COULTER® A^{C}•T diff™ Analyzer

Reference

PN 4237422CA (August 2010)

Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821

BECKMAN COULTER

WARNINGS AND PRECAUTIONS

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT. DO NOT ATTEMPT TO PERFORM ANY PROCEDURE BEFORE CAREFULLY READING ALL INSTRUCTIONS. ALWAYS FOLLOW PRODUCT LABELING AND MANUFACTURER'S RECOMMENDATIONS. IF IN DOUBT AS TO HOW TO PROCEED IN ANY SITUATION, CONTACT YOUR BECKMAN COULTER REPRESENTATIVE.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

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

BECKMAN COULTER, INC. 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 EYEWEAR, GLOVES, AND SUITABLE LABORATORY ATTIRE WHEN OPERATING OR MAINTAINING THIS OR ANY OTHER AUTOMATED LABORATORY ANALYZER.

WARNING Risk of operator injury if:

- All doors, covers and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers and panels are not opened, closed, removed and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers and panels with care.
- Use the proper tools when troubleshooting.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

REVISION STATUS

Initial Issue, 10/97
Software version 1.03

Issue B, 11/99
Software version 1.06

Page	Change
cover	updated illustration
xiv	added Cycle Counter icon and Patient Range icon
1-1	updated screen
1-2	added Patient Range information to Features
1-3	removed “cyanide-containing” from text
2-1	updated illustration
2-2	updated printer information
4-1	updated voltage rating to 120-240 VRMS and updated Consumption to120 W
4-3	added X = 0, 1, 2, or 3 to Sample Report
A-5	added X = 0, 1, 2, or 3 to Patient Report
A-26	updated screen
A-27	updated screen
B-3	added rows to the Action Log
B-5	added rows to the Maintenance Log
B-7	added rows to the Reagent Log
Trademarks	changed name to Beckman Coulter, Inc.

Issue C, 6/03
Changes were made to change the company name from Coulter Corporation to Beckman Coulter Inc.

Note: A black bar in the left margin indicates where a change was made from the previous version of the manual.

Issue CA, 8/10
Software Version 1.06.

Updates were made to the company corporate address.

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

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released to the Beckman Coulter website. For labeling updates, go to www.beckmancoulter.com and download the most recent manual or system help for your instrument.

REVISION STATUS

CONTENTS

ILLUSTRATIONS

TABLES

This introductory section contains the following topics:

- How to use your COULTER® A^{C}•T diff™ Analyzer Manuals
- About the Reference Manual
- Conventions
- Symbols
- Graphics
- Icon Tree
- Touch Screen Icons

HOW TO USE YOUR COULTER® A^{C}•T diff™ ANALYZER MANUALS

Use the **Reference** manual for in-depth information about:

- What the instrument does
- What special requirements the instrument has (for example, space, accessibility, power)
- What methods it uses
- What the instrument specifications are
- How to interface your A^{C}•T diff analyzer to your laboratory's host computer
- How to safely use the instrument.

Use the **Operator's Guide** for:

- Getting started
- Running your instrument day to day
- Reviewing unusual results, including how to read a result report and what flags mean
- Performing special procedures such as cleaning, replacing, or adjusting a component of the instrument
- Troubleshooting problems with your instrument.

Use the **Operating Summary** for:

- Running your instrument using a quick reference set of procedures
- Verifying screen icon definitions

Use the **Ticket Printer User's Guide** for:

- Understanding the printer's control panel
- Installing and setting up the printer
- Performing a printer self-test.

Use the **Roll Printer User's Guide** for:

- Understanding the printer's control panel
- Installing and setting up the printer
- Performing a printer self-test.

Use the **Graphics Printer User's Guide** for:

- Understanding the printer's control panel
- Installing and setting up the printer
- Performing a printer self-test.

ABOUT THE REFERENCE MANUAL

Your COULTER A^{C}•T diff Analyzer Reference manual is a reference source of information on what the system does.

This information is organized as follows:

- Chapter 1, Use and Function
  Contains the intended use of the instrument, a brief history of the methods used by the instrument, the reagents, calibrator and controls used, and a short description of the major components and options.
- Chapter 2, Installation
  Contains the instrument requirements for space, accessibility and power.
- Chapter 3, Operation Principles
  Contains the descriptions of the Coulter Method for cell counting, the normal sample flow through the instrument, how counting and sizing are accomplished, how the parameters are derived and a description of the Aperture Alert.
- Chapter 4, Specifications/Characteristics
  Details the instrument, performance specifications, characteristics, and interfering substances.
- Chapter 5, Precautions/Hazards
  Contains information regarding key safety issues. Contains information on biological hazards and hazards concerning moving parts on the instrument.
- Appendix A, Host Transmission Specifications
  Contains information regarding the host transmission specifications.
- Appendix B, Log Sheets
  Contains log sheets.
- This manual also includes recommended References, a Glossary, Abbreviations list, and an Index.

CONVENTIONS

This manual uses the following conventions:

Bold font indicates A^{C}•T diff analyzer manual titles.

Bold indicates a screen icon.

Italics font indicates screen text displayed by the instrument.

Instrument refers to the A^{C}•T diff analyzer.

Note

A Note contains information that is important to remember or helpful in performing a procedure.

SYMBOLS

Safety Symbols

Safety symbols alert you to potentially dangerous conditions. These symbols, together with text, apply to specific procedures and appear as needed throughout this manual.

Symbol	Warning Condition	Action
	**Biohazard**.Consider all materials (specimens, reagents, controls, calibrators, and so forth) as being potentially infectious.	Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.
	**Probe hazard.** The probe is sharp and may contain biohazardous materials, including controls and calibrators.	Avoid any unnecessary contact with the probe and probe area.
	**Electrical shock hazard**. Possibility of electrical shock when instrument is plugged into the power source.	Before continuing, unplug the A^{C}•T diff analyzer from the electrical outlet.

Procedure Symbols

Procedure symbols give direction.

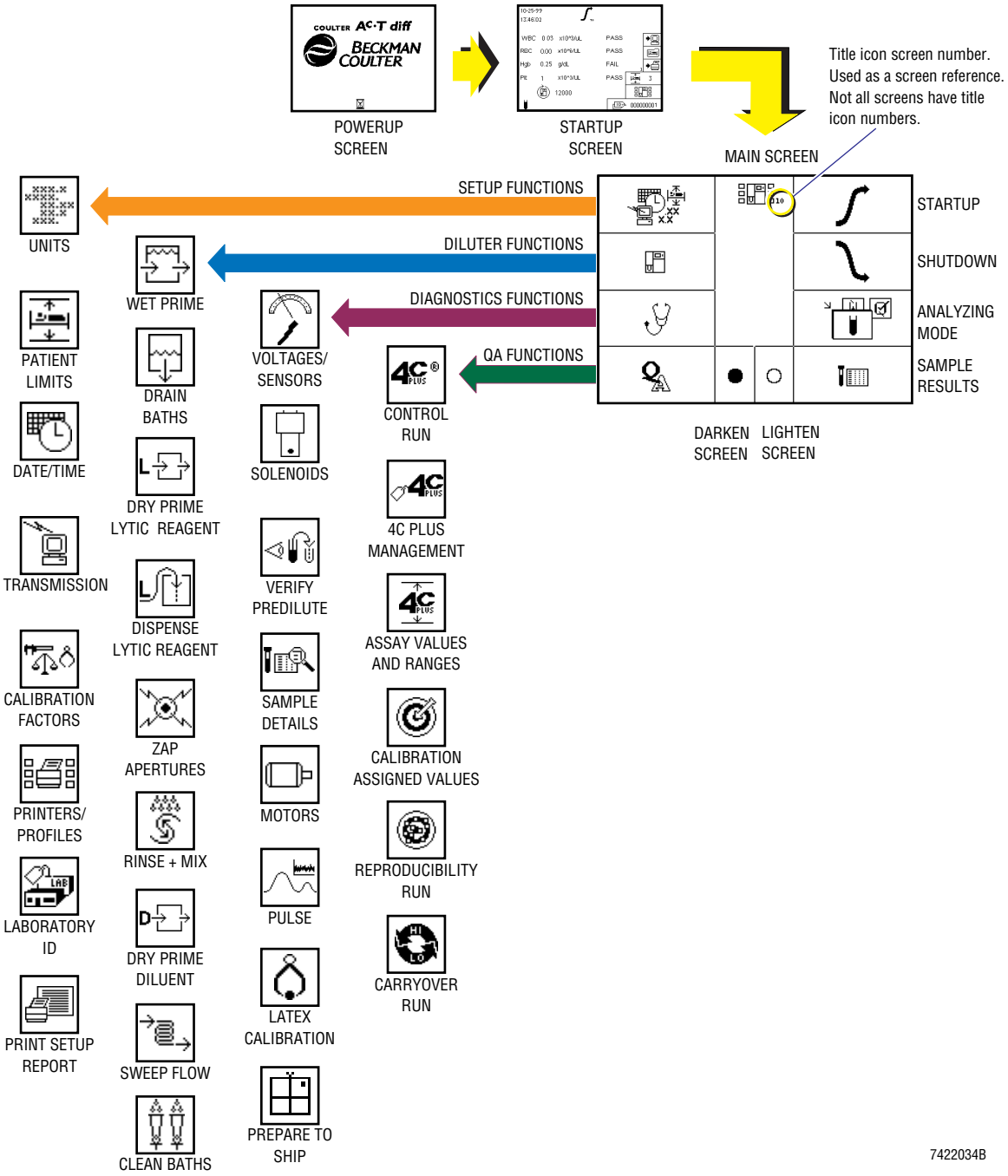
Symbol	Definition	Action
	**Go to step number**.	Go to the step number that appears after the icon.
	**Special Procedures and Troubleshooting**	See Special Procedures and Troubleshooting in the Operator's Guide for additional information.

GRAPHICS

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose.

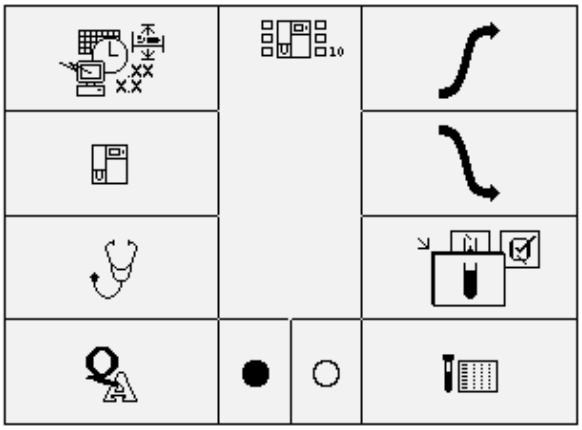
ICON TREE

Here is an overview of the icon tree. For additional information, see the next heading, TOUCH SCREEN ICONS.



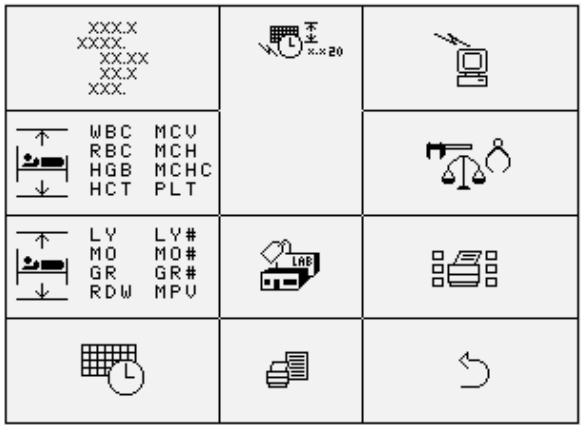
TOUCH SCREEN ICONS

Main Screen Icons



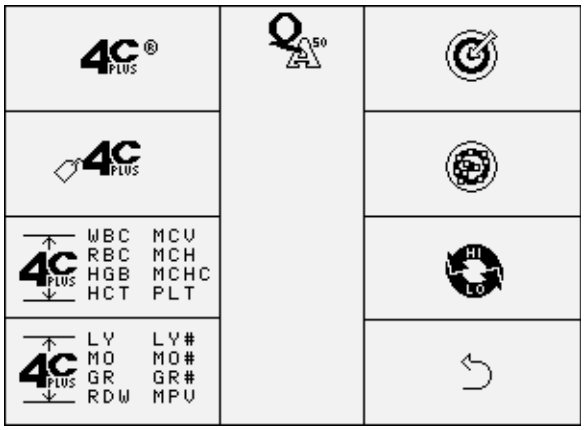
Setup	Startup
Diluter Functions	Shutdown
Diagnostics	Analyzing Mode
Quality Assurance	Whole Blood Mode
Darken Screen	Predilute Mode
Lighten Screen	A^{C}•T Tron Mode
	Sample Results Screen

Setup Screen Icons



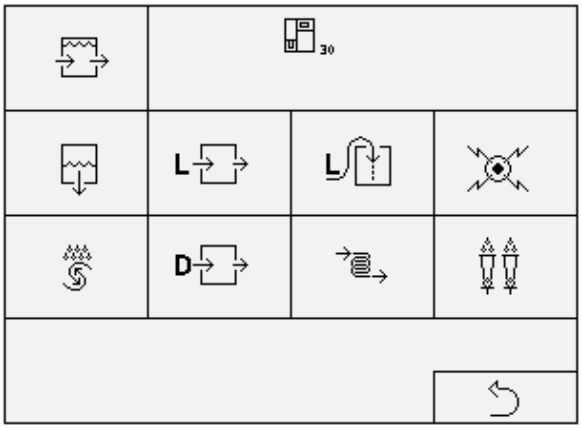
Units	Transmission
Patient Limits	Calibration Factors
Date/Time	Printers/Profiles
Laboratory ID	Exit
Print Setup Report	

QA Screen Icons



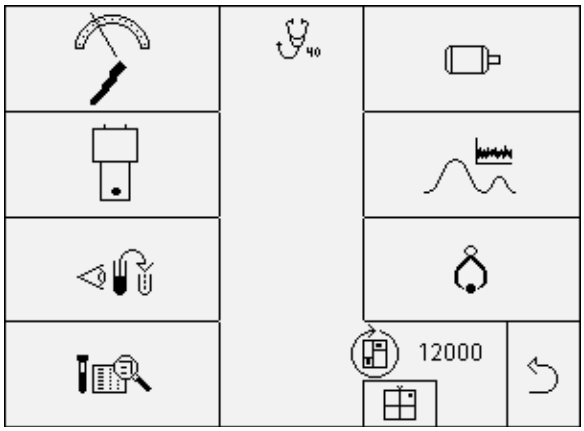
4C PLUS Run	Calibration Assigned Values
4C PLUS Management	Reproducibility Run
4C PLUS Limits	Carryover Run
	Exit

Diluter Functions Screen Icons



Wet Prime	Dispense Lytic Reagent
Drain Baths	Prime Sweepflow
Rinse + Mix	Zap Apertures
Dry Prime Lytic Reagent	Clean Baths
Dry Prime Diluent	Exit

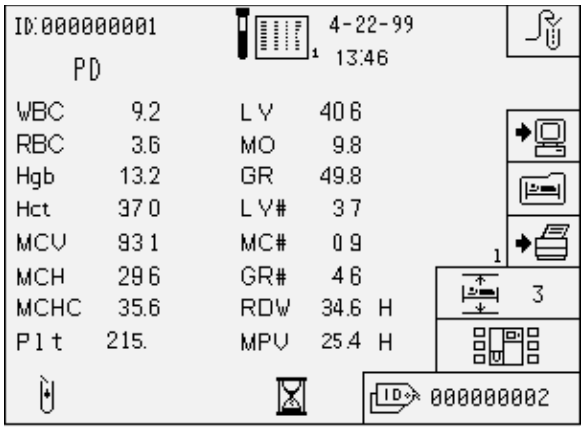
Diagnostic Functions Screen Icons



Voltages/Sensors	Motors†
Solenoids	Pulse Test
Verify Predilute	Latex Calibration
Sample Details	Prepare to Ship
Cycle Counter	Exit

†Do not use this function without proper instruction from your Beckman Coulter Representative.

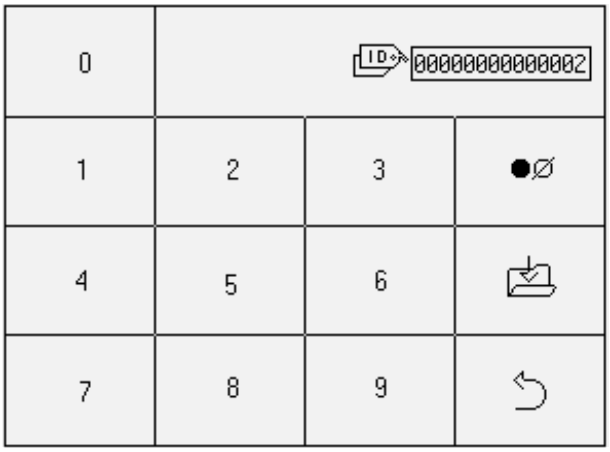
Sample Results Screen Icons



7422014B

Dispense Diluent	Go to Main Menu
Resend to Host	Next Sample ID
Retrieve Stored Data	In Progress
Print Sample Results	Patient Range

Sample ID Screen Icons



Next Sample ID	Delete
Exit	Save and Exit

1.1 INTENDED USE

General

The COULTER A^{C}•T diff analyzer (Figure 1.1) is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories.

Purpose

The purpose of the A^{C}•T diff analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.

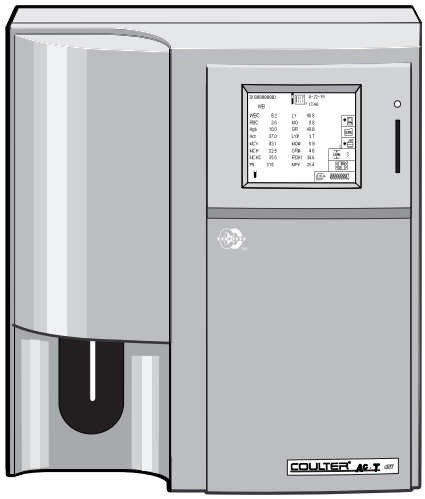


Figure 1.1 COULTER A^{C}•T diff Analyzer

Parameters

The A^{C}•T diff analyzer determines the following hematologic parameters of whole-blood specimens:

WBC	White Blood Cell or leukocyte count	
	LY#	Lymphocyte number
	LY%	Lymphocyte percent (or ratio)
	MO#	Mononuclear cell number
	MO%	Mononuclear cell percent (or ratio)
	GR#	Granulocyte number
	GR%	Granulocyte percent (or ratio)
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	
Plt	Platelet or thrombocyte count	
RDW	Red Cell (erythrocyte volume) Distribution Width	

MPV	Mean Platelet (thrombocyte) Volume
Pct‡	Plateletcrit
PDW‡	Platelet Distribution Width

‡Pct and PDW are derived parameters not intended for diagnostic use. Both parameters can be selected to be printed by selecting the 18 parameter option at the Printers/Profiles screen. The system uses the PDW value as an internal check on the reported platelet parameters, Plt and MPV.

Unless otherwise stated, all parameter results are shown in US unit format.

Features

Features of the A^{C}•T diff analyzer include: automated calibration, automated quality control evaluation, automated patient data storage, selectable print profiles, and patient ranges that can be customized.

Reports

You can print reports on a roll, ticket, or graphics printer. See the printer's operating manual for instructions on how to use the printer.

Histogram printing for the patient sample prints only if **Graphics Printer** was selected at the Printers/Profiles screen. Here are the available reporting profiles:

- CBC/Diff (default)
- WBC/Diff
- WBC/Hgb
- Hgb/Hct
- WBC/Hgb/Plt
- CBC/Plt
- CBC/Diff/Pct/PDW

1.2 METHOD HISTORY

Development

W.H. Coulter describes the Coulter principle:[1]

> A suspension of blood cells is passed thru a small orifice simultaneously with an electric current. The individual blood cells passing through 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.

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 analyzer was the first instrument that automated simultaneous multiparameter measurements on blood. Brittin et al., Gottmann, and Hamilton and Davidson, reviewed the performance and clinical value 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 interest in pathological erythrocyte size distribution, first aroused by Price-Jones.[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 error 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 discussed 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 the hydrodynamic method. Von Behrens and Paulus have also cited the feasibility of counting thrombocytes by the Coulter method.[12,13]

Hemoglobinometry

The lytic reagent prepares the blood so that leukocytes can be counted and the amount of hemoglobin sensed. The lytic reagent rapidly and simultaneously destroys the erythrocytes and converts a substantial proportion of the hemoglobin to a stable pigment, while it leaves the leukocyte nuclei intact. The absorbance of the pigment is directly proportional to the hemoglobin concentration of the sample.

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

Leukocyte Volume

Electronic leukocyte volume analysis, which is the basis of differential percentage, has been used since 1967.[15] It has been evaluated as a possible adjunct to the manual differential white cell count.[16,17,18,19]

Under the controlled condition of lysis, a chemical reaction demonstrates three distinct populations of leukocytes: lymphocytes, mononuclear cells, and granulocytes.[20] Correlation between the frequency of the different cell types using stained-film microscopy and this system is greater than 0.9 for lymphocytes and granulocytes, and 0.7 for mononuclear cells. In the absence of flags and with absolute concentration values within reference limits, a specimen can be accepted as normal with 95 percent confidence without further examination.[21] Further correlations and comparison substantiate these findings.[22-26]

1.3 CONTROLS AND CALIBRATORS

IQAP (Interlaboratory Quality Assurance Program)

Quality Assurance (QA) includes routine maintenance and service in conjunction with the use of controls and calibrators. The combination of these methods assures complete quality control and should be applied separately, or in combination, according to your laboratory, state, and federal protocols. Participation in Beckman Coulter's IQAP helps you interpret control results and correlate them with your other in-house quality control techniques. Your IQAP report will show you how your laboratory performed in comparison with other labs.

The A^{C}•T diff analyzer stores 4C® PLUS cell control results. This allows you to download your IQAP data to an old reagent management card. The number of runs, the mean and the SD for the 18 reported parameters for each level of control is calculated and loaded to the card, along with the control lot numbers and IQAP ID. For additional information on IQAP, including how to enroll in the program, contact your local Coulter Representative.

To help you determine laboratory procedures, you can purchase the Physicians Office Laboratory Guideline, POL2-T, from the National Committee for Clinical Laboratory Standards (NCCLS), 940 West Valley Road, Wayne, PA 19087-1898, USA.

Calibrator

The COULTER S-CAL® calibrator kit is a recommended alternative to the whole-blood reference method of calibration. S-CAL calibrator is traceable to reference methods and materials. Use S-CAL calibrator to ensure accurate instrument measurements.

Cell Controls

COULTER 4C PLUS cell control or COULTER A^{C}•T Tron cell control is available to supply a stable reference control for use with this system. Cell controls monitor the performance of the diluting, counting, sizing, and Hgb measurements.

Beckman Coulter suggests that you run controls daily. Federal, state or local regulatory or certification agencies may require more frequent quality control. Check with the appropriate agency for further information.

A^{C}•T Tron™ Cell Control

Available only outside of the United States of America. A^{C}•T Tron cell control monitors instrument performance for CBC parameters only.

4C® PLUS Cell Control

There are three setup files for 4C PLUS cell control where you can enter assay values and ranges. You can also print the assay setup screens. CBC assay values and ranges are displayed at the Expected Values 1 screen. Differential assay values and ranges are displayed at the Expected Values 2 screen.

The A^{C}•T diff analyzer stores up to 93 control results for each level of 4C PLUS cell control, for a possible storage capacity of 279 results (31 days x 3 runs per day x 3 levels of control).

1.4 REAGENTS

Beckman Coulter recommends these reagents. All stated performance characteristics in this manual are based on the use of the A^C•T diff analyzer with these reagents. Refer to the container's label for detailed information before using the reagent.

diff A^C•T Pak™ and diff A^C•T Tainer™ Reagent Packs

For use with the A^C•T diff analyzer, Coulter manufactures the diff A^C•T Pak reagent pack and diff A^C•T Tainer reagent pack. Both contain Reagent 1 diluent and Reagent 2 lytic reagent. The diff A^C•T Tainer reagent pack also contains A^C•T Rinse™ Shutdown Diluent, Reagent 3.

Diluent

Reagent 1 is an isotonic electrolyte solution that:

- Dilutes the whole-blood samples.
- Stabilizes cell membranes for accurate counting and sizing.
- Conducts aperture current.
- Rinses instrument components between analyses.
- Prevents duplicate cell counts by using the sweep-flow process.

Lytic Reagent

Reagent 2 is a lytic reagent that

- Lyses red blood cells (RBCs) for WBC count and hemoglobin measurement.
- Causes a differential shrinkage of leukocytes into predictable volume components.

Shutdown Diluent

A^C•T Rinse Shutdown Diluent prevents protein buildup that occurs in and around the apertures.

1.5 COMPUTER SOFTWARE

This system is run by computer software. Be sure to use only the Software Card supplied by Beckman Coulter. Observe the copyright statement on the card.

1.6 MATERIAL SAFETY DATA SHEETS (MSDS)

To obtain an MSDS for Beckman Coulter reagents used on the A^C•T diff analyzer:

1. In the USA, either call Coulter Customer Operations (800-526-7694) or write to:

   Beckman Coulter Inc.
   Attn: MSDS Requests
   P.O. Box 169015
   Miami, FL 33116-9015
2. Outside the USA, call your Coulter Representative.

2.1 DELIVERY INSPECTION

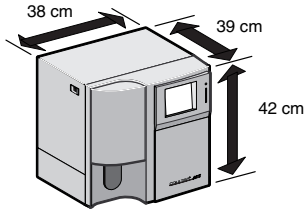
Your A^{C}•T diff analyzer is tested before it is shipped from the factory. International symbols and special handling instructions tell the carrier how to treat this electronic instrument.

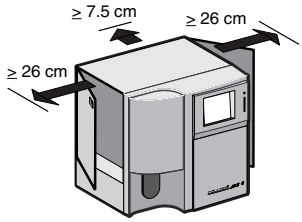
When you receive your instrument, carefully inspect the carton. If you see signs of mishandling or damage, file a claim with the carrier immediately. If the instrument is insured separately, file a claim with the insurance company.

2.2 PREINSTALLATION CHECKS

Space and Accessibility Requirements

Check the site for proper space allocation. The A^{C}•T diff analyzer doors require 26 cm to open fully. You must fully open the left door to replace the A^{C}•T Rinse™ Shutdown diluent.





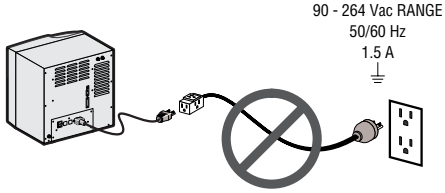
In addition to the space required for the unit itself, arrange for

- Comfortable working height.
- At least 26 cm (10 in.) on each side is the preferred access to perform service procedures.
- At least 7.5 cm (3 in.) behind for cabling and ventilation.

Power Requirements

IMPORTANT Risk of misleading results. If you use an extension cord, you could encounter electrical interference that could affect the instrument's results. Place the instrument close enough to a power outlet that an extension cord is not necessary.

Check for the availability of a power connector.



- 120/240 Vac
- 50/60 Hz
- 1.5 A
- Single phase with ground.

The power cord must plug directly into the outlet. Do not use an extension cord. This instrument requires:

- An independent protected circuit: for the printer and for the instrument itself.
- The building outlet to be properly grounded and the electrical panel to be protected against power fluctuations.
- A female receptacle outlet furnishing single-phase input power.
- A ground path capable of carrying the full current of the circuit (confirmed third-wire earth ground).

Ambient Temperature and Humidity

Keep ambient operating temperature between 16°C and 35°C (61°F and 95°F) and humidity no higher than 85 percent without condensation.

Printer

The following printers are supported for use with the A^{C}•T diff analyzer:

- Epson® ticket printer, Models TM-290P M145A and TM-U295P 011 M117A.
- Citizen® roll printer, Model iDP3110.
- Citizen® Dot Matrix Printer, Model GSX-190.
- Canon® Bubble Jet™ Printer, Model BJC®-250.
- Ithaca® PcOS® Series 90 Printer.

Safety Precautions

See Chapter 5, Precautions/Hazards for Safety information.

2.3 REAGENT CONNECTIONS

Reagent packs and the waste collection container tubing are attached to the connectors. You can place reagents below the instrument so long as they are no more than 91.4 cm (36 in.) below and you do not use more than the 182.9 cm (6 ft) of tubing provided. Do not place reagents above the instrument. See the Operator's Guide for additional information.

3.1 GENERAL PRINCIPLES

Coulter Method

The Coulter method accurately counts and sizes cells by detecting and measuring changes in electrical resistance when a particle (such as a cell) in a conductive liquid passes through a small aperture. Figure 3.1 illustrates this principle.

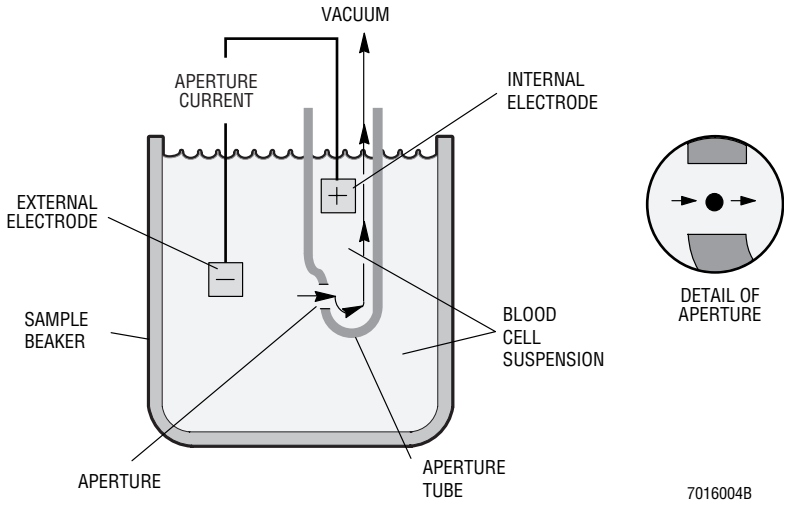


Figure 3.1 Coulter Method of Counting and Sizing

As each cell goes through the aperture, it impedes the current and causes a measurable pulse. The number of pulses signals the number of particles. The height of each pulse is proportional to the volume of that particle.

While the number of pulses indicates particle count, the amplitude of the electrical pulse produced depends on the cell's volume. Theoretical analysis of the behavior of particles within an aperture shows that the height of the electrical pulse produced by the cell is the characteristic that most nearly shows proportionality to the cell volume.[27,28,29,30]

Effect of Reagent on the Cells

In a counting system highly sensitive to the volume of the individual particles being counted, the conductive liquid, in which the particles are suspended, must have a minimum influence on their biological integrity and, thus, their size.

The reagents used for leukocyte counting must destroy erythrocytes without significantly affecting the ability to count leukocytes.They must work quickly enough to satisfy the processing time of the instrument.

3.2 NORMAL SAMPLE FLOW (Whole-Blood Mode)

1. The aspiration syringe draws 12 µL of whole blood into the probe. The instrument reads Hgb Blank 2. The WBC and RBC baths drain. The WBC bath rinses and drains. The diluent syringe dispenses diluent into the WBC bath to prefill it. The instrument reads Hgb Blank 1.

2. The probe moves to the WBC bath and the diluent and sample syringes dispense the sample (12 µL) and diluent into the WBC bath, making a 215:1 Dilution. The RBC bath rinses and mixing bubbles enter the WBC bath to mix the solution.
3. The aspiration syringe aspirates 100 µL of the 215:1 dilution into the probe for the RBC/Plt dilution. The Vacuum Isolator Chamber (VIC) drains. The RBC bath rinses and drains. The diluent syringe dispenses diluent into the RBC bath to prefill it.
4. The lytic reagent syringe sends lytic reagent to the WBC bath for a final 250:1 dilution, while the diluent and aspiration syringes dispense 100 µL of the 215:1 dilution and additional diluent into the RBC bath for a final RBC/Plt dilution of 6250:1.
5. Mixing bubbles enter the baths to mix (WBC for 2.4 seconds, RBC for 1.7 seconds) the bath contents.
6. Both dilutions (WBC and RBC/Plt) are drawn through the apertures via regulated vacuum.
7. The instrument counts for 12 seconds (three consecutive periods of 4 seconds each) to count the WBCs, RBCs and Plts. After counting finishes, the flow ends.
8. The RBC bath drains and rinses. The VIC drains. The instrument takes an Hgb sample reading.
9. The WBC drains and the instrument analyzes the data.
10. The WBC rinses. The VIC drains. The instrument analyzes the WBC count.
11. The WBC drains. The instrument displays results on the screen and prints the results (if a printer is available) and sends data to the host computer if available.
12. The WBC rinses. The probe moves to the aspirate position.
13. The VIC drains. The instrument zaps the apertures. The cycle counter increments as the diluent reservoir fills. The instrument is ready for the next sample.

3.3 COUNTING AND SIZING

The A^{C}•T diff analyzer uses triplicate counting, internal voting criteria and proprietary flagging algorithms to maximize the accuracy of results and confirm parameter results prior to reporting. After the computer corrects for coincidence, it compares the three counts each for WBC, RBC, and Plt. If the unit finds disagreement among all count periods or does not meet other internal criteria, the instrument displays a total voteout.

Red and White Cell Counting

Each bath has an aperture: one for counting RBC/Plt and one for counting WBC. The counts take place concurrently. The system draws the WBC dilution through the WBC aperture while it draws the RBC/Plt dilution through the RBC/Plt aperture. The system counts for three consecutive periods of 4 seconds each.

During the RBC count, pulses that represent cells of 36 fL or greater are classified as red cells. During the WBC count, pulses that represent cells of 35 fL or greater are classified as white cells.

Both counts then go to the computer for coincidence correction and voting.

The count cycle is monitored for abnormal variations using the Aperture Alert (see Aperture Alert heading).

Coincidence Correction

Depending upon concentration, more than one cell can go through the aperture at the same time. When cells coincide, however, the analyzer counts only one pulse. The frequency of coincidence is proportional to the concentration. The system corrects results for coincidence.

Voting

After the computer corrects for coincidence, it compares the three counts each for RBC, WBC, Plt, MCV, RDW, MPV, and differential parameters.

If there is disagreement among all three count periods for WBC, RBC, Plt, MCV, RDW, and MPV, there is a total voteout and dashes (- - - - -) appear on the display and the printout instead of results for the affected parameter.

WBC Count and Size Distribution

During the WBC sensing period, pulses that represent cells 35 fL to 450 fL are classified as white cells and are stored by size into 256 channels to build a histogram. Using a system of moving averages, the histogram curve is smoothed.

If the WBC distribution criteria are not met, an * flag (Review Results) appears next to the affected parameters.

RBC Count and Size Distribution

During RBC sensing, pulses that represent cells 36 fL and larger are classified as RBCs.

If the RBC distribution criteria are not met, an * flag (Review Results) appears next to the affected parameters.

Plt Count and Size Distribution

During RBC sensing, pulses from 2 fL to 20 fL are classified as platelets. To ensure that the Plt count accurately reflects the cell population, whenever the Plt data accumulation is below a predetermined value, Plt sensing is extended for up to eight 3-second sensing periods. The extended time is taken into consideration in the Plt calculations. Platelet pulses are sorted by size into 64 channels to produce a platelet histogram. The computer then checks to see if the Plt distribution fits the curve criteria that represent platelets from 0 fL to 70 fL. If the curve criteria are not met, there is a no-fit condition, and an * flag (Review Results) appears in the flag area.

Sweep Flow

The sweep flow is a steady stream of diluent that flows behind the RBC aperture during RBC/Plt sensing. This keeps cells from swirling back into the sensing zone and being counted as platelets. See Figure 3.2.

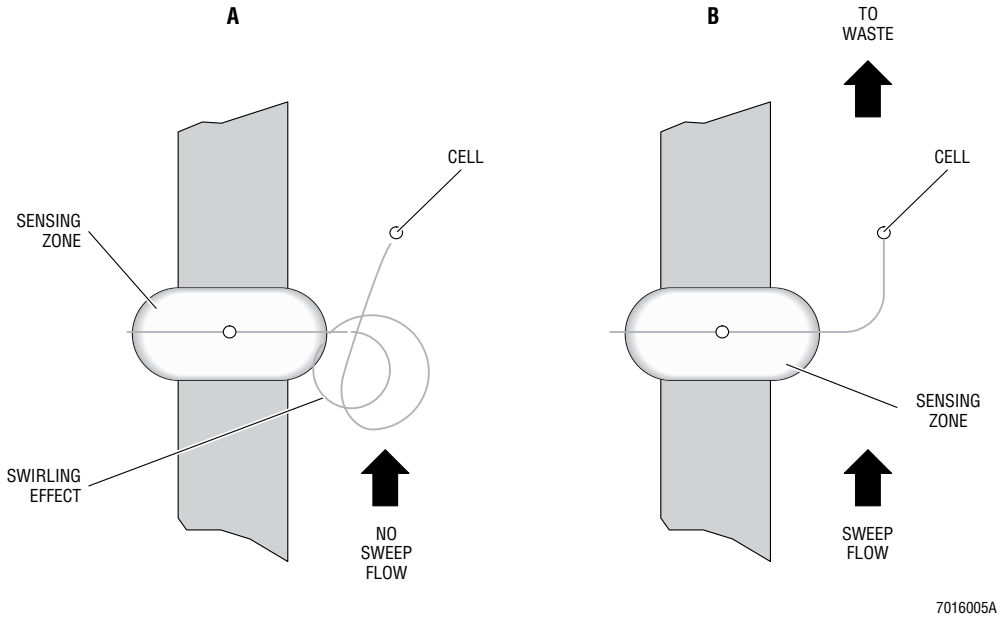


Figure 3.2 Sweep Flow

Histograms

The WBC, RBC and Plt printed histograms are a representation of the cell populations and the curves show the relative, not actual, number of cells in each size range.

Computed and Derived Parameters

The computer:

- Computes Hct, MCH, MCHC, LY#, GR#, and MO#.
- Derives MCV and RDW from the RBC histogram.
- Derives MPV and Plt count from the Plt histogram.
- Derives LY%, MO%, and GR% from the WBC histogram.

Aperture Alert

During the count and accumulation process the system monitors the condition in the aperture and the pulses being produced to confirm the validity of the data being collected.

The intention of this process is to minimize the possibility of reporting erroneous results caused by a partial or transient aperture clog or by other aperture disturbances.

If the system detects that one or more of the monitored criteria fails the internal limits, the results will be inhibited with XXXXX. If only a single criterion fails, the results will be flagged for review with an X.

In rare instances, a transient or partial aperture blockage may not be detected by the voting and Aperture Alert methods. Therefore, flagged results for accuracy should be reviewed; also review any result that exceeds your patient reference ranges.

3.4 MEASUREMENT OF HEMOGLOBIN CONCENTRATION

The system uses the lysed WBC dilution to measure Hgb. The absorbance of light from an incandescent lamp is measured at 525 nm through the optical path length of the bath. A beam of light from the lamp passes through the sample, through a 525-nm filter, and is measured by a photodiode. The signal is amplified and the voltage is measured and compared to the blank reference reading.

3.5 DERIVATION OF PARAMETERS

Mathematic expressions in this section are in US units of measurement. You can change the units of measurement in the instrument software (see Customize Software in the appropriate Installation and Training Guide).

White Blood Cell (WBC) Count

WBC is the number of leukocytes measured directly, multiplied by a calibration constant. Expressed in thousands of leukocytes per microliter of whole blood.

$$\text{WBC} = n \times 10^3 \text{ cells per } \mu\text{L}$$

Red Blood Cell (RBC) Count

RBC is the number of erythrocytes measured directly, multiplied by a calibration constant. Expressed in millions of erythrocytes per microliter of whole blood.

$$\text{RBC} = n \times 10^6 \text{ cells per } \mu\text{L}$$

Platelet (Plt) Count

Plt is the number of thrombocytes derived from directly measured platelet pulses, multiplied by a calibration constant. Expressed in thousands of thrombocytes per microliter of whole blood.

$$\text{Plt} = n \times 10^3 \text{ cells per } \mu\text{L}$$

Hemoglobin (Hgb) Concentration

Hgb is determined from the absorbance computed from the ratio of the blank to the sample photocurrent readings. This number is multiplied by a constant and expressed in grams of hemoglobin per deciliter of whole blood.

$$\text{Hgb (g/dL)} = \text{Calibration Factor} \times \text{Calibration Constant} \times \text{Absorbance}$$

$$\text{Absorbance} = \text{Log}_{10}\left(\frac{\text{Blank Photocurrent}}{\text{Sample Photocurrent}}\right)$$

Mean Corpuscular Volume (MCV)

MCV is determined by measuring the average volume of individual erythrocytes. This number is multiplied by a coincidence correction factor and a calibration factor. The reported value expresses MCV in femtoliters.

Hematocrit (Hct)

This is the computed relative volume of erythrocytes, expressed in percent.

$$\text{Hct (\%)} = \frac{\text{RBC} \times \text{MCV}}{10}$$

Mean Corpuscular Hemoglobin (MCH)

This is the computed weight of hemoglobin in the average erythrocyte, expressed in picograms.

$$\text{MCH (pg/cell)} = \frac{\text{Hgb}}{\text{RBC}} \times 10$$

Mean Corpuscular Hemoglobin Concentration (MCHC)

This is the computed average weight of hemoglobin in a measured dilution, expressed in grams of hemoglobin per deciliter of erythrocytes.

$$\text{MCHC (g/dL)} = \frac{\text{Hgb}}{\text{Hct}} \times 100$$

Mean Platelet Volume (MPV)

MPV is the average volume of individual platelets derived from the Plt histogram. It represents the mean volume of the Plt population under the fitted Plt curve multiplied by a calibration constant, and expressed in femtoliters (fL).

Red Cell Distribution Width (RDW)

RDW represents the size distribution spread of the erythrocyte population derived from the RBC histogram. It is the coefficient of variation (CV) expressed in percent of the RBC size distribution.

Coulter Histogram Differential

Percentages

The percentage of leukocytes that fall into each of the three population categories is derived from the WBC histogram. See Figure 3.3. Region marks (1 to 4) on the baseline show approximate boundaries for the LY, MO, and GR population.

- The LY area is approximately from 35 fL to 90 fL.
- The MO area is approximately from 90 fL to 160 fL.
- The GR area is approximately 160 fL to 450 fL.

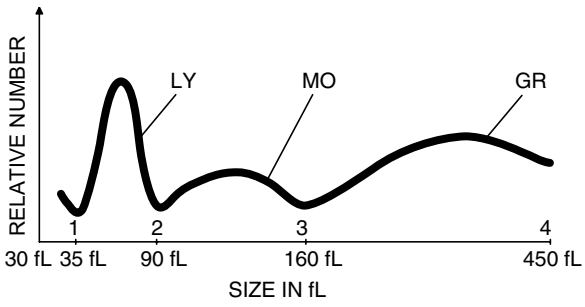


Figure 3.3 WBC Histogram Areas and Regions

- LY% is the relative number of leukocytes that are lymphocytes, expressed in percent.
- MO% is the relative number of leukocytes that are mononuclear cells, expressed in percent.
- GR% is the relative number of leukocytes that are granulocytes, expressed in percent.

$$LY\% = \frac{\text{no. of cells inside LY area}}{\text{no. of cells inside LY + MO + GR}} \times 100$$

$$MO\% = \frac{\text{no. of cells inside MO area}}{\text{no. of cells inside LY + MO + GR}} \times 100$$

$$GR\% = \frac{\text{no. of cells inside GR area}}{\text{no. of cells inside LY + MO + GR}} \times 100$$

Absolute Numbers

Absolute numbers of leukocytes in each category are computed from the differential percentages and the WBC count.

- LY# is the number of lymphocytes computed from the WBC count and expressed in thousands of leukocytes per microliter of whole blood.

$$LY\# = (10^3 \text{cells}/\mu L) = \frac{LY\%}{100} \times \text{WBC count}$$

- MO# is the number of mononuclear cells computed from the WBC count and expressed in thousands of mononuclear cells per microliter of whole blood.

$$MO\# = (10^3 \text{cells}/\mu L) = \frac{MO\%}{100} \times \text{WBC count}$$

- GR# is the number of granulocytes computed from the WBC count and expressed in thousands of granulocytes per microliter of whole blood.

$$GR\# = (10^3 \text{cells}/\mu L) = \frac{GR\%}{100} \times \text{WBC count}$$

4.1 INSTRUMENT SPECIFICATIONS

Dimensions/Weight

Width 38 cm (15 in.)
Height 42 cm (16.5 in.)
Depth 39 cm (15.4 in.)
Weight 14 kg (30 lb)

Power

Input

100 ±10%, 50/60 Hz
120 ±10%, 50/60 Hz
220 ±10%, 50/60 Hz
240 ±10%, 50/60 Hz

Note: For international applications, the electrical input line cord of the instrument may be replaced with an equivalent grounded and shielded line cord, to meet local wiring codes or ac plug standards. Use these specifications:

Voltage rating:	120-240 VRMS
Current rating:	6 A
Wire size:	3-18 AWG, Diameter = 1.19 mm, 41 x 34, stranded ASTM B-3
Color code:	International CEE standard 7
Shield:	Braided tinned copper, 85% coverage minimum (connected to earth at coupler connector)
Approvals:	UL listed, CSA approved, or applicable national standard

Consumption

Less than 120 W

Installation Category

Category II per IEC 1010-1

Temperature, Ambient Operating

16°C to 35°C (61°F to 95°F)

Humidity

20% to 85% without condensation

Recommended Reagents

diff A^{C}•T Pak or diff A^{C}•T Tainer reagent packs, both of which contain diluent (Reagent 1) and lytic reagent (Reagent 2).

A^{C}•T Rinse Shutdown Diluent (Reagent 3) prevents protein buildup that occurs in and around the apertures.

Recommended Controls

- 4C PLUS cell control: abnormal low, normal and abnormal high, or
- A^{C}•T Tron cell control (CBC parameters only). **Available only outside of the United States of America.**

Recommended Calibrator

S-CAL calibrator.

Recommended Anticoagulant

A salt of EDTA (K_2, K_3, or Na_2) with the proper proportion of blood to anticoagulant, as specified by the tube manufacturer.

Sample Volume Aspirated

12 µL whole blood in whole blood analyzing mode
735 µL prediluted blood in predilute analyzing mode

Aperture Size

WBC 100 µm x 75 µm

RBC 50 µm x 60 µm

Data Storage

Storing Patient Results

The A^{C}•T diff analyzer automatically stores up to 250 patient results, (numerical only, excluding histograms) which may be recalled by date of analysis.

Storing 4C PLUS Cell Control Results

The A^{C}•T diff analyzer stores up to 93 control results for each level of 4C PLUS Cell Control, for a possible storage capacity of 279 results (31 days x 3 runs per day x 3 levels of control).

Throughput

A minimum of 50 samples per hour with results displayed in 60 seconds or less.

Sample Identification

Mandatory sample identification. Configurable to autoincrement a 9 digit identification number or allow manual entry of up to 14 digits.

Output

The system can transmit startup, sample, and control data to a host computer.

Sample Results screen shows sample identification number, sample mode, sample results and any sample result flags.

The system provides a printout of all data. The printed report includes:

- date of analysis
- time of analysis
- mode of analysis
- sample ID#
- parameter results and flags
- header showing laboratory information, if entered
- histograms (if using a graphics printer).

See Figure 4.1 for an example of a report printed on a graphics printer for a sample run in whole blood mode.

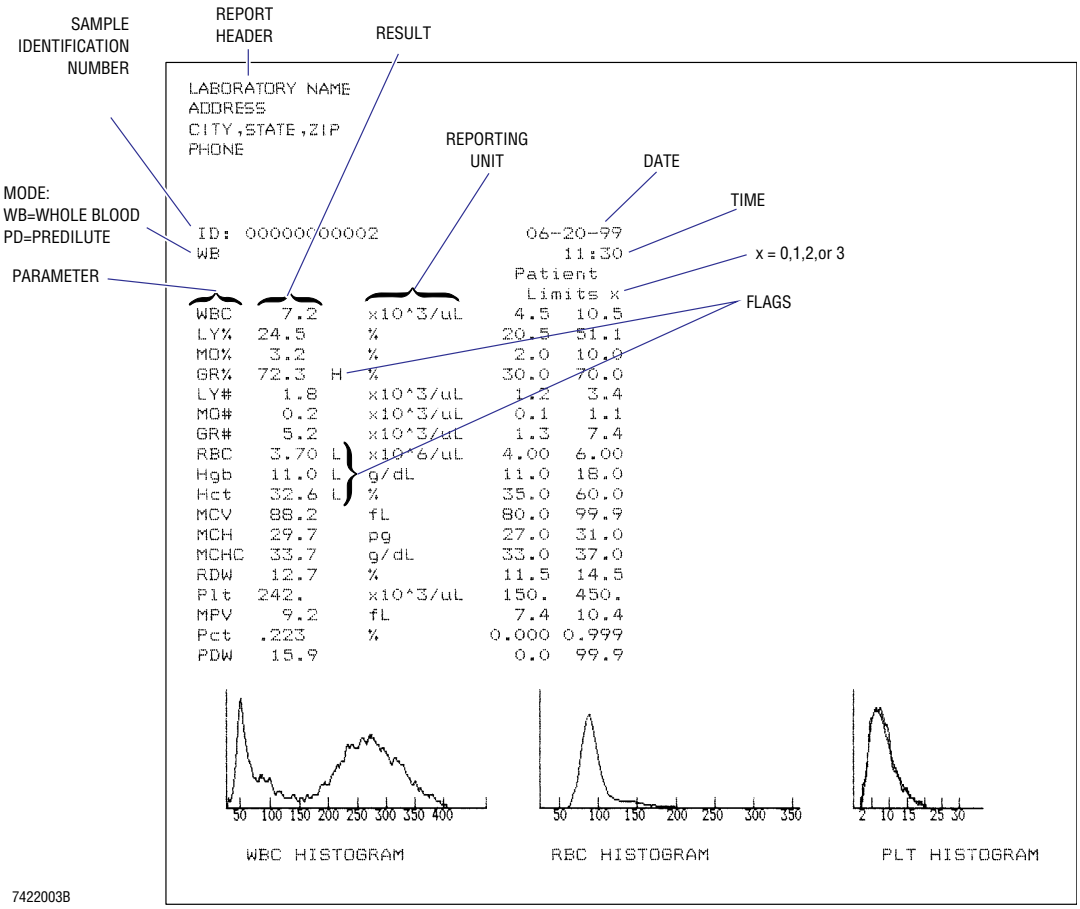


Figure 4.1 Sample Report for Whole Blood Mode

4.2 PERFORMANCE SPECIFICATIONS

The performance specifications stated apply only to an instrument that has been properly maintained as indicated in Special Procedures and Troubleshooting in the Operator's Guide, using a recommended reagent system.

Imprecision

Imprecision is based on 31 replicate determinations of the same sample. Imprecision limits for the Complete Blood Count (CBC) parameters are specified as a coefficient of variation (CV); the imprecision limits for the diff parameters (LY%, MO%, and GR%) are specified as a Standard Deviation (SD).

Results are acceptable when the %CV or SD values, as appropriate, are within the limits in Table 4.1.

Table 4.1 Imprecision Specifications

Parameter	Level	Units	CV%	SD
WBC	6.0 - 15.0	x 10^3 cells/µL	≤3.0	
RBC	3.00 - 6.00	x 10^6 cells/µL	≤3.0	
Hgb	12.0 - 18.0	g/dL	≤2.0	
MCV	80.0 - 100.0	fL	≤3.0	
Plt	200 - 500	x 10^3 cells/µL	≤7.0	
MPV	5.0 - 20.0	fL	≤3.0	
RDW	12.0 - 15.0	%	≤3.0	
LY	20 - 50	%		≤1.5
MO	2.0 - 10.0	%		≤1.5
GR	30.0 - 70.0	%		≤3.0

Operating Range

The operating range listed in Table 4.2 is the range of results over which the A^C•T diff instruments display, print and transmit results. The A^C•T diff analyzer flags values between the linear range and the operating range.

Table 4.2 Operating Range

Parameter	Range	Units
WBC	0.0 - 150	x 10^3 cells/µL
RBC	0.00 - 8.00	x 10^6 cells/µL
Hgb	00.0 - 30.0	g/dL
MCV	50.0 - 130.0	fL
Plt	000 - 3000	x 10^3 cells/µL
MPV	5.0 - 20.0	fL
LY	0 - 100	%

Table 4.2 Operating Range *(Continued)*

Parameter	Range	Units
MO	0 - 100	%
GR	0 - 100	%
LY#	0 - 99.9	x 10^3 cells/µL
MO#	0 - 99.9	x 10^3 cells/µL
GR#	0 - 99.9	x 10^3 cells/µL

Accuracy

Accuracy of the instrument is adjustable to within the resolution of the readout to agree with a predetermined reference value at any point in the operating range. Accuracy for WBC, RBC, Hgb and Plt is a correlation coefficient of greater than or equal to 0.95. The mean difference or mean percent differences for all parameters is within the limits in Table 4.3 and Table 4.4.

Accuracy of the differential parameters is specified using mean difference (in units %) when LY%, MO%, and GR% have a mean difference equal to or less than ±5.0%.

Accuracy determination must be performed on a valid data set (that is, acceptable performance of calibration, linearity and precision) as compared to a Beckman Coulter instrument with Coulter Histogram Differential (CHD).

Table 4.3 CBC Accuracy at 20-25°C

Parameter		Difference (whichever is greater)	95% Confidence
WBC	# 0 - 2.0	±0.3 or ±5%	±0.3 x 10^3 cells/µL
	2.1 - 4.0	±0.3 or ±5%	±0.4 x 10^3 cells/µL
	≥ 4.1	±0.3 or ±5%	±14%
RBC		±0.05 or ±5%	±10.0%
Hgb		±0.2 or ±3%	±8.0%
MCV		±5.0%	±6.0%
Plt	0 - 50	±10.0 or ±10%	±15.0 x 10^3 cells/µL
	51-250	±10.0 or ±10%	±30%
	251-500	±10.0 or ±10%	±60 x 10^3 cells/µL
	501-999	±10.0 or ±10%	±12%
MPV		±1.0 or 5%	±15%
RDW		±0.75 or 6%	±13%
LY%		±5.0	
MO%		±5.0	
GR%		±5.0	

Table 4.4 CBC Accuracy at 16-35°C

Parameter		Difference (whichever is greater)	95% Confidence
WBC	# 0 - 2.0	±0.4 or ±5%	±0.4 x 10^3 cells/µL
	2.1 - 4.0	±0.4 or ±5%	±0.5 x 10^3 cells/µL
	≥ 4.1	±0.4 or ±5%	±15%
RBC		±0.4 or ±5%	±12.0%
Hgb		±0.5 or ±5%	±10.0%
MCV		±5.0%	±6.0%
Plt	0 - 50	±20.0 or ±10%	±25 x 10^3 cells/µL
	51-250	±20.0 or ±10%	±35%
	251-500	±20.0 or ±10%	±70 x 10^3 cells/µL
	501-999	±20.0 or ±10%	±15%
MPV	5.0 - 20.0 fL	±1.0 or 5%	±15%
RDW	12 - 15%	±0.75 or 6%	±13%
LY%		±5.0	
MO%		±5.0	
GR%		±5.0	

Individual CBC parameter results flagged by algorithm generated flags or replaced by non-numeric values are excluded from analysis.

Linearity

When tested using a stable sample having no interfering substances, the A^C•T diff instrument values are equal to the expected value within the limits in Table 4.5. To get these same results, subtract background counts from the A^C•T diff instrument values and take multiple readings at each point to eliminate statistical effects of imprecision. Linearity limits apply only to directly measured parameters.

Table 4.5 Linearity Limits

Parameter	Linearity Range	Units	Difference (whichever is greater)
WBC	0 - 99.9	x 10^3 cells/µL	±0.3 or ±5.0%
RBC	0 - 7.0	x 10^6 cells/µL	±0.05 or ±5.0%
Hgb	0 - 25.0	g/dL	±0.2 or ±3.0%
Plt	0 - 999.0	x 10^3 cells/µL	±10.0 or ±10.0%

Background Counts

See Table 4.6 for the maximum acceptable background counts.

Table 4.6 Background Counts

Parameter	Units	Count
WBC	x 10^3 cells/µL	≤0.4
RBC	x 10^6 cells/µL	≤0.04
Hgb	g/dL	≤0.2
Plt	x 10^3 cells/µL	≤7.0

Carryover

The maximum acceptable high-to-low carryover is less than or equal to 2.0%.

Mode to Mode

The mean difference between the whole-blood mode and the predilute mode will be no greater than 5% for the RBC and Hgb parameters when the two modes are compared at identical temperatures using a predilution prepared by the instrument.

4.3 PERFORMANCE CHARACTERISTICS

Imprecision

Imprecision is stated in terms of Coefficient of Variation for the CBC parameters and Standard Deviation for the diff parameters. Imprecision was determined by simple replicate testing (n=31) with normal whole blood, 4C PLUS cell control at three different levels and by difference analysis of paired tests with clinical specimens. See Tables 4.7 through 4.10.

Table 4.7 Imprecision, Whole Blood in K_3EDTA

Parameter	Units	Mean	SD	CV%
WBC	x 10^3 cells/µL	7.6	0.10	1.56
RBC	x 10^6 cells/µL	4.31	0.05	1.11
Hgb	g/dL	12.3	0.10	0.95
MO	fL	84.7	0.40	0.49
Plt	x 10^3 cells/µL	228.0	8.00	3.44
MPV	fL	9.0	0.20	2.05
RDW	%	13.8	0.20	1.42
LY	%	35.2	0.60	1.61
MO	%	5.9	0.80	14.25
GR	%	58.9	0.80	1.32

Table 4.8 Imprecision, 4C PLUS Normal Cell Control

Parameter	Units	Mean	SD	CV%
WBC	x 10^3 cells/µL	8.94	0.10	1.15
RBC	x 10^6 cells/µL	4.134	0.05	1.14
Hgb	g/dL	12.72	0.14	1.12
MCV	fL	86.31	0.24	0.28
Plt	x 10^3 cells/µL	221.63	6.96	3.14
MPV	fL	9.97	0.14	1.45
RDW	%	13.25	0.26	1.98
LY	%	42.52	0.89	2.08
MO	%	11.61	0.61	5.27
GR	%	45.88	0.83	1.80

Table 4.9 Imprecision, 4C PLUS Abnormal Low Cell Control

Parameter	Units	Mean	SD	CV%
WBC	x 10^3 cells/µL	4.05	0.07	1.62
RBC	x 10^6 cells/µL	2.41	0.03	1.33
Hgb	g/dL	6.74	0.11	1.61
MCV	fL	80.98	0.50	0.62
Plt	x 10^3 cells/µL	68.87	3.15	4.57
MPV	fL	10.14	0.19	1.86
RDW	%	15.26	0.20	1.28
LY	%	31.55	1.01	3.21
MO	%	10.68	0.73	6.81
GR	%	57.77	1.02	1.77

Table 4.10 Imprecision, 4C PLUS Abnormal High Cell Control

Parameter	Units	Mean	SD	CV%
WBC	x 10^3 cells/µL	18.62	0.23	1.24
RBC	x 10^6 cells/µL	5.30	0.06	1.08
Hgb	g/dL	17.80	0.19	1.06
MCV	fL	93.68	0.45	0.48
Plt	x 10^3 cells/µL	434.16	10.29	2.37
MPV	fL	10.93	0.14	1.30
RDW	%	13.35	0.27	2.05
LY	%	48.31	0.62	1.29
MO	%	15.96	0.52	3.27
GR	%	35.73	0.63	1.75

Accuracy

Accuracy for the CBC and differential parameters was defined as the agreement between the comparator instrument and the A^C•T diff analyzer using clinical specimens with values covering the expected range of performance. Estimates of agreement were made by pair-difference analysis. The magnitude of the Mean Difference or Mean Percent Difference as well as the correlation coefficient express accuracy. See Tables 4.11 through 4.13.

Non-numeric results and results accompanied by instrument/algorithm generated flags for the A^C•T diff analyzer or comparator instrument were then excluded from the data used in the accuracy analysis.

Only parameters affected by individual flags were removed from the accuracy analysis. The "N" number for each parameter in the accuracy analysis may therefore vary.

Table 4.11 Accuracy, Compared Samples 20-25°C, Whole Blood Mode

Parameter	Units	N	Population Minimum	Population Maximum	Mean Diff	SD	Mean% Diff	Correlation Coefficient
WBC	x 10^3 cells/µL	121	1.40	68.3	0.20	0.34	2.41	0.9996
RBC	x 10^6 cells/µL	154	1.75	6.26	0.05	0.04	1.51	0.9992
Hgb	g/dL	157	5.70	18.80	0.24	0.14	2.03	0.9990
MCV	fL	154	67.70	118.40	-1.76	1.06	-1.94	0.9878
Plt	x 10^3 cells/µL	129	42.00	848.00	-4.67	17.97	-3.11	0.9946
MPV	fL	130	6.60	14.20	-0.21	0.40	-1.98	N/A
RDW	%	144	11.40	21.90	0.74	0.47	5.34	N/A
LY	%	93	8.00	54.40	0.99	1.91	N/A	N/A
MO	%	90	1.90	13.00	0.97	1.80	N/A	N/A
GR	%	95	36.00	86.10	-2.03	2.10	N/A	N/A

Table 4.12 Accuracy, Compared Samples 16-20°C, Whole Blood Mode

Parameter	Units	N	Population Minimum	Population Maximum	Mean Diff	SD	Mean% Diff	Correlation Coefficient
WBC	x 10^3 cells/µL	30	3.1	13.5	0.13	0.11	2.30	0.9989
RBC	x 10^6 cells/µL	30	3.67	6.08	-0.03	0.05	-0.55	0.9959
Hgb	g/dL	30	11.6	16.5	0.30	0.11	0.27	0.9944
MCV	fL	30	71.8	100.8	-2.12	0.86	-2.34	0.9899
Plt	x 10^3 cells/µL	30	174	418	-9.06	13.19	-4.32	0.9810
MPV	fL	30	6.9	10.4	-0.18	0.25	-1.94	N/A
RDW	%	30	11.8	15.3	-0.46	0.33	-3.56	N/A
LY	%	30	15.5	39.7	-1.45	1.14	N/A	N/A
MO	%	30	3.0	10.8	1.09	1.81	N/A	N/A
GR	%	30	51.8	79.7	0.36	2.16	N/A	N/A

Table 4.13 Accuracy, Compared Samples 30-35°C, Whole Blood Mode

Parameter	Units	N	Population Minimum	Population Maximum	Mean Diff	SD	Mean% Diff	Correlation Coefficient
WBC	x 10^3 cells/µL	26	4.10	11.70	0.16	0.13	2.49	0.9981
RBC	x 10^6 cells/µL	26	3.91	5.42	0.19	0.07	3.98	0.9865
Hgb	g/dL	26	11.90	15.80	-0.20	0.18	-1.42	0.9961
MCV	fL	26	82.60	95.00	-1.58	0.88	-1.77	N/A
Plt	x 10^3 cells/µL	26	142.00	349.00	-1.20	15.01	-1.35	0.9823
MPV	fL	26	7.00	10.60	0.10	0.24	-1.01	N/A
RDW	%	26	11.70	15.00	0.17	0.35	1.39	N/A
LY	%	26	19.30	42.50	2.19	1.79	N/A	N/A
MO	%	26	3.90	10.60	-1.67	2.33	N/A	N/A
GR	%	26	50.40	74.70	-0.53	2.16	N/A	N/A

Reference Ranges

A Normal Range Study was conducted to assess the Reference Ranges for the A^C•T diff analyzer. Whole-blood samples were collected from 50 donors (equal numbers of males and females). The selection of donors was consistent with guidelines stated in NCCLS, C28-A. See Table 4.14.

Table 4.14 Normal Population Study

Parameter	Units	Sex	Mean	95% Confidence Low Limit	95% Confidence High Limit
WBC	x 10^3 cells/µL	M/F	6.37	3.40	10.77
RBC	x 10^6 cells/µL	M/F	4.50	3.83	5.21
Hgb	g/dL	M/F	13.43	11.74	15.41
Hct	ratio	M/F	39.28	34.53	44.43
MCV	fL	M/F	87.46	79.23	96.04
MCH	pg	M/F	29.89	26.71	32.80
MCHC	g/dL	M/F	34.17	33.04	35.21
Plt	x 10^3 cells/µL	M/F	227.03	138.50	333.0
RDW	%	M/F	13.56	12.26	15.10
MPV	fL	M/F	8.57	6.96	10.13
LY	%	M/F	31.25	12.10	44.10
MO	%	M/F	6.45	3.20	10.10
GR	%	M/F	62.23	50.50	80.90

Carryover

Carryover (Table 4.15) was measured by analyzing three consecutive samples of normal whole blood (H1, H2, H3) followed by three consecutive blank cycles (air) (L1, L2, L3). This sequence was repeated 10 times. Mean Values for each directly measured parameter (WBC, RBC, Hgb, Plt) for each sample type (L1, L2, L3, and H1, H2, H3) were calculated. These Mean Values were then used in the following calculation:

High-to-Low Carryover (H/L%):= [(L1 - L3)/(H3)] x 100

Table 4.15 Imprecision Analysis By Carryover, Whole Blood Mode

Parameter	Units	High To Low Carryover
WBC	%	0.15
RBC	%	0.06
Hgb	%	0.00
Plt	%	0.07

Mode to Mode

Mode-to-mode testing (Table 4.16) included analysis of normal and abnormal whole blood specimens in both the Whole Blood and Predilute modes on the A^{C}•T diff analyzer. The Mean Values for WBC, RBC, Hgb, and Plt for each mode were calculated. The individual differences, the average expressed as a mean, and the mean percent difference for each of the four parameters were calculated.

Table 4.16 Whole Blood Mode vs. Predilute Mode

Parameter	N	Whole Blood Mean	Predilute Mean	Mean Diff	Mean % Diff
WBC	73	12.70	12.97	0.27	3.93
RBC	98	4.17	4.21	0.03	0.78
Hgb	109	12.46	12.57	0.11	0.89
Plt	82	242.38	249.35	6.97	3.11

4.4 INTERFERING SUBSTANCES

Beckman Coulter recommends you use K_3EDTA as the anticoagulant. You may also use K_2EDTA and Na_2EDTA. Use of other anticoagulants can yield misleading results.

The presence of certain interfering substances, as listed in this section, can also yield misleading results.

WBC

Certain unusual RBC abnormalities that resist lysing, nucleated RBCs, fragmented WBCs, any unlysed particles greater than 35 fL, very large or aggregated platelets as when anticoagulated with oxalate or heparin.[31,32,33,34]

RBC

Very high WBC count, high concentration of very large platelets, agglutinated RBCs and RBCs smaller than 36 fL.[35,36]

Hgb

Very high WBC count, severe lipemia, certain unusual RBC abnormalities that resist lysing, anything that increases the turbidity of the sample such as elevated levels of triglycerides.[37]

MCV

Very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments that fall below the 36-fL threshold, rigid RBCs.[29,35,37,38]

Plt

Very small red blood cells near the upper threshold, cell fragments, clumped platelets as with oxalate or heparin, platelet fragments or cellular debris near the lower platelet threshold.[29,33,34,38]

Hct

Known factors that interfere with the parameters used for its computation, RBC and MCV.

MCH

Known factors that interfere with the parameters used for its computation, Hgb and RBC.

MCHC

Known factors that interfere with the parameters used for its computation, Hgb, RBC and MCV.

MPV

Known factors that interfere with the Plt count and shape of the histogram, known effects of EDTA.[39]

RDW

Very high WBC count, high concentrations of very large or clumped platelets as in blood anticoagulated with oxalate or heparin, RBCs below the 36 fL threshold, two distinct populations of RBCs, RTC agglutinates, rigid RBCs.[29,33,34,38]

Diff Parameters (LY, MO, GR)

Known factors that affect the WBC count as listed above, high triglycerides that can affect lysing.

5.1 DEFINITIONS

Warnings

Anything that can cause user injury is considered a hazard. A hazardous condition is noted in the text as WARNING. Warnings appear where needed throughout the Product manuals.

Cautions

Anything that can cause instrument damage is considered a caution and is noted in the text as CAUTION. Cautions appear where needed throughout the Product manuals.

Importants

Anything that can cause misleading results or data corruption is considered an important and is noted in the text as IMPORTANT. Importants appear where needed throughout the Product manuals.

5.2 SAFETY PRECAUTIONS

Electronic

WARNING Risk of personal injury from electronic shock. Electronic components can shock and injure you. To prevent possible injury or shock, do not tamper with the instrument and do not remove any components (covers, doors, panels, and so on) unless otherwise instructed within this document.

Biological

Use care when working with pathogenic materials. A procedure should be available to decontaminate the instrument, provide ventilation, and dispose of waste liquid and sharps. Refer to the following publications for further guidance on decontamination.

- Biohazards Safety Guide, 1974, National Institute of Health.
- Classifications of Etiological Agents on the Basis of Hazards, 3d ed., June 1974, Center for Disease Control, U.S. Public Health Service.

WARNING Risk of personal injury or contamination. If you do not properly shield yourself while using or servicing the instrument, you may become injured or contaminated. To prevent possible injury or biological contamination, you must wear proper laboratory attire, including gloves, a laboratory coat, and eye protection.

Moving Parts

WARNING Risk of personal injury. Operating the instrument with doors and covers open can cause personal injury. When you operate the instrument, be sure all covers and doors are closed.

5.3 OPERATIONAL HAZARDS

Safety symbols alert you to potentially dangerous conditions. These symbols, together with text, apply to specific procedures and appear as needed throughout this manual.

Symbol	Warning Condition	Action
	**Biohazard**.Consider all materials (specimens, reagents, controls, calibrators, and so forth) as being potentially infectious.	Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.
	**Probe hazard.** The probe is sharp and may contain biohazardous materials, including controls and calibrators.	Avoid any unnecessary contact with the probe and probe area.
	**Electrical shock hazard**. Possibility of electrical shock when instrument is plugged into the power source.	Before continuing, unplug the A^{C}•T diff analyzer from the electrical outlet.

A.1 SCOPE AND PURPOSE

This appendix applies to the A^{C}•T diff analyzer host transmission option.

The purpose of this appendix is to define the contents of the records that an A^{C}•T diff analyzer transmits to a host computer. These records conform to the ASTM standards (see Heading A.2). This appendix specifically delineates what items appear in the fields defined in the high-level ASTM Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems. It also specifies which types of records to use to transmit patient samples and quality control samples. This information, in conjunction with the ASTM standards, provides all the details that you need to create a host interface to the A^{C}•T diff analyzer.

Most of the fields in the records identified in this appendix are optional (that is, they do not necessarily contain values). Also, not all components of a field are necessarily present. The only fields into which the A^{C}•T diff analyzer always puts values are those that the system requires to identify a record type and the sequencing of records.

This appendix defines the contents of the records described in the ASTM high-level standard, Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems. It also summarizes the field definitions for transmission, summarizes the ASTM Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems, and states any interpretations of the protocol that the A^{C}•T diff analyzer assumes.

A.2 ASTM STANDARDS

The A^{C}•T diff analyzer transmits patient and control sample results, according to the protocols specified in ASTM standards E 1381 and E 1394. Standard 1394 defines how data from the instrument is formatted. Standard 1381 specifies the low-level protocol for transmitting and receiving information across a communications link. You must understand these ASTM standards before you can create an interface to the A^{C}•T diff analyzer.

- Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems (E 1394), ASTM, June 1991.
- Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems (E 1381), ASTM, May 1991.

To obtain copies of the standards, contact:

American Society for Testing and Materials
1916 Race Street
Philadelphia, PA 19103

A.3 TRANSMISSION INFORMATION

The A^C•T diff analyzer transmits patient and quality-control sample results, according to the ASTM protocol. Currently, all communication from the A^C•T diff instrument is unidirectional in that the A^C•T diff instrument does not accept any transmissions from a host. If the A^C•T diff analyzer cannot successfully transmit a set of sample results immediately, it displays an error message with the **Transmission** icon and the **Continue** icon.

A.4 ADDITIONAL SUPPORT

Beckman Coulter Corporation provides a software package that facilitates the implementation of the ASTM protocol for the host system but is not intended to be a complete receiver system. Contact your Beckman Coulter Representative for more information.

A.5 HIGH-LEVEL RECORD FIELD DEFINITIONS

Introduction

Information from the A^C•T diff analyzer is formatted in accordance with ASTM Standard E 1394. The following description provides a more detailed definition of what appears in the records that the A^C•T diff analyzer transmits. A description of each record and field type appears in ASTM Standard E 1394.

Patient Sample Record Definitions

The patient sample information is transmitted in the following format:

```
HEADER
    PATIENT
        TEST ORDER
            RESULT 1
            RESULT 2
            .
            .
            .
            RESULT N-1
                RESULT N-1 COMMENT
            RESULT N
                RESULT N COMMENT
MESSAGE TERMINATOR
```

If you want to retransmit a sample result, you must do so before you run the next sample. See Heading A.11, COMMUNICATION MODE, for information about retransmission.

Table A.1 shows the contents of each field in the record types. Many of the fields in the ASTM Standard E 1394 are not mentioned here. These fields will be NULL (that is, will not contain a value). The information that follows uses an exclamation point (!) as a component delimiter and a vertical bar as a field delimiter; however, transmissions can use other valid delimiters as stated in ASTM Standard E 1394.

Table A.1 Patient Sample Record Definitions

Record	Field	ASTM Field #	A^{C}•T diff Analyzer Contents
Header	Record Type ID	1	H
	Delimiter Definition	2	Lists the field, repeat, component, and escape delimiters in the order specified in ASTM Standard E 1394.
	Sender Name or ID	5	Instrument Name!!!Software Revision
	Processing ID	12	P
	Version #	13	1
	Date & Time of Message	14	Date and time message sent in format: YYYYMMDDHHMMSS.
Patient	Record Type ID	1	P
	Record Sequence Number	2	1
Test Order	Record Type ID	1	O
	Record Sequence Number	2	1
	Specimen ID	3	**Sample ID** - where Sample ID is a string that identifies the sample.
	Priority	6	Any value specified in ASTM Standard E 1394.
Result	Record Type ID	1	R
	Record Sequence Number	2	**1** for first result record in the test order, **2** for the second, and so forth.
	Universal Test ID	3	**!!!Result Name** - where result name is any item listed in Heading A.7, Result Names.
	Data or Measurement Value	4	Heading A.8, Result Value Types, defines value.
	Units	5	Units corresponding to the result. **NULL** for results that are not associated with a single set of units.
	Reference Ranges	6	Range of values in format specified in ASTM Standard E 1394. **NULL** for results that do not have associated ranges.
	Result Abnormal Flags	7	See values specified in ASTM Standard E 1394.
	Result Status	9	See values specified in ASTM Standard E 1394.
	Operator Identification	11	See values specified in ASTM Standard E 1394. Operator ID is valid if password enabled.
	Date/Time Test Completed	13	Date and time message sent in format: YYYYMMDDHHMMSS
Message Terminator	Record Type ID	1	L
	Record Sequence Number	2	1
	Termination Code	3	See termination codes in ASTM Standard E 1394.

The following is an example of the contents of a patient sample transmission.

H|$!&|||ACT18!!!0605-EN-1.01972201|||||||P|1|19970818074716
P|1
O|1|000000021|||R
R|1|!!!WBC| 9.2|x10^3/uL| 4.5 to 10.5|N||F|||19970818074630
R|2|!!!LY%|43.1|%| 20.5 to 51.1|N||F|||19970818074630
R|3|!!!MO%|12.9|%| 2.0 to 14.0|N||F|||19970818074630
R|4|!!!GR%|44.0|%| 30.0 to 70.0|N||F|||19970818074630
R|5|!!!LY#| 4.0|x10^3/uL| 1.2 to 4.1|N||F|||19970818074630
R|6|!!!MO#| 1.2|x10^3/uL| 0.1 to 1.8|N||F|||19970818074630
R|7|!!!GR#| 4.0|x10^3/uL| 1.3 to 7.4|N||F|||19970818074630
R|8|!!!RBC| 4.72|x10^6/uL| 4.00 to 6.00|N||F|||19970818074630
R|9|!!!Hgb|13.1|g/dL| 11.0 to 18.0|N||F|||19970818074630
R|10|!!!Hct|42.2|%| 35.0 to 60.0|N||F|||19970818074630
R|11|!!!MCV| 89.4|fL| 80.0 to 99.9|N||F|||19970818074630
R|12|!!!MCH|27.7|pg| 27.0 to 31.0|N||F|||19970818074630
R|13|!!!MCHC|31.0|g/dL| 30.0 to 37.0|N||F|||19970818074630
R|14|!!!RDW|13.4|%| 11.5 to 14.5|N||F|||19970818074630
R|15|!!!Plt|254.|x10^3/uL| 150. to 450.|N||F|||19970818074630
R|16|!!!MPV|10.5|fL| 7.4 to 12.2|N||F|||19970818074630
R|17|!!!WBCHisto|00410@421P@92A4A5AdY;c4m?TI8?d=8?cdf<b`P8QTI4a0=30H;20P50`H51
PD61PP81`X;30\=2a4>418<3`hD2@`=3Ph920P81`X82PD50`<40`<310<40P<20`410`820P430083
0@4100<40P<30`<410@520D71PX720X=1`H72`P=30`=40d:30IB3`I>3A0A3P`=3A0<2P\?3a093`\
@2P`>3a4<30h;30\820`<1`\82PX:1P\=1`L92@P620@81PH91PL510@31P@410H30`D31P@31@840
`830`@30`<10P410P030P410P0100810@410`01004000|||||F|||19970818074630
R|18|!!!RBC Histo|00D10P42004100000P410@010P420P<51PP41`\B4Q965RH[=cY7D5mUMXBBY
[_0n<7^h=gPhMc\b[jj\8j7Q8aUEUA<<c4\9QhP5AD?3@\:1@D71@@30P@30P450`<310830`<30`@4
0`L71PL310H510H61P<51`L51@D41@D91PH41@@11PH6108610@20`<31@<20`830@010P810@010@0
00P0000000000001000000000001000000000000000000000000000000000000000000000000000000000
000000000000000000000000000000000000000|||||F|||19970818074630
R|19|!!!Plt Raw Histo|00L610<10@8410L82@X83`IC5ATL72007AdK6aXK6APG5a8@410@3@X1
PH61PT51P@60`<20P<20P420P8200|||||F|||19970818074630
R|20|!!!Plt Fit Histo|0000000000000000000@841@^C
L930h@4Q@F61TJ6a\K6aXI6ALF5A@C4Q0?3Pd<2PX920L61PD410@30`820P810@410000000000000
000000000000000000000000000000000000000000000000000000000000000000000000000000000000
000000000000000000000000000000000000000000000000000000000000000000000000000000000000
000000000000000000000000000000000000000000000000000000000000000000000000000000000000
|||||F|||19970818074630
L|1|N

Figure A.1 is a patient report representative of the above transmission.

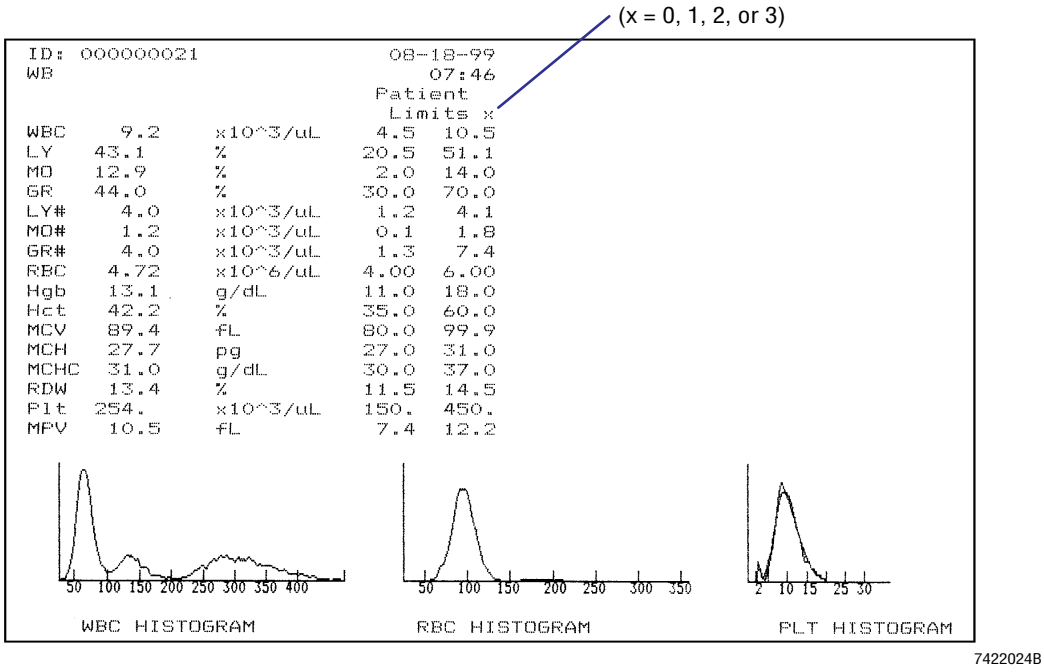


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Figure A.1 Patient Report Representing Sample Transmission

Quality Control Sample Record Definitions

The quality control sample information is transmitted in the following format:

HEADER
CONTROL (that is, corresponds to a PATIENT record)
TEST ORDER
RESULT 1
RESULT 2
.
.
.
.RESULT N
MESSAGE TERMINATOR

If a transmission fails, see Heading A.11, Communication Mode, to retransmit before running another sample.

Table A.2 shows the contents of each field in the record types. Many of the fields in the ASTM Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems are not mentioned here. These fields will be NULL. The information that follows uses an exclamation point (!) as a component delimiter, and a vertical bar as a field delimiter; however, transmissions can use other valid delimiters as stated in ASTM Standard E 1394.

Table A.2 Quality Control Sample Record Definitions

Record	Field	ASTM Field #	A^{C}•T diff Analyzer Contents
Header	Record Type ID	1	H
	Delimiter Definition	2	Lists the field, repeat, component, and escape delimiters in the order specified in ASTM Standard E 1394.
	Sender Name or ID	5	Instrument Name!!!Software Revision
	Processing ID	12	Q
	Version #	13	1
	Date & Time of Message	14	Date and time message sent in format: YYYYMMDDHHMMSS.
Patient (Control)	Record Type ID	1	P
	Record Sequence Number	2	1
	Laboratory Assigned Patient ID	4	Lot number of the control sample.
	Date of Birth	8	Lot expiration date specified in format described in ASTM Standard E 1394.
Test Order	Record Type ID	1	O
	Record Sequence Number	2	1
	Specimen ID	3	Lot Number!Control ID - where Control ID is a string that identifies type of control. For example, the Control ID could be a control level (Low, Normal, High).
	Priority	6	Any value specified in ASTM Standard E 1394.
	Action Code	12	Q
Result	Record Type ID	1	R
	Record Sequence Number	2	**1** for first result record in the test order, **2** for the second, and so forth.
	Universal Test ID	3	**!!!Result Name** - where result name is any item listed in Heading A.7, Result Names.
	Data or Measurement Value	4	Heading A.8, Result Value Types defines value.
	Units	5	Units corresponding to the result. **NULL** for results that are not associated with a single set of units.
	Reference Ranges	6	Range of values in format specified in ASTM Standard E 1394. **NULL** for results that do not have associated ranges. For automatic control, uses reference ranges from control disk. For manual control runs, use linearity ranges.
	Result Abnormal Flags	7	See values specified in ASTM Standard E 1394.
	Result Status	9	See values specified in ASTM Standard E 1394.
	Operator Identification	11	See values specified in ASTM Standard E 1394.
	Date/Time Test Completed	13	Date and time message sent in format: YYYYMMDDHHMMSS

Table A.2 Quality Control Sample Record Definitions *(Continued)*

Record	Field	ASTM Field #	A^{C}•T diff Analyzer Contents
Message Terminator	Record Type ID	1	L
	Record Sequence Number	2	1
	Termination Code	3	See termination codes in ASTM Standard E 1394.

There are two types of quality control transmissions: A^{C}•T Tron cell control and 4C PLUS cell control.

A^{C}•T Tron Cell Control Quality Control Transmission

```
H|$!&|||ACT18!!!0605-EN-1.01972201|||||||Q|1|19970818094126
P|1||
O|1||||R||||||Q
R|1|!!!WBC| 10.3!* |x10^3/uL|   0.0 to  100.0|N||F||||19970818094045
R|2|!!!RBC| 4.64!* |x10^6/uL|  0.00 to   7.01|A||F||||19970818094045
R|3|!!!Hgb| 8.0!* |g/dL|   0.0 to   25.1|A||F||||19970818094045
R|4|!!!Hct|33.5!* |%|   0.0 to  100.0|A||F||||19970818094045
R|5|!!!MCV| 72.3!* |fL|  50.0 to  130.1|A||F||||19970818094045
R|6|!!!MCH|17.3!* |pg|   0.0 to  100.0|A||F||||19970818094045
R|7|!!!MCHC|24.0!* |g/dL|   0.0 to  100.0|A||F||||19970818094045
R|8|!!!Plt|300.! *|x10^3/uL|    0. to  1000.|A||F||||19970818094045
L|1|N
```

4C PLUS Cell Control Quality Control Transmission

H|$!&|||ACT18!!!0605-EN-1.01972201|||||||Q|1|19970818093024
P|1||089200||||19970831085755
O|1|089200!H|||R|||||||Q
R|1|!!!WBC| 18.7|x10^3/uL| 17.7 to 20.2|N||F||||19970818093006
R|2|!!!LY%|47.4|%| 43.9 to 54.0|N||F||||19970818093006
R|3|!!!MO%|15.8|* |%| 11.3 to 21.3|A||F||||19970818093006
R|4|!!!GR%|36.8|%| 29.8 to 39.8|N||F||||19970818093006
R|5|!!!LY#| 8.9|x10^3/uL| 8.0 to 10.8|N||F||||19970818093006
R|6|!!!MO#| 3.0|* |x10^3/uL| 2.3 to 3.9|A||F||||19970818093006
R|7|!!!GR#| 6.9|x10^3/uL| 5.3 to 8.2|N||F||||19970818093006
R|8|!!!RBC| 5.96|H |x10^6/uL| 5.01 to 5.62|H||F||||19970818093006
R|9|!!!Hgb|18.2|g/dL| 17.0 to 18.7|N||F||||19970818093006
R|10|!!!Hct|58.4|H |%| 47.8 to 52.9|H||F||||19970818093006
R|11|!!!MCV| 97.8|H |fL| 91.6 to 97.7|H||F||||19970818093006
R|12|!!!MCH|30.5|pg| 30.3 to 36.8|N||F||||19970818093006
R|13|!!!MCHC|31.2|L |g/dL| 32.2 to 38.7|L||F||||19970818093006
R|14|!!!RDW|13.4|%| 11.2 to 15.3|N||F||||19970818093006
R|15|!!!Plt|475.|H |x10^3/uL| 350. to 471.|H||F||||19970818093006
R|16|!!!MPV|10.6|fL| 8.5 to 12.6|N||F||||19970818093006
R|17|!!!WBC Histo|00820PH52@\?4aHQ:cm:Efe\NgV>S8AmQVQYH5Q=?cLo:AdG5a4@2`d:30T:2
P|?40hD4QP|6QdL7R<R9B0Q8B4O6b0L7AT|5AHF2`h@3@\;2@T:2`T62@H71@@61`@41@<410830P@3
1@@210@210<41@D61`H52PH52`\72`XD2@\=2`h?3P`@4@\C3``?5Q@@4a4A4A<E5A<|3a4B4aLB3`d
@3`|=3`dD4P|>3`|D4`h;3PT?40`>3@`:3P|<40`>30T92PP;2PX81`P:1PT:1`T61P\920L71PD41@
L610<510@51@D5108210H30`<210@20`840`<40`8100||||F||||19970818093006
R|18|!!!RBC Histo|00H30P<30`000@000@000@<100810P<20P@41@P52@Pa2@hA5aPG8C0Y>dA:E
f1[ZhJJZk^h`];T`]?IhMC8c_jd[J2JQg]\KeA?@3T`;2P\6a<G4`I@40\920T81`D81`@40`850`45
0`831@<30`H510@520L51`L91`H:2@P@2@L:2@T:20T91PL82@T71`L620L820@710@410<50PD30PD
40P831@830P030P830@80004200400@0000400@4000410@000000000000010@0000400@4100800
000000000000040000000000000000000000000000000||||||F||||19970818093006
R|19|!!!Plt Raw Histo|00L30`820@<30`862@`@41DI6R<U;30];c@j=C8];BhY9bHS7APG4AHE2
`I:2@T91PH51PH30`<30@<20P8200||||||F||||19970818093^C
006
R|20|!!!Plt Fit Histo|000000000000000000000004310L:3A4E6QhR9BT[;BI`<2I^;B\Y9bDR8
1dK61HD4Q0>3@\:2@P71PD510@30`820P410@400000000000000000000000000000000000000000
000000000000000000000000000000000000000000000000000000000000000000000000000000
000000000000000000000000000000000000000000000000000000000000000000000000000000
000000000000000000000000000000000000000000000||||||F||||19970818093006
L|1|N

Startup Record Definitions

The startup (background) information is transmitted in the following format:

HEADER
- PATIENT
  - TEST ORDER
    - RESULT 1
    - RESULT 2
    - .
    - .
    - .
    - .RESULT N

MESSAGE TERMINATOR

If a transmission fails, see Heading A.11, Communication Mode to retransmit before running another sample.

Table A.3 shows the contents of each field in the record types. Many of the fields in the ASTM Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems are not mentioned here. These fields will be NULL. The information that follows uses an exclamation point (!) as a component delimiter, and a vertical bar as a field delimiter; however, transmissions can use other valid delimiters as stated in ASTM Standard E 1394.

Table A.3 Startup Record Definitions

Record	Field	ASTM Field #	A^{C}•T diff Analyzer Contents
Header	Record Type ID	1	H
	Delimiter Definition	2	Lists the field, repeat, component, and escape delimiters in the order specified in ASTM Standard E 1394.
	Sender Name or ID	5	Instrument Name!!!Software Revision
	Processing ID	12	Q
	Version #	13	1
	Date & Time of Message	14	Date & time message sent in format: YYYYMMDDHHMMSS.
Patient (Control)	Record Type ID	1	P
	Record Sequence Number	2	1
	Laboratory Assigned Patient ID	4	Lot number of the control sample.
	Patient ID # 3	5	BCK
Test Order	Record Type ID	1	O
	Record Sequence Number	2	1
	Priority	6	Any value specified in ASTM Standard E 1394.
	Action Code	12	Q

Table A.3 Startup Record Definitions *(Continued)*

Record	Field	ASTM Field #	A^{C}•T diff Analyzer Contents
Result	Record Type ID	1	R
	Record Sequence Number	2	**1** for first result record in the test order, **2** for the second, and so forth.
	Universal Test ID	3	**!!!Result Name** - where result name is any item listed in Heading A.7, Result Names.
	Data or Measurement Value	4	Heading A.8 , Result Value Types, defines value.
	Units	5	Units corresponding to the result. **NULL** for results that are not associated with a single set of units.
	Reference Ranges	6	Range of values in format specified in ASTM Standard E 1394. **NULL** for results that do not have associated ranges. For automatic control, uses reference ranges from control disk. For manual control runs, use linearity ranges.
	Result Abnormal Flags	7	See values specified in ASTM Standard E 1394.
	Result Status	9	See values specified in ASTM Standard E 1394.
	Operator Identification	11	See values specified in ASTM Standard E 1394.
	Date/Time Test Completed	13	Date and time message sent in format: YYYYMMDDHHMMSS
Message Terminator	Record Type ID	1	L
	Record Sequence Number	2	1
	Termination Code	3	See termination codes in ASTM Standard E 1394.

The following is an example of the contents of a startup transmission.

```
H|$!&|||ACT18!!!0605-EN-1.01972201|||||||Q|1|19970818092059
P|1|||BCK
O|1||||R|||||||Q
R|1|!!!WBC|  0.1|x10^3/uL||N||F||||19970818092032
R|2|!!!RBC| 0.01|x10^6/uL||N||F||||19970818092032
R|3|!!!Hgb| 0.0|g/dL||N||F||||19970818092032
R|4|!!!Plt|  1.|x10^3/uL||N||F||||19970818092032
L|1|N
```

A.6 LOW-LEVEL PROTOCOL DESCRIPTION

Introduction

Use the ASTM Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems to handle the transmission of the information defined in this appendix. Each high-level ASTM record is divided into one or more frames as described in the ASTM Standard E 1394. There is at most one record per frame. Each high-level ASTM record is equivalent to one ASTM low-level "message" which is divided into one or more frames.

The A^C•T diff instruments do not respond to receiver interrupts <EOT>; they treat the interrupts as acknowledgments.

The actual communications protocol for transmitting and receiving information is defined in the ASTM Standard E 1381. The following provides a summary of the low-level protocol using a state transition diagram.

ASTM Protocol States

See Heading A.9, STATE TRANSITION DIAGRAM, to determine the interaction among the various protocol states.

Busy State

The busy state indicates that the A^C•T diff instrument is unable to process ASTM messages. The A^C•T diff instrument will not respond to even an <ENQ>.

In certain situations, especially for an instrument, conditions might be such that the A^C•T diff instrument is unable to perform serial communications. This could be during certain critical data acquisition operations, and so forth. If this is the case, then the host may continue trying to establish communications indefinitely until a reply is received, or continue at some unspecified time later.

Idle State

The idle state is where the instrument or host computer is prepared to initiate the Establishment Phase via some external event. Such an event would typically be the reception of <ENQ> over the communications link, whereby the receiver would prepare to receive data, or the transmission of <ENQ> whereby the sender would prepare to transmit data at the completion of an operation, or by operator interaction.

While in the idle state, if <ENQ> is received then the receiver responds with <ACK> and starts a 30 second timer when prepared to receive data. If the receiver does not receive a data frame or an <EOT> within 30 seconds then a time-out has occurred. After the time-out, the receiver regards the line to be in the neutral state.

While in the idle state, if an external event occurs to initiate information transfer, then the sender transmits <ENQ>.

Contention State

Contention is considered part of the Establishment Phase. If both an instrument and a host computer try to establish communications simultaneously, then a contention state exists. For resolution purposes, the A^C•T diff instrument has priority to transmit information when contention exists. Contention resolution is performed as follows: Upon receiving a reply of <ENQ> to its transmitted <ENQ>, the host computer must stop trying to transmit and prepare to receive data. When the host computer receives the next <ENQ> it replies with an <ACK> if prepared to receive. Conversely, the A^C•T diff instrument must wait at least 1 second before transmitting the next <ENQ>.

During the Establishment Phase, if the host computer detects contention, it resolves itself to become the receiver. At this point the host computer starts a timer. If an <ENQ> is not received within 20 seconds, a time-out occurs. After a time-out, the receiver regards the line to be in a neutral state, and may then try to become the sender once again.

Establish Communications State

This is the state in which the Establishment Phase begins. This state, in conjunction with the contention state, determines the direction of information flow and prepares the receiver to accept information. The system with information available initiates the establishment of communications after determining the link is in a neutral state.

The sender starts a timer when transmitting the <ENQ>. After the sender has transmitted an <ENQ>, it must wait for a response. If a reply of <ACK>, <NAK>, or <ENQ> is not received within 15 seconds, a time-out occurs. After the time-out, the sender enters the Termination Phase.

When the receiver responds with <ACK>, it is signifying its readiness to receive data. This ends the Establishment Phase and begins the Transfer Phase.

When the receiver responds with <NAK>, it is signifying that it is not ready to receive data. The sender must then wait at least 10 seconds before again trying to establish communications.

When the receiver responds with <ENQ>, a contention condition exists. Refer to heading Contention State, for information about contention resolution.

Receive Message State

This state is part of the Transfer Phase. The receive message state is where message frames are received and processed.

Messages are sent in frames. Each frame contains a maximum of 247 ASCII characters, 240 of which are data and 7 are frame overhead characters. Messages longer than 240 characters must be divided between two or more frames. Multiple messages are never combined in a single frame. Every message must begin in a new frame.

A frame is one of two types:

- Intermediate Frame. Terminates with the characters <ETB>, two-character checksum, <CR> and <LF>. The frame structure is as follows: <STX> FN text <ETB> C1 C2 <CR> <LF>.
- End Frame. Terminates with the characters <ETX>, two-character checksum, <CR> and <LF>. The frame structure is as follows: <STX> FN text <ETX> C1 C2 <CR> <LF>.

The frame structure definition is as follows:

<STX> Start of Text transmission control character.

FN Single-digit Frame Number 0 to 7. The frame number permits the receiver to distinguish between new and retransmitted frames. It is a single ASCII digit sent immediately after the <STX> character. The frame number begins at 1 with the first frame of the transfer phase. The frame number is incremented by one for every new frame transmitted. After 7, the frame number rolls over to 0, and continues in this fashion.

<ETB> End of Transmission Block transmission control character.

<ETX> End of Text transmission control character.

C1 Most significant character of checksum. Range is 0 to 9 and A to F in ASCII hexadecimal. The checksum is encoded as two characters which are sent after the <ETB> or <ETX> character. The checksum is computed by adding the binary values of the characters, keeping the least significant eight bits of the result. The checksum is initialized to 0 with the <STX> character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum modulo 256. The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR> and <LF>.

The checksum is an integer represented by eight bits. It can be considered as two groups of four bits. The groups of four bits are converted to the ASCII characters of the hexadecimal representation (ASCII hexadecimal). The two characters are transmitted as the checksum, with the most significant character first.

C2 Least significant character of checksum. Range is 0 to 9 and A to F in ASCII hexadecimal.

<CR> Carriage Return ASCII character.

<LF> Line Feed ASCII character.

The receiver replies to each frame. When it is ready to receive the next frame, it transmits one of three replies to acknowledge the last frame. This reply must occur within 15 seconds or the sender considers a time-out to have occurred.

A reply of <ACK> signifies that the last frame was received successfully and the receiver is prepared to receive another frame.

A reply of <NAK> signifies that the last frame was not successfully received and the receiver is prepared to receive the frame again.

A reply of <EOT> signifies that the last frame was received successfully and the receiver is prepared to receive another frame, but <EOT> is a request to the sender to stop transmitting. The A^{C}•T diff analyzer treats an <EOT> as <ACK> and ignores the request to stop transmitting.

There are several methods used for Error Recovery when errors in data transmission are detected. The first is the detection of Defective Frames. The receiver checks every frame to guarantee it is valid. A reply of <NAK> is transmitted for invalid frames. Upon receiving the <NAK>, the sender retransmits the last frame with the same frame number. In this way, transmission errors are detected.

Secondly, any characters occurring before <STX> or after the end of block character (<ETB> or <ETX>) are ignored by the receiver when checking the frame. The criteria for rejecting a frame are as follows:

- Any character errors are detected (parity, framing, and so forth).
- The frame checksum does not match the checksum computed on the received frame.
- The frame number is not the same as the last accepted frame or one number higher (modulo 8).

Upon receiving a <NAK> or any character except <ACK> or <EOT> (considered a <NAK> condition), the sender increments a retransmit counter and retransmits the frame. If this counter shows that a single frame was sent and not accepted six times, the sender must abort this message by proceeding to the Termination Phase. An abort should be extremely rare, but it provides a mechanism to escape from a condition where the transfer phase cannot continue.

Send Message State

This state is part of the Transfer Phase. The send message state is where messages are broken down into frames and then transmitted to the receiver. Refer to heading Receive Message State, for frame definition details.

A message containing 240 characters or less is sent in a single-end frame. Longer messages are sent in intermediate frames with the last part of the message sent in an end frame.

The receiver replies to each frame. When the receiver is ready to receive the next frame, it transmits one of three replies to acknowledge the last frame. This reply must occur within 15 seconds or the sender considers a time-out to have occurred.

A reply of <ACK> signifies that the last frame was received successfully and the receiver is prepared to receive another frame. The sender must increment the frame number and either send a new frame or terminate.

A reply of <NAK> signifies that the last frame was not successfully received and the receiver is prepared to receive the frame again. The frame is sent without updating the frame number.

A reply of <EOT> signifies that the last frame was received successfully and the receiver is prepared to receive another frame, but <EOT> is a request to the sender to stop transmitting. The A^{C}•T diff instrument treats <EOT> as <ACK> and ignores the request to stop transmitting.

When a message has been completely transmitted and there is no more information to transfer, the sender transmits an <EOT> character to let the receiver know that all messages have been sent. This is known as the Termination Phase. At this point both the sender and the receiver regard the data link to be in a neutral state.

Restrictions

Data

The data link protocol is designed for sending character-based message text. Restrictions are placed on which characters may appear in the message text. The restrictions make it simpler for senders and receivers to recognize replies and frame delimiters. Additional characters are restricted to avoid interfering with software controls for devices such as multiplexers.

A <LF> character cannot appear in the message text; it can appear only as the last character of a frame.

None of the 10 transmission control characters, the <LF> format effector control character, or four device control characters may appear in message text. The restricted characters are: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3> and <DC4>.

Communications

The method of data transmission is serial-by-bit start/stop. The order of the bits in a character is:

- One start bit, corresponding to a binary 0.
- The data bits of the character, least significant bit (LSB) first.
- Parity bit.
- Stop bit(s), corresponding to a binary 1.

All devices must be capable of sending and receiving characters consisting of one start bit, eight data bits, no parity bit, and one stop bit. The default character structure consists of one start bit, eight data bits, no parity bit, and one stop bit. Eight data bit character sets are allowed but not specified by the ASTM standard. Other character structures can be used for specialized applications.

The data transmission rate for A^C•T diff instruments must be at least one of these baud rates: 300, 1200, 2400, 4800, 9600 or 19,200 bits per second (bps). The preferred rate is 9600 bps, and it should be the default setting of the instrument when more than one data rate is available. The computer system must have the capability for all four data rates.

A.7 RESULT NAMES

GR#	MPV
GR%	Pct
Hct	PDW
Hgb	Plt
LY#	Plt Fit Histo
LY%	Plt Raw Histo
MCH	RBC
MCHC	RBC Histo
MCV	RDW
MO#	WBC
MO%	WBC Histo

A.8 RESULT VALUE TYPES

Result values can be one of the following types: Parameter Values or Histogram Values. In the discussion that follows, an exclamation mark (!) is used as a component delimiter and a vertical bar as a field delimiter; however, transmissions can use other valid delimiters as stated in ASTM Standard E 1394.

Parameter Values

The Parameter Value is formatted as follows:

Result Value!Flags.

The Result Value is either the string representation of a number (for example, 4.39), a threshold designation (for example, <0.7), +++++ which indicates the parameter is over the reportable range, • • • • • which indicates an incomplete result, - - - - - which indicates voteout or XXXXX for Aperture Alert (See Special Procedures and Troubleshooting in the Operator's Guide for further information.).

Code	Type of Flag
*	Review flag
H	High flag
L	Low flag
+	Exceeds linear range
X	Aperture Alert (single criterion)
1	Region flag
2	Region flag
3	Region flag
4	Region flag
M	Multiple regions flag

The A^{C}•T diff instrument transmits only two codes for the Flags subfield.

Histogram Values

Histogram Values consist of ASCII characters. These characters are derived from the data points in the histogram. The data points in the histogram must be encoded so that they fall within the range of allowable characters in the ASTM protocol. The disallowed characters for the ASTM protocol are listed in the ASTM Specification for Low-Level Protocol to transfer

Messages Between Clinical Laboratory Instruments and Computer Systems. The encoded histogram characters do NOT include the field delimiter, repeat delimiter, component delimiter, or escape delimiter.

The encoding scheme used to represent histograms consists of converting every three data points in the histogram to four bytes that are within the range of allowable ASTM characters. The conversion consists of taking the 24 bits comprising 3 histogram data points and separating them into 4 groups of 6 bits. Each 6-bit value is then added to an offset (30_H) that ensures that the resulting byte falls between 30_H and $6F_H$. All characters is this range are allowable for the ASTM protocol. The field, repeat, component, and escape delimiters are chosen to be outside of this range.

H indicates hexadecimal notation.

The algorithm for encoding a histogram using this scheme is the following:

WHILE (there are at least 3 bytes left to convert) DO

Convert the next 3 bytes of the histogram into a 24-bit array, making the first of the 3 bytes the highest order 8 bits.

Set the next byte in the encoded histogram to be bits 19 - 24 of the array added to 30_H.

Set the next byte in the encoded histogram to be bits 13 - 18 of the array added to 30_H.

Set the next byte in the encoded histogram to be bits 7 - 12 of the array added to 30_H.

Set the next byte in the encoded histogram to be bits 1 - 6 of the array added to 30_H.

END WHILE

IF (there are 2 bytes left to convert) THEN

Convert the last two bytes of the histogram into an 18-bit array, making the next to last byte occupy bit positions 9 through 16, and making the last byte occupy bit positions 1 through 8. Bit positions 17 and 18 are both 0.

Set the next byte in the encoded histogram to be bits 13 - 18 of the array added to 30_H.

Set the next byte in the encoded histogram to be bits 7 - 12 of the array added to 30_H.

Set the next byte in the encoded histogram to be bits 1 - 6 of the array added to 30_H.

ELSE IF (there is only 1 byte left to convert) THEN

Convert the byte into a 12-bit array, where the uppermost 4 bits are 0, and the lower 8 bits correspond to the byte.

Set the next byte in the encoded histogram to be bits 7 - 12 of the array added to 30_H.

Set the next byte in the encoded histogram to be bits 1 - 6 of the array added to 30_H.

END IF

For example: consider a 4-byte histogram consisting of the following data points (in hex): $15_{H,}$ $A3_H$, $4B_H$, and 71_H. Figure A.2 shows how the first 3 bytes of the histogram would be encoded into 4 bytes that fall within the allowable ASTM range. Figure A.3 shows how the fourth byte would be encoded into 2 bytes that fall within the allowable ASTM range. The 4-byte histogram would be encoded to become a 6-byte string consisting of the following bytes: 35_H, $4A_H$, $3D_H$, $3B_H$, 31_H, and 61_H.

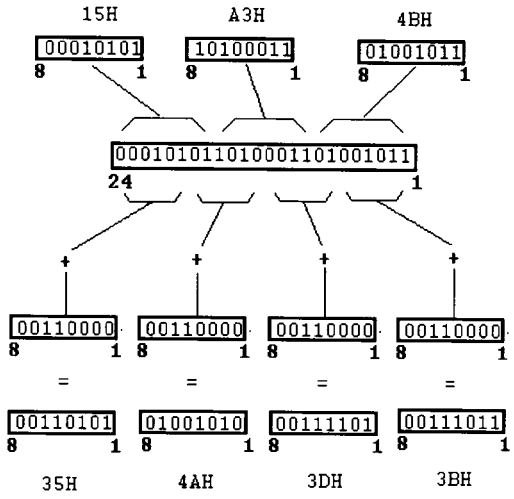


Figure A.2 Encoding 3 Bytes

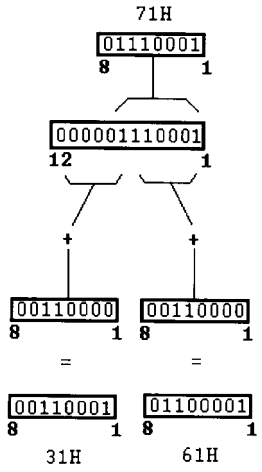


Figure A.2 Encoding 1 Byte

Decoding the histogram consists of taking the encoded histogram characters and converting them into the histogram data points. Each 4 encoded characters have to be converted into 3 histogram data points. The algorithm for decoding is as follows:

WHILE (there are at least 4 characters left to decode) DO

Convert the next 4 encoded characters into a 24-bit array. This is done by the following method:

Subtract 30_H from the first of the 4 characters.

Put the lowermost six bits of this result into bits 19 - 24 of the 24-bit array.

Subtract 30_H from the second of the 4 characters.

Put the lowermost six bits of this result into bits 13 - 18 of the 24-bit array.

Subtract 30_H from the fourth of the 4 characters.

Put the lowermost six bits of this result into bits 1 - 6 of the 24-bit array.

Set the next byte in the histogram to be bits 17 -24 of the 24-bit array.

Set the next byte in the histogram to be bits 9 - 16 of the 24-bit array.

Set the next byte in the histogram to be bits 1 - 8 of the 24-bit array.

END WHILE

IF (there are 3 encoded characters left to convert) THEN

Convert the last 3 encoded characters into an 18-bit array. This is done by the following method:

Subtract 30_H from the first of the 3 characters.

Put the lowermost six bits of this result into bits 13 - 18 of the 18-bit array.

Subtract 30_H from second of the 3 characters.

Put the lowermost six bits of this result into bits 7 - 12 of the 18-bit array.

Subtract 30_H from the third of the 3 characters.

Put the lowermost six bits of this result into bits 9 - 16 of the 18-bit array.

Set the next byte in the histogram to be bits 9 - 16 of the 18-bit array.

Set the next byte in the histogram to be bits 1 - 8 of the 18-bit array.

ELSE IF (there are 2 encoded characters left to convert) THEN

Convert the last 2 encoded characters into a 12-bit array. This is done by the following method:

Subtract 30_H from the first of the 2 characters.

Put the lowermost six bits of this result into bits 7 -12 of the 12-bit array.

Subtract 30_H from the second of the 2 characters.

Put the lowermost six bits of this result into bits 1 - 6 of the 12-bit array.

Set the next byte in the histogram to be bits 1 - 8 of the 12-bit array.

END IF

For example: consider the following array of 6 encoded histogram characters: 35_H, $4A_H$, $3D_H$, $3B_H$, 31_H, and 61_H. These encoded characters represent a 4-byte histogram. Figure A.4 shows how the decoding algorithm would convert the first 4 encoded characters into 3 histogram data points. Figure A.5 shows how the decoding algorithm would convert the last 2 encoded

characters into a single histogram data point. The histogram points derived from the encoded points are 15_H, $A3_H$, $4B_H$, and 71_H.

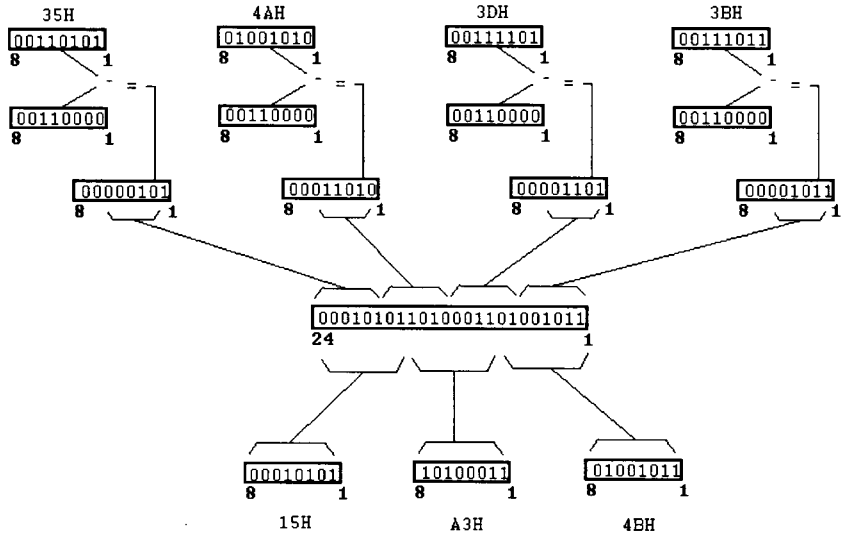


Figure A.2 Decoding 4 Bytes

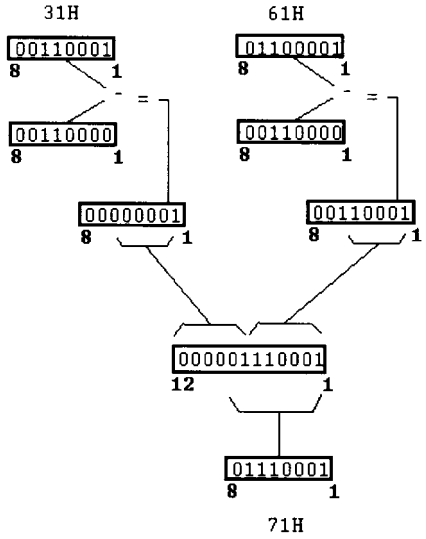


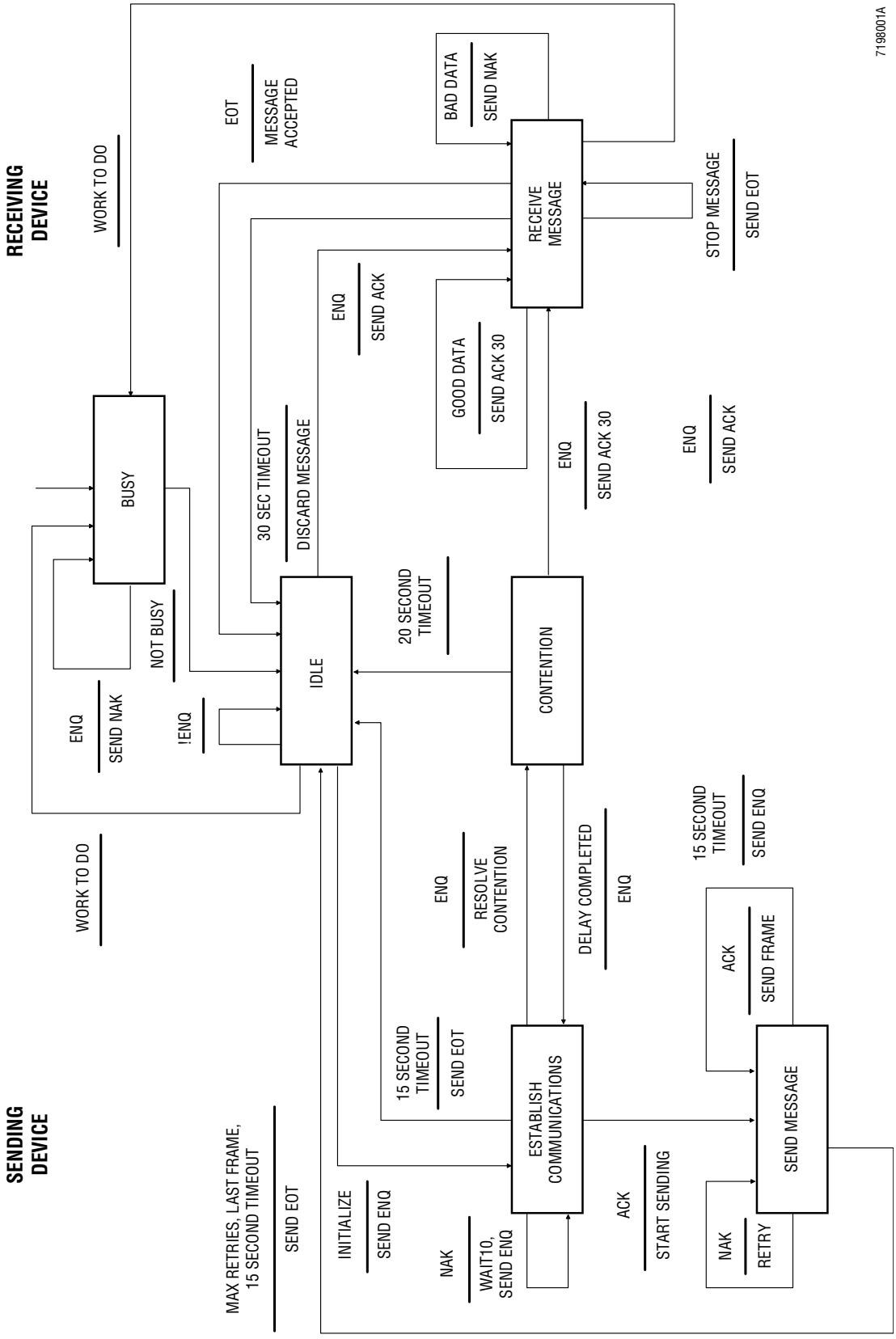
Figure A.2 Decoding 2 Bytes

The following C code fragments demonstrate an implementation of the encoding and decoding of the histograms:

```
#define OFFSET 0x30
void encode(byte *Histogram, Byte *ASMTOutput, int HistSize)
{
    int HistIdx, OutIdx;
    long BitArray;

    HistIdx = OutIdx = 0;
    /*Convert the histogram 3 bytes at a time*/
    while (HistIdx < HistSize - 2)
    {
        BitArray = Histogram[HistIdx];
        BitArray = (BitArray << 8) + Histogram[HistIdx+1];
        BitArray = (BitArray << 8) + Histogram[HistIdx+2];
        ASTMOutput[OutIdx] = ((BitArray & 0xFC0000) >> 18) + OFFSET;
        ASTMOutput[OutIdx+1] = ((BitArray & 0x03F0000) >> 12) + OFFSET;
        ASTMOutput[OutIdx+2] = ((BitArray & 0x000FC0) >> 6) + OFFSET;
        ASTMOutput[OutIdx+3] (BitArray & 0x00003F) + OFFSET;
        HistIdx +=3;
        OutIdx +=4;
    }
    if (HistIdx == HistSize - 2)
    {
        /* 2 bytes left in histogram */
        BitArray = Histogram[HistIdx];
        BitArray = (BitArray << 8) + Histogram[HistIdx+1];
        ASTMOutput[OutIdx] = ((BitArray & 0x03F0000 >> 12) + OFFSET;
        ASTMOutput[OutIdx+1] = ((BitArray & 0x000FC0) >> 6) + OFFSET;
        ASTMOutput[OutIdx+2] = (BitArray & 0x00003F) + OFFSET;
    }
    else if (HistIdx == HistSize - 1)

    {
        /* 1 byte left in histogram */
        BitArray = Histogram[HistIdx];
        ASTMOutput[OutIdx] = ((BitArray & 0x000FC0) >> 6) + OFFSET;
        ASTMOutput[OutIdx+1] = (BitArray & 0x00003F) + OFFSET;
    }
}
    void decode(byte *ASTMField, byte *Histogram, int FieldSize)
    {
        int FieldIdx, HistIdx:
        long BitArray;

        FieldIdx = HistIdx = 0;
        /* Decode four characters at a time */
        while (FieldIdx < FieldSize - 3)
```

```
        {
            BitArray = ASTMField[FieldIdx] - OFFSET;
            BitArray = (BitArray << 6)+ (ASTMField[FieldIdx+1] - OFFSET);
            BitArray = (BitArray << 6) + (ASTMField[FieldIdx+2] - OFFSET;
            BitArray = (BitArray6 << 6) + (ASTMField[FieldIdx+3] - OFFSET;
            Histogram[HistIdx] = (BitArray & 0xFF0000) >> 16;
            Histogram[HistIdx+1] = (BitArray & 0x00FF00) >> 8;
            Histogram[HistIdx+2] = (BitArray & 0x0000FF);
            FieldIdx +=4;
            HistIdx +=3;
        }

        if (FieldIdx == FieldSize -3)
        {
            /* Three bytes left to convert */
            BitArray = ASTMField[FieldIdx] - OFFSET;
            BitArray = (BitArray << 6) + (ASTMField[FieldIdx+1] - OFFSET;
            BitArray = (BitArray << 6) = ASTMField[FieldIdx+1] - OFFSET;
            Histogram[HistIdx] = (BitArray & 0x00FF00) >> 8;
            Histogram[HistIdx+1] = (BitArray & 0x0000FF0;
        }
        else if (FieldIdx == FieldSize - 2)
        {
            /* Two bytes left to convert */
            BitArray = ASTMField[FieldIdx] - OFFSET;
            BitArray = (BitArray << 6) + (ASTMField[FieldIdx+1] - OFFSET;
            Histogram[HistIdx] = (BitArray & 0x0000FF);
        }
}
```

A.9 STATE TRANSITION DIAGRAM



A.10 HARDWARE INTERFACE

A^{C}•T diff Analyzer Serial Interface

The A^{C}•T diff instrument is equipped with two interface connectors. These connectors let the system interface as follows:


Host Computer


Instrument's Printer

The serial port is configured as Data Terminal Equipment (DTE). See Table A.4.

Table A.4 A^{C}•T diff Analyzer Serial Interface

Function	Direction	SERIAL 9-Pin Male Connector
Chassis Ground	N/A	1
Transmitted Data	from A^{C}•T diff	3
Received Data	to A^{C}•T diff	2
Request to Send	from A^{C}•T diff	7
Clear to send	to A^{C}•T diff	8
Data set ready	to A^{C}•T diff	6
SIGNAL GROUND	N/A	5
Data terminal ready	from A^{C}•T diff	4
Ring indicator	to A^{C}•T diff	9

ASTM Interface

This description addresses the low-level (hardware) protocol for passing messages between clinical laboratory instruments and computer (host) systems. The A^{C}•T diff analyzer accommodates this requirement via an external adapter. This adapter allows the serial connector to function as an ASTM compatible HOST interface. The HOST specification requires a male 25-pin D-type connector. See Table A.5.

Note: If you connect to a host with a 25-pin connector, you must use a special 9-25 pin converter adapter.

Table A.5 ASTM Interface

Function	Direction	9-Pin Connector
Chassis Ground	N/A	N/A
Transmitted Data	from A^{C}•T diff	3
Received Data	to A^{C}•T diff	2
SIGNAL GROUND	N/A	5

Note: To avoid ground loops and to ensure proper instrument performance, do not connect pin 1 at the host computer.

No hardware handshake is required.

A.11 COMMUNICATION MODE

Host Settings

If your A^{C}•T diff analyzer is connected to a host computer, you can transmit sample results by using this feature. To set up the A^{C}•T diff instrument to transmit to a host computer, you must install the external ASTM adapter. Install the adapter with the INST arrow pointing toward the A^{C}•T diff instrument.

The Host receiver must comply with the ASTM Host Transmission Specification for the A^{C}•T diff analyzer.

Then you customize the software as shown in Table A.6.

Table A.6 Customizing Host Settings

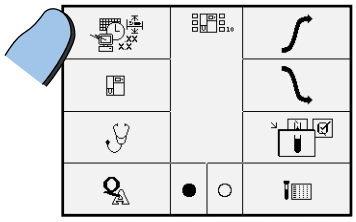
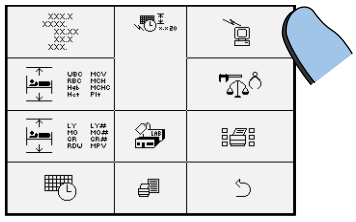
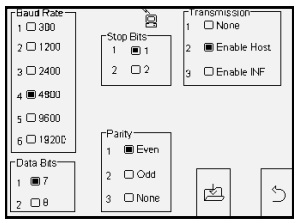
	
	The Host Transmission screen appears. Make selections as described below.

Table A.6 Customizing Host Settings *(Continued)*

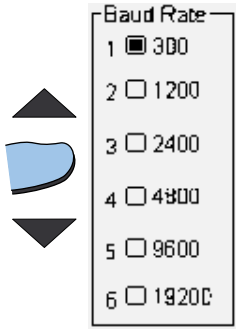
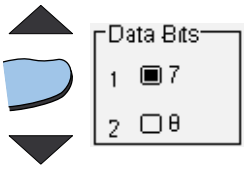
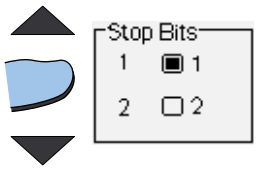
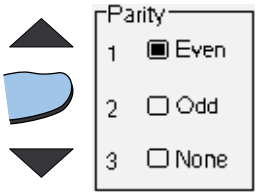
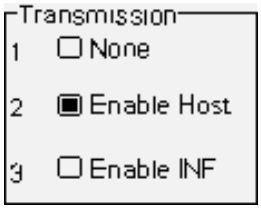
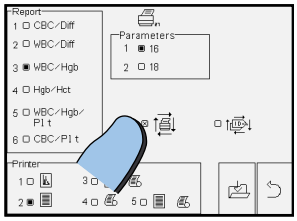
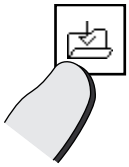
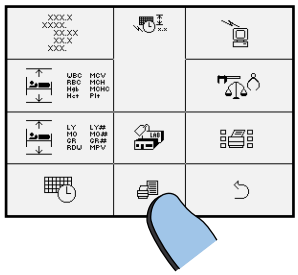
	Ensure that the baud rate is set the same on both the host computer and the A^{C}•T diff instrument. Touch the box for your selection.
	Set the same number of data bits as on your host computer. Touch the box for the data bits to be transmitted.
	Set the Stop Bit option to be the same on both the A^{C}•T diff instrument and the host computer. Touch the box for your selection.
	Set the same number of parity bits as on your host computer. Touch the box for your selection.
	Set **Enable Host** on.
	If you have a printer on your A^{C}•T diff instrument, set autoprint on so that the data sent to the host is printed as well.
	Save the settings you just entered.

Table A.6 Customizing Host Settings *(Continued)*

	If you have a printer on your A^{C}•T diff instrument, print all the customized values to save in your laboratory log book.

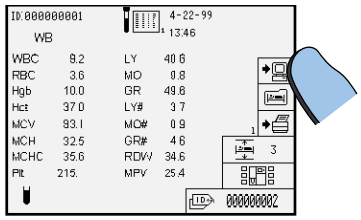
Transmitting to the Host

When transmitting to a host computer, the A^{C}•T diff instrument sends the results of each sample after they are analyzed. The A^{C}•T diff analyzer prints the data on the printer if you enabled the Auto Print feature, then it sends the data to the host. When printing is complete, the sample results remain on the screen.

- The A^{C}•T diff analyzer transmits the data in the units format that you selected at system customization time (See the appropriate Installation and Training Guide).
- Regardless of the date format that you select on the A^{C}•T diff analyzer, data transmission uses the standard ASTM date format.

Retransmitting a Sample

If you want to retransmit a sample result, you must do so before you run the next sample.

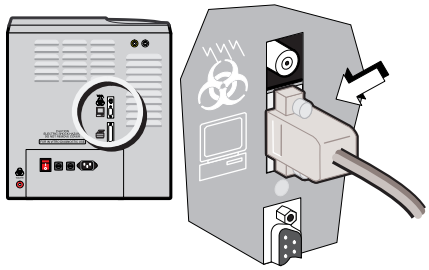


The A^{C}•T diff instrument retransmits the last sample.

Transmission Error

If a transmission error message appears:

- Verify that the host communications configuration (baud, parity, data and stop bits) is set the same on both the A^{C}•T diff analyzer and the host.
- Check cable connections on the host.
- Verify that the cable is connected to the serial connector on the A^{C}•T diff analyzer.



- Touch **Resend to Host** icon on Sample Results screen.

If retransmission fails, call your Beckman Coulter Representative.

This Appendix contains these Log Sheets.

Make photocopies of them as needed.

ACTION LOG

Action Log

Date	By	Activity

Serial No. _____ Lab._____

COULTER® A^{C}•T diff™ Analyzer

MAINTENANCE LOG

Maintenance Log

Date	By	Activity

Serial No. _____ Lab._____

COULTER® A^{C}•T diff™ Analyzer

REAGENT LOG

Reagent Log

Date Opened	Lot Number	Expiration Date	Who Changed it

Serial No. _____ Lab._____

COULTER® A^{C}•T diff™ Analyzer

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Accuracy	Ability of the instrument to agree with a predetermined reference value at any point within the operating range; closeness of a result to the true (accepted) value.
Ambient	Surroundings or environment.
Assay	Procedure of repeat testing to determine the assigned value for a given lot and level of control.
Assay Values	Values of all parameters in a control established by extensive assay of that control.
Assigned Values	Values of all parameters in a calibrator established by extensive testing of that calibrator.
Aspirate-Verify Cycle	Cycle used to verify the predilute process.
Background Count	Measure of the amount of electrical or particle interference.
Background Cycle	Cycle run to produce a background.
Baud	A rate defining how many data bits per second are transferred during communications between two pieces of equipment.
Blank Cycle	A cycle that runs diluent through the system and can be used to check the background.
Calibration	A procedure to standardize the instrument by determining its deviation from calibration references and applying any necessary correction factors.
Calibration Factors	These are correction factors that the system uses to fine-tune instrument accuracy.
Calibrator	A substance traceable to a reference method for preparation or material used to calibrate, graduate, or adjust a measurement.
Carryover	The amount, in percent, of the previous sample that remains to influence the next sample measured by cycling diluent after a sample.
Cell Control	A preparation made of human blood with stabilized cells and surrogate material. It is used for daily instrument quality control.
Clean Baths Cycle	You present bleach at the sample probe for aspiration into the baths; alternative to Shutdown.
Codes	On printouts, symbols such as +++++, -----, ..., +, that appear **in place of** sample results. See Special Procedures and Troubleshooting in the Operator's Guide for additional information.
Coefficient of Variation	An expression, in percent, of data (SD) spread as related to the mean. %CV = (SD/mean)*100
Coincidence	More than one cell within aperture sensing boundaries at the same time. The system senses these as one large cell rather than as two distinct cells, so it generates one large pulse.
Control	A substance used for monitoring the performance of an analytical process or instrument.
Coulter Histogram Differential (CHD)	The method by which the system produces the differential parameters LY, MO, and GR.
Coulter Principle	W.H. Coulter's method for counting and sizing cells and particles.
Conventions	Standard style or format used in a particular manual.
CV	(see Coefficient of Variation)
Data Bit	Computer code used to transfer each character of information.
Defaults	Original settings in the instrument. You can change these to tailor laboratory operation protocols.
Diluter	Prepares the proper dilutions for sample analysis.
Dispense Diluent Cycle	Provides the proper amount of diluent for preparation of a prediluted sample.
Dispense Lyse Cycle	Dispenses lyse into the WBC bath.

Dispense-Verify Cycle	Dispenses proper volume of diluent for preparation of a prediluted sample with 20 µL of whole blood aspirated by the aspirate-verify cycle.
Drain Cycle	Drains the RBC bath, WBC bath, and the vacuum isolator chamber.
Dry Prime Diluent Cycle	Primes the pickup tube and diluent reservoir. Fills the diluent path between the diluent container and the diluent reservoir, even if empty; it does not fill the diluent path between the diluent reservoir and the baths.
Dry Prime Lyse Cycle	Primes the lyse path of the fluidics system; fills the lyse path completely, even if empty.
Expiration Date	The last day when you can use that lot number of reagent, control or calibrator.
femtoliters	One quadrillionth (10^{-15}) of a liter.
Field	Area on a screen for entering data.
Flags	On printouts, letters, numbers and symbols (H, L, *, X, +, 1, 2, 3, 4, M) that appear **next to** parameter results to indicate specific conditions. See Special Procedures and Troubleshooting in the Operator's Guide for additional information.
Hemoglobinometry	Measurement of hemoglobin in the blood. In Beckman Coulter instruments, this is done by comparing the amount of light that passes through a diluted lysed sample in which the released Hgb has been chemically converted, with the amount of light that passes through a blank.
Icon	Pictorial representation for commands or options on an instrument.
IQAP (Interlaboratory Quality Assurance Program)	Beckman Coulter provides this program which statistically compares your 4C PLUS cell control data to a group of other laboratories' control recovery data.
Linearity	The ability of an instrument to recover expected results (reference values or calculated values) for such parameters as WBC, RBC, Hgb and Plt at varying levels of concentration of these parameters within specified limits.
Lot Number	A manufacturer's code that identifies when the reagent was manufactured.
Mean	Arithmetic average of a group of data.
Operating Range	Range of results over which the instrument provides a numeric result.
Outlier	Control result that falls outside the expected range.
Parameters	Components of blood that the instrument measures and reports.
Parity	Method of detecting errors in data handling. The computer generates a parity bit such that the sum of the data bits and the parity bit are odd or even for each data word.
Performance characteristics	Actual performance of the instrument.
Performance specifications	Targeted performance of the instrument based on established ranges and parameters.
Power up Cycle	Performs appropriate checks to ensure system is functioning correctly and prepares the instrument for running. This cycle is part of the entire power up procedure and cannot be directly selected.
Precision	Ability of the instrument to reproduce similar results when a sample is run repeatedly. Precision of the instrument is a %CV, or an SD for diff parameters, based on at least 31 replicate determinations of the same sample. Precision shows the closeness of test results when repeated analyses of the same material are performed. A measure of reproducibility. Also known as imprecision.

Predilute	The process of preparing a minimal amount of blood specimen for analysis by dispensing diluent into an empty tube then adding the blood specimen. A prediluted sample is different than a whole-blood sample. *See* whole blood.
Predilute Cycle	Allows analysis of prediluted samples.
Prime Sweepflow Cycle	Primes the fluidics path from the diluent reservoir through the sweepflow coil and the path between the RBC aperture and the vacuum isolator chamber.
Prime Timeout Cycle	Prepares the Diluter to run samples if Diluter has been idle for 2 hours or more.
Quality Check Cycle	Allows analysis of A^{C}•T Tron cell control.
QC (Quality Control)	A comprehensive set of procedures your laboratory sets up to ensure that the instrument is working accurately and precisely.
Reagent Management Card	A program card that manages your reagent usage.
Reproducibility	See precision.
Rinse and Mix Cycle	Drains the baths, supplies the rinse, and provides the air for mixing.
SD (Standard Deviation)	A measure of dispersion about the mean.
Shift	Consecutive values that abruptly move from one side of the mean to the other then maintain a constant level.
Shutdown Cycle	Cleans the fluidic lines and apertures to help prevent residue buildup, and turns off Hgb lamp.
Software Card	A program card that contains instructions to run the instrument.
Standard Deviation (SD)	See SD.
Startup Cycle	Ensures that the instrument is ready to run; includes turning on Hgb lamp and performing background test.
Stop Bit	A computer code that indicates the end of a character.
Sweep Flow	A steady stream of diluent that flows behind the RBC aperture during sensing periods to keep RBCs from swirling back into the sensing zone and being counted as platelets.
Table of Expected Results	Target values for a control material used for quality control parameters. Usually reported on a package insert shipped with the control material; can be a separate assay sheet.
Trend	Values that continue to increase or decrease gradually over a period of time.
Verification	Procedure to analyze cell controls or whole blood with known values to determine if your control results are within expected range.
Verify Predilute	Procedure that performs the aspirate-verify cycle followed by the dispense-verify cycle to confirm performance of the predilute.
Voting	In Beckman Coulter hematology instruments, the system compares the three counts for RBC, WBC, Plt. Unless at least two counts agree, the system does not accept the count. It displays a code (-----) to indicate a voteout.
Wet Prime Cycle	Primes the fluidics path of the Diluter and baths with diluent and removes small amounts of air that may have leaked into the diluent lines.
Whole Blood	Non-diluted blood; blood and anticoagulant only.
Whole Blood Cycle	Allows analysis of whole blood.
Zap Aperture Cycle	Clears the aperture using the zap current circuit.

ABBREVIATIONS

Abbreviation	Explanation
µL	microliter
µm	micrometer
A	ampere
AIM	aperture integrity monitor
ANSI	American National Standards Institute
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Materials
AWG	American Wire Gauge
bps	bits per second
CBC	complete blood count
CDC	Centers for Disease Control and Prevention
CEE	Commission for Electrical Equipment
CHD	Coulter histogram differential
cm	centimeter
CSA	Canadian Standards Association
CV	coefficient of variation
diff	differential
dL	deciliter
EDTA	ethylenediaminetetraacetic acid
FDA	Food and Drug Administration
fL	femtoliter
ft	foot or feet
g	gram
gal	gallon
GR	granulocyte
Hct	hematocrit
Hgb	hemoglobin
Hz	hertz
IEC	International Electrical Commission
IQAP	Interlaboratory Quality Assurance Program
L	liter
LY	lymphocyte
m	meter
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
MCV	mean corpuscular volume

Abbreviation	Explanation
mL	milliliter
mm	millimeter
MO	mononuclear cell
MPV	mean platelet volume
MSDS	material safety data sheets
mW	milliwatt
n	number
NCCLS	National Committee for Clinical Laboratory Standards
NEMA	National Electrical Manufacturers Association
nm	nanometer
pg	picogram
Plt	platelet
psi	pounds per square inch
QA	quality assurance
RBC	red blood cell
RDW	red cell distribution width
SD	standard deviation
UL	Underwriters Laboratory
Vac	volts of alternating current
Vdc	volts of direct current
VIC	vacuum isolator chamber
VRM	Volts Root Mean Square
WBC	white blood cell

Symbols

Numerics

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W

Z

INDEX

TRADEMARKS

A^{C}•T diff, A^{C}•T Rinse, A^{C}•T Tron, COULTER, COULTER COUNTER, the “CC” logo, diff A^{C}•T Pak, diff A^{C}•T Tainer, 4C and S-CAL are trademarks of Beckman Coulter, Inc.

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COULTER A^{C}•T diff Analyzer Documentation

▪ Reference PN 4237422	Use and Function • Installation • Operation Principles • Specifications/Characteristics • Precautions/Hazards • Host Transmission Specifications • Log Sheets • References • Glossary • Abbreviations • Index
▪ Operator's Guide PN 4237416	Routine Procedures • Cell Controls • Running Samples • Reviewing Results • Calibration • Service and Maintenance • References • Glossary • Abbreviations • Index
▪ Operating Summary PN 4237420	Overview of daily procedures and screen icons.
▪ Installation and Training Guide diff A^{C}•T Tainer PN 4237417	Installing the A^{C}•T diff Analyzer • Learning About the A^{C}•T diff Analyzer • Questions and Answers • Component Locations • Installation Checklist
▪ Installation and Training Guide diff A^{C}•T Pak PN 4237421	Installing the A^{C}•T diff Analyzer • Learning About the A^{C}•T diff Analyzer • Questions and Answers • Component Locations • Installation Checklist

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