



Purchase Specifications

CYT Cytoculture Cytotoxic Safety Cabinet

General Performance and Certifications

1. 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.
7. 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.
8. 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.
9. 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



- (c) 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 filter changing 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.
 1. 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.
35. 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.
44. 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.
47. 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.
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.
- 53.