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OPERATING AND MAINTENANCE INSTRUCTIONS

EXPERIMENTAL SYSTEM FOR THE CONTROL OF SURGICALLY INDUCED INFECTIONS

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MARTIN MARIETTA

DENVER DIVISION

EXPERIMENTAL SYSTEM FOR THE CONTROL OF SURGICALLY INDUCED INFECTIONS

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Marvin D. Tevebaugh Program Manager

MARTIN MARIETTA CORPORATION
DENVER DIVISION
P. O. Box 179
Denver, Colorado 80201

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1.0 GENERAL DESCRIPTION

The Experimental System for the Control of Surgically Induced Infections, herein referred to as the system, consists of: a portable clean room comprised of a Class 100 horizontal laminar flow filter system per Federal Standard 209a, and a transparent walled enclosure; a helmet-shoulder pad assembly; a communications system; a helmet ventilation system and surgical gowns.

The surgery room air is drawn into large blower towers located on each side of the filter bank and forced through High Efficiency Particulate Air (HEPA) filters. The HEPA filters remove all particulate larger than 0.3 micron with an efficiency of 99.97 percent. The air exits the filters in a horizontal laminar manner at a rate of 27.45 ± 6.10 meters per minute (90 ± 20 feet per minute) throughout the cross-section of the enclosure. The enclosure constrains the filtered air which exits at the open end. The air then circulates around the outside of the enclosure to the blowers for recirculation. Total air flowrate is nominally 217 cubic meters per minute (7650 cubic feet per minute) which provides approximately one and one-half complete filtered air exchanges per minute in a typical surgery room.

When the sliding doors are extended, a 3.05×3.05 meters (10 x 10 feet) work area is provided inside the enclosure with a ceiling height of 2.6 meters (8 feet 7 inches). The transparent walls and ceiling allows the use of the existing facility lighting and provides for observation of the operation without the use of surgical apparel.

The enclosure, filter modules and blower towers are mounted on casters to provide portability within the surgery room. The blower towers may be disconnected and rolled to an outside area for servicing. For storage within the surgery room, the enclosure ceiling and walls may be collapsed and folded toward the face of the filter modules and the blower towers located inside. In this stored configuration a floor space of approximately 1.5 x 3.4 meters (5 x 11 feet) is utilized. In addition, the capability is provided for dismantling the entire assembly for transfer to another surgery room.

Six full bubble transparent helmets which attach to shoulder pad-harness assemblies are provided for members of the surgery team. The helmets are ventilated by a vacuum system that pulls air through the helmet, out an umbilical at the rear of the shoulder pad and discharges into the main filter bank plenum. The ventilation system is provided with two vacuum blowers for redundancy. In case one blower fails, the other will supply a six-man team with a minimum air supply. Normally, the ventilation system can supply 170-350 liters per minute (6.0-12.3 cubic feet per minute) to each helmet depending upon the number of helmets in use. The air flow to each helmet can be individually regulated by valves at control panels located outside the enclosure.

The communications system provides a microphone/earphone headset for each helmet assembly. A microphone is provided on the outside of the enclosure for a circulating nurse. Another microphone is provided at the end of the enclosure for the anaesthetist or he may use an auxilliary communications cable and headset. A speaker is provided on both the inside and outside wall of the enclosure. Volume controls are provided for each individual microphone, earphone and speaker on the main control panel located outside the enclosure.

The disposable split-back surgical gowns fasten around the shoulder pad helmet neck ring. The gowns are low linting and are liquid repellant.

The helmets, shoulder pads and umbilicals are cleaned with antiseptic solutions after each usage. The harness may be removed and gas sterilized if necessary. With the exception of normal cleaning and care of the equipment, the only scheduled maintenance item is the replacing of the blower tower pre-filters every thirty days.

2.0 OPERATING INSTRUCTIONS

2.1 Operating Procedure

The following procedure assumes the system is in the assembled operational configuration and is ready for surgery usage.

2.1.1 Preparing the Clean Room

- a) Verify the three power cables are connected to the two blower towers and control panel.
 - b) Verify all switches are OFF on the main control panel.
- c) Verify all circuit breakers are ON on the main control panel.

d) Verify HELMET VENTILATION VALVE NO. 1 is in the OPEN position and all other valves are in the CLOSED position.

CAUTION: Whenever the helmet ventilation blowers are in operation at least one HELMET VENTILATION valve must be in the OPEN position to prevent overheating of the ventilation blowers.

- e) Turn HELMET VENTILATION BLOWER LEFT switch to the ON position. Verify by sound that the blower is operating. Turn switch to OFF position.
- f) Repeat the above step for HELMET VENTILATION BLOWER RIGHT.
- g) Turn COMMUNICATIONS SYSTEM switch to the ON position. Using the nurse microphone and pressing the talk lever, verify the communications system is functioning. Turn switch to the OFF position.
- h) Verify the anaesthetist microphone is connected to jack at top end of the enclosure.

NOTE: The anaesthetist has the option of using the microphone provided or a headset using the auxilliary communications cable and an unused helmet communications circuit.

i) At each blower tower, press the ON switch to start blowers. Check the pressure gage reading at each blower tower. The gage shall read 0.2 inches of water or greater.

NOTE: With a reading lower than 0.2 inches of water the air velocity within the enclosure is below minimum and the cause should be determined before continuing. See paragraph 3.1 for troubleshooting.

- j) Allow the blower towers to operate at least 15 minutes prior to setting out sterile instruments. This will allow the system to circulate the air within the room and remove air particles.
- k) Position surgery equipment to the side or open end of the enclosure.

NOTE: Do not position equipment between the face of the filters and the operating table.

- 1) After the patient and surgery team have entered the enclosure extend sliding wall sections.
- 2.1.2 <u>Preparing the Surgery Team</u> The following procedures are for the surgery team members that will be operating in the helmet assemblies. The shoulder pads and headsets are donned prior to scrubbing.
- a) The surgery team members shall be attired in normal scrub garmets.
- b) Don the shoulder pad-harness assembly by placing over the head with helmet latch facing the front.
- c) If necessary, adjust the height of the harness pad at the back by removing wing nut and raising or lowering. The pad should be positioned such that the wide straps will encircle the person just below the breasts in front. Replace and tighten wing nut.
- d) Snap the two wide straps to the 'D' ring on the front vertical strap loosening the straps if necessary.
- e) Tighten the horizontal straps, keeping the "D" ring centered, by pulling on the loose ends and the slides. The straps should be snug allowing the elastic sections to give with breathing.
- f) With the shoulder pad tilted as far forward as possible, tighten the narrow vertical strap by pulling on the loose end and slide buckle.
- g) Verify the comfort, mobility and stability. Adjust where necessary.
- h) Remove headset components from pouch provided. Assemble per the included instructions in the following manner.
 - i) Select the proper size earplug and attach to head set.
- j) Attach headset to head band by sliding over strut or if the person wears glasses, attach to frame of glasses.
- k) Place headset on head with headband pads on temples. Adjust headband size if necessary (or don glasses).

- 1) Insert earplug into ear adjusting on headband strut if necessary.
- m) Rotate microphone boom to a position approximately 1 cm. (1/2 inch) from the corner of the mouth.
- n) Attach headset connector to mating connector inside the rear of the shoulder pad. Align connector notches and push together until snapped in place.
- o) By rotating head and bending forward, verify comfort and stability of headset. Adjust as required.
 - p) The surgery team is now ready for scrubbing.

2.1.3 Umbilical Attachment

- a) Position the surgery team members in the respective positions around the operating table.
- b) Attach the umbilicals which consist of a ventilation line and a communications cable to the respective outlets on the lower enclosure walls. The ventilation line is connected by sliding the outer collar of the connector back, pushing the connector onto the mating plug and releasing the collar. The communications connector is mated by aligning the connector notches (raised outer spring band pointed away from the ventilation elbow) and pushing together until snapped in place.
- c) Uncoil the umbilicals such that they do not contain any loops.
- d) Attach each umbilical to the respective shoulder pad of the surgery team members using the same procedure as outlined above.

NOTE: If the anaesthetist is to use a headset instead of the microphone, connect auxilliary communications cable to an unused helmet, communications connector at the enclosure wall and don a headset per paragraph 2.1.2h thru 2.1.2m. Connect headset to mating end of cable.

2.1.4 Activating the Communications System

a) Check the position of the volume control knobs on the main control panel. The number at the top of the knob determines

the setting.

External Speaker

NOTE: The recommended settings for the volume controls are as follows: Control Setting 3 Helmet Microphones (all) 5 Anaes & Nurse Microphone Helmet Earphones (all) 5 5 Internal Speaker 5

Clockwise adjustments increase the volume. terclockwise adjustments decrease the volume.

- b) Deviations from the above settings may be necessary:
 - If a person normally speaks louder than others, compensate by decreasing his microphone volume.
 - (2) If a person normally speaks softer than others, compensate by increasing his microphone volume.
 - If a person normally has sensitive hearing, compensate by decreasing his earphone volume.
 - (4) If a person has difficulty hearing, compensate by increasing his earphone volume.
- Turn COMMUNICATIONS SYSTEM switch to the ON position.
- d) Each surgery team member shall "sound off" and verify all headsets are operating.

2.1.5 Activating the Ventilation System

a) Turn the HELMET VENTILATION valves for the respective surgery team members to the OPEN position.

NOTE: All unused HELMET VENTILATION control valves shall be in the CLOSED position to prevent suction of foreign materials into the ventilation system.

- b) At the main control panel, turn HELMET VENTILATION BLOWER LEFT and RIGHT switches to the ON position.
- c) Verify each surgery team member shoulder pad is pulling an air vacuum.

2.1.6 Helmet Donning

NOTE: Care shall be taken to prevent scratching or damaging helmets. Handle by the helmet ring only. Inspect each helmet before installing for scratches and imperfections. Install helmets with an unmarred viewing area to the front.

- a) Place a helmet over the head of each surgery team member.
- b) Slide helmet ring under one corner of the rear retaining clip of the shoulder pad and roll helmet ring under clip while pushing back until the helmet ring fits into the front retaining plate.
- c) Lock helmet latch on the front of the shoulder pad by engaging the latch hook into helmet ring slot and swinging latch handle up. Latch should pull helmet ring down snug with shoulder pad ring gasket. If necessary, latch may be adjusted by screwing hook shaft in or out.
- d) With all surgery team members in helmets, verify each helmet is receiving ventilation.
- e) Verify all headset, microphone and speaker communications by each team member "sounding off" in sequence including the anaesthetist and circulating nurse. The anaesthetist and nurse microphones are activated by pressing the lever on the side of the microphone to talk. Release lever when not talking. Adjust volumes as required in accordance with paragraph 2.1.4b.

2.1.7 Gown Donning

NOTE: Each sterile disposable gown shall be debagged within the enclosure by the circulating nurse. The nurse shall perform all of the gown handling except the tieing of the waist strap. The nurse shall touch only the inside surfaces of the gown, the rear portion of the neck band, the overlap flap and the red striped cover on the waist band unless she is wearing sterile gloves.

- a) Unbag a sterile gown for each surgery team member.
- b) Unfold gown, holding only inside gown surfaces, and position in front of person to be attired.
 - c) Insert arms all the way into gown sleeves.
 - d) Unfold gown around the body.
- e) Fit the gown neck below the helmet ring under the helmet latch.
- f) Overlap gown at the back under the umbilical connections and snap in place. (An optional method is to install the gown over the umbilical.)
 - g) Straighten overlap down the back of the gown.
- h) Pull on the two red striped tabs to release the waist straps.
- i) Pass the waist straps around to the front for the surgery member to tie and remove the red striped tabs.
 - j) Don surgical gloves.
- k) The surgery team members are now ready for performing an operation.

2.1.8 System Operation During Surgery

- a) During surgery the team members should attempt to always stay to the side or downstream (with respect to air flow) of the wound area. Passing of instruments should be done well above or downstream of the wound.
- b) The circulating nurse and the anaesthetist can communicate with the helmeted members by using the respective microphones. The microphones are activated by pressing the talk lever on the side of the microphone.
- c) If a helmeted member desires less ventilation flow, turn his respective HELMET VENTILATION valve to a lower setting.
- d) Communications volume adjustments may be made in accordance with paragraph 2.1.4.b.

e) Normally the system will not require any further adjustments during the surgery operation. If equipment malfunctions occur, the following table outlines some of the possible conditions and corrective actions.

Table 1 System Malfunctions and Corrective Action

System Malfunction	Corrective Action			
Communications				
a) Headset earplug falls out of ear.	 a) Turn respective helmet earphone volume up. 			
b) Headset earphone or micro- phone becomes inoperative.	b) Change umbilical to another set of wall connectors, change ventilation valve positions and adjust new communications circuit volume controls. If problem persists, remove helmet, change headset, and replace helmet.			
c) Nurse or anaesthetist microphone inoperative.	c) Use respective microphone that is operating for transfer of infor- mation or connect auxilliary com- munications cable to unused hel- met communications circuit and use headset.			
d) Internal or/and external speaker inoperative.	d) Turn up respective speaker that is operating to an acceptable level or connect auxilliary com- munications cable to unused hel- met communications circuit and use headset.			
e) Communications system "squelching".	e) "Squelching" is normally caused by microphone feedback. Assure nurse microphone when ON is not directly in front of external speaker. If not, nurse microphone systematically turn down each microphone volume setting and then back to normal until the microphone causing the feedback is found. When found, turn volume for that microphone down to an acceptable level or if persists, perform step b above. If squelching is only heard on the speakers, turn down speaker volumes to an acceptable level.			

Table 1 System Malfunctions and Corrective Action (continued) System Malfunction Corrective Action f) Entire communications f) Turn communications switch OFF. system inoperative. operation cannot be completed without communications, remove all helmets, don surgical masks, continue operation and turn helmet ventilation blowers OFF. Ventilation System a) One helmet ventilation a) Turn respective ventilation blower blower becomes inoperative. switch to OFF position. Continue operation. One blower will support six helmets with a sufficient air supply. b) Both helmet ventilation b) Remove all helmets and don surgical face masks. This may be done by blowers becomes inoperathe nurse if time permits to remove tive. each helmet. If done by the surgery team member, replace surgical gloves. Turn both helmet ventilation blower switches to the OFF position. Blower Towers a) One blower tower becomes a) Press respective blower tower switch off button. Continue operainoperative. tion. b) Squelling noises. b) Same as above. c) Attempt to determine on which side c) Odd rubber smell. of the enclosure the smell is the strongest. Press respective blower tower switch off button. Continue operation.

2.1.9 Post-Operation Procedures

- a) Remove surgery team member helmets by unlocking front latch, raising front edge of helmet ring, sliding forward until ring clears rear clip and raising over the head.
- b) If patient is still in enclosure, don surgical face masks.

- c) At main control panel turn HELMET VENTILATION BLOWER LEFT and RIGHT switches to the OFF position.
 - d) Turn COMMUNICATIONS SYSTEM switch to the OFF position.
 - e) Remove surgical gloves.
- f) Remove gown by untieing waist straps and unsnapping neck band. Immediately dispose of gown.
- g) Disconnect umbilicals from the shoulder pad assemblies. The communications cable is disconnected by pressing the raised spring band between the thumb and finger to release the lock and pulling. The ventilation line is disconnected by pulling back on the outer collar to release the latch and pulling.
- h) Disconnect headsets from the rear of the shoulder pad assemblies by squeezing the headset half of the connector at the raised lines and pulling connectors apart.
- i) Remove headsets, disassemble headbands and earplugs and store in pouches provided.
- j) Remove shoulder pads by unsnapping wide straps from "D" ring and lifting over head. Temporarily store shoulder pads before cleaning.
 - k) Surgery team members may now leave the area.
- 1) Disconnect umbilicals from the lower enclosure wall connectors similar to step g) above.
 - m) Coil umbilicals and temporarily store before cleaning.
 - n) At each blower tower, press the OFF button.
 - o) Retract enclosure sliding wall panels.

NOTE: The sliding wall panels should always be in the retracted position except during surgery usage to reduce the stress on the upper cantilevered beams.

- p) Clean enclosure, helmets, shoulder pads, harness and umbilicals per paragraph 2.1.10.
 - q) The system is now secured and ready for the next usage.

2.1.10 Cleaning Procedures

2.1.10.1 Clean Room (Enclosure, Filter Modules, Blower Towers)

- a) Painted and metal surfaces shall be cleaned by swabbing with an antiseptic solution of one part Dicrobe to 80 parts of water.
- b) Plexiglass panels shall be cleaned with a soft cloth saturated in a solution of one part Dicrobe to 80 parts of water. This shall be followed by a distilled water swab rinse and a 70% isopropyl alcohol swab rinse.

2.1.10.2 <u>Helmet</u>

- a) Inside and outside surfaces of the helmet shall be cleaned with a soft cloth saturated in a solution of one part Dicrobe to 80 parts water. This shall be followed by a distilled water rinse and a 70% isopropyl alcohol swab rinse.
 - b) After cleaning, encapsulate helmet in plastic film.

2.1.10.3 Shoulder Pad-Harness Assembly

- a) All surfaces except the harness webbing shall be cleaned by swabbing with a solution of one part Dicrobe to 80 parts water.
- b) The harness webbing may be cleaned by removing from shoulder pad. Launder and sterilize in the gas sterilizer.

NOTE: Do not sterilize in steam autoclave or finish on webbing snaps may be damaged.

2.1.10.4 Umbilicals

- a) Wipe the external surfaces of the umbilical with a cloth saturated in a solution of one part Dicrobe to 80 parts water.
 - b) Coil umbilical and seal in a plastic bag until next usage.
- 2.2 Preparation for Storage Mode If the portable clean room is to be collapsed and relocated, perform the following steps. If it is to be collapsed and left in place, omit step a) and b).

NOTE: A minimum of two personnel are required to perform the following procedure. The allen-wrench tool (provided with the system), a short step ladder, and a screwdriver are required.

- a) On main control panel turn all CIRCUIT BREAKER switches to the OFF position.
- b) At each blower tower and the main control panel, disconnect the electrical power cables from the facility outlets. To disconnect, twist connector counterclockwise and pull.
- c) Disconnect the anaesthetist microphone from outlet at the end of the enclosure ceiling. Store microphone.
- d) Remove the anaesthetist microphone outlet box from ceiling frame by lifting up on the box. Reattach the outlet box to extreme left edge of ceiling frame close to cable exit hole. Push cable back into hole in end of wall beam.
 - e) Verify both sliding wall panels are fully retracted.
- f) Position surgical lamps to provide clearance for lowering and removing outer center ceiling panel.
- g) At the end of the ceiling slots, unlatch the two reinforcing channels by swinging outward. A screwdriver may be necessary to pry the channel out.
- h) While holding the end of the center ceiling panel, unlock the two latches holding the center panel to the two outer panels. Use the allen-wrench tool to unlock latches.
- i) Swing the panel down slightly past a vertical position while lifting and disengage hinge hooks.

NOTE: Do not let panel hang from hinges unsupported or remaining ceiling panels may be damaged. When panel is removed, the remaining ceiling panels will sag slightly.

- j) Carry ceiling panel to rear of the left filter module.
- k) Set panel on guides located on filter module caster mounts. Position panel with hinge hooks facing away from the module.

- 1) Slide panel under clip at outer edge of module.
- m) While holding panel and using tool, unlock left outer ceiling panel and swing down against wall frame.
- n) At left wall beam hinge point, unlock fastener and rotate beam with attached panel 180° and set end of beam over clip provided.

NOTE: Support beam while being unlatched and rotated. Do not allow beam to hang unsupported while unlatched.

- o) While holding panel, unlock right outer ceiling panel and swing down against wall frame.
- p) At right wall beam hinge point, unlock fastener and rotate beam with attached panel 180° and set end of beam over clip provided.

NOTE: Support beam while being unlatched and rotated. Do not allow beam to hang unsupported while unlatched.

- q) Unlock fastener at center ceiling panel joint.
- r) While holding panel, unlock fastener attaching right center ceiling panel to the fixed panel. Swing panel down against wall frame.
- s) While holding panel, unlock fastener attaching left center ceiling panel to the fixed panel. Swing panel down against wall frame.
- t) Disconnect each blower tower from filter modules by turning black knob on front of unit counterclockwise until blower towers can be separated.
- u) If system is to be relocated, continue with the following steps. If system is to remain in place, proceed to step w.
- v) Raise filter modules and walls off floor by rotating each caster cap clockwise. The twelve casters shall be adjusted sequentially 1/2 to 2 turns each time until the system is raised approximately 0.5 cm (1/4 inch). If necessary, a block and lever may be used to relieve weight while turning casters.

w) Disengage left wall assembly wheel lock and rotate until parallel with ceiling panel.

NOTE: It may be necessary to raise sag in ceiling joint for wall assembly to fit under ceiling over-lap plate.

- x) Repeat step v) for right wall assembly.
- y) By pushing at corner frames roll entire assembly to planned storage location.
 - z) Open wall assemblies.
- aa) Roll blower tower modules in front of respective filter screens taking care not to damage screens.
- bb) Close wall assemblies by rotating inward toward filter raising ceiling panels if necessary.
 - cc) The system is now in the stored configuration.
- 2.3 Assembly from Storage Mode If the portable clean room is to be relocated from the storage position, perform the following steps as outlined. If it is already in usage position, omit non-applicable steps.

NOTE: A minimum of two people are required to perform the following procedure. The allen-wrench tool (provided with the system), a 7/16-wrench and a short step ladder are required.

- a) Open folding wall assemblies.
- b) Roll blower tower modules from inside storage position.
- c) Close folding doors to original position.
- d) Roll entire collapsed assembly to usage location. Visually align the rear of the modules perpendicular to the room axis. Center assembly with respect to the overhead surgery light tracks.
 - e) Fully open wall assemblies.
- f) Raise left center ceiling panel and fasten to fixed panel using tool provided.

- g) Raise right center ceiling panel and fasten to fixed panel. Push out on wall assemblies if necessary to provide mating clearance.
 - h) Lock center fastener between the above two panels.
- i) While lifting, unhook left wall beam, rotate 180° into position and lock beam fastener.

NOTE: Support beam while being rotated and latched. Do not allow beam to hang unsupported while unlatched.

- j) Repeat step i) for right wall beam.
- k) Raise right outer ceiling panel and check alignment and location with respect to overhead surgery lights. If necessary, move entire assembly until properly positioned. Lock fastener to center ceiling panel.
- 1) Raise left outer ceiling panel and fasten to center ceiling panel.
- m) Remove outer center ceiling panel from storage location at rear of left filter module.
- n) While lifting, hook panel hinges over hinge pins at center of ceiling and raise into position.

NOTE: Do not let panel hang from hinges unsupported or remaining ceiling panels may be damaged. It may be necessary to lift at center ceiling joint to remove sag while raising panel.

- o) Rotate reinforcing channels at end of ceiling over each outer panel joint until snug against frame.
 - p) Lock fasteners at the end of each slot.
- q) While pulling on cable, relocate the anaesthetist microphone outlet box near the left wall beam to a position on the center ceiling panel outer frame near the right reinforcing channel. Hook cable over clip provided and push excess cable back into hole in beam.
 - r) Plug anaesthetist microphone jack into outlet box.

- s) Lower entire portable clean room onto floor by rotating each caster cap counterclockwise. The twelve casters shall be adjusted sequentially 1/2 to 2 turns at a time until filter modules rest solidly on the floor. If necessary a block and lever may be used to relieve weight while turning casters.
- t) At the two outer wall casters, set the brakes by pressing foot down on wheel lever.
- u) If necessary, using a 7/16 wrench, adjust the spacer plates located at the base of the inside walls so they are flush with the floor.
- v) Roll left blower tower into position at filter plenum opening. Before pushing into opening, rotate black knob so that latch prongs on end of shaft are pointing up. Push blower tower into opening. Push black knob all the way in and rotate clockwise. Verify latch is engaged by pulling on knob. Screw knob clockwise until tight seal is made around plenum opening.

NOTE: For proper mating to the plenum opening, the blower tower casters may require adjusting for height. Turn caster caps clockwise for raising and counter-clockwise for lowering. When raising, care should be taken that casters are not completely unscrewed.

- w) Repeat step w) for the right blower tower.
- x) Press the OFF button on each blower tower to verify switch position.
- y) Connect both blower tower power cables to 208 volt facility connectors. Align connectors and twist clockwise.
- z) On main control panel verify all circuit breakers and switches are in the OFF position.
- aa) Connect main control panel power cable to 115 volt facility connector. Align connectors and twist clockwise.
 - bb) The system is now ready for operational usage.
- 2.4 <u>Disassembly and Transfer</u> The following procedure assumes the system is in the completely assembled condition. If the system is in the storage condition, open wall assemblies, remove blower towers and perform the following, omitting non-applicable steps. As the system components are disassembled, temporarily store against facility walls taking care not to damage.

NOTE: The following procedure may be performed by two personnel except for the de-erection of the filter modules which requires four personnel. The allen-wrench tool (provided with the system), a small screwdriver, a large screwdriver, hammer, 9/16 wrench, and short step ladder are required.

- a) On main control panel turn all CIRCUIT BREAKER switches to the OFF position.
- b) At each blower tower and the main control panel, disconnect the electrical power cables from the facility outlets. To disconnect, twist connector counterclockwise and pull.
- c) At main control panel, disconnect the nurse microphone and store.
- d) Disconnect the anaesthetist microphone from outlet at the end of the enclosure ceiling. Store microphone.
- e) Remove the anaesthetist microphone outlet box from ceiling frame by lifting up on box. Remove cable from ceiling frame hook and push cable back into hole in end of the wall beam. Using tape, securely attach outlet box to end of beam.
 - f) Verify both sliding wall panels are fully retracted.
- g) Position surgical lamps to provide clearance for lowering and removing outer center ceiling panel.
- h) At the end of the ceiling slots, unlatch the two reinforcing channels by swinging outward. A screwdriver may be necessary to pry the channel out.
- ·i) Swing the panel down slightly past a vertical position while lifting and disengage hinge hooks.

NOTE: Do not let panel hang from hinges unsupported or remaining ceiling panels may be damaged. When panel is removed, the remaining ceiling panels will sag slightly.

j) Carry ceiling panel and temporarily store by leaning against a facility wall.

NOTE: During the following steps the panel hinge pins are removed easiest by inserting a small screwdriver in the hole in the end of the hinge and driving the pin out as far as possible with a hammer. If necessary, use a large screwdriver and hammer on head end of pin. After removal of panel, replace hinge pins as a means of storage.

- k) While holding panel and using tool, unlock left outer ceiling panel. Remove hinge pins. Remove panel and store.
- 1) At left wall beam hinge point, unlock fastener and rotate beam 180° and set end of beam over clip provided.
- m) Repeat steps k) and l) for right outer ceiling panel and wall beam.
 - n) Unlock fastener at center ceiling panel joint.
- o) While holding panel, unlock fastener attaching right center ceiling panel to the fixed panel. Remove hinge pins. Remove panel and store.
 - p) Repeat step o) for left center ceiling panel.
- q) Remove sliding glass panels on each side by pulling out of tracks taking care to support panels as they become free. Store panels.
- r) Unlock brake on outer caster at each wall and partially close wall assemblies.
- s) Remove cover plates at bottom of the outside left wall by pulling, exposing cable and tubing.
- t) Disconnect communications cable connectors P-1 and J-1 by squeezing on raised portion of plug and pulling.
- u) Disconnect three flex lines from plastic pipe connections by pulling and bending back and forth.
 - v) Replace cover plates by sliding into applicable slots.
 - w) Repeat steps s) thru v) for right wall assembly.
- x) While supporting edges, remove left wall assembly hinge pins. Tilt wall assembly over such that upper hinged beam does not come loose. Store panel.

- y) Repeat step x) for right wall assembly.
- z) Disconnect each blower tower from filter modules by turning black knob on front of unit counterclockwise until blower towers are separated.
- aa) Remove the four filter screens by pulling out at the bottom and raising up to unhook.
- bb) Using a 9/16 wrench, unscrew all filter retaining latch bolts counterclockwise until approximately 7.5 cm (3 inches) of the bolt is exposed.
- cc) Remove filters and store. If necessary, loosen latch bolts further.

NOTE: Care must be taken not to damage filters. Handle by outer frame only.

- dd) Under the inside edge at the bottom center of filter frame, disconnect communications connectors P-2 and J-2.
- ee) At remaining ceiling panel joint, unlatch two fasteners connecting panels.
- ff) At front center joint of filter module, unlatch two fasteners holding frame together.
- gg) At the rear joint of the filter module disconnect electrical plug at the top of the unit.
- hh) Unlatch fasteners holding filter frame together at the top and rear.
 - ii) Separate filter frame sections.
- jj) Using four personnel, tilt the right filter frame back-wards. While supporting, turn onto the closed end of the plenum side and place on two four-wheeled dollies. While supporting filter frame transfer to new location.

NOTE: If ceiling height does not permit tilting the filter modules, distance may be shortened by removing rear filter casters and overlap plates on front edge of ceiling panels. This will allow clearance for a 4 meter (9 foot 6 inches) ceiling. If ceiling is shorter, the fixed walls and ceiling sections may be removed by removing internal speaker panel,

disconnecting right and left ventilation blower wires from terminal board and pulling thru top holes, removing communications cable clamps on front edge of filter frame, removing cover plugs on frame and removing bolts connecting walls and ceiling panels from filter frame. After relocation, reassemble hardware removed above.

- kk) Repeat step jj) for left filter frame.
- 11) Carry each panel individually to new location. Care shall be taken not to damage filters.
- 2.5 Assembly The following procedure assumes the system is in the dismantled condition.

NOTE: The following procedure may be performed by two personnel except for the erection of the filter modules which requires four personnel. The allenwrench tool (provided with the system), a 7/16 wrench, a 9/16 wrench, hammer, and short step ladder is required.

a) Position left filter frame to approximate usage location and while supporting, turn onto rear edge and erect into vertical position.

NOTE: If rear casters and ceiling overlap plates have been removed, replace. If fixed walls and ceiling panels have been removed, replace.

- b) Repeat step a) for the right filter frame.
- c) By turning clockwise on caster caps, raise filter modules until units can be rolled freely.
- d) Push two filter modules together aligning at plenum joint. Raise or lower casters as required.
- e) Latch fasteners on the front, rear and top of joint to mate units.
 - f) Connect power cord at top joint of units.
- g) Connect communications cable connectors P-2 and J-2 at lower front center edge of filter frame. Align connector notches and push together.

- h) At center fixed ceiling panel joint, latch two fasteners using allen-wrench tool. Verify edge of ceiling panel is aligned.
- i) Using a 9/16 wrench, adjust all filter retaining latch bolts until approximately 5 cm (2 inches) of the bolt is exposed.
- j) Install filters by placing in opening and pushing toward frame. Verify all latches snap in place adjusting bolts as necessary.
 - k) Tighten all filter latch bolts by screwing clockwise.
- 1) Install four filter screens by hooking over top brackets and pushing to latch at the bottom.
- m) While supporting, raise and position left folding wall assembly. Install hinge pins by tapping with hammer.
 - n) Repeat step m) for right wall assembly.
- o) Remove cover plates at bottom of the outside left wall by pulling.
- p) Connect three flex lines to plastic pipe connections by pushing and bending back and forth. Verify proper numbered line connection by tags on pipe and helmet number plates on inside of wall.
- q) Connect communications cable connector P-1 and J-1. Align connector notches and push together.
 - r) Replace cover plates by pushing into applicable slots.
 - s) Repeat steps o) thru r) for right wall assembly.
- t) Install right and left sliding glass panels into upper and lower tracks. Upper rollers will require alignment while installing. Slide panels into full retracted position.
- u) While supporting, raise left center ceiling panel into position and install hinge pins. Allow panel to hang down against wall frame.
 - v) Repeat step u) for right center ceiling panel.
- w) Repeat step u) for outer folding ceiling panels that attach to folded wall beam.

- x) Position entire assembly in usage location. Visually align the rear of the filter modules perpendicular to the room axis. Center assembly with respect to the overhead surgery light tracks.
- y) Assemble the remainder of the system per paragraph 2.3 starting with step e).

3.0 MAINTENANCE INSTRUCTIONS

The following paragraphs outline the maintenance functions to be performed on the system. For cleaning procedures see paragraph 2.1.10.

3.1 Blower Towers and Filter Modules

- 3.1.1 Prefilter Replacement Blower tower prefilters should be replaced every 30 days. If excessive lint loading is observed, replacement cycle may be shortened. Six each 63.5 x 50.1 x 2.5 cm (25 x 20 x 1 inches) fiberglass filters are required. Replace filters as follows:
 - a) Press OFF switch on blower tower.
 - b) Pull out on two outside rear corner panels of blower tower.
 - c) Turn retainer catches and slide filters out of place.
 - d) Install new filters and close panels.
- 3.1.2 Blower Tower Motor and Blowers Motor/blower units are permanently lubricated and require only a periodic (3 months) inspection of drive belts. This is done by removing the side panel of the blower tower. Drive belts are adjusted by turning motor base adjustment screw clockwise to tighten and counterclockwise to loosen.
- 3.1.3 <u>HEPA Filters</u> HEPA filters should not require servicing for at least five (5) years. At that time they must be replaced. In no case shall the unprotected surfaces of the filters be touched or attempted to be cleaned. This will result in damage and void the sterility certification of the system.
- 3.1.4 <u>Troubleshooting</u> The following symptoms are listed to assist in determining the probable cause in the event of trouble. If cause cannot readily be determined, hospital maintenance personnel should be contacted.

Table 2 Blower Tower and Filter Module Troubleshooting

Sym pto n			Correcti o n			
a.	Blower tower units do not operate - one or both units	a.	1)	Switch off - move switch to on position.		
	inoperative.		2)	Wall plug disconnected - Reconnect plug to wall.		
			3)	Facility power breaker tripped - Reset breaker at building panel location.		
			4)	One blower stopped - remove access panel and determine which blower is inoperative, check fusetrons inside explosion proof box inside cabinet, check drive belt and pulleys.		
b.	Increase in noise in blower tower.	ъ.	1)	Blower tower disconnected from filter wall - reconnect blower tower.		
			2)	One blower stopped - remove access panel and determine which blower is inoperative, check fusetrons inside explosion proof box inside cabinet, check drive belt and pulleys.		
c.	Unusual noise in blower tower.	c.	Loose belt or drive pulley - Remove access panel and determine cause.			

Table 2 Blower Tower and Filter Module Troubleshooting Contined --

Sym pt om			Correction		
đ.	Below normal pressure gage reading	d.	1)	One blower stopped - remove access panel and determine which blower is inoperative, check fuse- trons inside explosion proof box inside cabinet, check drive belt and pulleys.	
	ŷ.		2)	One blower operating at reduced speed - check drive belt tension, check adjustable pulley on motor to verify tight setscrew.	
			3)	HEPA filter service life expended - replace filters.	
e.	Unusual smell 1) Burning Rubber	e.	1)	Loose belt - remove access panel and tighten belt by adjustable motor base. (Motors are thermal over- load and fuse protected to prevent burn out)	
	2) Other		2)	Absorbed odor in filters - final filters will absorb odors released in the room and retain for several hours. Obnoxious odors may be lessened by spray- ing a deodorizer into system.	

3.2 Communications System

- 3.2.1 Amplifier and Mixers The amplifier and mixers are transistorized and should not require any servicing. If it becomes necessary to check the amplifier fuses perform the following:
- a) Disconnect control panel 115 volt connector from facility outlet.
- b. Remove left protective filter screen by pulling out at bottom and raising off upper hooks.

- c) Remove internal speaker panel by removing mounting screws and disconnecting speaker.
 - d) Check fuses and replace.
 - e) Reinstall speaker panel connecting speaker before mounting.
 - f) Replace filter screen.
- 3.2.2 Connectors All communications system connectors have soldered pins and contacts except for the headset connectors which are crimped. Repair should be done only by a qualified technician.
- 3.2.3 <u>Headsets and Microphones</u> The headsets and microphones cannot be repaired except for connector replacement. This should be done only by a qualified technician.
- 3.2.4 Troubleshooting The following symptoms are listed to assist in determining the probable cause in the event of trouble. If cause cannot readily be determined, hospital maintenance personnel should be contacted.

3.3 Helmet Ventilation System

- 3.3.1 <u>Ventilation Blowers</u> The ventilation blowers are permanently lubricated and do not require servicing.
- 3.3.2 <u>Helmet Ventilation Control Valves</u> The helmet ventilation control valves are made of PVC plastic and should not require servicing. If valve turning action seems excessively loose or tight, correct in the following manner:
- a) Remove all three valve handles on respective control panel by pulling.
 - b) Remove panel mounting screws.
 - c) Replace handle on suspect valve.
- d) Tighten or loosen depending upon symptom bottom large hand nut.
 - e) Turn handle to test turning action.
 - f) Remove handle.
 - g) Replace panel and valve handles.

Table 3 Communications System Troubleshooting

Symptom			Correction		
a.	Communications system does not operate.	a.	1)	Cycle main circuit breaker, communications circuit breaker and power switch to OFF and back to ON.	
			2)	Verify control panel 115 volt connector is plugged into facility outlet.	
	•		3)	Check amplifier fuses per paragraph 3.2.1.	
ъ.	Headset or microphone does not operate.	ъ.	1)	Verify volume control setting.	
			2)	Verify cable connections.	
	·		3)	Connect headset or micro- phone to another communi- cation circuit.	
c.	Communications system "squelching".	c.	"Squelching" is normally caused by microphone feedback. Verify microphone settings are not too high. Verify nurse micro- phone is not operated directly in front of external speaker.		

If it is necessary to replace valve, perform steps similar to the above except unscrew both hand nuts to remove valve body.

3.3.3 <u>Troubleshooting</u> - The following symptoms are listed to assist in determining the probable cause in the event of trouble. If cause cannot be readily determined, hospital maintenance personnel should be contacted.

Table 4 Ventilation System Troubleshooting

Symptom		Correction		
a.	One or both ventilation blowers inoperative.	a.	1)	Check control panel 115 volt connector is plugged into facility outlet.
		,	2)	Cycle main circuit breaker, ventilation blower circuit breakers and switches to OFF and back to ON.
			3)	If right ventilation blower, check connector at top of filter module joint.
b.	Helmet does not receive ventilation	b.	1) 2) 3) 4)	Check umbilical connections. Check helmet ventilation valve position. Verify ventilation blowers are operating. Check flex line connections behind cover panel on lower wall.
c.	Helmet ventilation inlet continues to suck air with valve closed.	c.	c. Loose or defective valve seat. Correct per paragraph 3.3.2.	

3.4 Electrical System

The electrical subsystems should not require any maintenance except for routine inspections of the power cable connectors. The blower towers contain explosion proof wiring. If it becomes necessary to checkout the main control panel 115 volt circuitry perform the following: (refer to drawing SK203613010 for electrical schematic)

- a) Disconnect control panel 115 volt connector from facility outlet.
- b) Remove left protective filter screen by pulling out at bottom and raising off upper hooks.

- c) Remove internal speaker panel by removing mounting screws and disconnecting speaker.
 - d) Circuitry is now exposed for checkout and/or repair.
 - e) Reinstall speaker panel connecting speaker before mounting.
 - f) Replace filter screen.

3.5 Enclosure

The enclosure requires no maintenance except cleaning per paragraph 2.1.10. Routine inspections should be made for structural damage or repair items.