

BC-3600

Auto Hematology Analyzer

**Operator's Manual**





© 2010-2015 Shenzhen Mindray Bio-Medical Electronics Co., Ltd. All rights Reserved.  
For this Operator's Manual, the issue date is 2015-10.

## Intellectual Property Statement

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this Mindray product and this manual. This manual may refer to information protected by copyright or patents and does not convey any license under the patent rights or copyright of Mindray, or of others.

Mindray intends to maintain the contents of this manual as confidential information. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

Release, amendment, reproduction, distribution, rental, adaptation, translation or any other derivative work of this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

**mindray**



**MINDRAY**

, , are the trademarks, registered or otherwise, of Mindray in China and other countries. All other trademarks that appear in this manual are used only for informational or editorial purposes. They are the property of their respective owners.

## Responsibility on the Manufacturer Party

Contents of this manual are subject to change without prior notice.

All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements; and
- the product is used in accordance with the instructions for use.

---

**⚠ WARNING**

- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.
  - Be sure to operate the analyzer under the situation specified in this manual; otherwise, the analyzer will not work normally and the analysis results will be unreliable, which would damage the analyzer components and cause personal injury.
- 

---

**NOTE**

- This equipment must be operated by skilled/trained clinical professionals.
-

## Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

### Exemptions

Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray or repairs by people other than Mindray authorized personnel.

This warranty shall not extend to:

- **Malfunction or damage caused by improper use or man-made failure.**
- **Malfunction or damage caused by unstable or out-of-range power input.**
- **Malfunction or damage caused by force majeure such as fire and earthquake.**
- **Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.**
- **Malfunction of the instrument or part whose serial number is not legible enough.**
- **Others not caused by instrument or part itself.**

### Company Contact

<b>Manufacturer:</b>	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
<b>Address:</b>	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R. China
<b>Website:</b>	<a href="http://www.mindray.com">www.mindray.com</a>
<b>E-mail Address:</b>	service@mindray.com
<b>Tel:</b>	+86 755 81888998
<b>Fax:</b>	+86 755 26582680

**EC-Representative: Shanghai International Holding Corp. GmbH(Europe)**

**Address:** Eiffestraße 80, 20537 Hamburg, Germany

**Tel:** 0049-40-2513175

**Fax:** 0049-40-255726



# Table of Contents

<b>1</b>	<b>Using This Manual</b> .....	<b>1-1</b>
1.1	Introduction .....	1-1
1.2	Who Should Read This Manual.....	1-2
1.3	How to Find Information .....	1-3
1.4	Conventions Used in This Manual.....	1-4
1.5	Safety Information .....	1-5
1.6	Symbols.....	1-7
<b>2</b>	<b>Understanding Your Analyzer</b> .....	<b>2-1</b>
2.1	Introduction .....	2-1
2.2	Intended Use .....	2-2
2.3	Main Structure .....	2-3
2.4	User Interface .....	2-14
2.5	Reagents, Controls and Calibrators .....	2-18
<b>3</b>	<b>Understanding the System Principles</b> .....	<b>3-1</b>
3.1	Introduction .....	3-1
3.2	Aspiration.....	3-2
3.3	Dilution.....	3-3
3.4	WBC/HGB Measurement .....	3-5
3.5	RBC/PLT Measurement.....	3-9
3.6	Wash.....	3-13
<b>4</b>	<b>Installing Your Analyzer</b> .....	<b>4-1</b>
4.1	Introduction .....	4-1
4.2	Installation Requirements .....	4-2
4.3	Unpacking.....	4-4
4.4	Installation Procedure .....	4-5
4.5	Starting the Analyzer.....	4-13
<b>5</b>	<b>Customizing the Analyzer Software</b> .....	<b>5-1</b>
5.1	Introduction .....	5-1
5.2	System setup .....	5-2
5.3	User Setup.....	5-19
5.4	Auxiliary Setup.....	5-23
5.5	Maintenance Setup.....	5-27
5.6	Reagent Setup.....	5-29
5.7	Gain Setup.....	5-31

---

<b>6</b>	<b>Operating Your Analyzer .....</b>	<b>6-1</b>
6.1	Introduction .....	6-1
6.2	Initial Checks .....	6-2
6.3	Startup and Logon .....	6-4
6.4	Daily Quality Control.....	6-5
6.5	Sample Collection and Handling .....	6-6
6.6	Sample Analysis .....	6-10
6.7	Using Tube Holder Adapters (for closed tube model) .....	6-19
6.8	Auto-sleep.....	6-21
6.9	Shutdown.....	6-22
<b>7</b>	<b>Reviewing Sample Results .....</b>	<b>7-1</b>
7.1	Introduction.....	7-1
7.2	Browsing All Sample Results.....	7-2
<b>8</b>	<b>Using the QC Programs .....</b>	<b>8-1</b>
8.1	Introduction .....	8-1
8.2	L-J Quality Control.....	8-2
8.3	"X-B QC" Program.....	8-18
8.4	"X-mean QC" Program .....	8-26
8.5	"X-mean R QC" Program.....	8-43
<b>9</b>	<b>Using the Calibration Programs .....</b>	<b>9-1</b>
9.1	Introduction .....	9-1
9.2	When to Calibrate.....	9-2
9.3	How to Calibrate .....	9-3
9.4	Calibration History .....	9-18
<b>10</b>	<b>Maintaining Your Analyzer .....</b>	<b>10-1</b>
10.1	Introduction.....	10-1
10.2	Maintaining Your Analyzer Manually.....	10-2
10.3	Preset Probe Cleanser Soak.....	10-16
10.4	Using the "System Status" Program .....	10-17
10.5	Valve Test .....	10-18
10.6	System Test .....	10-19
10.7	Version Information.....	10-20
10.8	Counter .....	10-21
10.9	Touchscreen Calibration .....	10-22
10.10	Using the "Log" Program .....	10-26
10.11	Cleaning the Tube Baffle (for closed tube model only).....	10-28
10.12	Replacing Air Filter .....	10-30
<b>11</b>	<b>Troubleshooting Your Analyzer.....</b>	<b>11-1</b>
11.1	Introduction .....	11-1

---



Table of Contents

---

11.2 Errors Indicated by Error Messages ..... 11-2

**12 Appendices .....A-1**

A Index .....A-1

B Specifications.....B-1

C Precautions, Limitations and Hazards .....C-1

D Communication.....D-1



# 1 Using This Manual

---

---

## 1.1 Introduction

This chapter explains how to use your BC-3600 operator's manual, which is shipped with your BC-3600 AUTO HEMATOLOGY ANALYZER and contains reference information about the BC-3600 and procedures for operating, troubleshooting and maintaining the analyzer. Read this manual carefully before operating your analyzer and operate your analyzer strictly as instructed in this manual.

---

### **NOTE**

- **Be sure to operate your analyzer strictly as instructed in this manual.**
-

## 1.2 Who Should Read This Manual

This manual contains information written for clinical laboratory professionals to:

- learn about the BC-3600 hardware and software.
- customize system settings.
- perform daily operating tasks.
- perform system maintenance and troubleshooting.

## 1.3 How to Find Information

This operator's manual comprises 11 chapters and 3 appendices. Refer to the table below to find the information you need.

If you want to ...	See ...
learn about the intended use and parameters of the BC-3600	<b>Chapter 2 Understanding Your Analyzer</b>
learn about the hardware, interface and software of the BC-3600	<b>Chapter 2 Understanding Your Analyzer</b>
learn about how the BC-3600 works	<b>Chapter 3 Understanding the System Principles</b>
learn about the installation requirements of the BC-3600	<b>Chapter 4 Installing Your Analyzer</b>
learn about how to define/adjust system settings	<b>Chapter 5 Customizing the Analyzer Software</b>
learn about the process of sample collection and analysis	<b>Chapter 6 Operating Your Analyzer</b>
learn about how to use the BC-3600 to perform your daily operating tasks	<b>Chapter 6 Operating Your Analyzer</b>
review sample results	<b>Chapter 7 Reviewing Sample Results</b>
learn about how to use the quality control programs	<b>Chapter 8 Using the QC Programs</b>
learn about how to calibrate the BC-3600	<b>Chapter 9 Using the Calibration Programs</b>
learn about how to maintain/service the BC-3600	<b>Chapter 10 Maintaining Your Analyzer</b>
learn about how to solve the problems of the BC-3600	<b>Chapter 11 Troubleshooting Your Analyzer</b>
learn about the technical specifications of the BC-3600	<b>Appendix B Specifications</b>
learn about the communication protocol of the BC-3600	<b>Appendix D Communication</b>

## 1.4 Conventions Used in This Manual




This manual uses certain typographical conventions to clarify meaning in the text:

- all capital letters enclosed in [ ] indicate a key name on the analyzer or external keyboard, such as [ENTER].
- bold letters included in “ ” indicate text you may find on the screen, such as “**Clean**”.
- bold letters indicate chapter titles, such as **Chapter 1 Using This Manual**.

All illustrations in this manual are provided as examples only. They may not necessarily reflect your analyzer setup or data displayed.

## 1.5 Safety Information

The following symbols are used to indicate danger and alert information in this manual.

When you see...	Then...
	read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
 <b>WARNING</b>	read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
 <b>CAUTION</b>	read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
<b>NOTE</b>	read the statement below the symbol. The statement is alerting you to information that requires your attention.



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
  - If leak happens to the analyzer, the leak liquid is potentially biohazardous.
- 

---

### **WARNING**

- Please check the firmness of all the doors and covers before running the analyzer.
  - Make sure all the safety measurements are adopted. Disable any safety device or sensor is prohibited.
  - Please take action to any alarm and problem indication immediately.
  - Do not touch the moving parts.
  - Contact Mindray or Mindray-authorized distributors in time if any damaged part is found.
-

- Be careful when opening/closing and removing/installing the doors, covers and boards of the analyzer.
  - Discard the analyzer according to government regulations.
- 





**⚠ CAUTION**

- Please use the analyzer strictly according to this manual.
  - Make sure only Mindray-authorized software is installed on the computer.
  - Please install the original edition software to prevent the computer from being infected by virus.
  - Please adopt proper measurements to prevent the reagents from being polluted.
  - It is recommended that the anti-virus software should be installed on the computer and run regularly.
-



















## 1.6 Symbols

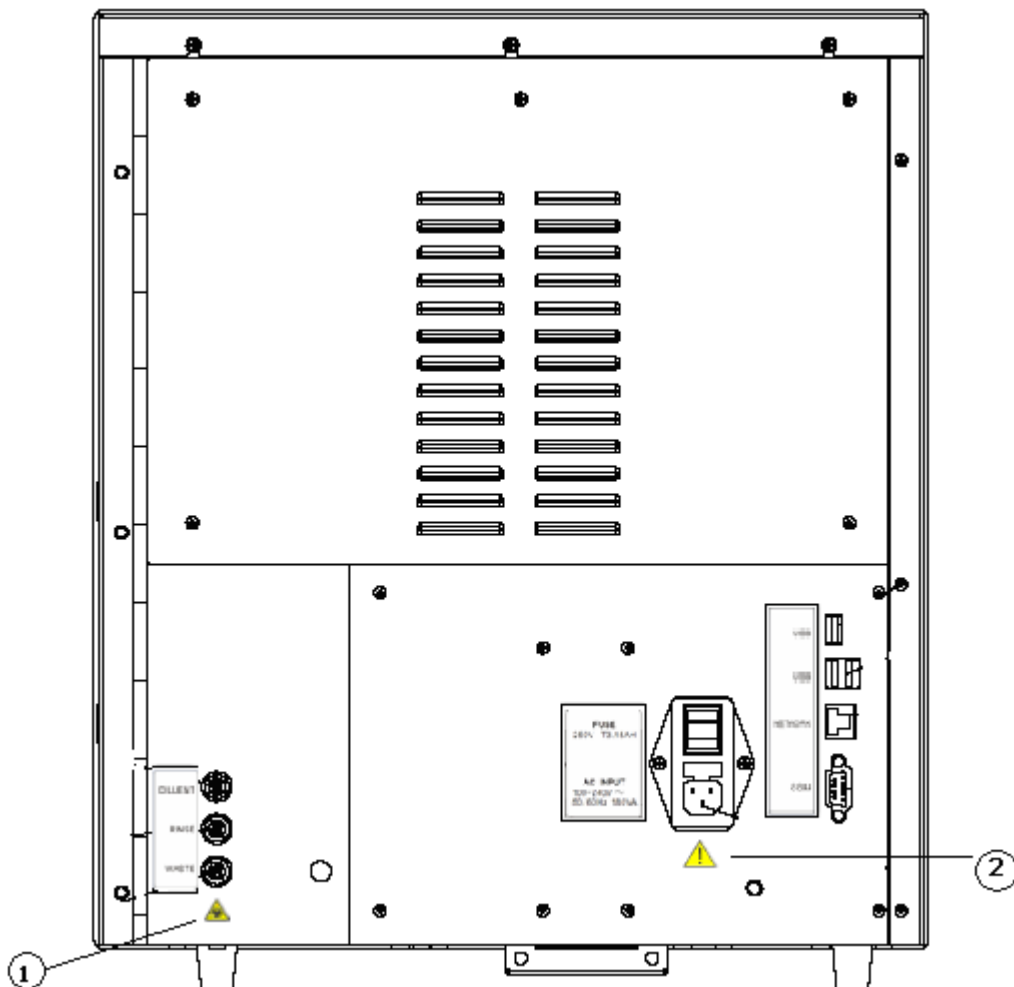
You will find the following symbols in this manual:

When you see...	Then...
	Read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
 <b>WARNING</b>	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
 <b>CAUTION</b>	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
 <b>NOTE</b>	Read the statement below the symbol. The statement is alerting you to information that requires your attention.

You may find the following symbols of the analyzer system:

When you see...	It means...
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS.
	BIOLOGICAL RISK
	EXERCISE CAUTION WHEN WORKING AROUND TO AVOID PRICKING
	PROTECTIVE EARTH (GROUND)
	ALTERNATING CURRENT
	FOR IN VITRO DIAGNOSTIC USE
	BATCH CODE

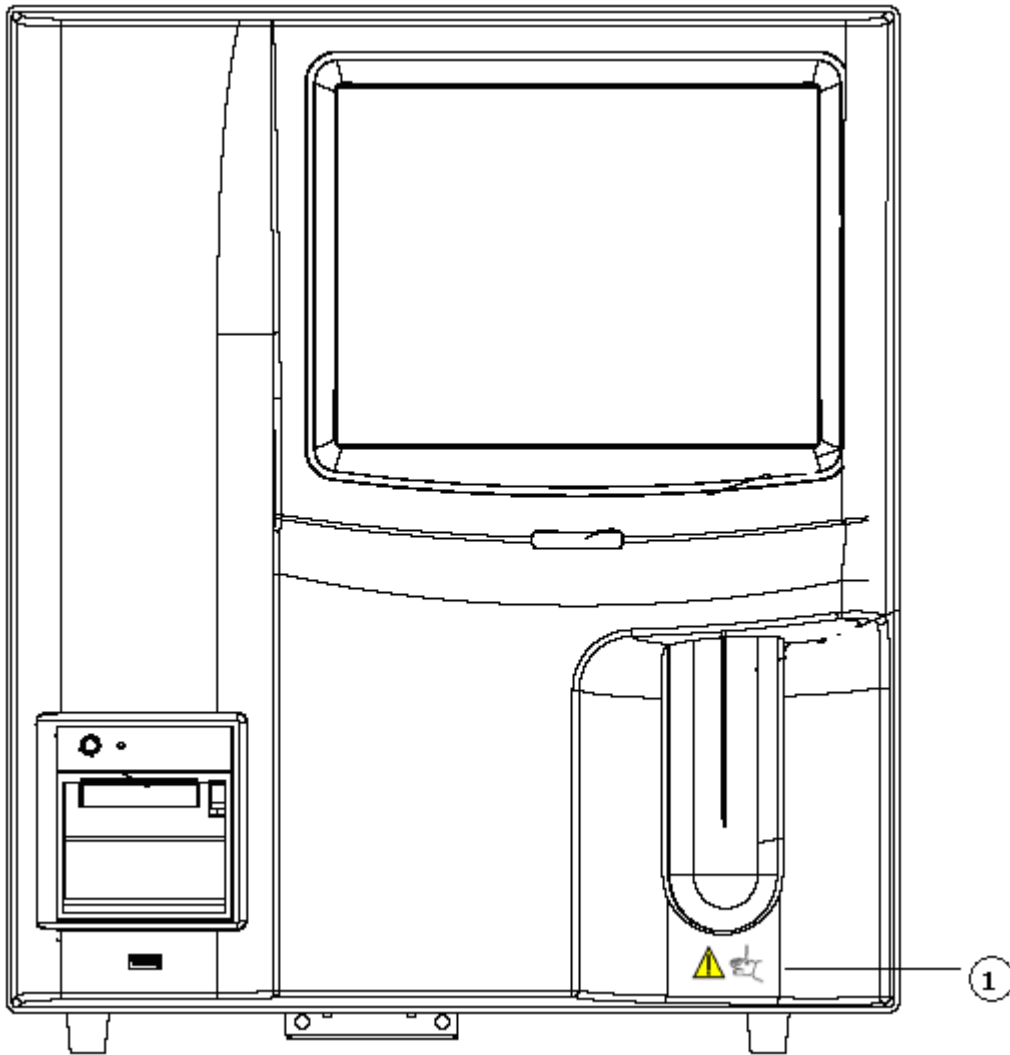
	USE BY
	SERIAL NUMBER
	DATE OF MANUFACTURE
	MANUFACTURER
	TEMPERATURE LIMITATION
Xi 	IRRITATING SUBSTANCE
	THE FOLLOWING DEFINITION OF THE WEEE LABEL APPLIES TO EU MEMBER STATES ONLY: THE USE OF THIS SYMBOL INDICATES THAT THIS PRODUCT SHOULD NOT BE TREATED AS HOUSEHOLD WASTE. BY ENSURING THAT THIS PRODUCT IS DISPOSED OF CORRECTLY, YOU WILL HELP PREVENT BRINGING POTENTIAL NEGATIVE CONSEQUENCES TO THE ENVIRONMENT AND HUMAN HEALTH. FOR MORE DETAILED INFORMATION WITH REGARD TO RETURNING AND RECYCLING THIS PRODUCT, PLEASE CONSULT THE DISTRIBUTOR FROM WHOM YOU PURCHASED THE PRODUCT.
	THE DEVICE IS FULLY CONFORMANCE WITH THE COUNCIL DIRECTIVE CONCERNING IN VITRO DIAGNOSTIC MEDICAL DEVICES 98/79/EC.
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY



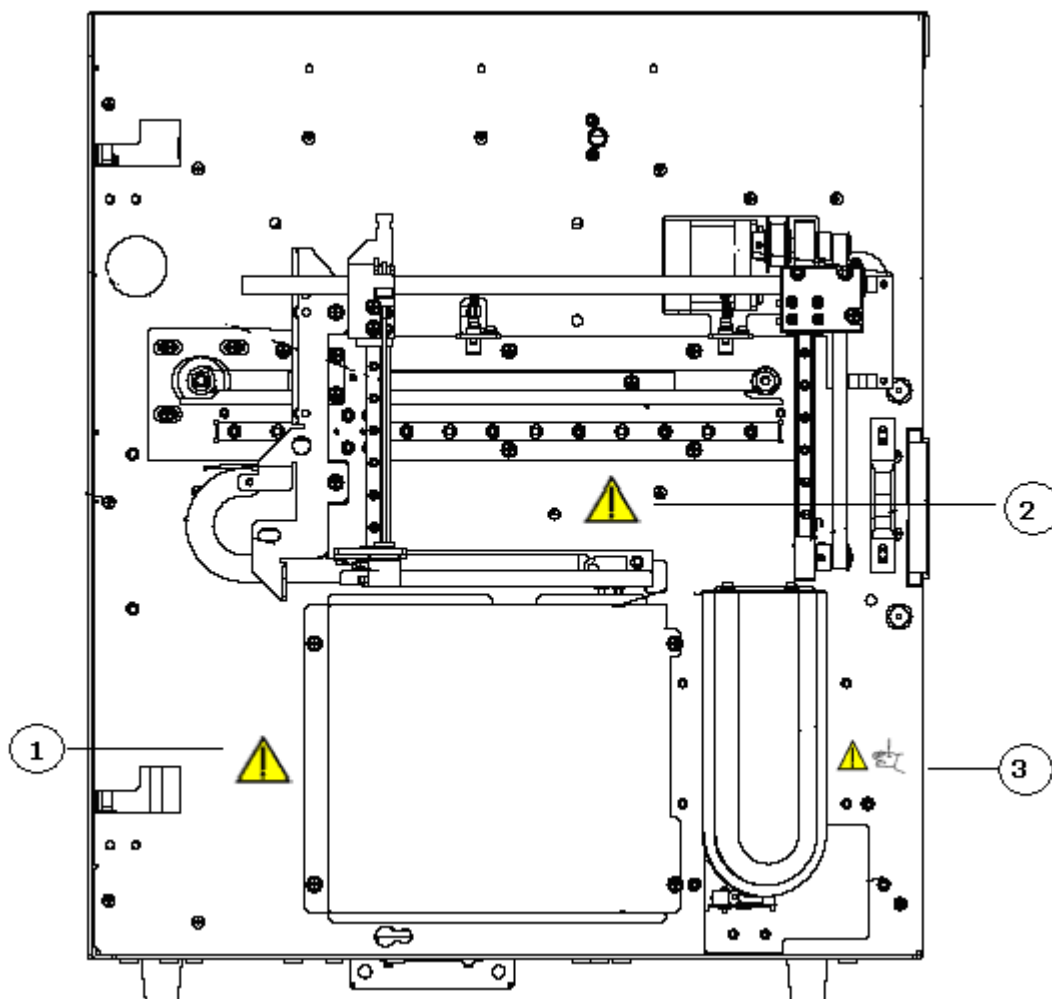
(1) Warning, potential biohazardous risk.



- (2)
- Connect only to a properly earth grounded outlet.
  - To avoid electric shock, disconnect power cord prior to removing or replacing fuse.
  - Replace fuse only with the type and rating specified.



The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.



(1)

Warning, make sure the protective cover is properly installed before operation.



(2)

Warning

- Do not put your hands close to the sampling assembly when the analyzer is running.
- The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.



(3)

The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.



# **2 Understanding Your Analyzer**

---

## **2.1 Introduction**

BC-3600 AUTO HEMATOLOGY ANALYZER is a quantitative, automated hematology analyzer and 3-part differential counter for in Vitro Diagnostic Use in clinical laboratories.

## 2.2 Intended Use

### **NOTE**

- **The purpose of this analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.**

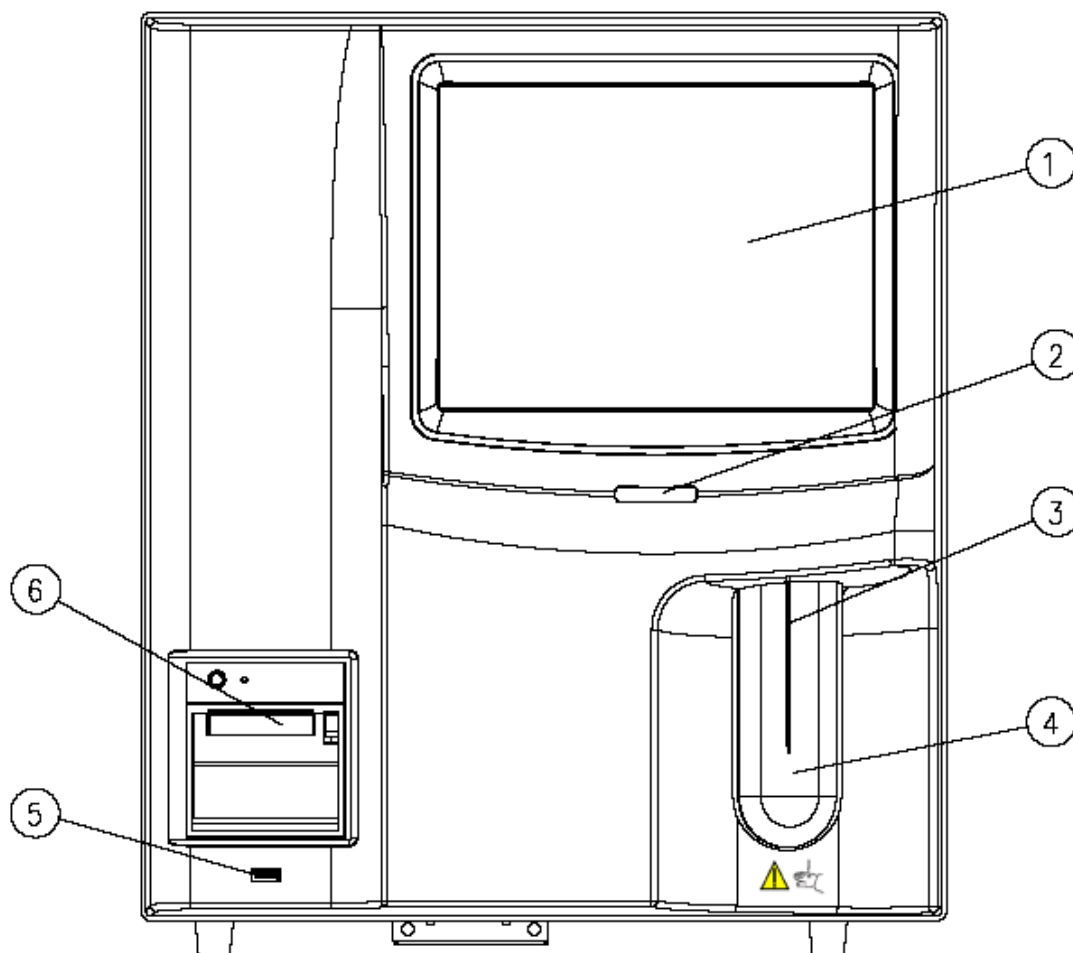
The analyzer determines 21 parameters and 3 histograms of blood samples.

White Blood Cell count	WBC
Lymphocyte number	Lymph#
Mid-sized cell number	Mid#
Granulocyte number	Gran#
Lymphocyte percentage	Lymph%
Mid-sized cell percentage	Mid%
Granulocyte percentage	Gran%
Red Blood Cell count	RBC
Hemoglobin concentration	HGB
Mean Corpuscular Volume	MCV
Mean Corpuscular Hemoglobin	MCH
Mean Corpuscular Hemoglobin Concentration	MCHC
Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV
Red Blood Cell Distribution Width Standard Deviation	RDW-SD
Hematocrit	HCT
Platelet count	PLT
Mean Platelet Volume	MPV
Platelet Distribution Width	PDW
Plateletcrit	PCT
Platelet Large Cell Ratio	P-LCR
Platelet Large Cell Count	P-LCC
White Blood Cell Histogram	WBC Histogram
Red Blood Cell Histogram	RBC Histogram
Platelet Histogram	PLT Histogram



## 2.3 Main Structure

The BC-3600 consists of the main unit (analyzer) and accessories.



**Figure 2-1 Front of the Analyzer (open vial model)**

1 ---- Touch screen

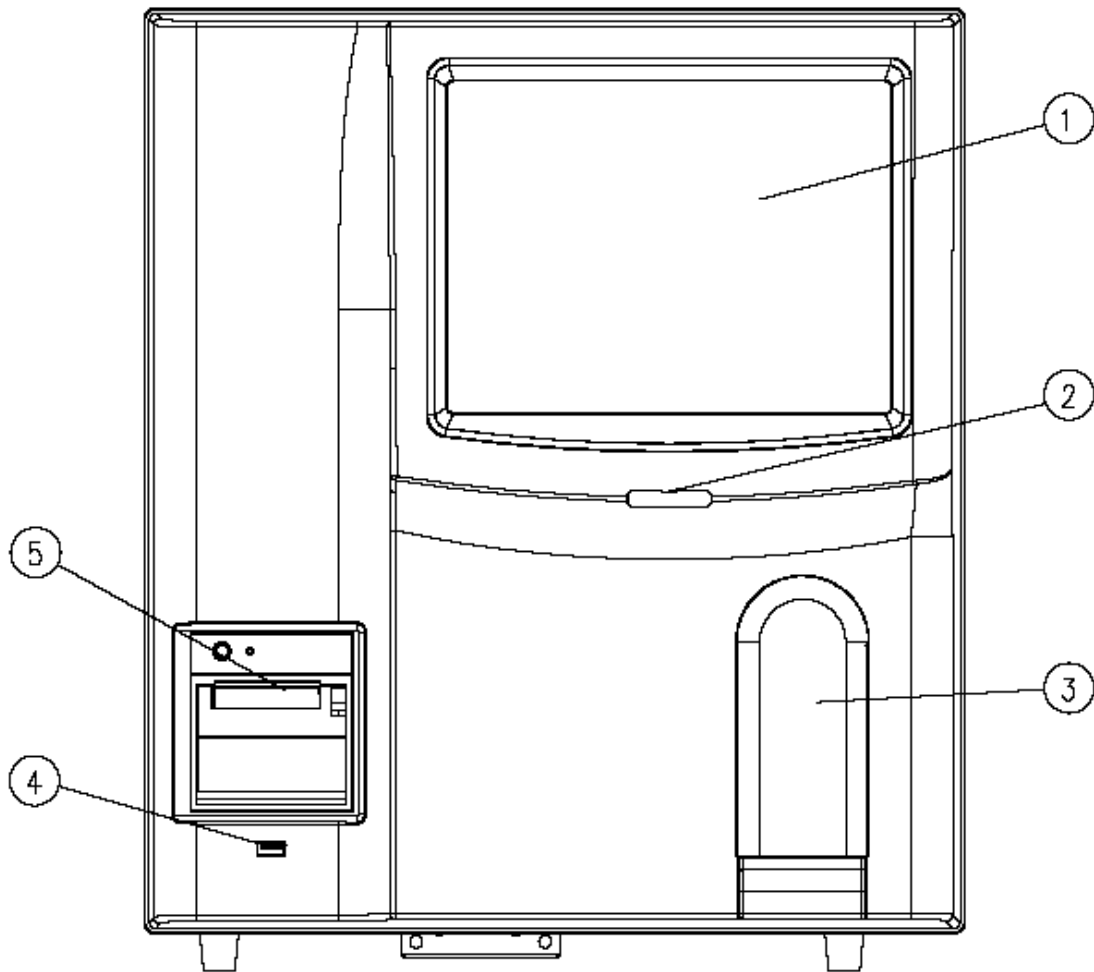
2 --- Power indicator

3 ---- Sample probe

4 ---- Aspirate key

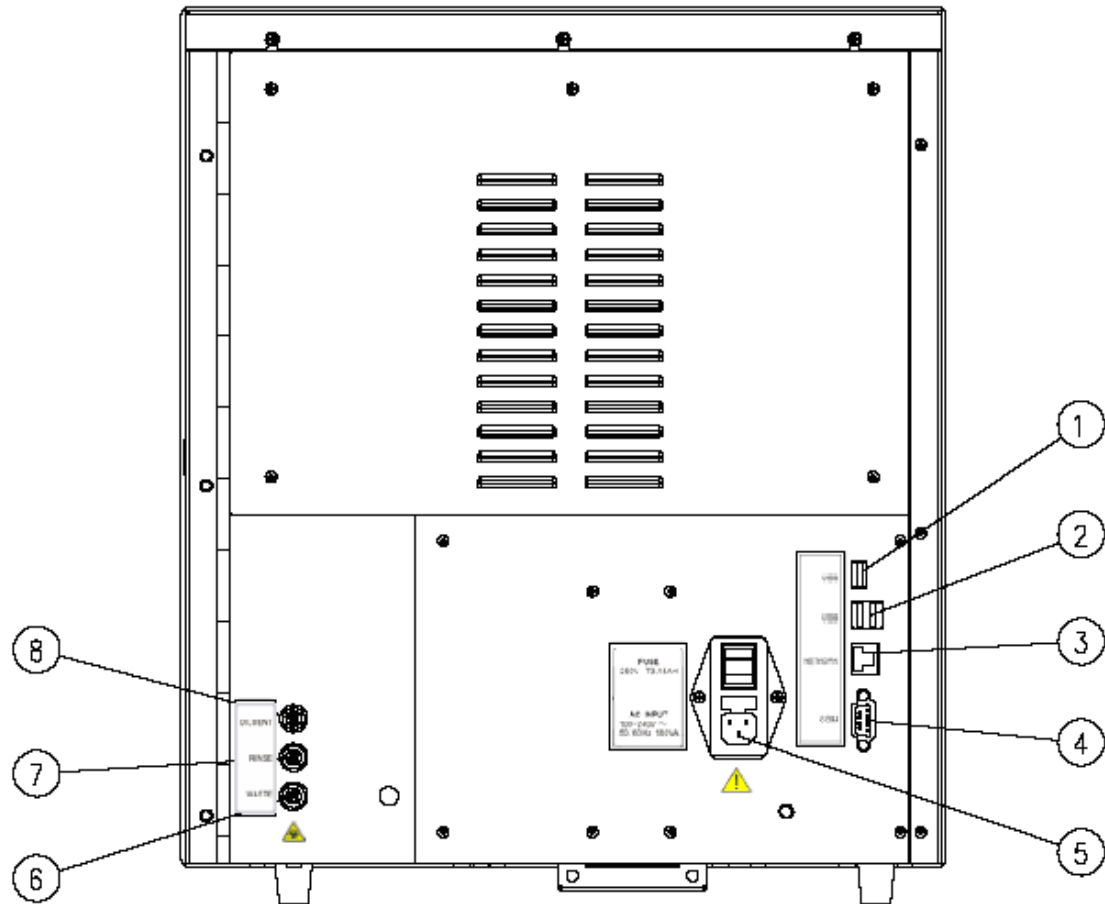
5 --- USB port

6 ---- Recorder



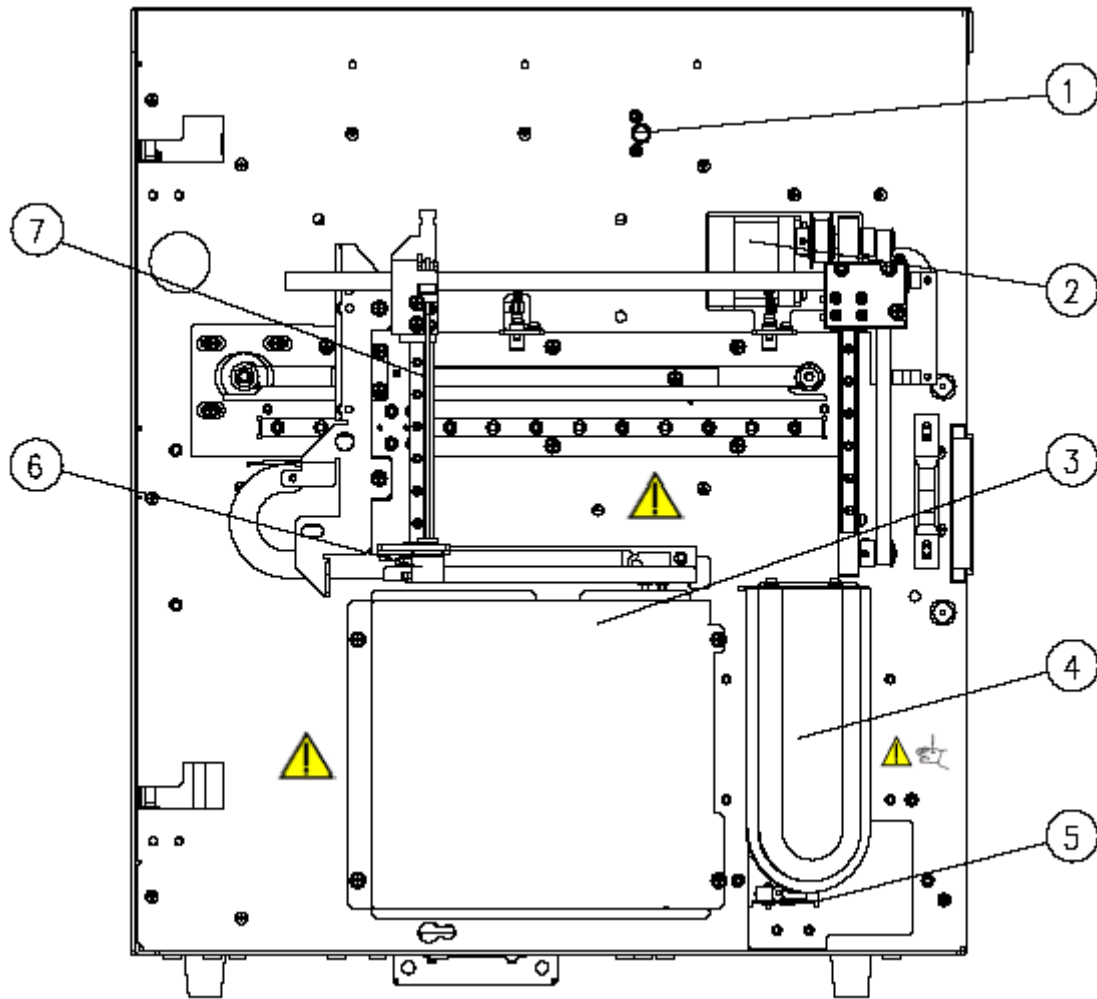
**Figure 2-2 Front of the Analyzer (closed tube model)**

- |                                |                        |
|--------------------------------|------------------------|
| 1 ---- Touch screen            | 2 ---- Power indicator |
| 3 ---- Sample compartment door | 4 ---- USB port        |
| 5 ---- Recorder                |                        |



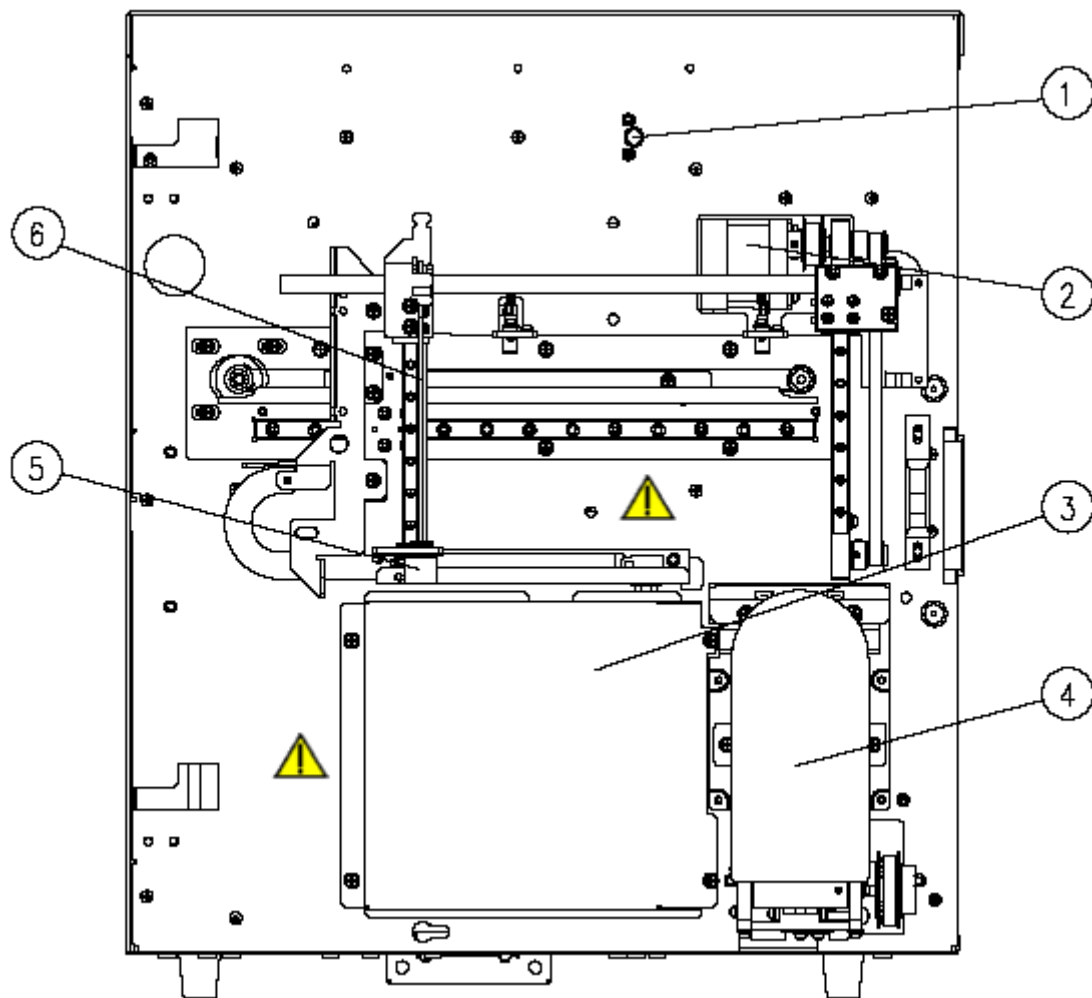
**Figure 2-3 Back of the Analyzer**

- |                    |                     |
|--------------------|---------------------|
| 1 --- USB port 1   | 2 --- USB port 2    |
| 3 --- Network port | 4 --- Serial port   |
| 5 --- Power switch | 6 --- Waste outlet  |
| 7 --- Rinse inlet  | 8 --- Diluent inlet |



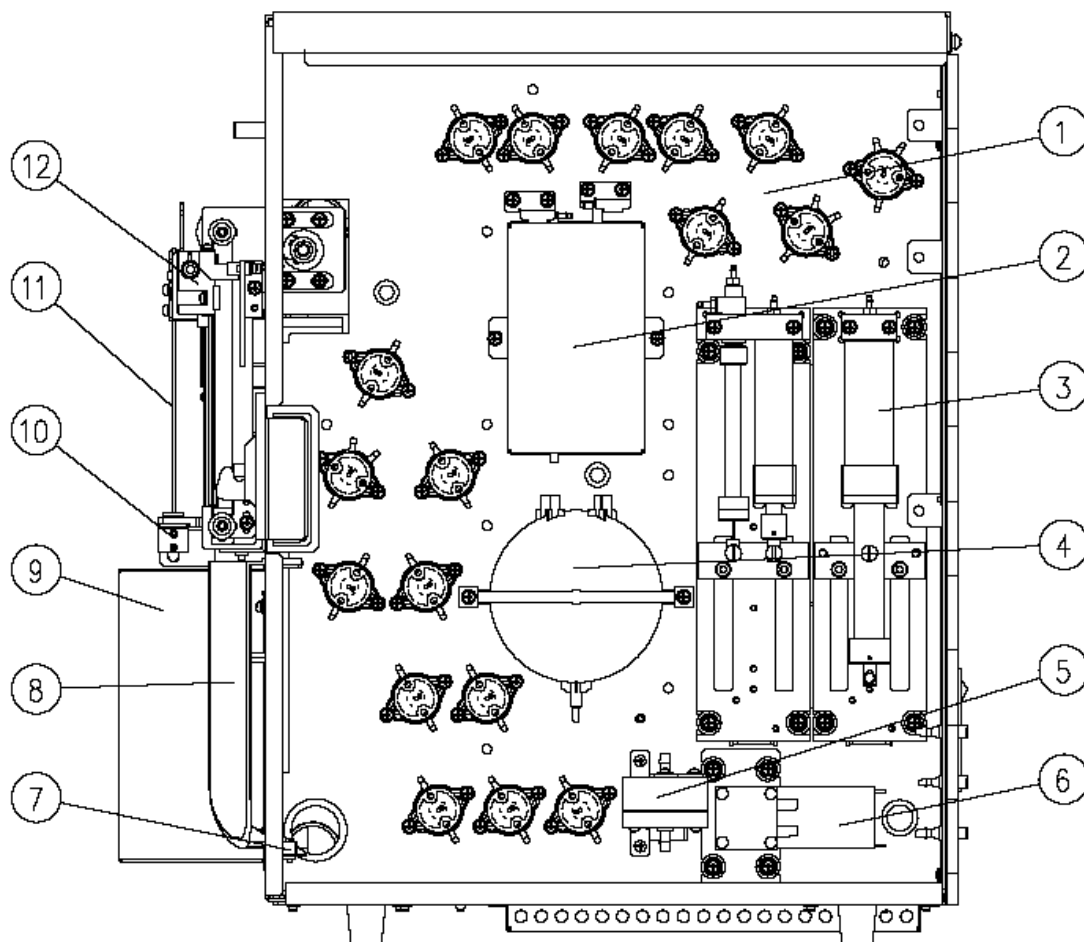
**Figure 2-4 Inside Front of the Analyzer (open vial model)**

- |                                   |                      |
|-----------------------------------|----------------------|
| 1 --- Front cover detect assembly | 2 --- Sampling motor |
| 3 --- Bath shielding box          | 4 --- Aspirate key   |
| 5 --- Micro switch                | 6 --- Probe wipe     |
| 7 --- Sample probe                |                      |



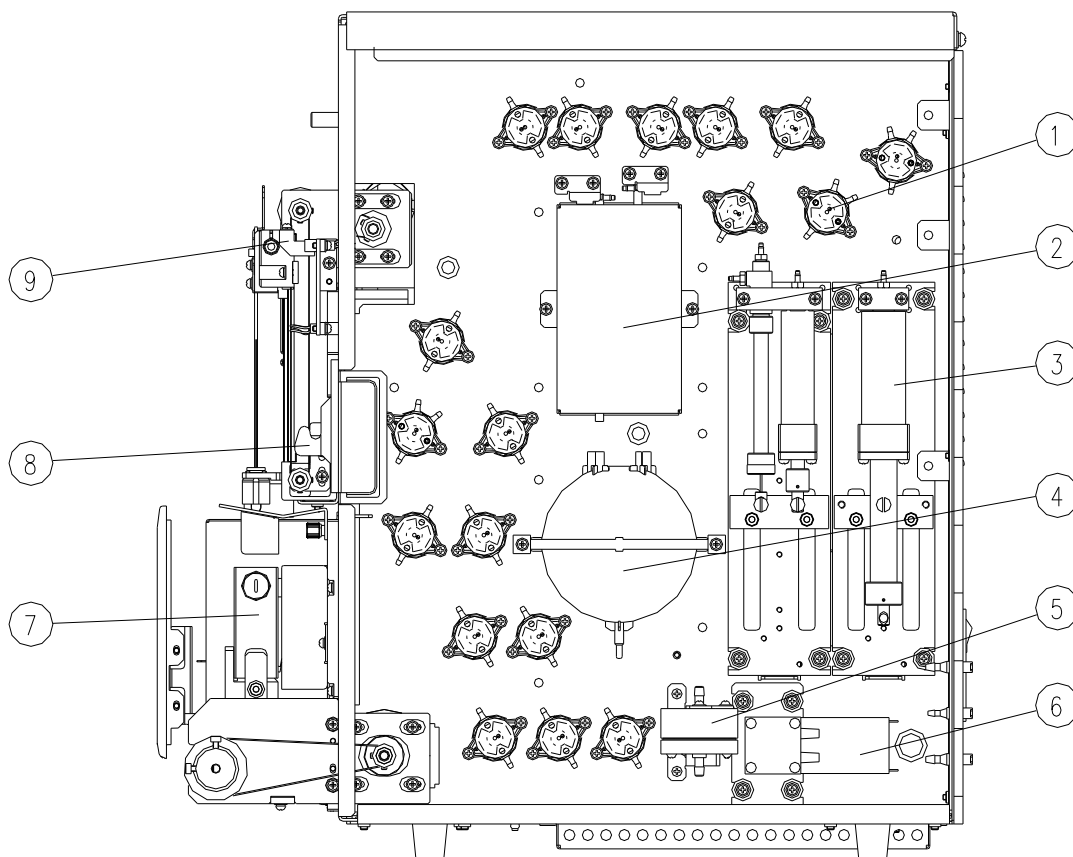
**Figure 2-5 Inside Front of the Analyzer (closed tube model)**

- |                          |                          |
|--------------------------|--------------------------|
| 1 --- Door switch        | 2 --- Sampling motor     |
| 3 --- Bath shielding box | 4 --- Sample compartment |
| 5 --- Probe wipe         | 6 --- Sample probe       |



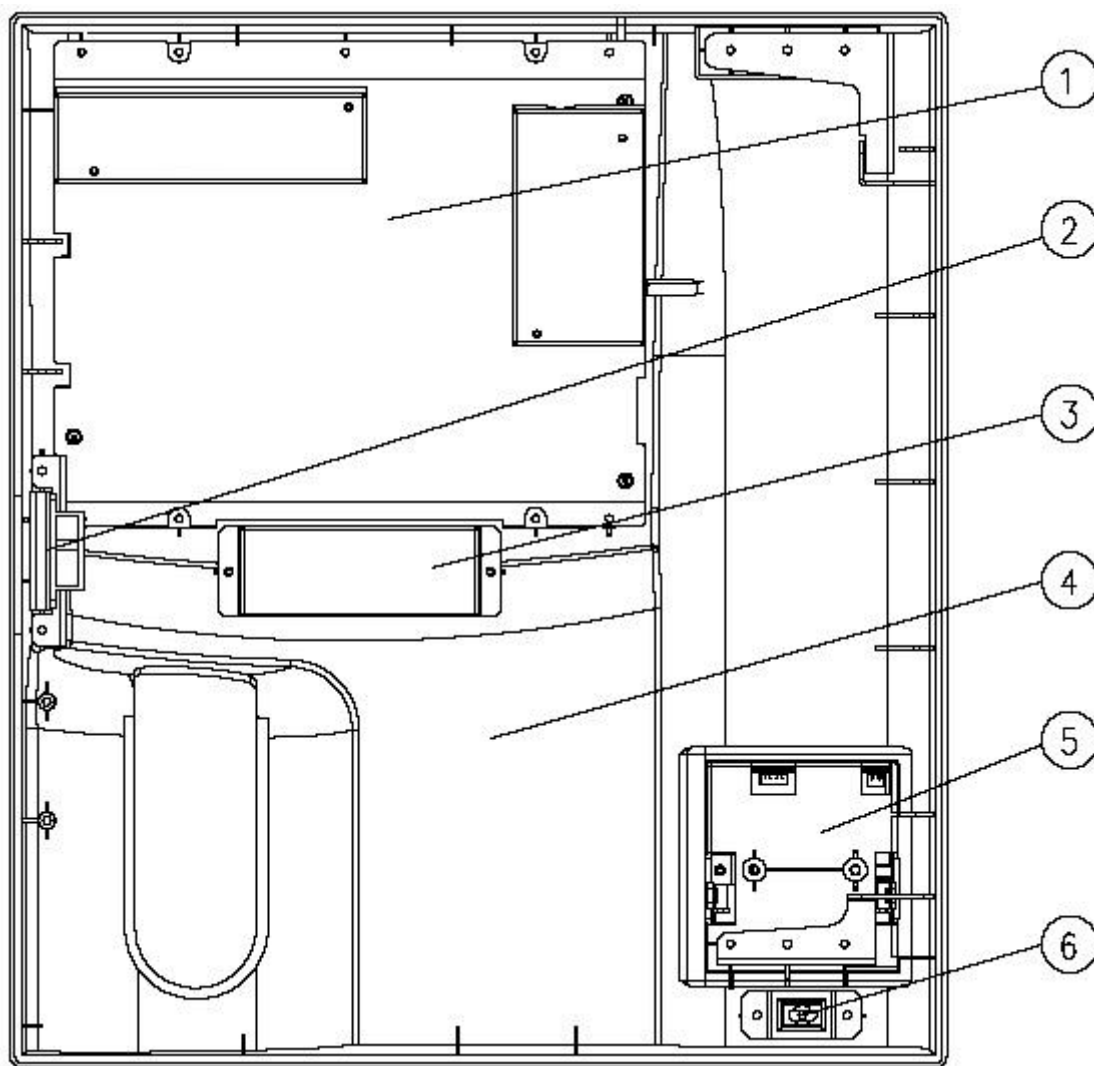
**Figure 2-6 Inside Right of the Analyzer (open vial model)**

- |                        |                          |
|------------------------|--------------------------|
| 1 --- Valve            | 2 --- Volumetric unit    |
| 3 --- Syringe assembly | 4 --- Vacuum chamber     |
| 5 --- Air Filter       | 6 --- Fluid pump         |
| 7 --- Micro switch     | 8 --- Aspirate key       |
| 9 --- Bath assembly    | 10 --- Probe wipe        |
| 11 --- Sample probe    | 12 --- Sampling assembly |



**Figure 2-7 Inside Right of the Analyzer (closed tube model)**

- |                                   |                       |
|-----------------------------------|-----------------------|
| 1 --- Valve                       | 2 --- Volumetric unit |
| 3 --- Syringe assembly            | 4 --- Vacuum chamber  |
| 5 --- Air Filter                  | 6 --- Fluid pump      |
| 7 --- Sample compartment assembly | 8 --- Door holder     |
| 9 --- Sampling assembly           |                       |



**Figure 2-8 Back of the Front Cover (open vial model)**

1 --- Screen assembly

2 --- Door holder

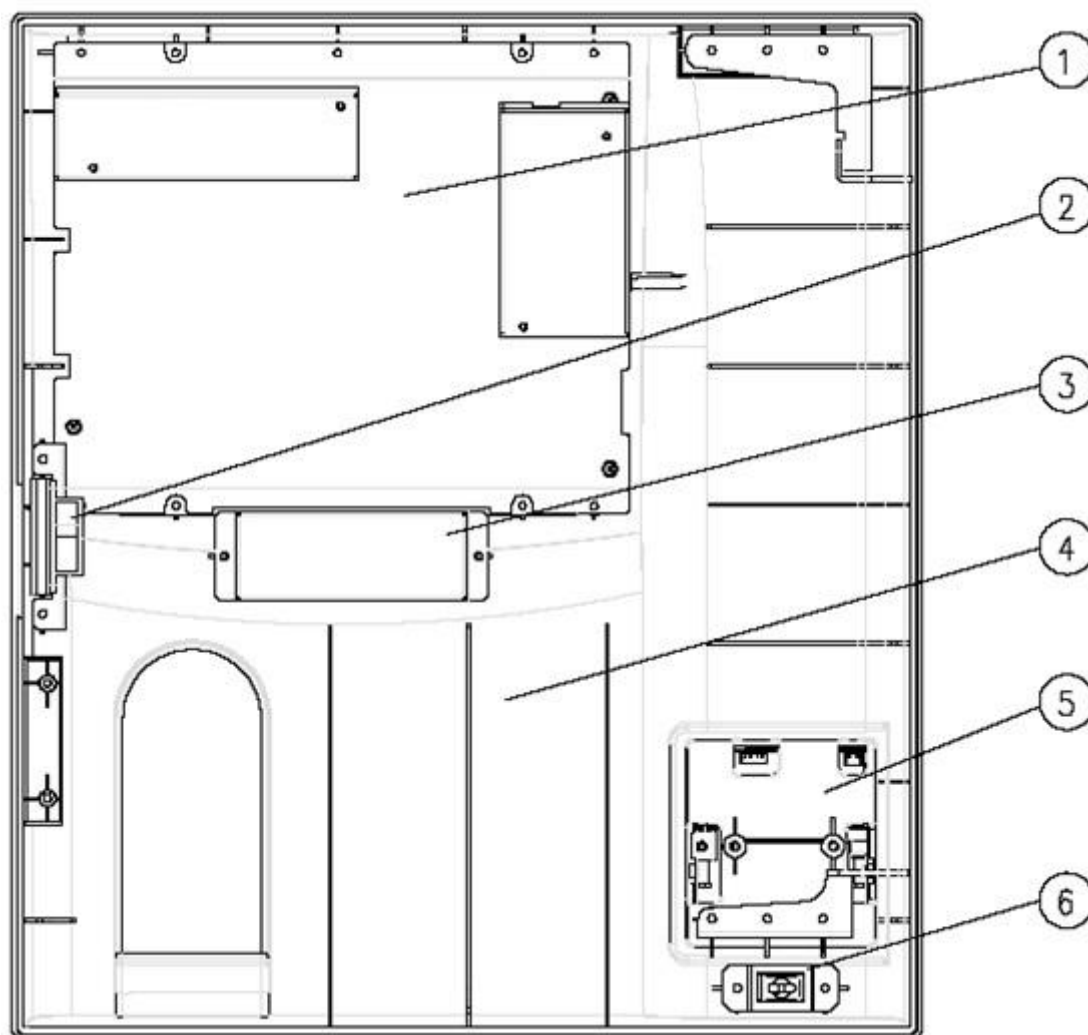
3 --- Indicator cover

4 --- Front cover

5 --- Recorder

6 --- USB port





**Figure 2-9 Back of the Front Cover (closed tube model)**

- |                       |                   |
|-----------------------|-------------------|
| 1 --- Screen assembly | 2 --- Door holder |
| 3 --- Indicator cover | 4 --- Front cover |
| 5 --- Recorder        | 6 --- USB port    |

### 2.3.1 Touch Screen

The touch screen is located on the front panel of the analyzer. It displays all alphanumeric and graphic data. You may use it to operate your analyzer.

### 2.3.2 Sample Compartment (for closed tube model)

The tube holder in sample compartment can be fitted with different tubes size adapters (See **6.7 Using Tube Holder Adapters** for details).

The specifications of supported tubes are:

Evacuated collection tube: diameter: 10~13.5mm; height (with cap): 40~85mm.

Capillary collection tube: diameter: 10~13.5mm; height (with cap): 40~65mm.

### **2.3.3 Aspirate Key (for open vial model)**

The aspirate key is located behind the sample probe. You may press the key to start analysis or dispense diluent or maintenance reagents.

### **2.3.4 Indicator**

The indicator indicates current status of the analyzer by illuminating in red, yellow and green. Solid green indicates the analyzer is ready for analysis; flickering green indicates the analyzer is running; solid red indicates error occurs, but the analyzer is not running; flickering red indicates the analyzer is running with error; and solid yellow indicates the analyzer is in standby mode.

### **2.3.5 USB Port**

4 USB ports are located on the back of the analyzer. They can be used to connect the keyboard, printer, etc.. USB ports can also be used to perform operation software upgrades.

### **2.3.6 Serial Port**

There is one RS-232 port to support the host connection with a LIS.

### **2.3.7 Network Port**

A network port is located on the back of the analyzer to connect computer and transmit data automatically.

### **2.3.8 External Equipment**

- Keyboard (Optional)

An external keyboard can be connected to a USB port on the back of the analyzer. You may use it to operate your analyzer.

- Mouse (Optional)

A mouse can be connected to a USB port on the back of the analyzer. You may use it to operate your analyzer.

- USB printer (Optional)

An USB printer can be connected to a USB port on the back of the analyzer. You may use it to print out a detailed report and other information displayed on the screen.

- Bar-code scanner (optional)

A bar-code scanner can be connected to a USB port on the back of the analyzer. You may use it to scan the bar-coded information into the analyzer.

## 2.4 User Interface

### 2.4.1 Screen

After the start-up process completes, the "Sample Analysis" screen will display.

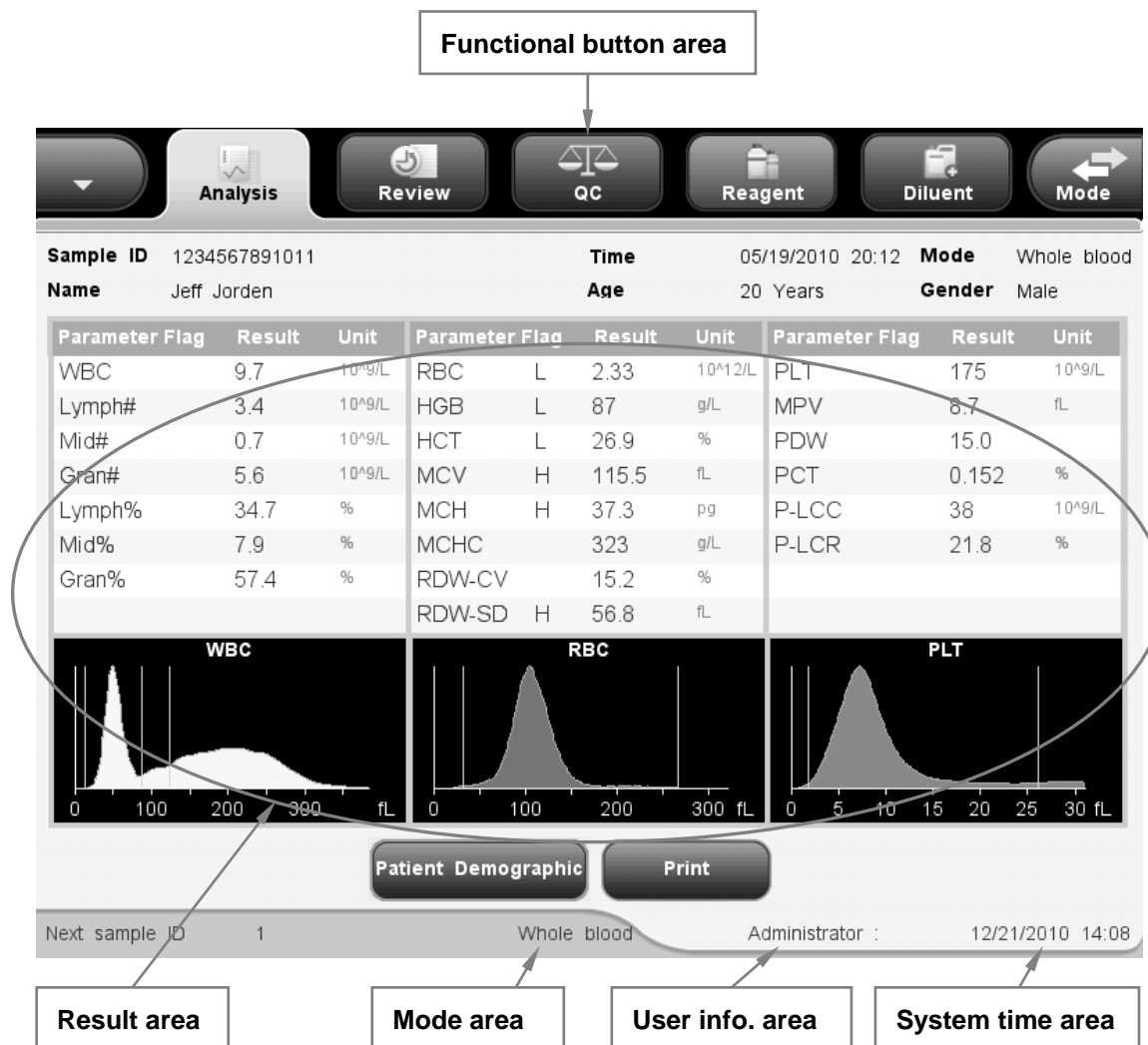


Figure 2-10 "Analysis" Screen

The screen can be divided into several areas as follows according to their functions:

- Error message area

This area overlaps with the user information area. If no system error is present, this area displays user information. And if error occurs in the analyzer system, this area displays error information. When there is more than one error, the error messages display in turn every two seconds.

- Functional button area

This area includes the following buttons:

### Analysis icon

This icon is activated on each screen. You may click the icon on any other screen to go to sample analysis screen.

### Review icon

The icon allows you to go to the table review screen from any other screens.

### QC icon

This icon indicates the normal/abnormal status of QC run; You may click it to go to the out-of-control QC file. When the current QC data are all numeric results without H/L flag, the QC analysis goes normally, then the icon is in normal background color. When the current sample result of any QC file contains H/L flag or non-numeric data, the QC analysis goes abnormally, the icon displays in red. When the icon is in normal background color, click it to go the QC analysis screen of the previous QC run. If the previous QC program is X-B QC, the X-B QC graph screen will display. When the icon is red, click it to go to the analysis screen of abnormal QC file; if there is more than one abnormal QC file, the analysis screen of the abnormal QC file with the smallest file No. will be displayed.

### Reagent setup icon

This icon displays the volume status of reagents, and you may click it to go to reagent setup screen.

The icon displays in two different colors to indicate if there are reagents remaining or not. Under normal status, the icon is in normal background color, indicating there are enough reagents to support analysis; Under "No Reagent" status, the icon turns red, a message will display asking you to prime reagents for further analysis.

### Mode switching icon

Click the icon to switch system mode manually. The icon is activated at each analysis screen.

### Diluent dispensing icon

Click the icon, the analyzer will dispense diluent automatically. The icon is activated under both whole blood and predilute mode, click it to dispense diluent.

- Analysis results area

This area displays analysis result of the current sample (including histograms).

- Analysis mode area

This area displays system analysis mode. When the mode is switched to predilute, the strip area at the bottom of the screen turns to yellow.

- User information area

This area displays username and access level of the current user. After logging in, the access level and username of the current user are always display in that area, with access level on

the left, and username on the right.

- **Print/communication status area**

The print and communication icons are on the left of the system time area with overlapped locations. When there is printing or communication task going on, the corresponding icon will be displayed. If both tasks are going on, the print and communication icons flicker by turns.

#### Print status icon

This icon indicates if there is any printing task going on and the printing status. Print status includes: printing, not printing and printing abnormal. The icon flickers when printing goes on; when there is no printing task, the icon is invisible; when printing status is abnormal (e.g. printer not connected), the icon turns red.

#### Communication status icon


This icon indicates if there is any communication task going on and the communication status. Communication status includes: communicating, not communicating and communication abnormal. The icon flickers when communication goes on; when there is no communication task, the icon is invisible; when communication status is abnormal (e.g. disconnection or communication failed), the icon turns red.

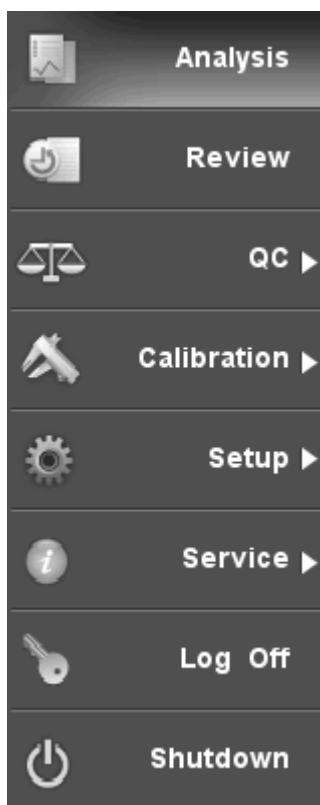
When there is printing or communication task going on, click the flickering icon, a dialog box will display suggesting you to stop the current printing or communication task. When printing or communication status is abnormal, click the area around the icon, a dialog box will display suggesting you to stop the current task and also showing message of the abnormal status.

- **System time area**

This area displays current system date and time. The system date and time is refreshed every minute.

## 2.4.2 System Menu

Press  button, the system menu will display.



**Figure 2-11 System Menu**

There are 8 options in the system menu; you may click on the options to enter corresponding screens and perform different functions.

The following table tells you about the function of each menu option.

**Table 2-1 Function of Each Menu Option**

<b>If you want to...</b>	<b>Select...</b>
analyze samples	Sample analysis
review sample results	Review
run the QC program	QC
calibrate the analyzer	Calibration
customize system settings.	Setup
maintain, inspect and service the analyzer	Service
switch the user	Log off
shut down the analyzer	Shutdown

## 2.5 Reagents, Controls and Calibrators

As the analyzer, reagents (diluent, rinse, lyses, and probe cleanser), controls, and calibrators are components of a system, performance of the system depends on the combined integrity of all components. You must only use the Mindray-specified reagents (see **Appendix B Specifications**), which are formulated specifically for the fluidic system of your analyzer in order to provide optimal system performance. Do not use the analyzer with reagents from multiple suppliers. In such use, the analyzer may not meet the performance specified in this manual and may provide unreliable results. All references related to reagents in this manual refer to the reagents specifically formulated for this analyzer.

Each reagent package must be examined before use. Product integrity may be compromised in packages that have been damaged. Inspect the package for signs of leakage or moisture. If there is evidence of leakage or improper handling, do not use the reagent.

---

### **NOTE**

- **Store and use the reagents as instructed by instructions for use of the reagents.**
  - **When you have changed the diluent, lyse or rinse, run a background to see if the results meet the requirement.**
  - **Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.**
  - **After installing a new container of reagent, let it equilibrate at room temperature for a few minutes before using.**
- 

### 2.5.1 Reagents

#### ■ M-30D Diluent

M-30D diluent is an azide-free, filtered isotonic solution for counting and sizing blood cells.

#### ■ M-30CFL Lyse

M-30CFL lyse is a cyanide-free lytic reagent for quantitatively determining hemoglobin and for counting and sizing leukocyte.

#### ■ M-30R Rinse

M-30R Rinse is an azide-free, filtered isotonic solution for cleaning hematology analyzer..

#### ■ Probe cleanser

Probe cleanser is used to clean the analyzer regularly.



## 2.5.2 Controls and Calibrators

The controls and calibrators used on this analyzer are B30 Control for Hematology Analyzer (Impedance Method) and S30 Calibrator for Hematology Analyzer (Impedance Method).

B30 Control for Hematology Analyzer (Impedance Method) mainly consists of generic white blood cells, human red blood cells, generic platelets, preserving reagents and preservatives. It is used for the quality control of parameters like WBC, RBC, HGB, MCV/HCT and PLT of Mindray 3-differential hematology analyzers to monitor or evaluate precision of analysis results. S30 Calibrator for Hematology Analyzer (Impedance Method) mainly consists of generic white blood cells, human red blood cells, generic platelets, preserving reagents and preservatives. It is used for the calibration of parameters like WBC, RBC, HGB, MCV/HCT and PLT of Mindray hematology analyzers to build the metrological traceability of analysis results.

All references related to controls and calibrators in this manual refer to the controls and calibrators specifically formulated for this analyzer by Mindray. You must buy those controls and calibrators from Mindray or Mindray-authorized distributors.



# 3 Understanding the System Principles

---

## 3.1 Introduction

The two independent measurement methods used in this analyzer are:

- the Impedance method for determining the WBC, RBC, and PLT data;
- the colorimetric method for determining the HGB.

During each analysis cycle, the sample is aspirated, diluted and mixed before the determination for each parameter is performed.

## 3.2 Aspiration

This analyzer can process two types of blood samples – whole blood samples and prediluted blood samples.

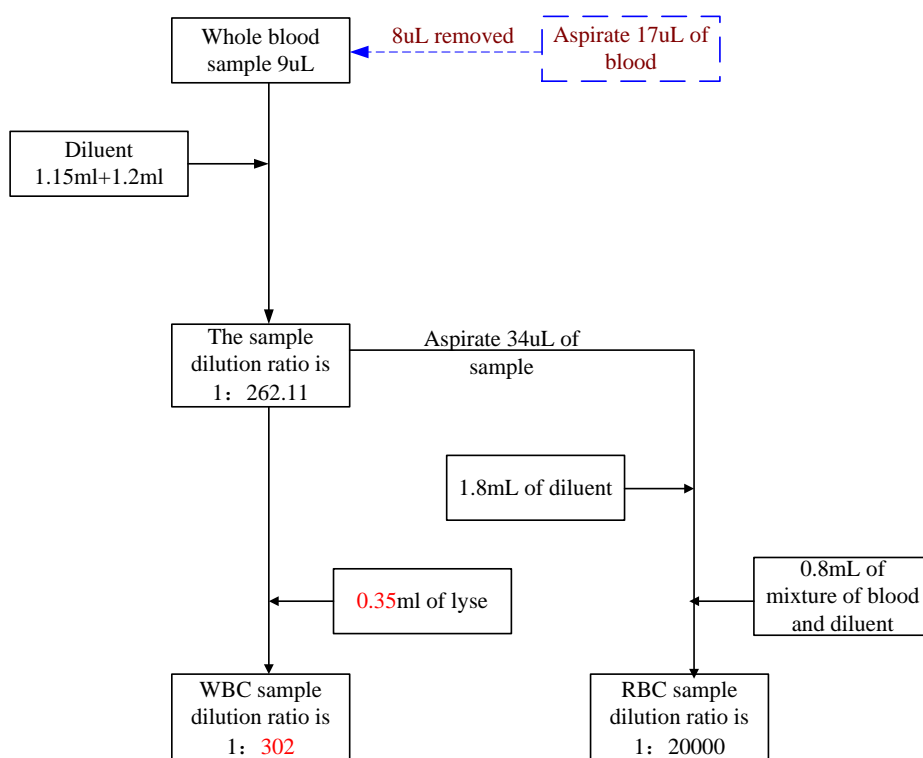
If you are going to analyze a whole blood sample, you may simply present the sample to the sample probe and press the aspirate key to aspirate 17 $\mu$ L of the sample into the analyzer.

If you are going to analyze a capillary blood sample, you need to first manually dilute the sample (20 $\mu$ L of capillary sample needs to be diluted by 0.38mL of diluent) and then present the pre-diluted sample to the sample probe and press the aspirate key to aspirate 146.34 $\mu$ L of the sample into the analyzer.

### 3.3 Dilution

Usually in blood samples, the cells are too concentrated to be analyzed. For this reason, the diluent is used to separate the cells so that they are drawn through the aperture one at a time as well as to create a conductive environment for cell counting. Moreover, red blood cells usually outnumber white blood cells by 1,000 times. For this reason, lyse needs to be added to the sample to eliminate the red cells before the WBC counting.

When analyzing a whole blood sample, this analyzer aspirates 17 $\mu$ L of the sample and follows the procedure presented in Figure 3-1 to dilute it before proceeding to the actual analysis.



**Figure 3-1 How a whole blood sample is diluted**

When analyzing a prediluted sample, you need to first collect 20 $\mu$ L of capillary sample and follows the procedure presented in Figure 3-2 to dilute it before proceeding to the actual analysis.

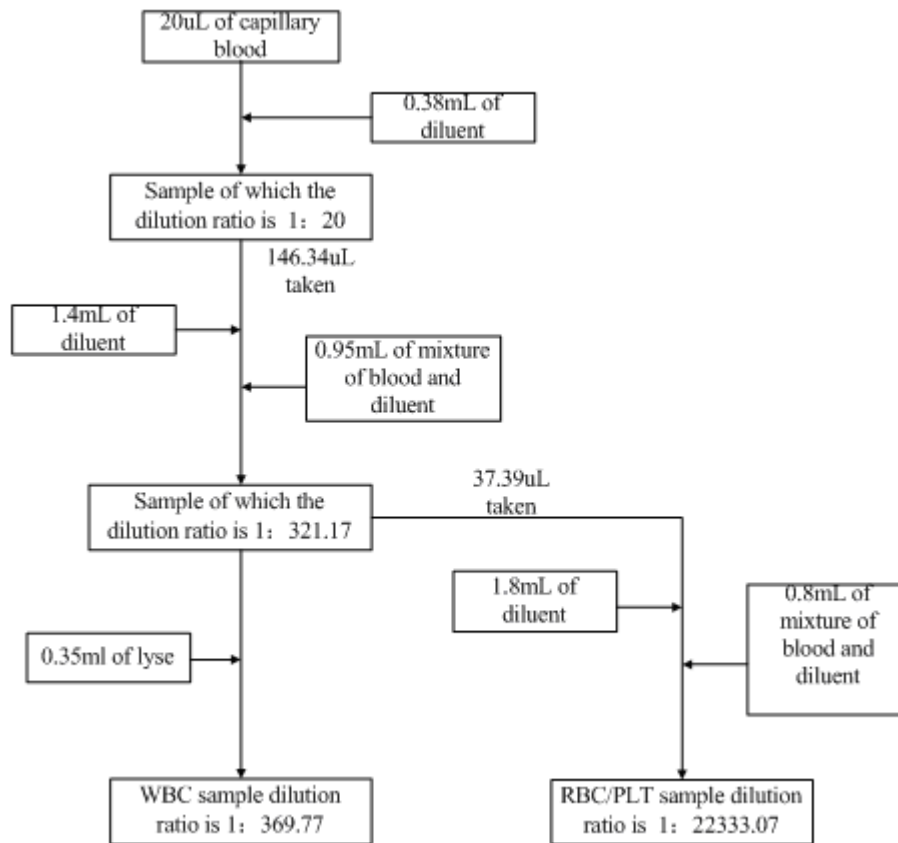


Figure 3-2 How a capillary sample is diluted

## 3.4 WBC/HGB Measurement

### 3.4.1 Volumetric Metering

An accurate cell count cannot be obtained unless the precise volume of diluted sample that passes through the aperture during the count portion of the analysis cycle (the count cycle) is known. This analyzer uses a volumetric metering unit to control the count cycle and to ensure that a precise volume of sample is analyzed.

The metering unit controlling the WBC count cycle consists of a metering tube with two optical sensors mounted on it. This tube ensures that a precise amount of diluted sample is measured during each count cycle. The exact amount is determined by the distance between the two optical sensors. The rinse is used to create a meniscus in the metering tube. The count cycle starts when the meniscus reaches the upper sensor and stops when the meniscus reaches the lower sensor. The amount of time required for the meniscus to travel from the upper sensor to the lower sensor is called the WBC Count Time and is measured in seconds. At the end of the count cycle, the measured count time is compared to the pre-defined reference count time. If the former is less than or greater than the latter by 2 seconds or more, the analyzer will report a WBC bubble or WBC Clog error. Seeing the error message, you may refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.

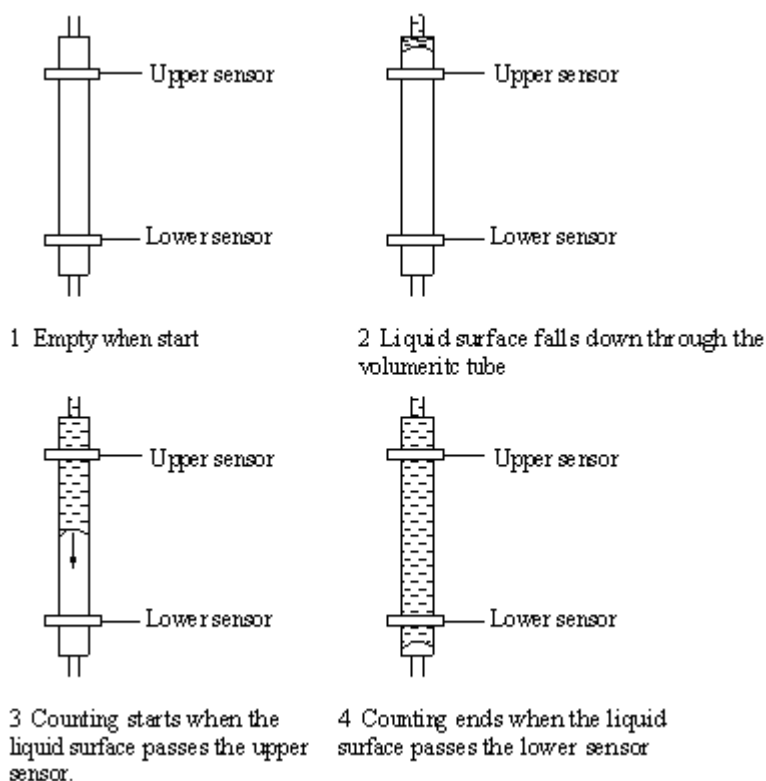


Figure 3-3 Volumetric metering process

### 3.4.2 Measurement Principles

#### ■ WBC measurement

WBCs are counted and sized by the Impedance method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated indicates the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle. Each pulse is amplified and compared to the internal reference voltage channels, which only accepts the pulses of a certain amplitude. If the pulse generated is above the WBC threshold, it is counted as a WBC.

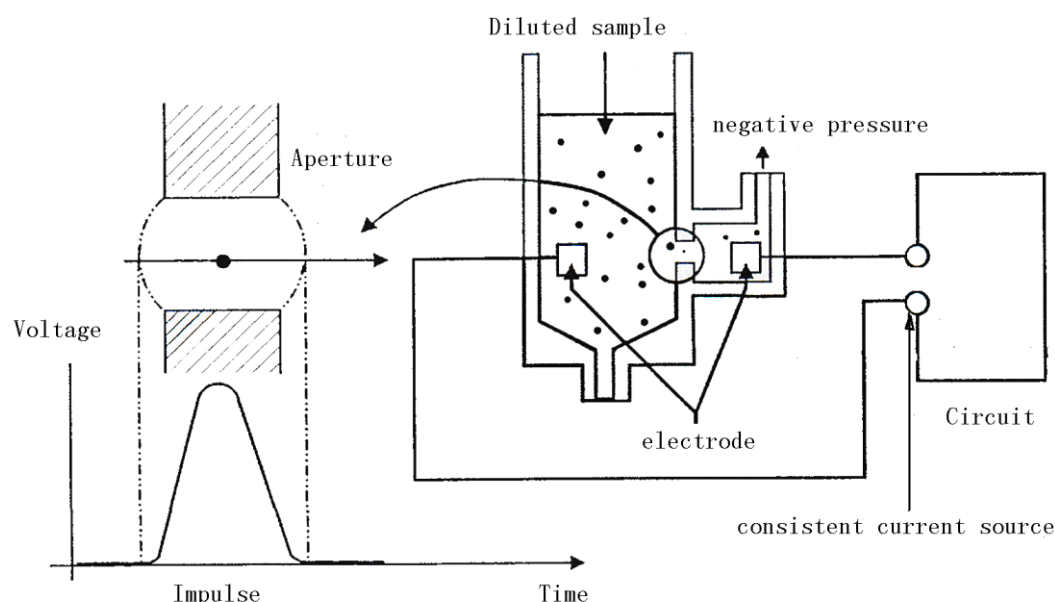


Figure 3-4

#### ■ HGB measurement

HGB is determined by the colorimetric method. The WBC/HGB dilution is delivered to the WBC bath where it is bubble mixed with a certain amount of lyse, which converts hemoglobin to a hemoglobin complex that is measurable at 525-535 nm. An LED is mounted on one side of the bath and emits a beam of light, which passes through the sample and a 525-535nm filter, and then is measured by a photo-sensor that is mounted on the opposite side. The signal is then amplified and the voltage is measured and compared to the blank reference reading (readings taken when there is only diluent in the bath). The HGB is calculated per the following equation and expressed in g/L.

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



### 3.4.3 Derivation of WBC-Related Parameters

#### ■ WBC

WBC ( $10^9/L$ ) is the number of leukocytes measured directly by counting the white blood cells passing through the aperture. Note that NRBCs do not react with the lyse and can be mistaken by the analyzer for white blood cells. If you observe NRBCs in the microscope, correct the system-generated result by the following formula,

$$WBC' = WBC \times \frac{100}{100 + NRBC}$$

where WBC represents the system-generated white cell number, NRBC the number of NRBCs counted in 100 white cells and WBC' the corrected white cell number.

#### ■ WBC differentia

With the help of the diluent and lyse, this analyzer can size the white cells into three sub-populations - lymphocytes, mid-sized cells (including monocytes, basophils and eosinophils ) and granulocytes. Based on the WBC histogram, this analyzer calculates Lymph%, Mid% and Gran% as follows and express the results in percent.

$$Lymph\% = \frac{PL}{PL + PM + PG} \times 100$$

$$Mid\% = \frac{PM}{PL + PM + PG} \times 100$$

$$Gran\% = \frac{PG}{PL + PM + PG} \times 100$$

where PL = particles in the lymphocyte region ( $10^9/L$ )

PM = particles in the mid size region ( $10^9/L$ )

PG = particles in the granulocyte region ( $10^9/L$ ).

Having achieved the three parameters above, this analyzer proceeds to calculate the Lymph#, Mid# and Gran# per the following equations and express them in  $10^9/L$ .

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

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

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

■ WBC histogram

Besides the parameters mentioned above, this analyzer also presents a WBC histogram, whose x-coordinate represents the cell volume (fL) and y-coordinate represents the number of the cells. The histogram is presented in the Analysis area of the “**Analysis**” screen when the analysis is done. You may also review the histograms of the stored patient results (see **Chapter 7 Reviewing Sample Results**).

### 3.4.4 HGB

Using the colorimetric method, this analyzer calculates hemoglobin concentration (g/L) as follows.

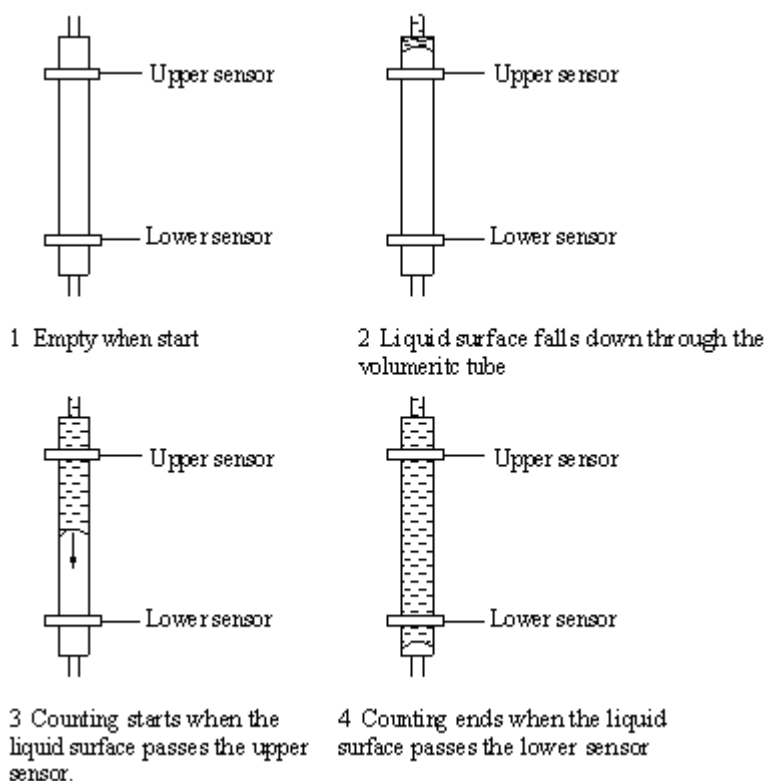
$$\text{HGB(g/L)} = \text{Constant} \times \text{Log}_{10} (\text{Blank Photocurrent} / \text{Sample Photocurrent})$$

## 3.5 RBC/PLT Measurement

### 3.5.1 Volumetric Metering

An accurate cell count cannot be obtained unless the precise volume of diluted sample that passes through the aperture during the count cycle is known. This analyzer uses a volumetric metering unit to control the count cycle and to ensure that a precise volume of sample is analyzed for the measurement.

The metering unit controlling the RBC/PLT count cycle consists of a metering tube with two optical sensors mounted on it. This tube ensures that a precise amount of diluted sample is measured during each count cycle. The exact amount is determined by the distance between the two optical sensors. The rinse is used to create a meniscus in the metering tube. The count cycle starts when the meniscus reaches the upper sensor and stops when the meniscus reaches the lower sensor. The amount of time required for the meniscus to travel from the upper sensor to the lower sensor is called the RBC Count Time and is measured in seconds. At the end of the count cycle, the measured count time is compared to the pre-defined reference count time. If the former is less than or greater than the latter by 2 seconds or more, the analyzer will report a RBC bubble or RBC Clog error. Seeing the error message, refer to **Chapter 11 Troubleshooting** for solutions.



**Figure 3-5 Volumetric metering process**

### 3.5.2 Measurement Principles

#### ■ RBC/PLT measurement

RBCs/PLTs are counted and sized by the Impedance method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions. An electrode is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses generated indicates the number of particles that passed through the aperture. The amplitude of each pulse is proportional to the volume of each particle. Each pulse is amplified and compared to the internal reference voltage channels, which only accepts the pulses of a certain amplitude. If the pulse generated is above the RBC/PLT lower threshold, it is counted as an RBC/PLT.

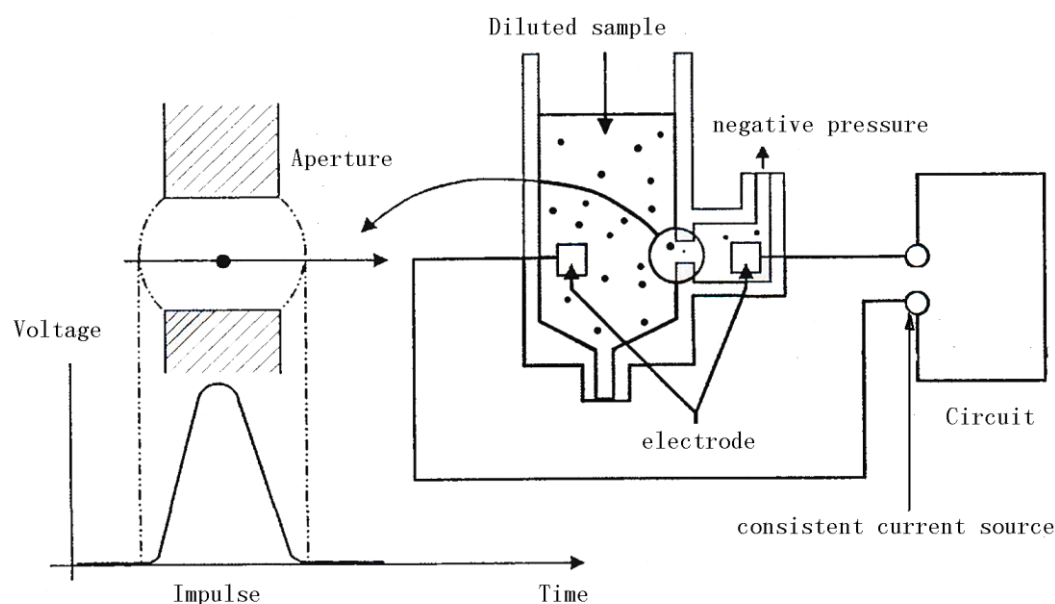


Figure 3-6

### 3.5.3 Derivation of RBC-Related Parameters

#### ■ RBC

RBC ( $10^{12}/L$ ) is the number of erythrocytes measured directly by counting the erythrocytes passing through the aperture.

■ MCV

Based on the RBC histogram, this analyzer calculates the mean cell volume (MCV) and expresses the result in fL .

This analyzer calculates the HCT (%), MCH (pg) and MCHC (g/L) as follows:

This analyzer calculates the HCT (%), MCH (pg) and MCHC(g/L) as follows:

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

$$\text{MCH} = \frac{\text{HGB}}{\text{RBC}}$$

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

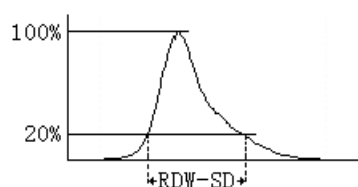
Where the RBC is expressed in  $10^{12}/\text{L}$ , MCV in fL and HGB in g/L.

■ RDW-CV

Based on the RBC histogram, this analyzer calculates the CV (Coefficient of Variation) of the erythrocyte distribution width.

■ RDW-SD

RDW-SD (RBC Distribution Width – Standard Deviation, fL) is set on the 20% frequency level with the peak taken as 100%, Figure 3-7 shows.



**Figure 3-7**

■ RBC Histogram

Besides the parameters mentioned above, this analyzer also presents a RBC histogram, whose x-coordinate represents the cell volume (fL) and y-coordinate represents the number of the cells. The histogram is presented in the Analysis area of the “Analysis” screen when the analysis is done. You may also review the histograms of the stored patient results (see **Chapter 7 Reviewing Sample Results**).

### 3.5.4 Derivation of PLT-Related Parameters

- PLT

PLT ( $10^9/L$ ) is measured directly by counting the platelets passing through the aperture. .

- MPV

Based on the PLT histogram, this analyzer calculates the mean platelet volume (MPV, fL).

- PDW

Platelet distribution width (PDW) is the geometric standard deviation (GSD) of the platelet size distribution. Each PDW result is derived from the platelet histogram data and is reported as 10(GSD).

- PCT

This analyzer calculates the PCT as follows and express it in %.

Where the PLT is expressed in  $10^9/L$  and the MPV in fL.

$$PCT = \frac{PLT \times MPV}{10000}$$

- PLT Histogram

Besides the parameters mentioned above, this analyzer also presents a PLT histogram, whose x-coordinate represents the cell volume (fL) and y-coordinate represents the number of the cells. The histogram is presented in the Analysis area of the “**Analysis**” screen when the analysis is done. You may also review the histograms of the stored patient results (see **Chapter 7 Reviewing Sample Results**).

## **3.6 Wash**

After each analysis cycle, each element of the analyzer is washed.

- The sample probe is washed internally and externally with diluent;
- The WBC bath is washed with diluent and rinse;
- The RBC/PLT bath is washed with diluent and rinse;
- The metering tube is washed with rinse.





# 4 Installing Your Analyzer

---

---

## 4.1 Introduction

This chapter introduces the installation procedure of the BC-3600. To ensure all system components function correctly and to verify system performance, a Mindray-authorized representative will handle the installation and initial software setup.

---

### **▲WARNING**

- **Installation by personnel not authorized or trained by Mindray may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of Mindray-authorized personnel.**
-

## 4.2 Installation Requirements

Before installation, you need to ensure that the following space, power, environmental and fuse requirements are met.

### 4.2.1 Space Requirements

Check the site for proper space allocation. In addition to the space required for the analyzer itself, arrange for

- at least 30 cm on each side, which is the preferred access to perform service procedures.
- at least 10 cm behind the analyzer for cabling and ventilation.
- enough room on and below the countertop to accommodate the reagents and waste containers.
- The countertop (or the floor) that accommodates the analyzer system shall be able to withstand a weight of at least 43Kg.

### 4.2.2 Power Requirements

#### **⚠ WARNING**

- Connect only to a properly earth grounded outlet.
- Before turning on the analyzer, make sure the input voltage meets the requirements.

#### **⚠ CAUTION**

- Using pinboard may bring the electrical interference and the analysis results may be unreliable. Please place the analyzer near the electrical outlet to avoid using the pinboard.
- Please use the original power cable shipped with the analyzer. Using other power cable may damage the analyzer or cause unreliable analysis results.

	Voltage	Input power	Frequency
<b>Analyzer</b>	(100V-240V~)±10%	≤180 VA	(50/60Hz)±1Hz

### 4.2.3 General Environment

- Optimal operating temperature: 15 °C - 30 °C
- Optimal operating humidity: 30% - 85%
- Running temperature: 15 °C - 35 °C
- Running humidity: 30% - 85%
- Atmospheric pressure: 70.0 kPa - 106.0 kPa

The environment shall be as free as possible from dust, mechanical vibrations, loud noises, and electrical interference. Do not place the analyzer in direct sunlight or in front of a source of heat or drafts. Do not use this analyzer in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation. It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer. Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close. The environment shall be ventilated. Only use this analyzer indoors.

---

#### **⚠ WARNING**

- Do not place the analyzer in a flammable or explosive environment.
- 

---

#### **NOTE**

- If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.
- 

### 4.2.4 Fuse requirement

---

#### **⚠ WARNING**

- Only install fuses of specified specification on the analyzer.
- 

Fuse specification: 250V T3.15AH

## 4.3 Unpacking

### 4.3.1 Unpacking and Inspecting the Analyzer

Your analyzer is tested before it is shipped from the factory. International symbols and special handling instructions tell the carrier how to treat this electronic instrument. When you receive your analyzer, carefully inspect the carton. If you see any signs of mishandling or damage, contact Mindray or your local distributor immediately.

- Place the carton on the floor upright with the arrows on the side upwards;
- Remove the tape and take out the accessory box. Check the accessories against the packing list. Notify Mindray customer service department or your local distributor immediately if you find anything missing.

Remove the top protective foam and the four corner supports. Have another person help you lift the instrument off the pedestal, and set it on the countertop.

### 4.3.2 Carrying or Moving the Analyzer

- Be sure to perform "Drain Tubing" operation and shut down the analyzer before you move it;
- For short-distance moving on a smooth ground, you may use a trolley to facilitate the transportation.
- The analyzer must be moved by two operators working together.
- During the moving process, protect the LCD and the sample probe from excessive force and from contact with other objects;
- Keep the analyzer upright during the moving process. Do not tilt or incline it.
- Do your best to minimize the mechanical shock when moving the analyzer. After a long-distance moving, check and tune the analyzer before using it.

---

#### **⚠ WARNING**

- **If your analyzer has been used for a while, when moving the analyzer, the operators must wear proper personal protective equipment (e.g. gloves, lab coat, etc.).**
-

## 4.4 Installation Procedure

---

### **⚠ WARNING**

- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
  - The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
- 

### 4.4.1 Releasing Sample Probe

Before the analyzer is shipped out, the sample probe is fixed by a plastic cable tie. After unpacking the analyzer, you need to release the sample probe as follows:

- Open the front cover.
- Cut the plastic cable tie to release the probe (see the following picture).

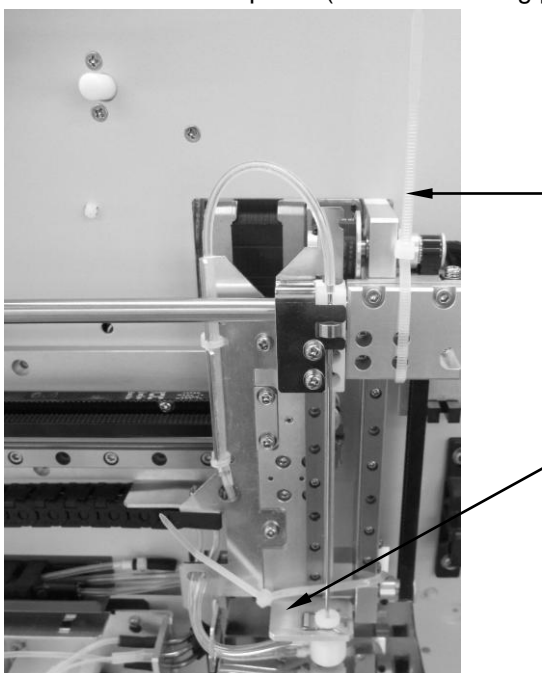


Figure 4-1 Cut the Plastic Cable Tie

- Close the front cover.

### 4.4.2 Connecting Reagent Containers

**⚠ WARNING**

- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
  - The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
  - If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.
- 

**⚠ CAUTION**

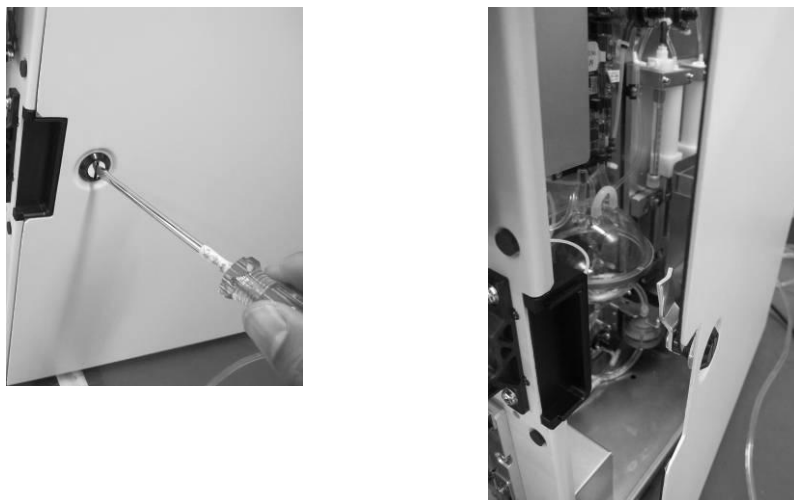
- Do not place reagents on or above the analyzer.
- 

**NOTE**

- Use the manufacturer-specified reagents.
  - After installing a new container of reagent, let it equilibrate at room temperature for a few minutes before using.
  - Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.
  - To avoid contamination; ensure the container caps are closed and sealed properly.
- 

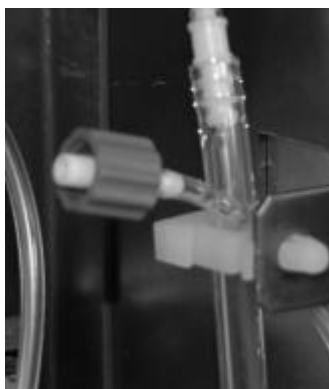
To prevent contamination of the fluidic system, a plastic cap is installed on each fluidic fitting of analyzer. Take off these caps by unscrewing them before connecting reagent containers and keep them in a safe place for future transportation.

- Connecting lyse container
  1. Rotate the lockhole on the right door with a slotted head screwdriver to open the door, see Figure 4-2.



**Figure 4-2**

2. Open the right door, you will see an orange fitting as Figure 4-3 shows.



**Figure 4-3**

3. Take out the lyse CAP component from the accessory kit, open the lyse container, put the pickup tube into the lyse container and rotate the cap clockwise until it is secured.

Place the lyse container on top of the shelf and connect the orange connector to the orange fitting. See Figure 4-4.



**Figure 4-4**

■ Connecting diluent container

1. Take out the diluent pickup tube (the one with a green fluidic connector) from the accessory kit.
2. Take out the diluent container and place it on or below the countertop.
3. Remove the container cap and insert the double-pronged end of the tube into the diluent container and tighten the cap until it is properly secured.



**Figure 4-5**

4. Locate the green fitting, marked "DILUENT", in the lower right corner of the back of the analyzer. Plug the green connector of the tube into the fitting and turn it clockwise until properly secured.





**Figure 4-6**

■ Connecting rinse container

1. Take out the rinse pickup tube (the one with a blue fluidic connector) from the accessory kit.
2. Take out the rinse container and place it on the countertop where the analyzer is placed or a countertop of the same level.
3. Remove the container cap and insert the double-pronged end of the tube into the rinse container and tighten the cap until it is properly secured.



**Figure 4-7**

4. Locate the blue fitting, marked "RINSE", in the lower right corner of the back of the analyzer. Plug the blue connector of the tube into the fitting and turn it clockwise until it is properly secured.



**Figure 4-8**

- Connecting waste container
  1. Take out the waste tube (the one with a red connector) from the accessory box.
  2. Locate the red fitting, marked "WASTE", in the lower right corner of the back of the analyzer. Plug the red connector of the tube into the fitting and turn it clockwise until it is properly secured.



**Figure 4-9**

3. Prepare a container to receive the waste and place it below the countertop.
4. Insert the waste tube into the waste container.

### 4.4.3 Installing Recorder Paper

---

**NOTE**

- Remove the protective paper between the recorder head and the roller inside the recorder before installing recorder paper.
-

Follow the procedure below to install the recorder paper.

1. Use the latch at the upper right corner of the recorder door to pull the door open.
2. Insert a new roll into the compartment as shown below.
3. Close the recorder door.
4. Check if paper is installed correctly and the paper end is feeding from the top.

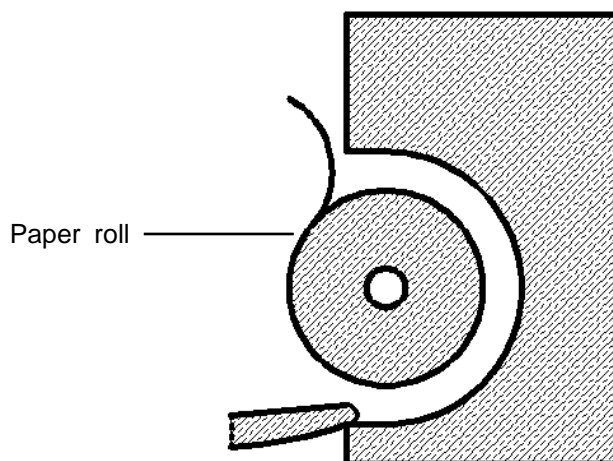


Figure 4-10 Installing Recorder Paper

---

**⚠ CAUTION**

- Use only specified recorder paper. Otherwise, it may cause damage to the recorder head, or the recorder may be unable to print, or poor print quality may result.
- Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.
- Do not leave the recorder door open unless you are installing paper or removing error.
- Improper installation of recorder paper may jam the paper and/or result in blank printout.

---

#### 4.4.4 LIS System Connection Description

BC-3600 can be connected to the data management software in your PC (LIS system) via the Ethernet port or the RS232 serial port. The data management software package contains the network cable and serial port cable. The serial port cable is a 9-pin direct-connected cable with 2 female plugs.

The serial port of the analyzer is a 9-pin male interface. See Figure 1 and Table 1 for the definition of the pins.

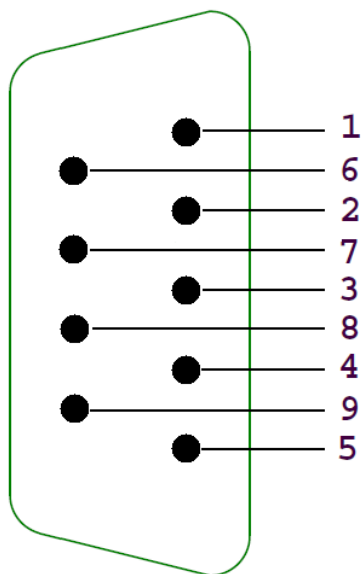


Figure 4-11 Signal description of the 9-pin serial port of the analyzer

Table 4-1 Signal definition of the 9-pin serial port of the analyzer

Pin	Signal Definition	Function	Input/Output
2	TXD	Send serial port data	Output
3	RXD	Receive serial port data	Input
5	GND	Ground	-
7	CTS	Allow data sending	Input
8	RTS	Request data sending	Output
1, 4, 6, 9	-	-	-

## 4.5 Starting the Analyzer

Take out the power cord from the accessory box. Plug the non-pronged end into the AC input at the back of the analyzer and the pronged end into a power outlet.

Place the power switch at the back of the analyzer in the ON position (I) to turn on the analyzer. The indicator light will be on and the screen will display "Initializing...". The analyzer will perform self-test and initialization. During the initialization process, a progress bar will show at the bottom with message on its top prompting "Initializing...", "Cleaning...", etc. The whole process lasts 3 to 5 minutes. After initialization completes, the analyzer will provide touch screen manual calibration procedure (See **10.8 Touch Screen Calibration**). Then the main screen will display and the login dialog box will display. You may enter the username and password to go to the sample analysis screen. The result of background checked will be displayed on the screen.

---

### **NOTE**

- **Running sample with the background abnormal error present will lead to unreliable results.**
-



# **5 Customizing the Analyzer Software**

---

## **5.1 Introduction**

The BC-3600 is a flexible laboratory instrument that can be tailored to your work environment.

The screen you see after the first startup is defaulted.

This chapter tells you how to customize analyzer software in the order of a menu option.

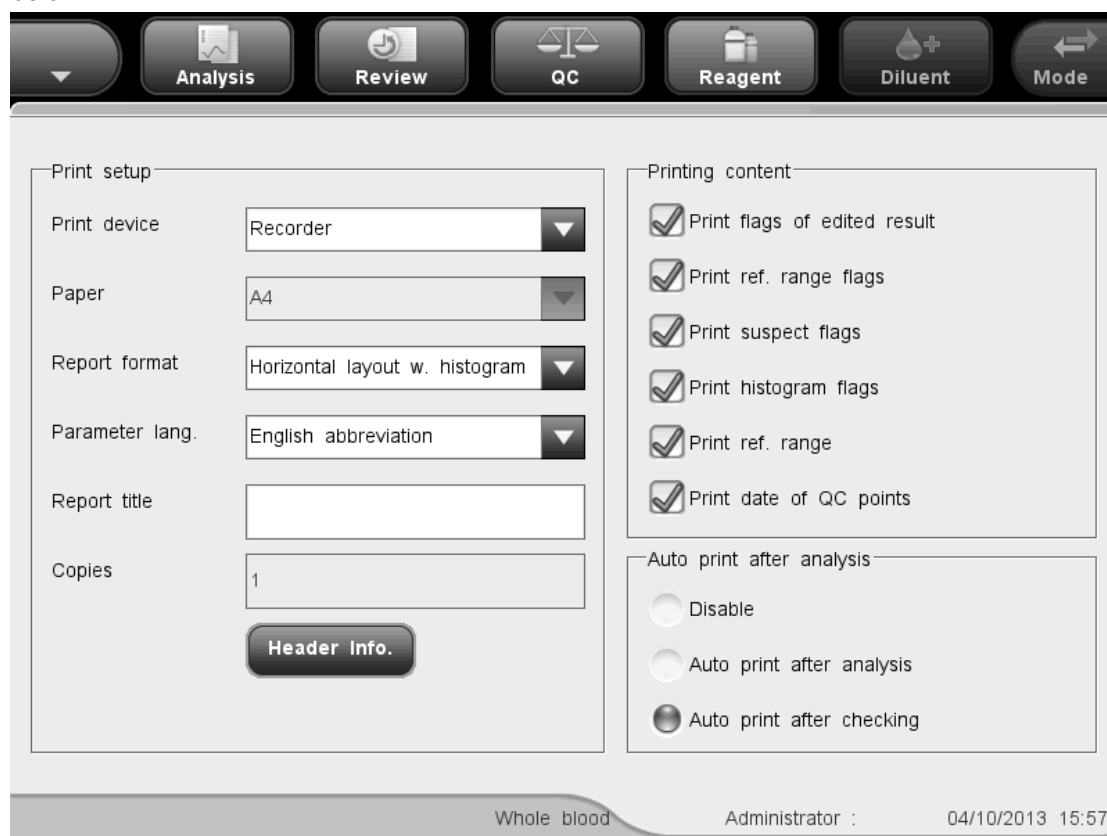
## 5.2 System setup

System setup options include "Print", "Transmission", "Date/Time", "Gain", "Ref. range", "Parameter units", "Lab info." and "Shortcut code". Read the following contents to understand how to set up each option.

### 5.2.1 Print

The option allows you to select printing device, format, etc.. Common users and administrators are all allowed to set up this option.

Click the menu option "Setup"→"System Setup"→"Print" to enter the "Print" screen as shown below.



**Figure 5-1 "Print" screen**

See the following setup procedure:

- **Setting up printing device**

Select printing device from the "Print device" pull-down list. You may select either the built-in recorder (default setting) or an external printer (if available) as the printing device. If "Printer" is selected, you may go on to set up "Paper", "Copies" and printer drive.



- Setting up paper type

Select paper type from the "Paper" pull-down list. You may select A4, A5, Continuous, or Letter paper.

- Setting up number of copies

Enter the number of copies to be printed for each report into the edit box "Copies". The maximum number is 100 and the default number is 1.

- Setting up printer drive

When you select printer as printing device, the "Printer" pull-down list will be displayed at the bottom of the screen. Select "Auto Identification" (default setting) or "PCL6" from the list.

If you select "Auto Identification", the analyzer will automatically identify the supported models of printers, like the HP ink-jet and laser printers, and Epson stylus printers (the printer models vary in different regions, and are updated rapidly, so please consult Mindray customer service department or you local distributors for the supported printer models).

If you select "PCL6", the analyzer will not identify the model of the printer inserted, but output printer drive of PCL6 format instead, which is applicable for all laser printers that support PCL6. Currently, brands like HP, Lexmark, Lenovo and OKI all have launched printers supporting PCL6 drive. You may consult the printer dealer for more details when you are purchasing your printer.

- Setting up report format

Select print format from the "Report format" pull-down list.

If you select "Printer" as the printing device, the following formats are available: One page with histogram, One page without histogram, Half page with histogram, and Half page without histogram (for A5, Continuous and Letter paper, the half-page formats are not available). The default format is "One page with histogram".

If you select "Recorder" as the printing device, the following formats are available: Horizontal layout with histogram, Horizontal layout without histogram, Vertical layout with histogram, and Vertical layout without histogram. The default format is "Horizontal layout with histogram".

- Setting up parameter language

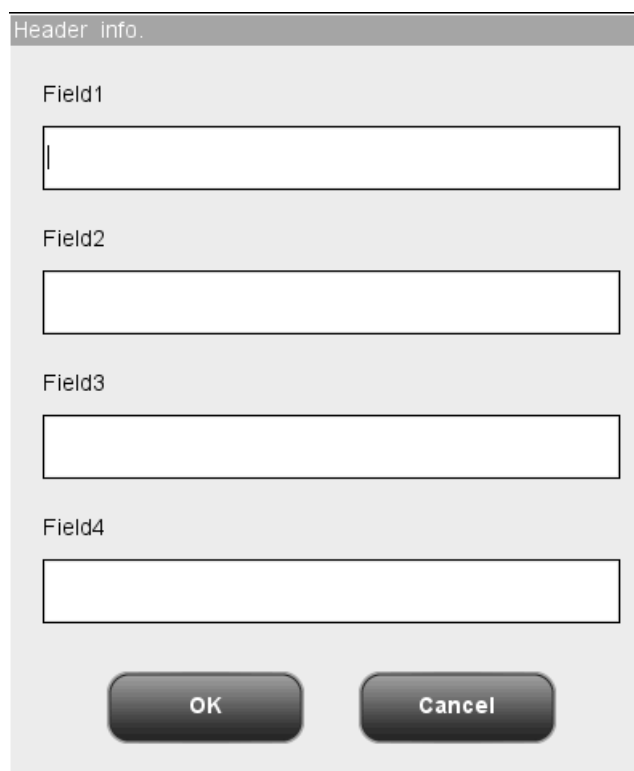
The parameter language provided is "English abbreviation"

- Setting up report title

Enter title of the report into the "Report title" box; the maximum number of characters allowed is 60.

- Setting up header info.

Click the "Header Info." Button, the following dialog box will be displayed. You may set up the information to be displayed on the header of the report.



**Figure 5-2 "Header info." Dialog Box**

■ **Printing flags for edited results**

You may select whether to print out the flags for edited results in the report.

Activate this function to print reports with flags for edited results. ("E" or "e").

Deactivate this function to print reports without flags for edited results. ("E" or "e").

Click the "Print flags for edited results" check box to activate it. Click the check box again to deactivate it.

■ **Printing ref. range flags**

You may select whether to print out the ref. range flags in the report.

Activate this function to print reports with ref. range flags ("H" or "L").

Deactivate this function to print reports without ref. range flags ("H" or "L").

Click the "Print ref. range flags" check box to activate it. Click the check box again to deactivate it.

■ **Printing suspect flags**

You may select whether to print out the suspect flags in the report.

Activate this function to print reports with suspect flags. ("R").

Deactivate this function to print reports without suspect flags. ("R").

Click the "Print suspect flags" check box to activate it. Click the check box again to deactivate it.

■ Printing histogram flags

You may select whether to print out the histogram flags in the report.

Activate this function to print reports with histogram flags("R<sub>1</sub>", "R<sub>2</sub>", "R<sub>3</sub>", "R<sub>4</sub>" or "R<sub>m</sub>").

Deactivate this function to print reports without histogram flags("R<sub>1</sub>", "R<sub>2</sub>", "R<sub>3</sub>", "R<sub>4</sub>" or "R<sub>m</sub>").

Click the "Print histogram flags" check box to activate it. Click the check box again to deactivate it.

■ Printing ref. range

You may select whether to print out the ref. range in the report.

Activate this function to print reports with ref. ranges.

Deactivate this function to print reports without ref. ranges.

Click the "Print ref. range" check box to activate it. Click the check box again to deactivate it.

■ Printing date of L-J QC points

You may select whether to print out the date of L-J QC points in the report.

Activate this function to print L-J QC graph with date of QC points.

Deactivate this function to print L-J QC graph without date of QC points.

Click the "Print date of QC points" check box to activate it. Click the check box again to deactivate it.

■ Auto print

You may select whether to print out the report automatically after analysis or after checking.

The default setting of the analyzer disables auto print, you may click the "Auto print after analysis" or "Auto print after checking" radio button to activate the corresponding function.

Click the radio button again to deactivate it.

■ Exiting the "Print" screen

To exit the "Print" screen, click menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the changes and switch to the corresponding screen. Click "No" to abort the changes and switch to the corresponding screen.



Figure 5-3 Save Changes Dialog Box

## 5.2.2 Transmission

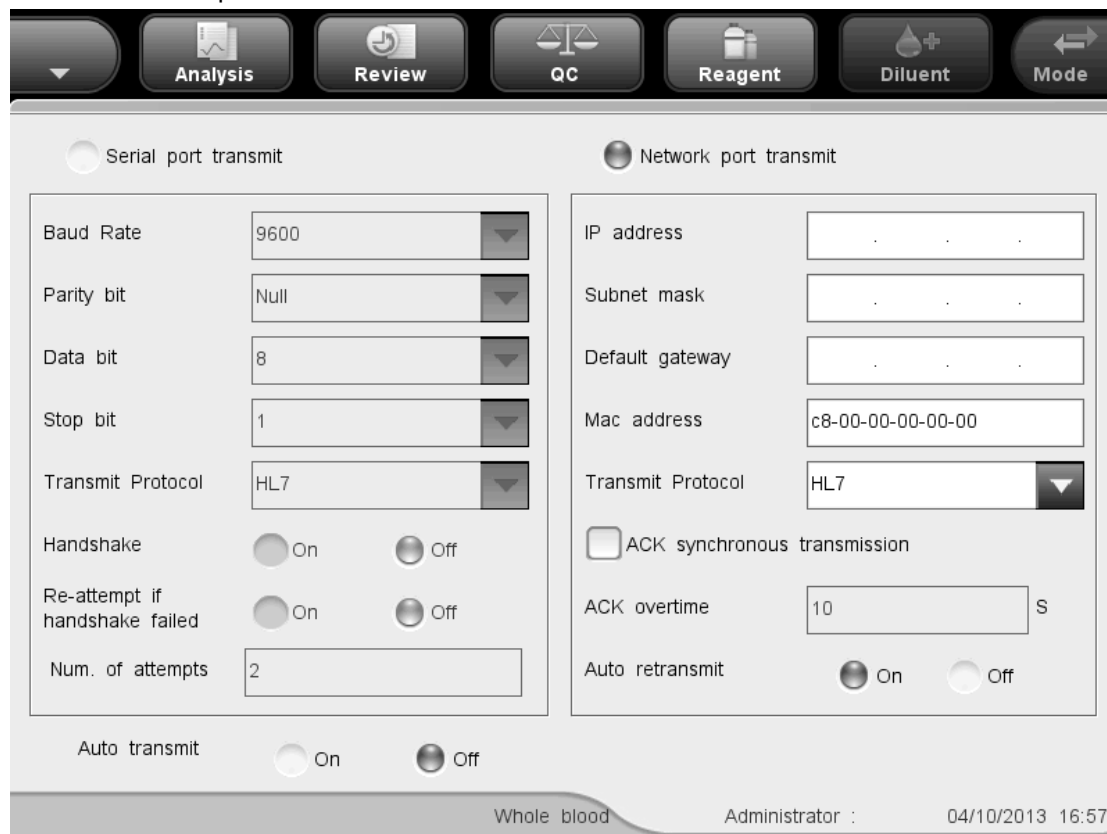
The "Transmission" screen is where you set transmit parameters. Common users are not

allowed to edit transmit settings.

**NOTE**

- If transmission is going on, you will not be able to edit transmit settings.

Click the menu option "Setup"→"System Setup"→"Transmission" to enter the following transmission setup screen.



**Figure 5-4 Transmission Setup Screen**

Do as follows to set up transmission parameters:

- Set up transmit type

Two transmit types are available: serial port transmit and network port transmit.

Click the radio button before the two options to select the corresponding transmit type. The default type is network port transmit.

- Serial port transmit settings

Selecting baud rate

You may select from "19200", "9600", "4800", "2400" and "1200", the default option is "9600". Click the "Baud rate" pull-down list to select one of the options.

#### Selecting parity

Three parity options are available: "Odd", "Even" and "None". The default option is "None". Click the "Parity" pull-down list to select one of the options.

#### Data bit

Two options are available: "7" and "8", the default option is "8". Click the "Data bit" pull-down list to select one of the options.

#### Stop bit

Three options are available: "None", "1" and "2", the default option is "1". Click the "Stop bit" pull-down list to select one of the options.

#### Transmit protocol

Under the "Serial port transmit" mode, you may select from 5 transmit protocols, which are 8ID, 10ID, 15ID, 15ID+2 and HL7.

#### Handshake

When "8ID" or "10ID" is selected, the "Handshake" box is activated, you may select to enable or disable handshake; if any other transmit protocol is selected, the "Handshake" box is deactivated, and handshake is enabled by default.

#### Re-attempt if handshake failed

When "Handshake" is activated, you may select "On" or "Off" to enable or disable "Re-attempt if handshake failed".

#### Num. of attempts

Enter the number of attempts after handshake failed into the "Num. of attempts" edit box.

#### ■ Network port transmit settings

Enter the legitimate addresses into the "IP address", "Subnet mask" and "Default gateway" boxes, the "Mac address" box cannot be edited.

#### Set up transmit protocol

Under the "Network port transmit" mode, you may select from 3 transmit protocols, which are 15ID, 15ID+2 and HL7. Click the "Transmit protocol" pull-down list to select one of the options.

#### ACK synchronous transmission

When HL7 transmit protocol is selected, you may choose to turn on the "ACK synchronous transmission". When the "ACK synchronous transmission" is on, you may set up the ACK overtime (S).

#### Auto retransmit

Select "On" or "Off" to enable or disable the automatic retransmit after network reconnection.

- Auto transmit

When the "Auto transmit," function is "On", the analyzer will send results to the external computer automatically; when the function is "Off", the analyzer will not send results to the external computer automatically. Click the "On" or "Off" radio button to select one of the options.

- Exiting the screen

To exit the "Transmit" screen, click a menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the changes and switch to the corresponding screen. Click "No" to abort the changes and switch to the corresponding screen.

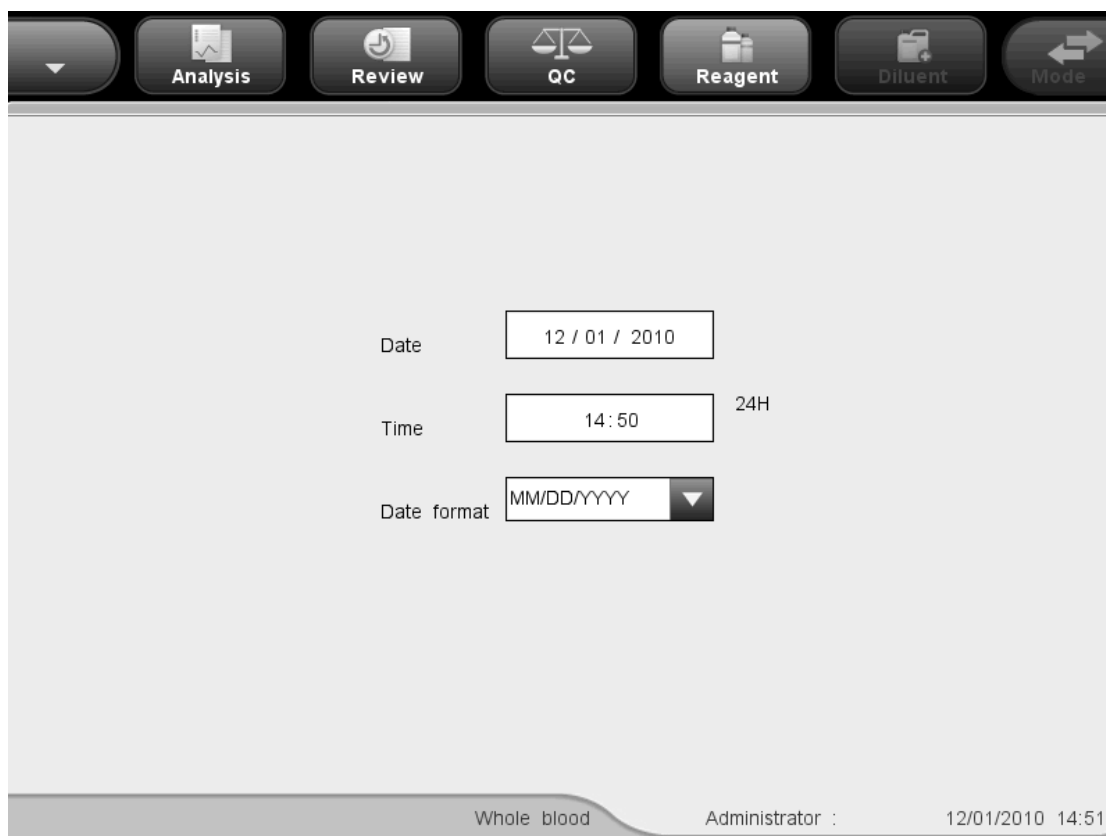


**Figure 5-5 Save Changes Dialog Box**

### 5.2.3 Date/Time

You may customize the date, time and the date format of the analyzer. The date and time on the screen and the printout will change if the settings are changed. Only administrators are allowed to edit date/time settings.

Click the menu option "Setup"→"System Setup"→"Date/Time" to enter the "Date/Time" screen as shown below.



**Figure 5-6 "Date/Time" Screen**

See the following setup procedure:

- Setting up system date

Click the "Date" box to enter system date.

If the year you entered is out of the range 2000 – 2036, a dialog box will display when you save the settings reminding you of invalid input. You need to re-enter a valid year before saving the settings.

- Setting up system time

Click the "Time" box to enter system time.

- Setting up date format

There are date formats: "YYYY-MM-DD", "MM-DD-YYYY" and "DD-MM-YYYY". Click the "Date format" pull-down list to select one of the formats.

- Exiting the "Date/Time" screen

To exit the "Date/Time" screen, click menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the changes and switch to the corresponding screen. Click "No" to abort the changes and switch to the corresponding screen.



**Figure 5-7 Save Changes Dialog Box**

## 5.2.4 Ref. range

The "Ref. range" screen is where you view and set the high and low limits for your patients. The analyzer flags any parameter value above (H) or below (L) these limits.

This analyzer divides patients into 5 demographic groups: General, Adult Male, Adult Female, Pediatric and Neonate. See the following table for details.

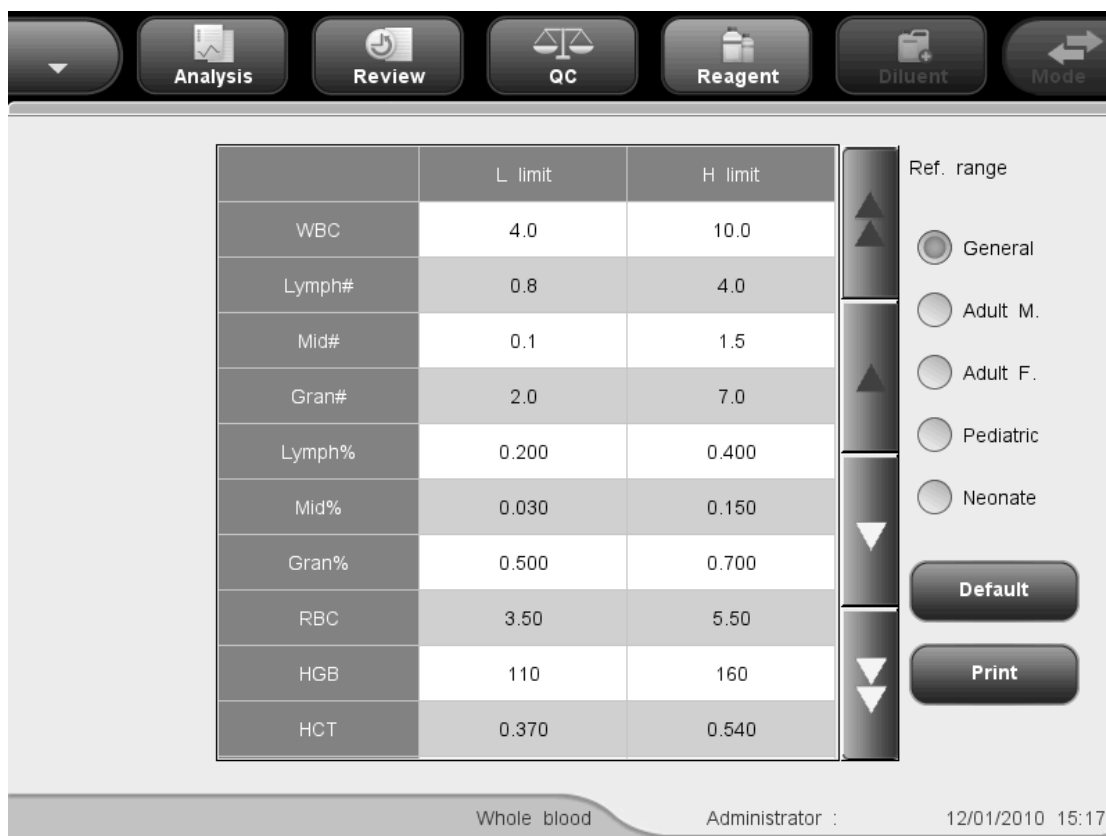
**Table 5-1 Reference Groups**

Group	Gender	Age
General	No input, male, female	No input
	No input	13 < Age ≤ 999
Adult M.	Male	13 < Age ≤ 999
Adult F.	Female	13 < Age ≤ 999
Pediatric	Male, female	28 days < Age ≤ 13
Neonate	Male, female	0 hour < Age ≤ 28 days

Only administrators can edit ref. range settings.

Click the menu option "Setup" → "System Setup" → "Ref. range" to enter the "Ref. range" screen as shown below.





**Figure 5-8 "Ref. range" Screen**

■ **Setting up ref. range**

See the following setup procedure (e.g. "General"):

1. Click "General" at the "Ref. range" combo box.
2. Click the "H limit" or "L limit" of the parameter you want to customize.
3. Enter the desired numbers.
4. When switching reference group after editing of "General" completes, system will identify the validity of its settings.
5. If you want to restore the factory default after the editing, click the "Default" button on the screen, the following dialog box will display. Click "Yes" to restore the factory default settings; click "No" to close the dialog box without restoring the factory default settings.



**Figure 5-9 Restore Default Dialog Box**

- Printing ref. range

Click "Print" button on the screen to print the reference range of the current group.

- Exiting the "Ref. range" screen

To exit the "Ref. range" screen, click a menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the changes and switch to the corresponding screen. Click "No" to abort the changes and switch to the corresponding screen.



**Figure 5-10 Save Changes Dialog Box**

## 5.2.5 Parameter units

The "Parameter Units" screen is where you view and set the reporting units of the parameters. Common users are only allowed to view the screen, to edit the units, you need the administrator level.

You may customize parameter units or select a whole set of pre-defined units.

### Customizing parameter units

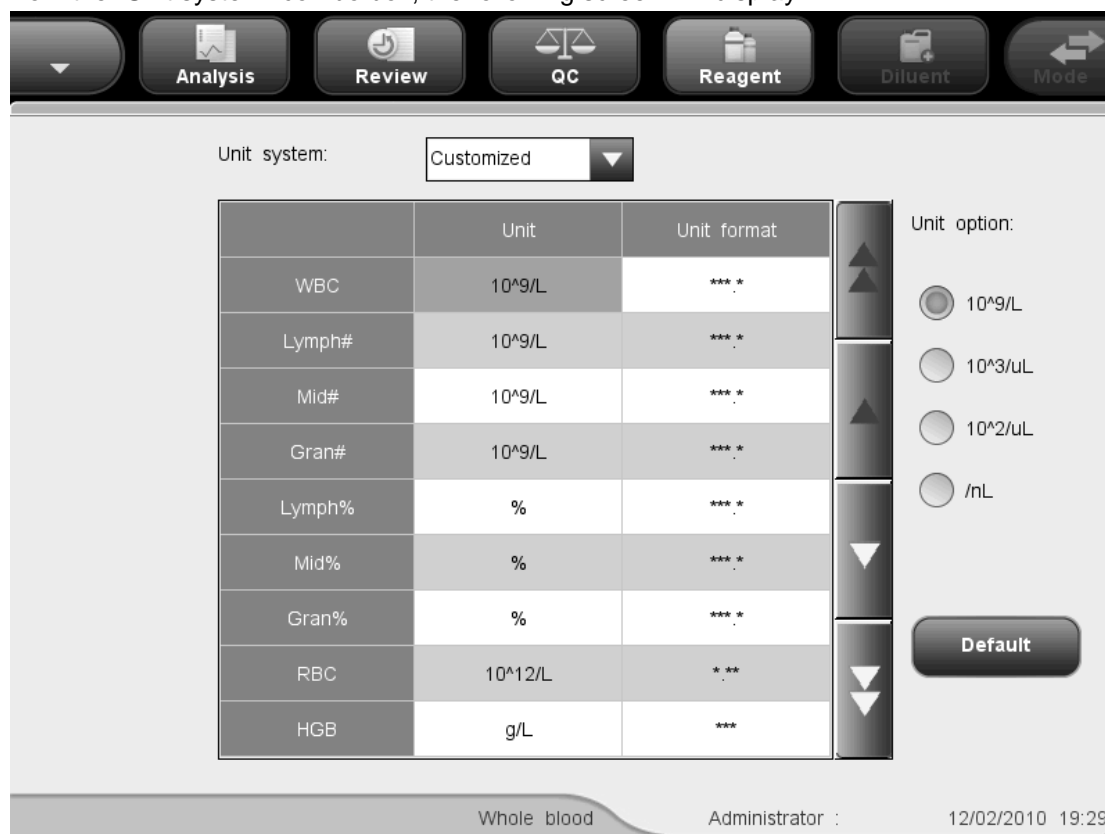
Under the "Customized" option, the default unit of each parameter is the one on top of the list. The parameters are classified into groups per their units. WBC, Lymph#, Mid# and Gran# share the same unit; Lymph%, Mid% and Gran% share the same unit; the units of MCV and RDW-SD are the same, and the units of PLT and P-LCC are also the same.

Note that if you choose g/L or g/dL for the HGB/MCHC group, the MCH unit will automatically change to pg and its reporting format will be **\*\*\*.\***; if you choose mmol/L for the HGB/MCHC group, the MCH unit will automatically change to fmol and its reporting format will be **\*\*.\*\***. See the following table for the available parameter units under the "Customized" option.

**Table 5-2 Customize Parameter Units**

Parameter group	Reporting format	Unit	Remark.
WBC	***.*	10 <sup>9</sup> /L	Default unit
Lymph#	***.*	10 <sup>3</sup> /μL	
Mid#	****	10 <sup>2</sup> /μL	
Gran#	***.*	/nL	
Lymph%	*.***	None	Default unit
Mid%	***.*	%	
Gran%	***.*	%	
HGB	***	g/L	Default unit
	**.*	g/dL	
	**.*	mmol/L	
MCHC	****	g/L	Default unit
	***.*	g/dL	
	***.*	mmol/L	
MCH	***.*	pg	Default unit
	**.**	fmol	
RBC	*.**	10 <sup>12</sup> /L	Default unit
	*.**	10 <sup>6</sup> /μL	
	***	10 <sup>4</sup> /μL	
	*.**	/pL	
HCT	.***	None	Default unit
	*.***	L/L	
	***.*	%	
MCV, RDW-SD	***.*	fL	Default unit
	***.*	um <sup>3</sup>	
RDW-CV	*.***	None	Default unit
	***.*	%	
PLT, P-LCC	****	10 <sup>9</sup> /L	Default unit
	****	10 <sup>3</sup> /μL	
	***.*	10 <sup>4</sup> /μL	
	****	/nL	
MPV	**.*	fL	Default unit
	**.*	um <sup>3</sup>	
PDW	**.*	None	Default unit
PCT	**.**	mL/L	Default unit
	*.***	%	
P-LCR	*.***	None	Default unit
	***.*	%	

Click the menu option "Setup"→"System Setup"→"Parameter Units", select "Customized" from the "Unit system" combo box, the following screen will display.



**Figure 5-11 "Parameter units" Screen**

■ Setting up parameter units

The setup procedure is as follows: select the parameter unit to be edited on the screen and then select unit from the upper right combo box.

Click the "Default" button on the lower right part of the screen, the following dialog box pops up. Click "Yes" to resume the default formats; click "No" to close the dialog box without resuming the default formats.



**Figure 5-12 Resume Default Dialog Box**

**Selecting a set of pre-defined units**

You may select a set of pre-defined units from the "Unit system" combo box. The available options are "China", "International", "USA", "Canada", "Netherlands" and "UK".

■ Exiting the "Ref. range" screen

To exit the "Parameter units" screen, click a menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the changes and switch to the corresponding screen. Click "No" to abort the changes and switch to the corresponding screen.



Figure 5-13 Save Changes Dialog Box

### 5.2.6 Lab Info.

The lab info. setup function allows you to record the analyzer locations for later maintenance. Only administrators are allowed to edit lab info.

Click the menu option "Setup"→"System Setup"→"Lab info." to enter the "Lab info." screen as shown below.

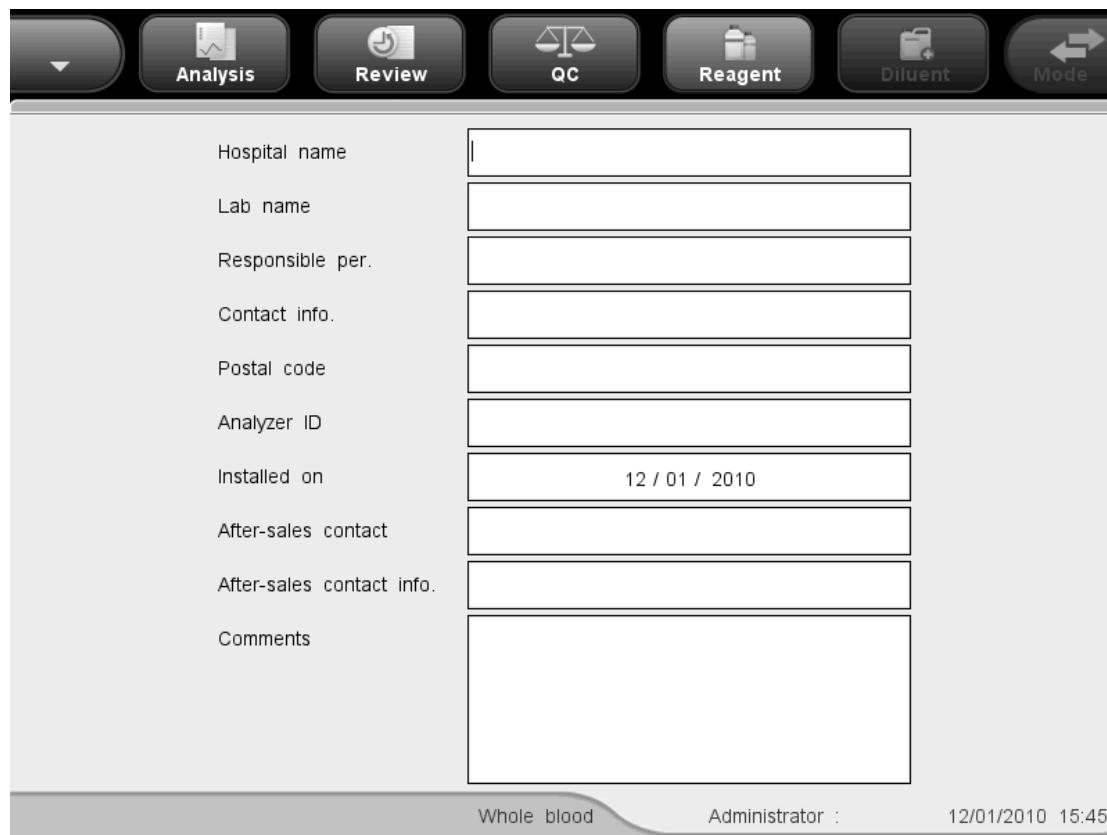


Figure 5-14 "Lab info." screen

To exit the "Lab info." screen, click a menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the changes and switch to the corresponding screen. Click "No" to abort the changes and switch to the corresponding screen.

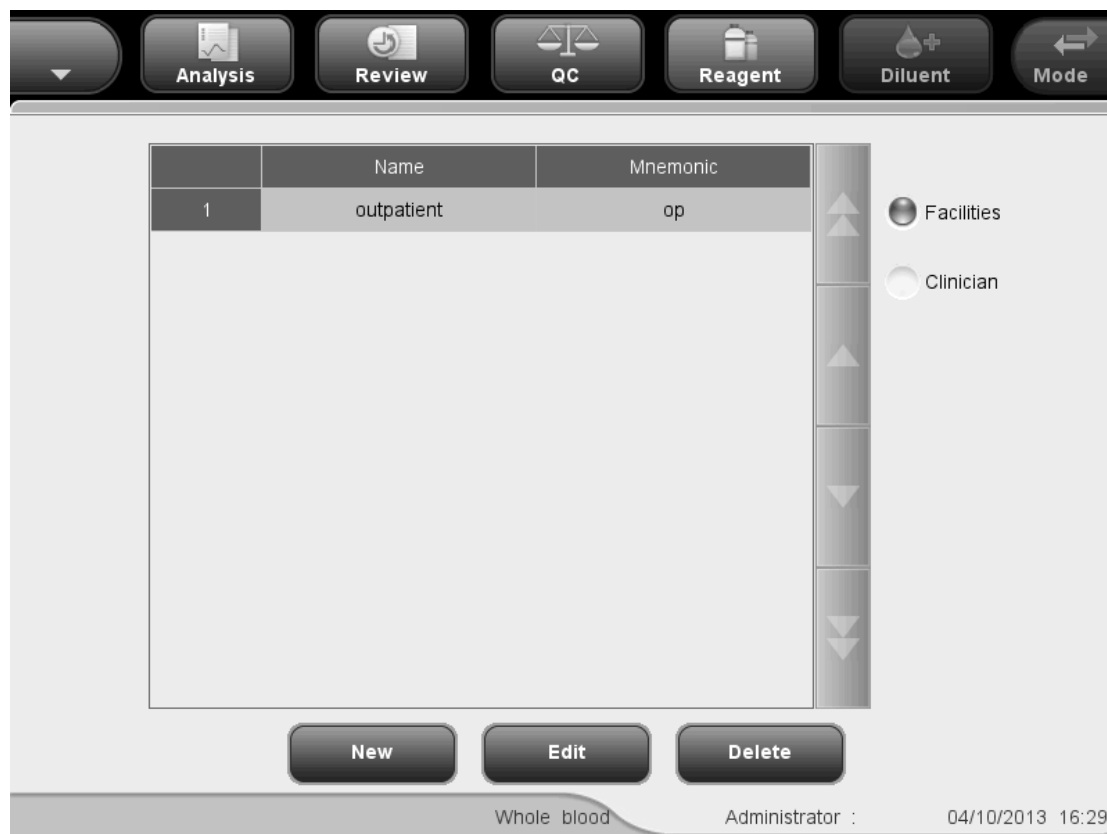


**Figure 5-15 Save Changes Dialog Box**

### 5.2.7 Mnemonics

The mnemonics setup function allows you to enter facilities and clinician information easily. Only administrators are allowed to set up shortcut codes.

Click the menu option "Setup"→"System Setup"→"Mnemonics" to enter the "Mnemonics" screen as shown below.



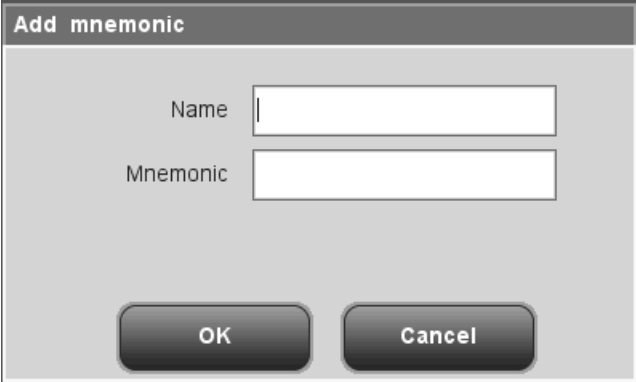
**Figure 5-16 "Mnemonics" screen**

See the following setup procedure:

1. Click the "Facilities" or "Clinician" button at the top left of the screen; you may start

to set up "Facilities" or "Clinician" mnemonics.

2. Click the "New" button at the bottom of the screen, and then the following dialog box will display.



**Figure 5-17 "New" Dialog Box**

3. Enter contents into the "Name" and "Mnemonics" edit boxes.
4. Click "OK" to save valid settings and close the dialog box.

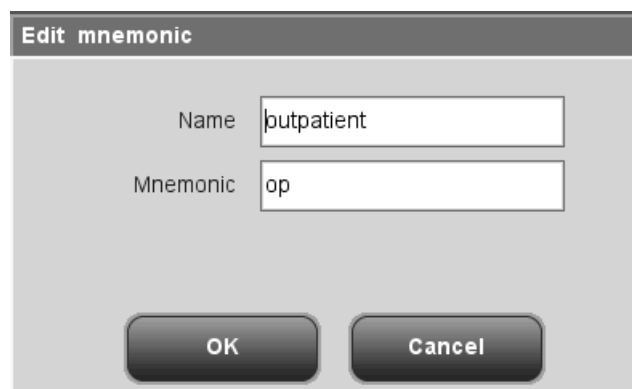
---

#### **NOTE**

- The "Name" box cannot be null. If it is null, a message will display prompting "Name cannot be null!".
  - The names and shortcut codes of different records cannot be the same. If so, dialog boxes will display prompting the name or code already exists. But the shortcut code and shortcut pinyin code of one record can be the same.
  - You may set up 500 Mnemonics maximum. When the number exceeds 500, the message "Maximum number of records has been reached!" will display.
- 

You may also edit shortcut codes per the following procedure.

1. Click the "Facilities" or "Clinician" button at the top left of the screen; you may start to edit "Facilities" or "Clinician" shortcut codes.
2. Click the "Edit" button at the bottom of the screen, and then the following dialog box will display.

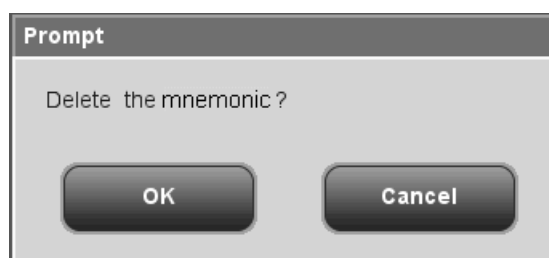


**Figure 5-18 "Edit" Dialog Box**

3. Edit the contents in the "Name" and "Mnemonics" edit boxes.
4. Click "OK" to save the settings (if valid) and close the dialog box.

You may delete mnemonics per the following procedure.

1. Select one record and click the "Delete" button.
2. The following dialog box will display. Click "OK" to delete the record and close the dialog box. Click "Cancel" to cancel deletion and close the dialog box.



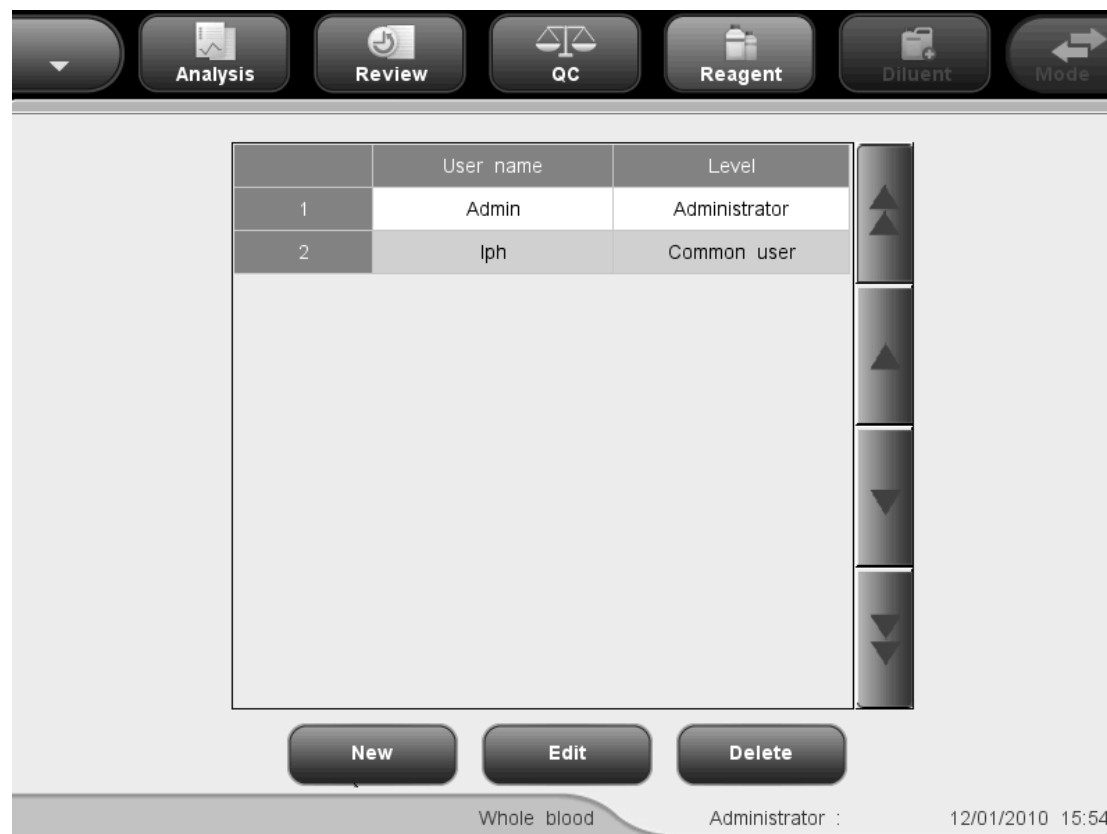
**Figure 5-19 Delete Mnemonics Dialog Box**



## 5.3 User Setup

System security setup function allows you to add, delete and modify user information, password and access level. Common users are only allowed to modify their own passwords. Administrators can add, modify and delete other users' information.

Click the menu option "Setup"→"User Setup" to enter the "User Setup" screen as shown below.



**Figure 5-20 "User Setup" Screen**

The screen displays the list of all administrators and common users. The current user is on top of the list. Common users can only see the records of their own on the screen. Administrators can see the list of all administrators and common users with the current user on top of the list.

### 5.3.1 Creating a new user

1. Click the "New" button on the screen, the following edit box will display.

The image shows a dialog box titled "Add user". It has a light gray background and a dark gray title bar. Inside the dialog, there are four text input fields stacked vertically, labeled "User name", "Old password", "New password", and "Confirm password". Below these fields is a section labeled "Level" which contains two radio buttons: "Common user" (which is selected) and "Administrator". At the bottom of the dialog are two buttons: "OK" and "Cancel".

**Figure 5-21 "New" Edit Box**

2. First select "Common user" or "Administrator" on the edit box, then enter username, new password and confirm new password.
3. Click "OK" to save the settings (if valid), a new record will be added to the user list; click "Cancel" to close the dialog box without saving the record.

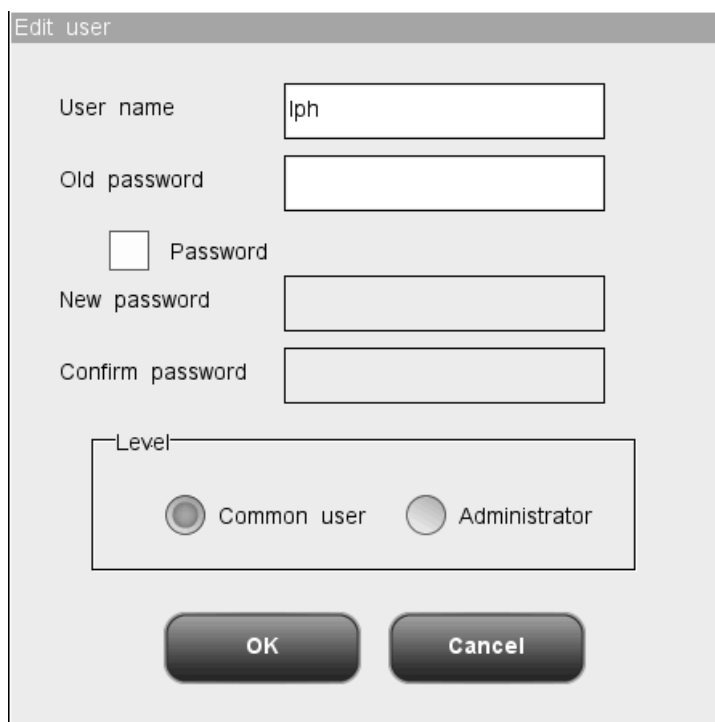
---

**NOTE**

- Username cannot be null, if so, the dialog box will display reminding you of invalid username.
  - You may create 10 administrators and 90 common users at the most.
  - Do not repeat any name when you add users.
  - Your password shall be kept to yourself to avoiding misuse by others.
- 

### 5.3.2 Editing user information

1. Select a user record on the "System Security" screen, click "Edit" button, the "Edit user" dialog box pops up.



**Figure 5-22 "Edit user" Dialog Box**

2. You may modify your own passwords by entering the old password first, then enter new password and confirm the new password. If your access level is Administrator and you want to modify level, username and password of other users, you should first select the record of the user, and then select "Common user" or "Administrator" in the "Level" edit box, then enter username, old password, and new password and confirm the new password.
3. Click "OK" to save the settings (if valid), a new record will be added to the user list; click "Cancel" to close the dialog box without saving the record.

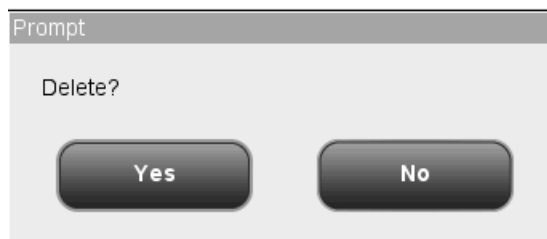
---

**NOTE**

- You cannot modify your own username.
  - Your password shall be kept to yourself to avoiding misuse by others.
- 

### 5.3.3 Deleting a user

1. Select a user record on the "System Security" screen, click "Delete" button, the following dialog box pops up.



**Figure 5-23 Dialog box of deleting a user**

2. Click "Yes" to confirm the deletion and close the dialog box. Click "No" to abort the deletion and close the dialog box.

---

**NOTE**

- You may delete records of common users and other administrators if your access level is "Administrator", but you cannot delete your own record.
  - Record of the default administrator cannot be deleted.
-

## 5.4 Auxiliary Setup

The auxiliary setup function allows you to set up the following items: "Sample ID auto increment ", "Power-up sample ID", "Entry of patient demographic info.", "Pop-up keyboard", "Layout of pop-up keyboard", "RBC std. histogram" and "Prompt for predilute count". You will need administrator level to be able to set up "Prompt for predilute count" and "RBC std. histogram".

Click the menu option "Setup"→"System Setup"→"Auxiliary" to enter the "Auxiliary Setup" screen as shown below.

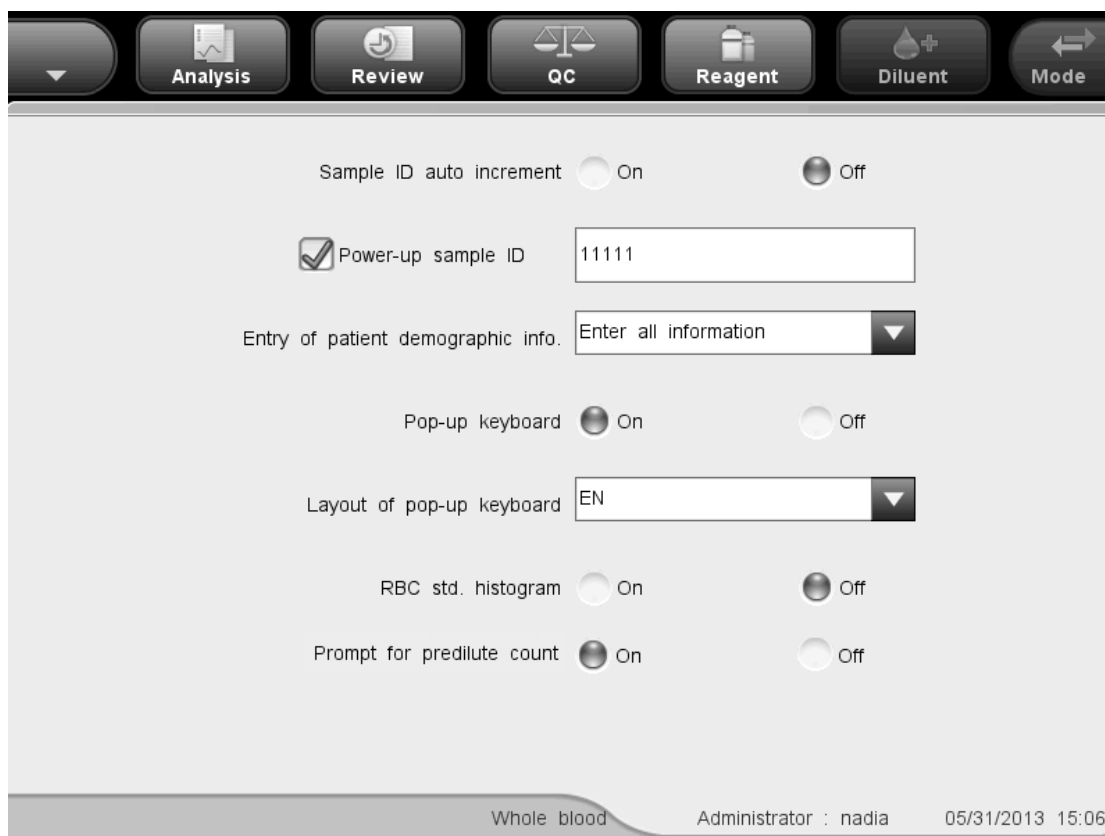


Figure 5-24 "Auxiliary setup" Screen (open vial model)

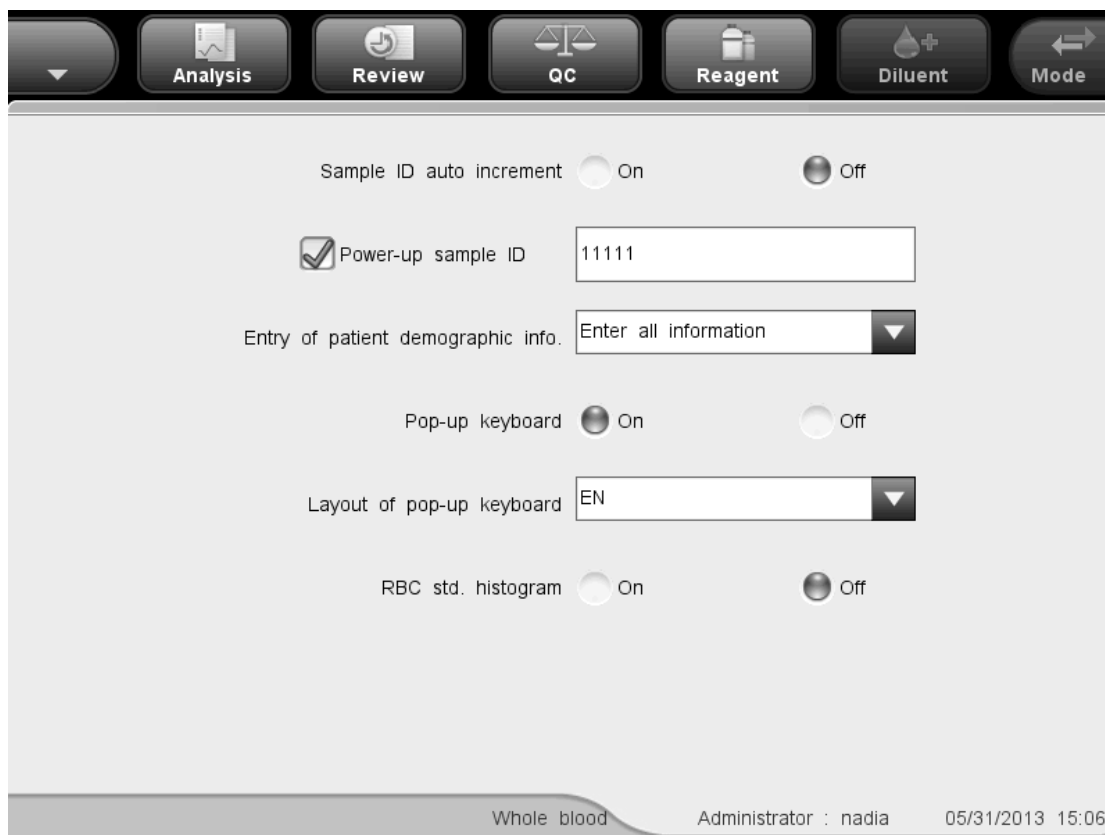
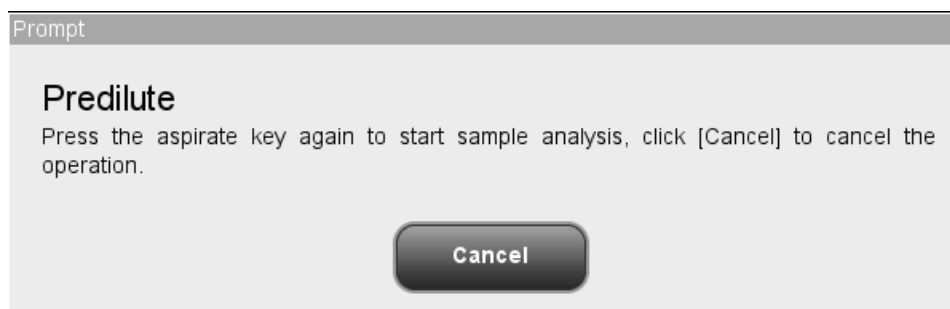


Figure 5-25 "Auxiliary setup" Screen (closed tube model)

See the following setup procedure

1. Select "On" or "Off" from the "Sample ID auto increment" pull-down list to activate or deactivate the function. Select "On", the next sample ID will increase by 1 automatically; select "Off," the next sample ID will be blank; you will have to manually enter or scan the new ID.
2. Enter the initial sample ID in the "Power-up sample ID " edit box.
3. Select "Enter sample ID only" or "Enter all information" from the "Entry of patient demographic info." pull-down list.
4. Select "On" or "Off" after the "Pop-up keyboard" item to enable or disable pop-up keyboard when editing.
5. Select the desired pop-up keyboard layout from the "Layout of pop-up keyboard" pull down list. The default layout is in line with the current system language.
6. Select "On" or "Off" after the "RBC std. histogram" item the enable or disable the display of RBC standard histogram. Select "On", the RBC standard histogram will be displayed at the sample analysis screen and the graph review screen.
7. The following setup function is for open vial model only: Select "On" or "Off" after the "Prompt for predilute count" item to enable or disable the function. When the function is enabled, when running predilute count at the sample analysis screen, the following dialog box will display.



**Figure 5-26 Prompt for Predilute Count**

Click "Cancel" to quit predilute count. The sample probe will be cleaned automatically and you need to press the aspirate key again to start sample analysis.

8. To exit the "Auxiliary setup" screen, click a menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the settings and close the dialog box. Click "No" to close the dialog box without saving the settings.



**Figure 5-27 Save Changes Dialog Box**



## 5.5 Maintenance Setup

The maintenance setup function allows you to set up "Daily maintenance starts at" and "Enter standby mode if inactive for" (administrator level required). "Preset daily maintenance time" defines the daily starting time of auto probe cleanser soak. "Enter standby mode if inactive for" defines the waiting time before entering standby mode after all sequence related operations stop.

Click the menu option "Setup"→"Maintenance", the following "Maintenance" screen will display.

The screenshot shows the "Maintenance" screen with a dark header bar containing several functional buttons: Analysis, Review, QC, Reagent, Diluent, and Mode. The main content area is light gray and contains two configuration rows. The first row is labeled "Daily maintenance starts at" and features a text input box containing "16:00" with a range indicator "[00:00,23:59]" to its right. The second row is labeled "Enter standby mode if inactive for" and features a text input box containing "60" with a range indicator "[30,60]" to its right. At the bottom of the screen, a status bar displays "Whole blood" on the left, "Administrator :" in the center, and "12/01/2010 16:59" on the right.

**Figure 5-28 "Maintenance" Screen**

- Setting up preset daily maintenance time

Enter the time into the "Daily maintenance starts at" edit box (range: 0:00,23:59).

- Setting up waiting time before entering standby mode

Enter number of minutes into the "Enter standby mode if inactive for" edit box (range: 30,60).

- Exiting the "Maintenance" screen

To exit the "Maintenance" screen, click a menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the settings and switch to the corresponding screen. Click "No" to switch to the corresponding screen without saving the settings.



**Figure 5-29 Save Changes Dialog Box**

## 5.6 Reagent Setup

### NOTE

- Be sure to reset the reagent expiration date before the first use of the analyzer or after replacing reagents.

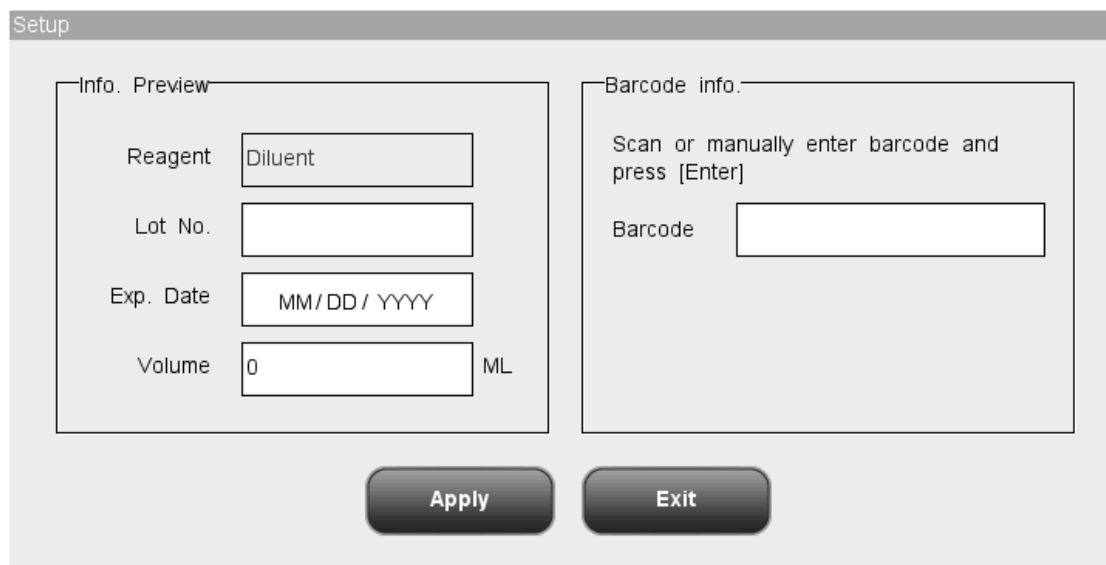
Click the menu option "Setup"→"Reagent Setup" to enter the "Reagent Setup" screen as shown below.



**Figure 5-30 "Reagent setup" Screen**

You may view reagent information list on the screen only; no editing available.

- Reagent setup
  1. Click the "Setup" button at the bottom of the screen, the following dialog box will display.



**Figure 5-31 "Setup" Dialog Box**

2. Enter barcode into the "Barcode" box manually or with a barcode scanner. If the barcode is valid, a green string "Loading barcode succeeded" will display under the "Barcode" box, and the reagent information will be refreshed.
3. Click "Apply" to load barcode that has been scanned successfully, and the dialog box will still be open for you to continue with barcodes scanning.
4. Or click "Exit" to close the dialog box without saving new barcode information.
5. After reagent barcode has been successfully loaded, the reagent will be selected in the reagent information list, and the analyzer will perform reagent priming automatically when you exit the setup screen.

- Priming with reagent

If automatic reagent priming fails, you may select one or more types of reagent manually on the screen, click "Prime" button to replace the corresponding reagents.

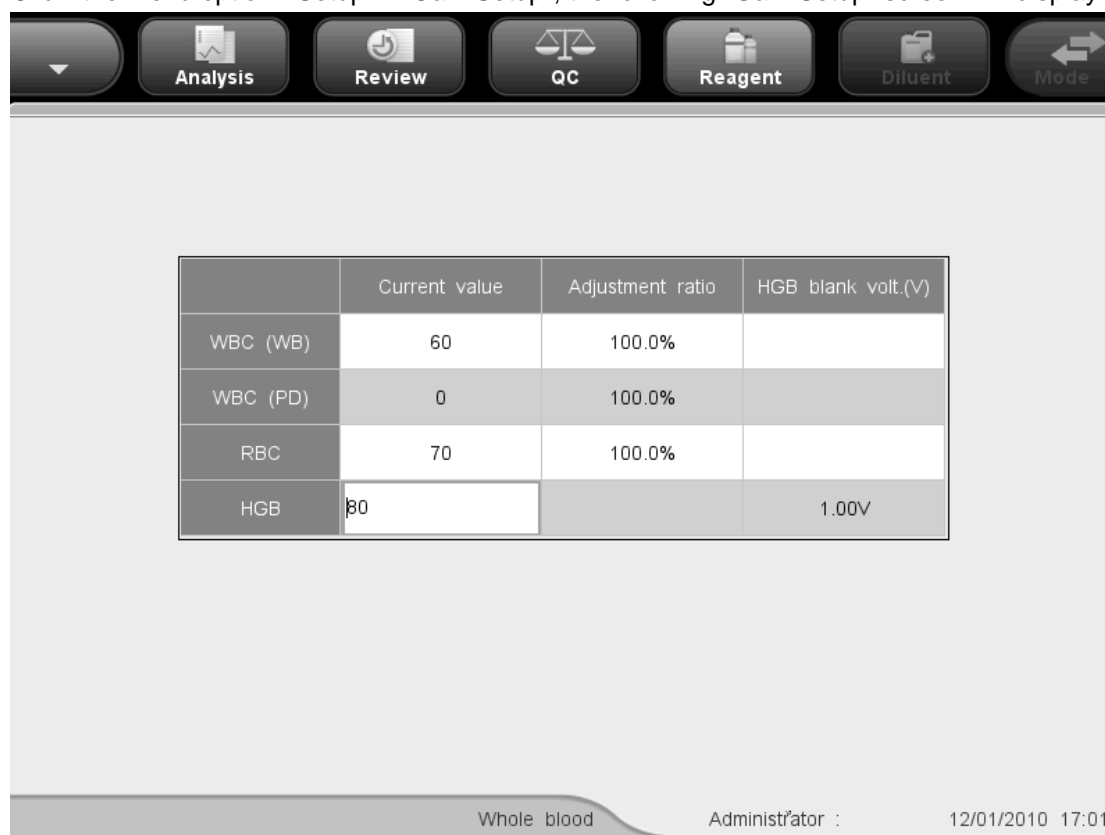
- Exiting the screen

After setting up all reagent information, click a menu option all other buttons at the functional button area to exit and switch to the corresponding screen.

## 5.7 Gain Setup

The gains of WBC (WB), WBC (PD) RBC and HGB can be manually adjusted. Common user can only view the screen. Administrators are allowed to set up HGB gain.

Click the menu option "Setup"→"Gain Setup", the following "Gain Setup" screen will display.



**Figure 5-32 "Gain setup" Screen**

- Setting up HGB gain

Administrators will find the HGB edit box activated on the screen. When adjusting HGB, the HGB blank voltage will change accordingly. If the gain entered exceeds valid range or is null, system will prompt for invalid input, and resume the original setting.

- Exiting the "Gain Setup" screen

To exit the "Gain Setup" screen, click a menu option or any button at the functional button area, a dialog box will display as follows. Click "Yes" to save the settings and switch to the corresponding screen. Click "No" to switch to the corresponding screen without saving the settings.



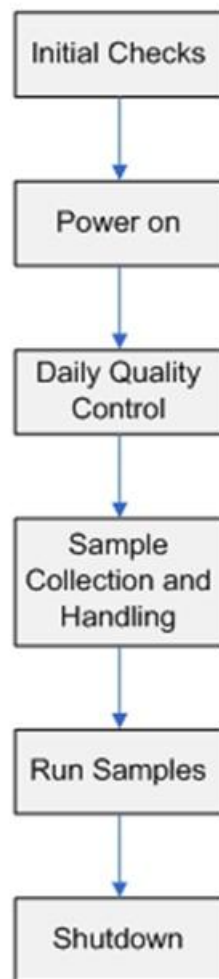
**Figure 5-33 Save Changes Dialog Box**

# 6 Operating Your Analyzer

---

## 6.1 Introduction

This chapter provides step-by-step procedures for operating your analyzer on a daily basis. A flow chart indicating the common daily operating process is presented below.



## 6.2 Initial Checks

Perform the following checks before turning on the analyzer.



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- 

### **⚠ WARNING**

- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
  - The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
  - If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.
  - Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- 

### **NOTE**

- Use the reagents specified by the manufacturer only. Store and use the reagents as instructed by instructions for use of the reagents.
  - Check if the reagent tubings are properly connected before using the analyzer.
  - After installing a new container of reagent, let it equilibrate at room temperature for a few minutes before using.
- 

#### ■ Checking the waste container

Check and make sure the waste container is empty.



■ Checking tubing and power connections

Check and make sure the reagents and waste tubing are properly connected and not bent. Check and make sure the power cord of the analyzer is properly plugged into the power outlet.

■ Checking the printer (optional)

Check and make sure enough paper is installed.

## 6.3 Startup and Logon

Place the power switch at the back of the analyzer to the ON position (I) to turn on the analyzer. The indicator light will be on and the screen will display "Initializing...". The analyzer will perform self-test and initialization. During the initialization process, a progress bar will show at the bottom with message on its top prompting "Initializing...", "Cleaning...", etc. The whole process lasts 3 to 5 minutes. Time needed for initializing the fluidic systems depends on how the analyzer was previously shut down. After the initialization process, the system will enter the main screen and the logon dialog box will display (see Figure 6-1).



**Figure 6-1 Logon Dialog Box**

Enter the current user name and the password respectively into the "User name" box and the "Password" box. Click "OK" to enter the sample analysis screen. The result of background checked will be displayed on the screen.

---

### **NOTE**

- **Running sample with the background abnormal error present will lead to unreliable results.**
  - **The system opens different function for the user according to the user level. The user level depends on the user name and the password when the user logs in.**
  - **If user switching is necessary, Click the "Log off" icon on the system menu. Enter the desired user name and the password into the popup dialog box and Click the "OK" button to log on.**
-

## 6.4 Daily Quality Control

Before running any samples, run the controls. See **Chapter 8 Using the QC Programs** for details.

## 6.5 Sample Collection and Handling

---



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- 

### **⚠ WARNING**

- Do not contact the patients' sample blood directly.
- 

### **⚠ CAUTION**

- Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.
- 

### **NOTE**

- Be sure to use clean K<sub>2</sub>EDTA anticoagulant collection tubes, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
  - Be sure to use the Mindray-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes etc.
- 

### 6.5.1 Whole blood Samples

1. Use clean K<sub>2</sub>EDTA(1.5 - 2.2mg/mL) anticoagulant collection tubes to collect venous blood samples.
  2. Mix the sample according to your laboratory's protocol.
-

**NOTE**

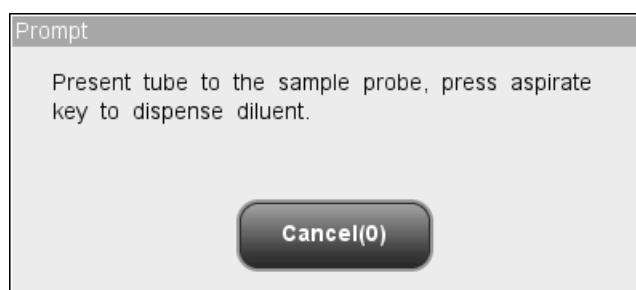
- When stored in room temperature, the whole blood samples to be used for WBC differential need to be run within 12 hours after collection.
  - If the samples are stored in a refrigerator (2°C - 8°C), they can be run within 24 hours after collection. You need to warm the refrigerated samples at room temperature for at least 30 minutes before running them.
  - Be sure to mix any sample that has been prepared for a while before running it.
- 

## 6.5.2 Prediluted Samples

The following section introduces the preparation procedure of prediluted samples for open vial model and closed tube model respectively.

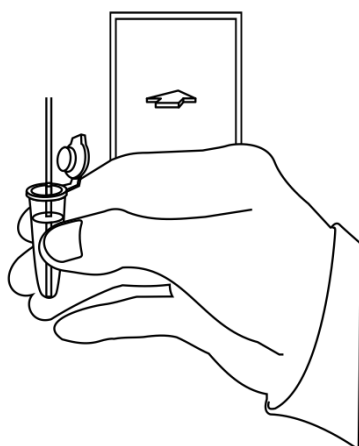
### Preparation procedure of prediluted samples for open vial model

1. Click the mode switching icon, system mode switches to "Predilute" from "Whole blood".
2. Click the diluent dispensing icon, the following dialog box pops up.



**Figure 6-2 Diluent Dispensing Prompt**

3. Present a clean centrifugal tube to the sample probe, press the aspirate key. Make sure the tube is tilted towards the probe, as the following figure shows, to avoid spills and bubbles. The dispensing progress bar will be displayed on the screen with message showing "Dispensing diluent...".



**Figure 6-3 Dispensing Diluent**

4. Then dispensing finishes, you will hear a beep, and then you may remove the tube. Then the message in the dialog box turns to "Present tube to the sample probe, press aspirate key to dispense diluent." again.
5. To continue with diluent dispensing, repeat the step 3-4; otherwise click "Cancel", the analyzer will clean the sample probe automatically with cleaning progress displayed. After the operation finishes, the dialog box will close automatically.
6. Add 20 $\mu$ L of capillary blood to the diluent, close the tube cap and mix it properly according to your laboratory's protocol.

---

**NOTE**

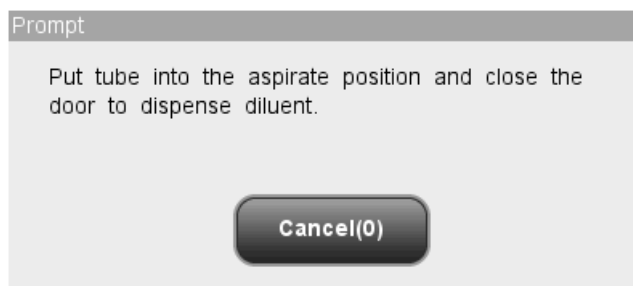
- **Be sure to keep dust from the prepared diluent.**
- **After mixing the capillary sample with the diluent, be sure to wait 3 minutes before running the sample.**
- **Be sure to run the prediluted samples within 30 minutes after the mixing.**
- **Be sure to mix any sample that has been prepared for a while before running it.**
- **Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.**

---

**Preparation procedure of prediluted samples for closed tube model**

1. Click the mode switching icon, the analysis mode switches to "Predilute".
2. Click the diluent dispensing icon, the compartment door opens automatically and

the following dialog box displays.



**Figure 6-1 Diluent Dispensing Dialog Box**

3. Make sure the black predilute tube holder adapter is at the aspirating position and put a centrifugal tube into the adapter, then close the compartment door.
4. The analyzer automatically dispenses diluent into the tube and the progress will be displayed on the dialog box.
5. When dispensing diluent is finished, the compartment door will open.
6. To continue with diluent dispensing, repeat the steps above; otherwise click "Cancel" to close the dialog box.
7. Add 20 $\mu$ L of capillary blood to the diluent, close the tube cap and mix it properly according to your laboratory's protocol.

---

**⚠ WARNING**

- **The centrifugal tube must not be capped when dispensing diluent.**
- 

**NOTE**

- **Before performing diluent dispensing, make sure a centrifugal tube has been put into the aspirating position.**
  - **Be sure to keep dust from the prepared diluent.**
  - **After mixing the capillary sample with the diluent, be sure to wait 3 minutes before running the sample.**
  - **Be sure to run the prediluted samples within 30 minutes after the mixing.**
  - **Be sure to mix any sample that has been prepared for a while before running it.**
  - **Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.**
-

## 6.6 Sample Analysis

Click "Analysis" button on the menu to enter the "Analysis" screen. Click the mode switching icon on the screen to select "Whole Blood" or "Predilute" mode.

### 6.6.1 Entering sample information

The analyzer provides two ways for you to enter sample information: entering sample ID only and entering all sample information.

If you want to enter sample information after analysis, you may skip this chapter, and enter sample information at the result review screen (see **Chapter 7 Reviewing Sample Results**). You may first set up the way to enter sample information at the "Setup→Auxiliary" screen as instructed in **Chapter 5 Customizing the Analyzer Software**, then you may enter sample information at the "Analysis" screen.

### Entering Patient Demographics

When the way to enter patient demographic information is set to "Enter all information", click "Patient Demographic" at the sample analysis screen, the following dialog box will display. You may enter complete information of the next sample into the dialog box. The "Ref. group" will be selected by the system.

**Figure 6-4 Dialog Box of Entering Patient Demographic**

- Entering the sample ID

Enter the sample ID in the "Sample ID" box.



**NOTE**

- Letters, numerics and all characters (including special characters) supported by the keyboard are allowed for sample ID entering.
  - The allowed length of sample ID is [1,20], and the ID cannot be null.
  - The ending character of sample ID must be a numeric, but sample ID consisted of "0" only is considered invalid.
- 

■ Entering last name of the patient

Entering last name of the patient into the "Last Name" box.

■ Entering first name of the patient

Entering first name of the patient into the "First Name" box.

■ Entering the medical record number

Enter the medical record number in the "MR Number" box.

■ Entering the date of birth

Enter the patient's date of birth into the "DOB" box. Its format must be the same with the system date format.

■ Entering the patient's age

The analyzer provides five ways for you to enter the patient's age – in years, in months, in weeks, in days and in hours. The first way is designed for the adult or pediatric patients no younger than one year; the second for the infant patients one month to two years; the third for the neonatal patients one week to ten weeks; the fourth for the neonatal no older than one month, and the fifth for the neonatal no older than 48 hours. You may choose one of the four ways to enter the patient age.

The "Age" pull-down list provides five ways for you to enter the patient age– in years, in months, in weeks, in days and in hours, and you may enter the patient age in the box followed by the age unit.

---

**NOTE**

- If the patient's date of birth is entered, his/her age will be calculated automatically, and the age field will gray out and cannot be edited.
  - If the entered date of birth is later than the current system, then it is
-

---

**considered invalid.**

---

■ **Selecting the patient gender**

Select patient gender from the "Gender" pull-down list. There are three options: "Male", "Female" and "Unknown", the default option is "Unknown".

■ **Entering the name of the clinician**

To enter the name of the person who sent the sample for analysis, enter the name into the "Clinician" box or select the desired name from the "Clinician" pull-down list (if there are previously saved names in the list).The saved contents will be added in the pull-down list automatically, 30 records can be saved maximum.

■ **Entering the department name**

Enter the name of the department into the "Department" box or select it from the "Department" pull-down list (when there are previously saved records in the list).The saved contents will be added in the pull-down list automatically, 30 records can be saved maximum.

■ **Entering the Bed No.**

Enter the bed No. of the patient in the "Bed No." box.

■ **Entering collection time**

Enter the collection time into the "Collection Time" box.

■ **Entering receive time**

Enter the receive time into the "Receive Time" box.

■ **Entering the comments**

Enter the comments in the "Comments" box.

■ **OK**

When you have finished entering the work list information, click the "OK" button to save the changes and return to the "Count" screen.

■ **Cancel**

If you do not want to save the entered work list information, click the "Cancel" button to return to the "Analysis" screen without saving the changes.

## Entering sample ID only

When the way to enter next sample information is set to "Enter sample ID only", click "Patient Demographic" at the sample analysis screen, the following dialog box will display.

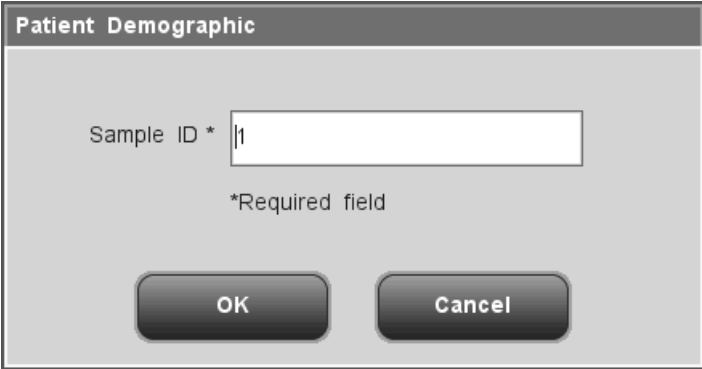


Figure 6-5 Dialog Box of Entering Sample ID Only

Enter the sample ID in the "Sample ID" box. Click "OK" to save the ID and close the dialog box, the ID will be displayed on the screen as the next sample ID.

## 6.6.2 Running the samples



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

---

### **⚠ WARNING**

- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.

---

### **⚠ CAUTION**

- Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.
  - Under the whole blood mode, do not count the same sample more than 3 consecutive times.
-

**NOTE**

- **The sample probe shall be well immersed and kept away from the tube bottom, when the probe is aspirating sample. Otherwise, the aspirated volume may be insufficient or imprecise.**
  - **Make sure the probe tip does not contact the sample tube to avoid potential spillage.**
- 

## **Running samples for open vial model**

### **Run whole blood samples as instructed by the following procedure:**

1. Make sure the analyzer indicator is green and the work mode is "Whole Blood".
2. Present the whole blood sample to the sample probe.
3. Press the aspirate key to start the analysis. The indicator flickers in green, indicating the analyzer is running.
4. The sample probe will automatically aspirate 17 $\mu$ L of sample. When you hear the beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample.
5. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.
6. If the auto print function is activated, the analysis result will be automatically printed out. If the auto transmission function is activated, the analyzer will automatically transmit the analysis result to LIS.
7. Run the rest samples as instructed above.

### **Run prediluted samples as instructed by the following procedure:**

1. Make sure the analyzer indicator is green and the work mode is "Predilute".
2. Present the prediluted sample to the sample probe.
3. Press the aspirate key to start the analysis. The indicator flickers in green, indicating the analyzer is running.
4. The sample probe will automatically aspirate 146.34 $\mu$ L of sample. When you hear the beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample.
5. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.
6. If the auto print function is activated, the analysis result will be automatically printed out. If the auto transmission function is activated, the analyzer will automatically

transmit the analysis result to LIS.

7. Run the rest samples as instructed above.

---

## **NOTE**

- **During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.**
  - **If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- 

## **Running samples for closed tube model**

**Run whole blood samples as instructed by the following procedure for closed tube model:**

1. Be sure the analyzer indicator is green and the analysis mode is "Whole Blood".
2. Open the compartment door. Make sure the translucent whole blood tube holder adapter is at the aspirating position and put the prepared control into it, then close the compartment door. The analyzer will perform control analysis automatically.
3. When sample aspiration is finished, the compartment door will open automatically.
4. When the analysis is finished, the results will be displayed on the screen.

**Run prediluted samples as instructed by the following procedure for closed tube model:**

1. Be sure the analyzer indicator is green and the analysis mode is "Predilute".
2. Open the compartment door. Make sure the black predilute tube holder adapter is at the aspirating position and put the prepared sample into it, then close the compartment door. The analyzer will perform sample analysis automatically.
3. When sample aspiration is finished, the compartment door will open automatically.
4. When the analysis is finished, the results will be displayed on the screen. The analyzer will be ready for the next analysis.
5. Run the rest samples as instructed above.

## **⚠ WARNING**

- The centrifugal tube must not be capped when running prediluted samples.
- 

## **NOTE**

- If the current tube holder adapter does not match with the analysis mode, a dialog box will display indicating “The analysis mode and tube holder adapter are mismatched, please switch modes or replace tube holder adapter.”. Click “OK”, the compartment door will open automatically.
  - During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.
  - If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.
- 

## **6.6.3 Processing Analysis Results**

### **Automatic saving of analysis results**

This analyzer automatically saves sample results. When the maximum number of results that can be saved has been reached, the newest result will overwrite the oldest.

### **Parameter flags**

See the following section for details about parameter flags.

- If the parameter is followed by a "H" or "L", it means the analysis result has exceeded the upper or lower limit of the reference range (See **Section 5.2.4 Ref. range**).
- If the parameter is followed by an “R”, it means the analysis result is questionable.
- If you see "\*\*\*\*\*" as opposed to the result, it means the result is invalid; if you see "+++++" as opposed to the result, it means the result is out of the display range (See **Table 6-1 Display Range** for details.).

- If the WBC result of the sample is less than  $0.5 \times 10^9/L$ , this analyzer will not perform the differential analysis and all the related parameter values will be non-numeric (\*\*\*\*\*).

**NOTE**

- The result of the background check will not be flagged.

**Table 6-1 Display Range**

Parameter	Display range
WBC	$0.0 \sim 999.9 \times 10^9/L$
RBC	$0.00 \sim 9.99 \times 10^{12}/L$
HGB	$0 \sim 300 \text{ g/L}$
MCV	$0.0 \sim 250.0 \text{ fL}$
PLT	$0 \sim 9999 \times 10^9/L$

**Histogram flags**

The system will flag abnormal histograms. Both WBC histogram and PLT histogram are flagged for abnormal results.

- WBC histogram flags

Abnormal WBC histograms will be flagged by one of the markings: R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub> and R<sub>m</sub>. The indications of the markings are as follows:

R<sub>1</sub> indicates abnormality on the left side of the lymphocyte hump and possible presence of platelet clumps, giant platelets, nucleated red cell, lyse resistant RBC, protein and lipid debris in sample, or electrical noise.

R<sub>2</sub>: indicates abnormality between the lymphocyte hump and the mid-sized cell area and possible presence of abnormal lymphocyte, plasma cell, atypical lymphocyte, original granulocytes in the sample and eosinophilia or basophilia.

R<sub>3</sub>: indicates abnormality between the mid-sized cell area and the granulocytes and possible presence of immature granulocytes, abnormal sub-population in the sample, or eosinophilia.

R<sub>4</sub>: indicates abnormality on the right side of the granulocytes hump and neutrophilia.

R<sub>m</sub>: indicates at least two R flags.

- PLT histogram flags

Abnormal PLT histograms will be flagged by one of the markings: P<sub>m</sub>, P<sub>S</sub> and P<sub>L</sub>. The indications of the markings are as follows:

P<sub>m</sub>: indicates blur demarcation between the platelet and red blood cell area and possible presence of large platelet, platelet coagulation, small red blood cell, cell debris or fibrin.

P<sub>S</sub>: indicates excessive small PLTs.

P<sub>L</sub>: indicates excessive large PLTs.

---

**NOTE**

- When the PLT value is less than  $100 \times 10^9 / L$ , a reexamination is recommended.
-



## 6.7 Using Tube Holder Adapters (for closed tube model)

### 6.7.1 Introduction of tube holder adapters

Tube holder adapters are necessary for holding tubes when analyzing samples. Three tube holder adapters are used on this analyzer: 1 translucent evacuated collection tube holder adapter (for normal evacuated collection tubes), 1 translucent capillary collection tube holder adapter (for capillary whole blood collection tubes) and one black predilute tube holder adapter (for centrifugal tubes). You may refer to **Appendix B Specifications** for details about the applicable tubes of each tube holder adapter. You must use tubes that are applicable to the adapters.

You may recognize the evacuated collection tube holder adapter and the capillary collection tube holder adapter by the labels on them. See the following figure.

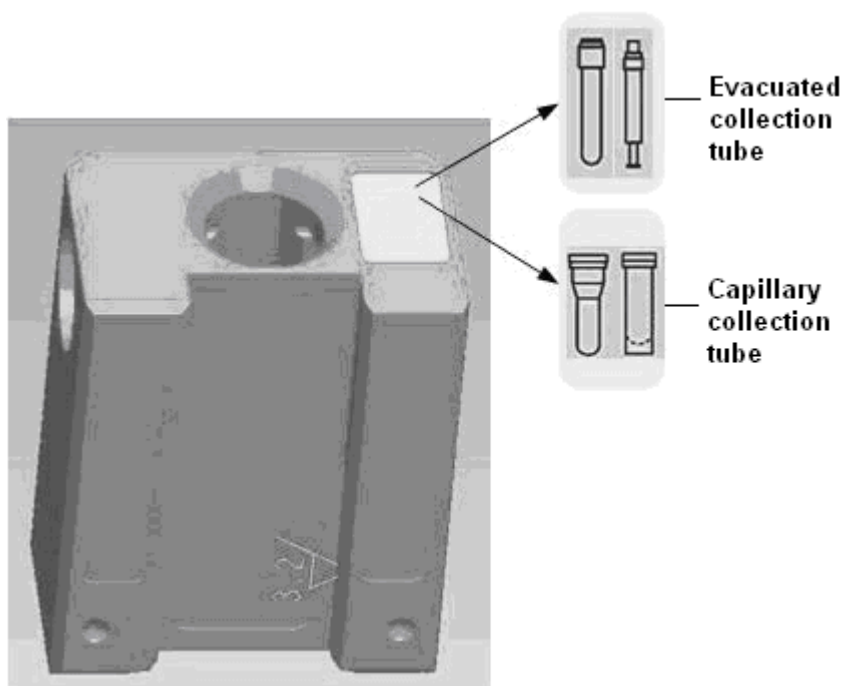


Figure 6-6 Labels on the Tube Holder Adapters

### 6.7.2 Replacing tube holder adapters

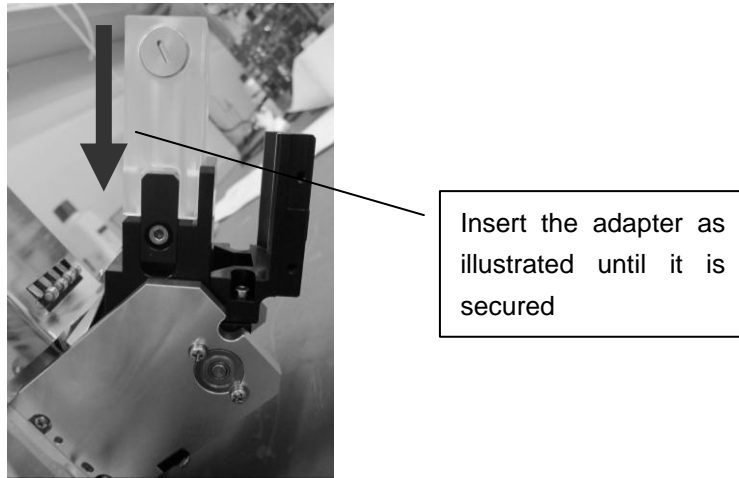
The way to replace the three tube holder adapters is the same. The following section introduces how to replace evacuated collection tube adapter as an illustration.

---

#### **NOTE**

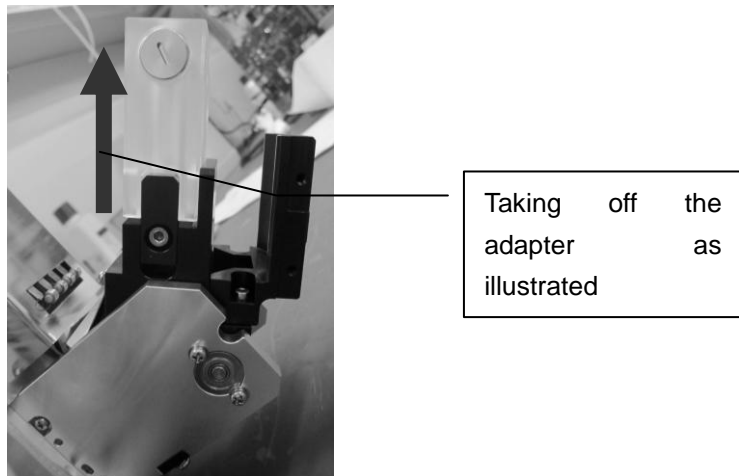
- You must take the tube out from the adapter before replacing it.
-

- Installing evacuated collection tube adapter



**Figure 6-7 Installing evacuated collection tube adapter**

- Taking off evacuated collection tube adapter



**Figure 6-8 Taking off evacuated collection tube adapter**

## 6.8 Auto-sleep

When the time for which the analyzer is free from fluidic operations reaches that you have set at the "Maintenance Setup" screen, a dialog box will display, prompting "Preparing to sleep, please wait...". During this condition, you may still perform any other operations other than relevant fluidic operations. After preparation finishes, the dialog box will close automatically, the screen blacks out and prompts "The analyzer is in standby mode, press the screen or the aspirate key to exit!".

To cancel the auto-sleep, press the aspirate key and a dialog box of "Exiting standby mode, please wait..." will display. After the auto-sleep is canceled, the dialog box will close automatically.

---

### **NOTE**

- **Refer to Section 5.5 Maintenance Setup for how to edit waiting time before entering standby mode.**
  - **Under stand-by mode, if there are unfinished printing or communication tasks, the analyzer will go on processing them.**
-

## 6.9 Shutdown

Perform the shutdown procedure to shut down the analyzer daily.



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- 

### **WARNING**

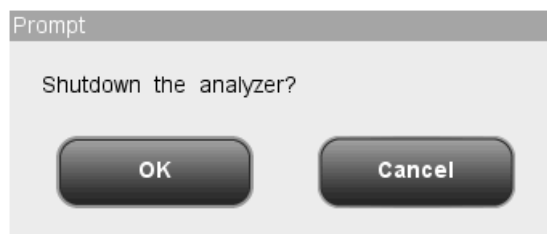
- The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
- 

### **NOTE**

- To ensure stable analyzer performance and accurate analysis results, be sure to perform the "Shutdown" procedure to shut down the analyzer after it has been running continuously for 24 hours.
  - Be sure to shut down the analyzer strictly as instructed below.
- 

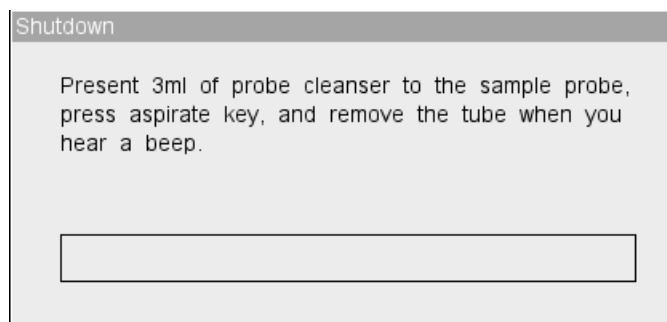
**Shutdown procedure of open vial model:**

1. Click the shutdown button on the menu and the following shutdown dialog box will display:



**Figure 6-9 "Shutdown" Dialog Box 1**

2. Click "OK", the following dialog box will display.

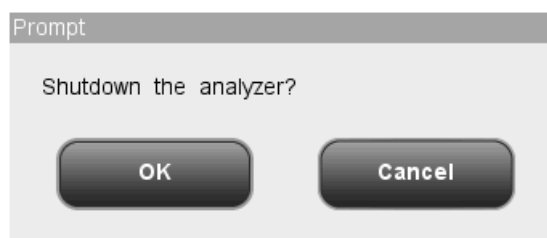


**Figure 6-10 Shutdown Dialog Box 2**

3. Present probe cleanser to the sample probe, press aspirate key. The probe will aspirate probe cleanser automatically. Then the analyzer will perform probe cleanser soak. A progress bar will be displayed on the screen.
4. After shutting down finishes, the message "Please power off the analyzer!" will be displayed. Press the Power switch on back of the instrument to power off.
5. Empty the waste container and dispose of the waste properly.

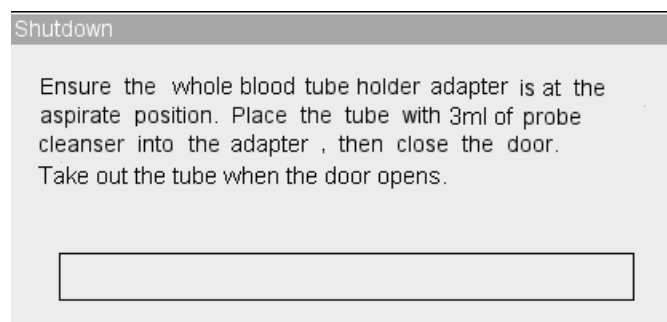
**Shutdown procedure of closed tube model:**

1. Click the shutdown button on the menu and the following shutdown dialog box will display:



**Figure 6-11 "Shutdown" Dialog Box 1**

2. Click "OK", the following dialog box will display.



**Figure 6-12 "Shutdown" Dialog Box 2**

3. Put the tube filled with probe cleanser into the translucent tube holder adapter according to the instruction and close the compartment door. The analyzer performs probe cleanser soak automatically with the progress displayed on the screen.
6. After shutting down finishes, the message "Please power off the analyzer!" will be

displayed. Press the Power switch on back of the instrument to power off.

7. Empty the waste container and dispose of the waste properly.

# 7 Reviewing Sample Results

---

---

## 7.1 Introduction

The analyzer automatically saves analysis results. Totally 40,000 results can be saved, each of which including 21 parameters and 3 histograms.

You may either browse all the saved sample results in general or search for the results of a particular sample or samples.

---

### **NOTE**

- Mindray recommends you backing up saved results regularly.
-

## 7.2 Browsing All Sample Results

You may browse sample results either in the table or graph mode.

### 7.2.1 Browsing in the "Table Review" mode

Click the "Review" button in the menu to enter the "Table review" screen of the sample database, as shown in the following figure. The screen displays serial No., sample ID, name, analysis date/time, parameters and other sample and patient information in a table. Under the table, you may see the following functional buttons from left to right: "Graph Review", "Edit Info.", "Validate", "Print", "Transmit", "Search", "Select", "Delete", "Export", "CV%" and "Exported Data". The "Graph Review" button is at the first position on the left all the time. Only administrator's screen may display the "Validate" and "Delete" buttons. You may click the buttons to realize their corresponding functions.



Figure 7-1 "Table Review" Screen

### Switching to "Graph Review" screen

You may click the "Graph Review" button to go to the "Graph Review" screen. For details about the "Graph Review" screen, see **7.2.2 Browsing in the "Graph Review" mode**.

### Editing sample information

You may edit sample information at the "Table Review" screen.



Click the desired sample result and it will be highlighted. Click the "Edit Info." button and the following dialog box will display. You cannot edit information of the "Ref. group", "Mode", "Time", "Technologist" and "Validator"..

**Figure 7-2 Editing Sample Information Dialog Box**

- Entering the medical record number

Enter the medical record number in the "MR Number" box.

**NOTE**

- Letters, numerics and all characters (including special characters) supported by the keyboard are allowed for sample ID entering.
- The allowed length of sample ID is [1, 20], and the ID cannot be null.
- The ending character of sample ID must be a numeric, but sample ID consisted of "0" only is considered invalid.

- Entering the patient ID

Enter the patient ID in the "Patient ID" box.

- Entering the date of birth

Enter the patient's date of birth into the "DOB" box. Its format must be the same with the

system date format.

■ Entering last name of the patient

Entering last name of the patient into the "Last Name" box.

■ Entering first name of the patient

Entering first name of the patient into the "First Name" box.

■ Entering the patient age

The analyzer provides four ways for you to enter the patient age – in years, in months, in weeks, in days and in hours. The first way is designed for the adult or pediatric patients no younger than one year; the second for the infant patients one month to two years; the third for the neonatal patients one week to ten weeks; the fourth for the neonatal no older than one month, and the fifth for the neonatal no older than 48 hours. You may choose one of the four ways to enter the patient age.

The "Age" pull-down list provides five ways for you to enter the patient age– in years, in months, in weeks, in days and in hours, and you may enter the patient age in the box followed by the age unit.

---

**NOTE**

- **If the patient's date of birth is entered, his/her age will be calculated automatically, and the age field will gray out and cannot be edited.**
- **If the entered date of birth is later than the current system, then it is considered invalid.**

---

■ Selecting the patient gender

Select patient gender from the "Gender" pull-down list. There are three options: "Male", "Female" and "Unknown", the default option is "Unknown".

■ Entering the name of the clinician

To enter the name of the person who sent the sample for analysis, enter the name into the "Clinician" box or SELECT the desired name from the "Clinician" pull-down list (if there are previously saved names in the list).The saved contents will be added in the pull-down list automatically, 30 records can be saved maximum.

■ Entering the department name

Enter the name of the department into the "Department" box or select it from the "Department" pull-down list (when there are previously saved records in the list).The

saved contents will be added in the pull-down list automatically, 30 records can be saved maximum.

- Entering the Bed No.

Enter the bed No. of the patient in the "Bed No." box.

- Entering collection time

Enter the collection time into the "Collection Time" box.

- Entering receive time

Enter the receive time into the "Receive Time" box.

- Entering the comments

Enter the comments in the "Comments" box.

- OK

When you have finished entering the work list information, Click the "OK" button to save the changes and return to the "Table Review" screen.

- Cancel

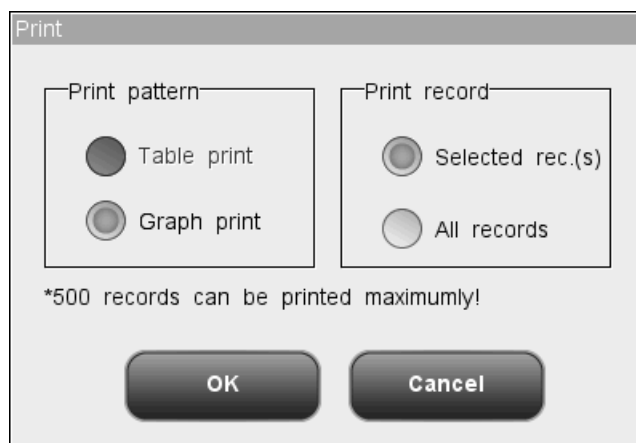
If you do not want to save the entered work list information, Click the "Cancel" button to return to the "Table Review" screen without saving the changes.

### **Checking the selected sample result**

Administrators can click the "Check" button to check the selected sample result. Then the "Check" button turns to be "Cancel Check" button, click the button again to cancel checking.

### **Printing**

Select a sample result and click "Print", the following dialog box will display.



**Figure 7-3 "Print" Dialog Box**

You may print selected or all sample results in the table or graph mode. 500 results can be printed at one time maximum. Click "OK" to start printing in the selected mode. When printing goes on, the print status icon flickers. Click "Cancel" to cancel the printing task.

---

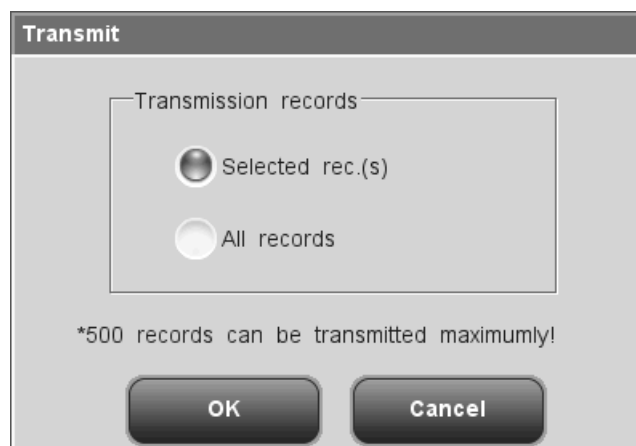
**NOTE**

- **Printing in "Table" mode is not supported by the recorder, if current printing device is the recorder, the "Table" button will be disabled.**

---

**Transmission**

You may transmit sample results to an external computer (a host) as instructed below. Select sample results first, and then click the "Transmit" button, the following dialog box will display.



**Figure 7-4 " Transmit " Dialog Box**

You may transmit selected records or all records. 500 records can be transmitted maximum. Click the "OK" button to start transmission. When transmission goes on, the communication status icon flickers. Click "Cancel" to close the dialog box.

## Searching for particular sample result (s)

You may search for a particular sample result(s) from the sample database.

1. Click the "Search" button, then the "Search" dialog box will display. "Range search" is selected by default. Click "Detail search", the "Detail search" dialog box will display.

The image shows a "Search" dialog box with the following elements:

- Title Bar:** Search
- Buttons (Left Side):** Range Search, Detail Search
- Search Criteria (Right Side):**
  - Sample ID: [Text Input]
  - MR Number: [Text Input]
  - Last name: [Text Input]
  - First name: [Text Input]
  - Match type:  Precise,  Include
- Range Search Fields (Right Side):**
  - Age: [Text Input] Years [Dropdown] To [Text Input] Years [Dropdown]
  - DOB: [Text Input] MM/DD/YYYY To [Text Input] MM/DD/YYYY
  - Date: [Text Input] MM/DD/YYYY To [Text Input] MM/DD/YYYY
  - Time: [Text Input] : To [Text Input] :
- Buttons (Bottom):** OK, Cancel

Figure 7-5 "Range search" Dialog Box

The image shows a 'Search' dialog box with a title bar. On the left side, there are two buttons: 'Range Search' and 'Detail Search'. The main area contains several search criteria, each with a text input field or a dropdown menu. The criteria are: Mode (dropdown), Gender (dropdown), Ref. group (dropdown), Flag (dropdown), Print (dropdown), Transmit (dropdown), Validate (dropdown), Facilities (dropdown), Clinician (dropdown), and Technologist (text input). At the bottom of the dialog box, there are two buttons: 'OK' and 'Cancel'.

**Figure 7-6 "Detail search" Dialog Box**

2. Enter search conditions into the edit boxes or select search conditions from the combo boxes.
3. After entering all search conditions, click "OK" to start searching; or click "Cancel" to cancel the operation.
4. After finding the result(s), a dialog box will display indicating "\*\*\* record(s) found.", click "OK" to close the dialog box, the results found will be displayed on the "Table of Searched Results" screen. If no result is found, a dialog box will display indicating "No sample found!", click "OK" to close the dialog box.

	9996	9997	9998	9999	10000	*10001
Sample ID	BQ-FY-L-01	BQ-FY-L-02	BQ-ZY-L-01	BQ-ZY-L-02	BQ-ZC-L-01	BQ-ZC-L-02
Last name	Jorden	Jorden	Jorden	Jorden	Jorden	Jorden
First name	Jeff	Jeff	Jeff	Jeff	Jeff	Jeff
Date	05/19/2010	05/19/2010	05/19/2010	05/19/2010	05/19/2010	05/19/2010
Time	11:17	11:18	11:19	11:20	11:21	11:23
Validator						
WBC	L 2.5	L 2.6	L 2.5	L 2.4	L 2.5	L 2.6
Lymph#	1.3	1.3	1.3	1.2	1.3	1.3
Mid#	0.2	0.3	0.2	0.3	0.2	0.3
Gran#	L 1.0	L 1.0	L 1.0	L 0.9	L 1.0	L 1.0
Lymph%	H 52.2	H 51.7	H 50.1	H 51.3	H 50.7	H 50.5
Mid%	9.2	10.2	11.3	10.5	9.9	11.2

Figure 7-7 "Table of Searched Results" Screen

The buttons of the screen are the same with that of the "Table Review" screen, except that the "Search" button turns into "Return". You may click the buttons to perform the corresponding functions. Click the "Return" button to return to the "Table Review" screen.

### Selecting/Deselecting sample results

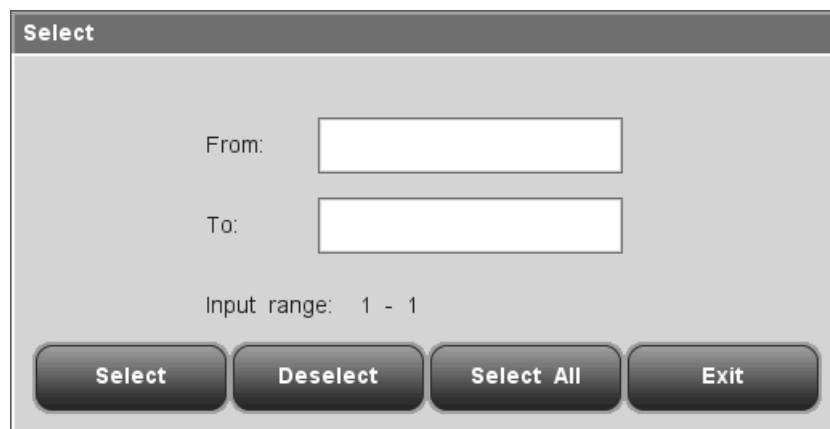
You may select sample results from the sample database to perform operations like communication and printing.

- Selecting/deselecting a single result

If you want to select a sample result, click any cell in that column, the column will be highlighted and a "\*" will appear in the column head. Click the column again to deselect it.

- Selecting/deselecting multiple results

1. If you need to select multiple sample results, click the "Select" button on the "Table Review" screen, the following dialog box will display:



**Figure 7-8 "Select" Dialog Box**

2. Enter serial numbers into the "From" and "To" edit boxes, then click "Select", the sample results within the entered range will all be selected.
3. If you want to deselect the selected sample results, enter the serial numbers into the "From" and "To" edit boxes, then click "Deselect", the selected results will be deselected.
4. If you want to select all sample results, click "Select all", the "Select" dialog box will be closed and all sample results will be selected.

---

**NOTE**

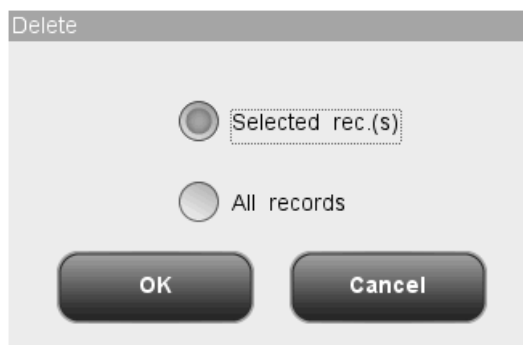
- The valid range of serial number is displayed under the edit boxes, if the entered serial numbers exceed the range, the dialog box " 'From' or 'To' value exceeds input range." will display when you click "Select". Click "OK" to close the dialog box and re-enter valid serial numbers.
- If the serial number is not entered in one or both of the edit boxes, click "Select", the dialog box "Both "From" and "To" ranges must be entered!" will display. Click "OK" to close the dialog box and re-enter valid serial numbers.
- If the "From" number is greater than the "To" number, the dialog box "Invalid input!" will display. Click "OK" to close the dialog box and re-enter valid serial numbers.

---

### Deleting sample results

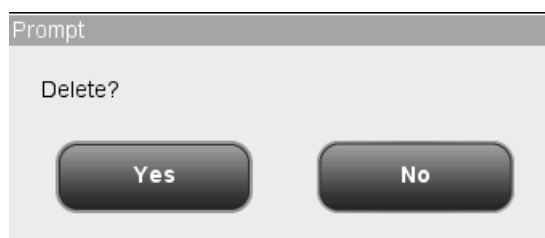
Administrators can delete sample results. Click "Delete", the following dialog box will display.





**Figure 7-9 "Delete" Dialog Box**

Select "Selected rec.(s)" or "All records", then click "OK", the following dialog box will display. Click "Yes" to confirm the deletion and close the dialog box. Click "No" to abort the deletion and close the dialog box.



**Figure 7-10 Deleting Records Dialog Box**

---

**NOTE**

- When the system is performing printing or transmission, click "Delete", the dialog box "System is busy, please try again later!" will display.
- If no result is selected, the dialog box "Please select data." will display.

---

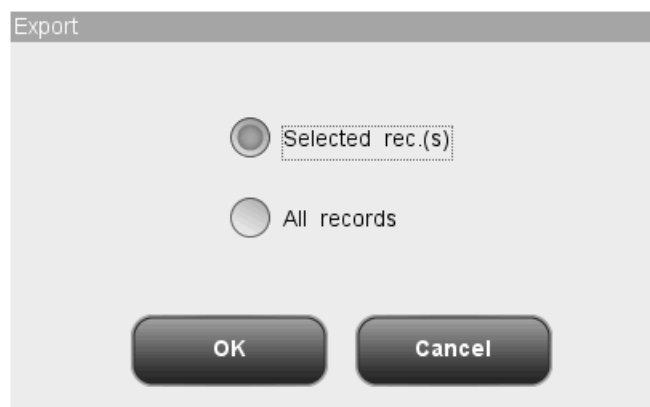
**Exporting data**

You may export selected sample data into a USB.

---

**NOTE**

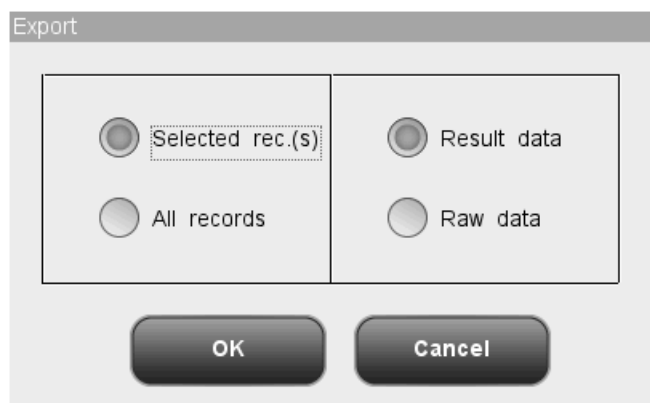
- Do not unplug the USB while exporting data.
- Select sample results first, and then click the "Export" button, the following dialog box will display for common users.



**Figure 7-11 "Export" Dialog Box (Common User)**

You may select to export the sample data of selected record(s) or all records. If "Selected rec.(s)" is clicked, but no record is actually selected, the dialog box "Please select data." will display. Click "OK" to export data, or click "Cancel" to cancel the operation. There will be system message indicating exporting failed or succeeded, and successful exporting operation will be recorded in system log.

- Select sample results first, and then click the "Export" button, the following dialog box will display for administrators.



**Figure 7-12 "Export" Dialog Box (Administrator)**

You may select to export the result data or raw data of selected record(s) or all records. Click "OK" to export data, or click "Cancel" to cancel the operation. There will be system message indicating exporting failed or succeeded, and successful exporting operation will be recorded in system log.

### Calculating CV%

Calculating CV% requires the access level of administrator. Select 3 or more sample results, click "CV%", the Mean, SD and CV% of the selected records will be calculated automatically, and the results will be displayed on the following dialog box.

Reproducibility

Parameter	Mean	SD	CV%
WBC	10.0	0.0	0.00
Lymph#	20.0	0.0	0.00
Mid#	30.0	0.0	0.00
Gran#	40.0	0.0	0.00
Lymph%	0.500	0.000	0.00
Mid%	0.600	0.000	0.00
Gran%	0.700	0.000	0.00
RBC	1.00	0.00	0.00
HGB	20	0	0.00
HCT	0.300	0.000	0.00
MCV	40.0	0.0	0.00
MCH	50.0	0.0	0.00

Print Return

Figure 7-13 "CV%" Dialog Box

Click "Print" at the bottom of the dialog box to print the results in the screen; Click "Return" to close the dialog box.

**NOTE**

- If less than 3 or more than 500 sample results are selected, the dialog box "Please select 3-500 records" will display.
- If a parameter result of a selected sample is invalid, then the calculated result of the parameter will be invalid and displayed as "+++++".

**Exported data**

You may review sample data that have been exported in table form.



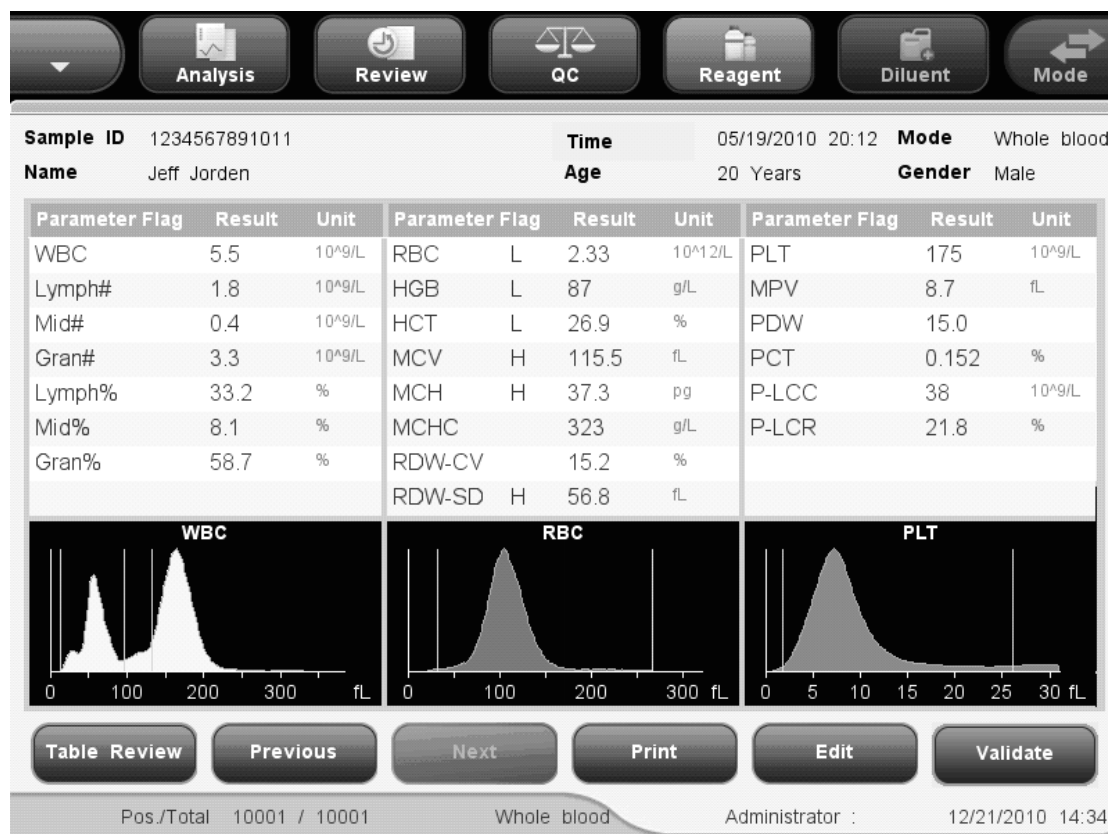
**Figure 7-14 Review Exported Data Screen**

You may click "Select" or "Print" on the screen to perform data selecting or printing.

## 7.2.2 Browsing in the “Graph Review” mode

Click "Graph Review" button at the table review screen to enter the following "Graph Review" screen. The sample information is displayed on top of the screen with sample results under it.

## Reviewing Sample Results



**Figure 7-15 "Graph Review" screen**

You may perform the following functions at the screen.

### Browsing sample results

You may click the "Previous" and "Next" button to browse sample results one by one.

### Returning to "Table Review" screen

You may click the "Table" button at the bottom of the screen to return to the "Table Review" screen.

### Printing

Press "Print" to print the contents of the current screen by the selected printer.

### Editing results

Click "Edit" at the screen, the following dialog box will display.

The screenshot shows a dialog box titled "Edit" with the following parameters and values:

WBC	10.0	10 <sup>9</sup> /L	RBC	1.00	10 <sup>12</sup> /L
Lymph%	0.500		HGB	20	g/L
Mid%	0.600		HCT	0.300	
Gran%	0.700		PLT	20	10 <sup>9</sup> /L

At the bottom of the dialog box are three buttons: "OK", "Cancel", and "Restore".

**Figure 7-16 "Edit results" Dialog Box**

The "Edit results" dialog box displays certain parameters and their results; you may edit the results in the edit boxes directly.

After editing the results, click "OK" to save the results and close the dialog box; click "Cancel" to close the dialog box without saving the results.

**NOTE**

- Only administrators are allowed to edit results, common users are not allowed to do so.
- If the result of one parameter is modified, then the result of other related parameter(s) will be changed accordingly and the high or low suspect flags will also be renewed.
- All parameter results are displayed on the graph review screen, but only the results of WBC, RBC, HGB, HCT, MCV, PLT and the differential parameters can be edited. When saving the edited results, system will judge if the sum of differential parameter results is 100%. If not, a prompt will be given.
- The sample results that have been checked cannot be edited. The parameter results that have been edited directly are flagged with an "E". The related results that change accordingly will be flagged with an "e".
- If the edited results exceed display range, the dialog box "Invalid editing!" will display when you save the results, and the result editing dialog box will stay open with the cursor in the first invalid edit box.

You may restore the original analysis results after editing the results. The flag information will also be restored when do so. The analyzer supports the restoration of 40,000 records maximum.

### **Validating sample results**

Administrators can click the "Validate" button to check the selected sample result. Then the "Check" button turns to be "Cancel Validate" button, click the button again to cancel checking.





# 8 Using the QC Programs

---

## 8.1 Introduction

Quality Control (QC) consists of strategies and procedures that measure the precision and stability of the analyzer. The results imply the reliability of the sample results. QC involves measuring materials with known, stable characteristics at frequent intervals. Analysis of the results with statistical methods allows the inference that sample results are reliable.

Mindray recommends you run the QC program daily with low, normal and high level controls. A new lot of controls should be analyzed in parallel with the current lot prior to their expiration dates. This may be accomplished by running the new lot of controls twice a day for five days using any empty QC files. The QC files calculate the mean, standard deviation and coefficient of variation for each selected parameter. The instrument-calculated means of these ten runs should be within the expected ranges published by the manufacturer.

This analyzer provides 4 QC programs: L-J QC, X-B QC, X-mean QC and X-mean R QC.

---

### **NOTE**

- **You should only use the Mindray-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents.**
-

## 8.2 L-J Quality Control

Using the "L-J Analysis" program, you may provide quality control for parameters. You are allowed to run QC for certain selected parameters base on your own needs. The analyzer provides 12 QC files for you to save QC settings and results. Up to 100 QC results can be saved in each QC file. When the saved QC results have reached 100, the system will ask you to delete the previous records first.

### 8.2.1 Editing L-J settings

Editing L-J settings requires the access level of administrator; common users can only print the settings.

Click the menu option "QC"→"L-J QC"→"Setup", the following screen will display.

Parameter	Mean	Range(#)	Parameter	Mean	Range(#)
WBC	6.0	0.5	MCH		
Lymph#			MCHC		
Mid#			RDW-CV		
Gran#			RDW-SD		
Lymph%			PLT		
Mid%			MPV		
Gran%			PDW		
RBC			PCT		

**Figure 8-1 L-J QC Setup Screen**

You may perform the following functions at the screen.

- Selecting the file number

Select the desired number from the "File No." pull-down list, ranging from 1 to 12.

- Entering the lot number

The analyzer provides two ways for you to enter the lot number: manual entering, and entering by importing QC file.

You may enter lot number into the "Lot No." box or select lot number from the "Lot No." pull down list (if there are previously saved lot No. in the list). You may also acquire lot number by importing QC file.

- Selecting the control level

SELECT the desired level (low, normal or high) from the "Level" pull-down list.

- Selecting the mode

SELECT the desired mode (whole blood or predilute) from the "Mode" pull-down list.

- Entering the Exp. Date

The analyzer provides two ways for you to enter the expiration date: manual entering, and entering by importing QC file.

You may enter the expiration date in to the Exp. Date box, or acquire the date by importing QC file.

---

**NOTE**

- **Refer to the instructions for use of the control for information on the lot number, expiration date, open vial stability days, expected results and limits.**
- **The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.**

---

- Entering QC sample ID

You may set the special sample ID of the selected QC file in "QC sample ID" box. If the QC sample ID of different QC files repeats, the message "ID already exists" will be displayed.

- Entering the expected results (mean) and limits (range)

The analyzer provides two ways for you to enter the expected results and limits: manual entering and entering by importing QC file.

You may enter the expected results and limits if desired QC parameters in to the "Mean" and "Range" boxes, or you may acquire the expected results and limits by importing QC file.

**NOTE**

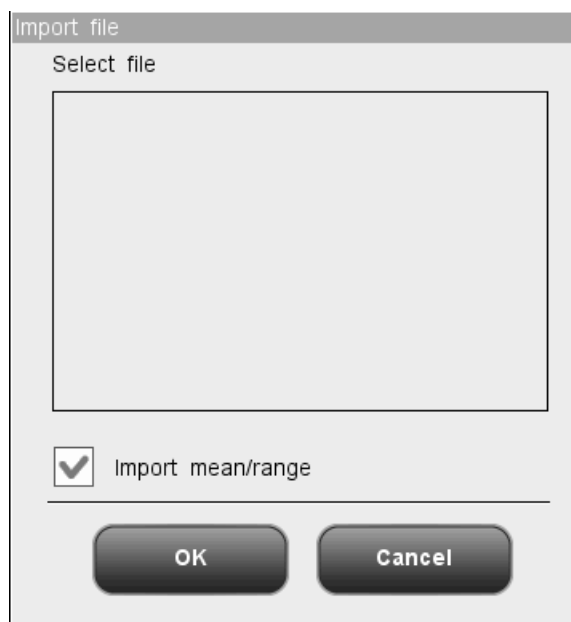
- The analyzer saves the expected result and limit of a parameter only when they are both valid.
- 

- Printing settings

Click "Print" to print the settings by the selected printer.

- Importing QC information

When there are no sample results in a QC file, you may import the control information including lot No., level, Exp. Date, mean and range values using a USB drive (with QC files saved in it). Connect the USB drive to the analyzer and click "Import File", the following dialog box will display.



**Figure 8-2"Import File" Dialog Box**

Select the desired QC file. If you do not want to import mean/range, click on the check box to deselect it, then click "OK" to import the file.

**NOTE**

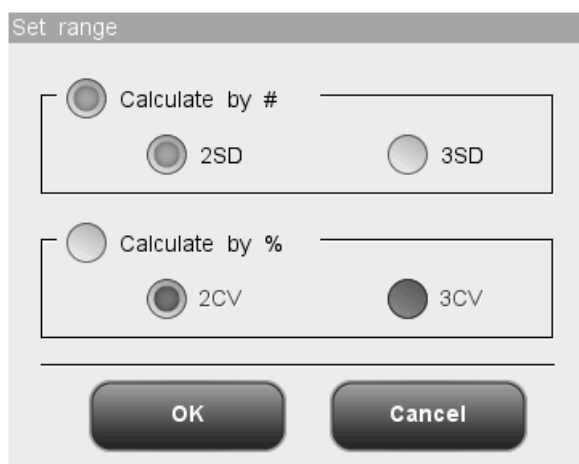
- If there are analysis results corresponding to the current file No. and lot No., the "Import File" button will be grayed out to disable the import function.
- 

- Clearing the expected results (mean)

Click "Del. Mean" to delete the expected results (mean) and limits (range) of the current QC file.

- Setting range

Click the "Set Range" button, and then the following dialog box will display.



**Figure 8-3 "Set range" Dialog Box**

You may select to calculate limits by absolute value or percentage, then click "OK" to save the settings and close the dialog box, or click "Cancel" to close the dialog box without saving the settings.

- Take preset value

Click the "Take Preset" button to import the saved preset value of the QC file into the "Mean" and "Range" edit boxes. If there is no such preset value, the button will be grayed.

- Exit the screen

After completing QC setup, click a menu option or other buttons at the function button area the exit the screen.

## 8.2.2 Running controls

After completing QC setup, click the menu option "QC" → "L-J QC" → "Count", you will enter the analysis screen of the lately operated QC file. If you have not run any control before, the count screen of File 1 will be displayed.

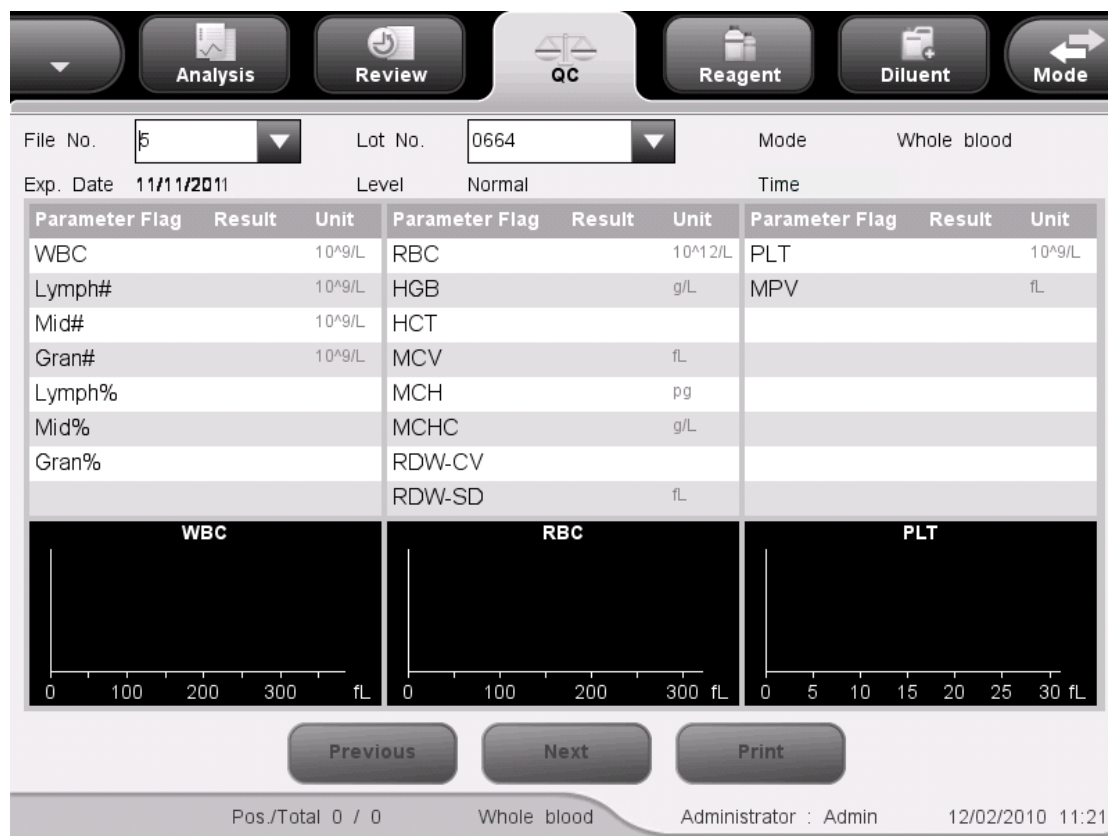


Figure 8-4 "Count" Screen



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

### **⚠ WARNING**

- The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
- The sample may spill from the uncapped collection tubes and cause biohazard. Exercise caution to the uncapped collection tubes.
- The breaking of collection tubes may cause personal injury and/or biohazard. Take precaution when loading and unloading collection tubes from the rack. Avoid breaking the sample tubes.
- Keep your clothes, hairs and hands away from the moving parts to avoid

**injury.**

- **The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
  - **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**
- 

**⚠ CAUTION**

- **Do not re-use disposable products like collection tubes, test tubes, capillary tubes, etc.**
- 

**NOTE**

- **You should only use the Mindray-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents.**
- 

Do as follows to run controls:

1. Select the desired numbers from the "File No." and "Lot No." pull-down lists.
2. Prepare the control as instructed by instructions for use of the controls.
3. Run controls

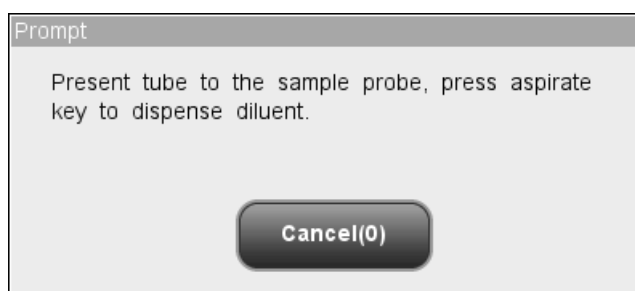
### **Running controls for open vial model**

**Running controls in the whole blood mode per the following procedure:**

1. Make sure the analyzer indicator is green and the work mode is "Whole Blood".
2. Present the control to the sample probe.
3. Press the aspirate key to start the analysis. The analyzer starts to run the control automatically and the indicator flickers in green.
4. The sample probe will automatically aspirate 17 $\mu$ L of sample. When you hear the beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample. The "No./Total" at the bottom of the screen will automatically increase by 1.
5. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.

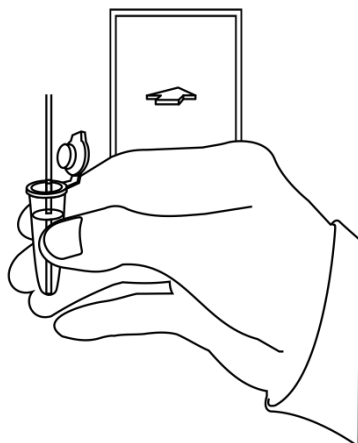
**Running controls in the predilute mode per the following procedure:**

1. Make sure the analyzer indicator is green and the work mode is "Predilute".
2. Click the diluent dispensing icon, the following dialog box pops up.



**Figure 8-5 Diluent Dispensing Prompt**

3. Present a clean centrifugal tube to the sample probe, press the aspirate key. Make sure the tube is tilted towards the probe, as the following figure shows, to avoid spills and bubbles. The dispensing progress bar will be displayed on the screen with message showing "Dispensing diluent...".



**Figure 8-6 Dispensing Diluent**

4. After the dispensing finishes, you will hear a beep, and then you may remove the sample. Then the message in the dialog box turns to "Present tube to the sample probe, press aspirate key to dispense diluent." again. Click "Cancel", the analyzer will clean the sample probe automatically with cleaning progress displayed. After the operation finishes, the dialog box will close automatically.
5. Add 20 $\mu$ L of control to the diluent, close the tube cap and mix it properly according to your laboratory's protocol.
6. Present the control to the sample probe.
7. Press the aspirate key to start the analysis. The analyzer starts to run the control automatically and the indicator flickers in green.



8. The sample probe will automatically aspirate 146.34 $\mu$ L of sample. When you hear the beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample.
9. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.

---

## **NOTE**

- **During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.**
  - **If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- 

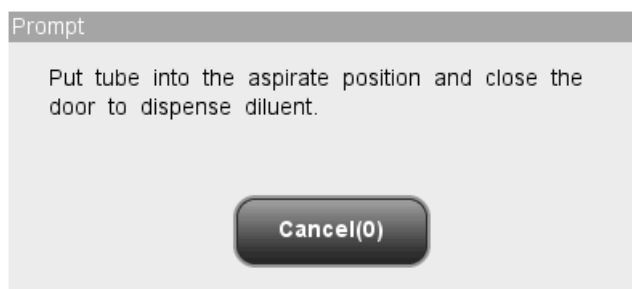
## **Running controls for closed tube model**

### **Running controls in the whole blood mode per the following procedure:**

1. Be sure the analyzer indicator is green and the analysis mode is "Whole Blood".
2. Open the compartment door. Make sure the translucent whole blood tube holder adapter is at the aspirating position and put the prepared control into it, then close the compartment door. The analyzer will perform control analysis automatically.
3. When sample aspiration is finished, the compartment door will open automatically.
4. When the analysis is finished, the results will be displayed on the screen.

### **Running controls in the predilute mode per the following procedure:**

1. Be sure the analyzer indicator is green and the analysis mode is "Predilute".
2. Click the diluent dispensing icon, the compartment door opens automatically and the following dialog box displays.



**Figure 8-7 Diluent Dispensing Dialog Box**

3. Make sure the black predilute tube holder adapter is at the aspirating position and put a centrifugal tube into the adapter, then close the compartment door.
4. The analyzer automatically dispenses diluent into the tube and the progress will be displayed on the dialog box.
5. When dispensing diluent is finished, the compartment door will open. Click "Cancel" on the pop-up dialog box to close it.
6. Add 20 $\mu$ L of control to the diluent, close the tube cap and mix it properly according to your laboratory's protocol.
7. Open the compartment door. Make sure the black predilute tube holder adapter is at the aspirating position and put the prepared sample into it, then close the compartment door. The analyzer will perform control analysis automatically.
8. When sample aspiration is finished, the compartment door will open automatically.
9. When the analysis is finished, the results will be displayed on the screen.

---

**⚠ WARNING**

- **The centrifugal tube must not be capped when running prediluted samples.**

---

**NOTE**

- **If the current tube holder adapter does not match with the analysis mode, a dialog box will display indicating "The analysis mode and tube holder adapter are mismatched, please switch modes or replace tube holder adapter.". Click "OK", the compartment door will open automatically.**
  - **During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.**
-

- **If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- 

You may perform the following functions at the screen.

- **Browsing data**

You may browse the results of QC analysis. Click the "Previous" and "Next" button to browse the results of QC analysis one by one.

- **Switching among QC count screens**

Click the "File No." or "Lot No." pull-down list to switch to the QC count screen of other QC files.

- **Printing**

Click "Print" to print the results by the selected printer.

### **8.2.3 Reviewing L-J QC Results**

After running controls, you may review the QC results in the following two ways:

- **Graph**
- **Table**

#### **"L-J Graph" mode**

Click the menu option "QC"→"L-J QC"→"Graph", you will enter the L-J graph screen of the lately operated QC file.

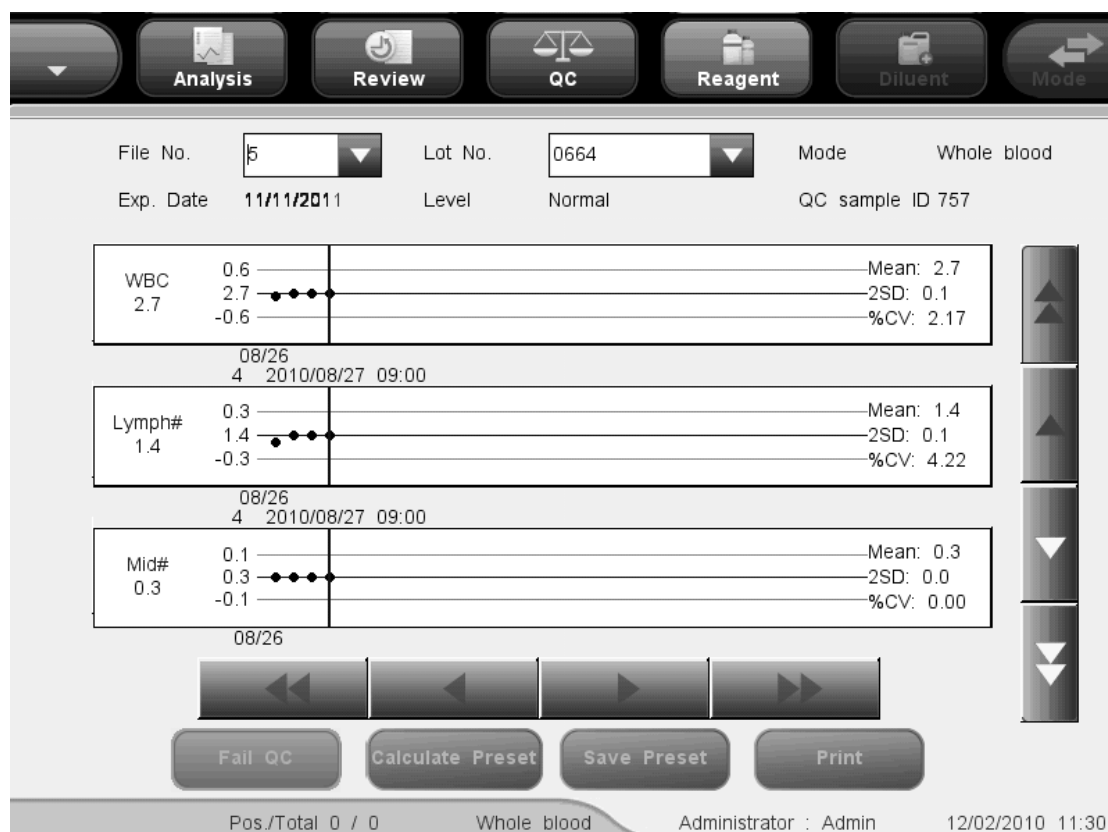


Figure 8-8 "L-J QC graph" Screen

Select the desired numbers from the "File No." and "Lot No." pull-down lists to switch to the corresponding QC graph screen.

### NOTE

- The "Mean", "SD" and "CV%" of each parameter are only available when there are 3 or more within-control results in the L-J QC graph.

The L-J QC graph can be interpreted as follows:

- The x-coordinate represents the QC run performed; the y-coordinate represents the values obtained from the QC run.
- Points linked by a blue line represent results from a same L-J analysis.
- For every parameter, its L-J QC graph can display up to 100 points, 31 per screen.
- For every parameter, the upper dash line represents the expected result + limit. For every parameter, the lower dash line represents the expected result – limit.
- For every parameter (e.g. WBC), the three numbers to the left of the graph are:  
Upper limit: the expected result + limit.  
Target: the expected result.  
Lower limit: the expected result – limit.

- For every parameter, the three numbers to the right of the L-J QC graph are defined and calculated as follows:

Mean - the average of the saved L-J analyses.

SD - Standard Deviation.

CV% - Coefficient of Variation.

$$\text{Mean} = \frac{\sum_{i=1}^n X_i}{n}$$

$$\text{SD} = \sqrt{\frac{\sum (X_i - \text{Mean})^2}{n - 1}}$$

$$\text{CV\%} = \frac{\text{SD}}{\text{Mean}} \times 100$$

Where, n is the number of the saved L-J analyses and  $X_i$  is the result of the  $i$ th L-J analysis.

The points in the graphs can be interpreted as follows:

"●": the point falls within the upper and lower limits, and has not been set as out-of-control point.

"○": the point falls outside the upper and lower limits, but has been set as out-of-control point. Red solid triangle means its value is outside the display range, but has not been set as out-of-control point. The triangle pointing upward means the value exceeds H limit, while the triangle pointing downward means the value exceeds L limit.

Red hollow triangle means its value is outside the display range, and has been set as out-of-control point. The triangle pointing upward means the value exceeds H limit, while the triangle pointing downward means the value exceeds L limit.

If you see any points fallen outside the control range, do as follows until the problem is solved. If all the steps have failed, contact Mindray customer service department or your local distributor for assistance.

1. Check the screen for error messages and refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
2. Check the L-J settings for inappropriate entries.
3. Do background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
4. Re-run the control.
5. Run another vial of control.
6. Check if the analyzer needs to be calibrated.

At the "L-J QC graph" screen, you may:

■ Browsing data

The L-J analysis results are sequentially displayed on the graph, the latest on the utmost right of the graph. You may click the arrow buttons on the right the QC graph to review result of each parameter.

Click the arrow buttons under the graph to review each QC result.

■ Set the preset-values

You (administrator level) can select results from the L-J QC graph to calculate the Mean, SD and CV%, and set the calculated results to be preset-value when editing the settings. In QC files, you may set a set of preset-values calculated for 3 lots of controls respectively.

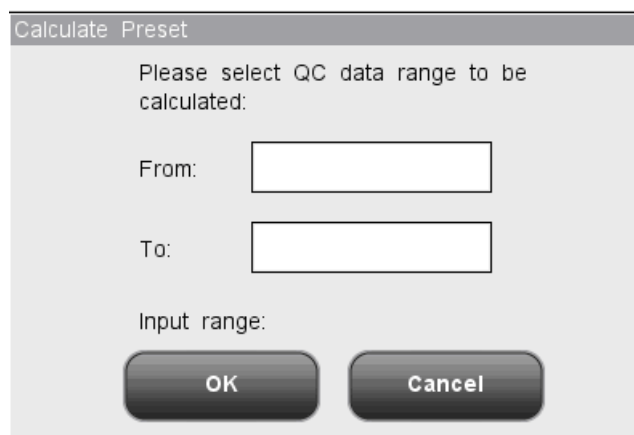
Do as instructed below.

---

**NOTE**

- **The preset-value can only be calculated by selecting within-control results of at least 3 QC runs.**
- 

1. Click the “Calculate Preset” button, and then a dialog box will display.



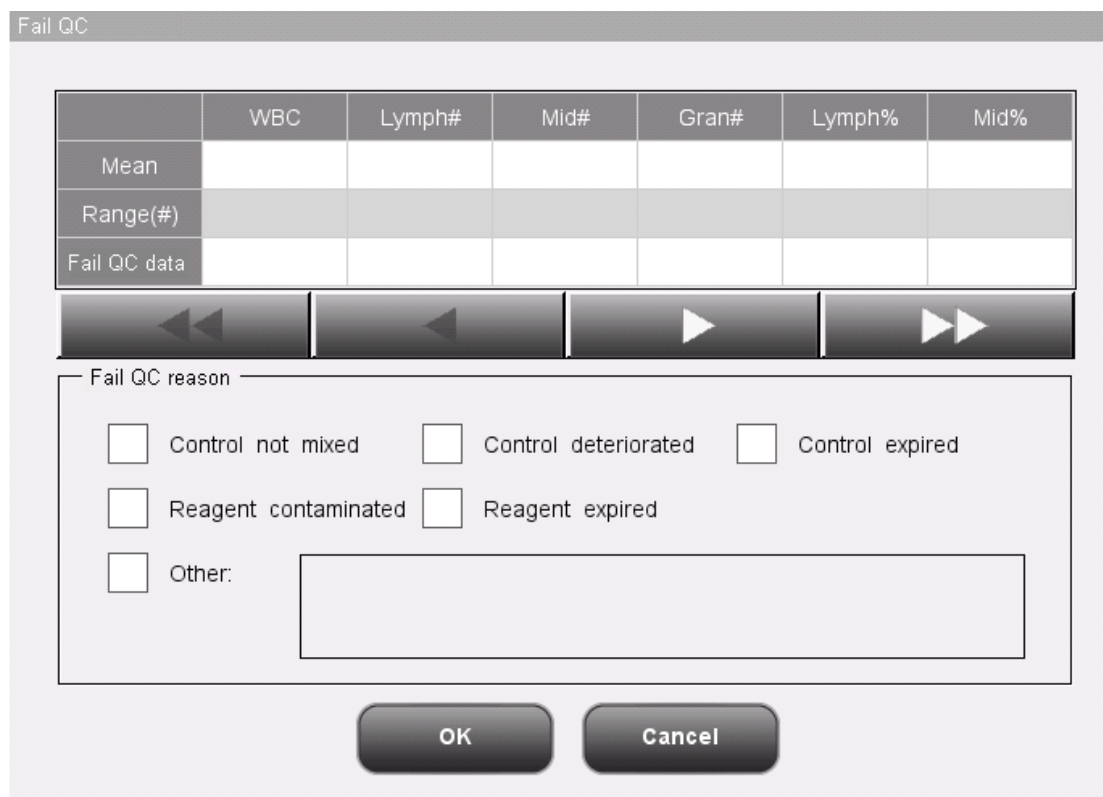
**Figure 8-9 Calculating the Preset Value**

2. Enter the desired data range into the “From” and “To” boxes.
3. Click "OK" to close the dialog box and return the "L-J QC graph" screen, the Mean, SD and CV% calculated from the selected data will be displayed on the right of the graph.
4. Click the “Save Preset” button, a dialog box will display. Click “Yes” to save the preset-value and return to the “L-J QC graph” screen.

■ Handling out of control

If out of control data appears, you (administrator level) can give the reasons as per the following instructions.

Move the blue vertical line in the graph to the out of control point; click the "Fail QC" (out of control) button, the following dialog box will display.



**Figure 8-10 "Fail QC" Dialog Box**

The dialog box will list all out of control data of the out of control point on the blue line, all L-J QC parameters, their expected results and limits.

Reasons of out of control points on the blue line are provided in the dialog box, you may click to select the desired ones. You may also enter reasons in the "Others" box manually, up to 60 characters.

After the edit, click the "OK" button to save the out of control reason, close the dialog box and return to the "L-J QC graph" screen. Click the "Cancel" button to abort the changes, close the dialog box and return to the "L-J QC graph" screen.

- Printing

Click the "Print" button to print the QC graph on the screen.

- Exiting

Click the menu options or other buttons in the functional button area to exit the screen.

### "L-J Table" mode

Click the menu option "QC" → "L-J QC" → "Table", you will enter the L-J QC table screen of the

lately operated QC file.

	Date	Time	WBC	Lymph#	Mid#
Mean			6.0		
Range(#)			0.5		

**Figure 8-11 "L-J QC table" Screen**

Select the desired numbers from the "File No." and "Lot No." pull-down lists to switch to the corresponding QC table screen.

At the "L-J QC table" screen, you may:

- Browsing data

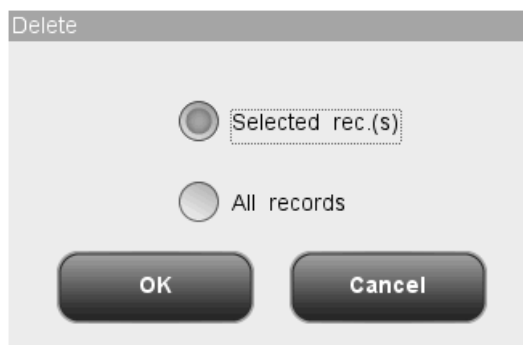
You may click the arrow buttons on the right of the QC table to review result of each parameter. The L-J analysis results are sequentially displayed in the table, the latest on the bottom of the table.

- Deleting sample results

You (administrator level) can delete any one or all of the L-J analysis results saved in the current QC file.

Click the result you want to delete, then Click the "Delete" button, the following dialog box will display:





**Figure 8-12 Deleting QC Results**

Select "Selected rec.(s)" or "All records", then click "OK" to perform deleting. The operation will be recorded into system log. Or click "Cancel" to abort deleting.

- Transmitting analysis results

You may click the "Transmit" button to transmit all the L-J analysis results to an external computer (a host).

- Data exporting

Click the "Export" Button at the L-J table screen to export the data in the current QC table to the USB drive.

- Printing

Click the "Print" button to print the QC table on the screen.

- Exiting

Click the menu options or other buttons in the functional button area to exit the screen.

---

**NOTE**

- Do not unplug the USB while exporting data.
-

## 8.3 "X-B QC" Program

The X-B analysis is a weighted moving average analysis that uses values obtained from patient samples. It uses the 3 red cell indices, MCV, MCH and MCHC to indicate the hematology instrument performance. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices.

### 8.3.1 Editing the X-B Settings

Editing X-B settings requires the access level of administrator, common users can only print the settings.

Click the menu option "QC"→"X-B QC"→"Setup", the following screen will display.

The screenshot shows the X-B QC Setup screen with a navigation bar at the top containing icons for Analysis, Review, QC, Reagent, Diluent, and Mode. The main content area is divided into three sections:

- Value setup:** A table with columns for Parameter, Mean, and Range(%).
 

Parameter	Mean	Range(%)
MCV	89.5	3.00
MCH	30.5	3.00
MCHC	340	3.00

 A "Set Range" button is located to the right of this table.
- Sample validity setup:** A table with columns for Parameter, L limit, and H limit.
 

Parameter	L limit	H limit
RBC	1.00	8.00
MCV	50.0	150.0
MCH	20.0	40.0
MCHC	240	440
- X-B QC:** A section with a text input field for "Num./group of sample" containing the value "20" and a range "[20, 200]". Below this is a radio button for "X-B QC:" with "Open" selected and "Close" as an alternative. A "Print" button is located to the right.

At the bottom of the screen, the text "Whole blood" is displayed on the left, "Administrator :" is in the center, and "12/21/2010 14:42" is on the right.

**Figure 8-13 X-B QC Setup Screen**

At the X-B QC setting screen, you may activate/deactivate X-B QC, set number of samples/group and mean/range, and configure the sample validity setup.

#### Activate/deactivate X-B QC

You may select to activate or deactivate X-B QC at the X-B QC setup screen.

## **NOTE**

- **Random samples are required for the X-B analysis. In case of known samples of a particular type (oncology, neonatal and so forth) that will seriously interfere with the X-B results, deactivate the X-B analysis.**
  - **Click the "Close" radio button on the screen to deactivate X-B QC.X-B QC is deactivated by default.**
- 

### **Set number of samples /group**

In the "Num. /group of sample" edit box, you may enter the amount of samples [within the range 20(recommended) to 200] to be included in calculating for an X-B QC point.

### **Set mean/range**

Enter the means and ranges for the parameters to be included in the X-B analysis into their respective boxes.

---

## **NOTE**

- **Be sure to calibrate your analyzer before trying to establish the expected results by calculating the averages of random patient samples.**
  - **The expected results vary with areas. It is recommended they are obtained by calculating the averages of at least 500 random patient samples.**
  - **The recommended limit is 3% - 5%.**
- 

### **Setting sample validity**

In X-B QC, sample results conforming to any of the following conditions will be considered as invalid and cannot be used in the QC calculation.

1. Sample results exceeding the linearity range;
  2. Background results;
  3. Sample results not conforming to the "Sample Validity Setup";
  4. QC data for QC programs other than X-B;
  5. Calibration data;
  6. Results generated while there are errors which could affect the accuracy of the results (insufficient aspiration volume or clogging for example).
-

"Sample Validity Setup" is to set up the ranges of valid RBC, MCV, MCH and MCHC results. Only when the results of all these four parameters are within the specified ranges, the sample results can be used for X-B QC calculation. Do as follows to set the sample validity:

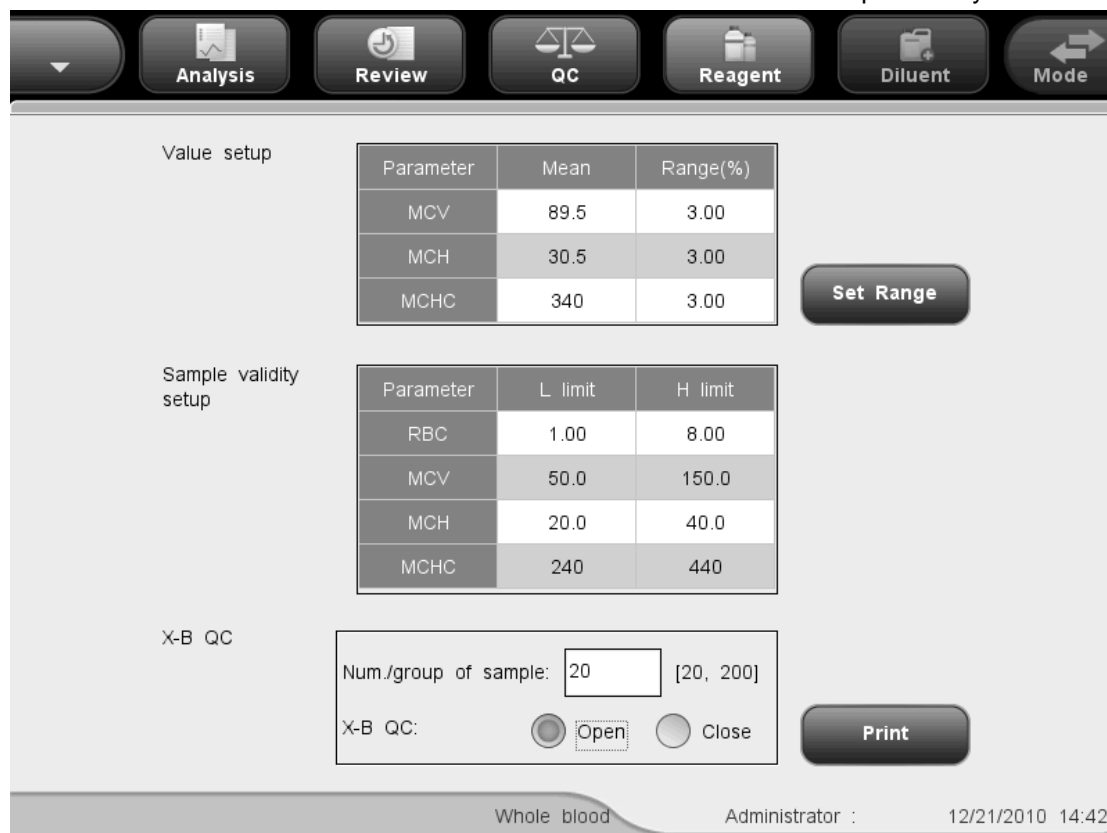


Figure 8-14 X-B QC Setup Screen

Click the "H limit" or "L limit" of the parameter you want to customize, and then enter the desired numbers within the ranges shown in the table below for the four parameters.

Parameter	L Limit	H Limit	Unit
RBC	0.00	8.00	10 <sup>12</sup> /L
MCV	0.0	250.0	fL
MCH	0.0	999.9	pg
MCHC	0	999	g/L

**NOTE**

- The default validity ranges for the four parameters are:  
 $1.0 \times 10^{12}/L \leq RBC \leq 8.0 \times 10^{12}/L$                        $50fL \leq MCV \leq 150fL$   
 $20pg \leq MCH \leq 40pg$      $240g/L \leq MCHC \leq 440g/L$
- All the entries should be numbers with only one decimal point.
- Once the validity range is changed, the previous results will not be used in

the QC calculation as valid results, for example, if 20 valid samples are needed for the X-B QC calculation, when you change the validity range after 10 groups of valid sample results have been acquired, these 10 groups of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.

---

- Printing

Click the "Print" button to print the contents on the screen.

- Exit the screen

After completing QC setup, click a menu option or other buttons at the function button area the exit the screen.

### 8.3.2 Running Controls

---



- **All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- 

After editing the X-B settings, the system will start the X-B run automatically.

After every 20~200 results (determined by the setting) are obtained, the system will perform the X-B calculation once automatically. You may review the result in X-B QC graph or X-B QC table.

### 8.3.3 Reviewing QC Results

After running controls, you may review the QC results in the following two ways:

- Graph
- Table

#### "X-B Graph" mode

Click the menu option "QC"→"X-B QC"→"Graph", the following screen will display.



**Figure 8-15 X-B QC Graph Screen**

The X-B QC graph can be interpreted as follows:

- The x-coordinate represents the QC run performed; the y-coordinate represents the values obtained from the QC run.
- Points linked by a blue line represent results from a same X-B analysis.
- For every parameter, its X-B QC graph can display up to 500 points, 31 points per screen.
- For every parameter, the upper dash line represents the expected result + limit.
- For every parameter, the lower dash line represents the expected result – limit.
- For every parameter (e.g. WBC), the three numbers to the left of the graph are:
  - Upper limit: the expected result + limit.
  - Target: the expected result.
  - Lower limit: the expected result – limit.
- For every parameter, the three numbers to the right of the X-B QC graph are defined and calculated as follows:
  - Mean - the average of the saved L-J analyses.
  - SD - Standard Deviation.
  - CV% - Coefficient of Variation.

$$\text{Mean} = \frac{\sum_{i=1}^n X_i}{n}$$

$$\text{SD} = \sqrt{\frac{\sum (X_i - \text{Mean})^2}{n - 1}}$$

$$\text{CV}\% = \frac{\text{SD}}{\text{Mean}} \times 100$$

where, n represents how many sample results are included in an X-B analysis and  $X_i$  is the  $i$ th sample result in any X-B analysis.

The points in the graphs can be interpreted as follows:

"●": the point falls within the upper and lower limits, and has not been set as out-of-control point.

"○": the point falls outside the upper and lower limits, but has been set as out-of-control point.

Red solid triangle means its value is outside the display range, but has not been set as out-of-control point. The triangle pointing upward means the value exceeds H limit, while the triangle pointing downward means the value exceeds Limit.

Red hollow triangle means its value is outside the display range, and has been set as out-of-control point. The triangle pointing upward means the value exceeds H limit, while the triangle pointing downward means the value exceeds L limit.

If you see any points fallen outside the control range, do as follows until the problem is solved. If all the steps have failed, contact Mindray customer service department or your local distributor for assistance.

1. Check the screen for error messages and refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
2. Check the X-B settings for inappropriate entries.
3. Do background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
4. Run a control.
5. Check if the analyzer needs to be calibrated.

At the "X-B QC graph" screen, you may:

■ Browsing data

The X-B analysis results are sequentially displayed on the graph, the latest on the utmost right of the graph. You may click the arrow buttons under the graph to review all the results.

- Printing

Click the "Print" button to print the X-B QC graph by the selected printer.

- Exiting

Click the menu options or other buttons in the functional button area to exit the screen.

### "X-B Table" mode

Click the menu option "QC" → "X-B QC" → "Table", the following screen will display.



**Figure 8-16 X-B QC Table Screen**

At the "X-B QC table" screen, you may:

- Browsing data

You may click the arrow buttons on the right of the QC table to review results of the three parameters. The X-B analysis results are sequentially displayed in the table, the latest on the bottom of the table.

- Printing

Click the "Print" button to print the X-B QC table by the selected printer.

- Deleting sample results

You (administrator level) can delete all X-B QC results. Click "Delete", a dialog box will display asking to confirm the operation. If you want to delete all X-B QC results, click "Yes";



otherwise click "No". The operation will be recorded into system log.

- Data exporting

You may export the data to an external USB. Click the "Export" Button to export the data in the current QC table to the USB drive.

- Exiting

Click the menu options or other buttons in the functional button area to exit the screen.

---

**NOTE**

- Do not unplug the USB while exporting data.
-

## 8.4 "X-mean QC" Program

Using the "X-mean Analysis" program, you may provide quality control for all parameters. You are allowed to run QC for certain selected parameters base on your own needs. The analyzer provides 12 QC files for you to save QC settings and results. Up to 100 QC results can be saved in each QC file. When the saved QC results have reached 100, the system will ask you to delete the previous records first.

### 8.4.1 Editing X-mean Settings

Editing X-mean settings requires the access level of administrator; common users can only print the settings.

Click the menu option "QC"→"X-mean QC"→"Setup", you will enter the setup screen of the lately operated QC file. If you have not run any control before, the count screen of File 1 will be displayed.

Parameter	Mean	Range(#)	Parameter	Mean	Range(#)
WBC			MCH		
Lymph#			MCHC		
Mid#			RDW-CV		
Gran#			RDW-SD		
Lymph%			PLT		
Mid%			MPV		
Gran%			PDW		
RBC			PCT		

**Figure 8-17 X-mean QC Setup Screen**

You may perform the following functions at the screen.

- Selecting the file number

Select the desired number from the "File No." pull-down list, ranging from 1 to 12.

■ Entering the lot number

The analyzer provides two ways for you to enter the lot number: manual entering, and entering by importing QC file.

You may enter lot number into the "Lot No." box or select lot number from the "Lot No." pull down list (if there are previously saved lot No. in the list). You may also acquire lot number by importing QC file.

■ Selecting the control level

SELECT the desired level (low, normal or high) from the "Level" pull-down list.

■ Selecting the mode

SELECT the desired mode (whole blood or predilute) from the "Mode" pull-down list.

■ Entering the Exp. Date

The analyzer provides two ways for you to enter the expiration date: manual entering, and entering by importing QC file.

You may enter the expiration date in to the Exp. Date box, or acquire the date by importing QC file.

---

**NOTE**

- **Refer to the instructions for use of the control for information on the lot number, expiration date, open vial stability days, expected results and limits.**
- **The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.**

---

■ Entering the expected results (mean) and limits (range)

The analyzer provides two ways for you to enter the expected results and limits: manual entering and entering by importing QC file.

You may enter the expected results and limits if desired QC parameters in to the "Mean" and "Range" boxes, or you may acquire the expected results and limits by importing QC file.

**NOTE**

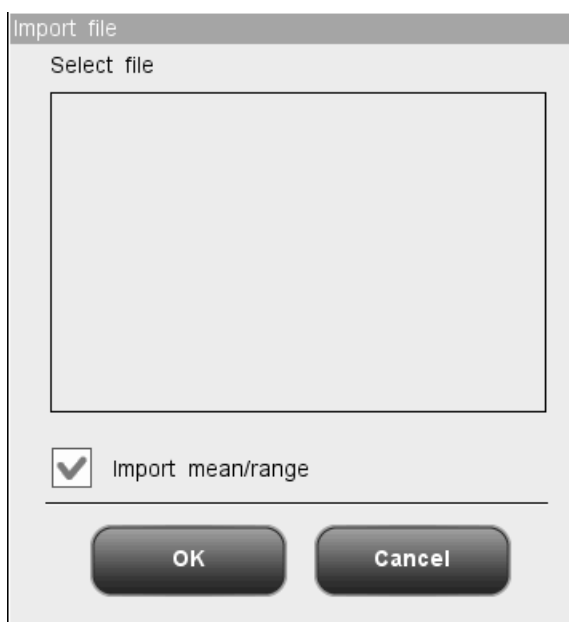
- **The analyzer saves the expected result and limit of a parameter only when they are both valid.**
- 

- **Printing**

Click "Print" to print the settings by the selected printer.

- **Importing QC information**

When there are no sample results in a QC file, you may import the control information including lot No., level, Exp. Date, mean and range values using a USB drive (with QC files saved in it). Connect the USB drive to the analyzer and click "Import File", the following dialog box will display.



**Figure 8-18 "Import File" Dialog Box**

Select the desired QC file. If you do not want to import mean/range, click on the check box to deselect it, then click "OK" to import the file.

---

**NOTE**

- **If there are analysis results corresponding to the current file No. and lot No., the "Import File" button will be grayed out to disable the import function.**
- 

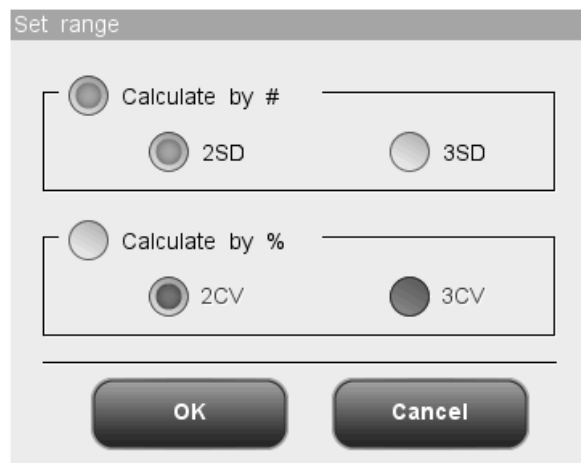
- **Clearing the expected results (mean)**

Click "Del. Mean" to delete the expected results (mean) and limits (range) of the current

QC file.

- Setting range

Click the "Set Range" button, and then the following dialog box will display.



**Figure 8-19 "Set range" Dialog Box**

You may select to calculate limits by absolute value or percentage, then click "OK" to save the settings and close the dialog box, or click "Cancel" to close the dialog box without saving the settings.

- Take preset value

Click the "Take Preset" button to import the saved preset value of the QC file into the "Mean" and "Range" edit boxes. If there is no such preset value, the button will be grayed.

- Exit the screen

After completing QC setup, click a menu option or other buttons at the function button area to exit the screen.

## 8.4.2 Running Controls

After completing QC setup, click the menu option "QC"→"X-mean QC"→"Count", you will enter the analysis screen of the lately operated QC file. If you have not run any control before, the count screen of File 1 will be displayed.

	First	Second	Mean	Unit
WBC				10 <sup>9</sup> /L
Lymph#				10 <sup>9</sup> /L
Mid#				10 <sup>9</sup> /L
Gran#				10 <sup>9</sup> /L
Lymph%				
Mid%				
Gran%				
RBC				10 <sup>12</sup> /L
HGB				g/L
HCT				

Figure 8-20"Count" Screen



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

### **▲WARNING**

- The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
- The sample may spill from the uncapped collection tubes and cause biohazard. Exercise caution to the uncapped collection tubes.
- The breaking of collection tubes may cause personal injury and/or biohazard. Take precaution when loading and unloading collection tubes from the rack. Avoid breaking the sample tubes.

- **Keep your clothes, hairs and hands away from the moving parts to avoid injury.**
  - **The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
  - **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**
- 

**⚠ CAUTION**

- **Do not re-use disposable products like collection tubes, test tubes, capillary tubes, etc.**
- 

**NOTE**

- **You should only use the Mindray-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents.**
- 

Do as follows to run controls:

1. Select the desired numbers from the "File No." and "Lot No." pull-down lists.
2. Prepare the control as instructed by instructions for use of the controls.
3. Run controls

## **Running controls for open vial model**

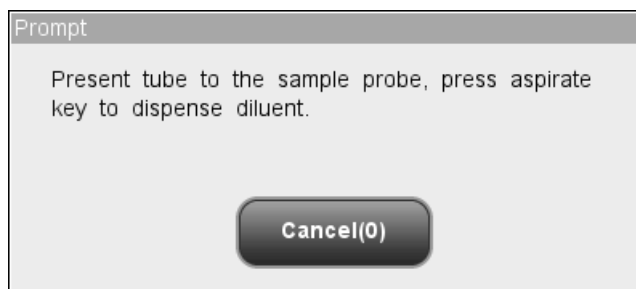
### **Running controls under the whole blood mode**

1. Make sure the analyzer indicator is green and the work mode is "Whole Blood".
  2. Present the control to the sample probe.
  3. Press the aspirate key to start the analysis. The analyzer starts to run the control automatically and the indicator flickers in green.
  4. The sample probe will automatically aspirate 17 $\mu$ L of sample. When you hear the beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample.
  5. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.
-

6. Follow the above steps to have another QC run. When you have obtained two valid QC results, the analyzer will calculate the average and take it as an X-mean analysis result. The average will be flagged "H" or "L" if it falls outside the expected range.

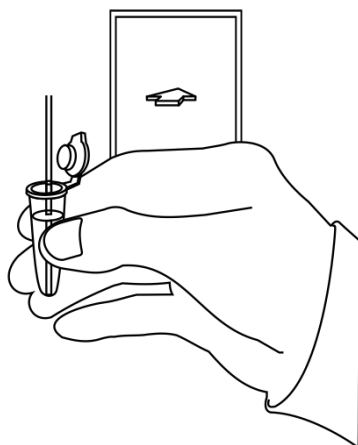
**Running controls under the predilute mode:**

1. Make sure the analyzer indicator is green and the work mode is "Predilute".
2. Click the diluent dispensing icon, the following dialog box pops up.



**Figure 8-21 Diluent Dispensing Prompt**

3. Present a clean centrifugal tube to the sample probe, press the aspirate key. Make sure the tube is tilted towards the probe, as the following figure shows, to avoid spills and bubbles. The dispensing progress bar will be displayed on the screen with message showing "Dispensing diluent...".



**Figure 8-22 Dispensing Diluent**

4. After the dispensing finishes, you will hear a beep and then you may remove the sample. Then the message in the dialog box turns to "Present tube to the sample probe, press aspirate key to dispense diluent." again. Click "Cancel", the analyzer will clean the sample probe automatically with cleaning progress displayed. After the operation finishes, the dialog box will close automatically.



5. Add 20 $\mu$ L of control to the diluent, close the tube cap and mix it properly according to your laboratory's protocol.
6. Present the control to the sample probe.
7. Press the aspirate key to start the analysis. The analyzer starts to run the control automatically and the indicator flickers in green.
8. The sample probe will automatically aspirate 146.34 $\mu$ L of sample. When you hear the beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample.
9. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.
10. Follow the above steps to have another QC run. When you have obtained two valid QC results, the analyzer will calculate the average and take it as an X-mean analysis result. The average will be flagged "H" or "L" if it falls outside the expected range.

---

## **NOTE**

- **During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.**
  - **If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- 

## **Running controls for closed tube model**

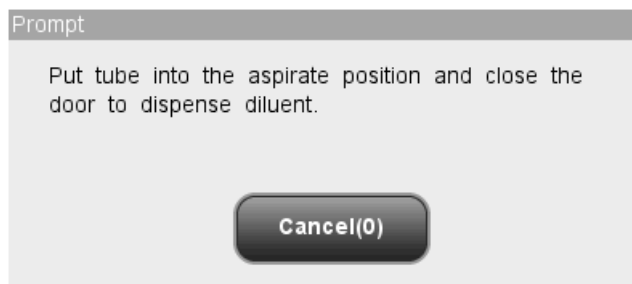
### **Running controls under the whole blood mode**

1. Be sure the analyzer indicator is green and the analysis mode is "Whole Blood".
2. Open the compartment door. Make sure the translucent whole blood tube holder adapter is at the aspirating position and put the prepared control into it, then close the compartment door. The analyzer will perform control analysis automatically.
3. When sample aspiration is finished, the compartment door will open automatically.
4. When the analysis is finished, the results will be displayed on the screen.
5. Follow the above steps to have another QC run. When you have obtained two valid QC results, the analyzer will calculate the average and take it as an X-mean

analysis result. The average will be flagged “H” or “L” if it falls outside the expected range.

#### Running controls under the predilute mode

1. Be sure the analyzer indicator is green and the analysis mode is “Predilute”.
2. Click the diluent dispensing icon, the compartment door opens automatically and the following dialog box displays.



**Figure 8-23 Diluent Dispensing Dialog Box**

3. Make sure the black predilute tube holder adapter is at the aspirating position and put a centrifugal tube into the adapter, then close the compartment door.
4. The analyzer automatically dispenses diluent into the tube and the progress will be displayed on the dialog box.
5. When dispensing diluent is finished, the compartment door will open. Click “Cancel” on the pop-up dialog box to close it.
6. Add 20 $\mu$ L of control to the diluent, close the tube cap and mix it properly according to your laboratory’s protocol.
7. Open the compartment door. Make sure the black predilute tube holder adapter is at the aspirating position and put the prepared sample into it, then close the compartment door. The analyzer will perform control analysis automatically.
8. When sample aspiration is finished, the compartment door will open automatically.
9. When the analysis is finished, the results will be displayed on the screen.
10. Follow the above steps to have another QC run. When you have obtained two valid QC results, the analyzer will calculate the average and take it as an X-mean analysis result. The average will be flagged “H” or “L” if it falls outside the expected range.

---

#### **▲WARNING**

- **The centrifugal tube must not be capped when running prediluted samples.**
-

**NOTE**

- If the current tube holder adapter does not match with the analysis mode, a dialog box will display indicating “The analysis mode and tube holder adapter are mismatched, please switch modes or replace tube holder adapter.”. Click “OK”, the compartment door will open automatically.
  - During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.
  - If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.
- 

You may perform the following functions at the screen.

■ Browsing data

You may browse the results of QC analysis. Click the “Previous” and “Next” button to browse the results of QC analysis one by one.

■ Switching among QC count screens

Click the "File No." or "Lot No." pull-down list to switch to the QC count screen of other QC files.

■ Printing

Click "Print" to print the results by the selected printer.

---



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
-

After editing the X-B settings, the system will start the X-B run automatically.

After every 20~200 results (determined by the setting) are obtained, the system will perform the X-B calculation once automatically. You may review the result in X-B graph or X-B table.

### 8.4.3 Reviewing X-mean QC Results

After the X-mean analysis, you may review the QC results in the following two ways:

- Graph
- Table

#### "X-mean Graph" mode

Click the menu option "QC"→"X-mean QC"→"Graph", you will enter the X-mean graph screen of the lately operated QC file.

The screenshot displays the X-mean QC Graph Screen. At the top, there is a navigation bar with buttons for Analysis, Review, QC, Reagent, Diluent, and Mode. Below the navigation bar, there are input fields for File No., Lot No., Exp. date, and Level. The main area contains three large text input fields labeled WBC, Lymph#, and Mid#. At the bottom, there are navigation buttons (left, right, double left, double right) and action buttons (Fail QC, Calculate Preset, Save Preset, Print). The status bar at the very bottom shows 'Pos./Total 0 / 0', 'Whole blood', 'Administrator :', and the date/time '05/31/2013 15:54'.

**Figure 8-24 X-mean QC Graph Screen**

Select the desired numbers from the "File No." and "Lot No." pull-down lists to switch to the corresponding QC graph screen.

#### **NOTE**

- The "Mean", "SD" and "CV%" of each parameter are only available when

---

**there are 3 or more within-control results in the X-mean QC graph.**

---

The X-mean QC graph can be interpreted as follows:

- The x-coordinate represents the QC run performed; the y-coordinate represents the values obtained from the QC run.
- Points linked by a blue line represent results from a same X-mean analysis.
- For every parameter, its X-mean QC graph can display up to 100 points, 31 points per screen.
- For every parameter, the upper dash line represents the expected result + limit.
- For every parameter, the lower dash line represents the expected result – limit.
- For every parameter (e.g. WBC), the three numbers to the left of the graph are:

Upper limit: the expected result + limit.

Target: the expected result.

Lower limit: the expected result – limit.

- For every parameter, the three numbers to the right of the X-mean QC graph are defined and calculated as follows:

Mean - the average of the saved L-J analyses.

SD - Standard Deviation.

CV% - Coefficient of Variation.

$$\text{Mean} = \frac{\sum_{i=1}^n X_i}{n}$$

$$\text{SD} = \sqrt{\frac{\sum (X_i - \text{Mean})^2}{n - 1}}$$

$$\text{CV\%} = \frac{\text{SD}}{\text{Mean}} \times 100$$

Where, n is the number of the saved L-J analyses and  $X_i$  is the result of the ith X-mean analysis.

The points in the graphs can be interpreted as follows:

"●": the point falls within the upper and lower limits, and has not been set as out-of-control point.

"○": the point falls outside the upper and lower limits, but has been set as out-of-control point.

Red solid triangle means its value is outside the display range, but has not been set as out-of-control point. The triangle pointing upward means the value exceeds H limit, while the triangle pointing downward means the value exceeds Limit.

Red hollow triangle means its value is outside the display range, and has been set as

out-of-control point. The triangle pointing upward means the value exceeds H limit, while the triangle pointing downward means the value exceeds L limit.

If you see any points fallen outside the control range, do as follows until the problem is solved. If all the steps have failed, contact Mindray customer service department or your local distributor for assistance.

1. Check the screen for error messages and refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
2. Check the X-mean settings for inappropriate entries.
3. Do background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
4. Re-run the control.
5. Run another vial of control.
6. Check if the analyzer needs to be calibrated.

At the “X-mean QC graph” screen, you may:

■ **Browsing data**

The X-mean analysis results are sequentially displayed on the graph, the latest on the utmost right of the graph. You may click the arrow buttons on the right the QC graph to review result of each parameter.

Click the arrow buttons under the graph to review each QC result.

■ **Set the preset-values**

You (administrator level) can select results from the X-mean QC graph to calculate the Mean, SD and CV%, and set the calculated results to be preset-value when editing the settings. In QC files, you may set a set of preset-values calculated for 3 lots of controls respectively.

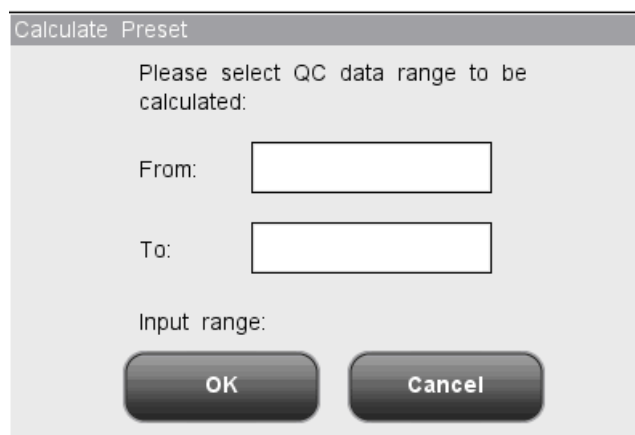
Do as instructed below:

---

**NOTE**

- **The preset-value can only be calculated by selecting within-control results of at least 3 QC runs.**

- 
1. Click the “Calculate Preset” button, and then a dialog box will display.



**Figure 8-25**Calculating the Preset Value

2. Enter the desired data range into the “From” and “To” boxes.
3. Click "OK" to close the dialog box and return the "X-mean QC graph" screen, the Mean, SD and CV% calculated from the selected data will be displayed on the right of the graph.
4. Click the “Save Preset” button, a dialog box will display. Click “Yes” to save the preset-value and return to the “X-mean QC graph” screen.

■ Handling out of control

If out of control data appears, you (administrator level) can give the reasons. Do as instructed below:

Move the blue vertical line in the graph to the out of control point, click the “Fail QC” (out of control) button, the following dialog box will display.

Fail QC

	WBC	Lymph#	Mid#	Gran#	Lymph%	Mid%
Mean						
Range(#)						
Fail QC data						

Fail QC reason

Control not mixed   
 Control deteriorated   
 Control expired  
 Reagent contaminated   
 Reagent expired  
 Other:

OK    Cancel

**Figure 8-26 "Fail QC" Dialog Box**

The dialog box will list all out of control data of the out of control point on the blue line, all X-mean QC parameters, their expected results and limits.

Reasons of out of control points on the blue line are provided in the dialog box, you may click to select the desired ones. You may also enter reasons in the "Others" box manually, up to 60 characters.

After the edit, click the "OK" button to save the out of control reason, close the dialog box and return to the "X-mean QC graph" screen. Click the "Cancel" button to abort the changes, close the dialog box and return to the "X-mean QC graph" screen.

- Printing

Click the "Print" button to print the QC graph on the screen.

- Exiting

Click the menu options or other buttons in the functional button area to exit the screen.

### "X-mean Table" mode

Click the menu option "QC"→"X-mean QC"→"Table", you will enter the X-mean table screen of the lately operated QC file.





**Figure 8-27 X-mean QC Table Screen**

Select the desired numbers from the "File No." and "Lot No." pull-down lists to switch to the corresponding QC table screen.

At the "X-mean QC table" screen, you may:

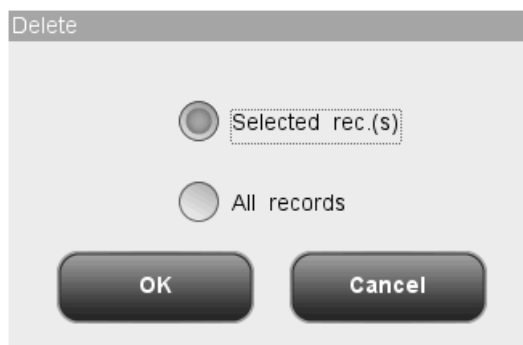
- Browsing data

You may click the arrow buttons on the right of the QC table to review result of each parameter. The X-mean analysis results are sequentially displayed in the table, the latest on the bottom of the table.

- Deleting sample results

You (administrator level) can delete any one or all of the X-mean analysis results saved in the current QC file.

Click the result you want to delete, then Click the "Delete" button, the following dialog box will display:



**Figure 8-28 Deleting QC Results**

Select "Selected rec.(s)" or "All records", then click "OK" to perform deleting. The operation will be recorded into system log. Or click "Cancel" to abort deleting.

- Data exporting

Click the "Export" Button at the X-mean table screen to export the data in the current QC table to the USB drive.

- Printing

Click the "Print" button to print the QC table on the screen.

- Exiting

Click the menu options or other buttons in the functional button area to exit the screen.

---

**NOTE**

- Do not unplug the USB while exporting data.
-

## 8.5 "X-mean R QC" Program

Using the "X-mean R Analysis" program, you may provide quality control for all parameters. You are allowed to run QC for certain selected parameters base on your own needs. The analyzer provides 12 QC files for you to save QC settings and results. Up to 100 QC results can be saved in each QC file. When the saved QC results have reached 100, the system will ask you to delete the previous records first.

### 8.5.1 Editing X-mean R settings

Editing X-mean R settings requires the access level of administrator, common users can only print the settings.

Click the menu option "QC"→"X-mean R QC"→"Setup", you will enter the setup screen of the lately operated QC file. If you have not run any control before, the count screen of File 1 will be displayed.

The screenshot displays the X-mean R QC Setup Screen. At the top, there is a navigation bar with buttons for Analysis, Review, QC, Reagent, Diluent, and Mode. Below the navigation bar, there are several input fields: File No. (set to 1), Lot No., Level (set to Normal), Mode (set to Whole blood), and Exp. Date (MM/DD/YYYY). A Print button is located at the bottom center. The status bar at the bottom shows 'Whole blood', 'Administrator : Admin', and the date/time '12/02/2010 12:01'.

**Figure 8-29 X-mean R QC Setup Screen**

You may perform the following functions at the screen.

- Selecting the file number

Select the desired number from the "File No." pull-down list, ranging from 1 to 12.

■ Entering the lot number

The analyzer provides two ways for you to enter the lot number: manual entering, and entering by importing QC file.

You may enter lot number into the "Lot No." box or select lot number from the "Lot No." pull down list(if there are previously saved lot No. in the list). You may also acquire lot number by importing QC file.

■ Selecting the control level

SELECT the desired level (low, normal or high) from the "Level" pull-down list.

■ Selecting the mode

SELECT the desired mode (whole blood or predilute) from the "Mode" pull-down list.

■ Entering the Exp. Date

The analyzer provides two ways for you to enter the expiration date: manual entering, and entering by importing QC file.

You may enter the expiration date in to the Exp. Date box, or acquire the date by importing QC file.

---

**NOTE**

- **Refer to the instructions for use of the control for information on the lot number, expiration date, open vial stability days, expected results and limits.**
- **The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.**

---

■ Printing

Click "Print" to print the settings by the selected printer.

■ Exit the screen

After completing QC setup, click a menu option or other buttons at the function button area the exit the screen.

## 8.5.2 Running controls

After completing QC setup, click the menu option "QC"→"X-mean R QC"→"Count", you will enter the analysis screen of the lately operated QC file. If you have not run any control before, the count screen of File 1 will be displayed.

	First	Second	Mean	R	Unit
WBC					10 <sup>9</sup> /L
Lymph#					10 <sup>9</sup> /L
Mid#					10 <sup>9</sup> /L
Gran#					10 <sup>9</sup> /L
Lymph%					
Mid%					
Gran%					
RBC					10 <sup>12</sup> /L
HGB					g/L
HCT					

Pos./Total 0 / 0      Whole blood      Administrator :      05/31/2013 14:23

Figure 8-30 X-mean R QC Count Screen



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

### **⚠ WARNING**

- The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
- The sample may spill from the uncapped collection tubes and cause

**biohazard. Exercise caution to the uncapped collection tubes.**

- **The breaking of collection tubes may cause personal injury and/or biohazard. Take precaution when loading and unloading collection tubes from the rack. Avoid breaking the sample tubes.**
  - **Keep your clothes, hairs and hands away from the moving parts to avoid injury.**
  - **The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
  - **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**
- 

### **⚠ CAUTION**

- **Do not re-use disposable products like collection tubes, test tubes, capillary tubes, etc.**
- 

### **NOTE**

- **You should only use the Mindray-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents.**
- 

Do as follows to run controls:

1. Select the desired numbers from the "File No." and "Lot No." pull-down lists.
2. Prepare the control as instructed by instructions for use of the controls.
3. Run controls

### **Running controls for open vial model**

**Running controls under the whole blood mode:**

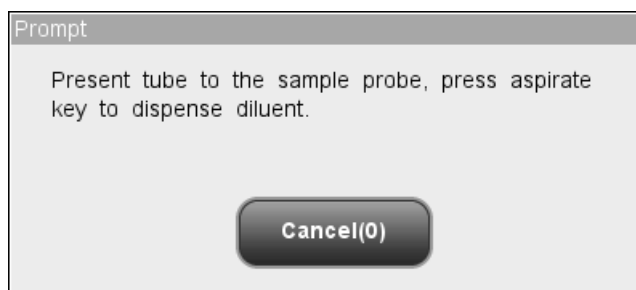
1. Make sure the analyzer indicator is green and the work mode is "Whole Blood".
  2. Present the control to the sample probe.
  3. Press the aspirate key to start the analysis. The analyzer starts to run the control automatically and the indicator flickers in green.
  4. The sample probe will automatically aspirate 17 $\mu$ L of sample. When you hear the
-

beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample.

5. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.
6. Follow the above steps to have another QC run. When you have obtained two valid QC results, the analyzer will calculate the average "X-mean" and the difference "R". The calculated X-mean and R will be respectively displayed on the screen.

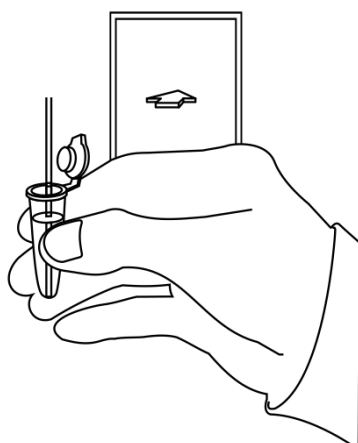
**Running controls under the predilute mode:**

1. Make sure the analyzer indicator is green and the work mode is "Predilute".
2. Click the diluent dispensing icon, the following dialog box pops up.



**Figure 8-31 Diluent Dispensing Prompt**

3. Present a clean centrifugal tube to the sample probe, press the aspirate key. Make sure the tube is tilted towards the probe, as the following figure shows, to avoid spills and bubbles. The dispensing progress bar will be displayed on the screen with message showing "Dispensing diluent...".



**Figure 8-32 Dispensing Diluent**

4. After the dispensing finishes, you will hear a beep, and then you may remove the

sample. Then the message in the dialog box turns to "Present tube to the sample probe, press aspirate key to dispense diluent." again. Click "Cancel", the analyzer will clean the sample probe automatically with cleaning progress displayed. After the operation finishes, the dialog box will close automatically.

5. Add 20 $\mu$ L of control to the diluent, close the tube cap and mix it properly according to your laboratory's protocol.
6. Present the control to the sample probe.
7. Press the aspirate key to start the analysis. The analyzer starts to run the control automatically and the indicator flickers in green.
8. The sample probe will automatically aspirate 146.34 $\mu$ L of sample. When you hear the beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample.
9. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.
10. Follow the above steps to have another QC run. When you have obtained two valid QC results, the analyzer will calculate the average "X-mean" and the difference "R". The calculated X-mean and R will be respectively displayed on the screen.

---

## **NOTE**

- **During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.**
  - **If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- 

## **Running controls for closed tube model**

### **Running controls under the whole blood mode:**

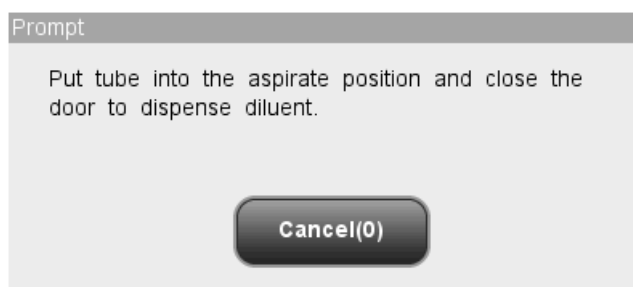
1. Be sure the analyzer indicator is green and the analysis mode is "Whole Blood".
2. Open the compartment door. Make sure the translucent whole blood tube holder adapter is at the aspirating position and put the prepared control into it, then close the compartment door. The analyzer will perform control analysis automatically.
3. When sample aspiration is finished, the compartment door will open automatically.



4. When the analysis is finished, the results will be displayed on the screen.
5. Follow the above steps to run the control again. When you have obtained two valid QC results, the analyzer will calculate the average X-mean and the difference R. The calculated X-mean and R will be respectively displayed on the screen.

**Running controls under the predilute mode:**

1. Be sure the analyzer indicator is green and the analysis mode is “Predilute”.
2. Click the diluent dispensing icon, the compartment door opens automatically and the following dialog box displays.



**Figure 8-33 Diluent Dispensing Dialog Box**

3. Make sure the black predilute tube holder adapter is at the aspirating position and put a centrifugal tube into the adapter, then close the compartment door.
4. The analyzer automatically dispenses diluent into the tube and the progress will be displayed on the dialog box.
5. When dispensing diluent is finished, the compartment door will open. Click “Cancel” on the pop-up dialog box to close it.
6. Add 20 $\mu$ L of control to the diluent, close the tube cap and mix it properly according to your laboratory’s protocol.
7. Open the compartment door. Make sure the black predilute tube holder adapter is at the aspirating position and put the prepared sample into it, then close the compartment door. The analyzer will perform control analysis automatically.
8. When sample aspiration is finished, the compartment door will open automatically.
9. When the analysis is finished, the results will be displayed on the screen.
10. Follow the above steps to run the control again. When you have obtained two valid QC results, the analyzer will calculate the average X-mean and the difference R. The calculated X-mean and R will be respectively displayed on the screen.

**▲WARNING**

- The centrifugal tube must not be capped when running prediluted samples.
- 

**NOTE**

- If the current tube holder adapter does not match with the analysis mode, a dialog box will display indicating “The analysis mode and tube holder adapter are mismatched, please switch modes or replace tube holder adapter.”. Click “OK”, the compartment door will open automatically.
  - During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.
  - If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.
- 

You may perform the following functions at the screen.

■ Browsing data

You may browse the results of QC analysis. Click the "Previous" and "Next" button to browse the results of QC analysis one by one.

■ Switching among QC count screens

Click the "File No." or "Lot No." pull-down list to switch to the QC count screen of other QC files.

■ Printing

Click "Print" to print the results by the selected printer.

### 8.5.3 Reviewing X-mean R analysis results

After QC analysis, you may review the QC results in the following two ways:

■ QC Graph

- QC Table

### "X-mean R Graph" mode

Click the menu option "QC"→"X-mean R QC"→"Graph", you will enter the X-mean R graph screen of the lately operated QC file.

**Figure 8-34 X-mean R QC Graph Screen**

Every screen displays the X-mean and R graphs of one parameter. Each point in X-mean graph represents the average result of two QC runs; each point in R graph represents the result difference of two QC runs. The points are sequentially displayed on the graphs.

The X-mean QC graph can be interpreted as follows:

- The x-coordinate represents the QC run performed; the y-coordinate represents the values obtained from the QC run.
- For every parameter, its X-mean graph can display up to 100 points, 31 per screen.
- For every parameter, the upper dash line represents the upper control limit =  $\bar{X} + A_2 \times \bar{R}$ ;
- For every parameter, the center dash line represents the  $\bar{X}$  (average of all the X-mean R analyses performed);

- For every parameter, the lower dash line represents the lower control limit =  $\bar{X} - A_2 \times \bar{R}$ .

The R QC graph can be interpreted as follows:

- The x-coordinate represents the number of the X-mean R analyses performed; the y-coordinate represents the difference between the two runs of every X-mean R analysis.
- For every parameter, its R graph can display up to 100 points, 31 per screen.
- For every parameter, the upper dash line represents the upper control limit  $D_4 \times \bar{R}$ ;
- For every parameter, the center dash line represents the  $\bar{R}$  (the average of all the differences);
- For every parameter, the lower dash line represents the lower control limit of the expected range  $D_3 \times \bar{R}$ .

The points in the graphs can be interpreted as follows:

"●": the point falls within the upper and lower limits, and has not been set as out-of-control point.

"○": the point falls outside the upper and lower limits, but has been set as out-of-control point.

Red solid triangle means its value is outside the display range, but has not been set as out-of-control point. The triangle pointing upward means the value exceeds H limit, while the triangle pointing downward means the value exceeds L limit.

Red hollow triangle means its value is outside the display range, and has been set as out-of-control point. The triangle pointing upward means the value exceeds H limit, while the triangle pointing downward means the value exceeds L limit.

If you see any points fallen outside the control range, do as follows until the problem is solved. If all the steps have failed, contact Mindray customer service department or your local distributor for assistance.

1. Check the screen for error messages and refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
2. Do background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
3. Re-run the control.
4. Run another vial of control.
5. Check if the analyzer needs to be calibrated.

**NOTE**

- **The system calculates the reference range and displays the QC graph of all data only after 10 groups of QC data (20 QC runs) are obtained.**
- 

At the X-mean R QC graph screen, you may:

- **Browsing data**

The X-mean analysis results are sequentially displayed on the graph, the latest on the utmost right of the graph. You may click the arrow buttons on the right the QC graph to review result of each parameter.

Click the arrow buttons under the graph to review each QC result.

- **Printing**

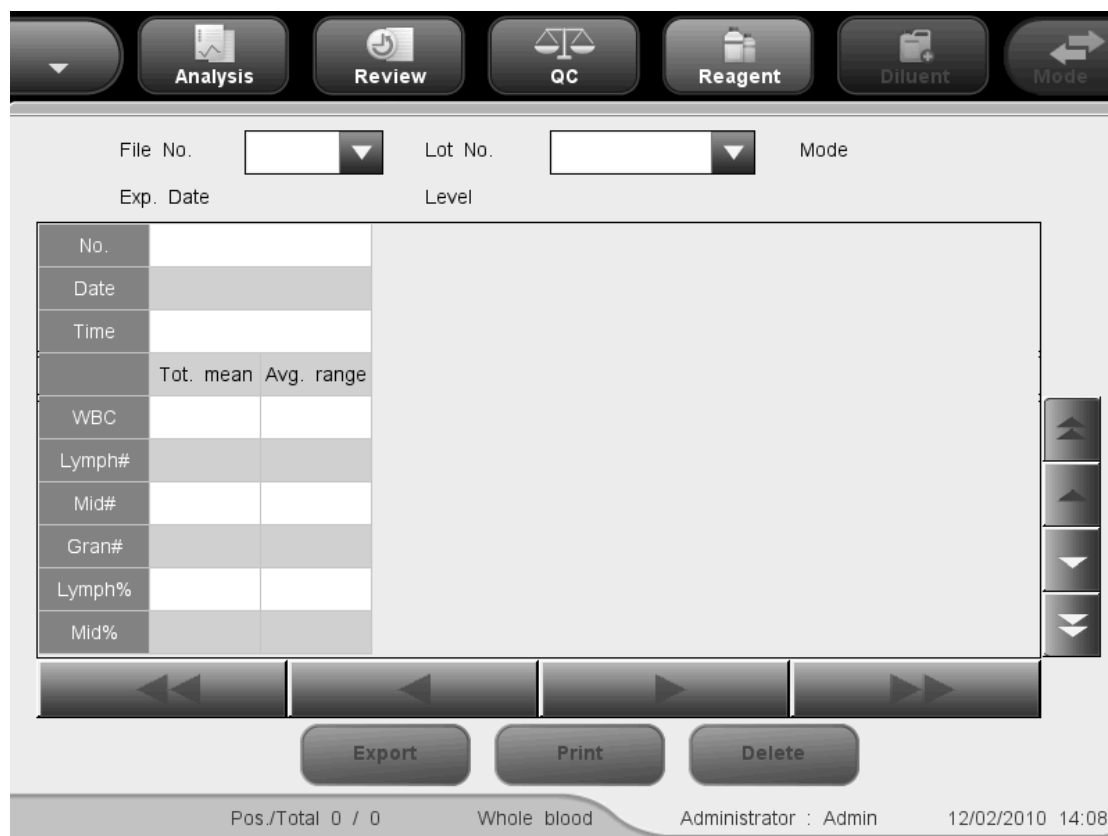
Click the "Print" button to print the X-mean R QC graph by the selected printer.

- **Exiting**

Click the menu options or other buttons in the functional button area to exit the screen.

### **"X-mean R Table" mode**

Click the menu option "QC"→"X-mean R QC"→"Table", you will enter the X-mean R table screen of the lately operated QC file.



**Figure 8-35 X-mean R QC Table Screen**

Select the desired numbers from the "File No." and "Lot No." pull-down lists to switch to the corresponding QC table screen. The X-mean R QC table displays means and ranges of all parameters, the total mean and average range of all results in the current QC file are also displayed on the screen.

At the "X-mean R QC table" screen, you may:

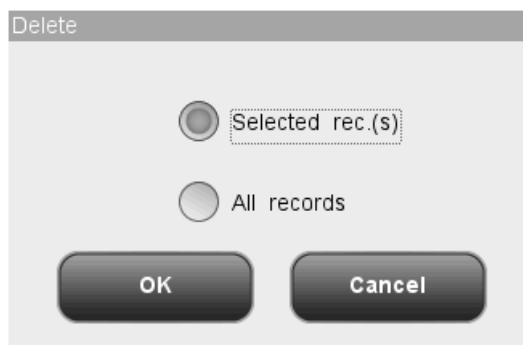
- Browsing data

You may click the arrow buttons on the right of the QC table to review result of each parameter. The X-mean analysis results are sequentially displayed in the table, the latest on the bottom of the table.

- Deleting sample results

You (administrator level) can delete any one or all of the X-mean R analysis results saved in the current QC file.

Click the result you want to delete, then click the "Delete" button, the following dialog box will display:



**Figure 8-36 Deleting QC Results**

Select "Selected rec.(s)" or "All records", then click "OK" to perform deleting. The operation will be recorded into system log. Or click "Cancel" to abort deleting.

- Data exporting

Click the "Export" Button at the X-mean R table screen to export the data in the current QC table to the USB drive.

- Printing

Click the "Print" button to print the QC table on the screen.

- Exiting

Click the menu options or other buttons in the functional button area to exit the screen.

---

**NOTE**

- Do not unplug the USB while exporting data.
-





# 9 Using the Calibration Programs

---

## 9.1 Introduction

Calibration is a procedure to standardize the analyzer by determining its deviation under certain specified conditions. In order to get accurate sample analysis results, you should calibrate the analyzer per the procedure below when necessary.

There are three calibration programs available on this analyzer: manual calibration, auto calibration using calibrators and auto calibration using fresh blood samples. The calibration programs shall be completed under “Whole Blood” mode.

---

### **NOTE**

- Calibration procedures can only be performed by users of the administrator-level.
  - You should only use the Mindray-specified calibrators and reagents. Store and use the calibrations and reagents as instructed by instructions for use of the calibrators and reagents.
  - Calculation of reproducibility is included in the calibration procedure.
-

## 9.2 When to Calibrate

This analyzer is calibrated at the factory just before shipment. It is electronically stable and does not require frequent recalibration if you operate and maintain it as instructed by this manual. You only need to recalibrate this analyzer if:

- it is the first time this analyzer has been used (usually done by a Mindray-authorized representative when installing the analyzer).
- an analytical component has been changed.
- you are going to re-use the analyzer after a long-term storage.
- the quality control results indicate there may be a problem.

---

### **NOTE**

- **All of the measured parameters must be calibrated before readings of this analyzer can be used as valid analysis results.**
-

## 9.3 How to Calibrate

### 9.3.1 Preparing Your Analyzer

Do the following pre-calibration procedures before calibration. If problems are detected during these checks, do not attempt to calibrate the analyzer. If necessary, call Mindray customer service department or your local distributor for assistance.

1. Check and make sure enough reagents have been prepared for the calibration. You need to start over the calibration if the reagents run out during the process.
2. Do the background check. If the analyzer alarms for abnormal background results, see **Chapter 12 Troubleshooting Your Analyzer** for solutions.
3. Enter the "Count" screen and run a vial of normal control for 10 consecutive times. Enter the "Review" screen to check the reproducibility of the ten runs and make sure they meet the requirements in Table 9-1.

**Table 9-1 Reproducibility**

Parameter	Range	Whole Blood Reproducibility (CV)
WBC	$(7.0 \sim 15.0) \times 10^9/L$	$\leq 2.0$
	$(4.0 \sim 6.9) \times 10^9/L$	$\leq 3.5$
RBC	$(3.50 \sim 6.50) \times 10^{12}/L$	$\leq 2.0$
HGB	$(100 \sim 180) \text{ g/L}$	$\leq 1.5$
MCV	$(80.0 \sim 110.0) \text{ fL}$	$\leq 1.0$
PLT	$(150 \sim 500) \times 10^9/L$	$\leq 4.0$
	$(100 \sim 149) \times 10^9/L$	$\leq 5.0$

4. Run a vial of high control three consecutive times and then immediately run the diluent three consecutive times. Calculate the carryover per the following equation.

$$\text{Carry over}(\%) = \frac{\text{First low - level sample result} - \text{Third low - level sample result}}{\text{Third high - level sample result} - \text{Third low - level sample result}} \times 100\%$$

The calculated carryovers shall meet the requirements in the following table.

Parameter	Carryover
WBC	$\leq 0.5\%$
RBC	$\leq 0.5\%$
HGB	$\leq 0.5\%$
PLT	$\leq 1.0\%$

5. It is recommended that you create a log table for your analyzer. This log table should contain all necessary information that is pertinent to your analyzer. Suggested items that you may want to include in the log table are: calibration date, supplier of calibrator, lot number, expected results and limits, and result of background check.
- 



- **All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
- 

### **⚠ WARNING**

- **The sample probe is sharp and potentially biohazardous, Exercise caution to avoid contact with the probe when working around it.**
  - **The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
  - **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**
  - **Keep your clothes, hairs and hands away from the moving parts to avoid injury.**
  - **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**
- 

### **⚠ CAUTION**

- **Do not reuse disposable products such as collection tubes, test tubes, capillary tubes and so on.**
- 

### **NOTE**

- **You should only use the Mindray-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the**
-

controls and reagents.

- Be sure to use the Mindray-specified disposable products including evacuated blood collection tube, anticoagulant collection tubes and capillary tubes etc.

### 9.3.2 Auto Calibration Using Calibrators

Log in the system as administrator.

Click the menu option "Calibration"→"Auto-Cal" to enter the following "Auto-Cal" screen.

The screenshot shows the 'Auto-Cal' screen with a navigation bar at the top containing icons for Analysis, Review, QC, Reagent, Diluent, and Mode. The main area features a table for calibration parameters and two input fields on the left.

Parameter	WBC	RBC	HGB	MCV	PLT
Target					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
Mean					
CV(%)					
New cal. factor(%)					
Old cal. factor(%)	100.00	100.00	100.00	100.00	100.00

On the left side of the screen, there are two input fields: "Lot No.:" with a text box and "Exp. date:" with a date picker showing "MM/DD/YYYY". Below these fields are "Export" and "Print" buttons. At the bottom of the screen, the text "Whole blood Administrator : Admin 12/02/2010 14:11" is displayed.

Figure 9-1 "Auto-Cal" Screen

Do as follows to calibrate the analyzer with calibrators.

#### Editing calibration settings

- Entering lot number

Enter lot number of the calibrator to be used into the "Lot No." box.

- Entering the Exp. Date

Enter expiration date of the calibrator to be used into the "Exp. Date" box.

- Entering the target

Enter the target for the desired parameter in the edit box "Target".

---

### **NOTE**

- See the instruction for use of the calibrators for the lot No., expiration date and the target.
  - The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.
  - If you start analysis without entering all calibrator information on an open vial model analyzer, a dialog box will display indicating "Invalid entry". Click "OK", the analyzer will automatically clean the sample probe, and then you may enter complete calibrator information and start running calibrators. If you start analysis without entering all calibrator information on a closed tube model analyzer, the sample compartment door will open automatically, and then you may enter complete calibrator information and start running calibrators.
- 

### **Running the calibrator**

Prepare the calibrator for calibration after editing the settings.

---



- Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
- 

### **NOTE**

- Only Mindray-specified calibrators shall be used. Mindray will not be responsible for any erroneous result caused by using other calibrators.
  - Store and use the calibrators as instructed by instructions for use of the calibrators.
  - Use fused silica glass/plastic test tubes and 20 $\mu$ L borosilicate glass
-

capillary tubes.

- The sample probe should be well immersed and kept away from the tube bottom, when the probe is aspirating sample. Otherwise, the aspirated volume may be insufficient or imprecise.
  - The probe tip should not contact the sample tube. Otherwise, the blood may spill.
- 

### **⚠ WARNING**

- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.
- 

### **⚠ CAUTION**

- Do not re-use disposable products like collection tubes, test tubes, capillary tubes, etc.
- 

**Do as follows to calibrate the analyzer with calibrators (for open vial model).**

1. Make sure the analyzer indicator is green and the work mode is "Whole Blood".
  2. Present the calibrator to the sample probe.
  3. Press the aspirate key to start the analysis. The analyzer starts to run the calibrator automatically and the indicator flickers in green.
  4. The sample probe will automatically aspirate 17 $\mu$ L of sample. When you hear the beep sound and the probe lifts up, you may remove the sample. The analyzer will automatically run the sample.
  5. When the analysis is finished, the sample probe returns to home position and the results will be displayed on the screen.
- 

### **NOTE**

- During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.
  - If the ambient temperature is outside the specified operating range, thus
-

---

**causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**

---

**Do as follows to calibrate the analyzer with calibrators (for closed tube model).**

1. Be sure the analyzer indicator is green and the analysis mode is "Whole Blood".
2. Open the compartment door. Make sure the translucent whole blood tube holder adapter is at the aspirating position and put the prepared sample into it, then close the compartment door. The analyzer will perform sample analysis automatically.
3. When sample aspiration is finished, the compartment door will open automatically.
4. When the analysis is finished, the results will be displayed on the screen. The analyzer will be ready for the next analysis.

---

**NOTE**

- **If the current tube holder adapter does not match with the analysis mode, a dialog box will display indicating "The analysis mode and tube holder adapter are mismatched, please switch modes or replace tube holder adapter." Click "OK", the compartment door will open automatically.**
  - **During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.**
  - **If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.**
- 

### **Saving the calibration results**

The analyzer will have different responses to different analysis results.

- If non-numeric parameter value is obtained, a dialog box will display indicating invalid result.

Click "OK" to clear the result.



- If all the parameter values obtained are numeric, a dialog box will display asking you to save the result.

Click "OK" to save the result, and display it on the "Auto-Cal" screen; or click "Cancel" to abort the result.

After obtaining 5 or more valid calibration results, the analyzer will automatically calculate the CV% and calibration factors. After obtaining 5 or more consecutive valid calibration results, the calibration factors can be saved.

The calculated calibration factor of a parameter should be within 75% - 125% and its CV% should meet the reproducibility requirement. If either of the conditions is not met, the calibration factor is invalid. The CV% values that fail to the reproducibility requirement are displayed in red. If the calibration factor of a parameter falls outside 75%-125%, the calibration factor will be flagged with a "?", its value and the "?" will both be displayed in red. In such case, try to find out the reason and if necessary, contact Mindray customer service department or your local distributor for assistance.

### **Verifying new calibration factors**

After obtaining a new calibration factor, press a menu option, a dialog box will display asking you to save the new calibration factor.

Click "OK" to save the new calibration factors to the "Manual" screen and enter the "Count" screen. At the "Count" screen, run the calibrator or a normal control material at least 5 consecutive times and calculate the mean of the results. The means should be within the expected ranges supplied by the manufacturer. If not, contact Mindray customer service department or your local distributor for assistance.

### **Other operations**

- Exporting data

Click "Export" to export the intermediate data and calibration results on the screen to an external USB.

- Printing

Click the "Print" button to print the contents displayed on the screen.

- Exiting the screen

After obtaining a new calibration factor, press a menu option, a dialog box will display asking you to save the new calibration factor. Click "OK" to save the new calibration factor to the auto calibration screen, exit the auto-cal screen and switch to the corresponding screen; or click "Cancel" to abort the new calibration factor, exit the auto-cal screen and switch to the corresponding screen.

**NOTE**

- Do not unplug the USB while exporting data.

### 9.3.3 Auto Calibration Using Fresh Blood

Log in the system as administrator.

Click the menu option "Calibration"→"Fresh Blood" to enter the following "Fresh Blood" screen.

Parameter	WBC	RBC	HGB	MCV	PLT
Target					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
Mean					
CV(%)					
Cal. factor1(%)					

Whole blood Administrator : Admin 12/02/2010 14:24

**Figure 9-2 "Fresh Blood" Screen**

Do as follows to calibrate the analyzer with fresh blood samples.

#### Editing calibration settings

Press "Sample 1"..."Sample 5" buttons to switch among "Sample 1" to "Sample 5" to select the sample for calibration. The following introduction takes Sample 1 as the example.

Enter the target for the desired parameter in the edit box "Target".

#### Running the calibrator

After you have finished editing the calibration settings of Sample 1, refer to the sample handling and analysis procedures introduced in **Chapter 6 Operating Your Analyzer** and

prepare the fresh blood samples to perform fresh blood calibration.

---

**NOTE**

- **You should prepare 3 – 5 normal fresh blood samples for the calibration.**
- 

### **Saving the calibration results**

The analyzer will have different responses to different analysis results.

- If non-numeric parameter value is obtained, a dialog box will display indicating invalid result.

Click "OK" to clear the result.

- If all the parameter values obtained are numeric, a dialog box will display asking you to save the result.

Click "OK" to save the result, and display it on the "Calibrator" screen; or click "Cancel" to abort the result.

After obtaining 5 or more valid calibration results, the analyzer will automatically calculate the CV% and calibration factors. After obtaining 5 or more consecutive valid calibration results, the calibration factors can be saved.

The calculated calibration factor of a parameter should be within 75% - 125% and its CV% should meet the reproducibility requirement, besides, the condition " $|\text{new calibration factor} - \text{original calibration factor}| < 5\%$ " must be met. If either of the conditions are not met, the calibration factor is invalid. The CV% values that fail to the reproducibility requirement are displayed in red. If the calibration factor of a parameter falls outside 75% - 125%, the calibration factor will be flagged with a "?", its value and the "?" will both be displayed in red. In such case, try to find out the reason and if necessary, contact Mindray customer service department or your local distributor for assistance.

You may enter the "Fresh Blood" screen of sample 2-5 by pressing the "Sample 2"..."Sample 5" buttons. Follow the calibration steps of sample 1 to run at least another two fresh blood samples. When you have obtained the calibration factors of at least 3 fresh blood samples, you may press "Calculate" to enter the "Calculate" screen as shown in the following figure. On the screen, "Calibration factor1 (%)" to "Calibration factor5 (%)" respectively correspond to the calibration factors of samples 1 - 5.

Parameter	WBC	RBC	HGB	MCV	PLT
Cal. factor1(%)					
Cal. factor2(%)					
Cal. factor3(%)					
Cal. factor4(%)					
Cal. factor5(%)					
Avg. cal. factor(%)					
Old cal. factor(%)	100.00	100.00	100.00	100.00	100.00

**Figure 9-3 "Calculate" Screen**

The "Calculate" screen can display 5 sets of calibration factors maximum. The calculated calibration factors should be within the range 75% - 125%. If the calibration factor of a parameter falls outside 75%-125%, the calibration factor will be flagged with a "?", its value and the "?" will both be displayed in red. For every parameter, the analyzer will calculate the average calibration factor, which serves as the new calibration factor, only when there are at least 3 valid calibration factors. Otherwise, the average calibration factor will be empty. Click the "Print" button at the "Calculate" screen to print the contents of the screen.

### Verifying new calibration factors

After obtaining a new calibration factor, press a menu option, a dialog box will display asking you to save the new calibration factor.

Click "OK" to save the new calibration factors to the "Manual" screen and enter the "Count" screen. Test the new calibration factors in either of the following ways.

Method one:

1. Prepare 3-5 normal fresh blood samples and run each one of them on a reference analyzer at least 3 consecutive times. Calculate the mean (MEAN 1) and SD (SD 1) of every sample.
2. Run the same samples on your analyzer for the same number of times and calculate the mean (MEAN 2). The MEAN 2 should be within  $MEAN 1 \pm 2SD$ . If any of the sample fails to reach the criterion, call Mindray customers service department or your local distributor.

Method two:

At the "Count" screen, run the calibrator at least 5 consecutive times and calculate the means of the results. The means should be within the expected ranges supplied by the manufacturer. If not, contact Mindray customer service department or your local distributor for assistance.

### Other operations

- Printing

Click the "Print" button to print the contents displayed on the screen.

- Exiting the screen

After obtaining a new calibration factor, press a menu option, a dialog box will display asking you to save the new calibration factor. Click "OK" to save the new calibration factor to the auto calibration screen, exit the calibrator screen and switch to the corresponding screen; or click "Cancel" to abort the new calibration factor, exit the calibrator screen and switch to the corresponding screen.

### 9.3.4 Manual Calibration

If needed, you may run the calibration material at the "Analysis" screen and calculate the calibration factors manually.

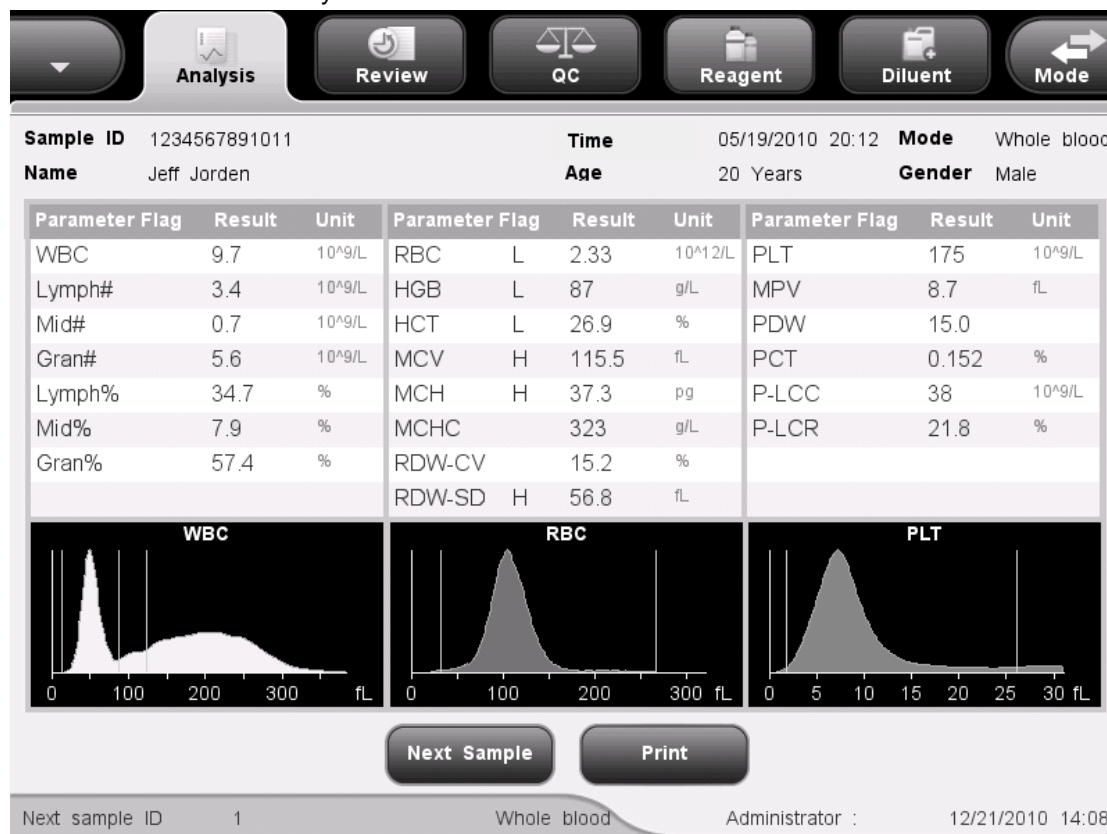


Figure 9-4 "Analysis" Screen

Do as follows to calibrate the analyzer manually:

## Running the calibrator

After you have selected the desired sample mode, refer to the sample handling and analysis procedures introduced in **Chapter 6 Operating Your Analyzer** and run the calibration material with known expected results 10 consecutive times.

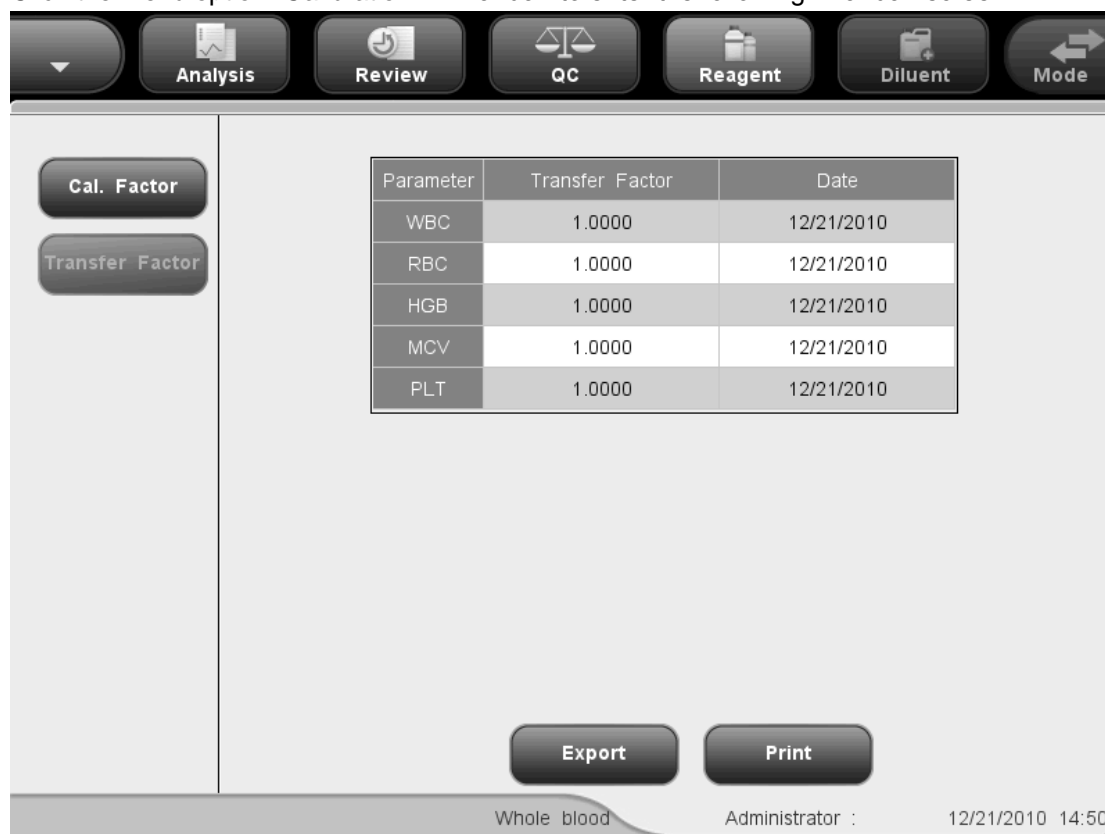
## Checking the reproducibility

When you have finished running the calibration material, refer to **7.2.1 Browsing in the Table Review Mode** for the way to check the CV% of the 10 results.

If the reproducibility of the calibrated parameter meets the requirement in Table 9-1, record the Mean of the 10 runs, and then calculate the new calibration factor at the “Manual” screen. If the reproducibility of the calibrated parameter does not meet the requirements in Table 9-1, you must try to find out the reason and re-run the calibrator after you have solved the problem. If necessary, contact Mindray customer service department or your local distributor for assistance.

## Calculating the new calibration factors manually

Click the menu option "Calibration"→“Manual” to enter the following “Manual” screen.



**Figure 9-5 “Manual” Screen**

The calibration factor of each parameter and the saving time of the factor are displayed on the screen.

Use the following formula to calculate the new calibration factor.

$$new\ factor = \frac{old\ factor \times reference\ value}{calculated\ mean}$$

The calculated new calibration factor should be within 75%-125%. If not, try to find out the reason and if necessary, call Mindray customer service department or your distributor for assistance.

### Entering the manually calculated factors

You (administrator level) can edit the calibration factor at the “Manual” screen.

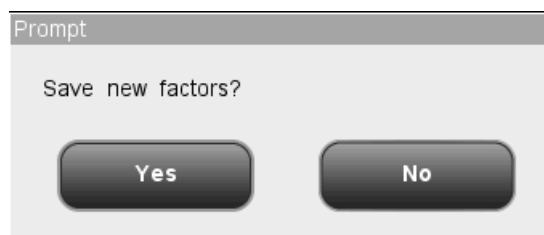
Parameter	Calibration factor(%)	Date
WBC	100.00	12/02/2010
RBC	100.00	12/02/2010
HGB	100.00	12/02/2010
MCV	100.00	12/02/2010
PLT	100.00	12/02/2010

**Figure 9-6 Editing Calibration Factor**

Enter the calculated calibration factor into the corresponding boxes.

### Verifying new calibration factors

Click a menu option or other buttons in the functional button area, a message box will display asking you to save the new calibration factors if they are within the valid range.



**Figure 9-7 Saving New Calibration Factor Dialog Box**

Click "Yes" to save the new calibration factor and close the dialog box; click "No" to close the dialog box without saving the factor.

If the new calibration factor is not within the valid range, the following dialog box will display.



**Figure 9-8 Invalid Calibration Factor Dialog Box**

Click "Yes" to go the desired screen without saving the new calibration factor; click "No" to stay in first edit box with invalid factor, and then re-enter valid data.

### Browsing transfer factors

Click the "Transfer Factor" button at the "Manual" screen to browse transfer factors. Transfer factor is the ratio between the true measured values under the whole blood and predilute mode.

Parameter	Transfer factor	Date
WBC	1.0000	12/02/2010
RBC	1.0000	12/02/2010
HGB	1.0000	12/02/2010
MCV	1.0000	12/02/2010
PLT	1.0000	12/02/2010

**Figure 9-9 Browsing Transfer Factors**

### Other operations

- Exporting data

Click the "Export" button to export the calibration data to an external USB.

- Printing

If the calibration factors are invalid, you will not be able to print them and the dialog box "Invalid setup" will display.

If the calibration factors are valid, a dialog box will display asking you to save the factors. Click "Yes" to save and print the factors.

Or click "No" to cancel the operation without saving them.

- Exiting the screen

After obtaining a new calibration factor, press a menu option, a dialog box will display asking you to save the new calibration factor. Click "OK" to save the new calibration factor to the auto calibration screen, exit the calibrator screen and switch to the



corresponding screen; or click "Cancel" to abort the new calibration factor, exit the calibrator screen and switch to the corresponding screen.

---

**NOTE**

- **Do not unplug the USB while exporting data.**
-

## 9.4 Calibration History

Click the menu option "Calibration"→"History", you will enter the following calibration history screen to review calibration record.



**Figure 9-10 " History" Screen**

The history list displays the information of the recent 100 times of calibration with the latest one listing in the first line (No.1). If more than 100 times of calibration are performed, the earliest record will be overwritten. You may click the arrow buttons to check the whole list but cannot edit and delete any content.

You may perform the following functions at the screen.

- Exporting data

Click the "Export" button at the bottom of the screen to export the calibration history record to an external USB.

- Printing

Click the "Print" button at the bottom of the screen to print the history list.

### **NOTE**

- **Do not unplug the USB while exporting data.**

# 10 Maintaining Your Analyzer

---

## 10.1 Introduction

Preventive and corrective maintenance procedures are required to keep the analyzer in a good operating condition. This analyzer provides multiple maintenance functions for this purpose.

This chapter introduces how to use the provided functions to maintain and troubleshoot your analyzer.



- All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.

---

### **CAUTION**

- Performing unauthorized maintenance procedures can damage your analyzer. Do not perform any maintenance procedures that are not described in this chapter.
- In case of problems not specified in this manual, contact Mindray customer service department or your local distributor for assistance.
- Only Mindray-supplied parts can be used for maintenance. For any questions, contact Mindray customer service department or your local distributor.
- Exercise caution to avoid contact with the sharp sample probe when performing maintenance.

---

The following table lists the tools that may be used in maintenance.

No.	Tools
1.	Cross-headed screwdriver
2.	Slotted head screwdriver
3.	Medical gloves
4.	Alcohol

## 10.2 Maintaining Your Analyzer Manually

Click “Service”→“Maintenance” to enter the “Maintenance” screen.

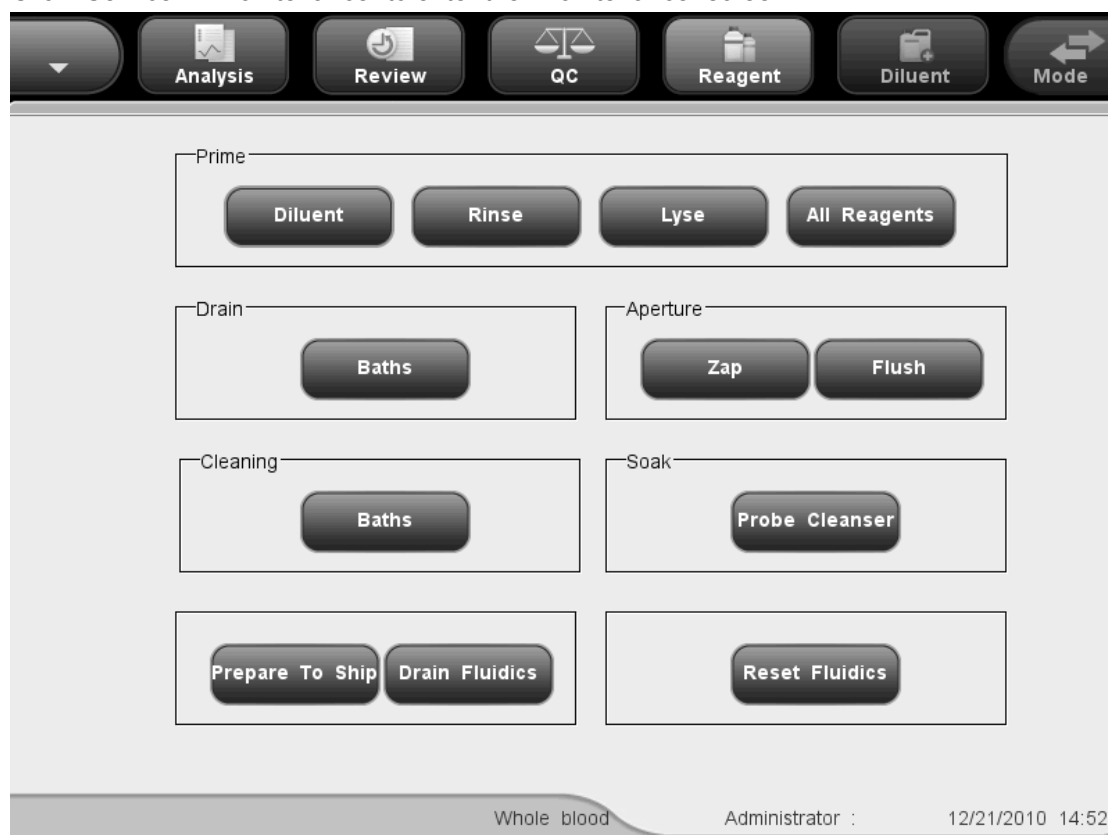


Figure 10-1 “Maintenance” Screen

### 10.2.1 Priming with reagents

#### **⚠ WARNING**

- The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
- If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.

#### **NOTE**

- After installing a new container of reagent, let it equilibrate at room

**temperature for a few minutes before using.**

- **When you have changed the diluent, lyse or rinse, run a background to see if the results meet the requirement.**
- 

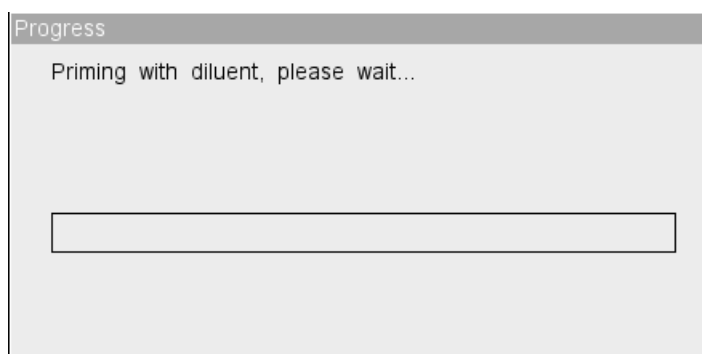
## Priming with diluent

You should perform the “Diluent Prime” procedure to prime the diluent tubing when:

- there are bubbles in the tubing; or
- the diluent in the tubing is contaminated; or
- the diluent ran out and a new container of diluent is installed.

Do as instructed below:

1. Click the “Diluent” button in the “Prime” box at the “Maintenance” screen.
2. You will start to prime the tubing and the priming progress will be displayed on the screen.



**Figure 10-2 Diluent Priming Progress Bar**

3. When the progress ends, a dialog box will display indicating “The operation succeeded!”, click “OK” to close the dialog box.

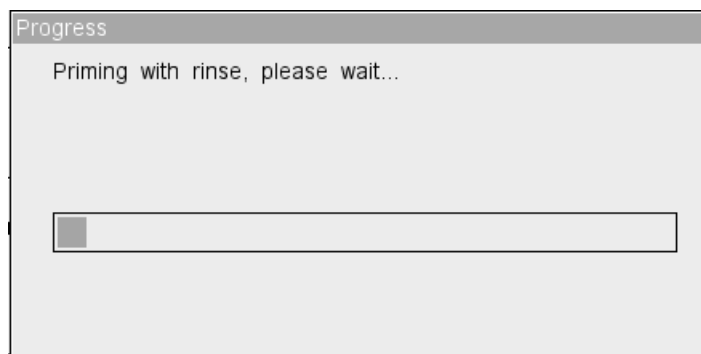
## Priming with rinse

You should perform the “Rinse Prime” procedure to prime the rinse tubing when:

- there are bubbles in the tubing; or
- the rinse in the tubing is contaminated; or
- the rinse ran out and a new container of rinse is installed.

Do as instructed below:

1. Click the “Rinse” button in the “Prime” box at the “Maintenance” screen.
2. You will start to prime the tubing and the priming progress will be displayed on the screen.



**Figure 10-3 Rinse Priming Progress Bar**

3. When the progress ends, a dialog box will display indicating "The operation succeeded!", click "OK" to close the dialog box.

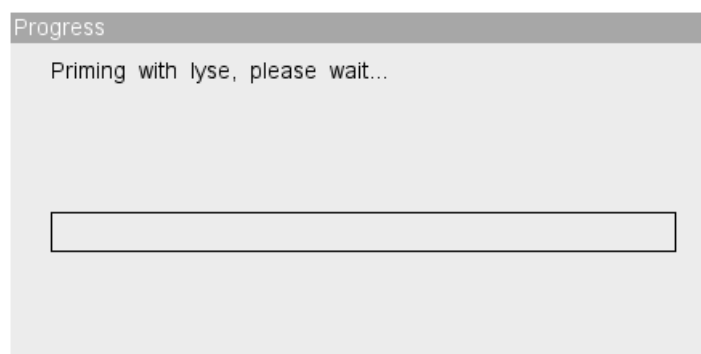
### Priming with lyse

You should perform the "Lyse Prime" procedure to prime the lyse tubing when:

- there are bubbles in the tubing; or
- the lyse in the tubing is contaminated; or
- the lyse ran out and a new container of lyse is installed.

Do as instructed below:

1. Click the "Lyse" button in the "Prime" box at the "Maintenance" screen.
2. You will start to prime the tubing and the priming progress will be displayed on the screen.



**Figure 10-4 Lyse Priming Progress Bar**

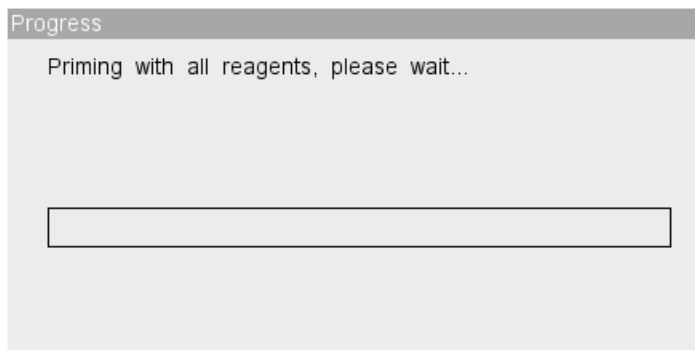
3. When the progress ends, a dialog box will display indicating "The operation succeeded!", click "OK" to close the dialog box.

### Priming with all reagents

The "All Reagents Prime" function allows you to prime all tubing with new reagents.

Do as instructed below:

1. Click the “All Reagents” button in the “Prime” box at the “Maintenance” screen..
2. You will start to prime all tubing and the priming progress will be displayed on the screen.



**Figure 10-5 All Reagents Priming Progress Bar**

3. When the progress ends, a dialog box will display indicating “The operation succeeded!”, click “OK” to close the dialog box.

## 10.2.2 Draining baths

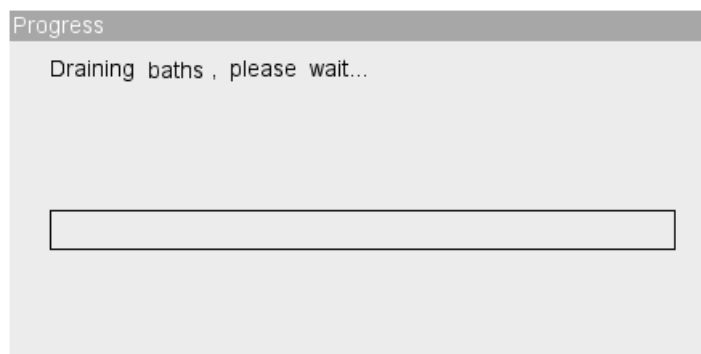


- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
- 

Draining baths will empty diluent in WBC and RBC baths.

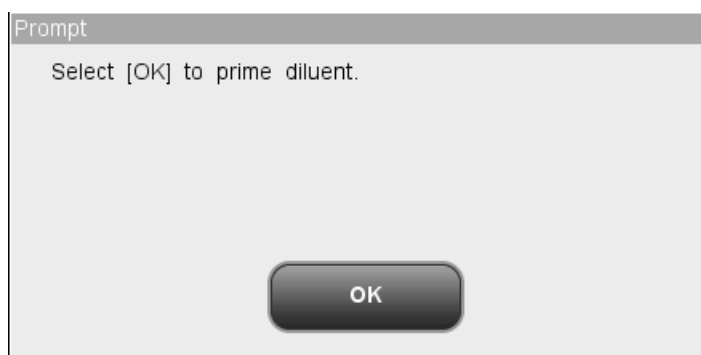
Do as instructed below:

1. Click the “Baths” button in the “Drain” box at the “Maintenance” screen.
2. You will start to drain the baths, and the draining progress will be displayed on the screen.



**Figure 10-6 Draining Baths Dialog Box**

3. When the draining progress ends, the following dialog box will display, click "OK" to prime the analyzer with diluent. The message "Priming with diluent, please wait...".



**Figure 10-7 Diluent Priming Dialog Box**

4. When the progress ends, a dialog box will display indicating "The operation succeeded!", click "OK" to close the dialog box.

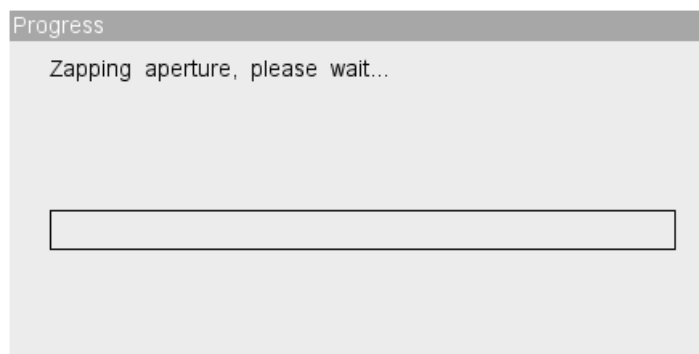
### 10.2.3 Zapping apertures

You should perform this procedure to unclog the apertures.

Do as instructed below:

1. Click the "Zap" button in the "Aperture" box at the "Maintenance" screen.
2. You will start to zap the apertures and the zapping progress will be displayed on the screen.





**Figure 10-8 Aperture Zapping Progress Bar**

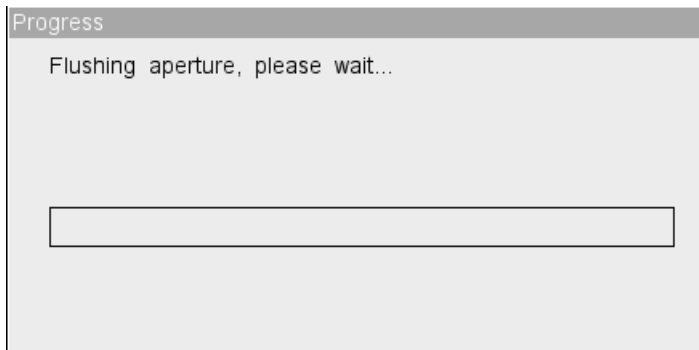
3. When the progress ends, a dialog box will display indicating "The operation succeeded!", click "OK" to close the dialog box.

### 10.2.4 Flashing apertures

You may perform this procedure to unclog the apertures or prevent clogging.

Do as instructed below:

1. Click the "Flush" button in the "Aperture" box at the "Maintenance" screen.
2. You will start to flush the apertures and the flushing progress will be displayed on the screen.



**Figure 10-9 Aperture Flushing Progress Bar**

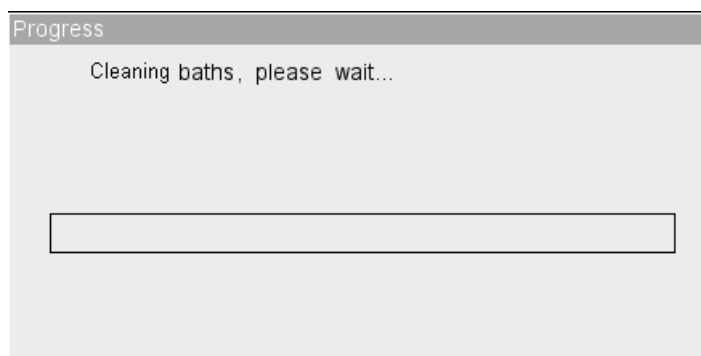
3. When the progress ends, a dialog box will display indicating "The operation succeeded!", click "OK" to close the dialog box.

### 10.2.5 Cleaning baths

If you suspect the baths are contaminated, follow the steps given below to clean the baths.

Do as instructed below:

1. Click the "Baths" button in the "Clean" box at the "Maintenance" screen.
2. The cleaning progress bar will be displayed on the screen.



**Figure 10-10 Cleaning Baths Progress Bar**

3. When the progress ends, a dialog box will display indicating “The operation succeeded!”, click “OK” to close the dialog box.

## 10.2.6 Probe cleanser soak

---

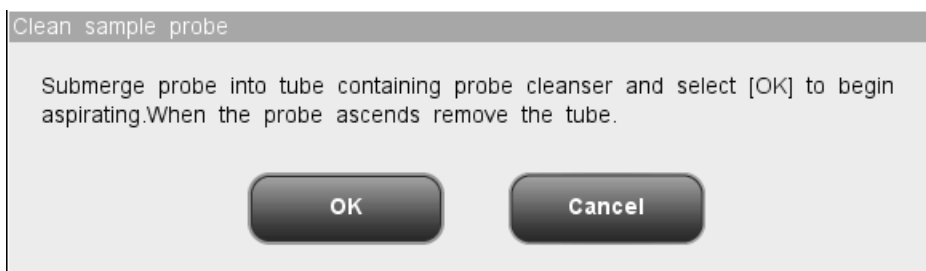
### **⚠ WARNING**

- **The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
  - **If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.**
- 

You should perform the probe cleanser soaking procedure weekly to maintain the analyzer.

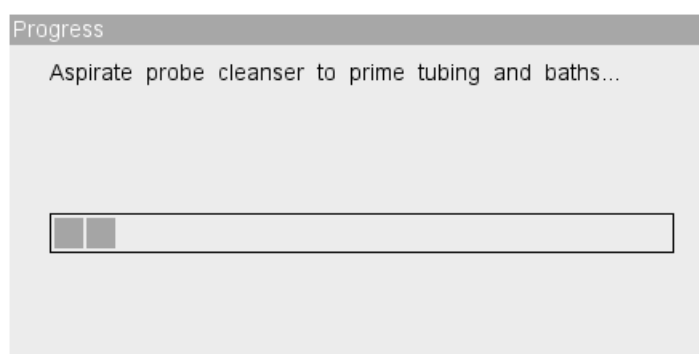
### **Probe cleanser soaking procedure for open vial model:**

1. Present the probe cleanser to the sample probe, click “Probe Cleanser” at the “Maintenance” screen, the following dialog box will display, click “OK” to start aspirating the probe cleanser.



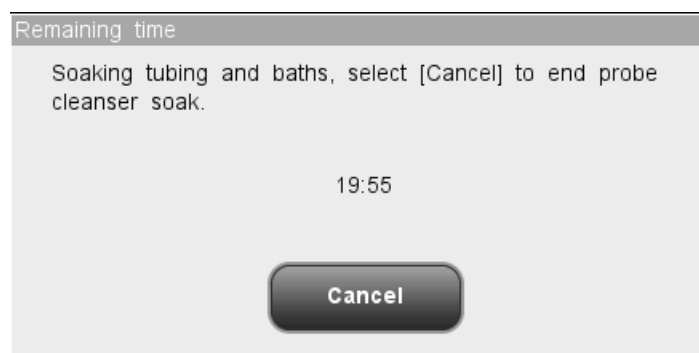
**Figure 10-11 Probe Cleanser Soak Dialog Box**

2. Remove the probe cleanser when the sample probe lifts up as instructed on the screen. The following progress bar and message will be displayed on the screen.



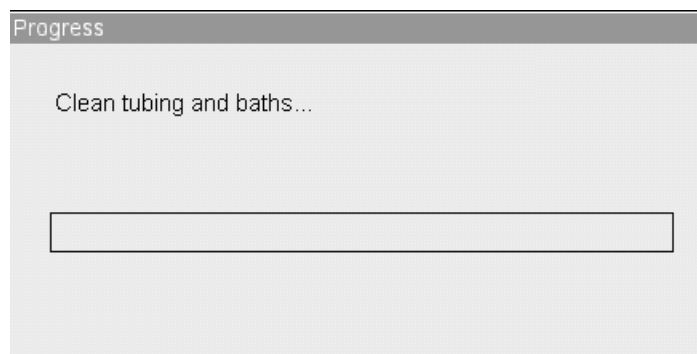
**Figure 10-12 Priming Progress Bar**

3. When the message "Submerge probe into tube containing probe cleanser and select [OK] to begin aspirating. When the probe ascends remove the tube." displays, do as instructed to aspirate probe cleanser again. The aspirating progress bar and message "Aspirate probe cleanser to prime tubing and baths again...".
4. When the progress ends, the following dialog box indicating the remaining time of cleaning procedure will display. The cleaning procedure will last for 20 minutes.



**Figure 10-13 The Remaining Time Dialog Box**

5. When soaking finishes, the following progress bar and message will be displayed.

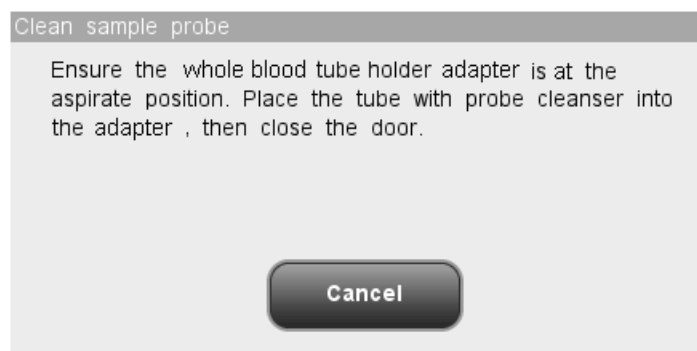


**Figure 10-14 Cleaning Progress Bar**

6. When the progress ends, a dialog box will display indicating "The operation succeeded!", click "OK" to close the dialog box.

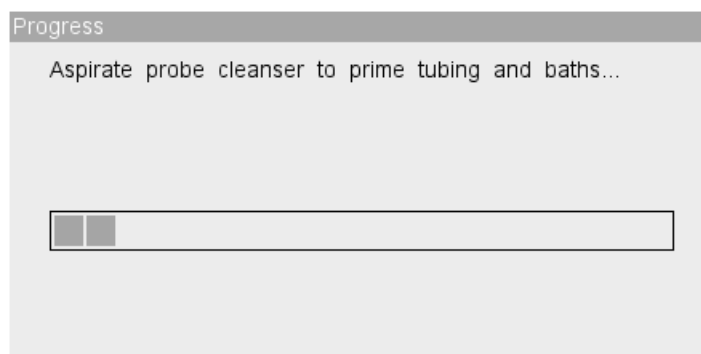
**Probe cleanser soaking procedure for closed tube model:**

1. Click "Probe cleanser soak" at the "Maintenance" screen.
2. The following dialog box will be displayed. Open the sample compartment door as instructed, put the translucent tube holder adapter to the aspirating position.
3. Pipette 3.5 mL of probe cleanser to a clean collection tube, then load the tube to the aspirating position and close the sample compartment door. Make sure the collection tube is not capped.



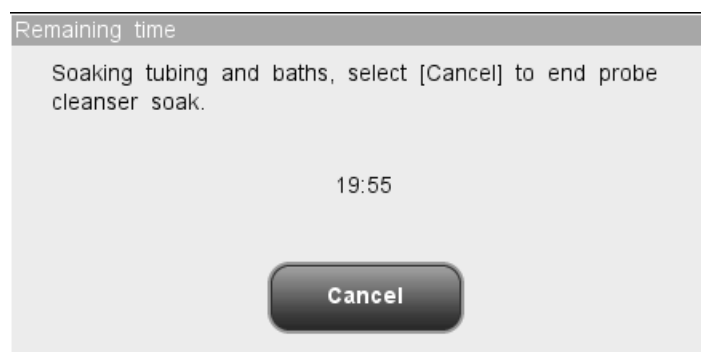
**Figure 10-15 Probe Cleanser Soak Dialog Box**

4. The following progress bar will be displayed on the screen. When the aspiration is done, the sample compartment door will open automatically. Take out the tube and close the sample compartment door.



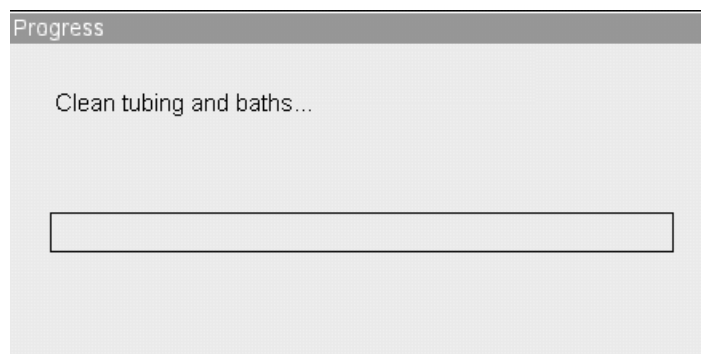
**Figure 10-16 Priming Progress Bar**

5. When the progress ends, the following "Remaining time" dialog box will be displayed, the cleaning progress will last for 20 minutes.



**Figure 10-17 Remaining Time Dialog Box**

6. When the progress ends, the following message and progress bar will be displayed.



**Figure 10-18 Cleaning Progress Bar**

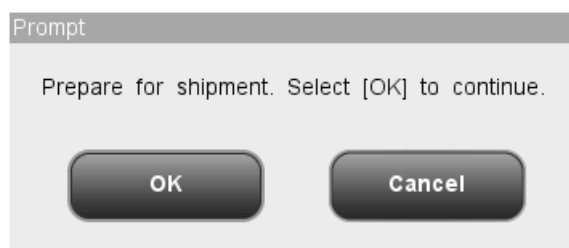
7. When Cleaning completes, a dialog box will display indicating "The operation succeeded!", click "OK" to close the dialog box.

## 10.2.7 Prepare to Ship

If the analyzer is not to be used for over 2 weeks, you should perform this procedure.

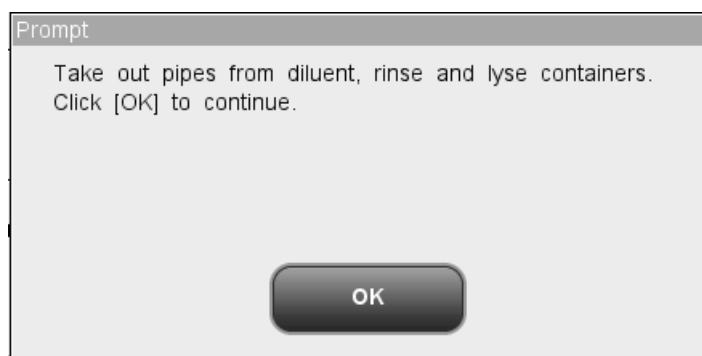
Do as instructed below:

1. Click the “Prepare to ship” button at the “Maintenance” screen, the following dialog box will display. Click “OK” to perform the procedure.



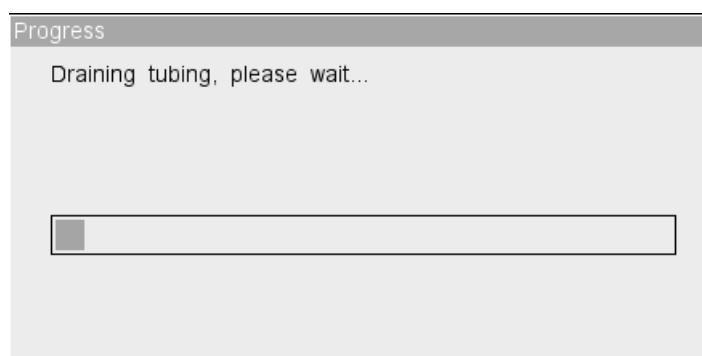
**Figure 10-19 “Prepare to ship” Dialog Box 1**

2. Remove the diluent, rinse and lyse pickup tubes from their containers and press “OK” to drain the tubing.



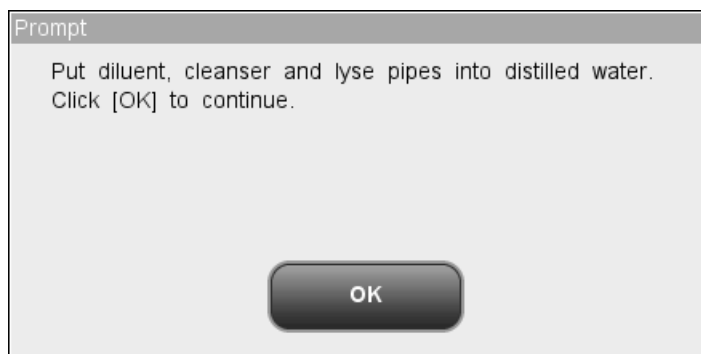
**Figure 10-20 “Prepare to ship” Dialog Box 2**

3. The draining progress bar and the message “Draining tubing, please wait...” will be displayed.



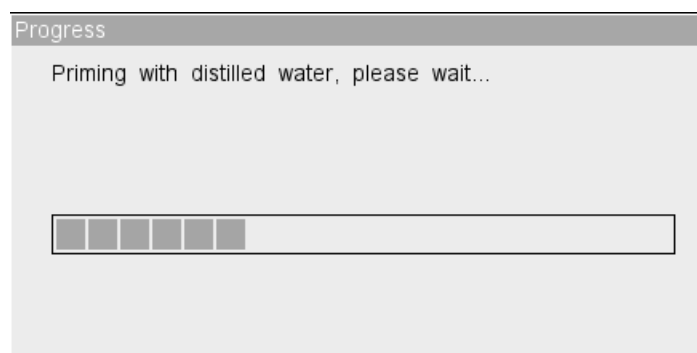
**Figure 10-21 Draining Tubing Progress Bar**

4. When the progress ends, do as instructed by the following dialog box to prime the tubing with distilled water.



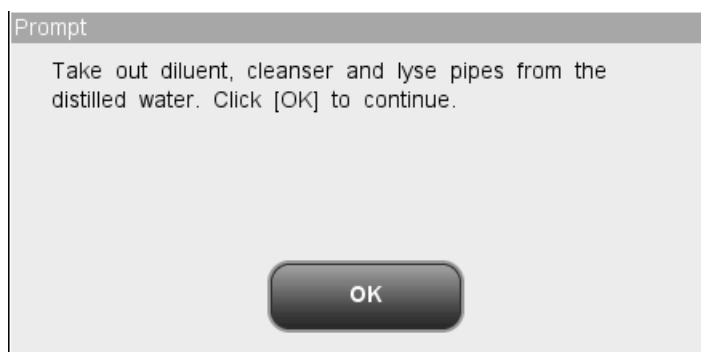
**Figure 10-22 “Prepare to ship” Dialog Box 3**

5. The priming progress bar and message “Priming with distilled water, please wait...” will be displayed on the screen.



**Figure 10-23 Distilled Water Priming Progress Bar**

6. When the progress ends, do as instructed by the following dialog box to drain the tubing.



**Figure 10-24 “Prepare to ship” Dialog Box 4**

7. The draining progress bar and the message “Draining tubing, please wait...” will be displayed.
8. When the progress end, the message “Please power off the analyzer!” will be displayed on the screen, do accordingly.
9. Wipe the analyzer to dry it and pack it in its original box.

## 10.2.8 Drain fluidics



- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
- 

### **NOTE**

- **You should drain the tubing before moving the analyzer.**
- 

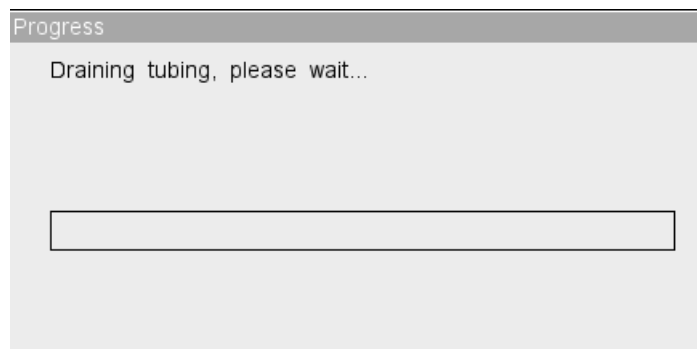
Do as instructed below:

1. Click the “Drain Fluidics” button at the “Maintenance” screen. Remove the diluent, rinse and lyse pickup tubes from the analyzer as instructed by the following dialog box, press “OK” to drain the tubing.



**Figure 10-25 Draining Fluidics Dialog Box**

2. The draining progress bar will be displayed on the screen.



**Figure 10-26 Draining Fluidics Progress Bar**

3. When the progress end, the message “Please power off the analyzer!” will be



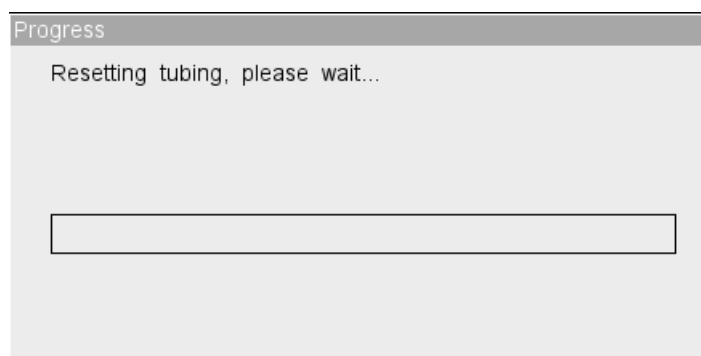
displayed on the screen, do accordingly.

## 10.2.9 Reset fluidics

Click the “Reset Fluidics” button at the screen to reset the tubing.

Do as instructed below:

1. Click the “Reset tubing” button, the following progress bar and message will be displayed on the screen.



**Figure 10-27 Resetting Fluidics Dialog Box**

2. When the progress ends, a dialog box will display indicating “The operation succeeded!”, click “OK” to close the dialog box.

## **10.3 Preset Probe Cleanser Soak**

When the preset time of probe cleanser soak has been reached and the analyzer has been running for over 24 hours, a dialog box will display asking you to perform probe cleanser soak. Click "Yes", the system will activate different soaking sequence base on the accumulated running times. If you click "No", the dialog box will display again 10 minutes later until you choose to perform the operation (it is recommended that you always select "Yes" when the dialog box is displayed).

## 10.4 Using the “System Status” Program

The items displayed on the “System Status” screen reflect how the analyzer is functioning and contribute significantly to diagnosing analyzer errors. You may follow the instructions given below to check those items.

Click “Service”→“System Status” to enter the following “System Status” screen.



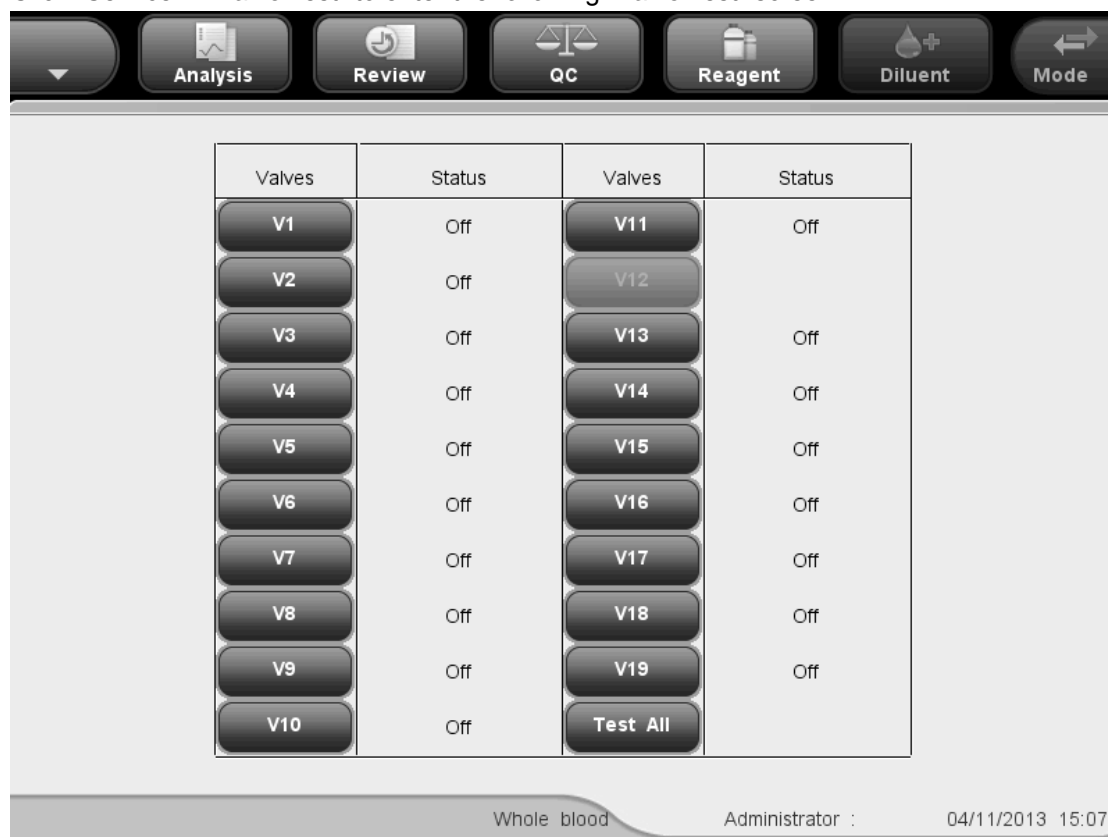
**Figure 10-28 “System Status” Screen**

When abnormal status of an item on the system status screen is detected, the system will give corresponding alarm. You may view and print the current status information.

Click a menu option to exit the screen, the message “Resetting tubing, please wait...” will be displayed. When the resetting progress ends, the corresponding screen will be displayed.

## 10.5 Valve Test

Click “Service”→“Valve Test” to enter the following “Valve Test” screen.

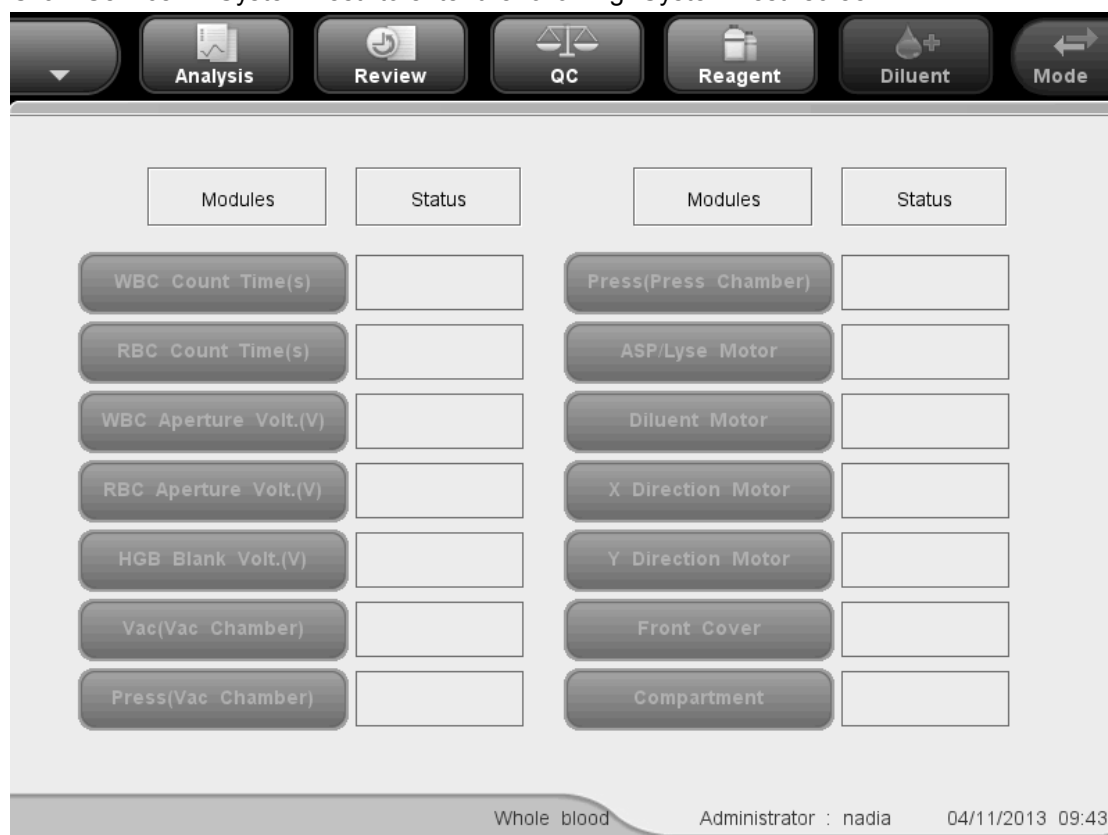


**Figure 10-29 “Valve Test” Screen**

Tap the valve you want to check to test it, or you may tap “Test All” to test all valves. If the valve goes through the Off-On-Off sequence without making any abnormal sound, it passes the test. Otherwise, something may be wrong with the valve.

## 10.6 System Test

Click “Service”→“System Test” to enter the following “System Test” screen.



**Figure 10-30 “System Test” Screen**

You may test status of the analyzer components on the screen. Click on each of the items to start testing. the result will be displayed in the status boxes.

See the testing of “Vac(Vac Chamber)” as an example of the testing procedure.

1. Click the “Vac(Vac Chamber)” button to test its status.
2. If its result is normal, the status box will display “Normal”; otherwise, it will display “Abnormal”. If so, you should refer to **Chapter 11 Troubleshooting Your Analyzer** or contact Mindray customer service department for assistance.
3. Click the a menu option button to exit the screen, the message “Resetting tubing, please wait...” will be displayed. When the resetting progress ends, the corresponding screen will be displayed.

## 10.7 Version Information

Click “Service”→“Version” to enter the following “Version” screen.

Section	Field Name	Value
Software version	Boot Software	1.0
	Kernel	1.0.1_win_demo
	System	01.00.00.365
	Print	1.2.0
	Print Template	1.0
	Sequence	1.0_win_demo
	Language	1.0
	Algorithm	1.0_win_demo
Hardware	Data Board FPGA	1.0_win_demo
	Drive Board FPGA	1.0_win_demo
	Drive on driver board	1.0_win_demo
Installation	CD	

**Print**

Whole blood      Administrator :      12/02/2010 15:08

**Figure 10-31 “Version” Screen**

The version information displayed on the screen includes software/hardware version information and CD version number. Software version information includes “Boot software”, “Kernel”, “System software”, “Print software”, “Print template”, “Sequence file”, “Language” and “Algorithm”. Hardware version information includes “Data board FPGA”, “Driver board FPGA” and “Driver on driver board”.

You may click the “Print” button on the screen to print the version information.

## 10.8 Counter

The counter counts the running times of the analyzer and the occurrence times of some major parameters. Common users as well as administrators can view statistic of the counter. Click “Service”→“Counter” to enter the following “Counter” screen.



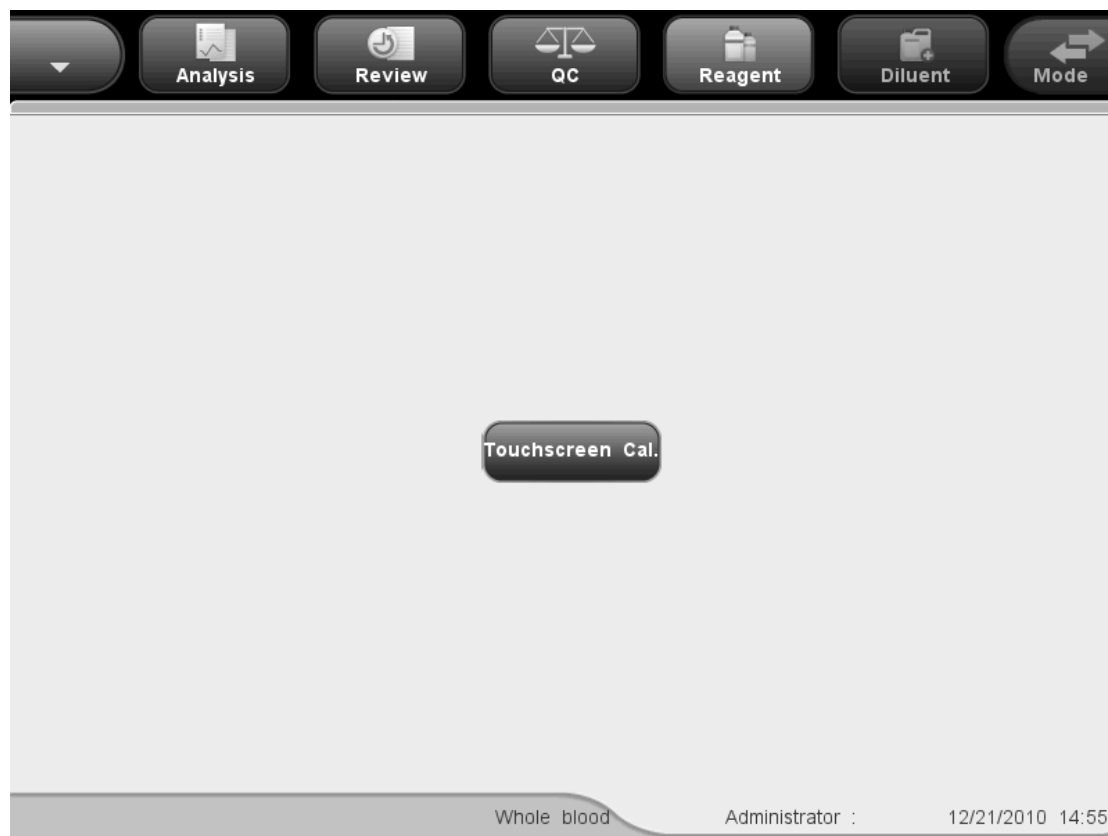
**Figure 10-32“Counter” Screen**

You may view the results of all counting items. Click the “Details” button after the “Total counts”, “QC counts” and “Calibration counts” items, you may view the running times under each of the three modes.

## 10.9 Touchscreen Calibration

If the touchscreen cannot respond correctly to the touch, you should perform this procedure to calibrate the touchscreen.

1. Click “Service”→“Touchscreen Cal.” to enter the “Touchscreen Cal.” screen.



**Figure 10-33 “Touchscreen Cal.” Screen**

2. Click the “Touchscreen Cal.” button in the center of the screen, the following message will be displayed.





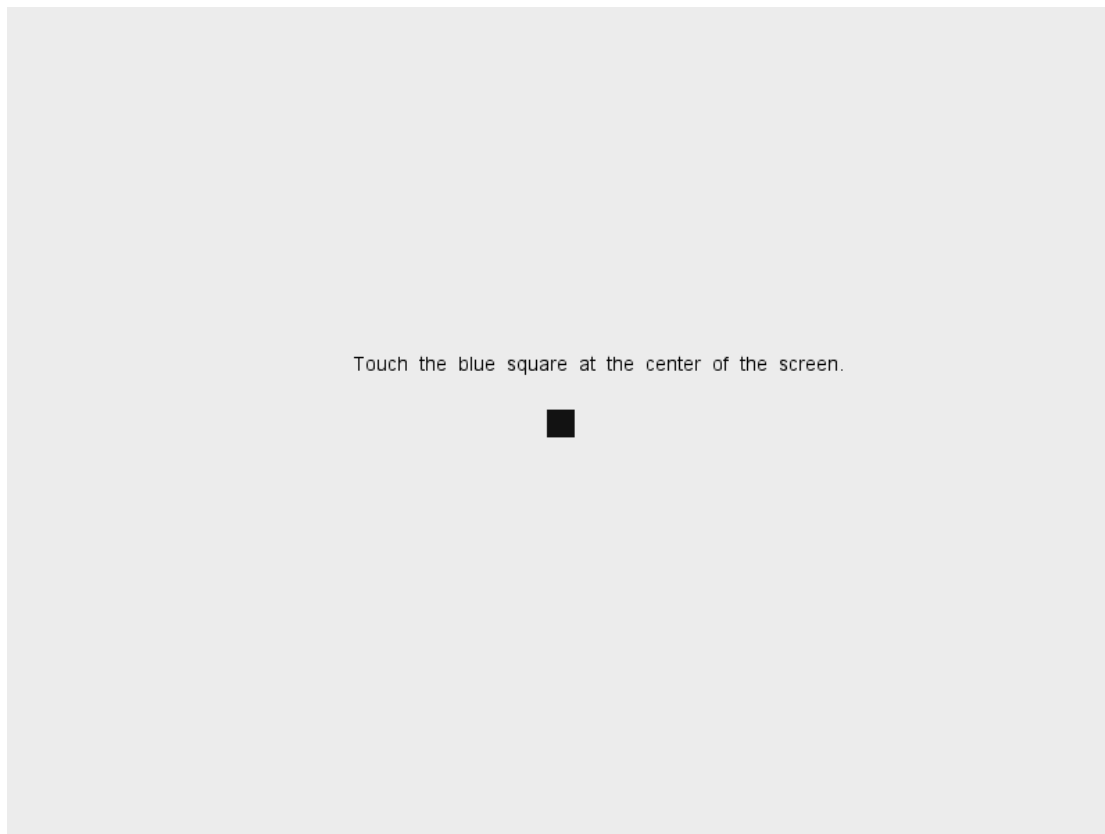
**Figure 10-34 Starting Touchscreen Calibration**

3. Click the red dot on the upper left of the screen, a red dot will appear on the bottom right of the screen and the following message will be displayed.”



**Figure 10-35 Touchscreen Calibration**

4. Click the red dot at the bottom right of the screen, a blue square will appear in the center, and the following message will be displayed.”



**Figure 10-36 Touchscreen Calibration Confirmation**

5. Click the blue square, the message "Calibration succeeded!" will be displayed on the screen, and the initial touchscreen calibration screen will be restored automatically after 1 second.

## 10.10 Using the “Log” Program

The “Log” screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer.

You may see the log records of the recent one year at the most. You may browse, print and export log records, but you cannot delete or modify them.

### 10.10.1 The “Log” screen

Click “Service”→“Log” to enter the following “Log” screen.



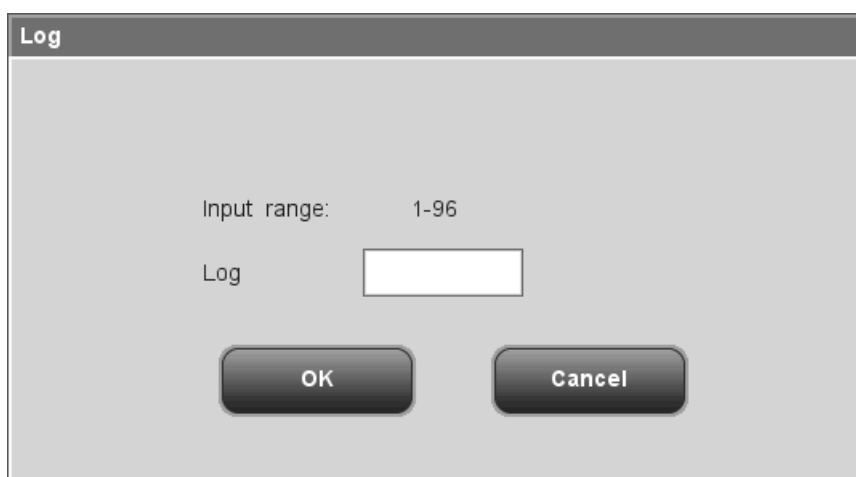
Figure 10-37 “Log” Screen

- Browsing log records

Common users can only see the “All Logs” and “Other Logs” buttons on the screen. Administrators can see 4 buttons on the screen: “All Logs”, “Parameter Modif.”, “Other Logs” and “Error Info.”. Click the buttons to browse the corresponding records.

- Going to the specified records

You may search for the specified record from the log list. Click the “Log” button, then the following dialog box will display.



**Figure 10-38 “Go to” Dialog Box**

Enter the desired log record number into the “Log” box, click “OK” to go to the specified record.

- **Printing**

You may click the “Print” button to print the logs in table format.

- **Exporting data**

You may click the “Export” button to export all logs, parameter modification logs, error information logs or other logs.

---

**NOTE**

- **Do not unplug the USB while exporting data.**
-

## 10.11 Cleaning the Tube Baffle (for closed tube model only)

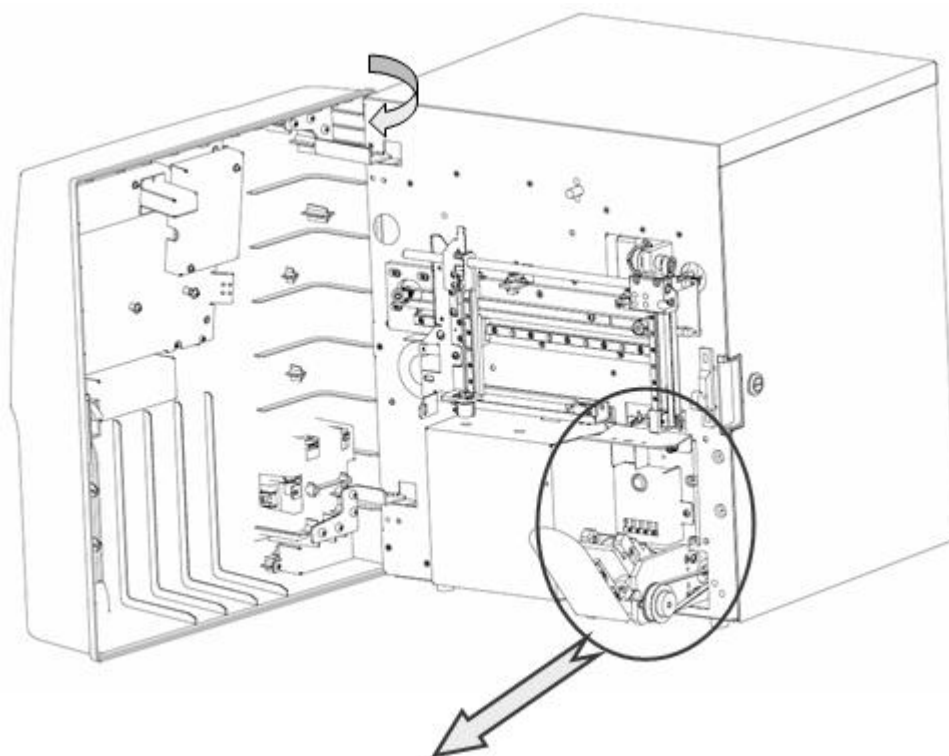
The tube baffle should be cleaned regularly to avoid possible biohazards. It is recommended that you clean it once every two months or whenever 2,500 analysis cycles have been run.

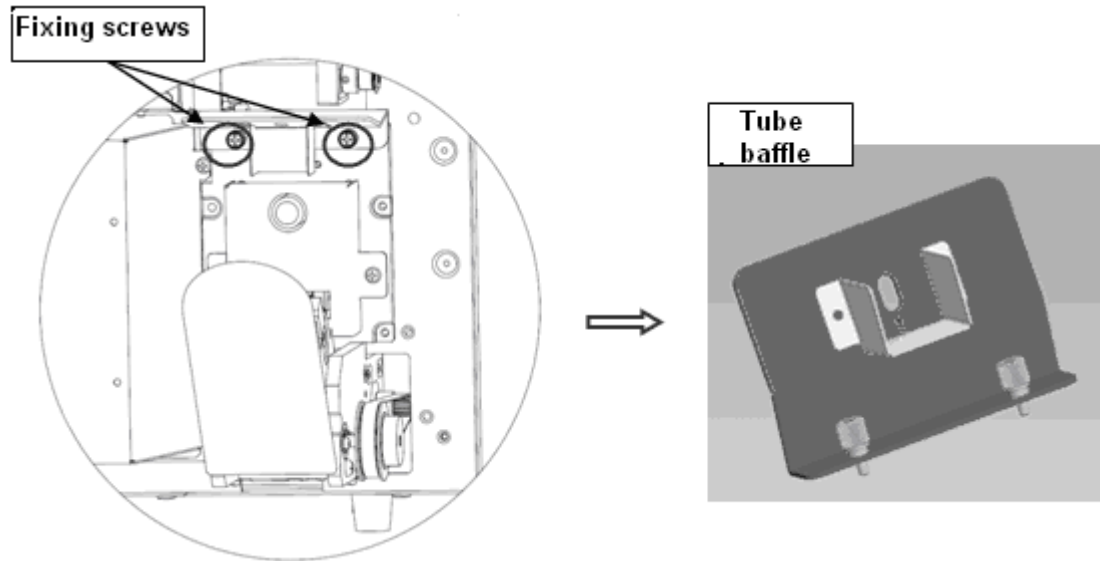


- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
  - **All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.**
- 

Do as follows to clean the tube baffle:

1. Open the front cover;
2. Pull out the sample compartment as illustrated in the following picture;
3. Loose the two fixing screws of the tube baffle to take it off;





**Figure 10-39 Taking off the Tube Baffle**

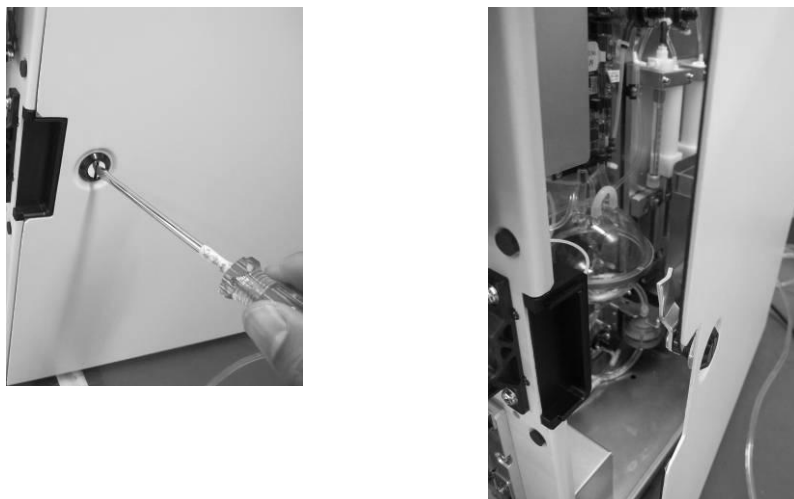
4. Clean the tube baffle with alcohol or other cleansers, or wash it with water.

## 10.12 Replacing Air Filter

When the analyzer reports bubbles in volumetric tubes frequently, you need to check if the air filters are covered by dust; if so, please replace the air filters.

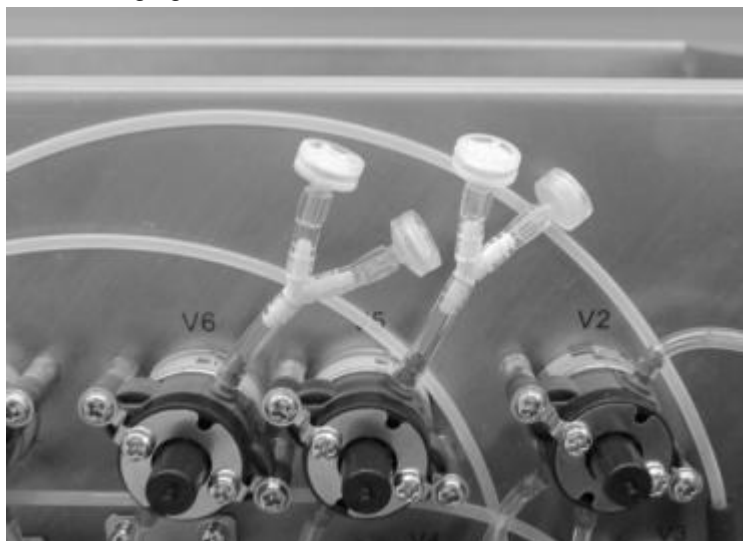
Do as follows to replace the air filter.

1. Open the right door of the analyzer using a slotted head screwdriver as instructed by the following figure.



**Figure 10-40 Open the Right Door**

2. See the following figure for the location of the air filter.



**Figure 10-41 Air Filter**

3. Remove the air filter and install a new one taken out from the accessory box.



# 11 Troubleshooting Your Analyzer

---

## 11.1 Introduction

This chapter contains information that is helpful in locating and correcting problems that may occur during operation of your analyzer.

---



- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.**
- 

### **NOTE**

- **This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer. If the recommended solution fails to solve the problem, contact Mindray customer service department or your local distributor.**
-

## 11.2 Errors Indicated by Error Messages

When abnormal status is detected, the analyzer will alarm you by displaying the corresponding error message in the user information area.

Click on the error information area, the following dialog box will display. Click the "Clear error" button to clear all the errors that can be removed currently.



**Figure 11-1 Clear Error Dialog Box**

See the table below for the error messages and their probable causes and recommended actions. If the problem still remains after you have tried the recommended solutions, contact Mindray customer service department or your local distributor for assistance.

The possible error(s) and the corresponding troubleshooting information are listed below:

Error Name	Actions
Sampling assembly failure	<ol style="list-style-type: none"> <li>1. Click "Clear error" button to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Confirm if the interfaces and connection wires are securely connected;</li> <li>4. Confirm if the photocouplers are damaged;</li> <li>5. Confirm if the driver board needs to be replaced;</li> <li>6. Confirm if the sample collection assembly is damaged and needs to be replaced.</li> </ol>
ASP/LS syringe cannot find home position	<ol style="list-style-type: none"> <li>1. Click "Clear error" button to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the</li> </ol>

## Troubleshooting Your Analyzer

	<p>latest and if the driver board operates normally;</p> <ol style="list-style-type: none"> <li>3. Confirm if the interfaces and connection wires are securely connected;</li> <li>4. Confirm if the photocouplers are damaged;</li> <li>5. Confirm if the driver board needs to be replaced;</li> <li>6. Confirm if the syringe assembly is damaged and needs to be replaced.</li> </ol>
Sampling/lyse syringe failure	<ol style="list-style-type: none"> <li>1. Click “Clear error” button to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Confirm if the interfaces and connection wires are securely connected;</li> <li>4. Confirm if the photocouplers are damaged;</li> <li>5. Confirm if the driver board needs to be replaced;</li> <li>6. Confirm if the syringe assembly is damaged and needs to be replaced.</li> </ol>
Sample compartment failure (for closed vial model only)	<ol style="list-style-type: none"> <li>1. Click “Remove error” button to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Confirm if the interfaces and connection wires are securely connected;</li> <li>4. Confirm if the photocouplers are damaged;</li> <li>5. Confirm if the driver board needs to be replaced;</li> <li>6. Confirm if the sample compartment assembly is damaged and needs to be replaced.</li> </ol>
Temperature exceeds normal range	<ol style="list-style-type: none"> <li>1. Adjust the operating ambient temperature to the required range</li> <li>2. Replace the sensor</li> </ol>
Rinse level low	Change a new container of rinse
Rinse empty	Change a new container of rinse
Diluent level low	Change a new container of diluent
Insufficient diluent	Change a new container of diluent
Lyse level low	Change a new container of lyse
Insufficient lyse	Change a new container of lyse
Waste full	Empty the waste container or use a new waste container
Electronic circuit voltage abnormal	<ol style="list-style-type: none"> <li>1. Click “Clear error” button to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Confirm if the interfaces and connection wires are securely connected;</li> <li>4. Confirm if the power board needs to be replaced;</li> <li>5. Confirm if the driver board needs to be replaced.</li> </ol>
Front cover open	Close the front cover
Pressure failure	<ol style="list-style-type: none"> <li>1. Click “Clear error” or go to the “System test” screen to</li> </ol>

## Troubleshooting Your Analyzer

	<p>see if the error can be removed;</p> <ol style="list-style-type: none"> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Confirm if the driver board and the volumetric board are firmly connected, and if tubes of the sensors on the volumetric board are securely connected;</li> <li>4. Confirm if the vacuum chamber and the pressure chamber are correctly installed;</li> <li>5. Restart to see if the error is removed.</li> <li>6. If the error persists, the pressure sensor may be damaged and the volumetric board needs to be replaced.</li> </ol>
Vacuum failure	<ol style="list-style-type: none"> <li>1. Click "Clear error" or go to the "System test" screen to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Confirm if the driver board and the volumetric board are firmly connected, and if tubes of the sensors on the volumetric board are securely connected;</li> <li>4. Confirm if the vacuum chamber and the pressure chamber are correctly installed;</li> <li>5. Restart to see if the error is removed.</li> <li>6. If the error persists, the pressure sensor may be damaged and the volumetric board needs to be replaced.</li> </ol>
WBC clog	<ol style="list-style-type: none"> <li>1. Press the "Clear Error" button to remove this error</li> <li>2. Replace the volumetric board</li> <li>3. Replace the valve V7</li> </ol>
WBC bubbles	<ol style="list-style-type: none"> <li>1. Replace the volumetric board</li> <li>2. Replace the valve V7</li> <li>3. Replace the WBC bath assembly</li> </ol>
RBC clog	<ol style="list-style-type: none"> <li>1. Press the "Clear Error" button to remove this error</li> <li>2. Replace the volumetric board</li> <li>3. Replace the valve V8</li> </ol>
RBC bubbles	<ol style="list-style-type: none"> <li>1. Replace the volumetric board</li> <li>2. Replace the valve V8</li> <li>3. Replace the RBC bath assembly</li> </ol>
HGB failure	<ol style="list-style-type: none"> <li>1. Run diluent priming and the daily check.</li> <li>2. Change a new container of diluent</li> <li>3. Rewriting the gain value to assure the HBG blank voltage is <math>4.5 \pm 0.1V</math></li> <li>4. Replace the HGB assembly</li> <li>5. Replace the data board</li> </ol>
RBC/PLT pulse data collection abnormal	<ol style="list-style-type: none"> <li>1. Click "Clear error" to see if the error can be removed;</li> <li>2. Restart the analyzer</li> </ol>
WBC pulse data collection abnormal	<ol style="list-style-type: none"> <li>1. Click "Clear error" to see if the error can be removed;</li> <li>2. Restart the analyzer</li> </ol>
Driver board chip failure	<ol style="list-style-type: none"> <li>1. Click "Clear error" button to see if the error can be</li> </ol>

## Troubleshooting Your Analyzer

	<p>removed;</p> <ol style="list-style-type: none"> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Restart the analyzer to see if the error is removed; if not, replace the driver board.</li> </ol>
System time error	Replace with new battery
Background abnormal	Check if there is any interference source around the analyzer and if it is properly grounded. Replace diluent and conduct background count for several times to solve the issue.
Diluent expired	Change a new container of diluent
Rinse expired	Change a new container of rinse
Lyse expired	Change a new container of lyse
Pack expired	Change the pack
Control command error	<ol style="list-style-type: none"> <li>1. Click "Clear error" button to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Restart the analyzer to see if the error is removed; if not, replace the driver board.</li> </ol>
Print Error	Check if the printer has run out of paper or if there are any other problems.
Recorder failure	Check if the recorder has run out of paper or if there are any other problems.
LIS communication failure	Confirm if the data transmission wire is securely connected, and try to solve the issue by replacing the wire or changing communication settings.
Diluent syringe cannot find home position	<ol style="list-style-type: none"> <li>1. Click "Clear error" button to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Confirm if the interfaces and connection wires are securely connected;</li> <li>4. Confirm if the photocouplers are damaged;</li> <li>5. Confirm if the driver board needs to be replaced;</li> <li>6. Confirm if the syringe assembly is damaged and needs to be replaced.</li> </ol>
Diluent syringe failure	<ol style="list-style-type: none"> <li>1. Click "Clear error" button to see if the error can be removed;</li> <li>2. Confirm if the software and hardware version are the latest and if the driver board operates normally;</li> <li>3. Confirm if the interfaces and connection wires are securely connected;</li> <li>4. Confirm if the photocouplers are damaged;</li> <li>5. Confirm if the driver board needs to be replaced;</li> <li>6. Confirm if the syringe assembly is damaged and needs to be replaced.</li> </ol>

## Troubleshooting Your Analyzer

---

Reaction temp. abnormal	Make sure if the ambient temperature is higher than 35°C, if so, lower the ambient temperature.
-------------------------	---

# 12 Appendices

## A Index

<b>A</b>		Manual Sleep ..... 10-5
analyzer		<b>P</b>
intended use..... 2-2		parameter
name ..... 2-1		ALY#(RUO)..... 2-2
Aspiration..... 3-2		ALY%(RUO) ..... 2-2
Auto calibration		Bas# ..... 2-2
using fresh blood samples ..... 9-13		Bas% ..... 2-2
Auto calibration using calibrators..... 9-10		Eos# ..... 2-2
		Eos% ..... 2-2
	<b>C</b>	LIC%(RUO) ..... 2-2
calibration		Lym# ..... 2-2
conditions ..... 9-2		Lym%..... 2-2
introduction..... 9-1		Mon#..... 2-2
Calibrators ..... 2-19		Mon% ..... 2-2
Cleaning..... 10-7		Neu# ..... 2-2
		Neu%..... 2-2
	<b>D</b>	WBC ..... 2-2
DIFF channel scattergram ..... 3-5		Power Requirements ..... 4-2
Dilution ..... 3-3		<b>Q</b>
	<b>F</b>	Quality Control
flags ..... 6-16		L-J..... 8-2
Flow Cytometry by Laser ..... 3-5		X-B..... 8-26
Flushing Apertures..... 10-11		X-R ..... 8-18
	<b>H</b>	<b>R</b>
HGB Measurement ..... 3-9		Reagents..... 2-18
	<b>I</b>	recorder
Initial Checks ..... 6-2		install paper ..... 4-11
	<b>M</b>	Replacing Reagent ..... 10-6
Main Structure..... 2-3		Running controls
		L-J..... 8-5
		X-B..... 8-35
		X-R ..... 8-21

**S**

Startup and login..... 6-4  
System Status..... 10-16

**T**

troubleshooting .....11-1

**U**

Unclogging..... 10-7  
User Interface ..... 2-14

**W**

WBC Measurement..... 3-5  
Worklist ..... 6-22

**Z**

Zapping Apertures..... 10-8



## B Specifications

### B.1 Classification

According to the CE classification, the BC-3600 belongs to In vitro diagnostic medical devices other than those covered by Annex II and devices for performance evaluation.

### B.2 Reagents

Hematology Analyzer Diluent	M-30D Diluent
Hematology Analyzer Lyse	M-30CFL Lyse
Rinse	M-30R Rinse
Probe cleanser	Probe cleanser
Hematology Analyzer Control(Impedance Method)	B30
Hematology Analyzer Calibrator(Impedance Method)	S30

### B.3 Applicable Tubes

- The following tubes can be used under the whole blood mode.

Tube No.	MFG	Product Name	Tube Material	Anti-coagulant	Size (mm)	Tube Cap	Bottom Type
367835	BD	Vacutainer Plus	Plastic	K2	13x75	Conventional, lavender	True Round
TH5COC	CML Aérotubes	Aerotubes	Plastic	K3	13x75	Conventional	True Round
VT-053ST K [v]	Terumo	Venoject	Glass	K3	13x75	Conventional, lavender	True Round
0959 0610	Kabe	Primavette S und V7	Plastic	K3	11.5x66	Narrow Single	Plastic Plunger
05.1167.0 01	Sarstedt	S-Monovette	Plastic	EDT A K	11X66	Narrow, Screw cap, pierceable	Plastic Plunger

Appendices

04.1901.1 00	Sarstedt	S-Monovette	Plastic	EDT A K	13x65	Narrow, Screw cap, pierceable	Plastic Plunger
367661	BD	Vacutainer	Glass	K3	13x75	Hemogard, lavender	
367841	BD	Vacutainer Plus	Plastic	K2	13x75	Hemogard, lavender	True Round
TV4COP NF	CML Aérotubes	Aerotubes	Plastic	K3	13x75	Hemogard- like	True Round
420303GL V	Estar	EstarVac	Glass	K3	13x75	Hemogard- like, rubber (Monocap)	True Round
454024	Greiner	VACUETTE Paediatric	Plastic	K2	13x75	Hemoguar d like, Ridged safety screw cap, white ring	True Round
454222	Greiner	VACUETTE Paediatric	Plastic	K3	13x75	Hemoguar d-like, Non-ridged pull cap	True Round
VF-052ST K [v]	Terumo	Venosafe	Plastic	K3	13x75	Hemogard- like	True Round
VF-053ST K [v]	Terumo	Venosafe	Plastic	K3	13x75	Hemogard- like	True Round
112325	Kabe	Kabette Vacuum	Plastic	K2	12.5x75	Hemagard- like, red top	True Round
102325	Kabe	Kabevette G	Plastic	K3	12.5x76	Hemogard- like	Plastic Plunger
VP-DK05 2LS	Terumo	Venoject II	Plastic	K2	13.2x78	Rubber/Foil , seal	True Round
4C-ES(GI ass)	Coulter	S-CAL calibrator	Glass		13x62	Pierceable	round
4C-ES(PI astic)	Coulter	4C -X	Glass		13x62	Pierceable	round
365974	BD	Microtainer	Plastic	K2		Microguard , lavender	False Bottom
454034	Greiner	VACUETTE Paediatric	Plastic	K3	13x75	Ridged safety screw cap, white ring	

Appendices

PAED01. P05	ISS	Pediatric	Plastic	EDT A	12.5x47	Screw cap, bore seal closure, pink	
0 30014	Kabe		Plastic	K2	11x40	Plastic (very thin)	False Bottom (little elevatio n)
0 77030	Kabe		Plastic	K2		Plastic flip cap (red, thin)	False Bottom (little elevatio n)
0 78001	Kabe		Plastic	K2		Plastic flip cap (thin)	True Round
07 7053 [s]	RAM Scientific	SAFE-T-FILL	Plastic	K2 liquid		Plastic flip, lavendar	
07 7056 [s]	RAM Scientific	SAFE-T-FILL	Plastic	K2 liquid		Plastic flip, lavendar, self sealing	
07 7058 [s]	RAM Scientific	SAFE-T-FILL	Plastic	K2 liquid		Plastic flip, lavendar	Flat bottom
41.1504.0 05	Sarstedt	Micro Tubes	Plastic	EDT A K	10.8x40	Push cap	Skirted conical base
41.1395.1 05	Sarstedt		Plastic	EDT A K	10.8x45	Screw cap w/ integral O ring	Skirted conical base
(3) T-MQK	Terumo	Capiject	Plastic	K2		Plastic	True Round

- The following tube can be used under the predilute mode.

Applicable tube under predilute mode: centrifugal tube;

Fill volume: 1.5ml.

Size: Φ11×40, 11 is the diameter of the tube top.

## B.4 Parameters

Parameter	Abbreviation	Default Unit
White Blood Cell count	WBC	10 <sup>9</sup> /L
Lymphocyte number	Lymph#	10 <sup>9</sup> /L
Mid-sized cell number	Mid#	10 <sup>9</sup> /L
Granulocyte number	Gran#	10 <sup>9</sup> /L

Lymphocyte percentage	Lymph%	None
Mid-sized cell percentage	Mid%	None
Granulocyte percentage	Gran%	None
Red Blood Cell count	RBC	10 <sup>12</sup> /L
Hemoglobin concentration	HGB	g/L
Mean Corpuscular Volume	MCV	fL
Mean Corpuscular Hemoglobin	MCH	pg
Mean Corpuscular Hemoglobin Concentration	MCHC	g/L
Red Blood Cell Distribution Width Coefficient of Variation	RDW-CV	None
Red Blood Cell Distribution Width Standard Deviation	RDW-SD	fL
Hematocrit	HCT	None
Platelet count	PLT	10 <sup>9</sup> /L
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	None
Plateletcrit	PCT	mL/L
Platelet-Large Cell Ratio	P-LCR	None
Platelet- Large Cell Count	P-LCC	10 <sup>9</sup> /L

## B.5 Sampling Features

### B.5.1 Sample Volumes Required for Each Analysis

Whole Blood Mode	≤ 17μL
Predilute Mode	≤ 20μL

### B.5.2 Throughput

Whole Blood Mode	no less than 60 samples per hour
Predilute Mode	no less than 60 samples per hour

## B.6 Performance Specifications

### B.6.1 Display Range

Parameter	Display range
WBC	$(0.0 \sim 999.9) \times 10^9/L$
RBC	$(0.00 \sim 9.99) \times 10^{12}/L$
HGB	$(0 \sim 300) \text{ g/L}$
MCV	$(0.0 \sim 250.0) \text{ fL}$
PLT	$(0 \sim 9999) \times 10^9/L$

### B.6.2 Requirements of blank counting

Parameter	Requirements of Blank Counting
WBC	$\leq 0.3 \times 10^9/L$
RBC	$\leq 0.03 \times 10^{12}/L$
HGB	$\leq 1 \text{ g / L}$
HCT	$\leq 0.5 \%$
PLT	$\leq 5 \times 10^9/L$

### B.6.3 Linearity Range

Parameter	Linearity range	Deviation range (Whole blood mode)	Deviation range (Predilute Mode)
WBC	$(0 \sim 100.0) \times 10^9/L$	$\pm 0.30 \times 10^9/L$ or $\pm 5\%$	$\pm 0.50 \times 10^9/L$ or $\pm 5\%$
	$(100.1 \sim 200.0) \times 10^9/L$	$\pm 9\%$	$\pm 18\%$
RBC	$(0 \sim 8.00) \times 10^{12}/L$	$\pm 0.05 \times 10^{12}/L$ or $\pm 5\%$	$\pm 0.05 \times 10^{12}/L$ or $\pm 5\%$
HGB	$(0 \sim 280) \text{ g/L}$	$\pm 2 \text{ g/L}$ or $\pm 2\%$	$\pm 2 \text{ g/L}$ or $\pm 3\%$
PLT	$(0 \sim 1000) \times 10^9/L$	$\pm 10 \times 10^9/L$ or $\pm 10\%$	$\pm 10 \times 10^9/L$ or $\pm 10\%$
	$(1001 \sim 3000) \times 10^9/L$	$\pm 12\%$	$\pm 20\%$
HCT	$(0 \sim 67)\%$	$\pm 4\%$ (HCT result) or $\pm 6\%$ (deviation)	/

### B.6.4 Reproducibility

#### Reproducibility Requirement (whole blood)

Parameter	Condition	Precision
WBC	$(7.0 \sim 15.0) \times 10^9/L$	$\leq 2.5$
	$(4.0 \sim 6.9) \times 10^9/L$	$\leq 3.5$
RBC	$(3.50 \sim 6.50) \times 10^{12}/L$	$\leq 2.0$
HGB	$(100 \sim 180) \text{ g/L}$	$\leq 1.5$
MCV	$(80.0 \sim 110.0) \text{ fL}$	$\leq 1.0$
PLT	$(150 \sim 500) \times 10^9/L$	$\leq 4.0$
	$(100 \sim 149) \times 10^9/L$	$\leq 5.0$
HCT	$30\% \sim 50\%$	$\leq 3.0$

Lymph%	20% ~ 50%	≤ 1.5 (SD)
Mid%	2% ~ 13%	≤ 1.5 (SD)
Gran%	30% ~ 70%	≤ 3.0 (SD)

**Reproducibility Requirement (predilute)**

Parameter	Condition	Precision
WBC	$(4.0 \sim 15.0) \times 10^9/L$	≤ 4.0
RBC	$(3.50 \sim 6.50) \times 10^{12}/L$	≤ 2.0
HGB	(110 ~ 180) g/L	≤ 2.0
MCV	(80.0 ~ 110.0) fL	≤ 1.5
PLT	$(100 \sim 500) \times 10^9/L$	≤ 8.0

**B.6.5 Carryover**

Parameter	Carryover
WBC	≤ 0.5%
RBC	≤ 0.5%
HGB	≤ 0.5%
PLT	≤ 1.0%

**B.7 Input/output Device**

**B.7.1 Touch Screen**

TFT color touch screen, 800x600.

**B.7.2 Indicator**

The indicator indicates the on/off, running or standby status of the analyzer.

**B.7.3 Keyboard (Optional)**

101-Key alpha-numeric keyboard, USB

**B.7.4 Mouse (Optional)**

USB mouse

**B.7.5 Bar-code scanner (Optional)**

USB barcode scanner.

**B.7.6 Printer**

The analyzer supports the following USB printers: black/white laser printer and inkjet printer, and USB dot-matrix printer Epson LQ-630K.

### B.7.7 Recorder

Built-in thermal recorder. Communication protocol: TR60-H serial communication protocol of recorders.

### B.7.8 Buzzer

The buzzer indicates errors of the analyzer. When you click the touch screen or the error is cleared, the alarming sound of the buzzer can be cleared.

## B.8 Interfaces

- One LAN interface, built-in network card, TCP/IP compatible
- One RS-232 port to support the host connected to LIS with serial port.
- 4 USB ports

## B.9 Power Supply

	Voltage	Input power	Frequency
Analyzer	(100V-240V~)±10%	≤180 VA	(50/60Hz)±1Hz

## B.10 Fuse

---

### NOTE

- Only install fuses of specified specification on the analyzer.
- 

Fuse specification: 250V T3.15AH

## B.11 EMC Description

- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.
- This equipment complies with the emission and immunity requirements of the EN61326-1:2006 and EN61326-2-6:2006.
- This equipment has been designed and tested to CISPR11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take

measures to mitigate the interference.

---

**NOTE**

- It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
  - It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
- 

## B.12 Sound

Maximal sound: 77 dB

## B.13 Operating Environment

- Optimal operating temperature: 15°C~30°C
- Optimal operating humidity: 30%~85%
- Atmospheric pressure: 70.0kPa~106.0kPa

## B.14 Storage Environment

- Ambient temperature: -10°C~40°C
- Relative humidity: 10%~93%
- Atmospheric pressure: 50.0kPa~106.0kPa

## B.15 Running Environment

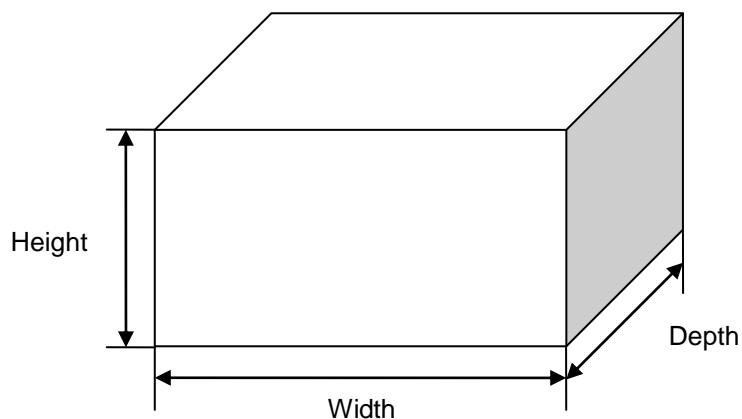
- Ambient temperature: 15°C~35°C
  - Relative humidity: 30%~85%
  - Atmospheric pressure: 70.0kPa~106.0kPa
- 

**NOTE**

- Be sure to use and store the analyzer in the specified environment.
-



## B.16 Dimensions and Weight



	<b>Analyzer</b>
<b>Width (mm)</b>	$\leq 395$
<b>Height (mm)</b>	$\leq 445$ (without foot)
<b>Depth (mm)</b>	$\leq 450$
<b>Weight (Kg)</b>	$\leq 28$

## B.17 Contraindications

None

## B.18 Safety Classification

Level of transient overvoltage: Category II.




Rated pollution degree: 2.



## C Precautions, Limitations and Hazards

### C.1 Precautions, Limitations and Hazards

The following symbols are used to indicate danger and alert information in this manual.

Symbols	Meaning
 <b>WARNING</b>	read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
 <b>CAUTION</b>	read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
<b>NOTE</b>	read the statement below the symbol. The statement is alerting you to information that requires your attention.
	read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.

#### C.1.1 Installation Requirements

All the space, power and environmental requirements listed in **Chapter 4 Installation** and **Appendix B Specifications** must be met. Establishing and maintaining proper grounding cannot be overemphasized.

#### C.1.2 Limitations

Whenever the results are outside the normal limits, it is recommended that the laboratory following whatever written protocol is in place for validating results.

If an error occurs, the analyzer displays the corresponding error message. In case of errors related to the fluidic system (such as clogging or bubbles), it is recommended that you re-run the sample after clearing the error.

When the PLT value is less than  $100 \times 10^9 / L$ , a reexamination is recommended.

#### C.1.3 Service

The maintenance instructions in *Chapter 10* describe corrective and preventive procedures that must be followed to ensure proper operation and performance of your analyzer.

## C.2 Warning

---

### **⚠ WARNING**

- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.
  - Be sure to operate the analyzer under the situation specified in this manual. Otherwise, the analyzer will not work normally and the analysis results will be unreliable, which would damage the analyzer components and cause personal injury.
  - Make sure the analyzer is properly grounded.
  - Before turning on the analyzer, make sure the input voltage meets the requirements.
  - Do not place the analyzer in a flammable or explosive environment.
  - Only install fuses of specified specification on the analyzer.
  - If your analyzer has been used for a while, when moving the analyzer, the operators must wear proper personal protective equipment (e.g. gloves, lab coat, etc.).
  - Keep your clothes, hairs and hands away from the moving parts to avoid injury.
  - The sample probe is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
  - Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
  - The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
  - If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water; seek medical attention immediately.
  - Do not contact patients' sample blood directly.
  - The centrifugal tube must not be capped when dispensing diluent.
  - The centrifugal tube must not be capped when running prediluted samples.
  - The sample may spill from the uncapped collection tubes and cause biohazard. Exercise caution to the uncapped collection tubes.
  - The breaking of collection tubes may cause personal injury and/or biohazard. Take precaution when loading and unloading collection tubes from the rack. Avoid breaking the sample tubes.
-

## C.3 Cautions

---

**⚠ CAUTION**

- Installation by personnel not authorized or trained by Mindray may cause personal injury or damage your analyzer. Do not install your analyzer without the presence of Mindray-authorized personnel.
  - Using pinboard may bring electrical interference and the analysis results may be unreliable. Please place the analyzer near the electrical outlet to avoid using pinboard.
  - Please use the original power cable shipped with the analyzer. Using other power cable may damage the analyzer or cause unreliable analysis results.
  - Do not place reagents on or above the analyzer.
  - Use only specified recorder paper. Otherwise, it may cause damage to the recorder head, or the recorder may be unable to print, or poor print quality may result.
  - Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.
  - Do not leave the recorder door open unless you are installing paper or removing error.
  - Improper installation of recorder paper may jam the paper and/or result in blank printout.
  - Do not re-use disposable products like collection tubes, test tubes, capillary tubes, etc.
  - Under the whole blood mode, do not count the same sample more than 3 consecutive times.
  - Performing unauthorized maintenance procedures can damage your analyzer. Do not perform any maintenance procedures that are not described in this chapter.
  - In case of problems not specified in this manual, contact Mindray customer service department or your local distributor for assistance.
  - Only Mindray-supplied parts can be used for maintenance. For any questions, contact Mindray customer service department or your local distributor.
  - Exercise caution to avoid contact with the sharp sample probe when performing maintenance.
-

## C.4 Notes

---

**NOTE**

- This equipment must be operated by skilled/trained medical professionals.
  - Be sure to operate your analyzer strictly as instructed in this manual.
  - The purpose of this analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.
  - Store and use the reagents as instructed by instructions for use of the reagents.
  - When you have changed the diluent, lyse or rinse, run a background to see if the results meet the requirement.
  - Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents.
  - After installing a new container of reagent, let it equilibrate at room temperature for a few minutes before using.
  - If the ambient temperature is outside the specified operating range, thus causing the analyzer temperature (the temperature tested by the sensor inside the analyzer) goes out its specified range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. See Chapter 11 Troubleshooting Your Analyzer for solutions.
  - Please keep the package for possible long-distance transportation.
  - The analyzer must be placed on a flat station, instead of on an inclined surface.
  - Use the manufacturer-specified reagents.
  - To avoid contamination; ensure the container caps are closed and sealed properly.
  - Remove the protective paper between the recorder head and the roller inside the recorder before installing recorder paper.
  - Running sample with the background abnormal error present will lead to unreliable results.
  - If transmission is going on, you will not be able to edit transmit settings.
  - When transmission is going on, the settings cannot be edited.
  - The "Name" box cannot be null. If it is null, a message will display prompting "Name cannot be null!".
  - The names and shortcut codes of different records cannot be the same. If so, dialog boxes will display prompting the name or code already exists. But the shortcut code and shortcut pinyin code of one record can be the same.
  - You may set up 500 shortcut codes maximum. When the number exceeds 500, the message "Maximum number of records has been reached!" will
-

display.

- Username cannot be null, if so, the dialog box will display reminding you of invalid username.
- You may create 10 administrators and 90 common users at the most.
- Do not repeat any name when you create users.
- Your password should be kept to yourself to avoiding misuse by others.
- You cannot modify your own username.
- You may delete records of common users and other administrators if your access level is "Administrator", but you cannot delete your own record.
- Record of the initial administrator cannot be deleted.
- Be sure to reset the reagent expiration date before the first use of the analyzer or after replacing reagents.
- You should only use the Mindray-specified reagents. Store and use the reagents as instructed by instructions for use of the reagents.
- Check if the reagent tubings are properly connected before using the analyzer.
- The system opens different function for the user according to the user level. The user level depends on the user name and the password when the user logs in.
- If user switching is necessary, click the "Logoff" icon on the system menu. Enter the desired user name and the password into the popup dialog box and Click the "OK" button to log on.
- Be sure to use clean K2EDTA anticoagulant collection tubes, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
- Be sure to use the Mindray-specified disposable products including evacuated blood collection tube, centrifugal tubes and capillary tubes etc.
- When stored in room temperature, the whole blood samples to be used for WBC differential need to be run within 12 hours after collection.
- If the samples are stored in a refrigerator (2°C - 8°C), they can be run within 24 hours after collection. You need to warm the refrigerated samples at room temperature for at least 30 minutes before running them.
- Be sure to mix any sample that has been prepared for a while before running it.
- Before performing diluent dispensing, make sure a centrifugal tube has been put into the aspirating position.
- Be sure to keep dust from the prepared diluent.
- After mixing the capillary sample with the diluent, be sure to wait 3 minutes before running the sample.
- Be sure to run the prediluted samples within 30 minutes after the mixing.
- Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

- Letters, numerics and all characters (including special characters) supported by the keyboard are allowed for sample ID entering.
- The allowed length of sample ID is [1,20], and the ID cannot be null.
- The ending character of sample ID must be a numeric, but sample ID consisted of "0" only is considered invalid.
- If the patient's date of birth is entered, his/her age will be calculated automatically, and the age field will gray out and cannot be edited.
- If the entered date of birth is later than the current system, then it is considered invalid.
- The sample probe should be well immersed and kept away from the tube bottom, when the probe is aspirating sample. Otherwise, the aspirated volume may be insufficient or imprecise.
- The probe tip should not contact the sample tube. Otherwise, the blood may spill.
- During the analysis process, if errors like clog or bubble occur, the analyzer will automatically display the results of related parameters as invalid, and alarm information will show on the error information area. See Chapter 11 Troubleshooting Your Analyzer for the way to remove errors.
- The result of the background check will not be flagged.
- When the PLT value is less than  $100 \times 10^9 / L$ , a reexamination is recommended.
- You must take the tube out from the adapter before replacing it.
- To ensure stable analyzer performance and accurate analysis results, be sure to perform the "Shutdown" procedure to shut down the analyzer after it has been running continuously for 24 hours.
- Be sure to shut down the analyzer strictly as instructed below.
- Refer to Section 5.5 Maintenance Setup for how to edit waiting time before entering standby mode.
- Under stand-by mode, if there are unfinished printing or communication tasks, the analyzer will go on processing them.
- Mindray recommends you backing up saved results regularly.
- Printing in "Table" mode is not supported by the recorder, if current printing device is the recorder, the "Table" button will be disabled.
- The valid range of serial number is displayed under the edit boxes, if the entered serial numbers exceed the range, the dialog box " 'From' or 'To' value exceeds input range." will display when you click "Select". Click "OK" to close the dialog box and re-enter valid serial numbers.
- If the serial number is not entered in one or both of the edit boxes, click "Select", the dialog box "Both "From" and "To" ranges must be entered!" will display. Click "OK" to close the dialog box and re-enter valid serial numbers.
- If the "From" number is greater than the "To" number, the dialog box "Invalid input!" will display. Click "OK" to close the dialog box and re-enter



valid serial numbers.

- When the system is performing printing or transmission, click "Delete", the dialog box "System is busy, please try again later!" will display.
- If no result is selected, the dialog box "Please select data."
- Do not unplug the USB while exporting data.
- If less than 3 or more than 500 sample results are selected, the dialog box "Please select 3-500 records" will display.
- If a parameter result of a selected sample is invalid, then the calculated result of the parameter will be invalid and displayed as "+++++".
- Only administrators are allowed to edit results, common users are not allowed to do so.
- If the result of one parameter is modified, then the result of other related parameter(s) will be changed accordingly and the high or low suspect flags will also be renewed.
- All parameter results are displayed on the graph review screen, but only the results of WBC, RBC, HGB, HCT, MCV, PLT and the differential parameters can be edited. When saving the edited results, system will judge if the sum of differential parameter results is 100%. If not, a prompt will be given.
- The sample results that have been checked cannot be edited. The parameter results that have been edited directly are flagged with an "E". The related results that change accordingly will be flagged with an "e".
- If the edited results exceed display range, the dialog box "Invalid editing!" will display when you save the results, and the result editing dialog box will stay open with the cursor in the first invalid edit box.
- You should only use the Mindray-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents.
- Refer to the instructions for use of the control for information on the lot number, expiration date, open vial stability days, expected results and limits.
- The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.
- The analyzer saves the expected result and limit of a parameter only when they are both valid.
- If there are analysis results corresponding to the current file No. and lot No., the "Import File" button will be grayed out to disable the import function.
- The "Mean", "SD" and "CV%" of each parameter are only available when there are 3 or more within-control results in the X mean QC graph.
- The preset-value can only be calculated by selecting within-control results of at least 3 QC runs.
- Random samples are required for the X-B analysis. In case of known

samples of a particular type (oncology, neonatal and so forth) that will seriously interfere with the X-B results, deactivate the X-B analysis.

- Click the "Close" radio button on the screen to deactivate X-B QC. X-B QC is deactivated by default.
- Be sure to calibrate your analyzer before trying to establish the expected results by calculating the averages of random patient samples.
- The expected results vary with areas. It is recommended they are obtained by calculating the averages of at least 500 random patient samples.
- The recommended limit is 3% - 5%.
- The default validity ranges for the four parameters are:

$$1.0 \times 10^{12}/L \leq RBC \leq 8.0 \times 10^{12}/L$$

$$50fL \leq MCV \leq 150fL$$

$$20pg \leq MCH \leq 40pg$$

$$240g/L \leq MCHC \leq 440g/L$$

- All the entries should be numbers with only one decimal point.
- Once the validity range is changed, the previous results will not be used in the QC calculation as valid results, for example, if 20 valid samples are needed for the X-B QC calculation, when you change the validity range after 10 groups of valid sample results have been acquired, these 10 groups of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.
- The system calculates the reference range and displays the QC graph of all data only after 10 groups of QC data (20 QC runs) are obtained.
- Calibration procedures can only be performed by users of the administrator-level.
- You should only use the Mindray-specified calibrators and reagents. Store and use the calibrations and reagents as instructed by instructions for use of the calibrators and reagents.
- Calculation of reproducibility is included in the calibration procedure.
- All of the measured parameters must be calibrated before readings of this analyzer can be used as valid analysis results.
- See the instruction for use of the calibrators for the lot No., expiration date and the target.
- The entered expiration date should be either the expiration date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.
- If you start analysis without entering all calibrator information on an open vial model analyzer, a dialog box will display indicating "Invalid entry". Click "OK", the analyzer will automatically clean the sample probe, and then you may enter complete calibrator information and start running calibrators. If you start analysis without entering all calibrator information on a closed tube model analyzer, the sample compartment door will open automatically, and then you may enter complete calibrator information and start running calibrators.

- **Only Mindray-specified calibrators shall be used. Mindray will not be responsible for any erroneous result caused by using other calibrators.**
  - **Store and use the calibrators as instructed by instructions for use of the calibrators.**
  - **Use fused silica glass/plastic test tubes and 20 $\mu$ L borosilicate glass capillary tubes.**
  - **You should prepare 3 – 5 normal fresh blood samples for the calibration.**
  - **You should drain the tubing before moving the analyzer.**
  - **This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer. If the recommended solution fails to solve the problem, contact Mindray customer service department or your local distributor.**
-

## C.5 Biohazard

---



- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
  - All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.
-

## C.6 Abnormal Results

### C.6.1 Abnormal Sample Analysis Results

The analyzer flags abnormal sample analysis results automatically, including parameter flags and histogram flags.

#### Parameter flags

See the following section for details about parameter flags.

- If the parameter is followed by an "H" or "L", it means the analysis result has exceeded the upper or lower limit of the reference range (See *Section 5.2.4 Ref. range*).
- If you see "\*\*\*\*\*" as opposed to the result, it means the result is invalid; if you see "+++++" as opposed to the result, it means the result is out of the display range (See **Table 6-1 Display Range** for details.).
- If the WBC result of the sample is less than  $0.5 \times 10^9/L$ , this analyzer will not perform the differential analysis and all the related parameter values will be non-numeric (\*\*\*\*\*).

#### Histogram flags

The system will flag abnormal histograms. Both WBC histogram and PLT histogram are flagged for abnormal results.

- WBC histogram flags

Abnormal WBC histograms will be flagged by one of the markings: R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub> and R<sub>m</sub>. The indications of the markings are as follows:

R<sub>1</sub>: indicates abnormality on the left side of the lymphocyte hump and possible presence of platelet clumps, giant platelets, nucleated red cell, lyse resistant RBC, protein and lipid debris in sample, or electrical noise.

R<sub>2</sub>: indicates abnormality between the lymphocyte hump and the mid-sized cell area and possible presence of abnormal lymphocyte, plasma cell, atypical lymphocyte, original granulocytes in the sample and eosinophilia or basophilia.

R<sub>3</sub>: indicates abnormality between the mid-sized cell area and the granulocytes and possible presence of immature granulocytes, abnormal sub-population in the sample, or eosinophilia.

R<sub>4</sub>: indicates abnormality on the right side of the granulocytes hump and neutrophilia.

R<sub>m</sub>: indicates at least two R flags.

- PLT histogram flags

Abnormal PLT histograms will be flagged by one of the markings: P<sub>m</sub>, P<sub>S</sub> and P<sub>L</sub>. The indications of the markings are as follows:

P<sub>m</sub>: indicates blur demarcation between the platelet and red blood cell area and possible presence of large platelet, platelet coagulation, small red blood cell, cell debris or fibrin.

P<sub>S</sub>: indicates excessive small PLTs.

P<sub>L</sub>: indicates excessive large PLTs.

### C.6.2 Abnormal QC Results

If you see any points fallen outside the control range, do as follows until the problem is solved. If all the steps have failed, contact Mindray customer service department or your local distributor for assistance.

For the L-J analysis program:

1. Check the screen for error messages and refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
2. Check the X-B settings for inappropriate entries.
3. Do background check. In case of an abnormal background result, refer to **Chapter 11**

**Troubleshooting Your Analyzer** for solutions.

4. Re-run the control.
5. Run another vial of control.
6. Check if the analyzer needs to be calibrated.

For the X-B analysis program:

1. Check the screen for error messages and refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
2. Check the X-B settings for inappropriate entries.
3. Do background check. In case of an abnormal background result, refer to **Chapter 11 Troubleshooting Your Analyzer** for solutions.
4. Run a control.
5. Check if the analyzer needs to be calibrated.

## D Communication

### D.1 Introduction

The BC-3600 provides five communication protocols to match the data management software in the PC connected to the analyzer based on the supported sample ID length. If the software supports sample IDs of up to 8 or 10 digits, select the 8ID or 10ID communication protocol; if the software supports sample IDs of up to 15 digits, select the 15ID/15ID+2/HL7 communication protocol. The difference between the 8ID and 10ID communication protocols is that the 10ID can support sample IDs of no more than 10 digits, while the 8ID can only support IDs of no more than 8 digits. For other differences, see the description in the following sections. The difference between the 15ID and 15ID+2 communication protocols is that the 15ID+2 supports the transmission of P-LCR. The HL7 communication protocol adopts international standard, data are read by separators, therefore there is no limitation on data length. And the parameter field is expressed by code, which facilitates extension. You may choose the proper communication protocol base on your own needs.

---

**NOTE**

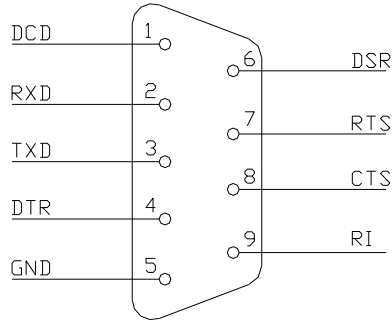
- While installing the analyzer, the authorized personnel will choose the appropriate communication protocol based on the data management software configured on site.
  - Contact Mindray customer service department or your local distributor to change the communication protocol for your analyzer.
  - When the communication symbol in the upper right corner of the screen appears animated, it indicates the communication is in process.
- 

The BC-3600 can transmit the sample data and QC data to an external computer (a host) through its RS-232 serial port or network port. The transmission can be conducted either automatically or through the command of the operator after the completion of the sample analysis. This section gives detailed discussion about the setup of transmission parameter, RS-232 serial port, the data transmission format and other relevant information, therefore, providing detailed information for the software engineers to program and for the user to conveniently perform transmission.

## D.2 Serial Port Communication Process

### D.2.1 Physical Connection

The BC-3600 can be connected with an external computer through a DB9 connector. The pins of the DB9 connector are shown in Figure D-1.



**Figure D-1 DB9 connector**

Pin description:

- DCD: Carrier Detect
- RXD: Receive Data
- TXD: Transmit Data
- DTR: Data Terminal Ready
- GND: Signal Ground
- DSR: Data Set Ready
- RTS: Request to Send
- CTS: Clear to Send
- RI: Ring Indicator

The BC-3600 communicates with a host through serial port 2, using Pin2, Pin 3 and Pin 5. The maximum transmission distance is 12 meters.

### D.2.2 8ID/10ID Serial Port Communication

Handshake control code

**Table D-1 8ID/10ID Control Codes**

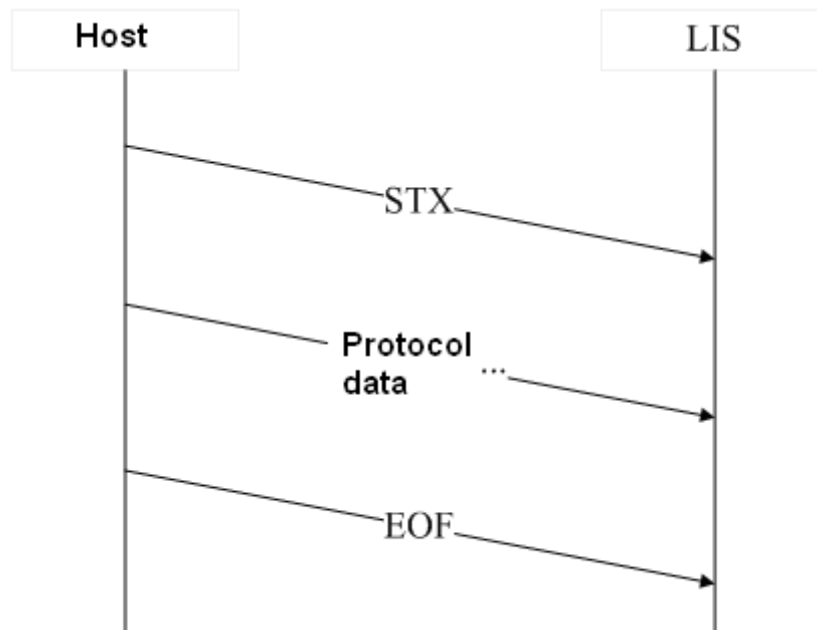
[ENQ]	0x05
[STX]	0x02
[EOT]	0x04
[EOF]	0x1A
[ETX]	0x03
[ACK]	0x06
[NACK]	0x15
"A"	0x41
"B"	0x42
"C"	0x43
"#"	0x30-0x39
"**"	0x2A

**Definition of data package**

Refer to Section *D.4* for details.



**Handshake off**



**Figure D-2 Data Transmission Process of 8ID/10ID (Handshake Off)**

**Handshake on**

When handshake is set to “on”, the data transmission process is as follows:

1. Building connection:

The BC-3600 sends ENQ (05 Hex), the external computer shall respond and send ACK (06 Hex) back; if ACK (06 Hex) is not returned in 4 seconds, the analyzer sends ENQ (05 Hex) again; and if no ACK data is returned in 4 seconds, the transmission will be terminated, and communication error will be reported.

2. Sending protocol data block, which ends with EOT.

3. Terminating connection: The BC-3600 sends ETX (03 Hex), then waits for the response of external computer, if no data is returned in 4 seconds, it sends ETX (03 Hex) again; then in 4 seconds, if there is still no data returned, the analyzer terminates the transmission and reports communication error.

If the external computer responds with ACK, then data block transmission succeeds. If NACK (15 Hex) is returned, the analyzer repeats step 2; if data other than ACK (06 Hex) and NACK (15 Hex) is returned, the analyzer sends ETX (03 Hex) again.

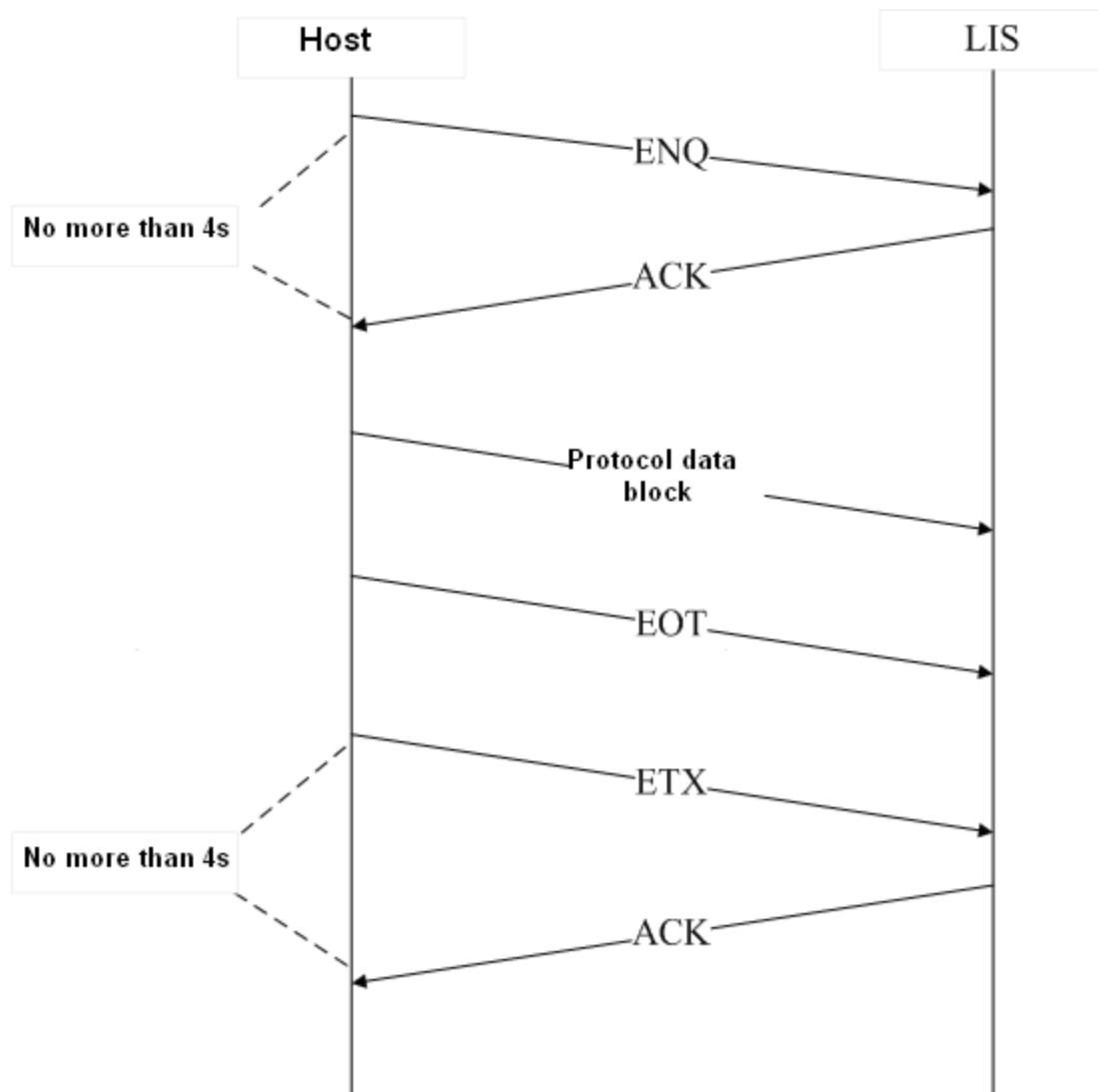


Figure D-3 Normal Transmission Process of 8ID/10ID

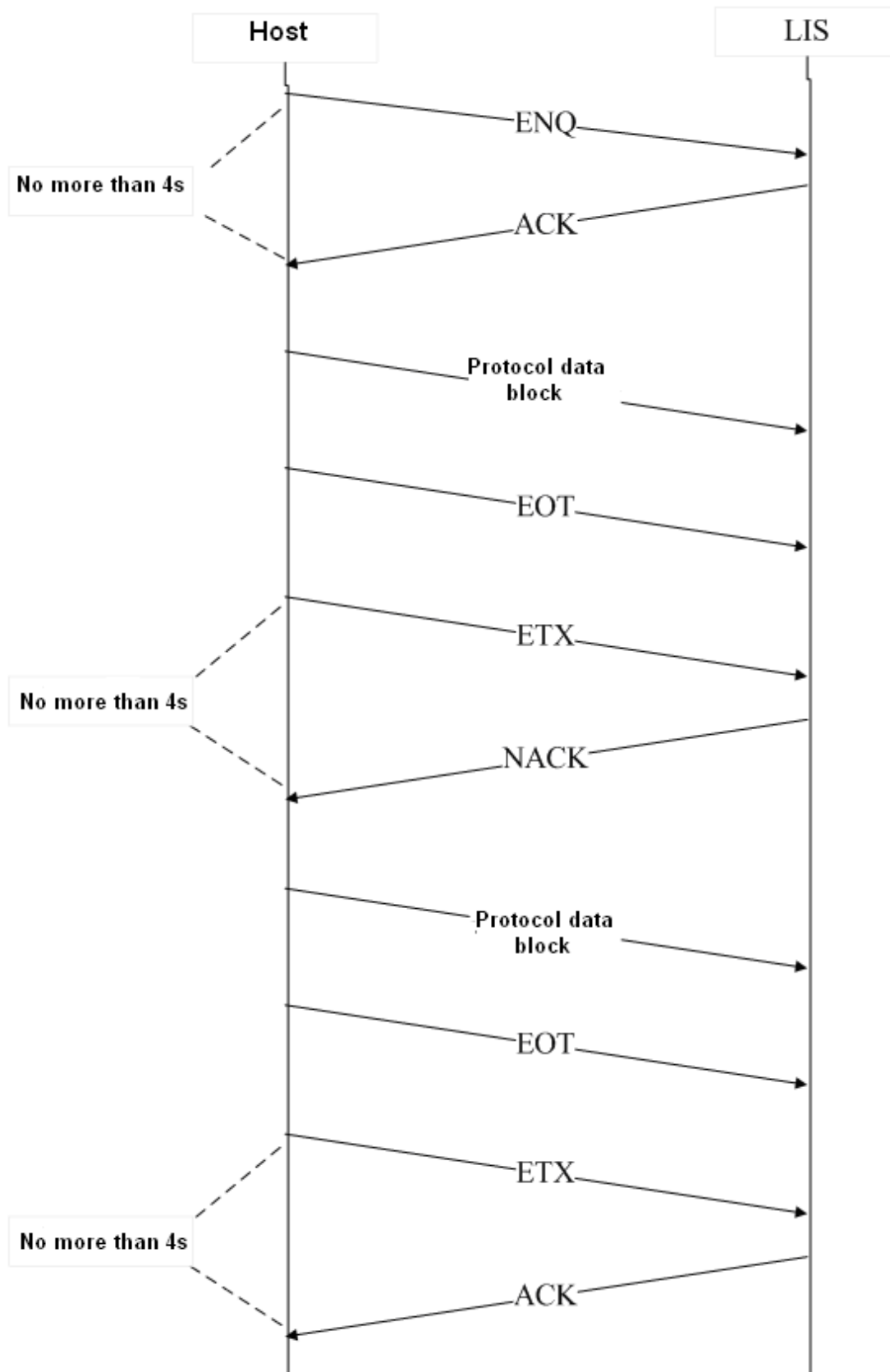


Figure D-4 8ID/10ID Handshake Message Resending Process

### D.2.3 15ID/15ID+2/HL7 Serial Port Communication

Handshake control code

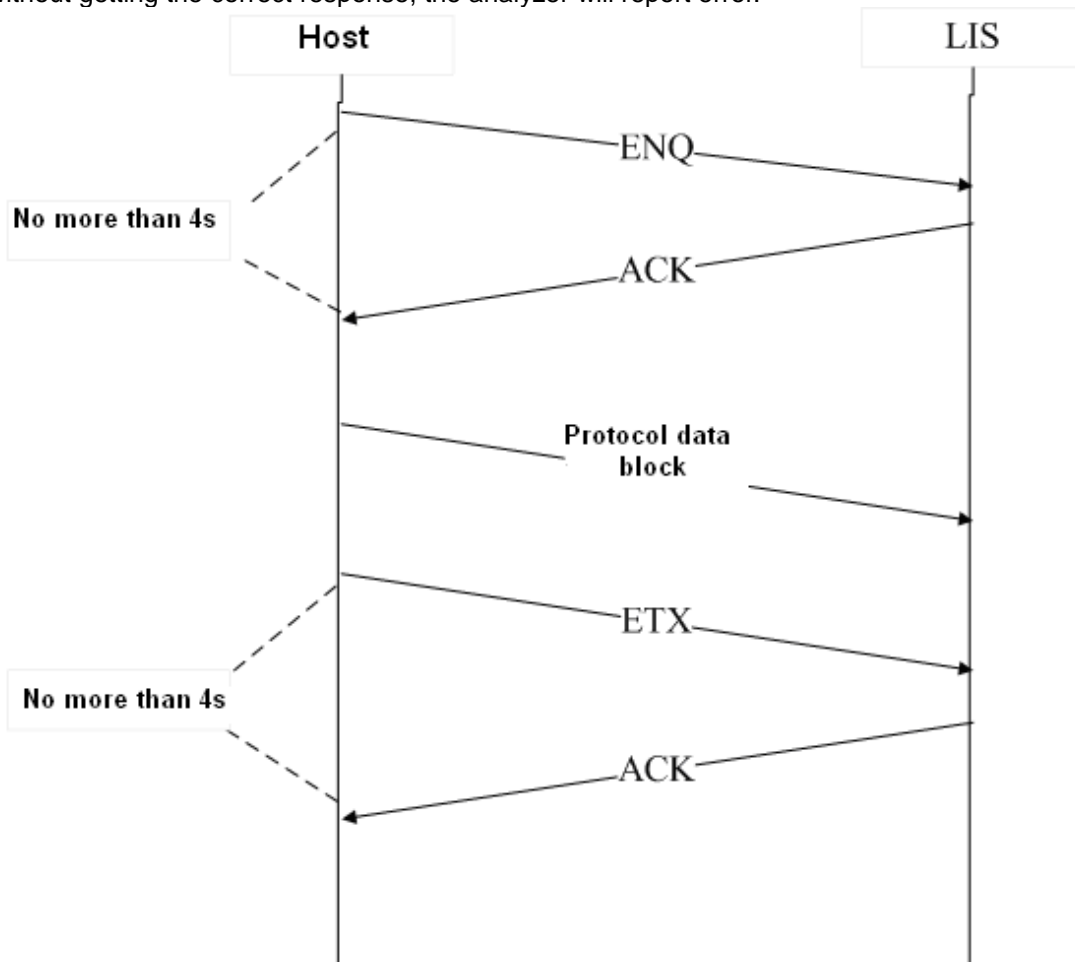
Handshake must be activated for 15ID/HL7 communication protocol.

Field	Code	Description
ENQ	0x10	Host communication command before data transmission
ACK	0x06	Terminal responded command before and after data transmission
ETX	0x0F	Host communication command after data transmission
NAK	0x15	Terminal response for message resent after data transmission

**Communication process**

**The process includes the following 3 steps:**

1. The analyzer sends ENQ to build connection, LIS sends ACK back in 4s, then the connection is built up successfully. If no response is received after 4s, the analyzer resends ENQ. If no response again, it will report error.
2. The analyzer sends protocol data block.
3. The analyzer sends EXT, LIS sends ACK back in 4s. If no ACK received in 4s, the analyzer resends EXT. If no ACK received again, it will report error. If NAK is sent back by the LIS in 4s after the analyzer sends EXT, the analyzer will repeat step 2, and if the message is sent twice without getting the correct response, the analyzer will report error.



**Figure D-5 Normal Transmission Process of 15ID/HL7**

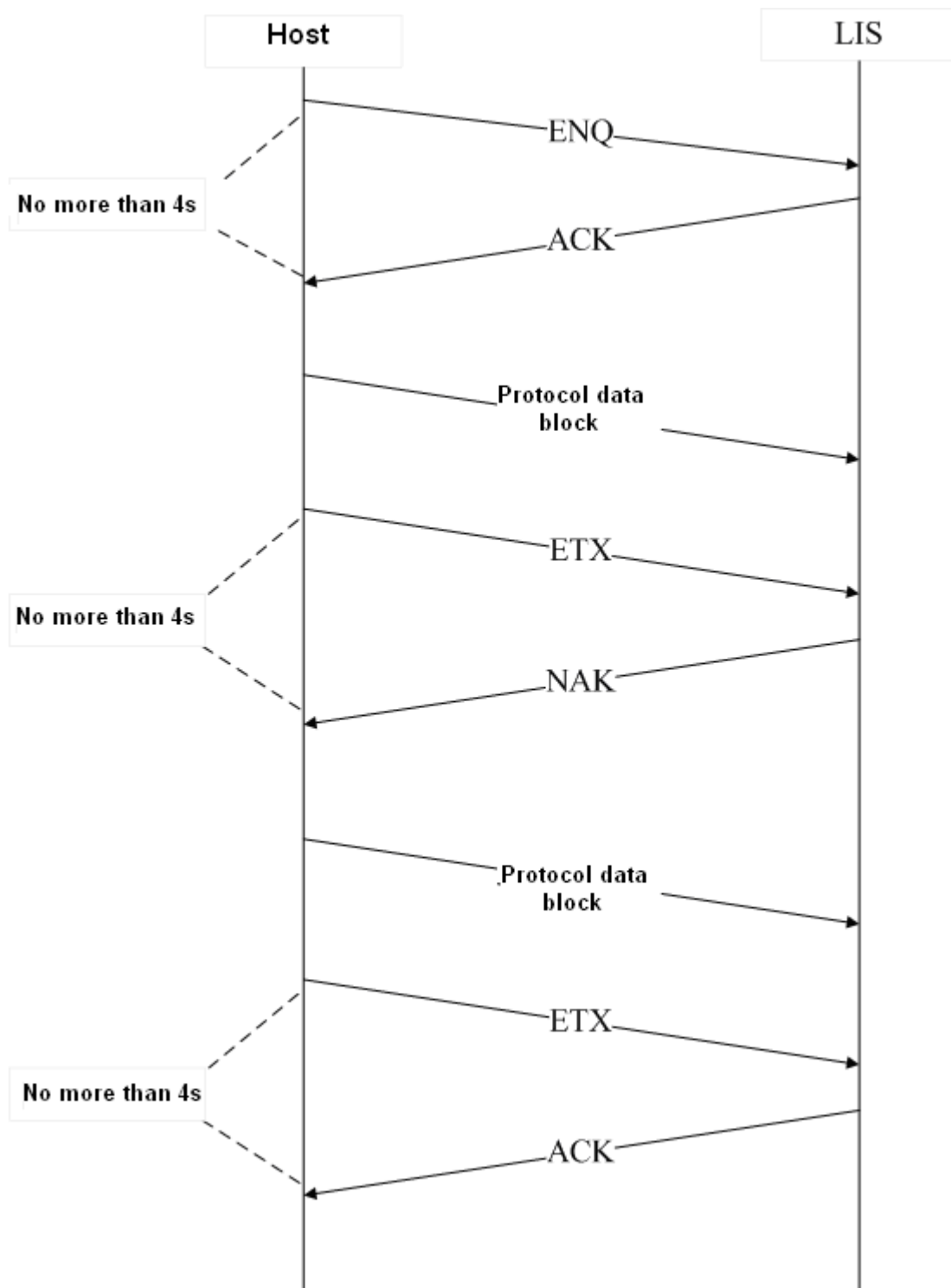


Figure D-6 Message Resending Process of 15ID/HL7

### **D.3 Network Port Connection**

The BC-3600 is configured with universal network port; it can be connected to PC or LAN with TCP communication protocol. After starting up, the analyzer monitors the message sent by LIS. After connection is built, the analyzer sends heartbeat control code 0x02 once in 3 seconds. Network port communication sends data directly without handshaking. For HL7 protocol, when the ACK synchronous transmission is activated, after the analyzer sends message, the LIS software shall response with ACK (Refer to *D.7* for details). Network communication does not support 8ID/10ID protocol.

## D.4 8ID Communication Protocol and 10ID Communication Protocol

### D.4.1 Transmission Data Format

### D.4.2 Description

#### Symbols

[ENQ]	0x05
[STX]	0x02
[EOT]	0x04
[EOF]	0x1A
[ETX]	0x03
[ACK]	0x06
[NACK]	0x15
"A"	0x41
"B"	0x42
"C"	0x43
"#"	0x30-0x39
"*"	0x2A

### D.4.3 Programming

If the Handshake is off, the BC-3600 will transmit the body of the text without acknowledging the presence of an external computer.

If the Handshake is on, the BC-3600 will communicate with the external computer in following procedures:

1. The BC-3600 sends an ENQ (05 Hex), then waits up to 4 seconds for the external computer to respond. If the external computer does not respond, then one more ENQ (05 Hex) is tried. If it fails again, the analyzer aborts the transmission and reports a transmission error.
2. The external computer must respond by sending an ACK (06 Hex). If any other response is received, another ENQ (05 Hex) will be sent by the analyzer (maximum two ENQ [05 Hex] will be sent).
3. The analyzer then sends:

Body of text  
 EOT (04 Hex)  
 ETX (03 Hex)

4. Disconnection.

The BC-3600 sends an ETX (03 Hex), then waits 4 seconds for the external computer to respond. If no response is received, one more ETX (03 Hex) is sent, the BC-3600 waits 4 seconds before giving up and gives alarm of communication error.

If the external compute responds ACK, the transmission is done successfully. If the external computer responds NACK (15 Hex), the analyzer repeat the transmission from step 3. If the received response from the computer is neither ACK (06 Hex) nor NACK (15 Hex), the analyzer sends ETX(03 Hex) again.

### D.4.4 Sample Data Format

If handshake is activated	[ENQ]
If handshake is deactivated	[STX]
Body of the text start	
Text Identifier	"A"
Version (for 10ID only)	##
ID length (for 10ID only)	###
The number of parameters (for 10ID only)	###
Number of the parameters having format descriptions (for 10ID only)	##
ID (8ID supports 8 digits/10ID supports 10 digits)	#####/#####
Sample Mode	#
Month	##
Day	##
Year	####
Hour	##
Minutes	##
WBC[10 <sup>9</sup> /L]	###.#
Lymph#[10 <sup>9</sup> /L]	###.#
Mid#[10 <sup>9</sup> /L]	###.#
Gran#[10 <sup>9</sup> /L]	###.#
Lymph%[%]	##.#
Mid%[%]	##.#
Gran%[%]	##.#
RBC[10 <sup>12</sup> /L]	##.#
HGB[g/L]	###
MCHC[g/L]	####
MCV[fL]	###.#
MCH [pg]	###.#
RDW-CV[%]	##.#
HCT[%]	##.#
PLT[10 <sup>9</sup> /L]	####
MPV[fL]	##.#
PDW	##.#
PCT[%]	.###
RDW-SD[fL]	###.#
Reserved	#####
Rm	#



R1	#
R2	#
R3	#
R4	#
Pm	#
Ps	#
PI	#
L1 Region	###
L2 Region	###
L3 Region	###
L4 Region	###
L5 Region	###
L6 Region	###
L7 Region	###
L8 Region	###
Reserved	#####
WBC Histo (256 channels)	###
RBC Histo (256 channels)	###
PLT Histo (256 channels)	###
Body of the text end	
If handshake is activated	[EOT]
If handshake is deactivated	[EOF]

For all the data formats, if the data are marked “\*”, then “\*” (2A Hex) will be transmitted to the host.

#### D.4.5 Standard L-J QC Data Format

If handshake is activated	[ENQ]
If handshake is deactivated	[STX]
Body of the text start	
Text Identifier	“B”
File No.	#
Lot No.	#####
Month	##
Day	##
Year	####
WBC[10 <sup>9</sup> /L]	###.#
RBC[10 <sup>12</sup> /L]	###
HGB[g/L]	###

PLT[10 <sup>9</sup> /L]	####
Lymph#[10 <sup>9</sup> /L]	###.#
Lymph%[%]	##.#
Gran#[10 <sup>9</sup> /L]	###.#
Gran%[%]	##.#
HCT[%]	##.#
MCV[fL]	###.#
MCH[pg]	###.#
MCHC[g/L]	####
WBC Limit[10 <sup>9</sup> /L]	###.#
RBC Limit[10 <sup>12</sup> /L]	###
HGB Limit[g/L]	###
PLT Limit[10 <sup>9</sup> /L]	####
Lymph# Limit[10 <sup>9</sup> /L]	###.#
Lymph% Limit[%]	##.#
Gran# Limit[10 <sup>9</sup> /L]	###.#
Gran% Limit[%]	##.#
HCT Limit[%]	##.#
MCV Limit[fL]	###.#
MCH Limit[pg]	###.#
MCHC Limit[g/L]	####
Body of the text end	
If handshake is activated	[EOT]
If handshake is deactivated	[EOF]
If handshake is activated	[ETX]

In the standard L-J QC data format, if any of the lot number, month, day or year fields in the L-J QC Edit screen is left blank, it will be transmitted as "\*" (2A Hex).

#### D.4.6 Run L-J QC Data Format

If handshake is activated	[ENQ]
If handshake is deactivated	[STX]
Body of the text start	
Text Identifier	'C'
Month	##
Day	##
Year	####
Hour	##
Minutes	##
WBC[10 <sup>9</sup> /L]	###.#

RBC[10 <sup>12</sup> /L]	#.##
HGB[g/L]	###
PLT[10 <sup>9</sup> /L]	####
Lymph#[10 <sup>9</sup> /L]	###.#
Lymph%[%]	##.#
Gran#[10 <sup>9</sup> /L]	###.#
Gran%[%]	##.#
HCT[%]	##.#
MCV[fL]	###.#
MCH[pg]	###.#
MCHC[g/L]	####
Body of the text end	
If handshake is activated	[EOT]
If handshake is deactivated	[EOF]
If handshake is activated	[ETX]

## D.5 15ID Communication Protocol and 15ID+2 Communication Protocol

### D.5.1 Protocol construction

Protocol data package is the smallest unit of the transmission. Every transmission shall meet the requirements of constructing a complete protocol data package, regardless the quantities of the data.

### D.5.2 Data pack construction

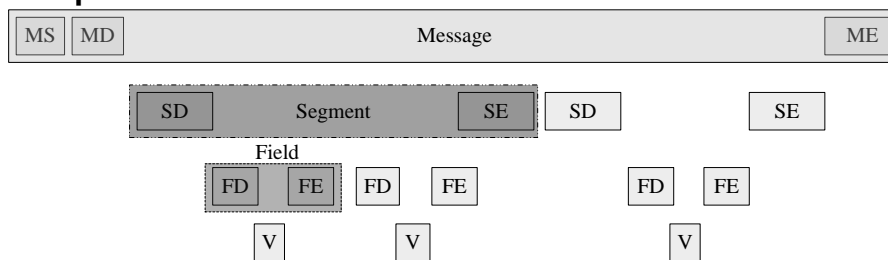


Figure D-2 Protocol data construction

A complete data package consists of data information of three levels:

- Message: a complete data package is called the message. There are three description fields:

MS: Message start field. MS is the first data unit of all messages.

MD: Message description field. It describes the Message type/meaning.

ME: Message end field. ME is the last data unit of all messages.

- Segment: Data segment. One piece of Message data consists of one or more Segment data. There are two description fields.

SD: Segment description field. It describes the Segment type/meaning.

SE: Segment end field. SE is the last data unit of all segments.

- Field: Property field. One Segment data consists of one or more field data. There are three description fields.

FD: Description field of Field. It describes the Field type/meaning.

V: Value of the Field. It is the final value of the field.

FE: End field of Field. FE is the last data unit of all fields.

### D.5.3 Symbols

■ Handshake symbol

During the communication, the two parties acknowledge the communication using these symbols.

Field name	Coding	Description
ENQ	0x10	Communication command from analyzer before data transmission
ACK	0x06	Response command from terminal before and after data transmission
ETX	0x0F	Communication command from analyzer after data transmission

■ Special symbols

The start and end signs of message and data segment.

Field name	Coding	Description
MS	0x05	Message start sign
ME	0x0a	Message end sign
SE	0x04	End sign field of metadata. Each metadata ends with SE
FE	0x08	End sign field of attribute data. Each attribute data ends with FE

■ Special delimiter

Delimiter sign between message body, data segment and attribute field.

Field name	Field name	Coding	Description
MD	SD	0x03	Delimiter between MD and SD
SD	FD	0x0C	Delimiter between SD and FD
FD	V	0x16	Delimiter between FD and V

■ Message description unit

Field name	Coding	Description
MD	CTR	Data package of normal analysis results
	QCR	Data package of QC running
	QCC	Data package of QC standard

### D.5.4 Sample data

Sample data consists of basic sample information, analysis results, histogram data and discriminators, and flags.

Data item	Description
SampleID	Sample ID

Appendices

---

Mode	Mode
TestTime	TestTime Format: YYYY-MM-DD HH: MM: SS
Name	Name
Gender	Gender
Age	Age (including age value and age type)
Group	Group
Dept	Department
ChartNo	Chart No.
BedNo	Bed No.
Clinician	Clinician
Tester	Tester
Validator	Validator
WBC	White Blood Cell count
Lymph#	Lymphocytes number
Mid#	Mid-sized cell
Gran#	Granulocyte
Lymph%	Lymphocytes percentage
Mid%	Mid-sized cell percentage
Gran%	Granulocyte percentage
HGB	Hemoglobin Concentration
RBC	Red Blood Cell count
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDWCV	Red Blood Cell Distribution Width Coefficient of Variation
RDWSD	Red Blood Cell Distribution Width Standard Deviation
PLT	Platelet count
MPV	Mean Platelet Volume
PDW	Platelet Distribution Width
PCT	Plateletcrit
P-LCR	Platelet-Large Cell Ratio (only for 15ID+2 communication protocol)
AlarmFlag	Histogram flag
SepLine	Discriminator information
WBCHisto	WBC Histogram
RBCHisto	RBC Histogram

FD field

Appendices

---

FD definition of analysis parameter	
FD	Description
Sample information	
SampleID	Sample ID
Mode	Analysis Mode (0:whole blood-all parameter; 1: predilute-all parameter; 2: whole blood- WBC/HGB; 3: predilute - WBC/HGB; 4: whole blood-RBC/PLT; 5: predilute - RBC/PLT)
TestTime	Test time, format: YYYY-MM-DD HH: MM: SS (if the digit is less than 10, add a 0 at the ten's place)
Name	Name
Gender	Gender (0: Empty; 1: Undefined; 2:Male; 3: Female)
Group	Group (0: General; 1: Man; 2:Woman; 3:Child; 4: neonate)
AgeVal	Age value
AgeType	Age type (0: Empty; 1: Year; 2:Month; 3:Day; 4: Hour)
Dept	Department
ChartNo	Chart No. (the empty string will be sent if No. is not entered yet/a o is entered)
BedNo	Bed No. (the empty string will be sent if No. is not entered yet/a o is entered)
Clinician	Clinician
Tester	Tester
Validator	Validator
Analysis parameter	
Val	Parameter value (transmitted as per the default unit)
Low	Lower limit of parameter
High	Upper limit of parameter
Unit	Parameter unit (default unit is whose index is 0, pure text)
Histogram alarm	
Rm	Indicates at least two R flags.
R1	Indicates abnormality on the left side of the lymphocyte hump.
R2	Indicates abnormality between the lymphocyte hump and the mid-sized cell area.
R3	Indicates abnormality between the mid-sized cell area and the granulocytes.
R4	Indicates abnormality on the right side of the neutrophilic granulocyte hump.
Pm	Indicates blur demarcation between the platelet and red blood cell area.
Ps	Indicates excessive small PLTs.
Pl	Indicates excessive large PLTs.
Histogram adjustment	
SepWBCLyLeft	WBC LymphLeft line
SepWBCLyMid	WBC LymphMid line
SepWBCGranMid	WBC MidGran line
SepWBCGranRight	WBC GranRight line
SepRBCLeft	RBC left discriminator

Appendices

SepRBCRight	RBC right discriminator
SepPLTLeft	PLT left discriminator
SepPLTRight	PLT right discriminator
Histogram	
DataLen	Binary Data flow length
MetaDataLen	Metadata length of binary data flow. For example, each metadata length in scattergram data flow is 4; in histogram data flow is 1. If the field is not included in binary data flow, the metadata length of binary data flow defaults to 1.
HistoData	Binary data flow of 256*1(Metadatalen=1) Byte

FD field

SD definition of analysis parameter

SD	FD						Description
Sample Info	FD1	FD2	FD3	FD4	FD5	FD6	Sample information
	Sample ID	Mode	TestTime	Name	Gender	Group	
	FD7	FD8	FD9	FD10	FD11	FD12	
	AgeVal	Age Type	Dept	ChartNo	BedNo	Clinician	
	FD13	FD14					
	Tester	Checker					
WBC	FD1 Val	FD2 Low	FD3 High	FD4 Unit			White blood cell count
Lymph#	The same with those of WBC						Lymphocytes number
Mid#	The same with those of WBC						Mid-sized cell
Gran#	The same with those of WBC						Granulocyte
Lymph%	The same with those of WBC						Lymphocytes percentage
Mid%	The same with those of WBC						Mid-sized cell percentage
Gran%	The same with those of WBC						Granulocyte percentage
HGB	The same with those of WBC						Hemoglobin Concentration
RBC	The same with those of WBC						Red Blood Cell count
HCT	The same with those of WBC						Hematocrit
MCV	The same with those of WBC						Mean Corpuscular Volume
MCH	The same with those of WBC						Mean Corpuscular Hemoglobin
MCHC	The same with those of WBC						Mean Corpuscular Hemoglobin Concentration
RDWCV	The same with those of WBC						Red Blood Cell Distribution Width Coefficient of Variation
RDWSD	The same with those of WBC						Red Blood Cell Distribution Width Standard Deviation

PLT	The same with those of WBC								Platelet count
MPV	The same with those of WBC								Mean Platelet Volume
PDW	The same with those of WBC								Platelet Distribution Width
PCT	The same with those of WBC								Plateletcrit
P-LCR	The same with those of WBC								Platelet-Large Cell Ratio (only for 15ID+2 communication protocol)
AlarmFlag	FD1	FD2	FD3	FD4	FD5	FD6	FD7	FD8	Histogram alarm
	Rm	R1	R2	R3	R4	Pm	Ps	P1	
SepLine	FD1		FD2		FD3		FD4		Discriminator information
	SepWBCLeft		SepWBCMid		SepWBCRight		SepWBCRight		
	FD5		FD6		FD7		FD8		
	SepRBCLeft		SepRBCRight		SepPLTLeft		SepPLTRight		
WBCHisto	FD1		FD2		FD3				WBC Histogram
	DataLen		MetaDataLen		WHistoData				
RBCHisto	FD1		FD2		FD3				RBC Histogram
	DataLen		MetaDataLen		RHistoData				
PLTHisto	FD1		FD2		FD3				PLT Histogram
	DataLen		MetaDataLen		PHistoData				

### D.5.5 Standard QC data

Standard QC data consists of basic QC information, QC expected results, and upper and lower limits.

Data item	Description
FileNo	QC File No
LotNo	QC Lot No
ExpDate	Expiration data, format: YYYY-MM-DD
WBC	Expected result of White Blood Cell count
RBC	Expected result of Red Blood Cell count
HGB	Expected result of Hemoglobin Concentration
PLT	Expected result of Platelet count
Lymph#	Expected result of Lymphocytes number
Lymph%	Expected result of Lymphocytes percentage
Gran#	Expected result of Granulocyte
Gran%	Expected result of Granulocyte percentage
HCT	Expected result of Hematocrit
MCV	Expected result of Mean Corpuscular Volume
MCH	Expected result of Mean Corpuscular Hemoglobin



Appendices

MCHC	Expected result of Mean Corpuscular Hemoglobin Concentration
WBC Limit	Upper and lower limits of White Blood Cell count
RBC Limit	Upper and lower limits of Red Blood Cell count
HGB Limit	Upper and lower limits of Hemoglobin Concentration
PLT Limit	Upper and lower limits of Platelet count
Lymph# Limit	Upper and lower limits of Lymphocyte number
Lymph% Limit	Upper and lower limits of Lymphocyte percentage
Gran# Limit	Upper and lower limits of Granulocyte
Gran% Limit	Upper and lower limits of Granulocyte percentage
HCT Limit	Upper and lower limits of Hematocrit
MCV Limit	Upper and lower limits of Mean Corpuscular Volume
MCH Limit	Upper and lower limits of Mean Corpuscular Hemoglobin
MCHC Limit	Upper and lower limits of Mean Corpuscular Hemoglobin Concentration

FD field

FD definition of standard QC parameter

FD	Description
QC information	
FileNo	File No
LotNo	Lot No
ExpDate	Expiration date, format: YYYY-MM-DD (if the digit is less than 10, add a 0 at the ten's place)
Sample information	
Mean	Expected result (transmitted as per default unit)
Range	Limit
Unit	Unit

SD field

SD definition of standard QC

SD	FD	Description
StQCInfo	FD1	Standard QC information
	FileNo	
WBC	FD2	White blood cell count
	LotNo	
RBC	FD3	Red Blood Cell count
	ExpDate	
	FD1	
	Mean	
	Range	
	Unit	
	The same with those of WBC	

HGB	The same with those of WBC	Hemoglobin Concentration
PLT	The same with those of WBC	Platelet count
Lymph#	The same with those of WBC	Lymphocytes number
Lymph%	The same with those of WBC	Lymphocytes percentage
Gran#	The same with those of WBC	Granulocyte
Gran%	The same with those of WBC	Granulocyte percentage
HCT	The same with those of WBC	Hematocrit
MCV	The same with those of WBC	Mean Corpuscular Volume
MCH	The same with those of WBC	Mean Corpuscular Hemoglobin
MCHC	The same with those of WBC	Mean Corpuscular Hemoglobin Concentration

### D.5.6 Running QC data

Data item	Description
FileNo	QC File No
LotNo	QC Lot No
TestTime	Format: YYYY-MM-DD HH: MM: SS
WBC	White Blood Cell count
RBC	Red Blood Cell count
HGB	Hemoglobin Concentration
PLT	Platelet count
Lymph#	Lymphocytes number
Lymph%	Lymphocytes percentage
Gran#	Granulocyte
Gran%	Granulocyte percentage
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration

FD field

FD definition of running QC parameter

FD	Description
QC information	
FileNo	File No
LotNo	Lot No

Appendices

---

TestTime	Test time, format: YYYY-MM-DD HH:MM: SS (if the digit is less than 10, add a 0 at the ten's place)
Sample information	
Val	Analysis result (transmitted as per default unit)
Unit	Unit

SD field

SD definition of running QC

SD	FD			Description
RunQCInfo	FD1	FD2	FD3	Running QC information
	FileNo	LotNo	TestTime	
WBC	FD1	FD2		White blood cell count
	Val	Unit		
RBC	The same with those of WBC			Red Blood Cell count
HGB	The same with those of WBC			Hemoglobin Concentration
PLT	The same with those of WBC			Platelet count
Lymph#	The same with those of WBC			Lymphocytes number
Lymph%	The same with those of WBC			Lymphocytes percentage
Gran#	The same with those of WBC			Granulocyte
Gran%	The same with those of WBC			Granulocyte percentage
HCT	The same with those of WBC			Hematocrit
MCV	The same with those of WBC			Mean Corpuscular Volume
MCH	The same with those of WBC			Mean Corpuscular Hemoglobin
MCHC	The same with those of WBC			Mean Corpuscular Hemoglobin Concentration

## **D.6 Transmission**

### **D.6.1 Defining Transmission Settings**

For the 8ID and 10ID communication protocols:

The data format is fixed for the transmission so that every byte to be transmitted has 7 data bits and 1 stop bit.

For the 15ID and 15ID+2 communication protocol:

The data format is fixed for the transmission so that every byte to be transmitted has 8 data bits and 1 stop bit.

Enter the **"Setup → Transmission"** screen and edit the communication settings as instructed by **Chapter 5.6**.

### **D.6.2 Transmission at Count Screen**

If the auto transmission function is on, once the analysis is done, the analyzer will automatically transmit the results to the external computer. If the auto transmission function is off, you may only transmit the results manually at the "Review" screen.

### **D.6.3 Transmission at Review Screen**

Select the results you want to transmit and transmit them to the external computer as instructed by **Chapter 7.2.1**.

### **D.6.4 Transmission at L-J QC Table Screen**

Transmit the results as instructed by **Chapter 8.2.3**.

## D.7 HL7 Communication Protocol

### D.7.1 Grammar

#### Bottom Protocol

HL7 messages use MLLP bottom protocol (refer to *HL7 Interface Standards Version 2.3.1* for related descriptions).

The messages are transmitted in the following format:

<SB> dddd <EB><CR>

where,

**<SB> = Start Block character (1 byte)**

ASCII <VT>, i.e., <0x0B>. Do not confuse with the SOH or STX character in ASCII.

**dddd = Data (variable number of bytes)**

dddd is the effective data of HL7 message and expressed in the form of UTF-8 string.

**<EB> = End Block character (1 byte)**

ASCII <FS>, i.e., <0x1C>. Do not confuse with the ETX or EOT character in ASCII.

**<CR> = Carriage Return (1 byte)**

ASCII carriage return character, i.e., <0x0D>.

#### Message constructing principles

Every HL7 message consists of several segments and ends up with the <CR> character.

Each segment consists of the segment name of three characters and field of changeable characters, and each field consists of the component and subcomponent. Each message begins with a MSH segment (including separators for the field, component and subcomponent).

For example:

MSH|^~\&| |||20361231235941||ORU^R01|2|P|2.3.1||||UNICODE

In this message:

The five characters following "MSH" define the separators to distinguish each field, component and subcomponent. Although they can be any non-text characters, HL7 standard recommends the characters in the table below:

Character	Meaning
	Field separator
^	Component separator
&	Subcomponent separator
~	Repetition separator
\	ESC

The first field of MSH includes every separator. Some field behind are empty because they are optional and not used by Mindray HL7 interface. Detailed field definition and selection will be stated in the following contents.

For message of any type, the segments behind MSH appear in the fixed order. The order will be described in the following contents and the grammar is used to organize the segments order.

The segment appeared in [] is optional.

The segment appeared in {} can be repeated once or more.

#### String transferring principles

For the field data of ST, TX, FT, and CF, etc., separators may be contained in the string data like remark, clinical diagnosis and customized gender etc. When coding, the separators in the

original strings shall be transferred into transferred character sequence; then, restore them when decoding. The transferring principles are shown in the table:

Transferred character	Original character
\F\	Field separator
\S\	Component separator
\T\	Subcomponent separator
\R\	Repetition separator
\E\	Transferred separator
\.br\	<CR>,i.e. segment end mark

Note: “\” in the transferred character sequence represents the transferred separator. Its value is defined in MSH segment.

### D.7.2 Message Types

In the HL7 communication, you may see the following types of messages.

#### ORU^R01 message

It is mostly used for the transmission of the test results and QC data.

ORU Observational Results (Unsolicited)	Description
MSH	Message Header, mandatory, including the communication information of message No., sending time, message separator and coding method, etc
{	
PID	Patient demographic information, including patient name, gender, MR Number, DOB, etc
[PV1]	Patient visit information, including patient type, department, bed No. and charge, etc
{	
	OBRsample information, including sample No., operator and run time, etc
{[OBX]}	test data, including test results and work mode, etc
}	
}	

#### ACK^R01 message

It is mostly used for acknowledging the receipt of ORU^R01 message.

ACK Acknowledgment	Description
MSH	Message Header
MSA	message acknowledgment, it describes whether message is received successfully.

### D.7.3 Segment Definitions

The definition of each segment will be listed in the following table. Each line in the table represents one segment. The columns in the table are:

1. No.: HL7 segments start with a 3-byte segment name, each separator is followed by the content of a segment. The No. is the order of the segment in all HL7 segments.

E.g.:

```

PID          | 1          | |7393670^^^MR||^Liu Jia||19950804000000|Female
  ↑          ↑          ↑
Segment name Segment1 Segment3
    
```

Note: MSH segment is slightly different, the separator after the segment name is considered as the first segment, representing the value of all separators in a message.

2. Segment name: the logical meaning of the segment.

3. Data type: the HL7 type of a segment, its structure will be described in **D.7.6 HL7 Data Type Definition**.

4. The recommended max length: the recommended max length is the standard HL7 recommended length. However in the actual transmission process, the data length may exceed the recommended length, so message segments shall be read base on separators.
5. Note: descriptions of the segment contents.
6. Samples: examples of segment contents.

**MSH**

The MSH (Message Header) segment contains basic information of HL7 message including separators' value, message type and coding method etc. It is the first field of every HL7 message.

Message example:

MSH|^~\&| |||20080617143943||ORU^R01|1|P|2.3.1|||||UNICODE

See Table D-2 for the definition of each field used in MSH segment.

**Table D-2 MSH field definitions**

No.	Field Name	Data type	Recommended max length	Note	Samples
1	Field Separator	ST	1	Includes the separator of the first field after the segment name; be used to determine the separator's value of the rest parts of the message.	
2	Encoding Characters	ST	4	Includes component separators, repetition separators, transferred separators and subcomponent separators; the value in the HL7 message of auto hematology analyzers is “^~\&”	^~\&
3	Sending application	EI	180	Application program of sending terminal.	
4	Sending Facility	EI	180	Device of sending terminal.	
7	Date/Time Of Message	TS	26	Created time of message (in the format of YYYY[MM[DD[HH[MM[SS]]]]]); adopts the system time.	20080617143943
9	Message Type	CM	7	Message type; in the format of “message type^event type”. e.g. ORU^R01	ORU^R01
10	Message Control ID	ST	20	Message control ID; be used to mark a message uniquely.	1
11	Processing ID	PT	3	Message processing ID values: “P”- sample and worklist searching information; “D”- QC setup information; “T” – QC results information; In Ack messages, it is consistent with the previously received message.	P
12	Version ID	VID	60	HL7 version information; the value is “2.3.1”.	2.3.1

18	Character Set	ID	10	Character set. The value is "UNICODE", indicating the message is expressed in the form of a UTF-8 string.	UNICODE
----	---------------	----	----	---	---------

**MSA**

The MSA (Message Acknowledgement) segment contains message confirming information. It is used in bi-directional LIS response messages.

Message example:

MSA|AA|1

See Table D-3 for definition of the fields used.

**Table D-3 MSA field definitions**

No.	Field Name	Data type	Recommended max length	Note	Samples
1	Acknowledgment Code	ID	2	Acknowledgement code: "AA"- receive, "AE" – error, "AR"- reject	AA
2	Message Control ID	ST	20	Message control ID; it's consistent with the MSH-10 of the received message.	1

**PID**

The PID(Patient Identification) segment contains the patient basic information.

Message example:

PID|1||CHARTNO^^^MR||^NAME||Male

See Table D-4 for definition of the fields used.

**Table D-4 PID field definitions**

No.	Field Name	Data type	Recommended max length	Note	Samples
1	Set ID - PID	SI	4	Sequence NO.; it is used to mark the different PID segments of a message.	1
3	Patient Identifier List	CX	20	To be used as the patient ID in the message of the sample test results, in the form of "Patient ID^^^MR". To be used as QC lot No. in the message of QC.	CHARTNO^^^MR
5	Patient Name	XPN	48	Patient name (dividing into two parts when sending: "FirstName" and "LastName"), e.g. "LastName^FirstName".	^NAME
7	Date/Time of Birth	TS	26	To be used as DOB in the message of sample results To be used as expiration date in the message of QC In the form of YYYY[MM[DD[HH[MM[SS]]]]]	
8	Sex	IS	1	Gender, string.	Male

**PV1**

The PV1 (Patient Visit) segment contains the patient visit information.



Message example:

PV1|1||DEPT^^BEDN11

See Table D-5 for definition of the fields used.

**Table D-5 PV1 field definitions**

No.	Field Name	Data type	Recommended max length	Note	Samples
1	Set ID - PV1	SI	4	Sequence NO.; it is used to mark the different PV1 segments of a message.	1
3	Assigned Patient Location	PL	80	Patient location information; in the form of "Department^ ^Bed No."	DEPT^^BEDN11

**OBR**

The OBR (Observation Request) segment contains the test report information.

Message example:

OBR|1||ABCDEF-0YT-4|00001^Automated Count^99MRC||20000706050000|20090626103851|||DELIVERY|||20000706070000|||||||HM|||||||Li

See Table D-6 for definition of the fields used.

**Table D-6 OBR field definitions**

No.	Field Name	Data type	Recommended max length	Note	Samples
1	Set ID - OBR	SI	10	Sequence NO.; it is used to indicate the different OBR segments of a message.	1
2	Placer Order Number	EI	22		
3	Filler Order Number +	EI	22	To be used as sample ID in the message of test results To be used as file No. in the QC message	ABCDEF-0YT-4
4	Universal Service ID	CE	200	Universal service ID, to identify different types of test results. See D.4.5 for detailed values.	00001^Automated Count^99MRC
6	Requested Date/time	TS	26	Requested Date/time To express the sampling date and time.	20000706050000
7	Observation Date/Time #	TS	26	Run Time	20090626103851
10	Collector Identifier *	XCN	60	Sample collector To indicate the deliverer	DELIVERY
13	Relevant Clinical Info.	ST	300	Relevant clinical information.	

Appendices

				It can be used as the clinical diagnostic information in the patient info.	
14	Specimen Received Date/Time *	TS	26	Sample received time To express the receive time.	20000706070000
15	Specimen Source *	CM	300	Sample source Its value in HL7 message on the auto hematology analyzers: "BLDV"- Venous blood "BLDC"- Capillary blood	
22	Results Rpt/Status Chng - Date/Time +	TS	26	Results report/Status Change - Date/Time To be used as validating time.	
24	Diagnostic Serv Sect ID	ID	10	Diagnostic ID, the value is "HM", means Hematology.	HM
28	Result Copies To	XCN	60	Result copies to To indicate the validator.	
32	Principal Result Interpreter +	CM	200	Principal result interpreter To be used as tester in the sample message To be used as "set by" in the QC message To be used as "Operator" in the QC run message	Li

**OBX**

The OBX(Observation/Result) segment contains the parameter information of each test result.  
Message example:

OBX|7|NM|6690-2^WBC^LN||9.55|10\*9/L|4.00-10.00|||F

See Table D-7 for definition of the fields used.

**Table D-7 OBX field definitions**

No.	Field Name	Data type	Recommended max length	Note	Samples
1	Set ID - OBX	SI	10	Sequence NO.; it is used to mark the different OBX segments of a message.	7
2	Value Type	ID	3	Data type of test results; the values can be "ST", "NM", "ED" and "IS", etc.	NM

Appendices

3	Observation Identifier	CE	590	Test item mark Form: "ID^Name^EncodeSys". The "ID" is the test item mark; "Name" the description information of the test item; "EncodeSys" is the coding system of the test item. For the values of the code of each test item, please see D.4.5. Note: "ID" and "EncodeSys" are used to identify a unique parameter, but "Name" is used for description only.	6690-2^WBC^LN
5	Observation Value	*	65535	Test results data. It can be numbers, strings, enumeration values and binary data, etc. (for the binary data, they are transferred using the Base64 coding method. See subsequent sections for details).	9.55
6	Units	CE	90	Units of test items. ISO standard units are used. The units used for communication are listed in D.4.5.	10*9/L
7	References Range	ST	90	Reference range; in the form of "lower limit-upper limit", "< upper limit" or "> lower limit".	4.00-10.00
8	Abnormal Flags	ID	5	Result flags: "N"- Normal "A"- Abnormal "H"- higher than upper limit "L"- lower than lower limit Note: The flag for normal or abnormal and that for high or low result may be displayed in this field at the same time. In this case, the two flags should be connected with a "~", e.g.: "H~A"	
11	Observ Result Status	ID	1	Test result status. The value is "F" - (Final Result);it means the final result.	F

13	User Defined Access Checks	ST	20	Customized contents. It stands for reagent expiration and modification mark, etc. The form is "mark 1-mark 2". There are 3 kinds of marks in all: O – Expired reagent E – Active editing e – Passive editing	
----	----------------------------	----	----	---	--

#### D.7.4 Example of a sample message

```

MSH|^~\&||||20101206164344||ORU^R01|1|P|2.3.1||||UNICODE
PID|1||ChartNo^^^^MR||LastName^FirstName||20040506070809|Male
PV1|1|Neike|Hema^^BN1|||||||||ChargeType
OBR|1||TestSampleID1|00001^Automated
Count^99MRC||20000102030405|20010203040506||Sender||Cold|20020304050607|||||20030405
060708||HM||||Auditer||||Tester
OBX|1|IS|08001^Take Mode^99MRC||O||||F
OBX|2|IS|08002^Blood Mode^99MRC||W||||F
OBX|3|IS|08003^Test Mode^99MRC||CBC||||F
OBX|4|IS|01002^Ref Group^99MRC||Common||||F
OBX|5|NM|30525-0^Age^LN||Age|yr||||F
OBX|6|ST|01001^Remark^99MRC||Remark||||F
OBX|7|NM|6690-2^WBC^LN||***.**|10*9/L|***.*_***.*|N||F
OBX|8|NM|731-0^LYM#^LN||***.**|10*9/L|***.*_***.*|N||F
OBX|9|NM|736-9^LYM%^LN||***.*|%|***.*_***.*|N||F
OBX|10|NM|789-8^RBC^LN||**.*|10*12/L|**.*_**.*|N||F
OBX|11|NM|718-7^HGB^LN||***.*|g/L|***.*_***.*|N||F
OBX|12|NM|787-2^MCV^LN||***.*|%|***.*_***.*|N||F
OBX|13|NM|785-6^MCH^LN||***.*|pg|***.*_***.*|N||F
OBX|14|NM|786-4^MCHC^LN||***.*|g/L|***.*_***.*|N||F
OBX|15|NM|788-0^RDW-CV^LN||***.*|%|***.*_***.*|N||F
OBX|16|NM|21000-5^RDW-SD^LN||***.*|fL|***.*_***.*|N||F
OBX|17|NM|4544-3^HCT^LN||***.*|%|***.*_***.*|N||F
OBX|18|NM|777-3^PLT^LN||***.*|10*9/L|***.*_***.*|N||F
OBX|19|NM|32623-1^MPV^LN||**.*|fL|**.*_**.*|N||F
OBX|20|NM|32207-3^PDW^LN||**.*|***.*_***.*|N||F
OBX|21|NM|10002^PCT^99MRC||*.*%|*.*_*.*|N||F
OBX|22|NM|10027^MID#^99MRC||***.**|10*9/L|***.*_***.*|N||F
OBX|23|NM|10029^MID%^99MRC||***.*|%|***.*_***.*|N||F
OBX|24|NM|10028^GRAN#^99MRC||***.**|10*9/L|***.*_***.*|N||F
OBX|25|NM|10030^GRAN%^99MRC||***.*|%|***.*_***.*|N||F
OBX|26|NM|10014^PLCR^99MRC||***.*|%|***.*_***.*|N||F
OBX|27|IS|12045^Multiple alerts^99MRC||T||||F
OBX|28|IS|12046^Lym left region alert^99MRC||T||||F

```

```

OBX|29|IS||T||||F
OBX|30|IS|12048^Mid gran region alert^99MRC||T||||F
OBX|31|IS|12049^Gran right region alert^99MRC||T||||F
OBX|32|IS|12050^Plt rbc boundary blur^99MRC||T||||F
OBX|33|IS|12051^Micro plt over aboundce^99MRC||T||||F
OBX|34|IS|12052^Macro plt over aboundce^99MRC||T||||F
OBX|35|NM|15004^WBC Histogram. Meta Length^99MRC||1||||F
OBX|36|NM|15010^WBC Lym left line.^99MRC||1||||F
OBX|37|NM|15011^WBC Lym Mid line.^99MRC||2||||F
OBX|38|NM|15012^WBC Mid Gran line.^99MRC||3||||F
OBX|39|NM|15013^WBC Gran right line^99MRC||4||||F
OBX|40|ED|15000^WBC Histogram.
Binary^99MRC||^Application^Octer-stream^Base64^AAAAAAAAAAAAAAAAAAAAAAAAA==|||
||F
OBX|41|NM|15051^RBC Histogram. Left Line^99MRC||5||||F
OBX|42|NM|15052^RBC Histogram. Right Line^99MRC||6||||F
OBX|43|NM|15053^RBC Histogram. Binary Meta Length^99MRC||2||||F
OBX|44|ED|15050^RBC Histogram.
Binary^99MRC||^Application^Octer-stream^Base64^AAAAAAAAAAAAAAAAAAAAAAAAA==|||
||F
OBX|45|NM|15111^PLT Histogram. Left Line^99MRC||7||||F
OBX|46|NM|15112^PLT Histogram. Right Line^99MRC||8||||F
OBX|47|NM|15113^PLT Histogram. Binary Meta Length^99MRC||4||||F
OBX|48|ED|15100^PLT Histogram.
Binary^99MRC||^Application^Octer-stream^Base64^AAAAAAAAAAAAAAAAAAAAAAAAA==|||
||F

```

**Sample response message**

Upon receiving a sample result, a sample response message shall be returned. The sample response message contains two segments: MSH and MSA. Correct response message shall meet the following two requirements: the content of MSH-9 segment shall be ACK^R01, which means the type of the message is sample response message. The value of MSA-2 segment shall be the same with the MSH-10 segment with result received, so that it can represent which analysis result that response message corresponds to. In the following sample the value of MSA-2 segment is 2.

```

MSH|^~\&|LIS|||20361231235956||ACK^R01|1|P|2.3.1|||||UNICODE
MSA|AA|2

```

**Sample of QC message**

The content and form of QC message are different from those of sample result message: the MSH-11 value of QC message is Q, which means the message type is QC data.

Sample of QC response message

The only difference between QC response message and sample result response message is the value of MSH-11 segment in QC response message is Q.

**D.7.5 Definitions of HL7 Coding and Constants**

**OBR-4 Message Type Coding**

OBR-4 fields are used to identify the type of the result. See Table D-8 for its values.

**Table D-8 ORC field definitions**

Data	Coding (ID)	Name	EncodeSys
Analysis result	00001	Automated Count	99MRC
LJ QC result	00003	LJ QCR	99MRC

**OBX-3 Parameter Type Coding**

Each OBX segment contains one test parameter or information of other data and consists of the following fields: OBX-2, it indicates the HL7 type of the data contained; OBX-3, it is the mark of the data in the form of "ID^Name^EncodeSys"; OBX-5, it contains the value of the data; OBX-6, it contains the unit for the parameter, expressing in the ISO standard.

Data	HL7 Type (OBX-2)	Coding (ID)	Name	EncodeSys	OBX-3 field example
<b>Other data</b>					
Take Mode	IS	08001	Take Mode	99MRC	08001^Take Mode^99MRC
Blood Mode	IS	08002	Blood Mode	99MRC	08002^Blood Mode^99MRC
Test mode	IS	08003	Test Mode	99MRC	08003^Test Mode^99MRC
Age	NM	30525-0	Age	LN	30525-0^Age^LN
Remark	ST	01001	Remark	99MRC	01001^Remark^99MRC
Ref Group	IS	01002	Ref Group	99MRC	01002^Ref Group^99MRC
QC Level	IS	05001	Qc Level	99MRC	05001^Qc Level^99MRC
Recheck flag	IS	01006	Recheck flag	99MRC	01006^Recheck flag^99MRC
<b>Analysis results data</b>					
WBC	NM	6690-2	WBC	LN	6690-2^WBC^LN
BAS	NM	704-7	BAS#	LN	704-7^BAS#^LN
BAS_PER	NM	706-2	BAS%	LN	706-2^BAS%^LN
NEU	NM	751-8	NEU#	LN	751-8^NEU#^LN
NEU_PER	NM	770-8	NEU%	LN	770-8^NEU%^LN
EOS	NM	711-2	EOS#	LN	711-2^EOS#^LN
EOS_PER	NM	713-8	EOS%	LN	713-8^EOS%^LN
LYM	NM	731-0	LYM#	LN	731-0^LYM#^LN
LYM_PER	NM	736-9	LYM%	LN	736-9^LYM%^LN
MON	NM	742-7	MON#	LN	742-7^MON#^LN
MON_PER	NM	5905-5	MON%	LN	5905-5^MON%^LN
ALY	NM	26477-0	*ALY#	LN	26477-0^*ALY#^LN
ALY_PER	NM	13046-8	*ALY%	LN	13046-8^*ALY%^LN
LIC	NM	10000	*LIC#	99MRC	10000^*LIC#^99MRC
LIC_PER	NM	10001	*LIC%	99MRC	10001^*LIC%^99MRC
RBC	NM	789-8	RBC	LN	789-8^RBC^LN
HGB	NM	718-7	HGB	LN	718-7^HGB^LN
MCV	NM	787-2	MCV	LN	787-2^MCV^LN
MCH	NM	785-6	MCH	LN	785-6^MCH^LN

Appendices

MCHC	NM	786-4	MCHC	LN	786-4^MCHC^LN
RDW_CV	NM	788-0	RDW-CV	LN	788-0^RDW-CV^LN
RDW_SD	NM	21000-5	RDW-SD	LN	21000-5^RDW-SD^LN
HCT	NM	4544-3	HCT	LN	4544-3^HCT^LN
PLT	NM	777-3	PLT	LN	777-3^PLT^LN
MPV	NM	32623-1	MPV	LN	32623-1^MPV^LN
PDW	NM	32207-3	PDW	LN	32207-3^PDW^LN
PCT	NM	10002	PCT	99MRC	10002^PCT^99MRC
GRAN-X	NM	10003	GRAN-X	99MRC	10003^GRAN-X^99MRC
GRAN-Y	NM	10004	GRAN-Y	99MRC	10004^GRAN-Y^99MRC
GRAN-Y(W)	NM	10005	GRAN-Y(W)	99MRC	10005^GRAN-Y(W)^99MRC
WBCMCV	NM	10006	WBC-MCV	99MRC	10006^WBC-MCV^99MRC
GainLasDiff	NM	10007	GainLasDiff	99MRC	10007^GainLasDiff^99MRC
GainMasDiff	NM	10008	GainMasDiff	99MRC	10008^GainMasDiff^99MRC
GainLasBaso	NM	10009	GainLasBaso	99MRC	10009^GainLasBaso^99MRC
GainMasBaso	NM	10010	GainMasBaso	99MRC	10010^GainMasBaso^99MRC
WBCBAX	NM	10011	WBCBAX	99MRC	10011^WBCBAX^99MRC
WBCBAY	NM	10012	WBCBAY	99MRC	10012^WBCBAY^99MRC
PLCC	NM	10013	PLCC	99MRC	10013^PLCC^99MRC
PLCR	NM	10014	PLCR	99MRC	10014^PLCR^99MRC
MID	NM	10027	MID#	99MRC	10027^MID#^99MRC
GRAN	NM	10028	GRAN#	99MRC	10028^GRAN#^99MRC
MID_PER	NM	10029	MID%	99MRC	10029^MID%^99MRC
GRAN_PER	NM	10030	GRAN%	99MRC	10030^GRAN%^99MRC
<b>Analysis results medium data (WBC, RBC, PLT histogram and scattergram data, etc.)</b>					
WBC Histogram Binary Data	ED	15000	WBC Histogram. Binary	99MRC	15000^WBC Histogram. Binary^99MRC
WBC Histogram Left Discriminator	NM	15001	WBC Histogram. Left Line	99MRC	15001^WBC Histogram. Left Line^99MRC
WBC Histogram Right	NM	15002	WBC Histogram. Right Line	99MRC	15002^WBC Histogram. Right Line^99MRC

Appendices

Discriminator					
WBC Histogram Middle Discriminator	NM	15003	WBC Histogram. Middle Line	99MRC	15003^WBC Histogram. Middle Line^99MRC
WBC Histogram Original Data Length	NM	15004	WBC Histogram. Meta Length	99MRC	15004^WBC Histogram. Meta Length^99MRC
WBC Histogram Left Discriminator Adjusted Mark	NM	15005	WBC Histogram. Left Line Adjusted	99MRC	15005^WBC Histogram. Left Line Adjusted^99MRC
WBC Histogram Right Discriminator Adjusted Mark	NM	15006	WBC Histogram. Right Line Adjusted	99MRC	15006^WBC Histogram. Right Line Adjusted^99MRC
WBC Histogram Middle Discriminator Adjusted Mark	NM	15007	WBC Histogram. Middle Line Adjusted	99MRC	15007^WBC Histogram. Middle Line Adjusted^99MRC
WBC Histogram Bitmap Data	ED	15008	WBC Histogram. BMP	99MRC	15008^WBC Histogram. BMP^99MRC
WBC Histogram. Total	NM	15009	WBC Histogram. Total	99MRC	15009^WBC Histogram. Total^99MRC
WBC Lym left Discriminator	NM	15010	WBC Lym left line.	99MRC	15010^WBC Lym left line. ^99MRC
WBC LYM MID Discriminator	NM	15011	WBC Lym Mid line.	99MRC	15011^WBC Lym Mid line. ^99MRC
WBC MID GRAN Discriminator	NM	15012	WBC Mid Gran line.	99MRC	15012^WBC Mid Gran line. ^99MRC
WBC GRAN right Discriminator	NM	15013	WBC Gran right line	99MRC	15013^WBC Gran right line^99MRC
RBC Histogram Binary Data	ED	15050	RBC Histogram. Binary	99MRC	15050^RBC Histogram. Binary^99MRC
RBC Histogram Left	NM	15051	RBC Histogram. Left Line	99MRC	15051^RBC Histogram. Left Line^99MRC



Appendices

Discriminator					
RBC Histogram Right Discriminator	NM	15052	RBC Histogram. Right Line	99MRC	15052^RBC Histogram. Right Line^99MRC
RBC Histogram Original Data Length	NM	15053	RBC Histogram. Binary Meta Length	99MRC	15053^RBC Histogram. Binary Meta Length^99MRC
RBC Histogram Left Discriminator Adjusted Mark	IS	15054	RBC Histogram. Left Line Adjusted	99MRC	15054^RBC Histogram. Left Line Adjusted^99MRC
RBC Histogram Right Discriminator Adjusted Mark	IS	15055	RBC Histogram. Right Line Adjusted	99MRC	15055^RBC Histogram. Right Line Adjusted^99MRC
RBC Histogram Bitmap Data	ED	15056	RBC Histogram. BMP	99MRC	15056^RBC Histogram. BMP^99MRC
PLT Histogram Binary Data	ED	15100	PLT Histogram. Binary	99MRC	15100^PLT Histogram. Binary^99MRC
PLT Histogram Left Discriminator	NM	15111	PLT Histogram. Left Line	99MRC	15111^PLT Histogram. Left Line^99MRC
PLT Histogram Right Discriminator	NM	15112	PLT Histogram. Right Line	99MRC	15112^PLT Histogram. Right Line^99MRC
PLT Histogram Original Data Length	NM	15113	PLT Histogram. Binary Meta Length	99MRC	15113^PLT Histogram. Binary Meta Length^99MRC
PLT Histogram Left Discriminator Adjusted Mark	IS	15114	PLT Histogram. Left Line Adjusted	99MRC	15114^PLT Histogram. Left Line Adjusted^99MRC
PLT Histogram Right Discriminator Adjusted Mark	IS	15115	PLT Histogram. Right Line Adjusted	99MRC	15115^PLT Histogram. Right Line Adjusted^99MRC
PLT Histogram Bitmap Data	ED	15116	PLT Histogram. BMP	99MRC	15116^PLT Histogram. BMP^99MRC
DIFF Scattergram Bitmap Data	ED	15200	WBC DIFF Scattergram. BMP	99MRC	15200^WBC DIFF Scattergram. BMP^99MRC
DIFF Scattergram Binary Data	ED	15201	WBC DIFF Scattergram. BIN	99MRC	15201^ WBC DIFF Scattergram. BIN^99MRC
DIFF Scattergram Type Data	ED	15202	WBC DIFF Scattergram. BIN type data	99MRC	15202^ WBC DIFF Scattergram. BIN type data^99MRC

Appendices

DIFF Scattergram Metadata Length	NM	15203	WBC Scattergram. Meta len	DIFF 99MRC	15203^ WBC Scattergram. Meta len^99MRC
DIFF Scattergram Metadata Count	NM	15204	WBC Scattergram. Meta count	DIFF 99MRC	15204^ WBC Scattergram. Meta count^99MRC
BASO Scattergram Bitmap Data	ED	15250	Baso Scattergram. BMP	99MRC	15250^ Baso Scattergram. BMP^99MRC
BASO Scattergram Binary Data	ED	15251	Baso Scattergram. BIN	99MRC	15251^ Baso Scattergram. BIN^99MRC
BASO Scattergram Type Data	ED	15252	Baso Scattergram. BIN type data	99MRC	15252^ Baso Scattergram. BIN type data^99MRC
BASO Scattergram Metadata Length	NM	15253	Baso Scattergram. Meta Len	99MRC	15253^ Baso Scattergram. Meta Len^99MRC
BASO Scattergram Metadata Count	NM	15254	Baso Scattergram. Meta count	99MRC	15254^ Baso Scattergram. Meta count^99MRC
<b>Abnormal alarm information</b>					
WBC Abn scattergram	IS	12000	WBC Abnormal scattergram	99MRC	12000^WBC Abnormal scattergram^99MRC
Abnormal WBC Histogram	IS	12001	WBC Abnormal histogram	99MRC	12001^WBC Abnormal histogram^99MRC
Leucocytosis	IS	12002	Leucocytosis	99MRC	12002^Leucocytosis^99MRC
Leucopenia	IS	12003	Leucopenia	99MRC	12003^Leucopenia^99MRC
Neutrophilia	IS	12004	Neutrophilia	99MRC	12004^Neutrophilia^99MRC
Neutropenia	IS	12005	Neutropenia	99MRC	12005^Neutropenia^99MRC
Lymphocytosis	IS	12006	Lymphocytosis	99MRC	12006^Lymphocytosis^99MRC
Lymphopenia	IS	12007	Lymphopenia	99MRC	12007^Lymphopenia^99MRC
Monocytosis	IS	12008	Monocytosis	99MRC	12008^Monocytosis^99MRC
Eosinophilia	IS	12009	Eosinophilia	99MRC	12009^Eosinophilia^99MRC
Basophilia	IS	12010	Basophilia	99MRC	12010^Basophilia^99MRC
WBC abnormal	IS	12011	WBC Abnormal	99MRC	12011^WBC Abnormal^99MRC
Left Shift?	IS	17790-7	WBC Left Shift?	LN	17790-7^WBC Left Shift?^LN
Immature Granulocyte?	IS	34165-1	Imm Granulocytes?	LN	34165-1^Imm Granulocytes?^LN
Abnormal/Atypical Lymphocyte?	IS	15192-8	Atypical Lymphs?	LN	15192-8^Atypical Lymphs?^LN

Appendices

RBC Lyse Resist?	IS	34525-6	rstRBC	LN	34525-6^rstRBC^LN
Erythrocytosis	IS	12012	Erythrocytosis	99MRC	12012^Erythrocytosis^99MRC
RBC abnormal distribution	IS	12013	RBC Abnormal distribution	99MRC	12013^RBC Abnormal distribution^99MRC
Anisocytosis	IS	15150-6	Anisocytosis	LN	15150-6^Anisocytosis^LN
Macrocytosis	IS	15198-5	Macrocytes	LN	15198-5^Macrocytes^LN
Microcytosis	IS	15199-3	Microcytes	LN	15199-3^Microcytes^LN
Dimorphologic	IS	10379-6	RBC Dual Pop	LN	10379-6^RBC Dual Pop^LN
Anemia	IS	12014	Anemia	99MRC	12014^Anemia^99MRC
Hypochromia	IS	15180-3	Hypochromia	LN	15180-3^Hypochromia^LN
HGB Abn/Interfere?	IS	12015	HGB Interfere	99MRC	12015^HGB Interfere^99MRC
PLT Abnormal Distribution	IS	12016	PLT Abnormal Distribution	99MRC	12016^PLT Abnormal Distribution^99MRC
Thrombocytosis	IS	12017	Thrombocytosis	99MRC	12017^Thrombocytosis^99MRC
Thrombopenia	IS	12018	Thrombopenia	99MRC	12018^Thrombopenia^99MRC
PLT Clump?	IS	7796-6	Platelet Clump?	LN	7796-6^Platelet Clump?^LN
Right Shift	IS	12020	Right Shift	99MRC	12020^Right Shift^99MRC
Sample Abnormal	IS	12021	Sample Abnormal	99MRC	12021^Sample Abnormal^99MRC
RBC Clump	IS	12022	RBC Clump	99MRC	12022^RBC Clump^99MRC
Platelets.small	IS	32208-1	Platelets.small	LN	32208-1^Platelets.small^LN
RBC HGB Abnormal	IS	12023	RBC HGB Abnormal	99MRC	12023^RBC HGB Abnormal^99MRC
Iron Deficiency	IS	12024	Iron Deficiency	99MRC	12024^Iron Deficiency^99MRC
RBC HGB doubt	IS	12025	RBC HGB doubt	99MRC	12025^RBC HGB doubt^99MRC
Multiple alerts, i.e. Rm	IS	12045	Multiple alerts	99MRC	12045^Multiple alerts^99MRC
Lym left region alert, i.e. R1	IS	12046	Lym left region alert	99MRC	12046^Lym left region alert^99MRC
Lym mid region alert, i.e. R2	IS	12047	Lym mid region alert	99MRC	12047^Lym mid region alert^99MRC
Mid gran region alert, i.e. R3	IS	12048	Mid gran region alert	99MRC	12048^Mid gran region alert^99MRC
Gran right region alert,	IS	12049	Gran right region alert	99MRC	12049^Gran right region alert^99MRC

i.e. R4					
Plt rbc boundary blur, i.e. Pm	IS	12050	Plt rbc boundary blur	99MRC	12050^Plt rbc boundary blur^99MRC
Micro plt over abundance, i.e.: Ps	IS	12051	Micro plt over abundance	99MRC	12051^Micro plt over abundance^99MRC
Macro plt over abundance, i.e. PI	IS	12052	Macro plt over abundance	99MRC	12052^Macro plt over abundance^99MRC

### Units of Analysis Parameters

The analysis parameters are expressed in standard units.

**Table D-9 Units of Analysis Parameters**

Parameters' units displayed on the screen of the BC-3600	Units of communication data (OBX-6)
10 <sup>12</sup> /L	10 <sup>12</sup> /L
10 <sup>9</sup> /L	10 <sup>9</sup> /L
10 <sup>6</sup> /uL	10 <sup>6</sup> /uL
10 <sup>4</sup> /uL	10 <sup>4</sup> /uL
10 <sup>3</sup> /uL	10 <sup>3</sup> /uL
10 <sup>2</sup> /uL	10 <sup>2</sup> /uL
mL/L	mL/L
/nL	/nL
/pL	/pL
g/L	g/L
g/dL	g/dL
L/L	L/L
mmol/L	mmol/L
%	%
fL	fL
um <sup>3</sup>	um <sup>3</sup>
pg	pg
fmol	fmol
amol	amol
Year (age unit)	yr
Month (age unit)	mo
Day (age unit)	d
Hour (age unit)	hr
Week (age unit)	wk

### Enumeration Values of Other HL7 Fields

Data item	Enumeration values
Take Mode	The values are the following enumerations: "O" – open vial "A" – autoloading

Blood Mode	The values are the following enumerations: "W" - whole blood "P" – prediluted "W_WBCHGB"- WBC/HGB whole blood "P_WBCHGB"- WBC/HGB predilute, for 3-differential analyzer only "W_RBCPLT"- RBC/PLT whole blood, for 3-differential analyzer only "P_RBCPLT"- RBC/PLT predilute, for 3-differential analyzer only
Test Mode	The values are the following enumerations: "CBC" "CBC+5DIFF"
Qc Level	The values are the following enumerations: "L" - low "M" - normal "H" - high
Adjusting marks of histogram discriminators and flags	OBX-2 data type is "IS"; the values are the following enumerations: "T" - true "F" - false

### D.7.6 HL7 Data Type Definition

- CE - Code Element

<identifier (ST)> ^ <text (ST)> ^ <name of coding system (ST)> ^ <alternate identifier (ST)> ^ <alternate text (ST)> ^ <name of alternate coding system (ST)>

- CM - Composite

The format is defined by the specific segment.

- CX - Extended composite ID with check digit

<ID (ST)> ^ <check digit (ST)> ^ <code identifying the check digit scheme employed (ID)> ^ <assigning authority (HD)> ^ <identifier type code (IS)> ^ <assigning facility (HD)>

- ED – Encapsulate Data

<source application (HD) > ^ <type of data (ID) > ^ <data sub type (ID) > ^ <encoding (ID) > ^ <data (ST) >

- EI - Entity Identifier

<entity identifier (ST)> ^ <namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

- FC – Financial Class

<financial class (IS) > ^ <effective date (TS) >

- HD - Hierarchic designator

<namespace ID (IS)> ^ <universal ID (ST)> ^ <universal ID type (ID)>

Used only as part of EI and other data types.

- FT - Formatted text

This data type is derived from the string data type by allowing the addition of embedded formatting instructions. These instructions are limited to those that are intrinsic and independent of the circumstances under which the field is being used.

- IS - Coded value for user-defined tables

The value of such a field follows the formatting rules for an ST field except that it is drawn from

a site-defined (or user-defined) table of legal values. There shall be an HL7 table number associated with IS data types.

■ ID - Coded values for HL7 tables

The value of such a field follows the formatting rules for an ST field except that it is drawn from a table of legal values. There shall be an HL7 table number associated with ID data types.

■ NM - Numeric

A number represented as a series of ASCII numeric characters consisting of an optional leading sign (+ or -), the digits and an optional decimal point.

■ PL - Person location

<point of care (IS)> ^ <room (IS)> ^ <bed (IS)> ^ <facility (HD)> ^ < location status (IS)> ^ <person location type (IS)> ^ <building (IS)> ^ <floor (IS)> ^ <location description (ST)>

■ PT - Processing type

<processing ID (ID)> ^ <processing mode (ID)>

■ SI - Sequence ID

A non-negative integer in the form of an NM field. The uses of this data type are defined in the chapters defining the segments and messages in which it appears.

■ ST – String

■ TS - Time stamp

YYYY[MM[DD[HHMM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] ^ <degree of precision>

■ XCN - Extended composite ID number and name

In Version 2.3, use instead of the CN data type. <ID number (ST)> ^ <family name (ST)> & <last\_name\_prefix (ST) ^ <given name (ST)> ^ <middle initial or name (ST)> ^ <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (ST)> ^ <source table (IS)> ^ <assigning authority (HD)> ^ <name type code (ID)> ^ <identifier check digit (ST)> ^ <code identifying the check digit scheme employed (ID)> ^ <identifier type code (IS)> ^ <assigning facility (HD)> ^ <name representation code (ID)>

■ XPN - Extended person name

In Version 2.3, replaces the PN data type. <family name (ST)> ^ <given name (ST)> & <last\_name\_prefix (ST)> ^ <middle initial or name (ST)> ^ <suffix (e.g., JR or III) (ST)> ^ <prefix (e.g., DR) (ST)> ^ <degree (e.g., MD) (IS)> ^ <name type code (ID) > ^ <name representation code (ID)>

■ VID - Version identifier

<version ID (ID)> ^ <internationalization code (CE)> ^ <international version ID (CE)>

### D.7.7 Binary Data Communication

The histogram data are transmitted as binary data. In the OBX segment, the value of the data type field is "ED"; the value of the data is in the form of "^Application^Octet-stream^Base64^.....histogram data....."; "Application" herein indicates that the data transmitted are application program data, "Octet-stream" is the byte stream type, and "Base64" indicates the coding method of the data.

The scattergram binary data are transmitted in a similar way.

Scattergram bitmap data communication: in the OBX segment, the value of the data type field is "ED"; the value of data is in the form of "^Image^BMP^Base64^.....scattergram bitmap

data.....". The "Image^BMP^Base64" indicates the bitmap data is of BMP type and coded based on Base64.

### D.7.8 Base64 Coding

(1) Select the 3 adjacent bytes (i.e. 24 bit) from the data stream to be coded; from left to right, divide them into 4 groups of 6-bit; then, ASCII string is obtained by mapping as per the Table D-10.

Initial data	15H	A3H	4BH	
Binary data	00010101	10100011	01001011	
6-bit group obtained after dividing	000101	011010	001101	001011
Corresponding coding value	5H	1AH	0DH	0BH
Corresponding character	F	a	N	L

**Table D-10 Base64 mapping**

Value/Code	Value/Code	Value/Code	Value/Code
0 A	17 R	34 l	51 z
1 B	18 S	35 j	52 0
2 C	19 T	36 k	53 1
3 D	20 U	37 i	54 2
4 E	21 V	38 m	55 3
5 F	22 W	39 n	56 4
6 G	23 X	40 o	57 5
7 H	24 Y	41 p	58 6
8 I	25 Z	42 q	59 7
9 J	26 a	43 r	60 8
10 K	27 b	44 s	61 9
11 L	28 c	45 t	62 +
12 M	29 d	46 u	63 /
13 N	30 e	47 v	
14 O	31 f	48 w	(pad) =
15 P	32 g	49 x	
16 Q	33 h	50 y	

(2) Repeat the coding of procedure (1) continuously till finish coding the data stream. When the data left is less than 3 bytes, 0 is used to complement to the right. If the whole 6-bit group obtained is composed of 0, then it is mapped to the "=" character. When one byte is left, then the obtained coding string consists of two "=" characters; when two bytes are left, then the obtained coding string consists of one "=" character. The two cases are demonstrated below:

① Initial data                    0AH

    00001010

Data obtained after complementing            00001010    00000000    00000000

6-bit groups obtained after dividing    000010    100000    000000    000000

Corresponding values                    02H            20H            00H            00H

Corresponding characters                C                    g                    =                    =

② Initial data                    0AH                    0BH

    00001010    00001011

Data obtained after complementing            00001010    00001011    00000000

6-bit groups obtained after dividing    000010    100000    101100    000000

Corresponding values                    02H            20H            2CH            00H

Corresponding characters                C                    g                    s                    =

