Safety

Throughout the manual, 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.

Operation, maintenance, and servicing of hematology systems may expose individuals to potential safety and health hazards. All work must be performed as described in the Operator's Manual or as directed by an Abbott representative.

Information relating to potential hazards may be found in **Section 8: *Hazards***.

WARNING: This equipment needs special precautions regarding general requirements for safety. Please consult **Section 7: *Operational Precautions and Limitations*** and **Section 8: *Hazards***, before operating the CELL-DYN Emerald.

NOTES

Revision Status

Document Control Number(s)	Revision Date	Section(s) Revised	Pages Revised and Added
New Release 9213300A 09H40-01	May/2008	Initial release: all sections new.	Initial release: all sections new.
9213300B	May/2008	9140859B—Revision Status	p. iii
		9140846B—Installation Procedures and Special Requirements	pp. 2-6, 2-8 and 2-9, 2-14, 2-17, 2-19 and 2-20, 2-23 through 2-25, 2-27 and 2-28
		9140847B—Principles of Operation	pp. 3-1, 3-5, 3-10 through 3-12, 3-16
		9140848B—Performance Characteristics and Specifications	p. 4-7 and 4-8
		9140849B—Operating Instructions	pp. 5-4, 5-17, 5-19
		9140853B—Service and Maintenance	p. 9-3
9213300C	February/2009	9140859C—Revision Status	pp. iii, iv
		9140840B—Foreword	pp. vii, viii, ix, xi, xv
		9140841B—Table of Contents	ALL
		9140842B—List of Figures	ALL
		9140843B—List of Tables	ALL
		9140845B—Use or Function	pp. 1-2, 1-4, 1-11
		9140846C—Installation Procedures and Special Requirements	pp. 2-4, 2-12, 2-13, 2-15 through 2-32

Document Control Number(s)	Revision Date	Section(s) Revised	Pages Revised and Added
		9140847C—Principles of Operation	pp. 3-3 through 3-7, 3-9, 3-10, 3-12, 3-14, 3-15, 3-17, 3-19, 3-20
		9140848C—Performance Characteristics and Specifications	pp. 4-7, 4-8, 4-10 through 4-18
		9140849C—Operating Instructions	pp. 5-1, 5-4 through 5-7, 5-9, 5-11 through 5-17, 5-19, 5-20, 5-23 through 5-33
		9140850B—Calibration	pp. 6-6 through 6-10
		9140851B—Operational Precautions and Limitations	pp. 7-4 through 7-10
		9140852B—Hazards	pp. 8-8, 8-10
		9140853C—Service and Maintenance	pp. 9-2 through 9-24
		9140854B—Troubleshooting	pp. 10-7 through 10-16
		9140855B—Quality Control	pp. 11-4 through 11-8, 11-11 through 11-13, 11-15
		9140861B—Appendix A	pp. A-3, A-4
		9140861B—Appendix B	ALL
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		9140861B—Appendix E	pp. E-2, E5 through E12
		9140861B—Appendix F	pp. F-5, F-6
		9140863B—Appendix G	ALL
		9140872B—Glossary	pp. 8-11
		9140862B—Index	ALL
9213300D	December/2009	9140859D—Revision Status	ALL
		9140840C—Foreword	ALL
		9140841C—Table of Contents	ALL
		9140842C—List of Figures	ALL
		9140843C—List of Tables	ALL

Document Control Number(s)	Revision Date	Section(s) Revised	Pages Revised and Added
		9140844B—How to Use This Manual	ALL
		9140845C—Use or Function	ALL
		9140846D—Installation Procedures and Special Requirements	ALL
		9140847D—Principles of Operation	ALL
		9140848D—Performance Characteristics and Specifications	ALL
		9140849D—Operating Instructions	ALL
		9140850C—Calibration	ALL
		9140851C—Operational Precautions and Limitations	ALL
		9140852C—Hazards	ALL
		9140853D—Service and Maintenance	ALL
		9140854C—Troubleshooting	ALL
		9140855C—Quality Control	ALL
		9140861C—Appendix A	ALL
		9140861C—Appendix B	ALL
		9140861C—Appendix C	ALL
		9140861C—Appendix E	ALL
		9140861C—Appendix F	ALL
		9140863C—Appendix G	ALL
		9140872C—Glossary	ALL
		9140862C—Index	ALL

Document Control Number(s)	Revision Date	Section(s) Revised	Pages Revised and Added
9213300E	June/2010	9140859E—Revision Status	ALL
		9140840D—Foreword	ALL
		9140846E—Installation Procedures and Special Requirements	ALL
		9140847E—Principles of Operation	ALL
		9140848E—Performance Characteristics and Specifications	ALL
		9140849E—Operating Instructions	ALL
		9140854D—Troubleshooting	ALL
		9140855D—Quality Control	ALL

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 Emerald 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

Foreword

Congratulations on your purchase of the CELL-DYN Emerald System. The CELL-DYN Emerald, which uses state-of-the-art technology, is designed to function consistently and dependably on a daily basis.

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

Abbott Hematology is dedicated to providing the highest quality, most reliable instrumentation available. We look forward to working with you and serving your needs.

Customer Service

If you need information or help in diagnosing a problem, technical assistance is available by telephone. In the USA, this service is available 24 hours a day, seven days a week by calling Abbott Diagnostics Customer Service.

United States: 1-877-4ABBOTT (1-877-422-2688).

For customer support in Canada 1-800-387-8378.

Outside of USA and Canada: contact your Country Service and Support representative.

For correspondence, the address in the USA is:

Abbott Diagnostics Division
Customer Service
200 Abbott Park Road
Abbott Park, IL 60064, USA

Intended Use

The CELL-DYN Emerald System is an automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories.

Proprietary Statement

The software and manual were developed solely for use with the CELL-DYN Emerald and for *in vitro* diagnostic applications as specified in the operating instructions.

The information and related graphics published herein (the "Information") are the sole property of Abbott Laboratories. Permission to use the Information is granted, provided that:

- the copyright notice appears on all copies;
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Patent Statement

The following worldwide patents are relevant to the CELL-DYN Emerald or its components. WO 200562015, WO 200510497. The following USA Patents are relevant to the CELL-DYN Emerald or its components: 6,632,676. There are other such patents and patent applications in the United States and worldwide.

Disclaimers

All samples (printouts, graphics, displays, screens, etc.) are for information and illustration purposes only and shall not be used for clinical or maintenance evaluations. Data shown in sample printouts and screens do not reflect actual patient names or test results. Labels depicted in the manual may appear different from actual product labels.

Abbott Laboratories makes no representations or warranties about the accuracy and reliability of the information contained in the CELL-DYN Emerald Operator's Manual.

The information was developed to be used by Abbott Laboratories trained personnel, by other persons knowledgeable or experienced with the operation and service of the product identified, or under the direct supervision and with cooperation from Abbott Laboratories technical sales or service representatives.

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Abbott Laboratories is not engaged in rendering medical advice or services.

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List numbers are unique identifiers that are used when ordering products. The list number and quantity provided in **Appendix A: *Accessories*** are intended for guidance only and are subject to change. Contact your Abbott representative for the most current information regarding list numbers.

All operating instructions must be followed. In no event shall Abbott be responsible for failures, errors, or other liabilities resulting from customers' non-compliance with the procedures and precautions outlined herein.

Warranty Statement for USA Customers Only

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 Abbott Diagnostics Customer Service 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 Diagnostics Customer Service: 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 Operator's 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 Emerald Hematology System is manufactured in France for Abbott Diagnostics Division, Abbott Laboratories, 200 Abbott Park Road, Abbott Park, IL, 60064, USA. Please direct all inquiries concerning information in this manual to the foregoing address.

NOTE: Direct all inquiries regarding equipment problems to Abbott Diagnostics Customer Service. (USA customers only.)

CE

Regulatory and Safety Agency Approvals

In Vitro Diagnostic Directive	98/79/EC
Legal Manufacturer	Abbott Laboratories Abbott Park, IL 60064, USA
Authorized Representative	ABBOTT Max-Planck-Ring 2 65205 Wiesbaden Germany +49 6122 580

UL	61010-1	Approved
CAN/CSA-C22.2	No. 61010-1	Approved
IEC 61010-1		Approved
UL		Listed

Trademark Statements

CELL-DYN and Emerald are trademarks of Abbott Laboratories in various jurisdictions.

All other trademarks are the property of their respective owners.

Symbols

The symbols listed below are used in labeling, including the instrument, reagents, calibrators, controls, and this manual. Please note that Warning and Caution symbols and statements are in this manual in **Section 8: *Hazards***.

Table 1 Instrument/Power-related

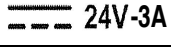
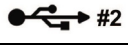
Symbol	Definition/Use	Location of Label
	Direct Current 24V-3A	Rear panel
	Barcode/Barcode scanner connection	Rear panel
	Caution, risk of electric shock	Behind flow panel, interior of instrument
DILUENT	Diluent	Rear panel
	Equipotentiality	Rear panel
	Ethernet/Ethernet connection	Rear panel
REF	Catalog Number	Serial Number Label
	Stand by / Power On/Off	Front
	Printer/Printer serial connection	Rear panel
REV	Revision	Serial Number Label
SN	Serial Number	Serial Number Label
	Serial Interface RS 232C/Serial Port connection	Rear panel
	USB ports, 1 and 2	Rear panel
		
WASTE	Waste	Rear panel
APPLICATION SOFTWARE	Application Software	On Flash Drive

Table 2 Reagent-related

Symbol	Definition/Use
CLEANER	Cleaner Reagent
DILUENT	Diluent Reagent
KEY	Key
LOT	Batch Code
LYSE	Lyse
SN	Serial Number
	Use By

Table 3 Calibrator/Control-related

Symbol	Definition/Use
ASSAY VALUE	Assay Value
MEAN RANGE	Mean Range
MEAN VALUE	Mean Value
PARAMETER	Parameter
SYSTEM	System
TOLERANCE LIMIT	Tolerance Limit
WB CAL	Whole Blood Calibrator
WB CONTROL TRI-LEVEL	Whole Blood Control, Tri-Level
WB CONTROL L/N/H or I//II/III	Whole Blood Control, Low, Normal or High Level; or Whole Blood Control Level I, II or III.

Table 4 Miscellaneous

Symbol	Definition/Use
EC REP ABBOTT Max-Planck-Ring 2 65205 Wiesbaden Germany +49-6122-580	Authorized Representative in the European Community
	Biohazard
	Caution (Note: for Instrument reagents)
	Caution, risk of danger / Caution, consult accompanying documents (Note: for Instruments)
IVD	For In Vitro Diagnostic Medical Device
	Manufacturer
	Consult instructions for use
MODEL	Model number
	Temperature limitation
	Separate collection for electrical and electronic equipment waste per Directive 2002/96/EC in the European Union
	Identifies an area where electrostatic discharge may be present. A ground strap must be worn while servicing the system.
	Indicates that the material is Harmful (Xn) or Irritant (Xi)

Labeling

The following labels are affixed to the CELL-DYN Emerald System:

The CELL-DYN Emerald is CE Marked to the European In Vitro Diagnostic Directive, which encompasses the requirements of the EMC and Safety Directives, and have the following labels:

Shipping Container

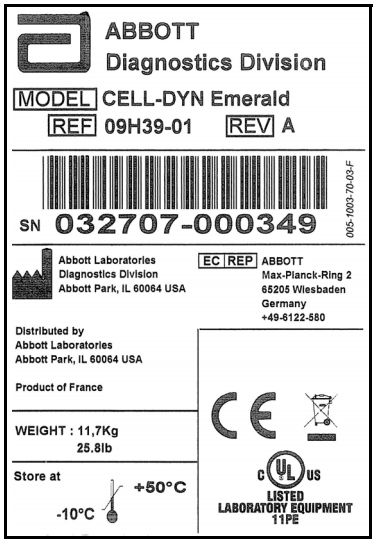


Figure 1: Shipping Container Label

Analyzer Front Panel

Figure 2: Biohazard Label

Analyzer Flow Panel

Figure 3: Hazard Label

Analyzer Rear Panel

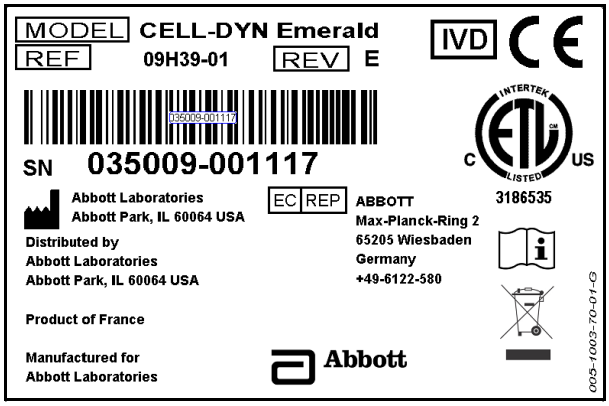


Figure 4: Serial Number Label

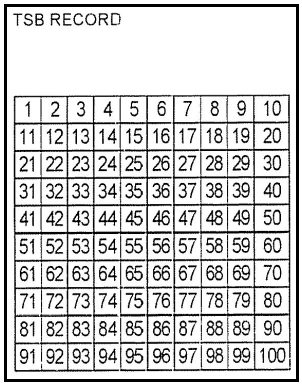


Figure 5: Technical Service Bulletin Record Label

Figure 6: Biohazard Label

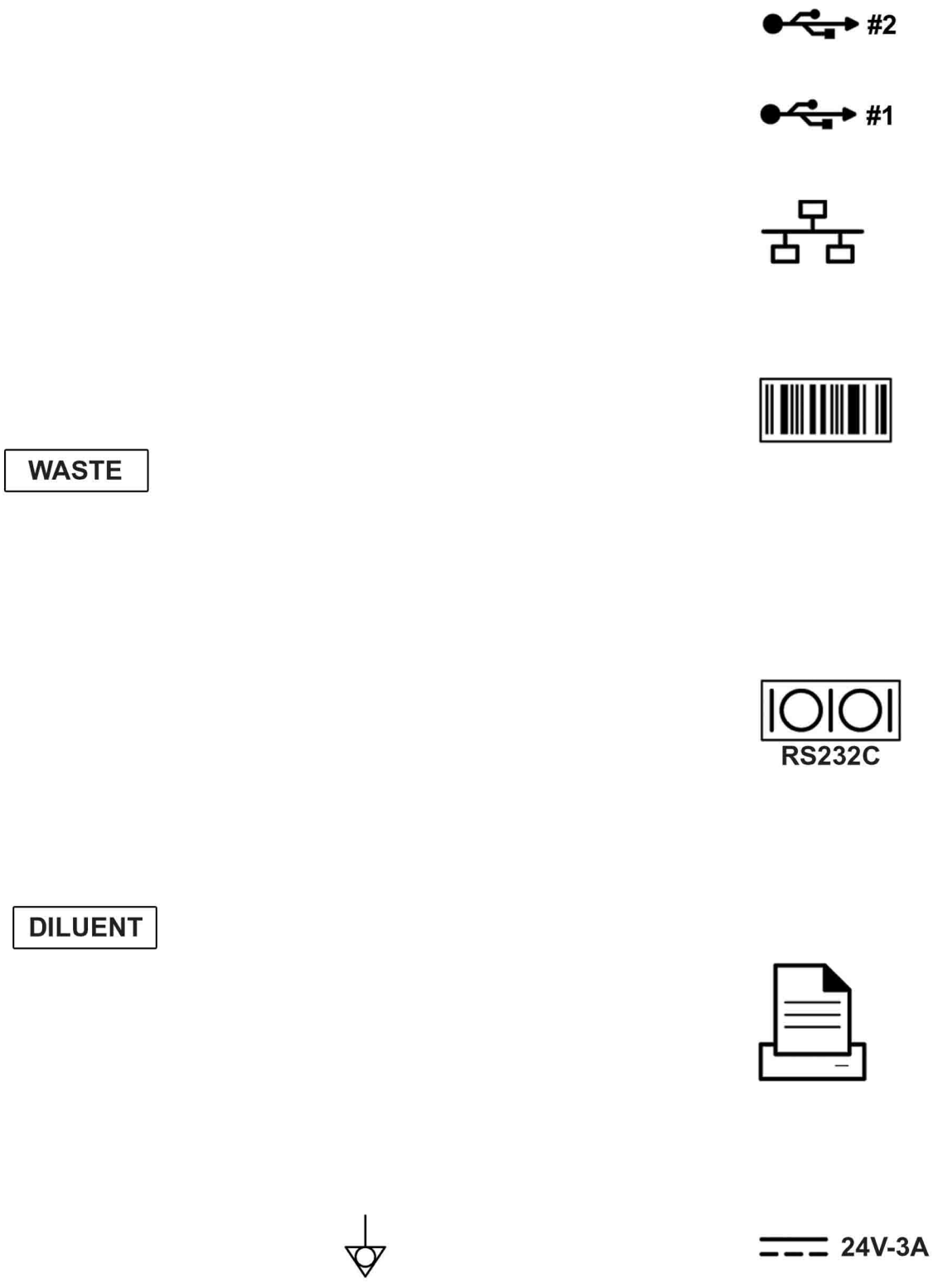


Figure 7: Rear Panel

NOTES

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How to Use This Manual

Manual Organization

The major sections of the manual and their contents are as follows:

Front Matter

The pages following the Master Table of Contents contain a Foreword that includes customer support information, and proprietary, patent, and trademark statements.

Section 1: Use or Function

This section provides an overall description of the system. It names the major system components and describes their uses or functions.

Section 2: Installation Procedures and Special Requirements

This section provides detailed instruction for system setup and configuration. It explains proper location, requirements, and steps for installation.

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 Specification

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

Section 5: Operating Instructions

This section explains the procedures for daily startup and shutdown, sample collection and handling, and the routine operation of the instrument including use of the data log and sample analysis.

Section 6: Calibration Procedures

This section describes the calibration process. It discusses calibration materials, guidelines, and methods.

Section 7: Operational Precautions and Limitations

This section contains a summary of the 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. Also included are detailed instructions for removing and cleaning certain 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.

Glossary

This appendix contains the words and terms used in hematology as they apply to the CELL-DYN Emerald, as well as terms that describe the actual operation, principles of operation, and components of the instrument.

Appendices

Appendix A

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

Appendix B

This appendix contains a table on potential causes of erroneous results.

Appendix C

This appendix contains step-by-step instructions for preparing sodium hypochlorite (bleach) solutions for use on the CELL-DYN Emerald.

Appendix D

This appendix contains a list of literature sources relating to CBC Reference Intervals (Patient Limits).

Appendix E

This appendix contains sample logs and worksheets to copy and use for your convenience in constructing an instrument log for your laboratory.

Appendix F

This appendix contains information about whole blood calibration and manual calculation of calibration factors.

Index

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

Text Conventions

Text Conventions Used in This Manual

In this manual, procedural instructions are explained in logical groups, using numbered steps. Illustrations and drawings appear where they are useful to the explanation. Text conventions are as follows:

Menu Name

The menu name is printed in bold, uppercase, sans serif letters; for example, **MAIN** menu.

Touch Screen Buttons

The CELL-DYN Emerald user interface includes a LCD touch screen where "buttons" are selected by touching the corresponding area of the display. When referring to these, the manual uses the term "button". Touching one of these buttons initiates an action. Touching other (non-button) areas on the display make selections or inserts a cursor for entry. Detailed descriptions of the actions initiated by the buttons are found in the applicable section(s) of this manual. Screen labels are shown in bold, uppercase, sans serif letters enclosed in brackets; for example, **[QUALITY CONTROL]**.

Data Entry Field Names

Fields that accept data entered by the Operator have their names shown in regular, mixed-case font enclosed within carats < >.

Keypad (Keys)

In addition to the display touch screen, the user interface for the CELL-DYN Emerald includes keys on the front panel of the instrument. When referring to these, the manual uses the term "key". Special function keys, such as the arrow keys, may appear as a symbol substituted for the word. Instructions for special function keys will read, for example "Press the [↑] arrow key."

Screen Messages

Screen messages or other screen displays will appear in bold, Courier letters, for example, **`Do you wish to continue?`**. If the screen message requires a response from the user, the touch screen button(s) will follow the convention as described in Touch Screen Buttons.

NOTES

Overview

The CELL-DYN Emerald is an automated hematology analyzer intended for in vitro diagnostic use in the clinical laboratory. It is menu-driven and controlled by a microprocessor.

Figure 1.1 CELL-DYN Emerald

The CELL-DYN Emerald aspirates blood from an opened collection tube held up to the aspiration probe. The CELL-DYN Emerald can aspirate blood from several types of collection devices which contain K_2EDTA. Refer to **Section 5:** ***Operating Instructions***, **Subsection:** ***Specimen Collection and Handling.***

The CELL-DYN Emerald provides the following:

White Blood Cell measurands:

- WBC – White Blood Cell or leukocyte count
- LYM % – Lymphocyte percent
- LYM # – Lymphocyte absolute number
- MID % – Mid Cells percent
- MID # – Mid Cells absolute number
- GRA % – Granulocyte percent
- GRA # – Granulocyte absolute number

Red Blood Cell measurands:

- RBC – Red Blood Cell or erythrocyte count
- HCT – Hematocrit
- MCV – Mean Cell Volume
- RDW – Red Blood Cell Distribution Width

Hemoglobin measurands:

- HGB – Hemoglobin concentration
- MCH – Mean Cell Hemoglobin
- MCHC – Mean Cell Hemoglobin Concentration

Platelet measurands:

- PLT – Platelet count
- MPV – Mean Platelet Volume

System Components

The CELL-DYN Emerald consists of eight main components:

1. Front Panel with LCD Display and Numeric Keypad
2. Fluidics
3. Main PCB Board
4. AC Adapter/Transformer
5. Reagent Tray
6. Rear Panel
7. Printer
8. Barcode Reader

Display and Numeric Keypad

1. **LCD** — Touch Screen Display.
2. **LED** — Red when cycle in process or not ready; Green when ready for next cycle; flickering Red during aspiration.
3. **ESCAPE** — Exits the current menu.
4. **Arrow Keys** — The Up and Down arrow keys move the cursor to the next line (when present). The Right and Left arrow keys move the cursor within an entry field.
5. **Numeric Keypad** — Used to enter numeric information.
6. **ENTER** — Used to enter typed information.
7. **DEL** (delete) — Used to delete entered information.
8. **ON/OFF** – Brings the system out of Standby, and system halt.

Figure 1.2 Front Panel Components

Main Menu

Menu items are discussed in detail in subsequent Sections.

1. **Date/Time** – Displays current date and time/
2. **TOOLS ICON** (Wrench) – Accesses the **TOOLS** menu containing context-specific options, such as Print and Send.
3. **RETURN ICON** (Curved Arrow) – Returns to the previous menu.
4. **HOME ICON** (House) - Returns to the **MAIN** menu.
5. **START UP** – Initiates the Start Up Cycle.
6. **EVENT LOG** – Accesses the Event Log.
7. **OPER. LOG IN/OUT** – Accesses the Log In/Log Out screen.
8. **REAGENTS** – Accesses the **REAGENTS** menu.
9. **SHUT DOWN** – Initiates the Shut Down Cycle.
10. **CALIBRATION** – Accesses the **CALIBRATION** menu.
11. **QUALITY CONTROL**– Accesses the **QUALITY CONTROL** menu.
12. **DATALOG** – Accesses stored results.
13. **SET UP** – Accesses the **SET UP** menu.
14. **MAINTENANCE** – Accesses the **MAINTENANCE** and **SERVICE** menu.
15. **RUN SAMPLE** – Accesses the Run Screen.

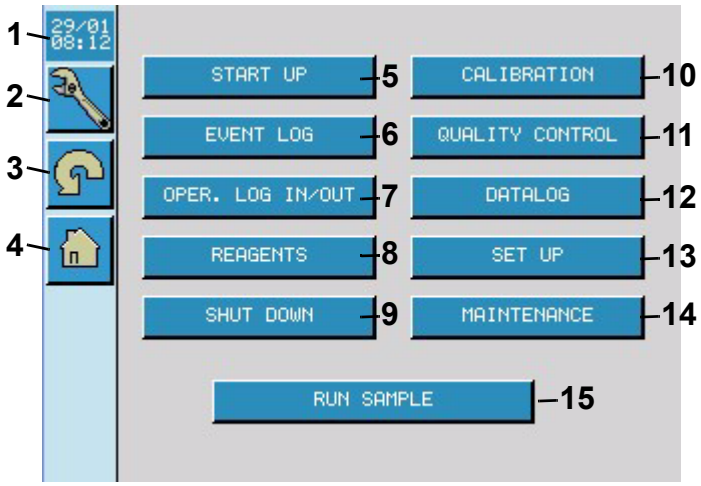


Figure 1.3 Main Menu

Fluidics

1. Sampling Module
2. Syringe Module
3. Counting Module

Figure 1.4 Fluidics

The fluidic components are located on the right side of the instrument and contain the following three modules:

Figure 1.5 Sampling Module

1. Sampling Module – consists of the rocker that performs the up/down and forward/back movement of the aspiration probe and the aspiration probe itself.

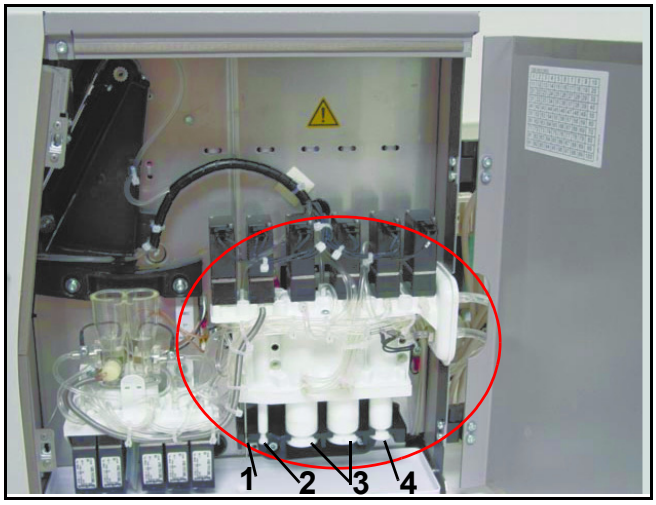


Figure 1.6 Syringe Module

2. Syringe Module – This module performs the following functions:
   - Moves the sample aspiration syringe down to aspirate a sample
   - Distributes the reagents
   - Drains the baths
   - Provides the vacuum for counting
   - Moves the waste to the waste container

   This module contains a manifold for the fluidic valves, the syringe pistons and the syringe block. The syringe block combines five syringes which are driven by one motor:
   - Sample aspiration syringe (1)
   - Lyse syringe (2)
   - Two vacuum/pressure and waste syringes (3)
   - Diluent syringe (4)

   The diluent input and waste output connections are located on the rear panel.

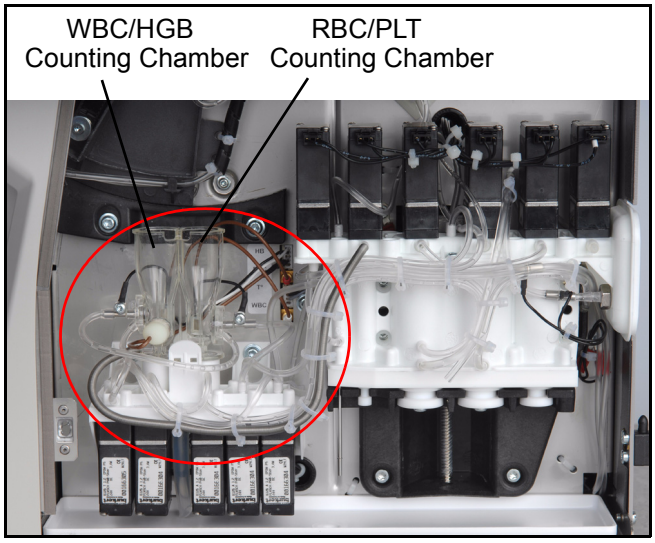


Figure 1.7 Counting Module

3. Counting Module – This module counts the WBCs, RBCs, and PLTs and measures the HGB. It includes:

- WBC/HGB Counting Chamber with the WBC Aperture and the Hemoglobin LED. Left bath.
- RBC/PLT Counting Chamber with the RBC/PLT Aperture. Right bath.
- Liquid valve manifold assembly with associated tubing. Below baths.

Main PCB Board

The Main PCB Board is located between the Fluidics and the Reagent Tray. It is driven by a 32-bit microprocessor and manages the following components:

- Aspiration probe, Rocker, and Syringe Block motors
- Display and Keyboard
- LIS Connection (RS232, Ethernet, etc.)
- Cell counting and Hemoglobin measurement
- Data Processing
- Bar code reader
- USB connections

WARNING: Internal Shock Hazard: Only qualified personnel should service the instrument.

AC Adapter/Transformer

Figure 1.8 AC Adapter/Transformer

The CELL-DYN Emerald is supplied with an external AC Adapter/Transformer. The use of another external AC Adapter/Transformer is not recommended. If necessary, contact Abbott Customer Service for assistance.

Two power cords are provided with the CELL-DYN Emerald: one for 110 Voltage (USA) and one for 220V. Replacement cords must comply with local regulations.

Reagent Tray

The Reagent Tray holds the Cleaner and Lyse reagent bottles.

1. Cleaner Reagent
2. Cleaner Reagent line (green collar)
3. Lyse Reagent
4. Lyse Reagent line (blue collar)

Figure 1.9 Reagent Tray

Reagent System

A reagent system, specifically formulated for the CELL-DYN Emerald instrument, provides optimal system performance. Use of reagents other than those specified in this manual is not recommended as instrument performance can be affected. Each instrument is tested at the factory using the specified reagents. All performance claims are generated using these reagents. Refer to **Appendix A: *Accessories*** for information on ordering CELL-DYN Reagents.

CELL-DYN Emerald Diluent Reagent

CELL-DYN Emerald Diluent Reagent is formulated to do the following:

- Act as the diluent for WBC, RBC, PLT, and Hemoglobin measurements
- Maintain cell volume during the counting and sizing portion of the measurement cycle
- Provide a conductive medium for impedance counting and sizing of cells and platelets
- Rinse the Aspiration Probe and fluidics

CELL-DYN Emerald CN-Free Lyse Reagent

CELL-DYN Emerald Cyanide-Free Lyse Reagent is formulated to meet the following requirements:

- Rapidly lyse the RBC and minimize resultant cell stroma
- Alter the WBC membrane to allow the cytoplasm to diffuse and shrink the membrane around the nucleus and any granules that may be present
- Convert hemoglobin to a modified hemoglobin complex that is measurable at 555 nm. (The quaternary ammonium lysate participates to form a chromagen for hemoglobin measurement.)

CELL-DYN Emerald Cleaner Reagent

CELL-DYN Emerald Cleaner Reagent is an enzymatic cleaner used to clean the measurement system and the fluidics.

Reagent Storage

Reagents must be stored as labeled to ensure optimal performance.

Each length of reagent inlet tubing is attached to a cap that minimizes reagent evaporation and contamination during use. Ensure that all reagent caps are undamaged and are securely attached to containers during use. If a waste container is used, ensure that the cap is securely attached during use. If a drain is used, ensure that the waste tubing is securely inserted in the drain.

Reagent quality can deteriorate with time; therefore, use all reagents before the expiration date on the label.

Reagent Handling

When handling reagents, pay special attention to the following:

- Wear lab coat, gloves, and protective eyewear when handling reagents.
- Never transfer the contents of a reagent container to an unmarked container or another reagent container.
- Thoroughly clean all spills. Remove any dried residue in and around the Diluent Inlet connector located on the rear panel.
- Dispose of reagents and waste fluids in accordance with local, state, and federal regulations.
- Always wash your hands after handling reagents.

Calibrator and Controls

Calibrator and Controls are reference materials used to set, test, and monitor the CELL-DYN Emerald performance. Refer to **Appendix A:** ***Accessories*** for information on ordering CELL-DYN Calibrator and Controls.

CELL-DYN Calibrator is used to calibrate the **WBC**, **RBC**, **HGB**, **MCV**, and **PLT** measurands. Calibration is discussed in **Section 6:** ***Calibration***.

Day-to-day verification of system calibration is performed using CELL-DYN controls. Each laboratory should determine the frequency of performing quality control. This may be specified by local regulatory agencies.

Overview

An Abbott-authorized representative should perform installation of the CELL-DYN Emerald System. This is to ensure that all system components are functioning correctly and to verify system performance. Installation procedures must be repeated if the instrument is moved from the original installation site.

This section provides information about installation and customization of the CELL-DYN Emerald. The beginning of this section provides the following requirements and guidelines for installing the system:

- Site requirements
- Guidelines for unpacking and inspection, connection and start up, and relocation
- Guidelines for instrument set up by the Operator

NOTES

Site Requirements

Site requirements for installation include the following:

- Space requirements
- Power requirements
- Waste disposal requirements
- Installation environment

NOTE: Refer to **Section 7:** ***Operational Precautions and Limitations*** for general requirements and precautions for system operation.

Space Requirements

Select an appropriate location for the CELL-DYN Emerald System. The instrument, printer and reagents weigh approximately 88 pounds (40 kg) and should be placed on a surface that is adequate to support the weight. Allow for sufficient space on the counter top to place the diluent at the same level as the instrument.

CAUTION: Diluent must be placed at the same level as the instrument for proper operation and to prevent bubbles from entering the diluent line.

Allow at least 4 inches (10 cm) of space behind the instrument for airflow. Make sure there is adequate space around the instrument to perform necessary procedures or service and allow the instrument to be easily disconnected from the power source.

NOTE: To ensure the instrument and reagents function properly, it is important to maintain the temperature between 64^{o} – 90^{o} F (18^{o} – 32^{o} C).

Place the instrument:

- On a stable, level surface.
- On a non-porous, non-absorbing work surface and flooring that can be easily cleaned and disinfected using recommended procedures.
- In an area that will not block the ventilation openings.
- Away from direct sunlight.
- Do not place the instrument near a centrifuge, X-ray equipment, video display terminal, computer, or copier.

CAUTION: Do not use mobile telephones, wireless telephones, mobile radios, or any other radio frequency (RF) transmitting devices in the same room as the instrument.

Power Requirements

CAUTION: When connections are made, check all connectors for particles or foreign material that can impair electrical contact.

Refer to **Section 4:** ***Performance Characteristics and Specifications*** for specific power requirements.

Waste Disposal Requirements

WARNING: Potential Biohazard. Observe all biosafety and chemical hazard precautions for waste disposal. For a detailed description of the hazards associated with the CELL-DYN Emerald, refer to **Section 8:** ***Hazards*****.**

Observe the following requirements for waste routing and disposal:

- Users are responsible for disposing of waste in accordance with local, state, and federal regulations.
- If a waste container is used, it must be labeled as biohazardous waste.
- If a drain is used, it must be suitable for waste that could present a biological or chemical hazard.

CAUTION: If routing waste to a sink, be sure that the waste outlet tube is placed securely in the drain hole. To prevent a possible hazard, ensure that all system components are located away from potential waste overflow.

Installation Environment

The following are environmental requirements:

- Indoor use only
- Altitude up to 6562 feet (2000 meters)
- Temperature range: $64^{o} – 90^{o}$ F ($18^{o} – 32^{o}$ C)
- Maximum relative humidity 80% for temperatures up to 90^{o} F (32^{o} C)

Installation

Inventory and Unpacking

Inspect the packaging before unpacking the instrument. Notify the shipper if there is any damage. An authorized Abbott representative will uncrate, inspect and place the instrument in the specified location.

Accessories

Ensure that the following accessories have been received:

Table 2.1 Accessories Kit

Item	Quantity
Diluent Reagent line with cap	1
Waste Line with cap	1
Hand-held barcode scanner	1

Table 2.2 Installation Kit

Item	Quantity
AC Adapter/Transformer	1
US Power Cord	1
European Power Cord	1
Flat Screwdriver (Key)	1
CELL-DYN Emerald Service Kit	1

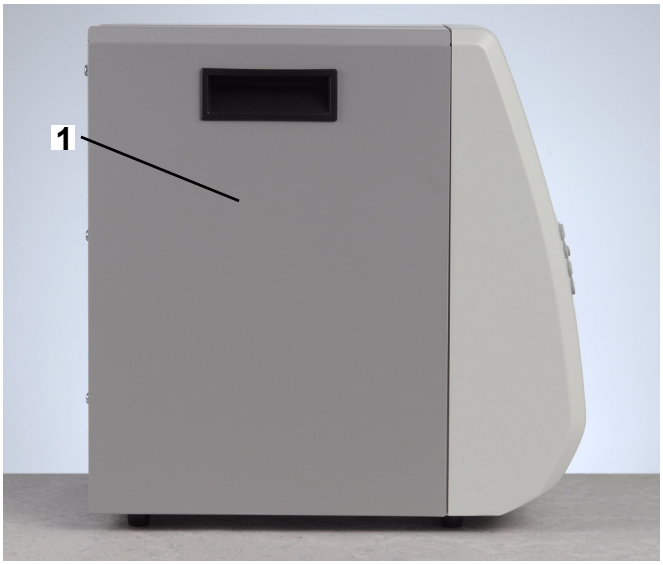
Table 2.3 Service Kit

Item	Quantity
Tubing L = 1000 mm 1.5 x 3.2 mm	1
Tubing L = 500 mm 2 x 4 mm	1
Tubing 9	1
Tubing 10	1
Cable Ties	5
Short Arm Torx T10 Tool	1
Short Arm Torx T20 Tool	1
O-ring Dia 13.1 x 1.6 Fluocarbon	2
O-ring Dia 1.4 x 1.25 Fluocarbon	1
O-ring Dia 5 x 1 Fluocarbon	2
Bottle cap filter	4
EMLD Grease 3 gm	1

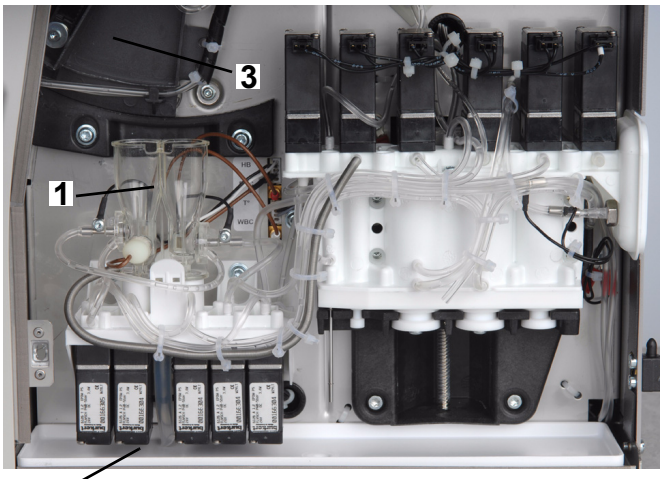
Instrument Preparation

1. Open the box from the top, remove the packing material and the Accessory kit.
2. Remove the CELL-DYN Emerald from the box and remove the plastic covering.
3. Perform the following visual checks:

1. Lift off the left side door (1) covering the reagent tray and remove the Installation kit. Remove the key from the kit and open the right side door.



1. Ensure the counting chambers (1) are locked in their manifold locations.
2. Ensure the aspiration probe's removable clip (2) is seated in the rocker (3).
3. Ensure that the rocker is moved all the way to the front position.
4. Remove foam packing material (4), if present, from below the valves.
5. Remove protective film from LCD display on the front of the analyzer.



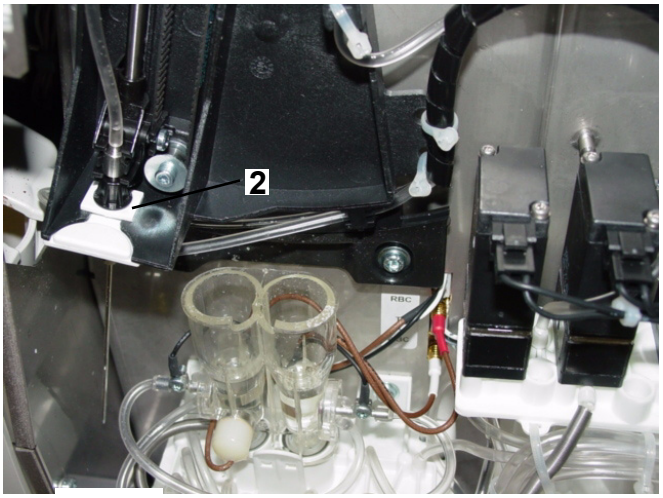


Figure 2.1 Instrument Inspection

CAUTION: Moving parts inside. Use care when instrument power is ON.

Electrical Connections

1. USB Port
2. USB Port
3. Ethernet Connection (TCP/IP)
4. External Bar Code Reader (RS232)
5. LIS Connection (RS232C)
6. Printer Connection
7. Power Cord Connection
8. For ground use

Figure 2.2 Electrical Connections

CAUTION: Only the printer, power, USB, and barcode reader connections can be made without authorization from Abbott.

AC Adapter

The CELL-DYN Emerald must be connected to power with the AC Adapter/ Transformer provided with the instrument. Place the AC Adapter/Transformer in a well-ventilated location at the rear of the instrument, away from any potential liquid spills.

1. Connect the appropriate power cord to the AC Adapter/Transformer.
2. Connect the AC Adapter/Transformer to the instrument.

   NOTE: Do not force connection. Connection is made when resistance is felt. Connector may not appear to be flush with instrument rear panel.
3. Connect the power cord and AC Adapter/ Transformer to a grounded power outlet.

IMPORTANT: To disconnect power to the CELL-DYN Emerald, unplug the power cord from the power outlet.

CAUTION: If it is necessary to replace the main power cord, the replacement must comply with local regulations and should be 12.3" (31.2 cm) cable with a 110V or 220V, 10A plug. The CELL-DYN Emerald has been certified with the Power Adapter provided. Use of another Power Adapter is not recommended.

Printer installation

IMPORTANT: The CELL-DYN Emerald System has been configured for and tested with the specific printer that is shipped with the instrument. For additional information about specific printer capability with the CELL-DYN Emerald System contact your local Abbott Customer Service representative. Use of a printer other than that recommended by Abbott Laboratories may lead to erroneous printer functionality.

Please refer to the documentation shipped with the printer for set-up instructions. For a parallel printer connection, use a parallel, shielded cable, maximum length 10 Ft. (3 M). Connect the cable to the printer connector at the rear of the instrument and to the connector on the printer. For a USB printer connection, use the cable provided or recommended by the printer manufacturer.

Reagent installation

CAUTION: Before handling reagents, refer to the information provided in **Section 1:** ***Use or Function***, **Subsection:** ***Reagent System***.

1. Remove the reagent door on the left side of the instrument.
2. Place the reagent bottles in their designated locations and remove the caps.
3. Place the green collar reagent tubing (2) and cap on the CELL-DYN Emerald Cleaner Reagent (1) bottle.
4. Place the blue collar reagent tubing (4) and cap on the CELL-DYN Emerald CN-free Lyse Reagent (3) bottle.

Figure 2.3 Lyse and Cleaner Reagent Connections

5. Connect the diluent tubing (male connector) to the diluent port (lower port) (5), insert the tubing in the CELL-DYN Emerald Diluent Reagent container and tighten the cap.
6. Place the diluent at the same level as the CELL-DYN Emerald.

   CAUTION: Diluent must be at the same level as the instrument for proper operation.

7. Connect the waste tubing (female connector) to the waste port (upper port) (7), insert the tubing into a properly labeled waste container and tighten the cap.

   CAUTION: Do not modify the type or length of the diluent and waste tubing.

   NOTE: Waste container or drain must be placed lower than the instrument.

Figure 2.4 Diluent Reagent and Waste Connections

Instrument Start Up

CAUTION: Ensure that the reagent and waste lines have been properly connected before starting this procedure.

1. Power ON the instrument.
   — Ensure the AC Adapter and power cord are connected
   — Press the **POWER/ON/OFF** key
2. The Cycle LED turns red and remains red until the initialization cycle is complete. The Cycle LED turns green and the **LOGIN** screen displays when the instrument is ready to use.

NOTE: Cycles Left indicates the number of runs available. This is automatically updated, using information from the reagent's bar code label whenever a reagent is changed, or based on available capacity in the waste container, whichever is less. At initial startup all reagent volumes are set to zero. Resetting of reagent volumes will be required as part of the installation process.

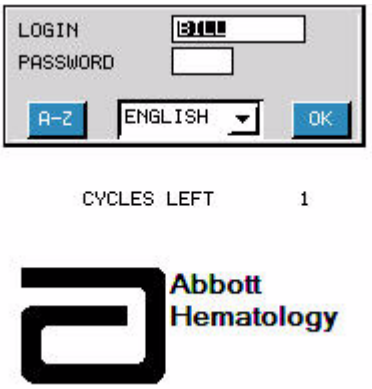


Figure 2.5 Power ON

3. Language Selection:
   a. Touch the **Dropdown** menu and touch the desired language to select it. It may be necessary to use the scroll bar at the right of the **Language Dropdown** menu to view all available languages.
   b. Touch **[OK]** to continue.

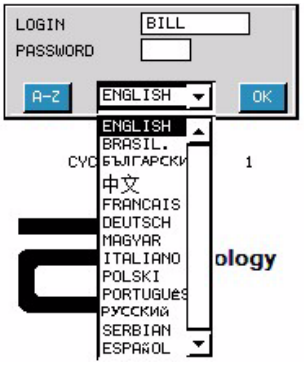


Figure 2.6 Language Selection

Instrument Set Up

Operator Log In and Log Out

Each operator should log in to the CELL-DYN Emerald when operating the instrument. Log In names can be up to ten characters in length. Each operator should log out when they have finished running specimens.

The CELL-DYN Emerald provides four access levels (three are password-protected). All passwords can be up to four characters in length.

a. User (Operator) – no password is entered
b. Lab Tech (Supervisor) – default password is 1-2-3. The Supervisor should enter a new password during the initial instrument set up.
c. Service – for Abbott Service Personnel Only
d. Factory – for Abbott Manufacturing Personnel Only

NOTE: After the instrument is initialized, the **<LOG IN>** field displays the last log in name that was entered.

1. If the Log In name is correct, proceed to step a. If not, proceed to step 2.
   a. Touch the **<PASSWORD>** field and then touch **[A-Z]** or use the numeric keypad to enter a password, if required for access. Touch each letter to enter it in the **<PASSWORD>** field.
   b. Touch **[CONFIRM]** from the alpha keyboard screen, if used.
   c. Touch **[OK]** to enter the password.

NOTE: To Log In, touch **[OPER. LOG IN/OUT]** at the **MAIN** menu and follow the steps below.

To Log Out, go to the **MAIN** menu and touch **[OPER. LOG IN/OUT]**. For added security, you may use the **DEL** key to delete your personal **LOGIN**.

NOTE: To Log In with a different access level, touch **[OPER. LOG IN/OUT]** at the **MAIN** menu and follow the steps above.

2. To enter a different **Operator LogIn** name, touch the data entry box to the right of **<LOGIN>**.
   a. Use the alpha or numeric keypads as described above to enter your login name and password.

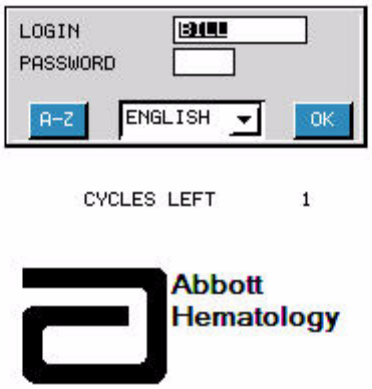


Figure 2.7 Operator Log In/Out

System Status

The current status of the CELL-DYN Emerald can be displayed at any time by touching the Date/Time display in the upper left corner of the display.

The status is displayed as follows in the Information window that opens when the Date/Time display is touched:

1. Instrument Serial Number (ID)
2. Operator ID (USER) – the current entry
3. Operator's access level for the current entry
4. Setup Version
5. Software (SW) Version
6. Loader – current version (used to launch the instrument software)

Touch **[EXIT]** to return to the previous menu.

NOTE: The information displayed will represent the current software version(s) installed on your instrument and may not match the screen shown in here.

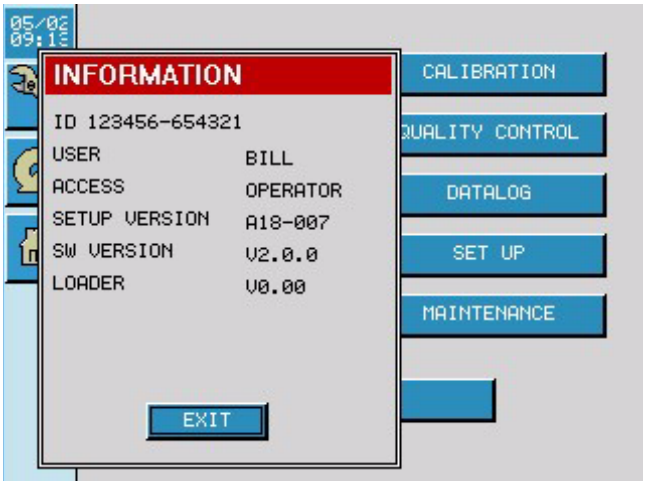


Figure 2.8 System Status

Loading or Replacing Reagents

CAUTION: Ensure that the reagent and waste lines have been properly connected before starting this procedure.

The first time the CELL-DYN Emerald is powered ON, it is necessary to load all three reagents and prime the system as described below.

Whenever a new lot of reagent is put into use, the lot number, expiration date, container serial number, verification key and container volume should be entered as directed in the following procedures.

After priming a new reagent, run a background cycle and verify that the results are within specifications. Repeat background, if needed, until all results are within specifications.

Replacing the Reagents – Diluent, Lyse, Cleaner

Using Reagent Bar Codes

Barcodes used on the CELL-DYN Emerald reagents monitor reagent usage and expiration date.

From the **MAIN** menu, touch **[REAGENTS]**, followed by **[DILUENT]** to access the Diluent screen.

1. Remove the empty container and replace it with a full one.
2. Scan the two barcodes on the label of the new reagent container to automatically populate all empty fields.

NOTE: Both barcodes must be scanned to auto-populate the reagent fields.

3. Verify that all fields are complete. If not, repeat the scan of both barcode labels. If entry of reagent information is still not complete, refer to ***Manual Entry of Reagent Information*** in this section.
4. Touch **[CONFIRM]**
   If the information entry is successful the **[PRIME DILUENT]** key turns green.
5. Touch **[PRIME DILUENT]**.
6. Touch **[ESC]** when finished.
7. To replace the Lyse or Cleaner, touch **[ESC]** to return to the **REAGENTS** menu and repeat the above steps for the desired reagent.

Figure 2.9 Reagent Bar Codes

Manual Entry of Reagent Information

From the **Main** menu, touch **[REAGENTS]**, followed by **[DILUENT]** to access the Diluent screen.

1. Remove the empty container and replace it with a full one.
2. Touch the box to the right of **<LOT>**.
3. Using the A-Z keys (touch **[A-Z]**) and the numeric keypad, enter the lot number.
4. Touch the box to the right of **<EXPIRATION>** and use the numeric keypad to enter the expiration date.

NOTE: The default date format is DDMMYY. To change the format for all date fields refer to **Section 2: *Installation Procedures and Special Requirements***, **Subsection: *Other Settings***.

5. Touch the box to the right of **<CAPACITY>** and use the numeric keypad to enter the reagent volume.
6. Touch the box to the right of **<BOTTLE SERIAL NUMBER>** – and use the numeric keypad to enter the information on the label.
7. Touch the box to the right of **<VERIFICATION KEY>** and use the numeric keypad to enter the information on the label.
8. Touch **[PRIME DILUENT]**.
9. Touch **[CONFIRM]** to save the entries. The entered information is recorded in the reagent logs.
10. Touch **[CONFIRM]** to save entries and return to the **REAGENTS** screen.
11. To replace the Lyse or Cleaner, repeat the above steps for the desired reagent.

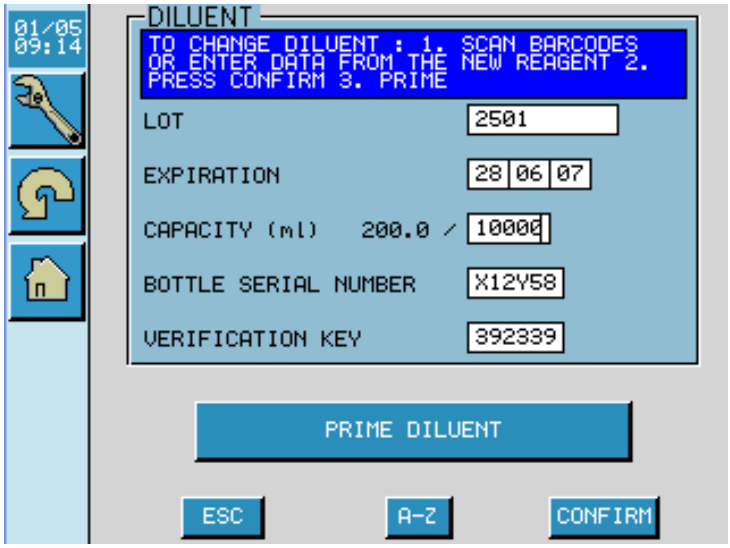


Figure 2.10 Manual Entry of Reagent Information

Replacing or Emptying the Waste Container

Be sure to label and dispose of waste properly.

CAUTION: Ensure that the waste line has been properly connected before starting this procedure.

The first time the CELL-DYN Emerald is powered ON, it is necessary to reset the waste volume as described below.

From the **MAIN** menu, touch **[REAGENTS]**, followed by **[WASTE]**.

1. Remove the full container and replace it with an empty one.
   NOTE: Waste container or drain must be lower than the instrument.
2. Touch the box below and to the right of **<CAPACITY>** and use the numeric keypad to enter the volume of the waste container.
3. Touch **[RESET]** or **[CONFIRM]** to enter the container capacity into the system memory.
4. The system will prompt, **`DO YOU WANT TO SAVE MODIFICATIONS?`** Touch **[YES]** to save and return to the Reagents screen or touch **[NO]** to return to the Waste screen.
5. Touch the **HOME** icon to return to the **MAIN** menu.

NOTE: If you are disposing of waste directly to a drain, enter “99999” in the capacity field, then proceed as described in Steps 3 through 5, above. The waste counter will need to be reset when the system has dispensed 99999 mL of waste.

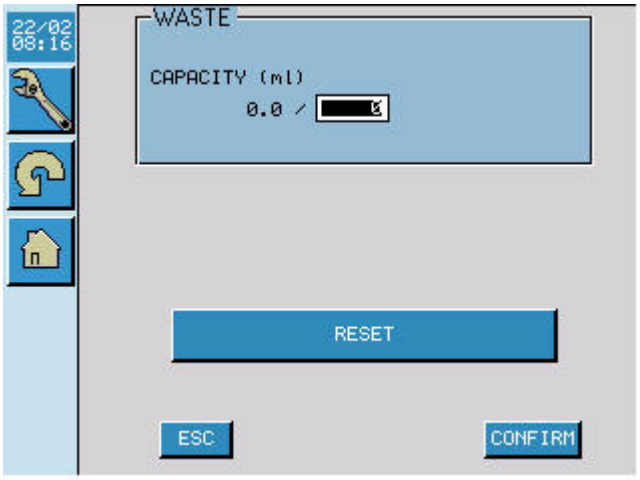


Figure 2.11 Changing the Waste Container

Other Reagent Menu functions

The remaining buttons on the **REAGENTS** menu are:

1. PRIME ALL - This button is used to prime all reagents at the same time.
2. CYCLE COUNTER – The CYCLE COUNTER button displays the information shown in the following figure.

1. **RUNS** – displays the total number of runs since the last reset.
2. **STARTUP** – displays the number of Startup cycles run since the last reset.
3. **SHUT DOWN** – displays the number of Shut Down cycles run since the last reset.

NOTE: Only authorized Abbott Personnel can reset the CYCLE COUNTER.

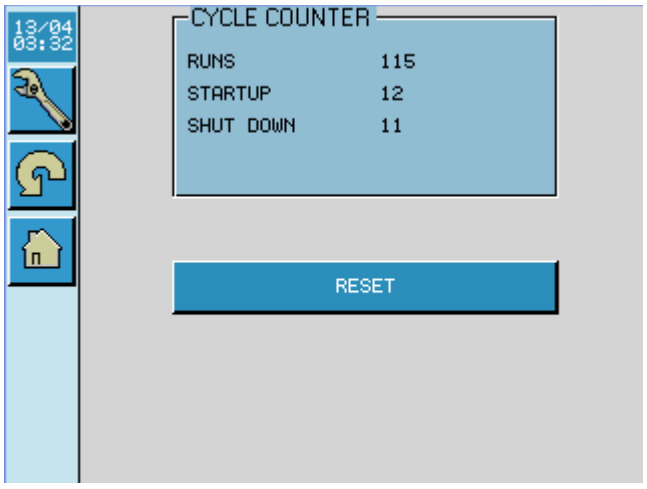


Figure 2.12 CYCLE COUNTER Screen

Set Up Menu

If necessary, touch the **HOME** icon to return to the **MAIN** menu. From the **MAIN** menu, touch **[SET UP]** to display the screen shown at the right.

1. **Date and Time:** Touch **<TIME>** and use the numeric keypad to enter the time in the desired (24 hour or AM/PM) format, If using AM/PM time format, check the box next to PM to select PM or deselect (uncheck) for AM. Touch **<DATE>** and use the numeric keypad to enter the date in the selected format. For information about selecting AM/PM time format and selecting date format, refer to **Subsection:** ***Other Settings*** within this section.

NOTE: The date format must match the format defined under the **ADVANCED** setup menu.

IMPORTANT: Changing time setting. It is possible to change the time ahead for the start of Daylight Savings Time without effect on data. To reset the time back one hour at the end of Daylight Savings Time, perform this step at the beginning of the day, after Start Up and before any samples are run to avoid deletion of results.

IMPORTANT: Changing the date setting. ***The Emerald system will delete results (from Datalog) if the date is reset to a past date***. Before results are deleted, the system prompts the user with a warning message that must be acknowledged. Ensure that the system date is set correctly prior to first use of the analyzer.

2. **Language:** Touch the Language dropdown menu arrow to display the available languages and touch the desired language to select it.

NOTE: Language may be set from either this display or at the **OPER. LOG IN/OUT** screen.

3. **Printer:** Touch the Printer dropdown menu arrow to display the available printers and touch the appropriate printer to select it. An option for no printer may also be selected.
4. **Paper size:** Touch the Paper Size dropdown menu to display the available paper sizes for the selected printer and touch the desired paper size to select it.

NOTE: Choose the correct paper size for proper printer functionality.

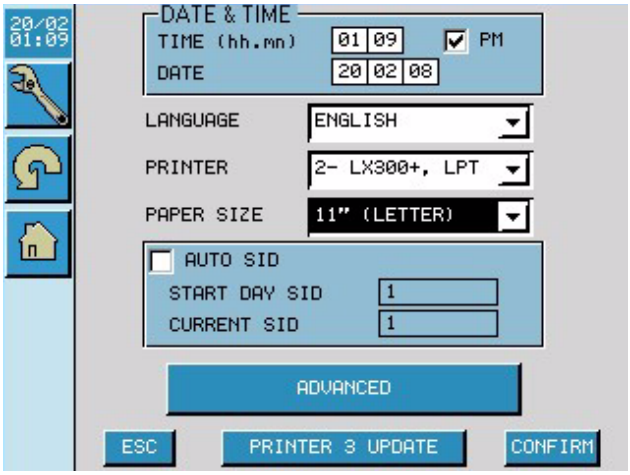


Figure 2.13 Date/Time Set Up

5. **AUTO SID:** Touch the **AUTO SID** box to select automatic incrementing of the SID. This should only be selected if auto-increment of the SID is required in your laboratory.
6. Touch **<START DAY SID>** and use the numeric keypad to enter the first SID for each day.
7. Touch **<CURRENT SID>** and use the numeric keypad to enter a new SID for the current run.

NOTE: The **AUTO SID** box must be checked in order to enter Start Day SID and Current SID.

8. **ADVANCED:** Information about the use of this button can be found in the next **Subsection:** ***Advanced Set Up***.
9. When entries are complete:

   Touch **[CONFIRM]** to save the entries. At the pop-up prompt **DO YOU WANT TO SAVE MODIFICATIONS?**, touch **[YES]** to save and exit. Touch **[NO]** to change the entry. Touch **[ESC]** to exit without saving changes.
10. **PRINTER 3 UPDATE:** For instructions on how to copy a new printer driver from a USB drive, refer to subsection: USB Drive (Thumb Drive) in **Section 5:** ***Operating Instructions***.

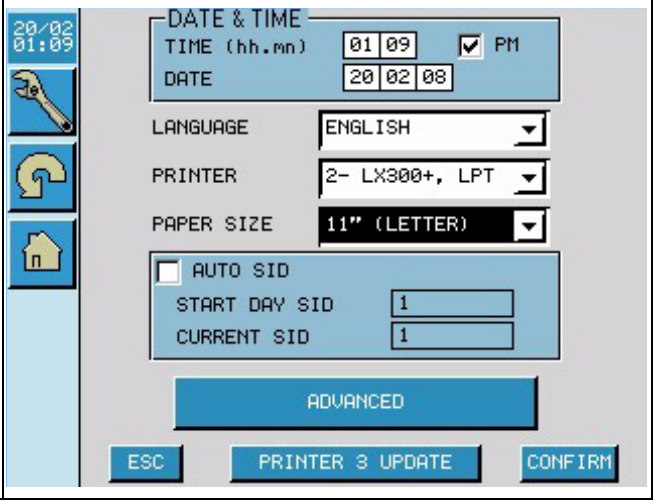


Figure 2.13 Date/Time Set Up (Continued)

Advanced Set Up

The Advanced Set Up button is available from Lab Tech access level and higher.

CAUTION: Any changes to these options can affect the quality of results. Do not modify these settings until you have been properly trained to do so.

1. From the **MAIN** menu, touch **[SET UP]**, and then touch **[ADVANCED]** to display the screen shown at the right.
2. Each button is described in detail on the following pages.

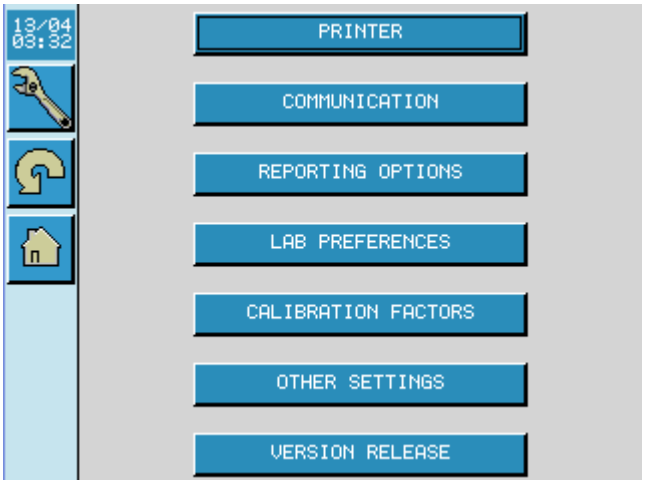


Figure 2.14 Advanced Set Up Menu

Printer Button

The Printer Button accesses the **PRINTER SET UP** menu that is used to configure the printed report.

Touch the corresponding check box to select from the following options:

1. **EXPECTED VALUES** – prints the laboratory's reference range (Patient Limits) on each report.
2. **HEADER** – prints a specified header. Touch the header entry fields below the Print Box and then touch **[A-Z]** and enter header information, if desired.
3. **COMMENTS** - provides space for handwritten comments on the printed report.
4. **UNITS** – prints the selected units on the report.
5. **INTERP. RPT** – prints the Interpretive Report messages based on the Patient Limits entered in step 1. Refer to the following sub-section for a description of the messages.
6. **FLAGS** – prints all flags on the report.
7. **GRAPHS** – prints all histograms on the report.
8. **AUTOPRINT** – To automatically print **ANALYSIS** (Patients Results), **QC** (Quality Control Result) or **STARTUP** (Startup Results) select the appropriate box(es).

To deselect an option, touch the check box again.

When all selections have been made, touch **[CONFIRM]** to exit and save the entries. Touch **[ESC]** to exit without saving changes.

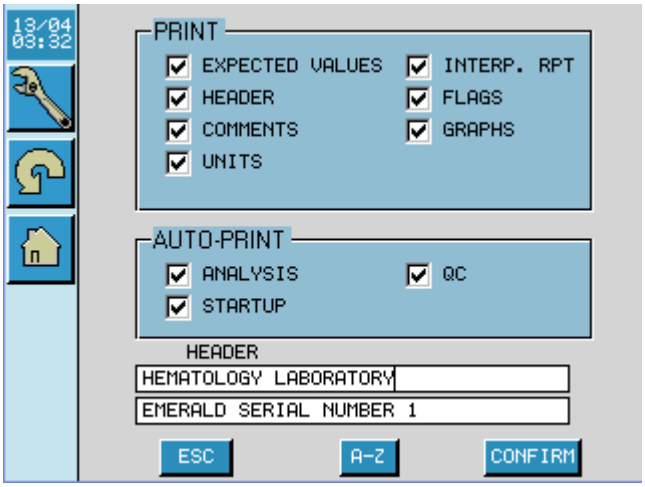


Figure 2.15 Printer Set Up

Interpretive Report

Interpretive messages display and are printed when the values entered for Patient Limits are exceeded. These messages display and print only when the Interpretive Messages (Interp. Rpt) option on the Printer Set Up screen is selected.

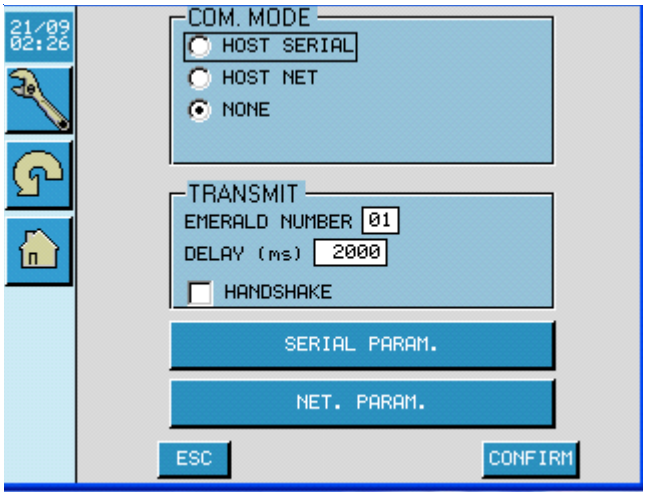
Refer to **Section 3: *Principles of Operation***, **Table 3.7*, Interpretive Report*** for a comprehensive listing of interpretive messages.

Communication Button

This button is used to configure the data transmission between the CELL-DYN Emerald and a host Laboratory Information System (LIS).

Touch the corresponding box to select the desired option.

1. **HOST SERIAL –** Used to select RS232 communication mode.
2. **HOST NET –** Used to select data TCP/IP communication mode.
3. **NONE –** Used when no data transmission is desired.
4. **EMERALD NUMBER –** Used to identify instruments when more than one Emerald is connected to the LIS system.
5. **DELAY (ms) –** Lag time for start of transmission in milliseconds.
6. **HANDSHAKE –** If this box is selected, data will not be transmitted if there are any errors in the acknowledgement process. If not selected, all data will be transmitted regardless of acknowledgement errors.
7. **SERIAL PARAM –** Used to access system configuration parameters for data transmission via the RS232 port.
8. **NET. PARAM.** Used to access system configuration parameters for data transmission via TCP/IP or UDP/IP using the Ethernet port.
9. Touch **[CONFIRM]** to save entries or touch **[ESC]** to return to Main Menu.



Reporting Options Button

The Reporting Options Button is used to select other options for running the instrument and for the printed report.

Touch the corresponding check box to select from the following options:

1. **NAME REQUIRED** - To run a specimen, operator must enter the patient's name.
2. **PID REQUIRED** - To run a specimen, operator must enter the patient's ID number.

NOTE: When Name and/or PID is selected, the name and/or PID must be entered or the probe will not descend.

3. **STARTUP ALARMS**
   When the **STARTUP ALARMS** box is selected:
   a. The message **STARTUP FAILED** displays and prints below the results when the Startup cycle failed.
   b. The message **STARTUP NOT DONE** displays and prints below the results when a Startup cycle has not been run.
4. **IUO** –For Abbott service use only.
5. **US MODE** – For Abbott service use only.
6. **ABSOLUTE LMG** – When selected, absolute values for Lymphocytes, Mid Cells and Granulocytes are displayed. When deselected, percent values for Lymphocytes, Mid Cells and Granulocytes are displayed. Regardless of selection, absolute and percent Lymphocytes, Mid Cells and Granulocytes are printed and sent to the LIS.
7. **QC ALARMS** – When the QC ALARMS box is selected:
   a. The message **QC ALERT** displays and prints below the patient results when the QC results are out of tolerance or the lot has expired. The system must be configured to display these flags. See **Section 2: *Installation Procedures and Special Requirements***, **Subsection: *Reporting Options Button***.
   b. The message **QC NOT DONE** displays and prints below the results when QC has not been run on the current date.
8. **Units*** – Three unit systems are available:
   a. USA
   b. SI (International System of Units)
   c. SI MOD (Modified International System of Units)

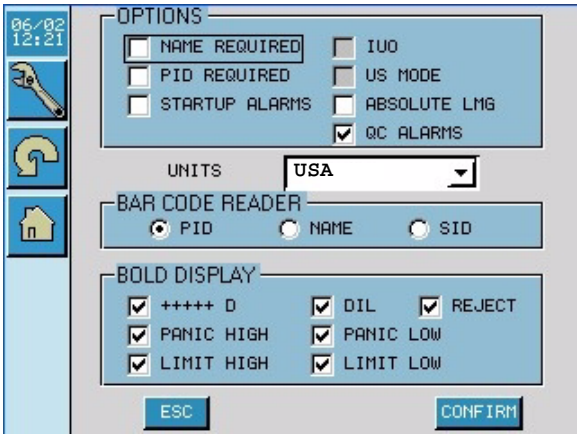


Figure 2.16 Reporting Options Set Up

9. **Bar Code Reader** – The bar code is assigned to the PID, name or SID 10. **BOLD DISPLAY** – Selected options will display and print in bold face type: a. **+++++ D** – result exceeds reportable range b. **PANIC HIGH** (H) – result exceeds entered high limit c. **LIMIT HIGH** (h) – result exceeds entered high Patient limit but below Panic High (H) limit d. **DIL** – result exceeds linearity limit (not used) e. **PANIC LOW** (L) – result is below entered low limit f. **LIMIT LOW** (l) – result is below entered low Patient limit but above Panic Low (L) limit g. **REJECT** (*) – count or measurement rejection h. When all selections have been made, touch **[CONFIRM]** to exit and save the entries. Touch **[ESC]** to exit without saving changes. **NOTE:** Flags are discussed in detail in **Section 3: *Principles of Operation***. *Refer to **Table 3.2*, Report Units***, **Section 3*, Principles of Operation*** for examples of each type of units.	

Figure 2.16 Reporting Options Set Up (Continued)

Lab Preferences Buttons

The options on the Lab Preferences menu allow the laboratory to configure the limits and calibration adjustments for specimen types other than STANDARD. It also allows the laboratory to define limits for the STANDARD specimen type.

NOTE: Thresholds and Specimen Cal. Adjustments cannot be edited for the STANDARD specimen type.

This menu is used to define the measurands associated with Specimen Types other than STANDARD. Descriptions of these options follow. The options are:

1. **TYPE**
2. **LIMITS**
3. **THRESHOLDS –** For Factory use only.
4. **ALARMS** – For Factory use only.
5. **SPECIMEN CAL. ADJUSTMENTS**
6. **RENAME SPECIMENS**

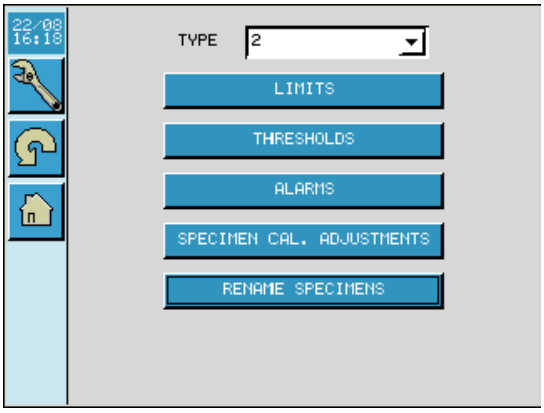


Figure 2.17 Modify Specimen Settings Menu

Type

This menu allows the operator to define up to 19 different types of specimens. For example, specimen types can be used to establish separate limits for males, females, neonatal, pediatric and other specimen types. In the Lab Preferences menu, one can define separate Limits & Calibration Factors for each specimen type. After defining specimen types in the Lab Preferences menu, the user can choose a specific specimen type from the Run Sample screen and the pre-defined limits and calibration factors set here will be applied.

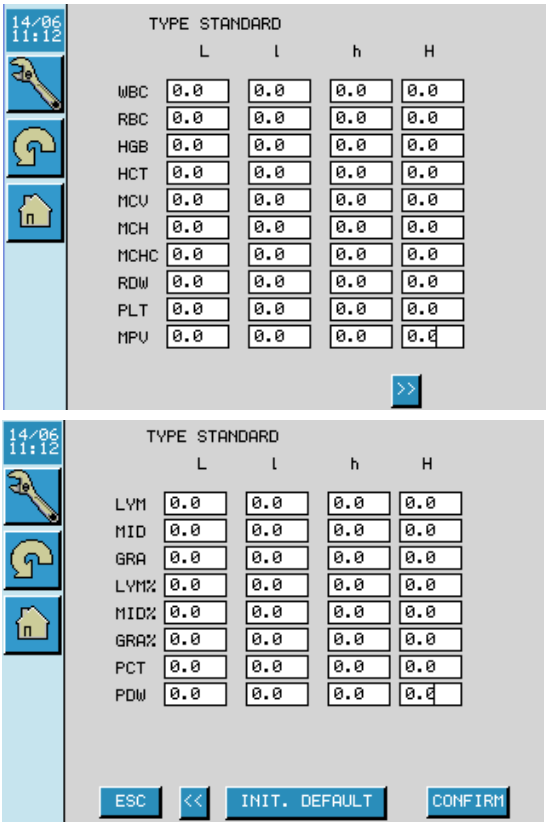
IMPORTANT: When a non-Standard specimen run is completed, be certain to select **Standard** from the dropdown menu on the **Next Sample** set up screen. The **Standard** selection re-sets the instrument to the Standard Limits and Calibration Factors.

Limits

This screen allows entry of the laboratory's Expected (l, h) and Panic (L, H) limits.

1. Touch each entry field and use the numeric keypad to type in the values.
2. Touch **[>>]** to display the remaining measurands as shown on the following screen.
3. Touch each entry field and use the numeric keypad to type in the values.
4. When all entries have been made, touch **[CONFIRM]** to exit and save the entries. Touch **[ESC]** to exit without saving changes.
5. Touch **[<<]** to return to the previous screen.

NOTE: Limits may be defined for any specimen type, including STANDARD.



NOTE: Stored Patient Limit Set Flagging can be affected if limits are changed.

NOTE: The CELL-DYN Emerald does not have limits Factory Set. It is the responsibility of each laboratory to determine limit sets appropriate for its patient population. A list of references for limit sets and limit set determination may be found in **Appendix D: *CBC Reference Intervals*: *Literature Sources***.

Figure 2.18 Limits Entry

SPECIMEN CAL. ADJUSTMENTS

This option allows the user to enter a manually calculated calibration factor for non-standard specimen types. For information about calculation of calibration factors, please refer to Appendix F.

IMPORTANT: Use care when modifying and using these factors so that results are not adversely affected.

Thresholds

Thresholds are only accessible to Abbott personnel.

Alarms

Alarms are only accessible to Abbott personnel.

1. From the **LAB PREFERENCES** menu, touch the **Type** dropdown menu to select the specimen type.
2. Touch **[Specimen Cal. Adjustments]**.
   NOTE: This option is not available for the Standard Specimen type.
3. Touch the entry field next to each measurand to edit, entering new values using the numeric keypad.
4. When entries are complete, touch **[CONFIRM]** to exit and save. Touch **[ESC]** to exit without saving changes.

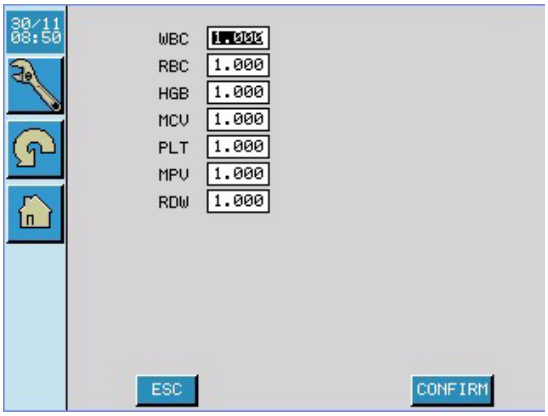


Figure 2.19 Calibration Factor Entry

Rename Specimen Type

This option is used to rename specimen types 2 through 20.

1. From **MAIN** menu touch **[SET UP]**.
2. Touch **[ADVANCED]**, then **[LAB PREFERENCES].**
3. Touch **[RENAME SPECIMENS].**
4. Touch Radio Button next to file to be renamed.
5. Touch **[A..Z]**.
6. Type in the specimen type name. Touch **[CONFIRM]** to save the entry. Touch **[ESC]** to exit without saving changes.
7. At the next screen, touch **[CONFIRM]** to save the entry.
8. Select **[YES]** at Pop Up `DO YOU WANT TO SAVE MODIFICATIONS?`
   Repeat this procedure to define additional specimen types.

Figure 2.20 Specimen Types Set Up

Calibration Factors

This option allows the operator to assign manually calculated calibration factors to the standard specimen type.

IMPORTANT: Modifying these factors without performing the calibration procedure will adversely affect results.

To change values for a selected specimen type:

1. Touch **[CALIBRATION FACTORS]**.
2. Touch the entry screen next to the desired measurand.
3. Use the numeric keypad to enter the value.
4. When entries are complete, touch **[CONFIRM]** to exit and save the entries. Touch **[ESC]** to exit without saving changes.

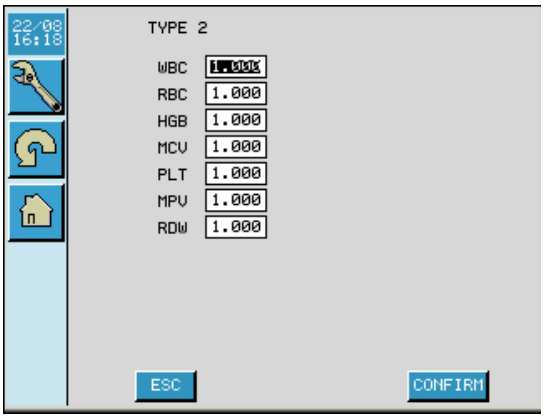


Figure 2.21 Changing Calibration Factors

Other Settings

The **Other Settings** Button displays the following screen.

The Delay Box is used to configure the following options:

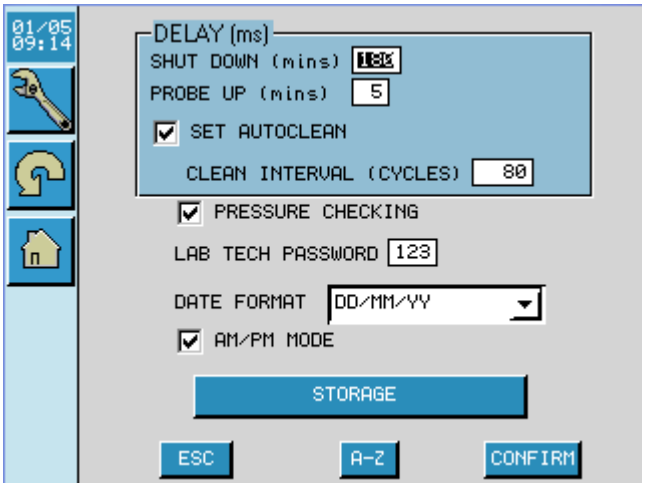
1. **SHUT DOWN** – Sets the time in minutes between automatic shut down cycles.
   a. Touch the entry field and use the numeric keypad to enter the time in minutes. The default value is 180 and the range is 30-480 minutes
2. **PROBE UP** – Sets the time in minutes to retract the probe when the instrument is not in use.
   a. Touch the entry field and use the numeric keypad to enter the time in minutes. The default value is 5 minutes and the range is 1 to 60 minutes.
3. **SET AUTOCLEAN** – Configures the system to automatically run an Auto-clean cycle when the specified number of cycles is reached.
   a. Touch the entry field next to **<SET AUTOCLEAN>** to select the option.
   b. Touch the entry field next to **<CLEAN INTERVAL>** and use the numeric keypad to enter the number of cycles. The default value is 80 cycles and the range is 10 to 5000 cycles.

NOTE: The maximum number of runs recommended between Autoclean cycles is 80.

NOTE: Automatic autoclean occurs only when the number of samples run since Start Up on a single day exceeds the number entered at **<CLEAN INTERVAL (CYCLES)>**.

4. **PRESSURE CHECKING** – For Abbott Service Personnel only.
5. The **LAB TECH PASSWORD** field can be used to change the current password. Touch the entry field and use either **[A-Z]** or the numeric keypad to enter a new password. Make sure to record the password for future reference.
6. The **DATE FORMAT** dropdown menu is used to select the format for the date. Available options are:
   a. DD/MM/YY
   b. MM/DD/YY
   c. YY/MM/DD

   Touch the dropdown menu button and then touch the desired format to select it.



7. When entries are complete, touch **[CONFIRM]** to exit and save the entries. Touch **[ESC]** to exit without saving changes.
8. **STORAGE**

The Storage option allows the operator to define specific data storage options.

a. DATALOG OPTIONS

There are two options for internal data storage management on the CELL-DYN Emerald.

i. If the box next to FIFO MODE is not selected, the datalog must be manually managed. When the internal CELL-DYN Emerald memory is full, the system prompts the user to delete results to allow additional results to be stored.

ii. If FIFO MODE is selected, the system manages datalog storage automatically. As the datalog becomes full, the system automatically deletes results on a first-in-first-out basis.

IMPORTANT: Because FIFO MODE automatically deletes results without notifying the operator, it is important to have a backup system in place to avoid loss of data. One example of a backup system is autoprinting of results and storage of the paper record.

b. EXT. STORAGE DEVICE OPTIONS

External storage device options allow the direct storage of datalog data to a formatted USB drive.

i. If REAL TIME RUNS SAVE is selected, the CELL-DYN Emerald will store the results directly onto the USB drive inserted into the analyzer.

ii. If REAL TIME RUNS SAVE is deselected, all datalog storage is in the system's internal memory.

This sub-menu allows you to format the USB drive before use on the Emerald system by using the **FORMAT EXT. STORAGE DEVICE** key. Refer to **Section 5: *Operating Instructions***, and **Subsection: *USB Flash Drive (Thumb Drive)*** for additional information.

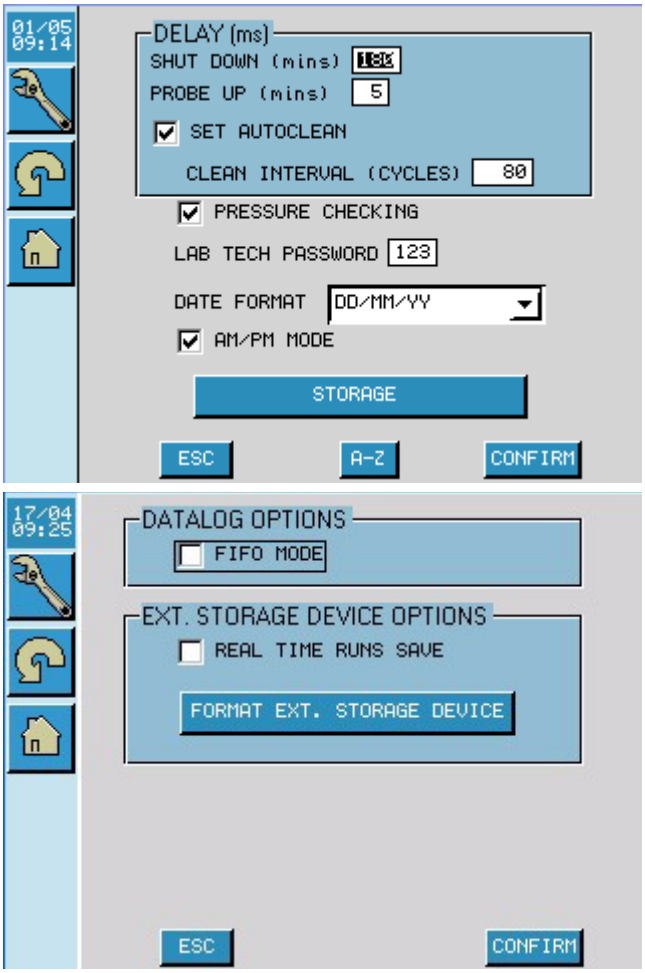


Figure 2.22 Other Settings Set Up

Version Release

The **VERSION RELEASE** button allows the operator to perform software upgrades from the USB storage device.

1. Insert the USB key with the software upgrade in a free USB port on the rear of the instrument.

NOTE: If another USB key is present in the other USB port, it must be removed before proceeding.

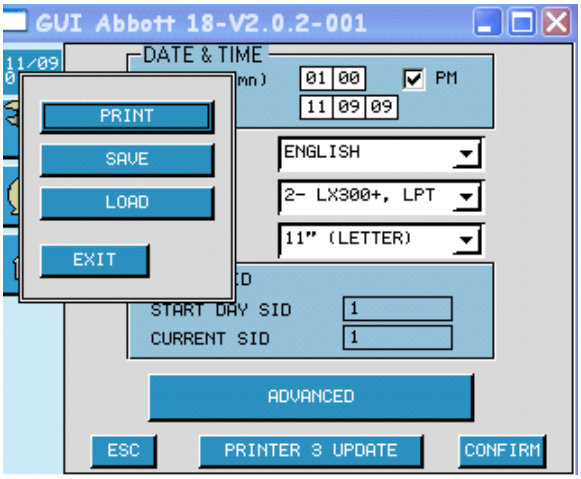
2. Touch the **[VERSION RELEASE]** button.
3. Select the software version in the table on the right side of the screen by touching the corresponding number in the left column.
4. The selected software version will display in the text entry field on the left side of the display, below **[VERSION RELEASE]**. After confirming the correct version of software is displayed, touch the **[LOAD]** button.
5. A pop-up message will display asking you to confirm loading the file. Touch **[YES]** to continue with the software upgrade or **[NO]** to escape without loading the software.
6. Follow any instructions on the screen during the software upgrade process.
7. When the software is successfully loaded, a confirmation message will appear on the display.

Setup Configuration Printout

This Option allows the operator to print a copy of their **SETUP** menu configuration.

From the **MAIN** menu touch **[SET UP]**.

1. Touch the **[TOOL]** Icon. Touch **[PRINT]**.
2. This print-out contains most of the setup menu configuration. Save this document for future use.



Instrument Quality Checks

When installation and set up are complete, the following procedures are used to finalize installation and prepare the instrument for running specimens. When all procedures have been successfully completed, the instrument is ready to run specimens and report results.

Start Up

From the **MAIN** menu, touch **[START UP]** to run the Start Up Cycle. The cycle takes approximately two minutes. The cycle primes and flushes cleaner out of the system, and checks the mechanical and electronic systems. At the end of the cycle, a background count is automatically run and printed (if a printer is connected and configured). When more than one background count is performed during Start Up, only the final count is printed. If the Start Up cycle is successful, the operator is returned to the **MAIN** menu**,** the Status LED turns green and the instrument is ready to run specimens. If the Start Up cycle is unsuccessful, the message **`START UP FAILED`** displays. If **`START UP FAILED`** displays, touch **[START UP]** again to repeat it a second time. If Start Up fails two times, refer to **Section 10, *Troubleshooting*** for guidance.

Background Count

A background count is automatically run at the end of the Start Up cycle. Background counts can be run at any time by touching the Start Switch located behind the Aspiration Probe. Results must be within specifications before proceeding.

Startup Specifications can be found in **Section 4:** ***Performance Characteristics and Specifications***:

If startup background counts exceed limits refer to **Section 10:** ***Troubleshooting***.

NOTE: The system must be configured to print the Start Up background count.

Carryover

Check the carryover as described in **Section 4:** ***Performance Characteristics and Specifications***.

Calibration

Complete the Pre-Calibration procedures and then verify calibration as described in **Section 6:** ***Calibration***.

Quality Control

When calibration has been verified, run three levels of control material as described in **Section 11:** ***Quality Control***.

Overview

The CELL-DYN Emerald is designed to automatically perform the following functions:

- Aspirate and dilute whole blood
- Count, size and classify cells present in a whole blood specimen
- Measure the hemoglobin concentration of a whole blood specimen
- Analyze the raw data that is collected
- Output results to the display, printer and laboratory information system

Two types of measurements and several innovative techniques are used to count, size and classify blood cells and to measure hemoglobin. The two types of measurements are:

- Electrical Impedance Counting – used for WBC, RBC and PLT measurements
- Absorption Spectrophotometry – used for HGB measurement

Hemoglobin measurement is carried out in the WBC Counting Chamber using absorption spectrophotometry. The reagent used for Hemoglobin measurement is cyanide-free. Each measurement is discussed in detail as it relates to each measurand.

This section also discusses Instrument Alarms and Data Flags.

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.

The CELL-DYN Emerald aspirates 9.8µL of whole blood from a well-mixed, open collection tube held under the Aspiration Probe. After the outside of the probe is rinsed, the Diluent Syringe dispenses 2mL of diluent to deliver the blood to the WBC Counting Chamber. The dilution is bubble mixed. The Aspiration Probe is rinsed and then aspirates 20µL of this dilution and delivers it to the RBC Counting Chamber where 1.5mL of diluent is added for the RBC/PLT dilution. Then, 0.38mL of lyse is added to the WBC Counting Chamber and the dilution is bubble mixed again for the WBC/HGB dilution. Final dilution ratios are:

WBC/HGB = 1:244

RBC/PLT = 1:15,000

Measurement Principles

Impedance Counting

Electrical Impedance counting is used to count and size WBCs, RBCs and platelets. This method is based on the measurement changes in an electrical current produced by particles (cells), suspended in a conductive liquid, as they pass through an aperture of known dimensions. An electrode is submerged in the liquid on either side of the aperture to create an electrical pathway through it.

As each cell passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses indicates the number of cells that traversed the aperture. The amplitude of each pulse is essentially proportional to the volume of the cell that produced it.

Each pulse is amplified and compared to internal reference voltage channels. These channels are delineated by calibrated size-discriminators to accept only pulses of certain amplitude. Thus, pulses are sorted into various size channels according to their amplitude.

WBC Analysis

The instrument aspirates 9.8µL from the whole blood specimen. The blood is mixed with 2mL of diluent and 0.38mL of Lyse in the WBC counting chamber. The lyse reagent destroys the RBC and resultant stroma and perforates the WBC cytoplasmic membrane allowing the cytoplasm to escape. The WBCs are counted directly by impedance and the Differential measurands are obtained from the graph:

WBC – White Blood Count

LYM% – Lymphocyte Percent

LYM# – Lymphocyte Absolute Number

MID% – Mid Cell Percent

MID# – Mid Cell Number

GRA% – Granulocyte Percent

GRA# – Granulocyte Absolute Number

The Mid Cell fraction includes monocytes, eosinophils and basophils.

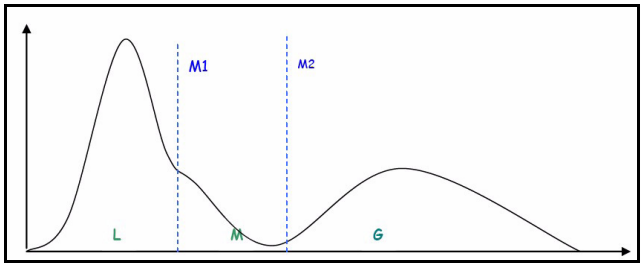


Figure 3.1 WBC Graph

The preceding figure shows the WBC Graph. The lymphocytes are located between the beginning of the curve and the M1 line. Mid Cells are located between M1 and M2. Granulocytes are located between the M2 line and the end of the curve. When the WBC result is outside the pre-set specification, the WBC differential measurands and the graph are suppressed.

The WBC measurands are expressed as follows:

WBC	# K/µL
LYM	# K/µL and %
MID	# K/µL and %
GRA	# K/µL and %

RBC Analysis

The instrument aspirates 20µL of the dilution from the WBC Counting chamber and adds 1.5mL of diluent to the RBC Counting Chamber for the RBC/PLT dilution. The RBCs are counted directly by impedance and four measurands are obtained:

RBC	–	Red Blood Count
HCT	–	Hematocrit
MCV	–	Mean Cell Volume
RDW	–	Red Blood Cell Distribution Width

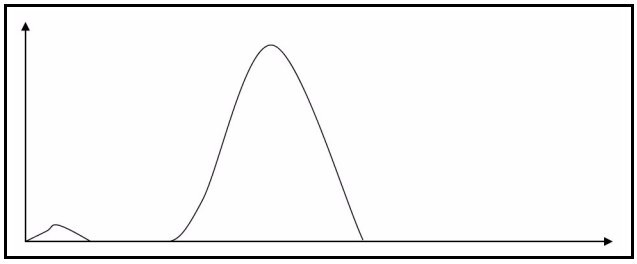


Figure 3.2 RBC Graph

The Hematocrit (HCT) is the ratio of red blood cells to plasma and is expressed as a percentage of the whole blood volume. It is derived from the volume of the RBCs that are counted during the measurement cycle.

The mean cell volume (MCV) is the average volume of individual RBCs.

$$MCV = \frac{HCT}{RBC} \times 10$$

The Red Cell Distribution Width (RDW) is a measurement of the heterogeneity of the RBC population. It is derived from the distribution of the RBC graph.

The RBC measurands are expressed as follows:

RBC	# M/µL
HCT	%
MCV	femtoliters (fL)
RDW	% CV (coefficient of variation)

Platelet Analysis

Platelets are counted directly by impedance in the RBC Counting Chamber at the same time as RBCs.

PLT – Platelet Count

MPV – Mean Platelet Volume

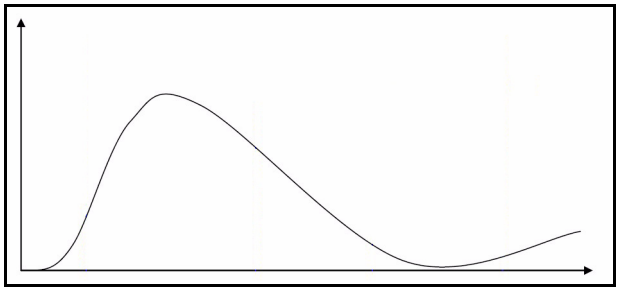


Figure 3.3 Platelet Graph

The MPV is derived from the platelet graph after the platelet count has been determined.

The PLT measurands are expressed as follows:

PLT	# K/µL
MPV	femtoliters (fL)

Absorption Spectrophotometry and Hemoglobin Measurement

Hemoglobin is measured using a methemoglobin chromagen formed using the cyanide-free lytic reagent. The methemoglobin is measured by means of absorption spectrophotometry using a 555 nm LED as the light source. The LED shines through the WBC counting chamber after the WBC count is completed. The Hemoglobin concentration is directly proportional to the absorbency of the sample. A blank reading is made during the rinse. The blank and sample readings are compared to determine the hemoglobin concentration of the sample. Three measurands are obtained:

HGB	–	Hemoglobin concentration
MCH	–	Mean Cell Hemoglobin
MCHC	–	Mean Cell Hemoglobin Concentration

The Hemoglobin value is used to calculate the MCH and MCHC as follows:

The MCH is the average amount of HGB contained in the RBC. It is calculated as follows:

$$MCH = \frac{HGB \times 10}{RBC}$$

The MCHC is the ratio of the weight of HGB to the volume of the average RBC. It is calculated as follows:

$$MCHC = \frac{HGB \times 100}{HCT}$$

The HGB measurands are expressed as follows:

HGB	g/dL
MCH	picograms (pg)
MCHC	g/dL

Measurand Reporting Conventions

Results can be expressed in different units of measurement as selected by using the Reporting Options button on the **ADVANCED SET UP** menu. For instructions for selecting units, refer to **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Instrument Set Up***.

Some units are reported as exponential units. For example, 10e9/L, meaning 10^9/L and 10e3/L, meaning 10^3/L.

The following exponents are also used for reporting numerical results. These may be used for number of cells, cell volumes, or grams of material per quantity of whole blood.

Table 3.1 Exponents Values

Exponents Value	Prefix	Symbol
10^{12}	tera	T
10^{9}	giga	G
10^{6}	mega	M
10^{3}	kilo	K
10^{-6}	micro	µ
10^{-12}	pico	p
10^{-15}	femto	f

Examples of the same specimen run with each of the available unit selections are shown in the following table.

Table 3.2 Report Units

	USA		SI		SI MOD	
Measurand	**Value**	**Units**	**Value**	**Units**	**Value**	**Units**
WBC*	5.32	K/µL	5.32	G/L	5.32	10e9/L
RBC	5.15	M/µL	5.15	T/L	5.15	10e12/L
HGB	16.2	g/dL	162	g/L	10.1	mmol/L
HCT	47.6	%	0.476	L/L	0.476	L/L
MCV	92.3	fL	92.3	fL	92.3	fL
MCH	31.5	pg	31.5	pg	1.96	fmol
MCHC	34.1	g/dL	341	g/L	21.2	mmol/L
RDW	12.5	%	12.5	%CV	12.5	%CV
PLT	323	K/µL	323	G/L	323	10e9/L
MPV	8.26	fL	8.26	f/L	8.26	fL

* LYM#, MID# and GRA# are reported in the same units as WBC

NOTES

Instrument Alarms, Operational Alerts, and Measurand Data Flags

The alarm messages and data flags on the CELL-DYN Emerald may be instrument or measurement-related. Flags display to the right of the result field on the instrument display and Alarm messages display in the Flags box, located below the results.

Instrument Alarms

There are two instrument alarm messages:

INS_T – Indicates that the ambient temperature is lower than 63° F (17° C) or higher than 91° F (33° C). Verify that the instrument is installed in an environment that is within the installation environment listed in **Section 2: *Installation Procedures and Special Requirements***.

All results are invalidated (flagged with *) when this alarm appears.

INS_H – Indicates that the hemoglobin channel is saturated. All results are invalidated. Perform a start up cycle.

Operational Alerts

There are four operational alerts:

- STARTUP NOT DONE
- STARTUP FAILED
- QC NOT DONE
- QC ALERT

STARTUP NOT DONE – A Start Up cycle has not been performed on the current date. **Action**: Perform a Start Up cycle. Do not perform QC or patient testing until the issue is resolved.

STARTUP FAILED – Indicates that the last Start Up cycle did not meet specifications. **Action**: Perform a Start Up cycle.

WARNING: Do not perform QC or patient testing until the Start Up passes.

If the Start Up cycle has been repeated twice without resolution refer to **Section 10: *Troubleshooting***, for additional information.

QC NOT DONE – Indicates that a QC run has not been performed on the current date. **Action**: Run QC according to your laboratory's requirements.

QC ALERT – Indicates QC failed for one or more measurands on one or more levels of control material. The system must be configured to display these flags.
See **Section 2: *Installation Procedures and Special Requirements***,
Subsection: *Reporting Options Button*.
Action: Refer to **Section 10: *Troubleshooting***, to resolve the out of range QC and repeat the QC test(s).

Measurand Data Flags

The CELL-DYN Emerald displays a measurand flagging message when a sample exhibits any reportable abnormalities as detected by the analyzer. The messages are created when one of the following sample abnormalities is present:

- Dispersional Data Alerts (H, h, L, l, ++++, D, ----)
- Suspect Measurand Flags (s)
- Count Invalidation Flags (*)

Dispersional Data Alerts

There are five levels of values for the CELL-DYN Emerald:

- **Patient Limits** are established closest to the normal or typical patient results and are set according to the type of patient samples to be run. The operator can define Patient Limits. Refer to **Section 2:** ***Installation Procedures and Special Requirements***.
- **Panic Limits** are set outside the Patient Limits but inside the Display Range. Panic limits serve to alert the Operator that results deviate from the Patient Limits by a significant degree. The Operator can define panic limits. Refer to **Section 2:** ***Installation Procedures and Special Requirements***.
- **Analytical Measurement Range (AMR or Linearity)** represents the range over which the system will yield accurate results. Consult **Section 4:** ***Performance Characteristics and Specifications*****,** for additional information on AMR.
- **Display Range** is set by the system software and reflects the defined limits of the screen display and printer output. The Operator cannot change these limits.
- The **Low Events Count** is defined by the system software. The Low Events Count limits applies only to WBC, RBC, and PLT are as follows:
  - WBC < 1.0 K/µL
  - RBC < 0.5 M/µL
  - PLT < 10.0 K/µL

Histograms are not displayed or printed for low event count results. WBC differential results are not displayed or printed for WBC low event count results. HCT, MCV, MCH, MCHC and RDW are not displayed or printed for RBC low event count results. MPV is not displayed or printed for PLT low event count results.

It is suggested that one Patient Limits set or the Panic Limits set be used to enter instrument-specific laboratory action limits. A result that falls outside a laboratory action limit can also indicate the need for the operator to follow a laboratory protocol, such as repeating the sample, performing a smear review or notifying the physician. In cases where a cellular abnormality is present that alters cellular morphology to the extent that the cells do not fit the criteria used by the instrument to generate a flag, dispersional data alerts may be the only flag(s) that will alert the operator to a potentially erroneous result.

Action: When a result is flagged with a Patient or Panic Limits alert, it is recommended that you follow your laboratory's review criteria, which may include review of a stained smear to verify the result and to check for the presence of any additional abnormality.

If results for a measurand exceed the upper end of the Display Range, a numeric result does not appear on the screen or printout. Instead, "plus" symbols (++++) appear in the results area and the letter "D" appears and prints to the right of the ++++.

Table 3.3 Dispersional Data Alerts

Flag	Result*	Interpretation	Applicable Measurands	Trigger	Other Affected Measurands	Affected Measurand result	Flag Color on Display	Result Color on Display
D	++++	Result is above the upper Display Range	WBC	>100K/µL	LYM GRA MID	---- ---- ----	Magenta	White
			RBC	>8.0M/µL	HCT MCV MCH MCHC RDW	---- ---- ---- ---- ----		
			MCV	>150fL	HCT RBC MCH MCHC RDW	---- ---- ---- ---- ----		
			HGB	>25g/dL	MCH MCHC	---- ----		
			HCT	>80%	MCV RBC MCH MCHC RDW	---- ---- ---- ---- ----		
			PLT	>1500K/µL	MPV	----		
h	XXXX	Result is above the upper Patient Limits, but below the upper Panic Limits.	All	Based on limit definition	N/A	N/A	Magenta	Magenta
l	XXXX	Result is below the lower Patient Limits, but above the lower Panic Limits.	All	Based on limit definition	N/A	N/A	Yellow	Yellow
H	XXXX	Result is above the upper Panic Limits.	All	Based on limit definition	N/A	N/A	White text on a red background	Magenta
L	XXXX	Result is below the lower Panic Limits.	All	Based on limit definition	N/A	N/A	White text on a red background	Magenta

*Where “XXXX” represents a numeric value.

WBC Flags

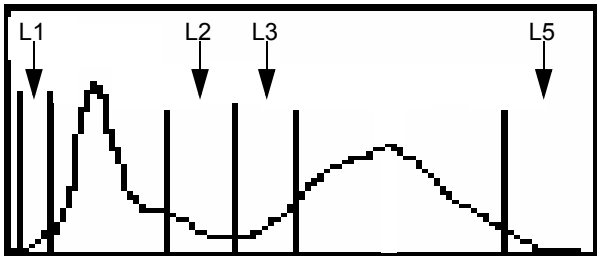


Figure 3.4 WBC Flags and Possible Causes

L1

- Platelet Aggregates
- NRBCs
- Giant Platelets
- Cryoglobulins
- Incomplete Lysis of RBC
- Small Lymphocytes
- Fibrin Clots
- Shift in WBC cell distribution due to EDTA anticoagulant equilibration

L2

- Myelocytes
- Lymphoblasts
- Basophils

L3

- Eosinophils
- Myelocytes

L5

- Large size cells present

The WBC Flagging Regions are shown in the previous figure. All WBC flags are shown in white text in the Flags box at the bottom of the result screen.

WBC Measurand Flags

An asterisk (*) for count invalidation or (s) suspect measureand flags are displayed with the corresponding results.

These flags are generated after the instrument evaluates the measured data for a particular measurand or group of measurands. The result may be suspect due to interfering substances or the inability of the instrument to measure a particular measurand due to a sample abnormality. The name of each flag, how it is displayed, the cause of the flag, and the action to be taken are given in the following explanations.

NOTE: Count Invalidation (*) flags will supersede Suspect Measureand (s) flags if generated at the same time.

Table 3.4 WBC Flags

Measurand	Result Flag	Text in Flags Box	Result Displayed	Cause	Action
WBC and Differential	*	L1 (white text)	XXXXX	May be due to platelet aggregates, NRBCs, giant platelets, cryoglobulins, incomplete lysis of RBC, small lymphocytes, fibrin clots, shift in WBC cell distribution due to EDTA anticoagulant equilibration.	Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required.
Differential	s	L2 (white text)	XXXXX	May indicate the presence of myelocytes, lymphoblasts, or basophils.	Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required.
Differential	s	L3 (white text)	XXXXX	May indicate the presence of eosinophils or myelocytes.	Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required.
Differential	*	L5 (white text)	XXXXX	Large-size cells present.	Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required.

Platelet (PLT) Flags

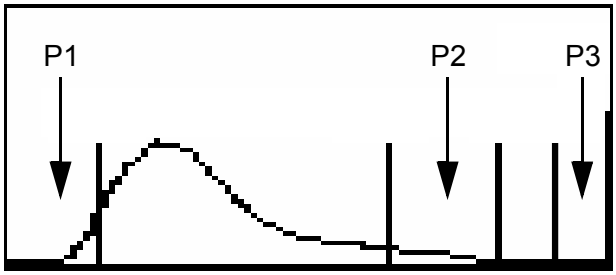


Figure 3.5 PLT Flags

The PLT Flagging Regions are shown in the previous figure. All PLT flags are shown in yellow text in the Flags box at the bottom of the result screen.

PLT Suspect Measurand Flags

These flags are generated after the instrument evaluates the measured data for a particular measurand or group of measurands. The result may be suspect due to interfering substances or the inability of the instrument to measure a particular measurand due to a sample abnormality. The name of each flag, how it is displayed, the cause of the flag, and the action to be taken are given in the following explanations.

PLT Suspect Measurand Flags invalidate the PLT count and all measurands calculated from the PLT count (MPV).

Table 3.5 Platelet Flags

Measurand	Result Flag	Text in Flags Box	Result Displayed	Cause	Action
PLT, MPV	*	P1 (yellow text)	XXXXX	May indicate the presence of an abnormal quantity of debris, contaminated reagent, electronic noise, microbubbles, or small cells.	Check the background count. Refer to **Section 5: *Operating Instructions***. If the background count is within the limits, perform another run on the same specimen. If the flag persists, review a stained smear to determine the cause of the interference and verify the PLT count by a different method.
PLT, MPV	*	P2 (yellow text)	XXXXX	May indicate the presence of schistocytes.	Review a stained smear to determine the cause and confirm the PLT count.
PLT, MPV	*	P3 (yellow text)	XXXXX	May indicate the presence of microcytic RBCs, schistocytes, giant platelets, sickle cells, platelet clumps.	Review a stained smear to determine the cause and confirm the PLT count.

Count Invalidating Flags

These flags are generated by the instrument when the measurement fails internal check criteria and appear in the Flags box below the displayed or printed results.

R_CL
W_CL
R_CLW_CL
HGB COUNT INVALID

Table 3.6 Count Invalidating Flags

Flag	Result	Interpretation	Applicable measurands	Flag Color on Display	Flag color in Flags box	Other affected results
R_CL	---- *	Measurement rejected/ invalidated, possible RBC/ PLT aperture clog.	RBC, PLT	white	red	All results are invalidated.
W_CL	---- *	Measurement rejected/ invalidated, possible WBC aperture clog.	WBC	white	white	All results are invalidated.
R_CLW_ CL	---- *	Measurement rejected/ invalidated, possible RBC/ PLT and WBC aperture clogs.	RBC, PLT, WBC	white	red	All results are invalidated.
HGB COUNT INVALID	---- *	HGB blank reading failed.	HGB	white	white	All results are invalidated.

Warning, Information, and Input Error Pop-Ups

Under certain circumstances the CELL-DYN Emerald will prompt the Operator with a Warning, Information, or Input Error Pop-Up message. These Pop-Ups display a message that requires a response from the Operator. In some cases, the message will display until the Operator acknowledges the message. Some of the circumstances, where Pop-Ups occur are as follows[1]:

1. This table is not inclusive of all Warning, Information, or Input Errors displayed by the CELL-DYN Emerald.

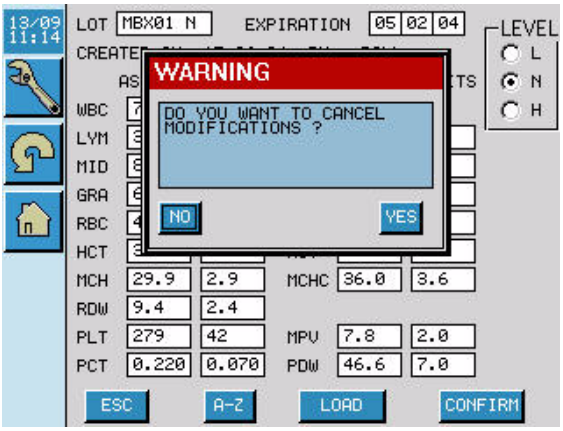
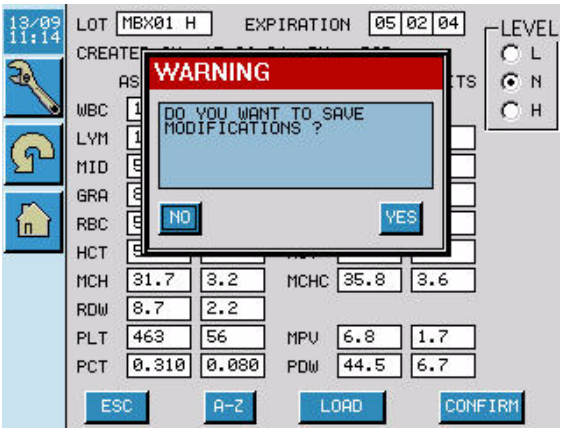
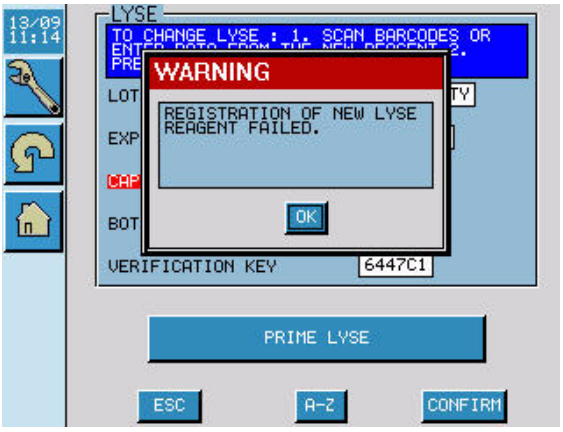
Operator exits a data input screen, by touching or pressing **[ESC]** key, without saving changes.	
Operator exits a data input screen by touching **[CONFIRM]**.	
Registration of a new reagent fails.	

Figure 3.6 Warning, Information and Input Error Pop-Ups

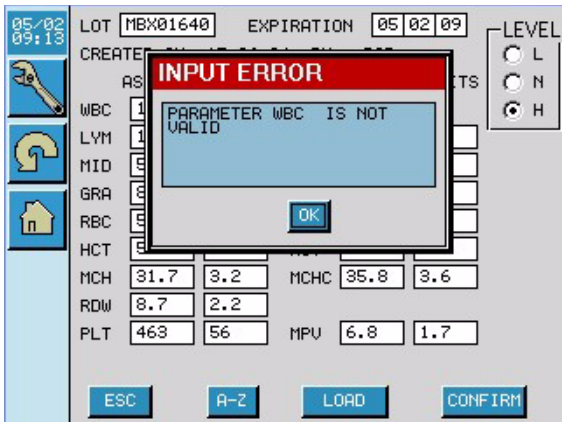
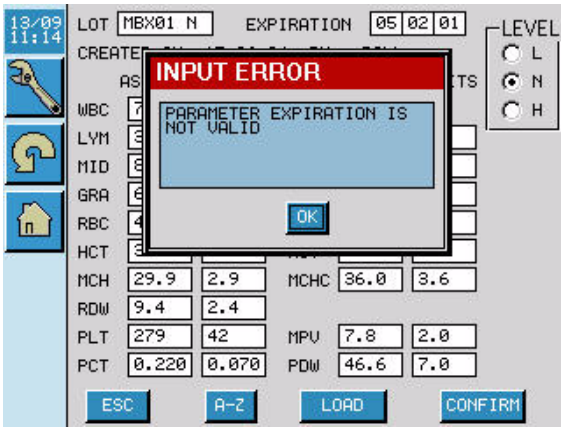
INPUT ERROR. The Operator has entered a value outside of a pre-defined range.	
INPUT ERROR. The Operator has entered an invalid value.	

Figure 3.6 Warning, Information and Input Error Pop-Ups

Interfering Substances

It is important to note there are commonly occurring interfering substances that can affect the results reported by hematology analyzers. While the CELL-DYN Emerald has been designed to detect and flag many of these substances, it may not always be possible to do so. **Appendix B:** ***Potential Causes of Spurious Results*** lists some of the substances that may interfere with specific measurands.

Interpretive Messages (Interpretive Report)

Interpretive messages display and are printed when the values entered for Expected Values (l and h) are exceeded. These messages display and print only when the Interpretive Messages (Interp. Rpt) option on the Printer Set Up screen is selected. Refer to **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Advanced Set Up*** for instructions for entering Expected Values.

Table 3.7 Interpretive Report

	Messages	
Measurand	**Result Below Low Expected Value**	**Result Above Expected Value**
WBC	Leukopenia	Leukocytosis
LYM%	Lymphopenia	Lymphocytosis
LYM#	Lymphopenia	Lymphocytosis
MID%	no message	no message
MID#	no message	no message
GRA	Granulocytopenia	Granulocytosis
GRA#	Granulocytopenia	Granulocytosis
RBC	no message	Erythrocytosis
HGB	Anemia	no message
MCV	Microcytosis	Macrocytosis
MCH	no message	no message
MCHC	Hypochromia	Cold Agglutinin
RDW	no message	Anisocytosis
PLT	Thrombocytopenia	Thrombocytosis
MPV	no message	Giant Platelets

Overview

This section describes the specification and performance characteristics of the CELL-DYN Emerald. The following is included in this section:

- Physical Specifications
- Power Specifications
- Environmental Specifications
- Operational Specifications
- Bar Code Specifications
- Performance Specifications

NOTES

Specifications

Physical Specifications

Physical specifications for the CELL-DYN Emerald are listed in the following tables.

Table 4.1 Dimensions

Dimension	Instrument
Height	13.8 in. (35 cm.)
Width	9.8 in. (25 cm.)
Depth	13.8 in (35 cm.)
Weight	19.8 lbs. (9 kg.)

Table 4.2 Dimensions in Shipping Carton

Dimension	Instrument
Height	18.3 in. (46.4 cm.)
Width	18.1 in. (46 cm.)
Depth	15.4 in (39 cm.)
Weight	25.8 lbs. (11.7 kg.)

NOTE: Refer to the Printer Manual for physical specifications for the printer.

Physical Specifications for the AC Adapter are as follows:

Table 4.3 Dimensions for the AC Adapter

Dimension	AC Adapter
Height	1.2 in. (3.1 cm.)
Width	2.3 in. (5.85 cm.)
Depth	5.2 in (13.2 cm.)
Weight	0.8 lbs. (0.35 kg.)

Power Specifications

Power requirements are as follows:

- The instrument requires a constant, non-fluctuating power source. Use of an AC line with dimmer switches can cause electrical current fluctuations that could affect proper instrument function and therefore, is not recommended.
- A circuit dedicated to the system is recommended but not required.

Table 4.4 Instrument Power Source Requirements

Nominal Line Voltage	Operating Range	Operating Cycles
120	99 – 132 VAC	50/60 HZ
220 – 240	198 – 264 VAC	50/60 HZ

The AC Adapter input is as follows:

100 – 240 VAC, 4.1 A, 50 – 60 HZ

Power consumption is as follows:

In cycle – 30 VA (-30% +10%)

On, but not in cycle – 20 VA (-30% +10%)

Maximum – 50 VA (-30% +10%)

Environmental Specifications

Operating Temperature from 64° – 90° F (18° – 32° C)

Storage Temperature from 14° – 122° F (-10° – 50° C)

CAUTION: If the CELL-DYN Emerald has been stored at a temperature of less than 50° F (10° C), it must remain at room temperature for 24 hours before switching on.

Relative Humidity – 80% maximum at 88° F (31° C)

Operational Specifications

Throughput	60 samples/hour (approximate)
Storage capacity	1500 records, including demographics, results, and histograms. Additional storage capacity is possible with use of a removable storage device.
	6 QC files, 100 records per file
Sample volume	9.8 µL (approximate)
Measurement Principles	Electrical impedance for WBC, RBC, and platelet
	Absorption Spectrophotometry for hemoglobin

Reagent consumption is shown in the following table:

Table 4.5 Reagent Consumption (in mL)

CYCLE		DILUENT	LYSE	CLEANER
Run sample*		12.6	0.32	0.55
Drain All		0	0	0
Refill		6	0	0
Back flush		6	0	0.55
Initialization**		10	0	1
Reagent Prime	All	28.2	4	10
	Lyse	10	3	0
	Diluent	30	0	0
	Cleaner	0	0	10
Clean cycle		6	0	2.2
Bleach clean		6	0	0
Start Up†		32.5	0.32	0.55
Shut Down		0	0	16
Auto Rinse		13	0	0

* A QC cycle uses the same amount of reagent as Run Sample.

** The initialization cycle is the cycle required after an emergency stop.

† Based on one background run. The amount of reagent will increase if two or three background cycles are run during the Start Up.

Bar Code Specifications

Quality and clarity in printed bar code labels is critical. High contrast (very dark bars and clean white spaces) is essential for the bar code reader to measure the difference in light reflection between the bars and spaces. The bars of the code must be printed with precise edges. The dimensional accuracy of the bars must be consistent throughout the label and consistent from label to label.

The Bar Code Reader reads the following bar codes: Chinese post, Codabar, Code39, Code39 Full ASCII, Code 93, Code128, EAN8, EAN13, EAN128, IATA, Industrial 2of5, Interleaved 2of5, Italian Pharmaceutical, Matrix 2of5, MSI/ Plessey, UK/Plessey, Telepen, TriOptic, S-Code, UPC A, UPC E.

Performance Specifications

Background Counts

Background values must be within the following specifications before testing patient samples, running QC, or performing calibration:

Table 4.6 Background Specifications

Measurand	Background Concentration Limits
WBC	≤ 0.5 K/µL
RBC	≤ 0.1 M/µL
HGB	≤ 0.2 g/dL
PLT	≤ 10.0 K/µL

NOTE: The Background Specification applies only to WBC, RBC, HGB, and PLT. There are no background specifications for other measurands, so if results are displayed they should be disregarded.

Carryover

The following table shows carryover percent for WBC, RBC, HGB and PLT. Carryover was determined by running whole blood specimens with high target values of WBC, RBC, HGB and PLT. Each specimen was run in triplicate followed by three aspirations of whole blood specimens with low target values. Carryover is calculated and expressed as a percentage using the following formula:

$$\text{Percent Carryover} = \frac{(\text{Low Target Value}_1\text{-Low Target Value}_3)}{(\text{High Target Value}_3\text{-Low Target Value}_3)} \times 100$$

Table 4.7 Carryover Specifications

Measurand* (units)	Target Values		% Carryover (95% Confidence Limit)
	Low Target Values	High Target Value	
WBC K/µL	>0 and <3	>90	<1%
RBC M/µL	>0 and <1.5	>6.20	<1%
HGB g/dL	>0 and <5.0	>22.0	<1%
PLT K/µL	>0 and <100	>900	<2.2%

* Results are expressed in USA units.

To prevent carryover effects verify background after abnormally elevated platelet results.

Display Range

The Display Ranges are the defined limits of the screen display and printer output. If a result exceeds the upper limit of the Display Range, "plus" symbols (++++) appear on the screen and printout instead of a numeric result[1] and the "**D**" flag appears.

Linearity/Analytical Measurement Range (AMR)

The Analytical Measurement Range (AMR) is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process.

The analytical measurement range (AMR) specifications in the following table were determined by analyzing dilutions and concentrations of fresh human whole blood, supplemented with commercial linearity materials. Because the Display Ranges are wider than the AMR, values can be displayed/printed that are beyond the limits of the AMR. In order to report patient results beyond the AMR, your laboratory must perform validation studies of this expanded range (often called the "Clinically Reportable Range"). For example, your laboratory may choose to report patient results as greater than or less than the specific AMR upper or lower limit, respectively, as determined by the Laboratory Director.

1. The number of "plus" symbols that display or print may vary.

Table 4.8 Display Range and Analytical Measurement Range

Measurand	Units*	Display Range	AMR
WBC	K/µL	0 – 100	0.4 – 96.1
RBC	M/µL	0 – 8	0.22 – 7.61
HGB	g/dL	0 – 25	3.3 – 24.6
HCT	%	0 – 80	5.3 – 75.6
MCV	fL	0 – 150	48.8 – 115
PLT	K/µL	0 – 1500	9 – 1375

* Results are expressed in USA units.

NOTE: Results displayed with "*" indicate suspect results that should not be reported. For additional information about flagged results, refer to **Section 3:** ***Principles of Operation*****, Subsection:** ***Instrument Alarms, Operational Alerts, and Measurand Data Flags***.

Imprecision (Reproducibility)

Imprecision is expressed as the standard deviation (SD) or coefficient of variation (CV) of analytic results in a set of replicate or duplicate measurements. Fresh whole blood specimens used to verify imprecision specifications should have mean values that fall within the range tested in the following table.

The table below represents the results of imprecision specifications for the hemogram parameters. The stated CV% in the table represents instrument imprecision from N=31 runs.

Table 4.9 Fresh Blood Imprecision Specifications

Measurand (units)	Ranges Tested	Observed %CV Range	%CV (95% Confidence Limit)
WBC (K/µL)	4.7 – 10.2	1.5 – 3.4	3.5
RBC (M/µL)	4.2 – 5.4	0.7 – 1.9	2.0
HGB (g/dL)	12.2 – 16.1	0.4 – 1.8	2.1
HCT (%)	35.7 – 50.7	0.9 – 1.6	1.7
MCV (fL)	73.4 – 96.0	0.3 – 0.8	0.8
RDW (%)	11.8 – 17.0	2.1 – 3.4	3.3
PLT (K/µL)	185.2 – 387	2.8 – 5.8	6.1
MPV (fL)	7.6 – 9.0	1.3 – 2.6	2.7
LYM %	13.1 – 50.1	1.7 – 5.0	5.4
MID %	6.3 – 11.0	3.4 – 7.3	8.1
GRA %	43.1 – 75.8	1.1 – 3.0	2.9

NOTE: Laboratories should confirm this imprecision performance using fresh whole blood specimens within the ranges shown above. Specimens with values outside these ranges may have higher or lower %CV.

Repeatability and Within-Device Imprecision (Long-Term Precision)

The following Tables provide simplified within-device mean imprecision for 6 CELL-DYN Emerald analyzers, using two lots of a commercial tri-level control.

For each measurand, at each control level, on each of 6 CELL-DYN Emerald analyzers, within-device imprecision estimate was calculated per section 10.8.2 in CLSI EP5-A2. By weighting each %CV value by the number of data points creating that particular %CV, an average %CV was calculated for all 6 analyzers and both lot numbers.

Table 4.10 Long-Term Commercial Control Imprecision: CBC

Control Level	Average %CV*
	CD-16
WBC X 10^9/L	
Low	5.4
Normal	3.0
High	2.4
RBC X 10^{12}/L	
Low	2.0
Normal	1.8
High	1.7
Hb g/dL	
Low	3.0
Normal	1.8
High	1.6
HCT %	
Low	2.2
Normal	1.9
High	1.8

* Values are the sample count-weighted averages of the individual instrument and individual lot %CV.

Table 4.10 Long-Term Commercial Control Imprecision: CBC (Continued)

MCV fL	
Low	1.0
Normal	0.9
High	0.8
MCH pg	
Low	2.9
Normal	1.6
High	1.4
MCHC g/dL	
Low	2.9
Normal	1.6
High	1.4
RDW %	
Low	3.4
Normal	3.0
High	2.8
PLT X 10^9/L	
Low	10.4
Normal	4.9
High	4.0
MPV fL	
Low	3.5
Normal	1.8
High	1.6

* Values are the sample count-weighted averages of the individual instrument and individual lot %CV.

Table 4.11 Long-Term Commercial Control Imprecision: WBC Differential

Control Level	Average %CV*
	CD-16 Control
Lymphocytes %	
Low	5.6
Normal	1.5
High	1.9
Mid %	
Low	9.7
Normal	5.1
High	2.9
Granulocytes %	
Low	2.9
Normal	1.5
High	2.4
Lymphocytes - absolute	
Low	10.5
Normal	3.2
High	3.6
Mid - absolute	
Low	19.1
Normal	6.5
High	4.2
Granulocytes - absolute	
Low	5.2
Normal	3.6
High	2.7

* Values are the sample count-weighted averages of the individual instrument and individual lot %CV.

Comparability (Correlation)

Evaluation of the correlation of the CELL-DYN Emerald is shown in the tables below. This data was computed from Passing-Bablock regression analysis of data obtained from studies performed on whole blood analyzed against a comparative instrument using similar technology. The results in individual laboratories may differ from these data.

The internal Abbott site obtained the following results on 330 blood samples.

Table 4.12 Comparability (Correlation) to CELL-DYN 1800 Internal Site

		Data Range			
Measurand*	**r-value**	**Min**	**Max**	**Intercept**	**Slope**
WBC (K/µL)	0.994	0.4	42.3	0.578	0.905
RBC (M/µL)	0.993	1.31	7.38	-0.147	1.032
HGB (g/dL)	0.997	4.8	24.4	0.222	1.004
HCT (%)	0.993	14.7	66.9	-0.158	1.036
MCV (fL)	0.921	63.6	119.6	-12.170	1.175
RDW (%)	0.758	11.8	20.9	6.320	0.558
PLT (K/µL)	0.990	2.0	1039.0	1.212	1.044
MPV (fL)	0.912	6.8	11.5	2.641	0.580
LYM (%)	0.970	4.0	75.6	1.240	1.011
MID (%)	0.761	1.6	17.8	1.560	0.895
GRA (%)	0.972	21.9	94.4	-1.782	0.990

* Results are expressed in USA units. Correlation coefficient, established by Passing-Bablock regression analysis.

The external laboratory GA-Atlanta obtained the following results on 569 blood samples.

Table 4.13 Comparability (Correlation) to CELL-DYN 1800 External Site

		Data Range			
Measurand*	**r-value**	**Min**	**Max**	**Intercept**	**Slope**
WBC (K/µL)	0.997	0.4	82.5	0.602	0.895
RBC (M/µL)	0.992	1.36	6.81	-0.270	1.074
HGB (g/dL)	0.994	4.3	19.6	-0.230	1.038
HCT (%)	0.988	12.9	57.5	-0.810	1.032
MCV (fL)	0.943	60.7	110.1	-8.067	1.097
RDW (%)	0.750	10.9	26.4	4.467	0.690
PLT (K/µL)	0.982	4.0	958.0	5.554	0.995
MPV (fL)	0.916	6.0	10.9	2.582	0.561
LYM (%)	0.986	2.5	76.9	1.057	1.034
MID (%)	0.819	1.7	19.8	2.005	0.979
GRA (%)	0.982	12.6	95.7	-7.150	1.048

* Results are expressed in USA units. Correlation coefficient, established by Passing-Bablock regression analysis.

Table 4.14 Comparability (Correlation) of WBC Differential to Microscopy

Measurand	Range Tested*	Replicates	r-value†	Slope	Y-intercept
GRA%	23.15 – 95.70%	180	0.932	0.943	1.302
MID%	1.800 – 19.25%	180	0.874	0.612	3.350
LYM%	2.500 – 62.10%	180	0.943	0.989	3.317

* Results are expressed in traditional USA units. These values do not represent the analytical measurement range, which is provided in another table.

† Correlation coefficient, established by Passing-Bablock regression analysis.

Interfering Substances

A wide variety of interfering substances have been shown to impact the results from automated hematology analyzers. A list of substances that can potentially interfere with CELL-DYN Emerald results is included in **Appendix B: *Potential Causes of Spurious Results***.

Reference Intervals

Table 4.15 Reference Intervals

Measurand (units)*	Sex	n	Range
WBC (K/µL)	M/F	270	4.70 - 10.30
RBC (M/µL)	M/F	270	4.03 - 5.46
HGB (g/dL)	M/F	270	12.40 - 16.90
HCT (%)	M/F	270	36.60 - 48.30
MCV (fL)	M/F	270	81.50 - 96.80
MCH (pg)	M/F	270	27.50 - 33.10
MCHC (g/dL)	M/F	270	32.40 - 35.70
RDW (%)	M/F	270	11.80 - 14.90
PLT (K/µL)	M/F	270	165 - 385
MPV (fL)	M/F	270	7.20 - 10.20
LYM %	M/F	270	12.70 - 47.80
MID %	M/F	270	6.30 - 14.00
GRA %	M/F	270	43.50 - 78.90

* Results are expressed in USA units.

These ranges do not represent globally applicable reference intervals, but reflect combined reference ranges tested in the validation study. Each laboratory should establish/verify its own reference intervals.

References

1. Clinical and Laboratory Standards Institute. *Preliminary Evaluation of Quantitative Clinical Laboratory Methods;* Approved Guideline – Third Edition. CLSI document EP10-A3 [ISBN 1-56238-622-0] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA, 19087-1898 USA, 2006.
2. Clinical and Laboratory Standards Institute. *Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach;* Approved Guideline. CLSI document EP6-A [ISBN 1-56238-498-8] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA, 19087-1898 USA, 2003.
3. Clinical and Laboratory Standards Institute. *Evaluation of Precision Performance of Quantitative Measurement Methods;* Approved Guideline – Second Edition. CLSI document EP5-A2 [ISBN 1-56238-542-9] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA, 19087-1898 USA, 2004.

NOTES

Overview

This section discusses the operation of the CELL-DYN Emerald System. The following topics are included:

- Software Menu
- Instrument Start Up
- Specimen Analysis
- Routine Operation
- DATALOG
- USB Flash Drive
- Bar Code Scanner

Additional information for operating the CELL-DYN Emerald is discussed in the following sections:

Calibration	**Section 6:** ***Calibration***
Maintenance	**Section 9:** ***Service and Maintenance***
Troubleshooting	**Section 10:** ***Troubleshooting***
Quality Control	**Section 11:** ***Quality Control***

Instructions for configuring the instrument are provided in **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Instrument Set Up and Advanced Set Up***.

NOTES

Instrument Logbook

It is suggested a logbook be created for the instrument. This logbook should contain all necessary calibration documentation and other information that is pertinent to the instrument. Suggested sections that you may want to include are:

- Installation documentation
- Your laboratory's operating procedure
- Quality Control
- Calibration
- Maintenance
- Reagent Lot Number Changes
- Troubleshooting and Problem resolution
- Service calls and problem resolution/service performed documentation
- Software upgrade information

Store the logbook near the instrument so that it is accessible to operators and Abbott Service Personnel. Sample log sheets may be found in **Appendix E: *Sample Logs and Worksheets***.

Software Menu

The software menu is shown in this section. All sub-menus are accessed from the **MAIN** menu, which displays when **HOME** is touched. The sub-menus used for setting up the instrument are described in **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Instrument Set Up and Advanced Set Up***. Remaining sub-menus are discussed in appropriate sections. For example, the Calibration menu is discussed in **Section 6:** ***Calibration*** and Quality Control is discussed in **Section 11:** ***Quality Control***.

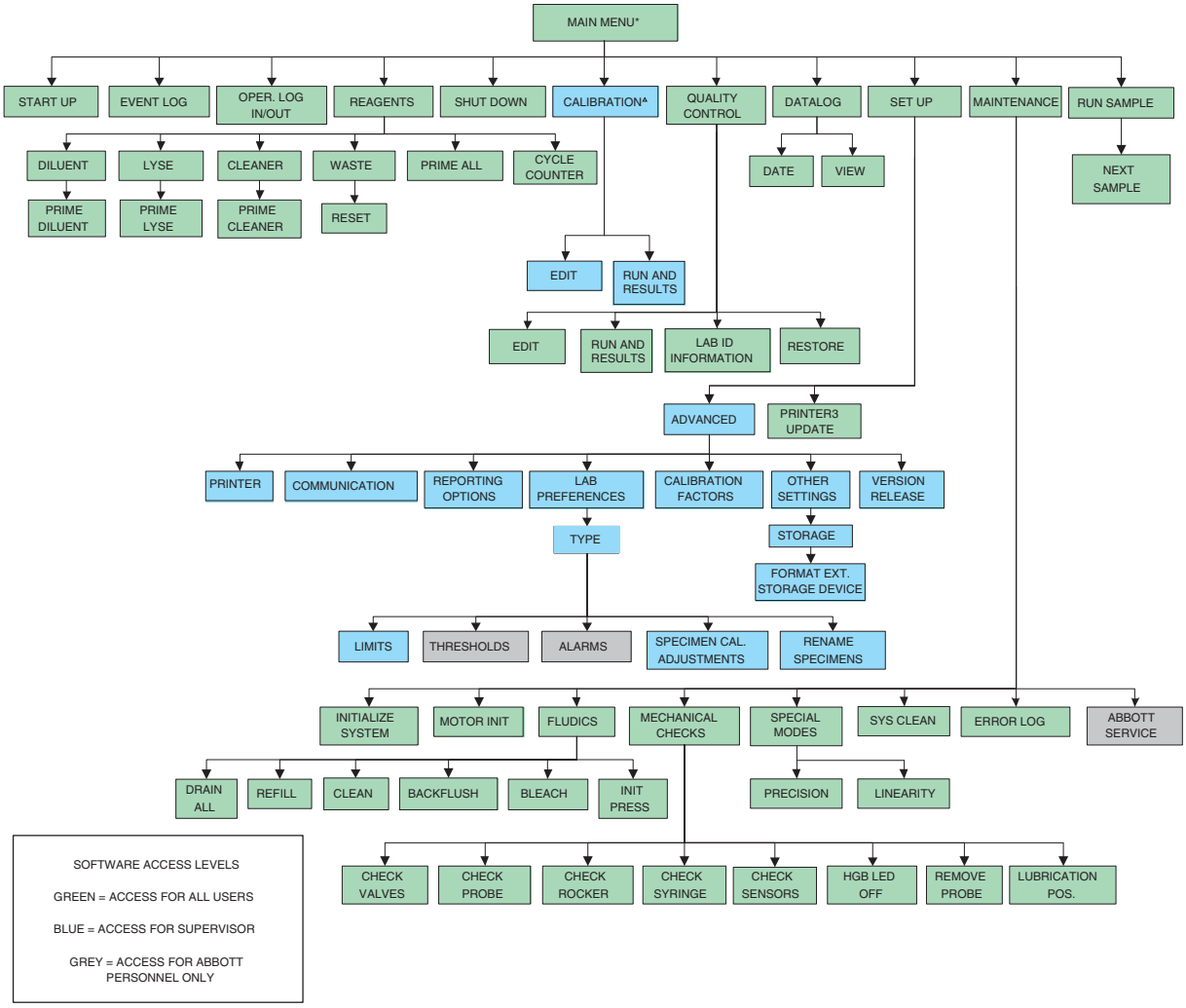


Figure 5.1 Software Tree

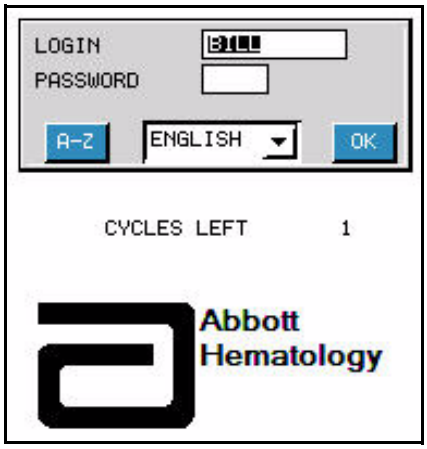
Instrument Power On

Check the reagent and waste levels before starting the day's run. If reagents need to be replaced or waste needs to be emptied, refer to instructions given in **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Replacing the Reagents – Diluent, Lyse, Cleaner***. Check that there is sufficient paper in the printer.

If the printer has been powered OFF, press the power button to turn it ON. If the instrument has been turned off, the display is black and the LED light is off. Press the Power button to turn the instrument on.

1. The instrument initializes and checks the motors.
2. The cycle LED turns red. The instrument cannot be cycled until initialization is complete and the LED turns green.
3. When initialization is complete, the **OPER. LOG IN/OUT** screen displays.

Operator Log In



If the instrument is ON, touch **[OPER. LOG IN/OUT]** and log in as described in **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Operator Log In***.

Specimen Analysis

Specimen Collection and Handling

WARNING: Potential Biohazard. Consider all clinical specimens, reagents, controls, surfaces or components that contain or have contacted blood, serum, or other bodily fluid as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29CFR Part 1910.1030) or other equivalent biosafety procedures.

NOTE: For additional information on collecting venous specimens, refer to CLSI Standards H3-A5[1].

All performance statements given in this manual were generated using venipuncture specimens collected in K_2EDTA anticoagulant.

Specimens must be mixed well before analysis. It is recommended that specimens be mixed for 10 minutes on a rotary mixer or rocker that rotates 20 – 30 times/minute.

Specimen Stability

Well-mixed fresh[5] whole blood specimens, collected in K_2EDTA anticoagulant is recommended. For optimal results, adequate time for sample mixing and stabilization with the anticoagulant post draw is recommended. Depending on collection method and environmental factors this period of stabilization may take up to 20 minutes. Increased morphological flagging may be observed if samples are not allotted adequate time for mixing and stabilization. If flagging does occur, follow corrective action(s) listed in Section 10 before reporting results.

Small shifts may be observed for MCV and MPV within a 30-minute post collection interval. Please note that published studies indicate that MPV results can be affected by EDTA for up to 2 hours after collection. Most accurate MPV results are obtained between 2 and 8 hours after collection.[3,4]

The stability of capillary specimens collected in microcollection[2] tubes can vary depending on the tube manufacturer. Refer to the tube manufacturer's package insert for stability claims.

Interfering Substances

It is important to note that there are commonly occurring interfering substances that can affect the results reported by hematology analyzers. While the CELL-DYN Emerald has been designed to detect and flag many of these substances, it may not always be possible to do so.

For additional information on interfering substances, refer to the table provided in **Appendix B:** ***Potential Causes of Spurious Results***.

Specimen Identification

Each specimen can be identified as follows:

- Name – 20 characters can be entered in the name field.
- Patient ID (PID) – this field can be used to enter a unique patient ID number, such as a medical record number. 16 characters can be entered in the PID field. If Name and/or PID Required option has been selected, this information must be entered for each sample before the sample can be run.
- Specimen ID (SID) – This field is used to enter a specimen ID. The instrument will automatically increment the SID if **AUTO SID** is selected on the **SET UP SCREEN**. When **AUTO SID** is selected, the SID can be set to start at one (or whatever number is desired) at the start of each day's run. 16 characters can be entered in the **SID** field. If **AUTO SID** is not selected and no SID is entered at the Run Sample screen, the **SID** field will be auto populated with "NO ID Entered".

Identification is entered by touching **[NEXT SAMPLE]** on the **RUN SAMPLE** screen as shown in the following figure.

1. Touch the **<Name>** field and use the alphabetic buttons to type the name.
2. Press the **ENTER** key on the keypad to enter the name and advance the cursor to the PID field.
3. Use the alphabetic buttons and/or the numeric keypad to enter the PID.
4. Press the **ENTER** key on the keypad to enter the PID and advance the cursor to the SID field.
5. If **AUTO SID** is selected, it is not necessary to type an entry in this field. If **AUTO SID** is not selected, use the numeric keypad to enter the SID.
6. Press the **ENTER** key on the keypad to enter the SID and advance the cursor to the Type Dropdown menu.
7. If the type is correct, touch **[CONFIRM]** to save the entries and return to the **RUN SAMPLE SCREEN**.
8. Touch **[ESC]** to exit the screen without saving the entries.
9. When the entries are confirmed, run the specimen as directed later in this section.

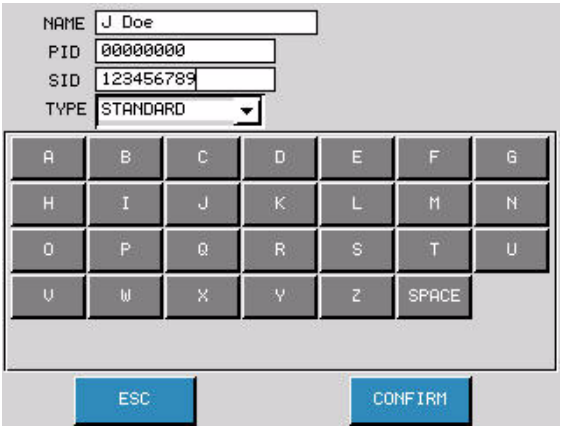


Figure 5.2 Entering Specimen Identification

NOTES

Routine Operation

Daily Start Up Procedures

The Daily Start Up procedures include:

- Running the Start Up Cycle and confirming that Background Counts are within acceptable limits
- Performing daily Quality Control checks

From the **MAIN** menu, touch **[START UP]** to run the Start Up Cycle. The cycle takes approximately two minutes. It primes and cleans the system, and checks the mechanical and electronic systems. At the end of the cycle, a background count is automatically run and printed if a printer has been connected and configured. Up to three (3) background counts may be automatically performed as part of the Start Up Cycle. The final background will be automatically printed, if a printer is configured. If the Start Up cycle is successful, the operator is returned to the **MAIN** menu, the Status LED turns green, and the instrument is ready to run specimens. If the Start Up cycle is unsuccessful, the message **START UP FAILED** displays. If **START UP FAILED** displays, touch **[START UP]** again to repeat it a second time. If Start Up fails two times, refer to **Section 10:** ***Troubleshooting*** for guidance.

1. If a Start Up Cycle failed the message **START UP FAILED** is displayed and printed with every result when the user is logged in as an Operator or Supervisor. The system must be configured to display these flags. See **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Reporting Options Button***.
2. Background counts must be within acceptable limits before running controls or patient specimens.

When the Start Up Cycle is successfully completed, perform daily Quality Control checks according to the regulations governing your laboratory before running patient specimens. Refer to **Section 11:** ***Quality Control***.

NOTE: The message **QC ALERT** displays and prints below the patient results when the QC results are out of tolerance or the lot has expired. The system must be configured to display these flags. See **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Reporting Options Button***. The message **QC NOT DONE** displays and prints below the results when QC has not been run for the day.

NOTES

Running Specimens

Ensure Background Counts are within acceptable limits and Quality Control results are acceptable according to your laboratory's Quality Control program. Ensure specimens have been properly mixed.

WARNING: Potential Biohazard. Consider all clinical specimens, reagents, controls, surfaces or components that contain or have contacted blood, serum, or other bodily fluid as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29CFR Part 1910.1030) or other equivalent biosafety procedures.

From the **MAIN** menu, touch **[RUN SAMPLE]**. To enter NAME, PID, or/and SID press the **[NEXT SAMPLE]** at the bottom of screen. Enter the desired information and press confirmation. To enter all of the identification, including the Name, PID, SID, and select the type, refer to the instructions provided in **Subsection: *Specimen Identification***, earlier in this section.

NOTE: Do not run linearity material in the patient mode. Run linearity material in the **LINEARITY** mode. Refer to **Section 9: *Service and Maintenance***.

1. If the Aspiration Probe is not visible, press the Start Switch (located directly behind the probe) and wait for it to descend. If more than one hour has elapsed since the last cycle, the instrument will initiate an auto rinse cycle before the probe is presented for aspiration. Refer to **Subsection: *Auto Rinse Cycle*** within this Section for additional information.

NOTE: If the system has been configured to require Name and/or PID (**SET UP-ADVANCED- REPORTING OPTIONS**), then the probe will not descend until that patient information has been entered under **RUN NEXT SPECIMEN**.

2. Remove the cap from the specimen tube.
3. Immerse the probe in the well-mixed specimen and press the Start Switch.

NOTE: Visually verify that the probe is well immersed into the sample. This is required to avoid short sampling.

4. The Cycle LED (located directly above the Aspiration Probe) turns Red and flashes.
5. Hold the tube under the probe until the Cycle LED turns Green.
6. Remove the tube and re-cap it.
7. Results will print automatically, if the printer has been configured, when the analysis is complete.
8. Enter the identification for the next specimen and run it as directed in steps 1-6 above.

It is not necessary to wait for the results to print before running the next specimen.

- Information displayed to the right of each measurand identifies results out of the range for patient and panic limits.
- Graphs are displayed on the right side of the screen.
- The Flags region (located below the results) displays analytical alarms and flags.

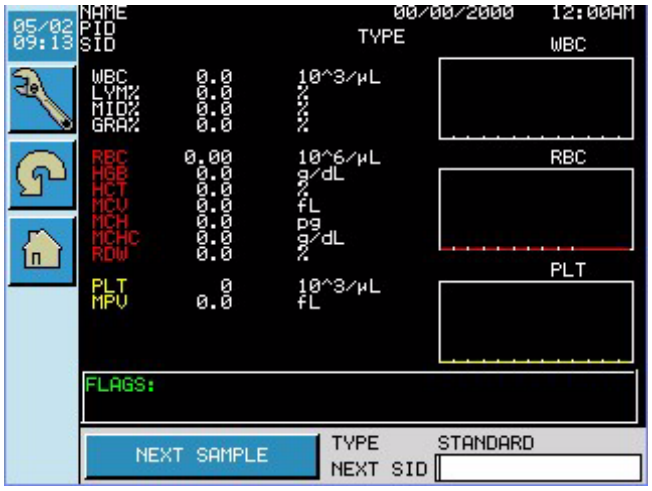


Figure 5.3 Results Screen

Results are automatically printed and sent to the LIS (if one is connected) at the end of each analysis cycle. Refer to **Section 2: *Installation Procedures and Special Requirements***, **Subsection: *Advanced Set Up*** for instructions for configuring the printed report.

Touch the **TOOLS** icon to make additional printouts, send or save results. When the tools icon is touched, the window shown at right displays.

- Touch **[PRINT]** to print the displayed result.
- Touch **[SEND]** to send the displayed result to the LIS.
- Touch **[EXIT]** to close the window.

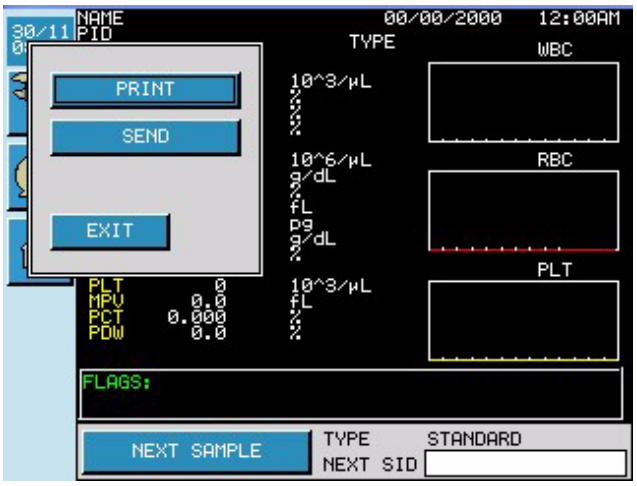


Figure 5.4 Printing Results

DATALOG

The CELL-DYN Emerald Datalog stores 1500 records, including demographics, results and graphs. Records are archived with a Sequence Number (SEQ), assigned by the instrument software. Sequence numbers begin at 0001 for the first sample of each day. Start Up Cycles, QC, and Precision runs are all assigned sequence numbers, but are not stored in the Datalog. From the **MAIN** menu, touch **[DATALOG]** to access the Datalog screen shown in the following figure. Follow the instructions provided to access the Datalog information.

NOTE: When the Datalog is first opened from the **MAIN** menu, the display shows the most current runs. If no results are stored in the internal memory and a USB flash drive is connected, the system will display results from the most current date stored on the drive.

The Datalog screen displays the following information:

1. The first column lists the measurands and the header row lists the sequence number.

NOTE: Sequence numbers are reset to 0001 for the first sample of each day. Start Up backgrounds are typically the first cycle run daily and are not stored in the Datalog. Therefore, sequence number 0001 will not usually be seen in the Datalog.

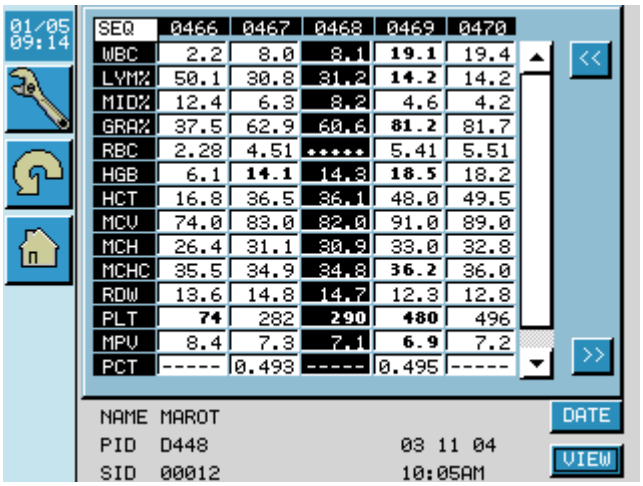
2. Touch **[<<]** and **[>>]** to scroll to the previous or next page, respectively.
3. Results are selected by touching the SEQ number of the result at the top of the result column. This highlights the results for that record.
4. The Name, PID, SID, date and time for the selected specimen are displayed on the bottom of the screen.
5. Touch **[VIEW]** to display the highlighted record, including graphs and flags. (See Figures 5.6 and 5.7) Touch **[PREVIOUS RESULT]** or **[NEXT RESULT]** to view the previous or next record, respectively. Touch the **RETURN** icon to return to the **Datalog** screen.

Results may also be accessed by date.

1. Touch **DATE**.
2. Select the location of the stored files you wish to access. The default setting is the system INTERNAL MEMORY. If the desired results are stored on an external USB drive, insert the drive into one of the ports on the rear of the instrument, then use the dropdown menu to select **MASS STORAGE**.
3. Select the desired YEAR and MONTH from the left column by touching the year on the left side of the row where the desired month is shown. Selecting the date in the month column will not select a file; the year to the left of the desired month must be selected.
4. Select the desired day by touching the appropriate date in the DAY column. The column to the right of DAY shows the number of samples tested on that day.

NOTE: The day cannot be selected by touching any field below the NUM. column.

5. Touch **VIEW** to display the results for the selected date.
6. Touch the **SEQ** for the desired result and touch **VIEW** to display an individual result.



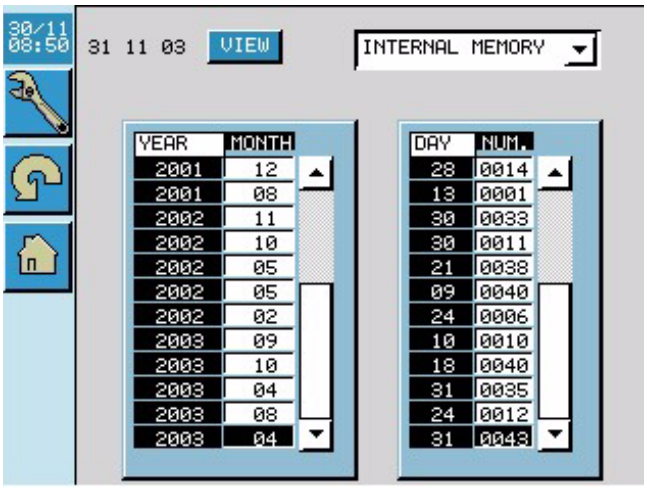


Figure 5.5 Datalog Screens

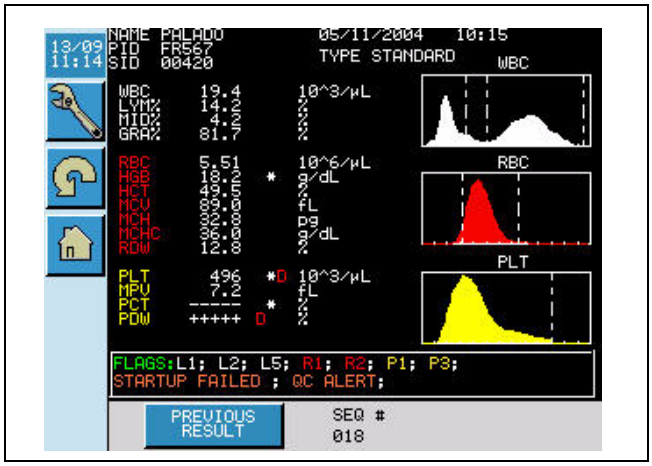


Figure 5.6 View Record Screen

To print, send, delete or save results from the Datalog, follow these steps:

1. Touch the **TOOLS** icon to print, send, delete or save the record. From the selection box, touch:
   a. **<ALL>** for all stored records within the selected date. The total number of pages to be printed is shown to the right of this field.

NOTE: The selection "**ALL**" refers to all results selected within a selected date. It does not refer to the entire datalog.

   b. **<SEQ>** and use the numeric keypad to enter the number(s) of the records.
2. Touch **[PRINT]** to print the selection(s).
3. Touch **[SEND]** to send the selection(s) to the LIS.
4. Touch **[DELETE]** to delete the selected results from datalog.
5. Touch **[SAVE]** to save the selected results on a USB drive.

NOTE: For instructions on how to save the results on a USB drive, refer to **Subsection:** ***USB Flash Drive (Thumb Drive)*** within this section.

6. Touch **[EXIT]** to return to the record.
7. Touch the **HOME** icon to return to the **MAIN** menu.

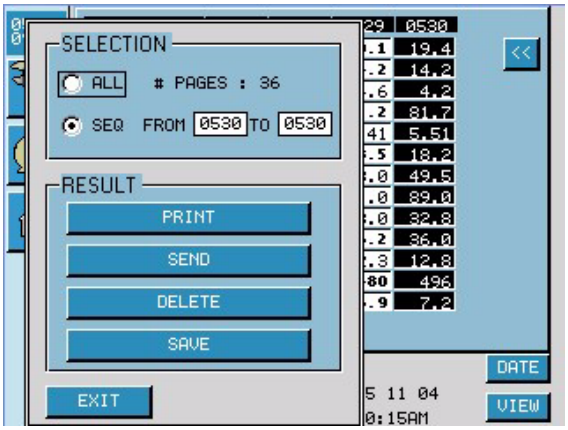


Figure 5.7 DATALOG Options

Daily Shut Down

The CELL-DYN Emerald must be put through a Shut Down cycle once during every 24 hours of operation. Auto Shut Down after a specified idle interval can be configured in the Other Settings menu under **[ADVANCED]** in setup, refer to **Section 2:** ***Installation Procedures and Special Requirements***. To shut down manually, follow the instructions below:

From the **MAIN** menu, touch **[SHUT DOWN]** to initiate the Shut Down Cycle.

- All of the fluidics are rinsed and cleaned with Cleaning Reagent.
- The cycle stops automatically when it is complete.
- To resume operation, press the ON/OFF; a Start Up Cycle will be automatically performed as described earlier in this section.

NOTE: If a Start Up Cycle is not successfully completed, the message **`START UP FAILED`** is printed with every result.

Auto Rinse Cycle

The CELL-DYN Emerald performs an automatic rinse of the fluidics pathway when a cycle is initiated following system idle time of one hour or more. Even when the instrument is off, the elapsed time count for the auto rinse remains active. While the rinse cycle is running, a pop-up message is displayed to notify the user. At completion of the cycle the instrument is ready to use.

While in the RUN SAMPLE mode the operator may enter ID information for the next sample while the auto rinse cycle is running. At the end of the cycle, the LED turns green and the sample probe descends.

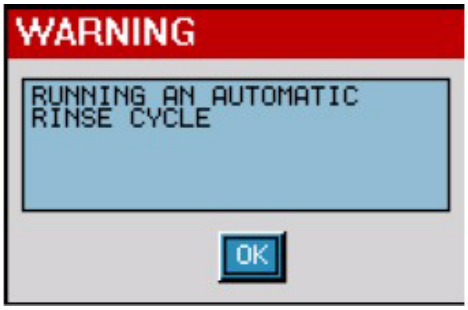


Figure 5.8 Autorinse

USB Flash Drive (Thumb Drive)

Overview

The CELL-DYN Emerald is capable of using either of the two USB ports on the rear of the instrument in conjunction with a USB flash drive. Use of an optional USB flash drive allows the operator to move data from the USB drive to the CELL-DYN Emerald (upload) or from the CELL-DYN Emerald to the USB drive (download). The different functions associated with use of a USB drive are described in the following sections.

A USB drive is a flash memory data storage device integrated with a USB interface (connector). USB drives up to eight gigabytes may be used on the CELL-DYN Emerald. Do not use USB drives larger than 8 GB. A maximum of 300,000 results can be stored on a 4-8 GB USB drive.

For current information about USB drives that have been validated for use on the CELL-DYN Emerald, USA customers please contact Abbott Diagnostics Customer Service. The following information applies only to USB drives formatted on the CELL-DYN Emerald.

Characteristics of CELL-DYN Emerald USB Drives

Any USB drive to be used with the CELL-DYN Emerald must be properly formatted. Instructions for formatting a drive can be found later in this Section.

More than one USB drive can be in use with a single CELL-DYN Emerald instrument. In addition, one USB drive can store data for one or more CELL-DYN Emerald instruments. Instrument-specific information is stored on the USB drive in files identified by the instrument serial number and cannot be accessed by other instruments. However, any CELL-DYN Emerald System can access data that is not instrument-specific.

USB Storage Information

- Average size of result file is approximately 5 kb.
- A 128 MB USB drive stores approximately 14,000 result files.
- A 256 MB USB drive stores approximately 28,000 result files.
- A 512 MB to 2 GB USB drive stores approximately 60,000 result files.

NOTE: 512 MB to 2 GB USB drives store the same number of results.

If USB drives are present in both USB ports, the CELL-DYN Emerald will only recognize/utilize the first drive listed.

IMPORTANT: When saving or reviewing Emerald files on a computer, do not change any file's name. Changing file names may prevent proper restoration of saved files or may lead to duplicate file names on the CELL-DYN Emerald.

Error messages associated with USB drives on the CELL-DYN Emerald

If a USB drive is recognized by the CELL-DYN Emerald, but contains an unsupported file structure, a pop-up message will display under these conditions, `THE USB THUMB DRIVE FILE SYSTEM IS NOT COMPATIBLE WITH THE EMERALD. EITHER REMOVE IT OR FORMAT IT.`

If an unsupported USB device is inserted into one of the USB ports, a pop-up message will appear, `THE USB DEVICE PLUGGED IN PORT _ IS NOT COMPATIBLE WITH THE EMERALD. PLEASE REMOVE IT FROM PORT _ .`

Formatting the USB drive for use on the CELL-DYN Emerald.

NOTE: USB drives can be formatted only under the Supervisor password.

WARNING: Formatting the USB drive will erase all data currently stored on the drive. Make sure to transfer data from the USB drive to another storage media before proceeding.

1. Insert a USB drive into either of the USB ports (1 or 2) on the back panel of the CELL-DYN Emerald.
2. From the **MAIN** menu, touch **[SET UP]**, then **[ADVANCED]**.
3. Touch **[OTHER SETTINGS]**.
4. Touch the **[STORAGE]** button.
5. In the box titled **EXT. STORAGE DEVICE OPTIONS**, touch **[FORMAT EXT. STORAGE DEVICE]**.
6. A pop up box will appear with the prompt, **`ALL THE DATA ON THE EXTERNAL STORAGE DEVICE WILL BE DELETED. DO YOU CONFIRM?`**

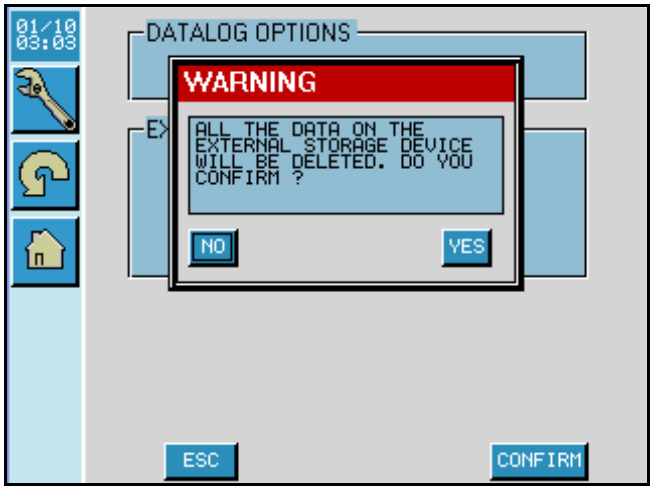


Figure 5.9 Delete Data from External Device

7. Select the **[YES]** button to proceed or select the **[NO]** button to exit without formatting the USB drive.
8. If **[YES]** was selected, the CELL-DYN Emerald will proceed to format the USB drive. Once the formatting is completed, an AB18 folder is created in the USB drive. When the formatting process is complete you will be returned to the **EXT. STORAGE DEVICE** screen.
9. Touch the **HOME** icon to return to the **MAIN** menu. The USB drive may now be removed. Your USB drive is ready to be used with the CELL-DYN Emerald.

USB File Folder Structure

Information is stored on the USB drive in the following folder structure:

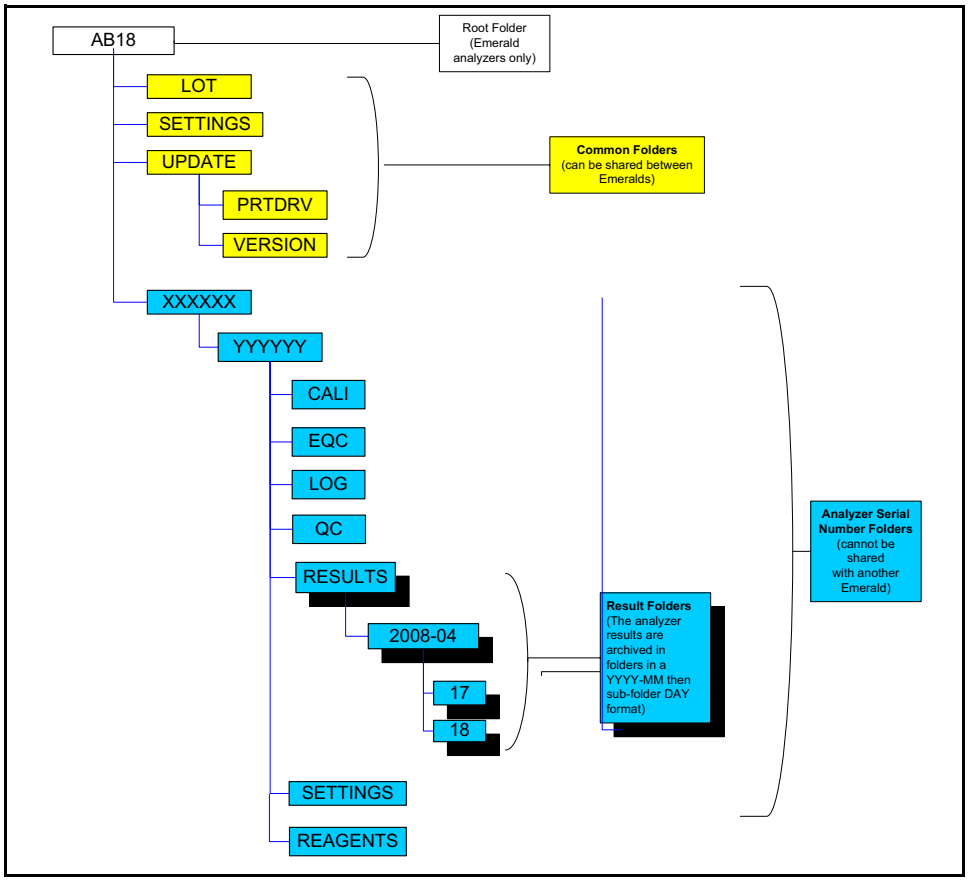


Figure 5.10 USB File Folder Structure

NOTE: Datalog files are saved to the USB drive in a format read by the CELL-DYN Emerald. To easily view the contents of the files, open the file from your CELL-DYN Emerald rather than on a PC.

From the **MAIN** menu, touch **[DATALOG]**, touch **[DATE]**, touch the dropdown menu at the upper right, select **MASS STORAGE** and review the desired date.

Available Functions for the USB Drive

USB drive functionality is not supported in the following selections from the **MAIN** menu: **START UP**, **OPER. LOG IN/OUT**, and **SHUT DOWN**.

Use of the USB drive in the EVENT LOG menu.

The information stored in the instrument **EVENT LOG** can be saved to the USB drive.

1. Touch **[EVENT LOG]** from the **MAIN** menu.
2. Touch the **[TOOLS]** button on the left side of the screen.

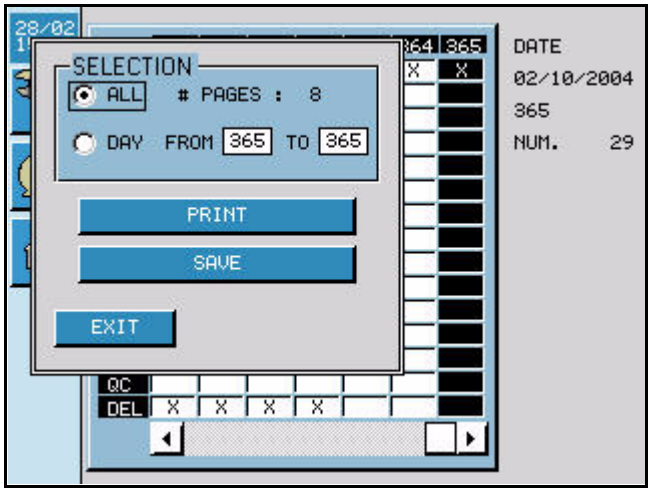


Figure 5.11 Save EVENT LOG to USB

3. Select **ALL** to save all data to the USB drive or select **DAY** and enter the sequence numbers corresponding to the date range you want to save.
4. Touch the **[SAVE]** button to save the selected data to the USB drive.
5. Touch the **[EXIT]** button to exit the menu.

Use of the USB drive in the REAGENT menu.

Use of the USB drive in the **REAGENT** menu is restricted to Abbott personnel.

Installing a Printer Driver

NOTE: Follow Abbott's specific instructions provided with the printer driver to copy a new printer driver onto the USB drive.

1. Insert the USB drive into either USB port on the rear panel of the CELL-DYN Emerald.
2. From the **MAIN** menu, touch the **[SET UP]** button.
3. Touch **[PRINTER 3 UPDATE]** at the bottom of the **SET UP** screen.

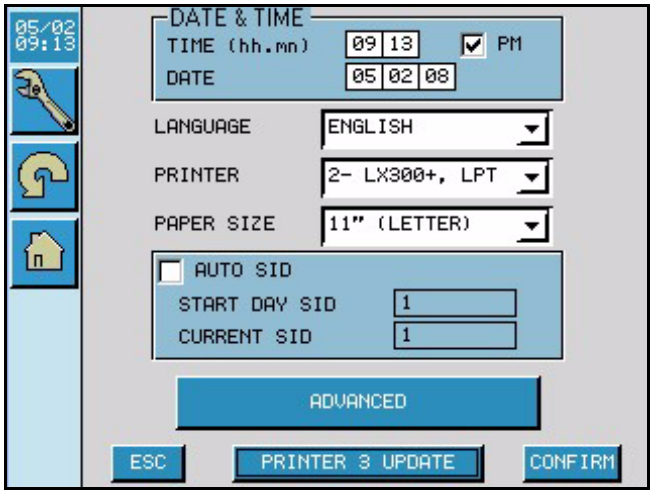


Figure 5.12 Printer Driver Upload

4. The CELL-DYN Emerald will display a list of the printer drivers that are available to be loaded.

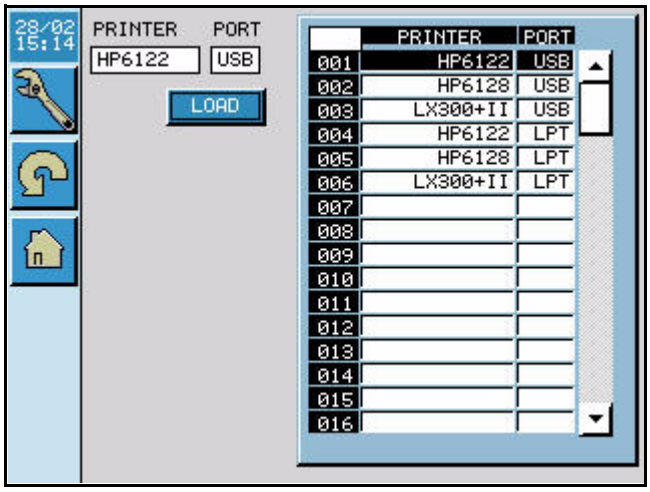


Figure 5.13 Printer Driver Selection

NOTE: Available printers may not appear as shown in example.

NOTE: In the pull-down box, printer drivers 1 and 2 are defaults and printer 3 allows the addition of a third approved printer driver. Loading a printer driver will automatically overwrite any existing driver for PRINTER 3.

5. Touch to select the desired printer driver from the table on the right side of the screen.

NOTE: Be sure to select the printer with the correct port type for your installation: USB for a USB connection between the instrument and the printer, LPT for a 25-pin printer cable.

6. Confirm the correct printer and port type appear in the upper left of the screen and touch **[LOAD]**.
7. A pop-up box will appear with the message: **`DO YOU CONFIRM TO LOAD THE FILE`** "selected printer name will appear here"**?** Touch **[YES]** to load the file and **[NO]** to exit without changes.
8. A pop-up box will appear with the message, **`THE PRINTER DRIVER XXX HAS BEEN SUCCESSFULLY LOADED`**. Touch **[OK]**.

Use of the USB drive in the CALIBRATION menu.

Saving current calibration data.

Data for the current calibration factors may be saved to the USB drive as a Calibration Report. The Calibration Report contains the following information for the current calibration stored on the instrument: Calibration date, operator ID for the calibration, calibration factors for all calibrated parameters, lot number of calibration material, expiration date of calibration material, assay values and limits for all calibrated parameters.

1. From the **MAIN** menu, touch the **[CALIBRATION]** button.

   The instrument will display a screen showing the current calibration factors (FCTR column) as well as the assay values used in that calibration. Lot number and expiration date are displayed at the top of the screen. All of this information may be saved to the USB drive.

2. Insert the USB drive into either USB port on the rear panel of the CELL-DYN Emerald.
3. Touch the **[TOOLS]** button.

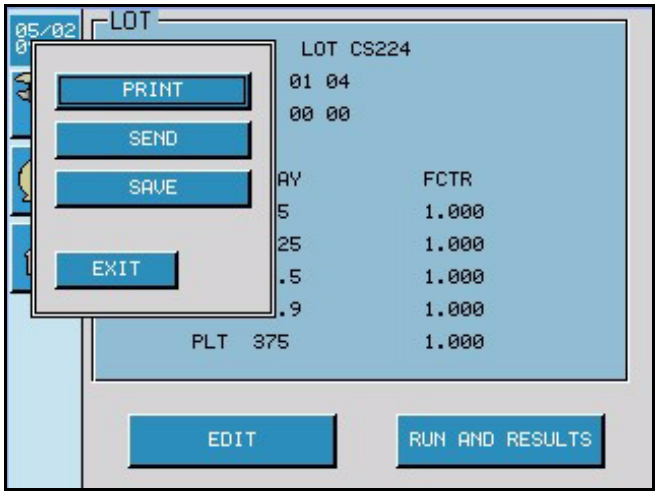


Figure 5.14 Save Calibration Data to USB

4. Touch the **[SAVE]** button.

5. When the pop-up box appears prompting: **YOU ARE ABOUT TO SAVE THE CALIBRATION REPORT. DO YOU CONFIRM?** Touch **[YES]** to save the report or **[NO]** to exit without saving the report.

Figure 5.15 Confirm Save of Calibration Report

Use of the USB drive in the QC menu.

Using the USB drive, an operator can upload QC material information (lot, expiration date, assay values and ranges), save QC, download QC data for peer group review, or restore QC data backed up previously.

Uploading commercial Quality Control material information.

An operator can upload QC material information (lot, expiration date, assay values and ranges) from a USB drive to the CELL-DYN Emerald.

1. Insert a USB drive into either of the USB ports (1 or 2) on the back panel of the CELL-DYN Emerald.
2. From the **MAIN** menu, touch the **[QUALITY CONTROL]** key.
3. Select the radio button corresponding to the file desired.

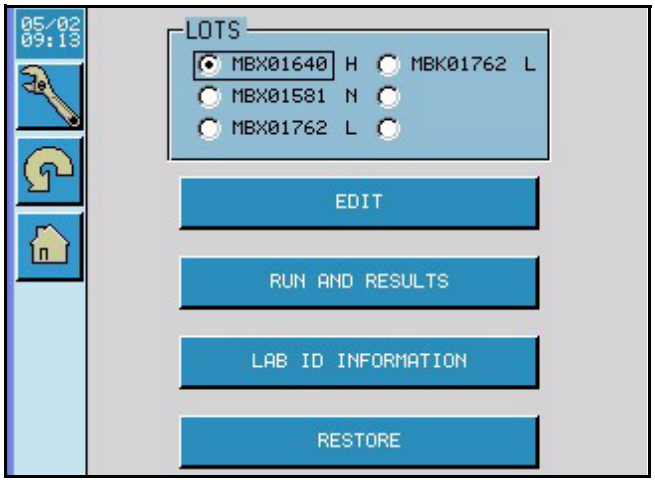


Figure 5.16 Selection of QC File for Upload

NOTE: If QC information is loaded to a file that has already been used, all existing information, including QC results, will be erased.

4. Select **[EDIT]**.

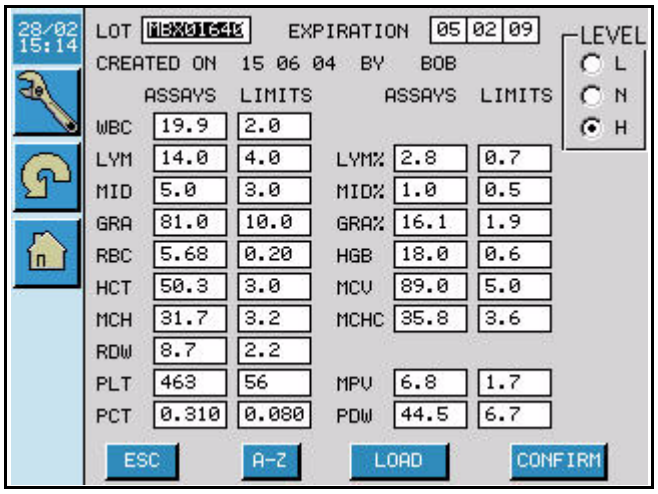


Figure 5.17 Display of Current QC Lot Information

5. Verify the LEVEL button (L, N, or H) is set to the corresponding level of control being loaded. If necessary, select appropriate level.
6. Touch **[LOAD]**.

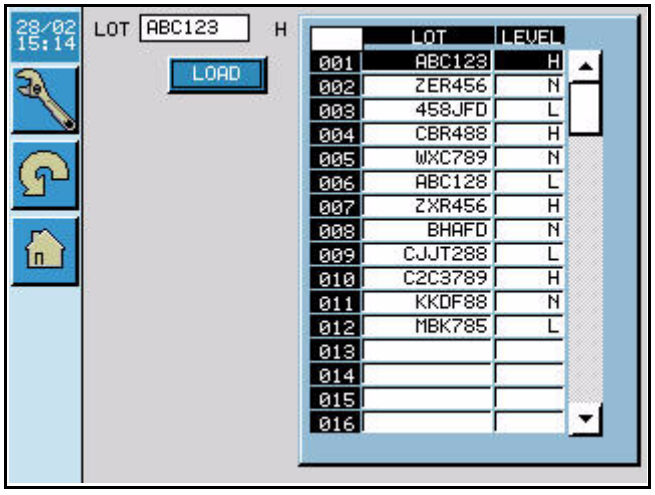


Figure 5.18 Select QC Lot and Level for Upload

7. Identify the desired lot number and level corresponding to the QC material you will be using in the table on the right side of the display and touch it to select.

   The selected lot will display in the box in the upper left side of the display, the level selected will be to the right of the lot number.

8. After verifying that this is the desired lot number and level, touch the **[LOAD]** button.
9. In the pop-up box **DO YOU CONFIRM TO LOAD THE FILE < >?**, select **[YES]** to load the file or **[NO]** to exit without loading the file.

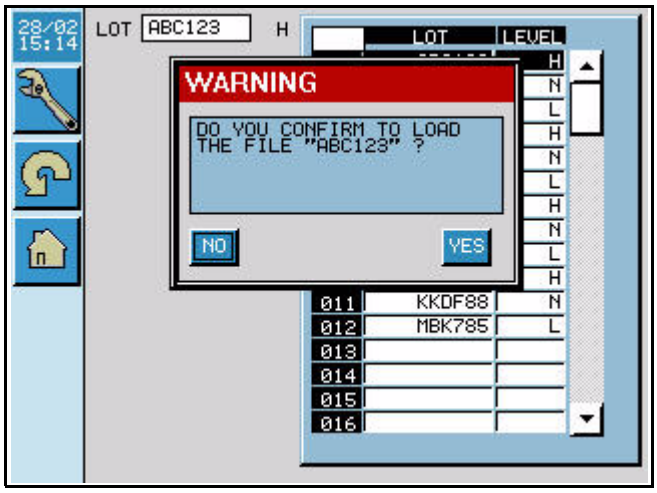


Figure 5.19 Confirmation of QC Upload

10. Confirm all information on the next screen against the product labeling provided with the Control material. Correct any information as necessary. Once the correct information is displayed, touch **[CONFIRM]** or touch **[ESC]** to exit without saving.

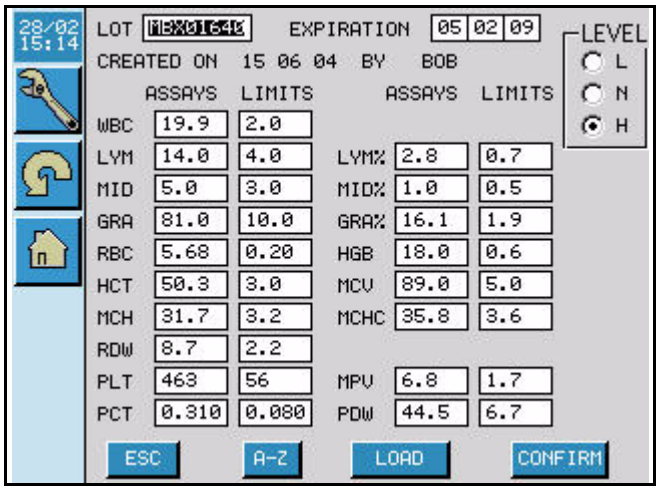


Figure 5.20 Upload QC Information

11. When prompted **DO YOU WANT TO SAVE MODIFICATIONS?**, touch **[YES]** to save the modifications or touch **[NO]** to exit without saving.
12. A pop-up box will appear, **YOU ARE GOING TO DELETE ALL ASSOCIATED RESULTS. DO YOU WANT TO CONTINUE?** touch **[YES]** to continue or **[NO]** to exit without saving.

Saving Current QC Data

QC data may be saved to the USB drive to back up, archive, or view on a personal computer.

1. From the **MAIN** menu, touch the **[QUALITY CONTROL]** key.
2. Touch the **TOOLS** icon.
3. Select one or more lot numbers using the radio buttons and touch the **[SAVE]** button.
4. To save the QC files, touch the **[BACKUP]** button.
5. You will see an information Pop-up box: **PROCESSING…PLEASE WAIT**.
6. After the message disappears it is safe to remove the USB drive.

Save QC data for eQC.

QC data may be saved to the USB drive to submit to eQC. For information about the eQC program, contact your local Abbott representative.

To submit QC data to the eQC program, LAB ID INFORMATION must be entered from the **QUALITY CONTROL** screen.

ENTERING LAB ID INFORMATION:

1. From the **MAIN** menu, touch the **[QUALITY CONTROL]** key.
2. Touch the **[LAB ID INFORMATION]** button.

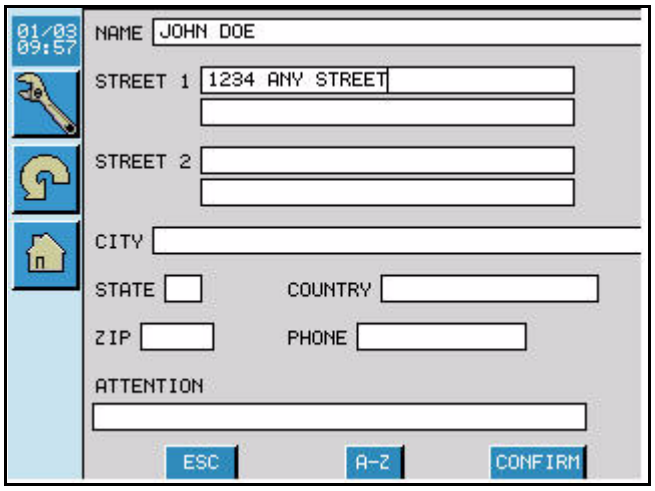


Figure 5.21 Enter Lab ID Information

NOTE: The instrument's Serial Number is not part of LAB ID INFORMATION but will be copied from the software with the eQC Identification file (ID.DAT).

3. Enter the desired information in the **<NAME>**, **<STREET 1>**, **<STREET 2>**, **<CITY>**, **<STATE>**, **<COUNTRY>**, **<ZIP>**, **<PHONE>**, and **<ATTENTION>** fields. Use the numeric keypad and/or the **[A-Z]** button to access the alpha keypad.

4. When using the alpha keypad to enter information, touch **[CONFIRM]** to enter the information and return to the **LAB ID INFORMATION** screen.

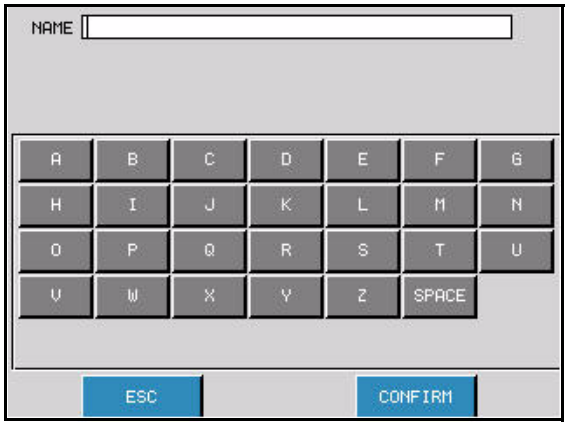


Figure 5.22 Alpha keypad for Lab ID Entry

5. When all information has been correctly entered, touch **[CONFIRM]** to save the information or touch **[ESC]** to exit without saving.
6. At the WARNING Pop-up: **`DO YOU WANT TO SAVE MODIFICATIONS?`**, touch **[YES]** to save or touch **[NO]** to exit without saving.

NOTE: Information must be entered into each field to successfully submit information to the eQC program.

Saving QC data to the USB key for eQC

1. Insert a USB drive into either of the USB ports (1 or 2) on the back panel of the CELL-DYN Emerald.
2. From the **MAIN** menu, touch the **[QUALITY CONTROL]** key.
3. Touch the **TOOLS** icon.
4. Select one or more lot numbers using the radio buttons and touch the **[SAVE]** button.

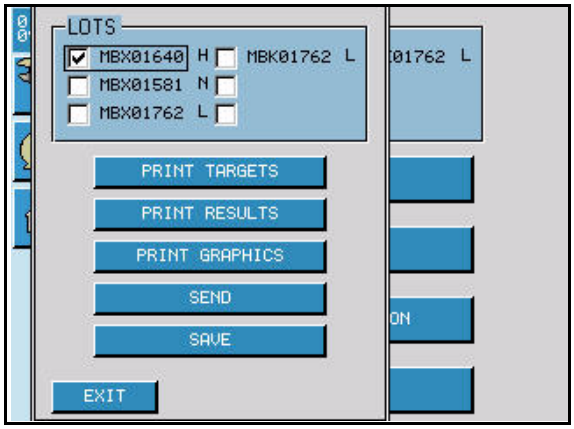


Figure 5.23 Selection of QC file(s) for eQC

5. To save the QC files, touch the **[eQC]** button.
6. You will see an INFORMATION Pop-up box: **PROCESSING…PLEASE WAIT**.

After the message disappears it is safe to remove the USB drive.

Restore previously saved QC data.

1. From the **MAIN** menu, touch the **[QUALITY CONTROL]** key.
2. Using the radio buttons, select the desired file.
3. Touch the **[RESTORE]** button.

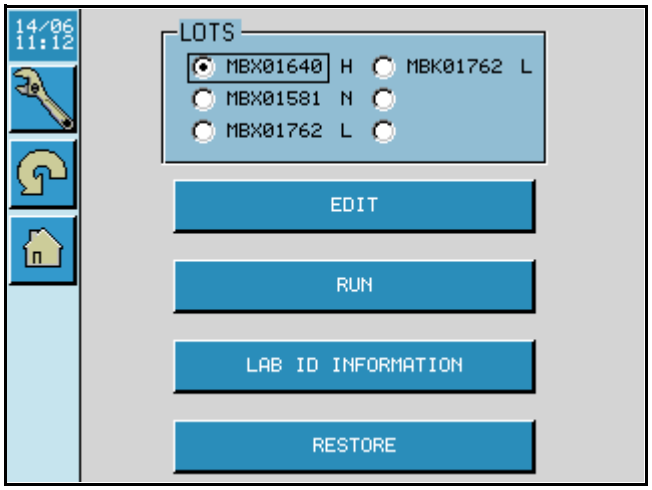


Figure 5.24 Restore Saved QC Data

NOTE: If a QC file containing data is selected you will see the WARNING Pop-up: **YOU ARE GOING TO DELETE ALL ASSOCIATED RESULTS. DO YOU WANT TO CONTINUE?** Touch **[YES]** to continue, or touch **[NO]** to exit without deleting data.

4. Select the lot and level to be restored from the list on the right side of the display by touching the desired row.

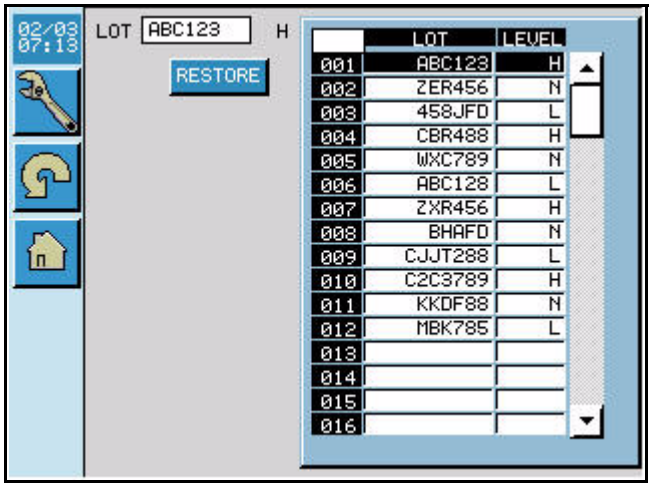


Figure 5.25 Selection of QC Lot and Level to Restore

The selected lot will appear in the box on the upper left side of the display with the level displayed to the right.

5. After verifying that the information is correct, touch the **[RESTORE]** button.
6. At the WARNING Pop-up: **`DO YOU CONFIRM TO RESTORE THE FILE`**..., touch **[YES]** to restore the file or **[NO]** to exit without restoring.

Use of the USB drive in the DATALOG menu.

The information stored in the instrument **DATALOG** can be copied to the USB drive.

1. From the **MAIN** menu, touch the **[DATALOG]** key.

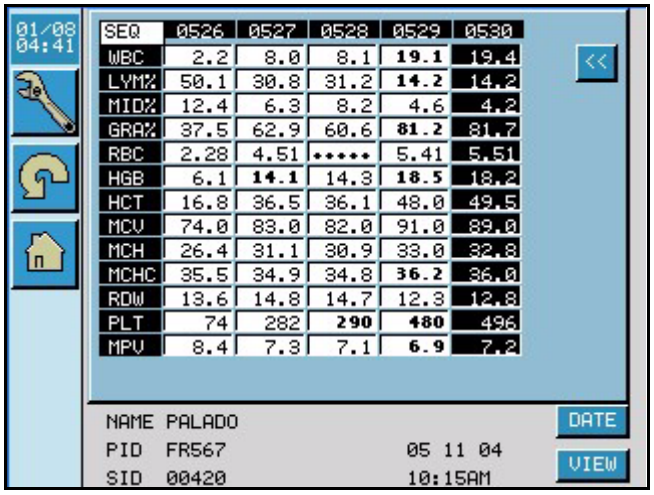


Figure 5.26 DATALOG

2. Touch the **TOOLS** icon.

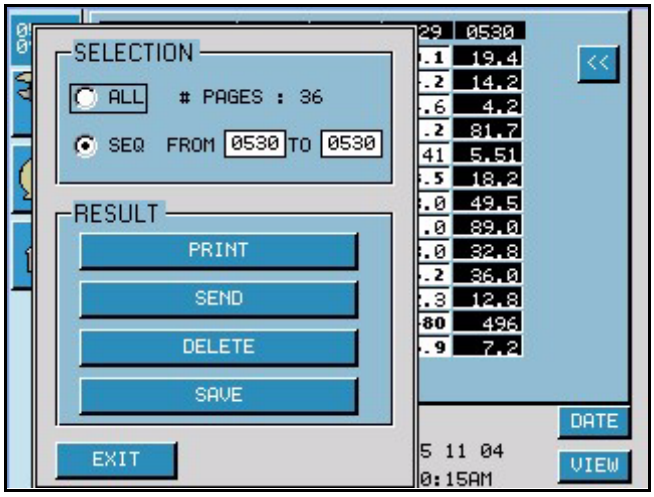


Figure 5.27 DATALOG Tools

3. Select the data to be saved by selecting the radio button for **ALL** or **SEQ**. If using **SEQ** for the selection, enter the SEQ numbers in **FROM** and **TO** fields corresponding to the data range desired.
4. Touch the **[SAVE]** button. At the **WARNING** Pop-up: **`YOU ARE ABOUT TO COPY RESULTS FROM DATALOG TO THE EXTERNAL STORAGE DEVICE. DO YOU CONFIRM?`** touch **[YES]** to save the data or **[NO]** to exit without saving.

If **YES** is selected a pop-up box will briefly appear showing the progress of the save operation. When the data has been saved this pop-up box disappears and it is safe to remove the drive.

Use of the USB drive in the SET UP menu.

The information stored in instrument SET UP can be copied to the USB drive.

1. From the **MAIN** menu, touch the **[SET UP]** button.
2. Touch the **TOOLS** icon.

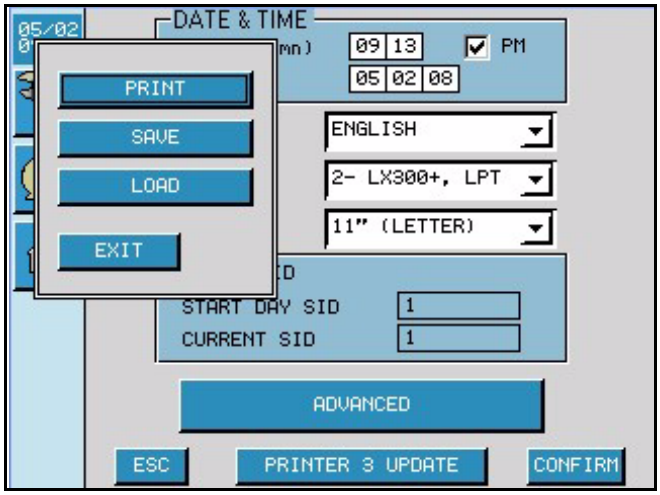


Figure 5.28 Saving to USB Drive Settings

3. Touch the **[SAVE]** button to save the current set up to the USB drive. At the **WARNING** Pop-up: **`YOU ARE ABOUT TO SAVE THE USER SETTINGS. DO YOU CONFIRM?`**, touch **[YES]** to save or **[NO]** to exit without saving.

NOTE: This function can be used to save SET UP information prior to service and restore the information afterwards.

Restoring SETUP information from the USB drive.

1. From the **MAIN** menu, touch the **[SET UP]** button.
2. Touch the **TOOLS** icon.

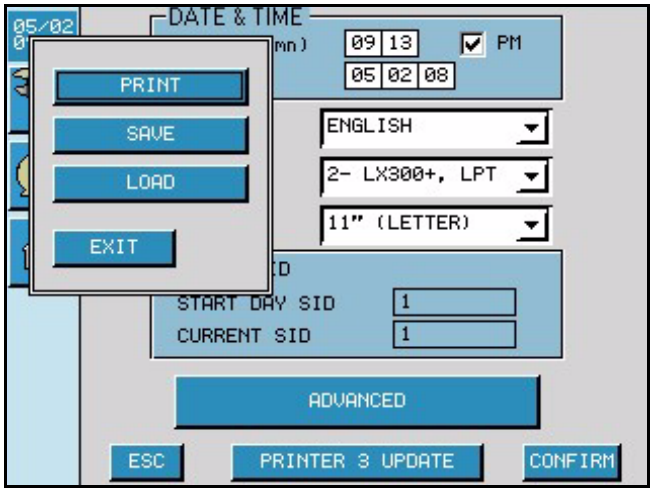


Figure 5.29 Restoring Settings

3. Touch the **[LOAD]** button.
4. You will see a pop-up **WARNING** message: **`YOU ARE ABOUT TO LOAD THE USER SETTINGS. DO YOU CONFIRM?`**

5. Touch **[YES]** to load the stored settings from the USB drive. This will overwrite all settings currently stored on the system. Touch **[NO]** to exit without loading the stored settings.

Use of the USB drive in the MAINTENANCE and RUN SAMPLE menus.

There are no USB functions available to operators in the **MAINTENANCE** or **RUN SAMPLE** menus.

Bar Code Scanner

Overview

The CELL-DYN Emerald is shipped with a bar code scanner that may be used for information entry in the **RUN SAMPLE** menu. The instrument software can be configured to input scanned information into either the PID, name, or SID fields. Please refer to **Section 2:** ***Installation Procedures and Special Requirements*** **Subsection:** ***Set Up Menu,*** for configuration instructions.

The barcode scanner is also used to input reagent information. Please refer to **Section 2:** ***Installation Procedures and Special Requirements,*** **Subsection:** ***Using Reagent Bar Codes*** for instructions on scanning reagent bar codes.

For additional information about the bar code scanner, such as instructions for use and troubleshooting, please consult the manufacturer's instructions packaged with the bar code scanner.

References

1. Clinical and Laboratory Standards Institute/NCCLS. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard – Sixth edition.* CLSI/NCCLS document H3-A6 (ISBN 1-56238-650-6) CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, 2007.
2. Clinical and Laboratory Standards Institute (CLSI). *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition.* CLSI document H04-A6 [ISBN 1-56238-677-8]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2008.
3. Thompson CB, Diaz DD, Quinn PG, Lapins M, Kurtz SR, Valeri CR. *The role of anticoagulation in the measurement of platelet volumes.* Am J Clin Pathol 1983 Sep;80(3):327-32.
4. McShine RL, Sibinga S, Brozovic B. *Differences between the effects of EDTA and citrate anticoagulants on platelet count and mean platelet volume.* Clin Lab Haematol 1990;12(3):277-85.
5. International Council for Standardization in Haematology (ICSH). *Protocol for Evaluation of Automated Blood Cell Counters.* Clinical and Laboratory Hematology 1984; 6:69-84.

NOTES

Overview

Calibration is a procedure that confirms the accuracy of the CELL-DYN Emerald. The instrument is initially calibrated at the factory. During installation, an Abbott representative will assist the laboratory in verifying the factory calibration.

The CELL-DYN Emerald is designed to remain stable without frequent calibration when it is operated and maintained according to the recommendations provided in this manual.

The following measurands can be calibrated by CELL-DYN Emerald operators:

WBC

RBC

HGB

MCV

PLT

The following measurands can be calibrated by Abbott service personnel or in the factory:

MPV

RDW

The following information is discussed in the section:

- When to Calibrate
- Calibration Guidelines
- Pre-Calibration Procedures
- Calibration Procedures
- Calibration Verification Procedure

NOTES

When to Calibrate

Scheduled calibration of the CELL-DYN Emerald must conform to the guidelines established by the regulatory agencies governing the laboratory.

Calibration should be confirmed on a regular basis according to your laboratory's protocols. The Quality Control program on the CELL-DYN Emerald provides confirmation of instrument calibration. The decision to re-calibrate can be based on Quality Control results. For information on Quality Control, refer to **Section 11: *Quality Control***.

Criteria should also be established for calibration verification. Calibration verification criteria include:

- When indicated by Quality Control data
- After major maintenance and service procedures
- At least every six months
- As directed by the regulatory agencies governing the laboratory

A common method for calibration verification is to process a commercial calibrator and compare the results with the assay values provided by the manufacturer. If instrument results exceed verification criteria, the instrument should be re-calibrated.

If needed, calibration is the last step in a troubleshooting sequence. Frequent, unnecessary, recalibrations can mask underlying instrument problems and should be avoided.

NOTE: If there are questions about when to re-calibrate, contact Abbott Diagnostics Customer Service.

NOTES

Calibration Guidelines

Calibration Materials

The CELL-DYN Emerald can be calibrated with commercial calibrator, such as CELL-DYN Calibrator, or with assayed whole blood specimens. Commercial calibrator is the method of choice.

- Commercial calibrator must be used before its expiration date and should be used according to the manufacturer's instructions.

Pre-Calibration Procedures

It is advisable to perform calibration when it can be completed without interruption. Pre-Calibration Procedures ensure proper instrument performance and a successful calibration. These steps should be completed just before starting the CELL-DYN Emerald calibration process. If problems are detected during these checks, *do not attempt to calibrate the instrument.* After the problems have been resolved, repeat the Pre-Calibration Procedures to verify proper instrument performance.

A Pre-Calibration Procedures Checklist is provided in **Appendix E:** ***Sample Logs and Worksheets***. The checklist outlines the procedures and is used to document the results. It can be duplicated as needed.

Calibration Menu

From the **MAIN** menu**,** touch **[CALIBRATION]** to display the Calibration screen shown in the following figure.

The Calibration screen displays the following information from the last calibration that was performed:

1. **LOT** – Lot number of the last calibrator used.
2. **EXPIRATION** – Expiration date of the calibrator
3. **CAL ON** – Date the calibration was performed

   NOTE: If one or more calibration factors have been manually entered, the letter "M" appears after the CAL. ON date on this screen.
4. **BY** – Operator name entered when the calibration was performed
5. **ASSAY** - Assay values entered for the last calibration
6. **FCTR** – Current Calibration Factors

Touch the **TOOLS** icon to print the displayed information, send the information to the LIS, or save the information to a removable storage device.

Touch **[EDIT]** to enter new information as shown in the following figure.

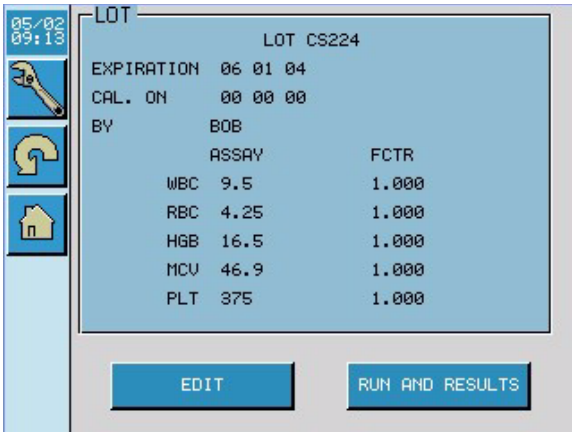


Figure 6.1 Calibration Screen

Automated Calibration Procedure

Entering Calibrator Information

NOTE: Before editing any information in the Calibration screen, touch the **[TOOLS]** icon then **[PRINT]** to print the current calibration factors.

This screen is used to enter new Calibration information as follows:

1. Touch the **<Lot>** entry field and use **[A-Z]** and the numeric keypad to type in the lot number of the calibrator.
2. Touch the **<Expiration>** entry field and use the numeric keypad to type in the calibrator's expiration date. Press the **Enter** key after each entry to advance the cursor to the next input field.

   NOTE: Expiration dates prior to the current date will not be accepted by the system.
   NOTE: Be sure to observe the date convention established by your laboratory when entering the expiration date.
3. Touch the **<Assays>** and **<Limits>** entry fields and use the numeric keypad to type in the assay value and limits from the calibrator's assay sheet.
4. Touch **[CONFIRM]** to save the information and return to the previous screen, which shows the newly entered information. You will be prompted: `DO YOU WANT TO SAVE MODIFICATIONS?` Respond **[YES]** to save or **[NO]** to return to the Calibration Entry Screen. Touch **[ESC]** to exit the screen without saving modifications. You will be prompted: `DO YOU WANT TO CANCEL MODIFICATIONS?` Respond **[YES]** to exit or **[NO]** to return to the Calibration Entry Screen.

   NOTE: If a previous calibration has been performed, a warning window will display, when you touch the **[EDIT]** or **[RUN AND RESULTS]** indicating: `YOU ARE GOING DELETE ALL ASSOCIATED RESULTS. DO YOU WANT TO CONTINUE?` Touch **[YES]** to delete all results.
5. Touch **[RUN AND RESULTS]** to display the screen shown in the following figure.

IMPORTANT: Be certain that the calibrator is at room temperature and has been mixed according to the instructions in the package insert before proceeding with the Automated Calibration Procedure.

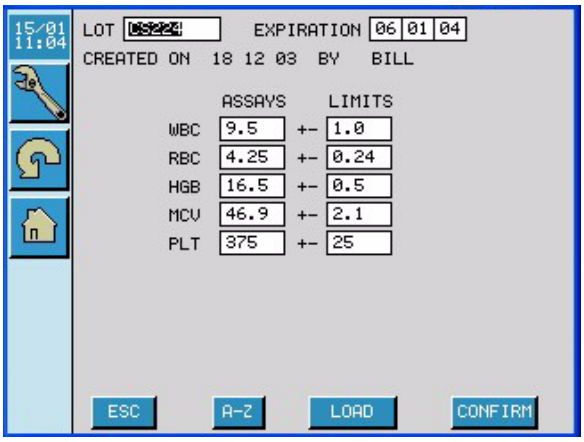


Figure 6.2 Calibration Entry Screen

Automated Calibration Procedure

1. Immerse the Aspiration Probe in a well mixed calibrator and press the Start switch.
2. The Cycle LED flashes during aspiration. The probe retracts when aspiration is complete.
3. Re-cap the calibrator vial and gently mix until the Cycle LED turns green and the probe extends.
4. Repeat the previous three steps to run the calibrator a minimum of five times. (maximum 10 runs.)

Results are stored in the calibration table shown at the right.

- Statistical calculations are done automatically with each run.
- Statistics and new Calibration Factors are shown at the bottom of the screen.
  NOTE: The calibration factors displayed on this screen (FCTR) are rounded to one decimal place due to display size constraints and are intended to provide a gross estimate of the calibration factors as obtained during the calibration process.
  Actual calibration factors are three decimal places as shown in Figure 6.1. Apparent discrepancies between the two values are due to rounding.
- The **SEL** column is used to select or deselect individual runs from the calculations.

Use of the SEL column:

- By default, all results in the calibration table are indicated by a "▷" in the column labeled SEL.
- All results with "▷" in the SEL column are included in the calculation table at the bottom of the calibration screen.
- To deselect one or more calibration runs from the Factor, Mean, SD, and CV% calculations, touch the "▷" to the left of the set of results you wish to exclude.
  NOTE: You cannot delete a run from the calibration run but you may deselect runs to remove that run's data from the calculations of the factor, mean, SD and CV%.
- Deselect any run with an error (short sample) or incomplete mixing.
- To select or deselect all runs touch **[SEL]** at the top of the column.
- Values displayed in bold text are outside of the defined target range.
  NOTE: The Numbers display or print in bold only if PANIC HIGH and PANIC LOW, in SETUP-ADVANCED-REPORTING OPTION has been configured.

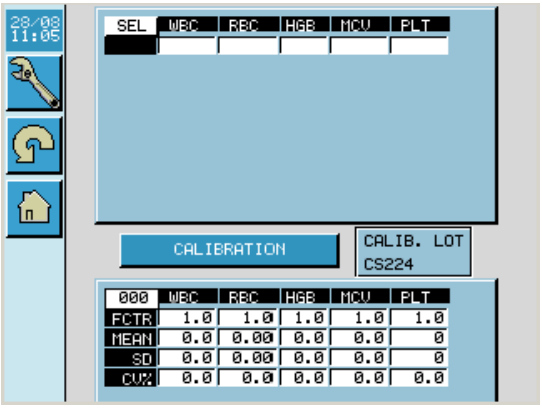


Figure 6.3 Calibration Result Table

5. If any of the results are excluded, ensure the calibrator is properly mixed, and run additional samples until the total number of runs equals five. Invalidated results should be excluded from calculations. When a minimum of five successful runs are completed, review the data again and if result are still unacceptable, refer to **Section 10: *Troubleshooting***.
6. Using the ***Calibration Verification Worksheet*** from **Appendix E**, enter the assay value into the first column and the mean from the result file into the second column. If the difference between the two columns for any measurands exceeds the +/- limit shown on the Calibrator Assay Sheet, calibration is required; proceed as follows. If all +/- limits are within tolerance, calibration is not needed.
7. Make a copy of the completed Calibration Worksheet and save for your records. (The Calibration Worksheet can also be found in **Appendix E**, Sample Logs and Worksheets.)
8. If calibration is not needed, touch **[EXIT]** to return to calibration run screen. Touch **[HOME]** to return to the **MAIN** menu.
9. If calibration is needed, touch **[CALIBRATION]** to display the Result window shown at right.
10. In the **CALIBRATION** section of the window, deselect the box next to the measurand(s) that do not need to be calibrated.

    NOTE: By default all the measurands are selected, which means all the measurands will be calibrated. If you do not wish to calibrate one or more measurands, deselect the appropriate measurand.
11. When selections are complete, touch **[CALIBRATION]** to calibrate the selected measurands.
12. A warning prompt displays: `YOU ARE GOING TO REPLACE CALIBRATION FACTOR(S). ARE YOU SURE?`, touch **[YES]**.
13. The selected measurands are now calibrated.
14. Touch **[EXIT]** to return to calibration screen.
15. Touch **[HOME]** to return to **MAIN** menu.
16. Touch **[CALIBRATION]** to display the calibration factors.
17. Touch the **[TOOL]** icon then touch **[PRINT]** to print the new calibration factor(s).
18. Verify Calibration as directed in the Calibration Verification procedure below.

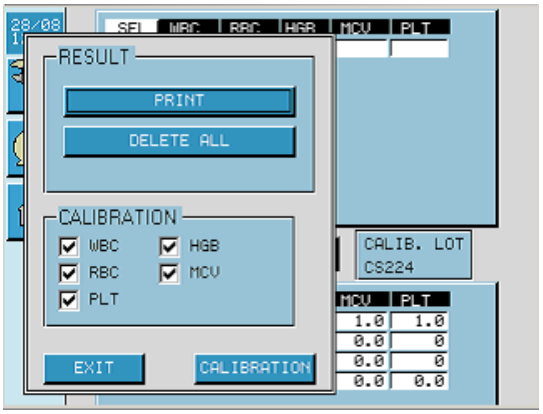


Figure 6.3 Calibration Result Table (Continued)

Calibration Verification Procedure

Calibration Verification is done to verify the accuracy of the calibration. It is accomplished by running the second tube of calibrator in the same manner as the first and comparing the results to the Assay Values.

1. When calibration is complete and all required information has been printed, touch **[HOME]** followed by **[MAINTENANCE]**, touch **[SPECIAL MODES]**, touch **[PRECISION]**.
2. Ensure that the second tube of calibrator is at room temperature and mixed according to the instructions given in the package insert.
3. Run the calibrator two times in the precision file.
4. Using the Calibration Verification Worksheet from **Appendix E: *Sample Logs and Worksheets***, enter the assay value from the assay sheet into the first column and the mean of the two runs from the result file into the second column. Verify the difference between the two columns is within the +/- tolerance limits as shown on the Calibrator Assay Sheet; if not, troubleshoot; if it is within the limits, complete the Calibration Verification Worksheet and make a copy for your records.

References

1. International Council for Standardization in Haematology (ICSH). Protocol for Evaluation of Automated Blood Cell Counters. Clinical and Laboratory Hematology 1984; 6:69-84.
2. Clinical and Laboratory Standards Institute/CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Guideline – Third edition.* CLSI document H7-A3 (ISBN 1-56238-413-9) CLSI, 940 West Valley Road, Suite 1400, Wayne, PA, 19087-1898 USA 2000.

NOTES

Overview

This section addresses operational requirements, precautions, and limitations to ensure operator safety and accurate test results. Failure to follow these requirements or take these precautions may cause damage to the system, impact system performance, or adversely affect results, or present a hazard to the operator. Operational precautions and limitations topics include:

- General requirements
- Precautions and requirements for System Operation
- Requirements for handling consumables
- Requirements for handling specimens
- Requirements for collecting, preparing and storing specimens
- Interfering substances and conditions
- Limitations of result interpretation
- Other factors you should consider when interpreting patient test results

NOTES

General Requirements

The following general CELL-DYN Emerald system requirements should be followed to help ensure proper system performance:

- Ensure the system is located out of direct sunlight, heat and drafts, and away from any heat-generating device. Exposure to heat and drafts can interfere with the ability of the system to maintain an operating temperature that is within the acceptable range.
- Place the instrument on a hard, level surface. Maintain the required space on all sides of the system. For more information about space requirements, refer to **Section 2:** ***Installation Procedures and Special Requirements***. This clearance is essential for:
  - Adequate ventilation and cooling of electrical components
  - Easy access for maintenance
  - Easy access for disconnecting the power cord when required
- Place the instrument away from centrifuges, x-ray equipment and copiers.

CAUTION: Do not use mobile telephones, wireless telephones, mobile radios, or any other radio frequency (RF) transmitting devices in the same room as the instrument.

NOTE: The CELL-DYN Emerald has been evaluated to EN 55011 and EN 61000 for electromagnetic emissions and immunity, respectively.

- Leave the system power on continuously unless instructed otherwise in a maintenance or troubleshooting procedure, or unless an emergency situation occurs.
- Ensure the waste line is connected to the appropriate outlet and is routed to a suitable waste container or drain. Dispose of all waste materials in accordance with local, state and federal regulations.
- If an external waste container is used, ensure the top of the waste container is placed below the bottom of the analyzer.
- If a drain is used for waste, ensure the waste outlet tube is secured in the drain hole. Ensure system components are located away from potential waste overflow.
- Perform maintenance procedures as recommended in **Section 9:** ***Service and Maintenance***.
- Do not attempt any maintenance or repairs that are not specified in documentation provided by Abbott Laboratories. An Abbott-authorized representative should perform all major service work.

CELL-DYN components are designed specifically for use with the CELL-DYN Emerald System. Substitution of unauthorized components may adversely affect system performance.

Precautions and Requirements for System Operation

These precautions should be taken and requirements followed when operating the CELL-DYN Emerald System. Failure to do so may cause damage to the system and may adversely affect test results.

Precautions Before Operation

Before operating the system:

- Read this manual thoroughly to understand the full functionality of the system and associated hazards.
- Read reagent labels and package inserts provided with calibrator and control material to understand:
  - warnings and precautions
  - safety precautions
  - handling precautions

Requirements Before Operation

Before operating the system:

- Ensure specimens are premixed according to your laboratory's procedure. Specimens collected in micro-collection tubes should be premixed according to the manufacturer's recommendations.
- Ensure background counts are within specifications before running controls or patient specimens. Background counts are performed automatically as part of Start Up.

Precautions During Operation

While operating the system:

- Keep all instrument covers in place unless instructed otherwise in a maintenance or troubleshooting procedure.
- Do not disconnect any electrical connection while the power is ON.

The following information is applicable to European Economic Area countries:

Battery Disposal Information

- The European Battery Directive requires separate collection of spent batteries, aiming to facilitate recycling and to protect the environment.
- This device contains batteries that are not intended to be serviced or removed by the user. The batteries in this product should be removed at the end of the life of the device by an Abbott Service technician or a qualified individual, and disposed in accordance with local regulations for separate collection of spent batteries.
- Your local Abbott product support office may be contacted for additional information.

Requirements for Handling Consumables

These requirements should be followed when handling reagents, calibrators and controls to help ensure operator safety and accurate results. Refer to the manufacturer's documentation, such as a product label, package insert, or Material Safety Data Sheet (MSDS) for detailed information. For a detailed description of the hazard symbols, refer to **Section 8: *Hazards***.

Requirements for Storage

Follow these requirements for storing reagents, calibrators and controls:

- Store reagents, calibrators and controls according to the directions provided on the label or in the package insert.
- Contact Abbott Customer Service if you receive CELL-DYN reagents, calibrators or controls that are in a condition contrary to the product's label or package insert, or are damaged.

Requirements for Use

Follow these requirements for using reagents, calibrators and controls:

- Do not substitute. Substitution of materials may affect CELL-DYN Emerald System performance, results, safety, and equipment life.
- Keep the diluent container at the same level as the instrument.
- Keep reagents away from direct sunlight and protect them from evaporation. The cap attached to each inlet tube minimizes evaporation and contamination.
- Use caution when handling reagents, calibrators and controls to prevent contamination and operator exposure.

- Prior to using the product, refer to the manufacturer's instructions for reagent, calibrator, and control temperature requirements and handling instructions.
- Wear clean gloves to avoid contamination and exposure when removing and replacing the reagent inlet lines.
- Do not smoke, eat, drink, apply cosmetics, or handle contact lenses in areas where specimens, reagents, calibrators and controls are handled.
- Do not use reagents, calibrators and controls after their expiration dates.
- Do not mix reagents, calibrators and controls within a lot or between lots.

Requirements for Handling Specimens

WARNING: Consider all clinical specimens, reagents, calibrators and controls that contain human-sourced materials as potentially infections. Consider all system surfaces or components that have come in contact with human-sourced materials as potentially infectious. Refer to **Section 8: *Hazards*** for additional information.

Collect all specimens according to your laboratory's procedures, following the recommendations of the collection tube manufacturer. Follow all usual precautions when collecting blood by venipuncture to avoid clotting and/or specimen hemolysis.

Requirements for Collecting, Preparing and Storing Specimens

Follow these requirements for collecting, preparing and storing specimens:

- Use fresh whole blood specimens to achieve the most reliable result data. The International Committee for Standardization in Haematology (ICSH) defines a fresh blood specimen as one processed within four hours after collection.[1]
- Maximum suggested elapsed time and storage temperatures after collection of venous whole blood:
- Four hours at room temperature.
  - For information on maximum suggested elapsed time for specimens collected using micro collection devices, refer to the manufacturer's package insert.
  - Any refrigerated specimens should be brought to room temperature before mixing and processing.

Interfering Substances and Conditions

Any substance or condition that can interfere with the CELL-DYN Emerald System's principles of operation should be considered an interfering substance or condition. Refer to **Section 3: *Principles of Operation***, **Subsection: *Instrument Alarms, Operational Alerts, and Measurand Data Flags*** for a list of interfering substances. For additional information on interfering substances, refer to the table provided in **Appendix B: *Potential Causes of Spurious Results***.

Limitations of Result Interpretation

The CELL-DYN Emerald has been validated for its intended use. However, error can occur due to potential operator errors and system technology limitations. Results obtained from the system should be used with other clinical data, for example, patient symptoms, other test results, patient history, clinical impressions, information available from clinical evaluation, and other diagnostic procedures. All data should be considered for patient care management. If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.

NOTES

Reference

International Council for Standardization in Haematology (ICSH). Protocol for Evaluation of Automated Blood Cell Counters. *Clin Lab Haemat.* 1984; 6:69-84.

NOTES

Overview

This section provides information on potential hazards to personnel and potential damage to the laboratory environment.

Hazard and safety topics include:

- Safety icons

Provides an illustration of each safety icon and sample text associated with the icon.

- Biological and chemical hazards

Provides an overview of the biological and chemical hazards and precautions to minimize exposure to these hazards.

- Electrical hazards

Provides an overview of precautions to avoid personal injury or damage to the system from its electrical components.

- Mechanical hazards

Provides an overview of the precautions to avoid personal injury or damage to the system from the system's mechanical components.

- Physical hazards

Provides an overview of the precautions to avoid physical injury when operating or moving the system.

NOTES

Operator Responsibility

Operators are responsible for using the CELL-DYN Emerald system only as designed. Operators should be trained before being allowed to operate the system. Failure to follow instructions for safe use of the system could cause personal injury, damage to the system, or could adversely affect results. See also **Section 7:** ***Operational Precautions and Limitations***.

Safety Icons

Safety icons in this manual and on the CELL-DYN Emerald System identify potentially dangerous conditions. Learn the icons and understand the type and degree of potential hazard they represent.

The following icons may be used with text or in lieu of text. If text accompanies the icons, it describes the nature of the hazard and is labeled with **WARNING** or **CAUTION**.

WARNING: is defined as a physical, mechanical, or procedural condition that could result in moderate to serious personal injury.

CAUTION: is defined as a condition that could result in minor injury or interfere with proper functioning of the system.

Table 8.1 Safety Icons

Icon	Hazard	Description
	**WARNING: Potential Biohazard.**	Identifies an activity or area where operators may be exposed to potentially infectious material.
	**WARNING: Electrical Hazard.**	Indicates the possibility of electrical shock if procedural or engineering controls are not observed.
	**CAUTION:**	Identifies an activity that may present a safety related hazard and advises you to consult the associated caution or warning instructions provided.
NOTE:	**Important Information:**	Indicates important additional information.

Biological and Chemical Hazards

You may be exposed to biological materials and hazardous chemicals while using the CELL-DYN Emerald system. The following information is presented to help you minimize the likelihood and degree of impact of any such exposure.

Biological and chemical hazard topics include:

- Biological hazards
- Chemical hazards
- Spill clean-up
- Waste handling and disposal
- Decontamination procedure requirements

Biological Hazards

The following activities may involve the presence of biological materials:

- Handling patient specimens, reagents, calibrators, and controls
- Cleaning spills
- Handling and disposing of waste
- Moving the system
- Performing maintenance procedures
- Performing decontamination procedures
- Performing component replacement procedures

Precautions

You should consider all clinical samples, reagents, calibrators, and controls that contain human-sourced material as potentially infectious. You should consider all system surfaces or components that have come in contact with human-sourced material potentially infectious. No known test method can offer complete assurance that products derived from human-sourced material will not transmit infection. Therefore, all products derived from human-sourced materials and system components exposed to human-sourced materials should be considered potentially infectious.

It is recommended that you handle all potentially infectious materials in accordance with the Standard on Bloodborne Pathogens[1]. You should use Biosafety Level 2[2] or appropriate biosafety practices[3,4] for materials that contain or are suspected of containing infectious agents. Precautions include, but are not limited to, the following:

- Wear gloves, lab coats, and protective eye wear when handling human-sourced material or contaminated system components.
- Do not pipette by mouth.

- Do not eat, drink, smoke, apply cosmetics, or handle contact lenses when handling human-sourced material or contaminated system components.

WARNING: Potential Biohazard. Identifies an activity or area where you may be exposed to potentially infectious material.

- Clean spills of potentially infectious materials and contaminated system components with an appropriate disinfectant, such as 0.5% sodium hypochlorite or another suitable disinfectant. Refer to **Appendix C: *Preparation of diluted sodium hypochlorite solutions***, **Subsection: *Decontamination Procedure***, for instructions for preparing the sodium hypochlorite solution.
- Decontaminate and dispose of all specimens, reagents, calibrators, controls, and other potentially contaminated materials in accordance with local, state, and federal regulations.

If you are exposed to biohazardous or potentially infectious materials, seek medical attention immediately and take steps to clean the affected area.

The following label is affixed to the CELL-DYN Emerald System:

Figure 8.1 Biohazard label

The Biohazard label is affixed to the Start Switch below the Aspiration Probe as shown in the following figure:

Figure 8.2 Biohazard Label location

The Biohazard label is also affixed to the rear of the instrument next to the waste outlet as shown in the following figure:

Figure 8.3 Waste Outlet Biohazard Label

Chemical Hazards

Operators and others may be exposed to hazardous chemicals when handling reagents, calibrators, and controls.

Exposure to hazardous chemicals is minimized by following instructions provided in the manufacturer's documentation, such as product labels, package inserts or Material Safety Data Sheets (MSDS).

Precautions

In general, observe the following precautions when handling chemicals:

- Consult MSDS for safe-use instructions and precautions.
- Avoid contact with skin and eyes. If contact with material is anticipated, wear impervious gloves, protective eye wear and clothing.
- Maintain good housekeeping. Do not eat, drink, or store food and beverages in areas where chemicals are used.
- Seek medical attention if irritation or signs of toxicity occur after exposure.

Hazard symbols that appear on CELL-DYN Emerald System product labeling may be accompanied by risk (R) and safety (S) numbers and represent risk and safety phrases defined by European Community Directives. The risk and safety phrases describe precautions to be used when working with a particular chemical or chemical mixture.

Spill Clean-Up

Clean spills in accordance with established biosafety practices and follow instructions provided in the MSDS. In general, use these safe work practices for cleaning spills:

1. Wear appropriate personal protective equipment, such as a lab coat, protective eyewear and gloves.
2. Absorb the spill with absorbent material.
3. Wipe the spill area with detergent solution.
4. Wipe the area clean with an appropriate disinfectant such as 0.5% sodium hypochlorite or another suitable disinfectant. Refer to **Section 9: *Service and Maintenance***, **Subsection: *Decontamination Procedure***, for instructions for preparing the sodium hypochlorite solution.
5. Dispose of spilled and contaminated material in accordance with local, state, and federal regulations.

Waste Handling and Disposal

Dispose of all waste materials in accordance with local, state, and federal regulations.

It is the responsibility of each facility to label all waste containers and to characterize its waste stream to ensure the waste is disposed in accordance with the appropriate waste disposal regulations.

Decontamination Procedure Requirements

The CELL-DYN Emerald system must be decontaminated before servicing, shipment, and relocation. Always wear appropriate personal protective equipment while performing decontamination activities. Refer to **Section 9:** ***Service and Maintenance***, **Subsection:** ***Decontamination Procedure*** for instructions.

Electrical Hazards

The CELL-DYN Emerald System does not pose uncommon electrical hazards to operators if it is installed and operated without alteration, and is connected to a power source that meets required specifications. Refer to **Section 4:** ***Performance Characteristics and Specifications*** for power requirements and specifications.

The electrical circuit spacing of the CELL-DYN Emerald system is based on pollution degree 2 and altitude [up to 2000 M (6562 ft)] as per IEC 61010-1[5]. Pollution degree 2 is defined as an environment where normally only non-conductive pollution occurs. Occasionally, however, a temporary conductivity caused by condensation should be expected.

Electrical Safety

WARNING: Electrical Hazard. Indicates the possibility of electrical shock if operating or servicing instructions are not followed.

Basic electrical hazard awareness is essential to the safe operation of any system. Only qualified personnel should perform electrical servicing. If the instrument is used or modified in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

Elements of electrical safety include, but are not limited to, the following:

- Inspect electrical cabling into and on the CELL-DYN Emerald system for signs of wear and damage.
- Use only approved power cords and electrical accessories, such as those supplied with the system, to protect against electric shock.
- Use a properly grounded electrical outlet of correct voltage- and current-handling capability.
- Do not disconnect any electrical connection or service any electrical or internal components while the power is ON.
- Keep liquids away from all electrical or communication component connectors.
- Do not touch with wet hands any switches or outlets.
- Keep the floor under and around the CELL-DYN Emerald system dry and clean.
- Clean spilled fluids immediately. Always unplug the instrument before cleaning up major liquid spills.

Mechanical Hazards

The CELL-DYN Emerald system is an automated system that operates under computer control. As with most automated equipment, there is potential for injury and bodily harm from moving mechanical components whenever the system is in operation.

The CELL-DYN Emerald System minimizes mechanical hazards by providing protective covers and locking mechanisms to protect against accidental contact with mechanical and moving components.

During operation of the CELL-DYN Emerald system, the operator is potentially exposed to the moving Aspiration Probe Assembly.

Basic elements of mechanical safety include, but are not limited to the following:

- Never bypass or override a safety device.
- Keep all protective covers in place.
- Never allow any part of the body to enter the region of movement of any mechanical component when the system is operating.
- Never perform manual tasks on the surface of the system.
- Open or remove covers only as directed during routine and as-needed maintenance, component troubleshooting, or reagent removal and replacement procedures described in **Section 9:** ***Service and Maintenance***, **Section 10:** ***Troubleshooting*** and **Section 2:** ***Installation Procedures and Special Requirements***, **Subsection:** ***Replacing the Reagents – Diluent, Lyse, Cleaner***.
- Use caution and wear a lab coat, protective eyewear and powder-free gloves when operating the instrument, cleaning the instrument, reagent handling, and when performing maintenance or service procedures. Always use protective equipment when specified.
- Do not wear long hair loose or articles of clothing or accessories that could catch on the system.
- Keep pockets free of items that could fall into the system.

Physical Hazards

Safe practices should be observed to avoid physical injury in the following situations:

Aspiration Probes

WARNING: Aspiration probes are potentially contaminated with infectious material. Avoid contact with the tip of the probe. Although the CELL-DYN Emerald system presents and lowers the probe for sample aspiration, never reach into the access area until the probe is in place.

Place the aspiration probe in an appropriately labeled, puncture-resistant, and leakproof container before treatment and disposal.

Heavy Objects

CAUTION: Identifies an activity where you may be required to lift or move a heavy object. Use proper lifting techniques.

The CELL-DYN Emerald Diluent and waste containers are heavy when full. Use proper lifting techniques to reduce the risk of injury when handling the containers.

The CELL-DYN Emerald System is heavy. Ensure there is adequate help before attempting to move the system.

Tripping Hazard

The CELL-DYN Emerald System is equipped with power cords. To avoid a tripping hazard, ensure that cords avoid high traffic areas or are properly stowed.

References

1. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, *Occupational Exposure to Bloodborne Pathogens*.
2. US Department of Health and Human Services. *Biosafety in Microbiological and Biomedical Laboratories*. Fourth Edition. Washington, DC: US Government Printing Office, May 1999.
3. World Health Organization. *Laboratory Biosafety Manual*. Geneva: World Health Organization, 1993.
4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections*; Approved Guideline – Third Edition. CLSI document M29-A3 (ISBN 1-56238-567-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA, 2005.
5. IEC 61010-1, International Electrotechnical Commission - World Standards for Electrical and Electronic Engineering, 61010: - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, 61010-1 (2001) Part 1: General Requirements.

NOTES

Overview

The CELL-DYN Emerald System has been designed to require minimal routine maintenance. To ensure optimum performance, the operator is encouraged to routinely perform the scheduled maintenance procedures described in this section. Failure to perform recommended maintenance can result in inaccurate or imprecise results.

This section describes the recommended preventative maintenance procedures and provides instructions for storing, relocating or shipping the instrument.

The maintenance schedule outlined in this section minimizes operational problems with the CELL-DYN Emerald. The recommended intervals are based on instruments operating in laboratories analyzing up to 50 specimens per day from a general patient population. If more than 50 specimens per day are typically analyzed, adjust the maintenance frequency proportionally. These intervals are affected by several factors, including:

- Number of specimens processed
- Work load schedule
- Operating environment
- Patient population being analyzed

Each laboratory must assess its own situation and modify these recommended intervals as necessary.

NOTE: Overdue maintenance is usually indicated by an increase in imprecision of one or more of the directly measured measurands. This increase may be due to carryover or dilution/sampling inconsistencies. If this occurs on more than a random basis, the appropriate maintenance should be performed more frequently.

WARNING: Potential Biohazard. Consider all clinical specimens, reagents, calibrators, controls or other materials and all system surfaces or components that contain or come in contact with human-sourced material as potentially infectious. Wear a lab coat, gloves and safety glasses when performing service or maintenance. Follow biosafety practices as specified in the OSHA Bloodborne Pathogen rule (29 CFR Part 1910.1030)[1] or other equivalent biosafety practices.[2, 3]

Gloves should be powder-free; powder can cause instrument problems. Maintenance procedures should not be performed without adequate training.

NOTES

Event Log

The instrument provides an Event Log. This log maintains a record of certain activities by date and holds 365 records, one for each day that the instrument is run. Access the log from the **MAIN** menu by touching **[EVENT LOG]**. The Event Log is shown in the following figure.

The days of operation are displayed in the first row with day 001 being the first day of the instrument operation - installation. When a specific day is selected, the date, day number, and the number of runs for the selected day are displayed to the right of the log. The abbreviations used in the log are as follows:

SPR: Supervisor log in
SVC: Service log in
FCT: Factory log in
INT: Service Operation(s) performed
SUP: Start Up Cycle passed
SUF: Start Up Cycle failed
SDN: Shut Down Cycle
DIL: Diluent Reagent changed
LYS: Lyse Reagent changed
CLN: Cleaner changed
ACN: Cleaning Cycle (either automatic or manual)
BLH: Bleach Cleaning
CAL: Calibration performed
QC: QC performed
DEL: Results deleted from Datalog

When the Event Log approaches capacity the operator will be alerted to print the Event Log. When the Event Log has 365 entries it will begin to delete entries on a first-in first-out basis or the operator can manually delete selected entries. The last 100 entries are maintained, even though other entries are deleted.

An x will appear in the day column if the specific event has occurred once or more in that day.

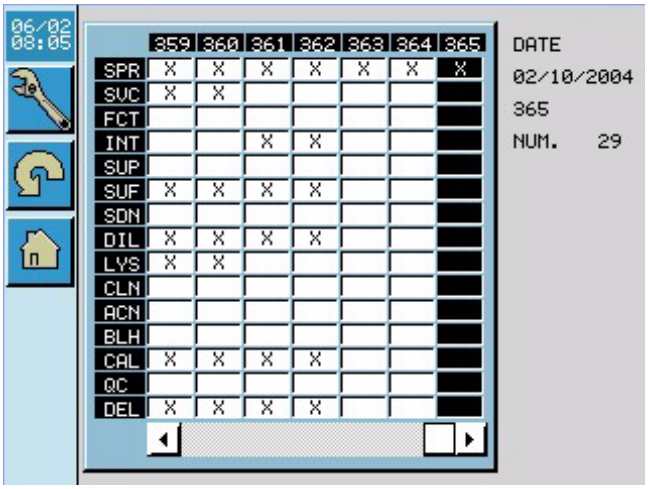


Figure 9.1 EVENT LOG Screen

Saving and Printing the Event Log

The EVENT LOG may be saved to a USB drive (see **Section 5:** ***Operating Instructions***) or printed to provide a permanent record.

1. From the **MAIN** menu, touch **[EVENT LOG]**.
2. Touch the **TOOLS** icon.

To print the **EVENT LOG**:

1. Select the range of records by touching either the **[ALL]** radio button or the **[DAY]** radio button. If using the DAY method, enter the number(s) representing the desired day(s) to print in the fields to the right.

NOTE: To see the date associated with a particular day in the **EVENT LOG**, touch the day on the display and the date will appear in the gray area on the right side of the display. To view a day not shown on the display, use the scroll bar to move right and left.

2. Touch **[PRINT]**.

To save the **EVENT LOG**:

1. Insert a formatted USB drive into either USB port on the rear panel of the CELL-DYN Emerald.
2. Select the range of records by touching either the **[ALL]** radio button or the **[DAY]** radio button. If using the DAY method, enter the number(s) representing the desired day(s) to print in the fields to the right.

NOTE: To see the date associated with a particular day in the **EVENT LOG**, touch the day on the display and the date will appear in the gray area on the right side of the display. To view a day not shown on the display, use the scroll bar to move right and left.

3. Touch **[SAVE]**.

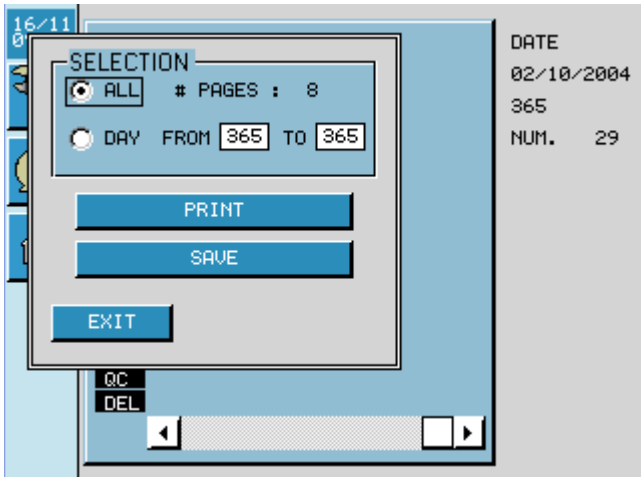


Figure 9.2 Saving and Printing the Event Log

Abbott recommends that CELL-DYN Emerald Operators keep a record of scheduled and unscheduled maintenance in an instrument logbook. (Refer to **Section 5:** ***Operating Instructions***, **Subsection:** ***Instrument Logbook***.)

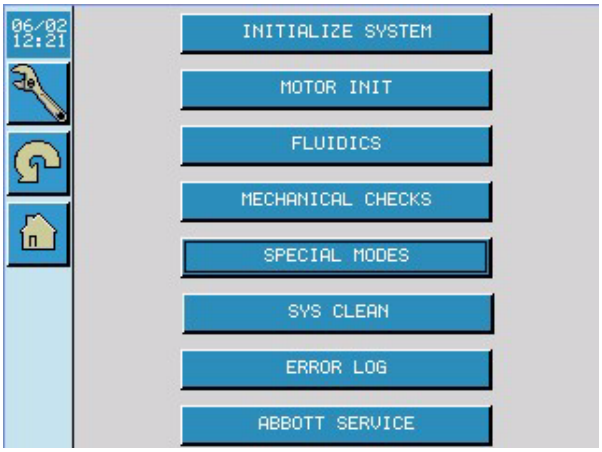
For your convenience, a blank **Maintenance Log** is included in **Appendix E:** ***Sample Logs and Worksheets***. This page can be photocopied as necessary.

Enter the month and year at the top of each page and initial each task when it is completed.

Maintenance Menu

The **MAINTENANCE** Button is found on the **MAIN** menu. The options accessible from the **MAINTENANCE** Button are described, below.

1. **Initialize System.** This button is used to initialize the Emerald following an Emergency Stop or as directed during instrument troubleshooting.
2. **Motor Init.** Used for troubleshooting as directed by an Abbott Representative.
3. **Fluidics.** Refer to **Subsection: *Fluidics Menu Options***, found later in this section.
4. **Mechanical Cycles.** Used for troubleshooting as directed by an Abbott Representative.
5. **Special Modes.** Used to access the **Precision** and **Linearity** buttons, described later in this section.
6. **Sys Clean.** Used as described in **Subsection: *Preparing for Storage, Relocation or Shipping***, found later in this section.
7. **Error Log.** An automatic log of all system errors generated by the CELL-DYN Emerald. For use in troubleshooting as directed by an Abbott Representative.



Special Modes Button

The **SPECIAL MODES** Button is accessed from the **MAIN** menu by touching the **MAINTENANCE** button.

Precision. The **Precision** Button allows an operator to perform a precision test consisting of up to 33 runs. The mean (+/-), SD (Standard Deviation) and CV% are calculated automatically for each parameter.

1. Touch **[MAINTENANCE]**, **[SPECIAL MODES]**, then **[PRECISION]**.
   If data is already present in the file from a previous precision test, the software prompts the user to delete the previous results. Touch **[YES]** to erase previous results, or **[NO]** to view or print previous results.

NOTE: If prior results are not deleted, the sample probe will not descend.

2. When the sample probe descends, present a well-mixed sample and touch the start switch. Repeat until the number of desired precision replicates is reached. The mean, SD, and CV% will update with each run.
3. Select or deselect individual runs by touching the (<>) to the left of the run. The mean, SD, and CV% will update as runs are selected and deselected.

Individual run reports are not printed for samples tested in Precision. To print a summary of the precision test results, touch the Tools icon, and touch **[PRINT]**.

Precision test results are not stored in the **DATALOG** and are accessible only through the **PRECISION** Button.

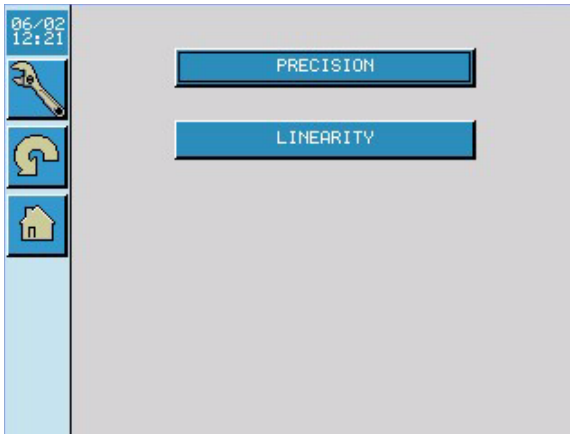


Figure 9.3 The Precision Button

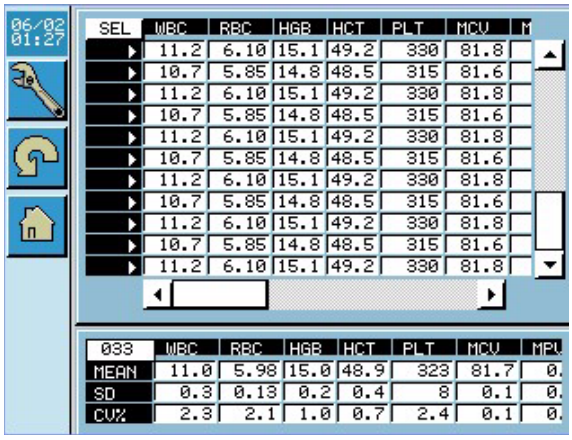


Figure 9.4 Precision Data

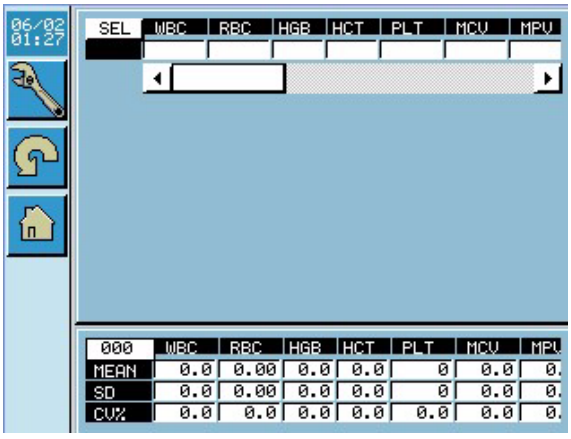


Figure 9.5 The Precision Run Screen (shown with an empty file)

Linearity. The Linearity Button allows an operator to test linearity material or other samples that consist of only one blood cell type. All samples tested in the Linearity mode will have LINEARITY in the NAME field.

1. Touch **[MAINTENANCE]**, **[SPECIAL MODES]**, then **[LINEARITY]**.
2. Enter additional information about the sample in the **<NEXT SID>** field, if desired. To utilize the alpha touch screen, or to enter information into the PID field, touch the **[NEXT SAMPLE]** button at the lower left of the display. Use the numeric keypad on the Emerald and/or the alpha keypad on the display to enter the desired information. Touch **[CONFIRM]** to save entries or **[ESC]** to exit without saving.
3. At the Linearity Run screen, aspirate the sample. All results of linearity testing are stored in the **Datalog**.

Figure 9.6 The Linearity Button

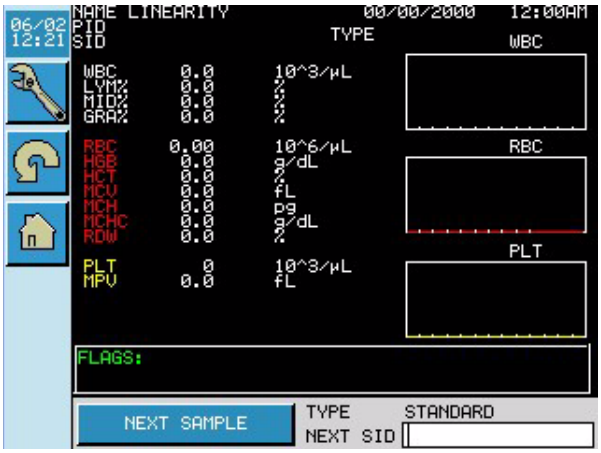


Figure 9.7 The Linearity Run Screen

NOTES

Fluidics Menu Options

The following options are available on the **FLUIDICS** menu. To access **FLUIDICS** from the **MAIN** menu, touch **[MAINTENANCE]**, then **[FLUIDICS]**.

These options are described for as-needed use during troubleshooting.

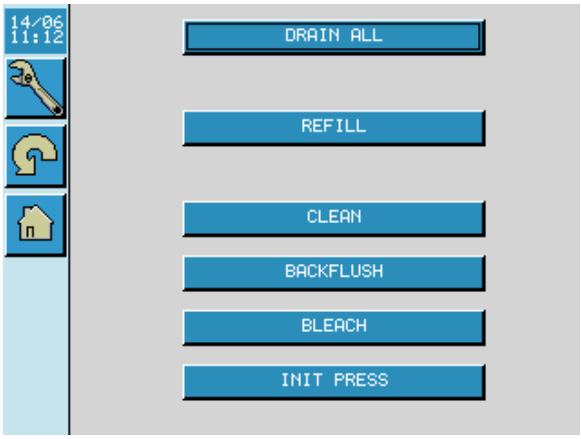
DRAIN ALL – Drains the counting chambers and the Waste/Vacuum Syringes. **REFILL** – Refills the counting chambers. **CLEAN** – Cleans the Apertures and Counting Chambers with Cleaner Reagent. **BACKFLUSH** – Applies backpressure to the apertures. **BLEACH** – Initiates the Bleach Cleaning cycle. **INIT PRESS** – For Abbott Service use only.	

Figure 9.8 Fluidics Menu

NOTES

Preventive Maintenance Schedule

The CELL-DYN Emerald does not require routine daily or weekly maintenance.

Monthly Maintenance

Bleach Cleaning

Cleaning the system with a bleach solution is performed monthly or as needed when a measurand is repeatedly rejected.

Materials Required

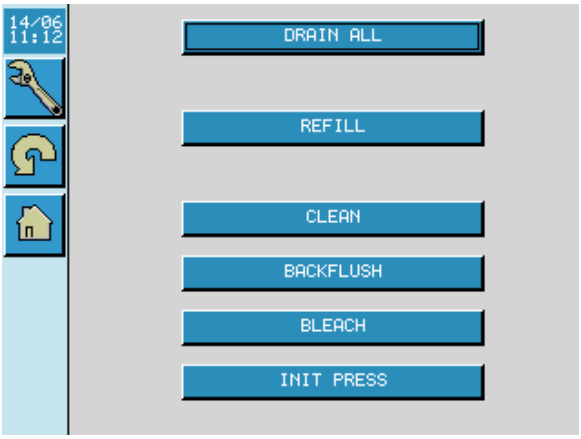
- Powder-free gloves, lab coat, safety glasses
- Sodium hypochlorite (undiluted, unscented purchased bleach)
- Plastic transfer pipette or other disposable pipette with 2 mL capacity
- Flat screwdriver

Prepare a 3.6% sodium hypochlorite (bleach) solution according to the formula in **Appendix C**. Transfer the prepared solution to the squirt bottle.

Procedure

Access the bleaching function as follows:

1. From the **MAIN** menu**,** touch **[MAINTENANCE]** to display the **MAINTENANCE** menu.
2. From the **MAINTENANCE**, touch **[FLUIDICS]** to display the **FLUIDICS** menu**.** (shown at the right)
3. From the **FLUIDICS** menu, touch **[BLEACH]** to start the bleaching process and drain the counting chambers.



When the warning window displays, proceed as follows:

4. Open the instrument's right side door using the flat screwdriver/key.
5. Measure 2mL of the prepared bleach solution into each counting chamber as shown, touch **[OK]**.
6. When the information box indicates , close the right side door using the flat screwdriver/key, and touch **[OK]**.
7. The instrument automatically draws the bleach through the apertures and then goes into a Stand-By mode for two minutes.
8. At the end of the Stand-By mode, the instrument automatically rinses the bleach out of the system.
9. When the status LED turns green the cycle is complete. Perform a Start Up and verify that all measurands are within specifications before running patient or other samples.
10. Run QC and verify that results are within specifications.
11. The instrument is now ready to run specimens.
12. Document the maintenance on the Maintenance log.

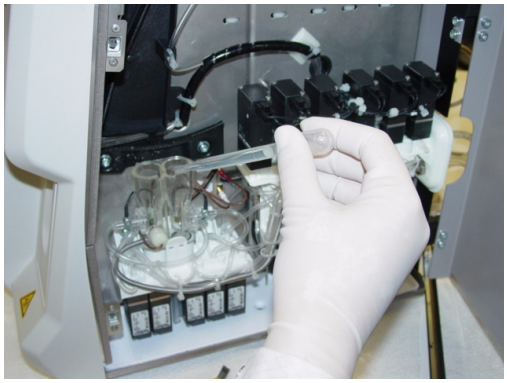


Figure 9.9 Bleach Cleaning

Semi-Annual Maintenance

Lubricating the Pistons

For optimal operation, the Syringe Pistons should be lubricated every six months as described below.

- Short arm T20 torx tool

NOTE: This procedure is used only for the 4 white teflon syringe pistons. The metal sample syringe piston should not be lubricated.

Materials Required

- Powder-free gloves, lab coat, safety glasses
- Silicone Grease supplied in the Installation Kit
- Short Arm Torx T20
- Flat screwdriver / key

Procedure

Move the syringe pistons to the lubrication position as follows:

1. From the **MAIN** menu, touch **[MAINTENANCE]** to display the **MAINTENANCE** menu.
2. From the **MAINTENANCE** menu, touch **[MECHANICAL CHECKS],** then touch **[LUBRICATION POS.]** to move the syringe pistons to the lubrication position.

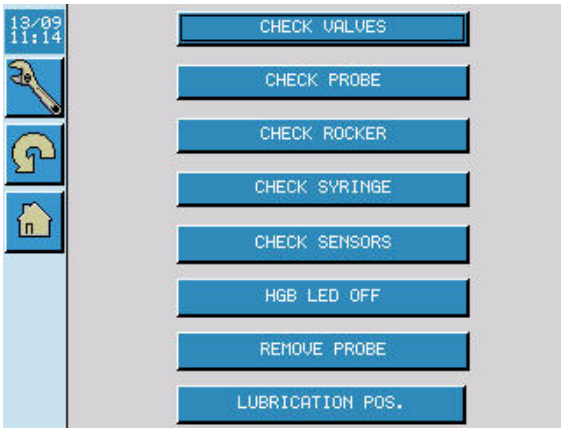


Figure 9.10 Mechanical Checks Menu

When the warning window displays, CONTINUE, proceed as follows:

3. Open the instrument's right side door using the flat screwdriver / key.
4. Put a small amount of lubricant on your fingertip.
5. Apply a thin film of lubricant around the white teflon pistons as shown. Small pistons (lyse (1) and diluent (3)) can be turned with your fingertips. The large pistons (Waste Syringes (2)) can be turned with the Short Arm Torx T20 Tool provided in the Service Kit. Insert the Torx Tool into the socket at the bottom of the syringes to turn the Waste Syringes.
6. When all pistons are lubricated, close the right side door using the key.
7. Touch **[OK]** on warning window to return the pistons to their operational position.
8. Run a background count and QC, verify that results are within specifications before processing any samples.
9. Document the maintenance on the Maintenance Log.
10. Touch **HOME** icon to go back to the **MAIN** menu.

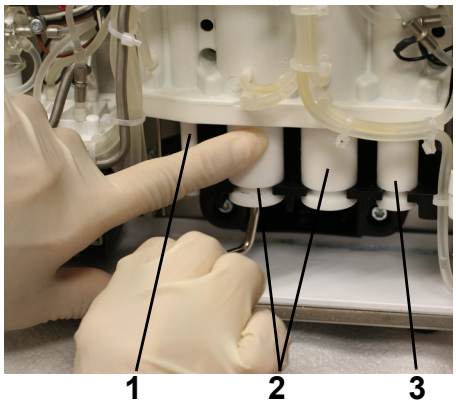


Figure 9.11 Lubricating the Syringe Pistons

As Needed Maintenance

Emergency Stop

If there is a mechanical or fluidic problem, press the **ON/OFF** button to immediately stop the instrument. Under certain conditions, the system may halt due to an internally detected fault condition. In either situation, when the problem is corrected, it is necessary to initialize the system. Before initializing the system, respond to any pop-up messages displayed. This function is accessible from the **MAINTENANCE** menu as shown in the following Figure.

Initialize System

To initialize the system after an Emergency Stop:

1. From the **MAIN** menu touch **[MAINTENANCE]**.
2. Touch **[INITIALIZE SYSTEM]**.
3. When initialization is complete, perform the Daily Start Up Procedures as described in **Section 5:** ***Operating Instructions*****, Subsection:** ***Daily Start Up Procedures***.

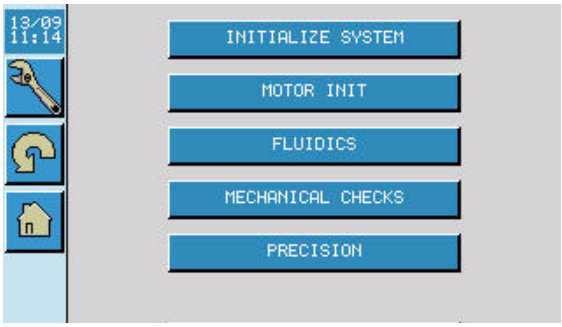


Figure 9.12 Maintenance Menu

Cleaning the cover

Material Required

- 0.5% Sodium Hypochlorite Solution
- Cotton gauze pads

Wipe the outside surfaces with a non-abrasive detergent cleaning solution to remove any soil. Then, wipe the surfaces with a tuberculocidal disinfectant, such as a 0.5% sodium hypochlorite solution. Instructions for preparing the hypochlorite solution are provided in **Appendix C**.

Preparing for Storage, Relocation or Shipping

Salt deposits and reagent residue can damage the fluidics if they are not removed before the CELL-DYN Emerald is stored (idle for two weeks or longer) or shipped. The System should be decontaminated prior to shipment or relocation.

The OSHA Bloodborne Pathogen Rule (29 CFR Part 1910.1030[1]) requires the decontamination of laboratory equipment prior to servicing or shipment. Wipe the surfaces of the System with a non-abrasive detergent cleaning solution to remove any soil. Then, wipe the surfaces with a tuberculocidal disinfectant such as a 0.5% sodium hypochlorite solution.

WARNING: Potential Biohazard. Consider all clinical specimens, reagents, calibrators, controls, or other materials and surfaces or components that contain or have contacted human-sourced material as potentially infectious. Wear gloves, lab coat, and safety glasses. Follow biosafety practices as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910.1030)[1] or other equivalent biosafety practices.[2, 3]

Materials Required

- Cotton gauze pads
- Three beakers, each filled with about 150 mL of deionized water (one for each reagent line)
- 0.5% sodium hypochlorite (bleach) cleaning solution (Refer to **Appendix C**)
- 3.6% sodium hypochlorite (bleach), for Clean Out cycle (Refer to **Appendix C**)
- Warm tap water
- Plastic bags – one each for diluent and waste tubing
- Packaging or cellophane tape
- Clean paper towels

Decontamination Procedure

1. Place 1 mL of the 0.5% sodium hypochlorite solution in a clean test tube, immerse the tip of the aspiration probe in the bleach solution, and touch **[RUN SAMPLE]** to decontaminate the fluidics.
2. When the instrument is ready for the next cycle, dampen a gauze pad with the 0.5% sodium hypochlorite solution and wipe the outside of the Aspiration Probe.
3. Initiate a **CLEAN OUT** cycle as follows:

NOTE: Use the 3.6% sodium hypochlorite (bleach) for these steps.

   a. From the **MAIN** menu touch **[MAINTENANCE]**
   b. Touch **[SYS CLEAN]** and follow the instructions step-by-step as displayed

4. When the cleaning procedure is completed, power off the instrument by pressing and holding the Power On/Off button until the display turns dark.
5. Remove the power cord from the rear of the instrument and then disconnect it from the power outlet.
6. Disconnect the AC Adapter from the power cord.
7. Disconnect the printer according to manufacturer's directions.
8. Disconnect the Diluent line from the rear of the instrument and allow any reagent in the line to drain into the container. Remove the cap from the container and remove the tubing. If necessary, wipe the outside of the tubing with a clean paper towel and then place the tubing in a plastic bag and close it.
9. Disconnect the waste line from the rear of the instrument and allow any waste in the line to drain into the container. Dispense 0.5% sodium hypochlorite solution into the tubing and allow it to drain into the waste container. Remove the cap from the container and remove the tubing. Rinse the tubing inside and out with warm running tap water. Wipe the outside with a clean paper towel, place the tubing in a plastic bag and close the bag.
10. Wipe the outside of the Cleaner and Lyse tubing with gauze dampened with deionized water.
11. Dispose of reagents, waste and containers according to your laboratory’s protocol.
12. Wipe the outside surfaces with a gauze pad dampened with 0.5% sodium hypochlorite, followed by a wipe with deionized water and drying with a paper towel.
13. Place the bags of tubing, power cord, AC Adapter and any other accessories in the accessory kit or a suitable container.
14. Store the instrument at temperatures within the range: 14°F to 122°F (-10°C to 50°C).
15. If the instrument is to be shipped, contact Abbott Diagnostics Customer Service for instructions.

Clean

The Clean procedure may be used for troubleshooting, as described in **Section 10: *Troubleshooting***. This is an automated process.

1. From the **MAIN** menu, touch **[MAINTENANCE]**.
2. Touch **[FLUIDICS]**.
3. Touch **[CLEAN]**.
4. When the Clean cycle is complete, the LED will turn green. Perform a Start Up to ensure backgrounds are within specifications before testing patient or control samples.

Backflush

The Backflush procedure may be used for troubleshooting, as described in **Section 10: *Troubleshooting***. This is an automated process.

1. From the **MAIN** menu, touch **[MAINTENANCE]**.
2. Touch **[FLUIDICS]**.
3. Touch **[BACKFLUSH]**.
4. When the Clean cycle is complete, the LED will turn green. Perform a Start Up to ensure backgrounds are within specifications before testing patient or control samples.

Sample Probe Removal and Replacement

Materials Required

- Powder free gloves, lab coat and safety glasses.
- Flat screwdriver / key
- Sampling Probe

WARNING: Potential Biohazard. The probe is sharp and potentially contaminated with infectious materials. Avoid contact with the tip of the probe.

Sample Probe Removal

1. From the **MAIN** menu, touch **[MAINTENANCE]**, **[MECHANICAL CHECKS]** then **[REMOVE PROBE]**.

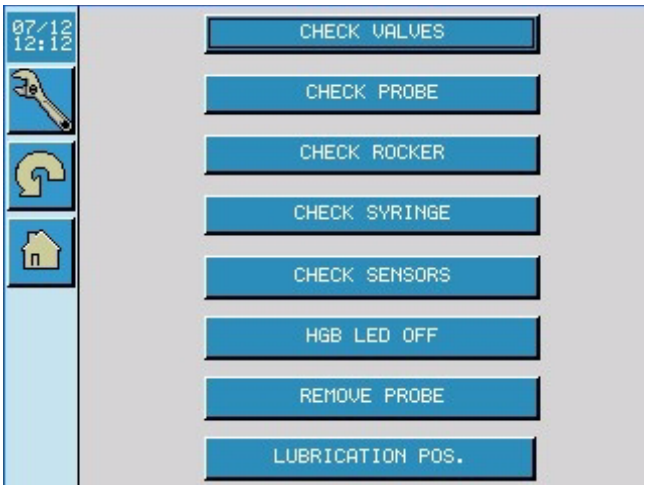


Figure 9.13 Sample Probe Removal

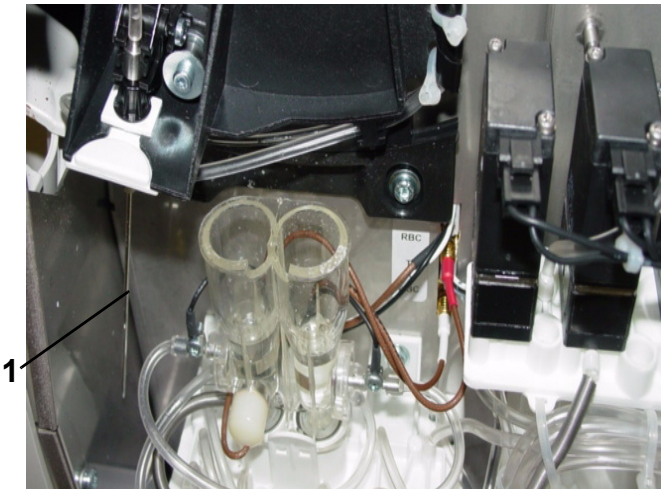
2. The rocker moves the sample probe to the disassembling position. When the warning pop-up displays **[CONTINUE]**, use the flat screwdriver to open the right side door to have access to the flow panel. **IMPORTANT:** Do not touch "**OK**" until replacement of the probe is complete. Turn the instrument so that the flow panel is facing you.	
3. The sample probe (1) is in front of the counting chambers.	

Figure 9.13 Sample Probe Removal (Continued)

4. To remove the sample probe, gently press down on the white plastic rinse head (1) and pull the rinse head and probe toward you until they disengage from the rocker.

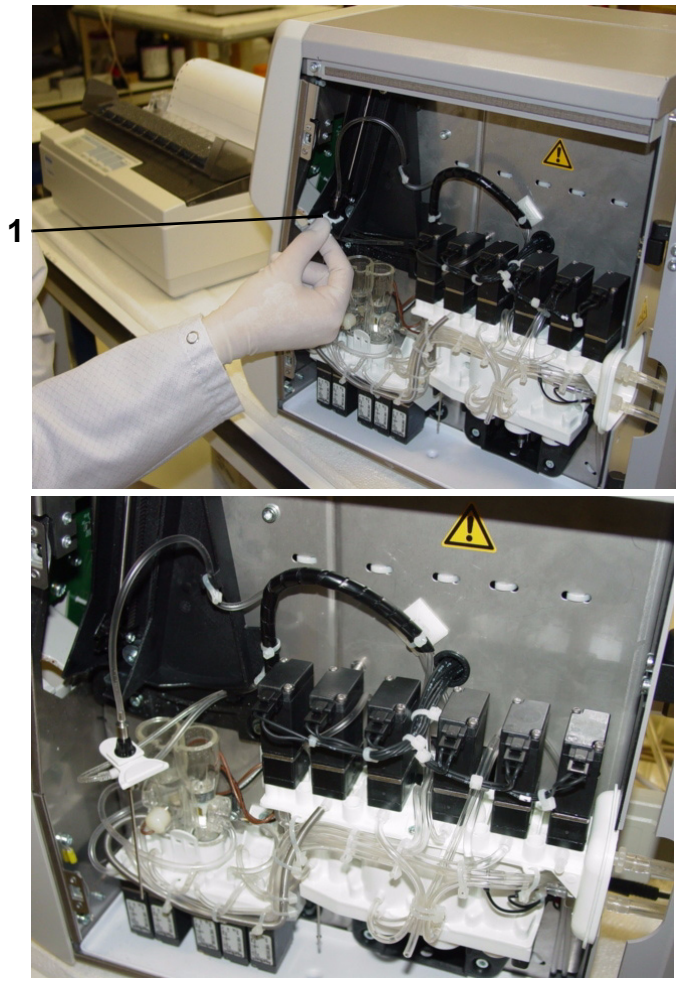


Figure 9.13 Sample Probe Removal (Continued)

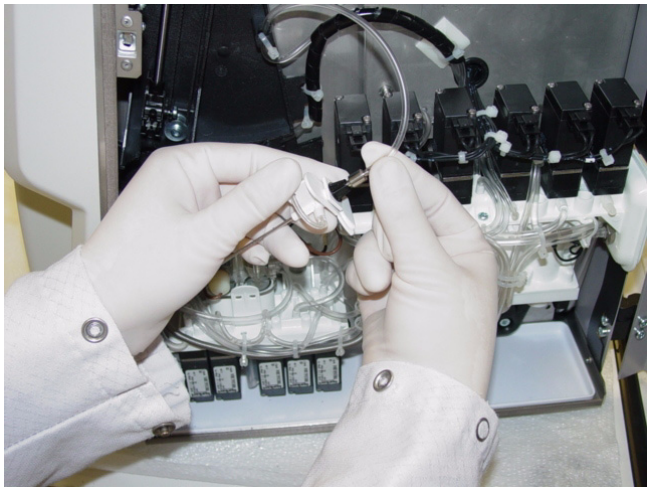
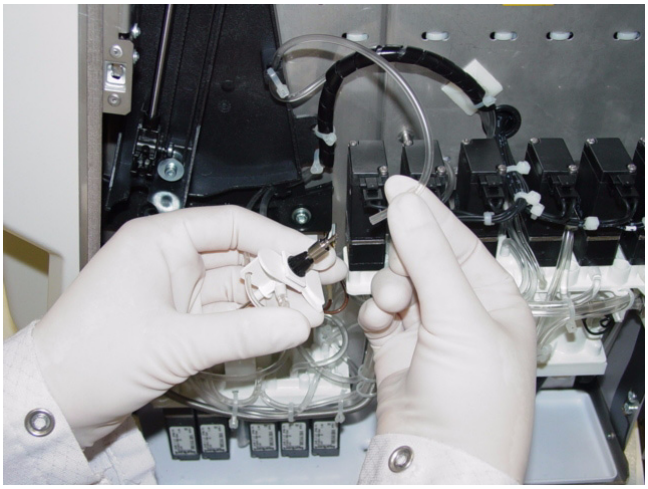
5. Disconnect the tubing from the top of the sample probe.	 
6. While holding the white rinse head with one hand, gently pull up on the sample probe until it is free from the rinse head.	
7. Dispose of the sample probe according to your laboratory's procedure.	

Figure 9.13 Sample Probe Removal (Continued)

Sample Probe Replacement

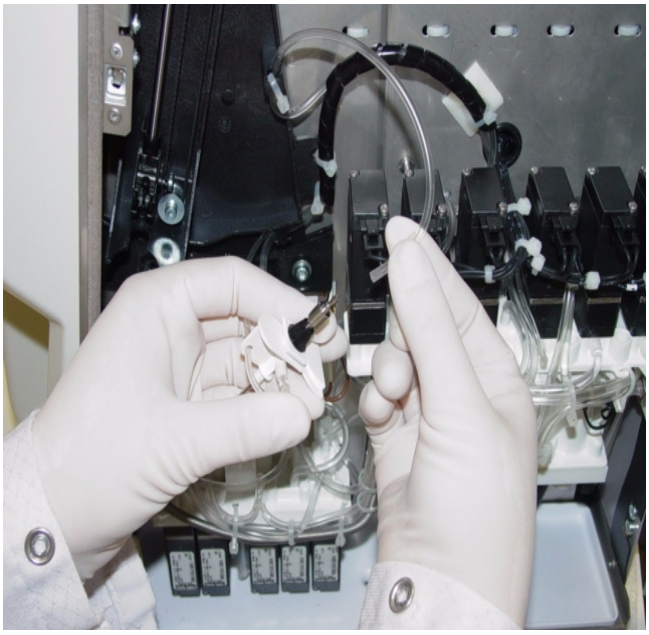
1. Holding the rinse head with the black fitting up, gently insert the probe from the top.	
2. Connect the tubing to the top of the sample probe. **NOTE:** If the tubing does not fit tightly at the probe connection disconnect the tubing from the probe, cut off up to 3mm of tubing and reconnect.	
3. Insert the rinse head into the rocker and press gently to make sure it is fully seated. Gently press the wide part of the sample probe above the rinse head to ensure that it is clipped into the rocker.	
4. Close and latch the right side door. Touch **[OK]** on the display.	
5. Run a background count and QC, verify that results are within specifications before processing any samples.	

Figure 9.14 Sample Probe Replacement

References

1. US Department of Labor, Occupational Safety and Health Administration. 29CFR Part 1910.1030. *Occupational Exposure to Bloodborne Pathogens.*
2. World Health Organization. *Laboratory Biosafety Manual*. Geneva: World Health Organization, 1993.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections*; Approved Guideline – Third Edition. CLSI document M29-A2 (ISBN 1-56238-567-4). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA, 2005.

NOTES

Overview

This section provides information for use in troubleshooting instrument problems. The CELL-DYN Emerald continuously monitors system status and provides instrument alarms and warnings when problems are detected.

NOTES

General Information

Conditions that are instrument-or reagent-related will usually be seen on all specimens, including controls. When patient results are suspect, it is important to confirm instrument performance by running controls. If control results are also suspect, troubleshoot as directed in this section.

WARNING: Potential Biohazard. Follow established biosafety practices when performing maintenance, service, or troubleshooting procedures. Refer to **Section 8: *Hazards*** for additional information.

Troubleshooting Guide

Understanding normal instrument operation is essential for identifying and resolving operational problems. Effective troubleshooting requires a logical, step-by-step approach to problem solving. Logical troubleshooting can be divided into three steps:

1. **Problem Identification** – requires the Operator to investigate not only what is wrong but to note what is right. The investigation should identify the problem area and eliminate areas that are working correctly. When this step is done, move to the next step.
2. **Problem Isolation** – further classifies an instrument problem. Problems are generally divided into three categories:

- Measurement-related to sample analysis
- Software-related
- Hardware component-related

Hardware and software problems may or may not be operator-correctable with technical assistance. Measurement problems are generally operator-correctable. They are further divided into problems related to sample handling, maintenance or calibration.

3. **Corrective Action** – involves taking appropriate steps to correct the problem. If the operator can correct the problem, with or without technical assistance, normal operation can quickly resume.

If additional information or assistance is needed, technical assistance can be obtained by contacting Abbott Customer Service as described in the Foreword of this manual. This is always facilitated by providing sufficient information and a clear and detailed description of the problem. When assistance is needed, please be prepared to provide the following information:

- Instrument model name
- Instrument serial number
- Software version in use
- Description of the problem
- Any alarms or error messages that are displayed
- Lot numbers and expiration dates of reagents, calibrators and controls currently in use
- Instrument maintenance history
- Examples of data to facilitate the discussion, such as, data from quality control runs, patient data, data from the last calibration, etc.

Troubleshooting Tables

The following tables are included in this section:

Table 10.1: Measurand-related problems

Table 10.2: Instrument-related problems

Table 10.3: Alarm messages

Each table lists the problem and suggested corrective action.

Troubleshooting Log

An example of a Troubleshooting Log is provided in **Appendix E: *Sample Logs and Worksheets***. This log can be used to keep a record of troubleshooting observations and problem resolution and can be photocopied as needed. This record can be useful for providing troubleshooting guidance.

Table 10.1 Measurand-Related Problems

NOTE: This table can be used for troubleshooting of patient results or QC.

Measurand	Problem	Corrective Action
WBC	No WBC and HGB results WBC Clog Error (W-CL)	1. Check the lyse reagent to be sure it is not empty or expired. 2. Check the lyse tubing connection to the WBC counting chamber. 3. Check the wires attached to the WBC counting chamber to be sure they are connected.
	No WBC result, HGB is OK WBC Clog Error (W-CL)	1. Perform Back Flush. 2. Perform Clean. 3. Perform Bleach Cleaning. 4. Perform a Shut Down and then a Start Up. 5. Check the wires attached to the WBC counting chamber to be sure they are connected.
	Imprecise, Inaccurate results or false Suspect Population Flags	1. Verify all samples are well-mixed prior to analysis. 2. Verify that Cleaner & Lyse connections are correct. 3. Perform a Shut Down and then a Start Up. 4. Perform Back Flush. 5. Perform Clean. 6. Perform Bleach Cleaning. 7. Look for evidence of leakage (liquid or dried reagent or blood) below the syringe block.

Table 10.1 Measurand-Related Problems (Continued)

NOTE: This table can be used for troubleshooting of patient results or QC.

Measurand	Problem	Corrective Action
RBC	No RBC, HCT or PLT results RBC Clog Error (R-CL)	1. Perform Back Flush. 2. Perform Clean. 3. Perform a Shut Down and then a Start Up. 4. Check the wires attached to the RBC counting chamber to be sure they are connected. 5. Perform Bleach Clean.
	Imprecise or inaccurate RBC, HCT and PLT results	1. Verify samples are well-mixed prior to analysis. 2. Perform Back Flush. 3. Perform Clean. 4. Perform a Shut Down and then a Start Up. 5. Perform Bleach Cleaning. 6. Look for evidence of leakage (liquid or dried reagent or blood) below the syringe block.
HGB	No results	1. Run a Start Up Cycle.
	Imprecise results	1. Check that there are no bubbles in the lyse tubing. 2. Perform Bleach Cleaning.
	Rejected results ---- *	1. Be sure the right side door is closed. 2. Run a Start Up cycle.
PLT	Imprecise or Inaccurate results	1. Perform Back Flush. 2. Perform Clean. 3. Perform Bleach Clean. 4. Verify reagent connections.
	Elevated background	1. Prime diluent.

Table 10.2 Instrument-Related Problems

Source	Problem	Corrective Action
CELL-DYN Emerald	Diluent leaks around the Aspiration Probe during the Run cycle.	Contact Abbott Customer Service.
	No power	Check the connections of the power cord to the instrument and AC Adapter. Check the connection of the AC Adapter to the power outlet.
	All results appear erroneous	Check the Diluent level and be sure the tubing is not pinched.
	No display	1. Press the Standby Button. 2. Call Abbott Customer Service.
	Unable to enter ID and/or PID	1. Check the settings. Touch **[SET UP]**, followed by **[ADVANCED],** followed by **[REPORTING OPTIONS]**. Note that a supervisor password is required to access the **ADVANCED SET UP** menu.
	Touch screen is unresponsive	Calibrate touch screen 1. Invoke Touch Screen Calibration by simultaneously pressing the "**.**" key and the " ← **DEL**" key on the numerical keyboard. 2. Touch the center of the cross shown on the screen. 3. Repeat Step 2 for two more screen locations. When complete, the Touch Screen Calibration returns to the original menu.
Printer	Printer does not print	1. Check the paper and then check the electrical connection. 2. Verify that the correct printer is configured in Setup.
	Print quality is bad	1. Check and/or replace the printer ribbon or cartridge.

Table 10.3 Alarm Messages

Message	Corrective Action
BACKUP: NO MEMORY AVAILABLE FOR STORAGE	Print and/or save results, then delete stored results.
BACKUP: PRECISION HISTORY IS FULL	Print and/or save Precision results and report, then delete stored results.
BACKUP:INCORRECT FOLDER DUPLICATION	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
BACKUP:CALIBRATION HISTORY IS FULL	Print and/or save calibration results and report, then delete stored results.
BACKUP:ERROR HISTORY IS FULL	Contact the Abbott Customer Support Center.
BACKUP:FILE SYSTEM FAILED	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
BACKUP:FOLDER NOT FOUND	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
BACKUP:LAST QC RESTORED	Indicates that QC has been restored.
BACKUP:LAST RESULTS RESTORED	Indicates that results have been restored.
BACKUP:LAST SETUP RESTORED	Indicates that SETUP values have been restored. No action required.
BACKUP:MEMORY ALMOST FULL. PLEASE DELETE RESULTS	Print and/or save results, then delete stored results.
BACKUP:QC HISTORY IS FULL	Print and/or save QC results and report, then delete stored results.
BACKUP:SECTOR FAILED	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
BACKUP:SETUP UPDATED WITH DEFAULT VALUES	Indicates that SETUP values have been restored to the default values.
BACKUP:SYSTEM ERROR	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
CLEAN NOT DONE	Perform a Clean cycle.
CLEANER REAGENT LOW	A Reagent Low Warning will be displayed when the reagent capacity is less than or equal to 25 samples. Press OK to continue or replace reagent.

Table 10.3 Alarm Messages (Continued)

CLEANER REAGENT IS EXPIRED. PLEASE REGISTER A NEW CONTAINER OF CLEANER REAGENT.	Replace the bottle and prime cleaner.
CLEANER REAGENT IS EMPTY. PLEASE REGISTER A NEW CONTAINER OF CLEANER REAGENT.	Replace the bottle and prime cleaner.
COM:CHECKSUM ERROR	Contact the Abbott Customer Support Center.
CRC CONTROL ERROR	Retry executing function. If not resolved, contact the Abbott Customer Support Center.
CONTROL CYCLE NOT DONE	Run an Initialization cycle.
CYCLE BAD PARAMETER INPUT	Alarm message for HGB entry.
CYCLE BUSY	Wait until LED is green before initiating the cycle.
CYCLE STOPPED BY USER	Initialize the system.
CYCLE: FLUIDIC DOOR OPENED	Close door and latch using the screwdriver. Initialize system.
CYCLE: EMERGENCY STOP	Initialize the system.
CYCLE: INIT NOT DONE	Initialize the system.
CYCLE:CMD FAILED	Contact the Abbott Customer Support Center.
CYCLE:PRESSURE DEFAULT	Check for empty reagents and replace if necessary. Check for disconnected tubing and reconnect, if needed. If not resolved, contact the Abbott Customer Support Center.
CYCLE:VALVE 1 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 2 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 3 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 4 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 5 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.

Table 10.3 Alarm Messages (Continued)

CYCLE:VALVE 6 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 7 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 8 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 9 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 10 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
CYCLE:VALVE 11 FAILED	Restart the Emerald. If not resolved call Abbott Customer Support Center.
DILUENT REAGENT IS EMPTY. PLEASE REGISTER A NEW CONTAINER OF DILUENT REAGENT.	Replace the container and prime Diluent.
DILUENT REAGENT LOW	A Reagent Low Warning will be displayed when the reagent capacity is less than or equal to 25 samples. Press OK to continue or replace reagent.
DILUENT REAGENT IS EXPIRED. PLEASE REGISTER A NEW CONTAINER OF DILUENT REAGENT	Replace the container and prime Diluent.
HGB CHANNEL SATURATION. PLEASE RUN A START UP.	Run a Start Up. If not resolved, call Abbott Customer Support Center.
HARDWARE:SYSTEM ERROR	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
HOST: TIME OUT	Re-start the Emerald.
NAME AND/OR PID MANDATORY	Enter an ID and/or PID.
INIT PRINTER	Verify that printer power is on, verify connections are correct, verify settings in Set Up. If not resolved, contact the Abbott Customer Support Center.
INITIALIZATION NOT DONE	Initialize the system.
INPUT PARAMETER FOR X (parameter specific) IS INCORRECT. ENTRY IS LIMITED TO Y (parameter specific) DECIMAL PLACE.	This message is parameter specific. Verify the parameter value being entered. Retry entering value with parameter specific decimal place.

Table 10.3 Alarm Messages (Continued)

INTERN: COUNT ERROR	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
INTERN: RESULT AREA IS LOCKED	Wait until LED is green before initiating the cycle.
INTERN:MEMORY CORRUPTED	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
INTERN:NO MEMORY AVAILABLE	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
LYSE REAGENT IS EMPTY. PLEASE REGISTER A NEW CONTAINER OF LYSE REAGENT.	Replace the bottle and Prime Lyse.
LYSE REAGENT LOW	A Reagent Low Warning will be displayed when the reagent capacity is less than or equal to 25 samples. Press OK to continue or replace reagent.
LYSE REAGENT IS EXPIRED PLEASE REGISTER A NEW CONTAINER OF LYSE REAGENT	Replace the bottle and Prime Lyse.
LAST RESULT SAVED	Print and/or save results, then delete saved results.
MECH: HOME NEEDLE NOT FOUND	Initialize the system.
MECH: MOTOR ROCKER GAP	Initialize the system, if not resolved, Contact the Abbott Customer Support Center.
MECH: MOTOR SYRINGE GAP	Initialize the system, if not resolved, Contact the Abbott Customer Support Center.
MECH: MOTOR NEEDLE GAP	Initialize the system, if not resolved, Contact the Abbott Customer Support Center.
MECH: PROBE NOT IN TOP POSITION	Initialize the system, if not resolved, Contact the Abbott Customer Support Center.
MECH:HOME ROCKER NOT FOUND	Initialize the system, if not resolved, Contact the Abbott Customer Support Center.
MECH:HOME SYRINGE NOT FOUND	Initialize the system, if not resolved, Contact the Abbott Customer Support Center.
MECH:MOTOR NEEDLE BUSY	Restart the Emerald and perform a Start Up cycle. If not resolved, contact the Abbott Customer Support Center.

Table 10.3 Alarm Messages (Continued)

MECH:MOTOR SYRINGE BUSY	Restart the Emerald and perform a Start Up cycle. If not resolved, contact the Abbott Customer Support Center.
NO PRINTER RESPONSE	Verify that printer power is on, verify connections are correct, verify settings in Set Up. If not resolved, contact the Abbott Customer Support Center.
NO PRINTER SELECTED	Verify printer settings in Set Up, check for correct printer driver. If not resolved, contact the Abbott Customer Support Center.
OUT OF RANGE	Check the value and re-enter.
PRINTER ERROR	This error will occur if the system is configured for a printer, but no printer is connected to the analyzer. Verify that printer power is on, verify connections are correct, verify settings in Set Up. If not resolved, contact the Abbott Customer Support Center.
PRINTER IS BUSY	Wait until current print job is complete then repeat Print request.
PRINTER:NO DRIVER ON	Contact the Abbott Customer Support Center.
PRINTER:NO PAPER	Add paper to printer.
PRINTER IS OFF	Turn the printer On.
REFILL NOT DONE	Perform a Refill cycle.
HOST:ACK ERROR	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
COM:INTERNAL ERROR	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
HOST:SYNCRO ERROR	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
RUNNING AUTO CLEANING	Wait until LED is green before initiating the cycle.
START UP CYCLE FAILED	Perform another Start Up cycle, up to two times. If not resolved, contact the Abbott Customer Support Center.
START UP CYCLE NOT DONE	Run a Start Up cycle.
SYSTEM:BUSY	Wait until LED is green before initiating the cycle.

Table 10.3 Alarm Messages (Continued)

SYSTEM:EEPROM COM ERROR	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
SYSTEM:FATAL ERROR	Restart the Emerald and perform a Start Up cycle. If not resolved, contact the Abbott Customer Support Center.
SYSTEM:INTERNAL TIME OUT	Contact the Abbott Customer Support Center.
THE DILUENT REAGENT LOG IS FULL.	Reagent log must be deleted. Contact Abbott Customer service.
THE LYSE REAGENT LOG IS FULL.	Reagent log must be deleted. Contact Abbott Customer service.
THE CLEANER REAGENT LOG IS FULL.	Reagent log must be deleted. Contact Abbott Customer service.
SYSTEM:UNKNOWN ERROR	Restart the Emerald. If not resolved, contact the Abbott Customer Support Center.
THE PRINTER IS OFF	Turn printer power on.
UNKNOWN COMMAND	Contact the Abbott Customer Support Center.
USB:UNABLE TO OPEN FILE	Read error. Try again. Format flash drive or replace it.
USB: EXTERNAL STORAGE DEVICE IS FULL	Delete files or replace flash drive.
USB:EMPTY FILE	Check the USB storage device.
USB:EXTERNAL STORAGE DEVICE IS NOT PRESENT	Connect flash drive.
USB:WRITE PROTECTED FILE	Check the USB storage device.
USB:DIRECTORY DOES NOT EXIST	Check the USB storage device.
USB: EXTERNAL STORAGE DEVICE I/O ERROR	Check the USB storage device.
FAILED TO LOAD THE REAGENTS LOG FILE. THE FILE IS NOT PRESENT OR UNVALID.	Check the USB storage device.
FAILED TO SAVE THE RESULT ONTO THE EXTERNAL STORAGE DEVICE. THE INTERNAL MEMORY IS USED INSTEAD.	Verify Storage device is present.
INVALID FORMAT	Reformat the USB storage device

Table 10.3 Alarm Messages (Continued)

THE LOT ALREADY EXISTS, ACTION IS ABORTED	Select another Lot.
MAXIMUM NUMBER OF FILES PER FOLDER IS REACHED. TO SAVE NEW FILES, OLDER FILES HAVE TO BE DELETED.	Delete some files on USB storage device.
VERSION RELEASE FAILED. THE CHOSEN RELEASE IS NOT COMPATIBLE WITH THE EMERALD SYSTEM.	Select correct version.
PRINTER DRIVER UPDATE FAILED. THE CHOSEN DRIVER IS NOT COMPATIBLE WITH THE EMERALD SYSTEM.	Select correct version.
NETWARE: SERVER INIT. FAILED	Check your analyzer configuration.
NETWARE: CLIENT INIT. FAILED	Check your analyzer configuration.
A USB THUMB DRIVE IS ALREADY MOUNTED ON PORT 2. PLEASE REMOVE THE THUMB DRIVE FROM THE PORT 1.	Remove extra flash drive.
A USB THUMB DRIVE IS ALREADY MOUNTED ON PORT 1. PLEASE REMOVE THE THUMB DRIVE FROM THE PORT 2.	Remove extra flash drive.
THE USB THUMB DRIVE FILE SYSTEM IS NOT COMPATIBLE WITH THE EMERALD. EITHER REMOVE IT OR FORMAT IT.	Format or replace flash drive.
THE USB DEVICE PLUGGED IN PORT 1 IS NOT COMPATIBLE WITH THE EMERALD. PLEASE REMOVE IT FROM PORT 1.	Format or replace flash drive.
THE USB DEVICE PLUGGED IN PORT 2 IS NOT COMPATIBLE WITH THE EMERALD. PLEASE REMOVE IT FROM PORT 2.	Format or replace flash drive.
A USB PRINTER IS ALREADY PLUGGED IN PORT 2. PLEASE REMOVE THE PRINTER FROM THE PORT 1.	Remove the unused printer cable.
A USB PRINTER IS ALREADY PLUGGED IN PORT 1. PLEASE REMOVE THE PRINTER FROM THE PORT 2.	Remove the unused printer cable.

References

1. US Department of Labor, Occupational Safety and Health Administration. 29CFR Part 1910.1030. *Occupational Exposure to Bloodborne Pathogens.*
2. World Health Organization. *Laboratory Biosafety Manual*. World Health Organization, Geneva 2003.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers from Occupationally Acquired Infections*; Approved Guideline – Third Edition. CLSI document M29-A3 (ISBN 1-56238-567-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, 2005.

NOTES

Overview

Quality Control (QC) procedures are performed at a frequency needed to monitor System results trueness. Quality Control procedures, both internal and external, allow the operator to verify the performance of the analytical system. Evaluation of results from commercial and patient controls facilitates the interpretation of laboratory data to determine the acceptability of patient results. This section discusses:

- When to Run QC
- Quality Control Methods and Materials
- QC File Set Up
- QC Guidelines
- Running Controls
- Levey-Jennings Graphs

NOTES

When to Run QC

Each laboratory should determine the frequency of performing quality control runs with commercial controls and/or retained patient specimens. This may be specified by the regulatory agencies governing the laboratory. Quality Control specimens must be run and results confirmed to be within acceptable limits before reporting patient results. Abbott recommends you, run controls:

- After daily Start Up procedures are completed and background counts are within specifications
- After a reagent lot number change
- After calibration (confirmatory step)
- When there is an unusual shift or trend in patient results
- After performing maintenance, a service call or component replacement
- After a software change or upgrade
- According to your laboratory's quality control protocol
- According to regulatory requirements

Quality Control Methods and Materials

Internal QC Methods consist of running commercial control material or retained patient specimens.

- Commercial controls contain fixed cells and are assayed by the manufacturer to determine expected recovery ranges. Abbott recommends CELL-DYN Control Materials for use on the CELL-DYN Emerald System. A tri-level control is available that provides three levels of monitoring for each measurand; the number of controls used is determined by each laboratory. Refer to **Appendix A: *Accessories*** for information on CELL-DYN Controls used with the CELL-DYN Emerald System.
- Patient controls are retained patient specimens with results that fall within the laboratory's defined ranges. They are tested by the laboratory to establish recovery against defined target ranges. They provide an accurate and cost-effective means of evaluating system performance.

External QC methods use resources available outside the laboratory to assess system performance. These programs use a peer-review process to allow a laboratory to compare its performance with that of other laboratories. For example, in the USA, laboratories are required to participate in proficiency testing programs. Proficiency testing provides independent validation of a laboratory's internal QC program.

QC File Setup

Six QC files are available on the CELL-DYN Emerald. Each file stores 100 results and the instrument automatically calculates the Mean, Standard Deviation and Coefficient of Variation % for those results. Levey-Jennings graphs are automatically plotted for each file. QC files are accessed from the **MAIN** menu by touching **[QUALITY CONTROL]**.

Overview of the QC window.

The **LOTS** window, shown at the right, shows the lot number for each file.

1. The last file that was used is identified with a dot in the circle to the left of the lot number.

NOTE: If files have not been set up, touch the file location (space next to the circle) to choose a file.

NOTE: The level of control (L=low, N=normal, H=high) material associated with each file is displayed to the right of the lot number. When the file is selected, a box appears surrounding the radio button and lot number. The selected level designation is not within the box.

2. Touch the lot number to select a file.
3. Touch **[EDIT]** to enter new Assay Values and Limits.
4. Touch **[RUN AND RESULTS]** to view file data.
5. Touch the **TOOLS** icon to print: Assays (and Limits), Results or Graphics (Levey-Jennings Graphs)
6. Touch **[SEND]** to send results to the LIS.
7. Touch **[EXIT]** to return to the previous screen.

NOTE: If using the instrument keypad arrows to navigate on this screen, it is necessary to press the **ENTER** key to complete the file selection.

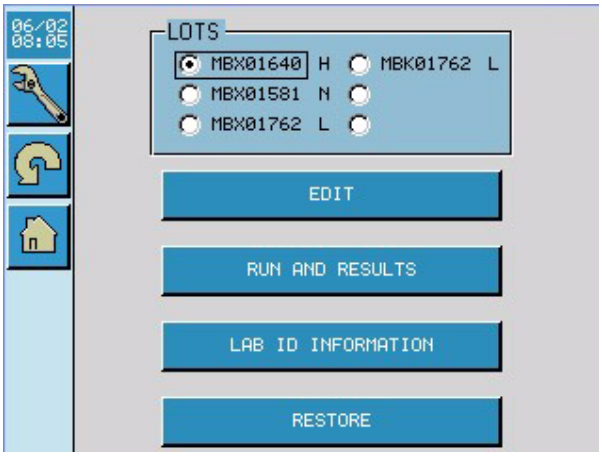
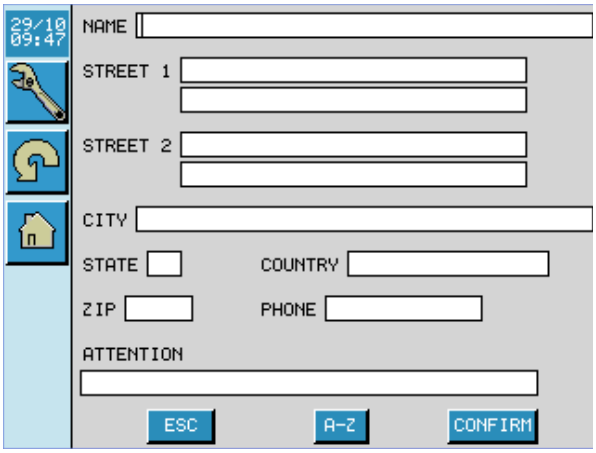


Figure 11.1 QC Window

The LAB ID INFORMATION button is used to input information used for eQC. For information about eQC, contact you local Abbott Customer Service.

1. Touch **[LAB ID INFORMATION]**.
2. Using the numeric keypad on the Emerald and/or the A-Z key to access the alphabetical screen keyboard, enter information in each displayed field. The NAME field is for the name of your facility. The ATTENTION field is used for the name of the person responsible for your laboratory's QC program.



NOTE: For proper eQC functionality, an entry must be made in each named field on the display. If a named field has two lines it is not necessary to enter information on both lines. If any named field is not applicable for your laboratory, enter a period, ".", in that field.

3. To save your entry, touch **[CONFIRM]**. At the Warning Pop-up: `DO YOU WANT TO SAVE MODIFICATIONS?` Touch **[YES]** to save or **[NO]** to return to the entry screen. To exit without saving, touch **[ESC]**.

The **[RESTORE]** button is used to load QC files that were backed up to an external storage device. Files can only be restored to the CELL-DYN Emerald on which they were created.

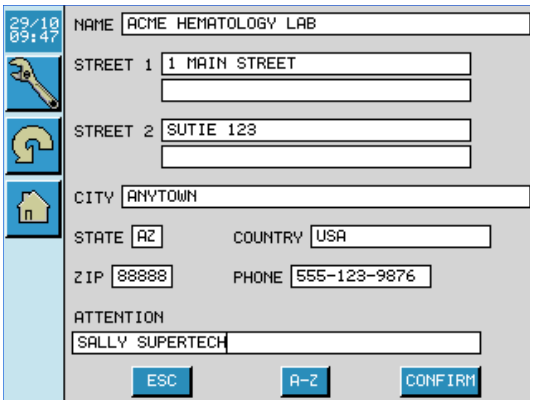
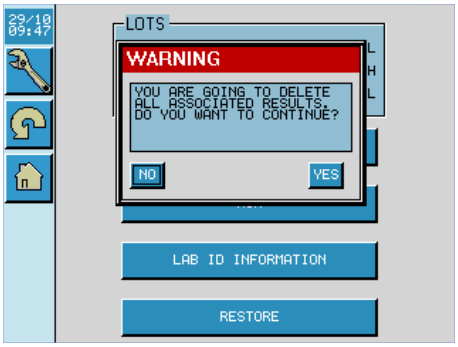
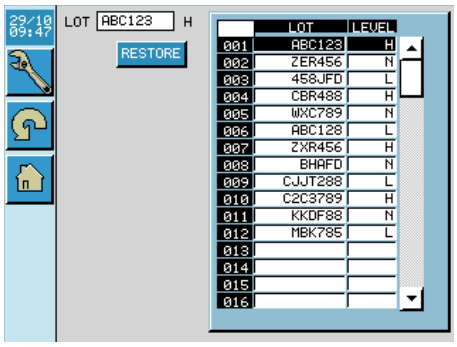


Figure 11.2 Lab ID Information

1. Touch the file to be used for the restored results. Note that if you select a file that has been previously used, restoring data will overwrite the current contents of that file. Thus, print, send or save the current results before proceeding.
2. Touch **[RESTORE]**. If the selected file contains data, you will see the Warning Pop-up: **`YOU ARE GOING TO DELETE ALL ASSOCIATED RESULTS.DO YOU WANT TO CONTINUE?`** If you have not already saved the current file data, touch **[NO]** and print the file before proceeding. If you are ready to delete results and proceed with restoring the file, touch **[YES]**.
3. Identify the file to be restored in the displayed table. Note that files are identified by lot number (LOT) and level (LEVEL) and each has a file sequence number listed to the left of the LOT.
4. To select a file, touch the corresponding file sequence number. The selected file will be highlighted and will also appear in the **<LOT>** field at the upper left of the display.
5. After verifying the selection, touch **[RESTORE]** to restore the file contents to the Emerald.





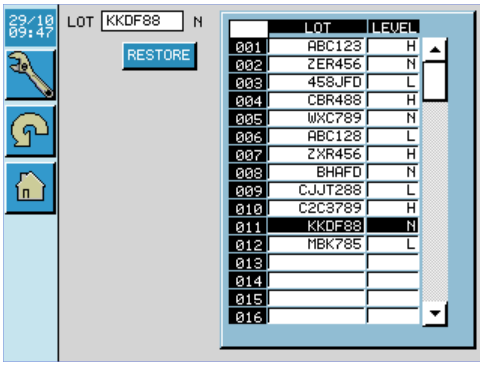


Figure 11.3 Restoring a QC file

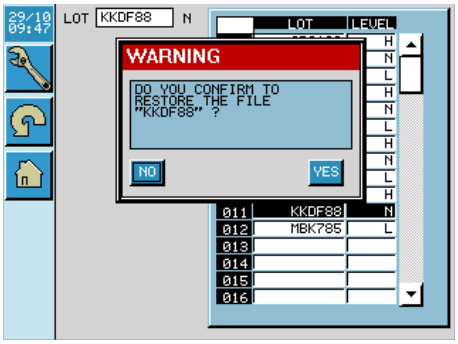
6. At the Warning Pop-up: **DO YOU CONFIRM TO RESTORE THE FILE "..."?**, touch **[YES]** to restore or **[NO]** to return to the restore selection screen. 7. When you return to the QC screen, the restored file name will appear in the LOTS area of the display at the selected file location.	

Figure 11.3 Restoring a QC file (Continued)

Entering QC Assay Values and Limits

QC Assay values and limits are entered as described below.

Files may be arranged in any order but it is suggested that the first three files be configured for the low, normal and high levels, respectively. The remaining three files can be used at the laboratory's discretion.

NOTE: Before entering information for a new lot number, ensure that all results have been printed for the current lot number. Results will be deleted when new information is entered. Only the assay and limit values may be edited without deleting all results from the QC file.

1. Touch the file location followed by **[EDIT]** to display the entry screen.
2. Touch the **<LOT>** entry field and use the numeric keypad to enter the lot number. If the lot number contains an alpha character, touch **[A-Z]** and use the alphabet and numeric keypad to enter the lot number. Press the **ENTER** key on the keypad to advance the cursor to the next entry field, or touch each field to enter information.
3. The cursor moves to the **<EXPIRATION>** entry fields. Use the numeric keypad to enter the expiration date and press the **ENTER** key on the keypad after each entry to save it and advance the cursor.
   NOTE: Be sure to enter the date in the format selected when the instrument was installed.
4. Select the radio button (L for low, N for normal, or H for high) corresponding to the level of control for this QC file.
   NOTE: Backup, restore & eQC (For information about eQC, please contact Abbott Diagnostics Customer Service.) functions will not operate as expected unless the radio button is selected.
5. After selecting the QC level, touch the **<WBC>** entry field. Use the numeric keypad to enter the **ASSAYS** (Target or Assay Values) and **LIMITS** (+/- Mean Range or your calculated range), then press the **ENTER** key to save each entry and advance the cursor to the next field. Alternatively, you may touch **[LOAD]** to upload control assay values from a removable storage device.
   NOTE: For instructions on how to load assay values from a removable storage device, refer to **Section 5:** ***Operating Instructions***, **Subsection:** ***Uploading commercial Quality Control material information.***
   NOTE: The values entered for ASSAYS must be greater than those entered for LIMITS.
6. When entries have been verified to be correct, touch **[CONFIRM]**.
7. Touch the **TOOLS** icon, then **[PRINT]** to generate a permanent record of your settings.
8. A window displays asking if you want to save the modifications. Touch **[YES]** to save the entries or **[NO]** to return to the entry screen.
9. When **[YES]** is touched, a second window displays.
   a. If the selected file already contains data, the window notifies that all results will be deleted for the previous lot.
   Touch **[YES]** to continue or **[NO]** to return to the entry screen.
   b. If the file is empty, a processing pop-up window appears.
10. Set up additional files as directed above.

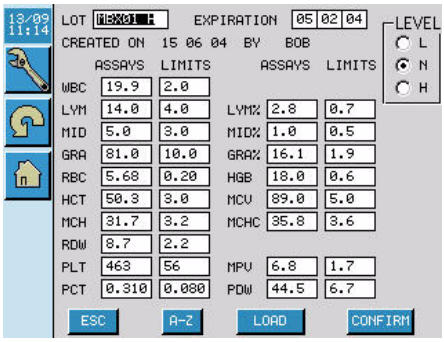


Figure 11.4 Targets and Limits Screen

QC Guidelines

General Information

Quality Control procedures must be performed in accordance with your laboratory's protocols, good laboratory practice, and according to regulatory requirements according to the following general guidelines:

- Before running patient specimens, run a minimum of two levels of control.
- Confirm that results are within acceptable limits and monitor the data for shifts and trends.
- If results fall outside acceptable limits, try another vial from the same lot. If results are still outside acceptable limits, refer to **Section 10: *Troubleshooting***.
- Always run controls in the same manner as patient specimens.

Control Material Guidelines

- Always mix and handle commercial controls according to the directions provided in the package insert. Proper handling and mixing are essential for accurate results.

Pay particular attention to the following:

- Check the condition of incoming control material. Be sure that vials are at the proper temperature and are not leaking. Check for hemolysis.
- If controls are stored inside a refrigerator, place them in a central location away from the door.
- Check the expiration date and open-vial Stability dating. Do not use products longer than recommended by the manufacturer or results can be compromised.

Normal Specimen Guideline: The Rule of Three

Because normal erythrocytes (RBC) are biconcave discs with a uniform quantity of hemoglobin (HGB) in each cell, there is a fairly constant numeric relationship involving RBC, HGB, and hematocrit (HCT)[5] that is informally known as the "rule of 3":

HCT = HGB X 3

HGB = RBC X 3

If there is no RBC pathology (*i.e.*, normal cell size, normal RBC hemoglobin concentration and no abnormal forms), a discrepancy in these numeric ratios suggests analytic error in one or more of the measurands. For example, a lipemic (fatty plasma) specimen may produce a falsely high HGB result due to turbidity interference; in this case the HCT:HGB ratio will be less than 3, while the HGB:RBC ratio will be greater than 3.

This “rule of 3” applies only to fresh normal human specimens, and not to commercial control materials.

Over the years, clinicians and technologists have used a quick mathematical check to ensure that HGB and HCT values are consistent. The HCT is roughly three times the HGB. This simple formula works only on specimens that are normochromic, normocytic (specimens with MCV and MCHC values within typical reference ranges). Typically, results from CELL-DYN instruments correlate within the narrow range of ± 3% on normal specimens. If the calculated HCT (HGB x 3) does not agree with the instrument value with an increasing frequency (>5%) of outliers, the system could be miscalibrated, malfunctioning or the specimen has pathology requiring further investigation.[1]

Running Controls

Before running controls, be sure the vials have been properly warmed and mixed according to the directions given in the manufacturer’s package insert.

NOTE: If a Start Up cycle has not been done, an error message will display indicating one must be run before running controls. It is not possible to run controls until the Start Up cycle is run.

From the **MAIN** menu**,** touch **[QUALITY CONTROL]**, access the QC file by touching the appropriate lot number and then touch **[RUN/ RESULTS]**.

1. Remove the cap from the control vial.
2. Immerse the aspiration probe in the control vial and press the start switch.
3. When the cycle LED turns red, the probe retracts.
4. Results are displayed in the upper part of the screen. The results are displayed with the most current run in the last row of the table. Numbers displayed in bold text are outside of the defined range for that measurand. Statistics are automatically calculated and shown at the bottom of the screen.

NOTE: The Numbers display or print in bold only if PANIC HIGH and PANIC LOW, in SETUP-ADVANCED-REPORTING OPTION has been configured.

5. Unacceptable results (for example, a short sample) can be removed from the calculation by touching the <SEL> entry field by the result.
6. Touch the **[QC LOT]** dropdown menu to select another file. Run the control as described above.

Comments:

1. Touch the scroll bar or the right **[>]** and left **[<]** arrow buttons below the results to display more data points. Touch **[<<]** or **[>>]** below measurands to display the remaining measurand results.
2. Touch **[LJ]** to display the Levey-Jennings graphs. Refer to **Subsection: *Levey-Jennings Graphs*** later in this Section for additional information.
3. Touch the **TOOLS** icon to print, send, save or delete results. Refer to the following **Subsection: *Use of Tools in the QC Menu*** for additional information.

   NOTE: Due to space limitations on the display, the MEAN, SD, and/or CV% are rounded. To view all digits used in the calculated values, touch the **TOOLS** icon and print the file. The MEAN, SD, and/or CV% on the printout are correct and, if there is an apparent discrepancy between the printed and displayed values, it is due to rounding only and the printed values should be used.

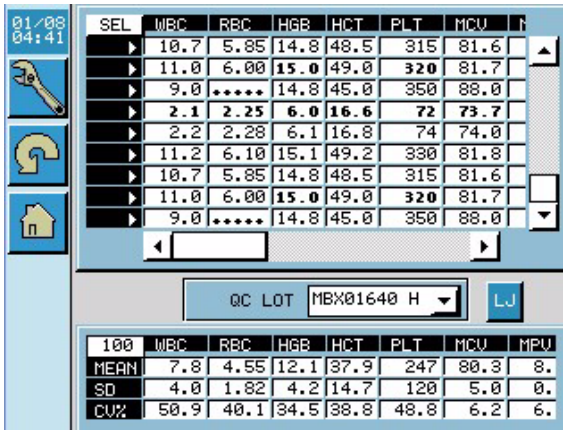


Figure 11.5 QC Results Screen

Use of Tools in the QC Menu

Printing QC Results

It is recommended to utilize the auto print feature so that the results of QC testing are printed for each run. Because results of QC testing are not stored in the Datalog, individual control results can only be printed at the time of testing or before another sample (QC, patient, or other). Summary reports may be printed at any time.

To print a QC result that has not been automatically printed, exit the **QUALITY CONTROL** menu by touching the **HOME** icon. Touch **[RUN SAMPLE]**. If no other tests have been performed since the QC run, the display will show the last QC results. Touch the **TOOLS** icon to print the result. Note that if another sample has been run since the last QC run, only a summary report can be printed.

To print a summary report of the contents of a QC file, touch the **TOOLS** icon and select **PRINT**. Note that use of this option does not print individual QC results.

For a Levey-Jennings report, touch the **[LJ]** button from the QC file, select **[TOOLS]**, then **[PRINT]**.

Sending QC Results

To send the contents of a QC file to the LIS, if configured, touch the **TOOLS** icon followed by the **[SEND]** button.

NOTE: If an empty file is selected when the PRINT command is made, a blank report will be printed.

Deleting QC Results

Each of the six control files stores up to 100 results.

The contents of a QC file are automatically deleted when certain fields of the file (expiration date, lot number, or limits) are edited.

Changing any field within a QC file by using the **[EDIT]** button will cause the system to prompt the user, **DO YOU WANT TO SAVE MODIFICATIONS?** If a modification has been made to the expiration date, lot number, or limits a second prompt will appear if the user has responded to **DO YOU WANT TO SAVE MODIFICATIONS?** with **[YES]**. The second prompt is a warning message, **YOU ARE GOING TO DELETE ALL ASSOCIATED RESULTS. DO YOU WANT TO CONTINUE?** Responding **[YES]** to this prompt will delete all results within this QC file.

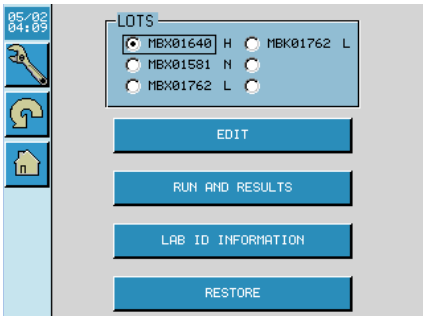
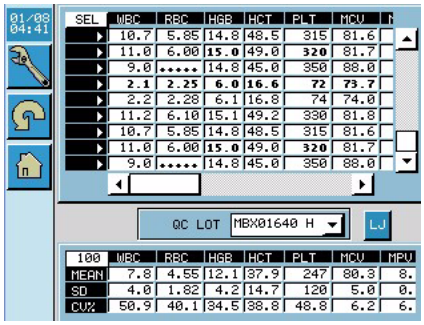
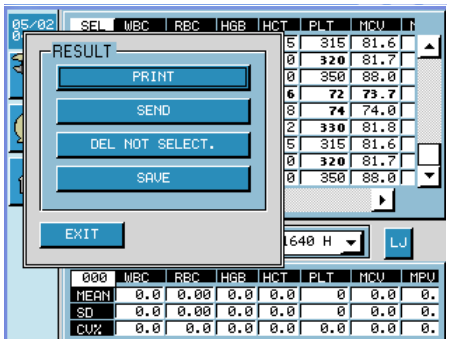
To manually delete results from a QC file: 1. From the **MAIN** menu, touch the **[QUALITY CONTROL]** button. 2. Touch the radio button to the left of the QC file you want to delete.	
3. Touch **[RUN AND RESULTS]**. Note that the SEL column in the display indicates that all results are selected. Before proceeding to the next step, touch the row in the SEL column corresponding to any QC results that you wish to delete. If you wish to select or deselect all results at once, touch the **SEL** box at the top of the column.	
4. Touch the **TOOLS** icon.	

Figure 11.6 Manually Deleting QC Results

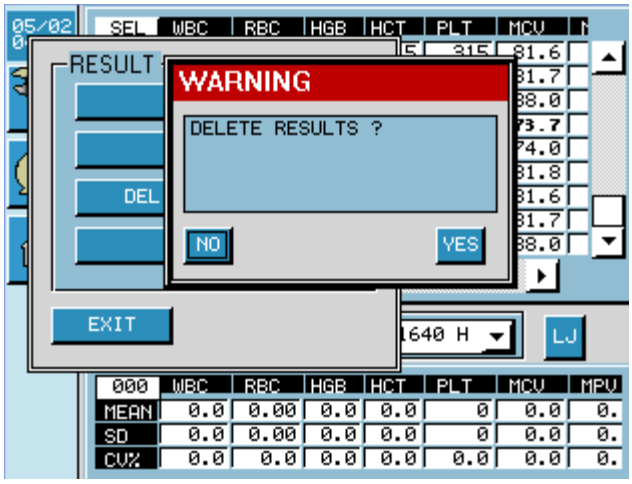
5. Touch the **[DEL NOT SELECT]** button to delete all “not selected” results, and touch **[YES]** to confirm deletion. Touch **[NO]**, followed by **[EXIT]** to exit without deleting results.	

Figure 11.6 Manually Deleting QC Results (Continued)

Saving QC Results

QC Results can be saved to a USB drive. For additional information, refer to **Section 5:** ***Operating Instructions***, **Subsection:** ***Saving Current QC Data***.

Viewing Results in the QC Menu

QC runs are added to the display in the RUN and RESULT screen at the bottom of the table. It is only possible to view a report with histograms for a QC run immediately after it has been tested and before any other samples have been tested.

Due to the size of the display, it is necessary to utilize scroll bars to view all measurands and results.

NOTE: To view date/time (hour) of QC runs, use the right/left scroll bar to scroll to the far right.

Viewing all QC Runs Within a File

The scroll bar at the right side of the display allows the operator to scroll up and down through multiple QC runs, with the oldest runs at the top of the table and the newest results at the bottom.

Viewing all Measurands Within the QC File

The scroll bar at the bottom of the result table is used to scroll right and left to view results for all measurands.

Viewing QC Statistics

Statistics associated with the data in a QC file are displayed at the bottom of the QC file screen.

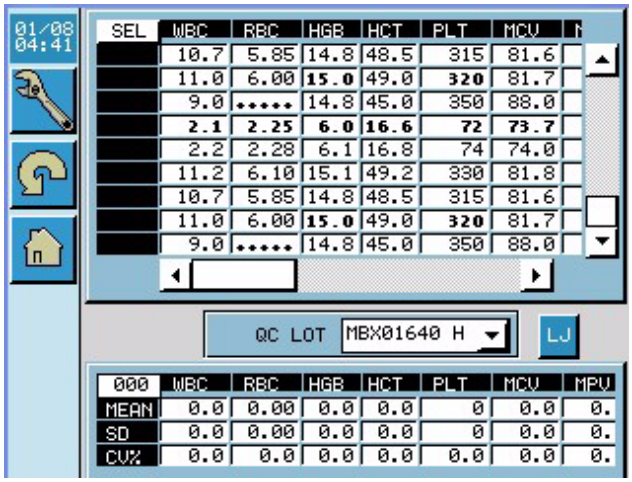


Figure 11.7 QC Statistics

The statistics displayed represent calculations based on the selected QC runs only. Thus, if no QC runs are selected, all values will be 0. The mean (MEAN), standard deviation (SD), and coefficient of variation percentage (CV%) may be rounded in this table due to available display space.

Levey-Jennings Graphs

Results are automatically plotted on Levey-Jennings graphs as shown in the following figure.

The Levey-Jennings (LJ) graphs are displayed by touching **[LJ]** on the Control Results screen.

- The left column shows each measurand with the target values and limits shown on the right side next to the plots.
- The upper and lower dashed lines represent the LIMITS entered during QC FILE Setup. The solid lines represent two times the **LIMITS** entered during **QC FILE** Setup.
- The number displayed directly under each measurand is the result for the run “selected” by the vertical line on the graphs. To move the line to another sample, use the **[<]** and **[>]** buttons to the left of the time displayed at the bottom of the screen.
- The scroll bar on the bottom of the screen moves the cursor to display select additional measurands.
- The arrow keys displayed under the scroll bar can also be used to move the cursor to a specific measurand.
- The number of the result at the cursor position and the date and time it was run are shown in the box on the bottom of the screen.
- Touch **[>>]** or **[<<]** to scroll through all results.
- The date and time displayed at the bottom of the screen correspond to the sample indicated by the vertical line on the graph. To move the line to another sample, use the **[<]** and **[>]** buttons to the left of the time displayed at the bottom of the screen.
- Only results that have been selected in the **RUN/RESULTS** screen are plotted on the L-J Graphs.

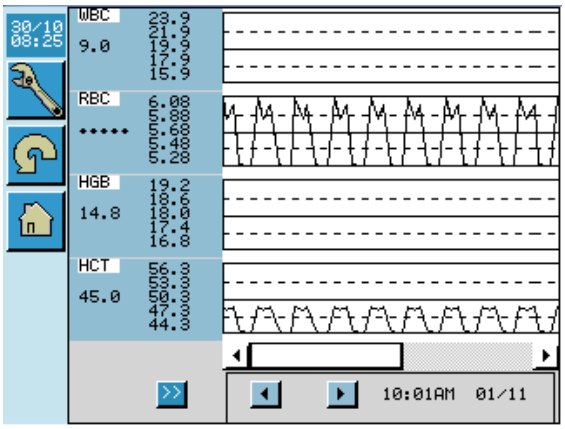


Figure 11.8 Levey-Jennings Screen

References

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NOTES

This section provides the list numbers for components, accessories, reagents, controls, and consumables used with the CELL-DYN Emerald System.

To place an order for the products listed or to obtain technical assistance, USA customers contact Abbott Diagnostics Customer Service at:

1-877-4ABBOTT (1-877-422-2688)

For customer support in Canada, call:

1-800-387-8378

For customer support outside the USA and Canada, call your local Hematology Customer Support representative.

NOTES

Accessories

List numbers are unique identifiers used when ordering products. List numbers and quantities provided in this section are intended for guidance only and are subject to change. USA customers, contact Abbott Diagnostics Customer Service at 1-877-4ABBOTT (1-877-422-2688) for the most current information regarding list numbers. Customers outside the USA, contact your local Abbott Customer Service Representative for assistance.

Table A.1 Accessories

List Number	Quantity	Name	Comments
09H40-01	1	CELL-DYN Emerald Operator's Manual, printed	
09H52-01	1	Bar Code Scanner	
25860-01	1	Label Dispenser, Bar Code	Dispenser for Bar Code Label rolls
09H58-01	1	Emerald Grease	
09H54-06	1	USA Power Cord	
09H54-02	1	European Power Cord	
09H54-04	1	Flat Screwdriver/Key	
09H50-01	1	Diluent Reagent line with cap	
09H51-01	1	Waste line with cap	

Table A.2 Consumables

List Number	Quantity	Name	Comments
03B96-02	500/pkg	Printer paper	8.5 x 11" sheets
99650-01	1 roll	Bar Code Labels, Tube ID	1000 labels per roll

Table A.3 Reagents

List Number	Quantity	Name	Comments
09H48-02	1	CELL-DYN Emerald Diluent Reagent	10L cubitainer
09H47-02	1	CELL-DYN Emerald CN-Free Lyse Reagent	960 mL Bottle
09H46-02	1	CELL-DYN Emerald Cleaner Reagent	960 mL Bottle

Table A.4 Calibrator and Controls

List Number	Quantity	Name	Comments
09H70-01	2 x 2.5 mL tubes	CELL-DYN 18 Plus Calibrator	
09H69-01	12 x 2.5 mL tubes	CELL-DYN 18 Plus Control	Tri-level
09H69-02	6 x 2.5 mL tubes	CELL-DYN 18 Plus Control	Tri-level, half pack

Potential Causes of Spurious Results

This table provides a detailed list of interfering substances. Note that some of the substances listed may not interfere with CELL-DYN Emerald results. Not all interferents were tested as part of the Emerald Medical-Clinical Validation Study performed by Abbott.

Table B.1 Potential Causes of Spurious Results with Automated Cell Counters

Measurand	Causes of Spurious Increase	Causes of Spurious Decrease
White Cell Count (WBC)	Cryoglobulin, cryofibrinogen Heparin Monoclonal proteins Nucleated red cells Platelet clumping Unlysed red cells	Clotting Smudge cells Uremia plus immunosuppressants
Red Cell Count (RBC)	Cryoglobulin, cryofibrinogen Giant platelets High white cell count (>50,000 K/µL)	Autoagglutination Clotting Hemolysis (in vitro) Microcytic red cells
Hemoglobin (HGB)	Carboxyhemoglobin (>10%) Cryoglobulin, cryofibrinogen Hemolysis (in vivo) Heparin High white cell count (>50,000 K/µL) Hyperbilirubinemia Lipemia Monoclonal proteins	Clotting
Hematocrit (Automated) (HCT)	Cryoglobulin, cryofibrinogen Giant platelets High white cell count (>50,000 K/µL) Hyperglycemia (>600 mg/dL)	Autoagglutination Clotting Hemolysis (in vitro) Microcytic red cells
Hematocrit (HCT) (Microhematocrit)	Hyponatremia Plasma trapping	Excess EDTA Hemolysis (in vitro) Hypernatremia

Table B.1 Potential Causes of Spurious Results with Automated Cell Counters (Continued)

Measurand	Causes of Spurious Increase	Causes of Spurious Decrease
Mean Cell Volume (MCV)	Autoagglutination High white cell count (>50,000 K/µL) Hyperglycemia Reduced red cell deformability Swollen red cells	Cryoglobulin, cryofibrinogen Giant platelets Hemolysis (in vitro) Microcytic red cells
Mean Cell Hemoglobin (MCH)	High white cell count (>50,000 K/µL) Spuriously high hemoglobin Spuriously low red cell count	Spuriously low hemoglobin Spuriously high red cell count
Mean Cell Hemoglobin Concentration (MCHC)	Autoagglutination Clotting Hemolysis (in vivo and in vitro) Spuriously high hemoglobin Spuriously low hematocrit	High white cell count (>50,000 K/µL) Spuriously low hemoglobin Spuriously high hematocrit
Platelets (PLT)	Cryoglobulin, cryofibrinogen Hemolysis (in vivo and in vitro) Microcytic red cells Red cell inclusions White cell fragments	Clotting Giant platelets Heparin Platelet clumping Platelet satellitosis

SOURCE: Cornbleet, J. “Spurious Results from Automated Hematology Cell Counters.” Laboratory Medicine, 1983. 14: 509-514.

Preparation of diluted sodium hypochlorite solutions

Use the following formula to calculate the percent (%) sodium hypochlorite concentration desired.

A = desired % sodium hypochlorite solution

B = % of purchased sodium hypochlorite (bleach) solution

X = parts water to be mixed with one part of the purchased sodium hypochlorite solution

$$X = \frac{B - A}{A}$$

Example:

If you need a 3.6% sodium hypochlorite solution and the label on the bleach bottle states that it is 5.25% sodium hypochlorite, then:

$$X = \frac{5.25 - 3.6}{3.6} \qquad X = 0.46$$

Add 0.46 parts deionized water to one part bleach to obtain the 3.6% sodium hypochlorite solution. For example, add 0.46 mL of deionized water to 1.0 mL of the 5.25% sodium hypochlorite solution (bleach) to obtain the 3.6% solution. Final volume in this example is 1.46 mL.

NOTE: In the US, commercially available sodium hypochlorite is often approximately 5% to 5.25%. Read the container labeling to verify the concentration.

NOTES

CBC Reference Intervals: Literature Sources

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Sample Logs and Worksheets

This section contains samples of logs and worksheets referenced in other Sections of this manual. All pages can be duplicated as needed.

The following worksheets are provided:

- Pre-Calibration Procedures Checklist
- Maintenance Log
- Troubleshooting Log
- Calibration Verification Worksheet
- Training Checklist
- Manual Calibration Factory Entry Worksheet

Worksheet E.1

Pre-Calibration Procedure Checklist

If problems are detected during these checks, *DO NOT attempt to calibrate the in*strument. Consult **Section 10: *Troubleshooting***, for assistance in resolving the issue. When problems are resolved, repeat these procedures to verify proper instrument performance.

Date: _____ Operator: _____

Initial each item after it is completed.

1. _____Ensure all maintenance is complete before calibrating the instrument. Refer to **Section 9**: ***Service and Maintenance*** for further information.
2. _____Confirm reagent containers are at least half full --- replace them as necessary.
3. _____Confirm the waste container is at least half empty --- replace it as necessary.
4. _____Verify all reagents have not expired. Record the lot numbers and expiration dates:
   Diluent Reagent: Lot # _____ Exp. Date _____
   CN-Free Lyse Reagent: Lot # _____ Exp. Date _____
   Cleaner Reagent: Lot # _____ Exp. Date _____
5. _____Verify the calibrator is not expired. Record the lot number and expiration date:
   Lot # _____ Exp. Date _____
6. _____Confirm the Background Counts are within acceptable limits. Refer to **Section 4: *Performance Characteristics and Specifications*** for Background Count specifications. Record results below or attach a printout to this document.

WBC	$\leq$ 0.5 K/µL
RBC	$\leq$ 0.1 M/µL
HGB	$\leq$ 0.2 g/dL
PLT	$\leq$ 10.0 K/µL

7. _____Verify instrument precision by running a fresh, normal whole blood specimen ten times into the PRECISION file. Refer to **Section 9: *Service and Maintenance***, **Subsection: *Precision*** for information on using QC files. Ensure that CV% results are within the limits as provided in **Section 4: *Performance Characteristics and Specifications***. Record the results below or attach a printout to this document.

NOTE: You may also use the PRECISION function within the **MAINTENANCE** menu to run precision. N=10.

Parameter	%CV Limit	%CV
WBC	3.5%	
RBC	2.0%	
HGB	2.1%	
MCV	0.8%	
PLT	6.1%	

8. _____If any problems are detected during these checks, document the problem and corrective action below:

_____
_____
_____
_____

Table E.1 Maintenance Log

		Month:																															Year:										
	Day	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										
Monthly	Bleach Cleaning																																									
Semi-Annually	Lubricate the Pistons																																									
Un-scheduled	Bleach Cleaning																																									
As Needed	Preparation for Storage, Relocation or Shipping																																									
	Day	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										

WARNING: Potential Biohazard. Consider all clinical specimens, reagents, calibrators, controls or other materials and all system surfaces or components that contain or come in contact with human-sourced material as potentially infectious. Wear a lab coat, gloves and safety glasses when performing service or maintenance. Follow biosafety practices as specified in the OSHA Bloodborne Pathogen rule (29 CFR Part 1910.1030)[1] or other equivalent biosafety practices.[2, 3] Refer to **Section 8: *Hazards*** for additional information.

Table E.2 Troubleshooting Log

Troubleshooting Log										
Instrument Serial No:										
Date	Operator Name	Control Lot No.	Diluent Lot No.	Lyse Lot No.	Cleaner Lot No.	Observation	Resolution			

Table E-3 CELL-DYN Emerald Diluent Log

Instrument Serial Number _____			
Lot Number	**Open Date**	**Expiration Date**	**Operator ID**

Table E-4 CELL-DYN Emerald Cleaner Log

Instrument Serial Number _____			
Lot Number	**Open Date**	**Expiration Date**	**Operator ID**

Table E-5 CELL-DYN Emerald CN-Free Lyse Reagent Log

Instrument Serial Number _____			
Lot Number	**Open Date**	**Expiration Date**	**Operator ID**

Worksheet E.2

Calibration Verification Worksheet

Date: _____

Operator: _____

Calibrator Lot # _____

Exp. Date: _____

	Calibrator Assay Value	Mean Value	Difference	+/- Limit	Calibration Needed (Y/N)
WBC					
RBC					
HGB					
MCV					
PLT					

Retain all calibration documentation in the instrument logbook.

Worksheet E.3

Training Checklist

TOPIC

Component and Features
- Analyzer
- Display and Numeric Keypads
- Printer
- Reagent
- Barcode Reader
- AC Adaptor/Transformer

Analyzer's Software
- Main Menu
- Software Navigation

Basic Operation
- Instrument Overview
- Power On
- Operator's Login
- Operator's Passwords
- Loading/Replacing Reagents
- Replacing Waste Containers
- Start-up
- Running Background
- Running Controls
- Specimen Identification
- Running Specimens
- Shutdown
- Daily Shutdown

TOPIC

Setup
- Header
- Date and Time
- Languages
- Printer
- Paper Size
- Date Format
- Auto Clean Interval
- Auto Shutdown
- Patient Limits
- Reagent Log
- Start-Up Alarms
- QC Alarms
- QC Setup

Data Interpretation
- QC Results Interpretation
- Accuracy and Precision
- QC Statistics
- Patient Result Interpretation
- Patient Report Overview
- Datalog

TOPIC

Calibration
- When to Calibrate
- Calibration Materials
- Pre-calibration Checklist
- Calibration
- Post Calibration Procedure

Maintenance
- Monthly
- Semi-Annual
- As-Needed
- Component replacement

Quality Control
- Review QC Data
- QC Log Editing
- Printing QC Log and LEVEY-JENNINGS
- External QC Program (eQC)

Troubleshooting
- Basic
- Abnormal/erratic RBC, WBC, HGB, MCV and PLT
- Background data unacceptable
- Erratic Results/Multiple Parameters
- Interfering substances
- Abbott Customer Service 1-877-4ABBOTT

PLEASE PRINT

ABBOTT CELL-DYN Emerald Training Checklist

Account Name _____ SN _____

Address _____ City/State _____ Zip _____

Trainee _____ Date _____

Trainee Signature _____

Trainer _____ Date _____

Supervisor _____ Date _____

Trainee License Number (if applicable) _____

Trainee Phone Number _____

REFERENCES: *CELL-DYN Emerald Operator's Manual*

NOTE: Completion of this checklist indicates the trainee has successfully completed training on the listed topics. This document can be used for regulatory review and as documentation of continuing education.

Upon completion of training:

1. Completely fill out information requested on both sides of the checklist. PLEASE PRINT.
2. The checklist trainer or Abbott facilitator must sign and date the certification statement below and as appropriate on the checklist side of this document.
3. If you wish to have P.A.C.E. continuing education credits, the Checklist Trainer or Abbott Facilitator must affix the P.A.C.E. seal to this document to validate your training.
4. Whether you are obtaining P.A.C.E. credits or not, make a copy of the checklist side of this document and return the copy to the Abbott address given below, preferably within two weeks of training.
5. Keep original for your records. If you need additional checklists, photocopy any unused checklist form or contact your Abbott Support Specialist.

Worksheet E.4

Manual Calibration Factor Entry Worksheet

Date:_____

Name:_____

Calculate all calibration factors to three decimal places.

New Calibration Factors

$$\frac{\text{Reference Mean}}{\text{CELL-DYN Emerald Mean}} \times \text{Current Calibration Factor} = \text{New Calibration Factor}$$

For example, if the Reference Mean Value for WBC is 6.6, the CELL-DYN Emerald Mean is 7.1, and the current Calibration Factor is 0.98, then:

$$\frac{6.6}{7.1} \times 0.98 = 0.91$$

and 0.91 is the new Calibration Factor.

	Reference Mean	÷	CELL-DYN Emerald Mean	X	Current Calibration Factor	=	New Calibration Factor	Range*
WBC		÷		X		=		0.50-2.0
RBC		÷		X		=		0.50-2.0
HGB		÷		X		=		0.50-2.0
MCV		÷		X		=		0.50-2.0
PLT		÷		X		=		0.50-2.0

* If factor exceeds limits, do not calibrate. Check all calculations and, if necessary, contact Abbott Diagnostics Customer Service for assistance.

NOTES

Manual Calibration Procedure

Calibration with fresh whole blood is accomplished by performing multiple analyses of each specimen using accepted reference methods or a reliably calibrated hematology analyzer. The mean value is calculated for each measurand and used to calibrate the CELL-DYN Emerald.

Requirements for Whole Blood Specimens

Following are the requirements for whole blood specimens used for calibration:

- The ICSH (International Committee for Standardization in Haematology) recommends that fresh specimens be less than four hours old. Specimen age should not exceed six hours at the conclusion of the calibration procedure.
- All measurand values should be within the laboratory's reference range.
- All cellular morphology should be normal.
- No known interfering substances should be present. Refer to the list of interfering substances provided in **Appendix B:** ***Potential Causes of Spurious Results***.
- All specimens should be collected in K_2EDTA according to the instructions provided by the tube manufacturer.

Requirements for Whole Blood Calibration

Minimum requirements for a whole blood calibration are provided in this section. Specimens should all meet the requirements for fresh whole blood specimens outlined in the previous section. Additional specimens and/or more replicates can be used to achieve accuracy beyond these recommendations.

1. Five different specimens assayed in duplicate by reference methodology and on the CELL-DYN Emerald.
2. No more than two hours should elapse between the assay by reference methods and the CELL-DYN Emerald run.

NOTE: If specimens are run on the CELL-DYN Emerald first, the assay by reference methods should be completed within one hour. Certain reference methods are sensitive to RBC swelling caused by in vitro deoxygenation.

3. Mean values should be calculated for each measurand, for each sample, from the reference assay results. Average the values to obtain the cumulative mean value for each measurand. (A worksheet, provided in **Appendix E: *Sample Logs and Worksheets***, can be used to assist in calculating the cumulative mean values and can be duplicated as needed.) These cumulative measurand values can then be entered into the Calibration screen on the CELL-DYN Emerald as target values. Alternatively, calibration factors may be calculated and manually entered, as described within this section.

Reference Methods

Values for Whole Blood Calibration should be determined according to the following ICSH recommendations.

WBC, RBC and PLT

Values for these measurands can be determined using multiple counts from a certified hemocytometer, from a cell counter that meters a fixed, calibrated sample volume or from a reliably-calibrated hematology analyzer.

HGB

Values for hemoglobin can be determined either using the reference cyanmethemoglobin method or a reliably-calibrated hematology analyzer.

NOTE: Do not use hemoglobin standards designed for the calibration of cyanmethemoglobin methods on the CELL-DYN Emerald. The instrument uses a different method, which is not designed to analyze these standards directly.

MCV

Values for MCV can be determined by calculation from the reference microhematocrit and the RBC results from a reliably-calibrated hematology analyzer.

NOTE: Reference microhematocrit values can be determined using the CLSI method for Packed Cell Volume (PCV). Use only plain, non-anticoagulated capillary tubes. Be certain to verify proper operation of the microhematocrit centrifuge and the timer as recommended by CLSI.

Manual Calibration Factor Entry

The Manual Calibration Factor Entry method is used to enter a predetermined factor to adjust calibration when a consistent bias exists between the CELL-DYN Emerald and a comparison instrument. A percent Bias Factor can be determined and entered through the **SET UP** menu to change calibration for the following measurands – WBC, RBC, HGB, MCV, PLT. (NOTE: MPV and RDW calibration factors, also accessible through the **SET UP** menu, are for Abbott service use only.) Calibrator or fresh whole blood may be used to calibrate the instrument with the Manual Calibration Factor Entry method. A set of worksheets is provided in **Appendix E:** ***Sample Logs and Worksheets*** that can be used for Manual Calibration Factor Entry.

Manual Calibration Factor Entry Procedure – Fresh Whole Blood

To perform a Manual Calibration Factor Entry with fresh whole blood, proceed as follows:

NOTE: No more than two hours should elapse between determining the Reference Mean Values and performing the calibration.

NOTE: Once testing has begun to determine the Reference Mean Values on an instrument, testing should not be interrupted.

Obtain five different fresh whole blood specimens that meet the requirements in **Subsection:** ***Requirements for Whole Blood Calibration***.
Using your reference method, test each of the five fresh blood specimens in duplicate. Print results, calculate the mean values for the calibratable measurands (RBC, WBC, HGB, MCV, and PLT) and set aside to use as the Reference Mean Values for the calibration factor calculation.

Manual Calibration Procedure

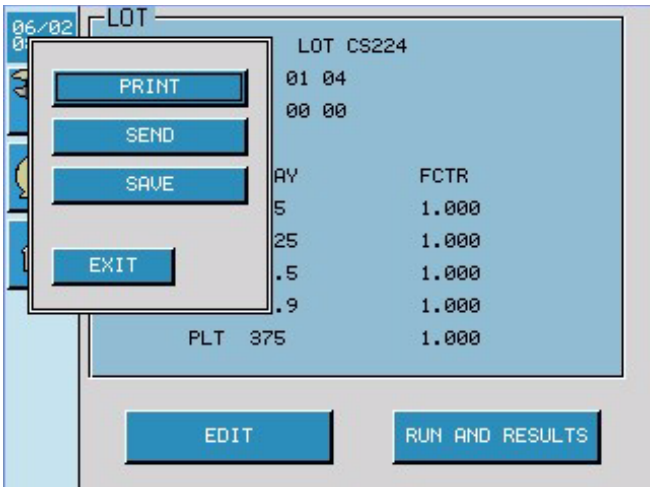
1. From the **MAIN** menu, touch **[MAINTENANCE]** followed by **[PRECISION]**. 2. At the WARNING Pop-up message, `DELETE RESULTS?` touch **[YES]**. **NOTE:** The probe will not descend for sampling until the previous results are deleted.	
3. Take the first fresh whole blood specimen and mix well by gently inverting the tube 10 to 15 times. Do not shake the tube. 4. Remove the cap from the specimen tube and place the tube under the probe. Raise the tube so that the end of the probe is deeply immersed in the specimen. 5. Press the Start Switch to aspirate the sample. Test each of the five samples in duplicate. If any run has invalid results, deselect that run by touching the "▷" symbol to the left of the results to deselect it. Repeat any invalid runs so that there are two valid runs for each of the five samples.	
6. Touch **[TOOLS]** and **[PRINT]** to print the results. The mean values for each measurand are the Reference Mean Values used later in this procedure.	
7. Touch **[HOME]** to return to the **MAIN** menu and touch **[CALIBRATION]**. 8. Touch **[TOOLS]** and **[PRINT]** to print the current calibration factors. Retain this printout for your records.	
9. To determine the new calibration factor(s): Use the Reference Mean Values determined above. Enter this information in the Manual Calibration Factor Entry Worksheet provided in **Appendix E: *Sample Logs and Worksheets*** to calculate the new calibration factor for each measurand.	

Figure F.1 Manual Calibration Procedure

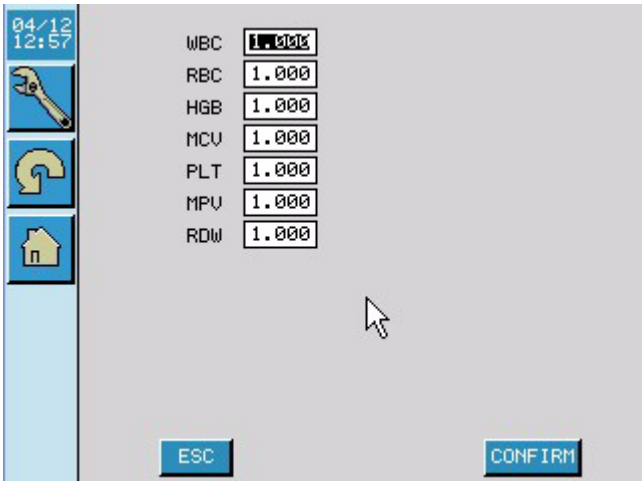
10. Touch **[HOME]** to return to the **MAIN** menu and touch **[SET UP]**. 11. Touch **[ADVANCED]** then **[CALIBRATION FACTORS]**. 12. Touch the entry field to the right of each measurand to enter the new calibration factor. When finished, touch **[CONFIRM]**, and answer **[YES]** when prompted to save the changes. 13. Touch the **HOME** icon to return to the **MAIN** menu. 14. Touch **[CALIBRATION]**.	
15. Touch the **TOOLS** icon and select **[PRINT]** to generate a paper copy of the new calibration factors. Verify that the calibration factors you entered in the previous steps match the factors displayed on the screen. **NOTE:** When calibration factors are manually entered, the calibration date will be followed by the letter “M” on the Calibration screen.	

Figure F.1 Manual Calibration Procedure (Continued)

CELL-DYN Emerald Quick Reference Card

Power on

1. Press the power button to power on the display.
2. Touch the **LOGIN** field then touch **[A-Z]** to enter operator ID.
3. Touch the **[PASSWORD]** field and use the on-screen keyboard or the numeric keypad to enter a password. Touch **[CONFIRM]** to continue.

NOTE: No password is required for user access.

4. Touch **[OK]**.

Daily Start Up

1. From the **MAIN** menu, touch **[START UP]**.
   At the end of the Startup cycle, a background count is automatically displayed.
2. The Background must be within specifications before proceeding to the next step. (See Table A)

NOTE: Refer to the ***CELL-DYN Emerald Operator's Manual*** **Section 2:** ***Installation Procedures and Special Requirements*** to set up autoprint of startup background.

3. Check the reagent levels and replace reagent(s) as needed.
4. Empty Waste as needed.
5. Check printer paper supply and add paper, if necessary.
6. Check the instrument maintenance log and perform any required maintenance.

Table A (Background Specifications)

Parameter	Specification
WBC	≤ 0.5 K/µL
RBC	≤ 0.1 M/µL
HGB	≤ 0.2 g/dL
PLT	≤ 10.0 K/µL

Manual Daily Shut Down

Daily shutdown is required once every 24 hours, refer to the
CELL-DYN Emerald Operator's Manual **Section 5:** ***Operating Instructions*** for detailed information.

1. From the **MAIN** menu, touch **[SHUT DOWN]** to manually initiate a Shut Down Cycle.
2. At the end of the Shut Down Cycle the system powers down.

NOTE: Daily Shutdown may be programmed automatically (refer to the ***CELL-DYN Emerald Operator's Manual*** **Section 2:** ***Installation Procedures and Special Requirements***).

Running Quality Control

1. From the **MAIN** menu, touch **[QUALITY CONTROL]**.
2. Access the QC file by touching the appropriate lot number. Touch **[RUN AND RESULTS]**.
3. Remove the cap from a well-mixed control specimen tube and place the open tube under the Sample Aspiration Probe. Raise the tube so that the end of the probe is deeply immersed in the specimen. Press the Start Switch.
4. The red LED flashes several times during aspiration. When the Cycle LED turns red, and the probe retracts, remove the tube.

Results are displayed at the top of the QC results table and will print automatically if a printer is connected and configured. Verify that control results are within the laboratory's acceptable limits.

5. Touch the **QC LOT** dropdown menu to select the next file.
6. Run the other levels of control as described above.

Running a Patient Sample

1. From the **MAIN** menu, touch **[RUN SAMPLE]**.
2. Touch **[NEXT SAMPLE]** at the bottom of screen and enter NAME, PID, or/and SID according to your lab's procedures. Press **[CONFIRM]**.
3. Place the well-mixed patient specimen under the Sample Aspiration Probe and raise the tube so that the end of the probe is deeply immersed in the specimen.
4. Press the Start Switch.
5. Remove the tube when the probe retracts.
6. Results will print automatically, if a printer is connected and configured, when the analysis is complete.

While a sample is running you may enter the demographics for the next specimen using the **[NEXT SAMPLE]** key at the bottom of the screen.

Background Count

1. From the **MAIN** menu, touch **[RUN SAMPLE]**.
2. Press the Start Switch.
3. Results must be within specifications before proceeding. Refer to Table A.

Replacing Reagents-Diluent, Lyse, and Cleaner

1. From the **MAIN** menu, touch **[REAGENTS]**, followed by **[DILUENT]** to access the Diluent Screen.
2. Remove the empty container and replace it with a full one.
3. **Scan the two barcodes on the label of the new reagent container to automatically populate all empty fields. Make sure the information on the screen is correct before proceeding.**
4. If the information entry is successful the **[PRIME DILUENT]** button turns green.
   a. Proceed to Step 5. If the entry is not successful, enter the reagent information as described in ***CELL-DYN Emerald Operator's Manual*** **Section 2:** ***Installation Procedures and Special Requirements*** **Subsection:** ***Manual Entry of Reagent Information***.
5. Press **[ESC]** when finished.
6. To replace the Lyse or Cleaner, touch **[ESC]** to return to the **REAGENTS** menu and repeat the above steps for the desired reagent.

Replacing Waste Container

1. From the **MAIN** menu, touch **[REAGENTS]**,
2. Touch **[WASTE]**.
3. Remove the full container and replace it with an empty one.
4. Touch the box to the right of **[CAPACITY]** and use the numeric keypad to enter the volume of the waste container.
5. Touch **[RESET]** to enter the container capacity into the system memory.
6. Touch **[ESC]** to return to the **REAGENTS** menu.
7. Touch the **HOME** icon to return to the **MAIN** menu.

NOTE: *If you are disposing of waste directly to a drain, enter "99999" in the capacity field. The waste counter will need to be reset when the system has dispensed 99999 mL of waste.*

Glossary

NOTE: The references provided in this Glossary, acquired from assorted reference works, may have been revised to reflect their meanings in relation to functions and operations of the CELL-DYN Emerald instrument.

absorption Uptake of light energy by an atom or a molecule, raising electrons from their ground state orbitals to orbitals at higher energy levels.

accuracy The level of agreement between the estimate of a value (the result generated by the method) and the "true" value. Accuracy has no numerical value; it is measured as the amount of (or degree of) inaccuracy [ICSH].

agglutination The action of cells or other biological particles clumping or sticking together because of an antigen-antibody reaction.

agglutinin An antibody present in the plasma or suspending media that reacts with an antigen to cause agglutination of blood cells.

aggregation *See* agglutination.

algorithm A step-by-step procedure, typically mathematical in nature, coded into computer software. On the CELL-DYN Emerald, algorithms are used to separate cell populations, determine concentrations, and flag selected results.

aliquot A fractional part of a solution or specimen.

amplitude of a pulse The magnitude of variation of an electrical signal from its baseline value.

analyzer The module of the CELL-DYN Emerald through which the blood sample passes and where measurements are made.

anticoagulant A substance that interferes with the normal clot-forming mechanism of blood.

aperture An opening of known dimensions that restricts or limits the passage of energy. In impedance counting, it is the opening at the entrance to the sensing zone through which the cells are made to pass.

assay An analysis to determine the presence, absence, or concentration of one or more components in a solution or specimen.

background — A measurement cycle performed in the absence of a specimen to check system performance. Often used to determine whether reagents contain excessive amounts of particulates. On the CELL-DYN Emerald, background cycles are done at Start Up and may also be done manually.

band — An immature granulocyte in a state of development before segmentation and maturity. Usually present in circulation in extremely low concentrations. *See also* immature granulocyte.

basophil — A granulocytic white blood cell usually present in circulation in extremely low concentrations. Associated with histamine release, allergy, and inflammation.

blast — The first stage of a blood cell lineage that can be morphologically identified on a stained blood film. Normally present in bone marrow but not in circulation.

blood, whole — A homogenous mixture of blood that has not been separated into cellular and liquid components.

calibration — The adjustment of a laboratory instrument to correct results to match "truth," defined by standards or reference procedures.

calibration factor — A multiplier obtained during calibration that can be applied to raw data to obtain accurate results.

calibrator — A material of known characteristics used in conjunction with a calibration procedure to adjust measurement accuracy. The values must be traceable to a national or international reference preparation or method for hematology.

carboxyhemoglobin — A moderately stable union of carbon monoxide with hemoglobin; its formation prevents the normal transport of carbon dioxide and oxygen during the circulation of blood; increasing levels result in varying degrees of asphyxiation, including death.

carryover — Significant interference from a previous specimen with the current specimen results.

CBC — Acronym for complete blood count. Includes WBC, RBC, HGB, HCT, MCV, MCH, MCHC, and PLT. On the CELL-DYN Emerald, the CBC also includes an automated three-part differential.

character self-checking — A Bar Code Symbology Character is considered self-checking if a single printing defect will not cause a character to be misread as another valid character in the same symbology. This feature increases the accuracy of decoding by checking whether each character is read accurately.

check character/digit An alphanumeric character that allows the decoder in the bar code reader to mathematically determine that it has read the bar code characters correctly. It immediately precedes the stop character in the bar code symbol.

CLIA Acronym for the Clinical Laboratory Improvement Amendments.

CLSI Clinical and Laboratory Standards Institute. Formerly known as NCCLS.

coefficient of variation (CV) A statistical calculation used to describe population heterogeneity. The expression of the standard deviation as a percentage of the mean. On the CELL-DYN Emerald, CVs are automatically calculated by various quality control programs.

cold agglutinin A substance in blood that, at low temperatures, aggregates compatible and incompatible red blood cells. Also called cold hemagglutinin.

cryoglobulin Any of several proteins similar to gamma globulins that dissolve at 37°C (98.6°F).

concentration The number of a particular type of cell or other biological particle detected in a known volume of sample.

control A substance used in routine practice for checking the performance of an analytical process or instrument. These materials must be similar in properties to and be analyzed in the same manner as patient specimens. Control materials can have pre-assigned values [ICSH, NCCLS].

correlation coefficient A statistic that indicates the degree to which two measurements are related, expressed as a value from –1.0 to +1.0, with +1.0 indicating that results are in total agreement and –1.0 indicating that results are exact opposites (i.e., 4 and –4). A 0.0 value indicates that the two measurements are unrelated. It is expressed as a value of "r", which has no dimension. Agreement does not mean that the results of the two measurements are identical. For example, if one method produces a hemoglobin concentration that is always exactly double that of the other method, r = 1 but there is important bias. Slope and Y-intercept must always be stated with an "r" value.

datalog On the CELL-DYN Emerald, the repository file that automatically accepts and stores all result data in chronological order.

diff Abbreviation for differential white blood cell count.

differential white blood cell count The process of classifying white blood cells in a specimen of whole blood into distinct subpopulations, either automatically or manually, and outputting a result for each identified subset as a concentration or percentage. The CELL-DYN Emerald produces a three-part differential.

dilution ratio A factor by which a sample is diluted before it is analyzed. Samples are diluted in different ratios to provide cell concentrations that are suitable for analysis.

drift A pattern of variation in the accuracy of a system over time.

EDTA Ethylenediaminetetracetic acid; an anticoagulant commonly used for hematology cell counting; may be in the form of a liquid or powder as dipotassium (K2) or tri-potassium (K3) salt.

eosinophil A mature granulocytic white blood cell normally present in circulation in low concentrations. Associated with host defense to certain parasites, allergy, inflammation, and phagocytosis.

error, random Variation, with no distinct pattern, between successive result data. Often assumed to be a normal (Gaussian) distribution around a mean.

error, systematic Directional or patterned variation between values obtained and the values expected.

erythroblast *See* nucleated red blood cell.

erythrocyte *See* red blood cell.

false negative A test result that erroneously excludes an individual from a specific diagnostic or reference group.

false positive A test result that erroneously includes an individual in a specific diagnostic or reference group.

flag Written or displayed output intended to signal or attract attention. Flags are output by the CELL-DYN Emerald Data Station to alert the operator to instrument malfunctions that occurred during sample processing or to data abnormalities that were detected during data analysis. Operator review and/or corrective action is usually required.

gain The amount of change in signal magnitude generated by an amplifier, presented as a ratio of the output to input signals.

Gaussian Term used to describe a normal frequency distribution or curve. The normal distribution is unimodal, bell-shaped and symmetrical about the mean.

GRA The identifier for the granulocyte absolute concentration result, calculated as the number of granulocytes per unit volume of whole blood.

G%	The identifier for the granulocyte percentage result, calculated as the percentage of granulocytes in the white blood cells.
granulocyte	A mature white blood cell that contains prominent cytoplasmic granules. Possesses nuclei with irregular shapes. Can be physiologically and morphologically differentiated into neutrophils, eosinophils, and basophils, but the CELL-DYN Emerald separates the eosinophils and basophils in MID.
HCT	The identifier for the hematocrit absolute concentration result, which is calculated as a percentage of red blood cells relative to the total volume of the sample.
heme	A component of hemoglobin that contains iron and binds oxygen.
hemoglobin	An intraerythrocytic, iron-containing protein that transports oxygen. It is composed of four globin chains, each containing a heme component.
hemolysis	The destruction of red blood cells resulting in the liberation of hemoglobin.
heparin	An anticoagulant that combines with and enhances anti-thrombin III to prevent blood clotting. Not recommended for specimens run on hematology analyzers.
HGB	The identifier for the hemoglobin result, calculated as the mass of hemoglobin per unit volume of whole blood. Also abbreviated as “Hb”.
histogram	Graphical presentation of frequency distribution. Often, an attribute (for example, cellular volume) is represented on the x-axis, and the relative frequency of various levels of the attribute is represented on the y-axis.
hyperglycemia	An abnormally high concentration of glucose in the circulating blood, especially with reference to a fasting level.
ICSH	Acronym for International Council for Standardization in Haematology.
ID	An acronym for identification.
ID, operator	An alphanumeric code that identifies the current operator of the CELL-DYN Emerald.
ID, specimen	An alphanumeric code that identifies a particular specimen. On the CELL-DYN Emerald, the specimen ID can be entered automatically by a bar code reader, from a Work List, or by activating the auto-increment feature. It also can be entered manually before running the specimen.

immature granulocyte — One of several cell types that are precursors to mature granulocytes. They may include (in order of maturity) promyelocytes, myelocytes, metamyelocytes, and bands.

impedance method — A process that detects and sizes cells suspended in a conductive medium as they are drawn through an aperture. Each cell creates a resistance to current flow that is directly proportional to its volume. Voltage pulses indicate the passage and volume of cells.

imprecision — Variation in the results of a set of replicates or paired (duplicate) measurements. Expressed as a standard deviation or coefficient of variation percentage. *See* Precision.

inaccuracy — The numerical difference between the mean of a set of replicate measurements and the expected value. The difference (positive or negative) may be expressed in the units in which the quantity is measured, or as a percentage of the expected value [ICSH].

indices, RBC — A group of calculated values for red blood cell properties: mean cell volume (MCV), mean cell hemoglobin (MCH), and mean cell hemoglobin concentration (MCHC).

interfering substance/condition — A specimen component or state that affects a measurand's measurement.

in vitro — Outside the living body.

in vivo — Within the living body.

leukocyte — *See* white blood cell.

Levey-Jennings graph — A visual presentation of data points from multiple runs for a single measurand. Useful for trend analysis. Derived from Shewhart control charts.

linearity — The ability of an analytical process to provide measurements proportional to an analyte measured over a defined range of concentrations or counts [CLSI].

LIS — Acronym for Laboratory Information System.

logarithm — The exponent (power) to which it is necessary to raise a number (the base) to produce a given value. Abbreviated as log.

LYM — The identifier for the lymphocyte absolute concentration result, which is calculated as the number of lymphocytes per unit volume of whole blood.

lymphocyte — A small, mature mononuclear white blood cell that is present in circulation in relatively high concentrations. It has a round or slightly indented nucleus and no granules in the cytoplasm.

lymphocyte, variant — A lymphocyte that has changed in response to a stimulus. Usually seen in nonmalignant reactive disorders. Also known as “atypical” or “reactive” lymphocyte.

L% — The identifier for the lymphocyte percentage result, calculated as the percentage of lymphocytes in the white blood cells.

lysis — Alteration or destruction of a cell by action of a chemical agent on the cell membrane.

macrocytic (giant) platelet — A large platelet in circulation.

macrocytic RBC — A large red blood cell in circulation.

MCH — The identifier for mean cell hemoglobin, the average hemoglobin mass in the red blood cells.

MCHC — The identifier for mean cell hemoglobin concentration, the average mass of hemoglobin per unit volume in the red blood cells.

MCV — The identifier for mean cell volume, the average volume of the red blood cells.

metamyelocyte — A cell present in the bone marrow that gives rise to a granulocyte and is not normally present in circulation. The maturation phase between myelocyte and band. *See also* immature granulocyte.

method, reference — A clearly and exactly described technique for a particular determination. A competent authority must judge whether the technique provides a sufficiently accurate and precise determination for it to be used to assess the validity of other laboratory methods. The accuracy of the reference method must be established by comparison with a definitive method, if one exists. The accuracy and degree of imprecision must be stated [CLSI].

microcytic platelet — A small platelet in circulation.

microcytic RBC — A small red blood cell in circulation.

monocyte — A large, mature mononuclear white blood cell that is normally present in circulation in low concentrations.

mononuclear — Referring to a subcategory of white blood cells that have unsegmented nuclei.

MPV — The identifier for the mean platelet volume result, the average volume of the platelets.

myelocyte — A cell in bone marrow that gives rise to a granulocyte and is not normally in circulation. Considered an immature granulocyte. *See also* immature granulocyte.

NCCLS — Acronym for the National Committee for Clinical Laboratory Standards. As of the year 2005, the revised NCCLS organizational name is Clinical and Laboratory Standards Institute (CLSI).

neutrophil — A mature granulocytic white blood cell present in circulation in high concentrations. Characterized by a segmented nucleus made up of two to eight lobes and a cytoplasm containing granules.

NRBC — An acronym for nucleated red blood cell.

nucleated red blood cell — A nucleated cell present in the bone marrow that gives rise to a mature red blood cell and is not normally present in circulation. Subtypes include erythroblasts, basophilic normoblasts, polychromatophilic normoblasts, and orthochromic normoblasts. *See also* NRBC.

nucleus — A cellular organelle that is essential to cellular functions such as cell division and protein synthesis.

measurand — A result output by a hematology analyzer. Examples are red blood cell concentration (RBC) and hemoglobin concentration (HGB).

plasma — The fluid part of whole blood as distinguished from the cells.

platelet — Circulating cytoplasmic fragment of a megakaryocyte present in moderate concentrations, averaging about 250,000/µL of whole blood. Platelets contain no nuclei, have some granules, and play a key role in blood clotting. Also called thrombocytes.

PLT — An acronym for platelet. On the CELL-DYN Emerald, PLT is used as the identifier for the platelet absolute concentration result, calculated as the number of platelets per unit volume of whole blood.

precision — The degree of agreement in the results of a set of replicate or paired (duplicated) measurements. Precision has no absolute numerical value. It is expressed as imprecision, calculated as a standard deviation or coefficient of variation percentage. *See also* imprecision.

promyelocyte — A cell present in the bone marrow that gives rise to a granulocyte and is not normally present in circulation. *See also* immature granulocyte.

QC file — On the CELL-DYN Emerald, a repository that stores data automatically each time a control specimen is run, for review and output in a summary or Levey-Jennings graph format. The mean, SD, and CV calculations are automatically updated each time data are received.

quality control (external) — A system of retrospectively and objectively comparing results from different laboratories by means of surveys organized by an external agency. The main objective is to establish between-laboratory and between-instrument comparability, if possible, with a reference standard, when one exists [ICSH].

quality control (internal) — A set of procedures undertaken by the staff of the laboratory for continual evaluation of the reliability of its work. The procedures determine whether the test results are reliable enough to be released to the requesting clinicians. These procedures should include tests on control material and statistical analysis of patient data [ICSH].

quiet zone — The quiet zone is the area immediately adjacent to the beginning and end of the bar code symbol. No writing or other printed material should be present in the quiet zone.

range — A measure of the dispersion of values. The difference between the largest and the smallest of a group of measurements.

RBC — An acronym for red blood cell. On the CELL-DYN Emerald, RBC is used as the identifier for the red blood cell absolute concentration result, calculated as the number of red blood cells per unit volume of whole blood.

RDW — An acronym for red cell distribution width. On the CELL-DYN Emerald, the identifier for the red blood cell distribution width result, calculated as the coefficient of variation percentage of the red cell volume distribution.

reagent — A solution used to dilute, and in some cases, alter the cells in a whole blood specimen, in preparation for measurement by the Analyzer. May also refer to a substance used to clean the instrument fluidics.

red blood cell — A biconcave, circular disk approximately 7.5 µm in diameter, with no nuclei. Red blood cells are mature cells present in greater concentrations than others in circulating blood (averaging 5 million cells per microliter of whole blood). Primary function is oxygen delivery to the tissues and carbon dioxide removal. Also called erythrocytes.

reticulocyte — The first non-nucleated red blood cell stage, identified by ribosomal material in the cytoplasm observed when red blood cells are stained with supravital dye.

RNA	Acronym for ribonucleic acid. Any of the various nucleic acids that contain ribose and uracil as structural components. Associated with the control of cellular chemical activities, such as protein synthesis.
sample	A part or unit taken at random from a large whole, and so presumed to be typical of its qualities. On the CELL-DYN Emerald, a representative part (aliquot) that is obtained from the collected whole blood specimen, diluted, and analyzed. Not used synonymously with specimen in this manual.
sample dilution	The mixture of sample and reagent that is analyzed by a hematology instrument.
sequence number	A cycle identifier that is automatically assigned to result data produced during that cycle.
shift	An abrupt change in results from specimens thought to be similar.
specimen	Collected whole blood that is presented to the Analyzer for sampling. Not used synonymously with sample in this manual.
stability	The ability of a specimen, reagent, or control to maintain a constant concentration of the analyte. May also refer to the ability of an analytical system to avoid drift.
standard deviation (SD)	A measure of the dispersion of a group of values around a mean. The square root of the variance expressed in the same units as the measurements themselves.
standard reference particle (SRP)	A polystyrene microparticle with measurement properties that can be traced to a reference standard. Used to verify or set WBC and/or RBC/PLT gains.
start and stop characters	Bar Code Readers use these characters to determine the order in which to read the characters in the code and identify the bar code symbology. Start and stop characters make it possible to scan the label in either direction and are located at the beginning and end of each bar code symbol.
test	An analysis to detect the presence or measure the concentration of an analyte.
thrombocyte	*See* platelet.
throughput	The number of tests an analytical instrument can perform in a given time.
trend	A situation in which results obtained from specimens thought to be similar move in the same direction for several consecutive runs.

unit of measure	A determinate quantity adopted as a standard of measurement. Associated with a numerical result for a measured quantity or property.
verification	A protocol or procedure followed to test the performance of a system or component to ensure that it meets stated specifications.
WBC	The identifier for the white blood cell absolute concentration result, which is calculated as the number of white blood cells per unit volume of whole blood.
Westgard Rules	A multirule system described by Westgard for identifying out-of-control QC results, based on control procedures described initially by Shewhart and later by Levey and Jennings. Uses a set of statistical rules to assess and validate QC data.
white blood cell	A cellular constituent of circulating blood that is present in lower concentrations than red blood cells or platelets, averaging 7,000/μL of whole blood. Primary function is to guard tissues against invasion by foreign organisms or chemicals. Also called leukocytes.

NOTES

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