

# **Healthcare Platform Isolator**

(Inflatable Seal Model)

#### Introduction

The Isoclean® Healthcare Platform Isolator – Inflatable Seal Model (HPI-G3-IS) facilitates the isolation of a product/process while providing the required sterile environment. HPI-G3 is designed with FDA-approved static seals, while HPI-G3-IS is designed with inflatable seals and automated dampers. The standard unit is integrated with auto pressure hold testing and mobile BioVap<sup>™</sup> (hydrogen peroxide biodecontamination system with H<sub>2</sub>O<sub>2</sub> sensors and catalytic converter). Integration of Esco mobile Biovap<sup>™</sup> allows master biodecon that can only be performed with internal doors open. It also comes with an automated sliding door feature for closing and opening of the inner passthrough chamber door. This improved design facilitates ease of isolation control especially during pressure decay testing and bio-decontamination process.

This model is available in positive or negative pressure regime, and in recirculating or total exhaust configuration.

#### **Applications**

- Aseptic and/or Potent Compounding
- Biosafety Facilities Level 3 or 4Benchtop/Small-scale Aseptic

Formulation and Filling

• Small-scale Potent Material

• Cosmetic/Cosmeceutical

R&D and Clinical Trials

Handling

- Pharmacy Compounding (TPN/ Chemotherapy)
- Sterility Testing
- Aseptic Filtration
- Cell and Gene Therapy
- Peptide Production

#### **Main Features**

- Capable of automated pressure hold testing (APHT)
- ULPA filters (as per IEST-RP-CC001.3 and 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 via auto pressure leak test (factory acceptance test) and Class 3 via automated pressure test as per ISO 10648-2 (prior to daily tasks).
- Inflatable seal and 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
- Electromagnetic interlocking doors with time delay effect ensures safety and containment during material transfer
- Foot switch activated auto sliding doors with light barrier

**Options:** 

 Available in Negative or Positive Pressure model, in Recirculating or Total Exhaust airflow

without ducting

FCCO

- Integration of Esco mobile BioVap<sup>TM</sup> biodecontamination system ( $H_2O_2$  biodecontamination with sensor and catalytic converter)
- Integration of a side-mounted 24L CO<sub>2</sub> Incubator
- Glove Leak Tester
- Glove Port sizes
   300mm
- 300 x 200 mm
- CCTV integration

• Height adjustable stand

\* Not representative of final image. Unit shown as individual units

- Access to rear view monitor system
- With option for three-way pass through chamber in between 2 units of 2-glove, 3-glove, or 4-glove isolator combination.
- Other configurations available:
  2-glove + 2-glove + 2-glove units
- 4-glove + 2-glove units
- NEBB Cleanroom Performance Testing for Validation
- Optional PQ Support

## Isoclean® Healthcare Platform Isolator – Inflatable Seal Model Airflow Pattern

#### Positive Pressure, Recirculating Model

Ambient air is pulled through the inlet pre-filter and main filter located on top of the isolator. The HEPA (H14) downflow filter creates a

laminar air flow providing ISO Class 5 air cleanliness (ISO 14644-1) to the main chamber.

A percentage of the air from the work zone is recirculated back to the chamber. The fan pulls the purged air back to the plenum which again passes through the HEPA (H14) downflow filters, resulting to the air being recirculated back to the work zone and pass-through.

Meanwhile, a percentage of air is pulled towards the perforations at the rear wall inside the work zone, which is then transferred to the pass

chamber via the network of HEPA (H14) filters located at its own rear walls. The filtered air is then exhausted out through the top portion of the PTC after passing through another stage of HEPA (H14) filters.

A percentage of purged air is exhausted through the filters to prevent heat build-up inside the isolator. Exhausted air will then be replenished by ambient air coming from the top inlet pre-filter and the main filter.

#### Negative Pressure, Recirculating Model

Ambient air is pulled through the inlet pre-filter and HEPA (H14) filter located on top of the passthrough chambers of the isolator. The air

is then pulled by the fan towards the rear wall of the PTC and goes to the back plenum.

It passes through the HEPA (H14) downflow filter again, resulting to the air being recirculated to the work zone.

The HEPA (H14) downflow filter creates a laminar air flow providing ISO Class 5 air cleanliness (ISO 14644-1) to the main chamber. Exhausted air is then replenished by ambient air coming from the top inlet pre-filter and the main filter.

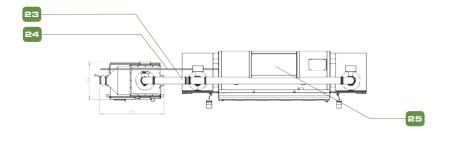


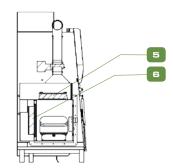


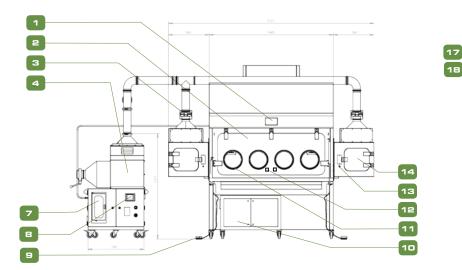
#### Isoclean® Healthcare Platform Isolator – Inflatable Seal Model

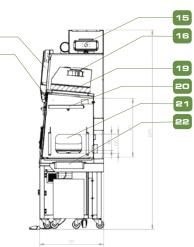
| Isolator Unit |   | Model |                    | No. of<br>Gloves |          | Voltage Code |                          | Pressure |          | Airflow |                               | Passthrough<br>Chamber |                  | Sharps Bin Inside |  |
|---------------|---|-------|--------------------|------------------|----------|--------------|--------------------------|----------|----------|---------|-------------------------------|------------------------|------------------|-------------------|--|
| HPI           | lsoclean®<br>Healthcare<br>Platform<br>Isolator | IS    | Inflatable<br>Seal | 2G               | 2 Gloves | 8            | 220-240 VAC,<br>50/60 Hz | N        | Negative | S       | Single-Pass/<br>Total Exhaust | 0                      | No PTC           | s                 | with Sharps Container<br>inside main chamber |
|               |   |       |                    | 3G               | 3 Gloves | 9            | 110-120 VAC,<br>50/60 Hz | Р        | Positive | R       | Recirculating                 | L                      | 1 PTC Left       | 0                 | Without Sharps<br>Container                  |
|               |   |       |                    | 4G               | 4 Gloves |              |                          |          |          |         |                               | R                      | 1 PTC Right      |                   |  |
|               |   |       |                    |                  |          |              |                          |          |          |         |                               | В                      | 1 PTC Both sides |                   |  |

### **ENGINEERING DRAWING**









1. Esco HMI

- 2. Polycarbonate hinged window with inflatable seal
- Automatic valve (exhaust)
  Catalytic converter with exhaust fan (optional)
- 5. Pass chamber exhaust filter
- 6. Pass chamber inlet filter



- 7. Esco mobile BioVap™
- (biodecontamination system)
- BioVap<sup>™</sup> controller display
  Ecotewitch for pass chamber i
- 9. Footswitch for pass chamber inner door 10. Onboard compressor (for BioVan™ &
- 10. Onboard compressor (for BioVap™ & pressure test)
- 11. Round glove port, 300mm
- 12. Electrical outlet (optional) electrical
- panel
- 13. Pass chamber outer door switch
- 14. Pass chamber outer door 15. Automatic valve (inlet)
- 15. Automatic valve (inlet) 16. Process chamber inlet fan
  - 24. 1
- 17. Electrical panel 18. LED light
- 19. Process chamber inlet HEPA filter
- 20. IV bar, sliding (optional) 21. Pass chamber inner door
- 22. Process chamber return HEPA filter
- 23.  $H_2O_2$  aeration piping
- 24.  $H_2O_2$  injection piping
- 25. Pre-filter (inlet air)





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