

CDC F RANGE NEGATIVE PRESSURE ISOLATORS

PRODUCT SHEET NO. 121
VERSION 2.0



FOR SAFE ASEPTIC HANDLING OF CYTOTOXICS

- Negative pressure for operator protection and safety
- EU GMP Grade A unidirectional airflow work area for aseptic work and product protection
- 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
- Automated pressure decay leak test for indicating results and monitoring trends
- PLC controls for easy set up, operation and maintenance
- Good access to all potentially contaminated areas to facilitate cleaning
- Safe to change main (primary) filter
- Two-glove and four-glove, ducted and recirculating models available



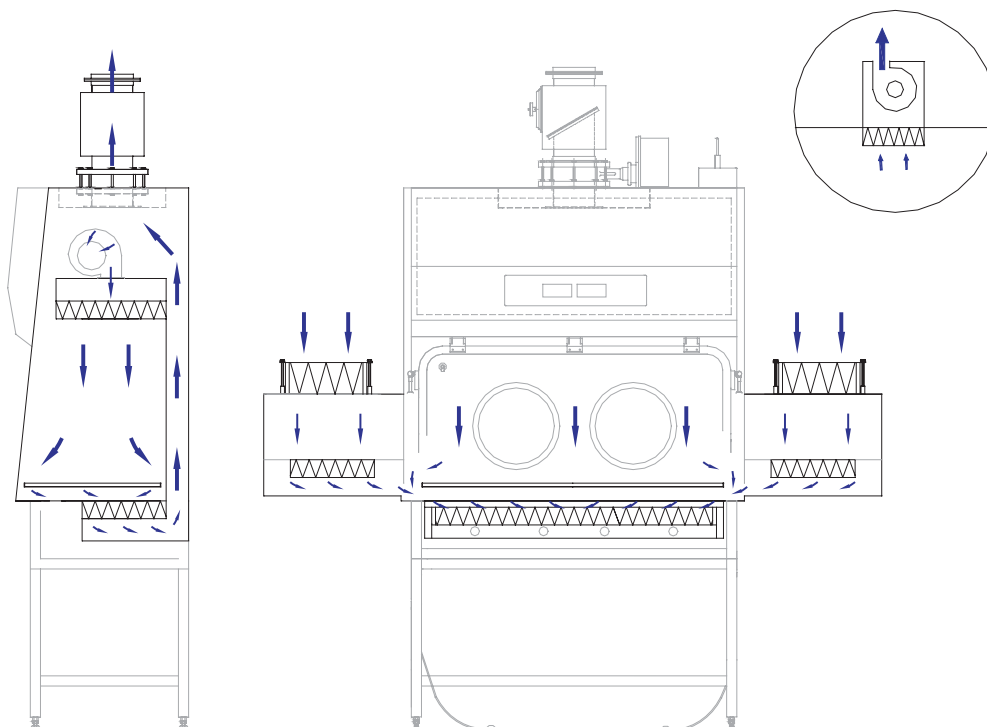
Transfer Chambers



Two-glove and four-glove models

AIRFLOW DIAGRAM

Ducted (D) unit – Inset: fan and second exhaust filter for Recirculating (R) unit



Standards compliance:

BS EN ISO 14644

EU GMP

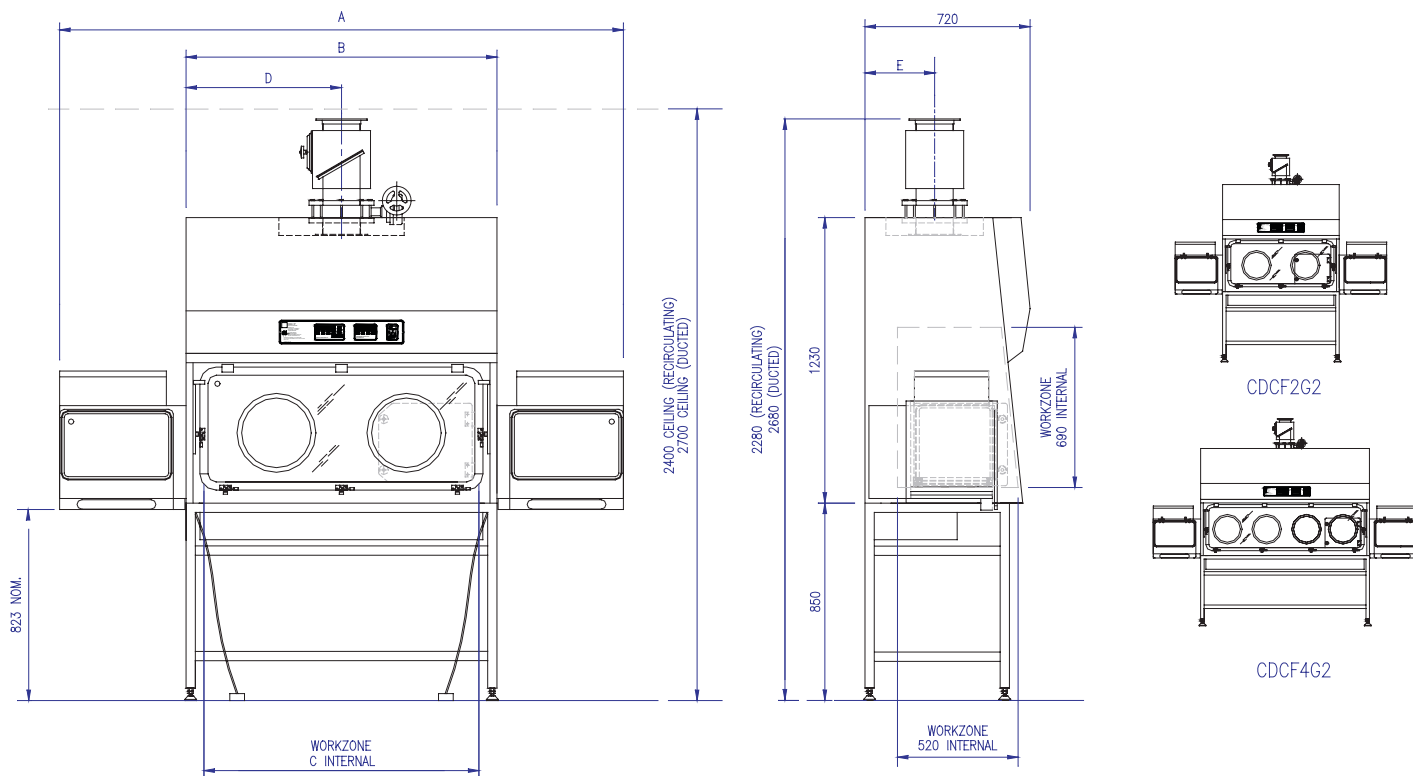
BS EN 1822 (HEPA filters)

IEC 61010-1:2001
(Electric wiring)

'Pharmaceutical Isolators'
Pharmaceutical Press 2004

AS 4273:1999 (when optional
activated carbon filter is fitted)

MODEL DESIGNATIONS AND DIMENSIONS



Model	Model Description	A mm	B mm	C mm	D mm	E mm	Wt Kg	Power Watts	Exhaust m³/s
2G2D	Two glove ports, two transfer chambers, exhaust spigot for connection to dedicated exhaust system (see note below) *	2432	1340	1180	670	280	330	600	0.1
2G2R	Two glove ports, two transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air back to room	2432	1340	1180	670	280	320	900	0.1
2G2D (1.5m)	Exactly as 2G2D but with a wider working area*	2750	1660	1495	830	280	365	660	0.1
2G2R (1.5m)	Exactly as 2G2D but with a wider working area	2750	1660	1495	830	280	365	1000	0.1
4G2D	Four glove ports, two transfer chambers, exhaust spigot for connection to dedicated exhaust system (see note below) *	3030	1940	1780	970	280	395	660	0.1
4G2R	Four glove ports, two transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air back to room.	3030	1940	1780	970	280	380	1000	0.1

* Exhaust systems for all model D isolators require remote fans which should be ordered from Envair or to Envair's specification

SPECIFICATION AND OPTIONS

Main chamber	<ul style="list-style-type: none"> White polyester coated stainless steel internally - <i>Optional 316L stainless steel polished internally*</i> Unidirectional airflow (vertically downwards) - 0.4 m/s +/- 20% Downflow air change rate indicative 2000 air changes per hour 316L stainless steel removable dished worktray - <i>Optional stainless steel hanging rail with six hooks*</i>
Transfer devices	<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 indicative 2000 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 adjustable levelling feet (D models) or lockable castors (R models) - <i>*Optional 'Vari-Height' electrically operated support frame (with bellows duct connection for D models)</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 - <i>Optional elliptical ports or other port diameters upon request*</i> Fabric lined polypropylene sleeves, universal cuff-rings and all associated O-rings for the Envair 'safer aseptic glove change' when used with sterile-wrapped, beaded, powder-free gloves suitable for cytotoxics
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 Semi-automatic (prompted) pressure decay test - <i>Optional fully automatic pressure decay test. Option includes actuated sealing lids for transfer chambers and motorised shut-off damper for exhaust*</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 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"> The primary HEPA filter underneath the work tray filters the mixture of downflow air and air that has entered through the double HEPA-filtered transfer chambers. The combined filtered airstream passes up behind the main chamber to the downflow fan/HEPA filter system and the exhaust system. Both the exhaust system and the downflow fans are thus downstream of the primary HEPA filter. The primary HEPA filter can be sealed and removed into a bag for safe disposal. Potentially contaminated airways and plenums are under negative pressure Vertically mounted anti-blowback damper and manual shut off valve on exhaust (D models only) Remote extract fan (D models only) - <i>Optional motorised shut-off damper for exhaust (D models only)*</i> Integral exhaust HEPA filter and fan box with fan downstream of filter (R models only) - <i>Optional connection for thimble system (R models only)*</i> All HEPA filters H14 (BS EN 1822-1:1998) - <i>Optional exhaust carbon filter for compliance with AS 4273:1999*</i>
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* 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* 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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