HPI Gen3

Isoclean®
Platform Isolator

Compounding Aseptic Isolator and
Compounding Aseptic Containment Isolator

Introduction

The Isoclean® Platform Isolator facilitates the isolation of a product or process while providing the required for sterile/aseptic environment. It is configured to operate at positive or negative pressure. This equipment provides a comprehensive range of personnel and product protection in addition to the surrounding work areas and the environment.

Applications

- Pharmacy Compounding (Chemotherapy/TPN)
- Small-scale Potent Material Handling
- Aseptic Processing
- Research and Development
- Cell processing

Main Features

- ULPA filters with a typical efficiency of 99.999% at 0.1 to 0.3 microns provide superior ISO Class 5 air cleanliness.
- Sentinel Gold™ Microprocessor Control System supervises all functions and monitors airflow and pressures in real-time.
- Safe glove change permits zero risk of contaminating the work zone or environment
- Robust construction and enhanced safety features qualify the Isoclean® Platform Isolator for the most demanding laboratory applications. The isolator is fully assembled and ready to install and operate when shipped.
- Ergonomically angled front gloveports improve reach and comfort.
- Esco ISOCIDE™ antimicrobial coating on all painted surfaces minimizes contamination.
- Sharps disposal system and adjustable hydraulic stand are available as options.

Air Filtration Principle

Ambient air is pulled through the inlet pre-filter located on top of the isolator. The prefilter traps large size particles to extend the life of the supply U15 ULPA filter.

Air from the top inlet and from work zone 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 work zone through the pass-through.

The U15 downflow filter creates a full unidirectional airflow and particle-free ISO Class 5 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.

Standard Compliance

Esco Isoclean® Platform Isolator provides a safe and clean environment for compounding of hazardous, sterile drug preparations in compliance with USP 797* criteria.

Cabinet Performance	Air Quality	Filtration
CETA CAG-001-2005, USA CETA CAG-002-2006, USA USP Chapter 797, USA	ISO 14644.1, Class 3,Worldwide JIS B9920, Class 3, Japan JIS BS5295, Class 3, Japan US Fed Std 209E, Class 1 USA	EN-1822, Europe IEST-RP-CC001.3, USA IEST-RP-CC007, USA IEST-RP-CC034.1, USA

** United States Pharmacopoeia (USP), Chapter 797, 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.*

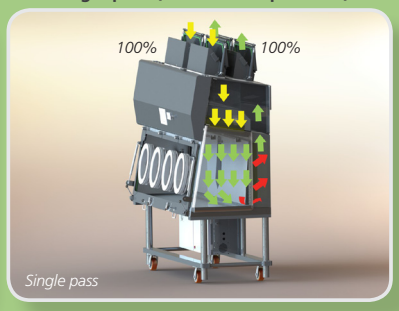
Warranty

One year warranty (excluding consumables). Consumables are ballast, fluorescent, and filters. The warranty will cover all other parts including the blower, fan switch, and electrical main board. During the period of warranty, any repair, modification, testing and commissioning performed by any unauthorized party other than Esco Service Team will void the warranty of the unit.

Recirculating (-ve pressure only)

80% recirculating 20% supply 20% exhaust.

Single pass (+ve and -ve pressure)



100% supply 100% exhaust.

Clean Air Air Filtered Air

Chamber Filtration

Process:

- Chamber Inlet Filter – Single G4 Filtration. Panel filter.
- Chamber Inlet Filter – Single H14 HEPA Filtration. Panel filter, gasket seal, glass fibre media.
- Chamber Return Filter – Single H14 HEPA Filtration. Panel filter, gasket sealed, Glass fibre (low contamination change).
- Chamber Outlet Filter-Single H14 Hepa filtration. Panel filter, gasket seal, glass fibre media (BIBO)
- Optional carbon filter for volatile chemotherapy agents.

Pass Chamber:

- Room Inlet Filter – Single G4 Filtration. Panel filter, polyester media.
- Chamber Inlet Filter – Single H14 HEPA Filtration. Panel filter, gasket seal, glass fibre media.

Filters: Camfil Farr, Switzerland.
Blowers : AC EBM, Germany

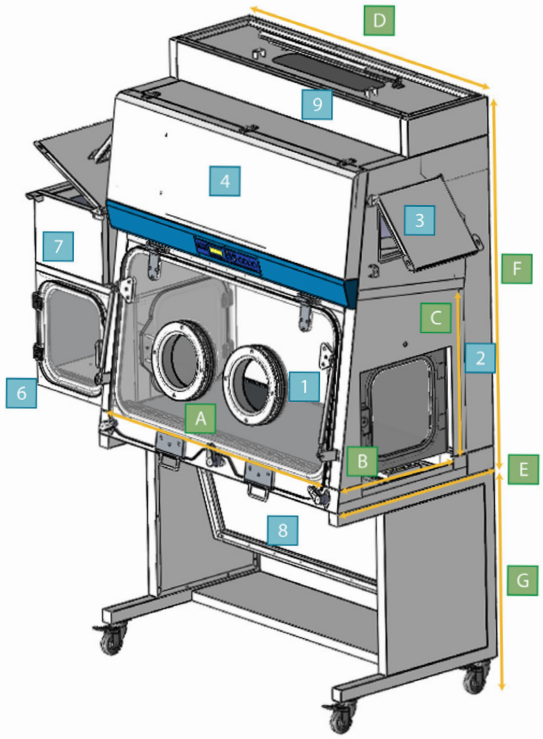
Sentinel™ Gold Microprocessor Control Monitoring System

- The Esco Sentinel™ Gold microprocessor-based control system supervises operation of all cabinet functions.
- Open loop fan controls to maintain constant pressure with EBM AC Fans
- Controls fan - ON/OFF
- Power socket - ON/OFF (if provided)
- Displays differential pressure drop across chamber
- Filtration via magnehelic gauges
- Displays downflow velocity (for unidirectional unit) and air changes per hour
- Glove Breach velocity for negative pressure 0.7 m/s
- Manual Pressure Testing
- Optional UV Lighting with timer

Cabinet Construction

- External surfaces are coated with Isocide™ antimicrobial coating to protect against surface contamination and inhibit bacterial growth. Isocide™ eliminates 99.9% of surface bacteria within 24 hours of exposure.
- The cabinet exterior structure is constructed of industrial-grade electrogalvanised steel.
- The cabinet interior is constructed of durable and pharmaceutical grade 316 L stainless steel.
- Optional single-piece stainless steel work surface for easy cleaning. Raised edges on all sides to contain spillages.
- Stainless steel drain pan below the work surface contains spills.
- Removable tray components to provide easy access and encourage surface decontamination.
- Hinged window may be opened for thorough access into the work zone.
- Standard glove port size is 200 mm x 200 mm.
- Option for filter below work zone

Process Chamber Dimensions



No.	Description	Dimension (mm)
A	Internal Width	2G – 840, 910, or 1215
B	Internal Depth	600
C	Internal Height	618
D	External Width	1340
E	External Depth	826
F	External Height	1554
G	Stand	710

Materials Options

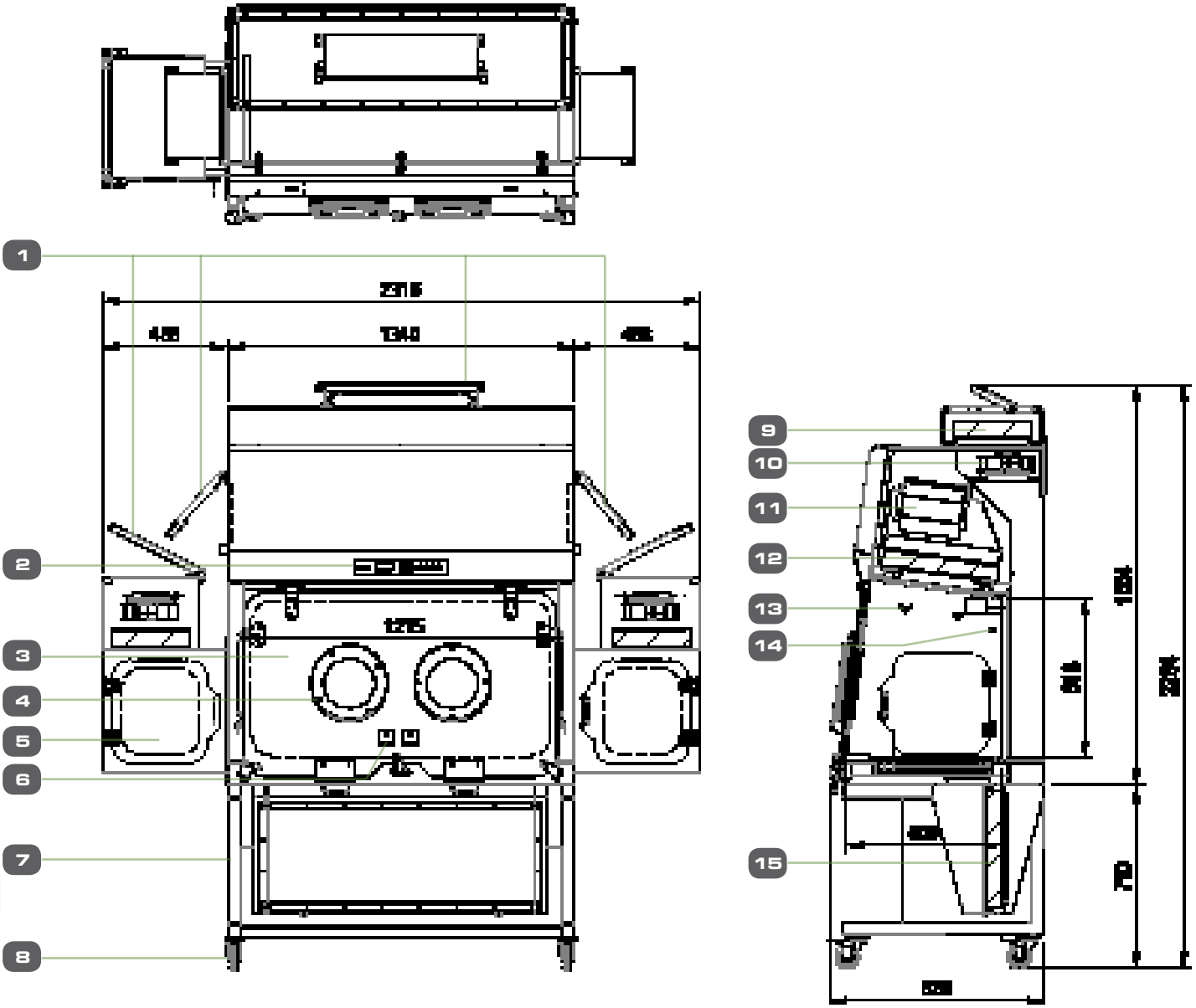
Material	1	2	3	4	5	6	7	8	9	10
PC		Y	Y	Y		Y	Y	Y	Y	Y
316	Y				Y					

6=PTC Return Plenum off screen not Shown in Drawing

Optional Accessories

General Options	Hydraulic Stand Control IV Bars for Handing Bags Glove Leak Tester Rear View Screen
Work Surface Options	Single Piece Multiple Trays
Transfer Options	Sharps Disposal (2) Continuous Liners for Bag In or Bag Out (BIBO) Bag Welder for Continuous Liner System

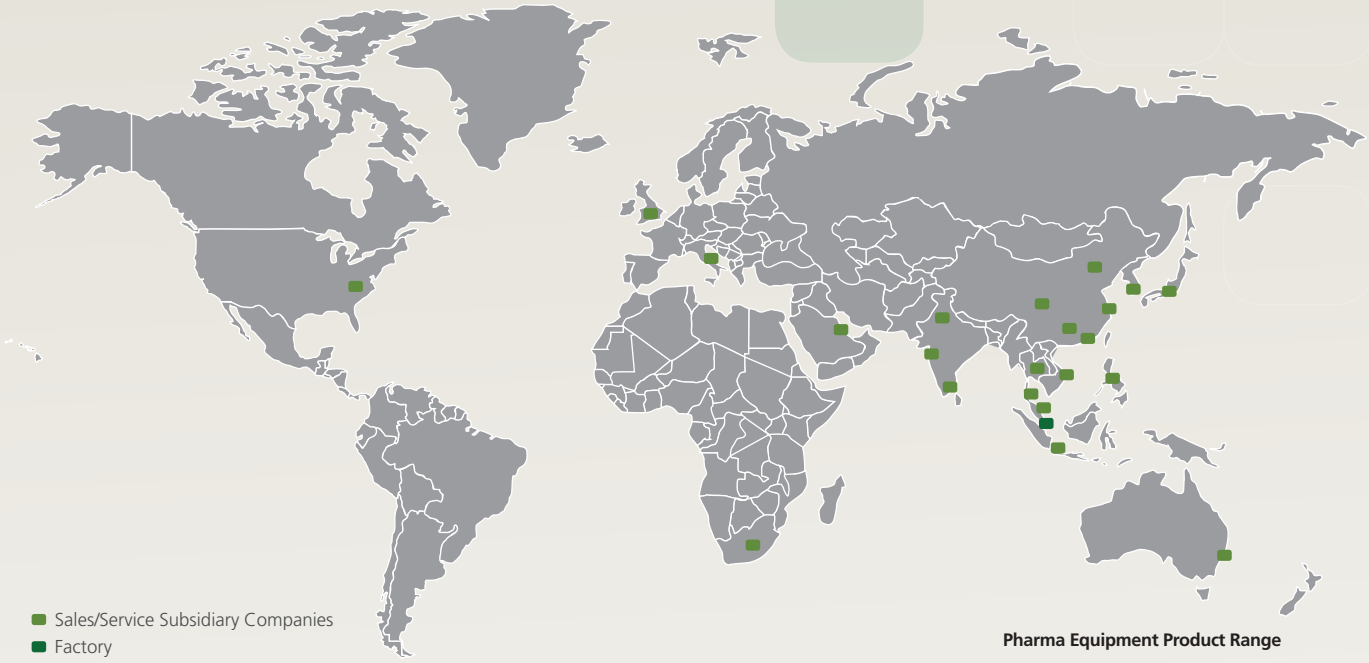
Technical Specifications



Engineering Controls Label

1.Dampers
2.Sentinel™ Gold Microprocessor Control System
3.Process Chamber
4.Glove Ports
5.Pass-through Chamber
6.Electrical Outlet (Optional)
7.Stand
8.Caster Wheel
9.Exhaust HEPA Filter
10.Exhaust Fan
11.Supply Fan
12.Supply HEPA Filter
13.IV Bar (Optional)
14.UV Lamp (Optional)
15.Exhaust Filter Below Work Zone (Optional)

ESCO GLOBAL NETWORK



- Sales/Service Subsidiary Companies
- Factory

Pharma Equipment Product Range

Air Shower
Aseptic Containment Isolator (ACTI)
Ceiling Laminar Airflow Units
Containment Barrier Isolator (CBI)
Dynamic Pass Box
Esco Straddle Unit Single
Evidence Drying Cabinet
Garment Storage Cabinet
General Processing Platform Isolator (GPPI)
Hard Capsule
Laminar Flow Horizontal Trolley
Laminar Flow Straddle Units
Laminar Flow Vertical Trolley
Pass Box
Soft Capsule
Sputum Booth
Weighing and Dispensing Containment Isolator (WDCI)

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

ESCO® PHARMA PLATFORM SPECIALIST.

Esco Pharma Pte Ltd
21 Changi South Street 1 Singapore 486777 • Tel: +65 65420833
Fax: +65 65426920 • Email: csis.pharma@escoglobal.com

Esco Technologies, Inc.
1661 Loretta Ave., Feasterville, PA 19053
Tel: 215 322 2155 • Email: eti.pharma@escoglobal.com

Esco Gb Ltd
Unit 9, Century Park Networkcentre, Dearne Lane,
Manvers, Rotherham, South Yorkshire, S63 5DE.
Tel: +44 (0) 1709 761 669 • Email: egb.info@escoglobal.com

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