



# Isoclean<sup>®</sup>

## Healthcare Platform Isolator

(Inflatable Seal Model)

Optimized Solution for Sterile/Aseptic Applications



**ESCO**<sup>®</sup>  
PHARMA

## 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™ (hydrogen peroxide biodecontamination system with H<sub>2</sub>O<sub>2</sub> sensors and catalytic converter).

Integration of Esco BioVap™ allows master biodecon and independent biodecon of main chamber and passthrough chambers.

This improved 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 biodecontamination with log 6 reduction
- HEPA (H14) filter (as per EN 1822) with a typical efficiency of > 99.999% at 0.1 to 0.3 microns; provide superior ISO Class 5 air cleanliness as per ISO 14644-1
- Containment enclosure classification: Class 2 as per ISO 10648-2
- Electromagnetic interlocking doors with time delay effect ensures safety and containment during material transfer

\* With built-in air compressor to support inflatable seals in the window and dampers, and the BioVap™ biodecontamination system.

## Applications

- Aseptic and/or Potent Compounding
- Pharmacy Compounding
- Sterility Testing
- Cell and Gene Therap
- Peptide Production
- Biosafety Facility Level 3 or 4
- Benchtop/Small-scale Aseptic Formulation and Filling
- Small-scale Potent Material Handling
- Cosmeceutical
- R&D and Clinical Trials

## Options:

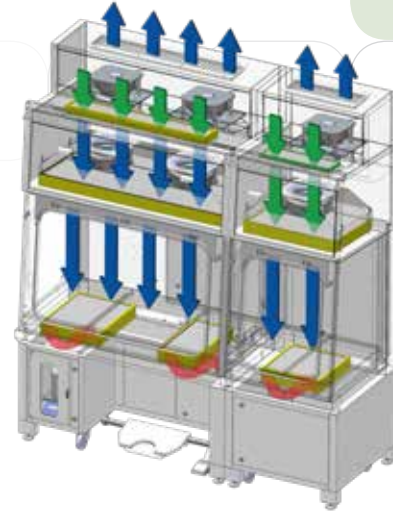
- Available in Recirculating or Total Exhaust Configuration
- Integration of a side-mounted CO<sub>2</sub> Incubator
- Glove Leak Tester
- Glove Port Sizes (300 mm or 300 x 200 mm)
- CCTV Integration
- Access to Rear View Monitor
- Addition of Sterility Test Pump
- Mechanical Integration of Viable/Non-viable Particle Monitoring (with separate software)

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

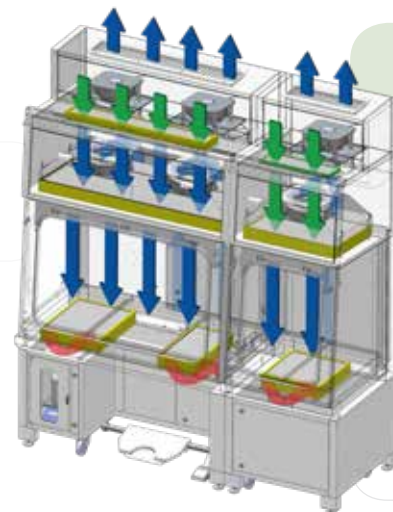


- HEPA-filtered air
- Unfiltered / potentially contaminated air
- Room air / Inflow air

### 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.



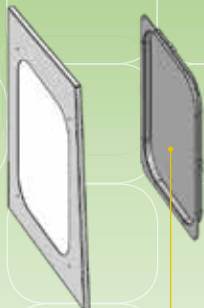
- HEPA-filtered air
- Unfiltered / potentially contaminated air
- Room air / Inflow air

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

**Esco HMI Control system**

supervises all cabinet operations and monitors cabinet performance in real time

Large graphical touch-screen display to illustrate isolator operating parameters



**Standard Side Adaptor**

**Inflatable Seal Flanges** allows integration of multiple HPI-IS modules

**Inflatable Seals**

**Hydrogen Peroxide Bottle Compartment** – Easy to access H<sub>2</sub>O<sub>2</sub> Bottle compartment for refilling procedure

**Foldable footrest** to provide better working ergonomics

**Main Chamber Module**

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

**Passthrough Chamber Module**

**Polycarbonate Main Window**

**300 mm Glove Ports**

**Pre-filter: F6** (for PTC) and **HEPA H14** (for Main Chamber) extends the HEPA (H14) Downflow Filter

• **Inlet F6 Pre-filter** (for PTC)

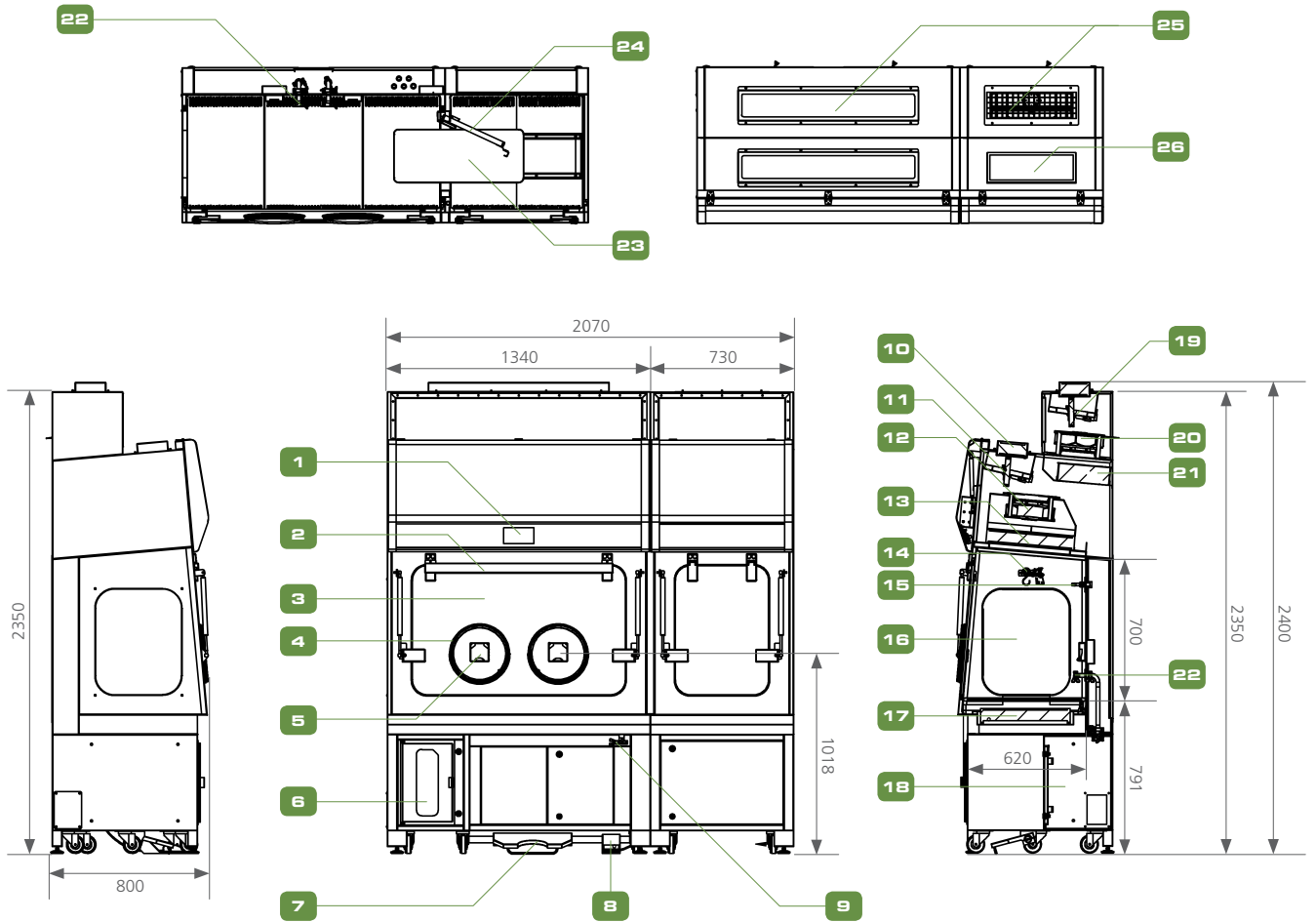
• **Inlet HEPA (H14) Filter** (for Main Chamber)

**Electromagnetic interlocking doors** with time delay effect ensures safety and containment during material transfer

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

|   |                          | 2-glove Main Chamber  | 3-glove Main Chamber | 4-glove Main Chamber | Passthrough Chamber        | 3-way Passthrough Chamber |
|---|--------------------------|---|----------------------|----------------------|----------------------------|---------------------------|
| External Dimension (W x D x H)                        |                          | 1340 x 800 x 2350 mm  | 1645 x 800 x 2350 mm | 1950 x 800 x 2350 mm | 730 x 800 x 2350 mm        | 730 x 800 x 2350 mm       |
| Internal Dimension (W x D x H)                        |                          | 1290 x 620 x 700 mm   | 1595 x 622 x 700 mm  | 1900 x 622 x 700 mm  | 680 x 620 x 700 mm         | 680 x 620 x 700 mm        |
| Passthrough Chamber - Tray Dimension                  |                          | N/A   | N/A                  | N/A                  | 270 x 660 mm               | 270 x 660 mm              |
| Isolator Construction                                 | External Body            | ISOCIDE™ Powder-coated electrogalvanized steel  |                      |                      |                            |                           |
|   | Internal Chamber         | Stainless steel 316L  |                      |                      |                            |                           |
| Airflow   |                          | Unidirectional/Laminar Airflow<br>(Recirculating or Total Exhaust/Single-Pass Airflow Models are available) |                      |                      |                            |                           |
| Process Chamber Pressure                              |                          | +37 Pa  |                      |                      | +25 Pa                     |                           |
| Process Chamber Downflow Velocity                     |                          | Selectable between -60 Pa to +75 Pa   |                      |                      |                            |                           |
| Process Chamber Downflow Velocity                     |                          | 0.45 m/s +/-20%   |                      |                      |                            |                           |
| Chamber Lighting                                      | Normal Operating Mode    | Warm White, Minimum 500 Lux   |                      |                      | no lighting for PTC Module |                           |
|   | Bio-decontamination Mode | Blue  |                      |                      | no lighting for PTC Module |                           |
|   | Alarm Mode               | Red   |                      |                      | no lighting for PTC Module |                           |
| Aeration Mode   |                          | With Integrated Catalytic Converter   |                      |                      |                            |                           |
| Pressure Hold Test                                    | During FAT and IQOQ      | Class 2 Containment as per ISO 10648-2  |                      |                      |                            |                           |
|   | Automated Daily Routine  | Class 3 Containment as per ISO 10648-2 (Pressure hold test prior to each biodecontamination)                |                      |                      |                            |                           |
| Net Weight  |                          | 525 Kg  | 650 Kg               |                      | 328 Kg                     |                           |
| Inflatable Sealed Side Adaptor Plate/ Retrofit Option |                          | RTP for sizes 105 mm, 190 mm, or 270 mm   |                      |                      | N/A                        |                           |
|   |                          | Up to 4 x 1" Tri-clover connection  |                      |                      | N/A                        |                           |

# ENGINEERING DRAWING



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|--|--|--|
| <ul style="list-style-type: none"> <li>1. Esco HMI Control</li> <li>2. LED Light</li> <li>3. Process Chamber Inflatable Seal</li> <li>4. Glove Port (ø 300 mm)</li> <li>5. Electrical Outlet</li> <li>6. Hydrogen Peroxide Bottle Compartment</li> <li>7. Foldable Footrest</li> <li>8. Foot switch</li> <li>9. Spare Drain (1" Tri-clover)</li> </ul> | <ul style="list-style-type: none"> <li>10. HEPA (H14) Pre-filter</li> <li>11. Inlet Damper Inflatable Seal</li> <li>12. Supply Fan</li> <li>13. Supply HEPA (H14) Filter</li> <li>14. IV Bar with 6 S-hooks</li> <li>15. Relative Humidity and Temperature Sensor</li> <li>16. Side Adaptor Inflatable Seal Flange</li> <li>17. Exhaust HEPA (H14) Filter</li> <li>18. Main Control Panel</li> </ul> | <ul style="list-style-type: none"> <li>19. Exhaust Damper Inflatable Seal</li> <li>20. Exhaust Fan</li> <li>21. Catalytic Converter</li> <li>22. Tri-clover Connection for Viable and Non-viable Particle Counter</li> <li>23. Pass Chamber Sliding Tray</li> <li>24. Pass Chamber Inner Door Inflatable Seal</li> <li>25. 2nd Exhaust HEPA (H14) or Carbon Filter (Optional)</li> <li>26. F6 Prefilter</li> </ul> |
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