Portable Aseptic Isolator (PAI)

EZIDOCK
LIFE SCIENCE PROCESS SOLUTIONS

The Ezi-Dock Portable Aseptic Isolator is a capable and cost-effective mobile isolator offering compact size and simplicity of use. The PAI offers multi-mode operation, so each PAI can be instantly switched from a Type 1 (positive pressure), to a Type 2 (negative pressure) or to a Class 3 Microbiological Safety Cabinet (MSC) and is compliant with all associated standards including ISO14644-7 and BSEN12469.

It is suitable for many applications such as clinical trials, chemotherapy and radio-isotope treatments that require a safe and clean micro-environment, close to the patient, and is available ex-stock for speedy supply. Since the PAI unit is NATO codified, it is also supplied in a permanent MSC Class 3 version for category 4 pathogenic work (e.g. Ebola sampling/handling) as used by military customers. This MoD variant can have a built-in formalin vaporiser and neutraliser system which is used for decontamination.

Key Features and Specifications

- Draws HEPA filtered air from the environment and returns it via a dual-in-line exhaust HEPA filter.
- Shoulder cuffs moulded into the front isolator screen complete with 3- part glove sleeve.
- Provides 0.36 m/s airflow across the working surface, 100mmaway from the filter surface.
- Two fans supply and exhaust the air in a 100% ‘Push-Pull’ configuration.
- Air Change Rate (ACR) and Internal Pressure are automatically controlled.
- Isolator can be run at a positive or negative pressure to provide product or operator protection.
- A 12L transfer hatch is also purged with HEPA filtered air.
- Built-in chamber integrity test performed using simple inlet and exhaust air magnetic covers.
- Variable oxygen and nitrogen-controlled environment.
- Can run on its own 24VDC battery system or from the mains with its 100V - 240V input.
- Can be supplied as a bench model or with its own electrically operated adjustable height trolley powered from the PAI’s integral 24VDC battery system.
- Inbuilt Filter Cleanliness monitoring with changeout indication.

Ezi-Dock Systems’ Portable Aseptic Isolator represents a major step forward in small glove boxes. With its revolutionary Multi-Mode capability and ergonomic design, the PAI economically provides a lightweight and self-contained environment for all types of laboratory isolation where atmospheric containment is required such as research labs, clean room facilities, and micro-electronics assembly. Each PAI features state-of-the-art micro-processor technology, enabling it to operate in the following modes:

Switching between ISO1 & ISOL 2 running condition can be performed by pressing the battery button on the control panel.
Class 3 Running Conditions are achieved by pressing and holding the battery button for 5 seconds.

ISOL1	ISOL1 (R)	ISOL2	ISOL2 (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 internalpressure. If the full running conditions of ISOL 2 are required, the battery button is depressed on the control panel.

Portable Aseptic Isolator (PAI)

Most hospital pharmacies are open 9 till 5 on weekdays only, whereas patient requirements are 24/7. The inevitable consequence is that aseptic treatments are very often made up on wards in uncontrolled conditions, putting both the patient and potentially 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.

The PAI represents a miniature version of a pharmacy's clean-air device, providing a cost-effective but inherently safe means of preparing aseptic treatments.

Critically, the isolator retains leak integrity and a simple leak testing method within the software of the PAI provides the highest possible protection for both operators and product.

When set to **ISOL1 / Type 1** Mode, the PAI 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 PAI creates a HEPA-filtered laminar airflow of better than ISO Class 5 (Class 100) condition within the working enclosure and prevents contaminants from the outside entering due to the over pressure.

Air is recirculated into the laboratory / work area after passing through dual in-line HEPA filters from the isolator and from the hatch. It is typically uses for aseptic preparation of IV additives and TPNs.

When set to **ISOL2 / Type 2** Mode, the PAI offers a contained negative pressure work area suitable for hazardous or potent pharmaceutical compounds, chemotherapy agents, or IV admixtures. The PAI creates a HEPA-filtered laminar airflow of better than ISO Class 5 (Class 100) condition within the working enclosure. The combination of this and the negative pressure, prevents migration of hazardous contaminants to the outside and minimises cross-contamination across the work area.

Air is recirculated into the laboratory / work area after passing through dual in-line HEPA filters from the isolator and from the hatch. It is typically used for aseptic dispensing of cytotoxics.

In **Class III Mode**, the PAI becomes 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 recirculated into the laboratory / work area after passing through dual in-line HEPA filters from the isolator and from the hatch.

This Mode provides the maximum level of personnel protection from biological and chemical (with carbon filter fitted) hazards. It is typically used for the manipulation of blood products.

The Portable Aseptic Isolator in Detail

The Portable Aseptic Isolator 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 two 150mm diameter glove ports carrying gauntlets situated on the optical-quality safety plastic visor. The visor hinges from the top of the PAI allowing initial loading of pharmacy instrumentation or equipment. The visor remains closed and locked during normal operation.

The PAI 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 fans, which do not require any adjustment as the microprocessor controls them automatically. As filters become soiled the fans automatically compensate, allowing conditions within the isolator to be in spec all the time, minimising 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 PAI provides 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 PAI to be used anywhere in the world. All electrics are 24 VDC making the unit inherently safe, with battery backup. There are two 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 running, 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 running. This key feature allows the PAI to be moved from ward-to-ward or lab to lab, without the need of a mains connection.

For maximum safety, the PAI 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

PERFORMANCE SPECIFICATION

Air Volume Flow	0.015 m3/s
Air Change Rate	620 TAC/hr
Transient Clean Up	102 secs
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 △P	238 Pa
System Symbol △P	714 Pa
Noise Level	60 dBa
Weight	25 Kgs

All HEPA Filters to 99.997% efficiency inline with BS 3928 (0.5-0.6m).

Also to 99.998% Efficiency Mil Standard 282 DOP (0.3µm).

Air filtered to:

BS 5295 Class F

EU GMP Class B

FED 209E Class 100

ISO 14644 Class 5

ELECTRICAL SPECIFICATION

Fan

2 x forward curved vane impellor 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 supplied for mains input, 24 VDC, 130 W, 504 A.

Batteries

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

Control Panel

Four-zone panel comprising Information, Main Control, Alarm Control and Metering display zones. Direct connection to circuit board via 4-conductor tail.

OPTIONS AND ACCESSORIES

For convenience many options and accessories are factory-installed and should be specified when ordering.

Commonly-requested Options

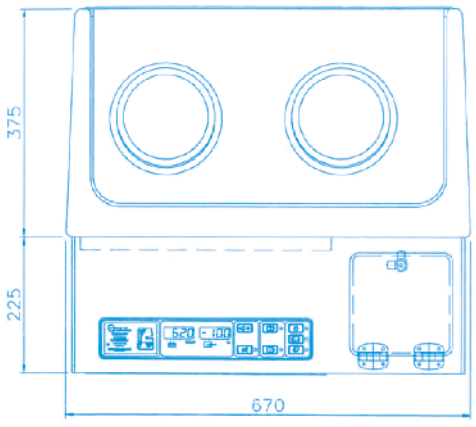
Gauntlets

Remote Pressure Holding Test Kit

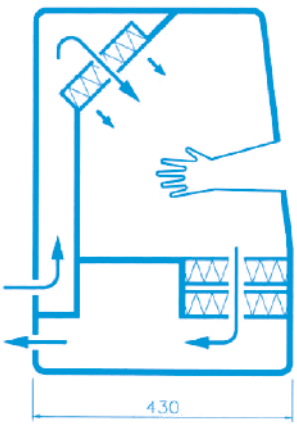
Variable Height Trolley

Special Applications

Variable Oxygen and Nitrogen environment.



FRONT ELEVATION



AIRFLOW DIAGRAM
(END ELEVATION SCHEMATIC)

APPLICATIONS

Preparation of biologicals

Preparation of short term items e.g. BCG, botulinium toxins, BCG bladder installations

Gene therapy

Topicals, steroids

Table breaking e.g. cytotoxins to half tablet doses

Antibiotic powders

Clinical trials

Out-of-hours cytotoxic medication, and other injectable medications

Monoclonal antibiotics e.g. Retuximal and Cryliximals

Compounding, small scale specialist materials that need separation from other materials

Blood line manipulation

Back-up for front line isolators

Quality analysis

Weighing/Manufacturing