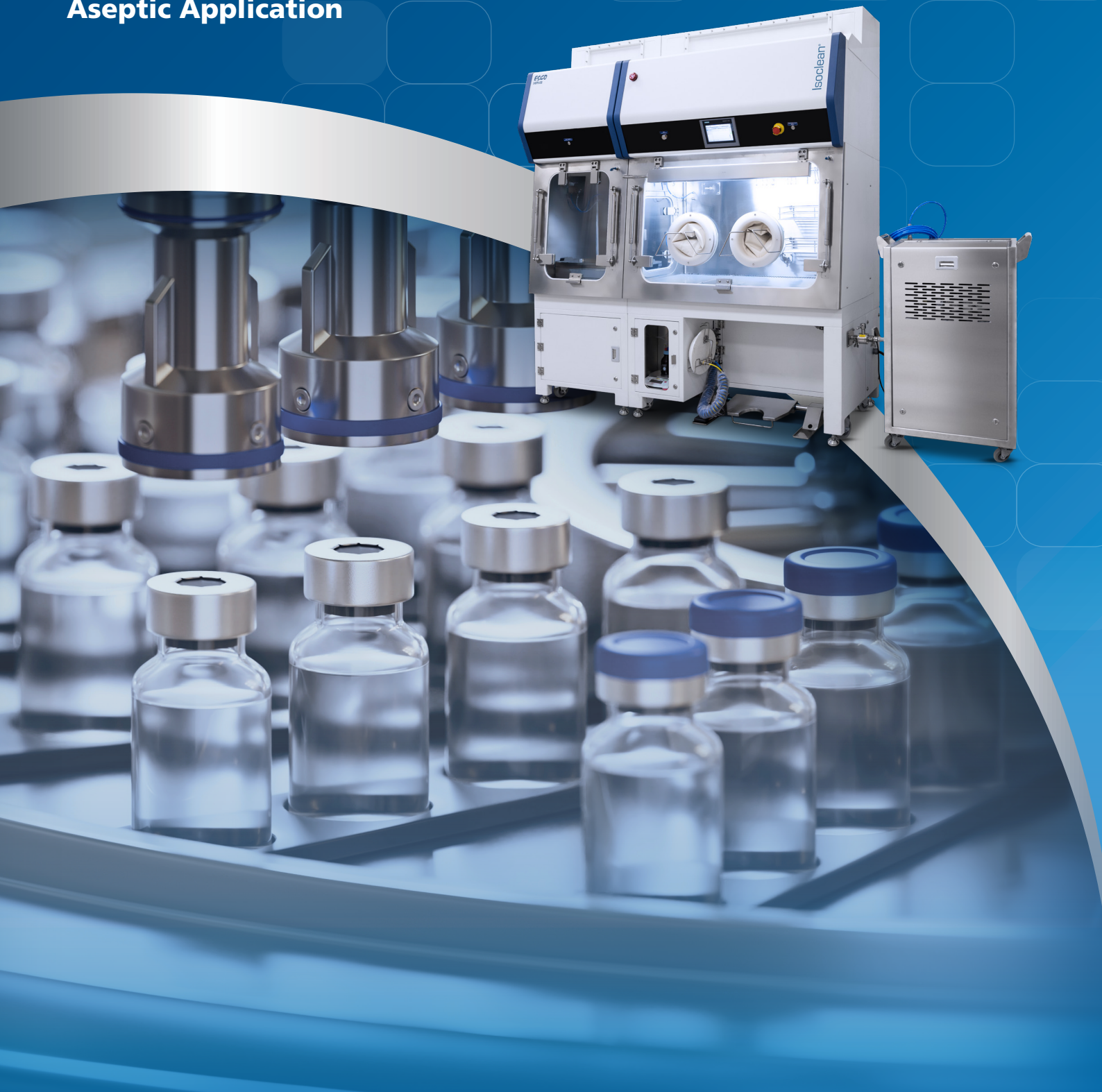
ESCO HEALTHCARE

"Discovery to Delivery"

Isoclean® Healthcare Platform Isolator - Inflatable Seal – BioVap™ (HPI-IS-BVP)

Optimized Solution for Sterile/ Aseptic Application



Intoduction

The **Isoclean® Healthcare Platform Isolator – Inflatable Seal with BioVap (HPI-IS-BVP)** 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 H_2O_2 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.

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

Isolation Technology

Isolation containment systems offer a significantly higher level of environmental control compared to open-front clean air devices such as laminar flow clean benches and biological safety cabinets. For sterility testing and other aseptic operations, isolators create a fully enclosed, pressure-controlled environment that minimizes the risk of false positives, accidental contamination, and operator influence as critical factors for ensuring test reliability and product sterility.

In accordance with USP and PIC/S guidance, isolators used for sterility testing may be located in areas with less stringent background classifications compared with open-front systems, without compromising product integrity.

When integrated into a robust aseptic workflow, including operator training, process simulation (media fill), validated cleaning and decontamination cycles, and appropriate environmental monitoring, isolators deliver consistent protection for the product, operator, and surrounding environment. They also offer advantages in operating cost, space efficiency, and maintainability, making them a reliable and sustainable solution for modern aseptic and sterility testing applications.

Maximum Protection and Sterility

- Capable of automated pressure hold testing (APHT) and automated biodecontamination with log6 reduction in bioburden
- The HEPA (H14) supply filters with measured efficiency of >99.995% at 0.1 to 0.3 microns as per EN1822; provide superior ISO Class 5 air cleanliness as per ISO 14644-1
- Laminar (Unidirectional) airflow within work zone and pass chamber.
- Airlock pass chamber ensures work zone remains sterile during ingress and egress of items.

- The electromagnetic interlocking door mechanism with time-delayed ingress/egress control allows sufficient time for air purging to minimize transfer of contamination.
- Improved safe-change cuff rings enable glove change with zero risk of contamination.

Ergonomic Enhancements

- Ergonomic enhancements minimize stress associated with long periods of operation.
- Ergonomically styled sloped front reduces glare and allows easier reach into the work area. Rounded edges minimize crevices and maximize door vision panel.
- Sliding tray facilitates material transfer without the operator having to reach into the pass chamber interchange area.
- Circular glove ports (200 x 200) mm with minimal crevices, no exposed bolts and nuts
- Adaptable glove system allows all common surgical gloves to attach to the cuff ring.
- Flexible glove-sleeve system accepts multiple glove sizes and compatible materials based on client selection**
- Lamps deliver >500 Lux to the work surface for superior over-all illumination in process chamber.
- Foot switch provides hands-free access to opening of the magnetic interlock minimizing operator fatigue during trans-fer procedures.
- Foldable footrest provides better working ergonomics.

***Note: the surgical gloves might not always provide compatibility against mechanical stress in the isolator, especially for the primary gloves, not double gloving*

Control System

- Intuitive HMI display with PLC supervises operation of all cabinet functions
- Optional 21 CFR Part 11 compliance enables secure, traceable electronic records and signatures.
- Optional SCADA integration allows seamless transmission of isolator sensor data to the client's EMS/BMS systems.
- Optional upgrade to an Industrial PC provides enhanced processing power for advanced data visualization, handling, and automation features

Cabinet Constructions

- Robust construction and enhanced safety features qualify the HPI-IS-BVP for the most demanding laboratory applications. The isolator is fully assembled and ready to install and operate when shipped.
- The cabinet exterior structure is constructed of industrial-grade electrogalvanized steel.
- External surfaces are coated with ISOCIDE™ antimicrobial coating to protect against surface contamination and inhibit bacterial growth. ISOCIDE™ eliminates 99.9% of surface bacteria within 24 hours of exposure.
- The cabinet interior is constructed of durable and pharmaceutical grade 316L stainless steel with large radius corners to simplify cleaning.
- Removable work trays for easy surface cleaning and decontamination.
- Hinged window may be opened for thorough access into the work zone.

Fan Safety

- The HPI-IS-BVP fan system is designed for maximum energy efficiency and minimal maintenance.
- Centrifugal, direct-drive, external rotor motors reduce operating costs.
- Esco motor/fan orientations minimize noise and vibration.
- A smart, PLC-controlled closed-loop system automatically maintains stable pressure and airflow as filter pressure drop increases.

Warranty

One year warranty (excluding consumables). Consumables are gloves, 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

Options

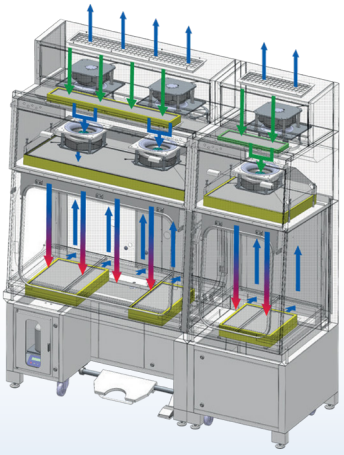
- Aseptic Liquid Transfer Port
- Available in Recirculating or Total Exhaust Configuration
- Integration of a side-mounted CO_2 Incubator
- Glove Leak Tester
- Glove Port Sizes Circular (200 x 200 mm) or Oval (200 x 300 mm)
- CCTV Integration
- Access to Rear View Monitor
- Provision for Tabletop Sterility 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 pro-viding 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.

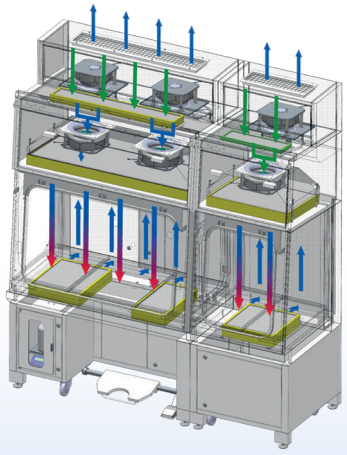


HEPA-filtered air
Unfiltered / potentially contaminated air
Room air / Inflow air

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 ex-hausted through the optional HEPA (H14)/Carbon Filter filter at the top portion of the isolator.



HEPA-filtered air
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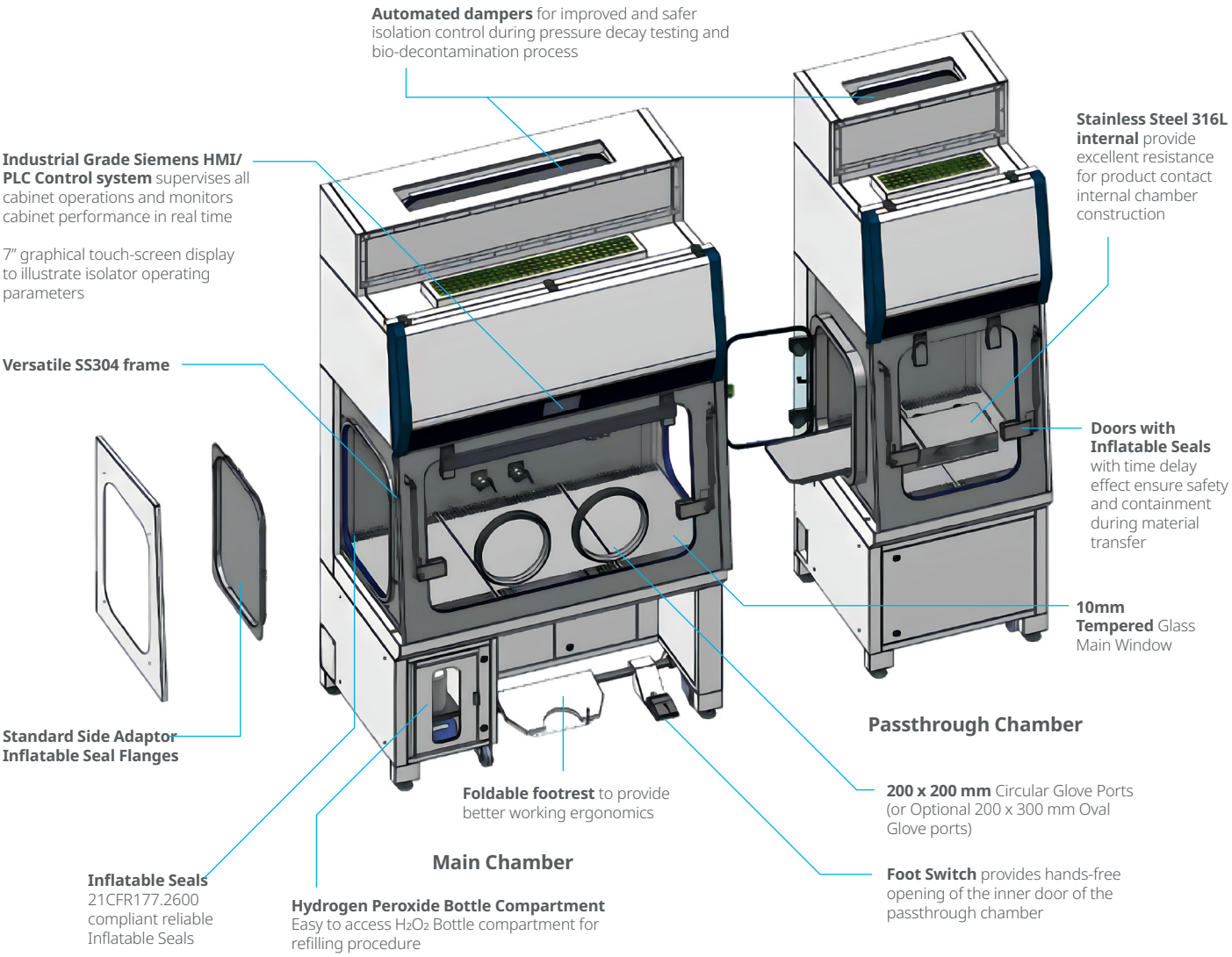
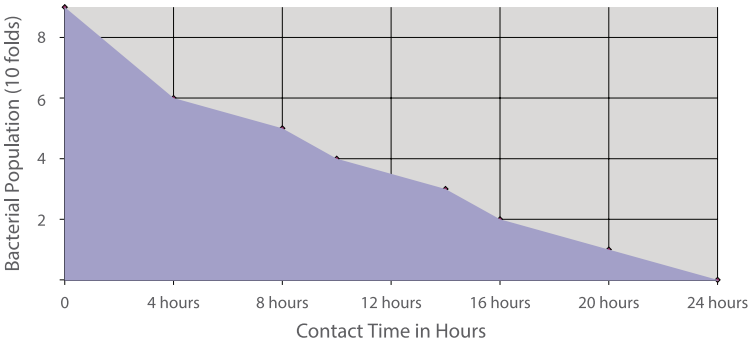
Room air / Inflow air



ISOCIDE™ Antimicrobial Powder-Coating



All exterior painted surfaces are powder-coated with Esco ISOCIDE™, an antimicrobial inhibitor to minimize contamination. ISOCIDE™ is integrated into the coating substrate and cannot be washed out or diminished by repeated cleaning.

Performance results are available upon request. Contact Esco or your Esco Sales Representative for details.

Design	Cabinet Performance	Air Quality	Electrical Safety
USP <797> and <800>, USA NIOSH, OSHA, Designed in compliance to international GMP standards	Class 2 Leak Tight Containment as per ISO 10648-2, CETA CAG-002-2006	ISO 14644-1 Class 5, EU GMP Grade A, Worldwide, JIS B9920, Class 5, Japan	IEC 60204, Worldwide

General Specifications

Isoclean® Healthcare Platform Isolator-Inflatable Seal-BioVap™ (HPI-IS-BVP)

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	Contact Esco office for more details
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	Contact Esco office for more details
Isolator Construction	External Body	ISOCIDE™ Powder-coated electrogalvanized steel				
	Internal Chamber	2.0 mm Stainless steel 316L				
	External Chamber	1.5mm Stainless steel 304				
	Outer Doors	10 mm Tempered Glass				
	Inner Doors	25 mm Acrylic				
Airflow Regime		Unidirectional/Laminar Airflow				
		(Recirculating or Total Exhaust/Single-Pass Airflow Models are available)				
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				
		Note: 3Ø is available upon request				
Compressed Air Requirement		Min 6 Bar-g, max 12 Bar-g with 200 Liter per Minute Flow				
IsolatorSurface Finish	Internal Chamber	≤ 0.4 Ra				
HMI Type		HMI Siemens 7"				
		Note: Industrial PC upgrade is available as optional				
Control System		Industrial Grade PLC Siemens				
Exhaust Duct Requirement (by Client)		250 mm (10") Duct from Isolator to Outside				
Net weight		560 kg (1234.6 lbs)	690 kg (1521.2 lbs)	850 kg (1873.9 lbs)	320 kg (705.5 lbs)	Contact Esco office for more details
Shipping weight		725 kg (1598.35 lbs)	1015 kg (2237.7 lbs)	TBA	560 kg (1234.6 lbs)	Contact Esco 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 m2500mm (41.33 x 43.30 x 98.42")	Contact Esco office for more details

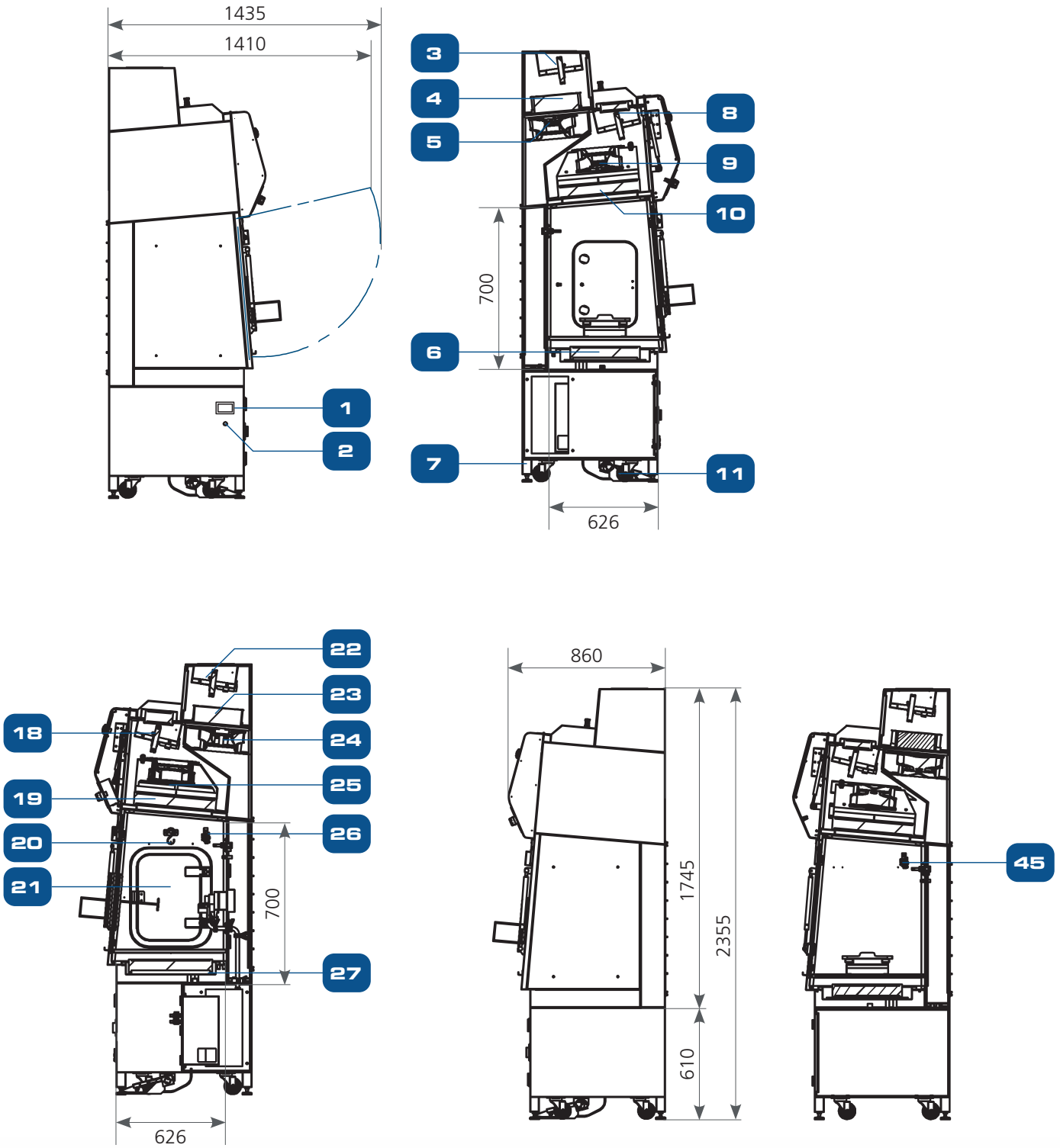
** Without Exhaust Collar*

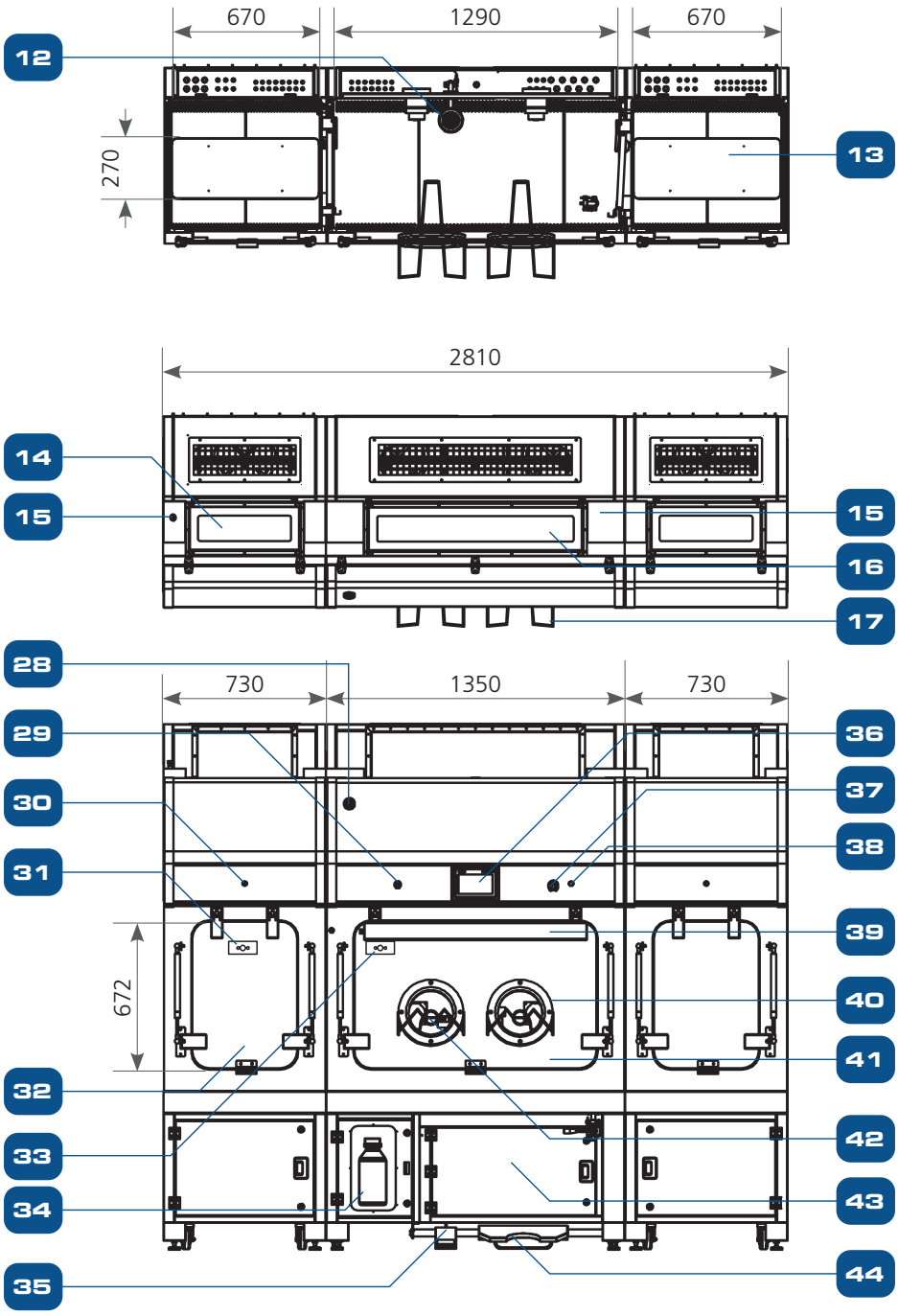
2-Glove Main Chamber		2-Glove Main Chamber	3-Glove Main Chamber	4-Glove Main Chamber
Total Exhaust (Single Pass)	Process Chamber	1100 cmh at 500 Pa	1100 cmh at 500 Pa	1600 cmh at 700 Pa
	Pass Chamber	410 cmh		
Recirculating	Process Chamber	550 cmh at 250 Pa	650 cmh at 300 Pa	800 cmh at 350 Pa
	Pass Chamber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

**Additional carbon filters may impact the building exhaust specifications.*

Engineering Drawing

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





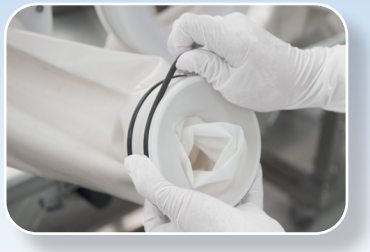
1. *Electrical Outlet for Mobile Compressor (Optional)*
2. *Power Inlet*
3. *Pass Chamber Exhaust Damper*
4. *Pass Chamber Catalytic Converter*
5. *Pass Chamber Exhaust Fan*
6. *Pass Chamber Exhaust HEPA Filter, H14*
7. *Levelling Feet*
8. *Pass Chamber Inlet Damper*
9. *Pass Chamber Supply Fan*
10. *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. *H_2O_2 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. *H_2O_2 Room Sensor (Optional)*
44. *Footrest*
45. *Pass Chamber Nozzle*

Safe Glove Change Procedure: Replacing Disposable Gloves

Safe change design system allows glove change at the middle of a process or when the equipment is in operation.

1. Pull the Glove/Sleeve outside the isolator.

2. Fold the fingers of the glove inside the cuff ring.



3. Remove the outer ring.

4. Carefully roll the gloves from the middle groove to the outer groove.

5. Take the new glove and ensure the thumb is at the top. Stretch the ring of the new glove over the port and over the old glove onto the middle groove.

6. Install the ring up to the middle groove.

7. Carefully loosen the old glove from the outer groove.

8. Put the glove/sleeve inside the isolator.

9. Working with one hand in the adjacent glove, carefully pull the old glove.

10. The procedure is now complete.

Safe Glove Change Procedure: Replacing the Sleeves

1. Remove the screws that secure the glove port cover

2. Remove the outer glove port cover

3. Remove the “O” ring

4. Carefully roll the ring of the sleeves/gloves from the inner groove to the outer groove of the port

5. Ensure that the old sleeves/gloves is inside the isolator

6. Take the new sleeves and ensure the thumb is at the top and stretch the “O” ring of the new sleeves over the port and over the old sleeves into the inner groove

7. Replace the “O” ring into the outer groove of the glove port

8. Working with one hand in the adjacent sleeves, carefully work from the outer ring and into the isolator. The old sleeves needs to be remove while under the new sleeves

9. Return the glove port outer cover.

10. Secure the port cover with the screws. The procedure is now complete

BioVap™ | Biodecontamination System

Esco BioVap™ is an effective hydrogen peroxide based biodecontamination system capable of achieving a 6-log reduction in bioburden. The spore log reduction has been validated using biological indicator stainless steel ribbons populated with *Geobacillus Stearothermophilus* spores.

BioVap™ has been developed in response to increasing demands from the pharmaceutical, biotech, pharmacy, veterinary, and other related industries for microbial-free environments and more stringent decontamination requirements. Hydrogen peroxide breaks down into oxygen and water on completion of the sterilization process which makes it one of the most environment-friendly decontaminants available. The BioVap™ is developed for performing bio-decontamination of aseptic barrier systems, pass-through systems, and Esco isolators.

Industries Served

- Hospital
- Food, Beverages & Confectionary
- Manufacturing Facilities
- Veterinary Surgeries
- Dentist
- Pharmaceutical
- Primary Healthcare Facilities

Science Behind the Process

Esco BioVap™ decontamination leverages the strong oxidizing properties of hydrogen peroxide, which, in vapor or atomized form, can effectively reach complex surfaces on any equipment. The process involves generating vaporized/atomized H_2O_2, distributing it evenly in a sealed space, and allowing it to dwell, during which reactive oxygen species (ROS) such as hydroxyl radicals cause oxidative damage to cellular proteins, lipids, and nucleic acids, effectively killing a broad spectrum of microorganisms, including bacteria, viruses, fungi, and spores.

The H_2O_2 is safely removed through aeration, breaking down into water and oxygen, making BioVap a highly effective and material-compatible sterilization method with the necessary safety protocols to handle its toxicity to humans. The Esco BioVap™ system comes with two systems that the client can choose depending on the requirement:

Esco BioVapTM Generation 1 (Gen 1) – Atomized Hydrogen Peroxide (AHP)

Esco BioVap™ Generation 1 (Gen 1) utilizes atomized hydrogen peroxide sterilant creating a dry fog as it is injected into the space. This system creates a charge on the atomized droplets as they pass through the ultrasonic nozzle.

This charge imparted on the droplets of sterilant creates two important synergies:

- Each droplet of the sterilant contains billions of reactive molecules to execute the microbial kill.
- Through mutual repulsion, the droplets repel each other and distribute quickly through the space achieving a superior distribution of the sterilant. The charged droplets are attracted to the uncharged surfaces within the space so on impact the droplets burst and immediately start the sterilization process.

This revolutionary bio-decontamination system is not affected by temperature or relative humidity therefore there is no requirement to precondition the space being bio-decontaminated and therefore leads to a reduced cycle.

Priming	Injection	Dwell	Aeration

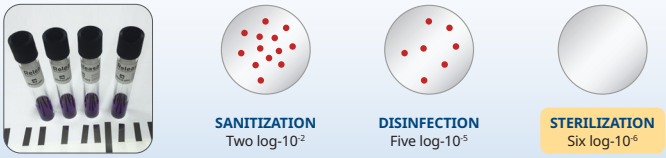
Esco BioVapTM Generation 2 (Gen 2) – Vaporized Hydrogen Peroxide (VHP)

Esco BioVap™ Generation 2 (Gen 2) utilizes vaporized hydrogen peroxide sterilant, creating a vapor that is evenly dispersed into the space. This advanced system vaporizes hydrogen peroxide, allowing it to permeate the environment thoroughly. The vaporized form of hydrogen peroxide exhibits two key advantages:

- The vapor phase allows for deeper penetration into porous materials and complex geometries, ensuring thorough decontamination even in difficult-to-reach areas.
- The controlled vaporization process maintains a consistent concentration of hydrogen peroxide throughout the entire space, resulting in a uniform and highly effective sterilization. This consistency minimizes the risk of under-dosing and ensures reliable microbial kill rates across all treated surfaces.

Dehumidification	Injection	Dwell	Aeration

Level of Biodecontamination



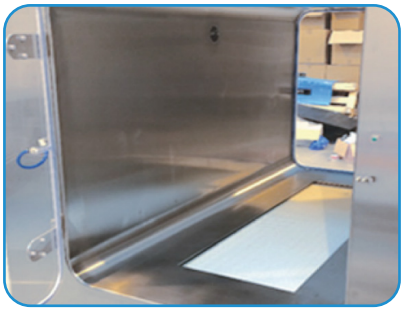
Process Step

The BioVap™ system bio-decontamination cycle will have the following phases

- Injection Phase – In this phase, the sterilant is injected into the space as a dry fog at a pre-set pressure and flow rate and at a given period of time. During this period, the atomising pressure injection airflow and injection air pressure are monitored.
- Dwell Phase – During this phase, the sterilant is allowed to settle on the surfaces inside the enclosure for a set period of time.
- Aeration Phase – In this phase, the hydrogen peroxide sterilant is removed from the space/enclosure.

Flexibility Features

Esco Pharma BioVap™ system is developed to be flexible enough to work in all areas, from Esco isolators and transfer hatches. Keeping in mind that every customer and facility has different requirements.



Esco Pharma Transfer Hatch and BioVap™ integrated system

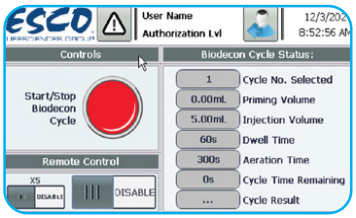
Esco Pharma BioVap™ system integrated into the isolator as our approach to a cost-effective bio-decontamination

BioVap™ Gen 1 utilizes an ultrasonic nozzle to breakdown hydrogen peroxide droplets to a fine mist provide excellent distribution inside the decontamination chamber

Controls

The BioVap™ system is PLC controlled with an operator interface via a touch screen HMI terminal giving operator log-on security and real-time display of cycle parameters. Cycle parameters are also recorded, and a printout of the cycle parameters is given at the end of a cycle for validation records. Electronic data recording of the cycles 21 CFR 11 compliant is available on request.

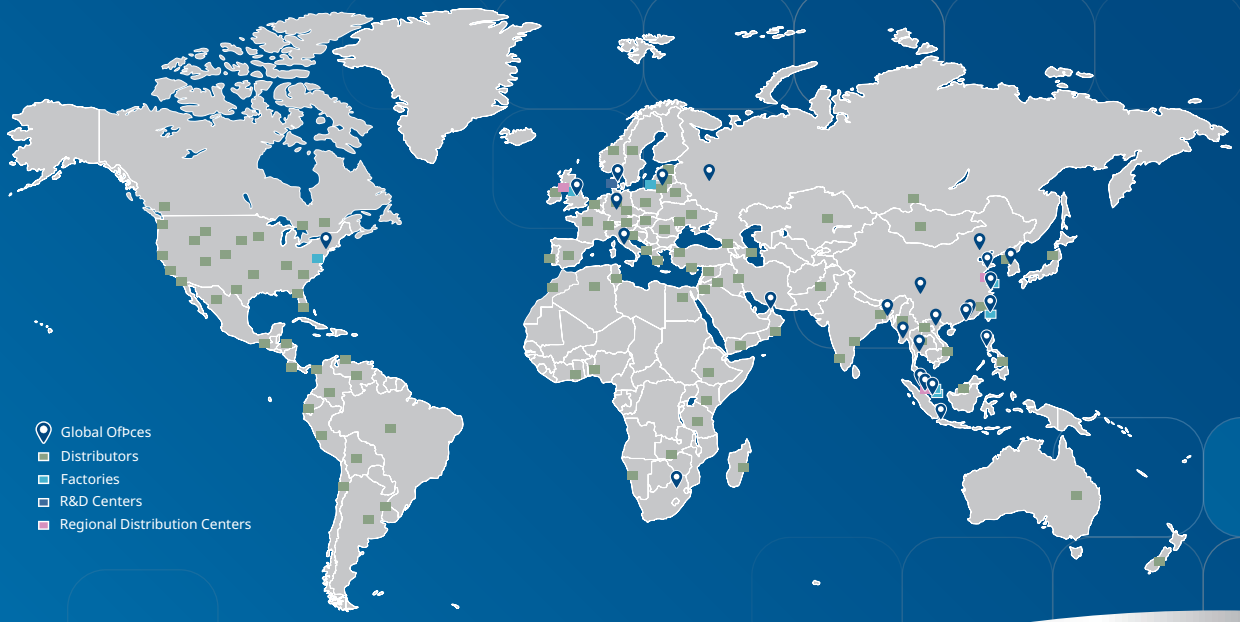
At least 10 pre-programmed cycles can be saved on the PLC system selectable from the interface terminal. The BioVap™ can be controlled locally via the HMI located on the BioVap™ generator or can be controlled remotely from an Isolator or Transfer Hatch control system.



HMI Controller

BioVap™

ESCO LIFESCIENCES GROUP NETWORK
42 Locations in 24 Countries All Over the World



Air Shower
Aseptic Containment Isolator (ACTI)
Ceiling Laminar Airflow Units
Cleanroom Transfer Hatch
Containment Barrier Isolator (CBI)
Downflow Booth (DFB)
Dynamic Floor Laminar Hatch
Dynamic Pass Box
General Processing Platform Isolator (GPPI)
Laminar Flow Horizontal Trolley
Laminar Flow Vertical Trolley
Pass Box
Ventilated Balance Enclosure (VBE)
Weighing and Dispensing Containment Isolator (WDCI)

Since 1978, Esco has emerged as a leader in the development of controlled environment, laboratory and pharmaceutical equipment solutions. Products sold in more than 100 countries include biological safety cabinets, fume hoods, ductless fume hoods, laminar flow clean benches, animal containment workstations, cytotoxic cabinets, hospital pharmacy isolators, and PCR cabinets and instrumentation. With the most extensive product line in the industry, Esco has passed more tests, in more languages, for more certifications, throughout more countries than any biosafety cabinet manufacturer in the world. Esco remains dedicated to delivering innovative solutions for the clinical, life science, research and industrial laboratory community.

ESCO® LIFESCIENCES

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