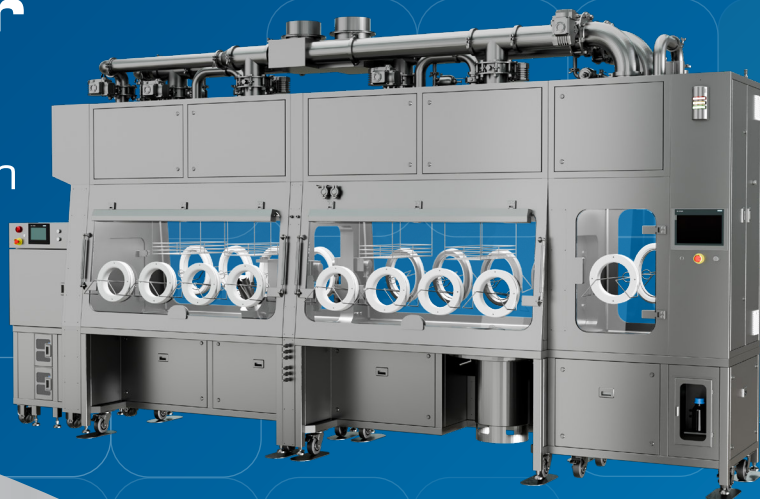
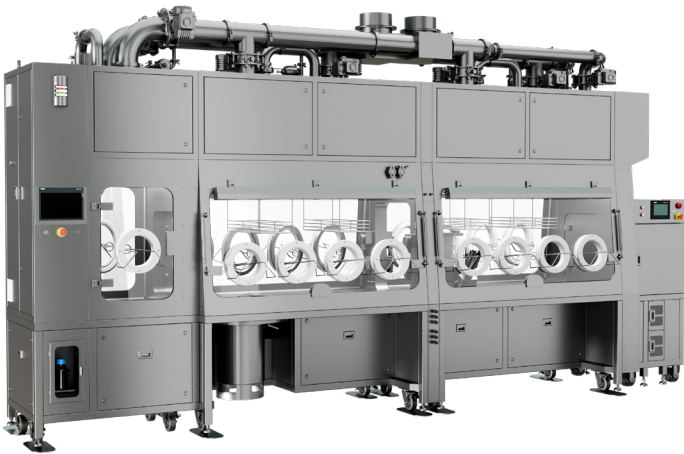


Turbulent Flow Aseptic Isolator (TFAI)

The Premium Extended Solution
for Excellent Protection





Introduction

Turbulent Flow Aseptic Isolator (TFAI) (Grade A) is a free-standing Isolator with strict containment enclosure class 2 with less than 0.25% volume loss per hour per ISO 10648-2.

The isolator has an automated airflow and pressure control to assure a safe, clean, and microbial-free environment in performing testing and other processes requiring the same environmental parameters. The TFAI's ability to meet turbulent grade A conditions provide a high degree of containment separation for product, operator, and environment.

The isolator can be supplied with or without a passthrough chamber. With automated close-loop airflow and pressure control, TFAI assure a clean and microbial free environment for various sensitive applications.

Esco Turbulent Flow Aseptic (Grade A) Isolator provide a safe and clean environment for many applications, such as:

- Aseptic processing or handling that allows turbulent flow
- Biohazard containment for Biosafety Level 3/4

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.



Process and Pass Chambers

Single Sided TFAI

- For small batch processing 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 operation.

Ergonomic Enhancements

Ergonomic enhancements minimize stress associated with long periods of operation.

Front Visors

- The front visor of the process chamber and of passthrough chamber 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 un-rivalled 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.



Filters

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



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.

Transfer Chamber

- Highly adjustable with sliding tray or flushed base with mobile trolley for easy material flow

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.

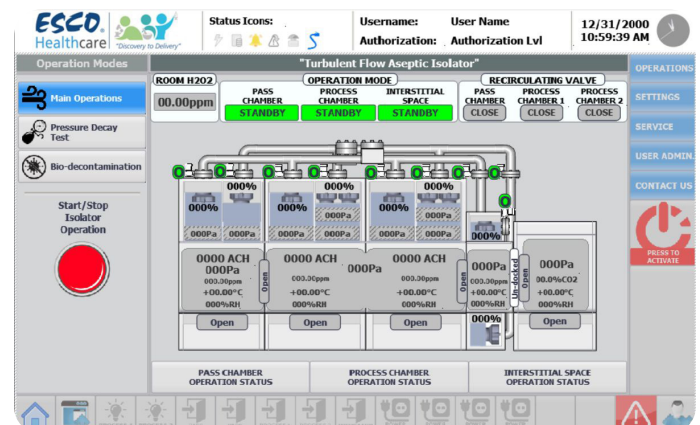


Internal Shelving & Racking

- 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.

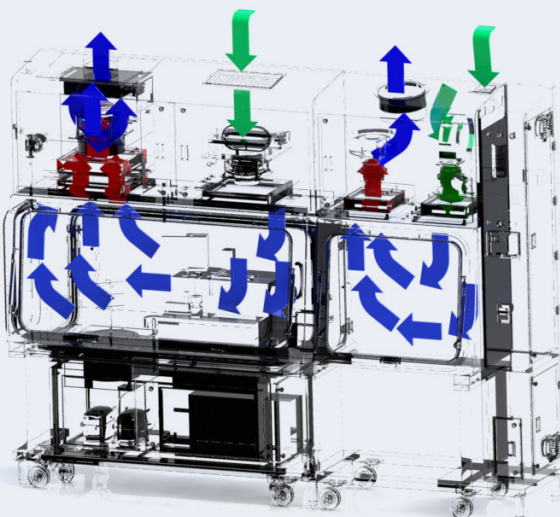
Controls

- 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 TP1200 Touch Colour screen HMI.



Surface Finishing

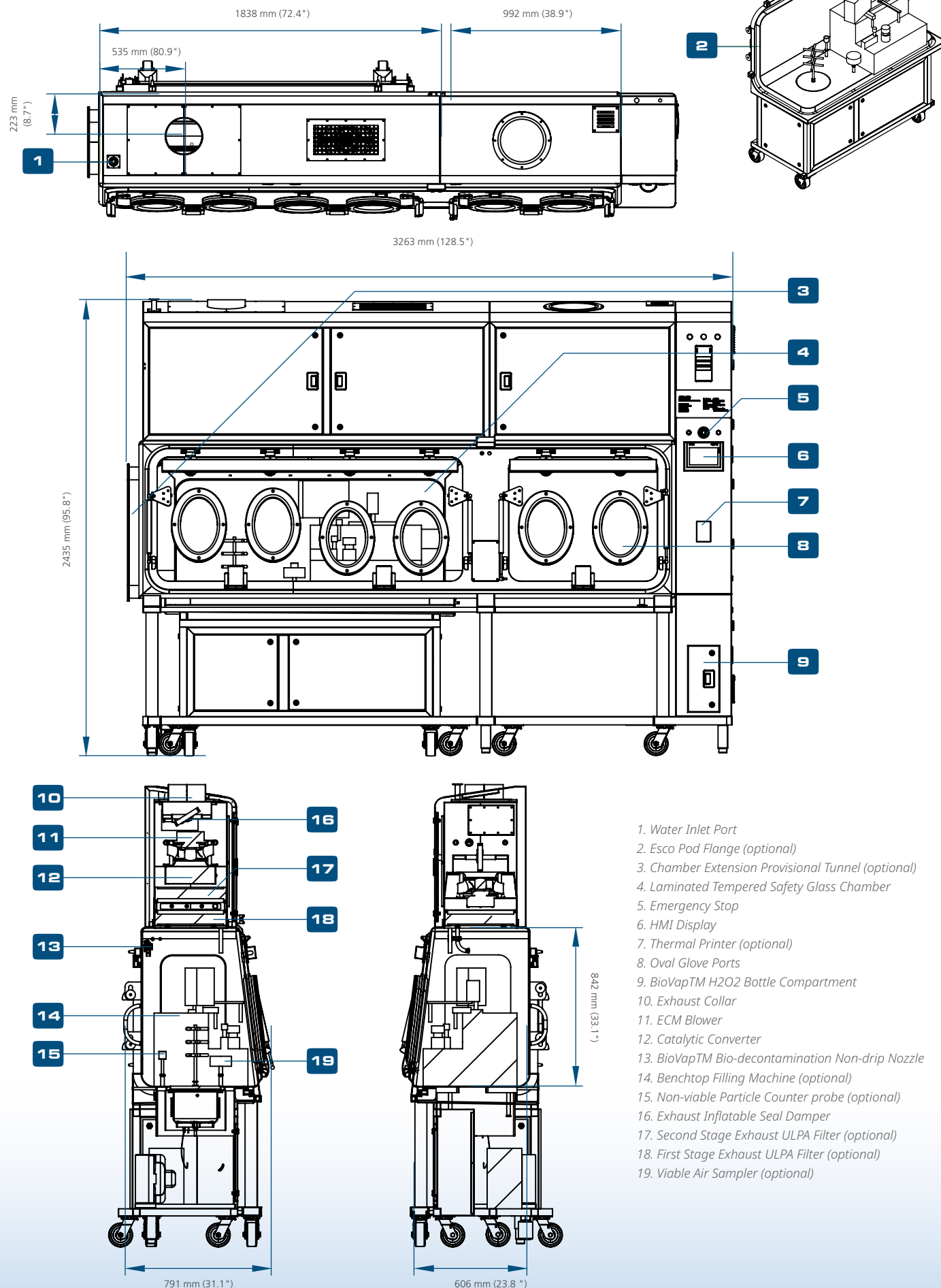
- Internal surfaces shall achieve a surface of not greater than 0.4 Ra μm to a brushed finish.
- External surfaces shall achieve a surface of not greater than 0.6 Ra μm to a brushed finish.



- 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.
- 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 process 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.

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

ENGINEERING DRAWING (MODEL: TFAI-4G)



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.



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 BioVap™ 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.

Esco BioVap™ 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.

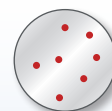
Dehumidification	Injection	Dwell	Aeration
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Priming	Injection	Dwell	Aeration
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Level of Decontamination



SANITIZATION
Two log- 10^{-2}



DISINFECTION
Five log- 10^{-5}



STERILIZATION
Six log- 10^{-6}

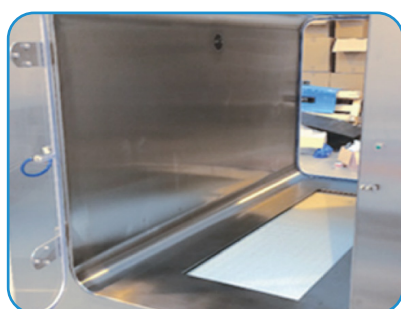
Process Step

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

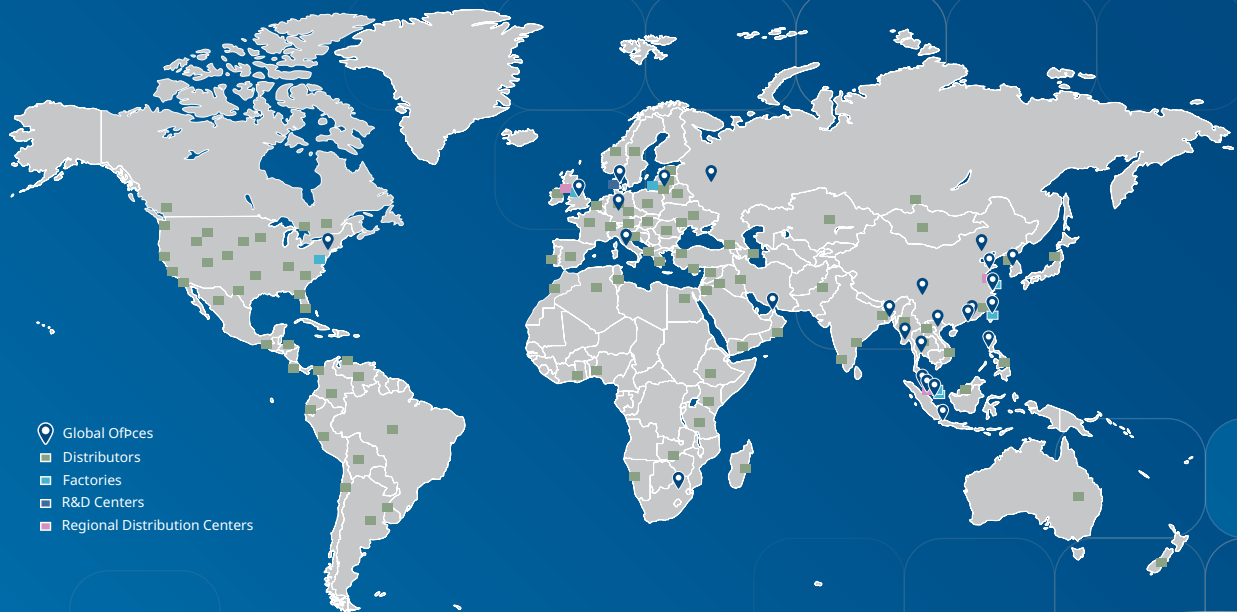


BioVap™



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42 Locations in 24 Countries All Over the World



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- Factories
- R&D Centers
- Regional Distribution Centers



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
 Evidence Drying Cabinet
 Garment Storage Cabinet
 General Processing Platform Isolator (GPPI)
 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 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

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