

AMERCARE

PROTECTING YOUR PRODUCT AND ENVIRONMENT

H₂O₂ Gassing Isolators



Amercare Gassing isolators are designed to provide a GMP environment for a wide range of applications including.

- Cytotoxic Dispensing
- CIVAS
- Sterility Testing
- Cell Therapy

The isolator has ECGMP Grade A air unidirectional flow and has the capability to run validated gassing cycles on any section of the isolator.

A wide range of isolator configurations and integrated equipment provides the user with exactly the right isolator for their application.

You can choose from standard configurations or choose a bespoke design as part of a fully validated supply package to include DQ, FAT, IQ, OQ and Gas Cycle Development.

KEY FEATURES

- Standard or bespoke design as part of a fully validated supply to include DQ, FAT, IQ, OQ and Gas Cycle Development.
- ECGMP Grade A air quality, Laminar Flow in the main isolator with high air change rate entry chamber to enable rapid gassing cycles to be achieved.
- Fully automated Gassing operations with the option of Integrated or shared Gas Generator. Suitable for operation with Bioquell or Steris gas generators.
- Entry chamber can be gassed independently with shortened cycle times.
- Microprocessor control with digital status display, data recording and thermal printer. Full integration with the gas generator, BMS and EMS.
- Sliding tray and hanging rail system which can be configured for your product and batch size requirements.
- Battery backup for key functions including reconfiguration to safe condition after power failure during gassing.
- Height adjustable baseframe with ample knee-room for seated operation.
- Automated Leak Classification Test and automated glove leak testing with hard copy printed reports.



TECHNICAL INFORMATION

Isolator Air Quality	Unidirectional ECGMP Grade A
Transfer Chamber Air Quality	Type E, High Flow Turbulent ECGMP Grade A
Carcass Materials	Grade 316L Stainless Steel
Main Chamber Pressure (+ve)	+100Pa (+ve) or -250Pa (-ve)
Transfer Chamber Pressure (+ve)	+70Pa (+ve) or -300Pa (-ve)
Leak Classification	ISO 14644 Class 3
Main Chamber Inlet Filter	HEPA Grade H14
Main Chamber Extract Filter	HEPA Grade H14
Transfer Chamber Inlet Filter	HEPA Grade H14
Transfer Chamber Extract Filter	HEPA Grade H14
Secondary Extract Filter	HEPA Grade H14
Air Extract Rate	0.08m ³ /s for main chamber plus 0.04m ³ /s for each transfer chamber.
Lighting	Low Energy lighting to provide glare free minimum 750lux at the working position.
Sound level	Less than 65DbA at the working position.
Power supply	Either 240v or 110v AC
Service requirements	Electrical supply & ducted extract with remote fan.

ISOLATOR CONFIGURATION OPTIONS

- Positive or Negative Pressure operation.
- Ducted or Recirculating installation.
- 2 Glove, 3 Glove or 4 Glove main chamber.
- Standard Entry Chamber or Gloved Entry Chamber with 2 gloves to enable preparation of the product in a Grade A background.
- Standard transfer chamber or Rapid Transfer Port for transferring product out of the isolator. RTP can be provided with rigid pods or heat sealable bagging out system.
- Fully integrated gas generator or connections to freestanding shared gas generator.
- Gassing circuits can be configured to suit customer requirements.

EQUIPMENT OPTIONS

- Sterility Test (Millipore, Sartorius etc) equipment to your choice.
- Continuous Particle monitoring sample points integrated to Environmental Monitoring system of customers' choice.
- Viable & non-viable sampling.
- Vacuum Chamber with footswitch to assist in bag filling operations.
- Centrifuge with or without refrigeration, fully integrated into the base of the isolator with flush fitting lid.
- Hot block/chiller block to maintain products at a controlled temperature.
- Integrated or shared VHP generator by Bioquell or Steris with integrated H₂O₂ gas sensor.
- Power and Dataports to the customer's requirements.
- Glove Leak Tester with automatic operation and automatic data printout.

