





Main Features

- ULPA filters with a typical efficiency of >99.999% at 0.1 to 0.3 microns provide superior ISO Class 3 air cleanliness, 100 times better than competing products.
 - Sentinel[™] Gold Microprocessor controller supervises all functions and monitors airflow and pressures in real-time.
- Work zone and pass-thru interchange are under negative pressure to the room in order to maintain operator protection in the event of a breach in the barrier isolation system.
- 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 changes with zero risk of contaminating the work zone or pharmacy environment.
- One piece work zone liner with no crevices is easy to clean.
 - Esco **ISOCIDE**[™] antimicrobial coating on all painted surfaces minimizes contamination.
 - Sharps disposal system and hydraulic height-adjustable stand are available as options.



Vertical Pass-thru Door

The vertical pass-thru 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.





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Airlock Pass-thru The airlock pass-thru ensures work zone remains sterile during insertion and

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Optional Sharps Disposal System

Optional sharps disposal system enables smoother work flow and minimizes transfers in order to enhance patient protection and sterility. Sharps may be disposed through the work surface into disposal bins while minimizing contamination of the work zone.







Product, Operator and Environment Protection

Esco Streamline Compounding Isolator (Recirculating) Models, provide a safe and clean environment for compounding of hazardous, sterile drugpreparations in compliance with USP 797* criteria.

Barrier Isolation Systems

Barrier isolation 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.

When used as part of a system that includes operator aseptic technique training, process validation, expiration setting and product quality maintenance after the CSP leaves the pharmacy, isolators are an effective solution especially for lower-volume pharmacies. They reduce operating and renovation costs, take up less space, and are easier to maintain.

The negative pressure, recirculating SCI model is suitable for work involving hazardous materials, antineoplastic, or cytotoxic compounding applications. The work zone and pass-thru interchange are under negative pressure to the room in order to maintain operator protection in case of a breach in the barrier isolation system.

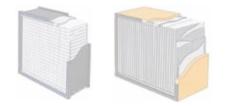
* United States Pharmacopoeia (USP), Chapter 797(1), enacted January 1, 2004, presents the first enforceable standards for sterile compounding. Following years of patient safety recommendations and professional guidelines, the intent of USP 797 is to set forth the procedural and practical requirements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

When hazardous drugs compounded have the potential to volatilize, the negative pressure, recirculating isolator should be ordered with the optional exhaust activated carbon filter and/or externally vented. Alternatively, a negative pressure, total exhaust isolator should be selected.

Maximum Patient Protection and Sterility

- The combination of downflow and exhaust ULPA filters gives the Esco Streamline Compounding Isolator a fully integrated envelope for product and operator protection in all configurations.
- Advanced mini-pleated supply ULPA filters are tested to >99.999% efficiency for 0.1 to 0.3 micron particulates, significantly better than conventional HEPA filters.
- An improved mini-pleat separation ٠ technique maximizes filter surface area, improves efficiency and extends filter life over conventional separation.
- The ULPA supply filter provides clean air to the work surface in a gentle vertical laminar flow.
- Superior air cleanliness of ISO Class 3, 100 times better than competing products.

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 (unidrectional) airflow within work zone and pass-thru enables recovery of chamber atmosphere to ISO Class 3 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.

- Airlock pass-thru ensures work zone remains sterile during insertion and removal of items. Items are inserted into the pass-thru, surface decontaminated, the outer pass-thru door is closed, while the atmosphere is allowed to purge. Finally, the inner pass-thru vertical door is opened from within the work zone in order to transfer materials into the main work area.
- ٠ Vertical sliding door between pass-thru and work zone minimizes ingress of particulates from the pass-thru during transfer operations compared with conventional swing door designs.
- Optional sharps disposal system enables smoother work flow and minimizes transfers in order to enhance patient protection and sterility. Sharps may be disposed through the work surface into disposal bins while minimizing contamination of the work zone. Interface between sharps disposal bin and isolator is aerosol tight to avoid ingress of contamination during the disposal operation.



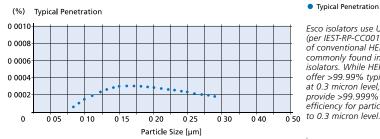
Safe-change cuff rings enable glove change with zero risk of contamination.

Ergonomic Enhancements

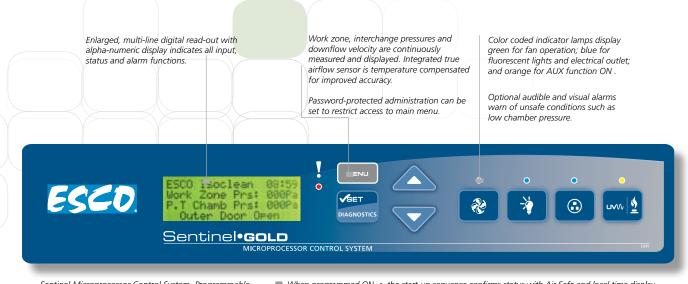
Ergonomic enhancements minimize stress associated with long periods of operation.

- Ergonomically styled sloped front reduces glare and allows for easier reach into the work area.
- Sliding tray facilitates material transfer

Esco Filter Efficiency



Esco isolators use ULPA filters (per IEST-RP-CC001.3) instead of conventional HEPA filters commonly found in pharmacy isolators. While HEPA filters offer >99.99% typical efficiency at 0.3 micron level, ULPA filters provide >99.999% typical efficiency for particle sizes of 0.1 to 0.3 micron level.



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.

without the operator having to reach into the pass-thru interchange area.

- Oval shaped gloveports improve reach into the work zone compared with conventional circular ports.
- Optional hydraulic stand allows the operator to adjust the work surface height to his / her height, for both sitting and standing operation.
- All common surgical gloves attach to the cuff ring, thereby making the system adaptable to operator preference.
- Instant-start 5000k fluorescent lamps operate on electronic ballasts for energy efficiency. Lamps deliver > 950 Lux (> 88 foot-candles) to the work surface for superior overall illumination.

Cabinet Construction Designed for Easy Cleaning

Robust construction and enhanced safety features qualify the Esco Streamline Compounding Isolator for the most demanding laboratory applications. The isolator 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 surface is easy to clean. Raised edges on all sides contain spillages.
- Stainless steel drain pan below the work surface contains spills.

- The interior work area is formed from a single piece of 304 stainless-steel with large radius corners to simplify cleaning.
- The cabinet work zone has no welded joints to collect contaminants or rust.
- Tray components lift and remove to provide easy access and encourage surface decontamination.
- The cabinet exterior structure is constructed of industrial-grade electrogalvanized steel.
- The downflow ULPA filter is protected by a diffuser which may be cleaned.
- There are no screws on the front or sides to trap contaminants or complicate cleaning.
- Hinged window may be opened for thorough access into the work zone.
- External surfaces are coated with



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

Isocide[™] antimicrobial coating to protect against surface contamination and inhibit bacterial growth. Isocide[™] eliminates 99.9% of surface bacteria within 24 hours of exposure.

Cleaning accessories are available from Fsco

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. Features of the main control panel include:

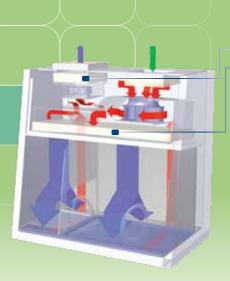
- Work zone and pass-thru pressures are monitored and displayed on the LCD screen.
- · Continuous monitoring and display of cabinet laminar (downflow) airflow on large, easy-to-read LCD display.
- An optional alarm package is available for users with more sophisticated requirements.

Fan Efficiency

The Streamline Compounding Isolator 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





ULPA-filtered air

Unfiltered / potentially contaminated air

Room air / Inflow air

Compounding Aseptic Containment Isolator (Recirculating)

Exhaust ULPA filter Supply ULPA filter

- Ambient air is pulled through the inlet pre-filter located on top of the Isolator. The pre-filter traps larger particles and extends the life of the supply ULPA filter.
- Air from the top inlet and from work zone is pulled by the main fan, which creates positive pressure on the plenum that creates downflow.
- The work zone and pass-thru interchange are under negative pressure to the room.
- The ULPA downflow filter creates a laminar and particle-free ISO Class 3 environment inside the isolator to protect the work material inside the main chamber and pass-thru.
- Air from the work zone and pass-thru 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 ULPA downflow filter again, it is re-circulated back to the work zone and pass-thru. The high rate of airflow re-circulation helps to prolong filter life.
- Approximately 10% of the recirculated air is exhausted through an ULPA filter to prevent heat build-up inside the isolator.

	Cabinet Performance	Air Quality	Filtration	Electrical Safety
Standards Compliance	CETA CAG-001-2005, USA CETA CAG-002-2006, USA USP Chapter 797, USA	ISO 14644.1, Class 3, Worldwide JIS B9920, Class 3, Japan BS 5295, Class 1, UK US Fed Std 209E, Class 1 USA	EN-1822, Europe IEST-RP-CC001.3, USA IEST-RP-CC007, USA IEST-RP-CC034.1, USA	UL-61010-1, USA CAWCSA-22.2, No.61010-1 EN 61010-1, Europe IEC 61010-1, Worldwide

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

The Esco Streamline Compounding Isolator comes with a 3-year warranty excluding consumable parts and accessories. Contact your local sales representative for specific warranty details.

Accessories and Options

Esco Streamline Compounding Isolator is available as a standard bench top unit. Additional accessories are available for further enhancement.

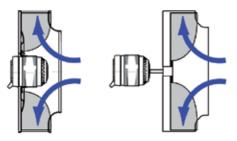
Electrical Outlets and Utility Fittings

- 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)

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

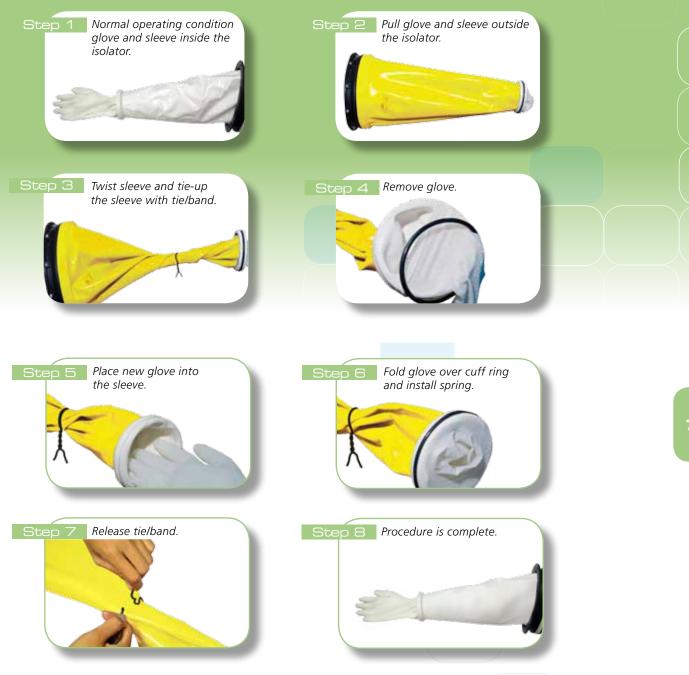


- Esco cabinets use German made ebm-papst[®] permanently lubricated, centrifugal motor/fans with external rotor designs.
- Integrated blades narrow the profile and eliminate need for a motor shaft.
- Motors are selected for energy efficiency, compact design, and flat profile. The completely integrated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

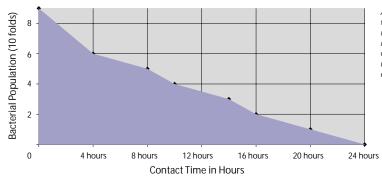
- Telescoping height stand for leveling feet (STL-__0), nominal range 660 mm to 960 mm (26"to 37.8")
- Telescoping height stand for casters (STC-__0), nominal range 660 mm to 880 mm (26" to 34.6")
 - Adjustable in 25.4 mm (1") increments
- Infinitely adjustable hydraulic stand, with casters, elevates to accommodate user preference for sitting or standing work surface height (SHM-_A0)



Glove Change Procedure



ISOCIDETM 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 zone space

Validated Performance

Comprehensive design qualification and factory acceptance tests are performed on the Esco Streamline Compounding Isolator.

- Filter Leak Tests verify the integrity of the ULPA filters as-installed.
- Downflow Velocity Tests verify adequate laminar air flow velocities and air change rates in the main chamber and pass-thru.
- Dynamic Pressure Test determines if main chamber and pass-thru pressures are adequate to aid in providing separation between the main chamber and ambient environment. Glove-pull's 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-thru.
- Product Ingress and Egress Tests

determine if the isolator work zone can maintain ISO Class 3, during material transfers with no wait or purge time during the transfer process, when used outside an ISO Class 7 cleanroom, as per USP 797.

- Recovery Time Test determines the amount of time the main chamber takes to recover to ISO Class 3 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.

PRODUCT CERTIFICATION AND APPLICATION

SCI-N recirculating isolator is designed only for hazardous (nonradiopharmacy, non-volatile) compounding applications. When volatile hazardous drugs are prepared, the negative pressure recirculating isolator should be ordered with the optional exhaust activated carbon filter and/or should be vented externally. The limitation, however, is that the volatile drugs will be recirculating within the work zone since the fiberglass filters are not able to filter off chemicals efficiently. For other applications, please contact our Application Specialist.

CETA Applications Guide for the Use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities -CAG-001-2005 (Revised December 2008) states that a total exhaust isolator must be used when handling volatile hazardous drugs, hence this is mandatory if a facility is built to comply with CETA guidelines.

Alternatively, a biosafety cabinet Class II B2 (total exhaust) with safe change filters at the exhaust connection should be selected.

It is the sole responsibility of the client to perform their own internal risk assessment with regards to the final system configuration and decide on the appropriate system design. As Esco will not know your final process, we will not be able to act to consult independently. Should you require our advice, Esco offices, distributors, sales agents, and individuals directly or indirectly promoting our products should not be quoted as the final authority in this matter.

Kindly engage with an independent consultant should you need further clarifications.

Both the internal process and pass-through chambers are not able to pass any pressure hold test in-situ according to AGS or ISO 10648-2 or other equivalent international standards.

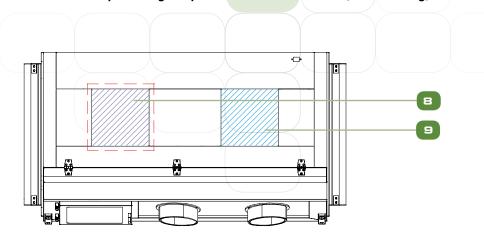
Particle Containment Integrity and Enclosure Leak Test is tested with a discrete particle counter as per the CETA Compounding Isolator Testing Guide - CAG-002-2006 (Revised December 2008) only. Standards can be obtained directly from CETA.

The system does not use FDA or USP 6 compliant seals in the construction.

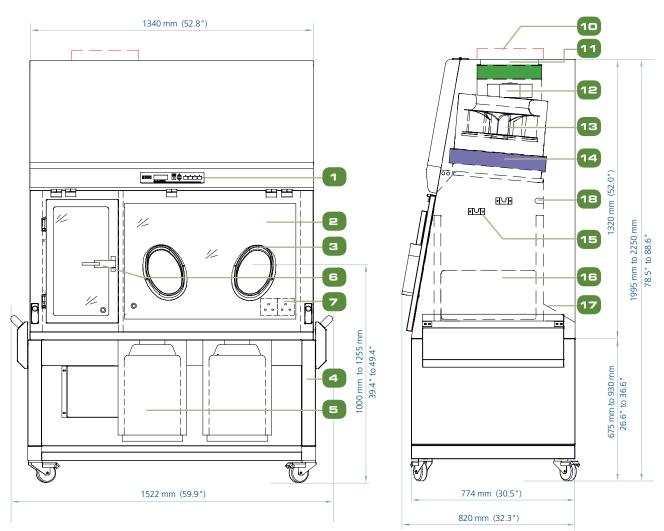
As the system is built in compliance with CAG-002-2006, no other test methods are permitted to be used in the validation of this system. It is the sole responsibility of the Esco appointed sales agent to verify system compliance should the system needs to comply with any other international standards.

Clients should perform their internal risk assessment to ensure that the correct unit is purchased fit for their application. As Esco distributes products via independent parties, any misrepresentation of this product complying with standards and specifications beyond what is stated here is the sole liability of Esco sales agent and not covered by our warranty.



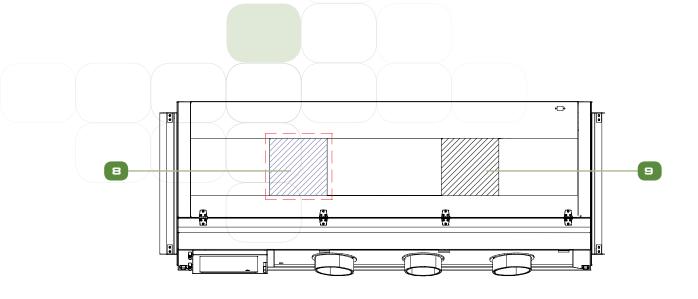


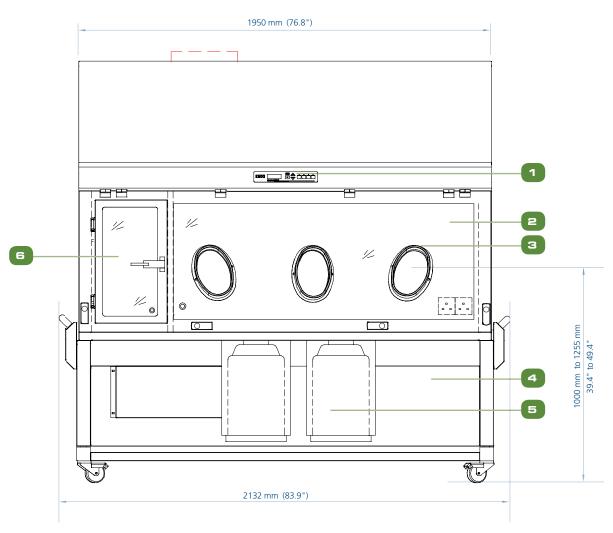
Model SCI, Compounding Aseptic Containment Isolator (Recirculating) Technical Specifications



Model SCI-4N_-_ (2 Gloves)







Model SCI-6N_-_ (3 Gloves)

- Esco Sentinel[™] microprocessor control system
- 2. Hinged front window
- 3. Oval glove ports
- 4. Hydraulic height adjustable base stand with casters (optional)
- 5. Sharps / garbage disposal system (optional)
- 6. Pass-thru, hinged outer door
- 7. Electrical outlet Retrofit Kit provision (2 single outlet on the right side of work area)
- 8. Exhaust ULPA filter
- 9. Intake ULPA filter
- 10. Carbon filter (optional)
- 11. Pre-filter

- 12. Exhaust fan 13. Main fan
- 14. Downflow ULPA filter
- 15. Staggered IV bar mounts
- 16. Pass-thru, inner door, vertical sliding
- 17. Removable paper catch
- 18. UV lamp retrofit kit provision (optional)
- Streamline® | Compounding Aseptic Containment Isolator (Recirculating)

	General Specifications,	Compounding Aseptic Containment I	solator (Recirculating)	
Model		SCI-4N	SCI-6N	
		1.2 meters (4')		
	Without Base Stand	1340 x 820 x 1320 mm (52.8" x 32.3" x 51.9")	1950 x 820 x 1320 mm (76.8" x 32.3" x 51.9")	
	With Base Stand (Min)	1522 x 820 x 1995 mm (59.9" x 32.3" x 78.5")	2132 x 820 x 1995 mm (83.9" x 32.3" x 78.5")	
	With Base Stand (Max)	1522 x 820 x 2250 mm (59.9" x 32.3" x 88.6")	2132 x 820 x 2250 mm (83.9" x 32.3" x 88.6")	
	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")	
		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")	
		ISO Class 3 (Class 1, Federal Standard 209E)		
		ULPA 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.)		
		>99.999% for particle size between 0.1 to 0.3 micron		
	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 ₂ O	30 Pa / 0.12 in H ₂ O	
Fluorescent Lamp Intensity		> 950 Lux (> 88 foot candles)		
	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		
			SCI -6N1	
	Cabinet Full Load Amps (FLA)	2.1 A	2.5 A	
	Optional Outlets FLA	5 A	5 A	
	Cabinet Nominal Power	295 W	440 W	
	Cabinet BTU	1007	1501	
		SCI-4N2	SCI -6N2	
	Cabinet Full Load Amps (FLA) **	6 A	8.2 A	
	Optional Outlets FLA **	5 A	5 A	
	Cabinet Nominal Power	410 W	600 W	
	Cabinet BTU	1399	2047	
		SCI-4N3	SCI -6N3	
	Cabinet Full Load Amps (FLA)	2.1 A	2.5 A	
	Optional Outlets FLA	5 A	5 A	
	Cabinet Nominal Power	295 W	440 W	
	Cabinet BTU	1007	1501	
Net Weight*		326.5 kg (720 lbs)	395 kg (871 lbs)	
		392.5 kg (865 lbs)	476.5 kg (1051 lbs)	
		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")	
		3.48 m ³ (122.9 cu.ft)	4.51 m ³ (159.3 cu.ft)	

* Pharmacy isolator only; excludes optional stand. ** Cabinet and GFCI outlet operate on a single power cord.

Models for Compounding Aseptic Containment Isolator (Recirculating)				
Model	Description			
SCI-4N0	4' Negative Pressure Isolator Only, No Sharps Provisions			
SCI-4NS**	4' Negative Pressure Isolator With Sharps Provisions			
SCI-6N0	6' Negative Pressure Isolator Only, No Sharps Provisions			
SCI-6NS **	6' Negative Pressure Isolator With Sharps Provisions			

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

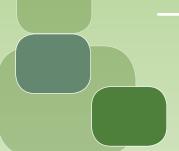
Sharps Disposal Container Complete With Mounting Base - 5.0qt (10.5" x 7.5"x 18")

All HPI systems except SCI-4N_-0 must be ordered with support stands. 5 types support stands available. Contact Esco Sales Representative for more information.



ESCO GLOBAL NETWORK





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ISOCIDE[™]

ESCO PLATFORM PHARMA SPECIALIST.

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