

## Negative Pharm-Assist range negative pressure isolators

Product Sheet No. 124 April 2009



### For handling of powders and liquids that are hazardous to personnel

- Negative pressure for operator protection and safety
- 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 high accuracy weighing balances 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
- Easy to clean internal workspace
- Safe to change main exhaust filter
- Automated pressure decay leak test for indicating results and monitoring trends
- PLC controls for easy set up, operation and maintenance
- 2-glove and 4-glove models available as standard
- 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

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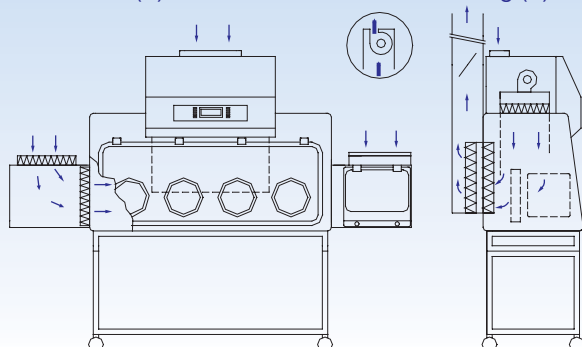
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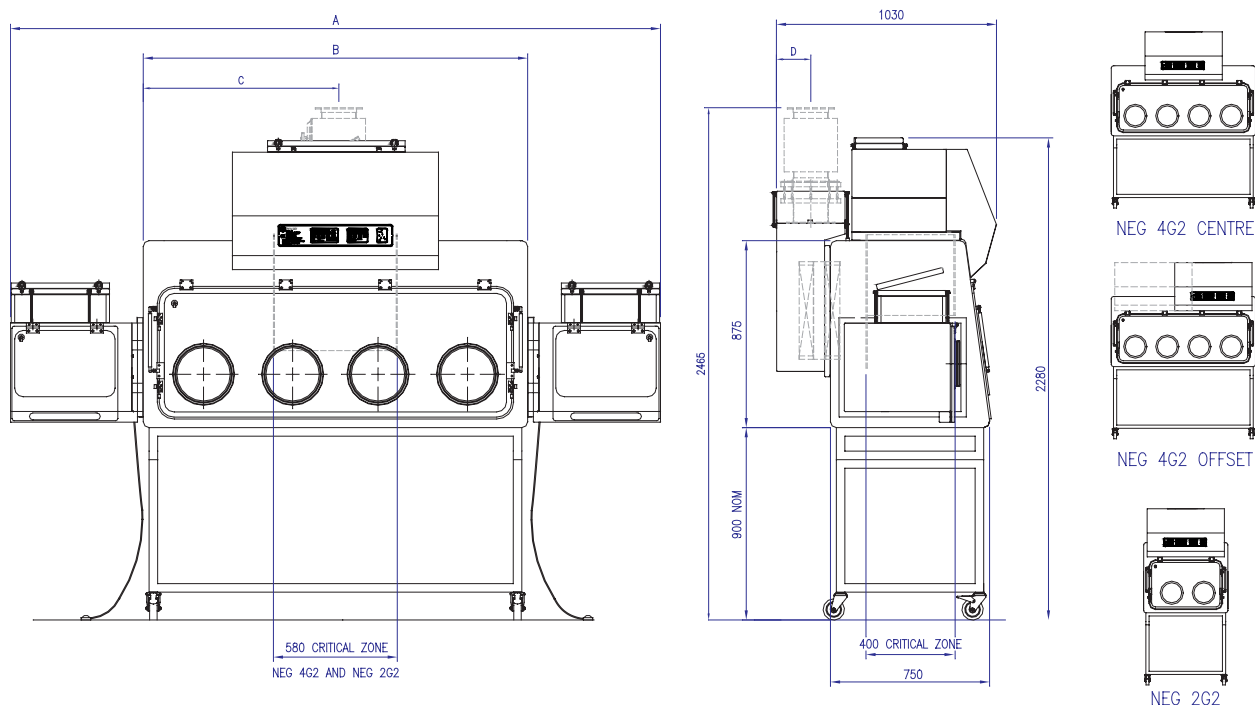
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**Airflow diagram** Ducted (D) unit – Inset: fan for recirculating (R) unit



## Model designations and dimensions



Model	Model Description	A mm	B mm	C mm	D mm	Wt Kg	Power Watts	Exhaust m <sup>3</sup> /s
2G2D	Two glove ports, two transfer chambers, primary and secondary exhaust HEPA filters, exhaust spigot for connection to dedicated exhaust system (see note below) *	2414	1170	580	165	395	293 (1.3A)	0.16
2G2R	Two glove ports, two transfer chambers, primary and secondary exhaust HEPA filter and integral exhaust fan. Recirculates air back to room.	2414	1170	N/A	N/A	395	668 (3.0A)	0.16
4G2D	Four glove ports, two transfer chambers, primary and secondary exhaust HEPA filters, exhaust spigot for connection to dedicated exhaust system (see note below) *	3040	1800	900	165	460	526 (2.5A)	0.16
4G2R	Four glove ports, two transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air back to room.	3040	1800	N/A	N/A	460	937 (4.0A)	0.16

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

### Standards compliance:

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)

## Specification and options

Main chamber	<p>Stainless steel, white polyester coated externally and polished internally</p> <p>Optional stainless steel hanging rail with six hooks supplied as standard</p> <p>Optional waste port or continuous liner or double bag out to clients specification</p> <p>Unidirectional airflow (vertically downwards) in defined zone - 0.4 m/s +/- 20%</p>
Transfer devices	<p>Two D type double HEPA filtered transfer chambers with electromagnetic interlocks on adjustable timers, footswitches for inner doors, and sliding trays</p> <p>Optional arrangement with one transfer chamber only</p> <p>High air change rate - 1600 air changes per hour</p> <p>Sealing lids for semi-automatic pressure decay leak test</p> <p>White polyester coated stainless steel externally and internally</p>
Stand	<p>Polyester coated mild steel table frame with adjustable feet (D models) or lockable castors (R models)</p> <p>Optional 'Vari-Height' electrically operated support frame(with bellows duct connection for D models)</p>
Access	<p>Large opening acrylic visor, supported by gas springs in the open position, and complete with bonded 300 mm diameter sleeve ports (R models)</p> <p>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</p>
Controls and electrics	<p>PLC control system with touch control membrane and two level password protection</p> <p>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</p> <p>Digital display for isolator functions and transfer chamber operation</p> <p>Selectable digital display for internal pressure, primary filter pressure drop and downflow air change rate</p> <p>Optional PLC upgrades including touch screens with control buttons and graphical displays</p> <p>Optional digital display of transfer chamber pressure</p> <p>Semi-automatic (prompted) pressure decay test</p> <p>Optional fully automatic pressure decay test. Option includes actuated sealing lids for transfer chambers and motorised shut-off damper for exhaust</p> <p>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.</p> <p>Sealed fluorescent lighting giving 500 lux minimum at the work surface</p> <p>Electrics designed for 230v/50Hz1Ph supply</p> <p>Optional alternative electrical supplies – to be specified by purchaser</p>
Airflow and filtration	<p>Prefiltered air is supplied into the main chamber by the downflow fan and through the downflow HEPA filter. This air is guided by acrylic downflow screens which define the unidirectional airflow zone. The remote exhaust fan (D models) or integral exhaust fan (R models) has a greater capacity than the downflow fan and draws additional air into the main chamber via the two double HEPA-filtered transfer chambers. All the air leaves via the primary and secondary exhaust HEPA filters.</p> <p>Optional motorised shut-off damper for exhaust</p> <p>All HEPA filters H14 (BS EN 1822-1:1998)</p> <p>Optional exhaust carbon filter</p>
Testing and maintenance	<p>DOP/particle counter test ports in visor of main chamber and in outer doors of transfer chambers</p> <p>All maintenance from front of unit with lockable front panel for control hardware and downflow system</p>
Additional options	<p>316L stainless steel polished internally and externally</p> <p>13 amp single splashproof socket</p> <p>Service taps</p> <p>Cable gland for computer connection</p> <p>CCTV monitoring and recording system</p> <p>Vapour phase hydrogen peroxide biodecontamination system pipework and valves only</p> <p>Vapour phase hydrogen peroxide biodecontamination system</p> <p>Glove sleeve leak test disc with digital manometer</p> <p>Validation with documentation for IQ/OQ including FAT and SAT, or to full GAMP</p>

Note: All items shown in blue are alternatives or additional options

Envair has a policy of continuous improvement and reserves the right to change this specification without notice

## Complete range of Envair products and services

### Isolators



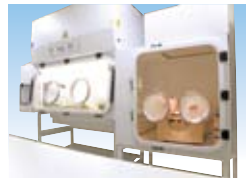
CDC F cytotoxic dispensing isolators



Pharm-Assist isolators



Technetium isolator for nuclear medicine



Blood labelling isolator for nuclear medicine



Negative Pharm-Assist isolators



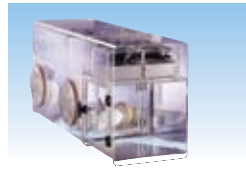
Customer specified isolators



Sterility test isolators



Controlled atmosphere isolators



Micro-Iso and Mini-Iso

### Unidirectional airflow products



HLF horizontal unidirectional (laminar) airflow cabinets



VLF R vertical unidirectional (laminar) airflow cabinets



C-Flow vertical unidirectional (laminar) airflow cabinets



VLF E vertical unidirectional (laminar) airflow enclosures



FFM fan filter modules

### Powder handling products



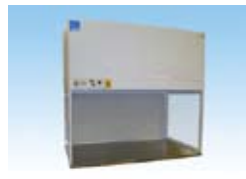
Downflow booths



High accuracy balance weighing isolators



C-Flow-W powder weighing cabinets



RHLF reverse flow cabinets

### Microbiological safety cabinets



Class I microbiological safety cabinets Bio 1+



Class II microbiological safety cabinets Bio 2+



Class III microbiological safety cabinets Bio 3+

### Fume cupboards



Carbon filtered recirculating fume cupboards



Ducted fume cupboards

### Turnkey projects

Envair clean air and containment products integrated with cleanrooms built by other members of the Bassaire Group.

### Service and maintenance

Full testing, service, maintenance and spares support for all Envair and other clean air and containment equipment.



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