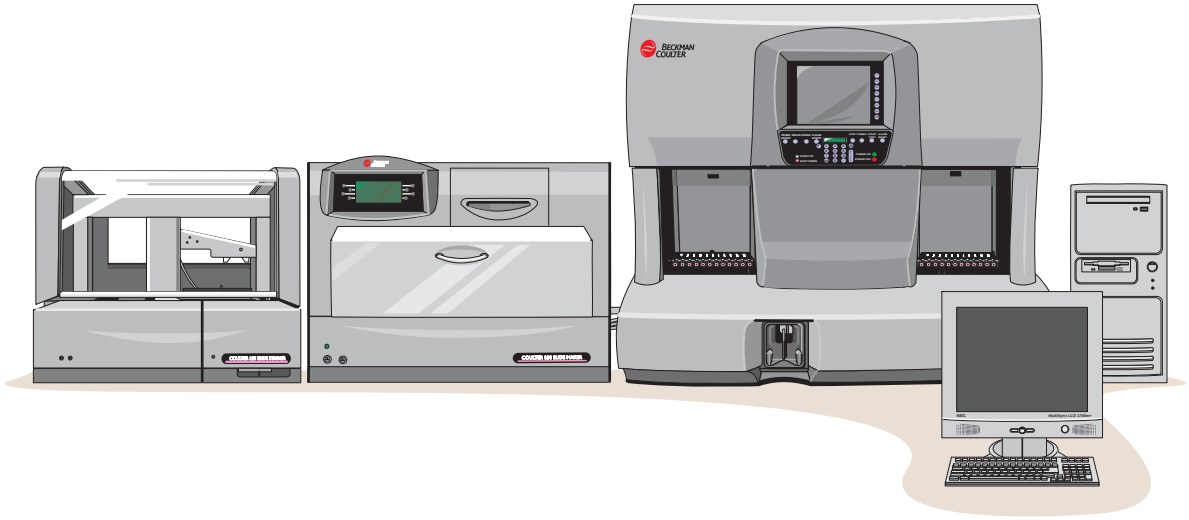
COULTER LH 780 System

Reference



PN 773021AD (January 2013)

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

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.

Issue A, 12/06
Software version 1A. Converted from Help Version 1A.062781.

Issue AA, 8/09
Software version 1B1. Converted from Help Version 1B1.091732.

Issue AB, 10/10
Software Version 1B1.

Updates were made to the company corporate address.

Issue AC, 12/10
Software Version 1B1.

Changes were made to:

- BAR-CODES AND THE LH 700 SERIES
- Codabar
- NW-7
- BAR-CODE LABEL SPECIFICATIONS
- Extended Digit Bar Code
- NW7 Decoding
- Code 39 Bar Code
- Code 128
- Table 4.29, Code-Related Specifications

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

Issue AD, 01/13
Software Version 1B3. Manual derived from Online Help version 1B3.

Changes were made to:

- SPECIAL REQUIREMENTS: HARDWARE
- Space and Accessibility
- Pneumatic/Hydraulic Tubing Connections
- Changing 9-pin and 25-pin connectors
- Added reference to the Hematology Tube List information

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

FIGURES

TABLES

This introductory section contains the following topics:

- How to use your COULTER LH 780 System hard-copy manuals
- About this manual
- Online Help System
- Conventions

HOW TO USE YOUR COULTER LH 780 SYSTEM HARD-COPY MANUALS

Use the Reference manual for in-depth information about what the instrument does, the methods it uses, its specifications, and information on installation, safety and software options. The Reference manual for the LH 780 System is included in the online Help system; it is available in hard copy by request.

Use the Special Procedures and Troubleshooting manual to run calibration; to clean, replace or adjust a component on the instrument; and for troubleshooting the instrument. This document is made up of procedures from the online Help system; it is available in hard copy by request.

Use the Operator's Guide for the day-to-day operation of your instrument. This document is made up of procedures from the online Help system; it includes Startup, running controls and samples, reviewing data, Shutdown, and the software on the Analyzer and the Workstation. This document is available in hard copy by request.

Use the SlideMaker Operator's Guide for in-depth information about what the SlideMaker does, the methods it uses, its specifications, and information on installation, safety and software, as well as day-to-day operating and troubleshooting your SlideMaker. This document is made up of procedures from the online Help system; it is available in hard copy by request.

Use the SlideStainer Operator's Guide for the day-to-day operating and troubleshooting of your SlideStainer. This document is made up of procedures from the online Help system; it includes in-depth information about what the SlideStainer does, the methods it uses, its specifications, and information on installation, safety and software. This document is available in hard copy by request.

Use the Host Transmission Specification to find the information needed to program the transmission interface between the LH 780 System and your laboratory's host computer. This document is available in hard copy by request.

See the Documentation page on the back cover of this manual for the contents of each manual. It can help you to determine quickly in which manual the information you need is located.

ABOUT THIS MANUAL

Your LH 780 System Reference Guide is a 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, the reagents, calibrators and controls used, and a short description of the major components.
- Chapter 2, Installation
  Contains the instrument requirements, and the diagrams of the reagent/pneumatic tubing connections and the interunit cable connections.
- Chapter 3, Operation Principles
  Contains descriptions of the Coulter Method, the normal sample flow through the instrument, how counting and sizing are accomplished, and what the DataPlots show.
- Chapter 4, Specifications/Characteristics
  Details the instrument and performance specifications, the performance characteristics, the interferring substances, and the bar-code label specifications.
- Chapter 5, Hazards
  Describes laser safety precautions and the location of the laser-related labels.
- References
- Glossary
- Index, hard copy only

ONLINE HELP SYSTEM

The LH Workstation has a comprehensive Online Help System, which includes reference information, all operating, maintenance and troubleshooting procedures. On the LH Workstation, select  to access Help.

CONVENTIONS

This document uses the following conventions:

 indicates a key on the Numeric keypad.

 indicates a key on the LH Workstation keyboard.

 is the icon for Patient results on the LH Workstation.

 is the icon for the Printer on the LH Workstation.

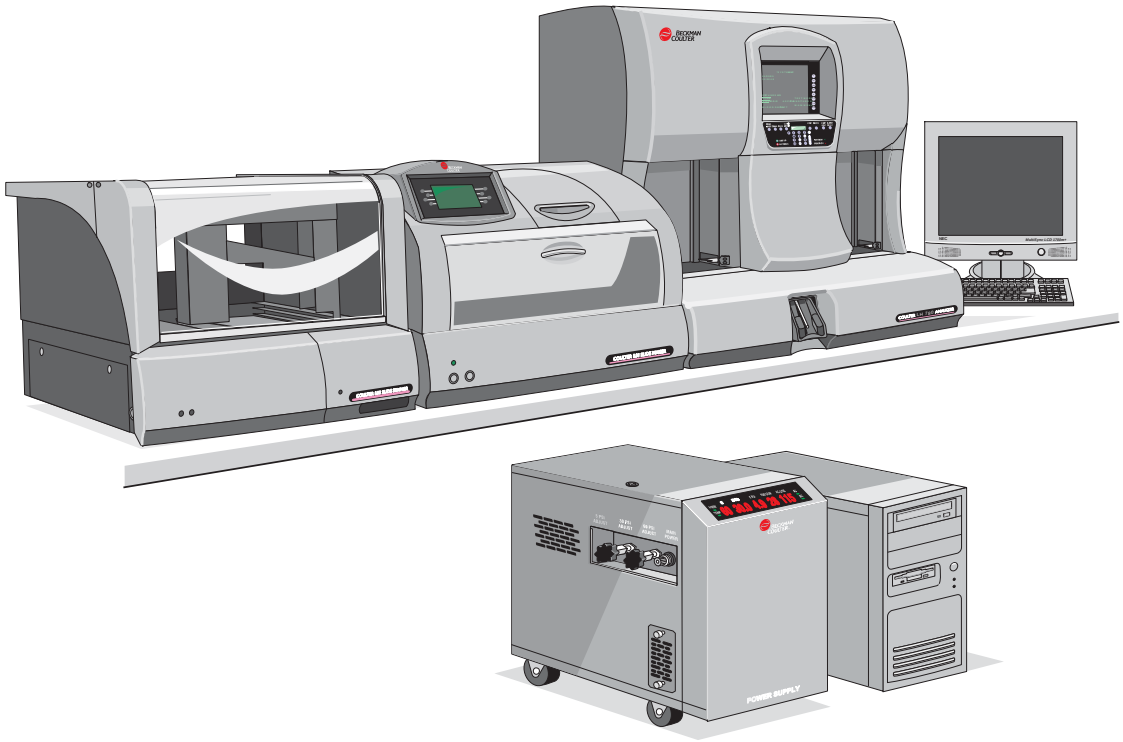
1.1 INTENDED USE

The COULTER LH 780 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 780 Hematology Analyzer also provides automated Reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.

1.2 INDICATIONS FOR USE

The purpose of the LH 780 is to separate the normal patient, with all normal system-generated parameters, from the patient who needs additional studies of any of these parameters. These studies might include further measurements of cell size and platelet distribution, manual WBC differential or any other definitive test that helps diagnose the patient's condition.

Figure 1.1 COULTER LH 780



Parameters

The system determines these hematologic parameters of whole-blood specimens:

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

Unless otherwise stated, all parameter results are shown in a US unit format throughout the manuals.

1.3 QUALITY CONTROL (QC)

Your laboratory can use these QC techniques with the LH 780:

- Daily instrument checks
- Commercial controls
- Delta checks

- Patient controls
- XB Analysis
- Extended QC
- Xm Analysis
- Interlaboratory Quality Assurance Program (IQAP)

Quality Assurance includes routine maintenance and service in conjunction with the use of controls and calibrators. The combination of these methods provides the assurance of complete quality control and should be applied separately or in combination, in accordance with your laboratory, state and federal protocols.

1.4 METHOD HISTORY

Development

W.H. Coulter (1956) describes the Coulter Principle:[1]

> A suspension of blood cells is passed thru [sic] a small orifice simultaneously with an electric current. The individual blood cells passing thru the orifice introduce an impedance change in the orifice determined by the size of the cell. The system counts the individual cells and provides cell size distribution. The number of cells counted per sample is approximately 100 times greater than the usual microscope count to reduce the statistical error by a factor of approximately 10 times.

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 sparked 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 contain the trapped plasma error of centrifugal Hct measurements.[8]

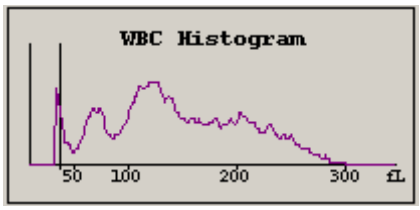
Bull et al. described the use of a COULTER COUNTER analyzer for counting thrombocytes.[9] This method, useful as it was, depended on preparing thrombocyte-rich plasma to avoid counting erythrocytes as thrombocytes. Mundschenk et al. and Schulz and Thom discussed the possibility of counting thrombocytes 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]

Corrected WBC Counts

The uncorrected WBC (UWBC) is adjusted for interfering substances when appropriate. If there is a population of interfering particles in the far left of the WBC histogram, the number of cells is derived and the WBC count is corrected. No further correction of the white count should be required.

Both the WBC and UWBC are reported. If no correction is required, then the WBC = UWBC. If a white count is corrected, the Cellular Interference Suspect message is displayed and an R flag is placed next to the UWBC. When the separation between the interfering particles and WBC populations is poorly defined on the WBC histogram, an R flag is placed next to the corrected WBC.

Figure 1.2 Corrected WBC



Hemoglobinometry

The lytic reagent used for the complete blood count (CBC) parameters prepares the blood so the system can count leukocytes and measure the amount of hemoglobin. The lytic reagent rapidly and simultaneously destroys the erythrocytes and converts a substantial proportion of the hemoglobin to a stable pigment while it leaves 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 Hematology. [14]

Differential Measurement

The COULTER VCS established WBC differential technology using three measurements: individual cell volume, high-frequency conductivity and laser-light scatter.

The combination of low-frequency current, high-frequency current and light-scattering technology provides abundant cell-by-cell information that is translated by the instrument into conventional stained-film leukocyte categories.

Volume Analysis

Electronic leukocyte volume analysis, using low-frequency current, has been used since 1967.[15] It has been evaluated as a possible adjunct to the differential white cell count.[16,17,18,19]

Conductivity Analysis

Cell walls act as conductors to high-frequency current. The current, while passing through the cell walls and through each cell interior, detects differences in the insulating properties of

cell components. The current characterizes the nuclear and granular constituents and the chemical composition of the cell interior. [20,21,22]

Light Scatter Analysis

Coulter's experience in flow cytometry dates back decades to Fulwyler's pioneering use of light scatter for cell analysis.[23] Loken et al. and Jovin et al. discuss the relationship of particle size and refractivity to the angle of light scattered from a laser beam.[24,25]

Reticulocyte (Retic) Analysis

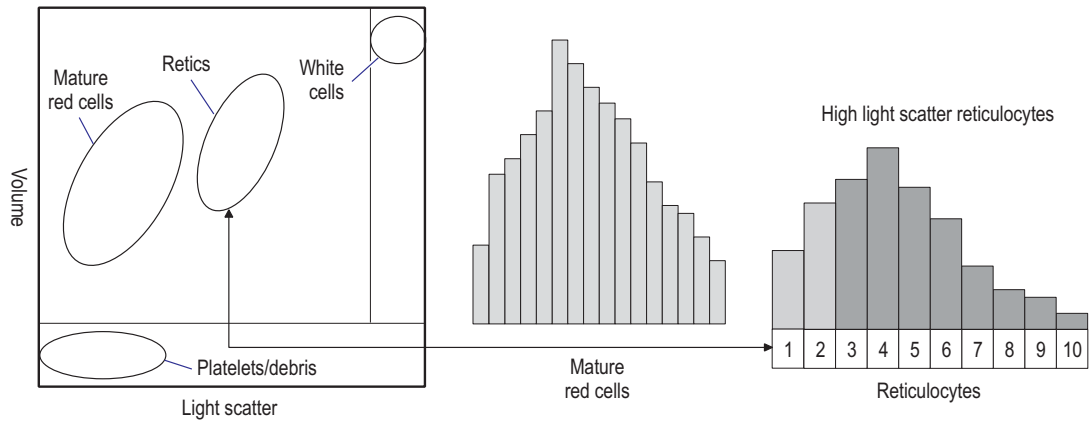
Reticulocytes are immature, nonnucleated erythrocytes retaining a small network of basophilic organelles, consisting of RNA and protoporphyrin. The enumeration of reticulocytes provides a simple, effective means to determine red cell production and regeneration.[26,27,28,29]

The most common means of measuring reticulocytes is to use supravital dyes, such as New Methylene Blue or Brilliant Cresyl Blue. These dyes precipitate and aggregate the basophilic substances within the reticulocyte, resulting in a granular, staining pattern easily seen with light microscopy.[30]

Reticulocyte immaturity is related to cell volume and light scatter. Since more immature reticulocytes are larger, contain more RNA and cause increased light scatter, the cell volume and light scatter will increase with immaturity of the cell.

Figure 1.3 illustrates the IRF and MRV algorithms. This figure is a representation of the VCS data that is shown on the two dimensional analyzer display.

Figure 1.3 Illustration of the Ten Light Scatter Regions



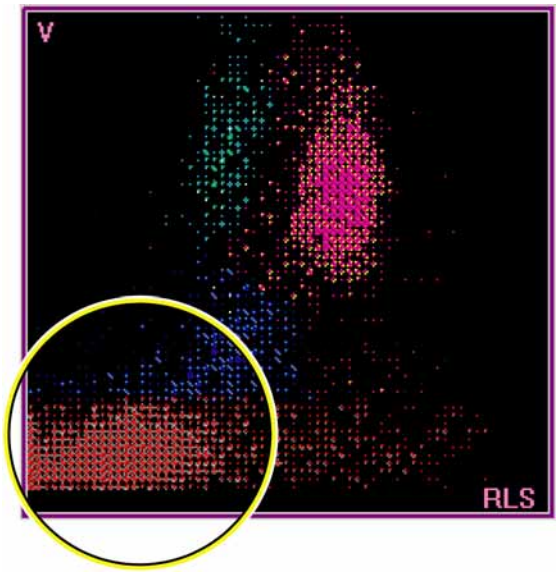
The RET% is calculated as the ratio of reticulocytes to the total number of red cells. The spectrum of light scatter intensity for the retic population is analyzed algorithmically. The detected light scatter intensity of the retic population is divided into equal regions as shown above. The IRF parameter is calculated as the ratio of the total number of retic events in the outermost eight regions (3 to 10) to the total number of retics (regions 0 to 10 - region 0 is not illustrated above). The MRV parameter is calculated as the average volume of all reticulocytes or the mean volume of all retic events.

NRBC Enumeration

The NRBC enumeration is achieved through the combined use of impedance and VCS technology and a proprietary algorithm.

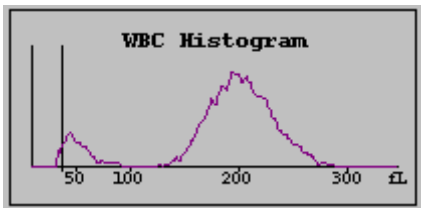
The first step in NRBC enumeration is the identification of particles in the NRBC signature position in the differential data plot. This information is generated from VCS analysis of the cells.

Figure 1.4 NRBC Signature Position on Differential Dataplot



Once cells have been identified in this region, the LH 780 examines the far left region of the WBC histogram for the presence of cells.

Figure 1.5 NRBC Location on WBC histogram



If the VCS dataplot and the WBC histogram both indicate the presence of NRBCs, then the combined information is further evaluated for special data patterns -- such as small lymphocytes, giant platelets, and aging blood. If the combined information from the VCS dataplot and the WBC histogram are consistent with NRBCs, the NRBC count is derived from the WBC histogram.

COULTER IntelliKinetics Application

The LH 780 utilizes the COULTER IntelliKinetics application. Control of reaction kinetics is extremely important to ensure the best performance of the automated white cell differential and reticulocyte analysis. The IntelliKinetics application is a management tool for the key

step of system optimization when fluctuations in external variables in the laboratory, such as temperature, occur.

The IntelliKinetics application management ensures consistent reaction kinetics. This application intelligently manages variations in ambient laboratory temperature through automatic adjustments to reagent reaction temperature, exposure time and delivery volumes. Enhancements in instrument electronics, such as improved signal-to-noise ratio, work with the IntelliKinetics application to provide better data signals for the system algorithms to analyze. Reagent temperature control helps to increase the speed of dye uptake, thereby improving instrument throughput. Analysis occurs under controlled conditions.

The LH 780 with the IntelliKinetics application shows improved separation of populations, both for the white cell differential and reticulocytes. Cell populations made available for analysis by the algorithms are in a more consistent location in three-dimensional space. The IntelliKinetics application, working in concert with new algorithms, provides the instrument with the best signals for analysis, even when the laboratory environment varies throughout the day.

XB Analysis

Dennis B. Dorsey, MD, proposed in 1963 that the relatively constant blood cell indices could be used to follow the performance of hematology instrumentation.[32] Brian Bull, MD, improved the technique and it is termed XB Analysis.[32]

XB Analysis uses a "weighted moving average" of patient sample results because Koepke and Protextor said that QC materials "ideally should be similar in structure and in reactivity to the patient constituent being measured. Therefore freshly drawn patient blood samples seem to be the most appropriate [QC material]."[33] Bull explains, "The analyser [sic] is considered to be 'in control' when mean MCV, MCH, and MCHC determined on a batch of 20 patients by use of the algorithm XB are within 3% of the expected mean indices of the population."[34]

Xm Analysis

Xm Analysis is a quality-control method that uses an Exponentially Weighted Moving Average (EWMA) of CBC, Diff, NRBC and Reticulocyte Parameters and compares them with known target values, to monitor instrument performance. The first form of moving average statistical analysis in hematology was XB Analysis.

Extended QC

Extended QC Rules are derived from the German Quality Control Guidelines for the Medical laboratory, known in Germany as Rili-BÄK. Rili-BÄK (Guidelines of the Federal Chamber of Physicians), was first published in 1987 and amended in 1990 and 1993 covering clinical chemistry, immunochemistry and other tests, but not hematology. In 2003, the guidelines were extended to include hematology.

Users can enable/disable Extended QC Rules for 5C Cell control.

1.5 SYSTEM COMPONENTS

The LH 780 Series is a modular system that consists of the following units.

Power Supply

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

Diluter

This unit is the primary operating unit of the system. It performs the mixing, transporting, pipetting, diluting, lysing, and sensing functions.

Analyzer

This unit controls the electronic sequence of each operating cycle. It receives count and size information directly from the Diluter while the sample is being cycled. Many of the controls and indicators needed for normal daily operation on the Analyzer.

Workstation

The Workstation holds the algorithms used to process the List Mode Data supplied by the Analyzer. From the List Mode Data, the Workstation computes Diff and Retic results, develops the histograms and DataPlots, and displays the results. The Workstation stores the data and transmits it to the Printer and Host computer.

The Workstation is equipped with a mouse that allows operator interaction with the software.

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

- This equipment is used in a manner other than specified.
- You introduce software that is not authorized by Beckman Coulter into your computer.
- You install software that is not an original copyrighted version.

Operate the instrument as instructed in your product documentation. Only operate your system's computer with software authorized by Beckman Coulter. Only use software that is an original copyrighted version to prevent virus contamination.

Handheld Scanner

Use the handheld scanner to manually read bar-code labels.

1.6 HARDWARE OPTIONS

Graphic/Laser Printer

You can use any printer that is supported by the Microsoft Windows' 2000 operating system. The Printer prints the data displayed on the LH Workstation screen, including parameter data and graphics.

LH SlideMaker

The LH SlideMaker makes blood smears from samples as they are being analyzed, according to user-defined criteria.

LH SlideStainer

he LH SlideStainer stains blood smears generated by the LH SlideMaker or by manually prepared blood smears introduced into the LH SlideStainer.

1.7 CONTROLS AND CALIBRATOR

Controls

Use stable reference controls to monitor the instrument performance as part of your quality control and to verify calibration. Refer to the package insert for detailed information before using a control.

5C Cell control monitors the CBC and differential (Diff) parameters.

LATRON primer prepares the tubing and instrument components for the LATRON control.

LATRON control monitors the performance of the volume, conductivity and light scatter measurements.

Retic-C Cell control monitors the reticulocyte (Retic) parameters.

Calibrator

The S-CAL calibrator kit is an acceptable 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. Refer to the package insert for detailed information before use.

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

1.8 REAGENTS

Beckman Coulter developed and tested this Beckman Coulter instrument exclusively for use with Beckman Coulter reagents. Because Beckman Coulter cannot guarantee the performance of the instrument using reagents not manufactured by Beckman Coulter, please be advised that the warranty on the instrument is conditioned upon the use of Beckman Coulter reagents.

Diluent

Beckman Coulter diluents, including LH Series diluent and ISOTON 4 diluent, are isotonic electrolyte solutions that:

- Dilutes the whole-blood samples.
- Stabilizes cell membranes for accurate counting and sizing.
- Conducts aperture current.
- Rinses instrument components between analyses.
- Carries and focuses the sample stream in the flow cell to direct the blood cells through the aperture.

Since cell size (volume) is measured, the effect of diluent on osmosis or other phenomena must be tightly controlled. The diluent must not contain particles and must not support growth of bacteria or molds.

CBC Lytic Reagent

LYSE S III Diff Lytic reagent:

- Rapidly lyses erythrocytes (RBCs), freeing hemoglobin (Hgb) and reducing the size of cellular debris to a level that does not interfere with leukocyte (WBC) count.
- Causes a substantial conversion of the Hgb to a stable cyanide-containing pigment, the absorbance of which is directly proportional to the Hgb concentration over the clinical range.

LYSE S 4 Lytic reagent:

- Rapidly lyses erythrocytes (RBCs), freeing hemoglobin (Hgb) and reducing the size of cellular debris to a level that does not interfere with leukocyte (WBC) count.
- Causes a substantial conversion of the Hgb to a stable oxyhemoglobin-based hemachromagen, the absorbance of which is directly proportional to the Hgb concentration over the clinical range.

LH Series PAK Reagent System

The LH Series PAK Reagent Kit contains Erythrolyse II Diff Lytic Reagent and StabiLyse Diff Preservative.

The Diff Lytic Reagent:

- Dilutes the blood samples
- Rapidly lyses erythrocytes (RBCs)
- Reduces cellular debris to an insignificant level

The Diff Preservative:

- Maintains leukocyte (WBCs) in their near-natural state
- Allows the leukocytes to be differentiated into their subpopulations through the volume, conductivity and light-scatter measurements.

LH Series RETIC PAK Reagent Kit

The LH Series RETIC PAK Reagent Kit contains Reagent A Retic Stain and Reagent B Retic Clearing Solution.

- Retic Stain is a special solution of New Methylene blue dye. The dye precipitates the basophilic RNA network found in the reticulocytes.
- Retic Clearing Solution is a hypotonic acid solution to clear hemoglobin from the cells without removing the precipitated dye.

Cleaner

LH Series Cleaner rinses and cleans the internal surfaces of instrument components that come into contact with blood samples. Daily use prevents protein buildup and eliminates the need for routine aperture bleaching and blood sampling valve maintenance.

1.9 MATERIAL SAFETY DATA SHEETS (MSDS)

To obtain an MSDS for Beckman Coulter reagents used on the LH 780:

1. On the internet, go to www.beckmancoulter.com and select MSDS from the Customer Support drop-down menu.
2. If you do not have internet access:
   - In the USA, either call Beckman Coulter Customer Operations (800-526-7694) or write to:

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

2.1 GENERAL

CAUTION Possible system damage can occur if you uncrate the instrument, install it or set it up. Keep the instrument in its packaging until your Beckman Coulter Representative uncrates it for installation and setup.

Your instrument is tested before it is shipped from the factory. International symbols and special handling instructions printed on the shipping cartons tell the carrier how to handle this electronic instrument.

Carefully inspect all cartons when they arrive. If you see any sign of mishandling or damage, file a claim with the carrier immediately. If the shipment is separately insured, file a claim with the insurance company.

2.2 SPECIAL REQUIREMENTS: HARDWARE

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

Space and Accessibility

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

- Comfortable working height.
- Access to perform service procedures. Allow at least 46 cm (18 in.) for the rear doors plus sufficient room for work space. Units can be moved to obtain additional work space.

Figure 2.1 Space for tower-type computers

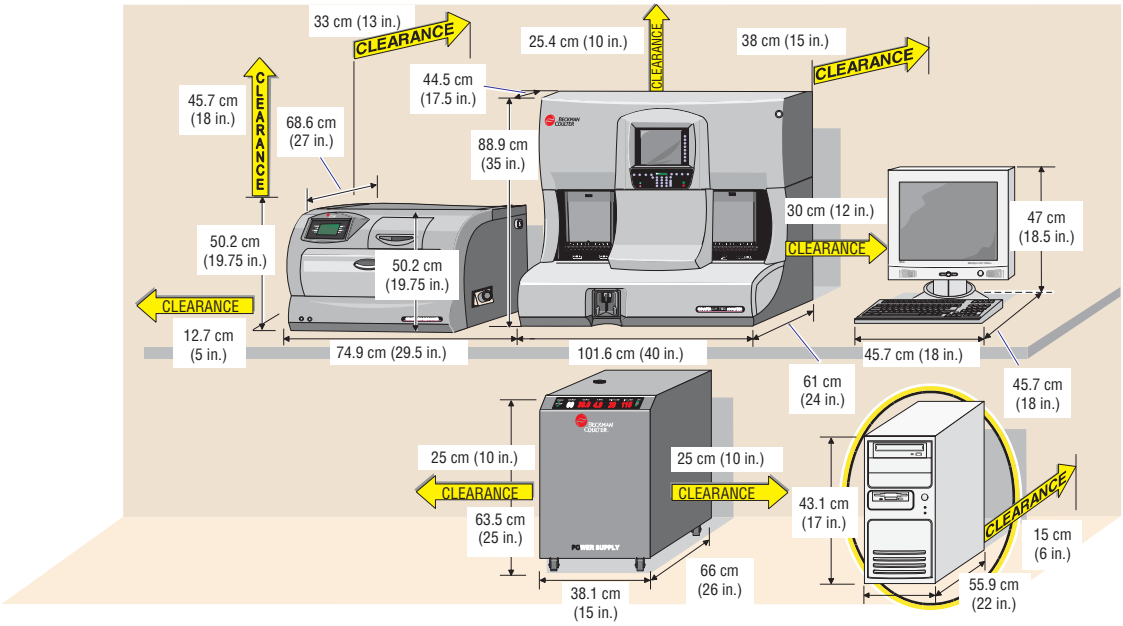
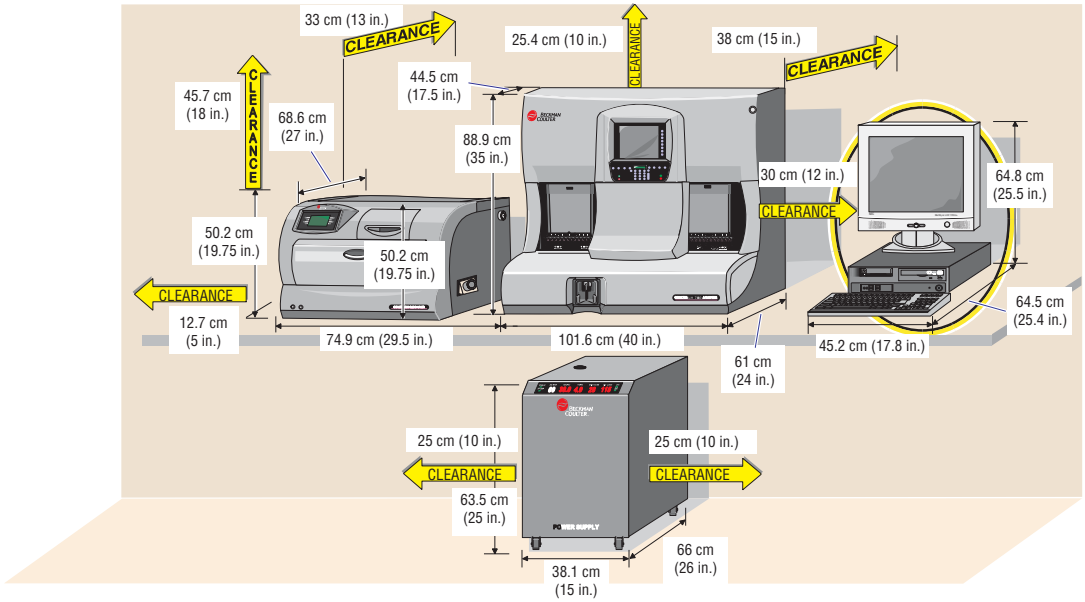


Figure 2.2 Space for Small Form Factor (SFF)-type computers



Electrical Input

CAUTION Introduction of electrical interference causing the instrument to lock up or reset frequently can occur if you do not plug the primary power cables directly into an electrical outlet. Overheating, melting and burning of the power lines can occur if you use an extension cord with the primary power cables. Plug the primary power cables directly into an electrical outlet. Place the instrument close enough to an electrical outlet that an extension cord is not needed.

This instrument requires:

- An independent protected circuit
- A three-wire outlet furnishing the applicable line voltage, single-phase input power
- A ground path capable of carrying the full current of the circuit (confirmed thirdwire earth ground)
- That the 3-m (10-ft) primary power cord on the rear of the Power Supply be plugged directly into the electrical outlet. Do not use an extension cord.

Current-carrying capacity of 20 A is recommended, although the actual power consumption is about 2080 W as shown in the table below:

Instrument Components	Watts
Analyzer, Diluter, Power Supply	860
SlideMaker	430
SlideStainer	430
Computer	300
Monitor	60
	2080

Building outlets must be properly grounded and transients protected.

Ambient Temperature and Humidity

Operate the system in a room with a temperature of 15.5° to 32°C (60° to 90°F) and humidity up to 95% without condensation.

If the average room ambient temperature changes more than 5.5°C (10°F) from the calibrating temperature, verify calibration and recalibrate if necessary to ensure conformance to specifications.

Air Conditioning

In air-conditioned environments, an additional 5,500 Btu is required to compensate for the heat the system generates.

Ventilation

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

Drainage

CAUTION Incomplete waste chamber drainage and eventual waste chamber overflow into the vacuum system can occur if the waste line is too long. Contact your Beckman Coulter Representative if you need to increase the length of the waste line supplied with the instrument.

WARNING Biohazardous contamination could occur from contact with the waste container and its associated tubing if not handled with care. Avoid skin contact. Clean up spills immediately. Dispose of the contents of the waste container in accordance with your local regulations and acceptable laboratory procedures.

The maximum waste line length is 3.7 m (12 ft). The waste drain tubing (rear panel of the Diluter) supplied with the system can be connected to either:

- An open drain, suitable for biohazardous waste, less than 76 cm (30 in.) above the floor
- A waste container with a minimum capacity of 20 L (5 gal.).

When using an open drain instead of a waste container:

- Mechanically secure the waste tube into the drain so the tube cannot accidentally come out of the drain. This prevents spillage.

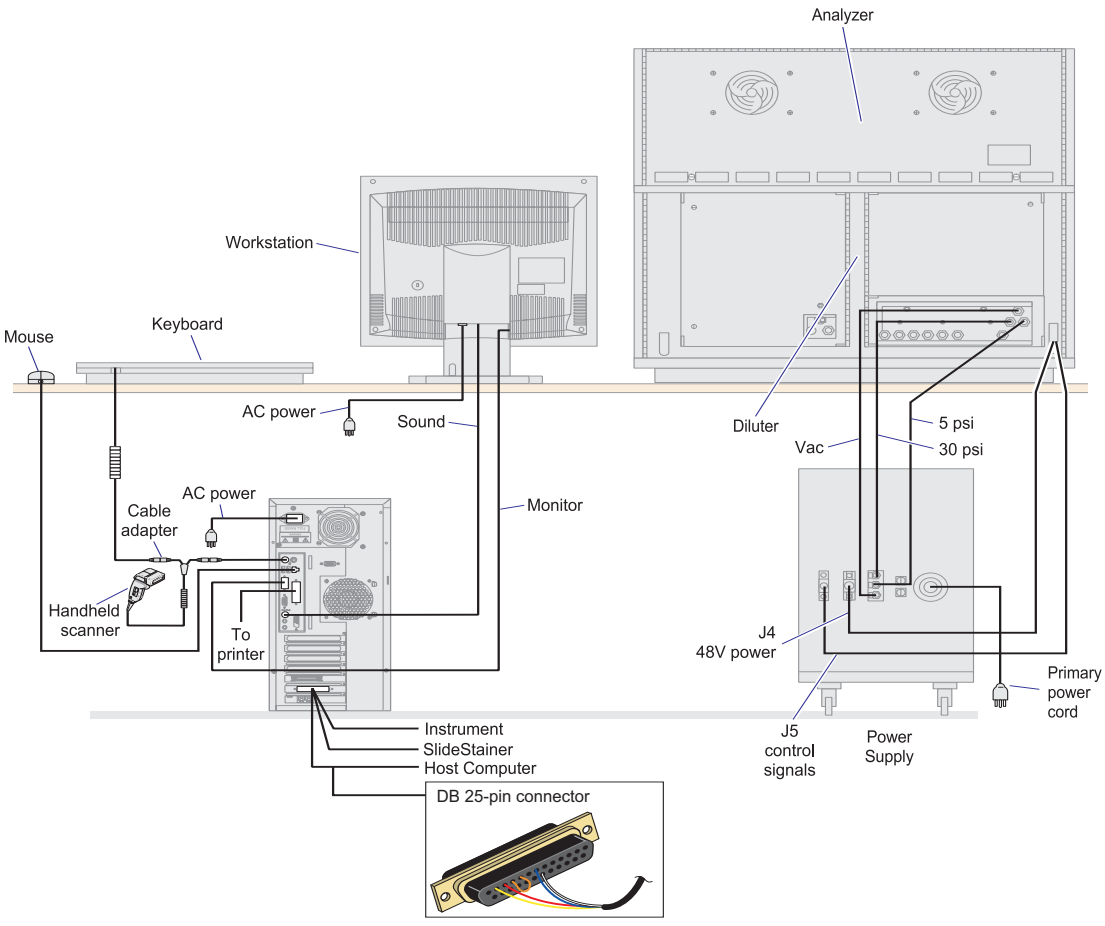
Be sure to dispose of waste in accordance with environmental protection regulations.

2.3 INTERUNIT CONNECTIONS

Power and Signal Cables

Figures 2.3 shows the interunit connections of the power and signal cables, highlighting the DB 25-pin connector. Your Beckman Coulter Representative makes these connections when installing the instrument.

Figure 2.3 Rear of instrument and accessories with DB-25 pin connector for tower-type computers

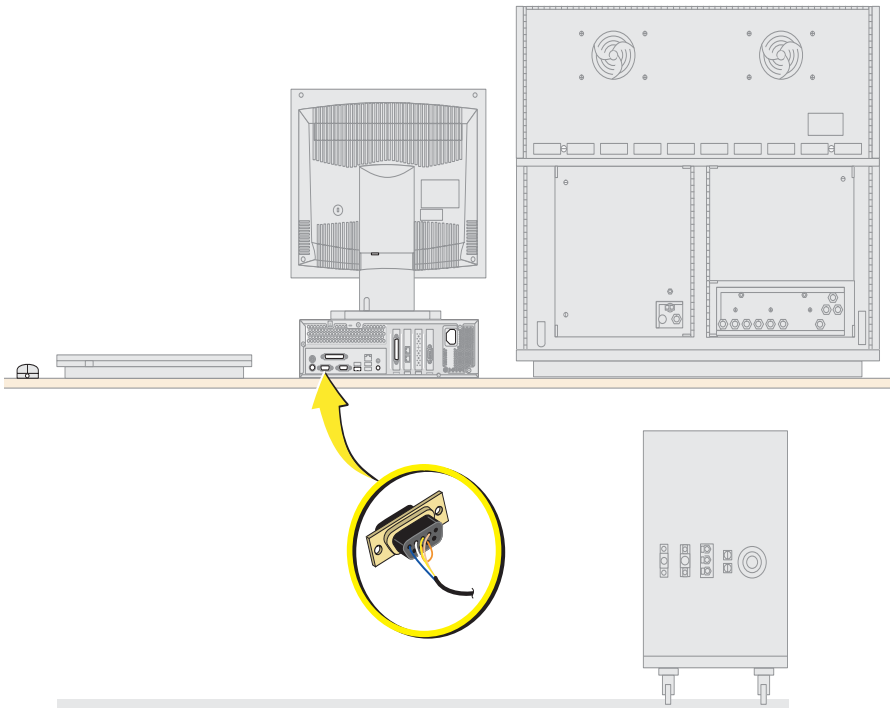


Changing 9-pin and 25-pin connectors

For LH 700 Series workstations, the COM Port can be configured to COM 1 or COM 6. The COM Port depends on the workstation to be used. Figure 2.3, Rear of instrument and accessories with DB-25 pin connector for tower-type computers shows the connector location when using the LH 700 Series tower-style computer. Figure 2.4, Rear of instrument with DB

9-Pin Connector shows the connector location when using the LH 700 Series Small Form Factor computer.

Figure 2.4 Rear of instrument with DB 9-Pin Connector



Note: The DB 9-pin connector on the computer base, designated as COM 1, is located beside the video display connector.

Pneumatic/Hydraulic Tubing Connections

CAUTION Possible reagent siphoning effect and priming problems can occur if a reagent container is placed above the level of the Analyzer. Do not place reagent containers above the level of the Analyzer.

IMPORTANT Placing Reagent Paks in any location other than on the counter next to the instrument may cause erroneous results.

Figure 2.2 shows the tubing connections between the Diluter and the:

- Reagent containers
- Waste container
- Power Supply pressure and vacuum supplies.

Figure 2.5 Pneumatic/Hydraulic Connections

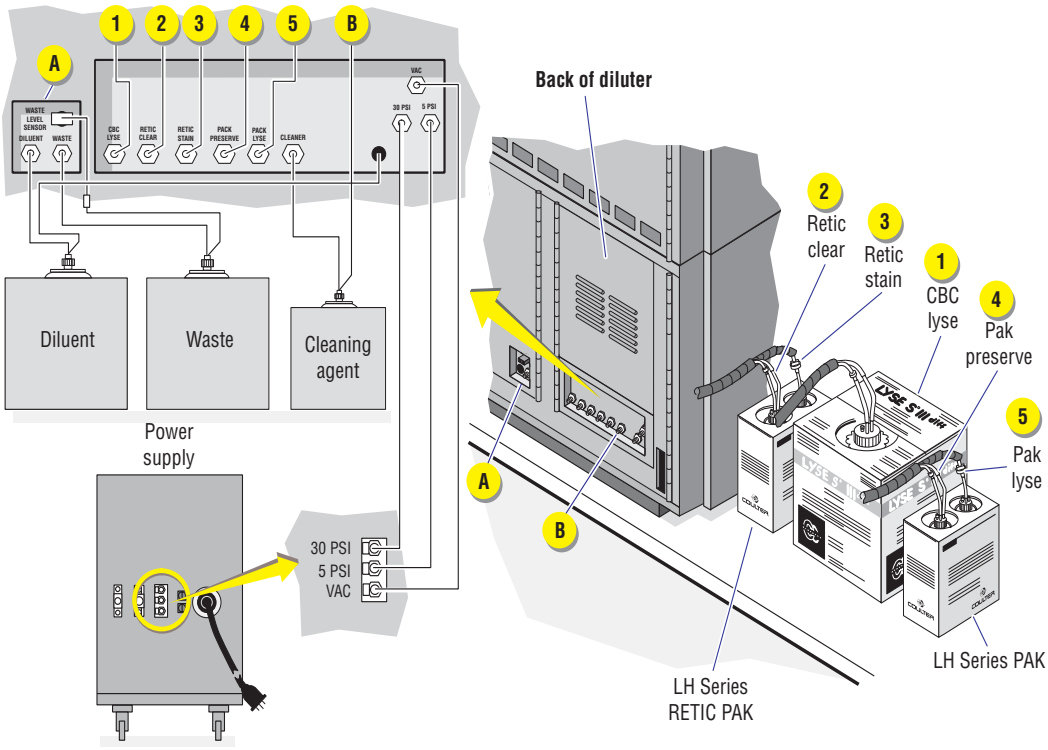


Table 2.1 Description of Pneumatic/Hydraulic Connections

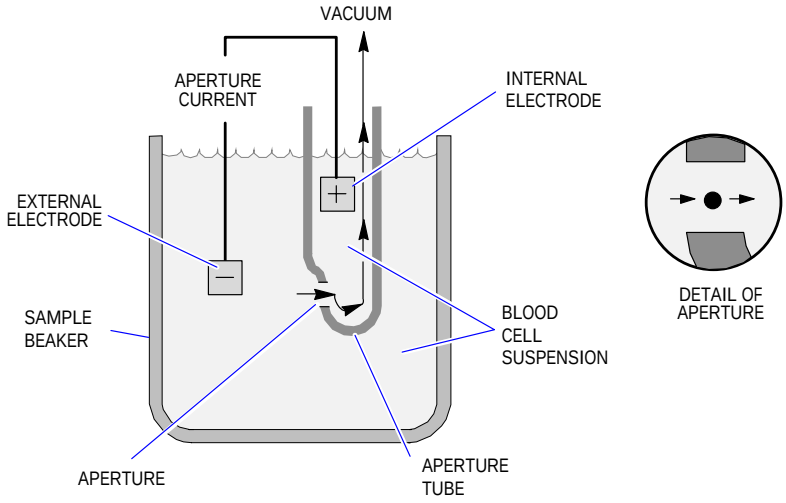
A	Diluent connection
B	Cleaner connection
1	CBC lyse connection
2	Retic clear connection
3	Retic stain connection
4	Pak preserve connection
5	Pak lyse connection

3.1 COULTER METHOD

CBC Analysis

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

Figure 3.1 Coulter Method of Counting and Sizing



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

While the number of pulses indicates particle count, the size of the electrical pulse is proportional to the cell volume.[35,36,37,38]

Differential Analysis

WBC differential analysis and classification occurs in the flow cell, where:

- Low-frequency current measures volume,
- High-frequency current senses cellular internal content through measuring changes in conductivity,
- Light from the laser bouncing off the individual WBC cells characterizes cellular surface, shape and reflectivity.

Effect of Reagents

The conductive diluent must affect cells minimally, if at all.

Both lytic reagents must destroy erythrocytes without significantly affecting leukocytes. They must work rapidly to satisfy the speed with which the system works.

The leukocyte preservative must

- Provide clear separation of the white blood cell populations, and
- Preserve leukocytes in their near-natural state for accurate cytometric measurement.

Reticulocyte Analysis

A supravital dye, New Methylene Blue, is incubated with whole-blood samples. The dye precipitates the basophilic RNA network found in reticulocytes. Hemoglobin and unbound stain are removed by adding a clearing reagent, leaving clear spherical mature RBCs and darkly stained reticulocytes.

Stained reticulocytes are differentiated from mature red cells and other cell populations by light scatter, direct current measurements, and opacity characteristics.

3.2 AUTOMATIC ASPIRATION MODE

The system automatically transports, mixes, aspirates and processes specimens.

Loading Specimens

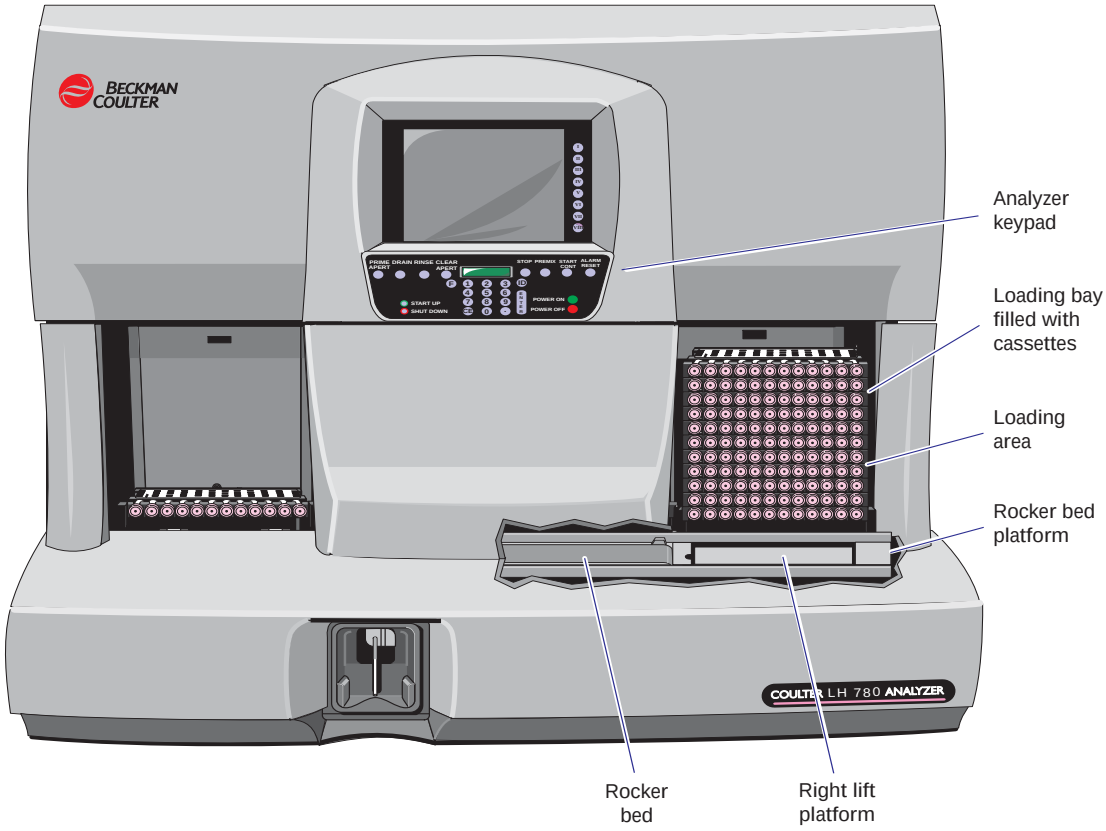
1. The operator places specimen tubes, which can be identified by bar-code labels, into cassettes. Each cassette and the tube positions in the cassette are identified by bar-code labels.
2. You can load up to 12 standard or Hemogard cassettes with 144 samples into the loading bay at one time. Figure 3.2 shows the loading bay filled with cassettes.

Transporting Cassettes

The system transports each cassette from the loading bay to the sampling station.

1. The right lift platform (Figure 3.2) rises beneath the stacked cassettes in the loading bay.
2. The bottom cassette is deposited on the platform.
3. The platform lowers the cassette to the level of the rocker bed.

Figure 3.2 Transport System



4. The cassette moves onto the rocker bed where it rocks back and forth, mixing the specimens.
5. The cassette moves toward the sensing station until it reaches the tube sensor.
6. When the first tube is sensed, the stripper plate locks onto the tube.
7. After at least 14 rocks from the time the cassette was loaded, the rocker bed locks in a 45-degree forward position.
8. At the sampling station, the tube is locked in position.
9. The tube ram pushes the tube out from the cassette, causing the needle to pierce the tube stopper.
10. The bar-code reader scans the cassette and tube labels. An audible indicator can be enabled to indicate each correctly-read bar-code.
    - If the bar-code read is successful, the bed continues to rock, and the cassette moves forward until the next available tube reaches the sampling station.
    - If the bar-code reader cannot read the cassette bar-code label, the Diluter stops, posts a message on the Analyzer, Diluter and Workstation displays, backwashes the system, then returns to the Ready state.
    - If Cass/Pos is the Positive Identifier, and the bar-code reader cannot read the tube bar-code label, dashes (-----) appear in the Sample ID field on the Workstation with the sample results.

11. After the last tube in the cassette is aspirated, the cassette continues along the rocker bed and is deposited onto the unloading bay platform. The left platform lifts the cassette into the exit bay, where up to 12 cassettes can be stacked.

Aspiration

At the sampling station, after the cap is pierced:

1. A pump draws a maximum of 300 µL (LH 700 Series only) or 550 µL (LH 780 System with LH SlideMaker) of sample through the needle and through the Blood Sampling Valve (BSV).
2. The blood detectors monitor the passage of sample through the BSV and aspiration lines.
3. The needle is withdrawn and the sample tube is reseated in the cassette.

Delivery

CBC

After the sample is aspirated:

- The center section of the BSV rotates and segments the sample into two separate volumes.
- Beginning a few seconds before the delivery of the dilutions to the appropriate baths, 5 psi of pressure is sent to the WBC bath. This pressure allows drainage of any residual liquid in the WBC bath, thus preventing carryover.
- The pressure continues during delivery and forms bubbles that mix each cell suspension before sensing begins.
- At the beginning of the delivery, any residual rinse in the Hgb cuvette drains into the waste chamber and the waste chamber drains.
- Diluent from the diluent dispensers drives the separated volumes of sample from the BSV to the baths.
- One volume of sample, 1.6 µL, is delivered with 10 mL of diluent to the RBC bath. This dilution is used for RBC/Plt counting and MCV/Plt sizing.
- The other volume, 28 µL, is delivered with 6 mL of diluent to the WBC bath. This dilution is used to count WBC and develop Hgb.
- During delivery to the WBC bath, 1 mL of lytic reagent is added to the dilution to lyse the red cells and convert Hgb.
- At the same time the lytic reagent is dispensed, 5 mL of diluent from the backwash tank is transferred into the Hgb cuvette for the Hgb blank reading.
- The final dilution in the WBC bath is 1 part whole blood in a total volume of 251 parts. The final dilution in the RBC bath is 1 part whole blood in a total volume of 6250 parts.
- The vent section of the piercing needle is rinsed, then dried by high vacuum.
- The center section of the BSV returns to the aspirate position.

Differential (Diff)

During aspiration of the blood sample, blood is pulled through two shear valves before it reaches the rear blood detector. These shear valves isolate the diff and retic sample segments for processing.

After aspiration of the blood sample, the sliding plate of the diff segment valve (shear valve) moves, aligning the reagent input and output ports with the diff segment isolated in the stationary plate of the valve.

The diff lytic reagent pump dispenses diff lytic reagent, displacing the reagent in the diff heater. The reagent from the diff heater flows through the diff segment valve, diluting the diff blood segment into the mixing chamber.

In the mixing chamber, the blood and diff lytic reagent mixture is incubated and mixed.

Then the diff preservative pump dispenses diff preservative into the mixing chamber. The final dilution of blood, diff lytic reagent and diff preservative is mixed and incubated.

Diff sample pressure is applied to the mixing chamber to push the final incubated dilution of sample from the mixing chamber into the sheath fluid stream in the flow cell for sensing.

Before the next sample is analyzed, the diff sample segment, the mixing chamber, and the flow cell are rinsed with diluent, and the diff sample segment and diff sample delivery line are primed with diff lytic reagent.

The diff lytic reagent pathways to and from the diff sample valve remain primed with diff lytic reagent.

Reticulocyte (Retic)

During aspiration of the blood sample, blood is pulled through two shear valves before it reaches the rear blood detector.

After aspiration of the blood sample, the sliding plate of the retic segment value (shear valve) moves, aligning the reagent input and output ports with the retic segment isolated in the stationary plate of the valve.

The stain pump dispenses retic stain through the retic segment valve, washing the retic segment into the stain chamber. Depending on the stain chamber temperature, the stain chamber heater may be activated to enhance the staining reaction.

After incubation, the 50 µL blood /stain aspiration pump is activated twice to pull a stained sample from the stain chamber and through the stained retic segment valve.

The retic clearing solution pump dispenses 2 µL of retic clearing solution, displacing the reagent in the Peltier module. The reagent from the Peltier module flows through the sample segment in the stained retic segment valve, diluting approximately 2 µL of the stained blood sample into the retic chamber.

In the retic chamber, the stained blood and retic clearing solution mixture is mixed and incubated.

Retic sample pressure is applied to the retic chamber to push the mixture from the retic chamber into the sheath fluid stream in the flow cell for sensing.

Before the next sample is analyzed the retic segment tubing, retic chamber and flow cell are rinsed with diluent, and the retic segment tubing and the retic sample delivery line are primed with stain.

In addition, the instrument activates the blood/stain pump to remove residual stained blood from the lines and activates the retic clearing solution pump to rinse the retic chamber and associated tubing.

CBC Sensing System

Vacuum, equal to 6 in. of mercury, draws a precise volume of suspension from each bath through the three apertures. At the same time, sweep flow is drawn behind the RBC apertures to prevent cells from re-entering the sensing zone.

When the vacuum starts to draw the suspension, current is supplied to the electrode. The electrical path allows sensing of the number and volume of each cell pulled through the apertures.

While the sample in each bath is sensed, the photometer reads the Hgb-blank and the Analyzer retains this reference voltage.

CBC Analysis in the Baths

The RBC and Plt data is generated by the RBC bath. The WBC and Hgb data is generated by the WBC bath and Hgb cuvette.

In the Analyzer the R/W Proc card counts and sizes the RBC and WBC data. The PLT Proc card sizes the PLT data. The Comm Intrfc card measures the HGB blank and sample. The RBC and WBC raw data consists of counts, wait time counts, count time, and channelyze time, as well as histograms for each of the three apertures. The PLT raw data consists of the histogram and channelyze time for each aperture. The HGB raw data consists of two voltage measurements for the blank and two measurements for the sample. The Analyzer then sends the raw data to the Workstation.

The Workstation then:

- Corrects the RBC and WBC raw counts for wait time and coincidence.
- Fits the PLT histogram and corrects the PLT histogram count for coincidence.
- Calculates HGB from the blank and sample readings.
- Scales for calibration and dilution.
- Performs voting on the three apertures for RBC, WBC, PLT.
- Derives parameters from the RBC histogram; MCV, RDW and RDW-SD.
- Derives the MPV parameter from the Plt histogram.
- Derives the calculated parameters.
- Displays results and histograms.

Diff and Retic Multiparameter Sensing System

The flow cell is located within the Triple Transducer Module (TTM). The TTM produces three measurement signals – volume, conductivity and light scatter. For the differential, the Analyzer counts for 19 seconds, or 8,192 events, whichever occurs first. For the retic, the Analyzer counts for 90 seconds, or 32,768 events, whichever occurs first. Raw data is routed to the Workstation.

Figure 3.3 shows the Triple Transducer Module and its protective housing as it resides in the Diluter.

WARNING The laser beam can cause damage to your eyes and to the instrument. Do not attempt to remove the laser from the Diluter module. If removal is required, it must be done only by a Beckman Coulter Representative.

Tamper-proof screws secure the protective housing; they can only be removed with a special tool.

The laser is a helium-neon laser that complies with the United States' performance standard for laser products, Title 21 Code of Federal Regulations 1040.10 and 1040.11. Figure 3.4 shows the laser module without its protective housing to display the flow cell and label locations.

Figure 3.3 Triple Transducer Module with Protective Housing

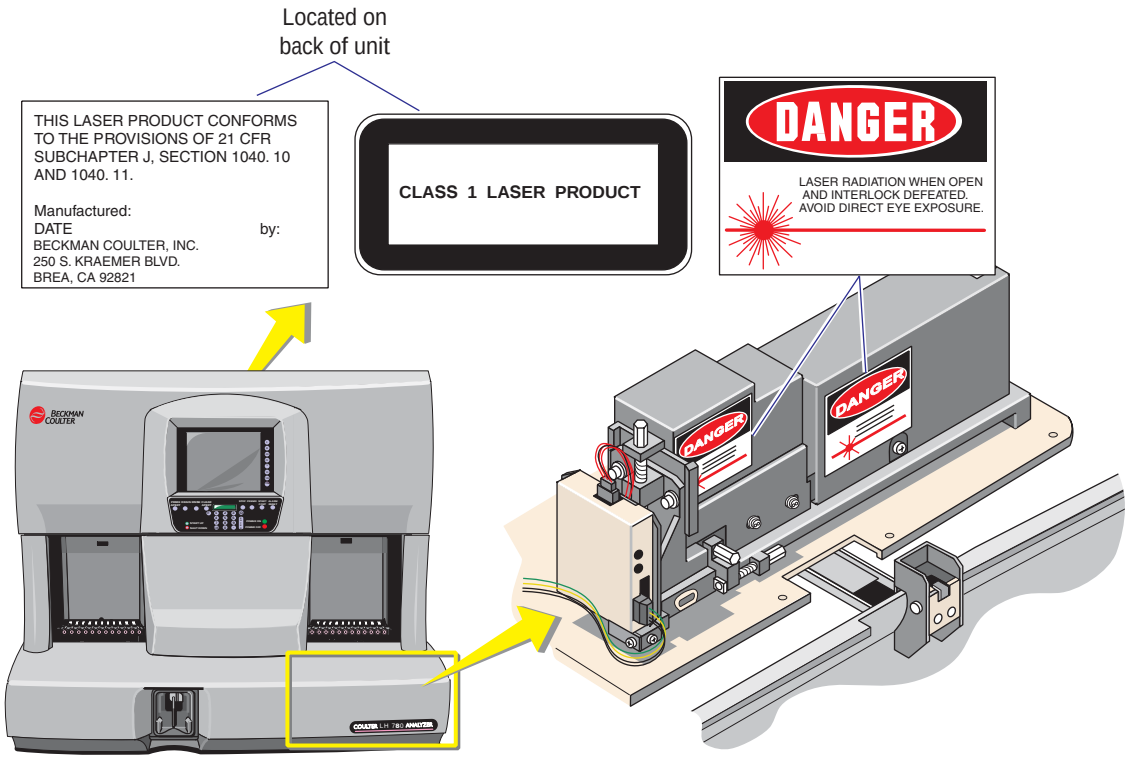
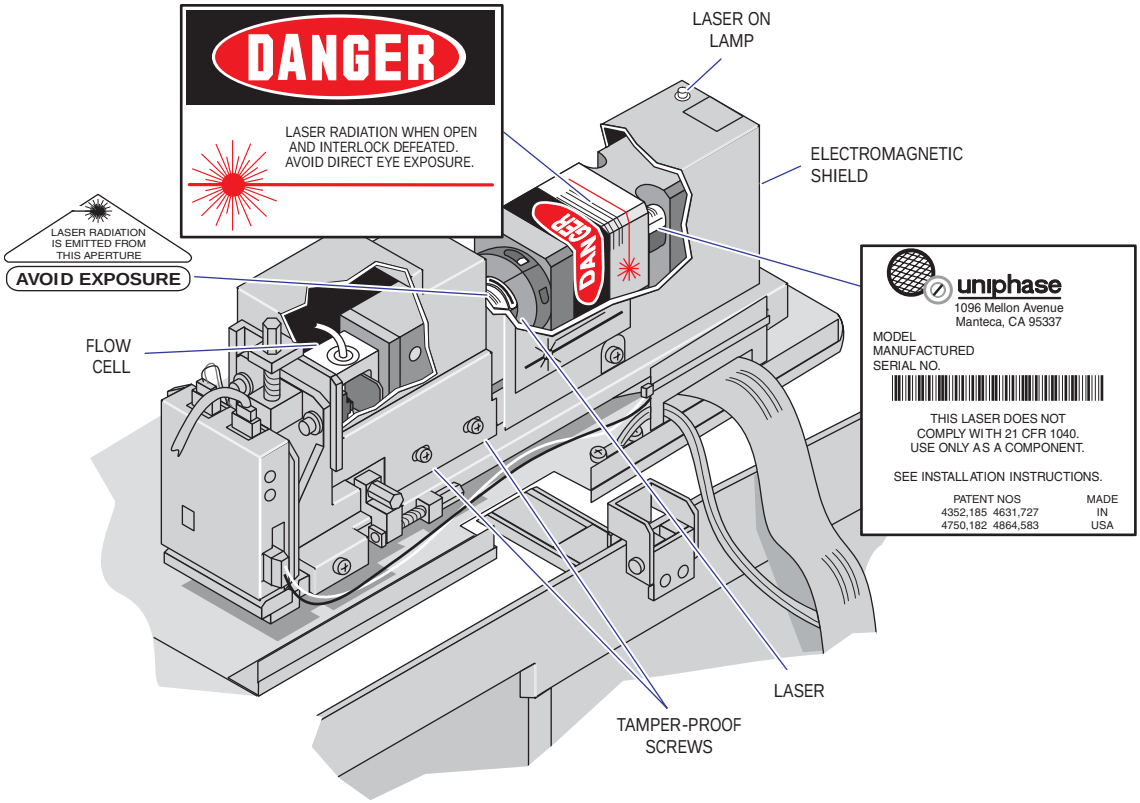


Figure 3.4 Triple Transducer Module with Protective Housing Cut Away



Note: As installed in the Triple Transducer Module (TTM) safety fixture, the laser presents no radiation hazard to users and complies with 21 CFR 1040.

Backwash and Rinse

The Diluter performs backwash of aspiration pathways and rinses its components.

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

10 mL of diluent rinse for the WBC bath comes from the RBC diluent dispenser, and 6 mL of diluent rinse for the RBC bath comes from the WBC diluent dispenser. The WBC bath needs a larger rinse volume to

- Remove RBC cell stroma after lysing
- Remove remaining lytic reagent
- Rinse above the 7 mL fill line
- Rinse the hemoglobin cuvette.

3.3 MANUAL ASPIRATION MODE

IMPORTANT Clots in the specimen can cause misleading results. The blood detectors are not active in the Manual mode. Be sure to inspect the specimen for clots and use good laboratory practices to verify results.

The Manual mode of operation is like the Automatic mode except:

- Before you run the sample, you enter the sample identification number by performing any of the following--
  - Scanning the bar-code label on the tube
  - Entering the ID number on the Numeric Keypad
  - Entering the ID number in the bar-code field on the LH Workstation from its keyboard.
- You use an open vial and introduce the sample at the aspirator tip.
- You begin the cycle by obstructing the optical sensor's beam
- The system aspirates a maximum of 200 µL of sample.
- The blood detectors are not active in the Manual mode.

3.4 COUNTING AND SIZING

Red and White Blood Cell Counting

The RBC and WBC baths each have three discrete apertures that function as independent systems. The six aperture currents are individually adjusted during calibration. When the Aperture Current/Signal Generator (API-SIG GEN) card applies current to the apertures, there is a delay. During this delay, the system conditions the electronics to perform the counting and sizing of the sample.

Regulated vacuum draws a precise volume of sample dilution through the apertures. At each aperture, the system gathers pulses for 4 seconds. The RED/WHITE PRE-AMP cards amplify these pulses and the Analyzer screen displays them.

The system sends these pulses to the RED/WHITE PROCESSOR card. The RED/WHITE PROCESSOR card counts and sizes the RBC and WBC data. The RBC and WBC raw data consists of counts, wait time counts, count time, and channelyze time, as well as histograms for each of the three apertures The Analyzer then sends the raw data to the Workstation.

The Workstation then:

- Corrects the RBC and WBC raw counts for wait time and coincidence.
- Fits the PLT histogram and corrects the PLT histogram count for coincidence.
- Calculates HGB from the blank and sample readings.
- Scales for calibration and dilution.
- Performs voting on the three apertures for RBC, WBC, PLT.
- Derives the parameters from the RBC histogram; MCV, RDW and RDW-SD.
- Derives the MPV parameter from the Plt histogram.
- Derives the calculated parameters.
- Displays results and histograms.

Coincidence Correction

Occasionally, more than one cell passes through the aperture at the same time. When cells coincide, the Analyzer counts only one pulse. As the frequency of coincidence is proportional to the actual count, the system automatically corrects results for coincidence.

Voting

To prevent data errors due to statistical outliers or obstructions that may block an aperture, the Analyzer votes on the data from all of the apertures, and rejects any questionable data. For the WBC count, RBC count, MCV, RDW, Plt count, and MPV, the Analyzer computer compares the data from the three apertures. It verifies that at least two apertures have produced data within an established statistical range of each other.

If the data from one aperture is outside the established statistical range, the computer votes out the data and histograms from that aperture. The computer derives the affected parameter by averaging the data from the two remaining apertures.

The data from at least two of the three apertures must be within an established statistical range of each other, or the system totally votes out the parameter and histograms. When a parameter totally votes out, the system does not give any results for the affected parameter or for any parameters that are derived from it. See your Online Help System or Operator's Guide for codes and messages that appear in these circumstances.

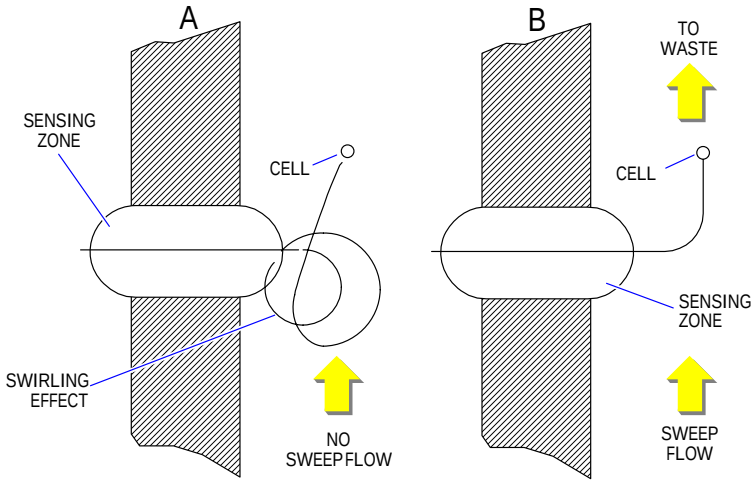
Pulse Editing

When cells pass through the aperture near the edge or at an angle rather than at the center, they create atypical pulses. The RED/WHITE PROCESSOR card edits RBC and WBC pulses to exclude these atypical pulses from analysis because they distort the true size of the cell. This prevents the atypical pulses from influencing size measurement. Each of the six apertures has an editor.

Sweep Flow

The sweep flow is a steady stream of diluent that flows behind the RBC aperture during the sensing period. This prevents cells from re-entering the sensing zone and being counted as platelets. See Figure 3.5.

Figure 3.5 Sweep Flow



RBC Size Distribution

After editing, the RED/WHITE PROCESSOR converts the three sets of both the RBC and WBC pulses. It converts each pulse to a number that corresponds to the size of the cell. The Analyzer Microcontroller card (AMC) reads this data and generates histograms. The digital information from each aperture is stored according to volume in 256-channel, size-distribution histograms.

To ensure that the size-distribution curve accurately reflects the true cell population, the system extends RBC sensing for up to eight additional 2-second sensing periods whenever the RBC data accumulations are below a predetermined value. The RBC size distribution curve reflects the total data accumulated in all of the sensing periods.

After the sensing periods are completed, the system sends these histograms through the Communication Interface (COMM INTFC) card to the Workstation for display.

Platelet Method

Pulses representing cells from 2 to 20 fL are classified as platelets. The Analyzer sorts the pulses into three 64-channel size distribution histograms. Data collection occurs between a two second minimum, up to 20 second maximum time, in one second increments. The data collection stops when at least 1500 cells are collected in each of the three histograms, or 20 seconds is reached.

The analyzer sends this information to the Workstation. At the Workstation, all histograms are smoothed. The mode channels, and left and right valleys, are identified for each of the three histograms. Information is analyzed to determine whether normal curve fitting and counting occurs, and whether special conditions for count correction need to be considered. For normal curve fitting, the following conditions have to be met for each histogram:

1. The PLT is >20,000 in the raw histogram.
2. The curve is positive and unimodal.
3. The mode is between 3 and 15 fL.

4. The height of pulses in channels 0 and 1 is <1.5 times the height of the mode channel.

The PLT is then calculated as the area under the fitted histogram.

Special conditions include, for example, the presence of microcytic red cells or red cell fragments that might interfere with counting in the platelet channels. All special cases result in no fitted curve (but there is high confidence in the platelet count unless the count is flagged with R).

For samples that are not special cases, but that fail normal curve fitting criteria, the raw histogram count is further examined for interference. This most frequently applies to platelet counts <20,000. The raw histogram count between the left and right low points is used to determine the platelet count.

The initial count is then coincidence corrected, voted on, averaged.

The histograms are also voted on and averaged.

Incomplete and overrange conditions are noted.

The counts are adjusted for calibration and predilute factors.

MPV is derived.

For flagging, all platelet data, plus data from the WBC and RBC histograms is further examined. The PLT is R flagged when specific conditions indicate the confidence in the count is low. Additionally, statistics and histograms are examined for the possible presence of Giant Platelets and Platelet Clumps.

It is possible to observe:

- A smoothed platelet histogram without a flagged platelet count (no PLT R).
- Giant Platelet and/or Platelet Clump Suspect message with or without a flagged platelet count.

3.5 MEASUREMENT OF HEMOGLOBIN CONCENTRATION

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

A beam of white light from an incandescent lamp goes through the cuvette and then through an optical filter that has a center transmission wavelength of 525 nm. Light passing through the filter falls on a photocell. The photocurrent thus generated is proportional to the transmittance of the contents of the cuvette at the chosen wavelength. It is sent to the COMM INTFC card where it is digitized. The digital information is sent to the Analyzer computer, then to the Workstation.

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

3.6 DATAPLOT DEVELOPMENT

At the Workstation, raw data is analyzed to:

- Position each cell within a three-dimensional space
- Plot the data on a two-dimensional DataPlot
- Display and report results.

The Workstation performs a series of operations on the stored digital raw values received from the flow cell to identify memberships (subpopulations) and calculate the frequency of cells within each membership group. It also produces the DataPlot displays for visual representation of the WBC Diff and Reticulocyte/RBC membership and density.

In the LH 780, the Beckman Coulter AccuGate algorithm uses adaptive contouring methods designed for finding optimal separation between overlapping clusters of data. The AccuGate algorithm provides a statistical analysis tool that discovers the overlapping populations using nonlinear separation techniques. The newly developed adaptive gating techniques use multidimensional data to distinguish the presence of even the faintest subpopulation. The AccuGate algorithm can adapt to unusual population shifts and overlaps. It can define highly irregular separation, and signal the need for further analysis. It can then make a subsequent analysis of the identified regions and correct deficiencies in separation.

In the DataPlots, different colors represent different memberships (types of cells). Shades of colors represent density (concentration): dark colors for low density, bright colors for high density.

DIFF:	Lymphocytes	Blue
	Neutrophils	Purple
	Eosinophils	Orange
	Monocytes	Green
	Basophils	White
	Non-white debris	Red
RETIC:	RBCs	Red
	Reticulocytes	Blue
	Platelets	Green
	WBCs	Purple

Two-Dimensional (2D) DataPlots

The 2D WBC Diff DataPlot shows the five memberships: lymphocytes (LY), monocytes (MO), neutrophils (NE), eosinophils (EO) and basophils (BA), plus the non-white cell populations. Cell volume (VOL), determined by the low-frequency impedance measurement, is plotted on the Y-axis; rotated light scatter (RLS) is plotted on the X-axis.

The Reticulocyte DataPlot shows mature red cells and Reticulocytes. Cell volume is plotted on the Y-axis, and linear light scatter (LLS) is plotted on the X-axis.

Three-Dimensional (3D) DataPlots

The 3D DataPlot view classifies by density, light scatter and opacity. The axes are color coded.

On the WBC differential DataPlot the axes are:

Volume = green
RLS (rotated light scatter) = red
OP (opacity) = blue

On the Retic DataPlot the axes are:

Volume = green
LLS (linear light scatter) = red
OP (opacity) = blue

3.7 PARAMETERS AND THEIR DERIVATION

Mathematical expressions in this section are in U.S. units of measurement. Parameter units can be changed to other International System of Units (SI) through Setup on the LH Workstation.

Parameter	Method	Description
WBC	Coulter Principle	**White Blood Cell Count** or Leukocyte Count • Measured directly, multiplied by the calibration factor. • Corrected for interference if necessary. Both the WBC and uncorrected WBC (UWBC) are reported. If no correction is required, then WBC = UWBC. • WBC = N X 10^3 cells/µL
RBC	Coulter Principle	**Red Blood Cell Count** or Erythrocyte Count • Measured directly, multiplied by the calibration factor • RBC = N X 10^6 cells/µL
Hgb	Photometric Measurement	**Hemoglobin** or Hemoglobin Concentration • Transmittance of light at 525 nm through a lysed WBC solution in the Hgb cuvette, compared to the transmittance of the same light through a reagent blank. The system converts this ratio to the Hgb value using a calibration factor. • Weight (mass) of Hgb determined from the degree of absorbance found through photo current transmittance expressed in g/dL • Hgb (g/dL) = [constant X $\log_{10}$ (Reference %T/Sample %T)]
Hct	Calculated	**Hematocrit** • The relative volume of packed erythrocytes to whole blood • Hct (%) = (RBC X MCV)/10

Parameter	Method	Description
MCV	Derived from RBC Histogram	**Mean Corpuscular Volume** • The average volume of individual erythrocytes derived from the RBC histogram • The system multiplies the number of RBC in each channel by the size of the RBC in that channel. The products of each channel between 36 and 360 femtoliters (fL) are added. This sum is divided by the total number of RBC between 36 and 360 fL. The Analyzer then multiplies by a calibration constant • Expressed in fL
MCH	Calculated	**Mean Corpuscular Hemoglobin** • The weight of Hgb in the average erythrocyte • MCH (pg) = (Hgb/RBC) X 10
MCHC	Calculated	**Mean Corpuscular Hemoglobin Concentration** • The average weight of Hgb in a measure dilution • MCHC (g/dL) = (Hgb/Hct) X 100
RDW	Derived from RBC Histogram	**Red Cell Distribution Width** • The size distribution spread of the erythrocyte population derived from the RBC histogram • Expressed as coefficient of variation (%)
RDW-SD	Derived from RBC Histogram	**Red Cell Distribution Width - SD** • The size distribution spread of the erythrocyte population derived from the RBC histogram • Expressed as a standard deviation in fL
PLT	Derived from Plt Histogram	**Platelet Count** or Thrombocyte Count • The number of platelets derived from the Plt histogram, multiplied by a calibration factor • Plt = n X 10^3 cell/µL
MPV	Derived from Plt Histogram	**Mean Platelet Volume** • The average volume of individual platelets derived from the Plt histogram, multiple by a calibration factor • Expressed in fL
NE%	VCS Technology	**Neutrophil Percent** • [NE events/(NE+LY+MO+EO+BA) events] X 100 • Expressed as a percentage (%)
LY%	VCS Technology	**Lymphocyte Percent** • [LY events/(NE+LY+MO+EO+BA) events] X 100 • Expressed as a percentage (%)
MO%	VCS Technology	**Monocyte Percent** • [MO events/(NE+LY+MO+EO+BA) events] X 100 • Expressed as a percentage (%)

Parameter	Method	Description
EO%	VCS Technology	**Eosinophil Percent** • [EO events/(NE+LY+MO+EO+BA) events] X 100 • Expressed as a percentage (%)
BA%	VCS Technology	**Basophil Percent** • [BA events/(NE+LY+MO+EO+BA) events] X 100 • Expressed as a percentage (%)
NRBC%	VCS Technology and WBC Histogram	**Nucleated Red Blood Cell Count** • The number of nucleated red blood cells (NRBC) per 100 WBC • Expressed as a percentage (%)
NE#	Calculated	**Neutrophil Absolute Count** NE# (10^3 cells/µL) = (NE%/100) X WBC
LY#	Calculated	**Lymphocyte Absolute Count** LY# (10^3 cells/µL) = (LY%/100) X WBC
MO#	Calculated	**Monocyte Absolute Count** MO# (10^3 cells/µL) = (MO%/100) X WBC
EO#	Calculated	**Eosinophil Absolute Count** EO# (10^3 cells/µL) = (EO%/100) X WBC
BA#	Calculated	**Basophil Absolute Count** BA# (10^3 cells/µL) = (BA%/100) X WBC
NRBC#	Calculated	**Nucleated Red Blood Cell Absolute Count** • Represents the total number of nucleated red blood cells • NRBC (10^3 cells/µL) = (NRBC%/100) X WBC
RET%	VCS Technology	**Reticulocyte Percent** • The number of reticulocytes per 100 RBC • Ratio of retics to the total number of red cells • RET% = (Retic Events / Red Cell Events) X 100
RET#	Calculated	**Reticulocyte Absolute Number** RET# X 10^6 cells/µL = (RET% X RBC) / 100
IRF	Calculated	**Immature Reticulocyte Fraction** • A percentage of the count of the highest light scatter retics (the most immature retics) relative to the total retic count • Expressed as a decimal ratio • IRF = (Retic Events Regions 3-10) / (Retics Regions 0-10)
MRV	Calculated	**Mean Reticulocyte Volume** • The average volume of all retic events • MRV (fL) = (Retic Volume Regions 0-10) / (Retics Events Regions 0-10)

3.8 XB ANALYSIS

Studies (Bull 1974, Koepke 1981) indicate that the red cell indices (MCV, MCH, and MCHC) of patient populations are stable over time.[39,40] This stability characteristic of the indices is the basis of a quality-control technique called XB Analysis. In a manually implemented system, population means (target values) are established by analyzing as large a sample as possible, at least 250, but ideally 1,000 blood samples. (The XB Analysis used in the Workstation does all the calculating automatically.) Once the target values have been established, the XB Analysis can be applied using quite small batches from the patient population. A 20-patient sample batch is a typical size, and can be used in the LH Workstation.

Here is the XB formula.

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

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

Where:

X(B,i)	= ith XB value
X(B, i-1)	= (i-1)th XB value
X(j,i)	= the jth X value in the ith batch
SGN	= the arithmetic sign of number in parentheses
N	= number of samples in the batch
x	= symbol used to represent multiplication

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

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

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

MCV

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

MCH

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

MCHC

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

Adjusting Initial XB Target Values

The recommended target values for initial entry are:

MCV	89.5
MCH	30.5
MCHC	34.0

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

If the CVs are greater than 1.5%, or the mean values are greater than 3% different from the recommended target values, there may be an instrument or population problem. In this case, repeat this procedure using the next 20 XB batches. If the indices themselves are stable in a hospital population, then any deviation from the Target Values and Action Limits may point to an instrument or reagent problem. These problems would involve the parameters directly measured by the instrument and used to calculate the red cell indices. Table 3.1 lists the directly measured parameters that would be involved with out-of-limits XB batch values for each of the red cell indices.

If the XB indices are still out-of-limits, you should investigate the instrument and reagent systems associated with the directly-measured parameter(s) as indicated by Table 3.1 and call your Beckman Coulter Service Representative.

Table 3.1 Effect of Directly-Measured Parameters on the Red Cell Indices

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

See the Glossary for terms used with the XB Analysis.

Xm Analysis

Xm Analysis is a quality-control method that uses an Exponentially Weighted Moving Average (EWMA) of CBC, Diff, NRBC and Reticulocyte Parameters and compares them with with known target values, to monitor instrument performance. The first form of moving average statistical analysis in hematology was XB Analysis.

Extended QC

Extended QC Rules are derived from the German Quality Control Guidelines for the Medical Laboratory, known in Germany as Rili-BÄK. Rili-BÄK (Guidelines of the Federal Chamber of Physicians), was first published in 1987 and amended in 1990 and 1993 covering clinical chemistry, immunochemistry and other tests, but not hematology. In 2003, the guidelines were extended to include hematology.

User's can enable/disable Extended QC Rules for 5C Cell control.

4.1 PHYSICAL SPECIFICATIONS

Dimensions

Unit	Height*	Width*	Depth*	Weight
Analyzer/Diluter	88.9 cm	101.6 cm	61 cm	93.2 k
	(35 in.)	(40 in.)	(24 in.)	(205 lb)
Power Supply	59 cm	35.5 cm	60 cm	56.7 k
	(23.3 in.)	(14 in.)	(24 in.)	(125 lb)

* ±5.1 cm (2 in.)

Power

Input

Power Supply:	90 - 264 Vac, 47 - 63 Hz
Workstation:	90-135 Vac, 47-63 Hz or 180-265 Vac, 47-63 Hz

Consumption

2080 W (5500 BTU/h) maximum

Installation Category: per IEC 1010-1, Category II

4.2 PHYSICAL SPECIFICATIONS

Dimensions

Unit	Height*	Width*	Depth*	Weight
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Consumption

2080 W (5500 BTU/h) maximum

Installation Category: per IEC 1010-1, Category II

4.3 PERFORMANCE SPECIFICATIONS--LH 780

The LH 780 consists of three subsystems, designated as "CBC" (Complete Blood Count), "WBC Differential" and "Retics." The CBC subsystem is based on the established Coulter principles of automated cell counting. The WBC differential subsystem is based on the Coulter principles of leukocyte differential counting as embodied in the COULTER VCS. The Retics subsystem is based on the Coulter volume, conductivity and light scatter technology.

Performance specifications stated apply only to an instrument that has been properly maintained as indicated in the COULTER LH 780 documentation, using the recommended reagents.

If the average room temperature should change more than 5.5°C (10°F) from the calibrating temperature, verify calibration and recalibrate if necessary to ensure conformance to specifications.

Precision

Within-Run Precision

Within-run Precision is based on at least 31 determinations of the same sample. See Table 4.1.

Table 4.1 Within-Run Precision (N = 31)

Parameter	@ Approximate Level	Limit
WBC	9 to 11 x 10^3 cells/µL	CV% ≤1.7
RBC	4.5 to 5.5 x 10^6 cells/µL	CV% ≤0.8
Hgb	14 to 16 g/dL	CV% ≤0.8
MCV	80 to 90 fL	CV% ≤0.8
RDW	12 to 14%	CV% ≤2.2
RDW-SD	45 to 55 fL	CV% ≤2.5
Plt	280 to 320 x 10^3 cells/µL	CV% ≤3.3
Plt	90 to 110 x 10^3 cells/µL	CV% ≤6.6
Plt	10.0 to 15.0 x 10^3 cells/µL	CV% ≤14.0
MPV	8 to 10 fL	CV% ≤2.2
NE%	50 to 60%	2SD ≤3.0
LY%	25 to 35%	2SD ≤3.0
MO%	5 to 10%	2SD ≤2.0
EO%	2 to 5%	2SD ≤1.0
BA%	0.5 to 1.5%	2SD ≤1.0
RET%	0.00 to 0.49%	SD ≤0.23 or CV% ≤16.5
RET%	0.50 to 1.49%	SD ≤0.23 or CV% ≤14.5
RET%	1.50 to 4.00%	SD ≤0.68 or CV% ≤11.0
RET%	4.01 to 15.00%	SD ≤0.68 or CV% ≤5.5

Accuracy

Accuracy Qualification

Accuracy is achieved using statistically significant number of non-flagged morphological normal samples analyzed between 10 minutes and 8 hours post venipuncture. Distributional abnormal samples should be included. NCCLS* H20-A criteria should be used in the sample selection and manual differential examination.

*National Committee for Clinical Laboratory Standards is now the Clinical and Laboratory Standards Institute (CLSI).

Accuracy, CBC

For the CBC parameters, the LH 780 can be adjusted within the resolution of the readout to agree with a predetermined reference value at any point in the operating range. Accuracy was tested against a predicate hematology analyzer. Table 4.2 lists the specifications for the mean difference and mean percent difference.

Table 4.2 Accuracy, CBC

Parameter		Mean Difference	Mean Percent Difference
WBC	0.00 to 100.0	±0.2	±3.0%
	100.1 to 400.0	N/A	±9.0%
RBC		±0.05	±2.0%
Hgb		±0.2	±3.0%
MCV*		N/A	±2.0%
RDW		±0.5	±5.0%
RDW-SD		±3.0	±10.0%
Plt		±10	±7.0%
MPV		N/A	±5.0%

*Due to the effect of temperature on red cell size, the specification applies to testing performed at a temperature range of 70 to 80°F.

Accuracy, WBC Differential

Accuracy of the WBC differential should be determined by comparison against either or both of two comparator methods. Accuracy can be tested against the manual differential reference method (CLSI H20-A [n = 400]). Accuracy was tested against a predicate hematology analyzer. When the LH 780 is compared to either method, using non-flagged, morphological normal samples, expect results within tolerance limits listed in Table 4.3.

Table 4.3 Accuracy Tolerance Limits, WBC Differential

Cell Type	Mean Difference % using CLSI H20-A	Mean Difference % using predicate analyzer
Lymphocyte	±3.0	±1.5
Monocyte	±3.0	±1.0
Neutrophil	±2.0	±2.0

Table 4.3 Accuracy Tolerance Limits, WBC Differential

Eosinophil	±1.0	±0.5
Basophil	±1.0	±0.5

Accuracy, Reticulocyte

Accuracy was tested against a predicate hematology analyzer. See Table 4.4.

Table 4.4 Accuracy, Reticulocyte, Using a Predicate Hematology Analyzer

Parameter/Population	Mean Difference
RET%	±0.5

Linearity

When tested using a stable material having no interfering substances, the LH 780 value should be equal to the expected value within the limits given in Table 4.5. To minimize the effects of imprecision, take multiple readings at each dilution point. Subtract the background count from the values obtained

Table 4.5 Linearity Limits

Parameter	Linearity Range	Limits (mean difference or % difference, whichever is greater)
WBC x 10^3 cells/µL	0.00 to 100.0 100.1 to 400.0	±0.2 or 3.0% ±9%
RBC x 10^6 cells/µL	0.00 to 8.00	±0.05 or 2.0%
Hgb g/dL	0.0 to 25.0	±0.2 or 3.0%
Plt x 10^3 cells/µL	0 to 3000	±10 or 7.0%

Background

Background counts for CBC parameters are performed during the Startup cycle. The background limits are

WBC	≤ 0.20
RBC	≤ 0.01
Hgb	≤ 0.20
Plt	≤ 3.00
DIFF	≤ 100 events
RETIC	≤ 600 events

Carryover

Blood-to-diluent Carryover on the LH 780 should meet these limits:

WBC	≤ 2.0%
RBC	≤ 1.0%

Hgb	≤ 2.0%
Plt	≤ 2.0%
DIFF	≤ 200 events
RETIC	≤ 600 events

Carryover is the discrete amount of analyte carried by the measuring system from one specimen reaction into subsequent specimen reactions, thereby erroneously affecting the apparent amounts in subsequent specimens" (NRSCL8-A 1998. Clinical Laboratory Standards Institute). It is conventionally expressed as a percentage of the concentration of the analyte in the first specimen which is carried into the subsequent specimen, as indicated by the specified limits listed above.

Operating and Reportable Ranges

The operating ranges reflect the range of values over which the instrument displays, prints and transmits results. Values that are between the linear range and the operating range, and values outside the reportable range, are displayed, printed and transmitted with an over linear range flag (+). Values that are above the operating range are inhibited, and the value is replaced by pluses (+++++). The reportable range identifies the values where the instrument is accurate, and reflects the range studied in accuracy testing. See Table 4.6.

Table 4.6 Operating and Reportable Ranges

Parameter	Operating Range	Reportable Range
WBC	0.00 to 900.00 x 10^3 cells/µL	0.00 to 400.00 x 10^3 cells/µL
RBC	0.00 to 20.00 x 10^6 cells/µL	0.00 to 8.00 x 10^6 cells/µL
Hgb	0.0 to 99.9 g/dL	0.0 to 25.0 g/dL
Hct	0.0 to 99.9%	N/A
MCV	0.0 to 300.00 fL	0.0 to 150.0 fL
MCH	0.0 to 99.9 pg	N/A
MCHC	0.0 to 99.9 g/dL	N/A
RDW	0.0 to 99.9%	N/A
RDW-SD	0.0 to 300.0 fL	N/A
Plt	0.00 to 5000 x 10^3 cells/µL	0.00 to 3000 x 10^3 cells/µL
MPV	0.0 to 99.9 fL	N/A
NE%, LY%, MO%, EO%, BA%	0 to 100%	0 to 100%
NE#, LY#, MO#, EO#, BA#	0.00 to 900.00 x 10^3 cells/µL	0.00 to 400.00 x 10^3 cells/µL
RET%	0.00 to 100%	0.00 to 30.0%
RET#	0.00 to 999.9 x 10^6 cells/µL	0.0000 to 0.7500 x 10^6 cells/µL
NRBC%	0.0 or 2.0 to 600%	0.0 or 2.0 to 600%

Mode-to-Mode Comparison

Automatic (closed vial) and Manual (open vial) mode-to-mode differences of the means of 10 normal blood specimens, measured in triplicate, should be less than or equal to the following:

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

In addition, 95% of the individual differences should be within the stated limits.

4.4 PERFORMANCE CHARACTERISTICS

The information in this section describes typical performance for an instrument that has been properly maintained as indicated in the COULTER LH 780 System documentation, equipped with either the LH Series Diluent / Lyse S III Diff lytic reagent or ISOTON 4 / Lyse S 4 Diff lytic reagent (performance is equivalent unless specifically noted).

Sample Stability - Long Term

The following tables show the average results for specimens from 21 normal donors collected in K_3EDTA. The specimens were stored at room temperature and cold temperature. For this study, room temperature was 69 - 72ºF (21 - 22ºC) and cold temperature was 37 - 39ºF (3 - 4ºC). At each time interval, the refrigerated samples were removed from the refrigerator, allowed to sit 15 minutes at room temp and mixed by 14 complete inversions prior to piercing. Hour one results for cold temperature data were analyzed at room temperature.

Table 4.7 CBC Sample Stability, Room Temperature

Hours	WBC	RBC	Hgb	MCV	RDW	RDW-SD	PLT	MPV
1	6.75	4.720	13.65	86.4	13.66	41.01	274.6	9.30
4	6.74	4.734	13.67	86.6	13.71	41.09	271.0	9.51
8	6.78	4.728	13.67	86.9	13.77	41.35	270.8	9.63
16	6.74	4.713	13.66	87.3	13.78	41.72	268.2	9.73
24	6.77	4.731	13.70	87.9	14.08	42.97	272.2	9.93

Table 4.8 CBC Sample Stability, Cold Temperature

Hours	WBC	RBC	Hgb	MCV	RDW	RDW-SD	PLT	MPV
1	6.75	4.720	13.65	86.4	13.66	41.01	274.6	9.30
4	6.74	4.730	13.65	86.5	13.68	41.00	270.4	9.38
8	6.74	4.714	13.67	86.5	13.65	40.96	267.7	9.52
16	6.73	4.721	13.73	86.7	13.65	40.92	262.6	9.50
24	6.73	4.726	13.68	86.6	13.65	40.88	264.7	9.91
36	6.59	4.719	13.75	87.0	13.61	40.95	256.1	9.78
48	6.53	4.722	13.66	87.0	13.56	41.04	261.8	10.18

Table 4.9 DIFF% Sample Stability, Room Temperature

Hours	NE	LY	MO	EO	BA
1	64.30	24.27	8.26	2.74	0.54
4	64.48	24.16	8.14	2.69	0.53
8	64.02	24.52	8.18	2.69	0.59
16	63.89	25.35	7.58	2.49	0.69
24	66.08	26.38	5.12	1.97	0.45

Table 4.10 DIFF% Sample Stability, Cold Temperature

Hours	NE	LY	MO	EO	BA
1	64.30	24.17	8.26	2.74	0.54
4	64.77	24.14	7.88	2.80	0.41
8	65.10	23.89	7.64	2.86	0.50
16	66.03	23.47	7.17	2.84	0.49
24	65.51	22.86	8.08	2.99	0.56
36	67.66	21.46	7.75	2.61	0.52
48	68.00	21.46	7.27	2.56	0.71

Table 4.11 DIFF# Sample Stability, Room Temperature

Hours	NE	LY	MO	EO	BA
1	4.35	1.61	0.56	0.19	0.04
4	4.36	1.61	0.56	0.19	0.04
8	4.36	1.64	0.56	0.19	0.04
16	4.32	1.69	0.51	0.17	0.05
24	4.49	1.76	0.34	0.14	0.03

Table 4.12 DIFF# Sample Stability, Cold Temperature

Hours	NE	LY	MO	EO	BA
1	4.35	1.61	0.56	0.19	0.04
4	4.38	1.61	0.53	0.19	0.03
8	4.40	1.59	0.51	0.20	0.03
16	4.45	1.56	0.49	0.20	0.03
24	4.43	1.51	0.54	0.21	0.04
36	4.48	1.39	0.51	0.18	0.03
48	4.48	1.38	0.45	0.17	0.05

Table 4.13 RETIC Sample Stability, Room Temperature

Hours	RETIC%	RETIC#	MRV	IRF
1	1.227	0.058	104.27	0.359
4	1.135‘	0.054	105.95	0.345
8	1.130	0.054	106.76	0.352
16	1.130	0.054	106.68	0.351
24	1.174	0.056	109.17	0.347

Table 4.14 RETIC Sample Stability, Cold Temperature

Hours	RETIC%	RETIC#	MRV	IRV
1	1.227	0.058	104.27	0.359
4	1.214	0.058	104.92	0.360
8	1.195	0.057	105.72	0.358
16	1.300	0.062	105.60	0.370
24	1.270	0.061	106.33	0.350
36	1.342	0.064	106.77	0.354
48	1.262	0.060	107.28	0.350
60	1.277	0.060	106.54	0.341
72	1.262	0.060	107.35	0.333

Table 4.15 NRBC Sample Stability, Room Temperature

Hours	NRBC%	NRBC#
1	0.00	0.00
4	0.00	0.00
8	0.00	0.00
16	0.00	0.00
24	0.00	0.00

Table 4.16 NRBC Sample Stability, Cold Temperature

Hours	NRBC%	NRBC#
1	0.00	0.00
4	0.00	0.00
8	0.00	0.00
16	0.00	0.00
24	0.21	0.02

WBC Differential Flagging Stability

The tables below indicate flagging at timed intervals for 21 samples using mid-level flagging sensitivity, with NRBC enumeration enabled. For additional information regarding flagging sensitivity, refer to Flagging Preferences section of the LH 700 SERIES System Operator's Guide. The number and consequence of Suspect Messages observed at each time interval is indicated below

Table 4.17 Differential Suspect Flagging at Room Temperature

Hour	# of Samples	Suspect Messages
1	0	N/A
4	0	N/A
8	1	Imm. NE 1
16	3	Imm. NE 1, Giant Platelets
24	17	LY Blast, MO Blast, Imm. NE 1, Imm. NE 2

Table 4.18 Differential Suspect Flagging at Cold Temperature

Hour	# of Samples	Suspect Messages
1	0	N/A
4	0	N/A
8	0	N/A
16	0	N/A
24	8	NE Blast, MO Blast, Imm. NE 1, Platelet Clumps, Giant Platelets
36	12	MO Blast, Imm. NE 1, Imm. NE 2, Variant LY, Platelet Clumps, Giant Platelets
48	19	NE Blast, LY Blast, MO Blast, Imm. NE 1, Platelet Clumps, Giant Platelets

Short Term Sample Stability

The following tables show the average results for specimens from 23 normal donors collected in K_3EDTA. The specimens were stored at room temperature and analyzed within the following time intervals: 5 min, 15 min, 30 min and 60 min. Average results are presented.

The addition of EDTA to blood can induce cell responses including a temporary shrinkage of cells. The vast majority of specimens quickly re-establish their native state characteristics (equilibration) within a very short time; others may take up to 20 to 30 minutes depending on the sample. [53] [54] An example is the initial shrinkage of platelets and the measurement of Mean Platelet Volume (MPV). The return to an equilibration state can be observed in this data set with the greatest change in MPV exhibited in the first 10 minutes after collection.

Table 4.19 CBC Sample Stability, Room Temperature

Hours	WBC	RBC	Hgb	MCV	RDW	RDW-SD	PLT	MPV
5	7.27	4.648	13.83	88.35	13.27	40.79	261.0	7.72

Table 4.19 CBC Sample Stability, Room Temperature

15	7.29	4.652	13.84	88.23	13.33	40.86	258.6	8.32
30	7.31	4.655	13.87	88.17	13.27	40.76	257.5	8.54
60	7.32	4.652	13.85	88.31	13.27	40.66	259.0	8.78

Table 4.20 Diff % Sample Stability, Room Temperature

Minutes	NE	LY	MO	EO	BA	NRBC
5	58.99	28.52	9.54	2.46	0.50	0
15	59.03	28.41	9.65	2.48	0.43	0
30	58.93	28.57	9.53	2.44	0.53	0
60	59.03	28.57	9.43	2.42	0.54	0

Table 4.21 Diff # Sample Stability, Room Temperature

Minutes	NE	LY	MO	EO	BA	NRBC
5	4.38	2.01	0.66	0.18	0.03	0
15	4.40	2.01	0.67	0.18	0.03	0
30	4.40	2.03	0.67	0.18	0.04	0
60	4.42	2.03	0.66	0.18	0.04	0

Table 4.22 Differential Suspect Flagging, Room Temperature

Minutes	# of Samples	Suspect Messages
5	0	N/A
15	0	N/A
30	1	Imm. NE 1
60	0	N/A

MCV Accuracy

Table 4.25 shows MCV accuracy at temperature extremes.

Table 4.23 MCV Performance Characteristics

Temperature	With LH Series Reagents	With ISOTON 4 / LYSE S 4
@ 60°F	-1.9%	-0.7%
@ 90°F	-0.1%	2.4%

NRBC Accuracy

NRBC Accuracy Characteristics was defined as the agreement between the LH 780 and the results given by the reference method (CLSI H20A) and a predicate hematology analyzer.

All NRBC % results ≥2 and ≤15 will be flagged with an R symbol. Beckman Coulter, Inc. recommends a slide review as per your individual laboratory protocol. The presence of this flag does not affect the correction of the white blood cell count in the presence of NRBCs.

Table 4.26 shows the NRBC results for whole blood specimens with and without NRBC collected in a salt of EDTA.

Table 4.24 NRBC Accuracy Characteristics, Compared Samples

	Units	Number of Samples	Clinical Range Low	Clinical Range High	Mean Difference
Against*	%	389	0.0	24.11	0.08
Against Manual†	%	393	0.0	61.50	-0.02

* predicate hematology analyzer
† CLSI

Platelet Accuracy Characteristics

Table 4.26 shows the Plt results for whole blood specimens collected in a salt of EDTA.

Table 4.25 Plt Accuracy Characteristics vs. Flow Cytometry (ICSH/ISLH Platelet Method)

Parameter	Units	N	Population Minimum	Population Maximum	Mean Difference	Mean % Difference
PLT	x 10^3 cells/µL	374	5.0	1053.5	13.85	6.58

Reference Ranges

A Normal Range study was conducted to assess the Reference Ranges for the LH 780. Whole-blood samples were collected from 126 donors (males and females). The selection of donors was consistent with guidelines stated in CLSI, C28-A.

Table 4.26 Normal Population Study, LH 750 Series Diluent / Lyse S III Diff Lytic Reagent

Parameter	Units	Mean	95% Confidence Low Limit	95% Confidence High Limit
WBC	x 10^3 cells/µL	6.32	3.57	11.01
RBC	x 10^6 cells/µL	4.67	3.84	5.62
Hgb	g/dL	13.67	11.41	16.40
Hct	%	40.29	34.35	47.72
MCV	fL	86.60	73.54	96.48
MCH	pg	29.37	23.90	33.58
MCHC	g/dL	33.90	32.27	35.07
RDW	%	13.67	12.14	16.49
RDW-SD	fL	41.04	36.75	46.74
Plt	x 10^3 cells/µL	258.21	150.05	372.26

Table 4.26 Normal Population Study, LH 750 Series Diluent / Lyse S III Diff Lytic Reagent

MPV	fL	9.03	7.57	11.58
NE	%	59.66	42.78	75.78
LY	%	29.28	16.82	45.30
MO	%	7.97	4.66	11.95
EO	%	2.54	0.36	8.35
BA	%	0.55	0.24	1.16
NE	x 10^3 cells/µL	3.82	1.69	7.50
LY	x 10^3 cells/µL	1.80	0.88	2.89
MO	x 10^3 cells/µL	0.49	0.28	0.86
EO	x 10^3 cells/µL	0.16	0.03	0.48
BA	x 10^3 cells/µL	0.03	0.01	0.07
RET	%	1.11	0.44	2.16
RET	x 10^6 cells/µL	0.05	0.02	0.11
MRV	fl	107.91	96.08	120.27
IRF	%	0.33	0.22	0.46

Table 4.27 Normal Population Study, ISOTON 4 Diluent / Lyse S 4 Lytic Reagent

Parameter	Units	Mean	95% Confidence Low Limit	95% Confidence High Limit
WBC	x 10^3 cells/µL	6.38	3.58	11.26
RBC	x 10^6 cells/µL	4.62	3.82	5.58
Hgb	g/dL	13.57	11.46	16.18
Hct	%	39.82	33.61	47.09
MCV	fL	86.37	73.28	97.16
MCH	pg	29.44	24.06	33.89
MCHC	g/dL	34.06	32.23	35.30
RDW	%	13.83	12.33	16.21
RDW-SD	fL	42.59	38.06	48.05
Plt	x 10^3 cells/µL	256.02	146.45	373.64
MPV	fL	8.78	7.31	11.31
NE	%	59.69	42.51	76.90
LY	%	29.12	15.63	44.65
MO	%	7.94	4.71	11.58
EO	%	2.70	0.57	8.48
BA	%	0.55	0.23	1.34
NE	x 10^3 cells/µL	3.90	1.75	8.09

Table 4.27 Normal Population Study, ISOTON 4 Diluent / Lyse S 4 Lytic Reagent

LY	x 10^3 cells/µL	1.81	0.81	2.85
MO	x 10^3 cells/µL	0.50	0.25	0.91
EO	x 10^3 cells/µL	0.17	0.03	0.49
BA	x 10^3 cells/µL	0.03	0.01	0.08
RET	%	1.12	0.29	2.31
RET	x 10^6 cells/µL	0.05	0.01	0.10
MRV	fl	111.09	98.31	126.66
IRF	%	0.23	0.14	0.33

Known Interfering Substances

All	Misleading results can occur if the specimen is not properly collected, stored or transported. Beckman Coulter recommends that you follow CLSI or equivalent procedures to ensure proper specimen collection, storage and transport. Always follow manufacturer's recommendations when using microcollection devices for specimen collection.
All	Misleading results can occur if specimens contain clots. Always use good laboratory practices for inspecting specimens for clots and verifying results.
All	Misleading results can occur if the specimen is not properly mixed. Always use good laboratory practices to ensure specimens are appropriately mixed. Do not bypass or circumvent the automated mixing process when using the automatic mode on the LH 780.
WBC	NRBCs, giant platelets, platelet clumps, malarial parasites, precipitated elevated proteins, cryoglobulin, microlymphoblasts, very small lymphocytes, fragmented white cells, agglutinated white cells, lyse resistant red cells, unlysed particles > 35 fL in size. Elevated WBC counts may have a carryover effect on subsequent leukopenic specimens, within the limits specified in the Carryover Section. **IMPORTANT** If a sample is run that has a WBC greater than 600 x 10^3 /µL and a prominent Lymphocyte population, the system will flag the WBC result with an "R" flag. The "R" Flag without Cellular Interference message indicates the need to perform a manual differential and rerun a diluted sample of the specimen.
RBC	Very high WBC count, high concentration of very large platelets, auto-agglutination If hemolysis is occurring in vivo, the instrument RBC may be flagged as low, reflecting the true circulating cells. If, however, the hemolysis is in vitro, the specimen may give falsely low RBC results. Cell counts due to in vitro hemolysis do not represent the number of circulating red blood cells.
Hgb	Very high WBC count, severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing.

MCV	Very high WBC count, high concentration of very large platelets, auto-agglutination.
RDW, RDW-SD	Very high WBC count, high concentration of very large platelets, auto-agglutination.
Plt	Giant platelets, platelet clumps, white cell fragments, electronic noise, very small red cells, red cell fragments
Hct	Known interferences related to RBC and MCV.
MCH	Known interferences related to Hgb and RBC.
MCHC	Known interferences related to Hgb, RBC and MCV.
NRBC	Known interferences related to lyse resistant red cells, platelet clumps, giant platelets, malarial parasites, very small or multi-population lymphocytes, precipitated elevated proteins. Small NRBC that are below the lower counting threshold will not be enumerated. Large NRBC>35 fL may be counted as WBC. The presence of a majority or NRBC that are very small or very large may result in a false negative condition. If an NRBC% is reported as zero and there are any suspect messages or parameter codes, Beckman Coulter, Inc. recommends a slide review per your laboratory protocol. Cord blood is a recognized source of high numbers of NRBC. However, due to the possible matrix effect of the sample constituents that may be introduced during sampling, cord blood is not recommended for NRBC studies.
Differential	Hypogranular granulocytes, agranular granulocytes, lyse resistant red cells, very small or multi-population lymphocytes, elevated triglycerides, precipitated elevated proteins.
Reticulocytes	Erythrocyte inclusions stained by New Methylene Blue, if sufficiently numerous within a sample, and some hemoglobinopathies (SS, SC) might affect the accuracy of the reticulocyte enumeration.[42]

Temperature

Ambient operating range: 15.5 to 32°C (60 to 90°F)

Humidity

0 to 95% without condensation

Sample Storage

CBC/Diff Parameters

- Store at room temperature (23.9°C or 75°F), up to 24 hours after collection
- Store between 2 and 8°C (35.6 and 46.4°F), up to 48 hours after collection

Reticulocyte Parameters

- Store at room temperature (23.9°C or 75°F), up to 24 hours after collection
- Store between 2 and 8°C (35.6 and 46.4°F), up to 72 hours after collection

NRBC Parameters

- Store at room temperature (23.9°C or 75°F), up to 24 hours after collection

- Store between 2 and 8°C (35.6 and 46.4°F), up to 24 hours after collection

Sample Type

Human whole blood anticoagulated in K_2EDTA or K_3EDTA

Sampling Modes

Aspiration

Automatic cap-piercing, whole blood

Manual, open vial, whole blood and diluted specimens.

Test/Cycle

CBC

CBC/DIFF

CBC/RETIC

CBC/DIFF/RETIC

RETIC

Throughput, Automatic Mode

Typical throughput performance is described for samples with elevated parameter levels. Approximate throughput performance data, not including sample preparation, is:

LH 780	Sample/hour
CBC	>110
CBC/Diff	>110
CBC/Diff/Retic	>45

LH 780 with LH SlideMaker and LH SlideStainer	Sample/hour
CBC	>105
CBC/Diff	>100
CBC/Diff/Retic	>45

Sample Volume Aspirated

Automatic, cap-piercing mode: maximum 300 µL

Manual, open-vial mode: maximum 200 µL

With optional LH SlideMaker and LH SlideStainer 550 µL

Waste

20-liter waste container

Pneumatic Supplies (Internally Regulated)

Pressure = 60 psi (pounds per square inch)

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

Calibration Stability

Variation with temperature: If ambient room temperature changes by less than 5.5ºC (10ºF) from the calibrating temperature, and the temperature is within the temperature specifications, then the LH 780 does not require calibration.

IMPORTANT The operating temperature influences the rate of kinetic reactions. The LH 700 Series System should be recalibrated whenever the ambient temperature changes by 10ºF. If you have to recalibrate due to a large change in laboratory ambient temperature, you should re-evaluate the differential flagging sensitivity settings for your typical patient population.

LH Workstation Storage

You can store up to 20,000 patient results with numeric, graphic and list mode data.

4.5 BAR-CODE SYMBOLOGY OVERVIEW

A bar-code symbol is a series of adjacent bars and spaces. The widths of the bars and spaces represent the actual data encoded within the symbol. A device, usually called a scanner, or reader is used to decode this data into human readable information. A bar-code symbology, such as Interleaved 2-of-5, describes the unambiguous conventions or rules used for the way in which data is encoded into the arrangement of the adjacent bars and spaces.

A symbology is defined by the following characteristics:

Character Set

This refers to the range of data characters that can be encoded for a specific symbology. There are essentially three types:

- Numeric—The symbology can encode only numeric characters.
- Alphanumeric—Can encode the full alpha and numeric characters of the ASCII character set.
- 128—Can encode all the 128 available ASCII characters.

Symbology Type

There are essentially two types:

- Discrete—Each character is separated from the next by an intercharacter gap. This allows each character to be decoded independently. Every character has a bar on each end.
- Continuous—Has no intercharacter gaps. Every character begins with a bar and ends with a space.

Fixed or Variable Length

Some symbologies can only encode messages of a fixed length. Some can be used to encode variable length data. Some should only be used as a fixed length to increase the security of data decoding.

Self-Checking

A self-checking symbology has the ability to prevent character transposition due to a single printing defect.

Start Code, Stop Code

Start and Stop Codes are bar and space patterns that are placed at the beginning and end of the encoded data. A start code indicates the beginning of the symbol, and indicates the start of the encoded information. The stop code indicates the end of the symbol and marks the end of the encoded information.

Check Character, Checksum Algorithm

Virtually all bar-code symbologies use a check character. The check character is derived by a mathematical calculation using the characters in the encoded information. It is used by the scanning device to verify that the correct information has been decoded. It is highly recommended that a check character, also called a checksum algorithm, is used.

Quiet Zone, Quiet Area

The Quiet Zone is a clear area on either side of the start and stop codes. It helps the scanning device establish the reflectivity characteristics of the label.

4.6 BAR-CODES AND THE LH 700 SERIES

IMPORTANT

1. DO NOT use the following characters # @ [\ ] `{ | } ~ in Specimen or Patient identifiers. There is a potential for Specimen or Patient misidentification to occur. The system will substitute or omit these characters when the system is configured in a language other than English or Chinese.
2. Risk of misidentification. Use of poor quality, dirty, improperly placed or damaged bar-code labels could keep the instrument from reading the bar-code labels. Ensure the bar-code labels are undamaged. Ensure the bar-code labels conform to the specifications provided in Chapter 4 of the Reference manual.
3. DO NOT use leading or trailing spaces in the ID.

The LH 700 Series supports the use of up to 16-character bar-code labels and a wide variety of bar-code symbologies. When choosing a symbology to use in your laboratory, it is important to understand the different bar-codes available. Some bar-codes are more stable, and therefore less prone to misreads than others.

The following information is intended as a guide to help you in your selection process.

Checksum Algorithm

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

IMPORTANT Use of bar codes is an extremely accurate and effective method of positive patient identification. Certain features, such as checksum digits, maximize accuracy in reading Codabar, Code 39 and Interleaved 2-of-5 labels. Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. If you must use bar-codes without checksums, Beckman Coulter recommends that you verify each bar-code reading to assure correct patient identification.

Bar-code Symbologies Supported by the LH 700 Series

Interleaved 2-of-5

Interleaved 2-of-5 is a high density, continuous numeric symbology. It is self-checking. Every character in the symbology encodes two digits, one in the bars and one in the spaces.

This symbology is susceptible to an incorrect read due to a partial scan (a scanning path that does not include both leading and trailing quiet zones). The most common incorrect read is a shorter, but valid decoding of the information. The presence of a checksum does not eliminate this risk. It is recommended that any Interleaved 2-of-5 label contain Bearer Bars. Alternatively, this label should be used with a fixed length only, with the scanning devices set to recognize labels of a specific length (for example 12 digits).

Code 39 (Also called 3-of-9 Code)

Code 39 was the first alphanumeric symbology developed. It is a self-checking, discrete and variable length symbology. The Health Industry Bar-code Council (HIBCC) has adopted the use of a check character for health care applications. This is encouraged, particularly where print quality is less than optimum.

Codabar

Codabar has a character set of 16 characters. It is a discrete, self-checking symbology and is most commonly used in libraries and blood banks.

NW-7

NW-7 is similar to Codabar. It uses numeric characters only and a different checksum algorithm.

Code 128/USS 128

Code 128 is a continuous, variable length symbology. This symbology has 106 different printed characters.

Code 128 is character dependent. See AIM Uniform Symbol Specification (USS) Rev. 1986 for additional required dimensional tolerances.

You must use and print a checksum character, and it must conform to the AIM USS 128 checksum generation procedure. DO NOT use the following values, as they are not recognized as valid values:

Code set A	0, 3, 32, 59, 60, 61, 64 through 102
Code set B	0, 3, 32, 59, 60, 61, 64, 91 through 102
Code set C	100 through 102

Bar-code Tips

No bar-code symbology is perfect. You will occasionally get a read error. Following are some tips to help you get the best performance from the symbology you choose:

- Use high quality labels.
- Always use a check character.
- Use fixed length bar-code information.
- Use Bearer Bars with Interleaved 2-of-5.
- When using the handheld scanner, check that the label was decoded correctly.

4.7 BAR-CODE LABEL SPECIFICATIONS

IMPORTANT

1. DO NOT use the following characters # @ [\ ] `{ | } ~ in Specimen or Patient identifiers. There is a potential for Specimen or Patient misidentification to occur. The system will substitute or omit these characters when the system is configured in a language other than English or Chinese.
2. Risk of misidentification. Use of poor quality, dirty, improperly placed or damaged bar-code labels could keep the instrument from reading the bar-code labels. Ensure the bar-code labels are undamaged. Ensure the bar-code labels conform to the specifications provided in Chapter 4 of the Reference manual.
3. DO NOT use leading or trailing spaces in the ID.

General

The LH 700 Series supports the use of up to 16-character bar-code labels. A bar-code consists of black lines (bars) and white lines (spaces), which are called elements. There are narrow elements (NE) and wide elements (WE); and their arrangement is determined by the code.

Optical Characteristics at 880 nm ±10% and 633 nm ±10%

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

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

Printing Method

Photographic, or thermal transfer.

Label Thickness

Maximum label thickness must be such that:

- The tube's outer diameter including the label is not greater than 13.3 mm.
- The label including adhesive =0.006 ±0.003 in.

NE/WE Ratio

Must remain constant over code length.

Label Dimensions and Data

The dimensional and data specifications are illustrated in Figure 4.1, Bar-Code Label Specifications. Table 4.28 Bar-Code Label Specifications explains the specifications called out in Figure 4.1, Bar-Code Label Specifications.

Figure 4.1 Bar-Code Label Specifications

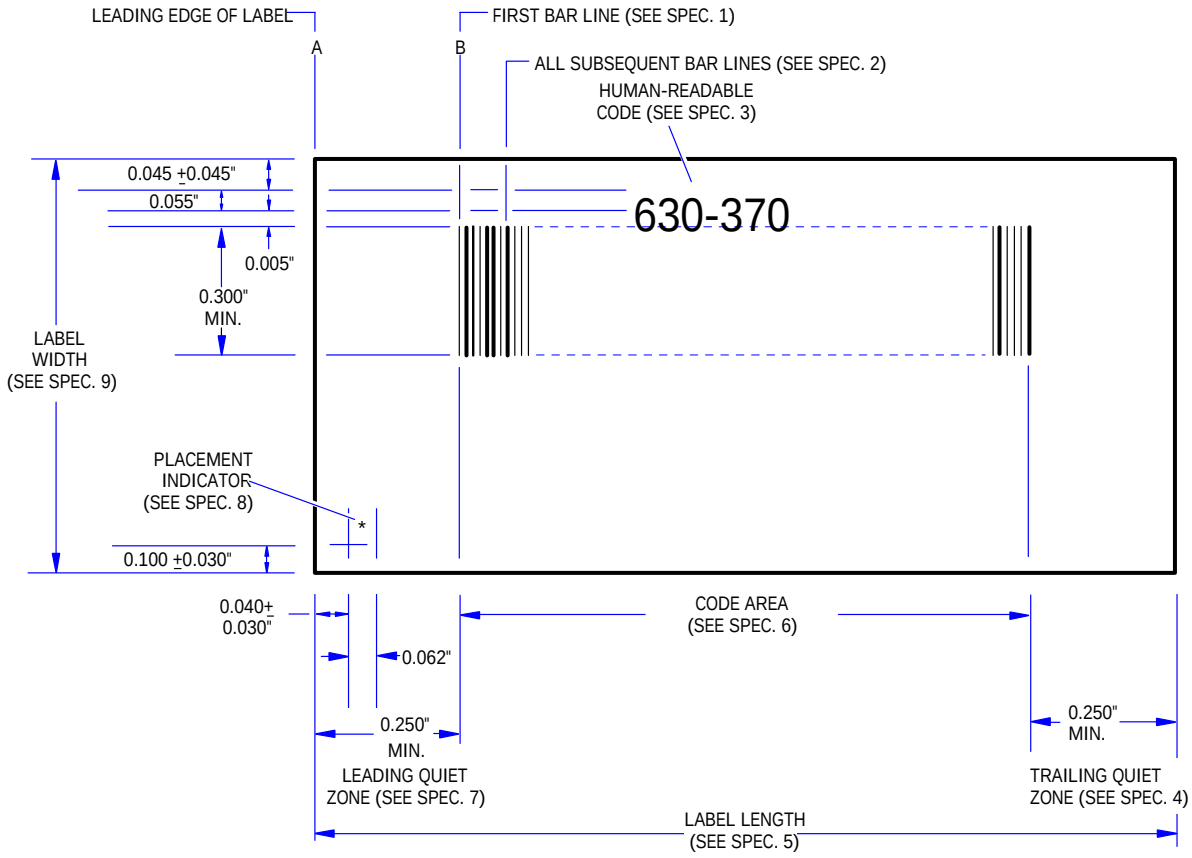


Table 4.28 Bar-Code Label Specifications

Specification Called Out in Figure 4.1	Explanation
1	The first bar of the code (B) must be parallel to the label edge (A) within 0.002".
2	All subsequent bar lines must be parallel to (B) within 0.001".
3	The human-readable code (HRC) does not include the checksum; the dash in the HRC is not encoded in the bar-code.
4	The trailing quiet zone must be 0.250" minimum.
5	The maximum label length is determined by the tube length. The scanner can accommodate labels up to 2.35". With HEMOGARD tubes, the maximum label length is 2.04".

Table 4.28 Bar-Code Label Specifications *(Continued)*

Specification Called Out in Figure 4.1	Explanation
6	The bar-code area contains the start character, data digits, checksum, and stop character.
7	The leading quiet zone must be 0.250" minimum.
8	The placement indicator shows you which end of the label goes next to the tube stopper. This is an optional feature, not a mandatory one.
9	The width of the label must leave at least a 1/8" window for viewing the contents of the tube. The maximum label width for a 10-mm diameter tube is 1.1". The minimum label width is 0.400".

Acceptable Bar-Codes

Within the given specifications, the scanner automatically distinguishes the following bar-codes.

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

Extended Digit Bar Code

When using bar-coded data lengths from 12 to 16 data characters, consider these recommendations:

- Use a tube that can accommodate a label length between 53.34 mm (2.1 in.) and 63.50 mm (2.5 in.) for 16-character bar codes.
- Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. Beckman Coulter strongly recommends the use of bar-code checksums to provide automatic checks for read accuracy.

IMPORTANT The use of bar codes is an extremely accurate and effective method of positive patient identification. Certain features, such as checksum digits, maximize accuracy in reading Codabar, Code 39, and Interleaved 2-of-5 labels. Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. If you must use bar-codes without checksums, Beckman Coulter recommends that you verify each bar-code reading to assure correct patient identification.

- Maintain the bar-code printer. To achieve the maximum number of digits on the bar-code labels, higher density symbols should be used. The system does not tolerate any void or speck when using the 177.8 µm (0.007 in.) narrow element width.
- Print bar code patterns on labels to allow for a minimum of 10 times the narrow element width as the leading and trailing quiet zones. If you are not using 16 digits on your label, use a quiet zone of at least 6.35 mm (0.25 in.) on either side of the bar-code label.
- Place the bar-code label on the tube to ensure that the printed area, including the quiet zones, are readily visible to the scanner.
- Configure your hand-held scanner for the specific bar code type as instructed in your Online Help.

Table 4.29 Code-Related Specifications

Code Type	Analyzer Readable Digit Length*	Narrow Element Width		Wide Element/Narrow Element Ratio	SlideMaker Label Scannable Bar Code Characters*
		Inches (Minimum)	µm (Minimum)		
Interleaved 2-of-5 with Checksum	3 to 15	0.010	254.0	(2.21 to 3):1	11
Interleaved 2-of-5 without Checksum	4 to 16	0.010	254.0	(2.21 to 3):1	10
(Do not use 0.007 N.E.W. for Interleaved 2 of 5)					
NW7 with Checksum	3 to 11	0.010	254.0	3:1	8
	12 to 16	0.007	177.8	3:1	
Codabar with Checksum	3 to 11	0.010	254.0	3:1	8
	12 to 16	0.007	177.8	3:1	
Codabar/NW7 without Checksum	4 to 11	0.010	254.0	3:1	9
	12 to 16	0.007	177.8	3:1	
Code 39 with Checksum	3 to 9	0.010	254.0	(2.21 to 3):1	8
	10 to 16	0.007	177.8	3:1	
Code 39 without Checksum	4 to 9	0.010	254.0	(2.21 to 3):1	9
	10 to 16	0.007	177.8	3:1	
Code 128: Character Sets A & B	4 to 14	0.010	254.0	(2 to 4):1	9 or 11 with hardware modification
	15 to 16	0.007	177.8	(2 to 4):1	
Code 128: Character Set C	4 to 16	0.010	254.0	(2 to 4):1	10

***** *Although the LH 700 Series analyzer with SlideMaker accepts up to 16-character bar codes, the SlideMaker only prints the human-readable information on the slide for bar-code labels with 12 or more digits.*

Checksum Algorithm

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

IMPORTANT Use of bar-codes is an extremely accurate and effective method of positive patient identification. Certain features, such as checksum digits, maximize accuracy in reading Codabar, Code 39 and Interleaved 2-of-5 labels. Use checksums to provide protection against occasional misread errors caused by problems such as damaged or misapplied labels. If you must use bar-codes without checksums, Beckman Coulter recommends that you verify each bar-code reading to assure correct patient identification.

The algorithm for determining the checksum for each code is as follows:

Interleaved 2-of-5

This code requires 3 to 15 data digits plus a checksum or 16 digits without checksum. The number of printed characters must always be even in length. Therefore, printers will automatically add a leading zero as a filler if an odd number of characters is chosen.

To determine the value of the checksum character:

1. Identify even- and odd- positioned characters in the message with the right-hand message character always defined as an even-positioned character.
2. Sum the numeric values of the odd-positioned characters.
3. Sum the numeric values of the even-positioned characters and multiply the total by 3.
4. Sum the odd and even totals from steps 2 and 3.
5. Determine the smallest number which, when added to the sum in step 4, results in a multiple of 10.
6. This number is the value of the checksum character.
7. Determine whether total number of characters (message plus checksum) is odd or even. If odd, add a leading nonsignificant zero to the message to produce an even number of characters as required by the symbology.
8. Example:

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

STEP 1: 1+5+7=13

STEP 2: (2+6+8)x3=48

STEP 3: 13+48=61

STEP 4: 61+9=70

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

Codabar

Codabar has a character set of 16 characters. It is a discrete, self-checking symbology and is most commonly used in libraries and blood banks.

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

Table 4.30 Codabar Character Value Table

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

The checksum technique is:

- The character value of a message is obtained from the above table and added together.
- This sum is divided by 16, and the remainder corresponds to the value of the checksum character.

Examples:

1.

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

2+3+4+7+1+3 = 20
20 ÷ 16 = 1, REMAINDER 4

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

2.

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

11+11+13+13+15+15+15+15 = 108
108 ÷ 16 = 6, REMAINDER 12

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

NW7 Decoding

This code uses three to 16 numeric data digits.

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

Table 4.31 NW 7 Character Value Table

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

The checksum technique is:

- The data digit value that is the difference between 11 and the Mod 11 sum of the weighted values of the data digits is used as the check digit. The start and stop digits are not used as part of the checksum calculation.
- NW7 is made up of 1 start digit, 16 data digits and 1 stop digit.
- The checksum digit immediately precedes the stop digit.

WEIGHTED MODULUS 11:

Checksum Technique:

- The start and stop digits are not used as part of the checksum calculation.
- The Checksum digit immediately precedes the stop digit.
- Weighted modulus 11 calculation method.

DIGIT POSITION (Right Justified)	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1
WEIGHT (1)	5	3	6	2	6	3	5	9	10	7	8	4	5	3	6	2
WEIGHT (2)	6	8	5	9	5	8	6	2	10	4	3	7	6	8	5	9

Example 1: Message 011529007

Use weight (1):

(9 x 0) + (10 x 1) + (8 x 5) + (4 x 2) + (5 x 9) + (3 x 0) + (6 x 0) + (2 x 7) = 124

124 ÷ 15 = 11, remainder 3

When the remainder is 0, 0 is the check digit.

11 - 3 = 8

The value 8 corresponds to the character 8, Therefore the Checksum is 8 and the final decoded message is 0115290078.

Example 2: Message 023229006

Use weight (1):

(9 x 0) + (10 x 2) = (7 x 3) + (8 x 2) + (4 x 2) + (5 x 9) + (3 x 0) + (6 x 0) + (2 x 6) = 122

122 ÷ 11 = 11, remainder 1

When the remainder is 1, the calculation must be repeated using weight (2).

Use weight (2):

(2 x 0) + (10 x 2) + (4 x 3) + (3 x 2) + (7 x 2) + (6 x 9) + (8 x 0) + (5 x0) + (9 x 6) = 160

160 ÷ 11 = 14, remainder 6

When the remainder is 0, 0 is the check digit.

11 - 6 = 5

The value 5 corresponds to the character 5, Therefore the Checksum is 5 and the final decoded message is 0232290065.

Code 39 Bar Code

This code uses three to 16 data digits with checksum enabled. Use of a 3-digit bar code without checksum enabled is not allowed.

The value assigned to each of the characters is:

Table 4.32 Code 39 Character Value Table:

CHARACTER	VALUE	CHARACTER	VALUE	CHARACTER	VALUE
0	0	F	15	U	30
1	1	G	16	V	31
2	2	H	17	W	32
3	3	I	18	X	33

CHARACTER	VALUE	CHARACTER	VALUE	CHARACTER	VALUE
4	4	J	19	Y	34
5	5	K	20	Z	35
6	6	L	21	-	36
7	7	M	22	.	37
8	8	N	23	SPACE	38
9	9	O	24	$	39
A	10	P	25	/	40
B	11	Q	26	+	41
C	12	R	27	%	42
D	13	S	28		
E	14	T	29		

The checksum technique is:

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

· Example:

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

28+29+30+31+32+33+34+15 = 232
232 ÷ 43 = 5, REMAINDER 17; 17 = H = CHECKCHARACTER

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

Code 128

This code uses four to sixteen data digits on the LH 700 Series and four to sixteen data digits for the SlideMaker bar-code label printing.

The checksum character immediately precedes the stop character. The checksum character used with Code 128 must conform to the AIM USS 128 checksum generation procedure. DO NOT use the following values because they are not recognized as valid values:

Code set A	0, 3, 32, 59, 60, 61, 64 through 102
Code set B	0, 3, 32, 59, 60, 61, 64, 91 through 102
Code set C	100 through 102

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

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

105 + (25 x 1) = 130

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

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

130 ÷ 103 = 1, REMAINDER 27

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

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

IMPORTANT Inaccuracies will occur when printing a SlideMaker slide label using certain Code 128 characters. Do not use the following characters when printing a slide label using Code 128: question mark (?), asterisk (*), or space.

VALUE	CODE A	CODE B	CODE C
0	SP	SP	00
1	!	!	01
2	"	"	02
3	#	#	03
4	$	$	04
5	%	%	05
6	&	&	06
7	'	'	07
8	(	(	08

VALUE	CODE A	CODE B	CODE C
9	)	)	09
10	*	*	10
11	+	+	11
12	,	,	12
13	-	-	13
14	.	.	14
15	/	/	15
16	0	0	16
17	1	1	17
18	2	2	18
19	3	3	19
20	4	4	20
21	5	5	21
22	6	6	22
23	7	7	23
24	8	8	24
25	9	9	25
26	:	:	26
27	;	;	27
28	<	<	28
29	=	=	29
30	>	>	30
31	?	?	31
32	@	@	32
33	A	A	33
34	B	B	34
35	C	C	35
36	D	D	36
37	E	E	37
38	F	F	38
39	G	G	39
40	H	H	40
41	I	I	41
42	J	J	42
43	K	K	43
44	L	L	44

VALUE	CODE A	CODE B	CODE C
45	M	M	45
46	N	N	46
47	O	O	47
48	P	P	48
49	Q	Q	49
50	R	R	50
51	S	S	51
52	T	T	52
53	U	U	53
54	V	V	54
55	W	W	55
56	X	X	56
57	Y	Y	57
58	Z	Z	58
59	[	[	59
60	\	\	60
61	]	]	61
62	^	^	62
63	___	___	63
64	NUL	`	64
65	SOH	a	65
66	STX	b	66
67	ETX	c	67
68	EOT	d	68
69	ENQ	e	69
70	ACK	f	70
71	BEL	g	71
72	BS	h	72
73	HT	i	73
74	LF	j	74
75	VT	k	75
76	FF	l	76
77	CR	m	77
78	SO	n	78
79	SI	o	79
80	DLE	p	80

VALUE	CODE A	CODE B	CODE C
81	DC1	q	81
82	DC2	r	82
83	DC3	s	83
84	DC4	t	84
85	NAK	u	85
86	SYN	v	86
87	ETB	w	87
88	CAN	x	88
89	EM	y	89
90	SUB	z	90
91	ESC	{	91
92	FS	|	92
93	GS	}	93
94	RS	~	94
95	US	DEL	95
96	FNC 3	FNC 3	96
97	FNC 2	FNC 2	97
98	SHIFT	SHIFT	98
99	CODE C	CODE C	99
100	CODE B	FNC 4	CODE B
101	FNC 4	CODE A	CODE A
102	FNC 1	FNC 1	FNC 1
103	START (CODE A)		
104	START (CODE B)		
105	START (CODE C)		

5.1 LASER SAFETY

WARNING Possible harm to operator. Do not use any controls, make any adjustments, or perform any procedures other than those specified herein. To do so may result in hazardous radiation exposure.

The Triple Transducer Module contains a laser. A laser is a unique light source that exhibits characteristics different from conventional light sources. The safe use of the laser depends upon familiarity with the instrument and the properties of coherent, intense beams of light. The beam can cause eye damage and instrument damage. There is enough power from the laser to ignite substances placed in the beam path, even at some distance. The beam might also cause damage if contacted indirectly from reflective surfaces (specular reflection). The laser on the LH 700 Series is covered by a protective housings that is held in place by tamper-proof screws.

WARNING Possible harm to operator. Do not attempt to remove the laser or to open it. Failure to comply can result in hazardous radiation exposure. If removal is required, it must be done only by a Beckman Coulter Representative.

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

5.2 RADIATION HAZARDS

In the design and manufacture of the LH 700 Series, Beckman Coulter Inc. has complied with the requirements governing the use and application of a laser as stipulated in regulatory documents issued by the

- U.S. Department of Health and Human Services, and
- Center for Devices and Radiological Health (CDRH).

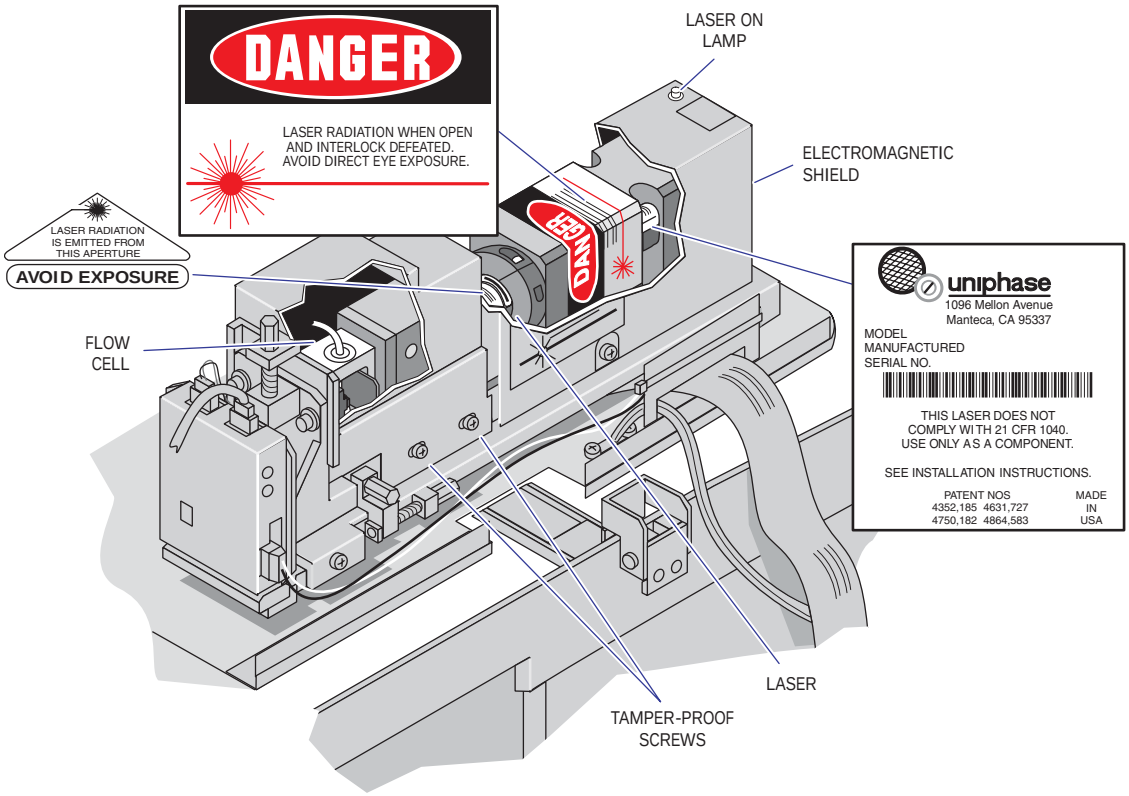
In compliance with these regulatory documents, every measure has been taken to ensure the health and safety of users and laboratory personnel from the possible dangers of laser use.

5.3 LASER WARNING LABELS

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

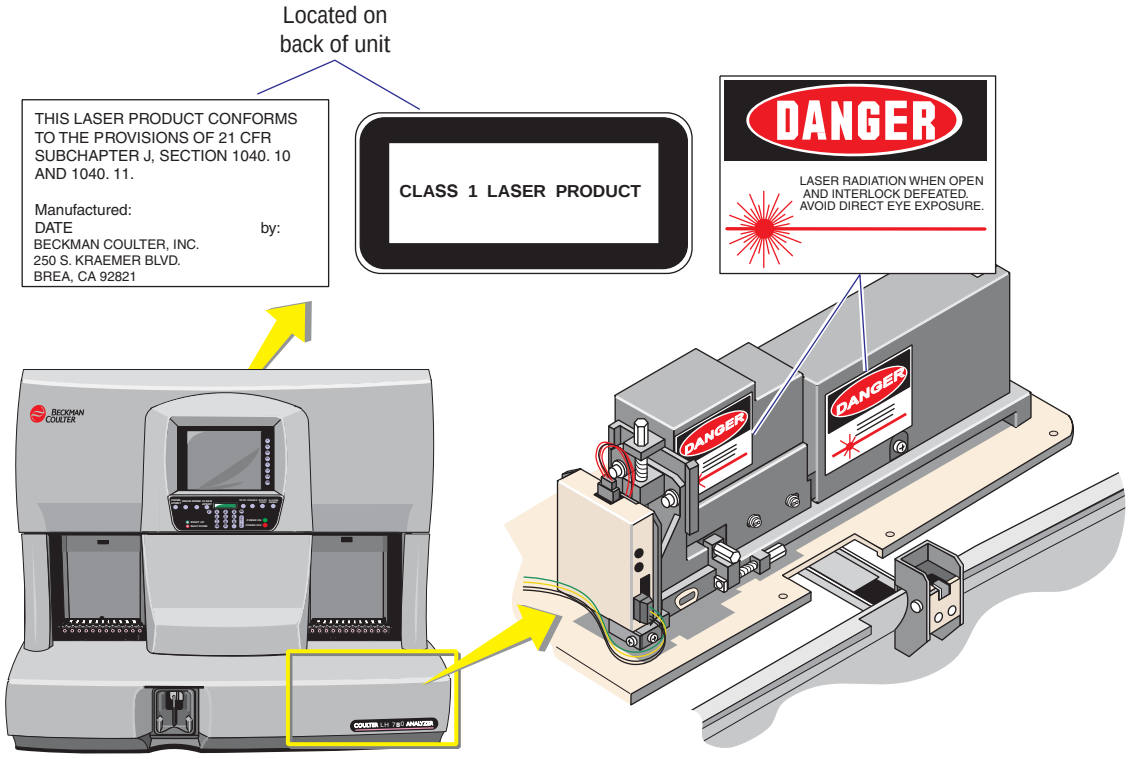
CDRH-approved labels are placed near or on those covers that, when removed, might expose laser radiation. Figure 5.1 shows the laser cover and the protective housing cut away. This illustration is intended only to show you what the system looks like, in compliance with CDRH. See Figure 5.1 for the labels and their locations on the laser head. See Figure 5.2 for the label location on the beam cover between the laser head and the sampling compartment. Figure 5.1 and Figure 5.2 show certification labels.

Figure 5.1 Laser Warning Label, Protective Housing Cut Away



Note: As installed in the Triple Transducer Module (TTM) safety fixture, the laser presents no radiation hazard to users and complies with 21 CFR 1040.

Figure 5.2 Laser Warning Label Locations, Protective Housing On



5.4 DISPOSAL OF ELECTRICAL INSTRUMENTATION

It is very important that customers understand and follow all laws regarding the safe and proper disposal of electrical instrumentation.

The symbol of a crossed-out wheeled bin on the product is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates:

1. 1. that the device was put on the European Market after August 13, 2005 and
2. 2. that the device is not to be disposed via the municipal waste collection system of any member state of the European Union.

For products under the requirement of WEEE directive, please contact your dealer or local Beckman Coulter office for the proper decontamination information and take back program which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of device.

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*National Committee for Clinical Laboratory Standards is now the Clinical and Laboratory Standards Institute (CLSI).

µL	Microliter, a unit of volumetric measurement equal to one millionth of a liter.
µm	Micrometer, a unit of linear measurement equal to one millionth of a meter.
A	Ampere, a unit of electric current.
Accuracy	Ability of the instrument to agree with a predetermined reference value.
Action Limits	Values established by your laboratory to flag results requiring action.
Active Set	For Flagging Limits, Decision Rules and Auto Validation logic, the Active Set of parameters are defined as those parameters that: • are enabled for the System (System Setup – Patient – Parameters window), • are enabled for the Report Profile you are using (System Setup – Patient –Reporting Options window), • are part of the Test Mode you are running (C, CD, CDR, CR, or R on the Command Center) or have been edited into the sample, and • are included in the parameter block of the validation code you are looking for.
ADMS	The computer hardware and software that controls instrument operation; displays, stores, and recalls sample data; automates QC and calibration procedures; and assists you in troubleshooting. Also called: ADMS, DMS, LH 700 Series Workstation.
Algorithm	A particular procedure for performing an analysis.
Analytical Station	The Analyzer, Diluter, and Power Supply of the LH 700 Series.
Analyzer Pulse	A graphical display on the Analyzer screen that indicates the condition of all the apertures. You can detect noise, bubbles, or a clogged flow cell by monitoring the pulses.
ANSI	American National Standards Institute.
Application	A computer program, generally started from a button or icon. For example, starts the Patient Tests application.
ASCII	American Standard Code for Information Interchange.
Aspiration Mode	The method of running a sample, closed vial (Automatic aspiration mode) or open vial (Manual aspiration mode).
Assay Values	Values of all parameters for a control established by extensive assay of that control. These values are provided by the manufacturer of the control. Also called: assigned values.
Assigned Value	Values of all parameters for a control established by extensive assay of that control. These values are provided by the manufacturer of the control. Also called: assay values.
ASTM	American Society for Testing and Materials.

AutoCollation	A Workstation feature that automatically combines results of different test modes (CBC/Diff and Retic) analyzed from a sample with an identical patient or sample ID. The different test modes must be performed within a predetermined time.
Automatic Aspiration Mode	The closed-vial method of running a sample. Also called: closed-vial mode, primary mode, automatic sampling mode.
Automatic Startup Cycles	When you press the Startup button, the system flushes the cleaning agent from all Diluter components and tubing if cleaning reagent is not already removed. It also performs electronic and fluidic checks to ensure the instrument is ready to analyze control or whole-blood samples.
AutoNumbering	A Workstation feature that assigns a number to each sample received from the instrument.
Autopurge	If 24 hours elapse with the power on, pneumatics off, and the instrument in shutdown, the system automatically turns on the pneumatics; drains and fills the baths; and purges the flow cell and associated sample lines with cleaning agent.
AutoSequencing	A Workstation feature used with the ToDo list to automatically increment the identifiers you specify (Patient ID, Cass/Pos, sample ID, and sequence number).
AutoStop	A Workstation feature that instructs the instrument to stop processing based on specific criteria.
Average Value	A value that is computed by dividing the sum of a set of values by the number of values. Usually referred to as the simple arithmetic mean.
BA # (Basophils)	A WBC differential parameter result from the Diff sample analysis. The number (#) is computed from the WBC count and the BA %.
BA % (Basophils)	A WBC differential parameter result from the Diff sample analysis. The percent (%) is measured directly using VCS technology.
Background Count	A measure of the amount of electrical or particle interference using a diluent sample or no sample.
Background Results	Background results indicate reagent quality and the presence of electronic noise or bubbles. Background results above certain levels cause concern since they might falsely elevate (or interfere with) the results obtained for blood and control samples.
Batch	A group or set of results. • For Xb Analysis, a batch equals 20 patient samples used for monitoring MCV, MCH and MCHC as an automated QC procedure. • For Xm Analysis, a batch can contain 2 to 1,000 samples used for monitoring any parameters. • For printing or transmitting, a batch equals the samples you selected from the database.

Batch Mean	The mean or average of a set of samples. For Xb and Xm Analysis, the batch mean is a value based on a statistical averaging technique and is a type of "weighted moving average." It is used to estimate what a simple average result of a very large number of samples (population mean) might be by using a small number of samples.
Batch Print Job	Selecting multiple items from the database, then selecting the print icon to print all of them at the same time.
Baud	A rate defining how many data bits per second are transferred during communications between two pieces of equipment.
Calibration	A procedure to standardize the instrument for accuracy by determining its deviation from calibration references and applying any necessary correction factors.
Calibration Disk	A data diskette containing the Assigned Values for the lot number of the S-CAL calibrator kit being used.
Calibration Factors	Values the system uses to fine-tune instrument accuracy.
Carryover	The percentage (WBC, RBC, Hgb and Plt) or particle count (for Diff and Retic) of blood cells that are retained from one sample to the next.
Cass/Pos	The Workstation considers this field an optional identifier for the cassette number and cassette position number. This identifier appears on bar-code labels so that cassettes and positions are automatically read using a bar-code reader.
Cassette	The cassette is the carrier for the sample tubes (patient, control, or special test) used in Automatic aspiration mode where automatic loading, mixing, and sampling occurs.
Cassette Clips	Clips that you permanently install in each opening of the special cassettes for tubes with HEMOGARD Closure. These clips allow the special cassette to accommodate additional types of tubes.
CBC (Complete Blood Count)	A measure of the cell number and the indices. CBC includes WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, Plt, MPV, RDW, and RDW-SD.
CDC	Centers for Disease Control and Prevention.
CEE	Commission for Electrical Equipment.
Cell Control	A preparation made of human blood with stabilized cells and surrogate material. It is used for daily instrument QC.
Characters	All letters A-Z and numbers 0-9.
Check Valve	A one-way valve that routes liquid or air through the Diluter. Also called: mono-flow valve, one-way valve
CLIA	Clinical Laboratory Improvement Amendments.
Closed-vial Mode	The closed-vial method of running a sample. You place a closed tube sample in a cassette and place the cassette on the LH 700 Series loading bay. The LH 700 Series automatically reads the cassette label and tube label (if present) and aspirates the sample. Also called: closed-vial mode, primary mode, automatic sampling mode.

CLSI	Clinical and Laboratory Standard Institute formerly known as the National Committee for Clinical Laboratory Standards (NCCLS).
cm	Centimeter, a unit of linear measurement.
Codes	On windows and printouts, symbols, such as -----, ++++, :::::, appear with or in place of sample or control results because of irregularities. A code can only be generated by the instrument.
Coefficient of Variation	An expression, in percent, of data spread as related to the mean. %CV = (SD/Mean) x 100
Coincidence	More than one cell within aperture-sensing boundaries at the same time. The system counts only one pulse and automatically corrects results for coincidence.
Collation	The process of combining the results of different test modes (CBC/Diff and Retic) analyzed from the same sample.
Command Center	A blue bar that appears at the bottom of the screen.
Control Disk	A data diskette that contains the assay values for the lot number of the control being used.
Control Folder Filters	Control Folder Filters allow you to filter control lots into three categories: Active - By default, control lots have an active status. Active control lots are files that are currently in use. Control lots with an Active status are evaluated and stored, and event log messages, alarms and stop conditions are triggered as applicable. Accumulating - Accumulating control lots are utilized during crossover studies. Control lots with an Accumulating status will not trigger event log messages, alarms and stop conditions. Processing is otherwise the same as Active State. lnactive - Control lots with an Inactive status are no longer in use. No new data will be added to a lot with an Inactive status.
Corrected RBC	When WBC >140 x 10^3/µL, the RBC value is corrected to eliminate interference with WBC.
Coulter Principle	A method of counting and sizing cells by detecting and measuring changes in electrical resistance when a particle in a conductive liquid goes through a small aperture.
Critical Limits	Values established by your laboratory to flag results requiring immediate action.
CSA	Canadian Standards Association.
Cursor	On the screen, a place shown by a little blinking indicator or by a highlighted area. The cursor shows where you can select an option or type information.
CV (Coefficient of Variation)	An expression, in percent, of data spread as related to the mean. %CV = (SD/Mean) x 100
Cycle Counter	A number that appears on the Analyzer MAIN MENU screen that represents the actual number of instrument cycles that have occurred.

DataPlot	A graphic representation of results. DataPlots present a combined view of population density and membership. Colors represent different types of cells. Shades of colors represent the number of cells--bright colors are the most dense.
Data Management System (DMS)	The computer hardware and software that controls instrument operation; displays, stores, and recalls sample data; automates QC and calibration procedures; and assists you in troubleshooting. Also called: ADMS, DMS, LH 700 Series Workstation.
Default	A setting the instrument uses automatically. For example, you can set up a default printer. Every time you print sample results, the Workstation automatically prints the sample results to the default printer.
Definitive Messages	Definitive messages appear in a separate area of the screen display, printout, and host transmission. Definitive messages such as Anisocytosis, Leukopenia, etc., are laboratory-defined. Definitive messages are defined based on numeric limits generated by your laboratory. If results exceed the limits, the Workstation generates a message. Results that generate these messages may require review. Check your laboratory's protocol for handling the particular message.
Delta Check	A check on sample results that is made by clinical laboratories to determine if the current result on a particular patient is within certain limits of the last result obtained on that same patient.
Density	The number of cells in a particular region, regardless of the type of cell. On DataPlots, as more cells appear in a region, the color of the region gets brighter.
Diff (Differential)	Leukocyte differential parameters (NE, LY, MO, EO, and BA and processes that relate to them.
Digits	All numbers 0-9.
Diluter	This is the fluidics portion of the LH 700 Series System. The Diluter is the subsystem that aspirates the sample, dilutes it and mixes it. Move the cursor over the illustration to see links to additional information.
dL	Deciliter, a unit of volumetric measurement equal to 0.1 liter.
DMS	The computer hardware and software that controls instrument operation; displays, stores, and recalls sample data; automates QC and calibration procedures; and assists you in troubleshooting. Also called: ADMS, DMS, LH 700 Series Workstation.
Double-click	If you are using: • Light Pen - Quickly pressing the light pen against the screen twice. • Mouse - Quickly pressing the left mouse button twice. • Touch Screen - Quickly touching the screen with your finger twice.
Drag	The process of selecting an item and maintaining the selection while you move the pointer to a different location.

EDTA	Ethylenediaminetetraacetic acid--the recommended anticoagulant for hematology analysis.
EO # (Eosinophils)	A WBC differential parameter result from the Diff sample analysis. The number (#) is computed from the WBC count and the EO %.
EO % (Eosinophils)	A WBC differential parameter result from the Diff sample analysis. The percent (%) is measured directly using VCS technology.
Expiration Date	A manufacturer's recommended last day of use for a reagent, control, or calibrator.
Extended QC	Extended QC Rules for 5C Cell control derived from the German Quality Control Guidelines for the Medical laboratory, known in Germany as Rili-BÄK.
Extended QC - Random Error	Random error is Extended QC's measurement of imprecision.
Extended QC - Systematic Error	Systematic error is Extended QC's measurement of bias. A systematic error is defined as the deviation of the mean from the target value.
Extended QC - Total Error	Total Error is Extended QC's measurement of inaccuracy, as compared to an established limit. Total Error is defined as the deviation of a single measurement from the Target Value that was setup for your 5C Cell control (e.g. BCI Assigned Value or Mean => Lab Target value).
Field	Area on a window or screen for entering or viewing data. When you move the cursor, you are moving it from field to field.
First Name	Refers to the patient's first name. The Workstation considers this field an optional identifier you can use for a sample. The field appears blank unless you provide the information when you add a sample request to the ToDo list or edit a sample result on the Edit Sample window.
fL	Femtoliter, a unit of volumetric measurement equal to 10^{-15} liter.
Flags	A flag is a single letter or symbol and will always appear to the right of a result. A flag can be instrument-generated (R, P), or laboratory-defined (H, L, c, a). On windows and printouts, the letters, such as H, L,and R appear next to parameter results to indicate specific conditions.
Flow Cytometry	A process for measuring the characteristics of cells or other biological particles as they pass through a measuring apparatus in a fluid stream.
Function Key	One of the keys labeled F1 to F12. To request a system or window-specific command, press the Function Key displayed on the screen next to the command. Sometimes these keys are used with other keys to access specific functions.
Future Draw Date	Draw date is accepted on inbound Host Transmissions up to 30 days (720 hours) into the future.
g	Gram, a unit of weight.

HCT (Hematocrit)	A computed value that represents the packed cell volume (PCV) relative to a given volume of whole blood. HCT (%)= (RBC x MCV) / 10
Hemoglobinometry	Measurement of hemoglobin in the blood. In the LH 700 Series, 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 (diluent).
HGB (Hemoglobin)	Hemoglobin results from the CBC analysis. This parameter is measured directly using Photometric Measurement. $$HGB\ (g/dL) = Constant \times \log_{10} \frac{Reference\ \%T}{Sample\ \%T}$$
Hgb Voltages	Electronic voltages measured through the hemoglobin cuvette.
Histograms	Graphic representations of cell frequency vs. size. Histograms provide information about leukocyte, erythrocyte and thrombocyte frequency and their distribution about the mean. They also might show the presence of subpopulations.
Hz	Hertz, a unit of frequency.
i.d.	Inside diameter.
IEC	International Electrotechnical Commission.
Information System	Any host or laboratory computer system.
Instrument	The Analyzer and Diluter portion of the LH 700 Series.
IQAP (Interlaboratory Quality Assurance Program)	Beckman Coulter Inc. provides this program, which statistically compares your 5C Cell control and Retic-C Cell control data to a group of other laboratories' control recovery data with the same control lot number.
IRF (Immature Reticulocyte Fraction)	This parameter is derived from VCS technology. IRF = High Light Scatter Reticulocytes / Total reticulocytes
L	Liter, a unit of volumetric measurement.
Lab Administrator	A person at your location who can access the full set of Workstation functions. The lab administrator creates user names and assigns access levels. A specific user name and password is assigned to the lab administrator in your laboratory.
Laser (Light Amplification by Stimulated Emission of Radiation)	The instrument uses a laser for WBC Diff and Retic analysis.
Last Name	Refers to the patient's last name. The Workstation considers this field an optional identifier you can use for a sample. This field appears blank unless you provide the information when you add a sample request to the ToDo list or edit a sample result on the Edit Sample window.

Levey-Jennings Control Chart	A commonly used control procedure in which control measurements are plotted directly on a control chart with limit lines drawn as mean plus or minus expected ranges.
Linearity	The ability of an instrument to recover expected results (reference values or calculated values) for such parameters as WBC, RBC, Hgb at varying levels of concentration of these parameters within specified limits. Beckman Coulter Inc. provides the LIN-C linearity control for your convenience. Use it according to the instructions on its package insert.
Lot Number	An identifier assigned by a manufacturer to identify a control, reagent or calibrator.
LY #(Lymphocytes)	A WBC differential parameter result from the Diff sample analysis. The number (#) is computed from the WBC count and the LY %.
LY % (Lymphocytes)	A WBC differential parameter result from the Diff sample analysis. The percent (%) is measured directly using VCS technology. $LY\ \% = \frac{\text{no. of cells inside LY area}}{\text{no. of cells inside NE+LY+MO+EO+BA}} \times 100$
m	Meter, a unit of linear measurement.
Manual aspiration mode	The open-vial method of running a sample. Also called: open-vial mode, secondary mode, manual sampling mode.
Manual Diff Box	A blank area included on a report where you can record your manual differential results for the sample.
Manual Print Job	Selecting the print icon to print a single item.
MCH (Mean Corpuscular Hemoglobin)	A computed value that represents the amount of hemoglobin by weight in the average red cell. The system automatically recalculates this value if HGB or RBC change. MCH (pg) = (HGB/RBC) x 10
MCHC (Mean Corpuscular Hemoglobin Concentration)	A computed value that represents the concentration of hemoglobin (weight/volume) in the average red cell. The system automatically recalculates this value if HGB or HCT change. MCHC (g/dL) = (HGB/HCT) x 100
MCV (Mean Corpuscular Volume)	The volume of the average red cell derived from the RBC histogram.
Mean	Arithmetic average of a group of data.
Membership	The different types of cells in a particular region, regardless of the number of cells. On DataPlots, membership is represented showing different types of cells in different colors.
mL	Milliliter, a unit of volumetric measurement, equal to 10^{-3} liter.
mm	Millimeter, a unit of linear measurement, equal to one-thousandth of a meter.

MO # (Monocytes)	A WBC differential parameter result from the Diff sample analysis. The number (#) is computed from the WBC count and the MO %. $MO\ (10^3\ cells\ \mu L) = \frac{MO\%}{100}$ xWBC count
MO % (Monocytes)	A WBC differential parameter result from the Diff sample analysis. The percent (%) is measured directly using VCS technology. $MO\ \% = \frac{\text{no. of cells inside MO area}}{\text{no. of cells inside NE+LY+MO+EO+BA}} \times 100$
Mode	The method of running a sample, closed vial (Automatic aspiration mode) or open vial (Manual aspiration mode).
Modes (Test)	Use Default Type on the Command Center to specify the test mode. It determines how the LH 700 Series processes data.
Mode-to-Mode Matching	Agreement between patient results in Automatic aspiration mode and Manual aspiration mode.
MPV (Mean Platelet Volume)	MPV is the mean cell volume for platelets. The system derives this parameter from the Plt histogram.
MRV (Mean Reticulocyte Volume)	Mean volume of the Retic population. This parameter is derived from VCS technology.
mW	Milliwatt, a unit of power equal to one-thousandth of a watt.
n	Number.
NCCLS	National Committee for Clinical Laboratory Standards has changed to Clinical and Laboratory Standards Institute (CLSI).
NE # (Neutrophil)	A WBC differential parameter result from the Diff sample analysis. The number is computed from the WBC count and the NE%. $NE\ (10^3\ cells\ \mu L) = \frac{NE\%}{100}$ xWBC count
NE % (Neutrophil)	A WBC differential parameter result from the Diff sample analysis. The percent is measured directly using VCS technology. $NE\ \% = \frac{\text{no. of cells inside NE area}}{\text{no. of cells inside NE+LY+MO+EO+BA}} \times 100$
NEMA	National Electrical Manufacturers Association.
nm	Nanometer, a unit of linear measurement, equal to 10^{-9} meter.
NRBC # (Nucleated Red Blood Cells)	A parameter that is calculated from the NRBC % and the total WBC count. NRBC # represents the total number of nucleated Red Blood Cells. $NRBC\ (10^3\ cells\ \mu L) = NRBC\% \times WBC\ count$
NRBC % (Nucleated Red Blood Cells)	A parameter derived from both the WBC histogram and VCS information and represents the number of nucleated Red Blood Cells per 100 White Blood Cells.
o.d.	Outer diameter.

Operator ID	A 16-character identifier that uniquely identifies the processor of the samples. If you forget your user name or password, contact your lab administrator. The user name works with your password to uniquely identify you to the system. Also called: operator ID.
Open-vial Mode	The open-vial method of running a sample. You immerse the aspirator tip in the sample. The instrument automatically aspirates the sample. If the instrument fails to aspirate automatically, you can press and release the activator to aspirate the sample. Also called: open-vial mode, secondary mode, manual sampling mode.
Outlier	A data value far outside the range of the rest of the data.
Output Device	A physical device that is capable of receiving information from a computer and formatting it in a logical fashion. Examples: printer, fax machine or another computer.
Parameters	Characteristics 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 for a data word are odd or even and stored in the parity bit for checking by the receiver of the data word.
Patient ID	The Workstation considers this field an optional sample identifier. Your laboratory may use it as a specific identifier for the patient, such as the medical record or Social Security Number. It is intended for laboratories that want to track results of several different samples or tests for the same patient.
Patient Population	A large number of patient sample results for Analysis, used to give a fairly consistent average result for each of the three red blood cell indices: MCV, MCH and MCHC.
pg	Picogram, a unit of gravimetric measure equal to one trillionth of a gram.
Photometric Measurement	A process where a beam of white light from an incandescent lamp goes through an optical filter and is read by a photocell. This generates a current that can be measured.
Plt Histogram	The portion of the Plt distribution curve between 0 fL and 36 fL
PLT (Platelet)	Platelet count results from the CBC analysis. The system derives this parameter from the Plt histogram. PLT = n x 10^3 cells/µL
Positive Identifier	An identifier that is linked irrevocably to the date and time of instrument analysis on a sample and the sample results. A positive identifier must be entered before a sample analysis can occur. You can use either sample ID or Cass/Pos as positive identifiers of the sample and its results. You can also choose to use both sample ID and Cass/Pos as positive identifiers.

Precision	A measure of the 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 differential results), based on at least 10 replicate determinations of the same sample. Precision shows the closeness of test results when repeated analyses of the same material are performed. Also called: reproducibility.
Precision Test	The precision test is performed as part of the automatic startup cycles. If any test value exceeds the reference value by 1% or more, the test value appears in red on the Workstation screen and is flagged with an H (high) or L (low).
Predilute	Dilution of a sample prior to analysis on the analyzer. The Predilute mode on the LH 700 Series may be used to dilute specimens that exceed the reportable range, or to run a citrated tube when clumped platelets are suspected. The Predilute mode runs in the CBC test mode via manual aspiration only. You may enter dilution factors from 1.1 to 5.0. The sample results are automatically multiplied by the dilution factor entered. After running a dilution, the Analyzer automatically disables predilute. The minimum amount of blood with which to make a dilution is 75 µL. Remember that Manual mode requires 200 µL of sample for aspiration.
Primary Mode	The closed-vial method of running a sample. You place a closed tube sample in a cassette and place the cassette on the LH 700 Series loading bay. The LH 700 Series automatically reads the cassette label and tube label (if present) and aspirates the sample. Also called: Automatic aspiration mode, closed-vial mode, automatic sampling mode.
Print Profile	A set of characteristics that define what you want printed and transmitted for sample runs. You can set up print profiles as part of System Setup. Also called: Reports, Reporting Options
psi	Pounds per square inch, a unit of pressure measurement.
QC (Quality Control)	A comprehensive set of procedures your laboratory uses to ensure that the instrument is working accurately and precisely.
Ramp Test	The ramp test is performed as part of the automatic startup cycles. If any test value exceeds the reference value by 1% or more, the test value appears in red on the Workstation screen and is flagged with an H (high) or L (low).
RBC (Red Blood Cell)	Red Blood Cell count results from the CBC analysis. This parameter is measured directly using the Coulter Principle. RBC = n x 10^6 cells/µL
RBC Histogram	An RBC distribution curve. The normal curve ranges from 36 to 360 fL. The display starts at 24 fL.
RDW (Red Distribution Width)	The size distribution spread of the erythrocyte population derived from the RBC histogram. Expressed as coefficient of variation (%)
RDW-SD	The size distribution spread of the erythrocyte population derived from the RBC histogram. Expressed as a standard deviation in fL

Record	A collection of related information, for example, sample identification and results information, stored in the database and treated as a unit.
Reflex Manager List	A list automatically generated by the Workstation based on sample result criteria set up by your laboratory. You can use this list as a management tool to allow automation of post-analysis decisions. As part of setting up the Reflex Manager List, you define the decision criteria and the follow-up action required.
Reportable range	This range represents the clinical limits of values that have been tested and found to be accurate, precise, and linear. Reportable range can be the same as the linear range, but it is usually a subset of the linear range.
Reproducibility	A procedure to check that the system gives consistent results (within established limits) every time it measures the same sample. Also called: precision.
RET # (Reticulocytes)	The number of reticulocytes per 100 RBC Ratio of retics to the total number of red cells RET% = (Retic Events / Red Cell Events) X 100.
RET % (Reticulocytes)	Reticulocyte count results from Retic analysis of samples or controls. The percent is measured directly using VCS technology.
Rili-BÄK	Richtlinien der Bundesarztekammer – Guidelines of the Federal Chamber of Physicians.
Sample ID (SID)	One of two possible positive identifiers for sample analysis. The other possible positive identifier is Cass/Pos. For Automatic aspiration mode, this identifier is read from the bar-code label of the sample. For samples using Manual aspiration mode, this is the identifier specified at the Numeric Keypad or read from the bar-code label on the sample by using the wedge scanner.
Screen Saver	The Workstation has a screen saver that appears when you are not interacting with the Workstation. You can set up the screen saver to appear at specific intervals of non-use. The screen returns to its normal view when the Workstation receives sample data or when you interact with the Workstation by pressing a key on the keyboard.
SD (Standard Deviation)	A measure of deviation from the mean. $SD = \sqrt{\frac{\Sigma(x - \bar{x})^2}{n - 1}}$
Select	When an item is selected, a visual cue is present. For example,  appears in a field.

Sequence Number	The Workstation considers this field an optional identifier you can use for a sample. The Workstation assigns a sequence number to a sample when a sample request is added to the ToDo list. If AutoSequencing is ON for the Patient Level Seq # field the Workstation automatically assigns the next available sequence number to the sample request.
Shift	Consecutive values that abruptly move from one side of the mean to the other, then maintain a constant level. Contrast with trend. A scheduled period of work.
SID (Sample ID)	One of two possible positive identifiers for sample analysis. The other possible positive identifier is Cass/Pos.
Standard Deviation (SD)	A measure of deviation from the mean. $SD = \sqrt{\frac{\Sigma(x - \bar{x})^2}{n - 1}}$
Status Bar	A horizontal bar that appears toward the bottom of the screen. It displays short instructions that can help you work with the LH 700 Series Workstation. It also displays information about various LH 700 Series options.
Stop Bit	A computer code that indicates the end of a character.
Suspect Messages	Suspect messages appear in a separate area of the screen display, printout, and host transmission. Suspect messages, such as Imm NE 1, Platelet Clumps, etc., are instrument-generated. Suspect messages appear for sample results based on an abnormal cell distribution or population. The system generates these messages according to an internal algorithm. Abnormalities should be confirmed by microscopic review.
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.
Test (Modes)	The LH 700 Series has five different test modes. The test mode determines how the LH 700 Series processes data. For example, in the CBC test mode the LH 700 Series performs a basic complete blood count on whole-blood samples. The test mode appears as a field on the QA Results & Graphics window.
ToDo List	A feature of the Workstation that lets you view a list of samples the instrument has not yet processed. You can view a list of all the unprocessed samples or a list of unprocessed samples for a particular test mode. You can sort these lists by any column you choose. Also called: Worklist, Pending List, Work Order.
Toolbar	A group of graphic buttons on a Workstation window. You can select a button on a Toolbar to quickly access commonly used functions.
Trend	Values that continue to increase or decrease gradually over a period of time. Contrast with shift.

Tube Adapters	Special holders that enable small tubes to fit in standard cassettes. Two sizes of gray sleeve adapters accommodate 2.0-mL tubes and 3.0-mL tubes.
UL	Underwriters Laboratory.
User Name	A 16-character identifier that uniquely identifies the processor of the samples. Also called: operator ID.
UWBC	UWBC (Uncorrected WBC) This field and parameter label do not appear on any screen if the parameter was excluded as part of parameter selection in setup. Uncorrected WBC, labeled "UWBC" is measured directly using the Coulter Principle. UWBC cannot be edited. The uncorrected WBC is displayed on the CBC Data tab.
Vac	Volts of alternating current.
VCS (Volume, Conductivity and Scatter)	A flow cytometry technology applied in hematology to enhance WBC subpopulation classification and percent Reticulocyte measurement.
Voting	After the computer corrects for coincidence, it compares the three count periods. Voting may occur for WBC, RBC, Plt, MCV, RDW and MPV. Agreement among the three count periods causes them to be averaged to determine the parameter result.
W	Watt, a unit of power.
WBC (White Blood Cell)	White Blood Cell count results from the CBC analysis. The WBC count is adjusted for interfering substances when appropriate. No further correction of WBC is required. Interfering substances include, but are not limited to NRBC, giant platelets, platelet clumps, unlysed RBCs and RBC fragments. This parameter is measured directly using the Coulter Principle. $WBC = n \times 10^3$ cells/µL
Wettability	The ability of any solid surface to be wetted when in contact with a liquid. Wettability affects the smear quality:
Window	A rectangular area on your computer screen that enables you to work with an application.
Windows 2000 Workstation Operating System	The Microsoft operating system for your computer.

XB Analysis	A method of quality control that automatically compares patient red blood cell indices (MCV, MCH and MCHC) with known target values. It is used to monitor for proper operation of automated instruments in hematology.
XM Analysis	XM is a method of quality control that uses an Exponentially Weighted Moving Average (EWMA) of CBC and Reticulocyte Parameters and compares them with known target values. See XM Analysis Overview for an explanation of intended use.

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COULTER LH 780 SYSTEM HARD-COPY DOCUMENTATION

▪ Host Transmission PN 4277303	Specifications for transmitting to a host computer. Available in hard copy by request.
▪ Reference PN 773021	Use and Function • Installation • Operation Principles • Specifications/Characteristics • Precautions/Hazards • References • Glossary • Index Available in hard copy by request.
▪ Operator's Guide PN 773021	Controls and Indicators • Startup • QC • Sample Analysis • Data Analysis • Shutdown • Analyzer CRT Functions • Workstation • Run Samples Display • To Do List • Database • Controls • Setup • Appendices Available in hard copy by request.
▪ Special Procedures and Troubleshooting PN 773023	Calibration • Cleaning Procedures • Replace/Adjust Procedures • Troubleshooting • Error Messages Available in hard copy by request.
▪ SlideMaker Operator's Guide PN 4277299	Use And Function • Installation • Operation Principles • Specifications/characteristics • Operating Procedures • Cleaning/Replacement Procedures • References Available in hard copy by request.
▪ SlideStainer Operator's Guide PN 4277300	Use And Function • Installation • Operation Principles • Specifications/characteristics • Operating Procedures • Cleaning/Replacement Procedures • References Available in hard copy by request.
▪ Body Fluids Instructions for Use PN 731113	Operating instructions regarding the use of the body fluids application.
▪ Hematology Tube List PN A70071	Tube List information

The information in the Reference manual, Operator's Guide, Special Procedures and Troubleshooting manual, SlideMaker Operator's Guide, SlideStainer Operator's Guide and Body Fluids Instructions for Use comes from the Online Help System.

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