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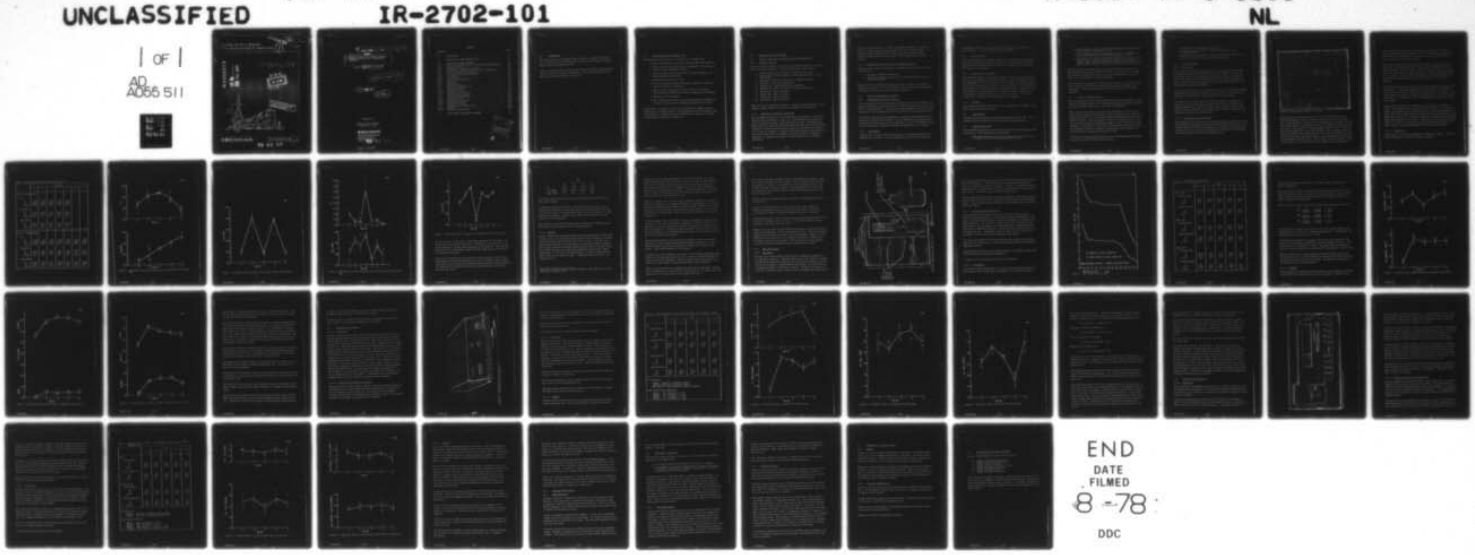

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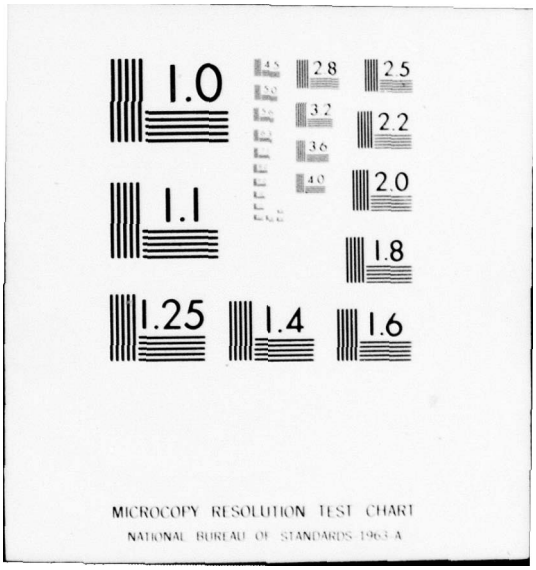
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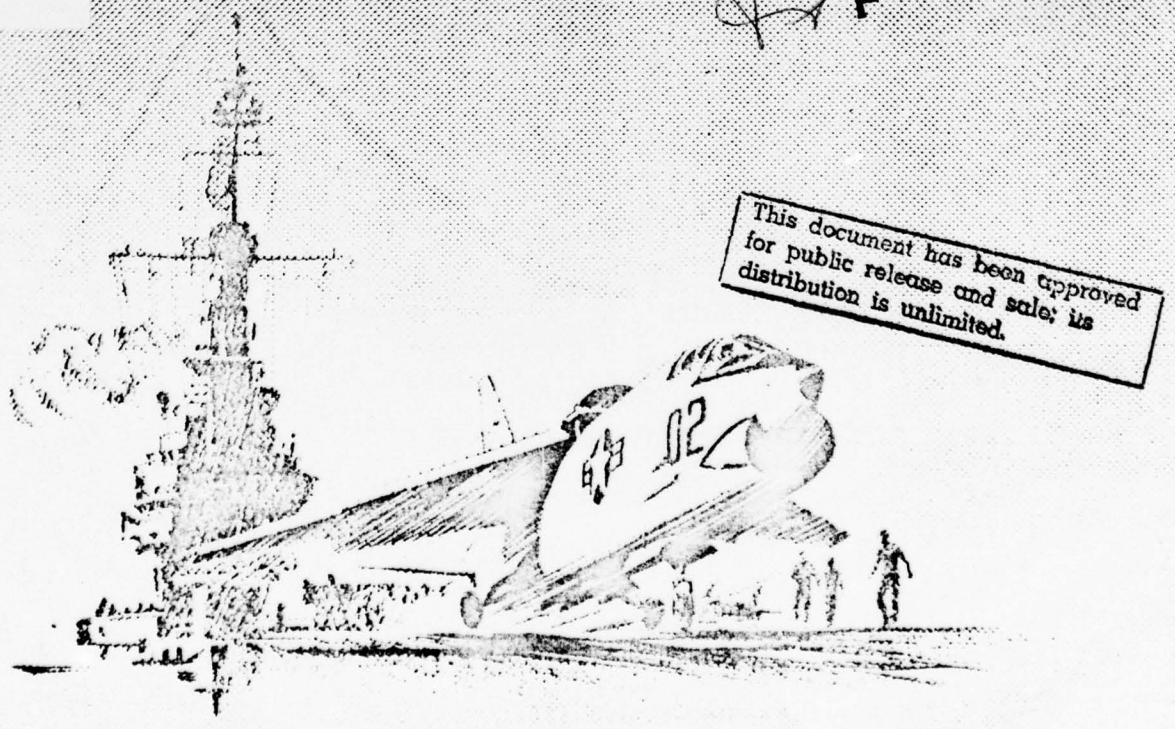
# Design and Test of an Integrated Modular Clinical Laboratory for Shipboard Use



MODULAB







BECKMAN

BECKMAN INSTRUMENTS, INC.
ADVANCED TECHNOLOGY OPERATIONS

(9) STATUS REPORT, 23 MAR-23 SEP 77.

MODULAB

(6) Design and Test of an Integrated Modular Clinical Laboratory for Shipboard Use (MODULAB).

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CONTENTS

## 1.0 INTRODUCTION

This Status Report for the MODULAB Program (Contract No. N00014-77-C-0153) for the U.S. Navy Office of Naval Research covers the first six months of effort--March 23, 1977, to September 23, 1977.

Section 2.0 describes the activities planned for the six-month reporting period. Section 3.0 describes the work accomplished. The activities planned for the next six months are described in Section 4.0.

## 2.0 PROGRAM PLAN--MARCH-SEPTEMBER, 1977

The MODULAB Program was planned to accomplish the following tasks:

- Review the measurement requirements and applicable specifications.
- Review the instruments that had been recommended for procurement to assure the most appropriate selection.
- Review the applicable specifications, selected instruments, and design approach with the Navy.
- Procure the instruments of choice.
- Test the instruments in the off-the-shelf condition to establish a reference baseline of performance.
- Make an engineering analysis of the electronic and mechanical assemblies and establish modifications to ruggedize the instruments.
- Implement the modifications.
- After modification, retest each instrument against the established baseline to ensure that no performance degradation had occurred.

At this time, our program is about one month behind our original schedule. This is due to a greater number of start-up problems with the instruments than we had expected. The details of these problems and a discussion of all the work performed is included in Section 3.0.

## 3.0 DESCRIPTION OF WORK PERFORMED

### 3.1 Review of Applicable Specifications and Navy Requirements

#### 3.1.1 Documents Reviewed

We reviewed several military specifications to determine whether they could be used as reasonable guidelines. The following documents were reviewed:

1. General Specification for Ships of the United States Navy
2. MIL-E-16400: Electronic Equipment, Naval Ships and Shore: General Specification
3. MIL-STD-167: Mechanical Vibrations of Shipboard Equipment
4. MIL-S-901: Shock Tests, High Impact
5. MIL-STD-1310: Shipboard Bonding and Grounding
6. NAVSHIPS 25-423-30: Shock Design of Shipboard Equipment
7. MIL-M-17185: Mounts, Resilient
8. MIL-M-17508: Mounts, Resilient
9. MIL-M-19379: Mounts, Resilient
10. MIL-M-19863: Mount, Resilient

Many were found not applicable, because of various program limitations, such as equipment design, weight of the equipment, and budget considerations.

#### 3.1.2 Limitation of Commercial Instruments

The instruments purchased are all off-the-shelf commercial units. The instruments meet the manufacturers' claims, are listed by Underwriter Laboratories, and are assembled according to good commercial practices. The manufacturers had no intent to design into these instruments any capability greater than that required for adequate performance under normal clinical laboratory conditions. As it is not our intention to change the functional designs in this program, we must limit modification to accessible areas involving parts replacement or additions, to ruggedize, and design to improve resistance to the shipboard environment.

The present configurations are suitable for bench-top operation. The operator must have access to the top, sides, and back of some of the instruments. To rack-mount these instruments where only the front panel would be readily accessible, modifications beyond the scope of this current effort would be required.

### 3.1.3 Specification Levels Selected for Present Instruments

The specification levels to be applied to the MODULAB instruments were selected on the basis of:

1. Anticipated shipboard environment;
2. Potential for modification that can be realized within the scope of the current program.

These levels are a compromise and could certainly be raised at a later date if found to be necessary. For now, the objective is the provision of an instrument set capable of being used on board to produce valid data.

## 3.2 Review of Recommended Instruments

### 3.2.1 Spectrophotometry Versus Clinicard

It was reported that Harleco had failed to develop kits for the determination of amylase α-HBDH with the Clinicard System. We had been informed earlier that these kits were being developed. A discussion was held regarding the deletion of these measurements from the required list, versus selection of an alternate approach.

The relative advantages and disadvantages of versatility and flexibility versus operational simplicity was discussed. It was concluded that guiding philosophy was operational simplicity, since this approach is central to the MODULAB concept. It was determined that analyses for amylase and α-HBDH will not be required.

### 3.2.2 Cell Counter

A substitution of a Hycel Blood Cell Counter for the originally proposed Clay Adams HA-4 was discussed. It was recognized that the Hycel Counter would not

accommodate the Unipet diluent system, which would have to be replaced by a pipetter/diluter. It was felt that this was acceptable.

### 3.2.3 Shock Resistance

It was pointed out that we would be unable to meet mil-spec shock requirements because of inherent instrument design limitations. We would, however, employ shock-protective mounting designs and make an assessment of shock resistance. This approach was acceptable.

### 3.2.4 Temperature Considerations

The temperature extremes listed in MIL-E016400 were discussed with particular reference to the high end of the specification. Since it is required to maintain temperatures at 37°C for several of the measurements, operation at temperatures above this level would require a cooling capability. It was pointed out that there were not sufficient funds in the current program to provide cooling modifications. It was determined that an analysis of the design impact of cooling provision should be made a part of the final report. These modifications may be accomplished in the next phase of the program.

### 3.2.5 Training

At the time of the Design Review, there was no requirement for training. This option should be kept open, however.

## 3.3 Design Review

A Design Review was held with the Navy R&D Command on April 19, 1977. The technical issues discussed are those just described in paragraph 3.2.

## 3.4 Hardware Procurement

The instruments purchased were from vendor stock and not specially prepared for this program. The following units were purchased:

- Clinicard Blood Chemistry System (Instrumentation Laboratory, Inc., 113 Hartwell venue, Lexington, Massachusetts 02173)

- Corning Blood Gas Analyzer, Model 165 (Corning Medical, Corning Glass Works, Medfield, Massachusetts 02052)
- Orion Biomedical Sodium/Potassium Analyzer, Model 55-30 (Orion Biomedical, 380 Putnam Avenue, Cambridge, Massachusetts 02139)
- Hycel Blood Cell Counter, Model HC-300 (Angel Engineering Corporation, 40 Mead Street, Stratford, Connecticut 06497). A Dade Diluter/Pipetter (Dade, Division of American Hospital Supply Corporation, P.O. Box 672, Miami, Florida 33152) was purchased to use with this unit.

The Hycel counter was chosen oven the Clay Adams Model HA-4 discussed in our MODULAB design report (FR-2697-102) of June 1976. Our review of the hardware now available revealed design features and construction details of the Hycel which we felt were superior for this application.

No difficulty was encountered in obtaining prompt delivery of any of the equipment. However, we did find more problems than expected in starting up the instruments. Details of the problems we found are covered in the following paragraphs.

## 3.5 Baseline Performance Tests

Since the instruments comprising the MODULAB system are to be modified as indicated by the design analyses, it is necessary to establish performance baselines in order to evaluate the effect, if any, of the modifications.

One of the selection criteria for each of the instruments was that it be in common use in clinical laboratories from which it follows that the principle of operation, accuracy, etc., are generally acceptable and would not require extensive evaluation. What was required, however, was to develop a set of data that would allow analysis of performance changes, if any, induced by the modifications. It was felt that this could be accomplished by analyzing for inter- and intradaily precision on secondary standards since such standards can be relatively easily controlled when compared to blood.

A test plan to evaluate baseline performance for each instrument was prepared. The salient features of the Test Plan are these:

- Comments on the standardization procedures;
- Results of precision tests: 10 analyses made daily for five consecutive days;
- Evaluation of radiated and line-generated electrical interference;
- Effects of 23-degree tilt on instrument performance.

### 3.5.1 Blood Gas Analyzer

#### 3.5.1.1 Description

Once calibrated, the Corning 165/2 Blood Gas Analyzer will provide six blood gas measurements from one sample within 90 seconds. Pushbutton controls provide digital readouts of directly-measured pH, $P_{O_2}$, and $P_{CO_2}$. An additional three pushbuttons give the calculated values for total $CO_2$ ($HCO_3$), and base excess. For base excess, the hemoglobin value of the sample (in g/dl) is the only additional required input datum.

A glass electrode measures pH; a modified electrode of the Stow and Severinghaus type measures $P_{CO_2}$; oxygen partial pressure is measured by a third electrode utilizing a platinum cathode, an Ag/AgCl anode, and an electrolyte.

An overall view of the Corning 165/2 is shown in Figure 1. Included in the system is a built-in flush system, calibration gases, buffer solution, and membrane-changing kits. There are no water baths or exposed glass elements. Electronic heating maintains close thermal control ($\pm 0.05°C$) of the block containing the electrodes and sample chamber.

#### 3.5.1.2 Testing the Blood Gas Analyzer

The Corning Blood Gas Analyzer was tested by performing ten analyses a day for five consecutive days using a tonometered bicarbonate-chloride solution. This solution appeared preferable for evaluating the precision of the instrument, since the collection, storage, and handling of whole blood is time consuming and difficult, and does not allow the desired control.

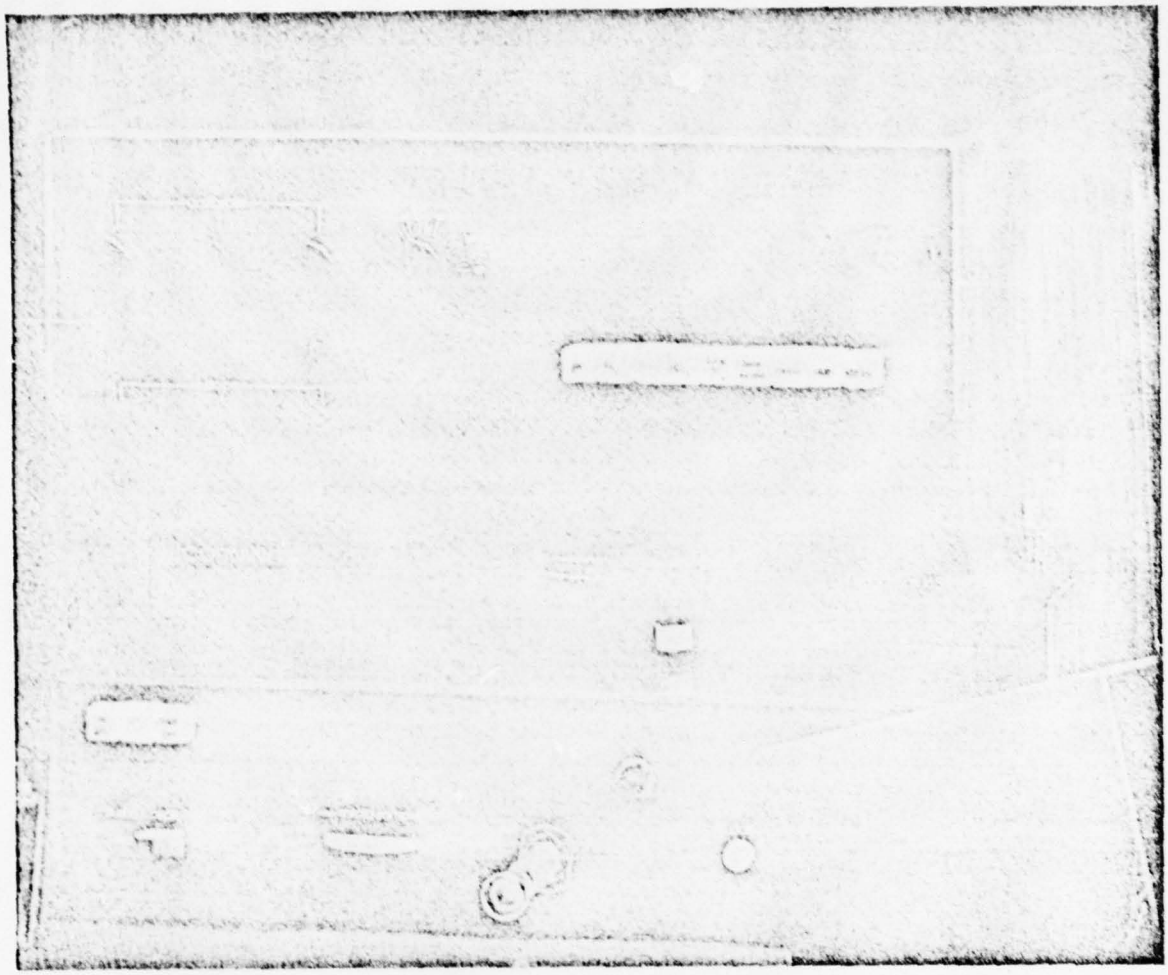


*Figure 1. Corning Blood Gas Analyzer, Model 165*

Our test solution was prepared according to a method reported in *Clinical Chemistry* by Daniel C. Noonan and Robert W. Burnett (Vol. 20, No. 6, 1974). Their formula specifies a solution of NaCl (150 mmol/liter) and $NaHCO_3$ (50 mmol/liter) equilibrated at room temperature with a gas composed of 21% $O_2$, 12% $CO_2$, and 67% $N_2$. This solution, in the Corning 165/2, gives a pH of 7.20 $\pm$0.02, a $P_{O_2}$ of 170 $\pm$10 mmHg, and a $P_{CO_2}$ of 110 $\pm$10 mmHg. The $P_{O_2}$ and $P_{CO_2}$ values are appreciably higher than the gas calibration values for the instrument, but the 21% $O_2$ of the solution has the advantage of not being appreciably affected by $O_2$ contamination from ambient air. Also, because of the high solubility of $CO_2$ in the solution, the loss of this gas to the ambient air is insignificant.

The Double Insertion Technique was performed for each sample measurement: a 0.5-mℓ injection followed by a pause of about 15 seconds, then a second 0.5-mℓ injection from the same syringe. Only the three direct measurements of pH, $P_{O_2}$, and $P_{CO_2}$ are made with this solution.

Before making sample measurements the analyzer must be prepared, as well as calibrated. The "Operating Procedures" give detailed introductions for the daily preparation of the instrument. Preparation consists largely of checking connections, gas flow rates, block temperature, condition of waste bottle and filter, action of flush mechanism, and changing the reference electrode solution. Special attention must be given to the condition of the electrode membranes.

Two standard buffer solutions are used to set the calibration and slope of the pH electrode. A two-point calibration of the gas electrodes is performed at the start of each day's work and should be repeated every 2 to 4 hours. A one-point calibration should be performed immediately prior to each unknown sample measurement. These procedures utilize a calibration and a slope gas, as well as pH buffers.

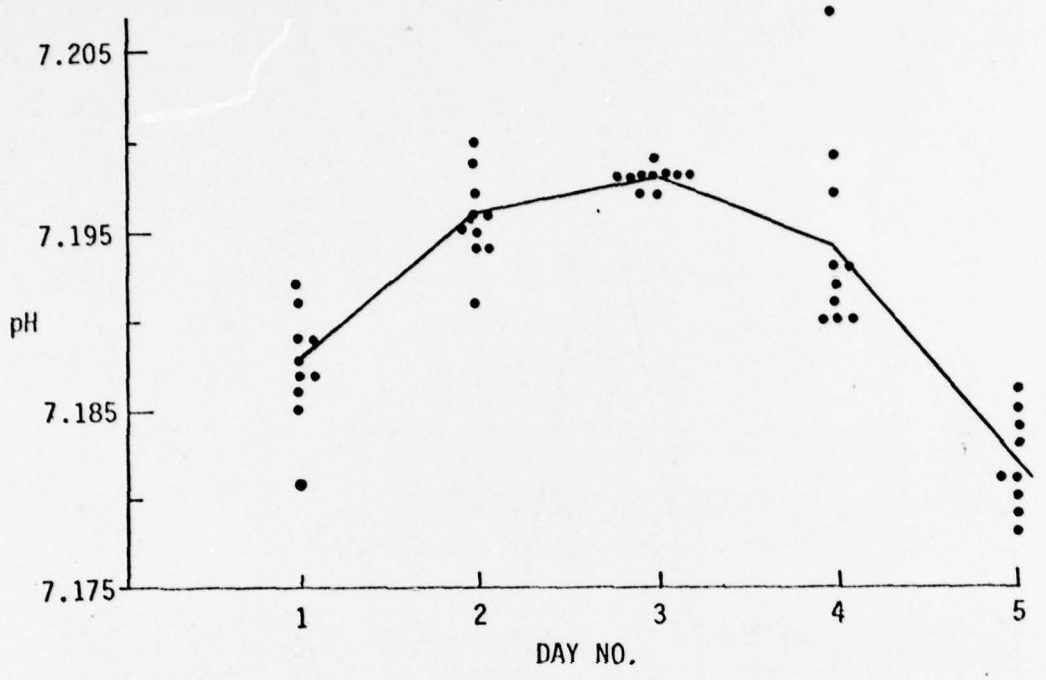
Preparation and calibration is somewhat involved and must be carefully performed. The complete procedure may require 15 to 30 minutes. The instrument remains fairly stable for the 20 minutes required to make the measurements, as evidenced by the one-point calibration made at the end of the test period. One should note, however, that a one-point calibration is suggested before each new sample and at the end of 2 to 4 hours. Since the gas electrodes tend to equilibrate very slowly, it is desirable to use the built-in timer (set for the slowest electrode) so that measurements will not be made prematurely.

### 3.5.1.3 Test Results

Test results for the Corning instrument are summarized in Table I. The individual measurements are plotted in Figures 2 through 5.

*TABLE I. TEST RESULTS FOR CORNING BLOOD GAS ANALYZER*

| | DAY NO. | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Set I: N=10 Samples | | | | | | | |
| pH: | | | | | | | |
| $\bar{X}$: | 7.188 | 7.196 | 7.198 | 7.194 | 7.182 | | |
| σ: | 0.003 | 0.003 | 0.001 | 0.006 | 0.003 | | |
| CV,%: | 0.04 | 0.04 | 0.01 | 0.10 | 0.10 | | |
| $P_{O_2}$ mmHg: | | | | | | | |
| $\bar{X}$: | 171.8 | 174.6 | 177.3 | 179.9 | 182.6 | | |
| σ: | 1.11 | 3.00 | 0.36 | 0.80 | 1.42 | | |
| CV,%: | 0.6 | 1.7 | 0.2 | 0.4 | 0.8 | | |
| $P_{CO_2}$ mmHg: | | | | | | | |
| $\bar{X}$: | 119.9 | 134.7 | 119.1 | 133.7 | 119.0 | | |
| σ: | 0.54 | 3.16 | 0.64 | 2.06 | 1.29 | | |
| CV,%: | 0.4 | 2.4 | 0.5 | 1.5 | 1.1 | | |
| Set II: N=10 Samples | | | | | | | |
| pH: | | | | | | | |
| $\bar{X}$: | 7.204 | 7.192 | 7.191 | 7.246 | 7.189 | 7.193 | 7.186 |
| σ: | 0.006 | 0.002 | 0.005 | 0.012 | 0.013 | 0.002 | 0.001 |
| CV,%: | 0.10 | 0.03 | 0.10 | 0.20 | 0.20 | 0.00 | 0.00 |
| $P_{O_2}$ mmHg: | | | | | | | |
| $\bar{X}$: | 175.7 | 180.7 | 179.1 | 183.4 | 172.2 | 178.6 | 174.2 |
| σ: | 3.19 | 2.60 | 3.02 | 0.99 | 1.10 | 1.43 | 2.00 |
| CV,%: | 1.8 | 1.4 | 1.7 | 0.5 | 0.6 | 0.8 | 1.2 |
| $P_{CO_2}$ mmHg: | | | | | | | |
| $\bar{X}$: | 120.2 | 126.0 | 134.4 | 103.2 | 127.9 | 125.2 | 129.1 |
| σ: | 1.10 | 3.97 | 2.21 | 2.16 | 2.03 | 0.62 | 0.93 |
| CV,%: | 0.9 | 3.1 | 1.6 | 2.1 | 1.6 | 0.5 | 0.7 |



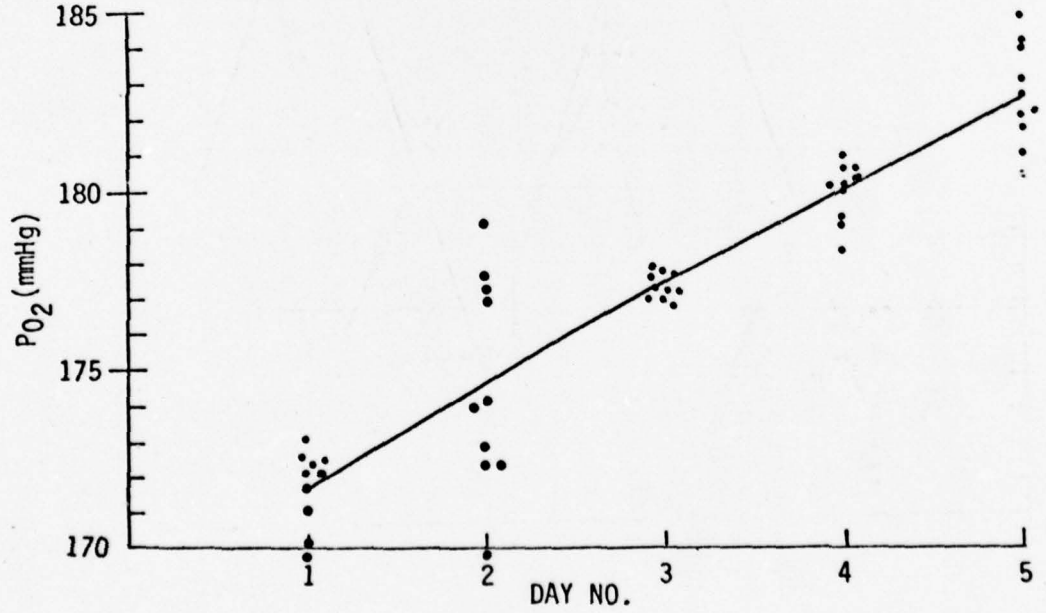




*Figure 2. Individual Values for pH and $P_{O_2}$, Set I (Corning 165/2)--Five-Day Test*

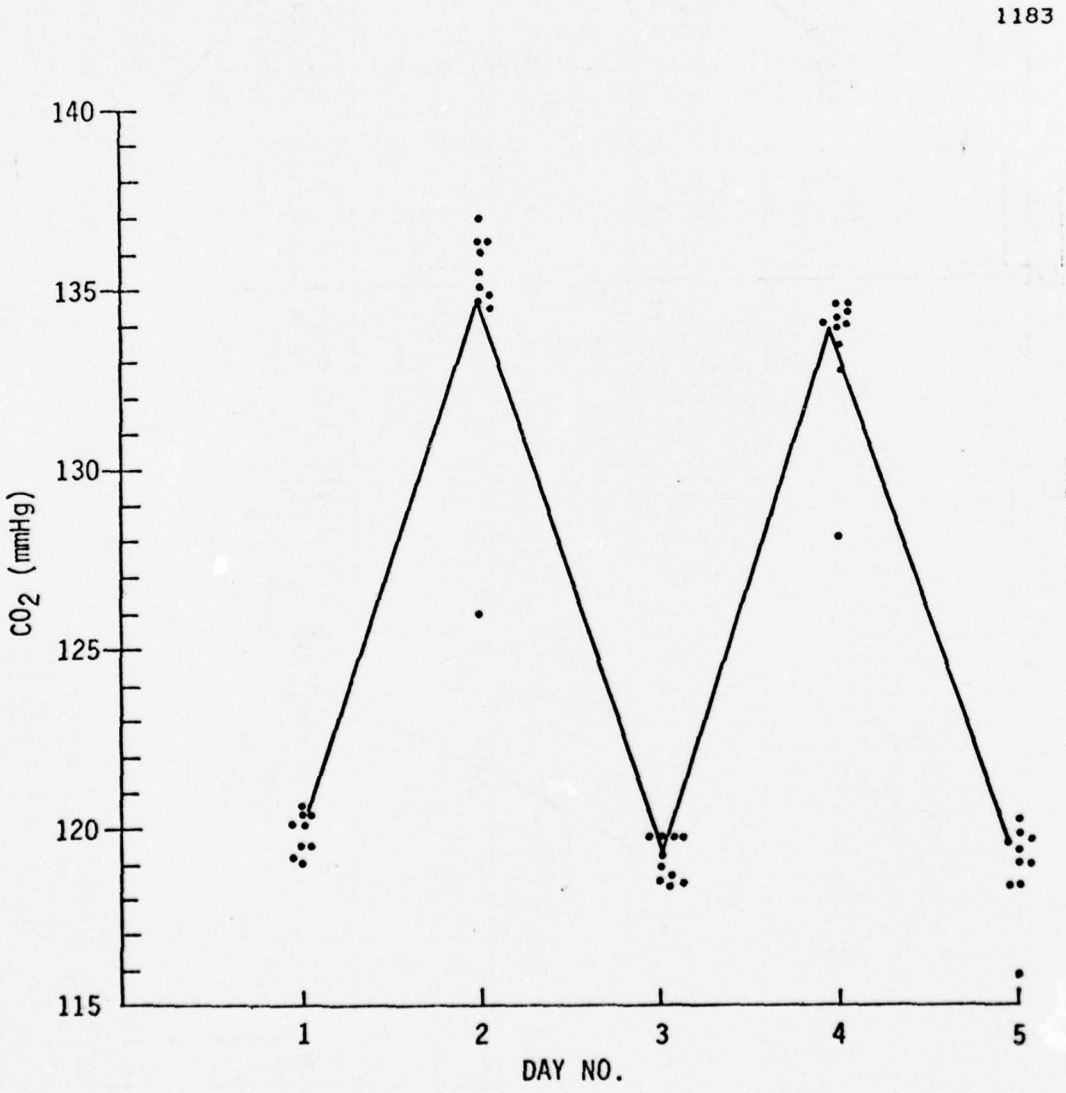



*Figure 3. Individual Values for $P_{CO_2}$, Set I (Corning 165/2)--Five-Day Test*

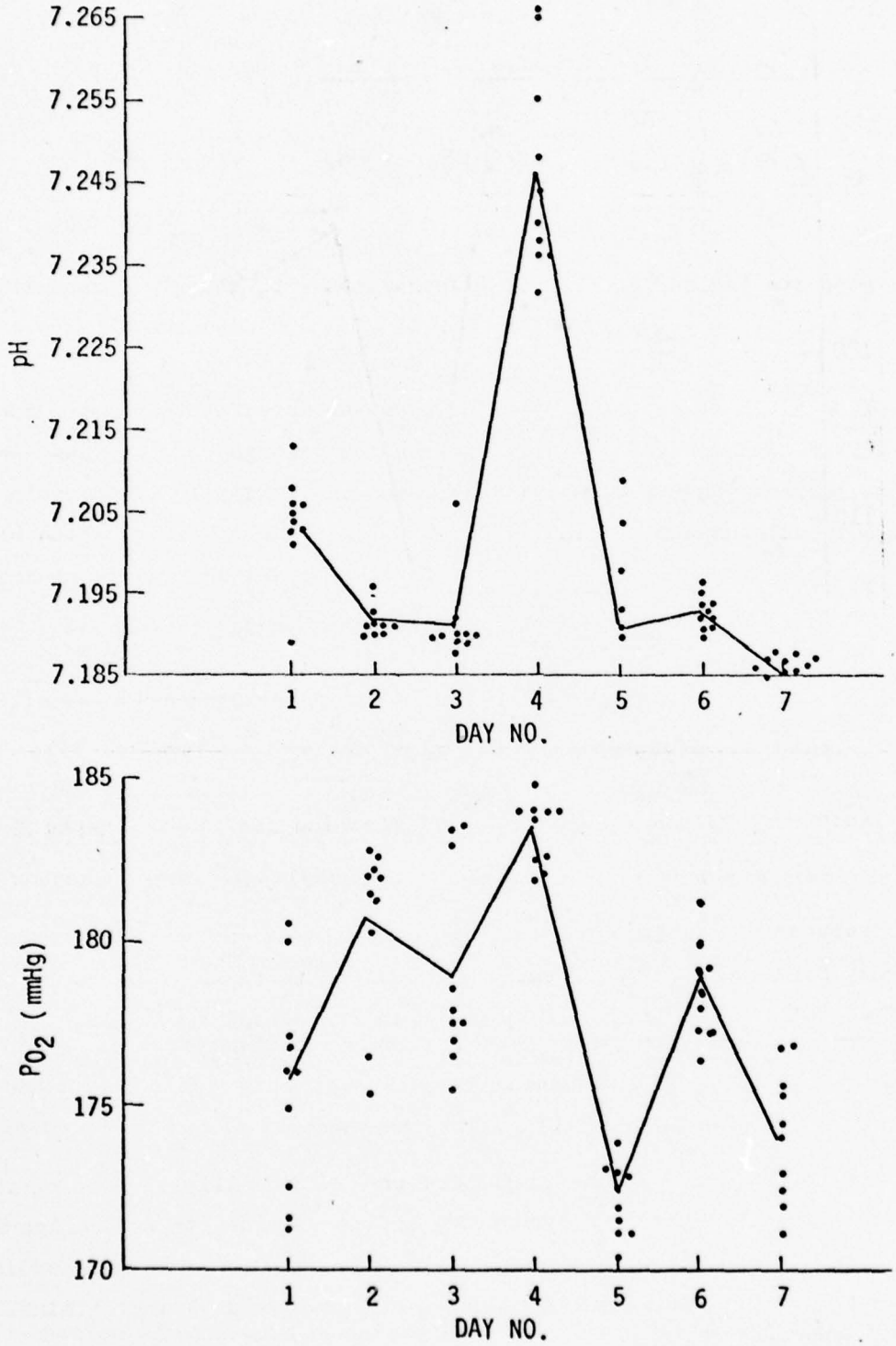



*Figure 4. Individual Values for pH and $P_{O_2}$, Set II (Corning 165/2)--Seven-Day Test*

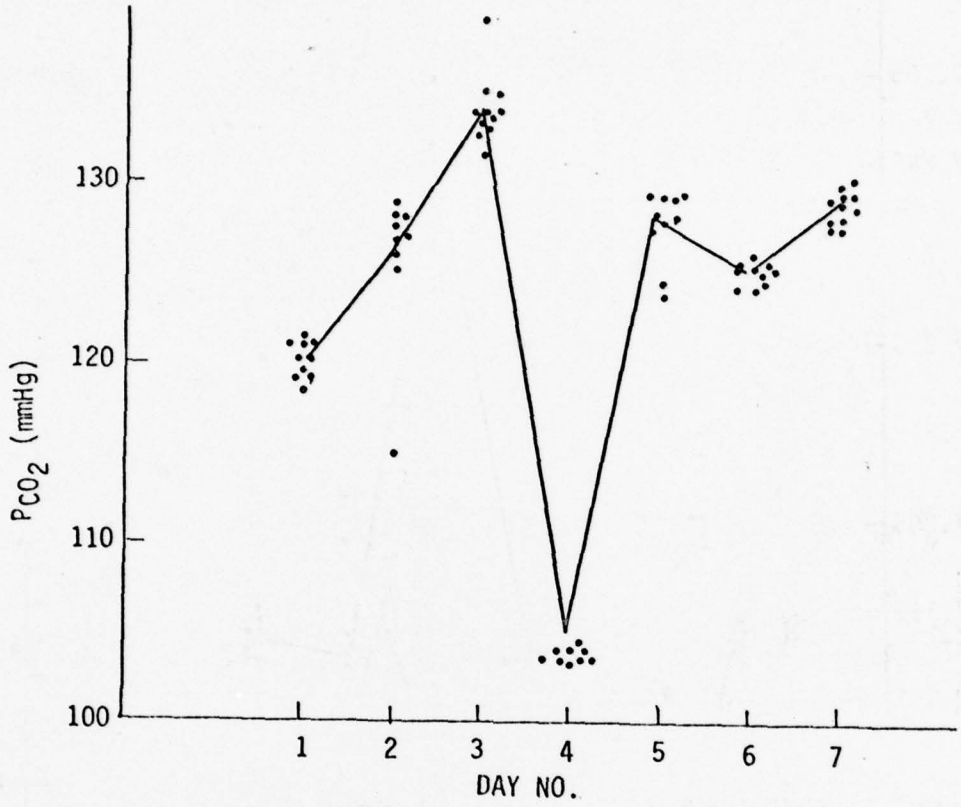



*Figure 5. Individual Values for $P_{CO_2}$, Set II (Corning 165/2)--Seven-Day Test*

The average values for $P_{O_2}$ in Set I increased from day-to-day, but there is no similar trend in the pH and $P_{CO_2}$ values. We decided to run a second set, over a seven-day period. No $P_{O_2}$ trend is apparent in the second set. The published data for the test solution shows similar five-day trends when the test period is extended to thirty days.

Another test solution which may be useful for on-board quality control of the measurements is made by General Diagnostics, and is provided in sealed ampules containing liquids and gases which simulate normal and abnormal blood conditions. We tested four of the normal-level ampules on consecutive days and obtained the following results:

| | DAY | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| pH | 7.381 | 7.395 | 7.387 | 7.374 |
| $P_{O_2}$ (mmHg) | 100.3 | 108.2 | 103.3 | 108.5 |
| $P_{CO_2}$ (mmHg) | 44.2 | 40.7 | 43.1 | 43.5 |

Still another system has been recently described* but has not been tested in this current program.

A Beckman Noise Generator was used to inject 100 Vac in 50-μs pulses, at a phase angle of 90 degrees, on the power line to the Corning 165/2. There was no discernible effect on the instrument readouts for any test parameter. Radiated noise, provided by a "noisy" electric drill, had no effect on the performance of the Corning 165/2.

The instrument was tilted from side-to-side approximately 23 degrees from the horizontal with no discernible effect on its performance.

3.5.1.4 Comments

Initial calibration of the Corning 165/2 and sample measurements required about an hour each day. The instruction manual assumes that the complete calibration and slope procedure will be carried out every 2 to 3 hours, and that a one-point calibration check will be made before each different sample measurement. Since we were using only the simple tonometered salt solution, we made the two-point calibration once a day and followed immediately with the test sample measurements. At the end of these measurements, a one-point calibration was made to check on any evidence of drift. In general, there was little or no evidence of drift.

*Evaluation of Ampuled Tonometered Buffer Solution, A.H.J. Maas, *et al.*, *Clin Chem* 23(9) 1718-1725 (1977).

Frequently, the first $P_{CO_2}$ measurement of a set has the lowest value. This would suggest dropping the first reading; however, this was not generally done. In one set, for example, including the low first $P_{CO_2}$ value, it gave an $\bar{X}$ of 103.2 mmHg, $\sigma$=2.16, and CV=2.1%. Omitting the low first value changed the results to $\bar{X}$=103.9 mmHg, $\sigma$=0.30, and CV=0.3%. Further investigation is indicated before coming to any conclusion about rejecting data points. (This effect is also mentioned later, in paragraph 3.5.3.4.)

During the testing of Set I, the red light warning for "Defective $O_2$ Membrane" persisted in coming on. The suggested remedies of washing, drying, or changing the membrane did nothing to eliminate the warning light. Subsequently, Corning informed us that several analyzers were known to have defective circuit boards controlling the warning light. When we replaced the faulty board, the problem disappeared.

A rubber stopper closing a humidifier vial in the instrument constantly worked its way out. This, too, was replaced. Although the original stopper was somewhat loose, it is also possible that too high a gas pressure in the line may force the stopper out. Although the manual gives 20.7 to 34.5 kPa (3 to 5 psi) for the gas pressure, the Field Representative prefers 13.8 to 20.7 kPa (2 to 3 psi), to avoid popping the stoppers.

When making adjustments on the back of the instrument, one must be careful to avoid moving a small projecting switch which adjusts the "$CO_2$ Zero." Accidentally moving this switch from "operate" to "adjust" will freeze the $CO_2$ readout. This should be mentioned in the manual.

It appears to be more convenient, in practice, to set the $P_{CO_2}$ calibration first, follow with the $P_{CO_2}$ slope adjustment, then set the $P_{O_2}$ Zero before making the final $P_{O_2}$ calibration adjustment. There is a minor error in the manual (paragraph 6.2.3), with respect to pushbutton settings for gas calibration.

There are no instructions for completely shutting down the instrument. However, this is readily done by leaving a buffer-filled syringe in the viewer socket and inserting the Gas Tubing outlet into the Sample Inlet Port.

The $P_{O_2}$ kit contained an obsolete fitting, our instrument was missing a Sample Viewer and two electrode cleaning reagents. The gas cylinders were out-dated, but probably all right to use. We did not receive a customer's manual. All of these items were eventually supplied. The friendly interest, full cooperation, and practical assistance given by Corning's Field Representative were greatly appreciated.

Membrane changing, frequently required, is readily accomplished by means of a convenient kit.

Because of the inherent nature of blood gas systems, strict adherence to scheduled maintenance routines is necessary to enjoy trouble-free service. There are daily, weekly, and monthly maintenance procedures to observe.

Corning also provides a variety of preventive maintenance agreements which, for this type of instrument, may be of value. Of course, this service could be implemented only when the ship was in port.

Perhaps more so than with the other MODULAB instruments, the blood gas analyzer requires a knowledgeable, careful, conscientious operator. That the instrument remains on does not mean it is ready to make a measurement. Manual, two-point calibrations must be made every 2 to 4 hours, and one-point calibration updates must be made before each sample. These procedures are time-consuming, and must be accurately performed in order to enjoy accurate results.

### 3.5.2 Blood Cell Counter

#### 3.5.2.1 Description

Blood cell counts and hemoglobin determinations for MODULAB are made with a Hycel 300 Counter (Figure 6). Measuring 30x21.5x33 cm (11-1/2x9/14-1/4 inches) this instrument measures RBC and WBC by the cell-conductivity method, and hemoglobin by the colorimetric cyanmethemoglobin methodology. The three tests can be performed accurately in less than two minutes. No tables are required to correct for coincidence counts, as this is done by automatic count compensation.

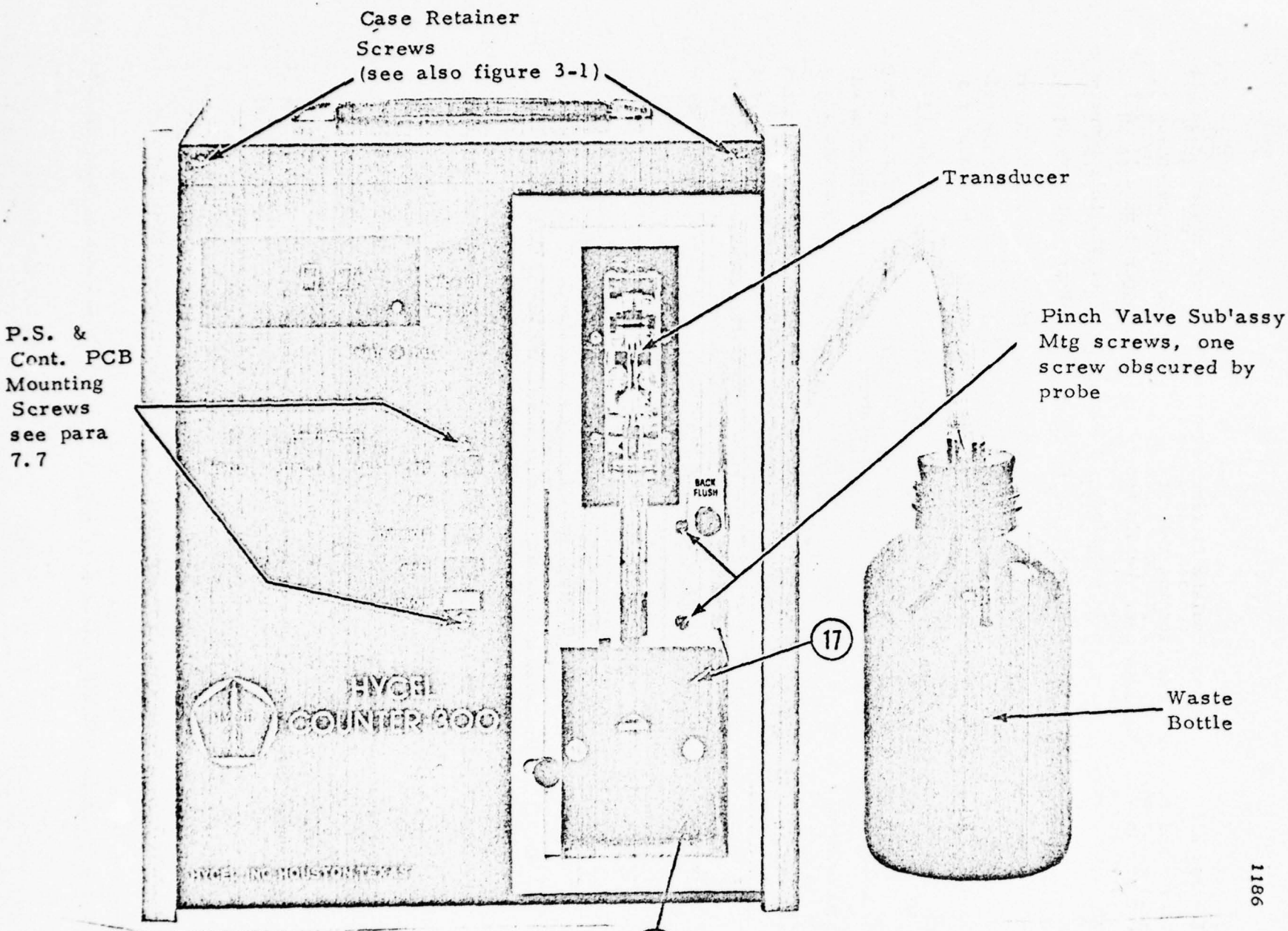



*Figure 6. Hycel Counter 300--Front View*

A dual light beam (540 nm) colorimeter makes the hemoglobin determination using the lysed WBC solution. The solid-state system is operated by pushbuttons. Only 25-μℓ samples are required. The readout is digital. An audible and visual signal indicates a clogged condition which is readily removed by a manual back-flush feature. No mercury is used in the volumetric system.

Although sampling and diluting may be performed manually, using pipettes, better repeatability and accuracy can be realized by using a highly precise automatic diluter. Hence, a Dade Automatic Diluter is used in conjunction with the Hycel Blood Cell Counter.

### 3.5.2.2 Testing the Blood Cell Counter

The Hycel Counter 300 requires several adjustments for setup and startup. First, the detergent and diluent are checked for possible contamination. Then, using a suitable hematology control, the threshold voltage is established for human blood cells. This procedure is performed for both red and white cells (RBC and WBC). Once established, the threshold voltage is checked daily (by depressing the THRESHOLD pushbutton). Diluent and lysing agent is used to set the hemoglobin zero. A hematology control for RBC is used to calibrate the colorimeter section of the Hycel for hemoglobin measurements.

Our test program required our making eleven RBC, WBC, and Hgb determinations daily for five consecutive days. This was done using both normal and abnormal hematology controls.

We also checked the Hycel for any abnormal effects on operation caused by radiated and line-imposed electrical interference.

A final test, the 23-degree tilt, has yet to be performed.

### 3.5.2.3 Test Results

The results of the threshold check on the Hycel counter are shown in Figure 7. The precision tests for RBC, WBC, and hemoglobin are tabulated in Table II.

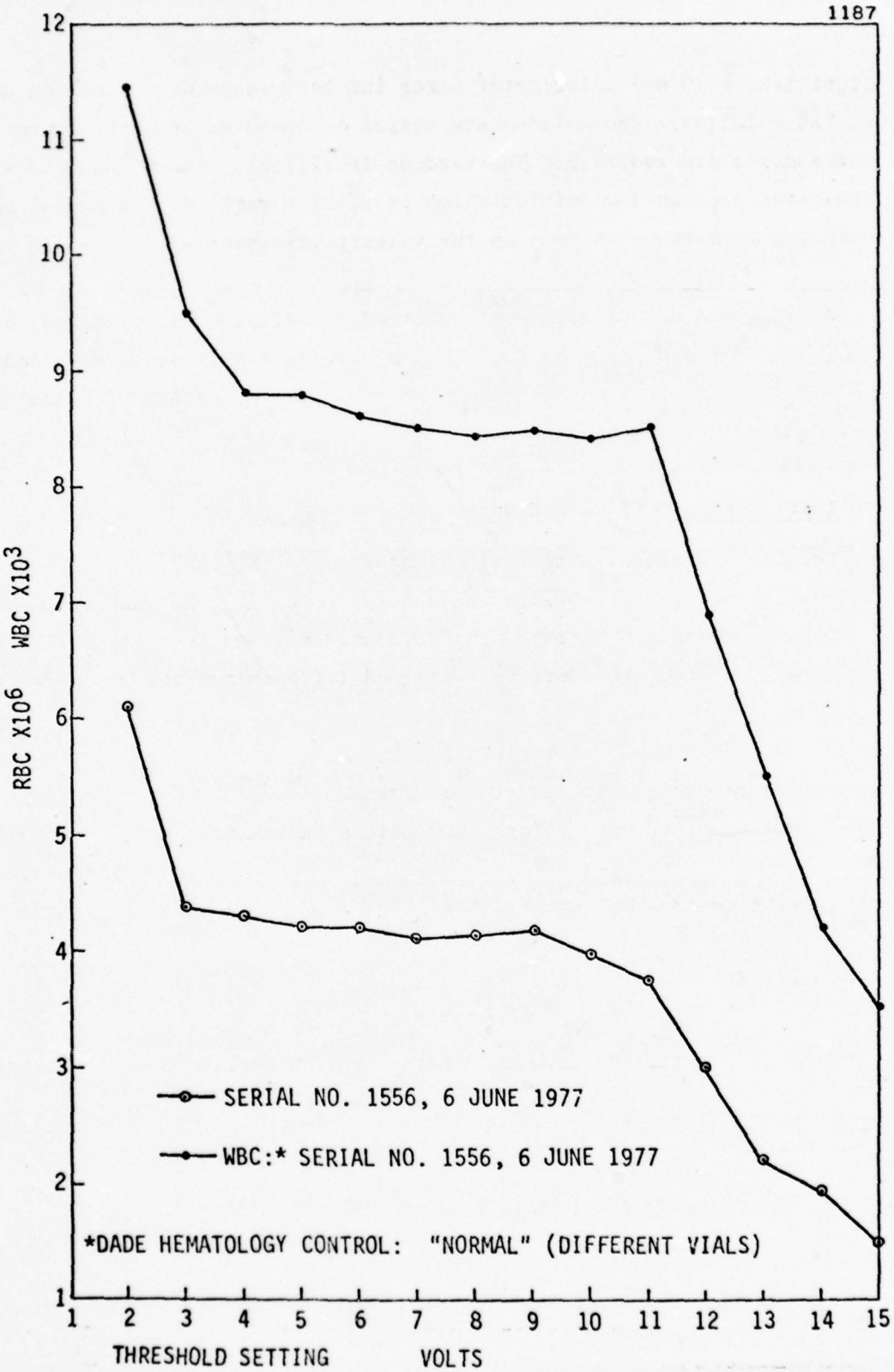



*Figure 7. Hycel Counter Threshold Plot*

*TABLE II. TEST RESULTS--RBC, WBC, Hgb*

| | DAY | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 |
| RBC: $x10^6$ | | | | | |
| Control-Normal | | | | | |
| $\bar{X}$: | 4.42 | 4.55 | 4.34 | 4.50 | 4.56 |
| σ: | 0.04 | 0.04 | 0.05 | 0.05 | 0.05 |
| CV,%: | 1 | 1 | 1 | 1 | 1 |
| Control-Abnormal | | | | | |
| $\bar{X}$: | 2.91 | 3.32 | 3.26 | 3.27 | 3.27 |
| σ: | 0.03 | 0.07 | 0.04 | 0.04 | 0.04 |
| CV,%: | 1 | 2 | 1.3 | 1 | 1 |
| WBC: $x10^3$ | | | | | |
| Control-Normal | | | | | |
| $\bar{X}$: | 8.1 | 8.5 | 8.4 | 8.5 | 8.5 |
| σ: | 0.08 | 0.12 | 0.08 | 0.12 | 0.13 |
| CV,%: | 1 | 1.4 | 1 | 1.4 | 1.5 |
| Control-Abnormal | | | | | |
| $\bar{X}$: | 13.6 | 14.8 | 15.2 | 15.2 | 14.8 |
| σ: | 0.18 | 0.14 | 0.14 | 0.20 | 0.14 |
| CV,%: | 1.4 | 1 | 1 | 1.3 | 1 |
| Hgb: gm/dl | | | | | |
| Control-Normal | | | | | |
| $\bar{X}$: | 12.5 | 14.2 | 13.7 | 13.6 | 13.4 |
| σ: | 0.18 | 0.24 | 0.11 | 0.11 | 0.17 |
| CV,%: | 1.5 | 1.7 | 1 | 1 | 1.3 |
| Control-Abnormal | | | | | |
| $\bar{X}$: | 8.2 | 9.3 | 9.5 | 9.5 | 9.0 |
| σ: | 0.09 | 0.09 | 0.21 | 0.09 | 0.11 |
| CV,%: | 1 | 1 | 2 | 1 | 1.3 |

Individual measurements contributing to the daily average are displayed in Figures 8 through 10.

Hematology controls (normal and abnormal) prepared by Dade Division of American Hospital Supply Corporation were used to make the measurements. These controls contain modified human and fixed avian blood cells in a buffered medium with added preservatives and stabilizers.

Dade's assay of the controls gives the following mean values (Coulter methods):

| | | |
|---|---|---|
| RBC - normal: | $4.49 \times 10^6$ | $\sigma = 0.05$ |
| - abnormal: | $3.28 \times 10^6$ | $\sigma = 0.05$ |
| WBC - normal: | $8.1 \times 10^3$ | $\sigma = 0.3$ |
| - abnormal: | $14.4 \times 10^3$ | $\sigma = 0.4$ |
| Hgb - normal: | 13.6 g/dl | $\sigma = 0.1$ |
| - abnormal: | 9.4 g/dl | $\sigma = 0.1$ |

Line-impressed electrical noise as low as 25 Vac (50 μs pulses) increased the background count from 0.05 to 0.5 ($\times 10^6$) in the RBC mode. In the WBC mode, the background count rose from 0.1 to 1.1 ($\times 10^3$).

Increasing the impressed noise voltage to 200 V made little difference. RBC counts rose from $3.4 \times 10^6$ to $3.9 \times 10^6$ when the noise generation was set at 200 V. WBC counts rose from $15.0 \times 10^3$ to $17.0 \times 10^3$. The noise effects were reduced by 50% when a voltage regulator was used between the noise generator and the counter.

Radiated interference was simply performed by approaching the counter with a "noisy" electric drill. Both the RBC and WBC readouts became very erratic when the drill was within two feet of the counter. The hemoglobin colorimeter was not affected by either of the EMI tests.

3.5.2.4 Comments

The daily RBC, WBC, and Hgb data were all obtained from one sample of the hematology control for "normal" blood, and from one sample for "abnormal" blood.

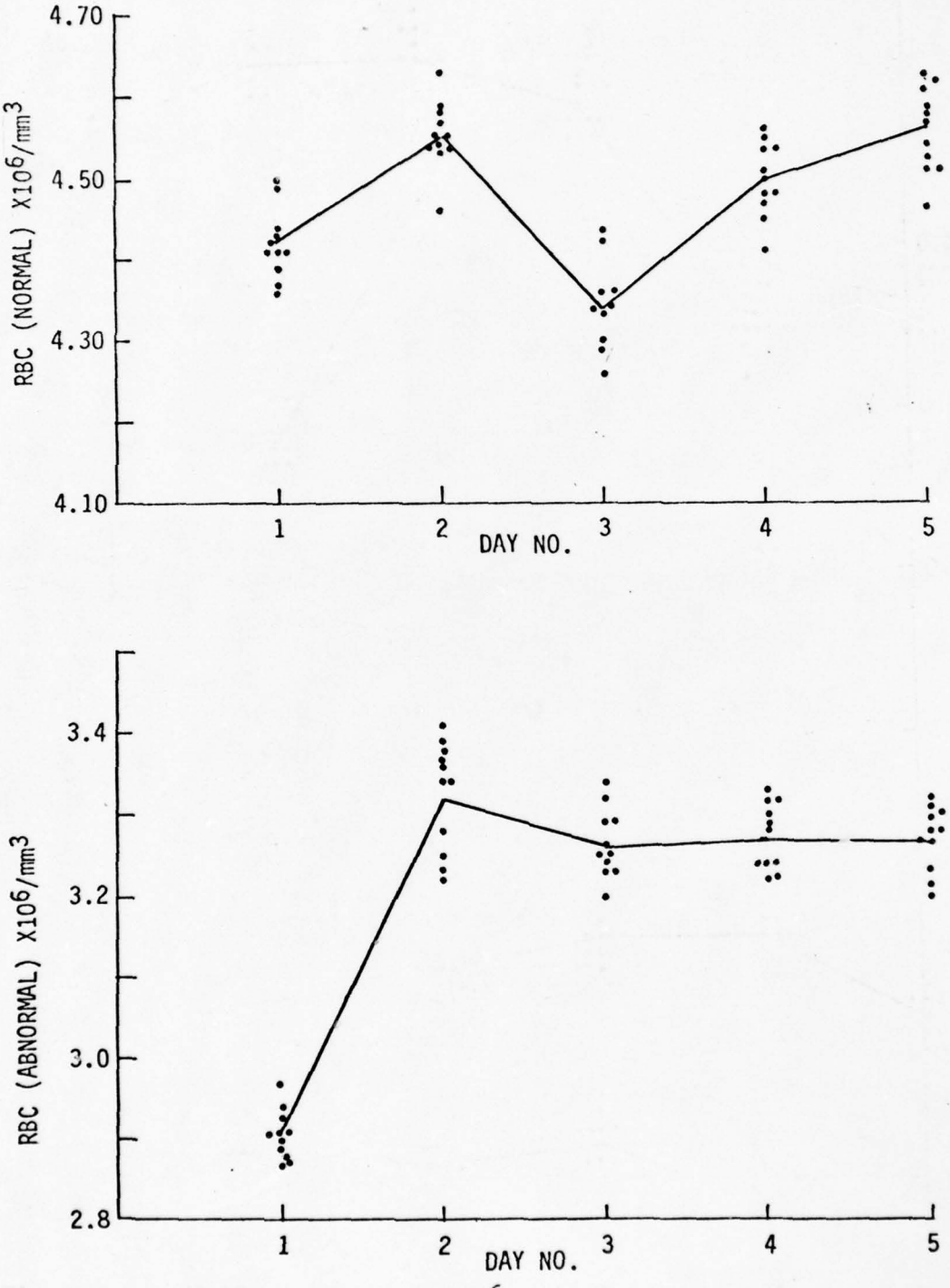



*Figure 8. Individual Values, RBCx10$^6$ (Normal and Abnormal)--Hycel Counter*

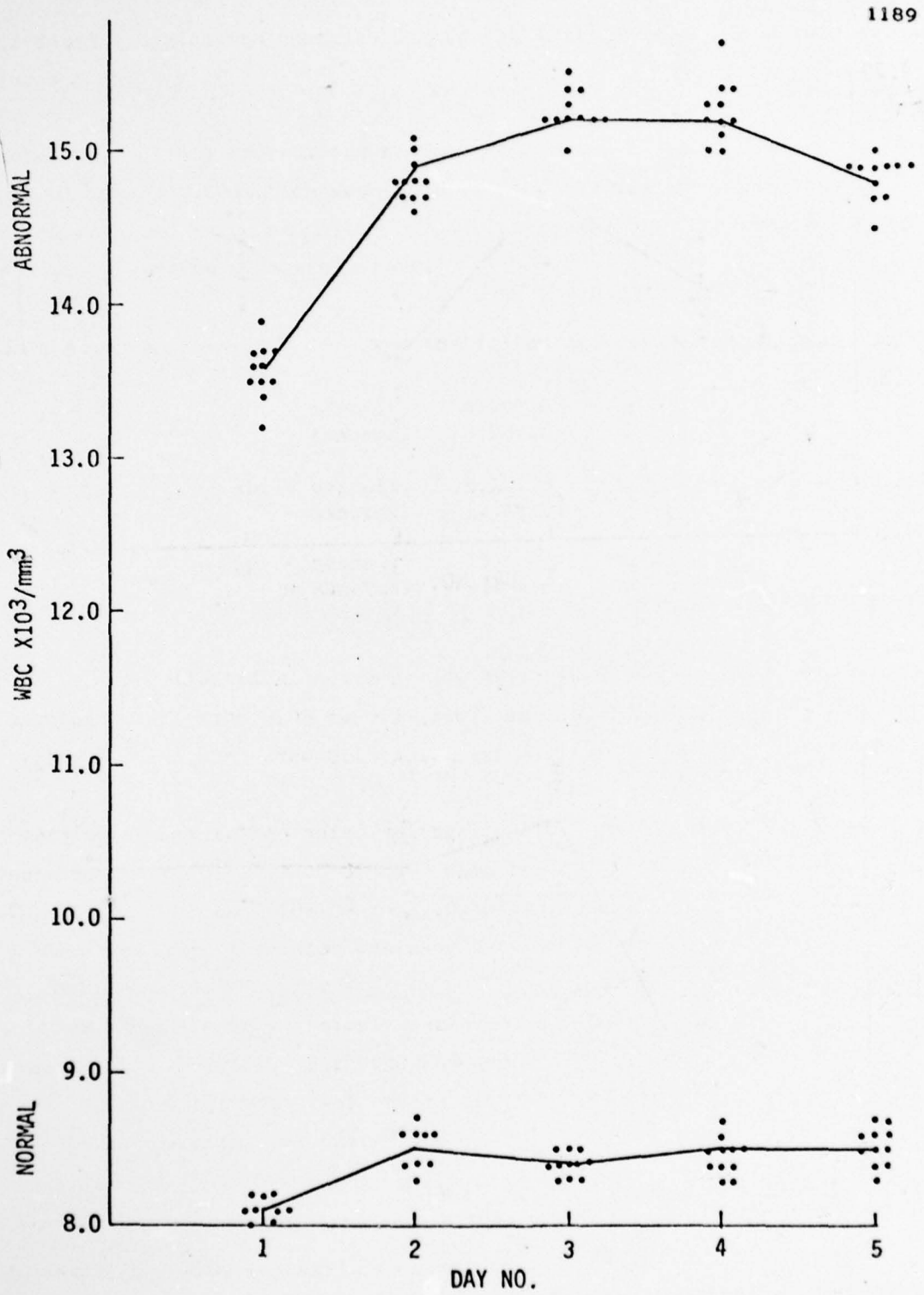



*Figure 9. Individual Values, WBCx10³ (Normal and Abnormal)--Hycel Counter*

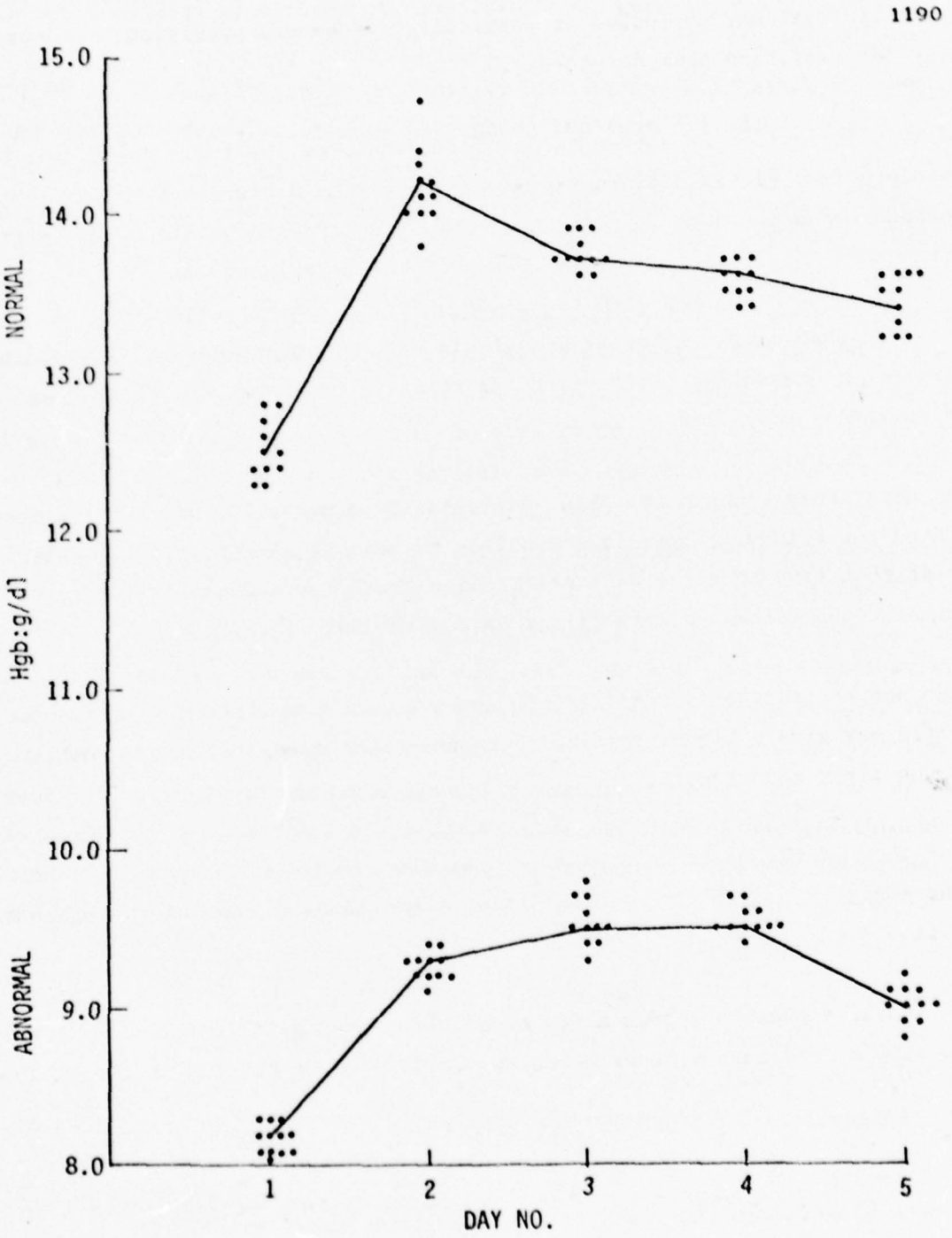



*Figure 10. Individual Values, Hgb:g/dl (Normal and Abnormal)--Hycel Counter*

The same vials of hematology controls were used for the five-day period. Thus, the tabulated data may be looked at vertically for sample precision, and horizontally for variation from day-to-day.

The daily distribution of eleven values for normal, or abnormal, hemoglobin was not obtained from eleven different preparations. The distributed values show what happens when the *same* cuvette is removed from the hemoglobin colorimeter compartment of the counter, rotated 90 degrees, and replaced for a new measurement. This process was repeated ten times (after the first determination). The data suggest that slightly better hemoglobin determinations may be obtained by this process of measuring, recovering and rotating, and remeasuring the hemoglobin cuvette perhaps three times.

Once an accurately known hemoglobin sample has been measured, and the instrument calibrated for this value, it is convenient to measure an appropriate optical filter at that time to serve as a calibration check thereafter. We found that an Eastman CC50R (pink) gelatin filter gave a reading of 19.3.

Although not statistically verified, it appears that the first measurement of an RBC sample may give a higher reading than subsequent ones. It may be well to reject the first measurement.

We found that if the operator's hand is near the cuvette (or touching it) *during* a measurement, the count rate will be greatly accelerated, causing a large error in the final count.

The Dade diluter must be cycled a few times before using it to aspirate or dispense a sample, and care must be taken to remove all air bubbles in the delivery tubing.

One cannot leave the Hycel counter on for any length of time, or the cell will deplete the beaker solution (even in a non-counting mode) and finally aspirate air. Aspirated air is difficult to purge, requiring extensive liquid flushing

to remove. When not in continuous use, this instrument should be turned off; it requires only 15 minutes to stabilize after turn-on.

The Hycel counter is simple and easy to operate and maintain. It gave excellent, trouble-free performance throughout the test period.

### 3.5.3 Sodium/Potassium Analyzer

#### 3.5.3.1 Description

Because it employs specific ion electrodes to measure the electrolytes sodium and potassium potentiometrically, the Orion Space-Stat 30 has been considered for the MODULAB system. This instrument was a spin-off of a prototype electrolyte analyzer (called Space-Stat) developed for NASA. The Model SS-30 is shown in Figure 11. This instrument determines serum sodium ($Na^+$) and potassium ($K^+$) values of whole blood (or serum) in 48 seconds. Less than 0.5 mℓ of sample is required (whole blood, plasma, or serum). The measurement range extends from 20 to 199.9 meq/ℓ for Na, to 0.2-19.9 meq/ℓ for K. The output is digital and terminals are provided on the back of the instrument for a recorder, if desired. Standardization and waste liquids are contained in a closed container with the instrument. The operator need only inject a sample, push a button, and read the results. Movement of sample and the necessary reagents through the instrument is accomplished with a 4-channel peristaltic pump. The pump and air valves operate in a timed cycle which moves the liquids and air through a network of tubing and the electrode module. In addition to the self-contained standardization solutions, calibration standards are also provided.

#### 3.5.3.2 Testing the Sodium/Potassium Analyzer

The Orion Space-Stat 30 Na/K Analyzer requires a specific checkout procedure to be performed daily. This procedure includes checking lubricant distribution over the tubing in the pump compartment, verifying the "set of standard" settings, and performing the Standardize and Calibration routine. During these exercises, the Set Slope procedure may also be required.

*Figure 11. Orion Space-Stat 30 Analyzer*

For our precision tests we made ten analyses at each of two levels (normal and abnormal), using reconstituted lyophilized serum. These analyses were repeated on five consecutive days.

Radiated and line-imposed electrical interference tests were made at the conclusion of the precision runs.

The 23-degree tilt test was also performed on this instrument.

3.5.3.3 Test Results

The Orion Space-Stat 30 Na/K Analyzer failed to meet its specification for the sodium response range. The electrode module was replaced but the instrument continued to show non-linear and non-repeatable results. The Set Slope mode was very noisy and difficult to use. The necessary Remove Syringe/Analyze signal failed so that an over-ride technique was required in order to obtain a test readout. It was noted, however, that during the periods the instrument was operating, the precision was excellent. All efforts to bring about normal operation failed and we rejected the instrument. Orion Biomedical replaced this instrument and we again began our tests. The second instrument performed faultlessly.

The test results are tabulated in Table III and the individual data points are displayed in Figures 12 through 14.

The electrical interference tests, line-impressed (to 100 Vac) and radiated, had no effect on the Orion Space-Stat 30.

Na/K measurements performed while the instrument was tilted about 23 degrees from side-to-side yielded all normal results.

3.5.3.4 Comments

Although the Orion Space-Stat 30 was on throughout the test period, and was always standardized daily, the first measurement of the day was invariably

*TABLE III. ORION SPACE-STAT 30--Na/K PRECISION TESTS (DAILY AVERAGES: MEQ/ℓ)*

| | DAY | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 |
| Na | | | | | |
| Control-Normal | | | | | |
| $\bar{X}$: | 141.0 | 140.3 | 141.6 | 141.9 | 140.8 |
| σ: | 0.69 | 0.89 | 0.67 | 0.58 | 0.48 |
| CV,%: | 0.5 | 0.6 | 0.5 | 0.4 | 0.3 |
| Control-Abnormal | | | | | |
| $\bar{X}$: | 127.1 | 128.5 | 129.8 | 125.5 | 129.0 |
| σ: | 0.46 | 0.44 | 0.41 | 0.46 | 0.67 |
| CV,%: | 0.4 | 0.3 | 0.3 | 0.4 | 0.5 |
| K | | | | | |
| Control-Normal | | | | | |
| $\bar{X}$: | 4.20 | 4.23 | 4.25 | 4.26 | 4.16 |
| σ: | 0.04 | 0.04 | 0.03 | 0.03 | 0.03 |
| CV,%: | 0.9 | 0.9 | 0.7 | 0.7 | 0.6 |
| Control-Abnormal | | | | | |
| $\bar{X}$: | 5.66 | 6.20 | 6.15 | 6.03 | 6.15 |
| σ: | 0.11 | 0.05 | 0.03 | 0.04 | 0.04 |
| CV,%: | 2.0 | 0.8 | 0.5 | 0.7 | 0.7 |

Test Material:

Normal: Moni-Trol I Chemistry Control
Abnormal: Moni-Trol II Chemistry Control
Dade Division, American Hospital Supply Corporation

Dade Assays (Flame Photometer):

Normal Na = 139 meq/ℓ, σ = 0.7
Abnormal Na = 124 meq/ℓ, σ = 1.19
Normal K = 4.1 meq/ℓ, σ = 0.02
Abnormal K = 5.8 meq/ℓ, σ = 0.03

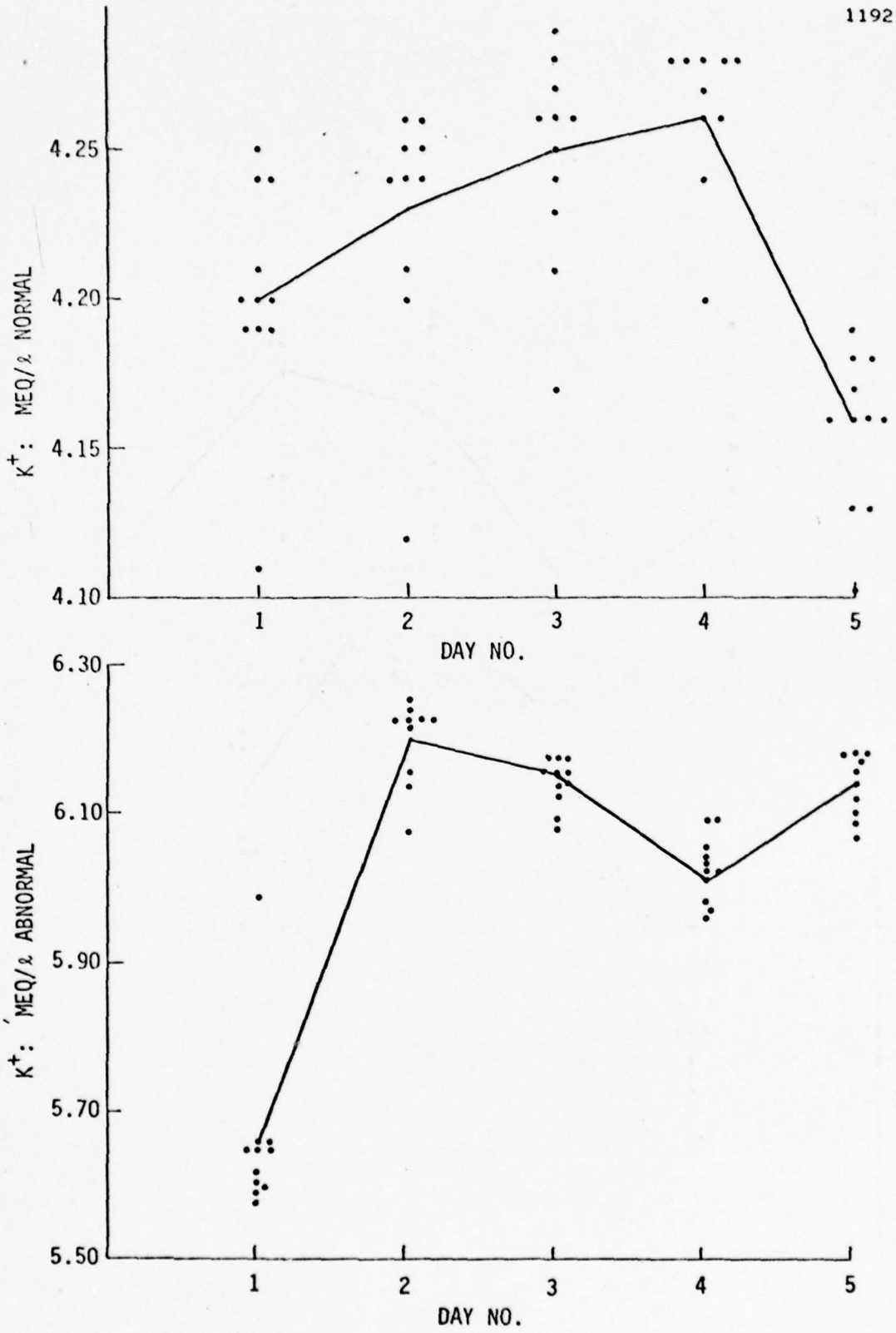



*Figure 12. Individual Values, Orion Analyzer--Five-Day Test*

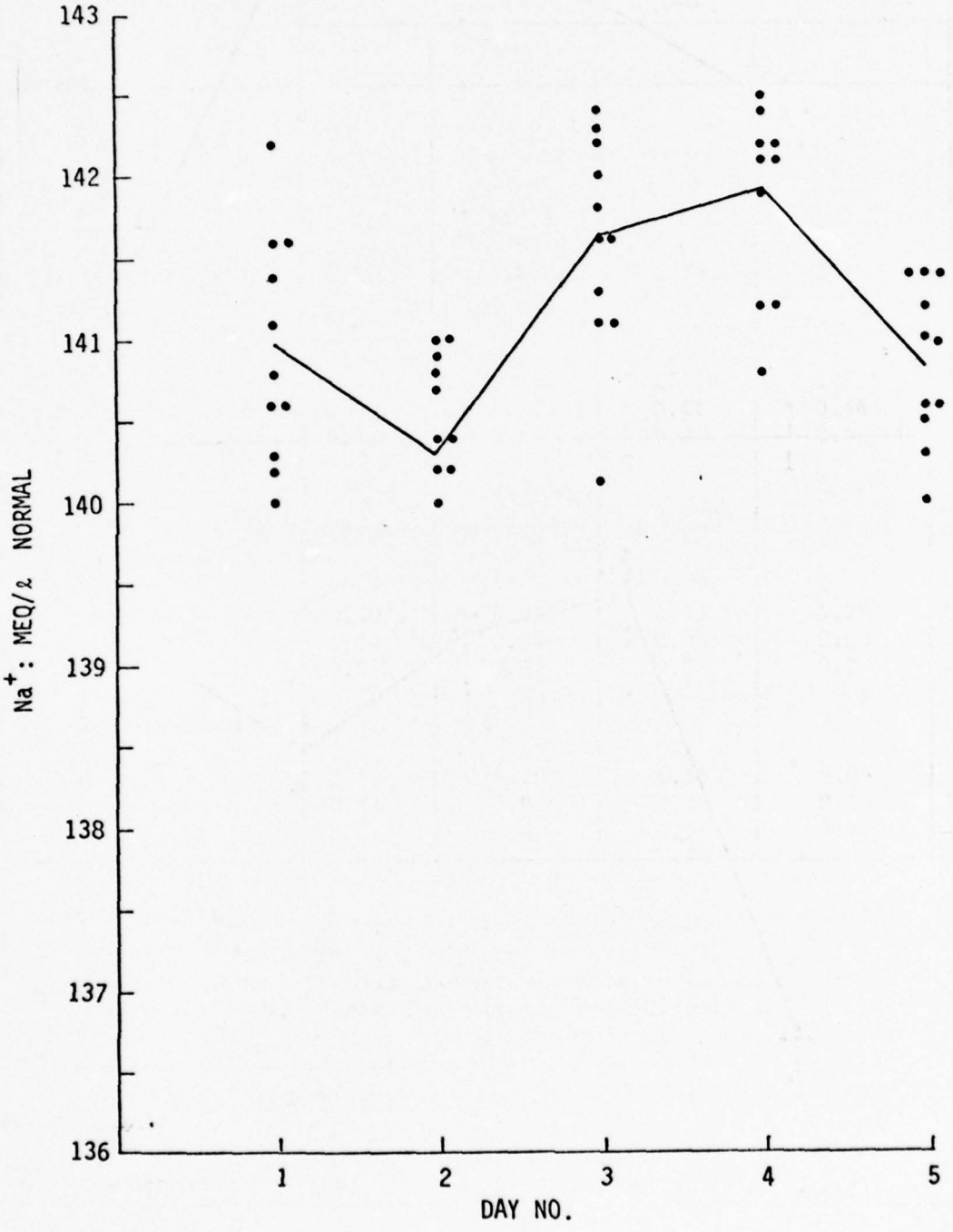



*Figure 13. Individual Values, Orion Analyzer--Five-Day Test*

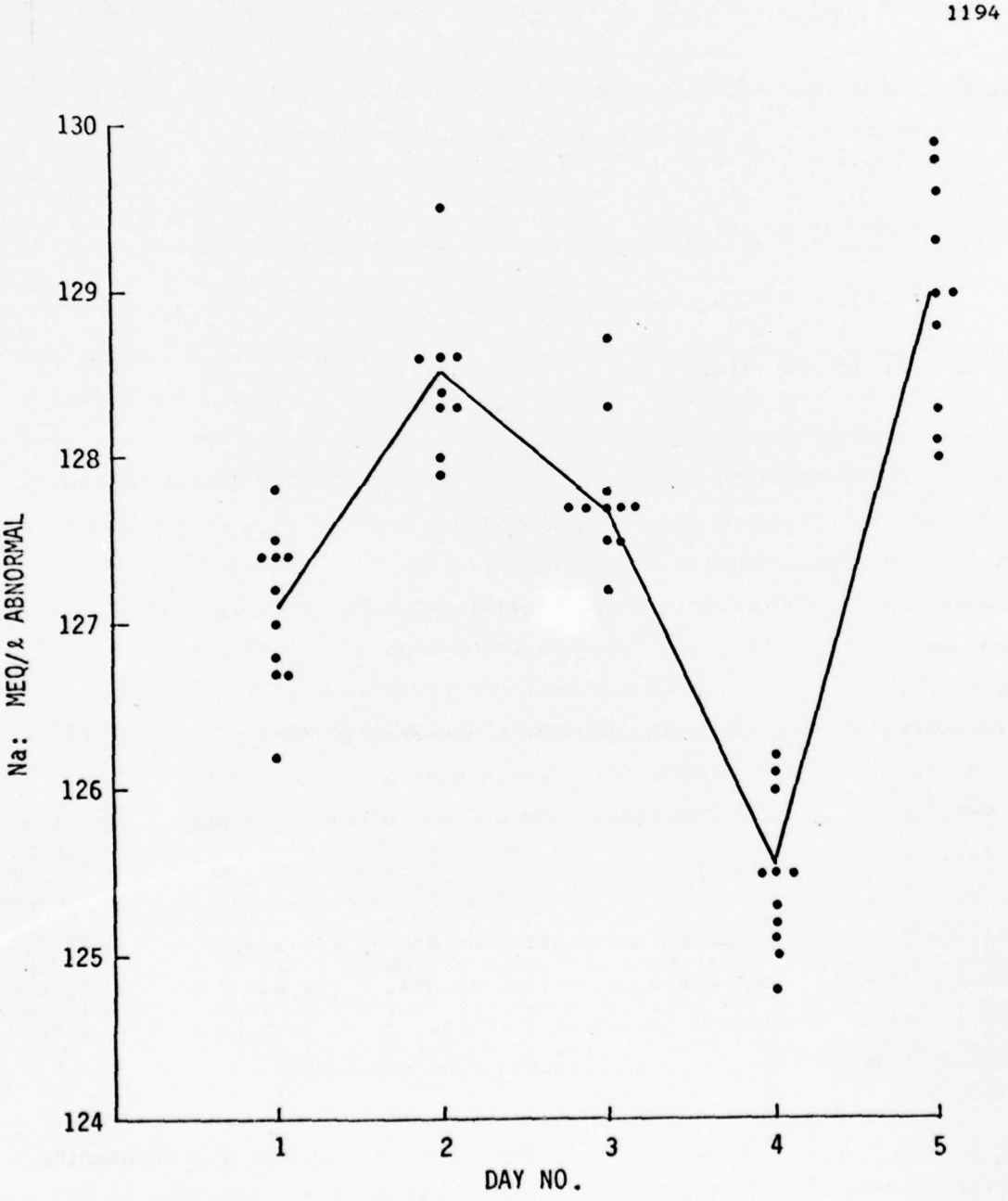



*Figure 14. Individual Values, Orion Analyzer--Five-Day Test*

lower than any other in the set. This low value (perhaps 3 meq/ℓ lower than average) of course affected the statistical calculations a little. As an example, the values for one set of "normal" Na/K determinations was, for Na:

$\bar{X}$ = 140.3 meq/ℓ, $\sigma$ = 0.89, CV = 0.6%

Omitting the lower value (137.8) gave

$\bar{X}$ = 140.6 meq/ℓ, $\sigma$ = 0.37, CV = 0.3%

For K in the same set we obtained

$\bar{X}$ = 4.23, $\sigma$ = 0.04, and CV = 0.9%

Omitting the K's lowest value

$\bar{X}$ = 4.24, $\sigma$ = 0.02, and CV = 0.5%

The distinction is of course academic, as the results are excellent whether the lowest value is kept or omitted. We would, however, like to determine why this phenomenon occurs. (Note similarity to test result described earlier in paragraph 3.4.1.4.)

The Field Representative who installed the Space-Stat 30 Analyzer found that several important parts were missing. One, a special bolt to hold down the module, was quickly made by our model shop and the others were supplied by the service man.

One problem after another beset this instrument during the next few weeks. It failed to consistently meet the span specifications. "Set Standards" could not be correctly used. The signal to analyzer failed, necessitating an over-ride mode. The counter for the Fluid Pack Consumption miscounted. A "Test Mode" signal light failed. Our very cooperative Field Representative labored assidiously to remedy these defects, but the instrument failed to give consistently normal performance. Nevertheless, when it was working the precision was excellent--the coefficient of variation was generally only a fraction of one percent!

This instrument was, of course, rejected. A second unit was delivered and installed; this one was complete, and provided excellent performance.

Once checked and calibrated, this instrument is extremely simple to operate. There are no external reagents (except calibration standards) to handle. Even the waste materials are collected in the fluids pack. The daily checkout procedure is simple and straightforward. Periodic (daily, weekly) maintenance is uncomplicated. A troubleshooting guide in the form of flow charts is quite helpful.

The "Orion Number Two" analyzer, as noted, worked exceptionally well throughout the test period.

One feature needs comment: the fluids pack. This package containing the standard and reference solution and a waste bag makes operation of the analyzer neat and convenient. It also enables the instrument to remain in the stat mode by automatically drawing upon the pack every four hours to flush the system. Even if no sample measurements are made, however, the pack will be depleted in two weeks just to maintain the stat mode. Seven of the available 220 counts are used when the pack is first installed; every four hours two counts are used by standardization in the stat mode, and each analytical cycle uses one count. If the instrument is shut down, the fluids pack must be discarded, even if only partially used. Considering the inexpensive reagents and simple packaging, the fluids pack appears expensive at $60 each.

### 3.5.4 Clinical Spectrophotometer

#### 3.5.4.1 Description

In the interests of methodologic simplification, the Clinicard system--supplied by Instrumentation Laboratory, Inc.--was selected for making colorimetric chemical analyses. This instrument is especially well adapted to meeting the design concepts of MODULAB.

Clinicard is an integrated analytical system (see Figure 15) consisting of a module containing a photometer, aspirator/dispenser, incubators, a punched card reader, shuttle mechanism, and digital readout. A Dead Light information

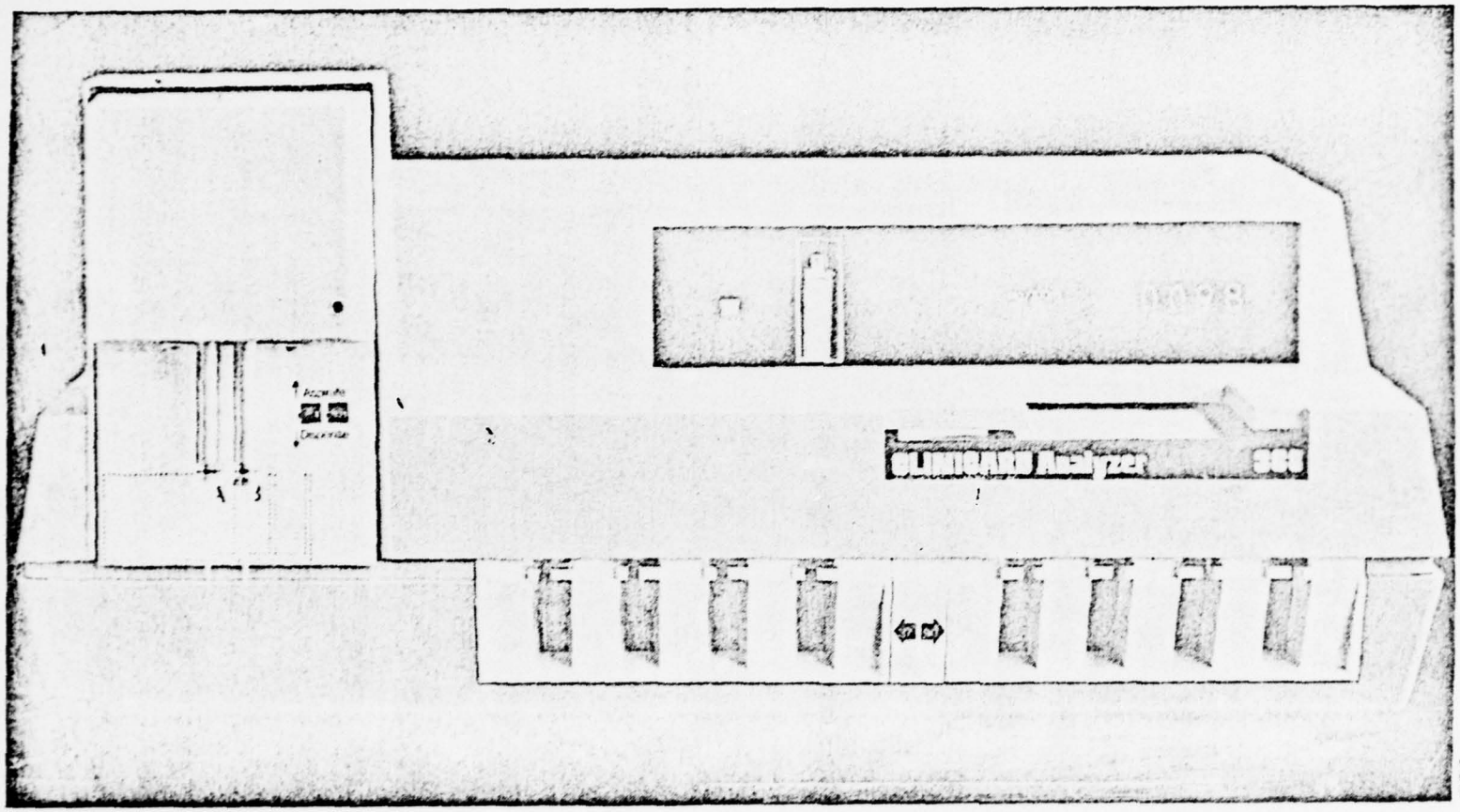


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*Figure 15. Clinicard Chemistry Analyzer*

center provides critical test status data. If a problem arises in the sequential operations, warning signs appear in the readout area indicating the source of the problem. This feature, together with a Clinicard Test Kit, helps the system stay in a precise test condition at all times.

All materials required to make a particular clinical measurement are individually prepackaged. These chemistry kits--manufactured by Harleco--contain the sample cuvettes, reagents, and punched cards for programming the Clinicard. A Procedure Organizer describing in detail each of the available twenty-three chemistries (more are being developed) is included with the Operator Manual.

To accommodate the various chemistries, three modes of analysis are available in the Clinicard: standard, absolute, and rate. The operator makes no adjustments to meet these modes--the applicable prepunched Clinicard automatically programs the instrument for reading the correct sections of the three-section cuvettes. A plastic flag on the cuvette ensures that the cuvette will receive the correct incubating temperature for the correct period of time.

An integral part of the analyzer is an aspirator/dispenser which eliminates the need for manual aspiration of samples or pipetting of reagents. The punched card for each test controls the action of the dispenser. Volumes of 25, 50, 100, or 200 µℓ are available.

3.5.4.2 Testing the Clinical Spectrophotometer

The Test Program for the Clinicard system is quite simple. Once the Clinicard Analyzer has been properly installed and checked by a Field Representative, there are no daily standardization procedures to be performed. It is assumed, of course, that the instrument remains on continuously. If the instrument has been off, it will require about an hour to reach temperature equilibrium and maximum stability.

Although there are no standardization procedures, as such, it is advisable to make a daily check of the analyzer by performing a series of eight tests using the Clinicard Test Kit; in less than four minutes, the operator can confirm

whether the instrument operates correctly. The eight punched test cards employ all program bits in some kind of combination and give readouts on the state of various decoding circuits, noise levels, etc. If the analyzer fails to pass a certain test, the test card gives a starting point towards isolating the source of the failure.

In addition to the Test Kit program, we made ten analyses a day for five consecutive days on two different chemistries, and at two levels for each. Reconstituted serum was used at the normal and abnormal levels. Blood Urea Nitrogen (BUN) and Total Protein were the two clinical tests selected for establishing the baseline performance of the Clinicard system.

This instrument was also tested for effect of electrical interference. The 23-degree tilt test has not yet been performed.

3.5.4.3 Test Results

The Clinicard Test Kit, consisting of a special cuvette and eight punched cards, was used as part of the daily test program. The test results were so non-varying during a ten-day period that statistical calculations are virtually meaningless--the Coefficient of Variation for all tests was zero to three decimals. These tests are valuable, nonetheless, as they give the operator assurance that the instrument is operating in a normal manner.

Test results are tabulated in Table IV. Individual measurements are charted in Figures 16 and 17. It will be noted that the Coefficient of Variation is somewhat higher than is desirable or normally acceptable. No attempt to ascribe this to the standard, chemistry kit, or instrument has been made to date.

Electrical interference tests, both line-impressed and radiated, had no effect in any of the eight Clinicard check tests.

The 23-degree tilt test has not yet been performed.

TABLE IV. *CLINICARD PRECISION TESTS: DAILY AVERAGES--BUN, mg/100 mℓ,* TOTAL PROTEIN, g/mℓ

| | DAY | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 |
| BUN | | | | | |
| Control-Normal | | | | | |
| $\bar{X}$: | 14.0 | 13.8 | 13.6 | 14.1 | 13.8 |
| σ: | 0.36 | 0.31 | 0.69 | 0.42 | 0.52 |
| CV,%: | 2.6 | 2.2 | 5.1 | 2.9 | 3.8 |
| Control-Abnormal | | | | | |
| $\bar{X}$: | 36.9 | 37.3 | 35.8 | 37.2 | 36.5 |
| σ: | 1.09 | 1.1 | 0.94 | 0.73 | 1.38 |
| CV,%: | 2.9 | 2.9 | 2.6 | 2.0 | 3.8 |
| Total Protein | | | | | |
| Control-Normal | | | | | |
| $\bar{X}$: | 7.8 | 7.4 | 7.4 | 7.7 | 7.2 |
| σ: | 0.18 | 0.16 | 0.17 | 0.30 | 0.30 |
| CV,%: | 2.3 | 2.2 | 2.3 | 3.9 | 4.2 |
| Control-Abnormal | | | | | |
| $\bar{X}$: | 5.6 | 5.9 | 5.9 | 6.0 | 5.8 |
| σ: | 0.26 | 0.23 | 0.12 | 0.62 | 0.22 |
| CV,%: | 4.7 | 4.0 | 2.1 | 10.1 | 4.0 |

Test Material:

Normal: Moni-Trol I Chemistry Control (Dade)
Abnormal: Moni-Trol II Chemistry Control (Dade)

Dade Assays (Clinicard:

Normal BUN: 139 mg/dl, σ = 0.43
Abnormal BUN: 37.6 mg/dl, σ = 0.58
Normal Total Protein: 7.2 g/dl, σ = 0.15
Abnormal Total Protein: 5.8 g/dl, σ = 0.20

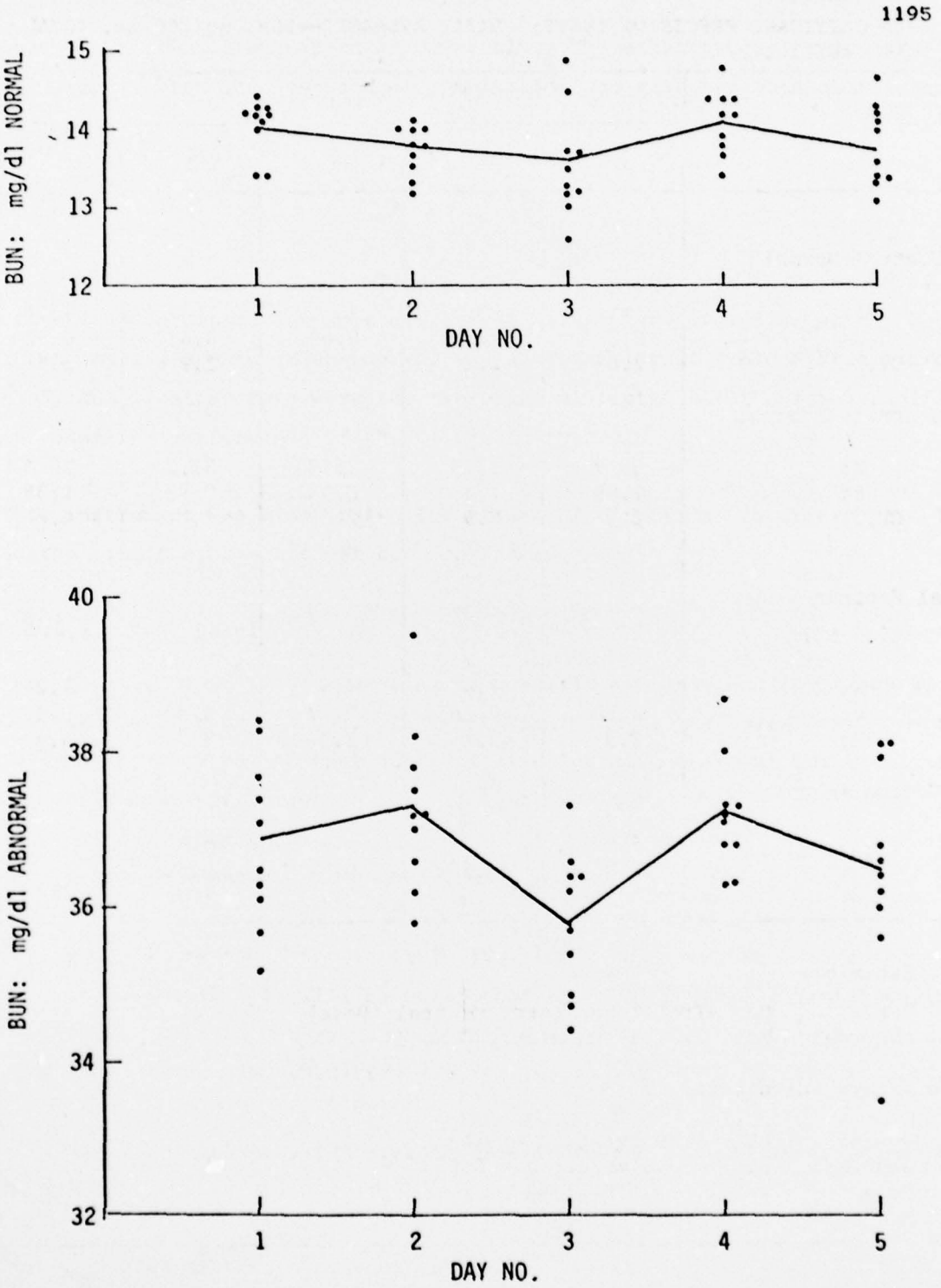
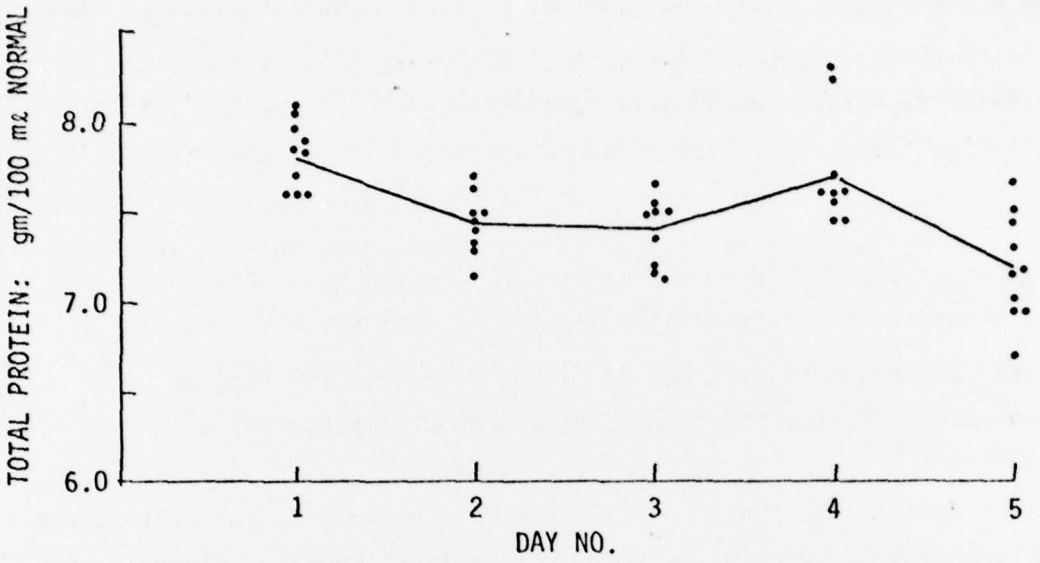



*Figure 16. Individual Values, Clinicard System, BUN--Five Day Test*



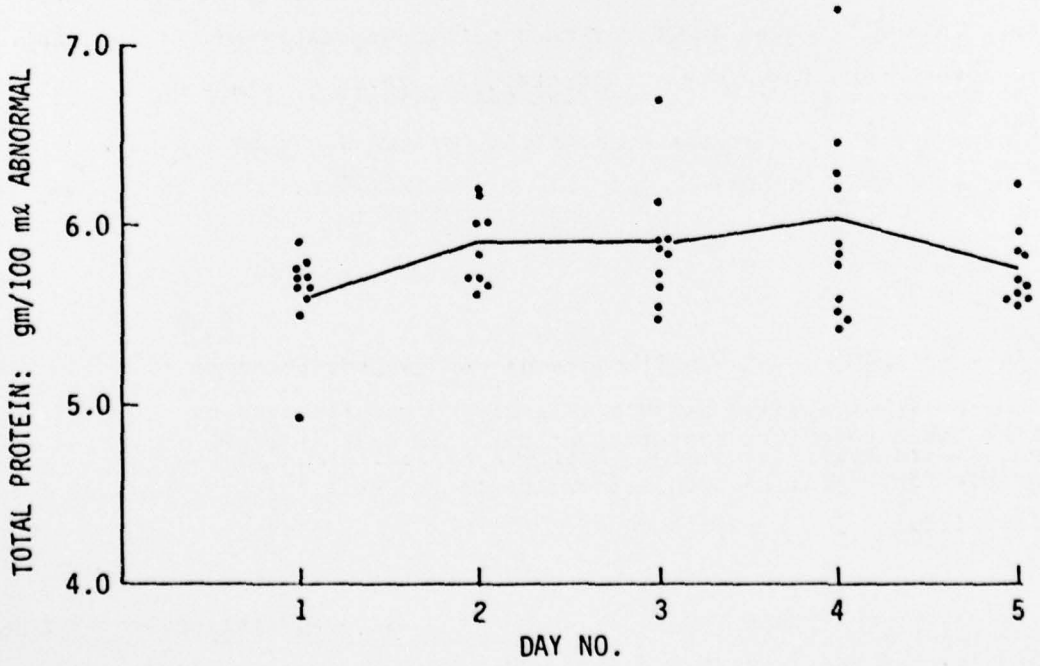




*Figure 17. Individual Values, Clinicard System, Total Protein--Five-Day Test*

3.5.4.4 Comments

In our work with the Clinicard system, we found that a timer, or stopwatch, was quite useful. Especially when making a series of ten determinations where incubation is the first step, a timer can alert the operator when to stop preparing cuvettes for incubation and when to start preparing for sampling. A timer can help one avoid being caught in a sampling procedure just when he is signaled to make a measurement.

We used only two chemistries: BUN and Total Protein. For BUN, we found it desirable to allow at least 50 seconds between cuvette preparations going into the incubators for the first time. It does not take long to prepare the cuvette (knock out stoppers, drop in reagent pills, remove labels), but it requires about 50 seconds to replace dispenser tips, aspirate sampler, dispense them, put stopper strip on, and insert into incubators for the second time. It is very important to practice a simple, straightforward procedure, allowing no variations in the protocol.

It was important to be on guard for knocked out caps floating in the cuvette light path. This will cause an "error message" to be displayed. The remedy is to tap the cuvette and immediately reinsert. But, even a slight delay can alter the reading.

Some cuvettes are almost too tight to go into either the incubator or the shuttle. If they are not inserted all the way into the incubators, no timing cycle will be initiated. If not all the way in the shuttle, "error" will be displayed.

Care must be taken to ensure that reagent pills go only into the intended cell. It is possible for a pill to bounce from the target cell into one already containing its pill.

The Clinicard system required no daily standardization, no startup procedures, no maintenance. It was left on and was always ready to make a Clinicard measurement.

Remarkably little operator training is required, even though some of the chemistries are quite involved. The operator, however, is not involved in complex chemistry. He merely opens the desired kit, adds one or two reagents as required, aspirates and dispenses the samples, incubates the cuvette as directed, inserts the cuvette, and reads the result.

The Clinicard system appears well suited to the Navy MODULAB program. Of all the instruments, this one requires the least attention and maintenance. The Test Kit, requiring only four minutes to use, gives assurance that all is well with the instrument. If, however, it indicates malfunction, there appears to be nothing the operator can do except contact a Clinicard Service Representative.

Indeed, such complete automation of a rather complex system may be something of a drawback. The operator is so isolated from the system that he is not allowed to over-ride the fixed automation in the event of malfunction and use his own capability and resources to operate in a manual mode.

## 3.6 Instrument Modifications

### 3.6.1 Design Philosophy

The major concern is to improve the reliability of the instruments for shipboard use. Our approach was to examine each instrument and determine which components or structural features would be susceptible to failure in the shipboard environment. Each case was then evaluated in terms of what might be done to improve the resistance to failure.

A list of recommended changes was then compiled. In some cases, recommended changes could not be carried out in this program. For example, some parts are proprietary and no substitute is available. The structural arrangement limited access to other parts.

It was not considered practical to attempt revisions to the basic instrument design. Therefore, nothing was done to intentionally change instrument performance. Verification tests will reveal any failure points--which may be on

the recommended change list--even though it may not be possible to make modifications at this time.

### 3.6.2 Modification Limitations

The difference between *desirable* modifications to the instruments and *possible* modifications is established by:

- Cost--many desirable modifications are too costly to consider;
- Practicality--in some areas, modifications to improve reliability may be desirable, but substitute components with acceptable performance specifications may not be available.

The imposition of cost restraints leads to a number of design guidelines. For example, repackaging to alter the size or shape of any of the instruments is not within the scope of this program. Protection against the full levels of high impact shock, per MIL-S-901, was likewise deemed impractical, although a measure of shock protection can be achieved. Implementation of full-level shock protection would have to start with the instrument design. This would also be the avenue of approach for eliminating some of the proprietary or non-approved components; it would also be a viable approach for an eventual procurement program. Within the scope of the present program, however, many of these desirable modifications are not practical.

### 3.6.3 Electronic Analysis

The instruments will be modified based on a visual inspection of the electronic assemblies. Commercial grade components will be replaced with components designed to withstand the more severe environment of a shipboard installation. For example, commercial capacitors will be replaced with hermetically sealed, military-quality units when packaging limitations are not a problem. All plastic low-power signal transistors are to be replaced with hermetically sealed, military-qualified JAN components where possible. In some instances, however, special components--such as semiconductors which are designed to a manufacturer's source control drawing--cannot be replaced without affecting the basic circuit design and instrument performance.

Cabling and harnesses will be rerouted to clear any sharp-edged metallic hardware to prevent chaffing of the insulation due to the continuous vibration of shipboard equipment. Cable clamps will be added as required to support harness wiring.

After functional checkout of each piece of equipment, all circuit boards will be removed and conformal coated to reduce moisture absorption.

### 3.6.4 Mechanical Analysis

Mechanical analysis has been completed on the Hycel Blood Cell Counter and the Clinicard Blood Chemistry Analyzer, and preliminary work done on the Orion Space-Stat 30 and the Corning Blood Gas Analyzer. The work was done by analyses and visual inspection of the instrument subassemblies and parts.

The Hycel counter was found to have inadequate retention of the rear corner of the large vertical board, and several poorly supported components. Also, the lower end of the liquid probe is retained in the cell body only by the friction of its O-ring seal, which is not adequate.

The Clinical Chemistry Analyzer was found to be basically sound in regard to case design, adequacy of subassembly mountings, etc. Areas requiring modification were pinpointed on some of the circuit boards, and in detail component areas. Several large capacitors needed extra support, as well as a few individual transistor heat sinks. The indicator lamps near the front of the instrument, over the ovens, were found to be inadequately supported. Finally, the small linear optical encoders in the diluter-dispenser portion of the instrument are not rugged enough. The mounting of the encoded glass strips is with adhesive, in such a manner that the adhesive can be stressed in peel. Breakage of the glass strips or failure of the adhesive are possibilities, and design features to relieve the bending stress on the encoder are needed.

A preliminary examination of the other two instruments has been completed; however, no documented inspection has yet been done, and modification parts have not been detailed.

## 3.7 Implementation of Modifications

### 3.7.1 Methods

In order to remedy the design and construction deficiencies noted above, modification parts will be designed and fabricated as necessary. The simplest effective design approach to these modification parts will be taken. In many cases, brackets, stiffeners, etc., are needed for the required reinforcement.

Observations, recommendations, measurements, and sketches are kept in laboratory notebooks. A book is maintained for each instrument. Many of the necessary parts to implement the required modifications are presently in fabrication (some are completed), and assembly of the modification parts to the instruments will be documented in the instrument log books.

### 3.7.2 Electronic Modifications

Currently, all instruments have been disassembled and examined for part replacement. All replacement components have been ordered. Components are expected to be complete by late October.

The Hycel Blood Cell Counter circuit board rework is complete, with the exception of replacing one capacitor and conformal coating.

Rework of three circuit boards in the Clinicard instrument is complete except for conformal coating each board.

Rework will continue as components are received.

## 4.0 WORK PLANNED FOR THE NEXT SIX MONTHS

The major tasks planned for the next six months are:

1. Complete instrument modifications
2. Complete retesting against baseline
3. Prepare system for shipment
4. Support Navy clinical laboratory tests
5. Support shipboard installation
6. Support verification tests
7. Prepare and submit final report

This activity will complete the program. At this time, we are working to improve delivery of components needed to complete modifications. (We have been quoted three months delivery on some capacitors.) If alternate components or improved deliveries cannot be obtained, there will be some impact on the program schedule.