

PERFORMANCE SPECIFICATION

Air Volume Flow: 0.015 m³/s
 Air Change Rate: 620 TAC/hr
 Transient Clean Up: 102 seconds
 HEPA Face Velocity: 0.36 m/s
 Breach Velocity: 0.93 m/s

Internal Pressure - Type 1: +50 Pa
 Internal Pressure - Type 2: -100 Pa
 Internal Pressure - Class III: -220 Pa

HEPA ΔP: 238 Pa
 System ΔP: 714 Pa

Noise Level: 60 dBA

Weight: 25 kg

All HEPA Filters to 99.997% Efficiency
 BS 3928 (0.5 to 0.6 μm). Also to
 99.998% Efficiency Mil Standard
 282 DOP (0.3 μm).

Air Filtered to:

BS 5295 Class F
 EU GMP Class B
 FED 209E Class 100
 ISO 14644 Class 5

ELECTRICAL SPECIFICATION

Fan

2 forward curved vane impeller
 Rated at: 24 VDC, 49 W, 2.2 A.
 Control by PWM signal.

Main Circuit Board

Proprietary design with functions
 controlled by PIC chip micro-
 processor, and inputs/outputs
 via push on terminal connectors.
 24 VDC input.

External Power Supply

Power supply unit (PSU) supplied
 for mains input, 24 VDC, 130 W, 5.4 A.

Batteries

2 off 12 V sealed lead-acid
 batteries with 3.2 Ah capacity.

Control Panel

4 zone panel comprising information,
 main control, alarm control, and
 metering display zones. Direct
 connection to circuit board via
 4-conductor tail.

OPTIONS & ACCESSORIES

For convenience many options,
 accessories and modifications are
 factory installed and must be
 specified when ordering.

**Commonly Requested Options
 are Listed Below**

Gauntlets
 Remote Pressure Holding Test Kit
 Variable Height Trolley (as below)

Special Applications
 Variable oxygen & nitrogen environment



Portable Compliant Isolator

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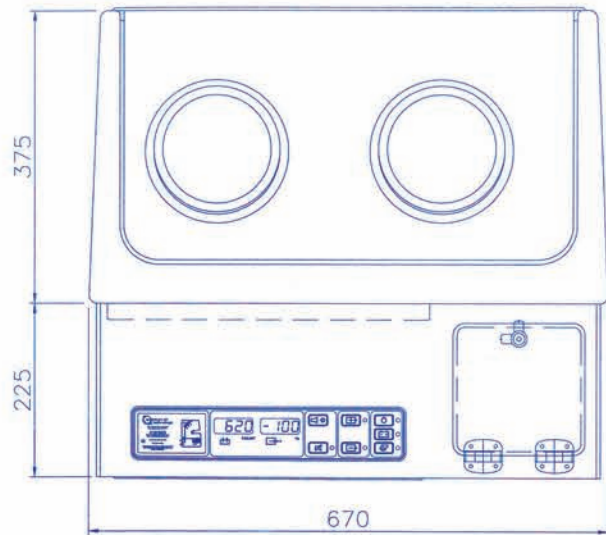
The Portable Compliant Isolator (P.C.I) is a small, portable aseptic isolator. The isolated environment can run at either negative or positive pressure and protect operator or product respectively. The P.C.I complies with all the latest BS and EN Standards and guidelines with respect to isolators such as HMSO: Isolators for Pharmaceutical Applications. It comprises of a small, lightweight construction providing a totally mobile sterile environment essential for the preparation of aseptic treatments, and with its special features such as battery backup, automatic fan speed control, digital displays, alarms, and data-communication capabilities, it is a must for all hospitals, laboratories and industries.

Multi-Mode Isolator

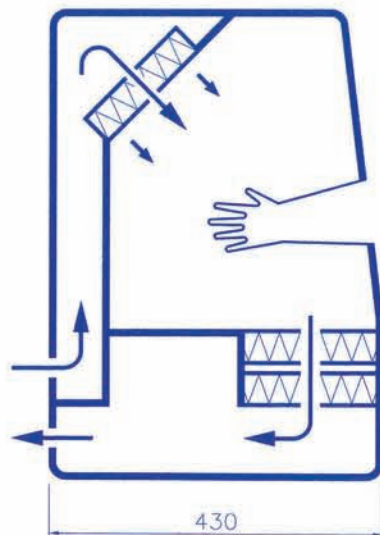
The P.C.I glove box from QAT represents a new generation for small glove boxes. With its revolutionary multi-mode capability and ergonomically sound design, the P.C.I provides an economically lightweight and self contained environment for all types of laboratory isolation where atmospheric containment is required, such as in research laboratories, clean room facilities and micro-electronics assembly. Each P.C.I is controlled with state-of-the-art microprocessor technology enabling each unit to operate in the following modes:

APPLICATIONS

- Preparation of biologicals
- Preparation of short term items e.g. BCG, botulinum toxins, BCG bladder installations
- Gene therapy
- Topicals, steroids
- Table breaking e.g. cytotoxins to half tablet doses
- Antibiotic powders
- Clinical trials
- Out-of-hours cytotoxics, and other injections
- Monoclonal antibodies e.g. Refliximal and Cryllximals
- Compounding, small scale specialist materials that need separation from other materials
- Blood line manipulation
- Back-up for front line isolators
- Quality analysis
- Weighing/Manufacturing



FRONT ELEVATION



AIRFLOW DIAGRAM
 (END ELEVATION SCHEMATIC)

ISOL I	ISOL I(R)	ISOL 2	ISOL 2(R)	CLASS III
Type 1 Isolator	Reduced Type 1 Isolator [1]	Type 2 Isolator	Reduced Type 2 Isolator [2]	Class III MSC
Zoned Laminar Airflow	Turbulent Airflow	Zoned Laminar Airflow	Turbulent Airflow	Turbulent Airflow
Controlled Pressure +50 Pa	Controlled Pressure +50 Pa	Controlled Pressure -100 Pa	Controlled Pressure -100 Pa	Controlled Pressure -220 Pa
Controlled Air Change Rate 620 TAC/Hr	Air Change Rate 150 TAC/Hr	Controlled Air Change Rate 620 TAC/Hr	Air Change Rate 200 TAC/Hr	Air Change Rate 500 TAC/Hr

[1] In the event of mains failure, the isolator will continue to run on batteries with single fan only (extending life of the batteries), maintaining the positive internal pressure. If the full running conditions of ISOL 1 are required the battery button is depressed on the control panel.

[2] In the event of mains failure, the isolator will continue to run on batteries with single fan only (extending life of the batteries), maintaining the negative internal pressure. If the full running conditions of ISOL 2 are required the battery button is depressed on the control panel.



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Portable Compliant Isolator

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Most hospital pharmacies are open 9 till 5 on weekdays only, whereas patient requirements are 24 hours a day, 7 days a week. The inevitable consequence of this is that aseptic treatments are very often made up on wards in uncontrolled conditions, putting both the patient and (if the preparation is active) the medic at risk. Reports have indicated that as little as 35% of aseptic treatments are made up in the aseptic suite (Hospital Pharmacist 2002; 9: 87-8). As the cost of running a 24-hour pharmacy operation is very high, one solution is to offer an aseptic preparation facility at ward level. This being the P.C.I, a miniature version of the pharmacy clean air device, that will enable a cheap yet inherently safe means of preparing aseptic treatments.

With the introduction of the P.C.I glove box, QAT offers an adaptive ergonomic design, combined with a unique airflow management system and proven containment technology, to improve comfort and increase productivity while assuring safety for both patient and glove box user alike. Work is carried out through 2 off 150mm diameter glove ports carrying gauntlets situated on the optical quality safety plastic visor. Such visor hinges from the top of the P.C.I allowing initial loading of pharmacy instrumentation or equipment. The visor remains closed and locked during normal operation.

The P.C.I has been specifically designed for ease of use and for easy cleaning and sanitisation. Work within the isolator is carried out on a stainless steel worktray and is easily removable for cleaning purposes. Due to the working enclosure of the isolator being moulded a highly contained environment is created complete with ball radius corners enhancing appearance and cleaning capabilities.

The controls are very simple to operate and are located on an easy-to-clean moisture-proof membrane panel at the front of the unit. The main control switch is for the fan, which does not require any adjustment, as the microprocessor controls the fans automatic i.e. as filters become soiled the fans automatically compensate, allowing conditions within the isolator to be in spec all the time, minimising service/maintenance visits. The unit is instrumented with digital displays showing both air change rate and internal pressure. These parameters are protected by digital alarms, which also give a warning when the HEPA filters require changing.

A D'Type pass box to the lower front right hand corner of the P.C.I enables a safe means of transferring equipment into and out of the working enclosure of the isolator without breaking containment within the main isolator working area. The air-handling module beneath the workspace is fabricated from coloured safety plastic and houses all the electronics, fans, supply filters and dual-in-line HEPA exhaust filters (for both the transfer hatch and main working enclosure). The circuit board and membrane control panel are also in this module.

Power to the unit is provided by a power supply unit running from the local mains supply. Thus allowing the P.C.I to be used anywhere in the world. All electrics are 24 VDC making the unit inherently safe with battery backup. There are 2 running modes whilst running on batteries; the first is normal running conditions of isolator parameters (see Mode Table) where battery duration is about 2 hours continuous; and the second is reduced running conditions of isolator parameters where only the pressure is maintained (single fan operation) where battery duration is about 10 hours continuous. This key feature allows the P.C.I to be moved from ward-to-ward without the need of a mains connection.

For maximum safety, the P.C.I has been designed to be compliant with all relevant international standards, such as:

- BS EN 12469:2000 Performance criteria for Microbiological Safety Cabinets
- BS EN ISO 14644-7:2004 Clean Rooms and Associated Controlled Environments
- H.M.S.O Isolators for Pharmaceutical Applications



In ISOL 1/Type 1 Mode the P.C.I glove box offers a contained, positive pressure work area for pharmacy applications enabling aseptic handling of non-hazardous drugs and to meet or exceed the requirements of Isolators for Pharmaceutical Applications. The P.C.I creates HEPA-filtered laminar airflow of better than ISO Class 5 (Class 100) air cleanliness conditions within the working enclosure and prevents contaminants from the outside entering due to the over pressure. Air is re-circulated back into the laboratory/room after passing through dual-in-line HEPA filters from the isolator and from the hatch. Critically the isolator retains the leak integrity and a simple leak testing method within the software of the P.C.I, enables the assurance of the highest possible protection for both operators and product. Typically used for aseptic preparation of IV additives and TPN's.



When set to ISOL 2/Type 2 Mode the P.C.I glove box offers a contained, negative pressure work area suitable for hazardous or potent pharmaceutical compounds, chemotherapy agents or IV admixtures that can be harmful to pharmacy personnel. The P.C.I creates HEPA-filtered laminar airflow of better than ISO Class 5 (Class 100) air cleanliness conditions within the working enclosure. The combination of this and the negative pressure prevents migration of hazardous contaminants to the outside and to minimize cross-contamination across the work area. Air is re-circulated back into the laboratory/room after passing through dual-in-line HEPA filters from the isolator and from the hatch. Critically the isolator retains the leak integrity and a simple leak testing method within the software of the P.C.I, enables the assurance of the highest possible protection for both operators and product. Typically used for aseptic dispensing of cytotoxics.



In CLASS 3 Mode the P.C.I glove box is a totally enclosed Class III Microbiological Safety Cabinet to BS EN 12469:2000 designed to provide operator safety and product protection for the handling of biological agents up to Hazard Group 4. Air is re-circulated back into the laboratory/room after passing through dual-in-line HEPA filters from the isolator and from the hatch. The maximum level of personnel protection from high-risk biological and chemical (If carbon filter fitted) hazards is obtained in this mode. Critically the isolator retains the leak integrity and a simple leak testing method within the software of the P.C.I, enables the assurance of the highest possible protection for both operators and product. Typically used for the manipulation of blood products.



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