

CDC F ABD Range

NEGATIVE PRESSURE SPRAY AND
WIPE ISOLATORS WITH AUTOMATED
BIO-DECONTAMINATION



Clean Air & Containment



Safe aseptic handling of cytotoxics

Envair Technology's trusted Pharmaceutical Isolator the CDC is now available with an automated, validated and controlled bio-decontamination process of the interior, using a sporicidal agent in a vaporised form to provide a 6-log overnight sporicidal kill.

This range of negative pressure isolators has been designed to prevent pharmacy and laboratory workers from dangerous exposure to cytotoxic drugs. They also ensure products are protected from microbiological contamination.

With a choice of two or four gloves, wide or narrower working areas and additional exhaust fans and filters, these high-performance isolators are easy to set up, operate and maintain.

KEY FEATURES

- Integrated Vaporised Hydrogen Peroxide (VHP) decontamination system, capable of providing a 6-log sporicidal kill bio-decontamination
- Closed loop configuration requiring no external ducting or room modifications
- Fully automated lids and valves providing a seamless process, with the bonus of making the pressure decay test fully automated
- Upgraded internal isolator materials - all internal surfaces are polished 316L Stainless steel to provide superior resistance to the VHP
- Upgraded Siemens TP700 Comfort HMI Panel, providing enhanced connectivity

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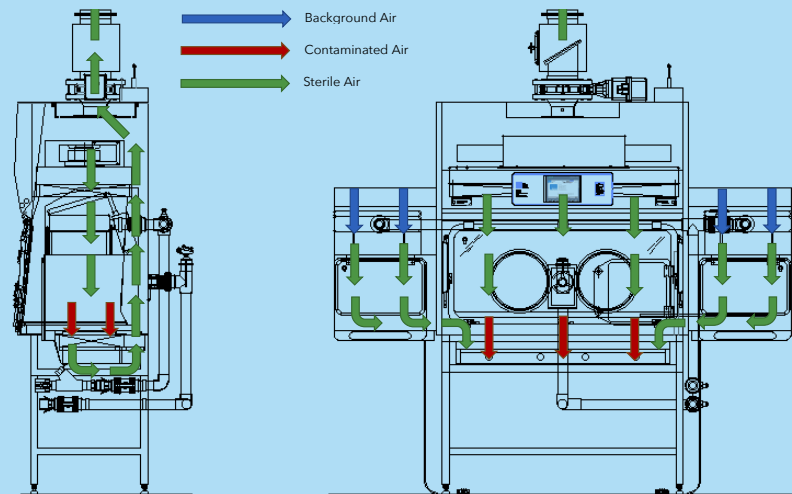
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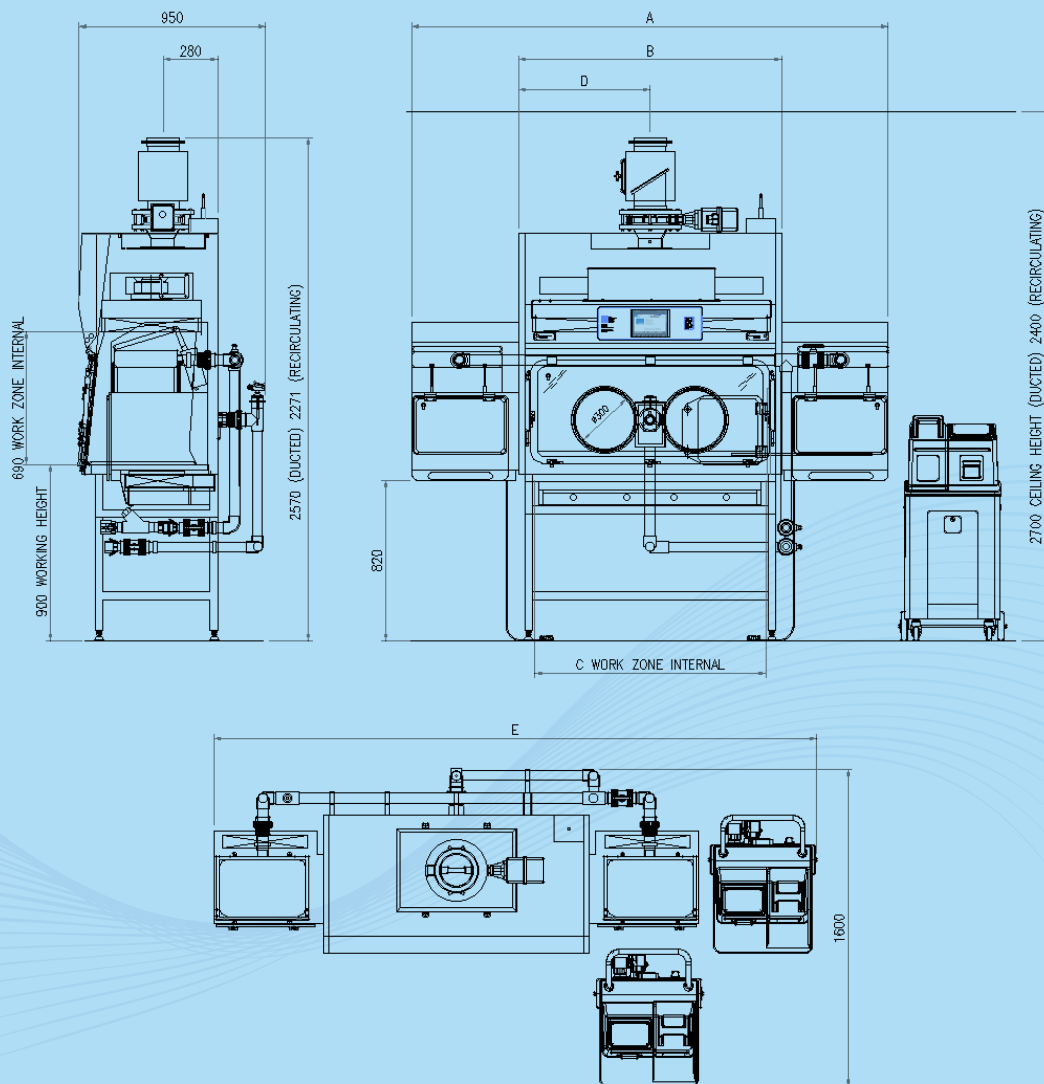


Airflow diagram

Ducted (D) unit shown – internal airflows are identical for recirculating and thimble extract versions.



Model designations and dimensions



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MODEL	MODEL DESCRIPTION	A (mm)	B (mm)	C (mm)	D (mm)	E (mm)	Wt (kg)	Power Watts
2G2D (1.2m)	2 glove ports, 2 transfer chambers, exhaust spigot for connection to dedicated exhaust system	2430	1340	1180	670	3035	350	600
2G2R (1.2m)	2 glove ports, 2 transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air back to room.	2432	1340	1180	670	3035	350	900
2G2RD (1.2m)	2 glove ports, 2 transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air into thimble extract system	2432	1340	1180	1437	3035	350	900
2G2D (1.5m)	2 glove ports, 2 transfer chambers, exhaust spigot for connection to dedicated exhaust system	2750	1660	1495	830	3345	380	660
2G2R (1.5m)	2 glove ports, 2 transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air back to room.	2750	1660	1495	830	3345	380	1000
2G2RD (1.5m)	2 glove ports, 2 transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air into thimble extract system	2750	1660	1495	1757	3345	380	1000
4G2D (1.8m)	4 glove ports, 2 transfer chambers, exhaust spigot for connection to dedicated exhaust system	3030	1940	1780	970	3625	400	660
4G2R (1.8m)	4 glove ports, 2 transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air back to room.	3030	1940	1780	970	3625	400	1000
4G2RD (1.8m)	4 glove ports, 2 transfer chambers, additional secondary exhaust HEPA filter and integral exhaust fan. Recirculates air into thimble extract system	3030	1940	1780	2037	3625	400	1000

* Exhaust speed for all models is 0.1 m/s. Model D isolators require remote fans which should be ordered from Envair Technology or to Envair Technology's specification.
Envair Technology has a policy of continuous improvement and reserves the right to change this specification without notice.



2 Glove model with optional viable and non-viable particle counting options



Optional height and angle adjustable foot rest

STANDARD SPECIFICATION		OPTIONAL UPGRADES
Main chamber	• 316L Stainless steel, polished internally to 0.8Ra • White polyester coated externally • 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 • Rigid VHP UPVC Corzan piping installed at the rear of each isolator with automated shut off valves (no trace heating or insulation on pipework). • VHP sample point (Bioquell PN 10073556) installed on generator side of the return pipework, after the automated ball valve • Rotating VHP injection nozzle installed through main chamber rear wall. • Fan cassettes, underduct, main shell/external back/rear/top and front access panel in 304 stainless steel mill finish • 2 or 4 glove sleeve extenders	• Stainless steel polished externally • Stainless steel hanging rail with six hooks • 17" Touchscreen monitor installed on the main chamber rear wall • Isokinetic head for continuous non-viable particle counting (counter not included) • Integration of free issued BD CATO hardware into the main chamber (scales & camera/scanner free issued) • Services – data power etc • CCTV camera
Transfer devices	• 2 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 • Electrically actuated sealing lids for fully automated pressure decay leak test • White polyester coated stainless steel externally • Internally 316L Stainless steel, polished internally to 0.8Ra • VHP return outlets installed at the rear of transfer hatches	• Arrangement with only 1 transfer chamber • Upgrade polypropylene sliding hatch transfer trays to stainless steel • Internal hatch pressure monitoring
Stand (Table Frame)	Polyester coated mild steel table frame with: • Adjustable levelling feet (D models) • Lockable castors (R & RD models)	• Optional 'Vari-Height' electrically operated support frame (with flexible connection for ducted models)
Access	• Large opening PeeraGuard™ hard coated 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 Technology '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 2-part safe change cuff system available
Controls and Electrics	• TP700 Comfort HMI Panel - including 2GB SD memory card • PLC control system with touch control membrane and password protection for different levels of access control • Touchscreen HMI displaying critical operating parameters, 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 transfer chamber door not closed, with alarm mute • Battery back-up for alarms • Sealed LED tubes giving 500 lux at the work surface • Electrics designed for 230v/50Hz1Ph supply	• Digital display of transfer chamber pressure • 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 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 required (D models only) • Integral exhaust HEPA filter and fan box with fan downstream of filter (R / RD models only) • All HEPA filters H14 (BS EN 1822-1:2019) • Stainless steel HEPA filter mesh	• Connection for thimble system (R models only) • Exhaust carbon filter for compliance with AS NZ 4273:1999

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STANDARD SPECIFICATION		OPTIONAL UPGRADES
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	
VHP Generator	• 1no Bioquell L-4 Hydrogen Peroxide Vapour Generator • Generator integration testing with 1no isolator. • 1no Gassing Cycle Development Service (Isolator empty system cycle) • 1no Gassing Cycle Performance Qualification (isolator single load system cycle) • 1no VHP supply & 1no return hose • IQ/OQ commissioning for 1no generator • 1no operator training day • 1no Portasens handheld low level H2O2 gas detector • Clients are required to purchase Hydrogen Peroxide bottles directly from Bioquell	• Additional Gassing cycles (with load)

OPTIONAL EXTRAS

- Cable gland for computer connection
- Glove sleeve leak test disc with digital manometer
- Validation with documentation for IQ/OQ including FAT and SAT, or to full GAMP
- Manual 300mm negative pressure glove sleeve test disc with digital manometer
- 5-minute uninterrupted power supply
- Licenced software: SCADA, Win CC Audit, Simatic Logon Server, Simatic Logon Client
- Panel mounted thermal printer installed beside the isolators HMI
- BMS interface signals
- Mobile footrest with inner hatch door pedal brackets
- Remote exhaust fan control



Rear view showing optional particle counter and valves



Close up of VHP injection pipework at rear

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Optional CCTV camera



Siemens PLC and HMI control



Optional viable and non-viable particle counting



Mobile VHP generator HMI

STANDARDS COMPLIANCE

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

PHARMACEUTICAL ISOLATORS BY PHARMACEUTICAL PRESS 2004
AS 4273:1999 (WHEN OPTIONAL ACTIVATED CARBON FILTER IS
FITTED)

QUALITY STATEMENT

Envair Technology provide world class design and manufacturing expertise for a full portfolio of cleanroom and containment solutions. We work with healthcare, pharmaceutical and laboratory facilities around the world, to protect the safety of teams handling hazardous compounds and maintain product integrity. Our engineers and production team are committed to the highest standards of excellence, meeting the requirements of ISO 9001:2015. We provide a comprehensive maintenance, testing and parts service for all our products, to ensure a lifetime of trouble-free use.

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