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
### Pharm-Assist range

#### Model designations and dimensions

<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
<th>Pharm-Assist R (Rigid)</th>
<th>Pharm-Assist F (Flexible)</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>A mm</td>
<td>B mm</td>
<td>Wt kg</td>
</tr>
<tr>
<td>2G2</td>
<td>Two glove ports, two transfer chambers, full width defined unidirectional airflow zone</td>
<td>2414</td>
<td>1170</td>
<td>320</td>
</tr>
<tr>
<td>4G2</td>
<td>Four glove ports, two transfer chambers, partial width defined unidirectional airflow zone</td>
<td>3040</td>
<td>1800</td>
<td>380</td>
</tr>
<tr>
<td>4G2 FLF</td>
<td>Four glove ports, two transfer chambers, full width defined unidirectional airflow zone</td>
<td>3040</td>
<td>1800</td>
<td>395</td>
</tr>
</tbody>
</table>

### Standards compliance:
- BS EN ISO 14644
- EU GMP
- BS EN 1822 (HEPA filters)
- IEC 61010-1:2001 (Electric wiring)
- ‘Pharmaceutical Isolators’ Pharmaceutical Press 2004
## Pharm-Assist range

### Specification and options

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Main chamber**   | Rigid (R) models: white polyester coated stainless steel externally and polished internally  
Optional external polished stainless finish (R models)  
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  
Optional waste port or continuous liner or double bag out to clients specification  
Unidirectional airflow (vertically downwards) in defined zone - 0.4 m/s +/- 20%  
Internal air change rate indicative 750 air changes per hour |
| **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 - 1500 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 lockable castors  
Optional adjustable levelling feet  
Optional 'Vari-Height' electrically operated support frame |
| **Access** | 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)  
Optional elliptical ports or other port diameters upon request  
Optional airtight zipped access port or large simple port for large equipment (F models)  
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** | 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  
Optional PLC upgrades including touch screens with control buttons and graphical displays  
Optional digital display of transfer chamber pressure  
Semi-automatic (prompted) pressure decay test  
Optional fully automatic pressure decay test. Option includes actuated sealing lids for transfer chambers and supply air inlet  
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  
Optional alternative electrical supplies – to be specified by purchaser |
| **Airflow and filtration** | 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** | 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 (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 |

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+
- CDC F cytotoxic dispensing 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

**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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