Pharmacy Isolators (Positive Pressure)

GPI-PS

Pharmacy Isolators, Positive Pressure Models, provide a safe and clean environment for compounding of non-hazardous, sterile drug preparations and IV admixtures in compliance with USP 797 criteria.

Barrier Isolation Systems

Barrier isolation system provide inherently superior sterility compared to open front clean air devices such as laminar flow clean benches and Class II biological safety cabinets. USP797 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, product quality maintenance after the CSP leaves the pharmacy, isolators are a cost-effective solution especially for lower-volume pharmacies. They reduce operating and renovation costs, take up less space, and are easier to maintain. The positive pressure HPI model is suitable for work involving non-hazardous materials.

The work zone and pass-thru interchange are under positive pressure to the room in order to maintain sterility in case of a breach in the barrier isolation system. Negative pressure models should be selected for antineoplastic or cytotoxic compounding applications.

* 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.

Maximum Protection

- The combination of downflow and exhaust ULPA filters gives the Pharmacy Isolator a fully integrated envelope for product protection in all configurations.
- Advanced mini-pleated supply ULPA filter is tested to >99.999% efficiency for 0.1 to 0.3 micron particulates, significantly better than conventional HEPA filters.
- An improved mini-pleat separation 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.
- Laminar (unidirectional) 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.
- 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.
- 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 ring enable glove change with zero risk of contamination.

General Specifications		GPI-4-PS	GPI-6-PS
External Dimensions (wxdxh)		52.8" x 32.3" x 51.9"	76.8" x 32.3" x 51.9X
Main Chamber Work Zone (wxdxh)		33.1" x 24.0" x 26.4"	57.1" x 24.0" x 26.4"
Pass Through (wxdxh)		13.9" x 24.0" x 26.4"	13.9" x 24.0" x 36.4"
Work Zone and Interchange Chamber		ISO Class 3 (Class 1, Federal Stand. 209E)	
Inlet Filter Type		80% efficiency filter	
Fluorescent Lamp		>950 Lux (>88 foot candles)	
Construction, Main Body	Main Body	1.2 mm (.05") 18 Gauge Electrogavinised steel with white oven baked epoxy ISOCIDE finish	
	Work Tray	1.5(0.6") 16 gauge stainless steel, type 304	
	Side Walls	1.2(0.5") 18 gauge stainless steel, type 304	

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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 without the operator having to reach into the pass-thru interchange area.
- Oval shaped glove ports 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 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

Robust construction and enhanced safety features qualify the Hospital Pharmacy 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 electrogalvanised 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 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 available.

SentinelTM Microprocessor Control, Monitoring System

The 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 pressure is 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 Hospital Pharmacy Isolator fan system is designed for maximum energy efficiency and minimal maintenance.

- Centrifugal, direct-drive, external rotor motors reduce operating costs.
- Unique motor/fan orientations minimize noise and vibration.
- Built-in solid-state variable speed controllers are infinitely adjustable from

Safety and Certification

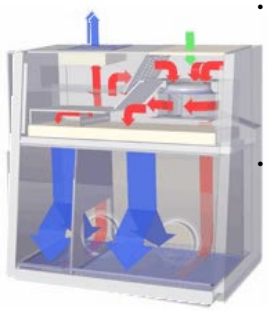
All components used in products meet or exceed all applicable safety requirements.

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

Warranty

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

Cabinet Airflow System



- Ambient air is pulled through the inlet pre-filter and 80% efficient filter located on top of the isolator. The pre-filter traps large size particles to extend the life of the 80% efficient filter.
- Air from the top inlet and from work zone is pulled by the fan, which creates positive pressure on the plenum that creates downflow. Work zone pressure is always higher than the pass-thru, to prevent contaminants from entering the work zone through the pass-thru.
- 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 out by the fan to keep the area clean. The 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 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. This exhausted air is replenished by ambient air coming from the top inlet pre-filter and 80% efficient filter.

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