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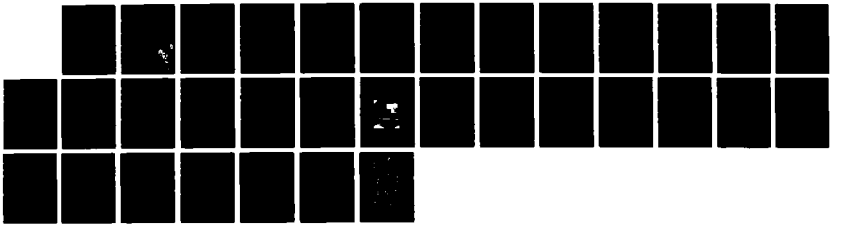

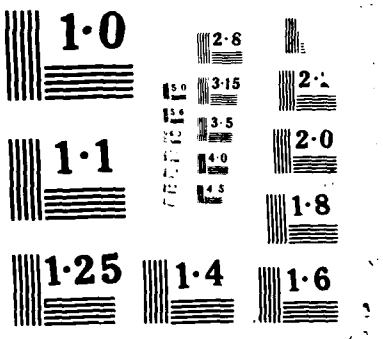
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TECHNICAL REPORT 8801

TECHNICAL FEASIBILITY TESTING OF MEDICAL MATERIEL:

EVALUATION OF A COMMERCIAL BLOOD GAS ANALYZER

Patricia M. Dubill, John W. Hodge, Jr.,
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27 January 1988

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19. freezing. A minor malfunction occurred with the analyzer following shock testing, but was easily remedied by the operator. Cartridge durability was a problem; however, the manufacturer is redesigning the cartridges to alleviate the weak point, so future versions should be acceptable. The instrument should be considered for deployment by the Army, pending review of the minor areas in which it does not meet the LR.

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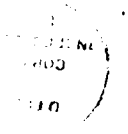

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PREFACE

In 1983 the Academy of Health Sciences developed a Letter Requirement (LR) for a Blood Gas/pH Analyzer for use in the Corps level hospitals, Area Medical Laboratory detachments, and Communications Zone hospitals. Field trials of several non-developmental items (NDI) were performed, with unsatisfactory results, and were followed by attempts to identify a more suitable instrument through a U.S. Army Medical Materiel Development Activity market survey. None of the devices identified in the survey satisfied all of the Essential Characteristics (EC's) defined in the LR, implicating a need for a developmental initiative; however, a novel device similar to one being proposed for development became commercially available, and was procured for testing. Evaluation of that commercial device is the subject of this report.

ACKNOWLEDGEMENT

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ABSTRACT

Arterial blood gas analysis is an important tool for making accurate diagnoses and therapeutic decisons regarding trauma patients. Several commercial blood gas analyzers were field tested by the U.S. Army and found to be insufficiently durable and reliable. A new product, the GEM-6 Portable Blood Gas Analyzer, may be more suitable for field hospital use because of the design concept it utilizes. The device incorporates a disposable cartridge containing all sensors and reagents, which minimizes tubing and moving parts. An instrument was procured for evaluation with regard to environmental susceptibility, in accordance with MIL-STD-810D, Environmental Test Methods and Engineering Guidelines. High and low storage temperature, transit vibration and shock were the test conditions studied, using the manufacturer's quality control solutions as samples. Results indicated that high storage temperature tripped a circuit breaker in the analyzer, preventing power from being supplied to the heater block. This problem could be rectified by using a standard fuse in place of the circuit breaker. Low storage temperature of the consumable supplies revealed that they will require protection to prevent freezing. A minor malfunction occurred with the analyzer following shock testing, but was easily remedied by the operator. Cartridge durability was a problem; however, the manufacturer is redesigning the cartridges to alleviate the weak point, so future versions should be acceptable. The instrument should be considered for deployment by the Army, pending review of the minor areas in which it does not meet the LR.

INTRODUCTION

Blood gas analysis generally includes direct measurement of the negative logarithm of hydrogen ion concentration (pH) and partial pressures of oxygen and carbon dioxide (PO_2, PCO_2). More complete analyses include computations of parameters derived from these values, such as base excess (BE), bicarbonate ion concentration (HCO_3^-) and total carbon dioxide concentration (TCO_2). The values of these parameters reflect the cardiovascular, respiratory, and metabolic status of a patient, and are used by physicians for diagnosis, prognosis and therapeutic determinations. For example, in trauma, blood gas values may be used to identify metabolic acidosis from hypovolemic shock, assess the survivability of head injured patients, or manage the ventilation of patients with airway crises (Baxt, 1985). Since some conditions arising in trauma patients are not easily identified or predicted by subjective means, the capability to perform blood gas analysis could be a significant factor in reducing morbidity and mortality in the combat casualty care environment.

Recognizing the need to perform blood gas analysis in the field, the Army developed a Letter Requirement (LR) for a Blood Gas/pH Analyzer (NSN assigned: 6530-01-185-3296) in 1983. Nondevelopmental Item (NDI) devices were surveyed and found to lack the necessary combination of automation, low maintenance, and durability to be efficacious in the field; however, the novel design of a new device may solve those problems and preclude the need for a developmental effort. The device is unique in that all wet chemistry components are incorporated into one disposable cartridge, eliminating the need for training intensive tasks such as refurbishing electrode membranes. The design also

minimizes tubing, valves, and other moving parts, making it inherently more durable and reliable.

Although the device has higher operational costs than more conventional instruments, it is probably the only blood gas analyzer that will come close to meeting the Essential Characteristics (EC's) for size, maintainability, and durability, and was selected for evaluation on that basis. A further offset to the cost issue is the instrument's capability to measure electrolytes, potentially eliminating the need for cumbersome and unreliable flame photometers for that purpose.

Research to assess the accuracy of the blood gas analyzer has been conducted (Riley et al., 1987), with favorable results, but no durability data is available. The purpose of this study was to determine whether the device is sufficiently durable for fielding by the U.S. Army.

MATERIALS AND METHODS

The instrument studied (Figure 1) was the GEM-6 Portable Blood Gas Analyzer (Diamond Sensor Systems, Ann Arbor, Michigan). The unit weighs 12.6 kg and has external dimensions of 23 cm by 45 cm by 21 cm, for a volume of 21735 cm^3. It measures pH, PO_2, PCO_2, ionized potassium (K^+), ionized calcium (Ca^{2+})[1], hematocrit (HCT) and temperature, and derives BE, HCO_3^-, TCO_2, and

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1. A newer version of the blood gas analyzer (GEM-STAT) measures ionized sodium (Na^+) instead of Ca^{2+}.

oxygen saturation of hemoglobin (SaO_2). Features include numeric displays for each measured parameter, an alphanumeric display for providing instrument status information, keyboard prompts, and other information, a membrane switch panel for command and data entry, automatic hard copy printout, patient temperature correction capability, and auxiliary battery backup to maintain memory of programmed instructions and data generated for up to 30 minutes.

Because of the degree of automation of the GEM-6, it is extremely simple to operate. A 45 minute warm-up period is initiated automatically upon insertion of a disposable GEM-PAK sensor/reagent cartridge, which contains electrochemical sensors, calibrating and flush solutions, and a waste container. No tanks of compressed gases are required for calibration. Upon operator command, a fixed volume of sample is aspirated, equilibrated to 37°C, and analyzed within 130 seconds. Up to 50 samples can be processed per cartridge over an 8 hour period. Cartridge life can be extended to 36 hours[2] with the utilization of up to 28 hours of "standby" time. Two-point calibrations are performed automatically 20 minutes following completion of the warm-up period and at one hour intervals throughout the remainder of the cartridge active life. A one-point calibration and rinse cycle is performed automatically following each sample analysis.

Environmental testing of the blood gas analyzer and associated supplies included subjecting the items to high and low storage temperatures, vibration, and shock, in accordance with MIL-STD-810D, Environmental Test Methods and

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2. For the GEM-STAT model, cartridge life will be extended to 48 hours.

Engineering Guidelines, Methods 501.2 (I), 502.2 (I), 514.3 (I), and 516.3 (IV). During these tests, the items were subjected to temperature extremes from 70°C to -54°C, the vibration spectrum of a tracked vehicle, and repeated drops from a height of 76 cm (Hodge et al., 1987). During the environmental tests, the blood gas analyzer was packaged in polyurethane foam material inside a size 6 aluminum field chest (MIL-C-0016775C(DM)), which is the maximum sized protective container permitted by the EC's. Since the EC's do not include specifications on packaging constraints for consumable supplies, the supplies were packaged separately from the analyzer in a manner that was convenient for testing purposes.

Because of the chemistry involved with the use of these products, the items' susceptibility to each of the environmental test conditions was evaluated individually. Nine cartridges were tested, using GEM-CHECK quality control solutions as samples. Three levels of controls are manufactured, representing acidosis (low level), normal values (normal level), and alkalosis (high level). Thirty ampules (ten per level) are supplied per box of quality controls. An attempt was made to use boxes with the same lot numbers, so that the expected results would be the same for all of the samples; however, one box had different expected results than the others, as shown in Tables 1 and 2. All but the first cartridge had the same lot number.

Samples were processed towards the beginning and end of each 36 hour cartridge life to enable a comparison of performance following warm-up to performance following a long period in standby. An initial functional evaluation of the instrument was performed using the first cartridge, which included verification of cartridge life, samples per cartridge, throughput,

performance following 30 minute power loss, and accuracy of temperature coefficients used for correcting results on quality controls not at room temperature. The latter was accomplished by analyzing controls that had been placed in water baths at 60-90°F. Subsequent cartridges involved some aspect of environmental testing related to storage or transit conditions, as shown in Table 3.

RESULTS

Overall, the test items performed well, although several minor problems were identified. Summarized results for each measured parameter are presented in Tables 4-8. Data from the control cartridge indicated that the blood gas analyzer was functioning within manufacturer's guidelines prior to exposure to environmental test conditions. No problems with electrode drift following long periods in standby mode were observed, and the device functioned correctly following a thirty minute power loss. The temperature coefficients (relevant only to PO_2 measurement) did not accurately compensate for the temperatures imposed on all of the low level quality control samples.

High temperature storage testing of the analyzer resulted in failure of a component associated with the analyzer's heater block, which maintains the sensor array at 37°C. Since measurements are incorrect when the analysis is not performed at the required temperature, testing was terminated after two samples, and these results are not presented.

The analyzer was returned to the company for elucidation of the cause of failure, and a loaner device was used to test the supplies exposed to high and

low storage temperatures. High storage temperature did not adversely affect the cartridge or quality controls; however, low storage temperature significantly affected the Ca^{2+} and pH values. For the cartridge that had been frozen, the values of Ca^{2+} and pH were high, and for the quality controls that had been frozen, these values were low.

Vibration and shock testing did not damage the quality control ampules, but did cause leakage of the cartridges at the calibration solution bag-fluid dispersion valve interface (see Figure 2). No samples were run on these damaged cartridges.

The original GEM-6 instrument was returned for the shock and vibration testing, and survived both test regimens with no significant damage. Following the shock tests, after approximately 26 hours of cartridge operation (and 36 sample analyses), the message "INSERT CARTRIDGE" appeared on the alphanumeric display (while the cartridge was still in use). This message is supposed to appear after the power is turned on and the instrument completes its self-diagnostics, or following removal of a cartridge. Nothing could be done to return the device to its operating mode, so the door to the cartridge chamber was opened and closed, initiating a new warm-up period. The device was placed in standby mode overnight, and the remaining samples were analyzed the following day to verify that the mechanical problem had been corrected. Because the cartridge had been in operation for more than 36 hours when those samples were analyzed, the results for those samples are not presented. Another problem noted with the running of this last cartridge was considerable variability in the PO_2 values, evident from the values of standard deviation for that cartridge.

DISCUSSION

The problems incurred during environmental testing are resolvable, such that the GEM-6 (or GEM-STAT) and associated supplies could be fielded with minimal changes and constraints. Overall, temperature posed more of a problem than transit shock and vibration. The only problem identified during study of the control cartridge was inaccurate compensation for temperature of the low level quality controls. Therefore, it is recommended that the controls be maintained in a specified temperature range while stored at field hospitals.

Failure of the heater block following high temperature storage was caused by a tripped circuit breaker, which prevented the heater from receiving power. A company representative discovered that the circuit breaker is not recommended for storage at temperatures above 50°C (testing was to 70°C), and suggested resolving the problem by replacing the circuit breaker with a standard fuse.

Cold temperature storage of the cartridge and quality control solutions caused calcium carbonate to precipitate, which invalidated the results for calcium and also shifted the pH, particularly in the solutions containing the most calcium. Results for the other three parameters (PCO_2, PO_2, and K^+) were unaffected by freezing. No physical damage was discovered as a result of freezing; however, a company representative reported that in several of the company's freeze tests, the valve assembly in the cartridge expanded, causing a hairline fracture and leakage of the calibration solutions. In view of these chemical and mechanical considerations, protection of the blood gas analyzer cartridges and quality controls from freezing is implicated.

The problem encountered with the "INSERT CARTRIDGE" message following shock testing is believed to be a hardware problem with one of the switches that senses the presence of a cartridge (one in the sensor array, and one in the cartridge chamber door). Since this condition was easily remedied by the operator, it should not negate fielding of the device. The problem with PO_2 measurements on that same cartridge was attributed to a bad PO_2 electrode, which is not usually a problem with the cartridges.

Leakage problems with the cartridges due to transit conditions are a concern. The company is redesigning the bag-valve interface to eliminate the stress concentration at the connection point, which should reduce the problems with cartridge durability to a packaging issue in the future. The new cartridge design will be available in February, 1988, and follow-up tests can be conducted by USABRDL personnel, if necessary.

Since the GEM-6 device has been shown to be sufficiently durable for fielding, its characteristics in comparison with the EC'S should be reviewed by appropriate personnel. The device meets the most clinically important EC's, which include requirements for measurement range, accuracy, and calculated parameters. There are several requirements that the device does not meet, however, which include minimum sample volume, multiple voltages without modification, and optional hard copy printout. The EC's require a minimum sample volume of 175 microliters, and the GEM-6 uses 2000 microliters (*the GEM-STAT model uses 400 microliters). Diamond Sensor Systems markets a model with electrical requirements for use in the U.S., and another for use in European countries, but not one for both electrical requirements. The printer is an integral part of the analyzer, so printouts are not optional. The

instrument sells for $2,000 less than the cost specified in the EC's, and additional considerations regarding the fiscal and logistical aspects of fielding the device are presented in Table 9.

CONCLUSIONS AND RECOMMENDATIONS

The GEM-6 blood gas analyzer performed reasonably well following exposure to field relevant environmental test conditions, and should be sufficiently durable for use by the U.S. Army, provided that several modifications are implemented and constraints imposed. Modifications include replacement of the circuit breaker for the heater block board with a standard fuse, and redesign of the calibration bag-fluid dispersion valve interface in the cartridges (which the company is doing of its own accord). A packaging constraint for deployment is provision of protection from freezing for the consumable supplies. Changes in the EC's to enable procurement of this device (or the GEM-STAT model) should be considered. The manufacturer is agreeable to making modifications to the cartridges for the Army, if required, such as extending the useful life to a week, and shelf life to over a year or two (via refrigeration).

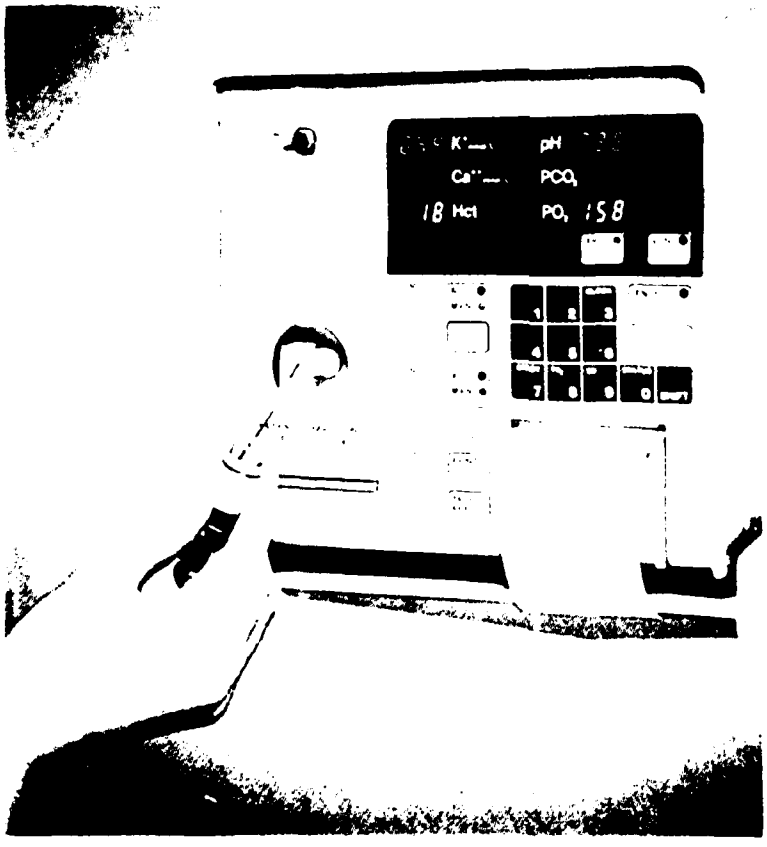

Figure 1. Front view of GEM-6 Portable Blood Gas Analyzer.

TABLE 1. Expected means and ranges for quality control solutions for all cartridges except #3. (specified by manufacturer for each box--PO_2, PCO_2 in mm Hg, K^+, Ca^{2+} in mmol/L)

	Low Level (I)		Normal Level (II)		High Level (III)	
Parameter	Mean	Expected Range	Mean	Expected Range	Mean	Expected Range
pH	7.05	7.00 - 7.10	7.35	7.31 - 7.39	7.57	7.53 - 7.61
PCO_2	77	65 - 89	47	42 - 52	22	15 - 29
PO_2	62	51 - 73	113	104 - 122	160	148 - 172
K^+	2.5	1.9 - 3.1	3.9	3.3 - 4.5	6.3	5.7 - 6.9
Ca^{2+}	0.9	0.6 - 1.2	1.2	0.8 - 1.6	1.6	1.4 - 1.8

TABLE 2. Expected means and ranges for quality control solutions for cartridge #3. (specified by manufacturer for each box--PO_2, PCO_2 in mm Hg, K^+, Ca^{2+} in mmol/L)

	Low Level (I)		Normal Level (II)		High Level (III)	
Parameter	Mean	Expected Range	Mean	Expected Range	Mean	Expected Range
pH	7.04	6.99 - 7.09	7.35	7.31 - 7.39	7.56	7.52 - 7.60
PCO_2	77	65 - 89	47	42 - 52	22	15 - 29
PO_2	63	54 - 72	115	106 - 124	162	150 - 174
K^+	2.5	1.9 - 3.1	3.9	3.3 - 4.5	6.4	5.8 - 7.0
Ca^{2+}	0.9	0.6 - 1.2	1.2	0.8 - 1.6	1.6	1.4 - 1.8

TABLE 3. Environmental tests studied for the analyzer and supplies.

Cartridge	Test condition for GEM-6	Test Condition for GEM-PAK	Test Condition for GEM-CHECK's
1	-	-	-
2	High and low temperature	-	-
3	-	High temperature	-
4	-	Low temperature	-
5	-	-	No treatment (15 samples) High temperature (15 samples) Low temperature (15 samples)
6	-	Vibration	-
7	Vibration	-	No treatment (15 samples) Vibration (30 samples)
8		Shock	
9	Shock	-	No treatment (12 samples) Shock (24 samples)

TABLE 4. Summary of results for environmental testing of GEM-6 blood gas analyzer: pH

LOW LEVEL QUALITY CONTROLS (ACIDOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	7.05	7.09	7.06	0.01	0.01	0
3	HOT CARTRIDGE	10	7.01	7.09	7.06	0.03	0.02	0
4	COLD CARTRIDGE	11	7.08	7.10	7.09	0.01	0.04	0
5	CONTROLS FOR TEMP QC'S	5	7.05	7.07	7.06	0.01	0.01	0
5	HOT QC'S	5	7.04	7.05	7.05	0.01	0.00	0
5	COLD QC'S	5	7.04	7.04	7.04	0.00	-0.01	0
7	VIBRATION ANALYZER	5	7.06	7.08	7.07	0.01	0.02	0
7	VIBRATION QC'S	10	7.05	7.06	7.05	0.01	0.00	0
9	SHOCK ANALYZER	4	7.05	7.06	7.05	0.01	0.00	0
9	SHOCK QC'S	8	7.05	7.07	7.06	0.01	0.01	0

NORMAL LEVEL QUALITY CONTROLS (NORMAL)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	16	7.36	7.38	7.37	0.01	0.02	0
3	HOT CARTRIDGE	8	7.31	7.36	7.33	0.02	-0.02	0
4	COLD CARTRIDGE	11	7.40	7.41	7.41	0.01	0.06	11
5	CONTROLS FOR TEMP QC'S	5	7.34	7.34	7.34	0.00	-0.01	0
5	HOT QC'S	5	7.34	7.34	7.34	0.00	-0.01	0
5	COLD QC'S	5	7.32	7.32	7.32	0.00	-0.03	0
7	VIBRATION ANALYZER	5	7.34	7.35	7.34	0.01	-0.01	0
7	VIBRATION QC'S	10	7.34	7.35	7.34	0.00	-0.01	0
9	SHOCK ANALYZER	4	7.34	7.35	7.34	0.01	-0.01	0
9	SHOCK QC'S	8	7.34	7.35	7.34	0.01	-0.01	0

HIGH LEVEL QUALITY CONTROLS (ALKALOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	7.58	7.60	7.59	0.01	0.02	0
3	HOT CARTRIDGE	10	7.52	7.54	7.53	0.01	-0.03	2
4	COLD CARTRIDGE	11	7.64	7.65	7.64	0.00	0.07	11
5	CONTROLS FOR TEMP QC'S	5	7.55	7.56	7.55	0.00	-0.02	0
5	HOT QC'S	5	7.55	7.56	7.55	0.00	0.02	0
5	COLD QC'S	5	7.51	7.51	7.51	0.00	-0.06	5
7	VIBRATION ANALYZER	5	7.54	7.56	7.55	0.01	-0.02	0
7	VIBRATION QC'S	10	7.54	7.55	7.55	0.00	-0.02	0
9	SHOCK ANALYZER	4	7.54	7.56	7.55	0.01	-0.02	0
9	SHOCK QC'S	8	7.55	7.56	7.55	0.01	-0.02	0

CART # = CARTRIDGE NUMBER; N = NUMBER OF SAMPLES AT GIVEN QC LEVEL; MIN/MAX = MINIMUM/MAXIMUM VALUES MEASURED; MEAN = MEASURED MEAN; MEAN DIFF = MEAN-EXPECTED MEAN; # OUT OF RANGE = NUMBER OF SAMPLES FOR WHICH MEASURED VALUE WAS OUTSIDE EXPECTED RANGE; QC'S = QUALITY CONTROLS; TEMP = TEMPERATURE

TABLE 5. Summary of results for environmental testing of GEM-6 blood gas analyzer: PCO_2 (mm Hg)

LOW LEVEL QUALITY CONTROLS (ACIDOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	67	78	74.6	2.9	-2.4	0
3	HOT CARTRIDGE	10	71	94	79.2	8.3	2.2	2
4	COLD CARTRIDGE	11	72	80	76.7	2.9	-0.3	0
5	CONTROLS FOR TEMP QC'S	5	74	79	76.8	2.6	-0.2	0
5	HOT QC'S	5	78	83	80.8	1.8	3.8	0
5	COLD QC'S	5	79	83	81.4	1.5	4.4	0
7	VIBRATION ANALYZER	5	72	76	73.8	1.8	-3.2	0
7	VIBRATION QC'S	10	76	81	78.8	1.5	1.8	0
9	SHOCK ANALYZER	4	76	82	79.3	2.5	2.3	0
9	SHOCK QC'S	8	74	86	80.6	3.9	3.4	0

NORMAL LEVEL QUALITY CONTROLS (NORMAL)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	16	46	49	47.1	0.9	0.1	0
3	HOT CARTRIDGE	8	46	52	48.5	2.1	2.5	0
4	COLD CARTRIDGE	11	45	49	47.4	1.1	0.4	0
5	CONTROLS FOR TEMP QC'S	5	47	49	47.6	0.9	0.6	0
5	HOT QC'S	5	47	49	48.0	0.7	1.0	0
5	COLD QC'S	5	48	50	48.6	0.9	1.6	0
7	VIBRATION ANALYZER	5	47	48	47.2	0.4	0.2	0
7	VIBRATION QC'S	10	47	48	47.4	0.5	0.4	0
9	SHOCK ANALYZER	4	47	48	47.5	0.6	0.5	0
9	SHOCK QC'S	8	46	50	47.8	1.6	0.8	0

HIGH LEVEL QUALITY CONTROLS (ALKALOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	20	22	20.8	0.7	-1.2	0
3	HOT CARTRIDGE	10	19	23	21.0	1.8	-1.0	0
4	COLD CARTRIDGE	11	20	22	20.6	0.7	-1.4	0
5	CONTROLS FOR TEMP QC'S	5	20	20	20.0	0.0	-2.0	0
5	HOT QC'S	5	20	20	20.0	0.0	-2.0	0
5	COLD QC'S	5	20	21	20.6	0.6	-1.4	0
7	VIBRATION ANALYZER	5	20	21	21.2	0.4	-0.8	0
7	VIBRATION QC'S	10	20	21	20.4	0.5	-1.6	0
9	SHOCK ANALYZER	4	19	20	19.8	0.5	-2.2	0
9	SHOCK QC'S	8	19	20	19.9	0.4	-2.1	0

CART # = CARTRIDGE NUMBER; N = NUMBER OF SAMPLES AT GIVEN QC LEVEL; MIN/MAX = MINIMUM/MAXIMUM VALUES MEASURED; MEAN = MEASURED MEAN; MEAN DIFF = MEAN-EXPECTED MEAN; # OUT OF RANGE = NUMBER OF SAMPLES FOR WHICH MEASURED VALUE WAS OUTSIDE EXPECTED RANGE; QC'S = QUALITY CONTROLS; TEMP = TEMPERATURE

TABLE 6. Summary of results for environmental testing of GEM-6 blood gas analyzer: PO_2 (mm Hg)

LOW LEVEL QUALITY CONTROLS (ACIDOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	59	81	65.9	6.9	3.9	3
3	HOT CARTRIDGE	10	62	73	66.2	4.0	3.2	0
4	COLD CARTRIDGE	11	54	80	66.4	7.3	4.4	1
5	CONTROLS FOR TEMP QC'S	5	65	69	67.2	1.5	5.2	0
5	HOT QC'S	5	59	67	63.8	3.0	1.8	0
5	COLD QC'S	5	58	66	62.6	3.0	0.6	0
7	VIBRATION ANALYZER	5	59	72	64.8	5.0	2.8	0
7	VIBRATION QC'S	10	57	70	62.9	4.2	0.9	0
9	SHOCK ANALYZER	4	58	74	64.3	7.1	2.3	1
9	SHOCK QC'S	8	51	79	61.3	9.0	-0.7	1

NORMAL LEVEL QUALITY CONTROLS (NORMAL)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	16	107	121	113.3	4.1	0.3	0
3	HOT CARTRIDGE	8	114	121	117.6	2.7	2.6	0
4	COLD CARTRIDGE	11	107	116	111.8	3.1	-1.2	0
5	CONTROLS FOR TEMP QC'S	5	109	118	113.4	3.3	0.4	0
5	HOT QC'S	5	111	114	112.6	1.1	-0.4	0
5	COLD QC'S	5	108	118	113.4	3.7	0.4	0
7	VIBRATION ANALYZER	5	109	116	113.0	2.7	0.0	0
7	VIBRATION QC'S	10	108	119	113.2	3.5	0.2	0
9	SHOCK ANALYZER	4	108	118	111.3	4.6	-1.7	0
9	SHOCK QC'S	8	105	124	112.9	5.8	-0.1	1

HIGH LEVEL QUALITY CONTROLS (ALKALOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	152	173	157.9	5.6	-2.1	1
3	HOT CARTRIDGE	10	165	173	168.9	2.8	6.9	1
4	COLD CARTRIDGE	11	158	165	161.5	2.2	1.5	0
5	CONTROLS FOR TEMP QC'S	5	157	164	159.2	2.8	-0.8	0
5	HOT QC'S	5	158	165	160.6	3.0	0.6	0
5	COLD QC'S	5	156	160	157.6	1.5	-2.4	0
7	VIBRATION ANALYZER	5	158	163	160.6	2.7	0.6	0
7	VIBRATION QC'S	10	159	164	161.5	1.6	1.5	0
9	SHOCK ANALYZER	4	156	229	174.8	36.2	14.8	1
9	SHOCK QC'S	8	156	169	161.0	4.1	1.0	0

CART # = CARTRIDGE NUMBER; N = NUMBER OF SAMPLES AT GIVEN QC LEVEL; MIN/MAX = MINIMUM/MAXIMUM VALUES MEASURED; MEAN = MEASURED MEAN; MEAN DIFF = MEAN-EXPECTED MEAN; # OUT OF RANGE = NUMBER OF SAMPLES FOR WHICH MEASURED VALUE WAS OUTSIDE EXPECTED RANGE, QC'S = QUALITY CONTROLS; TEMP = TEMPERATURE

TABLE 7. Summary of results for environmental testing of GEM-6 blood gas analyzer: K^+ (mmol/L)

LOW LEVEL QUALITY CONTROLS (ACIDOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	2.5	2.7	2.58	0.06	0.08	0
3	HOT CARTRIDGE	10	2.5	2.8	2.61	0.10	0.11	0
4	COLD CARTRIDGE	11	2.5	2.6	2.55	0.05	0.05	0
5	CONTROLS FOR TEMP QC'S	5	2.5	2.6	2.58	0.04	0.08	0
5	HOT QC'S	5	2.4	2.7	2.56	0.11	0.06	0
5	COLD QC'S	5	2.5	2.6	2.58	0.04	0.08	0
7	VIBRATION ANALYZER	5	2.5	2.6	2.56	0.05	0.06	0
7	VIBRATION QC'S	10	2.5	2.6	2.58	0.04	0.08	0
9	SHOCK ANALYZER	4	2.5	2.6	2.58	0.05	0.08	0
9	SHOCK QC'S	8	2.5	2.7	2.59	0.06	0.09	0

NORMAL LEVEL QUALITY CONTROLS (NORMAL)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	16	3.9	4.0	3.91	0.03	0.01	0
3	HOT CARTRIDGE	8	3.9	4.1	3.94	0.07	0.04	0
4	COLD CARTRIDGE	11	3.8	3.9	3.87	0.05	-0.03	0
5	CONTROLS FOR TEMP QC'S	5	3.8	3.9	3.88	0.04	-0.02	0
5	HOT QC'S	5	3.8	4.1	3.92	0.11	0.02	0
5	COLD QC'S	5	3.9	3.9	3.90	0.00	0.00	0
7	VIBRATION ANALYZER	5	3.9	3.9	3.90	0.00	0.00	0
7	VIBRATION QC'S	10	3.8	4.0	3.88	0.06	-0.02	0
9	SHOCK ANALYZER	4	3.9	3.9	3.90	0.00	0.00	0
9	SHOCK QC'S	8	3.9	4.0	3.93	0.05	0.03	0

HIGH LEVEL QUALITY CONTROLS (ALKALOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	6.1	6.4	6.20	0.10	-0.10	0
3	HOT CARTRIDGE	10	6.1	6.2	6.14	0.05	-0.26	0
4	COLD CARTRIDGE	11	5.9	6.2	6.05	0.08	-0.25	0
5	CONTROLS FOR TEMP QC'S	5	6.0	6.1	6.08	0.04	-0.22	0
5	HOT QC'S	5	6.1	6.2	6.12	0.04	-0.18	0
5	COLD QC'S	5	6.1	6.2	6.14	0.05	-0.16	0
7	VIBRATION ANALYZER	5	6.1	6.2	6.12	0.04	-0.18	0
7	VIBRATION QC'S	10	6.0	6.2	6.10	0.07	-0.20	0
9	SHOCK ANALYZER	4	6.2	6.4	6.25	0.10	-0.05	0
9	SHOCK QC'S	8	6.1	6.2	6.19	0.04	-0.11	0

CART # = CARTRIDGE NUMBER; N = NUMBER OF SAMPLES AT GIVEN QC LEVEL; MIN/MAX = MINIMUM/MAXIMUM VALUES MEASURED; MEAN = MEASURED MEAN; MEAN DIFF = MEAN-EXPECTED MEAN; # OUT OF RANGE = NUMBER OF SAMPLES FOR WHICH MEASURED VALUE WAS OUTSIDE EXPECTED RANGE; QC'S = QUALITY CONTROLS; TEMP = TEMPERATURE

TABLE 8. Summary of results for environmental testing of GEM-6 blood gas analyzer: Ca^{2+} (mmol/L)

LOW LEVEL QUALITY CONTROLS (ACIDOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	0.9	1.0	0.91	0.02	0.01	0
3	HOT CARTRIDGE	10	0.8	0.9	0.87	0.05	-0.03	0
4	COLD CARTRIDGE	11	3.9	4.8	4.40	0.31	3.50	11
5	CONTROLS FOR TEMP QC'S	5	0.8	0.9	0.84	0.05	-0.06	0
5	HOT QC'S	5	0.8	0.9	0.84	0.05	-0.06	0
5	COLD QC'S	5	0.6	0.7	0.66	0.05	-0.24	0
7	VIBRATION ANALYZER	5	0.9	1.0	0.92	0.04	0.02	0
7	VIBRATION QC'S	10	0.8	0.9	0.89	0.03	-0.01	0
9	SHOCK ANALYZER	4	0.8	0.9	0.85	0.06	-0.05	0
9	SHOCK QC'S	8	0.8	0.9	0.85	0.05	-0.05	0

NORMAL LEVEL QUALITY CONTROLS (NORMAL)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	16	1.2	1.3	1.24	0.05	0.04	0
3	HOT CARTRIDGE	8	1.1	1.2	1.14	0.05	-0.06	0
4	COLD CARTRIDGE	11	6.9	8.9	7.88	0.62	6.68	11
5	CONTROLS FOR TEMP QC'S	5	1.1	1.1	1.10	0.00	-0.10	0
5	HOT QC'S	5	1.1	1.2	1.12	0.04	-0.08	0
5	COLD QC'S	5	0.4	0.6	0.48	0.08	-0.72	5
7	VIBRATION ANALYZER	5	1.2	1.3	1.22	0.04	0.02	0
7	VIBRATION QC'S	10	1.2	1.2	1.20	0.00	0.00	0
9	SHOCK ANALYZER	4	1.0	1.2	1.13	0.10	-0.07	0
9	SHOCK QC'S	8	1.0	1.2	1.13	0.09	-0.07	0

HIGH LEVEL QUALITY CONTROLS (ALKALOSIS)

CART #	TREATMENT	N	MIN	MAX	MEAN	STD DEV	MEAN DIFF	# OUT OF RANGE
1	CONTROLS	17	1.6	1.9	1.72	0.07	0.12	0
3	HOT CARTRIDGE	10	1.5	1.6	1.51	0.03	-0.09	0
4	COLD CARTRIDGE	11	12.6	15.4	14.51	0.92	12.91	11
5	CONTROLS FOR TEMP QC'S	5	1.5	1.6	1.54	0.05	-0.06	0
5	HOT QC'S	5	1.5	1.6	1.52	0.04	-0.08	0
5	COLD QC'S	5	0.4	0.5	0.44	0.05	-1.16	5
7	VIBRATION ANALYZER	5	1.6	1.7	1.68	0.04	0.08	0
7	VIBRATION QC'S	10	1.6	1.7	1.65	0.05	0.05	0
9	SHOCK ANALYZER	4	1.5	1.6	1.55	0.06	-0.05	0
9	SHOCK QC'S	8	1.4	1.6	1.54	0.07	-0.06	0

CART # = CARTRIDGE NUMBER; N = NUMBER OF SAMPLES AT GIVEN QC LEVEL; MIN/MAX = MINIMUM/MAXIMUM VALUES MEASURED; MEAN = MEASURED MEAN; MEAN DIFF = MEAN-EXPECTED MEAN; # OUT OF RANGE = NUMBER OF SAMPLES FOR WHICH MEASURED VALUE WAS OUTSIDE EXPECTED RANGE; QC'S = QUALITY CONTROLS; TEMP = TEMPERATURE

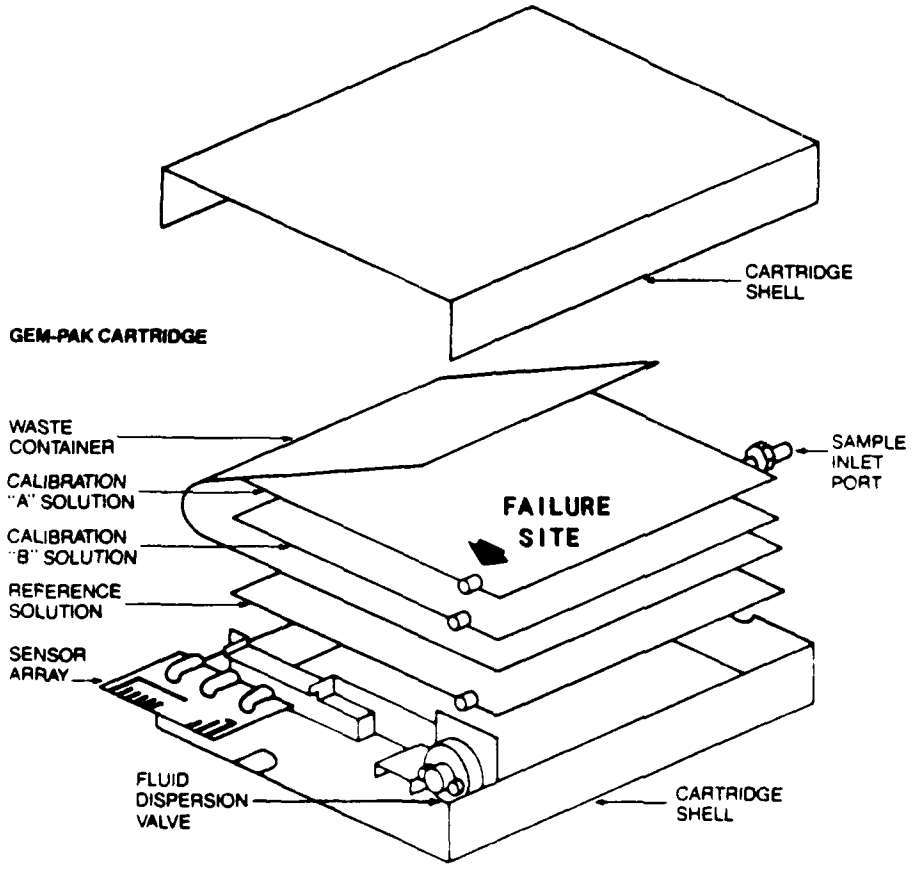

Figure 2. Site of failure on the cartridges subjected to shock and vibration.

TABLE 9. Current cost and storage considerations for GEM-6 and supplies.

Cost	GEM-6 Analyzer	$16,000
	GEM-PAK Cartridge	$300
	GEM-CHECK Quality Controls	$100
Shelf Life	GEM-PAK Cartridge	6 months
	GEM-CHECK Quality Controls	12 months
Recommended Operational Temperature	GEM-PAK Cartridge	15-25°C
	GEM-CHECK Quality Controls	20-28°C

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ABBREVIATIONS

BE	base excess
Ca^{2+}	calcium ion concentration
cm	centimeter
HCO_3^-	bicarbonate concentration
HCT	hematocrit
K^+	potassium ion concentration
kg	kilogram
L	liter
mm Hg	millimeters of mercury
mmol	millimoles
Na^+	sodium ion concentration
PCO_2	partial pressure of carbon dioxide
pH	negative logarithm of hydrogen ion concentration
PO_2	partial pressure of oxygen
SaO_2	oxygen saturation of hemoglobin
TCO_2	total carbon dioxide concentration

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