USAARL Report No. 92-6

Test and Evaluation Report of the Physio Control Blood Pressure Monitor Model LIFESTAT® 200

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September 1991

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United States Army Aeromedical Research Laboratory
Fort Rucker, Alabama 36362-5292

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UNCLASSIFIED
SECURITY CLASSIFICATION OF THIS PAGE

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1a. REPORT SECURITY CLASSIFICATION
UNCLASSIFIED

1b. RESTRICTIVE MARKINGS

2a. SECURITY CLASSIFICATION AUTHORITY

2b. DECLASSIFICATION / DOWNGRADING SCHEDULE

3. DISTRIBUTION / AVAILABILITY OF REPORT
Approved for public release, distribution unlimited

4. PERFORMING ORGANIZATION REPORT NUMBER(S)
USAARL Report No. 92-6

5. MONITORING ORGANIZATION REPORT NUMBER(S)

6a. NAME OF PERFORMING ORGANIZATION
U.S. Army Aeromedical Research Laboratory

6b. OFFICE SYMBOL (If applicable)
SGRD-UAD-IE

7a. NAME OF MONITORING ORGANIZATION
U.S. Army Medical Research and Development Command

6c. ADDRESS (City, State, and ZIP Code)
P.O. Box 577
Fort Rucker, AL 36362-5292

7b. ADDRESS (City, State, and ZIP Code)
Fort Detrick
Frederick, MD 21702-5012

8a. NAME OF FUNDING / SPONSORING ORGANIZATION

8b. OFFICE SYMBOL (If applicable)

9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER
Partial effort under contract No. DAMD 17-86-C-6215

8c. ADDRESS (City, State, and ZIP Code)

10. SOURCE OF FUNDING NUMBERS

PROGRAM ELEMENT NO.	PROJECT NO.	TASK NO.	WORK UNIT ACCESSION NO.
0603807A	3M463807D836	LC	201

11. TITLE (Include Security Classification)
Test and Evaluation Report of the Physio Control Blood Pressure Monitor Model LIFESTAT® 200

12. PERSONAL AUTHOR(S)
Jeffrey D. Hann, Joseph R. Licina, Bill Olding, Martin Quattlebaum

13a. TYPE OF REPORT
Final

13b. TIME COVERED
FROM _____ TO _____

14. DATE OF REPORT (Year, Month, Day)
1991 September

15. PAGE COUNT
63

16. SUPPLEMENTARY NOTATION

17. COSATI CODES		
FIELD	GROUP	SUB-GROUP

18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number)
Electromagnetic compatibility, test and evaluation, aeromedical equipment

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

The Physio Control Blood Pressure Monitor Model LIFESTAT® 200 was tested for electromagnetic interference/compatibility in the UH-60A helicopter under the U.S. Army Test and Evaluation of Aeromedical Equipment program. The tests were conducted using current military and industrial standards and procedures for electromagnetic interference/compatibility and human factors. The Physio Control Blood Pressure Monitor Model LIFESTAT® 200 was found to be compatible with U.S. Army medical evacuation UH-60A Blackhawk.

20. DISTRIBUTION / AVAILABILITY OF ABSTRACT
☒ UNCLASSIFIED/UNLIMITED ☐ SAME AS RPT ☐ DTIC USERS

21. ABSTRACT SECURITY CLASSIFICATION
UNCLASSIFIED

22a. NAME OF RESPONSIBLE INDIVIDUAL
Chief, Scientific Information Center

22b. TELEPHONE (Include Area Code)
(205) 255-6907

22c. OFFICE SYMBOL
SGRD-UAX-SI

DD Form 1473, JUN 86 *Previous editions are obsolete*

SECURITY CLASSIFICATION OF THIS PAGE
UNCLASSIFIED

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Section 1. Executive digest

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards (MIL-STD) and collective professional expertise to test and evaluate selected medical equipment proposed for use aboard Army aircraft. Equipment meeting these standards ensures the safety of the crew, patients, and aircraft by eliminating risks due to: (1) Interference by the medical equipment with aircraft systems/subsystems operation, (2) the aircraft system's interference with the operation of the medical equipment, (3) the medical equipment's susceptibility to environmental exposure, or (4) physical and/or functional incompatibility while in use on board selected rotary-wing aircraft. This program tests both developmental and nondevelopmental (off the shelf) medical equipment destined for use aboard Army medical evacuation aircraft.

1.1 TEST OBJECTIVES

1.1.1 To determine if the medical equipment is complete and operational per the manufacturer's operating instructions.

1.1.2 To ensure the electrical safety of the medical equipment.

1.1.3 To ensure the equipment will function as designed throughout the rated battery operation time.

1.1.4 To ensure the safety of the operator, the patient, and the aircrew.

1.1.5 To assess design considerations which potentially could contribute to an operator error.

1.1.6 To determine if the medical equipment can function as designed in a low pressure environment.

1.1.7 To determine the ability of the medical equipment to withstand the vibrational stresses expected in a rotary-wing flight environment without degradation or malfunction.

1.1.8 To determine the ability of the medical equipment to be stored and operated in a high temperature environment.

1.1.9 To determine the ability of the medical equipment to be stored and operated in a low temperature environment.

1.1.10 To determine the ability of the medical equipment to operate satisfactorily for short periods during exposure to high humidity conditions.

1.1.11 To assess the levels of electromagnetic emissions produced by the medical equipment within selected frequency ranges.

1.1.12 To assess the minimum electromagnetic susceptibility levels of the medical equipment within selected frequency ranges.

1.1.13 To assess the physical and/or functional compatibility of the medical equipment while in use on board the aircraft.

1.1.14 To assess the electromagnetic interference (EMI) and electromagnetic compatibility (EMC) characteristics of the medical equipment with the host aircraft and its installed systems.

1.2 TESTING AUTHORITY

Research and Technology Work Unit Summary, dated 5 October 1989. Project number 3M463807D836, titled, Army Program for Testing and Evaluation of Equipment for Aeromedical Operations.

1.3 SCOPE

1.3.1 This test was conducted at the United States Army Aeromedical Research Laboratory (USAARL), Cairns Army Airfield (CAAF), and designated test flight areas in and around Fort Rucker, Alabama.

1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was configured with the Physio Control blood pressure monitor, model LIFESTAT® 200 and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 2.5 flight hours.

1.3.3 Laboratory testing was accomplished at USAARL using government furnished equipment (GFE) by Universal Energy Systems, Inc. (UES), under contract No. DAMD 17-86-C-6215.

1.3.4 Prior to flight testing, the following tests were accomplished: Acceptance inspection, equipment training, electromagnetic compatibility, human factors and safety, environmental compatibility, and in-flight compatibility.

1.3.5 An airworthiness release (AWR) dated 12 July 1990 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the LIFESTAT® 200.

1.4 MATERIAL DESCRIPTION

The Physio Control LIFESTAT® 200* is a portable blood pressure (BP) and pulse measurement device. It is used for noninvasive determination of systolic, diastolic and mean arterial pressures, and pulse rate. The unit is capable of taking manually initiated or automatic measurements at timed intervals of 1, 2, 3, 5, 10, 15, or 30 minutes. The operation is controlled by a microprocessor-based system. The light emitting diode (LED) displays present the systolic, diastolic, and mean pressures in addition to the pulse rate, cycle time, elapsed time, and alarm settings. Membrane switches on the front panel select manual or automatic mode, cuff inflation or deflation, alarm settings, and alarm silence. The paper strip chart recorder is controlled by two membrane switches. The strip chart records systolic, diastolic and mean pressures and pulse rate, patient identification, date, and time for each measurement. The instrument is powered by either internal battery or AC line power which is selected by a rocker switch on the front panel. The battery is a rechargeable, sealed lead-acid type. The front panel of the instrument contains the LED displays, membrane switch controls, chart recorder output, and the power switch. A Luer fitting is provided on the side of the unit to connect the blood pressure cuff. A volume control, AC power input, and "SYSTEMS OUTPUT" connector are provided on the rear panel.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery Life Evaluation: The LIFESTAT® 200 was set to take automatic measurements at 2-minute intervals with the recorder on. In this mode, the BP monitor operated for an average of 39 minutes from a fully charged battery. This value agrees with the operator manual specification of 30 minutes operating time in this mode.

1.5.1.2 Electrical Safety Evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the LIFESTAT® 200. The limits for currents and resistances were in accordance with (IAW) the National Association of Fire Prevention (NAFP) standards.

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* See manufacturer's list

1.5.1.3 Human Factors Evaluation: The LIFESTAT® 200 was found to be satisfactory in all major categories of the evaluation criteria with one exception. There are no externally accessible fuses, circuit breakers, or calibration points. The "T" adaptor, which is used during calibration checks, must be supplied by the user.

1.5.1.4 Environmental Tests: The LIFESTAT® 200 can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of the environmental testing. The requirements for environmental tests are established in MIL-STD-810D, methods 500.2 (altitude), 514.3 (vibration), 501.2 (high temperature), 502.2 (low temperature), and 507.2 (humidity).

1.5.1.5 Radiated Emissions Tests (RE02): The LIFESTAT® 200 may be unsatisfactory for use in certain EMI sensitive environments. Narrowband (NB) and broadband (BB) radiated emissions were detected in the test frequency ranges. Some narrowband and broadband emissions exceeded the test limits. Emission limits are set forth in MIL-STD-461A, Notice 4.

1.5.1.6 Radiated Susceptibility Test (RS03): The LIFESTAT® 200 was not found to be susceptible to radio frequency interference in the testing range and magnitude.

1.5.1.7 Conducted Emissions Test (CE01, CE02, and CE04): Narrowband signals were detected in the frequency range 13 to 53 MHz, with magnitudes 0.2 to 13.3 dB over specification limits. Broadband emissions were detected in the frequency range 15.6 to 53 MHz, with magnitudes 3 to 4.5 dB over specification limits.

1.5.1.8 Conducted Susceptibility Test (CS02 and CS06): Noise generated on the power lines by the LifeStat® 200 was greater than the test signal level. The LifeStat® 200 was not affected by the presence of the test spikes on its power lines.

1.5.2 In-flight testing

1.5.2.1 During the in-flight human factors evaluation, the LIFESTAT® 200 was found to be satisfactory in all categories of the evaluation criteria with one exception. There are no externally accessible fuses, circuit breakers, or calibration points.

1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the LIFESTAT® 200 in any of the prescribed flight test modes.

1.5.2.3 The LIFESTAT® 200 was not affected by the aircraft and its subsystems during the in-flight testing.

1.6 CONCLUSIONS

Based on the results of laboratory and in-flight testing, the LIFESTAT® 200 was found to be compatible with the U.S. Army medical evacuation UH-60A Blackhawk with the subsystems listed in paragraph 3.2.2.

Section 2. Subtests

2.1 INITIAL INSPECTION

2.1.1 Objective

To determine if the LIFESTAT® 200 is complete and operational for testing per the manufacturer's operating instructions.

2.1.2 Criteria

2.1.2.1 The physical inventory is conducted solely for investigation and documentation.

2.1.2.2 The LIFESTAT® 200 will display consistent and accurate measurements as an acceptable performance test.

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the LIFESTAT® 200 was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the LIFESTAT® 200 was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

2.1.4 Test findings

2.1.4.1 The LIFESTAT® 200 was inventoried and found to be complete.

2.1.4.2 The LIFESTAT® 200 operated as prescribed in the manufacturer's operating manual P/N 802611-02. Criteria met.

2.2 BATTERY LIFE EVALUATION (Laboratory)

2.2.1 Objective

To ensure the equipment will function as designed throughout the rated battery operation time.

2.2.2 Criterion

Verify manufacturer's specified full power internal battery life expectancy of 30 minutes during continuous operation in the 2-minute cycle mode, with the recorder on, and blood pressure measurements taken automatically at 2-minute intervals.

2.2.3 Test procedure

2.2.3.1 Charging and operation cycles were conducted in ambient room conditions.

2.2.3.2 The LIFESTAT® 200 was operated continuously using its fully charged internal battery in the 2-minute cycle mode until a low battery indication occurred. The depletion time was noted and the battery was recharged. This procedure was repeated three times.

2.2.4 Test findings

The test was conducted using the fully charged internal battery. The average operating time in testing was 39 minutes at room temperature. This exceeds manufacturer specification of 30 minutes. Criterion met.

2.3 ELECTRICAL SAFETY EVALUATION

2.3.1 Objective

To ensure the electrical safety, by evaluation of case-to-ground resistance and case-to-ground current leakage, of the LIFESTAT® 200.

2.3.2 Criterion

The LIFESTAT® 200 shall meet the standards established in National Association of Fire Prevention (NAFP) 99 for electrical safety of medical equipment.

2.3.3 Test procedure

Measurements in the electrical safety evaluation were made, with a Neurodyne-Dempsey model 431F electrical safety analyzer* IAW the procedures described in Technical Bulletin (TB) Number 38-750-2. Case-to-ground resistance and various case-to-ground leakage currents were measured. Leakage currents were measured using a 10 by 20 centimeter aluminum foil sheet taped flush to the equipment case. Checks were made for safety concerns such as case integrity, breaks in power cord insulation, and connectors.

2.3.4 Test findings

Grounding conductor resistance was 53.3 milliohms and maximum case leakage current was 12.2 microamperes. These measurements are below the limits specified in NAFP 99. Criterion met.

2.4 HUMAN FACTORS EVALUATION (Laboratory)

2.4.1 Objectives

2.4.1.1 To assure the safety of the operator, the potential patient, and the aircrew.

2.4.1.2 To assess the design considerations which could potentially contribute to an operator error.

2.4.2 Criterion

The LIFESTAT® 200 must be rated satisfactory in all major categories of the evaluation. These include: (1) visual displays, (2) controls, (3) maintainability, (4) conductors, (5) fasteners, (6) test points, (7) test equipment, (8) fuses and circuit breakers, (9) labels and coding, and (10) safety.

2.4.3 Test procedure

2.4.3.1 The evaluation was conducted in a laboratory under fluorescent lighting and ambient room conditions.

2.4.3.2 The LIFESTAT® 200 was operated according to prescribed instructions through its full range of functions.

2.4.4 Test finding

The LIFESTAT® 200 was found to be satisfactory in all of the evaluation criteria with one exception. There are no externally accessible fuses, circuit breakers, or calibration points. Criterion partially met.

2.5 ALTITUDE (LOW PRESSURE) TEST [IAW MIL-STD-810D, METHOD 500.2]

2.5.1 Objective

To determine if the LIFESTAT® 200 can function as designed in a low pressure environment.

2.5.2 Criterion

The LIFESTAT® 200 will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.

2.5.3 Test procedure

2.5.3.1 A pretest performance check was conducted to ensure proper operation of the LIFESTAT® 200.

2.5.3.2 The altitude test was performed in a Tenney Engineering model 64S altitude chamber. This test is based on MIL-STD-810D, Method 500.2. The LIFESTAT® 200 was turned on in the standby mode and placed on the floor of the chamber. Chamber pressure was decreased to 420 mmHg (15,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to ambient conditions (760 mm Hg) over a 10-minute period. There are no provisions for the control of temperature or humidity inside this chamber.

2.5.3.3 A posttest performance check was conducted to ensure proper operation of the LIFESTAT® 200 after the exposure to low pressure.

2.5.4 Test findings

2.5.4.1 The pretest performance check met criterion 2.1.2.2.

2.5.4.2 No failures in the performance of the LIFESTAT® 200 were noted before, during, or after the altitude test. Criterion met.

2.5.4.3 The posttest performance check met criterion 2.1.2.2.

2.6 VIBRATION TEST [IAW MIL-STD-810D, METHOD 514.3]

2.6.1 Objective

To determine the ability of the LIFESTAT® 200 to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

The LIFESTAT® 200 will remain operational and be able to display consistent and accurate measurements while exposed to vibrational stresses.

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the LIFESTAT® 200.

2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TA115-40/CSTA vibration test system*. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are derived from measurements taken on the floor under the copilot's seat in a UH-1 helicopter traveling at 120 knots. The reference spectrum breakpoints are from MIL-STD-810D, Method 514.3; reference spectrum levels are based on field measurements with a conservatism factor of 1.5. Independent tests were conducted in the X, Y, and Z axes.

Z-axis

duration: 60 minutes
broadband intensity: 0.4506 G_{rms}
random vibration: initial slope : 99.00 dB/Hz
5 Hz level: 0.00006210 $G_{sqr/Hz}$
100 Hz level: 0.0006210 $G_{sqr/Hz}$
300 Hz level: 0.0006210 $G_{sqr/Hz}$
500 Hz level: 0.00006210 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .5450 G_{pk} at 11.25 Hz
.1690 G_{pk} at 22.50 Hz
.1200 G_{pk} at 33.75 Hz
.0310 G_{pk} at 45.00 Hz
.0530 G_{pk} at 56.25 Hz

X and Y axes

duration: 60 minutes each
broadband intensity: 0.3099 G_{rms}
random vibration: initial slope: 99.00 dB/oct
5 Hz level: 0.00002920 $G_{sqr/Hz}$
100 Hz level: 0.0002920 $G_{sqr/Hz}$
300 Hz level: 0.0002920 $G_{sqr/Hz}$
500 Hz level: 0.00002920 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .3200 G_{pk} at 11.25 Hz
.0670 G_{pk} at 22.50 Hz
.0950 G_{pk} at 33.75 Hz
.0350 G_{pk} at 45.00 Hz
.0770 G_{pk} at 56.25 Hz

The LIFESTAT® 200 was strapped to the vibration table fixture, and its performance was evaluated before, during, and after exposure to vibration.

2.6.3.3 A posttest performance check was conducted to ensure proper operation of the LIFESTAT® 200.

2.6.4 Test findings

2.6.4.1 The pretest performance check met criterion 2.1.2.2.

2.6.4.2 No failures in the performance of the LIFESTAT® 200 occurred before, during, or after exposure to vibration. Criterion met.

2.6.4.3 The posttest performance check met criterion 2.1.2.2.

2.7 HIGH TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 501.2]

2.7.1 Objective

To determine the ability of the LIFESTAT® 200 to be stored and operated in a high temperature environment.

2.7.2 Criteria

2.7.2.1 The LIFESTAT® 200 will display consistent and accurate measurements during the high temperature operation check.

2.7.2.2 The LIFESTAT® 200 will display consistent and accurate measurements after the high temperature storage cycle.

2.7.3 Test procedure

2.7.3.1 A pretest performance check was conducted to ensure proper operation of the LIFESTAT® 200.

2.7.3.2 The high temperature test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber. This test is based on MIL-STD-810D, Method 501.2. For the high temperature operation test, the LIFESTAT® 200 was turned on in the standby mode and placed on the floor of the environmental chamber. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent RH within 15 minutes. The environmental control system is capable of regulating temperature within ±2°C and humidity within ±5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the LIFESTAT® 200 was allowed to return to ambient conditions over a 30-minute period.

2.7.3.3 A posttest performance check was conducted to ensure proper operation of the LIFESTAT® 200.

2.7.3.4 The LIFESTAT® 200 was stored (not operated) at temperatures of 63°C for 1 hour, 71°C for 4 hours, then again at 63°C for 1 hour. The chamber and LIFESTAT® 200 then were returned to ambient conditions over a 30-minute period.

2.7.3.5 A post storage performance check was conducted to ensure proper performance of the LIFESTAT® 200.

2.7.4 Test findings

2.7.4.1 The pretest performance check met criterion 2.1.2.2.

2.7.4.2 No operational failures occurred during the high temperature test. Criterion met.

2.7.4.3 The posttest performance check met criterion 2.1.2.2.

2.7.4.4 The LIFESTAT® 200 functioned properly after the high temperature storage test. Criterion met.

2.8 LOW TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 502.2]

2.8.1 Objective

To determine the ability of the LIFESTAT® 200 to be stored and operated in a low temperature environment.

2.8.2 Criteria

2.8.2.1 The LIFESTAT® 200 will display consistent and accurate measurements during the low temperature operation check.

2.8.2.2 The LIFESTAT® 200 will display consistent and accurate measurements after the low temperature storage cycle.

2.8.3 Test procedure

2.8.3.1 A pretest performance check was conducted to ensure proper operation of the LIFESTAT® 200.

2.8.3.2 The LIFESTAT® 200 was placed on the floor of the environmental chamber and the temperature was lowered to 0°C within 25 minutes. The environmental control system is capable of regulating temperature within 2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant for 2 hours. The chamber door was opened briefly every 30 minutes to minimize the change in chamber conditions and

a performance check was conducted. The chamber temperature then was raised to ambient temperature within a 30-minute period.

2.8.3.3 A posttest performance check was conducted to ensure proper operation of the LIFESTAT® 200.

2.8.3.4 The LIFESTAT® 200 was "stored" in a nonoperational mode. The LIFESTAT® 200 was placed on the floor of the environmental test chamber and the temperature was lowered to -46°C for 6 hours. The chamber then was raised to ambient temperature over a 30-minute period.

2.8.3.5 A post storage performance check was conducted to ensure proper operation of the LIFESTAT® 200.

2.8.4 Test findings

2.8.4.1 The pretest performance check met criterion 2.1.2.2.

2.8.4.2 No operational failures occurred during the low temperature test. Criterion met.

2.8.4.3 The posttest performance check met criterion 2.1.2.2.

2.8.4.4 The LIFESTAT® 200 functioned properly after the low temperature storage test. Criterion met.

2.9 HUMIDITY TEST [IAW MIL-STD-810D, METHOD 507.2]

2.9.1 Objective

To determine the ability of the LIFESTAT® 200 to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

The LIFESTAT® 200 will display consistent and accurate measurements while exposed to a high humidity environment.

2.9.3 Test procedure

2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the LIFESTAT® 200.

2.9.3.2 The humidity test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 507.2. For the humidity test, the LIFESTAT® 200 was placed ready for operation on the floor of the environmental chamber. The chamber temperature was

raised to a temperature of 30°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within ±2°C and humidity within ±5 percent RH. At 45-minute intervals the performance of the blood pressure monitor was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and the LIFESTAT® 200 were returned to ambient conditions before the posttest performance validation check was conducted.

2.9.3.3 A posttest performance check was conducted to ensure the proper operation of the LIFESTAT® 200.

2.9.4 Test findings

2.9.4.1 The pretest performance check met criterion 2.1.2.2.

2.9.4.2 No failures were noted in the LIFESTAT® 200 performance checks conducted during the exposure to the high humidity environment. Criterion met.

2.9.4.3 The posttest performance check met criterion 2.1.2.2.

2.10 ELECTROMAGNETIC CHARACTERISTICS TEST [IAW MIL-STD-461A, Notice 4, MIL-STD-462, Notice 3, and MIL-STD-704C]

2.10.1 Objectives

2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the LIFESTAT® 200 in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the LIFESTAT® 200 within the 10 kHz to 10 GHz electric field.

2.10.1.3 To assess the maximum levels of conducted electromagnetic emissions produced by the LIFESTAT® 200 in the 10 kHz to 50 MHz frequency ranges.

2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the LIFESTAT® 200 within the range of 50 kHz to 400 MHz and power spikes.

2.10.2 Criteria

2.10.2.1 The LIFESTAT® 200 will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.

2.10.2.2 The LIFESTAT® 200 will not malfunction when it is subjected to radiated emissions as specified in MIL-STD-461A, Notice 4, paragraph 6.20.

2.10.2.3 The LIFESTAT® 200 shall not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.

2.10.2.4 The LIFESTAT® 200 shall not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.

2.10.3 Test procedure

2.10.3.1 The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method RE02. The LIFESTAT® 200 was positioned on a wooden test stand inside the EMI chamber, 1 meter away from the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to EMI receivers. The LIFESTAT® 200 was connected through an extended tube to a cuff outside the chamber. The cuff was placed around a test engineer's arm while the LIFESTAT® 200 took blood pressure measurements at 2-minute intervals. While the LIFESTAT® 200 was operating, the frequency spectrum (14 kHz to 12.4 GHz) was scanned for emissions. The LIFESTAT® 200 was operated with both AC and battery power.

2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The LIFESTAT® 200 was positioned on a wooden test stand inside the EMI chamber 1 meter away from the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to radio frequency (RF) transmitters. The LIFESTAT® 200 was connected through an extended tube to a cuff outside the chamber. The cuff was placed around a test engineer's arm while the LIFESTAT® 200 took blood pressure measurements at 2-minute intervals. While the LIFESTAT® 200 was operating, it was monitored for faulty operation during exposures to fields of 1 V/m from 10 kHz to 2 MHz, and 5 V/m from 2 to 30 MHz, 10 V/m from 30 MHz to 2 GHz, and 5V/m from 2 to 10 GHz. The LIFESTAT® 200 was operated with AC power only.

2.10.3.3 The conducted emissions tests were performed according to MIL-STD-462, Notice 3, Methods CE02 and CE04. The LIFESTAT® 200 was placed on a grounded, copper covered workbench. The top of the workbench was 1 meter from floor level, 1.37 meters long and 0.81 meters wide. Power was supplied via a pair of line impedance stabilization networks (LISN's) and a test jig. The test jig is a wooden tray with two power receptacles and two slots to hold current probes in place around power supply conductors. While the LIFESTAT® 200 was operating, the frequency range

(10 kHz to 50 MHz) was scanned for emissions conducted in the power cable from the LIFESTAT® 200.

2.10.3.4 The conducted susceptibility spike test was performed according to MIL-STD-462, Notice 3, Method CS06, on a chemical resistant counter top. Power was supplied via a customized metal connection box. The connection box has two power receptacles and four banana jacks on its front panel. Connections to the individual power lines are made in series through the banana jacks. Transient spikes of 100 volts, 10 microseconds were generated with a Solar Electronics model 8282-1 transient pulse generator* and induced onto the power leads at the connection box banana jacks. The spikes were monitored with a Tektronix 2235 oscilloscope* connected to a power receptacle on the connection box. The LIFESTAT® 200 was plugged into the other receptacle on the connection box and placed in operation. It was observed for correct operation and visual displays while it was subjected to the power line spikes.

2.10.3.5 The conducted susceptibility test was performed according to MIL-STD-462, Notice 3, Method CS02. The LIFESTAT® 200 was placed on a grounded, copper covered workbench. Radio frequency interference was induced on the power leads and measured at the LIFESTAT® 200 power cable. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the LIFESTAT® 200 was operated. It was observed for correct operation and visual displays while it was subjected to the radio interference on the power leads. Each frequency was held for 15 seconds.

2.10.4 Test findings

2.10.4.1 During the radiated emissions test, emissions which exceeded specification limits of MIL-STD-461, Notice 4, were detected in the narrowband frequency range 2 to 255 MHz, with magnitudes 0.3 dB to 41 dB over the specification limits, and in the broadband frequency range 15 to 45 MHz, with magnitudes 1.8 dB to 21.3 dB over the specification limits. Criterion partially met.

2.10.4.2 The LIFESTAT® 200 was not found to be susceptible to radio frequency interference in the testing range and magnitude. Criterion met.

2.10.4.3 Narrowband signals were detected in the frequency range 13 to 53 MHz, with magnitudes 0.2 to 13.3 dB over specification limits. Broadband emissions were detected in the frequency range 15.6 to 53 MHz, with magnitudes 3 to 4.5 dB over specification limits. Criterion partially met.

2.10.4.4 Noise generated on the powerlines by the LifeStat® 200 was greater than the test signal level. The LifeStat® 200 was not susceptible to test spikes during the conducted susceptibility tests. Criterion partially met.

2.11 IN-FLIGHT HUMAN FACTORS EVALUATION

2.11.1 Objective

To assess the physical and/or functional compatibility of the LIFESTAT® 200 while in use onboard the aircraft.

2.11.2 Criterion

The flight surgeon will be able to operate the LIFESTAT® 200 without physical or functional restrictions aboard the aircraft. Major areas of concern include: Proper operation, visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.11.3 Test procedure

2.11.3.1 A human factors evaluation was performed IAW MIL-STD-1472D, AAMI Human Factors Engineering Guidelines, and UL-544 to ensure the compatibility of the LIFESTAT® 200 and the in-flight environment. The flight surgeon conducted the test wearing a flight suit, flight gloves, and an SPH-4 flight helmet. An evaluation of the compatibility with the nuclear, biological, and chemical (NBC) protective equipment was not conducted. Due to restrictions of the AWR, testing was conducted during daylight hours only.

2.11.3.2 The LIFESTAT® 200 was placed on the floor of the aircraft next to the bottom pan of the litter carousel which was configured for four patients. The litter carousel was flown in the "load" position (perpendicular to the long axis of the helicopter). The LIFESTAT® 200 was tested with the cuff placed on the right arm of a simulated patient laying in the bottom pan of the litter carousel. The LIFESTAT® 200 was tested in both the defibrillation and monitoring modes in the flight scenarios noted in section 3.2).

2.11.4 Test findings

During the in-flight human factors evaluation, the LIFESTAT® 200 was found to be satisfactory in all but one of the categories of the evaluation criteria. A deficiency was noted in the lack of externally accessible fuses, circuit breakers, or calibration points as was noted in the laboratory evaluation (paragraph 1.5.1.3). The LED display was readable in all but direct sunlight which was not considered a problem in using the device. Another concern is the inability to vary the display intensity which could present a problem if used with night vision devices. Criterion partially met.

2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS TEST

2.12.1 Objective

To assess the EMI/EMC characteristics of the LIFESTAT® 200 with the host aircraft and its installed systems.

2.12.2 Criteria

2.12.2.1 The LIFESTAT® 200 will not radiate EMI to disrupt or interfere with other equipment or systems aboard the aircraft.

2.12.2.2 The aircraft will not radiate EMI to disrupt or interfere with the LIFESTAT® 200's operation.

2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the LIFESTAT® 200 and the aircraft operating as source and victim. The LIFESTAT® 200 and applicable aircraft instruments and systems were monitored for unusual operation, readings, surges, or power anomalies for each checklist item (see pages 3-5 through 3-8).

2.12.4 Test findings

2.12.4.1 There were no adverse instances of EMI/EMC noted with the LIFESTAT® 200 acting as either the source or victim. Criterion met.

2.12.4.2 There were no adverse instances of EMI/EMC noted with the aircraft acting as either the source or victim. Criterion met.

SECTION 3. Supporting documentation

3.1 DETAILED TEST INFORMATION

3.1.1 General information

3.1.1.1 LIFESTAT® 200 testing is not considered a major action significantly affecting the quality of the human environment and therefore qualifies for categorical exclusion A-28, appendix A, AR 200-1.

3.1.1.2 A safety pilot will be designated for each flight. Flight operations will be conducted IAW the aircraft operator's manual, appropriate aircrew training manuals, and test item technical data.

3.1.2 Material description

3.1.2.1 The Physio Control LIFESTAT® 200 is a portable blood pressure and pulse measurement device. It is used for noninvasive determination of systolic, diastolic, and mean arterial pressures, and pulse rate. The unit is capable of taking manually initiated or automatic measurements at timed intervals of 1, 2, 3, 5, 10, 15, or 30 minutes. The operation is controlled by a microprocessor-based system. LED displays present the systolic, diastolic, and mean pressures in addition to the pulse rate, cycle time, elapsed time, and alarm settings. Membrane switches on the front panel select manual or automatic mode, cuff inflation or deflation, alarm settings, and alarm silence. The paper strip chart recorder is controlled by two membrane switches. The strip chart records systolic, diastolic, and mean pressures and pulse rate, patient identification, date, and time for each measurement. The instrument is powered by either internal battery or AC line power which is selected by a rocker switch on the front panel. The battery is a rechargeable, sealed lead-acid type. The front panel of the instrument contains the LED displays, membrane switch controls, chart recorder output, and the power switch. A Luer fitting is provided on the side of the unit to connect the blood pressure cuff. A volume control, AC power input, and "SYSTEMS OUTPUT" connector are provided on the rear panel.

3.1.2.2 Method of Operation: The LIFESTAT® 200's operation is based on the oscillometric technique. Arterial pulsations acting against the inflated cuff are used to determine blood pressure and pulse rate. These pulsations are analyzed by an internal computer which determines systolic, diastolic and mean arterial pressures, and pulse rate. It is able to distinguish between real heart beats and a certain amount of motion artifact. With too much artifact the computer displays "---" rather than

incorrect information. Cuff inflation pressure is user variable to 165 mmHg (LO), or 220 mmHg (HI), or 50 to 290 mmHg (OVERRIDE) in the manual mode. Cuff inflation pressure is user variable to 165 mmHg (LO), or 220 mmHg (HI) in the automatic mode, with timed measurements at 1, 2, 3, 5, 10, 15, and 30-minute intervals.

3.1.2.3 Dimensions: 8.3 x 5.8 x 11.5 in (21.1 x 14.7 x 29.2 cm).

3.1.2.4 Weight: 15 lb (6.8 kg), not including accessories.

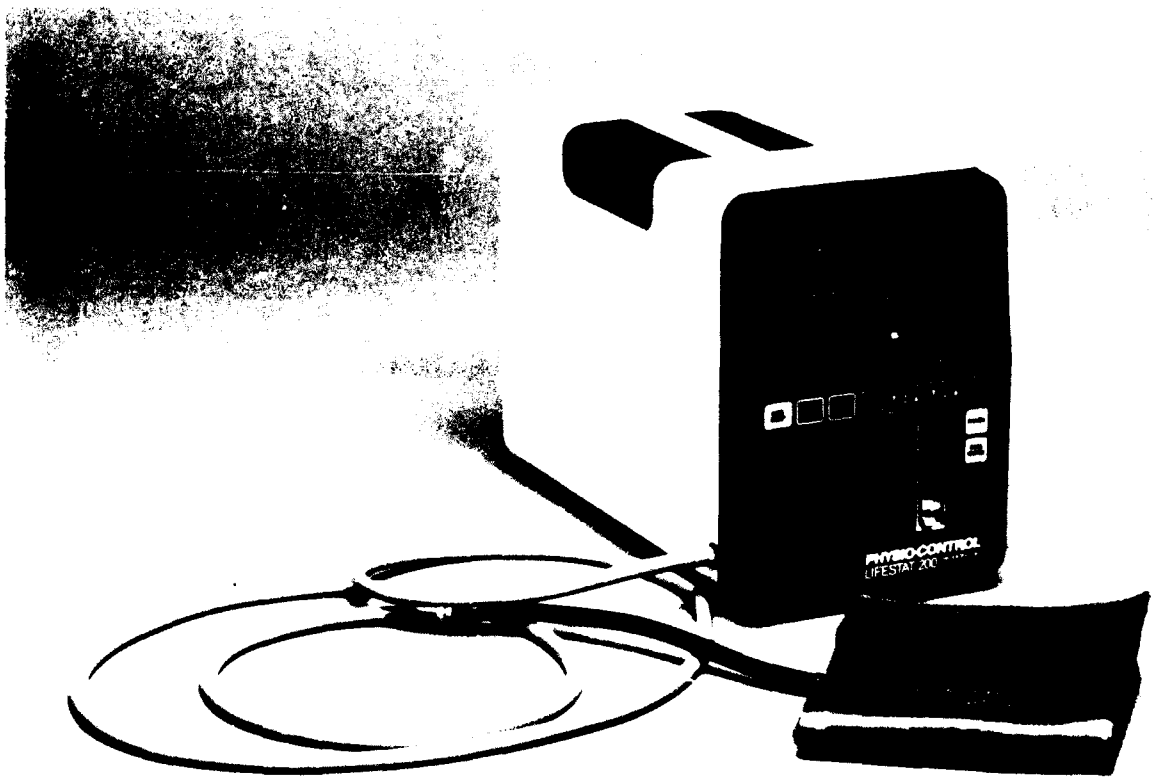
3.1.2.5 Standard accessories: Printer paper, writing pens, pediatric cuff, adult cuff, large adult cuff, thigh cuff, latex extension sets, operating and service manual operating instructions.

3.1.2.6 Power requirements: 90 to 132 VAC, 50 or 60 Hz, 70 watts maximum. Internal battery is a sealed lead-acid type, 9.8 V nominal, 2.5 Ah. Battery capacity is 30 minutes with a 16-hour full charge, in 2-minute cycle using adult cuff, 6 ft tube with printer on. Power cord is type SJTW-A, 16/3C AWG conductor, E58188 VW-1.

3.1.2.7 Environmental considerations: atmospheric pressure, less than 11000 ft; operating temperature, 5 to 45 degrees C; storage temperature, -30 to 65 degrees C; relative humidity, 0 to 95 percent.

3.2 TEST DATA

3.2.1 Photographic Description



3.2.2 Aircraft equipment list

Item No.	Nomenclature
1	Receiver radio -- R-1496A/ARN-89 (automatic direction finder)
2	Displacement gyro -- CN-1314/A
3	Gyro directional -- CN-998/ASN-43
4	Signal data converter -- CV-3338/ASN-128
5	Receiver -- R-2139/ARN-1[illegible]3 (VOR/LOC/MB/GS)
6	Command instrument system processor -- 70600-01038-101
7	SAS amplifier -- 70901-02908-104 (flight control stability augmentation system)
8	Rate gyro -- TRU-2A/A
9	Amplifier, impedance -- AM-4859A/ARN-89
10	Cargo hook -- FE-7590-145
11	Receiver, radar -- RT-1193/ASN-128 (doppler navigation receiver)
12	Barometric altimeter -- AAU-31/A-1
13	Barometric altimeter -- AAU-32A
14	Receiver/transmitter -- RT-1300/ARC-186 (VHF-AM and/or FM radio)
15	UHF-AM radio set -- RT-1518/ARC-164
16	Interphone control -- C6533/ARC (aircraft intercom control)
17	Receiver/transmitter -- RT-1115D/APN-209 (radar altimeter)
18	Indicator altimeter -- ID-1917C/APN-209 (radar altimeter)
19	Control radio set -- C-7392A/ARN-89 (automatic direction finder)
20	Comparator signal data -- CM-482/ARC-186 (comparator for ARC-186)
21	Receiver/transmitter -- RT-1296A/APX-100 (transponder with IFF)
22	Computer display unit -- CP-1252/ASN-128 (doppler navigation system)
23	Compass set controller -- C-8021E/ASN75
24	Magnetic compass - standby -- MS-17983-4

3.2.3 In-flight test data card

DATA CARD FORMAT

GUIDELINE FOR DATA COLLECTION

IN-FLIGHT SUITABILITY TEST OF MEDICAL ITEMS

1. Installation/removal.	Suitable Yes	Suitable No	Comments
a. Weight and balance (DD Form 365-4, Clearance Form F).	X		
b. Space/area allocation.			
(1) Operational requirements.	X		
(2) Storage requirements.	X		
c. Interface connections (safe, positive, secure).	X		
d. Installation/removal (expedient/easily achieved).	X		
e. Mounting/final configuration (functional/stable).	X		

2. Operations and performance.	Suitable Yes	Suitable No	Comments
a. Manufacturer's operating instruction.	X		
b. Medical item operation before aircraft run-up.	X		
c. System interface during aircraft engine run-up and medical item operation (EMI switchology checklist).	X		
(1) Aircraft voltage output.	X		

	Suitable Yes	Suitable No	Comments
(2) Flight control function (UH-60).			
(3) Stabilator function (UH-60).	X		
(4) Radio communication vs medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		
(5) Navigation equipment vs medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) DOPPLER	X		
(6) Radar altimeter operation vs medical item operation.	X		
d. System interface during aircraft hover and medical item operation (EMI switchology checklist).			
(1) Voltage output.	n/a		
(2) Radio communication vs medical item operation.			
(a) FM	X		
(b) UHF	X		
(c) VHF	X		

	Suitable Yes	No	Comments
(3) Navigation equipment operation vs medical item operation.			
(a) Transponder	X		
(b) ADF	X		
(c) VOR	X		
(d) DOPPLER	X		
e. Flight mission profile vs medical item operation (EMI switchology checklist).			
(1) Straight and level (1000 ft MSL for 20 minutes).			
(a) Compatibility of flight mode and medical item operation.	X		
(b) Radio communication vs medical item operation.			
a. FM	X		
b. UHF	X		
c. VHF	X		
(2) NOE (20 minutes). compatibility of flight mode and medical item operation.	X		
(3) FM homing (10 minutes).	X		
(4) DOPPLER navigation vs medical item operation.			
(a) Initialize function.	X		
(b) Fix function.	X		
(c) Update function.	X		

	Suitable Yes	Suitable No	Comments
(5) VOR navigation vs medical item operation.	X		
(6) ILS approach vs medical item operation.	X		
f. Medical item operation after engine shutdown (external power source).	X		
g. Restrictions to the medical item's use (i.e., electrical connectors).	X		
h. Deviations from the laboratory test results.			
(1) Electrical/ electronic.		None	
(2) Mechanical environment.		None	
(3) Human factors (user interface, controls, markings, lighting, egress).		None	
(4) Safety.		None	

3. Deviations from the in-flight test protocol.

a. The VOR navigation portion of the in-flight test conducted at 2000 feet MSL due to air traffic control clearance.

3.2.4 EMI switchology checklist

EMI SWITCHOLOGY CHECKLIST UH-60 AIRCRAFT

IN-FLIGHT SUITABILITY OF MEDICAL ITEMS

ENG INSTRUMENTS/CDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Fuel quantity	X			
Fuel indicator test	X			
XMSN oil temperature	X			
XMSN oil pressure	X			
#1 engine oil temperature	X			
#2 engine oil temperature	X			
#1 engine oil pressure	X			
#2 engine oil pressure	X			
#1 TGT	X			
#2 TGT	X			
#1 Ng speed	X			
#2 Ng speed	X			
CDU digits on/off	X			
CDU instruments dim	X			

ENG INSTRUMENTS/PLT PDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

ENG INSTRUMENTS/COPLT PDU	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 engine RPM	X			
#2 engine RPM	X			
Rotor RPM	X			
#1 torque	X			
#2 torque	X			

ENG CONTROLS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
#1 overspeed	X			
#2 overspeed	X			
RPM switch	X			
#1 engine anti-ice	X			
#2 engine anti-ice	X			
#1 inlet anti-ice	X			
#2 inlet anti-ice	X			

RADIO EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
ICS, C-6533 ARC	X			
VHF-FM, ARC-186/115	X			
VHF-AM, ARC-186/115	X			
UHF-AM, ARC-164(V)	X			
Crypto, KY-28	Not installed			
Radio retransmissions PLN	Not installed			
Transponder, APX-100(V)	X			
KIT-1A/TSEC IFF computer	Not keyed with code			

MISSION EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
RWR, APR-39(V)	Not installed			
IR CM, ALQ-144	Not installed			
Chaff dispenser, M-130	Not installed			
Cargo hook system	X			

HYDRAULIC CONTROL SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Backup hydraulic pump	X			
Servo off 1st stage/PLT	X			
Servo off 2nd stage/PLT	X			
Servo off 1st stage/COPLT	X			
Servo off 2nd stage/COPLT	X			
Hydraulic leak test	X			
Tail servo	X			
Boost servos	X			

FUEL SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Fuel pump switch	X			
Fuel boost pump #1	X			
Fuel boost pump #2	X			
Fuel cont panel ESSS	Not installed			

WARNING SYSTEM	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Low rotor RPM	X			
Master caution	X			
Caution advisory	X			
Fire warning	X			
AFCS	X			
Stabilator	X			
#1 engine out	X			
#2 engine out	X			

NAVIGATION INSTRUMENTS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
ADF	X			
Magnetic compass	X			
CONUS NAV, ARN-123	X			
DOPPLER, ASN-128	X			
Gyro mag compass (PLT)	X			
Gyro mag compass (COPLT)	X			
Compass cont panel, ASN-75	X			
HSI	X			

FLIGHT INSTRUMENTS	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Radar altimeter	X			
Stabilator pos indicator	X			
VSI	X			
CIS mode select	X			
SAS 1	X			
SAS 2	X			
FPS	X			
Trim	X			
Go-around enable	X			
Cyclic trim release	X			
Cyclic stick trim	X			
ALR encoder	X			

FLIGHT INSTRUMENTS (CONT)	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
HSI/VSI mode select (PLT)				
DPLR	X			
VOR/ILS	X			
BACK CRS	X			
FM HOME	X			
TURN RATE	X			
CRS HDG	X			
VERT GYRO	X			
BRG 2	X			
HSI/VSI Mode Select (COPLT)				
DPLR	X			
VOR/ILS	X			
BACK CRS	X			
FM HOME	X			
TURN RATE	X			
CRS HDG	X			
VERT GYRO	X			
BRG 2	X			

MISCELLANEOUS EQUIPMENT	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Blade deice	Not tested			Ambient temperature was out of test limits.
Windshield anti-ice	X			
Pitot heat	X			
Vent blower	X			
Windshield wiper	X			
Heater	X			
APU	X			
Generator #1	X			
Generator #2	X			
Generator APU	X			
Air source heat start	X			
Tail wheel lock	X			
Gyro erect	X			

LIGHTING	No EMI Affect	EMI Affected Gnd	EMI Affected Flt	Explanation
Cockpit utility	X			
Cockpit flood	X			
Cabin dome	X			
Search light	X			
Search light control	X			
Landing light	X			
Flt instr lights (PLT)	X			
Flt instr lights (COPLT)	X			
Nonflight instr lights	X			
Console lights, upper	X			
Console lights, lower	X			
Position lights	X			
Formation lights	X			
Anticollision lights	X			
NVG lighting	X			

3.2.5 Battery life evaluation

Battery Life Evaluation
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: None

Options installed: None

Manufacturer battery life specification: Approximately 30 minutes in 2-minute cycle, recorder on, when fully charged.

Specified battery recharge time: 16 hours to fully charge depleted battery; 2 hours to provide 70 percent of full charge capacity.

Specified mode of operation under battery power: 2-minute cycle mode, in which automatic blood pressure measurements are taken at 2-minute intervals and recorder on.

Overall performance: Pass

Measurements: The unit averaged 39 minutes of operation.

Comments: The unit was operated continuously in the 2-minute cycle mode until a low battery indication occurred. The depletion time was noted and the battery was recharged. This procedure was repeated three times.

3.2.6 Electrical safety test

Electrical Safety Test
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: None

Options installed: None

Date of test: 27 Oct 88

Measurements:

Grounding conductor resistance (milliohms): 53.3

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity	0.1
unit off, ungrounded, normal polarity	11.2
unit off, ungrounded, reverse polarity	12.1
unit on, grounded, normal polarity	0.1
unit on, ungrounded, normal polarity	11.2
unit on, ungrounded, reverse polarity	12.1

MAXIMUM LIMITS:

ground resistance (milliohms):	150
current (microamperes)	
current (grounded, type A unit):	10
current (ungrounded, type A unit):	100
current (grounded, type B unit):	50
current (ungrounded, type B unit):	500

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.7 Human factors evaluation

Human Factors Evaluation
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 0000385
Military item number: None

Options installed: None

Date of test: 27 Oct 88

Item configuration during test: Item prepared for operation, sitting on a countertop.

Checklist for HFE

RESULTS

VISUAL DISPLAYS: Satisfactory

display type, format, content
location of displays
indicator lights
scalar displays
color coding
legends and labels
cathode ray tubes
counters
flags, go/no go, center-null indicators

Comments: None

CONTROLS: Satisfactory

location
characteristics of controls
labeling
control - display relationships

Comments: None

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: Less than 5 minutes.

MAINTAINABILITY: Satisfactory

component location
component characteristics
rests and stands
covers, cases, access doors
handles
lubrication
component mounting
cord storage provisions
external accessibility
internal accessibility
list special tools required
list realistic inspection requirements
list realistic inspection intervals

Comments: No external calibration adjustments

CONDUCTORS: Satisfactory

binding and securing
length
protection
routing
conductor coding
fabrication
connectors

Comments: None

FASTENERS: Satisfactory

access through inspection panel covers
enclosure fasteners
device mounting bolts and fasteners

Comments: None

TEST POINTS: n/a

general
location and mounting
test point labeling and coding

Comments: None

TEST EQUIPMENT: Satisfactory

general
equipment self-test
indicators (list in comments)
controls
positive indication of proper operation

Comments: Test "T" connector not provided with unit

FUSES AND CIRCUIT BREAKERS: Unsatisfactory

external accessibility
easy replacement or reset by operator

Comments: No fuses are externally accessible.

LABELS AND CODING: Satisfactory

placed above controls and displays
near or on the items they identify
not obscured by other equipment components
describe the function of the items they identify
readable from normal operating distance
conspicuous placards adjacent to hazardous items

Comments: None

SAFETY: Satisfactory

manual
materials
fire and explosive protection
operator protection from mechanical hazards
patient protection from mechanical hazards
electrical safety (operator and patient)

Comments: None

3.2.8 Altitude test

Altitude Test
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: None

Options installed: None

Date of test: 25 Oct 88

Item configuration during test: Item turned on in the standby mode, operating on DC (battery) power, sitting on chamber floor.

Performance test criteria: Consistent and accurate displays and measurements

Ambient conditions outside chamber:

Temperature	71 degrees F
Humidity	57 percent RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None (battery)
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	Serial Port

IN-TEST DATA

Time of test start: 0908

POSTTEST DATA

Posttest performance check (complete check of item and accessories):

Time of test end : 1035

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): tested with test and evaluation item 7.

Comments on other data: None

3.2.9 Vibration test

Vibration Test
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: None

Options installed: None

Date of test: 24 Oct 88

Item configuration during test: Item strapped down on vibration table fixture; AC and DC operation.

Performance test criteria: Consistent and accurate measurements and displays.

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	None
list connections to dummy loads	Test engineer's arm
list unconnected terminals	Serial port

Ambient conditions

Temperature	73 degrees F
Humidity	76 percent RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Times and dates of test start: 0800

Time at first check:
X: 0800 Y: 0905 Z: 1325

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Time at second check:
X: 0855 Y: 1000 Z: 1430

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

POSTTEST DATA

Posttest performance check (complete check of item and accessories):

Item functional (based on performance test criteria): Yes

Item intact: Yes

Deviation from pretest: None

Comments on item setup or checks:
Times are on different days

Comments on test run (including interruptions):
Z-axis test aborted at 14 minutes because a strap loosened. Test was restarted after strap was tightened.

Comments on other data: None

3.2.10 High temperature test

High Temperature Test
(Equipment Operating)
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: None

Options installed: None

Date of test: 25 Nov 88

Item configuration during test: Unit was sitting on chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	23 degrees C
Humidity	63 percent RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check :
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	None
list connections to dummy loads	Test engineer's arm
list unconnected terminals	Serial port
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance form east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

IN-TEST DATA

Time of test start: 0815

Performance checks during test:

First check:

Time: 0
Temperature: 49 degrees C
Humidity: 16 percent RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes, all OK
Deviation from pretest: None

Second check:

Time: 0930
Temperature: 49 degrees C
Humidity: 16 percent RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes, all OK
Deviation from pretest: None

Third check:

Time: 1000
Temperature: 49 degrees C
Humidity: 15 percent RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes, all OK
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1100
Item functional (based on performance test criteria): Yes, all OK
Deviation from pretest: None

Comments on item setup or checks:
tested at same time with test and evaluation program item 7.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.11 High temperature storage test

High Temperature Test
(Equipment in Storage)
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: None

Options installed: None

Date of test: 29 Nov 88

Item configuration during test: Sitting on chamber floor, in storage, not operating.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	20 degrees C
Humidity	43 percent RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	all
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance form east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

Time of test start: 0820

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1445
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data:
Tested at same time with test and evaluation program item 7.

3.2.12 Low temperature test

Low Temperature Test
(Equipment Operating)
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: None

Options installed: None

Date of test: 25 Nov 88

Item configuration during test: Sitting on chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	23 degrees C
Humidity	20 percent RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes
All OK Pass

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	None
list connections to dummy loads	Test engineer's arm
list unconnected terminals	Serial port
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance form east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.0
distance from floor (meters)	0.0

Time of test start: 1200

Performance checks during test:

First check:

Time: 1230
Temperature: 0 degrees C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Second check:

Time: 1300
Temperature: 0 degrees C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Third check:

Time: 1330
Temperature: 0 degrees C
Humidity: n/a
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1405
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks:
Tested at same time with test and evaluation program item 7.

Comments on test run (including interruptions):
Condensation on EUT was allowed to dry before final performance check.

Comments on other data: None

3.2.13 Low temperature storage test

Low Temperature Test
(Equipment in Storage)
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 0000385
Military item number: None

Options installed: None

Date of test: 1 Dec 88

Item configuration during test: AC power cord and cuff tube coiled and laying on top of the unit. The unit is in storage, not operating.

Performance test criteria: Consistent and accurate displays and measurements

Ambient conditions outside chamber:

Temperature	20 degrees C
Humidity	49 percent RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance form east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

Time of test start: 0807

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1434
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: The unit was allowed to return to ambient conditions overnight before final performance check.

3.2.14 Humidity test

Humidity Test
Report Form

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: None

Options installed: None

Date of test: 5 Dec 88

Item configuration during test: The unit was sitting on the chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	19 degrees C
Humidity	49 percent RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:
Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	Test engineer's arm
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance form east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

IN-TEST DATA

Time of test start: 1110

Performance checks during test:

First check:

Time:	1155
Temperature:	29.5 degrees C
Humidity:	95 percent RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Second check:

Time:	1240
Temperature:	29.5 degrees C
Humidity:	95 percent RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Third check:

Time:	1325
Temperature:	29.5 degrees C
Humidity:	95 percent RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Fourth check:

Time:	1410
Temperature:	29.5 degrees C
Humidity:	95 percent RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

Fifth check:

Time:	1455
Temperature:	29.5 degrees C
Humidity:	95 percent RH
Barometric pressure:	1 atm
Item functional (based on performance test criteria):	Yes
Deviation from pretest:	None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)
Time of test end: 1550
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data:
This test item was tested with test and evaluation item 7.

3.2.15 Electromagnetic characteristics test

****

Electromagnetic Characteristics Testing
Evaluation of Performance
****

T & E Item Number: 06 Date: 1 Nov 1988

Nomenclature: Blood pressure monitor
Manufacturer: Physio Control
Model number: LIFESTAT® 200
Serial number: 00003850
Military item number: n/a

****

Conducted emissions tests

CE01
Testing configuration(s): n/a
Performance (pass/fail): n/a

Comments: n/a

CE02
Testing configuration(s): Operating on copper work bench.
Performance (pass/fail): Pass

Comments: Both hot and neutral conductors tested.

CE04
Testing configuration(s): Operating on copper work bench.
Performance (pass/fail): Fail

Comments: NB failure 0.2 to 13.3 dB over specifications in range 13 to 53 MHz; BB failure 3 to 4.5 dB over specifications in range 15.6 to 16 MHz.

Conducted susceptibility tests

CS02
Testing configuration(s): Operating on test bench, connected to test jig.
Performance (pass/fail): n/a

Comments: Unable to test because noise generated by the unit is greater than the test signal (unable to measure test signal).

CS06 Testing configuration(s): Operating on counter top.
Performance (pass/fail): Pass

Comments: Not susceptible to test spikes

Radiated emissions tests

RE02 Testing configuration(s): Operating on wooden test stand in the EMC chamber, AC and battery power.
Performance (pass/fail): Fail

Comments: NB failures 0.3 to 41 dB over specifications in range 2 to 255 MHz; BB failures of 1.8 to 21.3 dB over specification in range 15 to 45 MHz.

Radiated susceptibility tests

RS03 Testing configuration(s): Operating on the wooden test stand in the EMC chamber, AC power only.
Performance (pass/fail): Pass
Comments: No sign of failure noted.

3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

3.3.1 Criteria

Item No.	Criteria (Source)	Remarks	Applicable subparagraph
1	The physical inventory is conducted solely for investigation and documentation.	N/A	2.1.2.1
2	The LIFESTAT® 200 will display consistent and accurate measurements.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 30 minutes during continuous operation in the 2-minute cycle.	met	2.2.2
4	The LIFESTAT® 200 will meet the limits established in NAFP 99 for electrical safety of medical equipment.	met	2.3.2
5	The LIFESTAT® 200 will be rated satisfactory in all major categories of the evaluation. These include: Visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.	partially met	2.4.2
6	The LIFESTAT® 200 will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	The LIFESTAT® 200 will remain operational and display consistent and accurate measurements while exposed to vibrational stresses.	met	2.6.2

8	The LIFESTAT® 200 will display consistent and accurate measurements during the high temperature operation check.	met	2.7.2.1
9	The LIFESTAT® 200 will display consistent and accurate measurements after the high temperature storage.	met	2.7.2.2
10	The LIFESTAT® 200 will display consistent and accurate measurements during the low temperature operation check.	met	2.8.2.1
11	The LIFESTAT® 200 will display consistent and accurate measurements after the low temperature storage.	met	2.8.2.2
12	The LIFESTAT® 200 will display consistent and accurate measurements while exposed to a high humidity.	met	2.9.2
13	The LIFESTAT® 200 will not produce emissions in excess of the limits set forth in MIL-STD-461A Notice 4, paragraph 6.13.	partially met	2.10.2.1

14	The LIFESTAT® 200 will not malfunction when it is subjected to radiated fields as specified in MIL-STD-461A, Notice 4, paragraph 6.20.	met	2.10.2.2
15	The LIFESTAT® 200 will not conduct emissions in excess of the limits set forth in paragraphs 6.1 and 6.2, MIL-STD-461A, Notice 4.	partially met	2.10.2.3
16	The LIFESTAT® 200 will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.	partially met	2.10.2.4
17	The flight surgeon will be able to operate the LIFESTAT® 200 without physical or functional restrictions aboard the aircraft.	partially met	2.11.2.1
18	The LIFESTAT® 200 will not radiate EMI to disrupt or interfere with the other equipment or systems aboard the aircraft.	met	2.12.2.2
19	The aircraft will not radiate EMI to disrupt or interfere with the LIFESTAT® 200.	met	2.12.2.3

3.3.2 Significant problems which require corrective action

None

3.3.3 Suggested improvements

None

3.4 REFERENCES

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3.4.6 Department of Defense. 1985. Standard general requirements for electronic equipment. Washington, D.C. MIL-STD-454K. February.

3.4.7 Underwriters Laboratory's, Inc. 1978. Standard for safety, medical and dental equipment. Chicago, Illinois. UL-544.

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3.4.10 Department of the Army. 1978. Operator's manual, UH-60 and EH-60 helicopter, with changes 1-5. Washington, D.C. TM 55-1520-237-10. January.

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3.4.12 National Fire Protection Association. 1987. Standard for health care facilities. Quincy, Massachusetts. February.

3.4.13 Physio Control. 1987. Operating instructions, LIFESTAT® 200 noninvasive blood pressure monitor. Redmond, Washington. P/N 802611-02.

3.4.14 Mitchell, G. W., and Adams, J. E. 1988. Technical test and evaluation of aeromedical equipment. Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory. USAARL Letter Report LR-88-16-1-2.

3.5 ABBREVIATIONS

AVSCOM	Army Aviation Systems Command
AEST	aeromedical equipment suitability test
AWR	airworthiness release
BB	broadband
BPM	beats per minute
CAAF	Cairns Army Airfield
CRT	cathode ray tube
dB	decibel
DC	direct current
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EUT	equipment under test
fpm	feet per minute
GFE	government furnished equipment
Gpk	gravity, peak
G(rms)	gravity (root mean square)
Hz	hertz
IAW	in accordance with
ITOP	in-flight test operating procedure
IGE	in-ground effect
kHz	kilohertz
KIAS	knots indicated airspeed
LCD	liquid crystal display
LED	light emitting diode
LIFESTAT® 200	Physio Control blood pressure monitor, model LIFESTAT® 200
MEDEVAC	medical evacuation
MHz	mega hertz
MIL-STD	military standard
ml	milliliter
mm	millimeter
mmHg	millimeters of Mercury
MSL	mean sea level
NAFP	National Association of Fire Prevention
NB	narrowband
NBC	nuclear, biological and chemical

NVG	night vision goggle
RAM	random access memory
RF	radio frequency
RH	relative humidity
ROM	read only memory
TB	technical bulletin
TFT	technical feasibility testing
T & E	test and evaluation
UES	Universal Energy Systems, Inc.
USAARL	U.S. Army Aeromedical Research Laboratory
V/m	volts per meter

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Carson City, NV 89701

3.6.4 Tenney Engineering, Inc.
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3.6.5 Uholtz-Dickey Corporation
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3.6.6 BioTek Instruments, Inc.
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