PHARMACY PRODUCTS

ChemoSHIELD[®] Compounding Aseptic Containment Isolator (CACI)







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A level of safety that is built in, not bolted on, to provide both personnel and product protection

- Offers a contained, leak-tight negative pressure work area suitable for hazardous pharmaceutical compounds, chemotherapy agents or IV admixtures that can be harmful to pharmacy personnel
- Creates a unidirectional HEPA-filtered airflow of better than ISO Class 5 (Class 100) air cleanliness conditions within the negative pressure chamber to prevent migration of hazardous contaminants to the outside and to minimize cross-contamination in the direct compounding area
- Clean technology design improves the pharmaceutical compounding process by offering the finest environmental protection in the pharmacy laboratory
- One of the most comfortable isolators in the industry with a slanted, top-hinged viewscreen that allows for full opening for loading and unloading of pharmacy instrumentation or equipment
- Oval gloveports offer easy reach to interior surfaces for users of different heights, and multiple positions allow total access to the interior
- Spacious, negative pressure interchange (pass-thru chamber) allows for clean and easy transfer of materials into or out of the chamber

ChemoSHIELD®

Designed for aseptic compounding of hazardous chemotherapy and other agents and IV admixtures

The Baker ChemoSHIELD[®] negative pressure Compounding Aseptic Containment Isolator offers a contained, leak-tight (tested to AGS standard), negative pressure work area suitable for hazardous pharmaceutical compounds, chemotherapy agents or IV admixtures that can be harmful to pharmacy personnel.

ChemoSHIELD[®] creates a unidirectional HEPA-filtered airflow of better than ISO Class 5 (Class 100) air cleanliness conditions within the negative pressure chamber to prevent migration of hazardous contaminants to the outside and to minimize cross-contamination across the direct compounding area. CETA tested in accordance with CAG 002-06.



As one of the most comfortable isolators in the industry, the ChemoSHIELD features a slanted viewscreen with a top hinge that allows for full opening for loading and unloading of pharmacy instrumentation or equipment. Oval gloveports offer easy reach to interior

surfaces for users of different heights, and multiple positions allow total access to the interior. There is also a negative pressure interchange (pass-thru chamber) which allows clean and easy transfer of materials into or out of the chamber. An adjustable stand allows the cabinet to be configured for standing or seated operation.

ChemoSHIELD has no onboard motor/blower to maintain and service. All static pressure and airflow is supplied by the building exhaust system.

Uncompromised Safety and Performance

The ChemoSHIELD's industry-leading design features allow it to meet or exceed ISO Class 5 standards while also protecting personnel from exposure.

- \cdot A spacious, negative pressure interchange (pass-thru chamber) allows safe and easy transfer of materials into or out of the chamber.
- The viewscreen top hinge allows full opening for initial loading of pharmacy instrumentation or equipment.
- \cdot The viewscreen must be closed and locked during normal operation.
- \cdot Ambidextrous gloves are positioned in the main chamber to allow total access to the interior.
- \cdot The interchange door to the room includes one ambidextrous glove to permit manipulation of contents for surface decontamination of items moved into or out of the main chamber.

Ergonomic Features Maximize User Comfort and Ease of Use

A variety of design features make the ChemoSHIELD one of the most comfortable working environments in the industry.

- The adjustable stand permits work surface heights to be fixed at 36" (seated) or $44\frac{1}{2}"$ (standing).
- \cdot The slanted viewscreen is made of shatterproof acrylic, and angled at 10° for optimum ergonomic comfort and safety.
- · Oval gloveports offer maximum reach to all interior surfaces for users of different heights, standing or sitting.
- · Fluorescent lighting minimizes heat output and improves eye comfort.

Cabinet Containment, Personnel and Product Protection

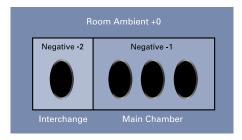
The isolator pass-thru interchange and main chamber pressure (vs. ambient) are negative to the room. In the standard configuration, the pass-thru interchange is slightly more negative than the main chamber to prioritize cleanliness in the main chamber while ensuring containment of hazardous compounds throughout the isolator. The interchange door and interchamber door are mechanically interlocked to prevent both doors from being opened simultaneously.

- \cdot Individual supply and exhaust HEPA filters service the main chamber and interchange.
- Front-loading HEPA filters are 99.99% efficient. They provide better than ISO Class 5 (Class 100) air in both the main chamber and pass-thru interchange.
- Unidirectional (downflow) air removes airborne particulates from the work area and sweeps them to the exhaust HEPA filter.
- Exhaust filters are safely and easily removed via bag-out provision to contain hazardous compounds prior to disposal.
- · A stainless steel air diffuser in the main chamber and pass-thru offers additional protection to supply filters.
- Key lock on cabinet front prevents unauthorized opening of fully-hinged front viewscreen that may compromise containment capability or aseptic environment.
- \cdot Mass airflow monitor audio/visual alarm system warns the user when the exhaust system has inadequate airflow.

The HEPA-Filtered Interchange Permits Secure Pass-Thru In and Out of the Work Area

The interchamber pass-thru door to the main work area swings open for easy transfer of materials between the interchange and main chamber.

- The clear-view outer interchange door is left-hand swing. The door seals against peripheral gaskets to maintain internal negative pressure. This door is opened only when interchamber door is closed.
- The interchamber pass-thru door to the main work area swings open while under negative pressure. This door is opened only when outer door is closed.
- Mechanical interlocks prevent both the interchamber door and exterior pass-thru door from being opened at the same time, maintaining containment and product protection.



The isolator pass-thru interchange and main chamber pressure (vs. ambient) are negative to the room. Both the main chamber and interchange are always negative to the room, and provide protection to both product and personnel.

ChemoSHIELD® Performance Summary

For aseptic compounding of hazardous chemotherapy agents and IV admixtures that can be harmful to pharmacy personnel	Pass-Thru Interchange Pressure	Work Chamber Pressure	Protection Profile Not intended for use with biologically hazardous materials			E ha ai
	Negative To Room	Negative To Room	Product Protection	Operator Protection	Environmental Protection	- Exhaust
Standard Ratio Product/ Personnel		-	Yes	Yes	Protects environment from particulates. Also protects environment from vapors and gases if connected to a treated exhaust system.	HEPA filter to facility exhaust system through hard connection via 8" collar.

Plenum Design Ensures Protection and Extends Filter Life

ChemoSHIELD[®] employs a high performance airflow system that provides optimum protection from particulates, together with extended filter life and reduced cost of ownership.

- The ChemoSHIELD® design creates an internal top-to-bottom airflow with a uniform piston effect to sweep particulates from the work area to the HEPA filter.
- \cdot The HEPA supply filter cross-section covers 100% of the work area.
- The unique plenum apportions and distributes air across, then through the HEPA supply filter, improving downflow uniformity and extending useful filter life.
- The filter mount provides a direct seal of the filter to the plenum and simplifies filter replacement.

Optimized Interior Work Space, Plus Simplified Cleaning

The main chamber work area offers more than 5.1 sq. ft. of work space measuring $31^{\circ}W \times 24^{\circ}D$ for the CS500. The CS600 offers more than 7.6 sq. ft. of work space measuring $46^{\circ}W \times 24^{\circ}D$. The interior back wall is vertical for maximum use of interior space.

- All interior surfaces of the main chamber and pass-thru interchange are Type 316 stainless steel for superior corrosion resistance.
- · Back and side walls are polished to a non-glare, easy-to-clean finish.
- · Interior surfaces can be accessed via gloves for sanitization.
- \cdot The interior cabinet's $\frac{7}{16}$ " radius corners permit easy wipe down.
- The sectional work surface trays are fully removable. Trays stack easily to either side to simplify cleaning and changing of exhaust HEPA filters.
- Exterior, scratch-resistant, PermaWhite™ powder coated finish provides durability required in pharmacy environments.

Controls Offer Superior Ease of Use

Because the cabinet airflow is created by a facility exhaust system external to the cabinet, on-board controls are minimized and streamlined.

- Large format, easy-to-read independent magnehelic gauges are positioned side-by-side to indicate relative negative pressure in the pass-thru interchange and the main work area with respect to the room.
- The externally mounted fluorescent lamps are controlled by an on/off switch on the main control panel.
- Mass airflow monitor measures airflow in exhaust and warns users of inadequate exhaust airflow (audible/ visual).

Utilities Designed for Convenience, Practicality, and Safety

- · A single power cord for electrical connection is included.
- Externally mounted fluorescent lamps illuminate both the pass-thru interchange and work area while minimizing heat buildup in the cabinet.
- An ergonomically styled multi-position IV bar allows hanging of IV bags or bottles.
- Duplex outlet, ground fault circuit interrupter (GFCI), 115V, AC, with weatherproof cover.



A viewscreen top hinge allows full opening for loading of instrumentation or equipment. The viewscreen is locked to prevent unauthorized opening.

Options and Accessories

Many options, accessories and modifications are available and should be specified when ordering. Commonly requested options are listed below. For detailed information on accessories and modifications, contact The Baker Company.

- \cdot Vinyl bags for filter disposal
- · Ergonomically adjustable footrest; field installed
- · Seismic restraints; field installed
- · Replacement gloves/sleeves

Ordering

For ordering information, terms and conditions of sale, contact The Baker Company or visit the Baker website at www.bakerco.com for the name of your authorized Baker Company representative.

ChemoSHIELD® Compounding Aseptic Containment Isolator (negative pressure)

I. Meets or exceeds CETA CAG 002-06.

2. Cabinet shall be tested to AGS standard for leak-tight work area.

3. Cabinet shall maintain a negative pressure in both the work area and the interchange.

4. Cabinet shall provide better than ISO Class 5 (Class 100) HEPA-filtered air across 100% of the work surface and in the interchange.

5. Filtered unidirectional airflow provides better than ISO Class 5 (Class 100) air cleanliness conditions within the chamber. Gas-tight construction coupled with negative pressure prevents contaminants from the outside from entering the chamber and contaminants from the work area from migrating to the outside.

6. Work surface airflow shall be from top to bottom to achieve a piston effect, sweeping particulates from the work area to the

HEPA filter.

7. Cabinet interchange negative pressure shall be visually verifiable by an independent magnehelic gauge on the main control panel.

8. The cabinet interchange outer door shall be of clear, shatterproof polycarbon. Door shall have left-hand swing.

9. The cabinet interchamber door to the work area shall be 12-gauge., 316 stainless steel with hinge for opening.

10. Cabinet work area negative pressure shall be visually verifiable by an independent magnehelic gauge on the main control panel.

11. The hinged viewscreen shall be slanted at an angle of 10° from vertical.

12. The viewscreen shall be capable of fully opening to load equipment or instruments.

13. The hinged viewscreen shall have a key lock to prevent unauthorized opening.

14. Viewscreen shall be constructed of shatterproof, clear polycarbonate.

15. Viewscreen shall have three gloveports for the CS600. Two gloveports for the CS500. Gloves shall be nitrile rubber. Gloves are ambidextrous.

16. Stainless steel gloveports shall be oval to permit easy reach to all work surface areas.

17. The pass-thru interchange shall have one oval gloveport with a nitrile ambidextrous rubber glove.

18. All contaminated ducts, plenums and work area side walls shall be permanent metal construction and maintained under negative pressure.

19. Dimensions of the cabinet interior shall be apportioned as follows:

a. work area: CS500 – 31 "W × 23¾"F-B × 25¾"H CS600 – 46"W × 24"F-B × 25¾"H

b. interchange: CS500/CS600 – 17½"W x 24"F-B x 25%"H

20. Cabinet shall employ plenum to provide more uniform airflow to the supply filter.

21. Supply HEPA filters shall be front-loading.

22. Exhaust HEPA filters shall be bag-out design.

23. Plenum assembly shall be provided to allow the filters to be directly clamped to the plenum against a closed-cell neoprene gasket. The plenum applies force to full perimeter of filters, rather than point force.

24. Complete unit shall be certified by Underwriters Laboratory (UL) for electrical, fire and mechanical safety.

- 25. Cabinet exterior construction:
 - a. seal panels of 16-gauge, cold-rolled steel
 - b. dress panels of 18-gauge, coldrolled steel, powder-coated finish, PermaWhite™.

26. Cabinet interior (work area) construction shall be one-piece, 16-gauge, Type 316 stainless steel, with a smooth, 7/6" radius between rear and side walls, and easily cleanable, radiused corners on the work surface tray.

27. Work area side walls and rear wall to be one-piece construction.

28. A straight back wall shall be provided to maximize work area and easily accommodate pharmacy equipment.

29. Work area shall be outfitted with protected work area duplex outlet with weatherproof cover and circuit breaker.

30. Cabinet shall have a unitized drain pan with 7/16" radius on all sides and a fully removable work surface to facilitate cleaning.

31. A Type 316 stainless steel air diffuser and filter protector shall be provided in work area and pass-thru chamber (Interchange).

32. Each unit, before shipping, shall have a complete physical test to assure cabinet meets performance requirements. A copy of this test will be provided with the unit.

33. External adjustable damper provided to compensate for changing resistance of exhaust and supply filters.

34. A single power cord and plug shall be provided for electrical power source.

35. The unit shall have standard HEPA filters for a protection effectiveness of 99.99% when filtering particles of 0.3 micron size.

36. The unit shall be configurable for use while sitting or standing.

37. The unit shall include an adjustable stand with telescoping legs to allow the work surface height to be fixed at 36" to $44\frac{1}{2}"$.

38. Cabinet shall pass a 30-minute leak test per the American Glove Box Society standard.

NIOSH Alert

NIOSH calls for cabinets used to prepare chemotherapy drugs to be exhausted to the outdoors because of the risk of vaporization of hazardous drugs. ChemoSHIELD is designed to comply with the NIOSH alert and requires connection to an externally vented exhaust system.

Warranty

The Baker Company, Inc., expressly represents and warrants all goods (a) to be as specified (and described) in The Baker Company catalogs and literature, and (b) to be free under normal use, service and testing (all as described in The Baker Company catalogs and literature) from defects in material and workmanship for a period of thirty-six months from the invoice date on units sold in the United States and twelve months for units sold internationally.

The exclusive remedy for any breach or violation of this warranty is as follows: The Baker Company, Inc., will F.O.B. Sanford, Maine, furnish without charge repairs to or replacement of the parts or equipment that proved defective in material or workmanship. No claim may be made for any incidental or consequential damages.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE UNLESS OTHER-WISE AGREED IN WRITING SIGNED BY THE BAKER COMPANY. (THE BAKER COMPANY SHALL NOT BE RESPON-SIBLE FOR ANY IMPROPER USE, INSTALLATION, SERVICE OR TESTING OF THE GOODS.)



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