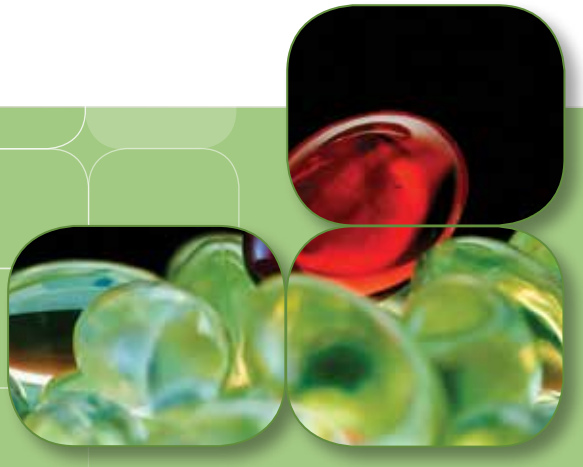
Esco Streamline® Closed Restricted Access Barrier System

Model SLC-RABS-4ON1-S

Streamline®

Closed - Restricted Access Barrier System (Recirculating)

Ensuring Sterility for High Quality Compounding



ESCO® PHARMA

Available in 1.2 and 1.8 meters models (4' and 6'). Esco Streamline® Closed Restricted Access Barrier System (Recirculating), Model SLC-RABS-4ON is shown with optional sharps disposal system and optional hydraulic height adjustable stand.

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 0.1 to 0.3 microns, providing ISO Class 5 air cleanliness as per ISO 14644-1.
- Sentinel™ Gold Microprocessor controller supervises all functions and monitors airflow and pressures in real-time.
- For negatively pressured RABS, the work zone and pass-through chambers are under negative pressure to the room to maintain operator protection in the event of a breach in the system.
- Positively pressured configurations are under positive pressure to the room to ensure product protection.
- Robust dual-wall construction. The work zone is surrounded by negative pressure plenums at the sides and back. Unique Esco Dynamic Chamber™ plenum surrounds filter seals with negative pressure.
- Ergonomically angled front and oval gloveports improve reach and comfort.
- Safe-change cuff rings permit glove changing with zero risk of contaminating the work zone and/or pharmacy environment.
- Easy to clean one-piece work zone liner without any crevices.
- Esco ISOCIDE™ antimicrobial coating on all painted surfaces to minimize contamination.
- Sharps disposal system and hydraulic heightadjustable stand are available as options.
- Instant-start 5000k LED lamps operate on electronic ballasts for energy efficiency.

Streamline® Closed - Restricted Access Barrier System

SLC-RABS-4CN3-S

Unit	Model	Nominal Width		Glove Port Design*		Pressure Scheme		Electrical Code		Sharps Provision	
Streamline® Closed - Restricted Access Barrier System	SLC-RABS	4	4 ft (1.2 m)	C	Circular glove port (300 mm x 300 mm)	N	Negative	1	220-240 V, AC, 50 Hz, 1Ø	0	No
								2	110-120 V, AC, 50 Hz, 1Ø		
		6	6 ft (1.8 m)	O	Oval glove port (200 mm x 300 mm)	P	Positive	3	220-240 V, AC, 60 Hz, 1Ø	S	Yes

**Please note: Customer can also opt to choose a circular glove port, but if not indicated in the Purchase Order, the default is a standard oval glove port.*

Vertical Pass-through Door

The vertical pass-through door prevents ingress of contamination into the work zone during transfer procedures. The built-in electrical interlock prevents both doors from being opened at the same time.

Horizontal Tray

The horizontal tray prevents operator fatigue during transfer procedures.

Optional Sharps Disposal System

The sharps disposal system enables smoother work flow and minimizes transfers via disposal of waste through the work surface into the bins below; thus, minimizing contamination of the work zone.

Airlock Pass-through

The airlock pass-through ensures work zone remains sterile during material ingress and egress.

Adjustable Hydraulic Support Stand

The motorized hydraulic stand option, is adjustable to accommodate user preference for a sitting or standing work position.

Criteria	RABS	ISOLATOR
Decontamination	Manually disinfected	Quantifiable and high reproducible method by an automated system
Assurance of Separation	No complete physical separation	Quantifiable hourly leak rate (closed) and continuously controlled differential pressure
Surrounding Environment	Passive: ISO 5 Active: ISO 7	US cGMP: ISO 8 EU cGMP: Grade D
Containment Applications	Low capability	Quantifiable leakage tightness (ISO 10648-2)
Glove Leak Test	Not applicable	Mandatory; Quantifiable glove integrity
Capital Costs	Higher than conventional cleanroom (CCR); reduced with renovation and retrofit application	High equipment costs
Operating Costs	Higher than CCR	Cost saving in energy consumption (HVAC) and clothing
Toxic Containment	Low capability	Good reliability

Closed Restricted Access Barrier Systems (cRABS)

As per USP <797> a restricted access barrier system (RABS) is an enclosure providing a HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to prevent the risk for cross-contamination.

A closed RABS provide superior sterility as compared to open front clean air devices (laminar flow clean benches and Class II biological safety cabinets). A pharmaceutical isolator on the other-hand is defined by USP <797> as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than the surrounding environment.

USP <800> states that a Compounding Aseptic Containment Isolator (CACI) is intended for the compounding of sterile Hazardous Drugs and is designed to provide operator, product, and environment protection. For facilities that do not need to comply with the United States Pharmacopoeia (USP), then the system can still be called an isolator, however, it will not be in line with international cGMP guidelines.

Product, Operator and Environment Protection

Esco Streamline® Closed - Restricted Access Barrier System (Recirculating) Models, provide a safe and clean environment for sterile drug compounding in compliance with USP <797> criteria.

Furthermore, RABS can reduce operating and renovation costs by taking up less space than a traditional cleanroom facility.

Negatively pressured, recirculating SLC-RABS model is suitable for work involving non-volatile hazardous materials, antineoplastic, or cytotoxic compounding applications. The work zone and pass-through interchange are under negative pressure to the room to maintain operator protection in case of a breach in the system.

Product Sterility and Integrity

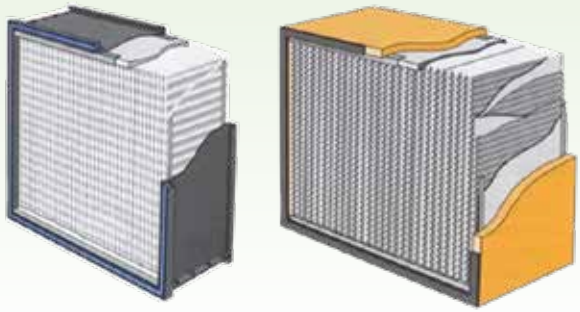
- SLC-RABS combination of downflow and exhaust H14 filters envelopes the main process chamber with ISO Class 5 air; providing operator and/or product protection in all configurations.
- Advanced mini-pleated supply H14 filters are tested to >99.999% efficiency for 0.3 micron particulates, significantly better than conventional filters.
- An improved mini-pleat separation technique maximizes filter surface area, improves efficiency, and extends filter.
- The supply filter provides clean air to the work surface in a gentle vertical laminar flow.
- 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.
- Laminar (unidirectional) airflow within work zone and pass-through enables recovery of chamber atmosphere to
- Airlock pass-through ensures work zone sterility during material ingress and egress.

SLC-RABS: A Safe and Efficient Solution

SLC-RABS is a safe and efficient solution for the production of low-volume pharmaceuticals as well as with practices concerning:

- Operator aseptic technique training
- Expiration settings
- Product quality maintenance (once CSP leaves the pharmacy)

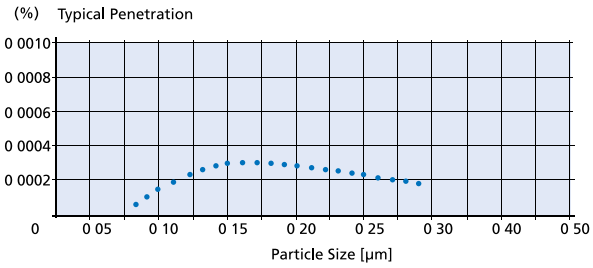
Mini-pleat Separatorless Filter (left) vs. Conventional Aluminum Separator Filter (right)



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.

** United States Pharmacopoeia (USP), Chapter 797(1), enacted January 1, 2004, presents the first enforceable standards for aseptic compounding. Following years of patient safety recommendations and professional guidelines, the intent of USP 797 is to set forth the procedural and practical requirements for safe compounding of aseptic preparations. The Chapter's requirements are applicable in all practice settings where aseptic preparations are compounded.*

Esco Filter Efficiency



Esco uses ULPA filters (as per IEST-RP-CC001.3 and HEPA (H14) filter as per EN 1822) with a typical efficiency of >99.999% at 0.3 microns, providing ISO Class 5 air cleanliness as per ISO 14644-1

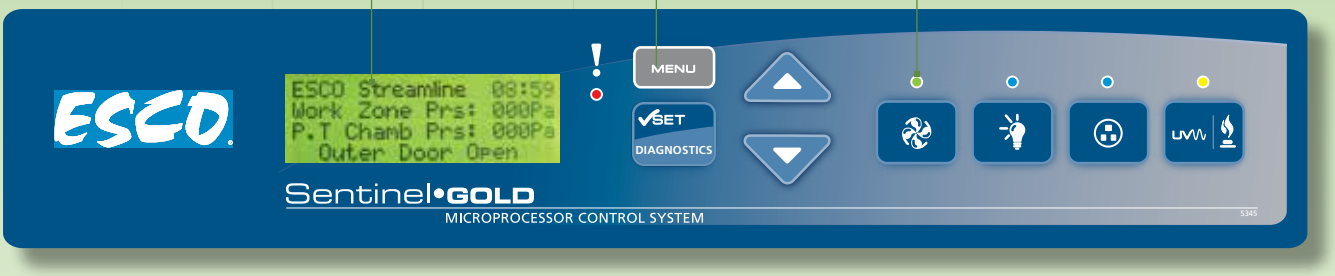
Enlarged, multi-line digital read-out with alpha-numeric display indicates all input, status and alarm functions.

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.*

- Vertical sliding door between the pass-through and work zone chambers minimizes ingress of particulates during transfer operations as compared with conventional swing door designs.
- Optional sharps disposal system enables smoother work flow and minimizes transfers to enhance patient protection and product sterility. Sharps disposal may be done in the work surface via the disposal bins, thus; minimizing work zone contamination.
- Safe-change cuff rings enable glove change.

The front visor opens up fully for maintenance access into the work zone.

Cabinet Construction Designed for Easy Cleaning

- Robust construction and enhanced safety features qualify the unit for the most demanding laboratory applications. SLC-RABS is fully assembled and ready to install and operate when shipped.
- The cabinet interior is constructed of durable and pharmaceutical-grade 304 stainless steel.
- Single-piece stainless steel work tray is easy to clean. Raised edges on all sides contain spillages.
- Stainless steel drain pan below the work surface contains spills.
- Tray components lift and remove to provide easy access and encourage surface decontamination.
- The cabinet exterior structure is constructed of industrial-grade electro-galvanized steel.
- The downflow HEPA filter is protected by a diffuser which may be cleaned.
- Hinged window may be opened for thorough access into the work zone.
- External surfaces are coated with ISOCIDE™ antimicrobial coating to protect against surface contamination and inhibit bacterial growth. ISOCIDE™ eliminates 99.9% of surface bacteria within 24 hours of exposure.

SentinelTM Microprocessor Control, Monitoring System

The Esco Sentinel™ microprocessor-based control system supervises operation of all functions. Controls are configurable to meet user requirements. Features of the main control panel include:

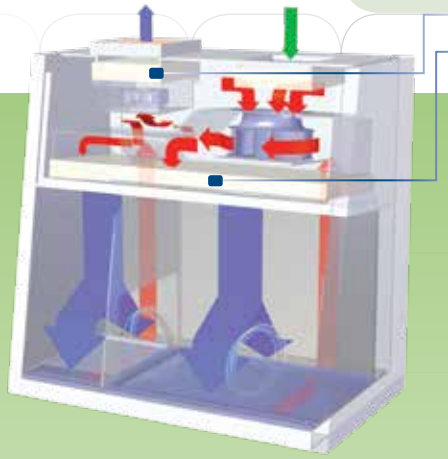
- Work zone and pass-through pressures are monitored and displayed on the LCD screen.
- Continuous monitoring and display of cabinet laminar (downflow) airflow on large, easy-to-read LCD display.
- An optional alarm package (pressure and airflow) is available for users with more sophisticated requirements.

Fan Efficiency

The unit's fan system is designed for maximum energy efficiency and minimal maintenance.

- Centrifugal, direct-drive, external rotor motors 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.

Streamline® Closed - Restricted Access Barrier System (Recirculating)



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

- Ambient air is pulled through the inlet pre-filter located on top of the SLC-RABS, which traps larger particles and extends the life of the supply HEPA filter. The prefilter traps larger particles and extends the life of the supply HEPA filter.
- Air from the top inlet and from work zone is pulled by the main fan, which creates positive pressure on the plenum and thus, downflow.
- The work zone and pass-through interchange are under negative pressure to the room.
- The HEPA downflow filter creates a laminar and particle-free ISO Class 5 environment to protect the work material inside the main and pass-through.
- Air from the work zone and passthrough is quickly purged by the fans to keep the area clean. The main fan pulls approximately 90% of the purged air back to the plenum and after passing through the HEPA downflow filter again, it is recirculated back to the two chambers. The high rate of airflow recirculation helps to prolong filter life.
- Approximately 10% of the recirculated air is exhausted through a HEPA filter filter to prevent heat build-up inside the RABS.

	Cabinet Performance	Air Quality	Filtration	Electrical Safety
Standards Compliance	CETA CAG-001-2005, USA CETA CAG-002-2006, USA	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	EN-1822, Europe IEST-RP-CC001.3, USA IEST-RP-CC007, USA IEST-RP-CC034.1, USA	IEC 61010-1, Worldwide EN 61010-1, Europe UL 61010-1, USA CAN/CSA-22.2, No. 61010-1

Safety and Certification

All components used in Esco products meet or exceed all applicable safety requirements.

- Each cabinet is individually factory tested for electrical safety.
- Documentation specific to the cabinet serial number is maintained on file.

Warranty

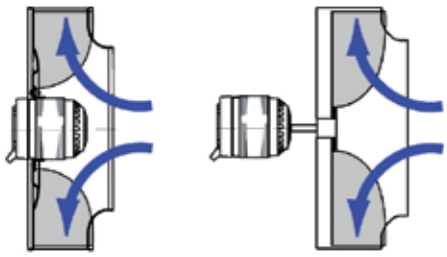
Esco's Streamline® Closed - Restricted Access Barrier System (SLC-RABS) comes with a 1-year warranty excluding consumable parts and accessories. Contact your local sales representative for specific details.

Accessories and Options

Esco's Streamline® Closed - Restricted Access Barrier System (SLC-RABS) is available as a standard bench top unit. Additional accessories are available for further enhancement. Electrical Outlets and Utility Fittings

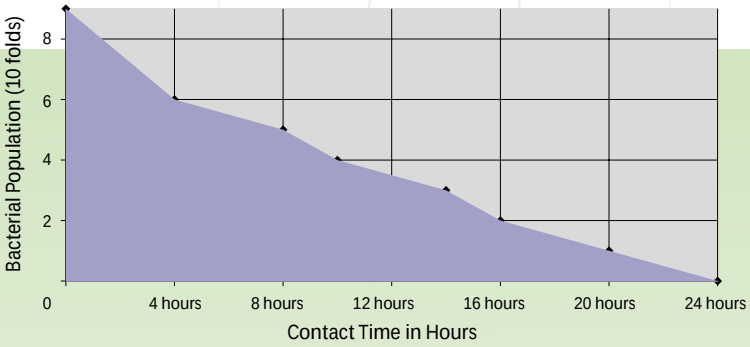
- Electrical outlet, ground fault, North America
- Electrical outlet, Euro/Worldwide Support Stands
- Fixed height, available 711 mm (28") or 864 mm (34")
  - With leveling feet, ±38.1 mm (1.5") (SAL-_ _ 0)
  - With casters (SPC-_ _0)
- Telescoping height stand for leveling feet (STL-_ _0), nominal range 660 mm to 960 mm (26"to 37.8")
- Telescoping height stand for casters (STC-_ _0), nominal range 660 mm to 880 mm (26" to 34.6")
  - Adjustable in 25.4 mm (1") increments
- Infinitely adjustable hydraulic stand, with casters, elevates to accommodate user preference for sitting or standing work surface height (SHM-_A0)

Esco Centrifugal Fan with External Rotor Motor (left) vs. Conventional Fan with Standard Motor (right)



- *Esco cabinets use German made **ebm-papst®** permanently lubricated, centrifugal motor/fans with external rotor designs.*
- *Integrated blades narrow the profile and eliminate need for a motor shaft.*
- *Motors are selected for energy efficiency, compact design, and flat profile. The completely integrated assembly optimizes motor cooling.*
- *All rotating parts are unitized and balanced for smooth, quiet, vibration-free operation.*

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.

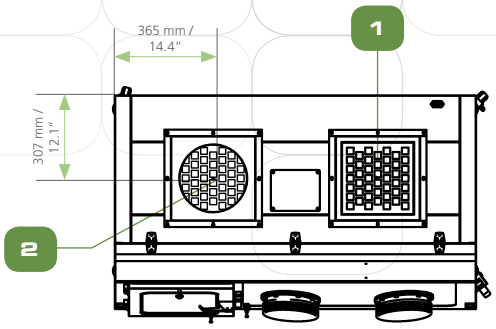
Other Options and Accessories

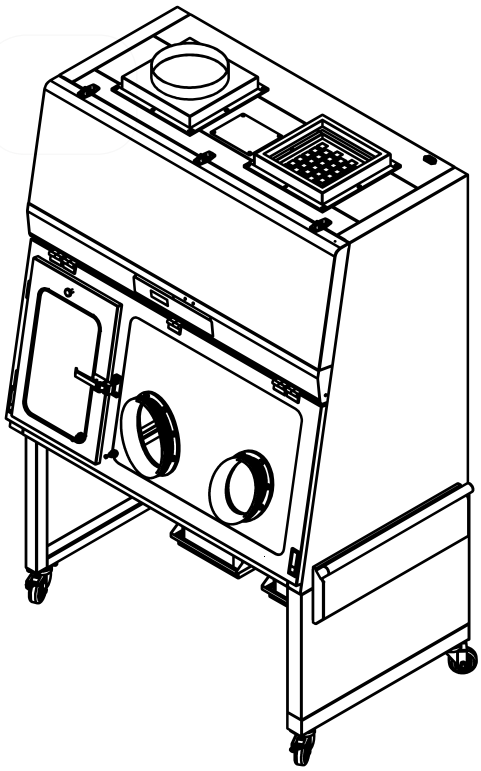
- Electrical outlets
- All stainless steel construction
- UV lamp
- IV bar, with hooks
- Sharps disposal system
- Cleaning accessories
- Alarm package
- Exhaust carbon filter
- Thimble exhaust collar
- Perforated shelf to increase work zonespace

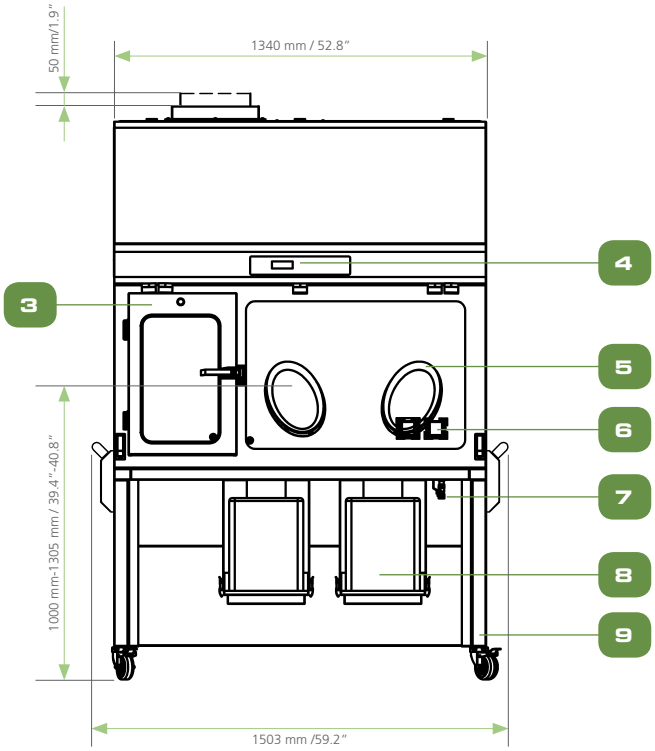
Validated Performance

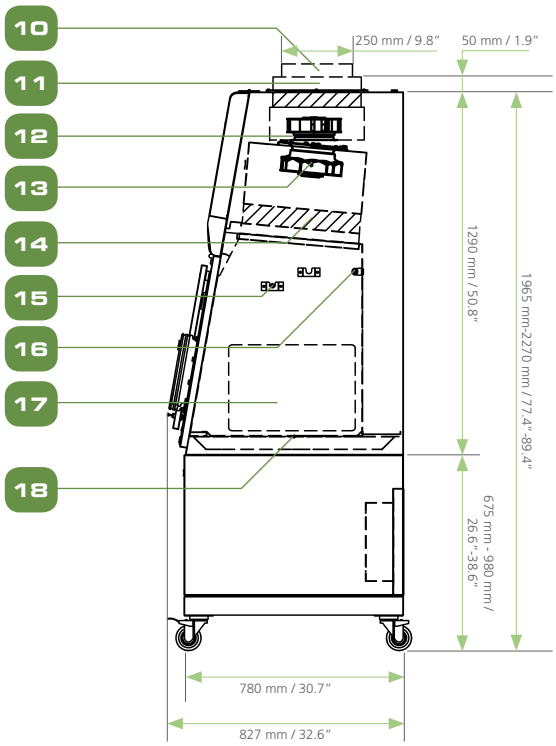
- Comprehensive design qualification and factory acceptance tests are performed on the Esco Streamline® Closed - Restriced Access Barrier System.
- Filter Leak Tests verify the integrity of the HEPA filters as-installed.
- Downflow Velocity Tests verify adequate laminar air flow velocities and air change rates in the two chambers.
- Dynamic Pressure Test determines if main and pass-through chambers pressures are adequate to aid in providing separation between the work zone and the ambient environment. Glove-pulls are simulated to ensure differential pressure is maintained during actual operation.
- Particle Counts (Air Cleanliness Tests) verify air cleanliness in accordance with ISO 14644-1 criteria for both the main chamber and pass-through.
- Product Ingress and Egress Tests determine if the work zone can maintain ISO Class 5, during material transfers without the need to wait for purging time during the transfer process, when used outside an ISO Class 7 cleanroom (USP <797>).
- Recovery Time Test determines the amount of time the main chamber takes to recover to ISO Class 5 after an event such as a full window opening or large scale contamination.
- Gauntlet Breach Test determines product protection in case of a glove failure.
- Operator Comfort Tests include noise, light, and vibration.

Model SLC-RABS, Closed - Restricted Access Barrier System (Recirculating) Technical Specifications



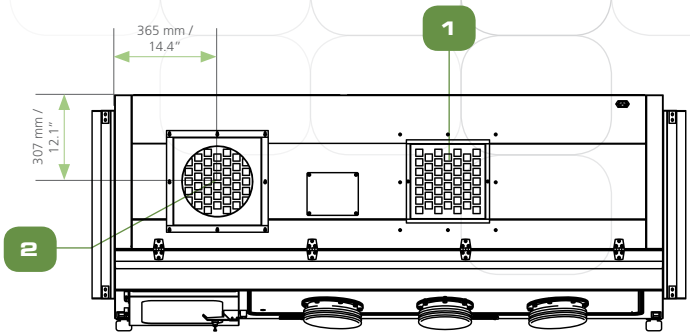


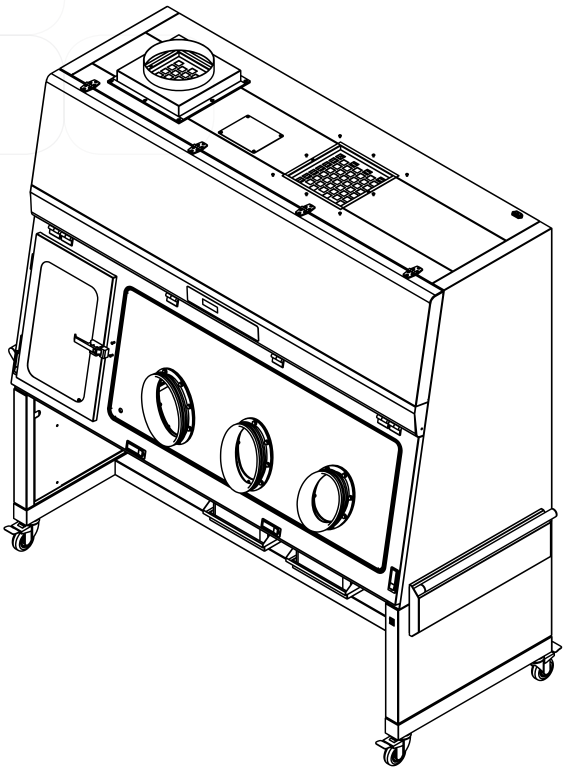


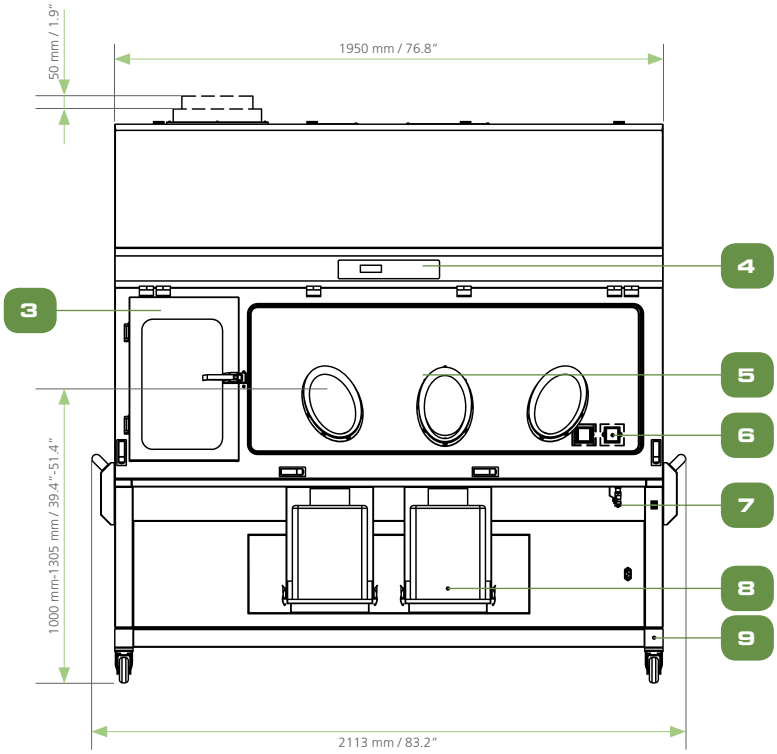


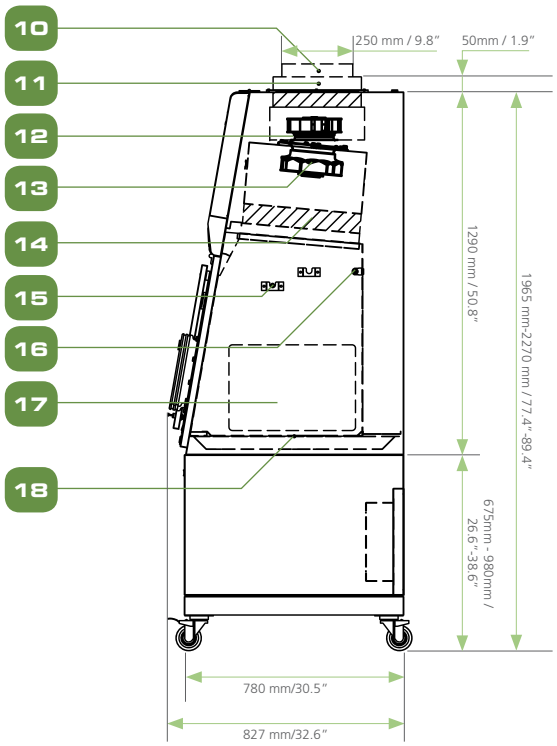
Model SLC-RABS-4O_ _-_ (2 Gloves)

1. *Air Inlet Filter, HEPA H14 Filter*
2. *Air Exhaust Filter, HEPA H14 Filter*
3. *Pass Thru, Hinged Outer Door*
4. *Esco Sentinel Microprocessor Control System*
5. *Oval Glove Ports*
6. *Electrical Outlet Retrofit Provision*
7. *Drain Valve*
8. *Sharp Disposal Container*
9. *Support Stand, SHM-4A1 (Optional)*
10. *Exhaust Collar (Optional)*
11. *Carbon Filter (Optional)*
12. *Exhaust Fan*
13. *Supply Fan*
14. *Supply Filter, HEPA H14 Filter*
15. *IV Bar Mounts*
16. *UV Lamp (Optional)*
17. *Pass Thru Inner Door, Vertical Sliding*
18. *Workzone Tray*









Model SLC-RABS-6O_ _-_ (3 Gloves)

1. *Air Inlet Filter, HEPA H14 Filter*
2. *Air Exhaust Filter, HEPA H14 Filter*
3. *Pass Thru, Hinged Outer Door*
4. *Esco Sentinel Microprocessor Control System*
5. *Oval Glove Ports*
6. *Electrical Outlet Retrofit Provision*
7. *Drain Valve*
8. *Sharp Disposal Container*
9. *Support Stand, SHM-6A1 (Optional)*
10. *Exhaust Collar (Optional)*
11. *Carbon Filter (Optional)*
12. *Exhaust Fan*
13. *Supply Fan*
14. *Supply Filter, HEPA H14 Filter*
15. *IV Bar Mounts*
16. *UV Lamp (Optional)*
17. *Pass Thru Inner Door, Vertical Sliding*
18. *Workzone Tray*

GENERAL SPECIFICATIONS

Closed - Restricted Access Barrier System (Recirculating)

		SLC-RABS-4_N_-_-	SLC-RABS-4_P_-_-	SLC-RABS-6_N_-_-	SLC-RABS-6_P_-_-
Nominal Size		1.2 meters (4')		1.8 meters (6')	
External Dimensions (W x D x H)	Witout Base Stand	1340 x 827 x 1290 mm (52.8" x 32.6" x 50.8")		1950 x 827 x 1290 mm (76.8" x 32.6" x 50.8")	
	With Base Stand (Min)	1503 x 827 x 1965 mm (59.2" x 32.6" x 77.4")		2113 x 827 x 1965 mm (83.2" x 32.6" x 77.4")	
	With Base Stand (Max)	1503 x 827 x 2270 mm (59.2" x 32.6" x 89.4")		2113 x 827 x 2270 mm (83.2" x 32.6" x 89.4")	
Main Chamber Work Zone (W x D x H)		840 x 610 x 670 mm (33.1" x 24.0" x 26.4")		1450 x 610 x 670 mm (57.1" x 24.0" x 26.4")	
Pass Through (W x D x H)		355 x 610 x 670 mm (13.9" x 24.0" x 26.4")		355 x 610 x 670 mm (13.9" x 24.0" x 26.4")	
Work Zone and Interchange Chamber Performance		ISO Class 5 (Class 1, Federal Standard 209E)			
Inlet Filter Type		80% efficient pre-filters			
Downflow and Exhaust Filter Type		HEPA filter with integral metal guards and filter frame gaskets; fully compliant with EN 1822 (H14) and IEST- RP-CC001.3 requirements (each cabinet has individual downflow, exhaust filters and inlet filters).			
Typical Filter Efficiency		>99.995% for particle size between 0.1 to 0.3 micron			
Fluorescent Lamp Intensity		> 950 Lux (>88 foot candles)			
RABS Construction	Main Body	1.2 mm (0.05") 18 gauge electro-galvanized steel with white oven-baked epoxy-polyester antimicrobial powder-coated finish			
	Work Tray	1.5 mm (0.06") 16 gauge stainless steel, type 304, with 4B finish			
	Side Walls	1.2 mm (0.05") 18 gauge stainless steel, type 304, with 4B finish			
Electrical	240-220V, AC, 50Hz, 1Ø	SLC-RABS-4_N1-_	SLC-RABS-4_P1-_	SLC-RABS-6_N1-_	SLC-RABS-6_P1-_
	Cabinet Full Load Amps (FLA)	2.1 A	2 A	2.5 A	2 A
	Optional Outlets FLA	5 A	5 A	5 A	5 A
	Cabinet Nominal Power	295 W	301 W	440 W	345 W
	Cabinet BTU	1007	1027	1501	1177
	120-110V, AC, 60Hz, 1Ø	SLC-RABS-4_N2-_	SLC-RABS-4_P2-_	SLC-RABS-6_N2-_	SLC-RABS-6_P2-_
	Cabinet Full Load Amps (FLA)	6 A	4 A	8.2 A	7 A
	Optional Outlets FLA	5 A	5 A	5 A	5 A
	Cabinet Nominal Power	410 W	264 W	600 W	456 W
	Cabinet BTU	1399	901	2047	1556
	240-220V, AC, 60Hz, 1Ø	SLC-RABS-4_N3-_	SLC-RABS-4_P3-_	SLC-RABS-6_N3-_	SLC-RABS-6_P3-_
	Cabinet Full Load Amps (FLA)	2.1 A	2 A	2.5 A	2 A
	Optional Outlets FLA	5 A	5 A	5 A	5 A
	Cabinet Nominal Power	295 W	301 W	440 W	345 W
	Cabinet BTU	1007	1027	1501	1177
Shipping Dimensions, Maximum (W x D x H)		1590 x 990 x 2210 mm (62.6" x 39.0" x 87.0")		2150 x 950 x 2210 mm (84.6" x 37.4" x 87.0")	
Shipping Volume, Maximum*		3.48 m³ (122.9 cu.ft)		4.51 m³ (159.3 cu.ft)	

* *SLC-RABS only; excludes optional stand.*
** *Cabinet and GFCI outlet operate on a single power cord.*

Note: *- If unit comes with exhaust collar, add 100mm height*
- If unit comes with carbon filter, add 50mm height

Airflow Volume of Negative Pressure SLC-RABS (Recirculating)

	SLC-RABS-4_N_-_	SLC-RABS-6_N_-_
Required Exhaust with Optional Hard Ducting	190 m³/h (112 cfm)	286 m³/h (168 cfm)
Static Pressure for Optional Hard Ducting	27 Pa/0.10 in H_2O	30 Pa/0.12 in H_2O

** *If ordering RABS with sharps provisions, order the following to complete the selection.*
*Only **2 sharps containers** can be mounted per unit.*

Sharps Disposal Containers

5170224	Sharps Disposal Container Complete With Mounting Base - 5.0qt (10.5" x 7.5"x 18")

Contact Esco Sales Representative for more information.

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 work zone. Check the material integrity of the two items.


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


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


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


5 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.


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


7 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.


8 Verify that the thumb of the new glove is positioned on top. Afterwards, carefully loosen the old glove from the outer groove.


9 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.

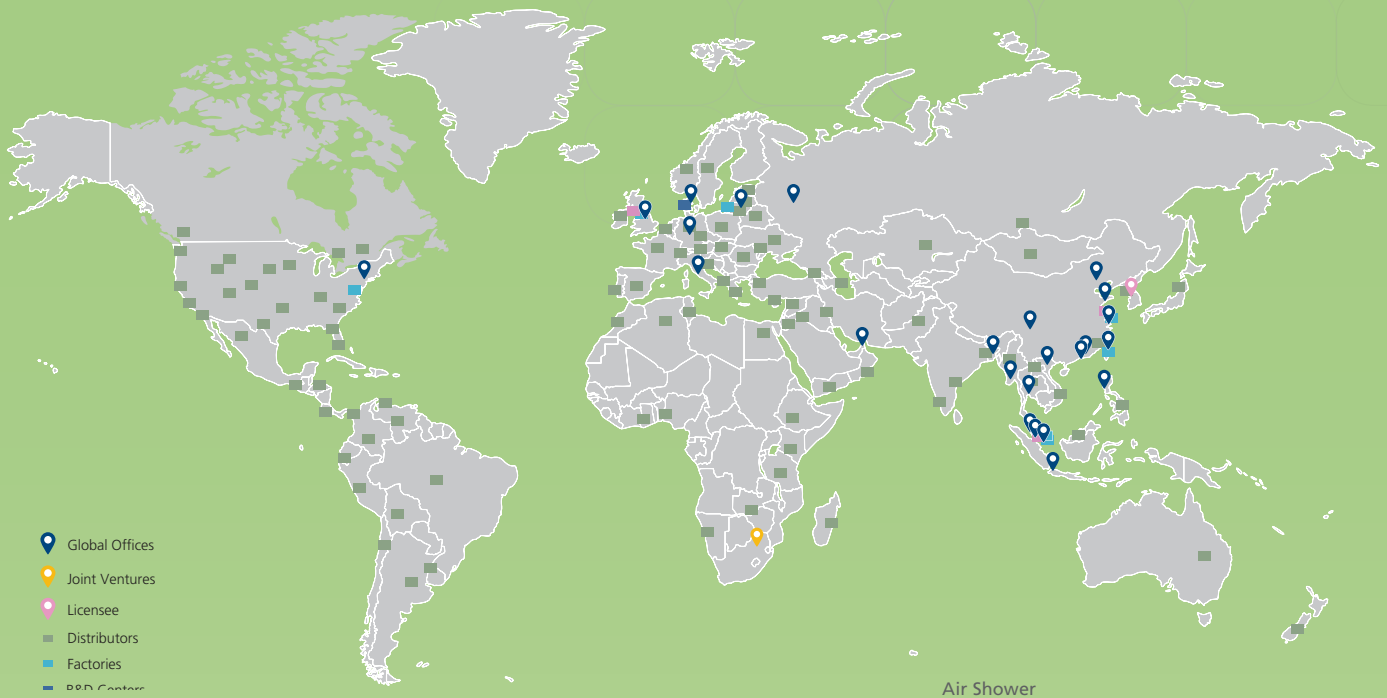

10 Put back the glove and sleeve into the work zone to properly discard the used glove without contaminating the outside environment.


11 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.

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)

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