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EVALUATION OF THE MODEL 185 AIRBORNE LIFE SUPPORT SYSTEMS INFANT TRANSPORT INCUBATOR

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NOTICES

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This report has been reviewed and is approved for publication.


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19. ABSTRACT (Continue on reverse if necessary and identify by block number) The Military Airlift Command (MAC) is the central manager for aeromedical evacuation in the Department of Defense. The safe evacuation of infants in MAC aircraft has always been an important concern because infants must be transported in a controlled environment. The Ohio Transport Incubator, now in use, is no longer manufactured. If an Ohio incubator breaks down, needed spare parts may not be available. The Model 185 Airborne Life Support Systems (ALSS) infant transport incubator has been selected to replace the Ohio incubator in the U.S. Air Force (USAF) inventory. Now available for use, the ALSS is lighter than the Ohio; it has an internal humidification system, an internal battery, and a digital temperature readout. The Aeromedical Equipment Evaluation Laboratory at the USAF School of Aerospace Medicine tested the ALSS incubator and found it to be a safe, adequate device for transporting an infant without jeopardizing the infant's health.					
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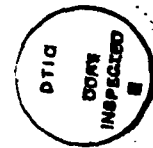
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EVALUATION OF THE MODEL 185 AIRBORNE LIFE SUPPORT SYSTEMS INFANT TRANSPORT INCUBATOR

BACKGROUND

Military Airlift Command (MAC) controls aeromedical evacuation (AE) missions for the United States Air Force (USAF). There has always been a need for a means to safely transport infants in a controlled environment within the AE arena. The OHIO Transport Incubator, currently in use, is no longer manufactured; consequently, there is a shortage in spare parts to repair those incubators still being used. The Model 185 Airborne Life Support Systems (ALSS) is the selected AE replacement incubator. This incubator is lighter than the OHIO and has an internal battery, a digital display (light emitting diode [LED]) temperature readout, and an internal humidification system. It is now available for use.

DESCRIPTION

During AE missions, the ALSS 185 Infant Transport Incubator supports an infant's thermal need in flight by circulating warmed, humidified air through the infant chamber.

The incubator dimensions are: height, 50.8 cm (20 in.); width, 101.6 cm (40 in.); depth, 55.9 cm (22 in.); and weight, 36.3 kg (80 lb). The infant chamber is enclosed in a clear Plexiglas double-walled hood. The mattress tray dimensions are 30.5 x 61 x 1.9 cm (12 x 24 x 3/4 in.). The rectangular mattress, slightly smaller than the tray, is a spongy foam material covered by a plastic outer shell. The infant chamber has a minimum vertical clearance of 22.9 cm (9 in.). There is a front access door with two hand ports 20.3 x 56.5 cm (8 x 22 1/4 in.), a standard size head access door, and two standard size tubing ports. Mounted to the incubator frame is a flexible 5-watt examination light. On the aft face of the unit an intravenous (IV) pole is secured with a well and lock pin. There is space for securing two "D" or two "E" size oxygen cylinders. The incubator has carrying handles on both ends with two securing devices. These securing devices are used to safely secure the incubator to a standard North Atlantic Treaty Organization (NATO) litter which is placed in the securing stanchions of the aircraft.

A two position rocker switch is used to turn the incubator power on and off. The infant chamber temperature is controlled by a thumb wheel rheostat located on the lower right corner of the front face of the incubator. Next to the thumbwheel control is an LED display ranging from 30.0-39.9 °C (87.6 - 103.8 °F). The operator uses the thumbwheel to increase or decrease the incubator temperature in 0.1 °C increments. There are two external ports on the front face of the incubator to control the humidification system. Using these ports, the operator can add or remove water from a sponge located in a compartment below the mattress tray without disturbing the infant or changing the internal incubator temperature. Heated air inside the incubator is humidified as it circulates across the sponge.

The unit can operate from an external power source of 115 volts alternating current (VAC) 50 to 400 hertz (Hz), 12 to 14.5 VDC, or from an internally mounted 12V/24 ampere hour (AH) sealed lead/acid rechargeable battery. When the incubator is connected to an AC source and the power switch is on, the AC operation mode is automatically selected and the AC operation (OP) indicator is illuminated. Battery operation is automatic when the power switch is turned on and no external power is applied. The battery (BAT) OPERATION indicator illuminates in this mode. External 12 VDC operation is automatic when applying external DC power and switching on the power switch. The DC OPERATION indicator illuminates to reflect external 12 VDC operation. Connecting AC power will supersede external DC operation.

Illumination of the LOW BATTERY indicator, accompanied by an intermittent audible alarm, indicates battery voltage is less than 11 VDC. The incubator will be able to supply the heater requirements for only a few minutes in the low battery operation mode. The LOW BATTERY alarm is non-resettable. The POWER FAIL indicator activates when the battery falls below 10 VDC, indicating that the battery has reached its safe discharge limit, and power to maintain the temperature in the infant chamber is no longer available. All power to the incubator, other than for this indicator and audible alarm, is disabled.

The HIGH TEMP alarm indicator, accompanied by an intermittent audible alarm, is triggered when the temperature of the primary sensor exceeds 38.5 °C (101.3 °F). The HIGH TEMP and SYSTEM FAIL alarms, coupled with a continuous audible alarm, indicate that the primary temperature sensor is over 39.0 °C (102.2 °F). The incubator's heater system is disabled and the incubator will cool to below 39.0 °C (102.2 °F) before re-energizing the heating system. The SYSTEM FAIL alarm alone, coupled with a continuous audible alarm, indicates that the secondary (backup) temperature sensor subsystem is reading over 39.2 °C (102.6 °F). The incubator's heater system is again disabled and the incubator will cool to below 39.2 °C (102.6 °F) before re-energizing this subsystem. The activation of this subsystem alarm indicates a problem with either the temperature sensors or with the control circuitry. This condition indicates a need for incubator service by qualified personnel.

The AIRFLOW alarm, coupled with a continuous audible alarm, indicates that there is an airflow blockage by some object, such as a blanket. The incubator's heater system is disabled and the incubator will cool until the thermal switch on the heater element drops below its selected temperature. After the airflow is restored and the heating element has cooled, the heater system will return to normal operation. The SENSOR FAIL alarm, coupled with a continuous audible alarm, indicates that the temperature being sensed by the primary temperature sensor subsystem is well outside the normal operational range of the incubator. The activation of this alarm indicates a problem with the temperature sensor or with the control circuitry, and a need for service by qualified personnel. An Indicator Test Switch, located on the operation panel, is used to test the LED on the display panel and the audible alarm.

METHODS

The Aeromedical Equipment Evaluation Laboratory (AEEL) Procedures Guide (1), an internal document, prescribes which tests are performed and provides a quantitative description of those tests. Not every piece of equipment we evaluate undergoes each and every test. Also, since every piece of equipment is different and unique, not every piece of equipment will be tested in the exact same way.

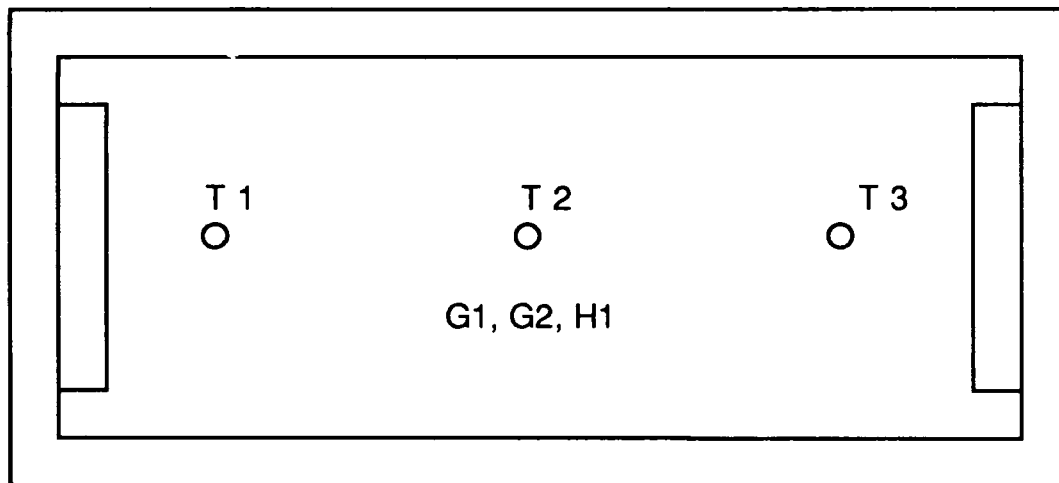


Figure 1. Probe placement.

1. Temperature Sensors (10.2 cm (4 in.) above the mattress)
 - a. T1 (Head) - Centered and 5.1 cm (2 in.) in from the incubator wall
 - b. T2 (Middle) - Centered within the incubator
 - c. T3 (Foot) - Centered and 5.1 cm (2 in.) in from the incubator wall
 - d. T4 (Ambient) - Outside the incubator monitoring room or chamber
2. Humidity Probe
 - a. H1 - Centered within the incubator and 10.2 cm (4 in.) above the mattress
 - b. H2 - Outside the incubator monitoring room or chamber
3. Gas Measurement
 - a. G1 (Oxygen) - During actual usage the placement of the oxygen sensor is 5.1 cm (2 in.) from the infant's airway. To approximate this position, we placed the gas analyzer 11.4 cm (4.5 in.) from the front access door and 20.3 cm (8 in.) from the incubator wall (head). Measurements within the electrical compartment were made centered within the compartment.
 - b. G2 (Carbon Dioxide) - Measurements were made at the same location as the oxygen sensor within the incubator. Carbon dioxide flow was administered at the center of the incubator compartment.

The tests described in this section simulate the environment under which the device must function, but under controlled laboratory conditions. We approximate field conditions as closely as possible for a limited time. The tests vary only one parameter at a time. Comparison to baseline measurements enables us to assess that parameter's effect on the item. The precise setup used to test the item is determined by the Project Coordinator (PC).

Data are collected by computer whenever possible to simplify data plotting and analysis. If data recording cannot be done by computer, the data are manually recorded on a "Data Collection Sheet." Information specifically relating to the test setup is recorded for each test on a "Test Information Sheet."

Figure 1 illustrates the location of the test probes: temperature, oxygen, carbon dioxide, and humidity. Ambient temperature was monitored during all tests. The infant chamber temperatures were measured at three locations across the infant mattress; each centered from front to back and 10.2 cm (4 in.) above the mattress; the head and foot probes were 5.1 cm (2 in.) in from the left and right Plexiglas walls; the middle probe was centered above the mattress. Power transformer temperature measurements were made by taping the temperature probe directly to the transformer. Grant EU-U-V5 minithermistors and a Grant Squirrel Model 1201 Datalogger were used throughout our evaluation. Oxygen and carbon dioxide concentrations were measured with a Perkin Elmer Model 1100 Medical Gas Analyzer. Oxygen samples were taken at two locations: centered and 10.2 cm (4 in.) above the mattress, and centered in the electronics compartment. Humidity was measured in and outside the incubator using a Grant L-type probe. Measurements inside the incubator were made centered and 10.2 cm (4 in.) above the mattress. Unless otherwise noted, the incubator was prewarmed to 37 °C (98.6 °F) on 110 VAC /60 Hz prior to each test.

Baseline Performance Assessment

The purpose of the Baseline Performance Assessment (BPA) was to measure and record the incubator's performance under standard ambient conditions (22.0 ± 2 °C (71.6 ± 4 °F), 750 ± 10 mmHg barometric pressure, $50 \pm 30\%$ relative humidity) prior to adverse testing. The BPA is used as a reference to measure subsequent performance against, to verify selected manufacturer and contract specifications, and to ensure safe operation and use prior to testing.

Human Factors and Physical Characteristics-- These are observations made throughout our evaluation. Observations and corrective action are listed in the Results section.

Warm-Up Time -- The time required to warm the incubator to a set temperature of 37 °C (98.6 °F) was measured while operating on 110 VAC/60 Hz and 400 Hz. Ambient temperature was approximately 21 °C (69.8 °F) during the 110 VAC/60 Hz test and approximately 24 °C (75.2 °F) during the 110 VAC/400 Hz test.

Temperature Accuracy and Uniformity -- The incubator's display temperature was compared to the mid-mattress temperatures to determine the display's accuracy. Temperature uniformity was determined by comparing the displayed temperature with all three mattress temperatures. Mattress temperature uniformity was evaluated during a 3-h period at standard ambient conditions with the incubator pre-warmed to 37 °C (98.6 °F).

Electrical Safety -- Electrical safety testing consisted of ground resistance and leakage current measurements, and a visual examination of the incubator's wiring and strain relief. Ground resistance was measured from the power plug's ground pin to the exposed metal chassis. The leakage current was measured with the power on and off, with all controls adjusted to yield the highest leakage current (unit off), with the power supply ground intact (normal polarity), with ground lifted (normal polarity), and ground lifted (reverse polarity). All measurements were made using a Dempsey Model 431 Safety Analyzer.

Battery Operation/Charging Characteristics -- These tests were performed to verify the incubator's battery operation time and charging characteristics. Battery operation and charging currents were measured by placing a precision resistor load of 25 milliohms in series with the positive battery terminal and calculating the current from the resulting voltage drop. Battery voltage was measured across the battery terminals. Temperatures and voltages were recorded on a Squirrel Datalogger at a sample rate of once per minute. The incubator's battery was first discharged until the low battery light illuminated and then charged for 6 h on 110 VAC/60 Hz. The incubator was then pre-warmed to 37 °C (98.6 °F) on 110 VAC/60 Hz in accordance with (IAW) the manufacturer's instructions. It was then disconnected from external power and allowed to operate on internal battery until the low battery light illuminated. This charge and operation cycle was repeated on 110 VAC/400 Hz power.

Extended Operation on 110 VAC/400 Hz -- Power sources of 110 VAC/400 Hz are unique to the aircraft. To ensure the incubator would safely operate on 110 VAC/400 Hz for an extended period, the unit was operated for 36 hours under ambient room temperature and humidity. The incubator and power transformer temperatures were measured during this period.

Tilt Test -- The incubator is placed in many different angles and axes during transport. To test for water leakage from the humidification reservoir into other areas of the incubator, we filled the reservoir with 250 ml (8.4 oz) of water, IAW the manufacturer's literature at that time, and tilted the incubator 45° from front to back and from side to side for a 1-min period. We then examined the incubator's bassinet and electrical compartment for any signs of fluid leakage or component securing problems; e.g., at the battery, bassinet or cylinder fasteners.

Interior Sound and Light Levels -- Bioenvironmental engineers from the USAF Clinic, Brooks AFB, took sound and light measurements using a Gen Rad Model 1982 Octave Band Analyzer Sound Meter and a Lite Mate III Model 504 Photometer. Sound level measurements were made at the infant's head location. Light measurements were made as indicated in the Results section.

Electromagnetic Compatibility

The purpose of these tests is to verify compliance with MIL-STD-461C, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e (2).

Radiated Emissions (RE-02) -- The RE-02 test measures radiated emissions generated by the incubator. Excessive emissions could interfere with aircraft navigation and communication equipment. The incubator was tested operating on 110 VAC/60 Hz, on 110 VAC/400 Hz, on internal battery, and while charging on 110 VAC/400 Hz. Incubator control settings were as follows: with temperature set to 37 °C (98.6 °F) with one front port door open to ensure heater circuit remained on, with light on, with Alarm Test button both on and off, with internal battery discharged (low battery LED on;) during AC tests, and with battery fully charged.

Conducted Emissions (CE-03) -- The CE-03 test measures conducted emissions generated by the incubator and conducted back up the power line. Excessive conducted emissions could affect the aircraft power supply and/or systems powered from it. The incubator was tested operating on 110 VAC/60 Hz, on 110 VAC/400 Hz, and while charging on 110 VAC/400 Hz. Incubator control settings were as follows: temperature set to 37 °C (98.6 °F) with one front port door open, with the light on, and with the Alarm Test button both on and off.

Radiated Susceptibility (RS-02) -- The RS-02 test determines whether the ambient electromagnetic fields encountered in flight interfere with incubator operation. The incubator was exposed to the electromagnetic induction fields described in the USAFSAM Test and Evaluation Planning Guide for Aeromedical Evacuation Equipment (3). During exposure, the incubator was operated on both 110 VAC/60 Hz and battery power while monitoring incubator temperatures and alarm functions.

Conducted Susceptibility (CS-06) -- The CS-06 test verifies that the incubator will safely operate from the aircraft's noisy fluctuating power supply. Electrical voltages and waveforms specified in MIL-STD-461 were used. During exposure, while the incubator was operated on both 110 VAC/60 Hz and 110 VAC/400 Hz, incubator temperatures and alarm functions were monitored.

Vibration

The vibration test, consisting of random and sinusoidal X, Y, and Z curves, tests an item's construction, durability, and performance during severe vibration. Because of the size of the incubator, the vibration table at USAFSAM could not accommodate this test; consequently, the incubator was taken to the US Army Aeromedical Research Laboratory (USAARL), Fort Rucker, Alabama, for testing support. The USAARL vibration table was used to test the incubator which was strapped to a .95 cm (3/8 in.) metal plate that had been bolted to the table. During the test, the table was controlled by a GenRad computer system. The vibration curve used, Figures 2 and 3, was derived from data collected during a helicopter mission. The incubator

was vibrated on each of the X, Y, and Z axes for 1 h each. An accelerometer attached to the plate allowed the GenRad system to monitor the exact vibration experienced by the plate. Following the tests, a visual inspection of the incubator was performed.

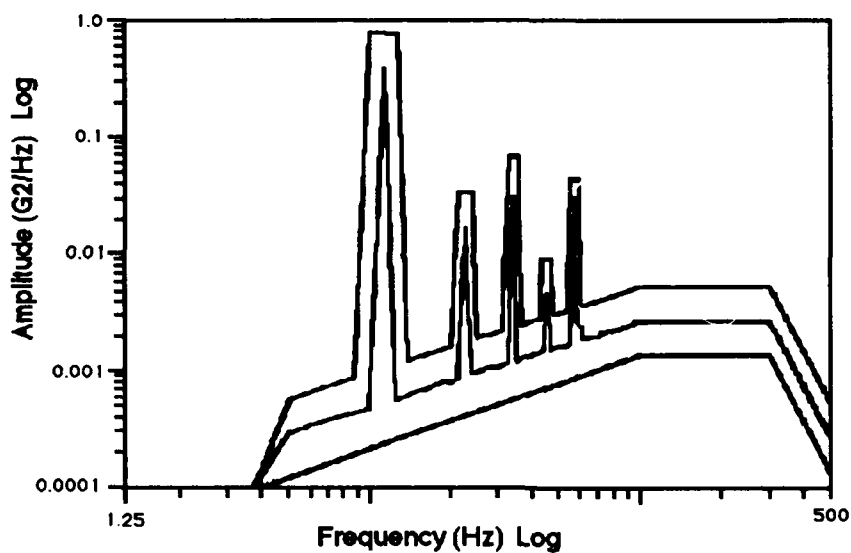


Figure 2. X and Y axis vibration test.

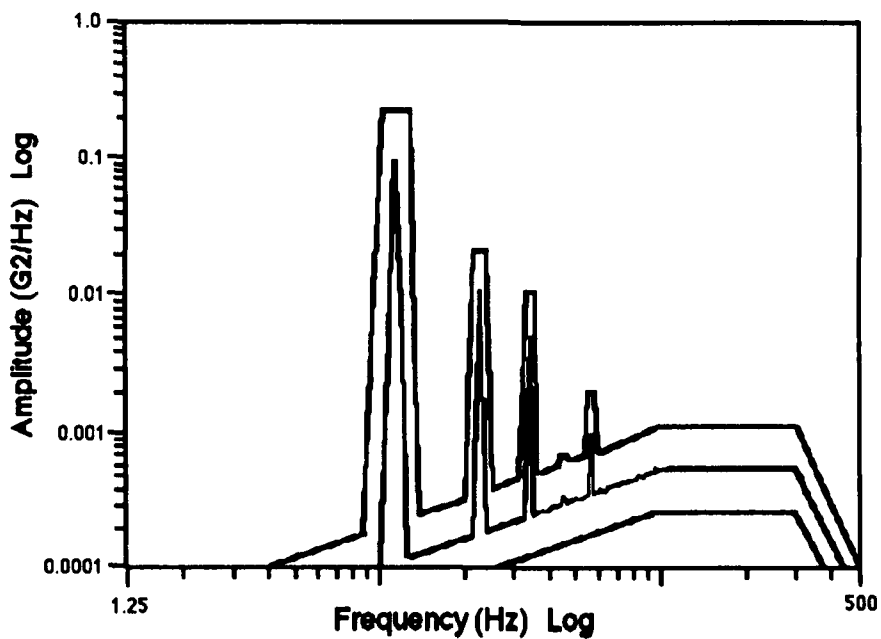


Figure 3. Z axis vibration test.

Environmental

The environmental tests measured the incubator's performance under varying temperature and relative humidity (RH) conditions encountered during transport. During each of these tests, except for the storage tests, the incubator was prewarmed to 37 °C (98.6 °F) and placed in an environmental chamber and operated for the specified period. The incubator was preheated to 37 °C (98.6 °F) and allowed to stabilize for 20 min prior to both operational and storage tests. The incubator was placed in the environmental chamber and operated on both line 110V AC/60 Hz and internal battery power for the specified periods.

High Temperature --

Operation: 49 °C $\pm$ 2 °C (120 °F $\pm$ 3.6 °F) for 2 h.

Storage: 60 °C $\pm$ 2 °C (140 °F $\pm$ 3.6 °F) for 6 h.

Low Temperature--

Operation: 0 °C $\pm$ 4 °C (32 °F $\pm$ 7.2 °F) for 2 h.

Storage: -40 °C $\pm$ 2 °C (-40 °F $\pm$ 3.6 °F) for 6 h.

Humidity --

Operation: 94 $\pm$ 4% RH, 29.5 °C $\pm$ 2 °C (85 °F $\pm$ 3 °F), for 4 h.

5% Humidity -- Specifications called for the incubator to maintain 20% RH within the infant chamber for 4 h while operating within a 5% RH ambient environment. This test was performed using a hypobaric chamber to create a 5% RH environment at an equivalent altitude of 3048 m (10,000 ft). With the incubator inside the chamber, a Grant Model 1201 Data Logger recorded both the interior incubator hood and the ambient chamber temperatures and RH. One humidity probe was placed inside the incubator mid-compartment, elevated approximately 5.1-7.6 cm (2-3 in.) above the mattress. A second humidity probe was positioned outside the incubator approximately 0.30 m (1 ft) away. The temperature was monitored inside the incubator hood mid-compartment, and outside the incubator at the end of the NATO litter. Per manufacturer's recommendations, 150 cm³ of water was injected into the incubator's humidification system. The Data Logger sampled humidity and temperature levels every minute. Occasionally, throughout the test, an attempt was made to extract excess water from the humidification system's drain port.

Direct Sunlight Exposure -- This test was conducted to determine the effects of direct sunlight on the clear Plexiglas hood assembly. The unit was prewarmed to 37 °C (98.6 °F) and exposed to direct sunlight while the Grant Data Logger monitored the incubator's infant chamber temperature at three locations, and the ambient temperature outside the incubator 0.30 m (1 ft) from the incubator. Sample readings were taken every 15 sec to observe the rapid temperature increase.

In a second test, the effect of shading the incubator hood area from the sun was examined. The test setup and environmental exposure was the same as for the first sunlight test. A standard white hospital bedsheet was folded in half and folded in half again, and placed over the Plexiglas hood. Following both tests, the incubator was taken indoors and allowed to stabilize at 37 °C (98.6 °F).

Altitude

We subjected the incubator to reduced atmospheric pressures of 564 mmHg, 2440 m (8,000 ft) equivalent, for a 30-min period on battery power.

Decompression

Decompressions are uncommon; however, if one were to occur, the incubator should not present a hazard to the infant, to the crew, or to aircraft operations. In the hypobaric chamber the incubator, operating at an equivalent cabin pressure of 2438 m (8,000 ft), was subjected to a series of three sudden decompressions to 12,190 m (40,000 ft) equivalent pressure in 1, 7, and 60 sec.

Fresh Air Flow

Air exchange within the infant chamber is a concern since an excessive buildup of carbon dioxide (CO₂) or oxygen (O₂) could worsen the condition of the child in the incubator.

Carbon Dioxide Concentration -- Fresh air flow through the incubator must be sufficient to prevent a buildup of CO₂. The maximum safe concentration of CO₂, as specified in the contract, is 0.5%. Thirty cc/min of CO₂* was injected into the infant chamber of the incubator that had been prewarmed to 37 °C (98.6 °F). The CO₂ concentration inside the infant chamber and the ambient concentration outside the incubator were monitored using the Perkin Elmer Model 1100 Medical Gas Analyzer.

Oxygen Concentration -- Maximum oxygen concentrations which could be maintained within the incubator at various oxygen flow rates were evaluated at an equivalent altitude of 3048 m (10,000 ft) in the hypobaric chamber. Oxygen was ducted into the prewarmed incubator through a flowmeter. A Biomarine Oxygen Analyzer measured the O₂ concentration inside the infant chamber at flow rates of 1, 2, 3, 4, 5, 6, 7, 10, and 15 liters per minute. The O₂ concentration at each flow rate was recorded.

In-Flight Feasibility

Two Aeromedical Research Technicians assigned to USAFSAM/VN performed the in-flight feasibility test in C-9, C-12, C-21, C-130, and C-141 aircraft and in UH-1, and H-60 helicopters. The purpose of in-flight testing was to evaluate the incubator's compatibility with each airframe, to verify that it was operationally sound, and to verify its structural ability to withstand the vibrations encountered during actual takeoff, in

* As suggested by the AAMI Draft Standard for Infant Incubators (May 1984).

flight, and during landing. The incubator was operated according to manufacturer's specifications for actual use. During each flight, the AE technicians measured ambient and incubator temperatures every 15 min both manually and using a Grant Squirrel Model 1201 Datalogger with Grant Type EU-U-V5 mini-thermistors. Relative humidity was recorded every 15 min on the C-141 mission, using a Hygrotest Model 6400 temperature/humidity probe. Decibel noise levels inside the incubator hood and within the aircraft cabin were measured every 15 min using Metrosonics Sound Level Analyzers Model dB-310. Ambient humidity levels within the aircraft cabins were measured with a Princo Humidity System (swing type) with slide conversion ruler. Following each mission the data derived from the evaluations were transferred to a Z-184 laptop computer. Other medical crewmembers on each mission were encouraged to help with on/off loading procedures, to help secure equipment onboard the aircraft, and to ask questions about the incubator, thereby providing user feedback.

RESULTS

Baseline Performance Assessment

Human Factors and Physical Characteristics -- The securing mount originally failed to safely secure the incubator to a NATO litter. The bulkiness and rounded edges of the incubator in combination with tilting the litter during loading caused the incubator to partially slide off the litter. The straps and metal hooks provided with the unit did prevent the incubator from totally falling off the litter. Nevertheless, the litter was very awkward and unstable to carry. The manufacturer later modified the mount, placing an additional aluminum ridge on each side of the existing mount which prevented slippage when carrying.

Several glued-on rubber feet, separating the hood's double wall construction, fell off during normal use. The manufacturer later added Plexiglas extensions to the internal wall construction eliminating the need for rubber feet. No secure storage or vertical securing mechanism was provided with the IV pole. A twistlock and spring-loaded locking mechanism was added later to prevent vertical dislodging during use. A securing mechanism was also added to prevent IV pole movement in the storage position.

Warmup Time -- The incubator warmup time to 37 °C (98.6 °F) was 16 min on 110 VAC/60 Hz and 8 min on 110 VAC/400 Hz. Differences in warmup times were attributed to the difference in ambient temperatures between the two tests. The ambient temperature was approximately 21 °C (70 °F) during the 110 VAC/60 Hz test and approximately 24 °C (75 °F) during the 110 VAC/400 Hz test. The warmup times were within the limits specified in the contract (no more than 20 min). Note that the manufacturer's operating instructions specifies a 20-min stabilization period at the selected temperature before placing the infant into the incubator.

Temperature Accuracy and Uniformity -- Accuracy of the incubator's display temperature was within the limits specified in the contract, ± 1 °C (2 °F) from the incubator's set temperature at an ambient temperature of 22.77 °C (73 °F), and the

manufacturer's specification, $\pm 0.5^{\circ}\text{C}$ (1°F) for display accuracy. It should be noted that during the incubator warmup period and during rapid extreme temperature changes the temperature accuracy and uniformity may exceed 1°C (2°F). However, this is an expected and an inherent characteristic of incubator heating systems which use heated circulating air. Example: The Ohio Transport Incubator currently in use has temperature variations greater than 10°F when exposed to environmental changes, i.e., 4.4°C (40°F), 22.7°C (73°F).

Electrical Safety -- The electrical safety check consisted of ground resistance and leakage current measurements as well as a visual inspection of the incubator's wiring and strain relief. Measured ground resistance from the ground pin of the power plug to the exposed chassis was $120\text{ m}\Omega$. Maximum chassis leakage current was $16\text{ }\mu\text{A}$. During disassembly, the battery lead wire's insulation frayed causing arcing between the exposed wire and the metal chassis. The wire's insulation was so thin it could be easily scraped off with fingernail pressure. The manufacturer later increased the insulation factor to its Underwriter Laboratory (UL) rating.

Battery Operation and Charging Characteristics -- Battery operation time was 3.7 h, after a 6-h battery charge on 110 VAC/60 Hz and 3.45 h, after a 6-h battery charge on 110 VAC/400 Hz. These battery operation/charge times were within the contract specifications (minimum 2-h operation, 24-h charge time) and the manufacturer's specifications (nominal 3-h operation, 6-h charge time).

Extended Operation on 110 VAC/400 Hz -- The incubator was operated for 36 continuous hours on 110 VAC/400 Hz. No excessive transformer temperatures or operational problems were noted.

Tilt Test -- Approximately 60 cm^3 of water overflowed from the reservoir past the heating pad, power switching transistor (Q-5), and into the air circulating fan when the incubator was tilted 45° . Fluid leaked around Q-5 and onto its soldered lead connections. Water within the circulating fan area did not leak into the motor or electronics beneath. The manufacturer resolved the problem by reducing the recommended reservoir volume from 250 to 150 cm^3 and using insulating sealant around Q-5. After making these changes, we repeated the tilt test with no water leaks noted. According to the incubator manufacturer, the chance of electrical hazards caused by water leaks is remote and has never been reported by customers over years of use. To further minimize the hazard, we recommend clearly identifying the sponge specifications within the operation manual. A sponge which is too thick may alter airflow and temperature characteristics; a sponge which is too small or using no sponge will increase the probability of fluid leakage from the reservoir.

Interior Sound and Light Measurements -- Sound measurements were below the 60 dBA specified in the contract under normal operation. Other noise levels are presented in Table 1 for information only. Light illumination levels, shown in Table 2, are within the contract limits of 30 fc at mattress level. However, illumination intensity varies considerably across the mattress.

TABLE 1. INTERIOR NOISE LEVELS.
(110 VAC/60 Hz Operation, 56.2 dBA ambient noise)

Inside incubator, normal operation	56.0 dB
Inside incubator, warmup	69.6 dBA
Inside incubator, alarms on	76.6 dBA
Inside incubator, charging	46.4 dBA
Inside incubator, ambient noise of 90 dBA	72.0 dBA
Inside incubator, ambient noise of 100 dBA	84.0 dBA

TABLE 2. INTERIOR LIGHT LEVELS.
(0.12 fc ambient light)

Center of mattress	67.3 fc
10.2 cm (4 in.) from center toward foot	10.8 fc
10.2 cm (4 in.) from center towards head	20.8 fc
10.2 cm (4 in.) from center towards front	33.5 fc
10.2 cm (4 in.) from center towards rear	13.8 fc
Centered at end of mattress (foot)	1.40 fc
Centered at end of mattress (head)	2.92 fc

Electromagnetic Compatibility

The incubator failed the first set of electromagnetic compatibility tests performed in May 1988, in the narrow band areas of RE-02 and CE-03. The incubator was sent back to the manufacturer to correct the problem areas. A retest was performed in August 1988, and the item passed. Modifications consisted of shielding the fan by encasing it in a metal can and placing a Sprague 735P μ F (5 microfarad $\pm$ 10%, 100 VDC) across the power transformer secondary lead.

Vibration

The incubator operated correctly throughout the vibration test. A visual inspection of the incubator, including the electronic compartment, revealed that everything was intact and operational. None of the components showed abnormal wear.

Environmental

High Temperature -- During the 2-h operation test in a 49 °C (120 °F) ambient temperature environment, the incubator reacted according to manufacturer's specifications (Fig. 4). Once 38.5 °C (101.3 °F) was sensed, the HIGH TEMP alarm activated followed by a SYSTEM FAIL alarm at 39 °C (102.2 °F). After the 2-h Hot Operation test was finished, the incubator was removed from the heated chamber environment. Approximately a 1.5 h cool-down period was required to lower the infant chamber temperature to the preset temperature of 37 °C (98.6 °F).

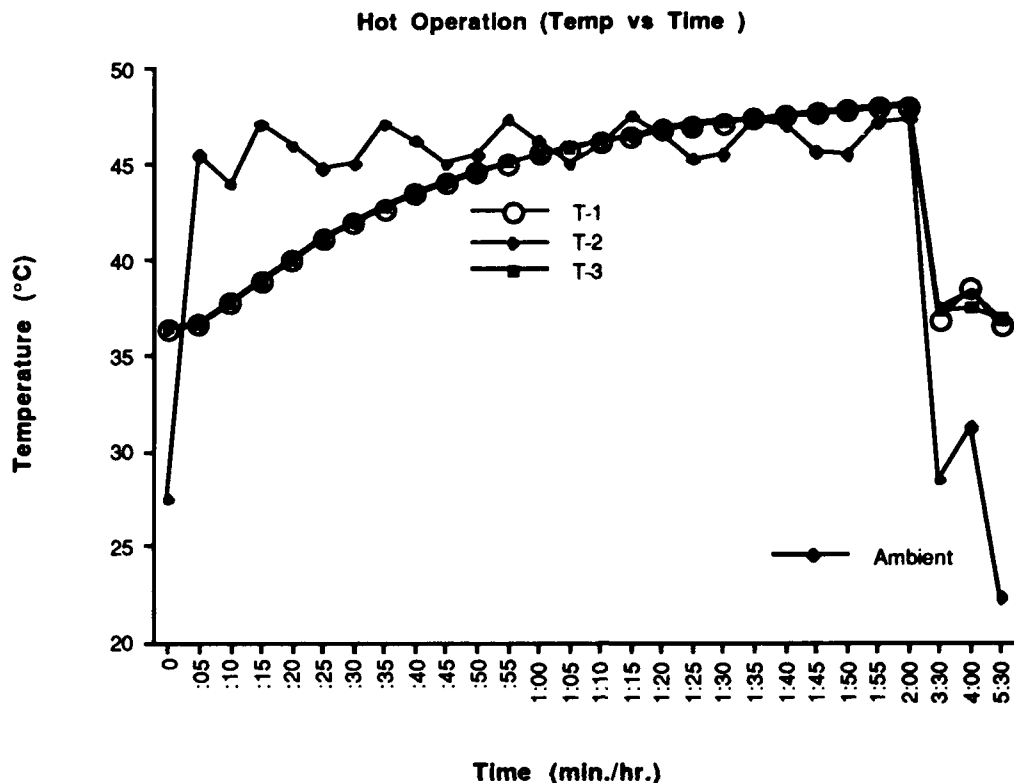


Figure 4. Hot operation test.

Low Temperature -- During the 2-h operation test at 0 °C (32 °F), the LOW BATTERY indicator illuminated approximately 1.5 h into the evaluation. The incubator indicated a temperature of 19.8 °C (67.6 °F). The incubator continued to operate for approximately 1 h longer before the POWER FAIL indicator illuminated signaling that the battery has reached its safe discharge limit (Operation Manual pg 2-3). After the 2 h Cold Operation test was finished, and the incubator was removed from the cooled chamber environment, it took approximately 1.5 h for the incubator to warm to 37 °C (98.6 °F). Following the cold storage test the incubator operated according to specifications and warmed to 37 °C (98.6 °F) (Fig. 5).

5% Humidity -- Figure 6 shows that the incubator performed well beyond the contract specification. With the incubator inside a 5% RH hypobaric chamber environment at an equivalent 3048 m (10,000 ft) altitude, the humidity within the incubator's infant compartment ranged from 43.2-50.5% over 8 h. The contract required the incubator to provide at least 20% humidity for 4 h. The item passed this test. No excess fluid was removed from the incubator's drain port. Our evaluations proved that 150 cm³ of water is adequate to provide the infant with a humidified environment without overfilling the well and sponge.

Cold Operation (Temp vs Time)

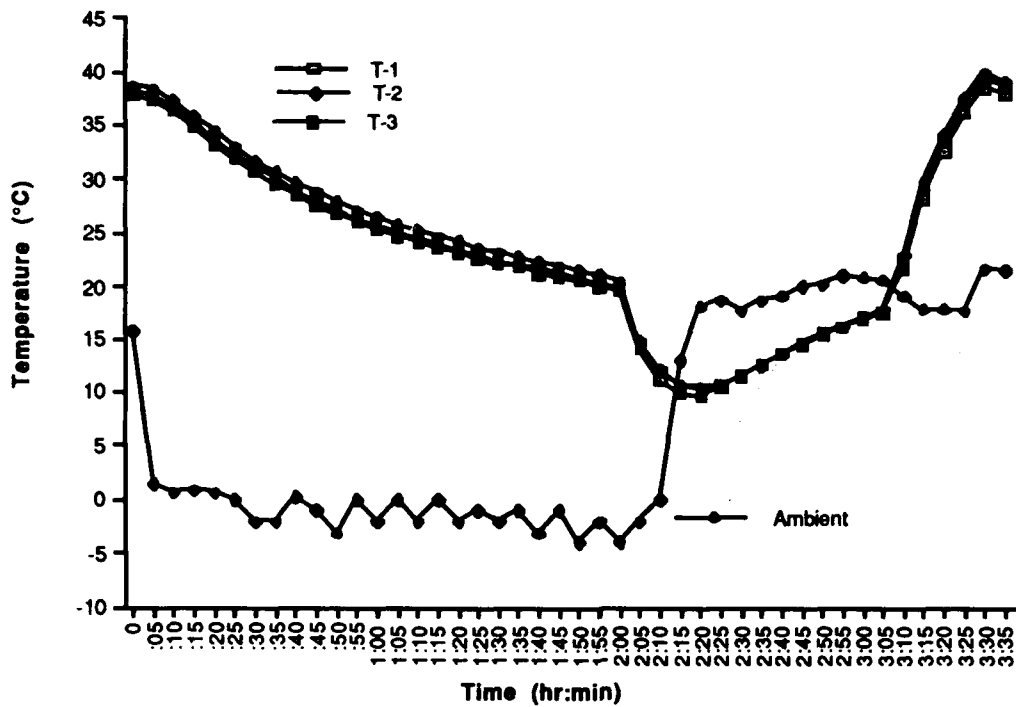


Figure 5. Cold operation test.

Humidity (Levels vs Time)

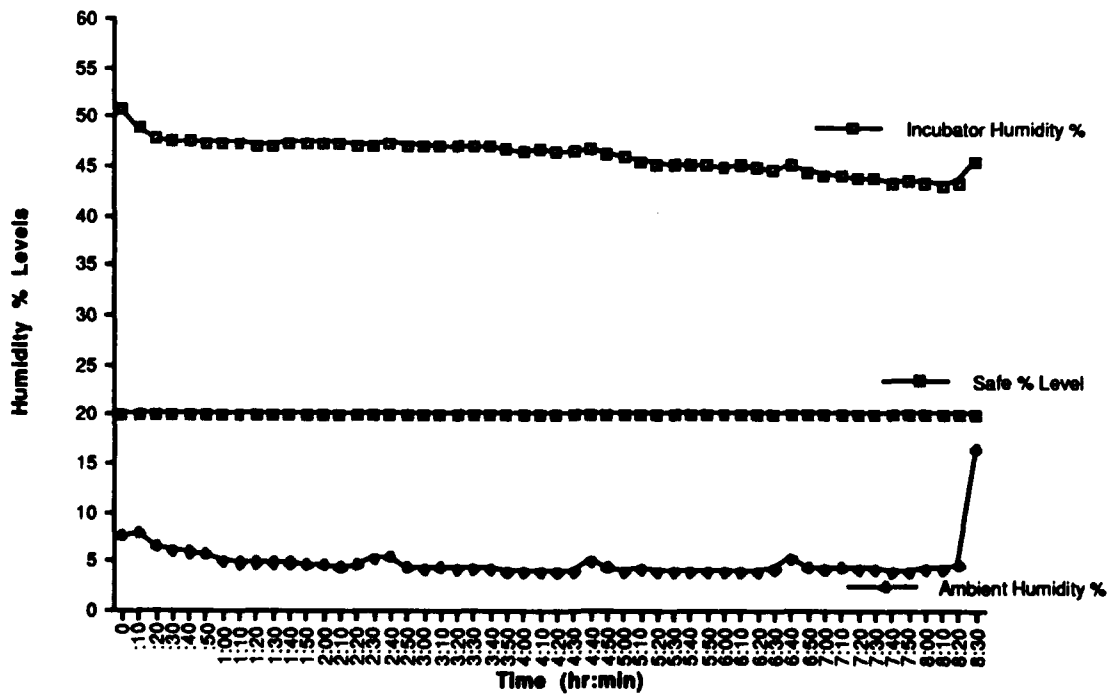


Figure 6. Humidity performance in a 5% RH environment.

Direct Sunlight Exposure -- A sudden temperature rise in the infant chamber occurs when the incubator is exposed to direct sunlight (Fig. 7). This sudden temperature increase could endanger the infant. Heat injury can be avoided by covering the clear, double-walled hood with material similar to the white cotton bedsheet used during our test. Shielding the Plexiglas hood keeps the incubator's infant chamber temperature below a level of concern, and still keeps the infant in view (Fig. 8).

Altitude

At an equivalent altitude of 2438 meters (8,000 ft), infant chamber temperatures were maintained within 1 °C (2 °F) of the incubator's display and set temperatures, Figure 9. No malfunctions were observed during or after the test.

Decompression

Incubator performance during the series of decompressions did not present a hazard to the infant, crew, or chamber operation. Incubator performance was acceptable and considered normal for operation in such a drastically changing environment. Observed temperature changes are illustrated in Figure 10. Immediately after each decompression, the ambient temperature in the hypobaric chamber increased, raising the incubator's temperature to 38.5 °C (101.3 °F) and activating the high temperature alarm. Incubator temperatures continued to increase and activated the system failure alarm at 39 °C (102.2 °F), turning the heater off. The high temperature alarms operated as expected and prevented temperatures capable of causing hyperthermia. As the hypobaric chamber airflow and temperatures changed less drastically during normal descent and at ground level, the incubator's temperature decreased below its selected temperature, turning the heater on.

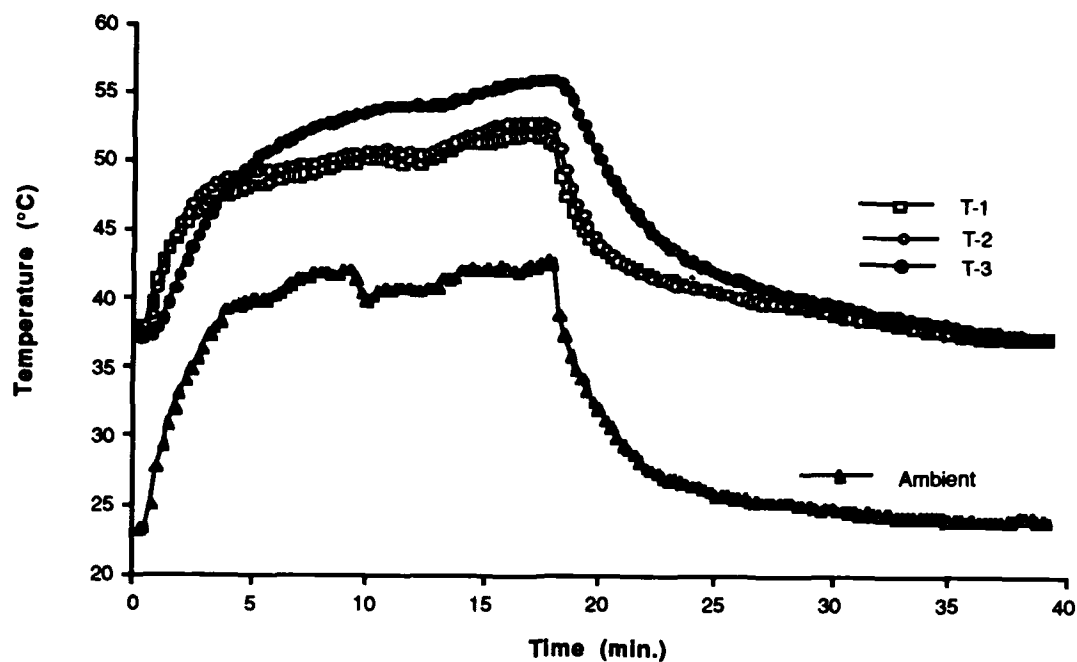


Figure 7. Direct sunlight exposure; no cover.

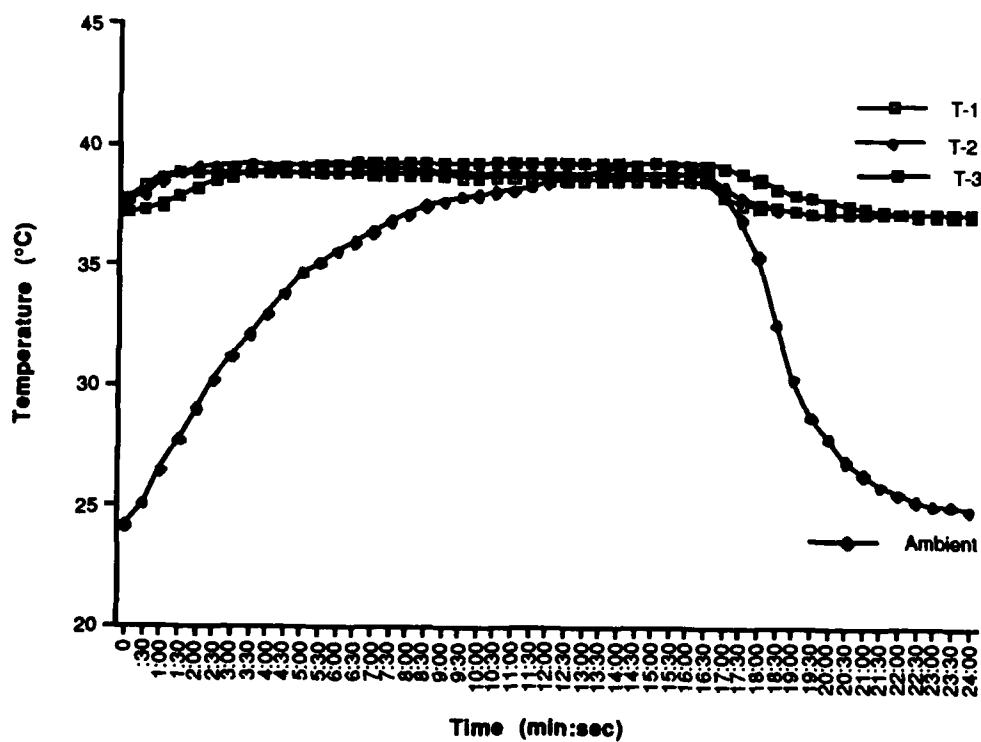
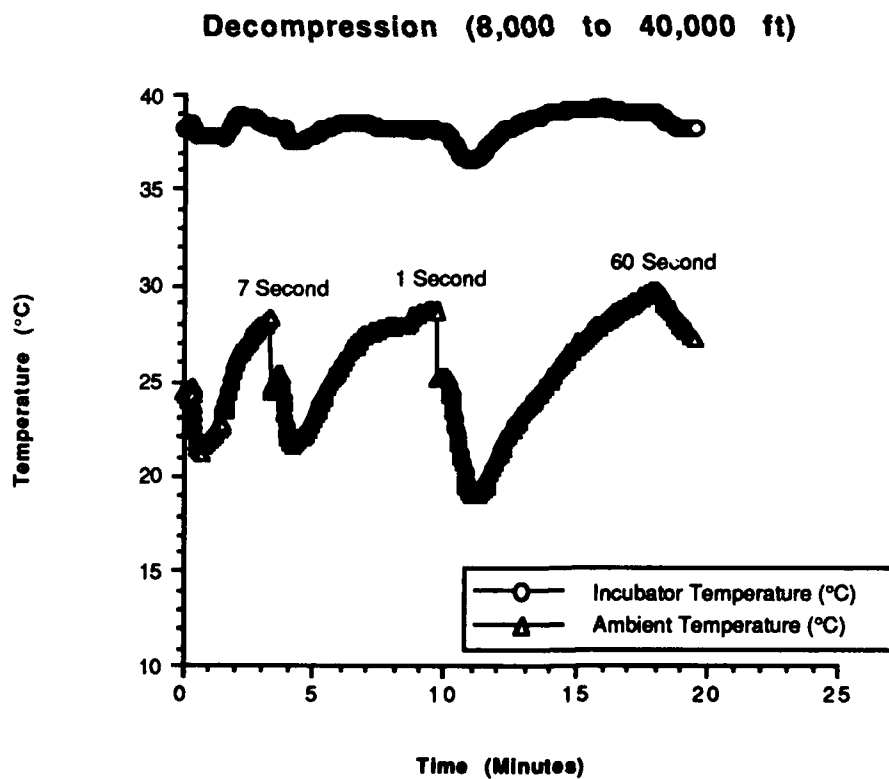
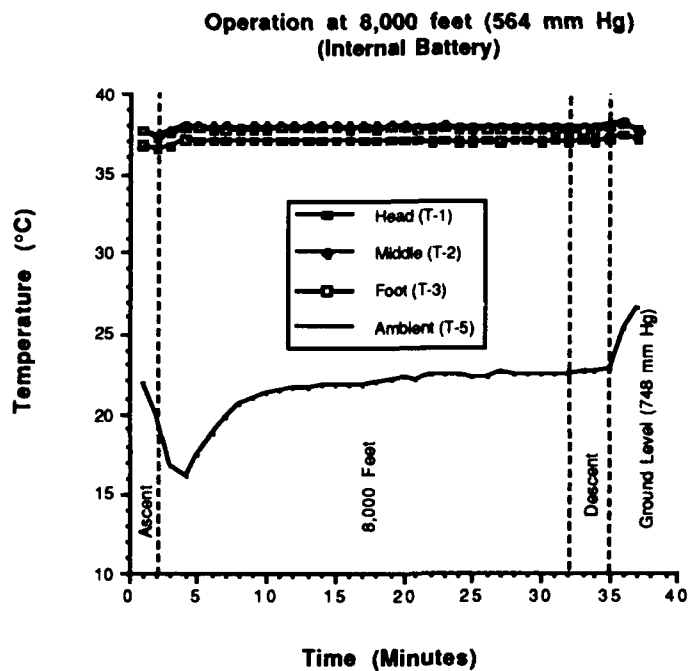


Figure 8. Direct sunlight exposure; with cover.



Fresh Air Flow

Carbon Dioxide Concentration -- The first time this test was performed at ground level, the CO₂ concentration climbed above 0.5% within the first 10 min. During the first 2 h of the test the concentration continued to rise to 0.93%, where it seemed to plateau. For the final 2 h, it remained between 0.93% and 0.99%.

On the original hood, there were three slots along the bottom of the hood to allow fresh air flow, one across the back and one on each side. Working together, one of our engineers and the contractor found that enlarging the two side slots and closing the back slot improved removal of CO₂ without affecting incubator temperature or humidity. When the test was repeated, the CO₂ concentration reached a plateau at approximately 0.27% (Fig. 11).

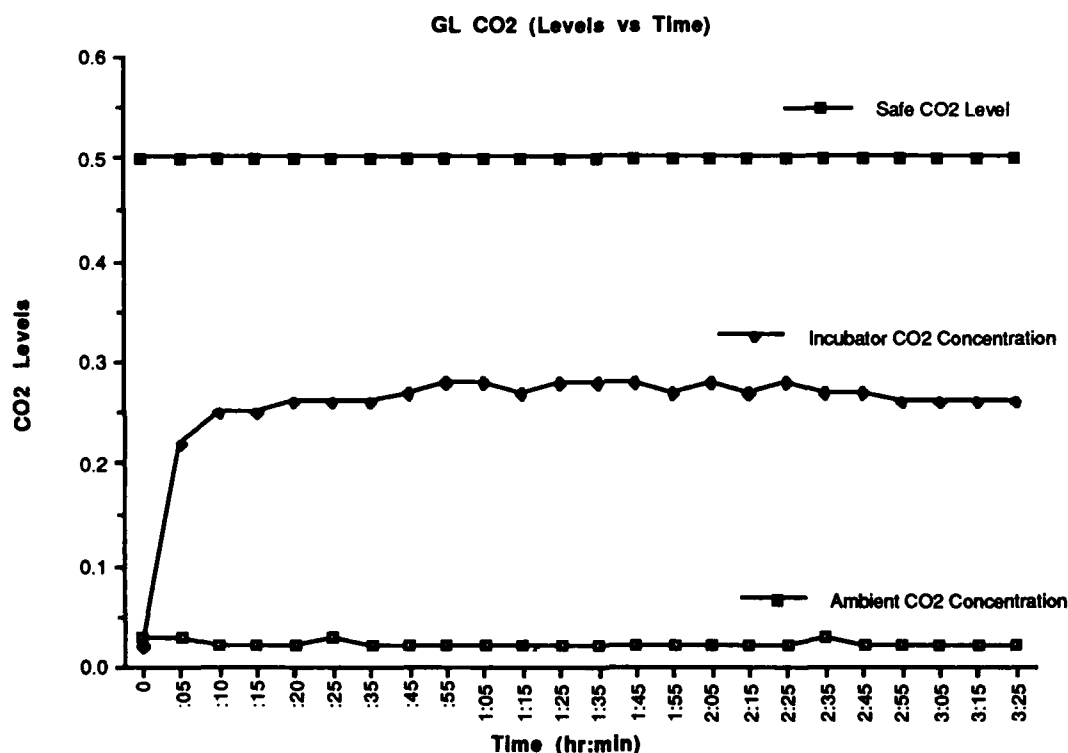


Figure 11. Ground level CO₂ concentration.

The test was repeated at an equivalent altitude of 3048 m (10,000 ft). During this test the CO₂ concentration inside the hypobaric chamber increased, which, in turn, increased the CO₂ concentration inside the infant chamber. Once the hypobaric chamber was vented with fresh air, both concentrations decreased to an acceptable level of 0.29% (Fig. 12).

Oxygen Concentration -- Figure 13 shows the O₂ concentration obtained at several different flow levels. At 15 liters per minute, the O₂ concentration was 85.5%. A maximum O₂ concentration of 98% oxygen was obtained at maximum flow (Flush).

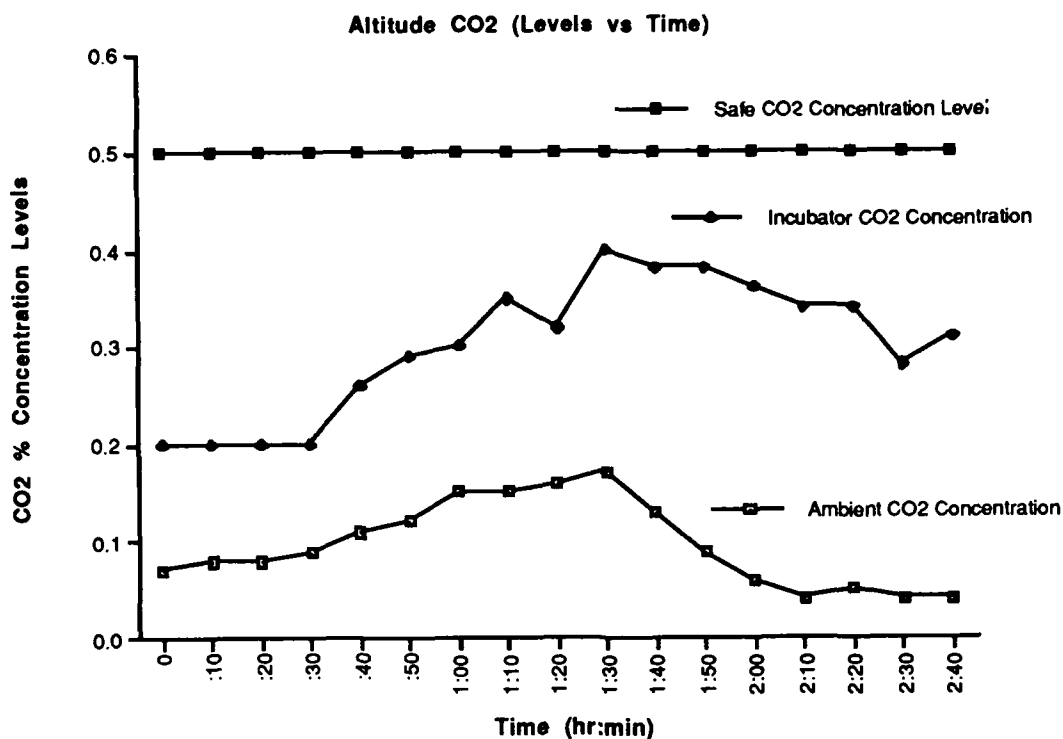


Figure 12. Altitude CO₂ concentration.

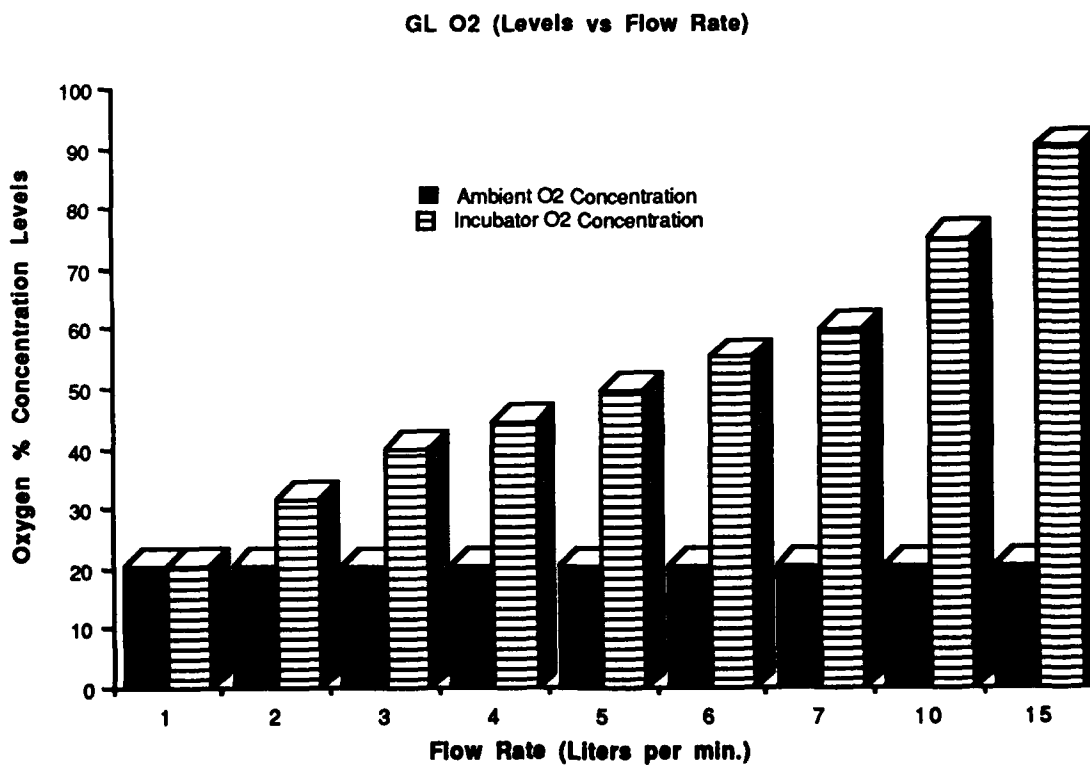


Figure 13. Ground level oxygen concentrations.

In-Flight Feasibility

The incubator performed on each of the aircraft IAW the manufacturer's description of performance. It secured easily to a standard NATO litter and remained secured throughout this testing phase. The litter-mounted incubator fit in the stanchions on each of the selected aircraft with the exception of the H-60 helicopter. Since the helicopter did not have a medevac carousel installed, the incubator was flown strapped to the floor of the helicopter using standard aircraft tiedown straps.

During ground transport of the incubator from the hangar to the helicopter, the incubator was exposed to direct sunlight, activating the High Temp alarm. The ports on the incubator were opened to release heat since the actual temperature within the incubator exceeded 39.7 °C (103.5 °F). Once we removed the incubator from direct sunlight into the helicopter, the temperature returned to 37 °C (98.6 °F), and the system operated normally for the remainder of that mission.

Ambient noise levels and noise levels inside the incubator hood assembly were recorded during the ascent, descent, and in-flight test phases for each aircraft. Environmental impact experts from the USAF Occupational and Environmental Health Laboratory (OEHL) at Brooks AFB evaluated this data and determined the C-9, C-12, and C-21 average in-flight noise levels inside the incubator did not exceed the Environmental Protection Agency (EPA) guideline of 70 decibels (dB) A-weighted (A), calculated over a 24-hour period. The UH-1 helicopter average in-flight noise level was slightly above 70 dB (A), but a 19-h exposure would be required to exceed a daily dose of 70 dB (A) if the remainder of that day's exposure were at or below 70 dB (A). The C-130 average in-flight noise levels in the incubator produced the greatest potential for exceeding the EPA guideline. The C-141 in-flight noise levels inside the incubator varied depending on the O₂ flow rate into the incubator, but never exceeded the EPA level of 70 dB (A) except for a short period during taxi. No reliable data were collected inside the incubator on the H-60 helicopter.

The incubator internal hood temperature was consistently monitored in three places as described earlier in this report. During in-flight feasibility testing, the ambient temperature was monitored within 0.61 m (2 ft) of the incubator at the end of the litter canvas. The internal temperatures remained fairly constant even though the exterior ambient temperatures varied greatly. The humidification delivery system, along with the incubator's ability to attain varying O₂ concentration levels, was tested during the C-141 mission because of its unique cabin environment and the long flights associated with these missions. The incubator provided adequate humidity and exceeded the requirements specified by the contract. The humidity test was performed IAW the manufacturer's recommendations for introducing 250 cm³ of water into the humidification well. The average level of humidity within the incubator was between 60-70% while operating in average ambient environments ranging from <10-80% RH.

During the in-flight Oxygen Concentration feasibility test, oxygen was introduced into the incubator using the aircraft O₂ system and manufacturer's recommended method of oxygen therapy. The O₂ concentration levels were monitored using the BioMarine Industries Model OA202R Oxygen Analyzer. The analyzer was affected by

aircraft vibration and displayed inaccurate readings. The O₂ Concentration Test was discontinued during this phase of testing and conducted back in the controlled laboratory environment. The incubator passed O₂ concentration tests following hood modifications to allow the escape of excessive CO₂ buildup.

CONSIDERATIONS

There is no physical connection between the inner and outer hood. During removal, the inner hood may slip and injure the infant, or may fall to the aircraft floor or onto another patient or crewmember. The infant securing strap metal fasteners may not adequately restrain an infant during transport. Their small size and construction, similar to a paper clip, may present a hazard to the infant if the metal fastener is separated from the strap. The incubator may not be able to accommodate a 4.5 kg (10 lb) infant safely.

The amount of water needed to provide humidity within the incubator was reduced from 250 cm³ to 150 cm³. We performed the contract required test at the 150 cm³ level and the incubator exceeded the minimum requirements. The operation manual should be changed accordingly.

USAF OEHL concluded that the noise levels generated by the different aircraft the incubator was tested in did not produce a significant risk to hearing within the incubator due to the relatively short period of exposure. No valid data were collected on incubator noise levels in the H-60. The OEHL also recommends not taping ear plugs over the infant's ear. Currently, there is no commercially available hearing protection equipment for infants.

When the incubator is exposed to direct sunlight, a sudden rise in the temperature within the infant chamber occurs, as was the case during the in-flight feasibility test phase when the incubator was transported on the ground from a hangar to a helicopter across a tarmac.

To prevent the sudden rise in temperature inside the preheated incubator subjected to direct sunlight exposure, we recommend shielding the clear Plexiglas hood assembly from the sun's rays. We tested this procedure using a folded white cotton bed sheet.

To prevent an excessive CO₂ buildup, the hood assembly was modified by enlarging slots on the two ends of the hood and closing the slot at the back of the hood to allow for ambient air exchange. It is recommended that AE crewmembers refrain from placing articles that may block the airflow at either end of the hood and incubator tray.

The aforementioned recommended improvement areas were forwarded to the 375 AAW/SGNL for action prior to the Operational Testing and Evaluation (OT&E) phase of the incubator contract. We considered all other items acceptable after manufacturer modifications.

CONCLUSIONS

Based upon careful analysis of the test results, we* have concluded the Model ALSS 185 Infant Transport Incubator is a safe, adequate means for transporting an infant without jeopardizing the infant's health. The incubator is acceptable in its ability to produce warmth, maintain humidity, and accommodate oxygen therapy.

FOLLOW-UP

Upon completion of our evaluation, the incubator underwent Operational Testing and Evaluation (OT&E) where it was actually used in the field. When this testing was completed, some modifications were made to the incubator based on recommendations from our testing and from the OT&E. The following changes were made:

1. The inner and outer hood were permanently connected so they could be removed as one piece.
2. The wire clips used on the restraining straps were removed. The straps were widened, and Velcro was used instead of wire.
3. The hood opening was enlarged by 1.27 cm (0.5 in.) in all directions.
4. The litter securing straps were modified to better stabilize the incubator on the litter.
5. The examination light was moved from the back center to the back right so that it could be reached when the incubator was secured in the aircraft.
6. The head access door was moved from the left to the right side of the hood so that, when it was opened the cold air would not affect the thermostat located under the left side of the mattress.
7. The one-way valve in the humidity fill port was removed because it prevented adequate cleaning.
8. The power cord length was changed from 1.83 m (6 ft) to 3.1 m (10 ft).

* There is a wide variety of medical backgrounds and knowledge among the members of our group. We have a Flight Surgeon (FS), a Flight Nurse (FN), a Biomedical Equipment Maintenance Technician (BEMT), a Medical Research and Development Technician, three Biomedical Engineers, and two Aeromedical Research Technicians (ART). The FN and ARTs remain current and flight qualified in aeromedical evacuation on the C-9A aircraft. Input is also requested from the 375th Aeromedical Airlift Wing (MAC), Aeromedical Equipment Function (SGNL), Scott AFB, IL.

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We would like to thank those who helped and advised us during the evaluation of the **ALSS Model 185 Infant Transport Incubator**. We would particularly like to thank ...

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Capt Sue Nagel
MSgt Thomas Philbeck
MSgt Rufino Navalta
MSgt John Yacalavitch
TSgt Gary Jenkins
SSgt Thomas Waters
Mr. John Jenkins
Mr. Al Lewis

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