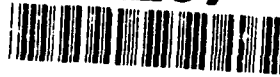


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ARMSTRONG
LABORATORY

**TESTING AND EVALUATION OF THE BIOCHEM
MICROSPAN 1040A PULSE OXIMETER**

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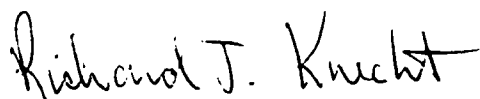
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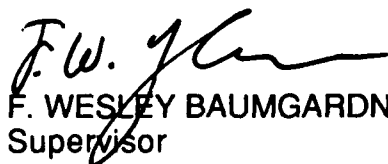
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TESTING AND EVALUATION OF THE BIOCHEM MICROSPAN 1040A PULSE OXIMETER

BACKGROUND

One of the fastest growing forms of medical technology, pulse oximetry, provides continuous, noninvasive monitoring of a patient's arterial hemoglobin saturation (SaO_2). It provides a quick indication of a patient's changing level of SaO_2 , allowing for medical intervention before significant hypoxia occurs. Before pulse oximetry was developed, the usual methods used to assess patient oxygenation were skin color observation and arterial blood gas analysis. Both of these methods have major disadvantages. Observation is not a consistent or reliable determinant of hypoxia, and although arterial blood gas analysis is accurate, it is also invasive, time-consuming, and not possible in the aeromedical evacuation environment. The 375th Aeromedical Airlift Wing (AAW/SGNL; now HQ Air Mobility Command/SG) requested the USAF School of Aerospace Medicine, Aeromedical Research Function (ARF* - now a function of Armstrong Laboratory/CFTS) to evaluate the pulse oximeter for patient use in the aeromedical evacuation environment.

DESCRIPTION

The Biochem microSpan 1040A pulse oximeter is small and portable with dimensions of 6.35 cm H x 13.97 cm W x 19.05 cm L (2.5 in. H x 5.5 in. W x 7.5 in. L) and a weight of .95 kg (2.1 lb). It operates on either its internal sealed battery, or 110VAC/60-400Hz via the AC battery charger, Model 1044. The microprocessor controlled pulse oximeter noninvasively monitors and determines arterial blood oxygen saturation and pulse rate by measuring the absorption of red (660 nanometers) and infrared (925 nanometers) light passed through pulsating blood in the vascular tissue. Features include: easy to read LED displays, perfusion status indicator, high/low SaO_2 audible and visual alarms, high/low pulse alarms, audible pulse tone, adjustable alarm volume from 60-80 dB, sensor alarm, 2-minute audio alarm silence button (Fig. 1), high/low pulse alarm-setting switches on bottom of unit, high/low SaO_2 alarm-setting switches on bottom and back of unit (Figs. 2 and 3), 20-hour internal battery life, and an 18-hour memory, which can be downloaded to a strip-chart recorder. The SaO_2 range is 0 - 100%, and the pulse rate range 18 - 300. The alarm ranges can be set as follows: low O_2 range 65 - 95% in 5% increments, high O_2 range OFF, 95%, or 97%, fast pulse range 125 - 275 in increments of 25, and slow pulse range 30 - 100 in increments of 10.

Component parts of the Biochem microSpan 1040A Pulse Oximeter include: securing bracket, patient cable, flex sensor, finger clip sensor, and ear clip sensor (Fig. 4).

* Aeromedical Research Function (ARF) - Comprised of a flight surgeon, flight nurse, two biomedical engineers, and two aeromedical evacuation/research technicians.

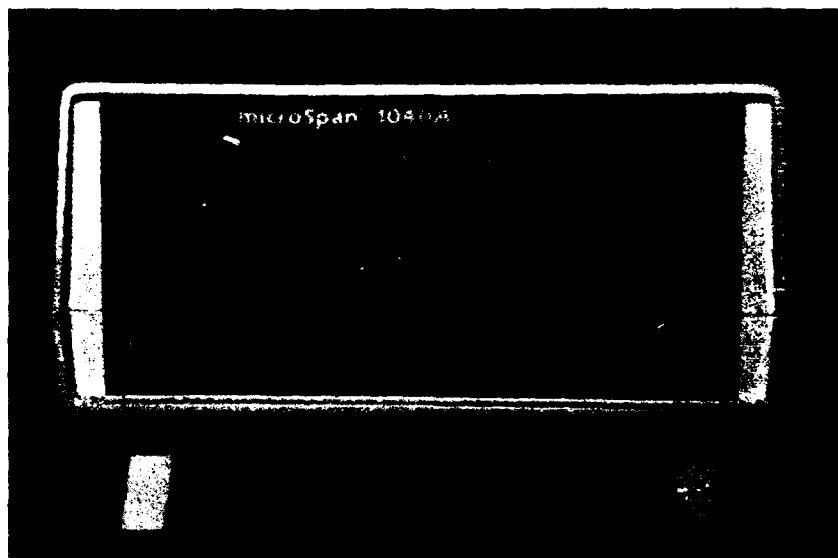


Figure 1. Front of unit: location of features.

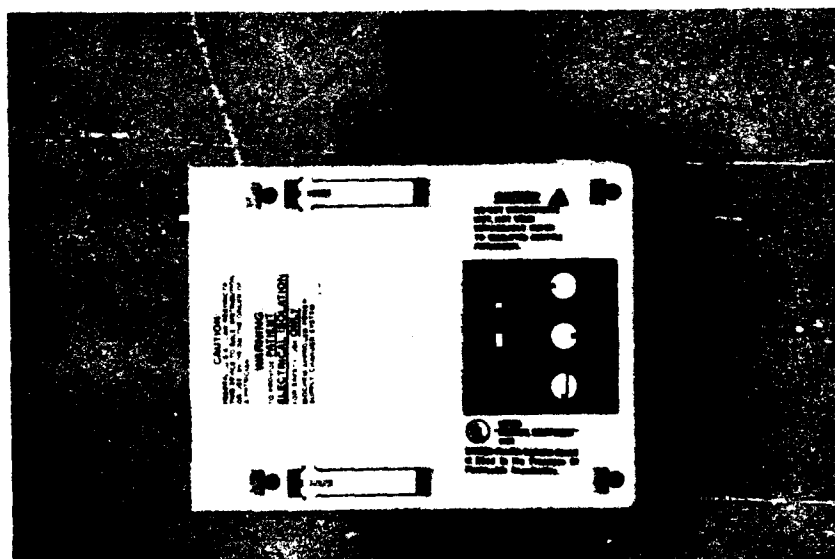


Figure 2. Bottom of unit: alarm-setting controls.

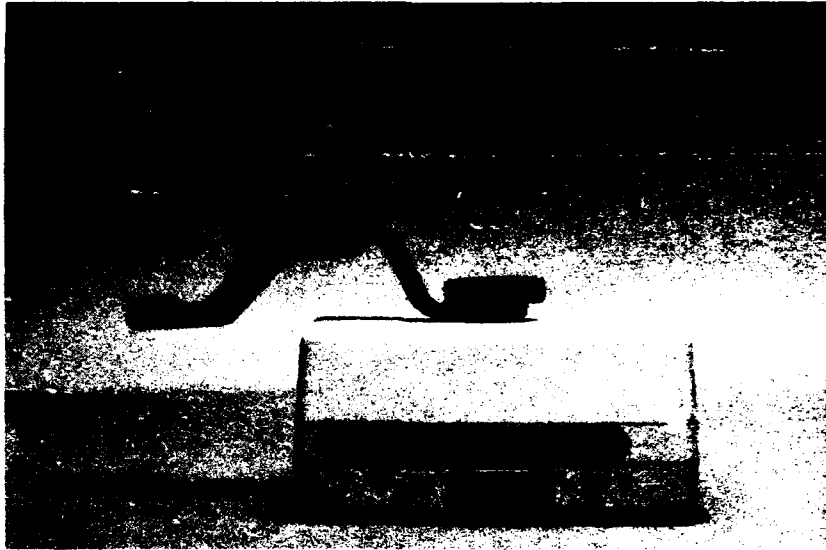


Figure 3. Back of unit: alarm-setting controls.

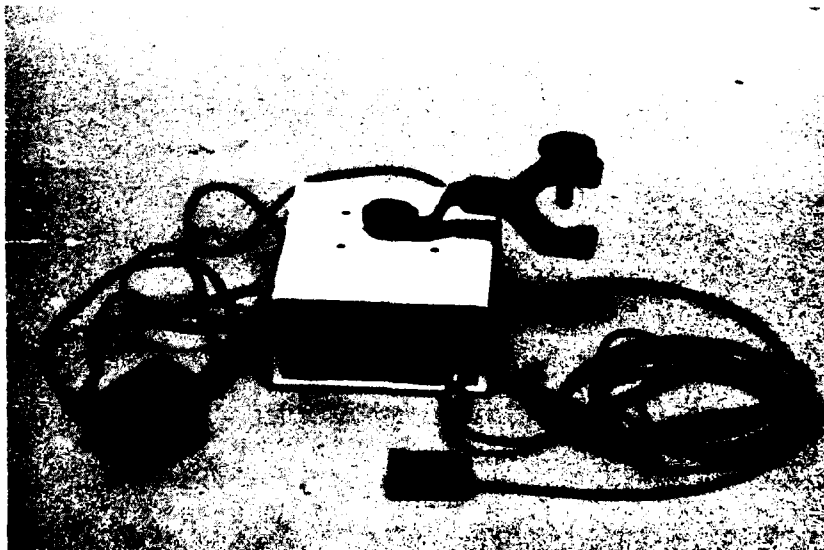


Figure 4. Pulse oximeter with components.

METHODS

The Aeromedical Research Function develops test procedures that cover safety and human factor issues regarding equipment to be tested. The Aeromedical Research Function Procedures Guide (1) and an article on the evaluation of pulse oximeters from ECRI's Health Devices (2) were used as guidelines for the development of the test procedures. A performance check was developed that verified proper functioning of the equipment. The device was subjected to various tests to check its performance under operational conditions to insure compliance with contract specifications (3). The tests involved repeating the performance check under the following conditions:

1. Electromagnetic Interference (EMI)
2. Vibration
3. Altitude
 - a. Hypobaric chamber testing
 - b. Rapid decompression testing
4. Inflight Feasibility

Each test included any special measurements or procedures; for example, the vibration testing was video taped due to the quick changes in displayed pulse rate. To record the displayed SaO₂ readings, a Grant Squirrel Meter/Logger Model 1201 was attached to the output of the oximeter. A control SaO₂ was provided by the Biochem patient simulator (supplied only for testing purposes) which sent a signal that simulated 97-99% SaO₂ and 79-81 pulse rate. It was attached to the pulse oximeter during each test for several minutes.

Performance Check

The pulse oximeter was set up in accordance with manufacturer's recommendations (Instruction Manual) (4). The unit was connected to the patient simulator to insure the displayed values were within the range of the simulator's preset values. Each sensor (finger clip, ear clip, and flex sensor) was attached to an ARF member in accordance with manufacturer's recommendations. A manual pulse rate was recorded along with the unit's displayed pulse rate and oxygen saturation. An alarm situation was caused by removing the sensor from the individual's finger. The pulse oximeter was operated on both 110VAC/60Hz and battery power.

Electromagnetic Interference (EMI)

The purpose of the EMI tests was to verify compliance with MIL-STD-461C, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e (5). For each of the following tests, the pulse oximeter was operated with the finger clip sensor, but not attached to a subject so the alarm was continuously activated.

1. Radiated Emissions (RE-02) - This test measured radiated emissions generated by the pulse oximeter. Excessive emissions could interfere with aircraft navigation and communication equipment. The pulse oximeter was tested while operating on its internal rechargeable battery, 110VAC/60Hz and 110VAC/400Hz.
2. Radiated Susceptibility (RS-02) - This test determined whether the ambient electromagnetic fields encountered in flight interfere with the operation of the pulse oximeter. During exposure to the electromagnetic induction fields the unit was operated on its internal battery as well as 110VAC/60Hz and 110VAC/400Hz.
3. Conducted Emissions (CE-03) - This test measures emissions generated by the pulse oximeter and conducted back up the power line. Excessive conducted emissions could affect the aircraft power supply and/or other systems powered from it. The oximeter was tested while operating on 110VAC/60Hz, and 110VAC/400Hz.
4. Conducted Susceptibility (CS-06) - This test verifies that the pulse oximeter will safely operate from the aircraft's fluctuating power supply. During exposure the pulse oximeter operated on both 110VAC/60Hz and 110VAC/400Hz.

Vibration

MIL-STD-810D, Environmental Test Methods and Engineering Guidelines (6), were used to test the oximeter's construction, durability, and performance, and the integrity of the mounting devices while withstanding random vibration and sinusoidal vibration on the X, Y, and Z axes. The Unholtz-Dickey Vibration Control Console and Vibration Table at Armstrong Laboratory Technical Operations Division (AL/DOJ)* were used for the tests. Using the mounting device provided by the manufacturer, the pulse oximeter was secured to a pole of a standard NATO litter setup secured to the vibration table. The table was operated by technicians from AL/DOJ, who programmed the control console for five 15-minute cycles, totaling 75 minutes at each axis for the sinusoidal testing; and 30 minutes at each axis for the random testing. Before and after the tests, visual examination and performance check were conducted.

During the tests, the unit was under close observation (video taped), and pulse rate and SaO₂ were recorded several times per minute. For each of the five 15-minute cycles for each axis, a different sensor and/or test condition was used. For the 1st cycle, the unit alone was vibrated while connected to the patient simulator; the simulator was placed on a stationary table. For the 2d cycle, the unit alone was vibrated using the finger clip sensor attached to a research technician's finger; the technician's hand was resting on a stationary table. For the 3d cycle, the unit and the finger clip were vibrated with the sensor attached to the technician's finger; the technician's hand was placed on the vibration table. For the 4th cycle, the unit and the flex sensor were vibrated, with the sensor attached to the technician's finger; the technician's hand was placed on the vibration table. The 5th cycle was a repeat of the first cycle.

* formerly USAFSAM/TSNB - Engineering and Maintenance Branch

Altitude

With the assistance of the personnel from Armstrong Laboratory Research Chamber Function (AL/CFTS) the pulse oximeter was subjected to reduced atmospheric pressures of 522.7 mmHg, 10,000 ft equivalent, several times for a total of 4 h at 10,000 ft. During this series of tests, the pulse oximeter and sensors were located inside the hypobaric chamber. While at the reduced pressure equivalent of 10,000 ft, the unit was connected to each of the ARF members present (2-4, depending on which chamber flight) to simulate a variety of patients and to compare the SaO₂ readings. Baseline measurements for each research technician were recorded prior to each altitude exposure. Specific observations recorded at altitude, included:

1. Reliability of the sensors
2. Reliability of the alarm functions
3. Effects of altitude on SaO₂ and pulse rate
4. Effect of 100% oxygen given at altitude after SaO₂ had reached a level of 90%; and the oximeter's response.

Rapid Decompression

Decompressions in flight are uncommon; however, if one were to occur, the pulse oximeter should not present a hazard to the patient, crew, or aircraft operations. The pulse oximeter was subjected to a series of rapid decompression (RD) tests, starting at an equivalent pressure altitude of 8,000 ft with subsequent changes of altitude to 40,000 ft over periods of 60, 7, and 1 s. The pulse oximeter (turned off) and all component parts, to include the charger, patient cable and sensors were secured to the floor of the RD chamber with tape, so they wouldn't be damaged by the violent nature of the RD. Before and after each RD, a performance check was done to ensure continued operability.

Airborne Feasibility

The Airborne Feasibility testing was performed by the two flight qualified Aeromedical Research Technicians on actual C-9A and C-141B aeromedical evacuation missions. On the C-9A, testing was conducted on a series of flights totalling approximately 7 hours, with a ceiling altitude of 31,000 ft and 7,000 ft equivalent cabin altitude. Itinerary on the first mission was from Kelly AFB TX to Travis AFB CA with an enroute stop at Miramar NAS CA. On the second mission, the itinerary was from Travis AFB CA to Kelly AFB TX with several enroute stops. On the C-141B, testing was conducted on one flight for 6 hours with a ceiling altitude of 40,000 ft and 6,500 ft equivalent cabin altitude. The itinerary on that mission was from Travis AFB CA to Hickam AFB HI. The purpose of these tests was to evaluate the pulse oximeter's compatibility with each aircraft and to verify that it operated properly and could withstand the vibrations encountered during takeoff, flight, and landing. The pulse oximeter was operated according to the manufacturer's instructions for use. The Grant Squirrel meter/logger was used to record the SaO₂ output from the oximeter for all flights. A Wallace & Tiernan absolute pressure gauge was used to determine cabin

altitude. The displayed pulse rate and SaO₂ were recorded periodically during the flights. Specific observations recorded inflight included:

1. Visibility of visual alarms
2. Audibility of audible alarms
3. Satisfactory mounting/securing locations of unit
4. Reliability of sensors
5. Reliability of alarms

Due to the small size of the pulse oximeter, and similarity between the C-141B and C-130 litter securing systems, form and fit evaluation on other aeromedical airframes, including the C-130, C-12, C-21, UH-1, and UH-60, was not deemed necessary.

RESULTS

Electromagnetic Interference (EMI)

The pulse oximeter passed the initial narrowband radiated emissions test, but failed the broadband radiated emissions test when operating on 110VAC/400Hz. The unit passed all conducted emissions testing. The problem observed while operating on 110VAC/400Hz was corrected by adding a 1000 μ F capacitor, in the battery charger, to reduce the pulsation caused by the half-wave rectified charger. Due to the inability to plug the recharger into the power outlets on the aircraft, one unit (not the same unit tested originally) was returned with a short adaptor cord for further EMI testing. The unit failed at 4 MHz in the narrowband radiated emissions test, where the original unit had not. Four more units were sent for further EMI testing, and all four failed at the same frequency as the first. All five of the units were returned to the manufacturer for correction of the problem. The problem was a wire protruding between two circuit boards, allowing a 4 MHz signal to escape. This was fixed by tucking the wire back between the circuit boards (as it had been on the unit tested originally) which acted as shielding for the wire. Once this was done, all of the units passed EMI testing.

Vibration

The pulse oximeter performed satisfactorily throughout testing, except for the following observations. The pulse rate display was erratic, with sensors on either a stationary table or on the vibration table. There were marked increases in the pulse rate at certain frequencies on all axes of vibration with no corresponding increase in actual pulse rate of the research technician (Figs. 5 and 6). The power cord plug which plugs into the back of the unit repeatedly came loose during vibration. The manufacturer-supplied securing device which attaches to the litter pole tended to slip down during vibration. When the bracket was secured over the fabric of the litter, the fabric moved and allowed the bracket and unit to slip downward. To prevent this, the bracket was secured to the litter pole itself, or

preferably, secured over the fabric, after the fabric had been tightened. At one point the pulse oximeter fell to the floor after the securing screw knob (which holds the unit to the bracket) came off. Also, after the completion of one axis of vibration, a rattle inside the unit was noticed, and upon opening it, one of the securing screws for the internal battery pack had come undone, and the other was loose. The screws were tightened and there were no other problems with this during the rest of the testing.

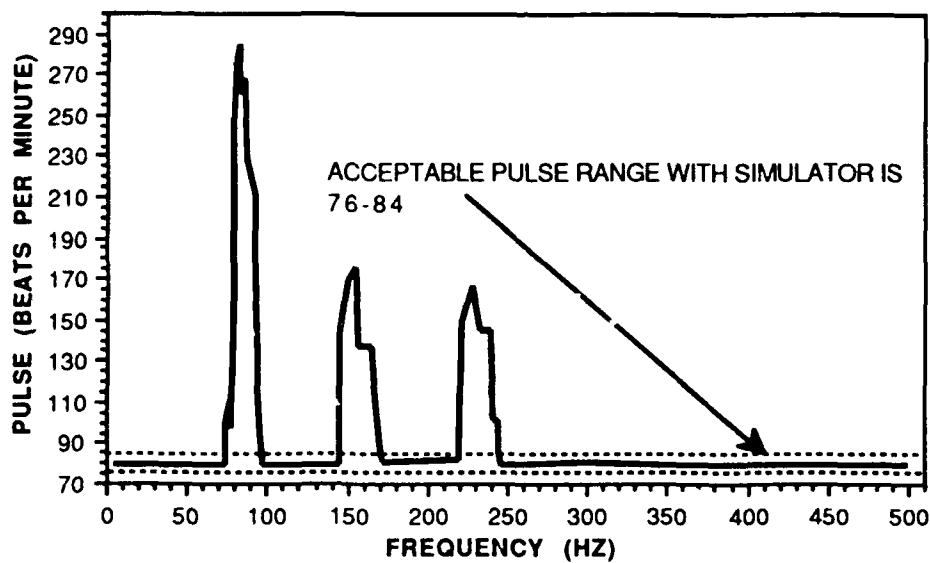


Figure 5. Erratic pulse rate with simulator.

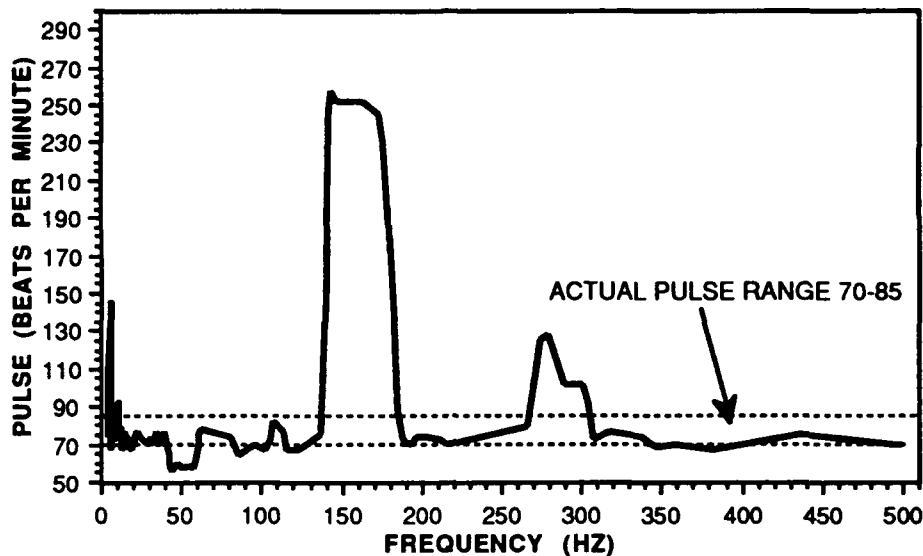


Figure 6. Erratic pulse rate during vibration; finger clip sensor on vibration table.

Altitude

While at an equivalent pressure altitude of 10,000 ft, the SaO₂ display decreased as expected while the sensor was attached to the research technician. The pulse rate was erratic at times due to the movement of the subject's finger or hand. Alarms functioned properly with poor sensor placement and sensor disconnect. As expected, when 100% O₂ was administered to the research technician, the SaO₂ display increased within 2 minutes from 90% to 98-99% and stabilized at that point. When the O₂ was removed, the technician's SaO₂ decreased back to 90% within 5 minutes.

Rapid Decompression

The pulse oximeter was still operable with no problems in operation and no damage to the unit after each decompression.

Airborne Feasibility

The pulse oximeter performed satisfactorily on each of the aircraft flown: Specific findings include the following:

1. The pulse oximeter "audible" alarms were audible in the C-9A up to approximately 20 ft. On the C-141B, the alarms were inaudible when the distance exceeded 1 ft. Therefore, the unit should be positioned for optimal visibility of the visual alarms.

2. The pulse oximeter is easily secured to the litter on both the C-9A and C-141B; however, when it is secured to the outside litter pole, it obstructs the aisle on both aircraft, but more so on the C-141B (Fig. 7). It can be secured on the inside litter pole with no aisle obstruction, but the view of the unit's display is obstructed. On the C-9A, the most satisfactory method of securing the pulse oximeter was to the cantilever arm itself (Fig. 8). This allowed for an unobstructed view of the display. On the C-141B, a short metal pole (Aeromedical Equipment Securing Pole) designed specifically for this and other equipment items, was secured in a litter clamp on the stanchion pole and the unit was secured to this pole (Fig. 9).

3. It is not recommended that the unit be mounted on the side of a litter attached to the litter pole when enplaning or deplaning. Due to the crowded conditions of the aircraft, the unit could be knocked off during litter movement.

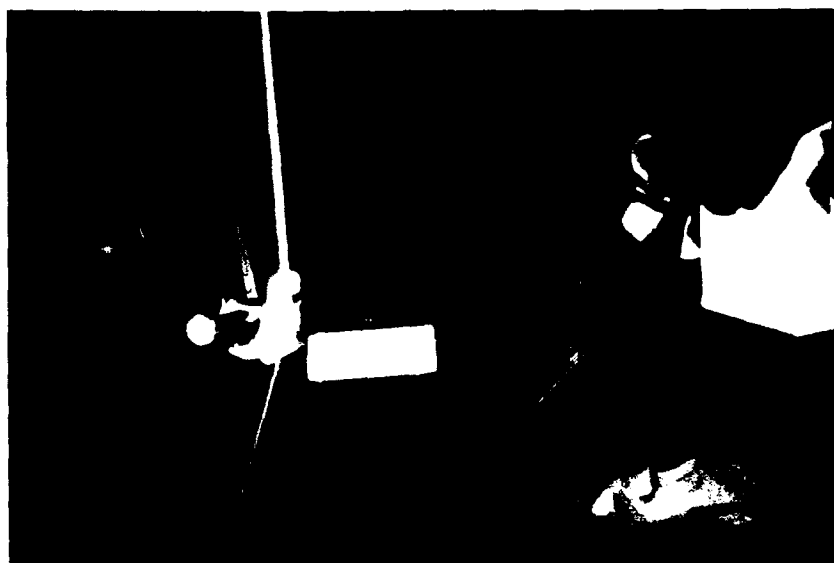


Figure 7. Unit secured on litter.

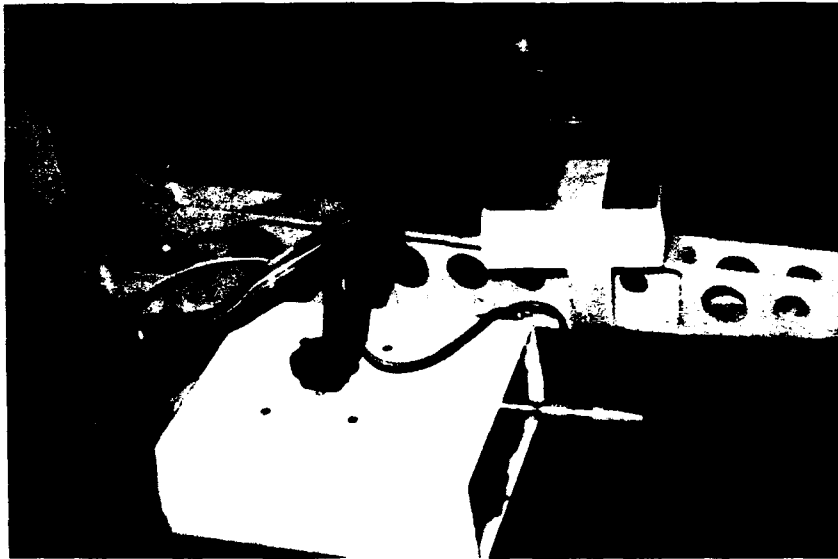


Figure 8. Unit secured to C-9A cantilever arm.

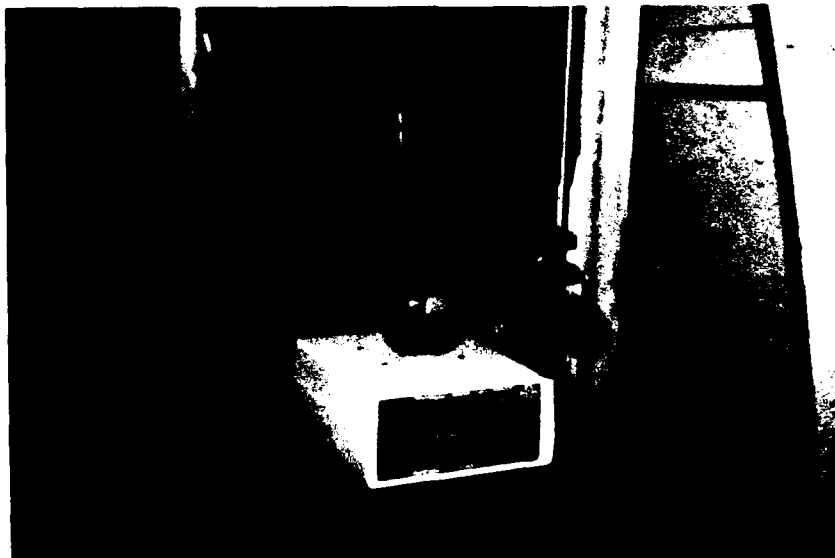


Figure 9. Unit secured to Aeromedical Equipment Securing Pole.

4. The displayed SaO_2 behaved as expected on ascent, level flight at altitude and descent. This was tested with the finger clip, ear clip, and flex sensors. The SaO_2 decreased in relation to the increase in altitude, leveled out at altitude, and increased in relation to the decrease in altitude. (Figs.10,11, and 12).

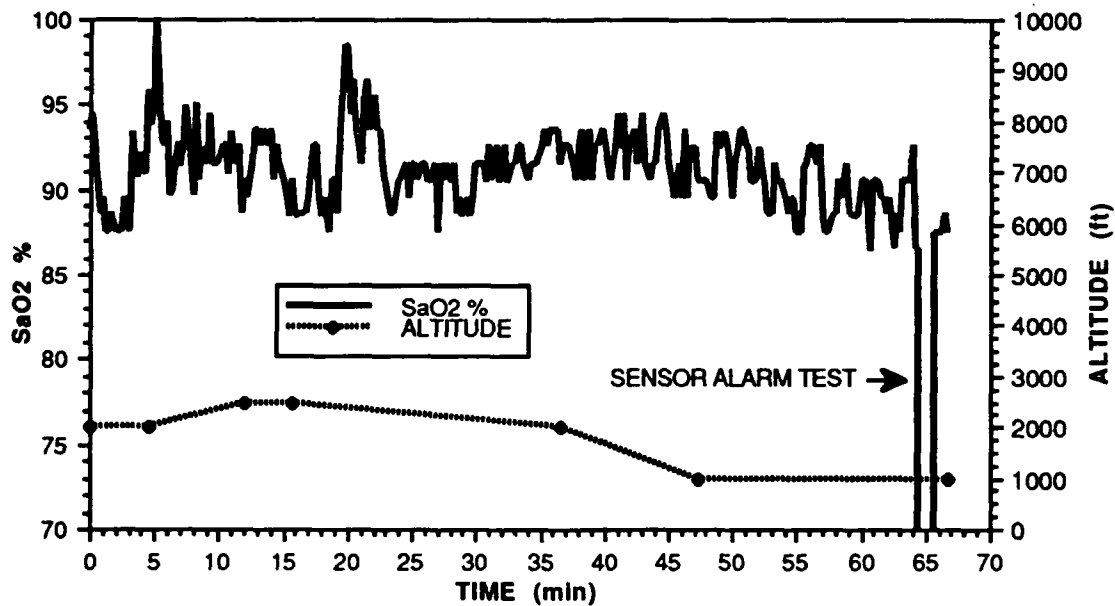


Figure 10. SaO_2 vs altitude; ear clip on C-9A.

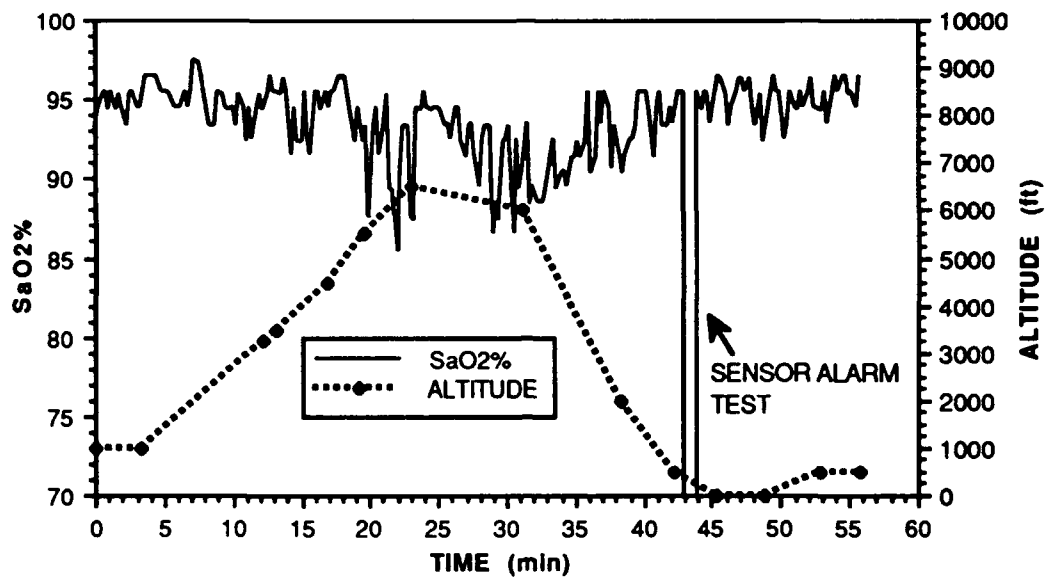


Figure 11. SaO_2 vs altitude; finger clip on C-9A.

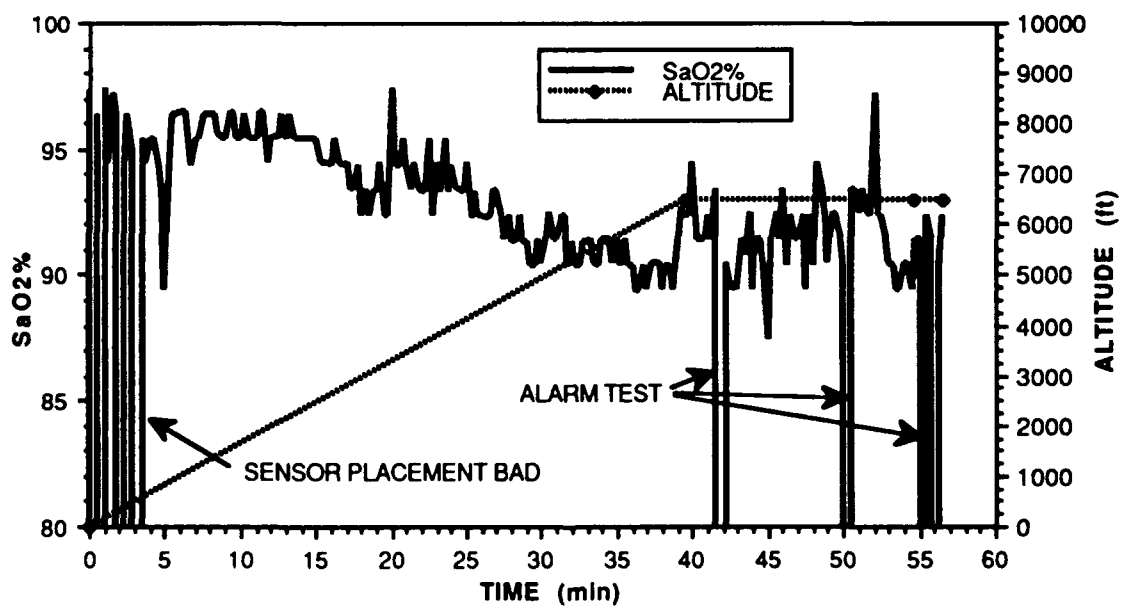


Figure 12. SaO_2 vs altitude; flex sensor on C-141B.

REQUIREMENTS AND RECOMMENDATIONS

The following requirements and recommendations (except for number 4, which was identified at a later date and briefed to 375 AAW/SGNL by phone) were submitted to the office of the Wing Surgeon, 375 AAW, in the form of an interim report, on 21 December 1989 (7). Personnel from the Wing Surgeon's office were personally briefed that same day.

Requirements

1. Use an acceptable battery charger rated at 110VAC/60-400Hz with a 1000 μ F capacitor to reduce the pulsation caused by the half-wave rectified charger.
2. Internal battery securing screws must have lock washers in place to prevent them from loosening. Without the lock washers, there is a high probability that aircraft vibration will cause the battery assembly to shake loose and possibly cause internal damage.
3. A screw with a large plastic knob attaches the 1040A to the mounting bracket. During vibration testing, the knob separated from the shaft of the screw, resulting in the 1040A falling from the bracket. The bonding of the knob to the shaft should be improved. Also, a washer or some other device should be attached to the shaft between the bracket and the knob, which will support the 1040A in the event the knob does come off.
4. The protruding wire between the circuit boards that allowed a 4 MHz signal to escape must be tucked between the circuit boards to shield this wire and prevent any EMI problems.

Recommendations

1. The threaded portion of the large screw that secures the mounting bracket to the litter is only 3.33 cm (1-5/16 in.) long. The threaded portion should be extended to 5.72 cm (2-1/4 in.) to allow mounting to smaller objects within the aircraft, as well as larger objects such as a litter pole.
2. When mounted on the litter pole, the unit protruded into the aircraft aisleway, presenting a hazard to the unit and to personnel; or could not be effectively seen if mounted on the other side of the litter. The following recommendations are made:
 - a. On the C-9A aircraft, the unit is most effectively mounted directly onto a cantilever arm.
 - b. On the C-130 and C-141B, the unit is most effectively mounted using a short 20.32 - 30.48 cm (8 - 12 in.) metal pole (such as the Aeromedical Equipment Securing Pole). The pole is clamped into a stanchion litter bracket, and the 1040A is secured to the pole. A prototype of the pole was provided to the 375 AAW/SGNL.

3. Due to the difficulty in hearing the audible alarm in flight, the 1040A should be placed so that the visual alarms can be easily viewed by medical crewmembers.
4. As with any pulse oximeter, the 1040A's saturated oxygen (SaO₂) reading should not be considered completely accurate. It should be used as an indication of change only, and not as a measurement of the absolute oxygen saturation.
5. Users should be aware that during testing, the ear clip sensor, at times, gave significantly higher SaO₂ readings (approximately 5-10%) than the other sensors. This characteristic can possibly be further evaluated during OT&E.
6. The Instruction and Operations Manual should be changed to indicate that the 1040A can be operated and charged using 110VAC/60-400Hz.
7. The 1040A normally displays an accurate pulse reading. However, due to patient movement, aircraft vibration, and other factors, it may display significantly higher readings than expected. Users should be aware of this, and not depend on the 1040A as a true indicator of the patient's heart rate.
8. During vibration testing, the power supply cable repeatedly dislodged from the rear of the 1040A. The manufacturer should modify the unit to prevent inadvertent disconnection of the cable. If this modification is not made, users should be aware of the possibility of cable disconnection and make frequent visual checks.

CONCLUSIONS

After all testing was completed, and the compiled data analyzed, the members of the Aeromedical Research Function were briefed on the findings. The Biochem microSpan 1040A Pulse Oximeter was found to be a safe, reliable device for monitoring changing levels in patient oxygenation. It is acceptable for worldwide aeromedical evacuation use, but only when all requirements stated above are fulfilled.

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