



# Turbulent Flow Aseptic Isolator (TFAI)<sup>™</sup>



**The Premium Solution for Sterility  
Testing and Aseptic Potent Powder Handling**





## Main Features:

The Esco Turbulent Flow Aseptic (Grade A) Isolator is a free standing Isolator that has a very low leakage rate, complying with the most stringent leakage criteria as stated in ISO 14644-7.

The isolator can be supplied with or without a pass through chamber. It has an automated airflow and pressure control to assure a clean and microbial-free environment for sterility testing.



*Esco Turbulent Flow Aseptic (Grade A) Isolator provide a safe and clean environment for aseptic production.*

The isolator's ability to meet Turbulent Grade A conditions and provide a high degree of containment separation for product, operator, and environment is unquestionable.

## It also offers the newest option:

The **Pod Flange™**, a flexible and detachable worktop which can be integrated with different equipment, according to the operator's application.

### **Optional integration can include:**

**Filling Machine** - Small scale filling machine is installed in the process chamber pod flange of the isolator to allow filling pre-filled syringes and cartridges, and filling and stoppering vials and bottles.

**Freeze Dryer** - for lyophilization purposes.



## Process and Pass Chambers

### Single Sided TFAI

- For small batch sterility testing and small scale processes where only 1-2 operators are needed.

### Single Chamber TFAI

- Designed for pre-loading of all test materials before biodecontamination

### Double Sided TFAI

- Enables operation from either front or back of the isolator.
- Suitable for integrated manufacturing processes and applications in a larger scale where multiple operators are needed.

### TFAI with Pass Chamber

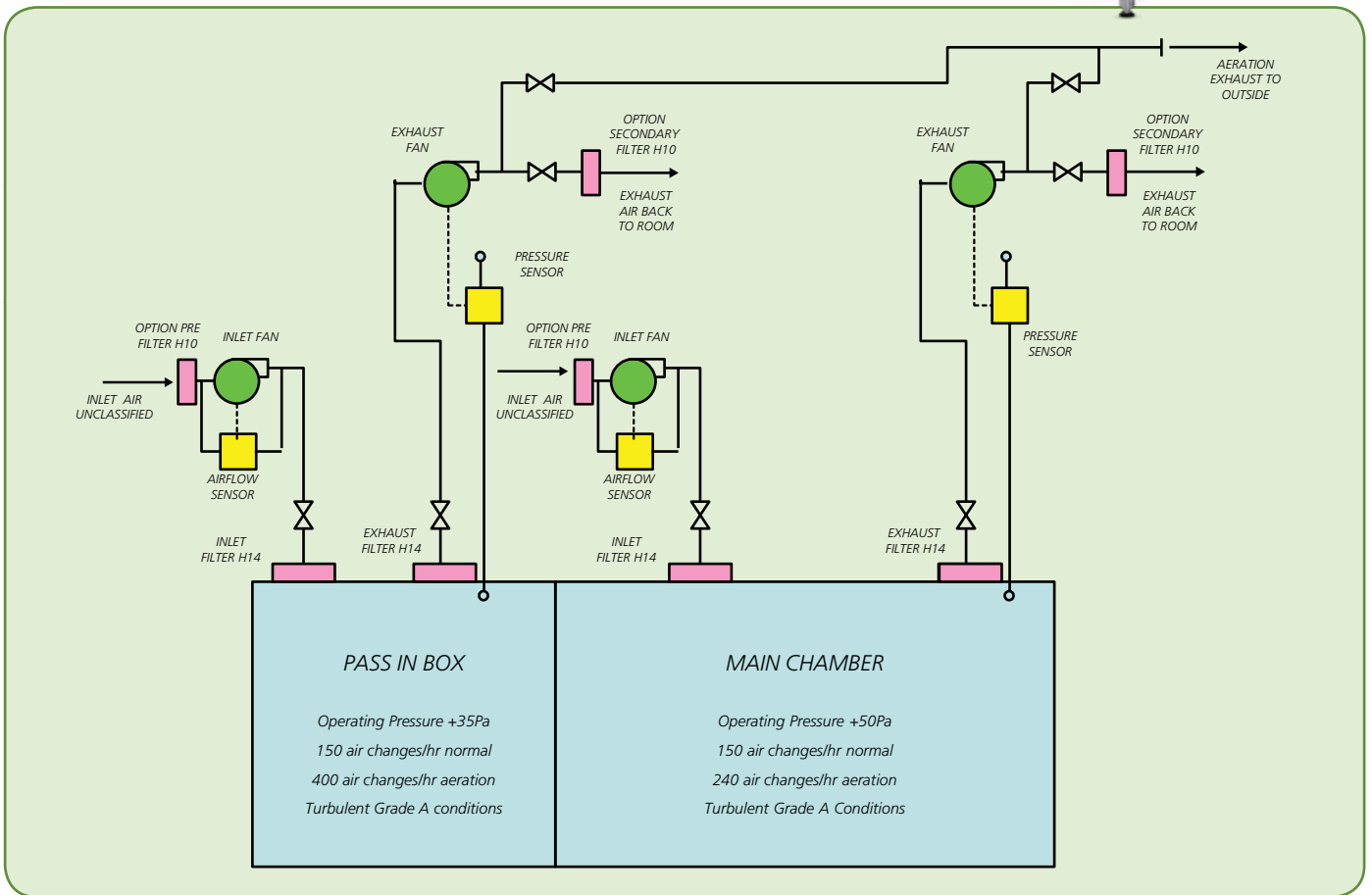
- Designed for continuous sterility testing.

### TFAI with Small Pass chamber

- Intended for small-scale applications.
- Push/push filter system provides ISO Class 5 (Grade A) air cleanliness.

### TFAI with Large Pass Chamber

- Intended for larger volume/scale processes.
- Clean air supplied through panel filters.



Filters are arranged using panel filters providing turbulent airflow whilst maintaining Grade A environment throughout the work zone.

There is an option for for Bag In Bag Out (BIBO) Safe Change Filter for aseptic potent powder handling. A BIBO filter is utilized to safely remove the filter after bio-decontamination. It provides protection against exposure to hazardous powders.



## Ergonomic Enhancements

Ergonomic enhancements minimize stress associated with long periods of operation.

### Front Visors

- The front visor of the main chamber and of the transfer hatch if applicable shall be a gull wing door type visor which hinges outwards and upwards. The visor is held open using gas supports and held closed using an FDA-approved inflatable seal.
- The vision panel is manufactured from 10 mm toughened safety glass.
- Sealing properties of the inflatable gasket are unrivalled and complies with cGMP standards.

The seal controls are designed for assurance of sterility they are fitted with a device to keep the seal inflated in the event of pneumatic failure and have interlocking facilities to prevent detriment to the isolator's integrity.



## Barrier Isolation Systems

Barrier isolation systems provide inherently superior sterility compared to open front clean air devices such as laminar flow clean benches and Class II biological safety cabinets. USP 797\* guidelines specify that isolators may be situated in an area subject to less severe environmental controls compared with open front clean air devices.

*\*United States Pharmacopoeia (USP), Chapter 797(1), enacted January 1, 2004, presents the first enforceable standards for sterile compounding. Following years of patient safety recommendations and professional guidelines, the intent of USP 797 is to set forth the procedural and practical requirements for safe compounding of sterile preparations. The Chapter's requirements are applicable in all practice settings where sterile preparations are compounded.*



### Inner Pass Through Door

- Pass-through chamber was manufactured from a 25 mm thick clear acrylic.
- Inflatable seals inlaid into the acrylic paint to maximize sealing properties and achieve good cGMP finish for sterilization and cleaning.



### Glove ports

- Oval shaped designed for good ergonomic use and maximize operator arm movement and reach into the work zone compared with conventional circular ports.
- Glove ports are GMP designed with smooth surface and round edges for cleanliness and eliminates any crevices at glove attachment to prevent bacterial growth.

### Gloves

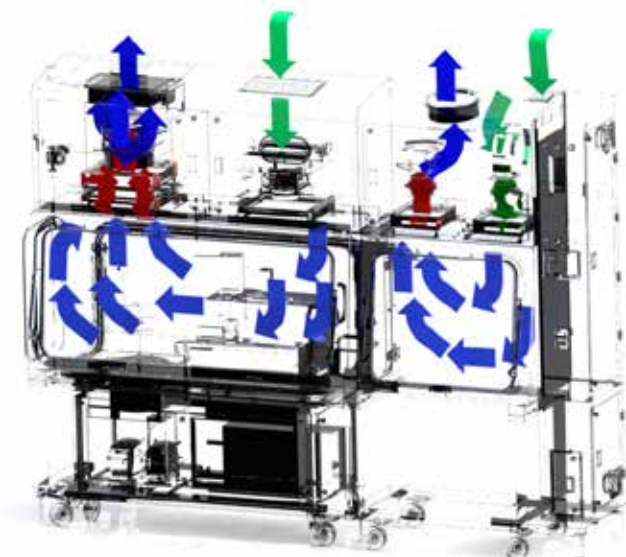
A 3-part system designed allowing the changing of glove without detriment to isolator's sterility, consisting of

- Sleeve**  
Hypalon material that suits 300 x 200 glove port at one end and 110mm cuff ring at the other.
- Cuff Ring**  
Plastic cuff ring assembly with outer cuff, inner cuff, sealing band and retaining ring.
- Glove** – Hypalon material.



### Transfer Chamber

Provides an easy manipulation of the mobile trolley from chamber to chamber.



- Ambient air is pulled through the inlet prefilter located on top of the isolator. The prefilter traps large size particles to extend the life of the supply HEPA filter.
- Air from the top inlet and from workzone is pulled by the main fan, which creates positive pressure on the plenum that creates downflow. Work zone pressure is always higher than the pass-through, to prevent contaminants from entering the workzone through the pass-through.
- The downflow filter creates a turbulent airflow and particle-free ISO Class 5 (Grade A) environment inside the isolator to protect the work material inside the main chamber and pass-through. Air from the work zone and pass-through is quickly purged by the fans to keep the area clean. The purge is completely exhausted through HEPA filter.

- ULPA-filtered air
- Unfiltered / Potentially contaminated air
- Room air / Inflow air



### Internal Shelving & Racking

- Suitable shelves and basket racks are provided internally within the isolator, purposely designed to accommodate loading of materials.
- Facilitates effective bio-decontamination on all surface areas of the isolator and materials.

### Integrated Sterility Test Pump

- Uses Millipore Steritest™ Equinox Pump, an intelligent liquid transfer pump for sterility testing in isolators.
- The pump is ergonomically placed to provide the most comfortable working position for operators.
- Operated via a foot switch minimizing movement and reducing operator fatigue.



### Controls

- Control interfaces are positioned at the operators head height for easy access and visibility.
- The controls shall be PLC platform using the Siemens S7-1200 series PLC and a TP170 Touch Colour screen HMI.

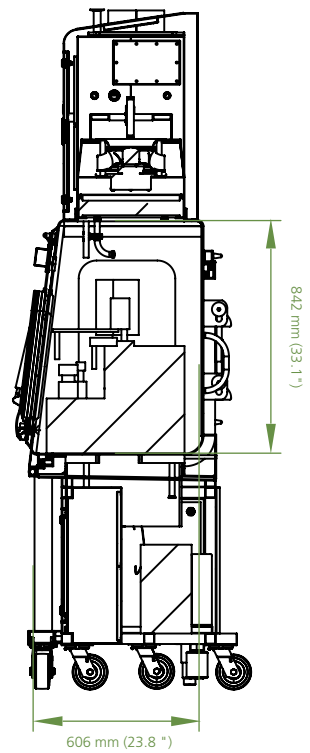
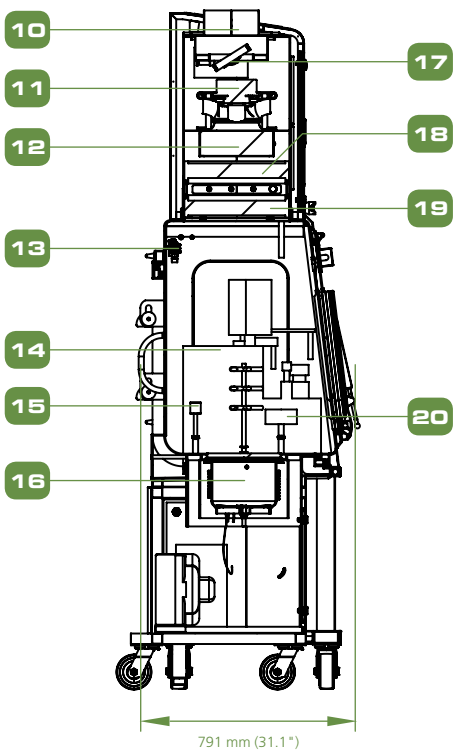
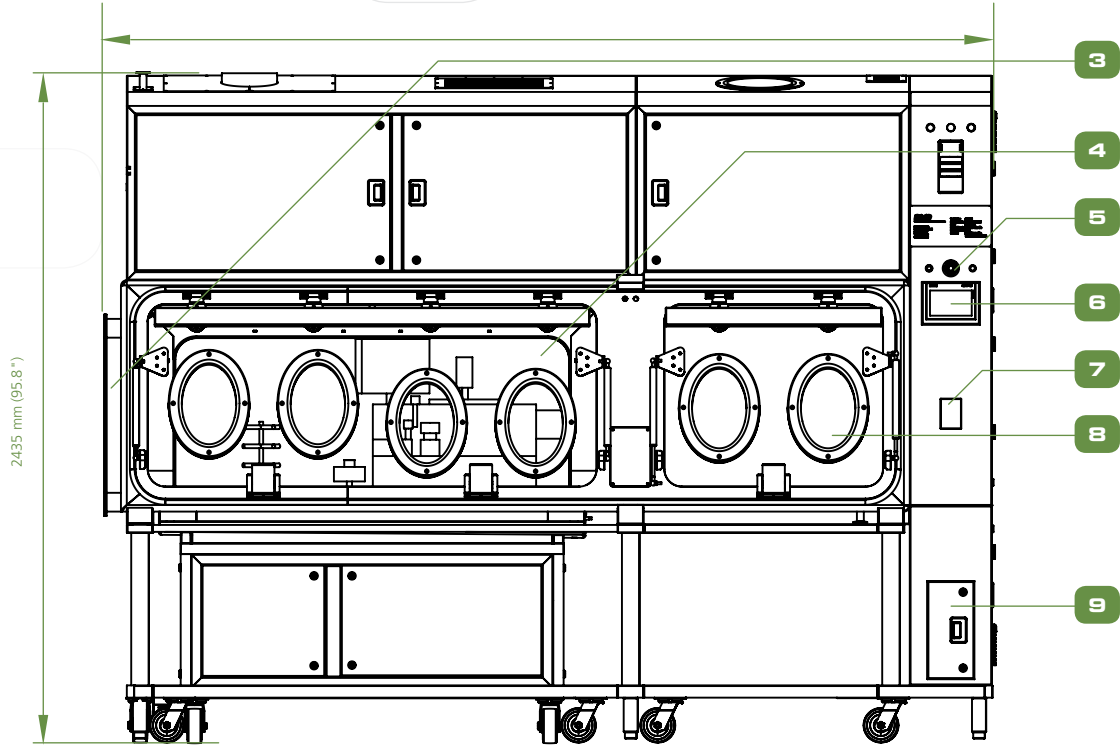
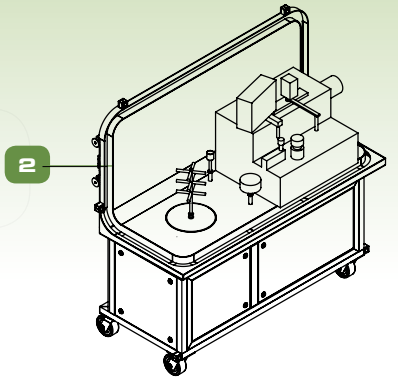
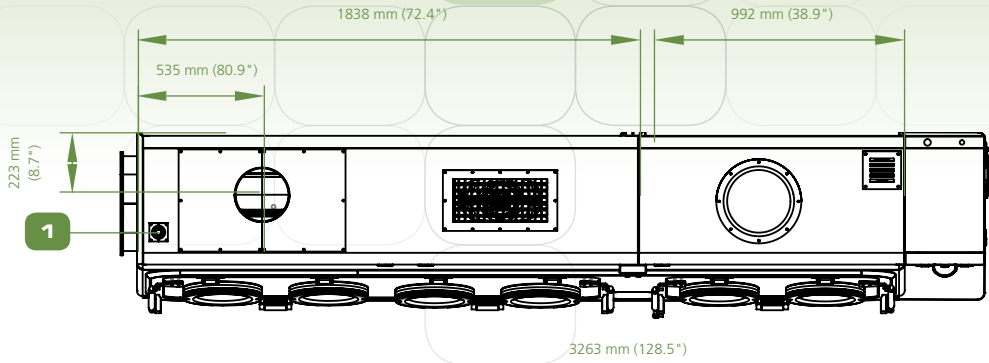


### Surface Finishing

- Internal surfaces shall achieve a surface of not greater than 0.4 Ra  $\mu\text{m}$  to a brushed finish.
- External surfaces shall achieve a surface of not greater than 0.8 Ra  $\mu\text{m}$  to a brushed finish.



# ENGINEERING DRAWING (MODEL: TFAI-4G)



- 1. Water Inlet Port
- 2. Esco Pod Flange (optional)
- 3. Chamber Extension Provisional Tunnel
- 4. Laminated Tempered Safety Glass Chamber
- 5. Emergency Stop
- 6. HMI Display
- 7. Thermal Printer
- 8. Oval Glove Ports
- 9. BioVap™ H<sub>2</sub>O<sub>2</sub> Bottle Compartment
- 10. Exhaust Collar
- 11. ECM Blower
- 12. Catalytic Converter
- 13. BioVap™ Bio-decontamination Non-drip Nozzle
- 14. Benchtop Filling Machine (optional)
- 15. Non-viable Particle Counter probe
- 16. Esco Sublimate® Freezedryer (optional)
- 17. Exhaust Inflatable Seal Damper
- 18. Second Stage Exhaust ULPA Filter
- 19. First Stage Exhaust ULPA Filter
- 20. Viable Particle Counter Probe

# General Specifications

## Turbulent Flow Aseptic Isolator (TFAI)<sup>TM</sup> – Single Sided

TFA-2G

TFAI-3G

TFAI-4G

No. of Chambers			2 (1 Process Chamber and 1 Pass Chamber)		
Nominal Size Main Chamber (Width)			1200 mm (47.2")	1600 mm (62.9")	2000 mm (78.7")
External Dimensions (W x D x H)	With Pod Flange	With BIBO	1200 mm x 780 mm x 3000 mm (47.2" x 30.7" x 118.1")	1600 mm x 780 mm x 3000 mm (62.9" x 30.7" x 118.1")	2000 mm x 780 mm x 3000 mm (78.7" x 30.7" x 118.1")
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Internal Dimensions (W x D x H)			1192 mm x 630 mm x 842 mm (46.9" x 24.8" x 33.1")	1592 mm x 630 mm x 842 mm (62.7" x 24.8" x 33.1)	1992 mm x 630 mm x 842 mm (78.4" x 24.8" x 33.1)
Chamber Sheet Metal			Stainless Steel Type 316L (interior) Stainless Steel Type 304 (exterior)		
Filter Type			ULPA filter (U15)		
Support Frame & Service Housing			Stainless Steel Type 304		
Chamber Environment			ISO Class 5 (Grade A)		
Airflow Type			Turbulent		
Lighting Intensity			≥ 500 Lux (≥ 47 foot-candles)		
Noise Level			≤ 65 dBA		
Electrical Requirement			AC 230-240 V, 50/60 Hz, 1 Ph, 25A		



## General Specifications

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Support Frame & Service Housing		Stainless Steel Type 304		
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Airflow Type		Turbulent		
Lighting Intensity		≥ 500 Lux (≥ 47 foot-candles)		
Noise Level		≤ 65 dBA		
Electrical Requirement		AC 230-240 V, 50/60 Hz, 1 Ph, 25A		

## 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 glove from the inner groove to the outer groove of the port



5. Ensure that the old glove is inside the isolator



6. Take the new glove and ensure the thumb is at the top and stretch the "O" ring of the new glove over the port and over the old glove 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 glove, carefully work from the outer ring and into the isolator. The old glove needs to be removed while under the new glove



9. Replace 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 bio-decontamination system capable of achieving a 6-log reduction in bioburden. This system can be integrated into the HPI-G3 as an approach to a cost-effective biodecontamination.

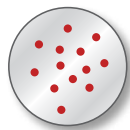
## Science Behind the Process

The Esco BioVap is a process of atomizing hydrogen peroxide sterilant creating a dry fog after it is injected into the space. This unique system (patent pending) creates a charge on the atomized droplets as it passes through the nozzle. This charge imparted on the droplets of sterilant creates two important phenomena.

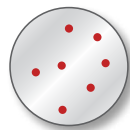
- a. Each droplet of the sterilant contains billions of reactive molecules to execute the microbial kill.
- b. Through mutual repulsion, the droplets repel each other and distribute quickly through the space achieving a superior distribution of the sterilant. The charged droplets are attracted to the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



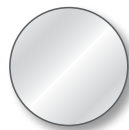
## Levels of Biodecontamination



**SANITIZATION**  
Two log-10<sup>-2</sup>



**DISINFECTION**  
Five log-10<sup>-5</sup>



**STERILIZATION**  
Six log-10<sup>-6</sup>

## Control System

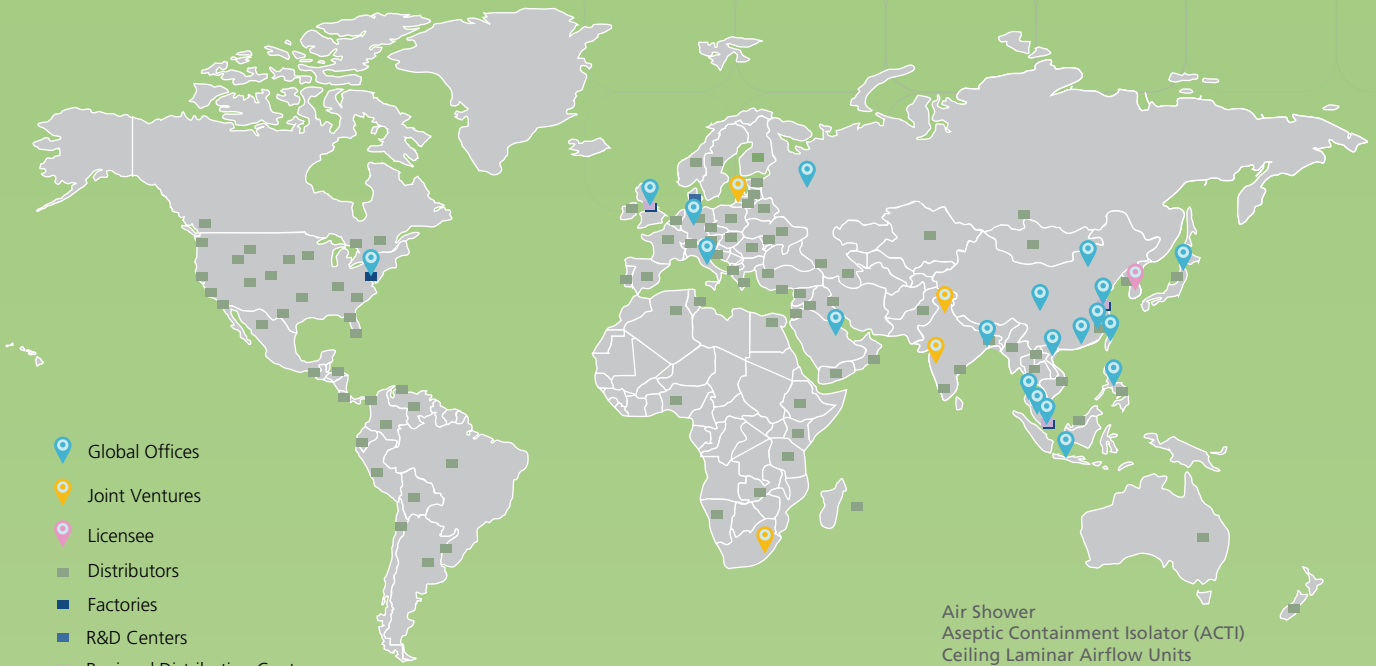
BioVap™ is controlled by PLC with operator interface via a touchscreen HMI terminal giving operator log on security and real-time display of cycle parameters.

Specifications	
Air Injection Pressure	4 bar ±10%
Air Injection Flow rate	32 lpm ±10%
Injection Time	30 seconds to 5 minutes
Dwell Time	15 to 45 minutes
Aeration Time	20 to 90 minutes
Total Decon Time	30 minutes to 3 hours
Sterilant Used in One Cycle	10 to 150 mL
Sterilant Injection Flow Rate	200 to 1000 µL/sec
Sterilant	30% Hydrogen Peroxide

## Testing and Validation

- Filter Leak Tests verify the integrity of the ULPA and HEPA filters as installed
- Downflow Velocity Tests verify adequate unidirectional airflow velocities
- Class 2 Containment Enclosure for process and pass chambers in accordance with ISO 10648-2
- Particle Counts (Air Cleanliness Tests) verify air cleanliness in accordance with ISO 14644-1
- Product Ingress and Egress Tests determines if the isolator work zone can maintain ISO Class 5 during transfer procedures
- Recovery Time Test determines the amount of time the main chamber takes to recover to ISO Class 4 in the event of a contamination event
- Breach Test verifies user protection in case of a glove failure. Unit will become negative pressure with inward velocity of 0.7 m/s
- Operator Comfort Tests include noise, light and vibration.

# ESCO GLOBAL NETWORK



- 📍 Global Offices
- 📍 Joint Ventures
- 📍 Licensee
- Distributors
- Factories
- R&D Centers
- Regional Distribution Centers

- Air Shower
- Aseptic Containment Isolator (ACTI)
- Ceiling Laminar Airflow Units
- Cleanroom Transfer Hatch
- Containment Barrier Isolator (CBI)
- Compounding Aseptic Isolator
- Compounding Aseptic Containment Isolator
- Downflow Booth (DFB)
- Dynamic Floor Label Hatch
- Dynamic Pass Box
- Evidence Drying Cabinet
- Garment Storage Cabinet
- General Processing Platform Isolator (GPPI)
- Healthcare Platform Isolator
- Laminar Flow Horizontal Trolley
- Laminar Flow Straddle Units, Single and Double Laminar
- Flow Vertical Trolley
- Pass Box
- Soft Wall Cleanroom
- Sputum Booth
- 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 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. [www.escoglobal.com](http://www.escoglobal.com).

## ESCO PHARMA PLATFORM SPECIALIST.

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