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

Airflow diagram
Ducted (D) unit – Inset: fan and second exhaust filter for Recirculating (R) unit
## Model designations and dimensions

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

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

### 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

<table>
<thead>
<tr>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
</table>
| **Main chamber**      | - White polyester coated stainless steel internally  
- Optional 316L stainless steel polished internally  
- 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  
- Optional stainless steel hanging rail with six hooks |
| **Transfer devices**  | - Two D type double HEPA filtered transfer chambers with electromagnetic interlocks on adjustable timers, footswitches for inner doors, and sliding trays  
- Optional arrangement with one transfer chamber only  
- 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**             | - Polyester coated mild steel table frame with adjustable levelling feet (D models) or lockable castors (R models)  
- Optional 'Vari-Height' electrically operated support frame (with bellows duct connection for D models) |
| **Access**            | - Large opening acrylic visor, supported by gas springs in the open position, and complete with bonded 300 mm diameter sleeve ports  
- Optional elliptical ports or other port diameters upon request  
- Fabric lined polypropylene sleeves, universal cuff-rings and all associated O-rings for the Envair 'safer aseptic glove change' when used with sterile-wraped, beaded, powder-free gloves suitable for cytotoxics |
| **Controls and electrics** | - PLC control system with touch control membrane and two level password protection  
- Digital display for isolator functions and transfer chamber operation  
- Optional digital display of transfer chamber pressure  
- Selectable digital display for internal pressure, primary filter pressure drop and downflow air change rate  
- Semi-automatic (prompted) pressure decay test  
- Optional fully automatic pressure decay test. Option includes actuated sealing lids for transfer chambers and motorised shut-off damper for exhaust  
- 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  
- Optional alternative electrical supplies – to be specified by purchaser |
| **Airflow and filtration** | - 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)  
- Optional motorised shut-off damper for exhaust (D models only)  
- Integral exhaust HEPA filter and fan box with fan downstream of filter (R models only)  
- Optional connection for thimble system (R models only)  
- All HEPA filters H14 (BS EN 1822-1:1998)  
- Optional exhaust carbon filter for compliance with AS 4273:1999 |
| **Testing and maintenance** | - 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** | - 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 |

*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.

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

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