AD-A094 580 TEXAS A AND M UNIV COLLEGE STATION BIOENGINEERING DIV F/G 6/19
APPROACHES TO INFLIGHT EAR OXIMETRY.(U)
OCT 80 W A HYMAN F33615-79-D-0629
UNCLASSIFIED SAM-TR-80-36 NL

Report SAM-TR-80-36 LEVEL II 12

APPROACHES TO INFLIGHT EAR OXIMETRY

William A. Hyman, Ph.D.
Bioengineering Division
Industrial Engineering Department
Texas A&M University
College Station, Texas 77843

October 1980

Final Report for Period 1 May 1979 - 31 December 1979

Approved for public release; distribution unlimited.

Prepared for
USAF SCHOOL OF AEROSPACE MEDICINE
Aerospace Medical Division (AFSC)
Brooks Air Force Base, Texas 78235

NOTICES

This final report was submitted by Texas A&M University, College Station, Texas 77843, under contract F33615-78-D-0629, Task 8, job order 7930-10-23, with the USAF School of Aerospace Medicine, Aerospace Medical Division, AFSC, Brooks Air Force Base, Texas. Captain Merrifield (USAFSAM/VNE) was the Laboratory Project Scientist-in-Charge.

When U.S. Government drawings, specifications, or other data are used for any purpose other than a definitely related Government procurement operation, the Government thereby incurs no responsibility nor any obligation whatsoever; and the fact that the Government may have formulated, furnished, or in any way supplied the said drawings, specifications, or other data is not to be regarded by implication or otherwise, as in any manner licensing the holder or any other person or corporation, or conveying any rights or permission to manufacture, use, or sell any patented invention that may in any way be related thereto.

This report has been reviewed by the Office of Public Affairs (PA) and is releasable to the National Technical Information Service (NTIS). At NTIS, it will be available to the general public, including foreign nations.

This technical report has been reviewed and is approved for publication.

John T. Merrifield

JOHN T. MERRIFIELD, Captain, USAF
Project Scientist

William F. Storm

WILLIAM F. STORM, Ph.D.
Supervisor

Roy L. DeHart

ROY L. DEHART
Colonel, USAF, MC
Commander

UNCLASSIFIED

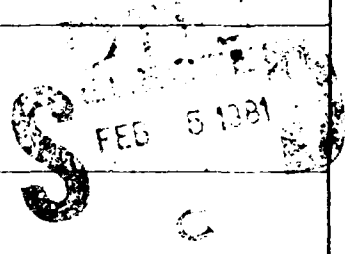
SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE	READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER: SAM-TR-80-36	2. GOVT ACCESSION NO.: AD-A094 580
	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle): APPROACHES TO INFLIGHT EAR OXIMETRY.	5. TYPE OF REPORT & PERIOD COVERED: Final Report. 1 May 1979 — 31 Dec 1979.
	6. PERFORMING ORG. REPORT NUMBER
7. AUTHOR(s): William A. Hyman, Ph.D.	8. CONTRACT OR GRANT NUMBER(s): F33615-78-D-0629, Task 8
9. PERFORMING ORGANIZATION NAME AND ADDRESS: Bioengineering Division, Industrial Engineering Department, Texas A&M University, College Station, Texas 77843	10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS: 62202F, 7930-10-23
11. CONTROLLING OFFICE NAME AND ADDRESS: USAF School of Aerospace Medicine (VNE), Aerospace Medical Division (AFSC), Brooks Air Force Base, Texas 78235	12. REPORT DATE: October 1980
	13. NUMBER OF PAGES: 12
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office)	15. SECURITY CLASS. (of this report): UNCLASSIFIED
	15a. DECLASSIFICATION/DOWNGRADING SCHEDULE

16. DISTRIBUTION STATEMENT (of this Report)

Approved for public release; distribution unlimited.

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)



18. SUPPLEMENTARY NOTES

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Ear Oximetry	Physiological measurement
Oximetry	Blood oxygen saturation
Noninvasive measures	Arterial blood oxygen saturation
Inflight measurement	G-stress
Airborne measurement	Acceleration stress

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

The USAF School of Aerospace Medicine, as part of its ongoing research in aircrew physiological response, has been interested in the capability of noninvasive measurement of arterial blood oxygen saturation during flying operations. This report addresses ear oximetry techniques as one of the candidate technologies for that measurement. A brief review of the history and present state-of-the-art of ear oximetry is presented. Related and alternate technologies for measurement of arterial blood oxygen saturation are also discussed. The study concludes that the current state-of-the-art of ear oximetry does not

DD FORM 1 JAN 73 1473

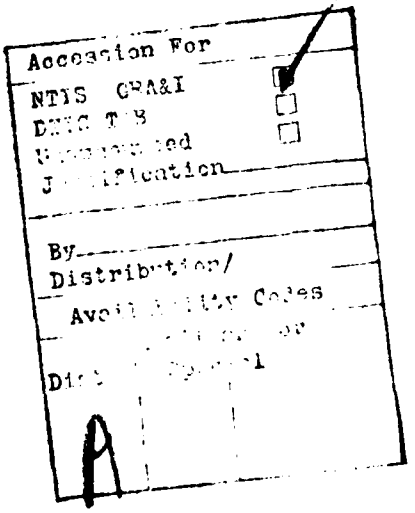
UNCLASSIFIED

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

4121

20. ABSTRACT (Continued)

yield itself to development of a noninvasive measurement device that satisfies the severely restrictive constraints of size, weight, and power consumption required by inflight applications. The report recommends that related or alternate technologies, **including transcutaneous oxygen electrodes, be investigated.**



APPROACHES TO INFLIGHT EAR OXIMETRY

INTRODUCTION

The USAF School of Aerospace Medicine (USAFSAM), as part of its ongoing research on aircrew physiological response, has been interested in the capability of noninvasive measurement of arterial oxygen saturation. For centrifuge experiments the Hewlett-Packard ear oximeter, Model 47201A, has been successfully used both at USAFSAM (1) and elsewhere (2). However, the configuration of the Hewlett-Packard device is not suitable for inflight use. The USAF School of Aerospace Medicine has therefore been interested in the development of an ear oximeter that would meet the restrictive inflight requirements associated with ease of use, reliability, size, weight, and power needs (see specifications--Appendix A).

This report is a review of the history and present state-of-the-art of ear oximetry with respect to its potential for inflight use. The report also contains recommendations with respect to specifications and possible alternative measurement techniques.

HISTORY

The observation that oxygenated blood is much more transparent to red light than deoxygenated blood and that this characteristic could be used to measure oxygen saturation is attributed to independent work by Kramer (3) and Matthes (4). This method requires the measurement of the transmission of light of a suitable wavelength through the blood. For this to be accomplished noninvasively, the ear flap was suggested because of its thinness and high vascularity.

A single wavelength method is inadequate, however, because the volume of blood and the amount and pigmentation of the intervening tissue also affect transmittance. The addition of a second wavelength that has equal transmittance through oxygenated and deoxygenated blood was suggested (5, 6). This second wavelength provided a reference value for the blood and tissue volume but still could not account for tissue effects.

It was therefore further suggested (7, 8) that a transmittance measurement be made at both wavelengths on the "bloodless" ear by squeezing the blood from the ear and that these values be used to correct those obtained during normal blood flow. While this technique offered considerable improvement (and is the basis for the currently available ear oximeter made by Waters Instruments, Inc., Model **0-1100A)**, the method still contains significant technical and practical difficulties that have resulted in this approach receiving limited clinical acceptance. These difficulties are perhaps even more significant with respect to inflight experimental use.

The difficulties are:

1. The bloodless ear is not truly bloodless and is somewhat difficult to obtain.

2. The optical characteristics of the tissue of the compressed ear differ from those of the ear in the normal state.

3. Any movement of the ear piece results in a different optical pathway; therefore, new bloodless calibrations must be frequently obtained.

4. To prevent movement, the ear piece must be tightly attached and the forces required to do so may impede blood flow.

In addition to these hardware-oriented problems, high blood flow in the ear is required at all times so that "arterialized" blood dominates the optical pathway. This high level of blood flow requires some kind of stimulation of the ear, such as by rubbing, chemicals, or heat.

Little had been reported with respect to further improvements **in ear oximetry** prior to the introduction of the Hewlett-Packard device in the mid 1970s.

THE HEWLETT-PACKARD EAR OXIMETER

The Hewlett-Packard ear oximeter (Model 47201A) employs a system which measures transmission at eight wavelengths between 650 and 1050 nm. Ear hyperperfusion is maintained with a heater in the ear piece. This system appears to eliminate most of the problems associated with the designs that use only two wavelengths. A mechanical system is used to filter the high-intensity light source into the eight required wavelengths and that system adds considerably to the size and power requirements of the oximeter.

A universal calibration which converts the eight transmission levels to percent oxygen saturation has been obtained through clinical trials and is incorporated in the internal calculations of the machine. A detailed description of the device is available (9), and a number of papers on both the clinical use (10-17) and the experimental use (1, 2, 18) of this equipment have been published since its introduction. As noted above, although successfully used in centrifuge experiments, the Hewlett-Packard device does not meet the inflight specifications.

OTHER EAR OXIMETERS

The USAFSAM has undertaken the development of two wavelength (640 and 805 nm) ear oximeters (19, 20). However, these devices, although technically sophisticated, apparently did not solve the fundamental problem of probe movement. In addition, the later device (20) was shown to be G-sensitive, with this sensitivity being attributed to lamp filament effects (21).

The National Aviation and Space Administration (NASA) has also reported an ear oximeter device of conventional two wavelength design (640 and 790 nm), including an occluder for the bloodless calibration (22). No information is given on movement artifact in the referenced document. The design and development of the Hewlett-Packard ear oximeter also grew out of research initiated by NASA on multiple wavelength devices.

RELATED TECHNOLOGIES

Closely related to the technology employed in ear oximetry are the in vitro determination of blood oxygen saturation, invasive fiber optic methods, and reflectance oximetry.

The in vitro approaches utilize blood withdrawn from the body, and transmission is again measured near 640 and 800 nm as in the two wavelength ear oximeter (23). In this application the interference of the ear tissue is, of course, eliminated and the method is in widespread commercial use (e.g., 24). Three-wavelength in vitro devices are also available (e.g., the ILCO-Oximeter) with the third wavelength providing increased accuracy and elimination of carbon monoxide interference. In the fiber optic, invasive method, an arterial catheter is introduced and the colorimetric measurement is made in the flowing bloodstream (25) (e.g., Corning Oximetrix system which uses three wavelengths (26)). Direct measurement with an arterial pO_2 electrode is also possible (e.g., IBC In-viv-OX), as well as mass spectrometer techniques using an arterial catheter (e.g., Searle Medspect). Neither of these methods is consistent with the USAFSAM requirement for noninvasive measurements.

In reflectance oximetry the same principles employed in ear oximetry are used, but in this case the light is reflected from the skin rather than transmitted through it. This method has been known for some time (27) and although it has continued to be reported (28), it has not seemed to have found practical use. The primary problem is the consistent extraction of useful information from the back scattered light intensities due to the variable effects of tissue pigmentation, local tissue anatomy, and blood volume.

All of the two-wavelength optical devices discussed above use a wavelength near 800 nm for the compensating channel and a red wavelength near 640 nm for oxyhemoglobin detection. More than two-wavelength devices cover a similar portion of the spectrum (the Hewlett-Packard device covers 650 to 1050 nm). Perhaps a more useful isobestic region exists between 1200 and 1400 nm (29). This region coincides with high skin transparency and independence from skin pigmentation.

POTENTIAL FOR INFLIGHT EAR OXIMETRY

The Hewlett-Packard ear oximeter has proved to be a very useful and reliable device but, as noted above, its current technology is not suitable for inflight use as envisioned by USAFSAM, and redesign would not seem to be feasible.

The fact that the traditional two-wavelength ear oximeter has received little acceptance for clinical use because of fundamental problems in this measurement technique suggests that further development for inflight use will not be fruitful. At this time there does not seem to be any way to overcome the need for the bloodless ear measurement, and even with this calibration step, the problem of ear piece movement is likely to be very difficult to overcome. Certainly any development proposal in this area should address these particular points in depth.

The potential for using the isobestic region above 1200 nm may be worthy of further development in that the available report suggests that it may eliminate the tissue artifact in the usual two-wavelength device.

ALTERNATIVE TECHNOLOGIES

A relatively recent development in noninvasive arterial oxygen measurement is the transcutaneous oxygen electrode (30). These devices employ a combination heating element and a membrane-sealed oxygen electrode contained in a single transducer head which is placed on the skin surface. The heating element is necessary to induce local hyperemia so that arterialized blood will be available. Oxygen in this arterialized blood equilibrates across the skin surface and the membrane. At least three commerical versions of this type of system are available (31, 32, 33). The major emphasis in the use of these devices is in the monitoring of newborns with a secondary clinical interest in adult intensive care (30). The advantage in newborns is their thin skin, which allows wide latitude in transducer placement. In adults a relatively thin region must be selected such as the area behind the ear. This equipment is far less cumbersome and has much lower power requirements than the Hewlett-Packard ear oximeter (Table 1) and may be more amenable to modification for inflight use. Also shown in Table 1 are the data for the Waters ear oximeter and the July 1978 USAFSAM specifications.

TABLE 1. A COMPARISON OF SIZE, WEIGHT, AND POWER REQUIREMENTS OF VARIOUS OXIMETRY SYSTEMS

	Ear oximeters		Transcutaneous			USAFSAM
	Hewlett-Packard	Waters	London	Litton	Roche	Requirements (Appendix A)
Size(mm)	191x425x425	119x279x295	150x290x300	109x177x178	165x356x359	— — —
cm^3	34,500	9,800	13,050	3,400	21,000	197
Weight(kg)	16.7	7.3	6.8	1.7	13	0.45
Power(VA)	160	20	28	33	51	self-powered 4 hours

USAFSAM SPECIFICATIONS
July 1978 (F33615-79-R-0606)

These specifications (34) (Appendix A) for an ear oximeter may be improved with respect to contractor acceptance by the following changes or considerations:

1. The title ("Noninvasive Instrumentation for Inflight Determination of G-Stress") is possibly misleading and should be changed to reflect the

actual aim which is to measure arterial blood oxygen saturation, i.e., "Noninvasive Instrumentation for Inflight Determination of Arterial Oxygen Saturation."

2. The words "ear oximeter" should not be used in the specification since there may be more desirable alternative methods.

3. The size, weight, and power requirements need to be reconsidered with respect to the possibility of having the instrumentation package attached to the aircraft rather than the pilot.

4. If 3 is not feasible, then the size, weight, and power requirements should be noted as restrictive but left open to be included in the proposal.

5. All proposals should address the historical problems with the proposed technology and the specific means by which the proposer intends to overcome these problems.

6. In any future specification it will be important to recognize the difference in expectations between a basic development effort and the actual ability to deliver a working device.

RECOMMENDATIONS

As a result of this study it is recommended that:

1. USAFSAM consider the use of the transcutaneous oxygen measurement beginning with a centrifuge test of the commercial versions of this technology. If successful, it appears much more likely that this approach could be configured to meet inflight requirements than present ear oximetry.

2. USAFSAM consider supporting a feasibility study of an ear oximeter using the above 1200-nm isobestic region.

3. USAFSAM reconsider the possibility of allowing the instrumentation to be aircraft rather than pilot mounted.

4. USAFSAM release a new specification based on the recommendations contained herein in order to ascertain current interest and capabilities.

REFERENCES

1. Besch, B. L., et al. Calibration of a new ear oximeter in humans during exposure to centrifugation. J Appl Physiol 44:483 (1978).

2. Voge, V. M. Comparison of several G-tolerance measuring methods at various seatback angles. Aviat Space Environ Med 49:377 (1978).

3. Kramer, K. Ein Verfahren zur Fortlaufenden, Messung des Sauerstoffgehaltes im Stromenden Blute an uneroffneten Gefassen. Z Biol 96:61 (1935).

4. Matthes, K. Untersuchungen uber die Sauerstoffsaittigung des Menschlichen Arterien blutes. Arch Exp Path Pharmakel 199:698 (1935).

5. Matthes, K., and F. Cross. Fortlaufende Registrierung der Lichtabsorption des Blute in Zwei vershiedenen Spektralbezirken. Arch Exp Path Pharmakel 191:381 (1978).

6. Millikan, G. A. The oximeter, an instrument for measuring continuously oxygen saturation of arterial blood in man. Res Sci Inst 13:434 (1942).

7. Goldie, E. A. G. A device for the continuous indication of oxygen saturation of circulating blood in man. J Sci Inst 19:23 (1942).

8. Wood, E. H., and J. E. Geraci. Photoelectric determinations of the arterial oxygen saturation in man. J Lab Clin Med 34:387 (1949).

9. Merrick, E. M., and T. J. Hayes. Continuous, non-invasive measurements of arterial blood oxygen levels. Hewlett-Packard Journal, Oct 1976.

10. Siffer, A. N., and W. E. Martin. Evaluation of an eight-wavelength arterial ear oximeter. Abstracts of Scientific Papers, Annual Meeting of the American Society of Anesthesiologists, 1975.

11. Arthur, J. L., et al. Patient monitoring in the operating room - an anesthetist's viewpoint. Med Instrum 10:105 (1976).

12. Suanders, K. A., et al. Ear oximetry: Accuracy and practicability in the assessment of arterial oxygenation. Am Rev Respir Dis 113:745 (1976).

13. Berman, L., and N. L. Jones. Fiberoptic bronchoscopy: Monitoring oxygenation with ear oximetry. Am Rev Respir Dis 11:651 (1976).

14. Flick, M. R., and A. J. Block. Continuous in vivo measurement of arterial oxygen saturation by oximetry. Heart Lung 6:990 (1977).

15. Flick, M. R., et al. Effect of ultrasonic nebulization on arterial oxygen saturation in chronic obstructive disease. Chest 71:366 (1977).

16. Scoggin, C., et al. Clinical evaluation of a new ear oximeter. Heart Lung 6:121 (1977).

17. Chaudhary, B. A., and N. K. Burk. Ear oximetry in clinical practice. Am Rev Respir Dis 117:173 (1978).

18. Phillipson, E. A., et al. Ventilatory and waking responses to hypoxia in sleeping dogs. J Appl Physiol 44:512 (1978).

19. Peters, W. S., and E. D. Michaelson. An ear oximeter for use on the human centrifuge. Medical Association Annual Meeting Abstracts, 66, 1972.

20. Patterson, R. USAF School of Aerospace Medicine, Personal communication re design effort c. 1975.

21. Thompson, R. W., et al. Engineering Test and Evaluation During High G. AF Contract FA 1609-75-C-0026, Technology Inc., San Antonio, Tex., 1976.

22. NASA Tech. Brief B72-10224, Patent No. 3, 412, 729, National Aeronautics and Space Administration, 1968.

23. Falholt, W. Blood oxygen saturation determined spectrophotometrically. Scand J Clin Lab Invest 15:67 (1965).

24. American Optical, Buffalo, N.Y., AO Unistat Oximeter. This system uses 670 and 940 nm.

25. Enson, Y., et al. In vivo studies with an intravascular and intracardiac reflection oximeter. J Appl Physiol 17:552 (1962).

26. Corning Medical, Medfield, Mass. Oximetrix Shaw Catheter Oximeter System.

27. Zijlstra, W. G., and G. A. Mook. Medical Reflection Photometry, V. Gorcum Ltd., 1962.

28. Cohen, A., and N. Wadsworth. A light emitting diode skin reflection oximeter. Med Biol Eng 10:385 (1972).

29. Mohapatra, S. N. Infrared isobestic region for whole blood. Med Biol Eng 13:929 (1975).

30. Huch, A., and R. Huch. Transcutaneous, non-invasive monitoring of pO_2. Hosp Pract 11:43 (1976).

31. Litton Medical Electronics, Elk Grove, Illinois, Oxymonitor.

32. Roche Medical Electronics, Cranbury, N.J., Cutaneous Oxygen Monitor.

33. London Co., Cleveland, Ohio, TCM1 TC Oxygen Monitor.

34. Flick, C. A., and J. T. Merrifield. USAFSAM specifications for an inflight ear oximeter. Unpublished manuscript, USAF School of Aerospace Medicine, 1978.

APPENDIX A

USAFSAM SPECIFICATIONS FOR AN INFLIGHT EAR OXIMETER

SECTION F DESCRIPTION/SPECIFICATIONS 31 July 1978

TITLE: NONINVASIVE INSTRUMENTATION FOR INFLIGHT DETERMINATION OF G-STRESS

1.0 INTRODUCTION

1.1 The United States Air Force School of Aerospace Medicine (USAFSAM) possesses an inflight physiological monitoring device which consists of an instrumented oxygen mask, and man-mounted sensors, which input to a cassette recorder positioned in available pockets of the crewmember's survival vest. The system provides multiplexed analog recording of data, presently configured to provide records of inspired/expired flow, inspired/expired oxygen concentrations, electrocardiogram, cabin pressure, acceleration, time-code, and voice communication. The present procurement seeks to supplement these data with additional record of the pilot's arterial oxygen saturation.

2.0 SCOPE

2.1 The contractor shall furnish the necessary personnel, services, equipment and facilities to design, fabricate, bench-test and deliver a bread-board and a miniature oximeter for use with the inflight physiological monitor.

2.2 The effort will be divided into three phases. Phase I will include the system design. Phase II will include fabrication and test of a bread-board model. Phase III will include the fabrication of the miniature oximeter.

3.0 GENERAL BACKGROUND

3.1 Subjects exposed to sustained acceleration forces exhibit a lowered arterial oxygen saturation which is caused by decreased efficiency of the cardiopulmonary system. Pilots of high performance aircraft are subjected to these forces and it is necessary to obtain a measurement of the arterial oxygen saturation inflight to determine the extent of the oxygen level reduction. This reduction could cause a performance decrement or possibly the loss of consciousness. The USAFSAM has measured the arterial oxygen saturation of subjects as they were exposed to acceleration forces on the centrifuge. These measurements were made using a Hewlett-Packard Model 47201A ear oximeter.

4.0 TECHNICAL REQUIREMENTS/TASKS

4.1 Characteristics required of the end product include the following. The bread-board device shall conform to all of the requirements except paragraph 4.1.1.

4.1.1 Size and weight: The total device shall not weigh more than 16 oz. The size of the power and electronics unit shall not exceed 12 cubic inches.

4.1.2 Power requirements: The device shall be self-powered for a period of 4 hours.

4.1.3 Output parameters: The device shall be sensitive to arterial oxygenation of a human subject in the range from 60 to 100 . The device will produce an electrical voltage from 0 to 5 volts to represent the measured value. The output current capability shall be great enough to drive a load of 10 kilohms or greater.

4.1.4 Operational environment: The device's behavior and accuracy shall be as specified herein when exposed to changes in ambient pressure from sea level to an altitude of 50,000 feet, humidity from 5% to 95% RH, temperature from 0°C to 85°C and acceleration forces from -3G to +12G.

4.1.5 Drift: The device shall be ble with long-term drift less than 1 saturation per hour.

4.1.6 Accuracy: The device accuracy shall be greater than ± 3.7 saturation.

4.1.7 Response time: If the measured oxygen saturation changes as a step function, the device output shall respond faster than an exponential curve which is asymptotic to the step function change and has a time constant of 2.5 seconds.

4.1.8 The device shall operate on a subject who is wearing standard flight safety equipment including helmet and oxygen mask. The device shall also operate without this equipment.

4.1.9 System safety: The device shall be safe for using in a fighter aircraft cockpit and not pose a hazard to the pilot. A system safety program, including hazard analyses, must be performed and documented in accordance with MIL-STD-882. Specific compliance with MIL-STD-461A "Electromagnetic Interference Characteristics: Requirements for Equipment" (1 Aug 68) is required also for safety/compatibility with cockpit navigation aids. The prime objective in a system safety program is to formalize an approach to eliminate hazards through engineering, design, education, management policy, and supervisory control for the optimum degree of safety within the constraints of operational effectiveness, time and cost throughout all phases of the equipment's life cycle.

4.1.9.1 If a part of the device is placed over the outer layer of clothing or over or under the helmet, that part shall be designed to prevent injury in the case of canopy jettison, or pilot ejection. Unrestrained cables or other parts of the device could cause injury when propelled by the high speed wind blast.

4.1.9.2 The device shall not restrict the blood circulation nor cause irritation or pain to the subject during a four-(4) hour flight containing frequent high G maneuvers (maximum 10G).

4.1.10 Calibration: The device shall be calibrated using standard electronic test equipment or special equipment supplied by the contractor. If the device must be adjusted for subject variation (skin pigmentation or transmissivity), this adjustment must be maintained when power is turned off. This adjustment shall not require more than 5 minutes to complete. If an adjustment is required after power is turned on, it shall be completed onboard the aircraft with portable equipment in less than one minute.

4.1.11 Reliability and maintainability: The study shall specifically include considerations of reliability and maintainability (R&M). R&M studies will be based upon sound, practical engineering judgement, experience and available data. No reliability testing program needs to be undertaken as part of this study or evaluation. An evaluation of the potential reliability/maintainability of the equipment as compared with existing devices performing a like function shall be made and predictions of the estimated mean-time-to-failure of the equipment shall be included in the final report. The evaluation shall be sufficient to afford a basis for determining realistic and meaningful reliability/maintainability requirements for the equipment.

4.2 In Phase I (approximately 3 months in length) the contractor shall prepare the initial design and provide a written report describing the design. A preliminary design review will be held at the contractor's facility after receipt of the report. USAFSAM personnel must review the intended design approach before the contract may proceed beyond Phase I.

4.2.1 In Phase II (approximately 8 months in length) the contractor shall assemble, bench-test and deliver the bread-board device. The contractor shall also prepare a test plan that may be used to evaluate the prototype device. The device shall be delivered to USAFSAM for validation testing in conjunction with existing components of the inflight monitor system. USAFSAM will furnish facilities and support personnel essential to the conduct of each test. The device performance will be evaluated using the Hewlett-Packard Model 47201A ear oximeter as the standard. The test will be completed 20 working days after receipt of device. The contractor shall submit an interim technical report at or before the delivery of the bread-board device. The report shall summarize the design and performance data.

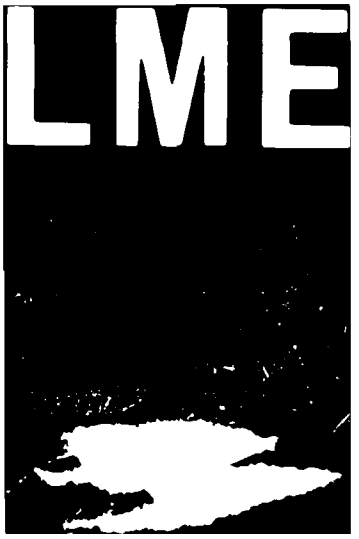
4.2.2 A critical design review (CDR) shall be held at the contractor's facility approximately one week after the completion of the breadboard tests. USAFSAM personnel must review the final design approach before the contract may proceed beyond Phase II.

4.2.3 In Phase III (approximately 6 months in length) the contractor shall use concepts and materials approved at the CDR to assemble, bench-test and deliver an end-product device meeting all of the performance

specifications of 4.1. Delivery of the functional device and necessary technical information in the form of a final report will end Phase III and fulfill all contract requirements.

SECTION G - PRESERVATION/PACKAGING/PACKING

The contractor shall provide preservation, packaging and packing which shall afford adequate protection against physical damage during shipment for all deliverable items in accordance with LEVEL C of MIL-STD-794.


LME