ESCO PHARMA

GPPI

General Processing Platform Isolator

Pass Chamber

Inflatable Sealed Visors

Integrated Glove Leak Tester

BioVap™ Biodecontamination System

Capable of Master and Independent Biodecontamination

Caster Wheels

Levelling Feet

Non-viable Particle Counter

(Fully Integrated)

Guide to General Processing Platf

GPPI-IS-4G-1PTC(2G)

Base Model	Code	Seal Design	Code	Process Chamber Design	Code
General Processing Platform Isolator	GPPI	Inflatable Seal	IS	2-glove (1200 mm)	2G
				3-glove (1600 mm)	3G
				4-glove (2000 mm)	4G
				5-glove Custom Unit	5G

Automated Pressure Hold Test (APHT)

Emergency Stop Button (E-stop)

HMI/PLC Control System

(with optional upgrade for 21 CFR Part 11 Compliance)

Process Chamber

Glove Ports

Viable Air Sampler

(Fully Integrated)

form Isolator

Pass Chamber Design	Code	Pass Chamber Size	Code
No Passthrough Chamber	NPTC	Non-glove	NG
1 Passthrough Chamber	1PTC	1-glove	1G
2 Passthrough Chamber	2PTC	2-glove	2G

Other Common Accessories:
IV Bars and S Hooks
SS 316 Trays and Shelves
Rapid Transfer Ports (RTP) – Alpha and Beta
Integration of Sterility Test Pump
Drain Valve
Electrical Outlets

Introduction

The General Processing Platform Isolator (GPPI) is a highly adaptable, unidirectional airflow isolator that can be used for sterility testing or other aseptic processes that require an ISO Class 5 (Grade A) environment. The GPPI's advanced control system allows the operator to select either single pass or recirculating airflow regime. These features along with the ability to perform safe change procedures on the supply and return filters make GPPI a highly versatile isolator that can be used for potent and non-potent aseptic materials.

In addition, the Esco GPPI's design offers over 20 standard options and configurations ensuring that Esco can provide a standard solution to fit your specific process and facility requirements. Should a standard option not fit your requirements, Esco can offer customized solutions as well.

Main Features

- Unidirectional airflow with 0.45 ± 20% m/s airflow ensuring product protection
- User selectable single pass or recirculating airflow regimes
- Fully integrated Hydrogen Peroxide (H_2O_2) biodecontamination system ensuring 6 log reduction in the bioburden
- Low Contamination Change Filter design allows the handling of potent and non-potent aseptic products
- Temperature and Relative Humidity (RH) real-time monitoring for critical processes

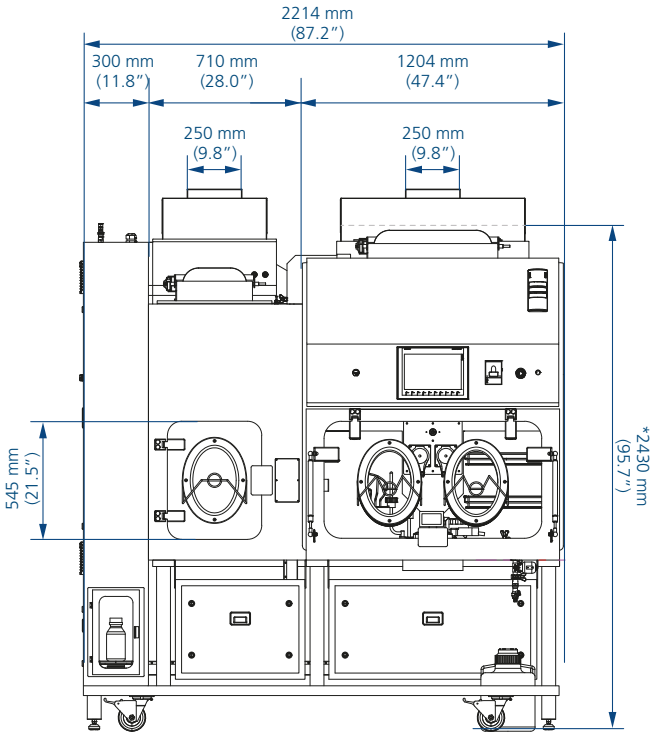
Applications

- Aseptic Processing
- Cell Processing
- Pharmaceutical Compounding (Chemotherapy/TPN)
- Potent Material Handling (Small-scale)
- Research and Development
- Sterility Testing

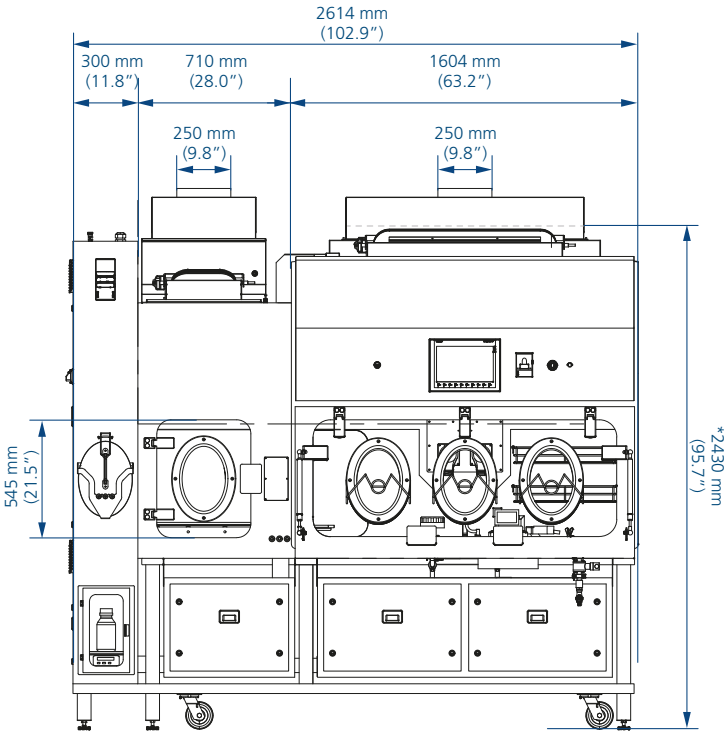
Standard Features

- Fully welded SS316L internal chambers with rounded coved corners
- Optional on-board exhaust catalytic convertor allows exhaust into the surrounding room without modifications to the facility
  - Unit is also fitted with an external interlocked H_2O_2 sensor for operator and environment safety
- Optional mobile air compressor eliminates the need for a site supplied compressed air connection; hence, allowing unit a plug and play design
- Self-contained design of control system & electrics allow for simple, plug-in installation
- Fully integrated particle monitoring connections and optional inclusion of the viable and non-viable monitoring equipment
- Class 3 Leak Tight Containment (ISO 10648-2) automated pressure hold test to ensure there are no leaks prior to decontamination and normal run
- Pre-Programmed system to function with multiple H_2O_2 system options
- Standard design incorporates cGMP compliant features; with the inclusion of an optional chart recorder or printer, the GPPI will meet the data handling requirements for 21 CFR Part 11
- Safe change glove system allows the changing of gloves while maintaining aseptic conditions inside the chambers

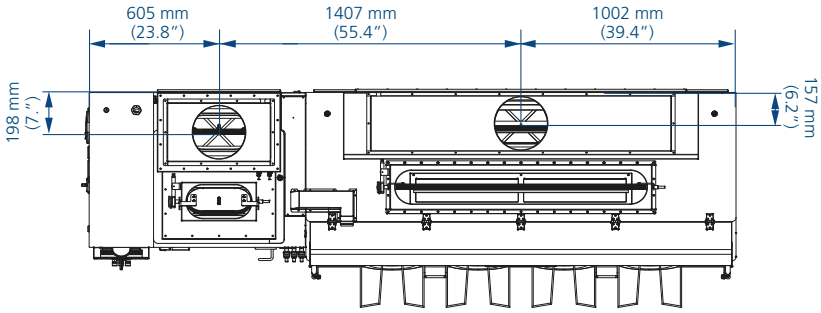
ENGINEERING DRAWING

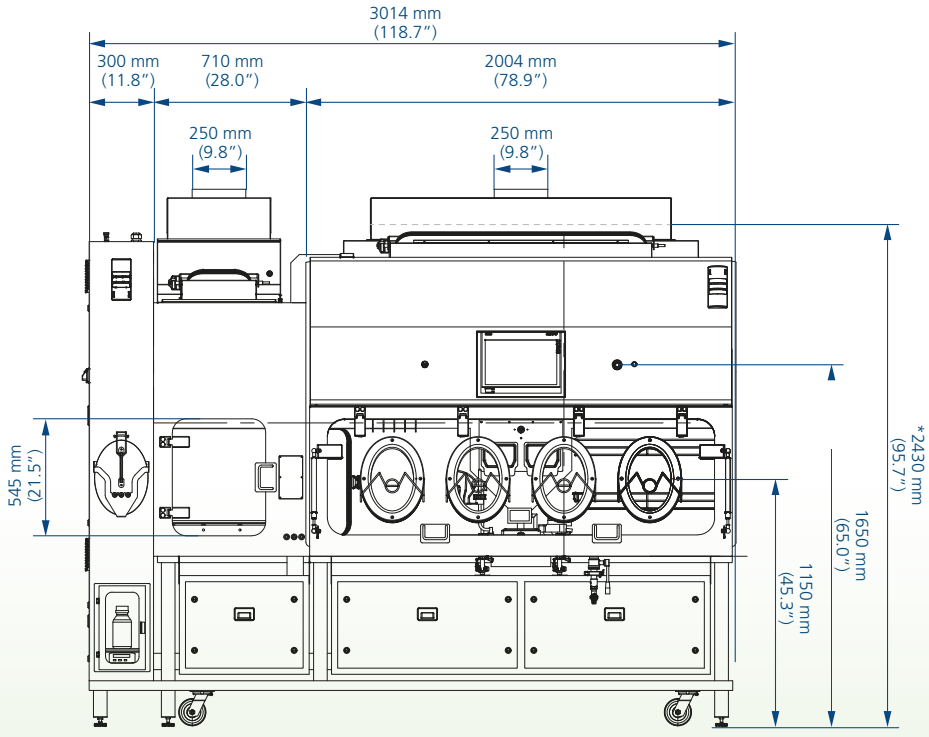


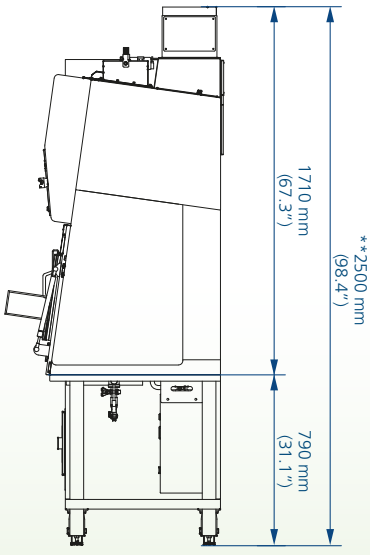
GPPI-2G



GPPI-3G





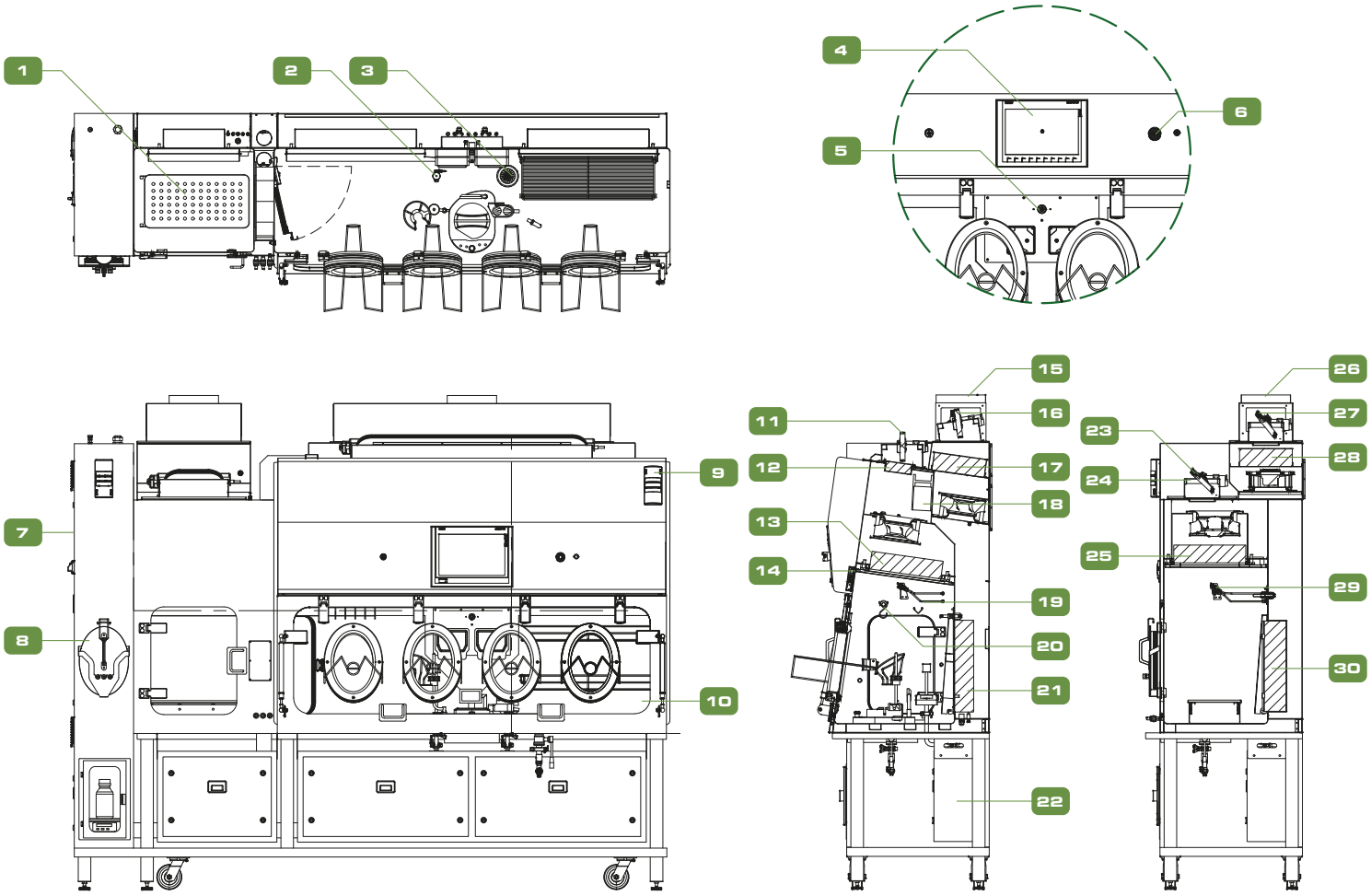


** Height without exhaust collar*
*** Height with exhaust collar*

GPPI-4G

External Depth - 881 mm
Internal Depth - 540 mm

PARTS AND ACCESSORIES



GPPI-4G

1. Pass Chamber Sliding Tray

2. Total Airborne Particle Counter Isokinetic Probe, (Esco offer a PMS IsoAir Pro-Plus as standard configuration)

3. Viable Air Sampler Holding Plate (Esco offer a PMS MiniCapt Remote Microbial Air Sampler 25R as standard configuration)

4. HMI 12"

5. RH and Temperature Sensor Probe

6. Emergency Stop Button

7. Main Control Panel (MCP)

8. Integrated Glove Leak Tester

9. Visual and Audible Alarm Beacon

10. Process Chamber Glass Door with Inflatable Seal

11. Process Chamber Air Inlet, Automatic Damper

12. Process Chamber Air Inlet Pre-filter, M6

13. Process Chamber Supply Filter, U15 ULPA Filter

14. Process Chamber LED Light

15. Process Chamber Exhaust Collar

16. Process Chamber Air Exhaust Collar, Automatic Damper

17. Process Chamber Catalytic Converter

18. Process Chamber Recirculation Damper

19. Process Chamber Decon Nozzle

20. Hanging Rail with S-hook

21. Process Chamber Exhaust Filter, H14 HEPA Filter

22. H_2O_2 Room Sensor (inside the ICP)

23. Pass Chamber Air Inlet, Automatic Damper

24. Pass Chamber Air Inlet Pre-filter, G4

25. Pass Chamber Supply Filter, U15 ULPA Filter

26. Pass Chamber Exhaust Collar

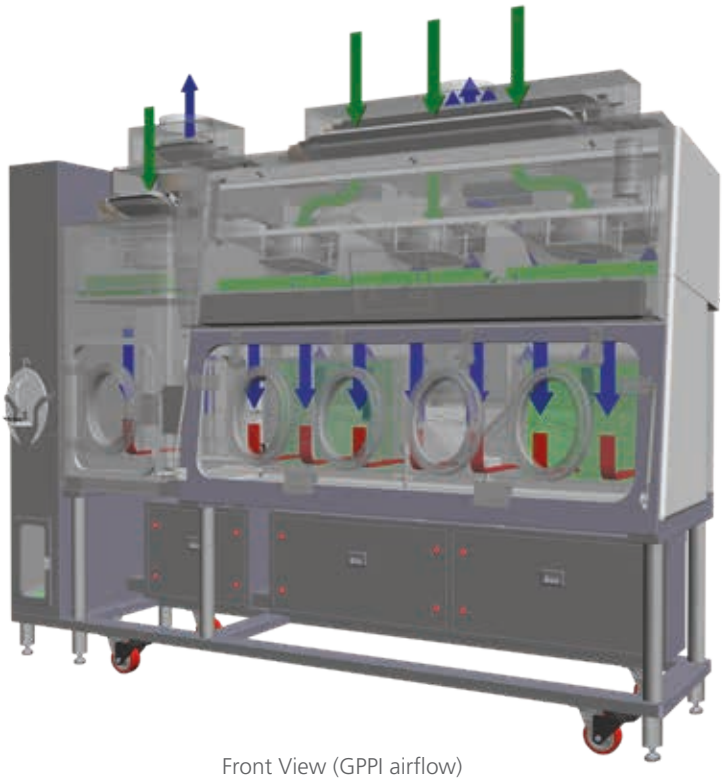
27. Pass chamber Air Exhaust, Automatic Damper

28. Pass Chamber Catalytic Converter

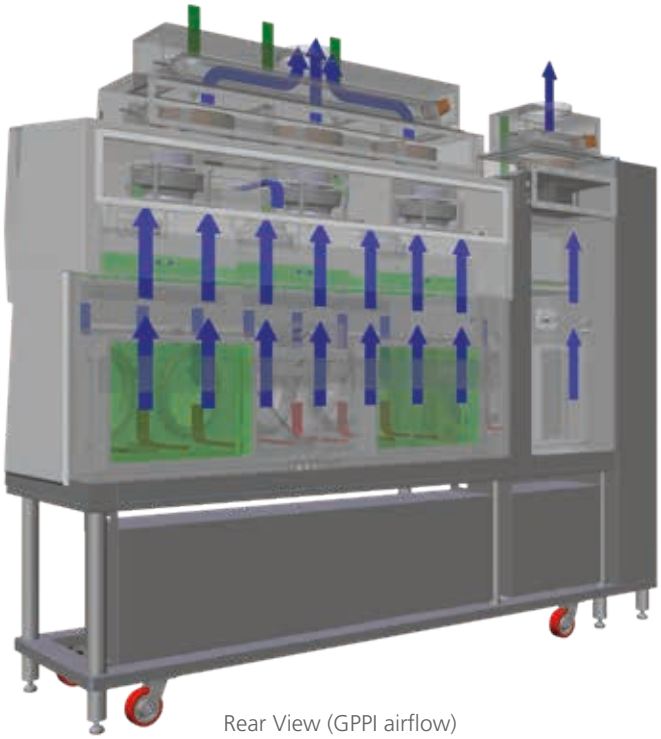
29. Pass Chamber Decon Nozzle

30. Pass Chamber Exhaust Filter, H14 HEPA Filter

AIRFLOW DIAGRAM



Front View (GPPI airflow)

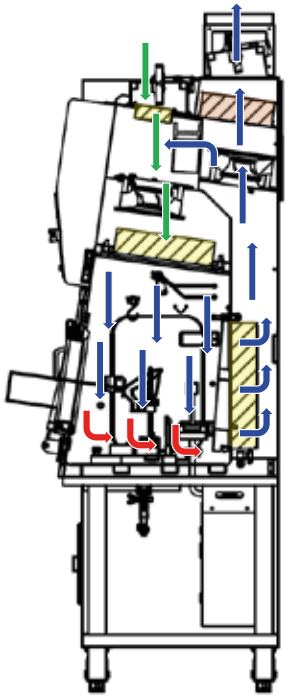


Rear View (GPPI airflow)

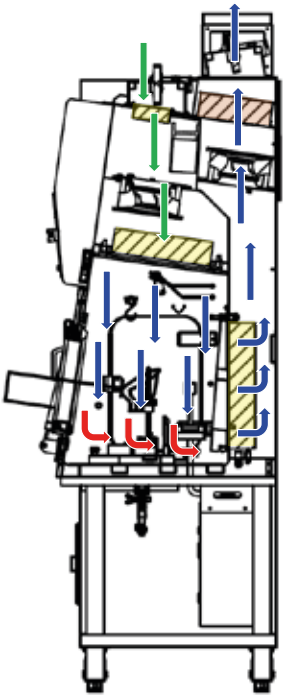
Room Air

Filtered Air

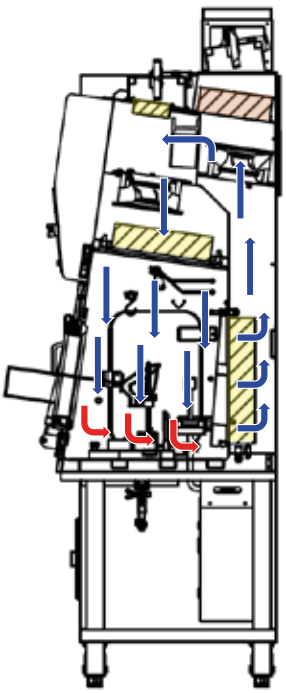
Contaminated Air



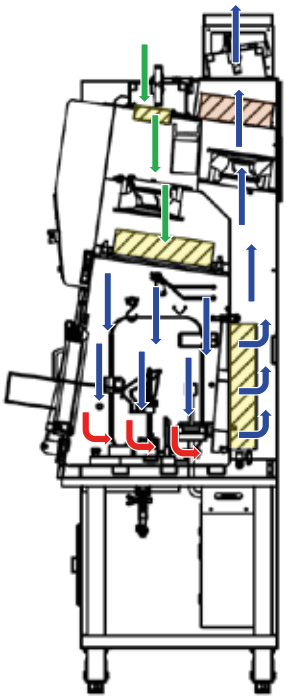
Normal Run
Recirculating Mode



Normal Run
Single Pass Mode



Decontamination Mode
Recirculating Mode



Aeration Mode
Single Pass Mode

GENERAL SPECIFICATIONS

GENERAL PROCESSING PLATFORM ISOLATOR (GPPI)

			GPPI-2G	GPPI-3G	GPPI-4G
Nominal Size Main Chamber (Width)			1200 mm (47.2")	1600 mm (63.0")	2000 mm (78.7)
External Dimensions (W x D x H)*		Process Chamber	1504 x 881 x 2430 mm (47.40" x 34.69" x 95.67")	1904 x 881 x 2430 mm (74.96" x 34.69" x 95.67")	2304 x 881 x 2430 mm (90.71" x 34.69" x 95.67")
		Pass Chamber**	710 x 772 x 2430 mm (27.95" x 30.4" x 95.67")		
Internal Dimensions (W x D x H)**		Process Chamber	1200 x 540 x 700 mm (47.24" x 21.26" x 27.56"	1600 x 540 x 700 mm (62.99" x 21.26" x 27.56")	2000 x 540 x 700 mm (78.74" x 21.26" x 27.56")
		Pass Chamber	606 x 458 x 790 mm (23.86" x 18.03" x 31.10")		
Glove Port Height			1150 mm (45.3")		
Chamber Environment			ISO Class 5 (Grade A)		
Filtration	Prefilter		M6 prefilter with ≥ 60% as per EN 779:2012		
	Chamber Supply	Filter Type	ULPA (U15) with Knife Edge Gel Seal		
		Filter Efficiency	99.9995% at Most Penetrating Particle Size (MPPS) as per EN1822:2009		
	Chamber Exhaust	Filter Type	HEPA (H14) with Gasket Seal and Integral Mesh Guard		
		Filter Efficiency	99.995% at Most Penetrating Particle Size (MPPS) as per EN1822:2009		
Lighting Level			≥ 600 Lux		
Sound Level			≤75 dBA		
Isolator Construction		Internal Chamber Wall	SS 316L		
		Service Housing	SS 304		
		Support Frame	SS 304		
		Main Control Panel (MCP)	In-house SS304 (IP-20)		
		Instrumentation Control Panel (ICP)	In-house SS304 (IP-20)		
		Chamber Glass Outer Door	10 mm (0.39") Tempered Glass		
		Pass Chamber Inner Door	25 mm (0.98") Acrylic		
Isolator Finish		Internal Chamber	≤ 0.4 Ra		
		External Chamber	≤ 0.6 Ra		
		External Service Housing	≤ 0.6 Ra		
Electrical Requirements		220-240V, AC, 50Hz, 1Ø	✓		
		110-120V, AC, 60Hz, 1Ø	✓		
		220-240V, AC, 60Hz, 1Ø	✓		
Compressed Air Requirement (By Client) (If no on-board compressor)		Min 6 Bar - Max 12 Bar, ≥ 200L/min	✓		
Exhaust Duct Requirements (By Client) (Unless Integral Catalytic Convertor is Included)			10" Duct from Isolator to outside		
Shipping Dimension (W x D x H)			2500 x 1100 x 2500 mm (98.4" 43.3" x 98.4")	2800 x 1100 x 2500 mm (110.23" x 43.3" x 98.4")	3250 x 1100 x 2500 mm (128.0 x 43.3 x 98.4)
Shipping Weight			1400 kg (3086.5 lbs)	1600 kg (3527.4 lbs)	1800 kg (3968.3 lbs)

** External height stated is WITHOUT Exhaust Collar. Provision of Exhaust Collar will increase +70 mm (2.8") of total external height*

*** The dimension stated is for 1-Glove Pass Chamber.*

OPTIONS AND ACCESSORIES

BIBO Exhaust Filter Options	Recirculating Airflow	Filter in Rear	With BIBO
		Filter in Bottom	Without BIBO
	Total Exhaust Airflow	Filter in Rear	With BIBO
		Filter in Bottom	Without BIBO
	Recirculating/Total Exhaust Airflow	Filter in Rear	With BIBO
		Filter in Bottom	Without BIBO
Options	Pass Chamber (Size may vary depending on requirements)		
	Biodecontamination System (other brands)		
	Non-viable Particle Counter		
	Viable Air Sampler		
	Sterility Test Pump	Mechanical Integration of Sterility Test Pump includes automatic drain valve, cable access, and test pump cut-out. *(Brand and model is up to client preference)*	
	Liquid Carboy Container - 10L or		
	Integrated Glove Leak Tester		
	Wireless Glove Leak Tester		
	Sterile Continuous Liner		
	Bag Welder with Table		
	RTPØ105, 190, 270, 350, 460 - Alpha		
	RTPØ105, 190, 270, 350, 460 - Beta Canister		
	RTPØ105, 190, 270, 350, 460 - Beta Liner		
	Weighing Scale		
	Spray Gun		
	H_2O_2 Monitoring System		
	Product Waste Entry/Exit Ports		
	Liquid Entry/Exit Ports		
	Integrated Catalytic Converter		
	Mobile Air Compressor		
	IV-bar with Stainless Steel Hooks		
	Stainless Steel Shelves and Racks		
	Stainless Steel Baskets		
	IP-Rated Main Control Panel		
	IPC Control System - Upgrade		
	SCADA Integration		

BUILDING EXHAUST REQUIREMENTS

		GPPI-2G	GPPI-3G	GPPI-4G
Total Exhaust (Single Pass)	Process Chamber	1021 cmh @500 Pa	1363 cmh @800 Pa	1703 cmh @1100 Pa
	Pass chamber	518 cmh @250 Pa		
Recirculating	Process Chamber	510 cmh	680 cmh	850 cmh
	Pass chamber	518 cmh *(Single Pass Mode Only)*		

BioVap™ Biodecontamination System

Esco BioVap™ is an effective hydrogen peroxide-based biodecontamination system capable of achieving a 6-log reduction in bioburden. The Esco BioVap™ system employs a process of atomizing the hydrogen peroxide sterilant creating a dry fog after it is injected into the space. This system creates a charge on the atomized droplets as it pass through the nozzle.

This system is fully integrated as a standard feature of the GPPI. This is Esco's approach to a cost-effective biodecontamination which is a common requirement for all aseptic processes and sterile product handling applications.

Each droplet of the sterilant contains billions of reactive antimicrobials to effect a microbial kill. Through mutual repulsion, the charged droplets repel each other and distribute through the space, and are attracted to the negatively charged surfaces. This causes the droplets to crash and burst onto the surfaces instead of gently settling. This revolutionary biodecontamination system is not affected by temperature or relative humidity therefore there is no pre-conditioning requirement for the chamber before use leading to a reduced cycle.

BioVap Control System

BioVap™ is controlled by the PLC with an operator interface via the same touchscreen HMI of the GPPI. This gives the operator log-on security and real-time display of cycle parameters. This enables BioVap to be fully compliant with 21 CFR Part 11 requirements.

LEVELS OF BIODECONTAMINATION

SANITIZATION
Two log-10^{-2}

DISINFECTION
Five log-10^{-5}

STERILIZATION
Six log-10^{-6}

Specifications	
Air Injection Pressure	4 bar ± 10%
Air Injection Flow rate	32 lpm ± 10%
Injection Time	30 sec - 20 mins
Dwell Time	15 - 45 min
Aeration Time	20 - 90 min
Total Decon Time	30 mins - 2 hr
Sterilant Used in One Cycle	10 - 150 mL
Sterilant Injection Flow Rate	200 - 1000 µL/sec
Sterilant	30% Hydrogen peroxide

** Specifications are highly dependent on the isolator unit specifications such as size, level of customization, Biovap design, etc.*

BioVap™ Biodecontamination System

WIRELESS GLOVE LEAK TESTER (WGLT)

Introduction

The **Esco Wireless Glove Leak Tester (WGLT)** facilitates the detection of any punctures or holes to guarantee the integrity of an isolator's gloves/ sleeves system. This accessory uses the principle the principle of pressure loss and method based on Class 3 Containment as per ISO 10648-2.

The WGLT comprises of two parts:

1. **Hardware** - refers to the wireless glove leak tester and its independent control.
2. **Software** - refers to the application used to remotely control and monitor the glove leak tester. This is generally installed on a Windows-based computer which meets the system requirements.

Quick View

1. Seal Button *2. Control Button and Operation Status (LED light up)* *3. USB Port* *4. Power Button and Battery Status (LED light up)* *5. Charging Port*

For items #2 and #4: The button will light up to showcase the WGLT's running status. Refer to the color legend below the buttons.

Key Features

- Sleek, easy to clean, and low-maintenance design
- FDA-approved inflatable seals
- HDPE glove port disc for increased durability
- Portable and wireless for on-the-go use
- Generates alarm and data logs and can be operated within assigned authority levels
- Remotely connects and controls the unit
- Glove port docking part can be customizable to match any existing glove port size. *(Note: Actual sample of the glove port will be needed for accurate sizing of the WGLT)*

Basic Principles

- Inflatable seals inflate to securely seal the glove
- The compact built-in pump of the glove leak tester injects air into the glove until it reaches the desired pressure
- The glove leak tester then stops the air injection and reads pressure loss within 5 minutes
- The glove leak tester determines whether the glove passes the leak tightness test or not in order to monitor the integrity of the isolator's gloves/sleeves system

SOFTWARE GENERAL SPECIFICATIONS		
Component	**Minimum**	**Recommended**
Processor (CPU)	Intel Core i3 or equivalent	Intel Core i5 or equivalent
Operating System	Microsoft Windows 8 x64, Windows Server 2012 x64	Windows 10 Professional x64
Memory (RAM)	2 GB	8 GB
Network Adapter	Dual-band WiFi-certified 802.11 a/g – compliant adapter	802.11ac Dual Band 2.4g/5g GHz wireless network adapter
Others	.NET Framework 4.6.1, MS Access Database Engine, Crystal Report Runtime *(included in the installer package)* Router that supports IPv4 NAT or IPv6 Drive storage consumption: 34.8 MB	

HARDWARE GENERAL SPECIFICATIONS	
Glove type	Oval Glove
External Dimension	295 mm x 164 mm x 395 mm (11.6" x 6.5" x 15.6")
Net Weight	3.5 kg (7.7 lbs)
Disc size	198 mm x 298 mm (7.8" x 11.7")
Exterior Material	HDPE
Battery	14.8 V, 5 Ah (21700 Li-Ion Battery 4S1P)
Charger	16.8 VDC, 1.8 A; 5 hours charging time from empty to full
Number of Tests	8 full cycle tests
Maximum pump pressure	250 kPa
Pressure Range	0 – 500 Pa
Processor	Single Core ARM 1 GHz
RAM, Runtime memory	512 MB
ROM, Data, and Log Memory	8 GB Flash MicroSD
USB Interface	1 x USB 2.0 Type A

ESCO LIFESCIENCES GROUP NETWORK

42 Locations in 21 Countries All Over the World

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. www.lifesciences.com.

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