

Streamline[®] Compounding Isolator

Compounding Aseptic Containment Isolators (Recirculating and Total Exhaust/Single Pass)

SCI-2G8-N1RL-1-0-EG

ESCO

SCI-3G8-N1SL-1-0-SS

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 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 passthrough 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 (minimum negative -37 Pa) is more negative than the PTC (minimum negative -25 Pa).

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

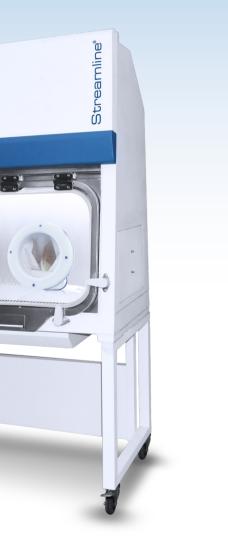






Main Features

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





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

Streamline® Compounding Isolator • Compounding Aseptic Containment Isolators







ESCO

Main Features

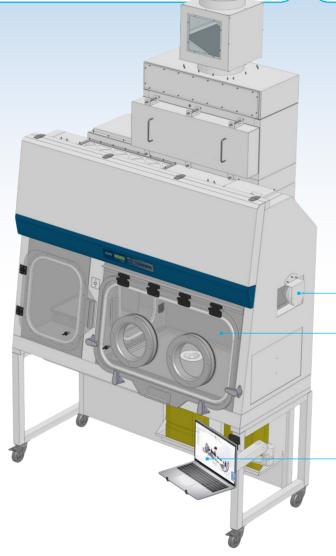
- ULPA filters (as per IEST-RP-CC001.3 and HEPA (H14) filter as per EN 1822) with a typical efficiency of >99.995% at Most Penetrating Particle Size (MPPS) 0.1-0.3 μm, providing ISO Class 5 air cleanliness as per ISO 14644-1.
- For SCI with Exhaust Type 1 and 3, Bag-In Bag-Out (BIBO) Exhaust Filter at 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 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 such as: Sharps Bin Beside the Work Zone, Service Fixtures, Electrical Outlets, etc.
- 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 static/compression 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







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.
- 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.
- Optional connectivity for external exhaust fan with 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.

CCTV integration:

- 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



Adjustable foot rest



IV bar with hooks



ссти



Audio-Visual Alarm Package for Sentinel Microprocessor Controller



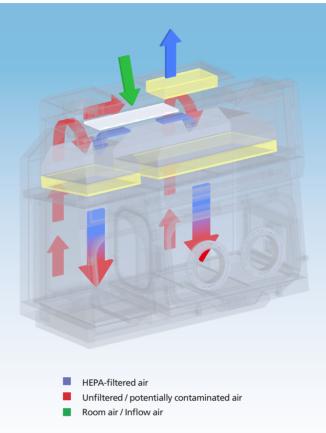
Granite Slab

- SS 316 Frame
- Leveling Feet

AIRFLOW PATTERNS FOR STREAMLINE® COMPOUNDING ISOLATOR MODELS

Recirculating Airflow

- Ambient air is pulled through the inlet pre-filter G4 and supply 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 pre-filter G4 that has 80% efficiency.



Guide to Streamline® Compour

SCI-3G8-N1R

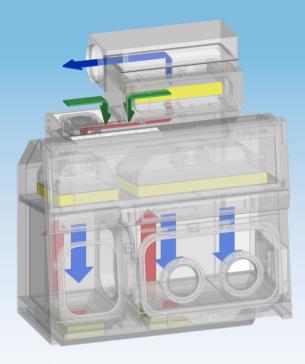
Isolator Unit	Model	No. of gloves - Nominal Width		Voltage Code		Pressure		
		2G	5 ft (1.6m)	8	220-240 V AC, 50/60Hz, 1Ø	PO	Process zone: + ≥ 37 Pa (min) Pass-through zone: + ≥ 25 Pa (min)	
Streamline® Compounding Isolator	SCI	3G	6 ft (1.95m)	9	110-120 V	N1 N2	Process zone: - 25 Pa (min) Pass-through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





Total Exhaust/Single Pass

- Ambient air is pulled through the inlet pre-filter G4 and supply 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 \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.

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

pounding Isolator (SCI) models

N1RL-1-SE-SS

Airfl	ow Scheme		-Through zone	Exhaust Type	Code	Sharps Provision		External Constru	ction
R	Recirculating	L	1 Left	Double HEPA Exhaust (BIBO Top and non- BIBO Bottom)	1	Without	0	Electrogalvanized steel	EG
S	Total Exhaust/ Single Pass			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
		R	1 Right	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		

reamline® Comp	PECIFICA oounding Isola		SCI-26	sci-36			
t Nominal Size (Width)			1645 mm (5')	1950 mm (6')			
		Without stand	1645 x 825 x 1330 mm (64.76 x 33.27 x 52.36")	1950 x 825 x 1330 mm (76.77 x 33.27 x 52.36")			
		With SPC-A/ SPL-A (720mm, 28")	1645 x 825 x 2050 mm (64.76 x 33.27 x 80.71")	1950 x 825 x 2050 mm (76.77 x 33.27 x 80.71")			
	Exhaust Type - 2 (Single Exhaust, Top, Non-BIBO)	With SPC-B/ SPL-B (860mm, 34")	1645 x 825 x 2190 mm (64.76 x 33.27 x 86.22")	1950 x 825 x 2190 mm (76.77 x 33.27 x 86.22")			
		With STL (660 to 960 mm)	1645 x 825 x 1990 to 2290 mm (64.76 x 33.27 x 78.35 to 90.16")	1950 x 825 x 1990 to 2290 mm (76.77 x 33.27 x 78.35 to 90			
External Dimension (W x D x H)		With SHM (685 to 935 mm)	1645 x 825 x 2015 to 2265 mm (64.76 x 33.27 x 79.33 to 89.20")	1950 x 825 x 2015 to 2265 mm (76.77 x 33.27 x 79.33 to 89			
(W X D X H) with 1 left pass chamber*		Without stand	1645 x 825 x 1650 mm (64.76 x 33.27 x 64.57")	1950 x 825 x 1650 (76.77 x 33.27 x 64.57")			
	Exhaust Type - 1 (Double Exhaust, Top BIBO,	With SPC-A/ SPL-A (720mm, 28")	1645 x 825 x 2370 mm (64.76 x 33.27 x 92.91")	1950 x 825 x 2370 mm (76.77 x 33.27 x 92.91")			
	Below Non-BIBO)**	With SPC-B/ SPL-B (860mm, 34")	1645 x 825 x 2510 mm (64.76 x 33.27 x 98.43")	1950 x 825 x 2510 mm (76.77 x 33.27 x 98.43")			
	Exhaust Type -3 (Single Exhaust, Top BIBO)**	With STL (660 to 960 mm)	1645 x 825 x 2310 to 2610 mm (64.76 x 33.27 x 90.55 to 102.36")	1950 x 825 x 2310 to 2610 mm (76.77 x 33.27 x 90.55 to 10			
		With SHM (685 to 935 mm)	1645 x 825 x 2335 to 2580 mm (64.76 x 33.27 x 91.54 to 101.18")	1950 x 825 x 2335 to 2580 mm (76.77 x 33.27 x 91.54 to 10			
ess Chamber Internal Dimensio	on (W x D x H)		960 x 625 x 625 mm (37.80 x 24.61 x 24.61")	1265 x 625 x 625 mm (49.80 x 24.61 x 24.61")			
Chamber Internal Dimension ((W x D x H)		450 x 625 x 625 mm (17.72 x 24.61 x 24.61")			
		Inner Door		(12.40 x 17.52")			
Chamber Opening Dimension H)		Outer Door	355 x 445 mm (13.98 x 17.52")				
Chamber and Process Chambe	er Door Material		355 X 445 mm (13.98 X 17.52°) Polycarbonate				
w Regime				ng or Total Exhaust/Single Pass			
surization				tive or Negative Pressure			
Port Diameter				(Circular)			
Port Quantity			2	3			
ber Environment				:hambers (Grade A)			
ess Chamber Downflow Velocity	y			n/s (1.31 fps)			
ilter				ester fiber media			
nflow and Exhaust Filter Type			HEPA (H14) Filter with Integral Metal Guards and Filter Frame Gaskets; Fully Compliant With EN 1822 (H14) and IEST-RPCC001.3 Requirements				
Efficiency			>99.995% for particle 0.1-0.3 i	nicrons (MPPS, as per EN1822)			
ing Level) Lux			
d Level			≤ 67 dBA				
			1.2 mm (0.05") 18 gauge electro-galvanized steel with white oven-baked epoxy-polyester antimicrobia				
		Main Body		ish"			
tor Construction		Work Tray	1.5 mm (0.06") 16 gauge stainle	ss steel, type 316L, with 4B finish			
	Side Walls		1.2 mm (0.05") 18 gauge stainle	ss steel, type 316L, with 4B finish			
		220-240V, AC, 50 Hz, 1Ø	SCI-2G8	SCI-3G8			
		Cabinet Full Load Amps (FLA)	10 A	11 A			
		Optional Outlets FLA	5 A	5 A			
		Cabinet Nominal Power	238 W, 1.5 A	333 W, 2.3 A			
		Cabinet BTU	812 BTU/hr	1136 BTU/hr			
rical		110-120V, AC, 50 Hz, 1Ø	SCI-2G9	SCI-3G9			
		Cabinet Full Load Amps (FLA)					
		Optional Outlets FLA					
		Cabinet Nominal Power	Contact Esco for more details				
		Cabinet BTU					
		Carbon Filter	Contact Esco f	or more details			
		CCTV Provision		0046			
		Drain		or more details			
		Electrical Outlet	Contact Esco for more details				
		Alarm package					
			5170227				
		Pre-filter, G4					
		Glove Leak Tester - Circular		0311 / With Mobile Compressor: 5180312			
ns		IV Bar with SS hooks	5170930	5170931			
		UV Lamp	5170251	5170255			
		Rear View Screen Adaptation	5180033				
		Anti-blow Back Valve (ABBV)	EG-Steel: 5170352 / Stainless Steel: 5170354				
		Additional Manual Latches	5180038				
		Top Exhaust Collar	EG-Steel: 5171251 / Stainless Steel: 5171253				
	Side Exhaust Collar		EG-Steel: 5171252 / Stainless Steel: 5171254				
		Automate d Deservice Under Telet	With client-supplied compressed air: 5180031 / With Mobile Compressor: 5180032				
		Automated Pressure Hold Test					
		Sharps Disposal Container, 18.7 L	Positive pressure: 5170223 /	Negative pressure: 5170224			
ing Weight			Positive pressure: 5170223 / 500 kg (1102.31 lbs)	Negative pressure: 5170224 700 kg (1543.68 lbs)			

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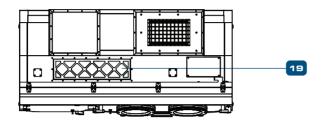
Note: *All common surgical gloves can be attached to the cuff rings; thereby, making the system adaptable to operator preference. *No different of height for the unit with and without sharps bin disposal below the workzone *To add ABBV, please add +420mm for the overall height *For Exhaust Type-2, to add Exhaust Carbon Filter, please add +65 mm for the overall height

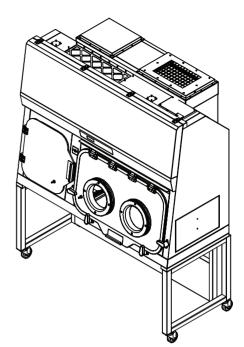
** For Exhaust Type-1 and 3, the standard base unit will need to be connected to ducting.

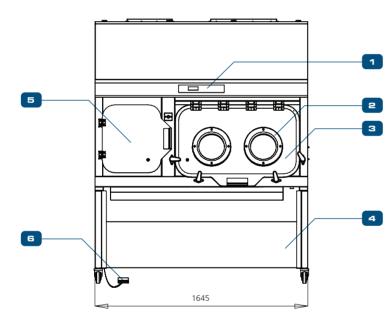


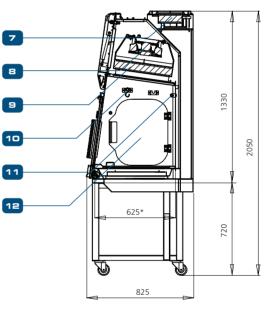
ENGINEERING DRAWING

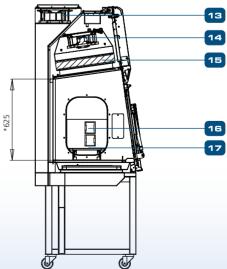
SCI Recirculating Model (SCI-2G8-N1RL-2-0-SS)









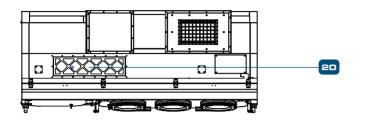


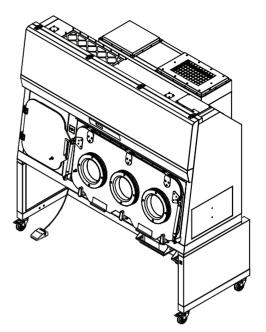
- 1. Esco Sentinel Microprocessor Control System
- 2. Circular Glove Ports 200x200mm
- З. Main Chamber Polycarbonate Door
- 4. Support Stand SPC-5A0-S-SS G2
- 5. Pass Chamber Polycarbonate Outer Door 15. Pass Chamber Supply HEPA H14 Filter
- 6. Inner Door Foot Switch
- 7. Exhaust HEPA H14 Filter
- 8. Main Chamber Supply Fan
- 9. Main Chamber Supply HEPA H14 Filter 19. G4 Air Inlet Pre-Filter
- 10. IV Bar With Hooks (6pcs)

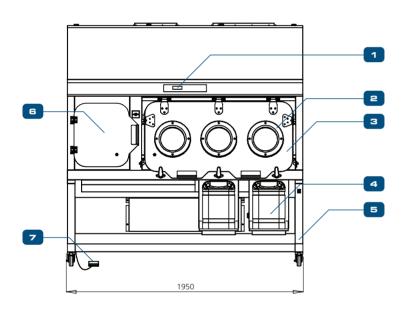
- 11. UV Tube 15w 12. Pass Chamber Polycarbonate Inner Door
- 13. Exhaust Fan
- 14. Pass Chamber Supply Fan
- 16. Electrical Outlet Code C
- 17. Pass Chamber Sliding Tray
- 18. LED Light

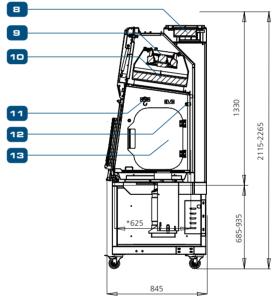
ENGINEERING DRAWING

SCI Recirculating Model (SCI-3G8-P0RL-2-SE-SS)









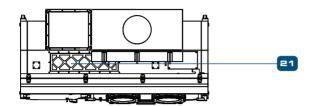
- 1. Esco Sentinel Microprocessor Control System 11. IV Bar With Hooks (6pcs)
- 2. Circular Glove Ports 200x200mm
- 3. Main Chamber Glass Door
- 4. Sharp Disposal Container (Red)
- 5. Motorized Hyd S/Stand Sh
- 6. Pass Chamber Glass Outer Door
- 7. Inner Door Foot Switch
- 8. Exhaust HEPA H14 Filter
- 9. Main Chamber Supply Fan
- 9.
 Main Chamber Supply Fan
 19.
 Pass Chamber Sliding

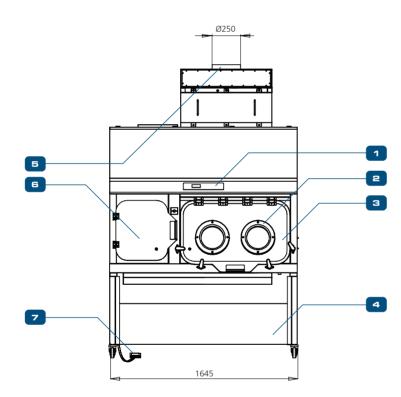
 10.
 Main Chamber Supply HEPA H14 Filter
 20.
 G4 Air Inlet Pre-Filter
- 12. UV Tube 30w
 - 13. Pass Chamber Glass Inner Door
 - 14. LED Light
 - 15. Exhaust Fan
 - 16. Pass Chamber Supply Fan
- 17. Pass Chamber Supply HEPA H14 Filter
- 18. Electrical Outlet Code C
- 19. Pass Chamber Sliding Tray

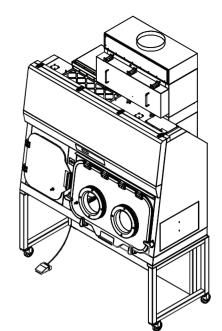


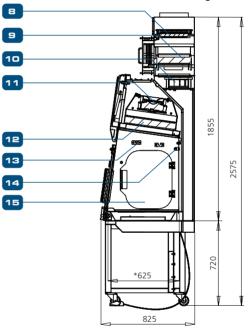
ENGINEERING DRAWING

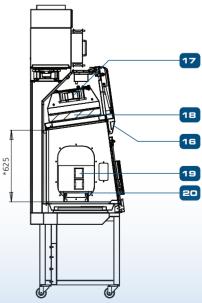
SCI Total Exhaust Model (SCI-2G8-N2SL-1-0-EG)











- 1. Esco Sentinel Microprocessor Control System 12. Main Chamber Supply HEPA H14 Filter
- 2. Circular Glove Ports 200x200mm
- 3. Main Chamber Polycarbonate Door
- 4. Support Stand SPC-5A0-S-G2
- 5. Exhaust Collar (Top of unit)
- Pass Chamber Polycarbonate Outer Door 6.
- 7. Inner Door Foot Switch
- 8. Exhaust Carbon Filter
- 9. Exhaust HEPA Filter, Bag-In Bag-Out (BIBO)
- 10. Exhaust Fan
- 11. Main Chamber Supply Fan

- 13. IV Bar With Hooks 6pcs
- 14. UV Tube 15w
- 15. Pass Chamber Polycarbonate Inner Door
- 16. LED Light
- 17. Pass Chamber Supply Fan
- 18. Pass Chamber Supply HEPA H14 Filter
- 19. Electrical Outlet (Provision Only)
- 20. Pass Chamber Sliding Tray
 - 21. 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.

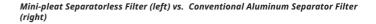
Isolators are an effective solution especially for lower-volume pharmaceutical processes. They reduce operating and renovation costs, take up less space, and are easier to maintain. Positive pressure isolators are designed for non-hazardous aseptic processes, while negative pressure isolators are intended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

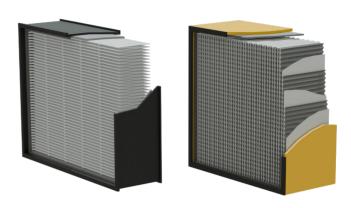
• For volatile hazardous drugs, it is recommended to have a negatively pressured, total exhaust isolator. Alternatively, a recirculating isolator with optional exhaust activated carbon filter and/or external ventilation, can be selected.

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.

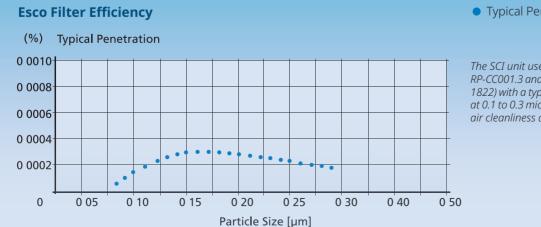
- Advanced mini-pleated supply HEPA filters are tested to >99.995% efficiency for to 0.3 micron particulates; significantly better than conventional filters.
 - An improved mini-pleat separation technique maximizes filter surface area, improves efficiency and extends filter life over conventional separation.
 - 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 filter integrity testing during gualification.
- 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.





Esco cabinets use Swedish Camfil Farr® mini-pleat filters without aluminum separators Filters include a lightweight aluminum frame for structural stability and elimination of the structural stabil 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.



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 to 0.3 microns, 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

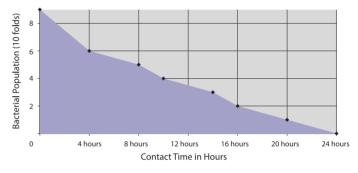


Electrical Outlets and Utility Fittings

- Electrical outlet, ground fault, North America
- UV lamp
- IV bar with hooks
- Latches
- Damper
- Alarm package
- Exhaust Collar
- Duplex and/or GFI outlet
- Perforated shelf to increase work zone space

- Sharps bin container
- Side exhaust connection (for Exhaust Type 1 and 3)
- Back-up battery for electromagnetic interlocking doors (Contact Esco for more information)
- Granite Slab
- Anti Blowback Valve

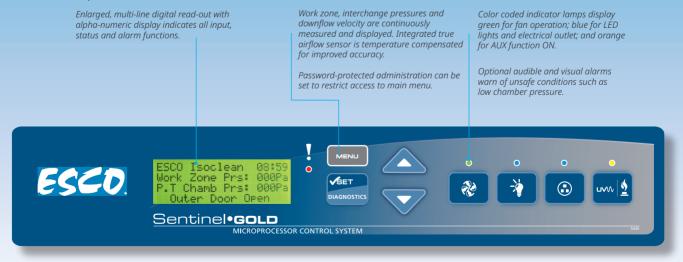
ISOCIDE[™] Antimicrobial Powder-Coating



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.



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 Ghange 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.



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



10. The procedure is now complete.



Safe Sleeve 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





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