CDC F Range

POSITIVE PRESSURE ISOLATORS

ENVAIR
Integrity in clean air

Positive pressure isolators for aseptic handling of pharmaceutical products

Safe aseptic handling of pharmaceutical products

This range of positive pressure isolators has been designed for pharmacy routines requiring the aseptic handling of pharmaceutical products in an EC GMP Grade A environment with a degree of operator protection.

They are widely used in NHS hospital pharmacies for CIVAS (Central Intravenous Additive Service), TPN compounding and bagging, preparation of IV solutions and eye-drops, ampoule filling, etc.

KEY FEATURES

- Positive pressure for product protection
- 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 primary exhaust HEPA
- Two-glove and four-glove, ducted and recirculating models available

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PART OF ENVAIR TECHNOLOGY

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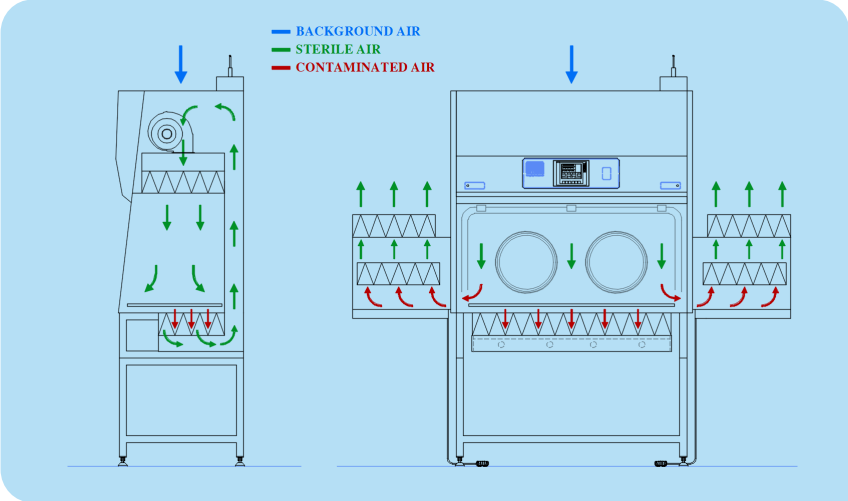
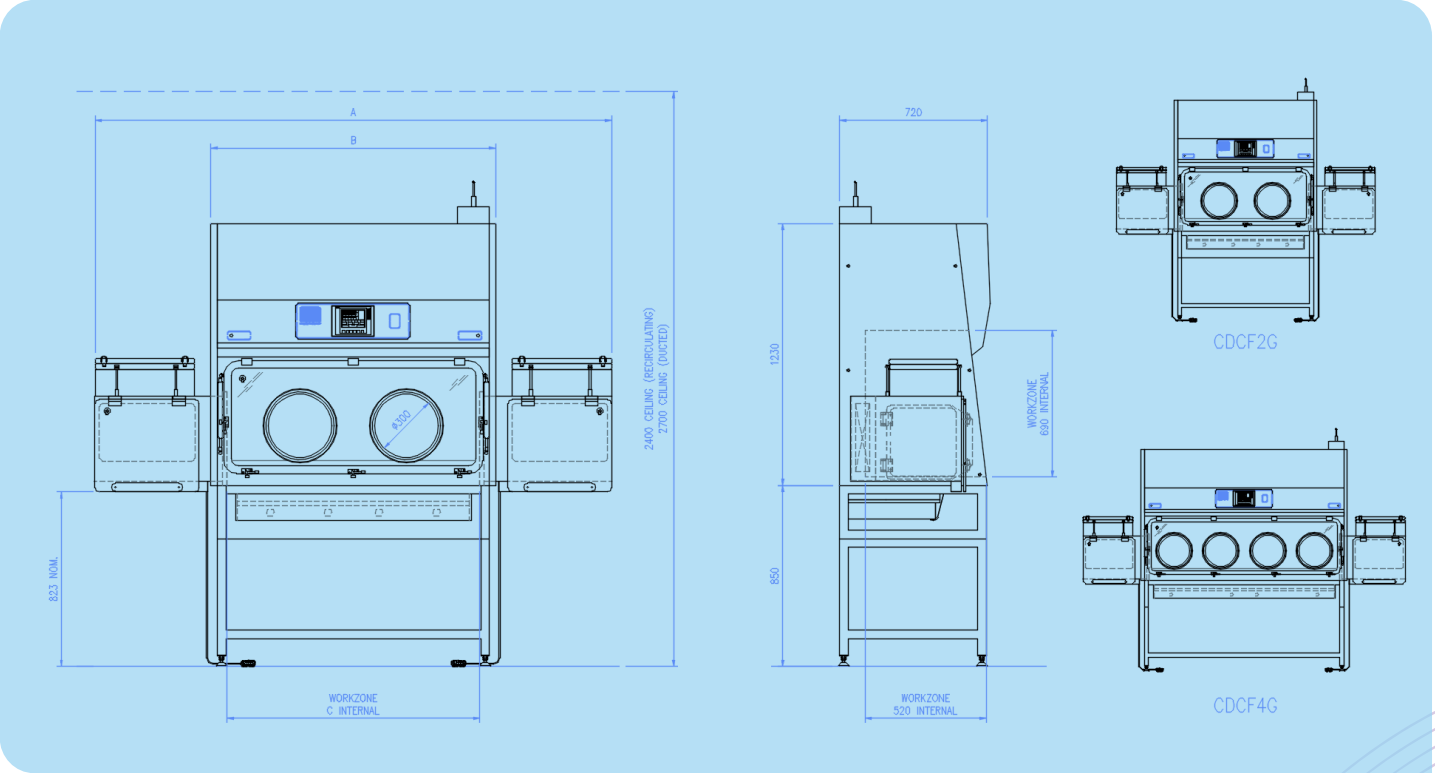
Airflow diagram

Recirculating (R) unit



Model designations and dimensions



MODEL	MODEL DESCRIPTION	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	Wt (kg)	Power Watts
2G2R (1.2m)	Two glove ports, two transfer chambers. Recirculates air back to room.	2432	1340	1180	670	280	320	900
2G2R (1.5m)	Two glove ports, two transfer chambers. Recirculates air back to room.	2750	1660	1495	830	280	365	1000
4G2R (1.8m)	Four glove ports, two transfer chambers. Recirculates air back to room.	3030	1940	1780	970	280	385	1000

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STANDARD SPECIFICATION		UPGRADES
Main chamber	• White polyester coated stainless steel internally • Unidirectional airflow (vertically downwards) - 0.4 m/s +/- 20% • Downflow air change rate indicative 1800 air changes per hour • 316L stainless steel removable dished worktray	• Optional 316L stainless steel polished internally
Transfer devices	• Two D type double HEPA filtered transfer chambers with electromagnetic interlocks on adjustable timers, footswitches for inner doors and sliding trays • High air change rate indicative 2500 air changes per hour • Manual sealing lids for automated pressure decay leak test • White polyester coated stainless steel externally and internally	• Optional arrangement with one transfer chamber only • Option for electrically actuated sealing lids for fully automatic pressure decay leak test
Stand	• Polyester coated mild steel table frame with adjustable levelling feet or lockable castors	• 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 • Fabric lined polyurethane sleeves, safe change 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	• Optional elliptical ports or other port diameters upon request • Alternative two part safe change cuff system available
Controls and electrics	• PLC control system with touch control membrane and password protection for different levels of access control • Touchscreen HMI displays critical operating parameters and interlock controls and status at all times • Internal pressure (Pa), Downflow Velocity (m/s), HEPA filter differential (Pa) and Total Air Change (TAC/Hr) displayed • Automated (prompted) pressure decay test • 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 LED Tubes giving 500 lux at the work surface • Electrics designed for 230v/50Hz1Ph supply	• Optional digital display of transfer chamber pressure • Optional fully automatic pressure decay leak test includes electrically actuated sealing for transfer chambers and high level exhaust • Optional alternative electrical supplies – to be specified by purchaser
Airflow and filtration	• The primary exhaust HEPA filter underneath the work tray filters the air leaving the work area before being exhausted back to the room through the double HEPA filtered transfer hatches • The primary exhaust HEPA filter can be sealed and removed into a bag for safe disposal • Potentially contaminated airways and plenums are under negative pressure • All HEPA filters H14 (BS EN 1822-1:2019)	• Optional exhaust carbon filter for compliance with AS NZ 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	

OPTIONAL EXTRAS

- 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

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Choice of two-glove and four-glove models

Transfer chambers

STANDARDS COMPLIANCE

BS EN ISO 14644, EU GMP, BS EN 1822 (HEPA FILTERS), IEC 61010-1:2001 (ELECTRIC WIRING), 'PHARMACEUTICAL ISOLATORS' PHARMACEUTICAL, PRESS 2004

QUALITY STATEMENT

Since 1972, Envair have been pioneering the engineering of bespoke GMP compliant ultra-clean and containment equipment for the medical, healthcare, biotech and pharmaceutical industries.

To ensure lifetime, trouble-free use, we provide a comprehensive maintenance, testing and parts service. Please ask us for details.

As part of Envair Technology, we can also offer access to a full portfolio of flexible containment and process solutions.

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