



For safe aseptic eluting of technetium generators and dispensing of radiopharmaceuticals in nuclear medicine

- Negative pressure for operator protection and safety
- EU GMP Grade A unidirectional airflow work area
- Transfer chamber with electromagnetic timed interlocks and high air change rate for elimination of airborne contamination during material transfers, and rapid evaporation of disinfecting agents
- Technetium transfer chamber with mechanically locked visor
- 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 standard model or linked suites built to customer requirements.
- Thimble exhaust units also available

Envair Limited

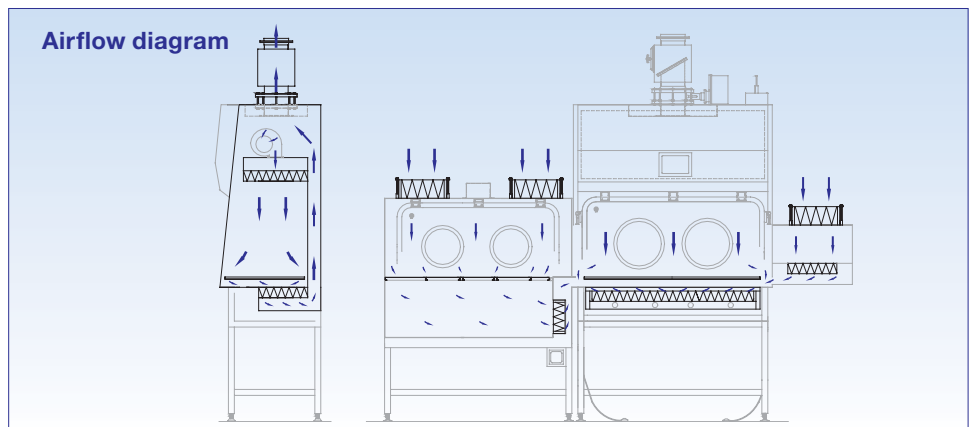
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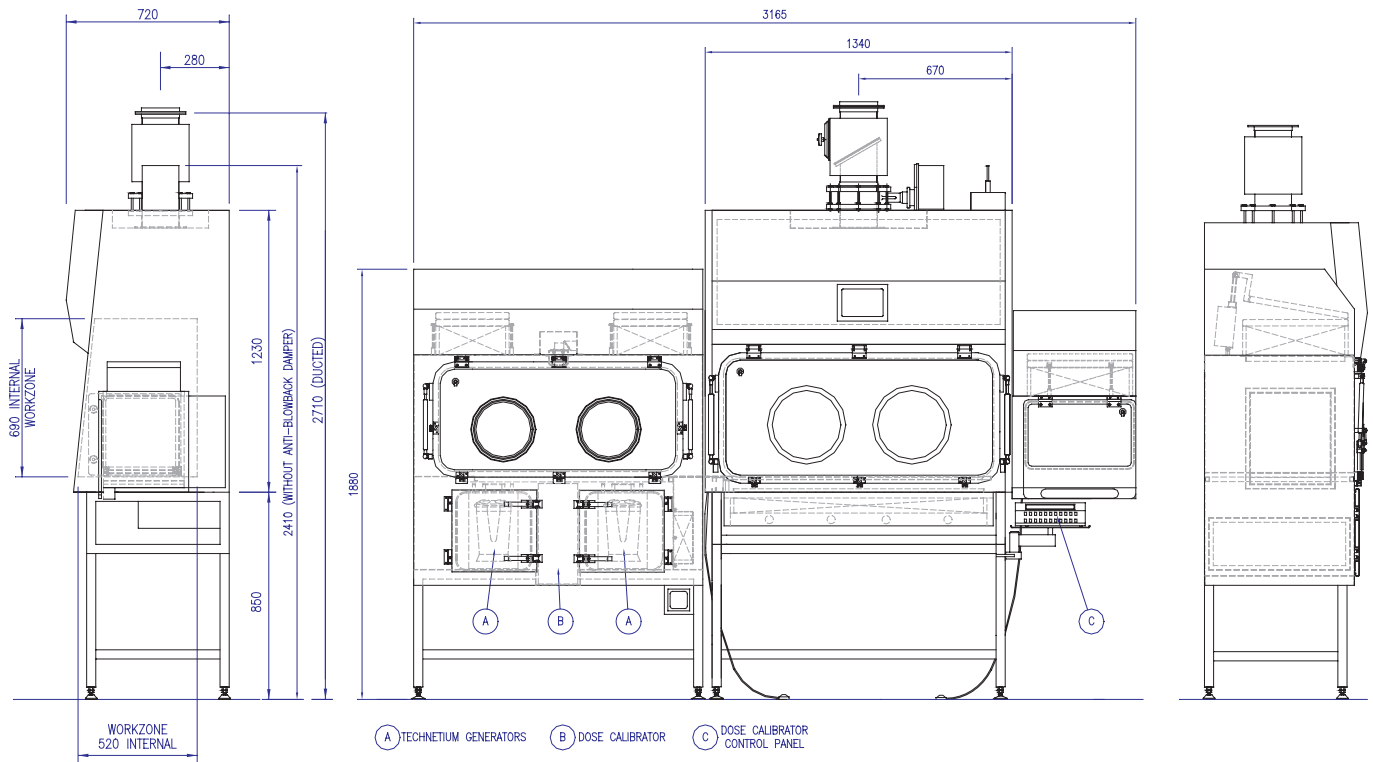
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Model designations and dimensions



Model	Model Description	Wt Kg	Power Watts	Exhaust m ³ /s
2G2D	Two glove ports, two transfer chambers, exhaust spigot for connection to dedicated exhaust system (see note below) *	530	600	0.1

* Exhaust system requires remote fan which should be ordered from Envair or to Envair's specification

Equipment:

Type of generator catered for (all with secondary shielding):

- Drytec
- Elumatic III
- Mallinckrodt

Type of dose calibrators catered for:

- Capintec CRC25R
- Atomlab 200

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>White polyester coated stainless steel internally</p> <p>Optional 316L stainless steel polished internally</p> <p>Unidirectional airflow (vertically downwards) - 0.4 m/s +/- 20%</p> <p>Downflow air change rate indicative 2000 air changes per hour</p> <p>316L stainless steel removable dished worktray</p> <p>Optional stainless steel hanging rail with six hooks</p> <p>3mm Lead lining to base and front lip</p>
Transfer device	<p>D type double HEPA filtered transfer chamber with electromagnetic interlocks on adjustable timers, footswitch for inner doors, and sliding tray</p> <p>High air change rate indicative 2000 air changes per hour</p> <p>White polyester coated stainless steel externally and internally</p> <p>Easy to clean transfer hatch cowl</p>
Technetium Transfer Device	<p>D type double HEPA filtered transfer chamber with mechanical locking on visor</p> <p>High air change rate indicative 770 air changes per hour</p> <p>Lead acrylic main visor (1.1mm Pb equivalent)</p> <p>Large base section for two technetium generators with secondary shielding, and dose calibrator</p> <p>Two access doors with lockable handles for generator loading/un-loading</p> <p>Sealed internal fluorescent light with easy clean diffuser</p> <p>316L stainless steel removable worktrays</p> <p>Access to generators and calibrator through glove ports</p> <p>Easy to clean transfer hatch cowl</p>
Stand	<p>Polyester coated mild steel table frame with adjustable levelling feet</p> <p>Optional stainless steel polished all over</p>
Access	<p>Large opening lead acrylic visor (1.1mm Pb equivalent), supported by gas springs in the open position, and complete with bonded 300 mm diameter sleeve ports</p> <p>Optional elliptical ports or other port diameters upon request</p> <p>Fabric lined polypropylene sleeves, universal cuff-rings and all associated O-rings for the Envair 'safer aseptic glove change' when used with suitable sterile-wrapped, beaded, powder-free gloves</p> <p>Optional gauntlets</p>
Controls and electrics	<p>PLC control system with touch control HMI panel and two level password protection</p> <p>Digital display for isolator functions and transfer chamber operation</p> <p>Optional digital display of transfer chamber pressure</p> <p>Selectable digital display for internal pressure, primary filter pressure drop and downflow air change rate</p> <p>Fully automatic pressure decay test including 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 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>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.</p> <p>The primary HEPA filter can be sealed and removed into a bag for safe disposal.</p> <p>Potentially contaminated airways and plenums are under negative pressure</p> <p>Vertically mounted anti-blowback damper and manual shut off valve on exhaust</p> <p>All HEPA filters H14 (BS EN 1822-1:1998)</p> <p>Optional remote extract fan</p> <p>Optional exhaust carbon filter for compliance with AS 4273:1999</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>Optional thimble system model</p> <p>316L stainless steel polished internally and externally</p> <p>13 amp single splashproof socket</p> <p>Cable gland for computer connection</p> <p>Sealed computer screen in rear wall of main chamber</p> <p>CCTV monitoring and recording system</p> <p>Stainless steel tri-clover connections for particle counting sampling head</p> <p>Vapour phase hydrogen peroxide biodecontamination system</p> <p>1.5mm or 2.2mm Pb equivalent lead acrylic visors</p> <p>3mm lead lining to work area sides and rear</p> <p>Small scissor lift table for generator handling from storage to isolator</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



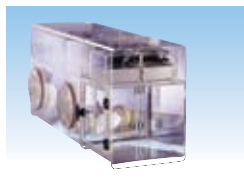
Customer specified isolators



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



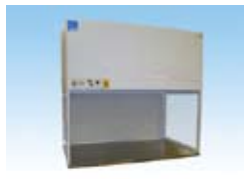
Downflow booths



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.

ENVAIR

Integrity in clean air

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