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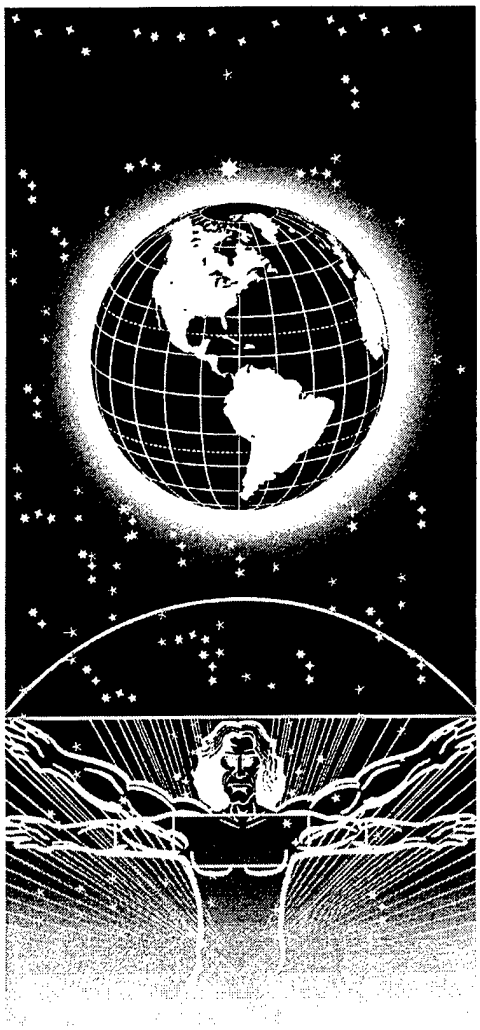

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE NORTHROP GRUMMAN CORPORATION MODEL 9602 LIFE SUPPORT FOR TRAUMA AND TRANSPORT (LSTAT) UNIT PART NUMBER ATBX01006A002.

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March 2000

NOTICES

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The Northrop Grumman Corporation Model 9602 Life Support for Trauma and Transport (LSTAT) Unit, Part Number ATBX01006A002 is conceptually designed for use in military medical evacuation on board USAF aeromedical evacuation aircraft. Specific components of the LSTAT that under went the evaluation process included: The Protocol Systems Inc., Propaq Model 106 LCD Physiological Monitor; IMPACT Corporation, Model 326 Continuous/ Intermittent Suction Unit (CISU); IMPACT Corporation, Model 754 "Eagle" Transport Ventilator; SurVivaLink Corporation, Automated External Defibrillator (AED); IVAC, Inc. Model MedSystem III Infusion Pump; i-STAT, Inc., Blood Analyzer; Internal 480 Liter Bottle Oxygen System; Display and Data Logging Subsystem (DDLS) to include Fujitsu Model Stylistic 1000 Secondary Display; and Electrical Power Subsystem (EPS).

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TABLE OF CONTENTS

LIST OF FIGURES

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TESTING AND EVALUATION OF THE NORTHROP GRUMMAN CORPORATION MODEL 9602 LIFE SUPPORT FOR TRAUMA AND TRANSPORT (LSTAT) UNIT PART NUMBER ATBX01006A002.

BACKGROUND

Dr. Frederick Pearce, U. S. Army (Walter Reed Army Institute of Research) requested the Air Force Medical Equipment Development Laboratory's (AFMEDL) participation in laboratory evaluation for in flight use of the Northrop Grumman Corporation Model 9602 Life Support for Trauma and Transport (LSTAT) unit part number ATBX01006A002, serial number 0002. The LSTAT is conceptionaly designed for use in military medical evacuation on board USAF aeromedical evacuation aircraft. Specific components of the LSTAT that under went the evaluation process included: The Protocol Systems Inc., Propaq Model 106 LCD Physiological Monitor; IMPACT Corporation, Model 326 Continuous/ Intermittent Suction Unit (CISU); IMPACT Corporation, Model 754 "Eagle" Transport Ventilator; SurVivaLink Corporation, Automated External Defibrillator (AED); IVAC, Inc. Model MedSystem III Infusion Pump; i-STAT, Inc., Blood Analyzer; Internal 480 Liter Bottle Oxygen System; Display and Data Logging Subsystem (DDLS) to include Fujitsu Model Stylistic 1000 Secondary Display; and Electrical Power Subsystem (EPS).

DESCRIPTION

Physical Description: The LSTAT is a portable individual intensive care unit (ICU) incorporated into a structure which serves as a resuscitation, stabilization, and evacuation platform for trauma casualty treatment. The casualty travels on the LSTAT. The LSTAT is designed to interface with multiple evacuation vehicles. The LSTAT platform accommodates standard NATO litters approximately 90 inches in length. The unit includes a head fairing with controls for medical device sub-components. The head fairing is approximately 13 inches high. The LSTAT is approximately 85.5 inches in length and 22 inches in width.

System Description: The LSTAT is a portable ICU platform to providing lifesaving and stabilizing therapies throughout the theater of operation. The LSTAT is designed to operate both in an austere forward environment and in static rear areas. It can operate in a temporary stand-alone configuration for short periods using internal resources or while utilizing existing external power, oxygen, and medical air resources for indefinite periods. A brief description of LSTAT sub-components follows.

Physiological Monitor: The LSTAT has the capability to continually monitor patient status and functions using a Protocol Systems Inc., Propaq Model 106 LCD physiological monitor. Monitoring functions include, Invasive Blood Pressure (2 channels), Non-Invasive Blood Pressure, ECG, arteriolar hemoglobin Oxygen Saturation (SpO_2), End-Tidal Carbon Dioxide ($ETCO_2$), Airway flow volume, and temperature (esophageal or skin). Each of the measured parameters has a known operating range and associated alarm condition based on set parameters. The monitored information is delivered to the DDLS and secondary display.

Suction Unit: The LSTAT incorporates an IMPACT Model 326 Continuous/ Intermittent Suction Unit (CISU) to remove secretions from the upper airway during oropharyngeal, nasopharyngeal and tracheal suctioning procedures. It is capable of being programmed to deliver intermittent suction intervals.

Ventilator: The IMPACT Corporation, Model 754 "Eagle" Transport Ventilator supplies the patient with medical grade air and medical grade oxygen via LSTATs on board support systems or through external gas ports. It is capable of operating in either the Synchronized Intermittent Mandatory Ventilation (SIMV), Assist Control Ventilation (ACV) or Continuous Positive Airway Pressure (CPAP) modes. A manual breath function allows the manual delivery of ventilation at any time. The ventilator is composed of an electronically controlled ventilator, compressor, air & oxygen blender. It is controlled by an internal microprocessor, which continuously monitors and displays airway pressure, control settings, alarm parameters, gas source(s), gas flows, gas blends, and power signals. ACV, SIMV, and CPAP modes are operable with or without Positive End Expiratory Pressure (PEEP). External (50±5 psi) medical air and oxygen gas line receptacles are also provided on either side of the LSTAT.

Defibrillator: The LSTAT uses a SurVivaLink Corporation, Automated External Defibrillator (AED). The SurVivaLink AED is a semi-automatic defibrillator that uses a shock advisory system. This software algorithm analyzes the patient's electrocardiograph (ECG) rhythm and indicates whether or not it detects a shockable rhythm. The AED requires operator interaction in order to defibrillate the patient. If the operator authorizes the discharge, then the discharge is applied through the patient monitoring/defibrillation electrodes. If the operator fails to authorize the shock application to the patient within 30 seconds, the charge is then dumped internally.

IV and Drug Administration: The LSTAT uses the IVAC MedSystem III Infusion Pump for IV fluid and drug administration. The MedSystem III Multi-Channel Infusion Pump can deliver 0.1-999 cc/hour on each of its three fluid administration channels. The pump possesses its own 6-hour Nickel-Cadmium operating battery, which allows it to function in the absence of power from the LSTAT. The unit also displays IV fluid types, rates, and related information to establish trends or other quantitations of input/output balance information into the Display and Data Logging Sub-system.

Clinical Analyzer: The LSTAT uses the i-STAT System to provide blood sample analysis. The i-STAT is portable, handheld and has the capability to perform various blood analysis tests using special cartridges. The i-STAT uses disposable cartridges, which once loaded with a blood sample are inserted into the instrument for analysis. The i-STAT can perform blood tests to measure sodium, potassium, chloride, glucose, urea nitrogen, hematocrit, ionized calcium, arterial blood gases, pH, PCO_2, PO_2, and bicarbonate. The i-STAT can also provide test results for carbon dioxide, base excess, anion gap, hemoglobin, and O_2 saturation by use of additional cartridges. The i-STAT operates on two 9 V lithium batteries. It can store up to 50 patient records and can transmit individual or groups of records via an infrared link to either a strip chart recorder or a central data station.

Oxygen System: A 480 liter gaseous oxygen system is located at the foot of the LSTAT. It consists of a 3,000 psi reservoir and associated internally mounted supply lines delivering medical grade oxygen at (50±5 psi) to the ventilator or by mask directly to a spontaneously breathing patient. The system provides oxygen for blended ventilation gas to the ventilator/patient. Sufficient oxygen is available for one hour of stand-alone operation running at 8 liters per minute (lpm). An external pressure gage is provided to indicate the status of the internal oxygen reservoir and is also provided in an electronic read-out for data logging and status reporting. Capability to interface with external gas (oxygen and air) sources (50±5 psi) is also available. An accessory external oxygen hose with fittings is provided for this purpose. Oxygen is replenished via changeable/disposable bottles.

Display and Data Logging Subsystem (DDLS): The DDLS performs data logging functions to record patient physiological data and display operational status of LSTAT sub-systems. The DDLS also provides the LSTAT with a secondary means of displaying medical data using a Fujitsu, Model Stylistic 1000, pen based tablet computer. The DDLS does not control any of the life support (medical) equipment functions on the LSTAT. Control of the DDLS is through an operator interface or an off board computer (not part of the LSTAT). The DDLS has six operational modes: "Power-up," "Test," "Initialization," "Run," "Shutdown," "Maintenance," and "Off."

Electrical Power (EPS) subsystem: the EPS is self-contained and interfaces with auxiliary power through five separate power adapters. Internally mounted nickel-cadmium batteries are used to power the LSTAT and can be recharged in place or exchanged and externally recharged. The EPS subsystem has the capability to be recharged. Once fully charged, the EPS subsystem can operate on internal battery power for at least 30 minutes. The power system can operate from the following sources:

105-120 VAC 60Hz
108-118/200 VAC 3 Phase 400Hz
210-220 VAC 50Hz
25-30 VDC

The EPS provides a smooth uninterrupted transition between self-powered and auxiliary modes. Controls are provided for managing any power sources and supports the automatic recharging of self-contained power stores during periods of auxiliary power connection. According to manufacturer's specification, a completely discharged system can be completely recharged within 24 hours.

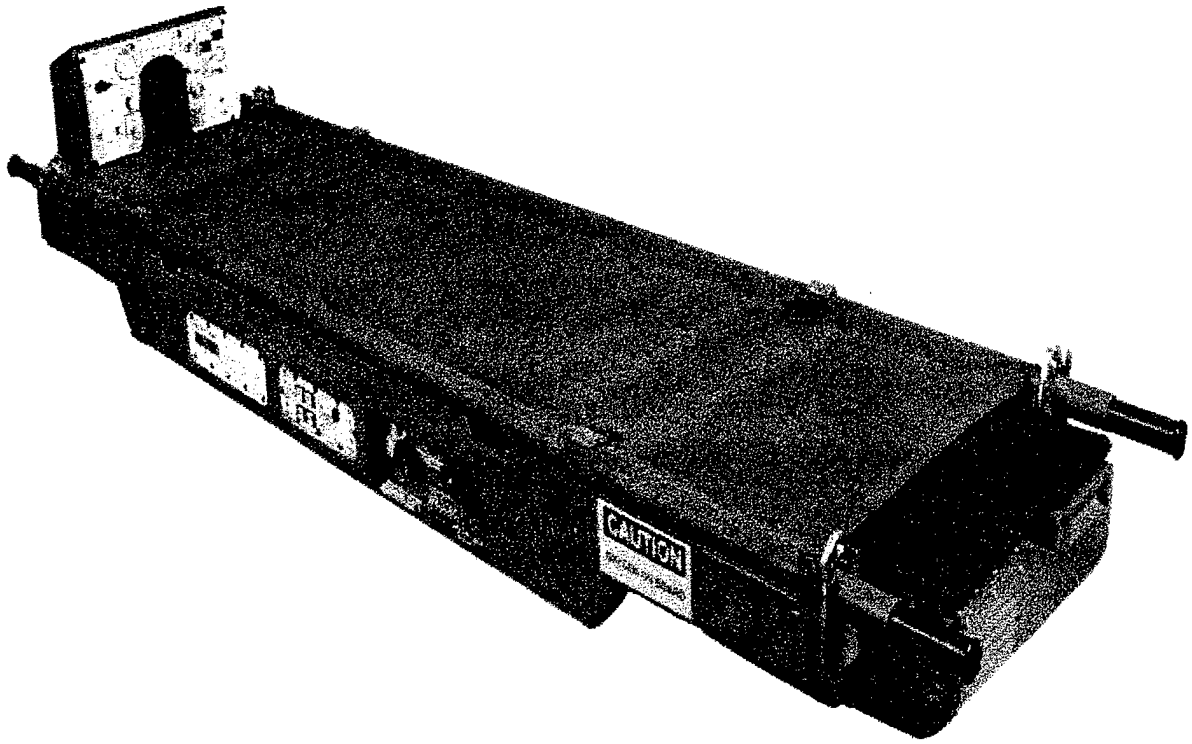

Figure 1. Northrop Grumman Corporation Model 9602 Life Support for Trauma and Transport (LSTAT) unit.

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-5), and manufacturer's literature (6). The AFMEDL Flight Performance Evaluation Procedure Guide and Testing Standards describes additional safety and human interface issues to be considered during equipment testing (7). A test setup and performance check was developed specific to the LSTAT to verify its proper functioning under various testing conditions. All tests were conducted by AFMEDL personnel assigned to the Protective Systems Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas unless otherwise noted. USAARL engineer was present during testing and provided inputs to test setup and design.

The LSTAT was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Thermal/ Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Temperature Storage

    e. Cold Temperature Storage

3. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to simulated flight level

4. Airborne Performance – Not assessed

INITIAL INSPECTION AND TEST PREPARATION

a. The LSTAT and sub-components were inspected for quality of workmanship, production techniques, and pre-existing damage.

b. The LSTAT and sub-components were checked to ensure they met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1), AFI 41-201, Equipment Management in Hospitals (3). This also includes testing for leakage current and ground resistance of all components, systems, and sub-systems.

c. The LSTAT and sub-systems were examined to ensure they met basic requirements for human factor design as outlined in MIL-STD 1472 (4).

d. A test setup and performance check was developed to evaluate LSTAT operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

Connect 115 VAC, 60 Hz Power to the LSTAT and use the "LSTAT Setup" as per reference (6).

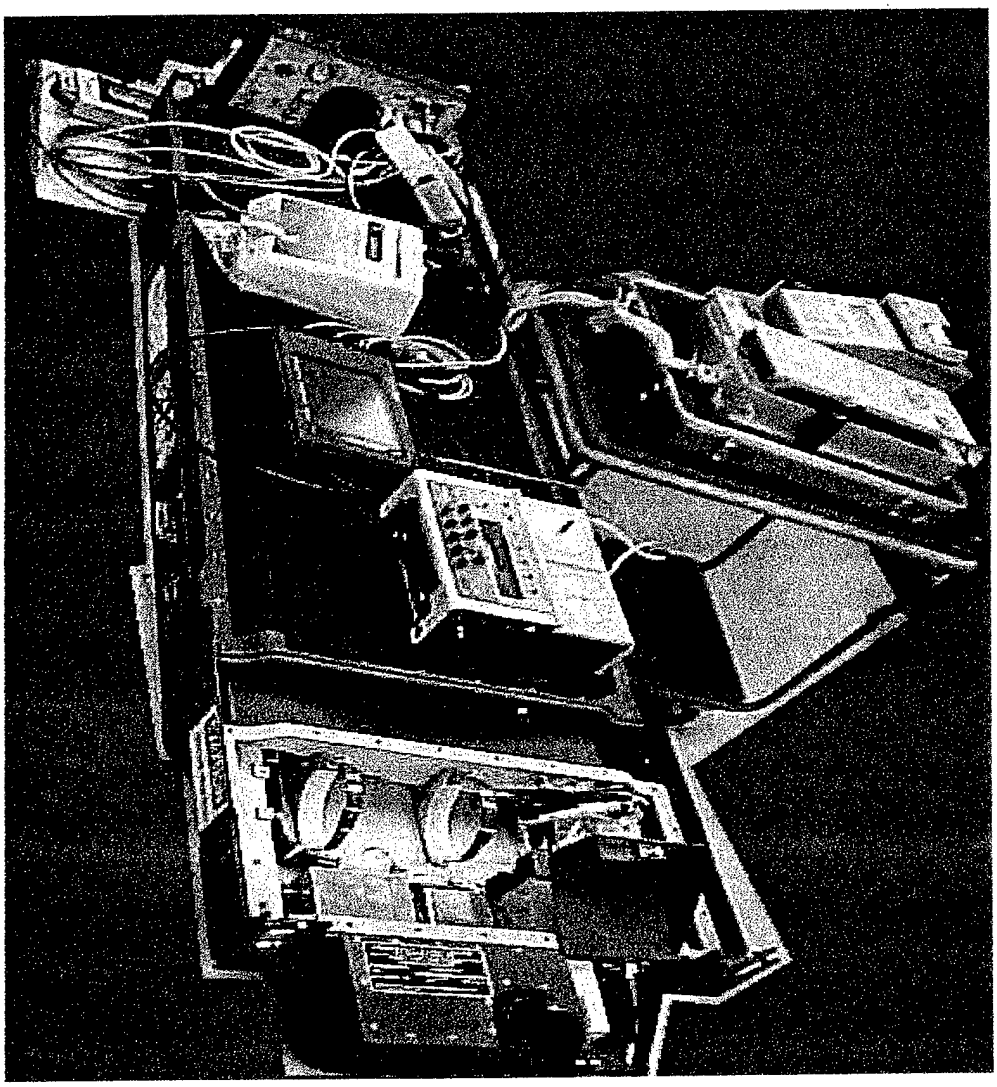

Figure 2. Test Setup

The following test simulators, analyzers, and environmental equipment were used to assess the LSTAT performance.

Bio-Tek, Electrical Safety Analyzer, Model 370
SN 11750, Cal due date: 9-99

Kiethly Model 179 Digital Multimeter
SN 15071, Cal due date: 22 Jul 99

Bio-Tek, Ventilator Tester, Model VT-2
SN 0198, Cal due date: 12-98

Bio-Tek, NIBP Monitor Tester
SN 138977, Cal due date: 7-1-99

Bio-Tek, SpO2 Simulator, Model Index 2FE
SN 139307, Cal due date: 6-99

Man Rated Thermal Research Altitude Chamber
Maintained and certified by AFRL chamber personnel

Bio-Tek, Universal Biometer, Model DPM-III
SN 27989, Cal due date: 28 Nov 98

Bio-Tek, Multiparameter Simulator, Model "Lionheart"
SN, Cal due date: Sep 99

Dynatech Nevada, Defibrillator Analyzer, Model Impulse 4000
SN 0326, Cal due date: 1-26-99

Michigan Instruments Model 260 Li Adult/Infant Training Test Lung (TTL)
SN 0302, Cal due date: 2-99

Stopwatch

PERFORMANCE CHECK

Component Testing:

Physiological Monitor

Performance Check: The following performance check was used to validate the function of the Propaq 106 LCD Physiological Monitor in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison.

Procedure:

1. Plug the 3-lead ECG cable into the ECG port on the physiologic monitor.
2. Attach the 3 ECG leads to the corresponding color-coded receptacles on the Bio-Tek Multiparameter Simulator.
3. Plug the temperature cable (1/4" phone jack) into the temperature port on the physiologic monitor. The other end of the cable will simply measure ambient temperature.
4. Plug the cannon plug end of the invasive blood pressure cable into the Lionheart and the other end into the P1 connection at the Operator/Patient Interface Panel on the head fairing.
5. Configure the Lionheart with the following setting: Invasive BP, "wave" (30/10). NOTE: The invasive BP signal needs to be "zeroed" before switching to the "wave" position.

6. Secure the non-invasive blood pressure (NIBP) tubing line to the NIBP port on the LSTAT and the "Pressure Port" on the Dynatech Cufflink NIBP Tester. Configure the NIBP tester with the following settings:

   Mode = Adult Settings, "Standard set of pressures #1"
   Systolic = 120
   Diastolic = 80
   Mean = 93
   Heart Rate = 60

7. Plug the SpO_2 cord into its corresponding SpO_2 port on the physiologic monitor. Attach the SpO_2 sensor to the "finger" probe on the Bio-Tek SpO_2 simulator. Set the simulator to monitor for Nellcor pulse oximeters, 98% and 60 bpm.
8. Plug the CO_2 sensor cord into its corresponding port on the monitor's CO_2 module. Attach an airway adapter and sensor to the CO_2 line. CO_2 module will be hanging and open to ambient conditions. Display should read "0" and no alarm present.
9. Configure the monitor to monitor ECG lead II, and display temperature in °C. The monitor will continuously monitor temperature, P1, SpO_2, and CO_2. Propaq temperature display will be compared to a second source calibration device. Program NIBP operation at intervals of one minute. Set the monitor so that it will not print Apnea tickets. When using the printer, limit paper usage by rewinding paper after individual tests.

Suction Unit

Performance Check: The following performance check was used to validate the function of the IMPACT 326 Suction Unit in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the unit is defined below and will be referenced throughout the Test Condition section.

Procedure: The Performance Check for the unit consists of four separate tests. These tests are outlined below (1-4).

(1) Time to Reach 300 mmHg. Attach collection canister with collection tubing to unit, turn unit on, set vacuum adjust to maximum. Occlude tubing and using a stopwatch measure how long unit takes to reach 300 mmHg. Repeat test 3 times and record results. Next, connect a flowmeter in the vacuum line to measure free airflow. Turn unit on and record results. NOTE: Unit must provide a vacuum level of 300 mmHg in four (4) seconds (or less) at 25 liters per minute free-flow.

(2) Maximum Vacuum Level. Attach collection canister with collection tubing to unit, select continuous mode, occlude collection tubing, set vacuum adjust to maximum, turn unit on, and record results.

(3) Vacuum Gauge Accuracy. Attach collection canister with collection tubing to unit, connect a calibrated vacuum gauge to collection tubing, select continuous mode, turn unit on, assess unit's gauge by setting vacuum adjust on unit to read 100, 150, 250, and 500 mmHg, record results. NOTE: This test will be performed one time during initial/baseline testing. However, a calibrated Universal Biometer, Model DPM-III will be inline with the collection canister during all phases of Aeromedical testing and will be used for gauge reading(s) comparison.

(4) Intermittent Operation. Attach collection canister with collection tubing to unit, select intermittent mode, set on/off times for 10 seconds each, vacuum adjust to maximum. Turn unit on and ensure vacuum level does not exceed 235 mmHg. Time on and off cycles with a stopwatch for accuracy.

Ventilator

Performance Check: The following performance check was used to validate the function of the IMPACT 754 Ventilator in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the Ventilator is defined below and will be referenced throughout the Test Condition section.

Procedure: Using the Michigan Instruments Model 260 Li Adult/Infant Training Test Lung (TTL) a Full Test will be accomplished whenever stated in this test plan, i.e., whenever a performance check is called out. A Full Test includes the following information.

- Breath rate
- Inspiratory/expiratory (I:E) ratio
- Inspiratory time
- Expiration time
- Tidal volume (exhaled)
- Minute volume (exhaled)
- Peak flowrate
- Peak prox pressure
- Peak lung pressure
- Mean airway pressure

1. The Ventilator will be configured with the following settings for the performance test:

   Mode: Control Assist
   Tidal Volume: 800 ml
   BPM: 15
   Inspiratory time: 1.6
   Resistance: 5
   Compliance: 20
   I:E ratio: 1:2

Flow: 50 lpm

2. Configure patient breathing circuit from ventilator connections in head fairing to the Michigan Instruments Test Lung/ Ventilator Analyzer in accordance with manufacturer's literature.

3. Configure PnewView Ventilator Control Software so as to display and record the above (#1) parameters.

4. At altitude, the ventilator's blender circuit will be tested using external and internal oxygen.

Defibrillator

Performance Check: The following performance check was used to validate the function of the SurVivaLink Automated External Defibrillator (AED) in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the AED is defined below and will be referenced throughout the Test Condition section.

Procedure:

1. Insert appropriate end of the AED simulator test lead (s) into the head fairing connector titled ELCTD and connect the other end to each of the Impulse 4000's test loads/pads. Select these Impulse 4000 settings: "Dif;" "energy;" "high;" "vfib"

2. Push the POWER on switch to turn on the defibrillator.

3. Wait approximately 30 seconds for the system to complete a self-test.

4. Press the RESUME button to continue.

5. The voice prompt will advise: "DO NOT TOUCH PATIENT, ANALYZING RHYTHM." At this time, the defibrillator will detect the VFIB signal from the Impulse 4000 and the voice prompt will advise: "CHARGING." When the charge is ready, the DISCHARGE button will flash and the voice prompt will advise: "STAND CLEAR! PUSH FLASHING BUTTON TO RESCUE."

6. Push the DISCHARGE button to deliver the first shock of 200 Joules (J). Record the energy delivered.

7. After a five-second pause, the defibrillator will analyze the cardiac rhythm again and charge. Push the DISCHARGE button for the second discharge and record energy delivered. NOTE: The second discharge should be 300 J.

8. Again the defibrillator will charge automatically and the voice prompt will advise: "CHARGING." Push the flashing DISCHARGE button for the third discharge and record energy delivered. NOTE: The third and each subsequent discharge should be 360 J.

9. Push the POWER button to disarm and power down the defibrillator.

Infusion Device

Performance Check: The following performance check was used to validate the function of the MedSystem III Multi-channel Infusion Pump in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the Infusion Pump is defined below and will be referenced throughout the Test Condition section.

Procedure(s):

1. Clamp the pump to the IV pole and connect an IVAC 28 series administration set to an intravenous (IV) bag and prime it. NOTE: It is important to prime the set properly in order to eliminate air bubbles.

2. Load the set into the pump in accordance with the operator's manual.

3. Program the pump for the following settings: channel A- 10 cc/hr, and channel B- 200 cc/hr.

4. Connect the free end of the administration set tubing into a 3-way stopcock. Connect one end of the 3-way stopcock to a Bio-Tek Model IDA-4, Infusion Device Analyzer using a 20-inch extension set.

5. The other port of the three way stopcock is used for priming/flushing the IV Pump Analyzer.

6. Set the IDA-4 Infusion Device Analyzer to measure flow and volumes. NOTE: This IDA-4 is a two-channel tester. Plug the 10 cc/hr set and the 200 cc/hr set (from the Infusion Pump) into channel one and two (IDA-4 Infusion Device Analyzer) respectively.

7. The rate indicated in the single rate test will be documented during the rate accuracy evaluation while infusing the above (#3) settings.

Portable Clinical Analyzer

Performance Check: The following performance check was used to validate the function of the i-STAT Portable Clinical Analyzer in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the i-STAT is defined below and will be referenced throughout the Test Condition section.

Procedure(s): Insert simulator (avoid touching the simulator contacts). System test takes 2 minutes and will display either PASS or FAIL. This performance test will be initiated at each test interval.

Oxygen System

Performance Check: The following performance check was used to validate the function of the LSTAT's Oxygen System during initial testing. Measurements were taken during initial operation at standard ambient conditions. The performance check for the Oxygen System is defined below.

Procedure:

1. Connect a Bio-Tek Universal Biometer inline with the LSTAT's Oxygen System. Monitor system pressure throughout AWT environmental testing. System pressure is spec'd by the manufacturer at 40-55 +5/-0 psi.
4. Follow manufacturer's instructions for connecting INTERNAL and EXTERNAL oxygen cylinders.
5. Insert a standard medical oxygen flowmeter into the BY-PASS FLOWMETER CONNECTION (Front of LSTAT head fairing).
8. Adjust for 6 lpm and then 15 lpm flow.
9. Record oxygen system pressure at each of these settings.
6. Turn ventilator on and configure for standard performance check parameters. Record system pressure with flowmeter set at 6 lpm and 15 lpm.

Display and Data Logging Sub-system (DDLS)

Performance Check: The following performance check was used to validate the function of the DDLS in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the DDLS is defined below and will be referenced throughout the Test Condition section.

Procedure(s): Setup DDLS in accordance with section 3.2.7 of the LSTAT Model 9602 Operation and Maintenance Manual. Record (at each test interval) each of the medical test parameters called out in all performance checks. This should be accomplished for the data logging sub-system and secondary display.

Electrical Power Subsystem:

Battery Performance Test: Specific equipment information and test data was recorded on AFMEDL battery evaluation form. Using battery status indicator on side of LSTAT, battery unit was charged to "full". Unit was then discharged by operating all systems at maximum settings. This discharge (or operating time) was recorded. Unit was recharged to full and discharged a total of three times and recorded. These data were averaged and recorded.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (5). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, corrosion, changes in electronic components, and mechanical failures due to rapid water or frost formation.

Testing was conducted in a calibrated AFRL environmental chamber. The LSTAT was placed in the center of the environmental chamber. The other components of the test setup remained outside the chamber. For operational thermal tests, the LSTAT and sub-components were monitored continuously, and a performance check was conducted every 30 minutes. For humidity testing a performance check was conducted every 45 minutes. For storage tests, the LSTAT was placed in the chamber and remained non-operational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hr

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hr

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hr

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hr

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hr

f. U.S. Army Cold Temp Operation: 13°F (-25°C) for 2 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation pressurizes their cabins to maximum barometric pressures of 8,000 - 10,000 ft above sea level. To incorporate unpressurized USAF helicopters medical devices are subjected to barometric pressures of 15,000 ft. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the LSTAT and sub-systems while ascending from ground level to 15,000 ft with performance checks at 2,000 ft increments to 10,000 ft and thereafter 2,500 ft increments to 15,000 ft. In addition, LSTAT and sub-systems underwent one-hour endurance test at maximum altitude. The rates of ascent and descent were 5,000 ft/min.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD to assess dangers to patients, personnel, or the aircraft. The LSTAT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes,

and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice more at a 7 and 1-second RD. The LSTAT was monitored throughout the series of decompressions. Performance checks were assessed each time the LSTAT returned to ground level.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no damage to the LSTAT or sub-components. However, the IMPACT 754 "Eagle" transport ventilator gave a "Ventilator Failure Total Flow Backup" alarm condition preventing the device from functioning. The problem was investigated and attributed to excessive condensation buildup on it's internal filter/screen for the patient breathing circuit. The IVAC MedSystem III channel "C" displayed "Service Required" prompt. This channel's function was not assessed during testing. No electrical safety deficiencies were discovered. Battery recharge time of 30 hours was in excess of stated LSTAT manufacturer claim of 24 hours. The LSTAT manufacturer representative stated the batteries were approaching the end of their useful service life. The delay in recharge time was attributed to this fact.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The LSTAT was evaluated IAW manufacturer's guidelines regarding hot operation, cold operation, and humidity. The LSTAT experienced some set backs in operation during hot and cold operation, hot and cold storage, and humidity testing. The following describes the problems encountered during testing.

HOT STORAGE: i-Stat – Excessive recovery time (1.5 hours)

COLD STORAGE: i-Stat - Excessive recovery time (1.5 hours); Suction unit- excessive recovery time (1 hour 50 min.); Ventilator- Excessive recovery time (2.0 hours); NIBP- Excessive recovery time (4.0 hours)

COLD OPERATION: AED would not deliver third discharge. i-Stat out of temperature range for both U.S.A.F. and U.S. Army test parameters.

HOT OPERATION: CO_2 sensor and i-Stat out of temperature range.

HUMIDITY: Ventilator LCD screen blacked out at 1.5 hours into testing and stayed blank throughout the remainder of test. i-Stat out of temperature range.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: Most of the LSTAT and sub-components performed in accordance

with manufacturer's specifications throughout testing. However, the Propaq 106 LCD alarmed at 15,000 ft showing an "Out of Range" condition for the CO_2 sensor. The secondary display showed episodes of interference (characterized as a sweeping vertical bar) at altitudes above 8,000 ft. However, the device remained functional during testing.

2. Rapid Decompression: The LSTAT and sub-components operated satisfactorily following each decompression event except the ventilator alarmed during each decompression event. However, it recovered upon return to ground level. Both functioning infusion pump channels alarmed "air in the line" during the 60 second RD. Channel B alarmed "air in the line" during the 7-second and 1-second RD. All infusion pump alarms cleared upon return to ground level. The Propaq CO_2 sensor alarmed "CO_2 altimeter fault" during 60 second RD and cleared at ground level. The Propaq ECG screen blacked out during the 1-second RD, but recovered upon return to ground level.

U.S. ARMY TEST PERFORMANCE REQUIREMENTS: See Appendix B, Additional Testing Done To Fulfill U.S. Army Requirements.

SUMMARY

AFMEDL finds the Northrop Grumman Corporation Model 9602 Life Support for Trauma and Transport (LSTAT) unit part number ATBX01006A002, serial number 0002 to be conditionally approved for limited use on all U.S. Air Force aeromedical evacuation aircraft. In accordance with AFI 11-202V3, the LSTAT requires certification by AFMC/ASC/ENAE for electromagnetic interference/compatibility testing. The LSTAT should not be operated on any electrical power sources until such certification is achieved. Form and fit testing may proceed onboard USAF aircraft in coordination with HQ AMC/SGXR. The operation of some sub-components could not be demonstrated within expected parameters when subjected to environmental extremes and simulated cabin altitudes. The LSTAT did not produce a hazard to patient or crew during rapid decompression. The ultimate operational use of the LSTAT for actual patient care will be based upon its demonstrated performance characteristics and modifications to overcome limitations discovered during this testing phase. Refer below for an analysis of sub-component performance and limitations.

Propaq Model 106 LCD physiological monitor – This unit experienced problems with the CO_2 sensor during hot and cold operation evaluation. AFMEDL recommends operating unit within manufacturer's temperature specifications. (50-104° F) The CO_2 sensor experienced an "out of range" alarm at 15,000 ft. AFMEDL does not consider this a significant failure for the use of the LSTAT by the U.S. Air Force.

IMPACT Model 326 Continuous/ Intermittent Suction Unit (CISU) – This unit experienced excessive recovery times exceeding one hour following cold storage testing. AFMEDL recommends operating unit within manufacturer's temperature specifications. (-20° to 40° C operating and -15° to 40° C storage and shipping)

SurVivaLink Automated External Defibrillator (AED) – This unit had trouble maintaining proper performance of Advanced Cardiac Life Support protocols. The AED, on more than one occasion, failed to deliver a third shock in a three shock series. This particular model of AED was previously assessed by AFMEDL as a stand-alone device for proposed use in the U.S. Air Force aeromedical environment. The manufacturer withdrew the device from testing. For these reasons, AFMEDL recommends this AED be removed and not to be used in-flight. AFMEDL considers this AED not approved for use in USAF aircraft.

IVAC MedSystem III Infusion Pump – This infusion pump displayed "air in the line" during the 60 second RD. Channel B alarmed "air in the line" during the 7-second and 1-second RD. However, all alarms cleared upon return to ground level. AFMEDL does not consider these events to put the patient at undo risk. Please be aware that the aforementioned event is possible and assess the patient and infusion pump accordingly.

IMPACT Model 754 "Eagle" Transport Ventilator – During rapid decompression the ventilator alarmed. However, it recovered upon return to ground level. The LCD screen went blank 1.5 hours into humidity testing and stayed blank throughout remainder of test. AFMEDL recommends operating the device when configured as a LSTAT sub-component IAW humidity restrictions set forth by the ventilator manufacturer. Also, a filter/screen inside the flow control valve became blocked by excessive condensation causing the ventilator to fail. A "Failure Code 3 – Total Flow Backup, Check Failure" alarm was displayed preventing the unit from functioning. To clear this problem, the NATO litter and an access panel had to be removed to gain entry into the LSTAT. Once inside the LSTAT, the flow control valve had to be disassembled, cleaned and replaced before the ventilator would function again. It took 40 minutes to finally clear this alarm condition. Specifically, the flow control valve on the ventilator breathing circuit needs to be moved to an area providing rapid access to the filter/ screen. AFMEDL recommends if possible to move this valve assembly to just proximal of the head fairing gas outlet connector. AFMEDL considers this a single point failure and the LSTAT is not approved for use in USAF aircraft until recommended modifications are made.

Display and Data Logging Subsystem (DDLS) – During altitude evaluation the secondary display showed episodes of interference (characterized as a sweeping vertical bar) at altitudes above 8,000 ft. However, the device remained functional and the display could be read. AFMEDL recommends monitoring LSTAT sub-components through their respective display screens.

i-Stat Blood Analyzer - The blood analyzer had multiple problems during temperature and humidity evaluations. It is important to note the LSTAT storage compartment for the i-Stat is not insulated against environmental extremes. The unit requires long lead times to recover from environmental extremes. AFMEDL recommends protecting the unit from environmental extremes and operate the unit IAW manufacturer specifications regarding ambient temperature and humidity. [16 to 30° C (61-86° F) operating, -10° to 50° C (14-122° F) transporting and 0 to 65% (min) non-condensing relative humidity]

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code

2. Emergency Care Research Institute (ECRI)

3. AFI 41-201, Equipment Management in Hospitals

4. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.

5. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.

6. Northrop Grumman Corporation Model 9602 Life Support for Trauma and Transport (LSTAT) unit, Operation Instructions.

7. AFMEDL Flight Performance Procedures Guide and Testing Standards, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.

APPENDIX A
MANUFACTURER'S SPECIFICATIONS OF NORTHROP GRUMMAN CORPORATION MODEL 9602 LIFE SUPPORT FOR TRAUMA AND TRANSPORT (LSTAT) UNIT PART NUMBER ATBX01006A002.

SPECIFICATIONS

General:

Size:	13" H. X 85.5" L. X 22" W.
Weight:	173.66 lbs. (with stretcher, O_2 bottle & regulator) 158.91 lbs. (without stretcher) 151.84 lbs. (without stretcher, O_2 bottle & regulator)
Cooling:	Internal ambient air for components.
Electrical Power:	115 VAC ±10% VAC, 60 Hz ±5 Hz, one phase 108-118 VAC 400 Hz ±7 Hz, one phase 230 VAC ±10% VAC, 50 Hz ±3 Hz, one phase 25 ±5 VDC Batteries: Nickel-Cadmium (NiCd), > 30 min., Rechargeable
Environmental:	Operating temp. +10° C to +40° C Storage temp. 0° C to +40° C Relative Humidity: Storage, 15% (6hrs) Operating, 95% 29° C (4hrs)

APPENDIX B
ADDITIONAL TESTING DONE TO FUFILL U.S. ARMY REQUIREMENTS
(Testing witnessed by a representative from USARRL)

THERMAL ENVIRONMENTAL CONDITIONS

Extreme temperature testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (5). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, corrosion, changes in electronic components, and mechanical failures due to rapid water or frost formation.

Testing was conducted in a calibrated AFRL environmental chamber. The LSTAT was placed in the center of the environmental chamber. The other components of the test setup remained outside the chamber. For operational thermal tests, the LSTAT was monitored continuously and a performance check was conducted every 30 minutes. The following describes the condition of the environmental test performed:

Cold Temperature Operation: 13°F (-25°C) for 2 hr

HYPOBARIC CONDITIONS

Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. The differences in pressures affect the operation of some medical equipment. The device must be able to function properly in this environment. Altitude testing consisted of operating the LSTAT while ascending from ground level to 15,000 ft. The rates of ascent and descent were 5,000 ft/min. Performance checks were assessed at 2,000 ft increments to 10,000 ft and thereafter 2,500 ft increments to 15,000 ft.

EVALUATION RESULTS

THERMAL ENVIRONMENTAL CONDITIONS

The LSTAT and sub-components were evaluated IAW respective manufacturer's guidelines regarding cold operation. The LSTAT experienced some problems in operation during Army cold operation testing. The following describes the problems encountered during cold testing.

Propaq Model 106 LCD physiological monitor – The NIBP mode failed to function upon the first performance check which occurred once the environmental chamber had obtained a

steady state temperature of -25°C. The CO_2 sensor displayed "Out of Range." The sensor recovered upon returning to ambient conditions. NIBP pump would not function throughout entire test, but recovered after test completion.

IVAC MedSystem III Infusion Pump – Upon reaching our desired steady state temperature, the infusion pump went inoperative and remained so throughout testing. This sub-component fully recovered following return to room temperature.

IMPACT Model 326 Continuous/ Intermittent Suction Unit (CISU) – The CISU maintained operation for 1.5 hours. However, the intermittent mode demonstrated a gradual decrease in suction at the 1.5-hour mark and failed to function thereafter. The unit recovered upon return to the room temperature ambient environment.

IMPACT Model 754 "Eagle" Transport Ventilator – The ventilator functioned according to manufacturer's specifications.

Display and Data Logging Subsystem (DDLS) – The DDLS remained operational during testing but required occasional contrast adjustments of the LCD.

i-Stat Blood Analyzer – The blood analyzer became inoperative upon exposure to the steady state temperature of -25° C. It did not recover until returning to ambient room temperature.

HYPOBARIC CONDITIONS

Propaq Model 106 LCD physiological monitor – The physiologic monitor operated IAW manufacturer's specifications.

IVAC MedSystem III Infusion Pump – The infusion pump operated IAW manufacturer's specifications.

IMPACT Model 326 Continuous/ Intermittent Suction Unit (CISU) – The CISU operated IAW manufacturer's specifications.

IMPACT Model 754 "Eagle" Transport Ventilator – The ventilator functioned according to manufacturer's specifications.

Display and Data Logging Subsystem (DDLS) – During the 15,000 ft performance test, the secondary display of the DDLS started randomly displaying vertical scroll lines at 30 minutes into the test. However, the secondary display data were still readable. The vertical scroll lines across the display did not effect the operation of the LSTAT. AFMEDL does not deem this as a test failure.

i-Stat Blood Analyzer – The blood analyzer operated IAW manufacturer's specifications.