EXPERIMENTAL SYSTEM FOR THE
CONTROL OF SURGICALLY INDUCED INFECTIONS

DEVELOPMENT TEST PROCEDURES
D203613-006
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CONTROL OF SURGICALLY INDUCED INFECTIONS

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D203613-006

CONTRACT NASW-2210

1 October 1971

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This document was prepared in accordance with the requirements of Contract NASW-2210, for Headquarters, National Aeronautics and Space Administration. This document defines the development test procedures to be followed by the Martin Marietta Corporation during the development testing of the experimental system developed and built in performance of the contract requirements.
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1.0 **SCOPE**

This document describes in detail the development tests to be performed on the Experimental System for the Control of Surgically Induced Infections as defined by MCR-71-208 Development Test Plan. The objective of each test will be defined, test equipment and test conditions will be identified and a test description and procedures outlined. All development tests will be performed at the Martin Marietta Corporation facility, Cold Flow Cell T-6.

2.0 **APPLICABLE DOCUMENTS**

The following documents form a part of this document to the extent referenced herein. Exceptions or modifications to the referenced documents contained herein take precedence over the referenced document.

Federal Standard No. 209a, Clean Room and Work Station Requirements, Controlled Environment.

MCR-71-208, Development Test Plan for the Experimental System for the Control of Surgically Induced Infections.

3.0 **DEVELOPMENT TESTS**

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 shall be to evaluate the physical design of the portable clean room.
The test shall 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 is to be performed in a room that simulates the St. Luke's surgery room size and volume. The surgery room doors and hallway shall also be simulated. Special tools and equipment required are 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 shall be fully assembled at the start of the test. Utilizing two personnel, the enclosure shall then be collapsed into the stored configuration. The stored envelope dimensions shall be measured.

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

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

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

For each of the above tests the time duration for each operation shall be noted on the data sheet provided.

3.1.1.4 Test Procedure

3.1.1.4.1 Collapsability

a) At the start of this test the portable clean room shall be in the fully assembled condition.

b) Start stop watch.

c) Disconnect power cables.

d) Using allen wrench tool provided, unlatch and remove outer center ceiling panel.

e) Store panel in the storage location provided at the rear of the left filter module.

f) Unlatch and lower left and right outer ceiling panels.

g) Move right and left sliding wall panels into retracted position.

h) Unlatch right and left upper beams and rotate 180 degrees into stowed position.
i) Unlatch and lower right and left center ceiling panels.

j) Disconnect right and left blower tower modules and position inside filter module-enclosure area.

k) Swing right and left wall assemblies 90 degrees into stowage position.

l) Record time duration. Record maximum envelope dimensions.

3.1.1.4.2 Portability

a) Open wall assemblies and remove blower tower modules.

b) Lower filter module and wall casters until the entire assembly is raised approximately 1/2 centimeter from the floor.

c) Close right and left wall assemblies.

d) Move the entire assembly approximately 2 meters (6 feet).

e) Open wall assemblies.

f) Position blower tower modules inside storage area.

g) Close right and left wall assemblies.

h) Record time duration. Record the number of personnel required to perform the above procedures.

3.1.1.4.3 Disassembly

a) Open wall assemblies.

b) Remove blower tower modules.

c) Remove protective screens from filter modules.

d) Remove HEPA filters. Care shall be taken not to damage filters.
e) Disconnect communications cable at the bottom center of filter modules.

f) Disconnect power cable between filter modules at the top of the units.

g) Close wall assemblies and disconnect ventilation lines and communications cables at hinge point.

h) Remove sliding wall panels.

i) Open wall assemblies.

j) Using hammer and screwdriver, remove hinge pins from the four folding ceiling panels.

k) Remove hinge pins from folding wall assemblies.

l) Unlatch fixed ceiling panels.

m) Remove ceiling panel stored at rear of filter module.

n) Unlatch filter modules.

o) Using four personnel, de-erect filter modules by tilting backwards.

p) Turn filter modules onto filter plenum joint side and place on four-wheeled dolly.

q) Record time duration.

3.1.1.4.4 Transfer

a) Simulate transferring the system to another room. Transfer the largest section which is the filter module with attached walls through a simulated St. Luke's surgery room doorway and hallway and verify clearance.
3.1.1.4.5 Assembly

a) With the system completely dismantled, assemble the system utilizing four personnel and recording the time duration.

b) Erect the filter modules. During this step, measure the maximum dimension from the floor to the highest point on the assembly required for erection.

c) Position filter modules and latch together.

d) Latch fixed ceiling panels together.

e) Connect power cable connecting the two filter modules.

f) Connect communications cable at the bottom center of the filter modules.

g) Erect wall assemblies and install hinge pins.

h) Close wall assemblies and install sliding glass panels.

i) Connect ventilation lines and communication cables at the hinge joints.

j) Open wall assemblies.

k) Raise center ceiling panels and latch together and to fixed panels.

m) Rotate upper beams 180° and latch into position.

n) Install outer ceiling panels and hinge pins.

o) Raise outer ceiling panels and latch into position.

p) Install outer center ceiling panel and latch into position.

q) Install blower tower modules on each side.
r) Install HEPA filters and protective screens.
s) Verify all circuit breakers and switches are in the OFF position.
t) Plug three power cables into facility outlets.
u) Record time duration.

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 will be assessed during this test. For the purpose of this test laminar flow will be defined as that air flow in which the entire body of air 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 area of the exit to within 2.54 centimeters (1 inch) of the containment surfaces.

3.1.2.2 Test Equipment/Conditions - The equipment required to perform this test includes the Portable Clean Room and a simulated surgery room. The Portable Clean Room shall be in the assembled condition and the simulated surgery room shall have all equipment removed from the area of the portable clean room enclosure. An air velocity meter capable of measuring 23-32 meters per minute (90 + 15 ft per minute) within an accuracy of ± 5% is required.
DATA SHEET 1
ASSEMBLY, COLLAPSABILITY, PORTABILITY & STORAGE TEST

<table>
<thead>
<tr>
<th>Task</th>
<th>Elapsed Time (min)</th>
<th>No. of Personnel</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1.1.4.1 Collapsability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1.1.4.2 Portability</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1.1.4.3 Disassembly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1.1.4.5 Assembly</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PLAN

ELEVATION

STORAGE DIMENSIONS

ERCEPTION DIMENSION

FILTER
MODULE &
FIXED WALL
3.1.2.3 Test Description - With the system assembled in a simulated surgery room, the main filter blowers and ventilation blowers shall be operated. Air velocity measurements shall be taken at selected locations throughout the portable clean room enclosure. If necessary, the filter blowers shall be adjusted to attain the required air velocity value of 27.45 plus or minus 6.10 meters per minute.

3.1.2.4 Test Procedures
   a) Start HEPA filter blowers.
   b) Start ventilation system blowers.
   c) Using the air velocity meter, record velocity measurements at each test position noted on Data Sheet 2.
   d) If the air velocities do not meet the required value, adjust filter blower pulleys to attain the required value of 23-32 meters per minute.
   e) Stop ventilation system blowers.
   f) Stop HEPA filter blowers.

3.1.3 Static Pressure Test

3.1.3.1 Test Objective - The objective of this test is to measure the pressure differential, if any, existing between the portable clean room enclosure and a simulated operating room. The purpose is to assist in determining the need for sealing the enclosure ceiling light slots.
### DATA SHEET 2 RATE OF LAMINAR FLOW

<table>
<thead>
<tr>
<th>Location</th>
<th>2.54 cm (1 inch) from Left Side</th>
<th>Center</th>
<th>2.54 cm (1 inch) from Right Side</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ft/min m/min ft/min m/min ft/min m/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.6 meters (2 ft) downstream of filter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.3 meters (1 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.9 meters (3 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8 meters (6 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5 meters (5 ft) downstream of filter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.3 meters (1 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.9 meters (3 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8 meters (6 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 meters (10 ft) downstream of filter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.3 meters (1 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.9 meters (3 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8 meters (6 ft) above floor</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Low Reading

High Reading
3.1.3.2 **Test Equipment/Conditions** - The portable clean room shall be 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 inch) of water in 0.5 cm (0.2 inch) increments shall be 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 of the enclosure and the ambient simulated surgery room shall be recorded at several points along the enclosure walls and ceiling. In addition, the pressure differential existing across the enclosure ceiling light slots shall be determined.

3.1.3.4 **Test Procedure**

a) Start HEPA filter blowers.

b) Start ventilation system blowers.

c) Measure and record the pressures for each location shown on Data Sheet 3.

d) Stop ventilation system blowers.

e) Stop HEPA filter blowers.

3.1.4 **Air Flow Pattern Test**

3.1.4.1 **Test Objective** - The objective of this test is to evaluate the laminar air flow patterns within the enclosure when occupied by a simulated operating team and equipment.
### DATA SHEET 3  STATIC PRESSURE TEST

<table>
<thead>
<tr>
<th>Location</th>
<th>2.54 cm (1 inch) from side walls or ceiling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Left Wall</td>
</tr>
<tr>
<td>0.6 meters (2 ft) downstream of filter</td>
<td>.</td>
</tr>
<tr>
<td>0.3 meters (1 ft) above floor</td>
<td></td>
</tr>
<tr>
<td>0.9 meters (3 ft) above floor</td>
<td></td>
</tr>
<tr>
<td>1.8 meters (6 ft) above floor</td>
<td></td>
</tr>
<tr>
<td>1.5 meters (5 ft) downstream of filter</td>
<td></td>
</tr>
<tr>
<td>0.3 meters (1 ft) above floor</td>
<td></td>
</tr>
<tr>
<td>0.9 meters (3 ft) above floor</td>
<td></td>
</tr>
<tr>
<td>1.8 meters (6 ft) above floor</td>
<td></td>
</tr>
<tr>
<td>3 meters (10 ft) downstream of filter</td>
<td></td>
</tr>
<tr>
<td>0.3 meters (1 ft) above floor</td>
<td></td>
</tr>
<tr>
<td>0.9 meters (3 ft) above floor</td>
<td></td>
</tr>
<tr>
<td>1.8 meters (6 ft) above floor</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ceiling Slots</th>
<th>2.54 cm (1 inch) from ceiling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Left Slot</td>
</tr>
<tr>
<td>15 cm (6 inches) upstream Center of Slot</td>
<td></td>
</tr>
<tr>
<td>15 cm (6 inches) downstream</td>
<td></td>
</tr>
</tbody>
</table>
3.1.4.2 **Test Equipment/Conditions** - The system shall be completely assembled in a simulated surgery room. An operating table and surgery room ceiling lights shall be simulated. A high concentration smoke or fog generator shall be utilized to release a single point source of fog at selected locations. Photographs shall be taken where possible to record air flow patterns.

3.1.4.3 **Test Description** - The system shall be operated with a group of four test subjects representing a surgery team. The surgery room operating table and overhead ceiling lights shall be simulated. A single point source stream of fog shall be released immediately downstream of the filter face. The fog stream shall be positioned at several locations such that the stream impinges upon obstructions such as the personnel, table and ceiling lights. The stream shall be evaluated for possible detrimental flow patterns that may cause contamination to migrate to a patient surgery wound area.

3.1.4.4 **Test Procedure**

a) Four personnel shall don shoulder pads, helmets and gowns.

b) With the system in operation, position the test subjects around a simulated surgery room table.

c) Locate the simulated overhead surgery lights into normal position for surgery.
d) Start fog generator.

e) Locate fog generator such that the stream impinges on one of the overhead lights. Move fog generator as necessary to evaluate the flow pattern around the light.

f) Record and/or photograph the flow pattern.

g) Repeat the above procedure for personnel and the surgery table.

h) For each of the above cases, attempt to determine the approximate dimension of the non-laminar flow pattern around an object.

i) Note any possible detrimental flow pattern conditions.

j) Stop fog generator.

k) Remove helmets.

l) Shut down system.

m) Remove shoulder pads and gowns.

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 shall be operated in a simulated surgery room. A static meter with a capability of ± 5 kilovolts shall be used to measure the electrostatic buildup.

3.1.5.3 Test Description - The portable clean room shall be completely assembled in a simulated surgery room. The main
filter blowers shall be operated for a continuous three hours. At the completion of the three hours, the electrostatic potential shall be measured at each of the plexiglass panels on the walls and ceiling of the enclosure.

3.1.5.4 Test Procedure

a) Activate the filter blower modules.

b) Allow blowers to run for three hours. (Note: this test may be run concurrent with other tests).

c) Measure the electrostatic potential at each plexiglass panel on the walls and ceiling of the enclosure. Record on Data Sheet 4.

d) Secure system.

3.2 Ventilation System Test

3.2.1 Test Objective - The objective of this test shall be 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 shall be operated in a simulated surgery room. Special equipment includes:

a) A CO₂ analyzer capable of measuring 0-1.0% by volume PCO₂ within an accuracy of ± 5%.

b) An air flowmeter capable of measuring 56-566 liters per minute (2-20 cubic feet per minute) within an accuracy of ± 5%.

c) A laboratory type thermometer.
### DATA SHEET 4 ELECTROSTATIC BUILDUP

#### LEFT WALL

<table>
<thead>
<tr>
<th>Inside</th>
<th>Inside</th>
<th>Inside</th>
<th>Control Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside</td>
<td>Outside</td>
<td>Outside</td>
<td>Control Panel</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### RIGHT WALL

<table>
<thead>
<tr>
<th>Inside</th>
<th>Inside</th>
<th>Inside</th>
<th>Inside</th>
<th>Inside</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside</td>
<td>Outside</td>
<td>Outside</td>
<td>Outside</td>
<td>Outside</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### CEILING

<table>
<thead>
<tr>
<th>Inside</th>
<th>Inside</th>
<th>Inside</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside</td>
<td>Outside</td>
<td>Outside</td>
</tr>
</tbody>
</table>
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 shall be taken with one to six personnel using the ventilation system. The ventilation system control valves will be in the full open position for each helmet in use. This will establish the maximum flowrate capability to each helmet with varying number of helmets being serviced.

b) Turn off the left ventilation blower and record measurements for one to six helmets on-line. Repeat with the left blower on and right blower off. This will establish 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, duplicate the condition and measure the PCO₂ percentage to verify below 0.75%.

d) Using two test subjects with umbilical flowrates equal to the value when three helmets were on-line, measure the flowrate entering the top of each helmet. Record the difference between umbilical and top of helmet flowrates. This is the amount of leakage around the shoulder pads and through the gowns. Also record the temperature inside the gowns.
e) Using the same test subjects, have the subjects jog in place for five minutes and record temperature and PCO$_2$. Note any comments with regard to head perspiration and fogging of helmet.

f) Using the same test subjects with a shoulder pad modified to provide an opening between the helmet and subject's body, repeat the tests noted in e) and f) above. This will determine any benefit of increasing the ventilation through the gown.

g) With one helmet on-line, measure the umbilical flowrates for each of the valve positions noted on the control panel. From this, the percentage of flow for each valve position can be determined if a setting other than full open is desired.

3.2.4 Test Procedure

3.2.4.1 Maximum Ventilation

a) Activate filter blowers, ventilation blowers and communications system.

b) Suit six test subjects in shoulder pads, helmets and gowns and connect umbilicals.

c) By alternately opening and closing valves and relocating the air flowmeter in the umbilical lines, record the flowrates for each helmet condition noted on Data Sheet 5.

3.2.4.2 Minimum Ventilation

a) Turn left ventilation blower off.

b) Repeat step 3.2.4.1.c.
### DATA SHEET 5 VENTILATION SYSTEM TEST

<table>
<thead>
<tr>
<th>Max. &amp; Min. Ventilation Valve Status</th>
<th>2 Blowers On</th>
<th>Left Blower OFF</th>
<th>Right Blower OFF</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. = Helmet</td>
<td>Flowrate, liters/min</td>
<td>Right ON</td>
<td>Left ON</td>
</tr>
<tr>
<td>(c) = Closed</td>
<td>Helmet Location</td>
<td>Flowrate, liters/min</td>
<td>Flowrate, liters/min</td>
</tr>
<tr>
<td>(o) = Open</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Each valve individually open, all others closed</td>
<td>1(o), 2(o), 3(c), 4(c), 5(c), 6(c)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1(1), 2(o), 3(o), 4(c), 5(c), 6(c)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1(o), 2(o), 3(o), 4(o), 5(c), 6(c)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1(o), 2(o), 3(o), 4(c), 5(o), 6(c)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All valves open</td>
<td>1(o), 2(c), 3(o), 4(c), 5(o), 6(c)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Minimum ventilation flowrate** ___________________________  

<table>
<thead>
<tr>
<th>Valve Control</th>
<th>Test Subject 1</th>
<th>Test Subject 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helmet No. 1 valve position and flowrate, L/M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

**PCO₂**
c) Turn left ventilation blower on and right ventilation blower off.

d) Repeat step 3.2.4.1.c.

3.2.4.3 Minimum Ventilation PCO₂ Level
a) Duplicate the lowest reading obtained in the above test.

b) Measure the PCO₂ level inside the helmet approximately 7.6 centimeters (3 inches) from the test subject's mouth.

3.2.4.4 Gown Ventilation
a) Using one test subject, install a thermometer in the gown. Between the waist and arm pit, cut a slit and insert the thermometer. Using tape and small pieces of cardboard, attach the thermometer such that it is spaced between the gown and subject's body approximately 2.54 centimeters (1 inch). The end of the thermometer shall protrude enough to be read externally.

b) Regulate the umbilical flowrate to equal that obtained during 3.2.4.1 when three helmets were on-line.

c) Measure the flowrate entering the top of the helmet and record on Data Sheet 5.

d) Record the difference between the two flowrates.

e) Record the gown temperature and room temperature.

f) Have the test subject jog in place for five minutes.

g) Immediately record temperature and PCO₂ level.

h) Note any comments with respect to head perspiration and helmet fogging.
i) Remove helmet, gown and shoulder pad.

j) Using a prototype shoulder pad, remove a 2.54 centimeter (1 inch) section of gasket at the front of the shoulder pad.

k) Have the same test subject don the modified shoulder pad and gown.

l) Repeat steps b) thru i).

m) Repeat steps a) thru l) with a second test subject.

3.2.4.5 Valve Control

a) Connect a test subject with helmet, shoulder pad and gown to Helmet No. 1 position.

b) Close all helmet ventilation system valves.

c) Measure the umbilical flowrate for each valve position marked on the control panel for Helmet No. 1 and record on Data Sheet 4.

d) Disconnect test subject and remove helmet equipment.

e) Secure system.

3.3 Human Factors Evaluation

3.3.1 Test Objective - The objective of this test is 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 shall be used for this test.
3.3.3 **Test Description** - Six test subjects shall don helmets, shoulder pads, headsets and gowns. The system shall be fully operated. The test subjects shall comment on the human factors considerations. This test may be run concurrently with Para. 3.2, Ventilation System Test. In addition, the communications volume controls shall be adjusted to determine "normal" settings. Three subjects shall simulate an emergency mode of having to remove helmets in the event of ventilation or communication failure.

3.3.4 **Test Procedures**

a) Suit six test subjects in helmets, shoulder pads, headsets and gowns.

b) Activate the filter blower, ventilation and communication systems.

c) Subjects shall comment on the considerations noted on Data Sheet 6.

d) Individually adjust each microphone, earphone and speaker volume controls to the test subject's desired levels. Record the final volume control settings.

e) Three subjects shall simulate an emergency condition and remove helmets. Note any difficulties with helmet removal.

f) Remove helmet and gown equipment.

g) Secure system.
<table>
<thead>
<tr>
<th>Consideration</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shoulder Pad &amp; Harness</strong></td>
<td></td>
</tr>
<tr>
<td>Donning</td>
<td></td>
</tr>
<tr>
<td>Fit</td>
<td></td>
</tr>
<tr>
<td>Comfort</td>
<td></td>
</tr>
<tr>
<td>Doffing</td>
<td></td>
</tr>
<tr>
<td><strong>Helmet</strong></td>
<td></td>
</tr>
<tr>
<td>Donning</td>
<td></td>
</tr>
<tr>
<td>Fit</td>
<td></td>
</tr>
<tr>
<td>Comfort</td>
<td></td>
</tr>
<tr>
<td>Visibility</td>
<td></td>
</tr>
<tr>
<td>Doffing</td>
<td></td>
</tr>
<tr>
<td>Emergency Doffing</td>
<td></td>
</tr>
<tr>
<td><strong>Gown</strong></td>
<td></td>
</tr>
<tr>
<td>Donning</td>
<td></td>
</tr>
<tr>
<td>Fit</td>
<td></td>
</tr>
<tr>
<td>Comfort</td>
<td></td>
</tr>
<tr>
<td><strong>Mobility of Subject</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Communications</strong></td>
<td></td>
</tr>
<tr>
<td>Headset comfort</td>
<td></td>
</tr>
<tr>
<td>Earphone setting</td>
<td></td>
</tr>
<tr>
<td>Microphone setting</td>
<td></td>
</tr>
<tr>
<td><strong>Ventilation Flow</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Noise</strong></td>
<td></td>
</tr>
</tbody>
</table>
3.4 Electrical Subsystem Tests

3.4.1 Test Objective - The objective of this test is to measure the operating amperages of the electrical subsystems under normal operating loads and to determine the ground leakage current.

3.4.2 Test Equipment/Conditions - All system electrical equipment shall be operated and a voltmeter and amp-probe used to obtain measurements.

3.4.3 Test Description - The filter blowers, ventilation system blowers and communications system shall be activated. Ventilation umbilicals and headsets shall be connected to all helmet locations. The operating voltages, amperages and ground leakage for each subsystem shall be measured and recorded. Ground leakage shall not exceed 1.0 milliamp.

3.4.4 Test Procedure

a) Connect ventilation umbilicals, communications cables, shoulder pads and headsets to all helmet connections.

b) Remove inside panel behind the control panel.

c) Activate filter blowers.

d) Measure voltage and amperage at the facility connection of each filter blower module. Record on Data Sheet 7.

e) Activate the ventilation system blowers and communications system.
### Operating Voltage and Amperage

<table>
<thead>
<tr>
<th>Subsystem</th>
<th>Volts</th>
<th>Amps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Filter Blower</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Filter Blower</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Ventilation Blower (TB-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Ventilation Blower (TB-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communications (TB-1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixer A (TB-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixer B (TB-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amplifier (TB-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>115 Volt Connector</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Ground Leakage

<table>
<thead>
<tr>
<th>Subsystem</th>
<th>Chassis MA</th>
<th>Ground Wire MA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left Filter Blower</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Filter Blower</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Ventilation Blower</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Ventilation Blower</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixer A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mixer B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amplifier</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enclosure Frame</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
f) At terminal board TB-1 measure the voltages and amperages for each individual ventilation blower and communications system.

g) At terminal board TB-2 measure the voltages and amperages for the individual mixers and amplifier.

h) At the 115 volt facility connection, measure total voltage and amperage.

i) Disconnect the 115 volt facility ground wire at TB-1.

j) Measure the ground leakage between each electrical subsystem chassis and ground connection and the facility ground wire removed in step i).

k) Secure system.

3.5 Material Compatibility Test

3.5.1 Test Objective - The objective of this test is 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 shall be used for items that may be sterilized. Solutions of dicrobe, distilled water and 70% isoprople alcohol are 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 shall be subjected to antiseptic cleaning fluids and/or sterilization procedures that might be
used by St. Lukes. Any detrimental effects shall be noted.

a) Samples of Kydex (shoulder pad), Armaflex (gasket), PVC hose (umbilical), PVC fitting (valves and plumbing) and plexiglass (helmet and walls) shall be swabbed daily, 5 days a week for one month with Dicrobe only.

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

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

d) Harness webbing and latch hardware shall be subjected to steam and gas sterilization.

3.5.4 Test Procedure

a) Obtain, identify and setup the following material samples in an area that cannot be disturbed for one month:

<table>
<thead>
<tr>
<th>Sample</th>
<th>Sample</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set No. 1</td>
<td>Set No. 2</td>
<td>Set No. 3</td>
</tr>
<tr>
<td>Kydex</td>
<td>Kydex</td>
<td>Kydex</td>
</tr>
<tr>
<td>Armaflex</td>
<td>Armaflex</td>
<td>Armaflex</td>
</tr>
<tr>
<td>PVC hose</td>
<td>PVC hose</td>
<td>PVC hose</td>
</tr>
<tr>
<td>PVC fitting</td>
<td>PVC fitting</td>
<td>PVC fitting</td>
</tr>
<tr>
<td>Plexiglass</td>
<td>Plexiglass</td>
<td>Plexiglass</td>
</tr>
</tbody>
</table>

b) Using a 1:80 Dicrobe-water solution, swab each sample in Set No. 1. Repeat daily, 5 days a week for one month. Record any effect on the samples.
c) Using sample set No. 2, repeat step b) except follow the Dicrobe swab with a distilled water rinse and then a 70% isopropyl alcohol rinse.

d) Using sample set No. 3, swab with the 1:80 Dicrobe-water solution once a week for one month.

e) Using a sample of harness webbing and harness latch, sterilize in the St. Luke's steam autoclave in accordance with standard procedures. After sterilization, note any detrimental effects.