

OPERATOR'S MANUAL

Edge GARD[®] HF

Horizontal Laminar Flow Clean Bench



MODELS:

IV22



Environments For Science™

175 Gatehouse Road / Sanford, Maine 04073 / USA
800-992-2537 / 207-324-8773 / Fax: 207-324-3869 / bakerco@bakerco.com / bakerco.com

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", with a long horizontal flourish extending to the right.

David Eagleson
President
The Baker Company, Inc.



Environments For Science™

175 Gatehouse Road / Sanford, Maine 04073 / USA
800-992-2537 / 207-324-8773 / Fax: 207-324-3869 / bakerco@bakerco.com / bakerco.com

Table of Contents

Function of the EdgeGARD® HF	2
Clean Bench Design	3
Regulatory Compliance	4
Standards	4
Cautionary Notes.....	4
Standard Features.....	5
Controls	5
Filters.....	5
High Velocity Return Air Slots	5
IV Bar	5
Lighting	5
Motor Speed Control	6
Outlets.....	6
Prefilter	6
Spill Guard	6
Optional Features	6
Pharmacy Configuration.....	6
Pressure Monitor	6
Stand	6
Proper Clean Bench Use	7
Controls.....	8
Operation.....	9
Receptacle/Outlets	9
Fluorescent Light.....	9
Blower	9
Start-up Procedure.....	9
Working in the Clean Bench	10



Environments For Science™

Using Ancillary Equipment	11
Reacting to Spills.....	11
Cleaning and Disinfecting Stainless Steel.....	12
Simple Cleaning.....	12
Disinfection	12
Cleaning Spills	13

Function of the EdgeGARD® HF

The EdgeGARD® HF is a horizontal flow clean bench that provides product protection by delivering HEPA filtered supply air to the work area. The EdgeGARD® HF does not provide any personnel or environmental protection. In operation, the EdgeGARD® HF delivers HEPA filtered, unidirectional airflow to the work area in a horizontal direction. Initially room air is pulled inward through the perforated front panel(s), where it passes through a prefilter which removes large particulate from the air stream. The pre-filtered air is then drawn into a supply fan which forces the air into a plenum directly behind the supply HEPA filter. The pressurized air is forced through the supply HEPA filter and diffuser delivering a relatively uniform airflow at an average velocity of 100 FPM (.51 m/s) to the work area providing a better than ISO Class 5 work area. Concurrently, room air is drawn into the negative pressure plenum of the clean bench through sections of high velocity air slots located along the work area sidewalls and leading edge of the work surface. The airflow into the high velocity air slots prevents the intrusion of particles from outside of the clean bench into the workspace maintaining the ISO Class 5 environment.

CAUTION

Proper equipment for any application should be determined after an assessment of risk by a qualified researcher and an industrial hygienist or bio-safety officer.

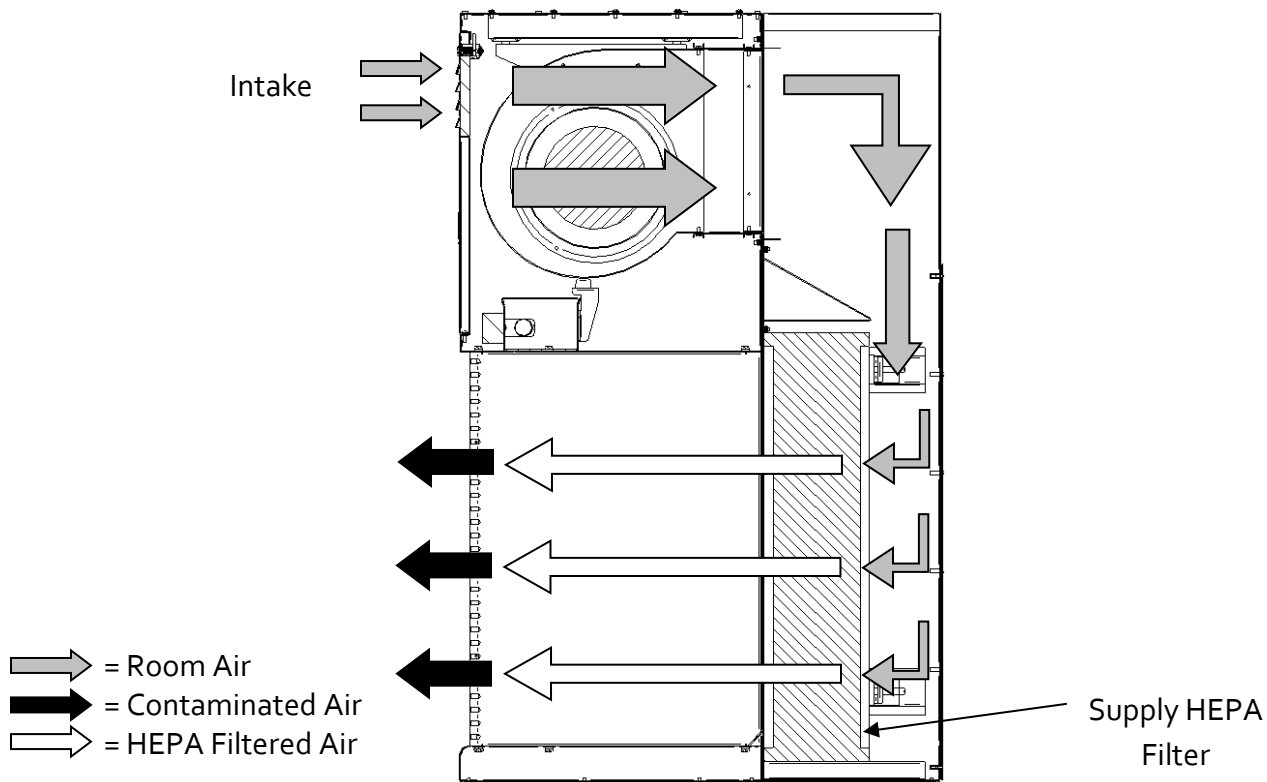


Figure 1. Clean Bench Airflow

Clean Bench Design

Figure 2 below shows the standard construction and components of the clean bench.

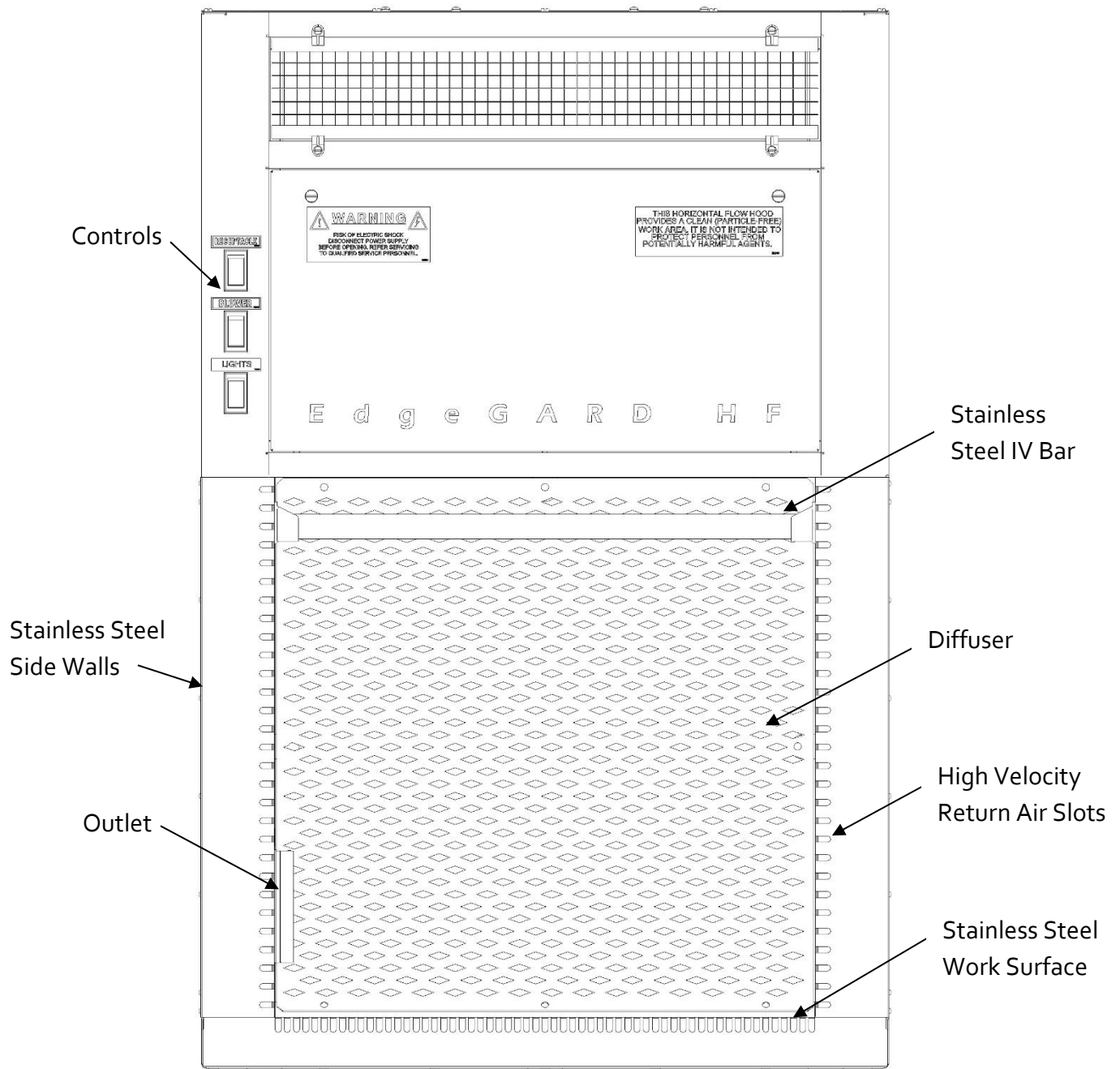


Figure 2. Clean Bench Features

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

Electromagnetic Compatibility:

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

INTERNATIONAL: Electro Magnetic Compatibility Directive 2004/108/EC; EN61326-1

Hazardous Waste Abatement:

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

Biological Safety:

US: Biosafety Cabinet Certification; NSF/ANSI 49

INTERNATIONAL: Biotechnology – Performance criteria for microbiological safety cabinets; EN 12469

Industry Guideline References:

IENT-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.ient.org

Cautionary Notes

Hazards may still exist, especially if the clean bench is not installed, operated and maintained according to the instructions in this manual and the service manual.

This clean bench 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 clean bench 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

Controls

There are rocker style switches to control power to the electrical outlets, fluorescent lights and the motor/blower on the clean bench.

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) filter is a disposable, dry type filter made of a continuous sheet of glass fibers which are pleated and sealed in a rigid metal frame. Baker clean benches are designed using HEPA filters with a minimum of 99.99% efficient on 0.3 micron size particle size (IEST-RP-CC001 Type C), or a minimum of 99.99% efficient at 0.1 to 0.2 or 0.2 to 0.3 micron particle size (IEST-RP-CC007 Type J). Each filter is leak checked after installation to ensure the integrity of the media and gasket seal perimeter.

High Velocity Return Air Slots

High velocity return air slots are located at the front access opening on both sidewalls and horizontally along the work surface. The purpose of the slots is to improve the clean bench integrity by capturing any particulates at these critical transitions.

IV Bar

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

Lighting

The work area is illuminated to provide sufficient light intensity at the work surface. This clean bench features solid-state electronic ballasts. These ballasts increase reliability, efficiency and service life with lower heat output.

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 clean bench filter(s) load. This helps to maintain airflow in the clean bench.

Outlets

The clean bench has one outlet in the left side wall for powering instruments inside the work area. The outlet is protected by a self-resetting circuit breaker rated at 7.5 Amps. On 115V clean benches these outlets are protected by a Ground Fault Circuit Interrupter (GFCI).

Prefilter

Prefilters are made of a coarse 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.

Spill Guard

The work surface has a raised lip at the rear to prevent accidental spills from entering the HEPA Filter area.

Optional Features

Pharmacy Configuration

The pharmacy kit delivers “first air” (unidirectional HEPA filtered air) to the critical site of the workspace. The configuration includes a hinged diffuser, hardware and support clips used to position the diffuser for easy work surface cleaning.

Pressure Monitor

An optional analog pressure gauge displays the air pressure in the supply plenum.

Stand

Powder coated steel support stand with adjustable leveling available in a 30 inch or 36 inch work surface height.

Proper Clean Bench Use

CAUTIONS

A clean bench provides product protection only.

Hazardous materials should never be used with this clean bench.

Explosive or flammable substances should never be used in this clean bench.

Biological, chemical, radiological, or other hazardous substances should never be used in this clean bench.

A clean bench is a valuable supplement to, but not a replacement for, good laboratory technique and safe practice.

If the operator does not operate the clean bench correctly, it may not provide adequate protection. To ensure product protection the workstation must be operated per the manufacturer's instructions.

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

Reference sources are *National Sanitation Foundation Standard 49 Annex E*, and *The Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th edition published by the U.S. Department of Health & Human Services as HHS Publication No. (CDC) 21-1112'.

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

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

All operators are thoroughly trained and competent regarding clean bench operation and all procedures they are required to perform.

That the clean bench operation, procedures, and operators are monitored at regular intervals to ensure that safety is maintained.

Controls

The standard operator controls and indicators are arranged on the front of the clean bench in the Left End Panel above the work area. There are rocker switches for the receptacle, fluorescent light and blower [Reference Figure 3]

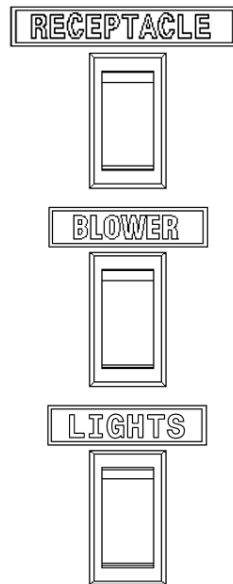
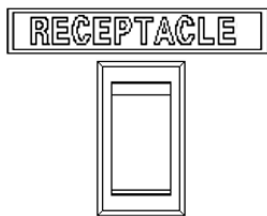
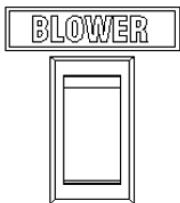


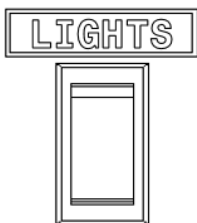
Figure 3. Operator Controls



Receptacle/Circuit Breaker On/Off – This rocker switch is a combination Switch/Circuit Breaker that controls the operation of the clean bench receptacle(s). The switch has a 7.5 Amp trip which is illuminated when power is supplied to the outlets and not tripped.



Blower On/Off – This rocker switch controls the operation of the clean bench blower. The switch is illuminated when the blower is on.



Fluorescent Light On/Off – This rocker switch controls operation of the clean bench fluorescent light. The switch is illuminated when the fluorescent light is on.

Operation

Receptacle/Outlets

Receptacle(s) are turned on/off by a rocker switch that includes overload protection via a circuit breaker internal to the switch.

For 115V AC/60Hz clean benches, a Ground Fault Circuit Interrupter (GFCI) is used. "Optional" receptacle(s) added are either GFCI receptacles or duplex receptacles that are GFCI protected by the GFCI installed. 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.

Fluorescent Light

The fluorescent lighting utilizes a high efficiency/high output T8 bulb designed to provide sufficient clean bench lighting at the work surface.

Blower

The motor control/motor/blower system is designed to deliver relatively uniform, horizontal flow of HEPA filtered air to the work area at an average velocity of 100 FPM (.51 m/s) providing a better than ISO Class 5 work environment.

Start-up Procedure

The operator should read and understand the controls and operation section of this manual prior to performing this procedure.

1. If the unit has not been left running continuously, turn on the blower. An indicator light located on the switch will illuminate when the switch is on and the running blower will make an audible sound.
2. **With optional analog pressure gauge:** check the reading on the analog pressure gauge; the displayed value should remain 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.
3. Turn on the fluorescent light. The indicator light on the switch will illuminate along with the interior work area.
4. Wipe down all interior surfaces of the clean bench work area 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.

5. Place all materials to be used for the next procedure inside the clean bench on the solid work surface. **Disinfect the exterior of these materials prior to placing them on the work surface.** Implements should be arranged in the clean bench's work area in logical order so that clean and dirty materials are segregated, preferably on opposite sides of the work area.
6. Begin working in the clean bench after it has run for at least 3 minutes.

Working in the Clean Bench

WARNING

Never work inside the clean bench when an alarm condition exists.

This section contains some suggested basic work practices that should be observed when using a clean bench. 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 & 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 germicidal soap both before and after working in the clean bench. 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 clean bench. This reduces unnecessary movement in and out of the work area. Because of the restricted access, pipetting within the clean bench 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 clean bench prior to starting a procedure, and removed at the end of the procedure.

Room airflow can significantly affect clean bench operation. Opening and closing doors in the laboratory can cause air disturbances which might interfere with clean bench airflow. This kind of activity should be kept to a

minimum while the clean bench is in use. Personnel should avoid walking by the front of the clean bench while it is in use. The location of facility air diffusers and personal fans can have an adverse effect on clean bench safety.

Use good aseptic techniques.

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 clean bench.

WARNING

Never use the clean bench to store supplies or laboratory equipment.

After removing all materials, culture apparatus, etc. from the clean bench, decontamination of all the interior surfaces should be repeated. Check the work area carefully for spilled or splashed solutions that might support bacterial growth or promote contamination.

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

Using Ancillary Equipment

The more equipment and material that is placed in the clean bench, the greater the possibility of disrupted airflow. The resulting turbulence can alter the designed airflow and reduce the effectiveness of the clean bench.

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 clean bench 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 experiment. 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. See Appendix B of the BMBL 5th edition for recommendations. Standard disinfectants include: Iodophor-detergent, ethanol, phenol and alcohol. Hypochlorite (chlorine bleach) may 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 to allow the disinfectant to deactivate the organism, which depends on the specific agent used (ref. *BMBL* 5th edition). Follow up with a sterile water rinse and wipe completely dry to protect the stainless steel surface.

Disinfect the work area and work surface before and after each procedure.

Disinfect surfaces of all equipment used.

Remove all items from the inside of the clean bench.

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 clean bench.

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

Spills in the work area should be first cleaned and disinfected. Completely decontaminate the work surface. The work surface spill guard will protect the HEPA filter from damage. If a pharmacy diffuser is installed, lift the diffuser and surface decontaminate the work surface, as well as diffuser if necessary.



Environments For Science™

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

Patent pending – Air Bypass Armrest, Cable Port

This manual includes information for proper biosafety clean bench operation.
We recommend that the manual be kept near the clean bench for ready reference.