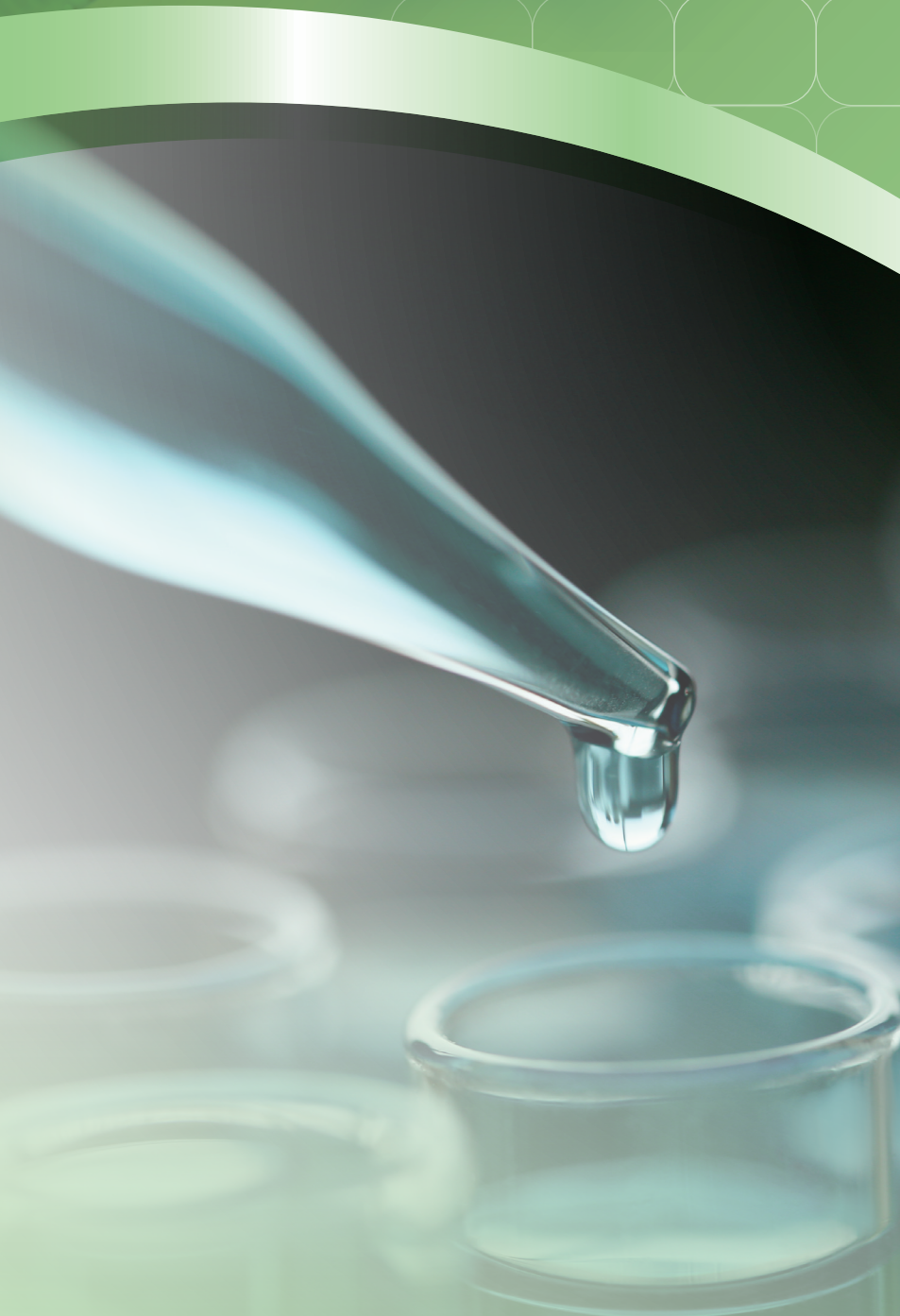


**ESCO**  
Healthcare



# Streamline<sup>®</sup> Compounding Isolator

Compounding Aseptic Containment Isolators  
(Recirculating and Total Exhaust)



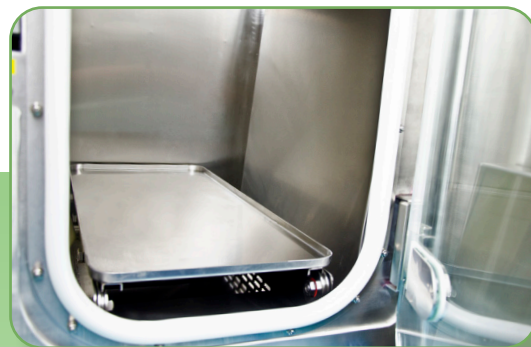
## STREAMLINE® COMPOUNDING ISOLATOR

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



SCI Stainless Steel Recirculating Unit



SCI Electrogalvanized Steel Recirculating Unit

### Applications

Pharmacy Compounding (Hazardous / Non-hazardous)

Potent Formulations

Sterility Testing (Small Scale)

TPN Formulation

Hazardous Drugs Compounding

Contained Powder Handling

Cell Culture

Gene and Cell Therapy

Tissue Engineering

## Main Features

- Class 3 Leak Tight Containment, as per ISO 10648-2.



*SCI Electrogalvanized Steel Total Exhaust Unit*

## Safety and Certification

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



SCI Total Exhaust Unit



SCI Recirculating Unit



### Main Features

- ULPA filters (as per IEST-RP-CC001.3 and HEPA (H14) filter as per EN 1822) with a typical efficiency of >99.995% at Most Penetrating Particle Size (MPPS) 0.1-0.2 µm, 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 maintain operator protection in the event of a breach in the isolation system.
- For positive pressure configuration, both the work zone and passthrough 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 pressure.
- Ergonomically angled front to improve reach and operator comfort.
- Adaptor plate for utilities/accessories (MiniBioAtom/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
- A hydraulic height-adjustable stand is available as an option.
- The unit is equipped with Foot Switch to open the inner doors.
- It has options to have a sharps disposal system:
  - bottom of the work zone
  - beside the work zone\*

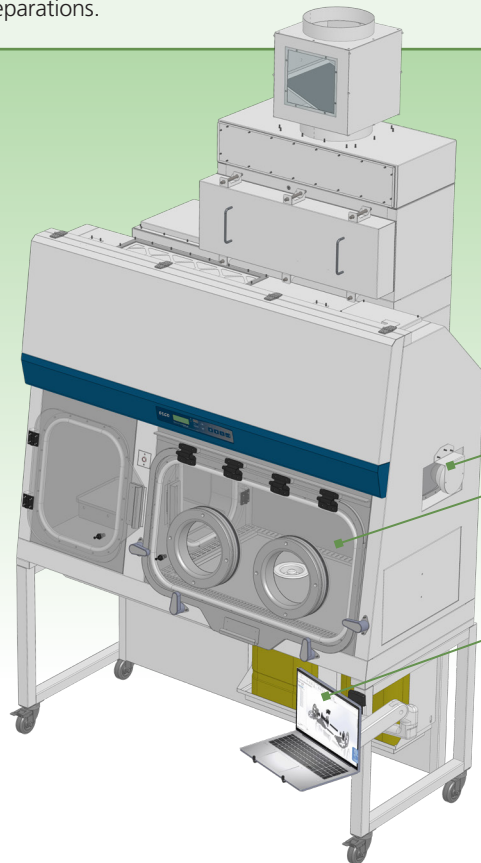


\* Sharps bin for these units (recirculating) can have a negative pressured enclosure.



- Utilizes energy-efficient light-emitting diode (LED) which has higher durability and better lighting quality.
- Internal chamber of SCI consists of two (2) planes made from single-piece SS 316L with 17.5 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.

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.



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.

**CCTV integration:**

- side 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

**MiniBioAtom 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 MiniBioAtom connection, or other retrofitted utilities/accessories.*



**Adjustable foot rest**



**Stainless steel turntable**



**Flexible ducting work**



**Laboratory cart**

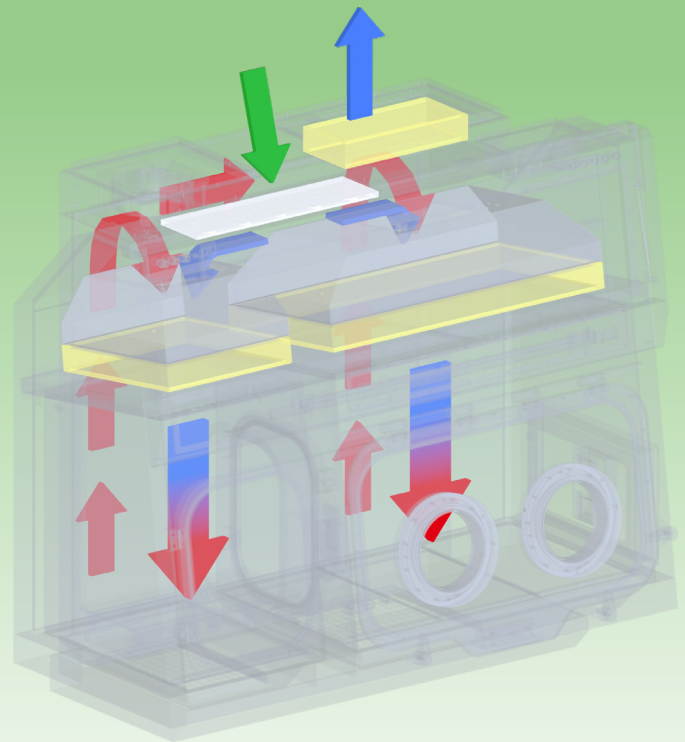


**Granite Slab**  
– SS 316L Frame  
– Leveling Feet

## 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 airflow 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 70% 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 30% 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.



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

### Guide to Streamline® Compo

## SCI-3G8-N1

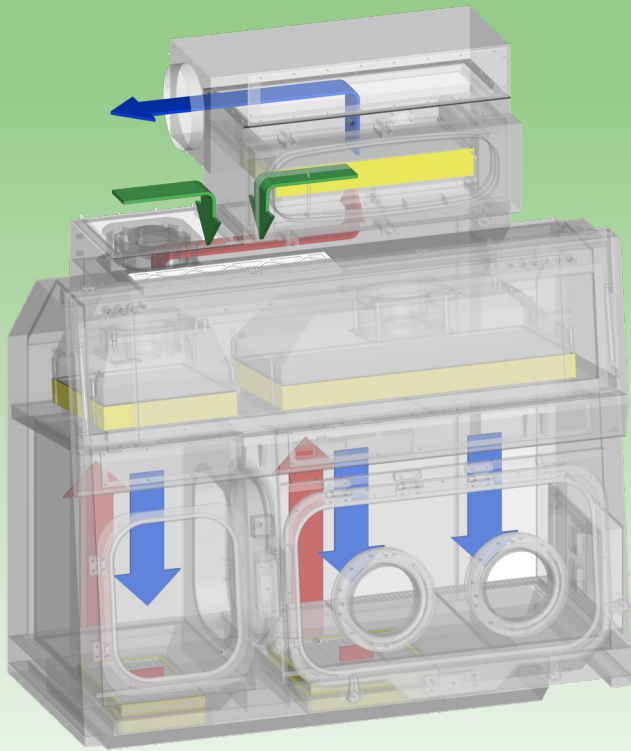
Isolator Unit	Model	No. of gloves - Nominal Width		Voltage Code		Pressure	
Streamline® Compounding Isolator	SCI	2G	5 ft (1.6m)	8	220-240 V AC, 50/60Hz, 1Ø	P0	Process zone: + ≥ 37 Pa (min) Pass-through zone: + ≥ 25 Pa (min)
		3G	6 ft (1.95m)	9	110-120 V AC, 50/60Hz, 1Ø	N1	Process zone: - 25 Pa (min) Pass-through zone: - 37 Pa (min)
						N2	Process zone: - 37 Pa (min) Pass-through zone: - 25 Pa (min)

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

▶ SS: Full stainless steel exterior

▶ EG: Electrogalvanized steel with ISOCIDE™ coating

\* The configuration allows for 1 sharps container and 1 stainless steel vessel for other laboratory waste.



### 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 m/s ± 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.

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

## ounding Isolator (SCI) models

### RL-1-SE-EG

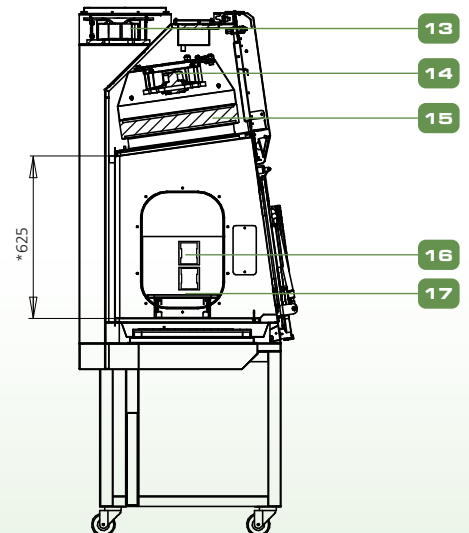
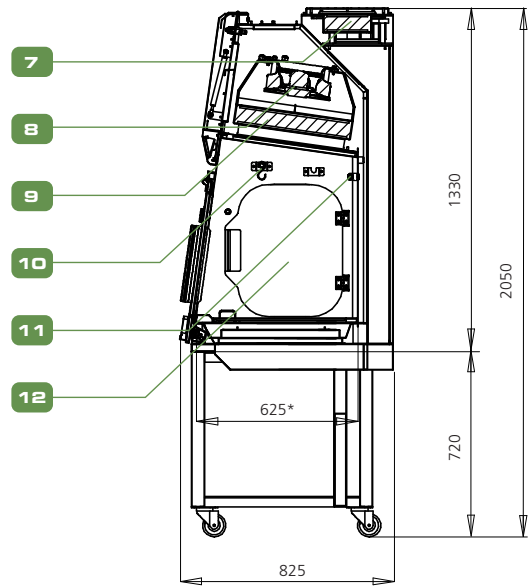
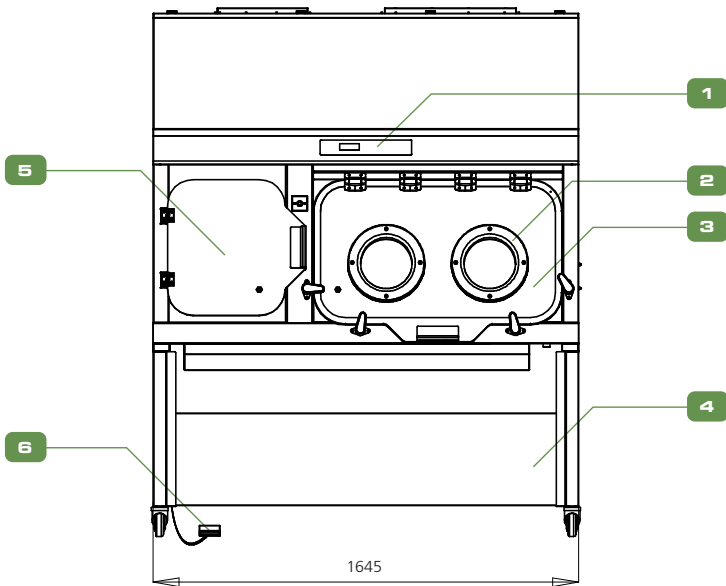
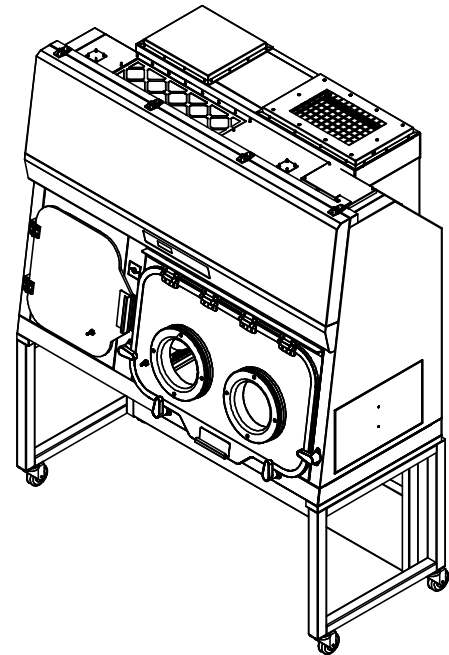
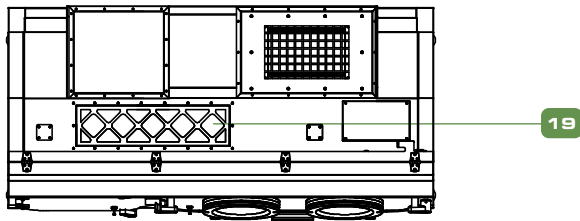
Airflow Scheme		Pass-Through Zone		Exhaust Type	Code	Sharps Provision		External Construction	
R	Recirculating	L	1 Left	Double HEPA Exhaust (BIBO Top and non-BIBO Bottom)	1	Without	0	Electrogalvanized steel	EG
S	Single Pass	R	1 Right	Single Exhaust (Top, non-BIBO)	2	With (below work zone) 5 gal: 190.50 x 266.70 x 431.80mm (7.5" x 10.50" x 17.0")	SB	Stainless steel	SS
				Single Exhaust (Top, BIBO)	3	With (beside work zone) 5 gal: 190.50 x 266.70 x 431.80mm (7.5" x 10.50" x 17.0")*	SE		





# ENGINEERING DRAWING

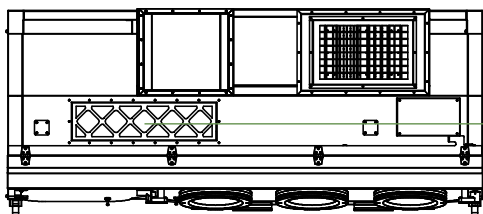
SCI Recirculating Model (SCI-2G\_-P0RL-2-0-SS)



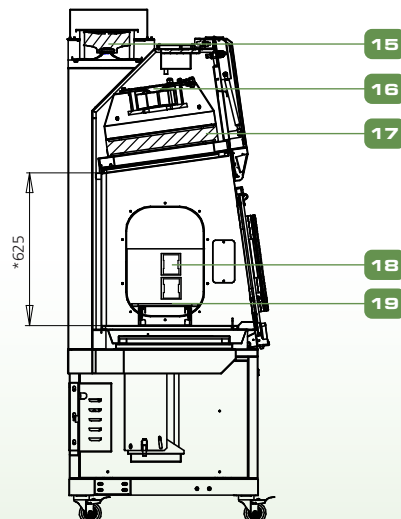
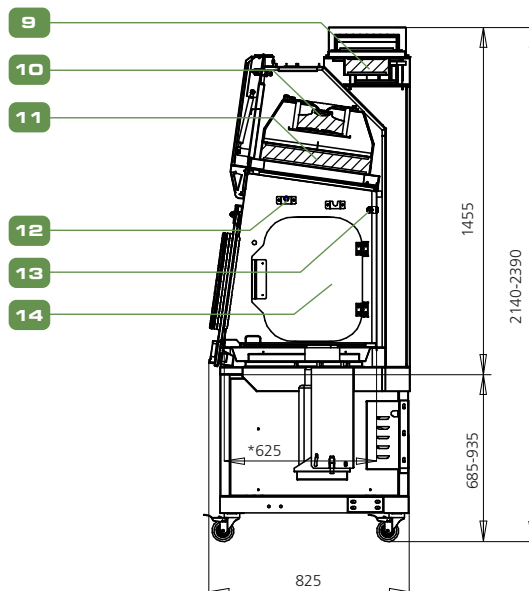
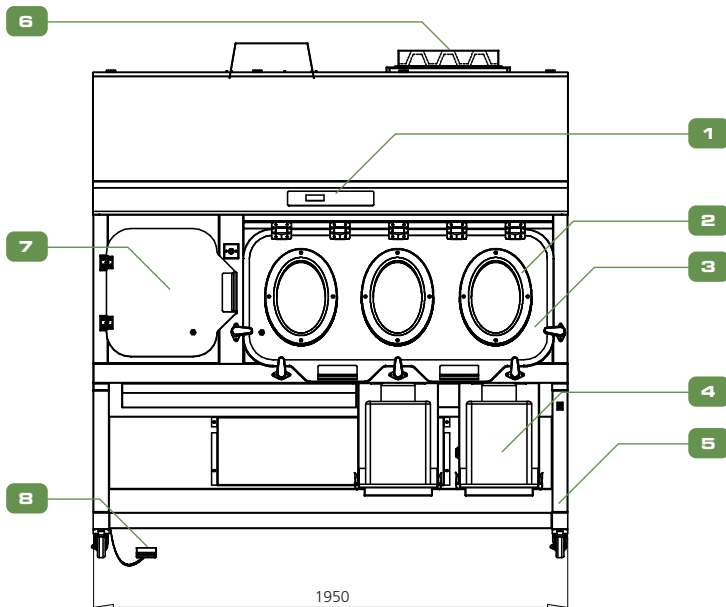
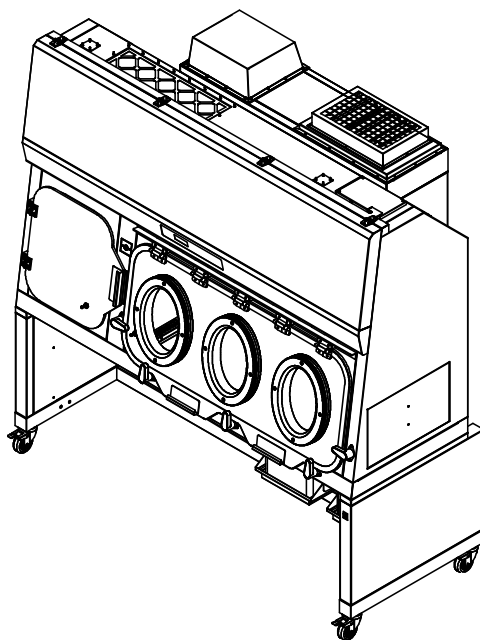
- |  |   |
|--|---|
| 1. Esco Sentinel Microprocessor Control System | 10. IV Bar With Hooks (6pcs)              |
| 2. Circular Glove Ports 200x200mm              | 11. UV Tube 15w                           |
| 3. Main Chamber Polycarbonate Door             | 12. Pass Chamber Polycarbonate Inner Door |
| 4. Support Stand SPC-5A0-S-SS G2               | 13. Exhaust Fan                           |
| 5. Pass Chamber Polycarbonate Outer Door       | 14. Pass Chamber Supply Fan               |
| 6. Inner Door Foot Switch                      | 15. Pass Chamber Supply HEPA H14 Filter   |
| 7. Exhaust Hepa H14 Filter                     | 16. Electrical Outlet Code C              |
| 8. Main Chamber Supply Fan                     | 17. Pass Chamber Sliding Tray             |
| 9. Main Chamber Supply HEPA H14 Filter         | 18. LED Light                             |
|  | 19. G4 Air Inlet Pre-Filter               |

## ENGINEERING DRAWING

SCI Recirculating Model (SCI-3G\_-N1RL-2-SB)



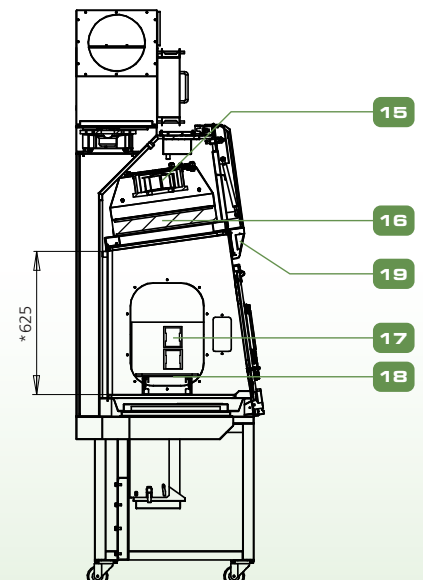
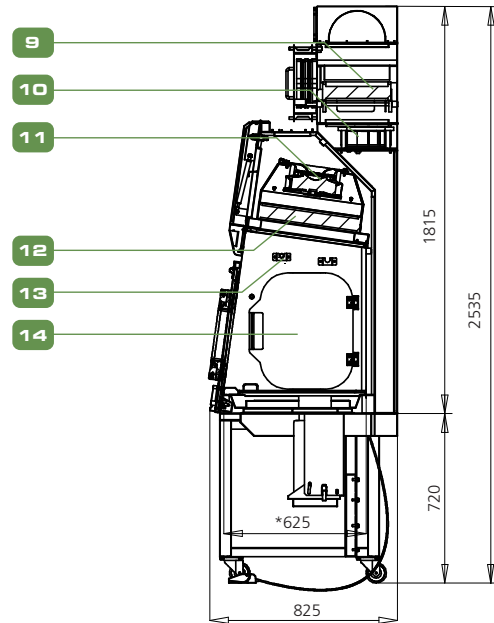
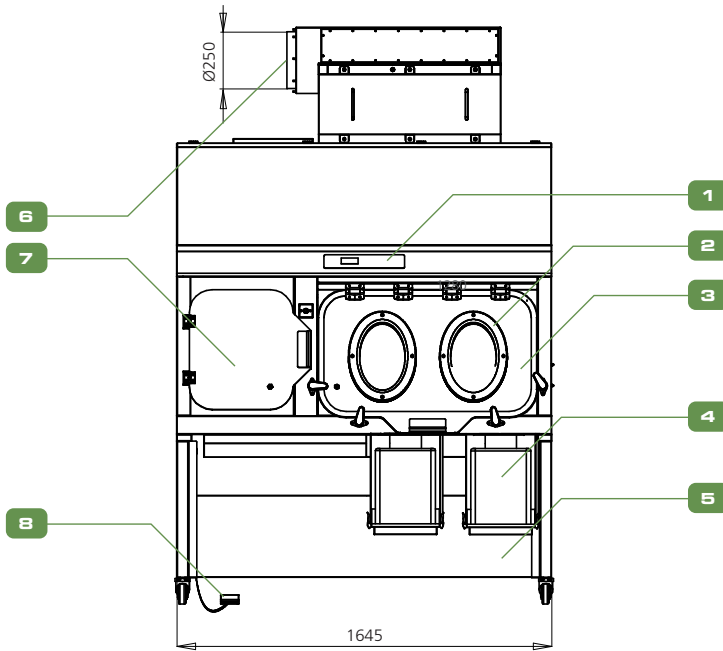
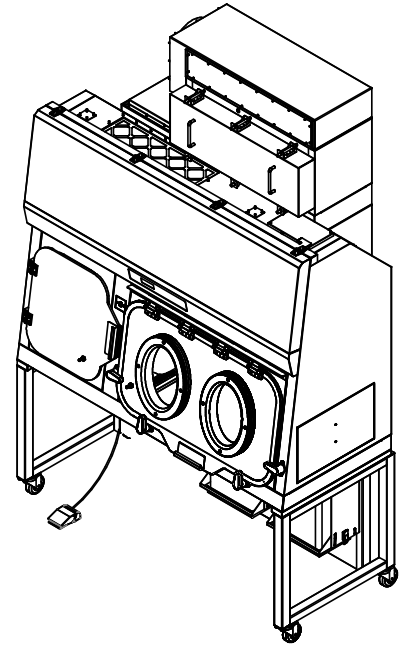
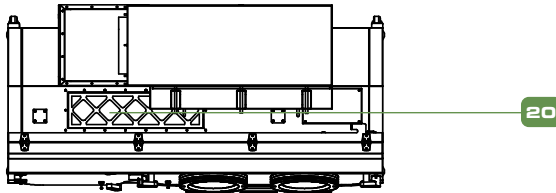
21



- |  |  |
|--|--|
| 1. Esco Sentinel Microprocessor Control System | 11. Supply HEPA Filter                 |
| 2. Oval Glove Ports 200x300mm                  | 12. IV Bar With Hooks                  |
| 3. Main Chamber Polycarbonate Door             | 13. UV Tube 30w                        |
| 4. 2x Sharp Disposal Container                 | 14. Pass Chamber Inner Door            |
| 5. Support Stand Shm-4g8                       | 15. Exhaust Fan                        |
| 6. Exhaust Carbon Filter (Non BIBO)            | 16. Pass Chamber Supply Fan            |
| 7. Pass Chamber Outer Door                     | 17. Pass Chamber Supply HEPA Filter    |
| 8. Inner Door Foot Switch                      | 18. Electrical Outlet (Provision Only) |
| 9. Exhaust HEPA Filter                         | 19. Pass Chamber Sliding Tray          |
| 10. Supply Fan                                 | 20. LED Light                          |
|  | 21. Air Inlet Pre-Filter               |

# ENGINEERING DRAWING

SCI Total Exhaust Model (SCI-2G\_-N2SL-3-SB)



- |  |   |
|--|---|
| 1. Esco Sentinel Microprocessor Control System | 10. Exhaust Fan                           |
| 2. Oval Glove Ports 200x300mm                  | 11. Main Chamber Supply Fan               |
| 3. Main Chamber Polycarbonate Door             | 12. Main Chamber Supply HEPA H14 Filter   |
| 4. Sharp Disposal Container Yellow             | 13. IV Bar With Hooks                     |
| 5. Support Stand SPC-5A0-G2                    | 14. Pass Chamber Polycarbonate Inner Door |
| 6. Exhaust Collar (Left Side Of Unit)          | 15. Pass Chamber Supply Fan               |
| 7. Pass Chamber Polycarbonate Outer Door       | 16. Pass Chamber Supply HEPA H14 Filter   |
| 8. Inner Door Foot Switch                      | 17. Electrical Outlet (Provision Only)    |
| 9. Exhaust HEPA Filter, Bag-In Bag-Out (BIBO)  | 18. Pass Chamber Sliding Tray             |
|  | 19. LED Light                             |
|  | 20. G4-Air Inlet Pre-Filter               |

## 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.

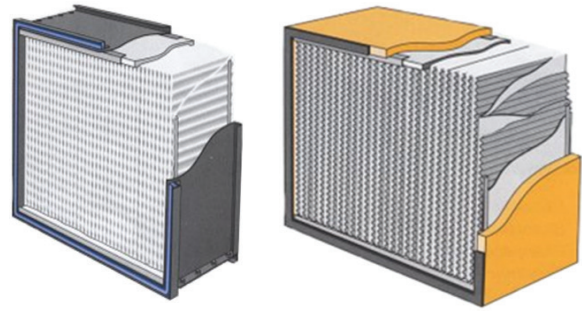
- For volatile hazardous drugs, it is recommended to have a negatively pressured, total exhaust isolator. Alternatively, a recirculating isolator with optional exhaust activated carbon filter and/or external ventilation, can be selected.

## 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 >99.995% efficiency at 0.1-0.2  $\mu\text{m}$ ; 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.
- Laminar airflow within the work zone and pass-through enables recovery of chamber atmosphere to ISO Class 5 conditions within 3 minutes following a worst-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.

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

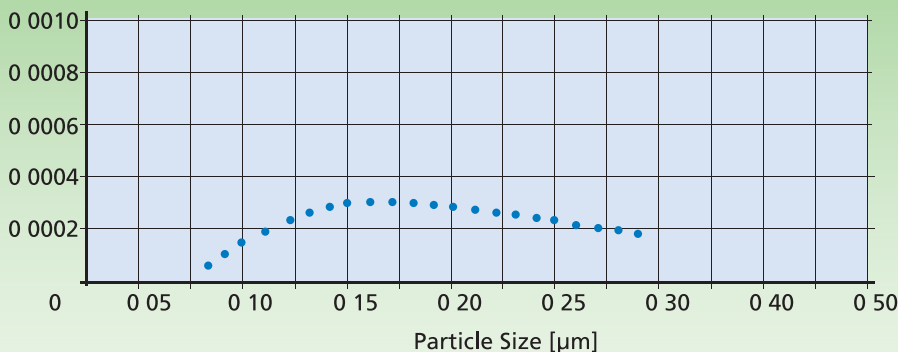


Esco cabinets use Swedish Camfil Farr® mini-pleat filters without aluminum separators to increase filter efficiency, minimize the chance of leakage, and prolong filter life. Filters include a lightweight aluminum frame for structural stability and elimination of swelling common to conventional wood frames.

- 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.

## Esco Filter Efficiency

(%) Typical Penetration



● Typical Penetration

The SCI unit uses ULPA filters (as per IEST-RP-CC001.3 and HEPA (H14) filter as per EN 1822) with a typical efficiency of >99.995% at 0.1-0.2  $\mu\text{m}$ , providing ISO Class 5 air cleanliness as per ISO 14644-1.

## 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

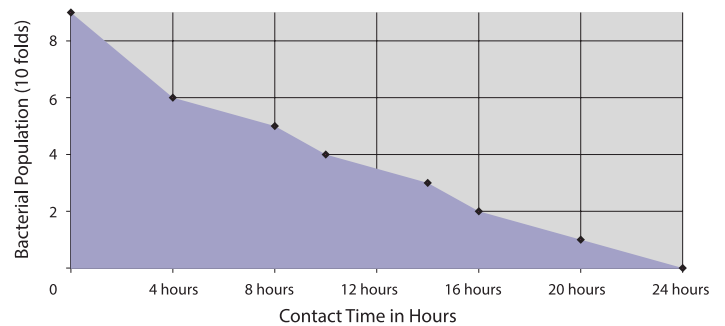
## Highlights

- 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

## Accessories

- Electrical outlet, ground fault, North America
- UV lamp
- IV bar with hooks
- Alarm package
- Exhaust collar
- Duplex and/or GFI outlet
- Perforated shelf to increase work zone space
- Storage Bin
- Side Exhaust Connection (for TE units)
- Back-up battery for electromagnetic interlocking doors (*Contact Esco for more information*)
- Manual Latches
- Granite Slab
- Anti Blowback Valve
- Damper

## 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.

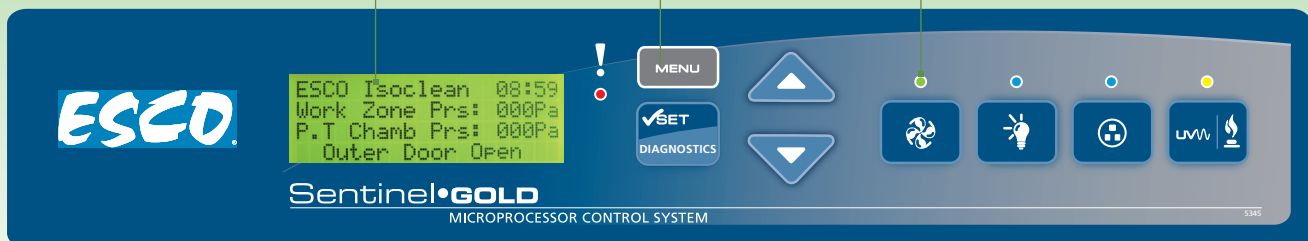
Enlarged, multi-line digital read-out with alpha-numeric display indicates all input, status and alarm functions.

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

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

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

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.



1. Pull the Glove/Sleeve outside the isolator.



2. Fold the fingers of the glove inside the cuff ring.



3. Remove the outer ring.



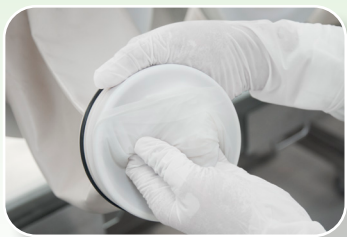
4. Carefully roll the gloves from the middle groove to the outer groove.



5. Take the new glove and ensure the thumb is at the top. Stretch the ring of the new glove over the port and over the old glove onto the middle groove.



6. Install the ring up to the middle groove.



7. Carefully loosen the old glove from the outer groove.



8. Put the glove/sleeve inside the isolator.



9. Working with one hand in the adjacent glove, carefully pull the old glove.



10. The procedure is now complete.

## SAFE GLOVE CHANGE PROCEDURE: REPLACING THE SLEEVES



1. Remove the screws that secure the glove port cover



2. Remove the outer glove port cover



3. Remove the "O" ring



4. Carefully roll the ring of the sleeves/gloves from the inner groove to the outer groove of the port



5. Ensure that the old sleeves/gloves is inside the isolator



6. Take the new sleeves and ensure the thumb is at the top and stretch the "O" ring of the new sleeves over the port and over the old sleeves into the inner groove



7. Replace the "O" ring into the outer groove of the glove port



8. Working with one hand in the adjacent sleeves, carefully work from the outer ring and into the isolator. The old sleeves needs to be remove while under the new sleeves



9. Return the glove port outer cover.



10. Secure the port cover with the screws. The procedure is now complete

# 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](http://www.lifesciences.com).

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