

QBC STAR™

System Operator's Manual



Fast, Simple CBC Analysis
Designed for the Point of Care

Document Number: 6000-300-000
Revision K

 **Drucker Diagnostics**
Innovative Solutions for a Healthier World

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The QBC STAR complies with the emission and immunity requirements described in section 9.103 of the IEC 61326 series.

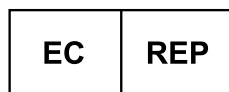
This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

The electromagnetic environment should be evaluated prior to operation of the QBC STAR.

Do not use this device in close proximity to sources of strong electromagnetic radiation e.g. unshielded intentional RF sources, as these may interfere with the proper operation.

INSTRUCTIONS FOR DISPOSAL OF WEEE BY USERS IN THE EUROPEAN UNION

This product must not be disposed of with other waste. Instead, it is the user's responsibility to dispose of their waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service, or where you purchased the product.



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1 – Introduction

Intended Use

The QBC STAR™ Centrifugal Hematology System provides a diagnostic hematology profile on venous or capillary blood providing values for:

- Hematocrit
- Hemoglobin
- Mean Corpuscular Hemoglobin Concentration (MCHC)
- Platelet count
- White blood cell count
- Granulocyte count (% and number)
- Lymphocyte/monocyte count (% and number)

Principles of the Test

It has been known for many years that the grayish-white layer (buffy coat) that appears above the red blood cells in a centrifuged hematocrit tube contains packed layers of leukocytes (white blood cells) and thrombocytes (platelets)¹⁻⁵. The QBC STAR Centrifugal Hematology System uses technologies that make it possible to quantify the buffy coat cells.

When the QBC STAR tube is filled with blood and placed into the QBC STAR instrument, the tube is spun at a high rate of speed causing the different types of cells in the blood to separate into layers or bands from the most dense to the least dense. The QBC STAR System uses a special tube designed to enhance the natural separation properties of a whole blood sample when it is centrifuged. A special coating in the QBC STAR tube stains the two white blood cell populations (granulocytes appear orange-yellow and lymphocytes/monocytes appear green) and the platelet layer (platelets appear yellow-orange). The ability to quantify the cells is also enhanced by the insertion of a precision plastic float into the QBC STAR tube that mechanically expands the buffy coat layers. The hematocrit, white blood cell counts, and platelet count are directly measured from the cell layers. The float, whose density approximates the buffy coat cells, will also penetrate the red blood cell layer. The QBC STAR hemoglobin measurement is directly related to the density of the red blood cells, and is based on the depth of penetration of the float into the red blood cell layer. Mean Corpuscular Hemoglobin Concentration (MCHC) is electronically calculated using the standard formula $[(\text{HGB} / \text{HCT}) * 100]^{\text{6-7}}$.

The QBC STAR tube is also internally coated with anticoagulants that allow collection of capillary blood directly from a skin puncture site.

The QBC STAR System is intended for *in vitro* diagnostic use.

WARNING

CAREFULLY OBSERVE ALL WARNINGS AND PRECAUTIONS IN THIS MANUAL AND ON LABELING OF QBC STAR TUBES CONCERNING THE SAFE HANDLING OF BLOOD AND BLOOD-DERIVED PRODUCTS.

System Overview

The QBC STAR Hematology System is a self-contained, whole blood, automated hematology system. Reported results include hematocrit, hemoglobin, total white blood cell count, combined lymphocyte and monocyte count, granulocyte count, platelet count, and MCHC. The test can be performed from either venous or capillary blood specimens. The system is factory preset and user calibration is NOT required. The system is powered by a universal voltage external power supply that plugs directly into an AC power source.

The QBC STAR Hematology System performs all tests using the QBC STAR Tube. The QBC STAR Tube is described below. When the QBC STAR Tube is placed into the instrument, it is automatically centrifuged and analyzed. The results are computed, displayed, and printed on the internal printer.

QBC STAR Blood Collection Tubes

The QBC STAR Tube is a two-component device. The tube assembly represents the first component. It consists of a precision glass QBC Tube and the plastic sleeve that serves as a carrier for the tube. A cap and float assembly comprise the second component. The float expands the buffy coat region by a factor of ten. It does this by reducing the cross sectional area of the tube.

The QBC STAR Tube is preassembled and consists of the following components :

- 3" long precision bore glass tube with dried coatings of acridine orange, heparin, K₂EDTA, potassium oxalate, monoclonal antibody and other reagents
- A vented plug at the end of the tube
- Protective plastic sleeve

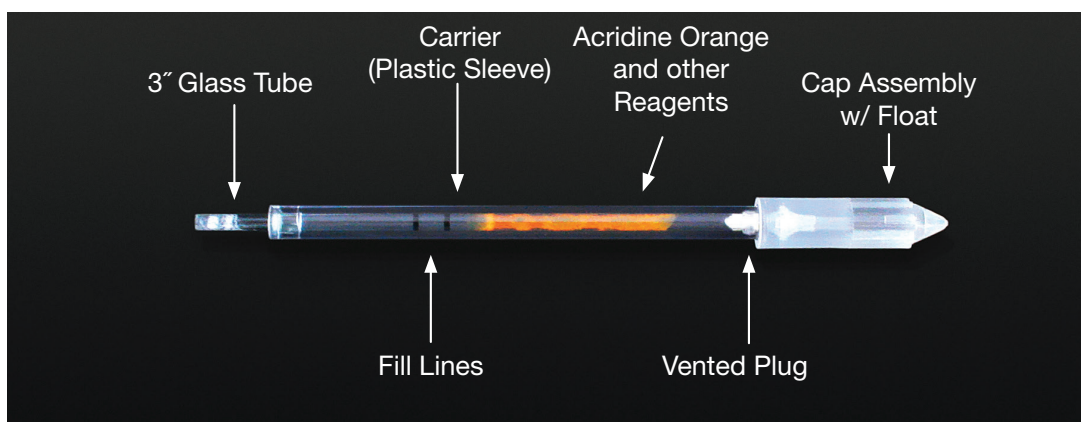


Figure 1 – QBC STAR Blood Collection Tube

Tubes are filled by capillary action with 65 to 75 μ L of whole blood. This is the volume when the tube is filled between the 2 fill lines marked on the QBC STAR Tube. The blood can come directly from a fingerstick or from a lavender top EDTA anticoagulant only. The plug has a vent allowing air to escape during filling of the tube. The vent closes off when the tube is capped.

After the tube assembly is filled with blood, the blood is mixed and the cap assembly is placed on the tube. The cap consists of the following components:

- A precision molded plastic float
- A float holder
- The cap

Placing the cap on the tube performs three actions simultaneously:

- Seals the tube protective plastic sleeve
- Inserts the float into the QBC STAR tube
- Closes the air vent

The density of the float is matched to the density of the buffy coat so that it centers itself in that region.

If a tube breaks during centrifugation, blood and glass are fully contained within the capped tube protective plastic sleeve. This design provides a high degree of user and instrument protection from exposure to blood and aerosols.

QBC STAR Instrument

The QBC STAR Instrument (Figure 2) is a compact, portable, centrifugal hematology analyzer. The instrument contains a single tube centrifuge for sample mixing and for separating the blood into the various cell populations. Analysis of the sample occurs in the centrifuge rotor after the centrifuge is finished.

A single filled QBC STAR Tube is placed into the rotor, the door is closed, and the “STAR” button pressed to start the test process. The centrifuge cycle mixes and then separates the blood into distinct cell layers. The instrument initially spins slowly for up to 30 seconds allowing the blood in the tube to mix. Once this initial mixing is done, the centrifuge accelerates to a higher speed which is maintained for 4.75 minutes. This stage separates the blood cell populations into distinct packed cell bands. After the cell populations have been separated, the centrifuge decelerates to measure the band lengths. Analysis of the tube occurs at the illumination/read station. This station consists of an LED light source and optical imaging system.



Figure 2 – QBC STAR Instrument

Hematological results are shown on the Liquid Crystal Display. Results are also automatically printed by the internal thermal printer onto a 2.25-inch paper tape.

The instrument contains the following subsystems:

- The centrifuge for mixing and separating the blood sample
- An embedded microprocessor for machine control, blood sample analysis, and communications
- An internal printer for printing results
- A Liquid Crystal Display to show results, prompts, and messages
- USB ports for communication with optional external devices such as a keyboard, barcode scanner, or external printer
- An ethernet connection for use with Laboratory Information Systems

Instrument Self-Testing and Calibration

When the instrument is powered on and the door is closed, the system software performs a self-test to verify proper operation (Or once every 8 hours if power is left on continuously). The self-test checks such things as: centrifuge motor at various speeds, emission filter assembly, optics assembly, light source, timing control, optical clarity and focus, internal printer, rotor timing, and setup keypad.

The instrument runs a built-in calibration check every time a sample is processed. Sample integrity checks include: statistical matching of bandlengths, ratios and absolute values for signal levels, ratios that are used to evaluate the quality of interfaces, measurement of float length, verification of optics and sensors, measurement and evaluation of sample fill volume. Additional tests performed as part of each assay cycle include centrifuge speed and electro-optical verification. Results are reported on tube tests only if all verification and integrity tests pass.

The power-on self-test and sample integrity tests provide verification of instrument parameters including but not limited to timing, speed, disposable integrity, and reagent stability.

In addition to these checks, the system monitors the temperature inside and outside the instrument before and during each test. The system will allow operation of the instrument if the temperature is higher than 32° C, but with limited reports. If the sample temperature exceeds 45° C, the unit will become too hot to operate.

Since the QBC STAR instrument contains a centrifuge, centrifuge speed measurements are verified each time a sample is processed.

If any part of the self-testing or calibration process fails, a message is displayed. Confirmation of the success of self-tests is provided by the "Ready" message. In addition, each results printout indicates the outcome of electronic QC.

Manual Structure

This Operator's manual contains the following sections:

- Section 1 – Introduction** – provides an overview of the QBC STAR hematology system, its major components, and its uses in the laboratory. An overview of this manual's structure and conventions is also included.
- Section 2 – Installation and Setup** – gives specifications for installation of the QBC STAR system and instructions for instrument installation and setup.
- Section 3 – Controls and Indicators** – explains the use and meaning of all controls and indicators of the system.
- Section 4 – Operation** – provides instructions for routine operation.
- Section 5 – Performance and Limitations** – provides information on instrument performance, such as operating ranges, precision, accuracy, interfering substances, expected values, etc.
- Section 6 – Maintenance** – explains all user system maintenance.
- Section 7 – Troubleshooting** – provides a convenient guide identifying errors and suggesting corrective actions.
- Section 8 – The Appendices** contain supplemental information, such as warranty, list of parts and accessories, a software update form, a listing of national contacts, specimen collection, and bibliography, and the Glossary explains several terms used in this manual, as well as abbreviations.

Getting Started

The QBC STAR system has been designed and tested for ease of use. However, before you begin to use the instrument, you will find it advantageous to familiarize yourself with the material in this manual, especially:

- Be sure to read the Summary of Warnings and Cautions on page 1–7.
- Refer to the material in Section 2 – Installation and Setup for information on where to place the instrument and how to set it up for operation.
- Read Section 3 – Controls and Indicators. It explains the lights, readouts, buttons, switches, etc. that are found on the instrument.
- Read Section 4 – Operation. It tells you how to perform routine system operations.

Use of this Manual

This Operator's manual is designed as a reference tool for personnel who operate the QBC STAR Hematology System on a regular basis. Every attempt has been made to include all information which would be needed during normal use and maintenance of the system. Should a question arise which is not answered in this manual, please refer to appendix D for information on how to contact us.

You can send in your comments or recommendations on this Operator's manual by sending an e-mail to qbcsupport@druckerdiagnostics.com

Other documentation that may be of interest includes:



QBC STAR *Tube Package Insert* – This document contains important information on specimen preparation and the use, storage, and limitations of the tubes. A package insert is included with each box of tubes, and is available upon request from Drucker Diagnostics, or may be downloaded from the Drucker Diagnostics website (www.druckerdiagnostics.com)

QBC STAR *Tube Quick Reference Guide* – This document contains a summary of steps for preparing venous and capillary specimens and testing them on the QBC STAR instrument.

Conventions

Symbols Used on the Equipment

The following symbol appears on the QBC STAR instrument

	
Figure 3a – Warning symbol Used on the QBC STAR Instrument	Figure 3b – Biohazard symbol used on the QBC STAR instrument

Notes, Cautions, and Warnings

Throughout this manual, important information is presented in boxes offset from the regular text, and is labeled as either a NOTE, CAUTION, or WARNING. These messages are formatted as shown below and bear the following meaning:

NOTE

Important information about system use worthy of special attention is presented as a NOTE.

CAUTION

Information on an activity that potentially could cause damage to the instrument or system is presented as a CAUTION.

WARNING

INFORMATION ON AN ACTIVITY THAT POTENTIALLY COULD CAUSE INJURY TO THE USER IS PRESENTED AS A WARNING.

Summary of Warnings and Cautions

Carefully observe all warnings and precautions in this manual and on labeling of QBC STAR tubes concerning the safe handling of blood and blood-derived products.

If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Do not, under any circumstances, remove the ground prong from the instrument power plug.

Blood and body fluids may contain the Hepatitis B virus (HBV), Hepatitis C virus (HCV), human immunodeficiency virus (HIV), or other disease-causing agents. Handle all patient specimens as potential biohazards capable of transmitting infection. Wear appropriate personal protective equipment, including laboratory gloves, when collecting, handling, and processing blood and body fluids.

In addition to wearing gloves, the use of disposable lab coats or gowns and protective glasses or goggles is recommended when working around the instrument.

ACRIDINE ORANGE REAGENT MAY BE TOXIC; DO NOT INGEST. AVOID CONTACT WITH SKIN, EYES, AND CLOTHING.

If a tube breaks in the unit, carefully remove the tube with a hemostat or other device, using puncture resistant utility gloves. CONTACT DRUCKER TECHNICAL SERVICES FOR ADDITIONAL INFORMATION.

Do not handle the QBC STAR tube by the glass collection end of the tube.

Do not use any QBC STAR tube if any part of the carrier or tube is chipped or cracked.

The user should not perform any servicing except as specifically stated in this manual. Refer other problems to trained personnel, or return the instrument to Drucker Diagnostics for repair.

Turn instrument power off and unplug the power cord before servicing.

Do not immerse the QBC STAR instrument in water or other liquid.

Do not attempt to move the instrument rotor by hand. Moving the rotor manually can cause damage to the instrument.

Ensure the device is turned off prior to connecting the external power supply to a device or AC outlet.

Do not attempt to insert your hand or any other object in the cavity located on the base of the instrument while in operation.

Do not lift or turn the instrument on its back or side while it is plugged in as damage may occur.

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2 – Installation and Setup

Unpacking and Setup

The QBC STAR instrument weighs approximately 19 pounds. Use caution when lifting and moving the instrument.

Carefully unpack the QBC STAR instrument, noting any damage to the shipping carton. If damage is observed, notify the carrier immediately. After unpacking, remove the instrument from the plastic bag, and place it on a level, stable, working surface.

An operator's clearance envelope while running the tube should be marked 11.8 in. (300 mm) from each side of the unit. The operator should not stand within the clearance envelope longer than necessary for operational purposes.

Proceed with electrical connection, described below.

Electrical Connection

- Connect the female end of the power pack to the back of the QBC STAR instrument (see Figure 4).
- Connect the male end of the power cord to the main AC power source. To avoid electrical shock, connect the power cord only to an approved power source such as a 3-wire grounded receptacle. If a 2-wire receptacle is all that is present, have it replaced with a properly grounded 3-wire receptacle in accordance with the National Electrical Code.
- Connect female end of power cord to male end of power pack.

WARNINGS

IF THE EQUIPMENT IS USED IN A MANNER NOT SPECIFIED BY THE MANUFACTURER, THE PROTECTION PROVIDED BY THE EQUIPMENT MAY BE IMPAIRED.

DO NOT, UNDER ANY CIRCUMSTANCES, REMOVE THE GROUND PRONG FROM THE INSTRUMENT POWER PLUG.

Should the power cord or plug become cracked, frayed, broken or otherwise damaged, replace them immediately (see Appendix B for part number).

Never attempt to override electrical safety interlocks of the instrument.

QBC STAR Specifications

Physical Specifications	
Height (loading door open)	16.3 in (41.4 cm)
Width	16 in (40.6 cm)
Depth	16.3 in (41.4 cm)
Weight	19 lbs (8.6 kg)
Clearance	2 in (5.1 cm)
Noise	< 70 dB @ 3 ft

Electrical Specifications for the Power Pack	
Input Voltage	100 – 240 VAC
Frequency	50 – 60 Hz
Current Output	5.21 A (Peak)
Power Output	250 Watts

Environmental Specifications	
Non-Operating Storage	
Temperature	-20 °C – 50 °C
Humidity	10% – 95% non-condensing
Operating	
Temperature	16 °C – 32 °C unrestricted (at > 32 °C use may be limited by instrument temperature shut-down or some results may be suppressed)
Humidity	10% – 95% non-condensing
Surface Inclination	10° any direction without restraint; 45° any direction with restraint
Decontamination	
Surface	10% dilution of household bleach solution
IEC 664 Pollution Degree	Category 2
IEC 663 Installation	Category II

Reporting Ranges		
Parameter	Lower Limit	Upper Limit
Hematocrit (Hct)	15%	65%
Hemoglobin (Hgb)	5.0 g/dL	20.0 g/dL
MCHC	25.0 g/dL	37.3 g/dL
White Blood Cells (WBC)	1.6 x 10 ⁹ /L	99.9 x 10 ⁹ /L
Granulocytes	0.8 x 10 ⁹ /L	70.0 x 10 ⁹ /L
% Granulocytes	1%	99%
Lymph/Mono	0.8 x 10 ⁹ /L	99.9 x 10 ⁹ /L
% Lymph/Mono	1%	99%
Platelets	20 x 10 ⁹ /L	999 x 10 ⁹ /L

External Connections

The following external connections are located on the rear of the QBC STAR instrument, and are shown in Figure 4:

- DC power input
- USB Port (3x) for external printer, keyboard, USB memory stick, or scanner
- Ethernet Port

You can attach a keyboard, USB memory stick, barcode scanner, and a full-size external printer (for printing results on standard letter or A4 size paper) via the USB ports in the back of the QBC STAR instrument.

You can also leave the internal instrument printer enabled even if you attach an external printer. If you do, results print on the internal printer and the external printer at the same time.

For information on what makes and models of printers can be used, contact Drucker Diagnostics Technical Support or visit www.druckerdiagnostics.com.



Figure 4 – External Connections

How to attach an external printer:

1. Unpack and set up the printer according to the manufacturer's operating instructions.
2. Connect the printer to the QBC STAR instrument's USB port (see Figure 4).
3. Turn on power to the QBC STAR instrument **first**.
4. Turn on power to the external printer **second**.

Note: Please contact Drucker Diagnostics for printer compatibility.

Upgrading the Software

Updated versions of the QBC STAR Hematology System software may be provided to you from time to time. You should install new software as soon as you receive it. You should also log the update on the form in Appendix C of this manual. Updated software is provided on a USB stick, labeled "QBC STAR Software."

To install a software update:

1. Verify your STAR analyzer is turned off
2. Insert the upgrade USB drive into any rear USB port
3. Turn on STAR
 - A. The STAR will automatically read the upgrade software from the USB drive.
 - B. The upgrade software will verify that it is being installed on compatible hardware.
 - C. The software will be installed and the STAR will progress through System Check.
 - D. Once installation is complete, the STAR will print the System Check with the date, time, software version, and QC label checks.
4. Confirm software version on print out matches upgrade version
5. Turn off the STAR
6. Remove USB drive from STAR and discard
7. Turn on the STAR
8. Remove printouts from step 4 and step 7 from device and mail to Drucker Diagnostics in Appendix D-1, scan a copy to qbcsupport@druckerdiagnostics.com, or fax to 814-692-7662.

DO NOT turn off the device while the software is upgrading. If you have any questions please contact Drucker Diagnostics Technical Support at +1-866-265-1486 (U.S Only) or +1-814-692-7661.

System Setup and Utilities

Before using the QBC STAR instrument for sample testing, you should review system setup parameters to see if they are suitable for your laboratory. These parameters include:

- LCD Contrast
- Date and Time
- Printer Settings
- Support
- Set Language
- Units
- Shipping Preparation

Any changes to configuration parameters are in effect from the time of the change forward. Also note that any changes you make cannot be "cancelled" per se – if you change a value, you must manually change the new value back to its previous state.

To Enter Setup Mode

1. Ensure the instrument door is closed and latched.
2. Lift and pull back the printer access door.
3. Turn on instrument power with the power switch on the rear of the instrument (Figure 4).
4. After the instrument completes a self-check and the door unlocks, press the ESC key on the setup keypad.
5. A menu appears listing all the setup functions:

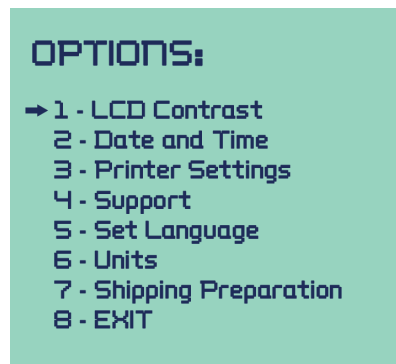


Figure 5 - QBC STAR Menu, Options

The arrow cursor (→) points to the option that is currently selected. (When you first access the menu, the first option, LCD Contrast, is selected.) To adjust the option that is selected, press on the keypad. To select another option, use the or key to move the arrow cursor up or down the list. When the desired option is selected, press on the keypad to adjust the setting.

Each of the setup options/utilities is described below.

LCD Contrast

The LCD Contrast option lets you adjust the contrast of the LCD screen. This can help improve the readability of the screen. Press the or key to increase or decrease the display contrast. When you reach the desired contrast, press .

Date and Time

The Date and time option lets you adjust the date and time that is printed on results reports. When you select the option, a sub-menu (Figure 6) appears. The arrow cursor (→) points to the item that is currently selected. (When you first access the menu, the first item, Time Format, is selected.) To adjust the current item, press on the keypad. To select another item, use the or key to move the arrow cursor up or down the list. When the desired option is selected, press on the keypad.

When you press , the menu disappears and the cursor appears next to the item you selected. Press the or key to increase or decrease the value. When the desired value is shown, press . To return the original value, press ESC.





Figure 6 - QBC STAR Menu, Date & Time

Printer Settings

Internal Printer

Internal Printer lets you enable or disable the QBC STAR system's built-in printer. When you select the "Printer Settings" option, a sub-menu titled "Printer Settings" appears.


When the printer is ENABLED, the menu lets you disable the printer by selecting option 2. You can disable the printer by confirming that the arrow cursor (→) is pointing to option 2 and pressing the  key. The status of the internal printer will now be displayed as "Disabled".

When the built-in printer is DISABLED, you can enable it by selecting option 1. You can enable the printer by confirming that the arrow cursor (→) is pointing to option 1 and pressing the  key. The status of the internal printer will now be displayed as "Enabled".

External Printer




An external printer can be enabled or disabled if it is attached to a USB port on the back of the instrument. When you select the "Printer Settings" option, a sub-menu titled "Printer Settings" appears.

Enable/Disable External Printer

When the printer is ENABLED, the menu lets you disable the printer by selecting option 4. External printing is disabled by default. When the printer is enabled, the status of the external printer will be displayed as "Enabled". You can disable the printer by confirming that the arrow cursor (→) is pointing to option 4 and pressing the  key. The status of the external printer will be displayed as "Disabled".



Support

Create Support File

1. Insert a USB drive into any available USB port.
2. Lift access panel to access menu keypad where paper comes out.
3. Press (ESC) key menu will display.
4. Press the down arrow key  to option #4 "Support" until side (→) indicator arrow is beside.
5. Press the Enter key to select Support option.
6. Press the Enter key  again to select option 1 "Create support file".
7. Menu screen should read "Writing support file to USB" (Wait 60 seconds).
8. Completion of file export is indicated by "Please remove USB drive".
9. Remove USB drive.
10. Press the Enter key .
- 11 To exit system menu press the ESC key twice.

Set Language


Set language lets you select from the following languages: German (Deutsch); English; Spanish (Español); French (Français); Italian (Italiano).

When you select the option, a sub-menu titled “LANGUAGES” appears. It lists these language selections. The arrow cursor (→) points to the item that is currently selected. (When you first access the menu, the cursor points to the first item, Deutsch.) To select the current item, press  on the keypad. To select another item, use the ▲ or ▼ key to move the arrow cursor up or down the list. When the desired option is selected, press  on the keypad.

Units

The units option allows you to select whether certain results are reported in SI units (Millimoles per liter) or STD units (Grams per deciliter). The results that are affected are hemoglobin and MCHC.

When “STD Units” Option 1 is selected, the status on the LCD display will be “STD Units”.

You can select SI units by using the ▲ or ▼ key to move the arrow cursor (→) up or down the list until it is pointing to option 2. Then press  on the keypad. The status on the LCD display will be “SI Units”.

Shipping Preparation

This option prepares the instrument to be physically shipped by allowing the rotor to spin freely by retracting the actuator. After you select this option, a message will be displayed indicating that shipping preparation has been completed. Ensure that the rotor can be freely spinned. The instrument can now be powered off.

3 – Controls and Indicators

General Discussion

The QBC STAR Hematology System has been designed so that there are only two routine user controls: the “STAR” Button, which has several functions that are described below; and the Door Release Latch, which is only used to open the door to insert or remove QBC STAR Blood Collection Tubes.

All the instrument controls (buttons, switches, etc.) and indicators (readouts, lights, etc.) are described below. The following items are discussed:

- Power Switch
- STAR Button
- Door Release Latch
- Liquid Crystal Display
- Printer
- Setup Keypad

Power Switch

The power switch is located on the rear panel of the QBC STAR instrument (Figure 7) on the left side. Place the switch in the “—” position to turn instrument power on. Place the switch in the “O” position to turn instrument power off. Drucker Diagnostics recommends that you turn the power off at the end of the day’s testing, and keep it in the off position until the device is connected to an AC outlet.



Figure 7 – Power Switch (toward left)

“STAR” Button

The “STAR” Button is located on the top of the QBC STAR instrument, (Figure 8) toward the right side. It is teal colored. This button has several functions:

- Start Testing – when an untested tube is in the analyzer and the door is closed.
- Abort Testing – when the instrument is in the process of testing.
- Reprint Test Results – after automatic test results printout, before opening door.

The button will only perform these functions at the times described above.

Door Release Latch

The door release latch is located on the front panel of the QBC STAR instrument, just below the door. It is used to open the door on the top of the instrument. The door can only be opened when the system determines that it is safe to do so. The door is locked electromechanically when it is unsafe to open the door (such as when a QBC STAR Tube is being centrifuged). Pressing the door release latch at such a time has no effect.

Liquid Crystal Display (LCD)

All system prompts (instructions for use) are presented on the Liquid Crystal Display (also called the LCD or LCD Readout). In addition, the test results are shown on the LCD. If any errors occur during the system's self-tests or during operation of the unit, this information is also shown on the LCD. See Figure 8.



Figure 8 – QBC STAR Controls and Indicators

Internal Printer

Test results print automatically at the end of the testing cycle. The printer is located on the top panel of the instrument (Figure 9). Samples of test results printouts are shown in Section 4 – Operation. See Figure 9 for printer controls.

To access printer controls, lift the rear of the printer panel and remove it from the unit.

Paper Release Lever

The paper release lever is located on the right side of the printer. Pull the lever forward to enable loading paper. When the lever is forward, the manual advance wheel (below) is operational. Push the lever toward the rear to lock the paper in place.

Manual Advance Wheel

The manual paper advance is located on the right side of the printer. It is a knurled wheel. Rotate the wheel toward the rear to advance paper when loading. Rotate the wheel forward to retract paper (for example, to correct a paper jam).

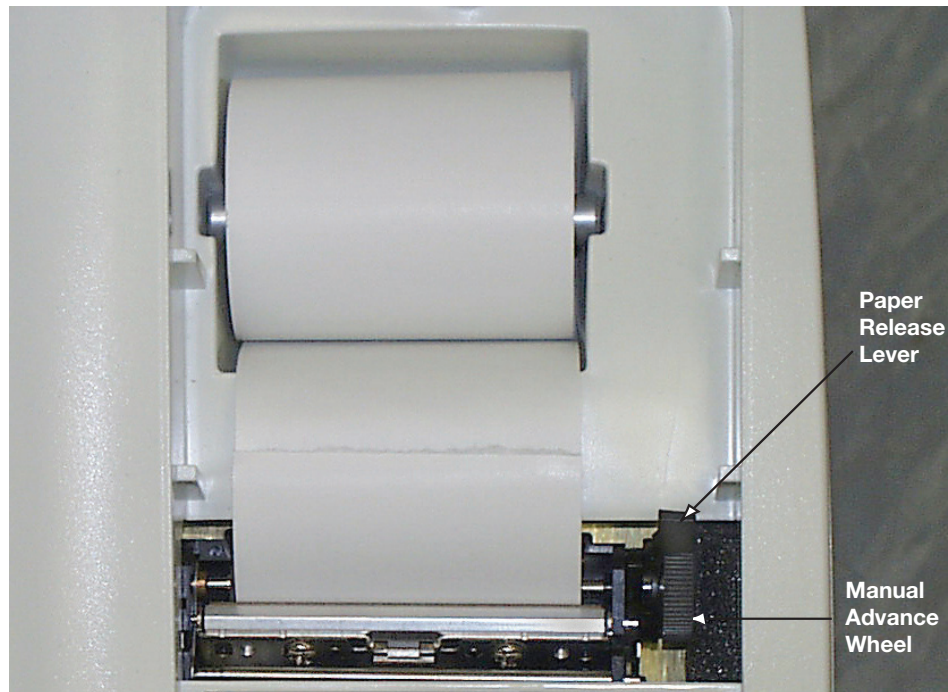


Figure 9 – Printer Controls

Setup Keypad

The setup keypad is located to the front of the printer beneath the printer access panel. It is used to enter setup information into the computer, such as the date and time, LCD contrast, etc.

The setup keypad keys (Figure 10) are described below. Setup functions are described in Section 2 – Installation and Setup.

ESC Key

Press this key to cancel an action or to return to a previous menu.

▲ Key

Press this key to increase a value or scroll upward in a list.

▼ Key

Press this key to decrease a value or scroll downward in a list.

⏪ Key

Press this key to select a menu option.

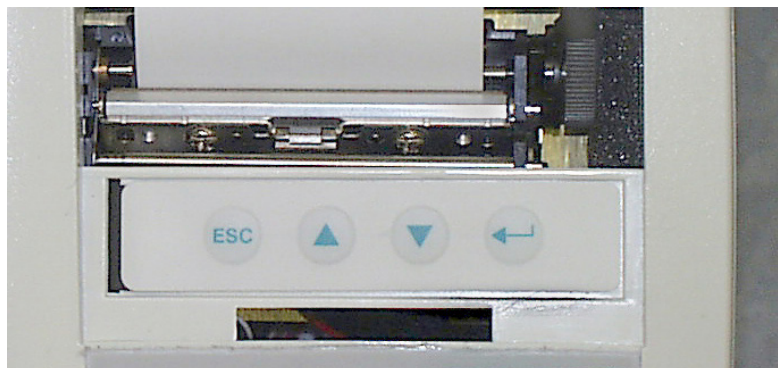


Figure 10 – Setup Keypad

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4 – Operation

WARNINGS

BLOOD AND BODY FLUIDS MAY CONTAIN THE HEPATITIS B VIRUS (HBV), HEPATITIS C VIRUS (HCV), HUMAN IMMUNODEFICIENCY VIRUS (HIV), OR OTHER DISEASE-CAUSING AGENTS. HANDLE ALL PATIENT SPECIMENS AS POTENTIAL BIOHAZARDS CAPABLE OF TRANSMITTING INFECTION. WEAR APPROPRIATE PERSONAL PROTECTIVE EQUIPMENT, INCLUDING LABORATORY GLOVES, WHEN COLLECTING, HANDLING, AND PROCESSING BLOOD AND BODY FLUIDS.

IN ADDITION TO WEARING GLOVES, THE USE OF DISPOSABLE LAB COATS OR GOWNS AND PROTECTIVE GLASSES OR GOGGLES IS RECOMMENDED WHEN WORKING AROUND THE INSTRUMENT.

ACRIDINE ORANGE REAGENT MAY BE TOXIC; DO NOT INGEST. AVOID CONTACT WITH SKIN, EYES, AND CLOTHING.

IF A TUBE BREAKS IN THE UNIT, CAREFULLY REMOVE THE TUBE WITH A HEMOSTAT OR OTHER DEVICE, USING PUNCTURE RESISTANT UTILITY GLOVES. CONTACT TECHNICAL SUPPORT FOR ADDITIONAL INFORMATION.

Summary of Operation Steps

Routine operation of the QBC STAR Hematology System consists of the following steps:


- Turn the instrument on
- Print out / save electronic controls
- Fill tube with blood
- Mix the tube of blood
- Place the cap onto the tube
- Place the tube into the instrument
- Close door and ensure it is latched
- Push the “STAR” button to start the test cycle
- Obtain the results from the printer
- Dispose of the QBC STAR tube in a biohazard sharps container

Each of these steps is described below.

Turn Instrument Power on

Turn on the QBC STAR instrument power, by placing the power switch on the rear of the instrument in the “—” position.

The instrument performs a self-test, which will take a few minutes. During this time, the message “System Check In Progress Please Wait” is displayed. When the self-test is complete and the system is ready, the following message appears on the LCD readout:

Ready
Insert Sample
Close Door
Press 

Note that if power is left on continuously and the sample door is closed, the power-on-self-test occurs automatically once per 8 hours when the door is closed.

Tri-level quality controls print automatically after the self-test is complete. Save the printout for control records.

Prepare the QBC STAR Tube

For additional information on preparing the QBC STAR Tube, refer to the package insert in the tube carton.

The blood source can be either a capillary fingerstick drop of blood, or a source of anticoagulated venous blood such as a K₂ or K₃ EDTA lavender top Vacutainer™ tube. The QBC STAR tube fills itself by capillary action. That is, when you touch the collection tip of the tube to the blood sample, it is drawn into the tube automatically.

NOTES

Use only QBC STAR Tubes in the QBC STAR instrument.

Place the tube into the instrument within 15 minutes of filling.

Whichever blood source you use, make sure you touch just the collection tip of the tube to the blood.

WARNINGS

DO NOT HANDLE THE QBC STAR TUBE BY THE GLASS COLLECTION END OF THE TUBE.

DO NOT USE ANY QBC STAR TUBE IF ANY PART OF THE CARRIER OR TUBE IS CHIPPED OR CRACKED.



Figure 11 – Sample Vial



Figure 12 – Inverting the Sample Vial

Open the QBC STAR Tube package by placing a fingernail between the foil seal and the molded plastic packaging, and lifting and peeling the foil layer away.

For Venous Blood Samples

1. Gently mix the sample by inverting the capped sample vial 12-15 times immediately before filling the tube, as shown in Figures 11 and 12.
2. After mixing, tilt the sample vial to bring the blood up to the open end. Place the collection tip of the QBC STAR Tube in contact with the blood as shown below. Figure 13 shows a venous blood sample.

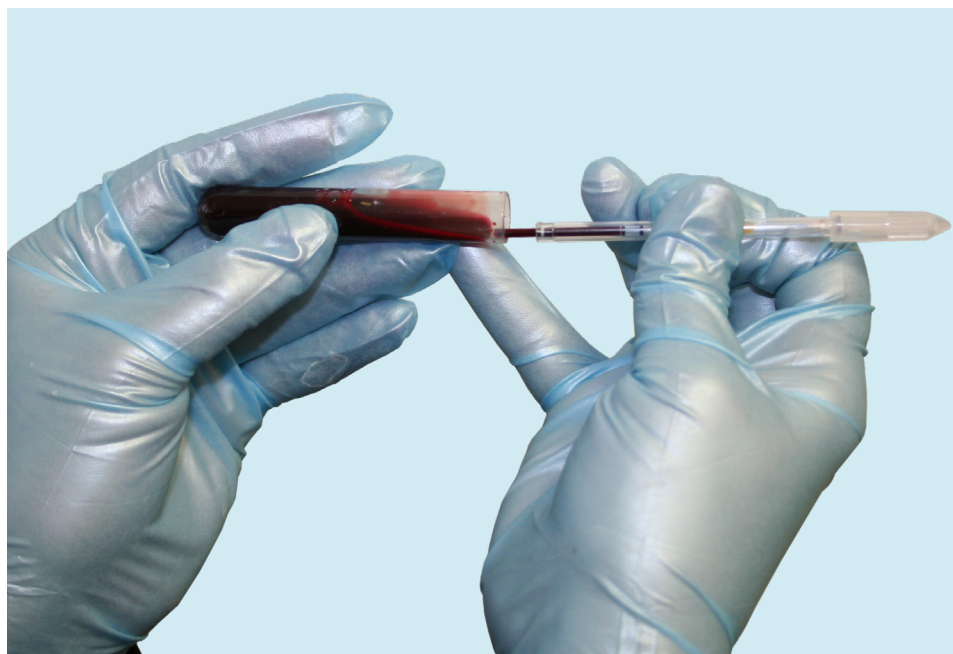


Figure 13 – Filling a Tube from Venous Blood

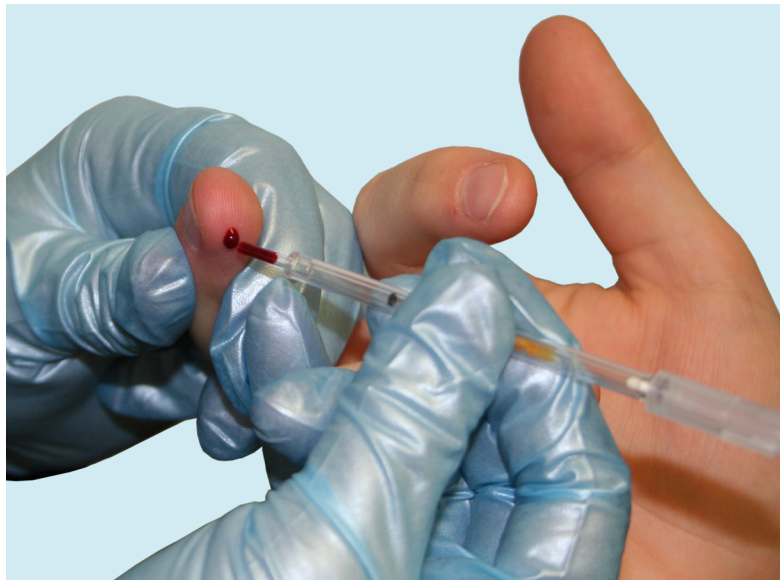


Figure 14 – Filling a Tube from Capillary Blood

For Capillary Blood Samples

Touch the collection tip of the STAR Tube to the sample while filling. The tube should be kept horizontal or slightly inclined. Figure 14 shows a capillary blood sample.

For Venous and Capillary Blood Samples

Fill the QBC STAR Tube between the black fill lines. Blood must always be filled to at least the first black line. This results in a blood volume of between 65 and 75 microliters. The instrument automatically detects if the fill volume is correct.

Mix the Tube

Rock the QBC STAR Tube back and forth at least four times to mix the blood with the acridine orange coating. Do not allow the blood to touch the white plug at the end of the tube.

Note: allowing the blood to flow from the collection end toward the plug end of the tube and back is equal to one rock.



Figure 15 – Mixing the Tube

Tilt the Tube

Tilt the QBC STAR Tube as shown, and allow the blood to move down the tube toward the center of the tube. See Figure 16.



Figure 16 – Tilting the Tube

Cap the Tube

Remove the cap from the tube by pulling it straight off. Ensure that the blood is centered in the tube before placing the cap on the tube. Place the cap over the collection end of the tube by guiding the glass end of the tube into the center of the cap. Push the cap on firmly. The pink float will be guided into the glass tube. See Figures 17 and 18.

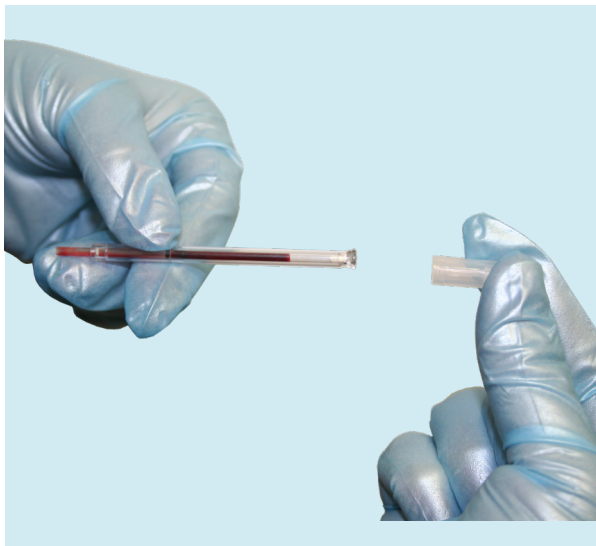


Figure 17– Uncapping the Tube

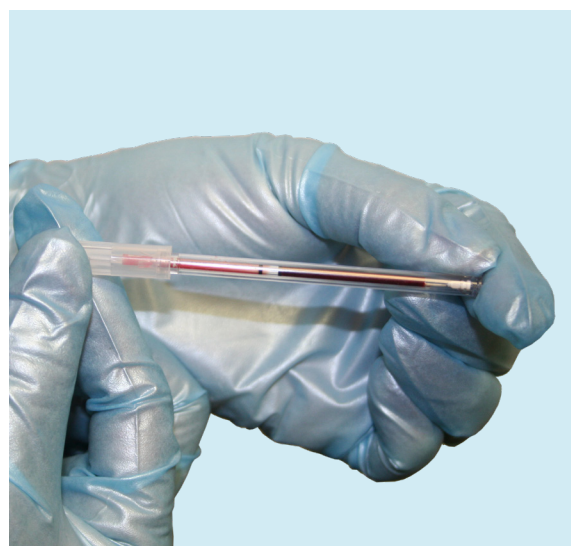


Figure 18 – Seating the Cap and Float

Insert the Tube into the Instrument

Insert the tube into the QBC STAR instrument oriented as shown in Figure 19. The tube must be inserted into the instrument within 15 minutes of being prepared and capped.

The best way to insert the tube is to first place the capped end into place, then pivot the uncapped end of the tube down into the recessed area.

If the capped end is not seated correctly the tube will not pivot down into place. If this happens, just lift the tube out, make sure the cap is seated fully, and place the tube back into the instrument as described above.

Close the Instrument Door

Make sure the door clicks into place.

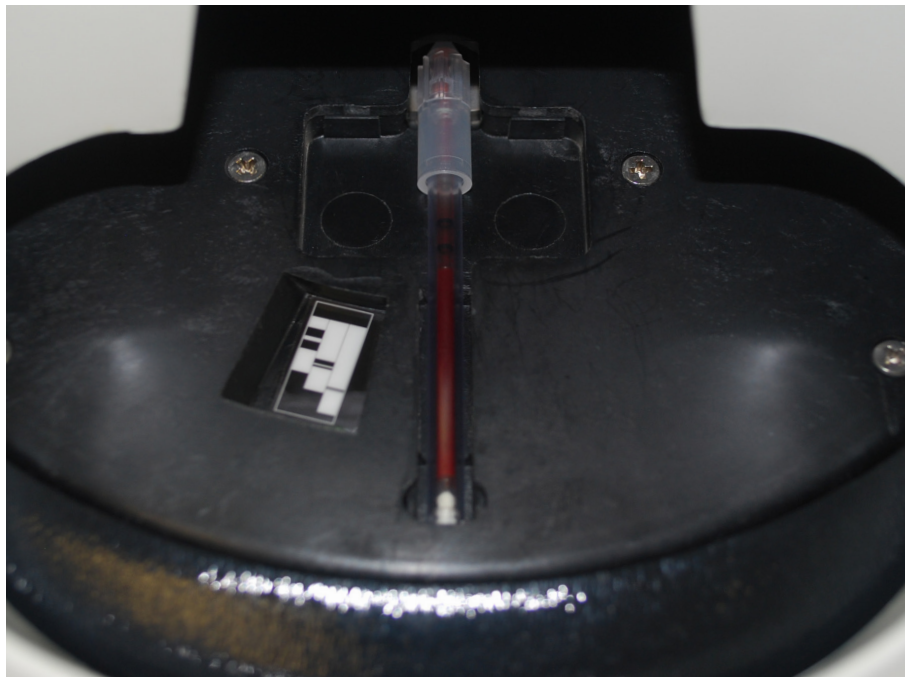


Figure 19 – Inserting the Tube into the Instrument

Start the Test

To start the test, press the “STAR” button. The system automatically locks the door electromechanically.

If there is no tube in the rotor or if the cap is not present, the message, “Sample Not Present (open door)” appears. To proceed, place the tube in the instrument and press the “STAR” button to resume testing.

The system can detect if a sample has already been tested. If this occurs, the message “Press “STAR” button to re-scan sample” appears on the LCD. See below for instructions on rerunning tubes.

The instrument mixes the tube contents for as long as 15 seconds using a low speed spin. The float descends from the top of the tube toward the closure end of the tube. This mixes the blood and reagents in the tube. A countdown displays the time remaining in the cycle.

After mixing is complete, the centrifuge accelerates to high speed to separate and pack the cell populations into distinct cell bands. A countdown displays the time remaining in the cycle.

Finally, a series of readings is taken. The messages “Reading Cycle In Progress,” is displayed while tests are being performed.

If an error message appears on the LCD display, please refer to section 7 (Troubleshooting) for error resolution.

Rerunning Tubes

The QBC STAR will process a tube that has been previously processed. To rerun a tube:

Insert a STAR Tube that has already been run into the STAR.

Close the Lid and press the run button.

The STAR will check the tube, and display the message “Press “STAR” button to re-scan sample”

Press the “STAR” button and the results are displayed on the LCD screen and internal printer.

Printing of Results

When the test is complete, the results are automatically displayed and printed.

NOTE

DO NOT OPEN THE INSTRUMENT DOOR UNTIL THE RESULTS ARE REVIEWED AND PRINTED. Test results are cleared from the display when the instrument door is opened.

You must manually keep track of the link between the test results and the patient (unless a keyboard is being used for patient identification). A space is provided on the printout for writing the patient name or ID number. In addition, the date and time and the analytical QC status (Pass, Failed) are printed.

The system only prints the actual measured or calculated results, with no interpretations or normal values. The following hematology results are reported:

Reported Results		
Parameter (abbreviation)	STD Units	SI Units
Hematocrit (Hct)	Percentage	Percentage
Hemoglobin (Hgb)	g/dL	mMol/L
Mean Corpuscular Hemoglobin Concentration (MCHC)	g/dL	mMol/L
White Blood Cells (WBC)	10 ⁹ /L	10 ⁹ /L
Granulocytes	10 ⁹ /L, Percentage	10 ⁹ /L, Percentage
Lymphocytes/Monocytes	10 ⁹ /L, Percentage	10 ⁹ /L, Percentage
Platelets (Plt)	10 ⁹ /L	10 ⁹ /L

Any results that are only slightly out of the operating range (specified in Section 2) are represented on the display with numerical values, and values that are significantly out of range will be represented by dashes only (as specified in Section 5). On the printout, if numerical values are not given for a parameter, this indicates that the results are either greater than or less than the maximum or minimum acceptable values, and the message "Out of Operating Range" is printed. Calculated values based on out of range readings will result in "No Report." If the Analytical quality control verifications fail, an error message is displayed.

Any errors that might occur are both displayed and printed on the results printout.

Test results are printed when the analytical QC checks have been successful. This is indicated on the results printout as “STAR Analytical QC: Passed.”

An example sample results printout is shown in Figure 20. A sample results readout is shown in Figure 21.

You can print additional copies of the results report by pressing the “STAR” button after the first printout completes. You must reprint the report BEFORE opening the door.

QBC STAR	
Hematology Results	
Control Sample:	
Date: MAY 23, 2014	Time: 10:20:40
Sample ID Number Q464_1	
Operator ID Number	

Software Version:	20140522 6.10
Instrument S/N:	614990010

Hematocrit	= 28.0 %
Hemoglobin	= 9.4 g/dL
MCHC	= 33.7 g/dL
Total WBC	= 11.9 x10 ⁹ /L
Granulocytes	= 7.8 x10 ⁹ /L
% Granulocytes	= 66 %
Lymphs+Monos	= 4.1 x10 ⁹ /L
% Lymphs+Monos	= 34 %
Platelets	= 399 x10 ⁹ /L

STAR Analytical QC: Passed	

Figure 20 – Sample Results Printout (Example)

Hematocrit	=	47.2%
Hemoglobin	=	16.0 g/dL
MCHC	=	33.9 g/dL
Total WBC	=	6.7 x10 ⁹ /L
Granulocytes	=	5.1 x10 ⁹ /L
% Granulocytes	=	76 %
Lymph+Monos	=	1.6 x10 ⁹ /L
% Lymph+Monos	=	24 %
Platelets	=	277 x10 ⁹ /L

Figure 21 – Sample Results Readout

Tube Disposal

After the results have been printed and you have reviewed the printout(s) for clarity, open the instrument door by pressing the door release latch. Remove the QBC STAR Tube. Discard the tube in a biohazard sharps container.

Power Down

If desired, after testing is completed you can turn instrument power off by placing the power switch in the off "O" position. Note that if you leave the power on continuously with door closed, the instrument will perform a power-on-self-test every eight hours and print analytical QC results.

Stopping the Centrifuge

If for some reason you must stop the test before it is complete, press the "STAR" key to stop the instrument.

Note: You cannot reuse or reanalyze a partially processed tube.

The system automatically stops testing if a power failure or system error occurs, or the unit breaks down. If this occurs, a message appears on the LCD display.

Emergency Door Unlock

In the event of a power failure or the failure of certain components, you may be unable to open the door with the door release latch. If this occurs, you can still open the door. The emergency door unlock is performed by tripping the internal latch with a screwdriver. Before attempting to perform the procedure below, ensure that the rotor has come to a complete stop.

To unlock the door:

- 1 Make sure the power switch is in the "Off" position (O).
- 2 Locate the door latch access hole in the bottom of the instrument. It is almost directly below the door release latch. (See Figure 22.)
- 3 Insert a small diameter screwdriver that has a shaft at least 2 inches long.
- 4 Place one hand gently over the closed access door to prevent over extension of hinge during release.
- 5 Press down against the internal latch by pivoting the screwdriver handle upward. This step may require a moderate amount of pressure.
- 6 When the door pops open, remove the screwdriver.

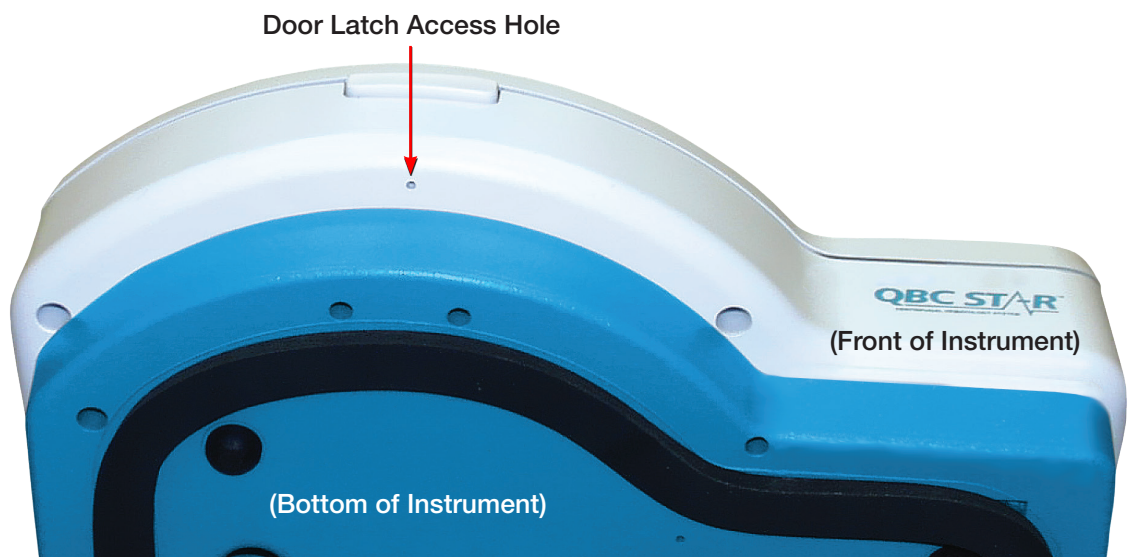


Figure 22 – Door Unlatch Access Hole

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5 – Performance and Limitations

Operating Ranges

Hematology parameters measured with the QBC Star system are considered valid over the following range of values:

Hematocrit	15 – 65%
Hemoglobin	5.0 – 20.0 g/dL
Mean Corpuscular Hemoglobin Concentration	25 - 37.3 g/d
Platelet Count	20 – 999 x 10 ⁹ /L
White Blood Cell Count	1.6 – 99.9 x 10 ⁹ /L
Granulocyte Count	0.8 – 70.0 x 10 ⁹ /L
Granulocyte %	1 - 99%
Lymph/Mono Count	0.8 – 99.9 x 10 ⁹ /L
Lymph/Mono %	1-99%

Results that fall outside these ranges may be confirmed by alternate methods.

As a reference, the STAR will display the numerical values of some parameters when they are slightly outside the Operating Ranges. On the printout, these values will be highlighted with double asterisks and marked as “**

Reference Result” below the area of results. On the LCD display, these values will be flashing.

If the results are much farther outside the Operating Ranges, the values will be withheld and the phrase “Out of Operating Range” will be printed on the printout instead.

QBC STAR
Hematology Results

Control Sample:
Date: MAY 23, 2016 Time: 05:58:22
Sample ID Number
Operator ID Number

Software Version: 20160321 7.02_rc
Instrument S/N: 615260050

Hematocrit = 32.8 %
Hemoglobin = 11.1 g/dL
MCHC = 33.9 g/dL
Total WBC = ** 2.2 x10⁹/L
Granulocytes = ** 0.7 x10⁹/L
% Granulocytes = ** 32 %
Lymphs+Monos = 1.5 x10⁹/L
% Lymphs+Monos = ** 68 %
Platelets = 21 x10⁹/L

** Reference Result

STAR Analytical QC: Passed

QBC STAR
Hematology Results

Control Sample:
Date: MAY 23, 2016 Time: 06:01:33
Sample ID Number
Operator ID Number

Software Version: 20160321 7.02_rc
Instrument S/N: 615260050

Hematocrit = 32.8 %
Hemoglobin = 11.1 g/dL
MCHC = 33.9 g/dL
Total WBC = No Report
Granulocytes-
Out of Operating Range
% Granulocytes = No Report
Lymphs+Monos-
Out of Operating Range
% Lymphs+Monos = No Report
Platelets-
Out of Operating Range

STAR Analytical QC: Passed

The table below listed the ranges between “Operating Ranges”, the ranges that numerical results will be given and the ranges that numerical results will not be given.

Parameter	Operating Ranges	Range Limits for “Reference Results” with Numerical Results	Range Limits for “Out of Operating Range” without Numerical Results
Granulocytes	0.8 – 70.0 x 10 ⁹ /L	0.6 -- 0.8 x 10 ⁹ /L	< 0.6 x 10 ⁹ /L
Lymph/Mono	0.8 – 99.9 x 10 ⁹ /L	0.3 -- 0.8 x 10 ⁹ /L	< 0.3 x 10 ⁹ /L
Platelets	20 -- 999 x 10 ⁹ /L	10 -- 20 x 10 ⁹ /L	< 10 x 10 ⁹ /L
WBC	1.6 – 99.9 x 10 ⁹ /L	0.9 – 1.6 x 10 ⁹ /L	< 0.9 x 10 ⁹ /L
% Granulocytes Or % Lymph/Mono	1% - 99%	If either Gr or LM is in this range and if both Gr and LM have numeric values	If either Gr or LM or both is in this range

Precision

Data on typical within-run precision tests on QBC STAR tubes tested in the QBC STAR system are shown in the two tables below. The precision data represents the analysis of eleven whole blood specimens, each assayed in replicates of 10.

Whole Blood Total Imprecision

Parameter	Mean Value	Mean %CV
HCT (%)	41.7	2.0 %
HB (g/dL)	14.0	1.9 %
PLT (x 10 ⁹ /L)	235	6.0 %
WBC (x 10 ⁹ /L)	6.0	6.4 %

Parameter	Range	Max S. D.
GRAN (%)	38 – 79	3.2
LYMPH/MONO (%)	21 – 63	3.2

In a separate precision study, intra- and inter-run precision were assessed using a dual level QBC Control (#424304). The controls were assayed on multiple days at three sites using QBC Star tubes and the QBC Star system. The results of this study are presented in the table below.

Control Precision

		Control Level 1					Control Level 2				
		Intra-Day*			Intra-Run**		Intra-Day*			Intra-Run**	
Parameter	Site	Mean Value	%CV	df	%CV	df	Mean Value	%CV	df	%CV	df
HCT (%)	BD	30.46	0.28	10	1.58	20	34.87	0.00	10	0.95	20
	POL #1	30.93	1.37	10	1.66	20	35.27	1.22	10	2.26	20
	POL #2	30.71	0.73	9	1.12	19	34.65	0.00	9	1.25	19
HGB (g/dL)	BD	10.07	0.00	10	1.52	20	11.65	0.00	10	0.99	20
	POL #1	10.16	1.49	10	1.48	20	11.69	1.06	10	2.34	20
	POL #2	10.22	0.82	9	1.00	19	11.66	0.14	9	1.18	19
PLT (x 10 ⁹ /L)	BD	443.33	0.00	10	10.64	20	194.55	6.50	10	18.86	20
	POL #1	382.78	4.06	10	4.02	20	163.48	2.08	10	3.31	20
	POL #2	459.37	0.00	9	11.08	19	204.18	0.00	9	12.84	19
WBC (x 10 ⁹ /L)	BD	9.18	0.00	10	5.83	20	21.31	0.00	10	7.45	20
	POL #1	9.74	0.00	10	7.22	20	21.67	1.03	10	5.40	20
	POL #2	9.32	4.33	9	5.17	19	19.88	5.61	9	9.57	19
GRAN (x 10 ⁹ /L)	BD	4.80	0.00	10	8.96	20	5.51	4.82	10	5.25	20
	POL #1	5.27	0.00	10	8.79	20	6.23	2.92	10	8.31	20
	POL #2	5.06	2.89	9	6.70	19	5.37	0.00	9	8.68	19
LYMPH/ MONO (x 10 ⁹ /L)	BD	4.38	1.49	10	5.62	20	15.81	0.00	10	8.96	20
	POL #1	4.48	0.00	10	6.52	20	15.44	1.75	10	7.59	20
	POL #2	4.26	5.35	9	6.56	19	14.52	7.63	9	12.61	19
*Variability between runs during the same days ** Variability between tubes on the same run during the same day (error)						df = degrees of freedom 0.00 denotes a negative variance estimate					

Accuracy

The performance of the QBC STAR system is based on data from venous blood samples collected in VACUTAINER® brand collection tubes containing K₂EDTA anticoagulant. Venous blood samples provide a more stable test system than capillary blood for comparing results from multiple methods. While skin puncture samples provide clinically relevant results, they are subject to more variation due to the nature of the sampling technique.

Two QBC STAR tubes were prepared on each of approximately 323 blood samples and analyzed on both the QBC STAR system and either the Coulter® STKS or Sysmex K1000 analyzers*. The correlation coefficients for the WBC, Gran, L/M, Hct, and Hgb, and Plt parameters were 0.95 or greater. Complete statistical results are presented on following page.

Parameter	Correlation Coefficient	Slope	Intercept	QBC Mean	Cell Counter Mean	Range of Values	Number of Samples
Hematocrit (%)	0.983	0.973	2.572	36.5	34.8	15.7 – 61.7	646
Hemoglobin (g/dL)	0.984	0.982	0.387	12.1	12.0	5.2 – 18.5	638
Platelet (x 10 ⁹ /L)	0.962	0.935	17.701	244	242	23 – 913	558
WBC (x 10 ⁹ /L)	0.974	1.124	-0.936	10.4	10.1	1.6 – 92.9	535
Granulocyte (x 10 ⁹ /L)	0.972	0.991	0.152	7.0	7.0	0.8 – 45.0	535
Lymph/Mono (x10 ⁹ /L)	0.987	1.206	-0.419	3.3	3.1	0.8 – 89.9	535

The hematocrit results shown above reflect the calibration methods of the Coulter or Sysmex analyzers used in the correlation study. The QBC STAR software has been calibrated to match the international reference standard for microhematocrit (MHCT) technology. The data shown in the table below was obtained by comparing the QBC STAR results against the microhematocrit reference method.¹²

Parameter	Correlation Coefficient	Slope	Intercept	QBC Mean	Cell Counter Mean	Range of Values	Number of Samples
Microhematocrit (%)	0.986	1.023	-0.650	36.5	36.3	15.7 – 61.9	646

* Products of Coulter Electronics, Hialeah, FL and TOA Medical Electronics, Kyoto, Japan.

Interfering Substances

- Hemolysis: Do not perform tests on visibly hemolyzed blood specimens.
- Bilirubin: No effects on test results have been observed at bilirubin concentrations up to 20 mg/dL.⁸
- Triglycerides: No effects on test results have been observed at triglyceride concentrations up to 1,800 mg/dL.⁸
- Coumadin: Anticoagulant therapy has been shown to have no clinically significant effect on performance.⁸
- Doxorubicin: Treatment with the anthracyclic drug Doxorubicin does not appear to interfere with the QBC test method.⁸
- Other Drugs: The effects of other potentially interfering drugs and their metabolites on QBC tests have not been established.^{9,10}

Limitations

Quality medical care requires that laboratory values be correlated with each patient's symptoms and signs by a trained practitioner.

Values above and below these validated ranges are not displayed or displayed with clear warning if certain conditions are met. They should be confirmed by an alternate method.

Operating Ranges lists the validated upper and lower limits of the operating range. Values above and below these validated ranges should be confirmed by an alternate method.

The QBC STAR reagent tube has been formulated to provide optimum packing and layering of normal cells. In a small number of patients, however, the system cannot read certain parameters and will not report a value. User errors in processing or use of outdated or inappropriately stored tubes can also result in non-reported results. Practitioners must not assume that unreported values are normal; further testing with an alternative method is essential.

Automated granulocyte and lymphocyte/monocyte differential counts cannot replace the conventional manual differential. Due to the grouping by density of the cell populations by the QBC test method, the system cannot discriminate between normal and abnormal cell types in disease states characterized by the presence of abnormal white cell types or nucleated red blood cells. If abnormal cell populations are suspected, verification of QBC test results or testing and diagnosis by alternative methods is essential.

The combined lymphocyte/monocyte count should not be used to test for lymphocytopenia in evaluating patients with known or possible immunodeficiencies. Further evaluation of lymphocyte/monocyte counts in relevant situations must include a manual differential and lymphocyte subset analysis.

The presence of abnormally sized platelets may lead to discrepancies between the QBC test method platelet count, which is based on platelet mass, and results obtained with an impedance counter, which are based on measurement of particle number¹².

Expected Values

The following table provides normal ranges reported in the literature.^{11, 13} Offices or laboratories may choose to develop normal hematology ranges based on the characteristics of their patient population.

Parameter	Range
Hematocrit Males (%)	42.0 – 50.0
Hematocrit Females (%)	36.0 – 45.0
Hemoglobin Males (g/dL)	14.0 – 18.0
Hemoglobin Females (g/dL)	12.0 – 16.0
MCHC (g/dL)	31.7– 36.0
Platelet Count (x10 ⁹ /L)	140 – 440
WBC (x10 ⁹ /L)	4.3 – 10.0
Granulocyte Count (x10 ⁹ /L)	1.8 – 7.2
Lymphocyte/Monocyte Count (x10 ⁹ /L)	1.7 – 4.9

The QC label tolerances are shown in the table below.

	Level 1			Level 2			Level 3		
	Min	Target	Max	Min	Target	Max	Min	Target	Max
HCT (%)	36.9	37.9	38.9	44.9	45.9	46.9	65.1	66.1	67.1
HGB (g/dL)	12.3	12.9	13.5	14.8	15.6	16.4	20.6	21.7	22.8
MCHC (g/dL)	31.6	34.0	36.6	31.6	34.0	36.5	30.7	32.8	35.0
PLT (x 10 ⁹ /L)	90	100	110	342	360	378	615	647	679
WBC (x 10 ⁹ /L)	4.6	5.7	6.8	9.5	10.6	11.7	48.5	53.5	58.5
GRAN (x 10 ⁹ /L)	2.2	2.7	3.2	6.0	6.5	7.0	28.3	31.3	34.3
%GRAN	38	47	57	56	61	67	54	59	63
L/M (x 10 ⁹ /L)	2.4	3.0	3.6	3.5	4.1	4.7	20.2	22.2	24.2
%L/M	43	53	62	33	39	44	37	41	46

Analytical Quality Control

The QBC STAR Centrifugal Hematology System has multiple built-in analytical quality control (QC) systems that maintain the overall system integrity and the quality of the test results it produces. The QBC STAR System has five analytical quality control elements:

1. Factory calibration. System calibration is set during manufacture and cannot be altered by the user.
2. Instrument Power On Self-Test. This test assures that each time the instrument is turned on, the computer, memory, optics, and motors are fully functional. Should you choose to leave the system on continuously; the test will automatically be repeated every 8 hours if the door is closed. A tri-level quality control label (QC label), designed to simulate 3 hematology specimens (simulating low cell counts, normal cell counts, and elevated cell counts) tests the system's optics against values established at the time of manufacture. At the end of the power on self-test, the instrument prints the values obtained from reading the QC label. The values may be plotted to evaluate for shifts or trends in the data. The instrument will flag any results that are outside the set limits, print an error code, and automatically shut down operation of the instrument until the problem is corrected and a valid power on self-test is performed.
3. Electronic QC (during each sample run). The built-in electronic checks during each sample run confirm the proper centrifuge speed, centrifugation profile, system communications, and internal temperature.
4. Sample Preparation QC (during each sample run). The built in checks confirm that the QBC STAR tube has not been previously processed. Tests confirm that the tube assembly is the proper length, the float is present and the correct length, and the tube is filled with the correct amount of blood.
5. Reagent QC (during each sample run). These built-in checks evaluate sample and reagent integrity using the data from the optical scan. This includes tests for fluorescent signal intensity, proper number, size and location of the cell layers and interface sharpness.

When these analytical quality control checks are successfully completed, the status of the instrument's analytical QC is printed on the patient record as "STAR Analytical QC: Passed." Results are reported only if all of the analytical quality control requirements have been satisfied.

6 – Maintenance

WARNINGS

CLEANING AND DECONTAMINATION MAY BE NECESSARY AS A SAFEGUARD BEFORE LABORATORY CENTRIFUGES, ROTORS, AND ANY ACCESSORIES ARE MAINTAINED, REPAIRED, OR TRANSFERRED.

THE USER SHOULD NOT PERFORM ANY SERVICING EXCEPT AS SPECIFICALLY STATED IN THIS MANUAL. REFER OTHER PROBLEMS TO TRAINED PERSONNEL, OR RETURN THE INSTRUMENT TO DRUCKER DIAGNOSTICS FOR REPAIR.

TURN INSTRUMENT POWER OFF AND UNPLUG THE POWER CORD BEFORE SERVICING.
FOR FURTHER ASSISTANCE CONTACT DRUCKER DIAGNOSTICS TECHNICAL SUPPORT AT
+1-866-265-1486 (TOLL FREE) OR +1-814-692-7661

Cleaning

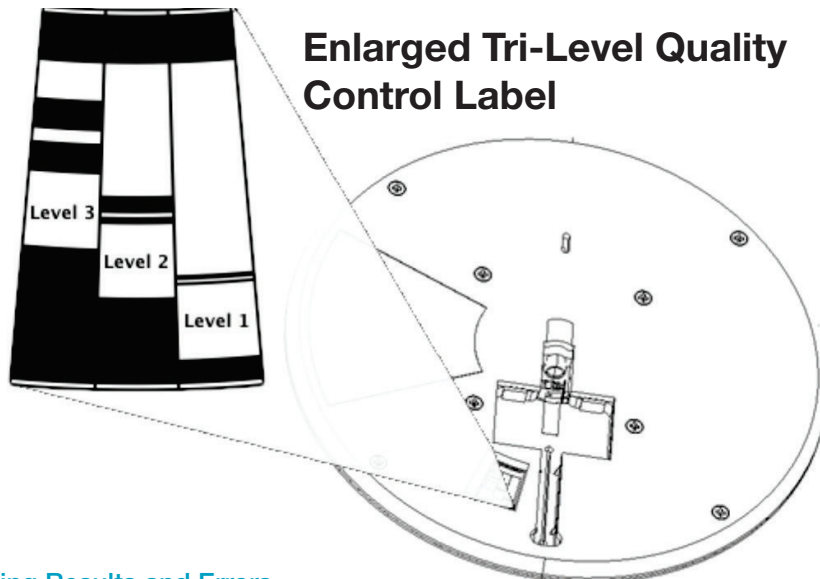
You should occasionally wipe interior and exterior surfaces of the QBC STAR instrument with a damp cloth. You can use a mild detergent to remove stains. Keeping these parts clean helps prolong the life of the instrument.

Tri-Level Quality Control Label

Routine checking and cleaning of the tri-level quality control label before use of the system will decrease the likelihood of system errors due to debris on the label surface.

1. Overview

Put the device into shipping preparation mode, per the instructions found in Section 2 of the QBC Star Operator's Manual and power off the device. This should put the rotor into a free spinning state.



Enlarged Tri-Level Quality Control Label

2. Understanding Results and Errors

During QBC Star system startup or daily POST check, the tri-level quality control label (QC label) is read and analyzed. When an error condition exists and the system is unable to properly capture and analyze the label image, the system operator will be notified by an on-screen E6-606, E7-708, E7-709 error code.

When cleaning the QC label please follow the instructions below to ensure proper operation and prevent potential damage to the QBC Star rotor.

Tri-Level Quality Control Example

-- Level 3 --		
Hematocrit	=	66.1 %
Hemoglobin	=	21.7 g/dL
MCHC	=	32.8 g/dL
Total WBC	=	53.5 x10 ⁹ /L
Granulocytes	=	31.3 x10 ⁹ /L
% Granulocytes	=	59 %
Lymphs+Monos	=	22.2 x10 ⁹ /L
% Lymphs+Monos	=	41 %
Platelets	=	647 x10 ⁹ /L

STAR Analytical QC: Passed		

Normal Passing Tri-Level QC Example

3. Tri-Level Quality Control Label Cleaning Recommendations

When cleaning the QC label please follow the instructions below to ensure proper operation and prevent potential damage to the QBC Star rotor.

1. Put the device into shipping preparation mode, per the instructions found in Section 2 of the QBC Star Operator's Manual and power off the device. This should put the rotor into a free spinning state.
2. Gently turn the rotor by hand until the QC label is visible in the operator accessible opening on the front of QBC Star. Do not apply excessive pressure to the rotor surface or damage could occur.
3. Gently wipe the label surface with an alcohol swab to remove any spillage, dust or debris. NOTE: DO NOT USE WATER, BLEACH OR OTHER HARSH CHEMICAL BASED CLEANERS as they may damage the label finish.

Disinfection

If a QBC STAR Tube breaks while in the instrument, the spread of blood and glass is substantially contained by the plastic protective tube. This device design provides a high degree of user and instrument protection from exposure to blood and aerosols.

If blood or glass should escape the plastic protective tube, please call technical support.

- 1 Clean any contaminated surfaces with 10% solution of household bleach (1 part bleach to 9 parts water). Allow to stand 10 minutes, then rinse thoroughly with water and dry. Household bleach is effective against bacteria, spores, and viruses. However, it is an oxidizing agent, and is corrosive to metal alloys. Bleach must be thoroughly wiped off the instrument with a damp cloth and dried. It should never be used if there is surface damage to any metal parts.

For any other cleaning methods, you must contact Drucker Diagnostics to verify that the proposed method does not damage the QBC STAR instrument.

CAUTION

Do not immerse the QBC STAR instrument in water or other liquid.

Replacing Printer Paper

When the printer paper is nearly exhausted, a colored edge appears on the roll of paper. You should replace paper at this time to avoid running out while printing patient test results. See Figure 23.

To replace printer paper:

- 1 Remove the printer panel and remove the old roll of paper.
- 2 Peel off the beginning of the new roll of paper.
- 3 Place the paper in the instrument, with the paper feeding up from the bottom.
- 4 Insert the paper between the two black rubber rollers on the printer.
- 5 Flip the paper release lever forward.
- 6 Roll the manual paper advance wheel rearward. Advance enough paper to clear the printer cover.
- 7 Flip the paper release lever backward.
- 8 Replace the printer panel, feeding the new strip of paper through the slot.

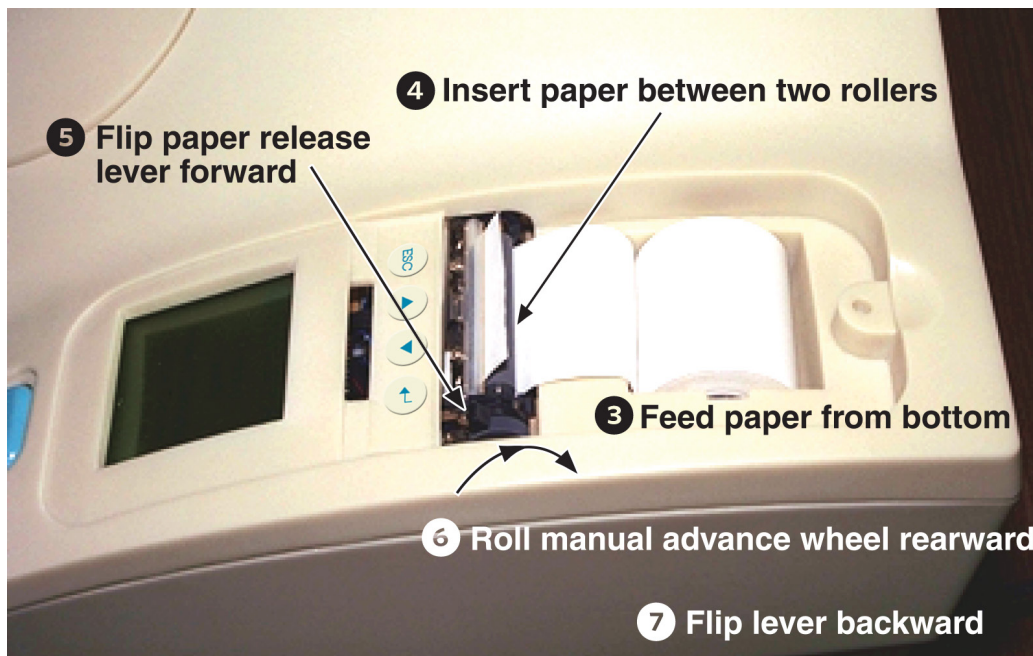


Figure 23 – Replacing Printer Paper

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7 – Troubleshooting

If the QBC STAR instrument fails to operate properly, consult the guides below. **DO NOT ATTEMPT TO PERFORM ANY SERVICE OR REPAIR THAT DOES NOT APPEAR IN THIS MANUAL.** Refer service problems to the Technical Support of Drucker Diagnostics, at +1-866-265-1486 (toll free) or +1-814-692-7661. Otherwise, contact your nearest Drucker Diagnostics. office for assistance.

The General Problems section presents some general symptoms that you might notice. It also suggests corrective actions. These problems do not cause error codes to appear on the LCD or printout.

General Problems

Consult the table below for general problems.

General Instrument Problems		
Symptom	Possible Causes	Corrective Actions
Instrument fails to operate	Power cord not plugged into unit or receptacle	Plug cord into unit and receptacle
	Door not latched	Close door and latch securely
	Other	Request authorized service
Instrument vibrates excessively	Foam pads worn or missing on bottom of instrument	Call Technical Support
Lid fails to open	Power has failed	Use emergency door unlock procedure in Section 4
	Defective lid solenoid or internal parts	Request authorized service

Resetting The External Power Supply

Should it become necessary to reset the external power supply please follow the directions below.

1. Turn off the QBC STAR using the switch in the back of the unit.
2. Unplug the AC power cord on the external power supply from the AC wall outlet.
3. Unplug the external power supply from the back of the QBC STAR.
4. Allow the external power supply and QBC STAR to sit in this condition for 15 minutes to fully discharge and reset the external power supply.
5. Plug the AC power cord of the external power supply back into the wall outlet.

Note: Drucker Diagnostics recommends plugging the STAR directly into the wall outlet without using a power strip or extension chord.

6. Verify that the green indicator light on the power supply is lit.
7. Plug the external power supply into the back of the QBC STAR.
8. Turn on the QBC STAR using the switch on the back of the unit and proceed with normal operation of the device.

System Error Codes

From time to time, the QBC STAR may display an error code. A USB flash drive is included with the QBC STAR to download a support file of the error code (see page 2-8 for instructions on how to download the support file). If any of the error messages below appear, please follow the corrective action. If the error code is still displayed, contact Technical Support at +1-866-265-1486 (U.S. only) or; +1-814-692-7661 for assistance.

E1 - Main Board		
Error Number	Description	Corrective Action
100	Main board error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
101	Main board/IO board communication error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
102	System runtime error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
E2 - Centrifuge Board and Motor		
Error Number	Description	Corrective Action
200	Motor/centrifuge control board error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
201	Centrifuge control board communication error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
202	Main board/centrifuge control board synchronization error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
203	Centrifuge motor stop error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
206	Centrifuge control board response error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support

207	Centrifuge motor profile error during Power On Self-Test (POST)	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Reset the power pack (Ref. page 7-1) 5. Turn the instrument Power on (Ref. page 4-2) 6. If the error persists contact Technical Support
209	Centrifuge motor profile error during operation	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Reset the power pack (Ref. page 7-1) 5. Turn the instrument Power on (Ref. page 4-2) 6. If the error persists contact Technical Support
210	Centrifuge control board/main board communication error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
211	Centrifuge motor failure to respond to system commands error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
216	Centrifuge motor initialization error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
217	Centrifuge motor index error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Reset the power pack (Ref. page 7-1) 5. Turn the instrument Power on (Ref. page 4-2) 6. If the error persists contact Technical Support
218	Centrifuge motor position error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Reset the power pack (Ref. page 7-1) 5. Turn the instrument Power on (Ref. page 4-2) 6. If the error persists contact Technical Support
220	Centrifuge motor not enabled error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
221	Centrifuge motor is disabled error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
222	Centrifuge motor deceleration error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support

225	Unable to get position of the rotor error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
226	Unable to capture encoder index error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
227	Centrifuge control board/ centrifuge motor synchronization error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
228	Centrifuge motor over speed error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Reset the power pack (Ref. page 7-1) 5. Turn the instrument Power on (Ref. page 4-2) 6. If the error persists contact Technical Support
229	Centrifuge motor under speed error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Reset the power pack (Ref. page 7-1) 5. Turn the instrument Power on (Ref. page 4-2) 6. If the error persists contact Technical Support
252	Centrifuge control board unable to process seek command error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
253	Centrifuge control board unable to process seek command error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
255	Centrifuge motor seek command failure because index location is unknown error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
256	Centrifuge motor setup error (Encoder doesn't match Hull Sensors)	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
258	Centrifuge motor unable to position +/- 4 steps error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support

258	Centrifuge motor unable to position +/- 4 steps error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
259	Centrifuge control board unable to find encoder index position error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact QBC Technical Support
261	Centrifuge motor stall during step positioning error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
262	Centrifuge motor stall during high speed centrifugation error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
263	Centrifuge control board unable to run sequence error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
265	Centrifuge motor/ encoder mismatch error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
266	Centrifuge motor overcurrent error (Motor current greater than 6 amps)	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
267	Centrifuge control board regeneration circuit overcurrent error (Current greater than 10 amps)	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
268	Centrifuge motor unable to maintain speed +/- 50 RPM error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
269	Centrifuge motor under speed error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support

271	Centrifuge motor low sustained voltage error (Sustained voltage less than 40 volts)	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
272	Centrifuge control board MOSFET Over Temperature error (Temperature greater than 70 deg C.)	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
273	Centrifuge control board PWM failure error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
279	Centrifuge control board internal temperature sensor initialization error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
282	Centrifuge control board connection error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
283	Centrifuge control board software version error	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support
285	Centrifuge control board temperature error (Temperature outside range of 2-66 deg C.)	<ol style="list-style-type: none"> 1. Record error message displayed on LCD screen 2. Export support file per Section 2, page 2-8 3. Power down instrument per Section 4, page 4-10 4. Turn Instrument Power on per Section 4, page 4-2, if error persists contact Technical Support

E3 - Camera Board		
Error Number	Description	Corrective Action
300	Camera board error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
301	Camera board device driver error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
303	Camera board data reading error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
304	Camera board parameter communications error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
305	Unable to verify commands sent to camera error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
311 thru 316	Camera board communication errors	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
317	Camera initialization error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
E4 - I/O Board		
Error Number	Description	Corrective Action
400	I/O board error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
401	Software version error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support

402	Start-up data error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
403	Printer hardware error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Turn off the external printer 4. Power down the instrument (Ref. page 4-10) 5. Check that the connector from the External Printer to the back of instrument is properly installed (Ref. page 2-5) 6. Turn the instrument Power on (Ref. page 4-2) 7. Turn on the power to external printer 8. If the error persists contact Technical Support
404	Internal printer communication error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Pull the printer paper release lever towards the front of unit (Ref. page 3-3) 4. Manually advance the paper using the manual advance wheel (Ref. page 3-3) 5. If the paper advances, push the printer paper release lever to lock the paper into place (Ref. page 3-3) 6. Power down the instrument (Ref. page 4-10) 7. Turn the instrument Power on (Ref. page 4-2) 8. If the error persists contact Technical Support
406	Internal printer head high temperature error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Pull the printer paper release lever towards the front of unit (Ref. page 3-3) 4. Manually advance the paper using the manual advance wheel (Ref. page 3-3) 5. If the paper advances, push the printer paper release lever to lock the paper into place (Ref. page 3-3) 6. Power down the instrument (Ref. page 4-10) 7. Turn the instrument Power on (Ref. page 4-2) 8. If the error persists contact Technical Support
407	Internal printer over/under voltage error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Pull the printer paper release lever towards the front of unit (Ref. page 3-3) 4. Manually advance the paper using the manual advance wheel (Ref. page 3-3) 5. If the paper advances, push the printer paper release lever to lock the paper into place (Ref. page 3-3) 6. Power down the instrument (Ref. page 4-10) 7. Turn the instrument Power on (Ref. page 4-2) 8. If the error persists contact Technical Support

408	Internal printer hardware error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Pull the printer paper release lever towards the front of unit (Ref. page 3-3) 4. Manually advance the paper using the manual advance wheel (Ref. page 3-3) 5. If the paper advances, push the printer paper release lever to lock the paper into place (Ref. page 3-3) 6. Power down the instrument (Ref. page 4-10) 7. Turn the instrument Power on (Ref. page 4-2) 8. If the error persists contact Technical Support
409	Internal printer connection error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Pull the printer paper release lever towards the front of unit (Ref. page 3-3) 4. Manually advance the paper using the manual advance wheel (Ref. page 3-3) 5. If the paper advances, push the printer paper release lever to lock the paper into place (Ref. page 3-3) 6. Power down the instrument (Ref. page 4-10) 7. Turn the instrument Power on (Ref. page 4-2) 8. If the error persists contact Technical Support
410	Internal printer communication port error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
411 thru 414	I/O board communication error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
415	Lid latch micro-switch error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. If the lid is closed, open lid manually (Ref. page 4-10) <ol style="list-style-type: none"> a. If the lid opens, turn the instrument Power on (Ref. page 4-2) b. If the error persists contact Technical Support c. If the lid does not open, contact Technical Support 5. If the lid opens, turn the instrument Power on (Ref. page 4-2)
416	Lid latch solenoid over current error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. If the lid is closed, open lid manually (Ref. page 4-10) <ol style="list-style-type: none"> a. If the lid opens, turn the instrument Power on (Ref. page 4-2) b. If the error persists contact Technical Support c. If the lid does not open, contact Technical Support 5. If the lid opens, turn the instrument Power on (Ref. page 4-2)

417	Actuator position error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Place the instrument into Shipping Prep (Ref. page 2-9) 4. Power down the instrument (Ref. page 4-10) 5. Confirm the rotor spins freely by hand 6. If the rotor spins freely <ol style="list-style-type: none"> a. Power down the instrument (Ref. page 4-10) b. Turn the instrument Power on (Ref. page 4-2) c. If the error persists contact Technical Support 7. If the rotor does not spin freely, contact Technical Support
418	Actuator current error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Place the instrument into Shipping Prep (Ref. page 2-9) 4. Power down the instrument (Ref. page 4-10) 5. Confirm the rotor spins freely by hand 6. If the rotor spins freely <ol style="list-style-type: none"> a. Power down the instrument (Ref. page 4-10) b. Turn the instrument Power on (Ref. page 4-2) c. If the error persists contact Technical Support 7. If the rotor does not spin freely, contact Technical Support
419	Exhaust temperature sensor error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Tip the instrument up and check for obstructions in the exhaust port 5. If there are obstructions, clear the obstructions and confirm the proper setup (Ref. page 2-1) 6. Turn the instrument Power on (Ref. page 4-2) 7. if the error persists contact Technical Support
420	Keypad error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power (Ref. page 4-2) 5. if the error persists contact Technical Support
421	Run button error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power (Ref. page 4-2) 5. if the error persists contact Technical Support
422	Lid latch release bar error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. If the lid is closed, open it manually (Ref. page 4-10) <ol style="list-style-type: none"> a. If the lid opens, turn the instrument Power on (Ref. page 4-2) b. If the error persists contact Technical Support c. If the lid does not open, contact Technical Support 5. If lid is open, turn the instrument Power on (Ref. page 4-2) 6. If the error persists contact Technical Support

E5 – File Operations		
Error Number	Description	Corrective Action
502	File operations communication error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power (Ref. page 4-2) 5. If the error persists contact Technical Support
503 thru 506	Software configuration file read or write error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power (Ref. page 4-2) 5. If the error persists contact Technical Support
518	No memory available error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power (Ref. page 4-2) 5. If the error persists contact Technical Support
E6 – Runtime Functions/Routines		
Error Number	Description	Corrective Action
600	General runtime error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power (Ref. page 4-2) 5. If the error persists contact Technical Support
601	Internal temperature of the instrument has exceeded 45 °C (113 °F)	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Tip the instrument up and check for obstructions in the exhaust port and clear is present 5. Confirm the instrument is set-up properly (Ref. page 2-1) <ol style="list-style-type: none"> a. Ensure there is at least 2 inches of clearance around the instrument for airflow b. Ensure adequate area above the device for airflow c. Ensure the instrument is not being operated outside of the environmental specifications (Ref. page 2-3) 6. Power down the instrument (Ref. page 4-10) 7. Turn the instrument Power on (Ref. page 4-2) 8. if the error persists contact Technical Support
602	Internal temperature of the instrument has fallen below 15 °C (59 °F)	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Tip the instrument up and check for obstructions in the exhaust port and clear is present 5. Confirm the instrument is set-up properly (Ref. page 2-1) <ol style="list-style-type: none"> a. Ensure the instrument is not being operated outside of the environmental specifications (Ref. page 2-3) 6. Power down the instrument (Ref. page 4-10) 7. Turn the instrument Power on (Ref. page 4-2) 8. if the error persists contact Technical Support

603	Sample door open during rotor motion error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. If the lid is closed, open it manually (Ref. page 4-10) <ol style="list-style-type: none"> a. If the lid opens, turn Instrument Power (Ref. page 4-2) b. If the error persists contact QBC Technical Support c. If the lid does not open, contact QBC Technical Support 5. If the lid opens, turn the instrument Power on (Ref. page 4-2) 6. If the error persists contact Technical Support
604	Low internal memory error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
606	QC label not in the camera field of view error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. If the lid is closed, open lid manually (Ref. page 4-10) 5. Check and clean the QC label (Ref. page 6-1) 6. Turn the instrument Power on (Ref. page 4-2) 7. If the error persists contact Technical Support
E7 – FSM State		
Error Number	Description	Corrective Action
700	General finite state machine error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
701	Power On Self-Test (POST) general error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
702	Power On Self-Test (POST) software error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
703	Actuator test failed during Power On Self-Test (POST)	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Place the instrument into Shipping Prep (Ref. page 2-9) 5. Confirm the rotor spins freely by hand 6. If the rotor spins freely <ol style="list-style-type: none"> a. Power down the instrument (Ref. page 4-10) b. Turn the instrument Power on (Ref. page 4-2) c. If the error persists contact Technical Support 7. If the rotor does not spin freely, contact Technical Support
704	Encoder failed to initialize during Power On Self-Test (POST)	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support

705	Encoder failed to position properly during Power On Self-Test (POST)	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
706	Power On Self-Test (POST) intensity check error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
707	Power On Self-Test (POST) speed check error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
708	Power On Self-Test (POST) QC label general error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. If the lid is closed, open lid manually (Ref. page 4-10) 5. Check and clean the QC label (Ref. page 6-1) 6. Turn the instrument Power on (Ref. page 4-2) 7. If the error persists contact Technical Support
709	Sample QC label check error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. If the lid is closed, open lid manually (Ref. page 4-10) 5. Check and clean the QC label (Ref. page 6-1) 6. Turn the instrument Power on (Ref. page 4-2) 7. If the error persists contact Technical Support

E8 – Software		
Error Number	Description	Corrective Action
800 thru 802	General software errors	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
803 or 812	Software initialization error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
804	Software start up error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
805 or 807	Software sample analysis error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
806	Software Power On Self-Test (POST) error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
808	Software fault handling error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
809	Software image acquisition error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
810	Software QC check error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
811	Software instrument idle error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
813	Software results generation error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support

814	Software tube check error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
815	Software keyboard check error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support
E9 - Undefined		
Error Number	Description	Corrective Action
900	Miscellaneous handling error	<ol style="list-style-type: none"> 1. Record the error message displayed on the LCD screen 2. Export the support file (Ref. page 2-8) 3. Power down the instrument (Ref. page 4-10) 4. Turn the instrument Power on (Ref. page 4-2) 5. If the error persists contact Technical Support

Tube Error Codes

If any of the following tube error messages appear on the printer results report and LCD display, fill and run a new tube.

Error Number	Description	Corrective Action
1	Low fill volume	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Prepare a new tube (Ref. pages 4-2 through 4-5) 4. Insert the tube into the instrument, close the door and press the "STAR" button
2	High fill volume	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Prepare a new tube (Ref. pages 4-2 through 4-5) 4. Insert the tube into the instrument, close the door and press the "STAR" button
3	Bad float length	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. If the lid is not open, depress the door release latch located on the front of the instrument. 4. Rotate the tube 180 degrees and reinsert it in the rotor 5. Close the lid and rerun the tube (Ref. page 4-7) 6. If the problem persists, prepare a new tube, insert it into the instrument, close the lid and press the "STAR" button 7. If the problem persists after rerunning a new tube, create a new support file and contact Technical Support
4	Bad float signature	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into the rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after rerunning a new tube, create a new support file and contact Technical Support
6	Unreadable buffy coat	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
7	Float not descended	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid and visually check the sample <ol style="list-style-type: none"> a. If the float did not descend or no visible buffy layer is observed, draw a new sample and retest b. If the float is descended or a visible buffy layer is observed, rotate the sample 180 degrees and rescan the sample 4. If the problem persists, create a new support file and contact Technical Support

10	Could not find closure	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid and visually check the sample <ol style="list-style-type: none"> a. If the closure is not present, draw a new sample and retest b. If the closure is present, rotate the sample 180 degrees and rescan the sample 4. If the problem persists, create a new support file and contact Technical Support
11	Could not find float bottom	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid and visually check the sample <ol style="list-style-type: none"> a. If no visible buffy layer is observed, draw a new sample and retest b. If a visible buffy layer is observed, rotate the sample 180 degrees and rescan the sample 4. If problem persists, create a new support file and contact Technical Support
12	Could not find RBC / Grans interface	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
13	Could not find Grans / LM interface	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
14	Could not find LM / PLT interface	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
15	Could not find LM / Control interface	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Drucker Technical Support

16	Could not find Control / PLT interface	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
17	Could not find PLT / Plasma interface	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
18	Could not find float top	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid and visually check sample <ol style="list-style-type: none"> a. If the float did not descend or the float top is not observed, draw a new sample and retest b. If the float is descended or the float top is observed, rotate the sample 180 degrees and rescan the sample 4. If problem persists, create a new support file and contact Technical Support
19	Could not find meniscus	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid and visually check sample <ol style="list-style-type: none"> a. If no visible meniscus is observed, draw a new sample and retest b. If a visible meniscus is observed, rotate the sample 180 degrees and rescan the sample 4. If the problem persists, create a new support file and contact Technical Support
20	Bad fill line length	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid and visually check sample <ol style="list-style-type: none"> a. If the fill lines are not visible or are scratched off, draw a new sample and retest b. If the fill lines are visible, rotate the sample 180 degrees and rescan the sample 4. If the problem persists, create a new support file and contact Technical Support
22	Unreadable Grans layer (L3)	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Record the age of the blood sample 3. Create a support file (Ref. page 2-8) 4. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 5. Close the lid and rescan the sample 6. If the problem persists, draw a new sample and retest 7. If the problem persists after retest, create a new support file and contact Technical Support

30	Tube not found	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid and visually check for the sample tube <ol style="list-style-type: none"> a. If the sample tube is present, rotate it 180 degrees and rescan the tube b. If the sample tube is not present, contact Technical Support for assistance
31	High exhaust temperature	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Record when during the cycle the system error occurred 3. Create a support file (Ref. page 2-8) 4. Check <ol style="list-style-type: none"> a. The setup of the device and confirm clearance envelope is 2.0 in. clearance minimum on each side of the unit b. There are no obstructions in the exhaust port on the bottom of the analyzer 5. Ensure <ol style="list-style-type: none"> a. The analyzer is not running in corner or under an overhead cabinet b. The analyzer is not being operated outside of the environmental specifications (Ref. page 2-3) 6. Turn the analyzer off. Wait 1 minute, and then turn it back on 7. If the problem persists contact Technical Support
40	Unreadable RBC / Grans interface (I3)	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
41	Unreadable Grans / LM interface (I4)	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
42	Unreadable LM / PLT interface (I5)	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
43	Unreadable PLT / plasma interface (I6)	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support

44	Bad LM color profile	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Record the age of the blood sample 3. Create a support file (Ref. page 2-8) 4. Open the lid, remove sample and stand the sample upright for 10 minutes 5. Reinsert the sample into the analyzer, close lid and rescan the sample 6. If the problem persists, draw a new sample and retest 7. If the problem persists after retest, create a new support file and contact Technical Support
50	RBC layer L1 is too small	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
51	RBC layer L1 is too large	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
52	Top of float I7 is too low	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
53	Top of float I7 is too high	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
54	Closure I1 is too high	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support

55	Closure I1 is too low	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
56	Meniscus out of view	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid and visually check sample <ol style="list-style-type: none"> a. If no visible meniscus is observed, draw a new sample and retest being careful to stop between the two black fill lines (Ref. 4-2 through 4-5) b. If a visible meniscus is observed, rotate the sample 180 degrees and rescan the sample 4. If the problem persists, create a new support file and contact Technical Support
80	Material on top of float	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
81	Material on float side	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support
99	Miscellaneous sample error	<ol style="list-style-type: none"> 1. Record the error message on the LCD display 2. Create a support file (Ref. page 2-8) 3. Open the lid, rotate the sample 180 degrees and reinsert it into rotor 4. Close the lid and rescan the sample 5. If the problem persists, draw a new sample and retest 6. If the problem persists after retest, create a new support file and contact Technical Support

8 – Appendices

A – Limited Warranty

This warranty gives you specific legal rights. Additionally, you may have other rights that vary from region to region.

The QBC STAR Centrifugal Hematology System is warranted to the original purchaser to be free from defects in materials and workmanship for a period of twelve months following installation. Drucker Diagnostics Inc., sole responsibility under this warranty shall be to repair or replace any instrument or its components (except for expendable supplies such as printer paper) which under normal operating conditions, prove to be defective within twelve months of delivery.

Drucker Diagnostics, will furnish new or remanufactured components upon its option. All replacements shall meet new part specifications and shall be warranted as above for the remainder of the twelve month period. Replaced components become the property of Drucker Diagnostics Inc.

It is understood that the equipment covered by this agreement has been installed in accordance with the recommendations and instructions in the QBC STAR System Operator's Manual.

Any damage to a QBC STAR system resulting from the insertion or removal of cables that connect this instrument to systems other than those approved or supplied by Drucker Diagnostics, or the failure of the owner to maintain reasonable care and precautions in the operation and maintenance of the system will void this warranty and terminate the obligations of the manufacturer as stated herein.

The warranty stated herein shall extend to the original consumer only and not to any subsequent consumer of the instrument.

This warranty is in lieu of all other warranties, whether express or implied, including but not limited to, warranties of merchantability, or fitness for a particular use. In no event will Drucker Diagnostics, be liable for indirect, incidental, special or consequential damages regardless of whether Drucker Diagnostics, has been advised of such.

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B – Parts and Accessories

Item	Catalog Number
Paper, Printer (3/pk)	429580
QBC STAR Tubes (box 100)	429625
1.8 mm Blade Lancets (box 100)	420000
2.3 mm Blade Lancets (box 100)	420001
Patient ID Upgrade Keyboard	429645
Patient ID Barcode Scanner	429642
Power Cord, U.K.	421554
Power Cord, Europe	421551
Power Cord, USA	421634
External Power Supply	429644

For a full list of accessories visit www.druckerdiagnostics.com

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D – Contact

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E – Blood Collection and Handling

General Comments

The quality of a test is only as good as the quality of the specimen. The following guidelines help ensure the quality of the blood specimens collected in your office, as well as the safety of the staff performing the tests.

These specimen collection guidelines are derived from those recommended by the National Committee for Clinical Laboratory Standards (NCCLS) in the specimen collection section of the “Physician’s Office Laboratory Guidelines” (NCCLS Document POL1 and POL2). For more information, contact NCCLS at 771 East Lancaster Avenue, Villanova, PA 19085 (215) 525-2435.

Universal Precautions for Specimen Handling

WARNINGS

BLOOD AND BODY FLUIDS MAY CONTAIN THE HEPATITIS B VIRUS (HBV), HEPATITIS C VIRUS (HCV), HUMAN IMMUNODEFICIENCY VIRUS (HIV), OR OTHER DISEASE-CAUSING AGENTS.

HANDLE ALL PATIENT SPECIMENS AS POTENTIAL BIOHAZARDS CAPABLE OF TRANSMITTING INFECTION.

WEAR APPROPRIATE PERSONAL PROTECTIVE EQUIPMENT, INCLUDING LABORATORY GLOVES, WHEN COLLECTING, HANDLING, AND PROCESSING BLOOD AND BODY FLUIDS.

IN ADDITION TO WEARING GLOVES, THE USE OF DISPOSABLE LAB COATS OR GOWNS AND PROTECTIVE GLASSES OR GOGGLES IS RECOMMENDED WHEN WORKING AROUND THE INSTRUMENT .

Venous Blood Collection (Venipuncture)

The following procedure can be used as a guideline for venous blood collection. Please consult your lab's standard operating procedure as it may differ from the procedure described below.

Supplies

- Disposable gloves
- Tourniquet
- Alcohol pads
- Sterile gauze
- Bandage
- VACUTAINER® Brand (or other) evacuated blood collection system:
 - Tubes containing EDTA anticoagulant (lavender top)
 - Needles
 - Needle holder/adaptor
- Sharps container
- Marking pen

Procedure

- 1 Identify the patient by having him or her (or a guardian) state his full name.
- 2 Select the appropriate blood collection supplies. Establish the order of evacuated tubes if multiple specimens are drawn.
- 3 Label all evacuated blood collection tubes with the patient's name and the time and date the specimen is drawn.
- 4 Position the patient with the elbow extended and the arm supported. Have the patient make a fist, but avoid vigorous pumping or other hand exercise.
- 5 Apply the tourniquet about 3 - 4 inches above the venipuncture site. Do not stop the blood flow for more than one minute before the blood is drawn. If necessary, release and reapply the tourniquet.
- 6 Select the venipuncture site. The median antecubital and cephalic veins are most commonly used.
- 7 Clean the venipuncture site with an alcohol pad, making one smooth, circular pass of the venipuncture site. Allow the skin to dry, to prevent hemolysis and to prevent the patient from having a burning sensation when the needle is inserted. Do not touch the vein site after cleaning it.
- 8 Perform the venipuncture:
 - a Wearing gloves, gently grasp the patient's arm near the venipuncture site, using the thumb to draw the skin tight.
 - b With the needle bevel facing up, line up the needle with the vein. Penetrate the skin and enter the vein at an angle of approximately 15 - 30 degrees. Holding the flange of the needle adaptor, push the evacuated tube forward, allowing the back end of the needle to puncture the stopper to engage the vacuum.

- c As the blood begins to flow into the tube, release the tourniquet and open the patient's fist to avoid bleeding at the puncture site.
 - d Keep constant, forward pressure on the tube to prevent the shutoff valve from closing and stopping the flow of blood.
 - e Allow tubes containing an anticoagulant to fill until the vacuum is exhausted and blood flow ceases, assuring the correct ratio of blood to anticoagulant.
 - f If a blood sample cannot be obtained, change the position of the needle. If the needle has penetrated too far into the vein, pull it back slightly. If it has not penetrated far enough, move it further into the vein, but do not probe with the needle. You may need to try another tube.
 - g Remove the tube from the needle adapter when the blood stops flowing. The automatic shut-off valve will stop any blood from flowing into the adapter. If necessary, insert other tubes in the proper order and repeat the collection procedure.
 - h Gently remove the needle from the venipuncture site. Apply sterile gauze to the site, while keeping the arm extended. Keep pressure on the site for at least 2 minutes. Ensure that bleeding has stopped, and apply a bandage over the site. Instruct the patient to wear the bandage for at least 15 minutes.
 - i Gently invert any tube(s) containing anticoagulant or clot activators, as in SST Brand tubes, five to ten times to mix the blood with the additive. Do not shake the tube vigorously, because this will damage the blood cells and possibly lead to erroneous test results.
- 9 Dispose of needle(s) in a sharps container. Dispose of gloves and gauze in an appropriate biological hazard container. Wash hands.

Collecting Multiple Specimens from a Single Venipuncture

When drawing more than one tube of blood from a single venipuncture using evacuated tubes with various additives, use the tubes in the following order:

- Blood culture
- Red Stopper or Red/Gray (SST Brand) tube
- Blue Stopper
- Green Stopper
- Lavender Stopper
- Gray Stopper

Areas to Avoid When Drawing Venous Specimens

- Scarred areas, such as healed burns.
- Thrombosed veins. These veins feel thick and cord-like and tend to roll.
- Bruised areas. If you cannot avoid collecting from a bruise site, then draw the specimen from the site farthest away from the bruised area.
- The arm on the side of a prior mastectomy. Because this surgery results in lymphostasis, specimen collection may be difficult.
- The arm that has the A-V shunt in a dialysis patient.
- A recent IV site, or the same side of the body as the IV site.

Errors to Avoid in Venous Blood Collection

- Do not underfill the tube. This may result in excess anticoagulant interfering with the test result, or cause hemolysis of the specimen.
- Completely mix the tube to avoid clot formation in specimens collected in tubes containing anticoagulants.
- Do not mix the specimen too vigorously. Overly vigorous mixing may result in cell damage and hemolysis.
- Do not overfill evacuated tubes when adding blood with a syringe. This could adversely affect the ratio of blood to anticoagulant. Overfilling anticoagulant tubes can also lead to excess pressure, causing the stoppers to come off.

Capillary Blood Collection

The following procedure can be used as a guideline for capillary blood collection. Please consult your lab's standard operating procedure as it may differ from the procedure described below.

Supplies

- Disposable gloves
- Lancet with blade no longer than 2.0 - 2.4 mm
- Alcohol swab or pad
- Sterile gauze
- Bandage
- Sharps container
- QBC STAR Tube

Procedure

- 1 Identify the patient by having him or her (or a guardian) state his full name.
- 2 Select and organize the appropriate blood collection supplies.
- 3 Select a puncture site. With older children and adults, use the third or fourth finger of the non-dominant hand. Choose a puncture site halfway between the center of the finger pad and the outer edge of the finger. For infants, punctures may be performed on the outer or inner portion of the plantar surface of the heel.
- 4 Make sure the site to be punctured is not cyanotic, edematous, or cold. If cyanotic or cold, cover the puncture site with a warm, moist towel for at least three minutes before puncture.
- 5 Clean the puncture site with an alcohol pad. To prevent hemolysis, allow the site to dry.
- 6 Wearing gloves, puncture the finger with a sterile lancet. Wipe away the first drop of blood to avoid diluting the specimen with excess tissue fluid.
- 7 Apply slight pressure above the puncture site. Avoid squeezing directly at the puncture area, because that may cause cell damage as well as dilute the specimen with tissue fluid.
- 8 Fill the QBC STAR Tube by placing the collection end of the tube directly in contact with the finger puncture blood. Fill the QBC STAR Tube to a level between the two black fill lines.
- 9 When collection is complete, apply slight pressure with sterile gauze pad and elevate the puncture site. Bandage, if necessary.

- 10 Dispose of lancet(s) in a sharps container. Dispose of gloves and gauze in an appropriate biological hazard container. Wash hands.

Avoiding Hemolysis during Capillary Blood Collection

- Allow the puncture site to dry after cleaning with alcohol.
- Do not squeeze the puncture site excessively.
- Do not press or scrape the collection device on the skin.
- To avoid clotting in capillary blood collection:
 - Keep the puncture site clean by wiping off excess blood on skin around puncture.
 - Touch collection device only to drop of blood as it exits the puncture site. Do not scoop off skin.

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G – Glossary

CBC

Complete Blood Count

g's

Unit of acceleration, 1g = acceleration of gravity

Gran

Granulocytes

Hgb

Hemoglobin

Hct

Hematocrit

L/M

Lymphocytes and Monocytes

Lymph/Monos

Lymphocytes and Monocytes

MCHC

Mean Corpuscular Hemoglobin Concentration

Plt

Platelets

rpm

Revolutions per minute

WBC

White blood cell count

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