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Note

This equipment is not intended for family usage.

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Warning

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Dirui is not responsible for the effects on safety, reliability and performance of the BCC-3000B Hematology Analyzer if:

- **Assembly operations, extensions, re-adjusts, modifications or repairs are carried out by persons other than those authorized by Dirui.**
- **Personnel unauthorized by Dirui repairs or modifies the instrument.**

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Return Procedure

In the event that it becomes necessary to return a unit to Dirui, the following procedure should be followed:

1. Obtain return authorization. Contact the Dirui Service Department and obtain a Customer Service Authorization (Dirui) number. The Dirui number must appear on the outside of the shipping container. Return shipments will not be accepted if the Dirui number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.
2. Freight policy. The customer is responsible for freight charges when equipment is shipped to Dirui for service (this includes customs charges).

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Section 1 Use and Function

1.1 General

The full name of the instrument is BCC-3000B Auto Hematology Analyzer. It is a quantitative, automated hematology analyzer and leukocyte differential counter for in Vitro Diagnostic use in clinical laboratories. The purpose of BCC-3000B auto hematology analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that required additional studies.

The analyzer is used for the quantitative determination of the following 20 parameters and 3 histograms of blood specimens.

1.2 Specification

Sample Volume :	Prediluted 20ul Whole Blood 13ul	
Aperture Diameter :	WBC 100um	
RBC:	70um	
Wavelength :	540 nm	
Throughput :	60 samples per hour	
Dilution ratios :		
	Whole Blood	Capillary Blood
WBC/HGB	1:308	1:428
RBC/PLT	1:44872	1:43355
Lyse Volume	Whole Blood 0.5 ml	Capillary Blood 0.36 ml
Parameters		
White Blood Cell or leukocyte		WBC
Lymphocyte		LYM#
Mid-sized cell		MON#
Granulocyte		GRA#
Lymphocyte percentage		LYM%
Mid-sized cell percentage		MON%
Granulocyte percentage		GRA%
Red Blood Cell or erythrocyte		RBC
Hemoglobin Concentration		HGB

Mean Corpuscular (erythrocyte) Volume	MCV
Mean Cell (erythrocyte) Hemoglobin	MCH
Mean Cell (erythrocyte) Hemoglobin Concentration	MCHC
Red Blood Cell (erythrocyte) Distribution Width Coefficient of Variatio	RDW-CV
Red Blood Cell (erythrocyte) Distribution Width Standard Deviation	RDW-SD
Hematocrit	HCT
Platelet	PLT
Mean Platelet Volume	MPV
Platelet Distribution Width	PDW
Plateletcrit	PCT
Platelet Larger cell ratio	P-LCR

WBC Histogram

RBC Histogram

PLT Histogram

Storage: 1000 testing results, 570 QC results

Language: English

Operation Environment:

Temperature : 15°C~35°C ;

Humidity : 30%~85% ;

Air Pressure : 76kPa~106kPa

Input/Output: RS-232, Internal thermal printer, 1 bar code reader (optional),1 parallel printer(optional)

Data transmitting rate: 19200bps

Power supply: 100~240VAC , 50/60Hz

Fuse: 250V 2A

Power: 200W

Weight: 25Kgs

Dimension: 460(L)×390(W)×410(H)

Electromagnetic Compatibility (EC)

Accord with EMC test standard EN61326: 1997+A1 1998+A2 2001+A3 2003;

Sound pressure : Max. 85dB

1.3 Principles of Operation

■ Cell Counting Principle

BCC-3000B samples the appropriate dilutions prepared from whole blood to count and size WBC, RBC, PLT, and to measure HGB.

The diluted specimens are aspirated into the RBC and WBC apertures under a negative pressure. The Volumetric Assembly contains a precision glass tube (volumetric tube) fitted with two optical sensors. This tube ensures that a precise amount of diluted specimen is measured during each count cycle. The distance between the two optical sensors determines the volume of diluted specimen.

White Blood Cell, Red Blood Cell and Platelet are counted and sized by the Electrical Impedance Method. This method is based on the measurement of changes in electrical resistance produced by a particle passing through an aperture. Electrodes are submerged in the liquid on each side of the aperture to create an electrical pathway. As blood cells are non-conductive, when they pass through the aperture, they cause an increase in impedance, electric impedance directly proportioned to the cell size.

The instrument counts individual cells and sorts them by size. The number of cells counted by the instrument is much greater than the number counted under a microscope, overcoming the unfavorable influence on the counting by human factors, thereby substantially improving the accuracy and reducing the statistical error.

■ Control of Samples

Volume Metering A volume of dilution is drawn through a 70 μ m aperture of RBC and a 100 μ m aperture of WBC to be counted. The BCC-3000B hematology analyzer employs an optically sensed volumetric metering system to determine the sample volume aspirated through the aperture. Each count cycle starts when the liquid surface passes the upper sensor of the volumetric tube and ends till the lower sensor is reached. If bubbles or an abnormal flow rate are detected, the system produces alarms. Refer to the Section 9 of this manual for troubleshooting.

● Dilution

In whole blood, the cells are too close to each other to identify and measure in the counting transducer. For this reason, dilutions are prepared for whole blood to disperse the cells so that, in most cases, the cells pass through the aperture individually. Also in this way, the conductive environment for cell counting and sizing is available.

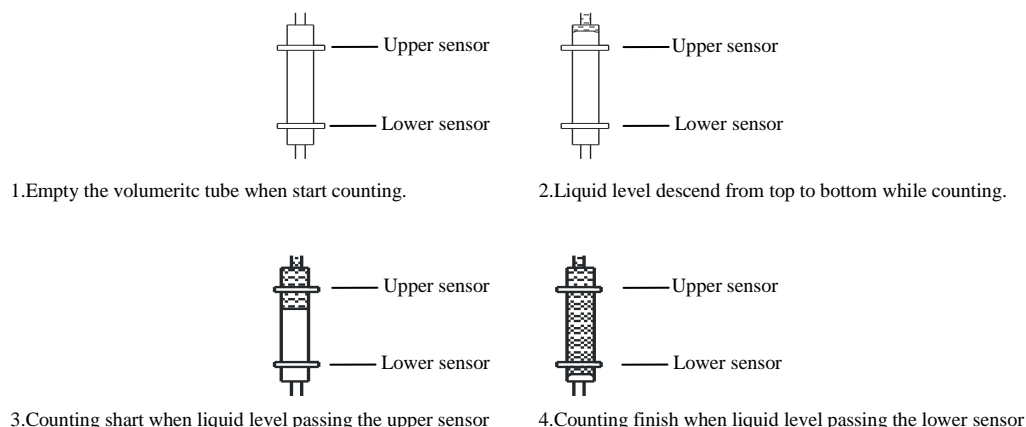


Figure 1-1

In whole blood mode, 13uL of whole blood specimen was aspirated and mixed with an addition of 3.5mL of diluent to achieve a ratio of 1:269.

The diluted sample is then divided into two samples.

15.6uL of the 1:269 sample dilution is aspirated and mixed with an addition of 2.6mL of diluent to achieve a ratio of 1:44833. The 1:44833 dilution is used for RBC and PLT counting.

The remainder of the 1:269 dilution is mixed with 0.5mL of lyse reagent to achieve a ratio of 1:308. This 1:308 dilution is used for WBC counting.

In prediluted mode, 20uL of blood specimen was added to 1.6mL of diluent in the sample cup to achieve a ratio of 1:80. 0.7mL of this 1:80 dilution is aspirated into the WBC bath. Then add 2.5mL of dilution into WBC

Bath to achieve a ratio of 1:366.

This 1:366 diluted sample is then divided into two samples. 24.8uL of the 1:366 diluted sample is aspirated and mixed with 3.0mL of diluent to achieve a ratio of 1:44274 used for RBC and PLT counting.

The remainder of the 1:366 is mixed with 0.36mL of diluent to achieve a ratio of 1:407 used for WBC counting.

After the second dilution and prior to the count, add the lyse into the diluted WBC sample to break down the red blood cell membranes. Generally the quantity of red blood cell is over 1000 times of white blood cell. Therefore before counting white blood cell, the interference of red blood cell must be removed. The normal red blood cell has no nucleus, the lyse is used to eliminate the red blood cell in the diluted white blood cell sample.

A cell passes through the aperture in the sensing zone, momentarily increasing resistance in the circuit. The change in impedance is proportional to the size of the cell. The instrument amplifies and records this pulse produced by the changes of impedance.

● **Coincidence Correction**

Affected by the concentration of blood sample, more than one cell may occasionally go through the aperture at the same time. Consequently, a certain error is introduced into the count as a result of this coincidence. Research shows that the frequency of this coincidence is proportional to the concentration of blood sample and also related to the diameter of aperture and flow rate. With consideration given to this factor during design, the BCC-3000B can automatically correct the cell count for coincidence, ensuring the accuracy of the counting result.

● **Size of Cells**

An important feature of the electrical pulses is the relationship of the pulse height to the size of the cell passing through the aperture. Larger particles or cells generate higher pulse amplitudes. Fortunately, each cell type falls within a predictable range of sizes making it possible to distinguish one type of cells from another. During cells sensing period, approximate normal size ranges for the different cells are:

WBC' s: 30-400 femtoliter

RBC' s: 30-250 femtoliter

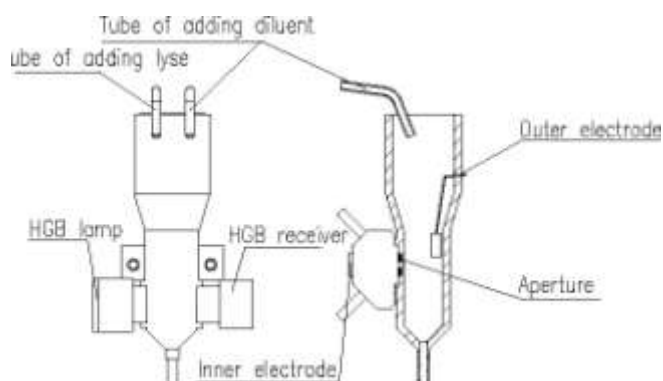
PLT' s: 2-25 femtoliter

Because of the evident difference of cell sizes, the cell counter is able to differentiate between red blood cell and platelet present at the same time in the same dilution. .

It should be noted that while the size ranges for platelets and red blood cells seem to be quite well separated, in reality, each type of cells has a range of sizes. When the number of cells is plotted against the cell size, the distribution of red blood cell and platelet each shows closely to bell-shaped curve within a range. These two bell-shaped curves normally come close to each other or even overlapping. In this case, special measures have to be taken to distinguish red blood cell from platelet. BCC-3000B adopts float discriminator for the division, thus raising the accuracy of counting result.

■ **WBC Unit**

● **Structure**



.Figure 1-2

• WBC Count

WBC is the number of leukocytes measured directly. $WBC = n \times 10^9 / L$

• WBC Differential

White cells are not all one type, and different types can be distinguished by size. Separation and counting by size is accomplished by controlling the conditions (that is, the diluent, lysing agent and timing). Under proper procedures, the chemical reaction permits the BC-3000plus system to use electronic sizing to determine three distinct white cell subpopulations---lymphocytes, mid-sized (including monocytes, basophils, eosinophils), and granulocyte. In some cases nucleated red blood cells (NRBC) may appear in peripheral blood. Nuclear of these cells are resistant to the lyse and are counted as white cells. When NRBC are viewed with microscope, the WBC count should be corrected as follow:

WBC value is obtained by measurement. NRBC, obtained by smearing, represents the quantity of NRBC in each 100 WBC. Refer to following equation:

$$WBC = WBC \times \left(\frac{100}{100 + NRBC} \right)$$

Lymphocytes are the smallest of the white cells. They are cells included in the 30 to 85fL size region of the white cell histogram.

There are three types of mid-size cells, eosinophils, basophils, and monocytes that are found in the size region between the lymphocytes and granulocytes. After lysing, these cells fall into the 85 to 125fL of the white cell histogram. Other, but rare, mononuclear white cells within this region is blasts and myelocytes.

Neutrophilic granulocytes are the largest white cells. Treatment with lyse/lysing reagent damages the cell membranes and allows the escape of cytoplasm. Cytoplasmic granules are then compressed around the nucleus by the residual cell membrane. Neutrophilic granulocytes, with their segmented nuclei and cytoplasmic granules, are found above the 125fL region of the white cell histogram.

The following equations are used to derive percentages of each population in the blood cell count.

$$LYM\% = \frac{PL}{(PL + PM + PG)} \times 100$$

$$MON\% = \frac{PM}{100 \times (PL + PM + PG)} \times 100$$

$$GRA\% = \frac{PG}{100 \times (PL + PM + PG)} \times 100$$

In these formulas:

PL = particles in the lymphocyte region

PM = particles in the mid size region

PG = particles in the granulocyte region

The following equations are used to derive the absolute numbers of each population.

$$\text{LYM\#} = \frac{\text{WBC} \times \text{Lymph \%}}{100}$$

$$\text{MON\#} = \frac{\text{WBC} \times \text{Mid\%}}{100}$$

$$\text{GRA\#} = \frac{\text{WBC} \times \text{Gran\%}}{100}$$

■ HGB Unit

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

$$\text{HGB(g/L)} = \text{Constant} \times \text{Log}^{10} (\text{Blank Photocurrent} / \text{Sample Photocurrent})$$

■ RBC Unit

● Structure

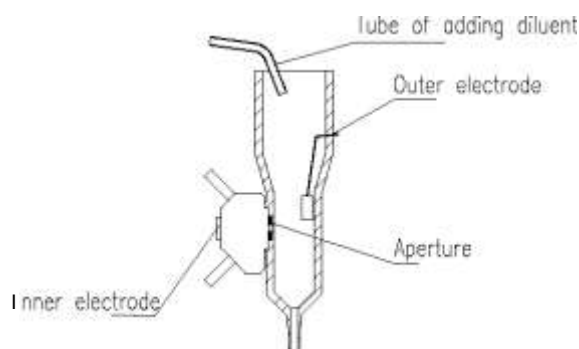


Figure 1-3

● RBC Count

RBC is the number of erythrocytes measured directly.

$$\text{RBC} = n \times 10^{12} / \text{L}$$

● Mean Corpuscular Volume (MCV)

For RBC volume parameters, MCV is that the instrument measures the amplitude of the electric pulse produced by each red blood cell passing through the RBC aperture. After the red blood cells are sorted and counted by size region, the microprocessor performs a volume summation over all cells counted. The summation is divided by the total number of red blood cells counted and multiplied by the MCV calibration factor to give an average size of the red blood cells, MCV.

- **Hematocrit (HCT), Mean Cell Hemoglobin (MCH), and Mean Cell Hemoglobin Concentration (MCHC)**

The following equations are used to derive HCT, MCH and MCHC:

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

$$\text{MCH (pg)} = \frac{\text{HGB(g/L)}}{\text{RBC(/L)}}$$

$$\text{MCHC(g/L)} = \frac{\text{HGB(g/l)}}{\text{HCT(\%)} \times 100}$$

- **Red Blood Cell Distribution Width Coefficient of Variation (RDW-CV)**

RDW-CV is expressed in percent of the RBC size distribution.

- **Red Blood Cell Distribution Width Standard Deviation (RDW-SD)**

RDW-SD indicates the width of the RBC histogram in figure 1-6. The width is concerned with the ordinate that drops from the peak to 20 percent of it. The unit of RDW-SD is fL.

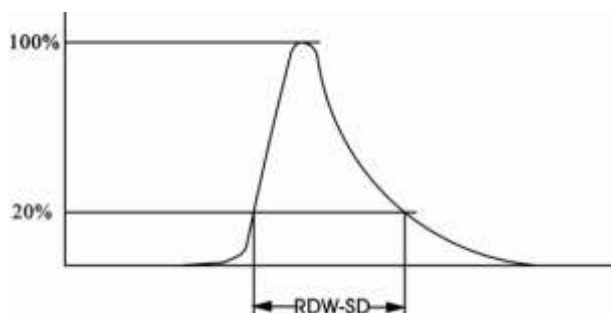


Figure 1-4

- **Platelet (PLT) Count**

PLT is the number of thrombocytes derived from directly measured platelet pulses.

$$\text{PLT} = n \times 10^9 / \text{L}$$

- **Mean Platelet Volume (MPV)**

MPV is the average volume of individual platelets derived from the PLT histogram with unit being fl.

- **Platelet Distribute Width (PDW)**

PDW is derived from PLT histogram. It is the geometric standard difference of PLT volume distribution (10 GSD) .

$$\text{PCT (\%)} = \frac{\text{PLT}(10^9) \times \text{MPV(fl)}}{100000}$$

■ Clog Detection

Human blood contains protein and other materials that may accumulate on the apertures during the count. The accumulation process of this material may lead to erroneous results.

Clogs are avoided through high-voltage zap after each counting and cleaning procedures as well as through the daily and weekly maintenance. In addition, the analyzer has a function used to monitor clogs. Once it detects that the count time is over the reference range, the instrument will give alarm prompt in the display of the results, record and printout so as to arouse the user's attention to removing clogs.

1.4 System Operation

■ Host Device

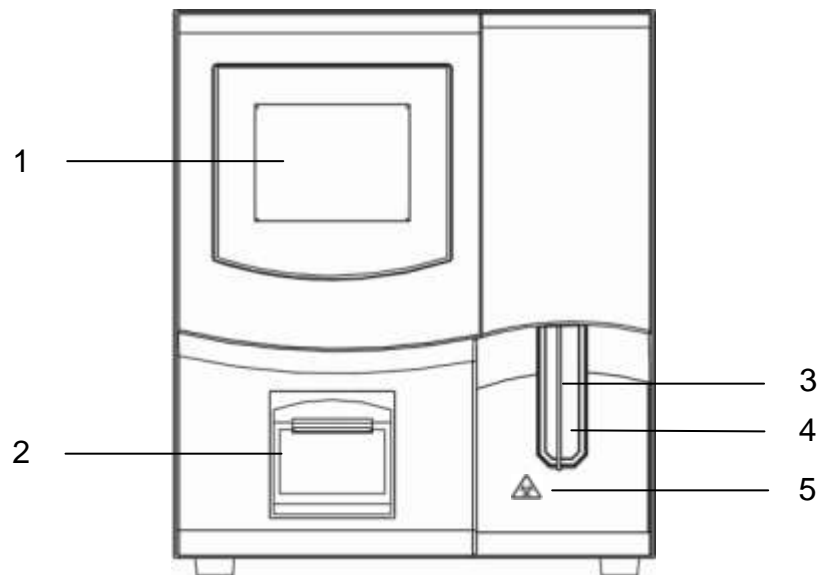


Figure 1-5

Description of each part of BCC-3000B front:

- 1 ---- Display Screen
- 2 ---- Recorder
- 3 ---- Sample Probe
- 4 ---- [Start] key
- 5 ---- [Biohazard] symbol

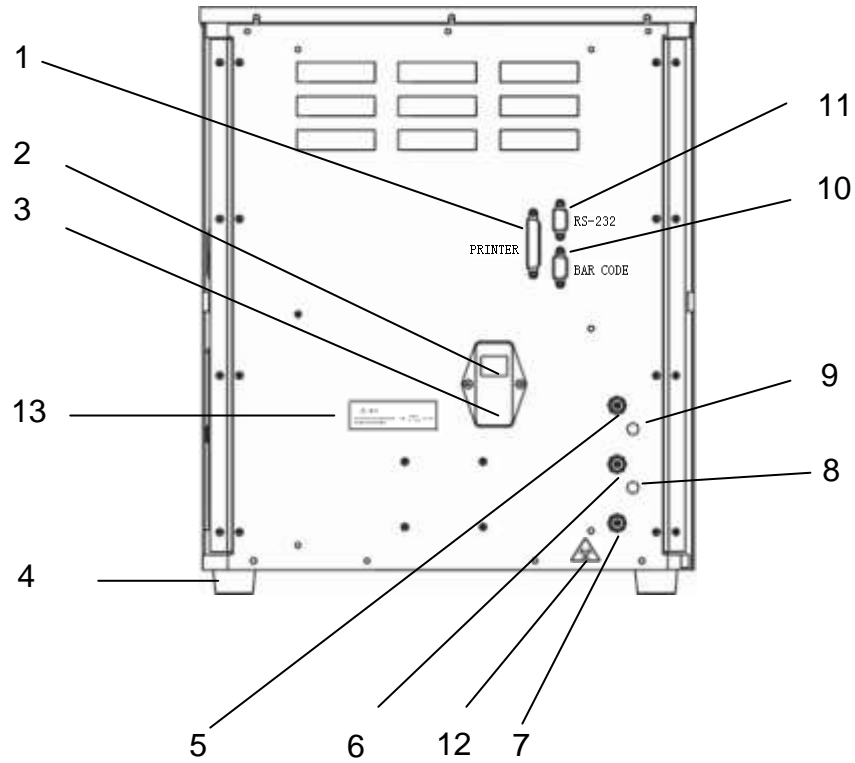


Figure 1-6

Description of each part of BCC-3000B rear

- | | | | |
|-------------------------------------|-----------------------------------|-----------------------|--------------|
| 1 --- Printer Interface | 2 --- Power switch | 3 --- power socket | 4 --- holder |
| 5 --- DILUENT Tubing Connector | 6 --- RINSE Tubing Connector | | |
| 7 --- WASTE Tubing Connector | 8 --- BNC socket for RINSE sensor | | |
| 9 --- BNC socket for DILUENT sensor | 10 --- Bar code reader connector | | |
| 11 --- RS-232C Serial Port | 12--- [Biohazard] Symbol | 13---[Warning] Symbol | |

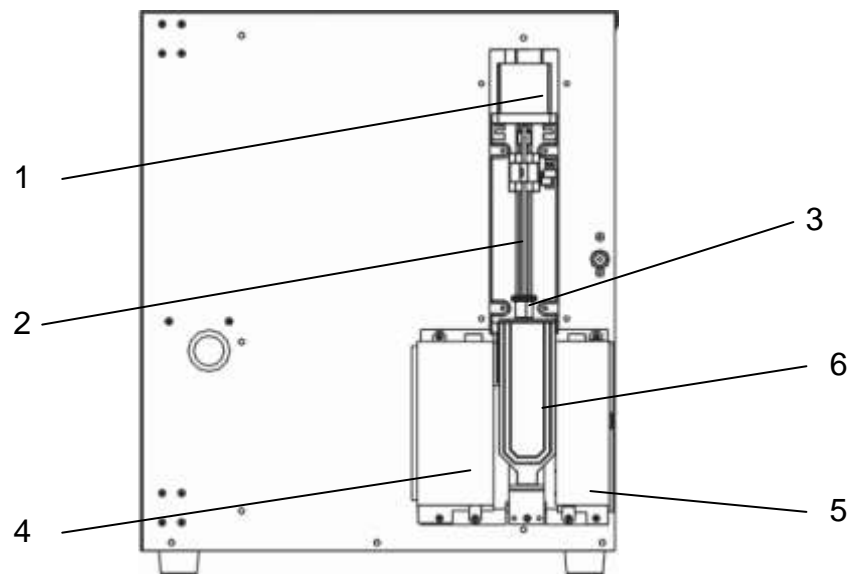


Figure 1-7

- 1--- Fluctuating Motor 2--- Sample Probe 3--- Sample Probe Wipe Block
 4--- WBC unit shield 5--- RBC/PLT unit shield 6--- [Start] key

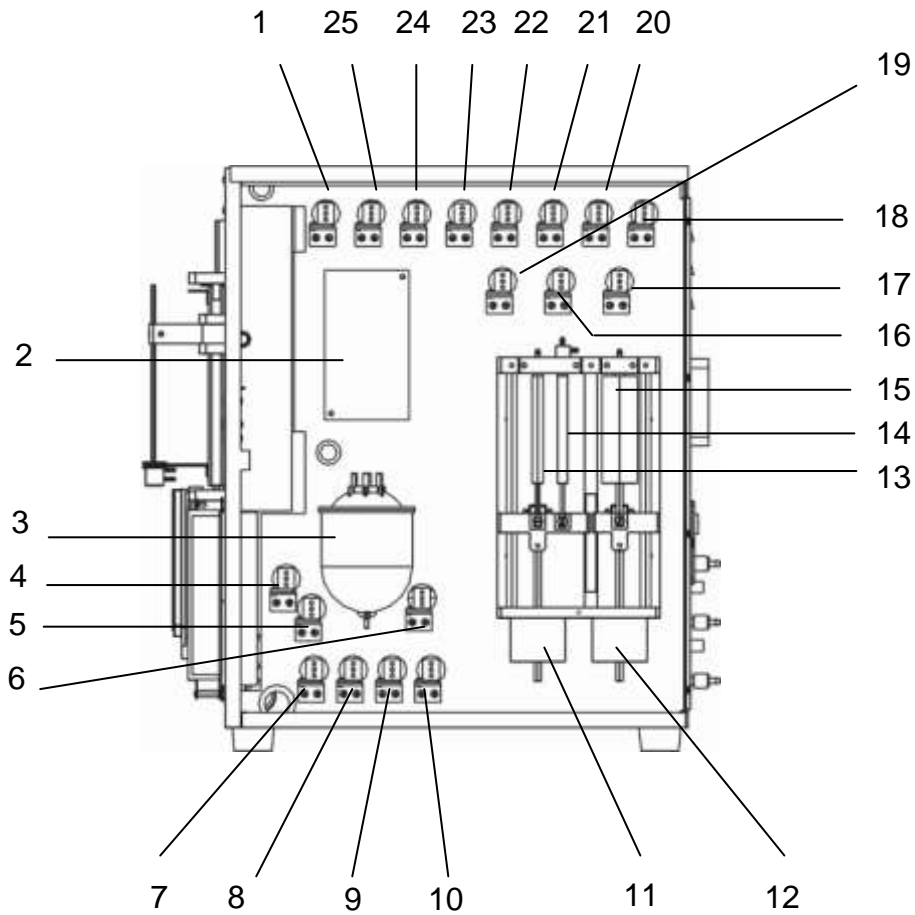


Figure 1-8

- | | | | |
|--------------------|---------------------|---------------------------|-----------------|
| 1--- valve 8 | 2---volumetric unit | 3---vacuum chamber | 4---valve 14 |
| 5---valve 13 | 6---valve 9 | 7---valve 12 | 8---valve 11 |
| 9---valve 10 | 10--- valve 2 | 11---2.5ml and 50ul motor | 12---10ml motor |
| 13---2.5ml syringe | 14---50ul syringe | 15---10ml syringe | 16---valve 4 |
| 17---valve 3 | 18---valve 1 | 19---valve 6 | 20---valve 5 |
| 21---valve 15 | 22---valve 16 | 23---valve 17 | 24---valve 7 |
| 25---valve 18 | | | |

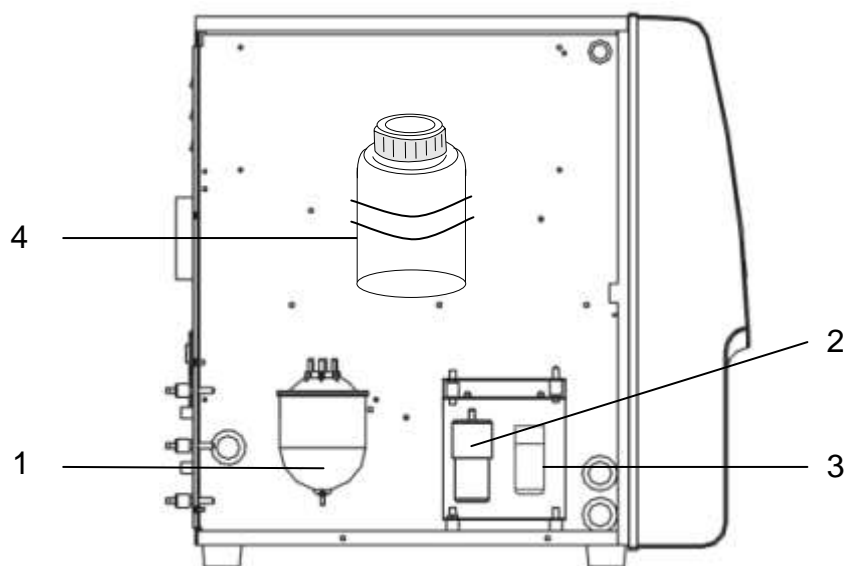
















Figure 1-9

- 1--- Pressure chamber
- 2--- Pressure pump
- 3--- Vacuum pump
- 4--- DiskOnModule disk

1.5 symbol

Safety Symbols

Symbol	Warning Condition	Action
	Biohazard: Consider all materials (specimens, reagents, controls, calibrators, or components that contain or have contacted human blood) as being potentially infectious.	Wear standard laboratory attire, glove and follow safe laboratory procedures when handling any material in the laboratory.
	Electrical Shock Hazard: The electrical warning icon alerts users to the possibility of electrical shock in the described activity or at the posted location.	Before continuing, unplug the BCC-3000B analyzer from the electrical outlet.
	Probe Hazard: The probe is sharp and may contain biohazardous materials, including controls and calibrators.	Avoid any unnecessary contact with the probe and probe area.
	NOTE: Indicate to the operator information of importance in the procedure to be performed. This heading is also used to indicate specific sample handling techniques that are helpful in operating the instrument.	
	CAUTION: Indicate to the operator information of importance that could result in damage to the instrument or affect the test due to improper operation if these instructions are not followed.	
	WARNING: Indicate to the operator information regarding potential hazards that may cause personal harm to the operator if these instructions are not followed.	

	AC symbol	
	In vitro Diagnostic	
	Lot number	
	Expiration	
	Serial number	
	Measurement control allowed	
	Production date	
	Storage temperature	

Section 2 Installation

2.1 Unpacking

The instrument should be unpacked carefully and examined for damage. A claim should be filed immediately with the shipping carrier if physical damage is discovered.

The equipment should be inspected and compared to the packing list to ensure that the shipment is complete. If the shipment appears incomplete, Dirui Customer Service Department or your distributor should be notified immediately.

2.2 Installation Requirements

■ Installation Environment

The environment should be as free as possible from dust, mechanical vibrations, loud noises and electrical interference. Avoid proximity to brush-type motors, flickering fluorescent lights and electrical contacts that regularly turn on and off. Avoid placing the instrument in direct sun or in front of a source of heat or draft.

■ Space and Accessibility Requirement

Check the site for proper space allocation. BCC-3000B require 40cm to open fully. You must fully open the left door to replace the lyse. In addition to the space requires for the unit itself, arrange for

Comfortable working height.

At least 28 cm on each side is the preferred access to perform service procedures.

At least 10cm behind for cabling and ventilation.

There is enough space for reagents.

**NOTE:**

Reagents must be placed at the same working height as the analyzer.

Power Requirement :

The BCC-3000B requires a properly grounded socket supplying 220 or 110 volts (For the proper input voltage, refer to the print above the power switch at the back of BCC-3000B). The fluctuation should be in the range of $\pm 10\%$. And the power frequency should be 50/60Hz.

The BCC-3000B requires a well-grounded receptacle whose maximum power consumption is less than 180VA.

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



NOTE

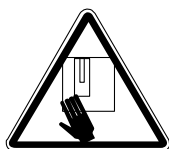
Verify that the input voltage is compatible with the instruments.

2.3 Installation



WARNING

Potential biohazard



WARNING

Avoid contacting with the sample probe

1. Push the switch as shown in figure 2-1 and open the right side door.



Figure 2-1

2. Lift up the switch as indicated in figure 2-2 and open the front panel. Figure 2-3 shows the sample probe fixed by plastic cable tie.

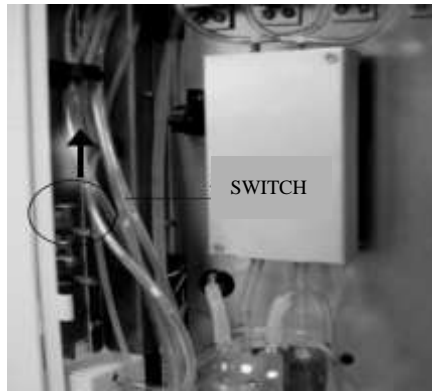


Figure 2-2

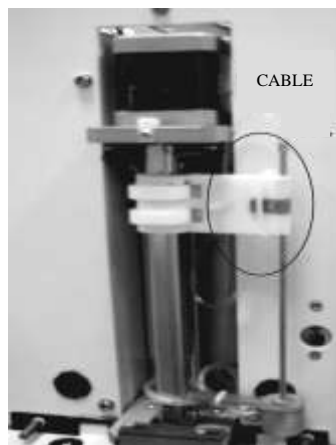


Figure 2-3

3. Cut the plastic cable tie and get rid of it, release the sample probe (Figure 2-4).



Figure 2-4

4. Move the sample probe to the middle position
5. After releasing the sample probe, close the front panel and the right side door, and then lock the switches.



WARNING

Potential biohazard

• **Diluent Connection**

Take out the diluent inlet tubing with blue connector from the accessory kit. Take out the container for diluent, in which there should be enough diluent. Place one end of diluent tubing into the diluent container, see figure 2-6 and turn the container cover clockwise until secure. Connect the blue tubing connector of the diluent inlet tubing to the tubing connector (red) marked with "DILUENT" on the rear panel of the instrument. Insert the BNC plug with wire into the BNC outlet of the DILUENT sensor on the rear panel of the instrument. Then turn until secure.

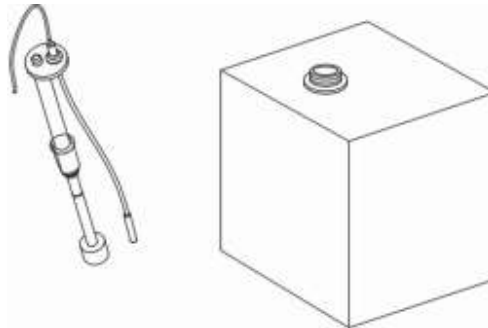


Figure 2-5

• **Cleanser Connection**

Take out the cleanser inlet tubing with blue connector from the accessory kit. Take out the cleanser container, in which there should be enough cleanser. Place one end of the inlet tubing into the cleanser container, see figure 2-5 and turn the container cover clockwise until secure. Connect the blue tubing connector of the cleanser inlet tubing to the tubing connector (red) marked with "CLEANSER" on the rear panel of the instrument.

Insert the BNC plug with wire into the BNC outlet of the cleanser sensor on the rear panel of the instrument. Then turn until secure.

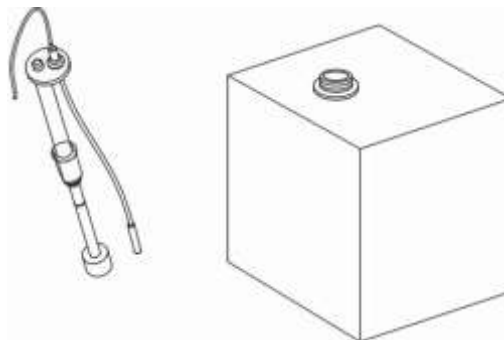


Figure 2-6

• **Lyse Connection**

1. Take out the lyse inlet tubing with liquid sensor from the accessory kit. Place one end of the lyse inlet tubing and the liquid sensor into the lyse container, see figure2-7, turn the container cover clockwise until secure.

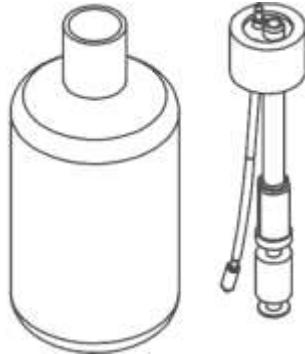


Figure 2-7

2. Push the switch as shown in figure 2-8 and open the left side door of the instrument.



Figure 2-8

3. Put the lyse container with the container cover to the position and Connect the lyse tubing connector and wire socket inside the BCC-3000B to the tubing connector and wire plug on the lyse container. shown in figure 2-9.



Figure 2-9

● **Waste Tubing Connection**

Take out the waste inlet tubing with blue tubing connector from the accessory kit. Connect the red tubing connector of the inlet tubing to the WASTE tubing connector (red) on the rear panel of the instrument. Turn clockwise until secure. Place the waste container on the same level as or lower than the instrument. Place the waste inlet tubing into the waste container.

■ **Waste Disposal**



WARNING

Potential biohazard



WARNING

Handle and dispose of the waste according to acceptable laboratory, local state and national standards.

■ **Recorder**

- **Open the door of the recorder.**



Figure 2-10

- **Uplift the bar of the recorder. Insert the paper into the paper entry.**



Figure 2-11

- Push the bar of the recorder.



Figure 2-12

- Close the door.

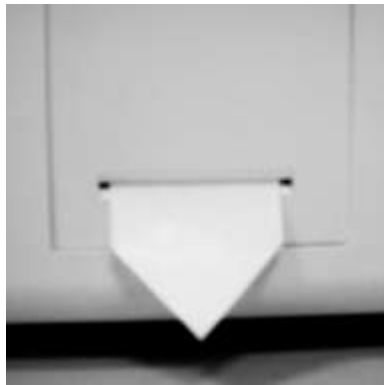


Figure 2-13

■ Printer

If the system is equipped with printer, the user can use printer cable to connect it to the printer interface on the instrument.

For the method of installation and use, refer to the operation manual of the printer.

Section 3 Sample Analysis

This section contains the following procedures:

Preliminary operating procedures

Startup cycle

Count screen

Daily quality control

Sample collection

Sample count

Daily Shutdown

3.1 Preliminary Operating Procedures

Prior to Power-On, the following checking procedures must be finished to make the instrument in ready status so as to ensure normal function of the instrument.

■ Check Diluent, Rinse and Lyse

The consumption of each reagent is:

	Diluent	cleanser	Lyse	E-Z
Normal Startup	125ml	27ml		
Test a sample (whole blood)	27ml	5ml	0.5ml	
Test a sample (prediluted)	27ml	5ml	0.36ml	
Normal Shutdown	20ml			0.65ml

■ Check Waste Container

The user should prepare a waste container and empty it



WARNING

Potential biohazard



WARNING

Handle and dispose of the waste according to acceptable laboratory, local state and national standards

■ Check Tubing and Cables

Check if the tubing of diluent, cleanser, lyse and waste has bends and if the tubing is connected securely.



WARNING

Electrical Shock Hazard

Check if the power plug of the instrument is correctly and securely inserted into the receptacle.

■ Check Recorder and Printer

● Check Recorder

Ensure sufficient paper supply and proper installation of the recorder.

● Check Recorder and Printer

Ensure sufficient paper supply and proper installation of the printer.



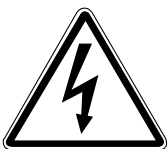
WARNING

Electrical Shock Hazard

Power plug is connected properly to the outlet, and the cable is correctly connected with the instrument.

3.2 Startup Cycle

1. If external printer is equipped, turn on the printer's power and ensure that it is in ready status.



WARNING

Electrical Shock Hazard

Press the power button of the instrument.

2. The instrument automatically performs initialization program. In the mean time, the "loading..." is display. This process needs about 160 seconds

3 The self-test window is displayed on the screen as shown in figure 3-1. Firstly, it tests if the system hardware's function is normally and if there is enough lyse, diluent and cleanser.

Upper screen:

From left to right , there are: ID number, Sample Mode and System Time.

ID: the identification number of the current sample.

Sample Mode: whole blood (WB) and prediluted (PD).

Whole Blood: Press [START] key, the sample probe aspirates 13uL whole blood.

Prediluted: Press [START] key, the sample probe aspirates 0.7mL diluted sample with dilution ratio being 1:80.

System Time: Display the current time..

• Enter Next ID with the bar code scanner

Connecting the scanner with the instrument.

Scanner Model: TYSSO CCD-82



WARNING
Electrical Shock Hazard

Ensure the power plug of scanner is connected properly to the outlet, and the cable is correctly connected with the instrument COM1.

Turn on the instrument. Then The operation as follows:

In menu operation.

Menu	Ver.1.00
1. Calibration 5. System maintenance 2. Sample review 6. System monitoring 3. QC 4. Setup	<input type="button" value="Return"/>

Figure 3-4

Press “ Setup” to access the “Function setup” screen.

Function	
1. Abnormal mark— Off 2. ID— Off 3. Auto transmission— On 4. Output histogram— On 5. Probe high position 6. Probe low position	<input type="button" value="Return"/>

Figure 3-5

Mark "ID" to "ON" to open this function. Then press "Return" to "menu", then press "Return" to access count screen. Once press [START] to run the "counting", "ID" screen will appear automatically as bellowed.

ID: -----		
9	8	7
6	5	4
3	2	1
0	-/.	←
Enter		Cancel

Figure 3-6

In this screen, there are two options for ID ser can set up ID by entering the numbers. To avoid incorrect operation, the numbers should be less than 10. Then press [ENTER] and the ID would appear on the count screen.

Once use bar code scanner, the numbers should be between 4 to 10 . Then press [ENTER] and the ID would appear on the count screen.

3.4 Daily Quality Control



WARNING
Potential biohazard

Before sample analysis, perform the quality control analysis once everyday. Further information and procedures are given in Section 4: Quality Control.

3.5 Sample Collection



WARNING
Potential biohazard



WARNING
Avoid directly contacting with the patient blood samples.

The operator must take proper precautions in handling the whole blood samples of patients to avoid exposure to potentially life-threatening diseases. The sample can be collected either from capillary blood or from venous blood.

■ Anticoagulant for Venous Blood

K2EDTA is recommended to be used as the anticoagulant, whose specified content is 1.5 ~ 2.2 mg/mL blood. K2EDTA is suitable for the count and morphological examination of RBC's and WBC's.

■ Prepare Samples in Prediluted Mode

No: 1	Mode: WB	07-12-10 17: 54
No.1 WBC 0.0 HGB 0 LYM# -.- LYM% -.- MON# -.- MON% -.- GRA# -.- GRA% -.- RBC 0.0 HCT -.- MCV -.- RDW-SD -.- MCH -.- RDW-CV -.- PLT 0 MCHC -.- MPV -.- PDW -.- PCT -.- P-LCR -.-		T-18°C WBC _____ RBC _____ PLT _____
Menu	Prime	Remove cloa Shut down

Figure 3-7

In menu operation area, press "Mode" to access the screen.

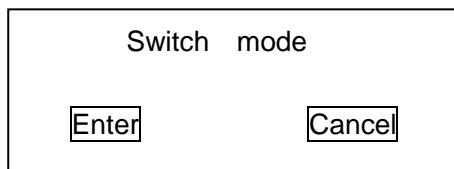


Figure 3-8

Press [ENTER] to switch the sample Mode between whole blood (WB) and prediluted (PD). Press [Enter] key to confirm the change and access the Count screen. Press [cancel] key to back the count screen.

In Sample Mode screen, set up Prediluted as the sample mode.

Clean area on and around puncture site thoroughly with alcohol to remove unwanted debris. Hold puncture site below heart level to improve blood flow. Wipe first drop of blood away and begin filling collection device once drops form at puncture site. Do not squeeze puncture site too hard or tissue fluid may contaminate the sample. Use lint-free tissue to wipe off the blood on the outside wall of the capillary tube.

Test the samples after 3 minutes.

The diluted samples should be analyzed for leukocyte differential within 30 minutes. The diluted samples should be analyzed for complete blood count within 2 hours. Avoid dust combining with the samples to make the result incorrect.

Each laboratory should evaluate predilute stability based on their sample population and specimen collection techniques or methods.

3.6 Sample Count



WARNING

Potential biohazard

■ **Count**

No: 1	Mode: WB	07-12-10 17: 54
No.1	ID:	T-18°C WBC
WBC 0.0	HGB 0	┌──────────────────────────┐
LYM# -.-	LYM% -.-	
MON# -.-	MON% -.-	RBC
GRA# -.-	GRA% -.-	┌──────────────────────────┐
RBC 0.0	HCT -.-	
MCV -.-	RDW-SD -.-	
MCH -.-	RDW-CV -.-	PLT
PLT 0	MCHC -.-	┌──────────────────────────┐
MPV -.-	PDW -.-	
PCT -.-	P-LCR -.-	
Counting		

Figure 3-12

Ensure that the recorder paper is already prepared.

if the "Auto Print" item in "Setup/Print" is "ON", the system will print out the results automatically after running.

If external printer is available, confirm that the cable and power are connected correctly and safely.

• **Whole Blood Mode**



WARNING
Potential biohazard



WARNING
Avoid contacting with the sample probe

Place the well-mixed sample to the probe so that the tip is well into the tube, and press the [START]. When the sample probe lifts up, remove the sample. Aspirate 13ul sample each time. In the mean time, “Counting” is displayed in the screen. After about 1 minute, the results are displayed in the screen. And the next ID increases automatically by 1.

• **Prediluted Mode**

Present the well-mixed, prediluted sample to the sample probe and press [START] key to start count procedure. When the sample probe lifts up, remove the sample. Aspirate 0.7mL sample each time. In the mean time, the count process is displayed with “Counting”. After about 1 minute, the results are displayed in the screen. And the next ID increases automatically by 1.



NOTE

Avoid sample probe contacting with the bottom of the sample cup, or else the result may be incorrect.

After counting, the results are displayed on the screen. If the “Auto Print” is ON, the recorder or the printer will automatically output the results.

During the count process, if Clog or Bubbles failure occurs, the alarm message should appear in the screen.

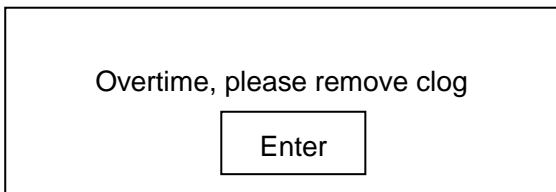


Figure 3-13

press the [Enter] to remove the clog.

When the room temperature is below 15°C or above 35°C, the results of sample analysis are unreliable. Refer to Section 9 for troubleshooting.

■ Results Display

After sample analysis, the results of 20 parameters and three histograms respectively for WBC, RBC and PLT will be displayed in the screen. The linear ranges for parameters are:

WBC	0.3 – 99.9×10 ⁹ /L
RBC	0.2 – 9.99×10 ¹² /L
HGB	0 – 300 g/L
PLT	10 - 999×10 ⁹ /L

The higher limit for screen display:

Parameter	Higher Limit	Parameter	Higher Limit
WBC	999.9 × 10 ⁹ /L	MCV	250.0 fL
LYM#	999.9 × 10 ⁹ /L	MCH	999.9 pg
MON#	999.9 × 10 ⁹ /L	MCHC	9999 g/L
GRA#	999.9 × 10 ⁹ /L	RDW-CV	100.0 %
LYM%	100.0%	RDW-SD	250.0fL
MON%	100.0%	PLT	3000 × 10 ⁹ /L
GRA%	100.0%	PDW	30.0
RBC	9.99 × 10 ¹² /L	MPV	30.0 fL
HGB	300 g/L	PCT	0.70 %
HCT	100.0 %	P-LCR	0.11-0.45

Figure 3-14

■ Parameter Alarm

[↑] or [↓] is marked at the right side of parameter name, indicating the data has exceeded the setup higher or lower alarm limit of the parameter.

■ Recorder and Printer

If the “Auto Print” item in “Setup/Print” menu is “On”, the recorder or the printer will output results automatically.

If the “Auto Print” item in “Setup/Print” menu is “Off”, go to Review and Press [PRINT] key, the recorder or the printer outputs the results of sample analysis.

Output formats of Printer.

One page with histogram ,One page without histogram.

● Output formats of Recorder

Histogram

No Histogram

For setup method, refer to Section 7: Print Setup.

■ **Auto Clean**

If count times are up to 20 (no key being pressed, the time is adjustable, refer to Section 7), the Auto Clean starts and the system automatically clean the tubing and baths and wipe block.

No: 1	Mode: WB	07-12-10 17: 54
No.1	ID:	T-18°C WBC
WBC 0.0	HGB 0	_____
LYM# -.-	LYM% -.-	
MON# -.-	MON% -.-	RBC
GRA# -.-	GRA% -.-	_____
RBC 0.0	HCT -.-	
MCV -.-	RDW-SD -.-	PLT
MCH -.-	RDW-CV -.-	_____
PLT 0	MCHC -.-	
MPV -.-	PDW -.-	
PCT -.-	P-LCR -.-	
Automatic clean		<input type="text"/>

Figure 3-15

3.7 Daily Shutdown

To ensure the optimum performance of the instrument , shutdown routine must be performed before turning off the power.

The procedures are: Press [Shutdown] in menu screen. Then Shutdown screen pops up.

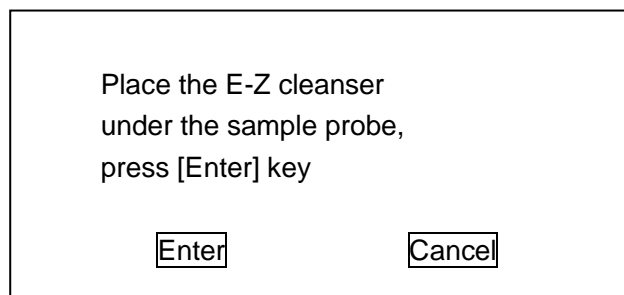



Figure 3-16

Select "Cancel" to Close the screen and exit the Shutdown operation.

Select "Enter", the prompt screen pops up as shown Figure 3-16:



Please wait...

WARNING

Potential biohazard



WARNING

Avoid contacting with the sample probe.

After Shutdown process, the screen displays "Please turn off the power of the instrument." Then turn off the power of the instrument.

Turn off the power of printer (if it is available).

Dispose the waste liquid.



WARNING

Potential biohazard



WARNING

Handle and dispose of the waste according to acceptable laboratory, local state and national standards.

Section 4 Quality Control

Controls are used to determine whether an instrument is operating with accuracy and precision. To maintain the reliability of the count results, periodic quality control of the instrument is required.

The Quality Control of the instrument includes two techniques: L-J, \bar{X} and X-B Analysis.

Menu	Ver.1.00
<ol style="list-style-type: none"> 1. Calibration 2. Sample review 3. QC 4. Setup 5. System maintenance 6. System monitoring 	
	Return

Figure 4-1

QC
<ol style="list-style-type: none"> 1.L-J 2. \bar{X} 3. X-B
Return

Figure 4-2

4.1 L-J

This system provides 9 QC files and 8 QC parameters.

When operating this instrument outside the optimal temperature range (20°C -25°C), control results may exceed the expected limits.

■QC Edit

QC
<ol style="list-style-type: none"> 1. QC edit 2. QC count 3. QC graph 4. Delete all QC data
Return

Figure 4-3

In menu operation, follow “QC/L-J/QC Edit/File 1” to access the QC Edit screen.

Lot No. []			Expiry date: []		
	Target	SD		Target	SD
WBC	nan	nan	MCV	nan	nan
RBC	nan	nan	MCH	nan	nan
HGB	nan	nan	MCHC	nan	nan
HCT	nan	nan	PLT	nan	nan
Enter					Return

Figure 4-4

■ Operation

Press [] and parameter and Press [0] – [9] to enter.

-		
9	8	7
6	5	4
3	2	1
0	-/.	←
Enter		Cancel

Figure 4-5

The “fixed decimal” format is adopted for entry, which does not require the user to enter decimal point.

The parameter is available for QC, the Target and SD should be input all together.

If of the Target and SD, only one item is entered, the parameter will not be saved. If the tested assigned is less than or equal to the limit (illegal assignment), the system takes the parameter as no assignment. The system does not verify the Exp. Date; moreover the illegal input of year, month and date will be stored.

Then Press [Enter] key to and return to QC menu.

QC
1. QC edit 2. QC count 3. QC graph 4. Delete all QC data
Return

Figure 4-6

■ **QC count**

Enter the Target and SD of the quality file and perform QC count of the specified file. It is recommended to run the three levels of controls (low, normal and high) prior to run patient samples every day. The user can perform the QC count of either all of the 8 parameters or just a few selected parameters



NOTE

Dirui recommends commercial controls as suggested. To unreliable results caused by using other controls, Dirui takes no responsibility.



WARNING

Potential biohazard

● **Mixing and Handling**

Always mix and handle commercial control materials according to the directions given in the package insert. Pay particular attention to the following.

Be sure the vials are at the proper temperature and are not leaking.

Store controls at recommended temperatures inside the refrigerator.

Carefully warm and resuspend the product according to the directions given in the package insert.

Proper mixing is essential for accurate results.

Check the shelf life and open-vial stability dating. Do not use products longer than recommended by the manufacturer.

Perform following steps to QC count:

1. Confirm that Target and SD have been entered in the QC file.
2. In menu operation, follow "QC/L-J/QC count/File 1".

No.1	L-J	07-12-10 17: 54
QC Lot No. WBC --- HGB --- LYM# --- LYM% --- MON# --- MON% --- GRA# --- GRA% --- RBC --- HCT --- MCV --- RDW-SD --- MCH --- RDW-CV --- PLT --- MCHC --- MPV --- PDW --- PCT --- P-LCR ---		WBC _____ RBC _____ PLT _____
Save	Return	Print

Figure 4-7

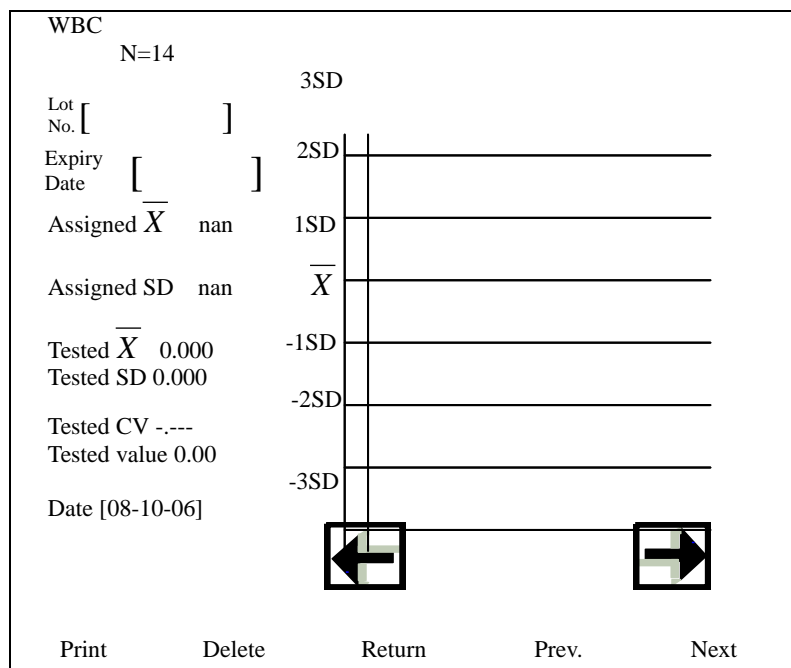


Figure 4-9

The X-axis of the graph represents “average value” and the Y-axis represents “standard deviation”
 Three parameters at the right side of QC graph:

\bar{X} : average value

SD: standard deviation

CV: coefficient of variation

Formulas are: n refers to the maximum value of running times.

Xi refers to the result value of No. i running of the specified parameter.

$$\bar{X} = \frac{\sum_{i=1}^n Xi}{n}$$

$$SD = \sqrt{\frac{\sum (Xi - \bar{X})^2}{n - 1}}$$

$$CV\% = \frac{SD}{\bar{X}} * 100$$

Press [Delete] key, Delete QC data.

4.2 \bar{X}

This system provides 9 QC files and 8 QC parameters.

When operating this instrument outside the optimal temperature range (20°C -25°C), control results may exceed the expected limits.

QC
1. QC edit
2. QC count
3. QC graph
4. Delete all QC data
<input type="button" value="Return"/>

Figure 4-10

■ QC Edit

-					
Lot No.: []			Expiry date: []		
	Target	SD		Target	SD
WBC	nan	nan	MCV	nan	nan
RBC	nan	nan	MCH	nan	nan
HGB	nan	nan	MCHC	nan	nan
HCT	nan	nan	PLT	nan	nan
Enter					Return

Figure 4-11

In menu operation, follow "QC/ \bar{X} /QC Edit/File 1" to access the QC Edit screen.

Operation: Press [] and parameter and Press [0] – [9] to enter.

-		
9	8	7
6	5	4
3	2	1
0	-. /	←
Enter		Cancel

Figure 4-12

The "fixed decimal" format is adopted for entry, which does not require the user to enter decimal point.

The parameter is available for QC, the Target and SD should be input all together.

If of the Target and SD, only one item is entered, the parameter will not be saved. If the tested assigned is less than or equal to the limit (illegal assignment), the system takes the parameter as no assignment. The system does not verify the Exp. Date; moreover the illegal input of year, month and date will be stored.

Then Press [Enter] key to and return to QC menu.

QC
1. QC edit 2. QC count 3. QC graph 4. Delete all QC data
Return

Figure 4-13

■ **QC count**

Enter the Target and SD of the quality file and perform QC count of the specified file. It is recommended to run the three levels of controls (low, normal and high) prior to run patient samples every day. The user can perform the QC count of either all of the 8 parameters or just a few selected parameters.



NOTE

Dirui recommends commercial controls as suggested. To unreliable results caused by using other controls, Dirui takes no responsibility.



WARNING

Potential biohazard

● **Mixing and Handling**

Always mix and handle commercial control materials according to the directions given in the package insert. Pay particular attention to the following:

Be sure the vials are at the proper temperature and are not leaking.

Store controls at recommended temperatures inside the refrigerator.

Carefully warm and resuspend the product according to the directions given in the package insert.

Proper mixing is essential for accurate results.

Check the shelf life and open-vial stability dating. Do not use products longer than recommended by the manufacturer.

Perform following steps to QC count:

1. Confirm that Target and SD have been entered in the QC file.

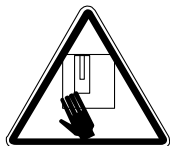
2. In menu operation, follow "QC/ \bar{X} /QC count/File 1"

No.1	\bar{X} : X1	07-12-10 17: 54
QC Lot No.		WBC
WBC --- HGB ---		┌──────────────────────────┐
LYM# --- LYM% ---		
MON# --- MON% ---		RBC
GRA# --- GRA% ---		┌──────────────────────────┐
RBC --- HCT ---		
MCV --- RDW-SD ---		
MCH --- RDW-CV ---		
PLT --- MCHC ---		PLT
MPV --- PDW ---		┌──────────────────────────┐
PCT --- P-LCR ---		
Save	Return	Print

Figure 4-14



WARNING
Potential biohazard



WARNING
Avoid contacting with the sample probe.

3. Ensure that Control is not past its expiration date and that it is at the correct storage temperature.
4. After warming at room temperature, mix each control gently according to instructions in the package insert. Inspect the vial contents to ensure that all cells are uniformly distributed; if not, repeat this step.

No.1	\bar{X} : X1	07-12-10 17: 54
QC Lot No.		WBC
WBC --- HGB ---		
LYM# --- LYM% ---		
MON# --- MON% ---		RBC
GRA# --- GRA% ---		
RBC --- HCT ---		
MCV --- RDW-SD ---		
MCH --- RDW-CV ---		
PLT --- MCHC ---		PLT
MPV --- PDW ---		
PCT --- P-LCR ---		
Counting...	<input type="text"/>	

Figure 4-15

5. Place the well-mixed Control to the probe so that the tip is well into the tube, and press the [START] to count QC. The process of QC count is the same as that of count.
6. After counting X1 and the screen displays counting screen for X2.

No.1	\bar{X} : X2	07-12-10 17: 54
QC Lot No.		WBC
WBC --- HGB ---		
LYM# --- LYM% ---		
MON# --- MON% ---		RBC
GRA# --- GRA% ---		
RBC --- HCT ---		
MCV --- RDW-SD ---		
MCH --- RDW-CV ---		
PLT --- MCHC ---		PLT
MPV --- PDW ---		
PCT --- P-LCR ---		
Save	Return	Print

Figure 4-16

7. press [START] to count again. After counting, press [Save] to store the data.

Each QC file can store up to 30 QC data. When the “Total” is 30, the earliest data will be over written.

Press [PRINT] key to output the QC data displayed in the screen.

QC Graph

The instrument stores the results after counting controls. Each file will store the data of up to 30 QC counts. The operator can use QC graph tool to graphically review the control data.

The graph provides a visual observation of the control data, allowing the operator to observe the

possible deviations, trends or shifts of the instrument performance. If the shifts of the instrument are over the limits, it is necessary to calibrate the instrument.

In menu operation, follow “QC/ \bar{X} /QC graph/File 1” to access the QC graph screen.

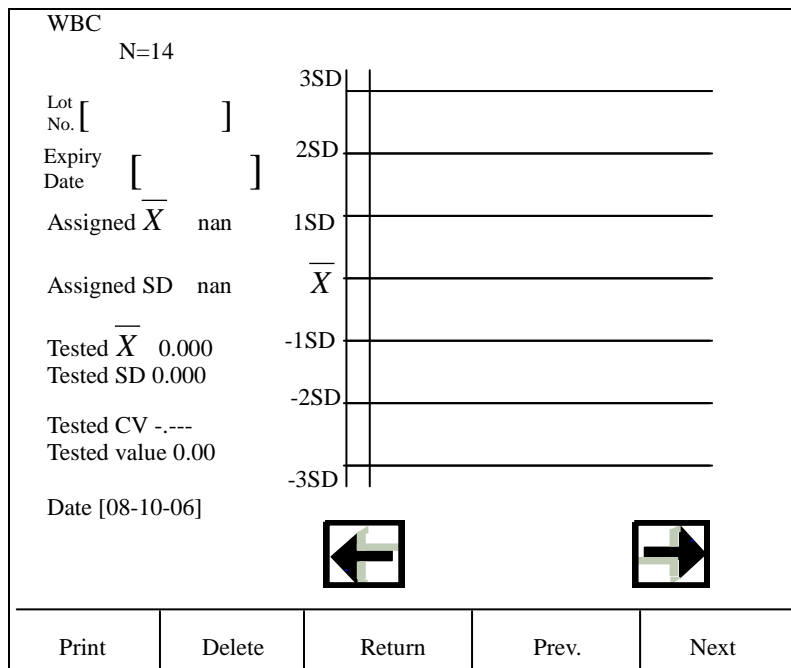


Figure 4-17

The X-axis of the graph represents “average value” and the Y-axis represents “standard deviation”

Three parameters at the right side of QC graph:

\bar{X} : average value

SD standard deviation

CV : coefficient of variation

Formulas are: n refers to the maximum value of running times.

Xi refers to the result value of No. i running of the specified parameter.

$$\bar{X} = \frac{\sum_{i=1}^n Xi}{n}$$

$$SD = \sqrt{\frac{\sum (Xi - \bar{X})^2}{n - 1}}$$

$$CV\% = \frac{SD}{\bar{X}} * 100$$

Press [Delete] key, Delete QC data.

4.3 X-B

Proposed by Dr. Brian Bull, X-B analysis examines the instrument performance through monitoring the stability of the parameters such as MCV, MCH, and MCHC. This is a method without using commercial control. However, X-B method differs from Commercial Control. These two methods cannot replace each other because they reflect the performance of the instrument from different angles.

X-B represents the moving average of hematology values, it requires large quantity of samples, at least 100. The target value and the higher and lower limits together form into a range. Based on this range, the operator can observe the changing trend of X-B values.

System calculates 3 parameters of a batch of samples for X-B analysis, which are MCV, MCH and MCHC. The number of samples for X-B analysis in each batch can be set up within the range from 20 to 200. The default is 20.

Edit Limits

When there are no X-B data, the user may edit the target and limit. follow "QC/X-B" screen and press QC edit.

X-B QC setup		
	Target	SD
MCV	0.0	8.349
MCH	0.0	0.000
MCHC	nan	nan
Samples batch	20/group	
X-B graph		
X-B ---On		
Delete		
		<input type="button" value="Return"/>

Figure 4-18

The target of the parameter is the average of the sample data resulted from the local testing that has undergone statistical analysis and calculation. There should be enough samples. The recommended quantity is 100. The samples must be randomly selected. For different areas, the targets are different. The recommended limit to be used is 5%-10%.

Target/SD should be entered by pressing the numbers.

The range of Sample Batch is from 20 – 200. Press [30/group] and enter the value.

In this menu, press [on/off].to change the statue.

On: start X-B analysis

Off: stop X-B analysis

■ X-B Graph

The operator can review the X-B analysis data in the way of graphs through the application of X-B graph.

In menu operation, follow “QC/X-B /X-B Graph” access X-B Graph screen.

MCV	8.3	-----
96.1	0.0	-----
	-8.3	-----
MCH	0.0	-----
27.2	0.0	-----
	0.0	-----
MCHC	nan	-----
271	nan	-----
	nan	-----
Time [2008-10-06 5: 35] 1/1 P1		
Prev.	Next	
		PgDn
		Return

Figure 4-19

X-B graph can save the X-B data of up to 300 points. Each page displays the X-B data of 60points.

Press [PgDn] to move by 60 points.

The broken line above the QC graph:

assigned value + tested value

The broken line below the QC graph:

assigned value - tested value

The three parameters at the left side of QC graph:

100: assigned value + tested value

90: assigned value

80: assigned value + tested value

Section 5 Calibration

5.1 General

BCC-3000B auto hematology analyzer is calibrated at the factory for cell size, electronic counting and sample volume accuracy. You may need to perform calibration procedures when you replace any instrument component that involves the primary measurement characteristics, or when the shift occurs during running controls

■ Purpose

Calibration of the instrument is to provide the assurance that the instrument is providing results with accuracy as design. It is to ensure accurate results that conduct calibration procedures as described in this section.

■ The Quality of Instrument Calibration

The quality of instrument calibration depends on the quality of the applied calibrators and reagents. Dirui's calibrators and reagents are recommended. Calibrators should be stored, handled and mixed properly, while reagents and calibrators must be within the expiration date. Before calibration, the calibrators must reach the room temperature and be well mixed.



Note

Results can only be considered valid after all parameters are calibrated

5.2 Pre-Calibration Procedures

Calibrator should be applied for the calibration of BCC-3000B. The user may contact the Dirui distributor for information concerning the suitability and acceptability of any commercial calibrator. All calibration factors are calculated and stored automatically by analyzer. The instrument accepts either whole blood or prediluted mode, to either of which, therefore, it supplies different calibration factors.

The Pre-Calibration procedures in this subsection help ensure proper instrument performance. If problems are detected during these checks, do not perform calibration.

Check the instrument and reagents. Ensure that the instrument functions normally, the reagents are adequate and all the required materials are available.

The instrument provides three ways of calibrations for whole blood.

Calibration
<ol style="list-style-type: none"> 1. Manual calibration 2. Auto calibration 3. Fresh blood calibration
Return

Figure 5-1

5.3 Manual Calibration



WARNING
Potential biohazard

1. In menu operation, follow "Calibration/Manual Calibration" to access Manual Calibration screen.

Manual calibration			
	Factor		Factor
RBC	1.000	PLT	1.000
MCV	1.000	MPV	1.000
WBC	1.000	HGB	1.000
<input type="button" value="Enter"/>		<input type="button" value="Return"/>	

Figure 5-2

The instrument allows the user to input the factors manually with the range between 75% and 125%.

For the information to calculate CV.

Calculate the new calibration factors.

Use parameters to calculate the new calibration factors.

$$\text{new factor} = \frac{\text{old factor} \times \text{reference value}}{\text{average of test value}}$$

Example: Reference value of WBC = 8.4

2. In whole blood mode, three running values of WBC are 8.1, 8.0, 8.1, 8.1 and 8.3. The mean value of WBC is 8.12. Old calibration factor in the whole blood mode is 98.9%.

Then new factor=102.3%

Enter the new calibration factors.

Manual calibration			
	Factor		Factor
RBC	1.000	PLT	1.000
MCV	1.000	MPV	1.000
WBC	1.000	HGB	1.000
<input type="button" value="Enter"/>		<input type="button" value="Return"/>	

Figure 5-3

In Manual Calibration screen, press parameter items to access the Edit Parameter state and then edit the factors by Pressing [0] – [9] to enter numbers. Press [ENTER] to back to the Manual Calibration and edit the other parameter's factor.

Press [ENTER] to confirm this new factors.

1.000		
9	8	7
6	5	4
3	2	1
0	—/.	←
Enter		Cancel

Figure 5-4

The factor should be within the range of 75%—125%.

5.4 Automatic Calibration



Note

Dirui recommends commercial calibrator specifically designed for the use of BCC-3000B instrument. To unreliable results caused by using other calibrator, Dirui takes no responsibility.

In menu operation, follow “Calibration/Auto Calibration” to access Auto Calibration screen.

Mode: WB	2007-12-10 16: 10	Cali. liquid
No. 1		
Target	1	2 3 4 5 Factor
WBC	6.9	
RBC	3.82	
HGB	100	
MCV	103.2	
PLT	230	
MPV	11.8	
Enter		Return

Figure 5-5

■ **Run Calibrator Procedure**



WARNING
Potential biohazard



WARNING
Avoid contacting with the sample probe.

Always mix and handle commercial calibrator according to the directions given in the package insert. Pay particular attention to the following:

- Be sure the vials are at the proper temperature and are not leaking.
- Store the calibrator at recommended temperatures inside the refrigerator.
- Carefully warm and resuspend the product according to the directions given in the package insert. Proper mixing is essential for accurate results.
- Check the shelf life and open-vial stability dating. Do not use products longer than recommended by the manufacturer.
- After warming at room temperature, mix calibrator gently according to instructions in the package insert. Inspect the vial contents to ensure that all cells are uniformly distributed; if not, repeat this step.
- Place the well-mixed calibrator to the probe so that the tip is well into the tube, and press the [START] to run. The process of run is the same as that of count.
- After running, the screen displays as shown in figure 5-6.

Mode: WB		2007-12-10 16: 10				Cali. liquid	
No. 1							
	Target	1	2	3	4	5	Factor
WBC	6.9						
RBC	3.82						
HGB	100						
MCV	103.2						
PLT	230						
MPV	11.8						
Counting...		[Progress Bar]					

Figure 5-6

Figure 5-9 shows an example of the results after five times of running.

Mode: WB	2007-12-10 16: 10					Cali. liquid	
No. 1	Target	1	2	3	4	5	Factor
WBC	6.3	6.5	6.5	6.5	6.7	6.5	96.3
RBC	4.02	4.07	3.96	4.00	4.02	4.04	100.5
HGB	115	118	119	119	118	119	97.2
MCV	81.3	81.9	82.8	82.2	81.9	82.1	98.4
PLT	200	218	208	216	210	216	94.6
MPV	10.4	10.4	10.5	10.8	10.6	10.5	95.6
Enter						Return	

Figure 5-7

The average value of calibration and the new calibration factors automatically calculated by the system are displayed in the right side of the screen.

“***” refers to invalid results, which means that the average value of the parameter and the calibration factor are invalid.

Maximum 5 samples can be counted for auto calibration. The auto calibration result will be displayed only after 3 samples are counted. If the calibration factor of a parameter is out the range of 75% ~ 125%, it will not be displayed, find the reason. If necessary, contact the Dirui Customer Service Department or the distributor.

Press [Enter] to Confirm the New Calibration Factors as shown in figure 5-8:

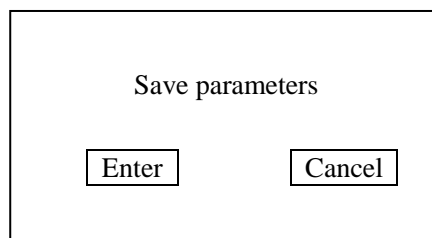


Figure 5-8

5.5 Fresh blood calibration



WARNING
Potential biohazard



WARNING
Avoid contacting with the sample probe.

In menu operation, follow "Calibration/Fresh blood Calibration" to access fresh blood Calibration screen.

Mode: WB	07-12-10 16: 10	Fresh blood					
No.	1						
	Target	1	2	3	4	5	Factor
WBC	0.0						
RBC	0.00						
HGB	0						
MCV	0.0						
PLT	0						
MPV	0.0						
Enter	Count						Return

Figure 5-9

■ Run Calibrator Procedure

Place the well-mixed fresh blood sample to the probe so that the tip is well into the tube, and press the [START] to run. The process of run is the same as that of count.

Mode: WB	2007-12-10 16: 10	Fresh blood					
No. 1							
	Target	1	2	3	4	5	Factor
WBC							
RBC							
HGB							
MCV							
PLT							
MPV							
Counting...	<input type="text"/>						

Figure 5-10

Shows an example of the results after five times of running.

Mode: WB	07-10-12 16: 10	Fresh blood					
No. 1							
	Target	1	2	3	4	5	Factor
WBC	6.3	6.5	6.5	6.5	6.7	6.5	96.3
RBC	4.02	4.07	3.96	4.00	4.02	4.04	100.5
HGB	115	118	119	119	118	119	97.2
MCV	81.3	81.9	82.8	82.2	81.9	82.1	98.4
PLT	200	218	208	216	210	216	94.6
MPV	10.4	10.4	10.5	10.8	10.6	10.5	95.6
Enter	Count						Return

Figure 5-11

The average value of calibration and the new calibration factors automatically calculated by the system are displayed in the right side of the screen.

“***” refers to invalid results, which means that the average value of the parameter and the calibration factor are invalid.

If the calibration factor of a parameter is out the range of 75% ~ 125%, it will not be displayed, find the reason. If necessary, contact the Dirui Customer Service Department or the distributor. Press [Enter] to start the next sample. And repeat all the above operations.5 samples at least are necessary.

Press [count] to calculate the average.

Mode: WB		2007-12-10 16: 10				Fresh blood	
Calculate							
Item	1	2	3	4	5	Average value	
WBC	96.3	98.5	97.8	99.4			
RBC	98.6	97.4	98.2	97.8		98.0	
HGB	97.2	97.7	98.2	98.5		98.0	
MCV	98.4	98.2	97.9	98.7		98.3	
PLT	94.6	89.6	95.2	90.4		92.5	
Enter						Return	

Figure 5-12

“***” refers to invalid results, which means that the average value of the parameter and the calibration factor are invalid.

If the calibration factor of a parameter is out the range of 75% ~ 125%, it will not be displayed, find the reason. If necessary, contact the Dirui Customer Service Department or the distributor.

Press [Enter] to Confirm the New Calibration Factors as shown in figure 5-13:

Save parameters	
Enter	Cancel

Figure 5-13

Section 6 Sample Review

The instrument can save the parameters and histograms of up to 1000 samples. The system can automatically store the results after each sample analysis. The operator can review parameters and histograms of all samples, output the stored data with the built-in recorder or the external printer, and delete the data and modify the histogram also. The search result can be reviewed in table or single sample with histogram.

Two ways are available to review the sample data: Sample Table Review and Sample Histogram Review.

6.1 Sample Table Review

■ Sample Table Review

In Menu operation, follow “Sample review / Sample table review” to access Sample Table Review screen.

In the screen, press [↑][↓] to scroll the sample data.

Sample table review					
No.	RBC	HCT	PLT	WBC	HGB
5	2007-10-06	17: 14			
	4.02	0.275	256	6.7	121
4	2007-10-06	17: 10			
	4.25	0.270	210	6.5	115
3	2007-10-06	17: 05			
	3.65	0.325	285	7.25	106
2	2007-10-06	17: 01			
	3.65	0.325	285	7.25	106
1	2007-10-06	16: 54			
	3.98	0.271	258	5.46	115
Transmit		Print	Delete	Return	

Figure 6-1

● Description of the Screen

5 sample parameters are displayed in each review screen in the order of time sequence.

Following operations are available in Table Review screen: Transmit, Delete, Print

Press [No.] key to select the data of the item and then the number would be marked by “■”.

After select the sample, User could press any operations from the options: Transmit, Delete, Print
If press the number again until “■” disappears, it would deselect the sample.

The default status is that all the parameters are in non-selected status (only the parameters in selected status can be used for search operation).

6.2 Sample Histogram Review

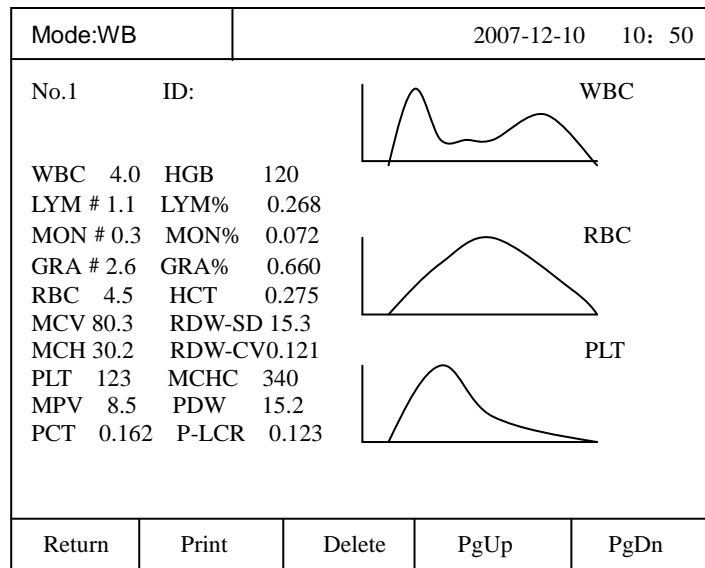


Figure 6-2

In menu operation, follow “Review / Sample Histogram Review” to access Sample Histogram Review screen.

Press [PgUp] [PgDn] to scroll by 1.

Press [PRINT] to print out the information displayed on the current screen.

Following operations are valid in Sample histogram Review screen: Print. Delete

■ Delete all reviews

In menu operation, follow Review / delete all reviews” to delete all reviews. Press [Enter] to confirm this delete.

Section 7 Setup

Dirui sales and service staff or persons authorized by Dirui are in charge of the installation and debugging of BCC-3000B system. For customers' convenience, most of the system parameters can be setup by the operator so as to meet various requirements of different laboratories.

In menu operation, press "Setup" to access the setup screen.

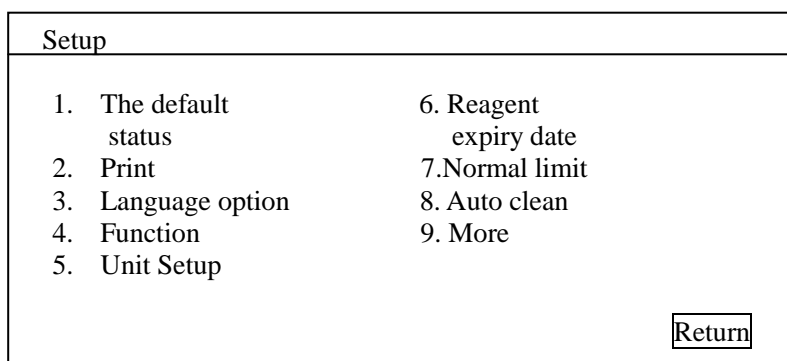


Figure 7-1

7.1 The default status

in menu operation, follow "Setup/The default status" to restore all the statuses before sales.

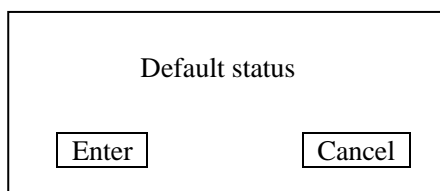


Figure 7-2

Press [Enter] to validate this operation.

7.2 Print

In menu operation, move the cursor to "Setup/Printer", then press [ENTER] to access Print screen.

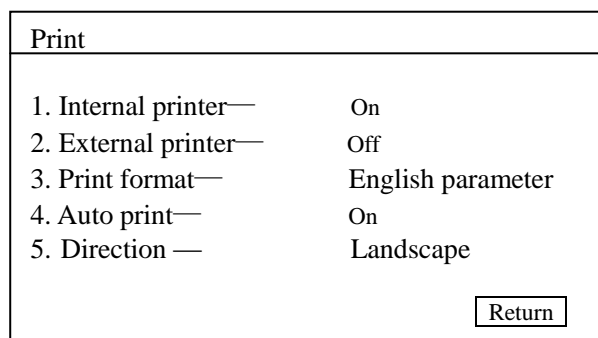


Figure 7-3

Internal Printer: ON, OFF

ON: Internal Printer will print out the results.

OFF: Internal Printer will not print out the results.

External Printer: ON, OFF

ON: the external printer will output the results.

OFF: the external printer will not output the results.

Output formats of Printer:

English parameter

Auto Print: ON, OFF

ON: After counting, the printer or recorder will automatically output the results.

OFF: After counting, the printer or recorder will not automatically output the results.

Direction: Portrait, Landscape

Portrait: the test result is printed in Portrait format.

Landscape: the test result is printed in Landscape format.

7.3 Language option

There is one language option: English

7.4 Function

In menu operation, follow "Setup/Function" to access function screen

Function	
1. Abnormal mark—	Off
2. ID—	On
3. Auto transmission—	On
4. Output histogram—	On
5. Probe high position	
6. Probe low position	
<div style="border: 1px solid black; display: inline-block; padding: 2px 10px;">Return</div>	

Figure 7-4

Abnormal mark: On, Off

On: for counting results, [↑][↓] would mark the abnormal result

Off: for counting results, [↑][↓] would not mark the abnormal result

ID: On, Off

On: the instrument can connect to bar code scanner

Off: the instrument can not connect to bar code scanner

Auto Transmission: On, Off

On: In Count screen, BCC-3000B automatically transmits the sample data to the external computer after count process.

Off: In Count screen, BCC-3000B does not automatically transmit the sample data to the external computer after count process.

Baud Rate: "9600", "4800", "2400", "1200"

Parity Bit: Odd, Even, No Odd: odd check. Even: even check. No: no check

Output histogram: On, Off

ON: After counting, the printer or recorder will automatically output the histogram.

OFF: After counting, the printer or recorder will not automatically output the histogram.

Probe high/low position function :

When abnormal occurred at sampling unit, the relevant position of probe and probe wipe block changed or probe wipe block need to be changed ,sample probe localizer should be used to fix the relative position of probe and probe wipe block with sample probe localizer (shows as figure 7-5). Specific operation procedure is show as follows:



Figure 7-5 sample probe localizer

1. Push the switch and open the right side door of the instrument, show as figure 7-6:

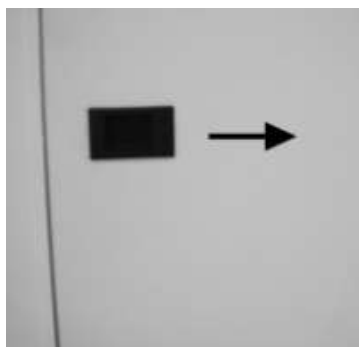


Figure 7-6

- Lift up the switch and open the front panel, show as figure 7-7:



Figure 7-7

- Press "5. Probe high position" in figure 7-4, the probe may automatically move to the highest point as figure 7-8 shows:

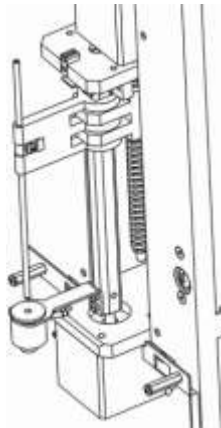


Figure 7-8

- Use screwdrivers to loosen the fixing screw of the sample probe. Show as figure 7-9:

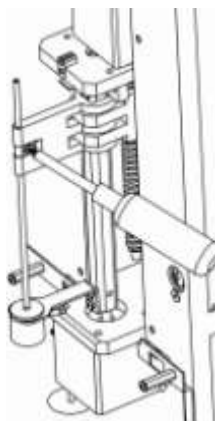


Figure 7-9

- Take the sample probe out from the probe wipe block and insert the localizer into the probe wipe block from the bottom. Show as figure 7-10:

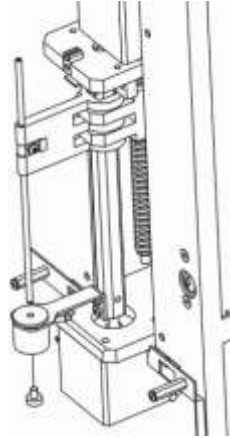


Figure 7-10

6. Insert the sample probe into the probe wipe block until it touches the localizer. Show as figure 7-11:

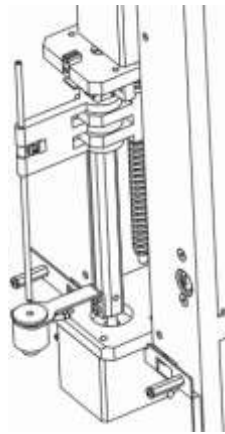


Figure 7-11

7. Tightly turn the fixing screw of the sample probe, Keep the localizer. After press “6 Probe low position” in figure 7-4, adjusting the position of the sample probe is finished.

7.5 Unit Setup

Press “5 Unit Setup” key in Figure 7-1, enter Unit Setup option, shows as Figure 7-13:

Unit Setup	
WBC - $10^9/L$	GRA% - %
LYM# - $10^9/L$	HGB - g/L
MON# - $10^9/L$	MCHC - g/L
GRA# - $10^9/L$	HCT - %
RBC - $10^{12}/L$	MCV - fL
PLT - $10^9/L$	MPV - fL
PCT - %	RDW-CV - %
MCH - pg	RDW-SD - fL
LYM% - %	
MON% - %	

Figure 7-13

Press parameter unit option to change the unit. The unit option is show as Table 7-1:

Parameter	Unit	Value format
WBC LYM# MON# GRA#	$10^9/L$	***.*
	$10^3/\mu L$	***.*
	$10^2/\mu L$	****
	/nL	***.*
RBC	$10^{12}/L$	*.**
	$10^6/\mu L$	*.**
	$10^4/\mu L$	***
	/pL	*.**
PLT	$10^9/L$	****
	$10^4/\mu L$	****
	$10^3/\mu L$	***.*
	/nL	****
PCT	%	*.***
	mL/L	*.***
MCH	pg	***.*
LYM% MON% GRA%	%	**.*
	ratio	*.***
HGB	g/L	***
	g/dL	**.*
MCHC	g/L	****
	g/dL	***.*
HCT	%	**.*
	L/L	***
MCV	fL	***.*
	μm^3	***.*
MPV	fL	**.*
	μm^3	**.*
PDW	--	**.*
PDW-CV	%	**.*
PDW-SD	fL	***.*

User could select parameter unit accordingly.

7.6 Reagent expiry date

In menu operation, follow “Setup/Reagent expiry date” access the Reagent Exp. Date screen.

Reagent expiry date	
Item	year/month/day
Diluent	17-01-01
Cleanser	17-01-01
Lyse	17-01-01
Enter	Return

Figure 7-14

- Enter the expiration date of Diluent, Rinse, Lyse. When the system date arrives at the Expiration Date, it will alarm and prompt to replace corresponding reagents.
- The open-vial life is as follows: Diluent: 60 days. Lyse: 60 days. E-Z Cleanser: 60 days. Probe Cleanser: 30 days.
- The input is the earlier day between the date that opening the reagent pack adds the open-vial life and the expiration date.

For examples:

Operation: Press [Diluent] to select items and Press [0] – [9] to enter numbers.

7.7 Normal limit

In laboratories, patient limits are set up based on the normal groups. If the results are outside the limits, it will be considered as clinical abnormality. The operator may setup the higher and lower limits of 20 parameters. Once the results are outside the limits, there will be a mark like ↑ or ↓ after the results either displayed in the screen or output through printer or recorder, indicating that the results are outside the limits.

↑: indicates that the results are above the higher limit.

↓: indicates that the results are below the lower limit.

In menu operation, follow “Setup/Normal limits” access Normal limits screen.

Normal limit
1. Whole blood 2. Prediluted blood
Return

Figure 7-15

To select the sample mode and enter , for example, access whole blood.

Whole blood					
	Low	High		Low	High
WBC	4.00	10.00	HGB	110.00	179.00
MON#	0.10	0.90	MON%	3.00	16.00
RBC	3.50	5.50	HCT	20.00	70.00
MCH	23.20	38.70	RDW-CV	10.00	17.00
MPV	4.00	15.20	PDW	6.00	23.00

Enter		PgDn		Return
-------	--	------	--	--------

Figure 7-16

And press [number] and change the the limit.

7.8 Auto Clean Time

In menu operation, follow the “Setup/Auto Clean” to access the Auto Clean Time screen. The default auto clean time should be between 20 and 200 sample-tests. When the system is in the idle status, it automatically executes clean operation according to the auto clean time.

Auto clean		
Test - 30 - auto clean		
Enter		Return

Figure 7-17

7.9 More

This option is for manufacturer. And please contact Dirui for the details.

Password: _		
9	8	7
6	5	4
3	2	1
0	-/.	←
Enter	Cancel	

Figure 7-18

Section 8 Maintenance

The BCC-3000B has been designed to provide several years of reliable service. However, like other precision laboratory instruments, accurate results and reliability depend on careful handling, cleaning and periodic preventive maintenance.

Spills and leaks are sources of contamination affecting not only the operation but also the analytical results of the instrument. They should be cleaned immediately and not allowed to dry in air. Leaks should be repaired by the operator or by a service technician.

This section gives descriptions about the maintenance information of the system tubing and the methods of testing other parts of the system.

8.1 Maintenance

In menu operation, follow the “System maintenance” item to access the Maintenance screen.

System maintenance	
1 . Diluent prime	6. Probe cleanser
2 . Cleanser prime	7. Clean baths
3 . Lyse prime	8. Wipe block cleaning
4 . Zap apertures	9. Empty tubing
5. Flush apertures	10. Empty baths
Return	

Figure 8-1

The tubing part of the instrument should be maintained to ensure its smooth and reliable performance. Following 12 procedures are to be carried out:

- Diluent Prime
- Rinse Prime
- Lyse Prime
- Flush Apertures
- Zap Apertures
- Probe Cleanser Cleaning
- Clean Baths
- Empty Baths
- Empty Tubing
- Wipe block cleaning
- Diluent Prime

When “Check Diluent” alarm occurs, the user needs to replace the diluent. After that, executes “Diluent Prime” to prime the diluent into the tubing.

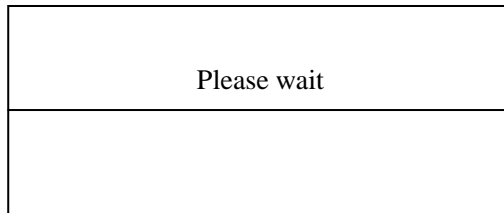


Figure 8-2

■ Cleanser Prime

When “Check cleanser” alarm occurs, the user needs to replace the cleanser. After that, executes “Cleanser Prime” to prime the cleanser into the tubing.

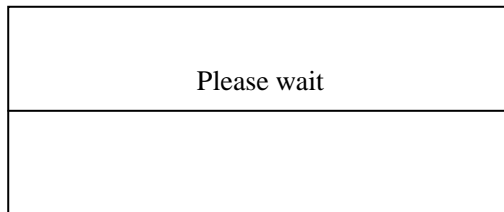
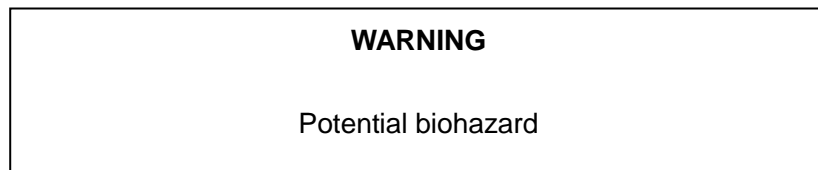


Figure 8-3

■ Lyse Prime



When “Check lyse” alarm occurs, the user needs to replace the cleanser. After that, executes “lyse Prime” to prime the lyse into the tubing.

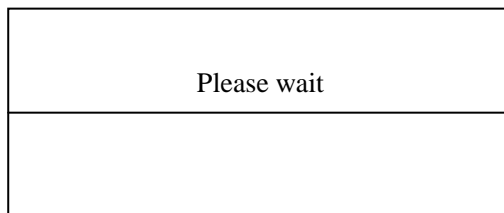


Figure 8-4

■ Zap Apertures

In menu operation, follow the “System maintenance/Zap Aperture” item to access this screen. And go back to “System maintenance” after “ please wait...” screen.

■ Flush Apertures

In menu operation, follow the “System maintenance/Flush Aperture” item to access this screen. And go back to “System maintenance” after “ please wait...” screen.

■ Probe Cleanser Cleaning



WARNING
Potential biohazard



WARNING
Avoid contacting with the sample probe.

In this operation, the system cleans the tubing and the baths.

If the user turns off instrument every day normally, the "Probe cleanser" should be executed once every week.

If the instrument works day and night, the "Probe cleanser" should be executed every three days.

Operation

In menu operation, follow the "System maintenance/ Probe cleanser" item to access this screen.

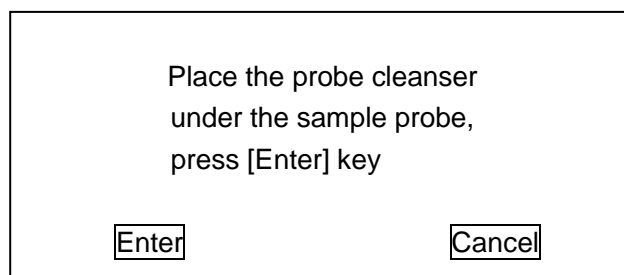


Figure 8-5

Present the bottle to the sample probe so that the tip is well into the probe cleanser, and press [ENTER] key to aspirate the probe cleanser. Remove hand after the sample probe rises up.

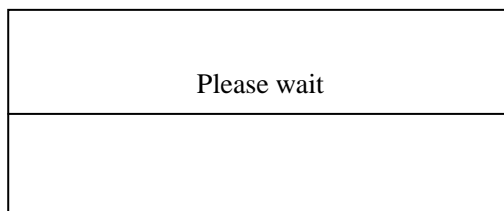


Figure 8-6

The procedure to clean the tubing and baths. The cleaning procedure takes approximately 5 minute to be completed as suggested. If you want to cancel the cleaning procedure before the 5 minute cleaning period ends, press [ENTER] key.

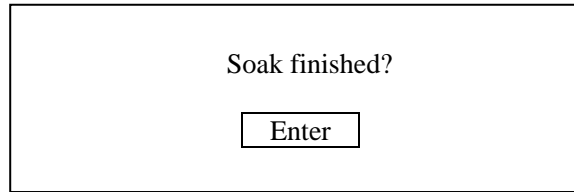


Figure 8-7

■ **Clean Baths**

When baths are polluted, execute this operation to clean WBC and RBC baths.

In menu operation, follow the "System maintenance/ Clean Baths " item to access this screen.

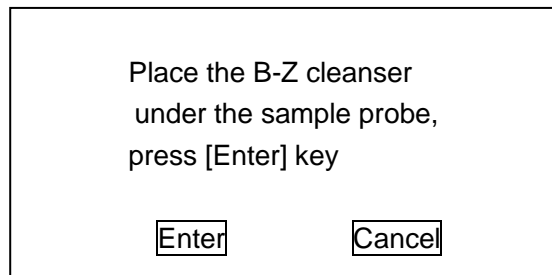


Figure 8-8

Present the bottle to the sample probe so that the tip is well into the probe cleanser, and press [ENTER] key to aspirate the probe cleanser. Remove hand after the sample probe rises up.

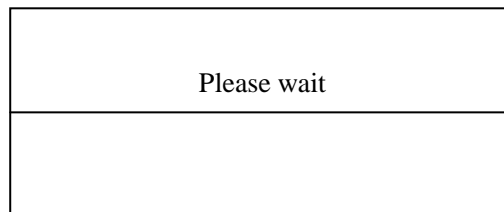


Figure 8-9

The procedure to clean baths. The cleaning procedure takes approximately 5 minute to be completed as suggested. If you want to cancel the cleaning procedure before the 5 minute cleaning period ends, press [ENTER] key.

Wipe Block Cleaning

Execute this program when the wipe block is polluted. The cleaning procedure takes about 5 minute as suggested.

Operation:

1. In menu operation, follow the "System maintenance/ Wipe Block Cleaning " item to access this screen. To avoid the liquid dropping out. The distance between the operator and the instrument should be kept not less than 30cm. After the cleaning, the screen goes back to "System maintenance".

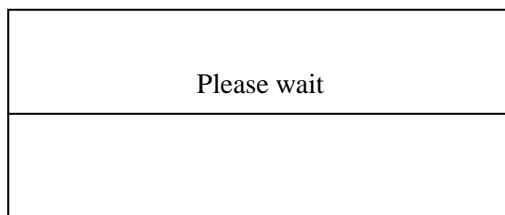


Figure 8-10

Procedure 2-4 is suggested

2. push the switch and open the right side door.



Figure 8-11

3. Lift up the switch and open the front panel.

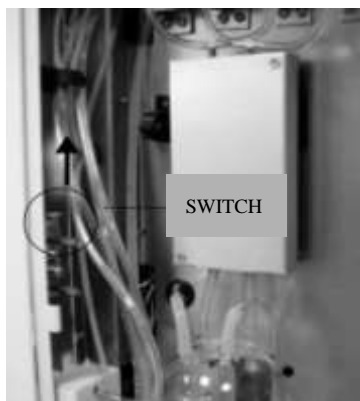


Figure 8-12

4. Open the front cover. Clean the bottom of the wipe block by lint-free tissue with probe cleanser.

■ Empty Tubing

Execute the program to empty the liquid in the tubing and baths.

Operation:

In menu operation, follow the “System maintenance/ Empty Tubing” item to access this screen. Remove the tubing from vessels of Diluent, cleanser and Lyse. After the operation, the screen goes back to “System maintenance”.

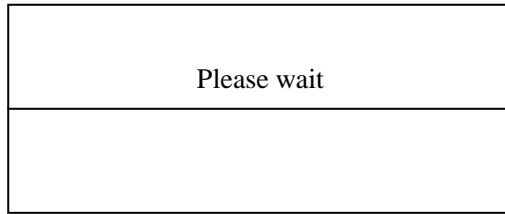


Figure 8-13

Empty Baths.

Empty the diluent of WBC and RBC baths.

Operation:

In menu operation, follow the “System maintenance/ Empty Baths” item to access this screen. After the operation, the screen goes back to “System maintenance”.

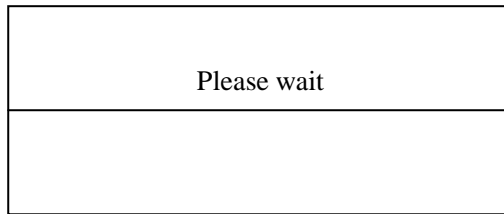


Figure 8-14

Section 9 System monitoring

9.1 System status

In menu operation, follow “System monitoring/System Status” to access the System Status screen.

System monitoring		
Item	Test value	Range
Envir. Temp.	21	15-30
HGBzero voltage	0.00	0-0.2
HGBbackground voltage	1.60	1.4-2.5
DC +12V	12.00	11.04-12.96
DC -12V	-11.8	-11.04--12.96
106V(V)	106.8	100-112
56V(V)	56.45	53.00-59.00
Vacuum Hp	206	100-200
Pressure Hp	66	40-70
Test		Return

Figure 9-1

There are 9 test items. If any of them is beyond the reference range, the user should remove the failure by referring to Section 10 troubleshooting.

9.2Valve Test

In menu operation, follow “System monitoring/ Valve Test” to access the Valve Test screen.

Valve test				
valve	valve	valve	valve	valve
V1 OFF	V5 OFF	V9 OFF	V13 OFF	V17 OFF
V2 OFF	V6 OFF	V10 OFF	V14 OFF	V18 OFF
V3 OFF	V7 OFF	V11 OFF	V15 OFF	
V4 OFF	V8 OFF	V12 OFF	V16 OFF	
Enter				Return

Figure 9-2

In the Valve Test screen, the user can test if the valves function normally.

9.3 Error Message

In menu operation, follow “System monitoring/ Error Message” to access the Error Message screen.

Error message			
No.	Error message	Time	
1	180	2008-03-24	10: 27
2	184	2008-10-06	15: 19
3	1000	2008-10-06	14: 56
4	1000	2008-10-06	14: 49
5	115	2008-10-06	14: 42
6	115	2008-10-06	20: 46
7	115	2008-10-06	20: 50
8	115	2008-10-06	15: 20
9	115	2008-10-06	15: 10
10	115	2008-10-06	15: 10
Enter			Return

Figure 9-3

9.4 Printer test

In menu operation, follow “System monitoring/ Printer test” to access the printer test screen.

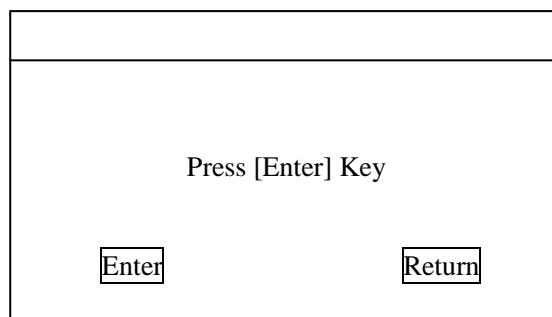


Figure 9-4

9.5 System Test

In menu operation, follow “System monitoring/ System Test” to access the System Test screen.

System Test					
No.	Item	Result	No.	Item	Result
1	WBC A/D Status		11	2.5ml and 50ul motor	
2	RBC A/D Status		12	10ml motor	
3	PLT A/D Status		13	Rotatory motor	
4	WBC A/D Interrupt		14	Fluctuating motor	
5	RBC A/D Interrupt		15	Print	
6	PLT A/D Interrupt		16	Vacuum	
7	WBC Time		17	Pressure 1	
8	RBC Time		18	Pressure 2	
9	WBC Aperture		19	Vacuum Filter	
10	RBC Aperture				
Enter		↑		↓	Return

Figure 9-5

OK: PLT A/D chip functions normally.

ERROR: PLT A/D chip functions abnormally.

WBC A/D Interrupt:

OK: WBC A/D interrupt is normal.

ERROR: WBC A/D interrupt is abnormal.

RBC A/D Interrupt:

OK: RBC A/D interrupt is normal.

ERROR: RBC A/D interrupt is abnormal.

PLT A/D Interrupt:

OK: PLT A/D interrupt is normal.

ERROR: PLT A/D interrupt is abnormal.

WBC Time and RBC Time: Measure the time required for both WBC and RBC count. The unit is "Second".

WBC Aperture and RBC Aperture: Measure the voltages of WBC and RBC apertures. The unit is "V".

Motor: Test if the 2.5ml & 50ul motor functions normally.

10ml Motor: Test if the 10ml motor functions normally.

Rotatory Motor: Test if the rotatory motor functions normally.

Fluctuating Motor: Test if the fluctuating motor functions normally.

Print: Test if the printer or the recorder (according to the current setup) functions normally.

Vacuum: Test if the vacuum system is in normal status.

Pressure 1: Test if the pressure in vacuum chamber is normal.

Pressure 2: Test if the pressure in pressure chamber is normal.

Vacuum Filter: Test if the vacuum filter functions normally.

9.6 Adjusting Position of Sample Probe and Probe Wipe Block

The relative position between the sample probe and probe wipe block has influence on the count results. In the accessory box, there is a sample probe localizer. See figure 9-6



Figure 9-6

As required by regular maintenance, the user shall use the localizer to adjust the position of the sample probe monthly. When the user is replacing the probe wipe block or the count results have deviation, use localizer to adjust the position of the sample probe.

■ Adjusting Sample Probe Position



WARNING

Potential biohazard



WARNING

Avoid contacting with the sample probe.

Operation:

1. Push the switch and open the right side door of the instrument.

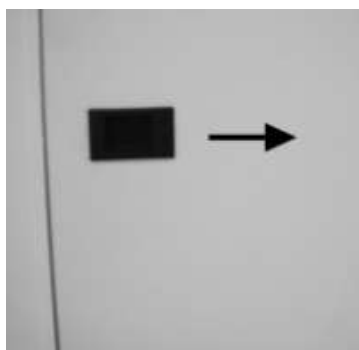


Figure 9-7

2. Lift up the switch and open the front panel.

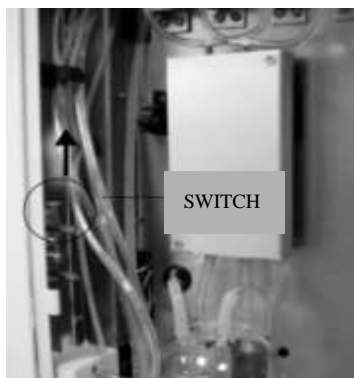


Figure 9-8

3. Figure 9-9 shows the instrument with the front panel opened.

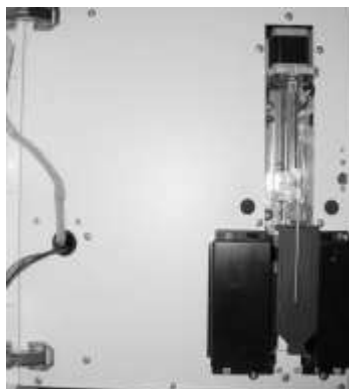


Figure 9-9

4. In menu operation, follow “System Monitoring /System Test” item to access the System Test screen. Press “Fluctuating Motor” , then move the sample probe to the upper position. See figure 9-10.

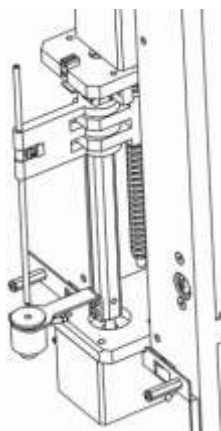


Figure 9-10

5. Use screwdrivers to loosen the fixing screw of the sample probe. See figure 9-11.

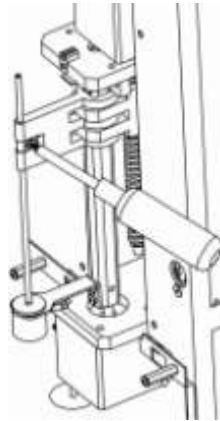


Figure 9-11

6. Take the sample probe out from the probe wipe block and insert the localizer into the probe wipe block from the bottom. See figure 9-12.

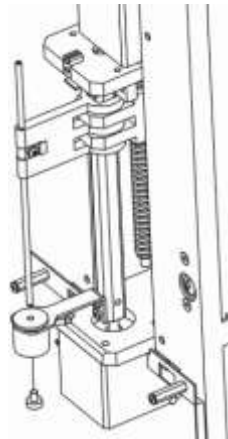


Figure 9-12

7. Insert the sample probe into the probe wipe block until it touches the localizer. See figure 9-13.

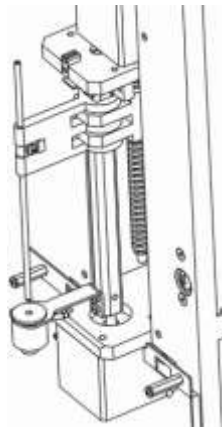


Figure 9-13

8. Tightly turn the fixing screw of the sample probe. Keep the localizer. Until now, adjusting the position of the sample probe is finished. Lift up the loosened sample probe and take out the probe wipe block. Remove the tubing connected to the probe wipe block. Pay attention to the corresponding relationship between the tubing and the tubing connector. Install the new probe wipe block. Connect the tubing with flag to the tubing connector at the bottom of the probe wipe block. Install the probe wipe block to the original position.

Execute the steps 6 through 8 of adjusting sample probe position to fasten the sample probe.

9.7 Replace Filter

■ Replace Vacuum Filter

If vacuum filter alarm occurs, replace the vacuum filter as follow procedure.

1. Push the switch and open the right side door of the instrument.



Figure 9-14

2. Replace the two vacuum filters.



Figure 9-15

3. Close the right side door of the instrument.
4. In menu operation, follow "Service monitoring/System Test" item to access the System Test screen. Press "Vacuum Filter".
5. If the result is ok, the instrument works normally. If the result is error, connect the Dirui Customer Service Department or the distributor.

Section 10 Trouble Shooting

10.1 General

This section contains information that is helpful in identifying and resolving instrument problems that may occur in the operation of analyzer. The suggestions presented below are not to be viewed as a complete service manual, but are limited to items that may be readily diagnosed and corrected by the user. If the problems cannot be corrected with the aid of this section, the user should contact the Dirui Customer Service Department or the distributor. Routine maintenance is in Section 8 and 9: Maintenance.

As for troubleshooting of any equipment, the more knowledge of the equipment the user has, the easier it is to identify and correct a given problem. Dirui strongly encourages the user(s) to read all sections of this manual to become as familiar as possible with the operations of the instrument. A major part of troubleshooting involves observing the instrument's operation and noticing the diagnostic messages. It is not expected that all or even most instrument problems can be corrected by the operator, however, when problems can be corrected without a service call, the instrument downtime can be greatly reduced.

In some cases the system is helpful in displaying messages and alarms when it detects one or more abnormal events. User should be trained to readily identify the significance of any message and know what corrective actions should be tried.

When errors appear, the operator can correct them with following actions:

- Find the errors in the following list according to the error information displayed in screen.
- Correct the problem with the suggestion.

10.2 System Failures and Trouble shooting Methods

■ 2.5ml & 50ul Motor Error

The single step motor drives both the 2.5ml and 50ul syringes. 2.5ml syringe is used for priming the lyse and 50ul syringe for aspirating sample and prime it into the WBC bath for the first dilution and also aspirating sample from the WBC bath and priming it into the RBC bath for the second dilution.

Error message : Error 17, Error 18, Error 19, Error 20, Error 21, Error 22, Error 23, Error 24, Error 25, Error 26, Error 27, Error 180, Error 181, Error 182, Error 183, Error 184, Error 185, Error 28, Error 177, Error 178

Press [ENTER] and The user accesses "System monitoring/System Test" screen to test 2.5ml & 50ul motor. If the failure is removed, the user can continue to use the system. If the failure keeps existing, the user should directly turn off the power and contact the Dirui Customer Service Department or the distributor.

■ 10ml Motor Error

The 10ml motor is used to drive the 10ml syringe for priming the diluent into the WBC and RBC baths during the testing process.

Error message : Error 32, Error 33, Error 34, Error 35, Error 36, Error 37, Error 38, Error 39, Error 40, Error 41, Error 48, Error 49, Error 50, Error 53, Error 54, Error 55, Error 64, Error 65, Error 66, Error 187, Error 188, Error 189, Error 61, Error 62, Error 180

Press [ENTER] and The user accesses "System monitoring/System Test" screen to test the 10ml motor. If the failure keeps existing, the user should directly turn off the power and contact the Dirui Customer Service Department or the distributor.

■ Rotatory Motor Error or related photocoupler

The rotatory motor is used for the rotation of the sample probe.

Error message : Error 112, Error115, Error 116, Error 180, Error 180, Error 186

Press [ENTER] and The user accesses "System monitoring/System Test" screen to test the rotatory motor.If the failure keeps existing, the user should directly turn off the power and contact the Dirui Customer Service Department or the distributor.

■ Fluctuating Motor Error or related photocoupler

The fluctuating motor is used for the elevation of the sample probe.

Error message : Error 113, Error114, Error 117, Error 118, Error 176

Press [ENTER] and The user accesses the "Service/System Test" screen to test the fluctuating motor. If the failure keeps existing, the user should directly turn off the power and contact the Dirui Customer Service Department or the distributor.

■Error 202

When 56V power error occurs, the system cannot perform count operation. The user should directly turn off the power and contact the Dirui Customer Service Department or the distributor.

■ 48V Power Error

When 48V power occurs, the system cannot perform count operation. The user should directly turn off the power and contact the Dirui Customer Service Department or the distributor.

■ A/D or Hydraulic pressure system

Error message : Error 3, Error4, Error 5, Error 200

Press [ENTER] and The user should access the "System Monitoring/System Test" screen to test the Vacuum. If the failure is removed, the user can continue to operate the system, otherwise perform the Shutdown operation and contact the Dirui Customer Service Department or the distributor.

Clog or Bubbles in the Hydraulic pressure system

Error message : Error 2, Error 201

Press [ENTER] and The user should access the "System Monitoring/System Test" screen to test the Vacuum. If the failure is removed, the user can continue to operate the system, otherwise perform the Shutdown operation and contact the Dirui Customer Service Department or the distributor.

Section 11 Transmission

The analyzer can transmit the sample data and QC data to the external computer through RS-232C serial port. The transmission can be conducted either automatically or through the command of the operator after the completion of sample analysis. This section gives detailed discussion about the setup of transmission parameter, RS-232C Serial Port and the Data Transmission Format, therefore, providing detailed information for the software engineers to program. Besides, the user can conveniently perform transmission.

11.1 Connection

BCC-3000B is connected with the external computer through RS-232, The pins of DB9 connector are shown in figure 11-1.

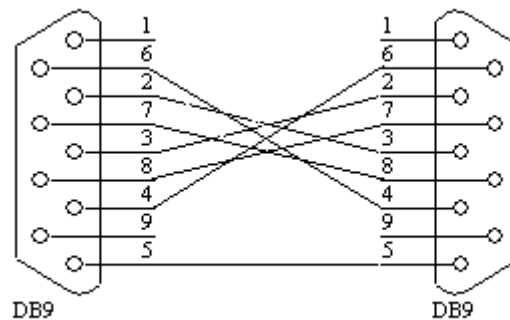


Figure 11-1

11.2 Transmission Parameters

Baud rate: 19200

Data bit: 8 bits

Stop bit: 1 bit

Verification: none

Handshake: none

Start symbol: 02h

2byte space: 20h

Newline Symbol: 0AH

Enter Symbol: 0DH

End Symbol: 03H

Communication format:

Name								Low limit value of normal range					High limit value of normal range					enter newline	
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
12	CR	LF																	
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	CR	LF
13																			

All numerical value are 16 ary, except the indicate No. of line 2, the sending unit is according the following parameter sequence:

- The 1 line: WBC
- The 2 line: LYM#
- The 3 line: MON#
- The 4 line: GRA#
- The 5 line: LYM%

The 6 line: MON%

The 7 line: GRA%

The 8 line: BC

The 9 line: HGB

The 10 line: HCT

The 11 line: MCV

The 12 line: MCH

The 13 line: MCHC

The 14 line: RDW-SD

The 15 line: RDW-CV

The 16 line: PLT

The 17 line: PCT

The 18 line: MPV

The 19 line: PDW

The 20 line: P-LCR

General test communication format:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
STX	CR	LF																			
x	x	x	x	x	x	x	x	x	x	CR	LF										
x	x	x	x	-	x	x	-	x	x	SP	x	x	:	x	x	CR	LF				
x	x	x	CR	LF																	
I	D	:	x	x	x	x	x	x	x	x	x	x	CR	LF							
W	B	C	-	c	h	a	r	t	:	x	x	x	x	x	,	x	x	x	x	x	,
x	x	x	x	x	,	x	x	x	x	x	,	x	x	x	x	x	,	CR	LF
R	B	C	-	c	h	a	r	t	:	x	x	x	x	x	,	x	x	x	x	x	,
x	x	x	x	x	,	x	x	x	x	x	,	x	x	x	x	x	,	CR	LF
P	L	T	-	c	h	a	r	t	:	x	x	x	x	x	,	x	x	x	x	x	,
x	x	x	x	x	,	x	x	x	x	x	,	x	x	x	x	x	,	CR	LF
R	B	C	:	x	x	.	x	x	CR	LF											
P	L	T	:	x	x	x	CR	LF													
H	C	T	:	x	.	x	x	x	CR	LF											
P	D	W	:	x	x	.	x	CR	LF												
R	D	W	-	S	D	:	x	x	x	.	x	CR	LF								
R	D	W	-	C	V	:	x	.	x	x	x	CR	LF								
P	C	T	:	x	x	.	x	x	CR	LF											
M	P	V	:	x	x	x	.	x	CR	LF											
M	C	V	:	x	x	x	.	x	CR	LF											
P	-	L	C	R	:	x	.	x	x	x	CR	LF									
W	B	C	:	x	x	.	x	CR	LF												
L	Y	M	#	:	x	x	x	.	x	CR	LF										
M	O	N	#	:	x	x	x	.	x	CR	LF										
G	R	A	#	:	x	x	x	.	x	CR	LF										
L	Y	M	%	:	x	.	x	x	x	CR	LF										
M	O	N	%	:	x	.	x	x	x	CR	LF										
G	R	A	%	:	x	.	x	x	x	CR	LF										
H	G	B	:	x	x	x	CR	LF													
M	C	H	C	:	x	x	x	x	CR	LF											
M	C	H	:	x	x	x	.	x	CR	LF											
ETX																					

Quality control test communication format:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	
STX	CR	LF																				
x	x	x	x	x	x	x	x	x	x	CR	LF											
x	x	x	x	-	x	x	-	x	x	SP	x	x	:	x	x	CR	LF					
x	CR	LF																				
x	x	x	x	x	x	x	x	x	CR	LF												
x	x	x	CR	LF																		
W	B	C	-	c	h	a	r	t	:	x	x	x	x	x	,	x	x	x	x	x	x	,
x	x	x	x	x	,	x	x	x	x	x	,	x	x	x	x	x	,	CR	LF	
R	B	C	-	c	h	a	r	t	:	x	x	x	x	x	,	x	x	x	x	x	x	,
x	x	x	x	x	,	x	x	x	x	x	,	x	x	x	x	x	,	CR	LF	
P	L	T	-	c	h	a	r	t	:	x	x	x	x	x	,	x	x	x	x	x	x	,
x	x	x	x	x	,	x	x	x	x	x	,	x	x	x	x	x	,	CR	LF	
R	B	C	:	x	x	.	x	x	CR	LF												
P	L	T	:	x	x	x	CR	LF														
H	C	T	:	x	.	x	x	x	CR	LF												
P	D	W	:	x	x	.	x	CR	LF													
R	D	W	-	S	D	:	x	x	x	.	x	CR	LF									
R	D	W	-	C	V	:	x	.	x	x	x	CR	LF									
P	C	T	:	x	x	.	x	x	CR	LF												
M	P	V	:	x	x	x	.	x	CR	LF												
M	C	V	:	x	x	x	.	x	CR	LF												
P	-	L	C	R	:	x	.	x	x	x	CR	LF										
W	B	C	:	x	x	.	x	CR	LF													
L	Y	M	#	:	x	x	x	.	x	CR	LF											
M	O	N	#	:	x	x	x	.	x	CR	LF											
G	R	A	#	:	x	x	x	.	x	CR	LF											
L	Y	M	%	:	x	.	x	x	x	CR	LF											
M	O	N	%	:	x	.	x	x	x	CR	LF											
G	R	A	%	:	x	.	x	x	x	CR	LF											
H	G	B	:	x	x	x	CR	LF														
M	C	H	C	:	x	x	x	x	CR	LF												
M	C	H	:	x	x	x	.	x	CR	LF												
ETX																						