ABBOTT

CELL-DYN® 3200 SYSTEM

OPERATOR'S MANUAL

LIST NO: 01H25-01

CD-TOC EXIT

Click on the Chapter Title to select.

NOTES

Foreword

Congratulations on becoming a proud operator of the CELL-DYN® 3200 System. Using state-of-the-art technology, we have designed your instrument to function consistently and dependably on a day-to-day basis.

The CELL-DYN 3200 System is backed by dedicated professionals who excel in engineering, training, and technical expertise. As you are a valued customer, we will teach you how to operate, maintain, and troubleshoot your system.

For continuing service, we also provide telephone technical assistance should you need additional information or assistance in diagnosing a problem. This service is available 7 days a week, 24 hours a day in the United States.

If a problem should arise that cannot be resolved by telephone, on-site support is offered by Abbott's Field Service Representatives. Our Field Service Representatives are extensively trained in all aspects of Abbott instrumentation, which assures proficiency in diagnosing, isolating, and correcting problems.

Abbott Laboratories is dedicated to manufacturing the highest quality, most reliable instrumentation available. We look forward to serving your needs in any way possible.

Customer Support

United States: 1 (800) CELL DYN or 1 (800) 235-5396

Abbott Diagnostics Customer Support Center:
5440 Patrick Henry Drive
Santa Clara, CA 95054

Canada: 1 (800) 387-8378

International: Call your local customer support representative.

Intended Use

The CELL-DYN 3200 is a multiparameter hematology analyzer designed for *in vitro* diagnostic use in clinical laboratories.

Proprietary Statement

solely for use with Abbott Laboratories equipment and for *in vitro* diagnostic applications as specified in the operating instructions. No part of this document may be reproduced, stored, or transmitted in any form or by any means (electronic, mechanical, photocopied, recorded, or otherwise) without the prior written permission of Abbott Laboratories.

Patent Statement

The following U.S. Patents are relevant to the CELL-DYN 3200 Instrument: 4,726,237; 5,017,497: and 5,378,633.

Instrument Disclaimer

All operating instructions must be followed. In no event shall Abbott be responsible for failures, errors, or other liabilities resulting from a customer's noncompliance with the procedures and precautions outlined herein.

Pictorial Disclaimer

The sample printouts/screens contained in this manual are for information and illustration purposes only. Abbott Laboratories makes no representations or warranties about the accuracy and reliability of the information on the printouts/screens, and this information is not to be used for clinical or maintenance evaluation.

Abbott Instrument Warranty

Abbott Laboratories warrants CELL-DYN Instruments sold by Abbott Sales Representatives (the "Instrument") to be free from defects in workmanship and materials during normal use by the original purchaser. This warranty shall continue for a period of one (1) year, commencing twenty-one (21) days from date of shipment to the original purchaser, or until title is transferred from the original purchaser, whichever occurs first (the "Warranty Period").

If any defects occur during the Warranty Period, contact your Abbott Customer Support Center immediately and be prepared to furnish pertinent details concerning the defect, the Instrument model number, and the serial number.

Abbott's Warranty coverage limits are as follows:

1. Abbott Customer Support Center: 24 hours per day, 7 days per week phone support in the United States.

2. Field Service Representative support: 8:30 A.M. to 5:00 P.M. Monday through Friday (excluding all Abbott-observed holidays).
3. Any on-site service performed at other times and all service required to correct defects or malfunctions not covered by this Warranty (as noted in the paragraph below) will be billed at Abbott's labor rates then in effect.

This Warranty does not cover defects or malfunctions which:

1. Are not reported to Abbott during the Warranty Period and within one week of occurrence.
2. Result from chemical decomposition or corrosion.
3. Are caused by customer or third party abuse, misuse, or negligence, or by failure to comply with any requirement or instruction contained in the applicable Abbott Operations Manual.
4. Result from maintenance, repair, or modification performed without Abbott's authorization.

Abbott's liability for all matters arising from the supply, installation, use, repair, and maintenance of the Instrument, whether arising under this Warranty or otherwise, shall be limited solely to the repair or (at Abbott's sole discretion) replacement of the Instrument or of components thereof. In no event shall Abbott be liable for injuries sustained by third parties, incidental or consequential damages, or lost profits. Replaced parts shall become the property of Abbott Laboratories.

THE FOREGOING IS THE SOLE WARRANTY MADE BY ABBOTT LABORATORIES REGARDING THE INSTRUMENT, AND ABBOTT SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE.

The CELL-DYN 3200 Series Hematology Systems are manufactured by Abbott Diagnostics, a wholly owned subsidiary of Abbott Laboratories, at 5440 Patrick Henry Drive, Santa Clara, CA 95054, U.S.A. Please direct all inquiries concerning information in this manual to the foregoing address.

NOTE: Direct all inquiries regarding equipment problems to the Abbott Customer Support Center. (U.S. customers only.)

Trademark Statements

TEFLON® is a registered trademark of E.I. DuPont de Nemours Co., Inc.

VACUTAINER® is a registered trademark of Becton, Dickinson, and Company.

TYGON® is a registered trademark of Norton Performance Plastics.

LEVEY-JENNINGS® is a registered trademark of Levey Jennings Company.

Canon® is a registered trademark of Canon Inc.

BJC-600e™ is a trademark of Canon Inc.

OKIDATA® is a registered trademark of Oki America, Inc.

MICROLINE® is a registered trademark of Oki America, Inc.

CELL-DYN® is a registered trademark of Sequoia-Turner Corporation, a wholly owned subsidiary of Abbott Laboratories.

DYN-A-WIPE™ is a trademark of Abbott Laboratories.

MAPSS™ is a trademark of Sequoia-Turner Corporation, a wholly owned subsidiary of Abbott Laboratories.

VenojectII® is a registered trademark of Terumo Medical Company.

How to Use This Manual

Overview

This Operations Manual contains complete instructions for using and maintaining the CELL-DYN® 3200 System.

This manual was designed to fill several needs, from providing step-by-step operating instructions to listing accessory part numbers. You will find it a valuable aid as you learn to use the system and an essential reference thereafter.

A basic principle of effective learning is to proceed from the general to the specific. That is the way the material in this manual is presented. And that is how we wish to present the manual to you.

The first and most important step is to get acquainted with the ***Master Table of Contents***. For this reason, we start with a brief overview to show you how the information is organized in sections.

After that, we explain how the manual is physically designed to help you locate desired information quickly and easily.

Finally, we discuss different ways material is presented for different purposes and explain various icons that identify specialized types of information in the text.

Please take the time to read and understand this brief preparatory section.

Manual Organization

Front Matter

The pages in front of the ***Master Table of Contents*** contain two main sections: A Foreword that includes customer support and intended use information, and How to Use This Manual that includes a description of the organization. These pages also contain proprietary, warranty, trademark statements, and Manuall Revision and Status Logs.

Section 1. *Use or Function*

This section provides an overall description of the system and its components. It names the major system components and tells what they are used for.

Section 2*. Installation Procedures and Special Requirements*

This section provides instructions for installing the CELL-DYN 3200 system. It explains proper location, installation, setup, and configuration to meet your laboratory's specific needs.

Section 3*. Principles of Operation*

This section explains the principles behind the system's operation. It describes what the system measures and how those measurements are made. It also explains the translation of those measurements into useful data and reports for the user.

Section 4*. Performance Characteristics and Specifications*

This section contains useful details on the dimensions of the instrument, proper operating environment, and performance specifications.

Section 5. *Operating Instructions*

This section contains detailed instructions to set up the instrument and explains the procedures for daily start-up and shutdown, sample collection and handling, routine operation of the instrument, sample analysis, and use of the data log.

Section 6. *Calibration Procedures*

This section takes you step by step through the calibration process. It discusses calibration materials, guidelines, and methods, including troubleshooting procedures and corrective action.

Section 7*. Operational Precautions and Limitations*

This section contains a summary of known factors that may adversely affect the proper operation of the instrument or the quality of the output.

Section 8. *Hazards*

This section covers possible hazards arising from the operation of the instrument, as well as decontamination and waste handling procedures.

Section 9*. Service and Maintenance*

This section discusses routine maintenance and cleaning on a daily, weekly, monthly, and "as needed" basis. Also included are detailed instructions for removing, cleaning, and replacing various components to ensure proper system performance.

Section 10. *Troubleshooting and Diagnostics*

This section discusses the diagnostics capability of the instrument. It contains a troubleshooting guide to help users identify probable causes of a system malfunction or of suspect data, and to suggest the proper corrective action.

Section 11. *Quality Control*

This section covers the proper mixing, handling, and running of control material, setting up QC files and using the QC capabilities of the instrument, and setting up and using the X-B Analysis Program. It also provides a review of the Westgard Rules.

Section 12. *Printers*

This section reviews the setup and use of printers for graphics output and ticket printing.

Section 13. *Sample Loader*

This section includes material from all the previous sections which pertains specifically to the installation, operation, and maintenance of the Sample Loader.

Appendices

Appendix A describes how to use bar codes on the CELL-DYN 3200 and contains information on bar code types and bar code labels.

Appendix B lists the part numbers of components, accessories, controls, reagents, and consumables associated with the CELL-DYN 3200 System for user convenience when placing orders.

Index

This section contains an alphabetical listing of subject matter to help users quickly locate specific information about the system.

Manual Construction

The physical construction of the manual supports its sectional organization.

Master Table of Contents

The Master Table of Contents at the beginning of this manual lists each section and its subsections.

Section Separators and Tables of Contents

A large separator tab marks the start of each section. A section table of contents is located immediately behind this tab in most sections.

Text Conventions Used in This Manual

The following list summarizes the text conventions that are used in this manual:

Information	Presentation	Examples
Menu name	Sans serif font, all capital letters,	MAIN MENU DATA LOG menu
Soft keys (screen label keys)	Sans serif font, all capital letters, enclosed in brackets	[RUN]
Keyboard/keypad keys	Regular font, initial capital letters only when appropriate	arrow keys ↑ arrow key Enter key ESC key Page Up key the pound (#) key the asterisk (*) key
Status	Regular font, all capital letters	READY STANDBY INITIALIZED
Data entry field	Regular font, enclosed in angle brackets	<OPERATOR ID> field
Screen message or other screen display	Courier	`Waste Full`
ON and OFF	All caps, regular font	ON OFF

Soft Keys (Screen Label Keys)

Screen labels are menu keys displayed at the bottom of the display screen. Directly below the display screen is a row of eight unlabeled pressure-sensitive keys which correspond to

the menu labels. Pressing one of these keys (on the membrane keypad) initiates the action specified by the corresponding menu label.

This manual indicates that one of these "soft keys" is to be pressed by showing the label in all caps, bold, sans serif font, and enclosed in brackets. For example, when the manual calls for the operator to press the key under the RUN label and then the key under the SPECIMEN TYPE label, the text will read "Press [RUN] followed by [SPECIMEN TYPE]."

Keyboard/Keypad Keys

In some cases, the operator must press a key on the PC keyboard or on the pressure-sensitive keypad on the front of the instrument. Such keys include the Enter key, the ESC key, the pound (#) key, and other special function keys. Special function keys, such as the arrow keys, are in regular type. The arrow symbol may be substituted for the word. For example, the text will read "Press the arrow keys" or "Press the ↑ key" or "Press the ↑ arrow key."

Graphic Conventions Used in This Manual

Throughout the text, signal words and icons appear where the nature of the information warrants special attention.

> **NOTE:** The *note* signal word appears adjacent to an important point of information that is relevant to the current subject matter.

This manual uses four icons to warn users of possible danger. These icons are:

WARNING: Potential Biohazard. The biohazard icon alerts users to an activity or area where they may be exposed to infectious materials or substances.

WARNING: Electrical Shock Hazard. The electrical hazard icon alerts users to the possibility of electrical shock in the described activity or at the posted location.

WARNING: The general warning icon alerts users to other potential health or safety hazards.

CAUTION: The general caution icon appears adjacent to an explanation of conditions that could interfere with the proper functioning of the instrument.

DANGER: Class III B Laser Light. The laser icon alerts warns against direct exposure to the laser light beam generated by the Optical Bench Assembly.

Revision Status

Document Control Number(s)	Revision Date	Section(s) Revised	Pages Revised and Added
Preliminary (9140181A)	7/97	Not Applicable	Not Applicable
Initial Release (9140181B)	11/97	All	All

NOTES

Revision Log

Instructions: Use this log to provide a permanent record to verify that revised chapter(s) and/or page(s) have been added to this manual.

1. Record the document control number of the revised section in the first column. You will find the number in the footer. Make an entry for each chapter you receive and place in the manual.
2. Record the revision date, also found in the footer, in the second column.
3. Record the current CELL-DYN 3200 System software version in the third column.
4. Write your initials or signature in the fourth column to verify that you have placed the revised page(s) in the manual.
5. Record the date that you added the revised section to the manual in the fifth column.

Document Control Number	Revision Date	Software Version	Revision Incorporated by	Date Incorporated

NOTES

Conclusion

We hope you have found this preview of the manual useful. The information in this section should help you better understand the construction and organization of this manual and help you get started easily and quickly.

NOTES

Table of Contents

Section Two. Installation Procedures and Special Requirements

Section Seven. Operational Precautions and Limitations

Section Eight. Hazards

Section Nine. Service and Maintenance

NOTES

List of Figures

Overview

The CELL-DYN® 3200 is a multiparameter, automated hematology analyzer designed for in vitro diagnostic use in clinical laboratories. The instrument has two versions, the automated sample loader (CELL-DYN 3200SL), and manual closed sampler (CELL-DYN 3200CS). An example of each version is shown in Figures 1.1 and 1.2.

The term CELL-DYN 3200 refers to both versions unless either the Closed Sampler (CS) or Sample Loader (SL) model is specifically stated. The terms open sample and closed sample are used interchangeably with open sampler and closed sampler. Generally, when referring to the mode of operation, the terms Open Sampler and Closed Sampler are used and when referring to components of the instrument, Open Sample and Closed Sample are used, e.g., Open Sample Aspiration Probe.

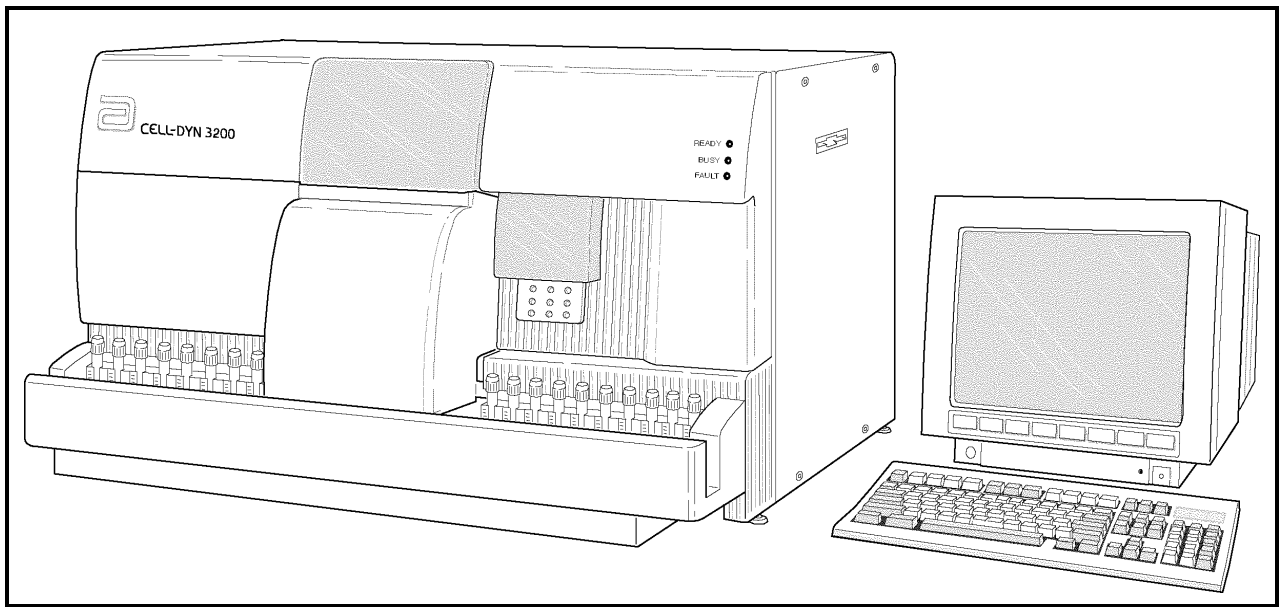

Figure 1.1: CELL-DYN 3200SL

The CELL-DYN 3200SL is equipped with a Sample Loader Module. The Sample Loader provides continuous automated closed sampling for up to 50 closed tube samples at a time. The Sample Loader may also be referred to as the Auto Sampler.

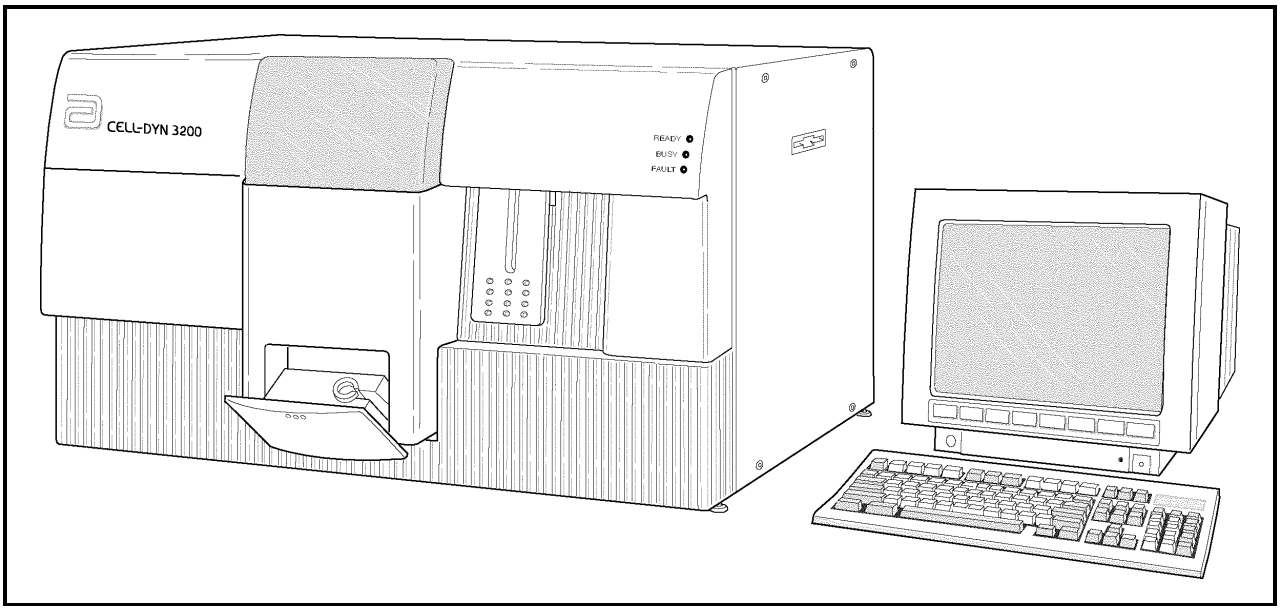

Figure 1.2: CELL-DYN 3200CS

The CELL-DYN 3200CS is equipped with a built-in manual Closed Sample Aspiration Module which aspirates blood from a closed collection tube that has been inserted in the Closed Sample Module.

Both models aspirate blood from open collection tubes. This method is referred to as the Open Sampler mode.

Intended Use

The CELL-DYN® 3200 is a multiparameter, automated hematology analyzer designed for *in vitro* diagnostic use in clinical laboratories.

The CELL-DYN 3200 generates the following hematologic measurements on EDTA anticoagulated whole blood:

WBC — White Blood Cell or leukocyte count

NEU — Neutrophil absolute count **%N** — Neutrophil percent

LYM — Lymphocyte absolute count **%L** — Lymphocyte percent

MONO — Monocyte absolute count **%M** — Monocyte percent

EOS — Eosinophil absolute count **%E** — Eosinophil percent

BASO — Basophil absolute count **%B** — Basophil percent

RBC — Red Blood Cell or erythrocyte count

HGB — Hemoglobin concentration

HCT — Hematocrit

MCV — Mean Cell Volume

MCH — Mean Cell Hemoglobin

MCHC — Mean Cell Hemoglobin Concentration

RDW — Red Cell Distribution Width

PLT — Platelet or thrombocyte count

MPV — Mean Platelet Volume

PDW* — Platelet Distribution Width

PCT* — Plateletcrit

* Clinical significance has not been established for these parameters. Therefore, they are not reportable.

NOTES

System Components

The CELL-DYN 3200 consists of three major modules, the Analyzer, Data Module, and the Display Station. The Analyzer and Data Module are housed in single chassis. The Display Station is a standalone module. Figure 1.3 lists the major subassemblies in each of the modules.

The Analyzer contains the hardware to aspirate, dilute, and analyze each whole blood specimen.

The Data Module contains the components for analyzing, storing, and reporting specimen results.

The Display Station module consists of a 15" color monitor and pressure-sensitive keypad for selecting the displayed commands that operate the system.

The Sample Loader attaches to the front of the CELL-DYN 3200SL Analyzer and is an integral part of the SL model. The Sample Loader is discussed throughout this manual where appropriate. It is also discussed in detail in Section 13.

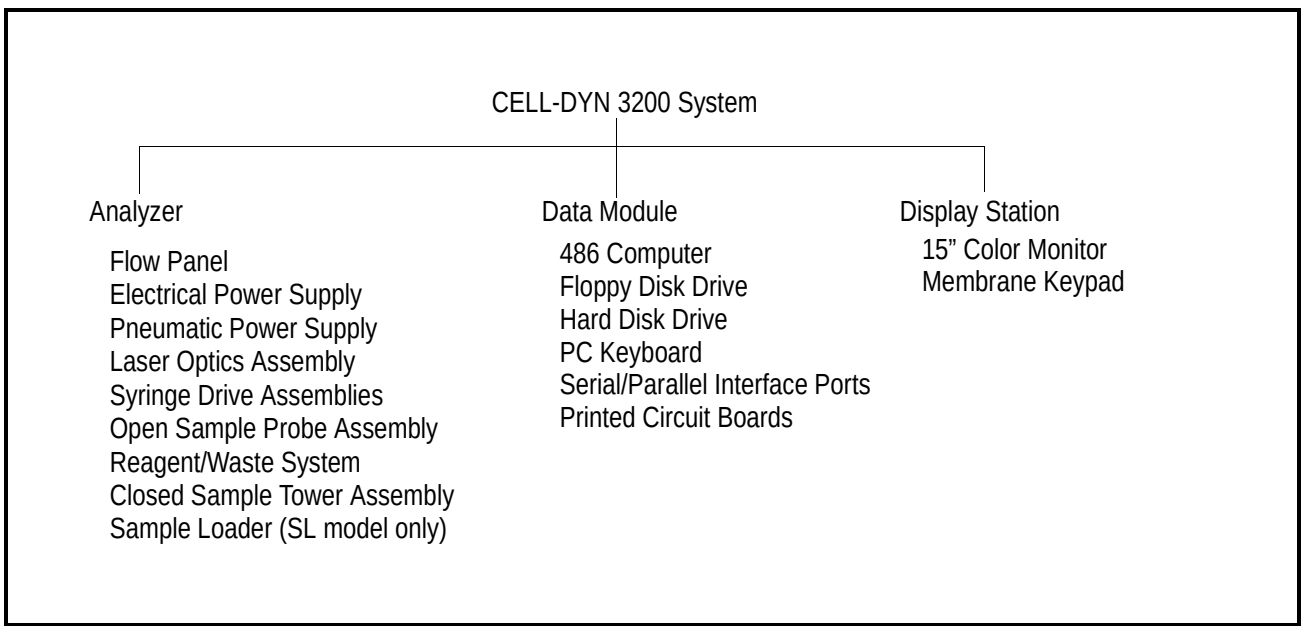

Figure 1.3: CELL-DYN 3200 System Components

Analyzer Components

The major components of the Analyzer are listed below and shown in Figures 1.4 through 1.8.

Front Panel

Right Front Cover
Left Front Cover
Front Skirt Cover (CS model)
Sample Loader (SL model)
Status Indicator Panel
Closed Sample Tower Cover
Open Sample Aspiration Probe with Touch Plate

Flow Panel

Closed Sample Aspiration Tower Module
Shear Valve Assembly
Syringes (4)
Sample Transfer Peristaltic Pump
Optical Flow Cell Assembly
Laser Optics Bench Assembly (behind Flow Panel)
HGB Flow Cell/Mixing Assembly
WBC Mixing Chamber
RBC/PLT Mixing Chamber
Open Sample Aspiration Probe and Wash Block
Normally Closed Valves (6)
Diluent Reservoirs (2)
Open/Closed Mode Switching Assembly (Y-Valve Assembly)
Sheath Filter
Waste Chambers (4)
Venting Chamber
Bubble Traps
Aerosol Filter
Normally Open Pinch Valves
Ultrasonic Sensor
LED Sensor

Left Side Panel

Fan with Air Intake Filter

Right Side Panel

Floppy Disk Drive Slot

Rear Panel

Main Power Switch
Main Power Connector
Display Station Communications Connector
Line Frequency and Line Voltage Select Switches
Fuse
Fan with Air Intake Filter
Serial and Parallel Interface Ports (Data Module)
Keyboard Connector Port
Touch Pad Connector Port
Waste Sensor Connector
Waste Outlet Tube Connector
Diluent/Sheath Inlet Tube Connector
WBC Lyse Inlet Tube Connector
HGB Lyse Inlet Tube Connector
Analyzer Serial Number Label
Disk Storage Container

Component Description

Front Panel

The major components of the Front Panel are depicted in Figure 1.4. A brief functional description of each component follows.

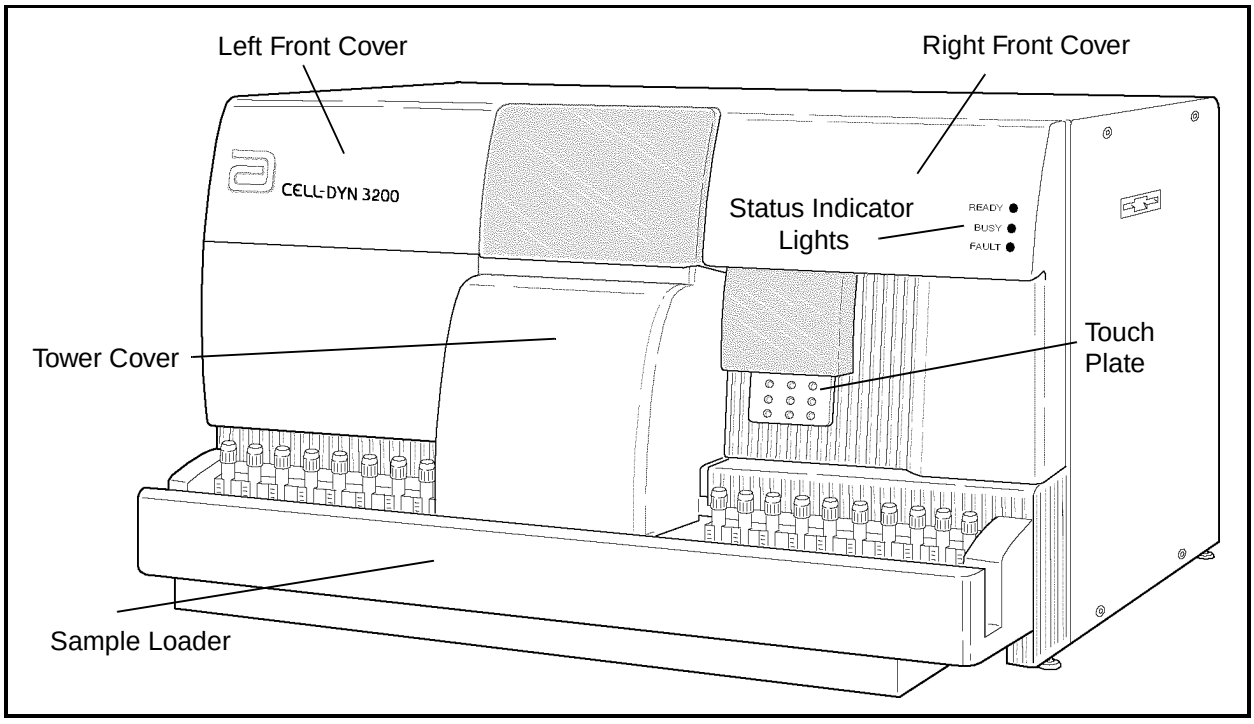

Figure 1.4: Cell-Dyn 3200SL Analyzer Front Panel

Left Front Cover

The **Left Front Cover** protects the left portion of the flow panel. The cover is hinged on the left, opening from the center to expose the left half of the flow panel. Access to the left half of the flow panel is necessary to view the operation of the left flow panel components, to access the solenoids, pinch valves, normally closed valves, and to perform certain maintenance procedures. The cover is held in place by hinges and a release latch. It may be removed from the instrument.

Right Front Cover

The **Right Front Cover** protects the right portion of the flow panel and supports the Touch Plate and Status Indicator Panel. The cover is hinged on the right, opening from the center to expose the right half of the flow panel. Access to the right half of the flow panel is necessary to view the action of the right flow panel components, to access the syringe assemblies, solenoids, pinch valves, normally closed valves, and to perform certain maintenance procedures.

The cover is held in place by hinges and a release latch. Because two sets of wires — one for the Status Panel and one for the Touch Plate — are connected to the inside of the Right Front Panel, this cover should be removed only if necessary. Before attempting to remove the cover, disconnect the connector attached to the Status Panel circuit board and the two connectors attached to the Touch Plate circuit board. Remember to re-connect the connectors when reattaching the cover.

Front Skirt Cover

The **Front Skirt Cover** protects the lower front part of the flow panel. The skirt should be removed to access the two lower Normally Closed Valves on the left side of the Flow Panel. The Skirt is removed from the instrument by removing the four Phillips-head screws holding the Skirt to the Analyzer. The Skirt on the SL model has two removable sections adjacent to the Flow Panel. The section on the right side should be removed to provide easy access to all four syringes and two syringe drives.

Closed Sample Tower Cover

The Closed Sample Tower Cover protects the Tower Assembly and Shear Valve. The Tower Cover for the SL model is larger than its counterpart on the CS model in order to cover the top central portion of the Sample Loader. Part of the cover is translucent to allow viewing of the Shear Valve's operation. The cover is held in place by two pins at the bottom and two release latches at the top. Both covers have an Interlock Sensor Switch which prevents the instrument from operating in the Closed Mode if the cover is not in place.

Status Indicator Panel

Three **Status Indicator Messages** (illuminated by green, yellow and red LEDs) indicate the status of the Analyzer. The status messages are:

- Ready (green light) —the Analyzer is ready to process a specimen
- Busy (yellow light) —the Analyzer is busy with a normal operational sequence
- Fault (red light) —the Analyzer is unable to process specimens due to an existing fault condition

Open Sample Aspiration Probe

The **Open Sample Aspiration Probe** is used to aspirate whole blood from an opened collection tube. The wash block moves down to the end of the probe and returns to a position that is covered by the Right Front Cover. When Closed Sampler mode is selected, the Wash Block moves down to the end of the probe and remains down until the Open Sampler mode is again selected.

Touch Plate

The **Touch Plate** is used to start the run cycle for (1) both the Open Sampler and Closed Sampler modes on the CS model and (2) Open Sampler mode only on the SL model. It is located directly behind the Open Sample Aspiration Probe and is part of the Right Front Cover. Pressing the Touch Plate starts the selected run cycle.

Closed Sample Aspiration Tower Module

The **Closed Sample Aspiration Tower** is used to aspirate whole blood from a closed collection tube. It is activated when the Closed Sampler mode is selected on either the SL or CS model and the Touch Plate is pressed. The configuration of the Tower Module differs depending on the model.

In the CS model, the Tower Module consists of the following components:

- Aspiration/Vent Needle
- Wash Block
- Tube Spinner (includes motor and belt)
- Door Assembly (includes Tube Holder, Bar Code Reader, Swivel Door, Solenoid, and Interlock Switch).

In the SL model, the Tower Module consists of the following components:

- Aspiration/Vent Needle
- Wash Block
- Tube Spinner (includes motor and belt)

The Door Assembly is eliminated from the Tower, and the Bar Code Reader is moved to the Sample Loader which also contains the Mixer Assembly.

The major components of the Tower Module are briefly described below:

- A two-part **Needle** consisting of a venting needle and an aspiration needle that pierces the collection tube stopper, vents vacuum or pressure from inside the tube, aspirates the whole blood, and is retracted for rinsing at the end of each cycle
- A **Tube Spinner** to grasp and spin the tube for bar code reading
- The **Driver Motor and Belt** to operate the Tube Spinner
- A **Closed Sample Door/Tube Retainer** which holds a single closed collection tube in the proper position for (1) reading the bar code if applicable, and (2) stopper penetration and sample aspiration by the needle

Flow Panel

The major components of the **Flow Panel** are depicted in Figure 1.5. A brief functional description of Flow Panel components follows.

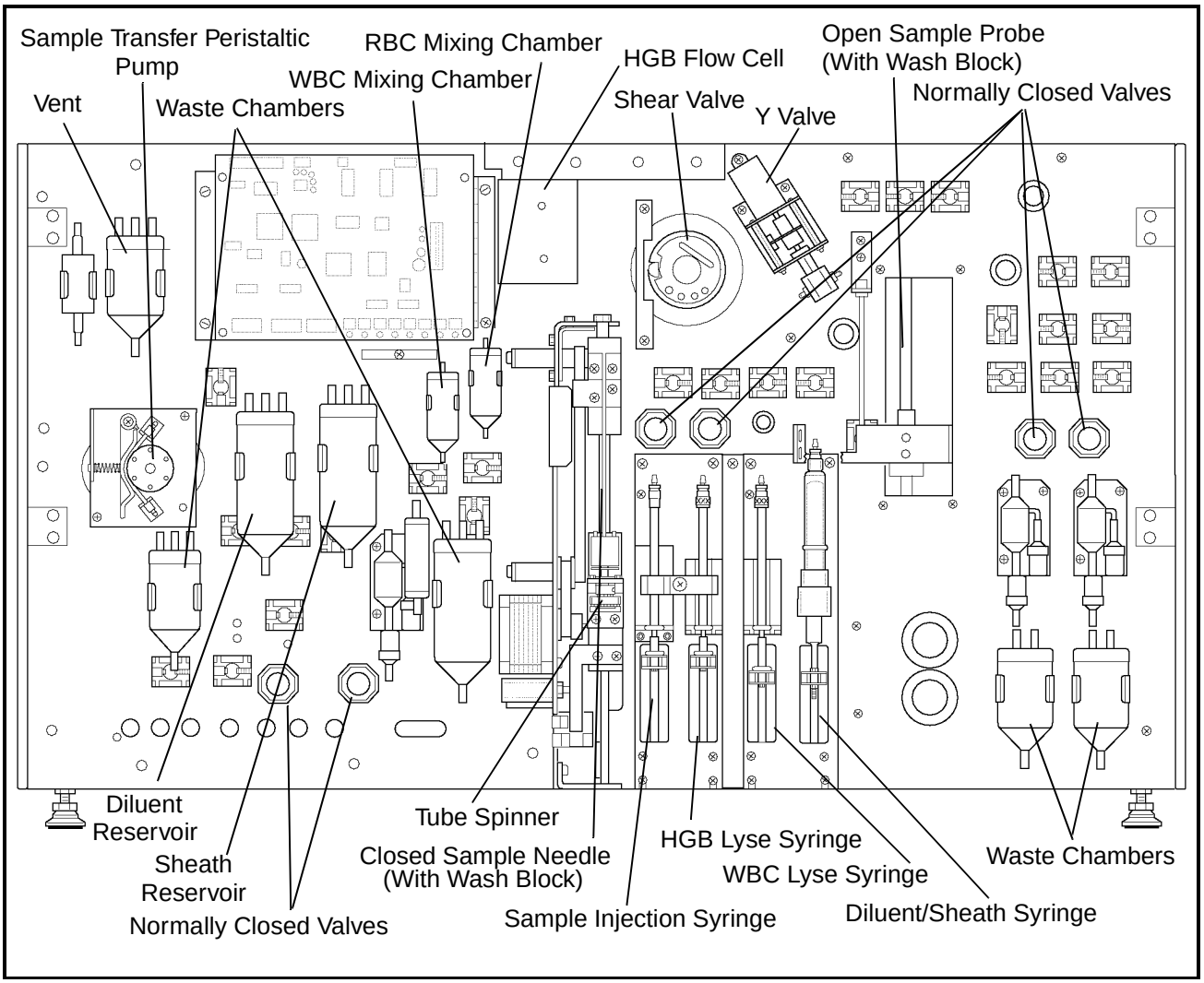

Figure 1.5: Flow Panel Components

Shear Valve Assembly

The three-piece ceramic **Shear Valve** isolates a precise volume of whole blood by means of a shearing action as the front and rear sections of the valve rotate. The aspirated blood is isolated in three separate volume segments — one for the WBC dilution, one for the HGB dilution and one for the RBC/PLT dilution.

Syringe Assembly

There are two syringe driver assemblies, each containing two syringes. Each syringe is operated by its own stepper motor. The function of each syringe is described below:

- **Diluent/Sheath Syringe** — (1) delivers a specific volume of diluent to transport the RBC segment from the Shear Valve to the RBC/PLT Mixing Chamber and to dilute the segment prior to measurement, and (2) delivers a specific volume of diluent to transport the HGB segment from the Shear Valve to the HGB Mixing Chamber and to dilute the segment prior to measurement.
- **HGB Lyse Syringe** — delivers a specific volume of HGB Lyse to the HGB Mixing Chamber/Flow Cell to further dilute the HGB segment prior to measurement.
- **WBC Lyse Syringe** — delivers a specific volume of WBC Lyse to transport the WBC segment from the Shear Valve to the WBC Mixing Chamber and to dilute the segment prior to measurement.
- **Sample Injection Syringe** — injects a specific volume of the diluted sample into the Optical Flow Cell for RBC/PLT, WBC (WOC), and WBC (NOC) measurements.

Sample Transfer Peristaltic Pump

The **Sample Transfer Peristaltic Pump** is composed of a rotor and a pump tube holder. It is used to transfer the WBC dilution, RBC/PLT dilution, and HGB/NOC dilution to the Optical Flow Cell from their respective mixing chambers.

HGB Flow Cell and Mixing Chamber

The **HGB Flow Cell Assembly** is integrated with a mixing chamber and contains the following components:

- A fully enclosed (light-tight) mixing chamber with optical windows and electronics
- An **LED Light Source**
- A **Photodetector** for measuring the light transmitted.

WBC Mixing Chamber

The **WBC Mixing Chamber** is used to swirl mix the WBC dilution.

RBC/PLT Mixing Chamber

The **RBC/PLT Mixing Chamber** is used to swirl mix the RBC/PLT dilution.

Wash Block

There are two **Wash Blocks** on the instrument, one for the Open Sample Aspiration Probe and one for the Closed Sample Needle. Both Wash Blocks work in a similar fashion: After aspiration, they move down the outside of the probe or needle, rinsing it with diluent. The diluent rinse is then transferred to the waste chamber.

Normally Closed Valves

The **Normally Closed Valves** prevent the backflow of reagents in critical areas when the power is turned off.

Diluent Reservoir

The **Diluent Reservoir** maintains the diluent supply for cleaning and sample dilution.

Sheath Reservoir

The **Sheath Reservoir** maintains a constant sheath supply for hydrodynamic focusing in the Flow Cell.

Waste Chambers

The **Waste Chambers** collect the waste liquid from the Analyzer flow panel.

Bubble Traps

The **Bubble Traps** (not shown) are used to prevent bubbles and liquid from being pulled into the vacuum accumulators and the vacuum pump.

Aerosol Filter

The **Aerosol Filter** (not shown) is used to prevent aerosols escaping into the atmosphere.

Pinch Valves

The **Pinch Valves** (not shown) are used to control air and liquid throughout the Analyzer.

Closed Mode Aspiration Tower

The **Aspiration Tower** contains the Aspiration/Vent Needle, Needle Wash Block, Sample Tube Spinner Assembly, and tubing to aspirate blood samples from closed sample tubes.

Vent/Aspiration Needle

The **Vent/Aspiration Needle** combines both venting and aspiration of blood samples from closed sample tubes.

Wash Block

Discussed in the previous subsection.

Spinner Assembly

The Spinner Assembly consists of a tube holder, motor, and belt. These are attached to the Closed Mode Aspiration Needle drive mechanism, and they move up and down in tandem with the needle. As the Spinner Assembly and needle descend together, the spinning tube holder centers and rotates the sample tube, allowing the Bar Code Reader to read the bar code on the sample tube. After the bar code is read, the needle penetrates the rubber stopper and aspirates the sample.

Bar Code Reader

The Bar Code Reader is an LED type and can accommodate Code 39, Code 128, CODABAR, and Interleave 2 of 5 formats. On the CS model, the Bar Code Reader is located to the right of the door opening on the Door Assembly. On the SL model, the Bar Code Reader is located to the left of the Mixing Assembly on the Sample Loader.

Door Assembly (CS Model)

The Door Assembly consists of a tube holder/door, Bar Code Reader, Interlock Switch, and electrical latch to open the door after aspiration has occurred. The Interlock Switch will cause the instrument to halt if the door is opened between the time the Touch Plate is pressed and the system emits a beep to indicate that aspiration is completed. Opening the door during this period will cause a Fatal Fault condition.

NOTES

Left Side Panel

The only major component on the Left Side Panel is the Fan, shown in Figure 1.6.

Fan

A **Fan** cools the internal components of the Analyzer.

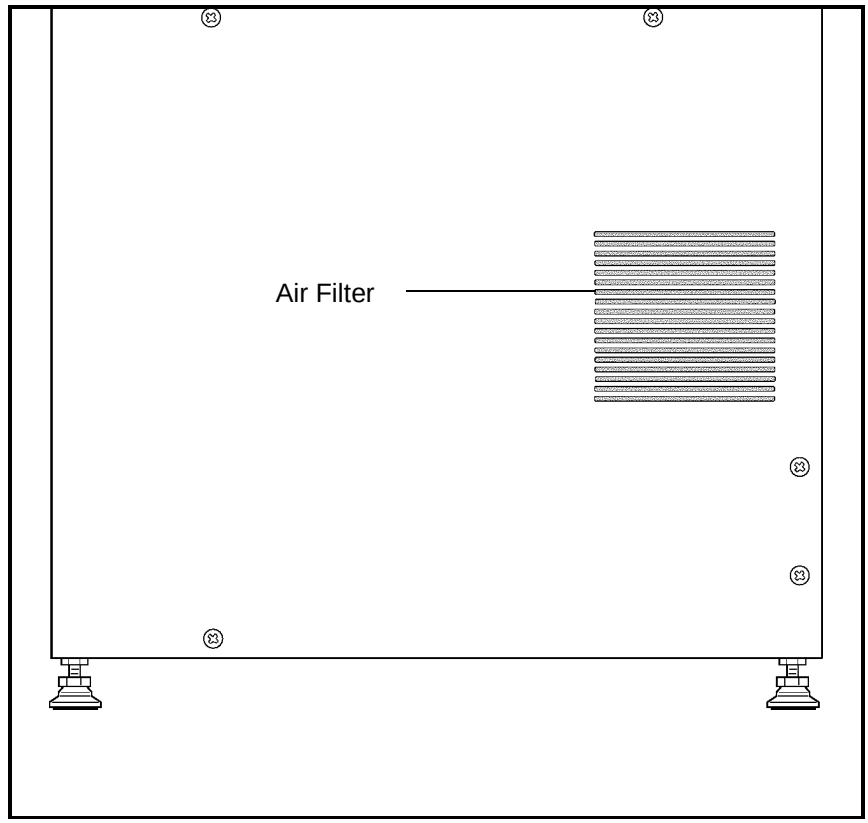

Figure 1.6: Left Side Panel

Right Side Panel

The major components on the Right Side Panel are depicted in Figure 1.7. A brief functional description of each component follows.

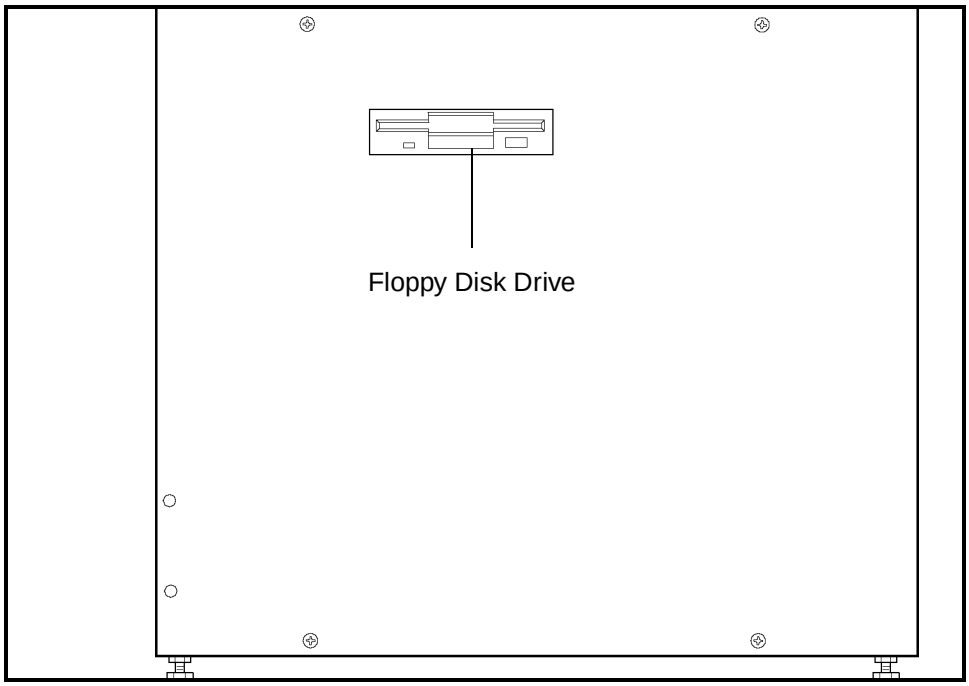

Figure 1.7: Right Side Panel Components

Floppy Disk Drive

The **Floppy Disk Drive** allows information to be downloaded or uploaded using a 3.5” floppy disk.

Rear Panel

The major components on the **Rear Panel** are depicted in Figure 1.8. A brief functional description of each component follows.

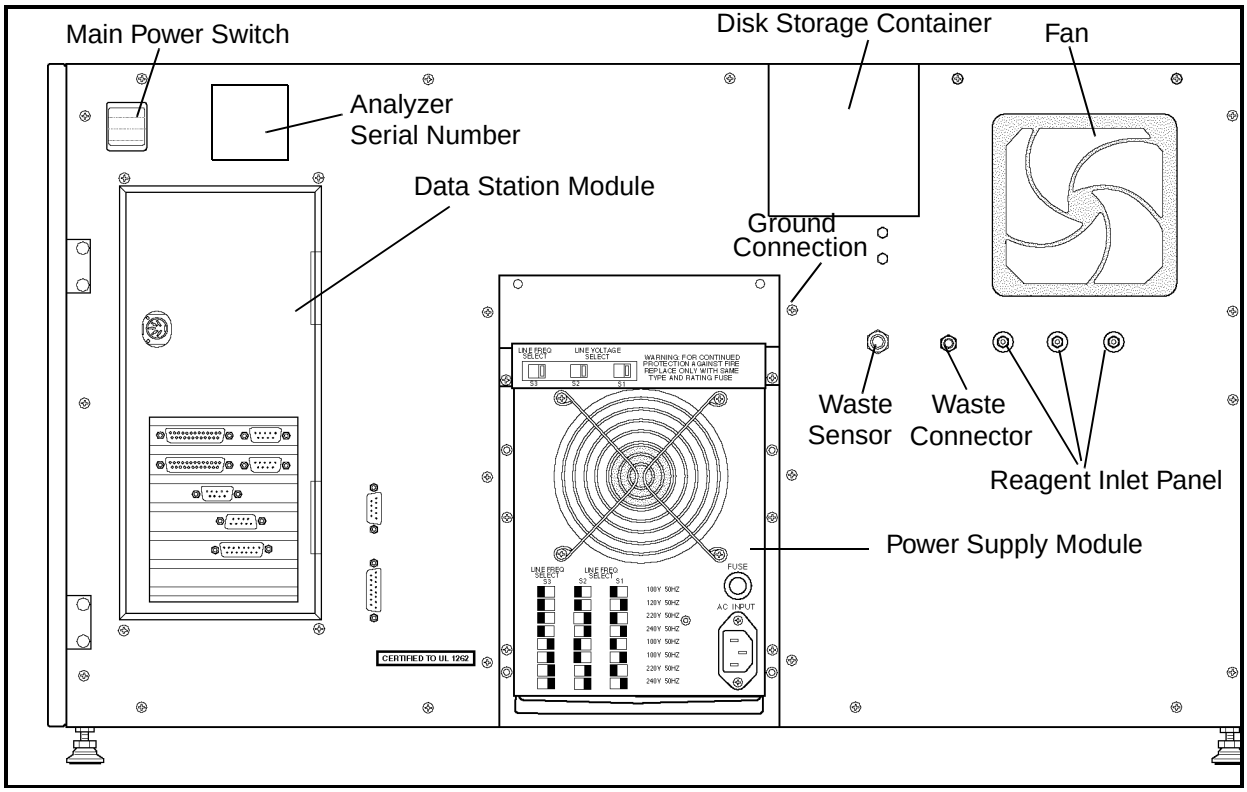

Figure 1.8: Rear Panel Components

Main Power Switch

The Main Power Switch turns on power for the Analyzer, Data Station, Display Station, and Sample Loader (SL model only).

Main Power Connector

This receptacle is used to connect the main power cord to the instrument.

Power Supply

The Power Supply Module supplies the power to operate the Analyzer and Data Module.

Line Frequency and Line Voltage Select Switches

These switches are used to select the **Line Frequency** and **Voltage** for the Analyzer (refer to Figure 1.9).

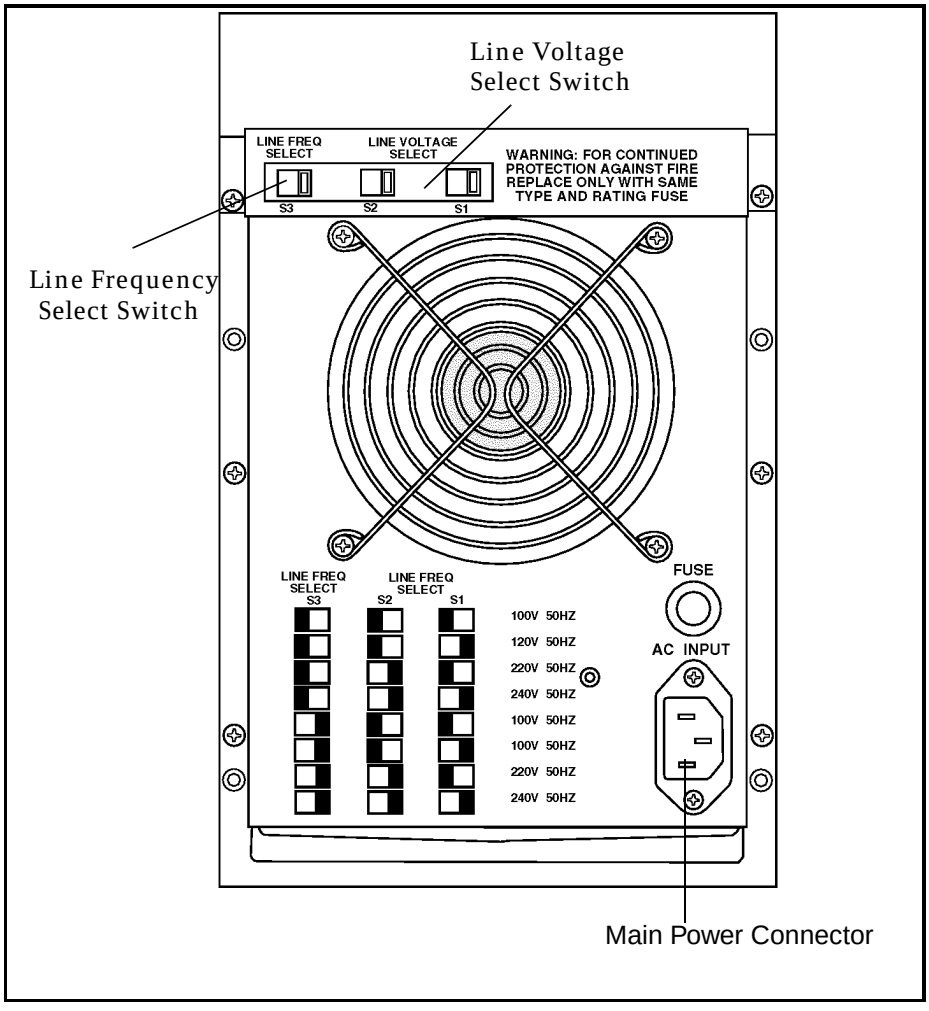

Figure 1.9: Power Supply Module

Fuse

An 8-amp (110/120 V) or 4-amp (220/240 V) **Fuse** protects the Analyzer from electrical spikes.

Fan

A Fan cools the internal components of the Analyzer.

Waste Sensor Connector

The waste-full sensor plug connects to the **Waste Sensor Connector** port. The ground shield on the cable should be attached to the ground connector on the rear panel. When the electrical sensor is tripped, the EXTERNAL WASTE FULL message is generated and the READY status is inhibited until the situation is corrected. The Analyzer interprets a disconnected plug the same way as a full waste container. Therefore, if the waste is routed to a drain, the dummy plug (supplied in the accessory kit) must be inserted in the connector.

Waste Outlet Tube Connector

This port is used to connect the waste outlet tube.

Diluent/Sheath Inlet Tube Connector

This color-coded (red) port is used to connect the diluent inlet tube with its associated cap, sinker and label.

WBC Lyse Inlet Tube Connector

This color-coded (purple) port is used to connect the WBC lyse inlet tube with its associated cap, sinker and label.

HGB Lyse Inlet Tube Connector

This color-coded (blue) port is used to connect the HGB lyse inlet tube with its associated cap, sinker and label.

Analyzer Serial Number Label

Although not an instrument component, the **Analyzer Serial Number** may be required when consulting with the Customer Support Center.

Disk Storage Container

This container is used to store the installation and Set Up disks.

Top Panel

Flow Cell Assembly

The **Flow Cell Assembly** contains the fluidics and hardware needed to hydrodynamically focus the RBC/PLT and WBC sample streams in the path of the laser beam for analysis. The primary components of this assembly are:

- **Sample Feed Nozzle** — a specially designed tube used to deliver the diluted sample into the sheath stream
- **Sample Flow Cell** — an optically clear quartz chamber with a central square opening of a specific size, which flares out into a cone at the bottom of the flow cell

Laser Optics Bench Assembly

The **Laser Optics Bench Assembly** (located behind the Flow Panel) contains the Helium-Neon laser, the flow cell, the optics and the detectors required for the enumeration and differentiation of the white blood cells, red blood cells, and platelets (refer to Figure 1.10).

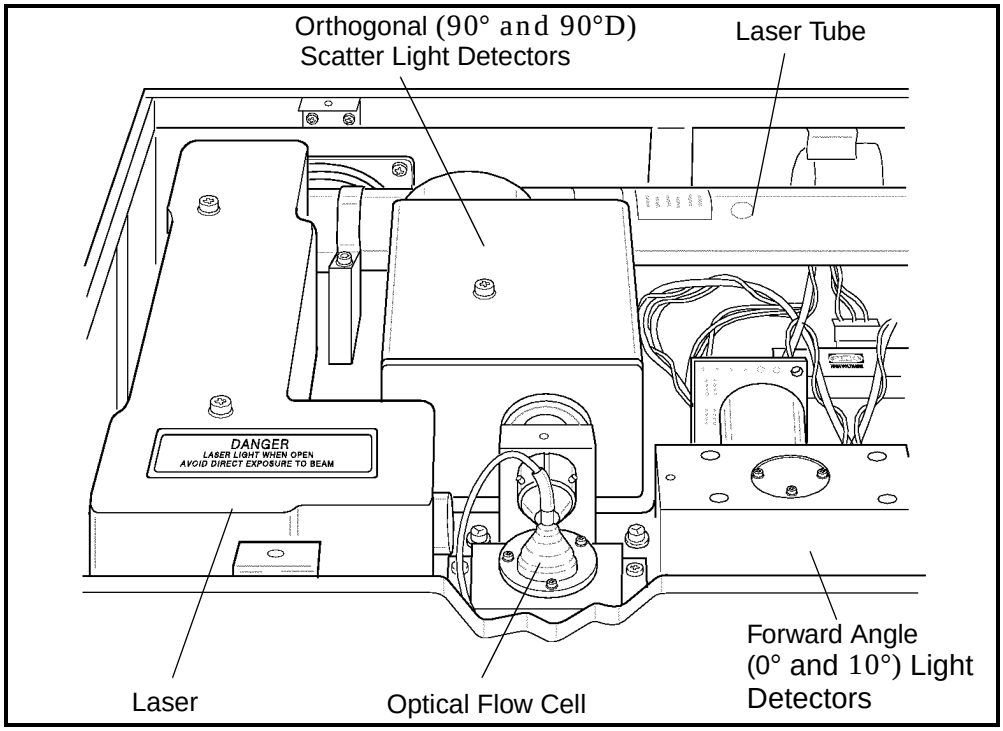

Figure 1.10: Optical Bench

Data Module Components

The major components of the Data Module are depicted in Figure 1.11. The functional description of each component follows.

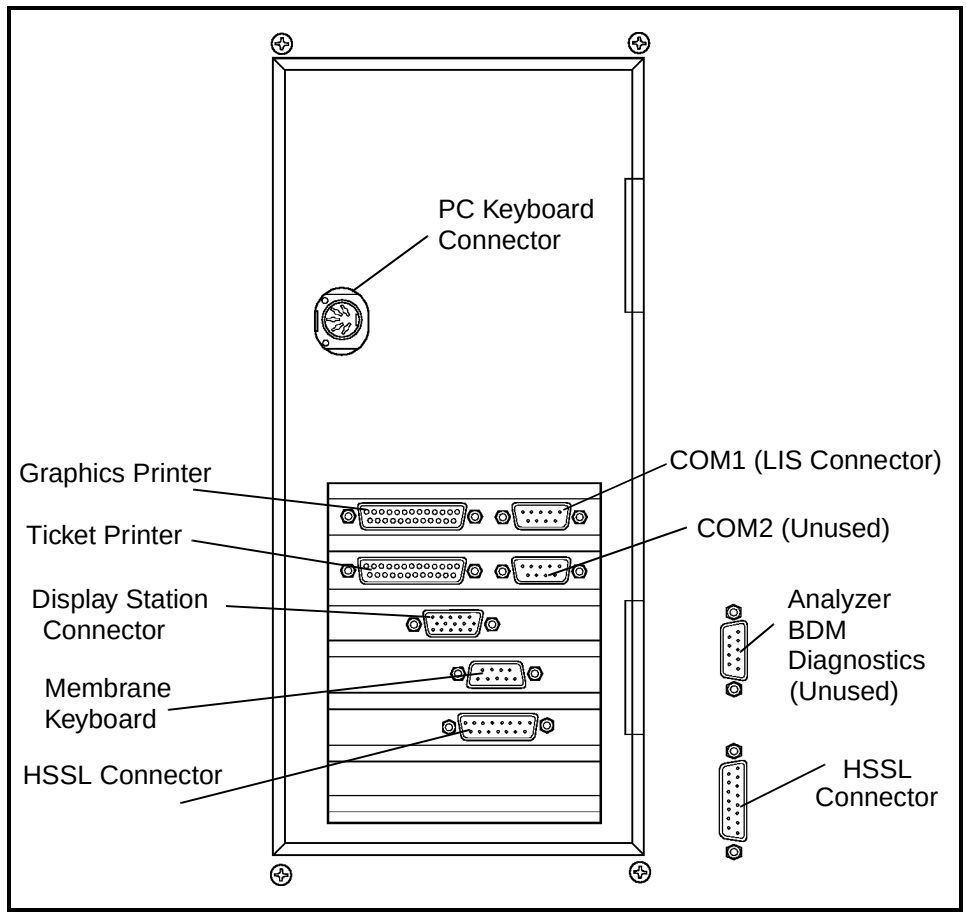

Figure 1.11: Data Module Components - Rear Panel

Computer

- Intel 486DX microprocessor
- 8 megabytes RAM (expandable to 16 megabytes)
- VGA graphics with 1 megabyte cache
- 2 enhanced parallel ports and 2 serial ports
- 2 FIFO UART Com1 and Com2 ports
- 3 PCI slots

Data Storage

Data storage consists of a 3.5-inch, 1.4 megabyte **Floppy Disk Drive** and a one gigabyte EIDE (enhanced IDE) **Hard Disk Drive**.

The floppy disk drive is used to update the software program and to download data. The hard drive is used to store the User Interface Software and Patient Data Log. It has sufficient capacity to store the most recent 10,000 cycles, including numeric and graphics data.

Printed Circuit Boards

A set of **Printed Circuit Boards** constitutes the measurement and control electronics for detection, amplification, and processing of signals.

Display Station Interface Connector

The **Display Station Interface Connector** allows data to be sent to the monitor and data to be received from the Membrane Keypad (Soft Keys) on the Display Station.

HSSL (High Speed Serial Link) Connector

The High Speed Serial Link transfers data between the Analyzer and the Data Station Module. The **HSSL Connector** on the Data Station Module connects to the **HSSL Connector** on the back panel of the Analyzer.

Membrane Keypad Interface Connector

The **Membrane Keypad Interface Connector** allows data to be sent from the Membrane Keypad on the Display Monitor to the Data Station.

Graphics Printer Connector

This port is used to connect the printer cable when the printer is used to print data in a graphics format.

Ticket Printer Connector

This port is used to connect the printer cable when the printer is used to print data in a ticket format.

LIS (Laboratory Information System) Connector

Two serial ports are provided. COM1 is used to connect the Laboratory Information System to the Data Station Module. COM2 is unused.

PC Keyboard Connector

The **PC Keyboard Connector** port is used to connect the standard computer keyboard.

Display Station Components

The major components of the Display Station are shown in Figure 1.12. The functional description of each component follows.

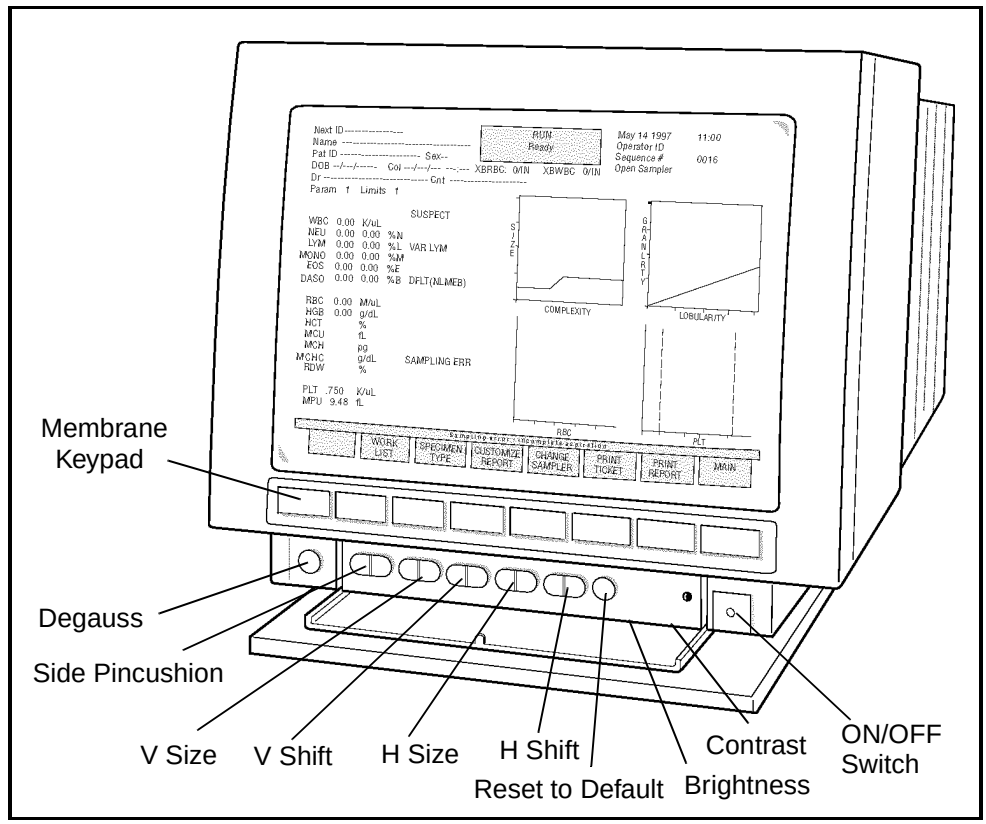

Figure 1.12: Display Station Components

Display Monitor

A 15-inch diagonal, high-resolution **Display Monitor** with 16-color illumination displays all alphanumeric and graphics data.

Soft Keys

A row of eight unlabeled pressure-sensitive **Soft Keys** (membrane keypad) is located directly below the screen. Each key initiates a function defined by the screen label currently displayed directly above it.

Membrane Keypad Cable

The **Membrane Keypad Cable** allows commands to be transferred from the Display Monitor to the Data Station.

Video Cable

The **Video Cable** allows data from the Data Station to be transferred to the Display Monitor.

Power Cord

A built-in **power cord** on the Display Station connects to an outside power supply and provides power to the monitor and keypad.

Screen Controls

The **Controls** available on the Display Monitor are shown in Figure 1.12. The Brightness and Contrast controls are located under the control panel shown in the figure.

Sample Loader Components

The major components of the **Sample Loader** are depicted in Figure 1.13. The functional description of each component follows.

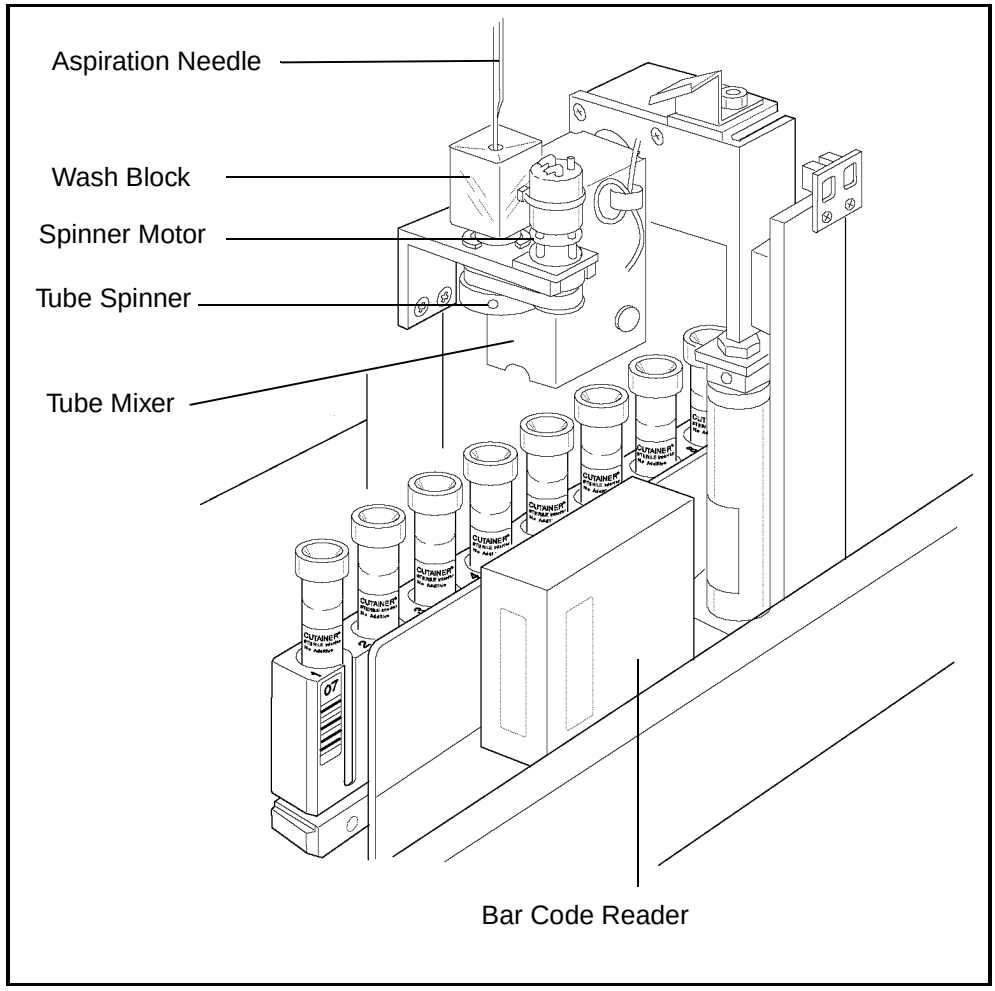

Figure 1.13: Sample Loader Components

Racks

Each **Sample Loader Rack** is able to accommodate up to 10 tubes. Racks are labeled with rack number and tube position, and with a 2-digit Bar Code 39 format.

Tower Cover

The **Tower Cover** on the SL model, although not part of the Sample Loader, has an Interlock Sensor Switch which prevents the loader from operating if the cover is not in place. If the cover is removed during operation, the Sample Loader comes to an immediate halt, causing a fatal fault. This feature provides further safety for the operator.

Bar Code Reader

The **Bar Code Reader** is an LED type and can accommodate Code 39, Code 128, CODABAR, and Interleave 2 of 5 formats. On the SL model, the Bar Code Reader is located on the Sample Loader. It reads the bar code on the tube when the tube is at the aspiration station.

Tube Sensor Assembly

The **Tube Sensor Assembly** senses the presence of a sample tube at each Mixing Station.

Mixer Assembly

The **Mixer Assembly** consists of a double-tube holder directly attached to a stepper motor. As the rack advances, the tube holder descends and grabs the tube. The tube holder rotates 15 times in an outward motion of approximately 135 degrees. The double-tube configuration of the tube holder allows each tube to be held and mixed twice in succession before it passes to the mixing station. An air cylinder governs the rotation movement of the tube holder.

Printer

The Printer is discussed in detail in **Section 12: *Printers***.

Reagent System

Introduction

The **Reagent System** is formulated specifically for the CELL-DYN 3200 Series instrument flow systems in order to provide optimal system performance. Use of reagents other than those specified in this manual is not recommended as instrument performance can be affected. Each CELL-DYN 3200 system is checked at the factory using the specified reagents and all performance claims are generated using these reagents.

The three reagents used with the CELL-DYN 3200 are:

- RBC/PLT Reagent - Diluent/Sheath
- WBC Reagent - WBC Lyse
- HGB Reagent - CN-Free HGB/NOC Lyse

Reagents must be stored at room temperature to ensure optimal performance. All reagents should be protected from direct sunlight, extreme heat and freezing during shipment and storage. Temperatures below 32° F (0°C) may cause reagent layering that changes the tonicity and conductivity of the reagents. If any reagent has been frozen, it should not be used.

The reagent inlet tubes have a cap attached that minimizes evaporation and contamination during use. However, reagent quality may deteriorate with time. Therefore, use all reagents within the dating period indicated on the label.

CELL-DYN Reagents

CELL-DYN 3200 Diluent/Sheath (L/N 03H79-01)

CELL-DYN **Diluent/Sheath** is formulated to meet the following requirements:

- Act as the diluent for the RBCs, PLTs and hemoglobin
- Maintain the stable diluted cell volume of each red cell and platelet during the count and sizing portion of the measurement cycle
- Serve as a sheath fluid for the hydrodynamic focusing process
- Serve as a rinsing agent for the fluidics system
- Provide background counts equal to or less than:

  WOC: 0.10 x K/µL

  NOC: 0.10 x K/µL

  RBC: 0.02 x M/µL

  HGB: 0.10 x g/dL

  PLT: 5.0 x K/µL

CELL-DYN 3200 CN-Free HGB/NOC Lyse (L/N 03H80-01)

- CELL-DYN **CN-Free HGB/NOC Lyse** is formulated to meet the following requirements:
- Rapidly lyse the red blood cells and minimize the resultant stroma
- Strip the white cell cytoplasm leaving the nuclear membrane intact so the white cell nucleii can be enumerated
- Convert hemoglobin to a stable chromagen complex that is measurable at 540 nm.

CELL-DYN 3200 WBC Lyse (L/N 03H78-01)

CELL-DYN **WBC Lyse** is formulated to meet the following requirements:

- Act as the diluent for the WBCs
- Osmotically lyse the red cells
- Maintain the light scattering properties of the WBCs for the duration of the measurement period
- Provide sufficient wetting action to prevent accumulation of air bubbles in the WBC flow system
- Maintain a WOC background count equal to or less than 0.10 x K/µL

Consumables

The following consumables are used with the CELL-DYN 3200 System:

- Preprinted tickets
- Color Ink Cartridges
- DYN-A-WIPE™ Lint-free pads
- Enzymatic Cleaner Concentrate

For information on ordering parts and accessories, reagents, controls, calibrators, and consumables, please refer to ***Appendix B - Parts and Accessories***.

Overview

Installation of the CELL-DYN 3200 should be performed by an authorized Abbott representative to ensure that all system components are functioning correctly and to verify system performance.

> **NOTE:** Installation of the Analyzer by an unauthorized or untrained person could result in damage to the system. Never attempt to install the system without an authorized Abbott representative present.

The remainder of this chapter gives general requirements for a successful installation. Procedures are also included for installing the Printer and Sample Loader.

Initial Preparation

Package Inspection and Inventory

The instrument is shipped from the factory as follows:

CELL-DYN 3200SL

- 1 crate containing the instrument including Sample Loader
- 1 box containing the CELL-DYN Accessory kit and Sample Loader Accessory kit
- 1 box containing the Color Graphics Printer
- 1 box containing the Ticket Printer (optional)
- CELL-DYN Reagents

CELL-DYN 3200CS

- 1 crate containing the instrument
- 1 box containing the CELL-DYN Accessory Kit
- 1 box containing the Color Graphics Printer
- 1 box containing the Ticket Printer (optional)
- CELL-DYN Reagents

CELL-DYN Accessory Kit

- Operator's Manual
- Keyboard Cover
- Fuse, SB 8.0 amps 110/120V (2)
- Fuse, SB 4.0 amps 220/240V (2)
- Printer Paper 9.5" x 11"
- Power Cord (Analyzer)
- Reagent Line Kit
- Printer Stand
- Printer Cable
- Large Peristaltic Pump Tubing
- Waste Dummy Plug
- Interface Specification
- Wire Puller (Solenoids)
- RS232 Plug (Loop back)

Sample Loader Accessory Kit

- 5 Tube Racks (Pre-labeled)

The instrument will be uncrated and inspected for damage by the trucking company when the system is delivered. If desired, the trucking company will transport the instrument to the laboratory and place it in the designated space.

Inspect the remaining boxes for damage. If there is any damage or any crates or boxes are missing, contact the Abbott Customer Support Center for assistance.

The reagents needed for installation are shipped when the instrument is shipped. This shipment includes: WBC Lyse Reagent, HGB Cyanide-free Lyse Reagent, and RBC Diluent/ Sheath.

The calibrator and controls needed for the installation are shipped when the instrument is shipped. This shipment includes: CELL-DYN Calibrator and Tri-level Control.

If any reagents, calibrator or control materials are missing, contact the Abbott Customer Support Center for assistance.

Space Requirements

Approximately 6 linear feet of space is required on the counter top to accommodate the instrument, display station, and printer. Sufficient space is required beneath for the reagents and the waste container (if one is used).

Allow six inches of space behind the instrument and 12 inches above and in front of the fan on the left side of the instrument for air flow. In addition, allow adequate space around the instrument to perform necessary maintenance procedures and to provide service access.

Locate the instrument:

- On a stable, level surface
- On a nonporous, nonabsorbent work surface and flooring that can be easily cleaned and disinfected using recommended procedures
- Away from direct sunlight
- Away from the path of a cooled or heated air outlet
- Away from any other instruments that may interfere with it, such as a centrifuge, any x-ray equipment, MRI equipment, a CRT, a video terminal, a computer, or a copier

Place the reagents below the instrument.

Waste Requirements

Allow room for a suitable waste container or position the instrument to permit the waste to be routed directly to a drain. The drain must be suitable for disposal of waste *with possible biological and chemical hazard*. Be sure that the waste outlet tube is secured in the drain hole.

Regulations on permissible substances, and their amounts, for disposal in public sewer systems vary from state to state and even community to community. Customers are advised to be knowledgeable about all applicable local, state, and federal requirements, and the contents of their effluent streams, before disposal of waste in public sewer systems.

Power Requirements

Be sure that the system is located at the desired site before attempting any connections. A minimum of three power outlets are required for either model: one outlet for the Analyzer, one for the Printer, and one for the Display Station. If a Ticket Printer will also be installed, a fourth power outlet will be needed. Grounded power outlets and a voltage regulator for the Analyzer are required for optimum performance.

Tubing Installation

Reagent and Waste Tubing

1. Locate the reagent tubing in the Accessory Kit.
2. Inspect each length of tubing carefully for damage or cracks.
3. Attach the non-weighted end of the tubing with the **Purple WBC Lyse** label to the **Purple** Connector on the right side of the Rear Panel. (Refer to Figure 2.1.) This reagent is for the WBC dilution. Wipe the outside of the tubing with a damp lint-free pad (such as DYN-A-WIPE™) and place the weighted end into the container of CELL-DYN Sheath Reagent. Secure the cap. *Place the container on the same level as or lower than the unit.*
4. Attach the non-weighted end of the tubing with the **Red Diluent/Sheath** label to the **Red** Connector. This reagent is for the RBC dilution and for rinsing the flow system. Wipe the outside of the tubing with a damp lint-free pad (such as DYN-A-WIPE™) and place the weighted end into the container of CELL-DYN Diluent/Sheath. Secure the cap. *Place the container on the same level as or lower than the unit.*
5. Attach the non-weighted end of the tubing with the **Blue HGB Lyse** label to the **Blue** Connector. This reagent is for the HGB dilution. Wipe the outside of the tubing with a damp lint-free pad (such as DYN-A-WIPE™) and place the weighted end into the container of CELL-DYN HGB Lyse. Secure the cap. *Place the container on the same level as or lower than the unit.*
6. Attach the **Waste Outlet Tubing** to the Waste Outlet Connector. Place the end of the tubing with the cap and sensor into the waste collection container. Ensure that the waste collection container is adequately labeled. Secure the cap, or remove the cap from the tubing and place the tubing into a drain suitable for collection of waste with *possible biological and chemical hazard*. Be sure that the tubing is secured to the drain hole.

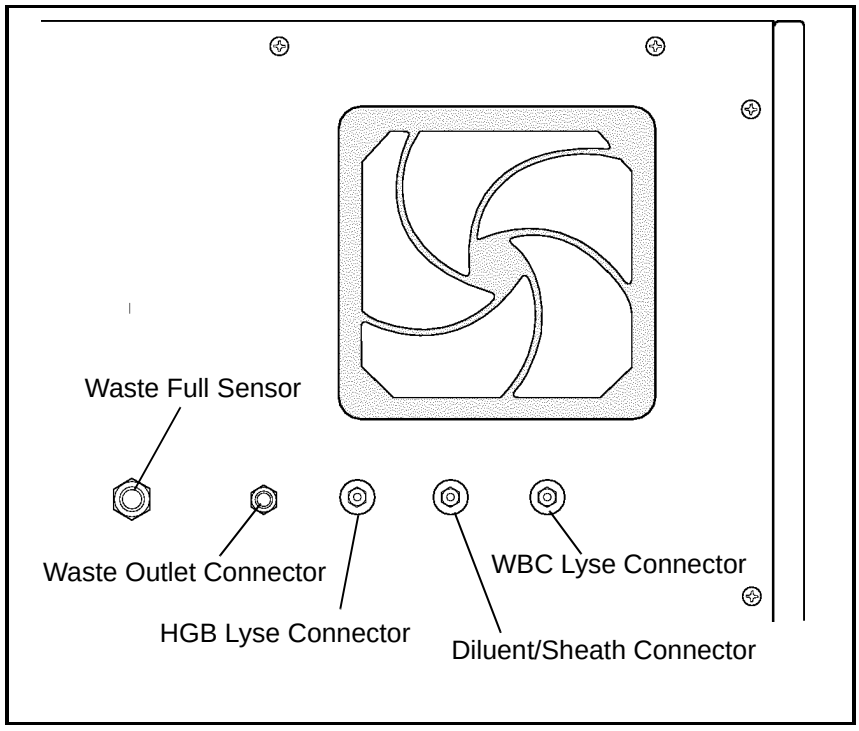

Figure 2.1: Reagent Inlet Panel

7. Locate the **Waste-Full Sensor** Plug attached to the cap's electrode wires. Insert the plug into the **Waste Sensor** connector located on the Reagent Inlet Panel. Attach the ground shield on the cable to the connection on the rear panel. When the waste tubing is placed directly into a drain, insert the **Dummy Plug** (found in the Accessory Kit) into the Waste Sensor Connector.

   If the waste tube is placed directly into a drain, insert the Dummy Plug (provided in the Accessory kit) into the Waste Sensor Connector, as the EXTERNAL WASTE FULL alert will activate if no plug is inserted. For information on ordering a Waste Dummy Plug, refer to ***Appendix B — Parts and Accessories***.

Normally Closed Valves

To gain access to all six Normally Closed Valves on the Flow Panel, open both the Left and Right Front Covers and remove the Tower Cover. Remove the Front Skirt (CS model) or move the Sample Loader (SL model) away from the instrument. (Refer to instructions later in this section for opening and removing these components.)

Before shipment, the tubing is removed from these valves. To ensure correct system operation, the tubing must be completely inserted in all the valves before the instrument power is turned ON. Follow the directions below to open the front covers and remove the Skirt or Sample Loader to allow access to all the Normally Closed Valves. Refer to Figure 2.2.

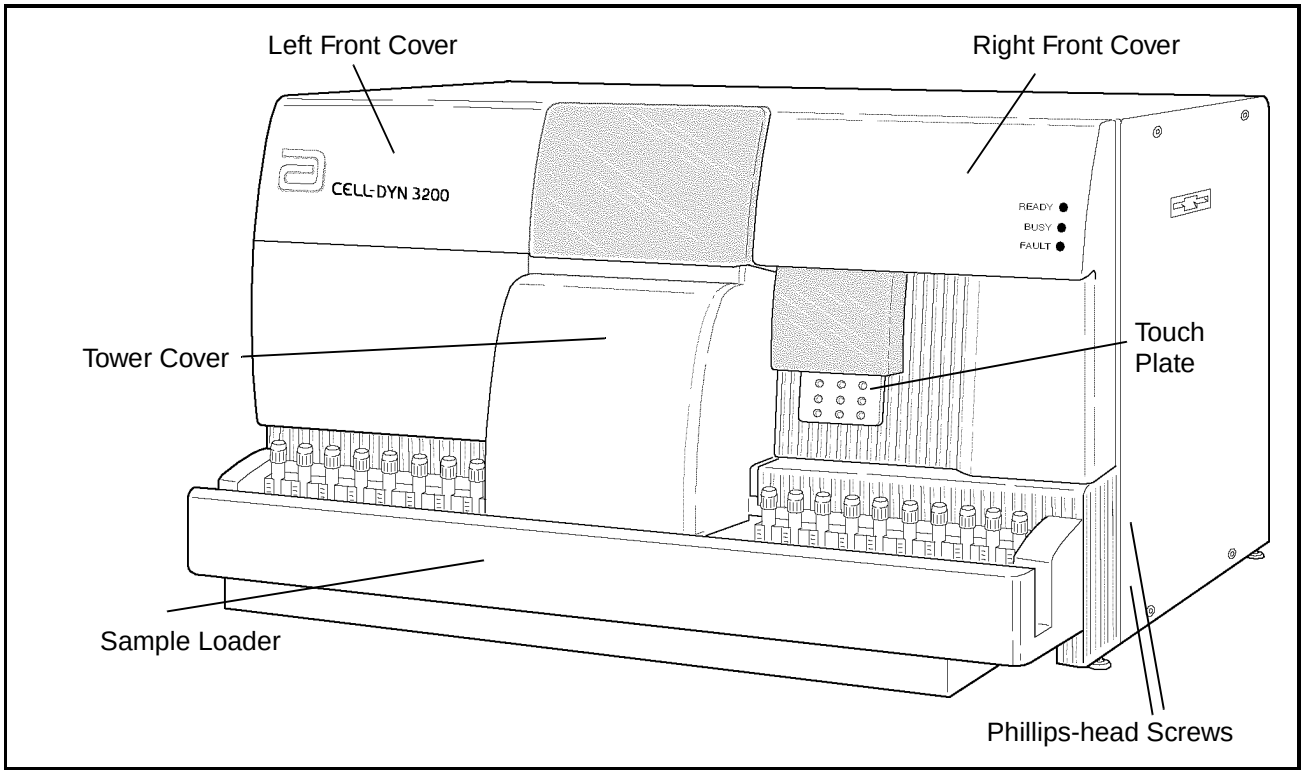

Figure 2.2: Analyzer Front Covers — SL Model

Open Left Front Cover

To open the Left Front Cover on both the SL and CS models, press the upper right corner of the cover to release the cover latch. Swing the cover all the way to the left to completely expose the left side of the Flow Panel. If necessary, it is possible to lift the cover off its hinges to completely remove it from the instrument.

Open Right Front Cover

To open the Right Front Cover on both the SL and CS models, press the upper left corner of the cover to release the cover latch. Swing the cover all the way to the right to completely expose the right side of the Flow Panel. Because of the attached Touch Plate and Status Panel, this cover should not be removed from the instrument.

Remove Tower Cover

To remove the Tower Cover on both the SL and CS models, press the window on the cover to release the cover latch. Lift the cover up and off the instrument.

Remove Front Skirt

To remove the Front Skirt Cover on the CS model, remove the four Phillips-head screws, two on either side of the instrument, which hold the skirt to the instrument frame. Pull the skirt away from the instrument.

Remove Sample Loader

To remove the Sample Loader on the SL model, remove the four Phillips-head screws, two on either side of the instrument, which hold the Sample Loader to the instrument frame. Carefully pull the loader away from the instrument approximately 2-3 inches. Do not stretch the wiring or tubing that connects the loader to the Analyzer.

Tubing Installation

NOTE: The tubing *must* be installed before the power is turned ON for the instrument to operate correctly. Follow the directions below to install the diluent tubing.

1. Locate the six normally closed valves on the flow panel. Refer to Figure 2.3 for the location of these valves.
2. The procedure described below applies to all the Normally Closed Valves on the Flow Panel. Refer to Figure 2.4.
3. Select any of the Normally Closed Valves. Carefully insert the diluent tubing into the slot at the top of the valve. Work the tubing firmly back and forth with a flossing motion until it is completely inserted into the valve and resting on the bottom of the slot. Unless this tubing is securely seated, the flow system will not function properly.

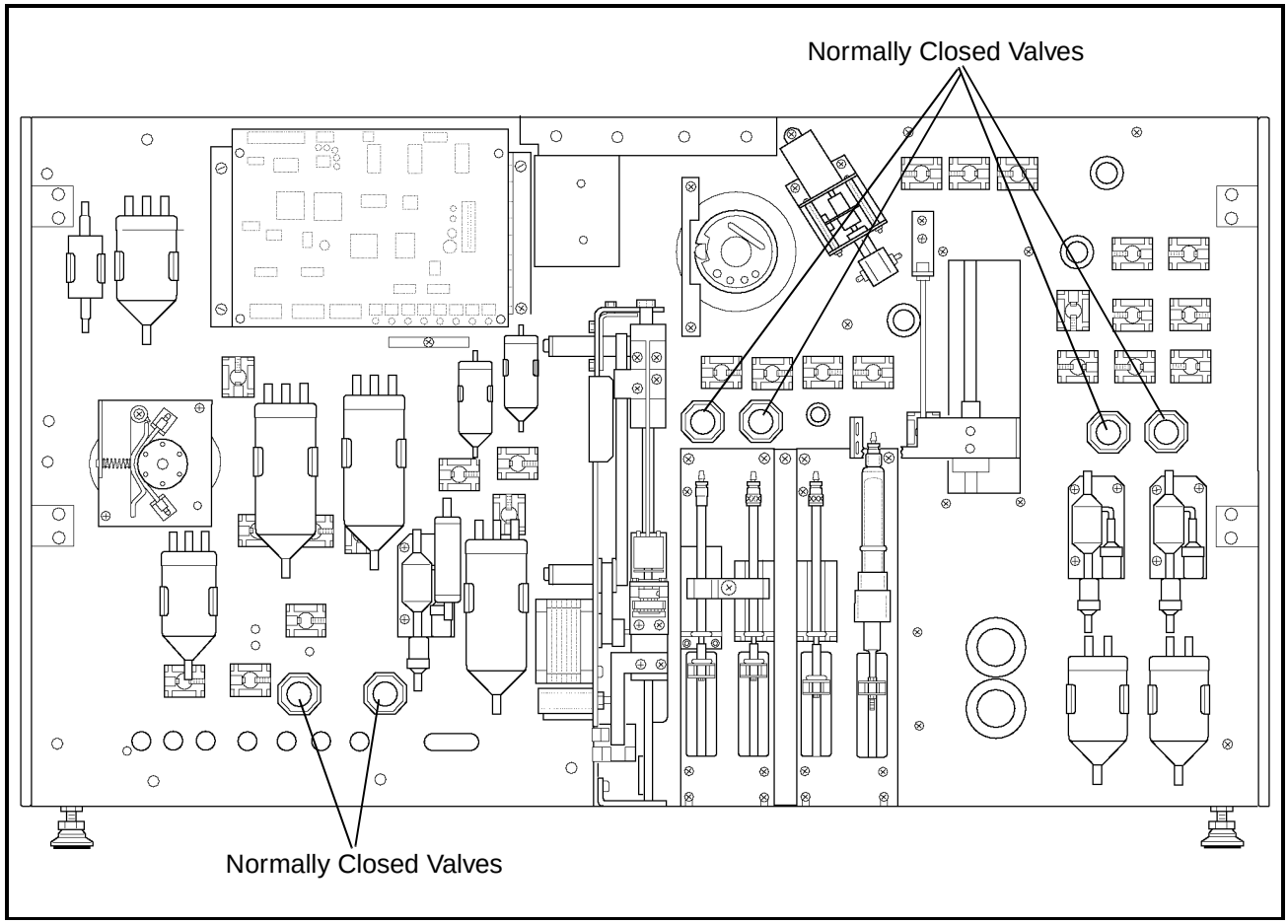

Figure 2.3: Normally Closed Valves

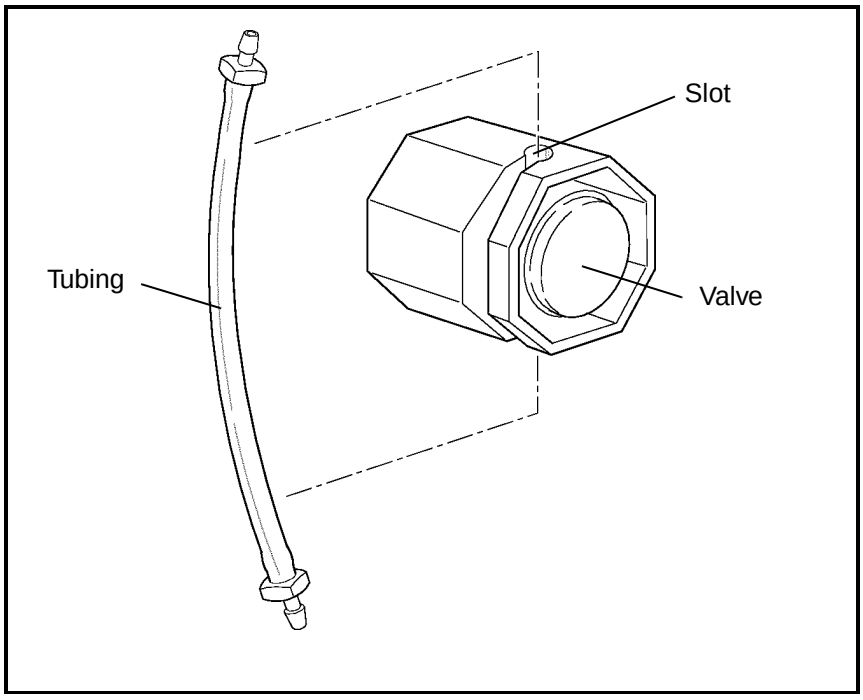

Figure 2.4: Tubing in a Normally Closed Valve

4. When the tubing has been installed properly, it should move back and forth freely.
5. Confirm that *both* ends of the diluent tubing are firmly attached to the connectors.
6. Repeat steps 3 through 5 until the tubing has been inserted in all six of the Normally Closed Valves.

Flow Panel and Syringe Inspection

1. Inspect the Flow Panel components for obvious damage and to ensure the tubing is properly positioned under all solenoid pinch valves.
2. If there is any damage, contact the Abbott Customer Support Center.
3. When the inspection of the Flow Panel is completed, turn the Main Power Switch to ON.
4. Before putting the front covers and skirt back on the instrument, run several background counts (by pressing the Touch Plate) to observe proper functioning of the instrument. Check for leaks, crimps in the tubing, and the opening of the Solenoid pinch valves. Observe the operation of the syringes. The syringes should move freely up and down with no evidence of air bubbles.

5. If no problems are detected, close the Left and Right Front Covers and press into place. Reattach the Tower Cover and press into place (for the SL model, line up the two holes on the bottom of the cover with the two pins on the Sample Loader molding). On the CS model, reattach the Front Skirt using the four Phillips-head screws. On the SL model, slide the Sample Loader forward using the center guide to properly align the loader with the Analyzer. Reattach the loader using the four Phillips-head screws.

NOTES

Printer Installation

Overview

Remove the printer(s) from its shipping container and visually inspect it for damage. Find a suitable location adjacent to the instrument. Be sure the printer power switch is in the OFF position. Retain the manuals shipped with the printer(s) and store them in a convenient location.

> **NOTE:** If the printer is placed on top of the instrument, be sure that the paper does not restrict air flow to the rear panel fan.

Basic installation procedures follow for the Ticket and Graphics Printers. When used with the CELL-DYN 3200, the Graphics Printer prints color or black-and-white graphic reports and the Ticket Printer prints tickets or black-and-white graphic reports. Depending on the output desired, one or both printers may be connected to the instrument.

Follow installation instructions carefully to be sure that the printer(s) is connected to the correct port. (See Figure 2.5.) For convenience, general instructions are provided for loading individual pre-printed tickets in the Ticket Printer. For a detailed description of the printer components and operating instructions, refer to the manuals that accompany the printer.

IMPORTANT: The CELL-DYN 3200 System has been configured for and tested on the following printers: Canon® BJC-620™ color ink jet printer for graphics output, and OKIDATA® MICROLINE® 320 dot matrix printer for ticket printing. Abbott recommends using only these printers. If other printers are substituted, problems may occur with your printouts.

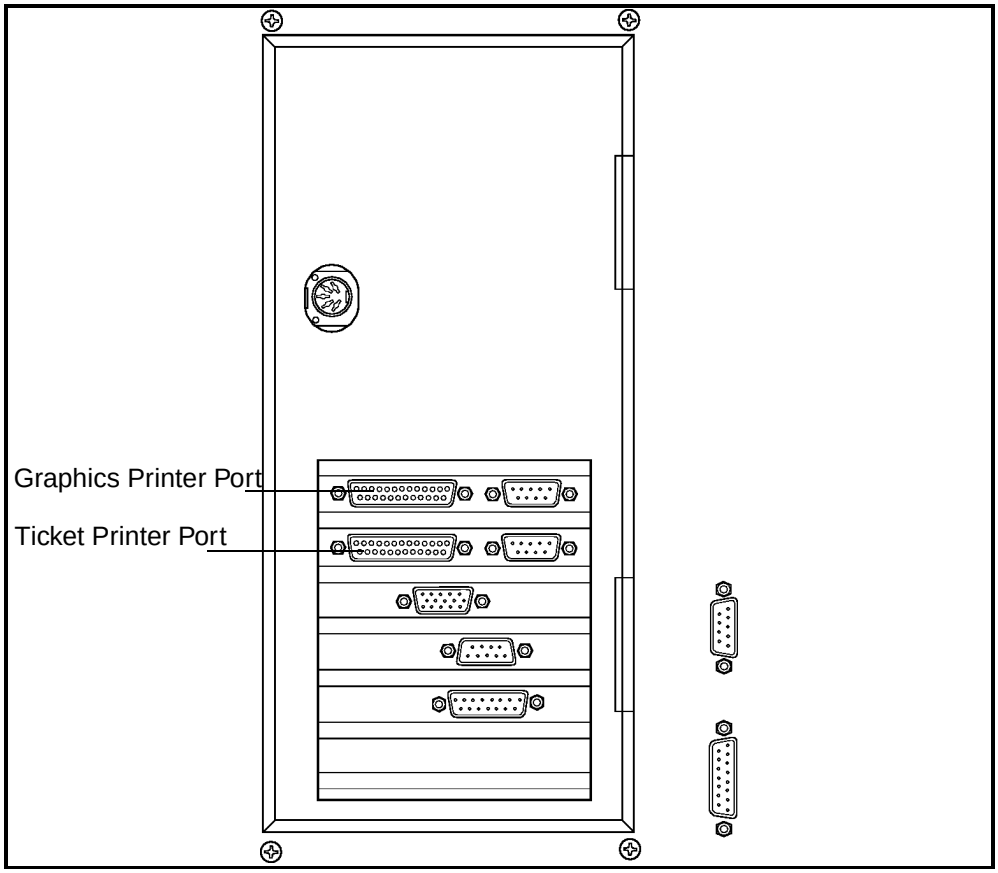

Figure 2.5: CELL-DYN 3200 Printer Ports

Graphics Printer Installation Procedure

The Graphics Printer is a Canon® BJC-620™ color ink jet printer or compatible printer.

1. Assemble the printer as directed in the printer manual.
2. Make sure that the printer power switch is OFF. Plug the power cord into the printer. Do not plug the other end into an outlet until you are ready to load paper.
3. Make sure that the power to the instrument is turned OFF. Remove the printer cable (which looks like a power cord with two connectors) from the Accessory kit and plug one end into the parallel port on the rear of the printer. (There is a metal plate covering the printer's serial port to avoid confusion.) Fasten the wire clips to the connector for a secure connection.

4. Plug the other end of the printer cable into the Graphics Printer port on the back of the Data Module. (See Figure 2.5) Tighten the screws on the connector for a secure connection.

   NOTE: This port is configured for use as a graphics printer only. To print tickets, you may connect a Ticket Printer to the Ticket Printer port.

5. Install the ink cartridge as directed in the printer manual.
6. Load the paper as directed in the printer manual.
7. If necessary, refer to **Section 5: *Operating Instructions*, Subsection: *Customize Report*** for instructions on customizing the printout.

Self-Test Printouts

Run any self-test printouts before using the printer for the first time. These self-tests may be run any time to verify proper printer operation.

IMPORTANT

The CELL-DYN 3200 software automatically controls and adjusts most print conditions for the Graphics Printer, including page width and ribbon color. Occasionally, a few settings may need to be changed in the *printer's* software for correct operation. If printing is not what you expect, refer to the printer manual for guidance in making adjustments. If you have additional questions or experience any problems, call the Abbott Customer Support Center for assistance.

Ticket Printer Installation Procedure

The Ticket Printer is an OKIDATA® MICROLINE® dot matrix printer or compatible printer.

The Ticket Printer is normally used to print result data on blank or pre-printed tickets but can be used to print a complete graphics report on continuous tractor-feed paper. (Blank tickets are available in continuous tractor-feed sheets. Pre-printed tickets must be loaded individually.)

1. Assemble the printer as directed in the printer manual.
2. Make sure that the printer power switch is OFF. Plug the power cord into the back of the printer and plug the other end into a grounded outlet.

3. Make sure that the power to the instrument is turned OFF. Remove the printer cable (which looks like a power cord with two connectors) from the Accessory kit and plug one end into the port on the rear of the printer. (The port is constructed so that the connector will only fit in the proper way.) Fasten the wire clips to the connector for a secure connection.
4. Plug the other end of the printer cable into the Ticket Printer port on the back of the Data Module. (See Figure 2.5.) Tighten the screws on the connector for a secure connection.

   NOTE: This port is configured for use as a ticket printer only. To print graphics reports, you may connect a Graphics Printer to the Graphics Printer port.

5. Install the ribbon as directed in the printer manual.
6. Load the paper or blank, continuous-feed tickets as directed in the printer manual, OR, if you are using pre-printed individual tickets, continue with the following procedure.

Loading Individual Tickets in the Ticket Printer

Instructions are given for loading individual tickets. If fanfold, continuous-feed tickets are used, they should be loaded as directed in the printer manual for tractor-feed paper.

NOTE: To print on these tickets, the printer cable must be connected to the Ticket Printer Connector.

1. Be sure that the printer is turned OFF and the printer cable is connected to the Ticket Printer connector on the back of the instrument. If the connection is incorrect, turn the instrument power OFF, change the position of the cable and turn the power back ON.
2. Set the ribbon cartridge headgap lever to adjust for the thickness of the tickets. Refer to the printer manual for detailed instructions.
3. Move the paper selection lever to the rear position to select single-feed paper.
4. Open the access cover and be sure the guide wire on the paper separator is pushed back into the locked position.
5. Raise the separator to its upright position.

6. Place a ticket on the paper separator and adjust the guides so that they barely touch the edges of the ticket.
7. Pull the bail lever forward. The ticket will automatically feed into place. Release the bail lever.
8. Be sure the printer is deselected (Sel indicator is not illuminated). Set the Top of Form by pressing and holding the TOF/Quiet key and pressing the Form Feed key to move the ticket up or pressing the Line Feed key to move the ticket down. (The ticket moves in very fine increments so it can be precisely positioned.)

   NOTE: The ticket will only move down to a certain point to prevent potential ticket jams. Do not move the top of the page below the paper bail.

9. Position the ticket so that the lower red line on the paper shield (located between the print head and the paper) is positioned where the first line of printing should occur.

   NOTE: When the Top of Form is set, the position is retained in the printer memory until it is reset.

10. Press the **Sel** key to select the printer. The printer is now ready to print.

Self-Test Printouts

Run any self-test printouts indicated in the printer manual before using the Ticket Printer for the first time. These self-tests may be run any time to verify proper printer operation.

Sample Loader Inspection (SL Model)

The Sample Loader is attached directly to the Analyzer to form an integrated unit, as shown in Figure 2.6.

Four screws, two on either side, hold the Sample Loader to the Analyzer. A power cord provides power from the Analyzer to the loader, and an interface cable allows communication between the Analyzer and loader. The Analyzer and Sample Loader are also connected by two quick-disconnect tube lines, one for pressure and one for vacuum.

The tube spinning and sample aspiration mechanism on the Tower Module is identical on both the SL and CS models. The Tower Cover on the SL model differs from its counterpart on the CS model in two ways:

1. It is larger in order to extend over the center portion of the Sample Loader which contains the Bar Code Reader and Mixing Assembly.
2. It serves as a safety cover, halting operation of the Sample Loader if it is removed.

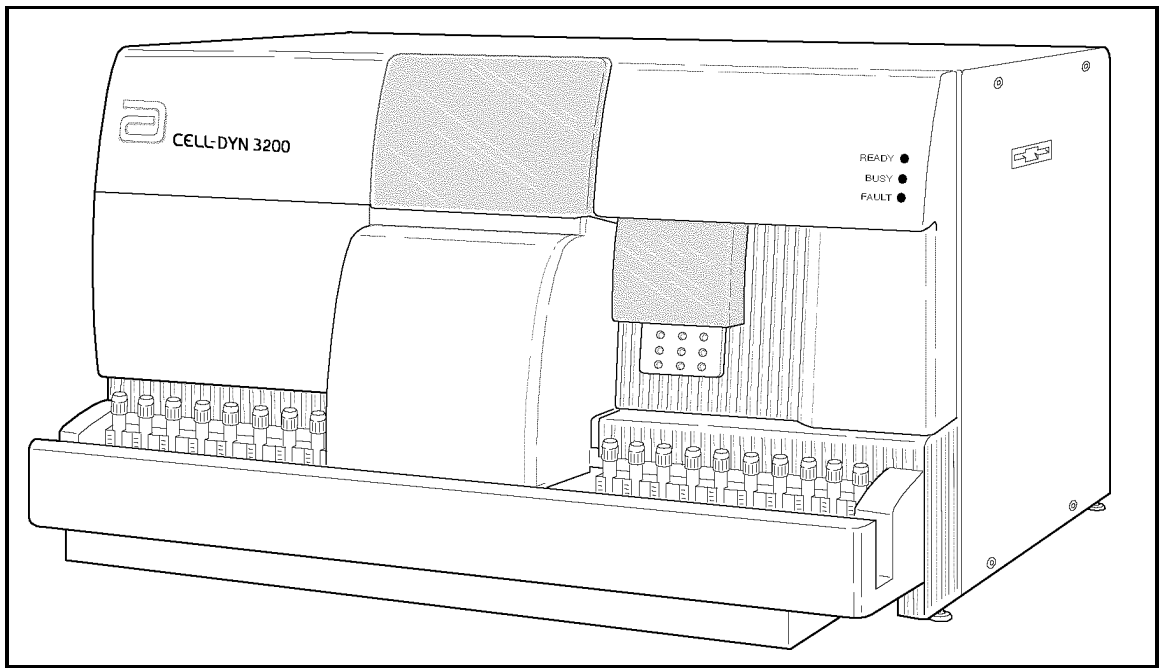

Figure 2.6: Analyzer With Sample Loader

To inspect the Sample Loader:

1. Unpack the instrument from its shipping container and place it on a flat surface.
2. Remove the protective plastic.
3. Inspect the Sample Loader for signs of obvious damage and verify the loader is securely attached to the Analyzer.
4. Remove the set of 5 tube racks from the Sample Loader Accessory Kit.
5. Inspect all the tubes for signs of damage.
6. Verify that each rack has a bar code label in position 1 and that the label is on the same side as the open slots. Refer to Figure 2.7 for proper label placement and alignment.

   NOTE: For the Sample Loader to operate properly, the racks must be placed to the right of the tower (the "load" area) with the labels and slots facing the operator, not the Analyzer, so that the Bar Code Reader can read the rack label and the tube labels through the rack slots. Refer to **Section 13: *Sample Loader*** for additional information on the Sample Loader.

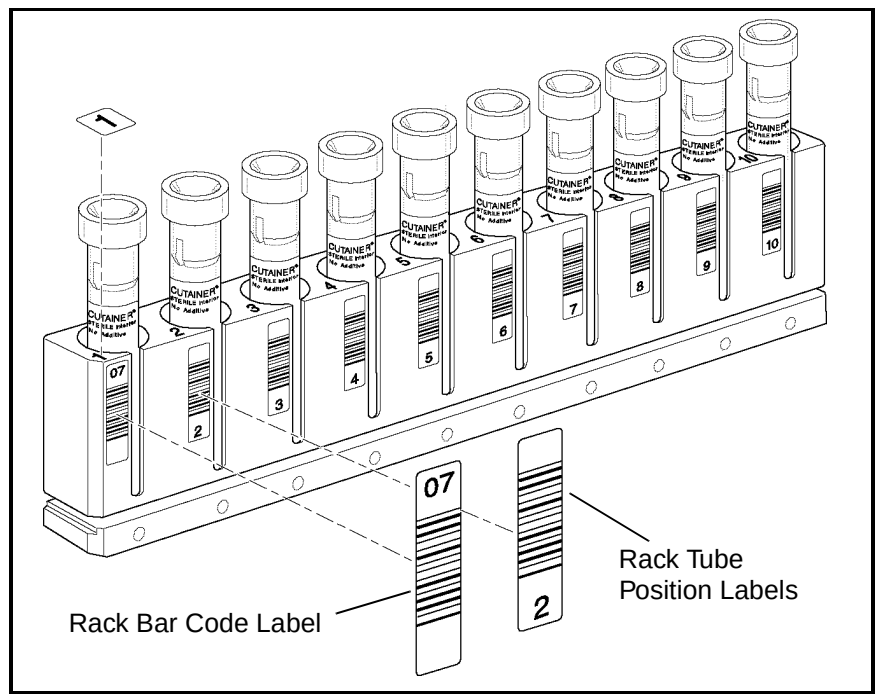

Figure 2.7: Tube Rack Showing Label Placement Locations

Power On

1. Turn the instrument's Main Power Switch to ON. When the initialization process is complete, press the [RUN] key to prime the instrument. When the priming process is complete, the READY light on the Analyzer's indicator panel is lit and the message **READY** is displayed in the Status Box on the monitor.
2. Prime the Sample Loader by running several blood samples in the Closed Mode. If necessary, refer to the directions given in **Section 5*: Operating Instructions*, Subsection: *Sample Analysis on the CELL-DYN 3200SL, Running Samples, Closed Mode Procedure***.
3. Confirm that the background count is acceptable before running patient samples.

Overview

The principles the CELL-DYN® 3200 uses to measure, count and calculate the hematological parameters are discussed in Sample Analysis Cycle Overview and Introduction to Flow Cytometry within this section. Subsequent sections discuss the measurement process for WBC, RBC, PLT, and HGB. The last subsection, Operational Messages and Data Flagging, discusses the flags generated by the instrument due to measured parameters outside predefined limits, sample abnormality, interference in the measurement process, or detection of an abnormal subpopulation. Quality Control methodology is discussed in **Section 11: *Quality Control***.

The two independent measurement channels used in the CELL-DYN 3200 are:

- The Optical channel for determining the WBC, NOC, and RBC/PLT data
- The Hemoglobin channel for determining the HGB

During each instrument cycle, the sample is aspirated, diluted and mixed before each parameter is measured.

> **NOTE:** An increase in flags will occur in RRBC and FWBC modes.

Sample Aspiration

There are two modes of whole blood sample aspiration on the CELL-DYN 3200. The operator selects the mode of aspiration from the RUN screen.

- The **Open Sampler Mod**e is used to aspirate the sample from a collection tube that has been opened and is held under the open sample aspiration probe.
- The **Closed Sampler Mode** is used to aspirate the blood directly from a closed collection tube by piercing the tube stopper. On the CS model, sample tubes are processed manually. On the SL model, sample tubes are processed automatically using the Sample Loader.

The aspiration volumes are:

Open Mode	120 µL ± 10%
Closed Mode (CS)	250 µL ± 10%
Sample Loader (SL)	250 µL ± 10%

Once the mode of aspiration is selected, the whole blood sample is aspirated to the Shear Valve by vacuum/pressure action. An ultrasonic sensor, located upstream of the Shear Valve, checks the integrity of the sample stream before it enters the Shear Valve. An LED sensor, located downstream of the Shear Valve, checks the sample stream to ensure the proper amount of blood has been transferred through the Shear Valve.

Sample Analysis Cycle Overview

NOTE: Sample and reagent volumes given in this section are stated as the nominal values. Slight differences between instruments may cause these volumes to vary. These differences are compensated for by factory-set internal dilution factors.

Sample Aspiration

A sample is aspirated either in Open Mode or Closed Mode and transferred to the Shear Valve. The sample volume in Open Mode is 120 µL. The sample volume in Closed Mode is 250 µL.

Sample Segments

The Shear Valve rotates in order to separate three volumes of the aspirated whole blood sample. The three volumes are:

20 µL for the WBC dilution
1.67 µL for the RBC/PLT dilution
12 µL for the HGB dilution

RBC/PLT Analysis

1. The Diluent/Sheath Syringe dispenses 2.79 mL of diluent through the Shear Valve where the 1.67 µL RBC/PLT volume is transferred to the RBC Mixing Chamber.
2. The segment and diluent are then routed to the RBC/PLT Mixing Chamber where the dilution is swirl mixed. The final dilution is 1:1672.
3. The Sample Transfer Pump transfers the RBC/PLT dilution from the RBC/PLT Mixing Chamber to the Optical Flow Cell Sample Feed Nozzle.
4. Diluent/Sheath reagent, under constant pressure in the Sheath Reservoir, is directed into the Optical Flow Cell.
5. Sequentially, the Sample Metering Syringe injects 24 µL of the RBC/PLT dilution into the flow cell at a pressure (and speed) lower than that of the diluent/sheath reagent.
6. The higher speed of the sheath, which surrounds the RBC/PLT dilution, and the special geometry of the flow cell combine to focus the RBC/PLT dilution stream so that individual cells can be counted.

7. A laser beam is focused on the flow cell. As the sample stream intersects the laser beam, the light scattered by the cells is measured by the forward (0° and 10°) detectors.

Hemoglobin Analysis

1. The Diluent/Sheath Syringe injects 2.29 mL of diluent through the Shear Valve where the 12 µL HGB volume is transferred to the HGB Flow Cell.
2. The HGB Lyse Syringe dispenses 0.30 mL of HGB Lyse into the line after the diluent has transferred the HGB volume to the HGB Flow Cell. The entry point for the HGB Lyse is between the Shear Valve and the HGB Flow Cell.
3. The segment, lyse, and diluent are routed to the HGB Flow Cell where the dilution is swirl mixed. The final dilution is 1:217.
4. A low-energy LED attached to the HGB Flow Cell measures the absorbance of light at 540 nm. The absorbance is proportional to the HGB concentration of the sample.

WBC Analysis

WBCs are analyzed optically as follows:

1. The WBC Lyse Syringe dispenses 0.973 mL of WBC Lyse reagent through the shear valve where the 20 µL WBC volume is transferred to the WBC Mixing Chamber.
2. The segment and reagent are then routed to the WBC Mixing Chamber where the dilution is swirl mixed. The final dilution is 1:49. The diluted sample remains in the mixing chamber for 14 seconds for the lysing of the red blood cells.
3. The Sample Transfer Pump transfers the WBC dilution from the WBC Mixing Chamber to the Optical Flow Cell Sample Feed Nozzle.
4. Diluent/Sheath reagent, under constant pressure in the Sheath Reservoir, is directed into the Optical Flow Cell.
5. Sequentially, the Sample Metering Syringe injects 46.5 µL of the WBC dilution into the flow cell at a pressure (and speed) lower than that of the diluent/sheath reagent.
6. The higher speed of the sheath, which surrounds the WBC dilution, and the special geometry of the flow cell combine to focus the WBC dilution stream so that individual cells can be counted.

7. A laser beam is focused on the flow cell. As the sample stream intersects the laser beam, the light scattered by the cells is measured at four different detectors located in the forward (0° and 10°) and side (90° and 90°D) angles.

Fragile WBCs and Resistant RBCs

When running samples in the normal Patient mode, the operator may suspect the presence of fragile WBCs when the FWBC flag is displayed or may suspect the presence of resistant RBCs when the RRBC and NRBC flags are displayed.

In the case of samples containing fragile WBCs or resistant RBCs, an alternate method is used to measure white blood cells. The results of this method are referred to as the Nuclear Optical Count (NOC). The NOC measurement is derived from the HGB dilution as described below. Refer to ***Nuclear Optical Count*** and ***Resistant RBC*** later in this section for additional information.

There are two different key labels on the RUN screen, one for fragile WBCs and one for resistant RBCs, but they activate the same alternate measurement procedure. Refer to ***Run Menu Soft Keys,* Subsection: *Specimen Type*** in **Section *5*: *Operating Instructions*** for a discussion of the Specimen Types available.

When the Fragile WBC specimen type is selected, both NOC and WOC are reported in the Data Log but only the NOC value is reported as WBC on the RUN screen and Laboratory Worksheet.

When the Resistant RBC specimen type is selected, both NOC and WOC are reported in the Data Log. Either NOC or WOC *is* reported as WBC (based on algorithmic decision-making) on the RUN screen and Laboratory Worksheet.

> **NOTE:** When QC specimen type is selected, both NOC and WOC are reported in the Data Log. Either NOC or WOC is reported as WBC (based on algorithmic decision-making) on the RUN screen.

The analysis for Fragile WBC and Resistant RBC is performed as follows:

1. The RBC/PLT analysis occurs as described in ***RBC/PLT Analysis*** above.
2. After the HGB sample is measured (refer to ***Hemoglobin Analysis*** above), the Sample Transfer Pump transfers the diluted solution from the HGB Flow Cell to the Optical Flow Cell Sample Feed Nozzle.

3. Diluent/Sheath reagent, under constant pressure in the Sheath Reservoir, is directed into the Optical Flow Cell.
4. Sequentially, the Sample Metering Syringe injects 140 µL of the HGB dilution into the flow cell at a pressure (and speed) lower than that of the diluent/sheath reagent.
5. The higher speed of the sheath, which surrounds the *HGB dilution, and the special geometry of the flow cell* focus the HGB dilution stream so that individual cells can be counted.
6. A laser beam is focused on the flow cell. As the sample stream intersects the laser beam, the light scattered by the cells is measured at the same four detectors used for the WBC Analysis. The nuclei of the lysed cells are counted.
7. The WBC Analysis occurs as described in **WBC** *Analysis* above except that the diluted WBC segment is lysed in the WBC Mixing Chamber for an additional 15 seconds.

Results Displayed

All data is transmitted to the Data Module for analysis. Results are computed for all parameters and are displayed on the RUN screen. Results are also stored in a log format called the Data Log.

Instrument Flushed

1. The remaining sample segment from the aspiration process is flushed to Waste Chamber #2.
2. The remaining segments in the WBC and RBC Mixing Chambers are flushed to Waste Chamber #3.
3. The segments sent to the Optical Flow Cell are flushed to Waste Chamber #4.

Instrument Rinsed

1. The Open Sample Aspiration Probe is rinsed internally and externally with diluent/sheath.
2. In Closed Mode, the needle is rinsed internally and externally with diluent/sheath.
3. The WBC and RBC/PLT Mixing Chambers are rinsed with diluent/sheath.
4. The Optical Flow Cell and Sample Line tubing are rinsed with diluent/sheath.
5. The HGB Flow Cell is rinsed with diluent/sheath.

Flow Cytometry

Introduction to Flow Cytometry

The CELL-DYN 3200 uses flow cytometric techniques to analyze the RBC/PLT, WBC, and NOC populations. This section gives a brief introduction to the principles of flow cytometry.[2]

Flow cytometry is a process in which individual cells or other biological particles in a single file produced by a fluid stream are passed through a beam of light. A sensor or sensors measure, by the loss or scattering of light, the physical or chemical characteristics of the cells or particles.[3]

Flow cytometry enables the rapid screening of large numbers of cells and provides quantitative cell analysis at the single-cell level. The basic components of a flow cytometer include:

A sample collector and transporter
A flow system to focus the sample flow stream
A light source and focusing optics
Light collectors, signal detectors, and polarizers
Data collection and storage
Data display and analysis

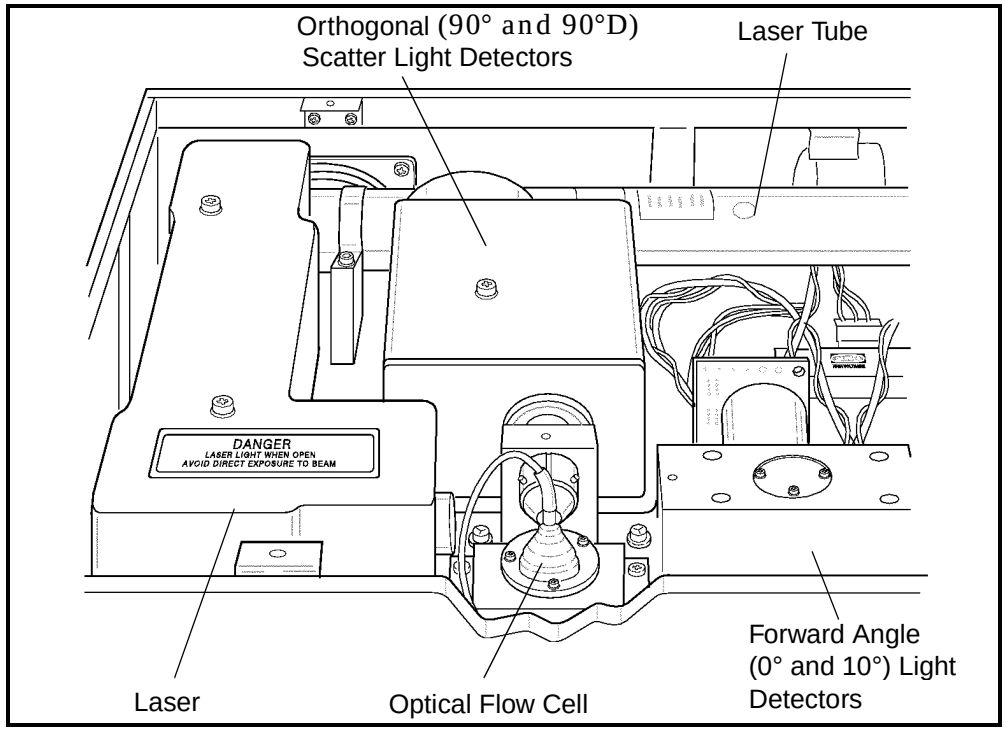

Figure 3.1: Optical Bench

Detection with the Optical Bench

The **optical bench assembly** contains the components that make up the flow cytometer. It is depicted in Figure 3.1. The main purpose of the optical bench is to detect the light scattered by the cells as they pass through the flow cell. The detection process is discussed in this section.

The light source is a vertically polarized 10 mW helium-neon laser with a wavelength of 632.8 nm. The laser beam passes through a cylindrical lens which changes the shape from a circle to an ellipse. The beam is then directed through a 125 µm slit which blocks the weaker outer edges. This process yields a uniformly intense beam approximately 80 µm wide that allows the cell stream to wander slightly in the flow cell and still be exposed to the same light intensity. An imaging lens centers the focused laser beam onto the quartz flow cell.

The Sample Transfer Syringe injects different sample dilutions into the sheath stream in the Optical Flow Cell. The sample is hydrodynamically focused into a small stream approximately 30 µm in diameter. This focused stream aligns the diluted cells in single file as they pass through the light beam, which allows them to be detected one at a time in the sensing region of the detectors.

Since the average diameter of the cells are smaller than the focused laser beam, the cells do not scatter much laser light. If the remaining unscattered light were allowed to reach the 0° and 10° (forward) detectors, it would saturate the electronics. Therefore, an obscuration bar blocks 0° – 1° of the forward unscattered light beam. The forward angles of scatter are directed to a perforated mirror. The 0° (1° – 3°) light scatter passes through the mirror to the 0° silicon photodiode detector. The 10° (7° – 10° or narrow angle) light scatter is deflected off the mirror to the 10° silicon photodiode detector.

The orthogonal scatter is directed through a 700 µm slit which blocks the scatter from the walls of the flow cell. A beam splitter then separates the orthogonal light scatter into two portions. One portion of the light is directed to the 90° PMT. The remaining light is directed through a horizontal polarizer. Only light that has changed polarization (depolarized) can pass through the polarizer to the 90°D PMT. (PMTs are used because relatively little light is scattered at this angle.)

The light signals collected by each detector are converted into electrical signals or pulses. The pulses are digitized based on intensity and sorted into 256 channels for each angle of light measured.

If a pulse falls above the hardware threshold in the 0° and 10° detectors, the cell counter counts the pulse and stores it for further evaluation. Pulses that fall below this threshold are not included in the count.

The information from each detector is collected in list mode. This format stores the channel information from each of the four dimensions. The data is then used to determine the WOC differential and RBC, PLT, and NOC counts. Data stored on floppy disks in the list mode format may be reconstructed into scatterplots at any time or analyzed by different algorithms as revisions are made.

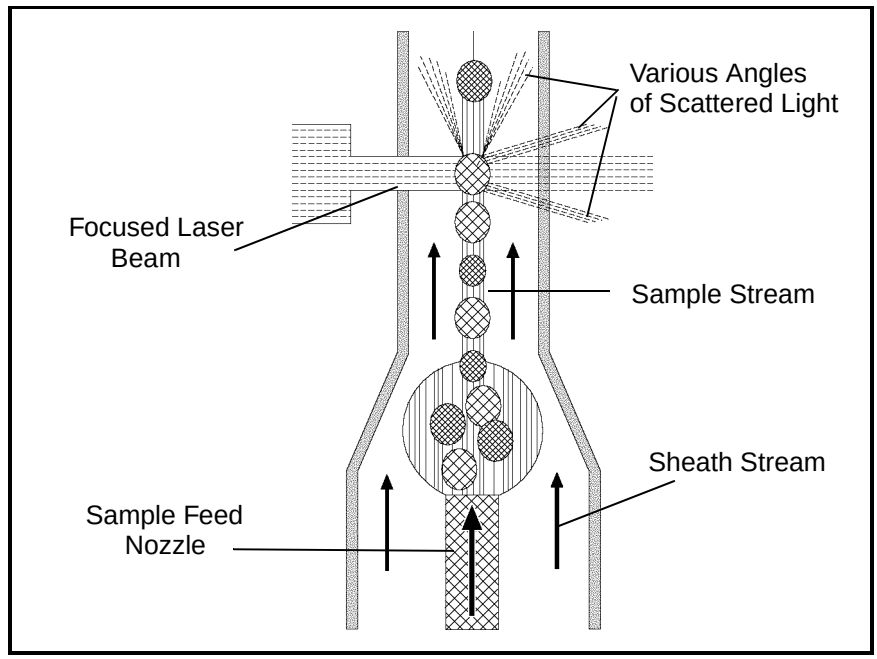

Figure 3.2: Optical Flow Cell

Optical Flow Cell

In a flow cytometer, the cell suspension is transferred from the mixing chamber through a sample tube into a special **flow chamber** with a small opening at the tip. The suspension is then injected into a stream of fast-moving, cell-free liquid **(sheath fluid)**. Since the two liquids travel at different rates of speed, they do not intermingle. The special geometry of the flow cell and the flow rate of the sheath fluid forces the cells into single file. This process is known as **hydrodynamic focusing**. (Refer to Figure 3.2 for a drawing of the Optical Flow Cell.)

As the cells enter the **view volume** (specific viewing area), they intersect with the laser beam. The different types of cells scatter the laser light at different angles, yielding information about cell size, internal structure, granularity and surface morphology. The optical signals the cells generate are detected and converted to electrical impulses which are then stored and analyzed by the computer.

Flow cytometers generally measure two angles of scatter. **Forward angle light scatter** is a measure of cell size. **Side angle (orthogonal) light scatter** is a measure of cell surface and internal structure but is primarily a measurement of internal granularity. Combining the information from the two scatter measurements provides more accurate discrimination between cell populations than either single measurement. (See Fig. 3.3 for an example of the light scatter measured by the CELL-DYN 3200.)

WBC Measurement

Overview

The **Optical Channel** is used for the determination of WBC data. During sample aspiration, 20 µL of sample is segmented in the Shear Valve for WBC measurement. The WBC Syringe dispenses 0.973 mL of WBC lyse to the Shear Valve. The sample and lyse are then transferred to the WBC Mixing Chamber where the dilution is swirl mixed, resulting in a 1:49 dilution ratio.

The Sample Transfer Pump transfers the WBC dilution from the mixing chamber to the sample feed nozzle in the Optical Flow Cell. At the same time, sheath reagent, under constant pressure in the Sheath Reservoir, is transferred to the sheath feed nozzle in the Optical Flow Cell and injected into the cell. At the same time, the Sample Metering Syringe injects 46.5 µL of the WBC dilution into a sheath stream. The sample stream is then hydrodynamically focused to align the cells in single file as they pass through the Optical Flow Cell, which is an optically clear quartz chamber. A vertically polarized **Helium Neon Laser** is the light source.

The instrument measures:

- Both types of forward angle light scatter (1° to 3°, referred to as 0°, and 7° to 11°, referred to as 10° or narrow angle)
- Both types of orthogonal (side) light scatter (70° to 110°, referred to as 90°, and 70° to 110° depolarized, referred to as 90°D).

This is referred to as **MAPSS™** (for Multi-Angle Polarized Scatter Separation) technology. Various combinations of these four measurements are used to classify the WBC subpopulations and provide morphological flagging.

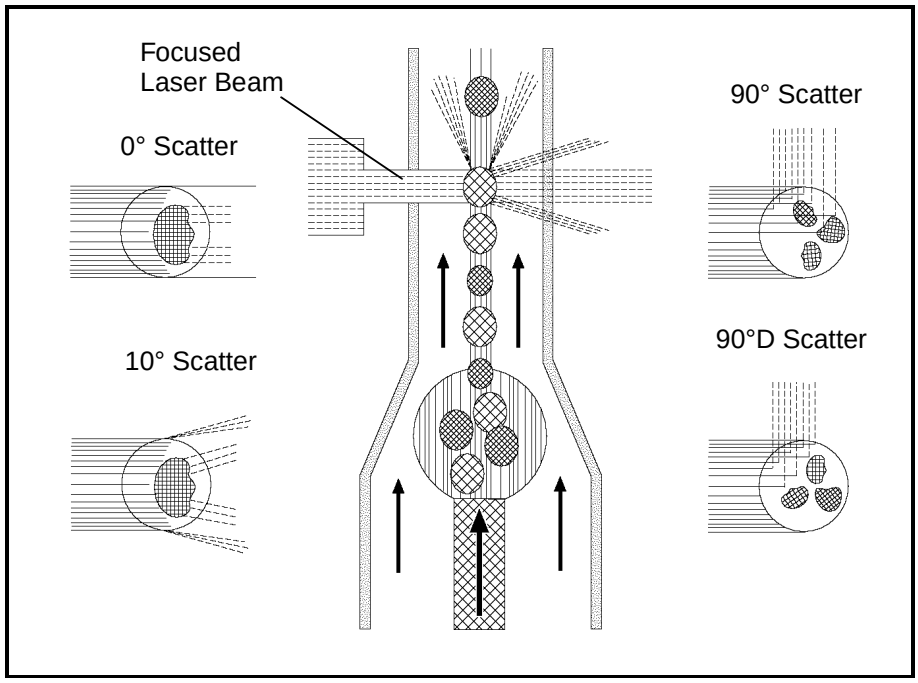

Figure 3.3: WBC Light Scatter

Figure 3.3 illustrates the measurement of light scattered during the WBC optical measurement process.

The WBC count is determined by enumerating the number of occurrences above a hardware threshold in the 0° channel. The information from all four measurements is used to differentiate the WBCs into five subpopulations:

Neutrophils
Lymphocytes
Monocytes
Eosinophils
Basophils

The WBC data is presented graphically as a scatterplot. It may also be presented in two histograms at operator request.

WBC Reagent

The **WBC reagent** used with the CELL-DYN 3200 instrument is the CELL-DYN WBC Lyse. It is an integral part of the WBC analysis. White blood cells diluted in the reagent maintain cellular integrity close to their native state. The structure of the basophils changes slightly due to the hygroscopic nature of the basophilic granules.

The RBCs are also altered by the reagent. The osmotic pressure of the RBC is higher than that of the reagent. Therefore, the hemoglobin in the RBC diffuses out of the cell and water from the reagent diffuses into the cell. The cell membrane remains intact but the RBC now has the same refractive index as the sheath, thereby rendering it invisible to the laser.

WBC Differential

The light scatter information is graphically presented in the form of scatterplots. (The data can also be presented in histograms, available on request.) Each cell analyzed is represented by a dot on the scatterplot. The dots are plotted at a point determined by the intersection of the channel information designated on the X and Y axes. For example, if a cell falls in channel 50 on the X axis and channel 50 on the Y axis, it is plotted at the intersecting point of the two channels.

The scatter information may be plotted in various combinations to yield different information. The CELL-DYN 3200 uses the scatterplots to differentiate the WBCs into five subpopulations:

Neutrophils

Eosinophils

Lymphocytes

Basophils

Monocytes

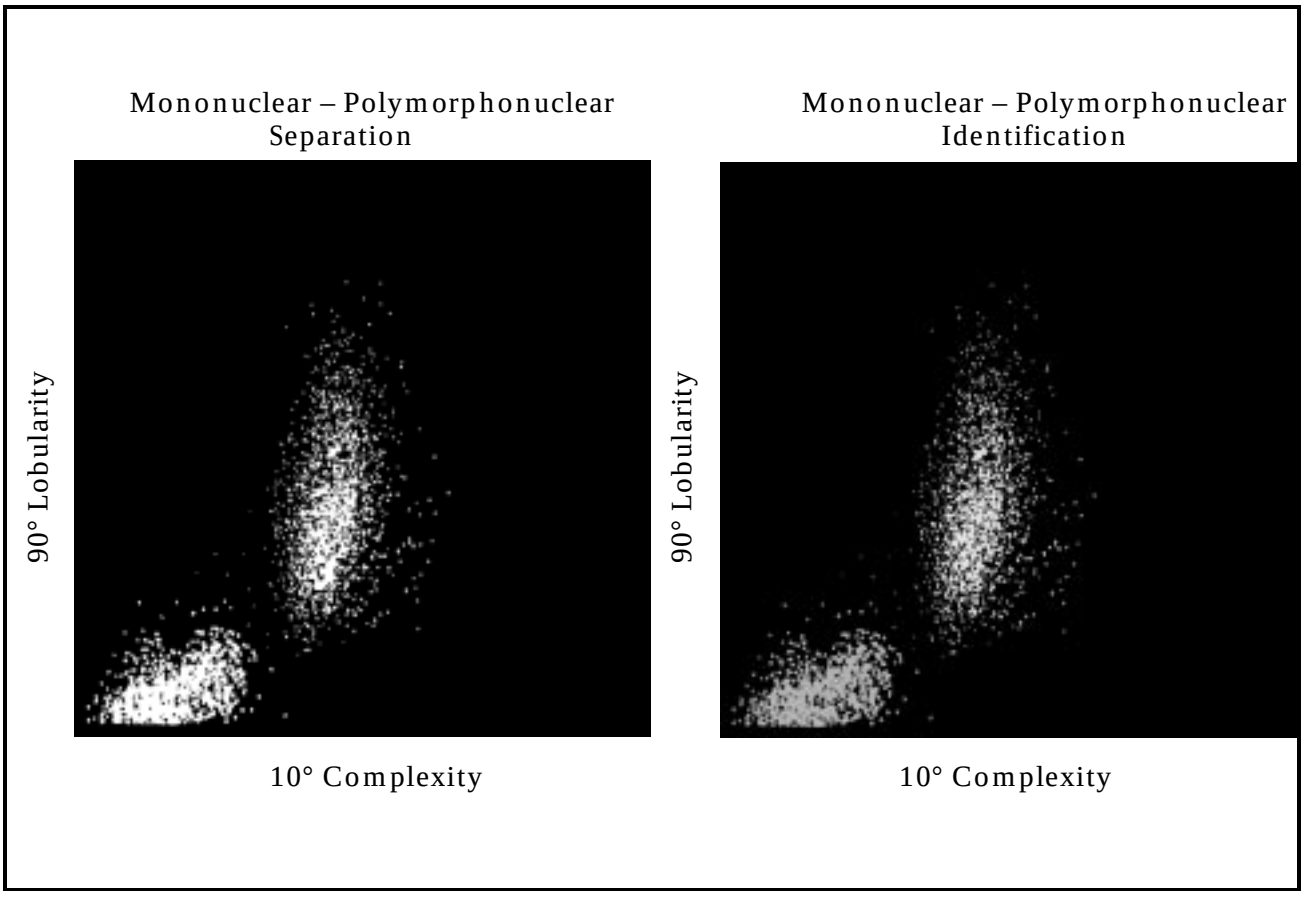

Figure 3.4: Mononuclear-Polymorphonuclear Scatter

Mononuclear-Polymorphonuclear Separation

The scatter information is plotted with the 90° scatter on the Y axis and the 10° scatter on the X axis. (The 90°/10° scatterplot is shown in Figure 3.4.) Two populations of cells are clearly seen on the display. The mononuclear cells fall in the cluster in the lower left corner of the scatterplot and the polymorphonuclear cells fall in the cluster above and to the right of them.

The instrument uses a dynamic threshold to determine the best separation between the two populations. Each cell is then identified as a **MONO** or a **POLY**. Once each cell is identified, it retains this classification no matter where it appears on other scatterplots.

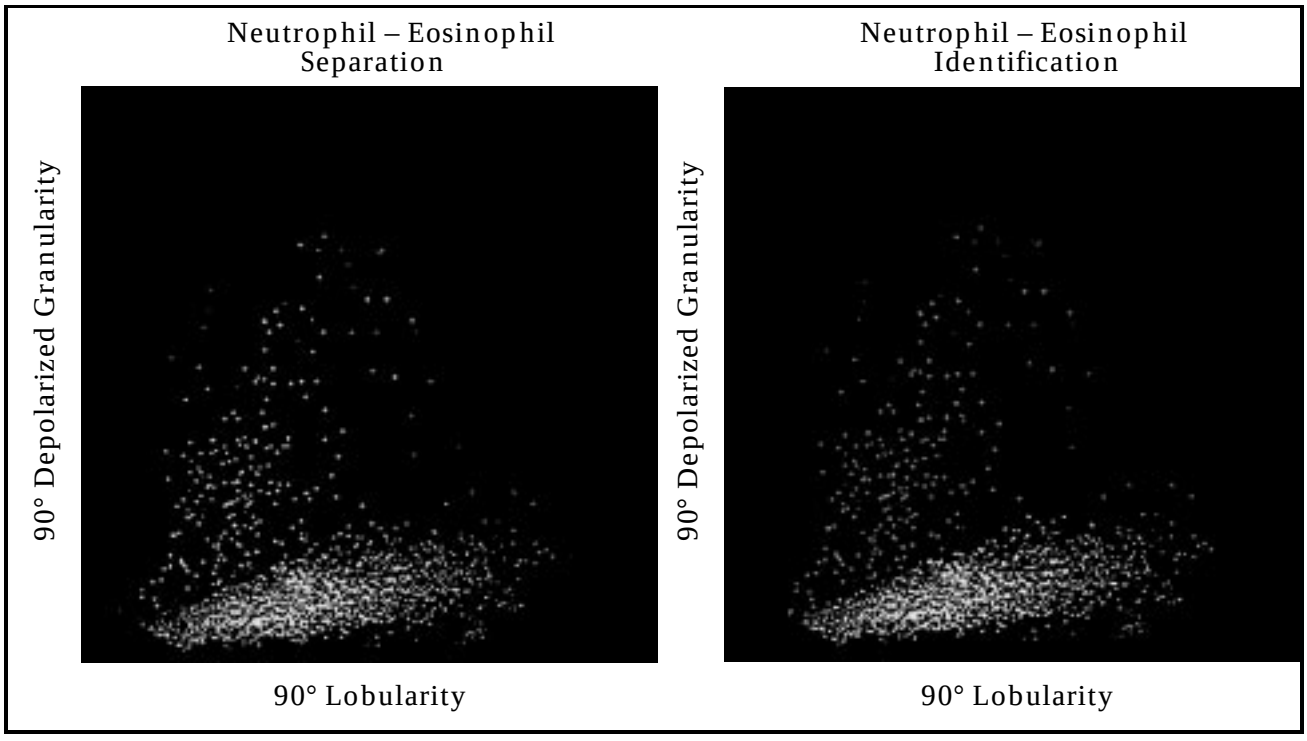

Figure 3.5: Neutrophil-Eosinophil Scatter

Neutrophil-Eosinophil Separation

The scatter information is plotted with the 90°D scatter on the Y axis and the 90° scatter on the X axis. (The 90°D/90° scatterplot is shown in Figure 3.5.) Only the polymorphonuclear cells are plotted on this scatterplot. The mononuclear cells have been identified and therefore do not interfere in the further classification of the polymorphonuclear cells.

Two populations of polymorphonuclear cells are clearly seen on the display. The neutrophils fall in the lower of the two clusters. The eosinophils fall in the upper cluster. The instrument uses a dynamic threshold to determine the best separation between the two populations. Each cell is then classified as a **NEUT** or an **EOS**.

All cells scatter a certain amount of 90°D light. The eosinophils scatter more 90°D light than any of the other cells because of the unique nature of granules they contain. This property of the eosinophils is used to positively identify them and thus clearly differentiate them from the neutrophil population.

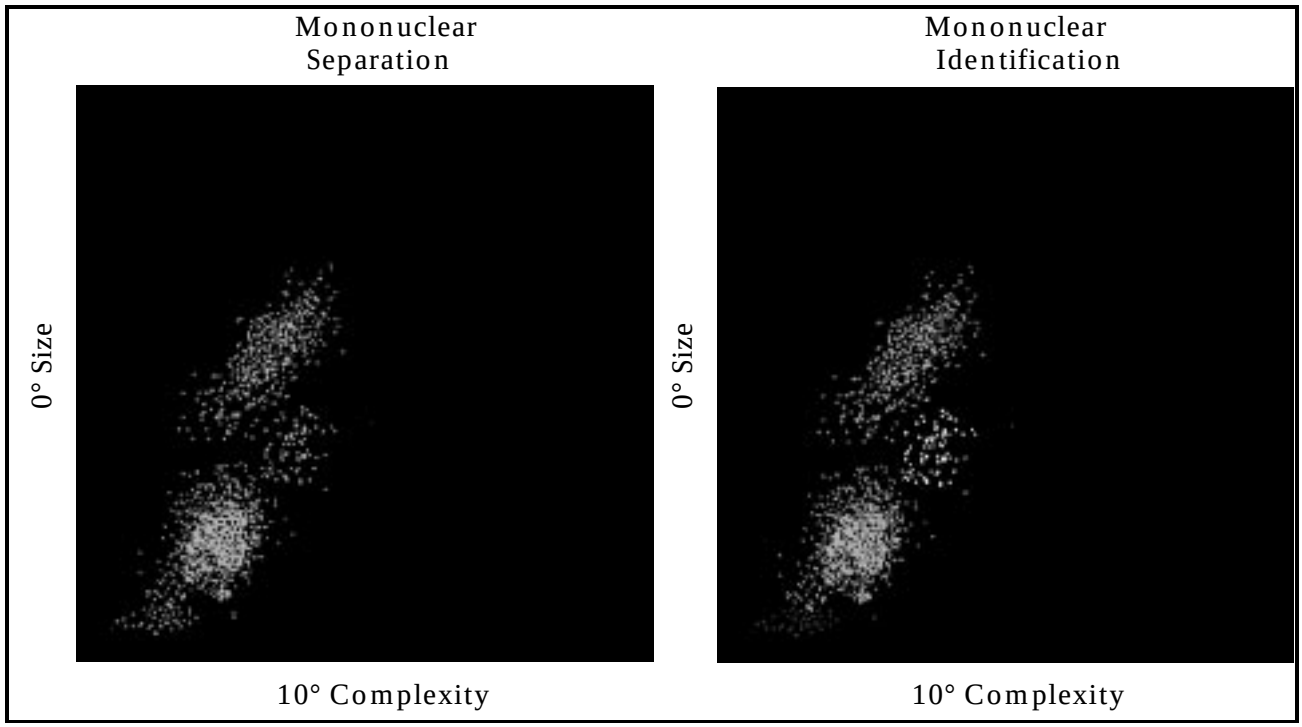

Figure 3.6: Mononuclear Scatter

Mononuclear Separation

The scatter information is plotted with the 0° scatter on the Y axis and the 10° scatter on the X axis. (The 0°/10° scatterplot is shown in Figure 3.6.) The mononuclear cells are plotted on this scatterplot. The algorithm also uses the orientation of the neutrophil cluster to aid in classifying the mononuclears. Three populations of mononuclear cells are clearly seen on the display.

There are three populations of mononuclears because basophils are included in the mononuclear cluster. Typically, basophils are granulated cells and therefore more complex than the mononuclear cells. However, the basophilic granules are water soluble and dissolve in the WBC Lyse reagent. Consequently, the degranulated Basophils becomes a less complex cell that falls into the mononuclear cluster.

The lymphocytes fall in the lowest large cluster. (The small population of cells below the lymphocytes contains particles that are unlikely to be WBCs.) The basophils fall in the cluster above and slightly to the right of the lymphocytes. The monocytes fall in the cluster above the lymphocytes and basophils. The instrument uses dynamic thresholds to determine the best separation between the three main populations. Each cell is then classified as a **LYMPH**, a **MONO** or a **BASO**.

Finally, the instrument evaluates the area below the lymphocyte cluster but above the hardware threshold (channel 23). Any particles that fall in this area are separated from the lymphocytes by a dynamic threshold. The following cell types may be present in this region:

- NRBCs
- Unlysed RBCs
- Giant PLTs
- PLT clumps

All particles in this region are excluded from the WBC count and the Differential.

Other Scatterplots

90°/0°

The scatter information is plotted with the 90° scatter on the Y axis and the 0° scatter on the X axis.

90°D/0°

The scatter information is plotted with the 90°D scatter on the Y axis and the 0° scatter on the X axis.

90°D/10°

The scatter information is plotted with the 90°D scatter on the Y axis and the 10° scatter on the X axis.

All scatterplots may be displayed and printed at operator request.

Nuclear Optical Count

Samples containing fragile WBCs are difficult to measure accurately because of the rapid breakdown of cells during the measurement process. To obtain an accurate WBC count, an alternate method using the HGB segment (instead of the WBC segment) is used to measure samples containing fragile WBCs.

The HGB sample segment, after being measured in the HGB Flow Cell, is transferred to the Optical Flow Cell instead of being sent to a waste chamber as in normal Patient cycles. While in the HGB Flow Cell, the HGB reagent lyses the cytoplasmic membrane of the white blood cells but allows the nuclear membrane to remain intact. This results is a greater stability of the white cells in the sample. The HGB segment is lysed for approximately 15 seconds before it is sent to the Optical Flow Cell.

As the HGB segment passes through the Optical Flow Cell, the nuclei of the cells are counted. The results of this measurement are stored in the Data Log as NOC.

Resistant RBC

When the WBC count is higher than expected in certain patient populations, lyse-resistant RBCs may be present. The WBC Lyse used to obtain the WBC count is generally strong enough to lyse RBCs that may be resistant to other lytic agents. However, the “soft” osmotic lysing ability of the WBC Lyse is usually insufficient to lyse the “resistant” cells in the time allotted for the WBC count. Consequently, unlysed RBCs are erroneously included in the WBC count resulting in a falsely elevated value. In all cases there is usually a significant amount of stroma (>2.9% of the total WBC count) present in the N1 region below the WBC dynamic threshold on the 0º/10º scatterplot. The WBC diluted sample is held in the mixing chamber 15 seconds longer than in the normal patient mode. This additional lysing time is to break down the resistant RBC cells.

> **NOTE:** A higher incidence of false positive band flags may be evident on specimens run under the Resistant RBC specimen type.

WBC Histograms

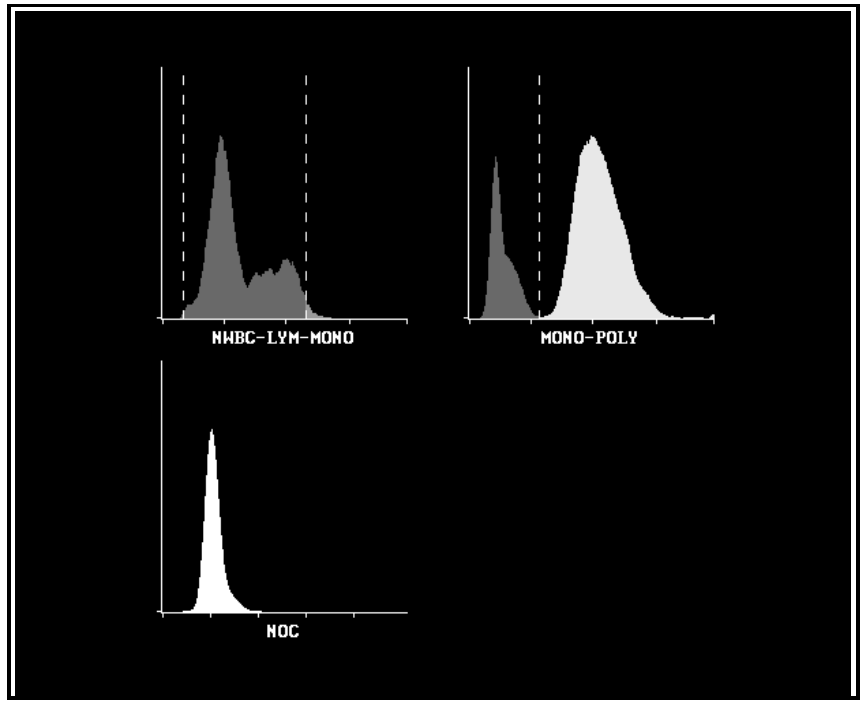

Figure 3.7: WBC Histograms

The CELL-DYN 3200 can present the WBC scatter information as two histograms: NWBC–LYM-MONO (N-L-M) and Mono-Poly (M-P). The NOC (Nucleated Optical Count) data can also be presented as a histogram. (Refer to Figure 3.7.) These histograms may be displayed and printed at the operator's request.

NWBC-LYM-MONO Histogram

The scatter information is plotted in a histogram format with the relative number of cells on the Y axis and the NWBC, Lymphocyte and Monocyte size distribution data on the X axis.

MONO-POLY Histogram

The scatter information is plotted in a histogram format with the relative number of cells on the Y axis and the mononuclear and polymorphonuclear size distribution data on the X axis.

NOC Histogram

The NOC data is plotted in a histogram format with the relative number of cells on the Y axis and the cell size distribution data on the X axis.

WBC Parameters

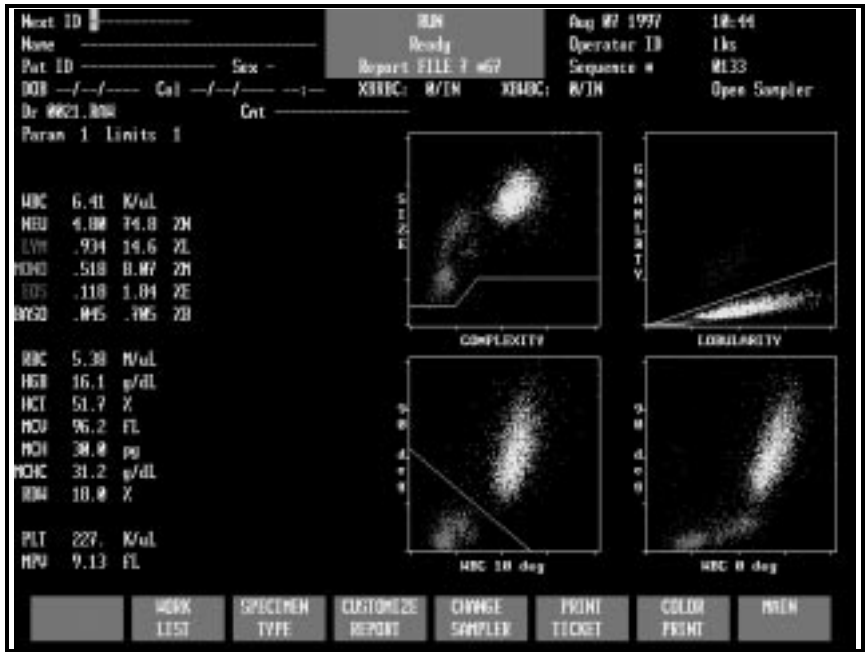

Figure 3.8: WBC Data and Scatterplots

The WBC data is generally displayed as depicted in Figure 3.8. All numeric and graphic data are automatically displayed on the RUN screen in the format selected. After the WBC scatter information has been plotted and the cells have been classified into the five subpopulations, the algorithms then determine the WBC and the percent of cells in each subpopulation.

Once the WBC count is determined, the absolute number of cells in each subpopulation is calculated by multiplying that WBC count by the percentage. The results are expressed as follows:

WBC	# x K/µL
NEU	# x K/µL and %
LYM	# x K/µL and %
MONO	# x K/µL and %
EOS	# x K/µL and %
BASO	# x K/µL and %

The decimal point moves to display up to three decimal places for the absolute number and percent.

The WBC subpopulations are further identified by the following colors:

Neutrophils — yellow
Lymphocytes — blue
Monocytes — purple
Eosinophils — green
Basophils — white

NOTE: The basophils are displayed as white dots but appear as black dots on color printouts.

The WBC scatter information is usually displayed in two scatterplots as shown in Fig. 3.8:

SIZE/COMPLEXITY	The size (0° scatter) information is plotted on the Y axis and the complexity (10° scatter) information is plotted on the X axis.
GRANLRTY/LOBULARITY	The granularity (90°D scatter) information is plotted on the Y axis and the lobularity (90° scatter) information is plotted on the X axis.

WBC Flagging

Refer to the "Operational Messages and Data Flagging" subsection of this section for WBC flagging information.

RBC/PLT Measurement

Overview

The **Optical Channel** is used for the determination of RBC and PLT data. During sample aspiration, 1.67 µL of sample is segmented in the Shear Valve for RBC/PLT measurement.

The Diluent/Sheath Syringe dispenses 2.8 mL of diluent to the Shear Valve. The sample and diluent are then transferred to the RBC/PLT Mixing Chamber where the dilution is swirl mixed, resulting in a 1:1,677 dilution ratio.

The Sample Transfer Pump transfers the RBC/PLT dilution from the mixing chamber to the sheath feed nozzle in the Optical Flow Cell. The Sample Metering Syringe injects 24 µL of RBC/PLT dilution into the sheath stream. The sample stream is then hydrodynamically focused to align the cells in single file as they pass through the Optical Flow Cell, which is an optically clear quartz chamber. A vertically polarized **Helium Neon Laser** is the light source.

There are 256 size channels for each of the parameters, each RBC size channel being equivalent to 1 fL and each PLT size channel being equivalent to 0.137 fL.

The RBC count is corrected for coincidence. MCV is determined from the RBC histogram. The PLT pulses are analyzed by the PLT algorithm as discussed in the PLT Measurement section.

The RBC count and distribution from the 0° channel is used to determine MCV. The total PLT count is taken from the 10° channel, the narrow-angle light scatter.

RBC Parameters

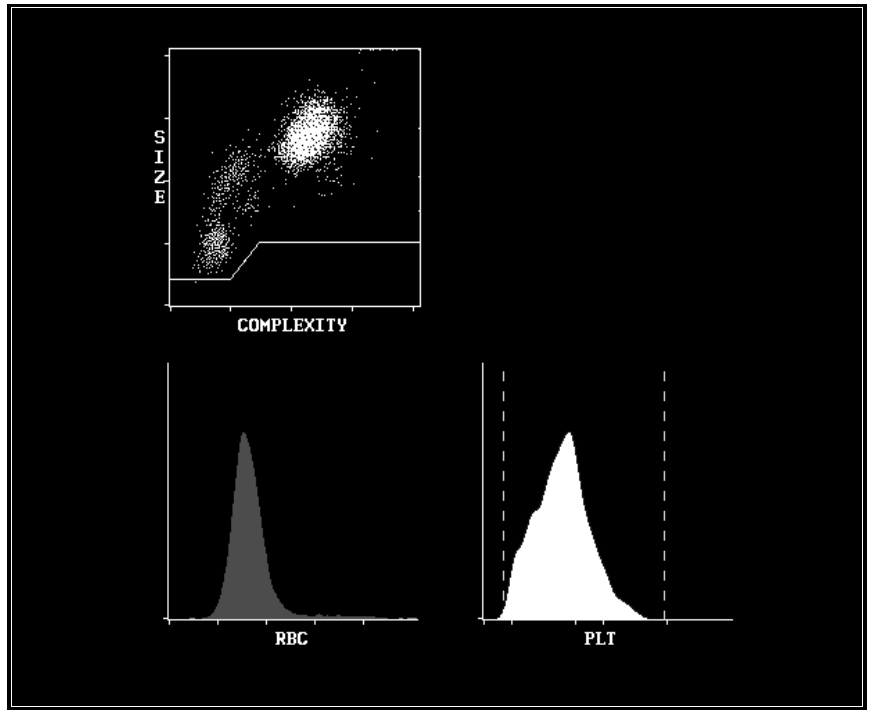

Figure 3.9: RBC Data and Histogram

All numeric and frequency size distribution data are automatically displayed on the RUN screen in the format selected. The size distribution data for the red cells is displayed graphically as a histogram. The size distribution data is plotted on the X axis. The relative number of cells is normalized and plotted on the Y axis. The RBC data are shown in Figure 3. 9.

RBC Count

The **Red Blood Cell Count** is directly measured, gives the number of RBCs and is expressed as follows:

RBC = # x M/µL

Counts below 1.0 x M µL are displayed to three decimal places.

MCV

The **Mean Cell Volume** is the average volume of the individual red blood cells. The MCV is derived from the RBC size distribution data and is expressed in femtoliters.

HCT

The **Hematocrit** is the ratio of red blood cells to plasma and is expressed as a percentage of the whole blood volume. The HCT is calculated from the red blood cell count and the mean cell volume as follows:

HCT = (RBC x MCV)/10

MCH

The **Mean Corpuscular Hemoglobin** is the average amount of hemoglobin contained in the red blood cell expressed in picograms. The MCH is calculated from the RBC and the HGB as follows:

MCH = (HGB/RBC) x 10

MCHC

The **Mean Corpuscular Hemoglobin Concentration** is the ratio of the weight of hemoglobin to the volume of the average red blood cell expressed in grams per deciliter. MCHC is calculated from the HGB and the HCT as follows:

MCHC = (HGB/HCT) x 100

RDW

Red Cell Distribution Width is a measure of the heterogeneity of the RBC population. The CELL-DYN 3200 reports a relative RDW equivalent to a CV in grams per deciliter. The RDW is derived from the RBC histogram using the 20th and 80th percentiles.

RBC Flagging

Refer to the “Operational Messages and Data Flagging” subsection of this section for RBC Flagging information.

PLT Measurement

Data recorded in the RBC/PLT dilution between 1 and 35 fL are included in the PLT data. If the raw PLT count is estimated to be below a predetermined value, the instrument automatically continues to count PLTs for an extended count period. The results from the two count periods are averaged. The PLT data is plotted as a histogram. An algorithm analyzes the histogram to eliminate interference and thus determine the lower and upper thresholds for the count.

If no interference is detected, the lower and upper thresholds are set at 2 and 30 fL respectively. If interference is detected, the thresholds float to determine the best separation between the interference and the PLT population. The lower threshold floats in the 1–3 fL region and the upper threshold floats in the 15–35 fL region. Once the thresholds have been determined, the PLT count is derived from the data between them.

Interference in the upper threshold region is generally caused by microcytic RBCs. Therefore, after the PLT upper threshold has been determined, the data between it and the RBC lower threshold is re-evaluated. If the PLT upper threshold is less than 35 fL, the counts above it (but less than the RBC lower threshold) are added to the RBC count.

If the interference in either threshold region exceeds a predetermined limit, the PLT count is flagged accordingly. The flags are discussed in the last section of this chapter.

Platelet Parameters

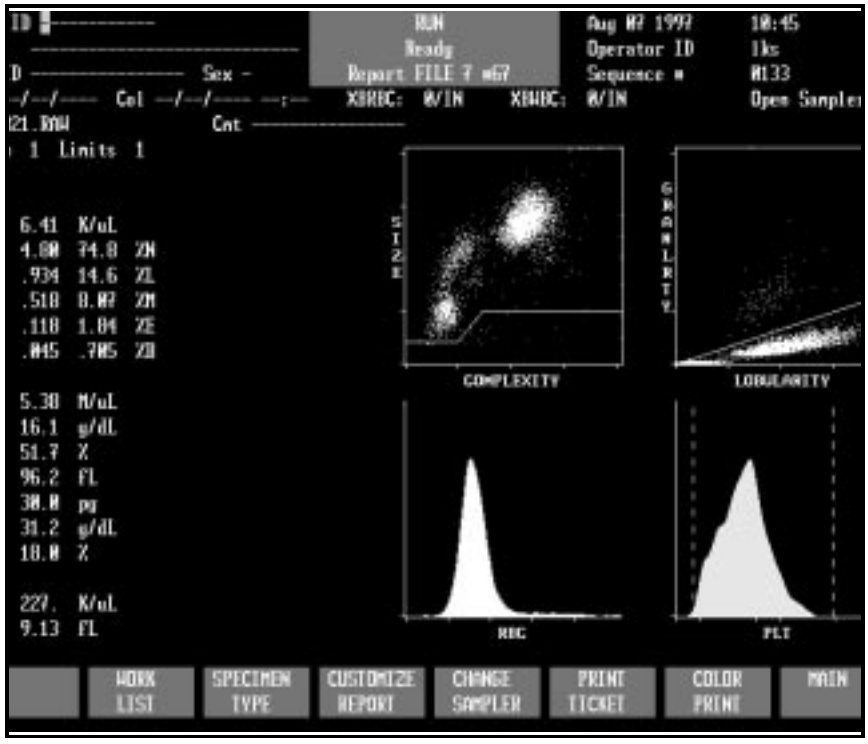

Figure 3.10: PLT Data and Histogram

All numeric and frequency size distribution data are automatically displayed on the RUN screen in the format selected. The size distribution data for the platelets is displayed graphically as a histogram with the size distribution data plotted on the X axis and the relative number of cells normalized and plotted on the Y axis. The PLT data and histogram are shown in Figure 3.10.

PLT Count

The **Platelet Count** is derived from the PLT histogram after the PLT data has been analyzed by the platelet algorithm. The PLT count is expressed as follows:

PLT = # x K/µL

MPV

The **Mean Platelet Volume** is derived from the PLT histogram after the PLT count has been determined. The MPV is expressed in femtoliters.

PCT

The **Plateletcrit** is the product of PLT and MPV and is analogous to the hematocrit. It is expressed in percent and is calculated as follows:

PCT = (PLT x MPV)/10

PDW

Platelet Distribution Width is a measure of the heterogeneity of the PLT population. It is expressed as the geometric standard deviation.

NOTE: Clinical significance has not been established for PCT and PDW. Therefore, they are not reportable.

Platelet Flagging

Refer to the "Operational Messages and Data Flagging" section of this chapter for PLT flagging information.

Hemoglobin Measurement

Overview

The HGB channel is used for the colorimetric determination of hemoglobin. During sample aspiration, 12 µL of sample is segmented in the Shear Valve for HGB measurement.

Before the HGB is measured, a reference value is obtained using the CD3200 Diluent/Sheath in the HGB Flow Cell. A zero or blank reading is obtained on the diluent to provide a reference to which the sample signal is compared. Five separate blank readings are made on each sample. The lowest and highest are eliminated and the remaining three are averaged to give the final HGB reference reading.

The Diluent/Sheath Syringe dispenses 2.29 mL of diluent/ sheath to the Shear Valve, transferring the HGB segment to the HGB Mixing Chamber. The HGB Lyse Syringe then dispenses 0.30 mL of HGB Lyse into the mixing chamber. The mixture is swirl mixed, resulting in a 1:216 dilution ratio. The HGB lyse reagent lyses the red blood cells, converting the hemoglobin that is released by a cyanide-free chemical process. When the lysing action is completed, a low-energy LED in the HGB Flow Cell, attached to the mixing chamber, measures the amount of absorbance which is proportional to the HGB concentration.

A LED with a wavelength of 540 nm is the light source. A photodetector measures the light that is transmitted.

Five separate HGB readings are made on each sample. The lowest and highest are eliminated and the remaining three are averaged to give the final HGB sample reading. After the hemoglobin readings have been made, the HGB Flow Cell is rinsed with diluent/sheath (in the normal run mode).

The reference and sample readings are compared to determine the HGB concentration of the sample. The HGB result is expressed in grams of hemoglobin per deciliter of whole blood. Up to two decimal places may be displayed for hemoglobin results less than 10 g/dL.

HGB Parameters

The Hemoglobin is directly measured and is expressed in grams of hemoglobin per deciliter of whole blood.

HGB Flagging

Refer to the "Operational Messages and Data Flagging" subsection of this section for HGB flagging information.

Laboratory Worksheet Screen

The LABORATORY WORKSHEET screen is provided to assist the laboratory staff in data review and validation (refer to Figure 3.11.) This screen is for laboratory use only. This screen displays the 5-Part Differential plus additional parameters. The RUN and DATA LOG screens display only the 5-Part Differential. The difference between the two formats is shown in Tables 3.1 and 3.2.

NOTE: The parameters MON and LYM have an "e" after the label, indicating that the values are estimated. MONe represents monos minus blasts. LYMe represents reported lymphs minus variant lymphs.

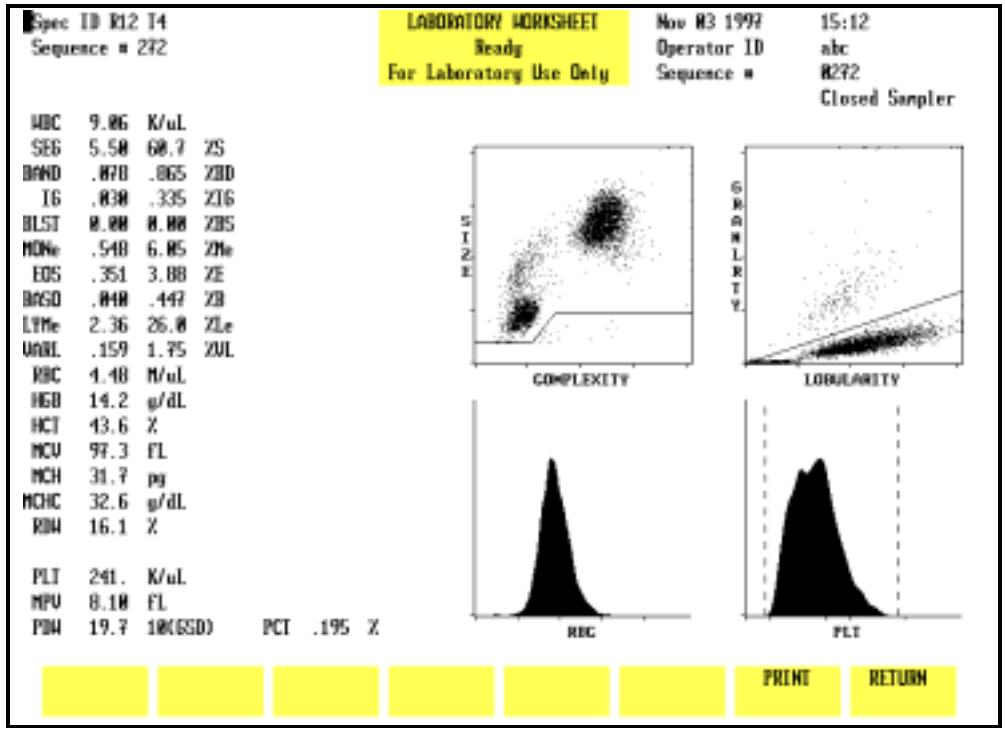

Figure 3.11: Laboratory Worksheet Screen

To access the LABORATORY WORKSHEET screen, press the Page Down key on the keyboard while the RUN menu is displayed or while the DISPLAY SPECIMEN screen (in the DATA LOG menu) is displayed. The format is fixed and cannot be changed. The specimen displayed on the screen is identified by the Specimen ID number and Sequence number in the upper left corner of the screen.

To print the LABORATORY WORKSHEET screen, press the [PRINT] soft key or the Print Screen key on the keyboard. Press [RETURN] to return to the RUN menu or DISPLAY SPECIMEN screen (in DATA LOG menu), depending on which menu was used to access the worksheet.

The 5-Part Differential separates WBC into 5 components: Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophils. The additional parameters further separate the Neutrophils, Lymphocytes, and Monocytes into their constituent components. Eosinophils and Basophils are the same in both tables.

Table 3.1: 5-Part Differential

	Parameter	Results (K/µL)
	WBC	11.15
1	NEU	5.91
2	LYM	3.16
3	MONO	2.06
4	EOS	0.02
5	BASO	0.00

Table 3.2: 5-Part Differential Plus Additional Parameters

	Parameter	Results (K/µL)
	WBC	11.15
	NEU	5.91
1	SEG	4.80
2	BAND	0.00
3	IG	1.11
	LYM	3.16
4	LYMe	2.01
5	VARL	1.15
	MONO	2.06
6	BLST	1.69
7	MONe	0.37
8	EOS	0.02
9	BASO	0.00

NOTES

Operational Messages and Data Flagging

Introduction

Operational messages and data flags appear on the RUN screen, on printed reports and can be transmitted to a laboratory computer system. The CELL-DYN 3200 monitors instrument conditions and data criteria that may affect the displayed results and these messages and flags are used to alert the operator. Instructions for interpreting all flags, and numeric, scatter and histogram data should be incorporated into the laboratory's procedure and used to determine the need for further action and/or review of results. Messages are divided into the following categories:

Instrument Messages:

- Fault Conditions
- Status Conditions

Parameter Flagging Messages:

- Dispersional Data Alerts
- Suspect Parameter Flags
- Suspect Population Flags
- Interpretive Messages

Detailed descriptions of the messages in each of the categories are given in this section.

Instrument Fault and Status Conditions

The Instrument Fault and Status conditions are discussed in Tables 10.1 through Table 10.4 in **Section 10: *Troubleshooting and Diagnostics***, **Subsection: *Troubleshooting Guide***. These messages are displayed when the instrument detects an inappropriate condition during specimen processing. When necessary, data is suppressed. When any of these messages are displayed, refer to the ***Troubleshooting Guide*** for assistance. Follow the instructions given and take the appropriate corrective action. When the problem is corrected, repeat the specimen.

Cell Populations and Flagging

Fragile WBCs

Typically, fragile WBCs are abnormal lymphocytes that are present in chronic lymphocytic leukemia (CLL) and are the "smudge cells" that appear when the blood smear is made.

When processing samples in the Patient mode (Patient is selected as the Specimen Type in the RUN screen), if fragile WBCs are present the WBC (WOC) count may be abnormally low due to the gradual destruction of the cytoplasmic membrane of these fragile cells by the lysing agents during the Run cycle.

If there is no significant stroma interference (< 2.9% of the total WOC count) or if LYM% > 80% and cell count > 4.0K/µl, the FWBC flag is displayed, alerting the user to run the specimen in the Fragile WBC mode (Fragile WBC is selected as the Specimen Type). The Fragile WBC mode utilizes the HGB sample segment which contains the intact nuclei of the WBCs to obtain a more accurate count of this cell type.

Lyse-Resistant RBCs

Resistant RBCs are red blood cells which contain abnormalities or whose membranes have been altered, making them more resistant to the lysing process.

When running samples in the Patient mode, the hypo-osmotic lysing ability of the WBC Lyse reagent is usually insufficient to lyse any lyse-resistant RBC cells, if present, in the time allotted for the WBC count. Consequently, the unlysed RBCs may be erroneously included in the WBC count, resulting in a falsely elevated count.

In normal patient samples, lyse-resistant RBCs are either absent or their number is negligible. In patient samples with a significant number of lyse-resistant RBCs, usually there is also a significant amount of stroma interference (> 2.9% of the total WOC count) present in the N1 region below the dynamic WOC threshold on the 0º / 10º scatterplot.

When the stroma interference > 2.9% of the total WBC count and other conditions are met, the RRBC (Resistant RBC) flag is displayed, alerting the user to run the specimen in the Resistant RBC mode (Resistant RBC is selected as the Specimen

Type). The WBC lyse time is extended, allowing for a complete lysing of the lyse-resistant RBCs to obtain an accurate WBC count.

Parameter Flagging Messages

Table 3.3 summarizes all of the parameter flagging messages by parameter and category.

Table 3.3: Parameter Flagging Messages

Parameter	Dispersional Data Alerts	Suspect Parameter Flags	Suspect Population Flags	Interpretive Messages
WBC	Result displays in yellow if below lower limit Result displays in purple if above upper limit Result underlined on graphics printout when limits exceeded Result underlined on blank ticket when limits exceeded Result marked with asterisk (*) on preprinted ticket when results exceeded	WBC	NWBC FWBC NRBC RRBC	Leukopenia Leukocytosis
Differential **NEU** **LYM** **MONO** **EOS** **BASO**	Same as WBC	DFLT (NLMEB)	BAND IG BLAST VARIANT LYM	Neutropenia Neutrophilia Lymphopenia Lymphocytosis Monocytosis Eosinophilia Basophilia
RBC **HGB** **MCV** **RDW**	Same as WBC		RBC MORPH	Anemia Polycythemia Microcytic RBC Macrocytic RBC Hypochromic Hyperchromic Anisocytosis
PLT **MPV**	Same as WBC	LRI URI LURI	The MPV value is suppressed (not displayed or printed) if an LRI, URI, or LURI condition exists.	Thrombocytopenia Thrombocytosis Microcytic PLT Macrocytic PLT

Dispersional Data Alerts

These alerts are triggered by the numeric limits entered into the four Patient Limit Sets (see **Section 5: *Operating Instructions*, Subsection: *Set Up Instructions*** for an explanation) or taken from the instrument's preset linearity limits. If results for a parameter exceed these limits, they are flagged on the screen and on the report. Dispersional alerts are displayed or printed as follows:

Screen display:	Result below lower limit shown in yellow Result above upper limit shown in purple Linearity Exceeded: Result displayed as >>>
Graphic Report:	Results outside limits are underlined
Blank Ticket:	Results outside limits are underlined
Preprinted Ticket:	Results outside limits are marked with an asterisk

Specimens with results that exceed the linearity should be diluted with diluent/sheath according to the laboratory's procedure and repeated. (Be sure to correct the results for the dilution factor used.)

> **NOTE:** MCV, MCH, MCHC and MPV are unaffected by dilution and do not require correction.

Suspect Parameter Flags

These flags are generated after the instrument evaluates the measured data for a particular parameter or group of parameters. The result may be suspect due to interfering substances or the inability of the instrument to measure a particular parameter due to a sample abnormality. The name of each flag, the location of the flag on the display, the cause of the flag and action to be taken are given in the following explanations.

Introduction to WBC Flagging

There are two WBC parameter flags: WBC and DFLT(NLMEB). The following WBC population flags may be displayed: NWBC, FWBC, NRBC, RRBC, BAND, IG, BLAST, VAR LYM. If any of the WBC or parameter flags is displayed, the message SUSPECT is displayed under and to the right of the Limits field on the RUN and LABORATORY WORKSHEET screens. This message also appears on printouts.

WBC Flags

WBC — displayed next to the WBC result

Cause	Action
WBC result exceeds the expected limits and one or both of the following conditions: 1. A declining kinetic rate was detected for WBC. 2. More than 10% of the WBC count was located in the stroma region. This situation is typically caused by lytic-resistant RBCs interfering with the WBC measurement.	Repeat the specimen using the Resistant RBC lyse cycle to eliminate interference caused by lytic-resistant RBCs. If the WBC flag persists, review a stained smear for the presence of NRBCs and verify the LYM and WBC values.

DFLT (NLMEB) — displayed next to the BASO %

Causes	Action
1. A default (preset) value or threshold was used to determine the five-part differential. This is typically due to the presence of abnormal cell clusters that the instrument cannot reliably discriminate between and therefore, a default threshold is selected. The flag may also be caused by an abnormally low number of cells in a specific subpopulation. 2. A declining kinetic rate for WBC.	Examine a stained smear to verify the differential values for the subpopulations identified by the descriptive information.

NOTE: The DFLT flag is always accompanied by additional descriptive information, NLMEB, in brackets. These letters indicate which subpopulation or group of subpopulations is suspect when the DFLT flag is displayed. (N = Neutrophils, L = Lymphocytes, M = Monocytes, E = Eosinophils, B = Basophils)

PLT Flags

LRI (Lower Region Interference) — displayed next to the MPV result

Cause	Action
Interference in the lower threshold region (1–3 fL) is greater than a predetermined limit. This is generally non-biologic interference. The flag may be caused by: Debris (Flow Cell) Contaminated reagent Microbubbles	Check the background count. If it exceeds the limits, troubleshoot accordingly. If it is within limits, repeat the specimen. If the flag persists, review a stained smear to determine the cause of the interference and verify the PLT count.

URI (Upper Region Interference) — displayed next to the MPV result

Cause	Action
Interference in the upper threshold region (15–35 fL) is greater than a predetermined limit. This is generally biologic interference. The flag may be caused by: Microcytic RBCs Schistocytes Giant Platelets Sickle Cells Platelet Clumps **NOTE:** A "bumpy" platelet histogram may indicate the presence of platelet clumps.	Review the MCV and the PLT histogram. If the MCV is low and/or the histogram indicates an overlap (poor separation at the upper discriminator) in the RBC and PLT populations, review a stained smear to determine the cause and confirm the PLT count.

LURI (Lower and Upper Region Interference) — displayed next to the MPV result

Cause	Action
Interference is present in both the upper and lower regions of the PLT histogram.	Follow the guidelines given above for the LRI and URI flags.

Suspect Population Flags

These flags are generated when the instrument's evaluation of the measured data for a particular parameter or group of parameters indicates the possible presence of an abnormal subpopulation. A stained smear should be reviewed whenever a suspect population flag is present. Therefore, instructions for interpreting these flags should be incorporated into the laboratory's review criteria for abnormal samples.

WBC Flags

BAND — displayed next to the NEU %

Cause	Action
1. The count in the region of scatter (on the 0°/10° plot) where bands are typically located is >12.5% of the total WBC count. 2. The ratio of suspected bands to mature neutrophils is >50%. 3. The CV of the neutrophil cluster on the 0° axis exceeds expected criteria.	Review a stained smear for the presence of bands and follow your laboratory's review criteria. When bands are present, they are included in the total neutrophil count.

IG (Immature Granulocyte) — displayed next to the NEU %

Cause	Action
The count in the region of scatter (on the 0°/10° plot) where immature granulocytes are typically located is >3% of the total WBC count.	Review a stained smear for the presence of immature granulocytes and follow your laboratory's review criteria. When IGs are present, they are included in the total neutrophil count.

BLAST — displayed next to the LYM %

Causes	Action
1. The count in the region of scatter (on the 90°/0° plot) where blasts are typically located is >1% of the total WBC count. 2. The MONO % is >20% of the total WBC count. 3. The MONO % is >3% of the total WBC count and the standard deviation of the monocytes on the 0° axis exceeds expected criteria.	Review a stained smear for the presences of blasts and follow your laboratory's review criteria. When blasts are present, they are typically included in the monocyte count.

VARIANT LYM — displayed next to the LYM %

Cause	Action
The position, density or CV of the lymphocyte cluster on the size/complexity (0°/10°) scatter plot exceeds expected criteria.	Review a stained smear for the presence of variant lymphocytes and follow your laboratory's review criteria. When VARIANT LYMs are present, they are included in the lymphocyte count.

NOTE: This flag may be displayed singly or in combination with the blast flag. If the flag is displayed with the blast flag it is displayed as VARL/BLAST.

NWBC (Non-White Blood Cells) — displayed next to the MONO %

Cause	Action
A non-WBC population is present in the N1 region below the dynamic WBC threshold on the size/complexity (0°/10°) scatter plot. The count in the N1 region is greater than 2.9% of the total WBC. The cell types that may be present in the N1 region are: Low levels of NRBCs Unlysed RBCs PLT clumps Giant PLTs	Review a stained smear and follow your laboratory's review criteria to determine the cause of the elevated count in the N1 region. Correction of the WBC count is not required. If no suspect parameter flags are present, the WBC and Differential may be reported.

FWBC (Fragile White Blood Cells) — displayed next to the MONO %

Cause	Action
The presence of fragile WBCs is suspected.	Select Fragile WBC as the Specimen Type and rerun the sample. The NOC value is always displayed as WBC on the RUN screen and LABORATORY WORKSHEET screen. Review a stained smear and follow your laboratory's review criteria to confirm the LYM values.

NRBC — displayed next to the MONO %

Cause	Action
1. The WBC result exceeds the expected limit. 2. The count in the area below the WBC threshold on the size/complexity (0°/10°) scatter plot is >2.9% of the total WBC count.	Review a stained smear for the presence of NRBCs and follow your laboratory's review criteria. If NRBCs are present, they should be quantified according to your laboratory's procedure. Correction of the WBC count is not required. If the WBC flag is displayed with the NRBC flag, repeat the specimen using the Resistant RBC cycle to eliminate interference from any lytic-resistant RBCs that may be present with the NRBCs.

RRBC (Resistant Red Blood Cells) **—** displayed next to the MONO %

Cause	Action
The presence of lyse-resistant RBCs is suspected.	Repeat the specimen using the Resistant RBC cycle to eliminate interference from any lytic-resistant RBCs that may be present. Either the NOC or WOC value is displayed as WBC on the RUN screen and LABORATORY WORKSHEET screen. If the WBC flag is displayed, review a stained smear to determine the cause of the interference. Verify the WBC value by an alternate method according to your laboratory's protocol.

RBC Flags

RBC MORPH — displayed next to the HCT result

Cause	Action
One or more of the following parameters exceeds expected limits: MCV <80fL or >100fL MCH <25pg or >34pg MCHC <29g/dL or >37g/dL RDW >18.5%	Review a stained smear for abnormal RBC or PLT morphology and follow your laboratory's review criteria.

PLT Flags

No MPV result displayed (data suppressed)

Cause	Action
The PLT histogram did not meet expected criteria (non-log normal distribution).	Review a stained smear for abnormal PLT morphology or the presence of PLT aggregates and follow your laboratory's review criteria. Verify the PLT count.

Interpretive Messages

Interpretive messages appear only on the graphics report and are generated when the numeric limits entered in the Patient Limit Sets are exceeded. (see **Section 5, Subsection: *Set Up Instructions*** for an explanation). These messages are printed only when the Interpretive Report option is selected on the CUSTOMIZE REPORT SCREEN. The Interpretive messages are summarized below.

WBC Messages

Message	Cause
Leukopenia	result exceeds the lower limit for WBC
Leukocytosis	result exceeds the upper limit for WBC
Neutropenia	result exceeds the lower limit for Neutrophil absolute number
Neutrophilia	result exceeds the upper limit for Neutrophil absolute number
Lymphopenia	result exceeds the lower limit for Lymphocyte absolute number
Lymphocytosis	result exceeds the upper limit for Lymphocyte absolute number
Monocytosis	result exceeds the upper limit for Monocyte absolute number
Eosinophilia	result exceeds the upper limit for Eosinophil absolute number
Basophilia	result exceeds the upper limit for Basophil absolute number

RBC Messages

Message	Cause
Anemia	result exceeds the lower limit for RBCs
Polycythemia	result exceeds the upper limit for RBCs
Microcytic RBC	result exceeds the lower limit for MCV
Macrocytic RBC	result exceeds the upper limit for MCV
Hypochromic	result exceeds the lower limit for MCHC
Hyperchromic	result exceeds the upper limit for MCHC
Anisocytosis	result exceeds the upper limit for RDW

PLT Messages

Message	Cause
Thrombocytopenia	result exceeds the lower limit for PLTs
Thrombocytosis	result exceeds the upper limit for PLTs
Microcytic PLT	result exceeds the lower limit for MPV
Macrocytic PLT	result exceeds the upper limit for MPV

References

1. ICSH, *The Assignment of Values to Fresh Blood Used for Calibrating Automated Cell Counters*, Clinical and Laboratory Hematology 1988, 10:203-212.
2. *Clinical Applications of Flow Cytometry,* ASCP National Meeting, Spring 1990.
3. Shapiro, Howard, *Practical Flow Cytometry*, 1984.

NOTES

Overview

This section is a collection of detailed information about the CELL-DYN® 3200 System.

Included in this section are:

- Physical Specifications
- Operational Specifications
- Bar Code Specifications
- Measurement Specifications
- Performance Specifications
- Performance Characteristics
- Sample Loader Specifications

Specifications for the Host Interface (LN 06H71-01) are not included in this section but can be ordered by calling Abbott Customer Support Center at 1 (800) 323-9100.

NOTES

System Specifications

Physical Specifications

Tables 4.1 and 4.2 contain physical specifications for both the CELL-DYN 3200SL and CS models.

Table 4.1: Instrument Dimensions

	Analyzer SL	Analyzer CS	Display Monitor	Ticket Printer (Dot Matrix)	Graphics Printer (Color Bubble Jet)
Height	19" (48.2 cm)	19" (48.2 cm)	15" (38.1 cm)	6" (15.2 cm)	7.2" (18.3 cm)
Width	32.8" (83.3 cm)	32.8" (83.3 cm)	14" (35.5 cm)	16.5" (41.9 cm)	16.1" (40.9 cm)
Depth	29.3" (74.4 cm)	23.3" (59.2 cm)	16" (40.6 cm)	14.5" (36.8 cm)	9.9" (25.1 cm)
Weight	232 lb (105.5 kg)	214 lb (97.3 kg)	30 lb (13.6kg)	16.5 lb (7.5 kg)	9.9 lb (4.5 kg)

Table 4.2: Dimensions After Packaging for Shipment

	Analyzer SL	Analyzer CS	Display Monitor	Ticket Printer (Dot Matrix)	Graphics Printer (Color Bubble Jet)
Height	38" (96.5 cm)	38" (96.5 cm)	20" (50.8 cm)	9.5" (24 cm)	12" (30.5 cm)
Width	34" (86.3 cm)	34" (86.3 cm)	18" (45.7 cm)	21" (53 cm)	19.5" (49.5 cm)
Depth	31" (78.7 cm)	31" (78.7 cm)	18" (45.7 cm)	18.5" (46 cm)	14.8" (37.6 cm)
Weight	273 lb (124 kg)	255 lb (116 kg)	37.5 lb (17 kg)	21 lb (9.5 kg)	16.4 lb (7.4 kg)

Power Specifications

Table 4.3 shows the power requirements for both the CELL-DYN 3200 SL and CS models.

Table 4.3: Power Specifications

Analyzer Input Requirements			
Module	**Voltage**	**Frequency**	**Max Current**
Analyzer	110 VAC ± 10% 120 VAC ± 10% 220 VAC ± 10% 240 VAC ± 10%	50/60 ± 3Hz 50/60 ± 3Hz 50/60 ± 3Hz 50/60 ± 3Hz	6 amps 6 amps 3 amps 3 amps
Analyzer & Sample Loader	110 VAC ± 10% 120 VAC ± 10% 220 VAC ± 10% 240 VAC ± 10%	50/60 ± 3Hz 50/60 ± 3Hz 50/60 ± 3Hz 50/60 ± 3Hz	6 amps 6 amps 3 amps 3 amps
Monitor	100–240 VAC	50/60 Hz	1.3 amps
Printer	120 VAC ± 10% 220 - 260 VAC	50/60 Hz	0.5 amps

Operational Specifications

Operating Environment

Laboratory Temperature	15–30°C (59°–86°F)
Relative Humidity	20–80%, RHNC

Startup/Shutdown Times

Auto-Startup (from STANDBY)	Approximately 5.0 minutes
Auto-Startup (from power OFF)	Approximately 7.0 minutes*
Shutdown (to STANDBY)	10 minutes

* The laser requires a 15 minute warm up time. If the power has been OFF longer than 5 minutes, wait 10 minutes after the Auto-Startup cycle is complete before processing samples.

Run Cycle Times

Table 4.4 shows the Run cycle times for different specimen types run in the Open and Closed Modes on the CS and SL models.

Table 4.4: Instrument Run Cycle Times

CS and SL - Open Mode	
Specimen Type	**Cycle Times READY to READY**
Patient	45 seconds
QC, Fragile WBC, Resistant RBC	89 seconds
CS and SL - Closed Mode	
Specimen Type	**Cycle Times READY to READY**
Patient	53 seconds
QC, Fragile WBC, Resistant RBC	97 seconds

Approximate Aspiration Volumes (Whole Blood)

Open mode	120 µL
Closed mode	250 µL

Batch Size

Up to 50 tubes per batch

Throughput

Table 4.5 contains sample throughput information for the CELL-DYN 3200SL and CS.

Table 4.5: Sample Throughput (Patient Mode)

CS Model	Samples Per Hour
Open	80
Closed	68
SL Model	**Samples Per Hour**
Open	80
Closed	68

NOTE: Maximum throughput may be achieved with normal samples that do not generate any instrument operational messages.

Collection Tube and Sample Volume

13 mm diameter x 75 mm high collection tubes

- Minimum sample volume $\geq$ 1 mL
- Maximum sample volume $\simeq$ 3 mL (Sample Loader)

  NOTE: The sample volume in the tube must be within the specified limits for adequate mixing and sampling.

Bar Code Specifications — CELL-DYN 3200SL

Bar Code Format

The following formats with or without check digits are acceptable:

- Code 39
- Code 128 (check digit only)
- Interleaved 2 of 5
- Codabar

Bar Code Label Specifications

Refer to Appendix A and ANSI specifications for complete information on bar code label formats, check digits and specifications.

Measurement Specifications — CELL-DYN 3200SL and CS

Measurement Channels

Laser optics for WBC and RBC/PLT

Hemoglobin Absorbance

WBC (WOC)

Method	Laser light scatter
Light source	Vertically polarized 5-10 mW helium-neon laser
Wave length	632.8 nm
Dilution	1:49 of blood in diluent
Data Collection	Four angles measured: 0°, 10°, 90°, and 90° depolarized. Data collected in 256 channels for each angle of light scatter

WBC (NOC)

Method	Laser light scatter

Light source	Vertically polarized 5-10 mW helium-neon laser
Wave length	632.8 nm
Dilution	1:216 of blood in diluent and HGB Lyse
Data Collection	Four angles measured: 0°, 10°, 90°, and 90° depolarized. Data collected in 256 channels for each angle of light scatter

RBCs and PLTs

Method	Laser light scatter
Light source	Vertically polarized 5-10 mW helium-neon laser
Wave length	632.8 nm
Dilution	1:1,677 of blood in diluent
Data Collection	Four angles measured: 0°, 10°, 90°, and 90° depolarized. Data collected in 256 channels for each angle of light scatter

HGB

Method	Modified methemoglobin
Light Source	LED, wavelength: 555 nm
Filter	Interference Filter Center wavelength: 540 nm Bandwidth at 1/2 peak: 22 nm
Wavelength	540 nm
Dilution	1:216 of blood in diluent and HGB Lyse
Data Collection	Average of 5 absorbance readings for the blank, average of 5 absorbance readings for the sample dilution

Performance Specifications

Background Counts

Background counts for the following parameters are acceptable up to the limits listed:

WOC ≤0.10 K/µL

NOC ≤0.10 K/µL

RBC ≤0.02 M/µL

HGB ≤0.10 g/dL

PLT ≤5.0 K/µL

Carryover

Carryover, shown in Table 4.6, is the degree of influence the previous sample has on the next sample and is expressed as a percent. Fresh whole blood samples that are used to verify carryover specifications should have results that fall within the laboratory's reference interval (normal range). Each sample is run in triplicate followed by three background cycles. The percent carryover is calculated using the following formula:

$$\% \text{ Carryover} = \frac{\text{Background}_1 - \text{Background}_3}{\text{Sample}_3 - \text{Background}_3} \times 100$$

$$\text{Absolute Carryover} = \text{Background}_1 - \text{Background}_3$$

Table 4.6: Carryover for WOC, NOC, RBC, HGB and PLT

Parameter	Specimen Range	Carryover
WOC	4.1–11.0 x K/µL	≤ 1% or 0.1 K/µL
NOC	4.1–11.0 x K/µL	≤ 1% or 0.1 K/µL
RBC	4.0–6.0 x M/µL	≤ 1% or 0.03 M/µL
HGB	12.1–17.0 g/dL	≤ 1% or 0.1 g/dL
PLT	150.0–400.0 x K/µL	≤ 1% or 6 K/µL

Precision

Precision is the measurement of how closely the instrument is able to reproduce the same results from repeated runs of the same sample.

Tables 4.7 and 4.8 present the limits of acceptable precision for specimens run in both the Open and Closed modes. The stated CV% in these tables represents the instrument's precision at a 95% confidence level from N=20 replicate runs based on the same sample.

> **NOTE:** 95% confidence limit means that at least 19 of the 20 determinations meet this limit.
>
> **NOTE:** N=20 is based on one whole blood sample aliquotted into 4 tubes, with each tube run 5 times in closed mode.

Fresh whole blood samples that are used to verify precision specifications should have results that fall within the laboratory's normal range. These samples should not display any of the following suspect parameter flags:

WBC

LRI

URI

LURI

The precision values listed in this section are applicable to Patient, Fragile WBC, and Resistant RBC (Open mode only) specimen types.

Hemogram Parameters

Precision specifications for the hemogram parameters are presented using coefficient of variation (CV).

The stated CV% in Table 4.6 represents the instrument precision at a 95% confidence level from N = 20 replicate runs based on the same sample.

Table 4.7: Precision of the Hemogram Parameters (N = 20)

Parameter	Specimen Range	CV
WBC WOC	4.1–11.0 x K/µL	≤ 2.7%
WBC (NOC)	4.1–11.0 x K/µL	≤ 2.7%
RBC	4.0–6.0 x M/µL	≤ 1.5%
HGB	12.1–17.0 g/dL	≤ 1.0%
MCV	81.0–100.0 fL	≤ 1.0%
RDW	12.0–16.0%	≤ 5.0%
PLT	150.0–400.0 x K/µL	≤ 4.0%
MPV	5.0–10.0 fL	≤ 5.0%

WBC Differential Parameters

Precision specifications for the WBC Differential parameters are given as a 95% confidence limit for N=20 replicate runs based on the same sample.

This confidence limit represents the allowable difference (plus or minus) of the individual results from the mean of the 20 determinations (runs). Specimens selected for the precision study must have means that fall within the specimen range listed in both tables.

These samples should not display any of the following suspect Parameter Flags: WBC or DFLT.

To determine the 95% confidence limit of a parameter:

1. Find the value listed in the Confidence Limit column for that parameter.
2. Add that value to the mean to determine the upper limit.
3. Subtract that value from the mean to determine the lower limit.

For example, if the mean of the Neutrophil parameter is 50, the 95% confidence limit is 47.9–52.1.

Table 4.8: Precision of the WBC Differential Parameters (N=20)

Parameter	Specimen Range %	95% Confidence Limit
Neutrophil %	46–75	± 2.2
Lymphocyte %	20–45	± 2.8
Monocyte %	3.5–11.5	± 2.7
Eosinophil %	0.5–8.0	± 1.0
Basophil %	0.5–2.0	± 1.0

Linearity

Linearity specifications are determined by analyzing dilutions of a linearity material that contains no interfering substances and displays no suspect parameter flags. Specifications are determined by taking multiple measurements on each dilution to minimize the effect of imprecision. The stated limits are determined by regression analysis with the line going through the origin (0,0). Table 4.9 contains the linearity specifications for the hemogram parameters.

Table 4.9: Linearity Specifications

Parameter	Linear Range	Absolute Deviation	Relative Deviation
WOC (WBC)	0.0–250 K/µL	± 0.4	4.0%
NOC (WBC)	0.0–250 K/µL	± 0.4	4.0%
RBC	0.00–8.00 M/µL	± 0.1	2.5%
HGB	0.0–25.0 g/dL	± 0.3	2.0%
MCV	35.0–180 fL	± 2.0	2.0%
PLT	0.0–1750 K/µL	± 10.0	7.0%
MPV	2.0–18.0 fL	± 1.0	9.0%

For MCV and MPV, three bead sizes were analyzed and the method of least-squares regression (not forcing the intercept through zero) was used for analysis of the data. It should be noted that the reference diameters of the latex particles were calculated by the manufacturer using electronic impedance volume analysis. The optical analysis on the CELL-DYN 3200 is sensitive to the refractive index of the latex particles and although the relationship is linear, a regression through zero is not possible.

Correlation

The CELL-DYN 3200 system can be calibrated to agree with reference values within the allowable calibration ranges. Both modes of operation, Open and Closed (CS and SL) may be calibrated. Thus, it is possible to compensate for differences between modes due to differing aspiration pathways or operational sequences. When each mode is properly calibrated according to the directions given in this manual, bias between the modes is clinically insignificant.

Accuracy specifications are determined by correlation to reference values obtained from comparison analyzers or analysis by reference methodology. Samples that are used for correlation studies should not display any suspect parameter flags.

Tables 4.10 and 4.11 demonstrate the accuracy of the hemogram parameters and WBC Differential parameters respectively.

Hemogram Parameters

Table 4.10: Accuracy of Hemogram Parameters

Parameter	Correlation Coefficient
WBC (WOC)	≥ 0.99
WBC (NOC)	≥ 0.99
RBC	≥ 0.98
HGB	≥ 0.98
MCV*	≥ 0.98
RDW	≥ 0.91
PLT	≥ 0.98
MPV*	≥ 0.72

* Correlation against the Technicon H·3 Systems (optical method).
Correlation against the CELL-DYN® 4000 (impedance method) was 0.90 for MCV and 0.59 for MPV.

WBC Differential Parameters

Table 4.11: Accuracy of WBC Differential Parameters

Parameter	Correlation Coefficient
Neutrophil # and %	≥ 0.95
Lymphocyte # and %	≥ 0.94
Monocyte # and %	≥ 0.86
Eosinophil # and %	≥ 0.84
Basophil # and %	≥ 0.73

Comprehensive Flagging

Table 4.12: Flagging Analysis Using both the Distributional and Morphological Flags

Agreement True Negative and True Positive	> 80%
False Positives	< 20%
False Negatives	< 1%

Performance Characteristics

Typical Precision

Within Sample

The pooled precision values (CVs) for the Hemogram parameters, shown in Table 4.13, are based on the analysis of data from N = 20 replicate runs based on the same sample.

> **NOTE:** N=20 is based on one whole blood sample aliquotted into 4 tubes, with each tube run 5 times.

The data was obtained from several CD3200 systems over a period of weeks. These precision values represent the typical performance from instruments that are maintained properly, are operating in acceptable environmental conditions and are using only recommended reagents and supplies.

Table 4.13: Typical Precision of Hemogram Parameters

Parameter	CV
WBC (WOC)	1.9%
WBC (NOC)	1.9%
RBC	0.6%
HGB	0.4%
MCV	0.5%
RDW	2.3%
PLT	2.3%
MPV	1.8%

Typical Paired Difference Precision Normal

The typical paired difference precision of the measured parameters is presented as the total CV calculated from samples run in duplicate on the same system. (Refer to Table 4.14.)

Table 4.14: Typical Precision of Hemogram Parameters

Parameter	Number of Pairs	Total CV
WBC (WOC)	10	2.01
RBC	10	0.81
HGB	10	0.72
MCV	10	0.38
RDW	10	1.76
PLT	10	3.11
MPV	10	3.68
%N	10	1.23
%L	10	2.07
%M	10	7.72
%E	10	8.06
%B	10	16.82

Sensitivity and Specificity of WBC Differential Flags

The sensitivity and specificity of the WBC flags were evaluated using the general principles for morphological classifications outlined in the NCCLS H20-A Standard: "Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods" as a guideline. The statistics were determined by comparing the CELL-DYN 3200 System results with results obtained from a reference CELL-DYN 3500 System. Discrepant results were arbitrated with a manual, microscopic, 400-cell differential count.

Abnormalities

The following tables present a list of abnormalities targeted during this evaluation and the resultant data.

Table 4.15 lists the various types of specimens that the sites attempted to collect during this evaluation:

Table 4.15: Abnormalities

1. RBC count <4.00 M/mL	19. Lipemic
2. RBC count >6.20 M/mL_	20. Basophils >3%
3. WBC count <4.0 K/mL	21. Icteric
4. WBC count >11.0 K/mL	22. Hemoglobinopathies S and C
5. WBC count >100.0 K/mL	23. Containing macrocytic PLTs
6. PLT count <150 K/mL	24. Uremic
7. PLT count >450 K/mL	25. Paraproteinemia
8. MCV <60 fL	26. Patient's on immunosuppressant therapy
9. MCV >110 fL	27. Containing cryoglobulins
10. Containing RBCs resistant to lysis	28. Containing micro clots
11. Containing agranular neutrophils	29. Containing Cell fragments
12. Containing variant lymphocytes	30. Platelet satellitosis condition
13. Containing lymphoblasts	31. Containing cold agglutinins
14. Containing bands >5%	32. Containing dual RBC populations
15. Immature granulocytes (myelos, metas, pros)	33. Containing Heinz and Howell-Jolly Bodies
16. Containing myeloblasts/monoblasts	34. Containing Malarial Parasites
17. Containing > 1 NRBC per 100 WBCs	35. Containing >5.0% Reticulocytes
18. Hypogranular eosinophils	36. Chronic Lymphocytic Leukemia (CLL)

Truth Table

The Truth Table, showing sensitivity and specificity and the analysis of the false negative results, is presented in this section. For the distributional analysis, absolute limits were used. The data is based on the evaluation of a total of 853 cases.

In Table 4.16:

TP = True Positive
TN = True Negative
FP = False Positive
FN = False Negative

Table 4.16: Flagging Analysis Truth Table

	CD3200 Normal	CD3200 Morphological Positive	CD3200 Distributional Positive	Total
Reference Normal	455 TN	15 FP	0 FP	470
Reference Morphological Positive	1 FN	167 TP	13 TP	181
Reference Distributional Positive	1 FN	49 TP	147 TP	197

Agreement = 98.0%
False Positives = 3.19%
False Negatives = 0.53%
Specificity = 96.81%
Sensitivity = 99.47%

Table 4.17 shows the manual differential and CELL-DYN 3200 differential for false negative results.

Table 4.17: Analysis of False Negative Results

	Manual Differential	CD3200
Morphological False Negative	2.5% Immature grans and 3.5 NRBCs	No flag generated
	CELL-DYN 3500	**CD3200**
Distributional False Negative	WBC = 4.596	WBC = 4.71

Sample Loader Specifications

Sample Loader Physical Specifications

The Sample Loader attaches to the front of the CELL-DYN 3200SL Analyzer and is an integral part of the SL model. Table 4.18 contains the physical specifications for the Sample Loader.

Table 4.18: Sample Loader Physical Specifications

	Sample Loader (with skirt)
Height	6" (15.2 cm)
Width	32.5" (82.5 cm)
Depth	6.4" (16.2 cm)
Weight	18 lb (8.1 kg)

Sample Loader Operational Specifications

Operations specifications for the Sample Loader are given in Table 4.19.

Table 4.19: Sample Loader Operational Specifications

Feature	Specification
Rack Capacity	5 racks on the load side; 5 racks on the unload side
Tube Capacity	50 (10 tubes per rack)
Sample Throughput (1) Patient (2) FWBC, RRBC, QC	 (1) xx samples/hour (2) xx samples/hour
Run Cycle Time (1) Patient (2) FWBC, RRBC, QC	 56 seconds 90 seconds
Number of Mixing Stations	2 - Mixing Stations #1 and #2
Degree of Mixing Rotation	0 - 135 degrees
Number of Mixing Rotations	15 times at Mixing Station #1 15 times at Mixing Station #2
Maximum Tube Size	16mm (DIA) X 80mm (High)
Bar Code Reader	LED type
Bar Code Labels	Code 39, I2of5, Codabar, Code 128

For information on tube types and size, refer to ***Tube Types*** in **Section 13: *Sample Loader*, Subsection: *Physical & Performance Specifications***.

For information on bar codes types and operation, refer to **Appendix A: *Bar Codes***.

For general information on Sample Loader operation, refer to **Section 13, Subsection: *Sample Loader Description***.

Overview

This section, which discusses the operation of the CELL-DYN® 3200, is divided into six major subsections:

Data Module Program Overview

Set Up Instructions

Specimen Collection and Handling

Routine Operation

Sample Analysis

Work List

Using the Data Log

The three major menus in the program that are used for routine operation — SET UP, RUN, and DATA LOG — are discussed in this section. The remaining parts of the program are discussed in the following sections:

Calibration	Section 6:	Calibration Procedures
Special Protocols	Section 9:	Service and Maintenance
Troubleshooting	Section 10:	Troubleshooting and Diagnostics
Quality Control	Section 11:	Quality Control

NOTES

Data Module Program Overview

The Data Module menus are presented as key labels displayed across the bottom of the screen. Each menu is accessed by pressing the soft key located directly below the label. From left to right, these soft keys correspond to keys F1–F8 on the standard computer keyboard.

When the system is powered ON, the MAIN MENU screen, depicted in Figure 5.1, is displayed. The key labels displayed across the bottom of this screen are used to access all of the sub-menus that are available. The main menu keys are listed below.

MAIN MENU keys:

- SET UP
- RUN
- DATA LOG
- QUALITY CONTROL
- CALIBRATION
- DIAGNOSTICS
- SPECIAL PROTOCOLS

Main Menu Screen

The MAIN MENU screen is divided into four sections. The upper left-hand corner shows the current version of the Data Module software. The upper right hand corner shows the current date and time, operator ID and the sequence number. The information in the upper right corner is displayed on every screen during operation.

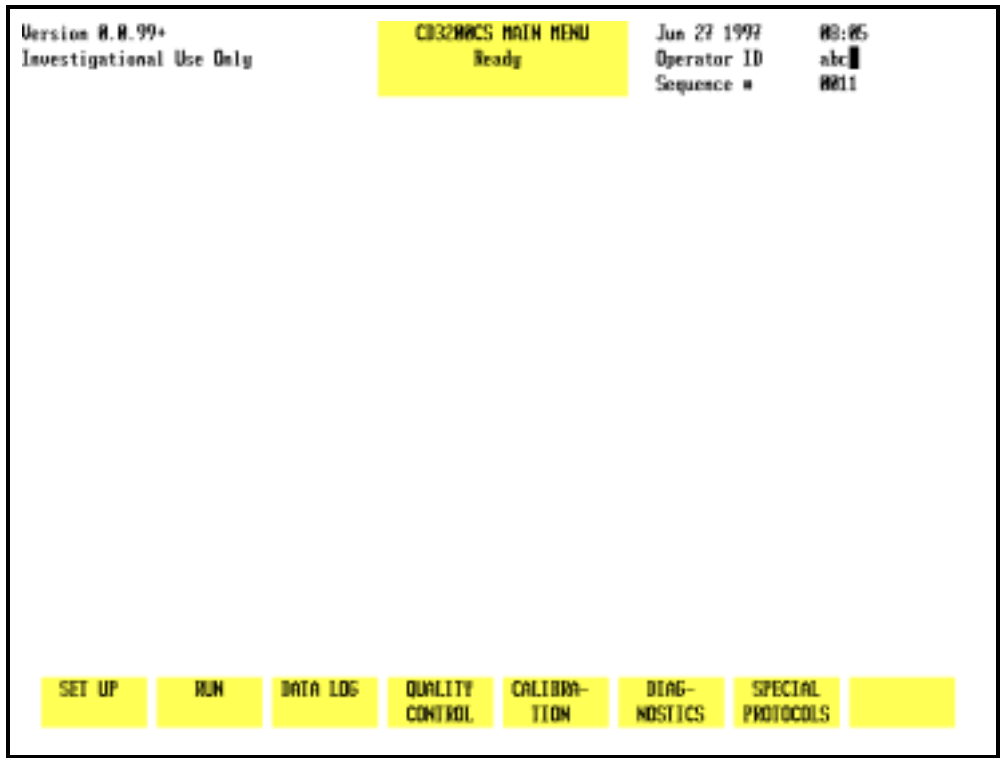

Figure 5.1: Main Menu Screen

NOTE: The cursor is positioned at the <OPERATOR ID> field when the MAIN MENU screen is displayed. An operator ID of up to three alphanumeric characters may be entered. (An operator ID may also be entered from the main CALIBRATION screen.) This operator ID will be displayed on all screens and printed on all reports.

The Status Box is displayed in the top center of the screen. This box appears on every screen to show the following:

Menu in use

Analyzer status

Other applicable information such as file identity, Sample ID number, and any existing fault conditions

The MAIN MENU key labels are displayed across the bottom of the screen.

Set Up Instructions

This section discusses the options available when the [SET UP] key is pressed. (See Figure 5.2.) These options are used to configure the system according to the laboratory's requirements. The function of each key is discussed and set up procedures are given where applicable.

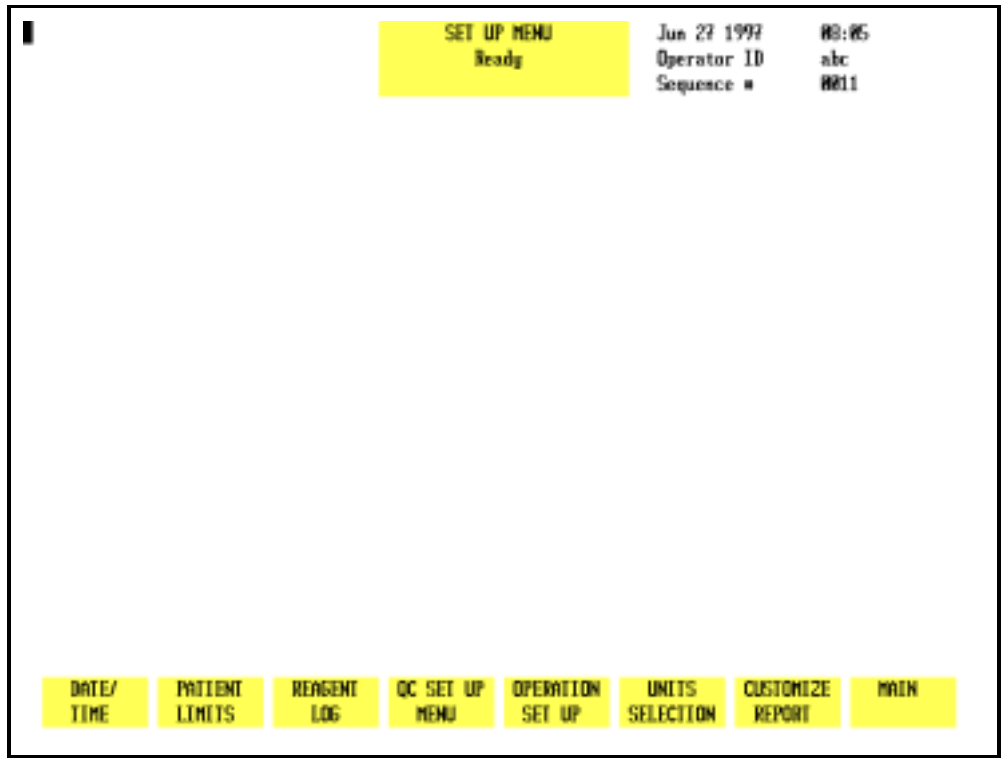

Figure 5.2: Set Up Menu Screen

Set Up Menu

When the [SET UP] key is pressed, the following soft key labels are displayed:

DATE/TIME
PATIENT LIMITS
REAGENT LOG
QC SET UP MENU
OPERATION SET UP
UNITS SELECTION
CUSTOMIZE REPORT
MAIN

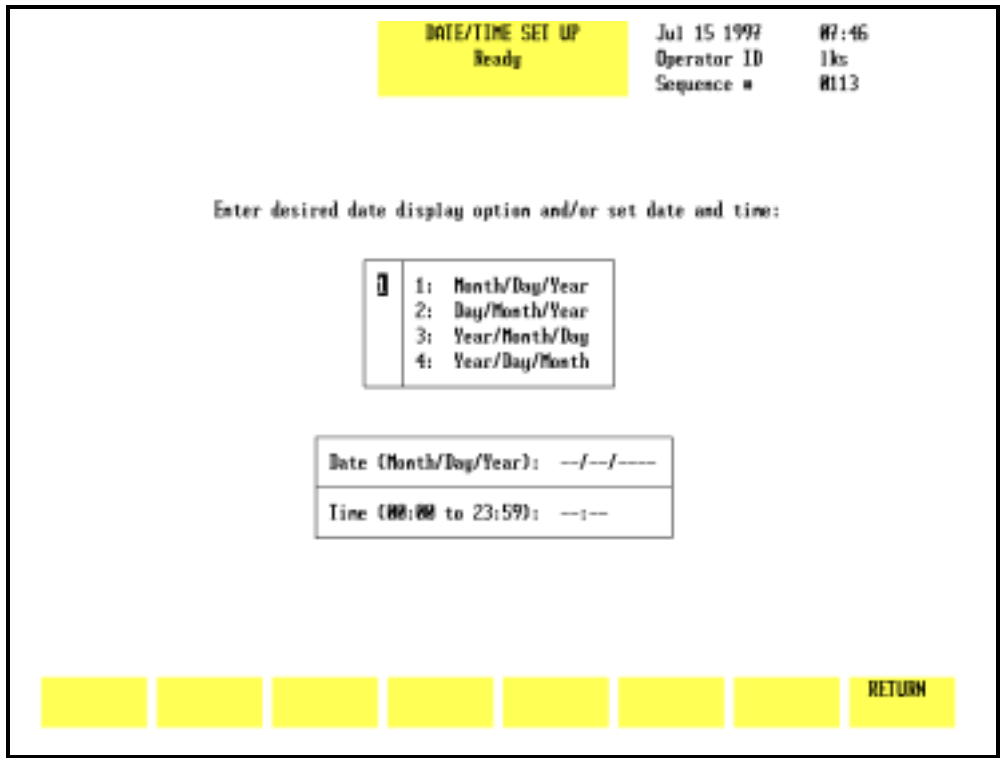

Figure 5.3: Date/Time Set Up Screen

Date/Time

The [DATE/TIME] key is used to enter the date and time. This screen allows the operator to select the format for displaying the date and to change the date and time as required. Four different date formats are available. The numbers on the DATE/TIME SET UP screen shown in Figure 5.3 correspond to the following numbered options:

1. Display Format selection box:
    1. Month/Day/Year
    2. Day/Month/Year
    3. Year/Month/Day
    4. Year/Day/Month
2. DATE entry field
3. TIME entry field

The desired format is selected by typing the corresponding number in the entry field displayed to the left of the list (1). When the Enter key on the keyboard is pressed, the selected format is displayed in the DATE entry field (2, below the format selection box) and the cursor moves to the entry position. After the date has been entered, the cursor moves to the TIME entry field (3).

To Set Date/Time

1. From the SET UP MENU screen, press [DATE/TIME] to display the DATE/TIME SET UP screen.
2. Type the number of the desired format at the cursor.
3. Press the Enter key on the keyboard to save the entry and advance to the DATE entry field.
4. Type the date in the selected format using one or two digits. Separate the day, month and year (year must be 4 digits) with a slash (/) or a period (.). The entry order of the date should conform to the date format just selected.
5. Press the Enter key on the keyboard to save the entry and advance to the TIME entry field.
6. Type the time in the 24-hour (military) time format using one or two digits. (For example, 00 for 12 midnight, 06 for 6 am, and 13 for 1 pm.) Separate the hours and minutes with a colon (:) or a period (.).
7. Press the Enter key on the keyboard to save the entry.
8. Press [RETURN] to return to the SET UP MENU screen.

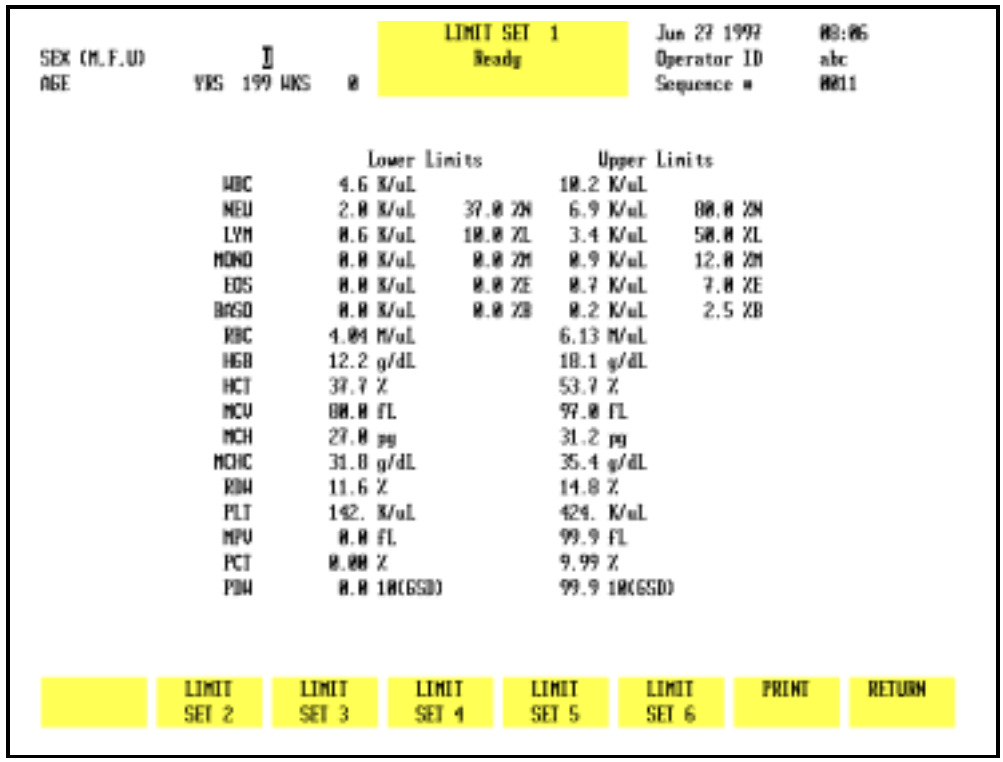

Figure 5.4: Patient Limits Screen

Patient Limits

The [PATIENT LIMITS] key is used to enter upper and lower flagging limits for groups of patient samples. (For example, limits may be entered for adult males, adult females, neonates, etc.) The following soft key labels are displayed (See Figure 5.4.) when the [PATIENT LIMITS] key is pressed:

LIMIT SET 1
LIMIT SET 2
LIMIT SET 3
LIMIT SET 4
LIMIT SET 5
LIMIT SET 6
PRINT
RETURN

NOTE: The key label for the limit set displayed on the screen is not shown.

Six different sets of limits may be entered. Whenever a parameter result exceeds an entered limit, the result is displayed in color on the screen to alert the operator. Results displayed in yellow are below the limit and results displayed in purple are above the limit. The flagged result is underlined on the graphics report and the blank ticket report. The flagged result is marked with an asterisk (*) on the pre-printed ticket report.

LIMIT SET 1 contains upper and lower limits pre-set at the factory. The operator shall be able to change these limits. Once these limits are changed, the operator can return to the factory-set limits by either manually inputting the factory-set limits or by re-installing the Set Up Disk.

LIMIT SETS 2 through 6 contain zeros for the lower limits and 9s for the upper limits when the instrument is first installed.

In addition to entering limit set data, the operator can also pre-assign limit sets to patients based on patient sex and age.

Automatic Patient Limit Set Assignment

Sex and Age fields for each Patient Limit Set are shown in the upper left corner of the LIMIT SET screen.

Limit Set 1 is the default Limit Set. It is assigned to any Patient without both an age and a sex designation or whose age and sex (if input) cannot be assigned by the system to a specific Limit Set. The operator cannot change the displayed data in the Sex and Age fields of Limit Set 1.

For Limit Sets 2 through 6, the operator can pre-assign a Limit Set based on age and sex. The options for Sex are:

M for Male

F for Female

U for Undefined (either the patient's sex is unknown or the Limit Set is intended to cover both male and female)

Patient age is entered in Weeks and/or Years. The range for Weeks is zero to 51. The range for Years is 1 to 199. Any number input shall be interpreted by the system as "equal to or less than." Age ranges are automatically established by using successively higher numbers. For example, if the number 1 is entered in the Years field for Limit Set 2 and the number 5 is entered in the Years field for Limit Set 3, then any patient whose age is 1 year or less will automatically be assigned Limit Set 2 and any patient whose age is greater than 1 year but equal to or less than 5 years will automatically be assigned Limit Set 3.

The appropriate Limit Set is automatically assigned when a patient's sex and date of birth are entered on the RUN screen or Work List.

To Set Patient Limits

1. Press [PATIENT LIMITS] to display the PATIENT LIMITS screen.

   A Patient Limit Set is displayed on the screen. When a Limit Set is displayed on the screen, the set number (Limit Set 1, Limit Set 2, etc.) is displayed in the status box and the soft key corresponding to that number is blanked out. The other limit sets may be selected by pressing the appropriate soft key.

2. Select a Limit Set by pressing the appropriate [LIMIT SET] soft key.

3. To pre-assign a Limit Set based on a patient's sex and age, enter one of the three Sex codes and press the Enter key. The cursor moves to the Years field. Enter a number for years and press Enter or use the arrow keys to move the cursor to the Weeks field. Enter a number for Weeks and press Enter or use the arrow keys to move the cursor to the desired limit entry field.

   NOTE: Limit Set 1 is the default Limit Set and cannot be altered.

4. With the cursor in the first entry field to be changed, type the desired number.

5. Press the Enter key on the keyboard to save the entry and automatically advance the cursor to the next entry position.

6. Repeat steps 4 and 5 until all desired entries have been made.

7. If desired, press [PRINT] to obtain a printout of the Limit Set.

   NOTE: Retaining a hard copy of each Limit Set is recommended, as the screens do not display names or categories for the limit sets.

8. Press the appropriate soft key to select another Limit Set and repeat steps 3–7 to pre-assign a Limit Set and to enter the desired limits.
9. Press [RETURN] to return to the SET UP MENU screen.

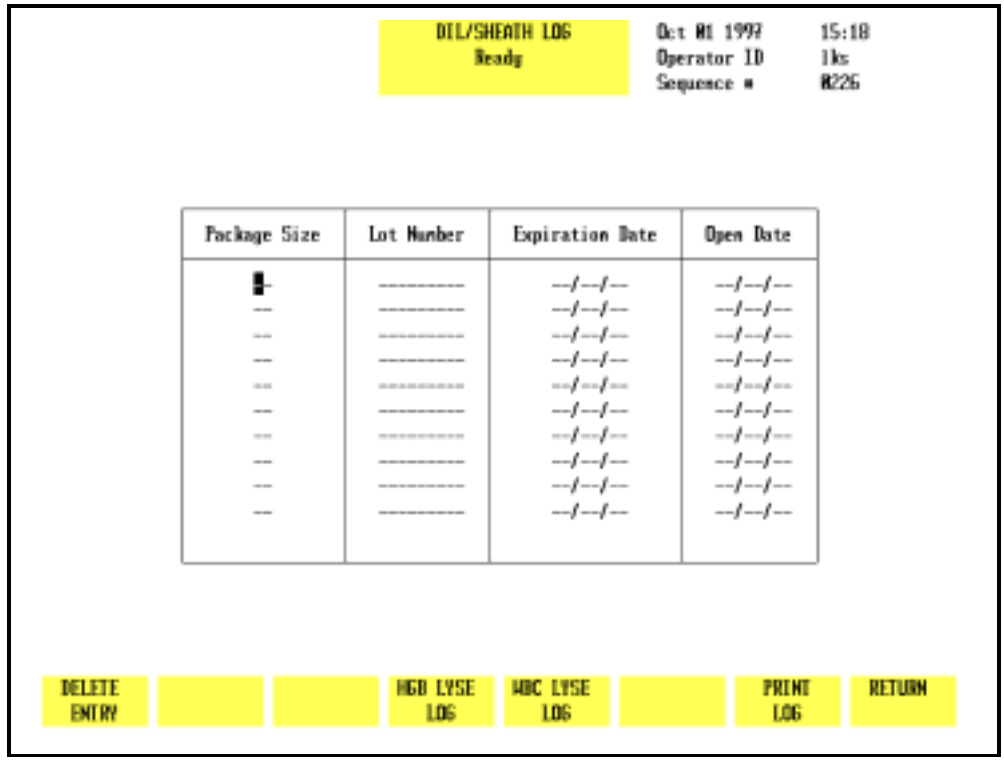

Figure 5.5: Diluent/Sheath Log Screen

Reagent Log

The [REAGENT LOG] key is used to enter current reagent information into the three reagent logs. The following soft key labels are displayed when the [REAGENT LOG] key is pressed:

DELETE ENTRY

DIL/SHEATH LOG

HGB LYSE LOG

WBC LYSE LOG

PRINT LOG

RETURN

NOTE: The key label for the reagent log displayed in the Status Box is not displayed with the other keys.

When the [REAGENT LOG] key is pressed, one of the logs is displayed as shown in Figure 5.5. (The name of the displayed log is indicated in the Status Box.) The other two logs may be displayed by pressing the appropriate soft key. Each log holds 10 entries. The following information may be entered for each reagent:

Package Size	Lot Number
Expiration Date	Open Date

To Complete Reagent Log Entry

1. Press [REAGENT LOG] to display a REAGENT LOG screen.
2. If the desired reagent log is not already displayed, use the soft key to select the appropriate log.
3. Use the arrow keys on the keyboard to move the cursor to the desired entry field.
4. Type the appropriate information.

   NOTE: Entries for each field of information are optional. Dates should be entered with a slash (/) or a period (.) separating the month, day and year.

5. Press the Enter key on the keyboard to save the entry and advance the cursor.
6. Repeat steps 3–5 until all desired entries have been made.
7. If desired, press [PRINT LOG] to obtain a printout of the log.
8. Press the appropriate soft key to select another reagent log and repeat steps 2–7 to enter and print data.

To Delete Entries

When the log is full (the log holds 10 entries), the oldest entry must be deleted to create space for a new entry. Abbott suggests that the log be printed when it is full for documentation purposes.

1. Press [REAGENT LOG] to display a REAGENT LOG screen. If necessary, press a soft key to display the appropriate log.
2. Move the cursor to the oldest entry in the log.
3. Press [DELETE ENTRY]. The [COMPLETE DELETION] and [RESTORE ENTRY] keys are displayed.

4. Press [COMPLETE DELETION] to delete the selected entry.
5. If desired, a new entry may then be made as described above.

   NOTE: New entries may also be made by typing over old entries without deleting them.

6. Press [RETURN] to return to the main SET UP MENU screen.

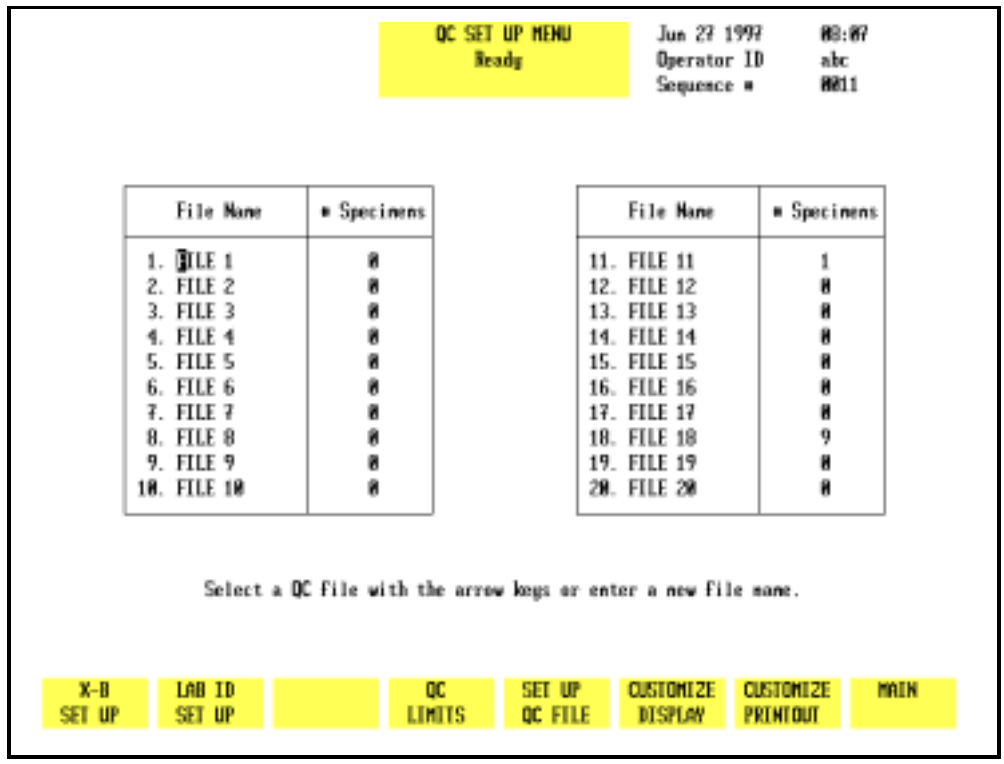

Figure 5.6: QC Set Up Menu Screen

QC Set Up Menu

The [QC SET UP MENU] key is used to display a list of the QC files (see Figure 5.6) and the following soft key labels:

X-B SET UP
LAB ID SET UP

NOTE: The LAB ID SET UP key is currently disabled.

QC LIMITS
SET UP QC FILE
CUSTOMIZE DISPLAY
CUSTOMIZE PRINTOUT
MAIN

This section discusses the procedures that are used to set up the QC files. Typically, a QC file(s) is set up, then QC Limits are established. Therefore, the keys in the QC SET UP menu will be discussed in this order.

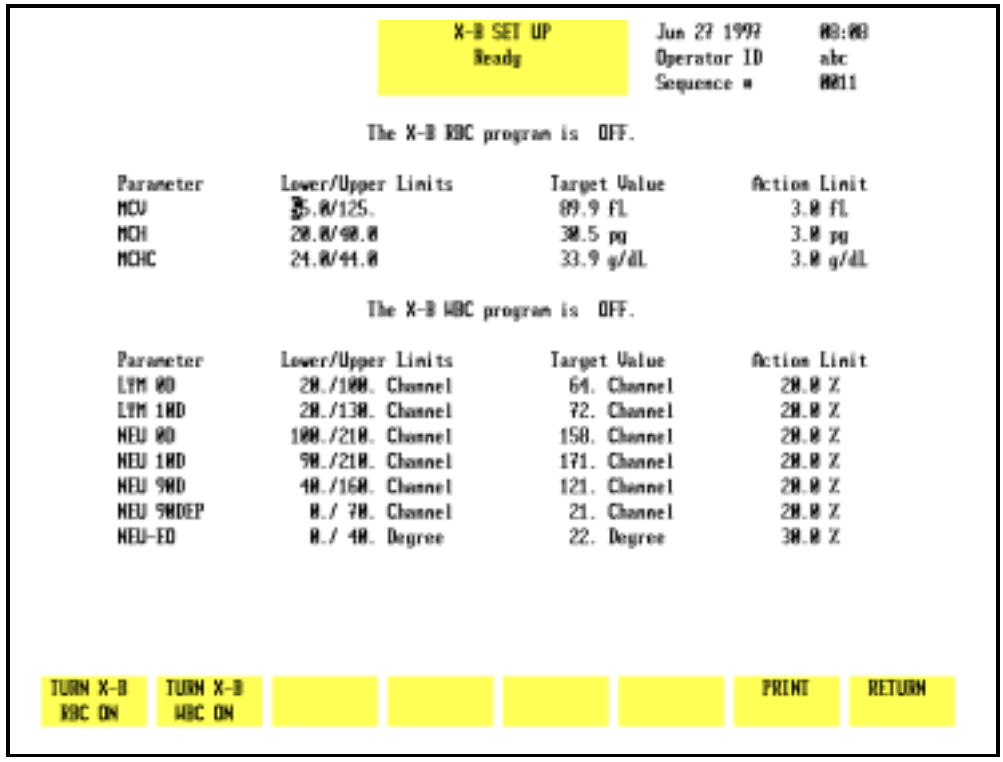

Figure 5.7: X-B Set Up Screen

X-B Setup Menu

The [X-B SET UP] key is used to select the X-B SET UP screen. (See Figure 5.7.) This screen is used to enter upper and lower acceptance limits, target values, and action limits for the X-B Moving Average QC Program for both the WBC and RBC parameters. The following soft key labels are displayed when the [X-B SET UP] key is pressed:

TURN X-B RBC ON/ TURN X-B RBC OFF	(The key alternates between the selections.)
TURN X-B WBC ON/ TURN X-B WBC OFF	(The key alternates between the selections.)
PRINT	
RETURN	

The following options are available on the X-B SET UP screen shown in Figure 5.7:

1. LOWER/UPPER LIMITS

   The **Lower and Upper Limits** determine which patient results will be used in the X-B Moving Average calculation. Results that fall outside these limits are automatically excluded from the X-B calculations. These limits should be set widely to exclude grossly abnormal samples (such as background counts) that would bias the calculation but should include at least 95% of the patient results.

2. TARGET VALUE

   The **Target Value** for X-B Analysis is similar to the assay value for a commercial control. It is derived from the patient population that is analyzed on the instrument.

3. ACTION LIMIT

   The **Action Limit** is the acceptable limit of variation around the target value.

   NOTE: The X-B Program is discussed in detail in **Section 11:** ***Quality Control***.

To Set Up X-B

1. Press [X-B SET UP] to display the X-B SET UP screen.
2. Use the Arrow keys on the keyboard to move the cursor to the desired entry field.
3. Type the numbers and press the Enter key on the keyboard to save the entry and advance the cursor to the next entry field.
4. Repeat steps 2 and 3 until all entries have been made.
5. If desired, press [PRINT] to obtain a printout of the entered values.
6. If the soft key [TURN X-B RBC ON] or [TURN X-B WBC ON] is displayed, press the appropriate key to enable the X-B program.

   NOTE: For example, when the X-B RBC program is enabled the screen displays the message THE X-B RBC PROGRAM IS ON and the [TURN X-B RBC OFF] key is displayed.

7. Press [RETURN] to return to the QC SET UP MENU screen.

Lab ID Set Up

The [LAB ID SET UP] key should not be used at this time.

QC Limits Menu

The [QC LIMITS] key is used to display the QC MEANS/LIMITS ENTRY screen and the following soft key labels:

RANGE ENTRY and MEANS/LIMITS	(The key alternates between the selections.)
UPDATE FROM FILE	(This key is displayed only when there are two or more results in the selected file.)
LOAD FROM DISK	(This key is not available at this time.)

NOTE: The feature enabling entry of QC limits into a QC file from a floppy disk is not available at this time. The feature enabling the download of data from a QC file to a floppy disk is not available at this time.

PRINT

RETURN

QC Limits Entry

QC Limits are entered by pressing the [QC LIMITS] key. This key is available on the QC SET UP MENU screen and the QC MENU screen. Two types of QC limits are available:

Means and Limits — used to enter the mean value and a ± range value that defines the upper and lower flagging limits (see Figure 5.8)

Range Entry — used to enter the upper and lower flagging limits as absolute numbers (see Figure 5.9)

If Range Entry is selected by pressing the [RANGE ENTRY] key, the current upper and lower limits for the selected file are displayed as described above. If Means/Limits entry is selected by pressing the [MEANS/LIMITS] key, the current means and limits for the selected file are displayed as described above.

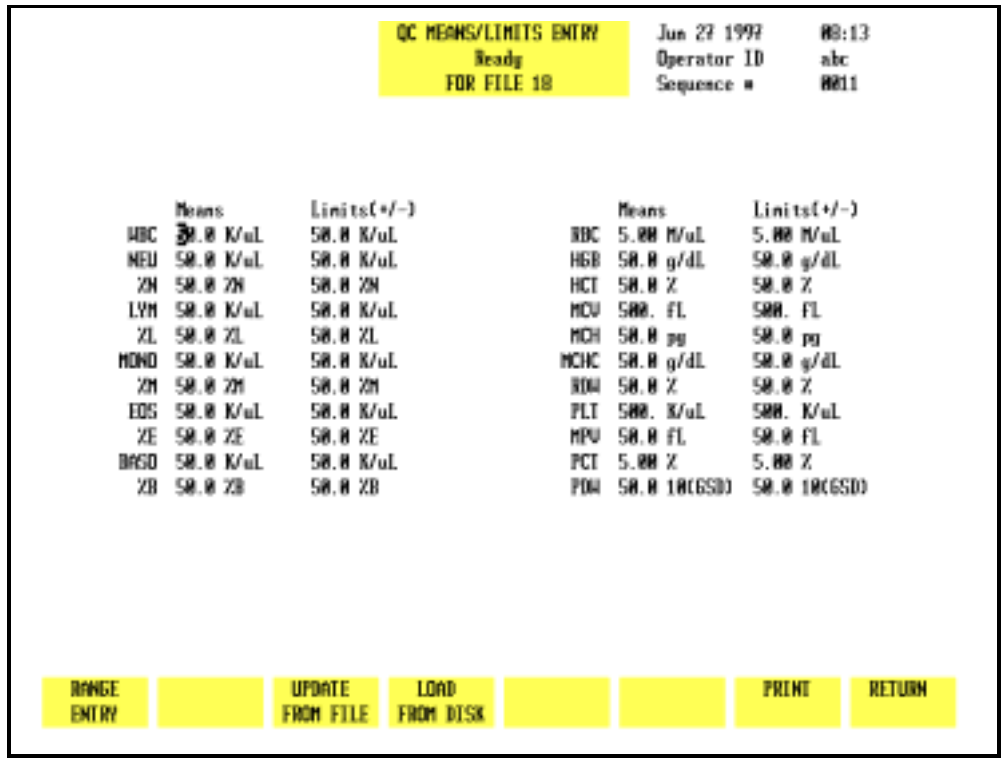

Figure 5.8: QC Means/Limits Entry Screen

Means/Limits Entry

1. Select a file from the QC SET UP MENU screen by using the Arrow keys on the keyboard to move the cursor into the desired file.
2. Press [QC LIMITS] followed by [MEANS/LIMITS] to display the QC MEANS/LIMITS ENTRY screen for the selected file [MEANS/LIMITS] and [RANGE ENTRY] .
3. Use the Arrow keys on the keyboard to move the cursor to the desired entry field.
4. Type the numbers and press the Enter key on the keyboard to save each entry and advance the cursor to the next entry field.
5. Repeat step 4 until all entries have been made.
6. If desired, press [PRINT] to obtain a printout of the entered values.
7. Press [RETURN] to save the entries and return to the QC SET UP screen.

NOTE: When the entries are saved by pressing the [RETURN] soft key, the software checks to see if any entries would result in a negative number for the lower limit (e.g., mean = 1.0, limit = 2.0). If a negative number is found, the values are automatically edited to adjust the lower limit to zero. The bulletin line displays the message:

```
LIMITS WERE CHANGED TO CORRECT OUT-OF-RANGE
VALUES.
```

In the above example, the mean would be adjusted to 1.5 and the limit would be adjusted to 1.5.

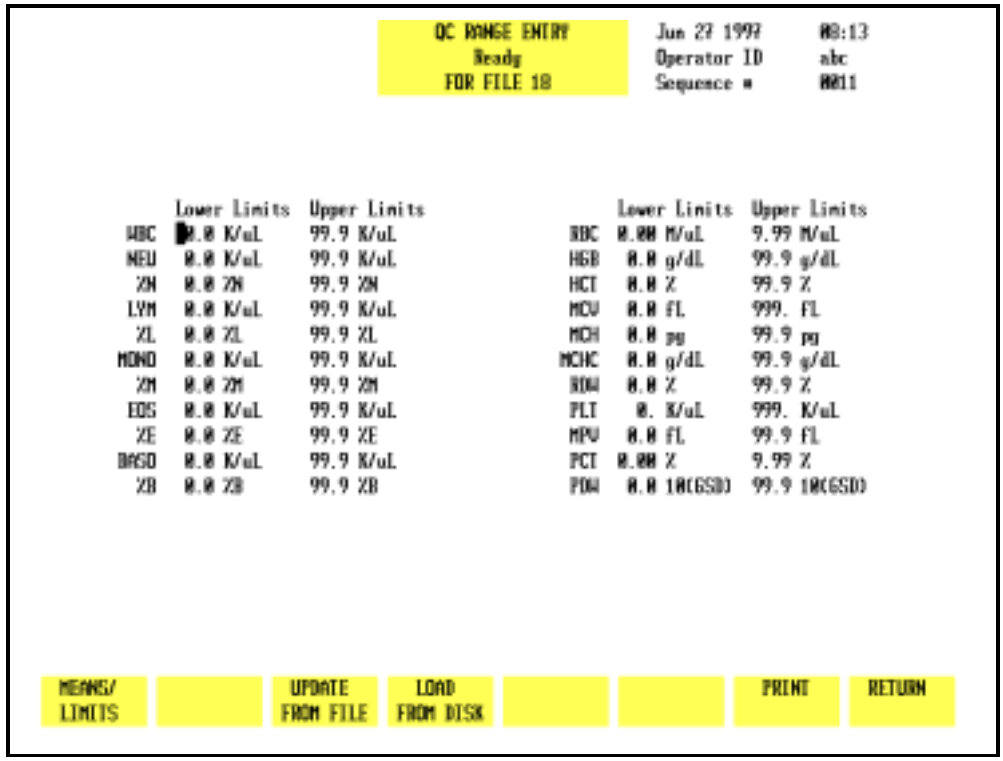

Figure 5.9: QC Range Entry Screen

Range Entry

1. Select a file from the QC SET UP screen by using the Arrow keys on the keyboard to move the cursor into the desired file.
2. Press [QC LIMITS] to display the QC RANGE ENTRY screen for the selected file.
3. Use the Arrow keys on the keyboard to move the cursor to the desired entry field.

4. Type the numbers and press the Enter key on the keyboard to save each entry and advance the cursor to the next entry field.
5. Repeat step 4 until all entries have been made.
6. If desired, press [PRINT] to obtain a printout of the entered values.
7. Press [RETURN] to save the entries and return to the QC SET UP screen.

NOTE: When the entries are saved by pressing the [RETURN] soft key, the software checks to see if any entries would result in the upper limit being less than the lower limit. If this situation occurs, the limits are automatically reversed. The bulletin line displays the message:

```
LIMITS WERE EXCHANGED TO MAKE UPPER > LOWER
```

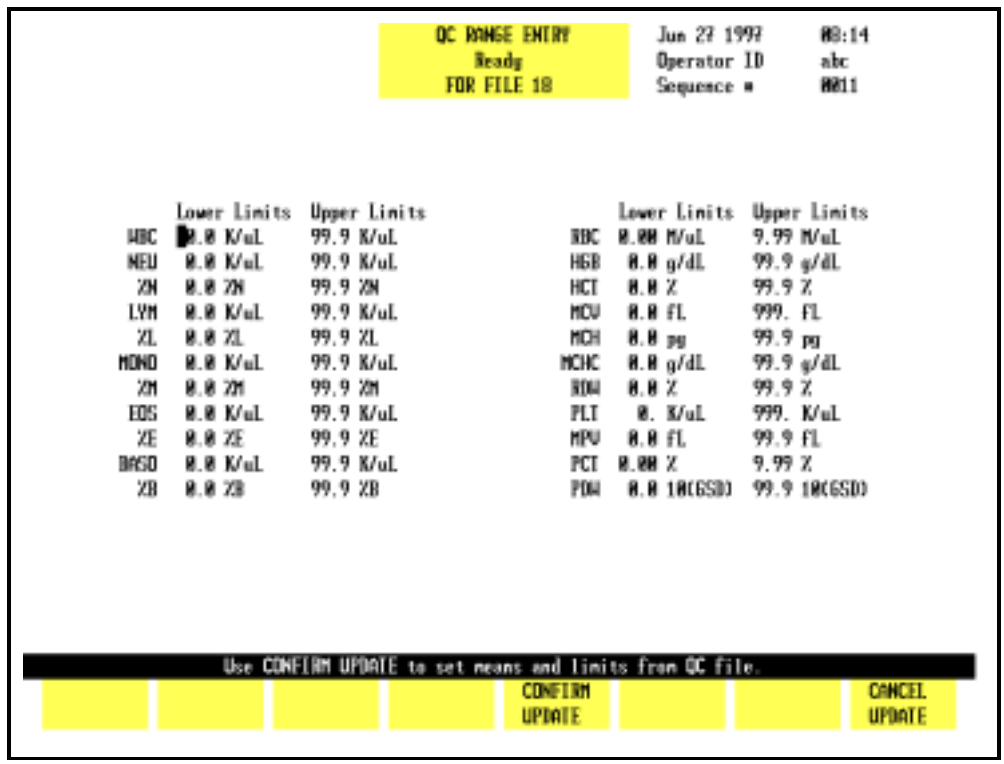

Figure 5.10: Update From File Key

Update From File

The [UPDATE FROM FILE] key is displayed on the QC MEANS/LIMITS ENTRY and QC RANGE ENTRY screens when there are two or more results in the file. (See Figure 5.10.) When the [UPDATE FROM FILE] key is pressed, the bulletin line displays the message USE CONFIRM UPDATE TO SET MEANS AND LIMITS FROM QC FILE and the following soft key labels are displayed:

CONFIRM UPDATE
CANCEL UPDATE

These keys are used to [CONFIRM] or [CANCEL] the Update From File command.

When the [CONFIRM UPDATE] key is pressed, the mean value for each parameter is computed from the values in the file. The parameter limits are set as follows:

WBC, PLT, RDW and MPV:	± 10% of the computed mean
NEU, LYM and MONO:	± 40% of the computed mean
Remaining Parameters:	± 5% of the computed mean

Load From Disk

The [LOAD FROM DISK] key should not be used at this time.

Set Up QC File

The [SET UP QC FILE] key is used to configure the QC file. If the file is used for a commercial control, the lot number and expiration date may be entered by pressing the [LOT NUMBER] key. If the file is used for a patient control, the ID number of the control may be entered by pressing the [REPLICATE ID] key.

> **NOTE:** The system defaults to the LOT NUMBER screen upon initial set up. Otherwise, the screen last selected will be displayed.

The QC SET UP screen is also used to select the Westgard Rules that will be applied to the QC data stored in the file. The following soft key labels are displayed when the [SET UP QC FILE] key is pressed:

REPLICATE ID/LOT NUMBER	(The key alternates between the selections.)

TOGGLE ON/OFF	(This key is only present when the cursor is in one of the Westgard Rule Selection fields.)
PRINT	
RETURN	

The Lot Number Entry and Replicate ID Entry screens are shown in Figures 5.11 and 5.12. The options available are as follows:

1. <LOT NUMBER> and <EXPIRATION DATE> entry fields

   These entry fields are displayed when the [LOT NUMBER] key is pressed. This designation is intended for QC Files that are used for commercial controls.
2. <REPLICATE ID> entry field

   This entry field is displayed when the [REPLICATE ID] key is pressed. This designation is intended for QC Files that are used for patient controls.
3. WESTGARD RULE SELECTION

   RULE 1: VALUE OUTSIDE 3 SD
   RULE 2: TWO CONSECUTIVE VALUES OUTSIDE SAME 2 SD
   RULE 3: TWO CONSECUTIVE VALUES OUTSIDE OPPOSITE 2 SD
   RULE 4: TWO OF THREE CONSECUTIVE VALUES OUTSIDE SAME 2 SD
   RULE 5: FOUR CONSECUTIVE VALUES OUTSIDE SAME 1 SD
   RULE 6: TEN CONSECUTIVE VALUES ON SAME SIDE OF MEAN

   NOTE: Westgard rules are discussed in detail in Section 11: ***Quality Control***.

The Westgard Rule selections are available on either of the QC FILE SET UP screens.

QC File Set Up

1. Press [QC SET UP MENU] to display the QC SET UP MENU screen.
2. Use the Arrow keys on the keyboard to move the cursor to the desired QC file.

3. Type the desired alphanumeric file name. (Up to 12 characters may be entered.)
4. Press the Enter key on the keyboard to save the entry and advance the cursor to the next QC file.
5. Use the Arrow keys on the keyboard to move the cursor back into the selected file.
6. Press [SET UP QC FILE] to display the QC FILE SET UP screen.

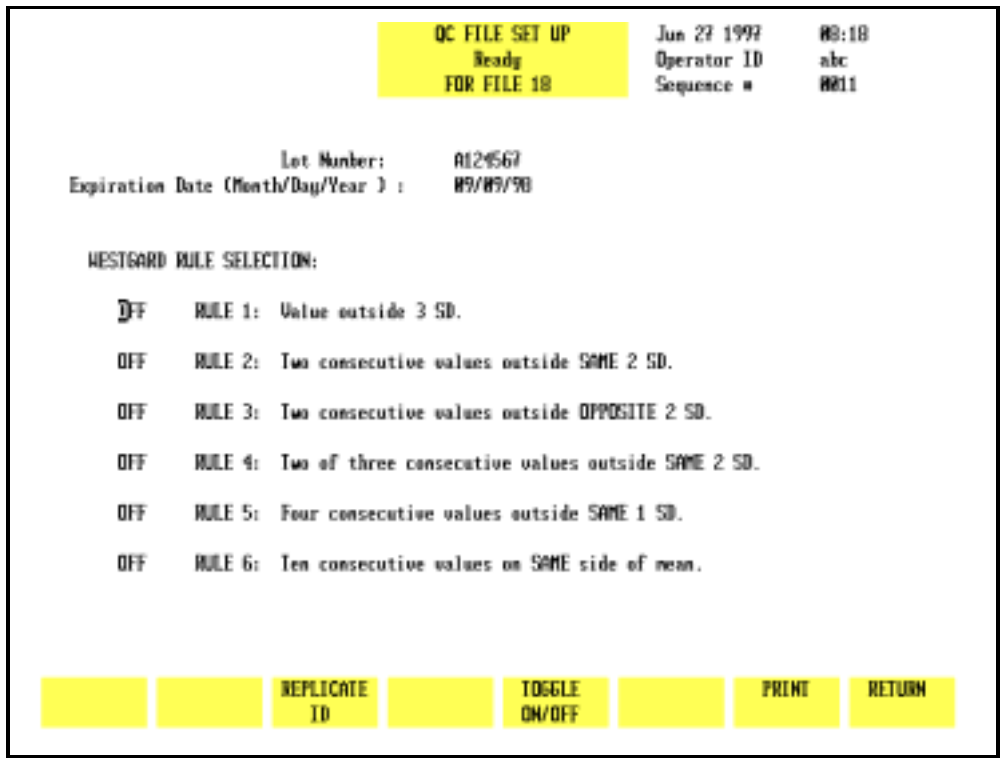

Figure 5.11: Lot Number Entry Screen

To Enter Lot Number Data

1. If necessary, from the QC FILE SET UP screen, press [LOT NUMBER] to display the <LOT NUMBER> and <EXPIRATION DATE> entry fields.
2. The cursor is in the <LOT NUMBER> entry field. Type the lot number and press the Enter key on the keyboard to save the entry and advance the cursor to the <EXPIRATION DATE> entry field.

3. Type the expiration date in the format indicated using one or two digits. This is the same format selected on the DATE/TIME SET UP screen. Separate the digits with a slash (/) or a period (.).
4. Press the Enter key on the keyboard to save the entry and advance the cursor to the <WESTGARD RULE SELECTION> entry fields.
5. Use the arrow keys on the keyboard to position the cursor at the desired Westgard Rule.
6. Press [TOGGLE ON/OFF] to enable the rule and advance the cursor.
7. Repeat steps 5 and 6 until all desired rule selections have been made.
8. If desired, press [PRINT] to obtain a printout of the entries.
9. Press [RETURN] to return to the QC FILE SET UP screen.

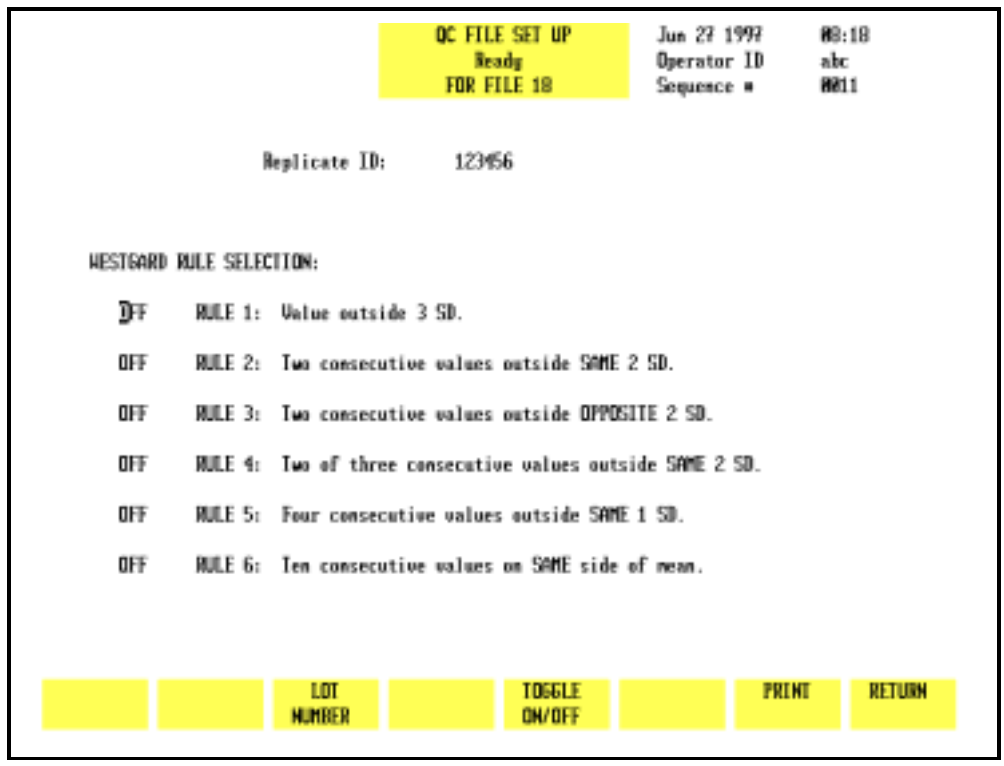

Figure 5.12: Replicate ID Entry Screen

To Enter Replicate ID Data

1. If necessary, from the QC FILE SET UP screen, press [REPLICATE ID] to display the <REPLICATE ID> entry field.
2. The cursor is in the <REPLICATE ID> entry field. Type the sample ID number (up to 12 alphanumeric characters may be entered) and press the Enter key on the keyboard to save the entry and advance the cursor to the <WESTGARD RULE SELECTION> entry fields.
3. Select the Westgard Rules as directed in the To Enter Lot Number Data procedure.

Customize Display

The [CUSTOMIZE DISPLAY] key in the QC SET UP MENU is used to customize the display of information in the QC logs. Figure 5.13 shows the CUSTOMIZE QC DISPLAY screen with the standard groups displayed. Figure 5.14 shows the CUSTOMIZE QC DISPLAY screen where the WBC and RBC groups have been customized.

The CUSTOMIZE QC DISPLAY screen and the following key labels are displayed when the [CUSTOMIZE DISPLAY] key is pressed:

SELECT PARAMETER
STANDARD GROUPS
RETURN

The screen displays a matrix of 4 rows of parameters that are currently selected in Groups 1 through 4. A list of all available parameters is displayed under the matrix. The standard groups, which include predetermined parameter sets, are identified as follows:

Group 1	WBC parameters
Group 2	RBC parameters
Group 3	PLT parameters
Group 4	WBC Diff parameters

On the CUSTOMIZE QC DISPLAY screen, Parameter Group 1 is displayed (in the order indicated from left to right) on the first VIEW QC LOG screen. The remaining groups are displayed on subsequent screens that are accessed by pressing the Right Arrow key on the keyboard. The Left Arrow key is used to page back through the screens to the first screen.

The [STANDARD GROUPS] key is used to select a predetermined group of parameters that will be placed on a designated page. The display may be customized by selecting the individual parameters, standard groups of parameters, or a combination of the two.

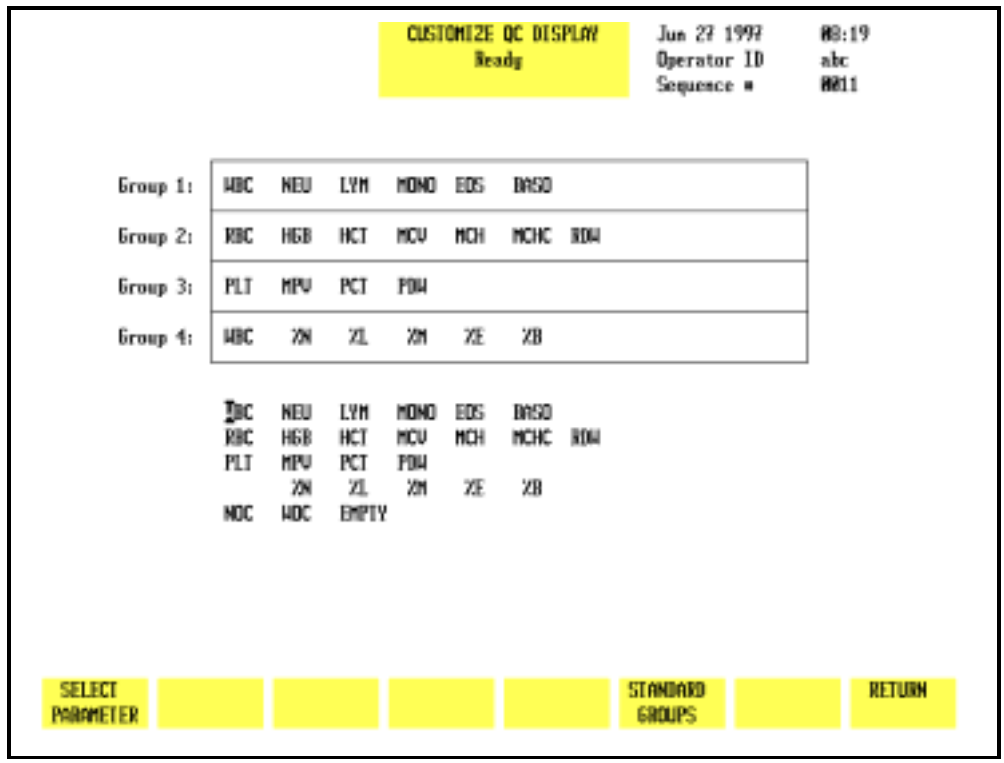

Figure 5.13: Customize QC Display Screen

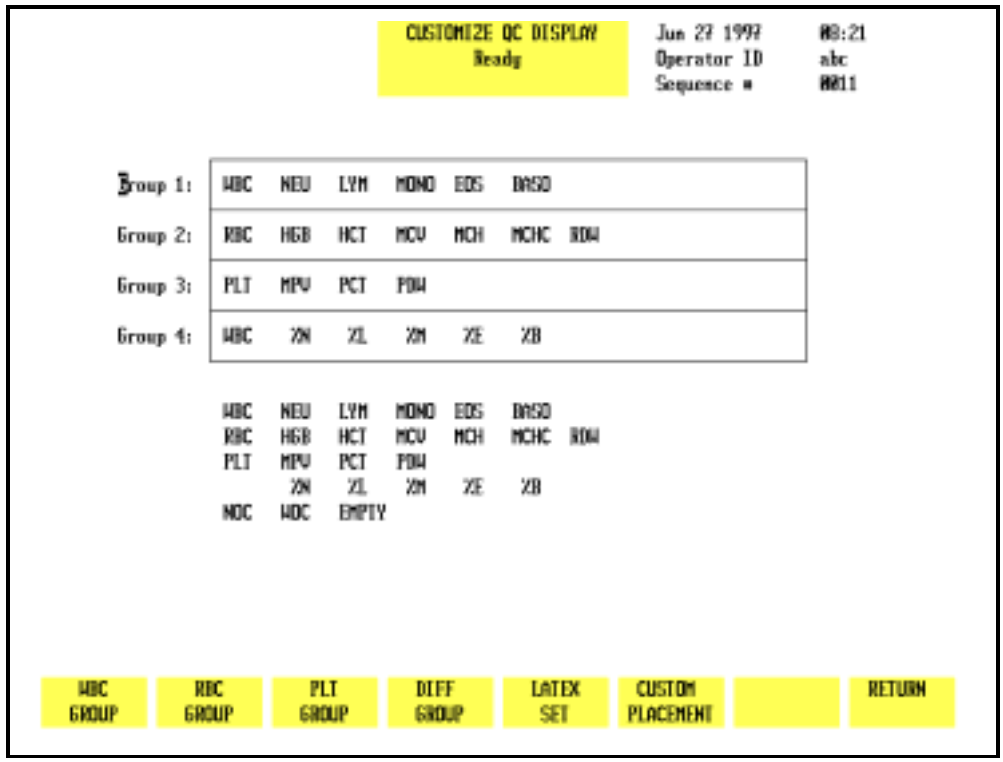

Figure 5.14: Customize QC Display Screen Showing Standard Groups

To Customize QC Log Display

1. Select a file from the QC SET UP MENU screen by moving the cursor to the desired file.
2. Press [CUSTOMIZE DISPLAY] to display the CUSTOMIZE QC DISPLAY screen for the selected file.
3. If necessary, press [CUSTOM PLACEMENT] to display the CUSTOMIZE QC DISPLAY screen and the [SELECT PARAMETER] key.
4. Use the Arrow keys on the keyboard to move the cursor to the desired parameter in the listing under the matrix.
5. Press [SELECT PARAMETER]. The selected parameter is highlighted and the cursor moves to the first position in Group 1.

   NOTE: The key label changes to [PLACE PARAMETER] and a [CANCEL SELECTION] key is displayed.

6. If necessary, use the Arrow keys on the keyboard to move the cursor to the desired location and press [PLACE PARAMETER].

NOTE: When the [PLACE PARAMETER] key is pressed, the selected parameter is displayed in the position indicated by the cursor and the cursor is then advanced to the next parameter in the listing under the matrix.

7. Repeat steps 4–6 until all selections have been made.
8. If desired, press the Print screen key on the keyboard to obtain a printout of the selected groups.
9. Press [RETURN] to return to the QC SET UP MENU screen.
10. Repeat this procedure to customize the display for other QC logs.

Standard Groups

Predetermined groups of parameters, called Standard Groups, may be selected by pressing the [STANDARD GROUPS] key (refer to Figure 5.14). When the [STANDARD GROUPS] key is pressed, the following soft key labels are displayed:

WBC GROUP
RBC GROUP
PLT GROUP
DIFF GROUP
LATEX SET
CUSTOM PLACEMENT*
RETURN

* This key is used to return to the CUSTOMIZE QC DISPLAY screen for operator-selected placement.

Customize QC Log Display (Standard Groups)

1. Select a file from the QC SET UP MENU screen by moving the cursor to the desired file.
2. Press [CUSTOMIZE DISPLAY] to display the CUSTOMIZE QC DISPLAY screen for the selected file.
3. Press [STANDARD GROUPS] to display the CUSTOMIZE QC DISPLAY screen and key labels for Standard Groups.
4. Use the Arrow keys on the keyboard to move the cursor to the desired group (1–4) location.

NOTE: This number indicates the order in which the group of parameters will be displayed (Group 1 on the first screen, Group 2 on the second, etc.).

5. Press the soft key corresponding to the desired parameter group. This group is displayed in the position indicated by the cursor.
6. Repeat steps 4 and 5 until all desired groups have been selected.
7. If desired, press the Print screen key on the keyboard to obtain a printout of the configuration.
8. Press [RETURN] to return to the QC SET UP MENU screen.
9. Repeat this procedure to select standard groups for other QC logs.

Latex Set

This key is intended to be used by Abbott Service personnel only. If the [LATEX SET] key is pressed, parameters in all groups will be affected. The [LATEX SET] key is available from the CUSTOMIZE QC DISPLAY screen for Standard Groups. This key is used to customize the QC file to store information generated by latex particles. Information is stored for each of the four angles of scatter which are used to determine the differential.

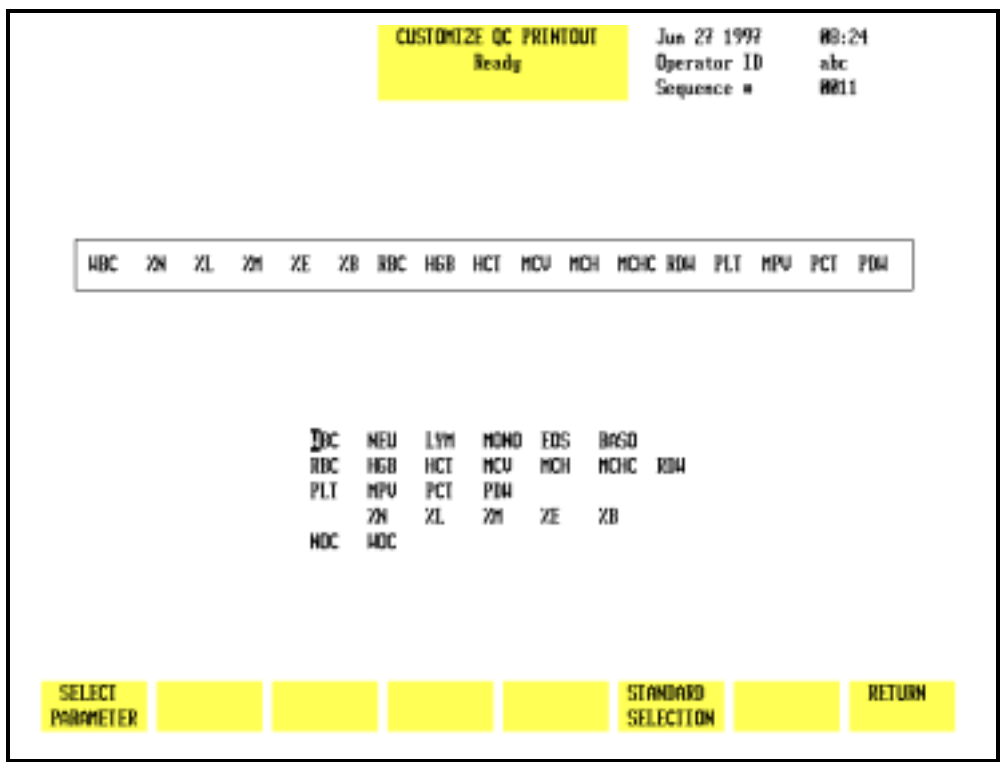

Figure 5.15: Customize QC Printout Screen

Customize Printout

The [CUSTOMIZE PRINTOUT] key in the QC SET UP menu is used to customize the printout format for the QC logs. (See Figure 5.15.) The following soft key labels are displayed when the [CUSTOMIZE PRINTOUT] key is pressed:

SELECT PARAMETER	(Toggles to PLACE PARAMETER when pressed)
STANDARD SELECTION	
RETURN	

The CUSTOMIZE QC PRINTOUT screen displays the group of parameters that is currently selected. A list of all available parameters is displayed under the group.

Standard Selection

The [STANDARD SELECTION] key is used to automatically arrange the parameters in a predetermined print group.

Select Parameter

The [SELECT PARAMETER/PLACE PARAMETER] key is used to customize the QC Log printout.

1. Select a file from the QC SET UP MENU screen by moving the cursor to the desired file.
2. Press [CUSTOMIZE PRINTOUT] to display the CUSTOMIZE QC PRINTOUT screen for the selected file.
3. Use the Arrow keys on the keyboard to move the cursor to the desired parameter in the list under the printout group.
4. Press [SELECT PARAMETER]. The selected parameter is highlighted and the cursor moves to the first position in the group.

   NOTE: The key label changes to [PLACE PARAMETER] and a [CANCEL SELECTION] key is displayed.

5. If necessary, use the Arrow keys on the keyboard to move the cursor to the desired location and press [PLACE PARAMETER].

   NOTE: When the [PLACE PARAMETER] key is pressed, the selected parameter is displayed in the position indicated by the cursor, the cursor advances to the next parameter in the list under the printout group, and the key label changes back to [SELECT PARAMETER].

6. Repeat steps 3–5 until all entries have been made.
7. If desired, press the Print Screen key on the keyboard to obtain a printout of the configuration.

8. Press [RETURN] to return to the QC SET UP MENU screen.
9. Repeat this procedure to customize the printout for other QC logs.

Standard Selection

When the [STANDARD SELECTION] key is pressed, the parameters are automatically arranged in the predetermined print group shown in Figure 5.14.

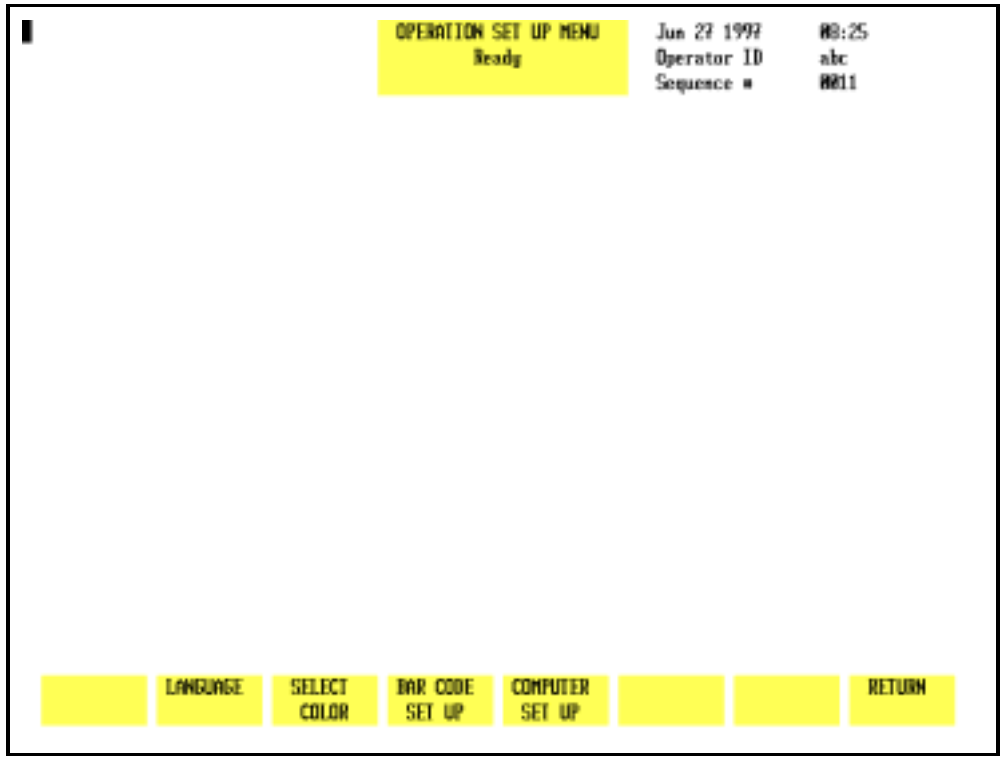

Figure 5.16: Operation Set Up Menu Screen

Operation Set Up Menu

The OPERATION SET UP MENU screen (see Figure 5.16) allows the operator to select screen colors, the type of bar code used, and to configure the transmission to an on-line (host) computer. The following soft key labels are displayed when the [OPERATION SET UP] key is pressed:

LANGUAGE
SELECT COLOR
BAR CODE SET UP
COMPUTER SET UP
RETURN

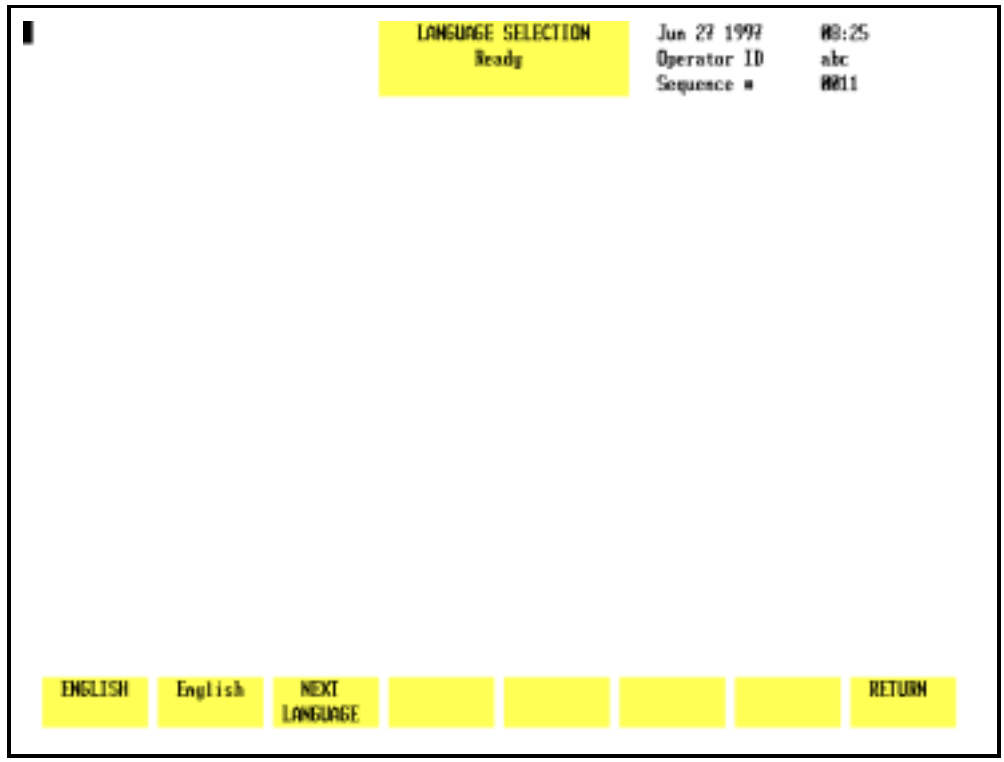

Figure 5.17: Language Selection Screen

Language Selection <English (default language)>

The LANGUAGE SELECTION screen, shown in Figure 5.17, will soon allow the user to select one of the following non-English languages for display and printout:

Spanish
French
German
Japanese
Italian

The following soft keys are displayed when the [LANGUAGE] key is pressed:

ENGLISH	(used to return to the default language)
English	(name of currently displayed language)
NEXT LANGUAGE	
RETURN	

Pressing the capitalized [ENGLISH] soft key allows the operator to return to English which is the default language.

The name of the currently displayed language is displayed next to [ENGLISH]. For example, if English is the displayed language, then [English] will be displayed in the second key position. The name of each language is displayed using the spelling convention of the host language: French is displayed as [français], German as [deutsch], and Spanish as [español].

Pressing the language key affects the display and printout of soft keys, bulletin and screen messages, and demographic data; it does not effect the measurement process or other functional aspects of the program.

In a future release, pressing the [NEXT LANGUAGE] soft key will allow the user to scroll through the available languages.

To Change the Language

1. In the OPERATION SET UP MENU, press [LANGUAGE SELECTION].
2. Press [NEXT LANGUAGE] to scroll through the list of languages available on the instrument.
3. When the desired language is displayed in the second soft key label position, press [RETURN] to save the selection and return to the OPERATION SET UP MENU.
4. If desired, attach a keyboard appropriate to the language selected.

   CAUTION: If a different keyboard will be attached to the instrument because of the change in language, the instrument (Analyzer only) should first be turned OFF before the old keyboard is unplugged and the new keyboard is attached. This will prevent accidental injury to the operator or damage to the instrument.

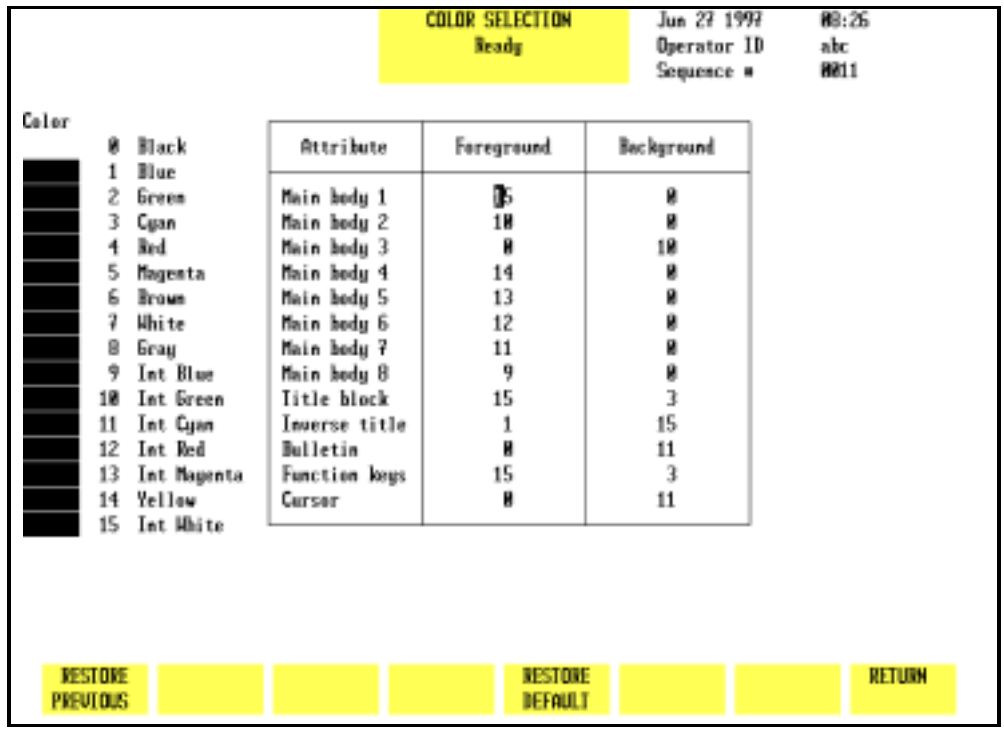

Figure 5.18: Select Color Screen

Select Color

The SELECT COLOR screen, shown in Figure 5.18, allows the user to select various colors for displaying parameter data and other information on the screen. The following soft keys are displayed when the [SELECT COLOR] key is pressed:

RESTORE PREVIOUS
RESTORE DEFAULT
RETURN

Color Reference

Main Body 1	**Main screen**
Main Body 2	**Flags**
Main Body 3	**Run mode description**
Main Body 4	**Values below limits**
Main Body 5	**Values above limits**
Main Body 6	**Sequence numbers in Data Log**
Main Body 7	**RBC Histogram/New entry before Enter key is pressed**
Main Body 8	**PLT Histogram/New entry after Enter key is pressed**

Title Block	**Top center of screen**
Inverse Title	**Title not currently used**
Bulletin	**Alert messages above function keys**
Function Keys	**Soft key descriptions**
Cursor	**Screen cursor**

To Change Color Settings

1. Press [SELECT COLOR] in the OPERATION SET UP MENU.
2. Use the Arrow keys on the keyboard to move the cursor to the desired location in either the Foreground or Background columns.
3. Enter the number corresponding to the desired color from the list on the left side of the screen. Press the Enter key to save the entry and move the cursor to the next position.

   NOTE: The one field which cannot be changed is Background for Main body 1. This background must always remain black.

4. When all desired changes have been made, press [RETURN] to return to the OPERATION SET UP MENU.
5. If the operator changes a color selection, then wishes to cancel the change and keep the original setting, pressing [RESTORE PREVIOUS] while this screen is still displayed will cancel all changes and restore the original color selection. Pressing [RESTORE DEFAULT] will cause the screen colors to revert to the configuration set at the factory prior to shipment.

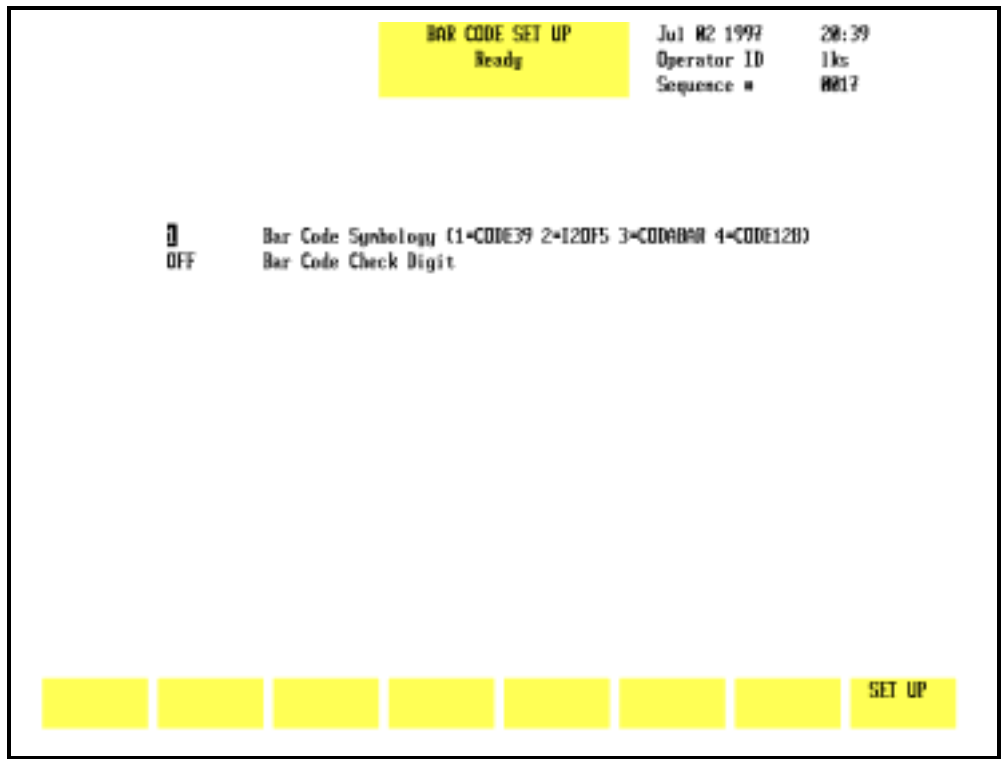

Figure 5.19: Bar Code Set Up Screen

Bar Code Set Up

The [BAR CODE SET UP] key is used to select the type of bar code to be read and to enable or disable the check digit option for the selected bar code. (See Figure 5.19.)

> **NOTE:** For more information about check digits and bar codes, refer to Appendix A, Bar Codes.

To Set Up Bar Code

1. From the OPERATION SET UP MENU screen, press [BAR CODE SET UP] to display the BAR CODE SET UP screen.
2. Type the number for the type of bar code that will be used:

   1 — Code 39

   2 — Interleaved 2 of 5

   3 — CODABAR

   4 — Code 128

   Press the Enter key on the keyboard to save the entry and advance the cursor to the Bar Code Check Digit field.

3. Press [TOGGLE ON/OFF] to enable or disable the check digit.

   NOTE: The [TOGGLE ON/OFF] key is displayed only when the cursor is positioned next to `BAR CODE CHECK DIGIT`.

4. Press [SET UP] to return to the OPERATION SET UP MENU.

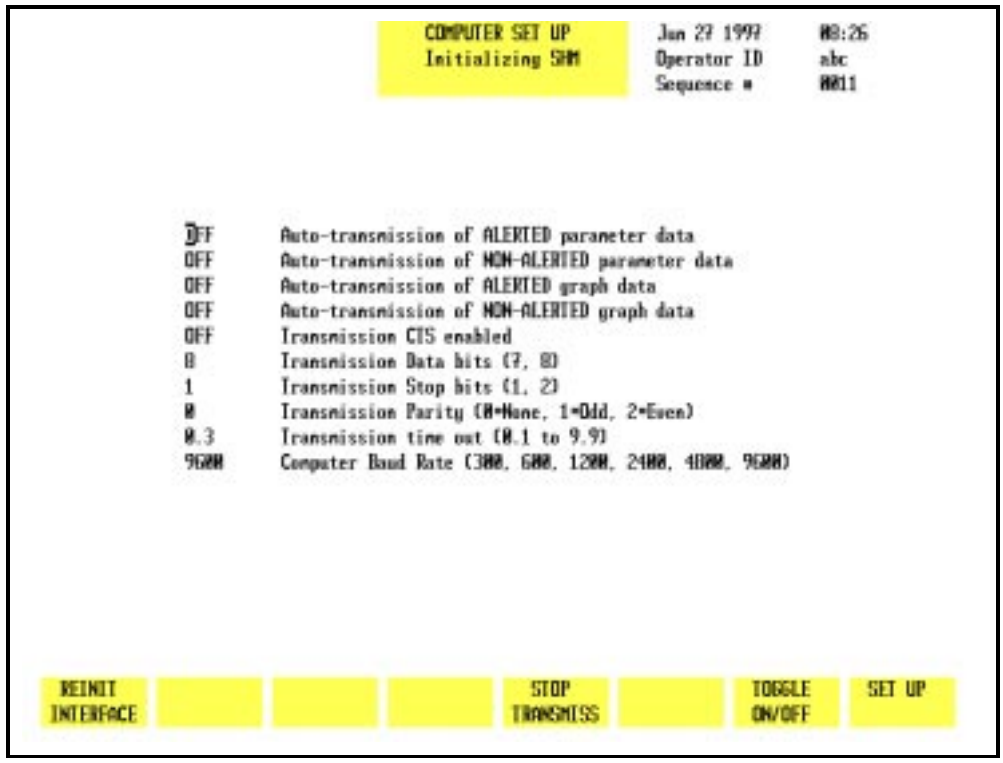

Figure 5.20: Computer Set Up Screen

Computer Set Up Menu

The [COMPUTER SET UP] key is used to display the COMPUTER SET UP screen (see Figure 5.20) and the following soft key labels:

REINIT INTERFACE
STOP TRANSMISS
TOGGLE ON/OFF
SET UP

The CELL-DYN 3200 can transmit data to an on-line computer (Laboratory Information System) using a direct serial link. Data may be transmitted automatically as each sample is run or at the operator's request. The CELL-DYN 3200 also can receive patient information transmitted to it by the on-line computer.

The COMPUTER SET UP screen is used to configure the transmission format to meet the requirements of the Laboratory Information System or on-line computer. Instructions for using this option are given after the following description of the soft keys.

Reinit Interface

The [REINIT INTERFACE] key is used to initialize the RS-232 interface for the displayed transmission configuration after it is entered. The interface is automatically initialized whenever the [STOP TRANSMISS] key is pressed.

> **NOTE:** Refer to the Interface Specification for complete information on interfacing.

Stop Transmiss

The [STOP TRANSMISS] key is used to terminate the current data transmission to an on-line computer. When the [STOP TRANSMISS] key is pressed, the following soft key labels are displayed:

CONFIRM STOP
CANCEL STOP

Pressing [CONFIRM STOP] causes the transmission to terminate. Pressing [CANCEL STOP] allows the transmission to continue.

Toggle ON/OFF

The [TOGGLE ON/OFF] key enables or disables the first five options in the list displayed on the COMPUTER SET UP screen.

A description of the options available on the COMPUTER SET UP screen is given below:

1. AUTO-TRANSMISSION OF ALERTED PARAMETER DATA

   When this option is enabled, a report is automatically transmitted to the LIS for any sample with flagged parameter results.

2. AUTO-TRANSMISSION OF NON-ALERTED PARAMETER DATA

   When this option is enabled, a report is automatically transmitted to the LIS for any sample without flagged parameter results.

3. AUTO-TRANSMISSION OF ALERTED GRAPH DATA

   When this option is enabled, histograms are automatically transmitted to the LIS for any sample with flagged results.

4. AUTO-TRANSMISSION OF NON-ALERTED GRAPH DATA

   When this option is enabled, histograms are automatically transmitted to the LIS for any sample without flagged results.

5. The remaining options are configured according to the requirements of the LIS:

   TRANSMISSION CTS ENABLED
   TRANSMISSION DATA BITS (7, 8)
   TRANSMISSION STOP BITS (1, 2)
   TRANSMISSION PARITY (0=NONE, 1=ODD, 2=EVEN)
   TRANSMISSION TIME OUT (0.1 to 9.9)
   COMPUTER BAUD RATE (300, 600, 1200, 2400, 4800, 9600)

   The numbers in parentheses after the options indicate the selections available.

   NOTE: Refer to the Interface Specification for complete information on interfacing.

Computer Set Up Procedure

1. From the OPERATION SET UP MENU, press [COMPUTER SET UP] to display the COMPUTER SET UP screen.
2. For the first five options on the list, use the Arrow keys on the keyboard to move the cursor to the desired selection and press [TOGGLE ON/OFF] to enable or disable the selection.

   NOTE: The [TOGGLE ON/OFF] key is displayed when the cursor is positioned in any of the first five entry fields.

3. For the last five options on the list, type the appropriate information and press the Enter key on the keyboard to save the entry and advance the cursor.
4. When all the information has been entered, press [REINIT INTERFACE] to initialize the interface for the selected configuration.
5. If desired, press the Print Screen key on the keyboard to obtain a printout of the configuration.
6. Press [SET UP] to return to the OPERATION SET UP MENU screen.
7. Press [RETURN] to return to the SET UP MENU.

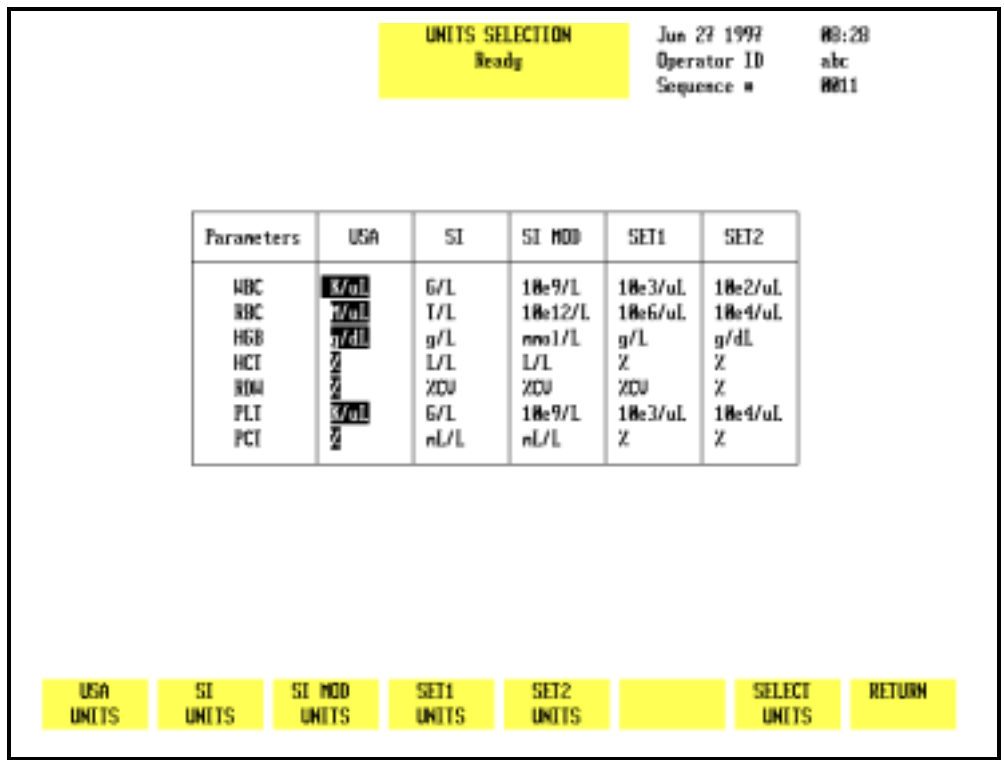

Figure 5.21: Units Selection Screen

Units Selection Menu

The [UNITS SELECTION] key selects the report units for the indicated parameters. Units may be selected for each parameter individually or a set of units may be selected by pressing the appropriate soft key. (See Figure 5.21.) The following soft key labels are displayed when the [UNITS SELECTION] key is pressed:

USA UNITS
SI UNITS
SI MOD UNITS
SET1 UNITS
SET2 UNITS
SELECT UNITS
RETURN

The units selected by each of the soft keys are shown on the screen display in Figure 5.21. The following table demonstrates how values are reported for the same sample under each "units" category.

Table 5.1: Report Units

Parameter	USA		SI		SI MOD		SET1		SET2	
	Value	**Units**	**Value**	**Units**	**Value**	**Units**	**Value**	**Units**	**Value**	**Units**
WBC*	5.32	K/µL	5.32	G/L	5.32	10e9/L	5.32	10e3/µL	53.2	10e2/µL
RBC	5.15	M/µL	5.15	T/L	5.15	10e12/L	5.15	10e6/µL	515.	10e4/µL
HGB	16.2	g/dL	162	g/L	10.1	mmol/L	162	g/L	16.2	g/dL
HCT	47.6	%	0.476	L/L	0.476	L/L	47.6	%	47.6	%
MCV	92.3	fL	92.3	fL	92.3	fL	92.3	fL	92.3	fL
MCH	31.5	pg	31.5	pg	1.96	fmol	31.5	pg	31.5	pg
MCHC	34.1	g/dL	341	g/L	21.2	mmol/L	341	g/L	34.1	g/dL
RDW	12.5	%	12.5	%CV	12.5	%CV	12.5	%CV	12.5	%
PLT	323	K/µL	323	G/L	323	10e9/L	323	10e3/µL	32.3	10e4/µL
MPV	8.26	fL	8.26	fL	8.26	fL	8.26	fL	8.26	fL
PCT	0.267	%	2.67	mL/L	2.67	mL/L	0.267	%	0.267	%
PDW**	17.5	10GSD	17.5	10GSD	17.5	10GSD	17.5	10GSD	17.5	10GSD

*NEU, LYM, MONO, EOS and BASO are reported in the same units as the WBC

**Report Unit is Geometric Standard Deviation

To Change Units Selection

1. From the SET UP MENU screen, press [UNITS SELECTION].
2. Press the appropriate soft key to select the desired units. The group of selected units is highlighted on the screen.

   OR

3. For individual unit selection, use the Arrow keys on the keyboard to move the cursor to the desired units.
4. Press [SELECT UNITS] to enter the selection. The chosen selection is highlighted on the display.

5. Use the Arrow keys on the keyboard to move the cursor to the next unit to be selected.
6. Repeat steps 4 and 5 until all selections have been made.
7. If desired, press the Print Screen key on the keyboard to obtain a printout of the selected units.
8. Press [RETURN] to return to the SET UP MENU screen.

Customize Report

The [CUSTOMIZE REPORT] key is used to customize displayed and/or printed reports. When the [CUSTOMIZE REPORT] key is pressed, the screen that was displayed last will appear (Graphics Printer is the default screen).

Customize Printout

The [CUSTOMIZE PRINTOUT] key is used to customize the printout for the Graphics Printer and the Ticket Printer. For ease of explanation, the two printer types are discussed individually. Specific instructions are given for customizing a report for the graphics printer, for a blank ticket, and for a pre-printed ticket. When the [CUSTOMIZE PRINTOUT] key is pressed, some of the soft key labels change with the type of printer that is selected. The following soft key labels are displayed when the key is pressed:

GRAPHICS PRINTER/ TICKET PRINTER	(The key alternates between the selections.)
CUSTOMIZE DISPLAY	
STOP PRINTING	
CUSTOMIZE HEADER	
TOGGLE ON/OFF	
SET UP	

When the [CUSTOMIZE PRINTOUT] key is pressed, the screen that was used for the last entry (graphics printer or ticket printer) is displayed. A brief description of the function of the soft keys is given in this section. For ease of explanation, the keys are grouped according to the type of printer selected.

When the [TICKET PRINTER] key is pressed, the following soft key label is also displayed:

BLANK TICKET/ PRE-PRNTD TICKET	(The key label alternates between the selections.)

The [CUSTOMIZE DISPLAY] key is used to customize the display as discussed in the next section.

The [STOP PRINTING] key is used to stop printing that is in progress. When the [STOP PRINTING] key is pressed, the following soft key labels are displayed:

CONFIRM STOP
CANCEL STOP

The [CANCEL STOP] key cancels the STOP PRINTING command. If [CONFIRM STOP] is pressed, the print buffer (the memory area where the material is stored while awaiting printing) is cleared and the bulletin line displays the message:

PRINTING STOPPED. RESET PAPER TO THE TOP OF THE PAGE

Two additional keys are displayed when the [CUSTOMIZE HEADER] key is pressed:

RESTORE HEADER
BLANK HEADER

The [TOGGLE ON/OFF] key enables or disables the option selected by the position of the cursor. The key label is not displayed when a numeric entry is required.

The [SET UP] key is used to return to the SET UP MENU screen.

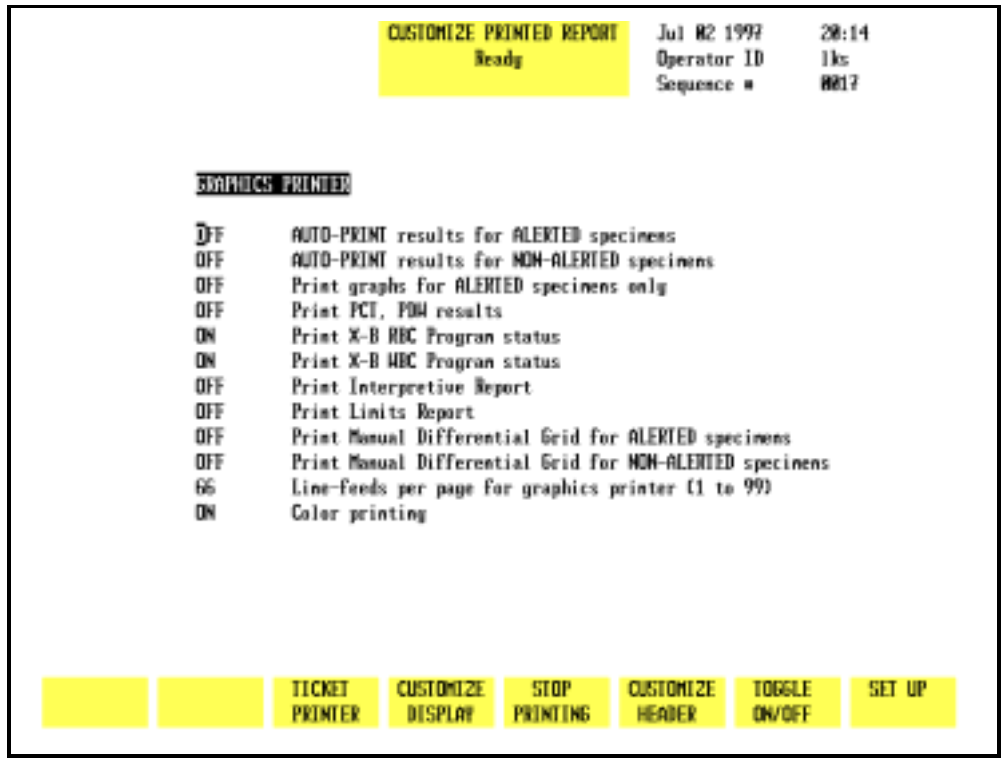

Figure 5.22: Customize Printed Report Screen for the Graphics Printer

Graphics Printer

When the [GRAPHICS PRINTER] key is pressed, the CUSTOMIZE PRINTED REPORT screen for the Graphics Printer is displayed. (See Figure 5.22.) A description of the options available on the CUSTOMIZE PRINTED REPORT screen is given below:

1. AUTO-PRINT RESULTS FOR ALERTED SPECIMENS

   When this option is enabled, a report is automatically printed for any sample with flagged results.

2. AUTO-PRINT RESULTS FOR NON-ALERTED SPECIMENS

   When this option is enabled, a report is automatically printed for any sample without flagged results.

3. PRINT GRAPHS FOR ALERTED SPECIMENS ONLY

   When this option is enabled, scatterplots and histograms are printed only for samples with flagged results.

4. PRINT PCT, PDW RESULTS

   When this option is enabled, the results for PCT and PDW are printed on the report.

NOTE: Clinical significance has not been established for these parameters. Therefore, they are not reportable.

5. PRINT X-B RBC PROGRAM STATUS

   When this option is enabled, the status of the X-B RBC program is printed on the report. The X-B status (for example, X-B RBC: 13/OUT2) is printed below the Status Box.

6. PRINT X-B WBC PROGRAM STATUS

   When this option is enabled, the status of the X-B WBC program is printed on the report. The X-B status (for example, X-B WBC: 13/OUT2) is printed below the Status Box.

7. PRINT INTERPRETIVE REPORT

   When this option is enabled, the Interpretive Report messages are printed on the report. These messages are generated when results exceed the Patient Limits and/or instrument-generated flags are present. Refer to **Section 3, Subsection: *Operational Messages and Data Flagging*** for an explanation of the Interpretive Report messages. (Also see the [PATIENT LIMITS] key discussion earlier in this section.)

8. PRINT LIMITS REPORT

   When this option is enabled, the Patient Limits set that was applied to the results is printed on the report.

9. PRINT MANUAL DIFFERENTIAL GRID FOR ALERTED SPECIMENS

   When this option is enabled, a grid that can be used to report a manual Differential is printed on the report for any specimen that is flagged.

10. PRINT MANUAL DIFFERENTIAL GRID FOR NON-ALERTED SPECIMENS

    When this option is enabled, a grid that can be used to report a manual Differential is printed on the report for any specimen that is not flagged.

11. LINE-FEEDS PER PAGE FOR GRAPHICS PRINTER (1 to 99)

    This option is used to select the size of the printed report.

12. COLOR PRINTING

    When this option is enabled, a color printout can be obtained on the CELL-DYN 3200 by pressing the [COLOR PRINT] key. It is not possible to automatically obtain color printouts.

To Customize the Graphics Report

1. Go to the Graphics Printer set up section of the CUSTOMIZE PRINTED REPORT screen (refer to Figure 5.22).
2. Use the Arrow keys on the keyboard to move the cursor to the desired selection.
3. Press [TOGGLE ON/OFF] to enable or disable any of the ON/OFF selections.
4. Repeat steps 2 and 3 until all selections have been made.
5. A numeric entry is required for the `LINE-FEEDS PER PAGE FOR GRAPHICS PRINTER` field. Type the desired number of line-feeds in the entry field and press the Enter key on the keyboard to save the entry and advance the cursor.
   (An 8.5" x 11" sheet of paper has 66 lines per page.)
6. If desired, press the Print Screen key on the keyboard to obtain a printout of the selections.
7. If desired, press [SET UP] to return to the SET UP MENU screen, or continue with the following procedure for customizing the header.

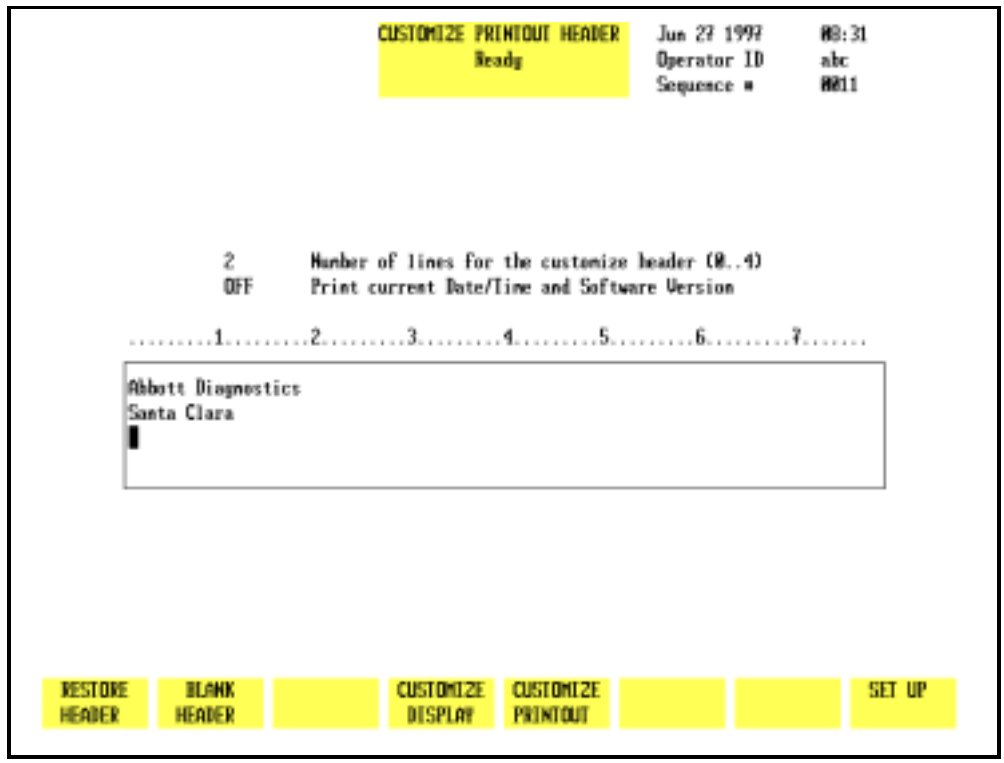

Figure 5.23: Customize Printout Header Screen for the Graphics Report

Customize Header

The [CUSTOMIZE HEADER] key is used to customize the header for the graphics report. (See Figure 5.23.) Any report printed in a graphics format will be printed with this header. The following soft key labels are displayed when the [CUSTOMIZE HEADER] key is pressed:

RESTORE HEADER
BLANK HEADER
CUSTOMIZE DISPLAY
CUSTOMIZE PRINTOUT
SET UP

Restore Header

The [RESTORE HEADER] key is used to restore the header to the previous entry. This key is only functional immediately after a new header has been entered. Once a new header is entered and the CUSTOMIZE PRINTOUT HEADER screen has been exited, the previous header is removed from the memory.

Blank Header

The [BLANK HEADER] key is used to erase the current header.

To Customize the Graphics Header

1. From any CUSTOMIZE PRINTED REPORT screen, press [CUSTOMIZE HEADER] to display the CUSTOMIZE PRINTOUT HEADER screen. Use the Arrow keys to skip a field.
2. Type the desired number of lines for the header in the indicated field. The header can include up to four lines.
3. Press the Enter key on the keyboard to save the entry and advance to the next entry field.
4. Press [TOGGLE ON/OFF] to enable or disable the `PRINT CURRENT DATE/TIME AND SOFTWARE VERSION` option.
5. Press the Enter key on the keyboard to save the entry and advance to the next entry field.
6. In the header box field, type the information to be displayed on the first line of the header. Each line holds 77 characters. Press the Enter key to move to the next header line.

NOTE: The number of lines of data in the header box cannot exceed the number of lines indicated in the first field. For example, if 3 were input in the first field, then a maximum of 3 lines will be accepted in the header box. The operator may type in 4 lines of data, but only the first three lines will be saved when the operator exists this screen. (Existing information may be typed over or an existing header may be deleted by pressing the [BLANK HEADER] key.)

NOTE: The numbers displayed above the header box on the screen indicate the position of the header on the printed page. For example, centering the header/ information under the number 4 centers the header on the page. Each line can be positioned independently of the other lines in the header box. Use the Space Bar on the keyboard to position the cursor for typing.

7. Press [SET UP] to return to the SET UP MENU screen.

Ticket Printer

Two options are available when the [TICKET PRINTER] key is pressed:

BLANK TICKET/ PRE-PRNTD TICKET	(The key alternates between the selections.)

The [PRE-PRNTD TICKET] key is used to customize the printed report for a pre-printed ticket. The [BLANK TICKET] key is used to customize the printed report for a blank ticket.

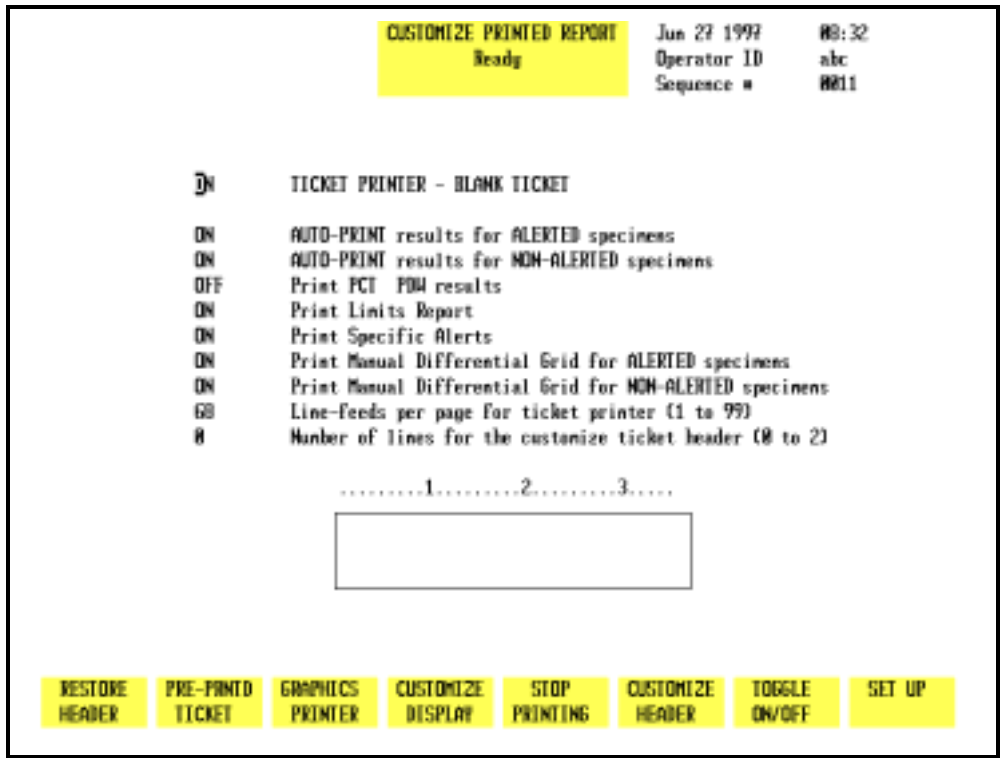

Figure 5.24: Customize Printed Report Screen for Blank Tickets

Blank Ticket

When the [BLANK TICKET] key is pressed, the CUSTOMIZE PRINTED REPORT screen for blank tickets is displayed. The following options are available:

1. TICKET PRINTER — BLANK TICKET

   When this option is enabled, the ticket printer is configured for a blank ticket. (The pre-printed ticket option is automatically turned OFF.)

2. AUTO-PRINT RESULTS FOR ALERTED SPECIMENS

   When this option is enabled, a ticket is automatically printed for any sample with flagged results. Flagged results are indicated by the letters “AL” (for alert) on the printout when the PRINT SPECIFIC ALERTS option is turned OFF (see number 6 below). Results that exceed Patient Limits are underlined on the printout.

3. AUTO-PRINT RESULTS FOR NON-ALERTED SPECIMENS

   When this option is enabled, a report is automatically printed for any sample without flagged results.

4. PRINT PCT, PDW RESULTS

When this option is enabled, the results for PCT and PDW are printed on the report.

NOTE: Clinical significance has not be established for these parameters. Therefore, they are not reportable.

5. PRINT LIMITS REPORT

   When this option is enabled, the Patient Limits set that was applied to the results is printed on the report.

6. PRINT SPECIFIC ALERTS

   When this option is enabled, the specific flag (BANDS, LRI, etc.) replaces the "AL" on the printout.

7. PRINT MANUAL DIFFERENTIAL GRID FOR ALERTED SPECIMENS

   When this option is enabled, a grid that can be used to report a manual Differential is printed on the report for any specimen that is flagged.

8. PRINT MANUAL DIFFERENTIAL GRID FOR NON-ALERTED SPECIMENS

   When this option is enabled, a grid that can be used to report a manual Differential is printed on the report for any specimen that is not flagged.

9. LINE-FEEDS PER PAGE FOR TICKET PRINTER (1 to 99)

   This option is used to select the size of the printed report. (A blank ticket typically has 68 lines.)

10. NUMBER OF LINES FOR THE CUSTOMIZE TICKET HEADER (0 to 2)

    This option is used to select the number of lines for the header on the blank ticket. The numbers across the top of the header can be used to center the header information on the ticket. Centering the information under the number 2 centers it on the ticket.

To Customize a Blank Ticket

1. If the Blank Ticket section of the CUSTOMIZE PRINTED REPORT screen is not displayed, press [BLANK TICKET].
2. Use the Arrow keys on the keyboard to move the cursor to the desired selection.

3. Press [TOGGLE ON/OFF] to enable or disable the selection.
4. Press the Enter key on the keyboard to save the entry and advance the cursor to the next field.
5. Repeat steps 2 through 4 until all ON/OFF selections have been made.
6. A numeric entry is required for the `LINE-FEEDS PER PAGE FOR TICKET PRINTER` field (A blank ticket typically has 68 lines) and the `NUMBER OF LINES FOR THE CUSTOMIZE TICKET HEADER` field.
7. Type the desired number of line-feeds in the entry field and press the Enter key on the keyboard to save the entry and advance the cursor.
8. Type the desired number of lines for the header (a maximum of 2 lines) and press the Enter key on the keyboard to save the entry and advance the cursor to the header box field.
9. With the cursor in the header box, type the first line of the header and press the Enter key on the keyboard to save the entry and advance the cursor. Each line holds 35 characters. If desired, type a second line and press the Enter key on the keyboard to save the entry and advance the cursor.

   NOTE: The number of lines of data in the header box cannot exceed the number of lines entered in step 8 above. For example, if 1 were input, then a maximum of 1 line will be accepted in the header box. The operator may type in 2 lines of data, but only the first line will be saved when the operator exists this screen.

   NOTE: The numbers displayed above the header box on the screen indicate the position of the header on the printed page. Each line can be positioned independently. Use the Space Bar on the keyboard to position the cursor for typing.

10. If desired, press the Print Screen key on the keyboard to obtain a printout of the selections.
11. Press [SET UP] to return to the SET UP MENU screen.

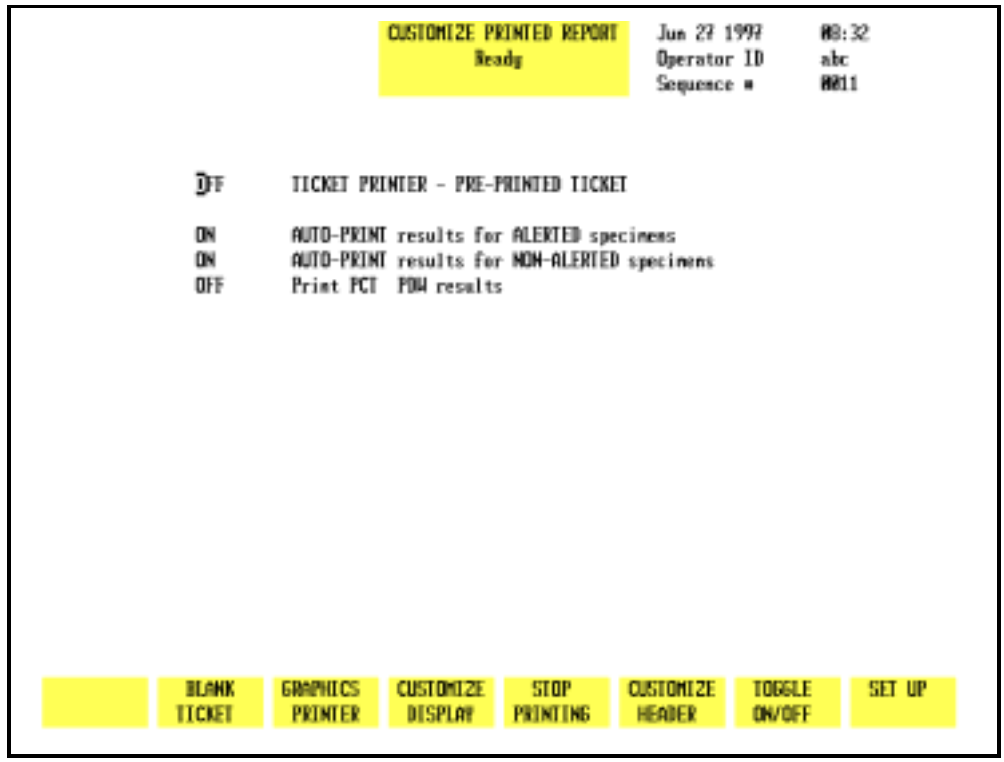

Figure 5.25: Customize Printed Report Screen for Pre-Printed Tickets

Pre-Printed Tickets

When the [PRE-PRNTD TICKET] key is pressed, the CUSTOMIZE PRINTED REPORT screen is displayed. The numbers on the screen shown in Figure 5.25 correspond to the following numbered options:

1. TICKET PRINTER — PRE-PRINTED TICKET

   When this option is enabled, the ticket printer is configured for a pre-printed ticket. (The blank ticket option is automatically turned OFF.)

2. AUTO-PRINT RESULTS FOR ALERTED SPECIMENS

   When this option is enabled, results for flagged specimens are automatically printed as tickets are inserted in the printer. Flagged results are marked with an asterisk (*).

3. AUTO-PRINT RESULTS FOR NON-ALERTED SPECIMENS

   When this option is enabled, results for specimens that are not flagged are automatically printed as tickets are inserted in the printer.

4. PRINT PCT, PDW RESULTS

   When this option is enabled, the PCT and PDW are printed on the ticket.

   NOTE: Clinical significance has not been established for these parameters. Therefore, they are not reportable.

To Customize the Pre-Printed Ticket

1. Go to the Ticket Printer - Pre-printed Ticket section of the CUSTOMIZE PRINTED REPORT screen (refer to Figure 5.25).
2. Use the arrow keys on the keyboard to move the cursor to the desired option.
3. Press [TOGGLE ON/OFF] to enable or disable the selected option.
4. Press the Enter key on the keyboard to save the entry and advance the cursor to the next field.
5. Repeat steps 2 through 4 until all selections have been made.
6. If desired, press the Print Screen key on the keyboard to obtain a printout of the selections.
7. Press [SET UP] to return to the SET UP MENU screen.

Customize Displayed Report

Customized displays can be established for each of the four parameter sets. The CUSTOMIZE DISPLAYED REPORT screen (see Figure 5.26) for the indicated parameter set (in this case PARAM SET 1) and the following soft key labels are displayed when the [CUSTOMIZE DISPLAY] key in the CUSTOMIZE PRINTED REPORT screen is pressed:

PARAM SET 1*
PARAM SET 2*
PARAM SET 3*
PARAM SET 4*
CUSTOMIZE PRINTOUT
CUSTOMIZE HEADER/
CANCEL GRAPH (The key label alternates between the selections.)
SELECT GRAPH/
PLACE GRAPH (The key label alternates between the selections.)
SET UP
*The soft key for the displayed parameter set is blanked out.

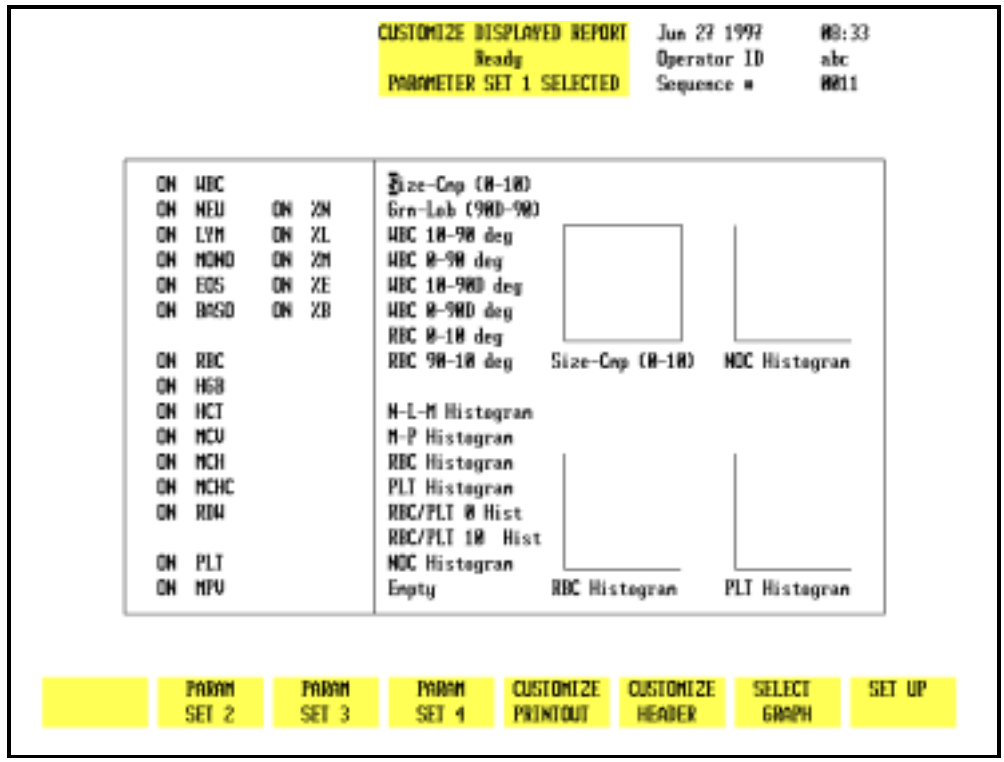

Figure 5.26: Customize Displayed Report Screen

The screen is divided into two sections. Individual parameters are listed in the left section and the scatterplots and histograms are listed in the right section.

Parameter Sets

Using the [PARAM SET "X"] key, the display may be customized for four different sets of parameters. Up to 20 individual parameters and up to four scatterplots and/or histograms may be displayed in each set.

The "Empty" selection at the bottom of the Histogram list may be used to "blank" the scatterplot or histogram display at the selected position. Move the cursor to Empty and press [SELECT GRAPH]. Move the cursor to the desired scatterplot or histogram and press [PLACE GRAPH].

To Customize the Display Screen

1. From the SET UP MENU screen, press [CUSTOMIZE REPORT] and if necessary, press [CUSTOMIZE DISPLAY] to display a parameter set.
2. If desired, press [PARAM SET "X"] to select a different parameter set.

3. Use the Arrow keys on the keyboard to move the cursor to the desired parameter in the list displayed on the left section of the screen.
4. Press [TOGGLE PARAMETER] to turn the display off or on and advance the cursor to the next parameter. The cursor moves through the entire list of parameters in this section of the screen and, when at the bottom, returns to the top of this list.

   NOTE: The [TOGGLE PARAMETER] key is displayed only when the cursor is positioned in the list of individual parameters displayed on the left side of the screen.

5. Repeat steps 3 and 4 until all parameter selections have been made. Use the Right Arrow key to move the cursor to the next section.
6. Use the Arrow keys to move the cursor to the desired scatterplot or histogram.
7. Press [SELECT GRAPH] to select it. The scatterplot or histogram name is highlighted and the cursor moves to a display position. The key label changes to [PLACE GRAPH] and the [CANCEL GRAPH] key is displayed.
8. If necessary, use the Arrow keys on the keyboard to move the cursor to the desired display position.
9. Press [PLACE GRAPH] to display the selection at the indicated position. The cursor moves to the next scatterplot or histogram in the list.
10. Repeat steps 6 through 9 until all selections have been made for the current Parameter Set.
11. If desired, press the Print Screen key on the keyboard to obtain a printout of the selected Parameter Set.
12. Press [PARAM SET “X”] to select another Parameter set and repeat steps 3 through 11 to customize the display for it.
13. Press [SET UP] to return to the SET UP MENU screen.

Interpretive Report Messages

If the `PRINT INTERPRETIVE REPORT` option on the CUSTOMIZE PRINTED REPORT screen for the Graphics Printer is enabled, Interpretive Report messages are printed on the report. Some of these messages are generated from the information entered for the Patient Limits. The following messages are generated by specimen results which exceed the Patient Limits:

WBC Messages

Leukopenia —result exceeds the lower limit for WBC

Leukocytosis —result exceeds the upper limit for WBC

Neutropenia —result exceeds the lower limit for Neutrophil absolute number

Neutrophilia —result exceeds the upper limit for Neutrophil absolute number

Lymphopenia —result exceeds the lower limit for Lymphocyte absolute number

Lymphocytosis —result exceeds the upper limit for Lymphocyte absolute number

Monocytosis —result exceeds the upper limit for Monocyte absolute number

Eosinophilia —result exceeds the upper limit for Eosinophil absolute number

Basophilia —result exceeds the upper limit for Basophil absolute number

RBC Messages

Anemia —result exceeds the lower limit for RBCs

Polycythemia —result exceeds the upper limit for RBCs

Microcytic RBC —result exceeds the lower limit for MCV

Macrocytic RBC —result exceeds the upper limit for MCV

Hypochromic —result exceeds the lower limit for MCHC

Hyperchromic —result exceeds the upper limit for MCHC

Anisocytosis —result exceeds the upper limit for RDW

PLT Messages

Thrombocytopenia —result exceeds the lower limit for PLTs

Thrombocytosis —result exceeds the upper limit for PLTs

Microcytic PLT —result exceeds the lower limit for MPV

Macrocytic PLT —result exceeds the upper limit for MPV

NOTES

Routine Operation

General Information

This subsection contains information and procedures that are recommended for the routine operation of the CELL-DYN 3200.

The following topics are included in this subsection:

- Instrument Start-up
- RUN menu
- Sample Collection and Handling
- Sample Analysis on the CELL-DYN 3200 SL
- Sample Analysis on the CELL-DYN 3200 CS
- Daily Shutdown Procedure

Unless stated otherwise, all subsections apply to both the Sample Loader and Closed Sampler versions of the CELL-DYN 3200. For convenience, instructions for running samples in the Open Mode are repeated in each of the two **Running Samples** subsections. Refer to **Section 13: *Sample Loader*** for additional information on Sample Loader operation and to ***Appendix A*** for information on the use of bar code labels.

Power ON Procedure

The System power switch on the back of the Analyzer should be left ON at all times. The instrument has been designed to automatically maintain itself when it is idle. If the instrument is idle for five minutes, a cleaning cycle is automatically initiated. If the instrument is idle for four hours, an automatic Shutdown cycle is initiated. The instrument is placed in the STANDBY state at the end of the automatic Shutdown cycle.

Power switches for the Display Monitor and printer should be left ON as long as power to the System is ON. Power to the monitor and printer should be turned OFF when the System is turned OFF, when a malfunction is suspected, or when maintenance is required.

Power to the Printer may be left on or off at the operator's discretion. Refer to ***Section 12: Printers*** for complete instructions on printer operation.

IMPORTANT: If the power has been OFF more than five minutes, the laser must be allowed to warm up for 15 minutes once the power is turned back ON. Do not process samples during this warm-up period.

To power-up the instrument:

1. Verify that all components are properly installed (syringes, tubing in the normally closed valves, Shear Valve, etc.).
2. Verify that all reagents are properly installed.
3. Verify that all necessary cables and power cords are properly connected.
4. Verify that the Analyzer covers are properly installed, including the Tower Cover.
5. If a condition caused power to the instrument to be turned OFF, verify that the condition has been corrected.
6. Turn the power switches ON in the following order:
   a. System (includes Analyzer, Data Module, and Sample Loader)
   b. Display Monitor
   c. Printer
7. When the INITIALIZED message appears in the Status Box on the MAIN MENU, press [RUN] to prime the system.

Initializing the System

The term *initialization* refers to the automatic process that occurs when the instrument is first turned ON, or after certain problems have been corrected and the instrument must again be brought to the READY state. Initialization is a two-step process:

1. Initializing the hardware and software
2. Priming the system with reagents

The system is initialized when the Analyzer is turned ON or when the [INITIALIZATION] key, located in the second DIAGNOSTICS MENU, is pressed. During the initialization process, the software located in the Data Module is accessed and downloaded to the Analyzer. When this has been accomplished, all Analyzer pumps and motors are moved to their "home" positions. (Increase motor noise is common during this period.) When the system has been initialized, the message INITIALIZED is displayed in the Status Box.

The next step is to prime the system with reagents. When the initialized message appears in the Status Box on the MAIN MENU, press [RUN] to prime the system. When the priming cycle is finished, the message READY is displayed in the Status Box.

Operating the Instrument

Activating The RUN Cycle

On the CS model, start the RUN cycle for either the Open or Closed Mode by pressing the Touch Plate.

> **NOTE:** The door Assembly must be closed for the Closed Mode RUN cycle to be activated.

On the SL model, Start the RUN cycle for Open Mode by pressing the Touch Plate. Start the RUN cycle for Closed Mode by pressing the [START LOADER] key in the RUN menu. For additional information, refer to ***Sample Loader Description, Soft Keys*** in **Section 13: *Sample Loader.***

Orderly Stops

The CS model, whether in Open or Closed Mode, automatically halts after each sample has been processed unless the Touch Plate is pressed again to start a new RUN cycle.

The SL model in Open Mode automatically halts after each sample has been processed unless the Touch Plate is pressed again to start a new RUN cycle.

The SL model in Closed Mode automatically halts when no more racks are detected on the load side and the last track has passed under the Tower to the Unload side.

Emergency Stops

To immediately halt all operation of the instrument, do one of the following:

1. Turn OFF the main power switch, located in the upper left corner of the back panel.
2. Push the window section of the Tower Cover toward the instrument to release the latches and break the safety interlock sensor connection. As soon as the connection is broken, the instrument halts. It is not necessary to remove the Tower Cover to stop operations. This method applies to both CS and SL models. In addition, the CS model has a safety interlock sensor attached to the swivel door mechanism which holds the sample tube.

Power OFF Procedure

It is not necessary to turn the system OFF under normal operating conditions. The system should be turned OFF when certain maintenance procedures will be performed, when the system will be moved, or when the system will be inactive for an extended period of time (longer than 2 weeks).

For Maintenance

When certain tests or maintenance procedures require power to be OFF, use the following procedure:

1. With the system still ON, perform any maintenance that is due.
2. Perform the Auto-Clean procedure in the SPECIAL PROTOCOLS menu. (If necessary, refer to **Section 9: *Service and Maintenance*, Subsection: *Daily Maintenance Procedures***.)
3. When the Auto-Clean cycle is finished, press [DAILY SHUTDOWN]. When the DAILY SHUTDOWN cycle is finished, the message STANDBY will be displayed in the Status Box.
4. Turn the power switches OFF in the following order:
   a. System (includes Analyzer, Data Module, and Sample Loader)
   b. Display Monitor
   c. Printer

   NOTE: In an emergency situation, turn power OFF in any order as quickly as possible.

For Extended Period

Additional procedures are required if the instrument will be inactive for an extended period of time (more than 2 weeks), moved to a different location in the lab, or shipped to a distant location. For detailed instructions, refer to ***Intermediate-term Shutdown*** and ***Prolonged Shutdown*** later in this section.

Start-Up Procedure

To startup the instrument, do the following:

1. If the instrument is OFF, first turn the power ON. When INITIALIZED is displayed in the MAIN MENU Status Box, press [RUN] to prime the instrument and bring it to the READY state.
2. If the instrument is already ON and STANDBY or INITIALIZED is displayed in the MAIN MENU Status Box, press [RUN] to prime the instrument and bring it to the READY state.
3. Perform the daily Quality Control checks as directed within this section.

Daily Start-Up Procedure

The daily start-up routine consists of the following procedures:

1. Check the reagent levels and replace reagent containers as necessary.
2. Check printer paper; add more paper as necessary.
3. Check tubing in the Normally Closed Valves and Sample Transfer Peristaltic Pump for breaks, crimps, or other obstructions.
4. Run background counts until acceptable results are obtained for all background parameters (WBC, RBC, HGB, and PLT). Acceptable results are specified in **Section 4: *Performance Characteristics and Specifications,* Subsection: *Background Counts***.
5. Quality control procedures (which confirm calibration) should be performed on a daily basis according to the laboratory's protocol. Commercial control materials should be properly warmed and mixed according to the manufacturer's recommendations. Patient controls should be handled according to the laboratory's protocol.

NOTES

Run Menu

The RUN menu and its sub-menus are described below, including soft keys, demographics area, Work List, and bulletin line.

To display the RUN menu, press [RUN] in the MAIN MENU. If the instrument has not been primed, the priming cycle occurs before the RUN menu is displayed.

RUN Screen Format

Upper Left Corner (Run Screen Demographics)

The Demographics Section of the RUN screen differs depending on the specimen type selected. These differences are discussed below.

Patient

The Upper Left Corner of the RUN screen for patient samples displays the following data entry fields:

NEXT ID –used to enter the ID number for the next sample to be run. (Up to 12 characters may be entered.)

NAME –used to enter the patient's name. (Up to 28 characters may be entered.)

PAT ID –used to enter patient identification information, such as a Social Security number. (Up to 16 characters may be entered.)

SEX–used to enter the sex of the patient.

DOB–used to enter the date of birth of the patient. (4 digits must be entered for the Year.)

COL–used to enter the collection date and time of the specimen.(4 digits must be entered for the Year.)

DR–used to enter the name of the patient's physician. (Up to 22 characters may be entered.)

CMT–used to enter operator comments. (Up to 16 characters may be entered.)

PARAM SET/LIMITS SET–displays the number of the Parameter Set (1–4) and Limit Set (1-6) that will be applied to the sample results

X-B Status–If the XB-RBC and/or the XB-WBC functions are enabled, the XB file status for each is displayed under the Status Box.

> **NOTE:** The Parameter and Limits sets applied to the sample may be changed after the sample has been run. Refer to the description of the Data Log [EDIT SPECIMEN] key given in the ***Using the Data Log*** later in this section.

An example of the RUN screen for patient specimens is shown in Figure 5.27.

Fragile WBC and Resistant RBC

If the specimen type selected is FRAGILE WBC, then the label "FrgWBC" appears instead of "Name" in the Demographics Section. If the specimen type selected is RESISTANT RBC, then the label "ResRBC" appears instead of "Name" in the Demographics Section.

QC Specimen, Background, Latex

If the specimen type selected is QC SPECIMEN, BACKGROUND, or LATEX, the following information is displayed in the Demographics Section:

Type–displays the name of the QC file or displays Background or Latex. For a QC file, the number of runs in the QC file and total file space is displayed to the right of the type as in the following example:

XX/120-current number of specimens in a batch of 120 (applies only to QC Specimens).

Param Set:–indicates the Parameter Set applied to the results run in the QC file. For BACKGROUND and LATEX, the default Param Set is 1.

Status Box

The Status Box is displayed in the Top Center of the RUN screen. It contains the following information:

- Menu in use

- The Status of the Analyzer — the READY, NOT READY and FAULT messages are displayed here
- Report or File identity for results currently displayed

The Status Box also displays status and instructive messages during the run cycle. These messages are:

```
Aspirating
Remove specimen
Dispensing
Counting
Rinsing
Ready
```

Upper Right Corner

The Upper Right Corner of the RUN screen displays the following information:

- Current date and time
- Operator ID — Identification of the current operator
- Sequence # — Automatically increments as cycles are run
- Selected Sampler mode — Open Sampler or Closed Sampler

Upper Center Section

The Upper Center Section of the RUN screen displays the following information:

Center Section

The Center Section of the RUN screen displays the results. A list of the parameters and results is displayed on the left side. Scatterplots and histograms are displayed on the right side. The area between the parameter data and the graphic data is used to display flagging messages.

Bulletin Line

The Bulletin Line is displayed immediately above the key labels. Messages appear in this line to identify status or fault conditions.

Run Menu Soft Keys

CS Model

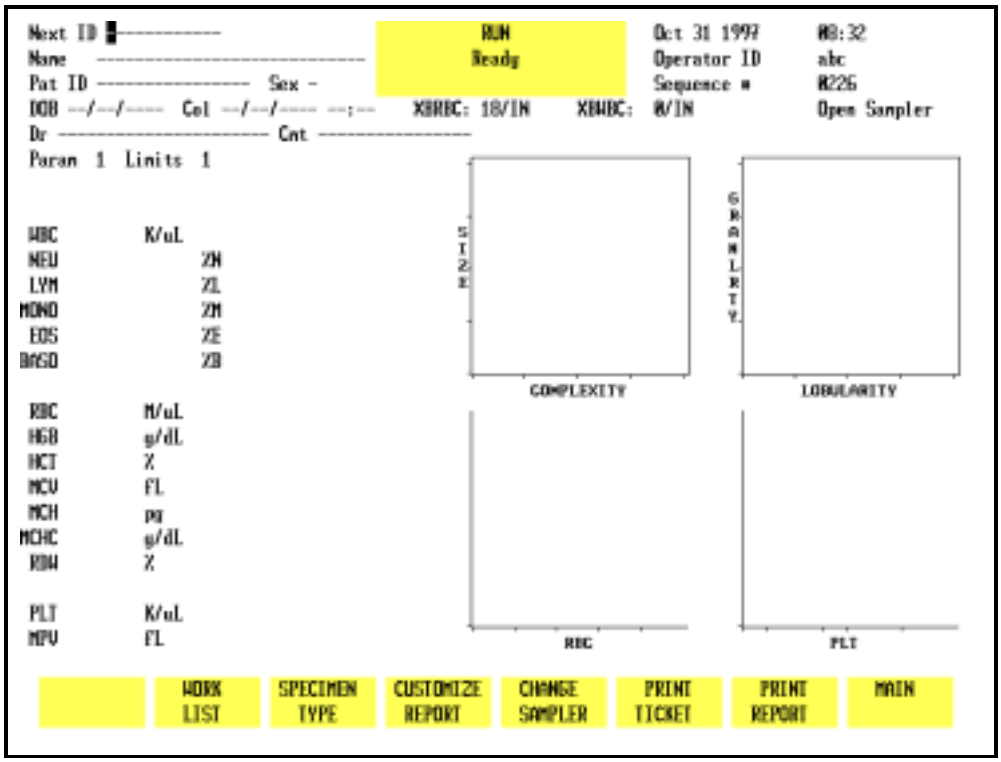

Figure 5.27: Run Screen for Patient Samples - CS Model

The soft keys displayed at the bottom of the RUN menu are used to access the menu options that are available. The soft keys displayed on the SL model are slightly different from the keys displayed on the CS model. The keys shown on the CS model are listed below. (See Figure 5.27.)

CLEAR FAULT	(This key label is blank unless a Fault occurs.)
WORK LIST	
SPECIMEN TYPE	
CUSTOMIZE REPORT	
CHANGE SAMPLER	
PRINT TICKET	

PRINT REPORT/
COLOR PRINT (This key label changes to COLOR PRINT when the color printing option is selected in the CUSTOMIZED PRINTED REPORT screen for the Graphics Printer)

MAIN

SL Model

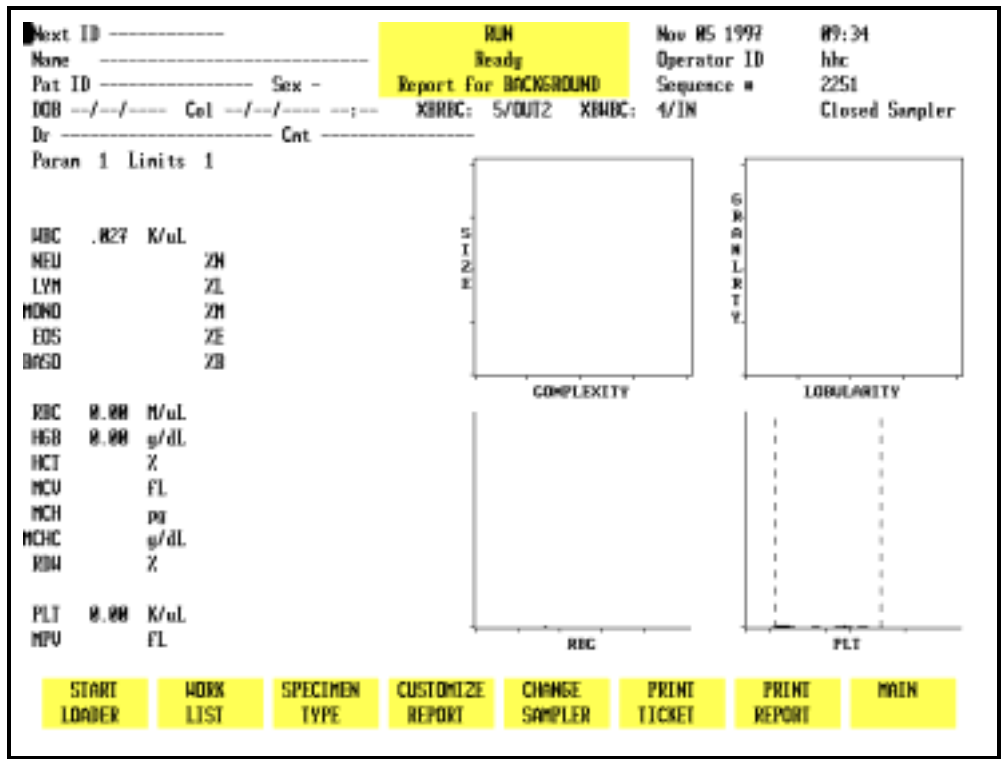

Figure 5.28: Run Screen for Patient Samples - SL Model

The soft keys shown on the SL model are similar to the CS model except for the first key (leftmost key label on the screen) in Closed Mode, shown below, which is used to operate the Sample Loader. (See Figure 5.28.)

START LOADER/
STOP LOADER (This key label alternates between the selections)

If a fault occurs, this key label changes to [CLEAR FAULT] similar to the CS model.

Soft Key Description

A brief description of the function of each key is given below. Instructions for running samples are given in ***Sample Analysis on the CELL-DYN 3200CS*** and ***Sample Analysis on the CELL-DYN 3200SL*** in this section.

Clear Fault

The blank key label in the CS model or the [START/STOP LOADER] key label in the SL model changes to [CLEAR FAULT] whenever a system fault occurs (e.g., Diluent Empty). This key is used to clear the fault message and return the Analyzer to the READY state after corrective action has been taken.

> **NOTE:** A message describing the fault appears in the bulletin line. A list of fault conditions and corrective action is given in **Section 10:** ***Troubleshooting and Diagnostics***.

Work List

This key is used to display the WORK LIST screen, shown in Figures 5.29 and 5.30. Use the left and right arrow keys to scroll between the pages. When the [WORK LIST] key is pressed, the WORK LIST screen appears and the following soft key labels are displayed:

INSERT/DELETE
DELETE ALL
WORK LIST SET UP
PRINT WORK LIST
RETURN

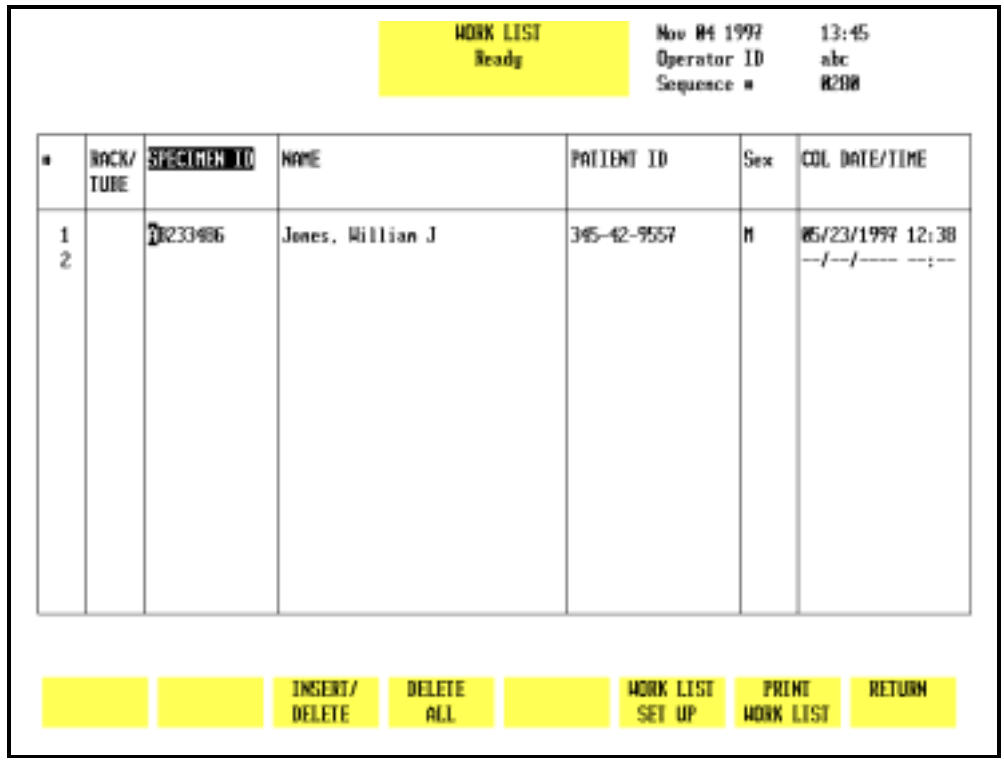

Figure 5.29: Work List Screen - Page 1

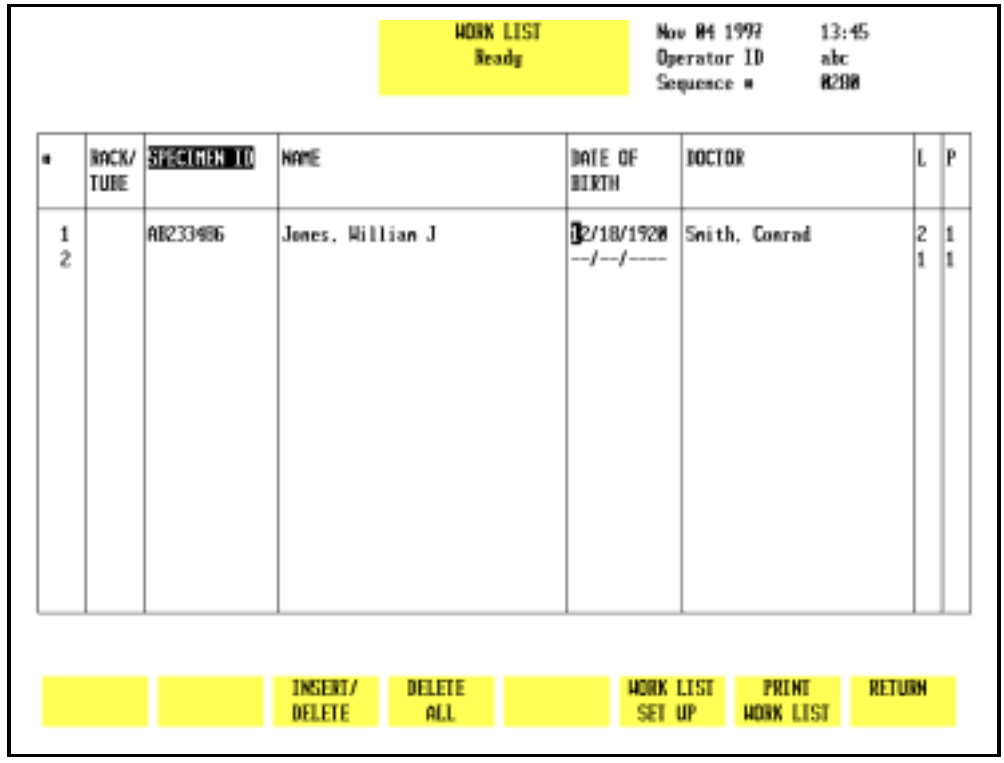

Figure 5.30: Work List Screen - Page 2

The Work List is used to pre-assign sample identification, display and print criteria for samples that will be run. It is essentially a list of samples (including the pre-assigned information) that the operator intends to run on the instrument.

The Work List may be used with or without bar code labels on the tubes. However, if bar codes are used on the tubes, they must contain more than two digits to avoid a possible mis-reading of the 2-digit bar code assigned to each rack.

For a detailed discussion of the Work List, refer to ***Using the Work List*** later in this section.

Specimen Type

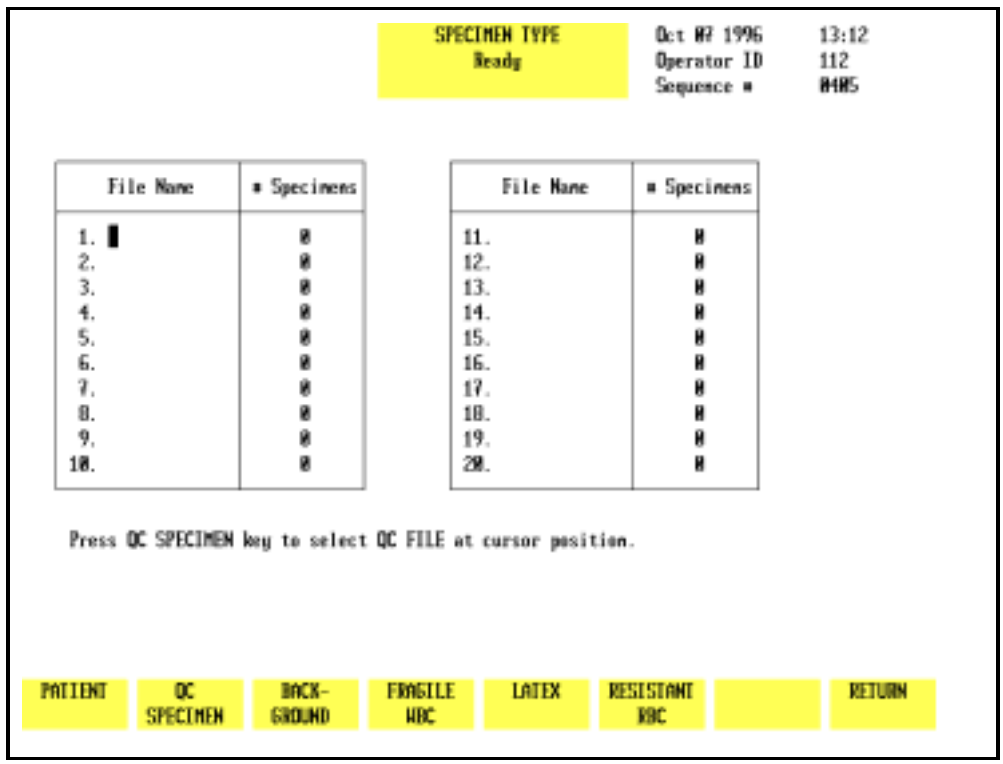

Figure 5.31: Specimen Type Screen

The [SPECIMEN TYPE] key is used to select the type of specimen that will be run. (See Figure 5.31.) When the [SPECIMEN TYPE] key is pressed, the screen displays a list of the QC files and the following soft key labels:

PATIENT
QC SPECIMEN
BACKGROUND
FRAGILE WBC

LATEX
RESISTANT RBC
RETURN

The function of each key is discussed below.

Selecting a Specimen Type

Most samples will be run in the Patient mode. If a FWBC or RRBC flag is displayed on the RUN screen, the presence of fragile WBCs or resistant RBCs is suspected. Depending on the flag, select either Fragile WBC or Resistant RBC as the Specimen Type and re-run the sample.

Patient

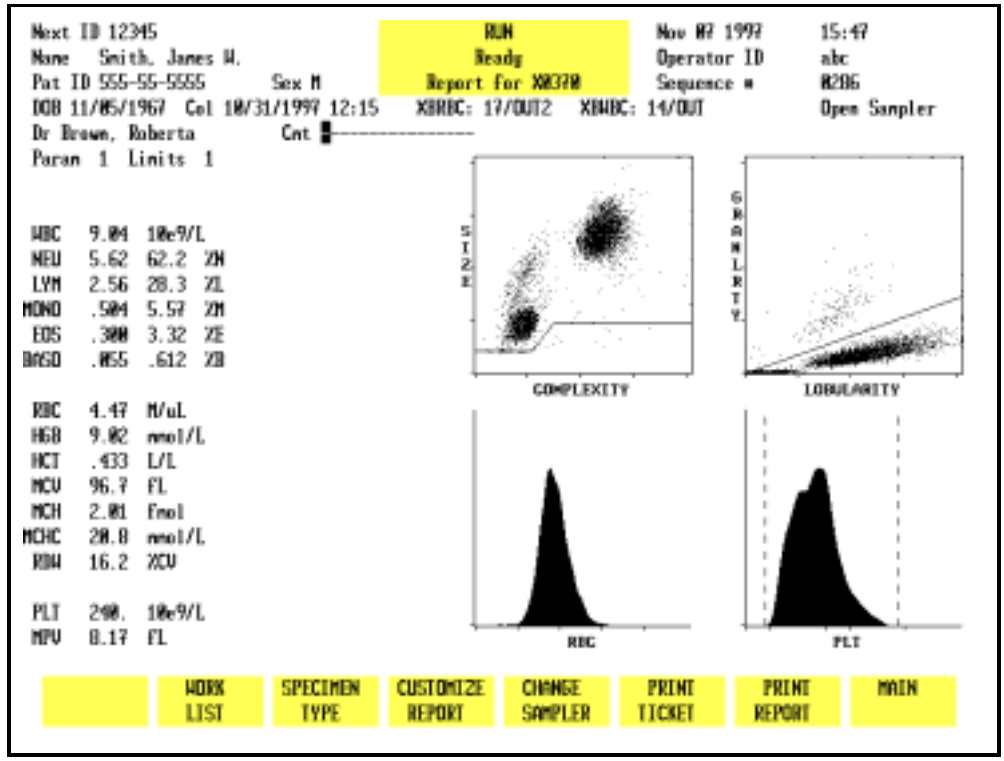

Figure 5.32: Run Screen Showing Patient Results

The [PATIENT] key is used to display the RUN screen for patient samples. (See Figure 5.32.) Patient identification and demographics may be entered on the RUN screen after this key is pressed. Results from this run option are stored in the Data Log.

QC Specimen

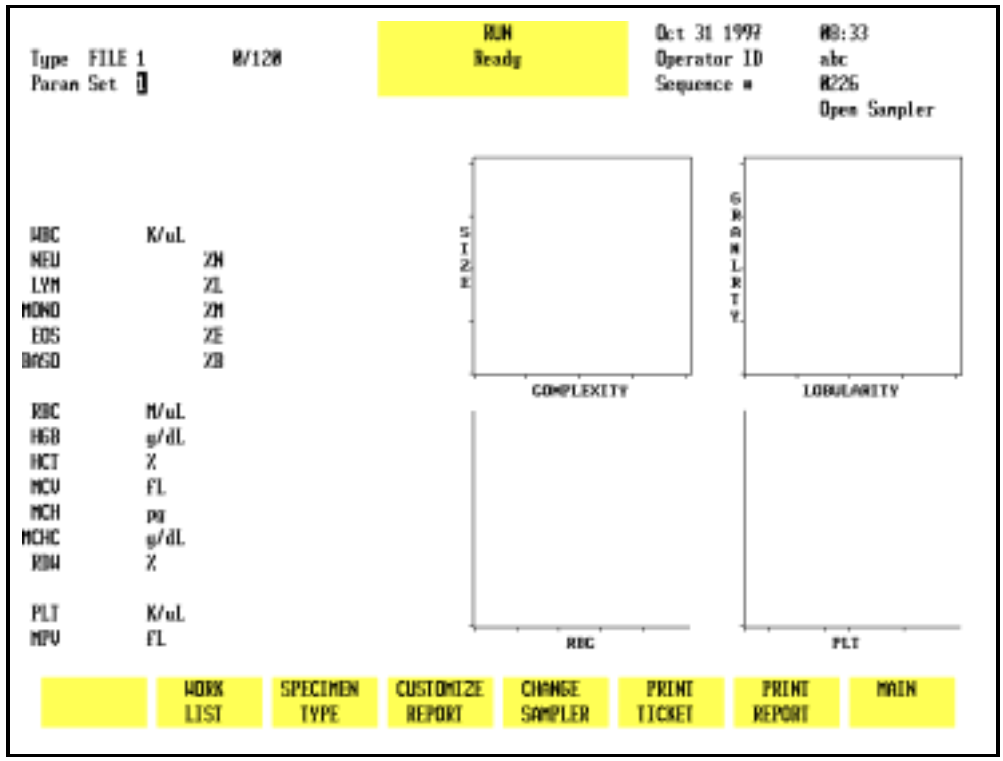

Figure 5.33: Run Screen for a QC File

This key is used to select a QC file designated by the position of the cursor on the screen. (Refer to Figure 5.31 for a display of QC files). After the cursor is moved to the desired file, the [QC SPECIMEN] key is pressed to display the RUN screen for the selected file. (Refer to Figure 5.33.) Results from this run option are stored in the selected file and in the Data Log.

> **NOTE:** The selected QC file is identified in the upper left section of the screen and is also identified in the Status Box after the sample has been run.

Background

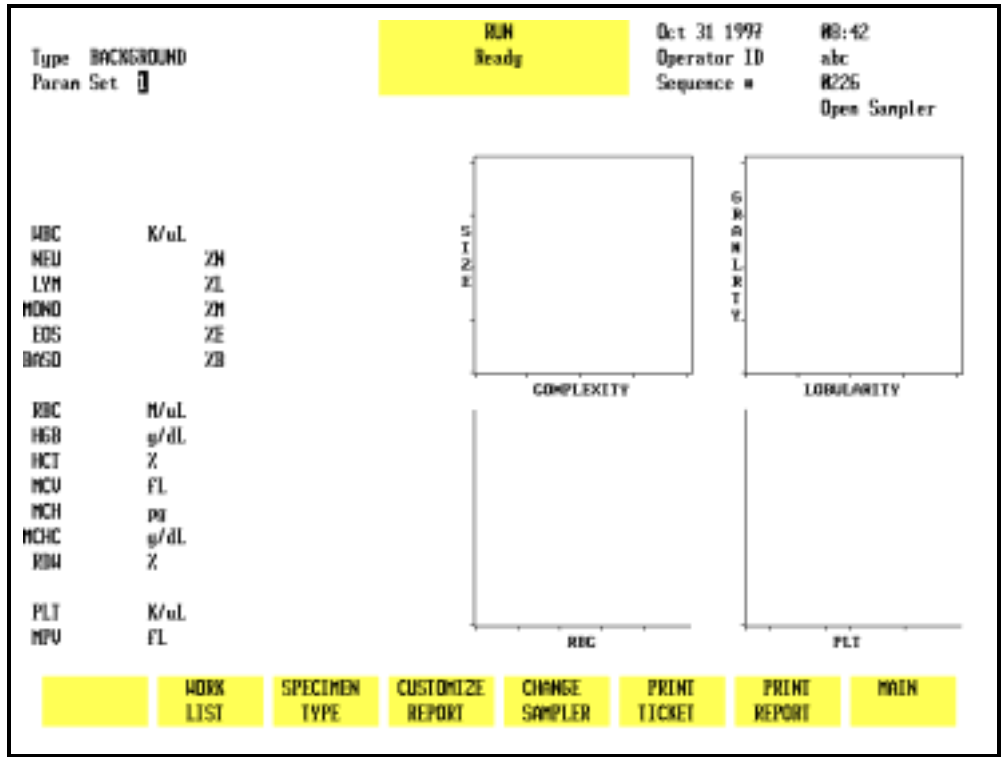

Figure 5.34: Run Screen for Background Counts

The [BACKGROUND] key is used to select the run mode and display the RUN screen for background counts. (Refer to Figure 5.34.) Results from this run option are identified by the designation BACKGROUND in the Data Log and are automatically excluded from the X-B analysis.

Fragile WBC

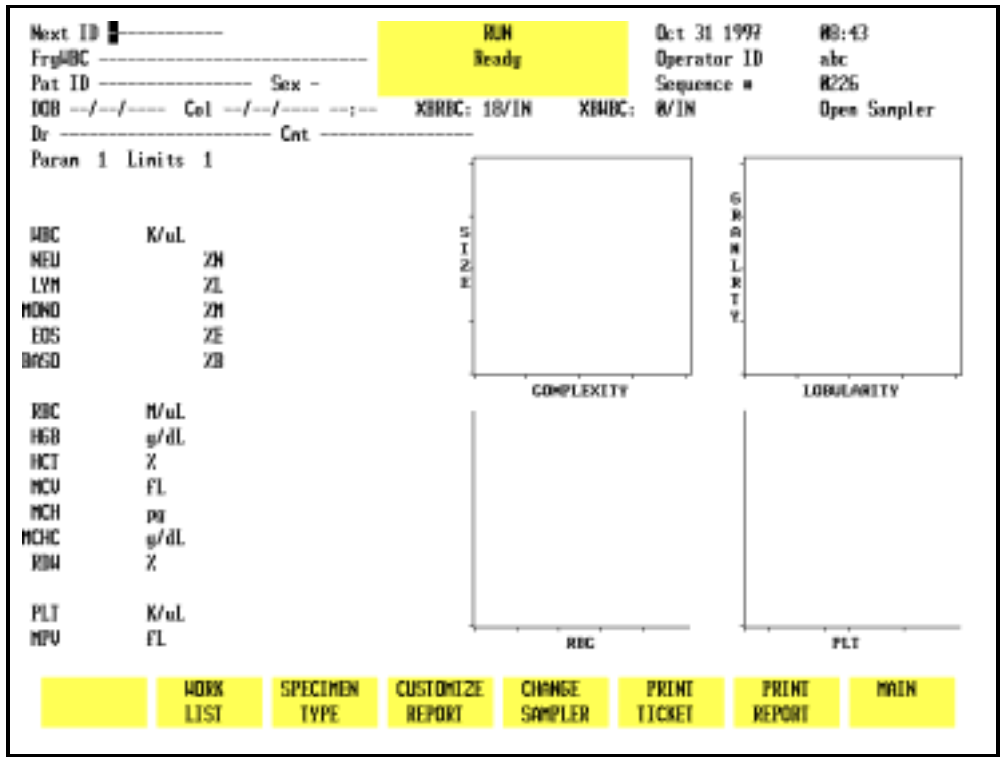

Figure 5.35: Run Screen for Fragile WBC Counts

The [FRAGILE WBC] key is used to select the Fragile WBC specimen type. This cycle is used to obtain an accurate WBC count for samples containing fragile WBCs. After HGB has been measured, the diluted HGB sample is sent to the Optical Flow Cell (instead of the Waste System) where the nuclei of the lysed white cells are counted. This count is referred to as the Nuclear Optical Count (NOC).

The Fragile WBC screen (refer to Figure 5.35) is similar to the Patient screen except that “FrgWBC” replaces “Name” in the Demographics Section.

Latex

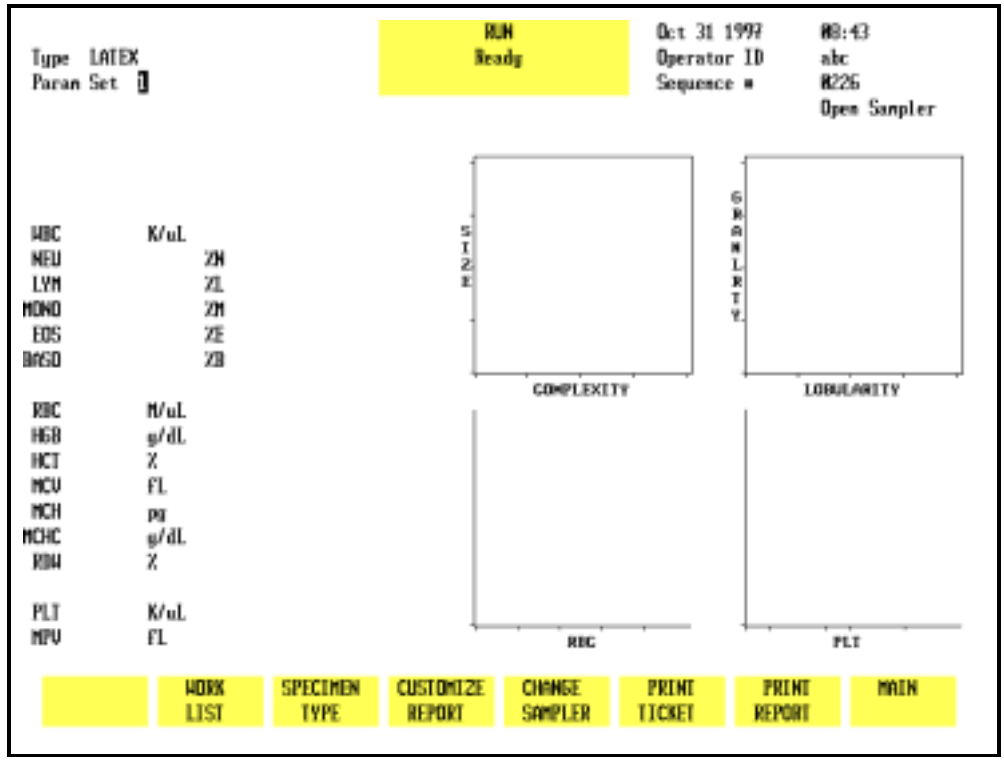

Figure 5.36: Run Screen for Latex Counts

The [LATEX] key is used to select the run mode for latex particles and display the RUN screen for them. The LATEX screen is similar to the QC FILE screen, except that “Latex” replaces the QC File name in the Demographics Section.

This key is for use by Abbott service personnel only.

Resistant RBC

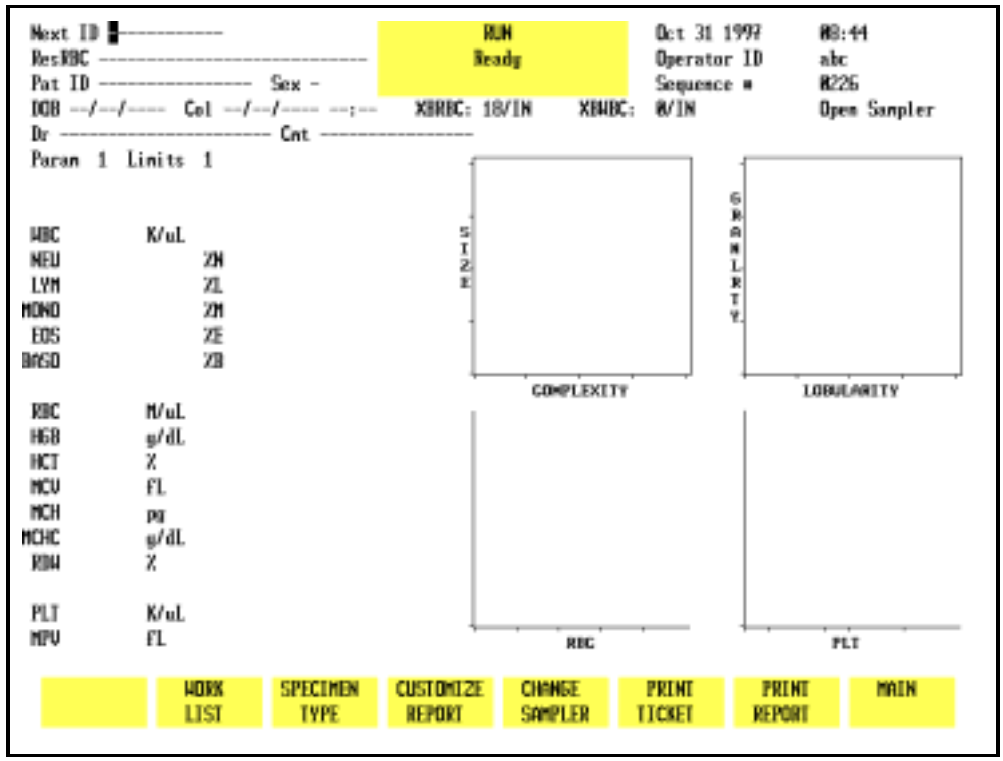

Figure 5.37: Run Screen for Resistant RBC Counts

The [RESISTANT RBC] key is used to select the Resistant RBC specimen type. This cycle is used to process samples containing RBCs that are resistant to lysis. The sample is held in the WBC Mixing Chamber for approximately 15 seconds longer than the normal mixing time. The extra time enhances the osmotic lysing effect of the WBC lyse and reduces interference from the lyse-resistant RBCs. (The interference caused by these RBCs frequently generates WBC and Differential flags. The Resistant RBC mode reduces the number of flags generated.)

The RESISTANT RBC screen (refer to Figure 5.37) is similar to the Patient screen except that “ResRBC” replaces “Name” in the Demographics Section.

Customize Report

The [CUSTOMIZE REPORT] key is discussed in the ***Set Up Instructions*** earlier in this section.

Change Sampler

The [CHANGE SAMPLER] key is used to select the Open or Closed Mode of operation. When the key is pressed, the mode changes from the mode currently selected to the other operating mode. The Status Box displays one of the two following messages:

```
SELECTING OPEN MODE
SELECTING CLOSED MODE
```

Prior to running a sample, if the [CHANGE SAMPLER] key is pressed, it will automatically clear any patient information entered in the demographics section of the RUN screen.

Print Ticket

The [PRINT TICKET] key is used to print a report on a ticket when a printer is connected to the Ticket Printer Port on the Data Module. The report is printed on the type of ticket that is selected from the CUSTOMIZE PRINTED REPORT screen.

Print Report

The [PRINT REPORT] key is used to print a graphics report when printer is connected to the Graphics Printer Port on the Data Module. When the color printing option on the CUSTOMIZE PRINTED REPORT screen is ON, the key label changes to [COLOR PRINT]. A color graphics report is printed when the [COLOR PRINT] key is pressed and the printer connected to the Graphics Printer Port is a color printer.

Main

The [MAIN] key is used to return to the MAIN MENU screen.

Additional Examples of Run Menu Screens

Flagging Messages

An example of some flagging messages is shown in Figure 5.38.

A detailed explanation of all flagging messages is given in **Section 3: *Principles of Operation***.

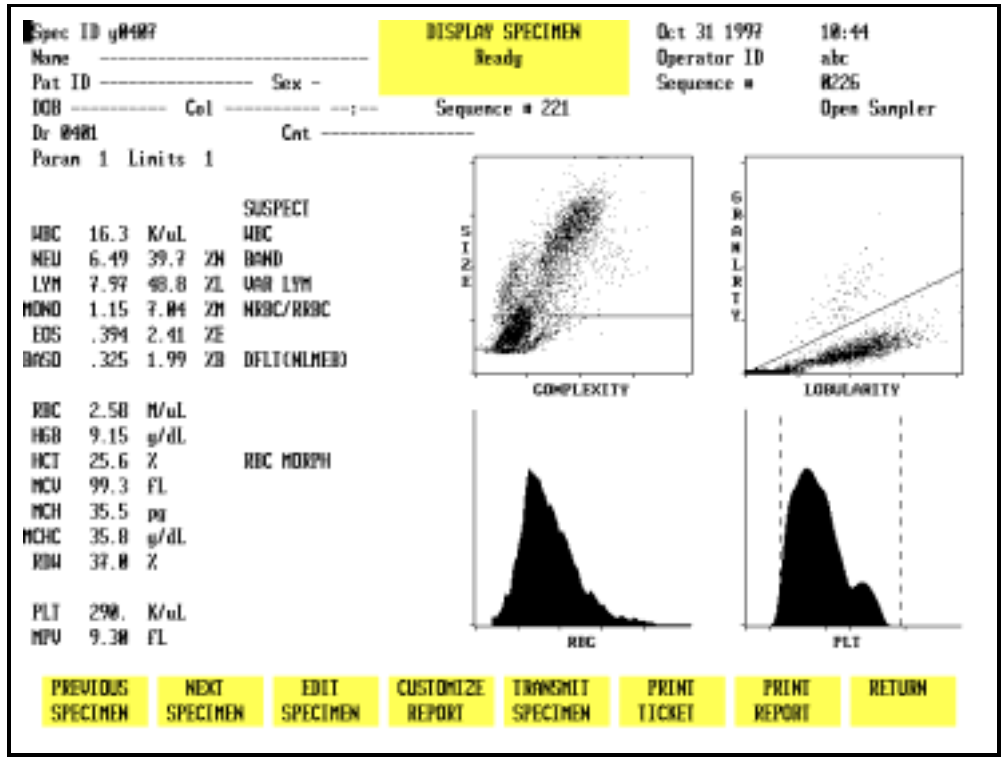

Figure 5.38: Run Screen Showing Flagging Messages and RBC MORPH Message

Bulletin Line Messages

Bulletin Line messages alert the operator to problems with the instrument or provide instructions. An example of a Bulletin Line message reading “Ticket printer unavailable” is shown in Figure 5.39.

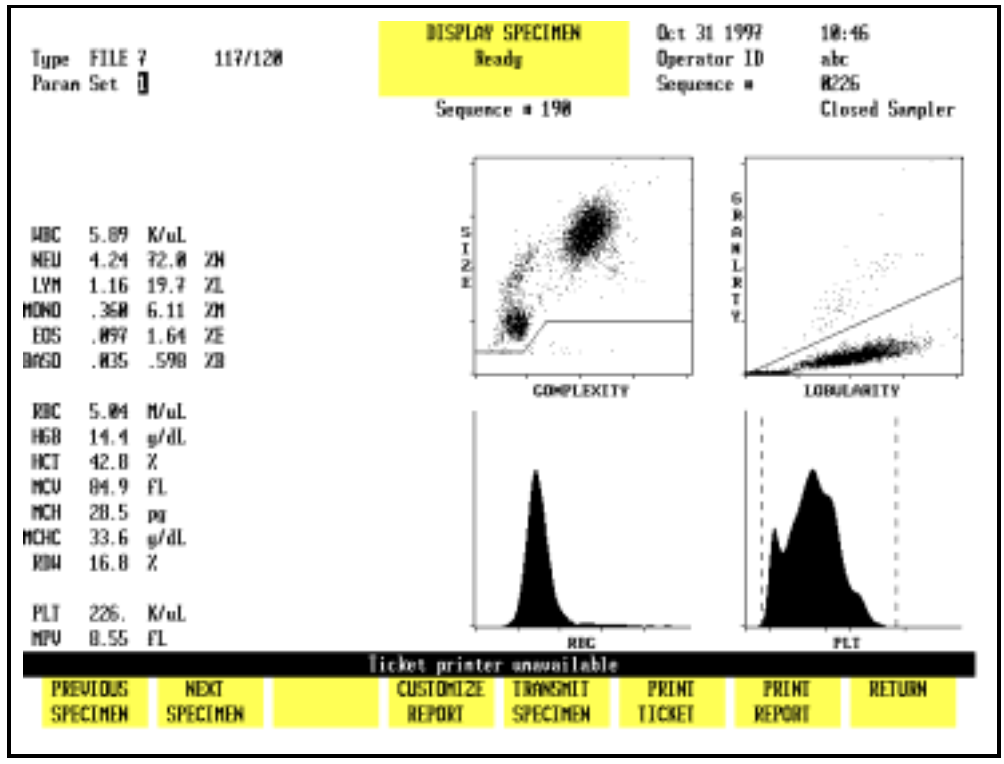

Figure 5.39: Run Screen Showing Bulletin Line Message

Laboratory Worksheet

To display the LABORATORY WORKSHEET screen, press the Page Down key on the keyboard while the RUN menu is displayed or while the DISPLAY SPECIMEN screen in the DATA LOG menu is displayed.

The LABORATORY WORKSHEET screen displays additional parameters as shown in Figure 5.40. This screen is for laboratory use only.

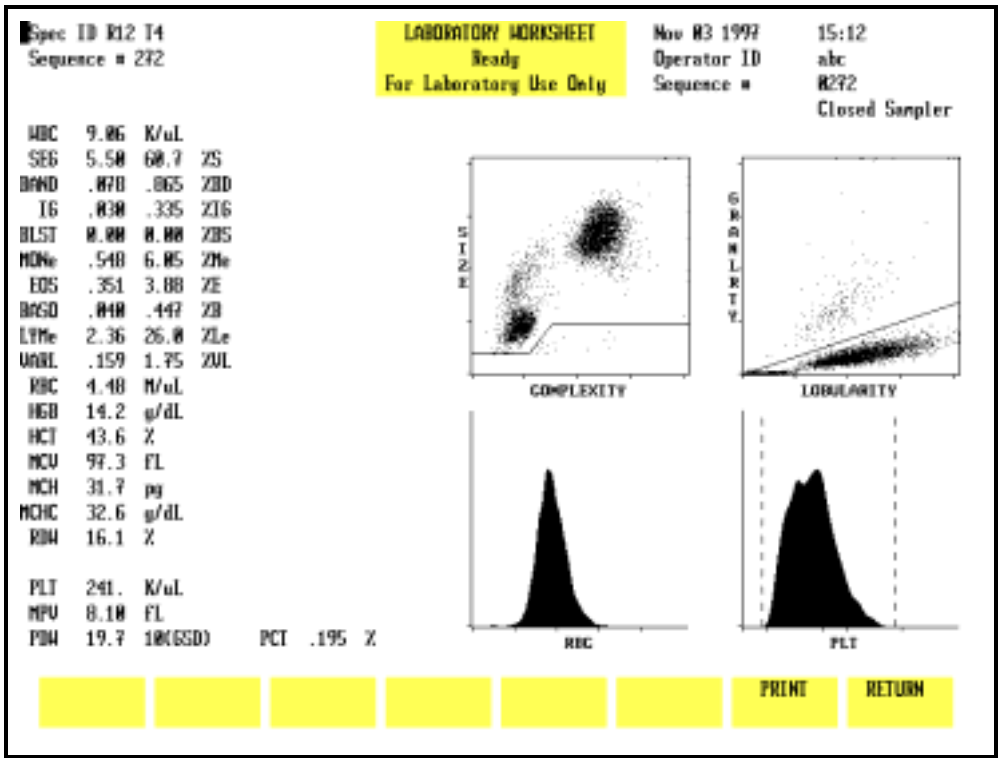

Figure 5.40: Laboratory Worksheet Screen

Sample Collection and Handling

Anticoagulant

All performance claims given in this manual were generated from samples collected in K_3EDTA.

Sample Stability

Any refrigerator-stored specimens should be brought to room temperature before processing. If specimens are to be run within eight hours after collection, storage at room temperature is recommended. If specimens are to be run more than eight hours after collection, storage at temperatures between 4° and 8° C is recommended.

Stability studies show that, when specimens are refrigerated at temperatures between 4° and 8° C, and brought to room temperature before mixing and processing, results for the RBC, HGB, MCV, PLT are stable (±5%) for up to 36 hours after collection. The total WBC and MPV is stable (±5%) for up to 24 hours after collection. The stability of the total WBC decreases to ±10% at 36 hours after collection.

The stability of capillary samples collected in microtainers may vary depending on the microtainer manufacturer. Refer to the manufacturer's package insert for stability claims.

Sample Collection

All samples should be collected using proper technique and following the tube manufacturer's recommendations.

NOTE: For additional information on collecting venous and capillary samples, refer to NCCLS Standards, H3-A3[1] and H4-A3[2].

WARNING: Potential Biohazard. Consider all specimens, reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1920, 1030) or other equivalent biosafety procedures.

Samples that will be run on the Sample Loader must have a minimum volume of 1.0 mL to ensure proper mixing by the Sample Loader.

A minimum of 180 µL should be collected for capillary samples. This ensures an adequate amount of blood for the Open Mode (120 µL) aspiration.

Interfering Substances

The CELL-DYN 3200 has been designed to detect and flag samples that contain interfering substances. The following list indicates the substances that may interfere with the listed parameters.

WBC: NRBCs, lytic-resistant RBCs, PLT clumps, cryoglobulin and cryofibrinogen, fragile WBCs

RBC: Elevated WBC count, increased numbers of giant PLTs, autoagglutination, *in vitro* hemolysis

HGB: Elevated WBC count, increased plasma substances (triglycerides, bilirubin, *in vivo* hemolysis), lytic-resistant RBCs

MCV: Elevated WBC count, hyperglycemia, *in vitro* hemolysis, increased numbers of giant PLTs

PLT: WBC fragments, *in vitro* hemolysis, microcytic RBCs, cryoglobulins, PLT clumping, increased numbers of giant PLTs. For a detailed description of the flags that are generated, refer to **Section 3: *Principles of Operation*, Subsection: *Operational Messages and Data Flagging***.

Preparing to Run Samples

Before running specimens, the operator should enter data in the demographics section of the RUN screen to properly identify patient samples.

Operator ID

The operator should enter an Operator ID before running samples. The Operator ID is displayed on all screens and printed on the graphics report and the blank ticket report. It is also retained in the QC logs and the Data Log.

The operator ID may be entered from the MAIN MENU or the CALIBRATION menu. When either menu is selected, the cursor is positioned in the OPERATOR ID entry field. Type up to three alphanumeric characters and press the Enter key on the keyboard to save the ID number.

Sample Identification

Sample identification information is entered in the upper left corner of the RUN screen. These entry fields are made available when the Patient, Fragile WBC, or Resistant RBC specimen types are selected. To select one of these three specimen types, do the following:

1. Go to the RUN menu and press [SPECIMEN TYPE].
2. Press one of the following keys to select the desired specimen type — [PATIENT], [FRAGILE WBC], [RESISTANT RBC].

Enter the sample identification information as follows:

1. A Sample ID number (Next ID field) of up to 12 characters may be entered in the NEXT ID entry field.
2. The remaining patient demographic information may be entered at the operator's discretion. Refer to ***Run Screen for Patient Samples*** earlier in this section for a discussion of these fields.

3. Parameter Set 1 and Patient Limits Set 1 are the default settings when the instrument is shipped from the factory. The results are displayed and printed using these settings unless the operator changes these entry fields. New parameter and/or limits sets can be entered anytime before a sample is run or after the results of a sample run are displayed by moving the cursor to the appropriate field and typing the desired number.

   NOTE: When the results are stored in the Data Log, other parameter and limits sets may be selected by using the [EDIT SPECIMEN] key. For complete instructions, refer to ***Using the Data Log*** later in this section.

Sample Analysis on the CELL-DYN 3200SL

Introduction

This section explains how samples are run on the 3200SL model, both Open and Closed Modes. Samples should not be run until daily QC checks have been performed and the instrument is in the READY state. For convenience, directions for Daily Start Up and QC are given in each section. Directions for running samples in the Open Mode are also included in each section.

Samples may be analyzed whenever the READY message is displayed in the Status Box on the RUN screen. *If the System has been idle for 15 minutes or more, run a background immediately prior to running a patient sample.*

Samples should be well mixed (a rotary mixer is preferred[3]) before they are run in the Open or Closed Mode on the instrument. The Sample Loader automatically mixes the samples before aspiration. However, samples must be well mixed before they are placed in the Sample Loader racks.

Instrument Preparation

1. Be sure that the green READY light on the Analyzer Status Indicator Panel is illuminated and the READY message is displayed in the Status Box on the RUN screen.
2. If the Status Box on the Data Station RUN screen displays STANDBY or INITIALIZED press [RUN] to initiate the automatic Start Up cycle.
3. When the automatic Start Up cycle is completed, a background count is automatically performed and the Open Mode is selected.
4. Verify that the background counts are acceptable. If the background counts are unacceptable, repeat the background cycle. If the counts are still unacceptable, troubleshoot accordingly.

   NOTE: Backgrounds may be repeated by pressing the Touch Plate.

5. If the Sample Loader is to be used, be sure that at least one rack (maximum of five) is in the load area to the right of the Tower Cover and that the Tower Cover is in place.
6. To switch from Open Mode to Closed Mode, press the [CHANGE SAMPLER] key. Wait until the message READY is displayed in the Status Box.
7. Perform the daily Quality Control checks as directed in subsection ***Sample Analysis on the CELL-DYN 3200***, ***Daily Quality Control Checks***.

Sample Loader Operating Tips

1. All Sample Loader tubing must be connected before turning ON the System.
2. All samples must be properly mixed before they are placed in the Sample Loader racks.
3. Place the labeled tubes in the Sample Loader rack and load the rack on the Sample Loader.
4. If a tube has multiple labels on it, spin the tube by hand after it is put in a rack to be sure it will spin freely and therefore mix properly. (Refer to **Section 13: *Sample Loader*** for labeling requirements.)

Daily Quality Control Checks

Quality Control checks (which confirm calibration) should be performed on a daily basis according to the laboratory's protocol. Commercial control materials should be properly warmed and mixed according to the manufacturer's recommendations. Patient controls should be handled according to the laboratory's protocol.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Open Mode QC Procedure

1. In the RUN screen, press [SPECIMEN TYPE].

2. Move the cursor to the desired QC file and press [QC SPECIMEN].
3. If necessary, press [CHANGE SAMPLER] to select the Open Mode.
4. Run the control.

   NOTE: Refer to the ***Running Samples*** subsection following this procedure for complete instructions on running samples.

5. Verify that the results are acceptable.

   NOTE: Out-of-range results are displayed in color.

6. If the results are unacceptable, repeat the run. If the results are still unacceptable, obtain a new bottle of the control, be sure that it is warmed and mixed properly and again repeat the run. If the results are still unacceptable, run the other levels of control material. If the results on all levels are unacceptable, troubleshoot as directed in **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide***.
7. When the control results are acceptable, patient samples may be analyzed.

Closed Mode QC Procedure

The operator must manually stop the Sample Loader as directed in this procedure when different levels of controls are run.

1. From the RUN screen, press [SPECIMEN TYPE].
2. Use the Arrow keys on the keyboard to move the cursor to the appropriate QC file and press [QC SPECIMEN].
3. If necessary, press [CHANGE SAMPLER] to select Closed Mode.
4. Place the controls in the Sample Loader rack in the order in which they are to be run.
5. Be sure the Tower Cover is in place and press the [START LOADER] key.
6. After the first control is aspirated, press the [STOP LOADER] key.
7. After the results are displayed, press [SPECIMEN TYPE].

8. Use the Arrow keys on the keyboard to move the cursor to the file for the next control to be run and press [QC SPECIMEN].
9. Press the [START LOADER] key.
10. Repeat steps *6 – 9* until all levels of controls have been run.
11. When all of the controls have been run, press [MAIN] followed by [QUALITY CONTROL].
12. Use the Arrow keys on the keyboard to move the cursor to the desired file.
13. Press [VIEW QC LOG] to display the QC LOG screen.
14. Verify that the results are acceptable.

    NOTE: Out-of-range results are displayed in color.

15. Press [RETURN] to return to the main QUALITY CONTROL screen.
16. Repeat steps 12–15 for all levels of controls that were run.
17. If the results are unacceptable, repeat the run. If the results are still unacceptable, obtain a new tube of control, be sure that it is warmed and mixed properly and again repeat the run. If the results are still unacceptable, run the other levels of control material. If the results on all levels are unacceptable, troubleshoot as directed in **Section 10, Subsection: *Troubleshooting Guide*.**
18. When the control results are acceptable, patient samples may be analyzed.

Running Samples

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Open Mode Analysis

The Open Sampler mode aspirates the sample from an open collection tube. OPEN SAMPLER is displayed in the upper right corner of the RUN screen when this mode is selected. The open sample aspiration probe is available (Wash Block raised) only when this mode is selected.

Open Mode Procedure

1. If necessary, from the RUN screen press [CHANGE SAMPLER] to select the Open Mode.
2. Be sure that the green READY light on the Analyzer Status Indicator Panel is illuminated and READY is displayed in the Status Box on the RUN screen.
3. With the stopper still in the tube, mix the sample well (invert the tube a minimum of 5 times to thoroughly mix the sample).
4. Open the sample tube and place it under the Open Sample Aspiration Probe. Raise the tube until the end of the probe is deeply immersed in the sample.

   ⚠ **CAUTION:** Do not let the probe touch the bottom of the sample tube. It may affect aspiration and produce erroneous results.

5. Press the Touch Plate located behind the probe to start the cycle. The yellow BUSY light on the Analyzer Status Indicator Panel is illuminated. The Status Box on the RUN screen displays messages to indicate the various stages of the cycle.
6. Remove the tube when the beep sounds. The message REMOVE SPECIMEN is displayed in the Status Box. The wash block moves down the probe and cleans it.
7. When the cycle is finished, the wash block moves up the probe, the green READY light on the Analyzer Status Indicator Panel is illuminated, and the results are displayed on the RUN screen.

   NOTE: Another sample may be aspirated at this point even though READY is not displayed in the Status Box on the screen. Generally, the READY light on the Analyzer Status Indicator Panel will be illuminated before the Status Box on the screen displays READY.

8. If automatic report printing has been specified, a report is printed according to the options selected during Set Up. If the Color Printing option was selected in the CUSTOMIZED PRINTED REPORT screen for the Graphics Printer, the printouts will be in color. Otherwise, the reports will be printed in black and white.

9. If automatic printing has not been specified, a report may be printed by pressing either [PRINT REPORT] or [COLOR PRINT]. The [COLOR PRINT] key will be displayed if the Color Printing option was selected.
10. Repeat this procedure for subsequent samples.

Closed Mode Analysis

The Closed Sampler mode on CELL-DYN 3200SL models aspirates the sample from a closed collection tube that has been placed in a Sample Loader rack and loaded into the Sample Loader. CLOSED SAMPLER is displayed in the upper right corner of the RUN screen when this mode is selected. The wash block moves down to the end of the open sample aspiration probe when this mode is selected.

Closed Mode Procedure

1. If necessary, in the RUN screen press [CHANGE SAMPLER] to select the Closed Mode.
2. Be sure that the green READY light on the Analyzer Status Indicator Panel is illuminated and READY is displayed in the Status Box on the RUN screen.
3. Place the well mixed samples in the Sample Loader racks.

   NOTE: The racks and tube positions are identified by the bar code label on the rack and indicated as RxTx. These numbers appear as the Sample ID number if bar code labels are not used. (If the Work List is used, the Sample ID number is taken from it. Refer to ***Using the Work List*** later in this section for more information.)

4. Place the racks in the Sample Loader to the right of the Tower Cover with the slotted side (with bar code labels) facing the operator.
5. Verify the Tower Cover is in place.

   NOTE: The Sample Loader will not operate without the Tower Cover in place.

6. Press the [START LOADER] key on the RUN screen.
7. The Sample Loader automatically processes all the samples. Processing stops when the last rack is finished or the [STOP LOADER] key is pressed. The last rack is finished when it has moved completely to the unload side of the Sample Loader.

Sample Analysis on the CELL-DYN 3200CS

Introduction

This section explains how samples are run on the 3200CS models, both Open and Closed Modes. Samples should not be run until daily QC checks have been performed and the instrument is in the READY state. For convenience, directions for Daily Start Up and QC are given in each section. Directions for running samples in the Open Mode are also included in each section.

Samples may be analyzed whenever the READY message is displayed in the Status Box on the RUN screen. Samples should be well mixed (a rotary mixer is preferred[3]) before they are run in the Open or Closed Mode on the instrument.

Instrument Preparation

1. Be sure that the green READY light on the Analyzer Status Indicator Panel is illuminated.
2. If the Status Box on the RUN screen displays STANDBY or INITIALIZED, press [RUN] to initiate the automatic Start Up cycle.
3. When the cycle is finished, a background count is automatically performed and the Open Mode is selected.
4. Verify that the background counts are acceptable. If the background counts are unacceptable, repeat the background cycle. If the counts are still unacceptable, troubleshoot accordingly.

   NOTE: Backgrounds may be repeated by pressing the touch plate.

5. If controls will be processed in Closed Mode, press [CHANGE SAMPLER].
6. Perform the daily Quality Control checks as directed in the following section.

Daily Quality Control Checks

Quality Control checks (which confirm calibration) should be performed on a daily basis according to the laboratory's protocol. Commercial control materials should be properly warmed and mixed according to the manufacturer's recommendations. Patient controls should be handled according to the laboratory's protocol.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

QC (Open or Closed Mode) Procedure

1. In the RUN screen, press [SPECIMEN TYPE].
2. Move the cursor to the desired QC file and press [QC SPECIMEN].
3. If necessary, press [CHANGE SAMPLER] to select the desired mode.
4. Run the control.

   NOTE: Refer to the ***Running Samples*** subsection following this procedure for complete instructions on running samples.

5. Verify that the results are acceptable.

   NOTE: Out-of-range results are displayed in color.

6. If the results are unacceptable, repeat the run. If the results are still unacceptable, obtain a new bottle of the control, be sure that it is warmed and mixed properly and again repeat the run. If the results are still unacceptable, run the other levels of control material. If the results on all levels are unacceptable, troubleshoot as directed in **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide*.**
7. When the control results are acceptable, patient samples may be analyzed.

Running Samples

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Open Mode Analysis

The Open Sampler mode aspirates the sample from an open collection tube. OPEN SAMPLER is displayed in the upper right corner of the RUN screen when this mode is selected. The Open Sample Aspiration Probe is available only when this mode is selected.

Open Mode Procedure

1. If necessary, in the RUN screen press [CHANGE SAMPLER] to select the Open Mode.
2. Be sure that the green READY light on the Analyzer Status Indicator Panel is illuminated and READY is displayed in the Status Box on the RUN screen.
3. With the stopper still in the tube, mix the sample well (invert the tube a minimum of 5 times to thoroughly mix the sample).
4. Open the sample tube and place it under the Open Sample Aspiration Probe. Raise the tube until the end of the probe is deeply immersed in the sample.

   NOTE: Do not let the probe touch the bottom of the sample tube. It may affect aspiration and produce erroneous results.

5. Press the Touch Plate located behind the probe to start the cycle. The yellow BUSY light on the Analyzer Status Indicator Panel is illuminated. The Status Box on the RUN screen displays messages to indicate the various stages of the cycle.
6. Remove the tube when the beep sounds. The message REMOVE SPECIMEN is displayed in the Status Box. The wash block moves down the probe and cleans it.

7. When the cycle is finished, the wash block moves up the probe, the green READY light on the Analyzer Status Indicator Panel is illuminated, and the results are displayed on the RUN screen.

   NOTE: Another sample may be aspirated at this point even though READY is not displayed in the Status Box on the screen. Generally, the READY light on the Analyzer Status Indicator Panel will be illuminated before the Status Box on the screen displays READY.

8. If automatic report printing has been specified, a report is printed according to the options selected during Set Up. The reports are printed in black and white. If automatic printing has not been specified, a report may be printed by pressing [PRINT REPORT].

   NOTE: To obtain a color printout, press [COLOR PRINT]. (The color printing option on the CUSTOMIZE PRINTED REPORT screen must be ON.)

9. Repeat this procedure for subsequent samples.

Closed Mode Analysis

The Closed Sampler mode on Closed Sampler (CS) instruments aspirates the sample from a closed collection tube that has been inserted in the Closed Sample Tower Module. CLOSED SAMPLER is displayed in the upper right corner of the RUN screen when this mode is selected. The wash block moves down to the end of the Open Sample Aspiration Probe when this mode is selected.

Closed Mode Procedure

1. Be sure that the green READY light on the Analyzer Status Indicator Panel is illuminated and READY is displayed in the Status Box on the RUN screen.
2. If necessary, in the RUN screen press [CHANGE SAMPLER] to select the Closed Mode.
3. With the stopper still in the tube, mix the sample well (invert the tube a minimum of 5 times to thoroughly mix the sample).
4. Place the well-mixed sample, with the stopper facing up, into the Tube Holder and push the door closed.

   NOTE: The Touch Plate will not operate if the door has not been closed.

5. Press the Touch Plate located behind the probe to start the cycle. The yellow BUSY light on the Analyzer Status Indicator Panel is illuminated.
6. Remove the tube when the door opens. A beep sounds when the door opens.

   NOTE: The door automatically opens whenever a sample has been aspirated in the Closed Mode or a background count has been run in Open Mode. There is also a tab under the Door Assembly that mechanically releases the door. This tab can be used if the door is closed and no tube is in the holder. The door will not open if the needle is in the tube. In case of an emergency stop, the operator will have to remove the Tower Cover and manually raise the needle out of the sample.

7. When the cycle is finished, the green READY light on the Analyzer Status Indicator Panel is illuminated and the results are displayed on the RUN screen.

   NOTE: Another sample may be aspirated at this point even though READY is not displayed in the Status Box on the screen. Generally, the READY light on the Analyzer Status Indicator Panel will be illuminated before the Status Box on the screen displays READY.

8. Repeat this procedure for subsequent samples.

NOTES

Alerts and Indicators

This subsection describes information displayed on the screen as the samples are analyzed and/or when reports are printed.This subsection does not discuss how to interpret parameter flags, which are displayed after the sample is run. Refer to **Section 3: *Principles of Operation,* Subsection: *Operational Messages and Data Flagging*.**

Out of Range

- Results that fall outside the range of the selected limit set are displayed in color. Yellow indicates that the result exceeded the lower limit and purple indicates that the result exceeded the upper limit. These results are underlined on the graphics and blank ticket printouts. They are indicated by an asterisk on a pre-printed ticket.
- Results that exceed a parameter's linear range are indicated by >>>> in place of the result.

Fault Conditions

The [CLEAR FAULT] key is displayed and a message (e.g. DILUENT EMPTY) appears in the Status Box if a fault condition is detected. The word "Fault" on the Analyzer status indicator is illuminated in red. The Status Box displays the message FAULT: SEE DIAG or SEE SPECIAL to direct the operator to the DIAGNOSTICS or
SPECIAL PROTOCOLS menu for further instructions.

After the problem has been corrected, press [CLEAR FAULT] to resume operation.

Flow Errors

If a RBC Flow Error occurs, results are suppressed for the RBC/PLT parameters and the RBC FLOW ERROR message is displayed on the Bulletin line. The RBC/PLT scatterplots are suppressed.

If a WOC Flow Error occurs, results are suppressed for the WBC and Differential and the WOC FLOW ERROR message is displayed on the Bulletin line. The WBC scatterplots are suppressed.

If a NOC Flow Error occurs, results are suppressed for the WBC and Differential and the NOC FLOW ERROR message is displayed on the Bulletin line. The NOC scatterplots are suppressed.

3 Consecutive Flow Errors

If the Sample Loader is being used and the instrument detects one of the following:

1. Three consecutive RBC flow errors.
2. Three consecutive WOC flow errors.
3. Three consecutive NOC flow errors.

The Sample Loader halts at the end of the cycle and the Bulletin line displays the appropriate message:

1. 3 CONSECUTIVE RBC FLOW ERRORS.
2. 3 CONSECUTIVE WOC FLOW ERRORS.
3. 3 CONSECUTIVE NOC FLOW ERRORS.

Sampling Errors

The message SAMPLING ERROR-INCOMPLETE ASPIRATION is displayed on the Bulletin line if insufficient sample was detected during aspiration. SAMPLING ERR is displayed on the screen and SAMPLING ERR is printed on the graphics report to the right of the MCHC. The same message is printed to the right of the WBC on the pre-printed ticket and printed above the list of parameters on the blank ticket.

3 Consecutive Sampling Errors

If the Sample Loader is being used and the Instrument detects three consecutive incomplete aspirations, the Sample Loader halts at the end of the cycle and the Bulletin line displays the message

3 CONSECUTIVE INCOMPLETE ASPIRATIONS.

Daily Shutdown Procedure

Daily Shutdown

The Daily Shutdown Procedure consists of rinsing the Flow System. Whether or not this procedure is followed on a daily basis depends on instrument usage and the laboratory's procedures. It may not be necessary to perform this procedure every day, since the instrument automatically goes into a STANDBY state (Automatic Shutdown) if it has been idle for four hours. Before the instrument enters the STANDBY state, the Flow Panel is automatically rinsed.

If desired, the operator may place the instrument in the STANDBY state by pressing the [DAILY SHUTDOWN] soft key in the second level SPECIAL PROTOCOLS menu. When this key is pressed or when Automatic Shutdown is initiated, the following occurs:

- The Flow System is rinsed.
- The timer control, which periodically opens all of the solenoid valves to prevent pinched tubing, is set.

The Daily Shutdown cycle takes approximately 10 minutes.

For a more thorough cleaning of the instrument prior to Daily Shutdown, perform the following procedures:

1. In the SPECIAL PROTOCOLS menu, press [AUTO CLEAN].
2. Clean Sample Loader including racks and Tower Cover.
3. Press [DAILY SHUTDOWN].
4. Empty Waste (as needed)

NOTE: The Auto-Clean cycle may be run as part of the Daily Start-Up Procedure, depending on operator preference. The Clean Needle process should be used if there is a problem with Closed Mode aspiration and an obstruction in the needle is a suspected cause.

The Auto-Clean and Clean Needle procedures are described in detail in **Section 9:** ***Service and Maintenance, Subsection: Daily Maintenance Procedures***. Procedures for cleaning the Sample Loader are described in detail in **Section 13:** ***Sample Loader***.

In addition to the daily procedures listed above, if the instrument will remain idle for a period of time, then supplemental shutdown procedures are required depending on the expected duration of the idle time — Short-term, Intermediate, or Prolonged Shutdown. These categories are discussed below.

Peristaltic Pump Tubing

IMPORTANT: By removing the tubing under the Sample Transfer Peristaltic Pump, the life of the tubing is significantly prolonged. The tubing should be removed if the instrument will be idle for more than 24 hours and reinserted prior to operating the instrument.

Short Term Shutdown

If the shutdown time is expected to be 72 hours or less, follow the procedure below:

1. In the MAIN MENU, press [SPECIAL PROTOCOLS].
2. If the instrument is to be cleaned first, press [AUTO CLEAN], otherwise go to step 3.
3. Press [DAILY SHUTDOWN].
4. Leave power ON.
5. Tubing should be removed from under the Peristaltic Pump.

Intermediate-term Shutdown

If the shutdown time is expected to exceed 72 hours (but less than 2 weeks), follow the procedure below:

1. With the system still ON, perform any maintenance that is due.
2. In the MAIN MENU, press [SPECIAL PROTOCOLS].
3. Press [AUTO CLEAN] to clean the instrument.
4. Press [DAILY SHUTDOWN].

5. When the DAILY SHUTDOWN cycle is finished, turn power OFF in the following order:
   a. System (includes Analyzer, Data Module, and Sample Loader)
   b. Display Monitor
   c. Printer

   NOTE: In an emergency situation, turn OFF power in any order as quickly as possible.

6. Remove the tubing from under the Sample Transfer Peristaltic Pump.

Prolonged Shutdown

If the shutdown time is expected to exceed two weeks, follow the procedure below:

1. In the MAIN MENU, press [SPECIAL PROTOCOLS].
2. Press [AUTO CLEAN] to clean the instrument.
3. Press [PREPARE FOR SHIPPING]. Follow the instructions on the screen.
4. When the procedure is completed, turn the power OFF.
5. Remove the following tubing:
   - Tubing in the Normally Closed Valves on the Flow Panel (refer to Figure 1.5).
   - Tubing under the Peristaltic Pump.
6. Record this maintenance in your maintenance log.

   CAUTION: Do not forget to reinsert the tubing securely in the Normally Closed Valves and under the peristaltic pump before turning the instrument back ON. Refer to **Section 2: *Installation and Special Procedures*, Subsection: *Tubing Installation***.

For the SL model, also refer to the Prolonged Shutdown Procedure in **Section 13: *Sample Loader***.

If the instrument will be shipped, refer to the instructions in **Section 9: *Service and Maintenance*, Subsection: *Prepare for Shipping or Extended Period of Non-Use***.

NOTES

Using The Work List

Introduction

The Work List is used to pre-assign sample identification and display and print criteria for samples that will be run. It is essentially a list of samples (including the pre-assigned information) that the operator intends to run on the instrument. Work List entries may be downloaded from a host computer to the CELL-DYN 3200 System, or the entries can be made by an operator at the instrument.

This section will provide an overall review of the Work List, discuss the WORK LIST menu and WORK LIST SET UP menu, and discuss the procedures for running samples under the following conditions:

1. Work List records with Bar Codes in the <Specimen ID> field are downloaded from the LIS.
2. Work List records with other sample identification (non Bar Code) in the <Specimen ID> field are downloaded from the LIS.
3. Work List records with Bar Codes in the <Specimen ID> field are entered at the instrument by the operator.
4. Work List records with other sample identification (non Bar Code) in the <Specimen ID> field are entered at the instrument by the operator.

As samples are processed, the Work List is accessed. If the identifying information on the sample, such as a bar code number, matches the identifying information of an entry in the Work List, then a “match” has occurred and that entry is removed from the Work List. The demographic data and the results of the sample run are displayed on the RUN screen and stored in the Data Log. The demographic data is also included on the printed report.

The Work List can accept a specimen identifier other than a bar code in the Specimen ID field. However, since both models come equipped with a bar code reader for the Closed Mode, it is expected that bar code numbers will be the preferred method for identifying samples.

The following bar code symbologies may be used in the <Specimen ID> field:

- Code 39, Code 128, Interleaved 2 of 5, and Codabar

  NOTE: Refer to Appendix A for complete information on the use of bar code labels.

  NOTE: The number on bar code labels must be greater than 2 digits to avoid possible confusion by the bar code reader with the 2 digit bar code label on the racks.

Quick Guide

The Work List has been designed with three objectives in mind:

1. Relieve the operator from the task of entering demographic data by downloading that data from a host.
2. Process samples quickly, efficiently, and accurately.
3. Upload sample results with corresponding demographic data to the LIS for distribution to authorized personnel.

SL Model

If the instrument is the SL model and bar codes are used with Work List entries, the operator should do the following:

1. Wait for Work List entries to be downloaded from the host.
2. Place the samples in the racks and load the racks onto the Sample Loader.
3. In the RUN screen, press [CHANGE SAMPLER] to select the Closed Mode if necessary.
4. Press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).
5. Press [START LOADER] to begin processing.
6. When processing is finished, verify that all entries have been deleted from the Work List, indicating that all samples were successfully matched to their corresponding entries.

CS Model

If the instrument is the CS model and bar codes are used with Work List entries, the operator should do the following:

1. Wait for Work List entries to be downloaded from the host.
2. Place a sample tube in the Door Assembly and close the door.
3. In the RUN screen, press [CHANGE SAMPLER] to select the Closed Mode if necessary.
4. Press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).
5. Press the Touch Plate to begin processing.
6. When processing is finished, verify that all entries have been deleted from the Work List, indicating that all samples were successfully matched to their corresponding entries.

Work List Review

General

1. The Work List is always ON.
2. A host can download Work List records at any time. The instrument will accept any record with data in the <Specimen ID> field. This field may contain a bar code number or other Specimen ID.
3. If a record is sent with a blank <Specimen ID> field, the instrument will reject that record and respond by sending a message back to the host identifying the record that was rejected and stating the reason for the rejection.
4. The Work List can contain “mixed” records: Some records may have bar code numbers in the <Specimen ID> field and some may have other Specimen ID numbers.
5. The Work List can hold a maximum of 600 records. If a batch of records is sent by the host but there is insufficient space in the Work List to accept all the records, the instrument will not accept any of the records and responds by sending a message back to the host stating the Work List is full.
6. When fields have been turned ON in the WORK LIST SET UP menu, those fields are highlighted on the Work List. The cursor automatically skips to the next highlighted field when the Enter key is pressed.

7. If the operator types in a bar code number or non-bar code Specimen ID into the Specimen ID field on the RUN screen and presses the Return key, the system immediately searches the Work List for a matching entry. If a match is found, the demographic information is displayed on the RUN screen.

   NOTE: This feature is not possible on the SL model Closed Mode because the operator cannot input data to the RUN screen.

Download from Host

1. In most cases, it is expected that Work List data will be downloaded from a host. As an alternative, the operator may enter all demographic data — including either a Bar Code, other Specimen ID, or Rack and Tube # — at the instrument.
2. If Work List records with Bar Codes are downloaded from the host, the samples given to the operator for processing must also have Bar Codes, otherwise no matches can occur.
3. If Work List records with Specimen IDs (non Bar Code) are downloaded from the host and the operator is given samples with Specimen IDs, the operator may do the following:
   a. For SL models Closed Mode: Enter the Rack and Tube # of each sample into the <Rack and Tube> field for the appropriate Work List entry.
   b. For SL models Open Mode: Enter the Specimen ID of each sample into the <Next ID> field on the RUN screen before processing the sample.
   c. For CS models Open and Closed Modes: Enter the Specimen ID of each sample into the <Next ID> field on the RUN screen before processing the sample.

Format

1. The Work List will be searched only when the following Specimen Types are selected in the RUN screen: Patient, Fragile WBC, or Resistant RBC. Work List cannot be used when Background or QC Specimen are selected.
2. There are 3 formats for matching samples with Work List entries: Bar Code, other Specimen ID, and Rack and Tube #.

3. The <Specimen ID> field in the Work List must have either a bar code number or other Specimen ID.
4. The <Rack and Tube #> is a separate field in the Work List record.

Matching Entries

As stated earlier, the Work List is always ON. If the Work List contains records when samples are processed in either Closed or Open Mode, the system will:

1. Attempt to match the bar code number (if any) on the sample tube with a bar code number in the Work List. The match must be exact, including upper/lower case.
2. Attempt to match the Specimen ID (non Bar Code) entered on the RUN screen with a Specimen ID (non Bar Code) in the Work List entry.
3. Attempt to match the rack and tube position of a sample with a Rack and Tube # in the Work List (the instrument reads the bar code on the rack and keeps track of each tube position).

If a match occurs, that entry is removed from the Work List. The results of that sample along with its demographic data are displayed on the RUN screen and stored in the Data Log.

If a sample cannot be matched with any of the entries in the Work List, no entries are deleted from the Work List. The results of that sample are displayed on the RUN screen without demographic data (except for the Bar Code, Specimen ID, or system-assigned Rack and Tube number) and stored in the Data Log in the same manner. To add demographic data to that sample, the operator must go the Data Log and, using the [EDIT SPECIMEN] soft key, enter the appropriate demographic information.

If the instrument is unable to read a Bar Code on the tube and is unable to read the bar code on the rack, a malfunction has occurred. Sample Loader processing is terminated to avoid possible sample mis-identification and a fault message is displayed.

SL Model — Closed Mode

In the SL Closed Mode, the Work List is searched after each tube bar code is read (the RUN cycle has begun).Work List entries are matched using one of the following two methods:

1. Bar Codes on the sample tubes (for Bar Code Reader).
2. Rack and Tube # entered into the Work List by the operator.

NOTE: Demographic data cannot be entered into the RUN screen in the Closed Mode on the SL model.

CS Model — Closed Mode

In the CS Closed Mode, the Work List is searched after each tube bar code is read (the RUN cycle has begun). Work List entries are matched using one of the following three methods:

1. Bar Codes on the sample tubes (for Bar Code Reader).
2. Bar Codes entered into the <Next ID> field of the RUN screen by the operator.
3. Non-Bar Code Specimen IDs entered into the <Next ID> field on the RUN screen by the operator.

SL Model — Open Mode

In the SL Open Mode, the Work List is searched as soon as the operator enters a bar code number or non-bar code Specimen ID in the <Next ID> field and presses the Enter key. If a match is found, the demographic information is immediately displayed on the RUN screen. This will occur even if the Touch Plate is not pressed. Work List entries are matched using one of the following two methods:

1. Bar Codes entered into the <Next ID> field of the RUN screen by the operator.
2. Non-Bar Code Specimen IDs entered into the <Next ID> field on the RUN screen by the operator.

NOTE: Although there is no built-in bar code reader in the Open Mode, it is possible to attach a hand-held bar code reader to the keyboard.

Under this condition, the operator places the cursor in the <Next ID> field on the RUN screen before reading the bar code label on the tube. The instrument will automatically check the Work List for a match.

CS Model — Open Mode

In the CS Open Mode, the Work List is searched as soon as the operator enters a bar code number or non-bar code Specimen ID in the <Next ID> field and presses the Enter key. If a match is found, the demographic information is immediately displayed on the RUN screen. This will occur even if the Touch Plate is not pressed. Work List entries are matched using one of the following three methods:

1. Bar Codes entered into the <Next ID> field of the RUN screen by the operator.
2. Non-Bar Code Specimen IDs entered into the <Next ID> field on the RUN screen by the operator.

   NOTE: Although there is no built-in bar code reader in the Open Mode, it is possible to attach a hand-held bar code reader to the keyboard.

   Under this condition, the operator places the cursor in the <Next ID> field on the RUN screen before reading the bar code label on the tube. The instrument will automatically check the Work List for a match.

Work List Menu

Work List

The [WORK LIST] key is displayed on the RUN screen. The WORK LIST screen and the following soft key labels are displayed when the [WORK LIST] key is pressed:

INSERT/DELETE
DELETE ALL
WORK LIST SET UP
PRINT WORK LIST
RETURN

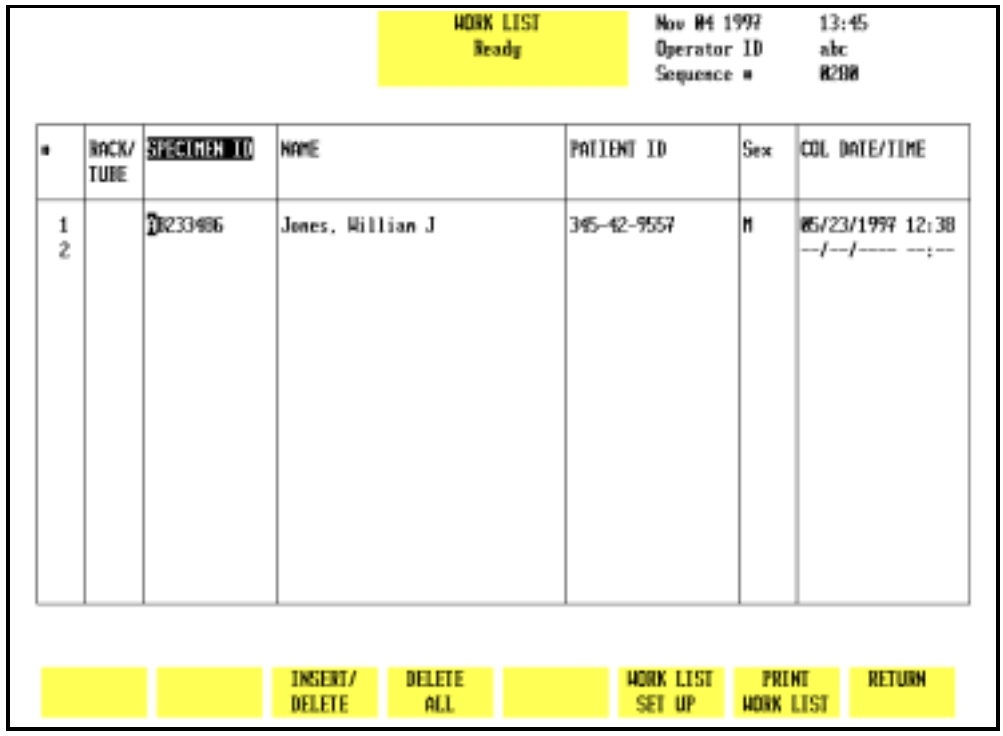

Figure 5.41: Work List Screen - Page 1

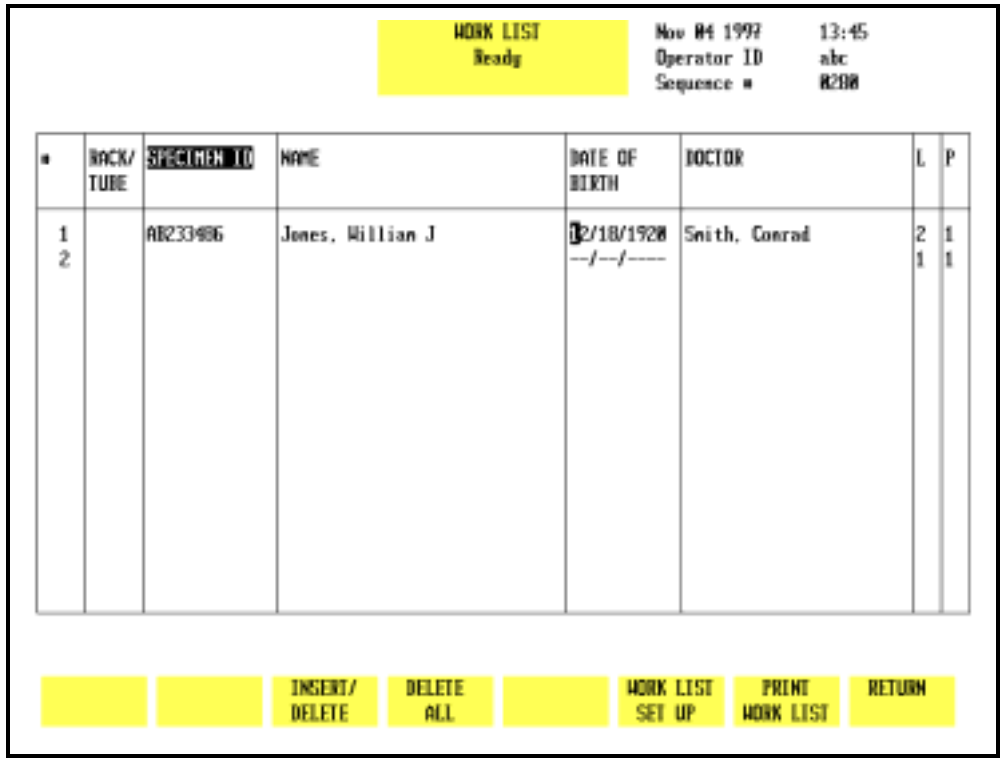

Figure 5.42: Work List Screen - Page 2

Work List Screen

The two pages of the WORK LIST screen are depicted in Figures 5.41 and 5.42. Use the left and right arrow keys to scroll between the pages.

1. Sequence #

   The sequential number of the Work List entries is displayed in this field. The Work List holds 600 entries. When the Work List is full, existing entries must be deleted before additional entries can be made. Work List entries are automatically deleted as samples are run and "matches" made.

2. RACK AND TUBE #

   The rack and tube number is displayed as xxyy where xx, the rack number, is any two digit number between 01 and 99 inclusively and yy, the tube number, is any two digit number between 01 and 10 inclusively.

   NOTE: Rack and tube number can only be entered by the operator at the instrument, not downloaded from a host.

   In the Work List, the cursor skips the <Rack and Tube> field when moving from entry to entry. The cursor always starts in the <Specimen ID> field. To place the cursor in the <Rack and Tube> field, the operator must use the left arrow key to move the cursor from the <Specimen ID> field to the <Rack and Tube> field.

3. SPECIMEN ID

   The specimen identification must consist of either a Bar Code number or other Specimen ID. Up to 12 characters may be entered. The sample is identified on the RUN screen, in the Data Log, and on the printed report using the information entered in this field.

   NOTE: An entry must be made in this field to create a Work List record. Also, an entry must be made in this field before a Work List record can be downloaded from a host.

4. PATIENT NAME

   The name entered in this field should be associated with the bar code number or rack and tube number entered in the <Specimen ID> field. Up to 28 characters can be entered in this field.

5. PATIENT ID

   The Patient ID can be a social security number or other identifier. Up to 16 characters can be entered in this field.

6. PATIENT SEX

   Either "M" or "F" may be entered for the sex of the patient.

7. PATIENT DOB

   The patient's date of birth may be entered in this field using the format selected in the Date/Time Set Up menu, such as *mm/dd/yyyy*. Note that 4 digits are used for the year.

8. COLLECTION DATE AND TIME

   The date and time the specimen was collected may be entered in this field. Date is entered as mm/dd for month and day only with no year. Time is entered as hh/mm where hh represents the hour (from 00 to 23) and mm represents the minute (from 00 to 59).

9. DR NAME

   The name of the patient's doctor may be entered in this field. Up to 22 characters may be entered.

10. LIMIT SET

    This field is used to enter the number of the Patient Limit Set that will be used for flagging the sample. If no entry is made, the default (pre-selected) Patient Limit Set is used.

11. PARAMETER SET

    This field is used to enter the number of the Parameter Set that will be used for the sample. If no entry is made, the default (pre-selected) Parameter Set is used.

Work List Soft Keys

The function of each of the soft keys displayed on the WORK LIST screen is discussed below.

Insert/Delete

When the [INSERT/DELETE] key is pressed, the following soft key labels are displayed:

INSERT
DELETE
RETURN

Insert

The [INSERT] key is used to insert a line of information into the Work List. The line is inserted at the cursor position and the remainder of the Work List is moved down one line.

Delete

The [DELETE] key is used to delete a line of information from the Work List. When the [DELETE] key is pressed, the following soft key labels are displayed:

CONFIRM DELETION
CANCEL DELETION

These keys are used to [CONFIRM] or [CANCEL] the Delete command.

The line is deleted at the cursor position and the remainder of the Work List is moved up one line.

Delete All

The [DELETE ALL] key is used to delete all data from the Work List. When the [DELETE ALL] key is pressed, the following soft key labels are displayed:

CONFIRM DELETION
CANCEL DELETION

These keys are used to [CONFIRM] or [CANCEL] the Delete All command.

Work List Set Up

Refer to ***Work List Set Up Procedure*** below for a discussion of the WORK LIST SET UP screen and options.

Print Work List

The [PRINT WORK LIST] key is used to print the Work List.

Return

The [RETURN] key is used to return to the RUN screen.

Work List Set Up Procedure

The [WORK LIST SET UP] key is used to display the WORK LIST SET UP screen shown in Figure 5.43.

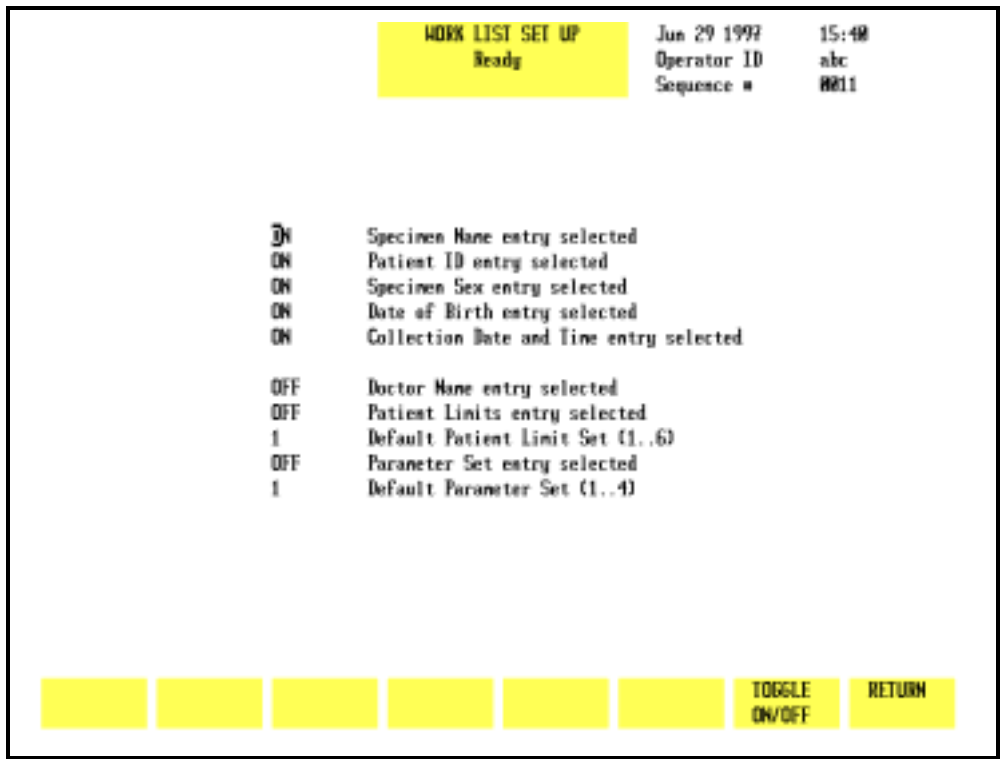

Figure 5.43: Work List Set Up Screen

The WORK LIST SET UP screen consists of eight ON/OFF toggle fields and two "number" fields.

Use the arrow keys to move the cursor to the desired field. Use the [TOGGLE ON/OFF] key to change an option and advance the cursor to the next field.

ON/OFF Fields

Turning fields ON or OFF in this screen affects the movement of the cursor in the WORK LIST screen when the operator makes entries to the Work List.

1. When the operator enters data into a <Work List> field and presses the Enter key, the cursor will move to the next field that was turned ON in the WORK LIST SET UP screen, skipping any intervening fields that were left OFF.
2. For example:
   a. Only the <*Dr Name*> field in the WORK LIST SET UP screen was turned ON, and

b. The operator is making new patient entries into the Work List.

In this case, when the operator enters data in the <Specimen ID> field and presses the Enter key, the cursor goes to the next ON field, which in this example is *Dr Name*. All intervening fields are skipped.

NOTE: OFF fields will still accept data. The operator can use the arrow keys to move the cursor to an OFF field and input data. Pressing the Enter key saves the data and moves the cursor to the next ON field.

Number Fields

The system will accept any number in the range 1 to 6 for Patient Limits and 1 to 4 for Parameter Set. The number selected for either field serves as the default for that field for subsequent entries and is independent of whether that field is ON or OFF.

For example:

1. If the <Patient Limits> field is OFF but the default setting is changed to 6, then 6 will be displayed as the default setting on the Work List.
2. Because the <Patient Limits> field is OFF, the cursor will bypass this field in the Work List.
3. If the <Patient Limits> field were ON, the cursor in the Work List would stop in this field, allowing the operator to select a different setting, such as 2, for that entry. The next entry would continue to display the default setting, which in this example is 6.

   NOTE: Regardless of the default value for either the <Limit Set> or <Parameter Set> fields, the operator can use the arrow keys to move the cursor to the field and enter another value. This new value will affect only that entry. All previous entries will retain their original settings, and all subsequent entries will use the default setting selected in the WORK LIST SET UP menu.

Work List Set Up Menu Fields

1. SPECIMEN NAME ENTRY SELECTED

   This field is used to specify whether or not a specimen (patient) name will be entered into the Work List. If this option is turned OFF, the cursor will skip to the next ON field. However, the operator can use the arrow keys to place the cursor in this field and enter data, if desired.

2. PATIENT ID ENTRY SELECTED

   This field is used to specify whether or not a patient ID will be entered into the Work List. If this option is turned OFF, the cursor will skip to the next ON field. However, the operator can use the arrow keys to place the cursor in this field and enter data, if desired.

3. PATIENT SEX ENTRY SELECTED

   This field is used to specify whether or not the sex of the patient will be entered into the Work List. If this option is turned OFF, the cursor will skip to the next ON field. However, the operator can use the arrow keys to place the cursor in this field and enter data, if desired.

4. PATIENT DOB ENTRY SELECTED

   This field is used to specify whether or not the patient's date of birth will be entered into the Work List. If this option is turned OFF, the cursor will skip to the next ON field. However, the operator can use the arrow keys to place the cursor in this field and enter data, if desired.

5. COLLECTION DATE AND TIME ENTRY SELECTED

   This field is used to specify whether or not the collection date and time of the specimen will be entered into the Work List. If this option is turned OFF, the cursor will skip to the next ON field. However, the operator can use the arrow keys to place the cursor in this field and enter data, if desired.

6. DR NAME ENTRY SELECTED

   This field is used to specify whether or not the name of the patient's doctor will be entered into the Work List. If this option is turned OFF, the cursor will skip to the next ON field. However, the operator can use the arrow keys to place the cursor in this field and enter data, if desired.

7. PATIENT LIMITS ENTRY SELECTED

   If this option is turned OFF, the prior setting will be entered automatically for each entry. The operator can, however, input a different setting for individual entries by using the arrow keys to place the cursor in this field and type in a new setting. The new setting applies only to the entry(ies) that was changed.

If this option is turned ON, the operator may then select another default setting by typing in a number from 1 to 6. This new setting will be automatically assigned to each new entry by the operator. The operator also has the ability to enter a different setting for individual entries. When the cursor moves to the <Patient Limits Set> field of a particular entry, the operator may override the default setting and type in a new setting for that entry.

8. DEFAULT PATIENT LIMIT SET (1 to 6)

This field is used to specify the default (pre-assigned) Patient Limit Set that is automatically assigned to each sample unless otherwise indicated in the Work List. Any number between 1 and 6 inclusively may be entered.

9. PARAMETER SET ENTRY SELECTED

If this option is turned OFF, the prior setting will be entered automatically for each entry. The operator can, however, input a different setting for individual entries by using the arrow keys to place the cursor in this field and type in a new setting. The new setting applies only to the entry(ies) that was changed.

If this option is turned ON, the operator may then select another default setting by typing in a number from 2 to 4. This new setting will be automatically assigned to each new entry. The operator also has the ability to enter a different setting for individual entries. When the cursor moves to the <Parameter Set> field of a particular entry, the operator may override the default setting and type in a new setting for that entry.

10. DEFAULT PARAMETER SET (1 to 4)

This field is used to specify the default (pre-assigned) Parameter Set that is automatically assigned to each sample unless otherwise indicated in the Work List. Any number between 1 and 4 inclusively may be entered.

Sample Analysis — SL Model

The procedures described below discuss the operation of the Work List in both Open and Closed Modes using either Bar Codes or other Specimen ID for sample identification.

Closed Mode

On the SL model, although the RUN screen is displayed in the Closed Mode it is not possible to enter data on this screen. If Closed Mode is selected, demographic data can only be entered on the WORK LIST or DATA LOG screens.

Using the Work List with Bar Codes

The Sample Loader has a built-in bar code reader that automatically reads a bar code label placed on the tube. Refer to Appendix A for a complete discussion of bar code labels and instructions for correct placement of the labels on the tubes.

When bar code labels are used in Work List entries, samples may be run in any order after the Work List has been created. If Work List records are not downloaded from a host, they may be entered by the operator at the instrument.

As samples are processed, the instrument does the following:

- Reads the bar code label on the tube and searches the Work List for that bar code number.
- If a match is found, the demographic data from the Work List is displayed on the RUN screen along with the results, and the entire record is stored in the Data Log. The Work List entry is deleted.
- If no match occurs, the Bar Code number is displayed on the RUN screen without demographic data and stored in the Data Log along with the results. No Work List entry is deleted.

Running Samples with Bar Codes

1. In the RUN screen, press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).
2. If necessary, press [CHANGE SAMPLER] to select the Closed Mode.
3. Be sure that each sample to be run has a bar code label on the tube.

4. If Work List records containing bar codes were downloaded from a host, go to step *6*. If entries are to be made by the operator at the instrument, go to step *5*.
5. If Work List records are entered by the operator at the instrument, do the following:
   a. Enter all the Work List records, including bar code and demographic data, associated with the samples to be run into the Work List. DOUBLE CHECK to ensure that each Bar Code was entered correctly into the <Specimen ID> field.
6. Place all the samples to be run into the Sample Loader racks and load the racks onto the Sample Loader (if not already done).

   NOTE: The samples in the racks do not have to be in the same order as the Work List entries.

7. Press [START LOADER] to begin sample processing.
8. The samples are processed in the order in which they were placed in the racks. The Sample Loader automatically stops when all samples in the last rack have been processed.

   NOTE: Additional entries may be made to the Work List while processing takes place. To input additional entries to the Work List, press [WORK LIST] to display the WORK LIST screen. Type in the new entries.

9. When all samples have been processed, check to see if all entries have been deleted from the Work List. Entries are automatically deleted from the Work List when a match occurs. Entries remaining in the Work List indicate a successful match did not occur. The operator should follow laboratory procedures to determine the cause of this discrepancy.

Using the Work List with Specimen IDs

When Work List entries contain Specimen IDs (non bar code), the operator *must* enter the rack and tube position of each sample into the <Rack and Tube #> field of the appropriate Work List entry, otherwise no match can occur. It is not necessary for the samples in the racks to be in the same order as the entries in the Work List, but the position of each sample in the racks must match its Rack and Tube # in the Work List.

Sample identification is made from the information entered in the <Rack and Tube #> field on the Work List.

If a match occurs (based on the Rack and Tube #), the sample results along with the demographic data (including the Specimen ID) are displayed on the RUN screen and sent to the Data Log.

> **NOTE:** The Rack and Tube # is not displayed on the RUN screen or sent to the Data Log. The Rack and Tube # is used only for the purpose of matching Work List entries with samples.

If a match does not occur, it indicates the operator typed an incorrect Rack and Tube # into the Work List. The operator may either:

1. Correct the Rack and Tube # in the Work List and re-run the sample (this avoids having to enter all the demographic data manually), OR
2. Go to the Data Log, find the entry by the Rack and Tube # assigned by the instrument, and enter the remaining demographic information.

> **NOTE:** If the instrument cannot match a sample with a Work List entry using Bar Code, Specimen ID, or Rack and Tube #, it identifies the sample by its actual rack and tube position and assigns that number to the <Specimen ID> field of that sample. The results along with the assigned rack and tube number are sent to the Data Log *without* deleting any records in the Work List, since no match was made. The sample is identified in the Data Log by the Rack and Tube # assigned by the instrument.

> **NOTE:** If the instrument is unable to read a Bar Code on the tube and is unable to read the Bar Code on the rack, a malfunction has occurred. Sample Loader processing is halted. Determine which rack position is the source of the problem before removing the rack. Check the bar code label for that position to determine the cause of the malfunction. If unable to fix or replace the label, use a new rack. Whichever rack is used, remove any samples that were aspirated and identified properly. Place the rack at the starting position on the load side of the Sample Loader. Press the [CLEAR FAULT] key followed by [RESET LOADER] to resume processing.

Running Samples with Specimen IDs

1. If Work List records were downloaded from a host, perform steps *a* through *e* below. If Work List records are to be entered by the operator at the instrument, go to step *2*.
   a. In the RUN screen, press [WORK LIST].
   b. For each sample to be run, find the matching entry in the Work List.
   c. Type the rack and tube number for that sample into the <Rack and Tube #> field for that entry in the Work List and place the sample into the appropriate rack and tube position. DOUBLE CHECK to ensure the sample was actually placed in the rack and tube position indicated in the Work List entry.

      NOTE: The samples in the racks do not have to be in the same order as the Work List entries, but the actual rack and tube number of each sample must be correctly assigned to the Work List entry for that sample.

   d. Repeat this process for all samples. When finished, place the racks on the Sample Loader.
   e. Go to step *3*.
2. To enter Work List records at the instrument, do the following:
   a. In the RUN screen, press [WORK LIST].
   b. Enter all the Work List records associated with the samples to be run, including the Rack and Tube #. DOUBLE CHECK to ensure that each Specimen ID was entered correctly in the <Specimen ID> field. DOUBLE CHECK to ensure that the actual rack and tube position for each sample was correctly entered in the <Rack and Tube #> field in the Work List.

      NOTE: The samples in the racks do not have to be in the same order as the Work List entries.

   c. When all entries have been completed, place the tubes in racks and load the racks onto the Sample Loader (if not already done).
3. Press [RETURN] to return to the RUN screen.
4. In the RUN screen, press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).
5. If necessary, press [CHANGE SAMPLER] to select the Closed Mode.

6. Press [START LOADER] to begin sample processing.
7. The samples are automatically processed in the order in which they were placed in the racks. The Sample Loader automatically stops when all samples in the last rack have been processed.

   NOTE: Additional entries may be made to the Work List while processing takes place. To input additional entries to the Work List, press [WORK LIST] to display the WORK LIST screen. Type in the new entries.

8. When all samples have been processed, check to see if all entries have been deleted from the Work List. Entries are automatically deleted from the Work List when a match occurs. Entries remaining in the Work List indicate a successful match did not occur. The operator should follow laboratory procedures to determine the cause of this discrepancy.

Running STAT Samples

1. STAT samples may be run in either the Closed or Open Modes on the SL model.
2. STAT samples with either Bar Codes or Specimen IDs may be run using the Work List.
3. STAT records may be downloaded from a host or entered into the Work List by the operator.
4. STAT samples are processed in the same manner as other Work List samples. Refer to ***Running Samples with Bar Codes*** and ***Running Samples with <Specimen ID>s*** discussed earlier in this section.

Open Mode

Using the Work List with Bar Codes

If Work List entries with Bar Codes have been downloaded from a host, the operator has two options for entering the bar code number in Open Mode:

1. Type the bar code number into the <Next ID> field on the RUN screen.
2. Use a hand-held bar code reader (if attached to the PC keyboard) to read the bar code on the sample into the <Next ID> field on the RUN screen.

   NOTE: The operator must first place the cursor in the <Next ID> field so that the bar code number is placed in the proper field.

Under either option, when the sample is run the system will automatically try to match the bar code number in the <Next ID> field on the RUN screen with a Work List entry. If a successful match occurs, the sample results along with the demographic data in the Work List will be displayed on the RUN screen and sent to the Data Log. That entry will be deleted from the Work List.

If a successful match does not occur, the results of the run are sent to the Data Log with only the bar code number entered by the operator (either manually or by the hand-held reader). The operator must then go to the Data Log and enter the remaining demographic data for that sample. No entry is deleted from the Work List.

Running Samples

1. In the RUN screen, press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).
2. If necessary, press [CHANGE SAMPLER] to select Open Mode.
3. Enter the bar code number into the <Next ID> field on the RUN screen.
4. Place the well-mixed sample under the Open Sample Aspiration Probe, make sure the end of the probe is deeply immersed in the sample, and press the Touch Plate to start the cycle.

   NOTE: Additional entries may be made to the Work List while processing takes place. To input additional entries to the Work List, press [WORK LIST] to display the WORK LIST screen. Type in the new entries.

5. When all samples have been processed, check to see if all entries have been deleted from the Work List. Entries are automatically deleted from the Work List when a match occurs. Entries remaining in the Work List indicate a successful match did not occur. The operator should follow laboratory procedures to determine the cause of this discrepancy.

Running STAT Samples with Bar Codes

STAT samples with bar codes are processed in the same manner as described in the sections ***Using the Work List with Bar Codes*** and ***Running Samples*** immediately above.

Using the Work List with Specimen IDs

If Work List records with Specimen IDs (non bar code) were downloaded from a host, the operator can use the Work List by entering the Specimen ID on the sample tube into the <Next ID> field on the RUN screen. When the sample is run, the instrument will attempt to match the number in the <Next ID> field on the RUN screen with a similar number in the <Specimen ID> field in the Work List.

If a match occurs, the sample results along with the demographic data from the Work List will be displayed on the RUN screen and sent to the Data Log. That entry will be deleted from the Work List.

If a match does not occur, only the sample results and Specimen ID entered on the RUN screen will be displayed on the RUN screen and stored in the Data Log. No entry will be deleted from the Work List. The operator must go to the Data Log to enter the remaining demographic information.

Running Samples

1. In the RUN screen, press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).
2. If necessary, press [CHANGE SAMPLER] to select Open Mode.
3. Enter the Specimen ID into the <Next ID> field on the RUN screen.
4. Place the well-mixed sample under the Open Sample Aspiration Probe, make sure the end of the probe is deeply immersed in the sample, and press the Touch Plate to start the cycle.

   NOTE: Additional entries may be made to the Work List while processing takes place. To input additional entries to the Work List, press [WORK LIST] to display the WORK LIST screen. Type in the new entries.

5. When all samples have been processed, check to see if all entries have been deleted from the Work List. Entries are automatically deleted from the Work List when a match occurs. Entries remaining in the Work List indicate a successful match did not occur. The operator should follow laboratory procedures to determine the cause of this discrepancy.

Running STAT Samples with Specimen IDs

STAT samples with Specimen IDs are processed in the same manner as described in ***Using the Work List with Specimen IDs*** and ***Running Samples*** immediately above.

Sample Analysis — CS Model

For the CELL-DYN 3200CS model, only a Bar Code or other Specimen ID may be used with the Work List to match entries. Because this model has no Sample Loader, rack and tube position cannot be used to identify specimens.

Samples are run individually in both Open and Closed Modes.

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Closed Mode

Using the Work List with Bar Codes

The Closed Sample Aspiration Tower has a built-in Bar Code Reader that automatically reads a bar code label placed on the tube. Refer to Appendix A for a complete discussion of bar code labels and instructions for correct placement of the labels on the tubes.

When bar code numbers are used in Work List entries, samples may be run in any order after the Work List has been created. If Work List records are not downloaded from a host, they may be entered by the operator at the instrument.

As samples are processed, the instrument does the following:

- reads the bar code label on the tube and searches the Work List for that bar code number
- If a match is found, the demographic data from the Work List is displayed on the RUN screen along with the results, and the entire record is stored in the Data Log. The Work List entry is deleted.
- If not match is found, the Bar Code number is displayed on the RUN screen without demographic data and stored in the Data Log along with the results. No Work List entry is deleted.

Running Samples with Bar Codes

1. If Work List records containing bar codes were downloaded from a host, perform steps *a* through *h* below. If entries are to be made by the operator at the instrument, go to step *2*.

a. In the RUN screen, press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).

b. If necessary, press [CHANGE SAMPLER] to select the Closed Mode.

c. Be sure that each sample to be run has a bar code label on the tube.

d. Place a well-mixed sample in the Tube Retainer and close the door.

e. Press the Touch Plate to run the sample.

f. When the sample has been aspirated, the door will open. Remove the tube.

g. Repeat steps *d* through *f* until all Work List samples have been processed.

NOTE: Additional entries may be made to the Work List while processing takes place. To input additional entries to the Work List, press [WORK LIST] to display the WORK LIST screen. Type in the new entries.

h. Go to step *3*.

2. If Work List records are entered by the operator at the instrument, perform steps *a* through *h* below:

a. In the RUN screen, press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).

b. If necessary, press [CHANGE SAMPLER] to select the Closed Mode.

c. Be sure that each sample to be run has a bar code label on the tube.

d. Enter all the Work List records associated with the samples to be run into the Work List. DOUBLE CHECK to ensure that each Bar Code was entered correctly into the <Specimen ID> field.

e. Place a well-mixed sample in the Tube Retainer and close the door.

f. Press the Touch Plate to run the sample.

g. When the sample has been aspirated, the door will open. Remove the tube.

h. Repeat steps *e* through *g* until all Work List samples have been processed.

NOTE: Additional entries may be made to the Work List while processing takes place. To input additional entries to the Work List, press [WORK LIST] to display the WORK LIST screen. Type in the new entries.

3. When all samples have been processed, check to see if all entries have been deleted from the Work List. Entries are automatically deleted from the Work List when a match occurs. Entries remaining in the Work List indicate a successful match did not occur. The operator should follow laboratory procedures to determine the cause of this discrepancy.

Using the Work List with Specimen IDs

To match Work List entries using Specimen ID, the operator must first enter a sample's Specimen ID into the <Next ID> field on the RUN screen before running the sample. As the sample is processed, the instrument searches the Work List for a matching Specimen ID.

If a match occurs, the sample results along with the demographic data from the Work List is displayed on the RUN screen and sent to the Data Log. That entry is deleted from the Work List.

If a match does not occur, only the sample results with the Specimen ID entered on the RUN screen is displayed and sent to the Data Log. No entry is deleted from the Work List.

Running Samples with Specimen IDs

1. In the RUN screen, press [SPECIMEN TYPE] followed by the appropriate specimen type (Patient, Fragile WBC, or Resistant RBC).
2. If necessary, press [CHANGE SAMPLER] to select the Closed Mode.
3. If Work List records were downloaded from a host, go to step *5*.
4. To enter Work List records at the instrument, do the following:
   a. In the RUN screen, press [WORK LIST].
   b. Enter all the Work List records, including demographic data and Specimen ID, associated with the samples to be run. DOUBLE CHECK to ensure that each Specimen ID was entered correctly in the <Specimen ID> field.
5. Select a sample tube and type the Specimen ID shown on the tube into the Next ID field on the RUN screen.

6. Place a well-mixed sample in the Tube Retainer and close the door.
7. Press the Touch Plate to run the sample.
8. When the sample has been aspirated, the door will open. Remove the tube.
9. Repeat steps *5* through *8* until all samples have been processed.

   NOTE: Additional entries may be made to the Work List while processing takes place. To input additional entries to the Work List, press [WORK LIST] to display the WORK LIST screen. Type in the new entries.

10. When all samples have been processed, check to see if all entries have been deleted from the Work List. Entries are automatically deleted from the Work List when a match occurs. Entries remaining in the Work List indicate a successful match did not occur. The operator should follow laboratory procedures to determine the cause of this discrepancy.

Running STAT Samples

The procedure for running STAT samples is similar to the procedure for running Work List samples described above. For STAT samples with bar codes, refer to ***Running Samples with Bar Codes*** above. For STAT samples with Specimen IDs, refer to ***Running Samples with Specimen IDs*** above.

Open Mode

Work List Samples

Work List samples are processed in the Open Mode on the CS model in the same manner as on the SL model. For a description of this procedure, refer to ***Sample Analysis — SL Model***, subsection: ***Open Mode***.

STAT Samples

STAT samples are processed in the Open Mode on the CS model in the same manner as on the SL model. For a description of this procedure, refer to ***Sample Analysis — SL Model***, subsection: ***Open Mode***.

Using The Data Log

Introduction

The Data Log stores all data and demographic information in a log format for the last 10,000 cycles run on the CELL-DYN 3200. The record information is stored chronologically by sequence number. Scattergrams and histograms are stored for all 10,000 records.

> **NOTE:** When the log is full, subsequent entries cause the oldest entry to be deleted and the remaining entries to move up one line, so that the current records are added to the bottom of the list.

The first part of this section gives a brief description of the DATA LOG menu keys. The Data Log Set Up portion gives instructions for customizing the display and printout of the Data Log. The final section gives instructions for data review from the Data Log.

Scrolling Through the Data Log

Each screen display (page) may contain up to 18 specimens.

Use the Left and Right Arrow keys to scroll through the complete list of parameters for all specimens displayed on a page. Use the Up and Down Arrow keys to move the cursor between specimens on a page.

Use the Page Up key to scroll through preceding pages. Use the Page Down key to scroll through succeeding pages.

DATA LOG Menu

The function of each of the soft keys in the DATA LOG menu, shown in Figure 5.44, is discussed in this section.

The Data Log consists of 5 pages (screens). The first page contains limited demographic data on the patient, and subsequent pages display parameter results. The following data is common to all 5 screens:

1. Sequence #

2. Specimen ID
3. Collection Date and Time
4. Operator ID

The second page displays the results for the WBC Parameters. The third page displays the results for the RBC parameters. The fourth page displays the results for the PLT parameters. The fifth page displays the results for the WBC parameters expressed as a percent.

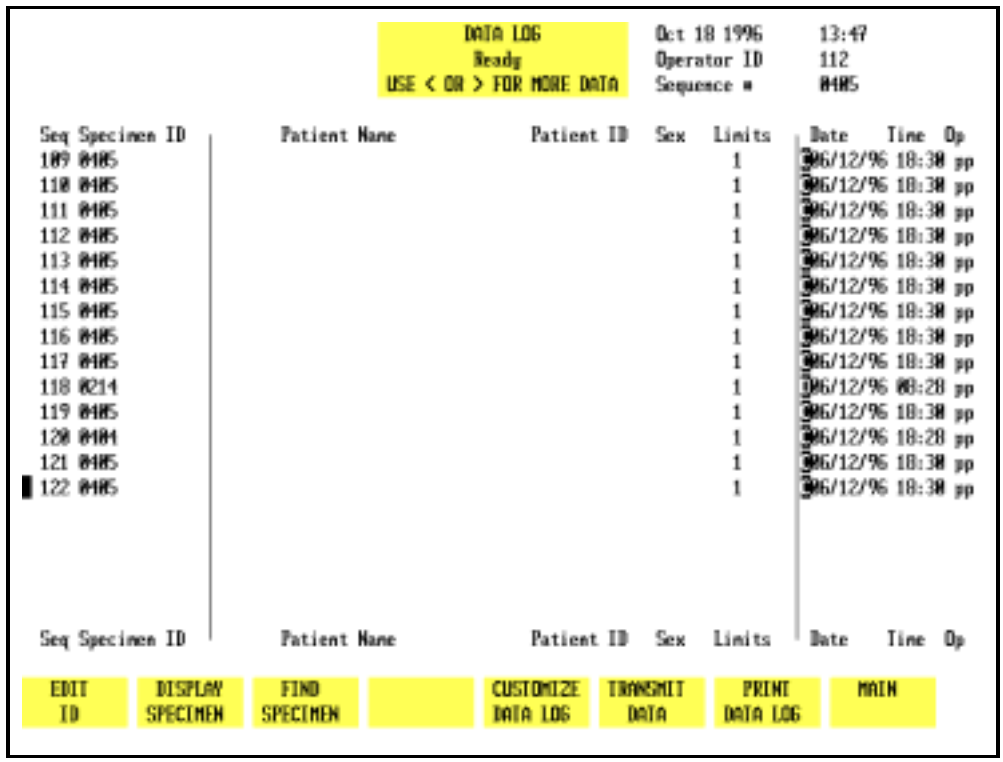

Figure 5.44: Data Log Screen - Page 1

When the [DATA LOG] key is pressed in the MAIN MENU, the DATA LOG menu and the following soft key labels are displayed:

EDIT ID*
DISPLAY SPECIMEN
FIND SPECIMEN
REJECT FROM X-B**
CUSTOMIZE DATA LOG
TRANSMIT DATA
PRINT DATA LOG
MAIN

*This key is displayed only if the cursor is positioned next to one of the following patient record types: Patient, Fragile WBC, and Resistant RBC.

**This key is displayed if the sequence number of the patient record is preceded by a “b”, “r”, or “w”.

Edit ID

The [EDIT ID] key is used to edit the Specimen ID from the DATA LOG screen. When the [EDIT ID] key is pressed, the cursor moves into the <Specimen ID> field and all key labels are blank. Edits are saved by pressing the Enter key on the keyboard.

NOTE: The [EDIT ID] key is available only when the cursor is positioned next to a Patient Record. It is not available for Background or QC records.

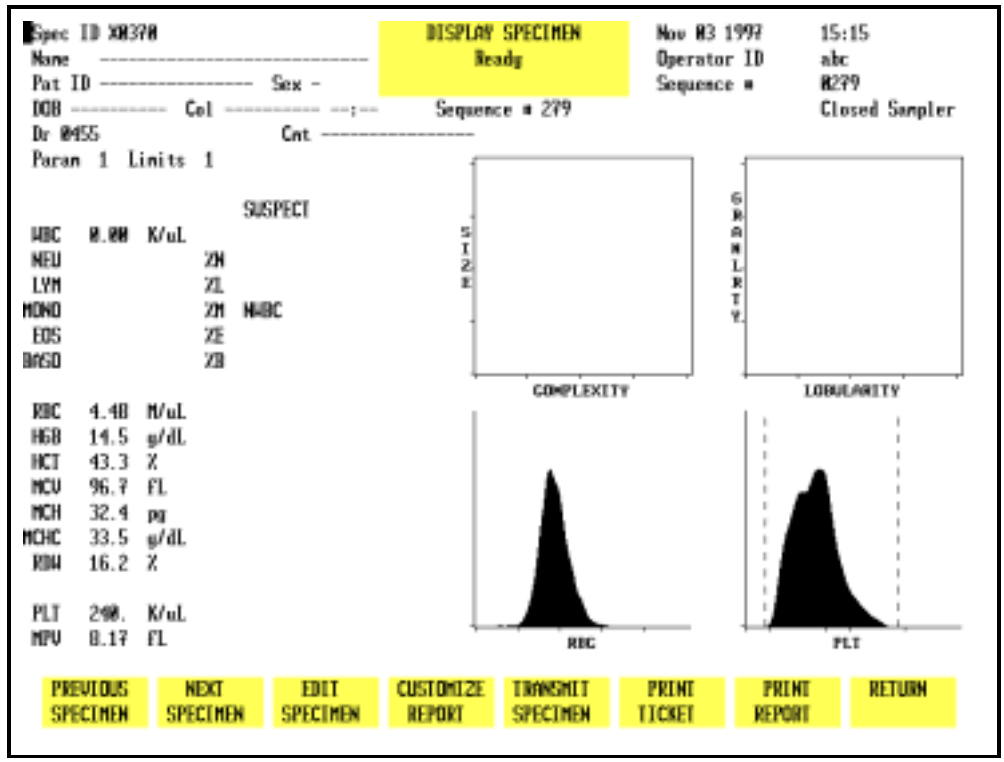

Figure 5.45: Display Specimen Screen

Display Specimen

The [DISPLAY SPECIMEN] key is used to display the results for the record indicated by the cursor position. (See Figure 5.45.) The following soft key labels are displayed when the [DISPLAY SPECIMEN] key is pressed:

PREVIOUS SPECIMEN*
NEXT SPECIMEN**
EDIT SPECIMEN***

CUSTOMIZE REPORT
TRANSMIT SPECIMEN
PRINT TICKET
PRINT REPORT/COLOR PRINT (The key label alternates between the selections.)
RETURN

* This key is not displayed when the first specimen in the log is on the screen.
** This key is not displayed when the last specimen in the log is on the screen.
*** This key is displayed only if the cursor is positioned next to one of the following patient record types: Patient, Fragile WBC, or Resistant RBC.

Previous Specimen

The [PREVIOUS SPECIMEN] key is used to display the results for the sequence number preceding the one currently displayed without returning to the main DATA LOG screen.

Next Specimen

The [NEXT SPECIMEN] key is used to display the results for the sequence number following the one currently displayed without returning to the main DATA LOG screen.

Edit Specimen

The [EDIT SPECIMEN] key is used to edit patient demographic information for the selected record. It may also be used to edit and display the results with a Parameter or Patient Limit Set different from the one currently displayed. The following soft key labels are displayed when the [EDIT SPECIMEN] key is pressed:

CONFIRM
CANCEL

These keys are used to [CONFIRM] or [CANCEL] the edits. The Bulletin line displays the message PRESS CONFIRM TO SAVE CHANGES OR CANCEL TO CANCEL CHANGES. When the [CONFIRM] key is pressed, the edited record is displayed.

Customize Report

The [CUSTOMIZE REPORT] key is used to customize the RUN screen display, header and printout as described in the Set Up Instructions section of this chapter.

Transmit Specimen

The [TRANSMIT SPECIMEN] key is used to transmit the displayed report to a Laboratory Information System or on-line computer.

Print Ticket

The [PRINT TICKET] key is used to print a ticket (in the currently selected format) for the displayed record.

Print Report

The [PRINT REPORT] key is used to print a graphics report (in the currently selected format) for the displayed record.

> **NOTE:** If color printing has been selected (refer to the Set Up Instructions), the key label changes to [COLOR PRINT].

Return

The [RETURN] key is used to return to the main DATA LOG screen.

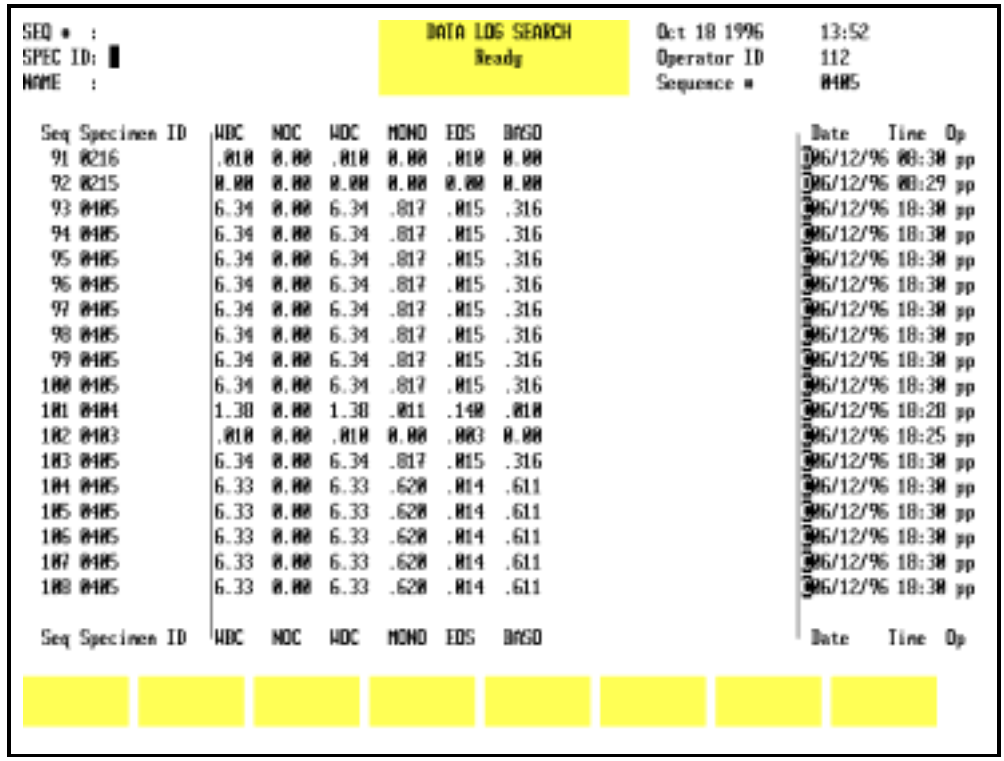

Figure 5.46: Data Log Search Screen

Find Specimen

The [FIND SPECIMEN] key is used to locate a particular record by entering the Sequence number, Specimen ID number or Patient Name for the desired record. When this key is pressed, the DATA LOG SEARCH screen is displayed. (See Figure 5.46.) If the record is not found in the Data Log, the Bulletin line displays the message: NO ENTRY FOUND.

Reject From X-B

If the cursor is positioned at a sample identified with a “r”, “w”, or “b” preceding the sequence number (indicating that the results are included in the XB analysis), the [REJECT FROM X-B] key label is displayed. (See Figure 5.47.)

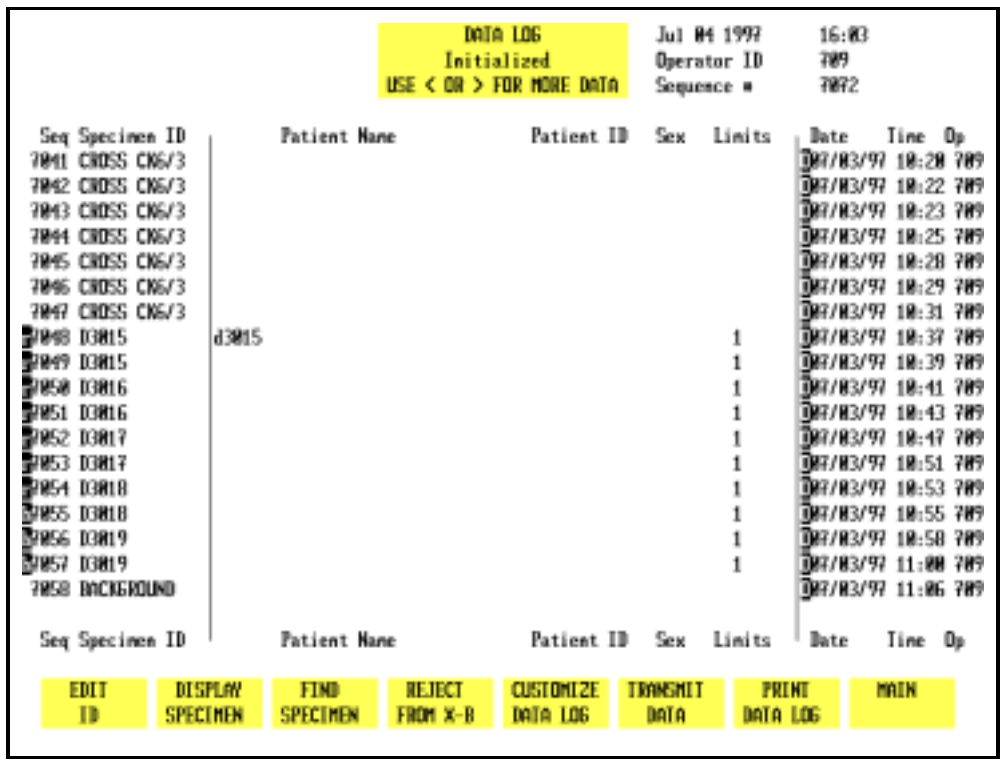

Figure 5.47: Data Log Screen Showing Reject From X-B Key

When the [REJECT FROM X-B] key is pressed, the sample is marked with an “R” following the Specimen ID, the results are excluded from the X-B analysis (the “R”, “w”, or “b” is deleted), and the key label changes to [ACCEPT INTO X-B]. (See Figure 5.48.)

If the [ACCEPT INTO X-B] key is pressed, the “R” is deleted, the “r”, “w”, or “b” is displayed and results are now included in the X-B analysis.

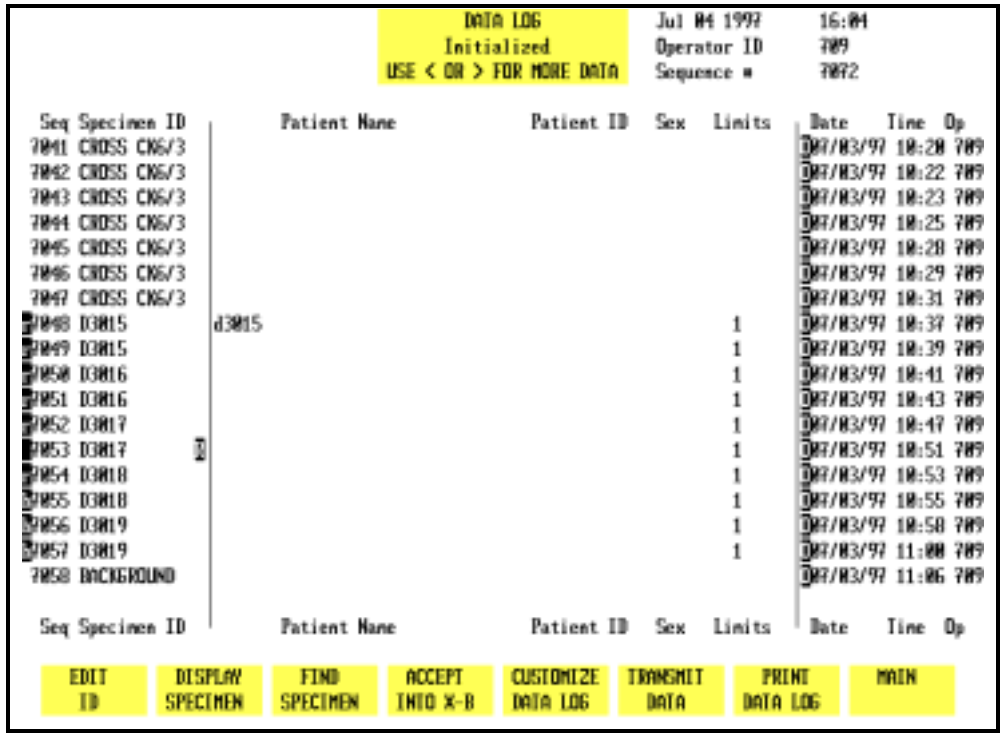

Figure 5.48: Data Log Screen Showing Accept Into X-B Key

Customize Data Log

The [CUSTOMIZE DATA LOG] key is used to customize the Data Log display. The CUSTOMIZE DISPLAY FOR DATA LOG screen (see Figure 5.49) and the following soft key labels are displayed when the [CUSTOMIZE DATA LOG] key is pressed:

SELECT PARAMETER/ PLACE PARAMETER	(The key alternates between the selections.)
STANDARD GROUPS/ CUSTOM PLACEMENT	(The key alternates between the selections.)

CUSTOMIZE PRINTOUT
RETURN

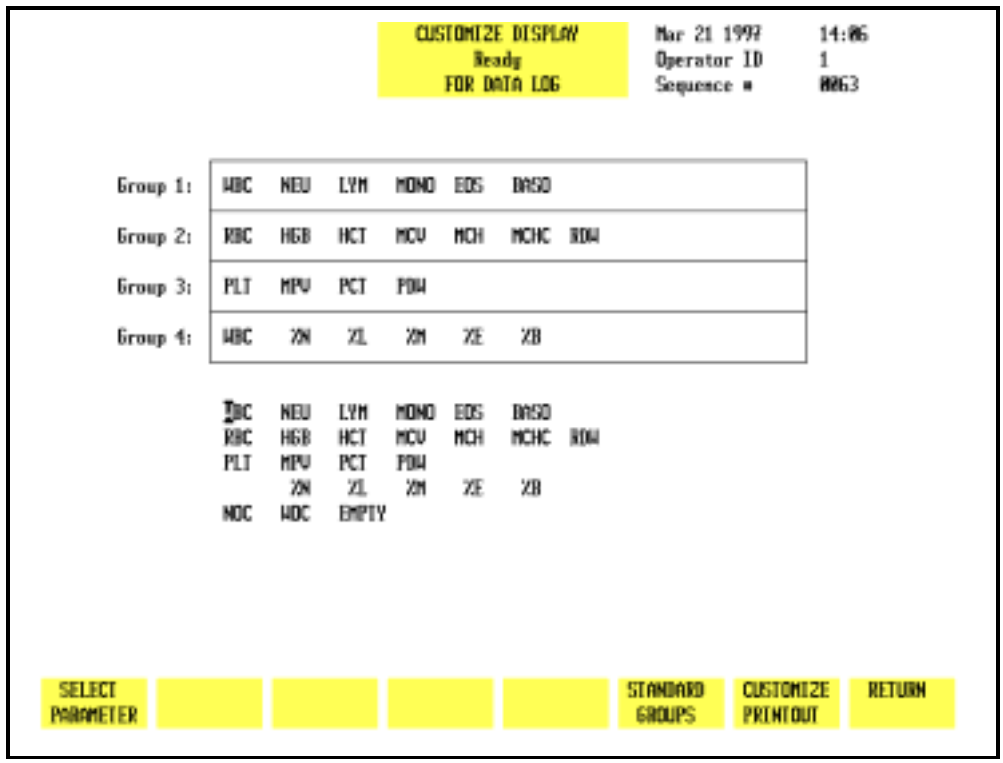

Figure 5.49: Customize Display for Data Log Screen Showing Standard Groups

The CUSTOMIZE DISPLAY FOR DATA LOG screen displays a matrix showing the four parameter groups and a list of the available parameters. Parameter Group 1 is displayed (in the order indicated from left to right) on the second DATA LOG screen. The remaining groups are displayed on subsequent screens that are accessed by pressing the Right Arrow key on the keyboard. The Left Arrow key is used to page back through the screens to the first screen. Figure 5.50 shows a customized Data Log display screen.

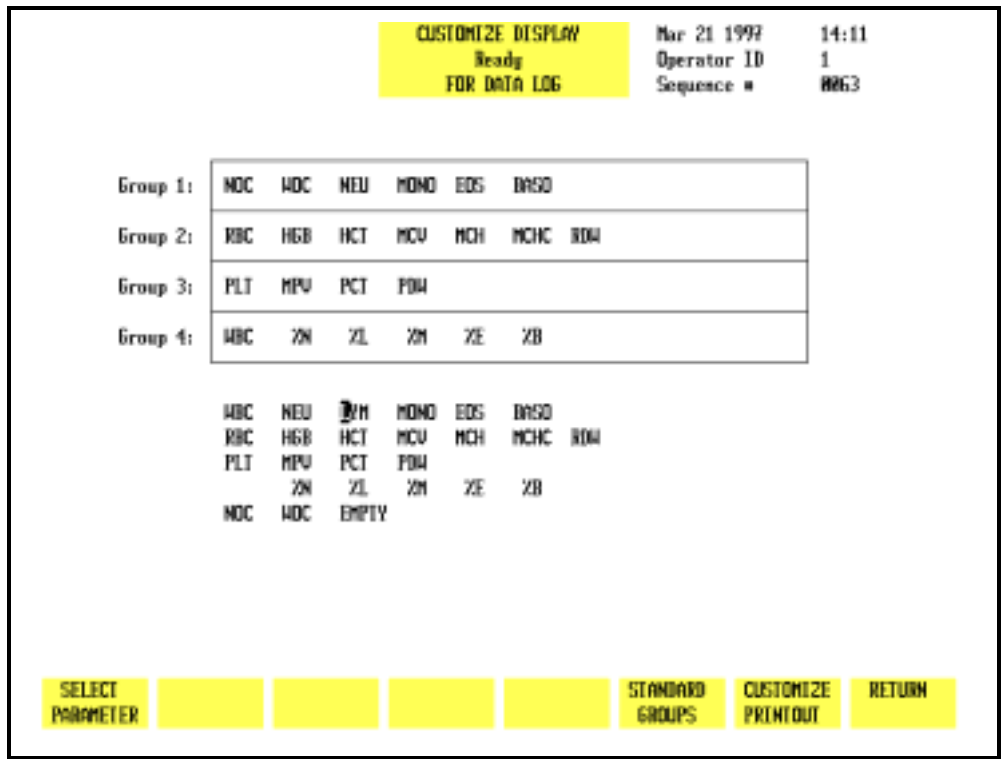

Figure 5.50: Customize Display for Data Log Screen Showing Group 1 Customized

Select Parameter

The [SELECT PARAMETER] key is used to select a parameter designated by the cursor. When the key is pressed, the selected parameter is highlighted, the label changes to [PLACE PARAMETER], and a [CANCEL SELECTION] key is displayed.

Place Parameter

The [PLACE PARAMETER] key is used to display the parameter in the location indicated by the position of the cursor.

Cancel Selection

The [CANCEL SELECTION] key is used to cancel the selection and display the [SELECT PARAMETER] key.

Standard Groups

Pre-determined groups of parameters, called Standard Groups, may be selected by pressing the [STANDARD GROUPS] key. Refer to Figure 5.49 which shows the CUSTOMIZE DISPLAY FOR DATA LOG screen with the standard groups displayed. The following soft key labels are displayed when the [STANDARD GROUPS] key is pressed:

WBC GROUP
RBC GROUP
PLT GROUP
DIFF GROUP
CUSTOM PLACEMENT*
CUSTOMIZE PRINTOUT
RETURN

*The [CUSTOM PLACEMENT] key is used to return to the CUSTOMIZE DISPLAY FOR DATA LOG screen for operator-selected placement.

Figure 5.49 shows the WBC Group placed in GROUP 1, the RBC Group placed in GROUP 2, the PLT Group placed in GROUP 3 and the Diff Group placed in GROUP 4.

When each soft key is pressed, the designated parameter group is placed in the position indicated by the cursor.

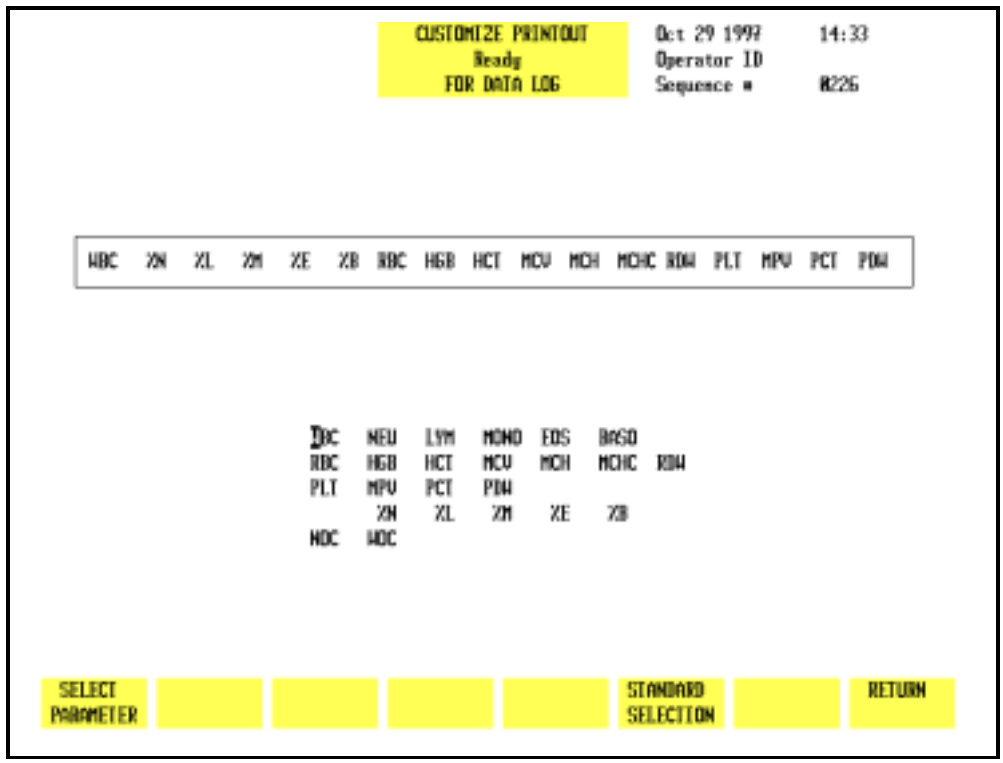

Figure 5.51: Customize Printout for Data Log Screen

Customize Printout

The [CUSTOMIZE PRINTOUT] key is used to customize the printout format of the Data Log. (See Figure 5.51.) The following soft key labels are displayed when the [CUSTOMIZE PRINTOUT] key is pressed:

SELECT PARAMETER/ PLACE PARAMETER	(The key alternates between the selections.)
STANDARD SELECTION	
RETURN	

The CUSTOMIZE PRINTOUT FOR DATA LOG screen shows the order (from left to right) in which the indicated parameters will be printed.

Select Parameter

The [SELECT PARAMETER] key is used to select a parameter designated by the cursor. When the key is pressed, the selected parameter is highlighted, the label changes to [PLACE PARAMETER] and a [CANCEL SELECTION] key is displayed.

Place Parameter

The [PLACE PARAMETER] key is used to display the parameter in the location indicated by the position of the cursor.

Cancel Selection

The [CANCEL SELECTION] key is used to cancel the selection and display the [SELECT PARAMETER] key.

Standard Selection

The [STANDARD SELECTION] key is used to configure the printout in the pre-determined print group shown in Figure 5.49. When the key is pressed, the print group is changed to the Standard Selection.

Return

The [RETURN] key is used to return to the main DATA LOG screen.

Transmit Data

The [TRANSMIT DATA] key is used to transmit a record to a Laboratory Information System or on-line computer. When the [TRANSMIT DATA] key is pressed, the screen prompts the operator to enter the starting and ending sequence numbers (from the lowest to the highest) for the desired transmission. Records may be transmitted singly or in batches as designated by the sequence number(s).

When the [TRANSMIT DATA] key is pressed, the <Starting Sequence #> field appears in the upper left corner of the screen and the cursor is positioned in this field. The operator should enter the sequence number of the first specimen to be transmitted and press the Enter key. If the number is valid, the system accepts the entry and the <Ending Sequence #> field appears in the upper left corner of the screen. The operator should type in the ending sequence number and press Enter. The system begins transmitting automatically. If only one record is to be transmitted, the starting and ending sequence number will be the same.

> **NOTE:** Use the ESC key to cancel this function and return to the DATA LOG menu. Use the Backspace key or left arrow key to cancel an entry and retype the sequence number.

Because specimen records are shown in summary form on the DATA LOG menu, only the summary data of these records will be transmitted. No histogram data accompanies the summary data.

Print Data Log

The [PRINT DATA LOG] key is used to print the Data Log. When the [PRINT DATA LOG] key is pressed, the screen prompts the operator to enter the starting and ending sequence numbers (from the lowest to the highest) for the desired printout. (See Figure 5.52.)

When the [PRINT DATA LOG] key is pressed, the <Starting Sequence #> field appears in the upper left corner of the screen and the cursor is positioned in this field. The operator should enter the sequence number of the first specimen to be printed and press the Enter key. If the number is valid, the system accepts the entry and the <Ending Sequence #> field appears in the upper left corner of the screen. The operator should type in the ending sequence number and press Enter. The system begins printing automatically. If only one record is to be printed, the starting and ending sequence number will be the same.

> **NOTE:** Use the ESC key to cancel this function and return to the DATA LOG menu. Use the Backspace key or left arrow key to cancel an entry and retype the sequence number.

Because specimen records are shown in summary form on the DATA LOG menu, only the summary data of these records will be printed. No histogram data accompanies the summary data.

NOTE: To print histogram data, the operator must press the [DISPLAY SPECIMEN] key in the DATA LOG menu to select and display an individual specimen. Then, the [PRINT REPORT] key will print the results of the specimen displayed on the screen, including histograms.

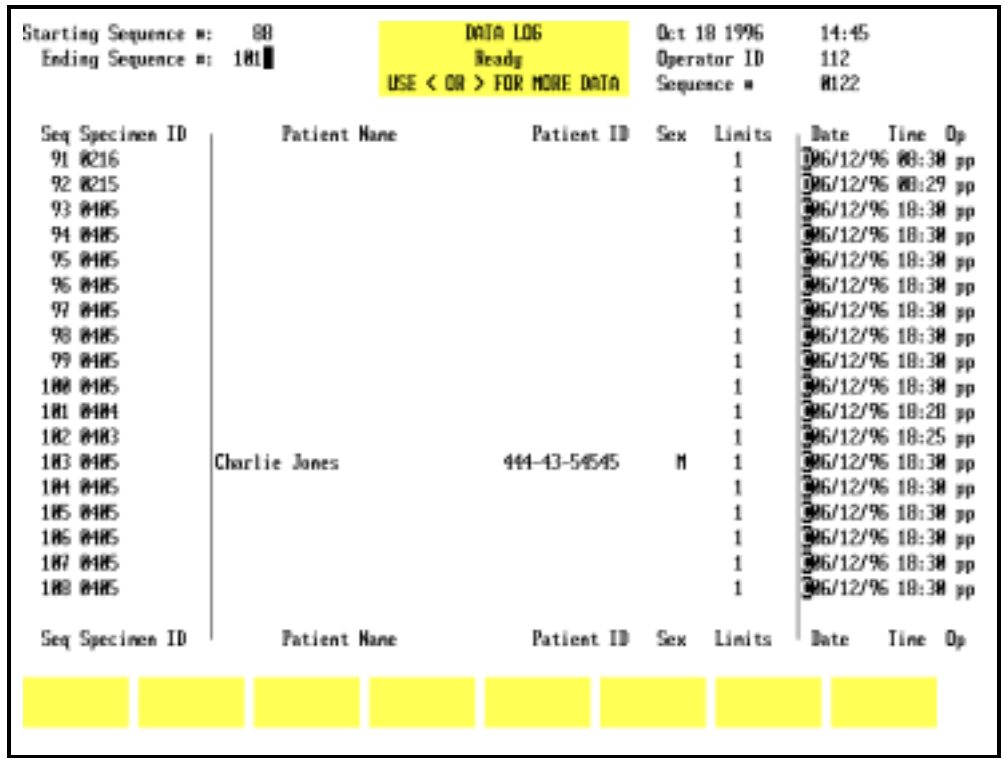

Figure 5.52: Print Data Log Screen

Data Log Codes

The Data Log Codes are displayed in the Data Log in the column immediately preceding the date (see Figure 5.52). These codes are displayed in the following order:

O — Sample was run in the Open Mode

C — Sample was run in the Closed Mode

N — Incomplete aspiration in the Open Mode

I — Incomplete aspiration in the Closed Mode

K — Flow Error

R — Resistant RBC key was used to run this sample

F — Fragile WBC key was used to run this sample

NOTE: For Background and Latex specimens, only the O and C codes are used.

An example of codes displayed in the Data Log is shown in Figure 5.53.

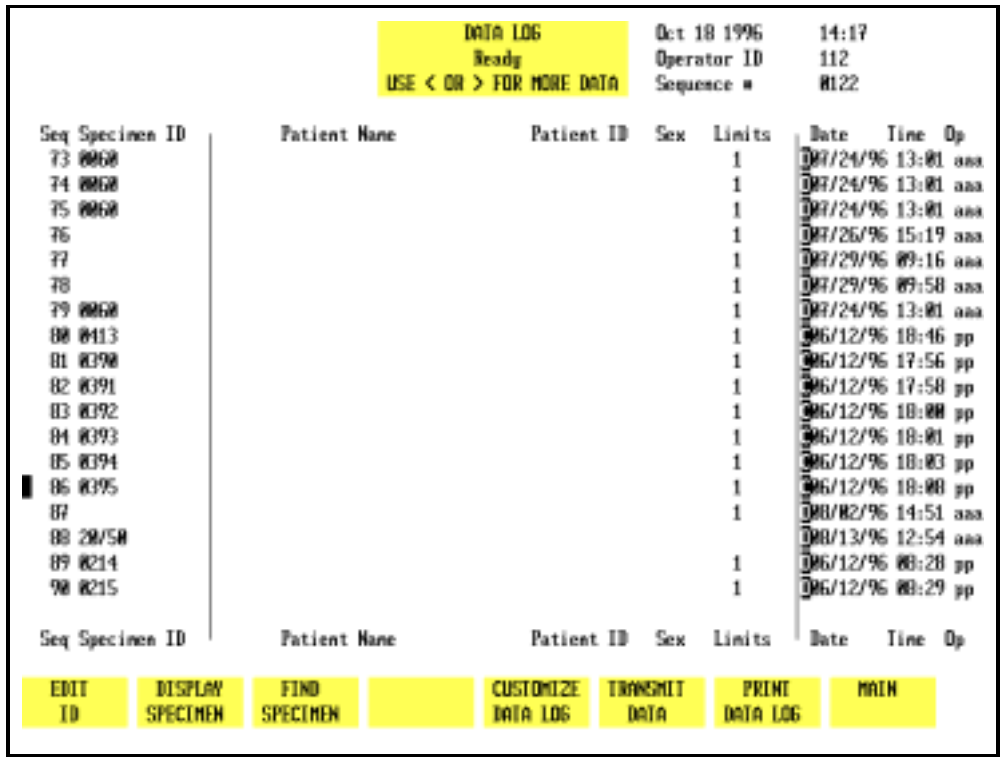

Figure 5.53: Data Log Codes Screen

Data Log Set Up Procedures

The Data Log may be configured to display and print results in the order selected by the operator. This section gives instructions for Customizing the Display and Printout.

Customizing the Data Log Display

The CUSTOMIZE DISPLAY FOR DATA LOG screen displays a matrix showing the four groups of parameters that will be consecutively displayed on the four Data Log screens. (Figure 5.54 shows the Standard Groups in the matrix.) A list of all available parameters is displayed under the matrix. The parameters are selected from the list and placed in the desired group to customize the display.

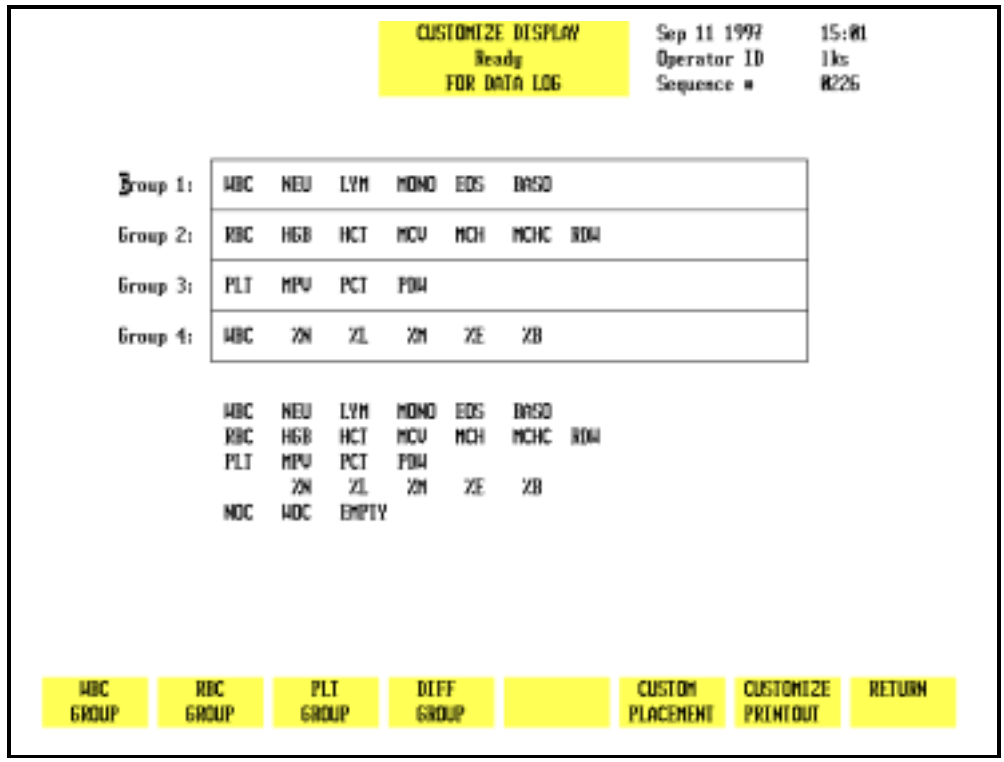

Figure 5.54: Customize Display for Data Log Screen Showing Standard Groups

The display may be customized by selecting the individual parameters, Standard Groups of parameters or a combination of the two. In addition to the usual Hematologic parameters, the following parameters may also be displayed in the Data Log:

NOC	Nuclear Optical Count
EMPTY	Inserts an empty column in the display

To Customize the Data Log Display

1. In the main DATA LOG screen, press [CUSTOMIZE DATA LOG] to display the CUSTOMIZE DISPLAY FOR DATA LOG screen.
2. If necessary, press [CUSTOM PLACEMENT] to display the CUSTOMIZE DISPLAY FOR DATA LOG screen and key labels for custom placement.
3. Use the Arrow keys on the keyboard to move the cursor to the desired parameter in the listing under the matrix.
4. Press [SELECT PARAMETER]. The selected parameter is highlighted and the cursor moves to the first position in Group 1.

   NOTE: The key label changes to [PLACE PARAMETER] and a [CANCEL SELECTION] key is displayed.

5. If necessary, use the Arrow keys on the keyboard to move the cursor to the desired location and press [PLACE PARAMETER].

   NOTE: When the [PLACE PARAMETER] key is pressed, the selected parameter is displayed in the position indicated by the cursor and the cursor is then advanced to the next position in the group.

6. Repeat steps 3–5 until all selections have been made.
7. If desired, press the Print Screen key on the keyboard to obtain a printout of the selected groups.
8. Press [RETURN] to return to the DATA LOG screen.
9. The Data Log is displayed configured with the selected parameters.

Standard Groups

The Data Log display may also be customized with pre-determined groups (Standard Groups) of parameters using the [STANDARD GROUPS] key. Figure 5.54 shows the WBC Group placed in GROUP 1, the RBC Group placed in GROUP 2, the PLT Group placed in GROUP 3 and the Diff Group placed in GROUP 4.

To Customize the Data Log Display for Standard Groups

1. From the main DATA LOG screen, press [CUSTOMIZE DATA LOG] to display the CUSTOMIZE DISPLAY FOR DATA LOG screen.
2. Press [STANDARD GROUPS] to display the CUSTOMIZE DISPLAY FOR DATA LOG screen and key labels for Standard Groups.

3. Use the Arrow keys on the keyboard to move the cursor to the desired group (1–4) location.

   NOTE: This number indicates the order in which the group of parameters will be displayed (Group 1 on the first screen, Group 2 on the second, etc.).

4. Press the soft key corresponding to the desired parameter group. This group is displayed in the position indicated by the cursor.
5. Repeat steps 3 and 4 until all desired groups have been selected.
6. If desired, press the Print Screen key on the keyboard to obtain a printout of the configuration.
7. Press [RETURN] to return to the DATA LOG screen.
8. The Data Log is displayed configured with the standard groups of parameters.

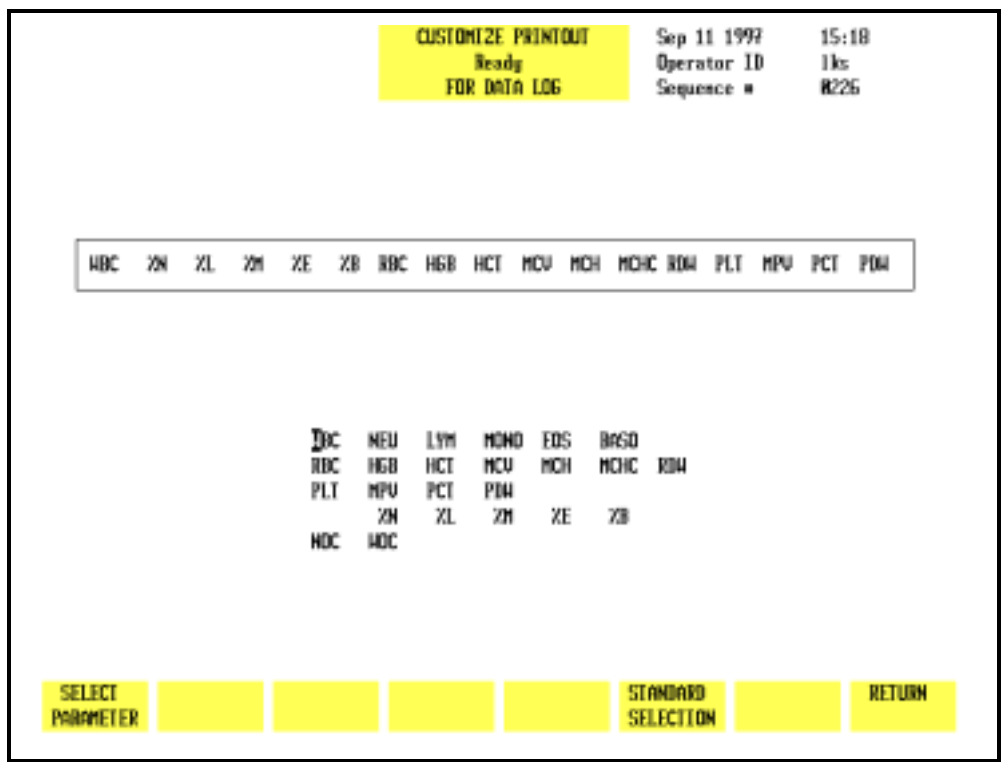

Figure 5.55: Customize Printout for Data Log Screen Showing Customized Print Group

Customizing the Printout

The CUSTOMIZE PRINTOUT FOR DATA LOG screen (see Figure 5.55) shows the group of parameters that will be printed on a Data Log printout. A list of the available parameters is displayed under the group. The parameters are selected from the list and placed in the desired position to customize the printout. In addition to the usual Hematologic parameters, the following parameter may also be printed in the Data Log:

NOC — Nuclear Optical Count

To Customize the Data Log Printout

1. From the main DATA LOG screen, press [CUSTOMIZE DATA LOG] followed by [CUSTOMIZE PRINTOUT].
2. Use the Arrow keys on the keyboard to move the cursor to the desired parameter in the list displayed under the printout group.
3. Press [SELECT PARAMETER]. The selected parameter is highlighted and the cursor moves to the first position in the group.

   NOTE: The key label changes to [PLACE PARAMETER] and a [CANCEL SELECTION] key is displayed.

4. If necessary, use the Arrow keys on the keyboard to move the cursor to the desired location and press [PLACE PARAMETER].

   NOTE: When the [PLACE PARAMETER] key is pressed, the selected parameter is displayed in the position indicated by the cursor and the cursor then advances to the next parameter in the list displayed under the printout group.

5. Repeat steps 2–4 until all selections have been made.
6. If desired, press the Print Screen key on the keyboard to obtain a printout of the configuration.
7. Press [RETURN] twice to return to the DATA LOG screen.

Standard Selection

The [STANDARD SELECTION] key is used to automatically arrange the parameters in a predetermined print group.

Data Review from the Data Log

Use the Page Up/Down keys and arrow keys to view Data Log records and parameters within a record as described earlier in ***Scrolling Through the Data Log.***

Displaying A Record

A copy of the RUN screen may be displayed for all 10,000 records in the CELL-DYN 3200 Data Log. A record is displayed by positioning the cursor at the record in the Data Log listing and pressing [DISPLAY SPECIMEN]. The record is displayed on the DISPLAY SPECIMEN screen. (See Figure 5.56.)

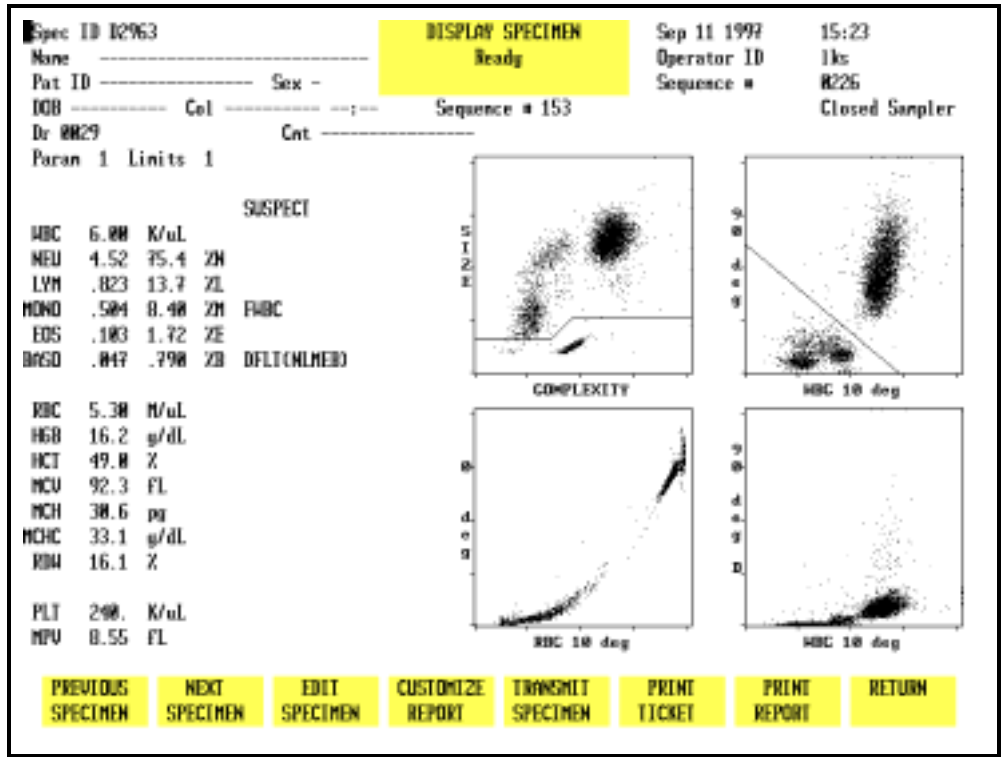

Figure 5.56: Display Specimen Screen

To Display a Record

1. From the MAIN MENU screen, press [DATA LOG].
2. Use the Arrow keys on the keyboard to move the cursor to the desired record (use the Page Up and Page Down keys to scroll between pages).
3. Press [DISPLAY SPECIMEN] to display the RUN screen for the selected record.

4. If desired, press [PRINT REPORT] to obtain a printout.

   NOTE: If a color printing has been selected, the key label changes to [COLOR PRINT] and a color printout is generated when the key is pressed.

5. The [PREVIOUS SPECIMEN] or [NEXT SPECIMEN] key may now be used to display records listed in the Data Log which are adjacent to the one currently displayed.

To Find a Record

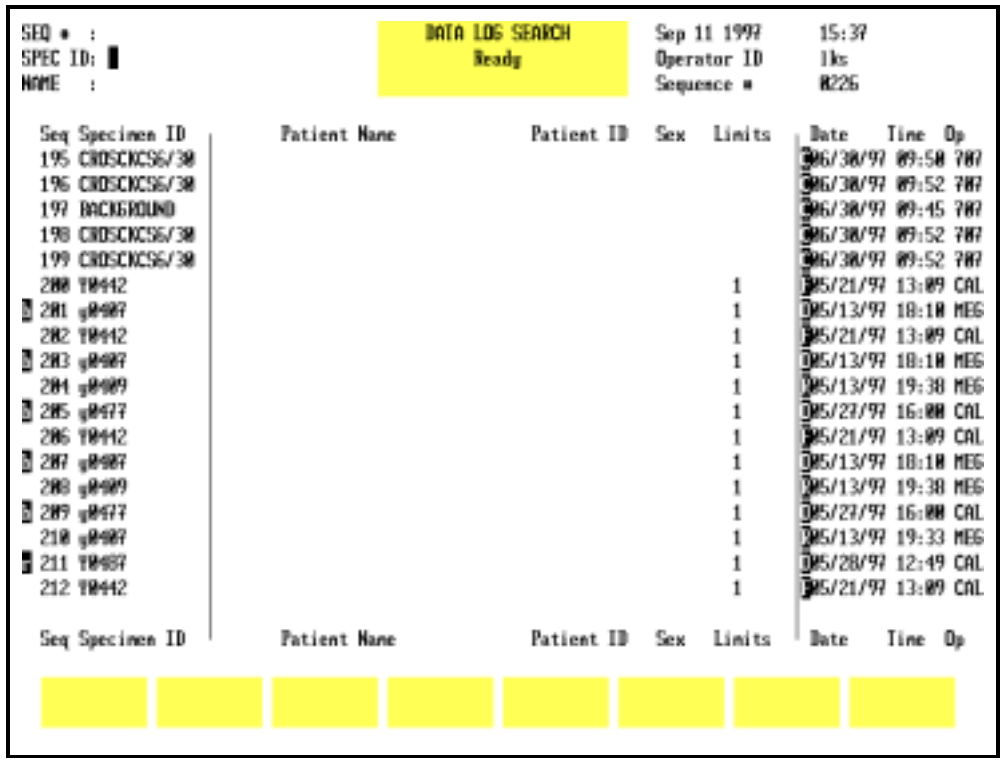

Figure 5.57: Find Specimen Screen

1. From the MAIN MENU screen, press [DATA LOG].
2. If the desired record is not displayed on the screen, press [FIND SPECIMEN] to display the DATA LOG SEARCH screen.
3. Use the Arrow keys on the keyboard to move the cursor to the desired identifier: Sequence Number, Specimen ID Number or Name. Refer to Figure 5.57.
4. Type the appropriate information and press the Enter key on the keyboard to start the search.

   NOTE: If necessary, you may press the Escape (ESC) key or the Enter key on the keyboard to exit from the search function and return to the DATA LOG screen.

5. If the requested record is available, the screen displays the Data Log page containing it. (The cursor is located at the sequence number of the record.)

To Edit a Record

The Patient Demographics and the Parameter and Patient Limits Sets may be edited for each record. (See Figure 5.58.)

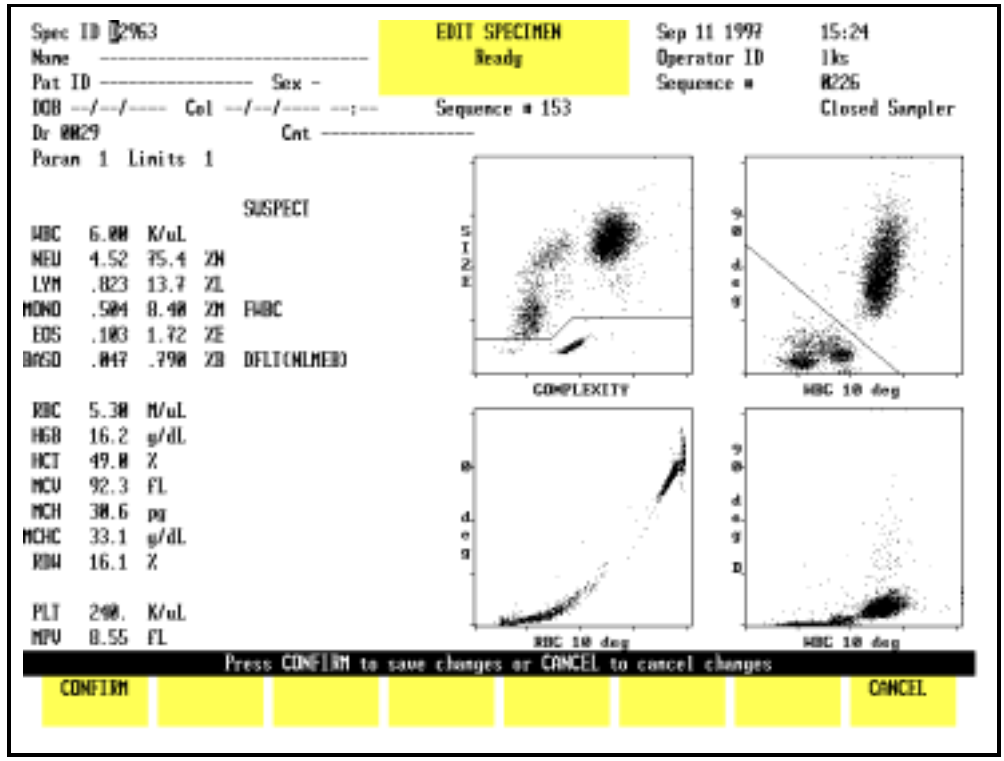

Figure 5.58: Edit Specimen Screen

To Edit a Specimen

1. From the MAIN MENU screen, press [DATA LOG].
2. Locate the desired record and press [DISPLAY SPECIMEN] followed by [EDIT SPECIMEN].
3. Use the Arrow keys on the keyboard to move the cursor to the line that will be edited and type the appropriate information. Press the Enter key on the keyboard to save the entry.
4. Press [CONFIRM] to display the RUN screen for the edited result.
5. If desired, press [PRINT REPORT] or [COLOR PRINT] to obtain a printout.

NOTES

References

1. NCCLS Standard H3-A3, *Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture*—Third Edition; Approved Standard (1991).
2. NCCLS Standard H4-A3, *Procedure for the Collection of Diagnostic Blood Specimens by Skin Puncture*—Third Edition; Approved Standard (1991).
3. ICSH, *Protocol for Evaluation of Automated Blood Cell Counters,* Clinical and Laboratory Hematology 1988, 10:203, 212.

NOTES

Overview

The CELL-DYN® 3200 System is calibrated at the factory just prior to shipment. An Abbott Field Service Representative will assist the operator in confirming the calibration during instrument installation. Calibration may be performed using commercial calibrator or fresh whole blood samples. Only the directly measured parameters — WOC, NOC, RBC, HGB, MCV, PLT, and MPV — may be calibrated.

Calibration should be confirmed on a regular basis according to the laboratory's schedule for maintaining good laboratory practice.

On-board quality control programs are designed to provide continual monitoring and verification of instrument calibration. The laboratory should make the decision to recalibrate based on the performance of the CELL-DYN 3200 in these quality control programs.

Instrument calibration is discussed in the following order:

- General Information
- Pre-Calibration Procedures
- Calibration Menu and Soft Keys
- Auto-Cal Method
- Enter Factor Method
- Calibration Worksheets

NOTES

General Information

The CELL-DYN 3200 System has two modes of operation:

- Open Mode
- Closed Mode

Both the Open and Closed Modes are calibrated individually. It is recommended that the primary mode be calibrated first.

> **NOTE:** The procedure for calibrating Closed Mode differs slightly between the SL and CS models.

Three methods of calibration are available on the CELL-DYN 3200 System: Auto-Calibration, Enter Factor, and Latex.

1. The Auto-Calibration method is designed to quickly and easily calibrate the system, using commercial control material or fresh whole blood.
   a. On the CS model, Auto-Calibration can be used in both the Open and Closed Modes.
   b. On the SL model, Auto-Calibration can be used only in the Open Mode. The Enter Factor Method must be used to calibrate the Closed Mode.
2. The Enter Factor method is a manual procedure for calibrating the instrument. With this method, Fresh Whole Blood is normally used but Calibrator may also be used.
3. Latex material may also be used to calibrate the instrument but this procedure should only be performed by Abbott service personnel.

When to Calibrate

Scheduled calibration of the CELL-DYN 3200 should conform to the guidelines established by regulatory agencies.

Calibration should be confirmed on a regular basis according to the requirements governing quality control in your laboratory. In keeping with good laboratory practices, this should include daily confirmation on each shift and following a reagent lot number change.

Unscheduled calibration is indicated following service adjustments performed by Abbott Field Service Representatives, such as major component changes.

Unscheduled calibration is also necessary when indicated by the results of the Quality Control program. Quality Control includes (1) statistical computations and Westgard Rules for commercial or patient controls, and (2) monitoring of patient samples for WBC parameters with moving averages and RBC parameters using Bull's Moving Average Program (X-B).

The laboratory should make the decision to recalibrate based on the results of the instrument's performance, as indicated by these quality control programs. However, calibration should be considered as the very last step in a troubleshooting sequence. Performing unnecessary calibrations may mask an underlying problem with the instrument's performance.

Calibration is also recommended following the replacement of any major instrument component, such as the Shear Valve, that could affect the accuracy of the instrument. Calibration should also be confirmed by running the same samples used to calibrate the instrument to test the accuracy of the reported results. The procedures for confirming calibration are described in subsections ***Auto-Cal Method*** and ***Enter Factor Method***.

Calibration Materials

WARNING: Potential Biohazard. Consider all specimens and reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Three calibration materials can be used to calibrate the CELL-DYN 3200:

- **CELL-DYN Calibrator** (L/N: 99120-01)

  CELL-DYN **Calibrator** may be used to calibrate the Open and Closed Modes. The same Calibrator used to calibrate should also be used to confirm calibration.

- **Fresh Whole Blood**

  F**resh whole blood** may be used to calibrate the Open and Closed Modes. The Auto-Cal method uses one sample to calibrate compared to the Enter Factor method which uses five samples. Reference values are obtained by running the sample(s) on a reference instrument, using acceptable reference methodology, and calculating the mean reference value for each parameter. The same sample(s) used to calibrate should also be used to confirm calibration.

- **Latex**

  Latex is used to calibrate the Optical Bench. This calibration is verified by an Abbott representative during installation of the instrument.

Instrument Logbook

Create a logbook for the instrument. This logbook should contain all necessary calibration documentation and other information that is pertinent to your instrument. Suggested sections that you may wish to include in the logbook are:

- Installation documentation
- Laboratory's operating procedure
- Quality control
- Calibration
- Maintenance
- Reagent lot number changes
- Troubleshooting
- Problem resolution
- Service calls
- Software upgrades

This logbook should be stored near the instrument and be accessible to all operators and Abbott Service Personnel.

NOTES

Pre-Calibration Procedures

Overview

The **Pre-Calibration Procedures** in this subsection verify proper instrument performance to ensure a successful calibration. These steps should be completed just prior to beginning the calibration procedure itself. If problems are detected during these checks, DO NOT ATTEMPT TO CALIBRATE THE INSTRUMENT. If necessary, CALL THE CUSTOMER SUPPORT CENTER FOR ASSISTANCE. After the problems have been resolved, repeat the Pre-Calibration Procedures to verify proper performance.

> **NOTE:** Instrument calibration, including the pre-calibration procedures, should be completed without interruption.

Calibration Guidelines

1. Always perform the Daily, Weekly and Monthly scheduled maintenance as directed in **Section 9:** ***Service and Maintenance*** before calibrating the instrument. Instrument cleanliness is essential for accurate calibration. Therefore, each laboratory should perform any additional maintenance according to its requirements.
2. Use only recommended CELL-DYN reagents.
3. Verify the precision for the Open and Closed Modes prior to calibration as directed in the Pre-Calibration Procedures Checklist.

   > **NOTE:** If necessary, refer to the directions for customizing the display and printout of a QC file given in **Section 5*: Operating Instructions,* Subsection:** ***Set-Up Instructions***.

4. Select and process all whole blood samples according to the requirements given in ***Fresh Whole Blood Requirements*** later in this section.
5. Try to obtain a sufficient amount of sample (calibrator or fresh whole blood) so that the same sample can be used for precision check, calibration in Open and Closed Modes, and confirmation in Open and Closed Modes. If sufficient sample is not available, use a different sample for precision check.

6. Be certain that all samples used are brought to room temperature and mixed well before aspiration.
7. Be certain that the technologist performing the calibration has read and understands the information contained in the package insert for the calibrator.
8. Be certain that the technologist performing the calibration has read and understands the calibration procedure(s) and the appropriate overviews described in this manual.
9. Confirm that reagent containers are at least one third full. Replace them as necessary.
10. Confirm that the waste container is no more than half full. If necessary, empty it as described in **Section 8: *Hazards*, Subsection: *Handling and Disposing of Biohazardous Materials*.**
11. Confirm that background counts are within limits. If the system has been idle for fifteen minutes or more, a Background count should be run immediately prior to running any calibration specimens.
12. Confirm that the Operator ID number is entered.

Calibration Materials

Calibrator Requirements

- For commercial calibrators, follow the directions given in the package insert. Be certain to carefully read and follow directions given for warming and mixing.
- Auto-Cal Method: The calibrator should be cycled for a minimum of 6 and a maximum of 10 consecutive runs when calibrating in either Open or Closed Mode.
- Enter Factor Method: The calibrator should be cycled for a minimum of 6 consecutive runs. Additional samples and/or repetitions of the specimens may be used to achieve calibration accuracy beyond NCCLS recommendations.
- The Calibrator sample should contain a minimum of 5.0 mL. If necessary, aliquot a sufficient amount of sample into a single tube for Closed Mode processing.

Fresh Whole Blood Requirements

The International Committee for Standardization in Hematology (ICSH) defines a fresh blood sample as one available for processing less than four hours following venous sampling.

Normal Sample

- Blood samples should be from the general patient population, with values for all parameters which are within the laboratory's normal range.
- All cellular morphology must be normal.
- No known interfering substances should be present (for example, lipemia, icterus, medications).
- All samples must be properly collected in the EDTA anticoagulant used by the laboratory.
- Each tube should contain at least 90% of the nominal collection volume of blood.
- Samples should be at room temperature and mixed properly.

Sample Age

- All blood samples should be less than four hours old when calibration begins.[1] These samples must be less than eight hours old by the time calibration is completed.
- No more than two hours should elapse between the CELL-DYN 3200 run and the assay by reference methodology or reference instrument. If samples are run on the CELL-DYN 3200 first, assay by reference methodology should be completed within one hour. (Certain reference methodologies are sensitive to RBC swelling caused by *in vitro* deoxygenation.)

Sample Amount

The whole blood sample volume should be at least 12 mL to accomplish the following:

- Obtain reference values on a reference instrument prior to calibration.
- Calibrate both the Open and Closed Modes.
- Confirm calibration of both modes.

NOTE: Because only one fresh whole blood sample is used in Auto-Cal, it is important that a representative sample be selected to calibrate the instrument. A sample containing abnormalities may adversely affect calibration.

Number of Cycles

- Samples should be assayed first on a reference instrument or by reference methodology and then on the CELL-DYN 3200.
- Auto-Cal Method: A single fresh whole blood sample should be cycled for 10 consecutive runs when calibrating in either Open or Closed Mode.
- Enter Factor Method: Five fresh whole blood samples should be cycled twice each for a total of at least ten runs when calibrating in either Open or Closed Mode. Additional samples and/or repetitions of the specimens may be used to achieve calibration accuracy beyond NCCLS recommendations.

Pre-Calibration Check List

Follow the procedures outlined in the Pre-Calibration Check List to ensure the instrument is ready for calibration. Use the Problem List to note any problems encountered. Make copies of both lists as needed.

NOTE: Always complete the Pre-Calibration procedures before beginning any calibration.

CELL-DYN 3200
PRE-CALIBRATION PROCEDURES CHECK LIST

Instrument: **Date:**

Operator:

1._____Perform all required maintenance.

2._____Verify that all reagent containers are at least 1/3 full and the waste container is less than 1/2 full.

3._____Verify that the reagents have not reached the expiration date.

Diluent/Sheath:Lot #_____ Exp. date _____

HGB Lyse: Lot #_____ Exp. date _____

WBC Lyse: Lot #_____ Exp. date _____

4._____If applicable, verify that the calibrator has not reached the expiration date.

Lot #_____ Exp. date _____

5._____After the maintenance has been completed, verify that the Background counts are within the acceptable limits. Record the background counts below or attach a printout to this document.

WOC $\leq$ 0.10 _____

NOC $\leq$ 0.10 _____

RBC $\leq$ 0.02 _____

HGB $\leq$ 0.10 _____

PLT $\leq$ 5.0 _____

6._____Verify the Open Mode precision by analyzing a fresh, normal whole blood sample 10 times in succession. Select an empty QC file in the SPECIMEN TYPE menu. Make sure Open Mode is selected. Run the sample 10 times. When the runs have been completed, write the CVs displayed on the screen in the appropriate spaces below or attach a file printout to this document.

PARAMETER	CV% LIMIT	CV%
WOC	≤ 2.7%	_____
NOC	≤ 2.7%	_____
RBC	≤ 1.5%	_____
HGB	≤ 1.0%	_____
MCV	≤ 1.0%	_____
PLT	≤ 4.0%	_____

7._____ If the CV for all parameters fall within the limits, go to step *8* to verify Closed Mode precision. If a parameter's CV exceeds the limit, run the sample again. If the over-limit condition persists, call the Customer Support Center for assistance.

8._____ Verify the Closed Mode precision as follows:

a. For the CS model: Use the same sample as in the Open Mode. Select an empty QC file in the SPECIMEN TYPE menu. Make sure Closed Mode is selected. Run the sample 10 times.

b. For the SL model: Use the same sample as in the Open Mode. Aliquot the blood in equal volumes into 10 5-mL tubes (each tube should contain a minimum of 1 mL of sample) containing no anticoagulant. Select an empty QC file in the SPECIMEN TYPE menu. Make sure Closed Mode is selected. Place the tubes in a rack, place the rack in the "loading" position, and press the [START LOADER] key.

c. When all the samples have been processed on either the CS or SL model, record the CVs below or attach a file printout to this document.

PARAMETER	CV% LIMIT	CV%
WOC	≤ 2.5%	_____
NOC	≤ 2.5%	_____
RBC	≤ 1.5%	_____
HGB	≤ 1.0%	_____
MCV	≤ 1.0%	_____
PLT	≤ 4.0%	_____

9._____ If any problems are detected during the procedures outlined above, document them on the form on the following page. Make copies of this form as necessary.

Problems Detected

NOTES

Calibration Menu

Overview

The CALIBRATION menu is accessed from the MAIN MENU by pressing the [CALIBRATION] key. The CALIBRATION menu displays the current calibration factors for the mode indicated, the date and time the factors were entered, and the operator ID. Figure 6.1 displays the calibration factors for the Open Mode, and Figure 6.2 displays the calibration factors for the Closed Mode. Note that Open Sampler is displayed in both figures, indicating Open Mode. The mode is independent of the calibration factors being displayed.

The following soft key labels are displayed:

ENTER FACTOR	
CALIBRATN LOG	
AUTO-CALIBRATE	
OPEN SAMPLER/ CLOSED SAMPLER	(Key label alternates between selections)
PRINT	
MAIN	

The function of each key is discussed briefly in this section.

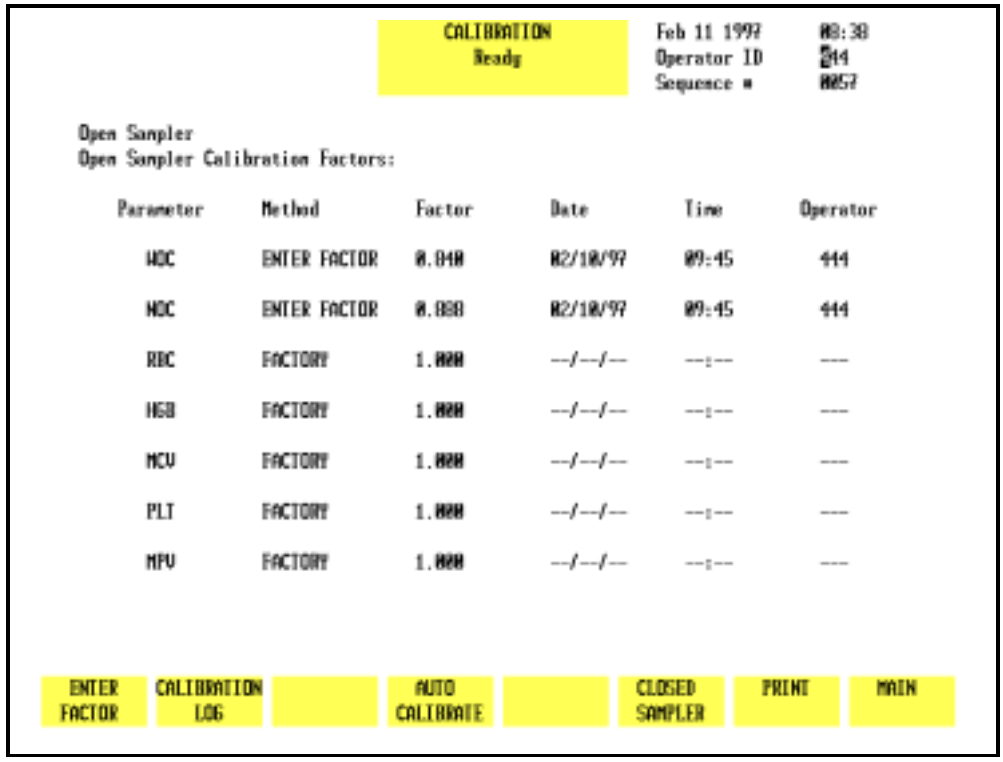

Figure 6.1: Calibration Menu Screen Displaying Open Sampler Calibration Factors

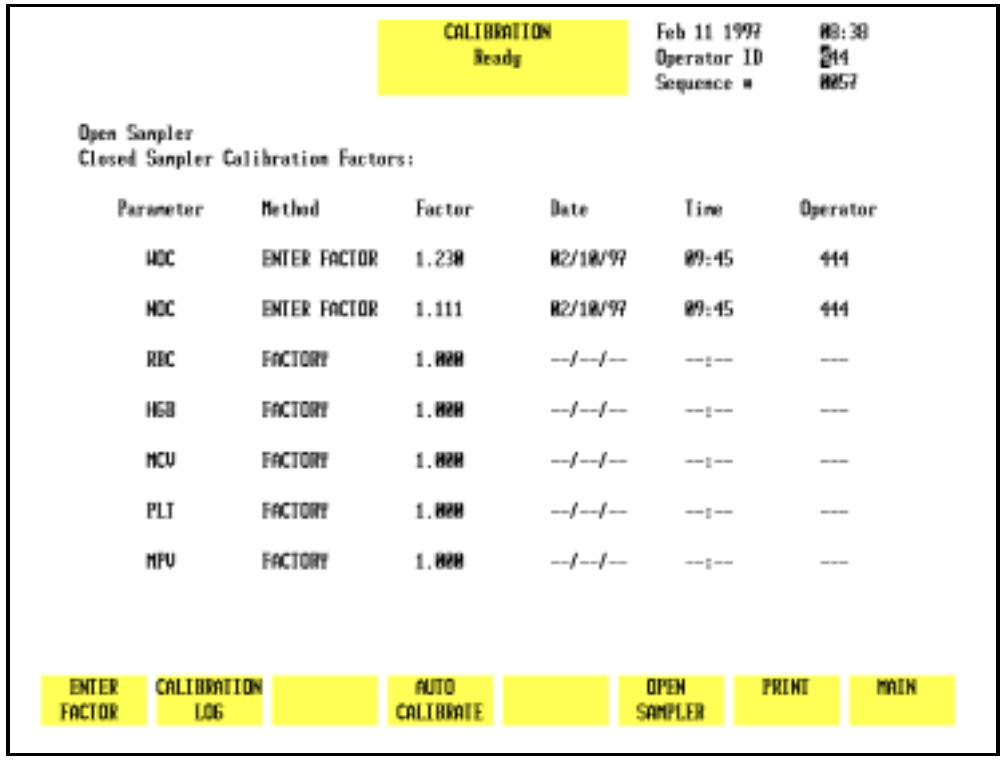

Figure 6.2: Calibration Menu Screen Displaying Closed Sampler Calibration Factors

Calibration Menu Soft Keys

Enter Factor

The [ENTER FACTOR] key is used to display the ENTER CALIBRATION FACTOR screen which displays the current whole blood factors for the displayed mode (refer to Figure 6.3). The soft keys available in this screen are:

RESTORE FACTORS
RESET ALL TO 1.000
RETURN

Restore Factors

The [RESTORE FACTORS] key is used to restore the previous calibration factors. This key is active only immediately after factors have been changed.

Reset all to 1.000

The [RESET ALL TO 1.000] key is used to reset all of the calibration factors to 1.000.

Return

The [RETURN] key is used to return to the main CALIBRATION menu.

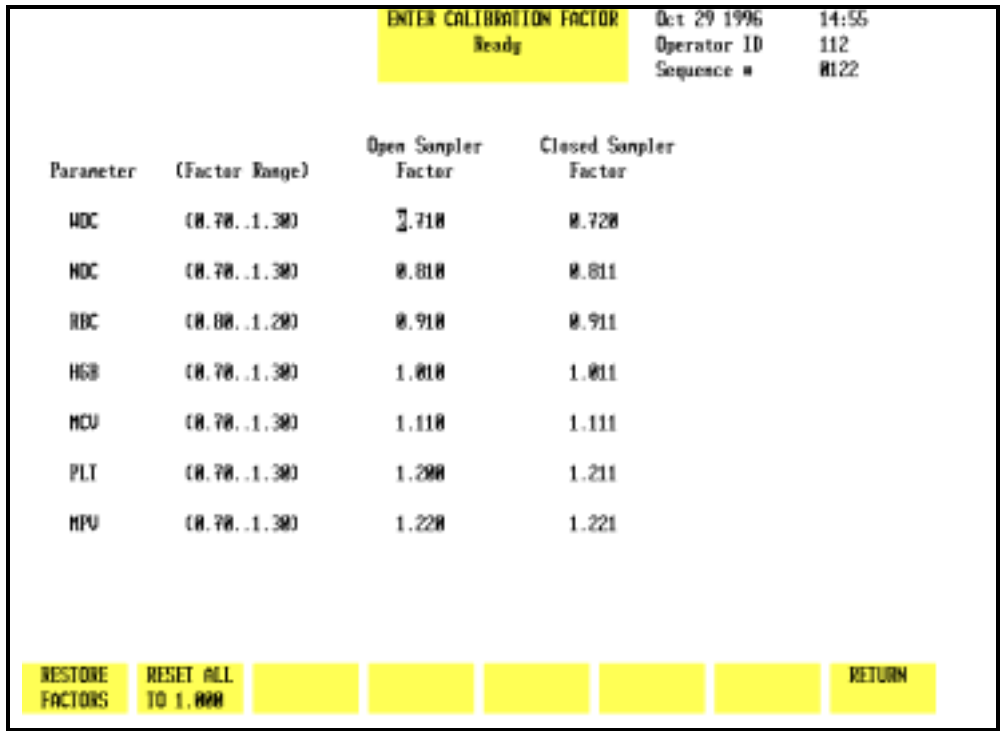

Figure 6.3: Enter Calibration Factor Screen

Calibration Log

The [CALIBRATION LOG] key is used to display the CALIBRATION LOG screen for the Open or Closed Mode (refer to Figure 6.4). The soft keys available in this screen are:

OPEN SAMPLER/CLOSED SAMPLER
PRINT LOG
RETURN

The CALIBRATION LOG holds 10 entries. The last 5 entries are displayed on the screen. To display any previous entries, press the Page Up key on the keyboard.

> **NOTE:** When the log is full, subsequent entries cause the oldest entry to be deleted and the remaining entries to move up one line, so that the current factors are added to the bottom of the list. Therefore, the log should be printed periodically for purposes of documentation.

The log displays the DATE, TIME, OPERATOR ID, CALIBRATION FACTORS and a line for COMMENTS.

> **NOTE:** The letters in parentheses after each factor indicate the method of factor derivation: F = Factory, A = Auto-Cal, E = Enter Factor (manual factor entry).

Type any comments in the COMMENTS field. Press the Enter key on the keyboard to save the entry and advance the cursor.

> **NOTE:** Comments may be added to the Calibration Log only after a calibration factor is changed or reentered.

Open Sampler/Closed Sampler

The [OPEN SAMPLER/CLOSED SAMPLER] key is used to display the calibration factors for the displayed mode. This key toggles between the Open and Closed Sampler Calibration Factors.

Print Log

The [PRINT LOG] key is used to print the Calibration Log for the displayed mode.

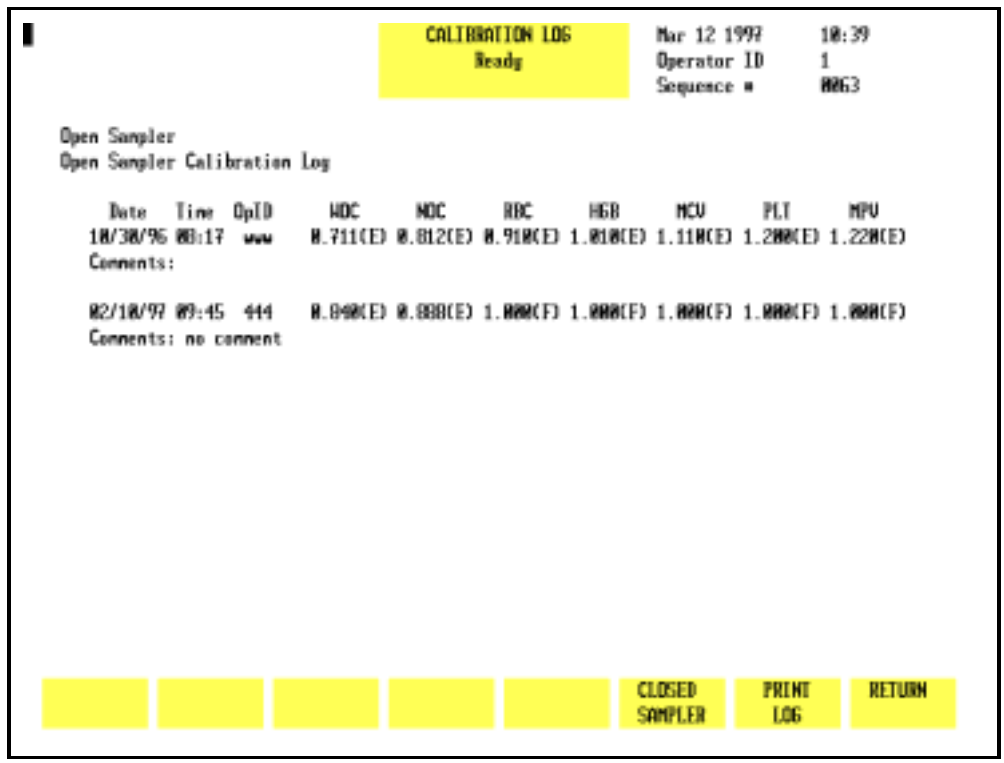

Figure 6.4: Calibration Log Screen

Return

The [RETURN] key is used to return to the main CALIBRATION menu.

Auto-Calibrate

The [AUTO-CALIBRATE] key is used to display the AUTO CALIBRATION screen (refer to Figure 6.5). The AUTO CALIBRATION screen changes during the calibration process as reference values are entered and as runs are completed. These changes are discussed in ***Auto-Cal Method*** later in this section.

When the [AUTO-CALIBRATE] key is pressed, the following soft key labels are displayed:

WHOLE BLOOD/ CALIBRATOR	(This key alternates between the selections)
PRINT	
RETURN	

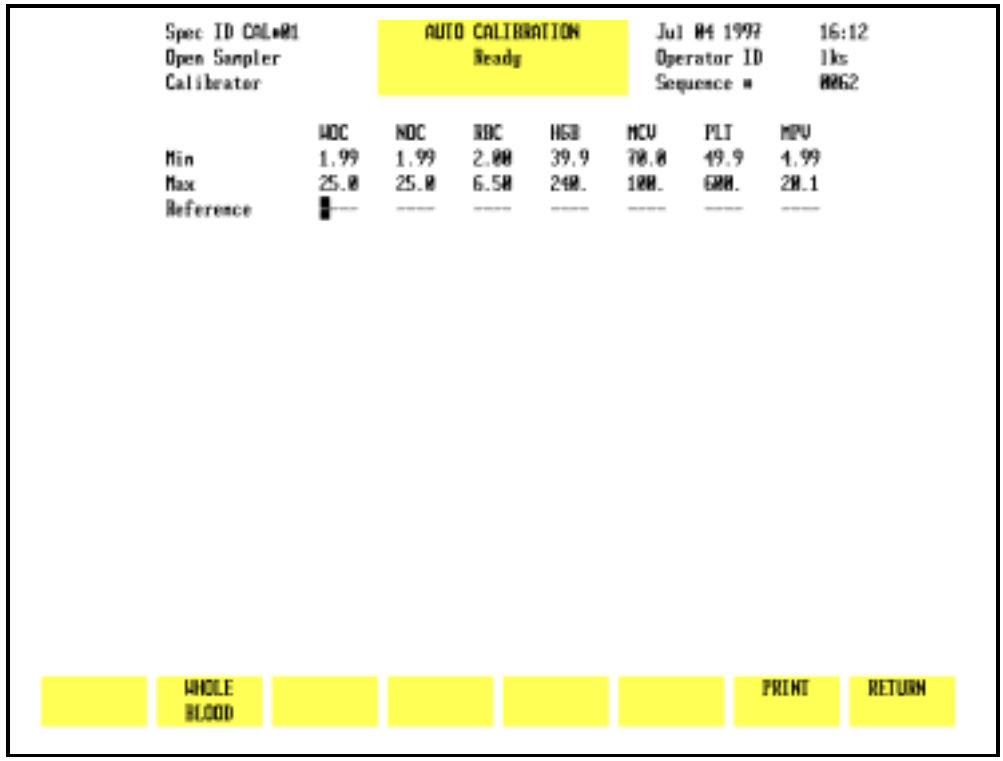

Figure 6.5: Auto Calibration Screen

The [WHOLE BLOOD] and [CALIBRATOR] keys alternate to display which type of calibration material is being used. This information is displayed in the upper left corner of the screen and stored with the updated calibration factors on the Calibration Log.

Print

The [PRINT] key is used to print the data displayed on the screen.

Auto-Cal Method

Overview

The Auto-Cal program provides an automated calibration method that prepares the CELL-DYN 3200 System for calibration, calculates new calibration factors, and calibrates the instrument.

> **NOTE:** Always complete the Pre-Calibration procedures before beginning any calibration.

Methodology

The instrument should be calibrated in both Open and Closed Modes using either the CELL-DYN Calibrator or normal, fresh whole blood.

> **NOTE:** Auto-Calibration is not available in the Closed Mode on the SL model. To calibrate Closed Mode, see ***Calibration Procedure — Closed Mode*** in subsection ***Enter Factor Method***.

The same reference values and the same samples should be used when calibrating both modes. Either mode may be calibrated first, but it is recommended to calibrate the primary mode first.

> **NOTE:** Calibrator is the preferred material for calibrating the CELL-DYN 3200 System.

When samples are run, Auto-Cal does the following:

1. Accepts up to ten consecutive sample runs for either calibrator or fresh whole blood samples.
2. Compares sample results against internal precision and reference checks, highlighting results that fail these checks.
3. Calculates the new calibration factors (Mean Factors) and Factor % Diff values.
4. Compares the Factor % Diff values to ranges in an internal table to determine which parameters require calibration.

NOTE: These ranges are shown in the Calibration Range Criteria worksheets (#3 for Open Mode and #6 for Closed Mode) in ***Manual Calibration Worksheets*** at the end of this section.

5. Highlights Factor % Diff values which require calibration or which are over-limit.

Determining Reference Values

The minimum and maximum values for each parameter, displayed above the reference value fields, apply to both calibrator material and fresh whole blood.

Calibrator

Obtain the reference values from the assay sheet that is packaged with the calibrator material.

Fresh Whole Blood

Follow the procedure below to determine the calibration reference values using fresh whole blood.

NOTE: No more than two hours should elapse between determining the Reference Mean Values and performing the calibration.

WARNING: Potential Biohazard. Consider all specimens potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

1. Go to a reference hematology instrument or use appropriate hematology methods with one sample of normal, fresh whole blood.
2. Run a minimum of 10 replicates from this sample on the reference instrument.

   NOTE: Because the same sample will be used to first obtain reference values on a reference instrument then to calibrate in the Open and Closed Modes, it is important to begin with a sufficient amount of sample.

3. If a mean value for each parameter based on at least 10 runs is not automatically calculated by the reference hematology instrument or hematology methods, use a calculator to determine the Reference Mean for each parameter. For example:

The cumulative Reference WBC Mean is 6.53 when the WBC results from each run are as follows:

- RUN 1 = 6.6, RUN 2 = 6.4, RUN 3 = 6.7
- RUN 4 = 6.5, RUN 5 = 6.6, RUN 6 = 6.4
- RUN 7 = 6.7, RUN 8 = 6.3, RUN 9 = 6.5
- RUN 10 = 6.6

The cumulative mean of 6.53 equals the sum of the values (65.3) divided by the 10 runs.

4. Save these values; they will be used to calibrate the CELL-DYN 3200 System.

Auto-Cal Menu

When the [AUTO-CALIBRATE] key is pressed in the main CALIBRATION menu, the AUTO-CALIBRATION menu is displayed (refer to Figure 6.6). Reference values are entered on this screen.

The Spec ID field in the upper left corner of the screen defaults to “CAL#01” to identify the sample as a “Calibration sample.” This field is user-definable and accepts up to 6 alphanumeric characters. As each calibration sample is run, the calibration program adds a “-” and the run number from “01” to “10.”

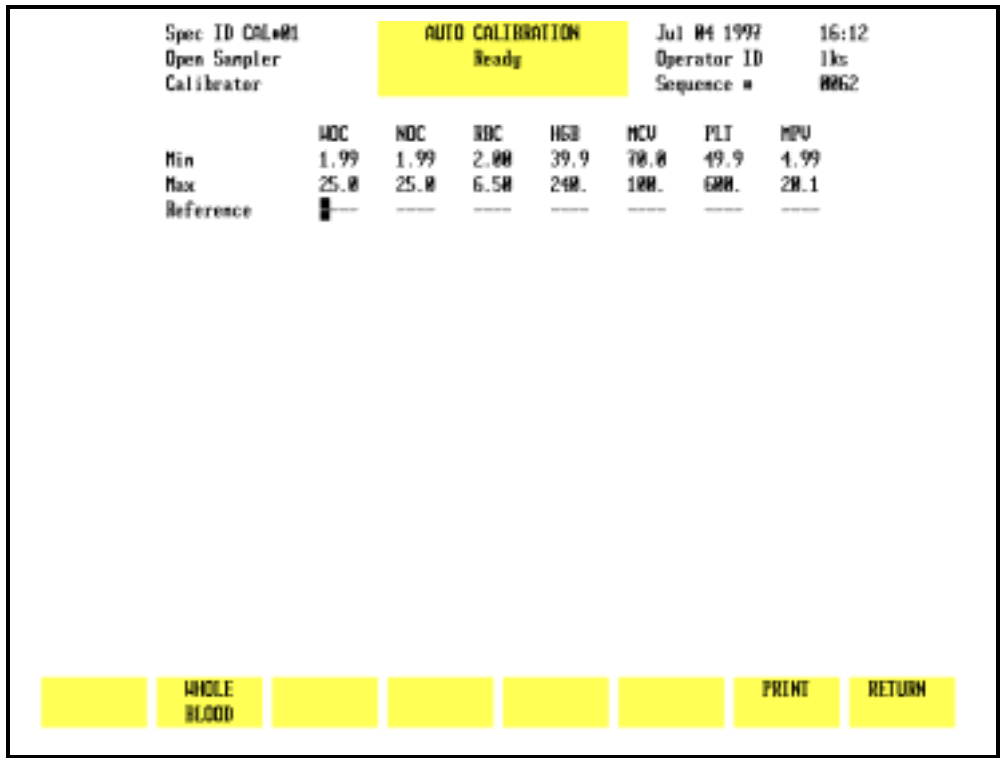

Figure 6.6: Auto Calibration Screen

Start Auto-Cal

Figure 6.6 shows the AUTO CALIBRATION screen before any reference values are entered. When the first reference value has been entered and the Enter key pressed, the [START AUTO CAL] and [QUIT] keys are displayed (refer to Figure 6.7).

After the [START AUTO CAL] key is pressed, the operator will not be able to toggle between Calibrator and Whole Blood nor make changes to the reference values, the Spec ID, or the Operator ID. The instrument is ready to begin processing samples.

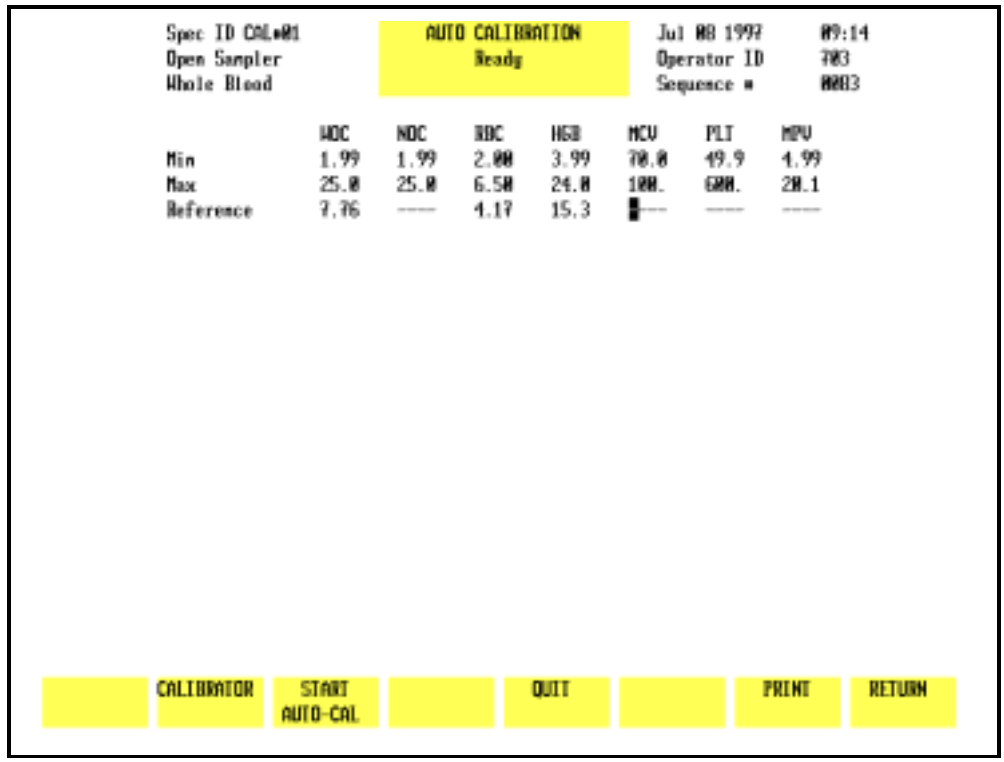

Figure 6.7: START AUTO CAL Key Displayed

A message is displayed on the bulletin line alerting the operator to start running samples.

As samples are processed, the results of each run are displayed as shown in Figure 6.8. The following soft keys are displayed:

ACCEPT	(Label appears after the 5th run)
DELETE A RUN	(Label appears after the 1st run)
QUIT	(Label appears after the 1st run)
PRINT	
RETURN	

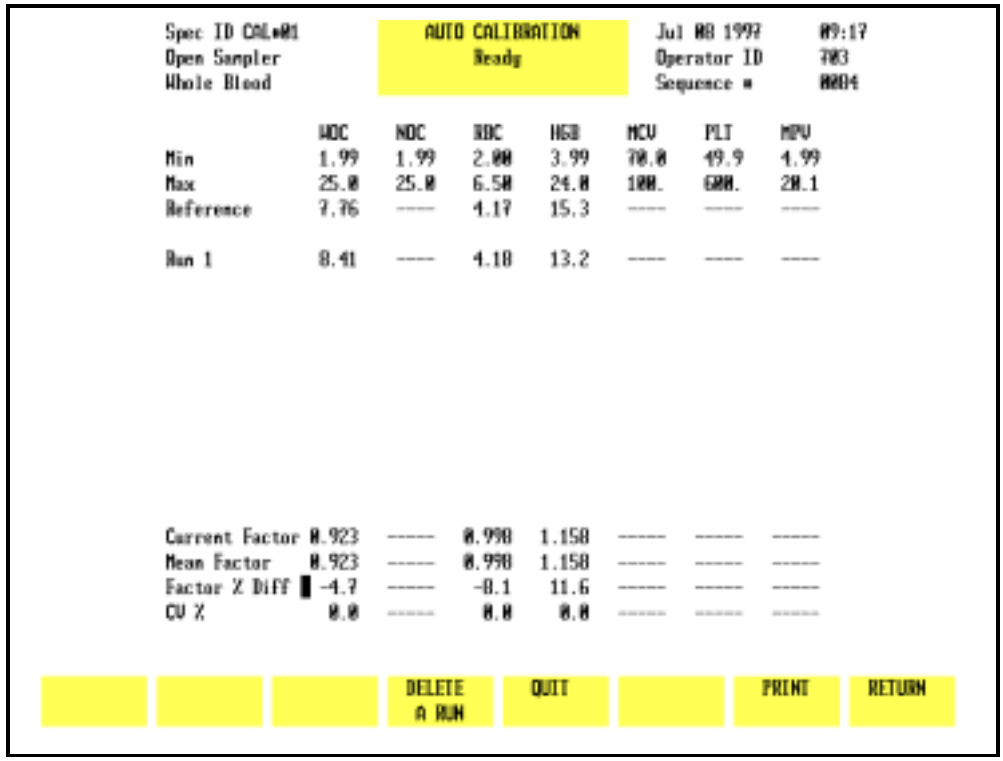

Figure 6.8: Results Display Screen

As the first sample is processed, the [START AUTO-CAL] key disappears and the [DELETE A RUN] key appears. The [ACCEPT] key appears after the results of the fifth run are displayed.

The following information is displayed in the lower portion of the screen:

- Current Factor
- Mean Factor (new Calibration Factor)
- Factor % Diff
- CV %

The Current Factor is calculated for each run. The Mean Factor is an average based on all runs. The Factor % Diff shows the difference between the Mean Factor and the existing Calibration Factor for that parameter. The CV (Coefficient of Variation expressed as a percent) measures the degree of variation between runs.

NOTE: The Mean Factor is the new Calibration Factor.

If a result is highlighted in Green on the Run line, it indicates that parameter has failed a reference or precision check. That result will not be included in the Mean Factor and Factor % Diff calculations for that parameter.

Consequently, the Mean Factor for some parameters may be based on fewer runs than other parameters and may even be based on fewer than 5 runs.

For example:

a. Five samples have been run and the [ACCEPT] is displayed after the 5th run

b. The Factor % Diff for WOC is green, indicating it needs to be calibrated

c. The WOC result for Run #4 is highlighted, indicating it failed a reference or precision check

d. The Mean Factor and Factor % Diff for WOC are based on only 4 runs because Run #4 failed its internal check

e. If the operator presses the [ACCEPT] and [CONFIRM ACCEPT] keys, a new calibrator factor will be entered for WOC but the new factor will be based on 4, not 5, runs.

Delete a Run

If a result for a parameter is outside a predetermined limit, that result is highlighted and not included in the Mean Factor and Factor % Diff calculations. The operator has the option of keeping or deleting the entire run. To delete a run, do the following:

1. Press [DELETE A RUN].
2. A prompt will appear at the bottom of the screen. Type in the number of the run to be deleted and press the Enter key.

   NOTE: Only one run can be deleted in each calibration session. The system does not allow a deleted run to be replaced with a new run. For example, if there are 10 runs and the operator deletes Run #5, then calibration will be based on 9 runs (remember, a highlighted result on a run will not be included in the Mean Factor or Factor % Diff for that parameter).

Quit

When [QUIT] is pressed, the [CONFIRM QUIT] and [CANCEL QUIT] keys are displayed. Pressing [CONFIRM QUIT] deletes all runs and reference values and returns the operator to the AUTO CALIBRATION screen shown in Figure 6.6. The screen is ready to receive new reference values. Pressing [CANCEL QUIT] returns the operator to the current screen.

Accept

This label appears after the results of the fifth run are displayed on the screen, allowing the operator to accept all the calibration factors shown in the lower portion of the screen (refer to Figure 6.9). When [ACCEPT] is pressed, two key labels [CONFIRM ACCEPT] and [CANCEL ACCEPT] are displayed (refer to Figure 6.10). Pressing [CONFIRM ACCEPT] saves the new calibration factors and displays the CALIBRATION LOG screen. Pressing [CANCEL ACCEPT] returns the operator to the Calibration results screen.

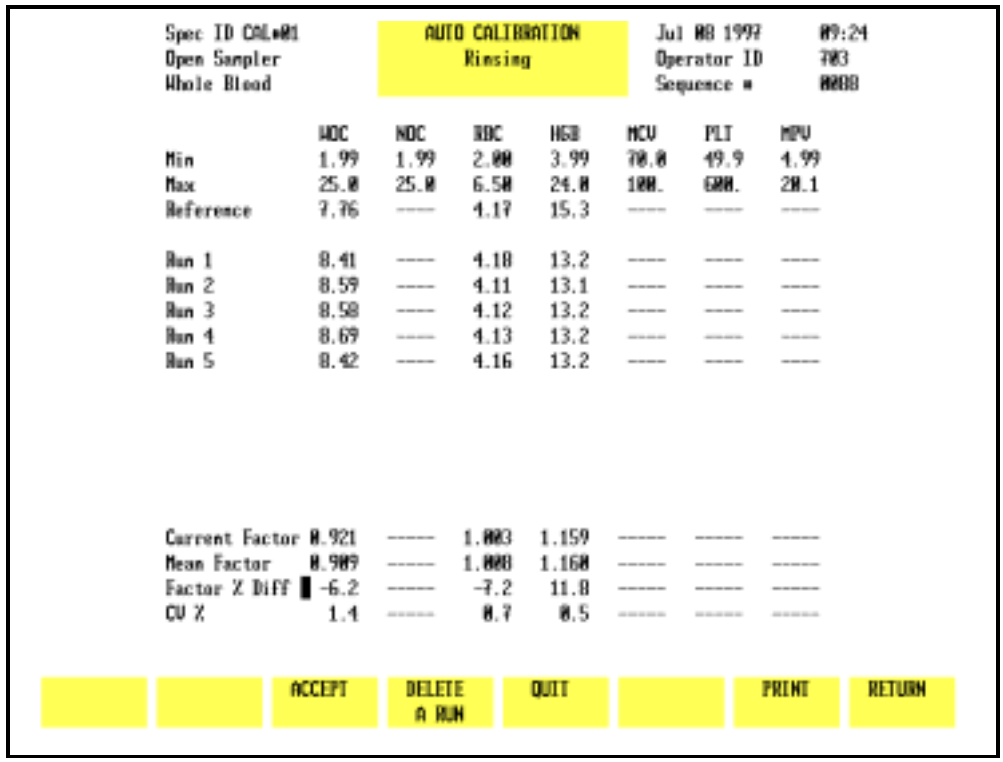

Figure 6.9: ACCEPT Key Displayed

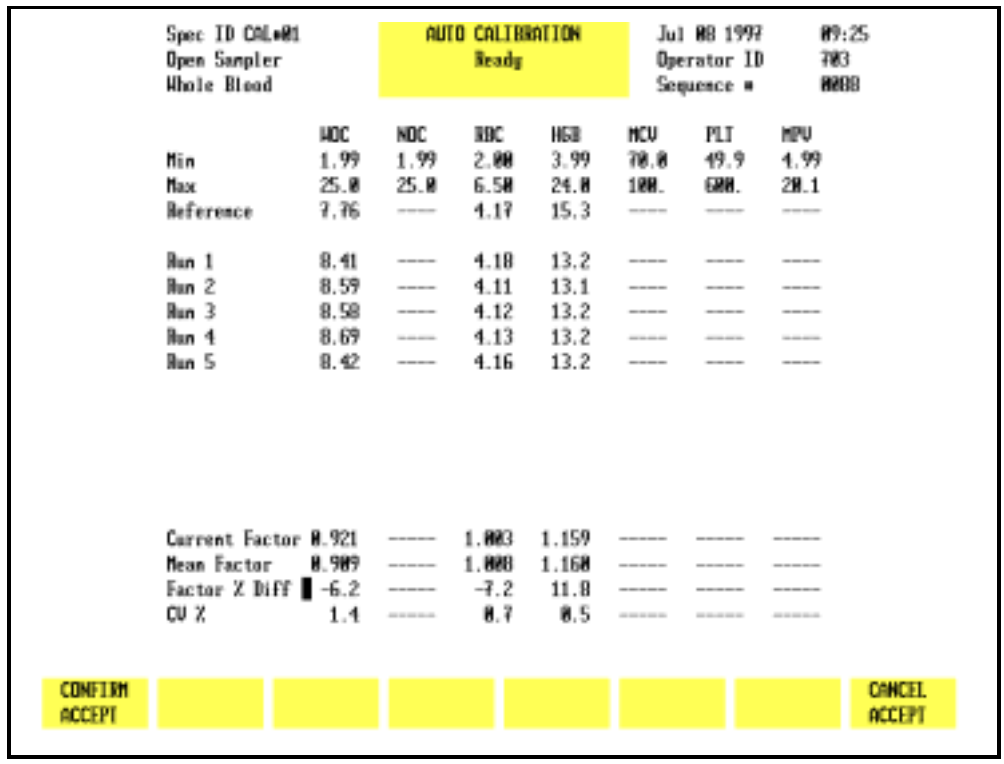

Figure 6.10: Confirm Acceptance of New Factors

Auto-Cal Procedure — Open Mode

Displaying the Auto-Cal Screen

1. If necessary, go to the RUN screen and press [CHANGE SAMPLER] to select the Open Mode.
2. In the MAIN MENU, press [CALIBRATION] to display the main CALIBRATION menu.
3. If necessary, press [OPEN SAMPLER] to display the Open Sampler Calibration Factors.

   NOTE: This key is used to display either the current Open Sampler Factors or Closed Sampler Factors. It does not change the mode.

4. Press [PRINT] to obtain a printout of the current Open Sampler Calibration Factors.
5. Press [AUTO-CALIBRATE] to display the AUTO-CALIBRATION screen.

Entering Reference Values

1. To enter reference values for each parameter to be calibrated:

a. If calibrator is used, enter the corresponding reference (assay) value from the sheet enclosed with the calibrator material.

b. If fresh whole blood is used, enter the mean value obtained from the procedure in subsection ***Fresh Whole Blood*** under ***Determining Reference Values*** above.

2. Press the Enter key after each entry to save the value and advance the cursor to the next parameter.

3. When all reference values have been entered, press [START AUTO-CAL] to ready the instrument for calibration. The message Ready to aspirate Cal sample is displayed.

Processing Samples

1. Specimen mixing:

   a. If calibrator material, prepare the calibrator for use according to the directions given in the package insert. Be certain to carefully read and follow directions given for warming and mixing.

   b. If fresh whole blood, mix the sample well by inverting the tube at least ten times. Do not shake the specimen.

2. Place the well-mixed specimen under the Open Mode Sample Probe and press the Touch Plate. The sample is analyzed and the results are displayed.

3. Repeat steps *1* and *2* above until the desired number of runs for either Calibrator or Fresh Whole Blood has been completed. Mix the sample well between each run.

Calibration Check

During the RUN cycle, if a parameter fails the internal reference/precision checks for calibration, the value for that parameter is backlit in green on the run line, dashes are displayed in the Current Factor field, and the Mean Factor is not updated.

Determining Which Parameters Need Calibration

1. After the [ACCEPT] key is displayed, you may continue processing samples until the desired number of runs has been completed.

2. Observe the Factor % Diff value for each parameter being calibrated:

   a. If the value is not highlighted (remains white), that parameter does not need calibration and the new calibration factor (Mean Factor) displayed on the screen will not replace the existing calibration factor when the [ACCEPT] key is pressed. White indicates the Factor % Diff is less than the value shown column 2 of Worksheet 3, Open Mode Calibration Range Criteria, provided in ***Manual Calibration Worksheets*** at the end of this section.

   b. If the value is highlighted in green, that parameter needs to be calibrated and the new calibration factor displayed on the screen will replace the existing calibration factor when the [ACCEPT] key is pressed. Green indicates the Factor % Diff is within the range specified in column 3 of Worksheet 3, Open Mode Calibration Range Criteria, provided in ***Manual Calibration Worksheets*** at the end of this section.

   c. If the value is highlighted in purple, it indicates the Factor % Diff is greater than the value shown in column 4 of Worksheet 3, Open Mode Calibration Range Criteria, provided in ***Manual Calibration Worksheets*** at the end of this section.

   d. If all Factor % Diff values are white, go to ***Calibration Not Required*** below. If at least one Factor % Diff is green, go to ***Some Parameters Need Calibration*** below. If at least one Factor % Diff is purple, go to subsection ***Over-Limit Parameters*** below.

Calibration Not Required

1. If all the Factor % Diff values are white, then calibration is not required in Open Mode. No update to the Calibration Log is required and no calibration confirmation is required.
2. If Closed Mode has not been calibrated, go to subsection ***Auto-Cal — Closed Mode***, otherwise return to the MAIN MENU by pressing [RETURN] followed by [MAIN].

Some Parameters Need Calibration

1. If at least one Factor % Diff value is green and if no Factor % Diff values are highlighted in purple, press [ACCEPT] followed by [CONFIRM ACCEPT] to calibrate the Open Mode. Go to subsection ***Completing Calibration Log*** below.

Over-Limit Parameters

1. If the Factor % Diff for a parameter is highlighted in purple, it indicates there may be an instrument problem. In this case, do the following:

   a. Determine if any component on the instrument was changed. This could affect calibration. Such components include the Shear Valve, Optical Flow Cell, Hemoglobin Flow Cell, or one of the syringes.

   b. If a component was changed, then treat the result as if it fell within the "calibration range" (even though it is greater than the upper limit). CALIBRATION IS REQUIRED for that parameter. Use the arrow keys to move the cursor to the Factor % Diff value. Press the Enter key to change the purple to green, indicating calibration is now required. Pressing [ACCEPT] followed by [CONFIRM ACCEPT] will calibrate this "over limit" parameter along with any other "calibration required" parameters. Go to subsection ***Completing Calibration Log*** below.

   NOTE: Because Factor % Diff values highlighted in purple can be changed to green using the Enter key, it is also possible for the operator to overwrite these values. However, the change only appears on the screen; the actual values calculated by the calibration program remain intact and the Mean Factors are not affected.

   c. If no component was changed and your calculations are correct, DO NOT CALIBRATE. CONFIRM THAT ALL PRE-CALIBRATION PROCEDURES WERE COMPLETED AND THEN CALL THE CUSTOMER SUPPORT CENTER FOR ASSISTANCE (at 1-800-CELL-DYN in the U.S.).

Completing Calibration Log

1. Complete the Calibration Log (adding comments) as required. If a printout of the log is desired, press [PRINT LOG].
2. Press [RETURN] to return to the main CALIBRATION screen.

3. Press [PRINT] to obtain a copy of the new Open Sampler Calibration Factors.

Confirming Open Mode Calibration

To confirm calibration in the Open Mode, follow the instructions below. Use the same Calibrator or Fresh Whole Blood Sample that was used to calibrate the instrument.

1. In the CALIBRATION menu, press [MAIN] to return to the MAIN MENU.
2. In the MAIN MENU, press [RUN] followed by [SPECIMEN TYPE] and [PATIENT].
3. Refer to Worksheet 7, Calibration Confirmation, in ***Manual Calibration Worksheets*** at the end of this section. Make copies of this worksheet as necessary.
4. Run the same Calibrator or Fresh Whole Blood sample 5 times. After each run, observe the values displayed on the RUN screen for those parameters that were calibrated and that now need confirmation. Write these values in the appropriate space on Worksheet 7.
5. Follow the instructions on this worksheet for calculating a mean and comparing the mean value against the reference value.
6. If the difference between the mean and reference (assay) value is within the stated tolerance limits, then calibration has been confirmed for that parameter. Go to step *8* below.
7. If a parameter mean is outside the tolerance limits, perform steps *4* and *5* again. If the mean is still outside the tolerance limits, call the Customer Support Center for assistance (at 1-800-CELL-DYN in the U.S.).
8. When Open Mode calibration has been confirmed, do one of the following:
   a. If Closed Mode has not yet been calibrated, go to subsection ***Auto-Cal Procedure — Closed Mode***.
   b. If Closed Mode calibration has been completed, press [MAIN] to return to the MAIN MENU.

Auto-Cal Procedure — Closed Mode

NOTE: Auto-Calibration is not available in the Closed Mode on the SL model. To calibrate Closed Mode, see ***Calibration Procedure — Closed Mode*** in subsection ***Enter Factor Method***.

Displaying the Auto-Cal Screen

1. If necessary, go to the RUN screen and press [CHANGE SAMPLER] to select the Closed Mode.
2. In the MAIN MENU, press [CALIBRATION] to display the main CALIBRATION menu.
3. If necessary, press [CLOSED SAMPLER] to display the Closed Sampler Calibration Factors.
4. Press [PRINT] to obtain a printout of the current Closed Sampler Calibration Factors.
5. Press [AUTO-CALIBRATE] to display the AUTO-CALIBRATION screen.

Entering Reference Values

1. To enter reference values for each parameter to be calibrated:
   a. If calibrator is used, enter the corresponding reference (assay) value from the sheet enclosed with the calibrator material.
   b. If fresh whole blood is used, enter the mean value obtained from the procedure in subsection ***Fresh Whole Blood*** under ***Determining Reference Values*** above.
2. Press the Enter key after each entry to save the value and advance the cursor to the next parameter.
3. When all reference values have been entered, press [START AUTO-CAL] to ready the instrument for calibration.

Processing Samples

1. Mix the sample well. If Calibrator, follow the directions on the package insert. If Fresh Whole Blood, invert the sample ten times. Do not shake the specimen. Place the well-mixed specimen in the Tube Retainer, close the door, and press the Touch Plate. The instrument performs RUN 1 and displays the values in the RUN 1 row.

2. Repeat step 1 above until the desired number of runs for either Calibrator or Fresh Whole Blood has been completed.

Calibration Check

During the RUN cycle, if a parameter fails the internal reference/precision checks for calibration, the value for that parameter is backlit in green on the run line, dashes are displayed in the Current Factor field, and the Mean Factor is not updated.

Determining Which Parameters Need Calibration

1. After the [ACCEPT] key is displayed, you may continue processing samples until the desired number of runs has been completed.
2. Observe the Factor % Diff value for each parameter being calibrated:
   a. If the value is not highlighted (remains white), that parameter does not need calibration and the new calibration factor (Mean Factor) displayed on the screen will not replace the existing calibration factor when the [ACCEPT] key is pressed. White indicates the Factor % Diff is less than the value shown in column 2 of Worksheet 6, Closed Mode Calibration Range Criteria, provided in ***Manual Calibration Worksheets*** at the end of this section.
   b. If the value is highlighted in green, that parameter needs to be calibrated and the new calibration factor displayed on the screen will replace the existing calibration factor when the [ACCEPT] key is pressed. Green indicates the Factor % Diff is within the range specified in column 3 of Worksheet 6, Closed Mode Calibration Range Criteria, provided in ***Manual Calibration Worksheets*** at the end of this section.
   c. If the value is highlighted in purple, it indicates the Factor % Diff is greater than the value shown in column 4 of Worksheet 6, Closed Mode Calibration Range Criteria, provided in ***Manual Calibration Worksheets*** at the end of this section.
   d. If all Factor % Diff values are white, go to ***Calibration Not Required*** below. If at least one Factor % Diff is green, go to ***Some Parameters Need Calibration*** below. If at least one Factor % Diff is purple, go to subsection ***Over-Limit Parameters*** below.

Calibration Not Required

1. If all the Factor % Diff values are white, then calibration is not required in Closed Mode. No update to the Calibration Log is required and no calibration confirmation is required.
2. If Open Mode has not been calibrated, go to subsection ***Auto-Cal — Open Mode***, otherwise return to the MAIN MENU by pressing [RETURN] followed by [MAIN].

Some Parameters Need Calibration

1. If at least one Factor % Diff value is highlighted in green and if no Factor % Diff values are highlighted in purple, press [ACCEPT] followed by [CONFIRM ACCEPT] to calibrate the Closed Mode. Go to subsection ***Completing Calibration Log*** below.

Over-Limit Parameters

1. If the Factor % Diff for a parameter is highlighted in purple, it indicates there may be an instrument problem. In this case, do the following:
   a. Determine if any component on the instrument was changed. This could affect calibration. Such components include the Shear Valve, Optical Flow Cell, Hemoglobin Flow Cell, or one of the syringes.
   b. If a component was changed, then treat the result as if it fell within the "calibration range" (even though it is greater than the upper limit). CALIBRATION IS REQUIRED for that parameter. Use the arrow keys to move the cursor to the Factor % Diff value. Press the Enter key to change the purple to green, indicating calibration is now required. Press [ACCEPT] followed by [CONFIRM ACCEPT] to calibrate this "over limit" parameter along with any other "calibration required" parameters. Go to subsection ***Completing Calibration Log*** below.

   NOTE: Because Factor % Diff values highlighted in purple can be changed to green using the Enter key, it is also possible for the operator to overwrite these values. However, the change only appears on the screen; the actual values calculated by the calibration program remain intact and the Mean Factors are not affected.

c. If no component was changed and your calculations are correct, DO NOT CALIBRATE. CONFIRM THAT ALL PRE-CALIBRATION PROCEDURES WERE COMPLETED AND THEN CALL THE CUSTOMER SUPPORT CENTER FOR ASSISTANCE (at 1-800-CELL-DYN in the U.S.).

Completing Calibration Log

1. Complete the Calibration Log (adding comments) as required. If a printout of the log is desired, press [PRINT LOG].
2. Press [RETURN] to return to the main CALIBRATION screen.
3. Press [PRINT] to obtain a copy of the new Closed Sampler Calibration Factors.

Confirming Closed Mode Calibration

To confirm calibration in the Closed Mode, follow the instructions below. Use the same Calibrator or Fresh Whole Blood Sample that was used to calibrate the instrument.

1. In the CALIBRATION menu, press [MAIN] to return to the MAIN MENU.
2. In the MAIN MENU, press [RUN] followed by [SPECIMEN TYPE] and [PATIENT].
3. Refer to Worksheet 7, Calibration Confirmation, in ***Manual Calibration Worksheets*** at the end of this section. Make copies of this worksheet as necessary.
4. Run the same Calibrator or Fresh Whole Blood sample 5 times. Refer to ***Processing Samples*** above for instructions on running samples on the CS model compared to the SL model.
5. After each run, observe the values displayed on the RUN screen for those parameters that were calibrated and that now need confirmation. Write these values in the appropriate space on Worksheet 7.
6. Follow the instructions on this worksheet for calculating a mean and comparing the mean value against the reference value.
7. If the difference between the mean and reference (assay) value is within the stated tolerance limits, then calibration has been confirmed for that parameter. Go to step *9* below.

8. If a parameter mean is outside the tolerance limits, perform steps *4* and *5* again. If the mean is still outside the tolerance limits, call the Customer Support Center for assistance (at 1-800-CELL-DYN in the U.S.).
9. When Closed Mode calibration has been confirmed, press [MAIN] to return to the MAIN MENU.
10. You may also elect to Run Commercial Control as a means of confirming calibration.

Enter Factor Method

Overview

The Enter Factor Calibration Method is used to enter a predetermined factor to adjust calibration when a consistent bias exists between the CELL-DYN 3200 System and a comparison analyzer.

Either Calibrator or Fresh Whole Blood can be used for calibration.

Fresh Whole Blood: Because the same sample will be used to first obtain reference values on a reference instrument then to calibrate in the Open and Closed Modes, it is important to begin with a sufficient amount of sample (12 mL recommended).

A set of worksheets is provided in ***Manual Calibration Worksheets*** at the end of this section to assist in the calibration process.

> **NOTE:** Always complete the Pre-Calibration procedures before beginning any calibration.

Enter Calibration Factor Screen

When the Enter Factor key is pressed in the main CALIBRATION menu, the ENTER CALIBRATION FACTOR menu is displayed (refer to Figure 6.12). New calibration factors are manually entered on this screen.

The following soft key labels are displayed:

RESTORE FACTORS
RESET ALL TO 1.000
RETURN

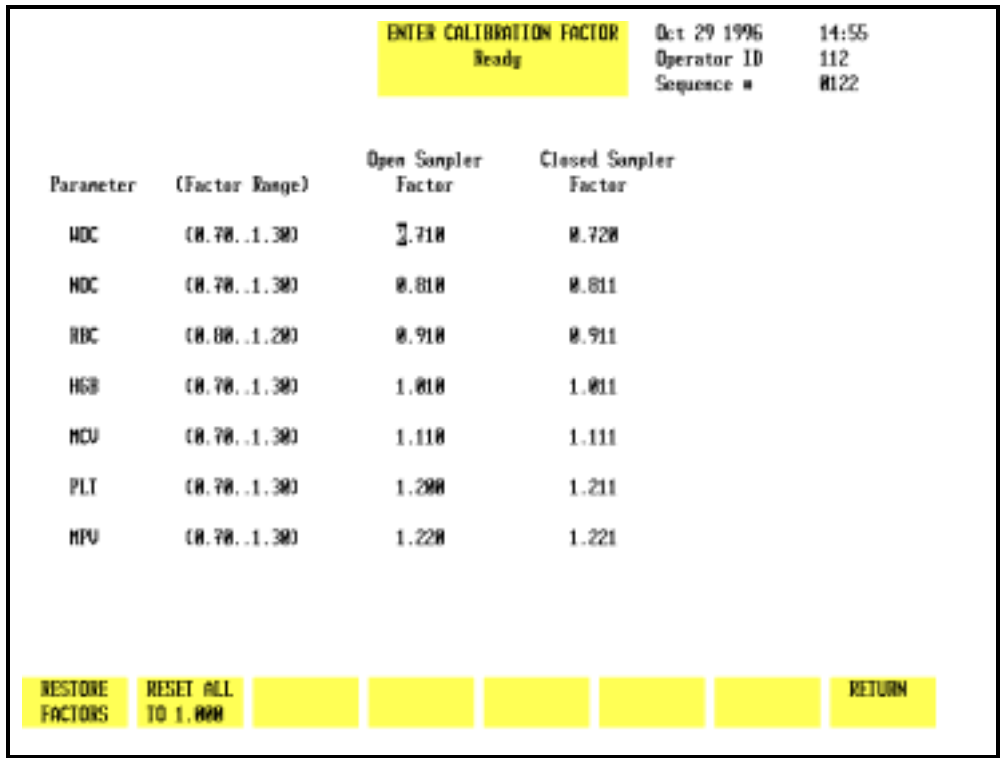

Figure 6.12: Enter Factor Screen

General Information

Calibrator

The requirements for using Calibrator in the Enter Factor method are similar to the Auto-Cal method. Refer to ***Calibrator Requirements*** under ***Calibration Materials*** earlier in this section.

Fresh Whole Blood

In addition to the requirements listed in ***Fresh Whole Blood Requirements*** under ***Calibration Materials*** earlier in this section, the following procedures apply when using the Enter Factor method:

1. A minimum of five samples are required for adequate calibration. (In Auto-Cal, only one sample is run.)
2. Mean values should be calculated for each parameter based on 10 runs (five samples, each run twice into one QC file). These mean parameter values can then be entered as reference values on the CELL-DYN 3200 System.

ICSH Recommendations

When using fresh whole blood samples, reference values should be determined according to the following ICSH recommendations.

WOC, NOC, RBC, and PLT

Reference values for white blood cells, red blood cells, and platelets may be determined using multiple counts from a certified hemocytometer, from a counter that meters a fixed, calibrated sample volume, or from a reliably calibrated hematology analyzer.

HGB

Reference values for hemoglobin may be determined using either the reference cyanmethemoglobin method or a reliably calibrated hemoglobinometer or hematology analyzer.

> **NOTE: DO NOT** attempt to calibrate the CELL-DYN 3200 System with a hemoglobin standard designed for the calibration of specific reference cyanmethemoglobin methods. The instrument uses a modified hemiglobinhydroxyalamine method which is not designed to analyze these standards directly.

MCV

Reference values for the mean cell volume may be determined by calculation from the reference microhematocrit and RBC measurements or from multiple analyses on a reliably calibrated hematology analyzer.

> **NOTE:** Reference microhematocrit values may be determined by multiple analyses using the NCCLS method for Packed Cell Volume (PCV).[2] Use only plain (non-anticoagulated) capillary tubes. Be certain to verify the proper operation of the microhematocrit centrifuge and the timer as recommended by NCCLS.

Determining Reference Values — Fresh Whole Blood

Follow the procedures below to determine the reference values that will be used to calibrate the instrument using fresh whole blood.

> **NOTE:** No more than two hours should elapse between determining the Reference Mean Values and performing the calibration.

WARNING: Potential Biohazard. Consider all specimens potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

1. Go to a reference hematology instrument (or use appropriate hematology methods) with 5 samples of normal, fresh whole blood. Run each sample at least twice for a minimum of 10 replicates on the reference instrument.

   NOTE: Because the same sample will be used to first obtain reference values on a reference instrument then to calibrate in the Open and Closed Modes, it is important to begin with a sufficient amount of sample.

2. If a mean value for each parameter based on at least 10 runs is not automatically calculated by the reference hematology instrument or hematology methods, use a calculator to determine the cumulative Reference Mean for each parameter. For example:

   The cumulative Reference WOC Mean is 7.15 when the WOC results from each run are as follows:

   - Sample 1 = 9.2, 9.1
   - Sample 2 = 4.5, 4.6
   - Sample 3 = 6.1, 5.9
   - Sample 4 = 7.0, 7.3
   - Sample 5 = 8.9, 8.9

   The cumulative mean of 7.15 equals the sum of the values (71.5) divided by the 10 runs.

   You may use the worksheet on the following page to record the values obtained from running samples on a reference instrument. Make copies of the blank worksheet as necessary.

Whole Blood Calibration Reference Values Worksheet

Date: **Technologist:**

Sample ID	Run #	WBC (WOC)	WBC (NOC)	RBC	HGB	MCV	PLT
	1						
	2						
	1						
	2						
	1						
	2						
	1						
	2						
	1						
	2						
Cumulative Mean							

NOTE: The WBC value obtained on the Reference Instrument should be used for calibrating both the WOC and NOC parameters on the CELL-DYN 3200 Instrument.

Calibration Procedure — Open Mode

Follow the procedure below for calibrating the instrument in the Open Mode.

NOTE: Use the same Calibrator or Fresh Whole Blood samples for calibrating Open and Closed Modes.

Determining New Calibration Factors

1. If necessary, go to the RUN menu and press [CHANGE SAMPLER] to select the Open Mode.
2. In the MAIN MENU, press [CALIBRATION] to display the main CALIBRATION menu.

3. Obtain a printout of the current Open Sampler Calibration Factors as follows:

   a. If necessary, press [OPEN SAMPLER] to display the Open Sampler Calibration Factors.

   b. Press [PRINT] to obtain a printout of these factors. Save this printout. It will be used when completing Worksheet 1 at the end of this section.

4. Open an empty QC file as follows:

   a. In the MAIN MENU, press [RUN] to display the RUN menu.

   b. If necessary, press [CHANGE SAMPLER] to select Open Mode.

   c. Press [SPECIMEN TYPE] to display the SPECIMEN TYPE menu.

   d. Use the arrow keys on the keyboard to move the cursor to an empty QC file and type the desired file name in the <File Name> field.

   e. Press Enter to save the name. Use the Up Arrow key to move the cursor back to the file name.

   f. Press [QC SPECIMEN] to return to the RUN screen.

5. If calibrator material is used, follow the mixing instructions found in the package insert. If fresh whole blood is used, mix it well by inverting the tube at least ten times. Do not shake the specimen.

WARNING: Potential Biohazard. Consider all specimens, calibrators, and controls that contain human blood as potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

6. If calibrator material is used, when READY appears in the Status Box, place the calibrator under the Open Mode Sample Probe and press the Touch Plate to run the specimen. The results of the run are placed in the QC file selected in step *1*. Repeat this step until the minimum number of recommended runs (6) is completed. Go to step *7*.

If fresh whole blood is used, when READY appears in the Status Box place the sample under the Open Mode Sample Probe and press the Touch Plate to run the specimen. The results of the run are placed in the QC file selected in step *1*. Repeat this process until 10 runs (2 from each sample) are completed.

7. When sample processing is completed, press [MAIN] followed by [QUALITY CONTROL]. Use the arrow keys to place the cursor on the appropriate QC file and press [VIEW QC LOG].
8. Press [PRINT QC LOG] to print the Summary Report for the selected QC file.
9. To determine the New Calibration Factor for each parameter:
   a. For Calibrator, use the values on the assay sheet and the CELL-DYN mean values determined in steps *2* through *8* above. Enter this information in columns 1 and 2 respectively of Worksheet 1, Open Mode Calibration — New Factors, provided in ***Manual Calibration Worksheets*** at the end of this section.
   b. For Fresh Whole Blood, use the Reference Mean Values determined in ***Determining Reference Values — Fresh Whole Blood*** described earlier (refer to the Whole Blood Calibration Reference Values Worksheet) and the CELL-DYN Mean values determined in steps *2* through *8* above. Enter this information in columns 1 and 2 respectively of Worksheet 1, Open Mode Calibration — New Factors, provided in ***Manual Calibration Worksheets*** at the end of this section.
   c. Enter the current Open Sampler Calibration Factors, obtained in step *3* above, in column 3 of Worksheet 1.

   NOTE: Be sure to make copies of this worksheet as needed.
10. Follow the instructions on Worksheet 1 to calculate the new Open Mode Calibration Factor for each parameter and enter this information in column 4 of the worksheet. The method for determining the new factors is:

    Calibrator Calibration:

$$\frac{\text{Calibrator Mean}}{\text{CELL-DYN Mean}} \times \text{Current Open Mode Calibration Factor} = \text{New Open Mode Calibration Factor}$$

Whole Blood Calibration:

$$\frac{\text{Reference Mean}}{\text{CELL-DYN Mean}} \times \text{Current Open Mode Calibration Factor} = \text{New Open Mode Calibration Factor}$$

For example, if the Reference Mean Value for WOC is 6.6, the CELL-DYN Mean for WOC is 7.1, and the current Open Mode Calibration Factor for WOC is 0.98, then:

(6.6 / 7.1) x 0.98 = 0.91

and 0.91 is your New Open Mode Calibration Factor for WOC.

Determining Which Parameters Need Calibration

To determine which parameters require calibration in the Open Mode, follow the procedure below:

1. Obtain the values derived in column 4 of Worksheet 1 and enter these values in the new Open Mode Factor column of Worksheet 2, Open Mode Factor% Difference, provided in ***Manual Calibration Worksheets*** at the end of this section.

   NOTE: Make copies of this worksheet as needed.

2. Follow the instructions on this worksheet to determine the Factor % Diff for each parameter.

3. Transfer the Factor % Diff values calculated in worksheet *2* to column 1 of Worksheet 3, Open Mode Calibration Range Criteria, provided in ***Manual Calibration Worksheets*** at the end of this section.

   NOTE: Make copies of this worksheet as needed.

4. For each parameter, if the Factor % Diff is **equal to or less than** the value in the Lower Limit column, then CALIBRATION IS NOT REQUIRED for that parameter because the value is within range.

5. For each parameter, if the Factor % Diff falls **between** the upper and lower calibration range, shown in the Calibration Range column, then CALIBRATION IS REQUIRED.

6. For each parameter, if the Factor % Diff is **greater than** the value in the Upper Limit column, there may be a computation error or an instrument problem. In this case, do the following:
   a. Recheck all numbers and calculations on Worksheets 1 and 2.
   b. Determine if any component on the instrument was changed. This could affect calibration. Such components include the Shear Valve, Optical Flow Cell, Hemoglobin Flow Cell, or one of the syringes.
   c. If a component was changed, then treat the result as if it fell within the "calibration range" (even though it is greater than the upper limit). CALIBRATION IS REQUIRED for that parameter.
   d. If no component was changed and your calculations are correct, DO NOT CALIBRATE. Confirm that *all* Pre-Calibration procedures were completed and call the Customer Support Center for assistance (at 1-800-CELL-DYN in the U.S.).
7. Based on the results from steps *1* through *6* above, do one of the following:
   a. If any parameter needs to be calibrated in the Open Mode, go to ***Entering New Calibration Factors — Open Mode***.
   b. If none of the parameters requires Open Mode calibration and Closed Mode has not been calibrated, go to ***Calibration Procedure — Closed Mode*** to determine if Closed Mode needs calibrating.
   c. If none of the parameters requires Open Mode calibration and Closed Mode calibration has already been completed, press [MAIN] to return to the MAIN MENU.

Entering New Calibration Factors — Open Mode

1. In the main CALIBRATION menu, press [ENTER FACTOR].
2. Use the arrow keys to select the first factor in the Open Sampler column to be changed. Type in the three-digit New Calibration Factor calculated in step *10* in ***Determining New Calibration Factors*** above. Press the Enter key to save the factor and advance the cursor. If necessary, use the arrow keys to select the next factor to be changed.

NOTE: Prior to exiting the screen, the operator may press the [RESTORE FACTORS] soft key to recall factors, stored on the Hard Disk, corresponding to the current mode — Open or Closed. [RESET ALL TO 1.000] is used to reset all factors displayed on the screen to 1.000.

3. When all new factors have been entered, press [RETURN] to display the CALIBRATION LOG screen with the new calibration factors.

   NOTE: If no changes are made in the ENTER CALIBRATION FACTOR screen, pressing [RETURN] will bypass the CALIBRATION LOG screen and display the main CALIBRATION menu.

4. Complete the Calibration Log (adding comments) as required. If a printout of the log is desired, press [PRINT LOG].

5. Press [RETURN] twice to return to the main CALIBRATION menu.

6. Press [PRINT] to obtain a copy of the new Open Sampler Calibration Factors.

7. Press [MAIN] to return to the MAIN MENU.

Confirming Open Mode Calibration

1. Press [RUN] followed by [SPECIMEN TYPE] and [PATIENT].
2. Refer to Worksheet 7, Calibration Confirmation, in ***Manual Calibration Worksheets*** provided at the end of this section.

   NOTE: Make copies of this worksheet as necessary.

3. Take each of the five samples used in the calibration process and run each sample once. After each run, write the results of the parameters just calibrated in the appropriate space on Worksheet 7.
4. Follow the instructions on the worksheet for calculating a mean and comparing the mean value against the reference value.

5. If the difference between the mean and reference value is within the tolerance limits, then calibration has been confirmed in the Patient mode for that parameter. Proceed to calibrate the Closed Mode if not already calibrated.
6. If a parameter's mean is outside the stated tolerance limits, repeat steps *3* and *4* above for that parameter. If the mean is still outside the stated tolerance limits, call the Customer Support Center for assistance (at 1-800-CELL-DYN in the U.S.).

Calibration Procedure — Closed Mode

Follow the procedure below for calibrating the instrument in the Closed Mode.

NOTE: Use the same Calibrator or Fresh Whole Blood samples for calibrating Open and Closed Modes.

Determining New Calibration Factors

1. If necessary, go to the RUN menu and press [CHANGE SAMPLER] to select the Closed Mode.
2. In the MAIN MENU, press [CALIBRATION] to display the main CALIBRATION menu.
3. Obtain a printout of the current Closed Sampler Calibration Factors as follows:
   a. If necessary, press [CLOSED SAMPLER] to display the Closed Sampler Calibration Factors.
   b. Press [PRINT] to obtain a printout of these factors. Save this printout. It will be used when completing Worksheet 4 at the end of this section.
4. Open an empty QC file as follows:
   a. In the MAIN MENU, press [RUN] to display the RUN menu.
   b. If necessary, press [CHANGE SAMPLER] to select Closed Mode.
   c. Press [SPECIMEN TYPE] to display the SPECIMEN TYPE menu.
   d. Use the arrow keys on the keyboard to move the cursor to an empty QC file and type the desired name in the <File Name> field.

e. Press Enter to save the name. Use the Up Arrow key to move the cursor back to the file name.

f. Press [QC SPECIMEN] to return to the RUN screen.

WARNING: Potential Biohazard. Consider all specimens, calibrators, and controls that contain human blood as potentially infectious. Wear gloves, lab coats, and safety glasses and follow other biosafety procedures as specified in the OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030) or other equivalent biosafety procedures.

5. Calibrating the CS model (Calibrator or Fresh Whole Blood):

   a. Mix the specimen well. If calibrator material is used, follow the mixing instructions found in the package insert. If fresh whole blood is used, mix it well by inverting the tube at least ten times. Do not shake the specimen.

   b. Place the well-mixed specimen in the Tube Retainer, close the door, and press the Touch Plate.

   c. If calibrator material is used, repeat this process until a minimum of 6 runs has been completed.

   d. If fresh whole blood is used, repeat this process until a minimum of 10 runs has been completed.

   e. Go to step *8*.

6. Calibrating the SL model with Calibrator or Fresh Whole Blood:

   a. Determine the number of runs you expect to make (6 runs should be the minimum for calibrator, 10 runs for fresh whole blood) and obtain the same number of empty 5-mL tubes containing no anticoagulant.

   b. Mix the specimen well. If Calibrator, follow the directions on the package insert. If Fresh Whole Blood, invert the sample ten times. Do not shake the specimen.

   c. Aliquot the sample as follows:

      1. For Calibrator, aliquot the sample in equal volumes into the tubes (each tube should contain a minimum of 1 mL of sample).

2. For Fresh Whole Blood, there should be a minimum of 5 samples (refer to ***Number of Cycles*** under ***Calibration Materials*** earlier in this section). Aliquot the first sample in equal volumes into two tubes. Aliquot the second sample in equal volumes into another two tubes. Repeat this procedure until all 5 samples have been aliquoted (for a total of 10 tubes).

d. Place the closed tubes on a rack and set the rack on the "load" side (refer to Figure 13.7).

e. Press [START LOADER]. Allow the instrument to process all the samples.

7. When sample processing is completed, press [MAIN] followed by [QUALITY CONTROL]. Use the arrow keys to place the cursor on the appropriate QC file and press [VIEW QC LOG].

8. Press [PRINT QC LOG] to print the Summary Report for the selected QC file.

9. To determine the New Calibration Factor for each parameter:

a. For Calibrator, use the values on the assay sheet and the CELL-DYN mean values on the printout from step *8* above. Enter this information in columns 1 and 2 respectively of Worksheet 4, Closed Mode Calibration — New Factors, provided in ***Manual Calibration Worksheets*** at the end of this section.

b. For Fresh Whole Blood, use the same Reference Mean Values determined in ***Determining Reference Values — Fresh Whole Blood*** described earlier and the CELL-DYN Mean values on the printout from step *8* above. Enter this information in columns 1 and 2 of Worksheet 4, Closed Mode Calibration — New Factors, provided in ***Manual Calibration Worksheets*** at the end of this section.

c. Enter the current Closed Sampler Calibration Factors, obtained in step 3 above, in column 3 of Worksheet 4.

NOTE: Make copies of this worksheet as needed.

10. Follow the instructions on Worksheet 4 to calculate the new Closed Mode Calibration Factor for each parameter and enter this information in column 4 of the worksheet. The method for determining the new factors is:

Calibrator Calibration:

$$\frac{\text{Calibrator Mean}}{\text{CELL-DYN Mean}} \times \text{Current Open Mode Calibration Factor} = \text{New Open Mode Calibration Factor}$$

Whole Blood Calibration:

$$\frac{\text{Reference Mean}}{\text{CELL-DYN Mean}} \times \text{Current Open Mode Calibration Factor} = \text{New Open Mode Calibration Factor}$$

For example, if the Reference Mean Value for WOC is 6.6, the CELL-DYN Mean for WOC is 7.4, and the current Closed Mode Calibration Factor for WOC is 1.04, then:

(6.6 / 7.4) x 1.04 = 0.93

and 0.93 is your New Open Mode Calibration Factor for WOC.

Determining Which Parameters Need Calibration

To determine which parameters require calibration in the Closed Mode, follow the procedure below:

1. Obtain the values derived in column 4 of Worksheet 4 and enter these values in column 1 of Worksheet 5, Closed Mode Factor % Difference, provided in subsection ***Manual Calibration Worksheets*** at the end of this section.

   NOTE: Make copies of this worksheet as needed.

2. Follow the instructions on Worksheet 5 to determine the Factor % Diff for each parameter.
3. Transfer the % Diff values calculated in Worksheet 5 to column 1 of Worksheet 6, Closed Mode Calibration Range Criteria, provided in subsection ***Manual Calibration Worksheets*** at the end of this section.

   NOTE: Make copies of this worksheet as needed.

4. For each parameter, if the Factor % Diff is **equal to or less than** the value in the Lower Limit column, then CALIBRATION IS NOT REQUIRED for that parameter because the value is within range.
5. For each parameter, if the Factor % Diff falls **between** the upper and lower calibration range, shown in the Calibration Range column, then CALIBRATION IS REQUIRED.

6. For each parameter, if the Factor % Diff is **greater than** the value in the Upper Limit column, there may be a computation error or an instrument problem. In this case, do the following:
   a. Recheck all numbers and calculations on Worksheets 4 and 5.
   b. Determine if any component on the instrument was changed. This could affect calibration. Such components include the Shear Valve, Optical Flow Cell, Hemoglobin Flow Cell, or one of the syringes.
   c. If a component was changed, then treat the result as if it fell within the "calibration range" (even though it is greater than the upper limit). CALIBRATION IS REQUIRED for that parameter.
   d. If no component was changed and your calculations are correct, DO NOT CALIBRATE. Confirm that all Pre-Calibration procedures were completed and call the Customer Support Center for assistance (at 1-800-CELL-DYN in the U.S.).
7. Based on the results from steps *1* through *6* above, do one of the following:
   a. If any parameter needs to be calibrated in the Closed Mode, go to ***Entering New Calibration Factors — Closed Mode***.
   b. If none of the parameters requires Closed Mode calibration and Open Mode has not been calibrated, go to ***Calibration Procedure — Open Mode*** to determine if Open Mode needs calibrating.
   c. If none of the parameters requires Closed Mode calibration and Open Mode calibration has already been completed, press [MAIN] to return to the MAIN MENU.

Entering New Calibration Factors — Closed Mode

1. In the CALIBRATION menu, press [ENTER FACTOR].

2. Use the arrow keys to select the first factor in the Closed Sampler column to be changed. Type in the three-digit New Calibration Factor calculated in step *10* in ***Determining New Calibration Factors*** above. Press the Enter key to save the factor and advance the cursor. If necessary, use the arrow keys to select the next factor to be changed.

   NOTE: Prior to exiting the screen, the operator may press the [RESTORE FACTORS] soft key to recall factors, stored on the Hard Disk, corresponding to the current mode — Open or Closed. [RESET ALL TO 1.000] is used to reset all factors displayed on the screen to 1.000.

3. When all new factors have been entered, press [RETURN] to display the CALIBRATION LOG screen with the new calibration factors.

   NOTE: If no changes are made in the ENTER CALIBRATION FACTOR screen, pressing [RETURN] will bypass the CALIBRATION LOG screen and display the main CALIBRATION menu.

4. Complete the Calibration Log (adding comments) as required. If a printout of the log is desired, press [PRINT LOG].

5. Press [RETURN] twice to return to the main CALIBRATION menu.

6. Press [PRINT] to obtain a copy of the new Closed Sampler Calibration Factors.

7. Press [MAIN] to return to the MAIN MENU.

Confirming Closed Mode Calibration

1. Press [RUN] followed by [SPECIMEN TYPE] and [PATIENT].
2. Refer to Worksheet 7, Calibration Confirmation, in subsection ***Manual Calibration Worksheets***. Make copies of this worksheet as necessary.
3. Take each of the five samples used in the calibration process and run each sample once. After each run, write the results of the parameters just calibrated in the appropriate space on the Worksheet 7.

4. Follow the instructions on the worksheet for calculating a mean and comparing the mean value against the reference value.
5. If the difference between the mean and reference value is within the stated tolerance limits, then calibration has been confirmed in the Patient mode for that parameter. Proceed to calibrate the Open Mode if not already calibrated.
6. If a parameter's mean is outside the stated tolerance limits, repeat steps *3* and *4* above for that parameter. If the mean is still outside the stated tolerance limits, call the Customer Support center for assistance (at 1-800-CELL-DYN in the U.S.).

Latex Calibration Method

Calibration is required when mean platelet volume (MPV) values for QC (Quality Control) specimens indicate that MPV is out of calibration.

This procedure should be performed only by an authorized Abbott representative.

NOTES

Post Calibration Procedures

The current calibration factors should be saved on the CELL-DYN 3200 Set-Up disk whenever calibration is changed. Data should also be saved whenever any Set-Up information is changed and after any service work is performed. The back-up procedure copies the following Set-Up information from the Data Module to the Set-Up Disk:

- Calibration Factors
- QC Limits
- Patient Limits
- Analyzer Module Set Points (e.g., gains, dil factors [internal calibration factors], thresholds, pressure/ vacuum settings)
- Units Selection

To back up the calibration factors, proceed as follows:

1. Turn the instrument power switch OFF.
2. Obtain the Set-Up Disk from the Disk Storage Container located on the back of the Instrument.
3. Insert the Set-Up Disk in the floppy disk drive.
4. Turn the instrument power switch ON.
5. The following information is displayed on the display monitor:

   ```
   THIS IS THE CD3200 SETUP DISK
   TO USE, TYPE EITHER SAVE [ENTER] OR RESTORE
   [ENTER] AND FOLLOW THE INSTRUCTIONS.
   ```

   

   NOTE: The restore option copies Set-Up information from the Set-Up disk to the hard disk. This option is used when a hardware or software failure occurs and should only be used at the direction of Technical Service or the Customer Support Center.

6. Type “SAVE” and press the Enter Key on the keyboard.
7. The screen displays the following:

   ```
   CD3200 FILE SAVE UTILITY (VERSION 1)
   ```

```
THIS UTILITY WILL SAVE YOUR DATA FILES ONTO
YOUR SETUP DISK TO KEEP THEM BACKED UP
SAFELY.
THE FOLLOWING FILES WILL BE SAVED:
     (1) NONVOL
     (2) QC LOG
     (3) CALIBRATION LOG
     (4) MAINTENANCE LOG
     PROCEED (Y/N)?
```

8. Type “Y” and press the Enter key on the keyboard. The Set-Up information is copied from the hard disk onto the Set-Up Disk. Previous Set-Up information that was stored on the disk is overwritten.
9. When the copy process is complete, the “a:>” prompt is displayed on the screen.
10. Remove the Set-Up Disk from the disk drive and return it to the Disk Storage Container.
11. Turn the instrument power switch OFF.
12. Wait five seconds and then turn the power switch ON.

Manual Calibration Worksheets

Seven worksheets are provided to assist in the calculation and determination of new calibration factors for the CELL-DYN 3200 System. Three worksheets are designed for the Open Mode procedure, three worksheets for the Closed Mode procedure, and one worksheet for confirmation.

- Worksheet 1 Open Mode Calibration — New Factors
- Worksheet 2 Open Mode Factor % Difference
- Worksheet 3 Open Mode Calibration Range Criteria
- Worksheet 4 Closed Mode Calibration — New Factors
- Worksheet 5 Closed Mode Factor % Difference
- Worksheet 6 Closed Mode Calibration Range Criteria
- Worksheet 7 Calibration confirmation — Patient Type

Make copies of these worksheets as necessary.

Worksheet 1

Open Mode Calibration — New Factors

Instrument: **Date:** **Operator:**

(Calculate All Factors To Three Decimal Places)

	(1) Assay Value or Ref Mean	/	(2) Open Mode Mean	x	(3) Current Open Mode Cal Factor	=	(4) New Open Mode Cal Factor	(5) Range
WOC		/		x		=		0.700–1.300
NOC		/		x		=		0.700–1.300
RBC		/		x		=		0.800–1.200
HGB		/		x		=		0.700–1.300
MCV		/		x		=		0.700–1.300
PLT		/		x		=		0.700–1.300

1. In column 1, enter the calibrator assay values or the fresh whole blood reference means that were used in the calibration process (refer to step 9 on page 6.47). Use the same WBC Reference Value for WOC and NOC.
2. In column 2, enter the mean values calculated in the QC file.
3. In column 3, enter the calibration factors that existed prior to running the current calibration procedure.
4. For each parameter, divide the value in column 1 by the value in column 2 and multiply the result by the value in column 3.
5. The value calculated in step 4 is the new calibration factor. Write this value in column 4.
6. Compare the new calibration factor in column 4 with the range shown in column 5. If the new factor falls within the range, go to Worksheet 2. If the new factor falls outside the range, check all calculations. If necessary, run the samples again into a new QC file and perform new calculations.

Worksheet 2

Open Mode Factor % Difference

(Calculate All Factors To Three Decimal Places)

	(1) New Open Mode Factor	–	(2) Current Open Mode Factor	/	(3) New Open Mode Factor	(4) x 100 =	(5) Factor % Diff
WOC		–		/		x 100 =	
NOC		–		/		x 100 =	
RBC		–		/		x 100 =	
HGB		–		/		x 100 =	
MCV		–		/		x 100 =	
PLT		–		/		x 100 =	

1. In column 1, enter the new factor calculated in column 4 of the previous worksheet.
2. In column 2, enter the calibration factor that existed prior to running the current calibration procedure.
3. Subtract the current factor in column 2 from the new factor in column 1 and divide the result by the current factor. Enter this result in column 3.
4. Multiply the result in column 3 by 100 and enter the result in column 5.

Worksheet 3

Open Mode Calibration Range Criteria

	(1) Factor% Diff	(2) Lower Limit Cal Not Required	(3) Calibration Range Cal Required	(4) Upper Limit Do Not Cal	(5) Cal? Y/N
WOC		≤2.0%	>2.0% but ≤10%	>10%	
NOC		≤2.0%	>2.0% but ≤10%	>10%	
RBC		≤2.0%	>2.0% but ≤10%	>10%	
HGB		≤2.0%	>2.0% but ≤10%	>10%	
MCV		≤2.0%	>2.0% but ≤10%	>10%	
PLT		≤3.0%	>3.0% but ≤15%	>15%	

1. In column 1, enter the new Factor % Diff from column 5 of the previous worksheet (disregard the sign).
2. If the new Factor % Diff exceeds the limit in column 4, DO NOT CALIBRATE. Call the Customer Support Center for assistance.

Worksheet 4

Worksheet 7

Calibration Confirmation

Patient Specimen Type

Sample #	WBC	RBC	HGB	MCV	PLT
1					
2					
3					
4					
5					
Mean Value of 5 Runs					
Reference or Assay Value					
Difference (absolute value)					
Tolerance Limits *					

1. Select Patient as the specimen type and run the calibrator or fresh whole blood sample 5 times.
2. Calculate a mean for each parameter that was calibrated.
3. Enter the reference or assay target values used to calibrate those parameters.
4. Calculate the difference between the mean and the reference value.
5. Compare the difference with the Tolerance Limit. If within the limit, calibration is confirmed in the Patient specimen type.

* For Calibrator, use the pre-established tolerance limits found on the Calibrator Assay Sheet.
For Fresh Whole Blood, each laboratory should establish tolerance limits according to its protocol.

References

1. ICSH, *Protocol for Evaluation of Automated Blood Cell Counters*, Clinical and Laboratory Hematology 1988, 10:203, 212.
2. NCCLS standard H7-A, *Procedure for Determining Packed Cell Volume by the Microhematrcrit Method*; Approved Standard (1985).

NOTES

Overview

This section deals with the precautions that need to be taken to ensure the performance and validity of the CELL-DYN® 3200 System and its test results.

The following system precautions and limitations are reviewed in this section:

- General Limitations
- Location Requirements
- Reagent Storage and Handling
- Printer Precautions

Limitations

The CELL-DYN 3200 System is designed for *in vitro* diagnostic use.

- Abbott has designed the CELL-DYN 3200 System components for optimal performance. Substituting reagents, calibrators, controls, and components manufactured by other companies may adversely affect the performance of the instrument.
- Follow the recommended maintenance schedules and procedures as outlined in **Section 9: *Service and Maintenance***.
- During the warranty period, all service and repair must be performed by Abbott-authorized representatives.

Location Requirements

The location of the CELL-DYN 3200 System is an important consideration that affects proper instrument functioning, operating safety, and ease of use.

- An Abbott-authorized representative must install the instrument.
- The location should have nonporous, nonabsorbing work surfaces and flooring that can be cleaned easily and disinfected using recommended procedures.
- Place the CELL-DYN 3200 System on a hard, level surface. Locate the system:
  - away from direct sunlight.

  - away from the path of a cooled air or heated air outlet.
  - away from other instruments that may interfere with the CELL-DYN 3200 System, such as drying ovens, centrifuges, x-ray equipment, MRI (magnetic resonance imaging) equipment, CRTs or computers, video terminals, copiers, ultrasonic cleaners, and patient areas.
- Do not place reagent containers above the Analyzer.
- The following space should be available to ensure proper ventilation:
  - Bench top space: approximately 6 linear feet to accommodate the instrument, display station, and printer
  - Below the instrument: sufficient space for reagents and waste container (if one is used)
  - Behind the instrument: 6 inches of space for proper ventilation
  - Above the instrument: 6 inches of space for proper ventilation
  - Left side of instrument: 12 inches of space in front of the fan for proper ventilation
  - Adequate space around the instrument to perform necessary maintenance procedures
- Care should be taken to prevent blocking of the air vents or fans on the sides and the back of the instrument.
- Before operating the instrument for the first time, verify that each reagent line is connected to the appropriate inlet and reagent container. Refer to **Section 2: *Installation Procedures and Special Requirements.***
- Make sure the waste line is connected to the appropriate outlet and routed to a suitable waste container or drain. If the waste is routed to a waste container, make sure the waste sensor is properly connected. If the waste is routed to a drain, make sure a Dummy Plug is inserted in the Waste Sensor Connector.
- The printer and Display Station can be placed on top of the instrument.

Precautions

Reagent Storage and Handling

- Store reagents, calibrators, and controls according to the directions contained in the package inserts.
- Protect reagents from extreme heat and freezing during storage. Temperatures below 0°C (32°F) may cause layering that changes the tonicity and conductivity of the reagent. If freezing occurs, do not use the reagent.
- Protect reagents from direct sunlight, evaporation, and contamination. Use the Reagent Container Cap attached to each length of inlet tubing to minimize evaporation and contamination.
- Never add remaining reagent from a container being replaced to a freshly opened container. This may contaminate the new reagent.
- Never use a hemoglobin standard other than the one specified for the CELL-DYN 3200 System. The CELL-DYN 3200 System uses a cyanide-free reagent.

Printer Precautions

The Printhead on dot matrix printers can get very hot during extended periods of printing. Allow it to cool before touching it. Heat is not a problem with ink jet or bubble jet printers.

NOTES

Overview

The CELL-DYN® 3200 System has been designed to minimize hazards to the operator and other personnel. However, some hazards are inherent to the operator of any electromechanical equipment. Therefore, safety awareness is important when operating the CELL-DYN 3200 System.

Safety Icons

Safety icons in this manual and on the instrument are used to identify potentially hazardous conditions or situations. A brief explanatory message labeled **DANGER**, **WARNING** or **CAUTION**, depending on the nature of the hazard, accompanies the icon.

For a summary of locations in the manual where safety icons are referenced, refer to the **Master Table of Contents, *List of Safety Icons*.**

WARNING: Potential Biohazard. The biohazard icon alerts users to an activity or area where they may be exposed to infectious materials or substances.

WARNING: Electrical Shock Hazard. The electrical hazard icon alerts users to the possibility of electrical shock in the described activity or at the posted location.

WARNING: The general warning icon alerts users to a potential health or safety hazard.

CAUTION: The general caution icon appears adjacent to an explanation of conditions that could interfere with the proper functioning of the instrument.

DANGER: Class III B Laser Light. The laser icon warns against direct exposure to the laser light beam generated by the Optical Bench Assembly.

NOTES

Types of Hazards

Biohazards

General Biohazard Information

Hematology analysis involves potentially harmful substances. Operators and other personnel working near the CELL-DYN 3200 System should be alert to biohazards. Operators should carefully follow all laboratory and instrument-specific procedures.

General principles for biosafety include the following:

- Consider all human-sourced materials as potentially infections. Specimens, controls, calibrators, and other reference materials can contain components derived from human sources
- Always wear a lab coat, powder-free disposable gloves, and protective eyewear when operating or maintaining the instrument
- Do not smoke, eat, or drink in areas where specimens are handled
- Do not pipette by mouth
- Observe biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Biohazard Information for the CELL-DYN 3200 System

WARNING: Potential Biohazard. Consider all specimens, reagents, controls, calibrators, etc. that contain human blood or serum as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1920, 1030) or other equivalent biosafety procedures.

WARNING: Potential Biohazard. The aspiration needle is sharp and potentially contaminated with infectious material. Avoid contact with needle.

Handling and Disposing of Biohazardous Materials

Handle and dispose of all clinical specimens, reagents, controls, calibrators, and reference materials carefully to avoid aerosols and spills. Clean up spills of potentially infectious materials in accordance with established biosafety practices. The following is generally accepted for cleaning up such spills:

1. Absorb the spill with a towel or other absorbent material.
2. Wipe the area with a detergent solution.
3. Wipe the area with an appropriate tuberculocidal disinfectant such as 10% bleach.

Dispose of all biohazardous materials in accordance with local, state, and federal regulations governing the treatment of regulated medical waste. Waste liquid is a possible source of biological hazard. Handle with extreme care during the disposal process. Sharps, such as contaminated probes, must be placed in an appropriately marked, puncture-resistant container before treatment and disposal.

Chemical Hazards

Prevent exposure to chemicals used in the operation and maintenance of the CELL-DYN 3200 System (including reagents) by using appropriate personal protective equipment, work procedures, and information on Material Safety Data Sheets (MSDS).

Electrical Hazards

Basic electrical hazard awareness is essential to the safe operation of any hematology analyzer. To ensure safe operation of the CELL-DYN 3200 System:

- Periodically inspect electrical cabling into and on the instrument for signs of wear or damage
- When moving equipment, lift all power cables clear of all system components

- Disconnect the instrument from electrical power by unplugging the power cord before removing any instrument panel that is securely fastened in place by screws or prior to replacing fuses. Replace only the externally accessible fuse located immediately above the power cord connector on the rear panel of the instrument. Use a replacement fuse of the specified type and electrical rating only
- Keep liquids away from all electrical connectors (such as electrical outlets) or communication connectors (such as the LIS connector)
- Keep the floor dry
- Follow instructions for correctly powering down the instrument and all connected equipment before performing service or maintenance
- Do NOT disconnect any electrical connection while the power is ON
- Use only the approved power cords supplied with the instrument. Connect power cords only to properly grounded outlets.

Mechanical Hazards

General Mechanical Hazard Information

Observe these basic rules for mechanical safety:

- Carefully follow all procedures and instructions
- Keep all protective covers in place when processing specimens
- Never allow any part of your body to enter the region of movement of any mechanical component when the instrument is operating
- Do not wear articles of clothing or accessories that could catch on the System; keep pockets free of items that could fall into the System; keep long hair from catching on the System
- Wear powder-free gloves and safety glasses when maintaining or repairing the instrument
- Avoid contact with needle tips at all times.

The CELL-DYN 3200 Instrument is a **Class I Laser Product per IEC 825-1 (1993)**. However, it contains a Class III B laser.

DANGER: Class III B Laser Light. Avoid Direct Exposure to Beam. Do not look directly into the laser beam or any reflections of the beam from a mirror-like surface. When the access door, instrument top cover or other inner protective cover are removed, Helium-Neon laser power up to 10 mW continuous wave at 632.8 nm in a beam with 1 mR divergence could be accessible in the interior of the optics bench. This amount of energy, with insignificant attenuation with distance, is sufficient to cause eye damage.

Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous laser light exposure. If the instrument is used or modified in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

During normal operation, the inner protective covers are to remain in place to prevent laser light exposure from the optics bench. The inner protective covers are to be removed only during servicing by qualified personnel.

The inner protective cover laser warning labels must not be removed and are to remain legible. The Protective Housing Label (Abbott P/N 9230701D), shown in Figure 8.1, consists of black lettering against a yellow background.

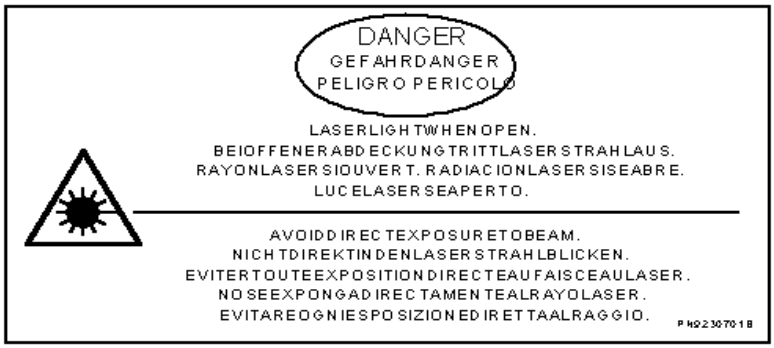

Figure 8.1: Laser Warning Label

This label is located in two places: on the black Laser Bench Protective Cover (under the Top Cover) that covers the laser bench (refer to Figure 8.2), and on the upper left side of the Flow Panel (refer to Figure 8.3).

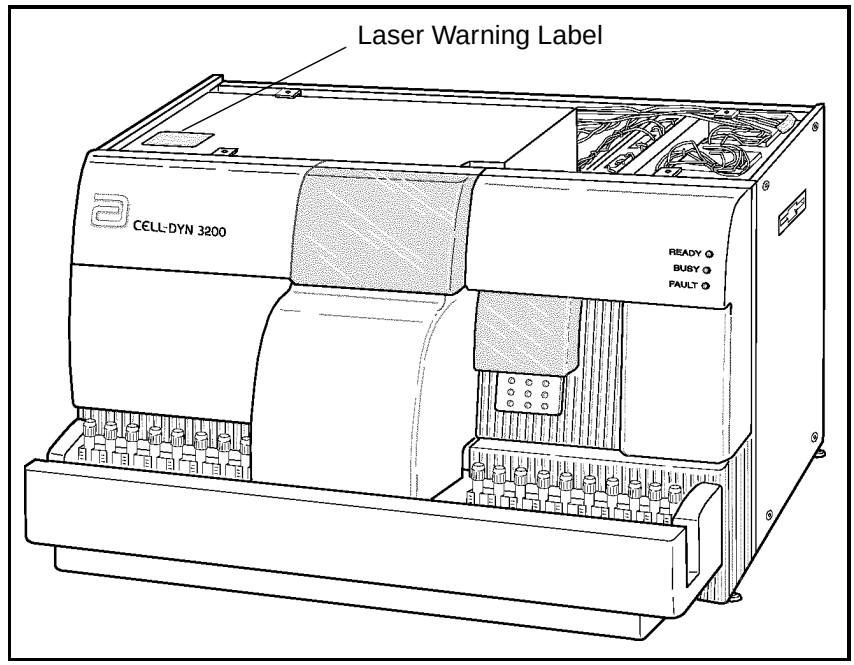

Figure 8.2: Laser Warning Label Position - Protective Cover

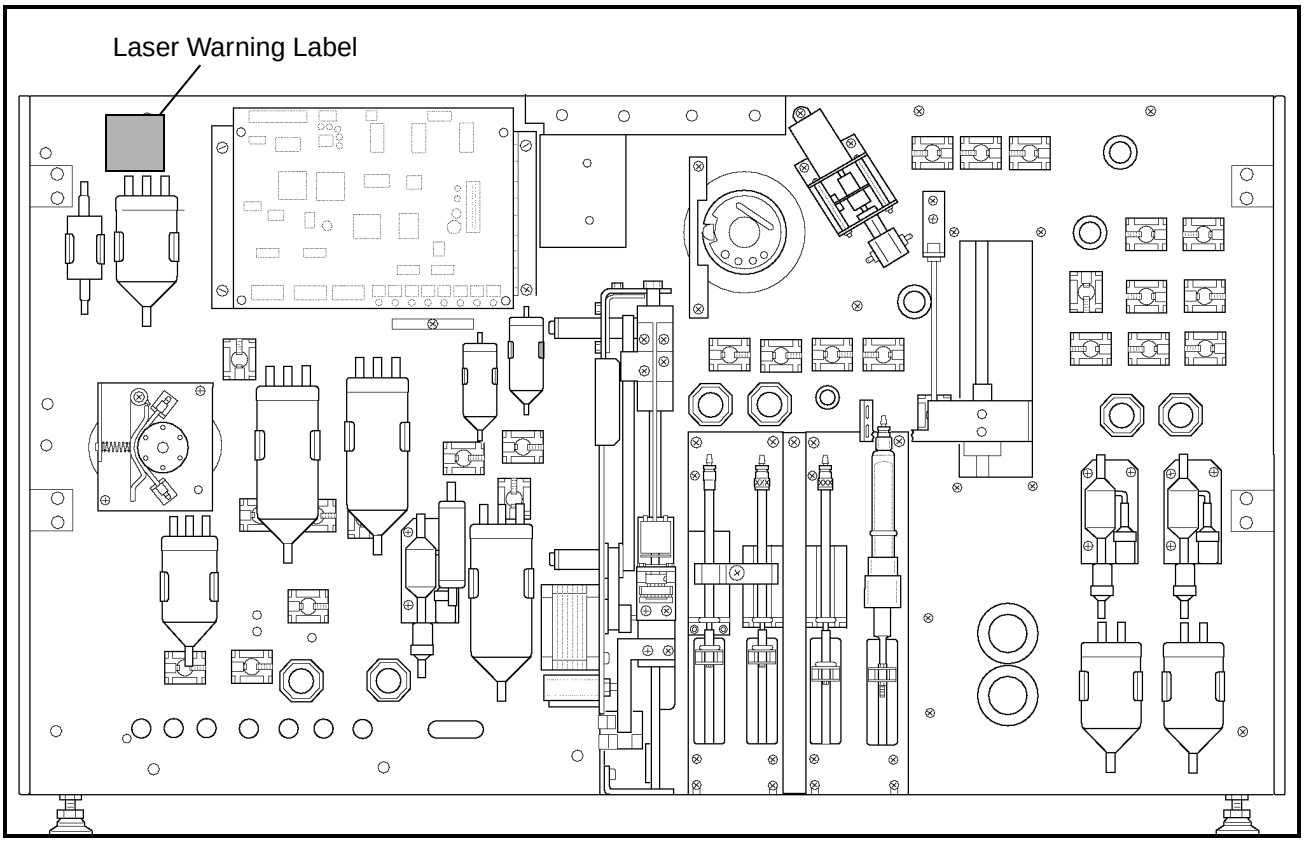

Figure 8.3: Laser Warning Label Position - Flow Panel

The Class 1 Laser Product Label (Abbott P/N 9230702A), shown in Figure 8.4, consists of black lettering against a white background.

Class 1 Laser Product
per
IEC 825 - 1(1993)

PN 9230702A

Figure 8.4: Class 1 Laser Product Label

The label is located on the upper left section of the instrument's Rear Panel and is positioned in a clearly visible location, as shown in Figure 8.5.

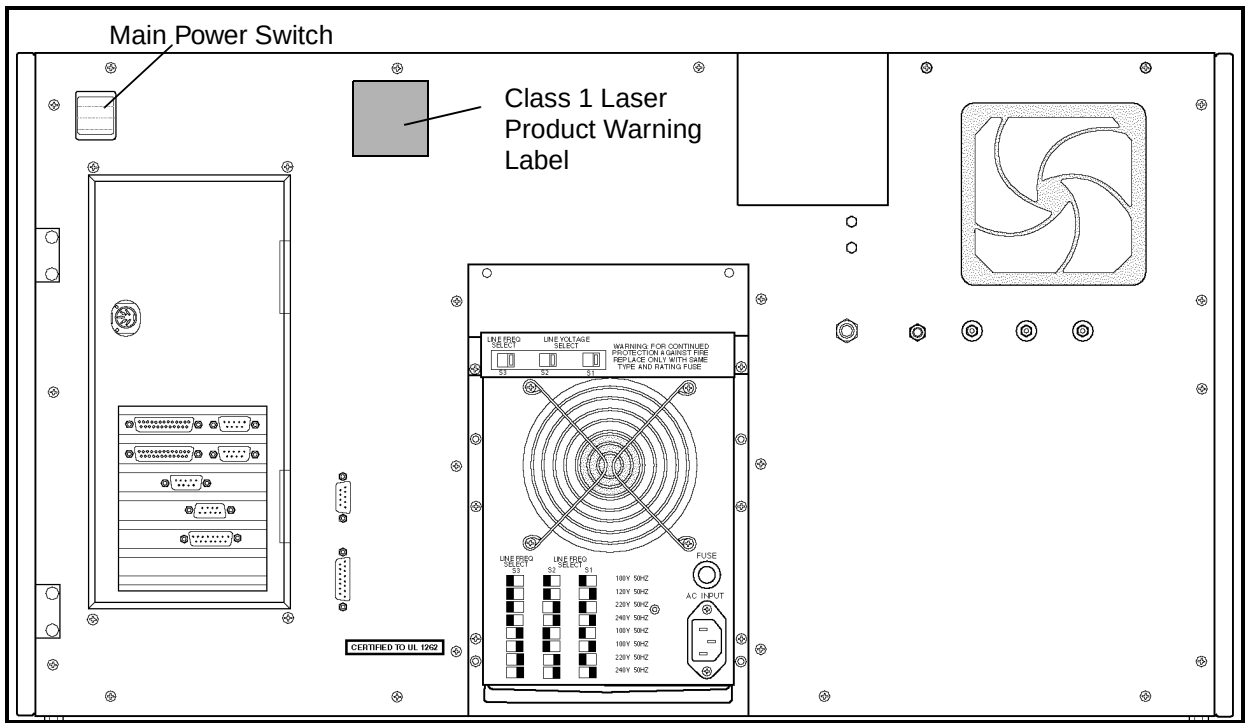

Figure 8.5: Class 1 Laser Product Label Location

NOTES

References

1. Occupational Safety and Health Administration, 29 CFR Part 1910, 1030. Department of Labor. *Occupational Exposure to Bloodborne Pathogens; Final Rule.* 235:64175-64182, 1991.
2. IEO 825-1, International Electromechanical Commission *World Standards for electrical and electronic engineering, 825: Safety of laser products, 825-1* (1993) Part 1: Equipment classification, requirements, and users guide.

NOTES

Overview

The CELL-DYN® 3200 is designed to require minimal routine maintenance. For example:

- The fluidics are automatically rinsed between samples.
- A thorough system rinse is performed automatically when the unit has been idle for five minutes after the last cycle is completed.
- The instrument is automatically placed in the Standby state if it has been idle for four hours after the last cycle is completed.

The operator is encouraged to routinely perform the required maintenance in order to ensure optimum performance. This section describes the recommended preventive maintenance procedures for the Analyzer. Instructions are also given for preparing the instrument for a prolonged period of inactivity.

Many required preventative maintenance procedures have been automated on the CELL-DYN 3200. These programs can be accessed by pressing the [SPECIAL PROTOCOLS] key. The SPECIAL PROTOCOLS menu is discussed in the next section followed by a discussion of Preventive Maintenance Schedule Procedures.

NOTES

Special Protocols

The SPECIAL PROTOCOLS menu is used to access various preventative maintenance procedures. There are two major screen levels in this menu. The first level is displayed when the [SPECIAL PROTOCOLS] soft key in the MAIN MENU is pressed. The second major screen level is accessed by pressing the [MORE] key in the first level. Within each major level are submenus. Figure 9.1 displays the key labels in the first SPECIAL PROTOCOLS menu.

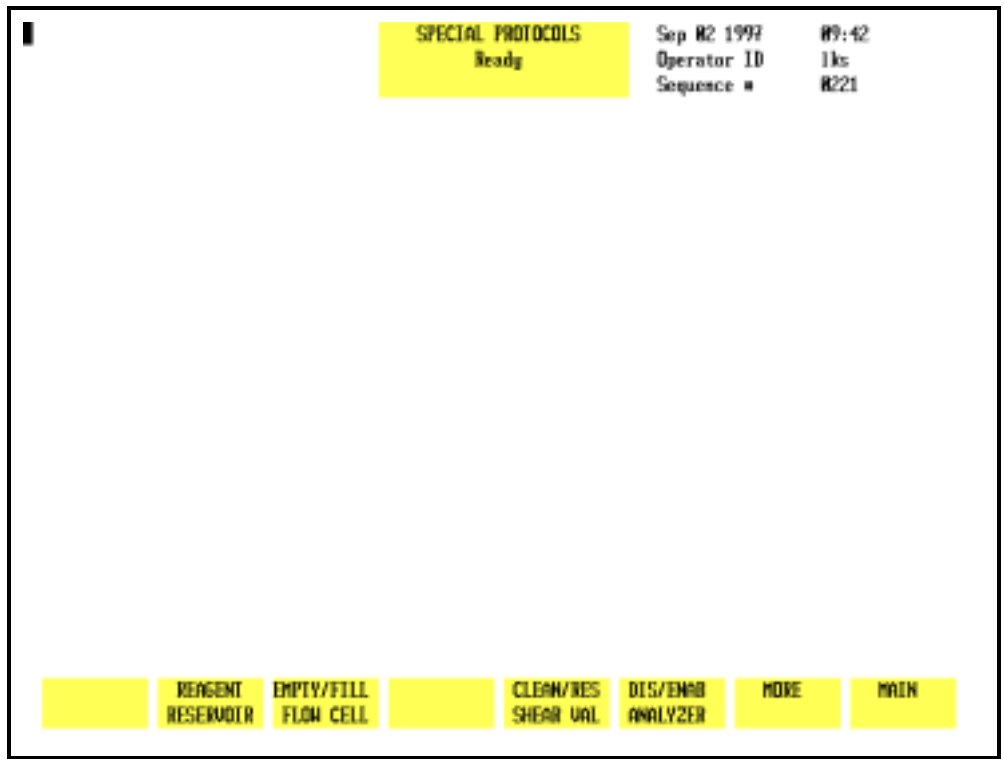

Figure 9.1: First Special Protocols Screen

Special Protocols Menu

When the [SPECIAL PROTOCOLS] key is pressed in the MAIN MENU, the following soft key labels are displayed:

REAGENT RESERVOIR

EMPTY/FILL FLOW CELL/
EMPTY FLOW CELL/
FILL FLOW CELL (Key label alternates between selections.)

CLEAN/RES SHEAR VAL/
CLEAN SHEAR VAL/
RESTORE SHEAR VAL — (Key label alternates between selections.)

DIS/ ENAB ANALYZER/
DISABLE ANALYZER/
ENABLE ANALYZER — (Key label alternates between selections

MORE

MAIN

A brief description of the function of each soft key follows. Instructions for the detailed use of each key are given in the appropriate maintenance procedure.

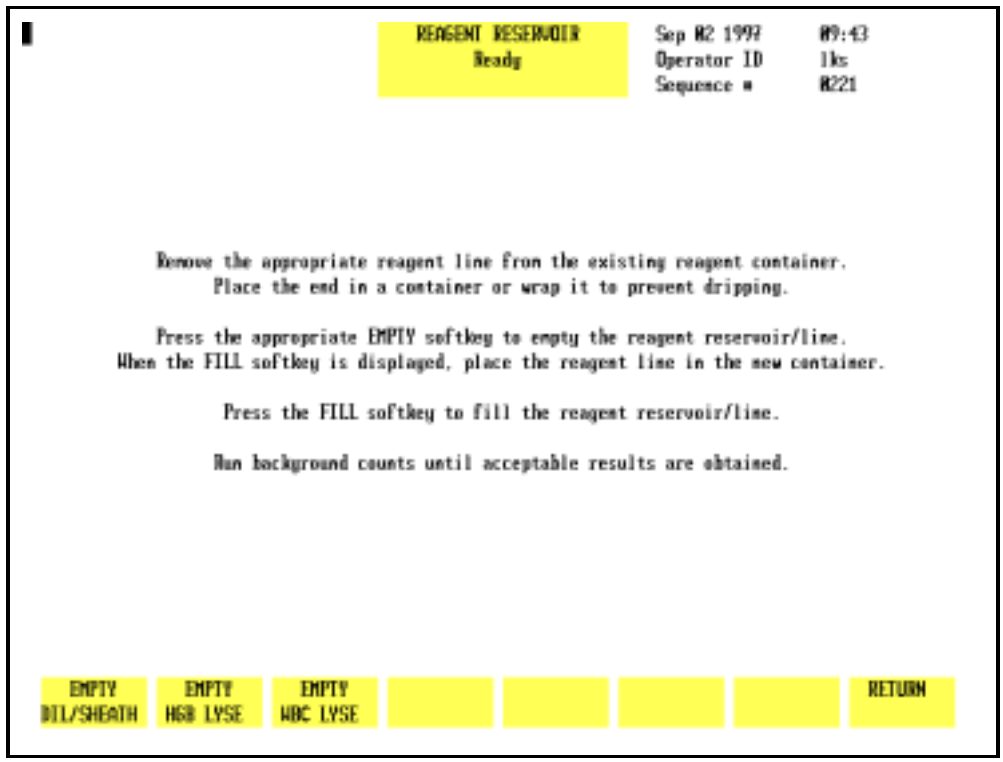

Figure 9.2: Reagent Reservoir Keys

Reagent Reservoir

NOTE: This procedure is performed only in the Open Mode. If necessary, press [CHANGE SAMPLER] in the RUN screen to select Open Mode.

The [REAGENT RESERVOIR] key is used to drain the reagent reservoirs located on the Flow Panel of the Analyzer. When the [REAGENT RESERVOIR] key is pressed, the following soft key labels are displayed as shown in Figure 9.2:

EMPTY DIL/SHEATH FILL DIL/SHEATH	(The key alternates between the selections.)
EMPTY HGB LYSE FILL HGB LYSE	(The key alternates between the selections.)
EMPTY WBC LYSE FILL WBC LYSE	(The key alternates between the selections.)
RETURN	

The screen displays instructions for draining and filling the reagent reservoirs, as shown in Figure 9.2.

Empty Dil/Sheath

When the [EMPTY DIL/SHEATH] key is pressed, the diluent and sheath reservoirs are drained and the key toggles to [FILL DIL/ SHEATH]. When the [FILL DIL/SHEATH] key is pressed, the diluent and sheath reservoirs are refilled.

Empty HGB Lyse

When the [EMPTY HGB LYSE] key is pressed, the HGB lyse supply tubing is drained and the key toggles to [FILL HGB LYSE]. When the [FILL HGB LYSE] key is pressed, the HGB lyse supply tubing is refilled.

Empty WBC Lyse

When the [EMPTY WBC LYSE] key is pressed, the WBC lyse supply tubing is drained and the key toggles to [FILL WBC LYSE]. When the [FILL WBC LYSE] key is pressed, the WBC lyse supply tubing is refilled.

Empty/Fill Flow Cell

> **NOTE:** This procedure is performed only in the Open Mode. If necessary, press [CHANGE SAMPLER] in the RUN screen to select Open Mode.

Pressing the [EMPTY/FILL FLOW CELL] key displays a submenu showing the [EMPTY FLOW CELL] and [RETURN] keys.

When the [EMPTY FLOW CELL] key is pressed, diluent/sheath in the Optical Flow Cell is drained and the key toggles to [FILL FLOW CELL] upon completion.

When the [FILL FLOW CELL] key is pressed, the flow cell is refilled with diluent/sheath. The system must be reinitialized after this procedure (the [INITALIZATION] key is located on the second level of the DIAGNOSTICS menu).

Clean/Restore Shear Valve

> **NOTE:** This procedure is performed only in the Open Mode. If necessary, press [CHANGE SAMPLER] in the RUN screen to select Open Mode.

The [CLEAN/RES SHEAR VAL] key is used to prepare the shear valve for cleaning. Pressing the [CLEAN/RES SHEAR VAL] key displays a submenu showing the [CLEAN SHEAR VAL] and [RETURN] keys.

When the [CLEAN SHEAR VAL] key is pressed, the System partially empties the syringes, flushing the reagents out of the shear valve and associated tubing. The shear valve then rotates into the position necessary for its removal. After the shear valve has rotated, the key toggles to [RESTORE SHEAR VAL].

When the [RESTORE SHEAR VAL] key is pressed, the syringes refill the shear valve and the associated tubing, and the shear valve rotates back to its operational position.

Disable/Enable Analyzer

When the [DIS/ENAB ANALYZER] key is pressed, a submenu is displayed showing the [DISABLE ANALYZER] and [RETURN] keys.

Pressing the [DISABLE ANALYZER] key prevents the Analyzer from cycling while certain maintenance procedures are performed. After the Analyzer has been disabled, the key toggles to [ENABLE ANALYZER].

When the [ENABLE ANALYZER] key is pressed, the Analyzer is returned to the state prior to disabling.

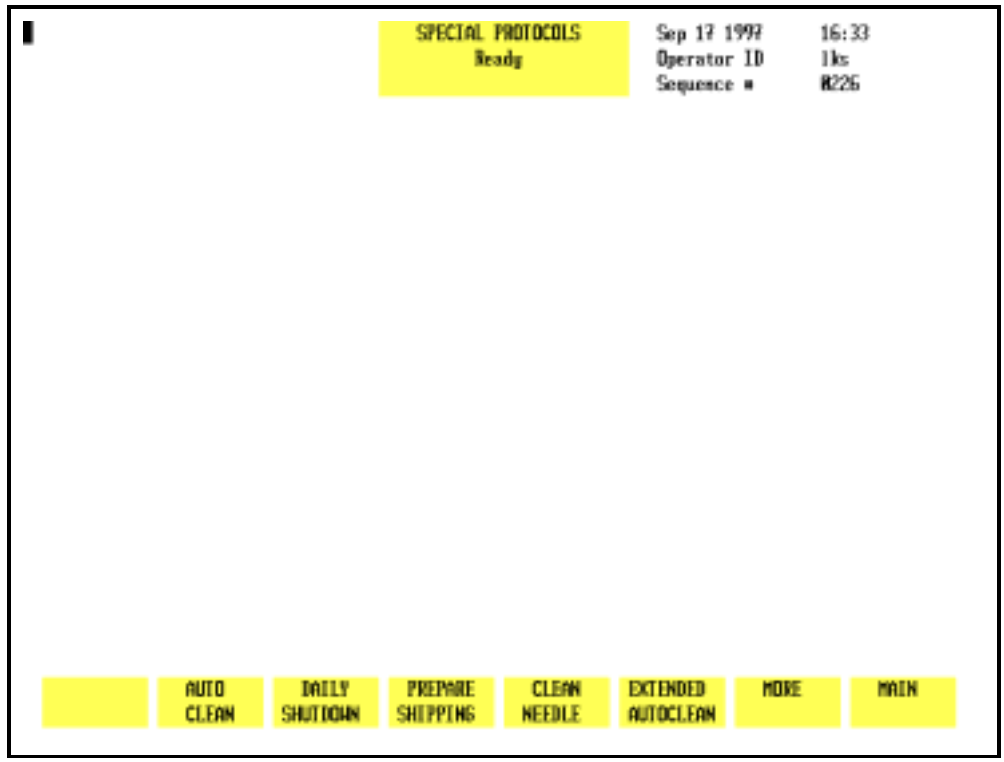

Figure 9.3: Second Special Protocols Screen

More

When the [MORE] key is pressed, the second SPECIAL PROTOCOLS screen and the following soft key labels are displayed, as shown in Figure 9.3:

AUTO CLEAN
DAILY SHUTDOWN
PREPARE SHIPPING
CLEAN NEEDLE
EXTENDED AUTOCLEAN
MORE
MAIN

Auto-Clean

NOTE: This procedure is performed only in the Open Mode. If necessary, press [CHANGE SAMPLER] in the RUN screen to select Open Mode.

The [AUTO CLEAN] key is used to initiate the Auto-Clean cycle. The Shear Valve, the RBC/PLT Mixing Chamber, the WBC Mixing Chamber, the Optical Flow Cell, the HGB Flow Cell, and all of the associated fluidics are automatically cleaned and rinsed during this cycle.

When the [AUTO CLEAN] key is pressed, the screen displays a set of instructions and the two following soft key labels:

AUTO CLEAN
RETURN

Press [AUTO CLEAN] again to activate the Auto-Clean cycle. Press [RETURN] to return to the second SPECIAL PROTOCOLS screen.

Daily Shutdown

The [DAILY SHUTDOWN] key is used to initiate the Daily Shutdown cycle. During the cycle, the fluidics are automatically drained and rinsed. At the end of the cycle, the Analyzer is placed in STANDBY. The electronic solenoid valves are automatically opened periodically while the Analyzer is in Standby to prevent the tubing from becoming pinched.

Prepare Shipping

> **NOTE:** This procedure is performed only in the Open Mode. If necessary, press [CHANGE SAMPLER] in the RUN screen to select Open Mode.

The [PREPARE SHIPPING] key is used to prepare the Analyzer for shipment or an extended period of inactivity. The cycle drains all of the reagents from the system and then rinses the fluidics with deionized water supplied by the operator.

Clean Needle

The [CLEAN NEEDLE] key is used to clean the needle in the Tower module. When the key is pressed, the needle is forcefully rinsed with diluent.

Extended Auto-Clean

> **NOTE:** This procedure is performed only in the Open Mode. If necessary, press [CHANGE SAMPLER] in the RUN screen to select Open Mode.

The [EXTENDED AUTOCLEAN] key is used to initiate the Extended Auto-Clean cycle, which is a longer version of the Auto-Clean cycle.

When the [EXTENDED AUTO CLEAN] key is pressed, the screen displays the message shown in Figure 9.9 in the ***Extended Auto-Clean*** subsection. The following soft key labels are displayed:

EXTENDED AUTO CLEAN
RETURN

Press [EXTENDED AUTO CLEAN] again to activate the Extended Auto-Clean cycle. Press [RETURN] to return to the second Special Protocols screen.

More

The [MORE] key is used to return to the first SPECIAL PROTOCOLS menu.

NOTES

Preventive Maintenance Schedule

Overview

The maintenance schedule outlined on the following page will minimize operational problems with the CELL-DYN 3200. The recommended intervals are based on instruments operating in laboratories that process samples from a general patient population. The intervals are affected by the following variables:

- Volume of samples processed
- Workload schedule
- Operating environment
- Patient population being analyzed

Each laboratory must assess its own situation and modify these recommended intervals as necessary.

⚠ **CAUTION:** Gloves should be worn during the maintenance procedures. They should be powder-free or rinsed before performing the maintenance as powder may cause instrument problems. (For example, powder may clog ports in the shear valve and cause it to leak.)

IMPORTANT: Overdue maintenance is usually indicated by an increase in imprecision of one or more of the directly measured parameters. This increase is due to carryover or dilution/sampling inconsistencies. If this occurs on more than a random basis, the appropriate maintenance should be performed more frequently.

A diagram of the analyzer flow panel is included to assist in component identification and location.

If you encounter trouble performing any of these maintenance procedures, contact the Abbott Customer Support Center at: 1 (800) CELL DYN.

To order any parts, accessories, or consumables, refer to ***Appendix B — Parts and Accessories.***

Preventive Maintenance Schedule

The following procedures should be performed at the scheduled time intervals or more often, depending on usage, as determined by each individual laboratory.

Keep a record of routine maintenance and parts replacement to ensure proper equipment care and to assist Abbott Customer Service Representatives and Abbott Field Service Representatives in diagnosing instrument problems.

Daily

Run Auto-Clean Cycle
Clean Closed Sample Aspiration Needle
Clean Closed Sample Tower

Weekly

Clean Sample Loader and Racks
Clean Exterior of Open Sample Probe
Check Sample Transfer Pump Tubing

Monthly

Clean Fan Filters
Run Extended Auto-Clean

Semi-Annual

Clean Printer

Nonscheduled Maintenance Procedures

Clean Shear Valve
Clean Interior of Open Sample Aspiration Probe
Unclog Open Sample Aspiration Probe
Clean Interior of Closed Sample Aspiration Needle
Unclog Closed Sample Aspiration Needle
Clean Syringes
Clean HGB Flow Cell
Clean Bar Code Reader Window
Clean Reagent Lines
Replace Open Sample Aspiration Probe
Replace Closed Sample Aspiration Needle
Replace Tubing in Sample Transfer Pump

Replace Tubing in Normally Closed Valves
Replace Syringes
Replace Fuse
Prepare for Shipping or Extended Period of Non-Use

Flow Panel Components

Figure 9.4 illustrates the Flow Panel components that may be inspected, cleaned, or replaced during normal maintenance procedures.

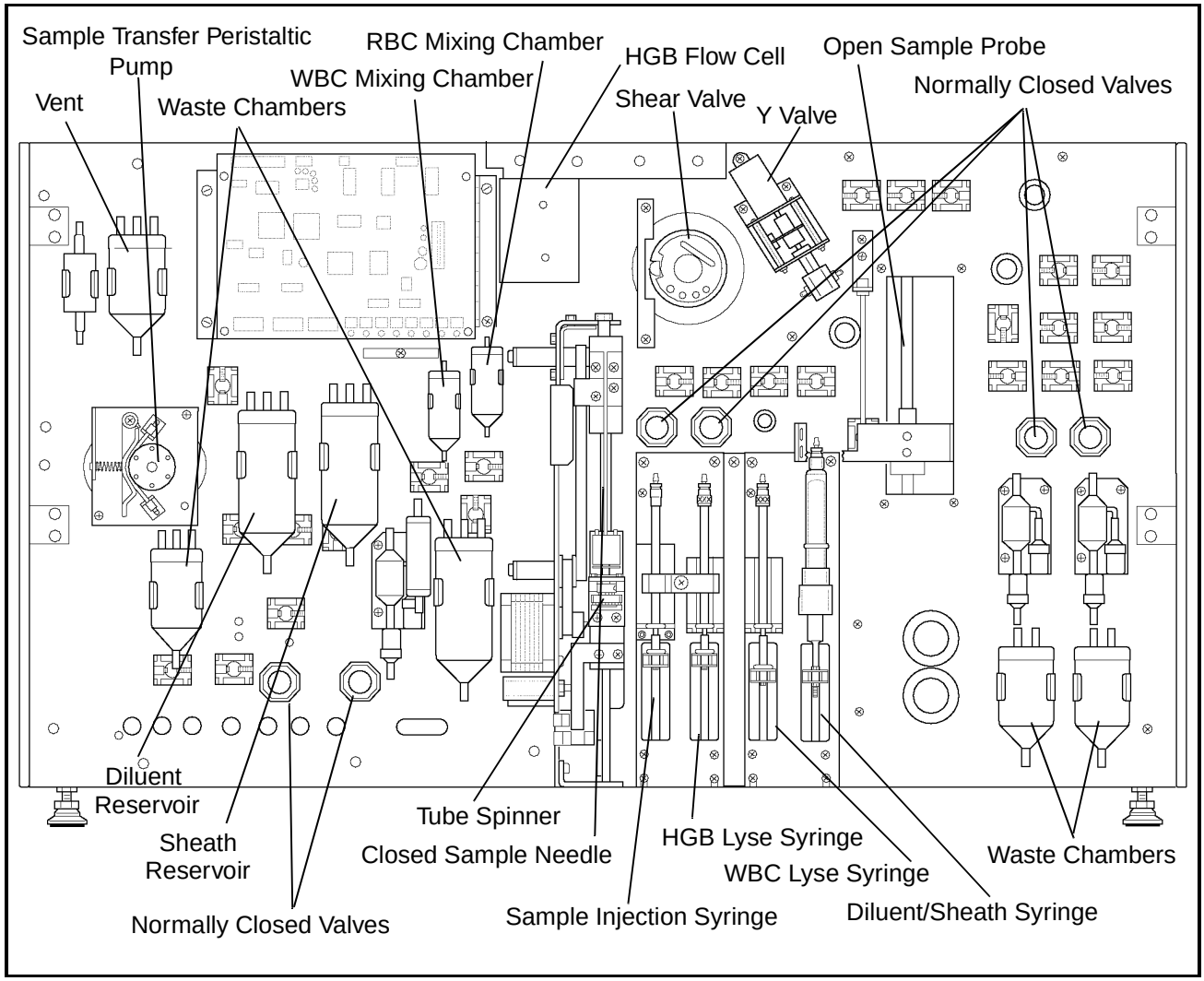

Figure 9.4: Analyzer Flow Panel Components

Decontamination Procedures

The OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) requires the decontamination of laboratory equipment prior to servicing or shipment:

- Decontaminate the instrument by performing the Auto-Clean cycle. This cycle flushes all of the fluid pathways with reagents to purge any waste from the fluid pathways. The Open Mode Sample Probe and the Closed Sample Needle (CS Model) or Sample Loader Needle (SL Model) are automatically rinsed after every cycle. The surfaces of the instrument should be wiped with a nonabrasive detergent solution to remove any soiling, then wiped with a tuberculocidal disinfectant, such as a 10% solution of filtered bleach.

If the instrument is to be shipped, it must be decontaminated prior to shipment. This is accomplished by pressing the [PREPARE FOR SHIPPING] key in the SPECIAL PROTOCOLS menu. Instructions for this procedure are given in section ***Preparation for Shipping or Extended Period of Non-Use.***

Daily Maintenance Procedures

Auto-Clean

WARNING: Potential Biohazard. Wear gloves, lab coats, and safety glasses and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

The **Auto-Clean Cycle** is a fully automated cycle designed to clean the Shear Valve, RBC/PLT Mixing Chamber, the WBC Mixing Chamber, the Optical Flow Cell, the HGB Flow Cell, Open Sample Probe, the needle in the Tower Module, and all the associated fluidics. The forward and reverse action of the peristaltic pump is used during this cycle to gently scrub and remove any fibrin or debris within the system. The Auto-Clean cycle takes approximately 11 minutes. When the [AUTO CLEAN] key is pressed, instructions are displayed on the screen, as shown in Figure 9.5.

NOTE: The Auto-Clean cycle should be run prior to performing any maintenance procedure. This ensures that all waste is purged from the fluid pathways.

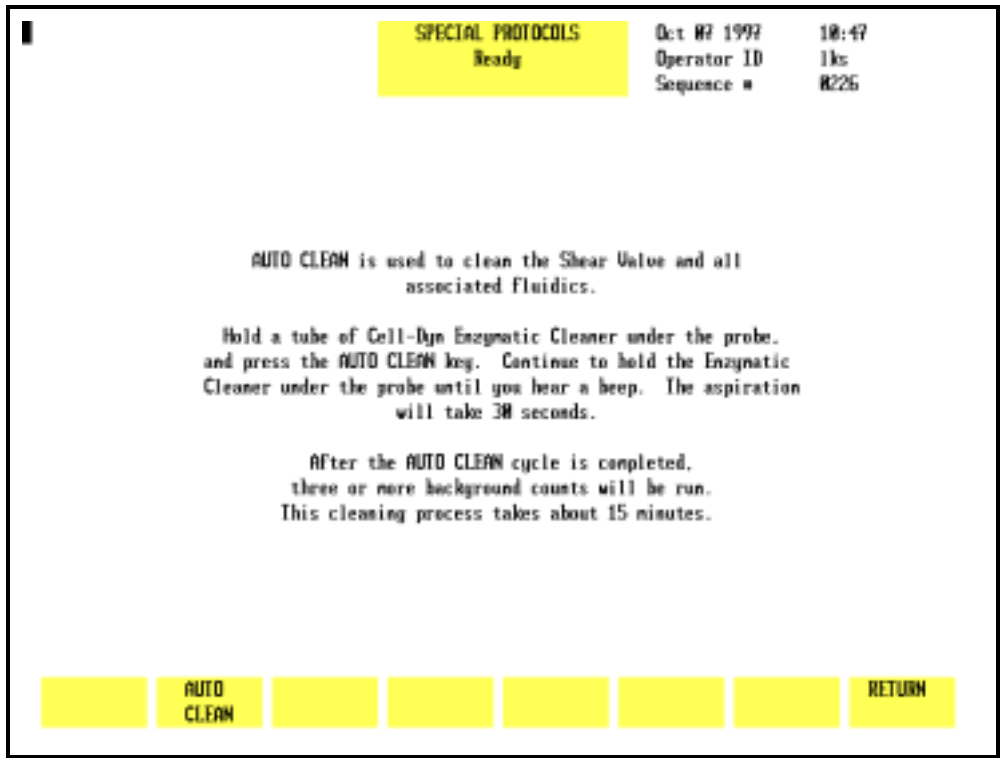

Figure 9.5: Auto-Clean Screen

Materials Required

1. CELL-DYN Enzymatic Cleaner. Enzymatic cleaner should be used at room temperature but stored at a temperature between 2°C and 8°C (36°F and 46°F).
2. Clean VACUTAINER® tube or other clean container.
3. DYN-A-WIPE™ Lint-free pads (or other lint-free pads).
4. Deionized water.

Procedure—CS and SL Models

1. The instrument should be in the Open Mode. If necessary, press the [CHANGE SAMPLER] key in the RUN screen to select the Open Mode.
2. With the Wash Block raised, carefully wipe the outside of the Open Sample Aspiration Probe and the bottom of the Wash Block with a DYN-A-WIPE™ (or other lint-free pad) that has been dampened with diluted enzymatic cleaner (one part distilled water to one part enzymatic cleaner).
3. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [MORE] to access the Auto-Clean function.

4. Press [AUTO CLEAN]. Instructions for performing the procedure are displayed on the screen.
5. Dispense approximately 1.5 mL of Enzymatic Cleaner into the VACUTAINER® or other clean container and hold the container under the probe.
6. Press [AUTO CLEAN] to activate the cleaning cycle.

   NOTE: Do not press the Touch Plate. The Auto-Clean cycle is only initiated by the [AUTO CLEAN] key.

7. Continue to hold the container under the probe until a beep tone is heard. Remove the container and discard the remaining enzymatic cleaner.
8. When the Auto-Clean cycle is completed, press [MAIN] followed by [RUN] to go to the RUN screen.
9. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.

Clean Aspiration Needle

The Aspiration Needle in the Tower Module should be cleaned regularly to remove protein buildup or debris and reduce the possibility of a blockage. The procedure for cleaning the needle differs slightly on the CS and SL models. Both procedures are described below.

WARNING: Potential Biohazard. The needle in the Tower Module is sharp and potentially contaminated with infectious materials. Avoid any contact with the needle.

Materials Required

1. CELL-DYN Enzymatic Cleaner
2. Diluent
3. Three empty VACUTAINER® tubes
4. Gloves, lab coat, and safety glasses

Procedure — SL Model

1. Aliquot approximately 2 mL of Enzymatic Cleaner into one of the VACUTAINER® tubes.
2. Aliquot approximately 2 mL of diluent each into the other two VACUTAINER® tubes.
3. If necessary, press the [CHANGE SAMPLER] soft key in the RUN screen to select the Closed Mode.
4. In the RUN screen, press [SPECIMEN TYPE] followed by [BACKGROUND].
5. Place the enzymatic cleaner tube followed by the two diluent tubes in a Sample Loader rack.

   NOTE: A convenient way to perform this procedure is to add the tubes to the end of the last run of the day.

6. Position the rack on the load side of the Sample Loader (refer to Figure 13.7 if necessary). Make sure the Tower Cover is closed.

   CAUTION: The Sample Loader will not operate unless the Tower Cover is in place.

7. Press the [START LOADER] key to initiate processing.
8. Audible beep tones indicate that processing is completed.
9. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics,* Subsection: *Troubleshooting Guide*)**.
10. When cleaning is completed, remain in the RUN screen to process patient samples or press [MAIN] to return to the MAIN MENU.

Procedure — CS Model

1. Aliquot approximately 2 mL of Enzymatic Cleaner into one of the VACUTAINER® tubes.
2. Aliquot approximately 2 mL of diluent each into the other two VACUTAINER® tubes.
3. If necessary, press the [CHANGE SAMPLER] soft key in the RUN screen to select the Closed Mode.

4. In the RUN screen, press [SPECIMEN TYPE] followed by [BACKGROUND].
5. Open the Tower Door, place the tube containing the Enzymatic Cleaner in the Door Assembly, and close the door.
6. Press the Touch Plate to run the Enzymatic Cleaner. When aspiration is finished, remove the tube.
7. Repeat steps 5 and 6 using the two diluent tubes.
8. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide*)**.

Closed Sample Tower

Daily cleaning of the Tower Module is recommended when the Closed Mode is used.

Materials Required

1. Cleaning solution (5 mL of 5% filtered bleach added to 5 mL of water)
2. Clean, warm water for rinse
3. DYN-A-WIPE™ Lint-free pads (or other lint-free pads)
4. Gloves, lab coat, and safety glasses

Procedure

1. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument.
2. Clean the following components with a lint-free wipe moistened with the cleaning solution prepared above.
   a. Spin mechanism, including belt if necessary
   b. Under the Wash Block if there is evidence of residue build-up
   c. Any other area that appears to have been contaminated by specimen or reagents.
3. Rinse the components using a lint-free wipe moistened with warm water.

4. Dry the components with a DYN-A-WIPE™ (or other lint-free pad).
5. When finished, reattach the Tower Cover and press it into place.

Sample Loader Tray and Tube Grippers

Daily cleaning of the Sample Loader tray and tube grippers is recommended when the Sample Loader is used.

Materials Required

1. Cleaning solution (5 mL of 5% filtered bleach added to 5 mL of water)
2. Clean, warm water for rinse
3. DYN-A-WIPE™ Lint-free pads (or other lint-free pads)
4. Gloves, lab coat, and safety glasses

Procedure

1. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument.
2. Remove any racks from the loader.
3. Clean the following components with a lint-free wipe moistened with the cleaning solution prepared above.
   a. Sample Loader tray (be sure to remove any dirt or debris that may impede the movement of the racks)
   b. Tube grippers inside the Mixing Block on the SL model (rotate the Mixing Block to gain access to the grippers)
   c. Any other area that appears to have been contaminated by specimen or reagents
   d. Periodically check the bottom of the racks to insure there is no residue of dirt build-up. Clean as necessary.
4. Rinse the components using a lint-free wipe moistened with warm water.
5. Dry the components with a DYN-A-WIPE™ (or other lint-free pad).
6. When finished, reattach the Tower Cover and press it into place.

Weekly Maintenance Procedures

WARNING: Potential Biohazard. Wear gloves, lab coats, and safety glasses and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Sample Loader and Racks

The Sample Loader surface areas and racks should be cleaned on a regular basis. Blood spills in the Sample Loader track or racks should be cleaned up immediately to allow proper movement of the racks. Weekly cleaning is recommended when the Sample Loader is used, but more frequent cleaning may be indicated by the laboratory workload.

Materials Required

1. Container (large enough to hold a rack) filled with a mild detergent solution made with warm (not hot) water
2. Clean, warm water for rinse
3. DYN-A-WIPE™ Lint-free pads (or other lint-free pads)
4. Gloves, lab coat, and safety glasses.

Procedure

1. Remove the racks from the Sample Loader.
2. Wash the racks in the detergent solution. Do not allow them to soak in the solution because the labels will come off.

   NOTE: Do not wash the racks in an automated dishwasher that operates at high temperatures because the heat may damage the racks.

3. Rinse the racks with warm water and dry thoroughly with a DYN-A-WIPE™ (or other lint-free pad).
4. Wipe the Sample Loader with a lint-free wipe moistened with water. Dry it with a DYN-A-WIPE™ (or other lint-free pad).
5. Wipe the sides of the Sample Loader with a lint-free wipe moistened with detergent solution. Wipe off the detergent solution with a lint-free wipe moistened with water. Dry the sides with a DYN-A-WIPE™ (or other lint-free pad).

Open Sample Probe Exterior Cleaning

Materials Required

1. Gloves, lab coat, safety glasses
2. CELL-DYN Enzymatic Cleaner. Enzymatic cleaner should be used at room temperature but stored at a temperature between 2°C and 8°C (36°F and 46°F).
3. DYN-A-WIPE™ lint-free pads (or other lint-free pads)
4. Deionized water

Procedure

During each run cycle, the Wash Block rinses whole blood from the outside of the Aspiration Probe. However, the exterior portion of the probe should be routinely cleaned to ensure that the Wash Block continues to move freely. This procedure can be done at any time (at least weekly) or in conjunction with other routine cleaning procedures.

WARNING: Potential Biohazard. The probe is potentially contaminated with infectious materials. Use caution when cleaning the probe.

1. With the power ON and Wash Block raised, carefully wipe the outside of the probe several times with a DYN-A-WIPE™ lint-free pad (or other lint-free pad) that has been dampened with diluted enzymatic cleaner (one part distilled water to one part enzymatic cleaner).
2. Wipe the outside of the probe with a DYN-A-WIPE™ (or other lint-free pad) that has been dampened with distilled water.
3. In the MAIN MENU, press [RUN] followed by [SPECIMEN TYPE] and [BACKGROUND].
4. Press the Touch Plate to run a background count. Run background counts until acceptable results are obtained for all background parameters.
5. Record this maintenance in your maintenance log.

Sample Transfer Pump Tubing Check

Constant pressure on the tubing under the Peristaltic Pump Wheel tends to flatten the tubing, thereby inhibiting the flow of liquid past the pump. This tubing should be checked at least weekly to ensure it is maintaining its original shape. Replace the tubing after 2000 cycles or as necessary (refer to the Peristaltic Pump Tubing Replacement procedure in **Subsection:** ***Nonscheduled Maintenance Procedures***).

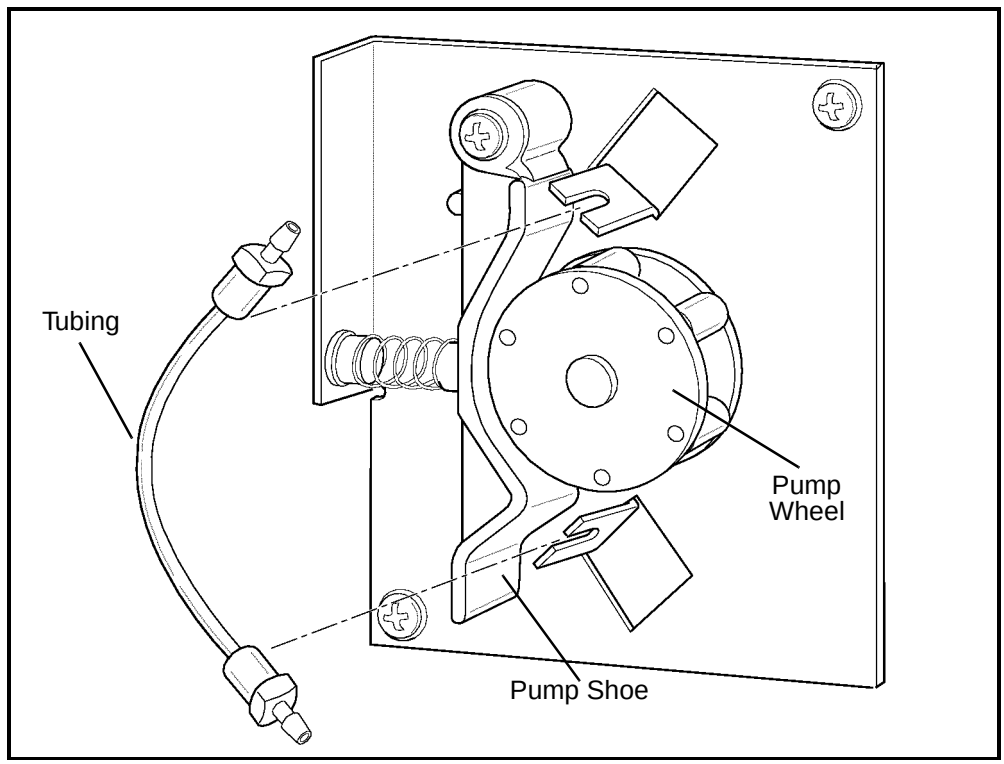

Figure 9.6: Sample Transfer Peristaltic Pump

To check the peristaltic pump tubing, follow the procedure below:

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER] to disable the Analyzer.
2. Press the upper right corner of the Left Front Cover to release the cover latch and swing the cover open.
3. Locate the Sample Transfer Pump on the left side of the Flow Panel. (Refer to Figure 9.6.)

4. Push the Pump Shoe away from the pump wheel and slip the tubing out. (Refer to Figure 9.6.)
5. Visually inspect the tubing for damage. If the tubing is damaged or flattened, change the tubing. (Refer to ***Peristaltic Pump Tubing Replacement*** later in this section.)
6. Using your fingers, massage the tubing to test its strength and resiliency and to remove any indentation caused by the wheel.
7. Push the Pump Shoe away from the pump wheel and slip the tubing back under the wheel. Make sure the tubing is securely positioned under the wheel.
8. Close the Left Front Cover and press into place.
9. Press [ENABLE ANALYZER] to return the instrument to the READY state.
10. Press [MAIN] to return to the MAIN MENU.

Monthly Maintenance Procedures

WARNING: Potential Biohazard. Wear gloves, lab coats, and safety glasses and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Fan Filter Cleaning

There are two air inlet filters that clean the air entering the Analyzer. One filter is located on the left side panel and the other is mounted on the back panel. Each filter requires monthly removal and cleaning to maintain a constant, unrestricted air flow.

> **NOTE:** More frequent cleaning is required whenever the instrument is located in a particularly dusty or warm area.

Figures 9.7 and 9.8 show the location of the rear panel fan and left side panel fan respectively.

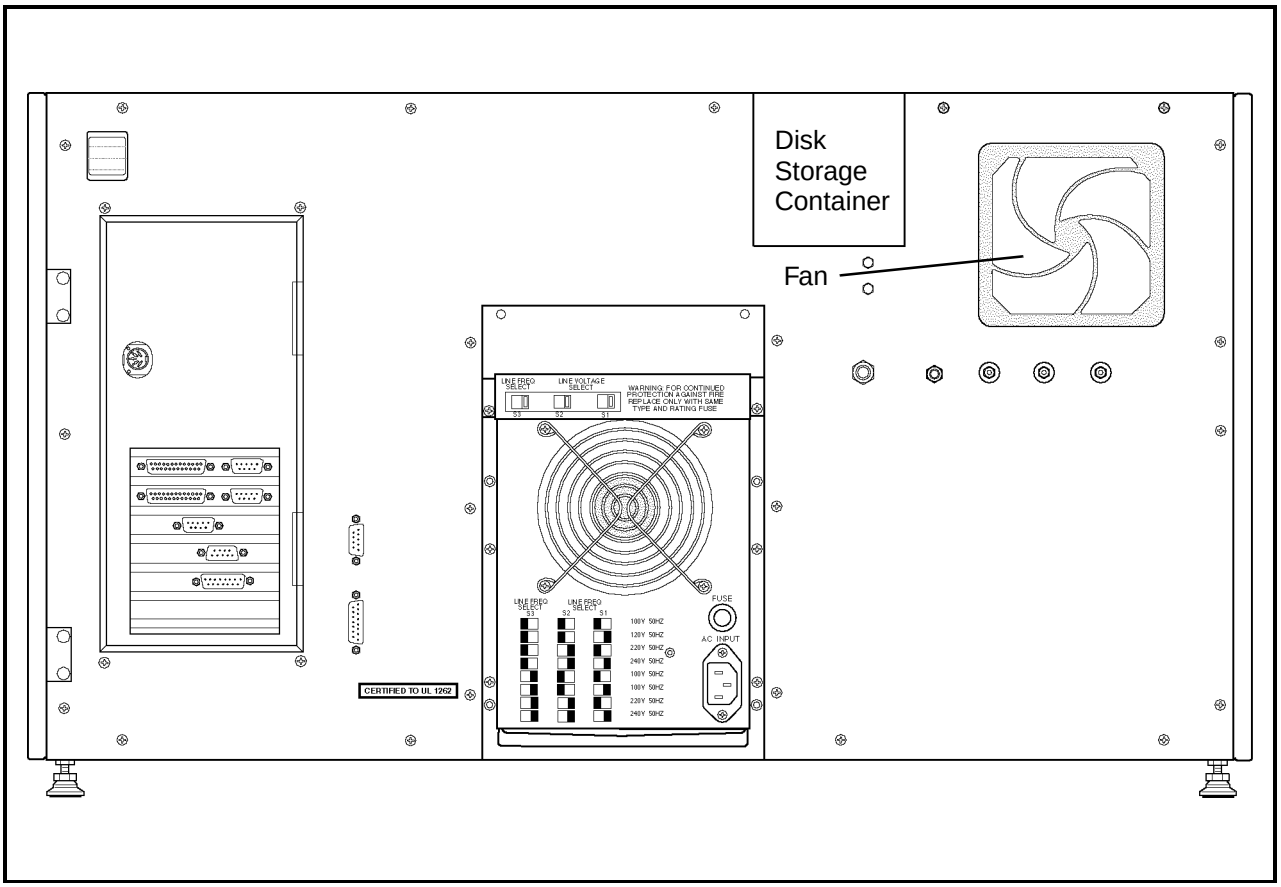

Figure 9.7: Analyzer Rear Panel

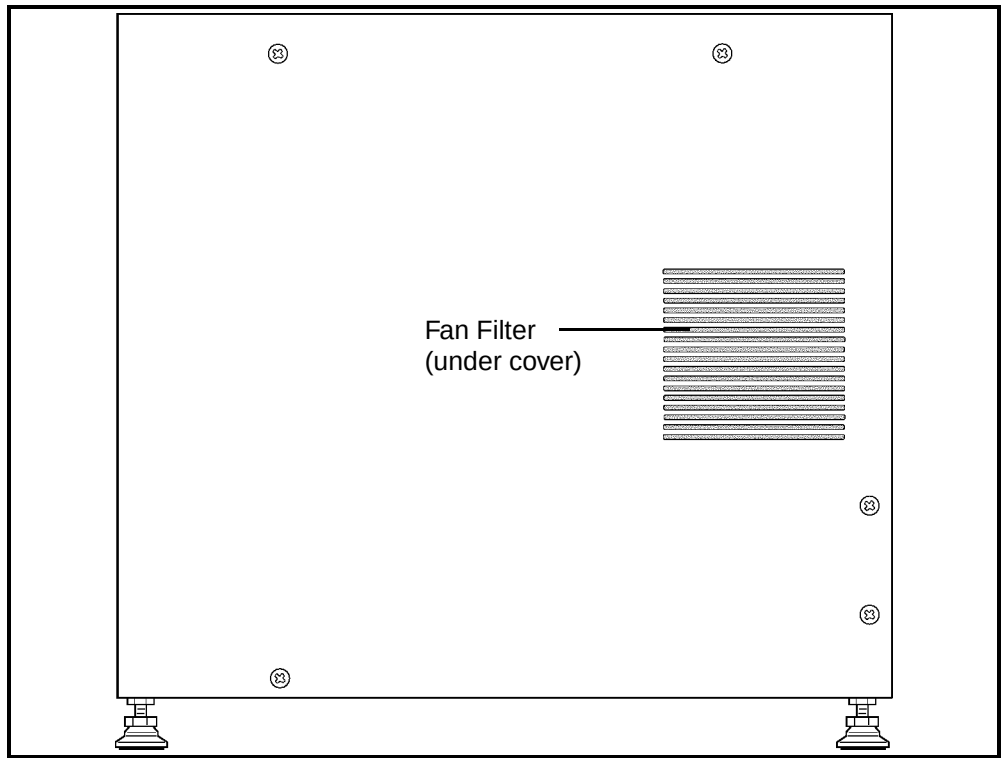

Figure 9.8: Analyzer Left Side Panel

Materials Required

1. Running water
2. DYN-A-WIPE™ lint-free pads (or other lint-free pads)
3. Small vacuum cleaner (optional)
4. Phillips-head screwdriver (#2)

Filter Cleaning Procedure

1. Perform the Daily Shutdown procedure to place the instrument in STANDBY. (Refer to ***Daily Shutdown Procedure*** in **Section 5: *Operating Instructions***.)
2. Turn the power switch to OFF.
3. Locate the Fan Filter on the rear panel. (Refer to Figure 9.7.)
4. Snap off the plastic frame which holds the filter in the mounting bracket.

5. To gain access to the Fan Filter on the left side, the Left Side Panel must first be removed. Using the Phillips-head screwdriver, unscrew the two upper and two lower screws holding the Left Side Panel to the frame and remove the panel. (Refer to Figure 9.8.) Snap off the plastic frame which holds the filter in the mounting bracket.
6. Remove the filters and run a medium-pressure stream of warm water over them, or clean the filters by vacuuming them.
7. Blot dry the filters with a lint-free pad.
8. Reinsert each cleaned filter into its frame and snap the frames back onto their mounting brackets.
9. Replace the Left Side Panel. Do not overtighten the four screws holding the panel to the frame.
10. Turn the power switch to ON. After the instrument is initialized, press [RUN] to prime the system and place it in the READY state.
11. Record this maintenance in your maintenance log.
12. If the filter appears unusually dirty when cleaned once a month, adjust the cleaning cycle accordingly.

Extended Auto-Clean

The Extended Auto-Clean cycle is a fully automated cycle designed to clean the Shear Valve, the RBC/PLT and WBC Mixing Chambers, the Optical Flow Cell, the HGB Flow Cell, the needle in the CS or SL model, and all the associated fluidics. The forward and reverse action of the peristaltic pump is used during this cycle to gently scrub and remove any fibrin or debris within the system.

The Extended Auto-Clean cycle takes approximately 2.5 hours to complete. During this time, the instrument is not available to process samples or manipulate data. (When the process is complete, the instrument is automatically put in the STANDBY state.) The cycle may be canceled after 15 minutes by pressing the [CANCEL] key, which is displayed at this time.

> **NOTE:** Once the Extended Auto-Clean cycle has been started, it cannot be cancelled.

Information on performing the Extended Auto-Clean procedure is displayed on the screen. (Refer to Figure 9.9.)

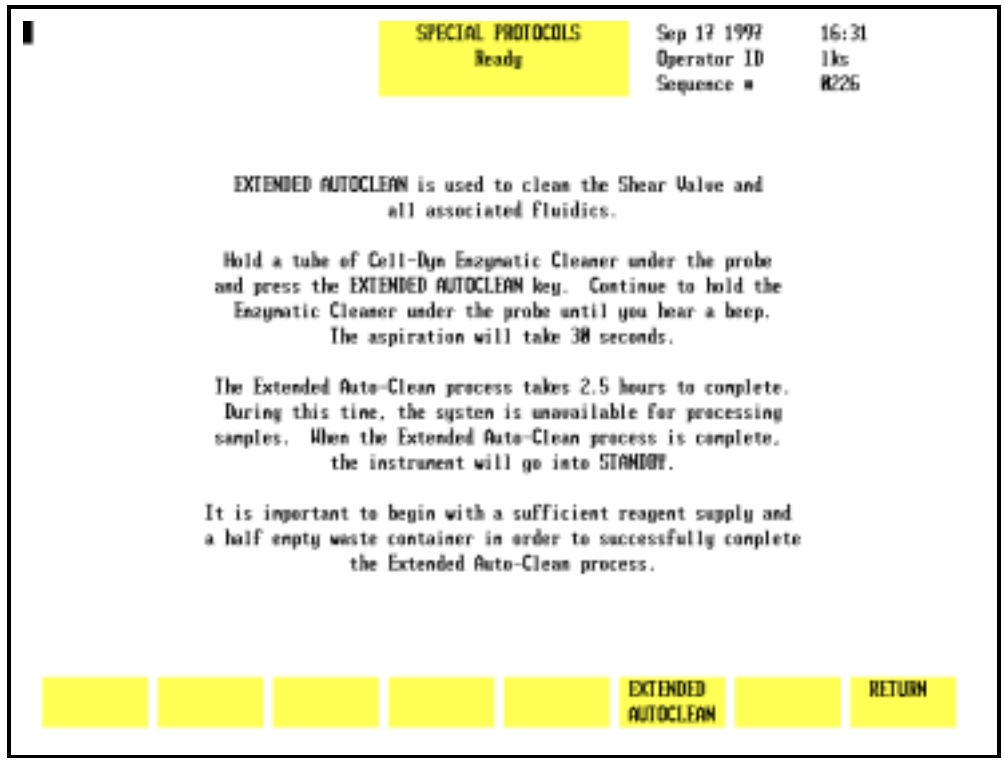

Figure 9.9: Special Protocols: Extended Auto-Clean Screen

Materials Required

1. CELL-DYN Enzymatic Cleaner (L/N 99644-01)
2. Clean test tube or container
3. DYN-A-WIPE™ lint-free pads (or other lint-free pads)
4. Warm water

Procedure

1. Make sure the Open Sampler mode is selected.
2. Carefully wipe the outside of the Open Sample Aspiration Probe and the bottom of the Wash Block with a DYN-A-WIPE™ (or other lint-free pad) dampened with warm water and a few drops of CELL-DYN Enzymatic Cleaner. Wipe any dried reagent or blood off the bottom of the wash block.
3. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [MORE] and [EXTENDED AUTOCLEAN].
4. Follow the instructions shown on the screen. (Refer to Figure 9.9.)

5. Dispense approximately 1.5 mL of Enzymatic Cleaner into a clean container and hold the container under the probe. Raise the container until the end of the probe is completely immersed in the solution.
6. Press [EXTENDED AUTOCLEAN] again to activate the cleaning cycle.

   NOTE: Do not press the Touch Plate. The Extended Auto-Clean cycle is initiated only by the [EXTENDED AUTOCLEAN] key.

7. Continue to hold the container under the probe until a beep tone is heard. Remove the container and discard the remaining Enzymatic Cleaner.

   NOTE: The complete procedure takes approximately 2.5 hours and may not be terminated.

8. At the end of the 2.5 hours, the instrument automatically goes into the STANDBY state. Press [RUN] to bring the Analyzer from STANDBY to READY and to prepare it for running samples.
9. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.
10. Record this maintenance in your maintenance log.

Semiannual Maintenance Procedures

Printer Cleaning

Every six months (or after about 300 hours of operation) turn the printer OFF, disconnect the power cord and use a clean, dry cloth to dust the area around the carriage shaft and platen or ink cartridge (depending on type of printer). Be sure to remove any loose particles of paper. Do not use solvents or strong detergents on the cabinet.

Refer to the printer manual that accompanied your printer for detailed cleaning and maintenance instructions.

NOTES

Nonscheduled Maintenance Frequency

Table 9.1: Nonscheduled Maintenance Frequency

Procedure	Frequency
Clean Shear Valve	When it is suspected of being the source of imprecision.
Clean Interior of Open Sample Aspiration Probe	When it is suspected of being the source of imprecision
Unclog Open Sample Aspiration Probe	When a blockage is suspected
Clean Interior of Closed Sample Aspiration Needle	When it is suspected of being the source of imprecision
Unclog Closed Sample Aspiration Needle	When a blockage is suspected
Clean Sample Injection Syringe, WBC and HGB Lyse Syringes	When they are suspected of being the source of imprecision
Clean Diluent/Sheath Syringe	When it is suspected of being the source of imprecision
Clean HGB Flow Cell	When Auto-Clean has not cleared away a restriction, or an organic buildup is suspected of causing any of the following: 1. Elevated HGB results 2. HGB imprecision
Clean Bar Code Reader Window	When particle buildup on the window interferes with bar code reading
Clean Reagent Lines	When contamination is suspected
Replace Open Sample Aspiration Probe	1. When the probe is bent 2. When there is a nonremovable obstruction in the probe

Replace Closed Sample Aspiration Needle	1. When the needle is bent 2. When there is a nonremovable obstruction in the needle
Replace Tubing in Sample Transfer Pump	When it shows signs of indentation or flattening
Replace Tubing in Normally Closed Valves	When it shows signs of indentation or flattening
Replace Syringes	1. When it develops a leak 2. When it is suspected of being a source of imprecision
Replace Fuse	1. When the fuse fails 2. When changing the power setting from 110/120 VAC to 220/240 VAC or vice versa
Prepare for Shipping or Extended Period of Non-Use	1. When shipping the instrument 2. When storing the instrument 3. Before an extended period of non-use 4. When the entire flow system is suspected of being the source of bacterial or fungal contamination

Nonscheduled Maintenance Procedures

WARNING: Potential Biohazard. Wear gloves, lab coats, and safety glasses and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

Shear Valve Cleaning

Regular cleaning of the Shear Valve ensures accurate and precise performance. Any reagent or blood residue may cause the valve to leak or function improperly. The shear valve assembly is depicted in Figure 9.10.

The shear valve is made of a ceramic material and consists of three separate sections — front, center and rear. The rear and front sections are connected to the CELL-DYN 3200 by tubing that should not be removed.

NOTE: The center section is not connected by tubing and must be handled carefully, as it will break if it is dropped. Care should be taken to avoid chipping, scratching or otherwise damaging any of the sections.

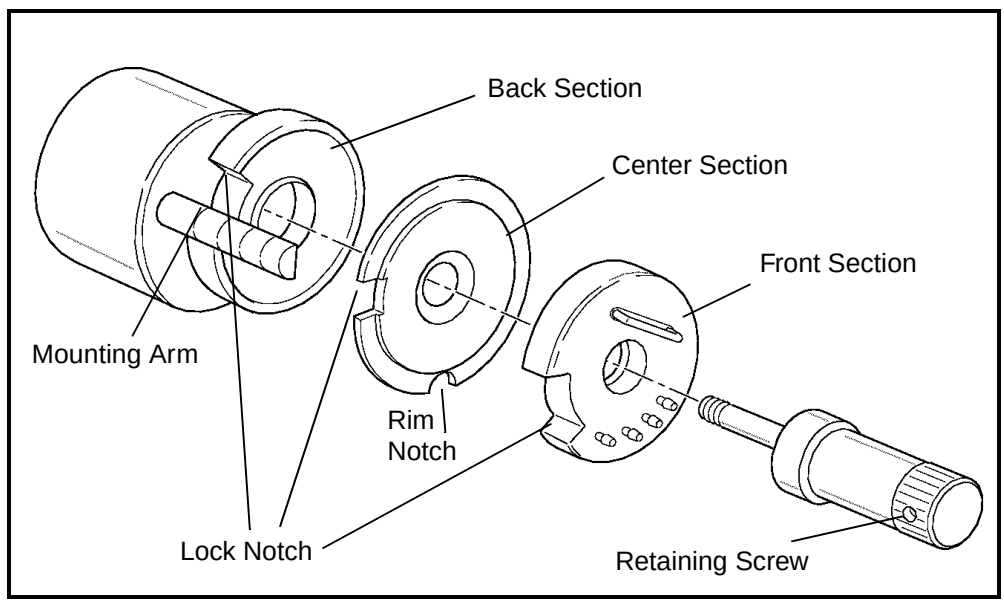

Figure 9.10: Shear Valve Assembly

Materials Required

1. DYN-A-WIPE™ Lint-free pads (or other lint-free pads)
2. A container of warm, deionized water
3. Gloves, lab coat, and safety glasses

Procedure

1. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument (Tower Door on the CS model must be open).
2. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [CLEAN/RES SHEAR VAL] and [CLEAN SHEAR VAL]. This prepares the Shear Valve for removal and puts the Analyzer into the NOT READY mode.
3. Place a clean gauze pad on the shelf in front of the Shear Valve.
4. Turn the Shear Valve Retaining Screw counterclockwise until it can be removed. (Refer to Figure 9.10.)
5. Pull the front section forward until it is free of the mounting arm. Place the front section with its attached tubes on the clean gauze pad.
6. Pull the center section forward until it is free of the mounting arm. Keep the rear section in place.

   NOTE: Be careful to keep a firm grip on the center section, as it is not attached to the front or back sections and it may break or crack if dropped.
7. Place the center section in a container of warm water and allow it to soak for the remainder of the cleaning procedure.

   NOTE: Do not soak the center section in bleach because the bleach may damage the ceramic.
8. Clean the mounting arm with a DYN-A-WIPE™ (or other lint-free pad) dampened with warm water to remove any blood or residue. Wipe the guide dry.
9. Pull out the rear section of the Shear Valve and wipe the inner surface with a DYN-A-WIPE™ (or other lint-free pad) dampened with warm water. Use care to avoid scratching the inner surface. Wipe both surfaces dry with a lint-free wipe.

   NOTE: Hold the section by the edges to avoid getting fingerprints on the inner surface.

10. Align the lock notch of the rear section with the mounting guide. Carefully slide this section back onto the mounting arm as far as it will go. Avoid crimping any of the attached tubing.
11. Remove the center section from the warm water, wipe the surfaces with a DYN-A-WIPE™ (or other lint-free pad) dampened in warm water and dry it with a lint-free wipe.
12. Place the center section aside on a clean gauze. Use care to avoid scratching the surfaces.
13. View each surface under reflective light to confirm that it is clean, dry, and free of lint and fingerprints.
14. Align the lock notch of the center section with the mounting guide. (Lock notch faces the mounting guide, smaller rim notch faces down.) Carefully slide this section back onto the mounting arm until it is flush with the rear section. (Refer to Figure 9.10.)

    CAUTION: Damage to the instrument can occur if the center section is installed backwards. *Be certain* the rim notch faces down.

15. Wipe the inner surface of the front section with a DYN-A-WIPE™ (or other lint-free pad) dampened with warm water. Use care to avoid scratching the inner surface. Wipe both surfaces dry with a lint-free wipe.

    NOTE: Hold the section by the edges to avoid getting fingerprints on the inner surfaces.

16. Align the lock notch of the front section with the mounting guide. A pin on the inner rim should align with the groove on the mounting arm. Carefully slide this section back until it touches the center section.
17. Firmly hold the three valve sections together and replace the Shear Valve Retaining Screw. Turn the screw clockwise until it stops.
18. Remove any cleaning materials (such as gauze pads) that may have been left on the instrument.
19. Press [RESTORE SHEAR VAL] to return the Shear Valve to its operating position and to return the instrument to the READY state.
20. Reattach the Tower Cover (Tower Door on the CS model must be open) and press into place.

21. Press [RETURN] followed by [MAIN] and [RUN] to display the RUN screen.
22. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.
23. Record this maintenance in your maintenance log.

Open Sample Probe Interior Cleaning

The Open Sample Aspiration Probe is thoroughly cleaned whenever the Auto-Clean cycle is performed. However, additional cleaning may be required from time to time. The probe may be cleaned manually, as described below.

Materials Required

1. Gloves, lab coat, and safety glasses
2. Syringe (10 cc or larger) with at least 3” of 1/32” silicone tubing attached to the tip
3. Small needle-nose pliers or similar tool
4. Small beaker or container
5. Deionized water
6. Cleaning solution (5 mL of 5% filtered bleach added to 5 mL of water)

Procedure

WARNING: Potential Biohazard. The probe is sharp and potentially contaminated with infectious material. Avoid contact with tip of probe.

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].
2. Locate the tubing attached to the top of the Open Sample Probe. (Refer to Figure 9.11.) Place a small beaker or container under the probe to catch the rinse solution. (Hint: Attach one end of a length of 1/32” tubing to the aspiration end of the probe and the place the other end of the tubing in the beaker to prevent splashing.)

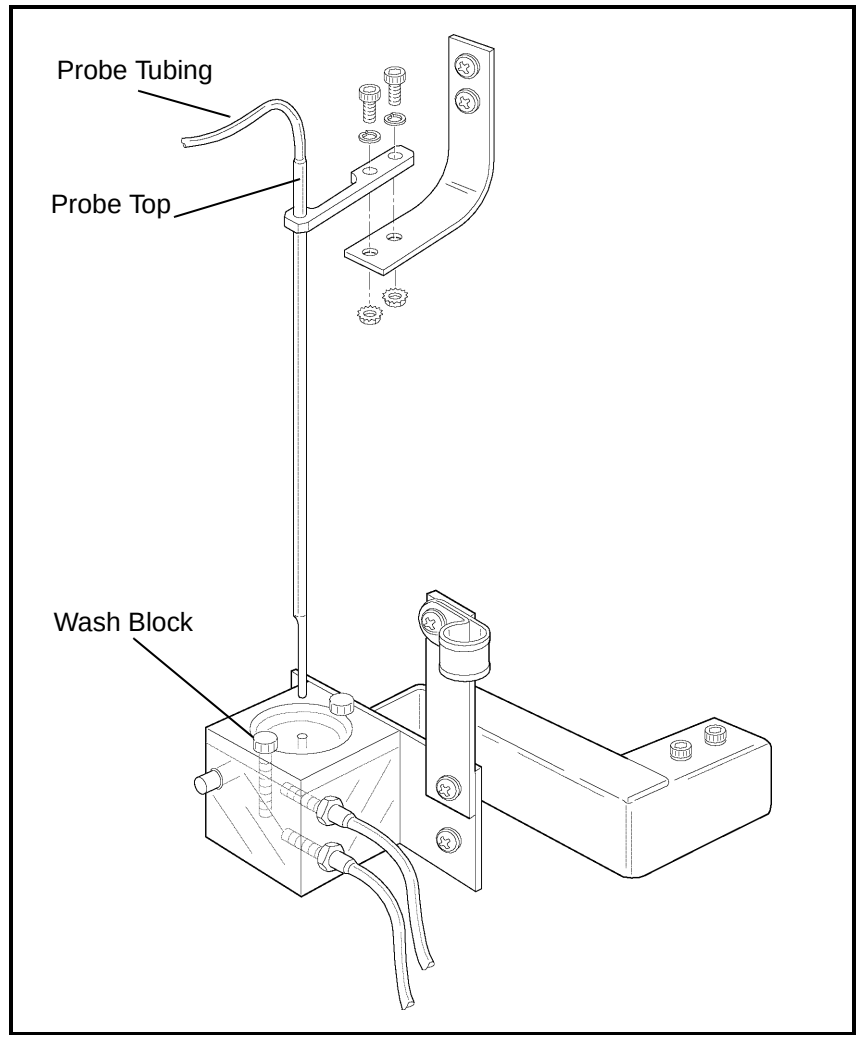

Figure 9.11: Open Sample Probe Assembly

3. Hold the probe firmly with one hand and with the other hand use the pliers to carefully work the tubing up and off the top of the probe.
4. Use a syringe with 1/32" (internal diameter) tubing attached. Fill the syringe with the cleaning solution prepared earlier. Insert the tubing attached to the syringe over the top of the probe and inject the solution to flush the probe.
5. Fill the same syringe with deionized water and inject the water into the probe from the top to rinse the probe. Repeat the procedure three times to thoroughly rinse the probe.

NOTE: Empty the container or tube between rinses as necessary.

6. Hold the probe steady and reinsert the tubing over the top. Use the pliers to carefully work the tubing down the probe. Be sure the tubing is firmly seated on the probe. (Remove any tubing that may have been placed on the aspiration end of the probe.)

   NOTE: Wetting the top portion of the probe will allow the tubing to slide more easily.

7. Be sure to remove the beaker containing the rinse solution from the instrument.
8. Press [ENABLE ANALYZER] followed by [RETURN] and [MAIN] to return to the MAIN MENU.
9. Press [RUN] followed by [SPECIMEN TYPE] and [BACKGROUND].
10. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics,* Subsection: *Troubleshooting Guide)***.
11. Record this maintenance in your maintenance log.

Unclogging the Open Sample Aspiration Probe

If a blockage is suspected, it may be cleared using the procedure described above in ***Open Sample Probe Interior Cleaning***.

Closed Sample Needle Interior Cleaning

The Aspiration Needle in the Tower Module should be cleaned regularly to remove protein buildup or debris and reduce the possibility of a blockage. In addition to the Auto-Clean method, use the procedure described below for cleaning the needle in the Tower Module.

Materials Required

1. Gloves, lab coat, and safety glasses
2. Syringe (10 cc or larger) with at least 3" of 1/32" silicone tubing attached to the tip
3. Small needle-nose pliers or similar tool
4. Small beaker or container (for SL model); empty, open VACUTAINER® tube (for CS model)
5. Deionized water
6. Cleaning solution (5 mL of 5% filtered bleach added to 5 mL of water)

Procedure

WARNING: Potential Biohazard. The sample needle is sharp and potentially contaminated with infectious material. Avoid contact with the tip of the needle.

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].
2. For the CS model, follow the procedure in step *a* below. For the SL model, follow the procedure in step *b* below.
   a. CS model: Press the window on the Tower Cover to release the cover latch. With the Tower Door open, lift the cover up and off the instrument. Place a small beaker or container on the shelf directly under the Aspiration Needle to catch the rinse solution. The container should be small enough to fit in the Door Assembly compartment when the door is closed. DO NOT attempt to fit a length of tubing over the needle point.

b. SL model: Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument. Remove any racks that may be under the Tower Module. Place a small beaker or container under the Aspiration Needle to catch the rinse solution. DO NOT attempt to fit a length of tubing over the needle point.

3. Locate the Aspiration Tubing and Vent Tubing attached to the top of the Closed Sample Aspiration Needle. (Refer to Figure 9.12.)

   NOTE: The Aspiration Needle consists of two separate needles joined together, one for venting and one for aspiration. The vent needle is the shorter of the two and faces the instrument. Note that the tubing attached to the opening at the top of the vent needle leads to a vent chamber on the left side of the Tower Module, while the tubing attached to the opening at the top of the aspiration needle leads to Y-valve located between the Shear Valve and the Open Sample Probe.

4. Hold the needle firmly with one hand and with the other hand use the pliers to carefully work the Aspiration Tubing up and off the top of the needle.

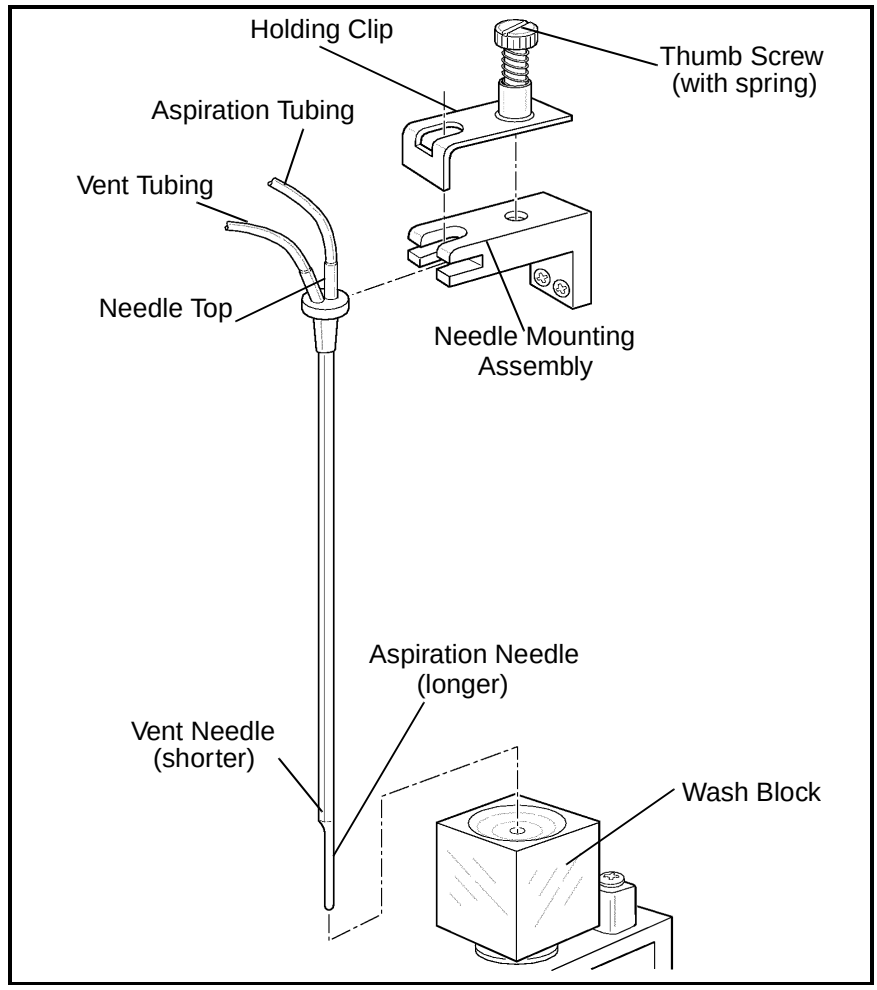

Figure 9.12: Closed Sample Needle

5. Use a syringe with 1/32" (internal diameter) tubing attached. Fill the syringe with the cleaning solution prepared earlier. Insert the tubing attached to the syringe over the top of the Aspiration Needle and inject the solution to flush the needle.

6. Fill the same syringe with deionized water and inject the water into the needle from the top to rinse it. Repeat the procedure three times to thoroughly rinse the needle.

   NOTE: Empty the container between rinses as necessary.

7. Hold the needle steady and reinsert the Aspiration Tubing over the top. Use the pliers to carefully work the tubing down. Be sure the tubing is firmly seated on the needle.

NOTE: Wetting the top portion of the needle will allow the tubing to slide more easily.

8. Be sure to remove the container from under the Aspiration Needle.
9. Reattach the Tower Cover (Tower Door on the CS model must be open) and press into place.
10. Press [ENABLE ANALYZER] followed by [RETURN] and [MAIN] to return to the MAIN MENU.
11. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.
12. Record this maintenance in your maintenance log.

Unclogging the Closed Sample Aspiration Needle

If a blockage is suspected, it may be cleared using the procedure described above in ***Closed Sample Needle Interior Cleaning***.

Syringe Cleaning

There are two syringe assemblies, each containing two syringes, on the Flow Panel of the CELL-DYN 3200 system. The syringe assemblies are depicted in Figure 9.13.

Syringes should be cleaned one at a time to ensure that each syringe is replaced in the correct position. Replace each syringe after it is cleaned and then remove the next one to be cleaned. Instructions for removing, cleaning, and replacing the Sample Injection, WBC Lyse, and HGB Lyse Syringes are given below. Instructions for removing, cleaning, and replacing the Diluent/Sheath Syringe are given in subsection ***Diluent/Sheath Syringe Cleaning***.

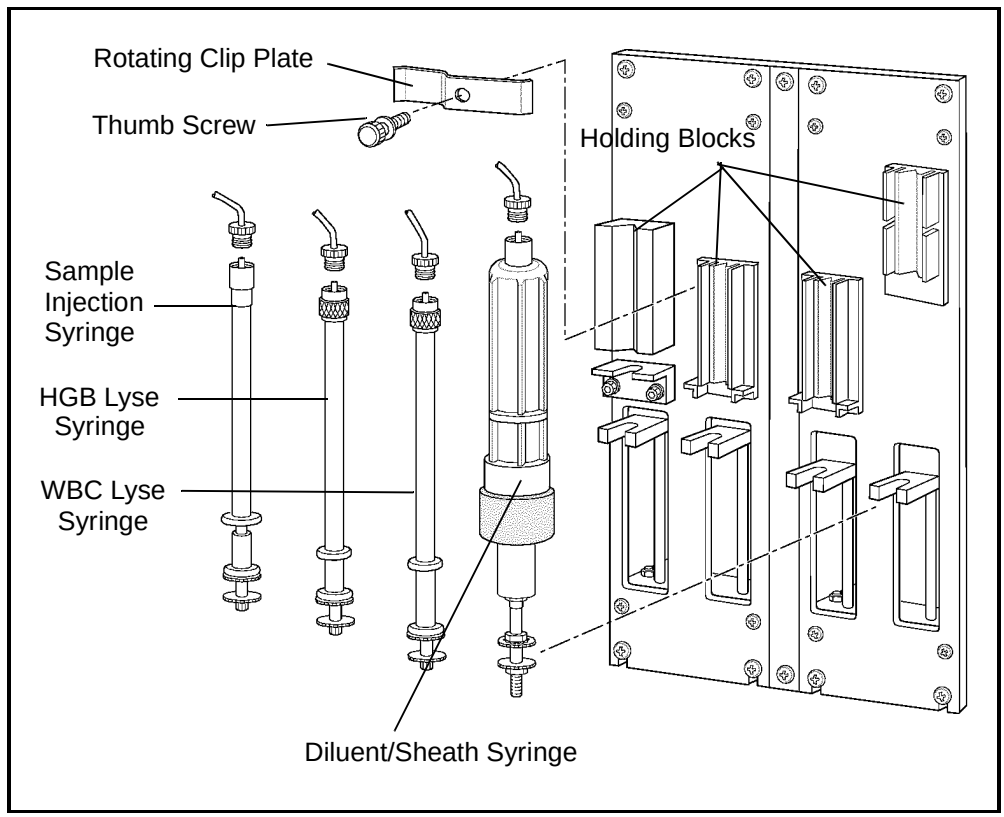

Figure 9.13: Syringe Assemblies

Materials Required

1. A large container filled with approximately 500 mL of warm, deionized water
2. DYN-A-WIPE™ lint-free pads (or other lint-free pads)
3. Distilled water
4. Small container of each reagent to refill the clean syringes
5. Phillips-head screwdriver (#2)

Disabling the Analyzer

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].

Procedure—Sample Injection Syringe

1. To gain access to the syringe assemblies, press the upper left corner of the Right Front Cover to release the cover latch. Swing the cover open. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument.
   a. On the CS model, remove the four Phillips-head screws holding the Front Skirt to the instrument and remove the skirt.
2. For the two syringes on the left — Sample Injection Syringe and HGB Lyse Syringe — loosen the Thumb Screw on the rotating clip plate holding the two syringes in place. Swing the plate to a vertical position to allow access to the syringes. There is no holding plate for the two syringes on the right. (Refer to Figure 9.14.)

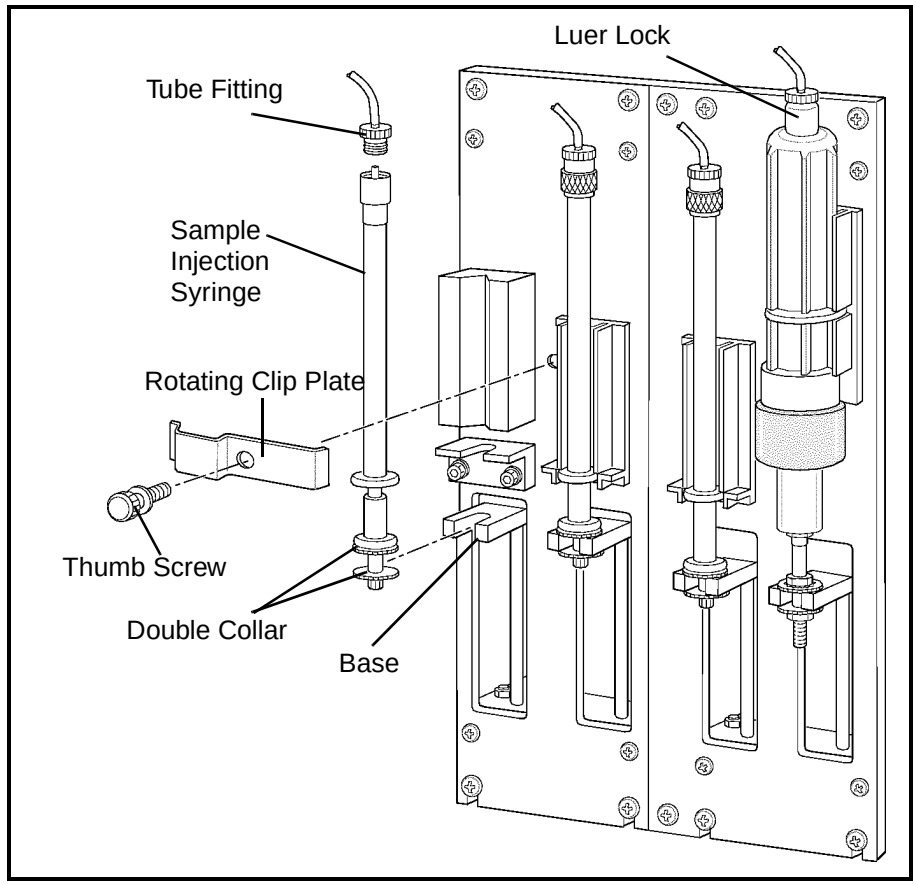

Figure 9.14: Sample Injection Syringe Removal

3. Pull the Sample Injection Syringe out of the holding block until the double collar attached to the bottom of the plunger clears the slot at the base of the mounting bracket. Note that the glass flange at the bottom of the barrel (which fits into a slot) has the narrow side facing the instrument.
4. Use one hand to grasp the tube fitting at the top of the syringe that attaches the tubing to the syringe. Use the other hand to carefully turn the syringe counterclockwise to release it from the fitting.
5. Note the level of reagent in the syringe, since the same amount of reagent will have to be added after the syringe is cleaned. Dispense the reagent into a sink or an appropriate waste container.
6. Aspirate warm water into the syringe until it is full. Continue to pull on the plunger until it is removed from the barrel.

NOTE: Do not push or pull on the plunger when the syringe is dry, as it may damage the plunger. Avoid touching the plunger because oil from the fingers may cause it to move erratically.

7. Rinse the plunger and barrel thoroughly with distilled water. Carefully reinsert the plunger into the wet barrel.
8. Refill the syringe with fresh Diluent/Sheath reagent to the same level as noted in step 5.
9. Insert the tube fitting into the top of the syringe and turn the syringe clockwise until the fitting is finger tight. Be careful not to overtighten the fitting or crimp the associated tubing.
10. Carefully adjust the position of the plunger as necessary to insert the double collar into the slot on the mounting bracket.
11. Insert the syringe into the holding block, making sure the narrow side of the glass flange on the barrel fits into the slot at the bottom of the block.
12. Return the rotating clip plate to the horizontal position, making sure it fits properly over both syringes. Tighten the Thumb Screw until the clip is secure.

Procedure—HGB Lyse Syringe

1. The procedure for removing, cleaning, and replacing the HGB Lyse Syringe is similar to the Sample Injection Syringe with two exceptions:
   a. This syringe snaps into the holding block. To remove the syringe, place one finger behind the upper portion of the barrel and one finger being the lower portion. Pull gently forward until the syringe barrel snaps free of the holding block.
   b. After cleaning, refill the syringe to the original level with fresh HGB Lyse reagent.
2. Refer to the instructions in ***Procedure—Sample Injection Syringe***.

Procedure—WBC Lyse Syringe

1. The procedure for removing, cleaning, and replacing the WBC Lyse Syringe is similar to the Sample Injection Syringe with three exceptions:
   a. There is no holding clip to be loosened.

b. This syringe snaps into the holding block. To remove the syringe, place one finger behind the upper portion of the barrel and one finger being the lower portion. Pull gently forward until the syringe barrel snaps free of the holding block.

c. After cleaning, refill the syringe to the original level with fresh WBC Lyse reagent.

2. Refer to the instructions listed in ***Procedure—Sample Injection Syringe***.

Procedure—Diluent/Sheath Syringe

Like the other three syringes on the CELL-DYN 3200 system, the Diluent/Sheath Syringe is cleaned only as necessary.

Materials Required

1. A large container filled with approximately 500 mL of warm, deionized water
2. DYN-A-WIPE™ lint-free pads (or other lint-free pads)
3. Distilled water
4. Small container of each reagent to refill the clean syringes
5. Phillips-head screwdriver (#2)

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].
2. To gain full access to the syringe assemblies:
   a. Press the upper left corner of the Right Front Cover to release the latch. Swing the cover open. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument (Tower Door on the CS model must be open).
   b. On the CS model, remove the four Phillips-head screws holding the Front Skirt to the instrument and remove the skirt.
   c. The skirt on the SL model has two removable sections adjacent to the Flow Panel. Remove the section on the right side of the Flow Panel by lifting it up and off its holding pins.

3. Locate the Diluent/Sheath Syringe (refer to Figure 9.15). Note that the plastic barrel of this syringe has four vertical edges, two of which fit into grooves on the holding block, and a circular plastic flange which also fits into a groove on the holding block.
4. Grasp the plastic tube fitting at the top of the syringe that attaches to the Luer Lock. Carefully turn the Luer Lock on the syringe clockwise to release it from the fitting. Use the lint-free pads to absorb excess reagent.
5. Grasp the syringe barrel below the Luer Lock with one hand. With the other hand, grasp the syringe plunger below the metal band. Pull and twist one side of the syringe to remove it from the snap-in holding block.
6. Note the liquid level in the syringe so that it can be refilled after cleaning to approximately the same level.
7. Dispense the reagent into a sink or other appropriate waste container.

   NOTE: Do not pull the plunger out of the barrel. Also, do not push or pull on the plunger when the syringe is dry, as it may damage the plunger. Avoid touching the plunger, because oil from the fingers may cause it to move erratically.

8. Immerse the tip of the syringe in the container of deionized water.
9. Aspirate deionized water into the syringe until it is full, and dispense the water into a sink or other appropriate waste container. Repeat this step several times to thoroughly rinse the syringe.
10. Refill the syringe with Diluent/Sheath reagent to the level noted in Step *6*.

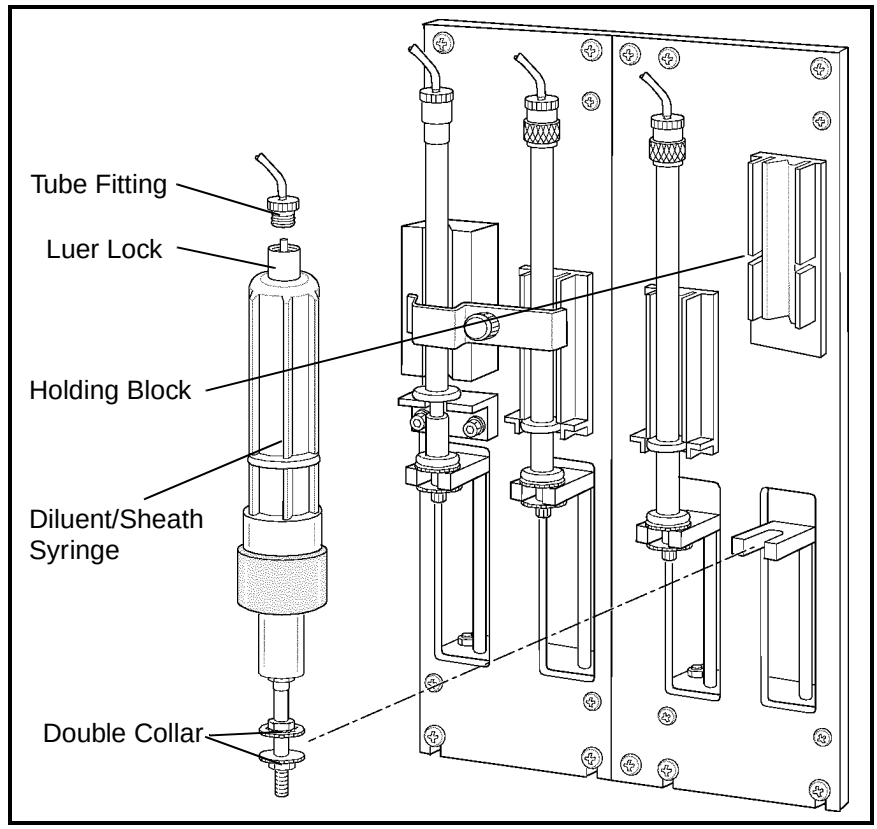

Figure 9.15: Diluent/Sheath Syringe Replacement

11. Insert the double collar on the plunger into the slot on the mounting bracket and line up the circular flange on the barrel with the slot on the holding block.
12. Insert one of the vertical edges on the barrel into a side groove on the holding block and carefully twist the barrel until the other side snaps into place. Make sure the syringe is firmly in place.
13. Place the tube fitting into the Luer Lock and turn the lock counterclockwise until the fitting is finger tight. Be careful not to overtighten the fitting or crimp the associated tubing.

Enabling the Analyzer

When all syringes have been re-installed, do the following:

1. Press [ENABLE ANALYZER] followed by [MAIN] and [RUN] to return to the RUN screen.

2. Run several background counts in the Open Mode and observe the action of the syringes during the cycle. The plungers should move smoothly up and down and should not leak.
3. After the operation of all the syringes has been verified, do the following:
   a. On the CS model, reattach the Front Skirt using the four Phillips-head screws. Do not pinch the tubing at the bottom.
   b. On the SL model, align the removable right side skirt panel over its holding pins and slide down.
   c. Reattach the Tower Cover (Tower Door on the CS model must be open) and press into place.
   d. Close the Right Front Cover and press into place.
4. Run at least three background counts. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.
5. Record this maintenance in your maintenance log.

HGB Flow Cell Manual Cleaning Procedure

NOTE: This is not a routine cleaning/maintenance procedure. It should only be performed if routine methods fail or at the request of the Abbott Customer Support Center.

Under normal circumstances, the Auto-Clean cycle is sufficient to ensure the cleanliness of the HGB Flow Cell. If the Auto-Clean cycle fails to adequately clean the flow cell, the procedure described below may be used. The HGB Flow Cell is depicted in Figure 9.16.

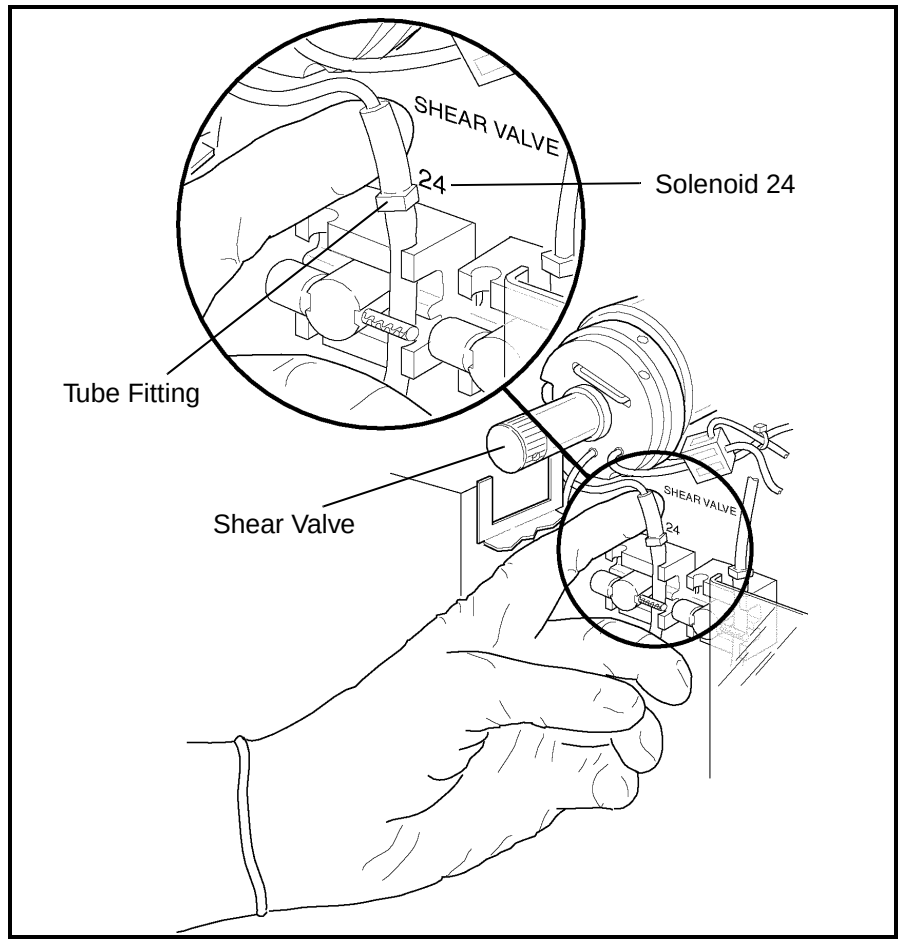

Figure 9.16: HGB Flow Cell Access Tubing

Materials Required

1. Cleaning Solution:

   Make a 25% bleach solution by adding 5 mL of bleach to 15 mL of deionized water.
2. 10 mL syringe
3. Gloves, Lab Coat, and Safety Glasses
4. Deionized water

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENABLE ANALYZER] and [DISABLE ANALYZER] to disable the Analyzer.
2. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument (Tower Door on the CS model must be open). Locate the HGB Flow Cell. (Refer to Figure 9.4.)

3. Remove the black plastic drip pan under the Shear Valve by sliding it up and off the support stand.
4. Fill the syringe with the bleach solution.
5. Locate the tubing just above solenoid #24 that attaches to the HGB Flow Cell. (Refer to Figure 9.14.) Attach a hemostat to the tubing between the fitting and the HGB Flow Cell.
6. Disconnect the tubing from the fitting and insert the syringe. Remove the hemostat. Dispense the cleaning solution into the flow cell.
7. Allow the bleach solution to remain in the flow cell for 5 minutes.
8. When the time has elapsed, aspirate the solution back into the syringe and reattach the hemostat.
9. Reconnect the tubing and remove the hemostat.
10. Reinsert the plastic drip pan by aligning the grooves on the pan with the upright support arms and sliding the pan down until it rests on the support.
11. Reattach the Tower Cover (Tower Door on the CS model must be open) and press into place.
12. Press [ENABLE ANALYZER] followed by [RETURN] and [MAIN] and [RUN].
13. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.
14. Record this maintenance in your maintenance log.

Bar Code Reader Window Cleaning

The cleaning procedure is similar for the SL and CS models even though the location of the Bar Code Reader is different.

Materials Required

1. Gloves, Lab coat, and Safety Glasses
2. Applicator swabs (non-sterile)
3. Microscope lens tissues
4. Isopropyl alcohol

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].
2. Take three applicator swabs and wrap a lens tissue around each swab.
3. Moisten one of the wrapped swabs in isopropyl alcohol.
4. Locate the Bar Code Reader Window.
5. Wipe the window with the moistened swab. Using one of the dry wrapped swabs, wipe the window dry. Use the second dry swab if necessary.
6. Visually inspect the window to ensure that blood, debris, and smudges have been removed.
7. Press the [ENABLE ANALYZER] key to bring the system to the READY state. Press [RETURN] followed by [MAIN] and [RUN] to return to the RUN screen.

Reagent Line Cleaning

The reagent lines should be cleaned if contamination is suspected. To clean the lines, refer to steps *1-4* under ***Procedure*** in subsection ***Preparation for Shipping or Extended Period of Non-Use*** later in this section.

Open Sample Probe Replacement

Materials Required

1. Gloves, lab coat, and safety glasses
2. Replacement probe
3. 7/64” Allen wrench
4. Small needle-nose pliers or similar tool

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].
2. Press the upper left corner of the Right Front Cover to release the cover latch. Swing the cover open to access the right side of the Flow Panel.

3. Locate the tubing attached to the top of the Open Sample Probe. (Refer to Figure 9.17.) Hold the probe firmly with one hand and with the other hand use the pliers to carefully work the tubing up and off the top of the probe.
4. Using the Allen wrench, remove the two hex nuts holding the Probe Bracket Arm to the Bracket Support Arm on the Probe Assembly Frame.
5. Pull the probe up and out of the Wash Block.
6. Insert the new probe into the Wash Block.
7. Place the Probe Bracket Arm on top of the Bracket Support Arm. Align the holes in the bracket arm to the holes in the Probe Assembly Frame. Insert and tighten the two hex nuts using the Allen wrench.

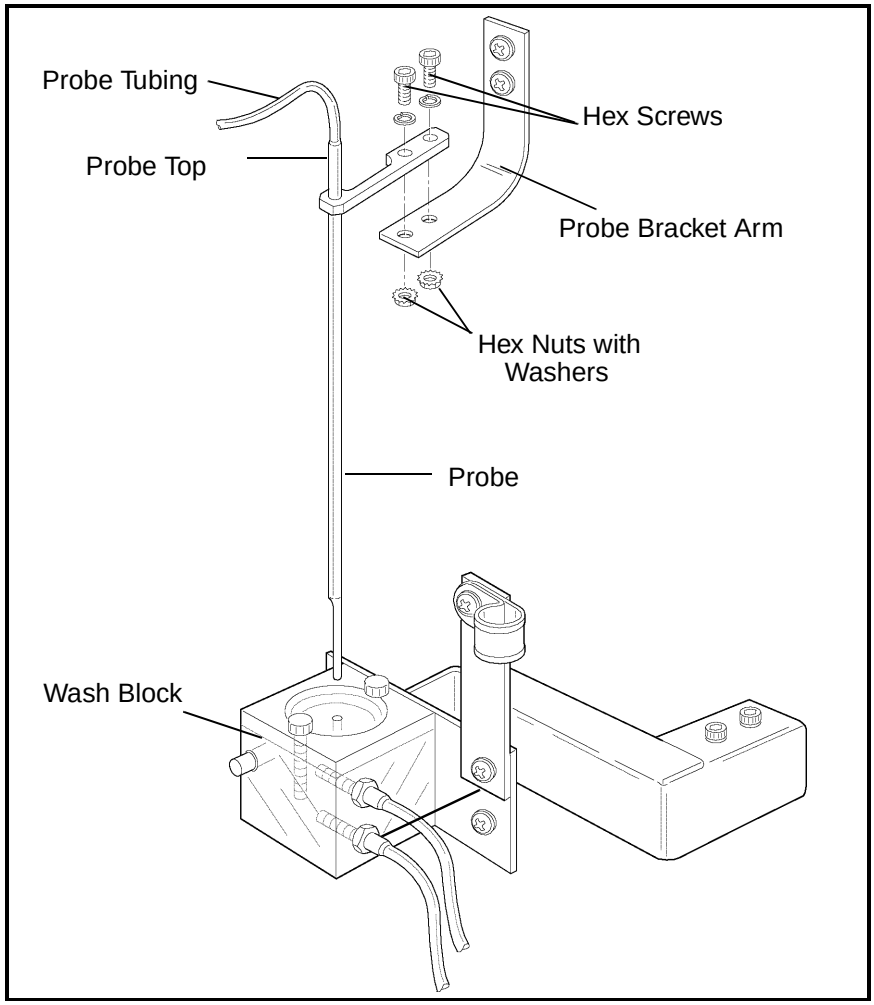

Figure 9.17: Open Sample Probe Replacement

8. Hold the probe steady and reinsert the tubing over the top. Use the pliers to carefully work the tubing down the probe. Be sure the tubing is firmly seated on the probe. (Remove the tubing from the aspiration end of the probe as necessary.)

   NOTE: Wetting the top portion of the probe will allow the tubing to slide more easily.

9. Press [ENABLE ANALYZER] followed by [RETURN], [MAIN], and [RUN].
10. Press the Touch Plate to run a background count. Observe the action of the probe assembly to ensure there are no leaks and that it is operating smoothly.
11. Close the Right Front Cover and press into place.
12. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide*)**.
13. Record this maintenance in your maintenance log.

Closed Sample Needle Replacement

If the Closed Sample Aspiration Needle becomes bent or becomes clogged (and cleaning does not remove the blockage), the needle should be replaced.

Materials Required

1. Gloves, lab coat, and safety glasses
2. Replacement needle
3. Phillips-head screwdriver (#2)
4. Small needle-nose pliers or similar tool

Procedure

WARNING: Potential Biohazard. The sample needle is sharp and potentially contaminated with infectious material. Avoid contact with tip of needle.

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].

2. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument (Tower Door on the CS model must be open).
3. Locate the Aspiration Needle.

   NOTE: The Aspiration Needle consists of two separate needles joined together, one for venting and one for aspiration. (Refer to Figure 9.12.) The vent needle is the shorter of the two and faces the instrument. Note that the tubing attached to the opening at the top of the vent needle leads to a vent chamber on the left side of the Tower Module, while the tubing attached to the opening at the top of the aspiration needle leads to Y-valve located between the Shear Valve and the Open Sample Probe.

4. Hold the needle firmly with one hand and with the other hand use the pliers to carefully work the tubing up and off the top of both ends of the needle.
5. Loosen the Thumb Screw at the top of the Needle Mounting Assembly and remove the clip holding the needle to the assembly.
6. Carefully pull the top of the needle forward until the flange clears the slot in the bracket. Lift the needle up and out of the Wash Block.
7. Place the new needle into the Wash Block, making sure the shorter part (venting needle) faces the instrument, and place the flange into its slot in the top bracket.
8. Reinstall the clip over the top of the needle and tighten the Thumb Screw.
9. Attach the vent tubing to the vent section of the needle and the aspiration tubing to the aspiration section.

   NOTE: It is important that the tubing be attached correctly.

   NOTE: Wetting the top portion of the needle will allow the tubing to slide more easily.

10. Reattach the Tower Cover (Tower Door on the CS model must be open) and press into place.
11. Press [ENABLE ANALYZER] followed by [RETURN] and [MAIN] to return to the MAIN MENU.

12. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.
13. Record this maintenance in your maintenance log.

Sample Transfer Pump Tubing Replacement

The tubing under the Sample Transfer Peristaltic Pump needs to be replaced on a regular basis to ensure proper fluid movement through the instrument. This tubing should be replaced at least every 2000 cycles. However, the frequency of replacement depends on instrument use in each laboratory. The Sample Transfer Pump is shown in Figure 9.6.

Materials Required

1. Sample Transfer Peristaltic Pump Tubing
2. Gloves, lab coat, and safety glasses

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].
2. Press the upper right corner of the Left Front Cover to release the cover latch and swing the cover open.
3. Locate the Sample Transfer Peristaltic Pump on the left side of the panel. (Refer to Figure 9.4.)
4. Push the Pump Shoe away from the pump wheel and slip the tubing out.
5. Remove the tubing from the metal brackets that hold it on each side of the rollers. (Refer to Figure 9.6.)
6. Disconnect the tubing at the plastic connector.
7. Connect the new tubing to the plastic connector.
8. Place the collars on the ends of the tubing into the metal guides. Hold the Pump Shoe open and push the tubing underneath the pump rollers.

   NOTE: Position the tubing in the center of the rollers.

9. Close the Left Front Cover and press into place.

10. Press [ENABLE ANALYZER] to bring the instrument to the READY state.
11. Press [RETURN] followed by [MAIN] and [RUN] to display the RUN screen.
12. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.
13. Record this maintenance in your maintenance log.

Normally Closed Valve Tubing Replacement

Tubing in the Normally Closed Valves should be replaced when it shows signs of indentation or flattening and is impeding the flow of fluid through the tubing.

Materials Required

1. Valve Tubing
2. Gloves, lab coat, and safety glasses
3. Phillips-head screwdriver (#2)

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [DIS/ENAB ANALYZER] and [DISABLE ANALYZER].
2. Press the upper left corner of the Right Front Cover to release the cover latch. Swing the cover open.
3. Press the upper right corner of the Left Front Cover to release the cover latch. Swing the cover open.
4. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument (Tower Door on the CS model must be open).
5. To gain access to the lower portion of the Flow Panel:
   a. On the CS model, remove the four Phillips-head screws holding the Front Skirt to the instrument and remove the skirt.

b. On the SL model, remove the four Phillips-head screws holding the Sample Loader to the instrument and pull the loader away from the Analyzer approximately 2-3 inches to allow easy access to all the Normally Closed Valves.

6. Locate all six Normally Closed Valves on the Flow Panel. (Refer to Figure 9.4.)

7. Remove the tubing from each valve.

   NOTE: On the SL model, space is limited between the inner edge of the Sample Loader and the two normally closed values on the lower left side of the Flow Panel. Use caution when accessing the tubing in these two valves.

8. Pull the tubing from the connectors on either side as shown in Figure 9.18.

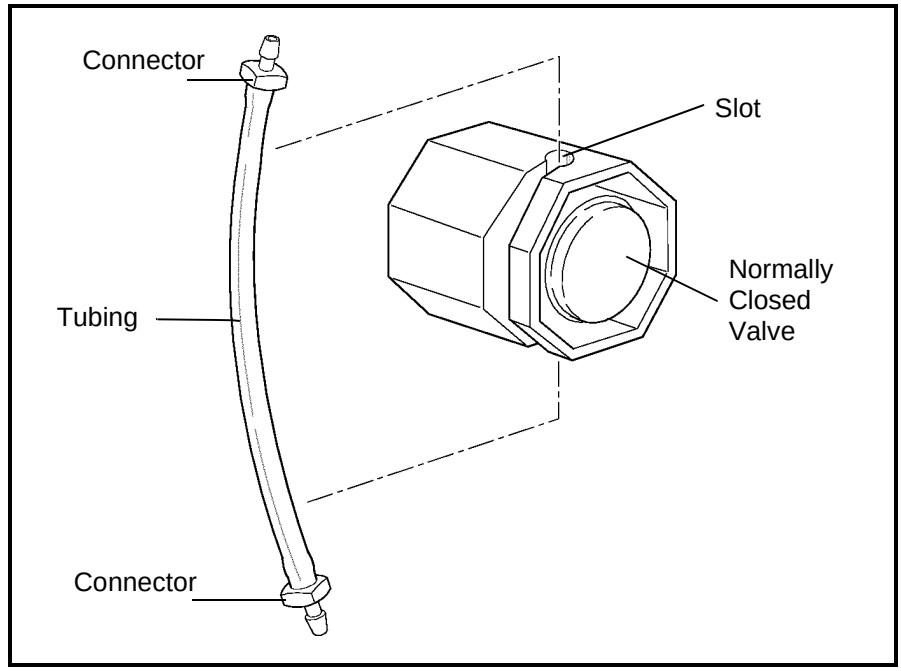

Figure 9.18: Tubing in Normally Closed Valve

9. Insert the new tubing section into both connectors. Make sure the tubing is pushed all the way into the connectors.

10. Reinsert the tubing into the slot on the valves. Work the tubing firmly back and forth until it is completely inserted into the valve and resting on the bottom of the slot. Unless the tubing is securely seated, the flow system will not function properly.

11. Close the Left Front Cover and press into place. Close the Right Front Cover and press into place. Reattach the Tower Cover and press into place (Tower Door on the CS model must be open).
    a. On the CS model, reattach the Front Skirt using the four Phillips-head screws. Do not pinch the tubing at the bottom.
    b. On the SL model, slide the Sample Loader forward using the center guide to properly align the loader with the Analyzer. Reattach the loader using the four Phillips-head screws.
12. Press [ENABLE ANALYZER] followed by [RETURN], [MAIN] and [RUN].
13. Run at least three background counts to rinse the system. Check that the background counts are acceptable before running controls or patient samples. If the counts are unacceptable, troubleshoot accordingly (refer to **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide)***.
14. Record this maintenance in your maintenance log.

Syringe Replacement

A syringe should be replaced under the following conditions:

1. There is evidence of leaking
2. Bubbles are observed in the syringe

Materials Required

1. Replacement syringe
2. Gloves, Lab coat, and Safety Glasses

Procedure

1. The procedures for removing and installing the Sample Injection Syringe, WBC Lyse Syringe, HGB Lyse Syringe, and Diluent/Sheath Syringe are described earlier in this subsection.
2. After the old syringe has been removed, select the replacement syringe in the Accessory Kit. Be sure it is the correct syringe.

3. Follow the instructions in ***Syringe Cleaning*** to reinstall the new syringe and bring the Analyzer back to the READY state.

Fuse Replacement

There are two conditions under which a fuse should be replaced:

1. If the fuse has failed, or
2. If the power setting is changed from 110/120 VAC to 220/240 VAC or vice versa.

Materials Required

1. Replacement fuse (8-amp for instruments operating at 110/120 VAC or 4-amp for instruments operating at 220/240 VAC)
2. Flathead screwdriver

Procedure

WARNING: Electrical Shock Hazard. Always turn the system OFF and disconnect the power cord before checking or changing the fuse.

1. Turn the system OFF. Locate the plastic fuse holder on the Rear Panel. (Refer to Figure 9.19.)
2. With the system OFF, insert a flathead screwdriver into the notch on the fuse holder.
3. Push in and turn the fuse holder counter clockwise to release the holder. Pull the holder with the fuse completely out of its slot.
4. Pull the fuse to remove it from the holder. Check the fuse.

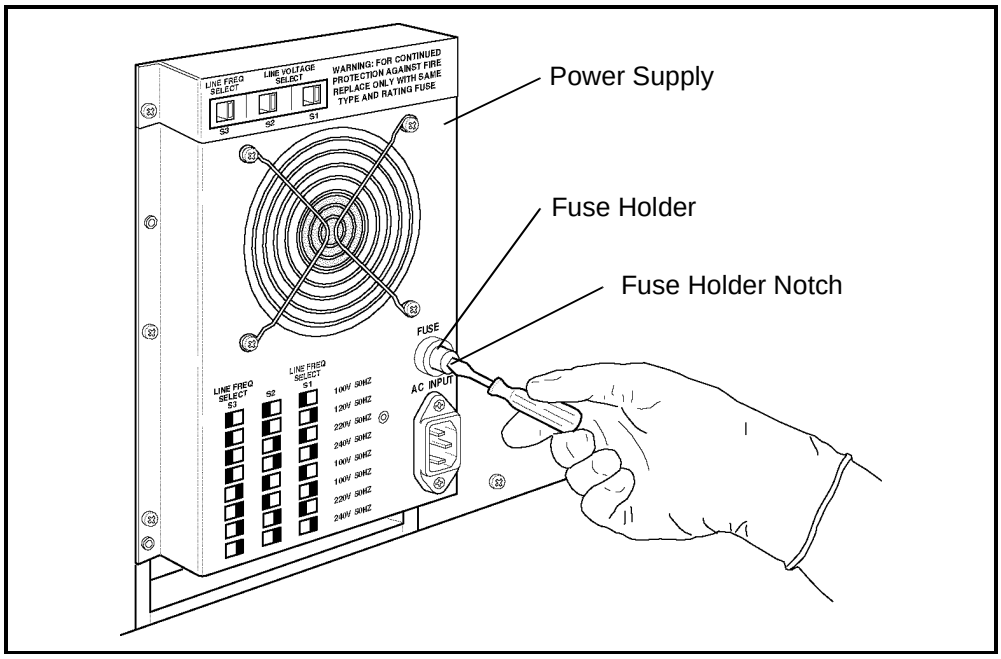

Figure 9.19: Fuse Replacement

5. If it has obviously failed, replace it. Note the amp reading on the fuse and be sure you replace it with the correct fuse (8-amp or 4-amp).

   NOTE: If the power setting is 110/120 VAC, use the 8-amp fuse. If the power setting is 220/240 VAC, use the 4-amp fuse.

6. If you are not sure if the fuse has failed, replace it and see if the problem is corrected.
7. To replace a fuse, insert the new fuse (either end) into the holder. Insert the holder (fuse first) all the way into the fuse slot.
8. Insert a flathead screwdriver into the notch on the fuse holder, push in, and turn clockwise to tighten the fuse holder.
9. Reconnect the power cord and turn the system ON.

Preparation for Shipping or Extended Period of Non-Use

The Prepare For Shipping cycle must be run if the instrument will not be used for two weeks or more. This cycle must also be run if:

a. The instrument will be shipped OR

b. The instrument will be moved (for example, to a different location within a laboratory) and movement will require detaching the reagent inlet tubing.

Salt deposits and reagent residue may clog the flow system if they are not removed prior to a prolonged period of inactivity or shipment. In addition, the tubing should be removed from behind the Peristaltic Pump and from all of the Normally Closed Valves. Leaving this tubing in the pump and in the valves while the instrument is inactive may cause it to crimp permanently. The Peristaltic Pump and Normally Closed Valves on the Analyzer flow panel are shown in Figure 9.4.

Materials Required

1. Gloves, lab coat, and safety glasses
2. Phillips-head screwdriver (#2)
3. Disinfectant (cleaning solution); 10% solution of filtered bleach in deionized water
4. Container with approximately 500 mL of deionized water.
5. Four plastic bags

   If the instrument will be shipped, the following are also needed:
6. Cardboard Disk Drive Protector
7. Shear valve dummy center section

Procedure

1. In the MAIN MENU, press [SPECIAL PROTOCOLS] followed by [MORE] and [PREPARE SHIPPING].
2. Follow the instructions displayed on the screen.
3. Press the [PREPARE SHIPPING] key again to begin the rinse cycle.

   NOTE: The message SPECIAL PROTOCOL CYCLE IN PROGRESS is displayed during the process.

4. When the process has finished, the message SPECIAL PROTOCOL CYCLE HAS COMPLETED is displayed.

If the reagent lines were cleaned because contamination was suspected and the operator intends to continue processing patient samples, do not perform any of the remaining steps. Instead, reconnect the reagent lines, go to the RUN screen, and run background counts until the counts are acceptable.

5. Turn the main power switch OFF. Also turn OFF power to the Display Monitor, printers, and any other devices attached to the instrument.
6. Press the upper right corner of the Left Front Cover to release the cover latch and swing the cover open. Press the upper left corner of the Right Front Cover to release the cover latch and swing the cover open. Press the window on the Tower Cover to release the cover latch. Lift the cover up and off the instrument (Tower Door on the CS model must be open).
    a. On the CS model, remove the four Phillips-head screws holding the Front Skirt to the instrument and remove the skirt.
    b. On the SL model, remove the four Phillips-head screws holding the Sample Loader to the instrument and pull the loader away from the Analyzer approximately 2-3 inches to allow easy access to all the Normally Closed Valves.
7. Carefully remove the tubing from all the Normally Closed Valves on the Flow Panel. Do not detach the tubing. If necessary, refer to Figure 9.4 for the location of these valves.
8. Carefully remove the tubing from behind the Sample Transfer Peristaltic Pump. Do not detach the tubing. If necessary, refer to Figure 9.6.
9. Remove all three Reagent Tubing lines, Waste Tubing line, and the Waste Sensor line from their fittings on the rear of the Analyzer. The waste line should be emptied and rinsed with disinfectant.
10. Place each length of tubing in a separate protective plastic bag and close the bag. (Keep the Waste line and Waste Sensor line together.)

    NOTE: Keep all tubing lines clean to prevent contamination.

11. Place the plastic bags containing the reagent and waste tubing in the Accessory Kit.

12. Wipe the instrument with the disinfectant prepared earlier.

If the instrument will be shipped, the following steps should also be done.

13. Insert the cardboard Disk Drive Protector into the Floppy Disk Drive (after removing any disk).
14. Remove and clean the Shear Valve as directed in ***Shear Valve Cleaning*** under ***Nonscheduled Maintenance Procedures***.
15. After the Shear Valve has been cleaned and dried, wrap the ceramic center section carefully for protection and place it in the Accessory Kit.
16. Obtain the Shear Valve Dummy Center section from the Accessory Kit. Reassemble the Shear Valve on the instrument using the dummy center section.
17. Remove the Analyzer power cord from its connector on the rear of the Analyzer and from the outlet receptacle. Place the cord in the Accessory Kit.
18. Remove the Display Monitor power cord from its outlet receptacle and secure it to the monitor.
19. Detach the Display Monitor Video Cable and the Membrane Keypad Interface Cable from their respective connectors on the Data Module and secure the cables to the monitor.
20. Detach the Data Station Interface Cable from the back of the Analyzer.
21. Close the Left and Right Front Covers and press into place. Reattach the Tower Cover and press into place (Tower Door on the CS model must be open).
    a. On the CS model, reattach the Front Skirt using the four Phillips-head screws. Do not pinch the tubing at the bottom.
    b. On the SL model, slide the Sample Loader forward using the center guide to properly align the loader with the Analyzer. Reattach the loader using the four Phillips-head screws.

CELL-DYN 3200
MAINTENTANCE LOG

Search TOC Go Back

Year	_____	Month	_____	Day of Month																												
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily	Run Auto-Clean																															
	Clean Aspiration Needle																															
	Clean Tower																															
Weekly	Clean Sample Loader																															
	Clean Exterior of Aspiration Probe																															
	Check Sample Pump Tubing																															
Monthly	Clean Fan Filters																															
	Run Extended Auto-Clean																															
Semi Annual	Clean Printer																															
Non Scheduled	Clean Shear Valve																															
	Clean Interior of Aspiration Probe																															
	Unclog Aspiration Probe																															
	Clean Interior of Aspiration Needle																															
	Unclog Aspiration Needle																															
	Clean Sample Injection Syringe																															
	Clean WBC Lyse Syringe																															
	Clean HGB Lyse Syringe																															
	Clean Diluent/Sheath Syringe																															
	Clean HGB Flow Cell																															
	Clean Bar Code Reader Window																															
	Clean Reagent Lines																															
	Replace Aspiration Probe																															
	Replace Aspiration Needle																															
	Replace Tubing in Transfer Pump																															
	Replace Tubing in NC Valves																															
	Replace Sample Injection Syringe																															
	Replace WBC Lyse Syringe																															
	Replace HBC Lyse Syringe																															
	Replace Diluent/Sheath Syringe																															
	Replace Fuse																															
	Prepare for Shipping/Non-Use																															
	Calibration																															

Overview

This section gives instructions for identifying, troubleshooting and correcting instrument problems. It is intended as a referral guide for customer troubleshooting and optimal instrument operation. The CELL-DYN® 3200 continuously monitors the status of the system and displays pertinent information in the Status Box or on the Bulletin Line. If a problem is detected, the Status Box displays FAULT: SEE DIAG or SEE SPECIAL, the Bulletin Line displays a message and the FAULT indicator light on the Analyzer status indicator panel is illuminated in red. A description of the fault can be obtained by pressing the [FAULT REPORT] key in the DIAGNOSTICS MENU screen.

The first part of this section discusses the DIAGNOSTICS MENU keys. The remainder of the section is devoted to the Troubleshooting Guide.

The Troubleshooting Guide is designed to assist the operator in identifying and resolving instrument problems. Instructions are also given for obtaining technical assistance from the Abbott Customer Support Center. The Guide includes Troubleshooting Procedures, Instructions for Component Replacement and Troubleshooting Tips and Techniques. The last part of this section describes the Instrument Messages and Fault Conditions. The tables in this section include instructions for corrective action.

NOTES

Diagnostics Menu

Overview

This subsection describes the soft keys available from the DIAGNOSTICS MENU screens. These keys enable the operator or service representative to obtain information and execute programs that assist in troubleshooting and identify corrective action.

Several keys listed are described “For Service Use Only.” The data these keys provide is meaningful only to trained field engineers and is not useful to the operator. If certain keys are pressed inadvertently, the system may have to be re-initialized.

There are five primary screens in the DIAGNOSTICS MENU. For ease of explanation, a diagram depicting the keys and functions available in each primary screen is shown below.

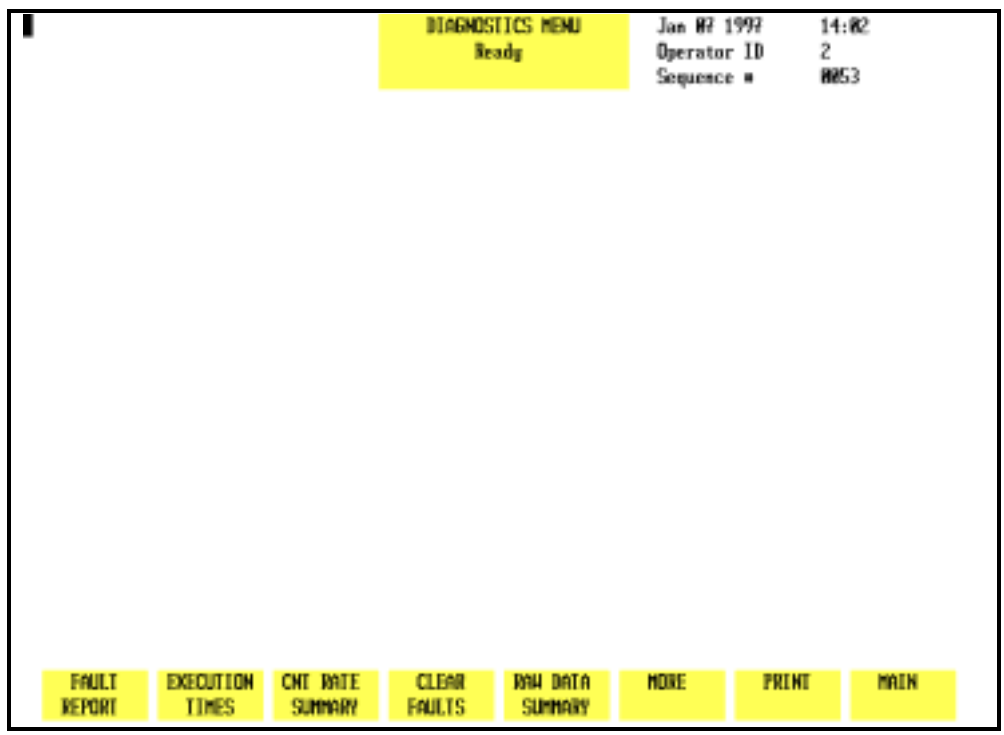

Figure 10.1: First Diagnostics Menu Screen

Diagnostics Menu Screen

The first DIAGNOSTICS MENU screen (see Figure 10.1) and the following soft key labels are displayed when the [DIAGNOSTICS] key is pressed:

FAULT REPORT
EXECUTION TIMES
CNT RATE SUMMARY
CLEAR FAULTS
RAW DATA SUMMARY
MORE
PRINT
MAIN

Fault Report

When the [FAULT REPORT] key is pressed, information regarding the pending fault is displayed on the screen. The screen displays the words `Operator Correctable Fault Report:` (see Figure 10.2) or `Fatal Fault Report:` (see Figure 10.3) and any additional information available. If there is no fault, the screen displays the words `No Fault Pending`. (See Figure 10.4.)

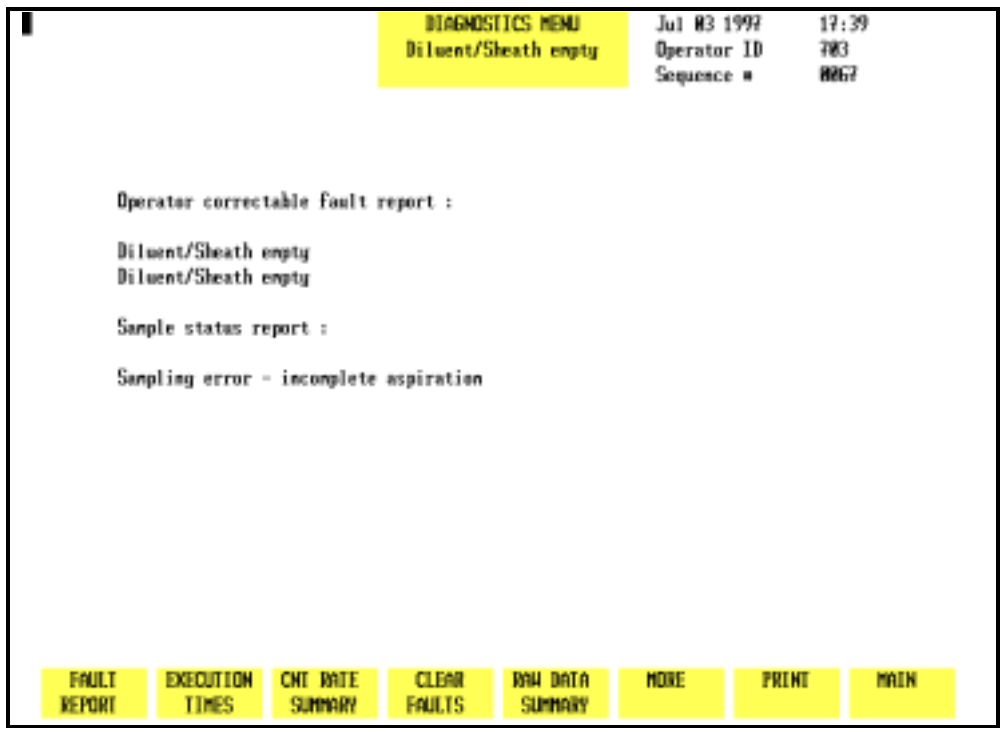

Figure 10.2: Operator Correctable Fault Report Screen

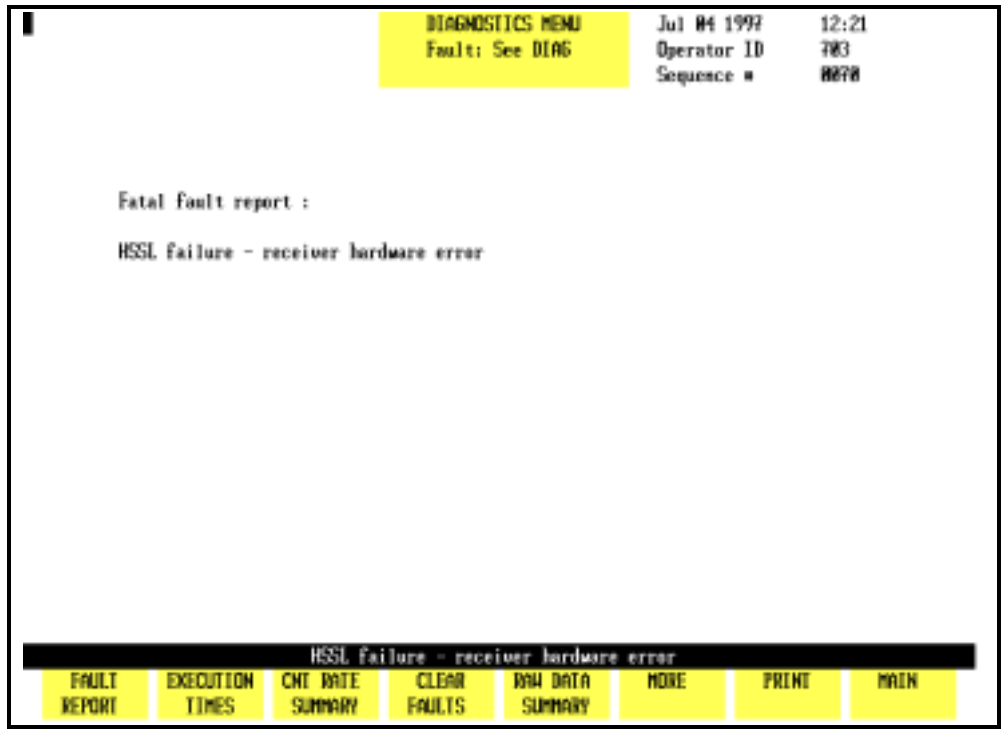

Figure 10.3: Fatal Fault Report Screen

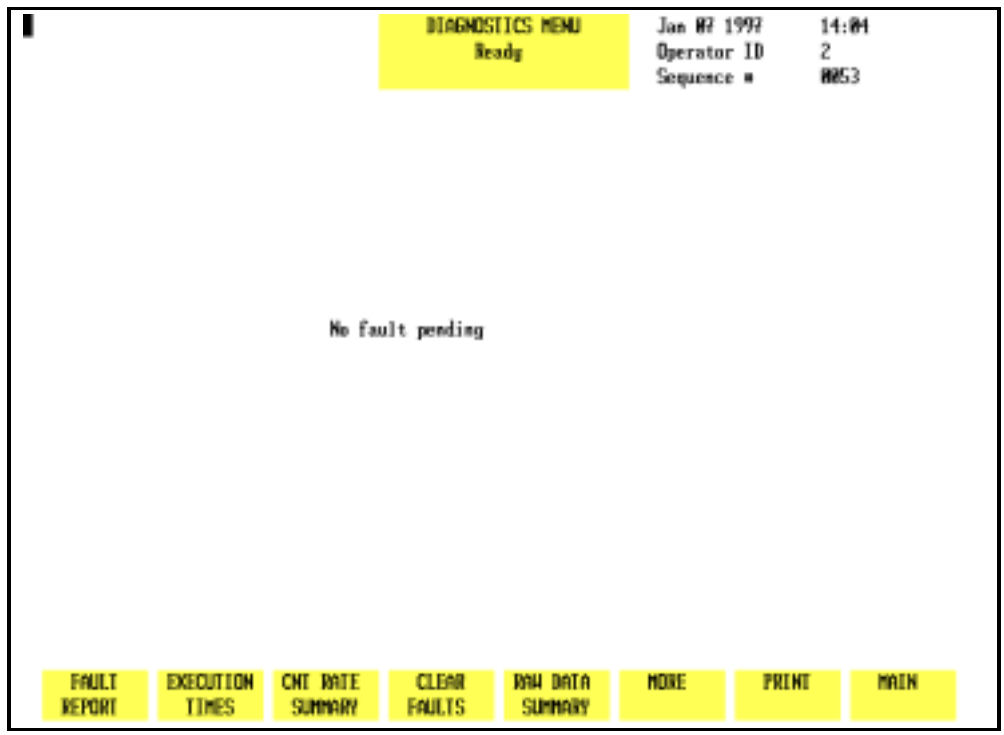

Figure 10.4: Fault Report — No Fault Pending Screen

Operator correctable faults (for example, waste full, diluent empty) can be cleared by pressing the [CLEAR FAULT] key after taking corrective action. After corrective action for a fatal fault, the system must be reinitialized by pressing the [INITIALIZATION] soft key in the second DIAGNOSTICS MENU screen (refer to Figure 10.9).

Execution Times

This key is for service use only.

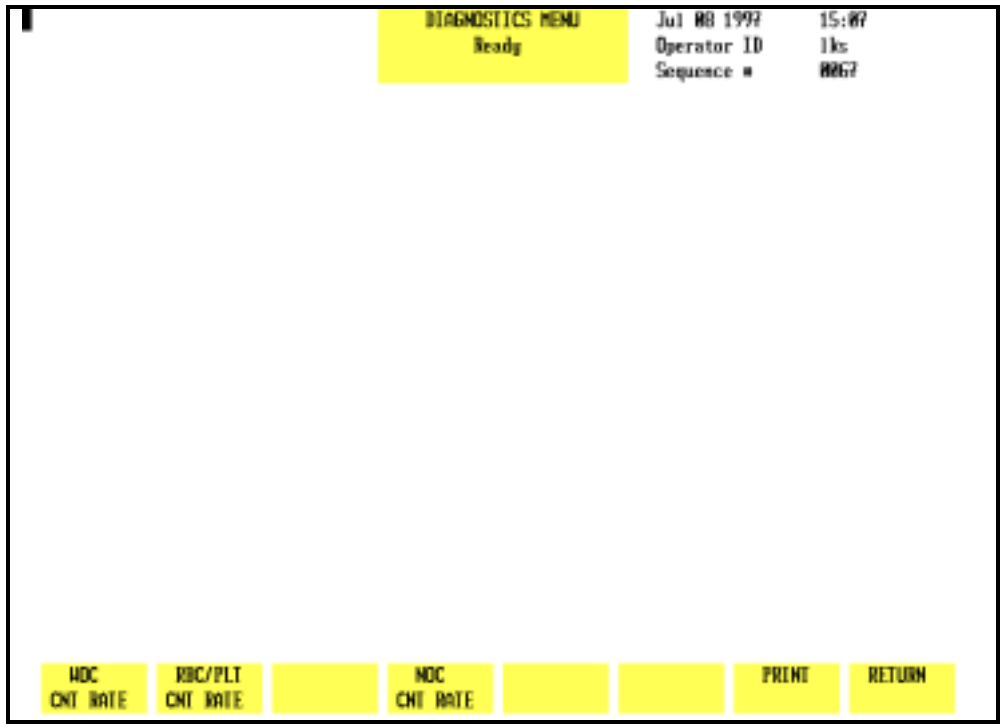

Figure 10.5: Count Rate Summary Screen

CNT Rate Summary

When the [CNT RATE SUMMARY] key is pressed, the following soft key labels (see Figure 10.5) are displayed:

WOC CNT RATE/WOC CNT GRAPH/WOC CNT DATA *
RBC/PLT CNT RATE/RBC/PLT CNT GRAPH/RBC/PLT CNT DATA *
NOC CNT RATE/NOC CNT GRAPH/NOC CNT DATA *
PRINT
RETURN

* Key labels alternate between the selections.

NOTE: Once a [CNT RATE] key is pressed, that key toggles between [CNT DATA] and [CNT GRAPH] until the operator exits the screen. The keys then revert to [CNT RATE].

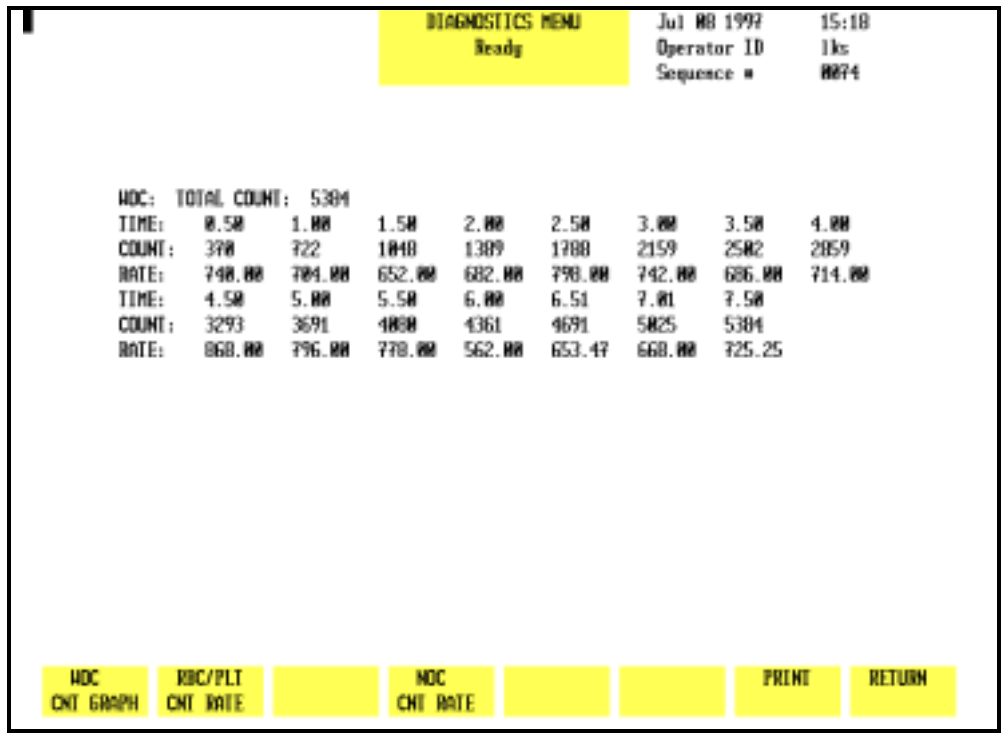

Figure 10.6: WOC Count Rate Data

Each key displays kinetic data for the selected parameter from the last cycle run. When each key is pressed, the count rate data is displayed (see Figure 10.6) and the key label changes to [CNT GRAPH] for that parameter.

Count rate data from the last cycle is displayed in a tabular format. The total count, time segments and rate per second are displayed for multiple data points from that cycle. (See Figure 10.6.) When the [CNT GRAPH] key for a particular parameter is pressed, the rate-per-second data is displayed as a graph. (See Figure 10.7.) The kinetic data and graph are useful when troubleshooting problems related to these parameters.

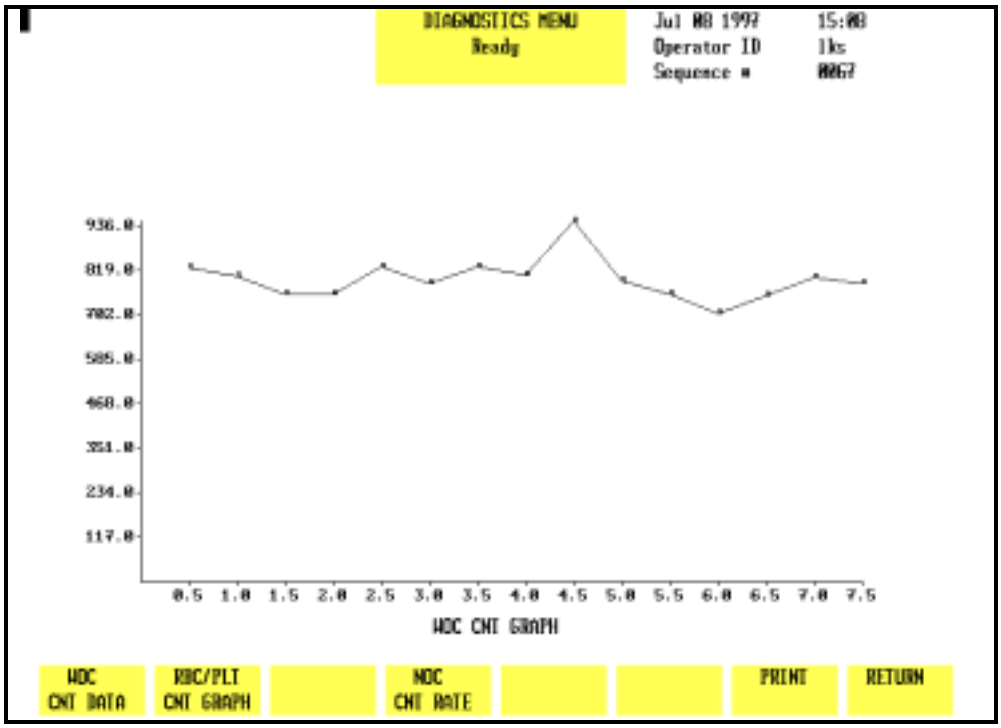

Figure 10.7: WOC Count Rate Graph

Clear Faults

When the [CLEAR FAULTS] key is pressed, the Analyzer returns to the READY state if the corrective action taken resolved the problem. If the corrective action did not correct the problem, the fault status does not change.

> **NOTE:** Only operator correctable faults can be cleared with the [CLEAR FAULTS] key.

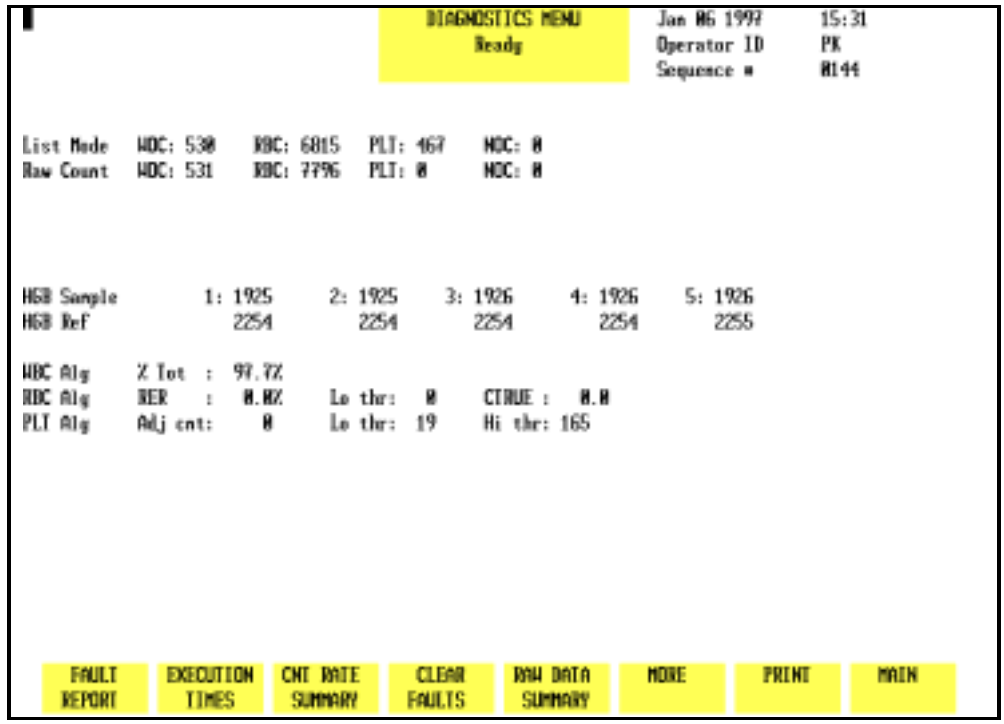

Figure 10.8: Raw Data Summary Screen

Raw Data Summary

When the [RAW DATA SUMMARY] key is pressed, detailed information pertaining to the last cycle run is displayed. An example of the RAW DATA SUMMARY screen is shown in Figure 10.8.

The HGB Reference and Sample readings may be used to assist in troubleshooting erratic or imprecise HGB results.

More

When the [MORE] key is pressed, the second DIAGNOSTICS MENU screen is displayed. The [MORE] keys on the remaining screens to be discussed always display the next DIAGNOSTICS MENU screen.

Print

When the [PRINT] key is pressed, a Diagnostic Report is printed. This report contains information pertinent to the data displayed on the screen at the time the key is pressed. If no data is displayed on the screen, the report prints the current fault status.

The [PRINT] key functions in this way on each screen. Therefore, it will not be discussed again in this section.

Main

The [MAIN] key is used to return to the MAIN MENU screen. The [MAIN] key appears on each primary DIAGNOSTICS MENU screen and works the same way on each screen. Consequently, it will not be discussed again in this section.

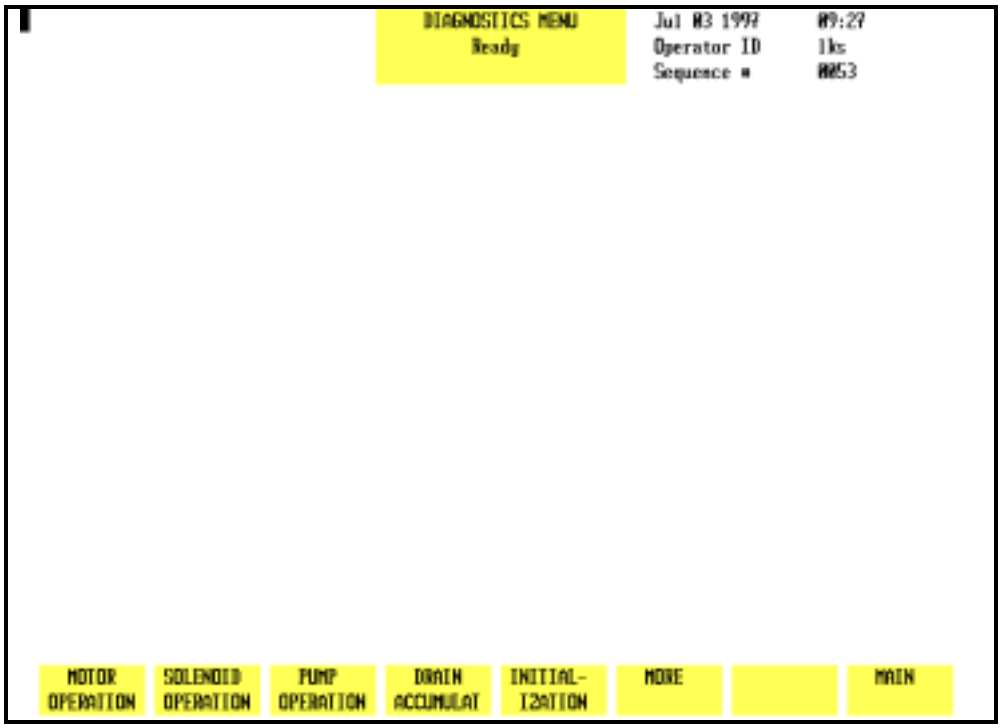

Figure 10.9: Second Diagnostics Menu Screen

Second Diagnostics Menu Screen

When the [MORE] key on the first DIAGNOSTICS MENU screen is pressed, the second DIAGNOSTICS MENU screen (see Figure 10.9) and the following soft key labels are displayed:

MOTOR OPERATION
SOLENOID OPERATION
PUMP OPERATION
DRAIN ACCUMULAT
INITIALIZATION
MORE
MAIN

Motor Operation

This key should be used only by an authorized Abbott representative. The system must be initialized after this key is pressed.

Solenoid Operation

This key should be used only by an authorized Abbott representative. The system must be initialized after this key is pressed.

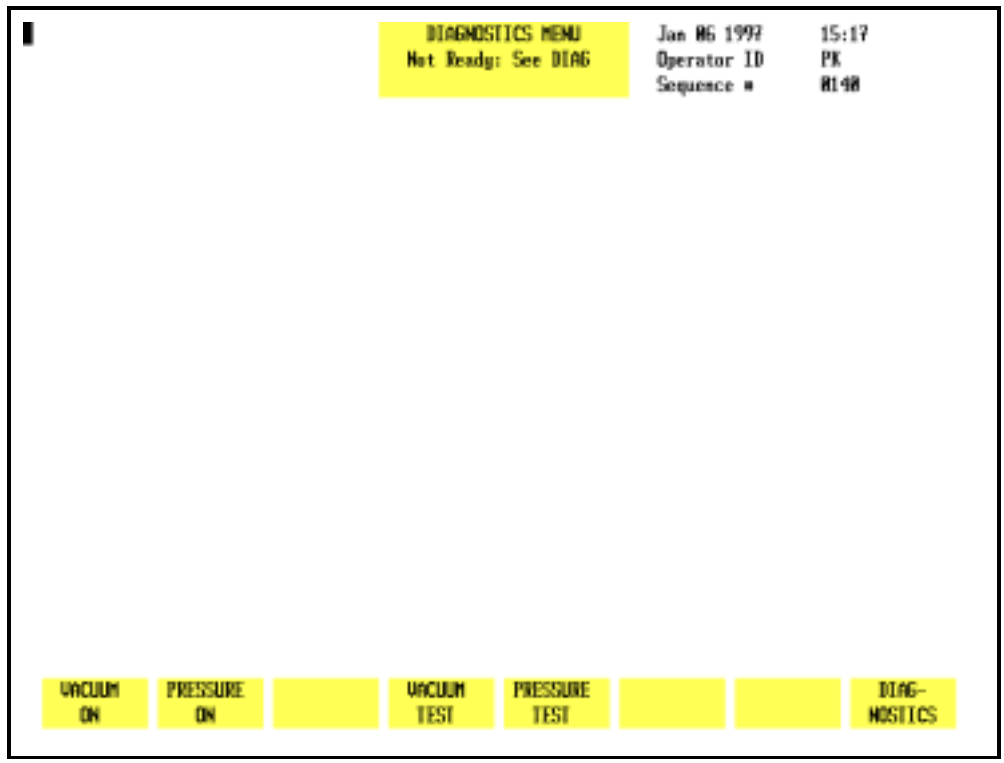

Figure 10.10: Pump Operation Screen

Pump Operation

When the [PUMP OPERATION] key is pressed, the following soft key labels (see Figure 10.10) are displayed:

VACUUM ON/VACUUM OFF	(The key label alternates between the selections.)
PRESSURE ON/PRESSURE OFF	(The key label alternates between the selections.)

INHIBIT PUMPS/ENABLE PUMPS	(Displayed when VACUUM or PRESSURE keys are pressed.)
VACUUM TEST	
PRESSURE TEST	
DIAGNOSTICS	

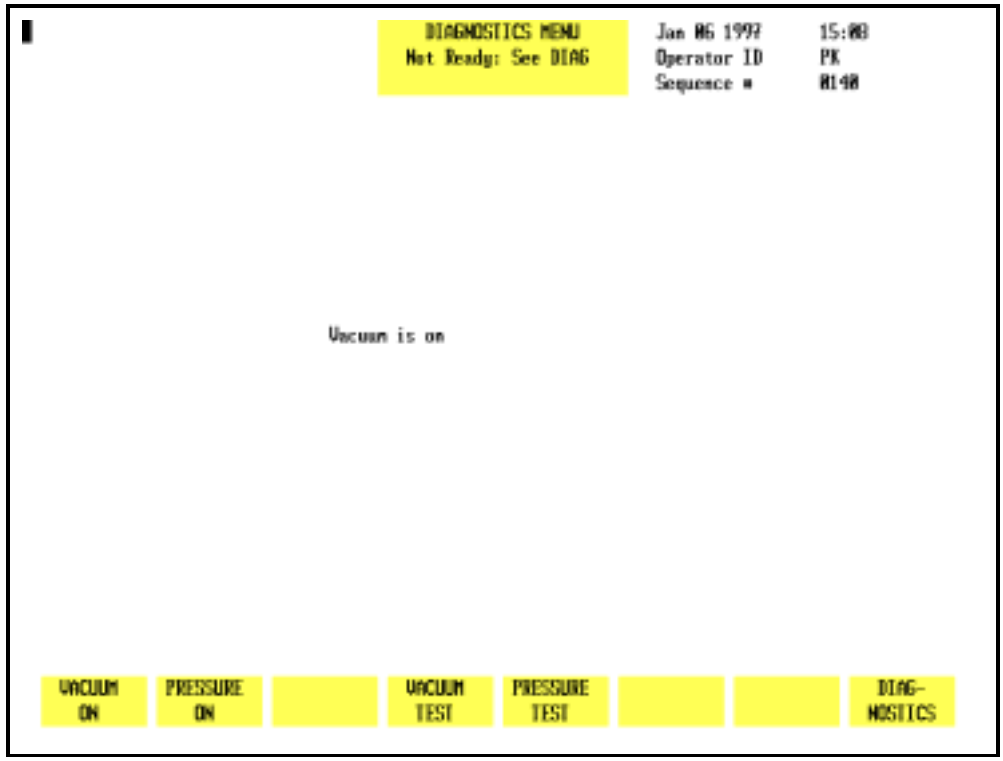

Figure 10.11: Pump Operation Screen — Vacuum ON

Vacuum On

When the [VACUUM ON] key is pressed, the key label changes to [VACUUM OFF], the vacuum pump is turned ON and the screen displays the message `Vacuum Is On`. (See Figure 10.11.) Press the [VACUUM OFF] key to turn the pump OFF.

> **NOTE:** The pump is automatically turned OFF and control of the pump is returned to the instrument when the screen is exited.

This key is useful for troubleshooting vacuum problems. If the pump does not turn ON when the key is pressed, the pump may be the cause of the vacuum problem.

Pressure On

When the [PRESSURE ON] key is pressed, the key label changes to [PRESSURE OFF], the pressure pump is turned ON and the screen displays the message `Pressure Is On`. Press the [PRESSURE OFF] key to turn the pump OFF.

> **NOTE:** The pump is automatically turned OFF and control of the pump is returned to the instrument when the screen is exited.

This key is useful for troubleshooting pressure problems. If the pump does not turn ON when the key is pressed, the pump may be the cause of the pressure problem.

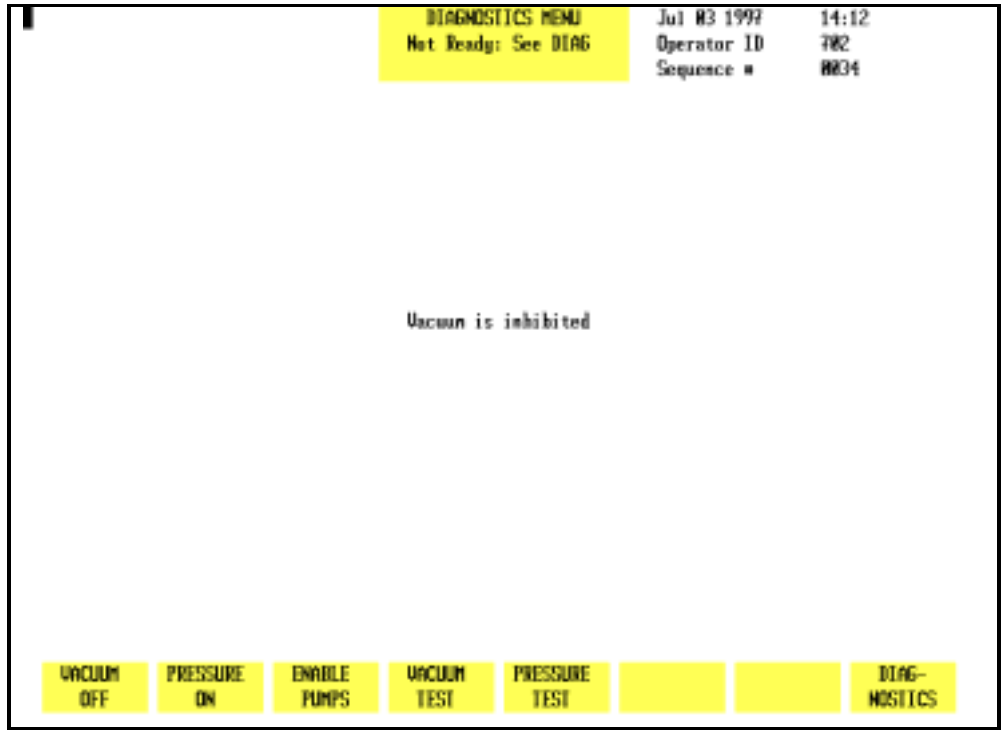

Figure 10.12: Inhibit Pumps Screen

Inhibit Pumps

When the [VACUUM] or [PRESSURE] key is pressed, the [INHIBIT PUMPS] key appears. (See Figure 10.12.) When the [INHIBIT PUMPS] key is pressed, the operation of the pumps is inhibited (no vacuum and pressure are produced), the screen displays the message `Vacuum Is Inhibited`, and the key label changes to [ENABLE PUMPS]. Press the [ENABLE PUMPS] key to enable pump operation.

> **NOTE:** The pumps are automatically enabled and control of them is returned to the instrument when the screen is exited, even if the pumps were disabled while in the screen.

This key is useful when performing maintenance or troubleshooting procedures that require a vacuum or pressure line to be removed.

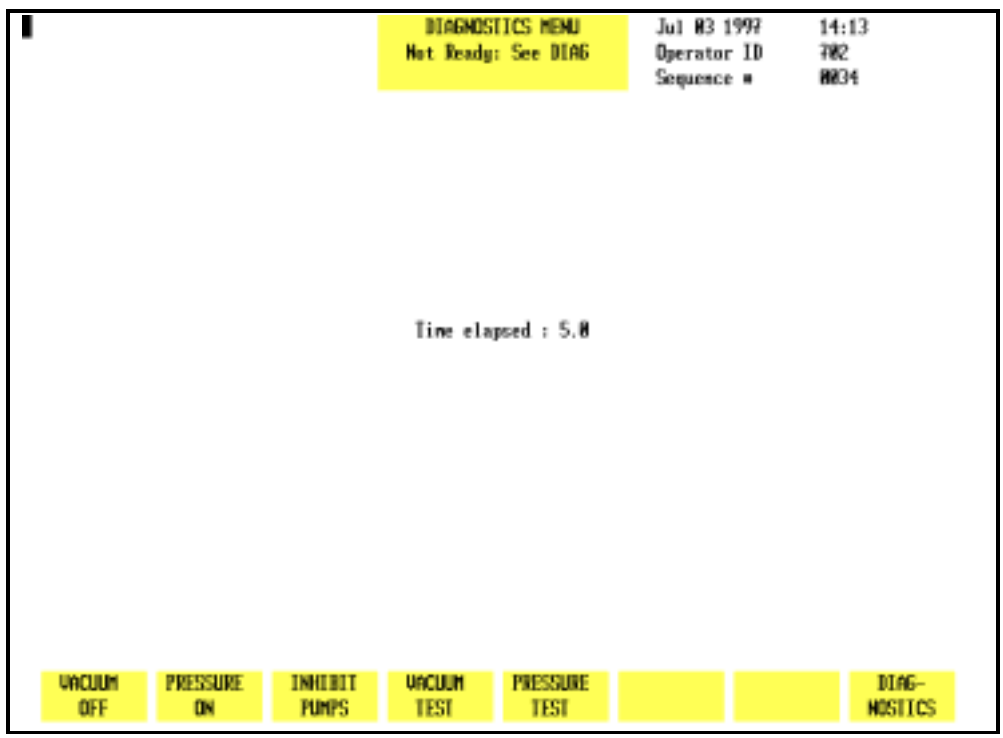

Figure 10.13: Vacuum Test Screen

Vacuum Test

When the [VACUUM TEST] key is pressed, the system releases the vacuum to atmosphere and then determines the amount of time required for it to return to the correct level. The key labels disappear and the incrementing time is displayed on the screen. (See Figure 10.13.) When the test is finished, the time stops incrementing and the key labels are displayed.

A vacuum recovery time greater than 5 seconds may indicate a vacuum problem.

Pressure Test

When the [PRESSURE TEST] key is pressed, the system releases the pressure to atmosphere and then monitors the amount of time required for it to return to the correct level. The key labels disappear and the incrementing time is displayed on the screen. When the test is finished, the time stops incrementing and the key labels are displayed.

A pressure recovery time greater than 4 seconds may indicate a pressure problem.

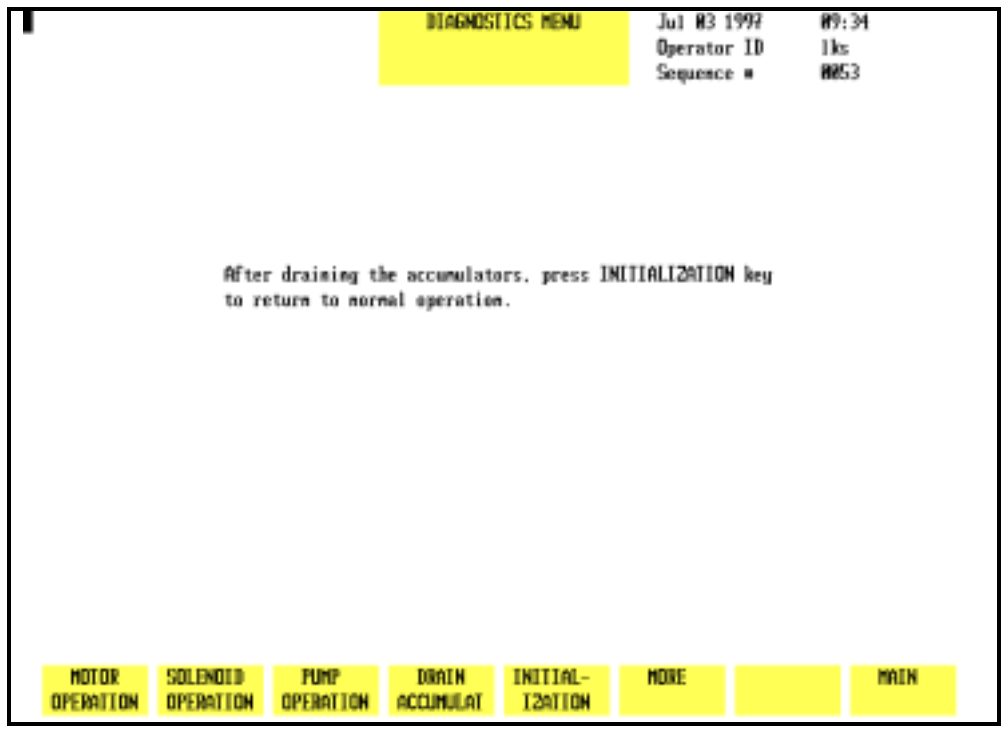

Figure 10.14: Drain Accumulators Screen

Drain Accumulat

When the [DRAIN ACCUMULAT] key is pressed, the internal vacuum accumulators are drained of accumulated fluid. This key is used to correct the "Vacuum Accumulator Wet" fault. The screen displays (see Figure 10.14) the following message:

After draining the accumulators, press initialization key to return to normal operation.

When the process is completed, the system must be initialized and primed. See ***Initialization*** below.

Initialization

When the [INITIALIZATION] key is pressed, the Analyzer is initialized. This is necessary when a fatal fault has occurred.

After the Analyzer is initialized, it must be primed. To prime the Analyzer, go to the MAIN MENU and press the [RUN] soft key.

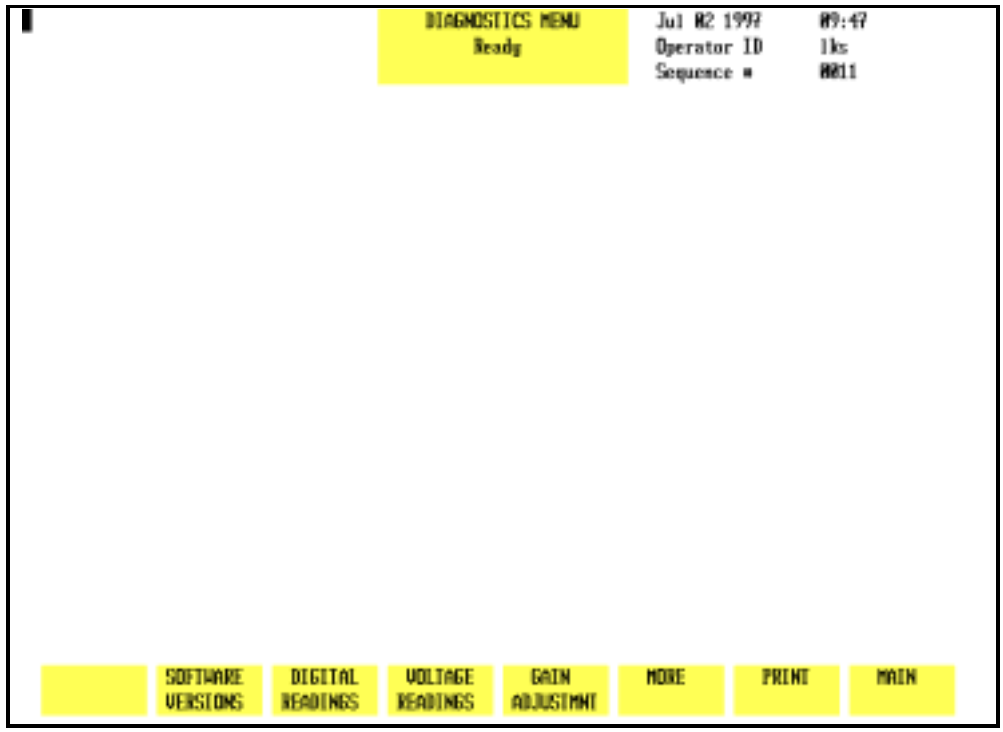

Figure 10.15: Third Diagnostics Menu Screen

More

When the [MORE] key is pressed, the third DIAGNOSTICS MENU screen is displayed.

Main

The [MAIN] key is used to return to the MAIN MENU screen.

Third Diagnostics Menu Screen

When the [MORE] key in the second DIAGNOSTICS MENU is pressed, the third DIAGNOSTICS MENU screen (see Figure 10.15) and the following soft key labels are displayed:

SOFTWARE VERSION *
DIGITAL READINGS *
VOLTAGE READINGS
GAIN ADJUSTMNT *
MORE
PRINT
MAIN

* These keys are for service use only.

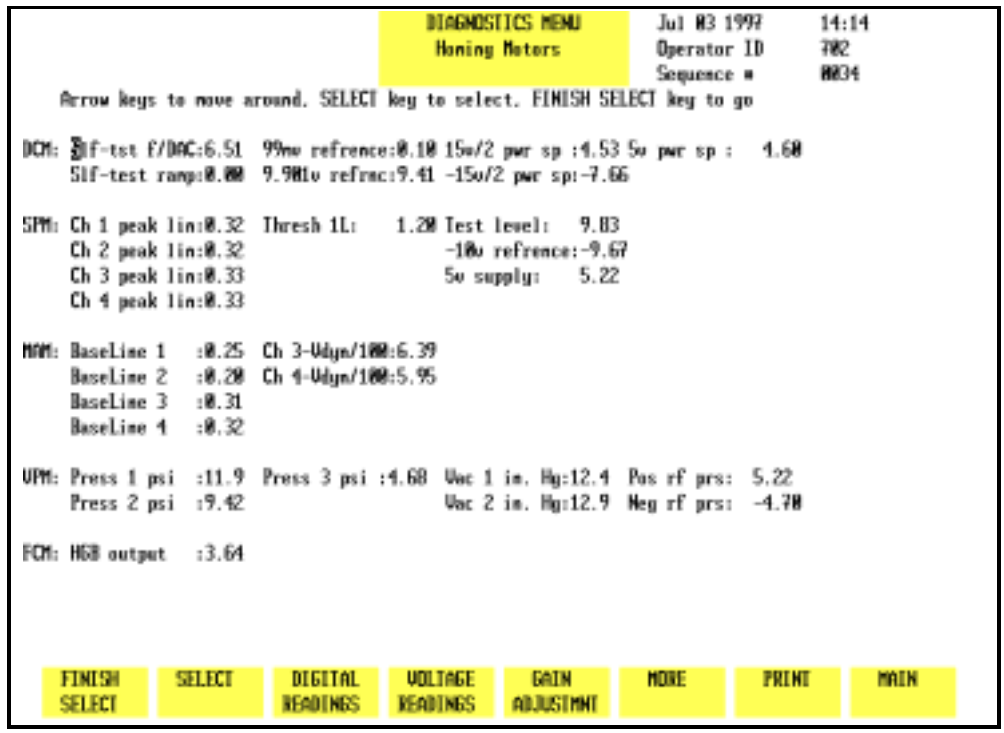

Figure 10.16: Voltage Readings Screen

Voltage Readings

When the [VOLTAGE READINGS] key is pressed, the voltage and vacuum/pressure value from a test point, measured at the moment when the key was pressed, is displayed. (See Figure 10.16.) The following additional soft key labels are displayed:

FINISH SELECT *
SELECT *

* These two keys are for service use only.

The data provided by the VOLTAGE READINGS screen can be useful in determining if a problem is caused by a hardware malfunction.

More

When the [MORE] key is pressed, the fourth DIAGNOSTICS MENU screen is displayed.

Print

When the [PRINT] key is pressed, a Diagnostic Report is printed. This report contains information pertinent to the data displayed on the screen at the time the key is pressed. If no data is displayed on the screen, the report prints the current fault status.

Main

The [MAIN] key is used to return to the MAIN MENU screen.

Fourth Diagnostics Menu Screen

When the [MORE] key in the third DIAGNOSTICS MENU is pressed, the fourth DIAGNOSTICS MENU screen (see Figure 10.17) and the following soft key labels are displayed:

WBC DATA *
RBC DATA *
PLT DATA *
NOC DATA *
MORE
PRINT
MAIN

* These keys are for service use only.

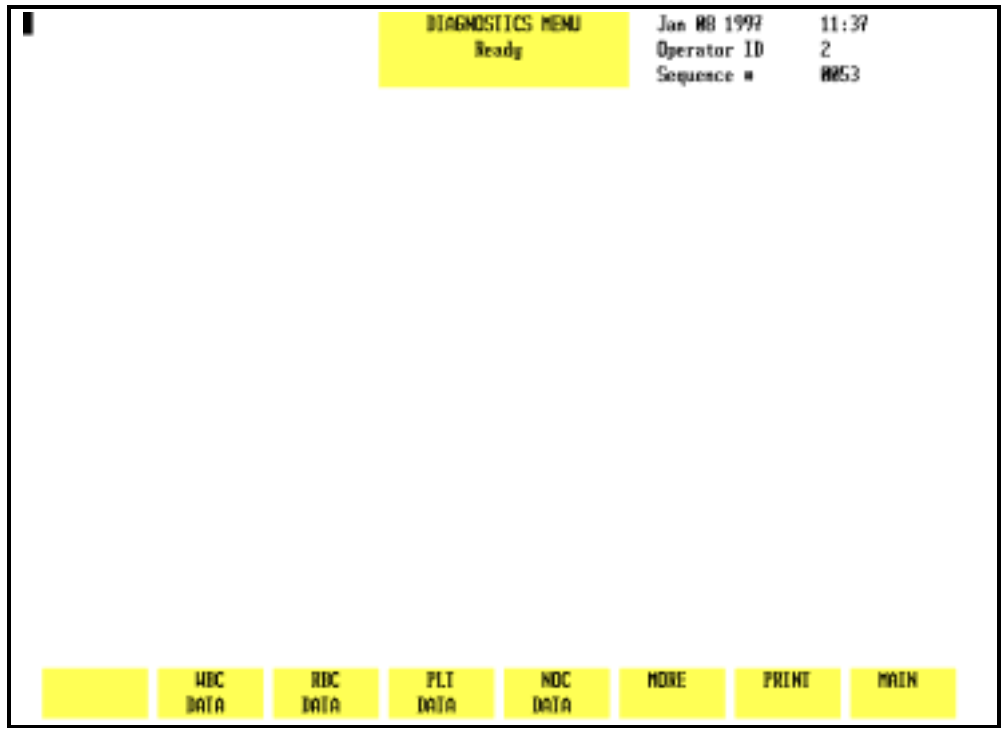

Figure 10.17: Fourth Diagnostics Menu Screen

Fifth Diagnostics Menu Screen — CS Model

For CS models, when the [MORE] key in the fourth DIAGNOSTICS MENU is pressed, the fifth and last DIAGNOSTICS MENU screen (see Figure 10.18) and the following soft key labels are displayed:

SERIAL TEST
BAR CODE ALIGNMENT *
BAR CODE VERIFY *
TOWER TEST *
TOWER DOOR TEST *
MORE
MAIN

* These keys are for service use only.

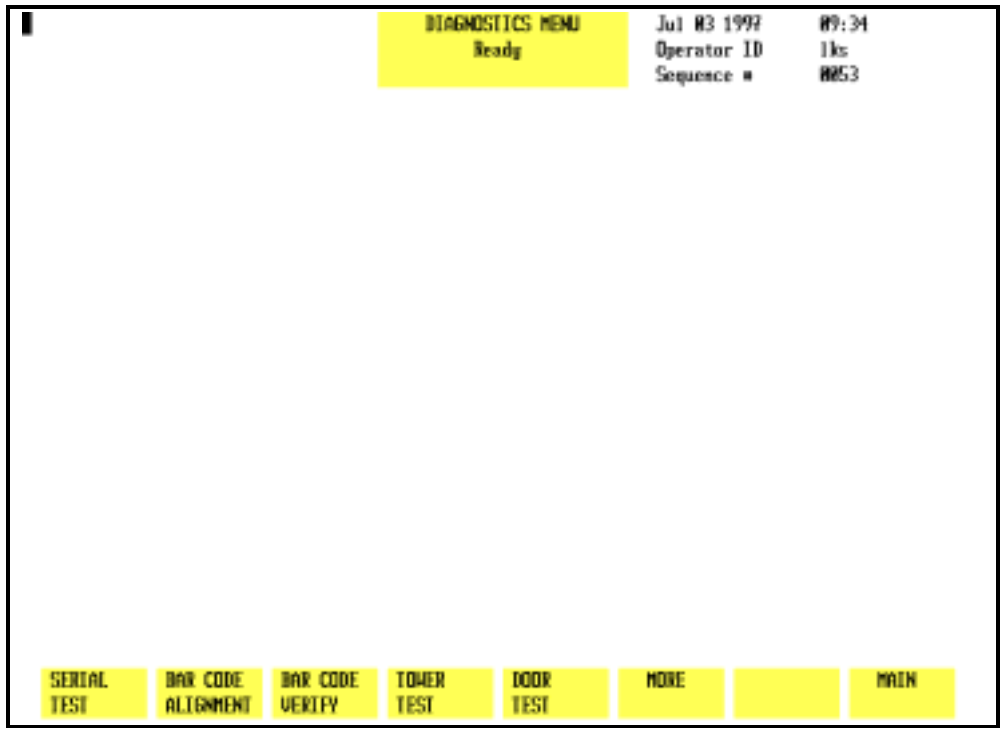

Figure 10.18: Fifth Diagnostics Menu Screen (CD3200CS)

Serial Test

The [SERIAL TEST] key is used to test the functionality of the COM1 port (referred to as the "serial interface connector") at the rear of the instrument. This test is designed to assist in troubleshooting problems with interfacing to a Laboratory Information System (LIS). The loop-back connector must be connected to the COM1 port before performing the test.

> **NOTE:** If the laboratory does not have a LIS, the loop-back connector may remain connected to the COM1 port for convenience, as it does not interfere with routine operation. If a LIS is usually connected, the loop-back connector should be stored near the instrument when the connector is not in use.

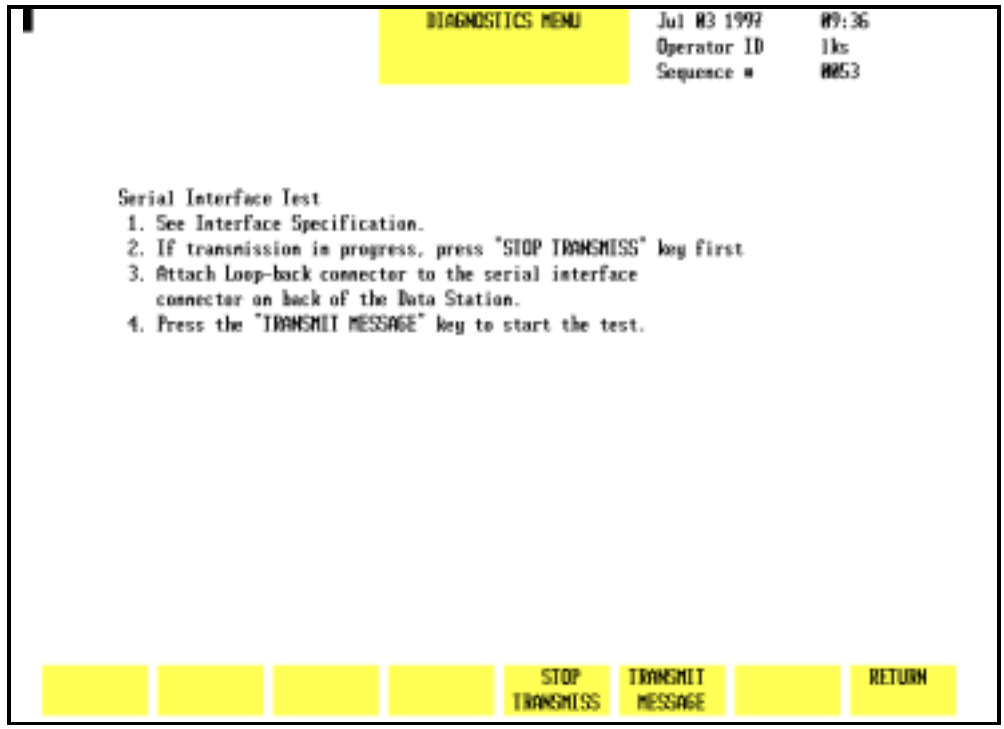

Figure 10.19: Serial Test Screen

When the [SERIAL TEST] key is pressed, the following soft key labels (see Figure 10.19) are displayed:

STOP TRANSMISS
TRANSMIT MESSAGE
DIAGNOSTICS

The screen displays the following:

`Serial Interface Test`

1. See Interface Specification.

2. If transmission in progress, press [STOP TRANSMISS] key first.

3. Attach Loop-back Connector to the serial interface connector on back of the Data Station.

4. Press the [TRANSMIT MESSAGE] key to start the test.

Stop Transmiss

The [STOP TRANSMISS] key is used to stop any transmission that is in progress to a LIS. When the key is pressed, any transmission in progress is aborted.

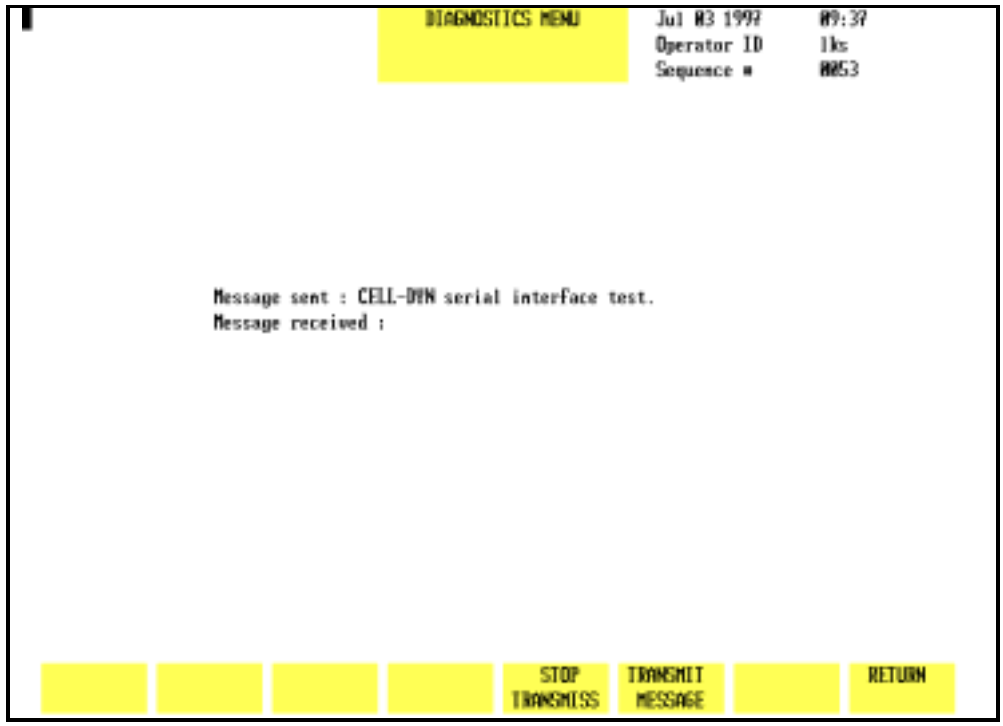

Figure 10.20: Serial Test Transmit Message Screen

Transmit Message

When the [TRANSMIT MESSAGE] key is pressed, the message "CELL-DYN serial interface test" is transmitted from the Analyzer to the COM1 port, through the loop-back connector and back to the Analyzer. The screen (see Figure 10.20) displays the message:

MESSAGE SENT: CELL-DYN serial interface test.

If the test is successful, the screen displays the message:

MESSAGE RECEIVED: CELL-DYN serial interface test.

This message indicates that the Data Station is communicating properly. If the test is not successful, no message appears.

MORE

When the [MORE] key is pressed in the fifth DIAGNOSTICS MENU screen, the first DIAGNOSTICS MENU screen is again displayed.

Fifth Diagnostics Menu Screen — SL Model

For SL models, when the [MORE] key in the fourth DIAGNOSTICS MENU is pressed, the fifth and last DIAGNOSTICS MENU screen (see Figure 10.21) and the following soft key labels are displayed:

SERIAL TEST
BAR CODE ALIGNMENT *
BAR CODE VERIFY *
TOWER TEST *
LOADER TEST *
MORE
MAIN

* These keys are for service use only.

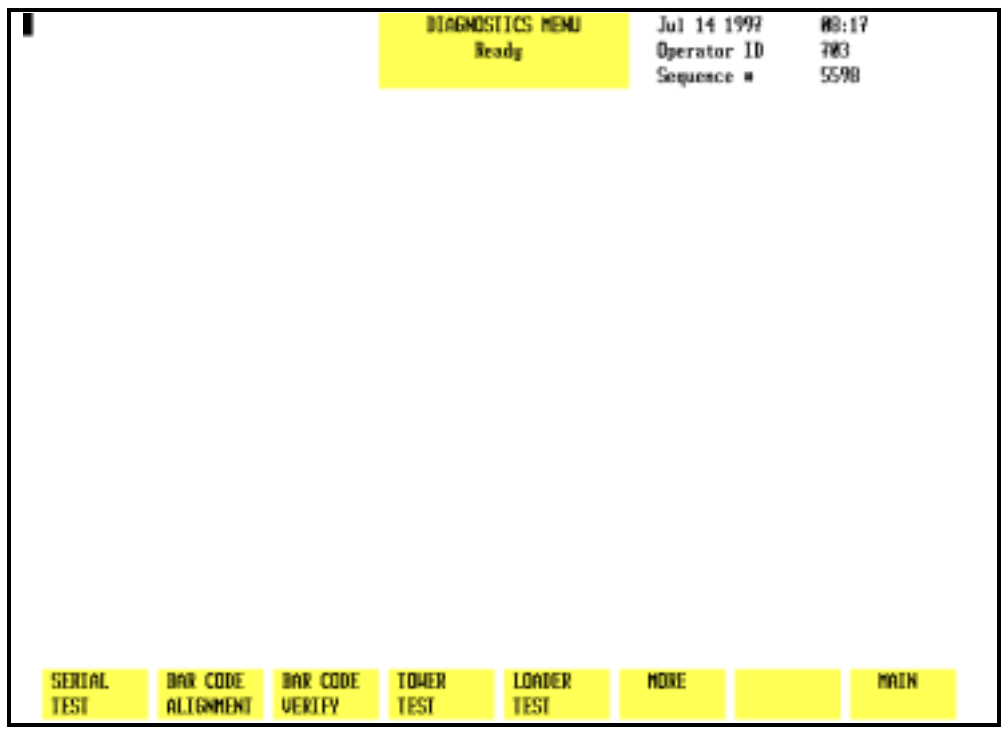

Figure 10.21: Fifth Diagnostics Menu Screen (CD3200SL)

The [SERIAL TEST] and [MORE] keys function in a similar manner to that described in section ***Fifth Diagnostics Menu Screen — CS Model***.

NOTES

Troubleshooting Guide

Introduction to Troubleshooting

Good troubleshooting skills are learned by using a logical, step-by-step approach to problem solving. The first step in the process is understanding normal instrument operation and preventative maintenance. A good working knowledge of the instrument is essential for identifying and resolving operational problems.

Logical troubleshooting may be divided into three steps:

1. Problem Identification
2. Problem Isolation
3. Corrective Action

Step 1, the problem identification step, is not only identifying what is wrong but also noting what is right. The investigation should identify the problem area and eliminate areas that are working correctly. Once this is done, the troubleshooting process moves quickly to the next step.

Step 2, Problem Isolation, further classifies the problem. Instrument problems are generally divided into three categories:

Hardware —	component related
Software —	computer program related
Measurement —	related to sample analysis

Typically, hardware and software problems are corrected by an authorized service representative. Measurement problems are generally operator correctable. This category is further subdivided into problems related to Sample Handling, Maintenance or Calibration.

Step 3, Corrective Action, involves taking appropriate action to correct the problem. If the operator can correct the problem, with or without technical assistance, normal operation can quickly resume.

This Troubleshooting Guide is designed to enhance the troubleshooting process by providing information to assist in problem identification, isolation and corrective action.

> **NOTE:** Generally, conditions that are instrument- or reagent-related will occur on all samples, including controls. Therefore, it is important to confirm instrument performance by rerunning controls and/or additional patient specimens.

Obtaining Technical Assistance

Technical Assistance is obtained by calling the CELL-DYN Customer Support Center. It is important to provide the Customer Support Specialist with a clear and detailed description of the problem. When assistance is needed, please be prepared to provide the following information for the Customer Support Specialist:

1. Instrument Model Name
2. Serial number of the Analyzer
3. Description of the problem
4. The lot numbers and expiration dates of the CELL-DYN reagents and controls currently in use
5. Examples of sufficient data to facilitate the discussion

Customer Support

United States: 1 (800) CELL DYN or 1 (800) 235-5396

Abbott Diagnostics Customer Support Center:
5440 Patrick Henry Drive
Santa Clara, CA 95054

Canada: 1(800) 387-8378

International: Call your local customer support representative.

Troubleshooting Procedures

The procedures in this section are for troubleshooting purposes only. A specific procedure should be performed under one of the following conditions:

1. To correct a problem described in this section
2. At the request of an Abbott Customer Support Specialist.

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Troubleshooting Tips and Techniques

Introduction

Effective troubleshooting is possible only when the problem is clearly recognized and the probable cause is isolated. This is always facilitated by obtaining sufficient information and data pertaining to the specific problem. Carefully observe the situation. Document the steps that have been taken and record all results.

The following section is designed to guide the operator through a logical series of steps to obtain information regarding the nature of the problem. If it is necessary to call for technical assistance, this information should be made available to the Customer Support Specialist.

Troubleshooting the Background Count

1. Determine which parameter(s) exceed the background count specifications: WBC, RBC, PLT, HGB, NOC.*

   *Background counts for NOC are available in the Data Log.

2. Check the Data Log to determine when the problem first occurred.
3. Check the Reagent Log, Maintenance Log and if applicable, service reports to see if the problem occurred immediately after a specific action. For example, did the problem occur immediately after the reagent was changed?

4. Check the Background count in the open and closed modes to see if the problem is common to both modes. To do this in closed mode, you must have a sample tube filled with diluent/sheath to aspirate for a background count.
5. Note the lot number of the reagent. Is it a new lot?
6. Configure the RUN screen to display the appropriate graphic for the parameter(s) for which the background exceeds the specifications:

Parameter	Appropriate Graphic
WBC	WBC histogram/scatterplots
RBC	RBC and PLT histograms
PLT	RBC and PLT histograms
HGB	WBC, RBC and PLT histograms
NOC	NOC histogram

Obtain several printouts of this information by running multiple background cycles.

> **NOTE:** Instructions for customizing the RUN screen display are given in **Section 5: *Operating Instructions*, Subsection: *Set Up Instructions, Customize Report, Customize Displayed Report***.

7. Configure the Data Log to display values for WBC, RBC, PLT, HGB, and NOC. Obtain printouts of the Data Log, including the sequence numbers of the background cycles.

> **NOTE:** Instructions for customizing the display and printout of the Data Log are given in **Section 5**, **Subsection: *Using the Data Log, Data Log Set Up Procedures***.

Troubleshooting Reagent Problems

If a reagent (or reagents) is suspected as the cause of a particular problem, replace the container. However, the Analyzer has reservoirs that contain a small amount of reagent to maintain the supply within the system. This supply must be depleted before installing the new reagent.

NOTE: There is no reservoir for the HGB Lyse reagent. The amount of lyse contained in the lyse supply tubing is sufficient to maintain the system's supply. The lyse tubing is drained and filled by pressing the appropriate reagent key displayed on the REAGENT RESERVOIR screen described below.

To ensure that the new reagent is actually in the system, proceed as follows:

1. From the first SPECIAL PROTOCOLS screen, press [REAGENT RESERVOIR].
2. From the REAGENT RESERVOIR screen, press the soft key for the desired reagent and follow the instructions given on the screen.
3. Wipe the reagent line with a lint-free wipe before placing it in the new container. Place the line in the container and secure the cap.
4. Press the appropriate soft key to refill the reservoir.
5. Run five Background counts before assessing the results.

Troubleshooting the "Sampling error-incomplete aspiration" Message

1. Check to see if the problem occurs in both the Open and Closed Modes of operation. If the problem is confined to one mode only, the other may be eliminated as the cause of the problem.
2. Determine whether the problem is a true incomplete aspiration. Run a sample and verify that blood is visible in the sample tubing above the appropriate probe or needle.
3. Verify that blood is pulled through the Shear Valve. Blood should be visible in the lines (approximately one inch) on both sides of the Shear Valve before it rotates. If blood is visible, there may be a sensor failure.

Troubleshooting a Flow Error Message

1. The flow error messages indicate a problem with the kinetic rate of the WBC, RBC/PLT, or NOC measurements. The kinetic information is only available immediately after the cycle is finished. Therefore, the screen should be printed immediately after the flow error occurs.

2. From the first DIAGNOSTICS MENU screen, press [CNT RATE SUMMARY].
3. Press the appropriate [COUNT RATE] key (WOC, RBC, PLT, or NOC) to display the data for the kinetic rate. Press [PRINT] to obtain a printout.
4. Press the appropriate [COUNT GRAPH] key to display the graph of the kinetic data. Press [PRINT] to obtain a printout.
5. Configure the RUN screen to display the Size/Complexity scatterplot and the NLM histogram. (If necessary, refer to the instructions given in **Section 5: *Operating Instructions,* Subsection: *Customize Displayed Report***.) Obtain several printouts. This information can help to determine if the flow is erratic or just momentarily interrupted.

Troubleshooting Imprecise or Inaccurate Data

1. Obtain a normal blood sample. Select an empty QC file and run a minimum of ten Open Mode runs into the file. Obtain a printout.
2. Run a minimum of nine Closed Mode runs into the same file. (For the CD3200SL, aliquot a sample into three tubes and run each tube three times.) Use the [REJECT SPECIMEN] key to reject the Open Mode runs and obtain a printout. This information can be used to determine if the problem is mode or measurement related.
3. Obtain printouts of related data as indicated in the following steps.
4. WBC:
   - Configure the RUN screen to display the following and obtain printouts by pressing the Print screen key on the keyboard. (This requires two printouts per sample.)

     Printout 1:
     Size-Cmp (0—10)
     Grn-Lob (90D—90)
     WBC 0—90 deg
     RBC 90—10 deg

Printout 2:
N-L-M histogram
M-P histogram
NOC histogram

If necessary, refer to the directions given in **Section 5** for customizing the display.

- Obtain printouts of the kinetic data for WBC for several samples. From the first DIAGNOSTICS MENU screen, press [CNT RATE SUMMARY]. Press [WOC CNT RATE] to display the data for the kinetic rate followed by [PRINT] to obtain a printout. Press [WOC CNT GRAPH] to display the graph of the kinetic data followed by [PRINT] to obtain a printout.

- If there is a flagging problem or a problem with an abnormal sample, obtain a printout of a normal sample for comparison.

- Obtain a printout of the RAW DATA SUMMARY screen immediately after the problem sample is run. From the first DIAGNOSTICS MENU screen, press [RAW DATA SUMMARY] followed by [PRINT] to obtain a printout.

- Configure the Data Log to display and print WBC values. (If necessary, refer to the instructions given in **Section 5**.) Print the results for the last 100 cycles.

5. RBC, HGB, MCV and PLT:

   - Configure the RUN screen to display the RBC and PLT histograms. Obtain printouts of problem samples.

   - Obtain a printout of the RAW DATA SUMMARY screen immediately after the problem sample is run. From the first DIAGNOSTICS MENU screen, press [RAW DATA SUMMARY] followed by [PRINT] to obtain a printout.

   - Obtain a printout of the X-B data. In the MAIN MENU, press [QUALITY CONTROL] followed by [X-B FILE]. If necessary, press [X-B RBC DATA] to display the X-B RBC data and press [PRINT] to obtain a printout.

6. NOC:

   - Follow the instructions given in step 5 for WBC, substituting the [NOC CNT] key for the [WOC CNT] key for displaying and printing rate and graph data.

NOTES

Instrument Conditions and Messages

Overview

Instrument conditions can be divided into two categories, those that generate messages, and those that do not. The messages will be displayed in the Status Box and/or the Bulletin Line.

> **NOTE:** For information on Suspect Parameter Flags, refer to **Section 3: *Principles of Operation*, Subsection: *Operational Messages and Data Flagging***.

Instrument messages fall into two categories:

1. Status Messages — inform the operator of the instrument's status or prompt the operator to take action relative to the last operator entry
2. Fault Messages — indicate fault or error detection

The status conditions are listed in Table 10.1. This table defines each message and indicates its display location.

The fault conditions and messages are listed as follows:

- General fault conditions are listed in Table 10.2.
- Sample-Related fault conditions are listed in Table 10.3.
- Non-functional fault conditions are listed in Table 10.4.

Each of the tables is designed with the Message or Condition, display location (if applicable), and additional information centered on the first line. The corresponding Explanation/ Action or Probable Cause/Corrective Action is indicated immediately below each Message or Problem.

NOTES

Tables for Instrument Conditions and Messages

Index of Table 10.1: Status Conditions

Table 10.1: Status Conditions

Each message is followed by one of the abbreviations shown below indicating where that message appears on the screen:

BL — Bulletin Line

SB — Status Box

Ready/SB

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – –

The Analyzer is ready to process samples.

Selecting open/closed mode/SB

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – –

The [CHANGE SAMPLER] key was pressed and the Analyzer is changing to the selected mode of operation.

Resume processing when the READY message is displayed in the Status Box.

Entering standby/SB

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – –

The instrument has been idle for four hours and therefore is automatically performing a cleaning cycle before entering the STANDBY state. (Pressing the [DAILY SHUTDOWN] key also initiates this message.)

When the cycle is finished, press [RUN] to prime the system and bring the instrument to the READY state. Resume operation when the cycle is finished.

Standby/SB

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – –

The instrument has entered the STANDBY state.

Press [RUN] to prime the system and bring the instrument to the READY state. Resume operation when the cycle is finished.

Table 10.1 : Status Conditions (*Continued*)

Initialized/SB

– – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The Analyzer hardware initialization is completed.

Press [RUN] to prime the system and bring the instrument to the READY state. Resume operation when the cycle is finished.

Unpinching valves/SB

– – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The Analyzer was in standby for a predetermined time period and therefore the valves are being exercised to be sure that tubing is not pinched shut.

Resume processing when the READY message is displayed in the Status Box.

Clearing fault/SB

– – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The [CLEAR FAULT] key was pressed after an operator-correctable fault was detected.

Resume operation when READY is displayed in the Status Box and the READY indicator light on the status indicator panel is illuminated in green.

Limits were changed to correct out-of-range values/BL

– – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

A mathematically incorrect limit was manually entered (using [MEANS/LIMITS]) during setup of a QC file. The numbers entered generated a range containing a number greater than the largest number allowed or less than zero. Therefore, the limits were automatically changed.

Check to be sure the entered values are correct. If appropriate, recalculate the mean and limits and enter correct values.

Table 10.1: **Status Conditions (*Continued*)**

Entries making upper limit = lower limit were rejected/BL

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – –

A mathematically incorrect limit was entered (using [RANGE ENTRY]) during setup of a QC file. The currently entered numbers are not accepted and the previously entered numbers for the parameter(s) remain.

Check to be sure the entered values are correct.

Limits were exchanged to make upper > lower/BL

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – –

A mathematically incorrect limit was entered (using [RANGE ENTRY]) during setup of a QC file. The numbers entered caused the upper limit to be less than the lower limit. Therefore, the numbers were automatically exchanged.

Check to be sure the entered values are correct. If appropriate, enter correct values.

Westgard Warning — See Levey Jennings/BL.

The message is displayed on the VIEW QC LOG screen only.

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – –

The Westgard Rules were selected during set up of the QC file and the data in the file has violated one or more of the selected rules.

Review the data in the QC file and take appropriate action.

No Entry Found/BL

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – –

The number (sequence number or specimen ID number) entered on the DATA LOG SEARCH screen is not present in the data log.

Check that the entry was correct. If appropriate, enter the correct number.

Table 10.1 : Status Conditions (*Continued*)

Duplicated Bar Code ID on the new line/BL

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The Work List already contains a bar code number that has been entered.

It is not possible to enter the same bar code number twice in the Work List. If appropriate, delete the previous entry and re-enter the number.

Sample Loader is busy/BL

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

An action was requested during Sample Loader operation and the Sample Loader cannot perform it.

Press the [STOP LOADER] soft key before requesting the desired action.

Change Sampler in Ready State Only/BL

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The [CHANGE SAMPLER] key was pressed while the Analyzer was busy.

The [CHANGE SAMPLER] key can only be pressed when the Analyzer is in the READY state.

Change Sampler when Sample Loader is not busy/BL

– – – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The [CHANGE SAMPLER] key was pressed while the Sampler Loader was busy.

Press the [STOP LOADER] soft key before pressing [CHANGE SAMPLER].

Table 10.1 : Status Conditions (*Continued*)

Change Specimen Type when Sample Loader is not busy/BL

– – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The [SPECIMEN TYPE] key was pressed while the Sample Loader was busy.

Press the [STOP LOADER] soft key before pressing [SPECIMEN TYPE].

Loader Status 143: samples completed

– – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The last rack in the load zone has been processed. NOTE: The Sample Loader halts.

No corrective action is necessary. When you wish to run additional samples in the Sample Loader, load racks and press the [START LOADER] key.

Loader Warning 145: unload area full

– – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The unload area contains 5 racks. NOTE: The Sample Loader halts.

No corrective action is necessary. When you wish to run additional samples in the Sample Loader, remove the racks from the unload area and press the [START LOADER] key.

Loader Warning 146: unload area nearly full

– – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The unload area contains 4 racks.

No corrective action is necessary. If a rack is being processed and there are no other faults, the Sample Loader will continue to operate.

Loader Status 158: load zone empty

– – – – – – – – – – – – – – – – Explanation/Action– – – – – – – – – –

The load zone empty sensor is not sensing the presence of a rack in the load zone. NOTE: The Sample Loader halts.

When you wish to run samples in the Sample Loader, load tubes in racks and press the [START LOADER] key.

Index of Table 10.2: General Fault Conditions

Table 10.2: General Fault Conditions

Each message is followed by one of the abbreviations shown below indicating where that message appears on the screen:
BL — Bulletin Line
SB — Status Box
Information for each message is listed in order from the most likely cause of the message to the least likely cause of the message. Therefore, always troubleshoot a problem in this order. If a problem cannot be resolved by the corrective action indicated in this table, call for technical assistance.

Not Ready: See DIAG or Not Ready: See Special/SB

If a fault condition has occurred, the FAULT indicator light on the Analyzer status indicator panel is illuminated in red.

– – – – Probable Cause – – – –	– – – – Corrective Action – – –
1. A situation that prevents the READY state has been detected. See the DIAGNOSTICS MENU screen or the SPECIAL PROTOCOLS MENU screen, whichever is indicated, for more information.	1. From the first DIAGNOSTICS MENU screen, press [FAULT REPORT] followed by [PRINT] to obtain a printout describing the problem. Refer to the appropriate table for corrective action.
2. A diagnostic test was run using one of the DIAGNOSTICS MENU screen keys.	2. The instrument must be initialized when the diagnostic test in progress is finished. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen.
3. A Special Protocols procedure is in progress.	3. Check the SPECIAL PROTOCOLS MENU screen and perform theaction necessary to complete the procedure.
4. System malfunction.	4. If the message occurs repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Uninitialized/SB

– – – – Probable Cause – – – –	– – – – Corrective Action – – –
1. Main power switch is ON but the Analyzer is not responding.	1. Turn the system OFF. 2. Ensure that all cables on the back of the instrument are properly attached. 3. Turn the System ON. 4. If the problem persists, contact your Hematology Customer Support Center.

Initialization Failed

Bottom of screen (MAIN MENU is not displayed)

– – – – Probable Cause – – – –	– – – – Corrective Action – – –
1. The instrument was unable to initialize. The CELL-DYN software does not display the MAIN MENU screen.	1. Initialize the Analyzer by following the instructions in the Power OFF and Power ON procedures given in **Section 5**, **Subsection: *Operation Overview***. If the Analyzer does not initialize, press the Print Screen key on the computer keyboard to document any screen messages, then contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Printer (Graphics or Ticket) Unavailable/SB

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The print buffer (the memory area where the material is stored while awaiting printing) is full.	1. Press the [STOP PRINTING] key on the CUSTOMIZE PRINTED REPORT screen for the appropriate printer.
2. The printer is turned OFF.	2. Turn the printer power switch ON.
3. The printer is not on-line.	3. Check that the printer "on-line" indicator is illuminated. If necessary, refer to the printer manual for assistance.
4. The power cord is loose or disconnected. The inter- face cable is loose or disconnected.	4. Check the power cable connection on the printer and power outlet. Make sure the connections are secure. Check the interface cable connectors on the printer and Analyzer. Make sure the connections are secure. Press [PRINT REPORT]. If the message is still displayed, turn the printer power switch OFF and ON to reset the printer.
5. Printer cable is connected to the wrong port.	5. Ensure that the graphics printer cable is attached to the graphics printer port and the ticket printer cable is attached to the ticket printer port.

Table 10.2: General Fault Conditions (*Continued*)

Diluent/Sheath, HGB Lyse, or WBC Lyse empty/SB and BL

– – – – Probable Cause – – – –	– – – – Corrective Action – – –
1. Container is empty.	1. Install a new container of reagent. Press [CLEAR FAULT] to resume operation.
NOTE: Do not pour any remaining reagent into the new container.	
2. Reagent inlet tubing is crimped or obstructed.	2. Inspect the inlet tubing to ensure it is not crimped and/or remove any obstruction.
3. Reagent line is not on the bottom of the container.	3. Ensure that the line is properly inserted in the container and the sinker is on the bottom of the container.
4. An incorrect reagent or a nonconductive liquid is connected to the inlet tube.	4. Check the label on the reagent container to be sure the correct reagent is installed. Trace the line to the inlet connector and ensure that it is connected to the correct one. Check the connection to be sure it is secure and then press [CLEAR FAULT].
5. Circuitry malfunction.	5. Contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

External waste full/SB and BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. Waste container full.	1. Empty the waste container and/or Replace it. Press CLEAR FAULT] to resume operation. NOTE: Make sure the Analyzer rinse process has been completed before removing the waste tube.
2. Waste sensor connector is loose or disconnected.	2. Reconnect the waste sensor connector and then press [CLEAR FAULT].
3. Shorted wire(s) or electrode(s) on the waste cap.	3. Visually inspect wires and electrodes and call for technical assistance.
4. Circuitry malfunction.	4. If the message appears repeatedly, contact your Hematology Customer Support Center.

Shear valve position fault/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The Shear Valve did not rotate properly or in the allotted time.	1. Clean the Shear Valve. Then, initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the system. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System.
2. Sensor or cable malfunction.	2. If the problem occurs repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

RBC diluent syringe overpressure/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The Shear Valve did not rotate completely or in the time allotted.	1. Clean the Shear Valve. Then, initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again reboot the system. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System.
2. The center section of the Shear Valve is installed backwards.	2. Verify that the center section of the Shear Valve is installed correctly. Then, initialize or reboot the System. 3. If the problem persists, contact your Hematology Customer Support Center.

Vacuum accumulator 1 wet/BL

Vacuum accumulator 2 wet/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The internal vacuum accumulator has filled with liquid beyond allowable limits.	1. From the second DIAGNOSTICS MENU screen, press the [DRAIN ACCUMULAT] key. When the cycle is finished, the cycle is finished, initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the fault recurs, repeat this action. If the fault persists, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Flow sequence time out <x,x>/BL

NOTE: Characters in the brackets identify the problem flow sequence number and name.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. An internal Analyzer flow sequence was not completed in the allotted time.	1. Record the characters in the brackets. 2. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. Continue processing samples. 3. If the problem recurs, contact your Hematology Customer Support Center.

Command sent at incorrect time <x>/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The Analyzer received a command from the System Software at the incorrect time and could not process it.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If necessary, contact your Hematology Customer Support Center. 2. Record the characters in the brackets. If the problem recurs, contact your Hematology Customer Support Center. 3. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. Continue processing samples. 4. If the problem recurs, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Command sent at incorrect time <x>/BL

– – – – Probable Cause – – – –	– – – – Corrective Action – – –
1. The Analyzer received a command from the System Software at the incorrect time and could not process it.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If necessary, contact your Hematology Customer Support Center. 2. Record the characters in the brackets. If the problem recurs, contact your Hematology Customer Support Center. 3. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. Continue processing samples. 4. If the problem recurs, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Data acquisition overlap/BL

The error may occur when several tasks are requested in rapid sequence. For example, print data log, transmit result, sample processing, print ticket, print report, etc.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The timing of communication between the Analyzer and the System Software is incorrect.	1. Record what happened when the message was displayed. 2. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. Continue processing samples. 3. If the fault recurs, contact your Hematology Customer Support Center.

List mode data phase error/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The order of the data received for display on the screen was incorrect.	1. Record what happened when the message was displayed and report the problem to the Customer Support Center. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. Continue processing samples. If the fault recurs, contact your Hematology Customer Support Center. 2. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. Continue processing samples. 3. If the fault recurs, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Message acknowledgment time out/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. Communication between the Analyzer and the Data Station did not occur when expected.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTIC MENU screen. If the fault recurs, contact your Hematology Customer Support Center.

Runtime error/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. An illegal software operation was requested by the Analyzer.	1. Record what happened when the message was displayed. 2. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. Continue processing samples. If the fault recurs, contact your Hematology Customer Support Center.

Bad checksum in non-volatile RAM/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. When the system was powered ON, the Analyzer did not transmit the correct message to the Data Station.	1. Power OFF and ON again. 2. If the fault recurs, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Bad monitor command/BL

NOTE: This message pertains to a software execution monitor on the Analyzer, not the video display screen (CRT).

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. During the initialization process, the Data Station Module and Analyzer did not communicate properly.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the fault recurs, contact your Hematology Customer Support Center.

Message retransmission failure

Communication from the Data Station to the Analyzer failed.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. A hardware failure or system error has occurred.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

HSSL failure – bad incoming messages

NOTE: HSSL stands for High Speed Serial Link.

The Data Station received unrecognizable messages from the Analyzer.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The communication line has become noisy, possibly due to a partial break in the line.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

HSSL failure – bad outgoing commands

The Analyzer received unrecognizable messages from the Data Station.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The communication line has become noisy, possibly due to a partial break in the line.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

HSSL failure – receiver hardware error

The HSSL receiver on the Data Station malfunctioned.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A hardware failure on the HSSL card has occurred.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Monitor power-on self-test error

NOTE: This message pertains to a software execution monitor on the Analyzer, not the video display monitor.

A failure occurred during self-test.

(e.g. test pattern not successfully read from memory)

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A failure in the Analyzer hardware has occurred.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Missing download program

Download program not present on Data Station.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. Installation error, damaged hard disk, or erased hard disk.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Missing flow sequence

Flow sequence not present on Data Station.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. Installation error, damaged hard disk, or erased hard disk.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Invalid substitutable parameter

Size or structure of parameter (e.g. gain) is invalid.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A software error has occurred.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

DMA controller error during list mode acquisition	
NOTE: DMA stands for Direct Memory Access. A memory access control problem occurred during data acquisition.	
– – – - Probable Cause – – –	– – – - Corrective Action –
1. A failure in the Analyzer hardware has occurred.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.
DMA controller setup error	
A problem occurred during setup of the memory access controller.	
– – – - Probable Cause – – –	– – – - Corrective Action –
1. A failure in the Analyzer hardware has occurred.	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Download program timeout

The allotted time for program downloading was exceeded.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A failure in the Analyzer hardware, possibly related to the HSSL cable, card, or memory, has occurred.	1. Check the HSSL cable connections. Then, initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: For the location of the HSSL ports, refer to Section 1: Use or Function, Subsection: Data Module Components. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Download flow sequence timeout

The allotted time for flow sequence downloading was exceeded.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The flow sequence did not compile, possibly due to interruption by a fatal fault, an improperly seated Tower Cover or door, or a fluidics problem.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Command transmission timeout	
The allotted time was exceeded for the Data Station to receive an acknowledgment that a command was transmitted to the Analyzer.	
– – – - Probable Cause – – –	– – – - Corrective Action –
1. A failure in the Analyzer hardware, possibly due to an unplugged or damaged HSSL cable, has occurred.	1. Check the HSSL cable connections. Then, initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: For the location of the HSSL ports, refer to Section 1: Use or Function, Subsection: Data Module Components. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System.
2. A software error has occurred.	2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Message reception timeout

The allotted time was exceeded for the Analyzer to receive an acknowledgment that a message was transmitted to the Data Station.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A communication error, possibly due to a loose HSSL cable, has occurred.	1. Check the HSSL cable connections. Then, initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: For the location of the HSSL ports, refer to Section 1: Use or Function, Subsection: Data Module Components. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Probable Cause	Corrective Action
Data acquisition timeout	
The Analyzer exceeded the allotted time for data acquisition.	
1. An Analyzer or Data Station software timing error has occurred	1. Initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If the message appears again, reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before initializing or rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.
Overflow in the HSSL queue	
The buffer for Analyzer-to-Data Station communication overflowed.	
1. The Analyzer message rate was too high for the Data Station to keep up with.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Analyzer is not communicating its mode	
The Analyzer is not communicating whether it is an SL or CS model.	
– – – - Probable Cause – – –	– – – - Corrective Action –
1. An Analyzer software setup error has occurred.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.
Tower/Loader Fault 3: transmission failure	
A transmission acknowledgment failure occurred between the Analyzer and the module that controls the tower and loader.	
– – – - Probable Cause – – –	– – – - Corrective Action –
1. A failure of the electronics or communication hardware has occurred.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Tower/Loader Fault 5: communication failure

A communication failure occurred between the Analyzer and the module that controls the tower and loader.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A communication timing or handshake error has occurred.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Tower/Loader Fault 16: direct command parameter error

The Analyzer command given to the module that controls the tower and loader is invalid.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A software error has occurred.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Tower/Loader Fault 17: motor command timing error

A motor in the Sample Loader was busy (e.g. in motion) when a command was received and could not respond.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A mechanical problem in the Tower or Sample Loader has occurred.	1. Check for an obstruction in the Tower or Sample Loader and, if one is found, remove it. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Tower/Loader Fault 18: invalid direct command

The Analyzer command given to the module that controls the tower and loader is invalid.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A software error has occurred.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

– – – - Probable Cause – – –	– – – - Corrective Action –
Tower/Loader Fault 19: invalid process command	
The Analyzer command given to the module that controls the tower and loader is invalid.	
1. A software error has occurred.	1. Reboot the System. NOTE: If you wish to use the Sample Loader, reset the racks before rebooting the System. 2. If the message appears repeatedly, contact your Hematology Customer Support Center.
Loader Fault 40: mix head stuck in angle position	
The Mix Head failed to return to its vertical position.	
1. A mechanical problem is preventing the Mix Head from rotating downward.	1. 1.Remove the Loader Cover. Check for an obstruction that is preventing the Mix Head from rotating downward and, if one is found, remove it. Then, rotate the Mix Head to its vertical position, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. A failure of the sensor or related electronics has occurred.	2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 41: mix head stuck in vertical position

The Mix Head failed to move from its vertical position.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A mechanical problem is preventing the Mix Head from rotating upward.	1. Remove the Loader Cover. Check for an obstruction that is preventing the Mix Head from rotating upward and, if one is found, remove it. Then, rotate the Mix Head to its vertical position, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], RESET LOADER].
2. A failure of the sensor or related electronics has occurred.	2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Loader Fault 42: mix head not at top position

The Mix Head failed to reach its top position.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A mechanical problem is preventing the Mix Head is from moving upward.	1. Remove the Loader Cover. Check for an obstruction that is preventing the Mix Head from rotating upward and, if one is found, remove it. Then, rotate the Mix Head to its vertical position, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. A failure of the sensor or related electronics has occurred.	2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 43: mix head stuck at top position

The Mix Head failed to move from its top position.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A mechanical problem is preventing the Mix Head from moving downward.	1. Remove the Loader Cover. Check for an obstruction that is preventing the Mix Head from rotating downward and, if one is found, remove it. Then, rotate the Mix Head to its vertical position, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. A failure of the sensor or related electronics has occurred.	2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 44: load zone empty detector malfunction

The system that detects when the load zone is empty failed to indicate that it is empty.

NOTE: This fault does not lead to a Sample Loader halt because any rack currently in the mixing zone is unaffected.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A mechanical problem has prevented the rack arms in the load zone from retracting.	1. Visually check for an obstruction that is preventing the rack arms in the load zone from retracting and, if one is found, press the STOP LOADER key to halt the Sample Loader. Remove the obstruction. Then, resume Sample Loader operation by pressing the following keys in order: [START LOADER], [RESUME LOADER].
2. A failure of the sensor or related electronics has occurred.	2. Reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
3. A failure of the sensor mechanics has occurred.	3. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Probable Cause	Corrective Action
Loader Fault 45: unload zone full detector malfunction The system is detecting an unload zone full condition (5 racks in unload zone) even though there are fewer than 5 racks in the unload zone.	
1. A mechanical problem has prevented the rack arms in the unload zone from retracting.	1. Check for an obstruction that is preventing the rack arms in the load zone from retracting and, if one is found, remove it. Then, resume Sample Loader operation by pressing the following keys in order: [START LOADER], [RESUME LOADER].
2. A failure of the sensor mechanics has occurred.	2. If the message appears repeatedly, contact your Hematology Customer Support Center.
Loader Fault 46: unload zone nearly full detector malfunction The system is detecting an unload zone nearly full condition (4 racks in unload zone) even though there are fewer than 4 racks in the unload zone.	
1. A mechanical problem has prevented the rack arms in the unload zone from retracting.	1. Check for an obstruction that is preventing the rack arms in the load zone from retracting and, if one is found, remove it. Then, resume Sample Loader operation by pressing the following keys in order: [START LOADER], [RESUME LOADER].
2. A failure of the sensor mechanics has occurred.	2. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Several Sample Loader-related error messages refer to tube positions 3 and 4, which are Mixing Stations 1 and 2 respectively. (Refer to Figure 13.7.)

Loader Fault 47: tube stuck in position 3

The sensor for tube position 3 in the mixing zone is sensing the presence of a tube when the tube should be lifted clear of the rack by the Mix Head

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The Mix Head has failed to lift the tube in position 3.	1. The Mix Head has failed to lift the tube in position 3.
a. The tube in position 3 has liquid on it.	a. Dry the tube in position 3. Then, reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
b. The tube in position 3 either has a loose bar code label or too many bar code labels.	b. If the bar code label is loose, secure it in place. If multiple bar code labels are on the tube, remove them and carefully apply a single bar code label. Then, reset the racks, and reset the Sample Loader. NOTE: For information concerning proper application of bar codes, refer to Section 13: Sample Loader, Subsection: Bar Code Label Placement.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 47: tube stuck in position 3 (continued)	
– – – – Probable Cause – – –	– – – – Corrective Action –
c. The Mix Head is dirty.	c. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with a 10% bleach solution, clean the Mix Head. Dry the Mix Head thoroughly. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader.
2. A failure of the sensor or related electronics has occurred.	2. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the tube sensors (the tube position 3 sensor is on the right). Dry the sensors thoroughly. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader. NOTE: For the location of the tube sensors, refer to the figure in Section 13: Sample Loader, Subsection: Processing Stations. 3. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 48: tube stuck in position 4

The sensor for tube position 4 in the mix zone is sensing the presence of a tube when the tube should be lifted clear of the rack.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The Mix Head has failed to lift the tube in position 4.	1. The Mix Head has failed to lift the tube in position 4.
a. The tube in position 4 has liquid on it.	a. Dry the tube in position 4. Then, reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
b. The tube in position 4 either has a loose bar code label or too many bar code labels.	b. If the bar code label is loose, secure it in place. If multiple bar code labels are on the tube, remove them and carefully apply a single bar code label. Then, reset the racks, and reset the Sample Loader. NOTE: For information concerning proper application of bar codes, refer to Section 13: Sample Loader, Subsection: Bar Code Label Placement.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 48: tube stuck in position 4 (continued)	
– – – – Probable Cause – – –	– – – – Corrective Action –
c. the Mix Head is dirty.	c. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with a 10% bleach solution, clean the Mix Head. Dry the Mix Head thoroughly. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader.
2. A failure of the sensor or related electronics has occurred.	2. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the tube sensors (the tube position 4 sensor is on the left). Dry the sensors thoroughly. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader. NOTE: For the location of the tube sensors, refer to the figure in Section 13: Sample Loader, Subsection: Processing Stations. 3. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Tower Fault 49: tower cover open

The circuit formed when the Tower Cover is in place has been broken.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The Tower Cover has been removed or is not seated properly.	1. Reinstall or reset the Tower cover. Make sure the cover is held in position by the latch hardware on the instrument frame. Then reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. A failure of the sensor or related electronics has occurred.	2. Reset the racks and reset the Sample Loader. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 50: probe stuck at home position

NOTE: The home position for the probe is the uppermost position.

The sensor indicates that the probe is in the home position when the System does not expect the probe to be homed.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A mechanical problem has prevented the probe from leaving the home position on the Aspiration Tower.	1. Remove the Loader Cover. Check for an obstruction on the Aspiration Tower that is preventing the probe from leaving the home position and, if one is found, remove it. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. A failure of the sensor or related electronics has occurred.	2. Reset the racks and reset the Sample Loader.
3. The tower, motor, or related electronics is defective.	3. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Tower Fault 100: probe unable to reach home position

The sensor system indicates that the probe is not in the home position when the system expects the probe to be homed.

– – – – Probable Cause – – –	– – – – Corrective Action –
1. A mechanical problem has prevented the probe from reaching the home position on the Aspiration Tower.	1. Remove the Loader Cover. Check for an obstruction on the Aspiration tower that is preventing the probe from reaching the home position and, if one is found, remove it. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. A failure of the sensor or related electronics has occurred.	2. Reset the racks and reset the Sample Loader.
3. The tower, tower motor, or related electronics is defective.	3. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Tower Fault 141: invalid tube height

The tube height sensor system indicates that the tube at the Aspiration Station is either too tall or too short.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The instrument cannot accommodate the height of the tube.	1. To run the sample in the Sample Loader, pour the sample into a tube without anti-coagulant that meets height specification. Then reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER]. NOTE: For tube height specifications, refer to Section 13: Sample Loader, Subsection: Physical and Performance Specifications.
2. Failure of the sensor or related electronics has occurred.	2. Reset the racks and reset the Sample Loader.
3. The tube height sensor or sensor flag on the Tower is not moving into position properly. a. The Guide Shafts are dirty.	3. The tube height sensor or sensor flag on the Tower is not moving into position properly. a. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the Guide Shafts. Then, reinstall the Loader cover, reset the racks, and reset the Sample Loader. NOTE: The Guide Shafts are the three vertical bars on the tower.

Table 10.2: General Fault Conditions (*Continued*)

Tower Fault 141: invalid tube height (continued)

– – – - Probable Cause – – –	– – – - Corrective Action –
b. A mechanical problem is preventing the tube spinning assembly or tube height sensor flag from moving up and down properly.	b. Remove the Loader Cover. Check for an obstruction that is preventing the tube spinning assembly or tube height sensor flag from moving up and down properly and, if one is found, remove it. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader.
c. The guide shafts are misaligned or the tube height sensor flag is bent.	c. Contact your Hematology Customer Support Center.

Tower Fault 142: no tube present

The tube height sensor did not sense a tube when one was expected.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The tube being processed exceeds height specifications.	1. To run the sample in the Sample Loader, pour the sample into a tube without anti-coagulant that meets height specifications. Then, reset the racks and rest the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER]. NOTE: For tube height specifications, refer to Section 13: Sample Loader, Subsection: Physical and Performance Specifications.
2. A failure of the sensor or related electronics has occurred.	2. Reset the racks and reset the Sample Loader.

Table 10.2: General Fault Conditions (*Continued*)

Loader Warning 144: excessive cycling

Twenty-five rack advances have occurred without a tube being sensed in the mix zone.

NOTE: The Sample Loader halts.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The System is functioning as intended.	1. No corrective action is necessary. When you wish to run additional samples in the Sample Loader, load tubes in racks and press the following keys in order: [CLEAR FAULT], [START LOADER], [RESUME LOADER].
2. The rack advance mechanism is not making contact with the racks.	2. Check for an obstruction that is preventing the rack arms from extending and holding the racks against the loader wall so the racks can engage with the rack advance mechanism. If an obstruction is found, remove it. Then, reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].

Table 10.2: General Fault Conditions (*Continued*)

Loader Warning 144: excessive cycling (continued)

– – – - Probable Cause – – –	– – – - Corrective Action –
3. A failure of the sensor or related electronics, or related mechanisms has occurred.	3. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the tube sensors. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader. NOTE: For the location of the tube sensor, refer to the figure in Section 13: Sample Loader, Subsection: Processing Stations. 4. If the message appears repeatedly, contact you Hematology Customer Support Center.

Loader Fault 147: unload area hardware malfunction

The sensor system is indicating that the unload area is full (contains 5 racks), but is not indicating that it is also nearly full (contains 4 racks).

– – – - Probable Cause – – –	– – – - Corrective Action –
1. One or more racks did not move properly in the unload area.	1. Check for an obstruction that is preventing rack movement in the unload area and, if one is found, remove it. Then, reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. A failure of the sensor system or related electronics has occurred.	2. Reset the racks and reset the Sample Loader. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 148: tube dropped during mixing

A tube was sensed as missing from tube position 3 or 4 after the mixing cycle.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A tube slipped out of a Tube Gripper in the Mix Head.	1. A tube slipped out of a Tube Gripper in the Mix Head.
a. The tube has liquid on it.	a. Remove the Loader Cover. Dry the tube. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
b. The Tube Gripper is dirty.	b. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the Tube Gripper. Then, reinstall the Sample Loader, reset the racks, and reset the Sample Loader.
2. A failure of the sensor system or related electronics has occurred.	2. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the tube sensors. Dry the sensors thoroughly. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader. NOTE: For the location of the tube sensors, refer to the figure in Section 13: Sample Loader, Subsection: Processing Stations
3. A failure of the bladder or bladder pressure system has occurred.	3. Contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 149: mix zone rack position error

The tube position bar code number read was not the number expected.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The rack did not advance.	1. The rack did not advance.
a. A mechanical problem is preventing the rack from advancing.	a. Check for an obstruction that is preventing the rack from advancing and, if one is found, remove it.
b. The rack and/or Sample Loader baseplate are dirty.	b. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with deionized water, clean the rack and Sample Loader baseplate. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
c. A failure of the Air Cylinder or the Air Cylinder pressure system has occurred.	c. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 150: unexpected tube in position 4 after rack advance

A tube was not sensed in tube position 3 before a rack advance, but a tube was sensed in tube position 4 after a rack advance.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The rack did not advance.	1. The rack did not advance.
a. A mechanical problem is preventing the rack from advancing.	a. Check for an obstruction that is preventing the rack from advancing and, if one is found, remove it.
b. The rack and/or Sample Loader baseplate are dirty.	b. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with deionized water, clean the rack and Sample Loader baseplate. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
c. A failure of the Air Cylinder or the Air Cylinder pressure system has occurred.	c. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 150: unexpected tube in position 4 after rack advance (continued)	
– – – - Probable Cause – – –	– – – - Corrective Action –
2. A failure of the sensor system or related electronics has occurred.	2. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the tube sensors. Dry the sensors thoroughly. Then reinstall the Loader Cover, reset the racks, and reset the Sample Loader. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 151: tube lost moving from position 3 to 4

A tube was sensed in tube position 3 before the rack advance, but a tube was not sensed in tube position 4 after the rack advance.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The rack did not advance.	1. The rack did not advance.
a. A mechanical problem is preventing the rack from advancing.	a. Check for an obstruction that is preventing the rack from advancing and, if one is found, remove it.
b. The rack and/or Sample Loader baseplate are dirty.	b. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lense cleaner or deionized water, clean the rack and Sample Loader baseplate. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
c. A failure of the Air Cylinder or the Air Cylinder pressure system has occurred.	c. If the message appears repeatedly, contact your Hematology Customer Support Center
2. A failure of the sensor system or related electronics has occurred.	2. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the tube sensors. Dry the sensors thoroughly. Then reinstall the Loader Cover, reset the racks, and reset the Sample Loader. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 152: mix zone must be cleared for reset

The sensor system indicates that a tube is present in tube position 4immedialtely after the Sample Loader was reset, but a rack has not yet been pushed into the mix zone.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. A rack remains in the mix zone when the Sample Loader is reset.	1. Remove the rack from the mix zone. Then, reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. There is an obstruction at tube position 4 that is activating the sensor.	2. Remove the Loader Cover. Check for an obstruction at tube position 4 that is activating the sensor and, if one is found, remove it. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader.
3. A failure of the sensor system or related electronics has occurred.	3. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the tube sensors. Dry the sensors thoroughly. Then reinstall the Loader Cover, reset the racks, and reset the Sample Loader. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 153: rack bar code read failure

The rack bar code label (the first label on the rack) could not be read. This label has a two-digit rack number.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The window on the Bar Code Reader is dirty.	1. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the window on the Bar Code Reader. Dry the window on the Bar Code Reader thoroughly. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER]. NOTE: For the location of the Bar Code Reader, refer to Section 13: Sample Loader, Subsection: Sample Loader Description.
2. The first rack bar code label is scuffed or dirty.	2. Clean or replace the tube position bar code label. Then, reset the racks and reset the Sample Loader. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 154: tube position bar code read failure

A tube position bar code label (the second through tenth labels on the rack) could not be read.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The window on the Bar Code Reader is dirty.	1. Remove the Loader Cover. Using a DYN-A-WIPE™ pad or lint-free wipe moistened with lens cleaner or deionized water, clean the window on the Bar Code Reader. Dry the window on the Bar Code Reader thoroughly. Then, reinstall the Loader Cover, reset the racks, and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER]. NOTE: For the location of the Bar Code Reader, refer to Section 13: Sample Loader, subsection: Sample Loader Description.
2. The tube position bar code label is scuffed or dirty.	2. Clean or replace the tube position bar code label. Then, reset the racks and reset the Sample Loader. If the message appears repeatedly, contact your Hematology Customer Support Center.

Table 10.2: General Fault Conditions (*Continued*)

Loader Fault 156: bar code reader failure

The tube sensors have sensed a tube, but the System was unsuccessful in reading both the rack and tube position bar code labels.

– – – - Probable Cause – – –	– – – - Corrective Action –
1. The rack and tube position bar code labels are not present or are unreadable.	1. Replace the rack and tube position bar code labels with new labels. Then, reset the racks and reset the Sample Loader by pressing the following keys in order: [CLEAR FAULT], [START LOADER], [RESET LOADER].
2. The Bar Code Reader cable has been disconnected, or the Bar code Reader or related electronics has failed.	2. Reset the racks and reset the Sample Loader. If the message appears repeatedly, contact your Hematology Customer Support Center.

NOTES

Index of Table 10.3: Sample-Related Fault Conditions

Table 10.3: Sample-Related Fault Conditions

Each message is followed by one of the abbreviations shown below indicating where that message appears on the screen:
BL — Bulletin Line
SB — Status Box
Information for each message is listed in order from the most likely cause of the message to the least likely cause of the message. Therefore, always troubleshoot a problem in this order.

Sampling Error — Incomplete Aspiration/BL

`SAMPLING ERR` is displayed on the RUN screen (and `SAMPLING ERR` is printed) to the right of the MCHC result.
"`SAMPLING ERR`" is printed on all reports.
Results may look like background counts.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The blood sensor system did not detect a sufficient amount of sample on either side of the Shear Valve at the expected time following aspiration.	1. Check the sample tube to be sure it contains a sufficient quantity of blood. 2. Clean the Open Sample Probe or the Closed Sample Needle as directed in **Section 9, *Subsections: Unclogging the Open Sample Aspiration Probe*** or ***Unclogging the Closed Sample Aspiration Needle*** to remove any obstructions. 3. Clean the Shear Valve as directed in **Section 9, Subsection: *Shear Valve Cleaning***. 4. Contact your Hematology Customer Support Center.

Table 10.3: Sample Related Fault Conditions *(Continued)*

3 consecutive incomplete aspirations/BL	
– – – – Probable Cause – – – –	– – – – Corrective Action – – –
1. During sample processing, three consecutive incomplete aspiration errors were detected and the Sample Loader halted.	1. Correct the situation on the Analyzer as follows: Check the appropriate tubing for a plug or a pinch. Clean the Closed Mode needle. (If necessary, refer to the instructions given in **Section 9**, **Subsection: *Unclogging the Closed Sample Aspiration Needle.*** 2. Press the [CLEAR FAULT] key followed by [RESUME LOADER] or [RESET LOADER] displayed on the RUN screen. The Sample Loader continues processing. 3. If unable to resolve this problem, contact your Hematology Customer Support Center.

Table 10.3: Sample-Related Fault Conditions (*Continued*)

WOC Flow Error/BL

WOC FLOW ERROR is displayed on the RUN screen to the right of the EO results.

"WOC FLOW ERR" is printed on the graphics report to the right of the NEO result.

Results for WBC and Differential are suppressed.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. An increasing WOC count rate was detected in the optical flow cell during the WOC measurement.	1. Repeat the sample. 2. Clean the Sample Injection Syringe as directed in **Section 9, *Subsection: Syringe Cleaning***. 3. Refer to the Trouble- shooting Tips and Techniques subsection of this section for help with collecting further information.

NOC Flow Error/BL

NOC FLOW ERROR is displayed on the RUN screen under the BASO result.

"NOC FLOW ERR" is printed on the graphics report to the right of the LYM result.

Results for WBC and Differential are suppressed.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. An increasing NOC count rate was detected in the optical flow cell during the NOC measurement.	1. Repeat the sample. 2. Clean the Sample Injection Syringe as directed in **Section 9, *Subsection: Syringe Cleaning***. 3. Refer to the Trouble- shooting Tips and Techniques subsection of this section for help with collecting further information.

Table 10.3: Sample-Related Fault Conditions (*Continued*)

RBC Flow Error/BL

RBC FLOW ERROR is displayed on the RUN screen to the right of the RDW result.

"RBC FLOW ERR" is printed on the graphics report to the right of the RDW result.

Results for RBC, PLT, and related parameters are suppressed.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. An increasing RBC count rate was detected in the optical flow cell during the RBC measurement.	1. Repeat the sample. 2. Clean the Sample Injection Syringe as directed in **Section 9, *Subsection: Syringe Cleaning***. 3. Refer to the Trouble-shooting Tips and Techniques subsection of this section for help with collecting further information.

---

3 consecutive WOC flow errors/BL

3 consecutive NOC flow errors/BL

3 consecutive RBC flow errors/BL

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. Three consecutive flow error messages occurred during Sample Loader operation.	1. Three consecutive flow errors of the same type will cause the Sample Loader to halt. Refer to the three previous messages and ***Troubleshooting Tips and Techniques*** earlier in this section. 2. If unable to resolve this problem, contact your Hematology Customer Support Center.

Table 10.3: Sample-Related Fault Conditions (*Continued*)

.

>>>> In Place of Results for WBC, RBC, or PLT	
– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. Data exceeds linear range for that parameter.	1. Dilute the sample with diluent/ sheath according to your laboratory procedures and rerun the sample. Multiply the results by the dilution factor.

High Rate of False Flagging

High number of false flags displayed on the RUN screen.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. Contaminated WBC Lyse.	1. Replace WBC Lyse reagent.
2. Dirty optical flow cell.	2. In SPECIAL PROTOCOLS menu, follow procedure for emptying and refilling optical flow cell.
3. Optical gains have shifted.	3. Contact your Hematology Customer Support Center.
4. Aging laser causes inaccurate measurements.	4. Replace laser.

Index of Table 10.4: Non-Functional Fault Conditions

Table 10.4: Non-Functional Fault Conditions

Analyzer will not power ON

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. Power cord is not securely connected to the Analyzer or is not connected to the power outlet.	1. Ensure that the power cord is securely connected to the Analyzer and verify that it is connected to the power outlet.
2. Power source is defective.	2. Turn the power switch OFF and connect the system to a different power source.Turn the power switch ON.
3. Analyzer fuse has failed or is incorrect.	3. Analyzer fuse is located above the power cord connector on the rear panel. Check the fuse as directed in the **Section 9**, **Subsection:** ***Fuse Replacement***.
4. Defective power switch or other system malfunction.	4. Contact your Hematology Customer Support Center.

No screen display on the Display Monitor

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. Display Monitor brightness control is turned down.	1. Adjust the brightness control under the front control panel of the Display Monitor until the image is visible.
2. Defective Display Monitor or other component.	2. Power OFF and ON again.
	3. Contact your Hematology Customer Support Center.

Table 10.4: Non-Functional Fault Conditions (*Continued)*

The FAULT indicator light on the Analyzer status indicator panel is illuminated in red

NOTE: This type of fault is usually accompanied by a message in the status box and/or on the bulletin line.

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The Analyzer has detected a fault situation and has stopped operating.	1. From the first DIAGNOSTICS MENU screen, press [FAULT REPORT]. Print a copy of the report and perform the indicated corrective action. When the action is completed, initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. 2. If the fault report does not indicate a message or action, document the situation and initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen.

Table 10.4: Non-Functional Fault Conditions (*Continued*)

Background count is outside acceptable limits	
– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The Analyzer front covers are removed.	1. Verify that the front covers are attached. Repeat the background count.
2. Debris is present in the system.	2. In the second SPECIAL PROTOCOLS MENU screen, perform an [AUTO CLEAN] cycle to clean the system. When the cycle is Background count.
3. The reagents are cold — less than 59°F (15°C).	3. Allow the reagents to warm to room temperature and then repeat the Background count.
4. The reagents are contaminated.	4. Replace the appropriate reagent according to the directions given in Troubleshooting Reagent Problems cited earlier in this section.
5. There is liquid in the vacuum accumulator.	5. In the second DIAGNOSTICS MENU screen, press the [DRAIN ACCUMULAT] key. When the cycle is finished, initialize the Analyzer by pressing the [INITIALIZATION] key on the second DIAGNOSTICS MENU screen. Repeat the Background count
6. There are bubbles in the Diluent/Sheath syringe.	6. Clean the Diluent/Sheath syringe.
7. The Shear Valve is dirty.	7. Clean the Shear Valve. Repeat the Background count.

Table 10.4: Non-Functional Fault Conditions (*Continued*)

The PC keyboard is not operational	
– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The computer is performing a function that inhibits the keys.	1. No action required. Refer to the screen for the current Status Box message.
2. There is an incomplete operator entry.	2. Complete the operator entry or press the Esc key on the PC keyboard.
3. A data transmission to the printer or laboratory computer is in progress.	3. No action required. Refer to the screen for the Status Box message.
4. Keyboard entry is not possible on the displayed screen.	4. No action required. Refer to the screen for the current Status Box message.
5. Computer, keyboard and/or circuitry malfunction.	5. Initialize the Analyzer by pressing the INITIALIZATION] key on the second DIAGNOSTICS MENU screen. If necessary, contact your Hematology Customer Support Center.

Table 10.4: Non-Functional Fault Conditions (*Continued*)

The Sample Loader does not respond when the START LOADER, RESUME, or RESET key is pressed

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The internal power cord connecting the Sample Loader to the Analyzer is loose or disconnected.	1. Contact your Hematology Customer Support Center.
2. Circuitry malfunction.	2. Press [FAULT REPORT] in the main DIAGNOSTICS MENU and record any fault listed. 3. Turn the instrument OFF and ON again and prime the instrument. 4. If the problem persists, contact your Hematology Customer Support Center.

The Sample Loader beeps but does not begin processing

– – – - Probable Cause – – – –	– – – - Corrective Action – – –
1. The internal cable that connects the Sample Loader to the Analyzer is loose or disconnected.	1. Contact your Hematology Customer Support Center.
2. Circuitry malfunction.	2. Press [FAULT REPORT] in the main DIAGNOSTICS MENU and record any fault listed. 3. Turn the instrument OFF and ON again and prime the instrument. 4. If the problem persists, contact your Hematology Customer Support Center.

Overview

This section contains two major subsections: Quality Control Menu, and Quality Control Guide. The Quality Control Menu describes the functions of the keys in the QC MENU. The Quality Control Guide discusses the interpretation of QC data.

QC Options

The CELL-DYN® 3200 offers several Quality Control options to monitor and validate instrument performance. The options are:

X-B Analysis — Bull's moving average program applied to the RBC Indices and some WBC Differential optical parameters. This QC option is useful for troubleshooting and confirming that the calibration of the red blood cell parameters has not changed.

20 QC Files — Utilizes commercial controls (low, normal, high) or fresh whole blood specimens to obtain statistical and graphical analyses. The data in each file is used to calculate the mean, standard deviation and coefficient of variation.

Westgard Rules — A multi-rule system applied to the data in each of the QC Files to detect drift and imprecision and to detect systematic or random error.

The above options may be used independently or in combination, depending on the operator's preference. Each option is discussed in detail in this section.

Quality Control procedures, both internal and external, allow the operator to verify the performance of an analytical system. The use of Quality Control procedures in evaluating both commercial controls and patient samples facilitates the interpretation of laboratory data to ascertain acceptability of patient results.

The information in this section conforms to Abbott Laboratories' recommended procedures for Quality Control for all Abbott hematology instruments. It is recommended that these guidelines be incorporated into the procedure manual for your laboratory. In addition, refer to your laboratory's Standard Operating Procedures and/or Quality Assurance plan for additional Quality Control requirements.

Quality Control Menu

QC Menu Softkeys

This section discusses the options available when the [QUALITY CONTROL] key is pressed. The options used to set up the QC Files are available from the QUALITY CONTROL menu (see Figure 11.1) and the QC SET UP menu. Refer to ***Set Up QC File*** in **Section 5: *Operating Instructions*** for an explanation of these keys as they will not be discussed in this section.

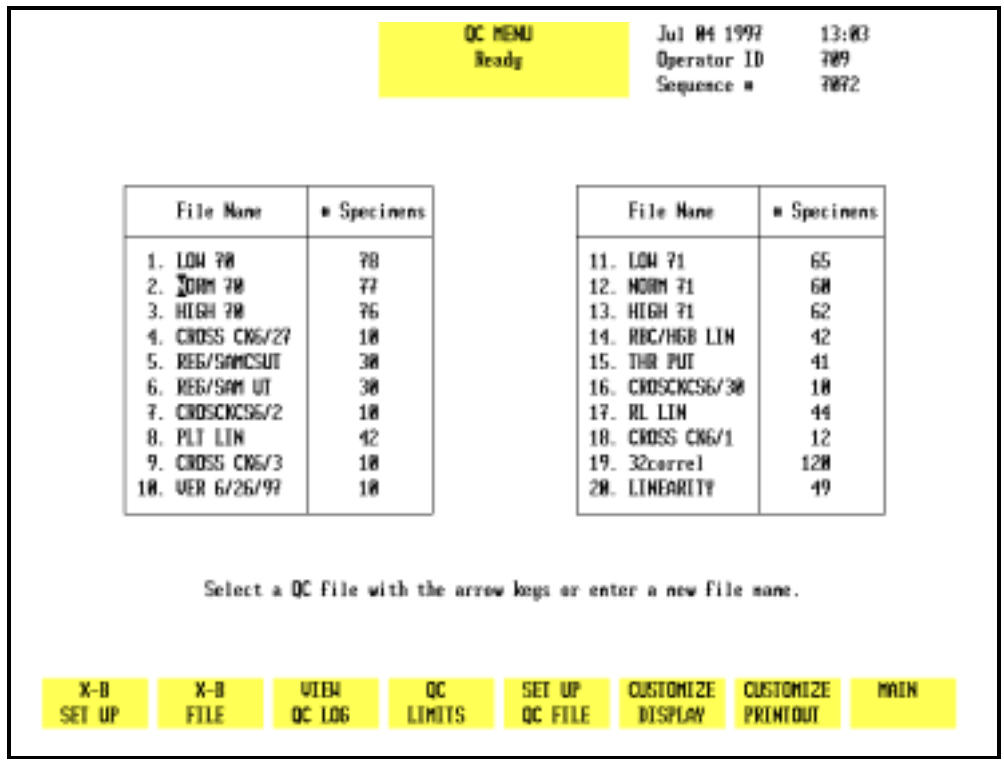

Figure 11.1: Quality Control Menu Screen

The following soft key labels are displayed when the [QUALITY CONTROL] key on the MAIN MENU screen is pressed:

X-B SET UP
X-B FILE
VIEW QC LOG
QC LIMITS*
SET-UP QC FILE*
CUSTOMIZE DISPLAY *
CUSTOMIZE PRINTOUT *
MAIN

* These keys are discussed in **Section 5*: Operating Instructions, Subsection: Set Up Instructions***.

X-B Set Up

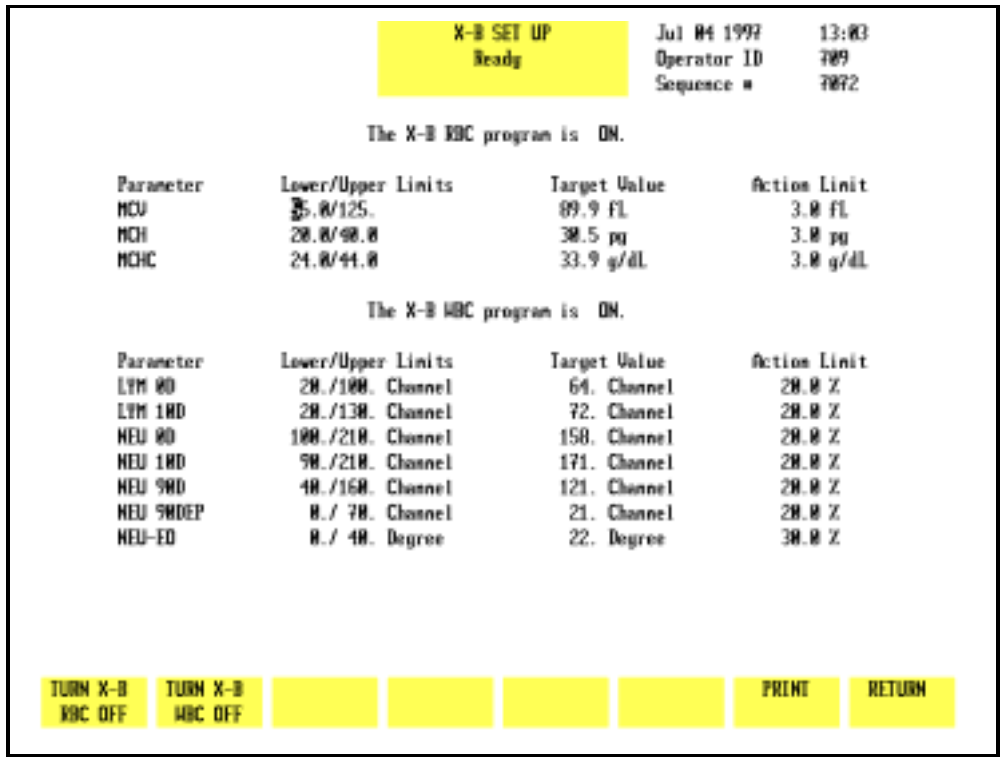

Figure 11.2: X-B Set Up Screen

The following soft key labels are displayed when the [X-B SET UP] key is pressed (refer to Figure 11.2):

TURN X-B RBC OFF	(Key label alternates between ON/OFF selections)
TURN X-B WBC OFF	(Key label alternates between ON/OFF selections)
PRINT	
RETURN	

X-B File

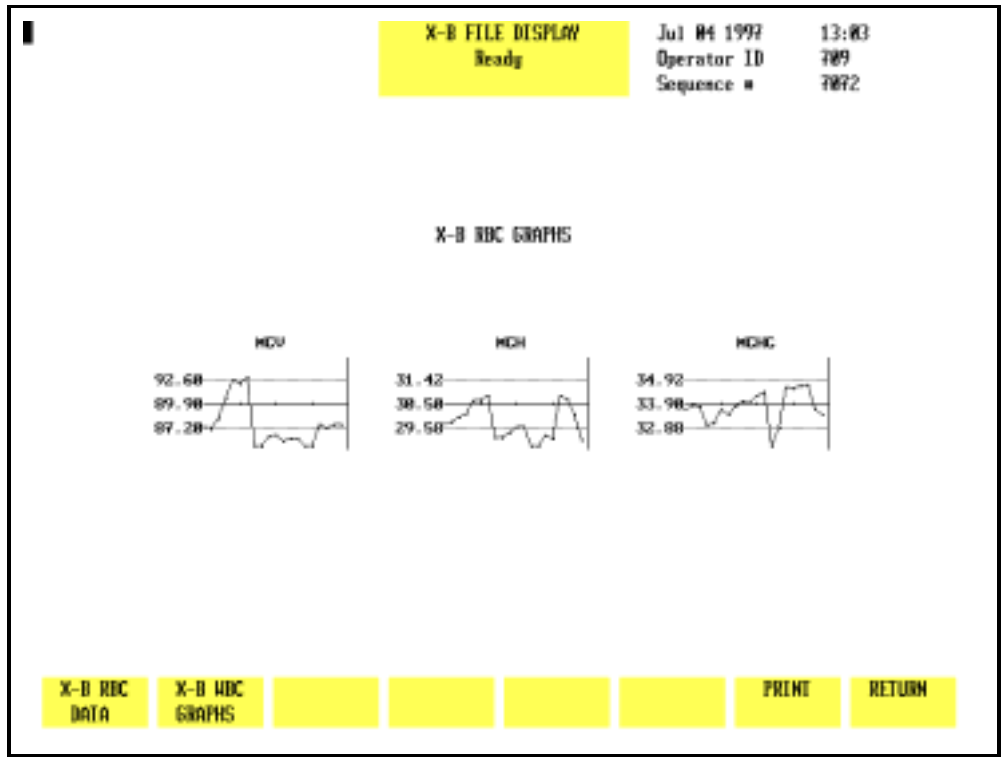

Figure 11.3: X-B RBC Graphs Screen

The following soft key labels are displayed when the [X-B FILE] key is pressed:

X-B RBC DATA/GRAPHS	(Key label alternates between selections)
X-B WBC DATA/GRAPHS	(Key label alternates between selections)
PRINT	
RETURN	

For a description of how the X-B Program works, refer to ***X-B Program Operation*** later in this section.

Show Graphs

When the [X-B RBC GRAPHS] key or [X-B WBC GRAPHS] key is pressed, the X-B GRAPHS DISPLAY screen for the appropriate parameter is displayed. (Refer to Figure 11.3.)

Show Data

When the [X-B RBC DATA] key or [X-B WBC DATA] is pressed, the X-B DATA DISPLAY screen for the appropriate parameter is displayed. This screen is depicted in Figure 11.4. The screen displays the results for X-B batches 1–10 and the lower and upper limits. The date and time that each batch was completed are also displayed. The Page Down key on the keyboard is used to display batches 11–20. When batches 11–20 are displayed, the Page Up key on the keyboard is used to display batches 1–10.

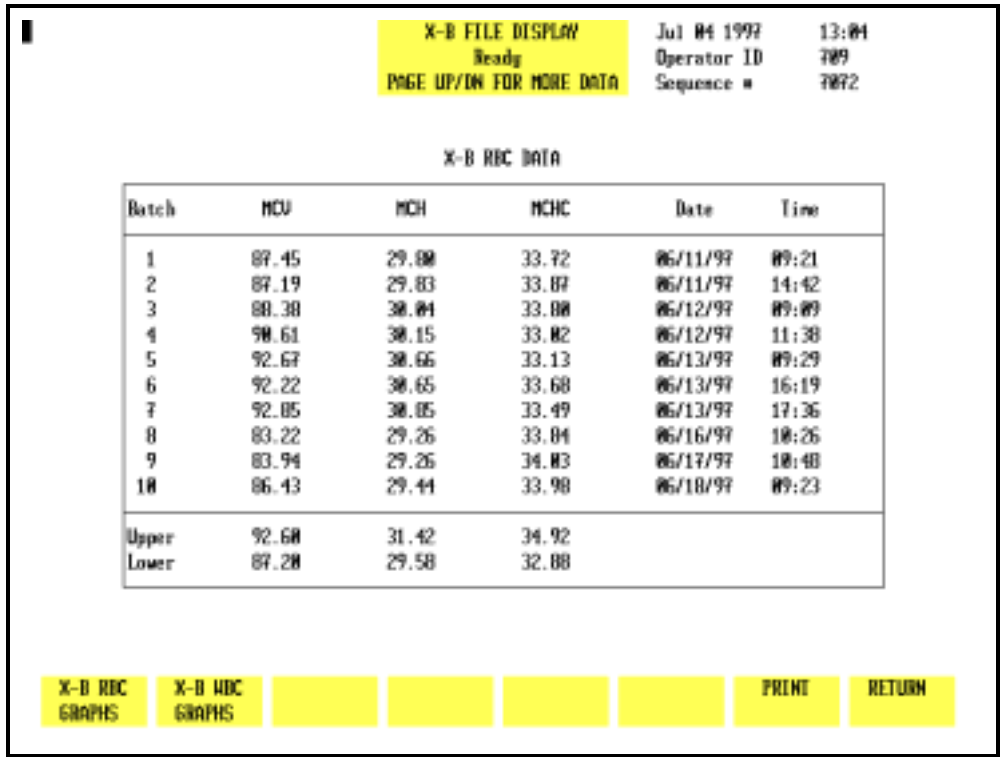

Figure 11.4: X-B RBC Data Screen

Print

The [PRINT] key is used to print the X-B data or graphs. When this key is pressed, the data for *all 20 batches* is automatically printed if the data is displayed. If the graphs are displayed, all ten of them are printed.

Return

The [RETURN] key is used to return to the QC MENU screen.

View QC Log

The [VIEW QC LOG] key is used to display the QC Log indicated by the position of the cursor.

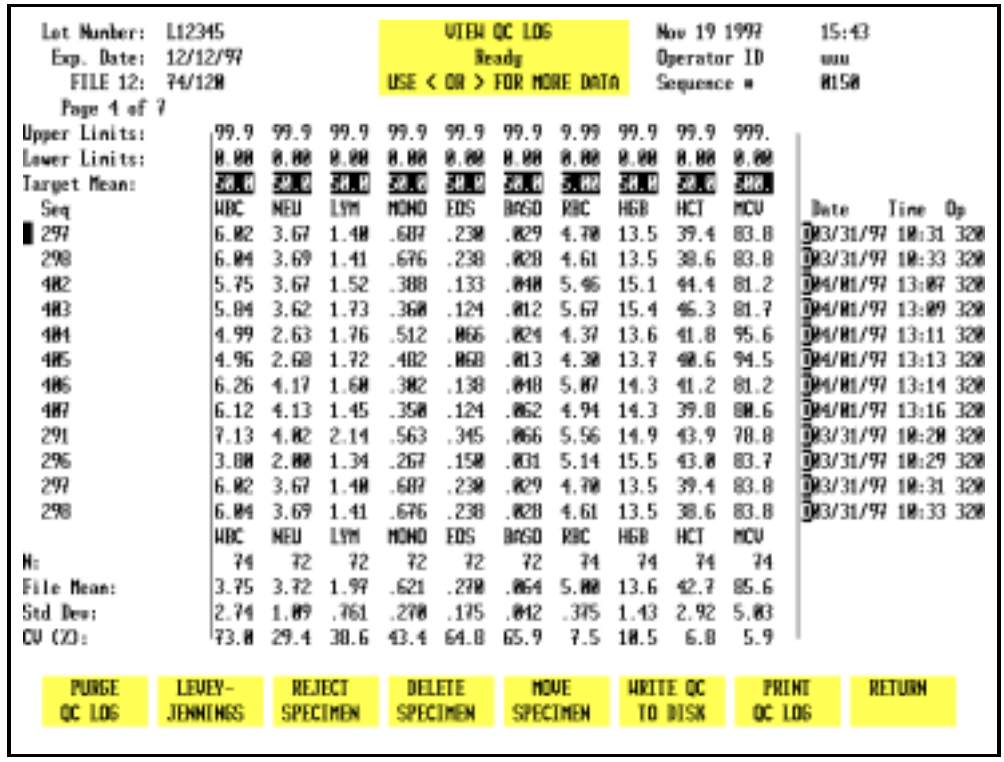

Figure 11.5: The View QC Log Screen

Each QC Log display shows the following information (see Figure 11.5):

1. Upper Left Corner

   LOT NUMBER and EXPIRATION DATE if the file was configured for this type of control. If the file was configured for a REPLICATE ID, it is displayed instead of the lot number and expiration date.

   File name, the number of runs currently in the file and the file capacity (e.g.: 39/120 indicates that the file contains 39 runs out of a possible 120).

   The page number of the display and the total number of pages in the file.

2. Status Box

   USE < OR > FOR MORE DATA. This message indicates that the Left and Right Arrow keys on the keyboard should be used to display the other groups of data.

3. Upper Right Corner

   The current DATE, TIME and OPERATOR ID are displayed along with the last SEQUENCE NUMBER that was used.

4. The remainder of the screen displays the file information and the data. The UPPER and LOWER LIMITS and TARGET MEAN entered are displayed immediately above the parameter names. The sequence number for each result is displayed to the left of the data. The DATE, TIME and OPERATOR ID when the sample was run are displayed to the right of the data.

5. The following QC Log codes are displayed in the column immediately preceding the date. These codes are the same as those used in the Data Log:

   O — Sample was run in the Open mode

   C — Sample was run in the Closed mode

   N — Incomplete aspiration in the Open mode

   I — Incomplete aspiration in the Closed mode

   K — Flow Error occurred

   Background and latex samples use only the O or C codes.

6. The statistics are displayed below the data as follows:

N:	the Number of runs used in the calculation
FILE MEAN:	the Mean value for the number of runs used in the calculation
STD DEV:	the Standard Deviation (+/-1) for the number of runs used in the calculation
CV (%):	the Coefficient of Variation in percent for the number of runs used in the calculation

The following soft key labels are displayed on the VIEW QC LOG screen:

PURGE QC LOG	
LEVEY-JENNINGS	
REJECT SPECIMEN/ ACCEPT SPECIMEN	(Key label alternates between selections)

DELETE SPECIMEN

MOVE SPECIMEN

WRITE QC TO DISK *

PRINT QC LOG

RETURN

* The feature enabling the download of data from a QC file to a floppy disk is not currently available. Therefore, the [WRITE QC TO DISK] key should not be used at this time.

The function of each of these keys is discussed in this section.

Purge QC Log

The [PURGE QC LOG] key is used to delete the contents of the QC Log. When the [PURGE QC LOG] key is pressed, the following soft key labels are displayed:

CONFIRM PURGE

CANCEL PURGE

These keys are used to [CONFIRM] or [CANCEL] the Purge QC Log command.

Levey-Jennings®

The [LEVEY-JENNINGS] key is used to display the Levey-Jennings® graphs of the data in the QC file. (Refer to Figure 11.6.) The following soft key labels are displayed when the [LEVEY-JENNINGS] key is pressed. The soft key for the group being displayed will not be shown.

GROUP 1

GROUP 2

GROUP 3

GROUP 4

PREVIOUS 10

NEXT 10

PRINT

RETURN

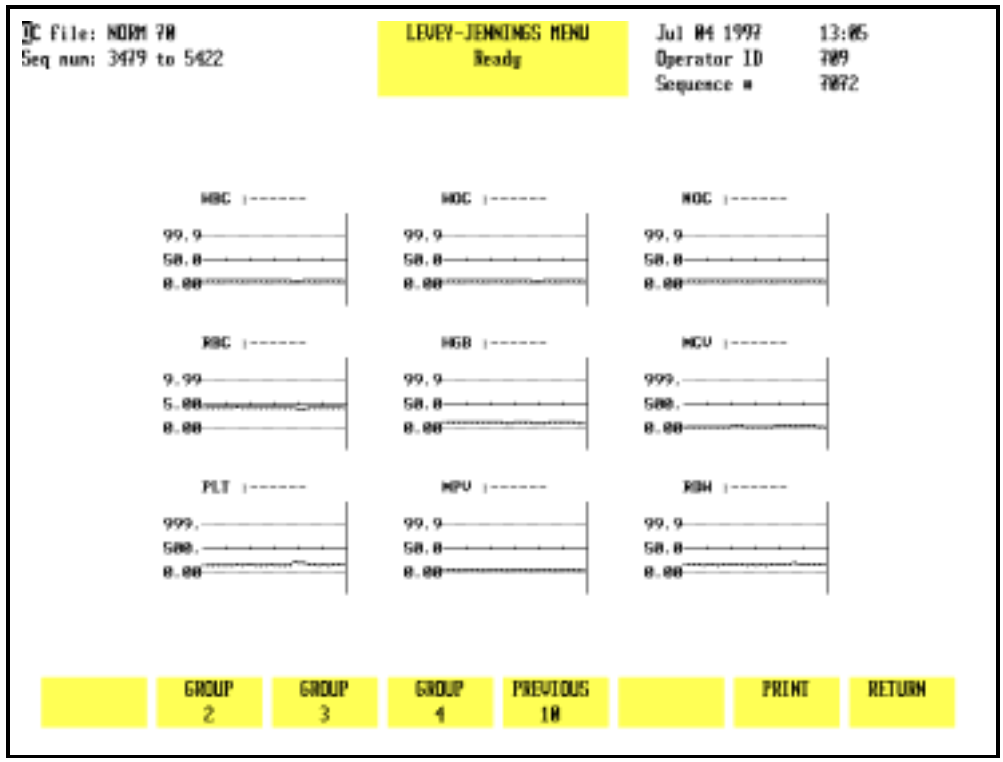

Figure 11.6: The Levey-Jennings® Menu Screen

If there are sufficient specimens in the QC file, when the [PREVIOUS 10] key is pressed, the [NEXT 10] key appears, allowing the operator to scroll both forward and background through the file. (Refer to Figure 11.7.)

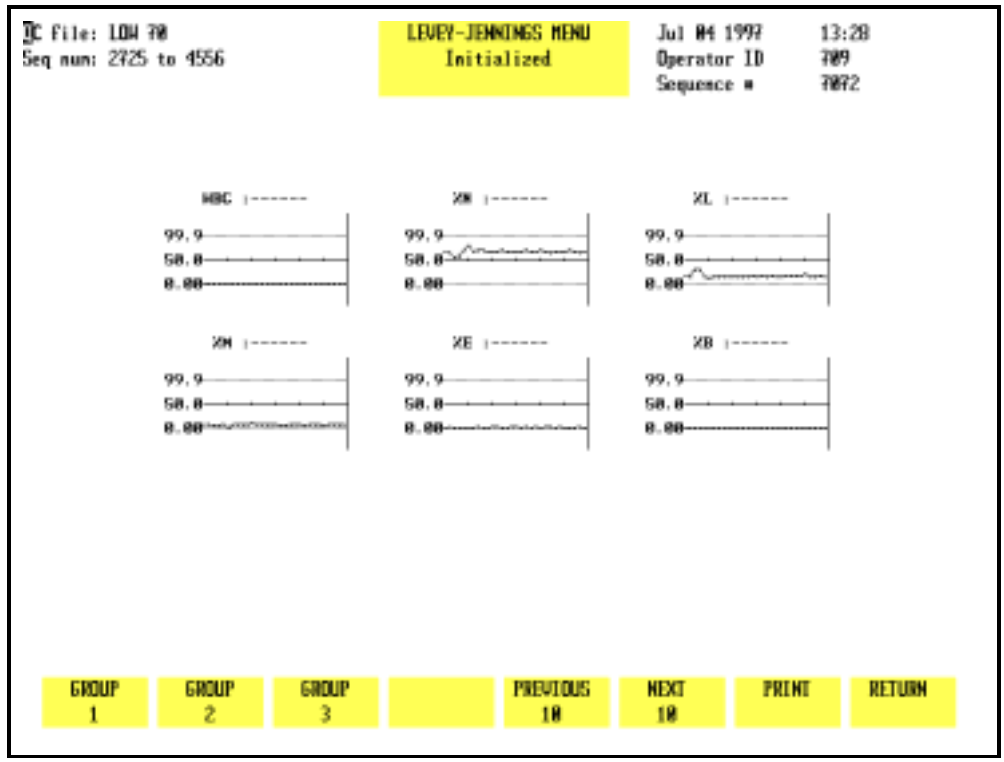

Figure 11.7: The Levey-Jennings® Menu Screen Showing Next 10

Group

Each of the Group keys is used to select the graphs for a group of data that correspond to the groups selected in the Customize QC Display option. Subsequent groups may be selected by pressing the appropriate soft keys.

> **NOTE:** The soft key for the group currently shown on the screen is not displayed.

Print

The [PRINT] key is used to print the Levey-Jennings graphs. When the [PRINT] key is pressed, all of the graphs are automatically printed.

Return

The [RETURN] key is used to return to the VIEW QC LOG screen.

Reject/Accept Specimen

The [REJECT SPECIMEN] key is used to exclude the results for the specimen indicated by the cursor position. When the key is pressed, the key label changes to [ACCEPT SPECIMEN], an "R" is displayed in the column immediately left of the results and the statistics are recomputed excluding those results. (Refer to Figure 11.8.) The data is still displayed and stored in the file but is excluded from the statistical calculation.

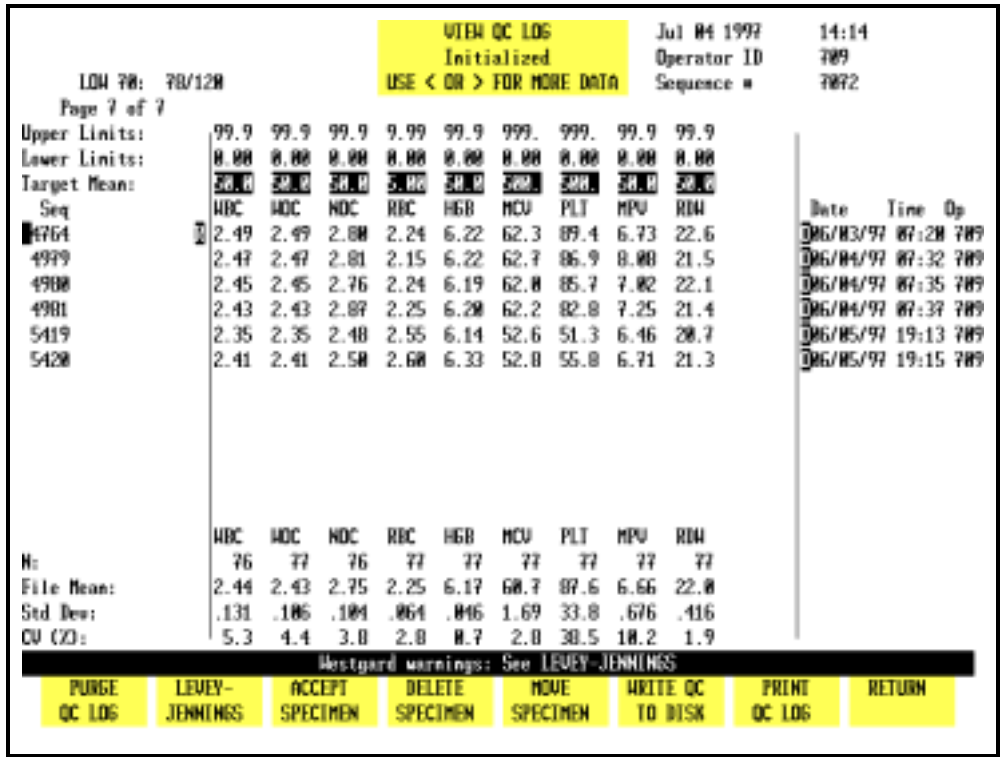

Figure 11.8: QC Log Screen With Rejected Results

When the [ACCEPT SPECIMEN] key is pressed, the "R" is deleted and the statistics are recomputed including those results.

Delete Specimen

The [DELETE SPECIMEN] key is used to delete the results for the specimen indicated by the cursor position. When the [DELETE SPECIMEN] key is pressed, the following key labels are displayed:

CONFIRM DELETION

CANCEL DELETION

These keys are used to [CONFIRM] or [CANCEL] the delete command. When the [CONFIRM DELETION] key is pressed, the results are deleted from the file (the data is not displayed or stored in the file) and the statistics are recomputed excluding those results.

The [MOVE SPECIMEN] key is used to move a QC result indicated by the cursor position to another QC file. When the [MOVE SPECIMEN] key is pressed, the QC MENU screen is displayed, allowing the desired file to be selected. When the [MOVE TO FILE] key is pressed, the result is moved to the indicated file.

Move Specimen Procedure

1. From the QC MENU screen, use the Arrow keys on the keyboard to move the cursor to the file containing the specimen to be moved.
2. Press [VIEW QC LOG].
3. Use the Arrow keys on the keyboard to position the cursor at the result that is to be moved.
4. Press [MOVE SPECIMEN] to again display the VIEW QC LOG screen.
5. Use the Arrow keys on the keyboard to move the cursor to the file in which the results are to be placed.
6. Press [MOVE TO FILE] to move the results to the designated file.

   NOTE: The result is moved to the end of the list of data that is currently in the file.

7. The VIEW QC LOG screen of the original file is displayed showing that the results have been moved.

Write QC to Disk

The [WRITE QC TO DISK] key should not be used at this time.

Print QC Log

The [PRINT QC LOG] key is used to print the entire QC log.

Return

The [RETURN] key is used to return to the QC MENU screen.

NOTES

Quality Control Guide

The Guide is divided into three parts. The first part discusses the handling and running of control material. The second part discusses the Westgard Rules used on the CELL-DYN 3200 System and gives guidance for their application in the hematology laboratory. The third part discusses the X-B Analysis program in monitoring quality control.

All QC data should be reviewed according to your laboratory's protocol.

CELL-DYN Controls

The following controls are recommended for use on the CELL-DYN 3200 System:

Tri-level, 1 box, 2.5-mL vials x 12, list number 93111-01

Tri-level, 1 box, 3.0-mL tubes x 12, list number 99129-01

* CELL-DYN controls are packaged in Vacutainer® tubes with Hemogard closure.

Use of Controls

Controls are used to determine whether an instrument is operating with accuracy and precision. Controls normally consist of fixed blood cells with assayed ranges for each measured parameter. Alternately, laboratories may use patient samples that were previously found to be within set patient limits. CELL-DYN Controls provide three control levels — low, normal, and high ranges — for each measured parameter.

All QC data should be reviewed according to your laboratory's protocol. Refer to the section on Westgard Rules for suggestions on how to use these rules in a review protocol. Refer to the section on X-B Analysis for suggestions and guidelines on interpreting X-B results.

Mixing and Handling

Always mix and handle commercial control materials according to the directions given in the package insert. Because directions may vary from manufacturer to manufacturer, pay particular attention to the following:

- Check the condition of incoming control material. Be sure the vials are at the proper temperature and are not leaking. Check for hemolysis.
- Store controls at recommended temperatures inside the refrigerator, preferably in a central location away from the door.
- Carefully warm and resuspend the product according to the directions given in the package insert. Proper mixing is essential for accurate results.
- Check the shelf life and open-vial stability dating. Do not use products longer than recommended by the manufacturer or the results may be compromised.
- Never subject any vial to excessive heat or agitation.

Assay Verification

New lots of control material should be analyzed in parallel with current lots prior to their expiration dates. Perform the following steps to accomplish the transition to a new lot:

1. Set up a control file for the new lot.
2. Verify values for each new control lot by running each level of control in triplicate along with either replicate QC specimens or the old control when it is still in date.
3. Run the new controls twice a day for five days to establish a mean.
4. Use the mean of the ten runs to verify that the new lot yields the expected results. The mean should fall within the range specified by the manufacturer in the package insert.
5. If the calculated mean falls within the range specified by the manufacturer, use it in place of the manufacturer's stated mean.

6. When results for any parameter(s) are flagged (outside of operator-defined limits or reportable range), reconfirm calibration for that parameter using specimens with known reference values. When calibration confirmation results are acceptable, establish a new working mean and limits for each level of the new lot of control.

A control file should be set up for the new lot number to easily establish the mean. If desired, this sample control file can then be used to run the control for the remainder of the dating period. It is not necessary to create another file.

The expected ranges published by manufacturers are generally too broad for effective Quality Control[1]. Therefore, each laboratory should establish acceptable ranges. These ranges may be determined by evaluating three to six months of data (data from the Interlaboratory QC Program may be used) for a particular level of control. The individual SD (standard deviation) values may be averaged as follows:

$$\text{Average SD} = \sqrt{\frac{(N1 \times SD12) + (N2 \times SD22) + ...+ (Ni \times SDi2)}{(N1 + N2 + ...+ Ni) - i}}$$

N = number of values obtained in a month
SD = standard deviation of values obtained in that month
i = total number of months

The resulting long-term instrument SD and the laboratory-established mean for each lot number should be used to monitor instrument performance.

Running Controls

Abbott recommends using CELL-DYN Control materials for performing Quality Control checks on the CELL-DYN 3200 System. Run a minimum of two levels of control at the beginning of each eight hours of operation prior to running patient samples. In addition, run controls after the following events:

- After calibration (confirmatory step).
- After Daily Start-Up procedures are completed.
- After a reagent lot number change.
- After maintenance, a service call, or component replacement.

- After detection of an unusual trend or shift in patient results.
- In accordance with the laboratory's Quality Control protocol.
- According to regulatory requirements.

Controls should be run in both operating modes, (Open or Closed). Always do the following:

- If the System has been idle for 15 minutes or more, run a background immediately prior to running a control specimen.
- Follow the proper warming and mixing procedures previously described, including those located on the control package insert.
- Run control samples for each measured parameter in the same manner as patient samples.
- Verify that control results are within the laboratory's acceptable limits.
- If the control results fall within acceptable limits, review the data for shifts or trends, record the results, and begin to process patient samples.
- If one or more result falls outside the laboratory's acceptable limits, review **Section 10: *Troubleshooting and Diagnostics*, Subsection: *Troubleshooting Guide***. Perform suggested maintenance steps for the parameter that is out-of-range, then try using another vial from the same lot. If the problem persists, contact the Abbott Customer Support Center.

CELL-DYN 3200 Westgard Rules

Overview

A control rule tests the control result against control limits to determine whether the CELL-DYN 3200 shows acceptable accuracy and precision. The limits are derived from the mean and standard deviation of control measurements obtained when instrument performance is stable and acceptable. The most common rule used in Hematology Quality Control is the mean ± 2SD limits. Ninety-five percent of the control results should fall within the ± 2SD limits.

Quality control rules detect random or systematic error. Random error may be defined as an increase in the SD (loss of precision). Systematic error may be defined as a shift in the mean value (loss of accuracy). A multi-rule quality control procedure combines several control rules to improve the detection of both types of error.

Westgard recommended a multi-rule approach to evaluating quality control results.[2] This approach has long been used in the chemistry laboratory[3] but is new in the hematology laboratory. A set of modified Westgard rules may be used to monitor quality control results on the CELL-DYN 3200.

Westgard Rules

The modified Westgard Rules (Westgard's nomenclature is given in parentheses) available on the CELL-DYN 3200 are:

Rule 1 (1_{3s}):	Value outside 3SD A control result exceeded the mean ± 3SD
Rule 2 (2_{2s}):	Two consecutive values outside the same 2SD Two consecutive results fell outside 2SD on the same side of the mean
Rule 3 (R_{4s}):	Two consecutive values outside opposite 2SD One result was greater than 2SD above the mean and the next result was greater than 2SD below the mean. Consequently, the range between the results is greater than 4SD.
Rule 4(2 of 3_{2s}):	Two of three consecutive values outside same 2SD Two of the last three results fell outside 2SD on the same side of the mean

Rule 5 (4_{1s}): Four consecutive values outside same 1SD
Four consecutive results fell outside 1SD on the same side of the mean

Rule 6 (10x): Ten consecutive values on the same side of mean
Ten consecutive results fell on the same side of the mean

The rules may be used singly or in combination depending on operator preference. Selections are made on the QC FILE SET UP screen.

When a rule is selected, a plus sign is displayed to the right of the parameter name on the LEVEY-JENNINGS MENU screens. (Refer to Figure 11.9.) A minus sign is displayed if a rule is not selected. Six plus signs indicate that all six rules are selected in order from left to right.

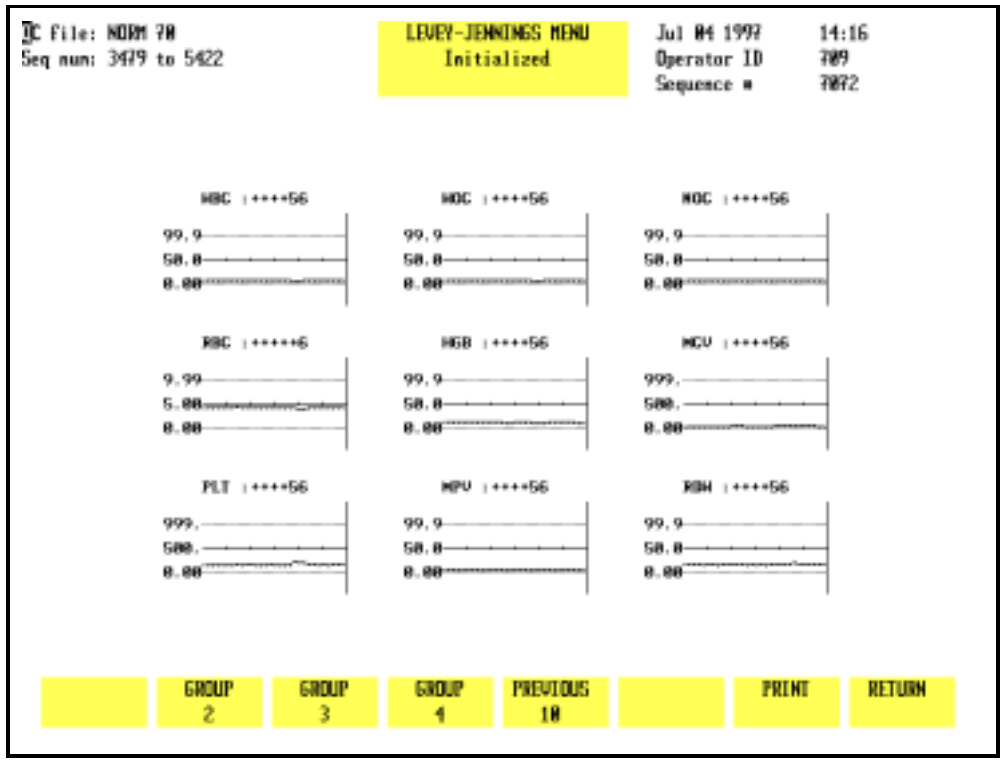

Figure 11.9: Levey-Jennings® Menu Screen Showing Westgard Rule Violations

Whenever a rule is violated, the bulletin line displays the message:

```
WESTGARD WARNINGS: SEE LEVEY-JENNINGS
```

The number of the rule that was violated is displayed in place of the plus sign. Figure 11.9 shows examples of the plus signs and rule-violation indications.

Rule Violations

Only the directly measured parameters need to be monitored with multiple rules.[4] In reference 4 (pp. 190–192), Cembrowski suggests a protocol for using the Westgard rules in Hematology. The following is a synopsis of that protocol.

Since three levels of control are typically used to monitor a hematology analyzer, it is reasonable to consider all three runs at the same time. In other words, check for rule violations across the three levels, not just within a particular level. If the same rule is violated for more than one level, determine whether the violation indicates a loss of precision or a loss of accuracy and troubleshoot accordingly.

Cembrowski suggests that the results for all three levels first be checked to see if they are within their 2SD limits. If all three levels meet this criterion, the instrument is in control.

If any control result exceeds the 2SD limits, check to see if it exceeds the 3SD limits. If a result exceeds 3SD, there are two possibilities. There is either an instrument problem or a problem with the particular level of control. Therefore, if a result exceeds 3SD, run another bottle of that control. If the problem persists, then additional investigation is required.

Check to see if either the 2 of 3_{2s} or R_{4s} rules have been violated for any level or across levels. If the problem is confined to one level of control, check for a 2_{2s} rule violation for that level. Again, if the violations are confined to one level of control, use another bottle and possibly another lot. Check expiration dates and data entry. Check to be sure that the control is run into the correct file.

If a combination of rules has been violated across the three levels, determine whether the violations indicate a loss of precision or a loss of accuracy and troubleshoot accordingly. If necessary, call the Abbott Customer Support Center for assistance.

When the problem has been resolved, Cembrowski suggests that all levels be run again in duplicate to confirm that it has in fact been corrected.

X-B Analysis

Introduction

X-B Analysis is an automated means of monitoring instrument performance by using the known stability of the red cell indices. The following values confirmed the values that Bull published in an earlier study[5,6,7]. Consequently, these values can be used as the Target Values to initiate the X-B Analysis program.

MCV 89.9 fL

MCH 30.5 pg

MCHC 33.9 g/dL

To enter X-B Target Values in the SET UP menu for MCV, MCH, and MCHC, do the following:

1. In the SET UP menu, press [QC SET UP MENU] followed by [X-B SET UP].
2. If necessary, press [TURN X-B RBC ON] to turn the X-B RBC program ON.
3. Use the arrow keys to move the cursor to the Target Value column and type in the following:

   "89.9" for MCV and press Enter

   "30.5" for MCH and press Enter

   "33.9" for MCHC and press Enter

4. Press [RETURN] to exit the X-B SET UP MENU and return to the main QC SET UP menu.

Laboratories seeing specialized patient populations, e.g. pediatric hospitals or tumor centers, may need to verify these values due to "abnormal" patient populations. Target values may be verified by evaluating approximately 500 samples and comparing the X-B means for those samples to the entered target values. This can be done as follows:

1. Collect data from at least 500 patients. Manually calculate the mean, SD, and CV for each index (MCV, MCH, and MCHC). The CV on 500 samples for each index should be less than 1.5%. (The 1.5% is one-half the allowable + 3% action limit.) If the CVs are greater than 1.5%, an additional 500 samples should be evaluated.
2. If the CVs calculated in step 1 are less than 1.5%, enter the mean as the Confirmed Target Value.

X-B Program Operation

The X-B program operates in the following manner:

1. The X-B RBC and X-B WBC fields are only displayed if the X-B functions for RBC and WBC are turned ON in the SET UP menu.
2. The X-B RBC and X-B WBC functions are independent of each other and each consists of a maximum of 20 batches.
3. A completed batch has a maximum 20 specimens.
4. As soon as a 20th specimen is added to the current batch, that batch is completed, and a new batch is started with the next included specimen.
5. Specimens in a current batch are identified with an X-B flag in the Data Log. The number of specimens in a current batch, either RBC or WBC, is shown on the RUN screen under the Status Box in the fields XBRBC: X/IN and XBWBC: X/IN where X is a number from 0 to 20.
6. When the X-B program is first turned from OFF to ON, the number of records in that batch is zero and 0 is displayed on the RUN screen. When a current batch reaches 20, the number 20 remains displayed on the RUN screen until the first specimen is added to a new batch. At that time, the number displayed changes to 1.
7. If there are records in a current batch and the operator turns the program for that batch OFF (e.g., there are 5 records in the RBC batch and the X-B RBC program is turned OFF), all records in the current batch are deleted. When the program is turned back ON again, the number zero is displayed for the current batch of that program.
8. The total number of completed batches, including both RBC and WBC, is limited to 40. The total number of batches is 42 which includes 40 completed batches plus 1 current batch for RBC and 1 current batch for WBC.

9. A completed batch can be viewed on the X-B File Display Screen.
10. Each X-B File Display page is able to display 10 batches.
11. A specimen may be assigned to X-B RBC, X-B WBC, or both. Included specimens are assigned flags in the Data Log. These flags precede the Sequence Number.
12. In the Data Log, the X-B flag "r" refers to RBC, flag "w" refers to WBC, and flag "b" means the specimen has been included in both the RBC and WBC batches.
13. When a batch is complete, the X-B flags in the Data Log are deleted from those specimens comprising the completed batch.
14. If a combination of "r" plus "b" or "w" plus "b" specimens becomes equal to 20, the “r” or "w" batch is completed, and the "r" *or* "w" flags for those specimens are deleted. The "b" flag changes to either "r" or "w", depending on which batch remains.
15. If any specimen in a current batch is rejected, the operator has the option of accepting the rejected specimen back into the X-B program. A rejected specimen has an "R" following the Specimen ID number in the Data Log.
16. For a current batch containing n specimens, the operator may reject up to n-1 specimens and still have the ability to re-accept any or all rejected specimens back into the current batch. However, if all n specimens are rejected, none of the rejected specimens can be re-accepted. The next specimen run into an X-B program becomes the first of a new batch of 20.
17. Each RBC batch has three means: one each for MCV, MCH, and MCHC. These means are updated whenever a new specimen is added to, or removed from, a batch.
18. Each WBC batch has 7 means: one each for LYM OD, LYM 10D, NEU 0D, NEU 10D, NEU 90D, NEU 90DEP, and NEU-EO. These means are updated whenever a new specimen is added to, or removed from, a batch.
19. If the current batch has 1 or more batch means outside the target value/action limits specified in the X-B Setup Menu, the message "X-BRBC: X/OUT" or "X-BWBC: X/OUT" is displayed where the X in X/OUT is the number of specimens in the current batch.

20. If the current X-B RBC batch and at least one previous X-B RBC batch are outside the target value/action limits specified in the X-B Setup Menu, the message "X-BRBC: X/OUT2" is displayed where the X in X/OUT is the number of specimens in the current batch.
21. If the current X-B WBC batch and at least one previous X-B WBC batch are outside the target value/action limits specified in the X-B Setup Menu, the message "X-BWBC: X/OUT2" is displayed where X is the number of specimens in the current batch.
22. If a current X-B batch (RBC or WBC) is turned OFF, all specimens in that batch are deleted.
23. If any value (Upper/Lower Limits, Target Value, or Action Limit) for RBC is changed in the X-B Set Up menu, all specimens in the current X-B RBC batch are deleted.
24. If any value (Upper/Lower Limits, Target Value, or Action Limit) for WBC is changed in the X-B Set Up menu, all specimens in the current X-B WBC batch are deleted.

X-B Analysis for RBC

Overview

The red cell indices (MCV, MCH, and MCHC) are known to be stable because the red cell apparently functions best in a very narrow range of size and hemoglobin content. Therefore, the body exerts tight physiologic control and will vary the number of red cells before altering the average volume or hemoglobin concentration of those red cells. Consequently, the average red cell indices of a given patient population will vary no more than 0.5 percent from day to day and even year to year, providing the population does not change.[5] The X-B algorithm provides a means of utilizing this information for quality control on the CELL-DYN 3200 System.

The X-B algorithm analyzes the indices on the patient samples run through the instrument in batches of 20. The mean of each batch is compared to a target value, and a percent deviation is computed and compared to the acceptable limits. This is similar to comparing the results of a commercial control run to the appropriate assay value to determine whether the result falls within the 2SD range. If the percent deviation exceeds acceptable limits, the message: X-B OUT is displayed on the screen.

Establishing the X-B RBC Target Value

A recent study[6] by Dr. Bull collected data from 1,767 hospitals and yielded the following mean values:

MCV 89.9 fL
MCH 30.5 pg
MCHC 33.9 g/dL

These values confirmed values that Bull had published in an earlier study.[7] Consequently, the values shown above can be used as the Target Values to initiate the X-B analysis program.

Laboratories seeing specialized patient populations (for example, pediatric hospitals or tumor centers) may need to verify these values due to "abnormal" patient populations. Target values may be verified by evaluating approximately 500 samples and comparing the X-B means for those samples to the entered target values.

The CV on 500 samples for each index should be $\leq$ 1.5%. (Dr. Bull's study found CVs from 0.5% to 1.2%. The 1.5% is one-half the allowable ± 3% action limit, which is acceptable for this confirmatory step.) If the CVs are >1.5%, an additional 500 samples should be evaluated.

Each laboratory should establish its own target value for the RBC indices. It is suggested that the process be started by using the default values (preset values from Dr. Bull's earlier studies) displayed on the X-B SET UP screen or by entering the values from Dr. Bull's recent study described above. The 3% action limits may be used or widened to 5% during the study and tightened to 3% when the Target Values are confirmed. The default values for the Lower/Upper Limits may also be used or widened depending on the specimen population analyzed by the laboratory.

Collect data from 25 batches of 20 specimens each for a total of 500 specimens. Data collection should be from specimens which represent the typical specimen population that is processed through the instrument. When all 25 batches are complete, print the X-B DATA DISPLAY screen for RBC. Calculate the mean, standard deviation (SD), and coefficient of variation (CV) for MCV, MCH, and MCHC. The CV for each index should be < 1.5%. If the CV for each index meets these criteria, enter the calculated mean value as the target value and set the action limits to 3%.

NOTE: Laboratories analyzing specialized patient populations (as described above) may need to widen the action limits slightly to accommodate results from these abnormal patients.

If the CV for each index is >1.5%, evaluate another 500 specimens and repeat the calculations.

When an acceptable target value has been entered, evaluate data from an additional 500 specimens to confirm the entered values.

Troubleshooting X-B RBC Results

When XB-RBC results are out of control, data should be reviewed for shifts and trends in the results.

Shifts in results are usually caused by a non-random batch of 20 specimens such as those from dialysis or pediatric units. Multiple repeats of the same abnormal specimen within a given batch of 20 may also cause a non-random population in that batch. Review the Data Log for the last 20 specimens and determine if this is the case. Shifts caused by non-random data will usually be corrected in the next batch of 20 as long as those data are random.

Shifts may also be caused by a change in reagent container or a lot number change. If containers or lot numbers recently changed, try another container and see if the problem persists.

Calibration changes may also cause a shift in results. If a shift cannot be explained as described above, run commercial controls or run a patient selected from a previous batch when X-B results were in control. If values are within acceptable limits, a calibration shift is not the cause of the problem.

Trends in X-B results are usually caused by instrument problems. A recent component change may also cause a trend in results. Use the following table to determine the directly measured parameter(s) involved, and troubleshoot accordingly. If a problem is not readily identified, perform routine maintenance and repeat the commercial and patient controls to see if results are acceptable.

Since two of the RBC indices are calculated parameters, their inter-relationships can be used to assist in troubleshooting. The following table uses the mathematical relationships between the indices to aid in determining which directly measured parameter(s) are involved when X-B is out of control. When the directly measured parameter(s) are identified, refer to **Chapter 10: *Troubleshooting*** for troubleshooting assistance with these parameters.

Table 11.1: Troubleshooting X-B RBC

X-B Pattern	If the MCV		If the RBC		If the HGB		Index Derivation
	is increased	is decreased	is increased	is decreased	is increased	is decreased	
MCV will be	High	Low	N/A	N/A	N/A	N/A	MCV
MCH will be	N/A	N/A	Low	High	High	Low	HGB/RBC
MCHC will be	Low	High	Low	High	High	Low	HGB/HCT

If all efforts fail to bring results within acceptable limits, contact the Customer Support Center (at 1-800-CELL-DYN in the U.S.) for assistance.

Interpreting X-B RBC Results

A suggested protocol and guidelines for interpreting X-B data can be found in Chapter 1 of *Laboratory Hematology: An Account of Laboratory Techniques*, edited by I. Chanarin.[8]

X-B Analysis for WBC

Overview

Since the WBC Differential parameters have a wide dynamic range, it is difficult to use a moving average algorithm to control these results. Therefore, the CELL-DYN 3200 System uses data obtained from the MAPSS™ technology used for the WBC Differential measurement.

Five main subpopulations of WBCs, which can vary widely in absolute number and percentage values, are identified by the CELL-DYN 3200 System. Even though these parameters have varying dynamic ranges, they maintain a relatively constant modal position on each axis of the scatterplots. It is expected that these optical characteristics of the WBC Differential subpopulations will remain stable over time without impact from the wide dynamic ranges of the individual parameters. This constant modal position, which is sensitive to changes in the instrument's optical measurement process, can be monitored by the instrument and used to control the WBC Differential parameters in much the same way that the RBC indices are used to control the RBC parameters.

The CELL-DYN 3200 System monitors the modal positions of the lymphocyte and neutrophil clusters on each axis of the 0°/10° scatterplot. It also monitors the modal positions of the neutrophil cluster on each axis and the angle of the neutrophil/eosinophil separation on the 90°/90° depolarized scatterplot. These seven measurements are then averaged for each batch of 20 patients using a moving average calculation similar to that developed by Dr. Bull for the RBC indices. For convenience, this process is called X-B WBC.

Establishing the X-B WBC Target Value

The Target Values for X-B WBC can be established in the same way as the Target Values for the RBC indices.

Each laboratory should establish its own target value for the X-B WBC parameters. It is suggested that the process be started by using the default (preset) values displayed in the following table. The action limits in the table may be used or widened during the study. Reenter the default action limits shown in the following table when the Target Values are confirmed. The values for the action limits may be widened depending on the specimen population analyzed by the laboratory. The values for the Lower/Upper Acceptance Limits may also be used or widened depending on the specimen population analyzed by the laboratory.

Collect data from 20 batches of 20 specimens each for a total of 400 specimens. Data collection should be from specimens which represent the typical specimen population that is processed through the instrument. When all 20 batches are complete, print the X-B DATA DISPLAY screen for WBC. Calculate the mean, standard deviation (SD), and coefficient of

variation (CV) for each parameter. The CV for LYM 0°, LYM 10°, NEU 0°, and NEU 10° should be <2.5%. The CV for NEU 90°, NEU 90° depolarized, and NEU-EOS should be <5%. If the CV for each index meets these criteria, enter the calculated mean value as the target value and set the action limits to 5% for LYM 0°, LYM 10°, NEU 0°, and NEU 10°, and to 10% for NEU 90°, NEU 90° depolarized, and NEU-EOS.

> **NOTE:** Laboratories analyzing specialized patient populations (as described above) may need to widen the action limits slightly to accommodate results from these abnormal patients.

If the CV for each index is more than the limits described above, evaluate another 400 specimens and repeat the calculations.

When an acceptable target value has been entered, evaluate data from an additional 400 specimens to confirm the entered values.

Default (Preset) X-B WBC Values

Parameter Limit	Acceptance Limits	Target Mean	Action
LYM 0°	48 - 70	59	7
LYM 10°	51 - 67	59	5
NEU 0°	141 - 179	160	4
NEU 10°	128 - 170	149	5
NEU 90°	87 - 163	125	10
NEU 90 DEP°	11 - 31	21	19
NEU-EOS°	14 - 32	23	13

Interpreting X-B WBC Results

A suggested protocol and guidelines for interpreting X-B data can be found in Chapter 1 of *Laboratory Hematology, An Account of Laboratory Techniques*, edited by I. Chanarin.[8]

References

1. Cembrowski GS, Carey RN. *Laboratory quality management*, p. 189.
2. Westgard JO et al. *A multi-rule Shewhart chart for quality control in clinical chemistry.* Clin Chem 1981; 27:3:493–501.
3. Cembrowski GS, et al. *Use of a multirule control chart for the quality control of PT and APTT analyses.* Lab Med June 1989; 418–421.
4. Cembrowski GS, Carey RN. *Laboratory quality management*. P. 190.
5. Bull BS, Korpman RA. *Intralaboratory quality control using patients' data*. In: Cavill I, ed. Quality Control. Edinburgh: Churchill Livingstone 1982, 121–150.
6. Bull BS, Jones AR, Gibson M, Twedt D. *A method for the independent assessment of the accuracy of hematology whole blood calibrators*. AJCP (accepted for publication), 1992.
7. Bull BS, Hay KL. *Are red blood cell indexes international?* Arch Pathol Lab Med 1985; 109:604–606.
8. Chanarin I, ed. *Laboratory hematology, an account of laboratory techniques*. Edinburgh: Churchill Livingstone, 1989:3–7.

NOTES

Overview

The CELL-DYN® 3200 system is configured with a color Graphics Printer (known in this manual as the Graphics Printer). The printer is set up to print reports, including complete graphic information, on 8.5” X 11” paper. The printer may be set up to print graphic information in color or black only.

If ticket printing is desired for the CELL-DYN 3200, a second printer (known as the Ticket Printer) can also be connected to the system at the same time as the Graphics Printer. Results are automatically printed at the completion of each run cycle or are printed on command by the operator. The Ticket Printer can be used to print reports with graphic information in black only, but the connection to the Analyzer must be changed.

IMPORTANT: The CELL-DYN 3200 System has been configured for and tested on the following printers: Canon® BJC-620™ color ink jet printer for graphics output, and OKIDATA® MICROLINE® 320 dot matrix printer for ticket printing. Abbott recommends using only these printers. If other printers are substituted, problems may occur with your printouts.

Refer to **Section 2:** ***Installation Procedures and Special Requirements*****, Subsection:** ***Printer Installation*** for instructions on installing both printers.

Complete directions for customizing the printout type and format are given in **Section 2, Subsection:** ***Customizing Printouts***.

NOTES

Maintenance and Troubleshooting

This section gives a brief overview of printer maintenance and troubleshooting. Instructions for installation are given in **Section 2: *Installation and Special Procedures*, Subsection: *Printer Installation***. For a detailed description of the printer components and instructions on changing the ribbon and loading paper, refer to the manuals that accompany the printer.

Cleaning

Every six months (or after about 300 hours of operation) turn the printer OFF and use a clean, dry cloth to dust the area around the carriage shaft and platen. Be sure to remove any loose particles of paper. Do not use solvents or strong detergents on the cabinet.

Troubleshooting

Refer to the printer manuals for a list of the most common printer problems and how to solve them. If the problem is not resolved, contact the Abbott Customer Support Center for assistance.

If, during routine system operation, the message PRINTER UNAVAILABLE is displayed on the bulletin line, check to see that the printer cable is securely connected to the Analyzer, the printer power switch is turned ON, and that the Select indicator is illuminated. Press the [PRINT] key. If the message is still displayed, turn the printer power off, wait about five seconds, turn the power on again and press the [PRINT] key. If the message is still displayed, there may be an internal printer error. Contact the Abbott Customer Support Center for assistance.

NOTES

Routine Operation

Graphics Printer

The CELL-DYN 3200 software automatically controls and adjusts most print conditions, including page width and ink color. Occasionally, a few settings may need to be changed in the *printer's* software for correct operation. If printing is not what you expect, refer to the printer manual for guidance in making adjustments. If you have additional questions or experience any problems, call the Abbott Customer Support Center for assistance.

Ticket Printer

For detailed information about loading continuous-feed tickets or paper and changing the ribbon in the Ticket Printer, refer to the manuals that accompany the printer. In particular, note the important safety instructions. This section gives information about ticket printing and instructions for loading individual pre-printed tickets in the Ticket Printer.

The Ticket Printer can be used to print a complete graphics report on continuous tractor-feed paper or to print result data on blank or pre-printed tickets. (Blank tickets are available in continuous tractor-feed sheets. Pre-printed tickets are loaded individually.) To print the graphics report, the printer cable must be connected to the Graphics Printer connector on the back of the Data Module.

Printing Tickets

To print tickets, the printer cable must be connected to the Ticket Printer connector on the back of the Data Module. (See Figure 2.5 for the location of these connectors.) Refer to **Section 2, Subsection:** ***Printer Installation*** for instructions for customizing either type of printout.

Loading Individual Tickets

Instructions are given for loading individual tickets. If fan-fold, continuous-feed tickets are used, they should be loaded as directed in the printer manual for tractor-feed paper.

1. Be sure that the printer is turned OFF and the printer cable is connected to the Ticket Printer Connector on the back of the Analyzer. If the connection is incorrect, turn the Analyzer power OFF, change the position of the cable and turn the power back ON.
2. Set the ribbon cartridge headgap lever to adjust for the thickness of the tickets. Refer to the printer manual for the location of the headgap lever and for detailed instructions.
3. Move the paper selection lever to the rear position to select single-feed paper.
4. Open the access cover and be sure the guide wire on the paper separator is pushed back into the locked position.
5. Raise the separator to its upright position.
6. Place a ticket on the paper separator and adjust the guides so that they barely touch the edges of the ticket.
7. Pull the bail lever forward. The ticket will automatically feed into place. Release the paper bail lever.
8. Be sure the printer is deselected (Sel indicator is not illuminated) and set the Top of Form by pressing and holding the TOF/Quiet key and pressing the Form Feed key to move the ticket up or pressing the Line Feed key to move the ticket down. (The ticket moves in very fine increments so it can be precisely positioned.)

   NOTE: The ticket will only move down to a certain point to prevent potential ticket jams. Do not move the top of the page below the paper bail.

9. Position the ticket so that the lower red line on the paper shield (located between the print head and the paper) is positioned where the first line of printing should occur.

   NOTE: When the Top of Form is set, the position is retained in the printer memory until it is reset.

10. Press the **Sel** key to select the printer. The printer is now ready to print.

Overview

The Sample Loader for the CELL-DYN® 3200SL is an automated microprocessor-based sample-handling system designed to be attached to the Analyzer (see Figure 13.1). The Sample Loader delivers mixed blood samples to the Analyzer for analysis and communicates sample identification information and the loader's operational status to the CELL-DYN 3200SL. The sample tubes, in an upright position, are transported in racks. Up to 50 tubes can be loaded onto the Sample Loader and processed with or without bar code labels.

The Sample Loader has been designed to provide fast and efficient throughput of patient samples. Used in conjunction with the Work List and Bar Codes, the Sample Loader can process approximately 70 samples per hour, including matching patient demographic information with samples results and storing completed sample information in the Data Log.

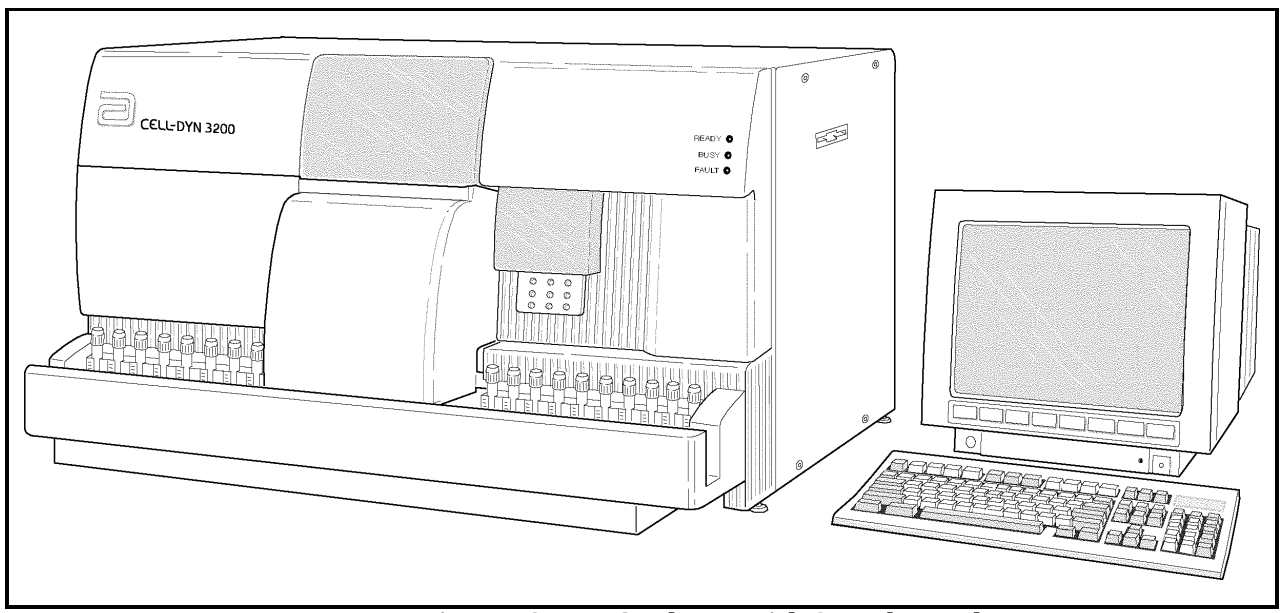

Figure 13.1: Analyzer With Sample Loader

NOTES

Physical and Performance Specifications

Specifications

Refer to **Section 4:** ***Performance and Specifications*** for complete performance specifications for the 3200SL. The following information on the Sample Loader is included here for convenience.

Dimensions and Weight

Height	6 in (15.2 cm)
Width	32.5 in (82.5 cm)
Depth	6.4 in (16.2 cm)
Weight	18 lbs (8.1 kg)

Tube Types

The Closed Sample Tower Module and the Sample Loader are able to accommodate the following tube types:

1. Beckton-Dickinson Type

- B-D Hemogard Stopper (5.0 mL)
- B-D Rubber Stopper (5.0 mL)
- Greiner (4.0 mL)
- Terumo Venoject® II (5.0 mL)

2. Starstedt Type

- Starstedt EDTA (2.7 mL)
- Starstedt Neutral (2.7 mL)

NOTE: All other tube types must be processed in the Open mode.

Rack and Tube Capacity

5 racks on the load side

5 racks on the unload side

50 tubes (10 tubes per rack)

Minimum Sample Volume

The minimum blood volume per sample tube is 1.0 mL in the Closed Mode.

Maximum Sample Volume

The maximum blood volume per sample tube is 3.0 mL in the Closed Mode.

Sample Loader Description

Sample Loader Components

The Sample Loader is an integral part of the CELL-DYN 3200SL model. It is attached to the Analyzer by four screws, two on each side of the Analyzer and is aligned to the Aspiration Tower through a common alignment block. The motors and mechanical arms for rack movement are located inside the loader. The electronic board for controlling the operation of the Sample Loader is mounted on the left side of the Sample Loader chassis. Cables connecting the Sample Loader with the Analyzer are installed at the factory and should not be removed.

The Sample Loader consists of four main assemblies: Sample Transport Assembly, Sample Tube Sensing Assembly, Sample Mixing Assembly, and Bar Code Reader. These components are depicted in Figure 13.2. (The Tube Sensor Assembly is located on the Sample Loader chassis directly behind Stations 1 and 2.)

NOTE: Several Sample Loader-related error messages refer to tube positions 3 and 4, which are Mixing Stations 1 and 2 respectively. (Refer to Figure 13.7.)

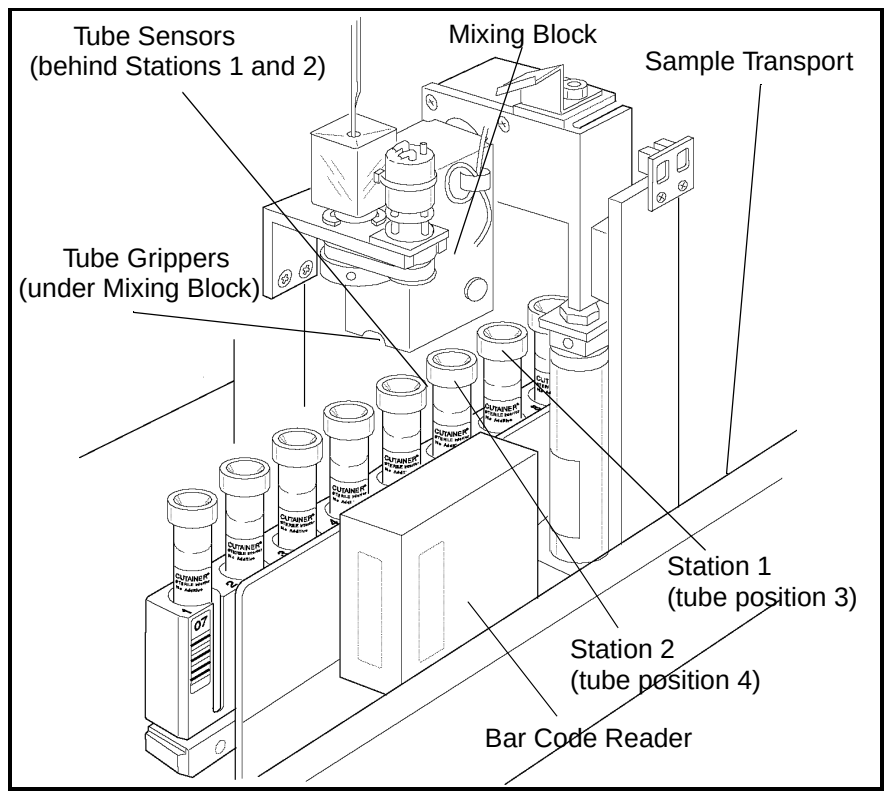

Figure 13.2: CELL-DYN 3200 Sample Loader

The **Sample Transport Assembly** consists of pneumatic-actuated arms that move the racks in an orderly process through the sample mixing, bar code reading, and aspiration stages of the processing cycle.

There are two **Sample Tube Sensors** at the two Sample Mixing positions. The sample tube is sensed at the first tube position on the Mixing Assembly and again at the second tube holder. The sample loader will continue to advance racks if there are no tubes present at both mixing positions.

The **Sample Mixing Assembly** consists of two tube grippers on the Mixing Block. The block is raised pneumatically and the mixing rotation is done by a stepper motor.

The **Bar Code Reader** is an LED type and can accommodate the following formats: Code 39, Code 128, CODABAR, and Interleaved 2 of 5. On the SL model, the Bar Code Reader is located on the Sample Loader directly in front of the aspiration needle/spinner assembly.

A **Power Cable** connecting the Sample Loader with the Analyzer provides power from the Analyzer to the loader. An **Interface Cable** connecting the Analyzer and Sample Loader provides bi-directional communication.

Bar Code Label Placement

Tube Labels

All labels should be placed on the tubes securely. Flaps or edges should not be sticking out. Labels should not cover the cap (high collar) or the bottom (tail) of the tube. Labels should be placed between 3/4 inches from the bottom of the sample tube and 3/4 inches from the top of the tube. (See Figure 13.3.) Layering more than 3 labels may prevent the bar codes from being read.

> **NOTE:** Refer to Appendix A for complete information on Bar Codes, Check Digits, and specifications.

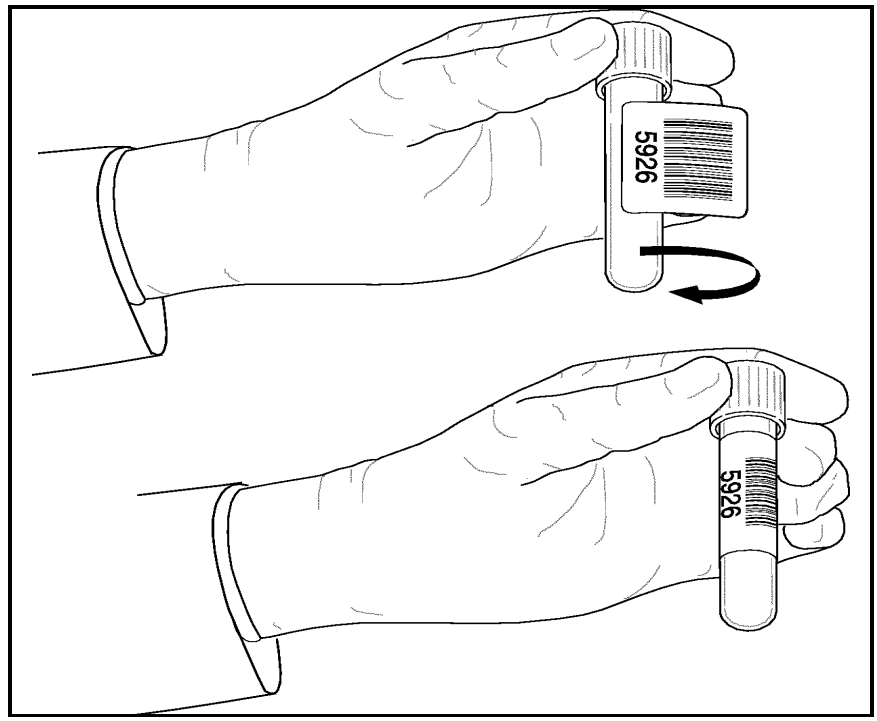

Figure 13.3: Tube Labeling Requirements

Rack Labels

Every rack and tube position is identified by a bar code label. (See Figure 13.4.) Bar code labels on tube racks are essential for proper Sample Loader operation. The rack label must be placed on each rack ahead of tube position 1. This label serves to identify the rack and tube position 1. The rack bar code label is read when the tube in the first position is moved from Mixing Station #2 to the Aspiration Station. Subsequent bar code labels on the rack identify tube positions 2 through 10.

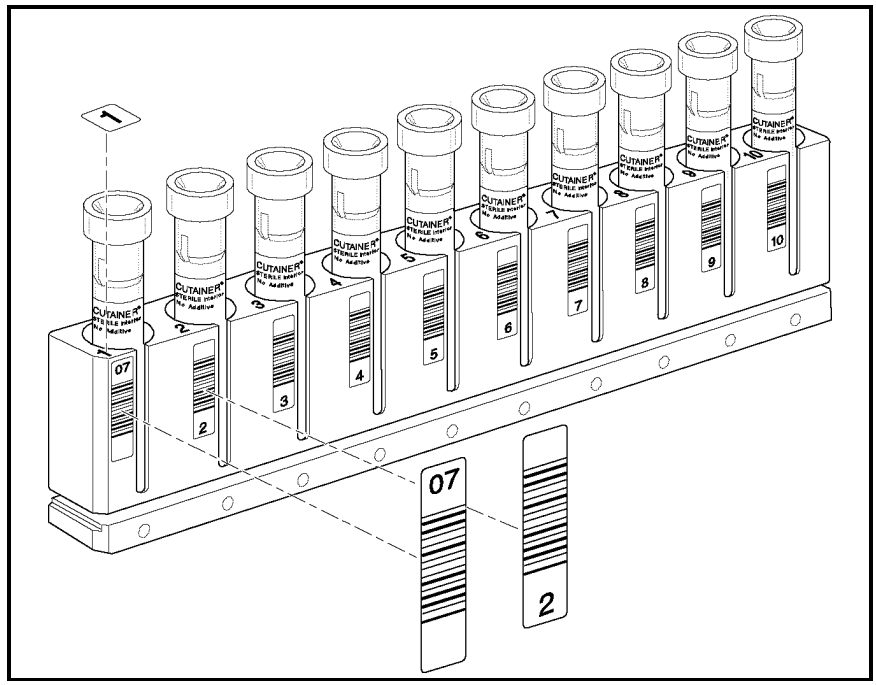

Figure 13.4: Rack with Bar Code Labels

RUN Screens

The RUN Screens for the 3200SL model, shown in Figures 13.5 and 13.6, are slightly different from the screen for the 3200CS model.

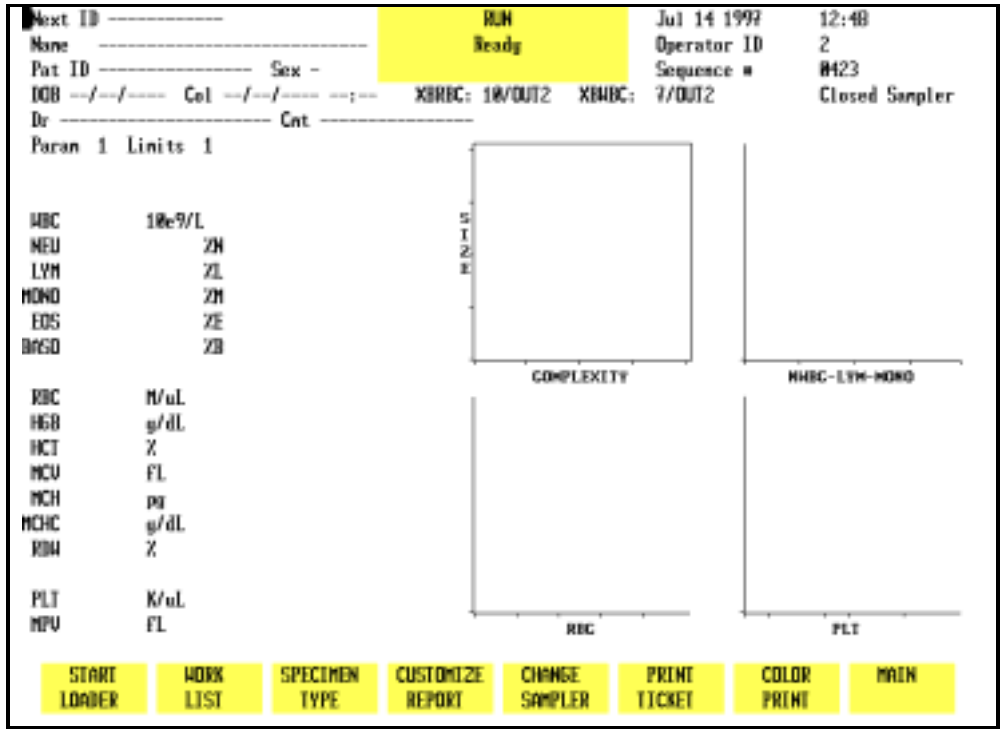

Figure 13.5: CELL-DYN 3200SL RUN Screen

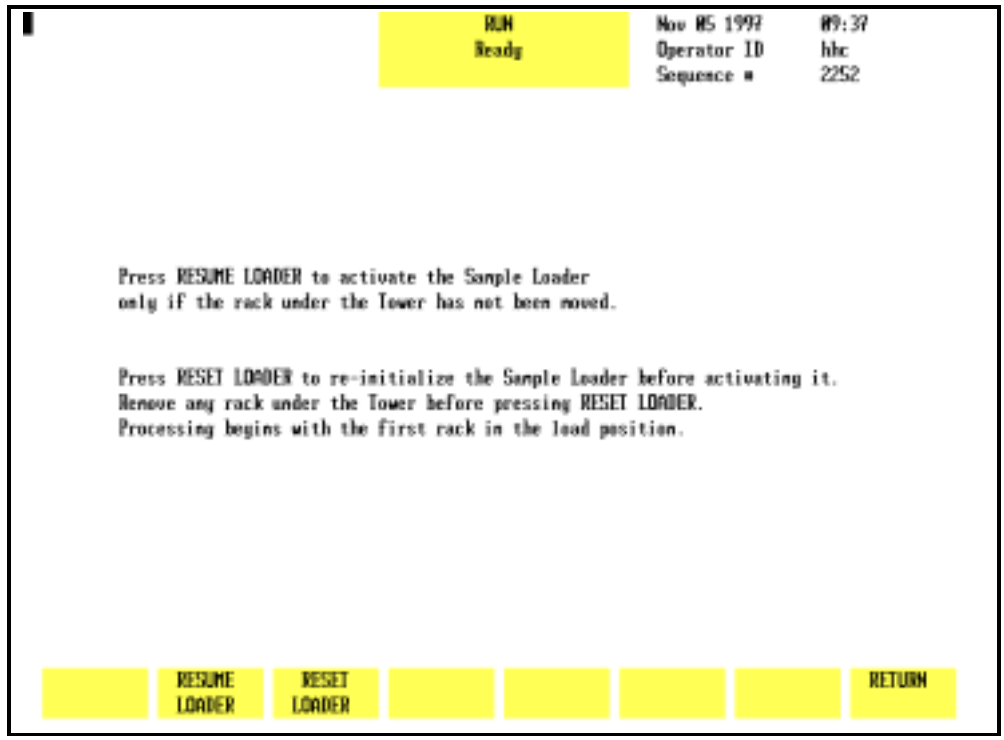

Figure 13.6: Sample Loader Restart Screen

Soft Keys

Overview

The soft key menu on the 3200SL model is similar to the menu on the 3200CS model except for the following:

1. The [START LOADER/STOP LOADER] key in the first position (refer to Figure 13.5).

   NOTE: The [CLEAR FAULT] key will appear in the first position whenever a Fault condition occurs.

2. A submenu that appears under certain conditions when the [START LOADER] key is pressed (refer to Figure 13.6).

Pressing the [START LOADER] key activates the Sample Loader and toggles to [STOP LOADER] without an intervening submenu under the following two conditions:

1. When the System has been initialized or when only the Sample Loader has been re-initialized.
2. When the Sample Loader has finished processing all loaded racks (without the [STOP LOADER] key being pressed) and comes to a halt.

Start Loader

Pressing the [START LOADER] key displays the RESTART menu shown in Figure 13.6 (the Sample Loader remains inactive) under the following two conditions:

1. When the [STOP LOADER] key was pressed while the Sample Loader was operating
2. When the [CLEAR FAULT] key was pressed.

Stop Loader

When the [STOP LOADER] key is pressed, the Sample Loader comes to a halt after the current sample cycle is completed and the key changes to [START LOADER].

Restarting the Loader

Pressing the [START LOADER] key after the [STOP LOADER] or [CLEAR FAULT] key was pressed will not automatically activate the Sample Loader. Instead, the Sample Loader RESTART menu (refer to Figure 13.6) is displayed with three soft keys:

RESUME LOADER
RESET LOADER
RETURN

NOTE: If a Sample Loader fault occurs, when the [CLEAR FAULT] and [START LOADER] keys are pressed one of two possible submenus will be displayed. Refer to ***Sample Loader Faults*** later in this section for an explanation.

The operator must decide which key to press to re-activate the Sample Loader based on whether or not the rack under the Tower was moved. Pressing either [RESUME LOADER] or [RESET LOADER] will activate the Sample Loader and display the main RUN screen with the [STOP LOADER] key again displayed in the first position.

Resume Loader

The [RESUME LOADER] key should be used to activate the Sample Loader under the following conditions:

1. When the [STOP LOADER] key was pressed and the rack under the Tower was not subsequently moved

2. When a Sample Loader fault occurred that did not require re-initializing the loader.

In this case, sample processing will resume from the point where the last specimen was aspirated. If any tubes are detected in either Mixing Station, the sample(s) will be mixed prior to the rack advancing.

> **NOTE:** If the rack was moved and the [RESUME LOADER] key is pressed, a Fault condition will occur.

Reset Loader

The [RESET LOADER] key should be used to activate the Sample Loader under the following conditions:

1. When the [STOP LOADER] key was pressed and the rack under the Tower was subsequently moved
2. When a Sample Loader fault occurred that required re-initializing the loader.

If the rack must be moved for any reason, it should be completely removed and placed in the starting position on the load side (or a new rack must be in the starting position). If the Sample Loader must be re-initialized after a fault, the Tower must be cleared and all racks placed on the load side. The [RESET LOADER] key re-initializes the Sample Loader before activating the loader transport mechanism.

> **NOTE:** If a rack is still under the Tower and the [RESET LOADER] key is pressed, a Fault condition will occur.

Return

The [RETURN] key on the RUN screen submenu returns the operator to the main RUN screen with the [START LOADER] key in the first position.

Fault Conditions

On the SL model, there are two sources of fault conditions: Instrument-related faults (Data Station or Analyzer) and Sample Loader-only faults.

Data Station/Analyzer Faults

Faults related to the Data Station or Analyzer may be either operator-correctable or fatal.

If the fault is operator-correctable, when [START LOADER] is pressed the RESTART menu is displayed with the choice of either resuming or resetting the sample loader.

In the case of fatal faults, the entire system must be re-initialized or rebooted. Any rack under the Tower must be removed and placed in the starting position on the load side.

Sample Loader Faults - Reset Loader

When a fault occurs in the Closed Mode, the [CLEAR FAULT] key replaces the [STOP LOADER] key. Some Sample Loader-only faults require the Sample Loader to be re-initialized. In this case, when the operator presses the [CLEAR FAULT] key followed by [START LOADER], a submenu is displayed showing only the [RESET LOADER] and [RETURN] keys. The [RESUME LOADER] key is not displayed because any rack under the Tower must be removed and placed in the starting position on the Load side. Refer to ***Restarting the Loader*** for a discussion on using the RESET key.

Sample Loader Faults - Resume Loader

Some Sample Loader-only faults do not require the Sample Loader to be re-initialized. In these cases, when the operator presses the [CLEAR FAULT] key followed by [START LOADER], a submenu is displayed showing both the [RESUME LOADER] and [RESET LOADER] keys as well as [RETURN]. The operator has the option of using either RESUME or RESET to activate the Sample Loader. Refer to ***Restarting the Loader*** for a discussion of when to use the RESUME key versus the RESET key.

Processing Stations

There are three processing stations on the Sample Loader. These stations are described below and shown in Figure 13.7. Mixing Station 1 corresponds to the first tube holder in the Mixing Block and Mixing Station 2 corresponds to the second tube holder.

Station 1, First Mixing:	A sensor detects the presence of a tube and activates the mixer. The sample is mixed in a 135° rotation for approximately 20 seconds.
Station 2, Second Mixing:	A second sensor detects the presence of a tube and activates the mixer. The sample is again mixed in a 135° rotation for approximately 20 seconds.

NOTE: Several Sample Loader-related error messages refer to tube positions 3 and 4, which are Mixing Stations 1 and 2 respectively. (Refer to Figure 13.7.)

Station 3, Vent/Aspiration: The tube is positioned for aspiration. The bar code is read. The spinner mechanism descends, detects the tube height, grips and spins the tube, allowing the Bar Code Reader to read the label. The tube stopper is punctured by the Vent/Aspiration Needle (the "Needle") in the Tower Module. The tube is vented and the sample is aspirated.

These three stations are adjacent to each other. Each sample is mixed twice before being vented and aspirated.

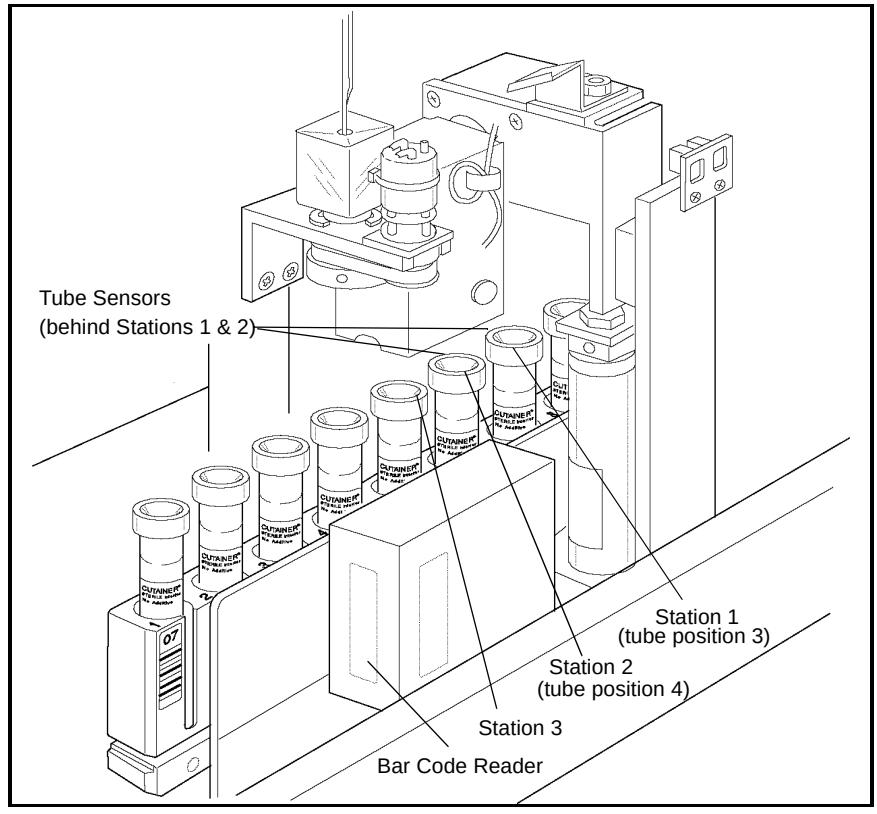

Figure 13.7: Sample Loader Stations

Rack Movement

The tube racks move from the load side, through the mixing and aspiration stations, to the unload side (refer to Figure 13.8). The rack closest to the Analyzer on the load side is the first to be processed. This is the starting position for a rack.

Load Side

A set of mechanical arms on the load side pushes the racks forward toward the Analyzer. If the arm does not sense a rack on the load side, the Sample Loader emits 3 beeps to alert the operator and displays a message on the Bulletin line stating `Loader Status 158: load zone empty.`

When the 5th tube of a rack is at the Aspiration Station and no more racks are detected on the load side, the Sample Loader will emit three beeps to alert the operator that the last rack has been processed. The message `Loader Status 143: samples completed` is displayed on the bulletin line. Continuous processing can be accomplished by adding more racks to the load side and removing the processed racks from the unload side.

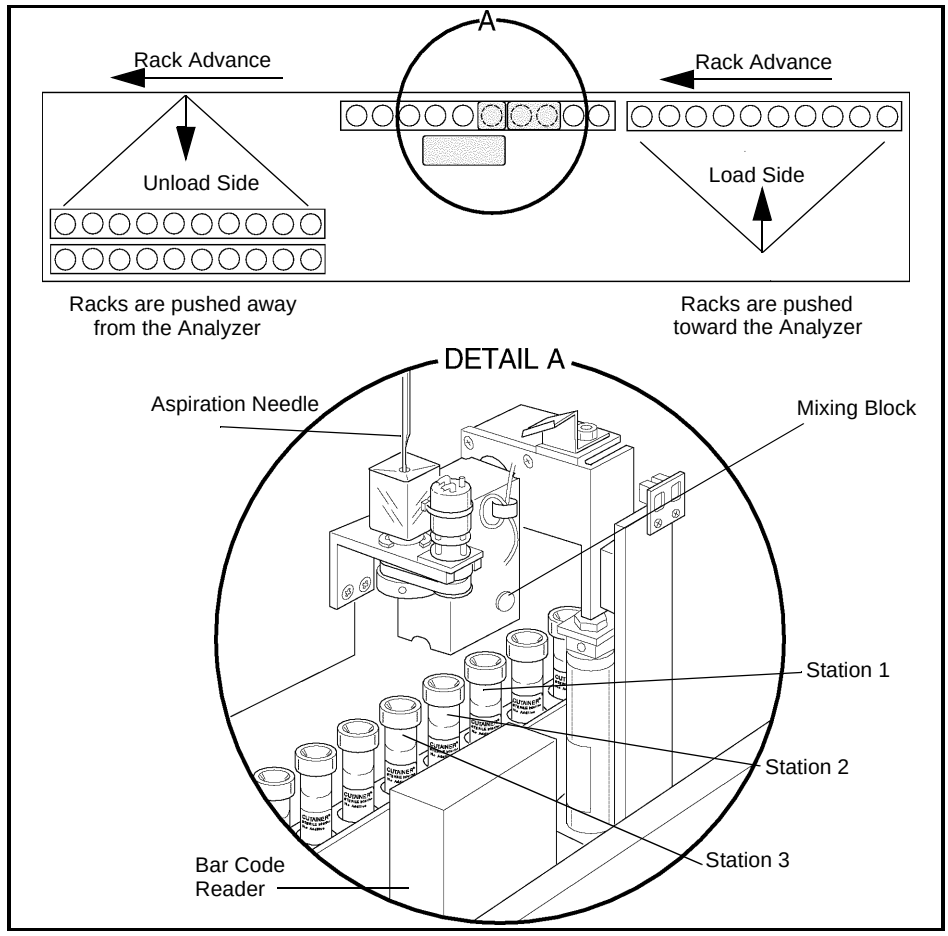

Figure 13.8: Rack Movement

Mixing and Aspiration Stations

A pneumatic-actuated mechanism advances the rack one position at a time through the mixing and aspiration stations. As the rack advances through the Mixing Stations, sensors detect if a tube is at Mixing Station #1 or Mixing Station #2.

If a tube is detected at either station, the Mixer descends, grabs one or both tubes, and mixes for approximately 20 seconds. Each tube is mixed twice, once at each mixing station. After being mixed at the second Mixing Station the tube advances to the Aspiration Station where it is vented and aspirated.

When the 6th tube is at Station 3 (aspiration), the next rack on the load side is pushed forward in preparation for processing. Racks continue moving to the preparation position until either the load side is empty or the unload side is full.

After the last tube in a rack has been processed, the rack continues moving until it reaches the left edge of the Sample Loader. At this point, the rack is pushed to the most forward position of the unload side to make room for the next racks.

If a malfunction occurs at the Mixing or Aspiration Stations, the Sample Loader halts operation and emits a beep to alert the operator. The [CLEAR FAULT] key is displayed, and a fault message is displayed on the bulletin line.

Unload Side

When the rack reaches the edge of the left side, a mechanical arm pushes the rack toward the front of the Sample Loader to make room for the next rack being processed. The unload side can accommodate 5 racks. A 5th rack, however, will prevent a 6th rack from being completely processed by interfering with that rack's movement through the Mixing and Aspiration Stations.

If the unload side is full (5 racks) and a 6th rack is being processed, the 6th rack can advance until the 6th tube position is at the Aspiration Station (refer to Figure 13.9). If position 6 has a sample, then that sample can be processed. When processing is completed for that sample, the Sample Loader will emit 3 beeps to alert the operator that the unload side is full and the Sample Loader has stopped. The [CLEAR FAULT] key is displayed, and the message `Loader Warning 145: unload area full` is displayed on the bulletin line. The operator must remove racks from the unload side for the 6th rack to be completely processed.

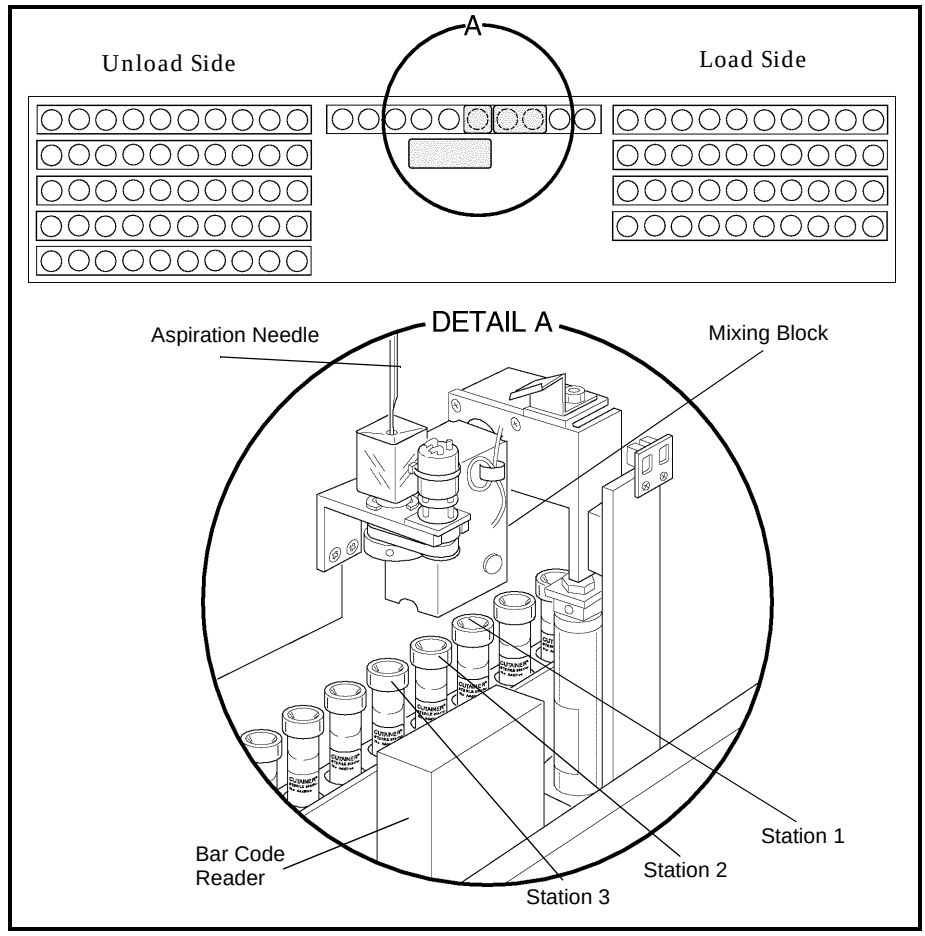

Figure 13.9: Unload Side Full

Sample Identification

Each rack must have a legible bar code label. If a rack has no bar code label or if the label cannot be read by the Bar Code Reader, the Sample Loader stops, and the message `Loader Fault 153: rack barcode read failure` is displayed on the bulletin line. No samples have been aspirated at this point.

The rack bar code label identifies each rack by number. The system tracks the rack number and tube position for each sample placed in the rack from the bar code reader signal.

The Sample Loader provides sample identification using an LED-based Bar Code Reader at Station 3 (tube spinning/ aspiration). As each tube reaches Station 3, the sample tube is rotated and the bar code reader is turned ON to read the bar code label on the tube. If no bar code label is present or the label is unreadable, the sample is identified by the rack number and tube position, in the format RxTx, on the RUN screen and in the DATA LOG.

Operation of the Sample Loader with non-bar-coded samples is allowed. However, the use of bar code labels is recommended for positive sample identification. Refer to **Section 5: *Operating Instructions***, **Subsection: *Using the Work List*** for a discussion of using the Work List with and without bar code labels for sample identification.

Normally, non-bar-coded samples should not be removed from the racks until all samples have been processed since the rack and tube number of each sample is important for positive sample identification.

If the rack being processed (under the Tower Cover) must be removed before processing is completed (for example, the system must be re-initialized to clear a Fatal Fault condition), make a note of which tube was under the Aspiration Needle before removing the rack. Follow the guidelines below:

1. Make sure the Sample Loader has stopped and the Aspiration Needle has retracted. Remove the Tower Cover if necessary.
2. If a fault occurred, correct the situation and press [CLEAR FAULT].
3. If bar code labels are used for identification:
   a. Check the Work List to determine if the entries corresponding to the processed samples have been deleted, indicating a match occurred and the data was sent to the Data Log. It is permissible to remove those samples before returning the rack to the starting position.
   b. Move the remaining tubes to the front of the rack and place the rack in the starting position.
   c. Go to step *5*.
4. If rack and tube numbers are used for identification:

a. Check the Work List to determine if the entries corresponding to the processed samples, based on rack and tube number, have been deleted, indicating a match occurred and the data was sent to the Data Log. It is permissible to remove those samples before returning the rack to the starting position.

b. DO NOT move the remaining tubes in the rack, otherwise Work List entries will also have to be changed to reflect the new rack and tube positions of the remaining samples. Place the rack in the starting position.

5. Replace the Tower Cover and press [START LOADER] followed by [RESET LOADER] to resume operations.

Stopping the Sample Loader

The Sample Loader automatically halts when all loaded racks have been processed. There are three ways to stop the Sample Loader during processing, as described below:

1. **Power OFF**. Turn the Main Power Switch on the Analyzer to OFF. This method is not recommended unless there is an emergency.
2. **Orderly Stop**. Press [STOP LOADER] for an orderly stop. Orderly stops allow the vent/aspiration/cleaning process to finish but doesn't allow the next sample to be aspirated. The [START LOADER] soft key appears and you should press it to start the sample loading process. If the sampling process has been interrupted for more than 20 seconds, the sampler will remix the sample before aspiration and the process will continue.
3. **Emergency Stop**. Push the window section of the Tower Cover toward the instrument to release the latches and break the safety interlock sensor connection. Emergency stops cause the Aspiration Needle to retract if already in the tube and the Mixer to return the tube(s) to the rack before bringing the Sample Loader to a halt. To completely remove the cover, lift it vertically. An emergency stop results in a Fatal Fault condition. To resume the sampling process:

   a. Re-initialize and prime the instrument. The Sample Loader is automatically initialized when the Analyzer is initialized.

NOTE: To initialize the instrument, in the main DIAGNOSTICS MENU press [MORE] followed by [INITIALIZATION]. Refer to **Section 10:** ***Diagnostics and Troubleshooting***, **Subsection:** ***Second Diagnostics Menu Screen***. To prime the instrument, press [RUN] in the MAIN MENU.

b. Move the rack that was under the Tower Cover to the starting position and remove all processed samples.

c. Re-attach the Tower Cover.

d. When the system has been initialized and primed, press [START LOADER] in the RUN menu to start processing samples.

NOTE: The rack will not advance until the tubes, if any, in Mixing Stations #1 and #2 are mixed again. If a tube is sensed at Mixing Station #2, the Mixer will perform two mixing cycles before the rack advances, thereby ensuring that each tube is mixed at least twice just prior to aspiration.

Sample Loader Operation

Prior to activating the Sample Loader, racks containing tubes to be processed should be placed on the load side of the Sample Loader (refer to Figure 13.8).

Sample Loader Cycle

The following sequence is a basic description of the events that occur from the time that the instrument is turned ON through the complete processing cycle. During the cycle, the number of tube racks is monitored by optical interrupt sensors located on the Transport Mechanisms.

> **NOTE:** The Sample Loader can operate with any number of racks, the minimum being one.

1. The Sample Loader is initialized each time the instrument is turned ON, each time the instrument is re-initialized, and each time it completes a cycle (at least one rack has moved through the Mixing and Aspiration Stations and no more racks are detected on the load side).
2. When the Sample Loader has been initialized and is in the READY state, the message READY is displayed in the Status Box.
3. When the [START LOADER] key in the RUN screen is pressed, the Sample Loader pushes the rack(s) on the load side closest to the Analyzer.
   a. As the rack advances, the sensor at Mixing Station 1 searches for a tube.
   b. Even if there are no tubes present in the rack, the Transport Mechanism continues to move the rack under the Tower Cover until a sample tube is sensed in Mixing Station 1.
   c. If a sample tube is detected, the mixing and vent/aspiration mechanisms will process the sample.
4. The Mixing Head moves down, picks up the tube, and begins mixing it.

5. The first sample is mixed by 135° rotation for approximately 20 seconds. If the loader is stopped and then allowed to resume (by use of the [RESUME LOADER] soft key) the sample tube in Mixing Station 2 will mix for 20 seconds, stop briefly, and resume mixing for another 20 seconds. The total mixing time for each sample is approximately 40 seconds.

   NOTE: Tubes with more than three layers of labels on them or with label flaps sticking out can cause problems for the Mixing Assembly. The assembly may not be able to pick the tube up because the labels cause the tube to stick to the rack. The assembly may also have trouble fitting the tube back into the rack for the same reason.

6. When a tube has been properly mixed, it moves to the Vent/Aspiration Station (Station 3).

   a. When the Needle begins to move down, the Spinning Assembly moves down to (a) position the tube so that the stopper is pierced at or near the center, and to (b) rotate the tube so that the bar code can be read.

   b. The needle stops moving while the bar code label is being read.

   c. After the label is read, the needle continues moving down. It pierces the stopper and moves to the bottom of the tube.

   d. The Sample Loader signals the Analyzer to vent the tube and aspirate the sample.

   e. The sample is pulled into the Shear Valve by vacuum action. The Analyzer then begins a normal count cycle.

7. When an empty space is detected by both Mixing Station sensors, the rack automatically advances without engaging the Mixer. When an empty space is detected by the sensor on the Tower, the Needle and Spinner are not engaged as the rack advances. The Mixing Assembly and Tower Assembly will not be engaged until a tube is sensed at either Mixing Station.

NOTE: The Instrument operates most efficiently when tubes in a rack are adjacent to one another. Generally, spacing between sample tubes will have an impact on overall throughput. If there are numerous empty spaces, then throughput time may be significantly slowed.

8. After the sample is aspirated, the Needle is retracted and washed. As the Needle moves up, the Spinning Assembly also retracts.
9. Steps *4-8* are repeated until all tubes in the rack have been processed.
10. Regardless of how many tubes are in a rack, when the rack has moved completely under the Tower Cover, the second rack is moved into position on the right side of the Cover in preparation for sample processing.
11. When all tubes in the last rack have been processed:
    a. The Sample Loader automatically stops and emits beeps to alert the operator that processing is completed
    b. The message `Loader Status 43: samples completed` is displayed in the bulletin line when the rack has traversed completely to the unload side.
    c. The [STOP LOADER] key toggles to [START LOADER].
    d. The Sample Loader is re-initialized.

Operating Procedures

1. Press the [START LOADER] key in the RUN menu. Based on which condition exists (refer to the ***Soft Keys*** section), either the Sample Loader will be activated or a submenu will be displayed.
2. If the submenu is displayed, press either [RESUME LOADER] or [RESET LOADER] (refer to the ***Soft Keys*** subsection for a discussion of when to use each key).
3. Racks are moved in sequential order from the load side, through the Mixing and Aspiration Stations to the unload side (refer to Figure 13.8).
4. For sample mixing and aspiration to occur, the sensors must detect a tube in the rack. The Sample Loader automatically stops after the last rack is processed and no more racks are detected on the load side.

5. When the tube is at the Vent/Aspiration Station, the Spinner positions the tube vertically in the rack, spins the tube for bar code reading, and holds the tube while it is vented and the sample aspirated. Proper positioning is necessary for the tube stopper to be pierced in the center.

6. The Tower Cover on the 3200SL model fits over the Mixing Station and Bar Code Reader on the loader. This cover prevents aerosol contamination and exposure to the needle while the Sample Loader is processing specimens.

   NOTE: The Sample Loader has an interlock switch that prevents operation when the Tower Cover is not in place. If the Tower Cover is removed during Sample Loader operation, processing is immediately halted. For an orderly stop, the operator must press the [STOP LOADER] key and wait for the Sample Loader and Analyzer to stop processing before lifting or removing the cover. Lifting the cover while the Sample Loader is operating causes an immediate Emergency Stop condition. The entire system must be re-initialized.

Routine Operating Procedures

Installation

For detailed instructions on how to install the SL model, refer to **Section 2:** ***Installation and Special Procedures***.

Running Samples

Instructions for Routine Operation of the 3200SL model are given in **Section 5:** ***Operating Instructions***.

Maintenance

Maintenance procedures on the SL model should be performed as directed in **Section 9:** ***Service and Maintenance***. These procedures consist of cleaning the Tower Cover, the Needle, the tray and the tube racks. If the Vent/Aspiration Needle requires replacement, refer to **Section 9: Subsection:** ***Closed Sample Needle Replacement***.

Troubleshooting

If a Sample Loader fault, error or other problem is detected, an alert message is displayed on the bulletin line of the screen. For a list of messages, descriptions of possible problems and recommended actions, refer to **Section 10:** ***Diagnostics and Troubleshooting***.

NOTES

Overview

This section gives a brief overview of what bar coding is, how bar code labels are used for data entry, and the different types of bar codes that may be used with the CELL-DYN® 3200 System.

Bar coding is an automated method of gathering alphanumeric information and transmitting it to a computer. Because it eliminates typing and associated errors, bar coding offers speed, increased accuracy, and efficiency. The following are the major elements in a bar coding system:

- The computer and appropriate software interprets and stores bar code data. For the CELL-DYN 3200 System, this is accomplished by the Data Station and its software.
- The scanning device "decodes" the information on the bar code labels. The Tower Module on the CELL-DYN 3200 System incorporates an integral bar code reader, allowing the use of bar codes on both the SL and CS models.
- The bar code labels contain the specimen identification codes.

Bar Code Function

The bar code label contains the actual identifying data for specimens in the form of a series of black bars and contrasting white spaces, which represent numbers and letters. The arrangement of the code follows one of several sets of rules for bar code languages, called symbologies. To decode the data in the label, a scanning device is used to pass a small spot of light over the bars and spaces to read them.

Since dark bars reflect little light back into the scanning device, while white space reflects a lot of light, a light detector inside the scanner can translate the differences in reflection into electrical signals. The signals are then converted into the sets of ones and zeros (the binary system used by computers) that stand for numbers and letters.

Understanding the Label's Code

In all bar code symbologies, the code consists of elements (single bars or white spaces) and characters (groups of elements that stand for numbers or letters). In code 39, a commonly used symbology, each code character contains nine elements, at least three of which must be wide. Wide elements (whether they are bars or spaces) in this symbology have a binary value of 1. Narrow elements have a binary value of 0.

Most contemporary bar code systems have several features in common. These include the following:

- The *Quiet Zone* is the area immediately before and after the bar code symbol. This zone enables the scanner to read the code properly.

- *Start and Stop Characters* indicate the beginning and end of the bar code symbol. They allow the label to be scanned from either right to left or left to right, ensuring that code information is transmitted correctly.

- *Intercharacter Gaps* act as spaces between each character in the bar code symbol. Code 39 contains these gaps. However, there are other codes, such as Interleaved 2 of 5, that do not use them.

- The *Interpretation Line* is an area at the bottom of the bar code label where human-readable information can be placed. This may or may not be the same data as in the label code.

- The *Check Digit* is an extra numeric character in the bar code that permits the scanning device to mathematically determine whether it read the code correctly. This keeps the error rate as low as one for every billion characters scanned.

Bar Code Types and Characteristics

The CELL-DYN 3200 System reads four types of bar code labels:

- Code 39
- Code 128
- Interleaved 2 of 5
- Codabar

Code 39

Also referred to as code 3 of 9, Code 39 encodes 43 data characters: 0-9, A-Z, six symbols, and spaces. Every Code 39 character has five bars and four spaces. Of these nine elements, three are wide and six are narrow, making Code 39 a two-width code.

Code 128

Code 128 has 106 different printed characters. Each character has three bars and three spaces comprising 11 modules. Each printed character can have one of three different meanings, depending on which of three different character sets is used. Three different start characters tell the reader which of the character sets is initially being used, and three shift codes permit changing the character set inside a symbol.

Interleaved 2 of 5

Interleaved 2 of 5 encodes the 10 numeric digits 0-9. The name is derived from the method used to encode two characters that are paired together. Bars represent the first character, and the interleaved spaces represent the second character. Each character has two wide elements and three narrow elements, for a total of five elements.

Codabar

Codabar uses four bars and three spaces to represent the 10 numeric digits 0-9 and certain special characters. The code is characterized by four unique start/stop codes and variable intercharacter spacing.

Specifications

Bar Code Label Formats

The Bar Code Reader on the CELL-DYN® 3200 System can read all four label types listed below. Code size, collection tube length, and cap style limit the number of digits to the following maximum numbers:

- Code 39 — 9 digits
- Code 128 — 11 digits
- Interleaved 2 of 5 — 10 or 12 digits only
- Codabar — 10 digits

NOTE: The maximum number of digits includes any check digits within the code. For example, if one check digit is used in Code 39, then only 8 digits can be used for the rest of the code.

Bar Code Check Digit Formats

Bar code Check Digits are used whenever the instrument is to read a specific type of bar code. To enable or disable the check digit option, refer to **Section 5: *Operating Instructions***, **Subsection: *Bar Code Set Up***.

Check Digit specifications are as follows:

- Code 39 - The modulus 43 sum of all the character values in a given message
- Code 128 - The check digit is built into the Bar Code Reader.
- Interleave 2 of 5 - The check digit is the complement of the weighted sum of the digits modulo 10. To determine the weight of the digits, multiply every other digit by 3, starting with the first.
- Codabar - The modulus 16 sum of all the character values in a given message.

NOTE: If a specific check digit option is selected and turned ON, the Bar Code reader will read only bar codes in that specific format. If more than one format will be used on the instrument, it is recommended that the check digit option be turned OFF.

Bar Code Label Specifications

Bar code labels must be printed on good quality label stock and must meet the following specifications:

- 0.25 inch minimum quiet zone on each end
- 0.01 inch (10 mils) minimum narrow bar width
- 2:1 to 3:1 wide to narrow bar ratio
- 0.5 inch minimum bar length
- 2 inch maximum label length
- 1.25 inch maximum label width
- Maximum possible contrast between bars and background label

CELL-DYN Bar Code Labels

CELL-DYN 4-digit Code 39 bar code labels, in rolls of 1000 labels each, can be ordered with list number L/N 99650-01. These labels may be used for positive specimen identification when laboratory-generated bar code labels are unavailable.

Bar Code Label Placement

The following two guidelines should be observed when placing bar code labels on specimen tubes (refer to Figure A.1):

1. All labels should be placed on the tubes securely and without flaps sticking out. Refer to the following figure.

2. The bar code label should be placed on the tube just below the stopper with the bars perpendicular to the length of the tube. This will ensure that the entire bar code can be viewed through the slot in the rack as the tube rotates. Be sure that at least 0.10 inch (about 1/8 inch) of space is left between (a) the bar code symbol and the bottom of the rack slot and (b) between the bar code symbol and tube cap. This spacing will satisfy the "quiet zone" requirement. Refer to the following figure for proper bar code placement.

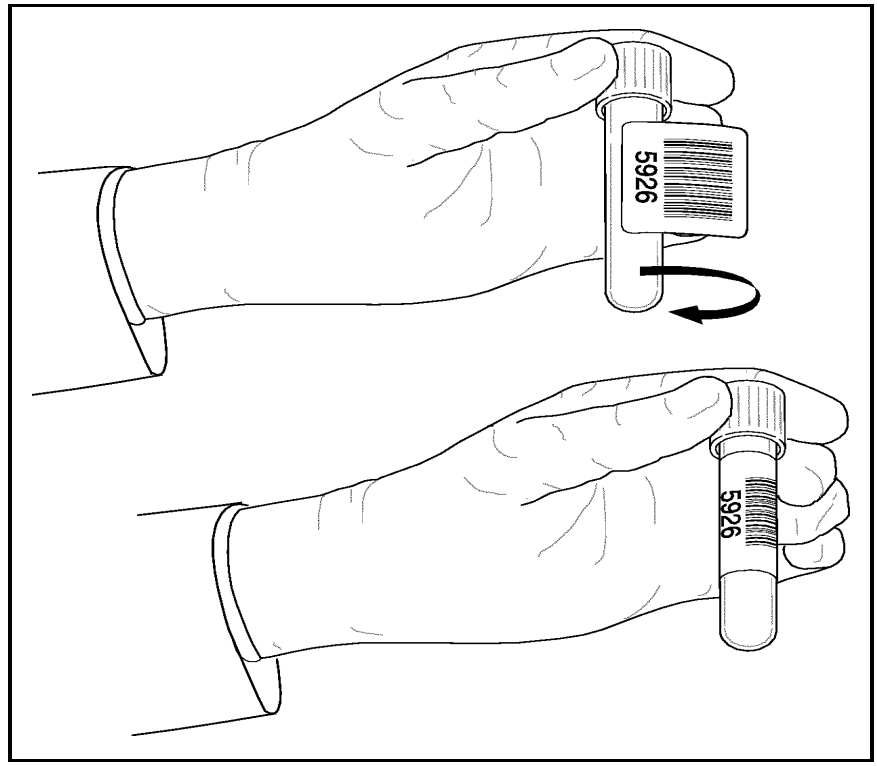

Figure 1.1: Bar Code Placement Guide

NOTES

Bar Code Operation

Tables A.1 and A.2 at the end of this section summarize how the bar code reader reads and interprets bar code labels under different Set Up scenarios, and what information is sent to the Data Log. Table A.1 shows bar code operation for the SL model, and Table A.2 shows it for the CS model. The system can take a number of actions depending on the Bar Code Set Up configuration and the symbology of the label. A brief description of each possible action is given below.

Code 39

If the Instrument is configured for Code 39 with Check Digit ON, the Instrument will:

a. read a Code 39 label with check digit.

   If the check digit on the label matches the check digit calculated by the Instrument, the "read" is good and the Work List is searched for a matching bar code number in the Specimen ID field. If a matching entry is found in the Work List, the entry is sent to the Data Log and deleted from the Work List. If no matching entry is found, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field.

   If the check digits do not match, the "read" is not good and a Check Digit Error message is displayed on the Bulletin line. The Work List is not searched. For SL models, the Rack and Tube # is assigned to the Specimen ID field for that specimen in the Data Log. For CS models, only the Sequence # is used to identify that specimen in the Data Log.

b. read a Code 39 label without a check digit.

   The system reports a Check Digit Error message on the Bulletin line. The Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number. The Specimen ID field is left blank.

c. ignore all other bar code symbologies.

   A Bar Code Error message is displayed on the Bulletin line and the Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

If the Instrument is configured for Code 39 with Check Digit OFF, the Instrument will:

a. read a Code 39 label with a check digit.

   The bar code reader reads the entire number including the check digit and the Work List is searched. Because the bar code label has one extra digit (check digit), no matching entry will be found in the Work List (which should not contain the check digit). For SL models, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

b. read a Code 39 label without a check digit.

   The "read" is assumed to be good (without a check digit the bar code number cannot be verified) and the Work List is searched for a matching bar code number in the Specimen ID field. If a matching entry is found in the Work List, the entry is sent to the Data Log and deleted from the Work List. If no matching entry is found, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field.

c. ignore all other bar code symbologies.

   A Bar Code Error message is displayed on the Bulletin line and the Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

I2of5

If the Instrument is configured for I2of5 with Check Digit ON, the Instrument will:

a. read an I2of5 label with check digit.

   If the check digit on the label matches the check digit calculated by the Instrument, the "read" is good and the Work List is searched for a matching bar code number in the Specimen ID field. If a matching entry is found in the Work List, the entry is sent to the Data Log and deleted from the Work List. If no matching entry is found, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field.

   If the check digits do not match, the "read" is not good and a Check Digit Error message is displayed on the Bulletin line. The Work List is not searched. For SL models, the Rack and Tube # is assigned to the Specimen ID field for that specimen in the Data Log. For CS models, only the Sequence # is used to identify that specimen in the Data Log.

b. read an I2of5 label without a check digit.

The system reports a Check Digit Error message on the Bulletin line. The Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number. The Specimen ID field is left blank.

c. ignore all other bar code symbologies.

A Bar Code Error message is displayed on the Bulletin line and the Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

If the Instrument is configured for I2of5 with Check Digit OFF, the Instrument will:

a. read an I2of5 label with a check digit.

If the check digit on the label matches the check digit calculated by the Instrument, the “read” is good and the Work List is searched for a matching bar code number in the Specimen ID field. If a matching entry is found in the Work List, the entry is sent to the Data Log and deleted from the Work List. If no matching entry is found, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field.

If the check digits do not match, the “read” is not good and a Check Digit Error message is displayed on the Bulletin line. The Work List is not searched. For SL models, the Rack and Tube # is assigned to the Specimen ID field for that specimen in the Data Log. For CS models, only the Sequence # is used to identify that specimen in the Data Log.

b. read an I2of5 label without a check digit.

The system reports a Check Digit Error message on the Bulletin line. The Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number. The Specimen ID field is left blank.

c. ignore all other bar code symbologies.

A Bar Code Error message is displayed on the Bulletin line and the Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

Codabar

If the Instrument is configured for Codabar with Check Digit ON, the Instrument will:

a. read a Codabar label with check digit.

If the check digit on the label matches the check digit calculated by the Instrument, the “read” is good and the Work List is searched for a matching bar code number in the Specimen ID field. If a matching entry is found in the Work List, the entry is sent to the Data Log and deleted from the Work List. If no matching entry is found, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field.

If the check digits do not match, the “read” is not good and a Check Digit Error message is displayed on the Bulletin line. The Work List is not searched. For SL models, the Rack and Tube # is assigned to the Specimen ID field for that specimen in the Data Log. For CS models, only the Sequence # is used to identify that specimen in the Data Log.

b. read an Codabar label without a check digit.

The system reports a Check Digit Error message on the Bulletin line. The Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number. The Specimen ID field is left blank.

c. ignore all other bar code symbologies.

A Bar Code Error message is displayed on the Bulletin line and the Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

If the Instrument is configured for Codabar with Check Digit OFF, the Instrument will:

a. read a Codabar label with a check digit.

The bar code reader reads the entire number including the check digit and the Work List is searched. Because the bar code label has one extra digit (check digit), no matching entry will be found in the Work List (which should not contain the check digit). For SL models, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

b. read a Codabar label without a check digit.

The “read” is assumed to be good (without a check digit the bar code number cannot be verified) and the Work List is searched for a matching bar code number in the Specimen ID field. If a matching entry is found in the Work List, the entry is sent to the Data Log and deleted from the Work List. If no matching entry is found, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field.

c. ignore all other bar code symbologies.

A Bar Code Error message is displayed on the Bulletin line and the Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

Code 128

If the Instrument is configured for Code 128, the check digit feature is automatically ON and the Instrument will:

a. read a Code 128 label.

If the check digit on the label matches the check digit calculated by the Instrument, the "read" is good and the Work List is searched for a matching bar code number in the Specimen ID field. If a matching entry is found in the Work List, the entry is sent to the Data Log and deleted from the Work List. If no matching entry is found, the specimen is identified in the Data Log by the tube bar code number in the Specimen ID field.

If the check digits do not match, the "read" is not good and a Check Digit Error message is displayed on the Bulletin line. The Work List is not searched. For SL models, the Rack and Tube # is assigned to the Specimen ID field for that specimen in the Data Log. For CS models, only the Sequence # is used to identify that specimen in the Data Log.

b. ignore all other bar code symbologies.

A Bar Code Error message is displayed on the Bulletin line and the Work List is not searched. For SL models, the specimen is identified in the Data Log by the Rack and Tube number assigned to the Specimen ID field by the Instrument. For CS models, the specimen is identified in the Data Log by the Sequence number only and the Specimen ID field is left blank.

NOTES:

TABLE A-1. Bar Code Operation - SL Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
Code 39 label with Check digit	Reads label. If check digit correct, Work List is searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log. If check digit incorrect, check digit error occurs and rack and tube # is assigned as Specimen ID and sent to Data Log.	Reads label. Check digit added to bar code number. Work List searched. Because check digit added to number, no Work List match. Tube bar code including check digit assigned as Specimen ID and sent to Data Log.	Unable to read label. Bar code error. Work List not searched. Rack and tube # assigned as Specimen ID and sent to Data Log.	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."

TABLE A-1. Bar Code Operation - SL Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
Code 39 label with-out Check Digit	Reads label. Check digit error occurs. Work List not searched. Rack and tube # is assigned as Specimen ID and sent to Data Log.	Reads label. Work List searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log.	Unable to read label. Bar code error. Work List not searched. Rack and tube # assigned as Specimen ID and sent to Data Log.	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON.".	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."

TABLE A-1. Bar Code Operation - SL Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
I2of5 label with Check Digit	Unable to read label. Bar code error. Work List not searched. Rack and tube # assigned as Specimen ID and sent to Data Log.	Same as "CODE 39 with Check Digit ON."	Reads label. If check digit correct, Work List is searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log. If check digit incorrect, check digit error occurs and rack and tube # assigned as Specimen ID and sent to Data Log.	Reads label. Check digit added to bar code number. Work List searched. Because check digit added to number, no Work List match. Tube bar code including check digit assigned as Specimen ID and sent to Data Log.	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."

TABLE A-1. Bar Code Operation - SL Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
I2of5 label without Check Digit	Unable to read label. Bar code error. Work List not searched. Rack and tube # assigned as Specimen ID and sent to Data Log.	Same as "CODE 39 with Check Digit ON."	Reads label. Check digit error occurs. Work List not searched. Rack and tube # assigned as Specimen ID and sent to Data Log.	Reads label. Work List searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log.	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."

TABLE A-1. Bar Code Operation - SL Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
CODABAR label with Check Digit	Unable to read label. Bar code error. Work List not searched. Rack and tube # assigned as Specimen ID and sent to Data Log.	Same as "Code 39 with Check Digit ON."	Same as "Code 39 with Check Digit ON."	Same as "Code 39 with Check Digit ON."	Reads label. If check digit correct, Work List is searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log. If check digit incorrect, check digit error occurs and rack and tube # assigned as Specimen ID and sent to Data Log.	Reads label. Check digit added to bar code number. Work List searched. Because check digit added to number, no Work List match. Tube bar code including check digit assigned as Specimen ID and sent to Data Log.	Same as "Code 39 with Check Digit ON."

TABLE A-1. Bar Code Operation - SL Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
CODABAR label with-out Check Digit	Unable to read label. Bar code error. Work List not searched. Rack and tube # assigned as Specimen ID and sent to Data Log.	Same as "Code 39 with Check Digit ON."	Same as "Code 39 with Check Digit ON."	Same as "Code 39 with Check Digit ON."	Reads label. Check digit error occurs. Work List not searched. Rack and tube # assigned as Specimen ID and sent to Data Log.	Reads label. Work List searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log.	Same as "Code 39 with Check Digit ON."

TABLE A-1. Bar Code Operation - SL Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
Code 128 label (built-in Check Digit)	Unable to read label. Bar code error. Work List not searched. Rack and tube # assigned to sample as Specimen ID and sent to Data Log.	Same as "Code 39 with Check Digit ON."	Same as "Code 39 with Check Digit ON."	Same as "Code 39 with Check Digit ON."	Same as "Code 39 with Check Digit ON."	Same as "Code 39 with Check Digit ON."	Reads label. If check digit correct, Work List is searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log. If check digit incorrect, check digit error occurs and rack and tube # assigned as Specimen ID and sent to Data Log.

NOTE: Bar Code # and Rack and Tube # are placed in Specimen ID field in the Data Log.

TABLE A-2. Bar Code Operations - CS Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
Code 39 label with Check digit	Reads label. If check digit correct, Work List is searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log. If check digit incorrect, check digit error occurs. Specimen ID field remains blank. Specimen identified only by Sequence # in Data Log.	Reads label. Check digit added to bar code number. Work List searched. Because check digit added to number, no Work List match. Tube bar code including check digit assigned as Specimen ID and sent to Data Log.	Unable to read label. Bar code error. Work List not searched. Specimen identified only by Sequence # in Data Log.	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."

TABLE A-2. Bar Code Operations - CS Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
Code 39 label with-out Check Digit	Reads label. Check digit error occurs. Work List not searched. Speci-men identified only by Sequence # in Data Log.	Reads label. Work List searched. If match found, Work List entry sent to Data Log. If no match found, specimen iden-tified only by Sequence # in Data Log.	Unable to read label. Bar code error. Work List not searched. Specimen iden-tified only by Sequence # in Data Log.	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."	Same as "I2OF5 with Check Digit ON."

TABLE A-2. Bar Code Operations - CS Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
I2of5 label with Check Digit	Unable to read label. Bar code error. Work List not searched. Specimen identified only by Sequence # in Data Log.	Same as "CODE 39 with Check Digit ON."	Reads label. If check digit correct, Work List is searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log. If check digit incorrect, check digit error occurs. Specimen ID field remains blank. Specimen identified only by Sequence # in Data Log.	Reads label. Check digit added to bar code number. Work List searched. Because check digit added to number, no Work List match. Tube bar code including check digit assigned as Specimen ID and sent to Data Log.	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."

TABLE A-2. Bar Code Operations - CS Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
I2of5 label without Check Digit	Unable to read label. Bar code error. Work List not searched. Specimen identified only by Sequence # in Data Log.	Same as "CODE 39 with Check Digit ON."	Reads label. Check digit error occurs. Work List not searched. Specimen identified only by Sequence # in Data Log.	Reads label. Work List searched. If match found, Work List entry sent to Data Log. If no match found, specimen identified only by Sequence # in Data Log.	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."

TABLE A-2. Bar Code Operations - CS Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
CODABAR label with Check Digit	Unable to read label. Bar code error. Work List not searched. Specimen identified only by Sequence # in Data Log.	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Reads label. If check digit correct, Work List is searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log. If check digit incorrect, check digit error occurs. Specimen ID field remains blank. Specimen identified only by Sequence # in Data Log.	Reads label. Check digit added to bar code number. Work List searched. Because check digit added to number, no Work List match. Tube bar code including check digit assigned as Specimen ID and sent to Data Log.	Same as "CODE 39 with Check Digit ON."

TABLE A-2. Bar Code Operations - CS Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
CODABAR label without Check Digit	Unable to read label. Bar code error. Work List not searched. Specimen identified only by Sequence # in Data Log.	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Reads label. Check digit error occurs. Work List not searched. Specimen identified only by Sequence # in Data Log.	Reads label. Work List searched. If match found, Work List entry sent to Data Log. If no match found, specimen identified only by Sequence # in Data Log.	Same as "CODE 39 with Check Digit ON."

TABLE A-2. Bar Code Operations - CS Model

	CODE 39 with Check Digit ON	CODE 39 with Check Digit OFF	I2OF5 with Check Digit ON	I2OF5 with Check Digit OFF	CODABAR with Check Digit ON	CODABAR with Check Digit OFF	CODE 128
Code 128 label (built-in Check Digit)	Unable to read label. Bar code error. Work List not searched. Specimen identified only by Sequence # in Data Log.	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Same as "CODE 39 with Check Digit ON."	Reads label. If check digit correct, Work List is searched. If match found, Work List entry sent to Data Log. If no match found, tube bar code assigned as Specimen ID and sent to Data Log. If check digit incorrect, check digit error occurs. Specimen ID field remains blank. Specimen identified only by Sequence # in Data Log.

NOTE:In the Data Log, Sequence # is placed in Seq # field, not in Specimen ID field.

Acknowledgment

The authors wish to acknowledge Computype, Inc. of St., Paul, Minnesota, for providing their booklet "Bar Coding and Productivity" to assist in the writing of this Appendix.

NOTES

Overview

This section gives a lists the part numbers of components, accessories, controls, reagents, and consumables associated with the CELL-DYN® 3200 System for user convenience when placing orders.

To place an order for these products, dial our toll-free Customer Service Network at 1 (800) 323-9100.

If you require technical assistance for your CELL-DYN System, contact the Customer Support Center at 1 (800) CELL DYN (235-5396).

CELL-DYN 3200 Accessories

TABLE 1. CELL-DYN® 3200 Accessories Kit (List Number 04H61-01)

Part/List Number	Quantity	Name	Description
9520877	1	Cable, Interface (Data Station)	For communication between Data Station and Analyzer computer
20005-01	1	Cable, Interface (printer), 6’	For communication between Printer and Data Station computer
2400516	2	Cable, Power, 6’7"	For Analyzer
50065-01	2	Fuse, 8-amp	Analyzer, 110 VAC
61164-01	2	Fuse, 4-amp	Analyzer, 220 VAC
06H60-01	1	Manual, Operator’s	English version supplied by factory
06H65-01	1 kit	Reagent Line Kit	See ***Reagent Inlet/Waste Outlet Tubing Kit*** for individual tubing information
92376-01	1 pkg	Tubing set, Transfer Pump	Package of one Transfer Pump Tubing Assembly
9310519	1 pkg	Ring, Pull Solenoids	Ring for Pulling Solenoid Pinch Valves

TABLE 2. CELL-DYN 3200 Sample Loader Accessories Kit

List Number	Quantity	Name	Comments
04H87-01	1 set	Racks, Sample Loader	Set of 5 Sample Loader racks pre-labeled with tube position numbers and rack number label

CELL-DYN 3200 Optional Accessories

TABLE 3. CELL-DYN 3200 Optional Accessories

Part/List Number	Quantity	Name	Description
01H11-01	1	Ink cartridge, Black	For use with Canon® Bubble Jet™ Printer
01H52-01	1	Ink cartridge, Cyan	For use with Canon Bubble Jet Printer
01H53-01	1	Ink cartridge, Magenta	For use with Canon Bubble Jet Printer
06H54-01	1	Ink cartridge, Yellow	For use with Canon Bubble Jet Printer
06H74-01	1	Keyboard, CELL-DYN 3200, English	NMB 120439-001 (supplied by factory)
06H75-01	1	Keyboard Protective cover	For use with NMB keyboard 120439-001
25860-01	1	Label Dispenser, Bar Code	Dispenser for Bar Code Label rolls
99650-01	1	Labels, CELL-DYN 3200 Tube ID Bar Code, 1 roll	Tube ID Bar Code Labels (1000 labels per roll)
06H62-01	1	Labels, CELL-DYN 3200 Rack Bar Code, set of 100	Bar Code Labels for Autoloader Racks (#s 0-99)
92532-01	1	Serial Loopback Device	For testing the Laboratory Information System (LIS)
06H63-01	1	Rack, Sample Loader	Single rack for CELL-DYN 3200
06H71-01	1	Specifications, Interface, CELL-DYN 3200	Description and specifications for communications between a Laboratory Information System (LIS) and the CELL-DYN 3200 System
02H82-01	1	Syringe, 10 mL	For dispensing Diluent/Sheath reagent
28561-01	1	Syringe, 2.5 mL	For dispensing WBC Lyse or HGB Lyse reagent
28560-01	1	Syringe, 500 µL	For injecting diluted sample into optical flow cell
03H99-01	1	Needle, Vent/Aspiration	For venting/aspirating samples in Closed Mode

TABLE 4. CELL-DYN 3200 Controls/Calibrator

List Number	Quantity	Name	Description
99120-01	1	Calibrator, CELL-DYN 3000	2.5-mL tube with pierceable cap, insert, and assay sheets
93111-01	1	Control, CELL-DYN 3000 (tri-level)	2.5-mL vials with insert cap, insert, and assay sheets
99129-01	1	Control, CELL-DYN3000 (tri-level)	3.0 mL vacutainer with piercable cap, insert, and assay sheets

TABLE 5. CELL-DYN 3200 Reagents

List Number	Quantity	Name	Single Container Size	Case Weight, Qty/Case
03H78-01	1	Reagent, WBC Lyse	960 mL bottle	1.0 kg ± .2 kg 1/case
03H79-01	1	Reagent, Diluent/Sheath	20-L cubitainer	21.9 ± 0.5 kg 1/case
03H80-01	1	Reagent, CN free HGB/NOC Lyse	960 mL bottle	1.0 kg ± .2 kg 1/case

TABLE 6. CELL-DYN 3200 Reagent Inlet/Outlet Tubing (List Number 9130313)

List Number	Quantity	Name	Comments
9212059	1	Tubing, Reagent, Diluent/Sheath	Includes reagent container cap, and sinker
9212115	1	Tubing, Reagent, HGB/NOC Lyse	Includes reagent container cap, and sinker
9212101	1	Tubing, Reagent, WBC Lyse	Includes reagent container cap, and sinker
9211559	1	Assy, Waste Line CD3200	Includes reagent container cap, and sensor
99644-01	1	Enzymatic Cleaner	
	1	DYN-A-WIPE	
		Preprinted Tickets™	

NOTE: All of the items in the Reagent Inlet/Outlet Tubing Kit are included in the Accessories Kit, but can also be ordered as a Reagent Line Kit (06H65-01).

NOTES

Index

D

K

L

M

N

O

P

Q

R

S

T

NOTES