

Table Top Designs  
For USP 797 Compliance

## **Flanders Corporation Introduction**

For over 50 years, the name Flanders stands for quality-built, innovative products. Starting in 1950, the company pioneered the HEPA filter industry. As the clean room industry developed in the 1960s, Flanders led the way with its fluid seal Technology. In the 1970s, Flanders became a dominant manufacturer of filter housings for the containment of chemical, biological, radiological or other dangerous airborne contaminants. In the early 1990s, Flanders/CSC began to manufacture DOE Gloveboxes and other process enclosures. In 1994, Flanders Absolute Isolation (FAI) was created to meet the increasing demand for isolators used in the pharmaceutical and biotechnology industries. Most recently, Flanders/CSC and Flanders Absolute Isolation (FAI) have merged to provide a full range of high quality equipment that will include high efficiency carbon adsorbers, ceiling hoods, low-leak and bubble-tight dampers, containment filter housings, remote operated (hot cell) filter housings, Gloveboxes, pharmaceutical enclosures, laminar flow modules, downflow booths and clean benches.

## **Custom Design Applications**

As each customer is unique, we believe that each Glovebox / Isolator is unique also. Flanders Corporation employees, a full staff of Design Engineers, tailor equipment orders to the specifications and desires of the customer. An extensive Design and Review Process is integrated into each Order. All products developed in our engineering department are prepared for examination by the customer through detailed drawings and models. The addition of Solid Modeling Design to our process has provided the ability for each product to be reviewed in a 3-D environment. This aids the end user in the ability to study the size, placement and ergonomics of each device prior to manufacturing. This ability places the user's needs at the forefront of each unit.

Incorporation of CIP, HMI, complex controls, Filtration Systems, Sterilization, and Atmospheric Monitoring are just a few of the Systems Flanders regularly incorporates into Custom Systems.

Special Materials of Fabrication, Coatings, Finishes and Ancillary Devices are common to our production facility. If there is a special need required, Flanders stands ready to research, design, specify and manufacture to the exacting demands of each unit application.

Because Flanders Corporation is the Foremost in Air Filtration, the Glovebox / Isolator Division of the Corporation has access to the finest Filtration Engineering and Design in the Industry.

## Mini Isolator

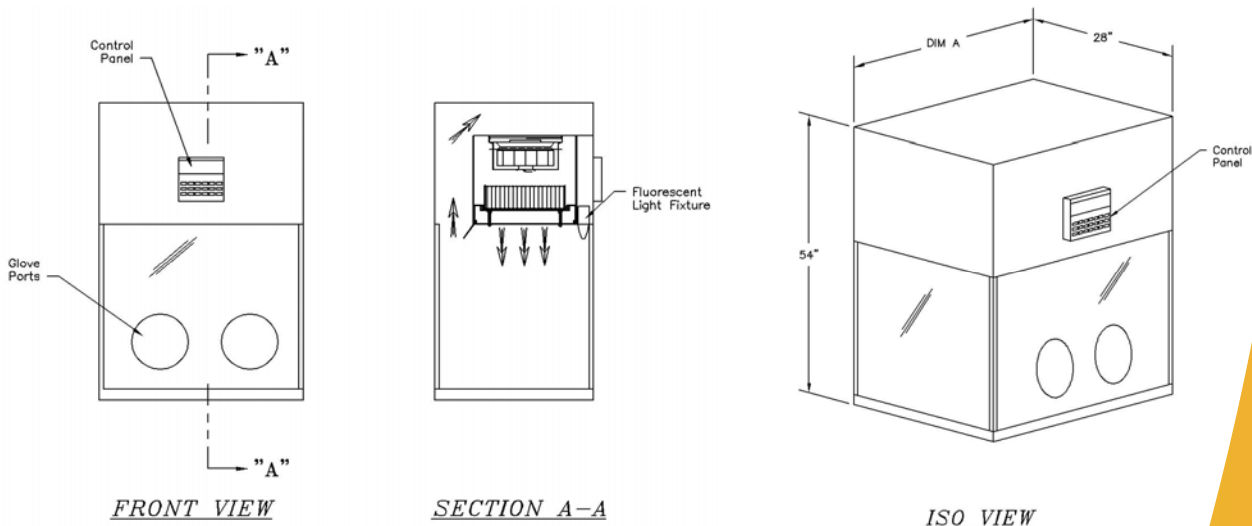
Since the inception of USP 797, Compounding pharmacies have needed a barrier isolator or ISO Class 5 clean room for sterile product preparation. Not all facilities have the room for budget for a full sized isolator system. Flanders recognizes that need, and introduces the Flanders Mini Isolator. This table top, 120V isolator cabinet, will give smaller pharmacies the ability to properly adhere to USP 797 without costly facility remodeling or outsourcing.

USP 797's Scope applies to health care institutions, pharmacies, physicians practice facilities and other facilities in which compounded sterile preparations are prepared, stored and dispensed.

Anywhere sterile products are compounded or prepared can be impacted by USP 797. Specific handling procedures must be developed and adhered to during compounding processes. This could affect hospitals, pharmacies, or physicians' offices and is FDA enforceable. Flanders previous work in this industry has enabled it to develop a budget friendly product for these smaller customers.

## Mini Isolator Description

- The unit shall meet the requirements set forth by the American Glovebox Society Design Guide for Enclosure Design.
- Enclosure shell in 11 ga. T-304L stainless steel with #4 finish (<35RA)
- All interior corners of shell shall be covered to minimum 5/8" radius for ease of cleaning
- Shroud for fan and lights over main chamber in T-304 stainless steel with #4 finish
- Clearview gloveports / no flange/no cracks or crevices
- Light fixture (fluorescent) min 85 foot candles avg.
- Instantaneous 100 fpm minimum glove breach velocity (12" diameter)
- Length: DIM "A" 24", 36", 48", 60"
- Depth: 28"
- Height: 54"
- Lift-up window sash shall be provided on the front of the unit to allow full access to interior.
- Front window shall employ no-scratch safety glass
- (2) 12" glove ports, ambidextrous butyl "one piece" sleeves
- Negatively pressurized
- Blower shall run on 120 Volts AC 60 Hertz
- (1) Inlet ULPA filter
- ULPA filters shall meet the demands of IEST Recommended Practice CC01.3 for the manufacture of HEPA filters (IEST-RP-CC01.3) and shall be tested in accordance with IEST Recommended Practice CC034.1 for testing HEPA filters (IEST-RP-CC01.3). Each filter shall be identified with a unique serial number and individual Test Reports shall be supplied.



## **Quality Control**

At Flanders Corporation, commitment to quality is the top priority. We are committed to delivering a high quality product that meets the customer's requirements. A rigorous quality assurance program controls all aspects from order entry to shipment. Our engineering staff works closely with customers or outside design firms to ensure the product meets the design requirements. Stainless steel construction with material traceability is a specialty. A variety of surface finishes are available. All welders are qualified to ASME Boiler and Pressure Vessel Code Section IX. NDE testing personnel are on staff to perform any type of testing required. Qualified electricians are available for integrating electrical equipment and controls. Customer satisfaction is the principal concern that drives the quality program. Flanders operates under an NQA-1 Nuclear Quality Assurance Program. This program follows the original 18 Points of Criteria set up to govern the Nuclear Industry by the Nuclear Regulatory Committee. This is important in that your Unit will be designed, manufactured, inspected and tested under the same strict requirements as the units being built for the Nuclear Industry.

## **Customer Support**

Flanders will supply support via electronic and telephone as well as field support if required. Flanders maintains extensive records of each product we manufacture as well as "as built" drawings and diagrams. We work closely with all suppliers to maintain a high level of service incase problems arise in the field. Telephone support for electronic components is crucial to the start up of any given unit. Manuals or all equipment and devices will be supplied upon delivery. As Built drawings and diagrams will be supplied (2) weeks after shipment.

## **Leak testing**

Flanders shall perform standard leak test at 0.5% of housing volume per hour.

## **Supervision of Installation and startup**

Flanders can provide personnel to witness and supervise installing the isolator and connection of utilities to the isolator, for additional fee.

## **Contact Information:**

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