Containment Technologies Group, Inc.

MIC 797P

Owner's Manual

Rev 1 – November 2010

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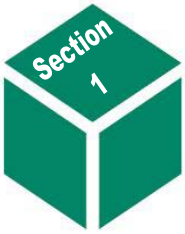


Introduction

The MIC-797P is a safe, economical, and portable workstation designed to provide an International Organization for Standardization (ISO) Class 5 environment for the preparation of parenteral preparations. The air handling is based on conventional unidirectional airflow. The MIC-797P provides an environment that is a secure, cost effective, and flexible alternative to the cleanroom approach. The MIC-797P is available only in positive pressure configuration. Inlet air is HEPA filtered.

Features

The MIC is fabricated from stainless steel and engineered plastics. The CAI creates a barrier that requires no procedural setbacks or special work zones that are common with laminar flow hoods. The MIC-797P is a positive pressure system for the preparation of IV admixtures. The MIC-797P utilizes a once through air system. An airlock is also an 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. The carousel transfer provides a means of moving materials from the airlock into the chamber without operator strain created by excessive reaches.

Safety

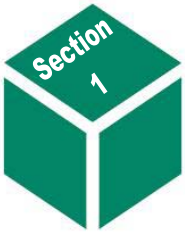
The ergonomic considerations in the MIC-797P help reduce fatigue and consequently, product errors. The MIC-797P has an adjustable height feature for comfortable working conditions. Chemical and shatter resistant plastics provide a clear view of the entire workspace and airlock, to ensure that materials are visible

Flexibility

The MIC-797P 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-797P 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.

Economy

The MIC-797P 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-797P 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 coved corners to eliminate hard to clean areas. A large side door allow for access during cleaning. 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 workstation height adjustment utilizes a hydraulic lift system.

Installation and Set-up

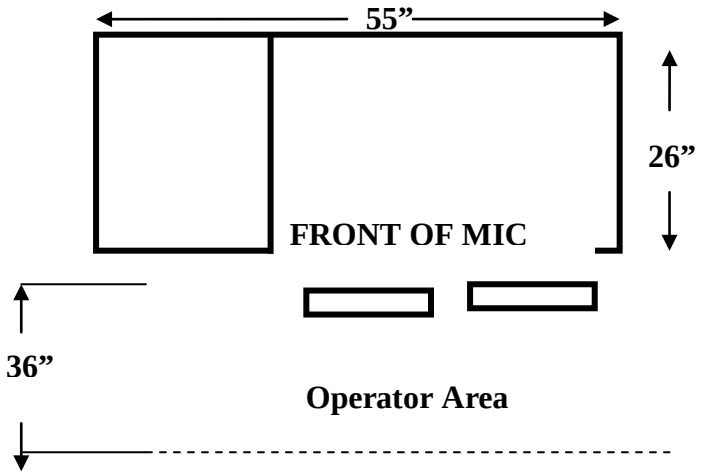
Instructions in this section are specifically for the ***initial*** set-up of the MIC 797P. The steps will describe site selection, assembly (if needed), set-up, and inspection for the MIC 797P. By the end of these steps, the MIC 797P will be ready to be placed into operation.

Site Selection

The MIC 797P's portability eases site selection decisions. Primary considerations for the installation of the MIC 797P are floor space available and electrical receptacle outlet accessibility.

Floor space requirements for the MIC 797P are 55 inches width by 26 inches depth (an 18 clearance is recommended for the right side of the unit to allow for easier cleaning):

To operate the MIC 797P, the pharmacist or pharmacy technician will require 36 inches in front of the workstation. for operation. A diagram is provided below:



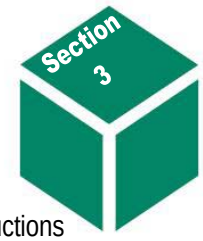
Some lighting conditions may cause glare in the viewing area of the MIC 797P. Position the workstation to minimize this affect. The power requirement for the MIC 797P is a grounded 120-volt, 60hz, 15 amp receptacle. There are no special requirements for air quality in terms of environmental particulates. The area should be air conditioned for the comfort of the operator and to ensure that product temperature requirements are met.

Assembly

In most cases, the MIC 797P is delivered as a fully assembled product. However, if required the cabinet can be removed from the base.

Always use a torque wrench when removing any nuts, the proper torque value for nuts on the MIC 797P is 26 inch-pounds.

NOTE: Do not use excessive force. Damage may result.



Standard Operating Procedures

This section will describe standard operating procedures and general usage of the MIC 797P. These instructions should be followed each time the CAI is used.

Inspection

Prior to operating the MIC 797P, an operational check should be performed. Use the following criteria to inspect the MIC 797P:

1. Visually inspect the MIC 797P 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 797P is operating within the desired positive pressure range of > + .04.
5. If the indicator is not within this range, perform the following checks:
    a. Make sure the doors are closed.
    b. 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.
    c. Make sure the sharps containers are installed properly and sealed. A loose clamp or container lid can disrupt the air pressure.
    d. Check the HEPA filter maintenance log. If the filters have not been serviced recently, it is possible they need replaced.
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 797P.

Cleaning

Clean the MIC 797P using sterile water for irrigation or a mild detergent mixture with a 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 following the recommendation contained in USP<797>. All cleaning materials shall be non-shedding (lint free), preferably composed of synthetic fibers and dedicated specifically for the area.

- Frequency of area cleaning per USP <797> is outlined on Page 28, Table 3 of the Revision Bulletin effective June, 2008.
- 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

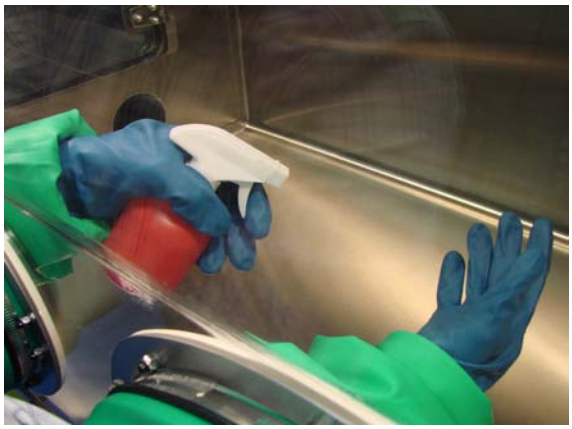
The MIC 797P provides the ISO Class 5 environment. Pharmacy personnel are responsible for the proper sanitizing of the MIC 797P. Proper sanitization requires the misting of all internal surfaces of the CAI with a disinfectant, such as sterile alcohol or hydrogen peroxide. Misting is the preferred method 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:

1. Prior to compounding, place a misting bottle containing a disinfectant inside the MIC 797P, if not already present.
2. Close the inner airlock door.
3. Use the gloves / sleeves to access the chamber and lightly mist all the interior surfaces of the MIC 797P, 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. Close the outer airlock door.



10. The inner door may now be opened and materials brought into the MIC 797P 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 alternate sanitizing agents monthly. Switching between sterile alcohol and hydrogen peroxide will reduce the possibility of organisms developing a resistance to the agents.

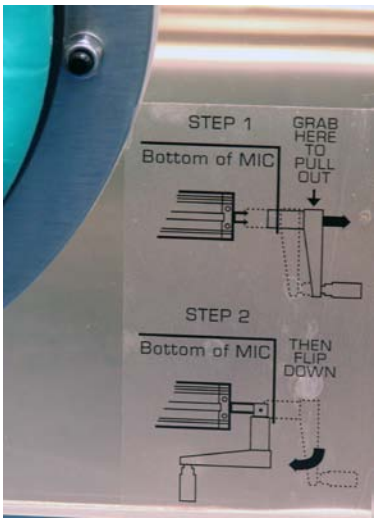
Adjustment

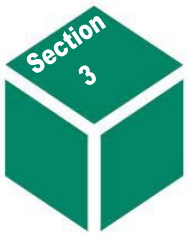
Height Adjustment

The height of the MIC 797P 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 797P:

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 reach, 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 pressure adjustment. Call CTG for service if the maintenance procedures in Section 4 do not correct any air pressure problems.

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 797P 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

Maintenance and Trouble Shooting

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

Maintenance

Daily

Inspect and sanitize the MIC 797P 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.

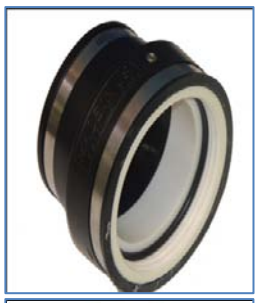
1. The reading may be taken any time while the MIC 797P is in normal use.
2. Make sure the air system has been running for at least three minutes.
3. Read the gage. The gage units are in inches of water.
4. Record the reading in the maintenance log to the nearest tenth.

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.
2. The sharps container is not intended to be reusable. Make sure a replacement is available for installation.
3. Switch on the MIC 797P 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 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 797P and verify proper air pressure.

Glove Replacement

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. Sterile gloves are required per USP <797>.

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

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 797P air system is running.
2. Reach into the CAI 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.
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.

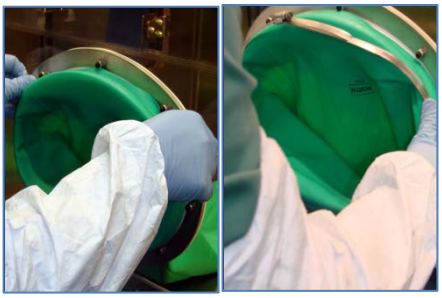


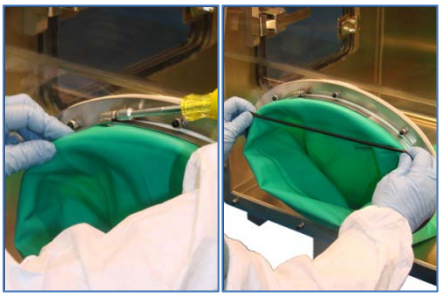


Sleeve Replacement – IV Admixtures and Non-Hazardous Drugs

Sleeves used for IV admixtures and non-hazardous drugs can be reused. Inspect and replace as needed or when deemed appropriate by pharmacy personnel, typically every 4 to 6 months.

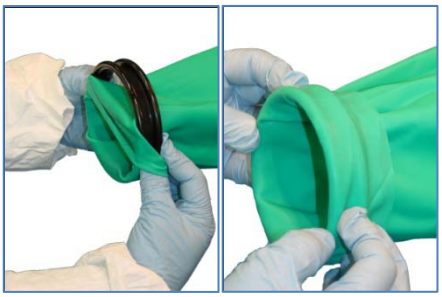
1. While wearing gloves, reach into the sleeve and glove and pull one sleeve inside out.
2. Remove the O-ring from the glove retainer.
3. Loosen the glove and sleeve together from the retainer.
4. Remove the retainer.
5. Fold the open end of the sleeve and glove over and over toward the glove port and push it inside the MIC 797P.
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 797P.
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 s stretch the sleeve around the ret the retainer completely. The fold smooth, with no wrinkles, and no 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.

HEPA Filter Inspection and Replacement

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

- The pressure in the MIC 797P 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

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.

Troubleshooting
Symptoms and Solutions

System	Problem	Solution
Lights	*The light doesn't work*	• Check to see if light is switched on • Check to see if power cord is plugged in • Check to see if light bulb has burned out • If problem(s) continue, contact CTG for service
Air System	*The MIC air system doesn't work*	• Check to see if the air system is switched on. • Check to see if the power cord is plugged in. • If problem(s) continue, contact CTG for service.
	The air system pressure is above 1.5 inches	• The HEPA filter might be obstructed and may need replacement. Reference Filter Change Log and replace filter if necessary. • If problem(s) continue, contact CTG for service.
Height Adjustment	*The hand crank no longer raises or lowers the MIC*	• Replace shear pin in hand crank. Reference shear pin replacement instructions earlier in this chapter. • If problem(s) continue, contact CTG for service.

797P 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. 797P 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:
   Cleaning of the 797P 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 797P. Sanitizing always follows cleaning.

3. Sanitizing:
   Misting the MIC using a sanitizing solution of either 70% sterile isopropyl alcohol or hydrogen peroxide 3%. The sanitizing process minimizes environmental microbial bioburden. Materials placed in the airlock should be sprayed down with a disinfecting agent such as hydrogen peroxide 3% to reduce bioburden on incoming materials.

FREQUENCY SCHEDULE

(a) Inside the 797P – 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. 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.

5. Products: Sterile medications manufactured by a drug company.

6. Preparations: Sterile extemporaneous medications compounded by the pharmacy staff.

7. Expiration date: Date assigned by drug manufacturer based upon regulatory guidelines, determined by scientifically valid, product/package-specific research studies.

8. 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.

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 **w**ritten 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 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.

G. Temperature is controlled and monitored in areas where drugs are stored. Room temperatures can range from 20^0 to 25^0 C, refrigerated item storage temperature range from 2^0 to 8^0 C, and frozen item storage temperature range form - 25^0 to – 10^0. Temperature shall be monitored at least daily and results documented.

H. A positive pressure 797P is utilized for the sterile compounding of standard preparations.

I. Storage is not required to be in a negative pressure environment but should be segregated from other drug products.

V. 797P:

A. The 797P 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 container, the blower on the barrier isolator is left ON.

C. The frequency of changes is as follows. Changes are documented on the monthly log.

1. Gloves (non-powdered, nitrile): Sterile gloves are recommended. For the IV admixture 797P, 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) For the IV admixture 797P, sleeves are to be changed every six months or at any sign of wear or breach of integrity.

3. Sharps containers: Change as they become full.

4. Blowers should be operated at all times. If the 797P is turned off, operate the 797P MIC for 2 minutes prior to compounding.

D. Interior Cleaning:

PURPOSE
Cleaning of the 797P 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 797P.

CLEANING - Clean the 797P 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.

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:

1. Sanitizing of the chamber shall be by misting the entire interior surfaces of the 797P 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 797P.
(2) The airlock should be misted with hydrogen peroxide with each entry.

VI. COMPOUNDING PERRSONEL RESPONSIBILITIES

A. Hand washing:

1. Wash hands and arms to elbow with an antimicrobial soap at the sink.

3. 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):

1. Materials entering the airlock are to be sprayed down with 3 % hydrogen peroxide.

2. When the final preparation(s) is completed, re-sanitize the interior of the 797P 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:

(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 797P.

(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

A. Check the pressure setting on the gauge of the 797P (positive).

B. Enter the 797P 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 797P.

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.

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.

11. Discard syringes, needles and trash into the appropriate containers attached to the 797P.

12. Sanitize/clean the surfaces of the 797P including gloves and sleeves.

13. Verify the inner airlock door is closed and remove the finished preparation for checking and delivery.

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.

VIII. 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.

IX. 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.

2. Routine checks, are outlined in the 797P owner's manual.

B. Environmental monitoring:

1. Viable airborne shall occur in the 797P every six months using a volumetric collection method.

2. Surfaces in the interior of the 797P are sampled monthly utilizing touch 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 797P 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 797P and e-mail the staff. Based upon the culture results, determine an appropriate remedy.

XII. HOUSEKEEPING DOCUMENTATION:

A. Housekeeping documents 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.

XIII. <u>RECORD RETENTION</u>:

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 797P.
   (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 797P (every 6 months).

8. Environmental monitoring logs
   (a) Viable air sampling results
      (1) In the 797P
      (2) In the compounding area
   (b) Surface sampling results
      (1) In the 797P
      (2) In the compounding area

9. Finger tip sampling results

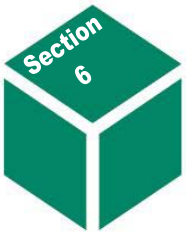
Product Specifications – MIC 797P

Physical Specifications

Dimensions	54 inches long x 26 inches deep x 74 inches high
Construction of Materials	316L stainless steel Chemical and shatter-resistant plastic
Weight	200 lbs.
Power Requirements	120 Volt 60 Hz – each circuit rated at 10 amps

Operational Specifications

Air Quality Requirement:	None for surrounding environment
Workstation:	Self-Contained, Lighted, and Portable (on locking casters)
Environment:	ISO Class 5
Method:	Barrier Technology
Pressurization:	Positive
Filtration	High Efficiency Particulate Air (HEPA)
Air Flow:	Single pass



Certification:

Certification Timelines

The MIC 797P requires certification testing every six (6) months. The CAI's are to be inspected and check by 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 797P. Ensure that the certification company performing any testing of the MIC 797P 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. Containment Technologies stocks and replacement filters.

5. Document on the filter log both checks and filter change outs.

6. The MIC 797P is based on barrier technology and complies with the definition of a CAI per USP <797>. The environment created by this technology offers ISO Class 5 conditions. ISO standards are described in ISO 14644-1 with test methods in ISO 14644-2 and ISO 14644-3

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.

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 this manual.

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

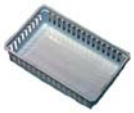
- Telephone: (317) 713-8200
- Fax: (317) 713-8201

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

Consumables currently available from CTG

	B/D Sharps Container (Red) Stock # – 30577/Red Size – 5 gallon Quantity – 8 per case		½ Finger Glove Liners Stock # - HFL-21 Size – 1 size Quantity – 12 pair per package
	Sharps Adapter Stock # – Sharp Adapter Size – 1 size Quantity – 1 each		Full Finger Glove Liners Stock # – FFL-22 Size – 1 size Quantity – 12 pair per package
Call for size, stock number, availability, and pricing.	Nitrile Gloves (11mil) Stock # Sizes – 7, 8, 9, & 10 Quantity – 12 pair per package		Tyvek Sleeve Liners Stock # – 1894P Size – 1 Size Quantity – 1 pair per package
	Blower Motor Stock # – Blower Motor 797 Size – 1 size Quantity – 1 each		HEPA Filter Stock # – HEPA 797 Size – 1 Size Quantity – 1 each
	Sleeve Clamp (oval) Stock # – SLC188 Size – 10 inch Quantity – 1 each		Nitrile Sleeves (oval) Stock # – N2710 Sizes – 10 inch port Quantity – 1 pair per package

REPLACEMENT PARTS

	O-ring (glove retainer) Stock # – 2-343N70 Size – 1 size Quantity – 1 each		Nut Driver Stock # – 61-807 Size – 5/16 inch Quantity – 1 each
	Black Glove Retainer Stock # – BLK/GR-01 Size – 1 size Quantity – 1 each		Plastic Spray Bottle Stock # – PSB8-OZ Size – 8 oz Quantity – 1 each
	Small Plastic Basket Stock # – SMB40-711 Size – Small Quantity – 1 each		Large Plastic Basket Stock # – LGB51-711 Size – Large Quantity – 1 each
	Squeegee – 15 inch Stock # – WS1524U Size – 15 inch Quantity – 1 each		Squeegee Head Only Stock # WSH24 Size – 1 size Quantity – 1 each
	Hooks Stock # – 44184ACE Size – 1 size Quantity – 12 per package		Shear Pin Stock # – SP5/32 Size – 1 size Quantity – 1 each
	Bar Keepers Friend Stock # – BKF-4.5 Size – 4 ½ oz Quantity – 1 size		Owner's Manual Stock # – Owner Manual 797P Size – 1 size Quantity – 1 each

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 affect 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.

Containment Technologies Group, Inc.
10329 Vandergriff Road
Indianapolis, IN • 46239-9593 • USA
Phone: 317-862-5945 • Fax: 317:862-9135
Email: MIC@MIC4.COM
WWW.MIC4.COM

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 797P 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

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 you 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 wall.
- Hold the stretch for 15 seconds.
- Repeat with the other leg.

Quad Stretch

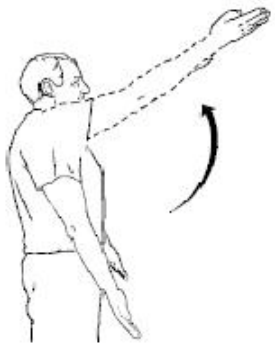
- Hold onto a stable object for support (e.g. a wall or chair).
- Bend one knee, grab your foot and gently pull your heel toward your buttock until a slight stretch is felt. Keep your knee pointed toward the floor.

- 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.

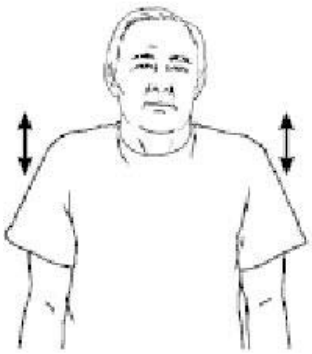
Overhead Reach



- 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.

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 t o 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

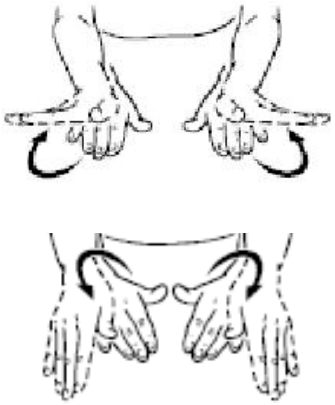
- Stand or sit with your arms hanging loosely at your sides.
- Gently turn your head as though you were looking over your shoulder. Try not to tilt your head sideways. Keep your upper body still and your shoulders facing forward.
- Hold 5 to 10 seconds, and then turn your head the other way.
- Repeat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

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.

Provide support equipment to reduce the potential for physical stress…

The MIC 797P 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 feed 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.

- **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.

Helpful Suggestions:

- Make sure the MIC 797P 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 797P).

- 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

- When reaching:
    - Understand the span of reach inside the MIC 797P. Span is the angle from the centerline of the glove ports with your arms extended and side-to-side.
    - When reaching for the door handle to the airlock, position your arm so that the your hand opens the handle from the bottom
    - The greater the length of your reach the less weight you can comfortably pick up.
    - 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.
    - Ideal working depth in the MIC 797P is 6 to 15 inches from the front of the unit.
    - Avoid reaches that create stress. Contact your supervisor if you are experiencing strain or discomfort.

- When lifting:
    - Lift with your major muscle group.
    - Lift with your wrist as straight as possible (Neutral position)
    - Lift as close to the body as possible with arms in a straight position
    - 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 797P, contact Containment Technologies Group to discuss possible positioning alternatives.