



Containment Technologies Group, Inc.

## **MOBILE ISOLATION CHAMBER (MIC)**

COUNTER TOP – SINGLE – DUAL – TPN – EDU

# **OWNER'S MANUAL**

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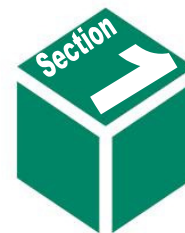
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# TABLE OF CONTENTS

<u>Section</u>	<u>Contents</u>
1	<b>Introduction</b> Features
2	<b>Getting Started</b> Installation & Set-up Site Selection Assembly Set-up
3	<b>Operation</b> Inspection Sanitizing Airlock Usage Adjustment General Use Guidelines
4	<b>Policies &amp; Procedures</b>
5	<b>Maintenance &amp; Troubleshooting</b> Daily Weekly Periodic Troubleshooting
6	<b>Product Specifications</b> MIC Counter Top MIC Single MIC Dual MIC TPN MIC EDU
7	<b>Certification</b> Certification Timelines Certification Protocol Recommended Practices and General Information
8	<b>Replacement Parts</b>
9	<b>Warranty</b>
10	<b>Ergonomic Considerations</b>

# INTRODUCTION



The Mobile Isolation Chamber (MIC) is a safe, economical, and portable workstation designed to provide an International Organization for Standardization (ISO) Class 5 environment for the preparation of parenteral products. The workstation provides the same ISO Class 5 environment to the hospital pharmacy and home health care areas that many pharmaceutical companies use. It combines the latest technology, creating a safe and efficient workspace that is user friendly. The MIC workstation uses barrier / isolator technology to provide an ISO class 5 environment. This technology utilizes a closed system that protects the pharmacist as well as the pharmaceutical products being prepared. The MIC provides an environment that is a secure, cost effective, and flexible alternative to the cleanroom approach. Five workstation models are available:

1. MIC Countertop
2. MIC Single
3. MIC Dual
4. MIC TPN
5. MIC EDU

## Features

The MIC is fabricated from stainless steel and engineered plastics. This creates a solid barrier that requires no procedural setbacks or special work zones that are common with laminar flow hoods. The MIC can operate as a positive pressure system for the preparation of IV admixtures or as a negative pressure system for the preparation of hazardous drugs. The MIC utilizes a recirculating air system and does not require outside venting. An airlock allows access to the ISO Class 5 environment. Manipulations take place through gloves and sleeves, allowing the pharmacist to leave and re-enter the workstation without compromising the ISO Class 5 environment. The MIC workstation requires no special wiring, plumbing, or room-air filtration. Comfort and efficiency of pharmacy personnel is also achieved by no requirement of goggles or gowning. Unlike laminar flow hoods, the MIC is self-contained and can be relocated in minutes.

## Safety

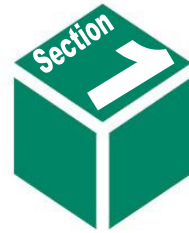
The ergonomic considerations in the MIC help reduce fatigue and consequently, product errors. The MIC is quieter than most laminar flow hoods and has an adjustable height feature for more comfortable working conditions. Chemical and shatter resistant plastics provide a clear view of the entire workspace and airlock, to ensure that materials are clearly visible. Inlet air and discharge air are both HEPA filtered.

## Flexibility

The MIC is self contained and fully portable. It can be wheeled on its heavy-duty casters through most pedestrian doorways. There is no special room air quality requirement or need for special gowning. Gloves come in a wide range of sizes and can be changed quickly. The MIC workstation requires a standard 110-volt receptacle. No other wiring, piping or venting is required. The MIC airlocks allow access to the critical area during compounding.

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# INTRODUCTION

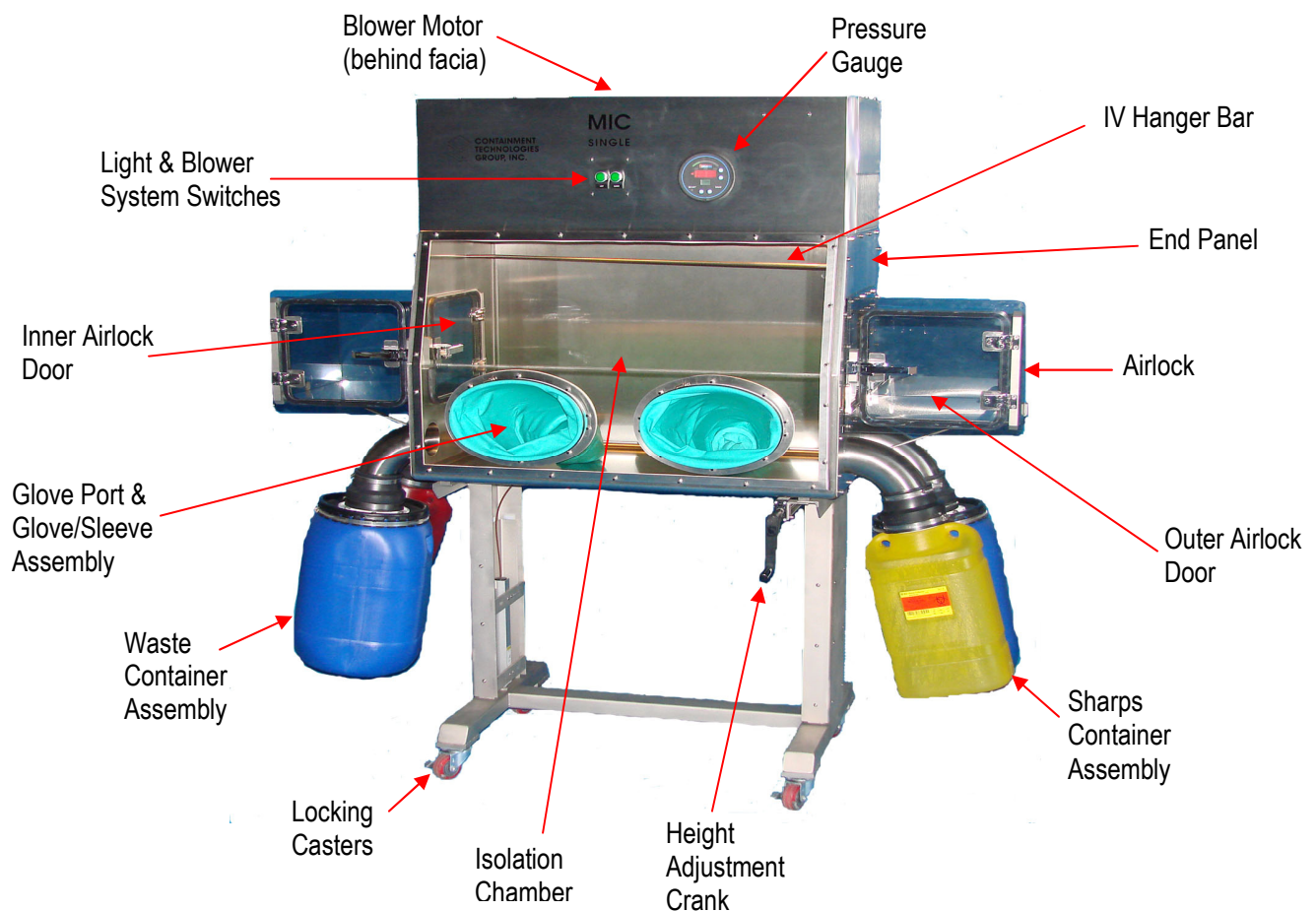


## Economy

The MIC saves energy costs by requiring much less air volume than laminar flow hoods. The MIC requires no room remodeling and very little set-up time. The two-piece glove and sleeve arrangement reduces the cost of consumables compared to single-piece sleeve/glove replacements. The MIC increases efficiency by reducing preparation time and procedural requirements.

## Quality

The MIC is constructed of 316L stainless steel. Stainless steel seams are ground smooth and corners are coved to eliminate hard to clean areas. The viewing area is comprised of engineered plastics that provide an unobstructed view of the work area. These surfaces are smooth and designed to be easy to clean and sanitize. The lighting and air handling systems are external to the chamber. This not only adds to the ease of sanitizing but also keeps maintenance out of the critical area. The airlocks use solidly built latches for repeated use. The workstation height adjustment utilizes a hydraulic lift system.



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# GETTING STARTED



## Installation and Set-up

Instructions in this section are specifically for the *initial* set-up of the MIC. These steps will describe site selection, assembly (if needed), set-up, and inspection for the MIC. By the end of these steps, the MIC will be ready to be placed into operation.

*Note: Installation and Operations videos are included, as well as an operations video.*

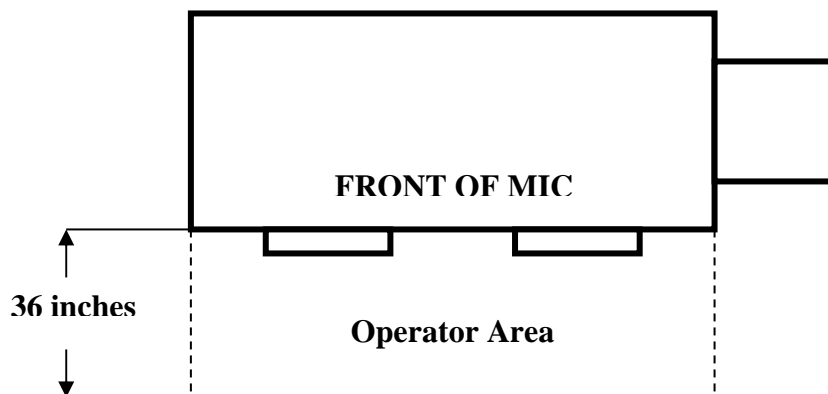
## Site Selection

The MIC's portability eases site selection decisions. Primary considerations for the installation of the MIC are floor space available and electrical receptacle outlet accessibility.

Floor space requirements for the MIC family of products:

<u>Product</u>	<u>Floor Space Requirement</u>
MIC Single with one airlock	56 inches long x 24 inches deep
MIC Single with two airlocks	72 inches long x 24 inches deep
MIC Dual	112 inches long x 24 inches deep
MIC TPN	96 inches long x 27 inches deep
	<i>Note: Allow an additional 16 inches for door swing</i>
MIC EDU Single	56 inches long x 27 inches deep
MIC EDU Dual	96 inches long x 27 inches deep

To operate the MIC, the pharmacist or pharmacy technician will require 36 inches in front of the workstation. for operation. A diagram is provided below:



Some lighting conditions may cause glare in the viewing area of the MIC. Position the workstation to minimize this affect. The power requirement for the MIC is a grounded 120-volt, 60hz, 15 amp receptacle. There are no special requirements for air quality in terms of environmental particulates. The area should be air conditioned for the comfort of the operator and to ensure that product temperature requirements are met.

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# GETTING STARTED



## Assembly

In most cases, the MIC workstation is delivered as a fully assembled product. However, shipping restrictions sometimes require that the end panel/airlock assembly be removed prior to transport. It is important to ensure that the end panel(s) and viewing area fasteners did not loosen during transport. The following instructions will explain how to check the end panel and viewing area fasteners for proper installation, mount the hangar bar, as well as how to install the end panel/airlock assembly.

### End Panel and Viewing Area Fastener Check

#### Materials needed:

1. A standard 3/8" wrench or nut driver (provided in start-up kit).

#### Instructions:

1. Using the 3/8" wrench or nut driver, check all nut for tightness. This is defined as approximately as approximately a 1/2 turn past hand tight.
2. If using a torque wrench, the proper torque value for nuts on the MIC family of products is 26 inch-pounds.

***NOTE: Do not use excessive force. Damage to the end panel may result.***

# GETTING STARTED



## End Panel/Airlock Installation & Hangar Bar Mounting

### Materials needed:

1. A standard 3/8" wrench or nut driver
2. A 1/8" allen wrench
3. One machine screw
4. Twenty 3/8" nuts (lock tight)
5. Thirty flat washers.

### Instructions:

1. Lift the end panel into position and align the top row of studs on the workstation with the holes in the panel.
2. Place the panel on the studs and loosely install a nut on each of the top corner studs.
3. Align the remaining studs and holes and fit the panel to the workstation.
4. Place a washer and nut on the two center studs and hand tighten.
5. Remove the top two nuts; place washers on the studs, re-install the nuts and hand tighten.
6. Place washers and nuts on the remaining end panel studs and hand tighten only. The nuts will be tightened after the hangar bar is mounted.
7. To begin mounting the hanger bar, place a washer on the machine screw.
8. Align the hangar bar with the hole in the end panel. Access to the bar is easiest through the glove port closest to the end panel.
9. Insert the machine screw through the end panel and into the bar.
10. Using the allen wrench, tighten the machine screw.
11. Using the 3/8" wrench or nut driver, tighten the 20 nuts until snug. This is defined as approximately as approximately a 1/2 turn past hand tight. If using a torque wrench, the proper torque value for nuts on the MIC family of products is 26 inch-pounds.

**NOTE: Do not use excessive force.**  
**Damage to the end panel may result.**

12. If required, repeat the process for the other end panel.
13. Once end panel assembly is complete, proceed to Set-up.



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# GETTING STARTED



## Set-up

Set-up of the MIC consists of a general cleaning followed by the installation of the sharps container, waste container, sleeves, and gloves. After set-up, the MIC will be inspected, sanitized, and then put into operation. Each MIC comes with a start-up kit. The start-up kit contains all the materials needed to make the workstation operational. Items that will be needed, but are not included, are waste container liners (plastic bag) and sanitizing solution. Items 1 through 5, in the photo below, are required for set-up of the MIC. Items 6 through 11 are supplied to assist in the operation and disinfecting of the workstation. Supplies and replacement parts can be ordered from CTG via phone, fax, or email. An order form is available at the back of this manual.



- |                                                                                                                                                                         |                                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| 1. Sharps Container Assembly <ul style="list-style-type: none"><li>• Rubber Connector</li><li>• Connector Clamp</li><li>• Disposal Cap</li></ul>                        | 5. 5/16 Nut Driver               |
| 2. Waste Container Assembly <ul style="list-style-type: none"><li>• Container Lid</li><li>• Rubber Connector</li><li>• Connector Clamps</li><li>• Liner Clamp</li></ul> | 6. Squeegee                      |
| 3. Sleeves <ul style="list-style-type: none"><li>• Sleeve Clamps</li></ul>                                                                                              | 7. Sleeve Liners                 |
| 4. Gloves <ul style="list-style-type: none"><li>• Glove Retainers</li><li>• O-rings</li></ul>                                                                           | 8. Cotton Glove Liners           |
|                                                                                                                                                                         | 9. Work Baskets                  |
|                                                                                                                                                                         | 10. Misting Bottle               |
|                                                                                                                                                                         | 11. IV & Piggyback Hangers       |
|                                                                                                                                                                         | 12. Bar Keepers Friend           |
|                                                                                                                                                                         | 13. (not shown) Hand Crank Shear |
|                                                                                                                                                                         | Pin Replacements                 |
|                                                                                                                                                                         | 14. (not shown) Inside & Outside |
|                                                                                                                                                                         | Port Covers                      |

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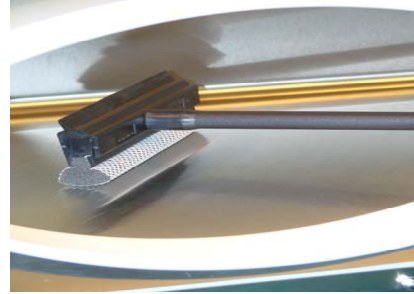


# GETTING STARTED



## Initial Cleaning

1. Thoroughly wipe the workstation down, inside and out, to remove any dust, dirt, or debris that may have accumulated during shipping.
2. Spray surfaces with a solution of water and mild detergent followed by a sterile water rinse.
3. Use the squeegee for hard to reach areas, such as the rear corners of the chamber.
4. Dry all surfaces to ensure all dirt and residues are removed.



# GETTING STARTED



## Sharps Container Installation

1. The sharps container assembly consists of a sharps connector and a disposable sharps container.



2. Thread the large end of the rubber connector onto the sharps container.
3. Securely tighten the connector onto the container.



4. Slide the container and connector assembly onto the side chute as shown.
5. Align the clamp to the wide side of the container. This alignment will make changing full containers easier.



6. With the clamp positioned toward the rear of the unit, securely tighten the clamp onto the chute.



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# GETTING STARTED



## Waste Container Installation

1. The waste container is designed to hold a plastic waste bag. Review your procedures to determine if this needs to be a hazardous waste bag.



2. Attach the waste bag to the waste container lid using the stainless steel clamp provided.



3. Place the waste bag inside the waste container and attach the lid by snapping it into place. Then tighten the container clamp.



4. Attach the reusable waste container to the waste chute by tightening the stainless steel clamp when the container has been properly positioned on the waste chute.
5. If you choose, the waste bag can be directly attached to the waste chute using the stainless steel clamp. The purpose of the waste container is to control the waste bag and provide secondary containment if the bag would break or leak.



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# GETTING STARTED



## Sleeve and Glove Installation

1. Each glove port requires a sleeve and glove assembly.
2. The sleeve and glove assembly consists of a sleeve, sleeve clamp, glove, glove retainer, and an O-ring.
3. Proper installation of the sleeves and gloves is important for safety and comfort. When sealing the sleeves to the MIC and the gloves to the sleeves, make sure all folds, overlaps and clamping surfaces are as smooth as possible. (Review Video)

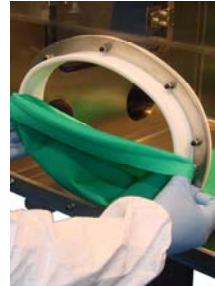
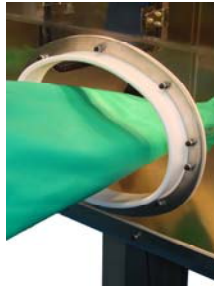
*CAUTION: The sleeve and glove installation procedures are different than a glove change. Failure to follow appropriate maintenance procedures may result in the exposure to hazardous materials. Refer to Periodic Maintenance in Section 4 for glove replacement.*

# GETTING STARTED



## Sleeve

1. Place the small end of the sleeve through the glove port in the MIC.
2. Stretch the large end over the outside of the port.

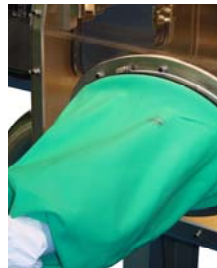


3. Place a sleeve clamp over the sleeve and orient the tightening screw downward. Positioning the screw downward will reduce the possibility of clothing snagging on the clamps.
4. Securely tighten the clamp.



*CAUTION: Hold both ends of the clamp while tightening; the clamp may rapidly uncoil during installation.*

5. Place large o-ring around glove port.
6. Reach into the port and pull out the small end of the sleeve.
7. Place a glove retainer over the small end and stretch the sleeve around the retainer.
8. Cover the retainer completely.
9. The fold should be smooth, with no wrinkles, and no portion of the retainer should be visible.
10. Repeat this process for the other sleeve.
11. The sleeves are now ready for the gloves.



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# GETTING STARTED



## Glove

1. Put on a glove and insert the gloved hand into the appropriate sleeve in a natural working position.
2. Place O-ring over glove for ease of installation as shown.
3. The open end of the glove should protrude from the sleeve by at least one inch.



4. Grasp the glove through the sleeve with the opposite hand and remove your hand from the glove.
5. The glove is aligned and ready to mount on the retainer.
6. To stretch the glove over the retainer, hold the sleeve and retainer in your hands with the glove opening facing away from you.
7. With thumbs under the retainer, grasp the glove opening with your fingers and pull the glove over the retainer. Smaller gloves will be more difficult to stretch, but this technique will ease the task.
8. Install the O-ring over the glove and sleeve and into the groove on the retainer. This will be the final orientation of the glove.



9. If the glove or sleeve is twisted or uncomfortable, reposition the glove and reinstall the O-ring.
10. Repeat this process for the other glove.



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# GETTING STARTED



## Miscellaneous

Now is a good time to place the misting bottle, squeegee and IV hangers into the MIC. These items were supplied in the start-up kit. It is best if these items are left in the chamber unless they need replaced. This will help to keep the items clean. Fill the misting bottle with a disinfectant such as alcohol or hydrogen peroxide and place it, the squeegee and hangers in the airlock. Use the barrier gloves to bring the items into the chamber. Place the IV hangers on the suspended rod and the misting bottle and squeegee within easy reach.

## Set-Up Inspection

This inspection is for the initial set-up only. See guidelines for inspection in the Maintenance & Troubleshooting section. Perform the following tests to confirm proper set-up:

1. Turn on the light and air system switches to confirm operation.
2. Verify the pressure indicator is displaying the desired pressure parameters (usually between 0.2 and .5 in a positive pressure state).
3. If the indicator is not within this range, check that the airlock doors are closed and sealed.
4. Also, inspect the airlock door seals for cracks, tears, or other damage that may have occurred during shipping. Any obstruction closed in the doors can also disrupt the air pressure.
5. Make sure the gloves and sleeves are installed correctly and sealed. A torn glove, loose clamp or missing O-ring can disrupt the air pressure.
6. Make sure the waste and sharps containers are installed properly and sealed. A loose clamp or container lid can disrupt the air pressure.
7. Tighten or replace loose clamps or torn gloves and/or sleeves.
8. Call CTG for service if the gauge still does not indicate 0.2 to .5

Once the inspection is complete, the MIC is ready to be sanitized and put into operation.



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# OPERATION



## Standard Operating Procedures

This section will describe standard operating procedures and general usage of the MIC. These instructions should be followed each time the workstation is used.

## Inspection

Prior to operating the MIC workstation, an operational check should be performed. Use the following criteria to inspect the MIC workstation:

1. Visually inspect the MIC for loose or damaged components.
2. Inspect for sign of obvious wear. If any items are found worn, replace the defective items. Refer to Section 4 for replacement procedures of damaged or worn parts.
3. Turn on the light and air system switches to confirm operation.
4. Verify that the MIC is operating within the desired pressure range (+0.2 - +0.5 for positive pressure & -0.2 - -0.5 for negative pressure)

*Note: The MIC can operate with positive or negative pressure. Positive pressure is used for aseptic manipulations such as IV admixtures or TPN's. Negative pressure adds a secondary containment feature when handling hazardous drugs.*

5. If the indicator is not within this range, perform the following checks:
  - a. Make sure the airlock doors are closed and sealed.
  - b. Inspect the airlock door seals for cracks, tears or other damage. Any obstruction closed in the doors can also disrupt the air pressure.
  - c. Make sure the gloves and sleeves are installed correctly and sealed. A torn glove, loose clamp or missing O-ring can disrupt the air pressure.
  - d. Make sure the waste and sharps containers are installed properly and sealed. A loose clamp or container lid can disrupt the air pressure.
6. Call CTG for service if the pressure gauge still does not indicate the desired operating pressure.
7. Once the inspection is complete, proceed with sanitizing the MIC.



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# OPERATION

## Cleaning both Standard and MIC-EDU

Clean the MIC using sterile water for irrigation with a mild detergent mixture followed by a sterile water rinse. Cleaning occurs at least once per shift. Sanitizing always follows cleaning. This process loosens and removes product residue.

Document this in the log.

### Physical Area

The IV compounding room is cleaned by the (identify cleaning responsibility) Department. All cleaning materials shall be non-shedding (lint free), preferably composed of synthetic fibers and dedicated specifically for the area.

- Counters and easily cleanable work surfaces to be cleaned daily.
- Floors to be cleaned daily.
- Walls to be cleaned monthly.
- Ceilings to be cleaned monthly.
- Storage shelves to be cleaned monthly.

## Sanitizing

Two factors determine the sterility assurance level of sterile products prepared in your pharmacy.

- Maintaining an ISO Class 5 environment
- Proper sanitization of the work environment

The MIC provides the ISO Class 5 environment. Pharmacy personnel are responsible for the proper sanitizing of the MIC. Proper sanitization requires the misting of all internal surfaces of the workstation with a disinfectant, such as sterile alcohol or hydrogen peroxide. Misting is the preferred method of applying the disinfectant because it provides a uniform coverage. A misting bottle is provided in the start-up kit for this task. A second misting bottle should be used outside the chamber to sanitize the airlock after inserting materials. The inner airlock door must be kept closed while the outside door is open. Details on proper airlock usage follow these sanitizing steps. The air system should be on during sanitization.

Sanitizing is required prior to compounding and immediately after compounding. The general rule is everything entering the critical area should be misted with a disinfecting agent. Follow these steps for sanitizing the workstation:

# OPERATION

1. Prior to compounding, place a misting bottle containing a disinfectant inside the MIC, if not already present.
2. Close the inner airlock door(s).
3. Use the gloves / sleeves to access the chamber and lightly mist all the interior surfaces of the MIC, including sleeves, gloves, and other items inside the chamber.

*Note: It is best to sanitize at the beginning of the work shift. Wait two minutes before compounding. During the shift, spray down after completion of compounding, but there is no need to wait two minutes.*



4. Document this activity in the Sanitizing Log.
5. Gather materials and organize baskets
6. After compounding is complete, mist gloves, sleeves, and the floor of the chamber with a disinfectant.
7. Place the prepared materials in the airlock. They are ready for removal.
8. Open the outer airlock door and place the gathered materials or workbaskets into the airlock.
9. If using a second misting bottle, lightly mist the inside of the airlock and gathered materials with hydrogen peroxide. Close the outer airlock door.
10. The inner door may now be opened and materials brought into the MIC for compounding.
11. Routine sanitizing during the day helps to maintain an aseptic environment.



It is a good practice to keep the misting bottle inside the workstation; even while refilling the bottle. This will help to keep the misting bottle clean. Another good practice is to use hydrogen peroxide for decontamination and sterile alcohol inside the MIC chamber. Switching between sterile alcohol and hydrogen peroxide will reduce the possibility of organisms developing a resistance to the agents.

# OPERATION



## Airlock Usage

The airlock separates the room environment from the ISO Class 5 environment. When used properly, the airlock allows access to the critical area without compromising the environment and provides a decontamination zone for incoming non-sterile components.

Once the air system is running, only one airlock door should ever be opened at a time. In the event that both doors are opened at the same time, it is imperative that the MIC be sanitized before further use.

Always follow these steps when inserting materials into the ISO Class 5 environment:

1. Make sure the inner airlock door is closed.
2. Open the outer airlock door.
3. Place all the needed materials into the airlock. The use of a tray or workbasket will ease handling.
4. Use a second misting bottle to sanitize the airlock, mist the inside of the airlock and its contents at this time.
5. Close the outer door.
6. Open the inner door and move the needed materials into the chamber. The workbasket can be returned to the airlock or remain in the chamber.
7. Close the inner door.

Always follow these steps when removing prepared materials from the ISO Class 5 environment:

1. Make sure the outer airlock door is closed and the prepared materials and critical area surfaces have been sanitized as described in the sanitization procedure.
2. Open the inner airlock door.
3. Place the prepared materials into the airlock. The use of a tray or workbasket will ease handling.
4. Close the inner door.
5. Open the outer door and remove the materials from the airlock.
6. Close the outer door after use.



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# OPERATION

## Adjustment

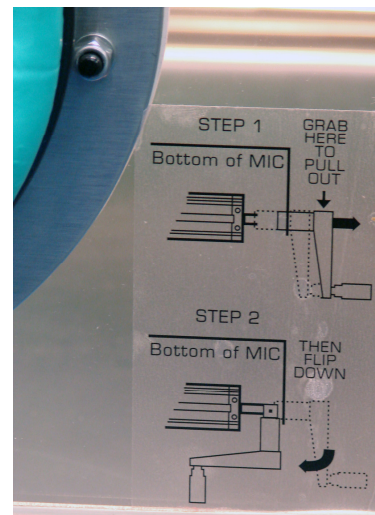
### Height Adjustment

The height of the MIC can be adjusted eight inches to accommodate different height personnel and/or allow a comfortable working position whether sitting or standing. Height adjustments can be made at any time by using the hand crank located just below the glove ports. Use the following steps to raise and lower the height adjustment of the MIC:

1. Swing the crank handle into position.
2. Turn clockwise to raise the MIC or counter-clockwise to lower the MIC.
3. Once the desired height is reached, return the crank to the folded position. First, pull straight out on the handle, and then swing it out of the way.
4. Operating instructions are on a sticker located near the crank handle.



*NOTE: Turning the crank requires only moderate force. The mechanism is equipped with a shear pin to disable the crank if an attempt is made to raise or lower the chamber beyond its limits. Refer to Periodic Maintenance in Section 4 for shear pin replacement*



### Air Pressure Adjustment

The MIC requires no manual adjustments for air pressure. Do not attempt to modify the MIC's pressure adjustment. Call CTG for service if the maintenance procedures in Section 4 do not correct any air pressure problems.

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# OPERATION



## General use Guidelines

Here are a few suggestions to improve productivity, comfort, and safety:

- Develop a sanitizing and airlock usage routine to help reduce mistakes. Although individual materials and supplies can be introduced into the MIC during operation, good planning will help maximize your efforts. Prior to compounding, create a check list of needed supplies and utilize the workbaskets to help organization.
- Place a misting bottle outside the airlock.
- Adjust the height of the workstation so there is approximately a 90° bend at the elbow when your arms enter the glove ports. This adjustment provides a comfortable working position.
- Sleeve and glove liners make working in the MIC sleeves and gloves more comfortable. The liners provide an easier entry and exit and keep the Nitrile gloves and sleeves clean longer. Sleeve and glove liners are provided with the start-up kit.
- Wipe up spills right away. This will reduce the possibility of cross-contamination.
- In the event of power loss, the MIC can provide adequate protection if entry and exit is limited.

## Range of Environmental Operating Conditions

1. Indoor Use
2. Altitude up to 2000 meters
3. Temperature 5 to 40 degrees centigrade
4. Maximum relative humidity 80% for temperatures up to 31 degrees centigrade decreasing linearly to 50% relative humidity at 40 degrees centigrade
5. Main supply fluctuations up to 10% of the nominal voltage
6. Transient over voltages typically present on the main supply (over voltage cat II)
7. Pollution degree 1

# MIC POLICIES & PROCEDURES



## I. PURPOSE

To establish standardized procedures and processes for the safe compounding of sterile preparations. The goal of the IV admixture program is to ensure that patients receive parenteral therapies as prescribed, free of microbial and particulate contamination, and unaltered by incompatibilities and interactions.

## II. POLICY

Pharmacy Service will provide IV admixtures and sterile compounded preparations for all areas within the hospital, except in limited emergency situations in which the preparation will be used immediately.

## III. ACTION

### A. Definitions:

1. MIC: Mobile Isolation Chamber is an ISO Class 5 environment.  
Compounding is to take place in the Direct Compounding Area. This area is where the critical sites are exposed during manipulation of the components used in compounding.
2. Cleaning both Standard and MIC-EDU:  
Cleaning of the MIC is to occur at least once per shift. Cleaning should also occur anytime there is a spill or a known introduction of contamination. The purpose of cleaning is to remove any solid materials that may cause cross-contamination from the surface of the MIC. Sanitizing always follows cleaning. See specific instructions for the cleaning process, page 5 of this section.
3. Sanitizing: Standard MIC:  
Misting the MIC using a sanitizing solution of either 70% sterile isopropyl alcohol or hydrogen peroxide 3%. The sanitizing process minimizes environmental microbial bioburden. Per the MIC operations video, materials placed in the airlock should be sprayed down with a disinfecting agent such as hydrogen peroxide 3% to reduce bioburden on incoming materials.



# MIC POLICIES & PROCEDURES



## FREQUENCY SCHEDULE

- (a) Inside the MIC – A complete sanitization process should occur after each cleaning routine (at least once per shift). This is the
- (b) routine where you allow the disinfecting agent to dry for at least 2 minutes. Sanitization should also occur continuously throughout compounding, this continuous process is described in detail in section V.E. (see page 6 of this section)
- (b) Daily cleaning and sanitizing – counters, work surfaces and floors
- (c) Monthly – walls, ceilings and shelving surfaces

Document this in the log.

### 4. Decontamination: MIC-EDU

The MIC-EDU has an automatic decontamination system that uses 35% hydrogen peroxide in a vapor form to reduce microbial bioburden. The system operating procedures are contained in the MIC-EDU standard Operating Procedures section titled Bio-Decontamination –Section 4 of the Operations Manual.

- 5. Medium Risk Level: Compounded sterile preparations are prepared using commercial sterile devices and medications involving simple aseptic transfers and manipulations. There may be a combination of three or more ingredients in one final preparation.
- 6. Products: Sterile medications manufactured by a drug company.
- 7. Preparations: Sterile extemporaneous medications compounded by the pharmacy staff.
- 8. Expiration date: Date assigned by drug manufacturer based upon regulatory guidelines, determined by scientifically valid, product/package-specific research studies.
- 9. Beyond-use date: Date (and time) beyond which the drug should not be used. The date/time is assigned by the compounder. The date/time is based on drug-specific, scientifically valid research studies when possible but may use more general guidelines when specific information is unavailable. The beyond-use date for sterile preparations is based on chemical stability in conjunction with microbiological limits, whichever is shorter.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



## B. Responsibilities:

1. Pharmacists and technicians working together provide sterile preparations to patients. Proper control over the equipment, environment, attire, hand washing and aseptic technique is an important factor in preventing contamination of a sterile compounded preparation.
2. Following written guidelines and procedures assures that all requirements for IV admixture and compounding sterile preparations are met.
3. Housekeeping or pharmacy staff clean and sanitize the IV compounding area daily.

## IV. PHYSICAL AREA:

- A. The IV compounding room is cleaned by the identified responsible person or department. All cleaning materials shall be non-shedding (lint free), preferably composed of synthetic fibers and dedicated specifically for the area.
  1. Frequency of area cleaning:

Counters and easily cleanable work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage Shelves	Monthly
- B. The IV compounding room is segregated from normal pharmacy operations. Segregation when using a MIC may be either by physical walls or defined boundaries. Access to the IV compounding area is restricted to authorized personnel in an effort to minimize unnecessary traffic, employee distraction and/or potential microbial contamination.
- C. Trash is removed daily.
- D. Paper, cardboard and particulate materials are minimized in the area. Supplies are unpacked in an external area.
- E. No food, chewing gum, or drinks are permitted in the IV compounding area.
- F. Trays utilized in the compounding process are sanitized daily and as necessary.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



- G. Temperature is controlled and monitored in areas where drugs are stored. Room temperatures can range from 20<sup>0</sup> to 25<sup>0</sup> C, refrigerated item storage temperature range from 2<sup>0</sup> to 8<sup>0</sup> C, and frozen item storage temperature range from - 25<sup>0</sup> to - 10<sup>0</sup>. Temperature shall be monitored at least daily and results documented.
- H. A positive pressure MIC or MIC-EDU is utilized for the sterile compounding of standard preparations.

A negative pressure MIC or MIC-EDU is utilized for the sterile compounding of hazardous substances. Refrigerated, frozen and controlled drug vials will be decontaminated in the MIC-EDU and stored in docking modules that can be placed in the proper environment until needed.
- I. Storage is not required to be in a negative pressure environment but should be segregated from other drug products.

## V. MOBILE ISOLATION CHAMBER (MIC):

- A. The MIC can be turned off without impacting the integrity of the system if both airlock doors remain closed.
- B. During routine changes of gloves, sleeves, sharps or trash containers, the blower on the barrier isolator is left ON.
- C. The frequency of changes is as follows. Changes are documented on the monthly log for each MIC:
  - 1. Gloves (non-powdered, nitrile): Sterile gloves are recommended for the standard MIC units. The MIC EDU automatically decontaminates gloves as part of the process.
    - (a) For the hazardous substance MIC, gloves are to be changed based on usage for low volume use 20-25 preparations per week, a weekly change is appropriate. For volume over twenty five per day, change daily or when personnel hand sizes require the change, and at any sign of wear or breach of integrity.
    - (b) For the IV admixture MIC, gloves are to be changed weekly, when personnel hand sizes require the change, or at any sign of wear or breach of integrity.
  - 2. Sleeves: (note: sleeves are not required to be sterile)
    - (a) For the hazardous substance MIC, sleeves are to be changed every six months or at any sign of wear or breach of integrity.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



(b) For the IV admixture MIC, sleeves are to be changed every six months or at any sign of wear or breach of integrity.

3. Sharps and trash containers: Change as they become full.
4. Blowers should be operated at all times. If the MIC is turned off, operate the MIC for 2 minutes prior to compounding.

## D. Interior Cleaning – MIC Family of Isolators:

### PURPOSE

Cleaning of the MIC is to occur at least once per shift. Cleaning should also occur anytime there is a spill or a known introduction of contamination. The purpose of cleaning is to remove any solid materials that may cause cross-contamination from the surface of the MIC.

**CLEANING** - Clean the MIC using sterile water and a mild detergent mixture followed by a surface rinse and sanitizing. Some materials are difficult to clean and may require a more aggressive cleaning agent than mild detergent. If areas prove to be difficult a more aggressive agent such as “Barkeepers Friend” a non-chlorinated cleaner may be used on the difficult areas.

### Items Needed

- Spray Bottle with sterile water
- Hydrogen Peroxide or Alcohol Spray Bottle
- Sterile wipes
- Squeegee
- Cleaning solution consisting of a mild detergent in a spray bottle

### PROCEDURE

#### Routine Cleaning:

- Remove all unnecessary items from the chamber.
- Mist all surface areas with sterile water (use a small amount of mild detergent mixed with sterile water in a spray bottle to clean surfaces).
- Use a squeegee (the webbed side) to scrub surfaces.
- Use the wiper blade side of the squeegee to remove excess liquid.
- Rinse the surfaces with sterile water using the spray bottle.
- Use the squeegee or sterile wipe to remove any liquid.
- Sanitize after allowing to dry.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



## Storage of the Squeegee Head

- The squeegee head is to be stored in a sealed zip lock bag and replaced monthly.
- Before placing the squeegee head in the bag, it is to be sprayed with a decontaminating agent such as sterile alcohol or hydrogen peroxide.

The routine cleaning cycle will be documented daily and weekly on a cleaning/sanitizing log.

## E. Interior Maintenance-Sanitizing / Decontamination –Standard MIC:

1. Sanitizing of the chamber shall be by misting the entire interior surfaces of the MIC with an effective sanitizing agent. Effective sanitizing agents are sterile 70% isopropyl alcohol and non-sterile hydrogen peroxide 3%.

(a.) A light mist of the sanitizing agent should be applied to all interior surfaces (top, bottom, sides, window, sleeves and gloves) and allowed to stand for two (2) minutes. Wiping should only occur if there is a visibility problem or puddles. Using a squeegee, wipe top to bottom, sides and back to front. This procedure should be done at the beginning of the work shift.

(Note: Place the squeegee into a zip lock bag and seal to remove it from the chamber.)

- (1) During the work shift as personnel complete preparation of doses; spray down the critical surfaces, including gloves and sleeves, before exiting the Mobile Isolation Chamber.
- (2) The airlock should be misted with hydrogen peroxide with each entry.

## F. Interior Maintenance-Sanitizing / Decontamination – MIC-EDU:

1. The MIC-EDU has an automatic decontamination system that uses 35% hydrogen peroxide in a vapor form to reduce microbial bioburden. The system operating procedures are contained in the MIC-EDU standard Operating Procedures section titled Bio-Decontamination –Section 4 of the Operations Manual.

# MIC POLICIES & PROCEDURES



## VI. COMPOUNDING PERSONNEL RESPONSIBILITIES – STANDARD MIC

### A. Hand washing:

1. Wash hands and arms to elbow with an antimicrobial soap at the sink.
2. Sanitize hands with alcohol foam/gel prior to entering the IV compounding area.

### B. Proper attire:

1. Authorized personnel who enter the IV compounding area are properly garbed. Proper garb is a long lab coat and gloves when handling drug products. It is recommended but not required.
2. Jewelry should not be worn on the hands or wrists since it may introduce bacteria or particles into the clean work area. If jewelry cannot be removed, cloth glove liners are worn to reduce the potential of puncturing the gloves.
3. Personnel who regularly or occasionally prepare sterile compounded preparations may not wear artificial fingernails or extenders.

### C. Setup (Preparation of materials for introduction into the airlock of the standard MIC):

1. Materials entering the airlock are to be sprayed down per CTG operations video with 3 % hydrogen peroxide.
2. When the final preparation(s) is completed, re-sanitize the interior of the MIC and begin a different medication/dose.
3. Using the IV label(s) header or the IV compounding report as a reference, assemble all materials (i.e. medications, diluents, IV solutions, syringes, needles, sterile wipes, security seals) needed to complete the final preparation. For hazardous substance compounding, add a zip lock transport bag labeled as 'chemotherapy' and/or auxiliary labels.

(a) Before compounding the following steps are recommended:

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



- (1) Visually inspect the products for signs of cloudiness, particulates, cracks, punctures, manufacturer expiration dates or other characteristics that may indicate that the product is defective.
  - (2) Record the lot number and manufacturer expiration dates of the additives and diluents on the IV compounding report or the IV label header. Note any dosage calculations.
  - (3) The pharmacist will validate the ingredients with the IV labels, verify the dosage calculations, and sign the report/label prior to compounding.
  - (4) Place the assembled non-paper items into a plastic tray (that has been previously sanitized). Remove the outer wrap of any IV solutions. Mist or wipe with the designated sanitizing agent before introduction into the MIC.
  - (5) Place paper items (syringes, needles, labels with appropriate post-compounding storage requirements, security seals) into a separate tray.
- (b) Verify the inner airlock door is closed.
- (c) Place the trays into the airlock, and mist with hydrogen peroxide.
- (d) Close and latch the airlock door.

## **VII. STERILE COMPOUNDING – STANDARD MIC**

- A. Check the pressure setting on the gauge of the MIC (positive or negative).
- B. Enter the MIC through the glove/sleeve ports.
- C. Verify the outer airlock door is closed.
- D. Open the interior air lock door and transfer the tray into the MIC
- E. Begin the sterile compounding preparation using proper procedures and aseptic technique. There are no restrictions for positioning the items. Aseptic manipulations are to occur in the direct compounding area of the isolation chamber.

*Protecting the Patient, Product, and Provider*



# MIC POLICIES & PROCEDURES



1. Spray all entry ports or ampoule necks. Enter medication ports using proper needle size, inserting needle bevel up and downward pressure.
2. Reconstitute medications, as needed, using appropriate diluents, volume, and syringe.
3. Check medications, diluents, and volumes to be used for the preparation with the IV label.
4. Withdraw desired amount of medication using an appropriate size syringe and needle. Inject into the infusion bag as needed. (Remove air bubbles from the syringe to obtain an accurate measurement.)
5. Mix/agitate the admixture after each addition and at the end of the preparation.
6. Visually inspect the final preparation for incompatibility, particulate matter, and color changes. If the final preparation is 'defective', dispose of the item and prepare an additional dose.
7. Compress IV bag to detect leaks.
8. Place a tamper evident seal over the injection port or syringe tip.
9. Document beyond use date and time on the IV label. Initial the label as 'prepared by'. Affix the IV label and any auxiliary labels (filters, storage requirements) to the final preparation.
10. Verify that the outer airlock door is closed. Place the finished preparation, the additive(s) and diluent(s) into the tray. Place into the airlock chamber. (If the preparation is a hazardous substance, insert the finished preparation into a properly labeled zip lock transport bag.)  
**NOTE:** Review MIC operations video for secondary containment procedures
11. Discard syringes, needles and trash into the appropriate containers attached to the MIC.
12. Sanitize/clean the surfaces of the MIC including gloves and sleeves.
13. Verify the inner airlock door is closed and remove the finished preparation for checking and delivery.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



14. Multi-dose vials are dated and initialed upon opening. After compounding has occurred; the partial vials are immediately placed into the proper storage area.

15. Partial single dose vials (no preservative) are immediately discarded after use.

F. TPN/PPN Compounding: In addition to the process list above include the following:

1. All additives are pre-drawn into syringes in the MIC.
2. Each syringe is aligned with the additive vial. Additives are arranged in the sequence to be added to the base solution. The base solution is gently agitated after each additive is injected.
3. The pharmacist checks the volume in the syringe with the additive vial prior to the addition of the additives into the base solution.

## **VIII. STERILE COMPOUNDING PREPARATION:**

### **MIC-EDU Standard Operating Procedures**

A. This section will describe standard operating procedures and general usage of the bio-decontamination unit. These instructions should be followed each time the bio-decontamination unit is used.

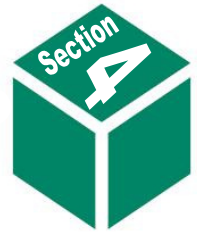
#### **Inspection**

Prior to operating the MIC workstation, an operational check should be performed. Use the following criteria to inspect the MIC EDU:

1. Visually inspect the MIC-EDU for loose or damaged components. Inspect for sign of obvious wear. If any items are found worn, replace the defective items (do not attempt service on the bio-decontamination unit). Refer to Section 7 for replacement procedures of damaged or worn parts.
2. Turn on the light and air system switches to confirm operation. Verify that the MIC is operating within the desired pressure range (+0.2 – +0.5 for positive pressure & -0.2 - -0.5 for negative pressure). If the indicator is not within this range, perform the following checks:

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



- (a) Make sure the airlock doors are closed and sealed.
- (b) Inspect the airlock door seals for cracks, tears or other damage.
- (c) Any obstruction closed in the doors can also disrupt the air pressure.
- (d) Make sure the gloves and sleeves are installed correctly and sealed. A torn glove, loose clamp or missing O-ring can disrupt the air pressure.
- (e) Make sure the waste and sharps containers are installed properly and sealed. A loose clamp or container lid can disrupt the air pressure.

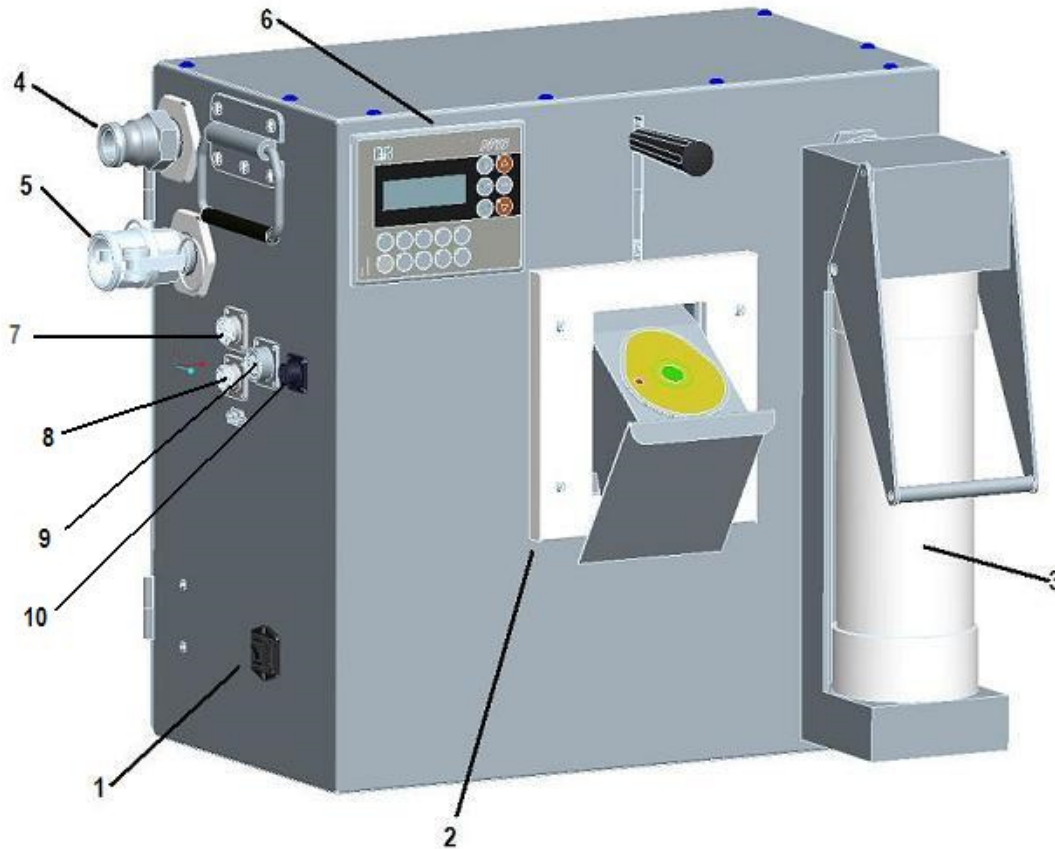
Call CTG for service if the pressure gauge still does not indicate the desired operating pressure. Once the inspection is complete, proceed with starting the VHP cycle for the MIC EDU.

# MIC POLICIES & PROCEDURES



## Product Detail – Decontamination Unit

### COMPONENT IDENTIFICATION (FIGURE 4.1)



1. Power Switch
2. Cartridge Holder
3. Re-usable or disposable Desiccant Dryer
4. Enclosure Return
5. Sterilant Outlet.
6. PP15 Display/Controller
7. Connection for Supply Diverter Valve
8. Connection for Return Diverter Valve
9. Connection for Isolator Interface
10. Connection for Isolator Interface

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



## B. Bio-decontamination Process

### Introduction

The Bio-decontamination System (see Figure 4.1) provides a simple and reliable method for bio-decontamination of single and dual chamber MIC units.

### The VHP Process

The bio-decontamination cycle is a closed loop process utilizing dry, heated air as a carrier gas to deliver Vaprox® Hydrogen Peroxide Sterilant vapor (VHP) to the exposed surfaces inside the isolator chamber. This closed loop process allows the bio-decontamination process to take place at, or near, atmospheric pressure.

H<sub>2</sub>O<sub>2</sub> vapor is continuously injected for the required exposure time to achieve bio-decontamination. The VHP antimicrobial evacuated from the isolator in a closed loop operation is catalytically converted by the bio-decontamination unit into water vapor and oxygen.

### The Bio-decontamination Cycle Phases

The bio-decontamination cycle consists of four phases: DEHUMIDIFY, CONDITION, BIO-DECONTAMINATION, and AERATION.

- **DEHUMIDIFY** — Dry, filtered air is circulated through the isolator to reduce humidity to a preset level in the 10-60% relative humidity range. This permits the necessary target Vaprox H<sub>2</sub>O<sub>2</sub> vapor concentration to be maintained below saturation (dew point) levels during the Condition and Bio-decontamination phases. The return air is dried as it passes through the dryer. The internal filter prevents contamination of internal machine components and prevents recontamination of the Isolator. This filter also protects the vaporizer from Dryer Cartridge particles.
- **CONDITION** — The flow of dry, filtered air continues while Vaprox vapor is injected into the air stream just before it leaves the unit.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



The Vaprox injection rate is higher than that of the Bio-decontamination phase, because the Condition phase is intended to quickly reach the target bio-decontamination concentration. Condition time is affected by sterilant injection rate, Isolator volume, Isolator contents and temperature, and is shorter than the Bio-decontaminate time.

- **BIODECONTAMINATION** — The target VHP antimicrobial concentration is maintained by continuing Vaprox vapor injection for a specific period of time throughout the Isolator.
- **AERATION** — Vaprox H<sub>2</sub>O<sub>2</sub> vapor injection is stopped and the re-circulating flow of dry, filtered air continues through the catalytic converter to reduce the H<sub>2</sub>O<sub>2</sub> vapor concentration within the Isolator.

## CYCLE DESCRIPTION

Two bio-decontamination cycles are available for a dual chamber Isolator, and one cycle is available for a Single chamber isolator:

1. **Storage Chamber cycle (dual chamber isolators):** The Aerate phase of this cycle allows transfer of items from the Storage to the Compounding chamber, and Condition and Bio-decontaminate injection rates and phase times developed specifically for the Storage chamber.
2. **Compounding chamber cycle (dual chamber isolators):** The Condition and Bio-decontaminate injection rates and phase times are developed specifically for the Compounding chamber.
3. **Single chamber cycle:** The Condition and Bio-decontaminate injection rates and phase times are developed specifically for the Single chamber isolator.

The user starts the bio-decontaminate cycle from the Bio-decontamination Unit main menu display. If a dual chamber isolator is connected, the user then selects either the Storage or Compounding cycle. An Operator Password is required to start the cycle.

The cycle is ready to run if:

- The Load and Transfer doors are closed for a Storage cycle.
- All doors are closed for a Compound cycle.
- The Unload door is closed on a Single Chamber Isolator.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



- Dual Chamber Units: After chamber selection by the user, the diverter valves have rotated to the Storage chamber position for a Storage cycle, or, they have rotated to the Compounding chamber position for a Compounding cycle,
- No alarm is occurring.

Once your inspection of the MIC-EDU is complete, you are ready to start the Bio-decontamination Process. Please be sure to read through all safety procedures (listed above) before operating the Bio-decontamination Unit. Below are listed the step-by step procedures for operating the Bio-decontamination unit through a bio-decontamination cycle.

Step-by-step:

1. Enter pass code
1. Press activation button
2. Wait...
3. Process will begin
4. Decontamination process is complete

C. Operations.

1. Perform alcohol foam/gel hand and forearm wash.
2. Enter the MIC through the glove/sleeve ports.
3. Locate and remove proper vial of medication from the storage rack/basket contained on the storage rack at the rear of the MIC-EDU chamber. Gather the correct IV bag solution, syringe, needle and supporting materials
4. Begin the sterile compounding preparation using proper procedures and aseptic technique. There are no restrictions for positioning the items. Aseptic manipulations are to take place in the direct compounding area of the isolation chamber.
  - (a) Spray all entry ports or ampoule necks..
  - (b) Enter medication ports using proper needle size, inserting bevel up and downward pressure.
  - (c) Reconstitute medications, as needed, using appropriate diluents, volume, and syringe.
  - (d) Check medications, diluents, and volumes to be used for the preparation with the IV label.
  - (e) Withdraw desired amount of medication using an appropriate size syringe and needle.

*Protecting the Patient, Product, and Provider*



# MIC POLICIES & PROCEDURES



- (f) Inject into the infusion bag as needed. (Remove air bubbles from the syringe to obtain an accurate measurement.
- (g) Mix/agitate the admixture after each addition and at the end of the preparation
- (h) Visually inspect the final preparation for incompatibility, particulate matter, and color changes. If the final preparation is 'defective', dispose of the item and prepare an additional dose.
- (i) Compress IV bag to detect leaks.
- (j) Place a tamper evident seal over the injection port or syringe tip.
- (k) Document beyond use date and time on the IV label. Initial the label as 'prepared by'. Affix the IV label and any auxiliary labels (filters, storage requirements) to the final preparation.
- (l) Place into the airlock chamber. (If the preparation is a hazardous substance, insert the finished preparation into a zip lock transport bag labeled as 'chemo'.)  
**NOTE:** Review MIC operations video for secondary containment procedures.
- (m) Discard syringes, needles and trash into the appropriate containers attached to the MIC.
- (n) Verify the inner airlock door is closed and remove the finished preparation for checking and delivery.
- (o) Multi-dose vials are dated and initialed upon opening. After compounding has occurred; the partial vials are immediately placed into the docker for removal to the refrigerator.
- (p) Partial single dose vials (no preservative) are immediately discarded after use.

## 5. Finished Preparation/Product Release Checks:

- (a) The pharmacist visually checks the finished preparation for:
  - (1) Particulates, color changes, and phase separation (oiling or cracking) using the black/white lighted box.
  - (2) The medications, diluents, IV solution and calculations are checked for accuracy with the IV label.
  - (3) The finished preparation is tested for leaks.
  - (4) The beyond-use date/time are checked.
  - (5) Appropriate storage instructions are affixed to the IV label.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



- (6) The pharmacist initials the IV label as 'checked by' to release the preparation/product for delivery.

6. Whenever possible, a double check is performed by a second person.

## **IV. STAFF TRAINING and COMPETENCY**

- A. All pharmacy personnel preparing sterile preparations receive didactic and experiential training and competency evaluation through demonstration or testing (written and practical). Aseptic technique is tested utilizing growth media (broth fill testing).
- B. Testing occurs upon hire and annually thereafter.
- C. Compounding personnel who fail written tests or who media-fill test shows gross colonization must be immediately re-instructed and reevaluated. Personnel who fail media-fill testing may not perform sterile compounding until the media-fill testing demonstrates competence.
- D. Documentation of employee training and process verification is retained for a period of three years.

## **X. QUALITY CONTROL:**

- A. Routine maintenance and certification shall take place based on the following schedule:
  - 1. The isolation chamber shall be certified by a qualified individual on a semi-annual basis, in accordance with the rules of the State. The bio decontamination unit shall be serviced annually by a qualified CTG service representative.
  - 2. Routine checks of the Mobile Isolation Chamber consisting of verification of pressure settings, changing of light sources and the blower motor, are outlined in the MIC owner's manual.
- B. Environmental monitoring:
  - 1. Viable airborne shall occur in the MIC and the MIC-EDU every six months using a volumetric collection method.
  - 2. Surfaces in the interior of the MIC are sampled monthly utilizing touch

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



plates. Surfaces tested are gloves, sleeves, floor, window, sidewalls.  
The day of the week and time of day are rotated.

3. Gloved finger tip sampling shall occur as follows:

- (a) Before compounding an individual must successfully complete an initial competency test using a sterile agar plate and touching it three time with results showing zero cfu's.
- (b) The finger tip test is required annually for low & medium risk and semi-annually for high risk.
- (c) This testing should be incorporated into the media-fill test procedure. Results should be recorded per hand per employee. The cfu action level will be based on the total cfu's on both hands.

4. Results of the sampling are documented in a log.

## **XI. ACTION PLAN WHEN (CFU's) ARE DETECTED:**

- A. 1-2 CFU's: send an e-mail reminder to staff of the results.
- B. 2-5 CFU's: thoroughly clean and sanitize the MIC and send E-mail to staff regarding the results.
- C. Greater than 5 CFU's: send the plate to microbiology or culture. Thoroughly clean and sanitize the MIC and e-mail the staff. Based upon the culture results, determine an appropriate remedy.

## **XII. HOUSEKEEPING DOCUMENTATION:**

- A. Housekeeping will document cleaning of the IV compounding room daily on a log.
- B. Housekeeping will document shelf-cleaning quarterly on the monthly log.
- C. The monthly log will list the cleaning agent utilized and the routine cleaning activities performed.
- D. A copy of the monthly log will be provided to the Inpatient Pharmacy Supervisor for inclusion with other records for retention.

*Protecting the Patient, Product, and Provider*

# MIC POLICIES & PROCEDURES



## **XIII. RECORD RETENTION:**

A. The following documentation are retained:

1. Refrigerator and freezer temperature logs.
2. IV compounding room and main pharmacy room temperature logs.
3. Cleaning/sanitizing logs
  - (a) For each MIC.
  - (b) For the compounding area.
4. Aseptic media-fill logs (low and medium risk annually and as necessary for high risk semi-annually).
5. Employee didactic skills assessment checklists (low and medium risk annually and as necessary for high risk semi-annually).
6. Compounding documents.
7. Engineering control certification of the MIC (every 6 months).
8. Environmental monitoring logs
  - (a) Viable air sampling results
    - (1) In the MIC
    - (2) In the compounding area
  - (b) Surface sampling results
    - (1) In the MIC
    - (2) In the compounding area
9. Finger tip sampling results

# MAINTENANCE & TROUBLESHOOTING



This section will provide instructions for daily, weekly and, periodic maintenance, as well as trouble shooting techniques.

## Maintenance

### Daily

Inspect and sanitize the MIC workstation as described in the Inspection and Sanitizing sections of Section 3 (Operation).

### Weekly

In addition to the Daily Maintenance criteria, an air pressure gage reading should be taken weekly and recorded in the maintenance log. This data will help monitor filter life and workstation function.

1. The reading may be taken any time while the MIC is in normal use.
2. Make sure the air system has been running for at least three minutes.
3. Read the gage. The gage units are in inches of water.
4. Record the reading in the maintenance log to the nearest tenth.

*Example: The reading on the gage in the photo should be written as "0.2 inches". Positive readings are to the right of the zero and negative to the left.*



# MAINTENANCE & TROUBLESHOOTING



## Periodic

The sharps containers, waste containers, sleeves, and gloves need periodic inspection and should be replaced as needed. The following paragraphs detail replacement of the items state above.

### Sharps Container Replacement

1. Replace the sharps container as needed or when deemed appropriate by pharmacy personnel.

**CAUTION:** Disposable gloves should be worn while changing the sharps container if the workstation was last used to prepare hazardous materials such as cytotoxins or other chemotherapy drugs.

2. The sharps container is not intended to be reusable. Make sure a replacement is available for installation.
3. Switch on the MIC air system.
4. Loosen the sharps container connector clamp, while holding onto container, with a 5/16 nut-driver. A nut-driver was provided with the MIC start-up kit.
5. Lower the container to the floor unscrew the connector from the sharps container.
6. Seal the container with the supplied cap and dispose.
7. Position the connector on the new sharps container and turn counter-clockwise until the threads align. Turn clockwise until the connector is tight.
8. Raise the connector and container assembly to the sharps port and securely tighten the clamp.
9. Sanitize the MIC and verify proper air pressure.



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# MAINTENANCE & TROUBLESHOOTING



## Waste Container Liner Replacement

1. Replace the waste container liner as needed or when deemed appropriate by pharmacy personnel.

**CAUTION:** Disposable gloves should be worn while changing the waste container liner if the workstation was last used to prepare hazardous materials such as cytotoxins or other chemotherapy drugs.

2. Loosen the clamp that attaches the waste container to the MIC.
3. Lower to the floor.
4. Loosen the stainless steel clamp on the trash container and remove the top. A 5/16 nut driver is the only tool required.
5. Twist the waste bag and using a twist tie, seal the bag.
6. After sealing, remove the bag from the waste container.
7. Install a new waste bag by feeding the top of the bag through the clamp and evenly spreading the bag around the opening.
8. Attach the clamp to the waste container lid.
9. Place the lid with the attached bag on the drum and seal with stainless steel clamp.
10. Attach waste container to MIC and securely tighten clamp.
11. Sanitize the MIC and verify proper air pressure.



*Protecting the Patient, Product, and Provider*



# MAINTENANCE & TROUBLESHOOTING



## Glove Replacement – General Information

The frequency of glove replacement should be based on usage and time. Weekly glove replacement is adequate for low volume applications (approximately 20 preparations a week). High volume applications should consider more frequent glove changes.

Glove replacement procedures will vary between hazardous compounding (chemotherapy) and non-hazardous compounding (IV admixtures)

**CAUTION:** *Failure to follow the appropriate glove change procedure may lead to exposure to hazardous materials.*

# MAINTENANCE & TROUBLESHOOTING



## Glove Replacement - Cytotoxins and Other Hazardous Drugs

Gloves used in the preparation of hazardous materials should not be reused. Nor should they be removed through the glove ports when replaced. Use the waste chute in the MIC to dispose of the gloves. Replace the gloves as needed or when deemed appropriate by pharmacy personnel.

1. Ensure that the MIC air system is running.
2. Reach into the sleeve and glove and pull the sleeve inside out.
3. Remove the O-ring from the glove retainer but do **NOT** loosen the glove.
4. Put the replacement glove on your hand. While wearing the replacement glove, loosen the old glove from the retainer and push it into the sleeve for later disposal.
5. Place the gloved hand in the appropriate sleeve, in a natural working position. The open end of the glove should protrude from the sleeve by at least one inch.
6. Grasp the glove through the sleeve with the opposite hand and remove your hand from the glove. The glove is aligned and ready to mount on the retainer. To stretch the glove over the retainer, hold the sleeve and retainer in your hands with the glove opening facing away from you.
7. With thumbs under the retainer, grasp the glove opening with your fingers and pull the glove over the retainer. Overlap the retainer completely. The fold should be smooth, with no wrinkles, and no portion of the retainer should be visible. Smaller gloves will be more difficult to stretch, but this technique will ease the task.
8. Install the O-ring over the glove and sleeve and into the retainer groove. This will be the final orientation of the glove.
9. If the glove or sleeve is twisted or uncomfortable, reposition the glove and reinstall the O-ring.
10. Repeat these steps for the other glove(s).
11. Once the replacement gloves are installed, push the old gloves into the chamber and place in the waste container chute.
12. Verify proper air pressure.



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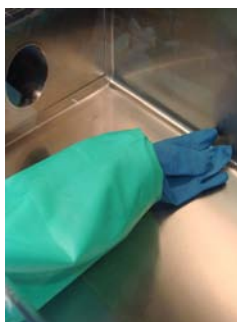
# MAINTENANCE & TROUBLESHOOTING



## Glove Replacement – IV Admixtures and Non-Hazardous Drugs

Gloves used in the preparation of non-hazardous materials can be reused. However, it is imperative that they are properly sanitized and undamaged. Inspect used gloves for holes and excessive wear. Discard damaged or excessively worn gloves. Change or replace gloves to fit individual hand sizes, when noticeably worn or when deemed appropriate by pharmacy personnel.

1. Ensure that the MIC air system is running.
2. Reach into the barrier / isolator sleeve and glove and pull the sleeves inside out.
3. Remove the O-rings from the glove retainers.
4. Loosen and remove the gloves from the retainers.
5. Dispose of the gloves or set aside for future use.
6. Put on a new glove and place the gloved hand in the appropriate sleeve, in a natural working position. The open end of the glove should protrude from the sleeve by at least one inch.
7. Grasp the glove through the sleeve with the opposite hand and remove your hand from the glove. The glove is aligned and ready to mount on the retainer. To stretch the glove over the retainer, hold the sleeve and retainer in your hands with the glove opening facing away from you.
8. With thumbs under the retainer, grasp the glove opening with your fingers and pull the glove over the retainer. Overlap the retainer completely. The fold should be smooth, with no wrinkles, and no portion of the retainer should be visible. Smaller gloves will be more difficult to stretch, but this technique will ease the task.
9. Install the O-ring over the glove and sleeve and into the retainer groove. This will be the final orientation of the glove.
10. If the glove or sleeve is twisted or uncomfortable, reposition the glove and reinstall the O-ring.
11. Repeat these steps for the other glove(s).
12. Verify proper air pressure.



*Protecting the Patient, Product, and Provider*

# MAINTENANCE & TROUBLESHOOTING



## Sleeve Replacement – General Information

Sleeve replacement procedures will vary between hazardous compounding (chemotherapy) and non-hazardous compounding (IV admixtures)

**CAUTION:** *Failure to follow the appropriate sleeve change procedure may lead to exposure to hazardous materials.*

# MAINTENANCE & TROUBLESHOOTING



## Sleeve Replacement - Cytotoxins and Other Hazardous Drugs

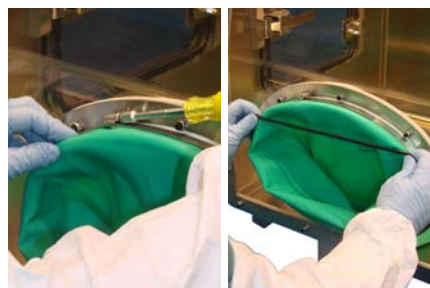
Sleeves used in the preparation of hazardous materials should not be reused. Nor should they be removed through the glove ports. Use the waste chute in the MIC to dispose of the sleeves. Replace the sleeves every six months, as needed, or when deemed appropriate by pharmacy personnel.

1. While wearing gloves, reach into the sleeve and glove and pull one sleeve inside out.
2. Remove the O-ring from the glove retainer.
3. Loosen the glove and sleeve together from the retainer.
4. Remove the retainer.
5. Fold the open end of the sleeve and glove over and over toward the glove port and push it inside the MIC.
6. Loosen the sleeve clamp with a 5/16 nut-driver. A nut-driver is provided with the MIC start-up kit.
7. Remove the clamp from the sleeve and glove port.



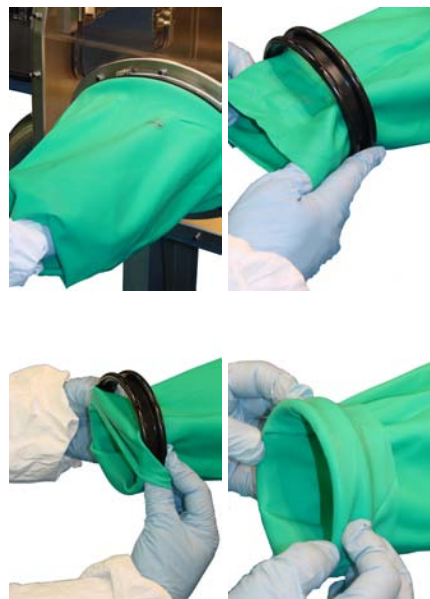
**CAUTION:** Hold both ends of the clamp while loosening; the clamp may rapidly uncoil during removal. Loosen the large end of the sleeve from the glove port and push the old sleeve into the chamber and place it in the waste container chute.

8. Place the small end of a new sleeve through the glove port in the MIC.
9. Stretch the large end over the outside of the port.
10. Place the sleeve clamp over the sleeve and position the tightening screw downward. This will reduce the possibility of clothing snagging on the clamp.
11. Securely tighten the clamp.



**CAUTION:** Hold both ends of the clamp while tightening; the clamp may rapidly uncoil during installation.

12. Reach into the port and pull out the small end of the sleeve.
13. Place a glove retainer over the small end and stretch the sleeve around the retainer. Cover the retainer completely. The fold should be smooth, with no wrinkles, and no portion of the retainer should be visible.
14. Install the barrier / isolator glove. Refer to barrier / isolator glove replacement.
15. Repeat the process for the other sleeve.
16. Confirm proper air pressure.



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# MAINTENANCE & TROUBLESHOOTING



## Sleeve Replacement – IV Admixtures and Non-Hazardous Drugs

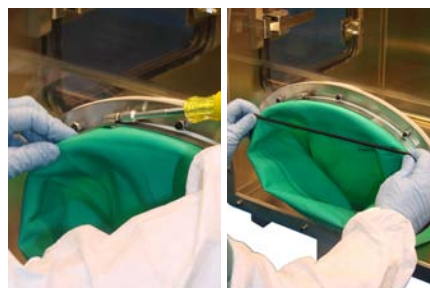
Sleeves used for IV admixtures and non-hazardous drugs can be reused. If sleeves are dirty, but in good condition, they can be laundered and reused. Replace as needed or when deemed appropriate by pharmacy personnel.

1. While wearing gloves, reach into the sleeve and glove and pull one sleeve inside out.
2. Remove the O-ring from the glove retainer.
3. Loosen the glove and sleeve together from the retainer.
4. Remove the retainer.
5. Fold the open end of the sleeve and glove over and over toward the glove port and push it inside the MIC.
6. Loosen the sleeve clamp with a 5/16 nut-driver. A nut-driver is provided with the MIC start-up kit.
7. Remove the clamp from the sleeve and glove port.



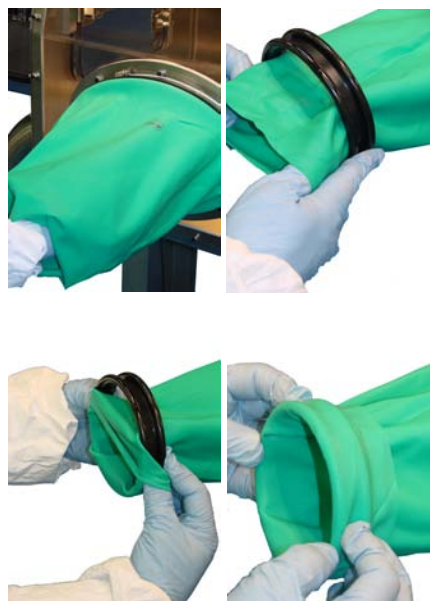
**CAUTION:** Hold both ends of the clamp while loosening; the clamp may rapidly uncoil during removal.

8. Place the small end of a new sleeve through the glove port in the MIC.
9. Stretch the large end over the outside of the port.
10. Place the sleeve clamp over the sleeve and position the tightening screw downward. This will reduce the possibility of clothing snagging on the clamp.
11. Securely tighten the clamp.



**CAUTION:** Hold both ends of the clamp while tightening; the clamp may rapidly uncoil during installation.

12. Reach into the port and pull out the small end of the sleeve.
13. Place a glove retainer over the small end and stretch the sleeve around the retainer. Cover the retainer completely. The fold should be smooth, with no wrinkles, and no portion of the retainer should be visible.
14. Install the glove. Refer to glove replacement section.
15. Repeat the process for the other sleeve.
16. Confirm proper air pressure.



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# MAINTENANCE & TROUBLESHOOTING



## HEPA Filter Inspection and Replacement

The MIC's HEPA filters should be tested on a routine basis. The filters should be replaced if:

- The pressure in the MIC becomes too high (reads above 1.5 inches water column)
- The filters fail to meet ISO Class 5 requirements
- When deemed necessary by pharmacy personnel

The anticipated life expectancy of the HEPA filters 10 years, unless they become damaged. This activity should be recorded in the Filter Change Log. Refer to Section 6, ISO Class 5 Certification.

Replacement filters are available from Containment Technologies Group. CTG also provides recommended procedures plus training materials. Have your certifying company contact CTG at 317-713-8200 if they do not have the materials.

## Shear Pin Replacement (Hand Crank Repair)

The hand crank shear pin is designed to break when too much force is applied to the crank. This prevents the workstation from being raised or lowered beyond its limits.

1. Replace the shear pin when the height-adjusting crank becomes disabled.
2. Replacement pins were affixed to a CTG business card and shipped with the MIC.
3. Remove the hand crank from the shaft.
4. Remove any remaining pieces of the old shear pin from the crank and the crankshaft.
5. Tap a new shear pin into the small hole in the handle.
6. Re-install the handle onto the shaft and align the pin with the hole in the shaft.
7. Tap the pin into the handle and shaft until the pin is flush with the crank.



# MAINTENANCE & TROUBLESHOOTING



## Troubleshooting Symptoms and Solutions Light

<u>System</u>	<u>Problem</u>	<u>Solution</u>
Lights	<i>The light doesn't work</i>	<ul style="list-style-type: none"> <li>• Check to see if light is switched on</li> <li>• Check to see if power cord is plugged in</li> <li>• Check to see if light bulb has burned out</li> <li>• If problem(s) continue, contact CTG for service</li> </ul>
Air System	<i>The MIC air system doesn't work</i>	<ul style="list-style-type: none"> <li>• Check to see if the air system is switched on</li> <li>• Check to see if the power cord is plugged in</li> <li>• If problem(s) continue, contact CTG for service</li> </ul>
	<i>The air system is turned on, but the gage shows pressure is less than 0.2 inches</i>	<ul style="list-style-type: none"> <li>• Check to see that airlock doors are closed and door seal are unobstructed</li> <li>• Check to see if sleeves and gloves are damaged or installed incorrectly</li> <li>• Check to see if sharps and waste container are damaged and installed incorrectly</li> <li>• Replace any parts found defective or re-install any parts that were installed incorrectly</li> <li>• If problem(s) continue, contact CTG for service</li> </ul>
	<i>The air system pressure is above 1.5 inches</i>	<ul style="list-style-type: none"> <li>• The HEPA filter might be obstructed and may need replacement. Reference Filter Change Log and replace filter if necessary.</li> <li>• If problem(s) continue, contact CTG for service</li> </ul>
Height Adjustment	<i>The hand crank no longer raises or lowers the MIC</i>	<ul style="list-style-type: none"> <li>• Replace shear pin in hand crank. Reference shear pin replacement instructions earlier in this chapter</li> <li>• If problem(s) continue, contact CTG for service</li> </ul>

# PRODUCT SPECIFICATIONS



## MIC Counter Top

### Physical Specifications

#### Dimensions

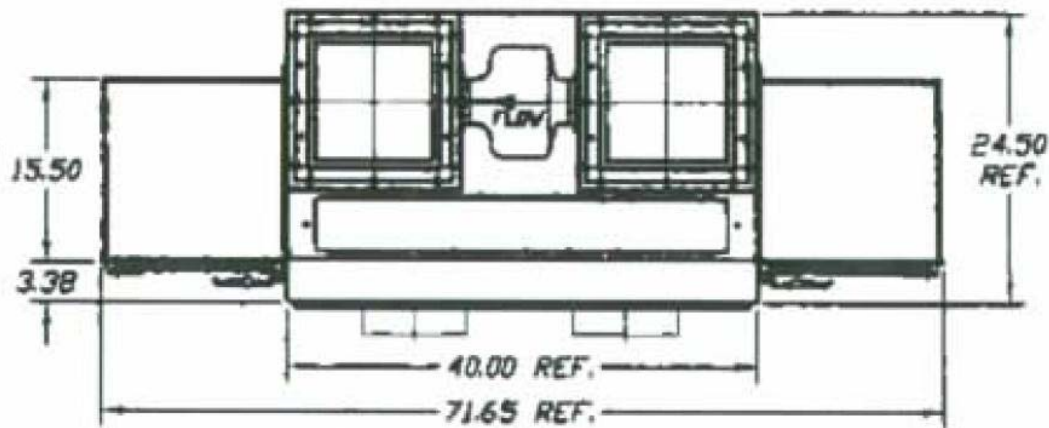
Chamber with one (1) airlock: 54 inches long x 24 inches deep x 41 inches high  
Chamber with two (2) airlocks: 72 inches long x 24 inches deep x 41 inches high

#### Construction of Materials

Chamber: 316L stainless steel  
Viewing window and airlock(s): Chemical and shatter-resistant plastic

Weight 300 lbs.

Power Requirements 120 Volt 60 Hz – each circuit rated at 10 amps



### Operational Specifications

Air Quality Requirement: None  
Workstation: Self-Contained, Lighted, and Portable (on locking casters)  
Environment: ISO Class 5  
Method: Barrier / Isolator Technology  
Pressurization: Positive or Negative  
Filtration: High Efficiency Particulate Air (HEPA)

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# PRODUCT SPECIFICATIONS



## MIC Single

### Physical Specifications

#### Dimensions

Chamber with one (1) airlock: 56 inches long x 24 inches deep x 76 inches high

Chamber with two (2) airlocks: 72 inches long x 24 inches deep x 76 inches high

*Note: The height listed is in the lowered position.*

*The workstation adjusts to a maximum height of 84 inches*

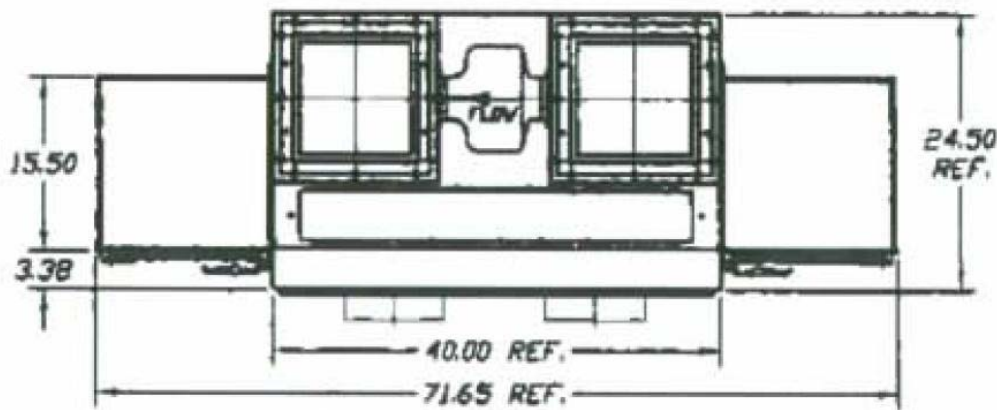
#### Construction of Materials

Chamber: 316L stainless steel

Viewing window and airlock(s): Chemical and shatter-resistant plastic

Weight 375 lbs. (170 kg)

Power Requirements 120 Volt 60 Hz – each circuit rated at 10 amps



### Operational Specifications

Air Quality Requirement: None

Workstation: Self-Contained, Lighted, and Portable (on locking casters)

Environment: ISO Class 5

Method: Barrier / Isolator Technology

Pressurization: Positive or Negative

Filtration: High Efficiency Particulate Air (HEPA)

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# PRODUCT SPECIFICATIONS



## MIC Dual

### Physical Specifications

#### Dimensions

Dual chambers with two (2) airlocks: 112 inches long x 24 inches deep x 76 inches high

*Note: The height listed is in the lowered position.*

*The workstation adjusts to a maximum height of 84 inches*

#### Construction of Materials

Chambers: 316L stainless steel

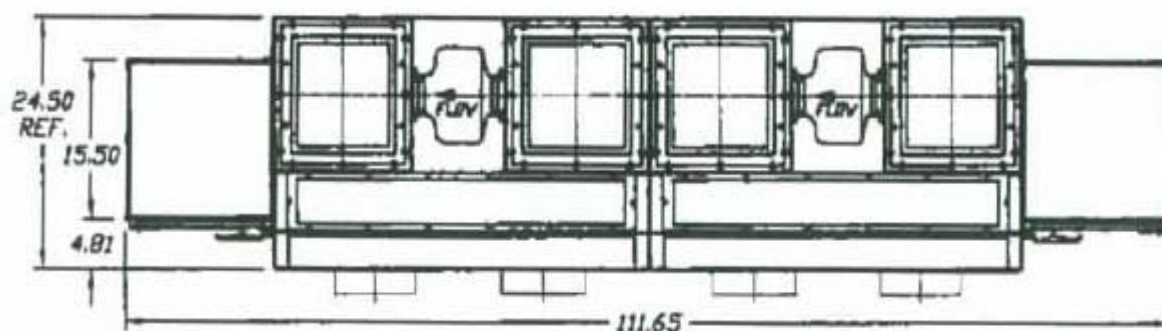
Viewing windows and airlock(s): Chemical and shatter-resistant plastic

#### Weight

700 lbs. (318 kg)

#### Power Requirements

120 Volt 60 Hz – each circuit rated at 10 amps



### Operational Specifications

Air Quality Requirement: None

Workstation: Self-Contained, Lighted, and Portable (on locking casters)

Environment: ISO Class 5

Method: Barrier / Isolator Technology

Pressurization: Positive or Negative

Filtration: High Efficiency Particulate Air (HEPA)

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# PRODUCT SPECIFICATIONS



## MIC TPN

### Physical Specifications

#### Dimensions

Dual chambers with one airlock: 96 inches long x 27 inches deep x 84 inches high (to top of blower)

*Note: When installing, allow an additional 16 inches for door swing.*

#### Construction of Materials

Chambers: 316L stainless steel

Viewing windows and airlock(s): Chemical and shatter-resistant plastic

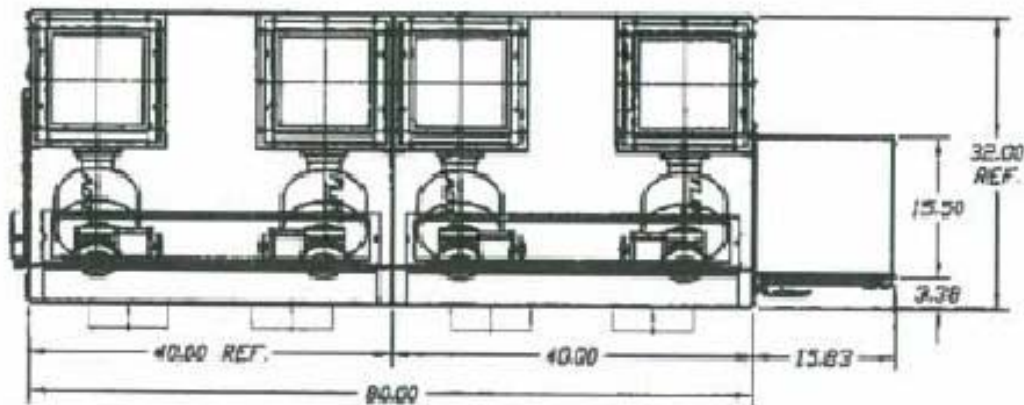
#### Weight

850 lbs. (386 kg)

#### Power Requirements

120 Volt 60 Hz – each circuit rated at 10 amps

*Note: Compounding machine receptacle rated at 5.0 amps.*



### Operational Specifications

Air Quality Requirement: None

Workstation: Self-Contained, Lighted, and Portable (on locking casters)

Environment: ISO Class 5

Method: Barrier / Isolator Technology

Pressurization: Positive

Filtration: High Efficiency Particulate Air (HEPA)

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# PRODUCT SPECIFICATIONS



## MIC EDU Physical Specifications

### Dimensions

Single: 56" long x 27" deep x 78" high

Dual chambers with storage chamber 96" long x 27" deep x 78" high  
and one (1) airlock: **Note: Allow 16 inches in length to accommodate loading area and docker .**

*Note: The height listed is in the lowered position.  
The workstation adjusts to a maximum height of 84 inches*

### Construction of Materials

Chambers: 316L stainless steel  
Viewing windows and airlock(s): Chemical and shatter-resistant plastic

Weight Single: 318 kg /375lbs (170kg)  
Dual: 170kg / 700lbs. Dual  
PIDS: decontamination unit weight is 37 kg. / 80 lbs

### Power Requirements

MIC-EDU: 120 Volt 60 Hz – each circuit rated at 10 amps  
PIDS Decontamination Unit: 120 Volt 60 Hz – 5 amps

### Operational Specifications

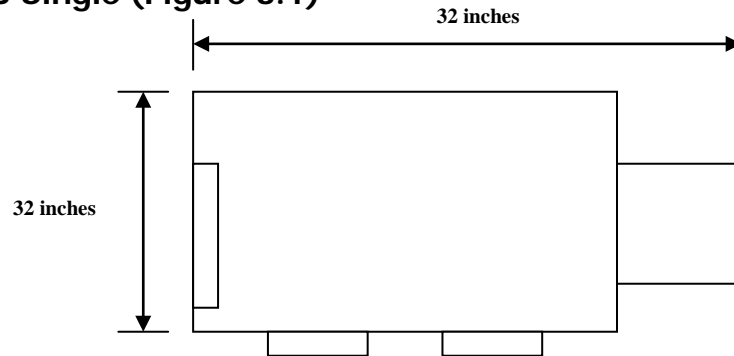
**Air Quality Requirement:** Surrounding environment less than 800,000 particles  
**Workstation:** Self-Contained, Lighted, and Portable (on locking casters)  
**Environment:** ISO Class 5  
**Method:** Barrier / Isolator Technology  
**Pressurization:** Positive or negative  
**Filtration:** High Efficiency Particulate Air (HEPA)  
**Decontamination:** Vaporized Hydrogen Peroxide (VHP)

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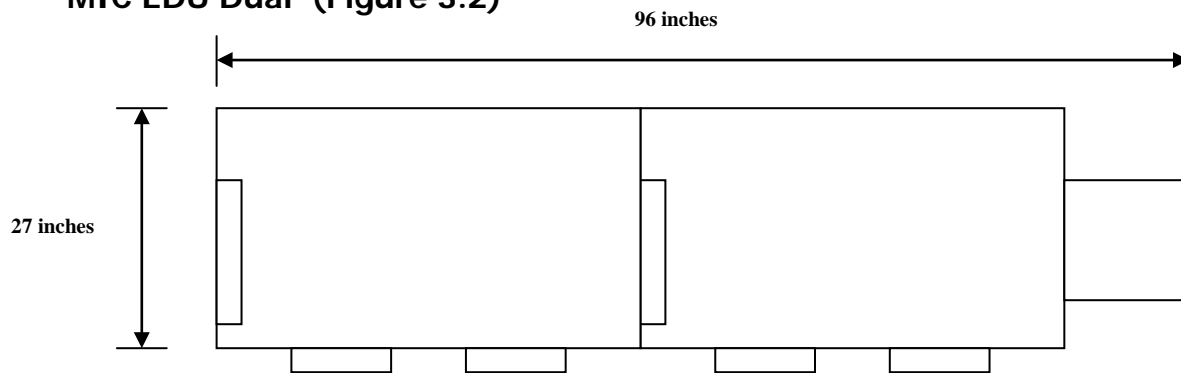
# PRODUCT SPECIFICATIONS



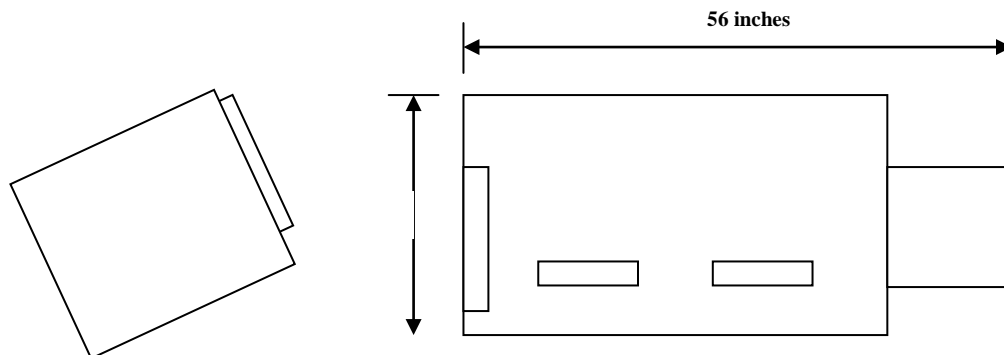
**MIC EDU Single (Figure 3.1)**



**MIC EDU Dual (Figure 3.2)**



**MIC EDU Single w/ storage chamber (Figure 3.3)**





# CERTIFICATION



## Certification Timelines

All MIC products require certification testing every six (6) months. The workstations are to be inspected and checked by independent certified personnel to ensure that they are functioning per the required specifications.

## Certification Protocol

The CTG Certification Network has developed a certification protocol that is required when testing MIC products. This protocol is located in section # 2 of the documentation manual. Ensure that the certification company performing any testing on the MIC adheres to the CTG Certification Network protocol.

## Recommended Practices and General Information

1. Ensure certification company provides the following to demonstrate competence:
  - References and qualification of testing personnel
  - Listing of equipment used in testing
  - Calibration dates of testing equipment and results are to be available from testing company upon request. This information should be kept for a period of three (3) years.
2. The certification company shall provide the following:
  - Test reports showing all data collected during testing (see certification protocol in Appendix A)
  - A listing of the equipment used including serial number(s)
  - A certification sticker should be affixed to the equipment to show that the equipment meets the defined standards.
3. Ensure there is a log for recording filter checks and changes.
4. If it is determined that the filter needs replacement then contact Containment Technologies Group for information on replacement filters and filter bag out sets. Containment Technologies stocks replacement filters.
5. Document on the filter log both checks and filter change outs.
6. The MIC workstations are based on barrier / isolation technology. The environment created by this technology offers ISO Class 5 conditions. The operating principle used creates an air-tight chamber with a HEPA filtration means of air exchange. Typically the quantity and velocity of the air is significantly less than that used in laminar flow technology.
7. Information concerning the model number and unit identification is located on the back or right side of the workstation. If any problems are encountered during certification call Containment Technologies Group for technical support.

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# REPLACEMENT PARTS



The MIC family of products is designed to utilize many “off-the-shelf” consumables and replacement parts. These items are available from various vendors, but usually in large quantities. CTG offers these products both in large and small quantities.

A current pricing list and order form can be found in Appendix B of this manual.

To place an order, contact CTG using any of the following methods:

- Telephone: (317) 713-8200
- Fax: (317) 713-8201

Taxes, shipping, and handling charges will be added to all orders. Allow 10 days for standard delivery.


## Consumables currently available from CTG

	<b>B/D Sharps Container (Red)</b> Stock # – 30577/Red Size – 5 gallon Quantity – 8 per case		<b>½ Finger Glove Liners</b> Stock # - HFL-21 Size – 1 size Quantity – 12 pair per package
	<b>B/D Sharps Container (Yellow)</b> Stock # - 305578/Chemo Size – 5 gallon Quantity – 8 per case		<b>Full Finger Glove Liners</b> Stock # – FFL-22 Size – 1 size Quantity – 12 pair per package
	<b>Blue Nitrile Gloves (9mil)</b> Stock # – CS113B Sizes – 7, 8, 9, & 10 Quantity – 12 pair per package		<b>Tyvek Sleeve Liners</b> Stock # – 1894P Size – 1 Size Quantity – 1 pair per package
	<b>White Nitrile Gloves (9mil)</b> Stock # – SK142W Sizes – 9 & 10 Quantity – 10 pair per package		<b>HEPA Filter</b> Stock # – HEPA Size – 1 Size Quantity – 1 each
	<b>Nitrile Sleeves (round)</b> Stock # – N2708 Sizes – 8 inch port Quantity – 1 pair per package		<b>Nitrile Sleeves (oval)</b> Stock # – N2710 Sizes – 10 inch port Quantity – 1 pair per package

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# REPLACEMENT PARTS



	<b>O-ring (glove retainer)</b> Stock # – 2-343N70 Size – 1 size Quantity – 1 each		<b>Sleeve Clamp (round)</b> Stock # – SLC128 Size – 8 inch Quantity – 1 each
	<b>Black Glove Retainer</b> Stock # – BLK/GR-01 Size – 1 size Quantity – 1 each		<b>Sleeve Clamp (oval)</b> Stock # – SLC188 Size – 10 inch Quantity – 1 each
	<b>Blower Motor</b> Stock # – Blower Motor Size – 1 size Quantity – 1 each		<b>Sharps/Trash Clamp</b> Stock # – S/TC080 Size – 5 inch Quantity – 1 each
	<b>Squeegee – 15 inch</b> Stock # – WS1524U Size – 15 inch Quantity – 1 each		<b>Trash Container w/ Lid</b> Stock # – TCw/L-01 Size – 1 size Quantity – 1 each
	<b>Squeegee – 20 inch</b> Stock # – WS2024U Size – 15 inch Quantity – 1 each		<b>Nut Driver</b> Stock # – 61-807 Size – 5/16 inch Quantity – 1 each
	<b>Sharps Adapter</b> Stock # – Sharp Adapter Size – 1 size Quantity – 1 each		<b>Plastic Spray Bottle</b> Stock # – PSB8-OZ Size – 8 oz Quantity – 1 each
	<b>Small Plastic Basket</b> Stock # – SMB40-711 Size – Small Quantity – 1 each		<b>Large Plastic Basket</b> Stock # – LGB51-711 Size – Large Quantity – 1 each

# REPLACEMENT PARTS



	<b>Waste Port Covers</b> Stock # – WPC-104 Size – 1 size Quantity – 1 each		<b>Hooks</b> Stock # – 44184ACE Size – 1 size Quantity – 12 per package
	<b>Arm Port Covers</b> Stock # – APC-106 Size – 1 size Quantity – 1 each		<b>Shear Pin</b> Stock # – SP5/32 Size – 1 size Quantity – 1 each
	<b>Bar Keepers Friend</b> Stock # – BKF-4.5 Size – 4 ½ oz Quantity – 1 size		<b>Owner's Manual</b> Stock # – Owner Manual Size – 1 size Quantity – 1 each

# WARRANTY



## LIMITED WARRANTY

For a period of one (1) year from initial installation, Containment Technologies Group, Inc. warrants that the workstation will be free of defects in materials and workmanship. Containment Technologies Group, Inc. will support the correction of defects that may substantially effect the operation of the workstation. If the customer identifies any potential defects, Containment Technologies Group, Inc. is to be informed immediately. This limited warranty does not cover damage caused by improper use or neglect. The proper protocol or standard operating procedure must be followed in operating the workstation and failure to do so negates the warranty. Containment Technologies Group, Inc. does not warrant factors beyond its control. These factors include but are not limited to: operation and maintenance by personnel improperly trained and certified in the use of the workstation, modifications, alterations, normal wear and tear, tampering, improper adjustments, accidents and Acts of Nature. This warranty does not cover equipment already covered under a manufacturer's warranty. Containment Technologies Group, Inc. shall not be liable under this limited warranty for incidental, special, indirect or consequential damages including without limitation loss of use, loss or delay of anticipated revenue, losses by reason of shut-down, cost of substitute facilities or service or other similar damages. Containment Technologies Group, Inc.'s sole liability, including liability arising out of contract, negligence, and strict liability in tort and warrant, shall not exceed amounts payable to Containment Technologies Group, Inc. for the equipment described herein. The above is a limited warranty and is the only warranty made by Containment Technologies Group, Inc. No other warranty, expressed or implied is given. In consideration for this warranty all liabilities or obligations of Containment Technologies Group, Inc. for damages arising out of or in connection with this equipment or use thereof is absolved.



**Containment Technologies Group, Inc.**

Model: \_\_\_\_\_

Serial: \_\_\_\_\_ Date: \_\_\_\_\_

### **Electrical Requirements**

Volts: \_\_\_\_\_ Phase: \_\_\_\_\_

Hertz: \_\_\_\_\_ Amps: \_\_\_\_\_

### **Warning:**

Use of this equipment is to be by authorized personnel only. Proper procedures and protocols must be strictly followed. Spare or replacement parts should be obtained from CONTAINMENT TECHNOLOGIES GROUP, INC. Use of this equipment beyond the annual certification date is strictly prohibited. Any deviations may invalidate your warranty.

5460 Victory Dr. Suite 300  
Indianapolis, In 46203  
Phone: 317-713-8200  
Fax: 317-713-8201  
[www.mic4.com](http://www.mic4.com)

***Protecting the Patient, Product, and Provider***

# ERGONOMIC CONSIDERATIONS



## Introduction

Containment Technologies Group recognizes the importance of proper preparation and positioning while performing routine activities during compounding. In order to maximize each participant's potential, it is important to prevent fatigue and personal injury. The Center for Disease Control (CDC) has determined that personnel can be at risk for repetitive injuries during routine laboratory procedures that, in many ways, are similar to the activities performed in the compounding of sterile products.

Fatigue is a major contributor to errors in compounding and can easily creep into the routine of workers who do not utilize the appropriate tools to avoid it. Employees may experience injury by creating stresses on their bodies, both during the performance of routine activities and by incorrect static positioning during work related duties.

Containment Technologies Group is committed to providing information that will allow our customers to train their employees in the use of proper body mechanics related to working with our products. The tools and techniques presented will minimize the potential for fatigue and personal injury in the work place while compounding sterile products using the MIC isolator.

## Basic Elements of a Sound Ergonomic Program

1. Encourage employees to engage in a stretching routine to warm up before starting their daily compounding routine.
2. Provide support equipment to reduce the potential for physical stress.
3. Encourage mini breaks throughout the process.
4. Provide training and follow-up on recommended work practices.

## Seven Habits for Ergonomics

1. Work at proper heights
2. Reduce pressure points
3. Reduce static load and fatigue
4. Keep items within easy reach
5. Reduce excessive force
6. Minimize awkward and sustained postures
7. Reduce repetitive motion

# ERGONOMIC CONSIDERATIONS



## Employee Daily Stretching and Warm-Up Routine

### Remember the basics!!

1. Pain is NOT gain. Stretch until you feel a mild tension that relaxes as you hold the stretch.
2. If a stretch creates discomfort, STOP.
3. Do not bounce.
4. Do not hold your breath. Breathing naturally helps muscles relax.

### Example Stretching Exercises:



#### Wall Sits

- Stand with your back against a wall with your heels positioned in front of your knees.
- Slowly lower your hips toward the floor until your thighs are almost parallel to the ground. Your legs may tire easily at first.
- Hold the position for 10 seconds.
- Repeat this strength exercise 3 to 10 times



#### Calf Stretch

- Lean forward, with your hands against a wall.
- Bend one leg with a lunge position (slight bend) in front of you. Keep your other leg straight behind you with your heel pressed toward the floor and your toes pointed straight toward the wall.
- Hold the stretch for 15 seconds.
- Repeat with the other leg.



# ERGONOMIC CONSIDERATIONS



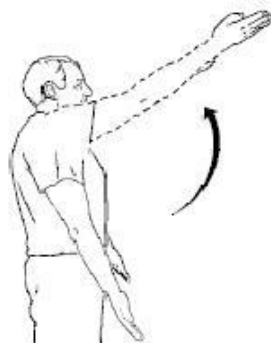
## Quad Stretch

- Hold onto a stable object for support (e.g. a wall or chair).
- Bend one knee, grab your foot and gently pull your heel toward your buttock until a slight stretch is felt. Keep your knee pointed toward the floor.
- Hold the stretch for 15 seconds.
- Repeat with your other leg.



## Back Stretch

- Stand with your feet about shoulder width apart. Do not lock your knees.
- Place your hands just above your hips with your fingers pointing downward.
- Gently push your palms forward, bending backward at the waist.
- Look straight ahead. Keep your head at midline with your ears aligned with your shoulders (do not throw your head back).
- Hold a comfortable stretch for 10 seconds and then return to the upright position.
- Repeat 3 times



## Overhead Reach

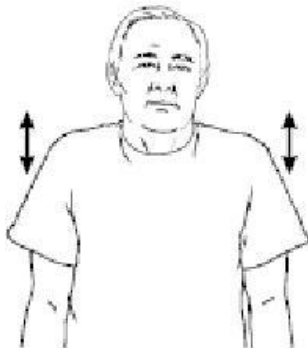
- Lean against a wall with your knees bent.
- Press your lower back flat into wall as you lift your arms overhead. Keep your elbows straight.
- Hold this stretch for 10 seconds.
- Repeat 3 times.

# ERGONOMIC CONSIDERATIONS



## Standing Side Bends

- Stand with your feet shoulder width apart one hand on your hip and one hand held overhead.
- Bend sideways until you feel a gentle stretch on the opposite side. Keep your stomach muscles tight.
- Hold to 5 to 10 seconds and then repeat to the opposite side.
- Repeat 3 times on each side.



## Shoulder Shrugs

- Stand up straight with your shoulders relaxed. Look straight ahead.
- Lift your shoulders toward your ears until you feel a slight tension in your neck and shoulders.
- Hold for 5 seconds.
- Relax your shoulders into their normal position.
- Repeat the exercise 5 to 10 times



## Neck Rotation

- Stand or sit with your arms hanging loosely at your sides.
- Gently turn your head as though you were looking over your shoulder. Try not to tilt your head sideways. Keep your upper body still and your shoulders facing forward.
- Hold 5 to 10 seconds, and then turn your head the other way.
- Repeat 3 to 5 times in each direction.

# ERGONOMIC CONSIDERATIONS



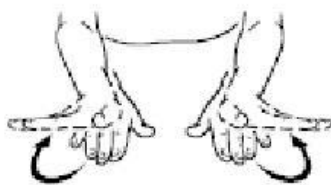
## Midline Cross Stretch

- Bring arms across chest trying to reach as far around your back as possible.
- Hug yourself until you feel a stretch across your back and arms.
- Hold 5 to 10 seconds
- Repeat 3 times.



## Wrist Stretch

- Bend elbows to 90 degrees at sides (may rest on arm rest of chair)
- With palms of hands facing down, bend wrist downward
- Hold 3-5 seconds
- Bend wrist upward
- Hold 3-5 seconds
- Repeat 3-5 times with each wrist



## Wrist Circles

- Place elbows at sides
- Circle wrists in opposite directions 3-5 times.
- Reverse directions and circle 3-5 times
- Repeat cycle 2 times.

# ERGONOMIC CONSIDERATIONS



## **Provide support equipment to reduce the potential for physical stress...**

The MIC isolator is equipped with an adjustable height feature that, when standing, allows the operator to work at an appropriate and comfortable height. On a routine basis, it is recommended that operators rotate between a standing and a sitting position. An ergonomic chair is critical to this rotation.

## **The following criteria should be considered in selection of a chair...**

- **Does the seat pan feel comfortable and fit your shape?**  
When you sit in the chair, the seat pan should be at least one inch wider than your hips and thighs on either side. The length of the seat should not impact your ability to bend your knees. If the seat touches too close to the back of the knee, it will prevent you from leaning fully back against the lumbar support. Most ergonomic chairs have a seat pan with a waterfall front that prevents the seat from catching behind the knees. The seat pan should also be contoured to allow even weight distribution and it should be comfortable to sit on.
- **Is the seat chair height adjustable?**  
For preference, the chair should be pneumatically adjustable so that you can adjust seat pan height while you are sitting on the chair. Some chairs have a mechanical height adjustment (spinning mechanism) that is also acceptable.
- **Is the range of height adjustment of the chair sufficient to meet the needs of all users?**  
You should be able to adjust the height of the seat pan so that the front of your knees is level or slightly below level (90 degrees) and your feet are firmly on the ground. In most cases there should be no need for you to use a footrest, however, if your feet do not touch the floor, a footrest may be necessary. The mechanism to adjust seat height should be easy to reach and operate when you are seated.
- **Does the chair have a comfortable lumbar (lower back) backrest?**  
Many chairs have cushioned lumbar supports that can be adjusted up and down and forward and backward to best fit your shape. If the chair will be used by multiple users, then various levels of adjustment may be required. If the chair has a fixed height lumbar support and it feels comfortable when you sit back against it, and there will be one primary user of the chair then a fixed lumbar support may be acceptable.

# ERGONOMIC CONSIDERATIONS



- **Is the chair backrest large enough to provide good back support?**  
Many chairs have back supports that are large enough to provide mid-back and upper-back support, in addition to good lumbar support.
- **When sitting back against the lumbar support is there ample space for hip room?**  
Insufficient hip room can make you sit too far forward on the seat pan so that you will not have enough thigh support. The seat should be at least 1 inch wider than your hips and thighs on each side.
- **Does the seat pan still feel comfortable after you've sat for 60 - 120 minutes?**  
If the seat pan is made from low-density foam then continuous use can cause it to become permanently deformed resulting in inadequate cushioned support. Insufficient cushioning and inappropriate contouring can cause discomfort, imbalance and hip and back fatigue.
- **Does the chair backrest recline and support your back in different positions?**  
Movement of the back while you are sitting helps to maintain a healthy spine. Look for chairs that allow you to easily recline, that provide you with good back support in different recline postures, and that have a back that tracks where you're the location of your back. Locking the chair backrest in one position generally isn't recommended or beneficial to users.
- **Does the chair have a 5-pedestal base?**  
If chair mobility is important to help you to do your work, then the chair should have at least a 5 pedestal base with casters that glide freely over the floor surface. You may also want to choose a chair that swivels easily.
- **Do you need armrests on your chair?**  
If so, are the armrests broad, contoured, cushioned and comfortable? While sitting can you easily adjust the height of the armrests and can you move the armrests closer together or further apart? Can you easily move the arms out of the way if you need to do this?

The environment in which the chair will be placed will require routine cleaning and sanitization. It is important to select a chair that will withstand the material used in these activities. Consider only evaluating "cleanroom" chair designs.

# ERGONOMIC CONSIDERATIONS



## Helpful Suggestions:

- Make sure the MIC is at the correct working height (review the video).
- Encourage mini breaks that include change of position (sitting to standing) and brief exercise (every 30 minutes if working continuously in the MIC).
- Wear under gloves to allow easier removal of hands from the gloves.
- Wear comfortable shoes
- When seated:
  - Place feet flat on the floor or footrest
  - Utilize a chair that provides adequate lower back support
  - The front edge of the chair should not press up against the back of the knees
  - Utilize a footrest if your feet do not reach the floor
  - Do not rest your arms or wrists on the glove ports for extended periods
- When standing:
  - Stand with your feet separated from front to back
  - Do not lock your knees
  - Move your foot positions from time to time
  - Do not rest your arms or wrists on glove ports for extended periods

# ERGONOMIC CONSIDERATIONS



- When reaching:
  - o Understand the span of reach inside the MIC. Span is the angle from the centerline of the glove ports with your arms extended and side-to-side.
  - o When reaching for the door handle to the airlock, position your arm so that the your hand opens the handle from the bottom
  - o The greater the length of your reach the less weight you can comfortably pick up.
  - o Position items in your workspace for reaching that will not cause strain. If the reach is not comfortable reposition the items in the workspace or request a reach tool.
  - o Ideal working depth in the MIC is 6 to 15 inches from the front of the unit.
  - o Avoid reaches that create stress. Contact your supervisor if you are experiencing strain or discomfort.
  
- When lifting:
  - o Lift with your major muscle group.
  - o Lift with your wrist as straight as possible (Neutral position)
  - o Lift as close to the body as possible with arms in a straight position
  - o Avoid lifts that create stress. Contact your supervisor if you are experiencing strain or discomfort.

**If a compounding activity creates an awkward position in the MIC, contact Containment Technologies Group to discuss possible positioning alternatives.**