

**PHARMACY
PRODUCTS**

SteriSHIELD®
Compounding Aseptic
Isolator (CAI)



Positive pressure sterility
assurance barrier isolator
for complete
product protection.



THE BAKER COMPANY



SterilSHIELD® Compounding Aseptic Isolator



Designed specifically for ultimate product protection
of non-hazardous drugs

- Offers a contained, positive pressure work area for pharmacy applications
- Designed specifically for aseptic compounding of non-hazardous drugs and to meet or exceed the requirements of USP<797>
- Creates a HEPA-filtered, unidirectional airflow of better than ISO Class 5 (Class 100) air cleanliness conditions within the direct compounding area to prevent contaminants from the outside entering the chambers
- Combines industry-leading airflow technologies with exceptional design and equipped with ergonomic features to improve worker comfort and increase productivity
- Spacious, positive pressure interchange (pass-thru chamber) allows clean and easy transfer of materials in or out of the chamber

SterilSHIELD®

Designed for aseptic compounding of non-hazardous pharmaceuticals

Industry-Leading Airflow Technology Provides Superior Product Protection

- CETA tested in accordance with CAG 002-06.
- Unidirectional airflow delivers optimum performance.
- Ensures immediate removal of contamination.
- Provides rapid recovery to ISO Class 5 (Class 100).
- Allows shorter wait time for ingress/egress of materials.
- HEPA-filtered pass-thru chamber enables better process flow.
- Combination door sash facilitates removal of outer packaging and wipe down.



A viewscreen top hinge allows full opening for loading of instrumentation or equipment.

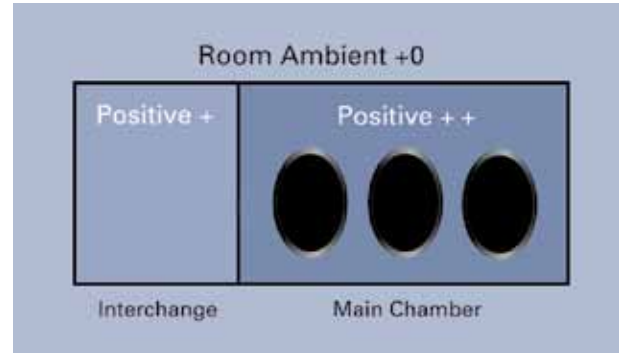
Ergonomic Design Offers Superior Comfort and Ease of Use

- The slanted viewscreen is made of shatterproof acrylic plastic, and angled at 10° for optimum ergonomic comfort and safety.
- The viewscreen with top hinge allows full opening for loading and unloading of pharmacy instrumentation or equipment.
- Oval gloveports offer easy reach to interior surfaces for users of different heights.
- In the main chamber, there are three glove positions on model SS600, two on models SS500 and SS400, and four—with two on each side—on model SS800, allowing total access to the interior.
- Spacious, positive pressure interchange (pass-thru chamber) allows clean and easy transfer of materials in or out of the chamber.
- An adjustable stand allows users to configure the cabinet for use standing or sitting.

Pressure Balance Ensures Product Protection

The Isolator main chamber pressure (vs. ambient) is positive to the room. Additionally:

- The main chamber is slightly more positive than the pass-thru interchange to maintain aseptic conditions in the main chamber.
- The pass-thru interchange is slightly less positive than the main chamber to assure aseptic conditions within the main working chamber.
- Full-ceiling, front-loading HEPA supply filter is 99.99% efficient; provides better than ISO Class 5 (Class 100) air within the pass-thru and main working chambers.
- Unidirectional (downflow) airflow purges airborne particulates from the work area.
- Stainless steel air diffuser in main chamber and pass-thru interchange provides unidirectional airflow and protects the HEPA filter.



The Isolator main chamber pressure (vs. ambient) is positive to the room. The main chamber is slightly more positive than the pass-thru interchange to ensure aseptic conditions within the main chamber.

SteriSHIELD® Performance Summary

For aseptic compounding of non-hazardous pharmaceutical compounds	Pass-Thru Interchange Pressure	Work Chamber Pressure	Protection Profile Not intended for use with biological or chemical hazards			Downflow	Exhaust
	Positive To Room	Positive To Room	Product Protection	Operator Protection	Environmental Protection		
Pressure Ratio	+	++	Yes	NA*	No	HEPA	Vented to Room

*Please note: the SteriSHIELD is not intended for use with biologically hazardous materials. The SteriSHIELD is constructed to UL standards for performance and safety.

Plenum Design Optimizes Protection and Extends Filter Life

SterilSHIELD® employs a unique, high performance airflow system that provides optimum protection from particulates, extends filter life and reduces cost of ownership.

- The filter configuration creates internal airflow from top to bottom for unidirectional piston effect to sweep particulates from work area to HEPA filter. The filter cross section covers 100% of the work area.
- The unique plenum apports and distributes air across, then through the HEPA supply filter, improving downflow uniformity, extending useful filter life and reducing noise.
- The filter mount provides a direct seal of the filter to the plenum and simplifies filter replacement.

Construction and Craftsmanship of the Highest Standard

All Baker cabinets feature seamless, coved corners and solid sheet construction. Interior back and side walls of the SterilSHIELD are stainless steel, polished to a non-glare, easy-to-clean finish.

- A telescoping stand adjustable from 30¹/₈" to 32⁵/₈" and 36¹/₈" to 38⁵/₈" work surface height is standard. An electric-overhydraulic ergonomic lift system is also available for the SterilSHIELD.
- The main chamber work area offers ample work space.
 - SS400, 31³/₈"W x 21¹/₈"D, 4.6 sq.ft.
 - SS500, 39³/₈"W x 20⁵/₈"D, 5.6 sq.ft.
 - SS600, 51³/₈"W x 20⁵/₈"D, 7.3 sq.ft.
 - SS800, 31³/₈"W x 21¹/₈"D, 4.6 sq.ft., each side
- Exterior, scratch-resistant PermaWhite™ powder coated finish provides durability for pharmacy environments.
- Interior surfaces of the main chamber can be accessed for initial and/or periodic sanitization by gloved hand.
- A separate work surface tray is fully removable.
- The interior cabinet and work tray have radius corners for easy wipe down.

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

- The outer interchange door is clear-view shatterproof acrylic plastic with left-hand swing. (The SS800 has doors on both ends. Left door swings left; right door swings right.)
- A convenient lift-up sash opens to 8" to permit quick transfer of small items without opening the door, and allows users to remove outer packaging and wipe down.
- The outer door seals against peripheral gaskets to maintain internal positive pressure; this door is opened only when interchange door is closed.
- The internal pass-thru door is vertical lift for maximum use of space and permits easy transfer of materials in or out of the positive pressure work area.

Microprocessor-Based Control Board Simplifies Operation

The microprocessor controller with touchpad membrane control offers simple, reliable operation.

- The unique moisture-proof membrane control surface is easily cleaned.
- Large format, easy-to-read independent magnehelic gauges are positioned side-by-side to indicate relative positive pressure in main work area and interchange with respect to the room.

StediVOLT® Motor Speed Controller Maintains Precise Airflow

The Baker exclusive StediVOLT motor speed controller reduces the risk of performance degradation due to line voltage fluctuations. StediVOLT minimizes changes in cabinet performance due to routine voltage fluctuations. StediVOLT reads incoming voltage and maintains proper blower speed to prevent periods of unbalanced airflow which may contribute to loss of aseptic conditions (product protection).

Functional Utilities

- A single power cord for electrical connection is included.
- An adjustable, ergonomically styled multi-position IV bar allows hanging of IV bags or bottles.
- A fluorescent lamp with ballast illuminates the work area.
- The 1/2" ball valve drain is located front left, to simplify cleaning.
- An exhaust connection is not required; exhaust air is vented to room.
- Cable ports to allow data cables to connect with exterior devices (standard on SS800)

Options and Accessories

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

- Duplex outlet, ground fault circuit interrupter (GFCI), 115V, AC, with weatherproof cover (main working chamber); and duplex outlet are standard on SS800
- Single petcock located right wall, center (option for 2 on right-hand side)
- Ergonomically adjustable footrest; field installed
- Seismic restraints; field installed
- Hydraulic ergonomic lift stand to allow infinite adjustments of work surface height from 22⁷/₈" to 40³/₈"
- Stainless steel work trays to help organize work and facilitate ingress/egress
- Glove liners
- Gloves and glove sleeves (nitrile)

Ordering

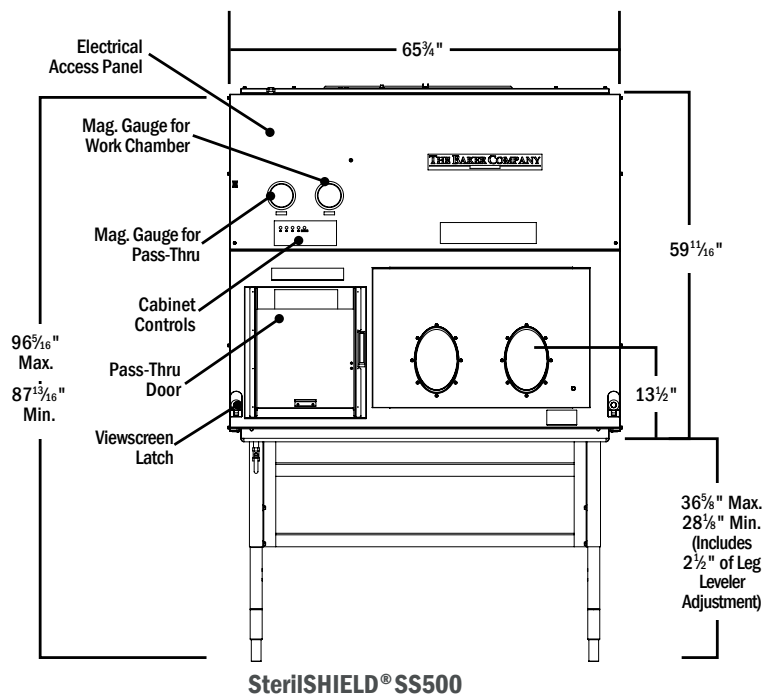
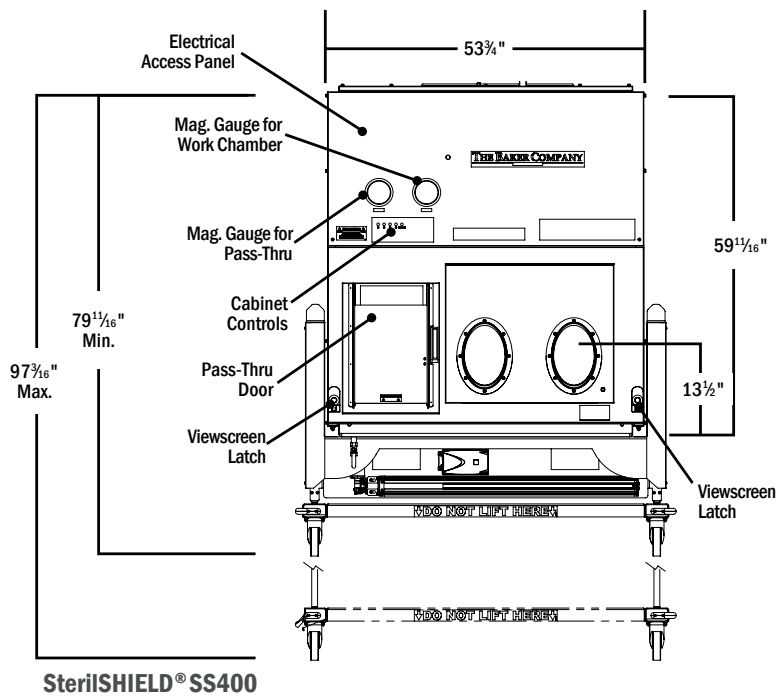
For ordering information, terms and conditions of sale, contact The Baker Company or visit the Baker website at www.bakerco.com for the name of your authorized Baker Company representative.

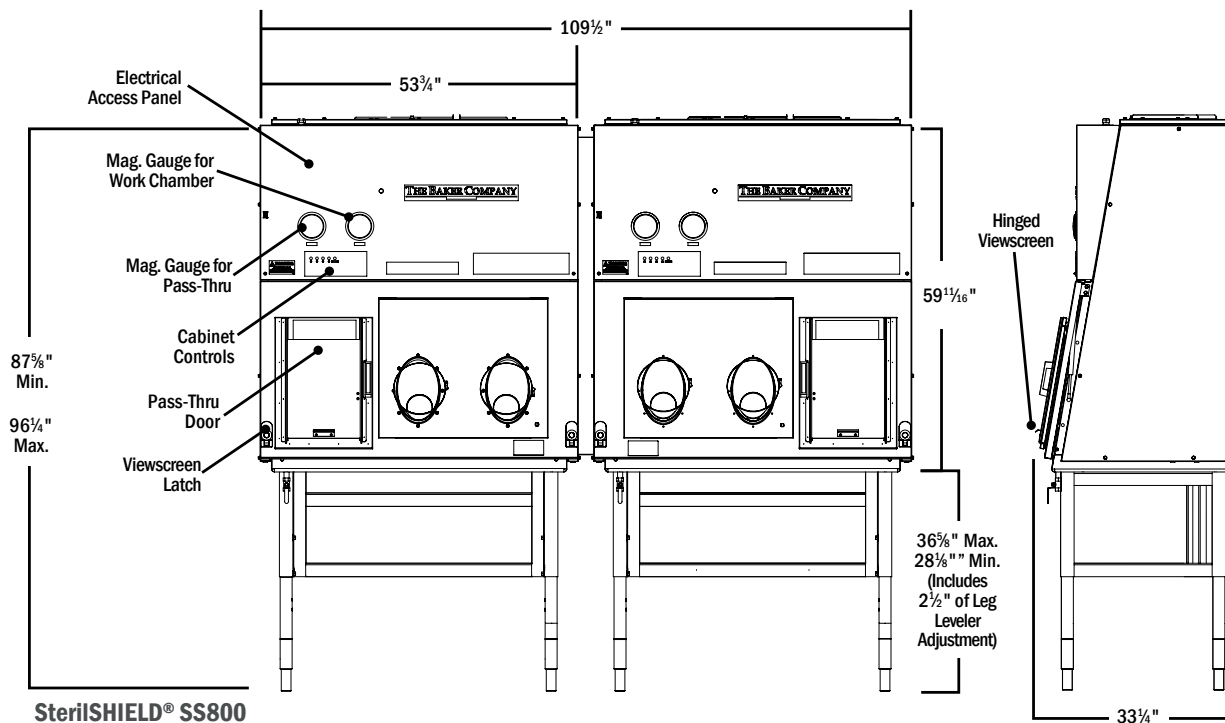
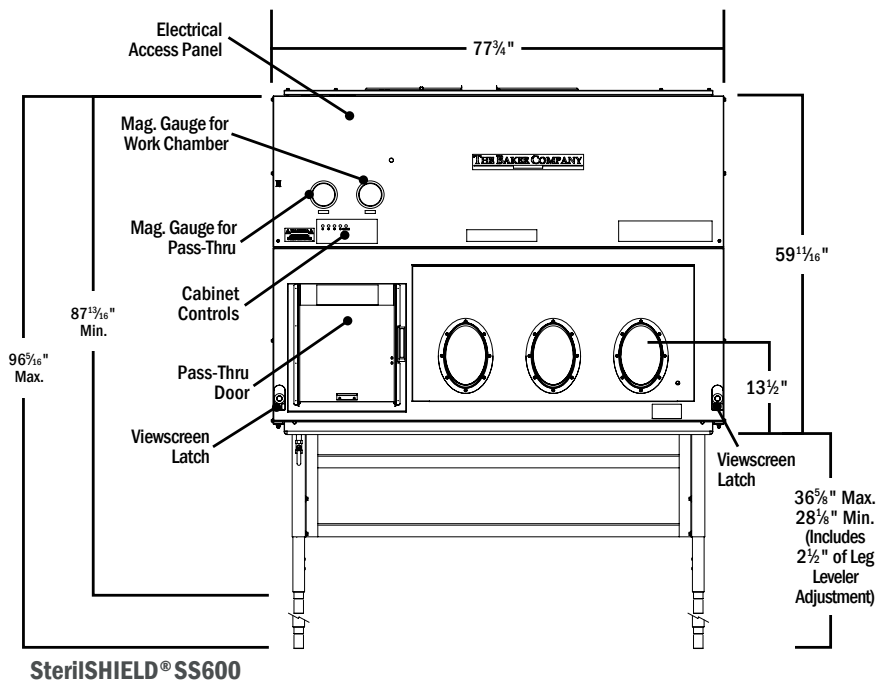
Site Preparation

Summary Specification, SteriSHIELD® Glovebox

MODEL NUMBER	SS400	SS500	SS600	SS800*
Size	4'	5'	6'	8'
Electrical	115V, AC	115V, AC	115V, AC	115V, AC
Amps (Total)	16	16	16	16
Interior Dimensions (Pass-Thru)	14 ⁹ / ₁₆ "W × 21 ¹ / ₈ " F-B × 26 ¹ / ₂ "H	18 ⁹ / ₁₆ "W × 20 ⁵ / ₈ " F-B × 26 ¹ / ₂ "H	18 ⁹ / ₁₆ "W × 20 ⁵ / ₈ " F-B × 26 ¹ / ₂ "H	14 ⁹ / ₁₆ "W × 26 ¹ / ₂ " F-B
Interior Dimensions (Main Chamber)	31 ³ / ₈ "W × 21 ¹ / ₈ " F-B × 26 ¹ / ₂ "H	39 ³ / ₈ "W × 20 ⁵ / ₈ " F-B × 26 ¹ / ₂ "H	51 ³ / ₈ "W × 20 ⁵ / ₈ " F-B × 26 ¹ / ₂ "H	30 ³ / ₈ "W × 26 ¹ / ₂ " F-B × 26 ¹ / ₂ "H
Exterior Dimensions, Nominal	53 ³ / ₄ "W × 33 ¹ / ₄ " F-B × 87 ¹³ / ₁₆ "H- 96 ⁵ / ₁₆ "H	65 ³ / ₄ "W × 33 ¹ / ₄ " F-B × 87 ¹³ / ₁₆ "H- 96 ⁵ / ₁₆ "H	77 ³ / ₄ "W × 33 ¹ / ₄ " F-B × 87 ¹³ / ₁₆ "H- 96 ⁵ / ₁₆ "H	109 ¹ / ₂ "W × 33 ¹ / ₄ " F-B × 87 ¹³ / ₁₆ "H- 96 ⁵ / ₁₆ "H
Net Weight	650 lbs	700 lbs	800 lbs	1270 lbs
Ship Weight	850 lbs	900 lbs	1000 lbs	1700 lbs

*SS800 is comprised of two SS400 models with a tunnel, is shipped in two pieces, and is assembled on site.





SterilSHIELD® Compounding Aseptic Isolator (positive pressure)

1. Cabinet shall maintain a positive pressure in both the work area and the interchange.
2. Cabinet shall provide better than ISO Class 5 (Class 100) internal air cleanliness conditions within main chamber and the interchange.
3. Filtered unidirectional airflow of better than ISO Class 5 (Class 100) air cleanliness conditions within the chambers prevents ingressive contaminants from the outside from entering the chambers. Factory test reports are shipped with the cabinet.
4. Work surface airflow shall be from top to bottom to achieve a piston effect, sweeping aerosols and particulates from the work area.
5. Cabinet interchange positive pressure shall be visually verifiable by an independent magnehelic gauge on the main control panel.
6. The cabinet interchange outer door shall be of clear-view plastic, ¼" Lexan®, with left-hand swing. (The SS800 has two doors, one on each end. The left side swings left and the right side swings right.)
7. The cabinet interchange inner door to the work area shall be solid clear-view plastic, ¼" Lexan®, with a vertical lift door for maximum use of work space.
8. Cabinet work area positive pressure shall be visually verifiable by an independent magnehelic gauge on the main control panel.
9. The hinged viewscreen shall be slanted at an angle of 10° from vertical.
10. The viewscreen shall be capable of fully opening to load equipment or instruments.
11. Viewscreen shall be constructed of shatterproof, clear-view plastic, ¼" Lexan®.
12. Viewscreen shall have three gloveports (SS600), two gloveports (SS400, SS500), four gloveports (SS800). Gloves are ambidextrous.
13. Standard gloves are 2-piece nitrile. Sleeve is a thick 15 mil and hand piece is thin and offers good dexterity. Hand piece is disposable.
14. Gloveports shall be oval to permit easy reach to all work surface areas.
15. Dimensions of the cabinet interior (wall to wall) shall be apportioned as follows:
 - a. work area:
 SS400 – 31⅜"W x 21⅛"D x 26½"H
 SS500 – 39⅜"W x 20⅝"D x 26½"H
 SS600 – 51⅜"W x 20⅝"D x 26½"H
 SS800 – 31⅜"W x 21⅛"D x 26½"H, each side
 - b. interchange:
 SS400 – 14⅞"W x 21⅛"D x 26½"H
 SS500/SS600 – 18⅞"W x 20⅝"D x 26½"H
 SS800 – 14⅞"W x 21⅛"D x 26½"H, each side
16. Cabinet features a unique plenum design to provide a unidirectional airflow system that provides uniform airflow to the supply filter and provides optimum protection from particulates, extends filter life and reduces cost of ownership.
17. Supply filter shall be front-loading.
18. A plenum assembly shall be provided to allow the filter to be directly clamped to the plenum against a closed-cell neoprene gasket. Plenum applies force to full perimeter of filters, rather than point force.
19. Complete unit shall be listed by Underwriters Laboratory (UL) for electrical, fire and mechanical safety.
20. Cabinet shall have a microprocessor-based membrane control panel mounted on the front of the cabinet.
21. Cabinet exterior construction:
 - a. seal panels of 16-gauge, cold-rolled steel
 - b. dress panels of 18-gauge, cold-rolled steel, powder-coated finish, PermaWhite™
22. Cabinet interior (work area) construction: one-piece 16-gauge, Type 304 stainless steel, with a smooth, ⅞" radius between rear and side walls, and easily cleanable radius corners on the work surface tray.
23. A straight back wall shall be provided to maximize work area and easily accommodate pharmacy equipment.
24. Work area shall be capable of being outfitted with a GFCI protected duplex outlet with weatherproof cover and circuit breaker.
25. Work area shall be capable of being outfitted with a petcock, right wall.
26. Cabinet shall have a unitized drain pan with ⅞" radius on all sides and a fully-removable work surface and work surface supports to facilitate cleaning.
27. Stainless steel air diffuser that provides unidirectional airflow and helps protect the HEPA filter shall be provided in work area.
28. Prior to shipping, each unit shall have a complete physical test to assure cabinet meets performance requirements. A copy of this test will be provided with the unit.
29. Speed controller shall automatically compensate for voltage change to maintain constant voltage to motor while allowing for manual adjustments during filter loading.
30. External adjustable damper shall be provided to compensate for changing resistance of supply filter.
31. A single power cord and plug shall be provided for electrical power source.
32. External plumbing connections for the optional petcocks shall be made through the back, bottom or top of the cabinet and not the sides, allowing zero clearance between the unit and the building walls or equipment to its right and left.
33. The unit shall have a standard HEPA filter for a protection effectiveness of 99.99% when filtering particles of 0.3 micron size.
34. The unit shall include an adjustable stand with telescoping legs to allow the work surface height to be set from 30⅛" to 38⅝".

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.

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 OTHERWISE AGREED IN WRITING SIGNED BY THE BAKER COMPANY. (THE BAKER COMPANY SHALL NOT BE RESPONSIBLE FOR ANY IMPROPER USE, INSTALLATION, SERVICE OR TESTING OF THE GOODS.)

THE BAKER COMPANY

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