UNITED STATES DEPARTMENT OF AGRICULTURE
Food and Nutrition Service
Washington, D.C. 20250

FNS INSTRUCTION 815-1

ACTION BY: Regional Offices
State Agencies

Purchase of Medical Equipment

I PURPOSE

This Instruction:

A Provides guidance on types of medical equipment that may be purchased with administrative grant moneys to be used for determining eligibility or ineligibility of applicants for the Special Supplemental Food Program for Women, Infants and Children (WIC Program) and the Commodity Supplemental Food Program (CSFP).

B Lists various criteria to be used when considering medical equipment purchases.

C Specifies the maximum allowable cost for specific types of equipment.

II AUTHORITY

Public Law 95-627 (Nov. 10, 1978), section 17(b)(1) which amended 42 U.S.C. 1786 authorizes the purchase of medical equipment for the WIC Program. 7 CFR 246.12(b)(3)(iii) specifies the allowable equipment and that expenditure limits are set by FNS. Expenditures that exceed limits must receive prior approval by the FNS Regional Office.

The authorizing legislation for CSFP, Public Law 95-113, does not specifically provide for the purchase of medical equipment. 7 CFR Part 247.11 (b)(1)(iii) specifies the allowable equipment and that expenditure limits are set by FNS. Expenditures that exceed limits must receive prior approval by the FNS Regional Office.

III DEFINITIONS

A Anthropometric Measurements. Scientific measurements of the human body, such as height, length and weight, which are used in determining normal or abnormal patterns of growth.

B Calibration. Specification and measurements of the properties or performance of a device so that it may be used for subsequent, accurate measuring procedures.

C CDC. Center for Disease Control, Public Health Service, Department of Health and Human Services, Atlanta, Georgia.

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

DISTRIBUTION:	MANUAL MAINTENANCE INSTRUCTIONS:	RESPONSIBLE FOR PREPARATION AND MAINTENANCE:	Page 1 Revised 7-13-81
AD,S	Major changes starred, Remove pages 1 thru 4 of basic Instruction from Manual. Insert these revised pages.	SF-100	

FORM FNS-620 (12-79) GPO 866 638

D Centrifuge. An apparatus for separating substances of different densities by centrifugal force, used for hematocrit determinations.

E Clinic. Facility where participants are certified for WIC Program and CSFP.

F Cuvette. A small laboratory vessel, or absorption cell for spectrophotometry.

G Hematofluorometer. An instrument which provides a rapid optical measurement of the erythrocyte protoporphyrin (EP) level. High EP levels indicate possible lead toxicity and iron deficiency.

H Hematologic Measurements. Measure presence of and/or amounts of ce tain substances such as hemoglobin in the blood.

I Hemoglobin. Iron containing conjugated protein respiratory pigment occurring in the red blood cells of vertebrates, often measured to detect iron deficiency.

J Hemoglobinometer. An instrument for determining the hemoglobin concentration of the blood. Hemoglobinometers are photometers designed for the single test of determining hemoglobin measurements.

K Measuring Board. Instrument used to measure height or length.

L Medical Equipment. Allowable WIC Program and CSFP certification equipment such as centrifuges, scales for measuring cell volume, skin fold calipers, spectrophotometers, hemoglobinometers, hematofluorometers, and adult or pediatric scales used for determining the eligibility of potential WIC Program and CSFP participants.

M Nutritional Assessment. Appraisal of the adequacy and quality of an individual's diet. This appraisal may be made through nutrition histories, 24-hour diet recalls, certain lab tests, and physical examination, or a combination of these.

N Packed (Red) Cell Volume. Space occupied by or the volume of red cells in the blood.

O Skin Fold Calipers. Instrument generally used to measure triceps skinfold and upper arm muscle size for assessment of nutritional status.

P Spectrophotometers. Instrument for measuring light intensity.

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

7-13-81

IV ALLOWABLE MEDICAL EQUIPMENT

Only medical equipment specifically listed in the WIC Program Regulations, section 246.12(b)(3)(iii) and the CSFP Regulations, section 247.11 (b)(1)(iii) may be approved for purchase. The list for both programs includes centrifuges, measuring boards, skin fold calipers, spectrophotometers (includes hemoglobinometers), hematofluorometers, and scales.

V MAXIMUM ALLOWABLE COSTS

The cost of medical equipment shall not exceed the maximum amount established by FNS in accordance with Office of Management and Budget Circular A-87 for capital expenditures which is $5,000.00. While this amount is the maximum allowed, equipment can most often be obtained for substantially less than the maximum. Should the cost of any one piece of equipment exceed the $5,000.00 maximum, the purchase of that equipment must be approved by FNS prior to purchase.

VI EVALUATION CRITERIA

The CDC publication, "A Review of Selected Anthropometric and Hematological Instruments Used in Nutrition Assessment," attached as Exhibit A, gives guidance on design principles and evaluations of selected equipment. This publication was developed early in 1980 and has not been revised by CDC since that time. Purchasers of medical equipment may still use this review as guidance when purchasing equipment keeping in mind that it was developed in 1980. For medical equipment, such as skin fold calipers, not listed in Exhibit A, base selection of such equipment on:

A Direct past experience with particular brands or devices;

B Recommendations of other professionals familiar with the medical equipment; and

C Other relevant data, such as published specifications or evaluations of equipment.

VII RESPONSIBILITIES

A State agencies:

1 Shall review and consider the criteria on medical equipment provided in section VI, above, and Exhibit A prior to approval of equipment purchase.

2 Shall analyze local needs to determine what types of equipment are appropriate for use at a particular clinic. For example, a hemato-fluorometer would be appropriate when a local agency is participating in a lead screening program, but may not be appropriate for routine screening for iron deficiency due to the expense involved.

7-13-81

3 May approve the purchase of medical equipment as listed in section IV, above, that is not included in Exhibit A, if such equipment is equivalent in performance to that equipment included in Exhibit A.

4 Shall obtain approval to purchase excess cost medical equipment by submitting to the appropriate FNS Regional Office written Justification covering the specific medical equipment to be purchased; why the equipment is needed; and why a lower cost substitute would not suffice.

B FNS Regional Offices shall approve in writing State agency requests to purchase medical equipment in excess of $5,000.00 based on the justification provided by the State agency and other relevant information about the equipment to be purchased.

Margaret O'K. Glavin
Deputy Administrator for
Special Nutrition Programs

Attachment

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

A Review of Selected Anthropometric and Hematologic Instruments Used in Nutrition Assessment

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

TABLE OF CONTENTS

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

PREFACE

One of the major sources of error in the nutritional assessment of children is the selection, maintenance and use of measuring, weighing, and hematologic equipment. As one approach to this problem, the Food and Nutrition Service (FNS), through an Interagency Agreement with the Nutrition Division, Center for Disease Control (CDC) asked the CDC to select and examine certain anthropometric and hematologic equipment for use in clinic settings.

There were no economically feasible ways to identify or examine all available measuring devices within the resource constraints of the evaluation. In accordance with the agreement and other discussions with FNS, a sample of known and readily available instruments was selected for review by CDC personnel based on subjective considerations of certain basic criteria (e.g., quality of workmanship and materials, reasonable cost, functional dependability, expected accuracy). This report contains the results of the evaluation.

Anthropometric Equipment

Seven devices for measuring length or stature were selected for evaluation. There exists no recognized battery of tests that objectively and in a practical sense evaluates infant and child measuring instruments. We have examined the test instruments using two approaches: objective (e.g., the use of a standard measuring rod), and subjective (e.g., a modification of the Habicht standardization procedure*).

Hematologic Equipment

There are many commercially available instruments designed to perform hematologic determinations including hemoglobin measurements. Some of these instruments are limited by design to solely performing hemoglobin determinations. We believe there is a greater potential for measurement error when instruments capable of doing more than one test are used lot a specific test. For this reason, only those instruments dedicated to the single test of determining hemoglobin measurements using the inter- nationally recommended hemiglobincyanide (HiCN, cyanmethemoglobin) method were considered for primary review. One battery operated hemo-globinometer, as an example of a relatively inexpensive and portable device, which some clinics require, was examined. In addition, one micro-hematocrit centrifuge was tested.

* Habicht, J.P., Standardization Procedures for Quantitative Epidemiologic Field Methods. Unpublished. Institute of Nutrition of Central merica and Panama, Guatemala, C.A.

In evaluating the hemoglobinometers, performance specifications provided by the manufacturer were checked, general performance of the instruments under routine laboratory conditions was assessed, and long-term performance monitored. The protocol of the International Committee for Standardization in Haematology (ICSH) for type testing equipment and apparatus was used in performing the hematological analysis.

During the performance evaluation of the instruments, it was apparent that the available HiCN reference materials and reagents would also need to be evaluated. This too was carried out and an extensive comparative study will be made available at a later date.

The results of tests of the selected anthropometric and hematologic equipment should not be accepted as recommendations for any specific manufactured item or that those examined necessarily reflect the best that may be available. Selection was based on what was known by CDC to be readily available at the time and probably widely used, or representative of types used in service delivery programs in the United States.

We realize instruments are constantly being modified for improved functions, and new equipment is reaching the market place daily. In this respect, we encourage a continuing sense of awareness as to the importance of equipment evaluation and an ongoing concern to identify those instruments which can help in attempts to improve the quality of nutrition assessment data.

Evaluation of Devices for Measuring Supine Length

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

I. Introduction

Three infant measuring devices were evaluated by the Center for Disease Control (CDC). Two of these were devices constructed and currently used by selected state health departments. The third, a highly accurate commercially available instrument specifically designed for growth studies, was used in the evaluation for comparison. In addition to the three tested, two other infant measuring devices which later became available were examined by CDC personnel.

II. Design Principles

Infant measuring boards were selected and evaluated using the following minimum design criteria:

A. Measurements readable to the nearest one-eighth inch or to the nearest one-quarter centimeter.

B. Functional dependability.

C. A rigid headpiece and a movable footpiece.

D. Constructed of durable materials and easy to clean.

E. No sharp edges or unfinished parts.

F. Measurement reproducibility.

III. Methods of Evaluation

All measuring devices were checked for accuracy using a standard measuring rod and were examined for sharp edges, protruding screws, and other defects in workmanship. Six experienced measurers from the Nutrition Division, CDC, measured 10 infants 2 times on each board. These measurements were evaluated using a modification of a standardization technique suggested by Habicht.* The boards were placed in a well-baby clinic and instructions regarding their use were given to clinic personnel. After the clinic measurers had become familiar with the equipment, comments were obtained concerning its suitability for use in clinic settings.

IV. Evaluation of Individual Measuring Devices

A. Infant Measuring Board - Tennessee. Cecil Ward, 114 Maureen Drive, Hendersonville, Tennessee 37075. Approximate cost $25.00. (Figure 1)

*Habicht, J.P., Standardization Procedures for Quantitative Epidemio-logic Field Methods. Unpublished. Institute of Nutrition of Central America and Panama, Guatemala, C.A.

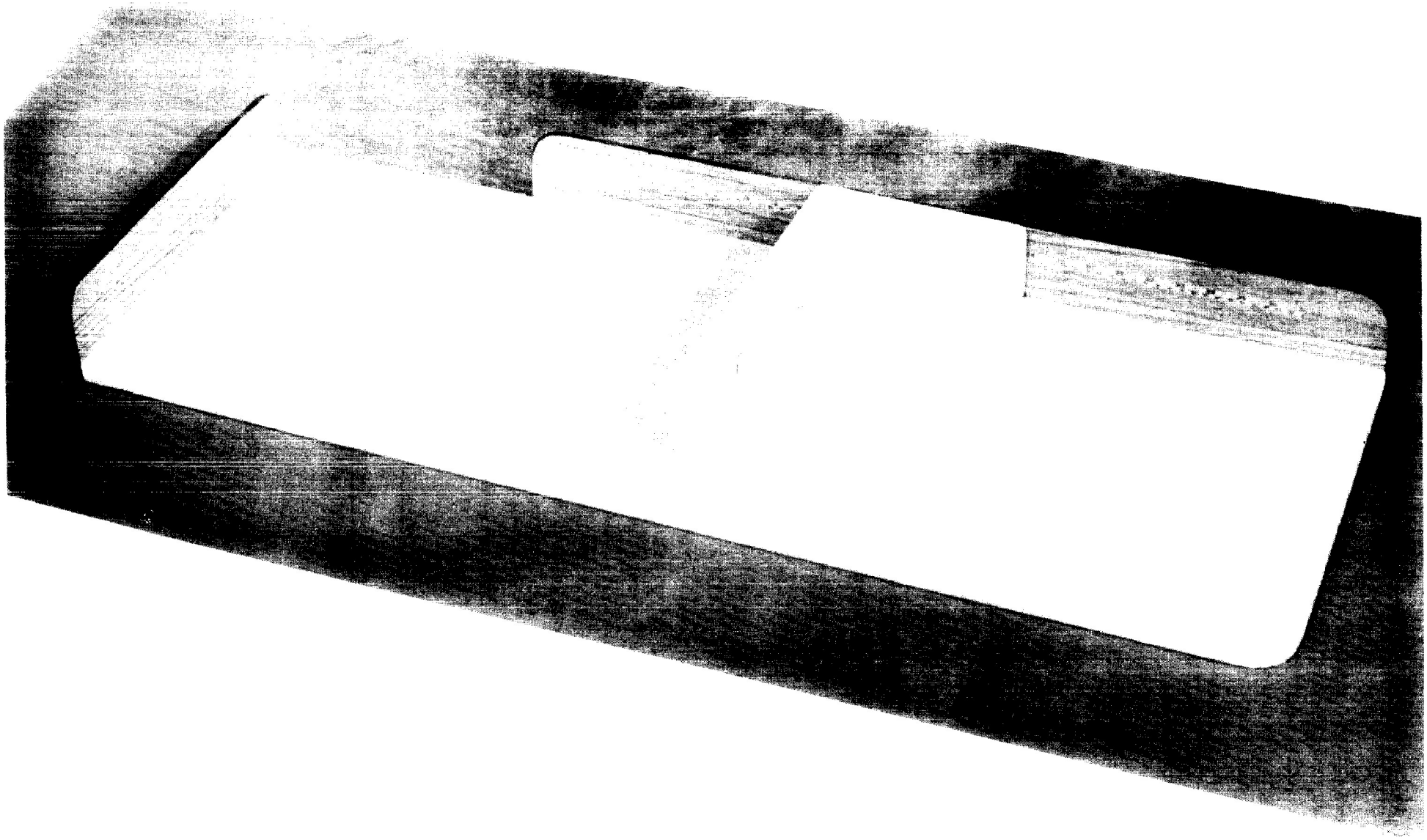


Figure 1

This instrument is constructed primarily of wood, masonite, and plywood. The headpiece is attached at one end of the board at a right angle. The footpiece is a right angle piece of wood. Measurements are read from a tape attached along the top edge of the board. The board is lightweight and can be easily carried from clinic to clinic. Measurements are made by placing the footpiece against the dorsal surface of the feet and reading the length from the tape. The three models tested by CDC were free of defects in materials and workmanship.

In tests performed by CDC measurers, measurements were not well replicated. Accuracy of the board in both laboratory and clinic testing was within 0.5 cm of the group mean.

In field tests, clinic personnel felt that this device was adequate to meet clinic needs.

B. Infant Measuring Board - Louisiana. Williams Cabinet Shop, 2664 Iroquois Street, Baton Rouge, Louisiana 70805. Approximate cost $82.00. (Figure 2)

This device is a modification of the portable length/height measuring board designed by CDC for use in international surveys. The headpiece of this measuring board is fixed, unlike the CDC board. The footpiece slides along a wooden column in which a metal tape is imbedded. Measurements are made by reading the tape at the end of the footpiece. The board is constructed of hardwood and plywood. Construction requires substantial carpentry skills. The two samples tested by CDC were free of defects in materials and workmanship.

In tests conducted by CDC measurers, the measuring board was extremely accurate. Measurements were within 0.5 cm of the group mean. Reproducibility of the measurements was good.

Clinic personnel felt that this board was the least suitable of those tested for use in their clinics. The large headboard blocked the measurer's access to the child's head. The wooden column in the center of the board was thought to be uncomfortable for longer children. One measurer felt that it would be difficult to keep this measuring board clean. Some clinic personnel had some difficulty in learning to read measurements from the distant, rather than the near end of the footpiece.

C. Recumbent Infant Length Board. TEAM, Total Engineering and Marketing, Inc., 938 Michigan National Tower, Lansing, MI 48933. Cost $49.00 F.O.B. Lansing. (Figure 3)

This board was received too late to be included in all of the clinic and field evaluation exercises; however, its superior

design merits inclusion in this report.

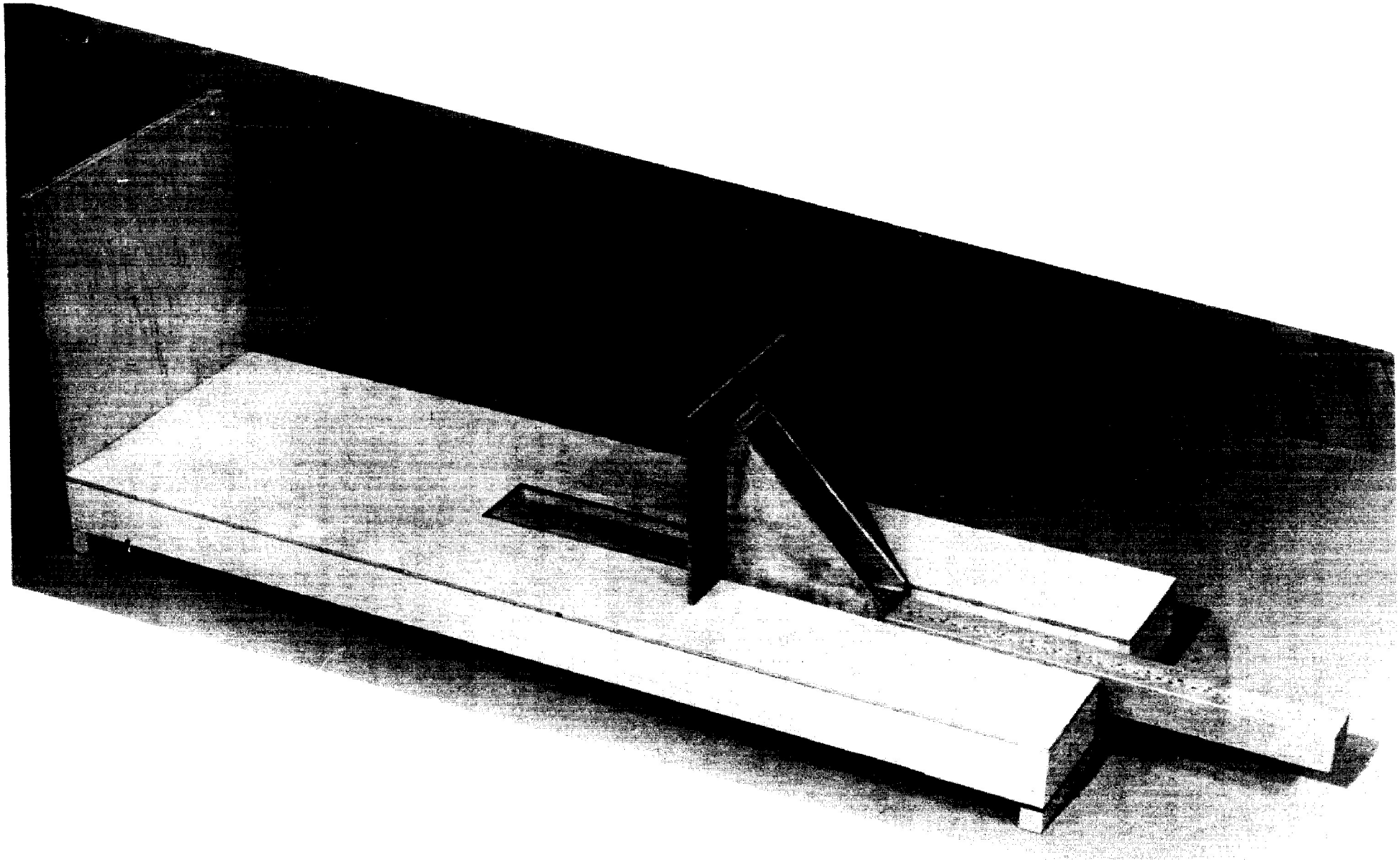


Figure 2

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

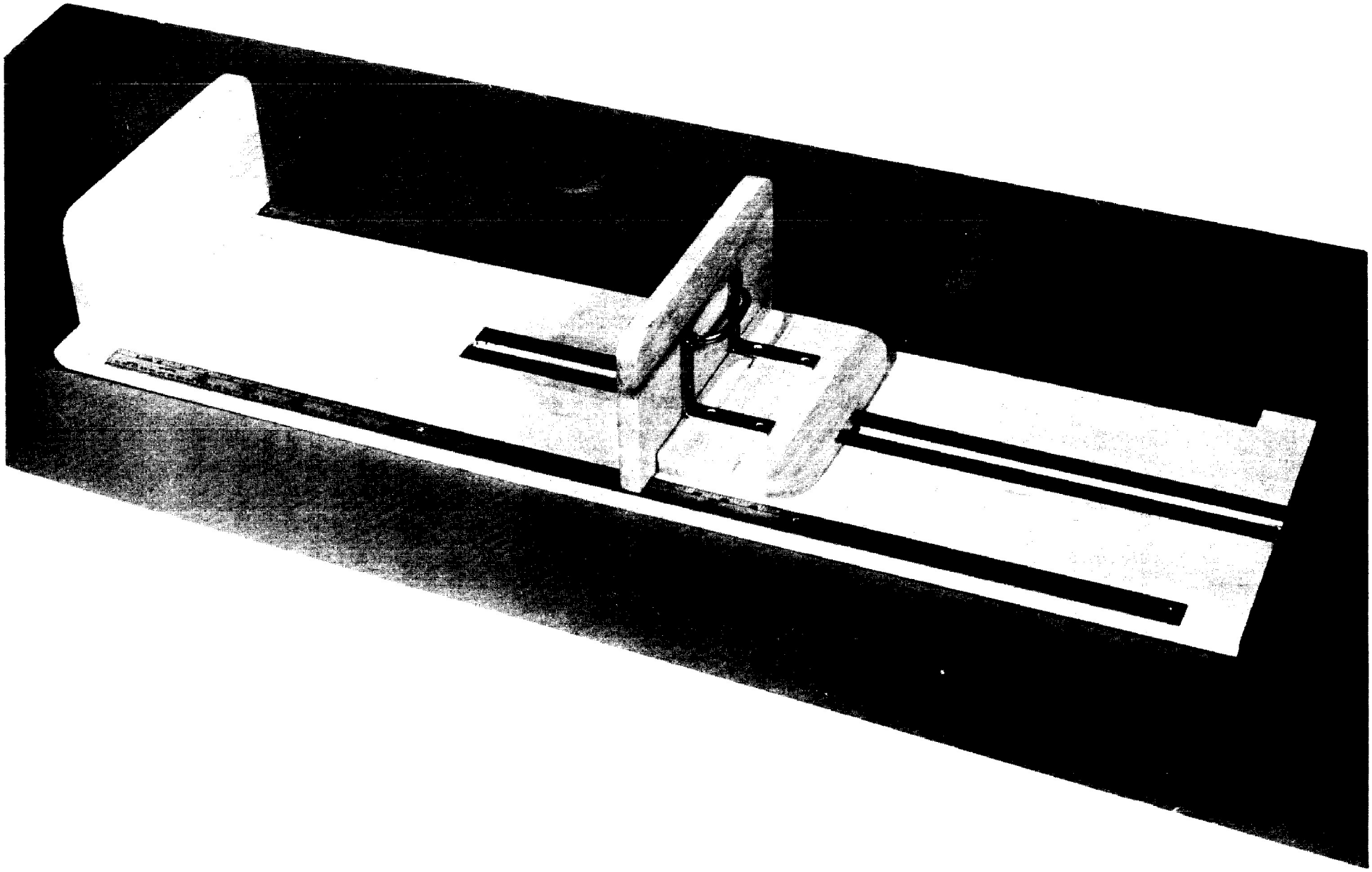


Figure 3

This board is lightweight; constructed of hardwood. The foot-piece, also constructed of hardwood, moves on a metal track which is countersunk in the center of the board. Measurements are read from two steel rules mounted along the upper and lower edges of the board.

The sample device received by CDC for testing had two defects:

1. The screws holding the rules were not smoothed which resulted in sharp edges capable of causing injury.

2. The footpiece was not centered on the metal track. Measurement differences of 2 mm were noted when reading from the upper as compared to the lower rule.

The manufacturer was notified of these quality control problems, and a subsequent production-line sample of this board received by CDC was free of these defects.

Measurements conducted by CDC personnel with the second board were accurate and reproducible within 0.2 cm.

D. GRAFCO Infantometer. Graham-Field, New Hyde Park, NY 11040. Approximate cost $40.00.

This instrument is constructed of bakelite and resembles a slide rule with its two sliding pieces. It is 20 inches long when compressed but can be extended to 38 inches. Two hinged end pieces fold out and function as head and/or footpieces. Measurements (in inches and centimeters) are made by placing the infantometer alongside the child and closing until it touches the head and feet. A small thumb screw on the bottom of the instrument is tightened to hold the sliding parts in position so a reading can be made.

E. Infantometer. Manufactured by Harpenden and Holtain, Ltd., available from Siberhegner & Co., Inc., 1250 Broadway, New York, NY 10001. Approximate cost $455.00. (Figure 4)

The infantometer, a British-made instrument constructed of metal, is specifically designed for growth studies. The board surface is covered with laminated plastic. The footpiece moves along the board on a metal gear track, and it can be locked into a fixed position. Measurements are read from a mechnical digital counter in millimeters. (Unit counters other than metric are not available.)

The sample boards evaluated were well-finished with no sharp edges or protruding screws.

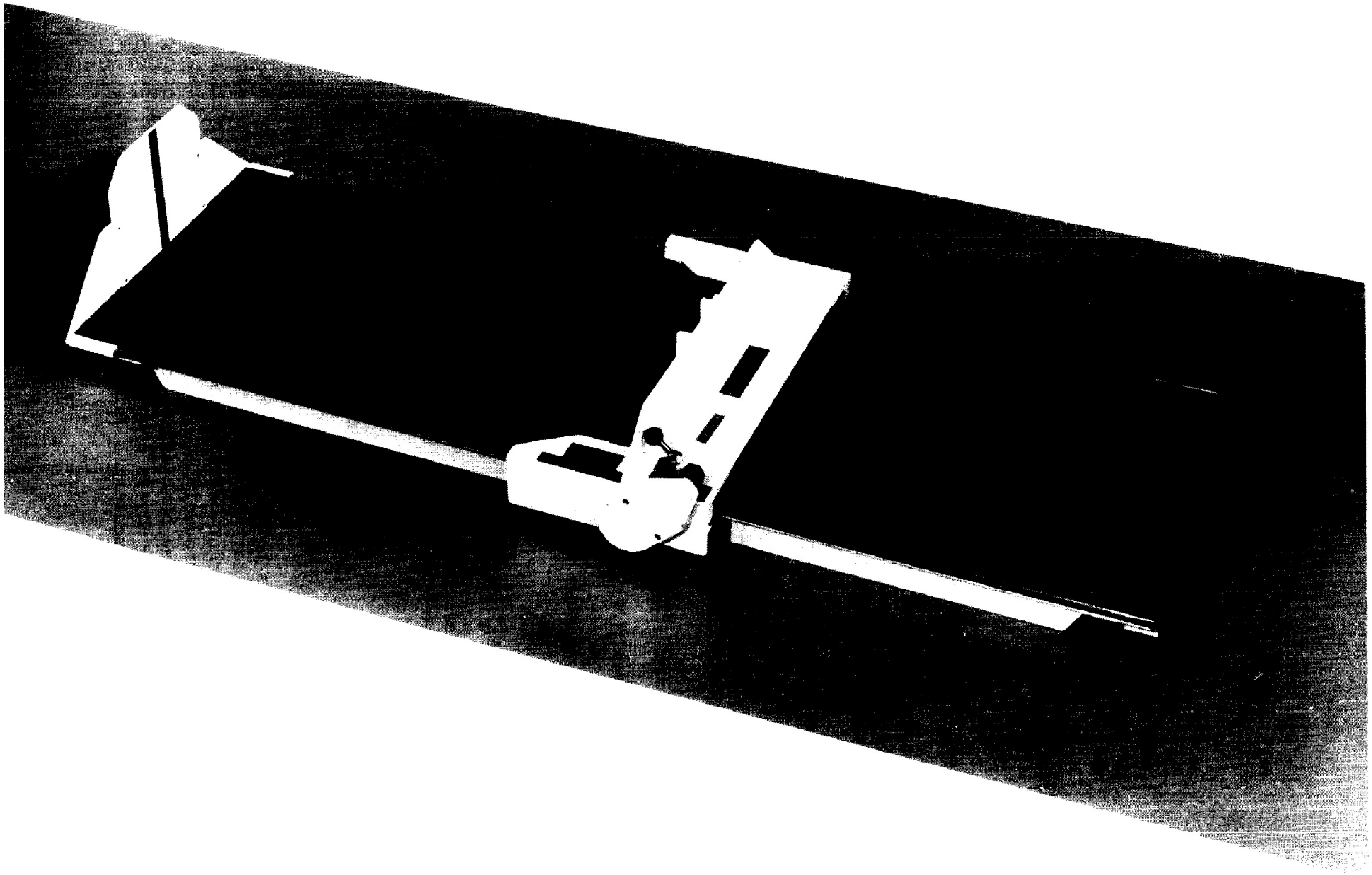


Figure 4

During testing at CDC on clinical subjects, all measurements were readily reproducible. Accuracy in a clinical setting was within 0.5 cm of the group mean.

In the clinic field use of the infantometer, measurers found that the locking footpiece and the digital readout greatly reduced measurement error. Measurements made with the infantometer were more accurate and more reproducible than those made with other instruments tested.

V. Results of Evaluation

ACCEPTABLE

TEAM Recumbent Infant Length Board

This low-priced board is well-designed for clinic use. Its accuracy and reproducibility are superior. It is made of durable materials and virtually maintenance-free.

Infant Measuring Board - Tennessee

This board is accurate and can be produced at a reasonable cost. Its primary disadvantage is that the detached footpiece compromises reproducibility of measurements.

Infant Measuring Board - Louisiana

Although accurate measurements can be made using this board, the difficulty involved in its construction, the size of the headpiece, and the problems some clinic personnel have with its use, may limit its acceptability.

Harpenden and Holtain Infantometer

This is a well-designed device for producing extremely accurate measurements. The digital readout and locking footpiece minimize human error. Its price may be a disadvantage.

UNACCEPTABLE

GRAFCO Infantometer

This instrument fails to meet some of the basic criteria for an infant measuring device: it does not have a rigid headpiece and, because of other inherent deficiencies, it is doubtful that measurements obtained are reproducible. The hinged parts tend to develop excessive play or become bent and overmeasuring may possibly occur. A portion of two hinges covers both the inch and centimeter scale making it difficult to measure a child less than 201/2 inches.

Evaluation of Devices for Measuring Stature

I. Introduction

Four devices for measuring stature were evaluated by the Center for Disease Control (CDC). Three of these were prototypal devices representing modifications of basic functional design. The fourth device examined was a Harpenden and Holtain Portable Stadiometer which was used for comparison.

II. Design Principles

The stature measuring devices were selected and evaluated using the following design criteria:

A. Measurements readable to the nearest one-eighth inch or to the nearest one-quarter centimeter.

B. Functional dependability.

C. Constructed of durable materials and easy to clean.

D. No sharp edges or unfinished parts.

E. Measurement reproducibility.

III. Methods of Evaluation

All measuring devices were checked for accuracy using a standard measuring rod, and were examined for sharp edges, protruding screws, and other defects in workmanship or materials. Six experienced measurers from the Nutrition Division, CDC, measured 10 children 2 times on each device. These measurements were evaluated using a modification of a standardization technique suggested by Habicht.~ The measuring devices were then placed in a well-baby clinic and instruction regarding their use were given to clinic personnel. After the clinic measurers had become familiar with the equipment, comments were obtained concerning its suitability for use in clinic settings.

IV. Evaluation of Individual Measuring Devices

A. Portable Length/Stature Measuring Board. Not commercially available. Plans available from Nutrition Division, CDC. Approximate cost of construction $75.00. (Figure 5)

This board was designed primarily for use in international surveys in developing areas. It is constructed of plywood

* Habicht, J.P., Standardization Procedures for Quantitative Epidemio-logic Field Methods. Unpublished. Institute of Nutrition of Central America and Panama, Guatemala, C.A.

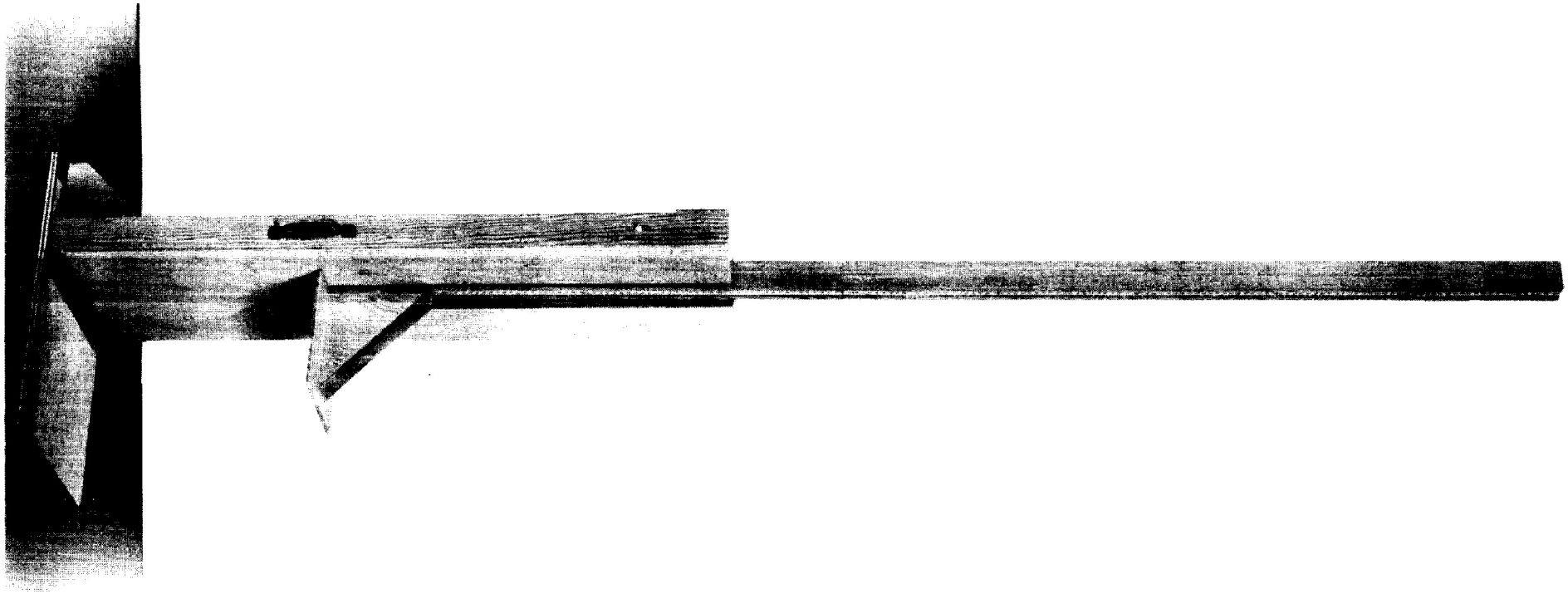


Figure 5

and hardwood. The base is hinged and the headpiece can be removed to permit carrying. Measurements are made by reading a tape at the upper end of the sliding headpiece. An extension can be used to measure subjects up to 190 centimeters in height. Construction of the board requires relatively sophisticated carpentry skills. In the prototypes constructed locally to CDC specifications, no defects in materials or workmanship were found.

In tests, this device produced consistently accurate and reproducible measurements. Accuracy was within 0.2 cm of the group mean. The device folds easily and can be carried from one clinic site to another with little difficulty. Most clinic personnel commented favorably on its compact size and portability.

B. CDC Prototype Height Board. Not commercially available. Plans available from the Nutrition Division, CDC. Approximate cost of construction $75.00. (Figure 6)

This board is designed for permanent attachment to a wall. Its construction is of wood and plexiglass. The headpiece slides on a wooden track. Measurements are read from a metal tape affixed to one side of the board. The prototype can measure subjects up to 190 cm in height. Those boards which were constructed locally to CDC specifications were free of workmanship or material defects.

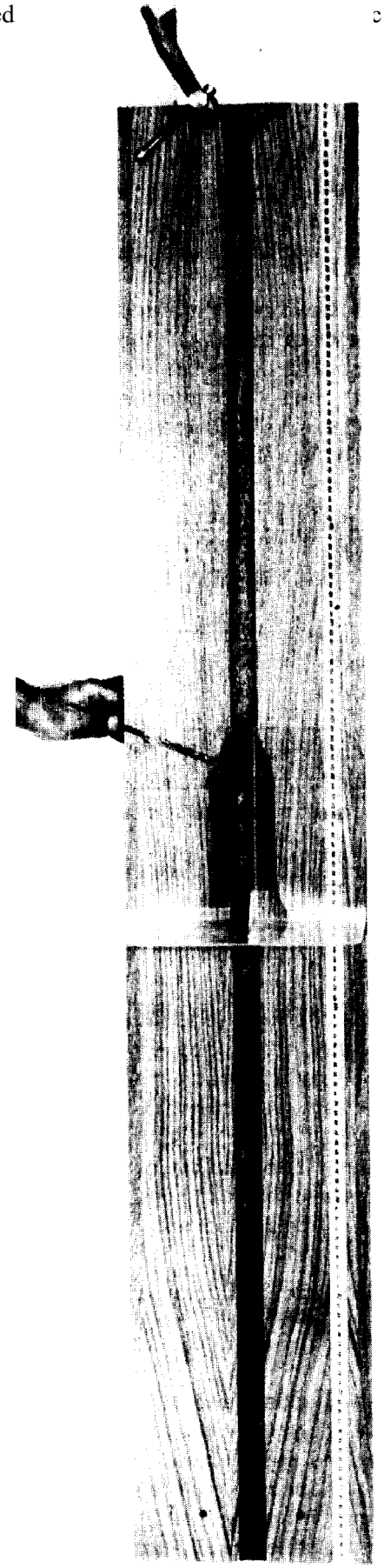
If mounted correctly on the wall (exactly 42 cm from the floor), this board produces extremely accurate measurements. Accuracy was within 0.3 cm of the group mean. Reproducibility was superior.

Clinic personnel found the board well suited to clinic use. They were pleased with the ease by which children could be measured and their heights recorded. One design improvement suggested by them was the installation of a locking device that would permit the child to be measured, the headpiece then locked in place, the child removed from under the headpiece, and then the measurement read. A prototype with this modification is being constructed.

C. Tennessee Board for Stature Measurements. Cecil Ward, 114 Maureen Drive, Hendersonville, TN 37075. Approximate cost $25.00. (Figures 7 and 8)

This instrument, designed and used by the Tennessee State Department of Health is constructed of plastic-covered masonite. It has a detached headpiece consisting of a right-angled piece of hardwood. Measurements are read from the edge of the headpiece to a tape imbedded in the board. The board

```
is designed to be mounted on the wall exactly 30 cm from the
floor. It can be mounted using either double-sided adhesive
or screws.
```



Figur \0

Figure 7

Figure 8

During field trials, personnel were able to perform accurate measurements but reproducibility was poor. This was probably due to the difficulty in lining up the edge of the headpiece with the markings on the measuring tape.

D. Harpenden and Holtain Portable Stadiometer. Siberhegner & Co., Inc., 1250 Broadway, New York, NY 10001. Approximate cost $614.00 (Figure 9)

The Stadiometer, like the same company's Infantometer, is British-made and is well constructed from metal and laminated plastic. It can measure subjects up to 190 cm in height. Measurements are read from a digital counter to the nearest millimeter. (Units other than metric are not available.) The Stadiometer weighs approximately 23 kilograms and is mounted on a base that measures 30 cm x 130 cm. Although the Stadiometer can be disassembled and placed in a metal box for transport, its size and weight make routine movement from site to site impractical. The two Stadiometers tested were free of defects in workmanship and materials.

In tests at CDC, measurement accuracy and reproducibility were exceptionally good. Clinic personnel liked the digital readout and the counter-weighted headpiece that permitted removal of the child prior to reading of the measurement. Some feel that the instrument occupied too much space in the examining room and that its size and weight prohibited moving it to a storage area when not in use.

V. Results of Evaluation

ACCEPTABLE

CDC Prototype Height Board

This board - still in prototype form - is easy to use and capable of producing accurate and reproducible measurements. The planned locking headpiece modification should make the production of accurate measurements easier if this change can be accomplished. A critical step prior to use is the mounting on a wall of the board exactly 42 cm from the floor. The device is easy to construct.

Tennessee Board for Stature Measurements

This is an acceptable board, but the detached headpiece contributes to the difficulty in obtaining reproducible measurements. Its relatively low cost and ease of operation makes it attractive for use in many clinics. If adhesive backing is used to fasten the device to the wall, damage to the wall can result when the device is removed.

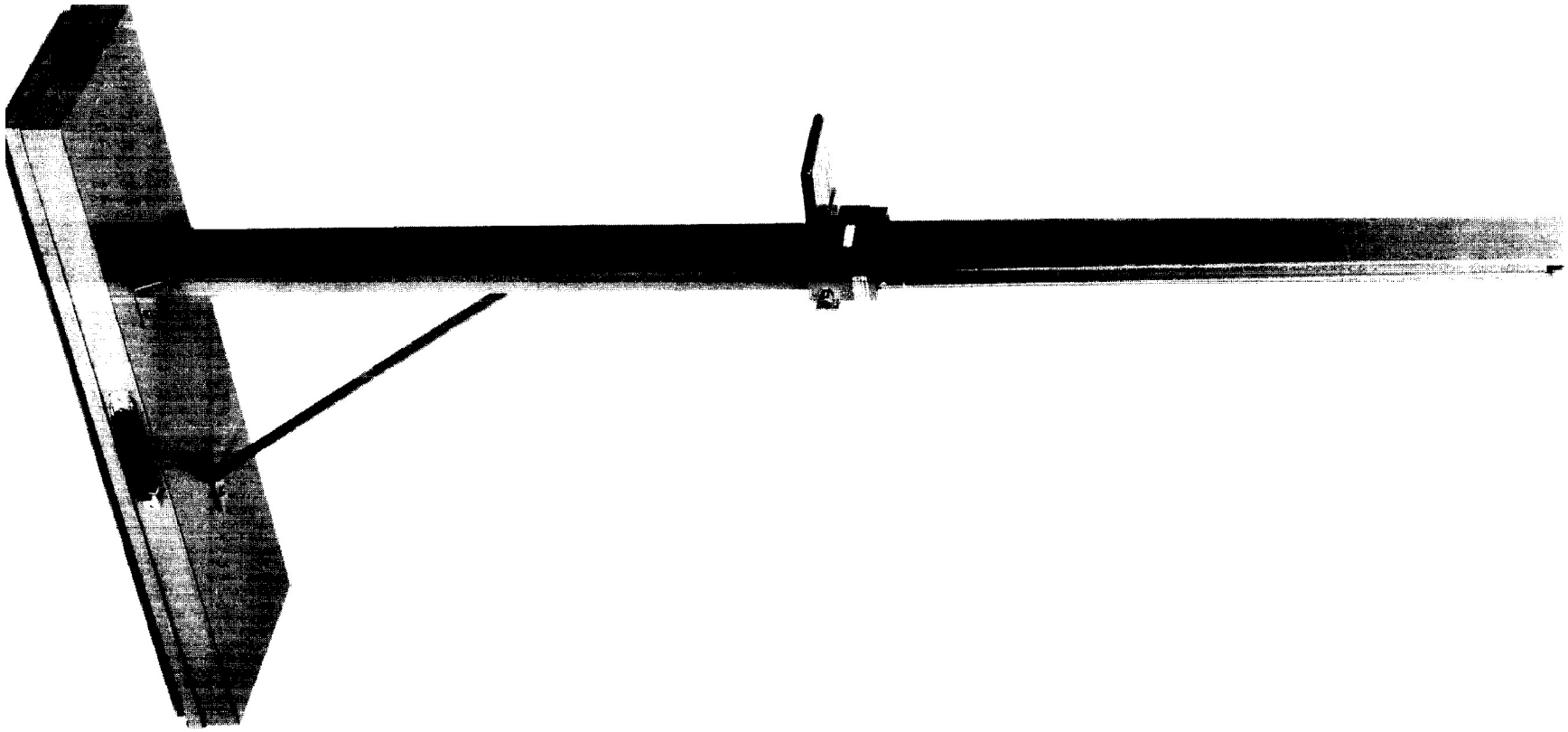


Figure 9

CDC Portable Length/Height Measuring Board

Although this board can be used to produce accurate height measures, we feel that its durability has been compromised in an effort to make it portable. For this reason, we believe the device would not withstand the rigors of daily clinic use over time.

Evaluation of Devices for Measuring Weight

I. Introduction

Five weighing devices were examined by the Center for Disease Control (CDC). Three of these devices were electronic scales with digital readout; two were beam balance scales. Each scale was examined for reproducibility and durability at the CDC headquarters. Examination in other areas was not carried out.

II. Design Principles

Weighing devices were selected and evaluated using the following minimum design criteria:

A. Accuracy of measurements within ½ ounce for pediatric scales, and within 4 ounces or 100 grams for other scales.

B. Scale has zero adjustment.

C. Measurements linear with minimum error at both low or high ranges (see A above).

D. Measurement reproducibility.

E. Durable and easy to maintain.

III. Discussion

A. Electronic Digital Scales

Of the three scales1 examined by the CDC, none were found satisfactory for routine clinic use. Zero adjustment was not available on one scale (Model 7047). Measurements were not consistently reproducible on all scales (variation between measurements was 100-400 grams). The scales had minor service problems and servicing was not readily available in the Atlanta area. The scales themselves were constructed of glass, plastic, and metal and, in our opinion, would not be durable under routine clinic conditions.

B. Beam Balance Scales

The two scales[2] examined were representative of the beam balance type. Both had non-detachable balance weights and a zero adjustment weight. Reproducibility was good. Both scales were maintenance free.

1 Detecto Model 8432 - Digital Pediatric - Approximate cost $410.00
Detecto Model 7047 - Doctor's Scale - Approximate cost $250.00
Detecto Model 8431 - Hospital Scale - Approximate cost $410.00

2 Health-0-Meter Model 230 - Doctor's Scale - Approximate cost $152.00
Detecto Gym Scale - Approximate cost $184.00

IV. Recommendations

On the basis of our review we recommend that beam balance scales with non-detachable weights, preferably without built-in measuring rods, be used in all clinic nutrition assessment programs. Although electronic scales may be satisfactory in certain home and office settings, we feel they are inappropriate for routine clinic use.

Spring balance scales such as bathroom scales are not recommended. Over time, the spring counter balance mechanism loses its accuracy. Host bathroom scales are difficult to read since measurements are read at floor level rather than eye or waist level and some of these scales are not capable of reading more accurately than one-half pound.

Evaluation of Non-automated Instruments For Determining Blood Hemoglobin Content and Packed Cell Volume Measurements

I. Introduction

The Center for Disease Control evaluated selected commercially available instruments used for the determination of hemoglobin content of blood, and for the determination of packed red cell volume. Three photometers for use with the internationally recommended hemiglobincyanide (HiCN; cyanmethemoglobin) method, one visual color comparator, and one microhematocrit centrifuge were examined.

This report presents the findings of the assessment.

II. Principles Considered and MethOds Used for the Evaluation of Photometers Designed, for Hemoglobin Determination

For the evaluation of the photometers for hemoglobin determination the following questions were considered:

1. Is the instruction manual clear and complete?
2. Is the instrument easy to install?
3. Are instrument controls simple and accessible?
4. How well does the instrument perform with respect to
   (a) zero stability,
   (b) calibration stability, and
   (c) linearity, range 0 to 21 g/d1?
5. What is the type, suitability, and consistency of cuvettes?
6. Are the hemoglobin values obtained with the instrument (system) comparable to the reference method values?
7. What are the instrument maintenance requirements?
8. Are accessories available and are they easy to install?

Accurate hemoglobin values of unknown samples were made according to International Committee for Standardization in Haematology recommendations (ICSH).

Dilution 1:251: **20 µl calibrated National Bureau of Standards (NBS) Sahli pipets**
5.0 ml calibrated class A volumetric pipets

pH of Reagent = 7.3, containing nonionic detergent

$K_3Fe(CN)_6$	200 mg
KCN	50 mg
KH_2PO_4	140 mg
Sterox SE	0.5 ml
Deionized H_2O ad	1,000 ml

The reagent was prepared and the measurements of the resulting HiCN solutions were made on a Beckman Acta M VI spectrophotometer, λ = 540 ram half intensity bandwidth 0.11 nm, 1.000 cm light path. Water was used as the reference. The spectrophotometer performance was checked weekly using NBS certified neutral density glass filters (absorbance), holmium oxide filter (wavelength). It was also checked frequently using D2 emission lines (wavelength) and appropriate liquid filters (stray light). Photometers were evaluated daily and if necessary calibrated using HiCN reference solutions meeting ICSH specifications. ICSH specifications of the HiCN reference solution were checked regularly with the Acta M VI spectrophotometer.

References

1. ICSH, Protocol for type testing equipment and apparatus used for haematological analysis. J. Clin. Path. 31, 275, 1978.

2. ICSH, Recommendations for reference method for haemoglobinometry in human blood and specifications for international hemiglobin-cyanide reference preparation. J. Clin. Path. 31, 139, 1978.

3. NCCLS, Proposed Standard: PSH-15 Reference Procedure for the Quantitative Determination of Hemoglobin in Blood. 1979.

III. Review of Instruments

A. HEMOMETER, LIC, Lars Ljungberg. Accurate Chemical and Scientific Corp., Hicksville, NY 11801. Approximate cost $530.00. (Figure 1)

1. Equipment and Accessories

The Ljungberg Hemometer is a hemoglobinometer equipped with a galvanometer scale, reading directly in grams (g) of hemoglobin per litre (top scale) and mmol hemoglobin (Fe) per litre (1) (bottom scale). The square glass cuvette, 1.3 x 1.3 x 7.0 cm, is standard; a flow-through cuvette plus hand-operated pumping device is available. Reagent and/or calibration material was not delivered with the instrument.

2. Manual

The instruction manual is incomplete, consisting of a one-page instruction sheet and a conversion table for hemoglobin concentration in g/100 ml to g/1 to "%" (16.0 g/100 ml = 100% relative). Principles and description of the recommended method are not given. There are no directions for setting, up the instrument. Available accessories are not mentioned, and there is no section on instrument maintenance or on trouble shooting. The distributor of the instrument is not listed. There are no instructions for installation and use of the flow-through cuvette assembly.

3. Installation

Installation of the photometer is simple, consisting of (a) unpacking the instrument, (b) connecting the line cord to a suitable power outlet, (c) inserting the cuvette into the well, and (d) switching the instrument on.

The installation of the flow-through cuvette assembly requires extreme care and patience.

4. Accessibility of Instrument Controls

Controls consist of a power switch, a zero control knob, and a calibration potentiometer (screwdriver setting). Controls are well placed, easy to reach and to operate.

5. Performance

5.1 Zero Point Drift: In daily use the zero point needs only minor adjustment, every 3 to 6 hours.

5.2 Calibration Point Drift: In daily use the calibration point shows only minor fluctuations. For accurate measurements, the calibration point should be checked twice daily.

5.3 Linearity: The instrument linearity was checked by comparing the hemoglobin values of a dilution series to values obtained with a Beckman Acta M VI spectropbo-tometer. The instrument was found to be slightly alinear. (Compare Figures 2 and 3 and Table A)

Table A

Hemoglobin Values (g/dl of Serially Diluted HiCN Reference Solution

Acta M VI	Hemometer	Δ	Acta M VI	Hemometer	Δ
20.6	20.4	-0.2	20.6	20.1	-0.5
15.3	15.6	+0.1	15.4	15.4	0
10.3	10.6	+0.3	10.3	10.6	+0.3
7.7	8.0	+0.3	7.8	8.1	+0.3
2.5	2.6	+0.1	5.2	5.5	+0.3
			2.6	2.8	+0.2

5.4 Comparative Measurements

Twenty blood samples obtained from an outpatient clinic were diluted in duplicate using the ICSH recommended method, and measured on a Beckman Acta M VI spectropho-tometer and on the Hemometer. Results are given in Table I. The mean difference was -0.06 g/dl, ranging from -0.3 to +0.3 g/d1. The Hemometer was recalibrated daily using HiCN reference solutions meeting ICSH specifications, equivalent hemoglobin concentration 14.6 g/d1. A single square glass cuvette was used for all measurements. (Table I)

6. Day to Day Maintenance

No day-to-day instrument maintenance was needed during the 4-week testing period. Instrument and cuvette were kept clean according to good laboratory practice.

TABLE I

Comparison of Ljungberg Hcmometcr Readings to Hemoglobin Values Calculated from A540 Readings (ICSH Recommended Method). Hemoglobin Values g/dl

Sample	Acta M VI	Ljungberg	L.-A.	Sample	Acta M VI	Ljungberg	L.-A.
1.1	15.6	15.4	-0.2	11.1	13.4	13.4	0
1.2	15.5	15.4	-0.1	11.2	13.3	13.3	0
2.1	15.4	15.3	-0.1	12.1	15.3	15.2	-0.1
2.2	15.5	15.4	-0.1	12.2	15.2	15.2	0
3.1	13.0	13.1	+0.1	13.1	15.6	15.6	0
3.2	13.0	13.0	0	13.2	15.7	15.5	-0.2
4.1	16.4	16.2	-0.2	14.1	14.4	14.2	-0.2
4.2	16.4	16.2	-0.2	14.2	14.3	14.2	-0.1
5.1	15.0	14.9	-0.1	15.1	16.2	16.1	-0.1
5.2	15.2	15.0	-0.2	15.2	16.2	16.1	-0.1
6.1	16.4	16.2	-0.2	16.1	16.3	16.2	-0.1
6.2	16.S	16.3	-0.2	16.2	16.5	16.4	-0.1
7.1	17.0	16.7	-0.3	17.1	12.7	12.7	0
7.2	17.0	16.7	-0.3	17.2	12.7	12.8	+0.1
8.1	13.3	13.2	-0.1	18.1	10.3	10.4	+0.1
8.2	13.2	13.2	0	18.2	10.2	10.4	+0.1
9.1	17.1	16.9	-0.2	19.1	6.6	6.9	+0.3
9.2	17.1	16.9	-0.2	19.2	6.6	6.8	+0.2
10.1	13.3	13.3	0	20.1	6.4	6.7	+0.3
10.2	13.2	13.2	0	20.2	6.4	6.7	+0.3
					Mean Difference		-0.0575

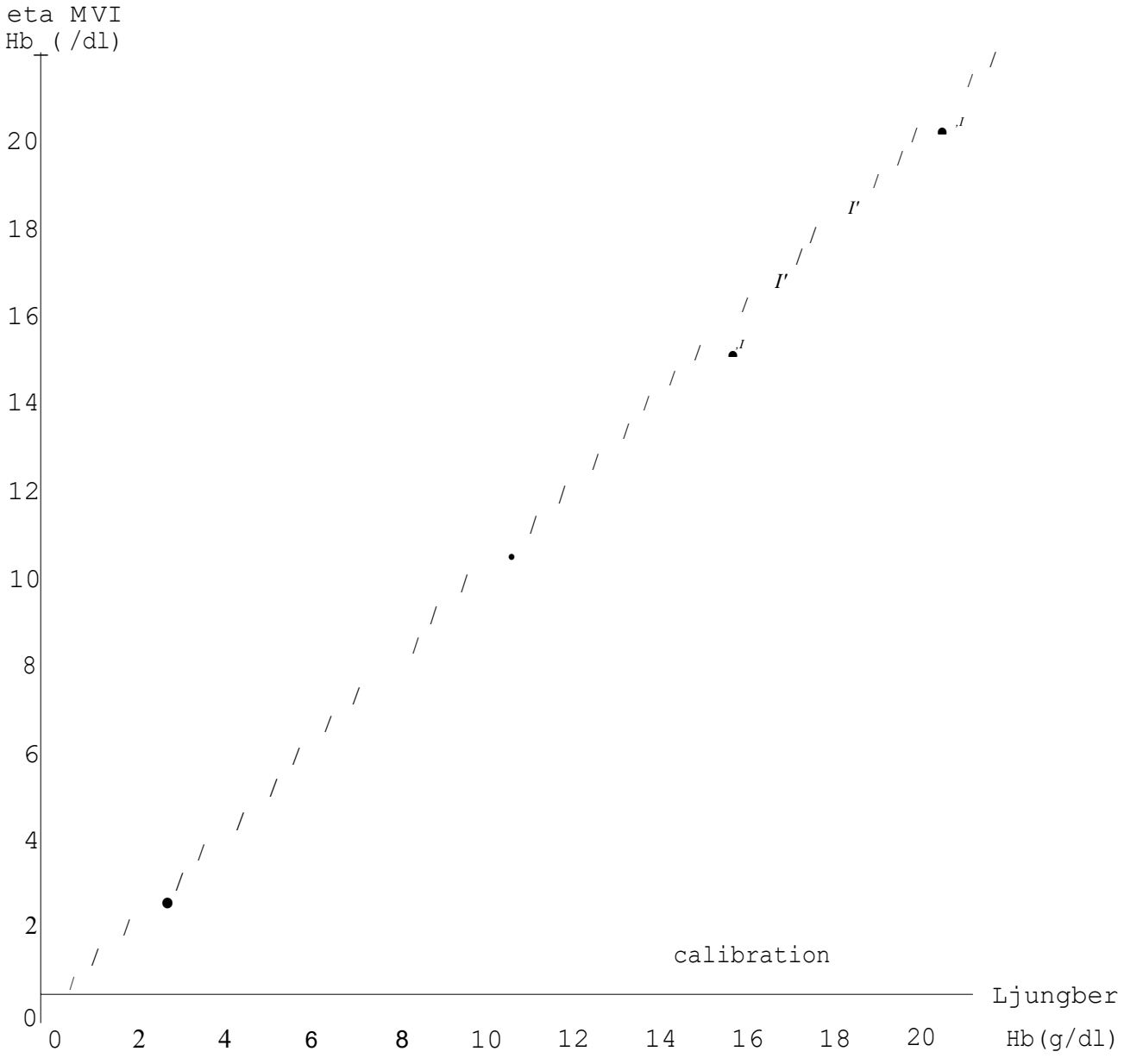
Samples from routine outpatient clinic diluted in duplicate (Sahli pipets, 5 ml class A volumetric pipets) using phosphate/Sterox reagent. Measured on both Beckman Acta M VI and Ljungberg. Ljungberg calibrated daily with ICSH HiCN solutions.

The contents
document is

FIGURE 1

Figure 2

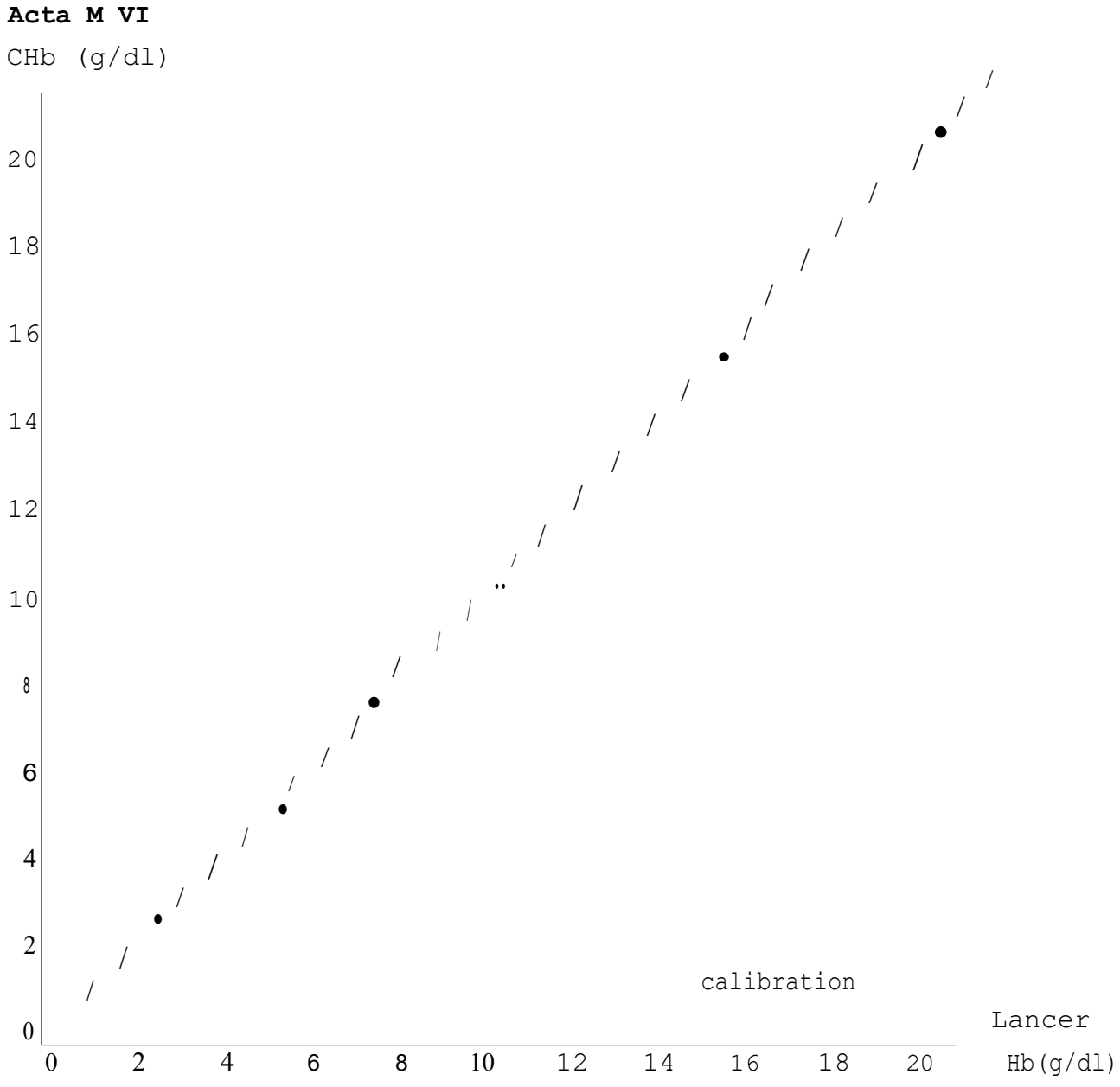
Assessment of Instrument Linearity by Comparing Hemoglobin Concentration Measured with a Beckman Acta M VI Spectrophotometer to Values Read on the Ljungberg Hemometer Calibrated at 14.4 g/dl with an HiCN Solution Meeting ICSH* Requirements



* International Conunittee for Standardization in Haematology

Figure 3

Assessment of Instrument Linearity by Comparing Hemo lobin Concentration Measured with a Beckman Acta M VI Spectrophotometer to Values Read on the Lancer Hemoglobin Analyzer Calibrated at 15.0 g/dl with the 15 g/dl Performance Check Set Solution



B. LANCER HEMOGLOBIN ANALYZER. Lancer Division of Sherwood Medical, St. Louis, MO 63103. Approximate cost $695.00. (Figure 4)

1. Equipment and Accessories

The Lancer Hemoglobin Analyzer is a hemoglobinometer reading directly (digital) in hemoglobin concentration expressed as g/100 ml. The instrument uses vial-type cuvettes which are prefilled with reagent. Available accessories include capillary tubes for sampling and a "Performance Check Set" to calibrate the analyzer. A flow-through cuvette is not available.

2. Manual

The accompanying manual consists of a number of data sheets and a plastic coated instruction card. The principle of the method is covered; installation procedures are clear and concise; and instructions for sampling, diluting and measuring are clear. Instructions in case of malfunction are given and quality control and calibration are discussed. Information on day-to-day instrument care is not given.

3. Installation

Installation of the instrument is simple, consisting of (a) unpacking, (b) connecting line cord to suitable power outlet, and (c) placing a water filled vial-cuvette in the well. The instrument should then give a zero (digital) reading.

4. Accessability of Instrument Controls

The instrument does not have a power switch or a zero control. A calibration potentiometer is found at the back of the instrument. A calibration pen (screwdriver} is included with the instrument. Although it is possible to turn the potentiometer by "blindly" inserting the calibration pen (or regular screw driver) in the appropriate opening, if the instrument is turned 90 degrees forward, better visibility for calibration is obtained.

5. Performance

5.1 Zero Drift: With a water-filled vial-cuvette in the well, a zero reading is obtained and automatically maintained.

5.2 Calibration Point Drift: In daily use the calibration point drifts slightly (+-0.1 g/dl). A twice-daily calibration point check was performed for most

accurate measurements. A "Performance Check Set" is available

as an accessory with equivalent hemoglobin concentrations of 5, 10, 15, and 20 g/dl. The 15 g/dl equivalent is used to calibrate the instrument.

5.3 Linearity: The instrument was found to have good linearity using a serially diluted hemoglobin reference solution and comparing instrument readings to hemoglobin values obtained from measured values with the Beckman Acta M VI. (Figure 5)

5.4 Cuvettes: Vial-type screw cap cuvettes containing 5 ml of reagent were used. To test vial light path reproducibility, 10 randomly taken vials were inserted into the well and slowly revolved, noting the highest and lowest reading. A range of -+0.05 g/dl was found. A diluted HiCN solution was added to each of eight other randomly selected empty vials. A mean of 17.9 g/dl (range: 17.8 to 18.2 g/dl) was found. To a third randomly selected group of 10 vials, 0.20 ul of sample was added using 10 Lancer capillary tubes. A mean of 17.95 g/dl (range 17.7 to 18.3 g/dl) was obtained.

5.5 Comparative Measurements

Twenty blood samples obtained from an outpatient clinic were diluted in duplicate using the ICSH recommended method and also diluted in duplicate into the Lancer reagent vials using 20 ul Lancer disposable capillaries. The results of measuring on a Beckman Acta M VI and on the Hemoglobin Analyzer are given in Table II. The mean difference was +0.09 g/dl. After the exclusion of one duplicate outlier (sample 14.1, 14.2), the mean difference was 0.06 g/dl (range: -0.4 to +0.4 g/dl). The Hemoglobin analyzer was recalibrated daily using the 15 g/dl vial from the Check Set. (Table II)

6. Day to Day Maintenance

No day-to-day maintenance was needed during the testing period (4 weeks). Instrument was kept clean according to good laboratory practice.

TABLE II

Comparison of Hemoglobin Values Using tha L ncer Hemoglobin Analyzer System and the ICSH Reco111111ended Method. Hemoglobin Values in g/dl.

Sam2le	Acta MVI	Lancer	La.-A.	Sam2le	Acta M VI	Lancer	La.-A.
1.1	15.6	15.5	-0.1	11.1	13.4	13.4	0
1.2	15.5	1.5.6	+o.1	11.2	13.3	13.3	0
2:.1	15.4	15.3	-0.1	12.1	15.3	15.2	-0.1
2:.2	15.S	15,6	+o.1	12.2	15.2	15.4	+o.2
3i.1	13.0	13.1	+o,1	13.1	15.6	15.3	-0.3
31.2	13.0	13.3	+o.3	13.2	15.7	15.3	-0.4
4.1	16.4	16.6	+o.2	14.1	14.4	15.1	+o.7
-.2	16.4	16.6	+o.2	14.2	14.3	14.8	+o.6
5,.1	15.0	15.1	+o.1	15.1	16.2	16.3	+o.1
5.2	15.2	15.3	+o.1	15.2	16.2	16.5	+o.3
6.1	16.4	16.6	+-0.2	16.1	16.3	16.3	0
6.2	16.5	16.3	-0.2	16.2	16.5	16.3	-0.2
7.1	17.0	17.3	+o.3	17.1	12.7	12.8	+o.1
7.2	17.0	17.4	+o.4	17.2	12.7	12.8	+o.1
8.1	13.3	13.6	-t-0.3	18.1	10.3	10.3	0
8.2	13.2	13.6	-t-0.4	18.2	10.2	10.2	0
9.1	13.3	13.3	0	19.1	6.6	6.6	0
9.2	13.2	13.3	+o.1	19.2	6.6	6.6	0
10.1	17.1	17.0	-0.1	20.1	6.4	6.4	0
10.2	17.1	17.2	+o.1	20.2	6.4	6.4	0
					Mean Difference		+o.09
					excluding 14.1, 14.2		+o.0575

San,ph•A from rontinr outpatient C'linl<- diluted in d11pl1.cate (Snhll pipets, 5 nil class A volumetric pipete) using phosphate/Sterox reagent, measuring on Beckman Acta MVI. For the Lancer duplicate dilutions made using Lancer reagent tubes and capillaries. Lancer calibrated daily with Performance Check Set.

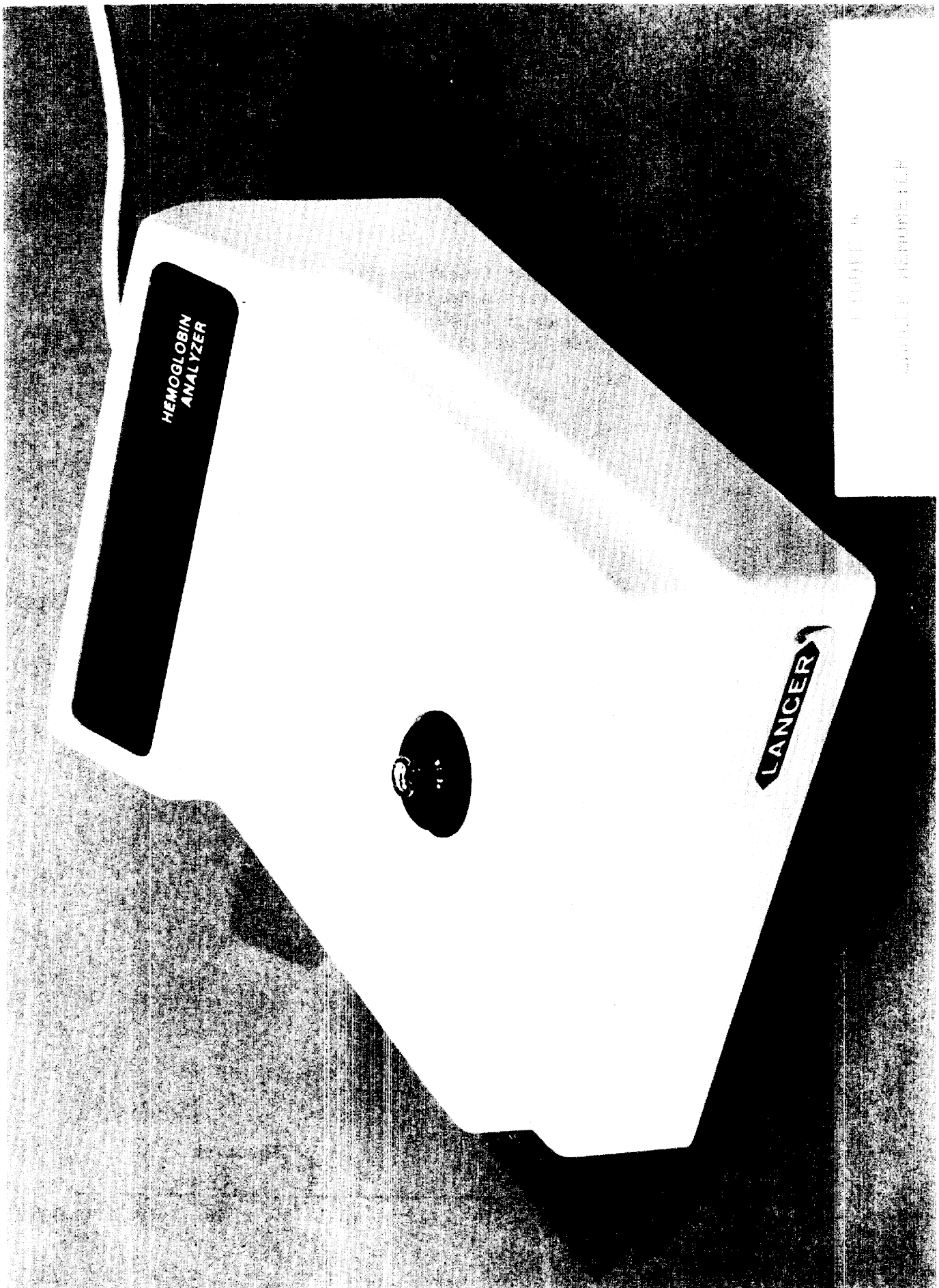
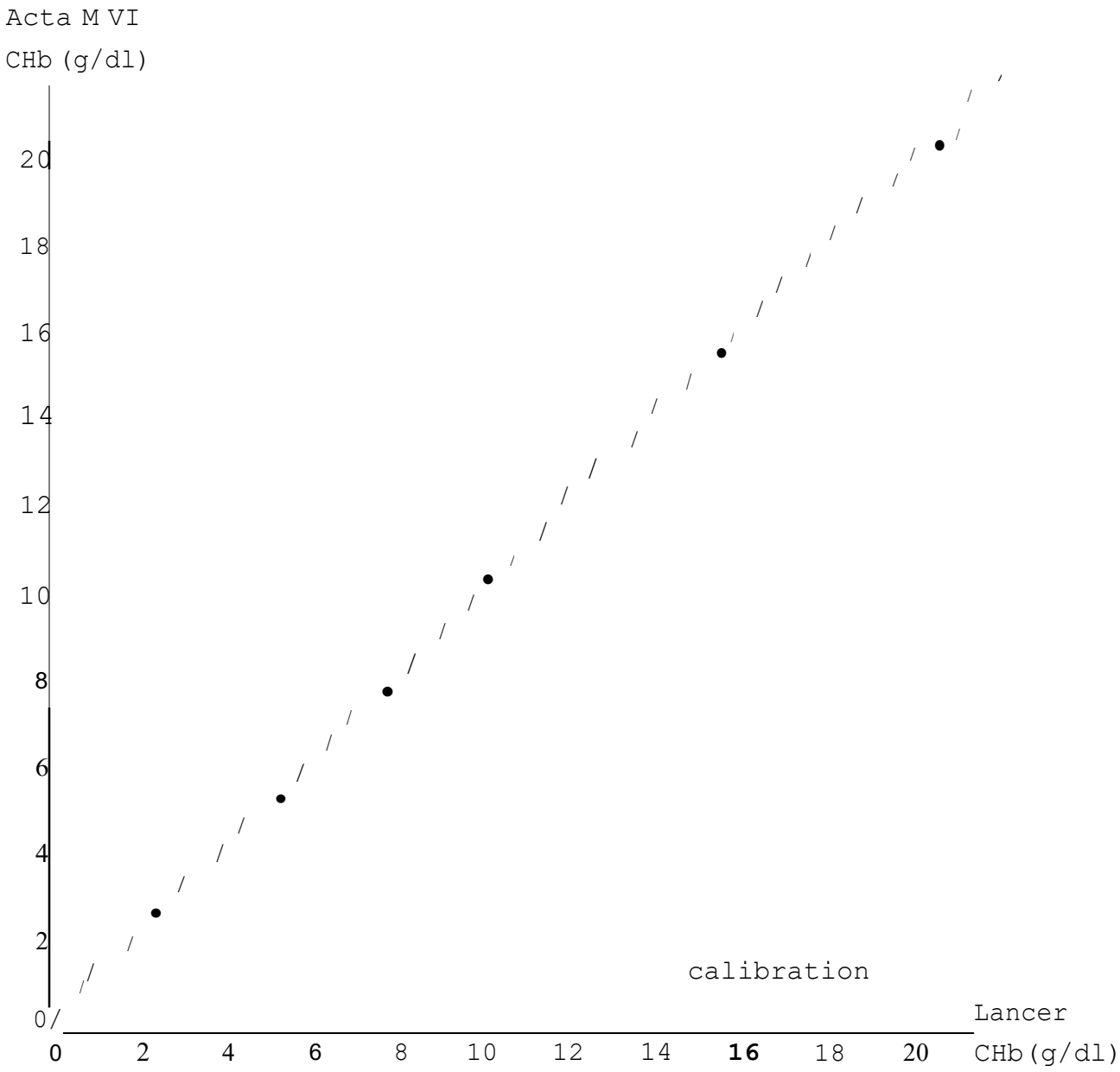


Figure S

Assessment of Instrument Linearity by Comparing Hemoglobin Concentration Measured with a Beckman Acta M VI Spectrophotometer to Values Read on the Lancer Hemoglobin Analyzer Calibrated at 15.0 g/dl with an HiCN Solution Meeting ICSH* Requirements



* International Committee for Standardization in Haematology

C. FISHER DIGITAL HEMOPHOTOMETER. Fisher Scientific Comp., Pittsburgh, PA 15219. Approximate cost $795.00. (Figure 6)

1. Equipment and Accessories

The Fisher Digital Hemophotometer is a hemoglobinometer having a direct digital readout in hemoglobin concentration expressed as g/100 ml. The instrument uses round, test tube type cuvettes available in matched sets. An accessory waste pump and flow-through cuvette is available. The instrument is equipped with a built-in neutral density filter that has a constant and reproducible transmittance value. The filter can be placed in the light path and used as a reference reading to indicate calibration point drift. A switch at the back of the instrument allows measurement of samples diluted 1:500 instead of 1:251. Reagent is available in powdered form. Hemoglobin reference (calibrator) solutions are not available.

2. Manual

The accompanying manual adequately covers the principle of method, installation procedure, calibration and measurement, trouble shooting, and parts replacement. There is no information on day-to-day instrument care. With respect to the availability of hemoglobin reference solutions, updating is needed.

3. Installation

Installation of the instrument is simple, consisting of (a) unpacking, (b) connecting the line cord to a suitable power outlet, (c) inserting a cuvette into the well, and (d) switching the instrument on. If the flow-through cuvette assembly is to be used, the instruction manual gives clear step-by-step instructions. Installation of the cuvette assembly is simple.

4. Accessibility of Instrument Controls

Controls consist of a power switch, a zero control, a calibration control knob, and a control for the neutral density transmittance filter. All controls are well placed and simply operated.

5. Performance

5.1 Zero Drift: The zero point needs only minor adjustment, every 3 to 6 hours.

5.2 Calibration Point Drift: In daily use the calibration point shows minor fluctuations, -+0.2 g/dl. The built-in neutral density filter allows continuous monitoring of drift. Calibration using HiCN reference solutions on a once-a-day basis is advisable. Adjustment of the calibration point causes a shift in the zero setting.

5.3 Linearity: Instrument linearity was checked by comparing the hemoglobin values of a dilution series to values obtained with a Beckman Acta M VI spectrophotometer. No alinearity was found. (Figure 7)

5.4 Cuvettes: The variability of the cuvette light path was checked by placing 10 filled cuvettes in the well and revolving them noting the highest and lowest readings. A range of readings not exceeding -+0.1 g/dl was observed.

5.5 Comparative Measurements

Twenty blood samples obtained from an outpatient clinic were diluted in duplicate using the ICSH recommended method. Duplicate dilutions were also made using Fisher Grampak(tin) reagent. Table III shows the results of samples 5 through 20, diluted in KH2PO4 and Sterox SE containing reagent, measured on a Beckman Acta M VI and the Hemophotometer. The mean difference found was -0.01 g/dl (range -0.3 to +0.1 g/dl). Table IV shows the results of samples 1 through 20 diluted in KH2PO4 and Sterox SE containing reagent, measured on a Beckman Acta M VI, and diluted with Grampak(tm) reagent, measured on the Hemophotometer. The mean difference was -0.21 g/dl, range -0.9 to +0.4 g/dl. Samples 1 through 4 were measured on the Hemophotometer using test tube-type cuvettes, and samples 5 through 20 were measured using the flow-through cuvette. The Hamophotometer was calibrated daily with HiCN reference solutions meeting ICSH specifications; equivalent hemoglobin concentration was 14.6 g/dl. (Tables III and IV)

6. Day to Day Maintenance

No day-to-day maintenance was needed during the 4-week testing period. Instrument and cuvette were kept clean according to good laboratory practice.

TABLE I l l

Comparison of He1110globin Values (g/dl) Using ICSH Recommended Method, Reading on Beckman Acta M VI and the Fisher Heaophot011eter

Sa!5!le	Acta M VI	Fisher	t,.	Sa!5!le	Acta M VI	Fisher	II, F.-A.
5.1	15.0	15.0	0	15.1	16.2	16.1	-0.1
5.2	15.2	15.2	0	15.2	16.2	16.2	0
6.1	16.4	1 fi••	-O.1	16.1	16.1	16.2	-O.1
6.2	16.5	16.5	0	16.2	16.5	16.5	0
7.1	17.0	16.9	-0.1	17.1	12.7	12.8	-+-0.1
7.2	17.0	16.9	-0.1	17·.2	12.7	12.6	-0.1
8.1	13.3	13.3	0	18.1	10.3	10.2	-0.1
8.2	13.2	13.3	-+-0.1	18.2	10.2	10.3	-+-0.1
9.1	13.3	13.3	0	19.1	6.6	6.5	-0.1
9.2	13.2	13.2	0	19.2	6.6	6.5	-0.1
10.1	17.1	17.2	+o.1	20.1	6.4	6.5	-+-0.1
10.2	17.1	16.9	-0.2	20.2	6.4	6.5	-+-0.1
11.1	13.4	13.2	-0.2				
11.2	13.3	13.Z	-0.1				
12.1	15.3	15.0	-0.3				
12.2	15.2	15.0	-0.2				
13.1	15.6	15.7	+o.1				
1'.3. 2	15.7	15.6	-0.1				
14.1	14.4	14.4	0				
14.2	14.3	14.1	-0.2				
					Mean Difference		-0.011

Samples fr0111 routine outpatient clinic diluted in duplicate (Sahli pipets, 5 ml class A volumetric pipets) using phosphate/Sterox reagent and measuring on Beeman Acta H VI and Fisher Hemophotometer, Fisher calibrated daily usin HiCN reference solutions.

TABLE IV

Comparison of Helll)globin Values (g/100 ml) using the ICSH Reco111111ended Method and Fisher Grampaktm Reagent with the Fisher Hemophotometer

Samele	Acta M VI	Fisher	F.-A.	Samele	Acta H VI	Fisher	F.-A.
1.1	15.6	15.0	-0.6	11.1	13.4	13.0	-0.4
1.2	15.5	15.0	-0.5	11.2	13.3	12.9	-0.4
2.1	15.4	15.0	-0.4	12.1	15.3	14.8	-0.5
2.2	15.5	15.2	-0.3	12.2	15.2	14.8	-0.4
3.1	13.0	12.2	-0.8	13.1	15.6	15.2	-0.4
1.2	13.0	I 2.1	-0.7	13.2	15.7	15.0	-0.7
4.1	16.4	15.6	-0.8	14.1	14.4	14.2	-0.2
4.2	16.4	15.5	-0.9	14.2	14.3	14.1	-0.2
5. l	15.0	15.0	0	15.1	16.2	15.7	-0.5
5.2	15.2	15.0	-0.2	15.2	16.2	**15.9**	-0.3
6.1	16.4	16.4	0	16.1	16.3	16.1	-0.2
6.2	16.5	16.4	-0.1	16.2	16.5	16.0	-0.5
7.1	17.0	17.2	+o.2	17.1	12.7	12.7	0
7.2	17.0	17.4	+o.4	17.2	12.7	12.8	+o.1
8.1	13.3	13.5	+-0.2	18.1	10.3	10.3	0
8.2	13.2	13.3	+-0.1	18.2	10.2	10.4	+-0.2
9.1	13.3	13.3	0	19.1	**6.6**	6.6	0
9.2	13.2	13.4	+-0.2	19.2	6.6	6.6	0
10.1	17.1	17.2	+o.1	20.1	6.4	6.5	+o.1
10.2	17.1	17.0	-0.1	20.2	6;,4	6.5	+o.1
					Mean Difference		-0.21

Samples fr011 routine outpatient clinic diluted in duplicate (Sahli pipets, *5* ml class A volumetric **pipets).** using phosphate/Sterox reagent and using Fisher Grampaktm reagent, measuring on Beckman Acta.M VI and Fisher Haaophoto-ter, respectively. The Fisher was calibrated daily **using** ICSR HiCN reference solutions.

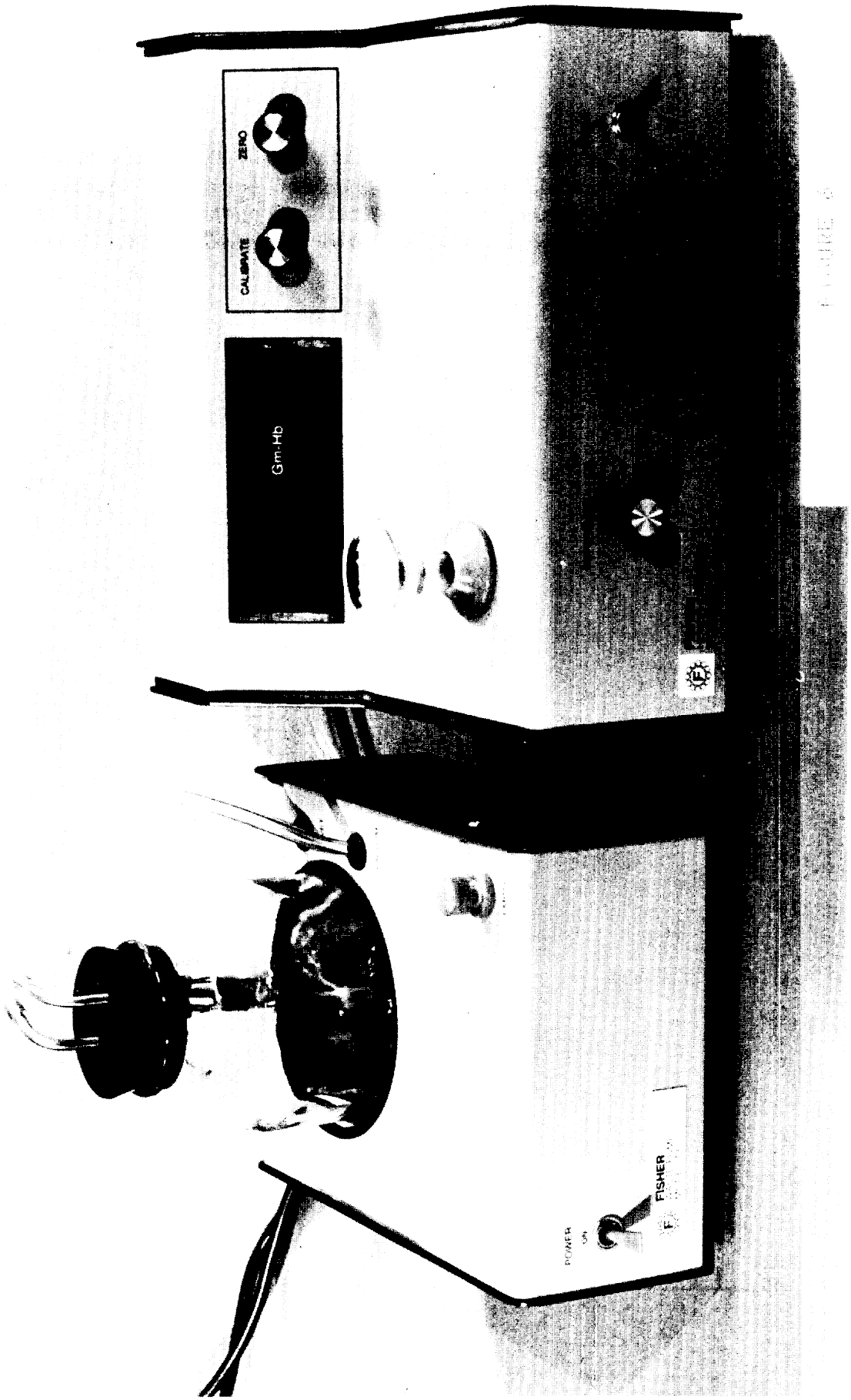
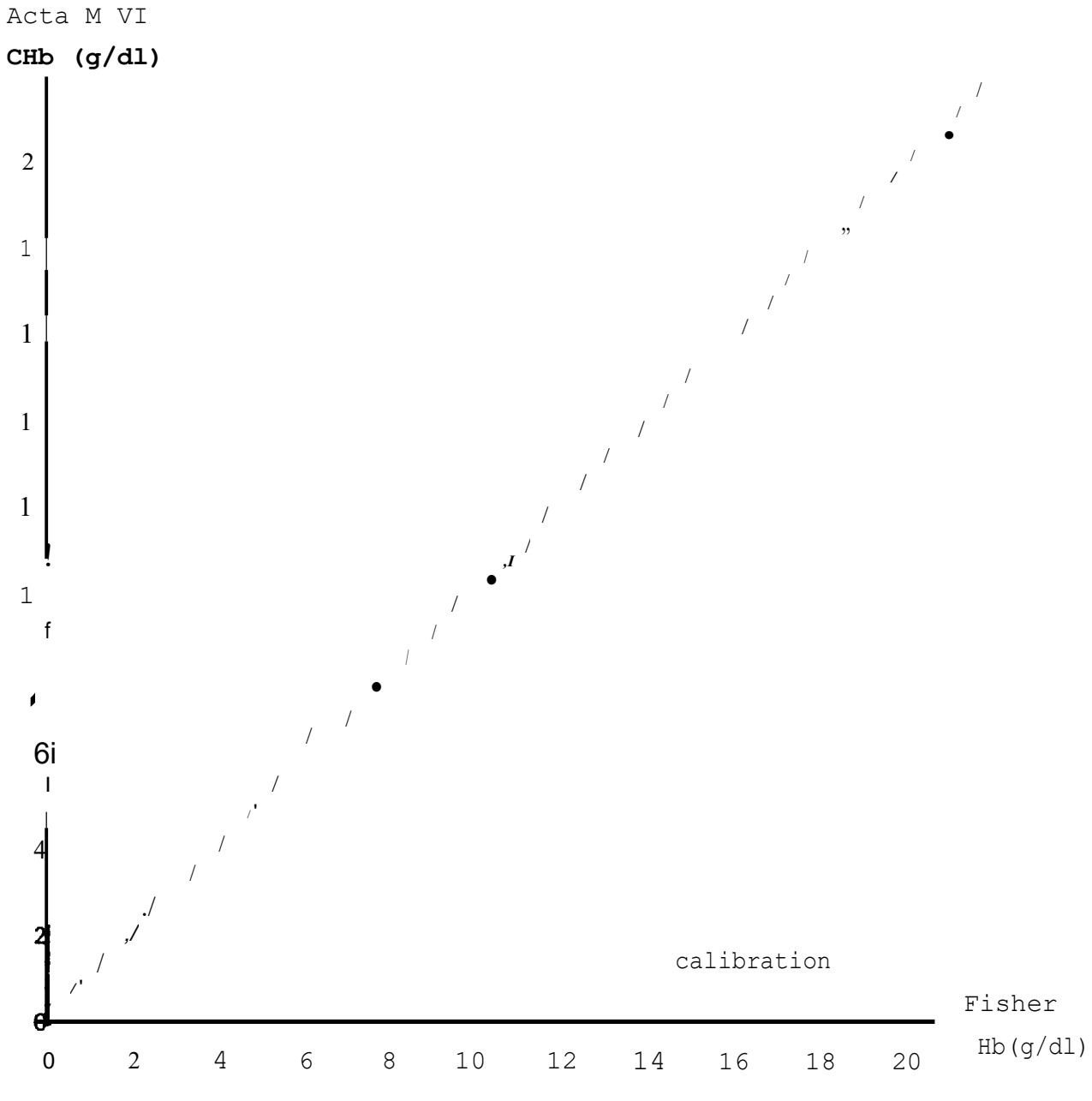


Figure 7

Assessment of Instrument Linearity hy Comparing Hemoglobin Concentration Measured with a Beckman Acta M VI Spectrophotometer to Values Read on the Fisher Digital Hemophotometer Calibrated at Vt. 6 g/dl with an HiCN Solution Meeting ICSH* Requirements



* International Committee for Standardization in Haematology

D. AO[R] HB-METER[R]. American Optical, Scientific Instrument Division, Buffao, NY 14215. Approximate cost $140.00. (Figure 8)

1. Equipment and Accessories

The AO Hb-meter is a battery operated hemoglobinometer. The color of a hemolyzed blood sample is visually compared to the color of a "standardized glass wedge." The instrument has scales reading in g/100 ml and in "percent," based on 100% - 15.6,= 14.5 and = 13.8 s/dl. Included with the instrument are a blood chamber assembly, hemolysis applicators and a case. A 50-60 cycle, 115 V AC transformer is available.

2. Manual

The instruction manual summarizes the principles of the method, and adequately covers setting up, operation and maintenance. Sample preparation and measurement procedure is covered. Performance specifications, quality control, and calibration and calibration check are not discussed.

3. Installation

Installation of the instrument is simple, consisting of (a) unpackinG, (b) installing two batteries and/or connecting the power transformer, and (c) adjusting the field illumination.

4. Accessibility of Instrument Controls

The illumination knob end the slide button used in obtaining split field-light-equality are easily accessible and simple to operate. The blood sample chamber slides easily into the instrument. Care must be taken in assembling, disassembling and cleaning the blood chamber.

5. Performance

Since calibration and quality control procedures cannot be conducted on an instrument of this design, instrument performance was evaluated by comparing fresh blood hemoglobin content as determined with the AO Hb-meter to the hemoglobin content determined by the recommended HiCN method. Results obtained on 10 samples by 3 independent operators are shown in Table V.

6. Day to Day Maintenance

During the short period tested (4 weeks) the interior of the instrument did not need cleaninG. The life expectancy of the light bulb and of the batteries is not known. It is useful to have more than one blood chamber assembly available.

TABLE V

Comparison of AO Hb-meter Readings (g/100 ml) to Hemoglobin Values (g/dl) Determined Using the ICSH Recommended Method with a Lancer Hemoglobin Analyzer and a Fisher Hemophotometer as the Measuring Instrument

		Hemoglobin Concentration					
Sample	HiCN!!./ Method	OP I"E..I	t,	OP nSJ	t,	OP Ill /	t,
1.1	15.8	15.2	-0.6	16.2	+o.4	15.9	+o.1
1.2	15.8	16.5	+o.7	16.0	+o.2	16.4	+o.6
2.1	15.8	16.0	+o.2	16.5	+o.7	15.4	-0.4
2.2	15.8	15.2	-0.6	16.0	+o.2	16.2	+o.4
3.1	17.7	17.2	-0.5	16.7	-1.0	17.5	-0.2
3.2	17.7	16.7	-1.0	17.2	-0.5	17.5	-0.2
4.1	14.1	14.0	-0.1	14.1	0	14.0	-0.1
4.2	14.1	13.9	-0.2	14.5	+o.4	14.3	+o.2
5.1	13.4	13.7	+o.3	13.3	-0.1	13.5	+o.1
5.2	13.4	13.4	0	13.5	+o.1	13.5	+o.1
6.1	13.5	14.0	+o.5	13.2	-0.3	13.3	-0.2
6.2	13.5	13.0	-0.5	13.0	-0.5	13.4	-0.1
7.1	14.8	14.5	-0.3	14.7	-0.1	14.7	-0.1
7.2	14.8	15,0	+o.2	14.7	-0.1	14.8	0
8.1	15.4	15.7	+o.3	15.5	+o.1	15.2	-0.2
8.2	15.4	15.5	+o.1	15.6	+o.2	15.0	-0.4
9.1	10.6	10.2	-0.4	10.9	+o.3	10.5	-0.1
9.2	10.6	10.5	-0.1	11.1	+o.5	10.5	-0.1
10.1	10,5	10.4	-0.1	10,4	-0.1	10.2	-0.3
10.2	10.5	10.1	-0.4	10.5	0	10.5	0
Htlan Diff rem·<.·			-0.12'3		+o.020		-0.045

/Values are mean of 2 determinations using the Lancer Hemoglobin Analyzer and 2 using the Fisher Hemophotometer; instruments calibrated using ICSH HiCN solutions.

.!!/op I • operator 1 {
{
EJOP II • operator 2 {completely independent
{
/op III • operator 3 {

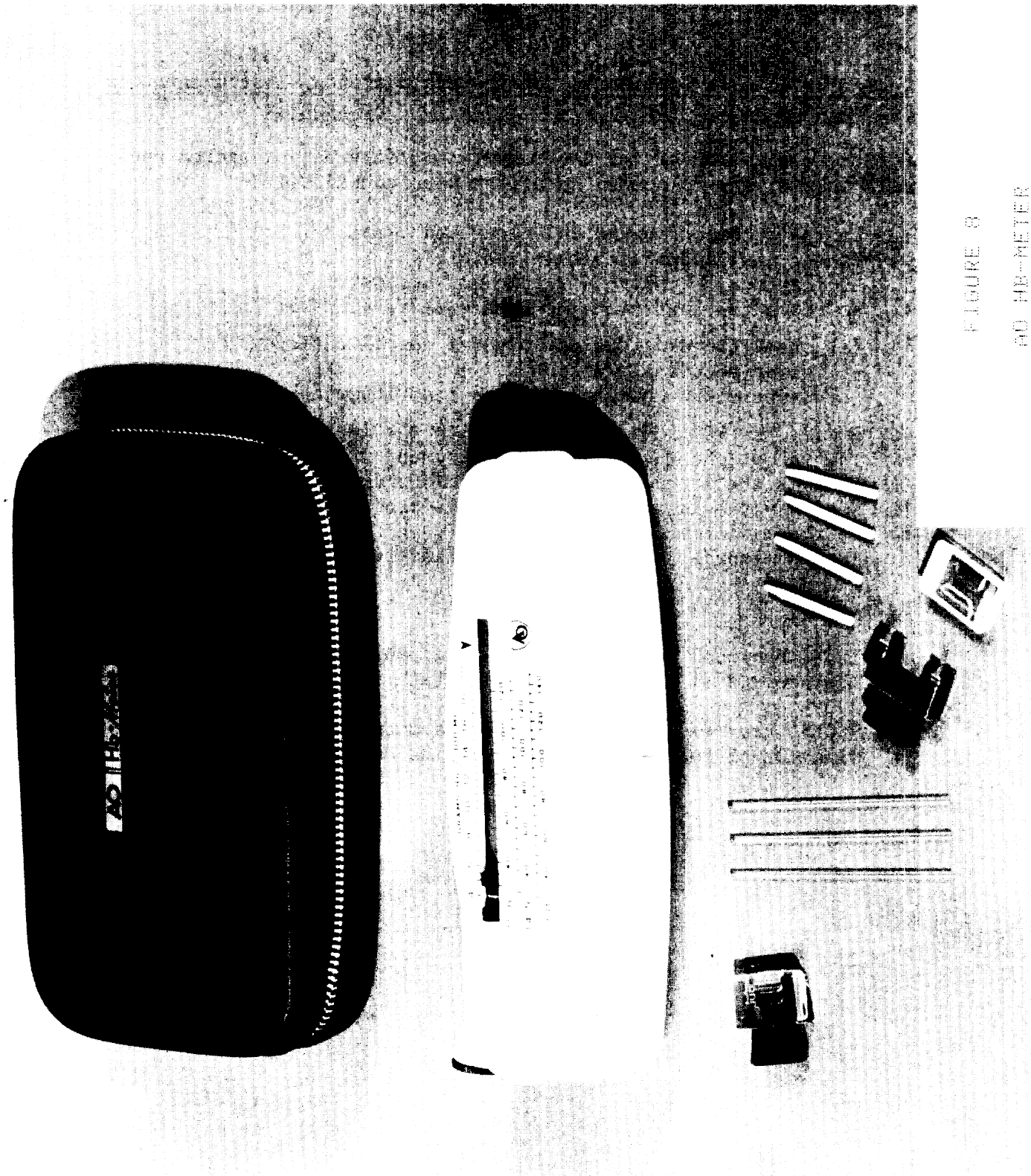


FIGURE 8
PD HR-METER

IV. Design Principles Considered for the Evaluation of Instruments for Determining Packed (Red) Cell Volume (PCV) Hematocrit

For the evaluation of the instruments for determining packed red cell volume, the following questions were considered:

1. Is the accompanying manual clear and complete?
2. Is the instrument simple to install?
3. Are instrument controls simple and accessible? How does the instrument perform with respect to:

   (a) speed (revolutions per minute) specifications,
   (b) timer accuracy, and
   (c) temperature changes when the centrifuge head is in use?

5. How do the PCV values obtained with the instrument compare to the values obtained with the instrument of known performance?
6. What is the accuracy of the PCV (microhematocrit) reading device?
7. What are the instrument maintenance procedures?
8. Is the instrument easy to clean?
9. Are accessories available for the instrument and easy to install?

References

1. ICSH, Protocol for type testing equipment and apparatus used for haematological analysis. J. Clin. Path. 31, 275, 1978.

2. NCCLS, Proposed Standard: PSH-7 Standard Procedure for the Deter-ruination of Packed Cell Volume by the Microhematocrit Method, 1979.

V. Review of Instrument

AUTOCRIT II CENTRIFUGE, Model 0574. Clay Adams, Division of Becton, Dickinson and Company, Parsippany, NJ 07054. Approximate cost $530.00. (Figure 9)

1. Equipment and Accessories

The Autocrit II consists of a centrifuge with scale plate used for reading the results, a carrying tray for up to 24 samples, and a head cover. A magnifying glass and spanner wrench are included as accessories. Capillary tubes and sealant clay are purchased separately.

2. Manual

The Autocrit II is accompanied by an extensive manual covering the method priciple, the instrument and its maintenance, and procedure. Procedures for the determination of the optimal cell packing time should be included in the manual.

3. Installation

Installation of the instrument is described in the manual and is simple. It consists of (a) unpacking the instrument, (b) installing the scale plate, and (c) connecting the power cord to a grounded outlet.

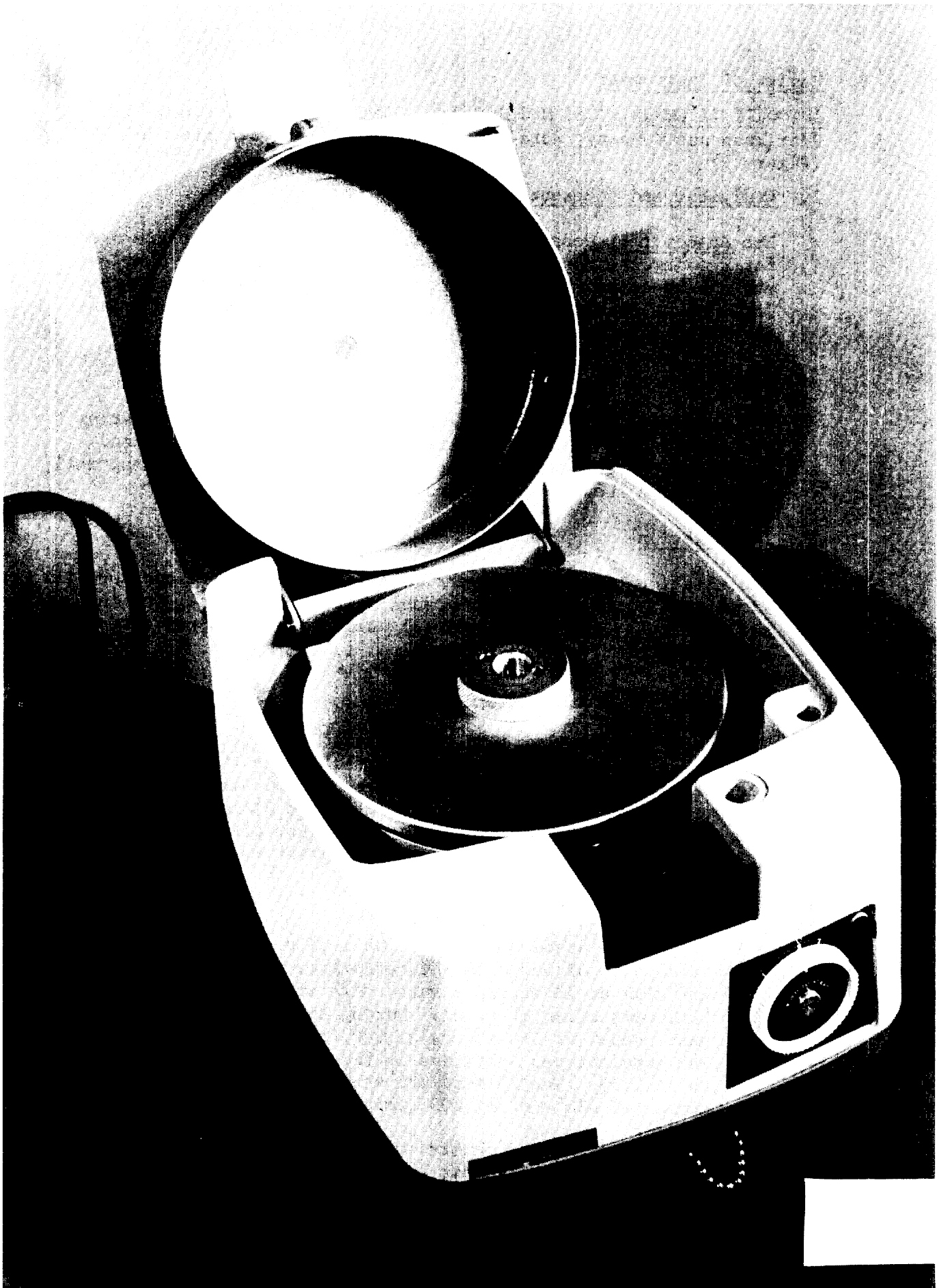
4. Accessibility of Instrument Controls

The timer is well placed on the front of the centrifuge and is easy to operate. The carrying tray slips over the spindle. Care must be taken when placing capillaries into or removing them from the tray; they break easily. The latch operating the lid lock is simple to operate. The scale plate does not offer sufficient grip to easily revolve the carrying tray for reading the results.

5. Performance

5.1 Centrifuge speed was checked at 1-minute intervals using a calibrated strobe with the centrifuge running continuously, and also on 10 separate runs, with each measurement obtained 2 minutes after starting. During the continuous run, the mean number of RPM's were 11,940 (range: 11,900 to 12,000). The manufacturer specifies an RPM of 11,700 (range: 10,500 to 14,275). The 10 separate measurements yielded a mean number of RPM's of 12,000 (range: 11,850 to 12,500).

5.2 Timer accuracy was checked by comparing the instrument timer set at 5 minutes against a stop watch. With the instrument timer, a mean time of 5 minutes 8 seconds was obtained (range: 5 minutes 2 seconds to 5 minutes 15 seconds).



5.3 The temperature of the centrifuge was checked by measuring the temperature in the middle and at the rim of the carrying tray using a calibrated thermistor probe.

The National Committee for Clinical Laboratory Standards (NCCLS) standard PSH-7 specifies centrifuge temperature may not exceed 45°C after 5 minutes of continuous operation. The initial temperature of the room and tray was 23.3°C. During 10 consecutive 2-minute runs, the temperature of the tray center rose to 42.3°C after 10 minutes, and 47.6°C after 20 minutes. The tray rim temperature rose to 39.8°C after 10 minutes and 45.8°c after 20 minutes.

6. Packed Cell Volume (PCV) Values

6.1 Optimal red cell packing times were determined by centrifuging samples in duplicate for 3, 5, and 7 minutes. They are listed below:

	Sample					
Time	1	2	3	4	5	6
3 min	0.41	0.45	0.45	0.42	0.39	0.40
	0.40	0.45	0.45	0.42	0.39	0.40
5 min	0.41	0.45	0.45	0.42	0.39	0.40
	0.41	0.45	0.45	0.42	0.39	0.40
5 min	0.40	0.45	0.45	0.415	0.39	0.40
	0.41	0.45	lost	lost	0.39	0.40
7 min	0.41	0.45	0.45	0.42	0.39	0.40
	0.41	0.45	0.45	0.42	0.39	0.40

2 samples "lost" due to capillary breakage.

Further determinations after 3 and 5 minutes centrifuging at different relative red cell volumes.

	Sample						
Time	1	2	3	4	5	6	7
3 min	0.125	0.16	0.21	0.33	0.41	0.51	0.58
5 min	0.13	0.16	0.21	0.33	0.41	0.51	0.58

6.2 PCV values were obtained by using a Clay Adams Centrifuge of known performance and by using the Autocrit II. The mean difference between the Autocrit II and the reference instrument was +0.0097. (Table VI)

TABLE VI

62 PCV Values Obtained Using a Clay Adams Centrifuge of Known Performance Compared to PCV Values Obtained with the Autocrit II (Sample centrifuges for 3, 5, and 7 **Minutes)**

Sample	Reference Value	Autocrit	Sample	Reference Value	Autocrit
1.1	0.405	0.41	13.1	0.40	0.41
1.2	0.41	0.42	13.2	0.40	0.41
2.1	0.44	0.45	14.1	0.43	0.44
2.2	0.45	0.46	14.2	0.44	0.45
3.1	0.44	0.45	**15.1**	0.44	0.44
3.2	0.44	0.46	15.2	0.44	0.45
4.1	0.41	0.42	16.1	0.41	0.41
4.2	0.42	0.42	16.2	0.40	0.41
5.1	**0.18**	0.39	17.1	0.18	0.39
5.2	**0.**38	0.39	17.2	0.39	0.38
6.1	0.40	0.41	18.1	0.40	0.41
6.2	0.40	0.42	18.2	0.41	0.42
7.1	0.4(1	0.41	19.1	0.40	0.41
7.2	0.40	0.42	19.2	0.40	0.41
8.1	0.43	0.44	20.1	0.44	0.45
8.2	0.44	0.45	20.2	0.43	0.44
9.1	0.44	0.45	21.1	0.44	0.45
9.2	0.45	0.44	21.2	0.44	0.45
10.1	0.41	0.42	22.1	0.40	0.42
1C.2	0.41	0.42	22.2	0.40	0.42
11.1	0.38	0.40	23.1	0.38	0.39
11.2	0.38	0.40	23.2	0.38	0.39
12.1	0.39	0.40	24.1	0.40	0.40
12.2	0.40	0.41	**24.2**	**0.39**	0.40

The samples 1-6 and 19-24 were spun for 3 minutes, 7-12 for 5 minutes and 13-18 for 7 minutes.

Mean difference Autocrit II - Reference instrument: +o.0097

7. Reading Device Accuracy

Accuracy of the reading scale was tested by comparing PCV values calculated from red cell column and plasma column length measurements made using a machinist caliper with Autocrit II readings.

Sample	Calculated	Autocrit
1	0.128	0.12
2	0.155	0.17
3	0.212	0.21
4	0.236	0.25
5	0.322	0.32
6	O.388	O.39
7	0.501	0.50
8	0.628	0.62

8. Instrument Maintenance

The centrifuge did not require maintenance during the time tested. Cleaning of the scale plate and carrying tray is relatively easy.

VI. Evaluation of HiCN Reference Materials

In the course of instrument performance evaluation, it was apparent that HiCN reference materials and reagents would also need to be evaluated. This was carried out and a summary of the results appear in Table VII as they relate to the instruments *tested.* A comprehensive comparative study of the reference materials and reagents will be available at a later date.

The contents of this guidance document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

Table VII

Com.pat"attve Heaaureaent• of HlCN Solution• co-rchlly Available
•• Callbrat.:lon/C.ontrol Material
Reference Value Measured on !eckun Ac ta MVI Spectrophotoaeter

	A.eta		Ljunebera		Lancer		Fiaher			
_A 50_	A54_0JA504	Hb (g/dl)	Hb (g_/d_IJ_	-	lib .!.&/.d..!!		Hb WdJl	/J.	5!t!!e_1_1!!	C OaE !! tJ!....
.002	**l.•.1J**	**l l•.11**	*!l b*	0	**19.H**	>(). /	**10.J**	**HJ./**	l.1	
.001	1.59	**L':1.6**	19 ,6	0	19.8	+o.2	20, 3	+o. 7	1.2	
.002	1 .59	**)Cl .6**	19 . 5	-0.1	19.7	,<J. I	20.1	+o.7	I. J	
.001	**. .f.1**	**l.o,1**	**.J(t.7.**	+0.1	**'/0. 1**	***+o.l***	**10.H**	***+O.h***	1.1	
.002	1.59	***w.o***	20.]	-+o.)	20.	+o.J	20.9	+o. 9	2 .I	
.001	1.60	20.0	20.3	+o.3	20.5	+o.5	20.9	+0,9	2 .)	
,006	1.53	211.7	20. 7	0	21.1	+o.4	21.)	+o.6	3.1	
.005	**1.5]**	***2().1***	20. 7	0	21.1	+o.4	21.3	+0.6	**3.2**	
.005	1.53	2U. 7	20. 7	0	21. 2	+o.s	21.3	**+0.6**	l.)	
.006	1.53	20.8	20.8	0	21.0	+o.2	21.3	+o.5	4.1	
,006	1.53	2().8	20.85	+-0.05	21.0	+o,2	21.3	+0.5	4.2	**}centrifuged }20 •in,**)16,000 **RPM**
,006	1.53	2().8	20.9	+-0.1	21. 0	+o.2	21.3	-+-0.5	4.)	I
.005	1.55	18.0	18.I	+o.1	18.3	+o.3	18. 5	-+-0.5	5.1	
,004	1.56	17.9	18. I	+-0. 2	18, 5	+o.6	**18.•**	-+-0, 5	5.2	
,OO•	1.55	**1:1.8**	18 .o	+o.2	18.1	+o.)	18. 3	-+-0.5	5 .]	
0	1.61	20.4	20. 2	-0.2	20.8	+o,4	21.0	**-+-0.6**	6 .1	
0	1.61	20,4	20, 2	-0.2	20.8	+o.4	**21.0**	**+o.6**	6 .2	
0	1.61	**:Z0.4**	20, 2	-0.2	20.8	+o.4	21.0	**-+0.6**	**6** .]	
0	1.62	14 .4	14 .4	0	14. I	-0. 3	14.4	0	**7**.1	
0	1.61	**tL. .4**	14 .4	0	14.0	-0.4	1 ' • ,	0	7.2	**}1wt }f1ltered**
0	1.62	14.4	14.4	0	14.1	-0. 3	14.4	0	7.J	)
0	1.61	**n.S**	21.8	-0.7	22.4	**-0.1**	**22.7**	+o.2	8.1	
0	1.61	**ıı1. 3**	14 .4	+o.1	14.	+o.4	14.4	+o.1	**8** .2	
0	1.60	3.6	3,9	+o.3	3.6	0	J.8	-+O. 2	8. 3	
.001	1.60	14.0	14 .2	+o.2	14.0	0	14.5	-+O. 5	*9* .1	) J
.001	1.M	14 .0	14 .2	+-0.2	11. 9	-0. I	14. 5	**-+0,5**	9. 2	) I
.002	1.59	15.9	15. 7	-0.2	15.6	-O.)	**1S7**	-0.2	10.1	I I
.002	1. 59	**l'i. 9**	15.8	-0.1	15.9	0	ll .6	-0.1	10.2	I **yaod** **)hlrmd**
.001	**l ,hO**	l .'/	11 -	0	11,,..	**-0. •;**	**ıı.ı**	**-u.;**	**ıı .ı**	I I
O	**l.M)**	**l •H**	11.11	**-tO,l**	11 .H	I)	lLi	-Hl."l	11.1	I I I
.002	1.59	**n. 0**	8 .2	+o .2	8.0	0	8.0	0	12. I	I I I
.002	1.59	11.0	8 .2	-+O. 2	7 .8	-0.2	8.2	.0.2	12.2	I
.002	1.55	19. 7	19 .6	-0.1	20.0	**.O.3**	200	.O.J	13.1	
.001	1.54	11.2	11 .6	**+0 .4**	11.)	+o.1	11.5	+o.J	13.2	
.002	1.48	**h.]**	6. 7	-!-0 .4	6 .0	-0. 3	6.4	-+-0.1	13. 3	
,004	1.56	**l'.). 4**	**15. 2**	-0. 2	**16.0**	+-0, 6	15. 1	-0.2	14.1	} }
.00)	1.55	D.5	1\	-O.J	16.0	+o.5	1>.1	-0.3	14.2	**}lysed }blood**
,0(11	**l. "'>4**	h.h	*h.* 7	+II. I	*h.;*	**-0.1**	*n.* s	**-rl.I**	**11,1**	I I
.002	1.52	**h, 6**	*h.* I	-H1.1	6.\	**-0.1**	*li,'>*	-O.1	lLI	I

Ljun1berg and Fiaher calibrated doily 1111th ICSH H1CN :Reference Solut on: Lancer c-.alibrat4td da11)' vlrh "rAlihration Het":; rheclc.ed with TCSH MiCN Re fer ■n t-e Solut lon. lyaed blood controls (11.. Mp lf',- 9-12. 14. Ill **dllutC'd J;Hl with lu-hnt11h• rt•:.$1,t>nt.** All **S.I""'I'I C'H fl1 tc-rrd,** P>U-t'1H vhrr1• lndl•·nh•1l, ,i J1111. ,, **Mi 11 lpn,**·,, 1111('1'"• IL :.! 'Jim I••·1t,,- 1,, ll'M'll-H1r,-111t•nl.

VII. Instrument Recommendations

A. Selected instruments examined by the CDC which are used for determining blood hemoglobin content utilizing the internationally recommended HiCN method.

Acceptable

Lancer Hemoglobin Analyzer

This direct reading digital hamoglobinometer is well designed, has minimal zero point and calibration point drift, and has good linearity. It is easy to operate and is packaged with a clear and concise instruction manual. It is American-made and distributed by a national distributor with service representation in most major cities.

Hemometer, LIC, Lars Ljungberg

This hamoglobinometer is equipped with a galvanometer scale that can be read directly in grams of hemoglobin per litre. Service for this Swedish made instrument, although distributed by an American manufacturer, was not available locally in the test area. Zero point and calibration point drifts are minimal. The instrument was found to be slightly alinear. Accuracy is good.

Fisher Digital Hamophotometer

This digital direct reading hemoglobinometer is no longer being manufactured.

B. Instruments for Packed Cell Volume Determination

Acceptable

Autocrit II Centrifuge, Model 0754

This centrifuge is acceptable for clinical use. Accuracy of the measuring scale is good and the centrifuge speed is accurate when checked to the manufacturer's specifications. It comes with an extensive procedural and maintenance manual.