

OPERATOR'S MANUAL

ChemoSHIELD®

Compounding Aseptic Containment Isolator (CACI)



MODELS:

CS500 / CS600

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.

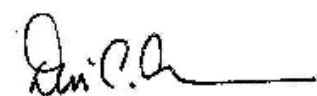
At Baker, nothing is more important to us than the trust you place in our solutions to help you achieve your goals. Whether you are involved with basic scientific research, drug discovery, or patient care, Baker has a proven record of delivering high-performing equipment through an uncompromising commitment 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,

A handwritten signature in black ink, appearing to read 'David Eagleson', followed by a horizontal line.

David Eagleson
President
The Baker Company, Inc.

Table of Contents

Function of the ChemoSHIELD®	1
ChemoSHIELD Design	2
Regulatory Compliance	3
Standards	3
Cautionary Notes.....	4
Standard Features.....	5
Air Flow Monitor (AFM)	5
Arm Ports	5
Base Pan	5
Chambers	5
Pass-Through Chamber	5
Work Chamber	5
Controls.....	6
Filters.....	6
Gloves.....	6
IV Bar	6
Lighting	6
Outlets.....	7
Pressure Monitors.....	7
Telescoping Stand	7
Work Surfaces	7
Optional Features	7
Air Tight Damper (ATD).....	7
Anchoring Systems.....	7
Anchors.....	7
Auxiliary Switch	8

Foot Rest	8
Plastic Storage Bins	8
Stand	8
Telescoping Stand with Casters	8
Powered Hydraulic Lift.....	8
Proper ChemoSHIELD Use.....	8
Controls.....	10
Operation.....	12
Outlets.....	12
Auxiliary Switch (Optional)	12
Powered Hydraulic Lift (Optional)	12
Alarm Conditions	13
Air Flow Monitor (AFM) Operation	13
Start-up Procedure.....	14
Working in the ChemoSHIELD	15
Using Ancillary Equipment	16
Reacting to Spills.....	16
Cleaning and Disinfecting Stainless Steel.....	16
Simple Cleaning.....	16
Disinfection	17
Cleaning Spills.....	18
Space Decontamination.....	18

Function of the ChemoSHIELD®

The ChemoSHIELD® is a Compounding Aseptic Containment Isolator (CACI) designed to provide personal protection from exposure to hazardous or potent pharmaceutical compounds throughout the compounding and material transfer processes, and also provide an aseptic environment for compounding sterile preparations. The ChemoSHIELD® meets the definition of a Restricted Access Barrier System (RABS) allowing the ingress and/or egress of materials through defined openings to prohibit the transfer of contamination to the critical site. The ChemoSHIELD® must be direct connected to a facility exhaust system to maintain proper exhaust flow and static pressure. Personnel protection is provided by a constant negative pressure within the work chamber. Product Protection is provided by HEPA filtered ISO Class 5 unidirectional downflow air and environmental protection is provided by exhaust HEPA filters.

In operation, the facility exhaust system pulls room air into the ChemoSHIELD® pass-through and main chambers via intake slots located above each chamber. All of the air then passes through a HEPA filter and air diffuser located within each chamber providing filtered unidirectional downflow air to the work space. The downflow air splits at the work surface level, enters the front and rear perforations, through HEPA filters below the work surface then is exhausted out of the unit through the facility exhaust system (See Figure 1). The pass-through chamber allows items to be introduced or removed from the work chamber without compromising personnel or product protection.

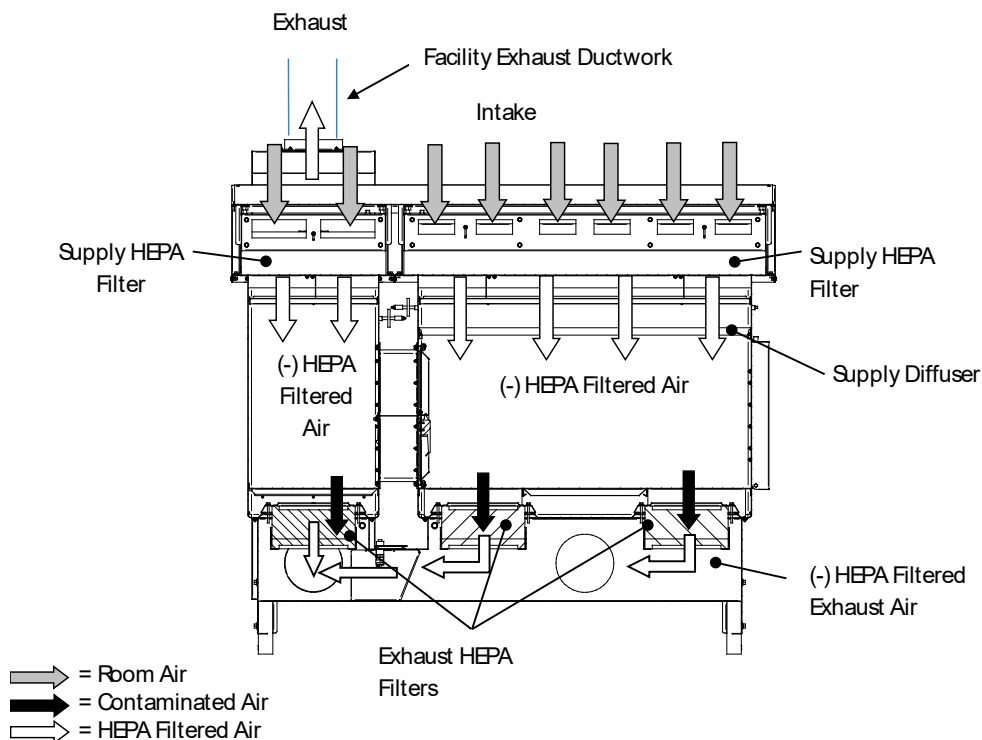


Figure 1- ChemoSHIELD Airflow

ChemoSHIELD Design

Figures 2A and 2B below show the standard construction and components of the unit.

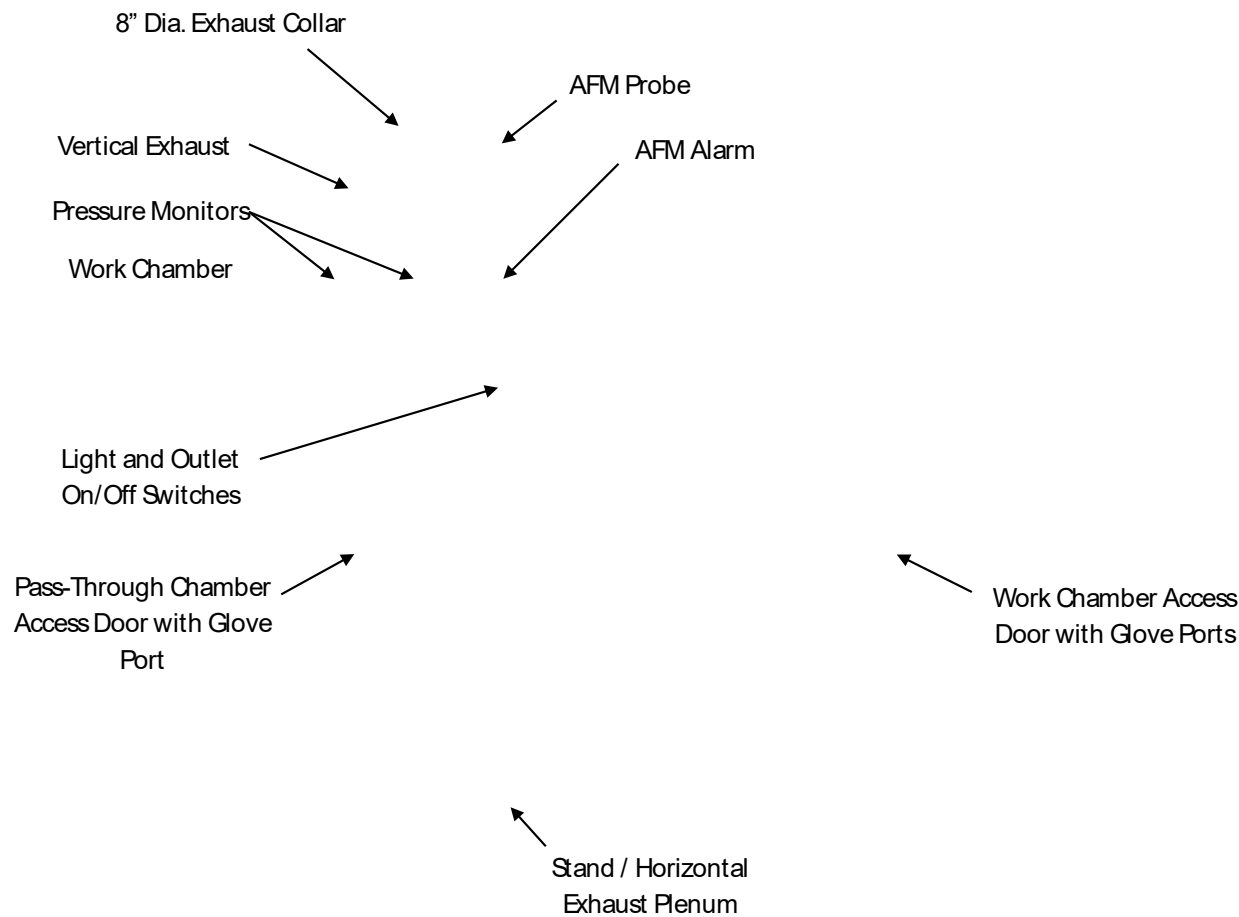


Figure 2A- ChemoSHIELD Features (External)

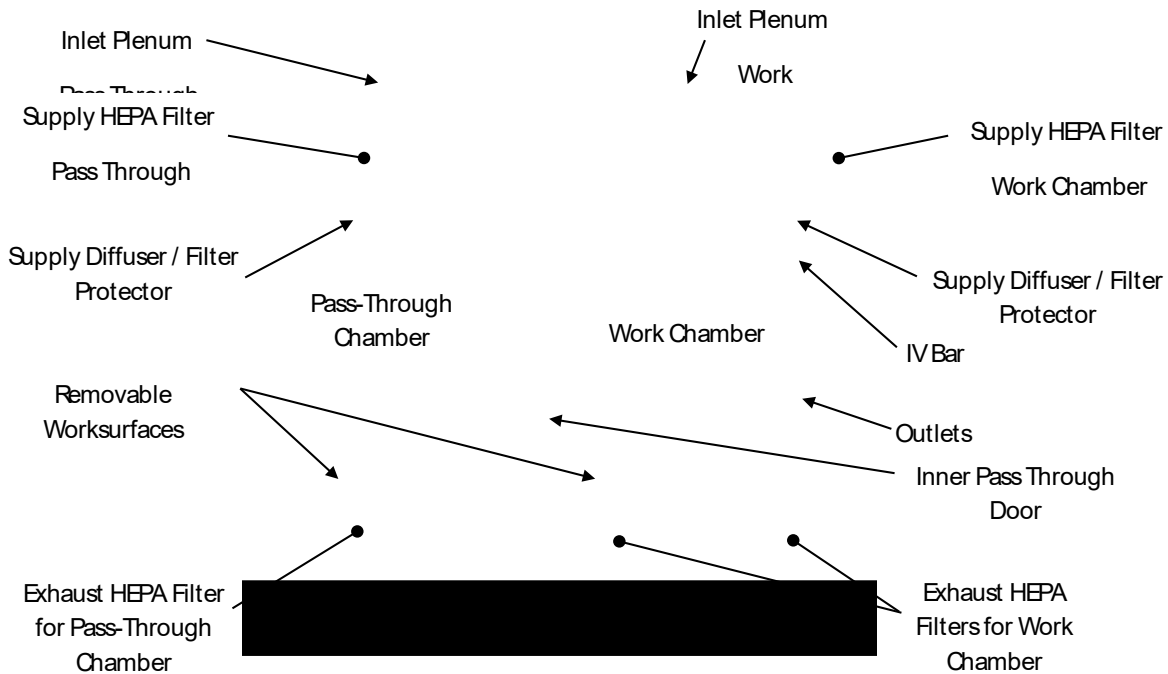


Figure 2B- ChemoSHIELD Features (Internal)

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

ANSI/ASHRAE 110-1995: Method of Testing Performance of Laboratory Fume Hoods

American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.

1791 Tullie Circle, NE, Atlanta, GA, 30329

www.ashrae.org.

Electromagnetic Compatibility:

Electrical Equipment for Measurement, Control and Laboratory Use, EMC Requirements

INTERNATIONAL: Directive on Electro Magnetic Compatibility, EMC Directive 2014/30/EU; EN61326-1

Hazardous Waste Abatement:

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

Directive on Waste Electrical and Electronic Equipment, WEEE Directive, 2012/19/EU

Biological Safety:

US: Biosafety Cabinet 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

www.iest.org

Compounding Isolators:

CAG-001-2005 (revised 12/08/2008): 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, www.cetainternational.org.

CAG-002-2006: CETA Compounding Isolator Testing Guide, Controlled Environment Testing Association, 1500 Sunday Drive, Suite 102, Raleigh, NC 27607, USA, www.cetainternational.org

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

Air Flow Monitor (AFM)

The AFM provides an audible and visual alarm relating to an unsafe exhaust flow as measured by a thermal anemometer probe installed in the unit exhaust collar.

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.

Base Pan

The base pan is constructed of stainless steel with smooth corners to facilitate cleaning and disinfection. The work surfaces can be repositioned for cleaning of the chamber pans.

Chambers

Pass-Through Chamber

The pass-through chamber is a negative pressure chamber designed to allow transfer of items in and out of the work chamber during operation without compromising product or personnel protection when proper procedures are used. It is composed of an inter-chamber door providing a physical barrier between the work chamber and the pass-through chamber, a chamber through which you can transfer items, and an external access door with a glove port. These doors have a mechanical interlock system preventing both doors from being open at the same time. This chamber contains HEPA filtered clean air and operates at a greater negative 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 is opened room air is pulled into the chamber helping provide personnel protection.

Work Chamber

The work chamber is a negative 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 with key lock latches 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.

CAUTION

All compounding materials must be introduced into the work chamber via the pass-through chamber.

The work chamber viewscreen door should never be opened until after the work chamber has been properly cleaned and decontaminated.

Controls

The operator controls and indicators are arranged in a switch assembly on the front of the unit. There are switches for fluorescent light and receptacle. See the **Controls** section in this manual for more detail.

Filters

CAUTION

Filter media is very delicate and should never be touched.

Only qualified technicians should replace HEPA filters.

The High Efficiency Particulate Air (HEPA) filters consist of a continuous sheet of glass fibers pleated and mounted in a rigid frame. Both the supply and exhaust filters inside the unit are scan-tested HEPA filters. They are 99.99% effective on removal of the most penetrating particle size (mpps) (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.

Gloves

The gloves and sleeves provided are ASTM standard D6978-05 certified for cytotoxic drug permeation.

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 light intensity 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.

Outlets

This unit has two outlets in the rear wall of the work chamber for powering instruments inside the work area. The outlets are rated at 10 Amps total all outlets. On 115V units these outlets are protected by a Ground Fault Circuit Interrupter (GFCI).

Pressure Monitors

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

Telescoping Stand

The telescoping stand has adjustable legs and leg levelers. The legs provide a minimum height (from the work surface to the floor) of 36 in (914mm) and a maximum height of 45 in (1143mm).

Work Surfaces

The work surface is constructed of stainless steel. This surface is finished to reduce light reflection. The work and pass-through chambers have multiple-piece flat work surfaces. The work surfaces are removable for cleaning and to gain access to the exhaust filters.

Optional Features

Air Tight Damper (ATD)

The air tight damper is used to seal the unit during decontamination.

Anchoring Systems

Anchors

Floor and wall restraints are available without California OSHPD approval.

Auxiliary Switch

The auxiliary switch option provides the ability to connect to a facility system blower or damper that will control exhaust air flow for the unit.

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.

Stand

Telescoping Stand with Casters

The telescoping stand with casters provide a minimum work surface elevation of: 36" to 45" [914 mm to 1,143 mm] and an overall height of 84" to 94" [2,134 mm to 2,388 mm]

Powered Hydraulic Lift

The unit can be provided with an electro-hydraulic lift system with adjustable feet providing work surface heights of 39 3/4" to 51" [1,010 mm to 1,295 mm]. Casters are not available for this option.

Proper ChemoSHIELD Use

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.

Baker ChemoSHIELDS are designed for continuous operation. It is recommended that the exhaust system connected to the unit be left on at all times to provide isolation and keep the interior work area clean and free of particulates.

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 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.

Controls

The operator controls with indicators are arranged on the front control panel of the unit. (See Figure 3)

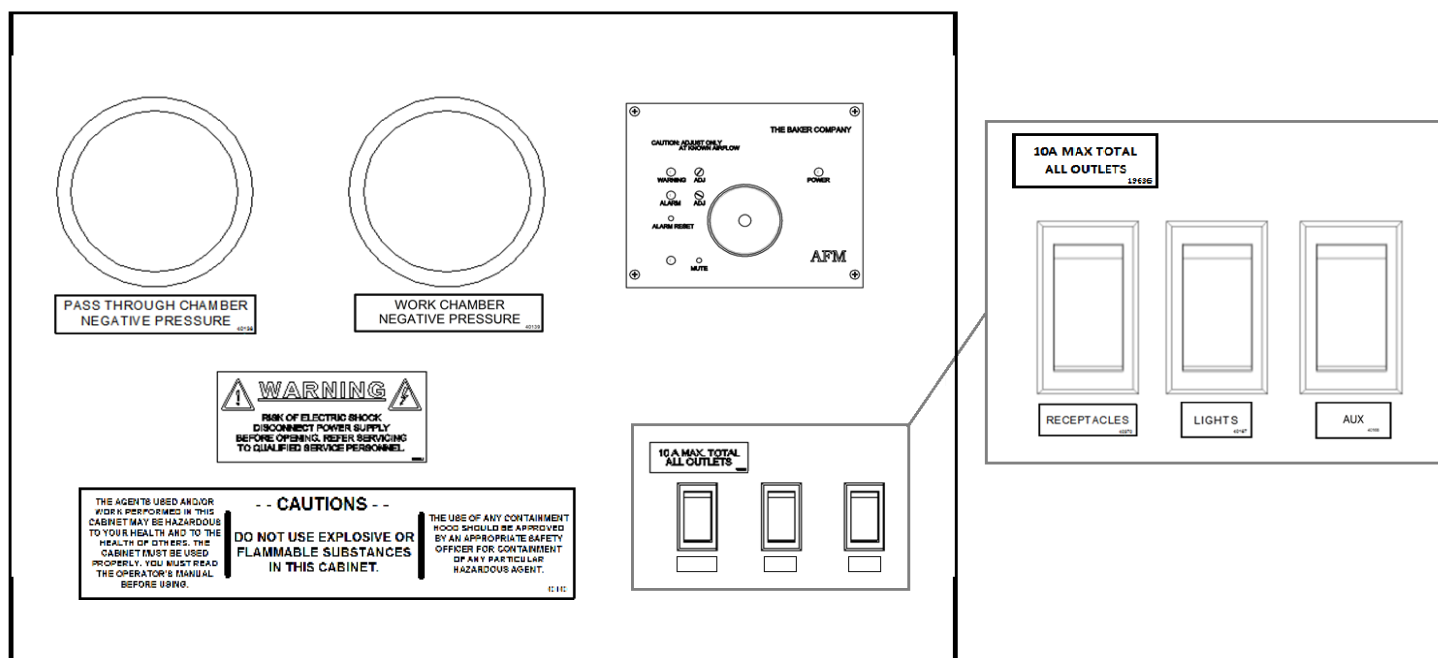
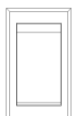
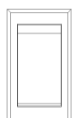


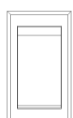
Figure 3 - Controls



Receptacle/Outlet Power On/Off– This switch controls power to the outlets in the work area. A red indicator light located on the switch will illuminate when the switch is on.



Fluorescent Light On/Off – This switch controls operation of the fluorescent light. A red indicator light located on the switch will illuminate when the switch is on.



Auxiliary ("AUX") Switch (Optional) - This switch can be used to control a facility exhaust system dedicated to the unit. A red indicator light located on the switch will illuminate when the switch is on.

 **Pressure Gauge (Pass-Through Chamber)** – This gauge displays the negative operating pressure in the pass-through chamber.

 **Pressure Gauge (Work Chamber)** – This gauge displays the negative operating pressure in the work chamber.

 **Airflow Monitor (AFM)** - The AFM provides visual and audible alarms and a mute function relating to unsafe exhaust air flow.

Hydraulic Lift (Optional) – The momentary control switch for operation of the hydraulic lift is located below the work area. This provides the ability to raise and lower the unit to a more ergonomic position for the user.

Operation

Outlets

The circuit powering the outlets is protected by a self-resetting circuit breaker which allows a total of 10 Amps on all outlets. The unit is typically equipped with outlets in the rear wall of the work area.

For 115V AC/60Hz units the outlets are also protected by a Ground Fault Circuit Interrupter (GFCI). The GFCI outlet is typically the left outlet installed in the rear wall. Additional outlets are wired such that they are also protected by the 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 outlets. 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.

Auxiliary Switch (Optional)

The auxiliary switch, when properly connected to a facility exhaust blower or damper control, can be used to turn the exhaust air flow on and off.

Powered Hydraulic Lift (Optional)

Powered hydraulic lift stands is provided with a 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 in but may have been custom programmed to have lower and/or upper stop positions that restrict allowable travel. Press the up arrow button to move the lift up, press the down arrow button to move the lift down. 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 lift 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.

Alarm Conditions

Air Flow Monitor (AFM) Operation

IMPORTANT

AFM adjustment should only be performed by a qualified certification company or biological safety professional.

The unit is equipped with an air flow monitor (AFM). The AFM monitors the exhaust air flow using a thermal anemometer probe located in the exhaust collar at the top of the unit which is connected to the AFM instrument located on the front control panel of the unit. When properly set, the AFM provides audible and visual alarms when the exhaust air flow is at an unsafe level.

The AFM has four LED indicators, green for power, yellow for low air flow warning, red for low air flow alarm and blue for mute. There is an audible alarm, a warning adjustment, and an alarm adjustment on the unit. There are also separate pushbuttons for alarm reset and mute.

When power is initially applied to the AFM, or when a power interruption occurs, the green power LED will flash continuously until acknowledged by pressing the alarm reset button. All indicators, warning, alarm and mute, will be on solid for approximately 20 seconds while the AFM stabilizes. The audible alarm will not be on during this period. Once the warm up period is complete, if there are no alarm conditions, all the indicators will turn off.

If the exhaust air flow drops below the set warning level the audible alarm will beep and the yellow warning LED will flash at a slow rate. If the exhaust air flow returns to a safe level, the yellow warning LED will change to on solid and the audible alarm will continue until the alarm reset button is pressed.

If the exhaust air flow drops below the set alarm level the audible alarm will beep and the red alarm LED will flash at a fast rate. If the exhaust air flow returns to a safe level, the red alarm LED will change to on solid and the audible alarm will continue until the alarm reset button is pressed.

When the audible alarm is active it can be muted for five minute periods by pressing the mute button. While the audible alarm is muted, the blue mute LED will flash. If the AFM returns to normal air flow while muted the mute LED will stop flashing and the unit returns to normal monitoring operation. If the alarm condition is not corrected the audible alarm will reactivate at the end of the five minute mute time.

The AFM also has an extended mute function. Pressing and holding mute button for five seconds when an alarm condition exists will activate the extended mute period. The audible alarm will remain muted for an indefinite period and the blue mute LED will flash at a slow rate during this time. A change in alarm condition, warning to alarm, or either warning or alarm to normal will cancel the extended mute function. Caution must be used when the alarm is muted as an unsafe condition may still exist!

If there is a broken or disconnected air flow probe both the yellow warning and red alarm LEDs will be on solid and the audible alarm will beep at a fast rate. Once the fault is corrected both LEDs remain on and the audible alarm changes to beep at a slow rate until the alarm reset button is pressed.

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 exhaust system be left on at all times.

1. If the unit has not been left running continuously, turn on the exhaust system. If the auxiliary switch option is installed and used an indicator light located in the rocker switch will illuminate when it is on. Listen for the sound of the facility exhaust system 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. The work chamber door latches have keyed locks.

3. Turn on the fluorescent lights. The indicator light within the switch will illuminate along with the interior work area.
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.
7. Leave the interior pass-through door closed while working in the main chamber.

Working in the ChemoSHIELD

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. A good reference source is *The Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th edition published by the U.S. Department of Health and Human Services as HHS Publication No. (CDC) 21-1112 advisory document for safe work practices.

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 contaminants, into the work area and to protect hands, arms, and clothing from contamination.

Avoid using floor-type pipette discard canisters. It is important that used pipettes be discarded into a tray or other suitable container inside the unit. This reduces unnecessary movement in and out of the work area. Because of the restricted access, pipetting within the unit will require the use of pipetting aids.

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 research agent should be enclosed and the entire work surface decontaminated. Trays of discarded pipettes, glassware, etc., should be covered. Once this has been done, remove all equipment from the unit.

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 exhaust system 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 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.

For additional information on cleaning and disinfecting stainless steel, please refer to: "Decontamination, Sterilization, Disinfection, and Antisepsis," Vesley, Donald and Lauer, James L., *Laboratory Safety Principles and Practices*, 2nd edition, 1995, Fleming, D.O., Richardson, J.H., Tulis, J.J. and Vesley, D., editors, ASM Press, Washington, D.C., pp. 219-237; and *Biosafety Reference Manual*, 2nd edition, 1995, Heinsohn, P.A., Jacobs, R.R. and Concoby, B.A., editors, AIHA Publications, pp.101-110.

Cleaning Spills

CAUTION

**It must be assumed that the base pan is contaminated.
Filter media is very delicate and should never be touched.**

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. Be sure not to touch the exhaust HEPA filters or expose them to any disinfection agents. Before reinstalling the work surface and supports, disinfect all surfaces.

Space Decontamination

WARNING

The unit must be decontaminated with an appropriate agent prior to conducting maintenance, service or repairs in any contaminated area of the unit. Before selecting a decontamination agent, the user and certifier must verify compliance with local, state and federal regulations. Any specialized equipment within the unit work area should be evaluated for material compatibility prior to using the decontamination agent.

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.

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 BSC must involve a risk assessment to determine the need and space decontamination method.



The Baker Company, Inc.
175 Gatehouse Road
Sanford, Maine 04073
Tel: (207) 324-8773 / (800) 992-2537
Fax: (207) 324-3869
Email: bakerco@bakerco.com
www.bakerco.com

This manual includes information for proper biosafety cabinet operation.

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