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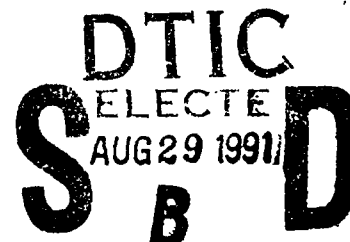
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**TESTING AND EVALUATION OF THE
INTERNATIONAL BIOMEDICAL INC.
NEONATAL TRANSPORT SYSTEM**

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December 1990

Final Report For Period April 1989 - April 1990

91-09071



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USAF SCHOOL OF AEROSPACE MEDICINE
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NOTICES

This final technical report was submitted by personnel of the Crew Systems Branch, Crew Technology Division, USAF School of Aerospace Medicine, Human Systems Division, AFSC, Brooks Air Force Base, Texas, under job order 7930-16-12.

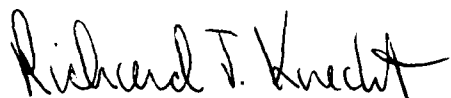
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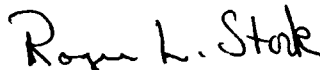
The voluntary, fully informed consent of the subjects used in this research was obtained as required by AFR 169-3.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.



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Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE December 1990		3. REPORT TYPE AND DATES COVERED Final - Apr 1989 to Apr 1990	
4. TITLE AND SUBTITLE Testing and Evaluation of the International Biomedical Inc. Neonatal Transport System				5. FUNDING NUMBERS PE - 62202F PR - 7930 TA - 16 WU - 12	
6. AUTHOR(S) Thomas E. Philbeck, Jr.; Howard S. Heiman; Ernest G. Roy					
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) USAF School of Aerospace Medicine/VNL Human Systems Division (AFSC) Brooks Air Force Base, TX 78235-5301				8. PERFORMING ORGANIZATION REPORT NUMBER USAFSAM-TR-90-23	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES					
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution is unlimited.				12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 words) The Military Airlift Command (MAC) is the central manager for aeromedical evacuation. Infants must be transported in a safe, controlled environment. The International Biomedical Inc. Neonatal Transport System (NTS) has been purchased by several Department of Defense medical treatment facilities for transporting the infants. The Aeromedical Research Function tested and evaluated the NTS, finding that 3 components must be modified to pass the electromagnetic interference standards. The incubator must be modified to allow for carbon dioxide venting and to keep the hood assembly intact during removal. The suction device must not be used outside the NTS structure. The NTS must be operated by a trained neonatal staff member. Wooden blocks and 4 cargo tie-down straps must be used to secure the NTS. The ventilator gas cylinders must not protrude. If the requirements are met, the International Biomedical Inc. NTS is a safe and reliable device for the airborne transport of neonatal infants.					
14. SUBJECT TERMS Aeromedical Evacuation; Neonatal Transport System; International Biomedical Inc.				15. NUMBER OF PAGES 38	
				16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT UNCLASSIFIED	18. SECURITY CLASSIFICATION OF THIS PAGE UNCLASSIFIED	19. SECURITY CLASSIFICATION OF ABSTRACT UNCLASSIFIED	20. LIMITATION OF ABSTRACT UL		

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TESTING AND EVALUATION OF THE INTERNATIONAL BIOMEDICAL INC. NEONATAL TRANSPORT SYSTEM

BACKGROUND

The Department of Defense (DOD) provides care at medical treatment facilities classified by 4 levels; Level I facilities having the least capabilities, and Level IV having the most (1). Newborns delivered at smaller DOD medical facilities often need rapid access to Level IV care. The larger DOD medical centers in each region are tasked with supporting the smaller medical treatment facilities, which are equipped and staffed with only Level I or II nurseries. When feasible, the Military Airlift Command (MAC) has provided the aeromedical support needed to transport infants from the smaller facilities to the larger facilities using equipment found acceptable by the USAF School of Aerospace Medicine (USAFSAM) at Brooks AFB, TX. In addition, Air Force, Army, Navy, and Coast Guard helicopter units have provided neonatal transport on a case-by-case basis, using a mixture of approved, unapproved, or untested medical equipment. To use the unapproved and untested equipment, a waiver is required by the 375th Aeromedical Airlift Wing surgeon (375 AAW/SG); a process that can consume precious time. (NOTE: The 375 AAW was later redesignated the 375th Military Airlift Wing, and the SG components were integrated with HQ MAC/SG.)

The life and death nature of most newborn referrals to Level IV facilities requires a quick response time. The standard of care for civilian regional centers involves use of trained neonatal transport teams who leave the Level IV facility, taking along all equipment and supplies needed for the transfer. These teams stabilize and transport the infant from the Level I or II facility to the Level IV facility, using the same equipment and a "hospital-to-hospital" concept. This concept allows the fastest delivery to Level IV care. There is no transfer of the baby to different incubators, monitors, pumps, or ventilators. Currently, MAC uses an "airfield-to-airfield" concept; and insists that only approved or waived equipment be used aboard the aircraft (2). This concept often results in 2 equipment changes; when the infant arrives at the aircraft from the Level I or II facility, and when the baby leaves the aircraft to proceed to the Level IV facility. The American Academy of Pediatrics guidelines call for continuous critical care between aircraft and ambulances (3). Changing equipment causes unnecessary risks to critically ill newborns.

A neonatal transport system (NTS), the Airborne Infant Life Support System, manufactured by International Biomedical Inc. of Houston TX, was purchased by 3 DOD Level IV medical facilities in 1988. The NTS was acquired to avoid the problems associated with in-transit equipment changes for use primarily on the C-21 Learjet; with the C-9A and C-141B as secondary aircraft.

Untested by USAFSAM, the NTS was used in this manner for several months, with the 375 AAW surgeon granting a waiver on each occasion. Eventually some flight safety issues were raised by pilots and operations personnel; primarily focusing on securing the NTS within the airframes, and the question of electromagnetic interference (EMI) from the medical equipment contained within the system affecting

aircraft navigation and communications. Early in 1989, the 375 AAW surgeon suspended granting waivers for the NTS, and directed that, if the system was to be further used on MAC aircraft, it must first be tested and evaluated by USAFSAM.

DESCRIPTION

The NTS measures 96.5 cm (38 in.) length; 48.3 cm (19 in.) width; and 111.8 cm (44 in.) height. The system weighs about 90.9 kg (200 lb). The base is made of tubular steel and sits on 10.2 cm (4 in.) rubber wheels (Fig.1). While individual components may be removed or added, depending on the preference of the neonatal staff, the following components were tested and evaluated at USAFSAM:

- Incubator, Airborne Life Support System (ALSS), Model 20H.¹
- Ventilator, Bio-Med Devices, Model MVP-10.²
- Neonatal Monitor, Corometrics, Model 506.
- Pulse Oximeter, Novamatrix, Model 505.
- Neonatal Blood Pressure Monitor, CAS Medical Systems Model 901.
- Air-Oxygen Blender, Bird, Model 3800A.
- Suction Unit, Laerdal, Model LSU.³
- Oxygen Monitor, Catalyst Research, Model MiniOX III.⁴
- Infusion Pump, Travenol, Model AS20S.
- Pulse Oximeter, Nellcor, Model N-200.
- Gas Cylinder, Pressed Steel Tank Co, Model 3HT1850.

¹ Extensive testing of ALSS Model 185 Infant Transport Incubator was conducted in 1988. The Model 185 is very similar to the Model 20H, which allowed minimal testing of the 20H. For further details, refer to USAFSAM-TR-89-35, Evaluation of the Model 185 Airborne Life Support Systems Infant Transport Incubator, dated March 1990.

² This item was previously tested for general aeromedical evacuation use in May 1986. At that time it was considered unacceptable due to the constant monitoring and adjustments required during altitude changes.

³ This item was previously tested for general aeromedical evacuation use in May 1987. At that time it was considered unacceptable due to excessive EMI emissions.

⁴ Extensive testing of the MiniOX III was conducted in 1988-89, which allowed minimal testing for use with the NTS. For further details, refer to USAFSAM-TR-90-25, Testing and Evaluation of the Catalyst Research MiniOX III Oxygen Monitor.

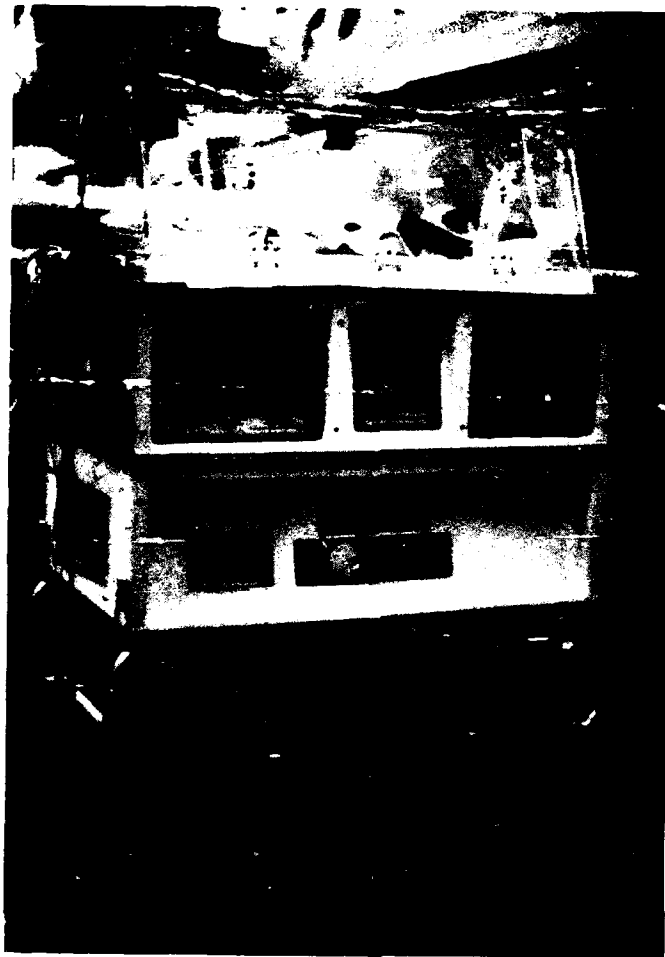


Figure 1. The International Biomedical Neonatal Transport System.

METHODS

Test methods and performance criteria used were derived from MIL-STD 461C (4), "Emergency Care Research Institute (ECRI) Health Devices" standards (5), and the Aeromedical Research Function Procedures Guide (6), covering safety and human factor issues regarding the equipment to be tested. A "performance check" was developed verifying proper functioning of the equipment under various test conditions. The following 3 tests generally involved repetition of the performance check under specified conditions:

- Electromagnetic Interference
- Altitude (encompassing hypobaric and decompression testing)
- Airborne Feasibility

Initial Inspection

Each item was inspected externally and internally for faulty manufacture and possible damage incurred during shipment. Each item, except the Travenol Infusion

Pump and the Bird Blender, was disassembled and inspected for workmanship and component leakage or damage. The Travenol and the Bird devices could not be disassembled without damage. The items were checked to ensure they met safety requirements and operating characteristics, established in AFM 67-1, Vol V, Ch 21, Medical Equipment Maintenance and Repair, and AFR 160-3, Electrical Safety in Medical Treatment Facilities. Ground resistance and leakage current measurements were made on each applicable electrical device. Operation and calibration procedures were verified with manufacturer specifications, and the performance check procedures described in the protocol developed by the Aeromedical Research Function staff. The following test equipment was used: Bio-Tek Instruments, Inc. DPM III Pressure Meter; DB&M Products Infant Test Lung; Grant Squirrel Meter/Logger, Model 1201; Mercury/Water Manometer; Bio-Tek Instruments, Inc. Lionheart Physiological Simulator; Perkin-Elmer Medical Gas Analyzer Model 1100; and Electrical Safety Analyzer, Model 431F Mod-1.

Test Setups and Performance Checks

Test setups and performance checks were established to evaluate each function featured on the components of the NTS. Test setups and performance checks were as follows:

ALSS Incubator. The function of the incubator is to provide the infant with a warm environment, fresh air exchange (to prevent CO₂ buildup), and delivery of supplemental oxygen from an external source. Four temperature sensors (Grant Model EU-UU-V5) measured the incubator's temperature characteristics within the infant chamber. One sensor was placed outside the incubator to measure ambient air temperature for comparison. The temperatures were measured and logged using a Grant Squirrel Meter/Logger, Model 1201. The incubator was then prewarmed to 37 °C (98.6 °F) using 110 VAC/60 Hz power. Temperatures were logged on the meter/logger every minute. The temperatures were also visually read and manually logged on Data Collection Sheets (DCS) every 5 min. Oxygen concentrations, and the flow required to achieve them, were measured at 10% increments up to the maximum achievable, depending on the altitude.

MVP Ventilator. This item, used to provide respiration for the infant, has 2 modes of operation: time-cycled operation, which can be volume or pressure limited with or without positive end expiratory pressure (PEEP); or non-cycled operation, with or without continuous positive airway pressure (CPAP) or continuous oxygen administration. The ventilator was connected to the DB&M Product Model 10115 infant test lung, using the patient breathing circuit. The test lung analog outputs were connected to the Gould Model 2800S strip-chart recorder for lung and airway pressure measurements during the initial inspection and altitude testing. Flow rates, inspiratory and expiratory times, and tidal volumes were measured manually; as was patient initiated spontaneous breathing. High and low airway pressure safety valves were also checked. The ventilator was first checked in the time-cycled mode, with initial settings as listed in Table 1.

Table 1. INITIAL MVP VENTILATOR SETTINGS DURING PERFORMANCE CHECKS

Setting	Time Cycled Mode	Non-Cycled Mode
Mode	Cycled	CPAP
Inspiratory Time	1.33	1.33
Expiratory Time	2.67	2.67
Airway Pressure	28 cm H ₂ O	28 cm H ₂ O
Flow	4 lpm	4 lpm
PEEP/CPAP	Off	Fully on
FiO ₂	30%	30%
Breath Rate	16	16

With the ventilator operating at the settings, a 1-min recording of the waveform was made. The PEEP was adjusted to 8, then to maximum, and back to 0. The maximum pressure control was set to 20, and returned to the maximum setting. Inspiratory time was changed to 0.5, and expiratory time to 1.0, which provided a breath rate of 40. This waveform was recorded for 1 min. The settings were returned to the original positions. The expiratory valve on the tubing was occluded, and the ventilator safety pressure valve activation point was recorded. The flow rate was measured by using a pneumotach at the expiratory valve outlet.

Next the ventilator was checked in the non-cycled mode, with settings listed in Table 1. The CPAP was adjusted to mid and then maximum pressure points, noting the pressures obtained.

Corometrics Monitor. Five physiological parameters are measured by the monitor: Invasive blood pressure, heart rate, ECG, respiration, and skin temperature. The monitor was connected directly to the Bio-Tek Lionheart Model MSP-I Multiparameter Simulator, using the Corometrics monitor cables. The Lionheart simulator was set to provide the following rates:

- Heart Rate: 30
- Respirations: 15
- Blood Pressure: 10 mmHg
- Temperature: 30 °C

After 1 min, the monitor reading was manually recorded on a DCS. The simulator settings were then set at:

- Heart Rate: 120 and 180
- Respirations: 60 and 120
- Blood Pressure: 100 and 200 mmHg
- Temperature: 37 and 40 °C

Novametrix and Nellcor Pulse Oximeters. These devices measure 2 physiological parameters: calculated blood oxygen saturation (SaO_2) and pulse rate. The sensor was attached to a finger of an Aeromedical Research staff member. Pulse readings were verified by palpating the radial pulse for 60 s. At the end of the 60 s, the pulse rate was taken from the pulse oximeter display and recorded, along with the actual palpated pulse. SaO_2 readings were not verified.

CAS Blood Pressure Monitor. This device measures 2 parameters: Blood pressure and pulse. A cuff was wrapped around an aluminum can, about 3.75 cm (1 1/2 in.) in diameter, simulating a patient's arm. The Bio-Tek pressure meter was placed inline with the pneumatic tubing connecting the cuff with the monitor. The monitor was manually cycled. While the monitor automatically released the air from the pneumatic circuit, the monitor display was watched. At the moment the monitor read the inline pressure as 100 mmHg, the pressure meter reading was noted; and again when the inline pressure was 50 mmHg. All readings from the monitor and the pressure meter were manually recorded for comparison.

Bird Blender. This device blends compressed air and medical grade oxygen for delivery to a ventilator at 50 psi (± 5); at percentages determined by the blender control knob; from 21 to 100%. There is also an auxiliary outlet for attaching a flow meter to supply oxygen to a manual resuscitator, and other low-flow applications. An oxygen flow meter was installed on the auxiliary outlet. Oxygen extension tubing was attached, to which the MiniOX Oxygen Monitor was attached, using the Tee-Adaptor. The blender was set to deliver 21% oxygen. After 3 min, the MiniOX reading was taken and recorded on a DCS. The procedure was repeated, with the blender set at 50 and 100%.

Laerdal Suction Unit. This device is for emergency oral-pharyngeal suctioning. The end of the suction tubing was adapted to connect directly to the Bio-Tek pressure meter. The suction, which has 2 settings (full and half), was set to half, and the pressure meter was observed. When the pressure was stabilized, the reading was recorded on a DCS. The procedure was repeated at the full setting.

Travenol Infusion Pump. This auto-syringe device can deliver intravenous (IV), intraarterial or subcutaneous solutions. This device accommodates all sizes of Plastipak or Monoject syringes. Syringes were connected to a 250-ml bag of 0.9% sodium chloride with standard IV extension tubing. This setup was also used to refill syringes when emptied. During the initial inspection, each size syringe of both manufacturers was evaluated. For subsequent testing, tuberculin, 30-ml and 60-ml syringes were used. The pump was set to deliver at an hourly rate equal to half the volume of the syringe; and the total volume was set to the same amount. For example, for a 30-ml syringe, the pump was set to deliver at 15 ml/h and the total volume was set at 15 ml. A stopwatch was started when the pumping was initiated. When the alarm activated, indicating the volume had been delivered, the markings on the syringe were checked to see how much volume had been actually delivered. Also the stopwatch was consulted to see if an hour had passed. The pump was then set to a rate equal to the volume of the syringe, and the total volume was set to the same amount. The

same procedure was followed. Volumes, elapsed time, and amounts actually infused were recorded on a DCS.

MiniOX Oxygen Monitor. Since this item had been evaluated and accepted for general aeromedical use 2 months earlier, no operational testing was required for use with the NTS.

Pressed Steel Tank Gas Cylinders. These cylinders are used to store and deliver the compressed air or oxygen which powers the ventilator. The cylinders were previously evaluated for use by the Department of Transportation. Extensive testing by USAFSAM was not deemed necessary.

Electromagnetic Interference

Working with the facilities and personnel from the USAFSAM Engineering and Maintenance Services Branch (TSNB), EMI evaluations were conducted on all electrical components; on the entire NTS, with each component operating simultaneously, and on each individual component operating independently.

The purpose of EMI testing is to verify compliance with MIL-STD-461C, Electromagnetic Emission and Susceptibility Requirements for the Control of EMI, Category A1e. The following specific tests were conducted:

Radiated Emissions (RE-02). This test measures radiated emissions generated by the components during operation. Both narrow-band and broad-band tests are performed. Excessive amounts of radiated emissions could interfere with aircraft navigation and communication equipment.

Conducted Emissions (CE-03). This test measures emissions generated by the components and conducted through the aircraft power lines. This test must be performed to ensure operating the device using line power does not affect other items connected to the same power source, particularly aircraft systems.

Radiated Susceptibility (RS-02). This test determines whether the ambient electromagnetic fields (noise) encountered in flight interferes with the operation of the components. The components were exposed to the electromagnetic fields described in the Test and Evaluation Guide for Aeromedical Equipment (7).

Conducted Susceptibility (CS-06). This test determines whether the components can withstand predefined levels of voltage spikes on their power lines.

A performance check was conducted on each individual component before and after EMI testing. All alarm functions were checked before and after testing. During EMI testing, the following components were set up and operated:

ALSS Incubator: Chamber light on. Temperature set at 37 °C (98.6 °F). Alarm test mode activated. Evaluated on both 110 VAC/60 Hz and battery.

Corometrics Monitor: The Lionheart physiological simulator provided the following signals:

- Heart Rate: 180
- Respirations: 30
- Blood Pressure: 30 mmHg
- Temperature: 37 °C (98.6 °F)

A blood pressure tracing was present on the monitor, and the heart rate alarm was activated. The monitor was tested on both 110 VAC/60 Hz and battery.

Travenol Infusion Pump (with charger Model CAS20-010853): Using a 60-ml syringe, the pump was operated at 10 ml/h. The pump was tested on both 110 VAC/60 Hz and battery.

CAS Blood Pressure Monitor (with charger Model 900C): The monitor was repeatedly cycled manually, and tested on both 110 VAC/60 Hz and battery.

Laerdal Suction Pump (with charger Model 791400): The pump was operated on the high setting, on both 110 VAC/60 Hz and battery.

MiniOX Oxygen Monitor: The monitor was operated on battery (its only power source), measuring the oxygen percentage of room air, with the low alarm activated.

Novamatrix and Nellcor Pulse Oximeters: The oximeter probes were connected to an Aeromedical Research staff member. Low alarms for pulse rate and saturation were activated. The oximeters were operated on both 110 VAC/60 Hz and battery.

In addition to each component being individually checked for EMI, the system was checked with all components in simultaneous operation. During the 110 VAC/60 Hz check, all components operating off that power source were plugged into the NTS electrical distribution system. By plugging a single cord into an outlet, the electrical distribution provided alternating current (AC) power to all applicable components.

Altitude

Testing was conducted in the research chambers; operated and monitored by chamber operations personnel assigned to the Systems Engineering Branch (VNS) of the Crew Technology Division at USAFSAM.

Hypobaric Chamber Testing. The NTS, with the various test setups, was placed inside the chamber. Pre- and post-test performance checks were conducted. At a rate of 5,000 ft per min, the chamber was depressurized to 10,000 ft equivalent (523 mmHg total pressure). While at altitude, standard performance checks were performed.

While all the components were tested at altitude, due to the expected effects and stresses imposed on the ventilator by a decrease in barometric pressure, the bulk of altitude testing concentrated on that device. In addition to the standard altitude of 10,000 ft, extensive testing was conducted at ground level and at simulated altitudes of 2,000, 4,000, 6,000, and 8,000 ft. The ventilator was tested both on the volume-limited and pressure limited modes. The manufacturer's operating instructions indicated adjustments of 2.5% in the inspiratory and expiratory times would be required for every 1,000 ft of elevation change (8). On both modes, the ventilator was tested with and without the indicated adjustments. At each altitude, inspiratory and expiratory times were measured and recorded. Adjustments were made to compensate for the altitude, and measurements were repeated and recorded. Measurements were recorded both manually, and by using the Gould strip-chart recorder.

Rapid Decompression. Each component was tested individually. As a pretest, performance checks were conducted. Components were placed in the chamber, the chamber sealed, and depressurized to the equivalent of 8,000 ft. The components continued to operate at this altitude for 5 min, and were observed through the door window. Then, the chamber was depressurized to an equivalent of 40,000 ft, over a period of 60 s. The components were then observed for 5 min. The chamber was pressurized to ground level, components removed, and a performance check performed. The components were again placed in the chamber, and the process was repeated twice; with rapid decompressions of 7 and 1 s duration.

Airborne Feasibility

Airborne testing on the C-9A and C-141B aircraft was conducted by 2 aeromedical research technicians, who were current and qualified as aeromedical evacuation crewmembers on the 2 aircraft used. Before airborne testing, the protocol was "dry run" in the C-9A, C-130, and C-141B mockups in Building 820 at Brooks AFB. Following these tests, airborne feasibility testing began on a C-141B aeromedical evacuation mission from Travis to Hickam AFB, HI to Yokota AB, JA. While in the Pacific Theater, testing resumed on a C-9A aeromedical evacuation mission from Yokota to Kadena AB, JA to Clark AB, RP; and on the return trip to Yokota aboard a C-141B cargo mission. The return trip to the continental United States (CONUS) was aboard a C-141B aeromedical evacuation mission from Yokota to Hickam to Travis. From there, the NTS was flown on a C-9A aeromedical mission to Kelly AFB, with 4 enroute stops. Typically, the C-9A aircraft was pressurized to 8,500 ft equivalent, and the C-141B to 9,500 ft. Altogether, during this phase of testing, the NTS was subjected to 12 takeoffs and landings, and over 40 h in flight.

Using the airborne feasibility protocol, developed by the aeromedical research staff, performance checks were done pre and postflight, and every 30 min while in flight. Using the "Aeromedical Research Function Airborne Feasibility Checklist" from the Procedures Guide, other issues were also evaluated including storage, ground transporting, form and fit, ease of setup and takedown, limitations, and crew acceptance.

C-9A. The NTS was set up centered in the TL-1 litter tier. D-rings were placed in the seat tracks, 1 forward and aft of each NTS wheel, about 30.5 cm (12 in.) away. Cargo tie-down straps were used to secure the NTS. The strap's clip-hooks were connected to the four 5-cm (2 in.) holes in the handlebars located at the top of each end of the NTS. The straps' large ratchet-hooks were connected to the D-rings, and the straps were tightened, 2 at a time, by 2 people, positioned diagonally from each other. While battery power was also evaluated, the NTS was initially plugged into the aircraft 115 VAC/60 Hz power supply. The ventilator was powered using the aircraft therapeutic oxygen system, and compressed air supplied by a Timeter Aridyne Model 3500 Medical Air Compressor.

C-141B. The NTS was set up in a center litter tier. D-rings were placed in the floor tracks, 1 forward and 1 aft of each front NTS wheel, about 30.5 cm (12 in.) away. These rings were used to secure the front of the NTS. A D-ring was also placed at the lowermost position on litter stanchions forward and aft of the NTS. These rings were used to secure the rear of the NTS. Cargo tie-down straps were used, with the strap's clip-hooks connected to the four 5-cm (2 in.) holes in the handle-bars located at the top of each end of the NTS. The straps' large ratchet-hooks were connected to the D-rings, and the straps were tightened; 2 at a time, by 2 people, positioned diagonally from each other. While battery power was also evaluated, initially the NTS was plugged into the Unitron Model PS-75-426-1 frequency converter, which was plugged into the aircraft 115 VAC/400 Hz power supply. The ventilator was powered using the aircraft therapeutic oxygen system, and compressed air supplied by a Timeter Aridyne Model 3500 Medical Air Compressor.

C-21. This phase was performed by an aeromedical research nurse, and an aeromedical research technician, who were both current and qualified as aeromedical evacuation crewmembers. Also assisting were a U.S. Air Force flight surgeon, and a U.S. Army neonatal physician with extensive experience in neonatal transport, including using the NTS. The initial C-21 evaluation was conducted on a training mission, which departed Randolph AFB TX, and returned 1 h later. Subsequent evaluation involved 3 follow-up trips to Randolph for evaluation on static airframes, primarily to fine-tune loading and securing procedures. The NTS was set up mid cabin on the left side, as described in the "Neonatal Transport Unit C-21 Mounting Instructions," Appendix A (Fig. 2). All electrical components were powered by internal batteries. The ventilator was powered by oxygen and compressed air, contained in medical gas cylinders which were themselves components of the NTS. To evaluate certain clinical aspects of using the NTS on the C-21 aircraft, a resusci-baby was placed in the NTS to simulate transporting an actual infant.

Clinical Aspects. A special clinical evaluation, developed by the Army neonatal physician and the Aeromedical Research Function's clinical staff, was conducted. Areas covered by the clinical evaluation included:

- Medical personnel's access to the infant and equipment.
- The ability to pass supplies from the kits to personnel.
- Available clearance and working space.

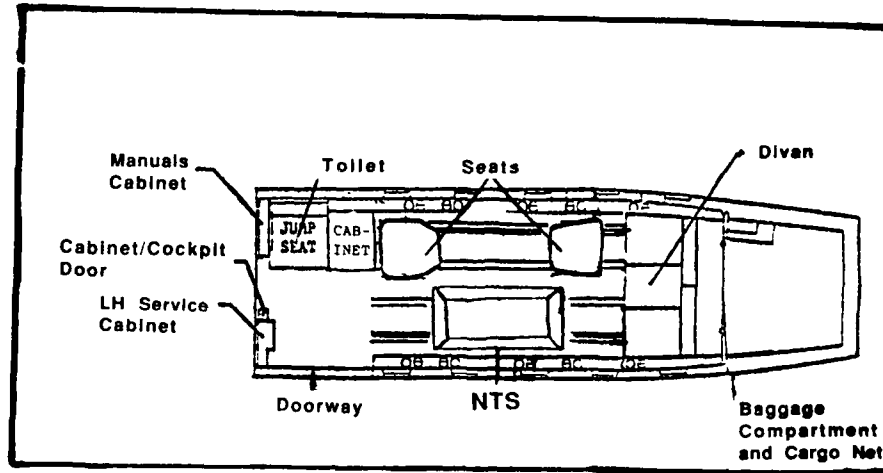


Figure 2. Diagram of the C-21 Interior.

- Personnel ability to move within the cabin.
- Ability to set up and start an intravenous line.
- Ability to accomplish chest-tube insertion.
- Ability to insert an umbilical vessel catheter.
- Ability to perform bag-mask ventilation.
- Ability to perform tracheal intubation.
- Ability to perform cardiopulmonary resuscitation.
- Removal of the incubator hood.
- Loading and unloading of the NTS with an infant in place.

RESULTS

Initial Inspection

During the visual inspection, no damage was noted. All electrical safety measurements were within the acceptable ground resistance (<500 milliohms) and leakage current (<10 μ A) limits, specified in AFR 160-3. No discrepancies were noted during the operational verification, and each component was in calibration. Alarms functioned as stated in the manufacturers' literature; however, audible alarms may not be effective in the noisy airborne environment. Table 2 shows operation times for each battery-operated component. **NOTE: The MiniOX oxygen analyzer was**

not evaluated with the other components for battery life, since it had already been evaluated for general aeromedical use earlier the same year.

Table 2. BATTERY OPERATION TIMES

Item	Manufacturer's Specifications	Test Results
ALSS incubator	3 h (@ 37 °C)	3 h
Travenol infusion pump	24 h	24 h
CAS blood pressure monitor	200 cycles	187 cycles
Laerdal suction pump	1 h (@ full power)	49 min
Novametrix pulse oximeter	2 h	1 h, 48 min
Nellcor pulse oximeter	2 h	1 h, 54 min

Manufacturers' specifications are nominal battery operation times under ideal conditions, with fully charged new batteries. Rechargeable batteries are not expected to remain in "new" condition for the duration of their usefulness. Batteries in the devices tested were not new; however, they were repeatedly charged and discharged during the tests. All devices operated for at least 80% of the specified time on battery mode, which was considered acceptable by the Aeromedical Research staff.

In conclusion, components of the NTS meet electrical safety requirements stated in AFR 160-3, and perform to manufacturers' stated specifications.

Electromagnetic Interference

ALSS Incubator. The incubator initially failed in the narrow-band areas of RE-02 and CE-03. A representative from International Biomedical came to USAFSAM to correct the problem. Modifications consisted of shielding the fan by encasing it in a metal can, and placing a Sprague 735P μ F capacitor ($5 \mu\text{F} \pm 10\%$, 100 VDC) across the power transformer secondary lead. Following the modifications, a retest was conducted and the incubator passed EMI.

Corometrics Monitor: The monitor initially failed in the narrow-band areas of RE-02; specifically at 35-45, 70-90, and 140 kHz; and 0.055-0.060 and 35-45 MHz. The monitor was returned to the manufacturer for correction. They modified the monitor by shielding the patient lead cable, and applying internal torroids. Following this modification the monitor was returned to USAFSAM, and a retest was conducted. Again, the monitor exceeded limits in the areas of 70-90 and 140 kHz. At that time, the EMI charts were sent to the Electronics Effects and Electrical Branch, of the Offensive Avionics Division (ENACE), at the Aeronautical Systems Division at Wright-Patterson AFB, OH. They reviewed the charts and decided, while the emissions did exceed the

limits, they would not interfere with communications or navigations onboard the aircraft.

CAS Blood Pressure Monitor. The monitor passed all EMI testing.

Laerdal Suction Pump. The pump passed EMI while within the NTS support structure; but failed while operating independently outside the support structure.

MiniOX Oxygen Monitor. The monitor passed all EMI testing.

Novamatrix Pulse Oximeter. The oximeter failed testing, initially in the RE-02 narrow-band areas of 47, 80, 96, 110, 140, 170, 260, 290, and 330 kHz; and 0.6, 0.95, 1.15, 1.90, 2.25, 16, 28, 45, 55-65, 130, and 155 MHz. Alarms were turned off, which made no appreciable difference in emissions. The probe cable was removed which reduced most emissions, but still failed at 45 and 78 MHz. The cable, probe, and test subject's finger were shielded with aluminum foil and the foil grounded. Failures were still noted in the areas of 8, 28, and 40-65 MHz. The device was sent to the manufacturer for evaluation and modification. The manufacturer was unable to modify the device, so no further testing was conducted.

Nellcor Pulse Oximeter. The oximeter initially failed EMI in the RE-02 narrow-band areas of 35-320 kHz, and 7-19, 22-30, 40-160, and 220 MHz, using 110 VAC/60 Hz as the power source. It also failed in the areas of 45-50 and 66-70 kHz, and 11, 13-32, 37, 45-160, and 220-230 MHz, using the internal battery as the power source. Additionally, while charging only, it failed in the areas of 18 and 40-50 MHz. Modification included placing ferrite chokes on the cable connecting the processor printed circuit board, placing a high frequency suppressor on the patient module cable, and wrapping the entire unit with a material called "KV-GARD." These modifications decreased the emissions to an acceptable level while operating on the internal battery; but not while plugged into an AC power source, whether for operation or charging.

Summary of EMI Testing. The Novamatrix pulse oximeter failed EMI, and must not be used in flight. The Laerdal suction may be used only when installed within the structure of the NTS cart. The ALSS incubator may be used in flight, provided modifications are made as previously described. It may be used as a component or independent of the NTS. The Corometrics monitor may be used in flight, provided modifications are made as previously described. It may be used as a component or independent of the NTS. The Nellcor pulse oximeter may be used in flight, provided modifications are made as described above. It may be used as a component or independent of the NTS. However, the device may be used only while operating on battery power. All other components passed EMI outright, and may be used as components, or independently of the NTS.

As an integrated system using the listed components, and providing all requirements are met as described in the previous paragraph, the NTS passes EMI.

Altitude

Hypobaric Chamber. The ALSS Incubator, Corometrics Monitor, CAS Blood Pressure Monitor, Laerdal Suction Pump, MiniOX Oxygen Monitor, Novamatrix Pulse Oximeter, Nellcor Pulse Oximeter, Bird Blender, and Pressed Steel Tank Cylinders all performed satisfactorily.

Generally, the MVP ventilator performed in an expected manner. Some additional changes to fine tune the desired rate and pressure were required. As stated in the operation manual, inspiratory and expiratory times increase with decreases in atmospheric pressure. This behavior, combined with the decreased atmospheric pressure, greatly increased the tidal volume delivered by the ventilator. Per the manufacturer's directions, when the inspiratory and expiratory times are manually adjusted by decreasing them 2.5% per 1,000 ft elevation change, the tidal volume increase was lessened; however, significant changes in tidal volume still occurred due to the decreased atmospheric pressure. Table 3 illustrates the results before and following adjustments.

Table 3. PERCENT CHANGE OF VENTILATOR MEASUREMENTS, AT 10,000 FT ALTITUDE V. GROUND LEVEL

Ventilator Settings	Insp Time (%)	Exp Time (%)	Tidal Vol (%)	Breath Rate (%)
Pressure Limited, wo/adj	37	26	68	23
Pressure Limited, w/adj	5	6	39	6
Volume Limited, wo/ adj	37	24	75	22
Volume Limited, w/adj	5	6	37	13

Rapid Decompression. During the 1 s decompression, the valves in the MVP ventilator froze up, rendering the device inoperable. The situation was self-correcting when the altitude was restored to 16,000 ft. This malfunction was not considered a failure due to the low incidence of such an event occurring; and because of the presence of a neonatal team member to manually ventilate the baby.

During the 1 s decompression, the Corometrics monitor's cathode ray tube was damaged, blanking out a portion of the monitor's display. This damage was not considered a failure due to the low incidence of such an event occurring, and because it did not present a safety hazard to patients or personnel.

All other NTS equipment items performed satisfactorily during and after rapid decompression testing.

Airborne Feasibility

The Corometrics Monitor, CAS Blood Pressure Monitor, Bird Blender, Laerdal Suction Pump, and MiniOX Oxygen Monitor all performed satisfactorily without

incident. The Novamatrix and Nellcor Pulse Oximeters were not evaluated in flight due to EMI failure. At the time of airborne feasibility testing, the EMI fix for battery operation of the Nellcor had not been established. Unless noted, other components may also be used provided certain conditions are met, which are specified in the following paragraphs.

Requirements.

-- As a system, the NTS may be used on aeromedical evacuation missions, but only by a trained neonatology team. The aeromedical crew should not be expected to operate the NTS. The aeromedical crew will be expected to secure the NTS and integrate the NTS with aircraft systems.

-- The MVP ventilator is relatively difficult for aeromedical crewmembers to operate at altitude, because the parameters require constant monitoring and frequent adjustments. For that reason it may be used but only by trained neonatology personnel. Controls requiring adjustment in response to altitude changes are: Inspiratory time, expiratory time, and pressure. Specific instructions are included in the manufacturer's operating manual. Also, to deliver the same oxygen saturation at altitude as at ground level, the blender setting requires adjustment.

-- Modifications must be made to the incubator hood assembly to keep the inner and outer shells connected, and to allow for carbon dioxide venting. The modifications must match those made to the Airborne Life Support System Model 185, approved for general aeromedical use in 1988; as described in USAFSAM-TR-89-35, Evaluation of the Model 185 Airborne Life Support Systems Infant Transport Incubator (9). (Note: Modifications have already been made to the NTS on loan from David Grant USAF Medical Center that was used for most of the testing. The modified neonatal monitor's serial number is 0781539, and the modified incubator's serial number is 155. A letter was received from International Biomedical stating in the event any DOD medical treatment facility purchases an NTS, modifications will be made before shipping. A copy of the letter was attached to an interim report sent to 375th Military Airlift Wing.)

-- When securing the NTS on the aircraft, wooden blocks must be placed under the frame to elevate the unit's wheels off the aircraft floor which removes stress to and from the NTS wheels. Four cargo tie-down straps must be used to secure the NTS to the aircraft floor and stanchions, as applicable. Using the 4 straps and wooden blocks will ensure the NTS is safely and securely tied down, without damaging the wheels or the aircraft floor (Figs. 3 and 4). Design and specifications of the blocks are included in Appendix B.

-- The Pressed Steel Tank Cylinders must be mounted so the regulators and valves do not protrude from underneath the NTS.

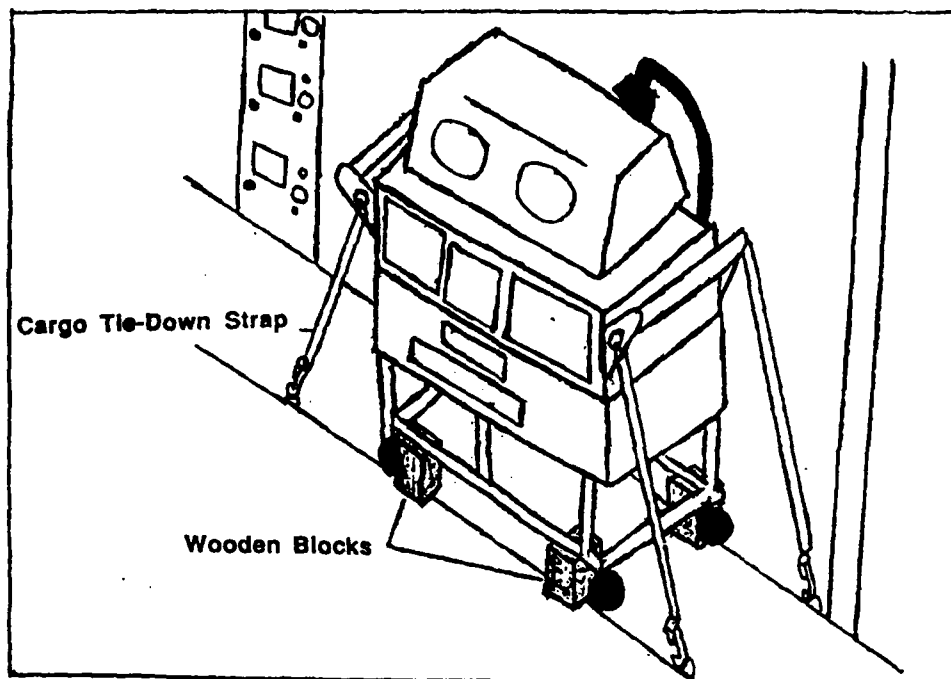


Figure 3. Securing the NTS on the C-9A aircraft.

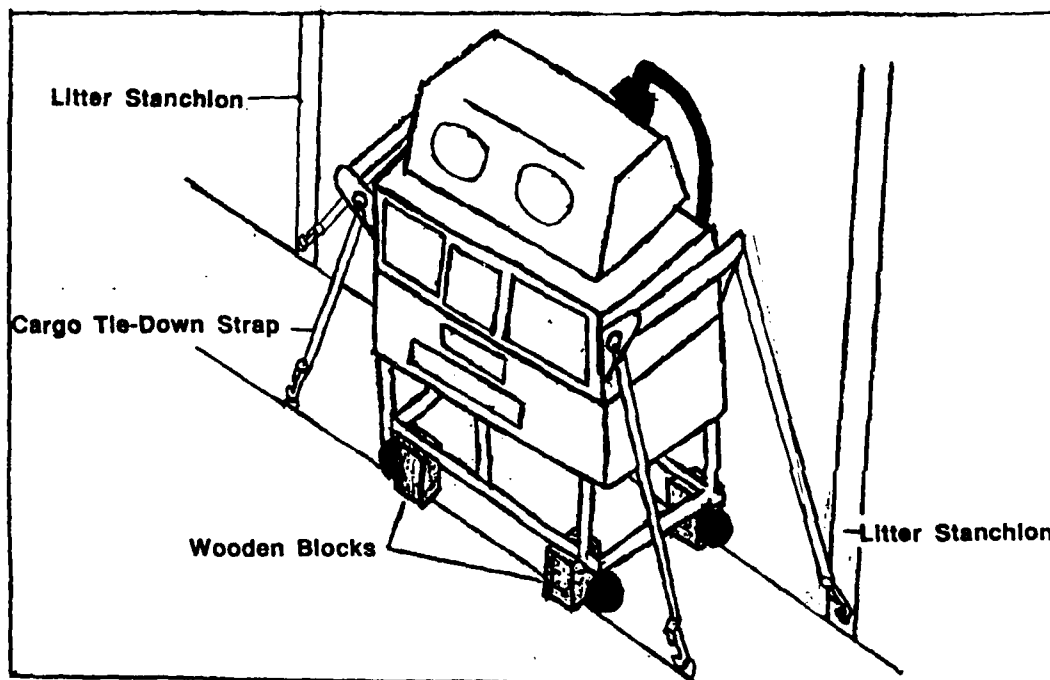


Figure 4. Securing the NTS on the C-141B Aircraft.

General Recommendations.

-- The breathing circuit specifically designed by the MVP ventilator's manufacturer, Bio-Med Devices Inc Catalog Number 2030, should be used. The other breathing circuit, manufacturer unknown, provided by David Grant USAF Medical Center was cumbersome and difficult to manage. It also came apart rather easily; a particularly undesirable feature for tubing to be used on a ventilator without any alarms. Due to the absence of ventilator alarms, it is strongly recommended the MiniOX III oxygen monitor, which does have alarms, be placed inline, to alert personnel in the event the tubing comes apart.

-- The MiniOX III oxygen monitor tee-adaptor should be obtained and used. It is necessary for proper calibration and inline oxygen concentration monitoring. Also, the mounting assembly needs slight modification. A dove-tailed plastic fitting, attached to the back of the MiniOX, slips into a corresponding slot mounted on the frame of the NTS. It is important the MiniOX III have 2 of the plastic devices "sandwiched" together and attached to the back, to ensure a snug fit into the metal slot. This fit will prevent the MiniOX III from inadvertently sliding out due to vibration or other factors.

-- A waterproof cover for the NTS, such as a tarp, should be fabricated and carried to protect the unit during transport in inclement weather. An example of its use would be when moving the NTS from ambulance to aircraft in a downpour.

-- Four personnel should be used to lift the NTS; for example, when lifting the NTS out of an ambulance.

-- If the incubator side door is located on the left side, opening of that door should be minimized. Frequent opening will result in the thermostatic sensor located near the door to sense the cooler external air. This change will cause the incubator to produce more heat to compensate for the perceived lower temperature. The effect is an overheating condition, without alarm activation.

-- For use on the C-9 and C-141, quick-release connectors for the ventilator gas lines should be installed. For example, if Schrader connectors were used, the lines extending from the blender could be fitted with a MALE Schrader. Separate lines extended from the aircraft oxygen and compressed air sources could be fitted with FEMALE Schrader-type connectors; as could lines from the portable gas cylinders secured at the lower level of the NTS. The lines with the FEMALE connectors could be prepositioned and installed at the aircraft, so that when the NTS arrives at the aircraft, with the infant, the ventilator could be disconnected from the NTS cylinders and connected to aircraft oxygen and air in seconds. This function will prevent having to remove the infant from the ventilator, while precious time is spent disconnecting and connecting gas lines with wrenches. As an alternative, the 61 cm (2 ft) air and oxygen lines leading from the blender to the "E" cylinders could be replaced with lines 305 cm (10 ft), or longer, to accommodate connection to aircraft oxygen and an air compressor.

-- By connecting the gas line directly to the ventilator, it will operate without using the air-oxygen blender. However, there will be no alarm if 1 of the gas sources is depleted. The gas mixture can also be more precisely controlled using the blender. For those reasons, it is recommended the blender be used to control the gas mixture.

General Observations.

-- While not particularly recommended, for enplaning and deplaning on the C-141B, the NTS will easily fit through the crew entrance and troop doors.

-- Securing the crewmember to the NTS for a standing-up take-off/landing was evaluated. Using the 3 litter strap method, with 1 strap through each side handle, is **NOT** recommended due to stress on the NTS and mounting system.

-- During the C-141B in flight testing, the respirator oxygen input line was connected to the Therapeutic Oxygen Manifold System (TOMS) for 4 h. During this time, there were no pressure fluctuations or any other problems noted when using the TOMS as the oxygen source for the ventilator.

-- Only 110-120 VAC/60 Hz may be used as an external power source for the NTS. On the C-130 and C-141 aircraft, a converter or inverter must be used. On the C-21 aircraft, flight time is limited by NTS internal battery duration, about 2-2 1/2 h.

-- It is recommended the Biochem Model 1040A pulse oximeter, manufactured by Biochem International Inc, be considered for use with the NTS. The oximeter functions satisfactorily on infants, and can operate on its internal battery for up to 20 h.

C-21 Recommendations/Observations.

-- The aircraft should be configured to allow placement of the unit on the left side of the cabin. Placement on the left side, rather than the right side, requires less preparation time by maintenance personnel, since the cabinet will not require removal; as it does when using the right side of the aircraft. Placement on the left side allows easy access to the infant from the head, side, and foot. Moreover, placement on the left side does not block the emergency exit, while placement on the right side does (Fig. 5).

-- For securing on the C-21, a special mounting system for attaching the cargo tie-down straps to the seat tracks on the floor has been devised with input and coordination from the Learjet Corp, the manufacturer of the C-21. Models of the components and a design package can be found in Appendix A. Once obtained, the components of the C-21 mounting system should be kept with the NTS.

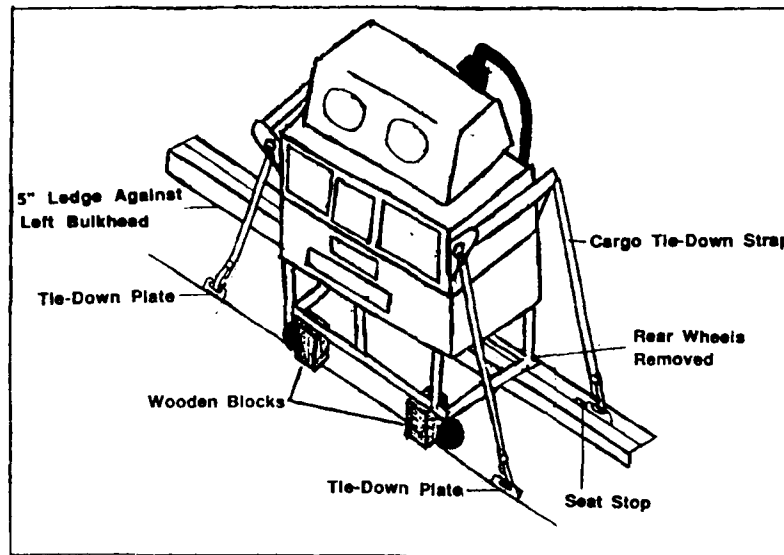


Figure 5. Securing the NTS on the C-21 Aircraft.

-- If "E" gas cylinders are used to power the ventilator, extra air and oxygen cylinders should be brought on board. When full, the "E" cylinders typically allow about 30 min of ventilator operation before 1 of them, usually the air cylinder, is depleted.

-- If possible, 105-120 VAC/60 Hz power should be used to pre-warm the incubator before enplaning. Doing so will prolong incubator battery-life.

-- When the NTS is placed in the C-21 cabin on the left side, the incubator hood **MAY** be removed, if necessary. To remove, the hood should be rotated from the rear to the front, pivoting on the front edge.

-- On the C-21 aircraft, the neonatal medical kits, extra gas cylinders, and other required articles can be easily stored behind the divan. This location provides easy access to the supplies, for personnel seated at the divan; particularly when 1 of the divan's seat-backs is brought forward.

Clinical Aspects. During the C-21 airborne feasibility testing, the following observations were made by Major (Dr) Howard S. Heiman of Brooke Army Medical Center, the Tri-Service Neonatal Transport Coordinator, and a participant of the C-21 testing.

-- The seating of 3 transport personnel allowed all 3 to work with the patient or each other simultaneously. The respiratory therapist could sit on the left divan to monitor the ventilator, suction equipment and medical gas gauges and be able to access the patient through the side door if bag-mask ventilation is needed. This person could also pass supplies to the team leader in the right seat in front of the divan.

-- The team leader sat in the forward facing right rear seat. For emergency procedures, the seat-back could be folded down and straddled sideways which allows extra height for working and easier access to supplies. The 15.2 cm (6 in.) clearance between the side of the seat and the front of the NTS allowed for passage to the rear storage area.

-- The team assistant sat in the single aft facing right seat. This person had full view of the intravenous (IV) pumps on the side of the transport as well as the front panel instruments and the patient. There was room for easy passage of the team members to the front of the cabin.

-- Simulation of starting a right hand IV line was successful. There was very little vibration in the cabin. The syringe pump, IV solution and extension tubing were easily set up and attached. The IV catheter was easily secured.

-- Simulated chest tube insertion was accomplished successfully with aseptic technique. The tray was placed in the lap of the assistant who faced the leader. They were close enough to allow for the assistant to aid with placing and securing the tube.

-- Simulated umbilical vessel catheter placement was accomplished under aseptic technique with similar personnel positions as with the chest tube insertion.

-- Simulated bag-mask ventilation was accomplished 3 ways:

-- Through the 2 cuffed porthole doors. This method would result in the least heat loss and therefore minimize battery power consumption.

-- Through the open front door. This method would only be done if using the port holes was not effective and the child needed a more detailed evaluation or other procedures done simultaneously.

-- Through the hood side door. This side door also acted as an extension of the mattress. It was supported by the horizontal carrying handles of the NTS. This was an effective aid in intubation without removing the incubator cover from the NTS.

-- Simulated tracheal intubation was accomplished using the side door. The resusci-baby was slid out of the head side door and the respiratory therapist or the team leader could intubate the patient without difficulty. Blow-by oxygen, bag-mask ventilation and suction were easily available. The top of the incubator did not have to be removed.

-- Simulated cardiopulmonary resuscitation (CPR) was successfully accomplished using 2 techniques:

-- Bag-mask ventilation through the hood side door and chest compressions through the cuffed portholes.

-- Bag-mask ventilation through the hood side door and chest compressions through the open front door.

-- The double walled incubator top could be removed from the NTS in the cabin if the team deemed it necessary for the immediate care of the patient.

-- The loading and unloading of the transport from the C-21 was done under simulated patient conditions. The unit could be loaded with 3 or 4 people keeping it in a horizontal position. The clearance between the cabinet and the side of the NTS was about 5 cm (2 in).

CONCLUSIONS

As a complete system, the NTS is not approved for general aeromedical use, and must be operated by a trained neonatal staff member. To be used aboard aeromedical evacuation aircraft, the incubator, cardiac monitor, and Nellcor pulse oximeter must be modified to pass the MIL-STD-461C EMI standard. The suction device must not be used outside the NTS structure. Adjustments must be made to the ventilator with every significant altitude change, by a trained neonatal staff member. Modifications must be made to the incubator hood assembly to allow for carbon dioxide venting, and to keep the hood assembly intact during removal. Wooden blocks must be used to elevate the NTS off the aircraft floor. Four cargo tie-down straps must be used to secure the NTS on the aircraft. The ventilator gas cylinders must be mounted on the NTS so that regulators and valves are protected and do not protrude. If those requirements are met, the International Biomedical Inc Neonatal Transport System is a safe and reliable device for the airborne transport of neonatal infants

ACKNOWLEDGMENTS

We would like to thank all those who helped and advised us during the evaluation of the Neonatal Transport System. We would particularly like to thank Lt Col (Dr) Mark Swedenburg, Lt Col (Dr) John Marshall, Lt Col Richard Knecht, Maj Garye Jensen, Capt Terry Lewis, Capt Susan Nagel, 1Lt Rebecca Schultz, MSgt Rufino Navalta, MSgt Victor Elizondo, TSgt R. J. Van Oss, SSgt Steve Simon, SSgt Thomas Waters, SSgt Richard Carvajal, and Mr Wayne Jensen.

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APPENDIX A

NEONATAL TRANSPORT SYSTEM/C-21 MOUNTING INSTRUCTIONS

1. Preparation. When available, the Neonatal Transport System (hereafter identified as "system") should be loaded into the C-21 by or under the direct supervision of the GLASCO Maintenance Contractors. When it is determined that a C-21 will be required, ask the Command Post to notify GLASCO that the "system" will be used and they will be able to prepare the aircraft before the system arrives. If GLASCO contractors are not available, the C-21 can be configured and the system loaded by crewmembers using ordinary hand tools.

a. Aircraft Preparation: (Takes about 15 min).

(1) Remove forward bulkhead.

(2) Remove individual seats on left side.

(a) First remove "hockey stick" shaped floor trim. This stick is located on the floor in front of the bulkhead near the door. The object is to clear the path in front of the seat rails so that the seats can be pulled out of the rails in front of the door.

(b) Remove seat stops. These blocks (about 2.22 cm (7/8 in.) x 1.9 cm (3/4 in.)) keep the seats from sliding along the rails. An Allen wrench is needed to remove the seat stops.

(c) Swivel the seats to face the aisle.

(d) Slide seats along rails towards the door and remove from rail.

(e) Replace hockey stick.

(3) Folding tables do not need to be removed.

b. Loading system onto the C-21: (Takes about 5 min).

(1) Slide one seat stop toward rear of aircraft on outboard rail (rail closest to the wall).

(2) Use a 4-man carry to lift and maneuver the system through the C-21 door. During this procedure, keep the bassinet level and do not lean on the system. The system is heavy and its wheels are small. It is important to load the system carefully so as not to overstress or damage the aircraft floor.

(3) Roll system into position.

2. Securing system to the C-21. (Takes about 10 min).

a. Remove system rear wheels. (Wheels next to aircraft wall.)

(1) Loosen setscrew.

(2) Manually support system.

(3) With 1 person on each end to support rear and maintain level of system, remove wheels.

b. Push system towards aircraft wall until rear frame rests on the aircraft's sidewall ledge.

c. Add front support blocks.

(1) Manually support system.

(2) Place blocks under the front frame close to the wheels.

Caution: The front support blocks are required any time system is transported in the C-21. Without the blocks, the aircraft floor may be overstressed and damaged by the system's wheels.

d. Attach mounting hardware.

(1) Slide second seat stop towards system on outboard rail.

(2) Position and tighten both outboard seat stops about 30.48 cm (12 in.) from the system.

(3) Place 1 tie-down plate approximately 30.48 cm (12 in.) from either side of the system on the inboard rail.

(4) Place 1 of the tie-down plates next to the outside edge of each seat stop on the outboard rail. Seat stops must be between system and tie-down plate.

(5) Tighten each of the tie-down plates. **Caution: The tie-down plates must not move along the seat rail! If one does, it must be used in conjunction with a seat stop! The purpose of the seat stop is to prevent the tie-down plate from sliding towards the system. Since seat stops may not be applied to the inboard rail, it is imperative that the tie-down plates applied to the inboard rail fit tight on the rail.**

e. Attach 4 cargo tie-down straps between the system and the tie-down plates.

(1) Attach the clip-hook end of 1 strap to 1 of the 4 holes in the unit's handle supports.

(2) Attach the ratchet-hook end of each of the straps to its associated tie-down assembly.

(3) *Tighten the strap until it is snug and the system is safely secured to the aircraft. **Caution: DO NOT OVERTIGHTEN THE TIE-DOWN STRAP. Once the system is firmly secured to the aircraft, further tightening may damage the seat rail or the aircraft floor.***

3. Mounting Hardware Needed

- 4 - Seat stops (With Allen head setscrews)
- 4 - Tie-down assemblies
- 4 - Cargo tie-down straps
- 2 - Support blocks

4. Mounting Tools Needed

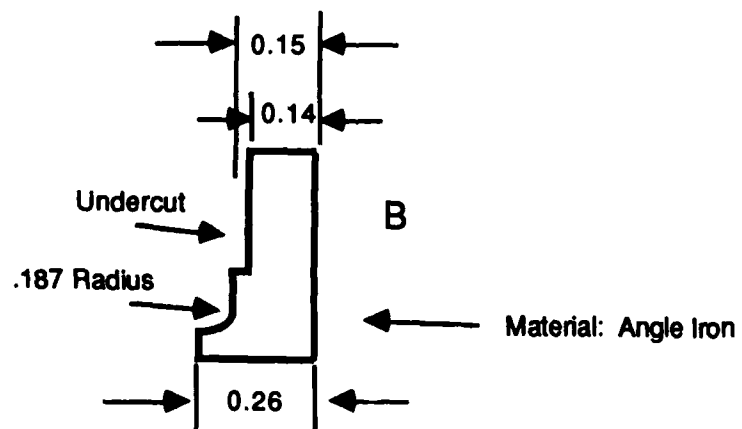
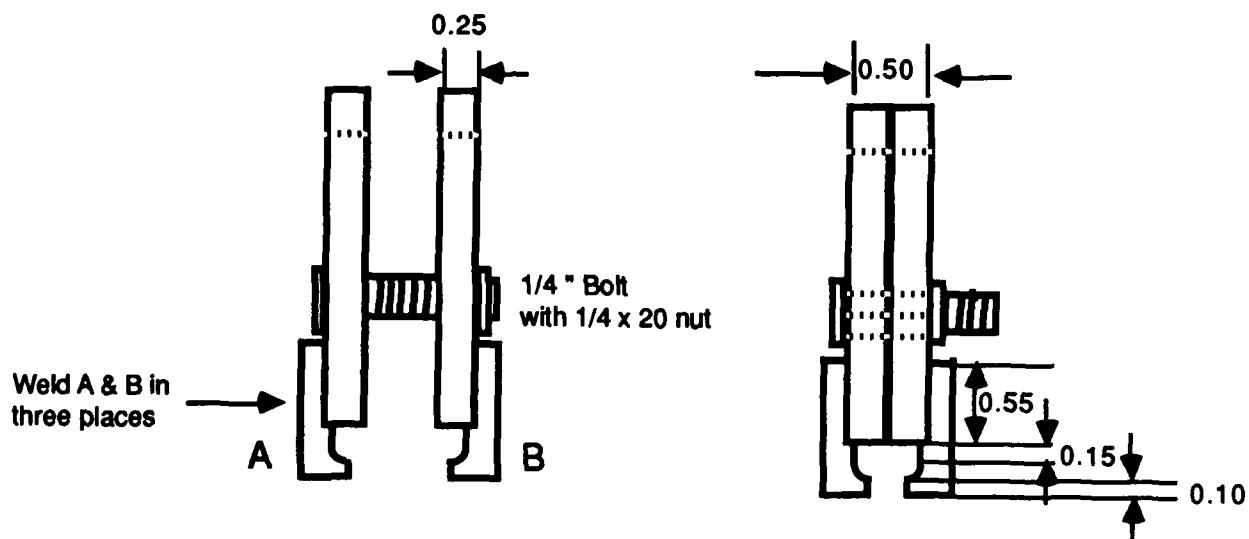
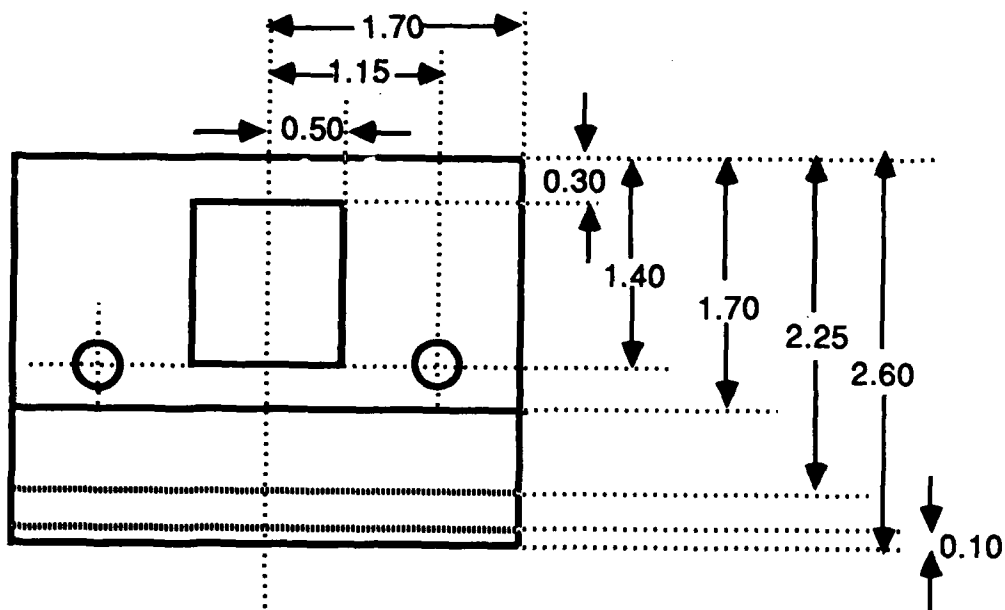
- 1 - 3/16" Allen Wrench
- 1 - #2 Phillips Screw Driver
- 1 - Medium-sized Common Screw Driver
- 1 - 8" Adjustable Wrench

APPENDIX B

DESIGN AND SPECIFICATIONS OF THE NEONATAL TRANSPORT SYSTEM WOODEN SUPPORT BLOCKS

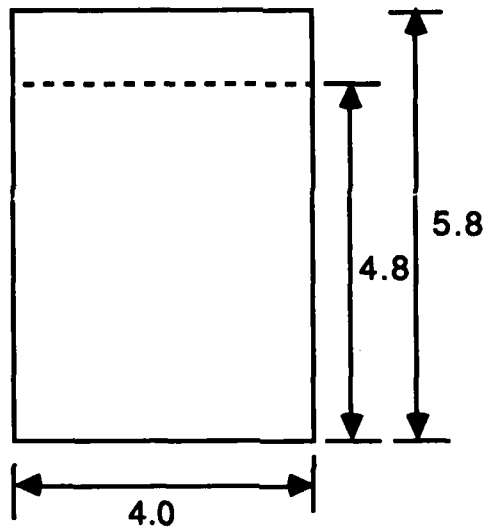
Tie Down Plate

All measurements are in inches

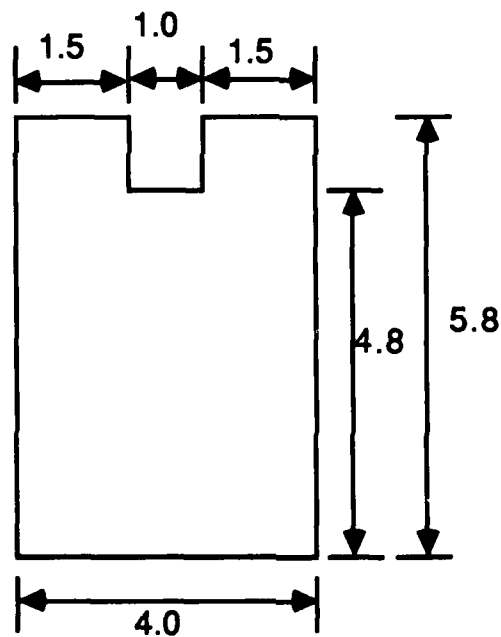


Support Blocks

All measurements are in inches



Front View



End View