

*"The Clinical Advantage"™*

BIODEX

**NEW**

# PORTABLE SHIELDED ISOLATOR

**CERTIFIED SHIELDED BARRIER  
LAMINAR FLOW ISOLATOR**



USP<797>

- Small footprint
- Antechamber located under the Isolator
- Large, full-view shielded window
  - Designed from the ground up for a Radiopharmacy
  - Stainless Steel, inside and out
  - Motorized height adjustable – 10-inch range
  - Work sitting or standing with correct ergonomics
- USP<797> compliant overcomes expensive ventilation renovations
  - Internal IV bar
  - Sealed shielded dose calibrator chamber in the work surface
    - Fits Atomlab and other dose calibrators
- Use for blood work or other compounding or drawing requirements
- Mobile, on four heavy-duty locking casters
  - Electric outlets in work area
  - HEPA air filtration
- Lead shielded (.25" thick) for compounding sterile radiopharmaceuticals
- ISO Class 5 (Class 100) Isolator

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[www.biodex.com](http://www.biodex.com)

**1-800-224-6339**

Int'l 631-924-9000

# CERTIFIED SHIELDED BARRIER LAMINAR FLOW ISOLATOR

The Biodex Germfree Shielded Isolator provides the ultimate in both product and operator protection. The shielded isolator functions as a "glovebox" using negative pressure to meet NIOSH recommendations while complying with USP<797> regulations for use outside a cleanroom.

HEPA filtered unidirectional (laminar) air bathes the work area to protect the product from contamination and removes any particulate generated by sample manipulation. The operator is provided a complete shielded barrier from materials being manipulated in the work area. The Biodex Germfree Shielded Isolator meets or exceeds ISO 14644-1, ISO Class 5 (Class 100) air quality. Each shielded isolator undergoes rigorous physical testing to assure the unit meets performance requirements as validated. It is required that independent certification be performed before use.



## ANTECHAMBER

- Sealed two-door air lock maintains complete environmental separation between work area and ambient conditions.
- HEPA filtered purge of trapped air lock air eliminates cross contamination between the work area and the room during both material ingress and egress.



*Shown antechamber on left and Sharps Shield on right.*

## What is a Barrier Laminar Flow Isolator?

In January 2004, USP<797> changed the way facilities that prepare compound sterile preparations (CSPs) approach their work. As the first official and enforceable requirement for CSPs, USP<797> deals with policies and practices for preparing CSPs. It applies to all facilities that prepare CSPs, including clinics, hospital care units, and main and satellite pharmacies. As facilities that prepare CSPs evaluate and change their procedures to meet USP<797> requirements, they are finding that barrier isolators provide an ideal alternative to more costly cleanrooms.

According to the Food and Drug Administration, a barrier isolator is "a decontaminated unit supplied with HEPA filtered air that provides uncompromised continuous isolation of its interior from the external environment, including surrounding cleanroom air and personnel."

By installing a certified barrier isolator, one can obtain cleanroom conditions within a contained workspace. Barrier isolators provide a ISO Class 5 (Class 100) environment for product preparation, with work occurring inside a closed, pressurized environment accessible only via sealed gloves that reach into the work area.

A Shielded Glovebox *is not* a certified barrier isolator. By choosing a certified barrier isolator, the requirement for a ISO Class 8 environment is eliminated. The Biodex Germfree Isolator is an excellent example of a well-designed shielded barrier Laminar Flow Isolator, meeting all of these standards and more.

## FILTRATION

- Full framed, standard size mini-pleat HEPA's filter 100% of inlet and exhaust air from both the work area and the antechamber to provide a fully contained environment.
- HEPA filters are full coverage and front loading for easy replacement by a certifier.

## ERGONOMICS

- Hydraulic assist height adjusting stand offers a full 10" range, allowing operators to sit or stand comfortably for extended time periods.
- Stainless steel sliding tray inside the antechamber air lock that pulls forward for loading and unloading items into the air lock, eliminating reaching strains. The sliding tray lifts up 7.5" when the interior antechamber door is opened.
- Two part sleeve/glove system allows the use of most types and sizes of commercially available gloves for better dexterity and tactility.
- Extra large oval glove ports are placed with bottoms together to provide an anthropometrically correct configuration that accommodates a wide range of body types and increases range of movement.
- Glove ports have a 3" armrest to reduce operator fatigue.
- Large viewing panel is at an angle to reduce glare and operator strain.



## Rapid Exchange Glove System



The GRx offers a fast, easy, efficient solution to the traditional glove changing methods. Gloves can now be changed in seconds, maintaining a clean environment.

### SHARPS CONTAINER

- One sharps container in a locking shielded holder, located under the isolator in a .25" lead shield.
- Sharps tube is a straight 2.5" diameter tube to facilitate quick drop of the largest syringes with an easily removable shielded seal/stopper to maintain work area containment.

### SAFETY

- Lock-out handle requires key for access to work area and sharps container.
- Digital pressure readout with low pressure alarm for work area.
- Inward face velocity is 95-100 LFM at glove port opening, to protect operator/product during massive breach of containment.
- Glove changes can be made without breaking containment.
- Locking casters are standard, seismic anchors are available.

### CLEANING

- Front viewing panel is top hinged and self supporting for easy access to the work area for cleaning and equipment ingress and egress.
- All filter diffuser / guard panels are removable for easy cleaning.
- Straight sides and back maximize work area to accommodate the many types and shapes of equipment and dose calibrators.
- All corners in work area, antechamber and work surface are easily reached and cleaned.

### CONFIGURATION OPTIONS

- Overall work area pressure is negative with the option to externally exhaust.
- Optional Thimble Exhaust Transition Kit is available for connection to external exhaust systems.
- Fits Atomlab and other dose calibrators.



### SPECIFICATIONS:

#### Dimensions:

Overall Dimensions: 36" w x 32.5" depth x 79" h (91.4 x 82.5 x 200.7 cm)

Designed to fit through standard door openings and elevators.

Height Adjustment: 79" – 89" (200.7 x 226 cm)

Work Area Dimensions: 35" w x 25" depth x 28" h (88.9 x 63.5 x 71 cm)

Viewing window: 30" w x 23" h (76.2 x 58.4 cm), 1.8"

(46 mm) thick leaded acrylic, 2 mm lead equivalency

Construction: Stainless steel with a pharmaceutical grade finish

Lead Shielding: .25" thick (.64 cm) on back, sides, bottom and front

Fluorescent Lights: High efficiency; externally mounted to minimize heat build up. Separate lighted power ON/OFF switch.

Motor/Blower: High capacity with speed control to extend HEPA filters life.

Separate lighted power ON/OFF switch.

Power: 115 VAC, 60 Hz (Optional 220 VAC, 50-60 Hz is available),

15 AMP line, running amperage = 6 AMP. Includes ten foot hospital grade power cord with molded grounded plug. Sealed outlet in work area.

Weight: 1600 lb (725.7 kg)

Warranty: Two years parts; one year labor

**190-215** Shielded Isolator

#### Related:

**214-129** Chair, Ergonomic

**190-217** GRX – Rapid Exchange Glove System

*Includes one pair of isolator sleeves, two outer rings, six inner rings and all necessary O-rings*

**190-219** Total Customer Care Plan

*Includes installation and training (see web for details)*

**190-220** Thimble Exhaust Transition Kit

*For connection to external exhaust systems*

#### Replacement:

**039-413** Sharps Container, 3.2 qt., 30/pkg

**119-206** Gloves, Nitrile, Sterile, Medium, 200/pair/cs (pkg individually)

**119-207** Gloves, Nitrile, Sterile, X-Large, 200/pair/cs (pkg individually)

**190-218** Hypalon Sleeves (pr)

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