

The Premium Solution for Aseptic Drug Compounding



STREAMLINE® COMPOUNDING ISOLATOR

Streamline® Compounding Isolator (SCI) provides an aseptic environment for pharmaceutical preparations. SCI provides an aseptic environment for pharmaceutical preparations. It can be configured to operate in a recirculating or total exhaust air flow scheme.

Also, aside from positive pressure, this particular unit has two negative pressurization classifications, the purposes of which are:

- N1: factory-configured to provide a more negative pressured pass-through chamber (PTC) in accordance with the CETA guideline for testing compounding isolators.
- N2: this unit is intended for powder handling applications, thus, the work chamber (- 37Pa) is more negative than the PTC (- 25Pa).

Overall, the SCI is designed to provide user, product, environment, and cross-contamination protection from exposure to hazards.





Applications

Potent Formulations

Aseptic Compounding

Chemotherapy

TPN Formulation

Contained Powder Handling

Cell Culture

Gene and Cell Therapy

Tissue Engineering

Streamline® Compounding Isolator

Main Features

- Designed in compliance to international cGMP standards.
- Class 3 Leak Tight Containment, as per ISO 10648-2.





ESCO

Safety and Certification

	Design	Cabinet Performance	Air Cleanliness	Electrical Safety
Standard Compliance	USP <797> and <800>, USA NIOSH, OSHA, Designed in compliance to international GMP standards	ISO Class III Leak Tight Containment as per ISO 10648-2, CETA CAG-002-2006	ISO 14644-1 Class 3 (at rest), Class 5 (in operation), EU GMP Grade A, Worldwide JIS B9920, Class 3, Japan BS 5295, Class 1, UK	IEC 61010-1, Worldwide EN 61010-1, Europe UL 61010-1, USA CAN/ CSA-22.2, No. 61010-1





Main Features

- 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, providing ISO Class 5 air cleanliness as per ISO 14644-1.
- Bag-In Bag-Out (BIBO) Exhaust Filter at the top allows for safe and convenient filter change.
- Sentinel™ Gold Microprocessor controller supervises all functions and monitors airflow and pressure in real-time.
- For negative pressure configuration, the work zone and passthrough interchange are under negative pressure to the room to the maintain operator protection in the event of a breach in the isolation system.
- For positive pressure configuration, both the work zone and pass-through chambers are under positive pressure to the room to ensure product protection.
- Robust dual-wall construction. Unique Esco Dynamic Chamber™ plenum surrounds filter seals with negative
- Ergonomically angled front to improve reach and operator comfort.
- Adaptor plate for utilities/accessories (BioVap™/Sharps bin)
- Safe-change cuff rings permit glove changes with zero risk of contaminating the work zone or environment.
 - Sleeves are made of Hypalon material while gloves are determined by user requirements.
- The unit has FDA-grade air-tight seals.
- It has easy to clean work zone without any crevices.
- Options for external material of construction:
 - Electrogalvanized steel with ISOCIDE™ antimicrobial powder coating
 - Full stainless steel 304

It has options to have a sharps disposal system:

- bottom of the work zone
- inside the work zone
- beside the work zone*
- A hydraulic height-adjustable stand is available as an option.
- The unit is equipped with Foot Switch to open the inner doors.



pressured enclosure.







The United States Pharmacopeia (USP) General Chapters <797> and <800> together with the FDA 503B Guidance, states the need for proper documentation of the standard operating procedures (SOPs) surrounding the activities for sterile pharmaceutical preparations.

- Utilizes energy-efficient light-emitting diode (LED) which has higher durability and better lighting quality.
- Connections for particle count probe and viable monitoring.
- Internal chamber of SCI consists of two (2) planes made from single-piece SS 316L with 19 mm radius coved corners.
- Work top with a drain pan at the bottom.
- Electromagnetic interlocking door with timedelayed ingress/egress control to minimize particle entry; assuring work zone sterility during material transfer.
- Unit's external exhaust fan has zero volt relay interlock.

Esco's integration options for a **CCTV** and a **monitor** and **keyboard mount** can easily provide real-time monitoring and recording of personnel activities; meeting the demands of international guidelines.



- front panel with a stainless steel mount
- rear wall of the work zone

Monitor and Keyboard integration:

- access to rear view monitor system
- beside the front panel equipped with a keyboard and mouse



Mobile BioVap™ Biodecontamination System capable of achieving a 6 log reduction in bioburden. This is usually integrated through the adaptor plate at the right-most part of the isolator's inner work zone.

Note: This adaptor plate can be used to house either the sharps bin (SE design), the mobile BioVap™ nozzle, or other retrofitted utilities/accessories.



Adjustable foot rest



Stainless steel turntable



Flexible ducting work



Laboratory cart



Butterfly Valve:

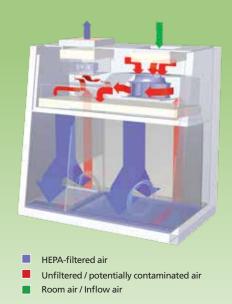
- Manual
- Automatic



AIRFLOW PATTERNS FOR STREAMLINE® COMPOUNDING ISOLATOR MODELS

Recirculating Airflow

- Ambient air is pulled through the inlet pre-filter and main filter located on top of the isolator.
- The downflow filter creates a laminar air flow providing ISO Class 5 air cleanliness (ISO 14644-1) to the main chamber and pass-through, with a down flow velocity of 0.40 m/s +/- 20%.
- Air from the work zone and pass-through is quickly purged out by the exhaust fan to keep the area clean. The fan pulls approximately 90% of the purged air back to the plenum, passes through the HEPA downflow filter again, and is recirculated back to the work zone and pass-through.
- Approximately 10% of the purged air is exhausted through the filter to prevent heat build-up inside the isolator.
- Exhausted air is replenished by ambient air coming from the top inlet prefilter that has 80% efficiency.



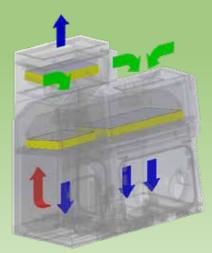
Guide to Streamline® Compo

SCI-3GC8-

Isolator Unit	Model		o. of gloves -		Glove port design	Vo	ltage Code		Pres	
	2G ne®		ominal Width 5 ft (1.6m)	С	Circular glove port (300 mm x 300 mm)	8	220-240 V AC, 50/60Hz, 1Ø	P0	F + Pas:	
Streamline® Compounding Isolator							110-120 V	N1	P - Pass	
		6 ft (1.95m)	0	Oval glove port (200 mm x 300 mm)	9	AC, 50/60Hz, 1Ø	N2	P - Pass -		

Upon ordering, input material of construction at the end of the model code: SCI-2GC_-N1RL-1-SE-SS or -EG

- **▶** SS: Full stainless steel exterior
- **▶** EG: Electrogalvanized steel with ISOCIDE™ coating



- HFPA-filtered ai
- Unfiltered / potentially contaminated air
- Room air / Inflow air

Total Exhaust

- Ambient air is pulled through the inlet pre and main filter via the main fans at the top of the isolator. This creates positive pressure on the plenum which provides the downflow of air with a velocity of $0.40 \text{ m/s} \pm 20\%$.
- -- The pre-filter extends the life of the filters by trapping larger particulates that can easily clog the main filters.
- This downflow supply then provides an ISO Class 5 environment and unidirectional airflow inside the isolator; thus, protecting the materials inside the main chamber and pass-through.
- Air from the work zone and pass-through is then quickly purged by the fans to keep the area clean. The purge is completely exhausted through HEPA filters as well; ensuring that only clean air is exhausted back to the environment.

unding Isolator (SCI) models

N1RL-1-SE

sure	Airflow Scheme		Pass-Through zone		Exhaust Type	Code	Sharps Provision	
ocess zone: : 37 Pa (min) through zone: : 25 Pa (min)	R	Recirculating	L	1 Left	Double HEPA Exhaust (BIBO Top and non- BIBO Bottom)	1	Without	0
ocess zone: 25 Pa (min) through zone: 37 Pa (min)	S	Single Pass			Single Exhaust (Top, non-BIBO)	2	With (inside work zone) 8 qts: 171.45 x 254 x 285.75mm (6.75" x 10" x 11.25")	SI
ocess zone: B7 Pa (min)			R	1 Right	Single Exhaust (Top, BIBO)	3	With (below work zone) 5 gal: 190.50 x 266.70 x 431.80mm (7.5" x 10.50" x 17.0")	SB
through zone: 25 Pa (min)							With (beside work zone) 5 gal: 190.50 x 266.70 x 431.80mm (7.5" x 10.50" x 17.0")*	SE

^{*} The configuration allows for 1 sharps container and 1 stainless steel vesel for other laboratory waste.



GENERAL SPECIFICATIONS SCI-2G -SCI-3G -Streamline® Compounding Isolator Main Chamber Nominal Size (Width) 1.6 meters (5') 1.95 meters (6') 1900 mm x 825 mm x 2535 mm 2205 mm x 825 mm x 2535 mm (74 8" x 32 5" X 99 8") (86 8" x 32 5" X 99 8") 1900 mm x 825 mm x 2385 mm 2205 mm x 825 mm x 2385 mm External (74.8" x 32.5" X 93.9") (86.8" x 32.5" X 93.9") 1645 mm x 825 mm x 2535 mm 1950 mm x 825 mm x 2535 mm $(W \times D \times H)$ (64.8" x 32.5" X 99.8") (76.8" x 32.5" X 99.8") 1645 mm x 825 mm x 2385 mm 1950 mm x 825 mm x 2385 mm (64.8" x 32.5" X 93.9") (76.8" x 32.5" X 93.9") 960 mm x 625 mm x 625mm 1265 mm x 625 mm x 625 mm Main Chamber Work Zone Internal Dimension (W x D x H) (37.8" x 24.6" x 24.6") (49.8" x 24.6" x 24.6") 450 mm x 625 mm x 625 mm 450 mm x 625 mm x 625 mm Pass-through Internal Dimension (W x D x H) (17.7" x 24.6" x 24.6") (17.7" x 24.6" x 24.6") ISO Class 3 (at rest), ISO Class 5 (in operation); Class 1, Work Zone and Interchange Chamber Performance Federal Standard 209E H14 filters with integral metal guards and filter frame gaskets; fully Downflow and Exhaust Filter Type compliant with EN 1822 (H14) and IEST-RP-CC001.3 requirements (each cabinet has individual downflow and exhaust filters) >99.999% for particle size 0.3 micron Typical Filter Efficiency Contact Esco for more information. 190m3 / h (112 cfm) Airflow Volume 27 Pa / 0.10 in H2O Contact Esco for more information. **LED Light Intensity** ≥ 800 lux 1.5 mm (0.06") 16 Gauge Electro-Galvanized Steel with White Oven-Baked Epoxy-Polyester ISOCIDE™ Antimicrobial Powder Coated Finish Isolator 1.5 mm (0.06") 16 gauge stainless steel, type 304, with 4B finish 1.5 mm (0.06") 16 gauge stainless steel, type 316L, with 4B finish Electrical 240-220 V AC, 60/50Hz, 1Ø SCI-2G-SCI-3G-Contact Esco for more information. 10 A Contact Esco for more information. 362 W Contact Esco for more information. 1235 SCI-3G-6A -9.5 A Contact Esco for more information. 5 A Contact Esco for more information. 362 W Contact Esco for more information. 1236 Net Weight Contact Esco for more information. 550 kg (1220 lbs) 392.5 kg (865 lbs) Shipping Weight 620 kg (1370 lbs) 1600 x 990 x 2210 mm 1600 x 990 x 2250 mm Shipping Dimensions, Maximum (W x D x H) (62.6" x 39.0" x 87.0") (86.7" x 37.8" x 88.6") Shipping Volume, Maximum* 3.48 m3 (122.9 cu.ft) 4.75 m3 (167.7 cu. ft) 5170543 5170543 5170225 5170225 Optional 5131175 5131177 Accessories

Note: A 4-glove port (4G) design is possible by combining two units of 2-glove port (2G) isolators interconnected by a vertical non-interlock door; it has pass-through chambers on both sides.

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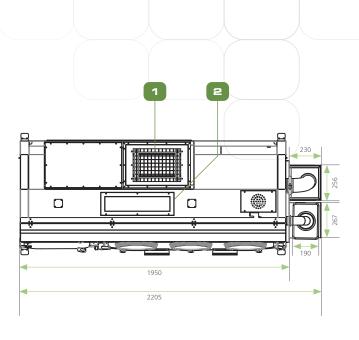
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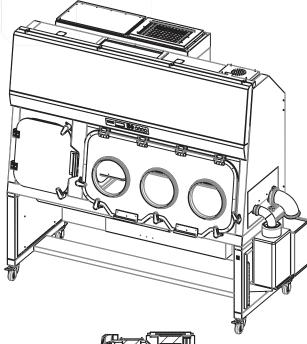
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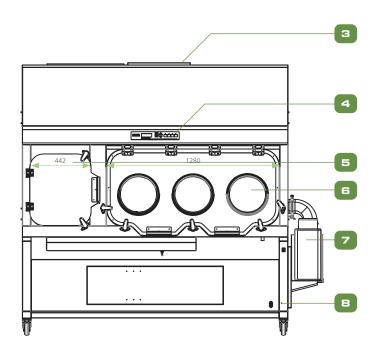
All common surgical gloves can be attached to the cuff rings; thereby, making the system adaptable to operator preference.

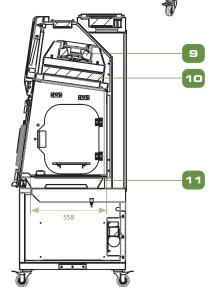
ENGINEERING DRAWING

SCI Recirculating Model (SCI-3GC_-N1RL-1-SE)









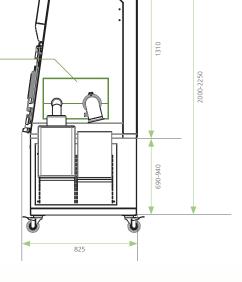


- 2. Air Intake H14 Filter
- 3. Exhaust Collar
- 4. Esco Sentinel™ Gold Microprocessor Controller
- 5. Pass-Through Hinged Outer Door
- 6. Circular Glove Ports
- 7. Sharps Disposal Container
- 8. Hydraulic-Height Adjustable Stand
- 9. Supply Fan
- 10. Supply H14 Filter
- 11. Single-Piece Stainless Steel Work Tray
- 12. Adaptor Plate

Note: Can cater to any of the following:

- sharps disposal (SE option)
- BioVap™ nozzle
- other retrofitted utilities/accessories

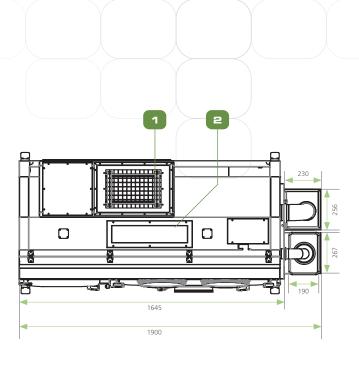
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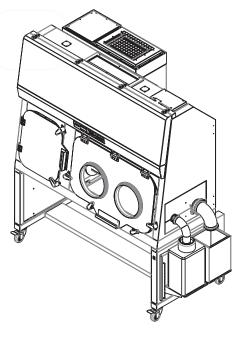


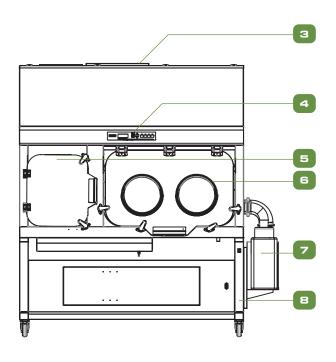


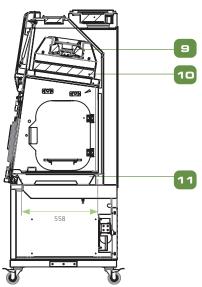
ENGINEERING DRAWING

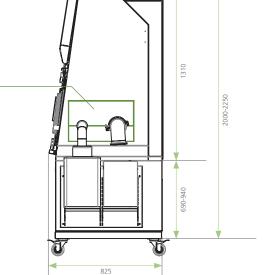
SCI Recirculating Model (SCI-2GC_-N1RL-1-SE)











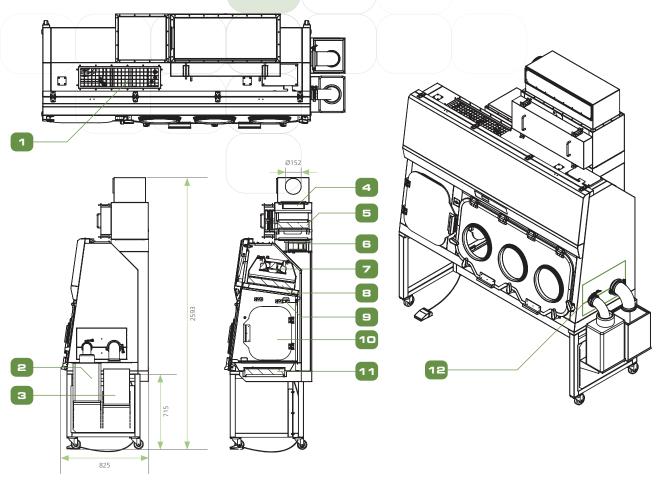
- 1. Exhaust H14 Filter
- 2. Air Intake H14 Filter
- 3. Exhaust Collar
- 4. Esco Sentinel™ Gold Microprocessor Controller
- 5. Pass-Through Hinged Outer Door
- 6. Circular Glove Ports
- 7. Sharps Disposal Container
- 8. Hydraulic-Height Adjustable Stand
- 9. Supply Fan
- 10. Supply H14 Filter
- 11. Single-Piece Stainless Steel Work Tray
- 12. Adaptor Plate

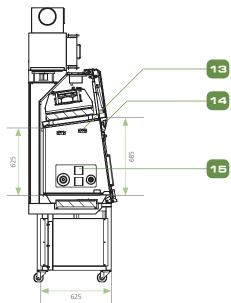
Note: Can cater to any of the following:

- sharps disposal (SE option)
- BioVap™ nozzle
- other retrofitted utilities/accessories

ENGINEERING DRAWING

SCI Total Exhaust Model (SCI-3GC_-N1SL-1-SE)





18 17 21 18 19 24 20 1950

- Air Inlet Pre-Filter
- 2. Sharp Container (Optional)
- Stainless Steel Waste Bin (Optional)
- Carbon Filter (Optional)
- Exhaust H14 Filter, Bag-In Bag-Out (BIBO)
- Exhaust Fan
- Supply Fan

- Supply H14 Filter
- Airflow Sensor
- 10. Pass Chamber Inner Door
- 11. First Exhaust H14 Filter
- 12. Adaptor Plate Note: Can cater to any of the following:
 - sharps disposal (SE option) BioVap™ nozzle
 - other retrofitted utilities/ accessories
- 13. IV Bar (Optional)
- 14. Lighting
- 15. Electrical Outlet (Optional)
- 16. Exhaust Collar
- 17. BIBO Filter Access Cover
- 18. Pass Chamber Outer Door
- 19. Pass Chamber Outer Door Switch
- 20. Footswitch For Inner Door
- 21. Esco Sentinel Control
- 22. Round Glove Ports Ø300mm
- 23. Main Chamber Polycarbonate Window
- 24. Support Stand SPC-6A0 (Optional)



Isolation Technology

Isolation containment systems provide inherently superior sterility compared to open front clean air devices such as laminar flow clean benches and Class II biological safety cabinets. USP <797> guidelines specify that isolators may be situated in an area subject to less severe environmental controls compared with open front clean air devices.

Isolators are an effective solution especially for lower-volume pharmaceutical processes. They reduce operating and renovation costs, take up less space, and are easier to maintain. Positive pressure isolators are designed for non-hazardous aseptic processes, while negative pressure isolators are intended to promote personnel and environment safety during processing of hazardous materials such as antineoplastic or cytotoxic compounds.

 For volatile hazardous drugs, it is recommended to have a negatively pressured, total exhaust isolator. Alternatively, a recirculating isolator with optional exhaust activated carbon filter and/or external ventilation, can be selected.

Maximum Patient Protection and Product Sterility

The combination of downflow and exhaust HEPA filters provides the Esco Streamline® Compounding Isolator, a fully integrated envelope for product and operator protection in all configurations.

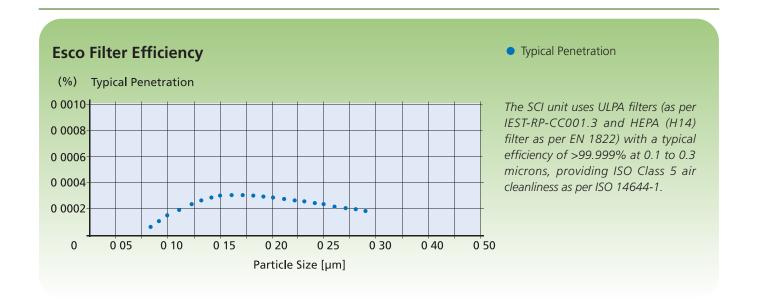
- Advanced mini-pleated supply HEPA filters are tested to >99.999% efficiency for to 0.3 micron particulates; significantly better than conventional filters.
 - An improved mini-pleat separation technique maximizes filter surface area, improves efficiency and extends filter life over conventional separation.
 - The HEPA supply filter provides an ISO Class 5 air in the work surface via a gentle vertical laminar flow.
 - All filters have sampling ports for maintenance services.

Mini-pleat Separatorless Filter (left) vs. Conventional Aluminum Separator Filter (right)



Esco cabinets use Swedish Camfil Farr® mini-pleat filters without aluminum separators to increase filter efficiency, minimize the chance of leakage, and prolong filter life. Filters include a lightweight aluminum frame for structural stability and elimination of swelling common to conventional wood frames.

- Laminar airflow within the work zone and pass-through enables recovery of chamber atmosphere to ISO Class 5 conditions within 3 minutes following a worse-case contamination event. The entire work zone air is changed 20-30 times per minute.
 - Refer to separate information on recovery testing carried out by Esco.
- Optional sharps disposal system enables a smoother work flow while minimizing material transfer to enhance patient protection and product sterility.
 - The interface between sharps disposal bin and isolator is aerosol tight to avoid ingress of contamination during the disposal operation.
- Safe-change cuff rings enable glove change with zero risk of contamination
- The exterior construction of an isolator can either be of full stainless steel or electrogalvanized steel with an ISOCIDE™ antimicrobial powder coating to minimize contamination.
 - Performance results are available upon request.



Fan Efficiency

The Streamline® Compounding Isolator fan system is designed for maximum energy efficiency with minimal maintenance.

- Designed with a centrifugal, direct-drive, and external rotor motors to reduce operating costs
- Unique Esco motor/fan orientations minimize noise and vibration.
- Built-in solid-state variable speed controllers are infinitely adjustable from Off to Maximum



Electrical Outlets and Utility Fittings

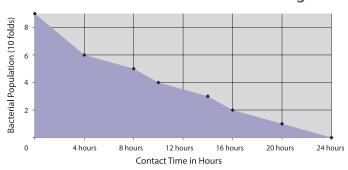
- Electrical outlet, ground Perforated shelf to increase fault, North America
- UV lamp
- IV bar with hooks
- Cleaning accessories
- · Cord pass-through (NSF standard)
- Alarm package
- Thimble exhaust collar
- Duplex and/or GFI outlet

- work zone space
- Storage Bin
- Side Exhaust Connection (for TE units)
- Back-up battery for electromagnetic interlocking doors (Contact Esco for more information)
- Side syringe pass-through chamber

Highlights

- Output 10 VDC, max. 1.1 mA, Tach output, Control input 0-10 VDC.PWM
- Motor current limit, soft start, locked-rotor protection, over temperature protected electronics/motor
- Condensate discharge holes: none, open rotor Ingress protection of IP54
 - Material: Fiberglass reinforced composite
 - Impeller: PA6
 - Direction of rotation: Clockwise, seen on rotor

ISOCIDE™ Antimicrobial Powder-Coating



All exterior painted surfaces are powder-coated with Esco Isocide™, an antimicrobial inhibitor to minimize contamination. Isocide™ is integrated into the coating substrate and cannot wash out or diminish by repeated cleaning. Performance results are available upon request. Contact Esco or your Esco Sales Representative for details

Sentinel™ Microprocessor Control, Monitoring System

The Esco Sentinel™ microprocessor-based control system supervises operation of all cabinet functions. Controls are configurable to meet user requirements.

Enlarged, multi-line digital read-out with alpha-numeric display indicates all input, status and alarm functions.

Work zone, interchange pressures and downflow velocity are continuously measured and displayed. Integrated true airflow sensor is temperature compensated for improved accuracy.

Password-protected administration can be set to restrict access to main menu.

Color coded indicator lamps display green for fan operation; blue for LED lights and electrical outlet; and orange for AUX function ON.

Optional audible and visual alarms warn of unsafe conditions such as low chamber pressure.



- Sentinel Microprocessor Control System, Programmable
- When programmed ON the start-up sequence confirms status with Air Safe and local time display.
 - the Personal Identification Number (PIN) access restricts unauthorized adjustments.

Main Control Panel Features

- Work zone and pass-through pressures are monitored and displayed on the LCD screen
- Continuous monitoring and display of cabinet laminar airflow on large, easy-to-read LCD display.
- An optional alarm package (pressure and airflow) is available for users with more sophisticated requirements.



SAFE GLOVE CHANGE PROCEDURE: REPLACING DISPOSABLE GLOVES

Safe change design system allows glove change at the middle of a process or when the equipment is in operation.





Pull the glove / sleeve outside the work zone. Check the material integrity of the two items.





Pold the fingers of the gloves and move it towards the work zone to ensure containment during replacement procedures.





Remove the outer O-ring from the cuff rings. This elastic ring is used to seal the gloves and sleeves together; preventing operator exposure.





Remove the second O-ring towards the sleeves to easily remove the gloves at a later stage.





Carefully roll the open end of the old glove from the middle groove to the outer groove of the cuff rings. Do not completely remove the glove to prevent exposure risk.





Take the new glove and attach it to the last groove of the cuff ring. Ensure that the thumb is positioned at the top.





Install the O-ring nearest the sleeves over the new gloves. This will tightly fasten the new gloves to the cuff rings while removing the old one.





Verify that the thumb of the new glove is positioned on top.

Afterwards, carefully loosen the old glove from the outer groove.





Place the other O-ring back and position it on the outer groove of the cuff ring. This will fasten the new gloves with the sleeves.





Put back the glove and sleeve into the work zone to properly discard the used glove without contaminating the outside environment.





Working with the adjacent gloved hand, carefully remove the old glove and properly dispose of it inside.





12 The procedure is now complete. Strict compliance to the process guarantees prevention from cross-contamination.

Streamline® Compounding Isolator

SAFE GLOVE CHANGE PROCEDURE: REPLACING THE SLEEVES







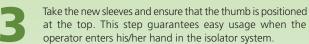


Roll the entire glove and sleeve into the isolator work zone.

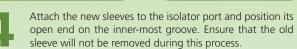
Afterwards, remove the O-ring attaching the sleeves to the glove port.

Carefully roll the open end of the old sleeves form the inner groove to the outer groove of the port. Ensure strict adherence to prevent breach in the isolation technology.



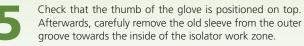














Re-attach the O-rings of the sleeves to the inner groove of the port. This will guarantee that the new sleeve is tightly attached to the port without any risk of operator occupational exposure.





Lastly, with the confirmation that the thumb of the newly attached sleeve is at the top, properly dispose the old sleeve through the isolator work zone. The procedure is now complete.



ESCO GLOBAL NETWORK

42 Locations in 21 Countries All Over the World



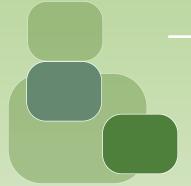


Air Shower
Aseptic Containment Isolator (ACTI)
Ceiling Laminar Airflow Units
Cleanroom Transfer Hatch
Containment Barrier Isolator (CBI)
Downflow Booth (DFB)
Dynamic Floor Laminar Hatch
Dynamic Pass Box
Evidence Drying Cabinet
Garment Storage Cabinet
General Processing Platform Isolator (GPPI)
Laminar 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.escoglobal.com.





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