# EXPERIMENTAL SYSTEM FOR THE CONTROL OF SURGICALLY INDUCED INFECTIONS

## DEVELOPMENT TEST REPORT

D203613-007



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MCR-71-329

# EXPERIMENTAL SYSTEM FOR THE CONTROL OF SURGICALLY INDUCED INFECTIONS

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CONTRACT NASW-2210

20 October 1971

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## FOREWORD

This document was prepared in accordance with the requirements of Contract NASW-2210, for Headquarters, National Aeronautics and Space Administration. This document describes the results of development tests performed by the Martin Marietta Corporation on the experimental system developed and built in performance of the contract requirements.

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## 1.0 SCOPE

This document describes the results of the development tests performed on the Experimental System for the Control of Surgically Induced Infections as defined by D203613-002 Development Test Plan. The objective of each test is defined, test equipment and test conditions identified, the test description outlined, and the test results noted.

## 2.0 SUMMARY

Tests were performed on the portable clean room to demonstrate the assembly, collapsability, portability and storage. Collapsing, relocating and storing within the surgery room can be accomplished in 12 minutes. The storage envelope dimensions are 1.65 m (5' 3-1/2") x 4.24 m (11' 3-1/4") x 2.62 m (8' 7-1/4") high. The disassembly, transfer to another room, and reassembly were demonstrated.

The laminar air flow velocity profile within the enclosure was measured. In the undisturbed area of the enclosure the air flow met the Federal Standard 209a requirements of 27.45 meters (90 ft) per minute $\pm$ 6.10 meters (20 ft) per minute. Smoke tests with simulated surgery equipment and personnel in the enclosure did not indicate any detrimental air flow patterns.

Electrostatic buildup readings taken while installed in the test facility were high. Readings repeated after installation in the hospital which has a grounded floor indicated zero.

Noise level readings taken within the enclosure were 70-71 on the "A" scale and 57 db to 70 db at 500, 1000 and 2000 cycles. All readings were considered acceptable for the intended usage.

Helmet umbilical ventilation flowrates ranged from a maximum of 357 L/min (12.6 CFM) to 212 L/min (7.5 CFM) minimum depending upon the number of helmets on line. In the contingency mode of one ventilation blower off and six helmets on line, the minimum flow rate was 135 L/min (4.8 CFM). At normal flowrates of 170 L/min (6 CFM) and above the $PCO_2$ measured in the helmet was 0.4% or less. Increasing the ventilation to the gown decreased the temperature inside the gown 1.5-3.0$^{o}$F.

A human factors evaluation by six test subjects did not reveal any significant objections. A loose fitting shoulder pad on a small person can be compensated by harness adjustments. Helmet visibility was good except some distortion was noted in the lower portion of the helmet. Noise of a person speaking inside the helmet was high but not objectionable after becoming accustomed to it.

Electrical subsystem operating voltages and currents were measured. Ground leakage currents could not be detected indicating a properly grounded system.

Material compatibility tests of hospital sterilization and cleaning procedures on materials used in the system were performed. No detrimental effects of the cleaning fluids on the materials were noted. Steam sterilization corroded harness hardware; gas sterilization did not.

The conclusions were that the system as designed will perform the functions required for its intended use.

## 3.0 DEVELOPMENT TESTS

The following tests were performed in accordance with the D203613-006 Development Test Procedures.

### 3.1 Portable Clean Room Test

#### 3.1.1 Assembly, Collapsability, Portability and Storage Test

3.1.1.1 Test Objective - The objective of this test was to evaluate the physical design of the portable clean room. The test was to demonstrate the assembly, collapsing and storing in place, portability within a surgery room, and disassembly and transfer of the portable clean room.

3.1.1.2 Test Equipment/Conditions - The test was performed in a room that simulated the St. Luke's surgery room size and volume. The surgery room doors and hallway were simulated. Special tools and equipment were required as follows:

a) One short 1 meter (3 foot) step ladder or equivalent;

b) One tape measure;

c) One stop watch;

d) Two small four-wheeled dollies;

e) One hammer;

f) One screwdriver;

g) One disassembly tool (allen wrench).

3.1.1.3 Test Description

a) The portable clean room was fully assembled at the start of the test. Utilizing two personnel, the enclosure was then collapsed into the stored configuration. The stored envelope dimensions were measured.

b) The portable clean room was relocated by lowering the casters and moving the entire assembly to demonstrate portability within a room.

c) The portable clean room was then dismantled and transfer to another room simulated. The Saint Luke's surgery room doors and hallways were simulated during this portion of the test. A maximum of four personnel was to be utilized.

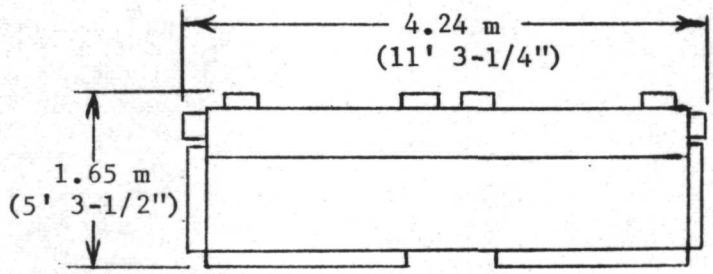
d) Starting from the completely dismantled condition, the filter modules were erected and the portable clean room was assembled into the functional configuration. The maximum height dimension from the floor required for erection of the filter modules was measured. A maximum of four personnel was to be utilized.

For each of the above tests the time duration for each operation was noted.

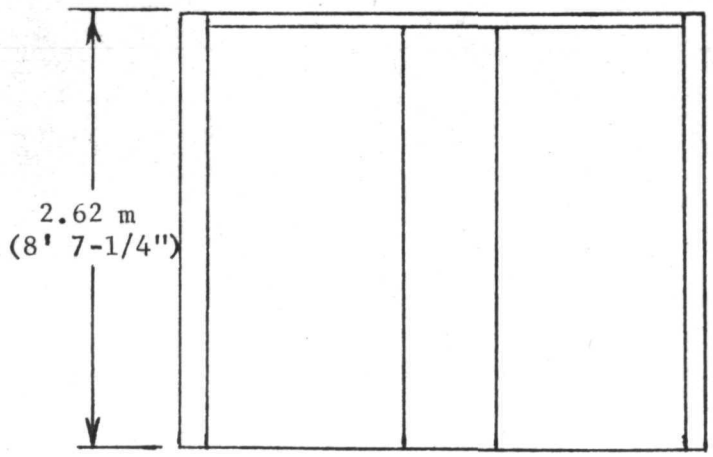
3.1.1.4 Test Results - The results of this test are noted on Figure 1 Data Sheet. Starting from the fully assembled condition (see Figure 2), the system was collapsed to the storage configuration by two personnel in six minutes. The system was raised on the casters and relocated in six minutes (see Figure 3).

FIGURE 1 DATA SHEET - ASSEMBLY, COLLAPSABILITY, PORTABILITY & STORAGE TEST

| Task | Elapsed Time (min) | No. of Personnel | Remarks |
|---|---|---|---|
| Collapsability | 6.0 min | 2 | |
| Portability | 6.0 min | 2 | |
| Disassembly | 47 min | 4-2 | 4 personnel for erection-de-erection, all other 2 personnel |
| Assembly | 78-1/2 min | 4-2 | |



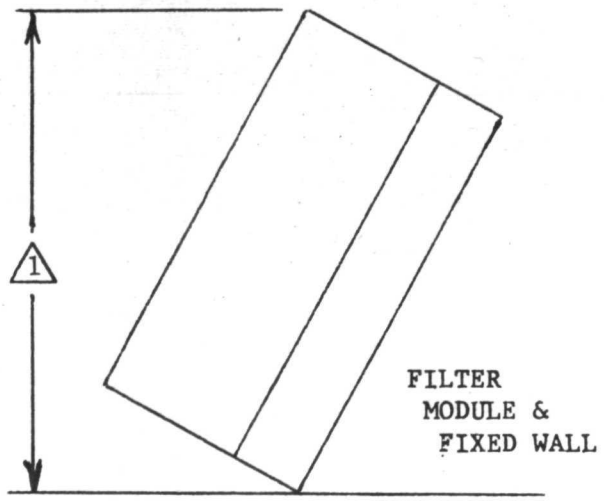

PLAN




ELEVATION

STORAGE DIMENSIONS

(1) 2.85 m (9' 6-3/4")
2.84 m (9' 5-3/4") without casters
2.82 m (9' 5") without casters and ceiling overlap plate




ERECTION DIMENSION


FIGURE 2 ASSEMBLED PORTABLE CLEAN ROOM

FIGURE 3 COLLAPSED PORTABLE CLEAN ROOM

Two personnel disassembled and assembled the system except for de-erecting and erecting the filter modules which requires four personnel. Due to the test facility ceiling height, the filter modules could not be physically erected or de-erected during this test. However, after delivery to Saint Luke's, this portion of the test was performed and the time required included in the figures shown (see Figure 4). Complete disassembly was accomplished in 47 minutes. Complete reassembly was done in 78-1/2 minutes.

The overall envelope dimensions in the storage mode are shown in Figure 1. Ceiling height erection dimensions also reflect removal of the rear filter module casters and ceiling overlap plate if required for clearance. Hallway and door clearances for transfer were verified.

One problem was noted in adjusting the caster height. Due to the weight in the assembled (or collapsed) condition, the casters are difficult to adjust. This difficulty is easily overcome by using a block and short lever bar. For any future build, wrench flats should be provided on the caster stems.

3.1.2 Rate of Laminar Flow Test

3.1.2.1 Test Objective - The ability of the filter banks to maintain a laminar flow velocity profile in the enclosure was to be assessed during this test. For the purpose of this test, laminar flow was defined as that air flow in which the entire body of air

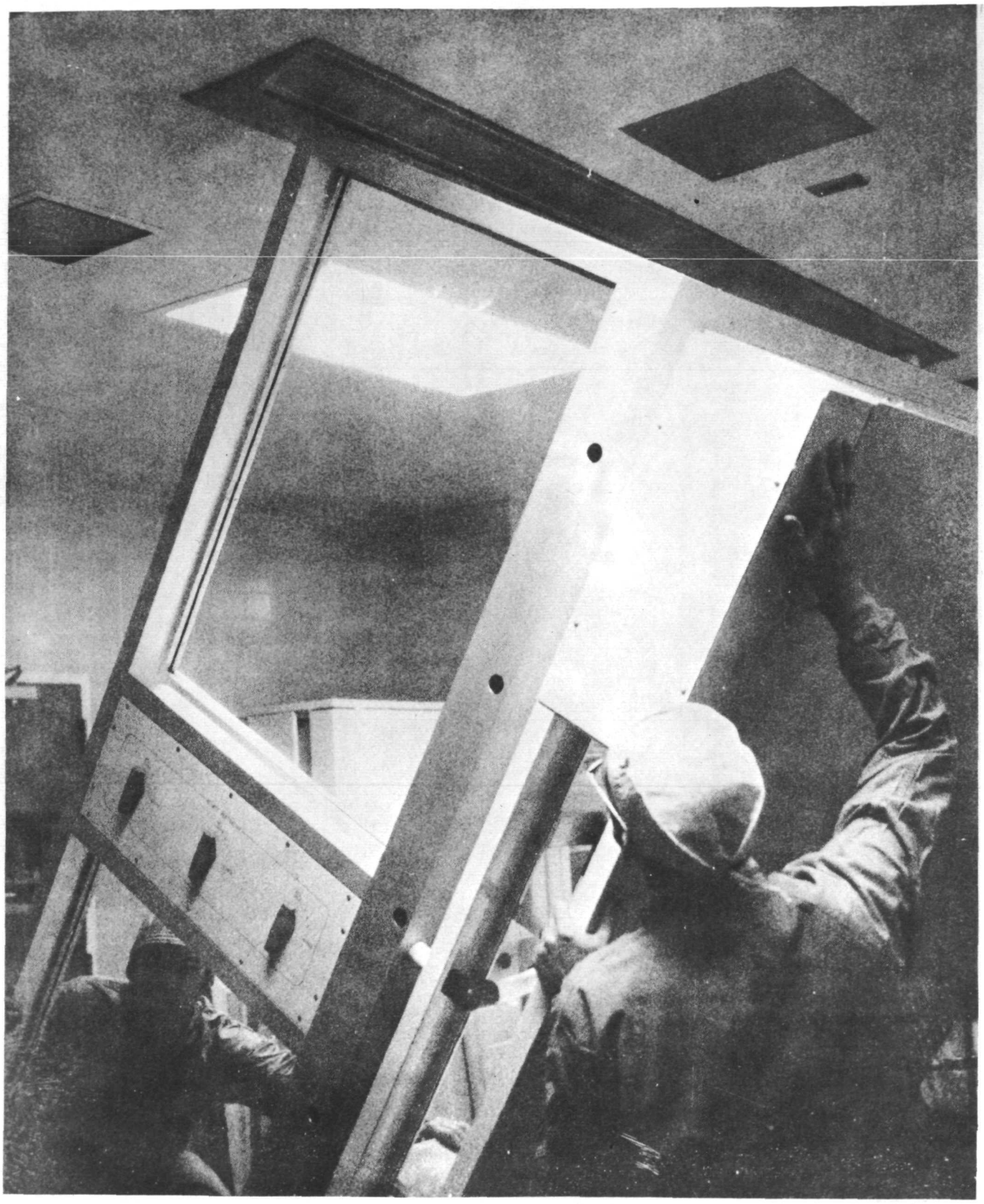


FIGURE 4 FILTER MODULE ERECTION AT ST. LUKE'S

within a confined area moves with uniform velocity along parallel flow lines.

Federal Standard 209a requires a rate of laminar flow of 27.45 meters (90 ft) per minute plus or minus 6.10 meters (20 ft) per minute measured across the entire cross-sectional area.

3.1.2.2 Test Equipment/Conditions - The equipment required to perform this test included the Portable Clean Room and a simulated surgery room. The Portable Clean Room was in the assembled condition and the simulated surgery room had all equipment removed from the area of the portable clean room enclosure. An anemotherm air velocity meter made by Anemostat Products Div. of Dynamics Corporation of America was used for measuring the air velocity.

3.1.2.3 Test Description - With the system assembled in a simulated surgery room, the main filter blowers and ventilation blowers were operated. Air velocity measurements were taken at selected locations throughout the portable clean room enclosure. It was necessary to adjust the filter blowers to attain the required air velocity value of 27.45 plus or minus 6.10 meters per minute.

3.1.2.4 Test Results - The air velocity measurements and locations are shown on Figure 5 Data Sheet. The data indicates an expected profile. At the undisturbed filter end of the enclosure the air velocities meet Federal Standard 209a requirements. Toward the ceiling the velocities increase along the walls as the

FIGURE 5 DATA SHEET - RATE OF LAMINAR FLOW

| Location | Rate of Flow m/min | | | | | |
|---|---|---|---|---|---|---|
| | From Left Side | | | From Right Side | | |
| | 0.3/m | 0.7/m | 1.2/m | 1.2/m | 0.7/m | 0.3/m |
| 0.6 meters (2 ft) downstream of filter | | | | | | |
| 0.3 meters (1 ft) above floor | 31.39 | 26.51 | 22.86 | 23.17 | 27.08 | 27.74 |
| 0.9 meters (3 ft) above floor | 32.61 | 23.17 | 23.47 | 23.17 | 22.25 | 25.29 |
| 1.8 meters (6 ft) above floor | 32.61 | 23.17 | 22.56 | 21.95 | 22.25 | 31.70 |
| 2.4 meters (8 ft) above floor | 30.78 | 26.51 | 26.83 | 23.47 | 24.08 | 26.51 |
| 1.5 meters (5 ft) downstream of filter | | | | | | |
| 0.3 meters (1 ft) above floor | 31.39 | 26.21 | 22.56 | 21.34 | 23.47 | 30.48 |
| 0.9 meters (3 ft) above floor | 27.74 | 24.38 | 24.08 | 23.78 | 22.56 | 25.90 |
| 1.8 meters (6 ft) above floor | 32.61 | 22.86 | 26.51 | 25.90 | 22.86 | 28.65 |
| 2.4 meters (8 ft) above floor | 31.70 | 27.43 | 35.65 | 33.22 | 27.43 | 33.53 |
| 3 meters (10 ft) downstream of filter | | | | | | |
| 0.3 meters (1 ft) above floor | 18.29 | 27.43 | 15.24 | 15.85 | 24.38 | 24.38 |
| 0.9 meters (3 ft) above floor | 24.08 | 22.56 | 11.58 | 11.88 | 25.90 | 26.21 |
| 1.8 meters (6 ft) above floor | 27.74 | 23.47 | 9.14 | 9.14 | 24.38 | 30.17 |
| 2.4 meters (8 ft) above floor | 35.97 | 30.48 | 20.73 | 21.34 | 28.34 | 36.58 |

air moves around the ends of the sliding doors to return to the blowers. Near the floor adjacent to the walls, the velocity decreases due to the air escaping under the sliding doors. The velocity immediately upstream of the ceiling slots is high and downstream low due to the air exiting through the slots. At the end of the enclosure the velocities are low in the center due to the air mass hitting the blank wall of the simulated surgery room creating a back pressure.

3.1.3 Static Pressure Test

3.1.3.1 Test Objective - The objective of this test was to measure the pressure differential, if any, existing between the portable clean room enclosure and a simulated operating room. The purpose was to assist in determining the direction of air leakage and the need for sealing the enclosure ceiling light slots.

3.1.3.2 Test Equipment/Conditions - The portable clean room was completely assembled and positioned in a simulated surgery room. An inclined water manometer with a range of -2.54 to +2.54 cm (-1.0 to +1.0 inches) of water in 0.5 cm (0.2 inch) increments was used to measure the pressure.

3.1.3.3 Test Description - With the filter blowers and ventilation system blowers in operation, the pressure differential between the inside and outside of the enclosure within the simulated surgery room were recorded at several points along the enclosure walls and ceiling. In addition, the pressure differential

existing across the enclosure ceiling light slots was to be determined.

3.1.3.4 Test Results - Attempts to measure the pressure differential were unsuccessful in that the values were less than the readout capability of the manometer available (0.2 inches of water increments). The cross-sectional area available outside the enclosure for the air flow return to the blowers was observed to be approximately the same as the enclosure, therefore, the differential pressure should be near zero. The decision was made to abandon this test and rely upon the following smoke tests to determine air leakage flow direction.

3.1.4 Air Flow Pattern Test

3.1.4.1 Test Objective - The objective of this test was to evaluate the laminar air flow patterns within the enclosure when occupied by a simulated operating team and equipment.

3.1.4.2 Test Equipment/Conditions - The system was completely assembled in a simulated surgery room. An operating table and surgery room ceiling lights were simulated. A high concentration smoke generator was utilized to release a single point source of smoke at selected locations. Polaroid photographs were taken where possible to record air flow patterns.

3.1.4.3 Test Description - The system was operated and the enclosure occupied with test subjects representing a surgery team. The surgery room operating table and overhead ceiling lights were

simulated. A single point source stream of smoke was released immediately upstream of the object under consideration. The fog stream was positioned at several locations such that the stream impinged upon obstructions such as the personnel, table and ceiling lights. The stream was evaluated for possible detrimental flow patterns that may cause contamination to migrate to a patient surgery wound area.

3.1.4.4 Test Results - Smoke tests were performed as described above and the following observations were made:

a) Around large objects such as the table and surgery lights the smoke stream maintained a distance of approximately 20 cm (8 inches) from the object (see Figures 6 and 7).

b) From a point near the table surface, the smoke would rise, slightly turbulent. See Figure 7.

c) Around a person's body the smoke would become turbulent with an excursion of approximately 15 cm (6 inches).

d) From a point approximately 30 cm (1 foot) above the surface of the table and in line with the front of a person standing at the side of the table, the smoke went behind the person. See Figure 6.

e) Around small objects such as an arm, the smoke excursion was approximately 8 cm (3 inches).

f) From any point between the ceiling and approximately 30 cm (1 foot) down and upstream of the ceiling slots, the smoke

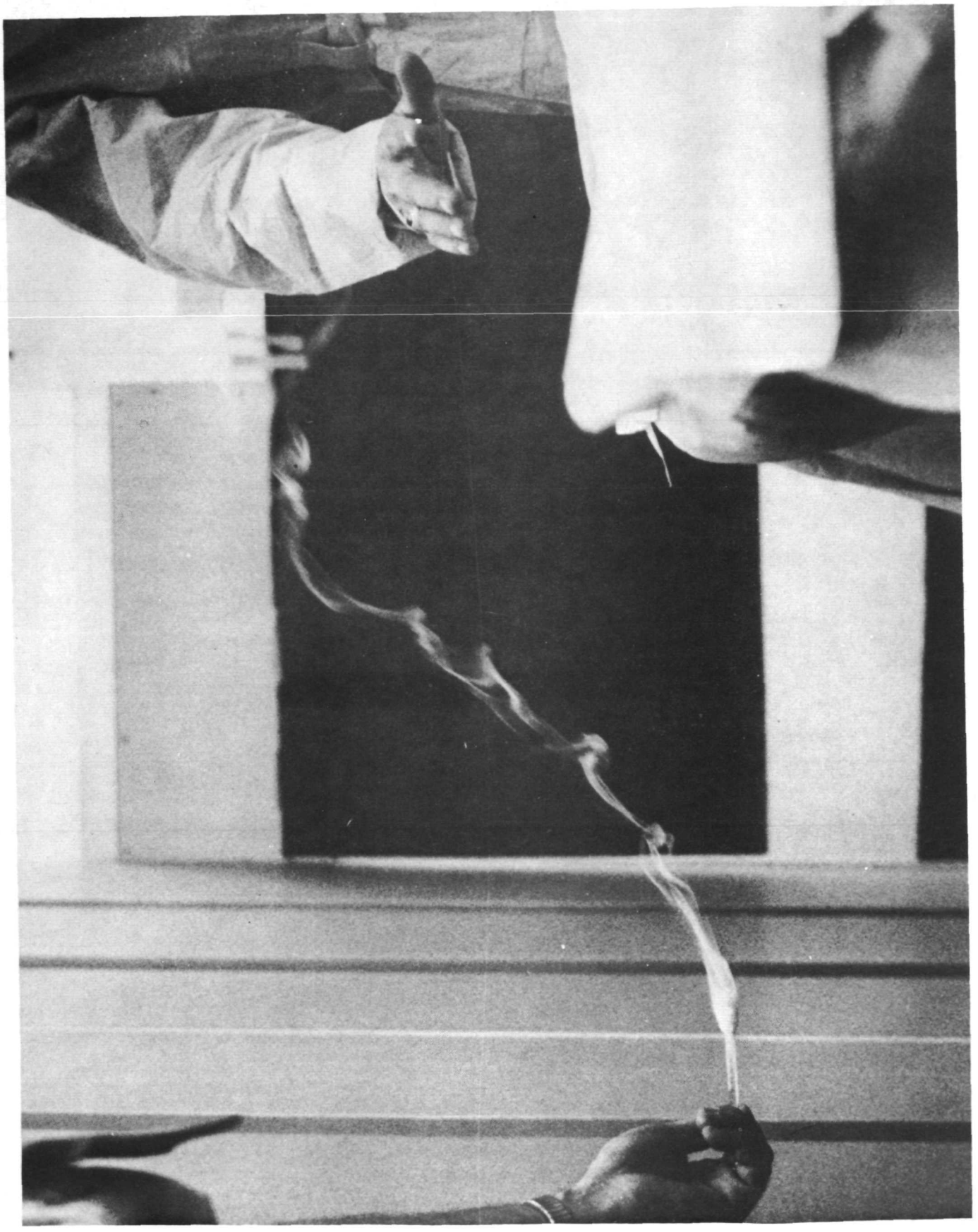
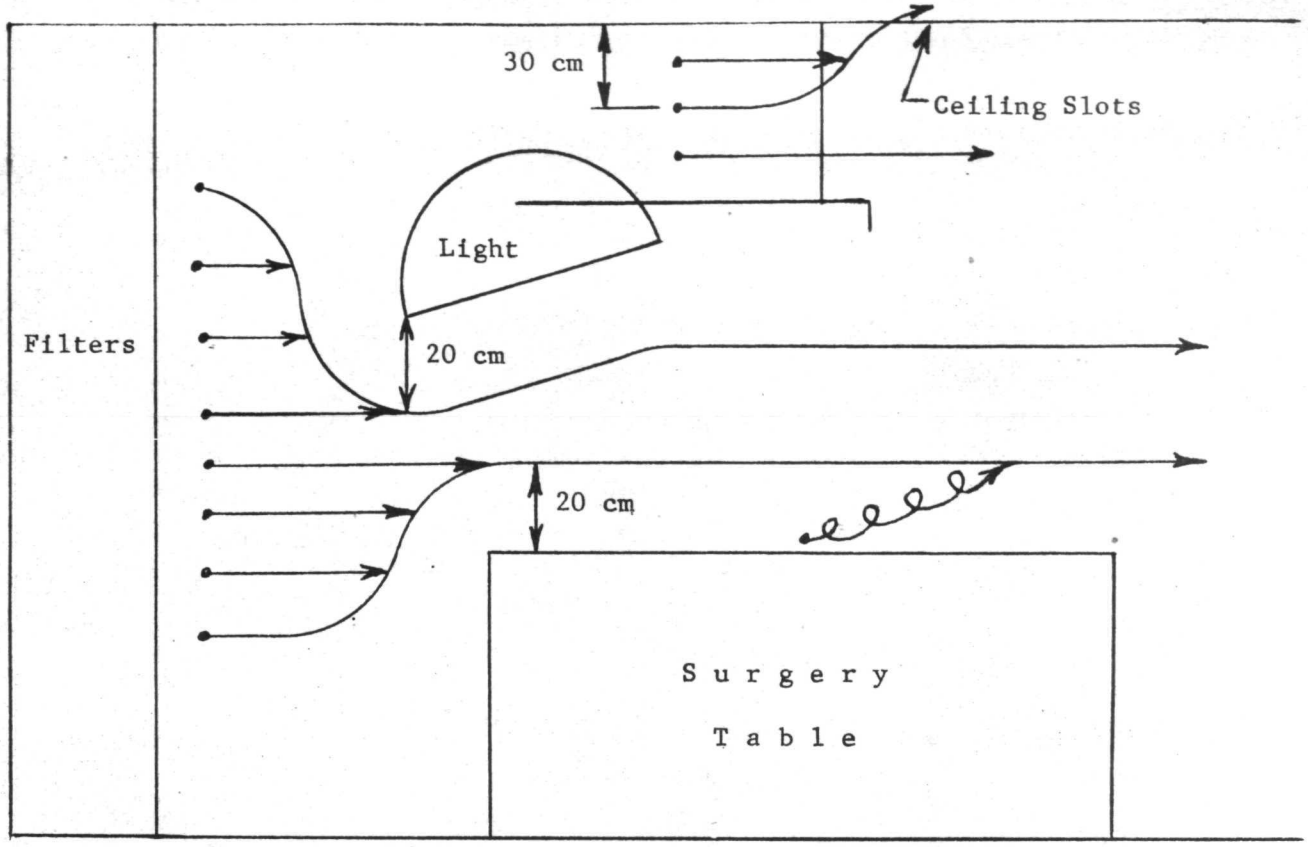
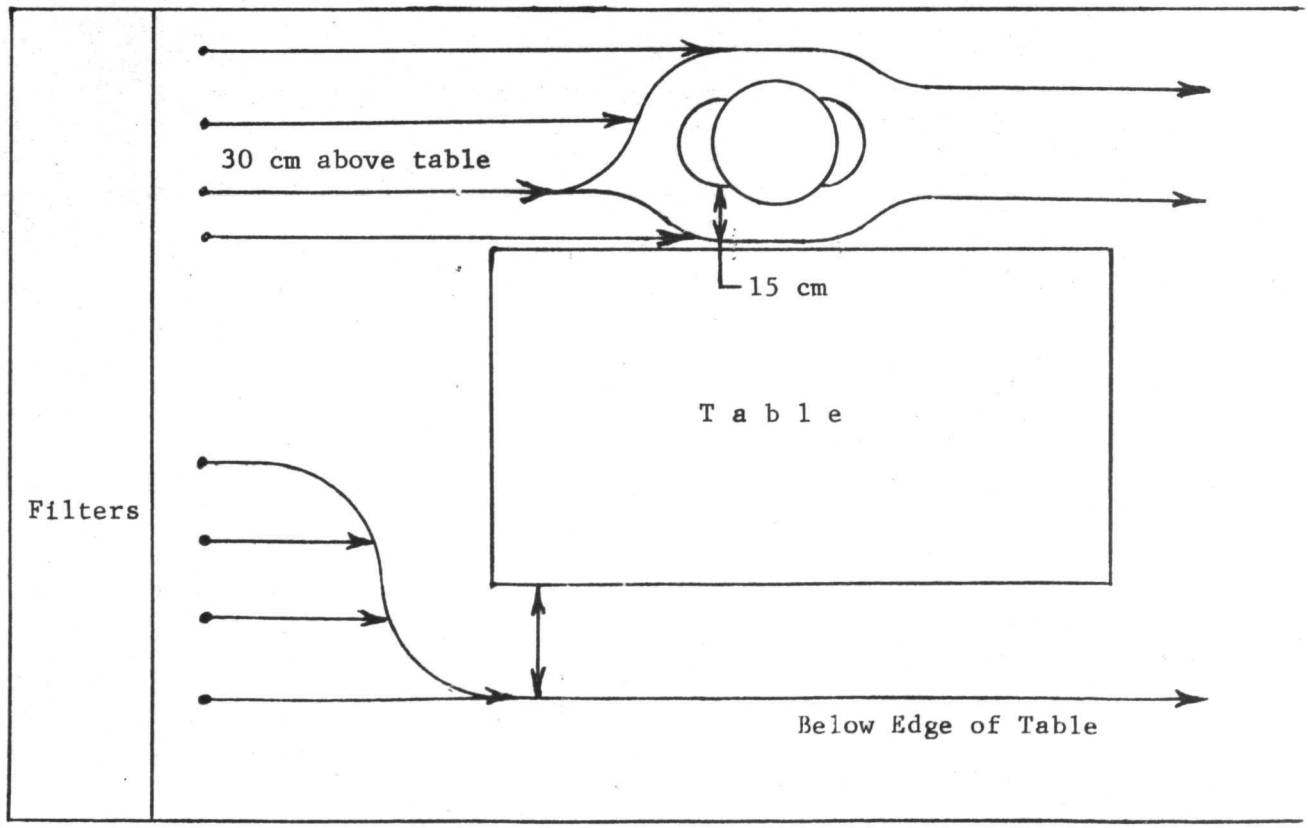


FIGURE 6 SMOKE PATTERN OVER TABLE

FIGURE 7 SMOKE PATTERNS AROUND OBJECTS




ELEVATION




PLAN

rises and exits through the ceiling slots.

g) Below table top level the smoke would travel parallel to the floor.

h) Air exits the enclosure around the sliding glass doors, under the sliding glass doors and around the edge of the ceiling.

i) No air leakage was observed in or out of the enclosure at the wall and ceiling joints.

It was concluded at the end of the test that there were not any air patterns that might be detrimental to a surgery operation. It is recommended that the following precautions be taken and included in the operating procedures:

a) Personnel should always stand at the side of the patient and avoid standing upstream of the table.

b) Equipment should not be placed in front of the filter face or upstream of the patient.

c) Passing of instruments across the table should be done 30 cm (1 foot) or more above or downstream of the wound incision.

It was also concluded that it is unnecessary to seal the ceiling slots.

3.1.5 Electrostatic Buildup Test

3.1.5.1 Test Objective - The objective is to evaluate the electrostatic buildup on the plexiglass walls of the enclosure.

3.1.5.2 Test Equipment/Conditions - The system was operated in a simulated surgery room. Two types of static meters were used

to measure the electrostatic buildup. A Sweeney Model SWE-1128 with a full-scale reading of ± 5 kilovolts was used to measure the voltage gradient of the air within the enclosure. A Sweeney Model SWE-1125 with a full scale equivalent to ± 6 volts and a green band of ± 3 volts was used to measure the buildup on the panels.

3.1.5.3 Test Description - The portable clean room was completely assembled in a simulated surgery room. The main filter blowers were operated for a continuous three hours. At the completion of the three hours, the electrostatic potential readings were taken at each of the plexiglass panels on the walls and ceiling of the enclosure and of the air within the enclosure. After installation in Saint Luke's, the readings of the enclosure air were repeated.

3.1.5.4 Test Results - All readings taken at each panel with the Model SWE-1125 were within the green band of ± 3 volts. Readings varied both positive and negative even on the same surface of a panel. Readings taken with the Model SWE-1128 15 cm (6 inches) away from the panels varied within a range of ± 1.3 kv with two exceptions. The inside surfaces of the upper left and lower right hinged wall panels both indicated spots registering a positive 3.3 kv.

These high readings were of concern for equipment usage in a hospital environment. It was felt that the high readings could be attributed to the fact that the test facility had an ungrounded

floor and system had been assembled and used for several weeks without any cleaning of panels.

After installation in Saint Luke's, the exterior surfaces of the system were thoroughly cleaned with antiseptic solutions. Approximately 48 hours later during the laminar flow certification tests and after the system had been operating for three hours, Model SWE-1128 readings were again taken. All readings registered zero.

3.1.6 Noise Level Test

3.1.5.1 Test Objective - The objective of this test was to measure the noise level within the enclosure.

3.1.5.2 Test Equipment/Conditions - The portable clean room was completely assembled in a simulated surgery room. The main filter blowers and ventilation blowers were all in operation. The sound was measured by a No. 2203 Bruel & Kjaer sound level meter which has an accuracy within the 20-30,000 cycle range of $\pm$ 1 db.

3.1.5.3 Test Description - Sound level readings were taken in several locations within the enclosure and also at the control panel on the outside. "A" scale, 500, 1000 and 2000 cycle readings were taken at an elevation of approximately 1.2 meters (4 feet). The design goal was for a maximum of 65 db at 500, 1000 and 2000 cycles.

3.1.5.4 Test Results - The sound level readings and locations are shown on Figure 8 Data Sheet. "A" scale readings were 70-71

FIGURE 8 DATA SHEET - NOISE LEVEL TEST

| Location & Type of Reading | Sound Level Reading, db | | |
|---|---|---|---|
| | 0.3 m (1 ft) From Left Wall | Center | 0.3 m (1 ft) From Right Wall |
| 0.6 m (2 ft) downstream of filter | | | |
| "A" scale | 71 | 70 | 71 |
| 500 cycle | 69 | 69 | 68 |
| 1000 cycle | 65 | 65 | 66 |
| 2000 cycle | 62 | 57 | 60 |
| 1.5 m (5 ft) downstream of filter | | | |
| "A" scale | 71 | 71 | 70 |
| 500 cycle | 70 | 69 | 68 |
| 1000 cycle | 66 | 67 | 66 |
| 2000 cycle | 62 | 58 | 57 |
| 3 m (10 ft) downstream of filter | | | |
| "A" scale | 70 | 70 | 70 |
| 500 cycle | 68 | 69 | 67 |
| 1000 cycle | 66 | 66 | 65 |
| 2000 cycle | 60 | 58 | 57 |
| Control Panel | | | |
| "A" scale | | 64 | |
| 500 cycle | | 61 | |
| 1000 cycle | | 56 | |
| 2000 cycle | | 48 | |

Note: All readings approximately 1.2 meters (4 ft) above floor.

within the enclosure and 64 at the control panel. 500, 1000 and 2000 cycle readings ranged from 57 db to 70 db within the enclosure and 48-61 db at the control. All readings are considered acceptable for the intended usage of the system.

3.2 Ventilation System Test

3.2.1 Test Objective - The objective of this test was to evaluate the ability of the ventilation system to deliver an adequate flow of air to the surgery team.

3.2.2 Test Equipment/Conditions - The system was operated in a simulated surgery room. Special equipment included:

a) A Beckman Infrared Model IR3-15A $CO_2$ analyzer capable of measuring 0-10% by volume $PCO_2$ within an accuracy of $\pm$ 5%.

b) An air mass flowmeter, Model DMF Technology/Versatronics Inc., capable of measuring 56-566 liters per minute (2-20 cubic feet per minute) with an accuracy of $\pm$0.5% was used to measure ventilation flowrates.

c) A laboratory type thermometer.

3.2.3 Test Description

a) With the system in full operation and test subjects suited in helmets and gowns, a matrix of measurements of air flow through each helmet umbilical was taken with one to six personnel using the ventilation system. The ventilation system control valves were in the full open position for each helmet in use. This established the maximum flowrate capability to each helmet with varying number of helmets being serviced.

b) With the left ventilation blower off, measurements were taken for one to six helmets on-line. This was repeated with the left blower on and right blower off. This established the minimum flowrate capability to each helmet in the contingency mode of a ventilation blower failure.

c) For the test subject in the above test that had the lowest flowrate, the condition was duplicated and the $PCO_2$ percentage was measured.

d) Using two test subjects with umbilical flowrates equal to the value when three helmets were on-line, the flowrate entering the top of each helmet was measured. The difference between umbilical and top of helmet flowrates was determined which is the amount of leakage around the shoulder pads and through the gowns. A thermometer was inserted through the gown in the area below the armpit and the temperature inside the gowns recorded.

e) Using the same test subjects, the subjects jogged in place for five minutes and temperature and $PCO_2$ recorded. Any comments with regard to head perspiration and fogging of helmet were noted.

f) Using the same test subjects, a shoulder pad was modified to provide an opening between the pad and subject's body. Tests noted in e) and f) above were repeated to determine any benefit of increasing the ventilation through the gown.

g) With only one helmet on-line, the umbilical flowrates for each of the valve positions noted on the control panel were

measured. This was repeated with all helmets on-line and measuring flowrates at the same umbilical for the valve positions. From this, the approximate percentage of flow for each valve position can be determined if a setting other than full open is desired.

3.2.4 Test Results - The results of the ventilation system tests are shown on Figure 9 Data Sheet. The mass flowmeter used for the helmet umbilical measurements had been calibrated just prior to the tests to read in standard liters per minute. Therefore, all flowrate values are for standard conditions of 1 atmosphere, 70°F, dry air. Results are as follows:

a) With both blowers in operation, the umbilical flowrates ranged from a single helmet only maximum of 357 L/min (12.6 CFM) to 212 L/min (7.5 CFM) minimum with all six helmets on line and all valves in the open position. The design value minimum of 226 L/min (8 CFM) with all helmets on line was attained by adjusting Helmet No. 1 and No. 6 valves to the 5 position with all other valves full open (the difference in flowrates helmet to helmet is due to the differences in subcircuit pressure drops).

b) In the contingency mode of one blower inoperative, the lowest flowrate recorded with all helmets on line was 135 L/min (4.8 CFM). This is above the required minimum of 113 L/min (4.0 CFM).

c) For the above low flowrate of 135 L/min, the $PCO_2$ level in the helmet was recorded as 1.1%. This was approximated from a reading range of 0.6-1.7% noted due to the breath to breath

FIGURE 9 DATA SHEET - VENTILATION SYSTEM TEST

| Max. & Min. Ventilation Valve Status<br>No. = Helmet (No.) Valve Setting<br>(c) = Closed<br>(o) = Open | 2 Blowers On<br>Flowrate, liters/min<br>Helmet Location | | | | | | Left Blower OFF<br>Right ON<br>Flowrate, liters/min<br>Helmet Location | | | | | | Right Blower OFF<br>Left On<br>Flowrate, liters/min<br>Helmet Location | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 1 | 2 | 3 | 4 | 5 | 6 | 1 | 2 | 3 | 4 | 5 | 6 |
| Each valve individually open, all others closed | 357 | 328 | 322 | 315 | 332 | 352 | 330 | 310 | 300 | 300 | 310 | 331 | 332 | 312 | 303 | 296 | 305 | 328 |
| 1(o), 2(o), 3(c), 4(c), 5(c), 6(c) | 330 | 300 | - | - | - | - | 278 | 255 | - | - | - | - | 285 | 262 | - | - | - | - |
| 1(o), 2(o), 3(o), 4(c), 5(c), 6(c) | 303 | 272 | 262 | - | - | - | 235 | 215 | 205 | - | - | - | 247 | 225 | 215 | - | - | - |
| 1(o), 2(o), 3(o), 4(o), 5(c), 6(c) | 282 | 252 | 242 | 265 | - | - | 205 | 182 | 172 | 203 | - | - | 212 | 196 | 185 | 202 | - | - |
| 1(o), 2(o), 3(o), 4(o), 5(o), 6(c) | 265 | 237 | 227 | 236 | 250 | - | 180 | 162 | 152 | 173 | 180 | - | 190 | 172 | 162 | 165 | 170 | - |
| All valves open | 250 | 227 | 212 | 212 | 222 | 226 | 165 | 143 | 136 | 145 | 152 | 165 | 170 | 160 | 148 | 135 | 142 | 155 |
| 1(o), 2(c), 3(o), 4(c), 5(o), 6(c) | 310 | - | 275 | - | 295 | - | 242 | - | 210 | - | 235 | - | 250 | - | 215 | - | 230 | - |
| 1(5), 2(o), 3(o), 4(o), 5(o), 6(5) | 228 | 228 | 226 | 227 | 227 | 226 | - | - | - | - | - | - | - | - | - | - | - | - |

Minimum ventilation flowrate 135 L/min $PCO_2$ 1.1% (0.6-1.7 range)

| Gown Ventilation Test Condition | Test Subject 1 | | | | | | Test Subject 2 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Umbilical Flowrate L/M | Top of Helmet Flowrate L/M | Flowrate Difference | Temp °F | Room Temp °F | $PCO_2$ | Umbilical Flowrate L/M | Top of Helmet Flowrate L/M | Flowrate Difference | Temp °F | Room Temp °F | $PCO_2$ |
| Unmodified Shoulder Pad | | | | | | | | | | | | |
| Prior to Jogging | 293 | 38 | 255 | 87 | 82 | 0.4 | 293 | 120 | 173 | 88 | 82 | 0.4 |
| After Jogging | | | | 89 | 82 | 1.2 | | | | 88 | 82 | 1.2 |
| Modified Shoulder Pad | | | | | | | | | | | | |
| Prior to Jogging | 293 | 43 | 250 | 85.5 | 82 | 0.3 | 293 | 71 | 222 | 85 | 82 | 0.4 |
| After Jogging | | | | 88 | 83 | 1.0 | | | | 85.5 | 82 | 1.1 |
| | (No Perspiration Noted) | | | | | | (Damp Forehead) | | | | | |

Valve Control - Helmet No. 1 valve position and flowrate, L/M:

| One Helmet Only | | | | All Valves Open | | | |
|---|---|---|---|---|---|---|---|
| Open 352 | 3 133 | Closed 0 | | Open 240 | 3 105 | Closed 0 | |
| 5 336 | 2 24 | | | 5 230 | 2 24 | | |
| 4 287 | 1 0 | | | 4 200 | 1 0 | | |

cycling of the meter. This was greater than the desired maximum of 0.75%, however, for all normal flowrates of 170 L/min (6.0 CFM) and above, the $PCO_2$ was measured at 0.4% or less.

d) Two test subjects were used to evaluate the effect of ventilation through the top of the helmet and through the gown. The umbilical flowrate was established at 293 L/min which was the average flowrate with three helmets on line (the normal number of the surgery team helmeted for the operations to be performed during the evaluation period). The air flow entering the top of the helmet was measured. The difference between the umbilical and top of helmet flowrates determined the amount of ventilation under the shoulder pad and through the gown. The $PCO_2$ inside the helmet and temperature inside the gown was measured.

The first test subject was physically small and the shoulder pad fit was relatively loose. The difference in flowrate was 255 L/min with 38 L/min entering the top of the helmet. The $PCO_2$ was 0.4% and the inside gown temperature was $87^{o}F$.

The second test subject had a good shoulder pad fit. The flowrate difference was 173 L/min with 120 L/min entering the top of the helmet. The $PCO_2$ was 0.4% and gown temperature $88^{o}F$.

e) The above test subjects were then asked to jog in place for five minutes. Temperature and $PCO_2$ were measured and signs of perspiration noted. The gown temperature increased to $89^{o}F$ for the first test subject and $88^{o}F$ for the second. $PCO_2$ increased to 1.2%

for both subjects. After jogging the second test subject had a damp forehead. Otherwise no signs of head or body perspiration on either subject was noted.

f) Tests d) and e) above were repeated with the same test subjects using a shoulder pad that had been modified to provide an opening between the shoulder pad and torso area. For the first test subject, the flowrate difference did not improve due to the shoulder pad fit. For the second test subject the flowrate difference increased to 222 L/min. In both cases, in the standing position, the gown temperature decreased 1.5°F and 3.0°F respectively. After jogging the temperature improvement was 1° and 2.5°F.

g) The flowrates for No. 1 helmet valve positions 1-6 were measured for conditions of: Helmet No. 1 only on line; and for all six helmets on line. Approximate percentage of full flow for each valve position was determined to be: open - 100%, 5 - 95%, 4 - 82%, 3 - 40%, 2 - 10%, 1 - 0%, and closed.

3.3 Human Factors Evaluation

3.3.1 Test Objective - The objective of this test was to evaluate the helmet, shoulder pad, harness, communications, and gowns from a human factors viewpoint with respect to comfort, fit, ease of donning and doffing, and operational usage.

3.3.2 Test Equipment/Conditions - Only system equipment was used for this test.

3.3.3 Test Description - Six test subjects were asked to don helmets, shoulder pads, headsets and gowns. The system was fully operated. The test subjects commented on the human factors considerations. In addition, the communications volume controls were adjusted to determine "normal" settings. Three subjects simulated an emergency mode of having to remove helmets in the event of ventilation or communication failure.

3.3.4 Test Results - The six test subjects were chosen to provide a range from small to large physical size. The human factors comments are summarized on Figure 10 Data Sheet. Figures 11 thru 14 show the donning and use of the shoulder pad, gown and helmet.

For the smaller personnel, a loose mate of the shoulders to the shoulder pad was noted, however, when properly strapped down with the harness, the stability and mobility was not affected. For the largest subject, tightness in the shoulders of the gown was noted.

Straight ahead visibility through the helmet was good although some distortion was noted in the lower portion where the material is thicker. The helmets could be readily removed in the simulated emergency. Some difficulty was encountered in installing the helmet ring under the clip at the rear of the shoulder pad, although with practice, it could be accomplished without undue strain.

FIGURE 10 DATA SHEET - HUMAN FACTORS EVALUATION

| CONSIDERATION | C O M M E N T | | | | | |
|---|---|---|---|---|---|---|
| Test Subject | 1 (MT) | 2 (MWB) | 3 (MB) | 4 (RC) | 5 (RS) | 6 (GP) |
| Chest Size | 44 | 38 | 39 | 38 | 40 | 52 |
| **Shoulder Pad & Harness** | | | | | | |
| Donning | No problem | No problem | No problem | No problem | No problem | Tilted glasses |
| Fit | Good | Good | Loose mate of pad | Loose mate of pad | Good | Snug fit |
| Comfort | Good | Good | Good | Good | Good | Good |
| Doffing | No problem | No problem | No problem | No problem | No problem | Some manipulation req'd to clear head |
| **Helmet** | | | | | | |
| Donning | No problem | No problem | Difficult to insert in ring clip | Difficult to insert in ring clip | No problem | Difficult to insert in ring clip |
| Fit | Good | Good | Good | Good | Good | Head close to top |
| Comfort | Good | Good | Good | Good | Good | Good |
| Visibility | No problem | Distortion in lower area noted | Good | Distortion in lower area noted | Good | Good |
| Doffing | No problem | No problem | Some tightness removing from ring clip | Some tightness removing from ring clip | Good | No problem |
| Emergency Doffing | Easily accompl. | - | Easily accompl. | - | - | Easily accompl. |
| **Gown** | | | | | | |
| Donning | No problem | No problem | No problem | No problem | No problem | Tight pull to snap |
| Fit | Good | Some looseness | Some looseness | Some looseness | Good | Tight in shoulder area |
| Comfort | Good | Good | Good | Good | Good | Good |
| Mobility of Subject | Good | Good | Good | Good | Good | Good |
| **Communications** | | | | | | |
| Headset Comfort | Good | Good, used glasses | Good | Good | Good | Good, used glasses |
| Earphone Setting | 5.0 | 5.0 | 4.0 | 4.5 | 5.0 | 5.0 |
| Microphone Setting | 3.0 | 3.0 | 2.5 | 2.5 | 3.0 | 3.0 |
| Ventilation Flow | Good, no problem breathing | Good | Noticed flow on top of head | Good | Good | Noticed flow on top of head |
| Noise | Helmet voice noise not objectionable | Helmet voice & ventilation noise noted, became adjusted | Not objectionable | Not objectionable | Not objectionable | Helmet voice & ventilation noise noted, not objectionable |

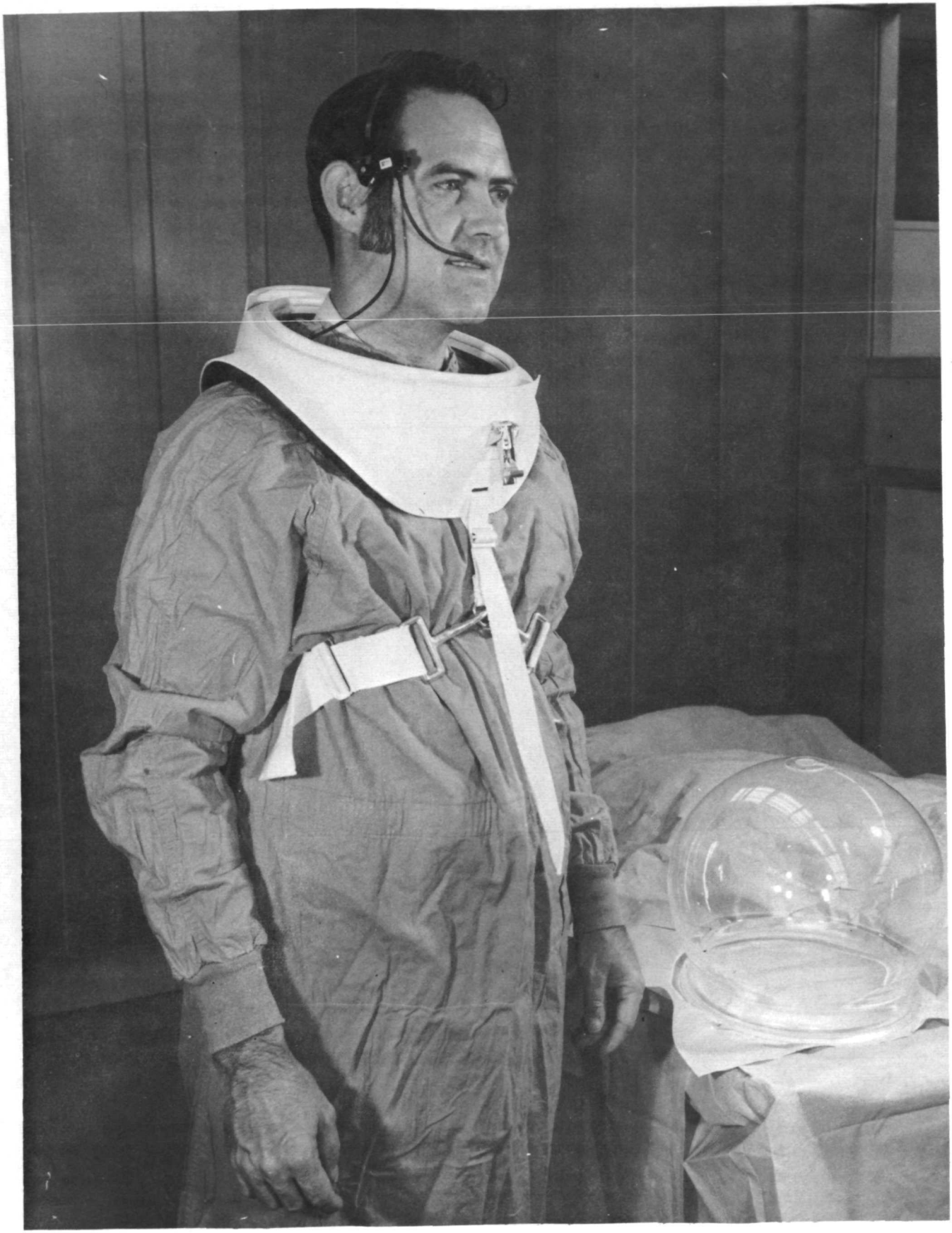


FIGURE 11 SHOULDER PAD DONNING, FRONT

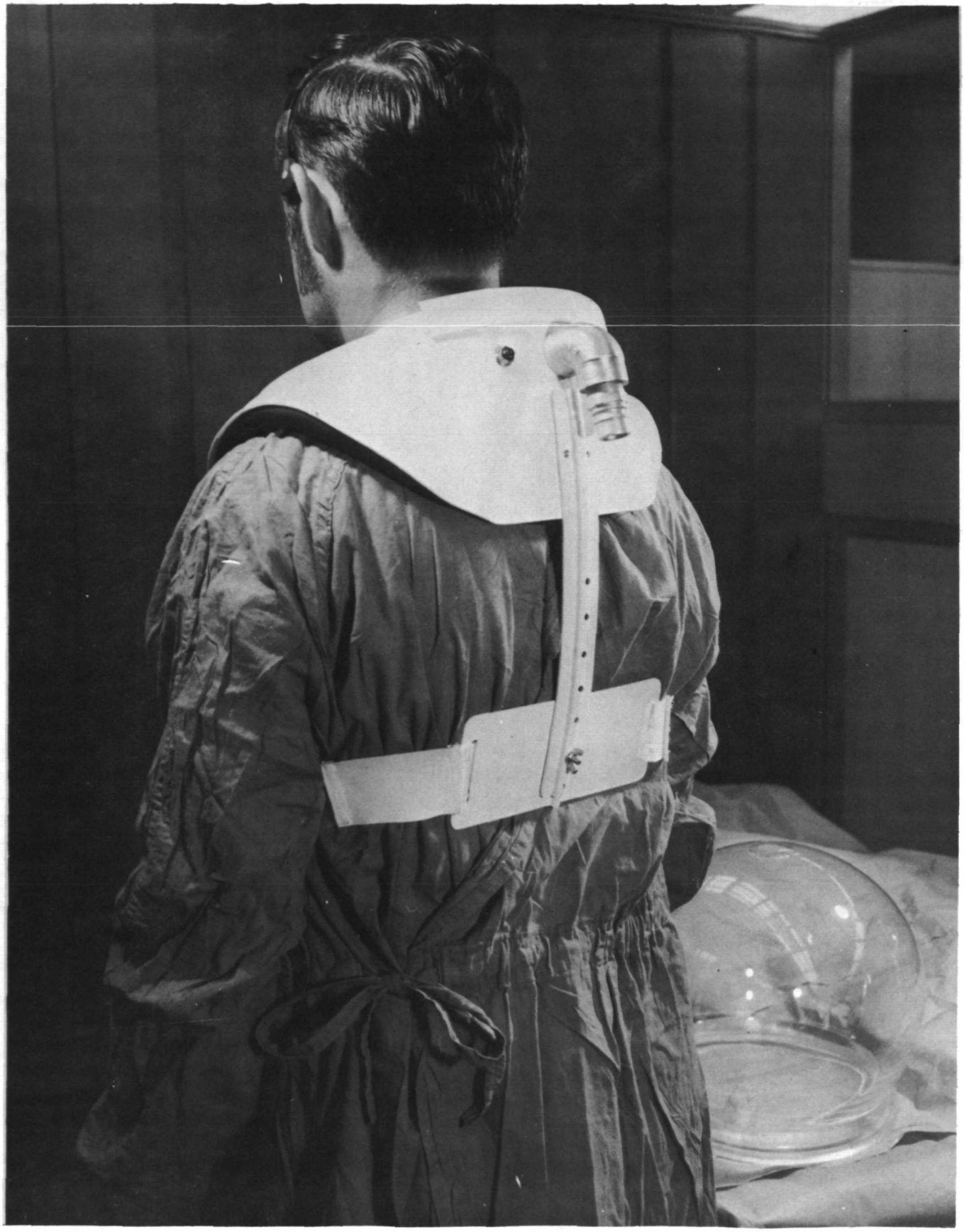


FIGURE 12 SHOULDER PAD DONNING, REAR

FIGURE 13 HELMET AND GOWN DONNING

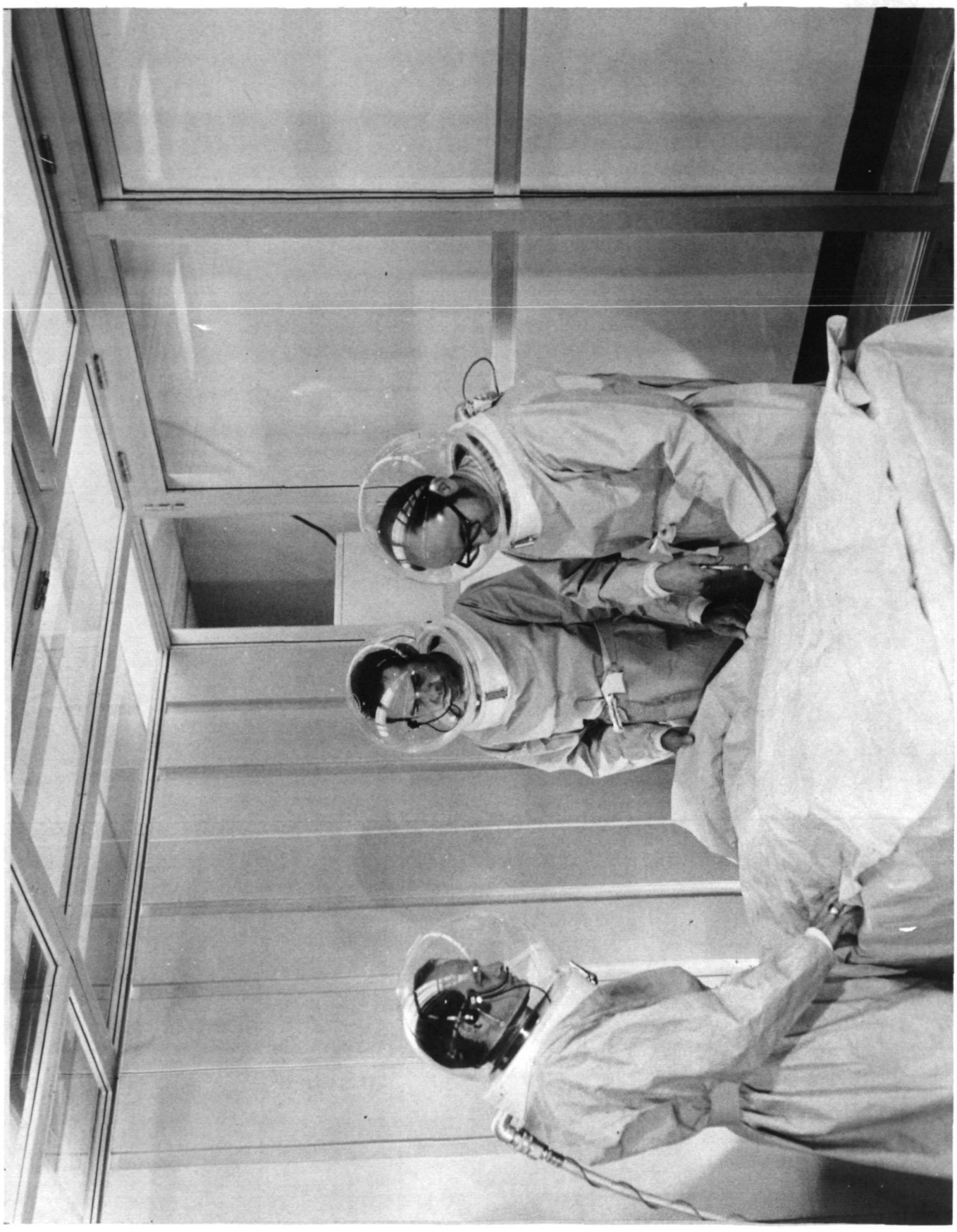


FIGURE 14 SURGERY TEAM SIMULATION

The ventilation flow through the top of the helmet was not objectionable. The noise of the air flow exit at the rear of the shoulder pad was noticeable but not excessive since all normal sounds outside the helmet cannot be heard.

The most notable effect of wearing the helmets was the inside sound when the person spoke. The sound is trapped in the helmet and at first seemed loud. Once the person was aware of the effect and became accustomed to it, the noise was not as noticeable or considered objectionable. Previous experiments had been performed using padded earphones and/or foam padding in the rear of the helmets without a significant noise reduction. In each case proper fit and mate of the gown to the shoulder pad was verified. Except for the tightness in the shoulders of the largest subject previously noted, the gowns did not restrict movements. With subjects completely attired, mobility to each end of the table with umbilicals attached was verified.

The communications system volume controls were adjusted for each test subject. The "normal" settings established to be included in the operating procedure were: helmet microphones - 3, helmet earphones - 5, outside microphones - 5, and outside speakers - 5.

### 3.4 Electrical Subsystem Tests

3.4.1 Test Objective - The objective of this test was to measure the operating amperages of the electrical subsystems under

normal operating loads and to determine the ground leakage current if any.

3.4.2 Test Equipment/Conditions - All system electrical equipment were operated and a voltmeter, amp-probe, ammeter and milliammeter used to obtain measurements.

3.4.3 Test Description - The filter blowers, ventilation system blowers and communications system were activated. Ventilation umbilicals and headsets were connected to all helmet locations. The operating voltages, amperages and ground leakage for each subsystem were measured and recorded.

3.4.4 Test Results - The operating voltages and amperages are shown on Figure 15 Data Sheet. In all cases ground leakage was not detected on a 0-1 milliammeter scale.

FIGURE 15 DATA SHEET - OPERATING VOLTAGES AND AMPERAGES

| Subsystem | Volts | Amps |
|---|---|---|
| Left Filter Blower | 207.5 | 8.7 |
| Right Filter Blower | 207.5 | 8.7 |
| Left Ventilation Blower (TB-1) | 112.5 | 2.4 |
| Right Ventilation Blower (TB-1) | 112.5 | 2.4 |
| Communications (TB-1) | 112.5 | 198 MA |
| Mixer A (TB-2) | 112.5 | 10.2 MA |
| Mixer B (TB-2) | 112.5 | 10.2 MA |
| Amplifier (TB-2) | 112.5 | 178 MA |
| 115 Volt Connector | 112.5 | 198 MA |

3.5 Material Compatibility Test

3.5.1 Test Objective - The objective of this test was to evaluate the compatibility of materials used in the system with sterilization and cleaning procedures used by St. Luke's Hospital.

3.5.2 Test Equipment/Conditions - St. Luke's sterilization equipment was used for items that may be sterilized. Solutions of Dicrobe, distilled water and 70% isoprople alcohol were required.

3.5.3 Test Description - Each of the type of materials used on the shoulder pad, harness, umbilical, helmet and enclosure that could be affected were subjected to antiseptic cleaning fluids and/or sterilization procedures that might be used by St. Luke's. Any detrimental effects were noted.

a) Samples of Kydex (shoulder pad), Armaflex (gasket), PVC hose (umbilical), PVC fitting (valves and plumbing) and plexiglass (helmet and walls) were swabbed daily, five days a week for one month with Dicrobe only.

b) Additional samples, following the same procedure, were cleaned with Dicrobe followed by a distilled water rinse and a 70% isopropyl alcohol rinse.

c) Samples of plexiglass and PVC hose were cleaned with Dicrobe only once a week for one month.

d) Harness webbing and latch hardware were subjected to steam and gas sterilization at St. Luke's Hospital.

3.5.4 Test Results - After one month application of the cleaning fluid procedures noted, none of the materials showed any signs of detrimental effects. Steam sterilization caused corrosion of the harness hardware. Gas sterilization did not affect the harness or hardware.

For the operating procedures, the Dicrobe solution only will be recommended for all surfaces except the plexiglass and harness. Even though detrimental effects were not noted in this test, the cleaning procedures for the helmets will reflect the three solution rinse at the recommendation of the Dicrobe manufacturer. The harness will be gas sterilized.

## 4.0 CONCLUSIONS AND RECOMMENDATIONS

As a result of the development tests performed, the following conclusions and recommendations are made:

### 4.1 Conclusions

a) The system as designed will perform the functions required for its intended use.

b) The portable clean room can be assembled, collapsed, relocated, disassembled, and transferred by two personnel except for filter module erection and de-erection which requires four personnel in reasonable time periods.

c) Laminar air flow velocities meet Federal Standard 209a and air flow patterns are not detrimental to surgery usage. Enclosure ceiling slots do not require sealing.

d) Electrostatic buildup on the plexiglass panels of the enclosure does not occur in the hospital environment.

e) The sound level within the enclosure is acceptable.

f) Helmet umbilical flowrates provide adequate ventilation to surgery team members and $PCO_2$ levels are acceptable.

g) From a human factors standpoint, the shoulder pad, helmet and gown are acceptable and the surgery team can adequately communicate when fully attired.

h) The materials used in the system are compatible with hospital sterilization and cleaning procedures.

4.2 Recommendations

a) Future design improvements should include wrench flats on the caster stems.

b) Improvement could be made in reducing the forces necessary to install the helmet ring under the rear shoulder pad clip.

c) Future helmet fabrication should consider alternate methods to reduce the distortion in the lower area.

d) If, during usage, the surgery team members desire additional ventilation through the gowns, modify the shoulder pads by removing a portion of the gasket.