



&
BIODEX

Leaded Negative Pressure Isolator
User/Service Manual

Biodex Model 190-215 & 190-214. Germfree LFGI Series (CACI)



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Made in the USA and available for purchase on the GSA

Safety, Operation and Additional Professional Training

The Portable Shielded Isolator (Radio Rx Stainless Steel Laminar Flow Glovebox /Isolator <LFGI>) provides a contained environment that allows for greater protection for both personnel and product than traditional open front laminar flow equipment. However, this protection can only be achieved through proper technique. The following is a list of topics that may apply to your operation. Many of these items may require additional professional study and practice beyond the information found in this manual.

1. Operation of the Laminar Flow Glovebox /Isolator
2. Understanding HEPA particulate filtration
3. Proper operator technique
4. Understanding chemical compatibilities for proper glove selection
5. Understanding chemical compatibilities for proper “cleaning” and “sterilization”
6. Understanding chemical compatibilities for proper “decontamination”
7. Understanding sterile product preparation and aseptic technique
8. Understanding hazards associated with the products handled in the Laminar Flow Glovebox /Isolator
9. Understanding proper maintenance and initial and periodic certification
10. Understanding Federal, State and Local applicable professional regulations.
11. Understanding Radiation Shielding

The Portable Shielded Isolator does not automatically provide a clean, sterile and safe working environment. In order for the LFGI to provide the required work environment a professional understanding of the first 10 items above along with a complete understanding of the tasks to be performed is essential.

To obtain this information and understanding may require additional professional training. If you need assistance in finding Professional Pharmacy Organizations offering additional training for any of the above items please call Pharmacy Equipment Sales at GERMFREE, 800.888.5357

GERMFREE, the LFGI and USP <797>

GERMFREE has strived to produce a primary engineering control that maintains a clean and microbe free environment through a combination of design elements and recommendations for good practice and technique.

USP <797> does not offer a great deal of guidance on the use of barrier isolators for the compounding of sterile products and has left much to the manufacturer's recommendation. In light of this, GERMFREE's policies will always be on the side of caution when making recommendations on the proper use of the LFGI.

GERMFREE recommends the following regarding the general use of the LFGI in the pharmacy environment:

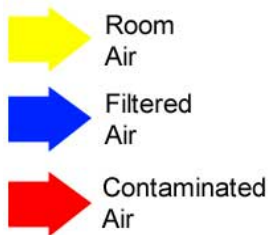
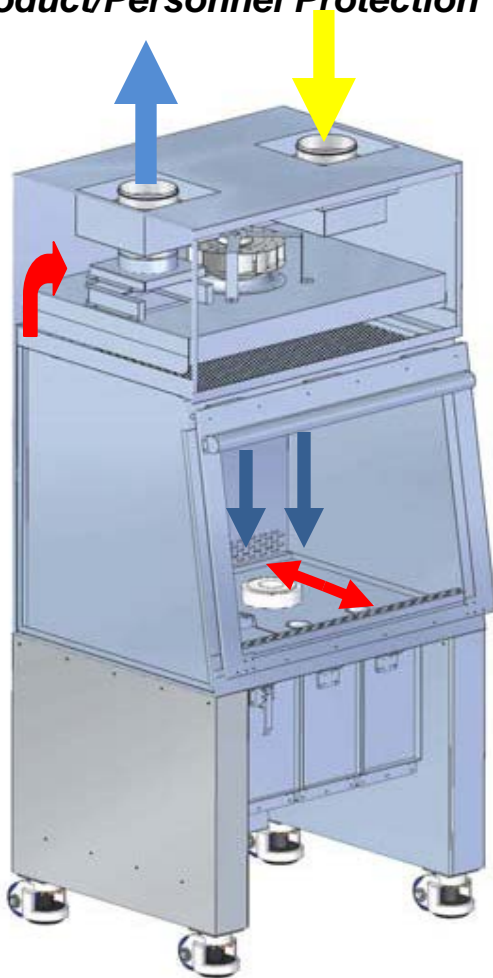
1. The LFGI should be placed in a controlled environment. A room with a window that opens to the out of doors or with high foot traffic is not appropriate for the compounding of sterile products. This is recommended to reduce the overall bioburden in the surrounding area. A classified environment or a room that conforms to a particular particle count is not necessary. The LFGI is designed with a sealed airlock that maintains complete environmental separation between the work area and the ambient room air. This sealed airlock is then purged with HEPA filtered air to equalize or better the cleanliness level of that contained air to the ISO Class 5 condition of the work area.
2. Operators should wear a gown or coat to protect themselves from accidental dermal contact with elements being compounded. This is especially important when compounding hazardous drugs.
3. Operators should always wear gloves when handling compounding elements before and after they are compounded in the work area. Studies show drug contamination on the outside of vials.
4. Operators should minimize fingernail length and jewelry since they increase the chances for glove puncture / tear.
5. All compounding elements should be wiped down before placement in the airlock to reduce any surface contamination that may be present.
6. Operators should don hair covers to decrease the chance of hair entering the work area.
7. Operators should be made aware that "first air" for the purposes of proper aseptic technique is now located above the work area. This will change how they utilize the work deck space.

Introduction

The LFGI with lead shielding is a complete barrier system. It provides sterile laminar flow air for aseptic pharmacy preparations while protecting pharmacy personnel from hazardous materials.

The LFGI uses an amalgamation of cleanroom and containment technologies designed specifically for critical pharmacy applications. This unit provides laminar flow air for product protection and complete containment and shielding for operator protection.

Product/Personnel Protection



Particulates and Gases/ Vapors

The LFGI provides personnel and product protection from particulates, dust, powders and aerosols. Microbiological particulates and aerosols are also removed. Personnel and product protection from gas and fumes are not provided by HEPA filtration, but limited protection from gas and fumes can be provided by venting or ducting.

Radioactive Materials Protection

The LFGI isolator for radio pharmacy provides additional protection (shielding) for laboratorians by employing lead shielding in the walls and floors as well as a leaded acrylic view screen. Gloves and sleeves are not leaded.

The Portable Shielded Isolator has ¼ inch lead in the sides, back, bottom, ante-chamber and sharps' compartment. The large lead window has 2mm of lead equivalency.

Containment

The Radio Rx LFGI maintains containment of the work area through a series of filters and its stainless steel construction. Joints are welded and polished for easy cleaning and all modular components are fully gasketed to ensure a gas tight seal. Adjustable compression hinges and positive-lock latches deliver consistent pressure at door openings.

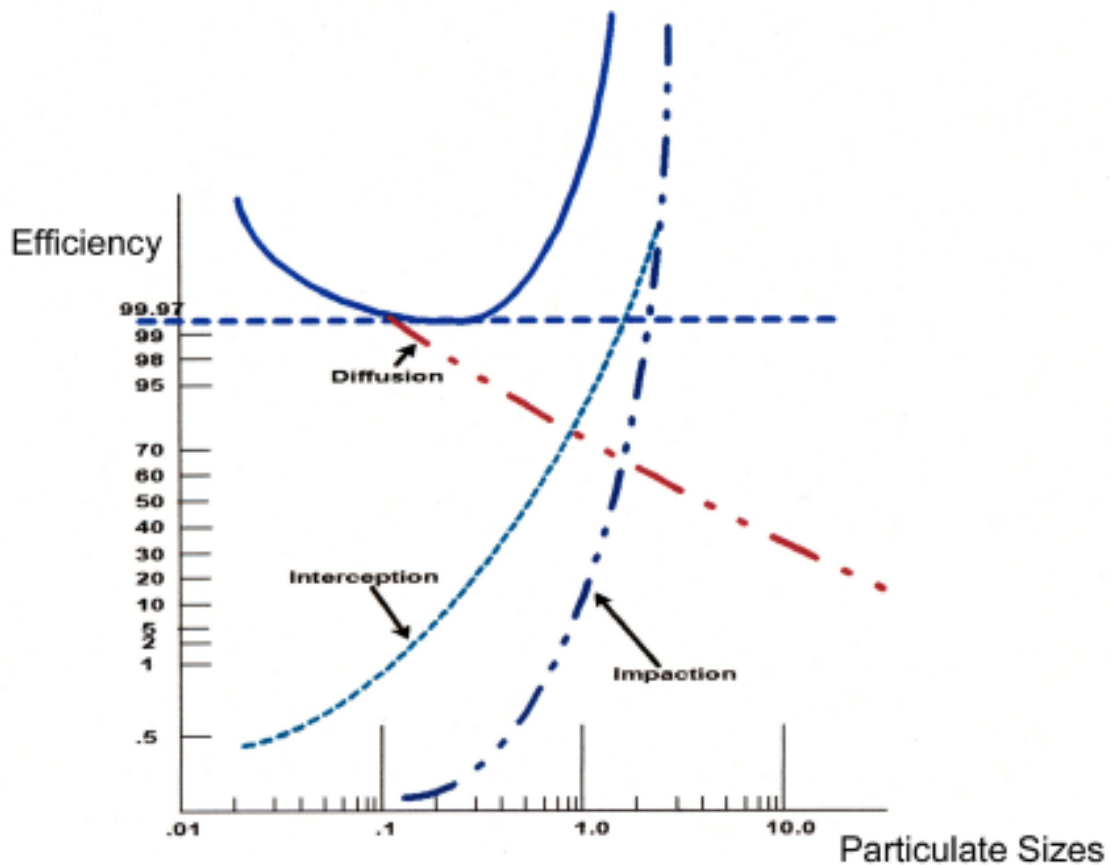
The two door airlock functions to maintain complete environmental separation between the room and work area air.

All air entering and exiting the LFGI is HEPA filtered to ensure ambient particulates stay out of the work area and materials being compounded stay in.

Theory

HEPA Filtration

The LFGI is equipped with High Efficiency Particulate Air (HEPA) filters to provide the highest level of personnel and product protection. These filters are the laminar flow supply HEPA filter, which filters all air passing over the entire work area, and the exhaust HEPA filter that filters all air exiting the Laminar Flow Glovebox /Isolator. Additionally, there are two HEPA filters located inside the HEPA Purge airlock that filter the purged air. All filters are rated to remove particulates and aerosols 0.3 micron in size with a minimum efficiency of 99.99%. These filters are even more effective at removing particulates both larger and smaller than 0.3 microns as the graph below depicts.



HEPA filters are recognized as one of the best forms of mechanical air filtration available for this application. HEPA filters improve or become more efficient as they load under use. There are a number of mechanisms involved in HEPA filtration which are briefly presented below:

1. Impingement - Large particulates, e.g. dust, are captured by the filter fibers as the air stream flows around the fibers.
2. Interception - Particulates follow air stream around filter fibers and become captured (physical interference between particles and fibers).
3. Diffusion - Very small “particles” are bombarded by gas molecules causing them to move erratically (Brownian motion) and contact the filter fibers.
4. Straining - Occurs when the smallest dimension of the particulate is greater than the distance between adjoining filter media fibers.
5. Electrostatic attraction - Enhances mechanical capture through attraction of oppositely charged particles.

Unidirectional (Laminar) Air Flow

The Radio Rx LFGI offers the highest level of product protection by providing vertical laminar flow HEPA filtered air to the complete work environment. This is the same technology used in the Laminar Flow Workstations and Biological Safety Cabinets that “barrier isolators” are intended to replace. The Radio Rx LFGI utilizes a full width and depth supply HEPA filter above the work surface. Any particle-laden air is swept from the work area with a wash of HEPA filtered air. Filtered air washes over the work area into the front and rear grilles. Particles that are generated by the work are immediately washed into the returns and out of the work zone. Internal cross-contamination from compounding different products in the same work area is drastically reduced.

Unpacking Instructions

The Radio Rx LFGI is shipped fully assembled and in most cases by an approved moving van white glove service provider. All equipment must be inspected immediately upon receipt. If there is visible damage to the container or unit it must be noted on the receiving documents by the driver. The carrier must then be notified to arrange for an immediate inspection to verify the damage to the equipment. If damage to the unit is found after it is uncrated (concealed damage), the receiver should notify the delivering carrier at once. Do not move the equipment or discard any of the shipping materials until a concealed damage inspection is performed. If the carrier will not perform this service, please contact the factory immediately at 800-888-5357. Without this inspection of the equipment and packing materials, the freight company may not accept a claim for damage or loss and take the position that the damage occurred after delivery.

Packed within the Cabinet

- Sleeves with gloves and O-rings. In most cases the Germfree GRX glove change system will be included
- 12 hanging hooks
- Sample Sterile Gloves/Sterile IPA Cleaning Wipes
- Monitor arm with brackets to mount dose calibrator display

Installation

The Radio Rx LFGI was designed to fit through standard size doors allowing for easy installation (32" Deep and 80" High).

The LFGI is a complete and self-contained unit and is shipped fully assembled. After unpacking, the unit can be moved into the desired location. Unlike an open front hood room air currents do not disrupt the LFGI; however, proper room placement and room access may be defined by professional and/or State regulations.

The sleeves and gloves will need to be installed before turning the unit on. See section on Sleeve and Glove Changes.

Electrical Requirements

Electrical Requirements are as follows:

LFGI-3RUSP- 115V, 15 amp plugs are required for the following:

- 1 plug for 10 ft. Power cord
- 1 plug for Electrical Height Adjustment

It is essential that the equipment be properly grounded; it is a violation of your warranty to operate without.

Additional electrical components may be required based upon equipment used inside the LFGI.

Certification

The Radio Rx LFGI is a complete and self-contained unit whose performance was tested and documented before shipping. It requires certification after the unit has been installed and prior to operation. This is especially important after transportation of the LFGI from our factory to your facility. The purpose of this retesting is to verify that the HEPA filters, airflows and pressures are within limits and the unit is performing properly.

It is always a good idea to review basic operation of your new LFGI with the certification company personnel due to their knowledge of this type of equipment.

Certification may also be a Governmental and /or Professional requirement.

LFGI certification needs to be performed by a company that has the proper equipment and training needed to test and measure HEPA filter performance. Certification of the LFGI should be continued at least annually or as regulations dictate.

Please contact GERMFREE at 800-888-5357 for a list of Certification Companies in your area if you do not already have this service.

Individual factory certification report is included in the user manual. Additional electronic copies can be provided by e-mail. Please call customer service at 800.888.5357.

Cleaning

****NEVER CLEAN LEAD ACRYLIC VIEWSCREEN WITH RADIACWASH****

Outside the LFGI

The outside of the LFGI can be cleaned at any time while the unit is closed and the procedure does not require Personal Protective Equipment (PPE) additional to that normally used when operating the LFGI. The stainless steel should be cleaned using a 70% alcohol solution or a solution specifically designated for the cleaning of stainless steel. The lead acrylic front should be cleaned with a soft cloth and a mild detergent, alcohol, or a solution specifically designated for the cleaning of acrylic surfaces. It is important to NEVER use abrasive cleaners or organic solvents on the lead acrylic view screen. Additionally, the lead acrylic should NOT be cleaned with any solution stronger than 50% ethyl or 70% isopropyl alcohol. DO NOT use glass cleaner with ammonia. DO NOT use Radiacwash or other decontaminating solutions on the lead acrylic.

Inside the LFGI

A water-based, high pH, disinfectant cleaner should be used, followed by 70% alcohol. This cleaning method, when properly performed, prevents dripping of dirty solution onto cleaned surfaces and does not carry contaminants from surfaces near the open front of the work area to the rear.

Cleaning inside the Radio Rx LFGI should be performed through the attached gloves and may require the use of a tool to reach all internal areas. Once cleaning is performed through the gloves, the front view panel may be opened. Germfree advises that the cabinet be running when the front is opened and personnel use proper PPE as additional protection.

See the Appendices for more detailed instruction.

Operation

Safety and Additional Training

In addition to the items previously in "Safety, Operation and Additional Professional Training" the successful use of the Laminar Flow Glovebox /Isolator depends on several factors, especially good practices and advanced planning. Providing good equipment will produce good results only if the personnel using the equipment employ proper technique. It is, therefore, the responsibility of the manager to train the personnel who will use the LFGI and see that good technique is maintained. If this is not done, a false sense of safety and cleanliness may prevail.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Start-Up

The Radio Rx LFGL should be certified and venting options should be installed before operation.

1. Ensure the LFGL is plugged into a functioning outlet.
2. Install Dose Calibrator (see appendix on this topic)
3. Install Sleeves and Gloves. (Please refer to the Appendix on this topic)
4. Inspect Sleeves and Gloves. Please refer to the Appendix on this topic. Any damage must be replaced prior to start-up.
5. Open the viewing panel and inspect under the work tray. Ensure there is nothing below the sliding work trays. Remove any foreign objects from the work area.
5. Clean the inside of the airlock. Please refer to the Appendix on this topic.
7. Ensure airlock doors are latched.
8. Push the silver end of the electrical outlet into the receptacle located above the airlock and tighten the retaining ring.
9. Clean inside the work area thoroughly. Please refer to the Appendix on this topic.
10. Ensure the stopper for the sharps is seated in place.
11. Close the work area latches and lock, if so desired. (Note the location of the key if removed)
12. Wipe down the outside of the LFGL. Please refer to the Appendix on this topic.
14. Turn on the work area light and watch for its operation.
15. Turn on the main blower switch. The low pressure alarm will sound until adequate pressure is achieved. Gloves should move into the work area under negative pressure.

Start-up time is 10 minutes minimum to achieve ISO Class 5 cleanliness.

16. Push the Airlock Purge button and ensure the accompanying red light illuminates. Purge time is factory set at 1 minute (+/- 10 seconds).

Operation

For safe and efficient use of the Radio Rx LFGI, you should take into account the equipment and materials necessary for the proposed operation and list the procedural details for each operation. The best way to accomplish this is through the use of a checklist and/or protocol that includes all equipment, apparatus, tools, products and supplies necessary for each specific procedure. The list should include the order of events in enough detail to successfully carry out the proposed operation. This list needs to be exhaustive, including such items as initial cleaning equipment, spill control equipment and even extra gloves in case a change is required in the middle of the operation.

It is recommended to perform several trial (practice) runs in the Radio Rx LFGI before initiating preparation.

1. Inspect Gloves and Sleeves. Please refer to Appendix on this topic. If appropriate, change gloves to the preferred type and size.
2. Clean the inside of the airlock. Please refer to the Appendix on this topic.
3. Ensure airlock door are latched.
4. Place Sharps collector as instructed in the section on this topic.
5. Clean the inside of the work area thoroughly. Please refer to Appendix on this topic.
6. Ensure the stopper for the sharps' tube is seated in place.
7. Turn on the work area light and observe its operation.
8. Turn on the main blower switch. The low pressure alarm will sound until adequate pressure is achieved. Gloves should move into the work area if the unit is under negative pressure and out of the work area if under positive pressure.
9. Push the Airlock Purge button and ensure the accompanying red light illuminates.
10. **Allow 10 minutes to pass to ensure all air inside of the work area has been filtered numerous times and an ISO Class 5 condition is met.**
11. Adjust the height of the Isolator stand to a comfortable working height.
12. Wipe down and place compounding elements into the airlock.
13. Push the airlock purge button, red light will illuminate.
14. Do not open the inner airlock door until light is off.
15. Open interior airlock door by pressing Ante-chamber Actuator Switch located on lower left front of Isolator (under door latch) view screen. Mechanical assist shelf raises items so they can be moved into main working chamber.

16. Remove items from the tray and slide tray back into the airlock.
17. Close the inside airlock door by pressing the Ante-chamber Actuator Switch.
18. Begin preparation.
19. Dispose of any waste by bagging and brining out via airlock as it is created.
20. Dispose of any sharps by removing the stopper and dropping the syringe/needle down the tube. Replace the stopper to maintain containment. Completely fill one of the two sharps containers before disposing to the second. This will allow time for the first full container to radioactively decay before it is removed and replaced.
22. Remove completed preparation from the work area by placing in the airlock.

Always operate with critical sites in first air. This may take practice since the source of the HEPA filtered air is now above the user instead of in front, as in the commonly used Horizontal Laminar Flow Workstation.

The LFGL is not a substitute for good aseptic technique. It will provide a clean environment for compounding but can be defeated with poor technique and disregard for cleaning and operational procedures.

Airlock Operation and Shielding

The Airlock Ante-chamber provides a sealed transfer area between the work area and the ambient room conditions. The sealed doors are fitted with adjustable compression hinges to ensure a tight seal against cross contamination.

The Airlock is equipped with a HEPA purge function to clean the air trapped in the sealed transfer area. A blower inside of the control panel pulls air out of the airlock. This air is replaced with air pulled through the HEPA filter on the rear of the airlock. The air being pulled from the airlock is also HEPA filtered. This filter is housed below the control panel.

The purge is timed and can be adjusted by your certifier to reflect cleaner ambient conditions. The timer is set for worse case scenario at the factory. The purge of air is initiated by pushing the large red button at the front of the control panel. During operation of the purge, a red light adjacent to the red button will illuminate. This light will remain on until all air is purged from the airlock and is replaced by clean HEPA filtered air.

This process ensures that the cleanliness level of the air inside of the airlock is equal to or greater than that of the work area.

Always close one airlock door before opening the other. If both doors are opened at once or the inner door is left open for a long period of time the low pressure alarm will sound.

Airlock purge may not be necessary when removing items from the work area. When the inner door is opened, the airlock is flooded with clean air from the work area.

If the LFGI is being used to compound hazardous drugs it is recommended that the completed preparations be wiped down before they are placed into the airlock for removal from the work area. GERMFREE also recommends an airlock Purge when taking preparations from a contaminated work area. This reduces the chance for operators to be exposed to particulate contained within the work area.

Airlock is equipped with a mechanical assist that allows items to easily be brought into the work area, reducing operator strain. Regular cleaning of the airlock ante-chamber is recommended.

Usage

Do not

- Lean materials against the back or front wall as they will block the return air grills.
- operate without gloves or sleeves.
- open both airlock doors at the same time.
- open the front viewing panel when compounding hazardous drugs. If a spill occurs and it is necessary to open the front panel, decontaminate the work area as best as possible first and don appropriate PPE.
- clean the viewing panel with ammonia based cleaner (glass cleaner is not plastic cleaner!)
- leave the plugs off the sharps discharge tubes.
- place anything inside of the work area that would contaminate the work area such as pictures, plants, ornaments etc.
- turn the LFGI off if under negative pressure for the compounding of hazardous drugs.

Do

- disinfect and sanitize the work area at the beginning and end of each shift and after any large spills
- change your hand gloves regularly.
- sanitize gloves and work area with alcohol between each preparation.
- adjust height and glove size to maximize operator comfort.
- wear gloves and body coverings (gowns and hair nets) to eliminate unnecessary contamination from the largest source of contaminates... YOU!
- purge airlock air before bringing materials into the work area.
- lock the caster wheels in place.

- wipe down all materials to remove surface contamination before placing them in the airlock.
- follow all existing internal procedures and policies- if you wouldn't do it in a laminar flow workstation or a biological safety cabinet you shouldn't do it in an LFGL.
- Leave the Dose Calibrator powered ON

Practice Proper Aseptic Technique

Techniques using the Barrier Isolator family of equipment is no different than that of the Laminar Flow Workstation or the Biological Safety Cabinet- the equipment is a tool to aid the operator in maintaining a clean environment for the compounding of preparations. The equipment will never be a substitute for proper aseptic technique. If the environment is not cleaned well or the operator's technique is poor, an aseptic media fill test will usually reveal the inadequacies.

Sharps' Container Removal

To remove the Sharp's container, make sure the cover inside the Isolator is in place. Open the door on the front of the Isolator and remove the plastic Sharps' Container from the Sharps' compartment.

Snap the cap onto the Sharps' container. Move the filled Sharps' container to your decay area and treat as radioactive waste. Place an empty Sharps' Container into the compartment, then close and lock the container door.

Waste Removal

Germfree recommends bagging any trash as it is created and bringing it out for disposal via the airlock.

Appendices

Warranty Information (2 year standard)

Limited Warranty

GERMFREE warrants equipment to be free from malfunctions and defects in both materials and workmanship for two years from the original purchase date, unless otherwise indicated on the sales order/invoice.

Limited Warranty Coverage

THIS LIMITED WARRANTY WILL BE HONORED ONLY WITHIN THE GEOGRAPHICAL LOCATION/FACILITY THAT GERMFREE EQUIPMENT WAS PLACED.

GERMFREE will REPAIR or REPLACE GERMFREE equipment if they fail to function properly during the warranty period, subject to any conditions and/or limitations stated herein. Such repair service **may** include labor as well as any necessary adjustments and/or replacement parts.

Such repair or replacement is the sole remedy under this warranty. If replacement parts are used in making repairs, these parts may be remanufactured, or may contain remanufactured materials. If it is necessary to replace the entire product, it may be replaced with a remanufactured product.

Limitations

This warranty does not cover circumstances beyond GERMFREE's control, nor problems caused by failure to follow the operating instructions in the GERMFREE equipment manuals.

THIS WARRANTY DOES NOT APPLY WHEN FAILURE IS DUE TO SHIPPING DAMAGE, ACCIDENT, ALTERATION, MODIFICATION, UNAUTHORIZED SERVICE, MISUSE, ABUSE, USE WITH INCOMPATIBLE ACCESSORIES OR ATTACHMENTS, FAILURE TO FOLLOW GERMFREE'S OPERATION, MAINTENANCE OR REPACKING INSTRUCTIONS, OR CLAIMS MADE AFTER THE DURATION OF THIS WARRANTY.

GERMFREE makes no other express or implied warranty for this product. In the event that the exclusion of any implied warranty is ineffective under the law, the duration of the implied warranty will be one year from the purchase date.

The option of replacement is GERMFREE's only obligation. GERMFREE will not be responsible for any special, consequential or incidental damages resulting from the sale, purchase, or use of this product, regardless of the cause. Liability for any special, consequential or incidental damages (including but not limited to loss of revenue or profit, downtime costs, loss of the use of the equipment, cost of substitute equipment, facilities or services, or claims of your customers for such damages resulting from the purchase, use or failure of the product), regardless of cause or for breach of any written or implied warranty is expressly disclaimed and excluded here from.

Your Rights

Some states or jurisdictions do not allow exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. Some states or jurisdictions do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

This warranty gives you specific rights, and you may have other rights which vary from state to state or by jurisdiction.

Outside the United States

In countries other than the United States, the terms and conditions of this warranty may be different. Unless specific GERMFREE warranty is communicated to the purchaser in writing by a GERMFREE company, no warranty or liability exists beyond any minimum requirements imposed by law, even though defect, damage, or loss may be by negligence or other act.

Maintenance

Typical life span of a glove sleeve is approximately 6 months and GERMFREE recommends that they be changed at that interval. See the appendix "Glove/Sleeve change" for instruction.

Typical life span of a prefilter is approximately 3 months but differing room conditions can require replacement more or less frequently. During the first 3 months of operation the pre-filter should be checked once per month to determine an average life span. Prefilters should be changed regularly thereafter.

Hydraulic lift system does not require any maintenance.

Regular certification will dictate life spans and replacement schedules of the supply, exhaust and airlock HEPA filters. Regular replacement of the prefilter will lengthen the life of your supply HEPA filter. The Digital Pressure Gauge is an indicator of differential pressure between the blower inlet and the Supply HEPA filter. It is a qualitative indicator of the HEPA filter condition. Your certifier should note the starting pressure and monitor it periodically. Large changes in observed readings, over a short time period, is indicative of possible failures. Typical HEPA filter life span is 3-5 years.

Light Bulb Replacement

The "T-5" fluorescent bulb used in the LFGI can be purchased at any hardware store.

1. Make sure the light switch is turned off.
2. Remove the external bolts that hold the housing to the outside of the viewing panel.
3. Check to make sure that the problem isn't something so simple as a poor contact. This can usually be corrected by giving the bulb a gentle turn a few degrees and then back to the lock position.
4. Hold the old bulb firmly at one end, and rotate it one quarter-turn clockwise. This should put the end prongs in line with the loading slot.
5. Slide the bulb free.
6. Lower the end of the bulb carefully out of the socket. When one end is free, pull slightly and the other end should come out also.
7. Set the old bulb aside and lift a new bulb into the fixture.
8. Hold the bulb horizontally, and rotate the new bulb until the prongs on each end are lined up with the grooves in the socket.
9. Insert the prongs in the socket and rotate the bulb a quarter-turn in a counterclockwise direction. The bulb should click into place on each end.
10. Test the light at the switch. If the light still doesn't come on you may need to replace the ballast. Contact GERMFREE @ 800-888-5357 for this replacement part.
11. Replace the light housing and secure the bolts.

Electronic Adjusting Stand

The electronic height adjusting stand is powered by a motor housed at the sides of the LFGI. Hydraulic lines run to a cylinder at each caster and are pressurized to move the work area up and released to lower it. This action is activated by a switch located under the work area on the outside of the unit. Direction is indicated by arrows on the switch.

Ducting

LFGI Venting Options

The new NIOSH and USP <797> regulations have made it necessary that the airflow design of barrier isolators be flexible to accommodate a variety of conditions.

For example, it is recommended that a safety cabinet used in the handling of hazardous drugs does not recirculate air within the work area. The potential vaporization of the hazardous material is of concern. The recirculated air is HEPA filtered but this filtration removes particulate only, not vapors. The recirculation of this vapor- laden air serves only to concentrate vapors within the work area thereby increasing the potential for worker exposure. To meet this recommendation the LFGI can be configured to exhaust all air from the work area. This requires the facility to provide a blower that is capable of moving approximately 100cfm through a thimble system transition piece. Please consult a Germfree representative for further instructions.

The standard LFGI configuration requires no venting. A small amount of HEPA filtered air is exhausted out of the unit into the surrounding room.

Dose Calibrators

GERMFREE 's Radio Rx LFGI is constructed to house a dose calibrator. The dose calibrator is shielded to protect users and the integrity of the reading. The control panel for the dose calibrator is external to containment and connects to the internal components via gas-tight connection.

The containment area for the Dose Calibrator chamber is shielded with ½ inch of lead. Spacers can be used under the chamber to raise the height of the top of the Dose Calibrator Ionization chamber so it is level with the stainless work surface.

Several Dose Calibrator models can be used in the Portable Shielded Isolator (LFGI) although the chamber was designed to optimally fit the Biodex Atom Lab 500 model.

When the chamber is placed into the shielded area, a seal is placed around the chamber to create a seal for the Isolator.

The Dose Calibrator power should be left ON at all times.

Gloves

We recommend a glove (hand piece) with a longer cuff length for use with the LFGI. The sleeve and "bracelet" system will accommodate almost any commercially available glove but some suggestions (this does not constitute product endorsement by GERMFREE) are as follows:

Alarm

When the low pressure alarm sounds, corrective action must be performed or the unit will require shut down to stop the alarm. Alarms are tested at the factory before shipping. Dramatic drops in pressure indicating possible containment failure sound alarm. Alarms will sound when operating work area pressures are between -0.05 and $+0.05$ inches water column (w.c.). Normal work area pressures are $0.1 (\pm 0.025)$ inches w.c. in either positive or negative overall pressures.

Troubleshooting for Alarm Sounding

Cause	Corrective Action
Glove Rip/Tear/Removal	Replace Glove
Sleeve Rip/Tear/Removal	Replace Sleeve
Inner Airlock Door open	Close Inner Airlock Door
View Panel not Sealed	Ensure latches are fastened on view panel
Pressure Hose Disconnected	Reconnect small tube between control panel and work area

After corrective action is taken, allow 30 seconds for alarm to reset. Observe the digital read-out to ensure that the magnitude of the number is increasing. If number does not increase and alarm continues to sound call your certifier or GERMFREE at 800-888-5357 for further troubleshooting.

Sleeve Changes

To change a sleeve during maintenance, simply remove the securing O-ring and pull the sleeve out of the work area and off of the gloveport.

Typically, new sleeves do not come with GOS or glove O-rings so save them from the existing sleeve. To order extras contact GERMFREE at 800-888-5357.

To replace while maintaining containment of the work area first remove the sleeve O-ring and move the sleeve to the outermost groove. Next push the new sleeve inside of the old and pull over the gloveport down to the innermost groove. Replace the sleeve O-ring over the new sleeve to secure it. Reach inside of the glovebox with the other glove and pull the old sleeve off and into the work area. Dispose of Sleeve through the airlock.

Glove and Sleeve Inspections

A visual inspection of all glove and sleeve surfaces is recommended at the beginning and end of each day. Any tears or punctures would require a replacement.

If the unit is operating and is under pressure the operator can run a hand on all surfaces to feel for any air moving into or out of the work area through imperfections in the surfaces. Soap solution can also be used. If the LFGI has pressure the soap will bubble at any cut, tear or puncture.

Cleaning the LFGI- Heavy Duty (Rigorous thorough cleaning)

Outside the LFGI

The outside of the LFGI can be cleaned at any time while the unit is closed and the procedure does not require PPE additional to that normally used when operating the LFGI. The stainless steel should be cleaned using a 70% alcohol solution or a solution specifically designated for the cleaning of stainless steel. The lead acrylic front panel should be cleaned with a soft cloth and a mild detergent, or a solution specifically designated for the cleaning of acrylic surfaces.

It is important to **never** use abrasive cleaners or organic solvents on the lead acrylic components. Additionally, the lead acrylic should not be cleaned with any solution stronger than 50% ethyl or 70% isopropyl alcohol. Do not use glass cleaner with ammonia.

Work from top to bottom. Do not remove or spray the prefilter at the top of the unit. When cleaning the Airlock HEPA filter housings do not directly spray, instead spray the cleaning agent into the cleaning cloth and wipe the outside surface off.

Raise the stand at least 3 inches from bottom position to wipe down the caster cross supports.

NEVER spray cleaner of any type directly at the control panel. Always spray onto a clean wipe and then wipe the surface, switches and knobs.

Inside the Airlock/ Sharps Containers

1. Open the outer airlock door. Spray a clean wipe with disinfectant cleaner and wipe the HEPA filter protector from top to bottom moving left to right with overlapping strokes.
2. Spray the wipe with cleaner and wipe the back HEPA filter protector from top to bottom, moving left to right with overlapping strokes.
3. Spray the cleaner on the inside of the outer airlock door and remaining side and wipe from top to bottom moving left to right with overlapping strokes.
4. Open the airlock door into the work area and spray the floor of the airlock with disinfectant cleaner and wipe down.
5. Spray the internal components with cleaner and wipe from left to right, and front to back with overlapping strokes. Slide the tray back into the airlock.
6. Repeat steps 1-6 using sterile water to rinse any disinfectant away.
7. Repeat steps 1-6 using 70% IPA to sterilize the surfaces and run a purge cycle.

Inside the LFGI

A water-based, high pH, disinfectant cleaner should be used, followed by 70% alcohol. This cleaning method, when properly performed, prevents dripping of dirty solution onto cleaned surfaces and does not carry contaminants from surfaces near the open front of the work area to the rear. It is recommended to clean the airlock prior to the work area.

The LFGI is under negative pressure all cleaning steps must be performed as described above with the viewing panel closed and through attached sleeves/gloves. GERMFREE can provide an isolator cleaning tool to assist you in this function, contact us at 800-888-5357 for more information.

1. Spray disinfectant cleaner on a lint-free cleaning wipe. Wipe the filter diffuser in the top of the work area wiping from side to side, overlapping strokes. Work outward from back to front.
Do not spray cleaners directly at the Supply HEPA filter- always spray the cleaner onto the cleaning wipe then clean the filter protector surface.
2. Spray the back wall of the work area. Wipe the wall beginning at the top and wipe top to bottom using overlapping strokes working downward toward the work surface and wipe the rear air return grill. Work sideways from left to right.
3. Spray the sides of the work area. Using overlapping strokes, wipe top to bottom working downward toward the work surface. Be sure to clean the entire airlock door surface that is exposed to the inside of the work area, including the handle.
4. Slide the left tray over the right tray; spray the interior bottom surface of the isolator. Clean by wiping from the back to the front using overlapping strokes. Be sure to clean the sides and back under the sliding work tray and air return grill.
Do not spray cleaners directly at the Exhaust HEPA filter- always spray the cleaner onto the cleaning wipe then clean the filter protector surface.
5. Remove glove sleeves and spray the inside of the open front access window. Using overlapping strokes, clean from top to bottom.
6. Spray a clean wipe with disinfectant cleaner and use it to clean glove ports.
7. Spray a clean wipe with disinfectant cleaner and use it to clean IV hanging bar and hooks.
8. Spray a clean wipe with disinfectant cleaner and wipe the front air return grill.
9. Close the front window. Clean the glove sleeves and gloves and replace on the front window.
10. Open the front window and repeat steps 1-13, without removing the sleeves and gloves, with sterile water to rinse away any disinfectant.
11. Turn on the LFGI and close the front access window.

12. Spray 70% IPA directly on all surfaces of the rest of the work area, under sliding work trays, the inside of the front access window, gloves and sleeves.
13. Allow the LFGI to run for 10 minutes before use.

NEVER CLEAN LEAD ACRYLIC VIEWSCREEN WITH RADIACWASH – IT WILL DAMAGE THE VIEWSCREEN

Cleaning the LFGI between preparations- Light

Sanitizing the LFGI work area between preparations is recommended to reduce the chances of cross contamination. 70% Isopropyl Alcohol is the most recommended agent for this task.

1. Open only the outer door of the airlock. Spray a clean wipe with alcohol and wipe the HEPA filter covers.
2. Spray the remaining surfaces, including the tray with alcohol and wipe with overlapping strokes.
3. Leave the spray bottle in the airlock and close the outer airlock door. Run a purge cycle.
4. Open the inner airlock door and remove the spray bottle.
5. Spray all vertical surfaces in the work area with alcohol and wipe from top to bottom with clean wipes, overlapping strokes moving left to right.
6. Spray the air grills and work surface with alcohol and wipe from left to right with overlapping strokes moving back to front.
7. Spray the sleeves and gloves and rub together, then wipe off.
8. Spray the same surfaces lightly and allow to air dry.

If all materials are wiped down prior to placement in the airlock, it should remain clean for a number of preparations in a row.

Cleaning Agents			
Class	Recommended Use	Examples	Name Brand Products
Phenolic Compounds	Bactericide, Fungicide, Tuberculocide, Viricide	Hil-Phene, LpH, Metar, Vesphene Brand	Decon-Cycle by Veltek Lysol® L-Stat Ultar Phene Medaphene® Amphyl®
70% Isopropyl Alcohol Solution	Cleaning certain instruments, cleaning skin		TexShield™ by Texwipe, Decon-Ahol® By Veltek
Chlorine Compounds	Spills of human bodily fluids, bactericide, fungicide, sporicide at >1000ppm Sodium Hypochlorite	Bleach Solutions (Sodium Hypochlorite),	Clorox, Cyosan, Purex
Quaternary Ammonium Compounds (QUATS)	Ordinary housekeeping of floors, furniture, walls, bactericide, fungicide, viricide (not as effective as phenols)	Quatsyl Coverage 258, End-Bac, Hi Tor	Decon-QUAT 100® By Veltek Lysol®-IC Alpha-Lemon QUAT by Alphasource
2% (W/W) Sodium Hypochlorite 1% (W/W) 0.9% Sodium Thiosulfate	Cleans and inactivates anti-cancer drugs on chemotherapy work surfaces		Surface Safe®

This list is by no means comprehensive nor does it constitute endorsement by GERMFREE.

Read the labels on the products you are currently using to categorize them then rotate cleaning agents to avoid developing any resistant strains. Contact your current disinfectant supplier or search the internet for purchasing information.

Cleaning Terms

Clean

Free from disease or infectious agents <a pullorum-*clean* flock> <keep installations *clean* of TB infection>

Deactivate

1 : to make inactive or ineffective

2 : to deprive of chemical activity

Decontamination

A process that reduces contaminating substances to a defined acceptance level.

To make safe by eliminating poisonous or otherwise harmful substances, such as noxious chemicals or radioactive material.

To rid of contamination (as radioactive material)

Disinfect

To destroy [pathogenic microorganisms](#) in or on any [substance](#) or to [inhibit](#) their [growth](#) and [vital activity](#).

To cleanse something so as to destroy or prevent the growth of disease-carrying microorganisms.

To free from infection especially by destroying harmful microorganisms

Sanitization

That part of decontamination that reduces viable microorganisms to a defined acceptance level, normally achieved by using a chemical agent or heat.

To make sanitary (as by cleaning or sterilizing) <if the apparatus is not properly *sanitized*, pathogens may be disseminated to subsequent patients —*Journal of the American Medical Association*>

Sterilize

To make free from live bacteria or other microorganisms.

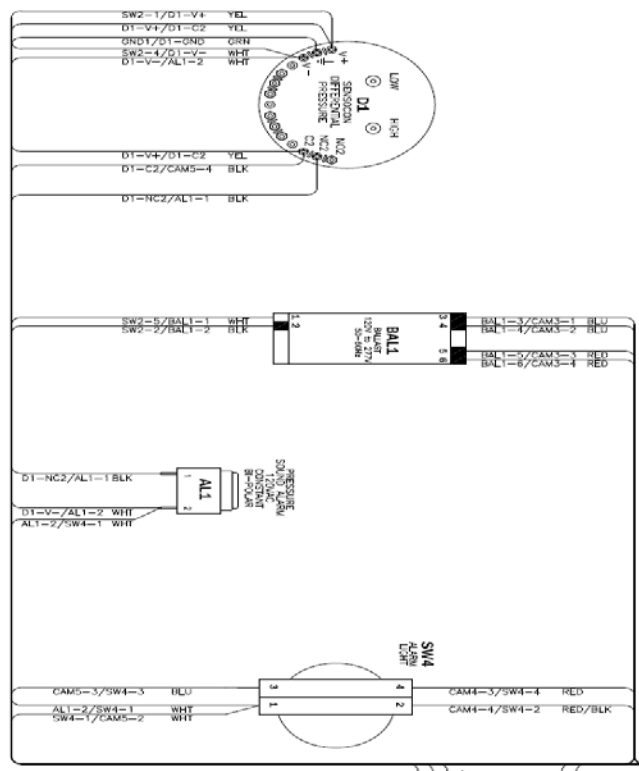
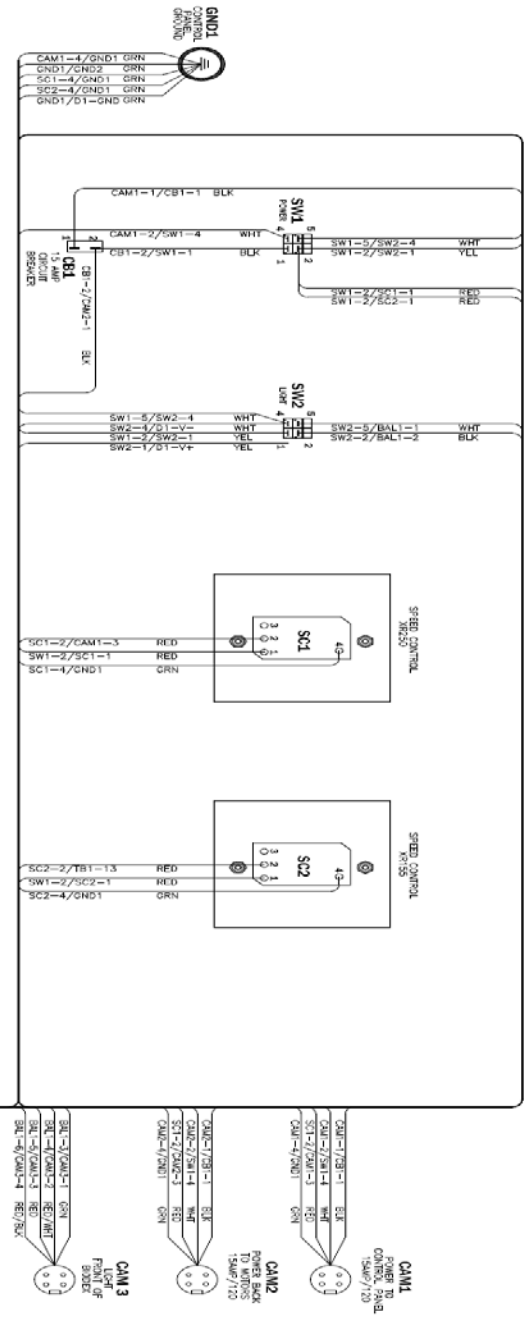
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REVISIONS		
ZONE/REV	DESCRIPTION	DATE APPROVED
REL 1 A	INITIAL RELEASE	11/17/10 WAE

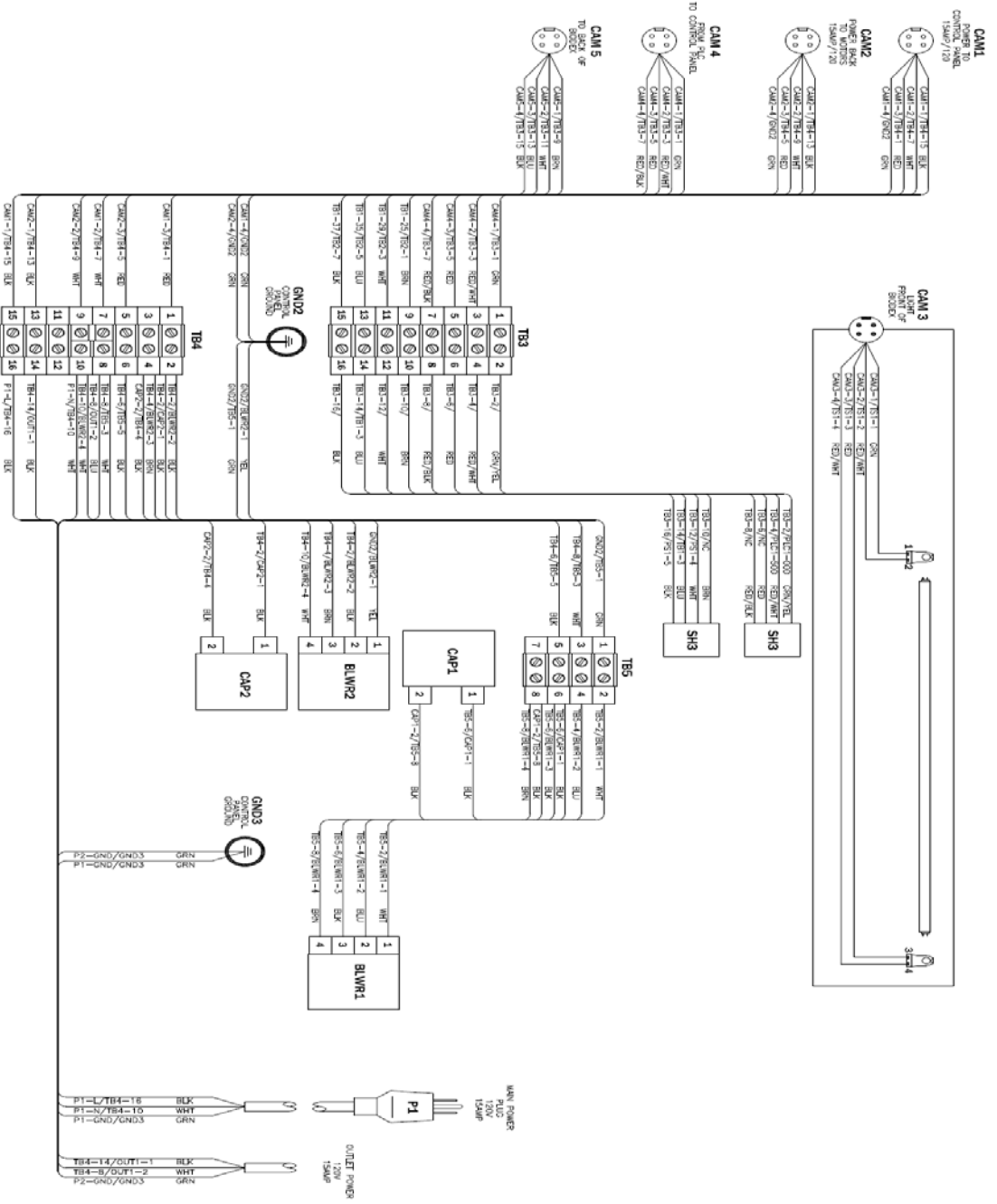


NOTES:
 1. DESIGNATIONS ARE READ "FROM/TO"
 EXAMPLE: T31-1/7SW1-1 IS READ "FROM T31 POSITION 1 TO SW1 POSITION 1"

UNLESS OTHERWISE SPECIFIED		DIMENSIONS		DATE	
UNIT	SCALE	DESCRIPTION	DATE	DESIGNED BY	APPROVED BY
INCHES	1"=16"	WIRING DIAGRAM, BROADCAST			
FEET	1"=2'				
MILLIMETERS	1"=25.4				
ANGLES	30°				
FINISH	AS MANUFACTURED				
DIMENSIONS ARE IN INCHES					
DO NOT SCALE					
PARTS LIST					
WIRE LIST					
KEY LIST					
REV	A				
SCALE	1 OF 3				

Wiring Diagrams for the LFGI-RUSP

ZONE NO.	DESCRIPTION	DATE	APPROVED
REL. K.	MINI. REVISE	10/29/10	WJC



NOTES:
 1. DESIGNATIONS ARE READ "FROM/TO"
 EXAMPLE: TB1-1/SWT-1 IS READ "FROM TB1 POSITION 1 TO SW1 POSITION 1"

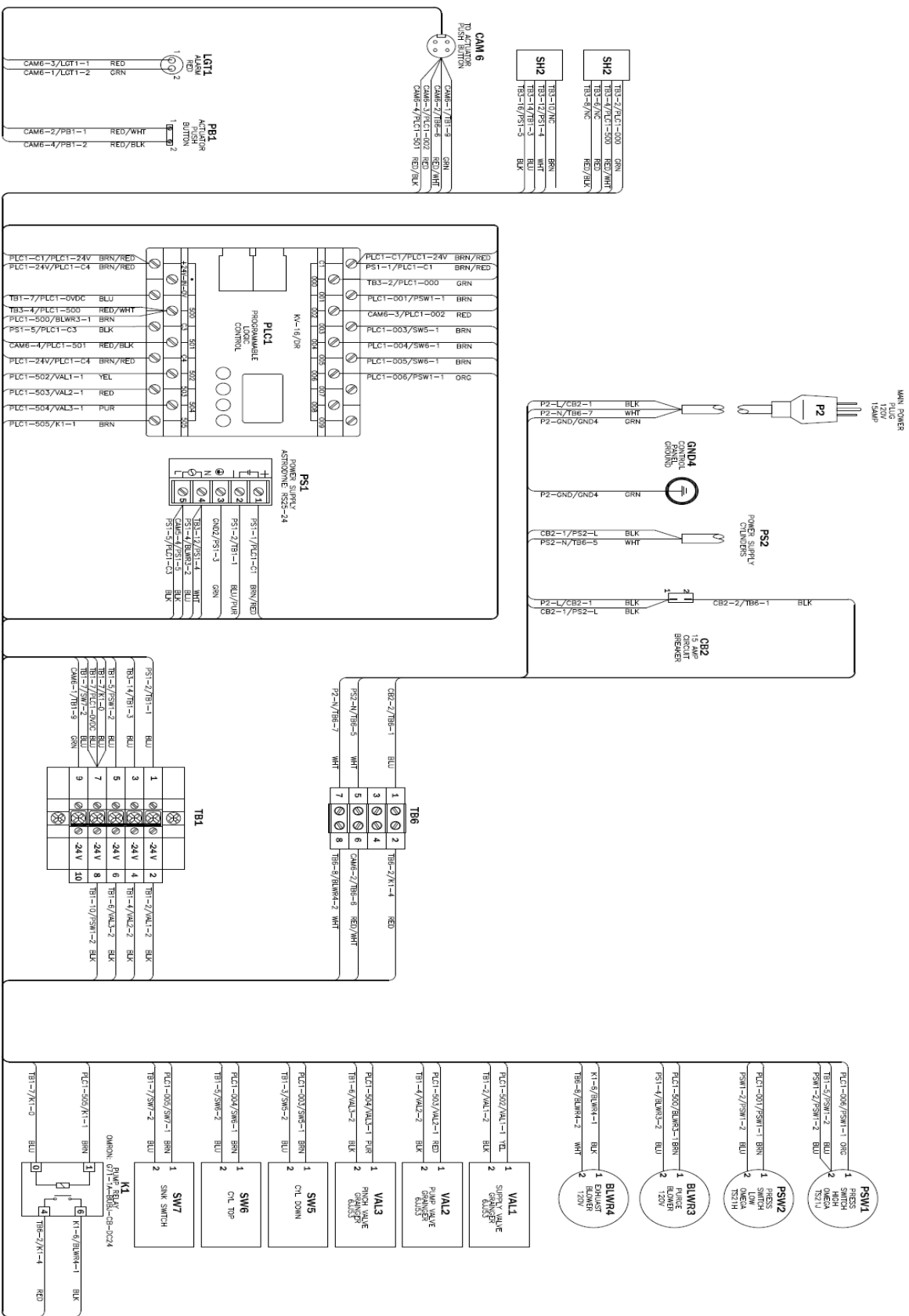
UNLESS OTHERWISE SPECIFIED	DATE	10/29/10
SCALE		
DATE		
DESIGNED BY		
CHECKED BY		
APPROVED BY		
DATE		
SCALE		
REVISIONS		
NO.	DESCRIPTION	DATE
1	WINNING DIAGRAM, D6385	
2	14297 D'CONFRID	
3		
4		
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6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		

Gernyfree Laboratories

WINNING DIAGRAM, D6385
 14297 D'CONFRID

DATE: 10/29/10
 SCALE: 2 OF 3

REVISIONS			
ZONE (REV)	DESCRIPTION	DATE	APPROVED
ALL	INITIAL RELEASE	10/29/10	WAL



NOTES:
 1. DESIGNATIONS ARE READ "FROM TO" EXAMPLE: TBL-10/NC-1 IS READ "FROM TBL1 POSITION 1 TO SW1 POSITION 1"

UNLESS OTHERWISE SPECIFIED	STANDARDS	DATE
WIRING DIAGRAM	W. DONOFRIO	10/29/10
APPROVAL		
MATERIAL		
FINISH		
SCALE	1:1	
HEET NO.	14297	3 OF 3
REV.	A	

Gemfree Laboratories
 WIRING DIAGRAM, DG85
 14297, DONOFRIO

NEET ASSY:
 WIRE LIST:
 PARTS LIST:

UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES.
 DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED.
 DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED.
 DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED.

Certification of GERMFREE Laminar Flow Glovebox / Isolator

Models: LFGI 3 RUSP

Product Overview

The new Radio Rx LFGI (Portable Shielded Isolator) was introduced in June 2010. Both the LFGI and the LFGI RUSP series provide the operator with an environment suitable to handle both sterile preparations and potentially hazardous radiopharmacy drugs.

The LFGI allows for all service and maintenance functions to be performed from the front of the unit (side access makes the job even easier). The Radio Rx LFGI has two Main HEPA filters, which require an integrity test and two airlock HEPA filters that are verified, in-place, with a particle counter. Additionally, supply velocities are measured and overall work area differential pressure is confirmed as part of the certification process.

Basic Operation

Supply air is brought into the unit and directed through the Supply HEPA filter by a series of backwards-inclined motorized impellers. This unidirectional air moves downward to the work deck then splits to the front and back air grills. Then moves under the work tray and through the exhaust HEPA filter.

Isolator Pressure

Work-area is negative pressure for containment. The unit provides unidirectional airflow and an ISO class 5 or better air quality. Pressurization should be set to negative inches of water on the digital pressure gauge marked work-area pressure. This overall pressure will provide greater than 100 fpm into the LFGI USP in the event of a complete glove and sleeve failure, approximately 70 cfm.

Supply Velocity

Average Velocity Range: 45-55 fpm average, all points +/- 25%.

Where: 12" below Diffuser

Grid: Velocity Profile Test Grid 6" from back and sides,
6 3/4" from front
LFGI 3 5/8" apart left to right, 6" apart front to back

Note: Above grid measurements made on work tray correspond to proper location at 12" below diffuser.

Particle Counts

The LFGI RUSP should maintain ISO Class 5 conditions in the work environment regardless of pressurization. To verify, divide the work tray into 1 square foot areas and sample the center of each zone for a minimum of 1 minute per zone.

Filter Integrity

The unit has two main HEPA filters, one above the work zone (supply) and one below (exhaust), see figure 1. The Supply HEPA filter should be scanned with a Photometer while challenged with DOP or equivalent. The aerosol challenge can be introduced to the upstream side of the HEPA filter through the supply blower inlet. An upstream challenge can be read through the port opposite the LFGI control panel by removing the hex head plug. If access to the side of the unit is not possible, the upstream challenge can be read through the port inside the control panel connected to the "supply HEPA filter" pressure gauge. For the exhaust HEPA filter the challenge is introduced into the work area and a mass flow reading should be measured in the air recycle plenum on the back top of the unit. All HEPA filters are 99.99%.



GERMFREE
Rapid Exchange
Glove System



www.germfree.com

Users Guide

Package Contents

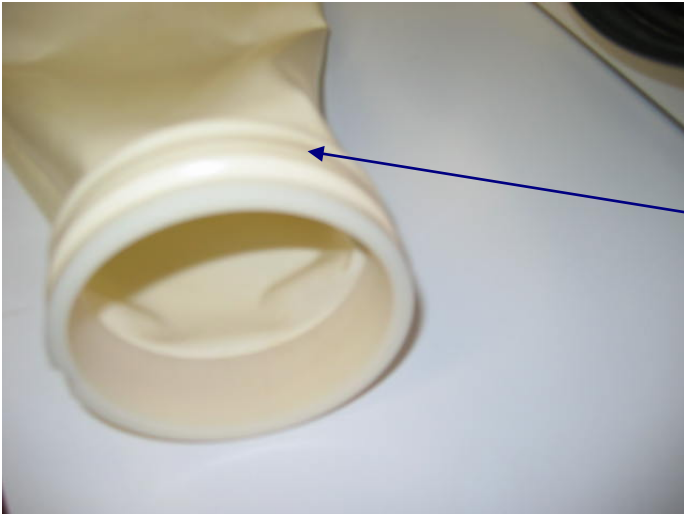


*For each sleeve:
One Alpha Ring
Three Beta Rings*



*2-(Top) Orange O-rings for Alpha Ring
2-(Middle) Black O-rings Beta Ring
2-(Bottom) Black O-rings Beta Ring, Glove*

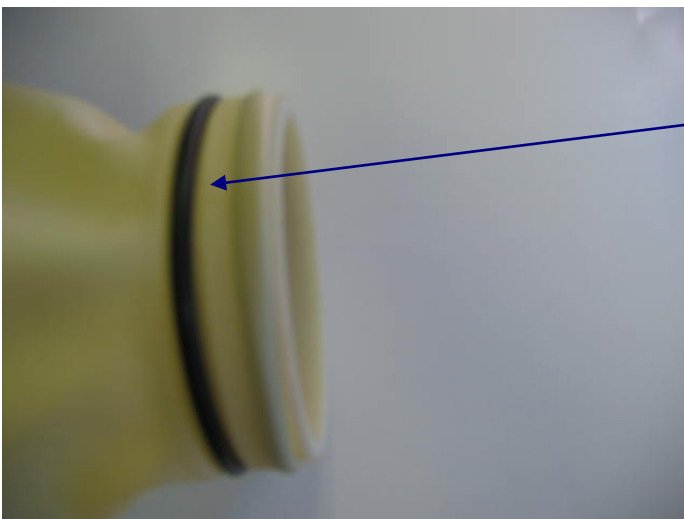
Instructions for Setting up GRx System Sleeves



Reverse Sleeve

Stretch Sleeve and insert Alpha Ring.

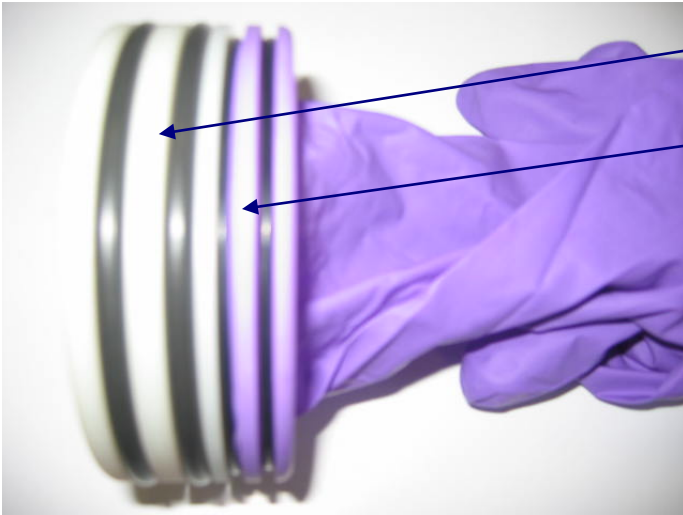
Apply one of the two the Alpha O-Rings to the first Groove Only. (Actual Color: Orange)



Reverse sleeve again to original position.

Apply Second Alpha O-Ring (Actual Color: Orange)

Setting Up for Beta Ring



Place the Larger Black Beta O-Rings into the Grooves.

Stretch Glove and place over the small grooves.

(Tip: Align thumb of glove to the half moon shape cut out for easy alignment into sleeve)

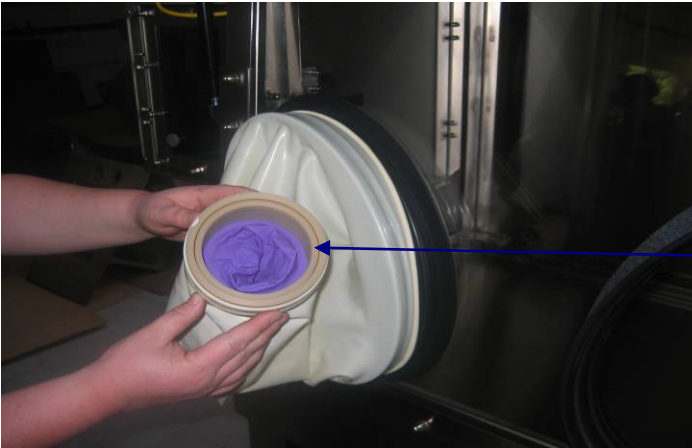
Lock the Gloves in place by using the Smaller Black Beta O-Rings. Fit the O-Rings into the smaller grooves.

(Tip: Pinch glove, push down O-Ring. O-Rings



Install Sleeves onto gloveports as normal.

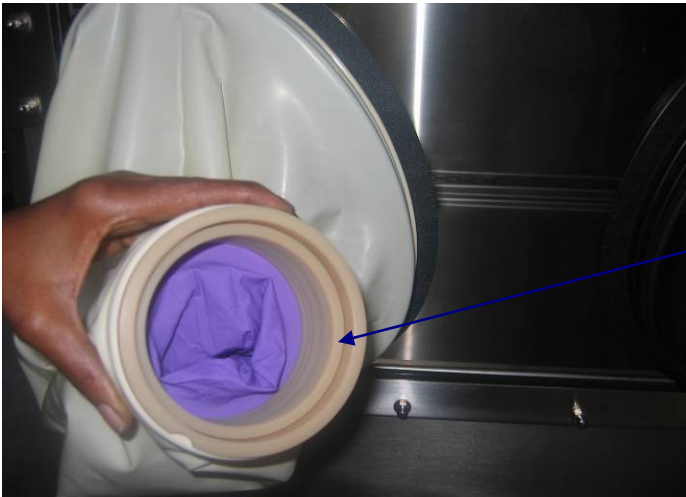
Changing Gloves



Glove end goes first, fold glove and push inside the Beta ring as shown.

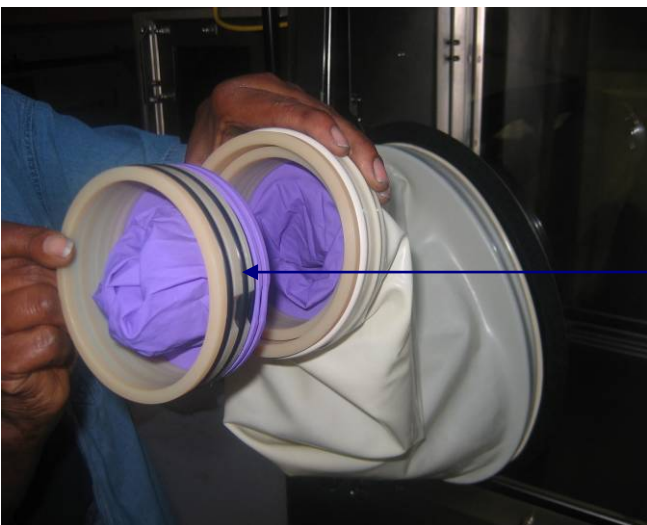
Place the new replacement Beta ring on top of the existing Beta ring.

(Line up the half moon cut out towards the position of the thumb placement)

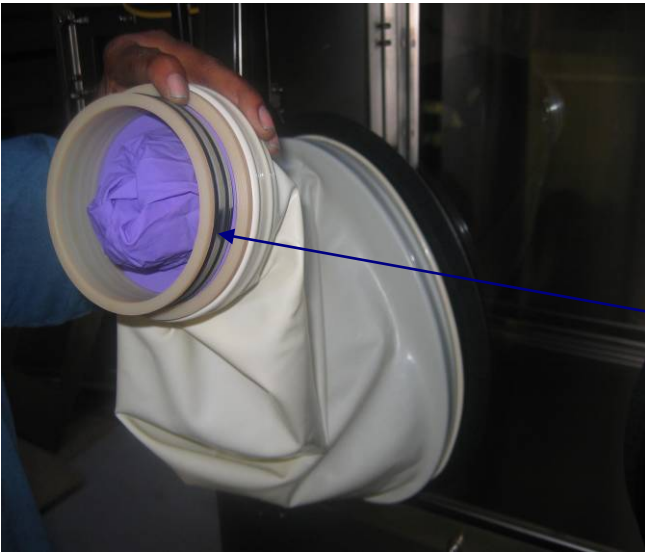


When changing gloves, pull sleeve out exposing both the Beta and Alpha rings. (Do not remove sleeve out of isolator)

The surface edge must be exposed for an easy glove exchange.



Push Beta ring in, to assist in lining up new Beta ring.



*Push new Beta ring through by applying an even amount of pressure.
(When pushing through, do not place fingers directly behind the alpha ring)*

*For potentially hazardous compounding, we recommend disposing the Beta Ports. Contact Germfree or your representative for additional information.

To clean, Remove all O-Rings, dispose of glove, clean with IPA and pass through purge chamber.

Replacement Filter Sizes & Part Numbers

The Radio Rx model of the LFGI has one supply filter for the main chamber (LFGI-RxS) as well as a secondary supply filter (LFGI-RxE) and exhaust HEPA filter (LFGI-RxE) to prevent any flow of unfiltered air into the laboratory. The airlock has both a supply HEPA filter (LFGI-RxE) and an exhaust HEPA filter (LFGI-RxE). A total of 5 HEPA filters are featured in the Radio Rx version of the LFGI. Please contact Germfree customer service for replacement parts.