OPERATOR’S MANUAL

SteriSHIELD

Compounding Aseptic Isolator (CAI)

MODELS:
SS400 / SS500 / SS600
Welcome to Baker

Thank you for choosing to join the growing number of people who are achieving excellence in science and clinical care through clean air, containment, and incubation solutions from Baker. As a fixture in laboratories and clinical settings around the world, Baker takes special pride in helping people just like you to create optimal environments for their work, while providing a safe and comfortable user experience.

At Baker, nothing is more important to us than the trust you place in our solutions to help you achieve your goals. Whether you are involved with basic scientific research, drug discovery, or patient care, Baker has a proven record of delivering high-performing equipment through an uncompromising commitment to safety, testing, quality, and craftsmanship. Additionally, as a Maine-based family owned business in operation for more than 60 years, you can rest assured that Baker will be there for you throughout the life cycle of your new equipment.

Baker is a pioneer in the field of biological safety, and our reputation is built on taking no shortcuts and making no compromises when it comes to user safety. We are the only manufacturer to routinely subject our own equipment to extensive microbiological aerosol testing in the most challenging conditions – above and beyond what the average user would ever encounter. However, the adequacy of any equipment for user safety in a specific application should always be evaluated. This risk assessment should be performed by an industrial hygienist, safety officer, or other qualified person representing the purchasing organization. Remember that you, the owner and user, are ultimately responsible and that you use this equipment at your own risk.

I recommend that you keep a copy of this manual, along with the factory test report (if applicable), near your new equipment for convenient reference by operators and qualified maintenance personnel. If you have any questions about the use or care of your Baker equipment, please do not hesitate to contact our Technical Service Department for assistance at (800) 992-2537 (+1 207 324-8773 outside the United States) or techsupport@bakerco.com.

Thank you for placing your trust in Baker.

Sincerely,

David Eagleson
President
The Baker Company, Inc.
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Function of the SterilSHIELD®

The SterilSHIELD® is a Compounding Aseptic Isolator (CAI) designed to provide product protection from airborne contaminants throughout the compounding and material transfer processes and provide an aseptic environment for compounding sterile preparations. The SterilSHIELD® meets the definition of a Restricted Access Barrier System (RABS) allowing the ingress and/or egress of materials through defined openings to inhibit the transfer of contamination to the work area. The SterilSHIELD® is vented directly into the laboratory. Product Protection is provided by HEPA filtered ISO Class 5 unidirectional downflow air.

In operation, the SterilSHIELD® blower pushes air into the supply plenum. From there most of the air passes through a HEPA filter and air diffusers located within the pass-through and work chambers, providing filtered unidirectional downflow air to the work space. The work chamber is under a more positive pressure than the pass-through chamber so that air moves from the work chamber and into the pass-through chamber aiding in providing product protection (see figure 2A). Some air in the plenum is exhausted out the top of the unit without any filtration. The downflow air splits at the work surface level, enters the front and rear perforations, then recirculates back to the blower (See Figure 1). The pass-through chamber allows items to be introduced to or removed from the work chamber without compromising product protection.

![SterilSHIELD® Airflow Diagram](image)

Figure 1- SterilSHIELD® Airflow

SterilSHIELD® Design

Figures 2A and 2B below show the standard construction and components of the unit.
Figure 2A- SterilSHIELD® Features (External)
Figure 2B - SterilSHIELD® Features (Internal)
SteriSHIELD® Operators Manual

Regulatory Compliance

Standards

This Baker product has been designed, manufactured and tested to comply with the following regulatory standards where applicable. Unless stated otherwise, the most recent edition of these standards has been applied.

Electrical, Mechanical, Fire and Personal Safety:
Electrical Equipment for Measurement, Control and Laboratory Use, General Requirements
US: UL61010-1
CANADA: CAN/CSA C22.2 No. 61010-1
INTERNATIONAL: Low Voltage Directive 2006/95/EC; EN61010-1

Safety for Laboratory Hoods and Cabinets
US: UL 1805

American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.
1791 Tullie Circle, NE, Atlanta, GA, 30329

Electromagnetic Compatibility:
Electrical Equipment for Measurement, Control and Laboratory Use, EMC Requirements

Hazardous Waste Abatement:
Directive on Restriction of Hazardous Substances, RoHS Directive, 2011/65/EU; EN50581


Biological Safety:
US: Biosafety Cabinetry Certification; NSF/ANSI 49
INTERNATIONAL: Biotechnology – Performance criteria for microbiological safety cabinets; EN 12469

Industry Guideline References:
IEST-RP-CC002.3: Unidirectional Flow Clean-Air Devices,
Institute of Environmental Sciences and Technology
2340 S. Arlington Heights Road, Suite 100, Arlington Heights, IL 60005-4516, USA
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Compounding Isolators:


Cautionary Notes

Hazards may still exist, especially if the unit is not installed, operated and maintained in accordance with the instructions in this manual and the service manual.

This unit may be affected by high levels of electromagnetic radiation from other electronic devices that are being used in close proximity or connected to the same facility power system.

This unit may cause radio interference or affect the operation of other equipment in close proximity. Mitigation measures such as relocation, re-orientation, or shielding may be required.

Standard Features

Arm Ports

Arm ports provide access between two spaces that the operator can reach through. They provide a physical barrier when appropriate sleeves/gloves are attached.

Drain Pan

The drain pan is constructed of stainless steel with smooth corners to facilitate cleaning and disinfection. Drainage is provided by a stainless steel ball valve.

Cable Port

The cabinet has one cable port located in the right sidewall. Cable ports provide a safe means of introducing power and/or data cables, siphoning tubes, etc. into the work area of the cabinet.

Cable Port Hooks

Stainless steel hooks are provided to suspend cables or tubing along the cabinet interior back wall when the cable port is used. The hooks should be located along the interior rear wall or work surface in the designated slots.
Pass-Through Chamber

The pass-through chamber is a positive pressure chamber designed to allow transfer of items in and out of the work chamber during operation without compromising product protection when proper procedures are used. It is composed of an exterior hinging pass-through access door for introduction of products and equipment. The door has a sliding viewscreen that can be opened for surface cleaning of products and equipment before bringing them into the work chamber. A vertical sliding inter-chamber door provides a physical barrier between the work chamber and the pass-through chamber. This chamber contains HEPA filtered clean air and operates at a lower positive pressure than the adjacent work chamber allowing the HEPA filtered clean air of the work chamber to flow into the pass-through chamber when the inter-chamber door is open. This ensures product protection in the work chamber. When the pass-through access door or sliding viewscreen is opened pass-through air is pushed out into the room helping to provide product protection.

Work Chamber

The work chamber is a positive pressure chamber that includes unidirectional HEPA-filtered downflow air to provide better than ISO Class 5 (Class 100) air cleanliness conditions. It has a hinged viewscreen door and glove ports equipped with gloves, providing a physical barrier between the operator and the product. The door is hinged along the top and may be fully opened for loading or unloading.

<table>
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<th>CAUTION</th>
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<tr>
<td>All compounding materials must be introduced into the work chamber via the pass-through chamber.</td>
</tr>
<tr>
<td>The work chamber viewscreen door should never be opened until after the work chamber has been properly cleaned and decontaminated.</td>
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Controls

The operator controls and indicators are arranged in a single, easily cleaned membrane switch assembly on the front of the cabinet. There are pushbuttons for blower, fluorescent light, and outlet. See the Controls section in this manual for more detail.

Filter

Supply
IMPORTANT

This pre-filter should be inspected and cleaned regularly by using a HEPA vacuum, washing with a mild detergent or autoclaved. The interval for cleaning will vary with the application.

The High Efficiency Particulate Air (HEPA) filters consist of a continuous sheet of glass fibers pleated and mounted in a rigid frame. The filter inside the unit is scan-tested before leaving Baker. It is 99.99% effective on removal of the most penetrating particle size (mpp) (0.3 micron). Each filter is leak checked after installation in the unit and prior to shipment. HEPA filters are not intended to filter gasses or vapors. Misuse of chemicals, Bunsen burners, or a heavy dust load will shorten the life of the filter.

PreFilters

A prefilter is located on the top left side of the unit upstream of the motor blower and supply HEPA filter. The prefilter is made of a course material placed upstream or before the work area HEPA filter used to capture large particles. The prefilters can be cleaned using a HEPA vacuum and mild detergent and reused.

Gloves

The gloves and sleeves provided are ASTM standard D6978-05 certified.

IV Bar

The unit is equipped with an intravenous (IV) bar to facilitate the hanging of required materials.

Lighting

The work chamber is illuminated to provide a typical average illuminance of 100 foot-candles [1076 lux] of illumination at the work chamber work surface and 45 foot-candles [484 lux] at the pass-through chamber work surface. This unit features solid-state electronic ballasts. These ballasts increase reliability, efficiency and service life with lower heat output.

Motor/Blower

The motor and blower are built as a single assembly and balanced to minimize vibration. The motor/blower system automatically compensates for some increase in pressure drop across the filter(s) without reducing
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the total air flow rate by more than 10%. The air flow capacity of the cabinet is measured by the ability to provide a nearly constant volume of air as the filter resistance to airflow increases.

Motor Speed Control

The StediVOLT™ speed controller compensates for normal fluctuations in line voltage and is designed to maintain relatively consistent air flow when the filter loads. This helps to maintain proper airflow.

Outlet

This cabinet has an outlet in the right sidewall of the unit for powering instruments inside the work area. The outlet is rated at 5 Amps total. On 115V cabinets this outlet is Ground Fault Circuit Interrupt (GFCI) protected.

Pressure Monitors

The unit has separate analog pressure gauges to display the positive operating pressure in the pass-through and work chamber. These pressure gauges are for reference only and should not be used to determine the unit setpoint.

Viewscreen

The unit door viewscreens are constructed of shatterproof, clear polycarbonate.

Work Surfaces

The work chamber and pass-through chamber have multiple-piece flat work surfaces. The work surfaces are constructed of stainless steel and finished to reduce light reflection. The work surfaces and work surface supports are removable allowing access to the drain pan.

Optional Features

Anchoring Systems

Anchors

Floor and wall restraints are available without California OSHPD approval.

Foot Rest

An adjustable ergonomic foot rest is available for added operator comfort.
Plastic Storage Bins

Plastic bins for storage can be purchased and are installed below the base of the unit.

Pull Bars

The unit can be equipped with pull bars to facilitate ease of movement within the laboratory when casters are installed.

Service Connections

Hardware

Additional factory installed services are available on either sidewall. Other optional configurations are available.

Quantity and Exiting Direction

Additional factory installed services are available on the right side wall of the work chamber.

Stand

Telescoping Stand

The telescoping stand has adjustable legs and leg levelers. The legs provide a minimum stand height of 28 1/8 in [714 mm] and a maximum height of 36 1/8 in [917.5 mm] with leg levelers in minimum position. The leg leveler provides an additional 2 1/2 in [63.5 mm] of height adjustment.

Powered Hydraulic Lift Stand

Cradle Lift

The cradle lift is a stand provided with an electric motor driven hydraulic pump that allows height adjustment to help with worker comfort. This stand is shaped to allow the unit to set in between the lifting cylinders giving greater ability to fit through doorways or into rooms with low ceiling heights. The lift stand has 5" [127mm] diameter casters for moving the unit.

Proper SterilSHIELD® Use
Baker SteriSHIELD®s are designed for continuous operation. It is recommended that the blower be left on at all times to keep the interior work area clean and free of particulates.


The facility industrial hygienist, pharmacist or biosafety officer shall ensure that:

The unit is appropriate for all operations and procedures to be performed.

All operators are thoroughly trained and competent regarding the operation of this unit and all procedures they are required to perform.

The unit operation, procedures, and operators are monitored at regular intervals to ensure that safety is maintained.

CAUTIONS

• Explosive or flammable substances should never be used in this unit.
• This unit is a valuable supplement to, but not a replacement for, good laboratory technique and safe practice.
• If the operator does not operate the unit correctly, it may not provide adequate protection. To ensure product protection the workstation must be operated per the manufacturer’s instructions.
The operator controls and indicators are arranged in a single, easily cleaned membrane switch assembly on the front of the cabinet. There are pushbuttons for the optional UV light, fluorescent lights, outlets, blower and alarm mute. [Reference Figure 3]

**Figure 3. Operator Controls**

**Ultraviolet (UV) Light On/Off** – Not available on this unit.

**Fluorescent Light On/Off** – This pushbutton controls operation of the fluorescent light. A blue indicator light located below the pushbutton will illuminate when it is on.

**Outlet Power On/Off** – This pushbutton controls the power to the outlet in the pass-through chamber and work area. A blue indicator light located below the pushbutton will illuminate when it is on.

**Blower On/Off** – This pushbutton controls the operation of the cabinet blower. A green indicator light located below the pushbutton will illuminate when it is on.

**Alarm Mute (Alarm Reset)** – Not available on this unit.
Operation

Fluorescent Light

The fluorescent lighting is designed to provide an average illuminance of 100 foot-candles [1076 lux] of illumination at the work chamber work surface and 45 foot-candles [484 lux] at the pass-through chamber work surface.

The blower must be on for the fluorescent light to operate.

Outlet

The circuit powering the outlet is protected by a self-resetting circuit breaker which allows a total of 5 Amps. The outlet is in the right side wall of the work area.

For 115V AC/60Hz units the outlet is also protected by a Ground Fault Circuit Interrupter (GFCI). If the GFCI is tripped by the presence of an unsafe condition a red indicator on the GFCI will be on and the reset button on the front of the GFCI will be extended. Once the fault condition is corrected press the [RESET] button to reconnect power to the outlet. There is also a [TEST] button on the front of the device. The manufacturer recommends that the GFCI device be tested monthly to assure safe operation.

Blower

The motor and blower are built as a single assembly and balanced to minimize vibration.

The blower motor control is designed to automatically compensate for an increase in pressure drop across the filters without reducing total air flow rate by more than 10%. The airflow capacity of the cabinet is measured by the ability to provide a nearly constant volume of air as the filter resistance to airflow increases. The motor control also compensates for normal variations in power to the cabinet.

The blower must be turned on for the fluorescent light to operate.

Powered Hydraulic Lift (Optional)

Powered hydraulic lift stands may be provided with either a rocker switch or pushbutton switch control which is used to raise and/or lower the lift stand position to the desired ergonomic height. The approximate maximum travel is 12 inches for the ergo lift and 19 inches for the cradle lift but may have been custom programmed to have lower and/or upper stop positions that restrict allowable travel. The lift has an operational duty cycle of 1 minute on and 9 minutes off. If this duty cycle requirement is not observed, overheating of the motor or controller may occur. There is internal thermal protection for these components. If the lift becomes unresponsive, allow it to cool for 10 minutes and then retry adjusting the lift. The stand should always be positioned at its lowest height when the unit is moved to minimize the possibility of damaging the lift cylinders or overturning the unit.
Start-up Procedure

The operator should have read and understood the Controls and Operation section of this manual prior to performing this procedure. It is recommended that the unit be left running at all times.

1. If the cabinet has not been left running continuously, turn on the blower. An indicator light located below the pushbutton will illuminate when it is on. Listen for the sound of the cabinet blower running.

2. With all doors closed and latched, check the readings on the analog pressure gauges; the displayed value should be consistent with the recorded value in the most recent certification report. A significant change in pressure should be cause for investigation. This device is not intended to be used for air flow set-point verification.

![IMPORTANT]

This unit should never be operated with the work chamber viewscreen door open or unlatched.

3. Turn on the fluorescent light. The indicator light below the pushbutton will illuminate along with the interior work area. The fluorescent light will not operate unless the cabinet blower is on.

4. Inspect gloves and sleeves for holes.

5. Wipe down all interior surfaces of the unit work chamber and pass-through chamber with an appropriate surface disinfectant.

![IMPORTANT]

Some disinfectants, such as bleach or iodine, may corrode or stain the steel surfaces. Good practice is to thoroughly clean the surface afterward with a detergent, rinse with sterile water and wipe completely dry to prevent corrosion.

6. Disinfect all materials prior to placing them on the solid section of the pass-through work surface inside the unit. Blocking the perforated grilles must be avoided. After closing the door wait 1 minute before opening the inner chamber door, allowing the pass-through chamber and tunnel enough time to purge with HEPA filtered air. Everything required, and only what is required, should be placed inside the unit before beginning work. Implements should be arranged in the work chamber in logical order so that clean and dirty materials are segregated, preferably on opposite sides of the work area. If wipes or absorbent towels are used on the work surface, be sure to keep them away from the grilles.
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7. Leave the interior pass-through door closed while working in the main chamber.

Working in the SterilSHIELD®

This section contains some suggested basic work practices that should be observed when using this unit. It is not intended to be a comprehensive list for all applications. Some good reference sources are USP 39-NF34: United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, www.usp.org and CAG-001-2005: Applications Guide for the use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities, Controlled Environment Testing Association, 1500 Sunday Drive, Suite 102, Raleigh, NC 27607, USA, www.cetainternational.org.

The operator’s hands and arms should be washed thoroughly with soap both before and after working in the unit. It is recommended that long-sleeved gowns or lab coats with tight-fitting cuffs and sterile gloves are worn, to minimize the shedding of skin, or related contaminates, into the work area and to protect hands, arms, and clothing from contamination.

It is important that used materials be discarded into a tray or other suitable container inside the unit. This reduces unnecessary movement in and out of the work area.

Work should be performed using slow movements, and the number of movements should be limited as much as possible. All materials required should be placed in the unit prior to starting a procedure.

When a procedure has been completed, all equipment that has been in contact with the compounding agents should be enclosed and the entire work surface decontaminated. Trays of discarded materials, glassware, etc., should be covered. Once this has been done, remove all equipment from the unit through the pass-through chamber.

**WARNING**

Never use the unit to store supplies or laboratory equipment.

After removing all materials, compounding agents, etc. from the unit, decontamination of the interior surfaces should be repeated. Check the work area carefully for spilled or splashed liquids that might support bacterial growth.

It is recommended that the unit be left running continuously to ensure cleanliness.

Using Ancillary Equipment

The more equipment and material that is placed in the unit, the greater the possibility of disrupted airflow. The resulting turbulence can alter the designed airflow and reduce the effectiveness of the unit. When equipment which rotates, vibrates or heats is used, be sure to place it at the rear of the work area if possible. This will help minimize the turbulence within the unit.
Reacting to Spills

Even when good work practices are used, occasional spills may occur. All spills should be dealt with immediately to prevent contamination and to avoid any damage to the stainless steel surfaces. It is recommended that the operator, in coordination with the facility safety professional, have a written plan available in case of an accidental exposure or spill. The safety plan should include all of the emergency procedures to be followed in the event of an accident. All employees who use the unit should be familiar with the safety plan.

Cleaning and Disinfecting Stainless Steel

**IMPORTANT**

After cleaning and disinfection, all surfaces should be rinsed with sterile water and wiped completely dry.

Simple Cleaning

**IMPORTANT**

Do not use steel wool or steel pads when cleaning stainless steel.

Dirt deposits on stainless steel (dust, dirt and finger marks) can usually be removed using warm water, with or without detergent. If this does not remove the deposits, a mild, non-abrasive household cleaner can be used with warm water and bristle brushes, sponges or clean cloths.

Iron rust discoloration can be treated by rubbing the surface with a solution of 15% to 20% by volume of nitric acid and water and letting it stand for one to two minutes to loosen the rust. The proper safety equipment should always be used when handling acids.

Disinfection

The purpose of disinfection is to destroy any organisms that could pose a potential hazard to humans or compromise the integrity of the process. To ensure an organism is killed it is important to use a disinfectant in the proper concentration that is known to be effective for the specific organism. Standard disinfectants include: Iodophor-Detergent, Ethanol, Phenol and Alcohol. Hypochlorite (chlorine bleach) can also be used in dilute concentrations. Caution should be used, as Hypochlorite can cause pitting and/or cracking of stainless steel if it is either too concentrated or not completely removed from the surface in a timely manner. Allow an appropriate time to lapse for deactivation purposes (ref. *BMBL 5th Edition*) depending on the type of
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disinfection agent used. Follow up with a sterile water rinse and wipe completely dry to protect the stainless steel surface.

**IMPORTANT**

To avoid damage, all chemical disinfectants should be evaluated for compatibility with the polycarbonate access doors prior to use.

Disinfect the work area, work surface, and glove sleeves before and after every procedure.

Disinfect surfaces of all equipment used.

Remove all items from the inside of the unit.

Place all items that may have come in contact with the agent(s), such as used pipettes, in a plastic bag or other suitable container.

Disinfect the entire inside surface of the unit.

Spills on the work surface should be first cleaned and disinfected. Spills that fall through the perforated grilles in the work surface should be cleaned up and all waste put in an appropriate disposal container inside the work area. To clean the base pan under the work surface, lift the work surface, completely surface decontaminate the work surface including the underside and work surface supports, then remove all decontaminated items from the work area. Removing these parts provides unobstructed access to the base pan for easy cleaning. Before reinstalling the work surface and supports, disinfect all surfaces.

Space Decontamination

The National Institute of Health, National Cancer Institute and the Centers for Disease Control recommend the use of formaldehyde gas, chlorine dioxide gas, or hydrogen peroxide vapor all proven successful against most microbiological agents. All space decontamination activities shall be performed by individuals experienced in the handling and use of decontamination agents such as an accredited biosafety cabinet certifier. The selected decontamination agent should be determined effective against all the biological agents within the unit. Personnel should always use the proper safety equipment (gas masks, protective clothing, etc.) for the specific hazard. The antidote for the selected agent should be immediately available, in a visible and nearby location.

A good reference for understanding space decontamination procedures is provided in the most current version of the NSF/ANSI Standard 49 in Annex G “Recommended Microbiological Decontamination Procedures,” NSF International, 789 North Dixboro Road, P.O. Box 130140, Ann Arbor, Michigan, 48113-0140.
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Carcinogens and other toxins present a unique chemical deactivation problem and standard biological decontamination will not be effective against chemicals or other non-biological materials. A qualified safety professional, knowledgeable of the hazard, should be consulted to determine the proper procedure in these cases. Relocation of a cabinet must involve a risk assessment to determine the need and space decontamination method.

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Patent pending – Air Bypass Armrest, Cable Port

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This manual includes information for proper biosafety cabinet operation.

We recommend that the manual be kept near the cabinet for ready reference.