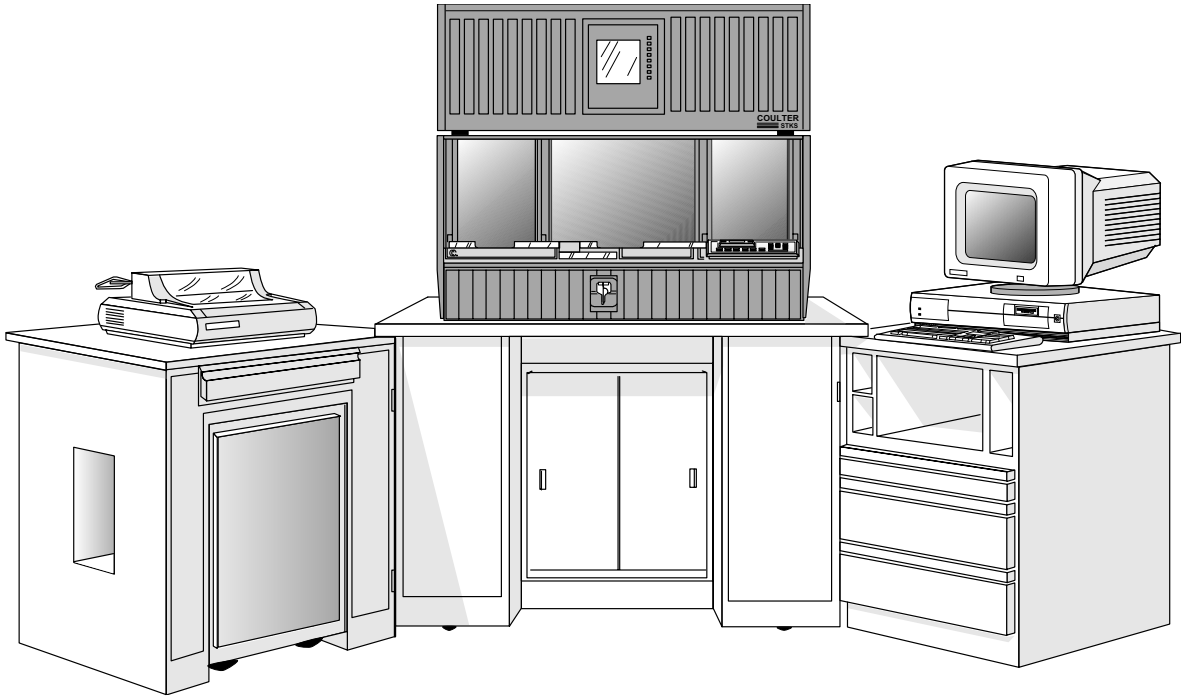
COULTER® STKS Analyzer with Reticulocyte Analysis

Reference



PN 4237182B (March 1995)

COULTER CORPORATION
Miami, Florida 33196

READ ALL PRODUCT MANUALS AND CONSULT WITH COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Might cause injury.
CAUTION - Might cause damage to the instrument.
IMPORTANT - Might cause misleading results.

CAUTION

System integrity might be compromised and operational errors might occur if:

- **This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.**
- **You introduced software that is not authorized by Coulter into your computer. Only operate your system's computer with software authorized by Coulter.**

Coulter Corporation urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but it is not limited to, protective eye wear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

In the USA, for Service call Coulter Customer Operations 1-800-526-7694.

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ILLUSTRATIONS

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1.1 INTENDED USE

The COULTER STKS, Figure 1, is a quantitative, automated hematology analyzer and leukocyte differential counter for in vitro diagnostic use in clinical laboratories. It incorporates complete blood count (CBC), WBC differential, and Reticulocyte analysis. If your system does not include Reticulocyte Analysis, disregard the references to it.

Reticulocyte (Retic) analysis on the COULTER STKS uses New Methylene Blue (NMB) for the quantitative enumeration of reticulocytes from human whole blood. It is intended for in vitro diagnostic use with STKS instrumentation using volume, conductivity and light scatter (VCS) technology.

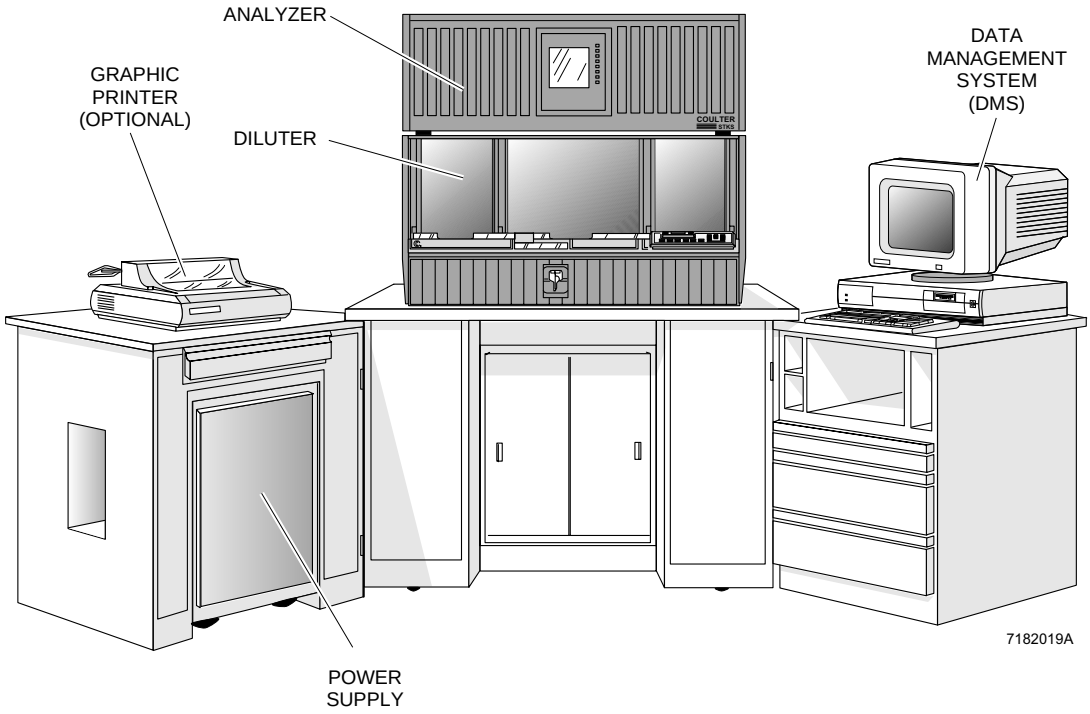

Figure 1 COULTER STKS

This system has two operating modes: Primary and Secondary. In the Primary mode, as many as 144 tubes with pierceable caps are loaded into cassettes and presented automatically to the system. The Primary mode is equipped with a bar-code reader. In the Secondary mode, open vials are presented manually to the aspirator tip.

This system determines the following hematologic parameter values:

WBC	White Blood Cell or leukocyte count
RBC	Red Blood Cell or erythrocyte count
Hgb	Hemoglobin concentration
Hct	Hematocrit (relative volume of erythrocytes)
MCV	Mean Corpuscular (erythrocyte) Volume
MCH	Mean Corpuscular (erythrocyte) Hemoglobin
MCHC	Mean Corpuscular (erythrocyte) Hemoglobin Concentration
RDW	Red Cell (erythrocyte volume) Distribution Width
Plt	Platelet or thrombocyte count
MPV	Mean Platelet (thrombocyte) Volume
LY%	Lymphocyte percent
LY#	Lymphocyte number
MO%	Monocyte percent
MO#	Monocyte number
NE%	Neutrophil percent
NE#	Neutrophil number
EO%	Eosinophil percent
EO#	Eosinophil number
BA%	Basophil percent
BA#	Basophil number
RET%	Reticulocyte percent
RET#	Reticulocyte number

Packed-cell volume (PCV) is the reference method for Hct values. PCV is defined as the volume percentage of erythrocytes in whole blood obtained by centrifuging the blood. Hct is defined as the relative volume of erythrocytes in whole blood as determined using the Coulter method of counting and sizing, or any other cell-by-cell volume-measuring system that does not rely on centrifugation.

The STKS also derives Plateletcrit (Pct) and Platelet Distribution Width (PDW). These parameters are not intended for diagnostic use; however, the value for PDW is used as an internal check on the reported platelet parameters, Plt and MPV.

The purpose of the STKS is to separate the normal patient, with all normal system-generated parameters, from the patient who needs additional studies of any of these parameters. These studies might include further measurements of cell size and platelet distribution, biochemical investigations, manual WBC differential, or any other definitive test that helps diagnose the discrepancy.

1.2 METHOD HISTORY

The STKS derives three groups of parameters: CBC, WBC differential, and Reticulocytes (referred to in these manuals as Retics).

The methods used to derive the CBC parameters are refinements of the well-established Coulter method of counting and sizing, in combination with an automatic diluting and mixing device for sample processing and a single-beam photometer for hemoglobinometry.

W. H. Coulter describes the principle: "The instrument employs a non-optical scanning system providing a counting rate in excess of 6,000 individual cells per second with a counting interval of 15 seconds. A suspension of blood cells is passed thru a small orifice simultaneously with an electric current. The individual blood cells passing thru the orifice introduce an impedance change in the orifice determined by the size of the cell. The system counts the individual cells and provides cell size distribution. The number of cells counted per sample is approximately 100 times greater than the usual microscope count to reduce the statistical error by a factor of approximately 10 times."[1]

This substantial improvement in precision over previous methods helped to establish the erythrocyte count as a sensitive index of erythropoietic dyscrasia, particularly when considered together with Hct and Hgb measurements.[2]

The COULTER COUNTER® Model S was the first instrument that automated simultaneous multiparameter measurements on blood. Brittin et al. Gottmann and Hamilton and Davidson reviewed the performance and clinical values of the Model S.[3,4,5]

Refinements of the COULTER COUNTER analyzer to provide accurate size (volume) distribution data led to a reawakening of the interest in pathological erythrocyte size distribution, first aroused by Price-Jones in 1922.[6,7]

Among the advantages offered by the Coulter method of counting and sizing was the ability to derive an accurate Hct measurement by summing the electronic volume of erythrocytes. England et al. speculated that electronic Hct measurements did not have the trapped plasma of centrifugal Hct measurements.[8]

Bull et al. described the use of a COULTER COUNTER analyzer for counting thrombocytes.[9] This method, useful as it was, depended on preparing thrombocyte-rich plasma to avoid counting erythrocytes as thrombocytes. Mundschenk et al. and Schulz and Thom indicated the possibility of counting thrombocytes in the presence of erythrocytes and classifying them by size.[10,11] Electronic refinements in the Model S-PLUS enhanced the accuracy of this hydrodynamic method. Von Behrens and Paulus also indicated the feasibility of thrombocyte counting by the Coulter method.[12,13]

The STKS requires the use of a diluent to disperse the erythrocytes, leukocytes, and thrombocytes in the blood sample sufficiently to minimize the possibility of an aperture (orifice) being occupied by more than one cell at a time. The system corrects for cell coincidence automatically.

Since cell size (volume) is measured, the effect of the diluent on osmosis or other phenomena must be tightly controlled. Also, the diluent must not contain particles nor must it support growth of bacteria or molds.

The hemoglobinometry process requires the conversion of hemoglobin to a stable pigment. This is done by a lytic reagent. The lytic reagent converts a substantial portion of the hemoglobin released by hemolysis to a stable cyanide-containing pigment, the absorbance of which is directly proportional to the hemoglobin concentration of the sample.

The accuracy of this method equals that of the hemiglobin cyanide method, the reference method of choice for hemoglobinometry recommended by the International Committee for Standardization in Hematology.[14]

The WBC differential technology has been established in the COULTER VCS. Analysis and classification of white blood cells are based on the Coulter method of leukocyte differential counting using three measurements: individual cell volume (V), high-frequency conductivity (C), and laser light scatter (S). The WBC differential method stems from the Coulter Principle. Pulse-height analysis provides a convenient and precise means to classify leukocytes in a way that closely correlates with the conventional categories defined by stained-film microscopy.[15,16,17,18]

From the outset, it had been recognized that the insulating (dielectric) property of the surface of a particle determines the characteristics of the pulse it generates. If you apply high-frequency current to the current field, the current penetrates the surface of the particle to reveal the internal composition.[19,20,21]

The angle of the scatter of laser light depends on particle size and refractibility.

Reticulocytes have been defined as immature nonnucleated erythrocytes that retain a small network of basophilic organelles comprised of RNA and protoporphyrin. The enumeration of reticulocytes provides a simple, effective means to determine red cell production and regeneration.[22,23,24,25]

The most common means of measuring reticulocytes employs the use of supravital dyes such as New Methylene Blue (NMB) or Brilliant Cresyl Blue. These dyes precipitate and aggregate the basophilic substances within the reticulocyte, resulting in a granular staining pattern easily discernable by light microscopy.[26]

The STKS uses VCS technology for Reticulocyte enumeration in whole blood samples. The reticulocytes are stained with NMB and hemoglobin is removed from the RBCs with a clearing agent. Simultaneous measurement of volume, conductivity and light scatter is used to discriminate reticulocytes from WBCs, mature RBCs and Plts.

1.3 SYSTEM FUNCTION

The STKS is available in 100, 115 and 230 V, 50 or 60 Hz configurations. This is a modular system that consists of the following units.

Power Supply

This unit consists of two assemblies. The Electronic Power Supply assembly provides the regulated and unregulated voltages required by the circuitry of the system. The Pneumatic Power Supply assembly is the source of air pressure and vacuum.

Diluter

This unit is the primary operating unit of the system. It performs the mixing, transporting, pipetting, diluting, lysing, and sensing functions. The majority of all controls and indicators needed for normal daily operation are on the front of the Diluter.

Analyzer

This unit controls the electronic sequence of each operating cycle, and calculates and analyzes the results. It receives count and size information directly from the Diluter while the sample is being cycled; then it counts, measures, and computes the parameters. The Analyzer then sends this information to the DMS.

Data Management System (DMS)

The DMS receives information from the Analyzer, displays it, stores it, and transmits it to the Graphic Printer, Ticket Printer and a host computer. The DMS provides storage for results, including scatterplots and histograms.

CAUTION

The computer installed with your instrument is an integral part of the system. It may not be used to operate personal software that has not been authorized for use by Coulter. The computer may only be used with software that is authorized by Coulter.

Introduction of non-authorized software may compromise system integrity and cause operational failures.

The DMS is not for use as a general purpose personal computer.

Reagent Subsystem

Except for the reagents used off line to prepare Retic samples, the required reagents are introduced into the system via tubing. The reagents are drawn from their individual external containers and dispensed automatically in measured amounts during the operating cycle. Coulter recommends the following reagents, or their equivalents, for use with the STKS. Refer to the container's label for detailed information before using the reagent.

Diluent

ISOTON® III diluent is an azide-free isotonic electrolyte that dilutes the blood sample, stabilizes the cell membranes for accurate counting and sizing, and conducts aperture current. Diluent also carries and focuses the sample stream in the flow cell of the Triple Transducer Module to direct the white blood cells individually through the aperture.

CBC Lytic Reagent

LYSE S® III diff lytic reagent is an azide-free lytic reagent that rapidly lyses erythrocytes, freeing Hgb and reducing the size of cellular debris to a level that does not interfere with leukocyte counts.

Diff Lytic Reagent

Erythrolyse II lytic reagent rapidly lyses erythrocytes and reduces the cellular debris to an insignificant level without altering the leukocytes. The Erythrolyse II used with the STKS is included in the COULTER SCATTER PAK as PAK LYSE.

Leukocyte Preservative

StabiLyse leukocyte preservative preserves the leukocytes in their near-natural state for differentiation through the volume, conductivity, and light scatter measurements. The StabiLyse used with the STKS is included in the SCATTER PAK as PAK PRESERVE.

Retic Reagents

The COULTER ReticPrep reagent kit includes two reagents: Reagent A, a special formula of New Methylene Blue (NMB) and Reagent B, a clearing solution. Use reagents when manually preparing samples for reticulocyte analysis. Follow the preparation instructions supplied with the kit.

Reagent A is a specially formulated new methylene blue dye that precipitates the basophilic RNA networks found in reticulocytes. Reagent B then clears the hemoglobin from the RBCs without removing the precipitated dye-RNA complex.

Cleaning Agent

COULTER CLENZ® cleaning agent prevents protein buildup, and keeps the system clean. Daily use eliminates routine aperture bleaching.

Control Material

- COULTER 5C® cell control, PN 7547001, (three levels in pierceable tubes) monitors both the CBC and differential parameters.
- 4C® PLUS cell control, PN 7546771 (three levels in pierceable tubes), monitors the CBC parameters.
- LATRON primer, PN 7546915, used immediately prior to running the LATRON control, prepares the tubing and components for the control process.
- LATRON control, PN 7546914, monitors the performance of the volume, conductivity, and light scatter measurements.
- Retic-C cell control, PN 7546979, monitors the performance of the reticulocyte parameters.

Calibrator

The S-CAL® kit, PN 7546808, is an acceptable alternative to the whole-blood reference method for calibrating the CBC parameters. Before using the S-CAL kit, read the instructions provided with the kit's package insert.

The differential measurement devices are set for optimum performance at the factory.

1.4 OPTIONS

Auto-Reporter 3

This Printer prints parameter data on HEMATOLOGY report forms. It has a bar-code reader that matches the bar codes on the report forms to the bar codes stored with the data files in the DMS.

This Printer does not print Retic results.

Graphic Printer

This Printer prints the data displayed on the DMS screen, including parameter data and graphics.

Laser Printer

This Printer prints the data displayed on the DMS screen, including parameter data and graphics. For a PCL5-compatible laser printer, select **PCL5**.

Matrix Printer

This Printer prints the data displayed on the DMS screen, including parameter data and graphics. For an EPSON LQ-compatible matrix printer, select **EPSON LQ**.

Bar-Code Wand

This wand scans 5C cell control data from the assay sheet and enters it in the setup file.

Sample Prep Kit

This kit includes pipettors for the 50 µL and 2 µL dilution steps in the retic procedure. Pipette tips, test tubes and a test tube rack are also included.

1.5 MATERIAL SAFETY DATA SHEETS (MSDS)

To obtain an MSDS for reagents used on the STKS:

1. In the USA, send a written request to:

   Coulter Corporation
   Attn: MSDS Requests
   P.O. Box 169015
   Miami, FL 33116-9015

2. Outside the USA, contact your local Coulter Representative.

1.6 CLIA COMPLEXITY CATEGORY

For the purposes of implementing CLIA Test Categorization (42 CFR 493.17), the COULTER STKS Analyzer with Reticulocyte Analysis has been assessed for its CLIA complexity category. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) in a joint review have determined the complexity category for the COULTER STKS Analyzer with Reticulocyte Analysis as MODERATE. CDC Analyte identifier code, 5506, and test system identifier code 10093.

2.1 GENERAL

Your instrument is tested before it is shipped from the factory. International symbols and special handling instructions are printed on the shipping cartons to inform the carrier of the precautions and care applicable to electronic instruments.

CAUTION

Do NOT uncrate the STKS; your Coulter Representative is responsible for uncrating, installing and initially setting it up.

When you receive your instrument, carefully inspect all cartons. If you see signs of mishandling or damage, file a claim with the carrier immediately. If the shipment was separately insured, file a claim with the insurance company.

2.2 SPECIAL REQUIREMENTS

Install and operate this instrument in a conventional clinical laboratory environment. Since the individual units are all interrelated, you must determine the overall layout before your Coulter Representative arrives to install the instrument. Consider the following special requirements.

Space and Accessibility

In addition to the space required for the individual components, consider the following:

- Comfortable working height.
- Access to the rear of the individual units is required for servicing. Allow at least 46 cm (18 in.) for the rear doors plus sufficient room for work space. Units may be moved to obtain additional work space.

Electrical Input

CAUTION

If you plan to use a power strip other than one recommended by Coulter, please call your Coulter Service Representative to be sure that your power strip is compatible with your instrument.

Supply the STKS from an independent, protected circuit. A three-wire outlet furnishing the applicable line voltage, single-phase input power is necessary. Current-carrying capacity of 20 A is recommended, although the actual power consumption is only 1650 W. The ground path must be capable of carrying the full current of the circuit (confirmed thirdwire earth ground). The 3-m (10-ft) primary power cord on the rear of the Power Supply must be plugged directly into the electrical outlet; do not use an extension cord.

Ambient Temperature and Humidity

Install in a room with a temperature of 15.5° to 29.4°C (60° to 85°F). Humidity up to 95% without condensation is permissible.

If the average room ambient temperature changes more than 10°F from the calibrating temperature, verify calibration and recalibrate if necessary to ensure conformance to specifications.

Air Conditioning

In air-conditioned environments an additional 5500 BTU is required to compensate for the heat the system generates.

Ventilation

All ventilation fans must be at least 25 cm (10 in.) away from walls or obstructions that could interfere with the flow of air.

Drainage

CAUTION

If it is necessary to increase the length of the waste line supplied with the system, contact your Coulter Service Representative before making any modifications.

The waste drain tubing (rear panel of the Diluter) supplied with the system can be connected to either:

- an open drain less than 76 cm (30 in.) above the floor
- a waste container with a minimum capacity of 5 gal. (20 L)

In either case the maximum waste line length is 3.7 m (12 ft). When using an open drain instead of a waste container, the waste level-sensing tube can be inserted into the drain. Be sure that the end of the tube is not below the normal level in the drain.

2.3 INTERUNIT CONNECTIONS

CAUTION

To ease reagent priming and prevent a siphoning effect, do not place any reagent containers above the level of the Diluter; place both CBC and SCATTER PAK lytic reagent containers on the same level as the Diluter.

The system is supplied with all power and signal cables, tubing, and pressure and vacuum lines required for interunit connections. Figure 2 illustrates the interunit power and signal cable connections; Figure 3 illustrates the pneumatic/hydraulic connections.

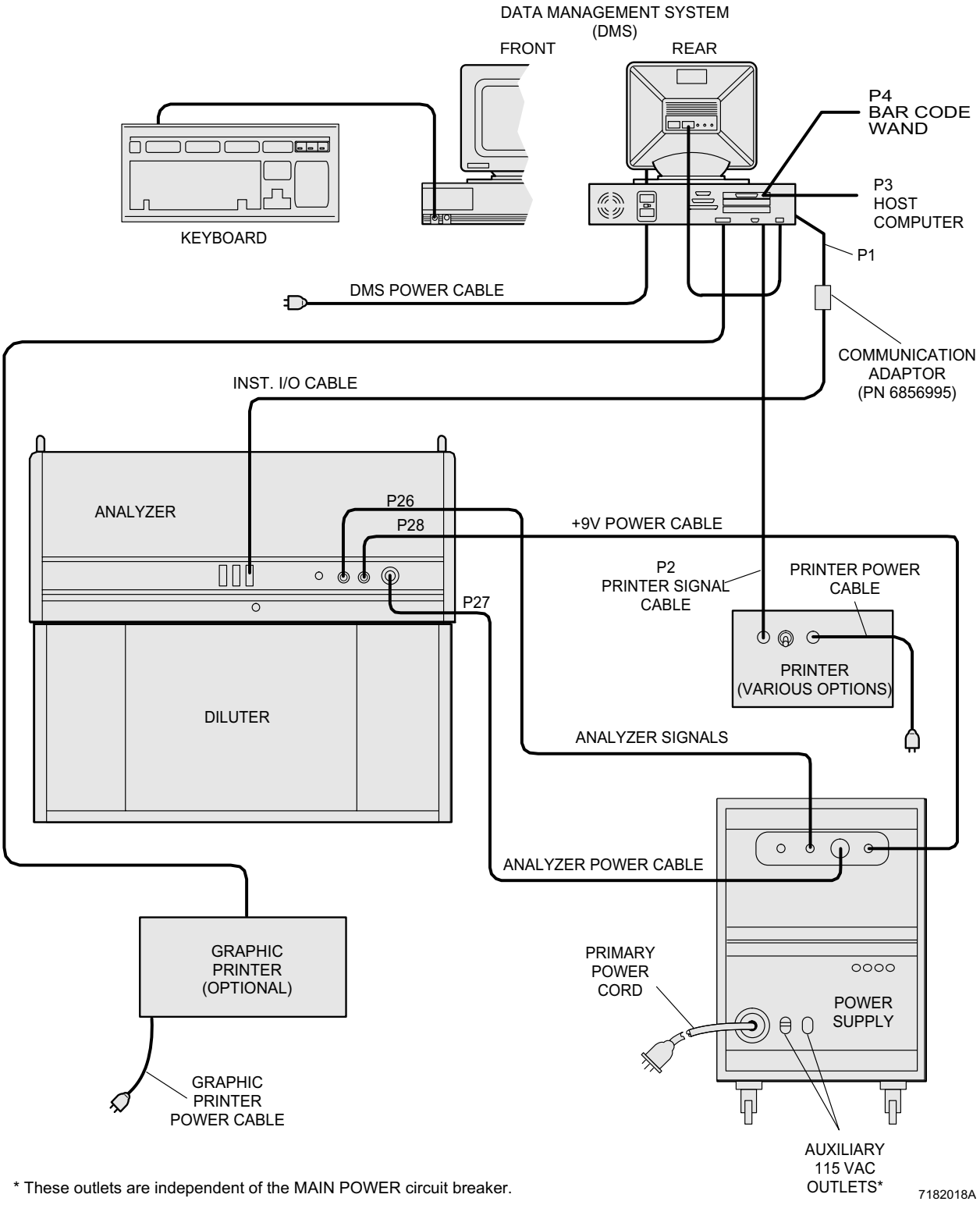

Figure 2 Interunit Power and Signal Cable Connections

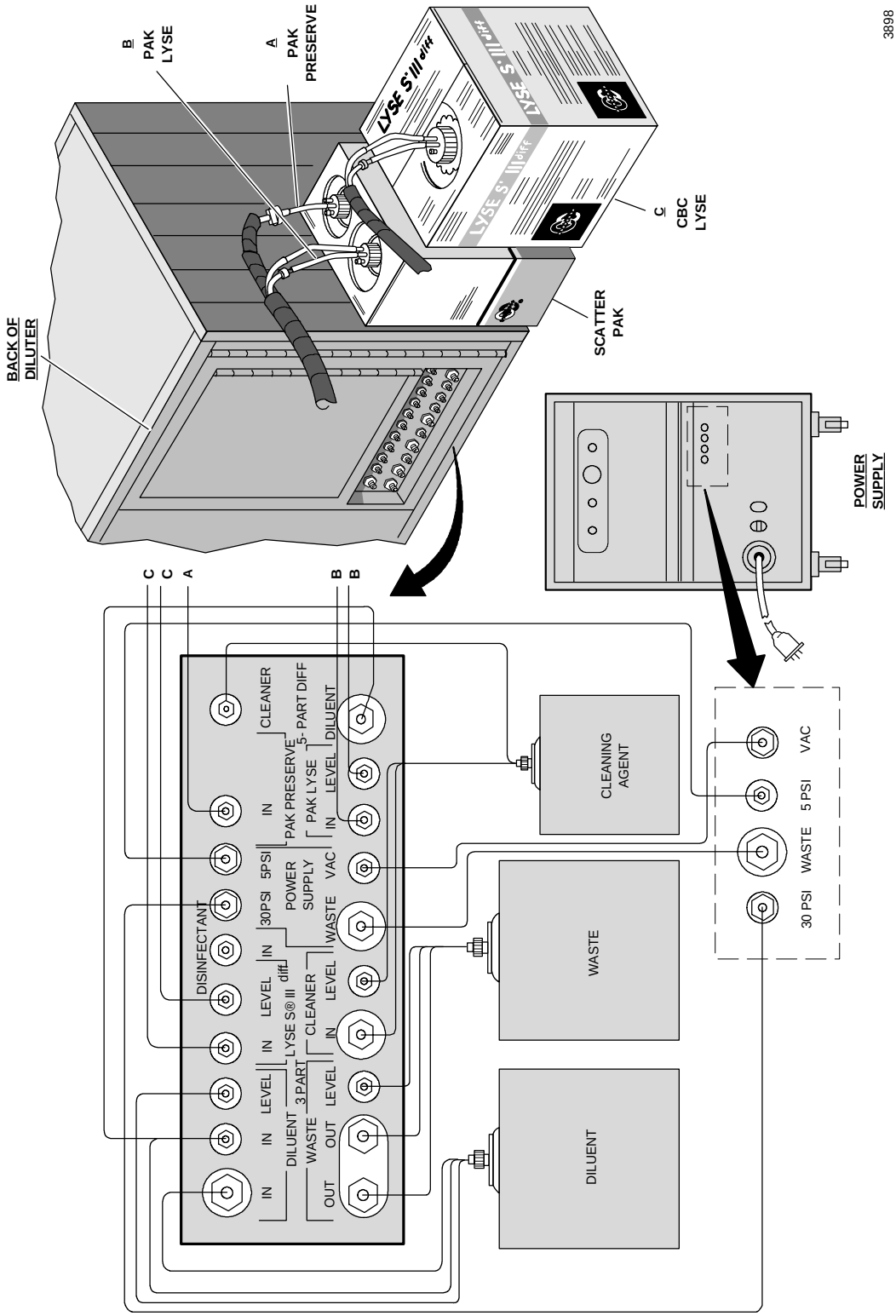

Figure 3 Pneumatic/Hydraulic Connections

3.1 GENERAL

This chapter describes the principles by which the STKS counts, measures, and computes the hematologic parameters.

3.2 COULTER METHOD

The Coulter method counts and sizes cells by detecting and measuring changes in electrical resistance when a particle in a conductive liquid goes through a small aperture. See Figure 4.

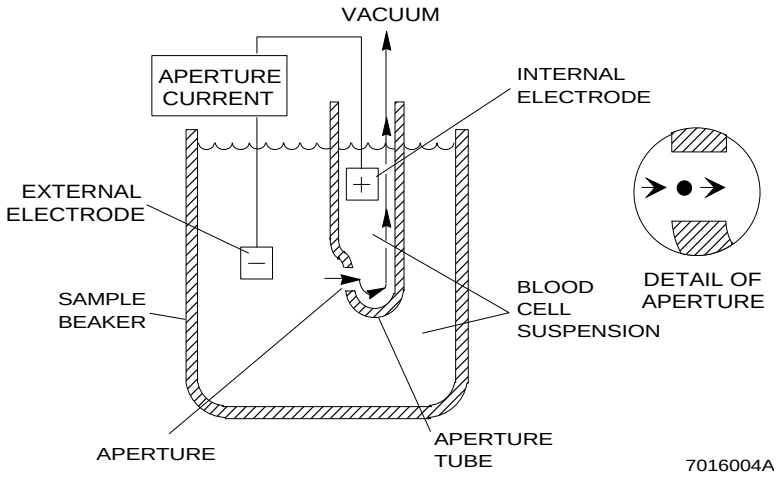

Figure 4 Coulter Method

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell goes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes, one located on each side of the aperture. This causes an electrical pulse that can be counted and sized.

While the number of pulses indicates particle count, the size of the electrical pulse is proportional to the cell volume.[27,28,29,30]

In the STKS, WBC differential analysis and classification are based on simultaneously measuring the cell volume, high-frequency conductivity, and laser light scatter. This yields the volume, content, and structural characteristics of each cell.

ReticPrep (NMB) is a two-step method that prepares whole blood samples for reticulocyte analysis. A supravital dye, New Methylene Blue, is incubated with whole blood samples. The dye precipitates to the basophilic RNA network found in reticulocytes. Hemoglobin and unbound stain are removed by adding a clearing reagent, leaving clear spherical mature RBCs and darkly stained reticulocytes.

Stained reticulocytes are differentiated from mature red cells and other cell populations by light scatter, direct current measurements, and opacity characteristics when using the STKS with volume, conductivity, light scatter, and reticulocyte counting technology.

3.3 PRIMARY OPERATING MODE

The Primary operating mode is for CBC and differential parameters only.

Operating Cycle

Samples in the loading bay are automatically transported, mixed, aspirated, and analyzed. Sample tubes, which can be identified by bar-code labels, are loaded into 12-tube cassettes. Cassettes and the tube position in the cassettes are also identified by bar-code labels. You can load up to 144 samples into the STKS at one time. Figure 5 illustrates the loading bay filled with cassettes.

Press [PRIME APERT], then cycle a normal whole blood in the Primary mode to prime the system. Place cassettes in the right stack, then press [START/CONT] on the Diluter keypad. The cycle begins.

Transport

The right lift platform (Figure 5) beneath the stacked cassettes rises and the bottom cassette is deposited on the transport. The platform lowers the cassette to the level of the rocker bed. The cassette is then moved onto the rocker bed where it is rocked back and forth, mixing the samples. The cassette continues to move toward the sensing station until it reaches the tube sensor. When the first tube is sensed, the stripper plate locks onto the tube. After at least 14 rocks from the time the cassette was loaded, the rocker bed locks in a 45° forward position.

At the sampling station the tube is locked in position and the piercing needle rotates upward. The tube ram pushes the tube out from the cassette causing the needle to pierce the tube stopper. The bar-code

reader scans the cassette and tube labels on both its forward and return passes; an audible indicator can be enabled to indicate each correctly-read bar code. If the bar-code reader detects a discrepancy between the two readings, it makes an additional pass. If there is a no-read situation, positive identification is not achieved.

Aspiration

After the cap is pierced, a pump draws 250 µL of sample through the needle into the Blood Sampling Valve (BSV). The blood detector monitors the passage of sample through the BSV and aspiration lines. The tube ram is withdrawn and the sample tube is reseated in the cassette. The needle rotates into the rinse trough where it is rinsed with diluent.

Delivery

The center section of the BSV rotates and segments the sample into two separate volumes. Beginning a few seconds before the delivery of the dilutions to the appropriate baths, 5 psi of pressure is sent to the WBC bath. This pressure allows drainage of any residual liquid in the WBC bath, thus preventing carryover. The pressure continues during delivery and forms bubbles that mix each cell suspension before sensing begins. At the beginning of the delivery, any residual rinse in the Hgb cuvette drains into the waste chamber and the waste chamber drains. Diluent from the diluent dispensers drives the separated volumes of sample from the BSV to the baths.

One volume of sample, 1.6 µL, is delivered with 10 mL of diluent to the RBC bath. This dilution is used for RBC/Plt counting and MCV/Plt sizing. The other volume, 28 µL, is delivered with 6 mL of diluent to the WBC bath. This dilution is used to count WBC and develop Hgb. During delivery to the WBC bath, 1 mL of lytic reagent is added to the dilution to lyse the red cells and convert Hgb. The final dilution in the WBC bath is 1 part whole blood in a total volume of 251 parts. The final dilution in the RBC bath is 1 part whole blood in a total volume of 6250 parts. At the same time the lytic reagent is dispensed, the Hgb-blank pump transfers 5 mL of diluent into the Hgb cuvette. The vent section of the piercing needle is rinsed, then dried by 5 psi of pressure. The center section of the BSV returns to the aspirate position.

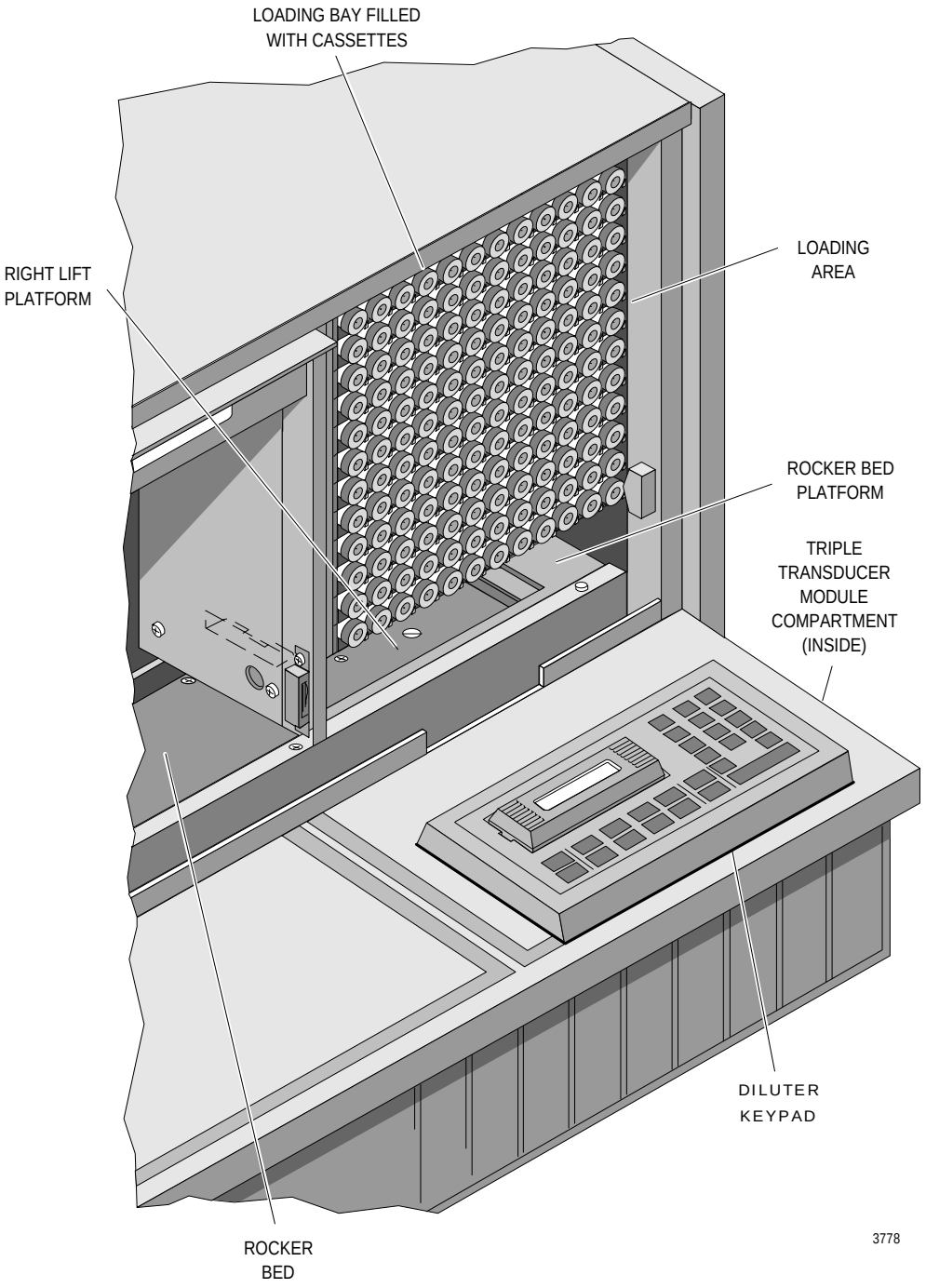

Figure 5 Transport System and Triple Transducer Location

At the same time as the segmented parts of the sample are being delivered to the baths, the Diff segmenting module segments an additional sample of approximately 24 µL of the blood for the WBC differential. The sample and approximately 0.53 mL of Erythrolyse II is delivered to the mixing chamber, which agitates to mix them thoroughly. During the mixing process, approximately 0.2 mL of StabiLyse enters the mixing chamber to preserve the leukocyte populations, and the instrument initiates the sheath stream of diluent in the triple-transducer flow cell.

The instrument injects the sample into the center of the sheath stream and activates the flow cell aperture current. The laminar flow guides the sample through the center of the flow cell aperture; the sheath stream on the exit side of the flow cell aperture prevents the sample's cells from reentering the aperture.

CBC Sensing System

Vacuum, equivalent to 6 in. of mercury, draws a precise volume of suspension from each bath through the three apertures. At the same time, sweep flow is drawn behind the RBC apertures to prevent cells from reentering the sensing zone. When the vacuum starts to draw the suspension, current is supplied to the electrode. The electrical path allows the number and volume of each cell pulled through the apertures to be sensed. While the sample in each bath is sensed, the Hgb-blank is read by the photometer and this reference voltage is retained by the Analyzer.

CBC Analysis in the Baths

The RBC and Plt data collected at the RBC bath, and the WBC and Hgb data collected at the WBC bath are sent to the Analyzer. There the data is:

- coincidence-corrected
- counted
- scaled for calibration and dilution
- voted on
- the RBC size-distribution curves (histograms) are compiled
- the Plt size-distribution curves (histograms) are compiled

The RBC histogram derives MCV and RDW parameters; the Plt histogram derives Plt and MPV parameters. These parameters and histograms are sent to the DMS along with the WBC count. The WBC

bath drains into the Hgb cuvette. The liquid in the cuvette is read photometrically and the Hgb concentration is calculated by comparing this reading with the Hgb-blank reference voltage retained in the Analyzer. This result is sent to the DMS at the end of the cycle. The test results and histograms are displayed at the DMS and a printout is generated.

Differential Multiparameter Sensing System

For the WBC differential, the multiparameter sensing system produces the three measurement signals. Figure 6 shows the Triple Transducer Module and its protective housing as it resides in the Diluter. Tamper-proof screws secure the protective housing; they can only be removed with a special tool.

WARNING

Do not attempt to remove the laser from the Diluter module.

The laser is a helium-neon laser that complies with the United States' performance standard for laser products, Title 21 Code of Federal Regulations 1040.10. Figure 7 shows the laser module without its protective housing to display the flow cell and label locations.

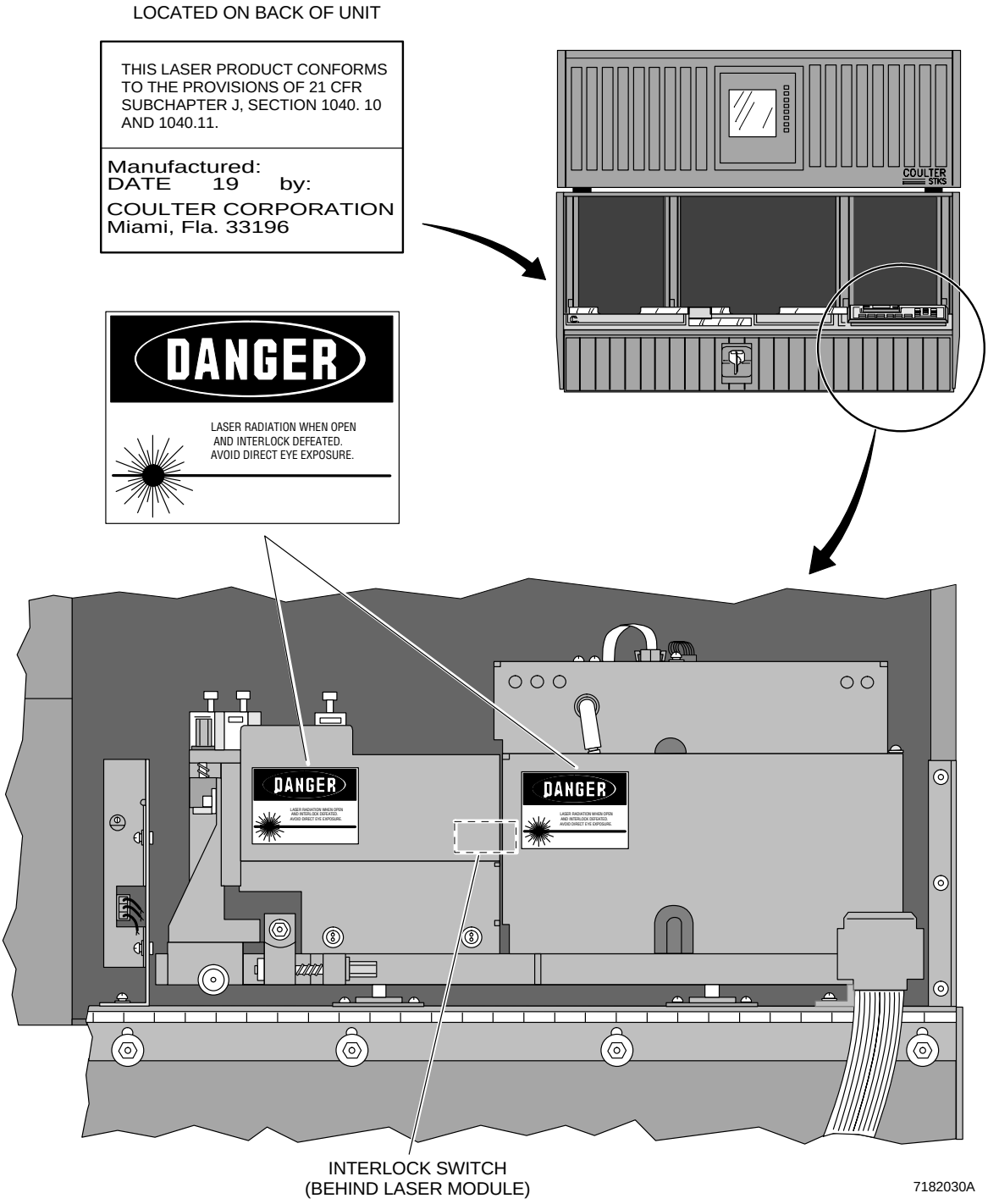

Figure 6 Triple Transducer Module with Protective Housing

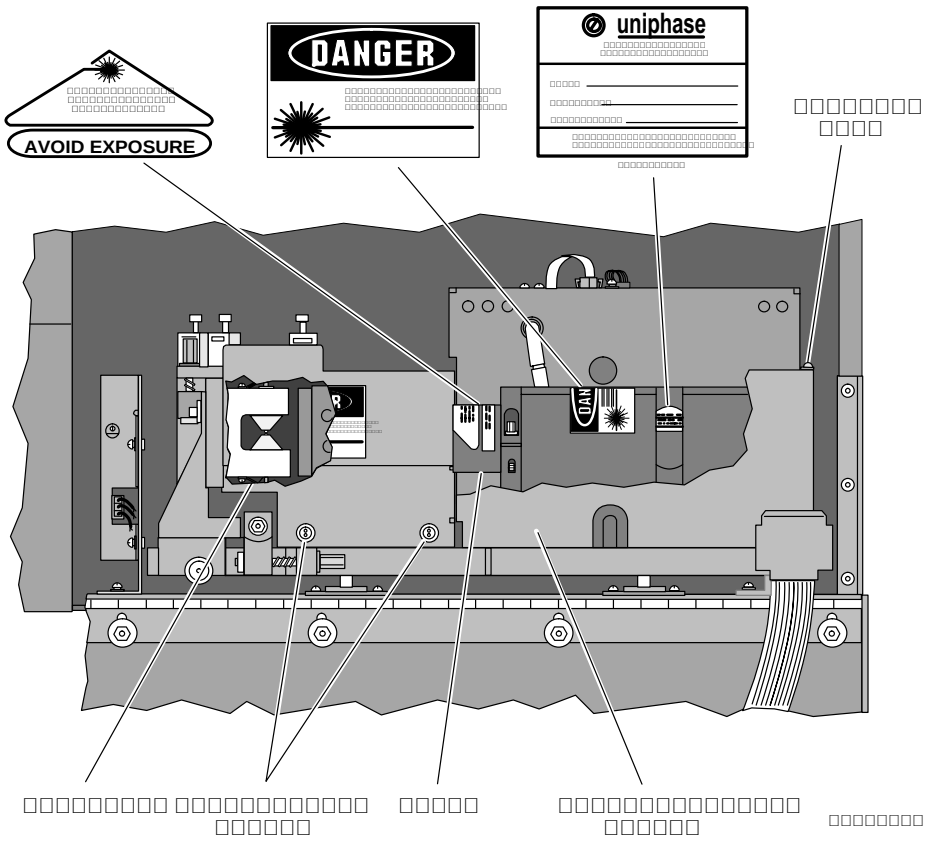

Figure 7 Triple Transducer Module without Protective Housing

WBC Differential Analysis

The STKS makes three measurements (volume, conductivity, and scatter) as each cell passes through the flow cell. The low-frequency impedance measurement defines the volume. The high-frequency conductivity measurement indicates the internal conductivity. The light-scatter measurement indicates the structure and shape. Three raw analog signals are sent to the Analyzer for amplification, signal processing, and computation and scatterplot generation of the five differential parameters. Parameter values and scatterplot data are sent to the DMS from the Analyzer with the CBC results. All results are displayed at the same time.

Backwash and Rinse

Backwash of aspiration pathways and rinse functions of Diluter components are performed on the Diluter.

Approximately 0.5 mL of Erythrolyse II is delivered to the mixing chamber to remove residual material from the previous cycle.

10 mL of diluent rinse for the WBC bath comes from the RBC diluent dispenser, and 6 mL of diluent rinse for the RBC bath comes from the WBC diluent dispenser. The WBC bath needs a larger rinse volume to remove RBC cell stroma after lysing, to remove remaining lytic reagent, to rinse above the 7 mL fill line and to rinse the hemoglobin cuvette.

3.4 SECONDARY OPERATING MODE

IMPORTANT

The blood detectors are not active in the Secondary mode. Be sure to inspect the specimen for clots, and use good laboratory practices to verify results.

The Secondary mode of operation is like the Primary mode except:

1. You enter the sample identification number on the Diluter keypad before you run the sample.

2. You introduce the sample at the aspirator tip and begin the cycle by pressing the panel behind the tip.

3. 150 µL of sample is aspirated for the CBC and CBC/Diff modes. After the sensing period, the aspirator tip is backwashed.

4. The blood detectors are not active in the Secondary mode.

5. You run all Retic samples in the Secondary mode.

6. You never aspirate whole blood in the RETICS mode of sample analysis.

Reticulocyte Analysis

Reticulocyte samples are run in the special RETICS mode, which is set at the Analyzer CRT. The samples are prepared outside the instrument and cycled in the Secondary mode.

The STKS uses the Triple Transducer Module to measure these parameters:

- **Reticulocyte percent (RET%)** - the number of reticulocytes per 100 RBCs, directly measured and reported as a percentage of RBCs.
- **Reticulocyte number (RET#)** - the absolute number of reticulocytes, calculated from RET% and RBC number. Expressed and reported as 10^6 cells/µL or 10^9 cells/L .

Three measurements are made as each cell passes through the flow-cell aperture:

1. The low-frequency impedance measurement defines the cell's volume.
2. The high-frequency impedance measurement indicates the cell's internal conductivity or opacity.
3. The light-scatter measurement indicates the cell's structure and shape.

3.5 COUNTING AND SIZING

Red and White Counting

Each bath, RBC and WBC, has three discrete apertures that function as independent systems. When aperture current is applied to the apertures from the Aperture Current/Signal Generator (AP CUR/SIG GEN) card, there is a delay. During this delay the electronics are conditioned to perform the counting and sizing of the sample. At each aperture the pulses are gathered for 4 seconds. These pulses are amplified on the Red or White Preamplifier (RED PRE-AMP or WHT PRE-AMP) cards and displayed at the Analyzer CRT module.

These pulses are sent to the Red/White Counter (RED/WHT CTR) card, where pulses from the RBC bath representing cells 36 fL and greater (volume calibration referenced to latex particles in ISOTON III diluent) are classified as red cells, and pulses from the WBC bath representing

cells greater than 35 fL (volume calibration referenced to latex particles in ISOTON III diluent) are classified as white cells. The RBC and WBC counts are sent to the Analyzer computer for coincidence correction and voting. The final counts are sent to the DMS where they are displayed, then to the optional Printer for hard-copy reporting.

Coincidence Correction

Occasionally, more than one cell may be within the boundaries of an aperture at the same time. When this occurs only one pulse is counted. However, the frequency of coincidence is a statistically predictable function of cell concentration. Coincidence correction is done by the Analyzer computer.

Voting

To prevent data errors due to statistical outliers or obstructions that may block an aperture, the Analyzer votes on the data from the apertures, and rejects any questionable data. For the WBC count, RBC count, MCV, RDW, Plt count, and MPV, the Analyzer computer compares the data from the three apertures to verify that at least two apertures have produced data within an established statistical range of each other. If the data from one aperture is outside the established statistical range, the data and histograms from that aperture are voted out. The affected parameter is derived by averaging the data from the two remaining apertures. If the data from the two or three apertures is not within an established statistical range from each other, the parameter and histograms are totally voted out.

Sweep Flow

The sweep flow is a steady stream of diluent that flows behind the RBC aperture during the sensing period. This prevents cells from reentering the sensing zone and being counted as platelets. See Figure 8.

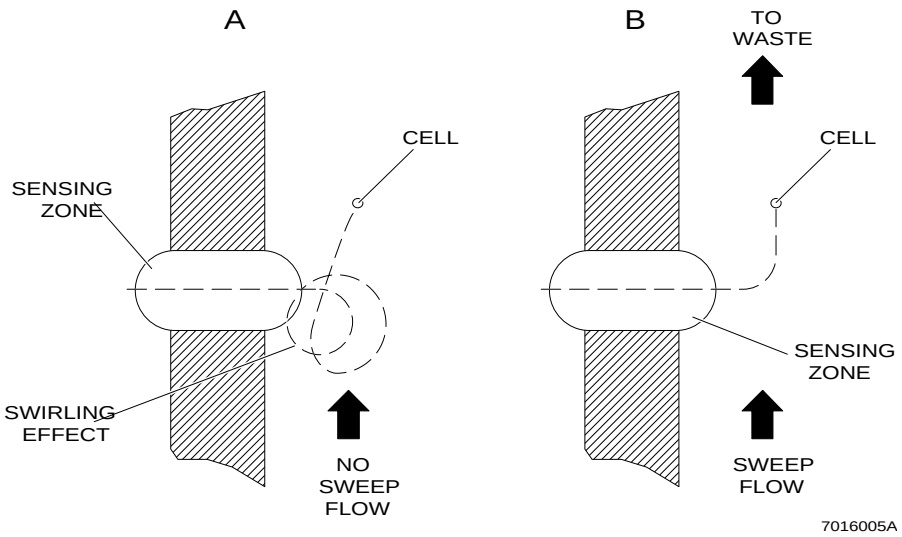

Figure 8 Sweep Flow

RBC Size Distribution

The three Red/White Editor (RED/WHT EDITOR) cards and the Delay Aperture Cleaning (DLY/APERT CLNG) card edit RBC and WBC pulses to exclude pulses produced by cells that may have passed through the aperture near the edge of the opening or at an angle, rather than at the center. There is a RED/WHT EDITOR card for each aperture.

After editing, the three sets of both the RBC and WBC pulses are sent to the Red/White Analog-to-Digital Converter (RED/WHT ADC) card where they are digitized. That is, each pulse is converted to a number that corresponds to the size of the cell. The digital information is sent to the Data Memory (DATA MEM) card where the pulse heights are stored. That is, the digital information from each aperture is stored according to volume in 256-channel, size-distribution histograms. After the sensing periods are completed, the size-distribution histograms are sent through the Power Supply Monitor Buffer (PS MON 2) card to the Analyzer computer. Using a system of moving averages, the computer smooths the RBC histogram. To ensure that the size-distribution curve accurately reflects the true cell population, RBC sensing is extended for not more than four additional 2-second sensing periods whenever the RBC data accumulations are below a predetermined value. The RBC size distribution curve reflects the total data accumulated in all of the sensing periods.

Plt Count and Size Distribution

In the Platelet Processor (PLAT PROC) card, pulses representing cells from 2 to 20 fL are classified as Plts. To ensure that the Plt count and size-distribution curve accurately reflect the cell population, Plt sensing is extended for not more than four additional 4-second sensing periods whenever the Plt data accumulation is below a predetermined value. When sensing time is extended, the Plt count is divided by the number of sensing periods; the Plt size-distribution curve reflects the total of data accumulated in all of the sensing periods. The Plt pulses are sent to the Platelet Analog-to-Digital Converter (PLAT ADC) card where they are digitized. The digital information from each aperture is sent to the DATA MEM card where it is stored in 64-channel, size-distribution histograms. After the sensing periods are completed, these histograms are sent through the PS MON 2 card to the Analyzer computer for analyses.

Plt Fitting Process

Before proceeding with the Plt fitting process, the Analyzer computer verifies that the Plt count per aperture is greater than 20 x 10^3 cells/µL.* Next, the computer smooths the histogram from each aperture, and locates in certain areas of each of the smoothed curves a maximum point and two minimum points. Using a least-squares fit method for a log-normal curve, a curve is fitted to the portion of the histogram between the two minimum points. The computer verifies that each of the fitted curves is positive, that their modes are from 3 to 15 fL, and that the PDW is less than 20.* The fitted curves have a range of 0 to 70 fL. Lastly, the computer votes on the Plt count, MPV, and PDW derived from the three fitted curves. If any of these criteria are not met, a no-fit condition exists. A NON POS, MODE OUT, or PDW OUT message appears on the Analyzer CRT in the SYSTEM RUN mode.

If a no-fit occurs, the computer smooths the histogram from each aperture, and locates in certain areas of each of the smoothed curves a maximum point and two minimum points. The computer then derives the Plt count for each aperture from the portion of the histograms between the minimum points. Then the computer votes on the Plt count, MPV, and PDW derived from the raw data.

*This is an approximate value since comparison is made based on raw data prior to multiplication by the calibration factor.

Derived and Computed CBC Parameters

The Analyzer computer derives MCV and RDW from the RBC histogram, and MPV and Plt count from the Plt histogram. It computes Hct, MCH, and MCHC. These results are sent to the DMS.

3.6 MEASUREMENT OF HEMOGLOBIN CONCENTRATION

After the WBC count, the lysed WBC dilution drains into the hemoglobin cuvette for Hgb measurement.

A beam of white light from an incandescent lamp goes through the cuvette and then through an optical filter that has a center transmission wavelength of 525 nm. Light passing through the filter falls on a photocell. The photocurrent thus generated is proportional to the transmittance of the contents of the cuvette at the chosen wavelength. It is sent to the Input/Output Calibration (I/O CAL) card where it is digitized. The digital information is sent to the Analyzer computer, then the DMS, and then the Printer.

A significant refinement in the COULTER COUNTER systems is the introduction of a reagent blank into the cuvette during each operating cycle. After the percent transmittance is converted to absorbance, the reagent-blank signal level provides a reference to which the sample signal is compared.

3.7 SCATTERPLOT DEVELOPMENT

The Analyzer performs a series of operations on the stored digital raw values to identify subpopulations and calculate percentage values. It also produces the scatterplot displays for visual representation of the WBC and Reticulocyte/RBC populations. Largest concentration is indicated on the scatterplot display by intensity. On a black and white graphics printout, darkest represents the greatest concentration; on the monitor or a color graphics printout, yellow represents the greatest concentration followed by red, green, and blue.

DF 1 Scatterplot

A two-dimensional scatterplot shows four of the five populations: lymphocytes (LY), monocytes (MO), neutrophils (NE), and eosinophils (EO). The fifth population, basophils (BA), is behind the upper right quadrant of the Lymphocyte population. For the purposes of the display,

the axes are labeled Volume and DF 1; DF 1 is a discriminant function derived primarily from the light scatter measurement.

Volume is determined by the low-frequency impedance measurement.

DF 2 Scatterplot

DF 2 discriminant function is another perspective of the five differential populations and is derived primarily from conductivity. DF 2 displays WBC volume on the y-axis and conductivity on the x-axis. This display shows the lymphocyte, monocyte and granulocyte populations. The granulocyte population includes the neutrophils, basophils and eosinophils.

DF 3 Scatterplot

DF 3 displays the same data as DF 2 with the eosinophil and primary neutrophil populations gated out. Basophil, lymphocyte and monocyte cell populations are easier to see with this display.

DF 5 Scatterplot

DF 5 is a two-dimensional scatterplot which shows mature red cells and reticulocytes. Cell volume is plotted on the y-axis and laser light scatter characteristics are plotted on the x-axis.

DF 6 Scatterplot

DF 6 is a discriminant function derived primarily from reticulocyte conductivity. DF 6 displays Retic volume on the y-axis and conductivity on the x-axis.

3.8 $\bar{X}_B$ ANALYSIS IN THE DMS

Studies (Bull 1974, Koepke 1981) indicate that the red cell indices (MCV, MCH, and MCHC) of patient populations are stable over time.[31,32] This stability characteristic of the indices is the basis of a quality-control technique called $\bar{X}_B$ Analysis. In a manually-implemented system, population means (target values) are established by analyzing as large a sample as possible, at least 250, but ideally 1000 blood samples. (The $\bar{X}_B$ Analysis used in the DMS does all the calculating automatically.)

Once the target values have been established, the $\bar{X}_B$ Analysis can be applied using quite small batches from the patient population. A 20-patient sample batch is a typical size, and is used in the DMS.

The formula, Figure 9, is easily implemented with a computer. Its function is to enable reliable estimates of the values for these parameters to be made for a population from small samples of that population. It is superior to the traditional moving average because it reacts quickly to changes. Small batch sizes allow for more frequent, therefore tighter quality control. The formula both trims the data by giving less weight to outliers, and smooths it by incorporating information from the previous patient batch in the analysis of the current batch. As each sample is processed, the mean of the previous set of samples is subtracted from each of the red cell indices. The square root of this deviation (difference between the means) is stored. After 20 samples have been processed, the sum of the square roots is divided by 20. The result is squared to recover the mean (average) deviation. The individual deviations carry a positive or negative sign, so then it can be added to or subtracted from the corresponding previous means. The resulting new mean is then used for the succeeding batch of 20 samples.

The hematology system is considered "in control" when the batch means are within established limits of the target values. Using the $\bar{X}_B$ Analysis, the direction and amount of change due to the instrument, the reagent, flagged samples or sample handling can be detected. Because of the characteristic appearance of the graphs of the $\bar{X}_B$ results, it is also often possible to identify changes.

Here's the $\bar{X}_B$ formula:

$$X(B,i) = X(B,i-1) + SGN\left\{\sum_{j=1}^{N} SGN\,[X(j,i)-X(B,i-1)] * \sqrt{|X(j,i)-X(B,i-1)|}\right\} * F$$

$$F = \frac{\left\{\sum_{j=1}^{N} SGN\,[X(j,i)-X(B,i-1)] * \sqrt{|X(j,i)-X(B,i-1)|}\right\}^2}{N^2}$$

Where:

X(B,i)	= ith $\bar{X}_B$ value
X(B, i-1)	= (i-1)th $\bar{X}_B$ value
X(j,i)	= the jth X value in the ith batch
SGN	= the arithmetic sign of number in parentheses
N	= number of samples in the batch
*	= symbol used to represent multiplication

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Figure 9 The $\bar{X}_B$ Formula

The DMS calculates and displays the percent difference between each batch mean and its corresponding preset target value. The percent difference is derived as follows:

1. MCV

$$\text{percent diff} = \left(\frac{\text{MCV Batch Mean}}{\text{MCV Target Value}} - 1 \right) \times 100$$

2. MCH

$$\text{percent diff} = \left(\frac{\text{MCH Batch Mean}}{\text{MCH Target Value}} - 1 \right) \times 100$$

3. MCHC

$$\text{percent diff} = \left(\frac{\text{MCHC Batch Mean}}{\text{MCHC Target Value}} - 1 \right) \times 100$$

Adjusting Initial $\bar{X}_B$ Target Values

The recommended target values for initial entry are:

MCV	89.5
MCH	30.5
MCHC	34.0

As samples are run and laboratory values established, the recommended target values can be adjusted to fit your laboratory's population.* After 20 $\bar{X}_B$ batches have been analyzed, calculate the mean and CV% for each of the $\bar{X}_B$ indices. The mean values should not differ from the target values by more than 3%, and the CV should be less than 1.5%. If the CVs are less than 1.5% and the means are less than 3% different from the target values, use the calculated means as new target values.

If the CVs are greater than 1.5%, or the mean values are greater than 3% different from the recommended target values, there may be an instrument or population problem. In this case, repeat this procedure

*Use average operating conditions to establish $\bar{X}_B$ target values to fit your laboratory's population.

using the next 20 $\bar{X}_B$ batches. If the indices themselves are stable in a hospital population, then any deviation from the TARGET VALUES and ACTION LIMITS may point to an instrument or reagent problem. These problems would involve the parameters directly measured by the instrument and used to calculate the red cell indices. Table 1 lists the directly-measured parameters that would be involved with out-of-limits $\bar{X}_B$ batch values for each of the red cell indices.

If the $\bar{X}_B$ indices are still out-of-limits, you should investigate the instrument and reagent systems associated with the directly-measured parameter(s) as indicated by Table 1 and call your Coulter Service Representative.

Table 1 Effect of Directly-Measured Parameters on the Red Cell Indices

	Directly-Measured Parameter					
	MCV		RBC		HGB	
Index	Increased	Decreased	Increased	Decreased	Increased	Decreased
MCV	HIGH	LOW	NORMAL	NORMAL	NORMAL	NORMAL
MCH	NORMAL	NORMAL	LOW	HIGH	HIGH	LOW
MCHC	LOW	HIGH	LOW	HIGH	HIGH	LOW

See the Glossary for terms used with the $\bar{X}_B$ Analysis.

4.1 PHYSICAL SPECIFICATIONS

Power

Input Supply Requirements

STKS: 90-110 Vac, 49-51 Hz and 59-61 Hz
99-121 Vac, 49-51 Hz and 59-61 Hz
198-242 Vac, 49-51 Hz and 59-61 Hz
DMS: 90-135 Vac, 47-63 Hz or 180-265 Vac, 47-63 Hz

Consumption

1650 W (5500 BTU/h) maximum
Installation Category: per IEC 1010-1, Category II

Temperature (ambient operating range for patient samples)

15.5° to 29.4°C (60° to 85°F)

Humidity

0 to 95% without condensation

Sample Stability

0 to 24 hours, based on independent studies. Refer to package insert for specific test applications.

Recommended Anticoagulant

K_3EDTA

Throughput

Typical throughput performance is described as "average" for samples exhibiting parameter levels within the normal range and "maximum" for samples with elevated parameter levels. The table below shows approximate throughput performance data which does not include sample preparation.

	Average	Maximum	
CBC	120	136	(Primary mode)
CBC/Diff	109	136	(Primary mode)
Retics	60	74	(Secondary mode)

Sample Volume Required

Primary mode: 250 µL
Secondary mode: 150 µL
Secondary mode with F55, F56, F57: 1.5 mL
Secondary mode with Retics: 2 mL prepared sample

Waste

20-liter waste container

Pneumatic Supplies (Internally Regulated)

Pressure = 60 psi (pounds per square inch)

Vacuum = 22 in. Hg (inches of mercury) at sea level

Calibration Stability

Electronic measurement system: < 1% per month

Variation with temperature: If ambient room temperature changes by less than 10°F from the calibrating temperature, and the temperature is within the temperature specifications, then the STKS does not require calibration. Under these conditions, the calibration factor % difference is:

WBC	< 1.25%
RBC	< 0.70%
Hgb	< 0.78 %
MCV	< 1.18%
Plt	< 2.70%
MPV	< 5.00%

DMS Storage

Patient results: 5,000 sets including all Sample Analysis screen displays
Patient + Sample sort capacity: 1,000 sets
Controls: 30 files, 100 runs/file

4.2 PERFORMANCE SPECIFICATIONS

The STKS consists of three subsystems, which we have designated as "CBC" (Complete Blood Count), "WBC Differential" and "Retics." The CBC subsystem is based on the established Coulter principles of automated cell counting. The WBC differential subsystem is based on the Coulter principles of leukocyte differential counting as embodied in the COULTER VCS. The Retics subsystem is based on the Coulter volume, conductivity and light scatter technology.

Performance specifications stated apply only to an instrument that has been properly maintained as indicated in the COULTER STKS with Reticulocyte Analysis manuals, using the recommended reagents.

If the average room temperature should change more than 10°F from the calibrating temperature, verify calibration and recalibrate if necessary to ensure conformance to specifications.

Precision

Replicate Precision, CBC

Precision of the CBC parameters is specified as a Coefficient of Variation (CV) based on at least 31 determinations of the same sample. See Table 2.

Table 2 Replicate Precision, CBC Parameters (n ≥31)

Parameter	CV
WBC at 10.0 x 10^3 cells/µL	<1.7%
RBC at 5.00 x 10^6 cells/µL	<0.8%
Hgb at 15.0 g/dL	<0.8%
MCV at 90.0 fL	<0.8%
RDW at 13.0%	<2.2%
Plt at 300 x 10^3 cells/µL	<3.3%
Plt at 30.0 x 10^3 cells/µL	<6.6%
Plt at 10.0 x 10^3 cells/µL	<10.0%
MPV at 9.0 fL	<2.2%

Replicate Precision, WBC Differential

Precision of the WBC differential parameters is specified at 95% confidence level based on at least 31 determinations of the same sample; see Table 3.

Table 3 Replicate Precision, WBC Differential Parameters

Parameter		95% Confidence Limits
LY% at 31;	WBC at 4.0 x 10^3 cells/µL	±3.0
MO% at 8;	WBC at 4.0 x 10^3 cells/µL	±2.0
NE% at 57;	WBC at 4.0 x 10^3 cells/µL	±3.0
EO% at 3;	WBC at 4.0 x 10^3 cells/µL	±1.0
BA% at 1;	WBC at 4.0 x 10^3 cells/µL	±1.0

Replicate Precision, Reticulocytes

Table 4 shows Replicate Precision (total system) validation limits for 31 separately prepared replicates of the same specimen.

Table 4 Replicate Precision, Reticulocyte

	LIMITS (Whichever is greater)	
Retic%	SD Limit	CV Limit
<1.00	0.23	≤23%
1.00 - 4.00	0.23	≤17%
4.01 - 15.00+	0.68	≤15%

Paired Precision, Reticulocytes

Validation of paired sample precision for reticulocytes is based upon the differences of Run 1 and Run 2 specimens. The limits over the clinical range of a minimum of 50 specimens from a general hospital population of no more than 30% abnormally elevated Reticulocyte specimens (Reticulocyte > 4%) are as follows:

Parameter	Mean Difference*	SD of Difference*
Retic%	± 0.4	0.8

* Both requirements must be met.

Paired sample precision limits over the clinical range for a minimum of 50 specimens with the following characteristics, are as described below:

- greater than 50% abnormally elevated Retic values
- elevated Retic values = Retic > 4%
- no greater than 5 of 50 specimens have Retic values > 20%.

Parameter	Mean Difference*	SD of Difference*
Retic%	± 0.5	1.5

* Both requirements must be met.

Accuracy

Accuracy, CBC

For the CBC parameters, the STKS can be adjusted within the resolution of the readout to agree with a predetermined reference value at any point in the operating range.

Accuracy, WBC Differential

Accuracy of the WBC differential, when determined by comparison against the reference manual differential method (NCCLS H-20 [n = 800]) or against current STKS instruments, should be within the tolerance limits listed in Table 5. Table 5 gives the mean difference in percentage units against H20 Reference values at mean normal concentrations. Note that an additional bias may be experienced by some laboratories due to the inherent variabilities in manual differential counting including sample population, number of cells counted, smear preparation, quality of stain, low incidence cells, and interpretation of cell types (monocytes, variant lymphocytes, and band neutrophils are most commonly affected by interpretation variances).[33,34] This systematic difference, when present, should not exceed the limits presented in Table 6.

Table 5 Accuracy Tolerance Limits, WBC Differential

Cell Type	Mean Difference %
Lymphocyte	±1.0
Monocyte	±0.5
Neutrophil	±1.0
Eosinophil	±1.0
Basophil	±0.5

Table 6 WBC Differential Bias

Cell Type	Limit %
Lymphocyte	0 to -2.7
Monocyte	0 to +2.9
Neutrophil	0 to -2.0
Eosinophil	0 to +0.7
Basophil	0 to +0.8

Accuracy, Reticulocyte

Reticulocyte parameter accuracy is the sum of the variables of linearity and precision for the test and the comparator method using specimens covering the reportable range. The comparator method for reticulocyte counting is the reference method described in the NCCLS document H16-P (n = 4000) or its pertinent successor document. Analysis is based on the differences [diff = Run 2 (instrument) - Reference].

The limits over the clinical range for a minimum of 50 specimens from a general hospital population of no more than 30% specimens with abnormally elevated reticulocyte values (Retic > 4%), are as follows:

Retic %	Mean Difference*	SD of Difference*
0.00 - 15.00	± 1.0	≤ 1.5

* Both requirements must be met.

The limits over the clinical range for a minimum of 50 specimens with the following characteristics are as described below:

- greater than 50% abnormally elevated Retic values
- elevated Retic values = Retic > 4%
- no greater than 5 of 50 specimens have Retic values > 20%.

Retic %	Mean Difference*	SD of Difference*
0.00 - 30.00	± 1.5	≤ 3.0

* Both requirements must be met.

CBC Linearity

When tested using dilutions made from a specimen having no interfering substances and a typical MCH of 30 pg, the STKS value is equal to the expected value within the limits given in Table 7. To obtain the same results, multiple readings must be taken at each point to eliminate the statistical effects of imprecision. Linearity of size measurements (MCV and MPV) are tested using appropriate techniques. Linearity applies only to directly measured parameters.

Table 7 Linearity Limits, CBC

Parameter	Linearity Range	Limits
WBC x 10^3 cells/µL	0 to 99.9	0.2 or 3.0% (whichever is greater)
RBC x 10^6 cells/µL	0 to 7.00	0.03 or 1.0% (whichever is greater)
Hgb g/dL		
Primary mode	0 to 18.0	0.2 or 2.0% (whichever is greater) with typical MCH of 30 pg
Primary mode	18.0 to 25.0	Increasing to 4% at 25.0 g/dL with a typical MCH of 30 pg
Secondary mode	0 to 25.0	0.2 or 2.0% (whichever is greater) with a typical MCH of 30 pg
MCV fL	50 to 200	2.0%
Plt x 10^3 cells/µL	0 to 999	10 or 7% (whichever is greater)
MPV fL	5.0 to 20.0	5%

Carryover

Sample A is a normal blood with WBC of 10,000 ±1,000. Sample B is diluent. The effect of sample A on the values obtained for sample B is less than 2.00% for WBC, Hgb and Plt; and less than 1.00% for RBC. This is true when:

- analysis is based on running two blood samples followed by three diluent samples, and
- calculating using the formula:

$$\frac{\text{1st diluent} - \text{3rd diluent}}{\text{2nd sample}} \times 100 = \% \text{ carryover}$$

Operating and Reportable Ranges

WBC Differential Operating Range*

LY%, MO%, NE%, EO%, BA%: 0 to 100%
LY#, MO#, NE#, EO#, BA#: 0 to 99.9 x 10^3 cells/µL

* When low differential count statistics occurs, the Differential % and #'s are flagged with *R* for *Review*. Follow your laboratory protocol for review.

Reticulocyte Reportable Range

The reportable range for the STKS with Reticulocyte analysis is the range of test values demonstrated by the total system as valid; see Table 8. Reticulocyte parameter reportable ranges are based upon accuracy and precision data.

Table 8 Reticulocyte Reportable Range

Parameter	Reportable Range
Retic %	0.20%* to 30.00%
Retic #	.0055 to .7500 x 10^6 cells/µL or 5.5 to 750.0 x 10^9 cells/L

*When Retic% is ≤0.5%, Retic% and corresponding Retic# are flagged with *R* for *Review*. Follow your established laboratory protocol for review.

Mode-to-Mode Comparison

Minor differences between the Primary (cap-piercer) and Secondary (manual) modes are due to differences in the flow characteristics of the aspiration pathways. Additionally, flow characteristics vary between samples. Verification of the minor mode-to-mode differences seen on the STKS requires elimination of effects of carryover and within mode precision in testing. For these reasons, the specification is based on the average values for 10 normal bloods measured in triplicate (three consecutive measurements). When verification is performed according to this protocol, difference between the averages of the two modes do not exceed the following limits:

WBC	0.4 x 10^3 cells/µL or 5%, whichever is greater
RBC	0.2 x 10^6 cells/µL or 2%, whichever is greater
Hgb	0.3 g/dL or 2%, whichever is greater
Plt	20 x 10^3 cells/µL or 7%, whichever is greater

Data collected using "blind paired" samples has demonstrated that variability observed in the paired samples between Primary and Secondary modes is similar to the variability observed within a mode.

4.3 PERFORMANCE CHARACTERISTICS

The CBC, WBC differential and Reticulocyte performance characteristics described in this section were analyzed on the COULTER STKS with Reticulocyte Analysis using the recommended reagents. Daily Startup, shutdown, calibration and control procedures were performed according to recommendations by Coulter Corporation.

Data collection and verification of claims was performed using the following:

- K_3EDTA anticoagulated whole blood specimens
- Air displacement pipettors for off-line Reticulocyte sample preparation.

The morphologically and distributionally abnormal specimen types used in the paired sample accuracy and precision studies are presented in Table 19.

Precision

Replicate Precision of the CBC Parameters

The results of replicate precision testing (n = 31) for each parameter measured by the STKS with Reticulocyte Analysis are given in Table 9.

Table 9 Replicate Precision, CBC

Parameter	Units	Mean	2 SD	%CV
WBC	x 10^9 cells/L	11.41	0.25	1.1
RBC	x 10^{12} cells/L	3.52	0.05	0.7
Hgb	g/dL	10.76	0.11	0.5
MCV	fL	84.40	0.87	0.5
RDW	%	12.69	0.35	1.4
Plt	x 10^9 cells/L	227.4	7.80	1.7
MPV	fL	7.74	0.16	1.0

Replicate Precision of the WBC Differential Parameters

Table 10 shows precision by replication 31 times with a single specimen.

Table 10 Replicate Precision, WBC Differential

Cell Type	Units	Minimum	Maximum	Mean Recovery	2 Standard Deviations
Lymphocyte	%	12.35	14.64	13.68	1.03
Monocyte	%	5.31	6.35	5.73	0.45
Neutrophil	%	77.81	80.13	79.09	0.95
Eosinophil	%	0.81	1.13	0.93	0.16
Basophil	%	0.36	0.70	0.57	0.19

Replicate Precision of the Reticulocyte Parameters

The typical Precision Characteristic is expressed in terms of Coefficient of Variation (CV). This was determined by simple replicate testing with a representative donor specimen sampled using 31 separate dilutions. For studies of whole blood specimens collected in K_3EDTA, Table 11 shows precision for Retic % and Table 12 shows precision for Retic #.

Table 11 Replicate Precision, Reticulocyte % n = 31

	Level I	Level II	Level III
Mean	1.18	8.95	17.91
SD	0.10	0.30	1.01
CV	8.5	3.4	5.6

Table 12 Replicate Precision, Reticulocyte # in 10^9 cells/L n = 31

	Level I	Level II	Level III
Mean	29.52	367.15	805.94
SD	2.53	12.11	45.27
CV	8.6	3.3	5.6

Paired Precision of the CBC/Differential Parameters

The results of paired difference analysis for 226 paired clinical blood specimens are given in Table 13.

Table 13 Paired Sample Precision, CBC

Parameter	Units	Population			Mean Difference	SD of Difference
		Low	Mean	High		
WBC	x 10^9 cells/L	0.80	8.91	82.30	-0.03	0.43
RBC	x 10^{12} cells/L	1.95	4.32	6.67	0.00	0.03
Hgb	g/dL	6.45	12.67	18.05	-0.02	0.09
Hct	Ratio	18.22	37.26	53.21	0.01	0.35
MCV	fL	65.77	86.65	111.82	0.05	0.53
MCH	pg	21.43	29.55	48.78	-0.03	0.29
MCHC	g/dL	32.07	34.07	45.41	-0.05	0.38
RDW	%	11.00	13.99	25.70	0.01	0.28
Plt	x 10^9 cells/L	0.00	229.55	890.32	-0.44	11.08
MPV	fL	3.96	8.76	12.92	0.01	0.27

Table 14 shows paired sample analysis using normal blood for 130 paired observations.

Table 14 Paired Sample Precision, WBC Differential

Cell Type	Unit	Population			Mean Difference	SD of Difference
		Low	Mean	High		
Lymphocyte	%	9.80	31.19	78.70	-0.04	0.88
Monocyte	%	4.60	9.30	22.10	-0.13	0.53
Neutrophil	%	12.30	55.31	74.80	0.17	0.86
Eosinophil	%	0.50	3.25	24.50	-0.01	0.31
Basophil	%	0.00	0.95	4.30	0.02	0.26

Paired Precision of the Reticulocyte Parameters

The typical Precision Characteristic for Paired Sample analysis is expressed as the Mean Difference and the Standard Deviation of the Differences for Run 1 and Run 2. Paired Sample Testing was performed using 101 clinical specimens. Table 15 shows Difference Analysis of Paired Samples in Percent (%). Table 16 shows Difference Analysis of Paired Samples in absolute numbers, expressed in 10^9 cells/L.

Table 15 Paired Sample Precision, Reticulocyte %

	Population Minimum	Population Maximum	Population Mean
(A) Replicate 1	0.2	26.5	2.90
(B) Replicate 2	0.2	23.9	2.91
Difference (A-B)			-0.01
SD of Differences			0.55

Table 16 Paired Sample Precision, Reticulocyte Absolute Numbers (x 10^9 cells/L)

	Population Minimum	Population Maximum	Population Mean
(A) Replicate 1	5.5	834.8	92.14
(B) Replicate 2	5.5	752.9	92.49
Difference (A-B)			-0.35
SD of Differences			18.05

Accuracy

Accuracy of the CBC/Differential Parameters

For CBC parameters, a COULTER S-PLUS IV provided reference data. The performance of this instrument had been independently validated against the following methods:

WBC: COULTER ZBI analyzer. Certified volumetric glassware
RBC: COULTER ZBI analyzer. Certified volumetric glassware
Plt: COULTER ZBI analyzer. Certified volumetric glassware
Hgb: NCCLS method H15-A
MCV: NCCLS packed cell volume method H7-A

For WBC differential parameters, the reference values were provided by the method described in NCCLS publication H20-A (n = 800).

Evaluation of CBC accuracy by subtraction of paired test results for 226 specimens is given in Table 17.

The magnitude of the mean differences expresses accuracy. The dispersion of differences (SD) expresses the inclusive errors of imprecision and bias.

Table 17 Accuracy, CBC

Parameter	Units	Clinical Range			Mean Diff.	SD
		Low	Mean	High		
WBC	x 10^9 cells/L	0.91	9.08	82.95	-0.17	0.30
RBC	x 10^{12} cells/L	1.95	4.32	6.82	0.00	0.06
Hgb	g/dL	6.36	12.64	18.37	0.03	0.13
Hct	Ratio	18.49	36.86	53.74	0.04	0.65
MCV	fL	65.76	85.84	111.28	0.81	1.12
MCH	pg	21.52	29.46	48.12	0.08	0.38
MCHC	g/dL	32.06	34.30	44.58	-0.23	0.62
RDW	%	11.30	14.06	25.50	-0.08	0.33
Plt	x 10^9 cells/L	2.02	237.39	886.24	-8.68	10.43
MPV	fL	3.70	8.87	18.09	-0.06	0.30

Accuracy of the Differential parameters is expressed as the mean difference between reference method (H20-A) values and the STKS values for 130 normal subjects. See Table 18.

Table 18 Accuracy, WBC Differential

Cell Type	Units	Clinical Range			Mean Difference	SD
		Low	Mean	High		
Lymphocyte	%	10.75	32.61	73.50	-1.42	2.40
Monocyte	%	1.63	7.34	19.38	1.96	1.59
Neutrophil	%	24.75	56.42	76.13	-1.11	2.58
Eosinophil	%	0.13	3.04	27.75	0.21	0.71
Basophil	%	0.00	0.40	1.88	0.55	0.60

Table 19 lists the numbers of abnormalities that were studied in the paired analysis testing according to NCCLS H20-A criteria for abnormal specimen types.

Table 19 Abnormalities

Abnormality Type	# of Cases Absolute Count	Criteria x 10^9 cells/L	# of Cases Percent	Criteria Percent
Lymphocytosis	19	≥ 3.50	19	> 50.0
Lymphopenia	42	≤ 1.00	14	< 7.0
Variant Lymphocytes	21	≥ 0.70	n/a	n/a
Monocytosis	28	≥ 0.80	30	> 10.0
Granulocytosis	12	≥ 9.00	20	> 80.0
Granulopenia	24	≤ 1.50	13	< 10.0
Bands	11	≥ 0.90	28	> 6.0
Eosinophilia	15	≥ 0.50	14	> 7.0
Metamyelocytes	13	≥ 0.10	13	> 2.0
Myelocytes	9	≥ 0.10	8	> 2.0
Promyelocytes	3	≥ 0.10	0	> 2.0
Blasts	6	≥ 0.10	5	> 2.0
Nucleated RBC	16	≥ 0.02	2	> 2.0

Accuracy of Reticulocytes

The typical Accuracy characteristic is expressed as the agreement between values given by the COULTER STKS with reticulocyte analysis and results from the NCCLS H16-P Method (where n=4000) at any point within the operating range where the Mean Difference and the Standard Deviation of the Differences of compared samples was found to be as follows. This was determined by using 101 clinical specimens with values covering the expected range of performance. Table 20 shows accuracy difference analysis of compared specimens in percent (%). Table 21 shows accuracy difference analysis of compared specimens in absolute numbers, expressed in 10^9 cells/L.

Table 20 Accuracy, Reticulocyte %

	Population Minimum	Population Maximum	Population Mean
(A) COULTER STKS	0.2	23.9	2.91
(B) NCCLS H16	0.00	19.97	2.47
Difference (A-B)			0.44
SD of Differences			1.20

Table 21 Accuracy, Reticulocyte # (x 10^9 cells/L)

	Population Minimum	Population Maximum	Population Mean
(A) COULTER STKS	5.5	752.9	92.49
(B) NCCLS H16	0.0	629.2	78.30
Difference (A-B)			14.19
SD of Differences			35.19

Reference Ranges

WBC Differential Reference Range

Table 22 shows the reference range of normal values for 160 subjects.

Table 22 Reference Range, WBC Differential

Cell Type	Lower %	Upper %	Low Absolute #	High Absolute #
Lymphocyte	18.50	46.90	1.40	2.90
Monocyte	4.20	12.40	0.20	0.90
Neutrophil	41.30	69.50	2.10	4.90
Eosinophil	0.10	4.50	0.00	0.30
Basophil	0.00	2.30	0.00	0.10

Retic Reference Range

The reference interval for the STKS with reticulocyte analysis was derived using donor specimens where the donor, based on a questionnaire, was not suffering from a hemorrhagic disorder and was not currently bleeding. The database was divided into groups based on age, race and sex. The upper and lower tails of each distribution of test values were deleted. The resulting minimum and maximum values of the normal variate continuum were reported as the lower and upper reference intervals by sex, race and age. Table 23 shows the 95% subclassification of data within the range for reticulocyte percent.

Normal Reference Interval:
Reticulocyte % - 0.66% to 2.85% at 95% confidence
Reticulocyte # - 27.9 to 121.6 at 95% confidence

Table 23 Subclassification of Data within the Range, Reticulocyte Percent

Population Description	Lower Limit	Upper Limit	Population Mean	Standard Deviation	n
Total	0.7	2.8	1.41	0.47	173
Male	0.7	2.8	1.46	0.46	70
Female	0.7	2.5	1.38	0.47	103
Black	0.7	2.8	1.37	0.48	57
White	0.7	2.5	1.44	0.46	116
Less than 18	0.7	2.5	1.50	0.55	15
18 to 30 yr	0.8	2.4	1.49	0.45	43
31 to 40 yr	0.7	2.5	1.40	0.47	59
41 to 50 yr	0.7	2.8	1.41	0.47	39
51 to 60 yr	0.7	1.9	1.11	0.40	14
over 61 yrs	1.2	2.0	1.57	0.40	3

Table 24 shows the normal range for Reticulocytes in Absolute numbers x 10^9 cells/L.

Table 24 Subclassification of Data Within the Range Absolute Numbers (x 10^9 cells/L)

Population Description	Population Minimum	Population Maximum	Population Mean	SD	n
Total	28.4	121.2	65.83	21.87	173
Male	32.3	121.2	71.24	21.66	71
Female	28.4	119.8	62.06	21.32	102
Black	28.4	121.2	62.47	22.15	57
White	31.2	119.8	67.48	21.64	116
Less than 18	34.7	112.3	70.13	22.99	15
18 to 30 yr	36.5	119.8	71.48	21.63	43
31 to 40 yr	31.2	119.4	64.86	22.27	59
41 to 50 yr	32.3	121.2	64.79	20.74	39
51 to 60 yr	28.4	82.8	49.94	17.52	14
over 61 yrs	51.1	90.6	70.04	19.79	3

Retic Specimen Stability

Table 25 shows specimen stability for Reticulocyte percent; Table 26 shows it for Reticulocyte number.

Mean Difference = (24 hour result - 0 hour result)
Based on 83 Clinical Specimens.

Table 25 Specimen Stability Reticulocyte Percent

0 Hour Mean	24 Hour Mean	Mean Difference	SD of Difference
2.46	1.93	-0.53	1.76

Table 26 Specimen Stability Reticulocyte Absolute Numbers (x 10^9 cells/L)

0 Hour Mean	24 Hour Mean	Mean Difference	SD of Difference
81.67	72.20	-9.47	30.90

PN 4237182A (December 1993)

Mode-to-Mode Performance of STKS CBC/Differential

Table 27 illustrates the Mode-to-mode comparison accuracy analysis by compared specimens of the CBC parameters, based on 50 clinical specimens of whole blood collected in K_3EDTA.

Table 27 Mode-to-Mode Comparison, CBC

Parameter	Units	Mean Difference	SD
WBC	x 10^9 cells/L	0.30	0.26
RBC	x 10^{12} cells/L	0.04	0.04
Hgb	g/dL	0.03	0.08
Hct	Ratio	0.55	0.37
MCV	fL	0.43	0.61
MCH	pg	-0.03	0.27
MCHC	g/dL	-0.48	0.48
RDW	%	0.03	0.27
Plt	x 10^9 cells/L	14.12	13.19
MPV	fL	0.01	0.17

Table 28 illustrates the Mode-to-mode comparison accuracy analysis by compared specimens of the Differential parameters, based on 44 nonflagged clinical specimens of whole blood collected in K_3EDTA.

Table 28 Mode-to-Mode Comparison, Diff

Parameter	Units	Mean Difference	SD
Lymphocyte	%	-0.23	0.81
Monocyte	%	-0.23	0.78
Neutrophil	%	0.08	1.36
Eosinophil	%	-0.06	0.31
Basophil	%	0.45	1.00

Interfering Substances

CBC

WBC — Certain unusual RBC abnormalities resist lysing, NRBC, fragmented WBC, any unlysed particle greater than 35 fL, very large platelets.

RBC — Very high WBC count, high concentration of very large platelets, auto-agglutination.

Hgb — Very high WBC count, severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing.

MCV — Very high WBC count, high concentration of very large platelets, auto-agglutination.

RDW — Very high WBC count, high concentration of very large platelets, auto-agglutination.

Plt — Very small erythrocytes or leukocytes, or cell fragments may cause no-fit conditions in some cases. The STKS provides accurate Plt counts in the presence of most hemolytic disorders. Chemotherapy may affect certain samples.

Hct, MCH, MCHC

Known interferences related to the parameter used for computation.

Differential

Interfering substances for the diff parameters: High triglycerides affect lysing.

Reticulocytes

Erythrocyte inclusions stained by New Methylene Blue, if sufficiently numerous within a sample, and some hemoglobinopathies (SS, SC) might affect the accuracy of the reticulocyte enumeration.[35]

5.1 SAFETY PRECAUTIONS

WARNING

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

The Triple Transducer Module contains a laser. The laser is a unique light source that exhibits characteristics different from conventional light sources. The safe use of the laser depends upon familiarity with the instrument and the properties of coherent, intense beams of light. The beam can cause eye damage and instrument damage. There is enough power from the laser to ignite substances placed in the beam path, even at some distance. The beam might also cause damage if contacted indirectly from reflective surfaces (specular reflection). The laser on the STKS is covered by a protective housing that is held in place by tamper-proof screws.

WARNING

Do not attempt to remove the laser or to open it. If removal is required, it must be done only by a Coulter Representative.

All service and maintenance of the laser must be done at the Coulter factory by trained personnel. If removal is required, it must be done by a Coulter Representative.

5.2 RADIATION HAZARDS

In the design and manufacture of the STKS, Coulter Corporation has complied with the requirements governing the use and application of a laser as stipulated in regulatory documents issued by the U.S. Department of Health and Human Services, and the Center for Devices and Radiological Health (CDRH). In compliance with these regulatory documents, every measure has been taken to ensure the health and safety of users and laboratory personnel from the possible dangers of laser use.

WARNING

This instrument contains components dangerous to the operator. If any attempt has been made to defeat a safety feature, or if this instrument fails to perform as listed in this manual, disconnect power and call your Coulter Service Representative.

CDRH-approved labels are placed near or on those covers that, when removed, might expose laser radiation. Figure 10 shows the laser cover open and the protective housing off. This illustration is intended only to show you what the system looks like, in compliance with CDRH. See Figure 10 for the label and its location on the laser head. See Figure 11 for the label location on the beam cover between the laser head and the sampling compartment. Figure 10 and Figure 12 show certification labels.

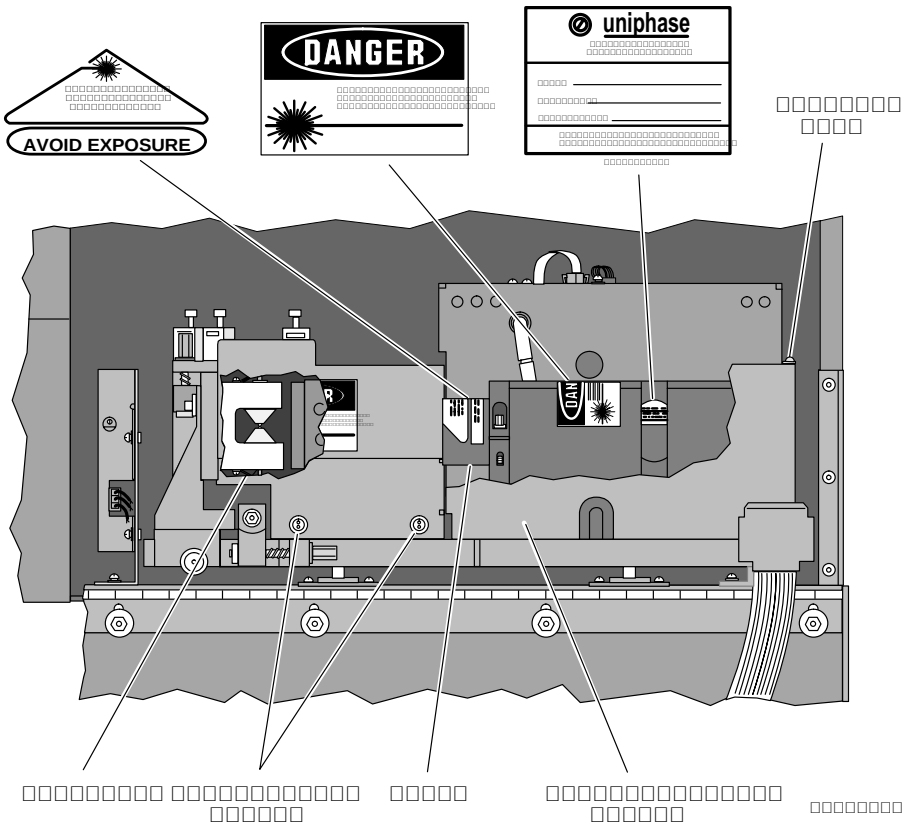


Figure 10 Laser Warning Label, Protective Housing Removed

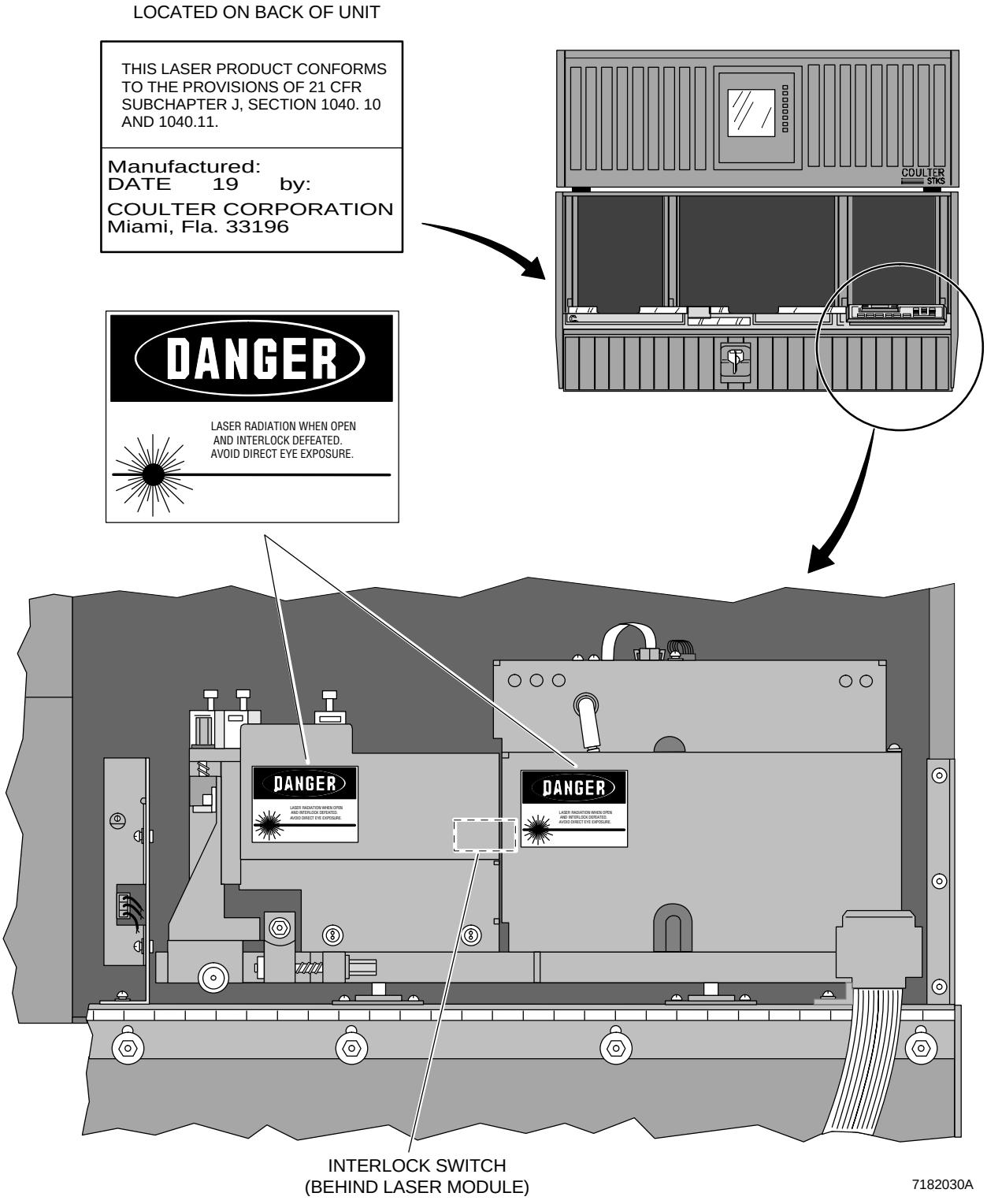
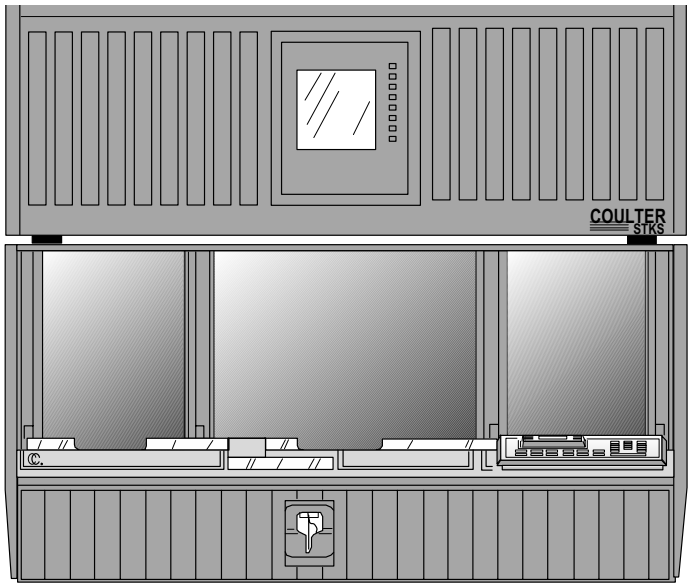


Figure 11 Laser Warning Label Locations, Protective Housing On



THIS LASER PRODUCT CONFORMS TO THE PROVISIONS OF 21 CFR SUBCHAPTER J, SECTION 1040. 10 AND 1040.11.

Manufactured:
DATE 19 by:
COULTER CORPORATION
Miami, Fla. 33196

LOCATED ON BACK OF UNIT

7182031A

Figure 12 Analyzer and Diluter

APPENDIX A
LOG SHEETS

This appendix includes the following log sheets. You can photocopy additional copies as needed. If your laboratory uses other methods of record keeping, disregard them.

COULTER® STKS

PREVENTIVE MAINTENANCE AND OPERATIONAL CHECKS

DAILY												MONTHLY	AS NEEDED					
START UP	PRIMARY				SECONDARY				VOLTS		SHUT DOWN	CLEAN AIR FILTERS	CLEAN BLOOD SAMPLING VALVE	BLEACH APER-TURES	INDICATE PROCE-DURE		
	WBC	RBC	Hgb	Plt	WBC	RBC	Hgb	Plt	Hgb BLANK	Hgb SAMPLE						TECH	DATE
	0.20 MAX	0.01 MAX	0.15 MAX	3.00 MAX	0.20 MAX	0.01 MAX	0.15 MAX	3.00 MAX									

SERIAL NO. _____ LAB. _____

7182020A

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Miami, FL

COULTER® STKS

RAMP-PULSE TEST RESULTS

RAMP												
WBC	RBC	Hgb	Hct	MCV	MCH	MCHC	RDW	Plt	Pct	MPV	PDW	TECH/DATE

SERIAL NUMBER _____ LAB._____

7182021A

COULTER CORPORATION
Miami, FL

COULTER® STKS

PRECISION-PULSE TEST RESULTS

PRECISION													
WBC	RBC	Hgb	Hct	MCV	MCH	MCHC	RDW	Plt	Pct	MPV	PDW	TECH	DATE

SERIAL NUMBER_____ LAB. _____

7182022A

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APPENDIX A

COULTER® STKS **REFERENCE VALUES**

RAMP REFERENCE VALUES

	AVERAGE		
	VALUE	TOLERANCE	
		FROM	TO
WBC			
RBC			
Hgb			
Hct			
MCV			
MCH			
MCHC			
RDW			
Plt			
Pct			
MPV			
PDW			

PRECISION REFERENCE VALUES

	AVERAGE		
	VALUE	TOLERANCE	
		FROM	TO
WBC			
RBC			
Hgb			
Hct			
MCV			
MCH			
MCHC			
RDW			
Plt			
Pct			
MPV			
PDW			

Hgb BLANK	TOLERANCE	
	FROM	TO
	7.5	9.5

Hgb SAMPLE	TOLERANCE	
	FROM	TO
	7.5	9.5

RECORDED BY_____
DATE_____
SERIAL NUMBER_____
LAB_____

SERIAL NUMBER_____ LAB_____

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Miami, FL

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APPENDIX A

COULTER © STKS **CALIBRATION FACTORS**

PARAMETER/APERTURE	CAL FACTOR
WBC AVG	
WBC AP2	
WBC AP3	
RBC AVG	
RBC AP2	
RBC AP3	
Hgb AVG	
MCV AVG	
Plt AVG	
Plt AP2	
Plt AP3	
MPV AVG	

Date _____

Reagent Lot Numbers:

Diluent _____

Cleaning Agent _____

CBC Lytic Reagent _____

SCATTER PAK _____

S-CAL® Calibrator Lot

Number _____

Tech Initials _____

SERIAL NO. _____ LAB. _____

7182024A

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APPENDIX A

COULTER® STKS

REAGENT LOG

DILUENT				CBC LYTIC REAGENT				CLEANING AGENT			SCATTER PAK				RETIC PREP			
DATE OPENED	LOT NUMBER	EXPIR. DATE	TECH (INT.)	DATE OPENED	LOT NUMBER	EXPIR. DATE	TECH (INT.)	DATE OPENED	LOT NUMBER	EXPIR. DATE	DATE OPENED	LOT NUMBER	EXPIR. DATE	TECH (INT.)	DATE OPENED	RGT A LOT#	RGT B LOT#	EXPIR. DATE

SERIAL NO._____ LAB._____

7182025A

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COULTER® STKS

ACTION LOG

DATE	CONDITION NOTED	TECH	DATE	ACTION TAKEN	TECH

SERIAL NO.———— LAB.————————

7182026A

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COULTER® STKS

DAILY QC WORKSHEET FOR THE STKS

MONTH _____ DAY _____ YEAR _____

SPECIMEN 1

CYCLE	NE%	LY%	MO%	EO%	BA%
1					
2					
TOTAL (Σ)					
Σ ÷ 2 = STKS 1					
TECH	**NE%**	**LY%**	**MO%**	**EO%**	**BA%**
1					
2					
TOTAL (Σ)					
Σ ÷ 2 = REF 1					

SPECIMEN 2

CYCLE	NE%	LY%	MO%	EO%	BA%
1					
2					
TOTAL (Σ)					
Σ ÷ 2 = STKS 2					
TECH	**NE%**	**LY%**	**MO%**	**EO%**	**BA%**
1					
2					
TOTAL (Σ)					
Σ ÷ 2 = REF 2					
GRAPH POINT					

SERIAL NO. _____

$$\text{GRAPH POINT} = \frac{(\text{STKS 1} - \text{REF 1}) + (\text{STKS 2} - \text{REF 2})}{2}$$

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7182027A

APPENDIX A

COULTER® STKS

GRAPH POINT SUMMARY

MONTH _____ YEAR _____

DAY	NE% 2 SD =		LY% 2 SD =		MO% 2 SD =		EO% 2 SD =		BA% 2 SD =	
	GRAPH POINT	STATUS	GRAPH POINT	STATUS	GRAPH POINT	STATUS	GRAPH POINT	STATUS	GRAPH POINT	STATUS
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
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22										
23										
24										
25										
26										
27										
28										
29										
30										
31										
Σ =										
$\bar{X}$ =										

2 SD NE%	=
2 SD LY%	=
2 SD MO%	=
2 SD EO%	=
2 SD BA%	=

$$SD = \sqrt{\frac{\Sigma (\text{EACH GRAPH POINT} - \text{THE MEAN FOR THAT COLUMN})^2}{\text{THE NUMBER OF GRAPH POINTS} - 1}}$$

STATUS

W = WITHIN 2 SD'S
H = MORE THAN 2 SD'S ABOVE THE MEAN
L = MORE THAN 2 SD'S BELOW THE MEAN

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7182028A

SERIAL NO. _____

APPENDIX A

COULTER® STKS

MONTHLY QC GRAPHS

MONTH _____

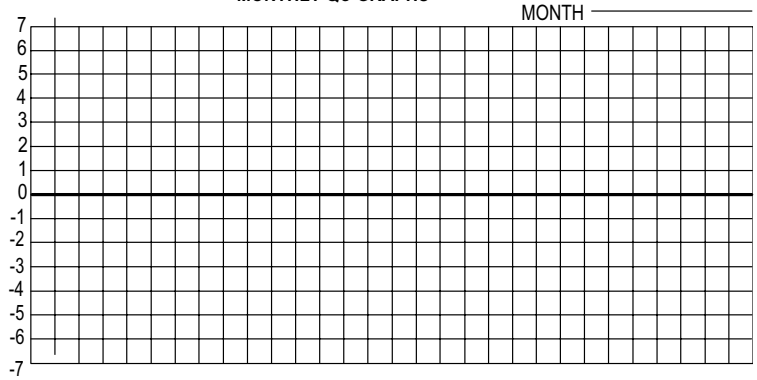
NE

2SD=+

1SD=+

1SD=-

2SD=-



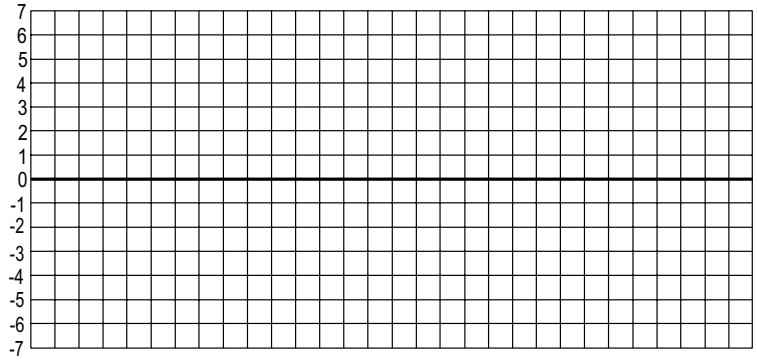
LY

2SD=+

1SD=+

1SD=-

2SD=-



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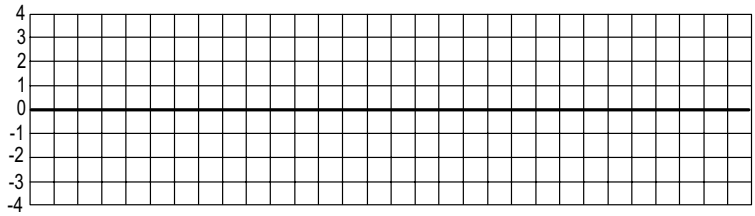
1SD=+

1SD=-

2SD=-



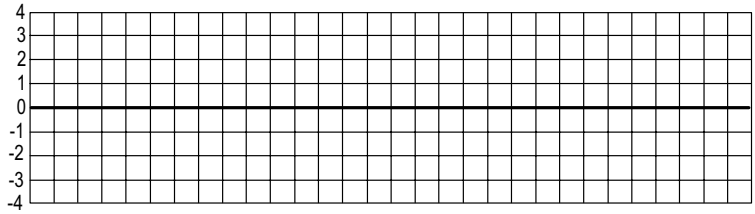
EO

2SD=+

1SD=+

1SD=-

2SD=-



BA

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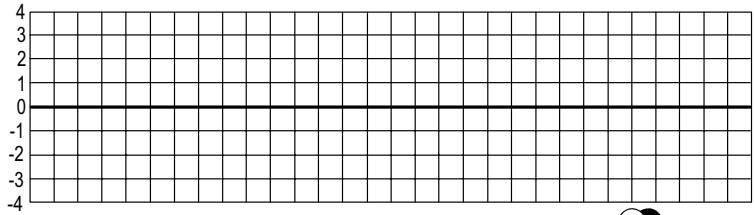
1SD=+

1SD=-

2SD=-



SERIAL NO. _____

COULTER

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Miami, FL

7182029A

APPENDIX A

APPENDIX B
TRANSMISSION TO A HOST COMPUTER

B.1 DESCRIPTION

This Host Transmission Specification (STKS Revision 2A) adds the following features to the basic STKS CBC/Diff parameter transmission:

- Reticulocyte parameters (including Date, Time)
- QC Data
- Worklist IDs with tests ordered as Profiles
- Worklist Status Messages
- Collated Reports

Use this specification if you are planning to send QC data to the Host, collate CBC/Diff + Retic results in the DMS and/or planning to transmit results from both STKS and MAXM reticulocyte systems.

Another option is Part.Asp/No Read. If you set the option from No (default) to Yes, and if AutoTransmit is turned on, a *Partial Aspiration* or *No Read* condition prompts the system to transmit the following information to the host computer.

- all sample information,
- identifiers,
- *Partial Aspiration* or *No Read* message, and
- dots (.....) for parameter results.

An alternative transmission specification is also available upon request from Coulter Customer Operations (STKS Revision 1G.1 + Retics) which adds **only** the retic parameter (including Date, Time and IDs) to the basic CBC/Diff transmission. QC data, collated profiles and additional items listed above are **NOT** included in this specification.

IMPORTANT

The COULTER STKS utilizes fail-safe sample management. The unique fail-safe features prevent data transmission to the host computer when specific status messages appear on the DMS. When the sample status is *NO MATCH*, *NO READ*, or *PARTIAL ASPIRATION*, samples will not be AUTOMATICALLY transmitted to the host computer in the sequence run. Nor will they be automatically printed in the sequence run. Sequence-dependent computer systems can compromise fail-safe sample reporting.

This information is intended for software engineers who need to maintain or modify the operation of the STKS DMS Host communication.

When the DMS receives data from the STKS Analyzer, it can automatically transfer that data to a host computer. This transfer takes place if:

- the Transmit to Host option is turned on, and
- there is positive sample identification. The positive identification can be either CASS/POS or ID#1, or both.

The transmission specification consists of data link (low level) and presentation (high level) protocols. Data link protocol provides the means of transmitting data without any regard to actual information. Presentation protocol describes the actual information and its format.

The high level protocol of the DMS 2A is capable of transmitting multiple results of multiple tests, and of control parameters.

IMPORTANT
To satisfy requirements, the host receiver must parse for all of the data. DO NOT ASSUME FIXED OFFSETS AND/OR FIXED FIELD LENGTHS.

STKS Host Communication Options

Transmission	2A	MAXM	1G.1
Retic %, Retic #	Yes	Yes	No
QC Data	Yes	No	No
Profile #s and Test IDs	Yes	No	No
Collated CBC/Diff Retic	Yes	Yes	No

B.2 HARDWARE INTERFACE

The system is equipped with an auxiliary connector (P3) on the back side of the DMS that lets the system interface with a host computer via a

Standard EIA-type 25-pin connector, and uses EIA Standard RS-232-C signals. This is a Data Terminal Equipment (DTE) configuration.

Connector Pinouts

The DMS/Host communications uses only the following signals:

P3 Pin No.	Signal Name	Flow Direction
2	Transmit Data	From DMS
3	Received Data	To DMS
4	Ready To Send (RTS)	From DMS
5	Clear To Send (CTS)	To DMS
6	Data Set Ready (DSR)	To DMS
7	Signal Ground	Reference
8	Carrier Detect	Reference
20	Data Terminal Ready (DTR)	From DMS
22	Ring Indicator	Reference

The DMS is the DTE, by RS232 standards, which explains the RTS/DTR pinouts. Whether the HOST is a DTE or DCE will determine its use of CTS/DSR or RTS/DTR. A DTE HOST requires the use of a NULL MODEM cable.

Note: Pin number 5 CTS must be active for DMS to send any transmissions. If the host computer does not support the above hardware handshake lines it will be necessary to connect pin 4 to pin 5 and to connect pin 20 to pin 6.

Handshake

During a transmission, when in full handshake mode, the host logically raises CTS to allow the DMS to send data, and logically lowers CTS to prevent the DMS from sending data.

Note: If CTS is lowered to hold off the DMS host transmission, it must be raised again within the DMS timeout period. If CTS is not raised within the timeout period, the DMS transmission to the host times out and aborts.

```
DMS (sender)          HOST (receiver)

                      <-- CTS on (send me data)
send data   ----->
send data   ----->
send data   ----->
                      <-- CTS off (stop sending data)
 wait
  .                       process received data
  .                           .
  .                           .
  .                           .
  .
                      <-- CTS on (send more data)
send data   ----->
send data   ----->

                  - etc.-
```

B.3 COMMUNICATION PARAMETERS

The DMS allows a number of communications parameters to be configured by the user. These parameters include communications modes, as well as parameters enabling the transmission of graphic data.

Modes

Time-Out

The time-out value determines the amount of time the DMS will wait for a response from the host before retrying to send data to the host. If the spooler is enabled the DMS will continue to transmit at the time-out intervals until the host successfully receives the data. If the spooler is not enabled the message will be aborted when the next available message is ready to be transmitted.

The time-out value can be 1 to 30 seconds. The default value is 9 seconds.

Baud Rate

The following baud rates are supported: 110, 300, 1200, 2400, 4800, 9600, 19200.

For nongraphic transmissions, the recommended baud rate is ≥2400. For graphic transmissions, the recommended baud rate is ≥9600.

Data Bits

The DMS/Host communications only supports the 8 bit Data Bit mode.

Note: For Host systems that only support 7 bit data, the DMS should be configured for No Parity and the Host should be configured for Marked Parity.

Parity

Odd, Even, and No parity modes are supported. Odd parity is the default value.

Stop Bits

Choose 1 or 2. Default is 2.

Block Size

The DMS/Host Communications support block sizes of 128 and 256 bytes. Default is 256 bytes.

Spooler Enable

When enabled, each host transmission is spooled and kept on the spool until the Host acknowledges the transmission was successfully copied.To transmit graphics to the Host, the spooler must be enabled.

Compatibility

The STKS DMS 2A supports the Host High Level Communication Protocol similar to that supported in STKS DMS 1G1 and MAXM 1G1 plus Retics, **if, and only if** the compatibility switch is set to one of these modes.

Graphics Data Enable

From the communication definition setup screen the operator can enable or disable the following graphic items:

- Diff Scatterplots
  DF1
  DF2, DF3
  VCS histograms

- Retic Scatterplots
  DF5
  DF6
  VCS histograms

- RBC histogram

- Plt histogram

B.4 DMS TO HOST COMMUNICATIONS

Datalink Protocol

All transmitted bytes are ASCII characters. All numeric values are hexadecimal. Hence, for example, the number FF(hex) is represented by the two ASCII bytes "FF" (46H, 46H). The first two bytes of the transmission are the number of blocks to be sent, followed by transmission of data blocks (see format below).

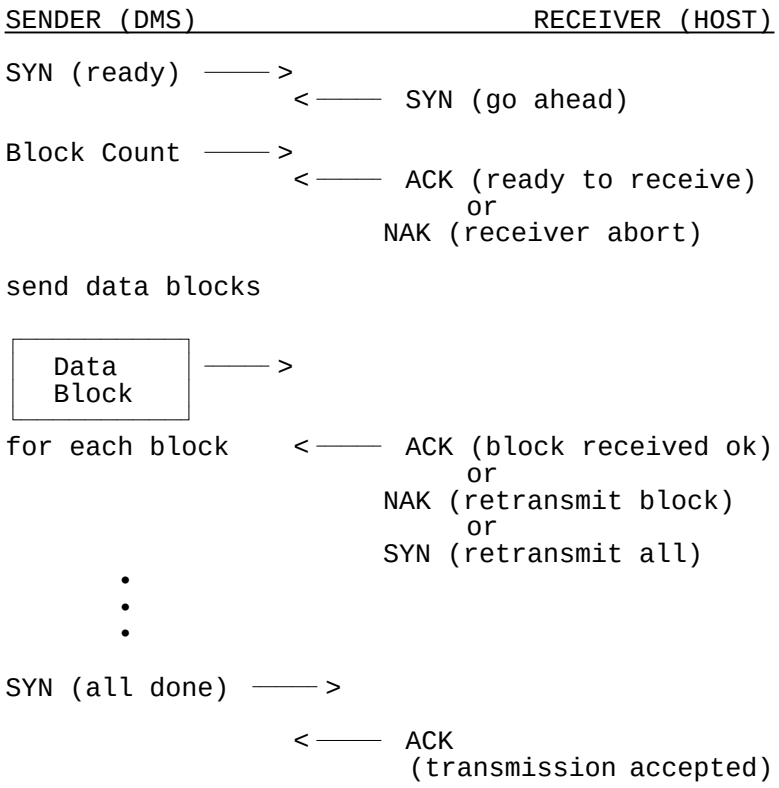
The final block is padded with ASCII spaces (20H) to fill a whole block. No NULL (00H) characters are transmitted.

Please note that the blocks will be padded by ASCII SP (20H) if data does not fill the whole block.

The DMS supports a full handshake and a no handshake protocol.

Full Handshake

The DMS sends the following control characters plus data and expects the indicated host response:



Up to 256 blocks of data can be sent. The actual number of blocks sent is specified by the two byte ASCII Block Count.

If the host NAKs a data block, the block will be retransmitted. It is up to the host to determine how many times it will retry receiving a NAKed block before aborting.

A SYN sent by the Host at any time other than the initial "go ahead" forces the DMS to retransmit all data starting with the first block. This does not include the initial SYN and block count. It is up to the Host to determine under what conditions to transmit a SYN.

If the spooler enabled option is selected, the DMS will continue to send the same message until the Host accepts (ACKs each block) the message.

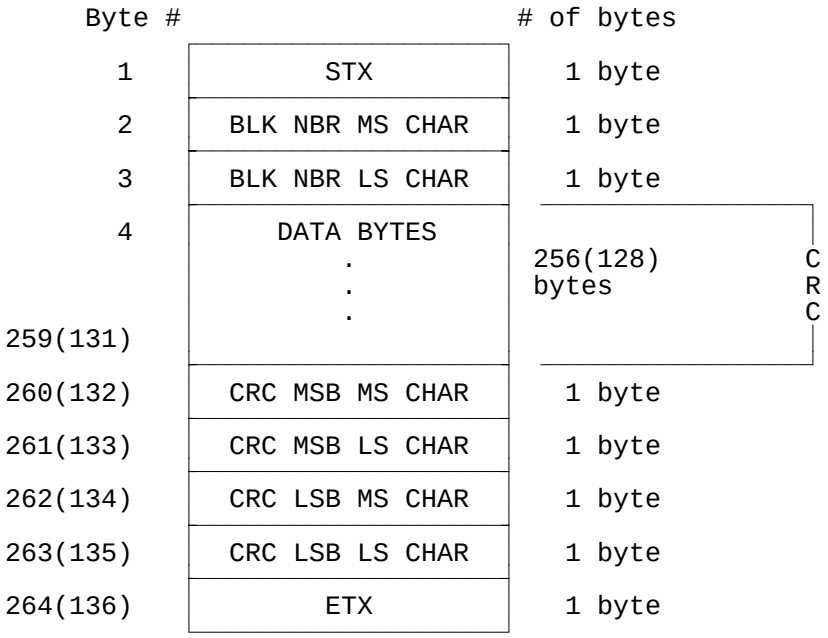
Note: To abort a transmission, when the spooler is enabled, the host must ACK each block of the transmission and discard it locally.

If the spooler enabled option is not selected, the DMS makes only one attempt at transmitting the message.

No Handshake

The No Handshake protocol ignores all hardware and software host responses. In addition, in the No Handshake mode the DMS does not send a SYN prior to transmitting the data.

Data Block Structure



Every data block will have either 128 or 256 bytes (whichever is chosen). If there is not sufficient data to fill a block, it will be padded with space characters.

The algorithm used to calculate the CRC for each block is a modified CCITT CRC16. CRC is only calculated on the data bytes.

Heading B.7 details the algorithm and includes application notes for implementing the algorithm in both C and assembly language.

Message Structure

The Presentation deals with the high level format of the message.

The data bytes of the transmission blocks, when collected together, exhibit the following high level format.

Preamble	Transmission Identification	Test a Identification	Group x_a		Group y_a	
		Test z Identification	Group x_z		Group y_z	Postamble

Preamble:

C R	L F	C R	L F	C R	L F	C R	L F	C R	L F	C R	L F	–	–	–	–	–	–	–	–	–	–	–	–	–	–	C R	L F

The preamble marks the beginning of a message.

Transmission Identification:

S	TEST TYPE COUNT	C R	L F	TEST TYPE 1	C R	L F		...		TEST TYPE N	C R	L F

The ASCII character "S" marks the beginning of the transmission.

TEST TYPE COUNT defines the number of tests that will be transmitted in this particular transmission. Not all Test Types are sent in all transmissions.

Each TEST TYPE defined in the following sections is identified by the order in which it appears after the preamble. The test types will never be transmitted out of order.

The test types are up to 32 characters long.

Available tests/controls are as follows:

1. "CBC" CBC test
2. "DIFF" DIFF test
3. "RETIC" RETICS test
4. "5CC" 5C Control
5. "4CC" 4C Control
6. "RETICC" Retic Control
7. "LATEXC" Latex Control

Test Identification :

T	TEST TYPE	C R	L F	GROUP COUNT	C R	L F

The ASCII character "T" marks the beginning of a test identification.

TEST TYPE: see transmission identification.

GROUP COUNT defines the number of groups of data in this particular test type.

Group:

G	GROUP NUMBER	C R	L F	FIELD COUNT	C R	L F	FIELD 1	C R	L F	...	FIELD N	C R	L F

The ASCII character "G" marks the beginning of the group.

GROUP NUMBER defines the group number. See Group definitions.

FIELD COUNT defines the number of fields in a particular group. See Field Count.

FIELD defines a field within a group. See Fields.

Note: When there are no data for a Group, the Group will not be sent.

Test Type Count:

The transmission identification section has a test type count that identifies the number of tests contained within the transmission. Valid test type count can be from 0 - 255. The test type count uses two characters to give the ASCII representation of the hexadecimal value.

MS CHAR	LS CHAR	Two Byte ASCII representation of Hex value between 00 and FF (0 to 255)

Group Count:

Each test identification has a Group Count that identifies the number of groups contained within the test. Valid group counts can be from 0 - 255. The group count uses two characters to give the ASCII representation of the hexadecimal value.

MS CHAR	LS CHAR	Two Byte ASCII representation of Hex value between 00 and FF (0 to 255)

Group Number:

Each group identifier has a Group Number that identifies the group number contained within the group identifier. Valid group numbers can be from 0 - 255. The group number uses two characters to give the ASCII representation of the hexadecimal value.

MS CHAR	LS CHAR	Two Byte ASCII representation of Hex value between 00 and FF (0 to 255)

Field Count:

Each Group has a Field Count that identifies the number of fields contained in the Group. Valid field counts can be from 0 - 255. The field count uses two characters to give the ASCII representation of the hexadecimal value.

MS CHAR	LS CHAR	Two Byte ASCII representation of Hex value between 00 and FF (0 to 255)

Fields:

Each Group is made up of variable length fields which may or may not be padded with SP (20H) or HT (09H) characters. A field may have a variable length Tag preceding the data separated with one or more SP (20H) or HT (09H) characters. The data portion of a field will only contain ASCII characters in the range of 20H to 7EH.

Heading B.6 tabulates the valid ASCII characters.

Fields are separated with a CR (0DH) and a LF (0AH) character.

All fields are a maximum of 32 characters unless otherwise noted.

The following abbreviations are used to describe the fields:

SEP - one or more SP (20H), or HT (09H) characters.

The syntax for the Data Format of a field is:

A - Alpha characters
(a..z and A..Z and space) or (61H..7AH and 41H..5AH and 20H)

N - Numeric characters
(0..9 and + - .) or (30H..39H and 2BH 2DH 2EH)

X - Printable characters
(20H..7EH)

H - Hexadecimal characters
(0..9 and A..F)

O - Other characters
(CR and LF) or (0DH and 0AH)

Note: A fields position within a Group must not be used to identify it. Fields within a Group may appear in any order or may be omitted. The CR/LF should be used to find fields and the Tag used to identify it.

Postamble:

C R	L F	C R	L F	–	–	–	–	–	–	–	–	–	–	–	–	–	–	C R	L F

The postamble marks the end of the current message.

There are 38 groups defined in the current implementation of the DMS. Future revisions of DMS may include additional groups. Any future additions will not disrupt the order of the groups as presently defined.

Group Definition

The abbreviations listed below describe the following table:

```
C       CBC
D       DIFF
R       RETICS
X       4C CONTROL
Y       5C CONTROL
Z       RETIC CONTROL
L       LATEX CONTROL
```

The groups and their order of transmission are as follows:

Test Type	Group Number	
CDR	1) General Information	Group
C	2) CBC Parameters	Group
D	3) DIFF Count Parameters	Group
D	4) DIFF Percent Parameters	Group
CDR	* 5) Comments	Group
CDR	* 6) Definitive Flags	Group
CDR	* 7) Suspect Flags	Group
CDR	* 8) Conditional Flags	Group
CDR	* 9) Other Flags	Group
CDR	* 10) Demographics	Group
D	11) DF1 Scatterplot	Group
D	12) DF2 Scatterplot	Group
D	13) DIFF Histogram	Group
C	14) RBC Histogram	Group
C	15) PLT Histogram	Group
R	16) RETICS Parameters	Group
R	17) DF5 LS Scatterplot	Group
R	18) DF6 OP Scatterplot	Group
R	19) RETICS Histogram	Group
L	31) DIFF Latex Parameters	Group
L	32) Retic Latex Parameters	Group
XYZL	34) Control Information	Group
XY	35) Control CBC Parameters	Group
Y	36) Control DIFF Count Parameters	Group
Y	37) Control DIFF Percent Parameters	Group
Z	38) Control RETICS Parameters	Group

*** Group will not repeat with every test.**

Details of Group fields are defined in following sections.

General Information Group Fields

Date Field:

Tag				Sep	Data Format							
D	A	T	E		N	N	/	N	N	/	N	N

Data Length - 8 bytes typical

Comments - Date output is month/day/year.

Time Field:

Tag				Sep	Data Format							
T	I	M	E		N	N	:	N	N	:	N	N

Data Length - 8 bytes typical

Comments - Time output is hours:minutes:seconds.

ID #1 Field:

Tag			Sep	Data Format															
I	D	1		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length - 16 bytes typical

Preassigned ID #1 Field:

Tag				Sep	Data Format															
P	I	D	1		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length - 16 bytes typical

Cassette/Position Field:

Tag							Sep	Data Format						
C	A	S	S	P	O	S		A	X	X	X	X	X	X

Data Length - 7 bytes typical

Comments - CASSPOS output is cassette number/cassette position.

Data Values:
'S' - Secondary
'P' - Primary

Preassigned Cassette/Position Field:

Tag								Sep	Data Format					
P	C	A	S	S	P	O	S		X	X	X	X	X	X

Data Length - 6 bytes typical

Comments - PCASSPOS output is cassette number/cassette position. The sample mode is unknown.

ID #1 Status Field:

Tag									Sep	Data Format
I	D	1	S	T	A	T	U	S		A

Data values:
'P' - positive id
'E' - edited id

Data Length - 1 byte typical

Cassette/Position Status Field:

Tag									Sep	Data Format
C	/	P	S	T	A	T	U	S		A

Data values:
'P' - positive id
'E' - edited id

Data Length - 1 byte typical

Sample Status:

Tag								Sep	Data Format							
S	A	S	T	A	T	U	S		A	A	A	A	A	A	A	A

Data values:
'PART ASP' - partial aspiration
'NO READ ' - barcode not read
'NO MATCH' - match not found in Worklist
'ID MISMATCH' - non-positive ID did not match

Data Length - 8 bytes typical

Note: There may be others such as Preliminary Report.

CBC Parameter Group Fields

Each field in the CBC Parameter Group has the following format:

Tag					Sep	Data Format								
A	A	A	..	A		X	X	X	X	X	X	X	X	X

5 char numeric data max.
1 char (space) separator min.
3 char flag data max.

Tags:

'WBC '
'RBC '
'HGB '
'HCT '
'MCV '
'MCH '

'MCHC'
'RDW '
'PLT '
'PCT '
'MPV '
'PDW '

Numeric Data:

If the numeric data of each format (e.g. xx.xx) does not contain a decimal number, then it contains one of the following:

'-----' = Total Voteout.
'+++++' = Count Exceeds Maximum.
'.....' = Incomplete Computation.

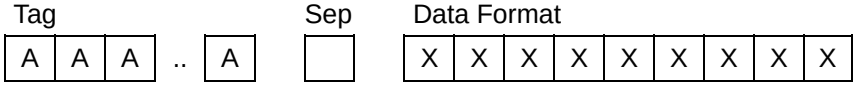
Flag Data:

The three flag data characters can be '*', 'R', 'H', 'L', 'E' or ' ' defined as:

'*R' - parameter affected by other parameter
'R' - review parameter
'H' - exceeds high laboratory set patient high action limit
'L' - exceeds low laboratory set patient low action limit
'E' - edited result
(Reference Operator's Guide)

Diff Count Parameter Group Fields

Each field in the DIFF Count Parameter Group has the following format:



5 char numeric data max.
1 char (space) separator min.
3 char flag data max.

Tags:
'LY# '
'MO# '
'NE# '
'EO# '
'BA# '

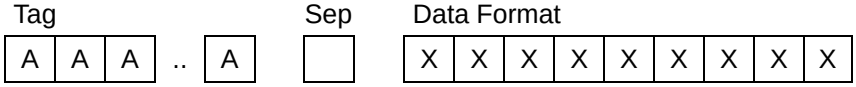
Numeric Data:

If the numeric data of each format (e.g. xx.xx) does not contain a decimal number, then it contains one of the following:

'.....' = Incomplete Computation.
'?????' = Invalid analyzed data.
':::::' = Flow cell clogged.

DIFF Percent Parameter Group Fields

Each field in the DIFF Count Parameter Group will have the following format:



5 char numeric data max.
1 char (space) separator min.
3 char flag data max.

Tags:
'LY% '
'MO% '
'NE% '
'EO% '
'BA% '

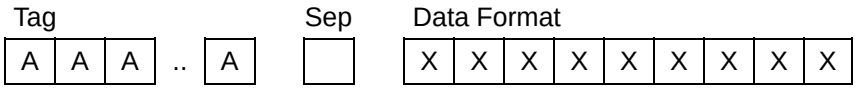
Numeric Data:

If the numeric data of each format (e.g. xx.xx) does not contain a decimal number, then it contains one of the following:

'.....' = Incomplete Computation.
'?????' = Invalid analyzed data.
':::::' = Flow cell clogged.

RETICS Parameter Group Fields

Each field in the RETICS Parameter Group will have the following format:



5 char numeric data max.
1 char (space) separator min.

3 char flag data max.

Tags:
'RET%'
'RET#'
'MRV'
'MI'
'OTHER' "MRV and MI parameters are not for Diagnostic Use"

Numeric Data:

If the numeric data of each format (e.g. xx.xx) does not contain a decimal number, then it contains one of the following:

'.....' = Incomplete Computation.
':::::' = Flow cell clogged.

Diagnostic Parameters:

MRV and MI parameters are only sent when a Retics II or Retics III option is installed.

Comment Group Fields

This group will be transmitted with the first test only.

Comment Field:

Tag							Sep	Data Format							
C	O	M	M	E	N	T		X	X	X	....	X	X	X	

Data Length - 64 bytes typical

Flag Groups

The four Flag Groups will be transmitted with the first test only.

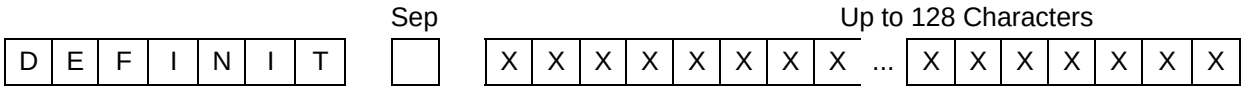
Suspect Flag String:

							Sep	Up to 128 Characters													
S	U	S	P	E	C	T		X	X	X	X	X	X	X	X	...	X	X	X	X	X	X	X

Possible flag values:

Blasts
Imm Grans/Bands (1 or 2)
Variant Lymphs
Review Slide
NRBCs
Dimorphic RBC Pop
Micro RBCs/
RBC Fragments
RBC Agglutination
Platelet Clumps
Giant Platelets

Definitive Flag String:

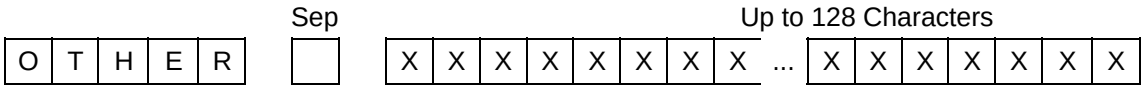


Possible flag values:

Leukopenia
Leukocytosis
Neutropenia %
Neutropenia #
Neutrophilia %
Neutrophilia #
Lymphopenia %
Lymphopenia #
Lymphocytosis %
Lymphocytosis #
Monocytosis %
Monocytosis #
Eosinophilia %
Eosinophilia #
Basophilia %
Basophilia #
Anemia
1+ Anisocytosis
2+ Anisocytosis
3+ Anisocytosis
1+ Microcytosis
2+ Microcytosis
3+ Microcytosis
1+ Macrocytosis
2+ Macrocytosis
3+ Macrocytosis

1+ Hypochromia
2+ Hypochromia
3+ Hypochromia
1+ Poikilocytosis
2+ Poikilocytosis
3+ Poikilocytosis
Erythrocytosis
Pancytopenia
Thrombocytopenia
Thrombocytosis
Small Platelets
Large Platelets

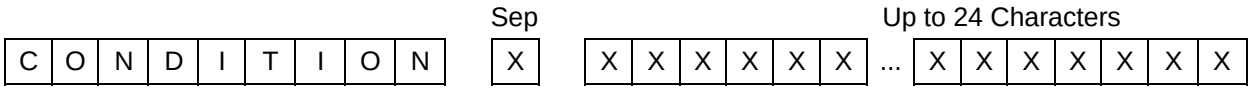
Other Population Flag String:



Possible flag values:

"Edited data"
"PRELIMINARY REPORT
"COLLATE FAILED

Conditional Flags:



Possible flag values:

Normal WBC Pop
Abnormal WBC Pop
Normal RBC Pop
Abnormal Rbc Pop
Normal PLT Pop
Abnormal PLT Pop
Verify Retic

Demographics Group Field

This group will be transmitted with the first test only.

Date of Birth Field:

Tag					Sep	Data Format									
B	I	R	T	H		N	N	/	N	N	/	N	N	N	N

Birth field is month/day/year.

Data Length - 10 bytes typical

User Field #1:

Tag			Sep	Data Format															
U	F	1		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length - 16 bytes typical

User Field #2:

Tag			Sep	Data Format															
U	F	2		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length - 16 bytes typical

User Field #3:

Tag			Sep	Data Format															
U	F	3		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length - 16 bytes typical

Sex Field:

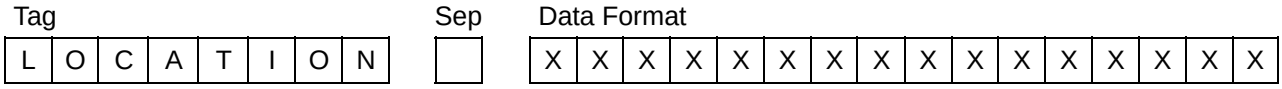
Tag			Sep	Data Format	Space
S	E	X		A	

Data Length - 1 byte typical

Data value:

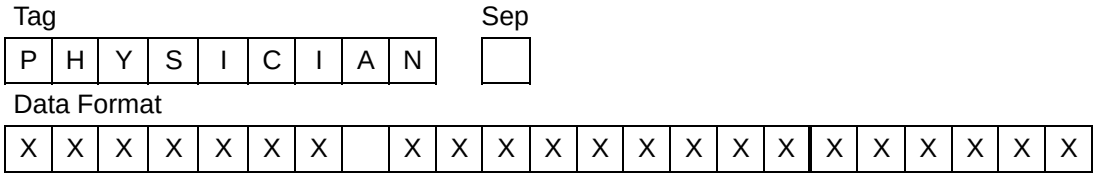
'M' - Male
'F' - Female
'U' - Unknown
'O' - Other

Location Field:



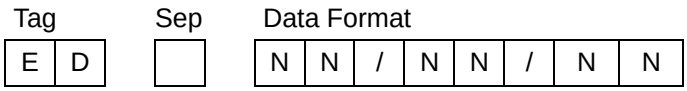
Data Length - 16 bytes typical

Physician Field:



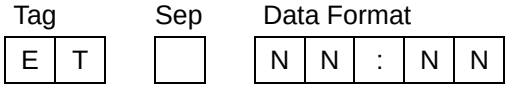
Data Length - 22 bytes typical

User Entry Date Field:



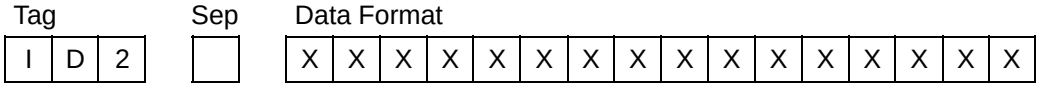
Data Length - 8 bytes typical

User Entry Time Field:



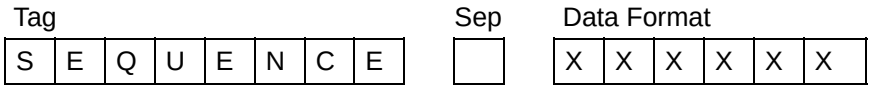
Data Length - 5 bytes typical

ID #2 Field:



Data Length - 16 bytes typical

Sequence Number:



Data Length - 6 bytes typical

Profile Field:

Tag		Sep	Data Format
P	F		N

Data Length - 1 byte typical

Note: Profile can be between "1" and "9". If 0 this field will not be transmitted.

DF1 Scatterplot Group Fields

Valley 1 Field:

Tag				Sep	Data Format		
V	A	L	1		N	N	N

Data Length - 3 bytes typical

Valley 2 Field:

Tag				Sep	Data Format		
V	A	L	2		N	N	N

Data Length - 3 bytes typical

Valley 3 Field:

Tag				Sep	Data Format		
V	A	L	3		N	N	N

Data Length - 3 bytes typical

Valley 4 Field:

Tag				Sep	Data Format		
V	A	L	4		N	N	N

Data Length - 3 bytes typical

Valley 5 Field:

Tag				Sep	Data Format		
V	A	L	5		N	N	N

Data Length - 3 bytes typical

DF 1 Scatterplot Field:

Tag			Sep	Data Format									
D	F	1		H	H	H	. . .	H	H	H	H	H	H

Data Length - 4096 bytes typical

The DF 1 scatterplot data is transmitted as a 4096 byte ASCII array.

DF 2 Scatterplot Group Field

DF 2 Scatterplot Field:

Tag			Sep	Data Format									
D	F	2		N	N	N	. . .	H	H	H	H	H	H

Data Length - 4096 bytes typical

The DF 2 scatterplot data is transmitted as a 4096 byte ASCII array.

DIFF Histogram Group Fields

V Histogram Field:

Tag	Sep	Data Format											
V		H	H	H		. . .		H	H	H	H	H	H

Data Length - 512 bytes typical

C Histogram Field:

Tag	Sep	Data Format											
C		H	H	H		. . .		H	H	H	H	H	H

Data Length - 512 bytes typical

S Histogram Field:

Tag	Sep	Data Format										
S		H	H	H		. . .		H	H	H	H	H	H

Data Length - 512 bytes typical

RBC Histogram Group Field

RBC Histogram Field:

Tag				Sep	Data Format										
R	B	C	H		H	H	H		. . .		H	H	H	H	H	H

Data Length - 512 bytes typical

PLT Histogram Group Fields

PLT Histogram Field:

Tag				Sep	Data Format										
P	L	T	H		H	H	H		. . .		H	H	H	H	H	H

Data Length - 256 bytes typical

PLT Fit Histogram Field:

Tag				Sep	Data Format										
P	L	T	F		H	H	H		. . .		H	H	H	H	H	H

Data Length - 512 bytes typical

DFS LS Scatterplot Group

LLS X1 Valley:

Tag				Sep	Data Format		
L	L	S	1		N	N	N

Data Length - 3 bytes typical

LLS X2 Valley:

Tag				Sep	Data Format		
L	L	S	2		N	N	N

Data Length - 3 bytes typical

DC Valley:

Tag		Sep	Data Format		
D	C		N	N	N

Data Length - 3 bytes typical

LLS Valley:

Tag				Sep	Data Format		
L	L	S	3		N	N	N

Data Length - 3 bytes typical

DF 5 LS Scatterplot Field:

Tag			Sep	Data Format									
D	F	5		H	H	H		. . .		H	H	H	H	H	H

Data Length - 4096 bytes typical

The LS Scatterplot Data is transmitted as a 4096 byte ASCII array.

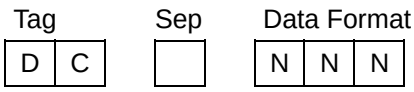
DF 6 OP Scatterplot Group

OP 3 Valley:

Tag			Sep	Data Format		
O	P	3		N	N	N

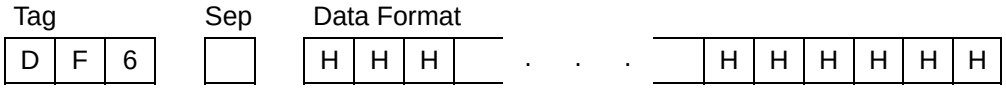
Data Length - 3 bytes typical

DC Valley:



Data Length - 3 bytes typical

DF 6 OP Scatterplot Field:

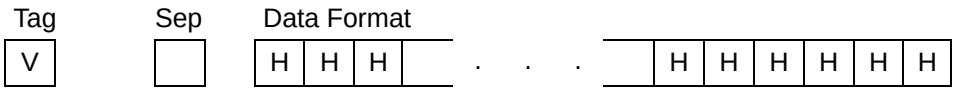


Data Length - 4096 bytes typical

The OP Scatterplot Data is transmitted as a 4096 byte ASCII array.

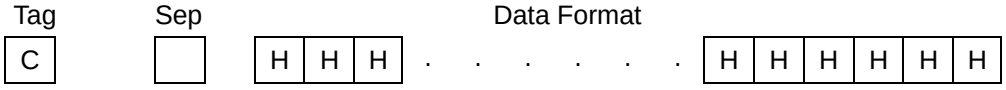
RETICS Histogram Group Fields

V Histogram Field:



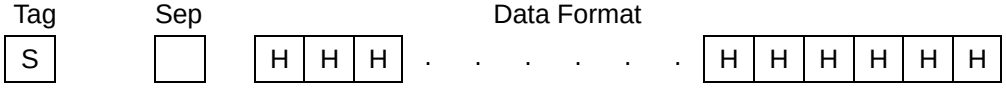
Data Length - 512 bytes typical

C Histogram Field:



Data Length - 512 bytes typical

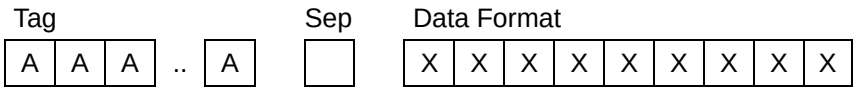
S Histogram Field:



Data Length - 512 bytes typical

DIFF Latex Parameter Group Fields

Each field in the DIFF Latex Parameter Group has the following format:



5 char numeric data max.
1 char (space) separator min.
3 char flag data max.

Tags:

'PRIMER'
'V_MN'
'C_MN'
'S_MN'
'V_CV'
'C_CV'
'S_CV'

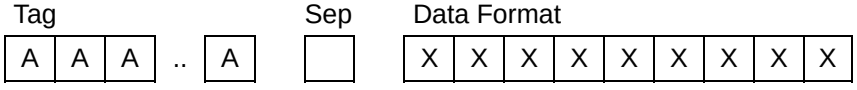
Numeric Data:

If the numeric data of each format (e.g. xx.xx) does not contain a decimal number, then it contains one of the following:

'.....' = Incomplete Computation
':::::' = Flow cell clogged

RETIC Latex Parameter Group Fields

Each field in the RETIC Latex Parameter Group has the following format:



5 char numeric data max.
1 char (space) separator min.
3 char flag data max.

Tags:

'PRIMER'
'V_MN'
'C_MN'
'S_MN'

'V_CV'
'C_CV'
'S_CV'

Numeric Data:

If the numeric data of each format (e.g. xx.xx) does not contain a decimal number, then it contains one of the following:

'.....' = Incomplete Computation
':::::' = Flow cell clogged

Control Information Group

Run# Field:

Tag				Sep	Data Format		
R	U	N	#		X	X	X

Data Length - 3 bytes typical

Lot# Field:

Tag				Sep	Data Format					
L	O	T	#		N	N	N	N	N	N

Data Length - 6 bytes typical

User Control Name Field:

Tag						Sep	Data Format									
U	C	N	A	M	E		X	X	X	X	X	.	.	.	X	X

Data Length - 12 bytes typical

Expiration Date Field:

Tag						Sep	Data Format							
E	X	D	A	T	E		N	N	/	N	N	/	N	N

Data Length - 8 bytes typical

Comments - Date output is month/day/year.

APPENDIX B

Date Field:

Tag	Sep	Data Format
D A T E		N N / N N / N N

Data Length - 8 bytes typical

Comments - Date output is month/day/year.

Time Field:

Tag	Sep	Data Format
T I M E		N N : N N : N N

Data Length - 8 bytes typical

Comments - Time output is hours:minutes:seconds.

Operator Field:

Tag	Sep	Data Format
O P E R A T O R		X X X

Data Length - 3 bytes typical

IQAP ID Field:

Tag	Sep	Data Format
I Q A P		X X X . . . X X X

Data Length - 12 bytes typical

Delete Flag (Run was deleted from review screen) Field:

Tag	Sep	Data Format
D F L A G		X

Data Length - 1 byte typical

Note: Y means run was deleted. Otherwise it is 'N' and will not be transmitted.

Shift Field:

Tag					Sep	Data Format
S	H	I	F	T		X

Data Length - 1 byte typical

Note: Possible are 0, 1, 2 or 3. See your Operator's Guide, Control Management by Shift, for more detail.

Cassette/Position Field:

Tag							Sep	Data Format						
C	A	S	S	P	O	S		A	X	X	X	X	X	X

Data Length - 7 bytes typical

Comments - CASSPOS output is cassette number/cassette position.

Reference RBC Count Field:

Tag				Sep	Data Format				
R	R	B	C		X	X	X	X	X

5 char numeric data max.

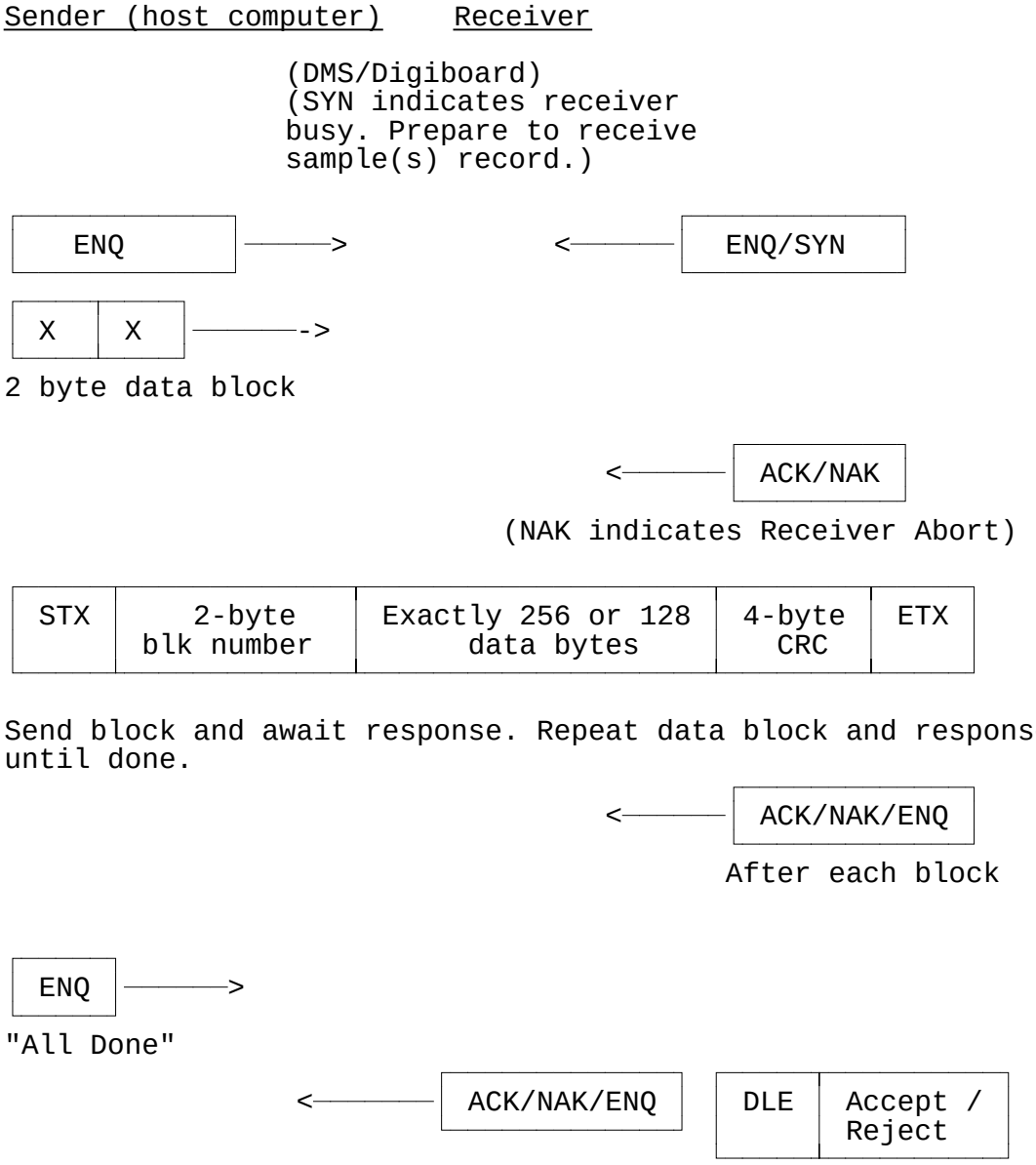
B.5 HOST TO DMS COMMUNICATIONS (HOST WORKLIST)

Datalink

Protocol

The DMS requires full handshaking to receive data. The protocol is similar to that used for DMS to Host transmissions with the SYN character replaced with the ENQ character.

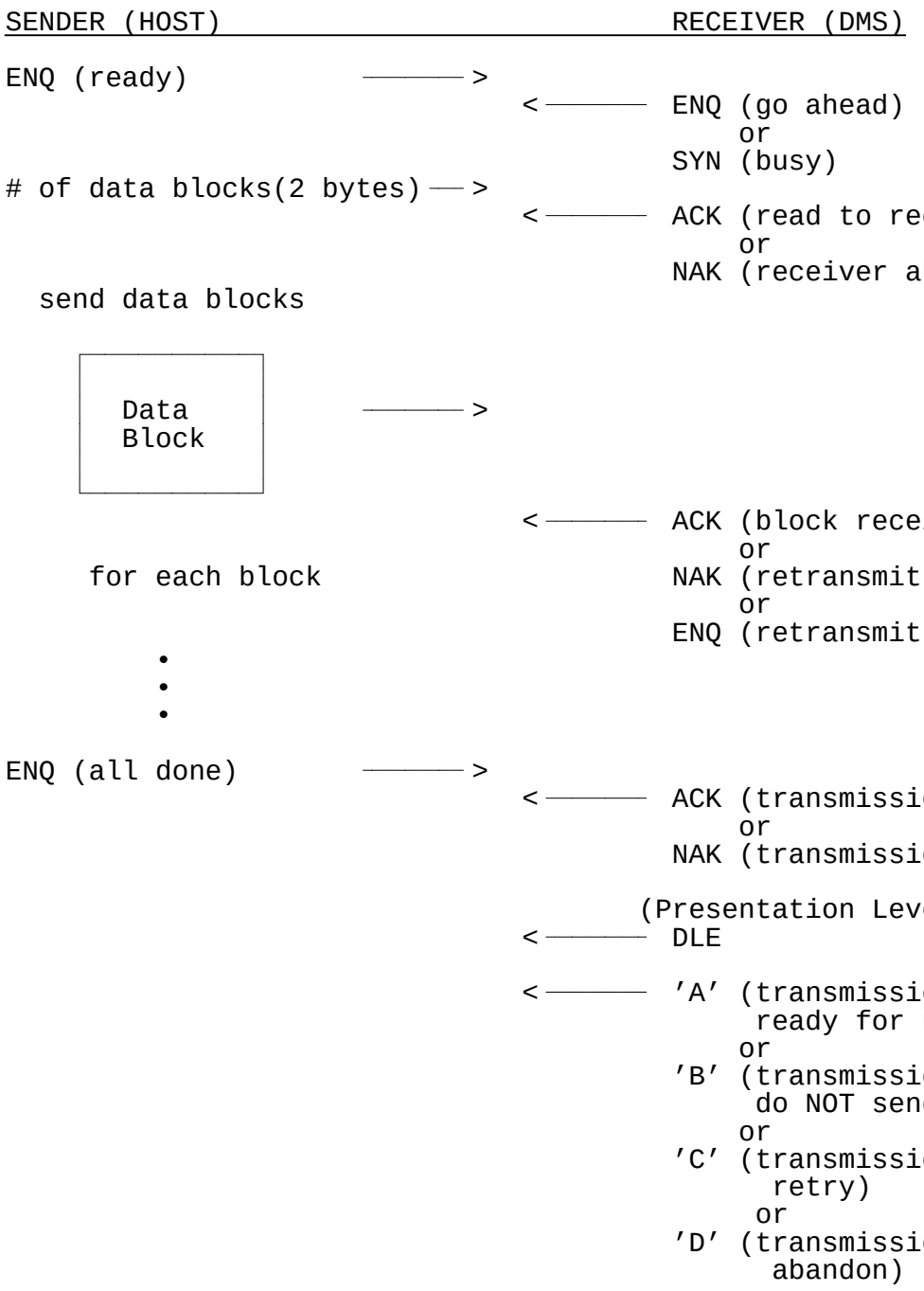
The data is transmitted as a sequence of up to 255 blocks of data of 256 (or 128) bytes each. Generally, these blocks contain 256 data bytes each, but due to the unique needs of differing hosts, the system is configurable to allow shorter blocks with 128 data bytes.



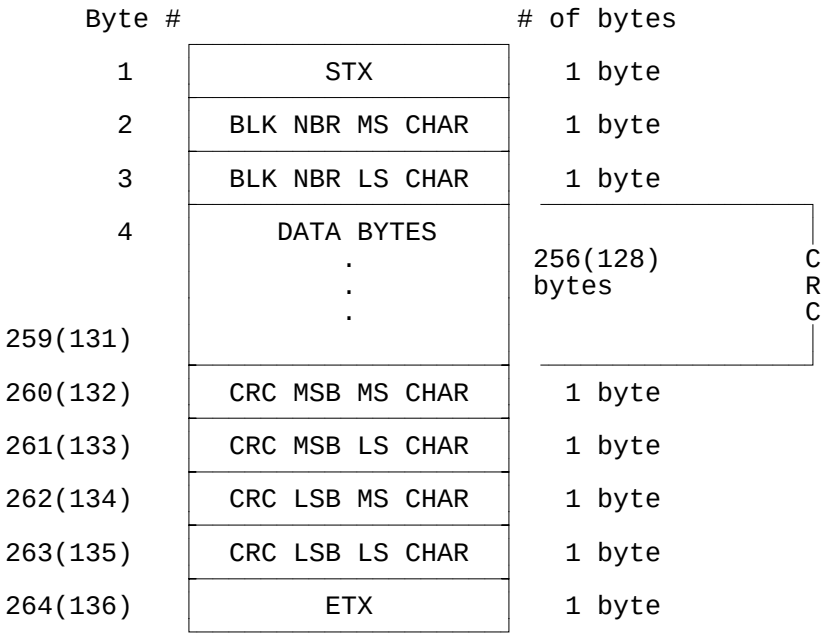
The last ACK/NAK sent by DMS/Digiboard indicates to the Host whether DMS/Digiboard accepts or rejects the entire transmission at the Data Link level. DMS/Digiboard then transmits a DLE character followed by a single ASCII character indicating whether the transmission is accepted or rejected at the presentation level. The ASCII character following the DLE may be one of the following:

Transmission Accepted, Ready for next: 'A'
Transmission Accepted, DO NOT send more: 'B'
Transmission Rejected, Please retry: 'C'
Transmission Rejected, Please abandon: 'D'

The following demonstrates the above protocol:



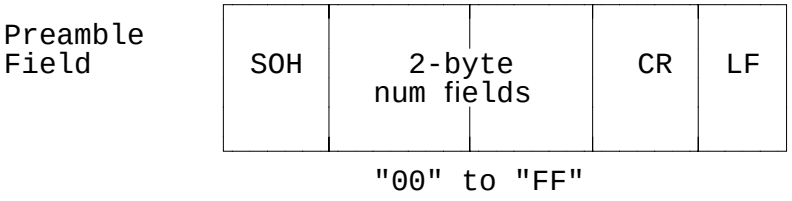
Data Block Structure

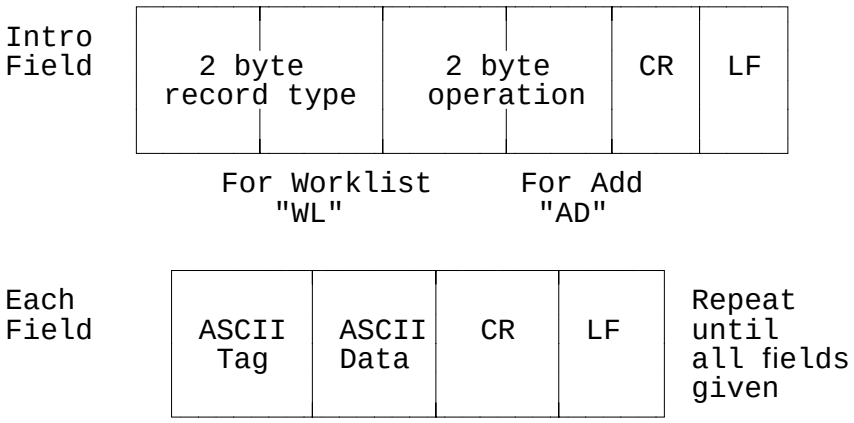


Presentation

Message Structure

The data which is blocked for transmission consists of a sequence of ASCII lines each terminated by a CR/LF pair. The block boundaries for the 256 (or 128) byte blocks would have no special significance with respect to this data. The data may be thought of as a large ASCII buffer which is being sent 256 (or 128) bytes at a time.





The 2-byte num fields indicate the number of fields that follow the preamble field, that is, the intro field plus all data fields.

The record type indicates the target data set, for example, "WL" for Worklist.

The operation code indicates the action to be performed; for example, "AD" for add this record.

The ASCII Tag is unique to each field within each record type and is always 2 bytes. The ASCII tag TS can repeat itself for as many tests as may be required.

Message Definition

The Host Worklist consists of the information about a number of blood samples, each of which has a number of fields. Internally the structure is the same as that used for the Active Worklist. Most of these fields may be transmitted from the Host to the DMS. Below is the list of possible fields, their field width and the appropriate ASCII Tag to be used for transmission.

FIELDS CANNOT HAVE LEADING OR TRAILING SPACES (MESSAGE WILL BE REJECTED)

Cassette Number & Position Field:

Tag		Data Format					
C	P	N	N	N	N	N	N

Data Length : 6 bytes maximum

STKS DMS 1G1 SPECIFIC. The 1G1 switch must be on otherwise this field will be ignored by the Host Worklist.

Identifier 1 Field:

Tag		Data Format														
I	1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length : 16 bytes maximum

STKS DMS 1G1 SPECIFIC. The 1G1 switch must be on otherwise this field will be ignored by the Host Worklist.

Identifier 2 Field:

Tag		Data Format														
I	2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length : 16 bytes maximum

Sequence Number Field:

Tag		Data Format					
S	N	N	N	N	N	N	N

Data Length : 6 bytes maximum

Birth Date Field:

Tag		Data Format									
B	D	N	N	/	N	N	/	N	N	N	N

Date - Month/Day/Year
example: 12/31/1999

Data Length : 10 bytes maximum

Sex Field:

Tag		Data Format
S	X	A

Data value:
- 'M' - Male
- 'F' - Female
- 'U' - Unknown
- 'O' - Other

Data Length : 1 byte maximum

Location Field:

Tag		Data Format														
L	N	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length : 16 bytes maximum

Physician Field:

Tag		Data Format																				
P	H	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length : 22 bytes maximum

User Field 1 Field:

Tag		Data Format														
U	1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length : 16 bytes maximum

User Field 2 Field:

Tag		Data Format														
U	2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length : 16 bytes maximum

User Field 3 Field:

Tag		Data Format															
U	3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Data Length : 16 bytes maximum

Comments 1 Field:

Tag		Data Format													
C	1	X	X	X	X	X		. . .		X	X	X	X	X	

Data Length : 32 bytes maximum

STKS DMS 1G1 SPECIFIC. The IG1 switch must be on otherwise this field will be ignored by the Host Worklist.

Comments 2 Field:

Tag		Data Format													
C	1	X	X	X	X	X		. . .		X	X	X	X	X	

Data Length : 32 bytes maximum

STKS DMS 1G1 SPECIFIC. The IG1 switch must be on otherwise this field will be ignored by the Host Worklist.

Comments Field:

Tag		Data Format													
C	M	X	X	X	X	X		. . .		X	X	X	X	X	

Data Length: 64 bytes maximum
This is a new field introduced in **STKS DMS 2A** replacing COMMENT 1 and COMMENT 2.

Note: COMMENT 1, COMMENT 2 - For the sake of **STKS DMS 1G1** backward compatibility, these two items (C1, C2) are concatenated and called comment (CM) **ONLY IF** the **STKS DMS 1G1** backward compatibility switch is set otherwise C1 and/or C2 are ignored.

Profile Field:

Tag		Data Format
P	F	N

Data Length - 1 byte maximum

Note: Profile can be between 1 and 9. If 1G1 compatibility switch is set, this value defaults to profile 1.

Entry Date Field:

Tag		Data Format							
E	D	N	N	/	N	N	/	N	N

Date - Month/Day/Year
example: 12/31/99

Data Length: 8 bytes maximum

Entry Time Field:

Tag		Data Format				
E	T	N	N	:	N	N

Time - Hour:Minute
example: 20:59

Data Length: 5 bytes maximum

Test Field:

Tag		Data Format											
T	S	X	X	X	X	X		. . .		X	X	X	X	X

Data Length : 64 bytes maximum

STKS DMS 2A SPECIFIC. The 1G1 switch must be off otherwise this field will be ignored by the Host Worklist.

This is a new field introduced in **STKS DMS 2A** to indicate a test type. The host may transmit as many as three test types such as CBC, DIFF, RETIC with the same tag (TS) in any order. This special field can also handle the ID1 and the CP for that particular test.

Example: TEST, ID1, Cass/pos the **commas are required** as separators. The following shows the possibilities of the data format for RETIC.

RETIC,	Invalid, ID1 or Cass/pos not given.
RETIC, CASS/POS	OK, ID1 not given.
RETIC, ID1,	OK, CASS/POS not given.
RETIC, ID1, CASS/POS	OK, Both are specified.

The sample will be rejected if any of the commas, or the test type, or a positive identifier is missing.

Sample Mode Field:

Tag		Data Format	Space
S	M	A	

Data Values:

'P' - Primary
'S' - Secondary

Data Length - 1 byte maximum

SAMPLE MODE - This field is ignored in STKS DMS 2A.

B.6 ASCII TABLES

7 Bit ASCII Codes

	0	0	0	0	1	1	1	1
	0	0	1	1	0	0	1	1
	0	1	0	1	0	1	0	1
7 6 5 4 3 2 1								
X X X 0 0 0 0	NUL	DLE	SP	0	@	P	‘	p
X X X 0 0 0 1	SOH	DC1	!	1	A	Q	a	q
X X X 0 0 1 0	STX	DC2	"	2	B	R	b	r
X X X 0 0 1 1	ETX	DC3	#	3	C	S	c	s
X X X 0 1 0 0	EOT	DC4	$	4	D	T	d	t
X X X 0 1 0 1	ENQ	NAK	%	5	E	U	e	u
X X X 0 1 1 0	ACK	SYN	&	6	F	V	f	v
X X X 0 1 1 1	BEL	ETB	’	7	G	W	g	w
X X X 1 0 0 0	BS	CAN	(	8	H	X	h	x
X X X 1 0 0 1	HT	EM	)	9	I	Y	i	y
X X X 1 0 1 0	LF	SUB	*	:	J	Z	j	z
X X X 1 0 1 1	VT	ESC	+	;	K	[	k	{
X X X 1 1 0 0	FF	FS	,	<	L	\	l	|
X X X 1 1 0 1	CR	GS	-	=	M	]	m	}
X X X 1 1 1 0	SO	RS	.	>	N	^	n	~
X X X 1 1 1 1	SI	US	/	?	O	_	o	DEL

Valid Host Communications ASCII Codes

	0	0	0	0	1	1	1	1
	0	0	1	1	0	0	1	1
	0	1	0	1	0	1	0	1
7 6 5 4 3 2 1								
X X X 0 0 0 0		**DLE**	SP	0	@	P	‘	p
X X X 0 0 0 1		DC1	!	1	A	Q	a	q
X X X 0 0 1 0	**STX**		"	2	B	R	b	r
X X X 0 0 1 1	**ETX**		#	3	C	S	c	s
X X X 0 1 0 0			$	4	D	T	d	t
X X X 0 1 0 1	**ENQ**	**NAK**	%	5	E	U	e	u
X X X 0 1 1 0	**ACK**	**SYN**	&	6	F	V	f	v
X X X 0 1 1 1			’	7	G	W	g	w
X X X 1 0 0 0			(	8	H	X	h	x
X X X 1 0 0 1	HT		)	9	I	Y	i	y
X X X 1 0 1 0	LF		*	:	J	Z	j	z
X X X 1 0 1 1			+	;	K	[	k	{
X X X 1 1 0 0			,	<	L	\	l	|
X X X 1 1 0 1	CR		-	=	M	]	m	}
X X X 1 1 1 0			.	>	N	^	n	~
X X X 1 1 1 1			/	?	O	_	o	

Highlighted only used for Datalink control.

B.7 CRC

CRC Algorithm

The CRC algorithm used is a modified CCITT CRC16 algorithm. The polynomial for this algorithm is:

X**16 + X**12 + X**5 + 1.

Note: D = current data byte that is input to the algorithm. CRCLSB,CRCMSB = data byte. Least significant and most significant CRC accumulator bytes.

x>>n means x is shifted n bits to right or is the same as x divided by 2^n.

x<<n means x is shifted n bits to left or is the same as x multiplied by 2^n.

at beginning,

CRCLSB = 0FFH (octal 377) (decimal 255)
CRCMSB = 0FFH (octal 377) (decimal 255)

then for each data byte in a block,

```
X = D XOR CRCMSB
X = X XOR ( X >> 4 )
CRCMSB = CRCLSB XOR ( X >> 3 ) XOR ( X << 4 )
CRCLSB = X XOR ( X << 5 )
```

and at end,

```
CRCLSB = CRCLSB XOR 0FFH
CRCMSB = CRCMSB XOR 0FFH
```

CRC Example Written in ASM86

The following is an example of CRC16 code written in assembler for 8086:

```
------------------------------------------------------------------------
GET_CRC_BYTES  PROC
               PUSH       CX
This is the Algorithm used (CCITT CRC16):

               X = D XOR CRCMSB
               X = X XOR ( X >> 4 )
               CRCMSB = CRCLSB XOR ( X >> 3 ) XOR ( X << 4 )
               CRCLSB = X XOR ( X << 5 )

Data arrives in AL.
Finished CRC is in BX ( BH = MSB, BL = LSB )
To use this algorithm:
   1. Initialize BX to 0FFFFH.
   2. At end:
       CRCLSB = CRCLSB XOR 0FFH.
       CRCMSB = CRCMSB XOR OFFH.

               XOR    AL,BH      ;X=D XOR CRCMSB (AL=X) <--- 1

               MOV    AH,AL      ;Save X for later in AH
               SHR    AL,4       ;Then AL=X >> 4

               XOR    AL,AH      ;X=X XOR ( X >> 4 )   <--- 2

               MOV    AH,AL      ;Save X
               MOV    CH,AL      ;Save X
               SHR    AL,3       ;Then AL= ( X >> 3 )
               XOR    AL,BL      ;AL=CRCLSB XOR ( X >> 3 )
               SHL    AH,4       ;AH=( X << 4 )

               XOR    AL,AH      ;CRCMSB=CRCLSB XOR
               MOV    BH,AL      ; ( X >> 3 ) XOR ( X << 4 )<--- 3

               MOV    AL,CH      ;Recover X in AL
               SHL    AL,5       ;AL=( X << 5 )
               XOR    AL,CH      ;AL=X XOR ( X << 5 )


               MOV    BL,AL      ;CRCLSB=X XOR ( X << 5 )<--- 4

               POP    CX
               RET
GET_CRC_BYTES  ENDP
------------------------------------------------------------------------
```

CRC Example Written in C

The following is an example of CRC16 code written in C.

```
void calc_crc ( unsigned char data_byte )
    {
        data_byte ^= crcmsb;
        data_byte ^= ( data_byte / 16 );
        crcmsb = crclsb ^ ( data_byte / 8 ) ^ ( data_byte * 16 );
        crclsb = data_byte ^ ( data_byte * 32 );
    }
```

APPENDIX C
BAR-CODE LABEL SPECIFICATIONS

C.1 GENERAL

A bar code consists of black lines (bars) and white lines (spaces), which are called elements.

There are narrow elements (NE) and wide elements (WE); their arrangement is determined by the code.

IMPORTANT

For accurate reading by the scanner, it is important that bar-code labels for specimen tubes and printout tickets adhere strictly to the specifications given in this Appendix. Labels that meet these specifications are available from Coulter: PN 7546856.

C.2 OPTICAL CHARACTERISTICS at 880 nm ±10% and 633 nm ±10%

1. Print Contrast Signal (PCS): 80% min.
2. Reflectivity of Media (RW): 80% min.
3. Reflectivity of Ink (Rb): 16% max.
4. No spots or voids; no ink smearing.
5. Edge roughness is included in the bar and space tolerances.

$$PCS = \frac{RW - Rb}{RW} \times 100\%$$

Measurement method is according to American National Standards Institute's MH10-8M-1983.

C.3 PRINTING METHOD

Photographic, or thermal transfer.

C.4 LABEL THICKNESS

Maximum label thickness must be such that:

1. The tube's outer diameter including the label is not greater than 13.3 mm.

2. The label including adhesive = 0.006 ±0.003 in.

C.5 NE/WE RATIO

Must remain constant over code length.

C.6 LABEL DIMENSIONS AND DATA

The dimensional and data specifications are illustrated in Figure 13. Table 29 explains the specifications called out in Figure 13.

C.7 ACCEPTABLE BAR CODES

Within the given specifications, the scanner automatically distinguishes the following bar codes:

Interleaved 2-of-5
Code 39® bar code
Codabar
NW7
Code 128/USS 128

Table 30 summarizes the code-related specifications.

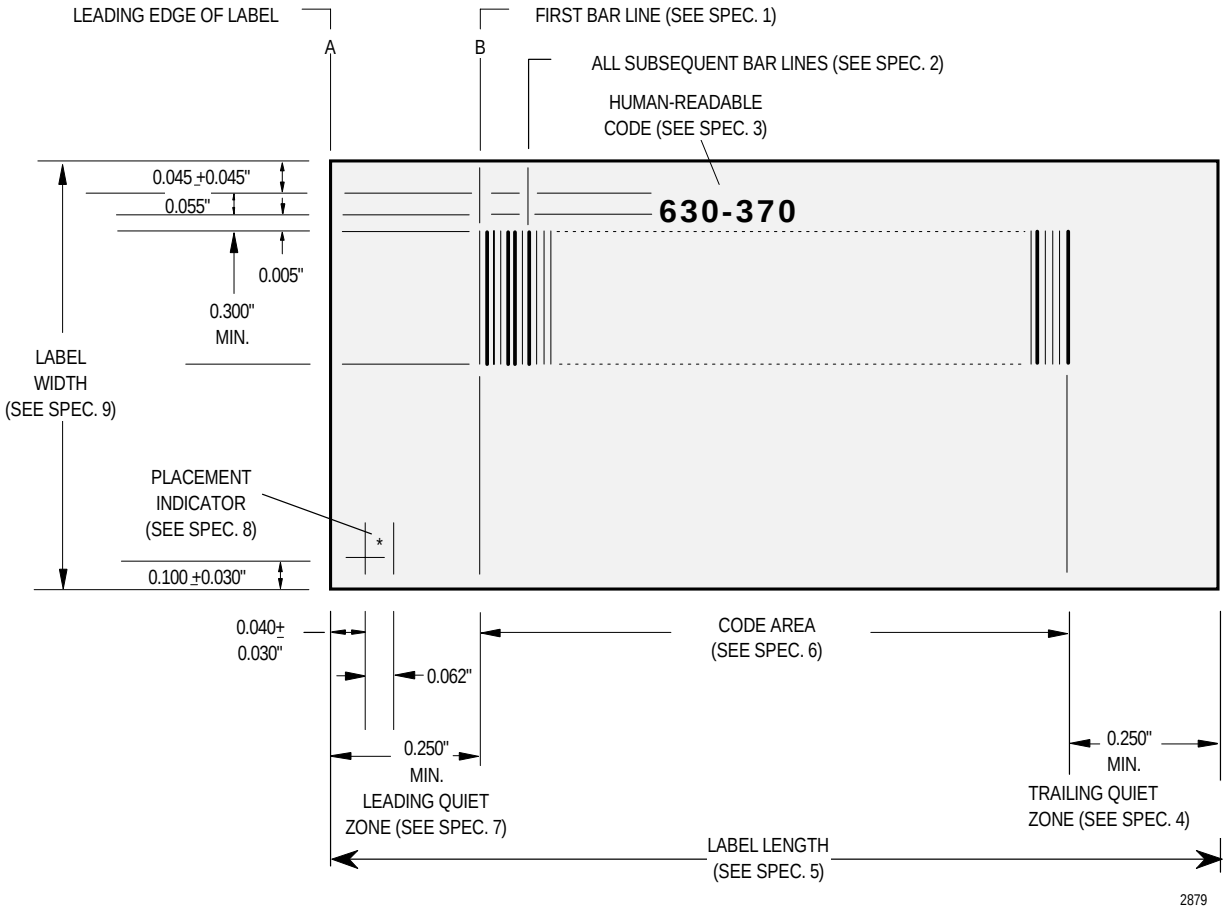


Figure 13 Bar-Code Label Specifications

Table 29 Bar-Code Label Specifications

Specification Called Out in Figure 13	Explanation
1	The first bar of the code (B) must be parallel to the label edge (A) within 0.002".
2	All subsequent bar lines must be parallel to (B) within 0.001".
3	The human-readable code (HRC) does not include the checksum; the dash in the HRC is not encoded in the bar code.
4	The trailing quiet zone must be 0.250" minimum.
5	The maximum label length is determined by the tube length. The scanner can accommodate labels up to 2.35". With HEMOGARD™ tubes, the maximum label length is 2.04".
	continued

Table 29 Bar-Code Label Specifications

Specification Called Out in Figure 13	Explanation
continued	
6	The bar-code area contains the start character, data digits, checksum, and stop character.
7	The leading quiet zone must be 0.250" minimum.
8	The placement indicator shows you which end of the label goes next to the tube stopper. This is an optional feature, not a mandatory one.
9	The width of the label must leave at least a 1/8" window for viewing the contents of the tube. The maximum label width for a 10-mm diameter tube is 1.1". The minimum label width is 0.400".

Table 30 Code-Related Specifications

Code	Interleaved 2-of-5	Codabar	Code 39 ****	NW7	Code 128 **** USS 128
Narrow element (NE) width	0.0105" ±0.001"	0.010"* Scaling Factor = 1.538*	0.010" ±0.001"	0.0105" ±0.001"	0.010" ±0.001"
Wide element/narrow element ratio (WE/NE)	(2.2 to 3): 1	N/A	(2.21 to 3): 1	(2.2 to 3): 1	(2 to 4): 1**
Intercharacter gap	No	0.010" Min.	≥NE	0.010" Min.	No
Data digits	3 to 11	3 to 9	3 to 9 (3 to 8 with HEMOGARD tubes)	3 to 9	3 to 11 Checksum always printed*** (3 to 9 for AUTO-REPORTER 3)

* According to American National Standard for bar code specifications that yield 10 characters per inch at NE = 0.0065".

** Code 128 is character dependent. See AIM® Uniform Symbol Specification Rev. 1986 for additional required dimensional tolerances.

*** You must use and print a checksum character, and it must conform to the AIM USS 128 checksum generation procedure. Do not use these values:
Code set A - 0, 64 through 102
Code set B - 0, 95 through 102
Code set C - 100 through 102

**** Do not use leading or trailing spaces in the ID.

C.8 CHECKSUM ALGORITHM

Coulter strongly recommends the use of bar code checksums to provide automatic checks for read accuracy.

IMPORTANT

Use of bar codes is an extremely accurate and effective method of positive patient identification. Certain features, such as checksum digits, maximize accuracy in reading Codabar, Code 39 and Interleaved 2-of-5 labels. In one study, the use of checksum digits detected 97% of misread errors.

Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. If you must use bar codes without checksums, Coulter recommends that you verify each bar-code reading to assure correct patient identification.

The algorithm for determining the checksum for each code is given below.

Interleaved 2-of-5

This code requires 3 to 11 data digits plus a checksum.

To determine the value of the checksum character:

1. Identify even- and odd-positioned characters in the message with the right-hand message character **always** defined as an even-positioned character.

2. Sum the numeric values of the odd-positioned characters.

3. Sum the numeric values of the even-positioned characters and multiply the total by 3.

4. Sum the odd and even totals from steps 2 and 3.

5. Determine the smallest number which, when added to the sum in step 4, results in a multiple of 10.

   This number is the value of the checksum character.

6. Determine whether total number of characters (message plus checksum) is odd or even. If odd, add a leading nonsignificant zero to the message to produce an even number of characters as required by the symbology.

Example:

MESSAGE	1	2	5	6	7	8
PARITY	0	E	0	E	0	E

STEP 2 1+5+7=13
STEP 3 (2+6+8)x3=48
STEP 4 13+48=61
STEP 5 61+9=70

Therefore, the checksum is 9, and the final decoded message is 01256789.

Codabar and NW7

Note: Codabar and NW7 codes have the same character set and the same checksum algorithm. The difference between these two codes is that Codabar has 18 different bar and space dimensions, and NW7 has only NE and WE structure.

The value assigned to each of the characters is presented in the following table.

CHARACTER	VALUE	CHARACTER	VALUE
0	0	-	10
1	1	$	11
2	2	:	12
3	3	/	13
4	4	.	14
5	5	+	15
6	6	A	16
7	7	B	17
8	8	C	18
9	9	D	19

The checksum technique is:

- The character value of a message is obtained from the above table and added together.

- This sum is divided by 16, and the remainder corresponds to the value of the checksum character.

Examples:

1.

MESSAGE	2	3	4	7	1	3
VALUE	2	3	4	7	1	3

$$2+3+4+7+1+3 = 20$$

$$\frac{20}{16} = 1, \text{ REMAINDER} = 4$$

The value 4 corresponds to character 4; therefore, the checksum is 4 and the final decoded message is 2347134.

2.

MESSAGE	$	$	/	/	+	+	+	+
VALUE	11	11	13	13	15	15	15	15

$$11+11+13+13+15+15+15+15 = 108$$

$$Q = \frac{108}{16} = 6, \text{ REMAINDER} = 12$$

The value 12 corresponds to character :, therefore, checksum is :, and the final decoded message is: $$//++++:

Japan Red Cross NW7 Decoding

Japan Red Cross Hospitals use the following NW7 values:

CHARACTER	VALUE
0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

The checksum technique is:

- The data digit value that is the difference between 11 and the Mod 11 sum of the weighted values of the data digits is used as the check digit. The start and stop digits are not used as part of the checksum calculation.
- NW7 is made up of 1 start digit, 9 data digits and 1 stop digit.
- The checksum digit immediately precedes the stop digit.

WEIGHTED MODULUS 11:

DIGIT POSITION (Right Justified)	12	11	10	9	8	7	6	5	4	3	2	1
WEIGHT (1)	6	3	5	9	10	7	8	4	5	3	6	2
WEIGHT (2)	5	8	6	2	10	4	3	7	6	8	5	9

The first 9 digits from the right are used for the calculation of the check digit.

Examples:

1. MESSAGE 011529007
   USE WEIGHT (1): 6 3 5 9 10 7 8 4 5 3 6 2

DIGIT POSITION (Right Justified)	0	0	0	0	1	1	5	2	9	0	0	7
WEIGHT (1)	6	3	5	9	10	7	8	4	5	3	6	2
Result	0	0	0	0	10	7	40	8	45	0	0	14

0 + 10 + 7 + 40 + 8 + 45 + 0 + 0 + 14 = 124

124 ÷ 11 = 11, REMAINDER 3
When the REMAINDER IS 0, 0 is the check digit.
11 - 3 = 8
The value 8 corresponds to character 8, therefore the checksum is 8 and the final decoded message is 0115290078

2. MESSAGE 023229006
   USE WEIGHT (1): 6 3 5 9 10 7 8 4 5 3 6 2

DIGIT POSITION (Right Justified)	0	0	0	0	2	3	2	2	9	0	0	6
WEIGHT (1)	6	3	5	9	10	7	8	4	5	3	6	2
Result	0	0	0	0	20	21	16	8	45	0	0	12

0 + 20 + 21 + 16 + 8 + 45 + 0 + 0 + 12 = 122

122 ÷ 11 = 11, REMAINDER 1

When the REMAINDER is 1, the calculation must be repeated using weight (2): 5 8 6 2 10 4 3 7 6 8 5 9

DIGIT POSITION (Right Justified)	0	0	0	0	2	3	2	2	9	0	0	6
WEIGHT (2)	5	8	6	2	10	4	3	7	6	8	5	9
Result	0	0	0	0	20	21	6	14	54	0	0	54

0 + 20 + 12 + 6 + 14 + 54 + 0 + 0 + 54 = 160

160 ÷ 11 = 14, REMAINDER 6
When the REMAINDER is 0, 0 is the check digit.
11 - 6 = 5
The value 5 corresponds to character 5, therefore the checksum is 5 and the final decoded message is 0232290065.

Code 39 Bar Code

The value assigned to each of the characters is:

CHARACTER	VALUE	CHARACTER	VALUE	CHARACTER	VALUE
0	0	F	15	U	30
1	1	G	16	V	31
2	2	H	17	W	32
3	3	I	18	X	33
4	4	J	19	Y	34
5	5	K	20	Z	35
6	6	L	21	-	36
7	7	M	22	.	37
8	8	N	23	SPACE	38
9	9	O	24	$	39
A	10	P	25	/	40
B	11	Q	26	+	41
C	12	R	27	%	42
D	13	S	28		
E	14	T	29		

The checksum technique is:

- The character values of the message are obtained from the above table and added together.
- This sum is divided by 43, and the remainder corresponds to the value of the checksum character.

Example:

CHARACTER	S	T	U	V	W	X	Y	F
VALUE	28	29	30	31	32	33	34	15

$$28+29+30+31+32+33+34+15 = 232$$

$$\frac{232}{43} = 5,\ \text{REMAINDER} = 17;\ 17 = \text{H} = \text{CHECKCHARACTER}$$

The value 17 corresponds to character H; therefore, checksum is H, and the final decoded message is: STUVWXYFH.

Code 128

The checksum character immediately precedes the stop character. The checksum character used with Code 128 must conform to the AIM USS 128 checksum generation procedure. Do not use these values:

Code set A - 0, 64 through 102
Code set B - 0, 95 through 102
Code set C - 100 through 102

The checksum value (see table) is equal to the modula 103 sum of the value of the start character and the weighted values of the data/special characters. The weights are one for the first data/special character and continuing with two, three, four and so forth for the following data/special characters.

For example, a label contains a START character (Code C), Data (25), a Check character, a STOP character. The value of the Start character C is 105, and the data character for 25 is 25. The weight of the first data character is one, so the check character value is calculated as follows:

105 + (25 x 1) = 130

where 105 and 25 are the values and 1 is the weight.

The checksum is equal to 130 modula 103 (the remainder of 130 divided by 103):

130/103 = 1, remainder 27

Therefore the check character equals character value 27, which is ; in Code Set A.

For additional information on this procedure, refer to AIM USS-128 Rev. 1986, published by AIM, Inc., 1326 Freeport Road, Pittsburgh, PA 15238.

VALUE	CODE A	CODE B	CODE C
0	SP	SP	00
1	!	!	01
2	"	"	02
3	#	#	03
4	$	$	04
5	%	%	05
6	&	&	06
7	’	’	07
8	(	(	08
9	)	)	09
10	*	*	10
11	+	+	11
12	,	,	12
13	-	-	13
14	.	.	14
15	/	/	15
16	0	0	16
17	1	1	17
18	2	2	18
19	3	3	19
20	4	4	20
21	5	5	21
22	6	6	22
23	7	7	23
24	8	8	24
			continued

VALUE	CODE A	CODE B	CODE C
continued			
25	9	9	25
26	:	:	26
27	;	;	27
28	<	<	28
29	=	=	29
30	>	>	30
31	?	?	31
32	@	@	32
33	A	A	33
34	B	B	34
35	C	C	35
36	D	D	36
37	E	E	37
38	F	F	38
39	G	G	39
40	H	H	40
41	I	I	41
42	J	J	42
43	K	K	43
44	L	L	44
45	M	M	45
46	N	N	46
47	O	O	47
48	P	P	48
49	Q	Q	49
50	R	R	50
51	S	S	51
52	T	T	52
53	U	U	53
54	V	V	54
55	W	W	55
56	X	X	56
57	Y	Y	57
			continued

VALUE	CODE A	CODE B	CODE C
continued			
58	Z	Z	58
59	[	[	59
60	\	\	60
61	]	]	61
62			62
63	___	___	63
64	NUL	‘	64
65	SOH	a	65
66	STX	b	66
67	ETX	c	67
68	EOT	d	68
69	ENQ	e	69
70	ACK	f	70
71	BEL	g	71
72	BS	h	72
73	HT	i	73
74	LF	j	74
75	VT	k	75
76	FF	l	76
77	CR	m	77
78	SO	n	78
79	SI	o	79
80	DLE	p	80
81	DC1	q	81
82	DC2	r	82
83	DC3	s	83
84	DC4	t	84
85	NAK	u	85
86	SYN	v	86
87	ETB	w	87
88	CAN	x	88
89	EM	y	89
90	SUB	z	90
			continued

VALUE	CODE A	CODE B	CODE C
continued			
91	ESC	{	91
92	FS	|	92
93	GS	}	93
94	RS	~	94
95	US	DEL	95
96	FNC 3	FNC 3	96
97	FNC 2	FNC 2	97
98	SHIFT	SHIFT	98
99	CODE C	CODE C	99
100	CODE B	FNC 4	CODE B
101	FNC 4	CODE A	CODE A
102	FNC 1	FNC 1	FNC 1
103	START (CODE A)		
104	START (CODE B)		
105	START (CODE C)		

APPENDIX D
AUTO-REPORTER 3 TICKET SPECIFICATIONS

D.1 GENERAL INFORMATION

The layout in Figure 14 illustrates the three parts of the Standard Patient Report Form available through CMS (#275-277, Coulter PN 7546921). Note that this form:

1. Allows the printout of all STKS parameters and flags these Suspect and Definitive messages:

Suspect	Definitive	Definitive
Blasts	Lymphopenia	Hypochromia
Imm Grans/Bands 1	Lymphocytosis	Poikilocytosis
Imm Grans/Bands 2	Neutropenia	Small Platelets
Variant Lymphs	Neutrophilia	Large Platelets
NRBCs	Monocytosis	
Micro RBCs/ RBC Fragments	Eosinophilia	
	Basophilia	
RBC Agglutination	Anisocytosis	
Platelet Clumps	Microcytosis	
Giant Platelets	Macrocytosis	

2. Provides spaces for Pct and PDW. In the DMS SET UP screen, you can set these parameters to ENABLED or DISABLED. When set to DISABLED, results for these parameters do not print, and the line spaces are skipped.

3. Contains strict formatting layout for some areas. The SHADED areas in the example in Figure 15 indicate the restricted areas that cannot be adjusted or changed in any way. The DMS program does not allow you to disable any parameters other than Pct or PDW, or to reorder the parameters.

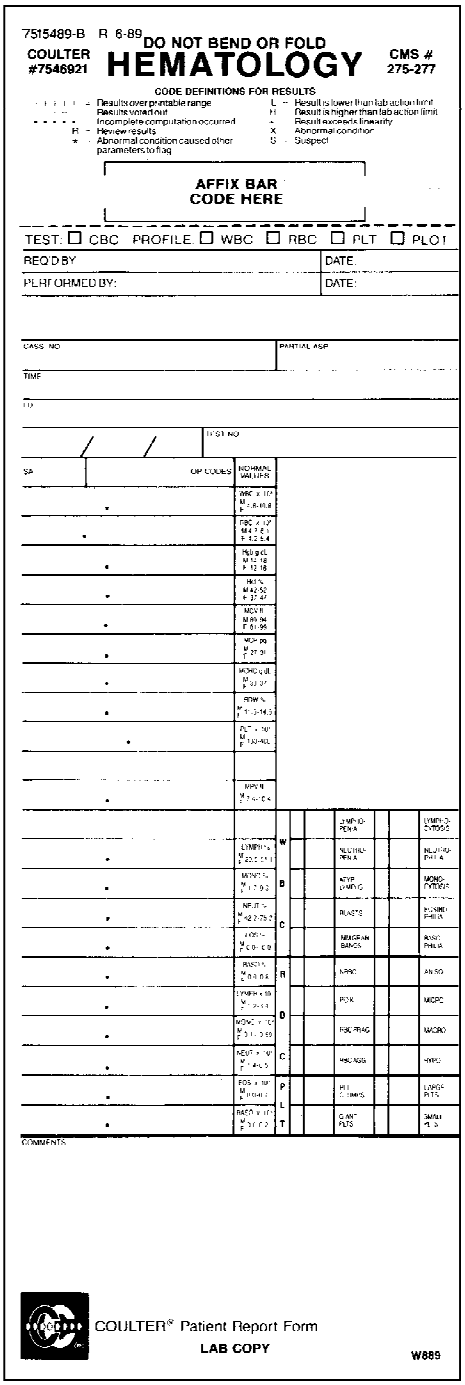
D.2 CUSTOMIZING THE FORM

Coulter no longer customizes tickets. We recommend that you:

1. Use vendors that are familiar with Coulter forms, especially the Auto-Reporter forms.

2. Strictly follow specifications given in the Specifications section.

PART #1



NOTE: FORM ALIGNMENT FROM COPY TO COPY MUST BE WITHIN 0.031 INCH OF TOP COPY.

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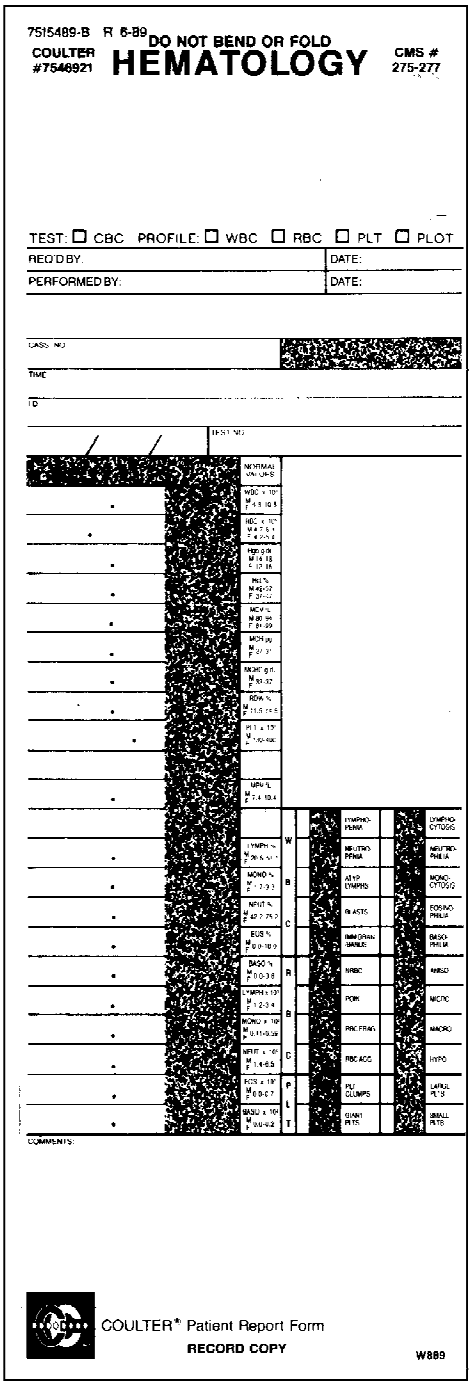
PART #2 & 3



(Chinese blockout obscures codes. Bar code label area and definition of codes have been removed from these copies.)

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Figure 14 Composite Patient Report Form

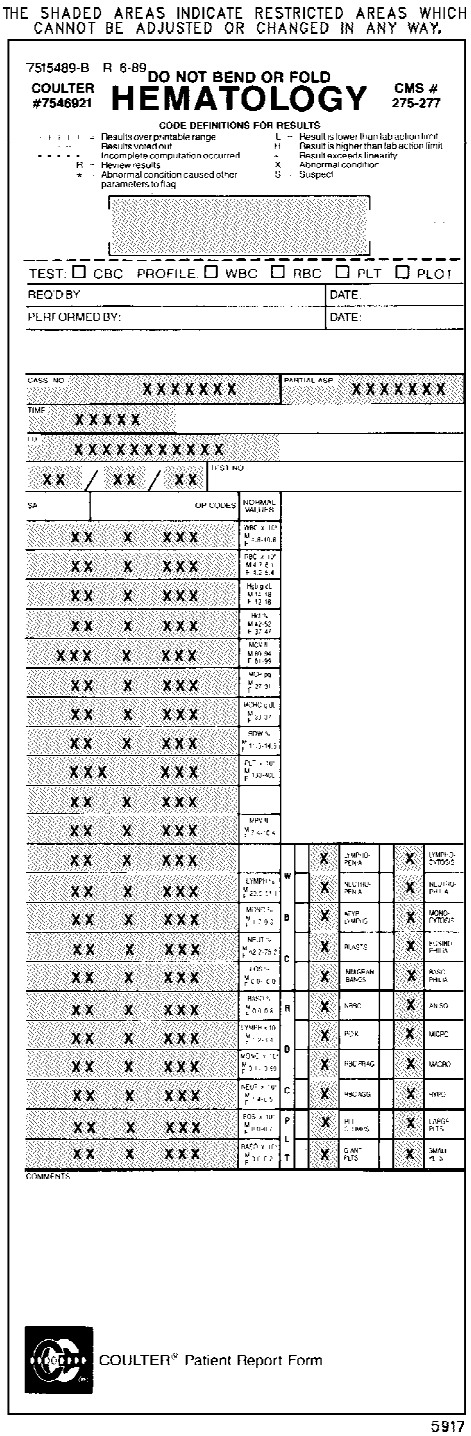

Figure 15 Ticket Format

3. Use ONLY THE UNSHADED areas (see Figure 15) for customizing the form to add your name and address or other laboratory information or tests.

4. Modify placement of perforations carefully. Our standard form contains perforations on the LAB and PATIENT/CHART copies (Parts 1 and 2) that are 1 1/2 in. down from the top of the form. This location of the perforation allows you to continue to file a copy similar in length to our previous shorter tickets. The form can be customized to place the perforations farther up on the form if you wish; however, since the ticket is 10 in. long, your storage system/process may need to be altered.

   NO PERFORATIONS ARE ALLOWED ON THE LAST (TAG) COPY UNLESS THEY ARE PLACED AT LEAST 1 1/2 in. DOWN FROM THE TOP.

5. May print the tickets on continuous-feed computer paper if all specifications are met. Special instructions include:

   - Limiting the roughness of the edge of the ticket after "tearing" the ticket away from the computer form. Rough edges cause dust and confetti that might build up around the printer roller, causing a "jam."

   - Staying within the thickness specification for the total ticket and the limitation on the punch holes.

   - Meeting the specifications for the last copy (that is, must not contain any perforations unless they are at least 1 1/2 in. from the top).

D.3 SPECIFICATIONS

The shaded areas shown in Figure 15 indicate restricted areas that cannot be adjusted or changed in any way.

Size

Length: 8.97 in. to 10.019 in.
Width: 3.23 in. to 3.25 in.

Paper

- The first copy must be self-contained since the printer has no ribbon, and must have a smoothness minimum of 200 using the Sheffield Device or equivalent.
- Last copy should be 125 lb manila tag for optimum feeding through the printer.
- Form thickness: 0.013 to 0.019 in.
- Forms exceeding three parts may not produce acceptable print quality on all copies.
- Forms must be free of die-cut dust or confetti.

Copies

For clarity and ease of copying, carbons and the image of printed results are black. Forms exceeding three parts may not produce acceptable print quality on all copies.

Adhesive Strip (Optional)

- Total thickness of adhesive and strip should not be thicker than the bar-code label (0.009").
- Cannot be located in the same area of the bar-code label.
- Cannot be located along the edges as specified in Ticket Areas, #10.
- Cannot be located in any printout areas shown in Figure 15.
- Cannot be located on the last copy of the Report Form (Tag copy).

Ticket Areas

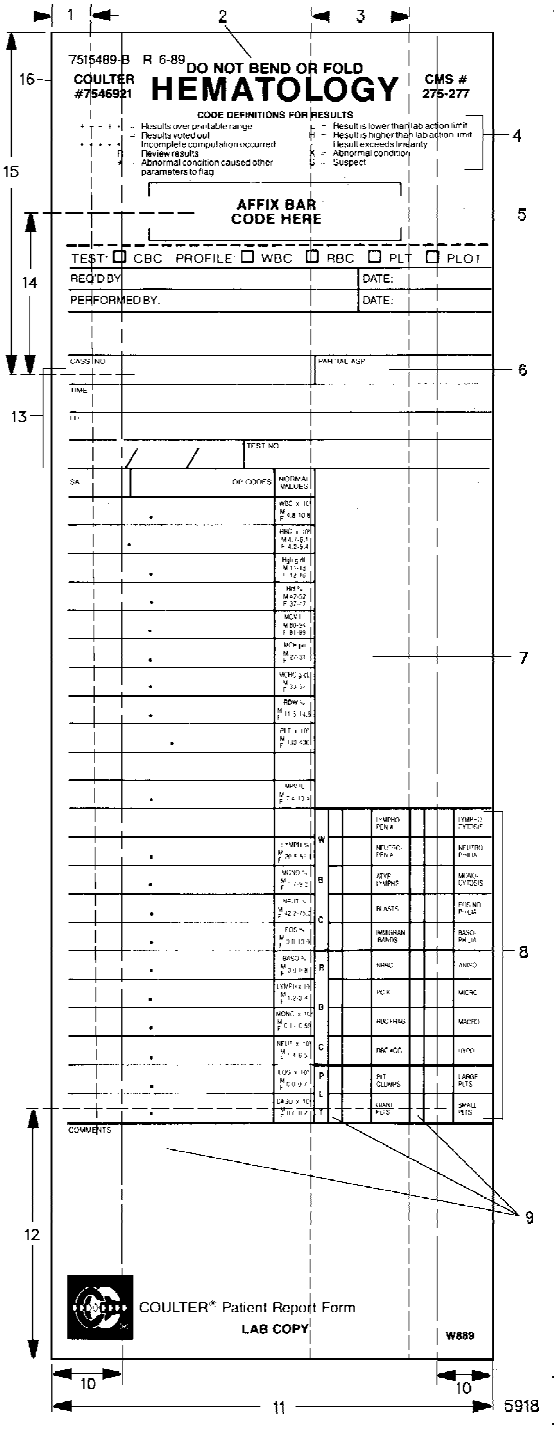

Figure 16 Ticket Specifications

Numbers below refer to corresponding numbers on Figure 16. All dimensions are in inches.

1. Nominal dimension from left edge of form to center of first column is 0.248 ± 0.010 (throughput length of form to avoid skewness).

2. Do not bend or fold the form. We suggest a statement to that effect be printed in red on the form.

3. Sensing area. If punch holes exist, limit holes to 1/8 in. in diameter. Holes larger than 1/8 in. diameter must be kept out of this area to avoid jams.

4. Having a definition of codes is helpful. The definitions can appear only on the Laboratory Copy if Chinese blockout obscures codes on other copies.

5. When using the BAR CODE option, reserve this area on Part 1 for labels. No characters should be printed here. On any copy except Part 1, this area can be omitted.

6. Reserve this area for CASSETTE NO. in case of incomplete aspiration.

7. Additional Comment or Addressograph area.

8. Reserve this area for instrument printout of suspect and definitive messages.

9. Comment area.

10. Along each edge of the form, an area of 0.45 in. in width should be free of labels. We suggest a screen indicating this area.

11. Form width: 3.250 + 0.00, - 0.02.
    Form length: 10.019 maximum, 8.970 minimum.

12. Center of last line printed to bottom of form is 1.690 minimum.

13. Reserve this area for CASSETTE NO, TIME, ID and DATE.

14. Center of bar-code scanner to center of first line printed is 1.20 ±0.01.

15. Top of form to center of first line printed is 2.497 ±0.015.

16. Closed end of form (stub). When perforations are used, a perforation on the last (tag) copy must be at least 1 1/2 in. from the top of the form. Top copies may have perforations at 1/2 in. or below. Glue line must not cross the perforation line. Edge of action paper copies must not roll up.

APPENDIX E
BAR-CODE WAND

E.1 DESCRIPTION

The optional Hewlett Packard Smart Wand HBCR-8200 (CC# 2016513) is a bar-code reader that fits into the wand case. It consists of:

- an optical sensor
- digitizing electronics
- a decode microprocessor
- an output line driver

The wand case is made of a polycarbonate material with:

- O-ring seals at each end
- a bend and strain relief for the cord
- a sealed sapphire tip

The required wand interface and power supply (CC# 2016512) provides the power and communication logic to interface to the DMS. The interface connection is to the P4 communication port from the Digiboard Communication Processor assembly. This connection also requires interface software on the DMS to integrate the two products.

The typical wand characteristics are defined below.

Parameter	HBCR-8200 Smart Wand
Nominal Narrow Element width	0.0075 in.
Wavelength	655 nm
Scan speed	3 to 50 in. per second
Tilt angle	0 to 45°
Minimum contrast	45%
Operating temperature	-20 to +70°C (-4 to +158°F)
Humidity	5 to 95% (non condensing)
Shock	500 g's at 1 ms
Ambient light	0 to 100 kLux (direct sunlight)
Symbology supported	Code 128 with checksum

E.2 HOW TO SCAN A BAR CODE

Use the wand to scan the bar-cod fields on the 5C cell control assay sheet.

1. Go to a CBC/DIFF Control Set Up screen.

2. Hold the wand like a pencil. The wand works best when tilted from 10 to 30° from vertical, but works at any angle from 0 to 45°.

3. Place the tip of the wand on the white space on either side of the bar code to be scanned.

4. Draw the wand smoothly and lightly across the bar code from one end to the other without lifting the tip of the wand.

5. The system beeps to indicate a successful scan, and the information from the assay sheet now appears on the DMS screen.

   If the system does not beep, scan the label again. If there are no positive results after three tries:

   a. Check the cable connections, then retry.

   b. Power the DMS off and on, then retry.

   c. Call your Coulter Service Representative.

E.3 INSTALL THE WAND

The wand comes in a kit, Coulter PN 6912949, for the 115 Vac version.

1. Carefully unpack the wand and the interface power supply.

2. Turn off the DMS.

3. On the back of the DMS, locate the communication port P4. If the raw data collection cable is connected to P4, you must remove it.

4. Connect the 25-pin connector side of the interface assembly to port P4.

5. Connect the wand's 9-pin connector to the reciprocal 9-pin connector on the interface box.

6. Plug the wand into a 115 Vac outlet.

7. Turn on the DMS. If any error messages occur during the first two minutes after power on, note them and call your Coulter Service Representative.

APPENDIX F
REPORTING UNITS

Table 31 US-1 Format
Reporting Units

Parameter	Formula	Unit Label	Display Format
WBC		$10^3/\mu L$	999.9
NE%		%	999.9
LY%		%	999.9
MO%		%	999.9
EO%		%	999.9
BA%		%	999.9
NE#	(NE% x WBC) ÷ 100	$10^3/\mu L$	999.9
LY#	(LY% x WBC) ÷ 100	$10^3/\mu L$	999.9
MO#	(MO% x WBC) ÷ 100	$10^3/\mu L$	999.9
EO#	(EO% x WBC) ÷ 100	$10^3/\mu L$	999.9
BA#	(BA% x WBC) ÷ 100	$10^3/\mu L$	999.9
RBC		$10^6/\mu L$	99.99
HGB		g/dL	999.9
HCT		%	999.9
MCV	(HCT x 10) ÷ RBC†	fL	999.9
MCH	(HGB x 10) ÷ RBC†	pg	999.9
MCHC	(HGB x 10) ÷ HCT†	g/dL	999.9
RDW		%	999.9
PLT		$10^3/\mu L$	99999
MPV		fL	999.9
PCT*		%	9.999
PDW*		(ratio)	999.9
RET%		%	99.99
RET#	(RET% x RBC) ÷ 100	$10^6/\mu L$	.9999‡

* Parameter for Investigational Use Only.
† Calculation formula commonly used in laboratories for these red cell indices.
‡ When the internal value is greater than the displayed format, the value will be displayed with one less decimal place.

Table 32 US-2 Format
Reporting Units

Parameter	Formula	Conv Factor	Unit Label	Display Format
WBC		1.0	$10^3/\mu L$	999.9
NE%		1.0	%	999.9
LY%		1.0	%	999.9
MO%		1.0	%	999.9
EO%		1.0	%	999.9
BA%		1.0	%	999.9
NE#	(NE% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
LY#	(LY% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
MO#	(MO% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
EO#	(EO% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
BA#	(BA% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
RBC		1.0	$10^6/\mu L$	99.99
HGB		1.0	g/dL	999.9
HCT		1.0	%	999.9
MCV	(HCT x 10) ÷ RBC†	1.0	fL	999.9
MCH	(HGB x 10) ÷ RBC†	1.0	pg	999.9
MCHC	(HGB x 10) ÷ HCT†	1.0	g/dL	999.9
RDW		1.0	%	999.9
PLT		1.0	$10^3/\mu L$	99999
MPV		1.0	fL	999.9
PCT*		1.0	%	9.999
PDW*		1.0	(ratio)	999.9
RET%		1.0	%	99.99
RET#	(RET% x RBC) ÷ 100	1000	$10^9/L$	999.9‡

* Parameter for Investigational Use Only.
† Calculation formula commonly used in laboratories for these red cell indices.
‡ When the internal value is greater than the displayed format, the value will be displayed with one less decimal place.

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Table 33 S.I. 1 and S.I. 5 Format Reporting Units

Parameter	Formula	Conv Factor	Unit Label	Display Format
WBC		1.0	10^9/L	999.9
NE%		1.0	%	999.9
LY%		1.0	%	999.9
MO%		1.0	%	999.9
EO%		1.0	%	999.9
BA%		1.0	%	999.9
NE#	(NE% x WBC) ÷ 100	1.0	10^9/L	999.9
LY#	(LY% x WBC) ÷ 100	1.0	10^9/L	999.9
MO#	(MO% x WBC) ÷ 100	1.0	10^9/L	999.9
EO#	(EO% x WBC) ÷ 100	1.0	10^9/L	999.9
BA#	(BA% x WBC) ÷ 100	1.0	10^9/L	999.9
RBC		1.0	10^{12}/L	99.99
HGB		10	g/L	99999
HCT		0.01	L/L	9.999
MCV	(HCT x 10) ÷ RBC†	1.0	fL	999.9
MCH	(HGB x 10) ÷ RBC†	1.0	pg	999.9
MCHC	(HGB x 10) ÷ HCT†	10	g/L	99999
RDW		1.0	%	999.9
PLT		1.0	10^9/L	99999
MPV		1.0	fL	999.9
PCT*		1.0	%	9.999
PDW*		1.0	(ratio)	999.9
RET%		1.0	%	99.99
RET#	(RET% x RBC) ÷ 100	1.0	10^{12}/L 10^9/L**	.9999‡

* Parameter for Investigational Use Only.

** For S.I. 5 format.

† Calculation formula commonly used in laboratories for these red cell indices.

‡ When the internal value is greater than the displayed format, the value will be displayed with one less decimal place.

Table 34 S.I. 2 and S.I. 6 Format Reporting Units

Parameter	Formula	Conv Factor	Unit Label	Display Format
WBC		1.0	10^9/L	999.9
NE%		0.01	(ratio)	9.999
LY%		0.01	(ratio)	9.999
MO%		0.01	(ratio)	9.999
EO%		0.01	(ratio)	9.999
BA%		0.01	(ratio)	9.999
NE#	(NE% x WBC) ÷ 100	1.0	10^9/L	999.9
LY#	(LY% x WBC) ÷ 100	1.0	10^9/L	999.9
MO#	(MO% x WBC) ÷ 100	1.0	10^9/L	999.9
EO#	(EO% x WBC) ÷ 100	1.0	10^9/L	999.9
BA#	(BA% x WBC) ÷ 100	1.0	10^9/L	999.9
RBC		1.0	10^{12}/L	99.99
HGB		10	g/L	99999
HCT		0.01	L/L	9.999
MCV	(HCT x 10) ÷ RBC†	1.0	fL	999.9
MCH	(HGB x 10) ÷ RBC†	1.0	pg	999.9
MCHC	(HGB x 10) ÷ HCT†	10	g/L	99999
RDW		1.0	%	999.9
PLT		1.0	10^9/L	99999
MPV		1.0	fL	999.9
PCT*		1.0	%	9.999
PDW*		1.0	(ratio)	999.9
RET%		0.01	(ratio)	.9999
RET#	(RET% x RBC) ÷ 100	1.0	10^{12}/L 10^9/L**	.9999‡

* Parameter for Investigational Use Only.

** For S.I. 6 format.

† Calculation formula commonly used in laboratories for these red cell indices.

‡ When the internal value is greater than the displayed format, the value will be displayed with one less decimal place.

Table 35 S.I. 3 Format
Reporting Units

Parameter	Formula	Conv Factor	Unit Label	Display Format
WBC		1.0	$10^3/\mu L$	999.9
NE%		1.0	%	999.9
LY%		1.0	%	999.9
MO%		1.0	%	999.9
EO%		1.0	%	999.9
BA%		1.0	%	999.9
NE#	(NE% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
LY#	(LY% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
MO#	(MO% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
EO#	(EO% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
BA#	(BA% x WBC) ÷ 100	1.0	$10^3/\mu L$	999.9
RBC		1.0	$10^6/\mu L$	99.99
HGB		1.0	g/dL	999.9
HCT		0.01	L/L	9.999
MCV	(HCT x 10) ÷ RBC†	1.0	fL	999.9
MCH	(HGB x 10) ÷ RBC†	1.0	pg	999.9
MCHC	(HGB x 10) ÷ HCT†	1.0	g/dL	999.9
RDW		1.0	%	999.9
PLT		1.0	$10^3/\mu L$	99999
MPV		1.0	fL	999.9
PCT*		1.0	%	9.999
PDW*		1.0	(ratio)	999.9
RET%		1.0	%	99.99
RET#	(RET% x RBC) ÷ 100	1.0	$10^6/\mu L$	.9999‡

* Parameter for Investigational Use Only.
† Calculation formula commonly used in laboratories for these red cell indices.
‡ When the internal value is greater than the displayed format, the value will be displayed with one less decimal place.

Table 36 S.I. 4 and S.I. 7 Format Reporting Units

Parameter	Formula	Conv Factor	Unit Label	Display Format
WBC		1.0	10^9/L	999.9
NE%		1.0	%	999.9
LY%		1.0	%	999.9
MO%		1.0	%	999.9
EO%		1.0	%	999.9
BA%		1.0	%	999.9
NE#	(NE% x WBC) ÷ 100	1.0	10^9/L	999.9
LY#	(LY% x WBC) ÷ 100	1.0	10^9/L	999.9
MO#	(MO% x WBC) ÷ 100	1.0	10^9/L	999.9
EO#	(EO% x WBC) ÷ 100	1.0	10^9/L	999.9
BA#	(BA% x WBC) ÷ 100	1.0	10^9/L	999.9
RBC		1.0	10^{12}/L	99.99
HGB		0.6205	mmol/L	999.9
HCT		0.01	L/L	9.999
MCV	(HCT x 10) ÷ RBC†	1.0	fL	999.9
MCH	(HGB x 10) ÷ RBC†	0.06205	fmol	99.99
MCHC	(HGB x 10) ÷ HCT†	0.6205	mmol/L	999.9
RDW		1.0	%	999.9
PLT		1.0	10^9/L	99999
MPV		1.0	fL	999.9
PCT*		1.0	%	9.999
PDW*		1.0	(ratio)	999.9
RET%		1.0	%	99.99
RET#	(RET% x RBC) ÷ 100	1.0	10^{12}/L 10^9/L**	.9999‡

* Parameter for Investigational Use Only.

** For S.I. 7 format.

† Calculation formula commonly used in laboratories for these red cell indices.

‡ When the internal value is greater than the displayed format, the value will be displayed with one less decimal place.

APPENDIX F

Table 37 Japan Format Reporting Units

Parameter	Formula	Conv Factor	Unit Label	Display Format
WBC		10	$10^2/\mu L$	99999
NE%		1.0	%	999.9
LY%		1.0	%	999.9
MO%		1.0	%	999.9
EO%		1.0	%	999.9
BA%		1.0	%	999.9
NE#	(NE% x WBC) ÷ 100	10	$10^2/\mu L$	99999
LY#	(LY% x WBC) ÷ 100	10	$10^2/\mu L$	99999
MO#	(MO% x WBC) ÷ 100	10	$10^2/\mu L$	99999
EO#	(EO% x WBC) ÷ 100	10	$10^2/\mu L$	99999
BA#	(BA% x WBC) ÷ 100	10	$10^2/\mu L$	99999
RBC		100	$10^4/\mu L$	99999
HGB		1.0	g/dL	999.9
HCT		1.0	%	999.9
MCV	(HCT x 10) ÷ RBC†	1.0	fL	999.9
MCH	(HGB x 10) ÷ RBC†	1.0	pg	999.9
MCHC	(HGB x 10) ÷ HCT†	1.0	g/dL	999.9
RDW		1.0	%	999.9
PLT		0.1	$10^4/\mu L$	999.9
MPV		1.0	fL	999.9
PCT*		1.0	%	9.999
PDW*		1.0	(ratio)	999.9
RET%		1.0	%	99.99
RET#	(RET% x RBC) ÷ 100	100	$10^4/\mu L$	99.99‡

* Parameter for Investigational Use Only.

† Calculation formula commonly used in laboratories for these red cell indices.

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Batch - A group or set of results. For $\bar{X}_B$ Analysis, a batch consists of 20 patient samples.

Batch Mean - The mean or average of a set of samples. For $\bar{X}_B$ Analysis, the batch mean is a value based on a statistical averaging technique and is a type of "weighted moving average." It is used to estimate what a simple average result of a very large number of samples (population mean) might be by using a small number of samples.

Current Batch - The number of samples currently being collected. The samples are listed line by line in a table called "Current XB Batch" under XB in the Sample Analysis option on the DMS.

Data Management System (DMS) - The computer attached to the STKS instrument. It automatically stores patient results and performs $\bar{X}_B$ Analysis as one of its functions.

Indices - Term that refers to the three red cell (erythrocyte) parameters which reflect the size and hemoglobin content of the red cells. The three indices are: mean cell volume (MCV), mean cell hemoglobin (MCH), and the mean cell hemoglobin concentration (MCHC).

MCH - Mean cell hemoglobin, measured in picograms. Calculated by dividing the total hemoglobin by the total number of red cells and multiplying by 10. Calculated automatically by the STKS.

MCHC - Mean cell hemoglobin concentration, measured in grams per deciliter. Calculated by dividing the total hemoglobin by the hematocrit. Also calculated automatically by the STKS.

MCV - Mean cell (or corpuscular) volume, measured in femtoliters and derived from the RBC histogram. Manually calculated by dividing the packed cell volume by the red cell count and multiplying by 10.

Mean - The average value of a set of numbers. Refers to a simple arithmetic average or a more complicated statistical estimate.

N or n - The number of samples in a set or batch.

Parameters - Refers to the easily measurable elements of a blood sample. Hematology parameters include:

white cell count - WBC
red cell count - RBC
hemoglobin - Hgb
hematocrit - Hct
MCV
MCH
MCHC
red cell distribution width - RDW
platelet count - Plt
mean platelet volume - MPV
the differential parameters
reticulocyte - Retic or RET

Patient Population - A large number of patient sample results, used to give a fairly consistent average result for each of the red blood cell indices.

Quality Control - A system of checks that provides the laboratory with a way to monitor the reliability of patient results. Several techniques are available to assure laboratories that they are reporting the most accurate results possible. There are five basic methods now in use in hematology to monitor automated instrument results:

1. performing daily instrument checks
2. using commercially available controls
3. reviewing patient results
4. participating in an interlaboratoy control program
5. using X_B Analysis

In addition, the STKS system uses a comparison procedure for controlling diff parameters, using instrument diff and manual diff results.

Stability - One of the requirements for a good quality control material -- the parameter values to be measured must not fluctuate on their own, but remain stable.

Target Value - The constant for each index calculated from a large number of patients of varying ages and disease states. The values are the same for all acute care general hospital populations.

$\bar{X}_B$ Analysis - A method of quality control that frequently compares patient indices with known target values. Used to monitor automated instruments in hematology.

S

T

V

X

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This warranty is limited to the repair and replacement of parts which prove to be defective during the warranty period. This warranty is not valid for parts damaged, lost or which fail because of accident, fire, theft, acts of nature (storms, floods, etc.) negligence of the use of chemicals which have a deleterious effect.

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REVISION STATUS

Issue A, 12/93
Software version 2A.

Issue B, 3/95
Software version 2B. Change pages: cover, inside front cover, i-viii, 5, 9, 10, 42, 81, 129, 151, 152, 154, 163, 164, trademarks and back cover.

Note: Changes that are part of the most recent revision are indicated in text by a black bar in the margin.

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Reference PN 4237182 (White binding)	Use and Function Installation Operation Principles Specifications Precautions/Hazards Appendices References Glossary
Special Procedures and Troubleshooting PN 4237187 (Silver binding)	General Procedures Calibration Cleaning Procedures Replace/Adjust Procedures Troubleshooting
Operator's Guide PN 4237188 (Clear binding)	Controls and Indicators Startup Sample Analysis Data Analysis Shutdown Analyzer CRT Functions DMS Basics Sample Analysis Display Worklist Data Base Controls Apendices
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