

Cytotoxic Safety Cabinet

The Premium Solution for Cytotoxic Drug Processing







Main Features

Sentinel[™] Microprocessor controller supervises all functions.

- Meets the requirements of the European Std. EN 12469 for microbiological safety cabinets.
- Provides you with the highest level of operator safety to protect you and your personnel from the hazardous compounds used in cytotoxic drugs.
- Motorized sash helps simplify transfer of materials into the work zone.
- Highest level of cleanliness within the work zone for patient safety and product cleanliness.
 - Esco ISOCIDE[™] antimicrobial coating on all painted surfaces.
- Dual long-life ULPA filters for supply and exhaust airflow.
- Additional secondary HEPA exhaust filter.
- Spacious knee room maximizes operator comfort, 245mm (9.6") inward
- Available in 1.2 and 1.8 m models (4' and 6').

Introduction

The Esco Cytoculture Cytotoxic Safety Cabinet is the premium solution for cytotoxic/antineoplastic drug processing, providing the highest level of patient, pharmacist and environmental protection. This revolutionary product builds on Esco's experience of more than 20 years as a global leader in biological safety containment technology.

The unique demands of handling and preparing cytotoxic drugs for use in chemotherapy require a specialized cabinet. As cytotoxic drugs cannot be inactivated by chemical decontamination, Class II biosafety cabinets should not be used. With this in mind Esco has developed a highly specialized range of cabinets designed especially for handling these potentially dangerous drugs.

Esco Cytoculture Cytotoxic Safety Cabinet, Model CYT-4A_. When used as a Class II biological safety cabinet, the Cytoculture meets the requirements of the European EN 12469 std. for microbiological safety cabinets and offers an added level of safety and personnel protection by permitting a filter change without decontamination.



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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. • an airflow alarm warns of deviations from normal velocities.

With a range of specialist features incorporated into our Cytoculture Cytotoxic Safety Cabinets (CYT), Esco brings you the ideal solution to your cytotoxic drug preparation challenges. Our CYT cabinets are designed to:

- Maintain the highest level of cleanliness within the work zone ensuring the best possible level of patient safety and product cleanliness.
- Provide the highest level of operator safety to protect you and your personnel from hazardous compounds used in cytotoxic drugs.
- Incorporate an advanced range of additional safety features, including a specialized Tri-Filter[™] design, to guarantee the highest possible levels of environmental, operator and product protection. Contaminated air from the work zone is immediately filtered by a HEPA filter below the work zone to minimize the possibility of airborne contamination.
- Meet the requirements of all relevant safety standards for handling cytotoxic drugs (see technical specifications for details).
- Provide ISO Class 3 air cleanliness within the work zone.

With an additional HEPA filter placed directly below the work zone, filters on our CYT cabinets can be changed without exposing the ambient environment and service personnel to potential hazards. This unique design allows contaminated filters to be removed easily, and all contaminated areas to be sterilized without compromising safety.

Designed and Built for Enhanced Usability

All Esco Cytotoxic Safety Cabinets are ergonomically designed for a high level of usability and efficiency. They incorporate a number of features to ensure operator comfort and enhanced productivity.

- The ergonomic angled front improves reach into the work zone and prevents glare off the sliding sash.
- The aesthetically pleasing stainless steel interior will never rust, chip or generate particles, enhancing operator and product protection.
- The interior back and side walls are fabricated from a single piece of stainless steel, with no joints or sharp corners. This makes the cabinet exceptionally easy to clean.
- Built-in warm white, electronically ballasted, 5000K lighting provides excellent illumination of the work zone to reduce operator fatigue. The reliable lighting system is zero-flicker and instant start.
- The front sliding sash window is motorized for movement, facilitating easy transfer of reagents and equipment into and out of the work zone.
- Spacious knee room is provided for the operator in a sitting position, ensuring comfort during use.

• The easily removable multi-piece stainless steel work surface construction increases cleanability.

Enhanced Filtration System

The enhanced filtration system is designed to provide the highest level of air quality within the work zone.

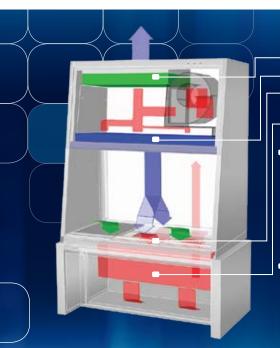
- Esco CYT cabinets provide ISO Class 3 air cleanliness within the work zone (as per ISO 14644.1), significantly "cleaner" than the usual Class 5 classification on cabinets offered by the competition.
- A highly specialized Tri-Filter design incorporates two ULPA filters and an additional secondary HEPA exhaust filter, providing a world class level of air cleanliness to protect the operator, the product and the environment.

Mini-pleat Separatorless Filter (left) vs. Conventional Aluminium 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 to prolong filter life. Filters include a lightweight aluminum frame for structural stability and elimination of swelling common to conventional wood frames.





Cytoculture Cytotoxic Safety Cabinet Airflow

Exhaust ULPA filter

Supply ULPA filter

Dynamic air barrier, inflow and forward directed downflow air converge

Secondary exhaust HEPA filter

- Air enters the cabinet through perforations located along the front of the work zone before mixing with used downflow air in a common chamber below the work zone (this inflow air does not mix with the filtered downflow air in the cabinets main chamber). The mixed air then passes through the HEPA filter located beneath the work zone.
- The HEPA filtered air then passes through internal ducting in the back wall of the cabinet to a common air plenum where 35% is exhausted through the ULPA

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

exhaust filter and 65% is forced evenly through the ULPA supply filter. This sterilized air then passes through the main chamber as downflow air, flushing all contaminates from the work zone.

At the work surface the downflow airstream splits and enters the common air chamber beneath the work zone through perforations located at the front and back of the main chamber, from where the cycle is repeated.

- Advanced minipleat separatorless HEPA and ULPA filter technology maximizes surface area. This energy efficient design reduces operating costs, extends filter life, and delivers increased laminar airflow uniformity, ensuring better product protection than conventional filters.
- The high quality ULPA filters (per IEST-RP-CC001.3) operate at typical efficiency of >99.999% at 0.1 to 0.3 micron sizes, providing superior product protection.

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- The minipleat separatorless secondary exhaust HEPA filter (per IEST-RP-CC001.3) fitted provides >99.99% efficiency at 0.3 microns.
- For enhanced safety the first exhaust filter can be changed easily without time consuming decontamination.

- An integral metal filter guard protects the HEPA and ULPA filters from accidental damage.
- Unique U-channels in work surface construction protect the main filters from liquid spills and small parts.

User-Friendly Control System

The user-friendly Esco Sentinel microprocessor-based control system, fitted to our CYT cabinets, supervises the operation of all cabinet functions. The controls are easily configurable to meet your requirements and comes equipped with a number of enhanced features to promote cabinet usability and safety.

 All critical cabinet airflow parameters can be monitored using the built-in accurate true airflow velocity sensing technology. Temperature compensated sensors ensure increased accuracy.

- Audible and visual alarms ensure product protection by alerting the user in the event of low airflow.
- Password-protected administration can be set to restrict access to the main menu ensuring that the cabinet cannot be operated by unauthorized personnel.
- Built-in solid state variable speed controllers, with integral RFI and noise filters, are superior to conventional "step" controllers and offer infinite adjustment from zero to maximum setting.

Cabinet Construction

All Esco products are manufactured to the highest quality, using the finest materials, for the most demanding laboratory applications.

 All components are designed for maximum chemical resistance and enhanced durability for a long service

8 6 4 2 0 4 hours 8 hours 12 hours 16 hours 20 hours 24 hours Contact Time in Hours

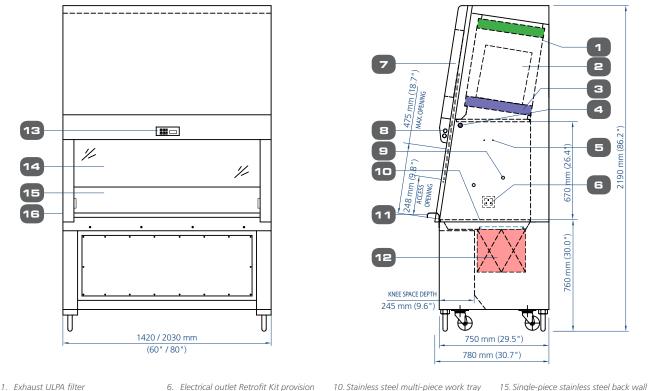
All exterior painted surfaces are powder-coated with Esco Isocide, an antimicrobial inhibitor to diminish contamination. Isocide is integrated into the coating substrate and cannot wash out or diminished by repeated cleaning. Performance results are available upon request. Contact Esco or your Esco Sales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

ISOCIDETM Antimicrobial Powder-Coating

toculture

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Model CYT Cytotoxic Safety Cabinet Technical Specifications



- 2. Blower
- 3. Downflow ULPA filter 4. Standard UV light Retrofit Kit™ provision
- 5. Standard IV bar Retrofit Kit provision
- (two single outlets in workzone)
- 7. Electrical and electronics panel
- 8. Fluorescent lamp
- 9. Plugged service fixture provisions
 - (2 on each side)
- 11. Stainless steel armrest
- 12. Exhaust HEPA filter 13. Esco Sentinel microprocessor
- control system
- 14. Motorized laminated glass sliding sash window
- 15. Single-piece stainless steel back wall and side walls 16. Removable side panel for plumbing
- access

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Standards Compliance	General Requirements	Air Quality	Filtration	Electrical Safety
	DIN 12980, Germany EN 12469, Europe	ISO 14644.1, Class 3, Worldwide IEST-G-CC1001, Worldwide IEST-G-CC1002, Worldwide	EN-1822 (H14), Europe IEST-RP-CC001.3, USA IEST-RP-CC007.1, USA IEST-RP-CC034.1, USA	UL-C-61010A-1, USA CSA C22.2, No.1010-92, Canada EN-61010-1, Europe IEC61010-1, International

life, making Esco's CYT cabinets one of the most cost effective solutions on the market.

- The main body of the cabinet is constructed of industrial-grade electrogalvanized steel for durability and enhanced safety.
- All cabinet components are cleanroom compatible.
- The external structure of all our cabinets is coated with Esco Isocide antimicrobial coating to protect against contamination and inhibit bacterial growth. Isocide eliminates 99.9% of surface bacteria within 24 hours of exposure to further ensure the cleanliness of the work zone.

Blower Efficiency

• Esco Cytotoxic Safety Cabinets incorporate permanently lubricated direct drive centrifugal blowers. The energy efficient external rotor motor design reduces operating costs and has extremely low vibration.

• The blower system automatically maintains airflow as the filters become loaded, ensuring optimum efficiency and product protection without the need for constant manual adjustment.

Designed and Built to Exceed Safety Criteria

At Esco safety is of paramount importance. We take extra care in the design and construction of all cabinets to ensure all components used in our products meet or exceed all applicable safety requirements.

• Each cabinet is individually factory tested for safety and performance in accordance with international standards. Each unit is shipped with a documentation outlining the tests undertaken and the units individual results for each cabinet.

• All electrical components are UL listed or UL recognized, ensuring superior electrical safety for the operator.

Warranty

Esco Cytotoxic Safety cabinets include an extended 3 year warranty, excluding consumable parts and accessories. Contact your local Sales Representative for specific warranty details.



	Ge	neral Specifications, Cytotoxic Safety Ca	binets	
	Note to customer	: Insert electrical voltage number into last model number	digit _ when ordering.	
Model		CYT-4A_	СҮТ-6А_	
Nominal Size		1.2 meters (4')	1.8 meters (6')	
External Dimensions (W x D x H)		1420 x 780 x 2190 mm 55.9" x 30.7" x 86.2"	2030 x 780 x 2190 mm 79.9" x 30.7" x 86.2"	
Internal Work Area, Dimensions (W x D x H)		1260 x 603 x 670 mm 49.6" x 23.7" x 26.4"	1870 x 603 x 670 mm 73.6" x 23.7" x 26.4"	
Internal Work Area, Space		0.60 m² (6.4 sq.ft.)	0.90 m² (9.7 sq.ft.)	
Average Airflow Velocity	Inflow	0.45 m/s (90 fpm)		
	Downflow	0.30 m/s (60 fpm)		
Exhaust Volume with Thimble Duct	CBV Exhaust Volume	611 m³/ h (360 cfm)	931 m³/h (548 cfm)	
	Static Pressure at CBV Exhaust Volume	39 Pa / 0.15 in H ₂ O	63 Pa / 0.25 in H ₂ O	
HEPA Filter Typical Efficiency		>99.99% for particle size of 0.3 microns		
ULPA Filter Typical Efficiency		>99.999% for particle size between 0.1 to 0.2 microns		
Sound Emission Per EN 12469*		<62 dBA	<64 dBA	
Fluorescent Light Intensity At Zero Ambient		>1375 Lux (>128 foot candles)	>1270 Lux (>118 foot candles)	
Cabinet Construction		1.5 mm (0.06") 16 gauge electrogalvanized steel with Isocide white oven-baked epoxy powder-coating		
Net Weight		383 kg (844 lbs)	500 kg (1102 lbs)	
Shipping Weight		443 kg (977 lbs)	575 kg (1268 lbs)	
Shipping Dimensions, Maximum (W x D x H)		1570 x 940 x 2210 mm	2200 x 940 x 2210 mm	
Shipping Volume, Maximum		3.26 m³ (115 cu.ft)	4.61 m³ (163 cu.ft)	
Electrical**		Model	Voltage	
		СҮТ-4А1, СҮТ-6А1	220-240 VAC, 50Hz, 1 phase	
		СҮТ-4А2, СҮТ-6А2	110-120 VAC, 60Hz, 1 phase	
		СҮТ-4А3, СҮТ-6А3	220-240 VAC, 60Hz, 1 phase	

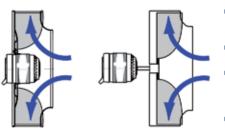
* Noise as measured in open field / anechoic chamber.
** Additional voltages may be available; contact Esco for ordering information.

Customized to Meet Your Specific Needs

Esco CYT cabinets can be configured to meet unique needs including:

- Lead shielding for nuclear medicine applications.
- An optional carbon filter impregnated with KI (potassium iodide) in place of the additional HEPA filter (this configuration does not protect service technicians when changing contaminated filters).

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/ blowers 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.

Comprehensive Performance Testing At Esco



Every Cytoculture CYT model manufactured by Esco is individually tested, documented by serial number and validated with the following test methods.

- Inflow / downflow velocity
- PAO aerosol challenge for filter integrity
- Light, noise and vibration
- Airflow pattern visualization
- Electrical safety to IEC61010-1
- Additional KI-Discus containment and microbiological testing is performed on statistical sampling basis.

<u>Cytoculture</u>.

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Purchase Specifications

CYT Cytoculture Cytotoxic Safety Cabinet

General Performance and Certifications

- The cytotoxic safety cabinet shall comply with one or more of the following international standards for cytotoxic safety, biosafety, electrical and other functional characteristics: DIN 12980 (Cytostatic Workbenches), Class II per EN 12469.
- 2. The cabinet shall protect: (a) the operator and laboratory environment from hazardous drug compounds used in the work zone; (b) the product and process within the work zone from airborne contamination from ambient air; (c) and the product and process within the work zone from cross contamination.
- 3. The retention efficiency for the front aperture shall be not less than 99.999% Microbiological testing for cabinet performance shall be performed on a statistical sampling basis.
- 4. Each 220-240V, AC, 50Hz model shall be listed by CE for electrical safety.
- 5. Original documentation specific to each cabinet serial number shall be provided with the cabinet and maintained in the manufacturers' records. Test data verifying all performance criteria shall be available upon request to include: (a) inflow velocity through direct inflow measurement method; (b) downflow velocity and uniformity; (c) filter leak scan with aerosol challenge for all three filters; (d) light, noise, vibration; (e) and electrical safety.

Filtration System

- 6. The cabinet shall employ a triple-filter design with one supply downflow filter and two exhaust filters. Both downflow and the final (main) exhaust ULPA filters shall be ULPA-type per IEST-RP-CC001.3 or H14 per EN 12469 with filter media complying with EN 1822 fire retardant performance.
- The secondary exhaust filter shall be V-Bank design HEPA-type per IEST-RP-CC001.3 or H13 per EN 12469 with media complying with EN 1822 fire retardant performance.
- The filters shall be within an aluminum frame with mini-pleat design without aluminum separators; no wood or fiberboard shall be used in the filter assembly.
- Typical ULPA filter efficiency shall be more than 99.999% for particle size between 0.1 to 0.3 microns.
- **10.** Typical HEPA filter efficiency shall be more than 99.99% at 0.3 microns.
- 11. An integral filter guard shall be affixed to prevent damage to the filter media.
- 12. The filters shall be (a) individually scan tested by the manufacturer, (b) individually scan tested after assembly, and (b) easily accessible for scan testing in situ by means of a dedicated upstream sampling port accessible from within the cabinet.
- 13. The supply filter shall be angled and oriented to the 10° cabinet front angle to maximize downflow uniformity over the work surface.
- 14. A removable, perforated metal diffuser shall be installed below the supply filter to optimize airflow uniformity and to protect from damage.
- **15.** The secondary exhaust HEPA filter shall be installed beneath the work zone surface.
- 16. The secondary exhaust HEPA filter fitting shall be designed for easy and safe filterchanging operations without the need for prior decontamination of the cabinet.

Blower System

- 17. The cabinet shall have a direct drive, permanently lubricated centrifugal blower/motor dynamically balanced in two planes compliant to ISO 2710 for low noise, low vibration and long filter life.
- 18. The blower/motor shall have an external rotor design and include an automatic thermal cut-out to disable the motor in case of overheating.
- **19.** The blower/motor shall have an semi automatic ability to compensate for filter loading.
- 20. The blower/motor system shall be enclosed within a dynamic chamber shaped steel plenum and integrated with the removable supply filter assembly to simplify filter changing.

Cabinet Design, Construction, Cleaning

- 21. The cabinet shall be of triple wall design whereby all positive pressure plenums capable of handling contaminated air shall be surrounded by negative pressure. No positive pressure areas shall be accessible external to the cabinet. The third wall shall conceal utilities.
- 22. The cabinet shall maintain containment performance even when removable work area components are removed for cleaning.
- 23. The work tray shall be multi-piece, removable, stainless steel.
- **24.** The closed sidewall shall be sealed without perforations, return air slots or concealed areas which can contain contaminants.
- 25. The cabinet shall be free of sharp edges, nonfunctional protrusions, bolts, screws or hardware, and all metal edges shall be deburred.
- 26. The cabinet exterior top shall be slanted to discourage placement of foreign objects and to maintain proper exhaust airflow.

Ergonomics and Convenience

- 27. The front sash shall be frameless to maximize visibility, and accessible for cleaning front and back. Sash glass shall be laminated safety glass to maintain containment in the event of accidental breakage.
- 28. The front sash movement shall be motorized and the movement shall be controlled from the cabinet's microprocessor control panel.
- 29. Magnetic, not mechanical, proximity sensors shall work in conjunction with the control system to indicate proper sash position for containment.
- 30. Fluorescent lamps shall be mounted behind the control panel module out of the work zone. Electronic ballasts shall be used to eliminate flicker, extend lamp life and reduce heat output.
- **31.** The UV lamp, if installed, shall be mounted behind the control panel and away from the user's line of site for protection.
- 32. The UV lamp shall operate via an automatic timer with automatic shut-off managed by the microprocessor controller and shall be interlocked with the blower/motor and fluorescent lights for safety.
- 33. The cabinet shall be designed with a 10° angled front to optimize user comfort, reduce glare and maximize reach into the work area.
- 34. The arm rest shall be raised above the front air grille to prevent airflow blockage and improve comfort.
- Penetrations for petcocks and service fittings shall be provided; penetrations shall be offset to improve user access.
- 36. The cabinet shall provide a 245 mm (9.6") knee space inward for sitting operators.
- **37.** The cabinet shall be freestanding on castor wheels with leveling rod supports.

Control and Alarm System

- 38. All cabinet functions shall be managed by a programmable microprocessor control system capable of software updates via Internet downloads.
- **39.** The microprocessor controller shall be mounted on the main control panel facing down toward the user.
- 40. The controller shall include soft-touch keypad controls and backlit LCD displays to permit operation of the blower/motor, light, UV lamp, electrical outlet(s) and menu.
- 41. The controller shall be user programmable in situ to enable or disable functions such as PIN (personal identification number) access restriction, cabinet start-up protocol, airflow alarm and other microprocessor controlled operations outlined in the user manual.
- 42. When programmed ON, the start-up protocol shall perform an automatic pre-purge and postpurge cycle to ensure proper cabinet operation.
- 43. The controller shall include a blower/motor hours meter to display aggregate motor running time to assist in predictive maintenance.
- Audible and visual alarms shall be provided for unsafe conditions such as improper airflow or sash position.
- 45. Airflow shall be monitored by a temperature compensating, thermistor-based, true air velocity sensor mounted in the cabinet.
- **46.** The airflow display and alarm system shall be individually calibrated before shipment.
- The main control panel shall exhibit continuous display of air velocity and a 24-hour clock display.

Certification, Service and Decontamination

48. The secondary exhaust HEPA filter design shall allow for the filter to be changed while the cabinet blower is still activated to protect service personnel. 7

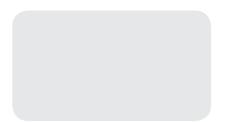
- 49. The cabinet shall be approved for both hydrogen peroxide vapor (HPV) and formaldehyde decontamination protocol, before the removal of secondary exhaust HEPA filter.
- **50.** All panels leading to potentially contaminated and/or hazardous areas shall be color coded red (with the exception of the secondary exhaust HEPA filter directly below the work zone surface).
- 51. All components with the exception of blower / motor and ULPA, HEPA filters shall be located outside of contaminated air spaces to facilitate servicing without the need to decontaminate the cabinet.
- **52.** All exterior surfaces shall be painted with a permanent antimicrobial inhibitor coating to minimize contamination.





Since 1978, Esco has emerged as a leader in the development of controlled environment, laboratory and cleanroom equipment solutions. Products sold in more than 100 countries include biological safety cabinets, cleanroom products, compounding pharmacy equipment, containment / pharma products, ductless fume hoods, in vitro fertilization workstations, lab animal research products, laboratory fume hoods, laboratory ovens and incubators, laminar flow clean benches and PCR products and instrumentation. With the most extensive product line in the industry, Esco has passed more tests, in more languages, for more certifications, throughout more countries than any biosafety cabinet manufacturer in the world. Esco remains dedicated to delivering innovative solutions for the clinical, life science, research and industrial laboratory community. www.escoglobal.com.

Biological Safety Cabinets • Cytotoxic Safety Cabinets • Laminar Flow Clean Benches • Pharmacy Isolators



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