CDC 'F' range

Optional Extras	2G2D	2G2R	4G2D	4G2R
• Actuated sealing devices (transfer chambers and exhaust) for fully automatic pressure decay test	O	O	O	O
• Motorised shut off damper	O		O	
• Glove-sleeve leak test disc with digital manometer	O	O	O	O
• 'Vari-Height' electrically operated support frame (+bellows duct conection for ducted units)	O	O	O	O
• PLC upgrades including colour touchscreens with control buttons, graphical displays and transfer chamber pressure monitoring	O	O	O	O
• Exhaust carbon filter	O	O	O	O
• Stainless steel hanging rail with six hooks	O	O	O	O
• 316L stainless steel polished internally and externally	O	O	O	O
• 13 amp single splashproof socket(s)	O	O	O	O
• Cable gland for computer connection	O	O	O	O
• CCTV monitoring and recording system	O	O	O	O
• H202 vapour phase biodecontamination system	O	O	O	O
• Validation (including documentation) to IQ/OQ including FAT and SAT or to full GAMP	O	O	O	O
• Standard specification with only 1 transfer hatch	O	O	O	O

Useful Information

BS EN ISO 14644-4: 2001 DEFINITIONS

Unidirectional airflow:

Controlled airflow through the entire cross section of a clean zone with a steady velocity and approximately parallel streamlines.
Note: This type of airflow results in a directed transport of particles from the clean zone.

Non-unidirectional airflow:

Air distribution where the supply air entering the clean zone mixes with the internal air by means of induction.

EC GMP REVISION TO ANNEX 1: MANUFACTURE OF STERILE MEDICINAL PRODUCTS (September 2003)

Airborne particulate classification

	at rest		in operation	
Grade	Maximum permitted number of particles /m^3 equal to or above			
	0.5 µm	5 µm	0.5 µm	5 µm
A	3 500	1	3 500	1
B	3 500	1	350 000	2 000
C	3 50 000	2 000	3 500 000	20 000
D	3 500 000	20 000	not defined	not defined

"The particulate conditions given in the above table for the "at rest" state should be achieved after a short "clean up" period of 15 - 20 minutes (guidance value) in an unmanned state after completion of operations. The particulate conditions for grade A "in operation" given in the table should be maintained in the zone immediately surrounding the product whenever the product or open container is exposed to the environment".

Recommended limits for microbiological monitoring of clean areas during operation

	Recommended limits for microbiological contamination			
Grade	Air sample cfu/m^3	Settle plates (dia.90mm) cfu/4 hours	Contact plates (dia.55mm) cfu/plate)	Glove print 5 fingers cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

The first 2 columns represent limits for airborne microbial contamination and the last 2 represent limits for microbial contamination of surfaces. Clean air equipment is designed to minimise the possibility of airborne contamination. Surface contamination should be addressed by a suitable sanitisation or disinfection process with a validated SOP.

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Product Sheet 121
April 2006

ENVAIR

NEGATIVE PRESSURE ISOLATORS - CDC 'F' range

Negative pressure rigid isolators with EC GMP Grade A unidirectional airflow, functionally designed for the safe aseptic handling of hazardous materials.

Applications

Reconstitution and dispensing of cytotoxics and other medical products that are hazardous to personnel, manipulation of radiopharmaceuticals and blood labelling (RAD versions), high level containment of biological materials, balance weighing and other processing of materials subject to COSHH regulations.

Benefits

- Carefully designed, extensively tested and widely used to provide assurance of operator safety for the handling of toxic liquids and powders (subject to proper siting, operation and maintenance)
- Negative pressure to satisfy the predominant requirement of operator protection and safety
- EC GMP Grade A unidirectional downflow of HEPA filtered air in the controlled workspace to provide the best possible aseptic environment for product and process protection
- High air change rate in transfer chambers giving rapid clean-up of airborne contamination for safe aseptic transfers and rapid evaporation of disinfecting agents.
- PLC control system to provide improved monitoring and control, automation of certain functions that would otherwise require SOPs, and options to integrate with other equipment
- Uncomplicated validation

Standards Compliance

- BS EN ISO 14644-7: 2004
- Air classification in controlled workspace Grade A (unidirectional airflow) to EC GMP and ISO Class 5 to BS EN ISO 14644-1: 1999
- All HEPA filters to BS EN 1822-1: 1998
- Electrical wiring designed to IEC 61010-1: 2001
- 'Isolators for Pharmaceutical Applications' HMSO 1994
- 'Pharmaceutical Isolators' Pharmaceutical Press 2004
- AS 4273: 1999 (when optional activated carbon filter is fitted)

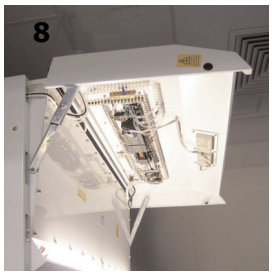
Principal Design Features

- Large round 300mm dia. glove ports for easy operation, good visibility and operator comfort
- EC GMP Grade A unidirectional airflow in the whole controlled workspace
- Main chamber and transfer chambers in high quality white polyester coated stainless steel externally and internally
- Safe to change main filter directly under work tray to eliminate contaminated ducts and plenums
- PLC control system with (1) integration of metering, alarms, door interlock controls and semi-automatic prompted pressure decay test; (2) comprehensive alphanumeric displays and recording of key parameters; (3) capability of interfacing with other machines
- D type (double filtered) transfer chambers with sliding trays, large doors, solid-state magnetic locking and interlocking (no handles), footswitch for inner doors and fully flexible interlock timings
- Safe aseptic quick-change glove system that does not compromise the internal atmosphere of the isolator and suitable for most types and sizes of sterile-packed beaded hospital gloves
- Wipe down keyboard facia
- Easy to clean inside and out
- Easy to monitor, test and service
- Battery back-up for alarms

ENVAIR

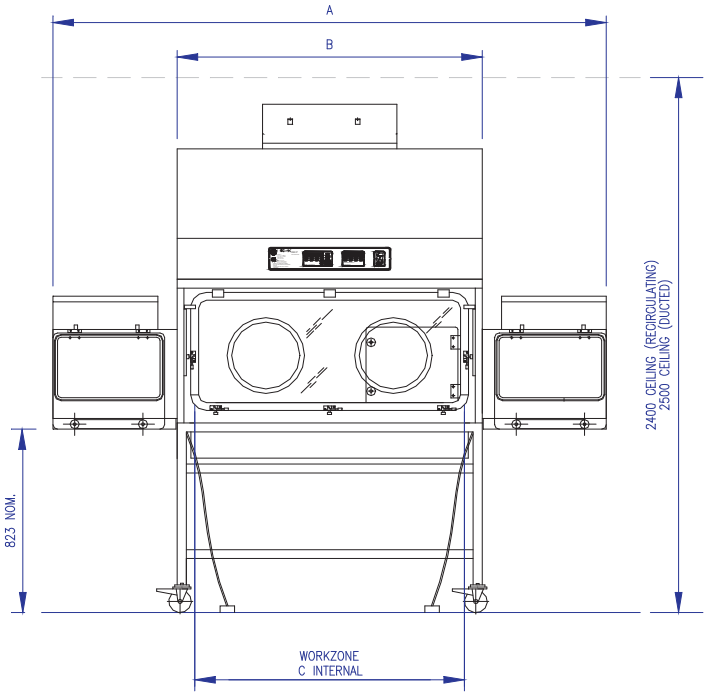
www.envair.co.uk

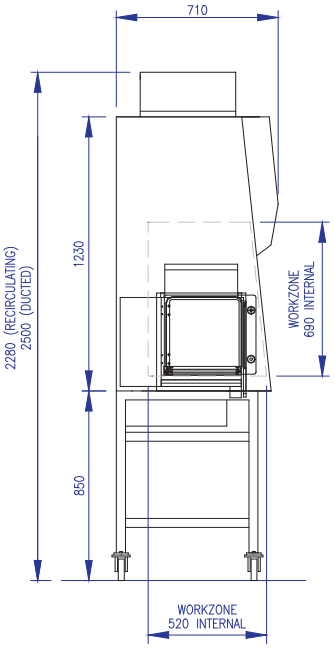
CDC 'F' range

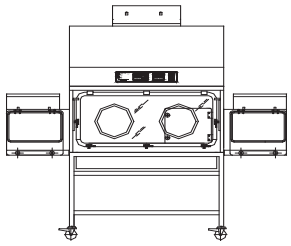


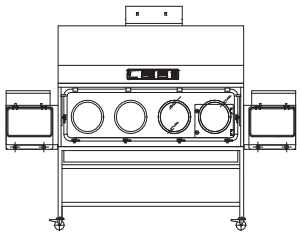
1. Clean interior **2.** Full unidirectional airflow HEPA filter, lighting behind sealed acrylic panel **3.** Sliding tray for easy transfers **4.** Simple safer aseptic glove change system **5.** Simple cam-action visor clamps
6. Comprehensive wipe-clean PLC control panel **7.** Foot-switch for inner door **8.** Easy access for maintenance
9. External access to lighting **10.** Test port in visor for DOP and particle counter probes

Dimensions









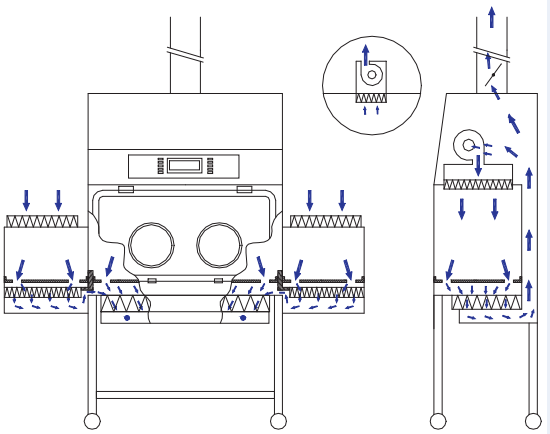
Model	A mm	B mm	C mm	Weight Kg	Power Watts	Exhaust rate m^3/s
2GR	2432	1340	1180	330	900	0.1
2GD	2432	1340	1180	320	600	0.1
4GR	3030	1940	1780	395	1000	0.1
4GD	3030	1940	1780	380	660	0.1

CDC 'F' range

MODEL DESIGNATIONS

2G2D	The CDC'F' 2G2D has two glove ports and two transfer chambers and is designed to exhaust HEPA filtered air to atmosphere via a dedicated ducting system and a remote mounted extract fan
2G2R	The CDC'F' 2G2D has two glove ports and two transfer chambers and is designed to exhaust HEPA filtered air back to the room via an additional secondary exhaust HEPA filter and an integral exhaust fan
4G2D	The CDC'F'4G2D has four glove ports and two transfer chambers and is designed to exhaust HEPA filtered air to atmosphere via a dedicated ducting system and a remote mounted extract fan
4G2R	The CDC'F' 4G2D has four glove ports and two transfer chambers and is designed to exhaust HEPA filtered air via an additional secondary exhaust HEPA filter and an integral exhaust fan
RAD	RAD models with suitable radiation shielding are available for blood labelling and for use with technetium generators. Further information is available on request.

Airflow diagram



Specification	2G2D	2G2R	4G2D	4G2R
• Primary (main and exhaust) HEPA filter to H14 (BS EN 1822) below the worktray	S	S	S	S
• Downflow HEPA filter to H14 (BS EN 1822)	S	S	S	S
• Secondary exhaust HEPA filter to H14 (BS EN 1822)		S		S
• Vertically mounted anti-blowback damper	S		S	
• Manual shut off damper	S		S	
• Sealing lids for semi-automatic pressure decay test	S	S	S	S
• Integral exhaust filter and fan box with fan downstream of filter		S		S
• Downflow fans downstream of primary HEPA filter for long life and safe maintenance	S	S	S	S
• Two type D double HEPA filtered transfer chambers complete with electromagnetic timed interlocks, footswitches (for inner doors) and sliding trays	S	S	S	S
• 316L stainless steel removable dished worktray	S	S	S	S
• Large hinged acrylic visor, supported by gas struts in the open position, and complete with bonded 300mm diameter sleeve ports, fabric lined polypropylene sleeves, universal cuff-rings and all associated securing O-rings	S	S	S	S
• DOP/Particle Counter test ports in main chamber and transfer chambers	S	S	S	S
• Potentially contaminated plenums under negative pressure	S	S	S	S
• PLC control system with touch control membrane and text display panels	S	S	S	S
• Digital user information menu	S	S	S	S
• Digital display for isolator functions and transfer chamber operation	S	S	S	S
• Selectable digital display of internal pressure, primary filter pressure drop and downflow air change rate	S	S	S	S
• Semi-automatic pressure decay test	S	S	S	S
• Fully automatic pressure decay test (see options)	O	O	O	O
• Latched audible and visible alarms for internal pressure and downflow air change rate, alarm mute	S	S	S	S
• All maintenance behind lockable front access panel	S	S	S	S
• Internal flourescent lighting behind sealed acrylic panel giving 500 lux at the work surface	S	S	S	S
• Support frame with adjustable levelling feet	S		S	
• Support frame with lockable castors		S		S
• Electrical wiring: 230v/50Hz/1Ph or as required (please specify)	S	S	S	S

S = Standard **O =** Optional