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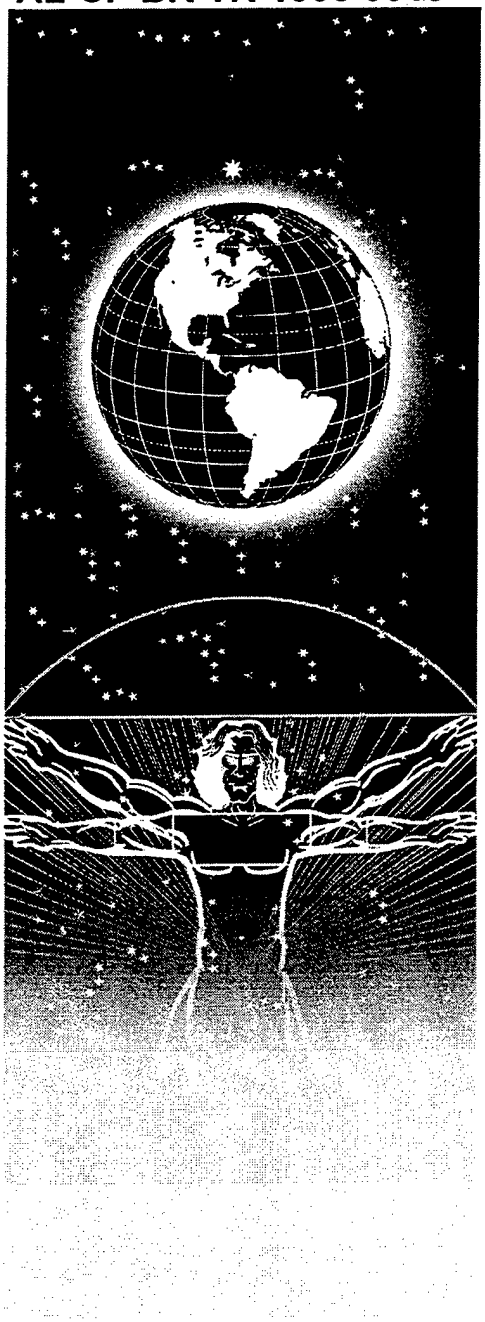

UNITED STATES AIR FORCE
ARMSTRONG LABORATORY

TESTING AND EVALUATION OF THE I-STAT BLOOD GAS ANALYZER

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NOTICES

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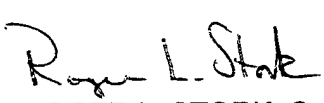

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The i-STAT, Inc., Blood Gas Analyzer is a portable hand-held unit designed to analyze and provide data on human blood. e.g., chemistries and blood gases. The unit use cartridges and a very small amount of blood to analyze various parameters in the blood depending upon the cartridge being used. The unit runs on two 9v lithium batteries and weighs 18.34 oounces, and is 2.52 in. W. X 8.26 in. L. X 2.05 in. D.

14. SUBJECT TERMS

i-STAT	aircraft	medical equipment	analyzer
iSTAT	approved	aeromedical	blood gas analyzer
istat	airworthy	blood gas	blood

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TESTING AND EVALUATION OF THE i-STAT BLOOD GAS ANALYZER

BACKGROUND

Representatives of Wilford Hall USAF Medical Center requested Aeromedical Research to evaluate and certify the i-STAT Blood Gas Analyzer for use on board USAF aeromedical evacuation aircraft. The i-STAT Blood Gas Analyzer system consists of the blood gas analyzer, an electronic simulator, an infrared data transfer system, cartridges that perform different types of analysis (see page 15), and an infrared printer. The i-STAT blood gas analyzer and ^{EC}6+, ^{EC}8+, 6+, and ^{EG}7+ cartridges were the only parts tested during this procedure.

DESCRIPTION

The i-STAT unit uses cartridges and a very small amount of blood to analyze various parameters in the blood depending upon the cartridge being used. The unit runs on two 9v lithium batteries. The unit has a sleep mode that is initiated automatically to save the batteries.

The unit has a liquid crystal display, a numeric keypad with additional keys for clear(clr), enter(ent), print(prt), *, display(dis), and arrow up and arrow down.

The following information defines the general specifications of the i-STAT Blood Gas Analyzer. Size: Width 6.41 cm (2.52 in), Length 20.97 cm (8.26 in), Depth 5.21 cm (2.05 in). Weight: 520 grams (18.34 ounces).

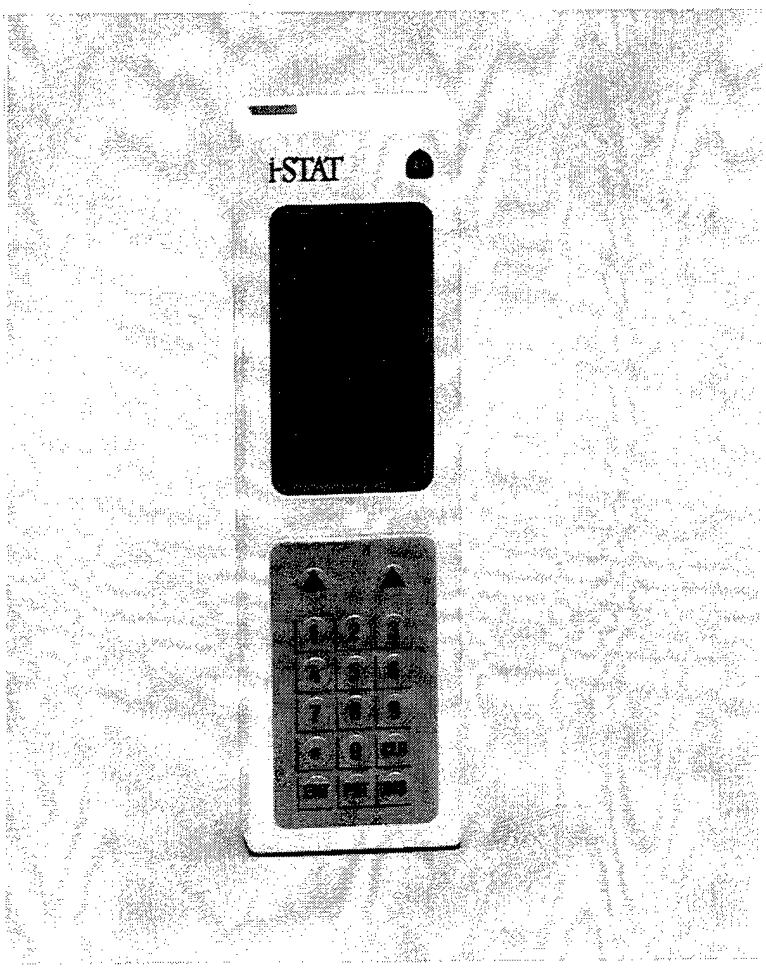


Figure 1. i-STAT Blood Gas Analyzer

PROCEDURES

Test methods and performance criteria were derived from military standards (1-3, 8 & 9), nationally recognized performance guidelines (4 & 7), and manufacturer's literature (5). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (6). A test setup and performance check were developed specifically for this product to verify proper functioning of the equipment under various test conditions. Unless otherwise noted all testing is conducted and monitored by Aeromedical Research personnel assigned to the Systems Research Branch (CFTS), Crew Technology Division, Armstrong Laboratory, Brooks AFB, TX.

The device was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic interference (EMI)

4. Thermal/Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Storage

    e. Cold Storage

5. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to Ambient Pressure

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The i-STAT Blood Gas Analyzer was inspected for quality of workmanship, production techniques, and possible damage incurred during shipment.

b. The i-STAT Blood Gas Analyzer was checked to ensure it met basic requirements for good human factors design as outlined in Mil STD 1472 (3).

c. A test setup and performance check were developed to evaluate the i-STAT Blood Gas Analyzer operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The i-STAT Blood Gas Analyzer was first tested with the electronic simulator. After this test was complete the unit was tested using ^{EC}8+ and 6+ cartridges (see page 15) with level 1 and level 3 controls provided by i-STAT for testing of the unit. The controls are used to test proper operation of the unit. A list of test values is provide by the company to be compared with the readings from the unit to check for proper operation.

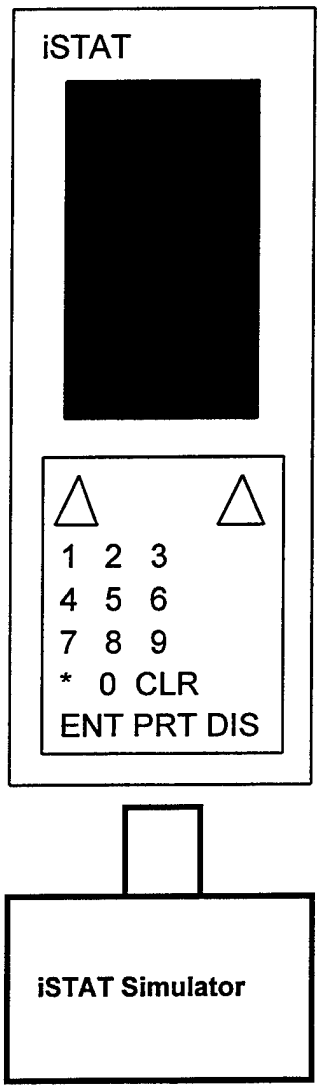


Figure 2. Test Setup

PERFORMANCE CHECK

A cartridge was filled using one of the level controls. The cartridge was inserted into the unit and when the values were displayed they were compared to the values listed on the information provided with the level controls.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (2). Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of the i-STAT Blood Gas Analyzer's three axes - X, Y, and Z, with the unit mounted on the NATO litter segment. (Figure 3). The unit was subjected to vibration curves with reduced levels that are derived from Mil STD 810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

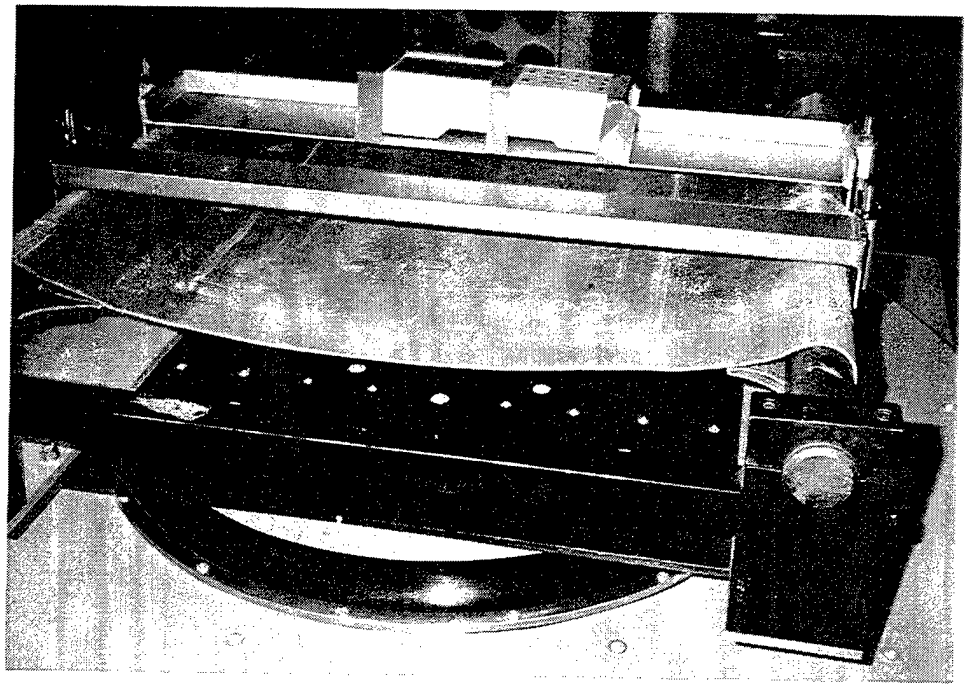
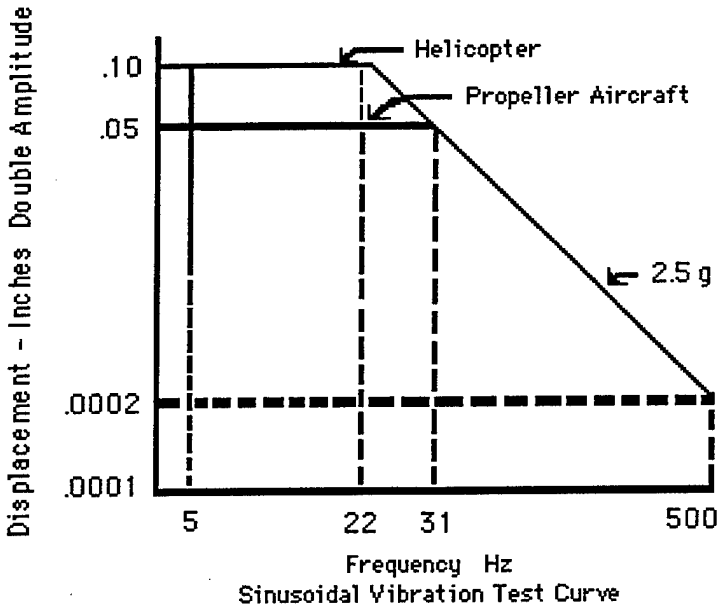


Figure 3. Vibration Table Mounting



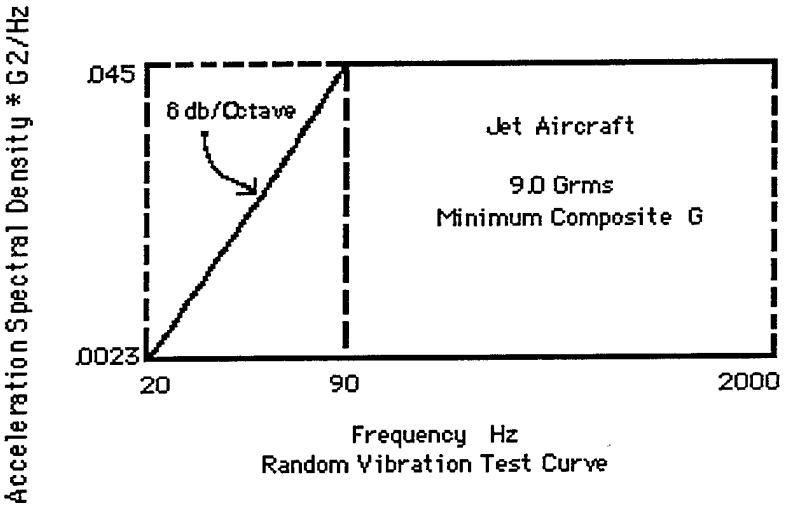


Figure 4. Aeromedical Research Vibration Curves

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Ensuring the safety of everyone on board is the driving factor in assessing the effects of electromagnetic emissions emitted by medical devices on aircraft navigation and communication equipment. Medical devices may also be susceptible to EMI fields generated by the aircraft equipment or other medical devices.

The i-STAT Blood Gas Analyzer was evaluated for compliance with Mil STD 461D (1). WL/AASW Wright Patterson AFB performed the evaluation in their electromagnetic compatibility facility. ASC/ENAI, Wright-Patterson AFB, evaluated the electromagnetic emissions data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the system under test during its operation.

b. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (field strength values from Table IV, category Aircraft Internal, of 461D). This test measured the resistance of the system under test to set levels of EMI generated by antennas both internal and external to the aircraft.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing is critical to determine if aeromedical equipment can be stored and operated during severe environmental conditions "without experiencing physical damage or deterioration in performance" (2). Extreme environmental conditions can have detrimental effects on medical equipment including, but not limited to: changes in material characteristics and size, possible overheating, changes in electronic component characteristics, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operations personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, Tx. The i-STAT Blood Gas Analyzer was placed in the center of the environmental chamber. The manufacturer states in their literature that the unit will operate in a temperature range of 16 - 30 °C. This range may change slightly with each software update. A decision was made to modify the normal thermal and humidity test since the

manufacturer states in the literature that the unit will not function outside of its normal operating range.

a. Humidity: 94 +/- 4% RH, 29.5 +/- 2°C (85 +/- 3.6°F) for 4 hours
The chamber was set to the noted RH and temperature and the unit (at room temperature) was placed inside the chamber. After ten minutes the unit displayed "analyzer error code 92". The unit was removed from the chamber and required 22 minutes at room temperature before it would recover and function properly. The chamber was reset to 65% RH and 23°C and the unit was placed into the chamber. The unit operated one hour without any problems. The humidity level was increased to 70% and the unit operated for 45 minutes with no problems. The humidity was increased to 75% and after 45 minutes the unit displayed "Fail see manual". The unit was removed from the chamber and after five minutes at room temperature the unit functioned normally.

b. Hot Operation: 49 +/- 2°C (120 +/- 3.6°F) for 2 hours
The chamber was set to the noted conditions and the unit (at room temp) was placed inside the chamber. After ten minutes the unit displayed 33.8°C and an error message. The unit was pulled from the chamber and allowed to cool down at room temperature. When the temperature value displayed by the unit reached 29.5°C the unit began to function normally.

c. Cold Operation: 0 +/- 2°C (32 +/- 7.2°F) for 2 hours
The chamber was started at 16°C. The unit was at room temperature when placed in the chamber. The unit required 2.5 hours to cool to 16°C at the 16°C chamber temperature. The chamber temperature was lowered to 0°C and when the unit displayed a temperature of 15.8°C the unit display indicated "ready to use" but when a cartridge was inserted a message of "temperature out of range" was displayed.

d. Hot Storage: 60 +/- 2°C (140 +/- 3.6°F) for 6 hours
The unit was tested at the noted temperature and time. A pre test was done and the values were correct for the level control used. The unit took one hour to return to its operational range after being removed from the chamber. A post test was done and all values were correct except for GLU which displayed "***".

e. Cold Storage: -40 +/- 2°C (-40 +/- 3.6°F) for 6 hours
The unit was tested at the noted temperature and time. A pre test was done and the values were correct for the level control used. The unit took one hour to return to its operational range after being removed from the chamber. The unit displayed a low battery message initially but then cleared itself. A post test was run and the values were correct for the level control used.

HYPOBARIC CONDITIONS

Testing was conducted in the Armstrong Laboratory research chambers operated and monitored by chamber operation personnel assigned to the Systems Research Branch (CFTS) of the Crew Technology Division at Armstrong Laboratory, Brooks AFB, Tx.

a. Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to the potential effects of barometric pressure changes on the equipment. A majority of the aircraft, which are characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000 - 10,000 feet above sea level. The differences in pressures can be critical to the effective operation of some medical equipment. Altitude testing consisted of operating the i-STAT Blood Gas Analyzer while ascending from ground level to 10,000 ft (maintaining altitude for one hour) and then descending back to ground at rates of 5,000 ft/min, while stopping at 2,000 ft increments to allow for performance checks.

b. Rapid Decompression Testing: Rapid decompressions are caused by the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressure. It is important to determine how medical equipment will function during and after such a decompression to ensure that it will not endanger a patient, the aircraft personnel, or the aircraft itself. The i-STAT Blood Gas Analyzer operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent altitude of 8,000 ft (2,430 meters). Then, the chamber altitude was brought to 45,000 ft (13,716 meters) over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground level at a rate of 10,000 - 12,000 ft/min. This sequence was repeated for the seven second and one second period.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating a piece of equipment's clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment in the actual operational environment, Aeromedical Research ensures that all pertinent patient care issues are adequately addressed by the test protocols. Ensuring safe and reliable operation of this medical device is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by an aircraft-qualified aeromedical research technician on board a C-9 aeromedical evacuation mission. The i-STAT Blood Gas Analyzer was carried by the Aeromedical Research technician and tested using the control fluid. Human factors characteristics, securing methods, and equipment setup times and location were also evaluated.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Since the unit has an all plastic case no electrical safety tests were done.

VIBRATION

During initial vibration testing the iCa reading appeared to be inaccurate. In later testing this did not seem to reoccur.

ELECTROMAGNETIC COMPATIBILITY

The i-STAT Blood Gas Analyzer met all limits for emissions and susceptibility testing. ASC/ENAI Wright-Patterson AFB certified that the emissions from the unit were within limits and the system was acceptable for use during all phases of flight on all Air Force aircraft

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The normal testing parameters were changed due to the company literature concerning the unit operating range. The company stated clearly in their literature and manuals that the unit would only operate over a temperature range of 20°F. The normal thermal/humidity tests were modified to test whether the unit would stop functioning at the temperature/humidity specified by the company. The unit performed exactly as the company said it would over the temperature/humidity range Special attention should be given to the Thermal/Humidity parameters and the results encountered. The test parameters and the results are in the Procedures section, subsection Thermal/Humidity. The i-STAT Blood Gas Analyzer operated satisfactorily during all five phases of testing.

HYPOBARIC CONDITIONS

1. Cabin pressure/Altitude: No problems were noted.

2. Rapid Decompression: The cartridges used leaked control fluid into the unit causing a malfunction during the sixty second period test. Test of the cartridges alone showed that there was uncontrolled fluid flow in the cartridges and rupturing of the cartridge membrane. The cartridges will not survive a rapid decompression. Testing continued using the backup i-STAT and the simulator. No problems were noted with the unit. After several days of drying out, the original unit began to function again.

AIRBORNE PERFORMANCE

The in-flight evaluation of the i-STAT Blood Gas Analyzer was performed on a C-9 aeromedical evacuation mission. There were no problems noted.

SUMMARY

Aeromedical Research found the i-STAT Blood Gas Analyzer to be conditionally acceptable for use on all U.S. Air Force aeromedical evacuation aircraft during all phases of flight. The requirement that the operating temperature be within a very narrow range will present some problems but many hospitals have found ways to overcome this limitation, such as storing the unit in Igloo ice chest or placing the i-STAT inside of the flight suits worn by medical personnel. The operating range limitation is a restriction found on all blood gas analyzers evaluated by this organization. The failure of the filled cartridge to survive rapid decompression is not considered serious. The i-STAT and empty cartridges will survive rapid compression.

REFERENCES

1. Mil-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.

2. Mil-STD 810E, Environmental Test Methods and Engineering Guidelines.

3. Mil-STD 1472, Human Engineering Design Criteria for Military Systems.

4. Emergency Care Research Institute (ECRI).

5. i-STAT Blood Gas Analyzer, Operator's Manuals.

6. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

7. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code.

8. AFI 41-203, Electrical Shock Hazards.

9. AFI 41-201, Equipment Management in Hospitals.

APPENDIX

MANUFACTURER'S SPECIFICATIONS OF THE i-STAT BLOOD GAS ANALYZER

SPECIFICATIONS

General

Size	Width 6.41 cm (2.52 in), Length 20.97 cm (8.26 in), Depth 5.21 cm (2.05 in)
Weight	520 grams (18.34 ounces)
Power	Two 9v lithium batteries
Environmental	Temperature (Operating) 16 -- 30 °C (64 -- 86 °F) Operating temperature range may change with software updates. (Transport) -10 -- 50 °C (14 -- 122 °F) Relative Humidity 0 -- 65% (minimum) noncondensing
CALIBRATION	Factory (electronic, mechanical, thermal, pressure)
MEMORY/CLOCK BACKUP POWER:	Internal lithium battery

DISPLAYS, INDICATORS, & KEYS

Display	Dot matrix supertwist liquid crystal
CLR	Clear entry
DIS	Recall display after blanking
ENT	Enter inputs
PRT	Output data to Infra-red link
up/down arrows	Select areas of display to activate
Keys	0-9 numeric keys, *

EXPECTED VALUES

Test(Measured)	Units	Reportable Range	Reference Range
Sodium/Na	mmol/L	100 - 180	138 - 146
Potassium/K	mmol/L	2.0 - 9.0	3.5 - 4.9
Chloride/Cl	mmol/L	65 - 140	98 - 109
pH		6.8 - 8.0	7.35 - 7.45 (arterial)
PCO_2	mmHg	10 - 100	34 - 45 (arterial)
PO_2	mmHg	5 - 800	80 - 105 (arterial)
Ionized Calcium/iCa	mmol/L	0.25 - 2.50	1.12 - 1.32
Urea Nitrogen/BUN	mg/dl	3 - 140	8 - 26
Urea	mmol/L	1 - 50	2.9 - 9.4
Glucose/GLU	mg/dl	20 - 450	70 - 105
Glucose/GLU	mmol/L	1.1 - 25.0	3.9 - 5.8
Hematocrit/Hct	%PCV	10 - 75	38 - 51

Test (Calculated)	Units	Reportable Range	Reference Range
Hemoglobin/Hb	g/dL	3 - 26	12 - 17
TCO_2	mmol/L	5 - 50	19 - 24
HCO_3	mmol/L	5 - 50	18 - 23
BEecf	mmol/L	N/A	(-2) - (+3)
Anion Gap	mmol/L	-10) + (+99)	10 - 20
sO_2	%	N/A	95 - 98

COMMUNICATIONS LINK infrared light-emitting diode.

BATTERY

Type — 9v Lithium (2), user replaceable.

Indicator — LO BATT indication on display.

i-STAT Cartridge Listing

$^{EC}_{8+}$	$^{EG}_{7+}$	$^{EC}_{6+}$	$^{EG}_{6+}$	6+	$^{EC}_{4+}$	$^{G}_{3+}$	$^{E}_{3+}$	G
Sodium	Sodium	Sodium	Sodium	Sodium	Sodium	pH	Sodium	Glucose
Potassium	Potassium	Potassium	Potassium	Potassium	Potassium	PCO_2	Potassium	
Chloride	Ionized Calcium	Glucose	pH	Chloride	Glucose	PO_2	Hematocrit	
Urea Nitrogen	pH	Ionized Calcium	PCO_2	Urea Nitrogen	Hematocrit	Bicarbonate*	Hemoglobin*	
Glucose	PCO_2	pH	PO_2	Glucose	Hemoglobin*	Total Carbon Dioxide*		
pH	PO_2	Hematocrit	Hematocrit	Hematocrit		Base Excess*		
PCO_2	Hematocrit	Hemoglobin*	Bicarbonate*	Hemoglobin*		O_2 Saturation*		
Hematocrit	Bicarbonate*		Total Carbon Dioxide*					
Bicarbonate*	Total Carbon Dioxide*		Base Excess*					
Total Carbon Dioxide*	Base Excess*		O_2 Saturation*					
Base Excess*	O_2 Saturation*		Hemoglobin*					
Anion Gap*	Hemoglobin*							
Hemoglobin*								
Catalog # 125000	Catalog # 220300	Catalog # 123000	Catalog # 220200	Catalog # 121000	Catalog # 121500	Catalog # 220100	Catalog # 120500	Catalog # 120100

*** Calculated values**