

PHARM-ASSIST RANGE POSITIVE PRESSURE ISOLATORS

PRODUCT SHEET NO. 123
VERSION 2.0



FOR ASEPTIC HANDLING OF PHARMACEUTICAL PRODUCTS

- Unidirectional airflow in defined critical zone to give EU GMP Grade A air quality for aseptic work and product protection
- Capable of housing equipment such as automatic compounders or sterility testers in the base-tray
- Transfer chambers with electromagnetic timed interlocks and high air change rates for total suppression of airborne contamination during material transfers in and out, and for rapid evaporation of disinfecting agents
- PLC controls for easy set up, operation and maintenance
- Automated pressure decay leak test for indicating results and monitoring trends
- 2-glove and 4-glove models available in rigid (coated stainless steel) or flexible (PVC) construction
- Design and features lend themselves to adaptation into customer specified isolators, for applications ranging from the simple to the highly complex – for more information please contact Envair

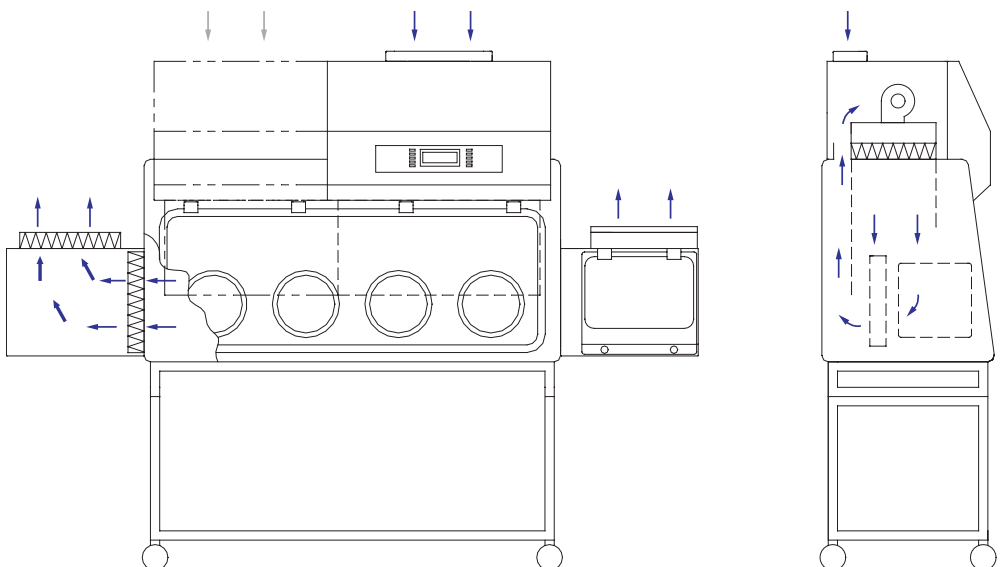


2-glove and 4-glove models



PLC controls for easy set up

AIRFLOW DIAGRAM



AIRFLOW DIAGRAM POSITIVE Pharm-Assist

Standards compliance:

BS EN ISO 14644

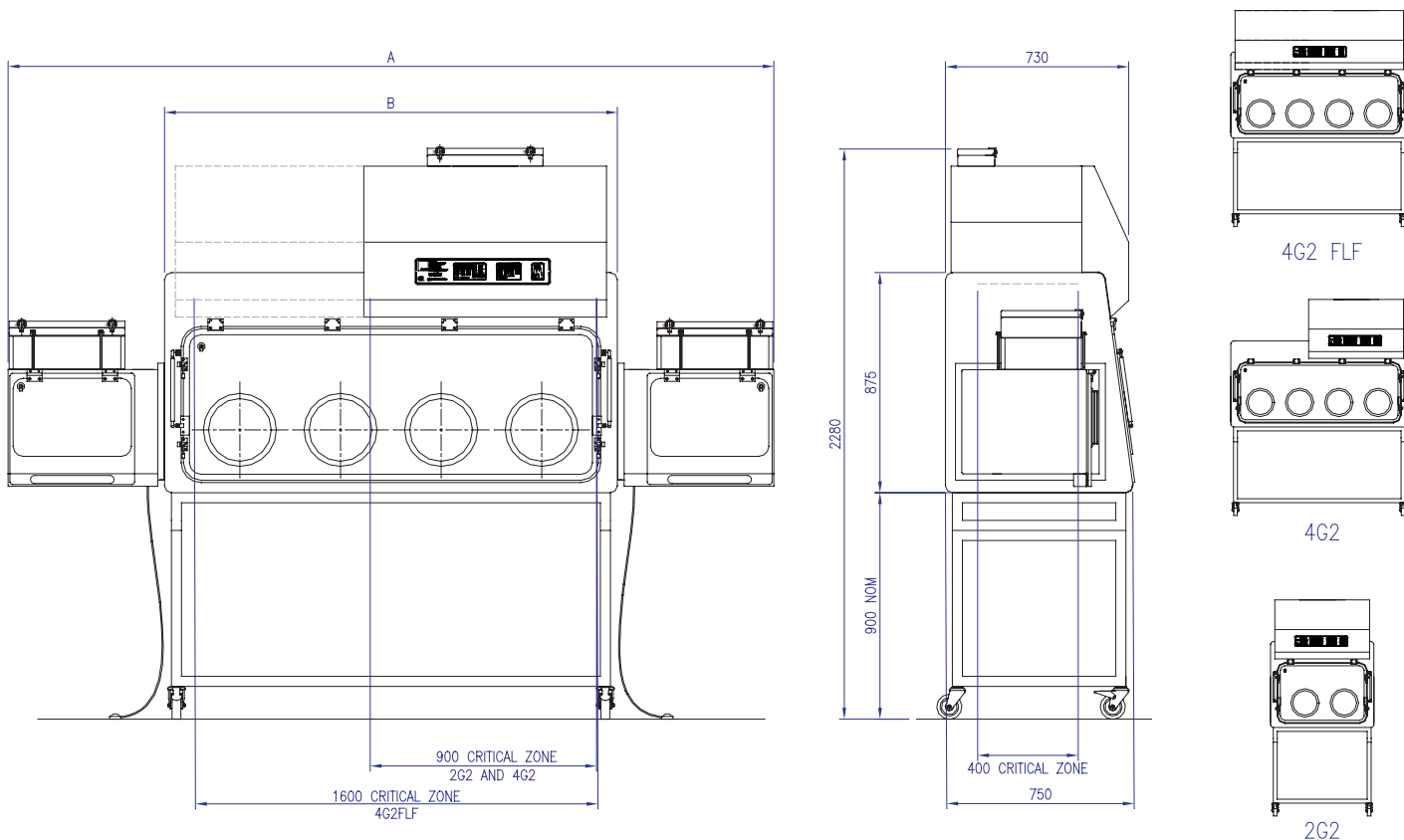
EU GMP

BS EN 1822 (HEPA filters)

IEC 61010-1:2001
(Electric wiring)

'Pharmaceutical Isolators'
Pharmaceutical Press 2004

MODEL DESIGNATIONS AND DIMENSIONS



Model	Model Description	Pharm-Assist R (Rigid)			Pharm-Assist F (Flexible)			All
		A mm	B mm	Wt kg	A mm	B mm	Wt (kg)	Power (Watts)
2G2	Two glove ports, two transfer chambers, full width defined unidirectional airflow zone	2414	1170	320	2290	1050	220	500 (2.2A)
4G2	Four glove ports, two transfer chambers, partial width defined unidirectional airflow zone	3040	1800	380	2920	1800	240	500 (2.2A)
4G2 FLF	Four glove ports, two transfer chambers, full width defined unidirectional airflow zone	3040	1800	395	2920	1800	265	630 (6.3A)

SPECIFICATION AND OPTIONS

Main chamber	<ul style="list-style-type: none"> Rigid (R) models: white polyester coated stainless steel externally and polished internally. <i>Optional external polished stainless finish (R models)</i> Flexible (F) models: high quality 0.5mm PVC canopy sealed to dished 316L stainless steel base-tray, all supported on tubular stainless steel framework Stainless steel hanging rail with six hooks supplied as standard. <i>Optional waste port or continuous liner or double bag out to clients specification</i> Unidirectional airflow (vertically downwards) in defined zone - 0.4 m/s +/- 20% Internal air change rate indicative 750 air changes per hour
Transfer device	<ul style="list-style-type: none"> Two D type double HEPA filtered transfer chambers with electromagnetic interlocks on adjustable timers, footswitches for inner doors, and sliding trays. <i>Optional arrangement with one transfer chamber only</i> High air change rate - 1500 air changes per hour Sealing lids for semi-automatic pressure decay leak test White polyester coated stainless steel externally and internally
Stand	<ul style="list-style-type: none"> Polyester coated mild steel table frame with lockable castors. <i>Optional adjustable levelling feet. Optional 'Vari-Height' electrically operated support frame</i>
Access	<ul style="list-style-type: none"> Large opening acrylic visor, supported by gas springs in the open position, and complete with bonded 300 mm diameter sleeve ports (R models) Optical quality vision panel with welded 300 mm diameter sleeve ports (F models) <i>Optional elliptical ports or other port diameters upon request</i> <i>Optional airtight zipped access port or large simple port for large equipment (F models)</i> Fabric lined polypropylene sleeves, universal cuff-rings and all associated O-rings for aseptic glove changes when used with sterile-wrapped, beaded, powder-free gloves
Controls and electrics	<ul style="list-style-type: none"> PLC control system with touch control membrane and two level password protection Digital display for isolator functions and transfer chamber operation. <i>Optional digital display of transfer chamber pressure</i> Selectable digital display for internal pressure, primary filter pressure drop and downflow air change rate. <i>Optional PLC upgrades including touch screens with control buttons and graphical displays. Optional digital display of transfer chamber pressure</i> Semi-automatic (prompted) pressure decay test <i>Optional fully automatic pressure decay test. Option includes actuated sealing lids for transfer chambers and supply air inlet</i> Latched audible and visible alarm for internal pressure and downflow air change rate failure and for transfer chamber door not closed. Alarm mute. Battery back-up for alarms. Sealed fluorescent lighting giving 500 lux minimum at the work surface Electrics designed for 230v/50Hz1Ph supply. <i>Optional alternative electrical supplies – to be specified by purchaser</i>
Airflow and filtration	<ul style="list-style-type: none"> Air is supplied into the main chamber by the downflow fan and HEPA filter. This air is guided by acrylic downflow screens which define the unidirectional airflow zone. A proportion of the air returns to the downflow fan via a duct at the top rear of the main chamber to mix with the pre-filtered supply air from the room before returning to the downflow fan and HEPA filter. The rest of the air leaves via the two double HEPA-filtered transfer chambers. All HEPA filters H14 (BS EN 1822-1:1998)
Testing and maintenance	<ul style="list-style-type: none"> DOP/particle counter test ports in visor of main chamber and in outer doors of transfer chambers All maintenance from front of unit with lockable front panel for control hardware and downflow system
Additional options	<ul style="list-style-type: none"> 316L stainless steel polished internally and externally (R models) 13 amp single splashproof socket Service taps Cable gland for computer connection Sealed computer screen in rear wall of main chamber CCTV monitoring and recording system Vapour phase hydrogen peroxide biodecontamination system pipework and valves only Vapour phase hydrogen peroxide biodecontamination system Glove sleeve leak test disc with digital manometer Validation with documentation for IQ/OQ including FAT and SAT, or to full GAMP

**All items are alternatives or additional options
Envair has a policy of continuous improvement and reserves the right to change this specification without notice*



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