Solpharma Technologies

BioPass™

Pass Through

Floor standing airtight transfer chamber with onboard ventilation and integrated hydrogen peroxide based biodecontamination system designed for passing large equipment into a ISO Class 5 cleanroom in an aseptic manner.

BioPass provides a flush threshold enclosure to allow materials to be wheeled into the enclosure with the minimum of effort. Fully 316 L stainless steel assembly returning a cGMP design.

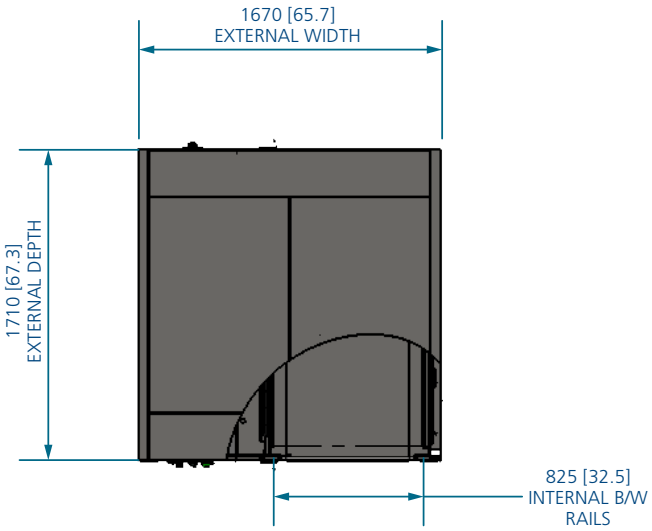
Industries Served

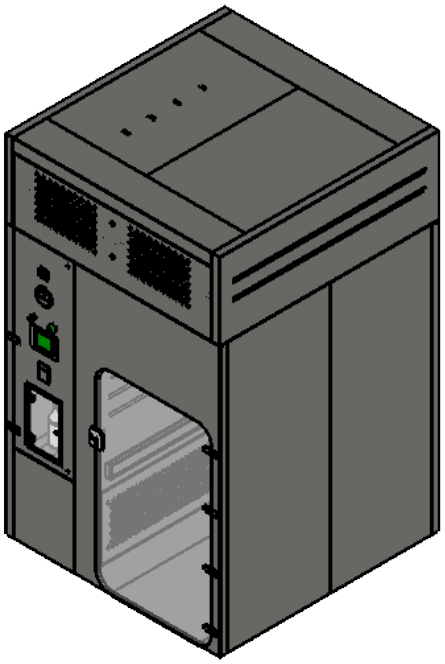
- Hospital
- Food, Beverages & Confectionary
- Manufacturing Facilities
- Veterinary Surgeries
- Dentist
- Primary Healthcare Facilities
- Pharmaceutical

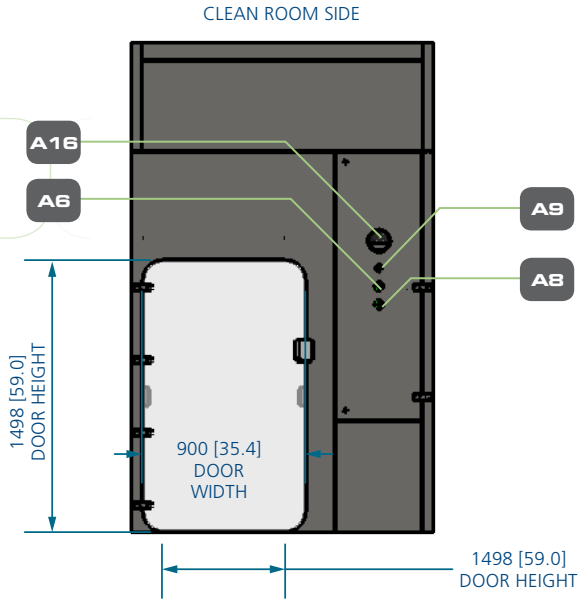
Features

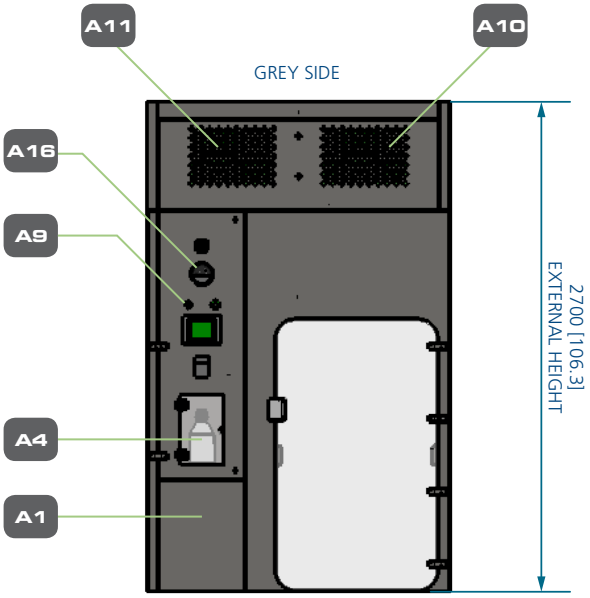
- The interior and cleanroom side face is made of 316 L stainless steel with a smooth interior and coved corners to ensure easy cleaning and biodecontamination.The interior surface is polished to 0.6 Ra µm or better and external surfaces exposed to cleanrooms 1.2 Ra µm or better. The cleanroom wall interface allows a flush finish with the surface for cleanliness.
- Chamber doors are constructed from FDA compliant materials with integrated FDA approved silicone inflatable seal around the perimeter. Doors shall give >90° opening for full access. The doors are not held closed with a mechanical latch, they are the same as our isolators where the seal locks them closed.
- Direct reading pressure gauges are provided to both sides of the pass through to give indication of the chamber pressure.
- Integrated with Esco BioVAP bio-decontamination system with PLC control, HMI operator interface and ticket roll printer to give hard copy of the bio-decontamination cycle.
- Interlocking doors to prevent opening at the same time and also to prevent the sterile unloading doors from opening until after a bio-decontamination.
- Optional on-board Catalytic Converter to allow air to be taken from the room and exhausted back to room, with interlocked safety exhaust H_2O_2 sensor. Avoids costly HVAC ducting.

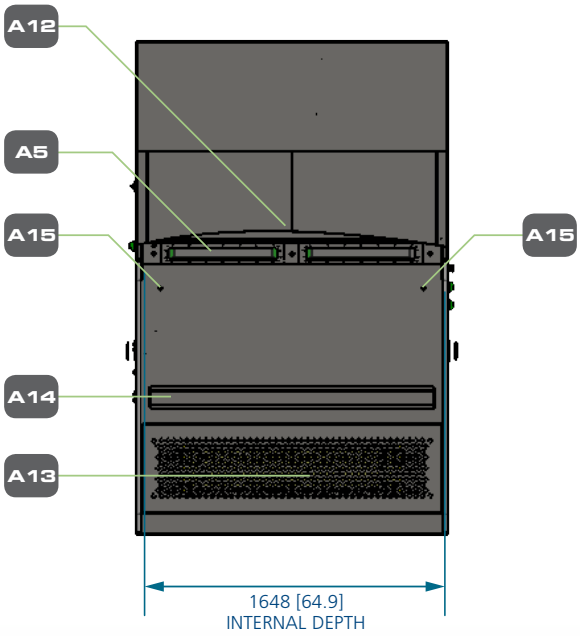
ENGINEERING DRAWING











A1 Technical Housing
A2 HMI (ON LOP)
A3 H_2O_2 Ticket Printer (ON LOP)
A4 H_2O_2 Bottle Loader
A5 Chamber Light Assembly
A6 Open Door Request Push Button
A7 Chamber Alarm / Siren Assembly (ON LOP)
A8 Door Available Indicator
A9 Emergency Stop (Qty:2)
A10 Air Inlet w/ Coarse Filter
A11 Air Exhaust w/ Coarse Filter
A12 Sypply Hepa Filter
A13 Exhaust Hepa Filter w/ Diffuser
A14 Bumper Rails
A15 Internal Safety Egress Button (Qty: 2)
A16 Chamber Pressure

STANDARD INTERNAL DIMENSIONS

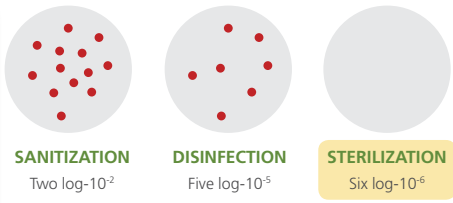
W x D x H (meters)	1.2 m x 0.9 m x 1.2 m	0.9 m x 1.6 m x 1.5 m	1.6 m x 1.6 m x 2 .5 m	2 m x 2 m x 2.7 m	2 m x 3 m x 2.7 m	3 m x 4 m x 2.7 m
W x D x H (inches)	48 in x 35 in x 47 in	35 in x 66 in x 59 in	63 in x 63 in x 98 in	79 in x 79 in x 107 in	79 in x 119 in x 107 in	119 in x 158 in x 107 in
W x D x H (feet)	4 ft x 3 ft x 3 ft 11 in	2 ft 11.4 in x 5 ft 6 in x 4 ft 11 in	5 ft 3 in x 5 ft 3 in x 8 ft 2 in	6 ft 7 in x 6 ft 7 in x 8 ft 11 in	6 ft 7 in x 9 ft 10 in x 8 ft 11 in	9 ft 10 in x 13 ft 2 in x 8 ft 11 in

TECHNICAL SPECIFICATIONS

Air Classification:	ISO Class 5 (EUGMP Grade A)
Airflow Pattern:	Single Pass uni-directional airflow (not laminar)
Operating Pressure:	Chamber +50Pa with respect to the grey side area
Leak Tightness	The acceptable leakage rate of the chamber will be no greater than 0.5% vol/hr, equivalent to a class 3 Isolator
Lighting	Internal lighting shall be provided giving average 200 lux illumination over the whole area of the chamber when measured at 1 m above the floor level.
Noise Levels:	Less than 65dBA
Temperature:	Uncontrolled
Humidity:	Uncontrolled
Inlet Filtration:	HEPA H14 Filtration
Exhaust Filtration:	HEPA H14 Filtration
Pre-Filter:	G4 Pre-filters.
Bio-decontamination:	A minimum of log 6 reduction in spore forming micro-organisms validated using a BI challenge validation

Integrated Bio-decontamination System

Esco Pharma has developed an effective hydrogen peroxide based bio-decontamination system capable of achieving a log 6 reduction in bio-burden. The spore log reduction has been validated by biological indicator challenge using biological indicator stainless steel ribbons populated with Geobacillus Stearothermophilus spores.



Optional Items

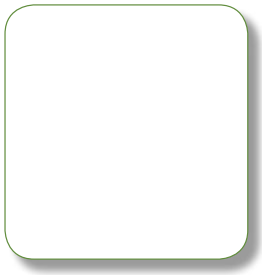
DESCRIPTION

H_2O_2 Monitoring System - (One per Biopass Needed)

H_2O_2 sensor 0-100ppm to ensure the concentration of hydrogen peroxide inside the chamber to confirm end of aeration

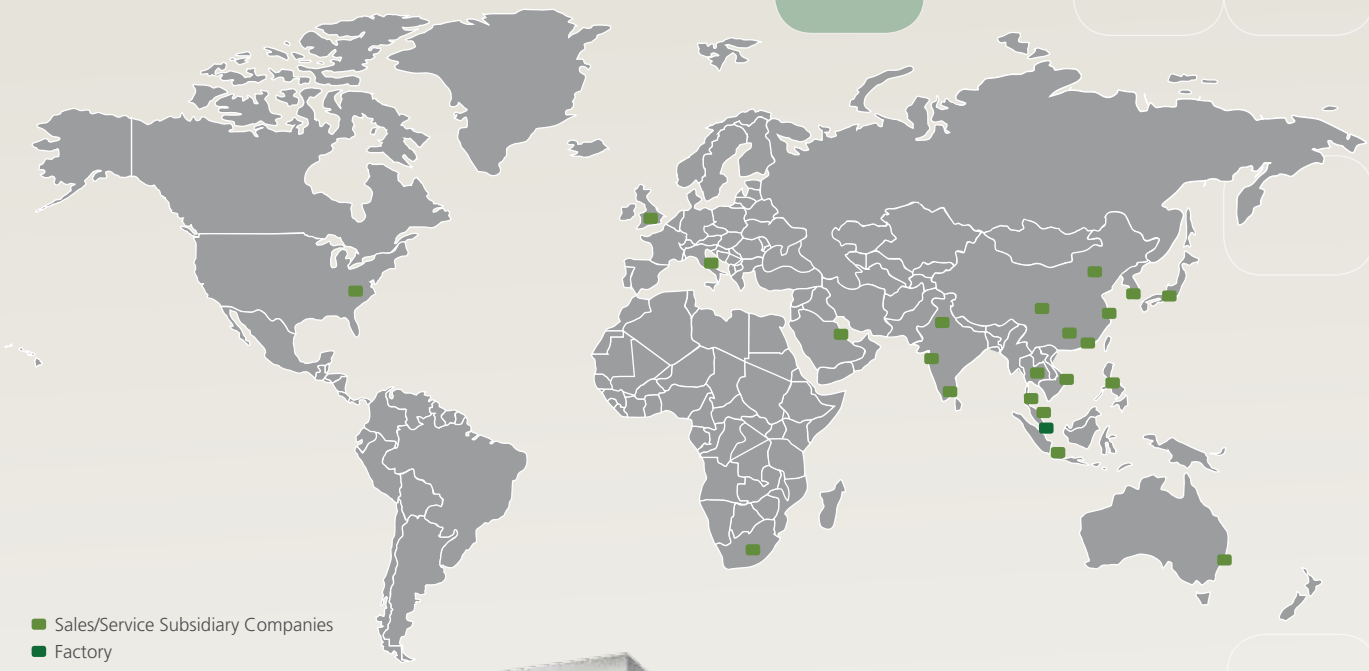
Remote Catalytic Converter

Allows aeration of the system and operation without the need for site ducting. The system can exhaust to the room following aeration



H_2O_2 Monitoring System

Catalytic Converter



Pharma Equipment Product Range

Downflow Booths
General Processing Platform Isolators
Aseptic Containment Isolators
Weighing & Dispensing Containment Isolators
Laminar Flow Trolleys (Horizontal & Vertical)
Dynamic & Static Pass Boxes
Ceiling Laminar Airflow Units

Esco Pharma dedicated R&D engineers have a combined 30 years of experience in systems design of a variety of containment and aseptic process equipment. Compared to industry averages, Esco invests a significant percentage of annual revenues in research and development. As a result of our investment, and with continuous feedback and idea evaluation among our research, global sales, marketing, purchasing and manufacturing teams, Esco products reflect the best contemporary designs in performance, ergonomics and customer satisfaction. www.escopharma.com

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Technologies

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