

BC-30 Vet

Auto Hematology Analyzer

Operator's Manual



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- **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.**
-

NOTE

- **This equipment must be operated by skilled/trained clinical professionals.**
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1 Using This Manual

1.1 Introduction

This chapter explains how to use your Operator's Manual of BC-30 Vet Auto Hematology Analyzer which is shipped with your instrument and contains reference information about the BC-30 Vet and procedures for operating, troubleshooting and maintaining the instrument. Read this manual carefully before operating your BC-30 Vet analyzer and operate your BC-30 Vet analyzer strictly as instructed in this manual.

NOTE

- **Use the analyzer strictly as instructed by this manual to avoid unexpected product damage or personal injury.**

1.2 Who Should Read This Manual

This manual is intended to be read by clinical laboratory professionals to:

- learn about the BC-30 Vet hardware and software;
- set up system parameters;
- perform daily operating task;
- perform system maintenance and troubleshooting

1.3 How to Find Information

This operator's manual comprises 11 chapters and 4 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-30 Vet analyzer	Chapter 2 Understanding Your Analyzer
learn about the hardware and software of the BC-30 Vet	Chapter 2 Understanding Your Analyzer
learn about how BC-30 Vet works	Chapter 3 Understanding the System Principles
learn about the installation requirements of the BC-30 Vet analyzer	Chapter 4 Installing Your Analyzer
learn about how to define/adjust system settings	Chapter 9 Customizing the Analyzer Software
learn about how to collect, prepare and analyze the samples	Chapter 5 Operating Your Analyzer
learn about how to use the BC-30 Vet analyzer perform your daily operating tasks	Chapter 5 Operating Your Analyzer
learn about how to review the saved analysis results	Chapter 6 Reviewing Sample Results
learn about how to use the quality control programs of the BC-30 Vet analyzer	Chapter 7 Using the QC Programs
learn about how to calibrate the BC-30 Vet analyzer	Chapter 8 Calibrating Your Analyzer
learn about how to maintain/service the BC-30 Vet	Chapter 10 Servicing Your Analyzer
learn about how to solve the problems of the BC-30 Vet analyzer	Chapter 11 Troubleshooting Your Analyzer
learn about the technical specifications of the BC-30 Vet	Chapter A Specifications
learn about the communication protocol of the BC-30 Vet	Chapter B Communication

1.4 Conventions Used in This Manual

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

Form	Meaning
[xx]	all capital letters enclosed in [] indicate a key name
"xx"	xx indicates text you can find on the screen of BC-30 Vet.
xx	xx indicates titles of the chapters that are referred to.

All illustrations in this manual are provided as examples only. They may not necessarily reflect your BC-30 Vet analyzer setup or data displayed.

1.5 Terms Used in Software Operation

Name	It means...
Click	to press the desired item xx lightly with your finger; or to left click xx with the mouse.
Enter	to click the desired edit box "xx" and use the external keyboard or the pop-up keyboard to enter the desired characters or digits.
Delete	to left click with the mouse, or directly tap the touch screen, or use the [←][→][Home][End] key on the external keyboard to move the cursor to the desired position, and then delete the character after the cursor by pressing [Del], or delete the character before the cursor by pressing [Backspace] ([←] on the upper right part of the soft keyboard).
SELECT from xx pull-down list (for pull-down list)	to click the down arrow button of the desired box "xx" to display the pull-down list, and drag scroll bar to browse and then click the desired item; or to press the keys ([↑][↓][Page Up][Page Down]) to browse the current list then press [Enter] to select the desired item.

1.6 Symbols

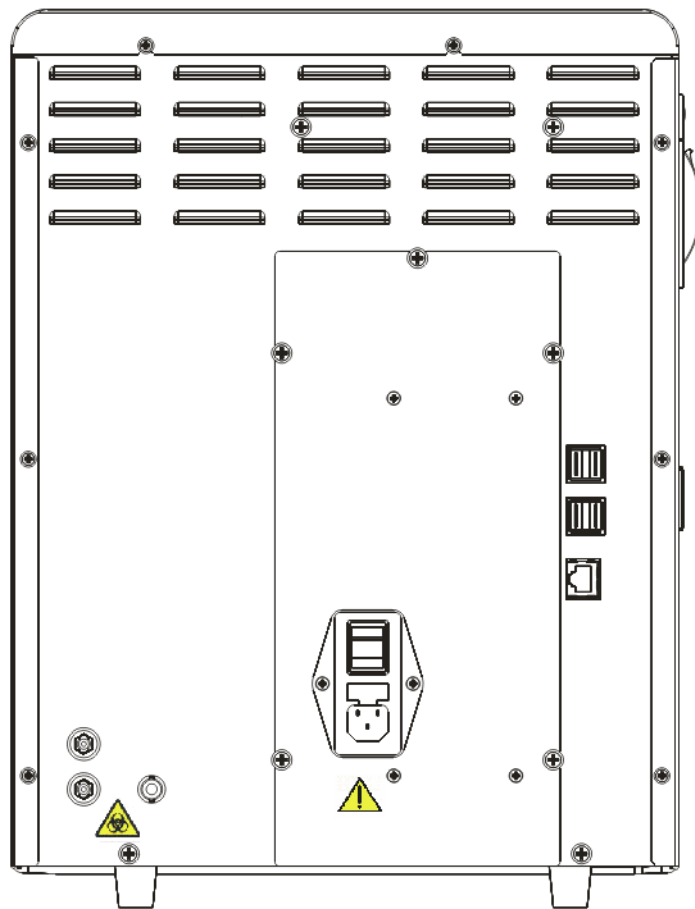
Symbols used in this manual:

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

You may find the following symbols on package or the body of the instrument:

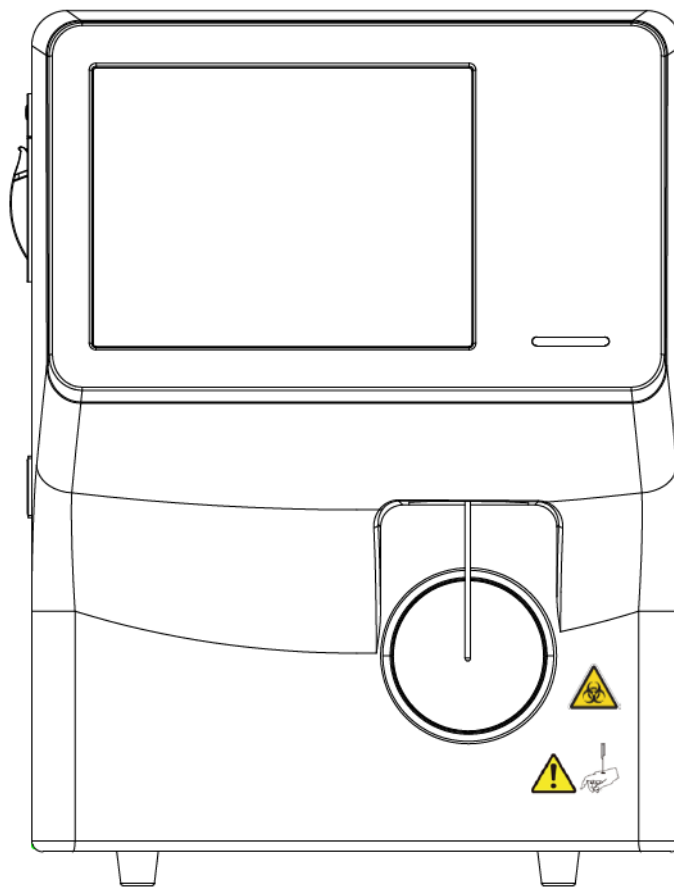
When you see...	It means...
	Caution Note: Consult the accompanying documents in all cases where this symbol is marked to find the nature of the potential HAZARDS and any actions have to be taken to avoid them
	Biological risks
	The sample probe is sharp and potentially biohazardous. Exercise caution when working around it!
	Off (Power)
	On (Power)
	USB PORT
	NETWORK PORT
	PROTECTIVE CONDUCTOR TERMINAL
	ALTERNATING CURRENT
	Serial number
	Humidity limitation
	Atmospheric pressure limitation
	Date of manufacture
	Manufacturer

When you see...	It means...
	Temperature limit
	EC Low Voltage Directive (2006/95/EC) EC Directive of Electromagnetic Compatibility (2004/108/EC)
	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.
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

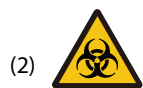


- (1) 
Biological risk.

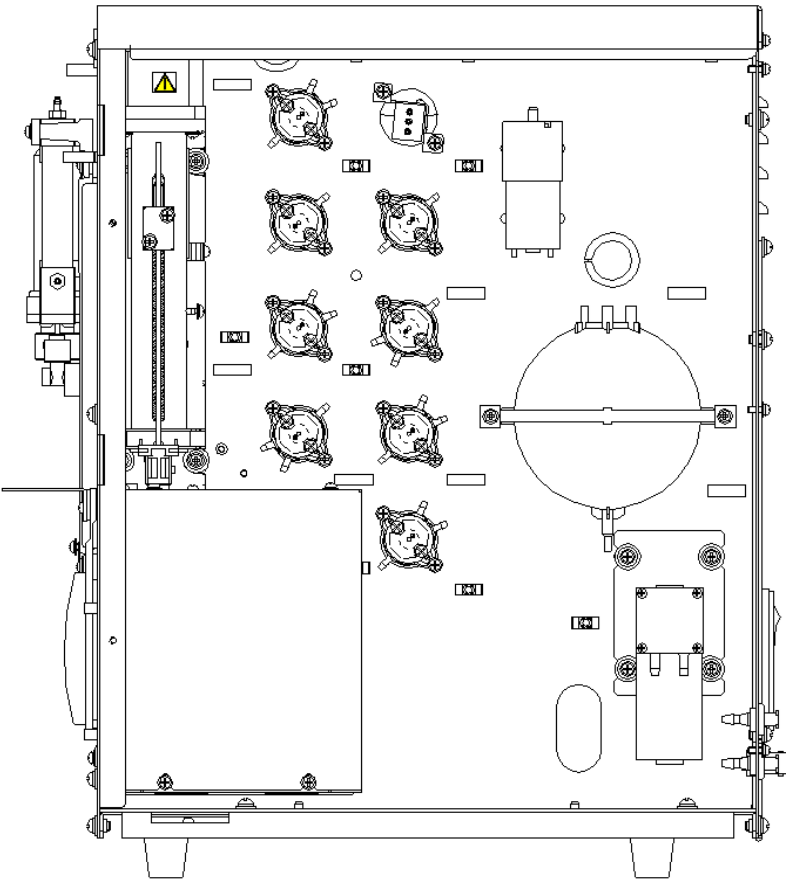
- (2) 
- Connect only to a properly earth grounded outlet.
 - To avoid electrical shock, disconnect power prior to maintenance.
 - To prevent fire, only use the fuse of specified type and rating.

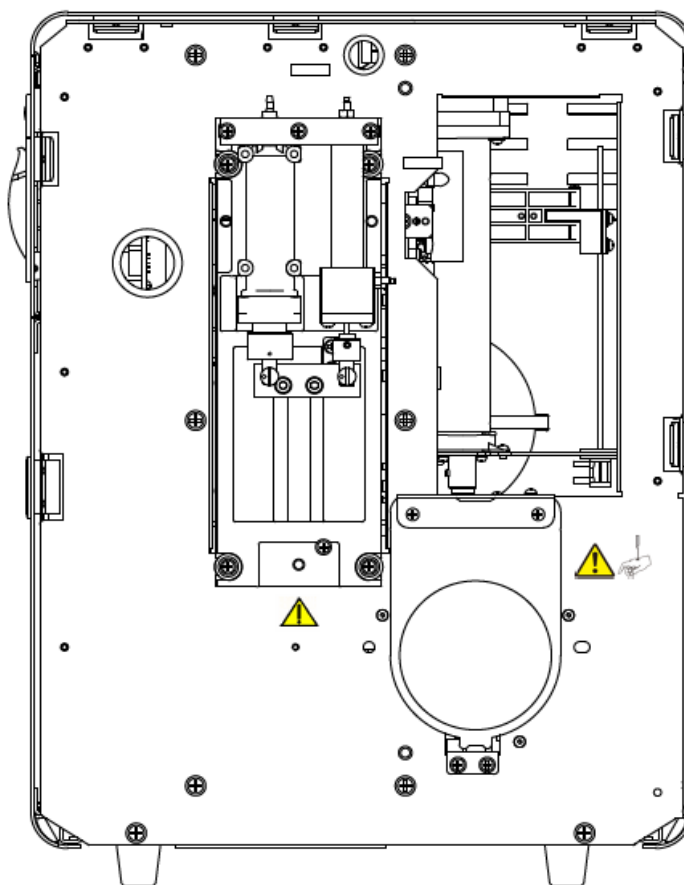


Warning: the sample probe is sharp and potentially biohazardous. Exercise caution when working around it!



Biological risk.





Warning: make sure that the protective cover is closed before operating the analyzer.



Warning

- To avoid injury, do not place your hands anywhere near the aspiration module when the analyzer is working.
- The sample probe is sharp and potentially biohazardous. Exercise caution when working around it!

2 Understanding Your Analyzer

2.1 Introduction

BC-30 Vet Auto Hematology Analyzer is used for analyzing animal blood samples, provides complete blood count, leukocyte differential and hemoglobin concentration measurement results.

2.2 Parameter

NOTE

- **The product identifies the normal patient, with all normal system-generated parameters for In Vitro Diagnostic Use. The product flags or identifies patient results that require additional studies.**

2.2.1 Parameters for Cat and Dog

The analyzer provides 4-part leukocyte differential count and reports 23 parameters for dog samples.

The analyzer provides 4-part leukocyte differential count and reports 21 parameters for cat samples.

Table 2-1 Report parameters of blood sample test (applied to cat and dog samples)

Group	Parameter name	Abbreviation
WBC group (9)	White Blood Cell count	WBC
	Neutrophils number	Neu#
	Lymphocytes number	Lym#
	Monocytes number	Mon#
	Eosinophils number	Eos#
	Neutrophils percentage	Neu%
	Lymphocytes percentage	Lym%
	Monocytes percentage	Mon%
	Eosinophils percentage	Eos%
RBC group (8)	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

PLT group (6)*	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*

* Note: P-LCR and P-LCC are available only in the dog samples.

2.2.2 Parameters for Other Animals

The analyzer provides 3-part leukocyte differential count and reports following 21 parameters for horse, rat, mouse, rabbit, monkey, pig, cow, sheep, llama, and camel samples.

The analyzer provides 3-part leukocyte differential count and reports following 15 parameters for goat samples.

Table 2-2 Report parameters of blood sample test (applied to horse, rat, mouse, rabbit, monkey, pig, cow, sheep, llama, camel, and goat samples)

Group	Parameter name	Abbreviation
WBC group (7)	White Blood Cell count	WBC
	Lymphocytes number	Lym#
	Monocytes number	Mon#
	Granulocyte number	Gran#
	Lymphocytes percentage	Lym%
	Monocytes percentage	Mon%
	Granulocyte percentage	Gran%
RBC group (8)	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
PLT group (6)*	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

* Note: The parameters in the PLT group are not available in the goat samples.

2.2.3 Histograms

Table 2-3 Histograms

Parameter name	Abbreviation
White Blood Cell Histogram	WBC Histogram
Eosinophils Histogram	EOS Histogram
Red Blood Cell Histogram	RBC Histogram
Platelet Histogram	PLT Histogram

Note: The EOS Histogram is only applied to the dog and cat samples.

2.3 Main Structure

The BC-30 Vet analyzer consists of the sample processing unit, data management unit, result output unit and accessories.

The accessories include reagent container cap assemblies, waste tube assembly, and power cords.

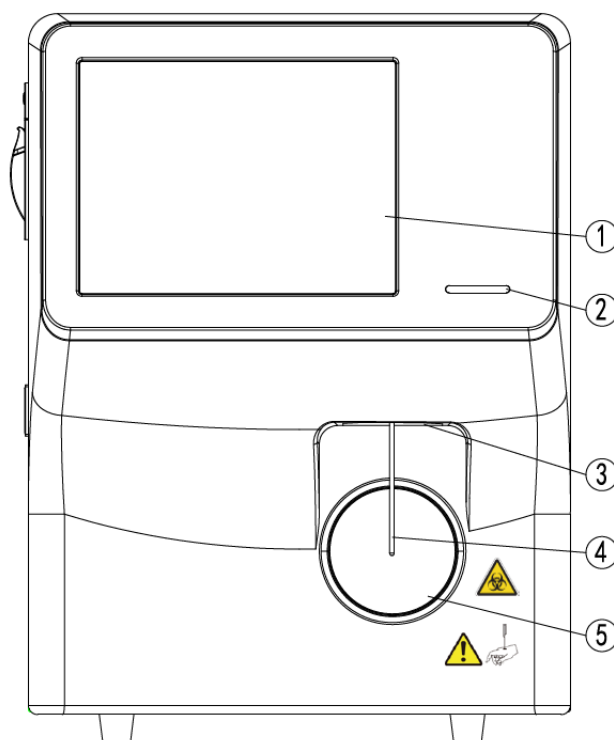


Figure 2-1 Front of the analyzer

- | | |
|-------------------------|---------------------|
| 1 ---- Touch screen | 2 ---- Indicator |
| 3 ---- Probe wipe block | 4 ---- Sample probe |
| 5 ---- [Aspirate] key | |

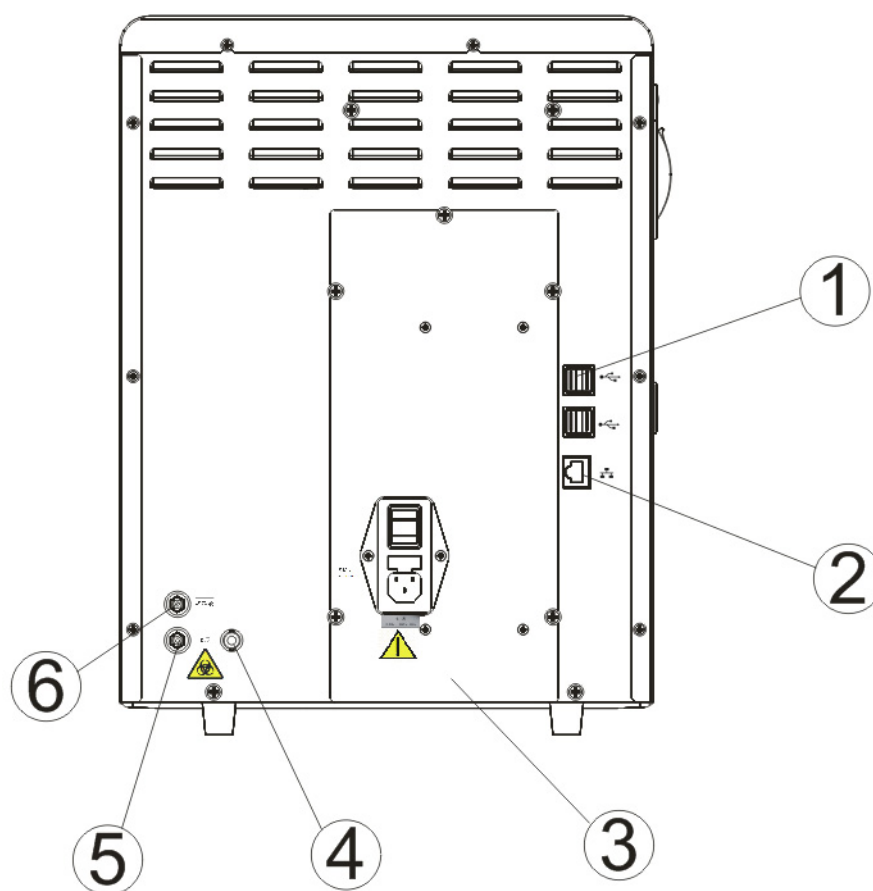


Figure 2-2 Back of the analyzer

- | | |
|----------------------|------------------------------|
| 1 --- USB port | 2 --- Network interface |
| 3 --- Power assembly | 4 --- Waste sensor connector |
| 5 --- Waste outlet | 6 --- Diluent inlet |

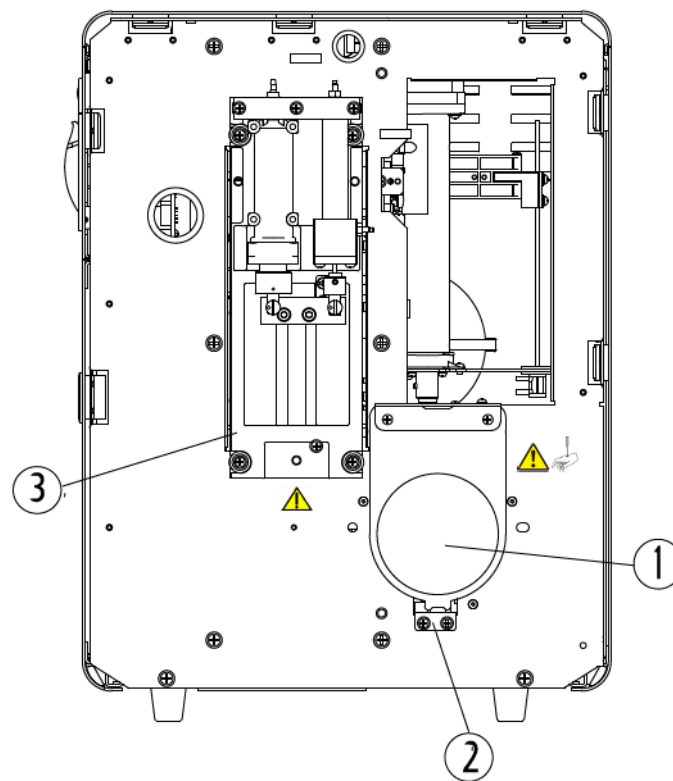


Figure 2-3 Inside of the analyzer (front cover removed)

1 --- [Aspirate] key
3 --- Syringe module

2 --- Start assembly

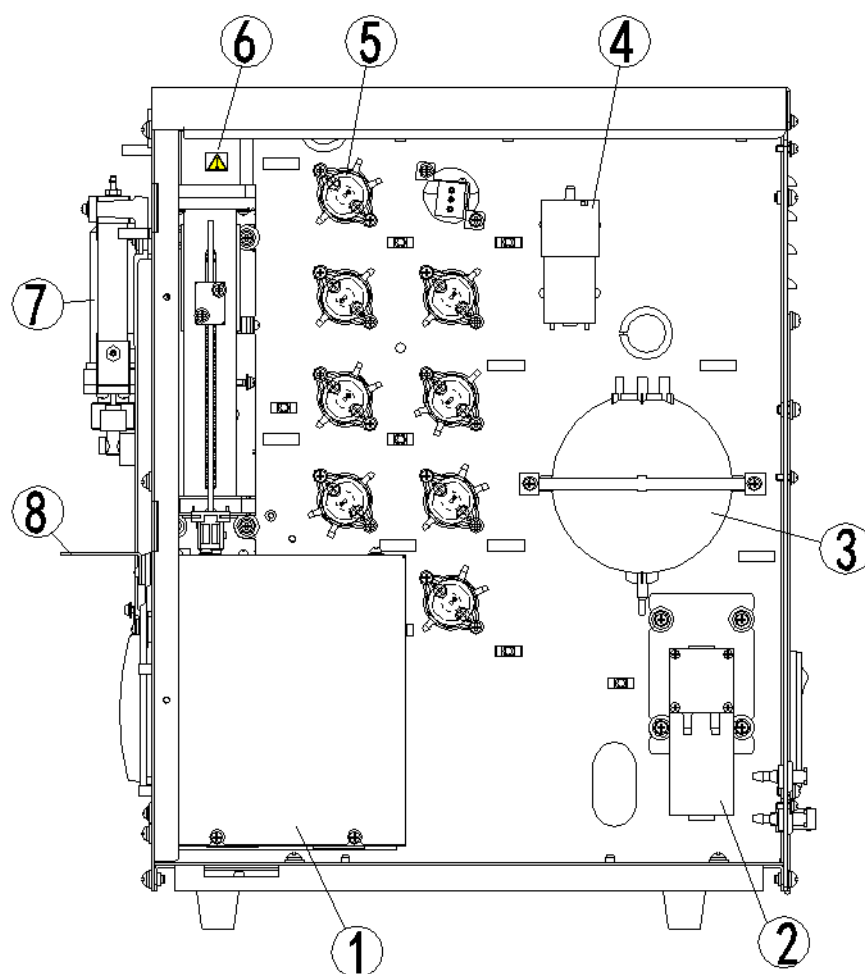


Figure 2-4 Right side of the analyzer (right door open)

- | | |
|-----------------------|------------------------|
| 1 --- Bath | 2 --- Waste pump |
| 3 --- Vacuum chamber | 4 --- Air pump |
| 5 --- Valves | 6 --- Syringe module |
| 7 --- Sampling module | 8 --- Probe wipe block |

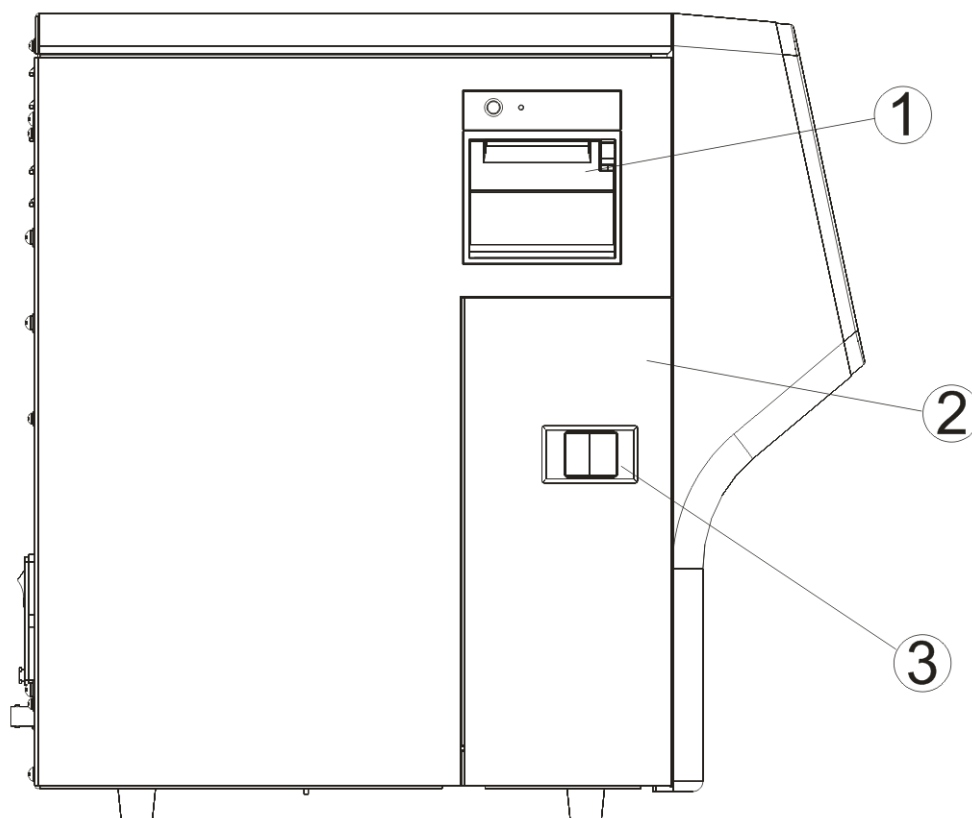


Figure 2-5 Left side of the analyzer

1 --- Recorder

2 --- Left door

3 --- Lock latch of the side door

2.3.1 Touch Screen

The touch screen locates on the front of the main unit, which can be used to operate the instrument and display information.

2.3.2 Aspirate Key

The aspirate key is located behind the sample probe. You can press the key to start the analysis, dispense diluent or perform reagent maintenance.

2.3.3 Indicator

The indicator may light in red, yellow and green to indicate current status of the system.

Steady green: the analyzer is ready for use.

Flashing green: the analyzer is running.

Steady red: the analyzer is faulty and is not running.

Flashing red: the analyzer is faulty and is running.

Steady yellow: the analyzer is in standby status.

2.3.4 USB Ports

The analyzer has 4 USB ports to connect the keyboard, printer, barcode scanner, recorder, wireless network card, etc.. The analyzer supports software upgrade through USB.

2.3.5 Network Interface

A PC can be connected to the network interface located on the back of the analyzer for automatic data transmission.

2.3.6 Peripherals

■ Keyboard (optional)

A Keyboard can be connected to a USB port on the analyzer. You can use it to operate your analyzer.

■ Mouse (optional)

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

■ USB printer (optional)

A USB printer can be connected to a USB port on the back of the analyzer. You can use it to print out reports or other interested information displayed on the screen.

Supported model: HP LaserJet P1606dn, HP Ink Tank 319, HP Ink Tank 310, HP DeskJet Ink Advantage 1115, and HP LaserJet P2035.

■ Barcode scanner (optional)

A barcode scanner can be connected to a USB port on the back of the analyzer. You can use it to scan the barcode information into the analyzer.

■ Wireless network card (optional)

Supported model: NETGEAR® WNA3100M.

NOTE

- **The Wi-Fi module purchased by the user must comply with relevant local laws and regulations.**

2.3.7 Accessories

Accessories are listed in the following table.

Table 2-4 Accessories

	Configured
Reagent container cap assembly	√
Waste tube assembly	√
Power cords	√

NOTE

- **For any questions about the configured/optional accessories, consult your sales representative.**
- **The actual accessories may vary based on your product configuration.**



CAUTION

- **Only use the accessories and consumables manufactured or recommended by Mindray to achieve the promised system performance and safety. For more information, contact Mindray Customer Service Department or your local distributor.**
- **Use the original power cord provided by the manufacturer. Using other electrical wire may damage the analyzer or lead to unreliable analysis results.**

2.4 User Interface

2.4.1 Screen

After the starting procedure, you will enter the "**Sample Analysis**" screen as shown in below figure.



Figure 2-6 Sample Analysis screen

2.4.2 Menu

Tap the "**Menu**" button to display system menu.

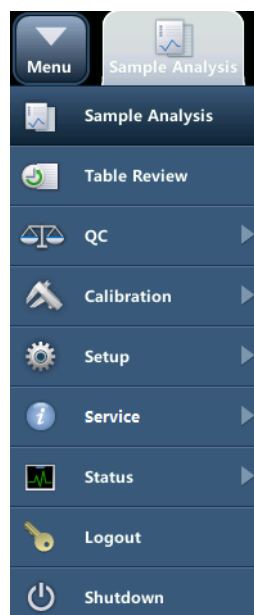


Figure 2-7 System menu

Tap one of the 9 options on the system menu to enter corresponding screen.

2.5 Reagents, Controls and Calibrators

As the analyzer, reagents, 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 A 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.

WARNING

- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**
 - **The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective instrument (such as gloves, lab coat, and goggles) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.**
 - **If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.**
-

NOTE

- **Store and use the reagents as instructed by instructions for use of the reagents.**
 - **When you have changed the diluent or lyse, run a background test 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. Do not mix the new container of reagent with the residue in the replaced container to ensure accurate measurement.**
 - **After installing a new container of reagent, keep it still for a while before use.**
 - **After connecting the reagent and the analyzer, put the lid back to the reagent to prevent it from being contaminated.**
-

The analyzer supports the following reagents, controls and calibrators.

NOTE

- **For any questions about the reagents, controls and calibrators configuration, please consult your sales representative.**
-

2.5.1 Reagents

V-3D DILUENT

As an isotonic reagent and with specified conductivity, V-3D DILUENT provides stable environment for hematology analysis.

V-3CFL LYSE

V-3CFL LYSE is formulated to lyse red blood cells and transform the hemoglobin released from red blood cell into hemoglobin complex. It is used for WBC count and HGB determination.

Probe Cleanser

Probe Cleanser is used for the regular cleaning of the analyzer.

2.5.2 Controls and Calibrators

The analyzer supports B30 Hematology Controls, BC-3D Hematology Controls, S30 Calibrator, and SC-CAL PLUS Hematology Calibrator.

B30 and BC-3D controls are suspension of simulated white cells, human erythrocytes and simulated platelets in a medium containing stabilizers and preservatives. They are used for the quality control of BC-30 Vet hematology analyzer; the QC program monitors and evaluates the precision of the measurement parameters like WBC, RBC, HGB, MCV and PLT.

S30 and SC-CAL PLUS calibrators are suspension of simulated white cells, human erythrocytes and simulated platelets in a medium containing stabilizers and preservatives. They are used to calibrate some parameters (WBC, RBC, HGB, MCV and PLT) of BC-30 Vet hematology analyzer.

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.

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3 Understanding the System Principles

3.1 Introduction

The analyzer uses the electrical impedance method to determine the count and size distribution of RBC, WBC and PLT; and uses the colorimetric method to determine HGB. Based on the above data, the analyzer calculates other parameters.

3.2 Aspiration

If you use the whole blood mode, present the sample to the analyzer directly.

If you use the predilute mode, manually dilute the 20 μ L blood sample with 0.7 mL of diluent. Then present the prediluted sample to the analyzer.

3.3 Dilution

Usually in blood samples, the cells are too close to each other to be identified or counted. For this reason, the diluent is used to separate the cells so that they draw 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 need to be added to the sample to eliminate the red blood cells before the WBC count. Because red blood cells usually have no nucleus, they are eliminated when the lyse breaks down their cell walls. The analyzer provides whole blood mode for the analysis of different sample types, but only rat and mouse samples can be analyzed using the predilute mode.

3.4 WBC/HGB Measurement

3.4.1 Measurement Principle

3.4.1.1 WBC measurement principle

The WBCs are counted by the impedance method. The analyzer aspirates certain volume of sample, dilutes it with certain volume of conductive solution, and delivers the dilution to the metering unit. The little opening on the metering unit is called "aperture". A pair of electrodes is positioned on both sides of the aperture to create a constant-current supply. As cells are poor conductors, when each particle in the diluted sample passes through the aperture under the constant negative pressure, a transitory change in the direct-current resistance between the electrodes is produced. The change in turn produces a measurable electrical pulse which is proportional to the particle size. And when the particles pass the aperture in succession, a series of pulses are produced between the electrodes. The number of pulses generated indicates the number of particles passed through the aperture; and the amplitude of each pulse is proportional to the volume of each particle.

Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of a certain amplitude. All the collected pulses are thus classified based on the reference voltage ranges of different channels, and the number of the pluses in the WBC channel indicates the number of the WBC particles. The cell size distribution width is represented by the number of particles falling in each channel.

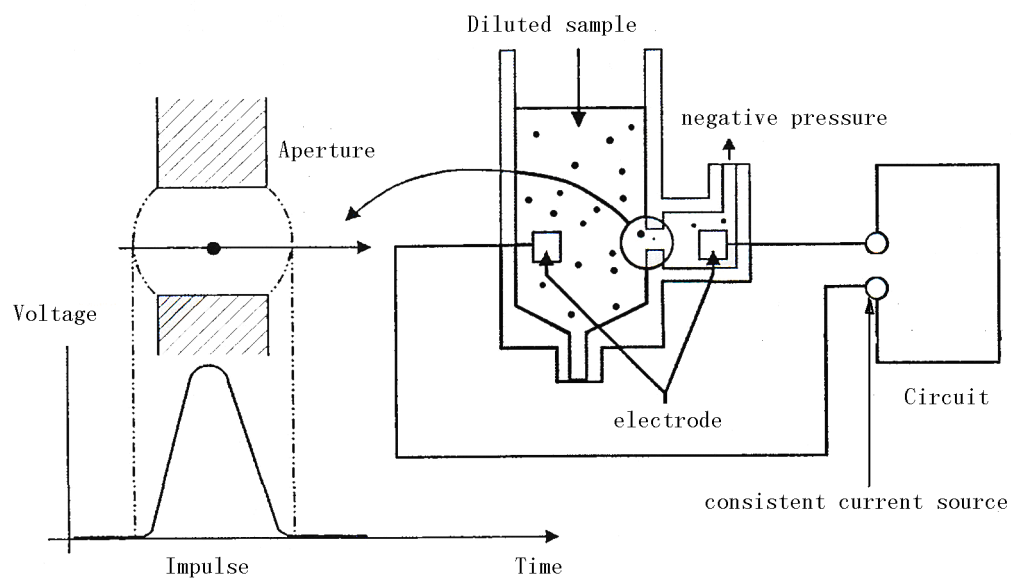


Figure 3-1 Metering diagram

3.4.2 WBC-Related Parameters

3.4.2.1 WBC Count

WBC ($10^9/L$) is the number of leukocytes, measured directly by counting the leukocytes passing through the aperture.

3.4.2.2 WBC 4-part Differential

Lyses and diluents change the sizes of each type of WBCs in various ways and at different time. The WBCs are thus separated into 4 parts with certain reagents. The WBC 4-part differential for dog and cat samples is implemented through counting white blood cells for two times.

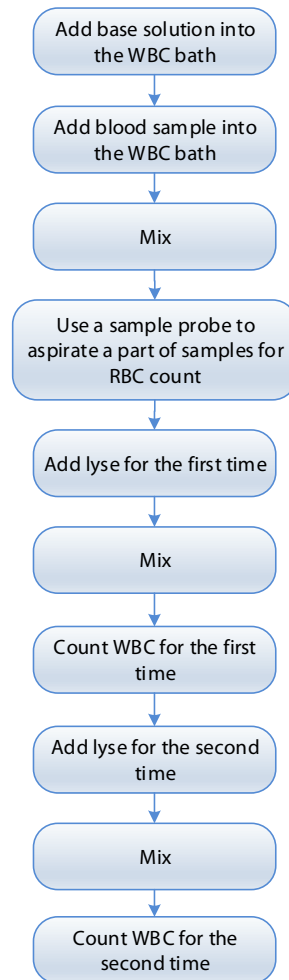


Figure 3-2 WBC twice counting procedure

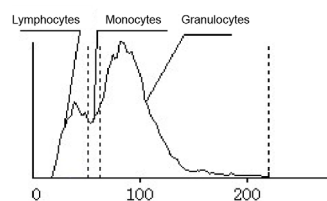


Figure 3-3 Histogram of the first WBC count procedure

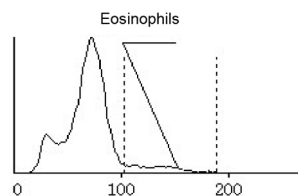


Figure 3-4 Histogram of the second WBC count procedure

WBC1 is obtained during the first WBC count procedure.

WBC2, HGB and Eos% values are obtained during the second WBC count procedure.

WBC2 is used as the WBC count result.

Based on WBC2 and WBC1 count results, remove the achromatocyte on the left of the first WBC count histogram first. Then, divide the area in this histogram into three parts: Lym% (lymphocyte percentage), Mon% (monocyte percentage), and Gran% (granulocyte percentage).

$\text{Neu\% (Neutrophils percentage)} = \text{Gran\%} - \text{Eos\%}$

$\text{Lym\#} = \text{WBC} * \text{Lym\%}$

$\text{Mon\#} = \text{WBC} * \text{Mon\%}$

$\text{Neu\#} = \text{WBC} * \text{Neu\%}$

$\text{Eos\#} = \text{WBC} * \text{Eos\%}$

3.4.2.3 WBC 3-part Differential

Lyses and diluents change the sizes of each type of WBCs in various ways and at different time. The WBCs are thus separated into 3 parts (from the largest size to the smallest): lymphocytes, monocytes, and granulocytes. The WBC 3-part differential for horse, rat, mouse, rabbit, monkey, pig, llama, and camel samples is implemented through counting white blood cells for one time, while the WBC 3-part differential for sheep, goat, and cow samples is implemented through counting white blood cells for two times.

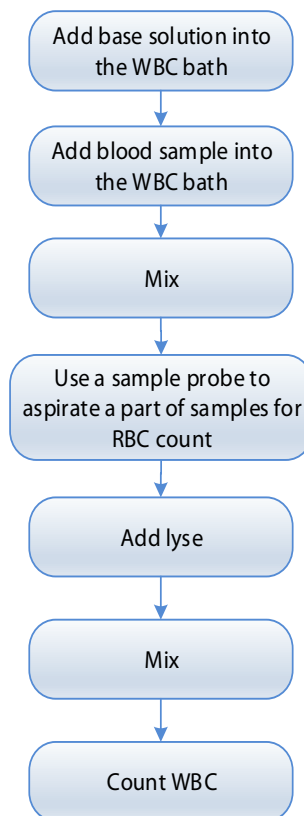


Figure 3-5 WBC counting procedure

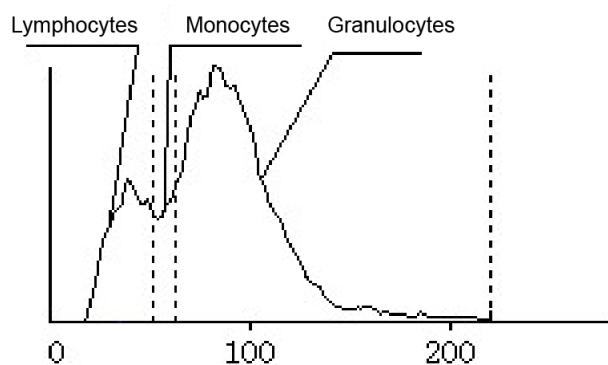


Figure 3-6 Histogram of the WBC count procedure

$$\text{Lym}\% + \text{Mon}\% + \text{Gran}\% = 100\%$$

$$\text{Lym}\# = \text{WBC} * \text{Lym}\%$$

$$\text{Mon}\# = \text{WBC} * \text{Mon}\%$$

$$\text{Gran}\# = \text{WBC} * \text{Gran}\%$$

3.4.2.4 White Blood Cell Histogram

Besides the count results, the analyzer also provides a WBC histogram which shows the WBC size distribution, with the x-axis representing the cell size (in fL) and the Y-axis representing relative cell number (in $10^9/\text{L}$). After each analysis cycle, you can either check the WBC histogram in the analysis result area on the "**Sample Analysis**" screen or review the histogram on the "**Graph Review**" screen.

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

3.4.3 HGB Measurement

The HGB is determined by the colorimetric method. The diluted sample is delivered to the WBC count bath where it is bubble mixed with a certain amount of lyse, which breaks red blood cells, and converts hemoglobin to a hemoglobin complex. An LED is mounted on one side of the bath and emits a beam of monochromatic light with 530~535nm central wavelength. The light is received by an optical sensor mounted on the opposite side, where the light signal is first converted to current signal and then to voltage signal. The voltage signal is then amplified and measured and compared to the blank reference (taken when there is only diluent in the bath), and the HGB (g/L) is measured and calculated automatically. The whole measurement and calculation process is completed automatically. You can review the results in the analysis result area on the "**Sample Analysis**" screen.

HGB is expressed in g/L.

$$\text{HGB(g/L)} = \text{Constant} \times \text{Ln} \left(\frac{\text{Blank Phot ocurrent}}{\text{Sample Photocurrent}} \right)$$

3.5 RBC/PLT Measurement

3.5.1 Impedance Method

RBCs/PLTs are counted by the electrical impedance method. The analyzer aspirates certain volume of sample, dilutes it with certain volume of conductive solution, and delivers the dilution to the metering unit. The little opening on the metering unit is called "aperture". A pair of electrodes is positioned on both sides of the aperture to create a constant-current supply. As cells are poor conductors, when each particle in the diluted sample passes through the aperture under the constant negative pressure, a transitory change in the direct-current resistance between the electrodes is produced. The change in turn produces a measurable electrical pulse which is proportional to the particle size. And when the particles pass the aperture in succession, a series of pulses are produced between the electrodes. The number of pulses generated indicates the number of particles passed through the aperture; and the amplitude of each pulse is proportional to the volume of each particle.

Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of a certain amplitude. All the collected pulses are thus classified based on the reference voltage thresholds of different channels, and the number of the pluses in the RBC/PLT channel indicates the number of the RBC/PLT particles. The cell size distribution width is represented by the number of particles falling in each channel.

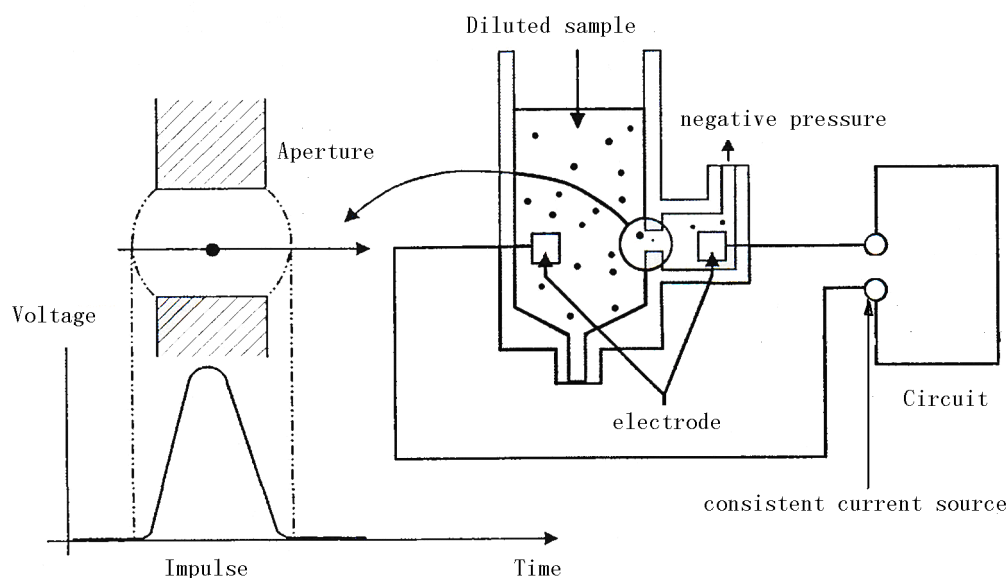


Figure 3-7 Metering diagram

3.5.2 RBC-Related Parameters

Red Blood Cell count

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

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

Mean Corpuscular Volume

The analyzer calculates the mean cell volume (MCV, in fL) based on the RBC histogram.

HCT, MCH and MCHC

The following formula can be used to calculate HCT (unit: %), MCH (unit: pg) and MCHC (unit: g/L).

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

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

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

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

RDW-CV

Red Blood Cell Distribution Width - Coefficient of Variation (RDW-CV) is derived based on RBC histogram. It is expressed in %, and indicates the variation level of RBC size distribution.

RDW-SD

Red Blood Cells Distribution Width - Standard Deviation (RDW-SD, in fL) measures the width of the 20% level (with the peak taken as 100%) on the RBC histogram, as shown in **Figure 3-8**.

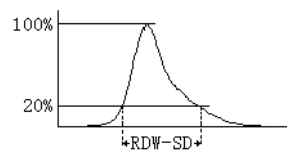


Figure 3-8 Diagram

RBC Histogram

Besides the count results, the analyzer also provides a RBC histogram which shows the RBC size distribution. After each analysis cycle, you can either check the RBC histogram in the analysis result area on the "**Sample Analysis**" screen or review the histogram on the "**Graph Review**" screen.

3.5.3 PLT-Related Parameters

Platelet count

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

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

Mean Platelet Volume

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

Platelet distribution width

Platelet distribution width (PDW) is derived from the platelet histogram, and is reported as 10 geometric standard deviation (10 GSD).

Plateletcrit

The analyzer calculates the PCT (unit: %) as follows:

Where, the PLT is expressed in $10^9/\text{L}$ and the MPV in fL.

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

Platelet-large cell ratio

Based on the PLT histogram, this analyzer calculates the platelet-large cell ratio (P-LCR) (unit: %).

Platelet-large cell count

Based on the PLT and the P-LCR, the analyzer calculates the platelet-large cell count ($10^9/L$) as follows:

$$P - LCC = PLT \times P - LCR$$

PLT histogram

Besides the count results, the analyzer also provides a PLT histogram which shows the PLT size distribution. After each analysis cycle, you can either check the PLT histogram in the analysis result area on the "**Sample Analysis**" screen or review the histogram on the "**Graph Review**" screen.

3.6 Wash

After each analysis cycle, all elements of the analyzer that the sample runs through are washed to ensure no residue is left.

- The sample probe is washed internally and externally with diluent;
- The baths are washed with diluent;
- Other elements of the fluidic system are also washed with diluent.

4 Installing Your Analyzer

4.1 Introduction

This chapter introduces how to install the BC-30 Vet. To ensure all system components function correctly and to verify system performance, Mindray-authorized representatives will handle the installation and initial software setup. Do not move or install your analyzer without the presence of Mindray-authorized personnel.

CAUTION

- **Unpacking, handling or 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.**
- **The installation, test, update, and modification of the software associated with the analyzer shall only be performed by personnel authorized by Mindray.**
- **The safety of any system incorporating the equipment is the responsibility of the assembler of the system.**
- **After you open the package, check the integrity of the product according to the packing list. If there are any missing part, contact Mindray Customer Service Department or your local distributor immediately.**

The analyzer is tested and packed with care before it is shipped from the factory. When you receive your analyzer, carefully inspect the carton. If you see any signs of mishandling or damage, contact Mindray Customer Service department or your local distributor immediately.

4.2 Installation Requirements

Before installation, you should ensure that the following space, power, environmental and fuse protection 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 to both left and right sides;
- at least 10 cm behind the analyzer;
- enough room on or below the countertop to accommodate the diluent and waste containers.
- the table (or the floor) where the analyzer is placed shall be able to withstand at least 40kg of weight.

4.2.2 Power Requirements

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

Fuse: 250V T3.15AH

⚠ WARNING

- Make sure the analyzer is properly grounded.
- Before turning on the system, make sure the input voltage meets the requirements.
- When installing the instrument, ensure that the power switch is in close proximity to the equipment and within easy reach of you.

⚠ CAUTION

- Using pinboard may bring electrical interference and the analysis results may be unreliable. Place the analyzer near the electrical outlet to avoid using the pinboard.
- Use the original power cord provided by the manufacturer. Using other electrical wire may damage the analyzer or lead to unreliable analysis results.

4.2.3 Environment Requirements

	Normal operation environment	Storage and transportation environment	Running environment
Ambient temperature	15°C ~ 30°C	-10°C ~ 40°C	10°C~40°C
Relative humidity	20% ~ 85%	10% ~ 90%	10% ~ 90%
Atmospheric pressure	70.0kPa ~ 106.0kPa ^{Note1}	50.0kPa ~ 106.0kPa	70.0 kPa ~ 106.0 kPa

Note: The altitude requirement for instrument normal - operation is -400m ~ 3000m.

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. Please use a separate power socket; do not use the same socket with devices like air conditioning, refrigerator and ultrasonic system, as they may interfere with the proper operation of the analyzer. It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer. Keep the device away from strong electromagnetic interference sources. Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close. The environment shall be well ventilated. Do not place the analyzer in direct sunlight. Connect only to a properly earth grounded outlet. Only use this analyzer indoors.

⚠ WARNING

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

NOTE

- If the ambient temperature is out of the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. When temperature errors are reported in the error information area after analysis, see Chapter 11 Troubleshooting Your Analyzer for solutions.

4.2.4 Moving and Installing the Analyzer

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.
- To prevent personal injury during the operation, keep your clothes, hairs and hands from the moving parts like sample probe.
- The sample probe tip is sharp and may contain biohazardous materials. Exercise caution to avoid contact with the probe when working around it.

NOTE

- To protect it from being damaged during transportation, the aspiration module is fixed by cables ties and clamps before the analyzer is shipped out of factory. Remove the cable ties and clamps before using the analyzer.

Moving and installation of the analyzer shall be conducted by Mindray-authorized personnel. Do not move or install your analyzer without the presence of Mindray-authorized personnel.

4.3 Connecting the System

Connect the power and the reagents as shown below. Make sure the connections are correct and firm.

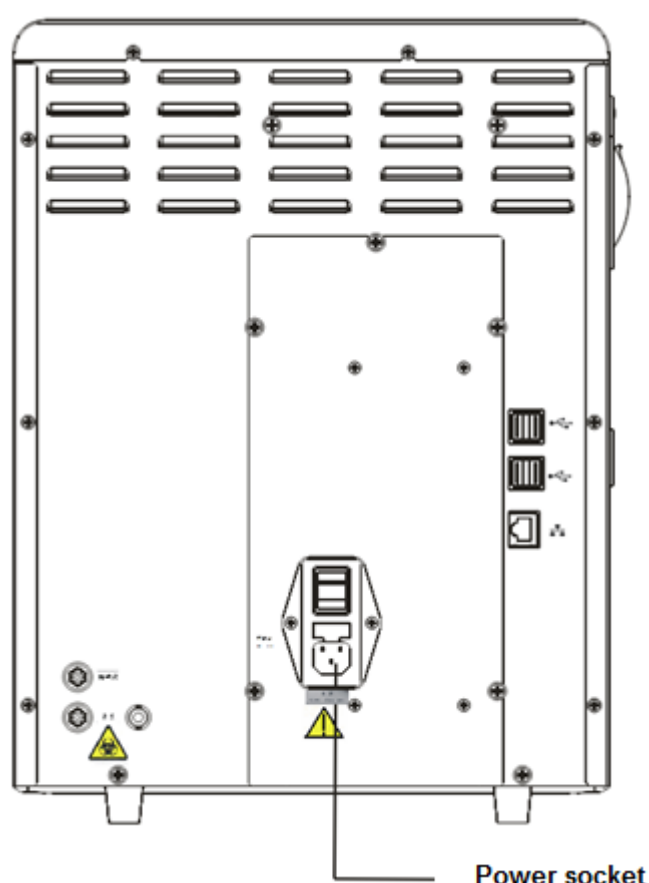


Figure 4-1 Connecting the analyzer to a power socket

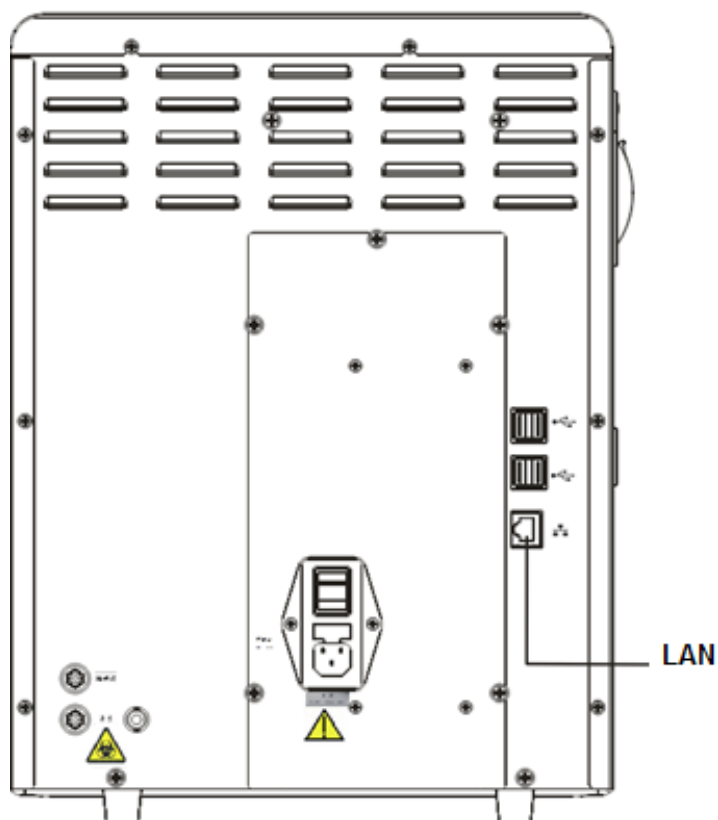


Figure 4-2 Connecting the network port on the analyzer

WARNING

- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
- The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective instrument (such as gloves, lab coat, and goggles) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.
- Remove the waste container cap and replace the waste container only when the power indicator is not flickering, in order not to make the waste overflow from the container.
- When you are using a waste container to dispose waste, make sure the pickup tube is smooth, not bend, and is above the cap assembly of the waste container.

CAUTION

- Do not place the reagent container on the top of the analyzer.

NOTE

- Use the Mindray-specified reagents.
- After installing a new container of reagent, keep it still for a while before use.
- Pay attention to the expiration dates and open-container stability days of all the reagents. Never use expired reagents.
- To prevent contamination, tighten the container caps when the installation is finished.

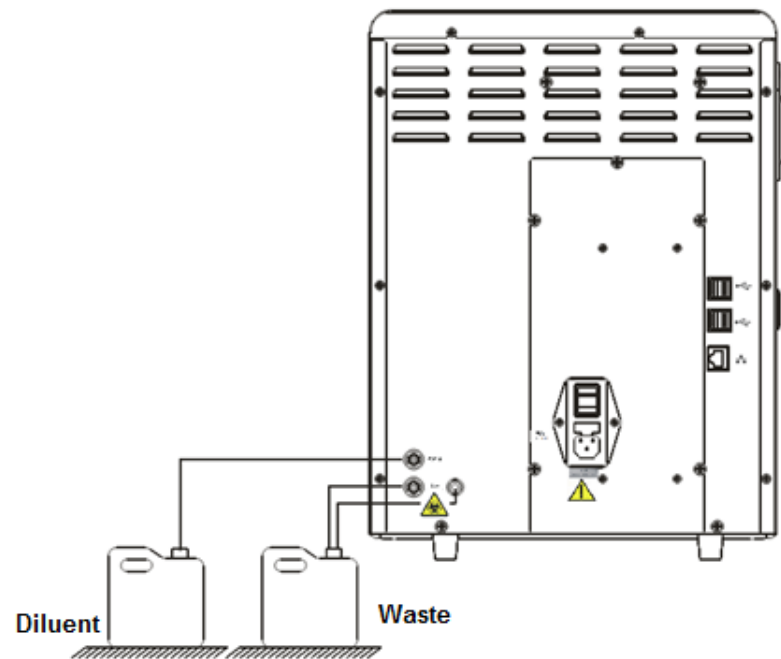


Figure 4-3 Connecting reagents placed outside the analyzer

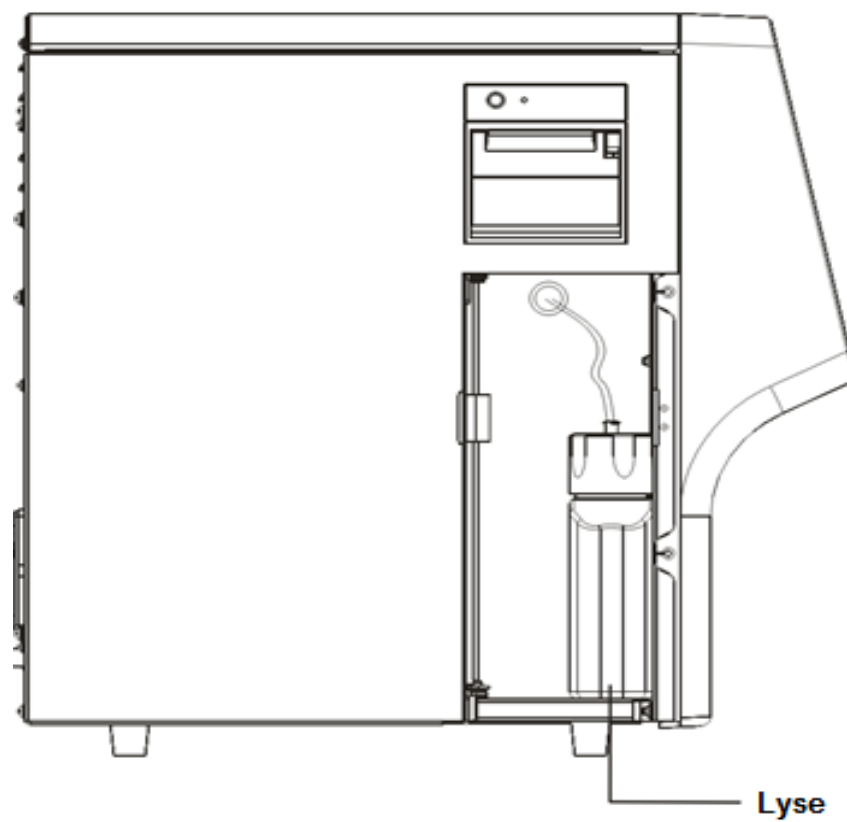


Figure 4-4 Connecting reagents placed inside the analyzer

CAUTION

- The top of the waste container and the diluent container should be lower than the countertop where the analyzer is placed.
-

4.4 Installing the Recorder Paper

NOTE

- Remove the protective paper in the recorder before installing recorder paper.
-

Follow the procedure below to install the record 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 with the paper end out of the recorder exit, as shown below.
3. Close the recorder door.
4. Check whether the paper is installed correctly and the paper end is feeding from the top.

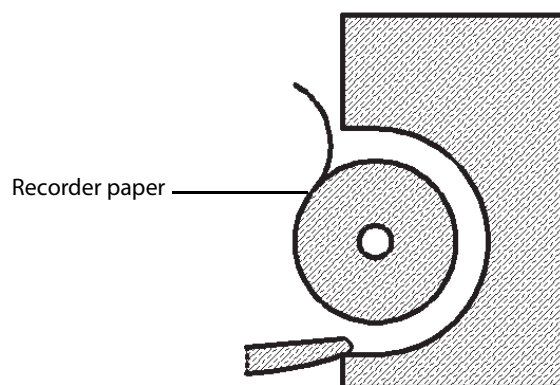


Figure 4-5 Installing recorder paper

CAUTION

- Use only specified thermal 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 the recorder may be damaged.
 - Do not leave the recorder door open unless you are installing paper or removing errors.
 - Improper installation of recorder paper may jam the paper and/or result in blank printout.
-

4.5 Precautions

- If the analyzer is kept in an environment with heavy dust for a long time, its performance may be reduced.
- It is recommended to clean and sterilize the outer surface of the analyzer with 75% ethanol.
- The probe wipe block of the analyzer (see *Figure 2-1 Front of the analyzer*) shall be wiped with 75% alcohol regularly.
- The probe wipe shall be cleaned regularly.
- Collect and prepare samples in accordance with the standard procedure of your laboratory; otherwise it may result in inaccurate analysis results or damage to the analyzer.
- If any of the pipes or fluidic components are worn out, stop using the analyzer and contact Mindray customer service department immediately for inspection or replacement.
- Make sure the tubings of the reagents (including diluent, lyse and waste) are not pressed by heavy objects or bent over.
- Use only Mindray-specified reagents; otherwise it may result in inaccurate results or damage to the analyzer.
- Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents. Otherwise it may result in inaccurate results.

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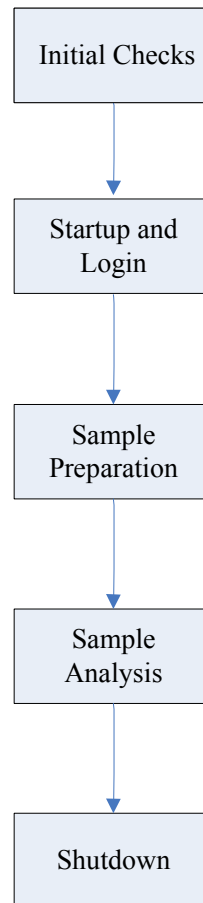
5

Operating Your Analyzer

5.1 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.



5.2 Initial Checks

Perform the following checks before turning on the analyzer.



BIOLOGICAL RISKS

- 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 diaphragm. Wear proper personal protective instrument (such as gloves, lab coat, and goggles) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.
- To prevent personal injury during the operation, keep your clothes, hairs and hands from the moving parts like sample probe.
- Before using the analyzer, make sure that the instrument is in normal running status, the indicator on the analyzer is steady green, and there is no temperature, liquid level or other alarms on the software interface.
- Use the analyzer strictly as instructed by this manual to avoid unexpected product damage or personal injury.
- Improper service may damage the system. Make sure you service the instrument strictly as instructed by this manual.

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 tubes are properly connected before using the system.
- After installing a new container of reagent, keep it still for a while before use.

Checking the waste container

Check and make sure the waste container (not supplied) is empty.

Checking tubing and power connections

Check and make sure the reagent, waste and pneumatic unit tubes are properly connected and not bent.

Check and make sure the power cord of the analyzer is properly plugged into the power outlet.

Checking recorder (optional) and printer (optional)

Check and make sure the printer and recorder are properly installed, and have enough paper.

5.3 Startup and Login

5.3.1 Power on the analyzer:

1. Place the power switch at the back of the analyzer in the "I" position. The switch will light on.
2. Make sure that the power indicator on the analyzer lights on.
3. Enter your user ID and password in the login dialog box.

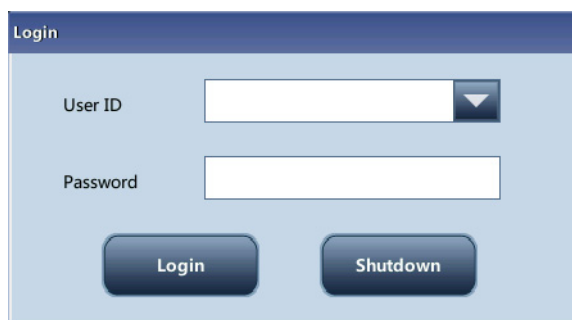
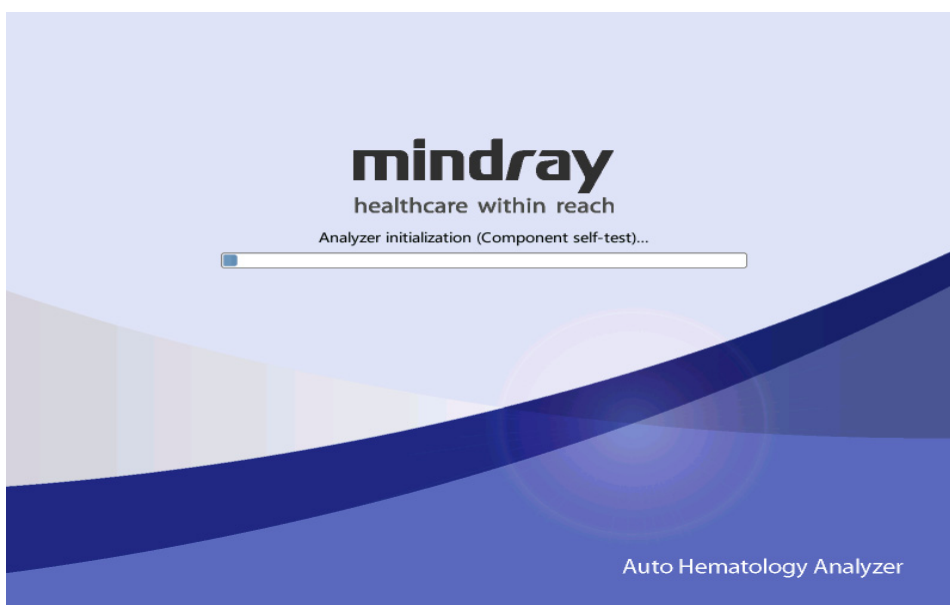


Figure 5-1 Login dialog box

4. The analyzer will sequentially do the self-test and initialize the system.



NOTE

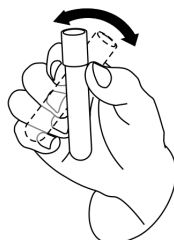
- When "Background abnormal" is reported during the startup process, follow the corresponding troubleshooting instruction for the error in Chapter 11 Troubleshooting Your Analyzer.
- The system opens different function for the user according to the user level. The user level depends on the user ID and the password when the user logs in.
- To switch to another user, tap "Menu" -> "Logout" first, and then tap "OK" to return to the login interface. Enter the user ID and password in the displayed login dialog box, and then tap "Login" to log in.
- If you failed to run the software continuously, please contact Mindray Customer Service Department or your local distributor.
- After startup, please make sure the date/time of the computer is correct.
- The default user ID and password for administrator are both "Admin".
- 1-12 characters are allowed for user ID and password; Chinese characters are not allowed.

5.4 Sample Preparation

The analyzer supports two sample types: whole blood sample and predilute sample.

CAUTION

- Prepare samples following the recommend procedure of the manufacturer.
- Always shake the samples as shown below to well mix it.



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

BIOLOGICAL RISKS

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

WARNING

- Do not contact the sample blood directly.

5.4.1 Whole Blood Samples

1. Use clean EDTAK₂ or EDTAK₃ anticoagulant collection tubes to collect the venous blood sample.
2. Mix the sample immediately with the anticoagulant K2EDTA (1.5~2.2 mg/ml).

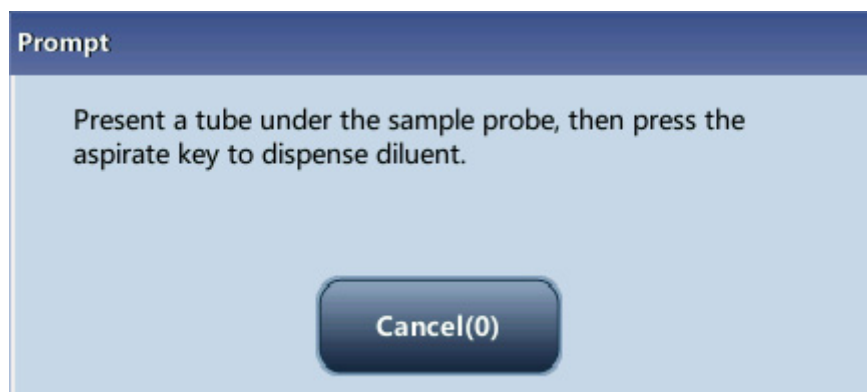
NOTE

- Samples stored in a refrigerator at the temperature of 2°C~8°C must be analyzed within 24 hours after collection. The refrigerated samples must be kept at room temperature for at least 30 minutes before analysis.
- Be sure to mix any sample that has been prepared for a while before running it.

5.4.2 Prediluted Samples

Do as follows to prepare samples in the predilute mode:

1. Tap the "Diluent" button on the top status bar, a message box will pop up.



2. Present a tube to the analyzer, and tap the [Aspirate] key on the analyzer to dispense the diluent (700µL). The screen will display a progress bar during the dispensing procedure.
3. If more portions of diluent are needed, repeat the step 2.
4. Add 20µL of blood samples to the tube with diluent inside, close the tube cap and shake the tube to mix the sample.
5. After the prediluted sample is prepared, tap the **"Cancel"** button.

NOTE

- You can also dispense 700µL of diluent into the tube by the pipette.
- Take methods to prevent the diluent from dust and volatilization; otherwise the results may be unreliable.
- After well mixing the blood samples with the diluent, be sure to wait for at least 3 minutes, then mix the samples again before the analysis.
- Complete the analysis within 30 minutes after diluting the sample. It is recommended to complete the analysis as soon as possible.
- 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.

5.5 Sample Analysis

Tap **"Sample Analysis"** to enter the sample analysis screen.

CAUTION

- Before running samples, make sure the analyzer background results are in an acceptable range.

5.5.1 Enter Sample Information

If you want to enter the sample information based on sample ID or sample result saving time after analysis, skip this section, and check Chapter 6 Reviewing Sample Results.

Tap **"Next Sample"** on the **"Sample Analysis"** screen, and a dialog box pops out as below. You can enter full sample information for the next sample except for **"Ref. group"**, for the system will assign a matched group automatically.

Next Sample

Sample ID * Species

Patient ID Patient

Gender Age

Owner Last Name Ref. group

Draw Time Delivery Time

Veterinarian Mode

Comments

* Required field

Figure 5-2 Enter all information

■ Entering the sample ID

Enter the ID into the "**Sample ID**" box.

NOTE

- You can enter letters, digits and all other characters on the keyboard (including special characters) for sample ID.
- 1 to 20 characters are allowed. It cannot be left empty.
- The sample ID must end with a digit; and it cannot only consist of "0".

■ Selecting the species

Select animal from the "**Species**" pull-down list..

■ Entering the patient ID

Enter the patient ID into the "**Patient ID**" box.

■ Entering the animal name

Enter the animal name into the "**Patient**" box.

■ Selecting the gender

Select the desired item (Male, Female, or null) from the "**Gender**" pull-down list. The default option is null.

■ Entering the animal age

The analyzer provides four ways for you to enter the animal's age - in years, in months, in days and in hours. You may choose one of the four ways to enter the animal age.

Select the desired item from the "**Age**" drop-down list (**Years**, **Month(s)**, **Days** and **Hours**), and you may enter the animal age in the box followed by the age unit.

■ Entering the owner name

Enter the last name of owner into the "**Owner Last Name**" box.

■ Selecting the reference group

The reference group is automatically selected.

- Entering the draw time

Enter the time when the sample is collected into the "**Draw Time**" box.

- Entering the delivery time

Enter the time when the sample is sent into the "**Delivery Time**" box.

- Entering the veterinarian name

Enter the corresponding name into the "**Veterinarian**" box.

- Selecting the mode

Select the sample mode from the "**Mode**" pull-down list. The "**PD**" mode only can be chosen when "**Rat**" or "**Mouse**" is selected in the "**Species**" pull-down list.

- Entering the comments

Enter necessary information into the "**Comments**" box.

- OK

When you have finished entering the sample information, tap "**OK**" to save the information and return to the "**Sample Analysis**" screen.

- Cancel

If you do not want to save the entered sample information, tap "**Cancel**" to return to the "**Sample Analysis**" screen without saving the changes.

5.5.2 Running the Samples



BIOLOGICAL RISKS

- **All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (such as gloves, lab coat, and goggles) 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 sharp sample probe when working around it.**



CAUTION

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

NOTE

- **Make sure that the sample probe is fully immersed into the sample and not in contact with the tube bottom; otherwise the aspiration volume may be insufficient, or the aspirated volume may not be accurate.**
- **Make sure the sample probe tip does not touch the tube wall; otherwise the blood sample may spill.**

5.5.2.1 Sample Analysis

Do as follows to run samples:

1. Make sure the analyzer indicator shows that the analyzer is ready for analysis, and the sample mode is "**WB**" or "**PD**".
2. Present a well-mixed sample to the sample probe for aspiration.
3. Press the Aspirate key to start sample analysis. When the analyzer indicator flickers in green, the analyzer is running.

- The sample probe will automatically aspirate certain volume of samples. When you hear the beeps, remove the sample tube. The probe will ascend and add the aspirated sample to the count baths. The analyzer will automatically run the sample.
- When the analysis is finished, the result will be displayed in the analysis result area on the screen. The sample probe returns to the original position and gets ready for the next analysis.
- When **"Auto print after sample analysis"** ("Menu" > "Setup" > "System Setup" > "Print Setup") is set to **"Auto print after analysis"**, the analyzer will automatically print the analysis result report in the preset format; when **"Auto Communicate"** ("Menu" > "Setup" > "System Setup" > "Communication") is checked, the analyzer will automatically upload the eligible sample results as well as sample and patient information to the LIS system.
- Repeat above steps to run other samples.

NOTE

- If the analyzer detects clogging or bubbles during the analysis, the corresponding error message will be displayed in the error message area and the results of all related parameters will be invalidated. See Chapter 11 Troubleshooting Your Analyzer for solutions.
- If the ambient temperature is out of the specified operating range, the analyzer will alarm you for abnormal ambient temperature and the analysis results may be unreliable. When temperature errors are reported in the error information area after analysis, see Chapter 11 Troubleshooting Your Analyzer for solutions.

5.5.3 Editing Current Sample Information

- After analysis, tap the sample information area on the **"Sample Analysis"** interface and **"Graph Review"** interface ("Table Review" > "Graph Review").



2. On the displayed **"Edit Info"** screen, you can edit the analyzed sample information.

The 'Edit Info' screen contains the following fields:

- Sample ID: 3-1113-C2-12
- Patient ID: (empty)
- Gender: (dropdown menu)
- Owner Last Name: (empty)
- Draw Time: MM-DD-YYYY HH:MM
- Veterinarian: (dropdown menu)
- Mode: WB
- Comments: (text area)
- Species: Cat
- Patient: (empty)
- Age: (empty) Years (dropdown menu)
- Ref. group: Cat Default (dropdown menu)
- Delivery Time: MM-DD-YYYY HH:MM
- Time: 11-13-2019 16:44
- Operator: rd

Buttons: OK, Cancel

5.5.4 Processing Analysis Results

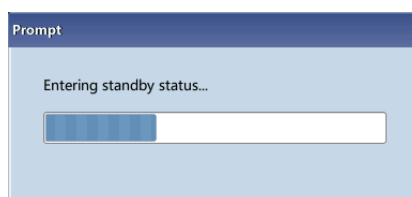
5.5.4.1 Saving of analysis results

The analyzer automatically saves sample results. When the maximum number has been reached, the newest result will overwrite the oldest.

"+++++" means the analysis results are too long to display, "*****" means the analysis results are invalid.

5.6 Standby

When the fluidics system stops working for 15 minutes (default value, which can be set in **"Menu" > "Setup" > "Maintenance"**), the analyzer will enter the standby status automatically.



After entering the standby mode, the bottom right of the screen displays **"Standby. Press the aspirate key to exit."**

Standby. Press the aspirate key to exit.

Administrator : Admin

01-14-2015 15:56

NOTE

- On the **"Status"** screen, the analyzer can not enter the standby status.
- If it is the time for standby but the analyzer has an error, then only after the error is removed will the auto-standby starts accordingly.
- You can perform the operations not involving the analyzer when it is on standby, such as communication and print etc.
- Refer to *Section 9.2.5 Maintenance(for Administrators Only)*.
- Under stand-by mode, if there are unfinished printing or communication tasks, the analyzer will go on processing them.

Press the Aspirate key on the analyzer to exit the standby mode.



After canceling the standby mode, the progress bar will be closed automatically, the analyzer will exit the standby mode.

NOTE

- Different maintenances will be performed by the analyzer automatically when exiting the standby status, and the exiting time depends on how long the analyzer was in the standby status.
- If any error happens during the process of exiting the standby status, see *Chapter 11 Troubleshooting Your Analyzer* for details to remove the error.
- After exiting standby mode, the analyzer will return to the status before standby. The indicator on the analyzer displays in green at the same time.

5.7 Shutdown



BIOLOGICAL RISKS

- All the samples, controls, calibrators, reagents, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (such as gloves, lab coat, and goggles) 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 sharp sample probe when working around it.



CAUTION

- Be sure to shut down the analyzer strictly as instructed below.
- Do not force power off the analyzer during the "Shutdown" procedure.
- If error that will affect shutdown occurs during the shutdown process, the analyzer will resume to its original status and report the error. See *Chapter 11 Troubleshooting Your Analyzer* for solutions.

Perform the "Shutdown" procedure to shut down the analyzer:

1. Tap the "Shutdown" button on the main menu, the shutdown dialog box will be shown as below:

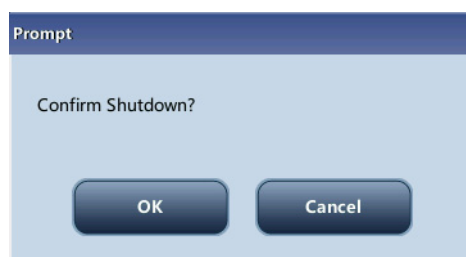


Figure 5-3 Shutdown

2. Tap **"OK"**, and follow the instruction to present probe cleanser to the sample probe, then press the Aspirate key. The sample probe automatically aspirates the probe cleanser; then the probe cleanser maintenance starts. A progress bar will be displayed on the screen to indicate the probe cleanser maintenance progress.
3. When the shutdown procedure is finished, the screen will display **"Please turn off the power of the analyzer!"**. Turn off the analyzer.
4. Empty the waste container and dispose of the waste properly.

**WARNING**

-
- **Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.**
-

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6 Reviewing Sample Results

6.1 Introduction

After every analysis cycle, the analyzer automatically saves the analysis results into the sample database. Totally 100,000 records (including parameter results and histograms) can be saved.

You can either choose the **"Table Review"** mode to review the parameter results of all samples saved in the sample and search databases; or the **"Graph Review"** mode to review both the parameter results and the histograms of each sample.

NOTE

- The sample result data must have proper backup in case of data lost caused by hardware or software error.

6.2 Table Review

You can browse, search, edit and export previous saved data on the **"Table Review"** screen. Tap **"Table Review"** to enter the **"Table Review"** screen.

Menu	Sample Analysis	Table Review	QC	Reagent Setup	Diluent	Print
	30*	31	32	33	34	35
Sample ID	3-1113-C2-12	3-1113-C2-13	3-1113-C2-14	3-1113-C2-15	3-1113-C2-16	3-1113-C2-17
Patient ID						
Patient						
WBC	17.42	H 20.75	14.63	15.94	14.98	16.45
Neu#	10.00	H 14.64	8.21	7.23	7.65	7.44
Gran#						
Lym#	5.91	4.11	4.46	6.54	5.23	6.81
Mon#	0.78	1.02	0.88	0.97	0.87	1.00
Eos#	0.73	0.98	1.08	1.20	1.23	1.20
Neu%	0.574	0.706	0.561	0.454	0.511	0.452
Gran%						
Lym%	0.339	0.198	0.305	0.410	0.349	0.414
Graph Review	Search	Edit Info	Export	Comm.	Trend Graph	→
Pos./Total	30 / 36		Administrator : Admin		12-18-2019 10:40	

6.2.1 Table area

The table area lists the analyzed samples with basic information such as sample ID, patient ID and patient.

	30*	31	32	33	34	35
Sample ID	3-1113-C2-12	3-1113-C2-13	3-1113-C2-14	3-1113-C2-15	3-1113-C2-16	3-1113-C2-17
Patient ID						
Patient						
WBC	17.42	H 20.75	14.63	15.94	14.98	16.45
Neu#	10.00	H 14.64	8.21	7.23	7.65	7.44
Gran#						
Lym#	5.91	4.11	4.46	6.54	5.23	6.81
Mon#	0.78	1.02	0.88	0.97	0.87	1.00
Eos#	0.73	0.98	1.08	1.20	1.23	1.20
Neu%	0.574	0.706	0.561	0.454	0.511	0.452
Gran%						
Lym%	0.339	0.198	0.305	0.410	0.349	0.414

NOTE

- The latest sample record is on the utmost top of the table.

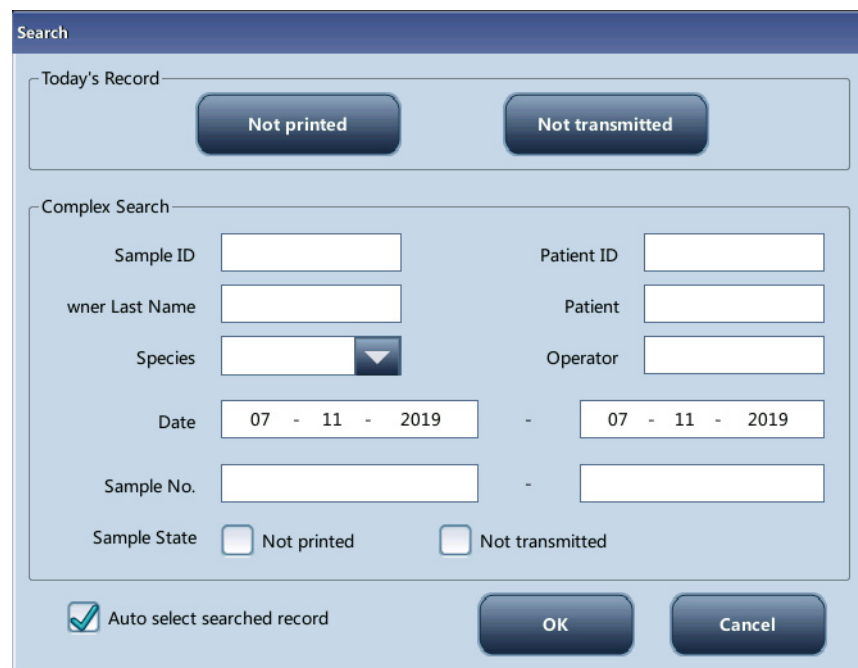
6.2.2 Graph Review

You can either tap the "Graph Review" button on the "Table Review" screen or tap "Previous" on the "Sample Analysis" screen to review the detailed results of each sample.



6.2.3 Search

1. Tap **"Search"**. The following dialog box will display.



The **Search** dialog box contains the following fields and controls:

- Today's Record** section:
 - Not printed** button
 - Not transmitted** button
- Complex Search** section:
 - Sample ID**: text input field
 - Patient ID**: text input field
 - Owner Last Name**: text input field
 - Patient**: text input field
 - Species**: dropdown menu
 - Operator**: text input field
 - Date**: date range selector (07 - 11 - 2019)
 - Sample No.**: text input field
 - Sample State**:
 - ☐ Not printed
 - ☐ Not transmitted
- Bottom section:
 - ☒ Auto select searched record
 - OK** button
 - Cancel** button

2. Enter searching conditions into the edit boxes or select them from the drop-down lists.
3. Tap **"OK"** to start search. The results will be displayed in the table.

6.2.4 Edit information

Tap the desired sample result on the **"Table Review"** screen and it will be highlighted. Tap the **"Edit Info"** button and the following dialog box will display.



The **Edit Info** dialog box contains the following fields and controls:

- Sample ID**: text input field (value: 2)
- Species**: dropdown menu (value: Dog)
- Patient ID**: text input field
- Patient**: text input field
- Gender**: dropdown menu
- Age**: text input field (value:) and **Years** dropdown menu
- Owner Last Name**: text input field
- Ref. group**: dropdown menu (value: Dog Default)
- Draw Time**: text input field (format: MM-DD-YYYY HH:MM)
- Delivery Time**: text input field (format: MM-DD-YYYY HH:MM)
- Veterinarian**: text input field
- Time**: text input field (value: 07 - 11 - 2019 15 : 12)
- Mode**: dropdown menu (value: WB)
- Operator**: text input field (value: Administrator)
- Comments**: text area
- Bottom section:
 - OK** button
 - Cancel** button

Modify the sample and animal information as necessary, and tap **"OK"** to save the changes. The information on the table review screen will be refreshed.

6.2.5 Export

1. Select the sample record to be exported.
2. Tap **"Export"**, the following dialog box will display.

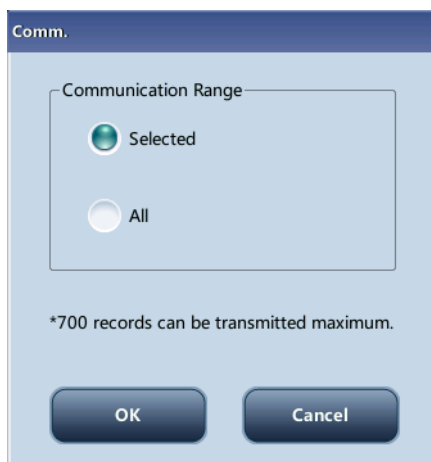


3. Select **"Selected"** or **"All"** in the **"Export Range"** area.
4. Tap **"OK"** to export the record. The dialog box will be closed.

6.2.6 Communication

6.2.6.1 Transmit selected data

1. Select sample(s) to be transmitted on the **"Table Review"** screen.
2. Tap **"Comm."**. The following dialog box will display.



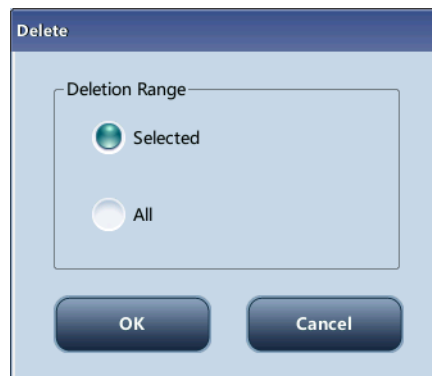
3. Tap the **"Selected"** radio button.
4. Tap **"OK"** to start transmitting specified results to the data management software.

6.2.6.2 Transmit all data

1. Tap **"Comm."**. The following dialog box will display.
2. Tap the **"All"** radio button.
3. Tap **"OK"** to start transmitting all results to the data management software.

6.2.7 Delete (for Administrators Only)

1. Select the sample record to be deleted.
2. Tap the **Delete** button, the following dialog box will display.



3. Select **Selected** or **All** in the **Deletion Range** area.
4. Tap **OK** to delete the record. The dialog box will be closed.

6.2.8 Trend Graph

Tap the **Trend Graph** button to see the trend graph of sample results.



6.2.9 Print

Print reports as per the default report template

Select sample records to be printed, and then tap **Print** to print them.

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7 Using the QC Programs

7.1 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.

This analyzer provides a kind of QC program.

NOTE

- Use the controls and reagents specified by the manufacturer only. Store and use the controls and reagents as instructed by their instructions for use.

7.2 Quality Control

7.2.1 Editing QC Settings (for Administrators Only)

Before running a new lot of controls, you must set up a QC file for each lot of controls.

1. Choose "Menu" > "QC" > "Setup".
2. Enter the QC setup screen.

The screenshot displays the QC Setup interface. At the top, there is a navigation bar with buttons: Menu, Sample Analysis, Table Review, QC (highlighted), Reagent Setup, Diluent, and Print. Below the navigation bar is a table with the following columns: File No., Lot No., Level, Exp. Date, Mode, Control Type, QC Sample ID, and Data/Capacity. The table has 10 rows. At the bottom of the table, there are five buttons: New, Edit, Delete, Clear All, and Count. Below the buttons, there is a status bar showing "WB", "Administrator : Admin", and "01-14-2015 16:02".

You may set up QC information by any of the following two ways.

- Reading the information provided by the manufacturer
- Manual Entry

7.2.1.1 Reading the Information Provided by the Manufacturer

1. Enter the QC setup screen.
2. Tap **"New"**, or select a QC file without QC results, and then tap **"Edit"**.
3. Tap **"Import File"**.

The screenshot shows the QC setup interface. At the top is a navigation bar with icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. Below this are input fields for Lot No., Level (Normal), Exp. Date (MM-DD-YYYY), Mode (WB), Control Type (B30), and QC Sample ID. A table of parameters is displayed, with columns for Parameter, Target, and Limit(#). The table is organized into three sections: WBC, Neu#, Lym#, Mon#, Eos#, Neu%, Lym%, Mon% on the left; Eos%, Eos_P, RBC, HGB, HCT, MCV, MCH, MCHC in the middle; and RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCC, P-LCR on the right. At the bottom are buttons for Import File, Save, and Return. The footer shows File No. 6, WB, Administrator: Admin, and the date/time 07-11-2019 15:29.

Parameter	Target	Limit(#)	Parameter	Target	Limit(#)	Parameter	Target	Limit(#)
WBC			Eos%			RDW-CV		
Neu#			Eos_P			RDW-SD		
Lym#			RBC			PLT		
Mon#			HGB			MPV		
Eos#			HCT			PDW		
Neu%			MCV			PCT		
Lym%			MCH			P-LCC		
Mon%			MCHC			P-LCR		

4. Select the QC file to be imported.
5. Tap **"OK"** to close the dialog box and return to the QC setup screen.
6. Tap **"OK"** to read the selected QC information to the current QC file.

NOTE

- The **"Import target/limits"** check box is selected by default. If it is deselected, the operator must enter the target and limits of QC parameters manually.

7. Select the QC mode.
8. Select **"Control Type"** from the pull-down list.
9. Set **"QC Sample ID"**: if you are used to analyze control together with blood samples, you can set a unique ID for the control. The analyzer will recognize the sample as control when it reads the unique ID. After the analysis completes, the results will be saved into the QC file of the QC sample ID.
10. Tap other icons to switch screen and save the QC information.

7.2.1.2 Manual Entry

1. Enter the QC setup screen.
2. Tap **"New"**, or select a QC file without QC results, and then tap **"Edit"**.
3. Enter the **"Lot No."** of the controls in the edit box manually.

Menu Sample Analysis Table Review QC Reagent Setup Diluent Print

Lot No. BC20519N-1 Level Normal Exp. Date MM-DD-YYYY

Mode WB Control Type B30 QC Sample ID

Parameter	Target	Limit(#)	Parameter	Target	Limit(#)	Parameter	Target	Limit(#)
WBC			Eos%			RDW-CV		
Neu#			Eos_P			RDW-SD		
Lym#			RBC			PLT		
Mon#			HGB			MPV		
Eos#			HCT			PDW		
Neu%			MCV			PCT		
Lym%			MCH			P-LCC		
Mon%			MCHC			P-LCR		

Import File Save Return

File No. 6 WB Administrator : Admin 07-11-2019 15:29

NOTE

- The lot No. shall not be empty; and up to 16 digits can be entered. You can enter characters, numbers, and letters. But Chinese characters are not supported.
4. Select the control level.
 5. Enter the expiration date of the lot.
 6. Select the QC mode.
 7. Select "Control Type" from the pull-down list.
 8. Set "QC Sample ID": if you are used to analyze control together with blood samples, you can set a unique ID for the control. The analyzer will recognize the sample as control when it reads the unique ID. After the analysis completes, the results will be saved into the QC file of the QC sample ID.
 9. Enter the target and limit into the edit boxes according to the package insert of the lot of controls.
 10. Tap other icons to switch screen and save the QC information.

7.2.2 Running Controls

You can select one of the two ways below to run controls:

- Run controls on the QC screen.
- Put controls together with normal samples, and run the controls on the "Sample Analysis" screen

7.2.2.1 Running Controls on the QC Screen

After editing the QC information, you can start QC analysis by one of the following ways according to the selected QC mode.

- Whole blood
- Predilute

⚠ CAUTION

- Running QC sample with error present will lead to unreliable results. If errors are reported during QC analysis, remove the errors first and then continue with the analysis. If errors are reported during QC analysis, remove the errors first and then continue with the analysis.
- Sample agglutination may result in inaccurate analysis results. Check the control samples to see if there is any agglutination, if yes, process the samples according to your laboratory's protocols.

- Tap "Menu" > "QC" > "Count" to enter the QC count screen.

NOTE

- Be sure that the level of the control to be run is the same with the current QC file, and the control is not expired.
- The expiration date of expired controls is displayed in red.

The screenshot shows the QC Count screen with a top navigation bar containing icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. Below the navigation bar are input fields for File No., Lot No., Level, Exp. Date, Mode, Control Type, and QC Sample ID. The main area is divided into two sections: a table of parameters and results, and a section for graphics.

Parameter	Result	Unit	Parameter	Result	Unit
WBC		10 ⁹ /L	RBC		10 ¹² /L
Neu#		10 ⁹ /L	HGB		g/L
Lym#		10 ⁹ /L	HCT		
Mon#		10 ⁹ /L	MCV		fL
Eos#		10 ⁹ /L	MCH		pg
Neu%			MCHC		g/L
Lym%			RDW-CV		
Mon%			RDW-SD		fL
Eos%			PLT		10 ⁹ /L
Eos_P		fL	MPV		fL
			PDW		
			PCT		mL/L
			P-LCC		10 ⁹ /L
			P-LCR		

Below the table are three buttons: Setup, QC Graph, and QC Table. To the right of the table are four empty graphs labeled WBC, EOS, RBC, and PLT. At the bottom right, it says "Administrator : Admin 12-10-2019 17:23".

- Prepare the control as instructed by instructions for use of the controls,
- Run QC analysis:
 - Make sure the analysis mode is "WB" or "PD" and the indicator of the analyzer is green.
 - Shake the vial of sample as instructed by instructions for use of the control to mix the sample thoroughly.
 - Present the control sample to the sample probe. Press the Aspirate key to start QC run.
 - When you hear the beep, remove the control.
- When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

NOTE

- Up to 100 QC results can be saved in each QC file.

- Do the above procedures to continue running QC analysis if necessary.

7.2.2.2 Putting Controls Together with Normal Samples, and Running the Controls on the "Sample Analysis" Screen

After setting special "QC Sample ID" for a control under the QC setup screen, you can put the control together with normal samples, and run it under the "Sample Analysis" screen.

When editing worklist or entering next sample information in the "Next Sample" dialog box before daily analysis, enter the special "QC Sample ID" as "Sample ID".

Based on the QC mode selected, you can choose to run QC analysis from one of the following ways:

- Whole blood
 - Predilute
1. Prepare the control as instructed by instructions for use of the controls.
 2. Refer to *Section 5.4 Sample Preparation* to prepare samples under whole blood and predilute modes.
 3. When it is ready to run a sample (i.e., the analyzer indicator is steady green), present the sample under the sample probe, and press the Aspirate key to start QC run.
 4. When you hear the beep, remove the control.
 5. When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

NOTE

- Up to 100 QC results can be saved in each QC file.

6. Do the above procedures to continue running QC analysis if necessary.

7.2.3 Reviewing QC Results

After QC analysis, you can review the QC results in the following ways:

- QC Graph
- QC Table

7.2.3.1 QC Graph Review

1. Tap the "QC Graph" button on the QC count screen to enter the corresponding QC graph screen.



2. You can tap the arrow buttons on the right of the graph to browse graphs of the parameters. You can tap the arrow buttons under the graph horizontally to browse all the QC results.

NOTE

- If a parameter target/limits of the QC files with QC results are modified and saved, and the targets/limits of other parameters changes accordingly, those changed data will be highlighted in yellow.

Print

Tap the **"Print"** icon in the status bar to print information of the current QC file and the QC graph of all parameters.

NOTE

- The green vertical line and values of the corresponding QC points will not be printed.

7.2.3.2 QC Table Review

1. Tap the **"QC Table"** button on the QC count screen to enter the corresponding QC table screen.

File No.	2	Lot No.	B1119N	Level	Normal	Exp. Date	02-05-2020	
Mode	WB	Control Type	BC-3D	QC Sample ID				
	Date	Time	WBC	Neu#	Lym#	Mon#	Eos#	Neu%
Target	/	/	7.90	4.22	2.54	0.53	0.61	0.534
Limit(#)	/	/	1.30	0.90	0.80	0.53	0.61	0.100
*5	11-22-2019	16:06	7.59	3.97	2.54	0.43	0.65	0.524
4	11-22-2019	16:03	7.82	4.10	2.51	0.49	0.72	0.524
3	11-22-2019	16:01	7.58	3.86	2.56	0.46	0.70	0.509
2	11-22-2019	16:00	7.39	3.98	2.39	0.44	0.58	0.538
1	11-22-2019	15:57	7.28	3.78	2.40	0.52	0.58	0.518

2. You can tap the arrow buttons on the right of the QC table to browse all QC records. You can tap the arrow buttons under the QC table to browse all the parameter results.

NOTE

- If a parameter target/limits of the QC files with QC results are modified and saved, and the targets/limits of other parameters changes accordingly, those changed data will be highlighted in yellow.

Delete (for Administrators Only)

1. Tap **"Delete"**, the following dialog box will display.

2. Tap **"Yes"** to delete the selected records.

NOTE

- The operation will be recorded in the system log.

Print

You can tap the **"Print"** icon in the status bar to print the QC table.

Communication

To transmit QC data to external data management software or HIS/LIS, tap the "**Comm.**" button to transmit specified results to the data management software.

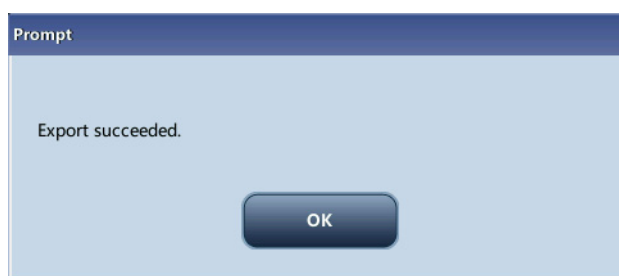
NOTE

- If auto-communication is enabled and a sample is run during the transmission of the QC data, then only when the QC data transmission finished will the auto-communication of the sample result start.
- The QC data saved in the process of transmission will not be transmitted.

Export

To export QC information and results of the current QC file, do as follows:

1. Insert an USB and then tap "**Export**".
2. The system will detect the USB and export data automatically.
3. The prompt "**Export succeeded.**" will display.



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8

Calibrating Your Analyzer

8.1 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 two calibration programs available on this analyzer: manual calibration and auto calibration using calibrators; and two calibration modes, namely "WB" and "PD".

All the parameters or part of the parameters of WBC, RBC, HGB, MCV and PLT can be calibrated by the calibration programs.

NOTE

- **Calibration procedures can only be performed by users of the administrator-level.**
- **Use the calibrators and reagents specified by the manufacturer only. Store and use the calibrators and reagents as instructed by their instructions for use.**
- **Calculation of repeatability is included in the calibration procedure.**

8.2 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:

- 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.**

8.3 How to Calibrate

8.3.1 Preparing Your Analyzer

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.

8.3.2 Manual Calibration (for Administrators Only)

Tap "Calibration" > "Manual" in the menu to enter the following screen.

Calibration Factor

WB			PD		
Parameter	Calibration Factor (%)	Date	Parameter	Calibration Factor (%)	Date
WBC	100.00	03-12-2012	WBC	100.00	03-12-2012
RBC	100.00	03-12-2012	RBC	100.00	03-12-2012
HGB	100.00	03-12-2012	HGB	100.00	03-12-2012
MCV	100.00	03-12-2012	MCV	100.00	03-12-2012
PLT	100.00	03-12-2012	PLT	100.00	03-12-2012

Administrator : Admin 07-11-2019 15:44

NOTE

- If you log in at the operator access level, you can only view the calibration factors. To perform calibration, please log out and then log in at the administrator access level.

Do as follows to calibrate the analyzer.

1. On the manual calibration screen, check the calibration factors and calculate the new factors per the following equation:

$$\text{New calibration factor} = \frac{\text{Current calibration factor} \times \text{Reference value}}{\text{Mean}}$$

For example: Suppose the WBC reference value of a calibrator is 8.4, and the current calibration factor of the whole blood mode is 98.90%.

Run the calibrator in whole blood mode for 10 consecutive times and take the WBC results to calculate: 8.1, 8.0, 8.1, 8.1, 8.3, 8.3, 8.2, 8.0, 8.1, 8.3. The obtained CV is 1.5% and Mean is 8.16, which meet the requirements.

The new calibration factor is obtained:

$$\text{New calibration factor} = \frac{98.90\% \times 8.4}{8.16} = 101.81\%$$

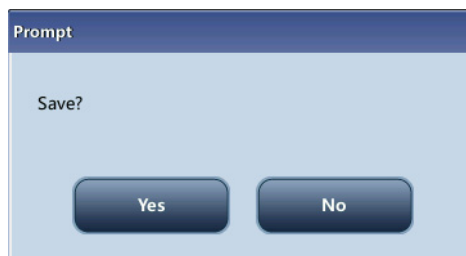
The calculated calibration factors shall be between 75.00% and 125.00%. In case of an invalid calibration factor, try to find out the reason (e.g. calibration material not thoroughly mixed, misoperation, etc.). Then recalibrate the analyzer and recalculate the calibration factors.

2. Enter the new calibration factors into the factor cell of the parameter that require calibration.
3. When you switch screen after entering the new calibration factor, a prompt will display.
 - ◆ If the entered calibration factors are valid, a dialog box will pop up asking you to save the new factor when you are exiting the screen. And the calibration date of the corresponding parameter changes to current system date.
 - ◆ If the entered calibration factors are invalid, a dialog box will pop up prompting "Invalid factor entered, exit?" when you are switching to another screen. The new calibration factor will not be saved, and the calibration date will not be refreshed.

8.3.2.1 Other Operations

Print

- Tap **"Print"** to print the current calibration factor.
- If the calibration factors are invalid, you will not be able to print them and the dialog box **"New calibration factor is invalid."** will display.
- If the calibration factors are valid but not saved, a dialog box will display asking you to save the factors.



Tap **"Yes"** to save and print the factors. Or tap **"No"** to cancel the operation without saving or printing them.

8.3.3 Calibration with Calibrator (for Administrators Only)

Tap **"Calibration"** > **"Calibrator"** in the menu to enter the following screen.

Menu Sample Analysis Table Review QC Reagent Setup Diluent Print							
Lot No.		Select	WBC	RBC	HGB	MCV	PLT
	Target						
	1						
Exp. Date	2						
MM - DD - YYYY	3						
	4						
Analysis Mode	5						
WB	6						
PD	7						
	8						
	9						
	10						
Import File	Mean						
	CV (%)						
Export	New Factor (%)						
	Old Factor (%)		100.00	100.00	100.00	100.00	100.00
Mode WB			Administrator : Admin 12-10-2019 17:23				

NOTE

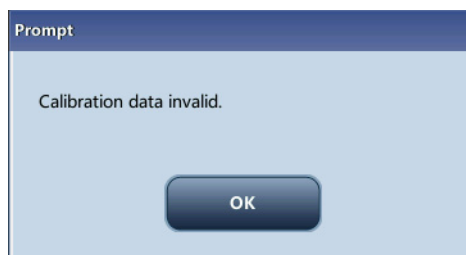
- Only Mindray-specified calibrators shall be used. Mindray will not be responsible for any erroneous result caused by using other calibrators.
- See the instruction for use of the calibrators for the lot No., expiration date and the target.
- The out-of-range CV% does not influence the display of calibration factors.

Do as follows to calibrate the analyzer with calibrators.

1. Check the **"Analysis Mode"** on the analyzer screen.
2. Enter the lot No. of the calibrator into the **"Lot No."** field.
3. Enter the **"Exp. Date"**. The expiration date defaults to the current system date. When you need to modify it, tap the **"Exp. Date"** edit box, and reset the date. The expiration date shall not be earlier than the current system date.

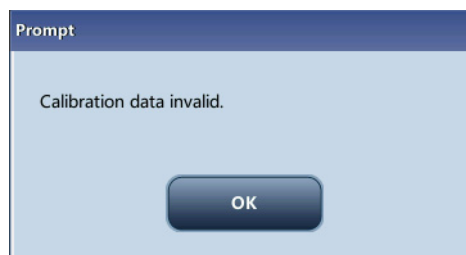
The entered expiration date should be either the expiration date printed on the instructions for use or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: the date that container is opened + the open-container stability days.

4. Enter the targets into the "**Target**" cells.
5. Prepare the calibrator as instructed by instructions for use of the calibrators.
6. Press the Aspirate key to start calibration.
7. When the current calibration is done, the progress bar will close. The analyzer will have different responses to different analysis results.
 - ◆ If there is a parameter whose calibration data is out of its linearity range but still within the display range, then the calibration data will be displayed in the list and a message box will also pop up.



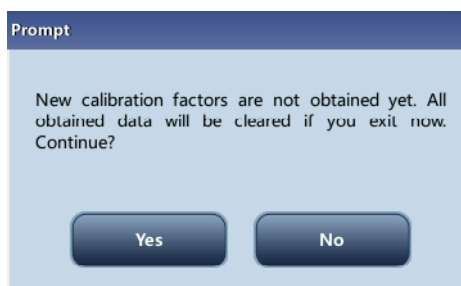
Tap "**OK**" to close the message box, and the data will be deleted from the table without saving automatically.

- ◆ If there is a parameter whose calibration data is out of the display range, then the non-numeric parameter values "****" will be displayed in the list and a message box will pop up.



Tap "**OK**" to close the message box, and the data will be deleted from the table without saving automatically.

- ◆ The valid results within the linearity range will be displayed directly. Valid calibration results will be marked with "√" per the default setting, and will be taken to calculate calibration factors.
- ◆ If the calibration factors have not been calculated but you switch to another screen, then a message box will pop up.



Tap "**Yes**" to switch to another screen while discarding the calibration data and closing the message box. The original calibration factors remain.

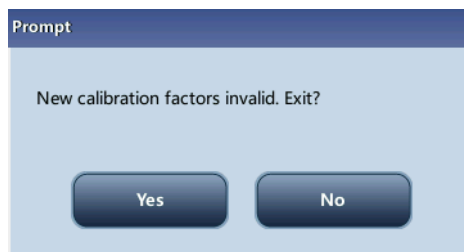
8. When calibration count has been performed to a sample for n times ($n \geq 5$), the analyzer will calculate the Mean, CV% and calibration factors of all the calibration data marked with "√" (calibration data of the first run is not marked with "√", so it is not included in the calculation).

You can select several data to calculate the calibration factors, but only after at least 5 groups of the data are marked with "√" can you get the calibration factors. The calibration factors will be refreshed whenever you select "√" or deselect "√".

When the amount of valid calibration data in the list reaches 10, a message box **"Calibration is completed."** will pop up. Then, if you press the Aspirate key again, the analyzer will beep without starting analysis.

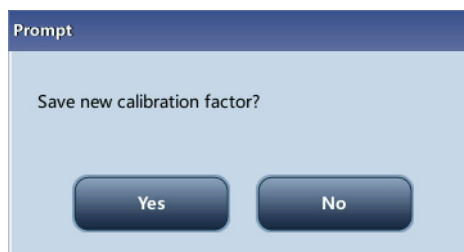
9. There may be two cases when you are switching to another screen:

- ◆ If the calibration factors of any parameter is out of the range [75%-125%] or the CV% of any parameter exceeds the repeatability range, then the calculated calibration factors of all parameters will not be saved and a message box will also pop up.



Tap **"Yes"** to close the dialog box and switch to another screen. The calibration factors and dates of all parameters will not be changed.

- ◆ If the calculated calibration factors of all parameter are within the range [75%-125%] and the CV% of all parameter are also within the repeatability range, then a message box will pop up.

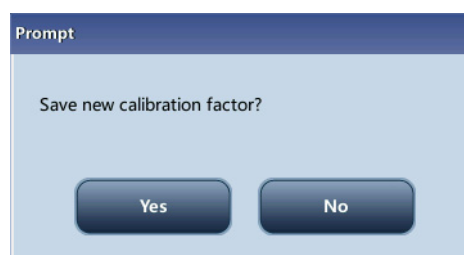


Tap **"Yes"** to save the new calibration factors while closing the message box and switching to another screen.

8.3.3.1 Other Operations

Print

- If the calibration factors are invalid, tap print, the dialog box **"New calibration factor is invalid."** will display.
- If the calibration factors are valid, tap **"Print"**, a dialog box will display.



Tap **"Yes"** to close the dialog box, save and print the calibration results. Or tap **"No"** to cancel the operation without saving or printing them.

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9 Customizing the Analyzer Software

9.1 Introduction

The analyzer is a flexible laboratory instrument that can be tailored to your work environment. You can customize the software options as introduced in this chapter.

Menu functions are introduced as below.

See the following figure for the setup menu.



9.2 Setup

9.2.1 System Setup

9.2.1.1 Date/Time Setup

Tap the menu option **"Setup"** > **"System Setup"** > **"Date/Time Setup"** to enter the **"Date/Time Setup"** screen as shown below. You can set up the date, time and date format of the analyzer at the screen.

Menu Sample Analysis Table Review QC Reagent Setup Diluent Print

Date 07 - 11 - 2019

Time 15 : 46 24 hours

Date Format MM-DD-YYYY ▼

Administrator : Admin 07-11-2019 15:46

9.2.1.2 Print Setup

Tap the menu option **"Setup"** > **"System Setup"** > **"Print Setup"** to enter the **"Print Setup"** screen as shown below. You can set up the following contents:

- **Print Setup**
- **Printing content**
- **Auto print after sample analysis**

Print Setup

■ Print Device

You can select "**Printer**" or "**Recorder**" from the "**Print Device**" pull-down list.

■ Printer Driver

Tap the pull-down list to select printer driver of the analyzer.

■ Paper

Tap the pull-down list to select the paper of the reports to be printed.

Paper	A4
Report Title	A4
	A5

■ Report Title

Report Title	Hematology Analysis Report
--------------	----------------------------

■ Report Template

Report Template	One page with histogram
Para. Language	One page with histogram
	One page without histogram

■ Para. Language

English abbreviation parameter names are displayed.

■ Copies

Enter the number of copies to be printed for each report into the edit box "**Copies**".

Copies	1	[1, 20]
--------	---	---------

Printing content

You can choose to select the functions based on your needs by tapping on the check boxes.

Printing content

☐ Prompt for abnormal printing

Auto print after sample analysis

You can choose to disable auto print or set up printing conditions.

9.2.1.3 Communication

Tap the menu option "**Setup**" > "**System Setup**" > "**Communication**" to enter the communication setup screen as shown below. You can set up the following contents:

- **Communication**
- **Network Device**
- **Protocol Setup**
- **Transmission Mode**

Communication

You can select "**Network port comm.**" or "**Serial port comm.**".

Network Device

You can select "**Wireless**" or "**Wired**" from the "**Network Type**" pull-down list.

If you select "**Wireless**", tap the wireless network setup icon  , and choose a Wi-Fi hot spot from the popped out dialog box to establish connection.

Protocol Setup

Tap the "**IP Address**", "**Subnet Mask**" and "**Default Gateway**" edit boxes to enter the contents.

■ Comm Protocol

Tap the "**Comm Protocol**" pull-down list to select the communication protocol.

Transmission Mode

You can select the functions based on your needs by tapping on the check boxes.

1. **ACK Synchronous Transmission**
2. **Auto Retransmit**
3. **Auto Communicate**
4. **Transmit as Print Bitmap Data**

■ ACK Synchronous Transmission

Tap the "**ACK Synchronous Transmission**" check box to activate the function.

When the function is activated, ACK overtime is 10 seconds by default. You can re-enter the ACK overtime in the edit box.

■ Histogram transmitted as

Tap the drop-down list to select the transmission mode of histogram.

1. **Not to be transmitted**
2. **Bitmap**

9.2.1.4 Manage Animal Type

1. Choose **"Setup" > "System Setup" > "Manage Animal Type"** to enter the following screen.

Menu Sample Analysis Table Review QC Reagent Setup Diluent Print

Custom Species	Source Species
----------------	----------------

Add Delete

Administrator : Admin 07-11-2019 15:48

2. Tap **"Add"** to add an animal type.

Menu Sample Analysis Table Review QC Reagent Setup Diluent Print

Custom Species

Custom Species

Source Species

OK Cancel

Add Delete

Administrator : Admin 07-11-2019 15:49

3. Select a record, and then tap **Delete** to delete an animal type.



9.2.1.5 Shortcut Code Setup

Tap the menu option **Setup** > **System Setup** > **Shortcut Code Setup** to enter the screen as shown below. This function allows you to set up shortcut codes for the contents on the **Next Sample** screen and the **Edit Info** screen of **Table Review**.



- Add shortcut codes
 1. Tap **Add**, a line will be added in the table.
 2. Enter the **Name**, **Shortcut Code** and **Digital Code** based on your needs.
- Edit shortcut codes
 1. Select the line of the shortcut code to be edited.
 2. Modify it directly in the table.

■ Delete shortcut codes

1. Select the line of the shortcut code to be deleted.
2. Tap "**Delete**" to delete a line of information.

9.2.1.6 Lab Info Setup

Tap the menu option "**Setup**" > "**System Setup**" > "**Lab Info Setup**" to enter the screen as shown below. Operators may enter, save and view lab information. Tap on the edit boxes to enter the information.

Hospital Name	
Lab Name	
Supervisor	
Contact Info	
Zip Code	
Analyzer Model	
Analyzer SN	KF-31170006
Date of Installation	05 - 13 - 2019
Customer service contact person	
Customer service contact info	
Comments	

Administrator : Admin 07-11-2019 15:51

NOTE

- The analyzer SN cannot be edited.
- The date of installation is the date the analyzer is installed by default. It can be edited, but cannot be later than the current system date.

9.2.2 Access Setup

Tap **"Setup"** > **"Access Setup"** in the menu to enter the following screen.



9.2.2.1 Add New User

1. Tap **"New"**. The following dialog box displays.

Add User

User ID:

Name:

Password:

Confirm Password:

Access Level: ☒ Operator ☐ Administrator

OK Cancel

2. Enter the **"User ID"**, **"Name"** and **"Password"** information. The **"User ID"** refers to your login account; and the **"Name"** will be displayed in the **"Operator"** field on the **"Table Review"** screen and on the printed reports.
3. Select the access level of the user:
 - ◆ **Administrator**
 - ◆ **Operator**
4. Tap **"OK"** to save the change and close the dialog box.

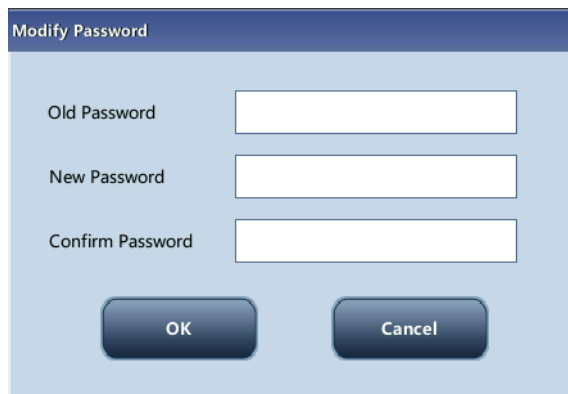
NOTE

- The user ID cannot be null and up to 12 characters can be entered.
- The password can be null and up to 12 characters can be entered.
- The name cannot be null and up to 20 characters can be entered.

9.2.2.2 Modify Password

You can modify your own password.

1. Select the current user, and then tap "**Modify Password**". The following dialog box will display.

A screenshot of a 'Modify Password' dialog box. The dialog has a title bar at the top. Below the title bar, there are three text input fields labeled 'Old Password', 'New Password', and 'Confirm Password'. At the bottom of the dialog, there are two buttons: 'OK' and 'Cancel'.

2. Enter the required information in the text boxes.
3. Tap "**OK**" to save the change and close the dialog box.

NOTE

- Up to 12 characters can be entered.

9.2.2.3 Delete User

Select a user and then tap "**Delete**" to delete it.

NOTE

- The current login user cannot be deleted.

9.2.3 Auxiliary Setup

Tap "**Setup**" > "**Auxiliary Setup**" in the menu to enter the following screen. You can set up the following contents:

- Setting of the next sample
- Setting of the first sample after startup
- Other Settings

The screenshot shows the 'Setting of the next sample' section with the following options:

- Entry of next sample ID: Auto Increase (selected from a dropdown)
- Not counted as an auto increase character: 0 (text input)
- Auto fill info.: On (radio button selected)

The 'Setting of the first sample after startup' section shows:

- First sample after startup: Custom (selected from a dropdown)
- Sample ID: 1 (text input)

The 'Other settings' section shows:

- Predilute Mode Prompt: On (radio button selected)
- Pop-Up Keyboard: On (radio button selected)
- Flags: High H (selected from a dropdown), Low L (selected from a dropdown)

At the bottom right, it says 'Administrator : Admin 07-11-2019 15:53'.

9.2.3.1 Setting of the Next Sample

This close-up shows the 'Setting of the next sample' section with the following options:

- Entry of next sample ID: Auto Increase (selected from a dropdown)
- Not counted as an auto increase character: 0 (text input)
- Auto fill info.: On (radio button selected)

Entry of next sample ID

Tap the pull-down list to select the way to enter the next sample ID.

- **Auto Increase**
- **Manual Entry**

Not counted as an auto increase character

Operators can set up the number of characters in the sample ID that will not be auto increased.

When "**Auto Increase**" is selected as the way to enter the next sample ID, this edit box will be activated.

Enter a number (n) into the edit box of "**Not counted as an auto increase character**". The first n characters in the sample ID will not be auto increased.

9.2.3.2 Setting of the First Sample after Startup

Operators may:

customize the first sample ID after startup by entering it into the edit box, or select "**Run the suspended sample after restart**".

This close-up shows the 'Setting of the first sample after startup' section with the following options:

- First sample after startup: Custom (selected from a dropdown)
- Sample ID: 1 (text input)

9.2.3.3 Other Settings

Other settings

Predilute Mode Prompt ☒ On ☐ Off

Pop-Up Keyboard ☒ On ☐ Off

Flags High Low

On/Off radio buttons

Select "On" or "Off" to activate or deactivate the functions.

Flags

Operators may set up the high/low flag by entering two characters into the edit boxes, or selecting two letters from the pull-down lists (the default character of high flag is "H", and that of low flag is "L").

9.2.4 Parameter Setup

9.2.4.1 Reference Unit Setup

Tap the menu option "Setup" > "Parameter Setup" > "Reference Unit Setup" to enter the screen as shown below. You can set up parameter unit at this screen.

Parameter	Unit	Format	Parameter	Unit	Format
WBC	10 ⁹ /L	****	HGB	g/L	***
Neu#	10 ⁹ /L	****	HCT		****
Gran#	10 ⁹ /L	****	MCV	fL	****
Lym#	10 ⁹ /L	****	MCH	pg	****
Mon#	10 ⁹ /L	****	MCHC	g/L	****
Eos#	10 ⁹ /L	****	RDW-CV		****
Neu%		****	RDW-SD	fL	****
Gran%		****	PLT	10 ⁹ /L	****
Lym%		****	MPV	fL	****
Mon%		****	PDW		****
Eos%		****	PCT	mL/L	****
Eos_P	fL	****	P-LCC	10 ⁹ /L	****
RBC	10 ¹² /L	****	P-LCR		****

Unit System:
International

Default

Administrator : Admin 12-09-2019 15:11

■ Select unit system

Tap the "Unit System:" pull-down list to select unit system.

■ Customizing parameter units

Under each unit system, you can tap the "Unit" cell to customize the parameter unit. Tap the "Default" button to restore the default units.

Parameter	Unit	Format	Parameter	Unit	Format
WBC	10 ⁹ /L	***.##	HGB	g/L	***
Neu#	10 ⁹ /L	***.##	HCT		*.***
Gran#	10 ⁹ /L	***.##	MCV	fL	***.##
Lym#	10 ⁹ /L	***.##	MCH	pg	***.##
Mon#	10 ⁹ /L	***.##	MCHC	g/L	***.##
Eos#	10 ⁹ /L	***.##	RDW-CV		*.***
Neu%		*.***	RDW-SD	fL	***.##
Gran%		*.***	PLT	10 ⁹ /L	***.##
Lym%		*.***	MPV	fL	***.##
Mon%		*.***	PDW		***.##
Eos%		*.***	PCT	mL/L	***.##
Eos_P	fL	***.##	P-LCC	10 ⁹ /L	***.##
RBC	10 ¹² /L	***.##	P-LCR		*.***

Unit System: International

Unit option: 2

10⁹/L
10³/uL
10²/uL
/nL

Default

Administrator : Admin 12-09-2019 15:11

NOTE

- The units displayed will be different when different unit system is selected.

9.2.4.2 Reference Range Setup

Tap the menu option "Setup" > "Parameter Setup" > "Reference Range Setup" to enter the screen as shown below. 8 factory reference group and 10 customized reference groups are provided for your choice. Each laboratory shall select a proper reference range of its own based on its patient demographics. The reference range differs among animal types, genders, ages and geographic locations.

Parameter	Lower Limit	Upper Limit	Parameter	Lower Limit	Upper Limit
WBC	6.00	17.00	MCV	60.0	76.0
Neu#	3.60	12.30	MCH	20.0	27.0
Lym#	0.80	4.90	MCHC	300	380
Mon#	0.00	2.00	RDW-CV	0.125	0.172
Eos#	0.00	1.60	RDW-SD	33.2	46.3
Neu%	0.520	0.850	PLT	117	490
Lym%	0.120	0.330	MPV	8.0	14.1
Mon%	0.000	0.130	PDW	12.0	17.5
Eos%	0.000	0.100	PCT	0.90	5.80
RBC	5.10	8.50	P-LCC	28	92
HGB	110	190	P-LCR	0.105	0.476
HCT	0.330	0.560			

Species: Dog

Ref. group: Dog Default

Default
Edit
New
Delete

Administrator : Admin 07-11-2019 15:54

Customizing reference groups

1. New: Tap **"New"** to add a new reference group.

The screenshot shows the 'New' button highlighted with a red rectangle. The interface includes a top navigation bar with icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. Below this is a table of parameters with their lower and upper limits. To the right of the table are dropdown menus for 'Species' (set to 'Dog') and 'Ref. group' (set to 'Dog Default'). Below these are buttons for 'Default', 'Edit', 'New' (highlighted), and 'Delete'. At the bottom, it shows 'Administrator : Admin' and the date '07-11-2019 15:54'.

Parameter	Lower Limit	Upper Limit	Parameter	Lower Limit	Upper Limit
WBC	6.00	17.00	MCV	60.0	76.0
Neu#	3.60	12.30	MCH	20.0	27.0
Lym#	0.80	4.90	MCHC	300	380
Mon#	0.00	2.00	RDW-CV	0.125	0.172
Eos#	0.00	1.60	RDW-SD	33.2	46.3
Neu%	0.520	0.850	PLT	117	490
Lym%	0.120	0.330	MPV	8.0	14.1
Mon%	0.000	0.130	PDW	12.0	17.5
Eos%	0.000	0.100	PCT	0.90	5.80
RBC	5.10	8.50	P-LCC	28	92
HGB	110	190	P-LCR	0.105	0.476
HCT	0.330	0.560			

NOTE

- The name of the reference group cannot be null.
- The names of the customized reference groups must be different from the names of the 8 default groups and they shall not repeat each other either.

2. Default: Tap the **"Default"** button, the reference ranges of the selected factory reference group can be restored to the default settings.

The screenshot shows the 'Default' button highlighted with a red rectangle. A confirmation dialog box is displayed in the center, asking 'Restore reference range of all parameters in current reference group?' with 'Yes' and 'No' buttons. The 'Yes' button is also highlighted with a red rectangle. The background interface is the same as the previous screenshot, but the 'Ref. group' dropdown is now set to 'Custom Group 2'.

Parameter	Lower Limit	Upper Limit	Parameter	Lower Limit	Upper Limit
WBC	6.00	17.00	MCV	60.0	76.0
Neu#	3.60				
Lym#	0.80				
Mon#	0.00				
Eos#	0.00				
Neu%	0.520				
Lym%	0.120				
Mon%	0.000				
Eos%	0.000	0.100	PCT	0.90	5.80
RBC	5.10	8.50	P-LCC	28	92
HGB	110	190	P-LCR	0.105	0.476
HCT	0.330	0.560			

3. Edit: Select a reference group and tap **"Edit"** to enter the reference group setup screen.

Parameter	Lower Limit	Upper Limit	Parameter	Lower Limit	Upper Limit
WBC	6.00	17.00	MCV	60.0	76.0
Neu#	3.60	12.30	MCH	20.0	27.0
Lym#	0.80	4.90	MCHC	300	380
Mon#	0.00	2.00	RDW-CV	0.125	0.172
Eos#	0.00	1.60	RDW-SD	33.2	46.3
Neu%	0.520	0.850	PLT	117	490
Lym%	0.120	0.330	MPV	8.0	14.1
Mon%	0.000	0.130	PDW	12.0	17.5
Eos%	0.000	0.100	PCT	0.90	5.80
RBC	5.10	8.50	P-LCC	28	92
HGB	110	190	P-LCR	0.105	0.476
HCT	0.330	0.560			

Species: Dog

Ref. group: Custom Group 2

Buttons: Default, Edit, New, Delete

Administrator : Admin 07-11-2019 15:56

You can set up the name and parameter range. Tap **"Save"** to save the changes.

Parameter	Lower Limit	Upper Limit	Parameter	Lower Limit	Upper Limit
WBC	6.00	17.00	MCV	60.0	76.0
Neu#	3.60	12.30	MCH	20.0	27.0
Lym#	0.80	4.90	MCHC		
Mon#	0.00	2.00	RDW-CV		
Eos#	0.00	1.60	RDW-SD		
Neu%	0.520	0.850	PLT		
Lym%	0.120	0.330	MPV	8.0	14.1
Mon%	0.000	0.130	PDW	12.0	17.5
Eos%	0.000	0.100	PCT	0.90	5.80
RBC	5.10	8.50	P-LCC	28	92
HGB	110	190	P-LCR	0.105	0.476
HCT	0.330	0.560			

Species: Dog

Ref. group: Group 3

Buttons: Default, Save, New, Delete

Administrator : Admin 07-11-2019 15:58

4. Tap **"Delete"** to delete the current customized reference group.

Parameter	Lower Limit	Upper Limit	Parameter	Lower Limit	Upper Limit
WBC	6.00	17.00	MCV	60.0	76.0
Neu#	3.60	12.30	MCH	20.0	27.0
Lym#	0.80	4.90	MCHC	300	380
Mon#	0.00	2.00	RDW-CV	0.125	0.172
Eos#	0.00	1.60	RDW-SD	33.2	46.3
Neu%	0.520	0.850	PLT	117	490
Lym%	0.120	0.330	MPV	8.0	14.1
Mon%	0.000	0.130	PDW	12.0	17.5
Eos%	0.000	0.100	PCT	0.90	5.80
RBC	5.10	8.50	P-LCC	28	92
HGB	110	190	P-LCR	0.105	0.476
HCT	0.330	0.560			

Species: Dog

Ref. group: Custom Group 3

Buttons: Default, Edit, New, **Delete**

Administrator : Admin 07-11-2019 15:58

NOTE

- The name and parameter range of default reference group cannot be modified or deleted.

9.2.5 Maintenance(for Administrators Only)

Tap **"Setup"** > **"Maintenance"** in the menu to enter the following screen. You can set up the following contents:

Standby

Wait: 90 [10, 90] minutes

Probe Cleanser Maintenance

Time-based maintenance: 16 : 00 [00:00, 23:59]

Remind every: 10 [5, 10] min

Administrator : Admin 07-11-2019 15:59

9.2.5.1 Standby

Tap the text box **"Wait"** and enter the waiting time before entering the standby status. The range is 10 - 90 minutes, and the default setting is 15 minutes.

9.2.5.2 Probe Cleanser Maintenance

If the probe cleanser maintenance procedure is not performed for 7 days, or 100 samples have been tested from the last maintenance, the analyzer will carry out the probe cleanser maintenance.

Set the start time of the maintenance in the **"Time-based maintenance"** box, and set the remind time of probe cleanser maintenance by entering a value in the remind dialog box.

9.2.6 Reagent Setup

Tap "**Setup**" > "**Reagent Setup**" in the menu to enter the following screen.

The screenshot shows the 'Reagent Setup' screen with a top navigation bar containing icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup (selected), Diluent, and Print. The main area is divided into two panels: 'Diluent' and 'Lyse'.

Diluent Panel:

- Open Date: 07 - 05 - 2019
- Exp. Date: 07 - 11 - 2019
- Use Before: 07 - 11 - 2019
- Residual Volume: 15.941 L
- Replace button

Lyse Panel:

- Open Date: 07 - 05 - 2019
- Exp. Date: 09 - 11 - 2019
- Use Before: 09 - 02 - 2019
- Residual Volume: 422.790 mL
- Replace button

At the bottom right, it says 'Administrator : Admin 07-11-2019 16:00'.

You can use this program to replace the reagent in fluidics after replacing a new container of reagent or as needed.

Replacing the diluent:

1. Tap "**Replace**". The following page is displayed.

The screenshot shows a 'Reagent Information' dialog box with the following fields:

- Reagent Name: Diluent
- Exp. Date: 07 - 11 - 2019
- Residual Volume: 15.941 L

Below the fields, there are instructions:

1. Use a new reagent to replace the old one.
2. Tap the reagent card to the RFID area, the analyzer will replace the reagent automatically after successfully reading this card.

At the bottom is a 'Cancel' button.

2. Follow instructions on the screen to replace the diluent. After successful replacement, the reminder page disappears.

Note: Tap "**Cancel**" to terminate the reagent replacement. Perform the procedures above to replace other reagents if necessary.

NOTE

- The diluent must be kept still for at least a day after long-term transportation.
- When you have changed the diluent, lyse or rinse, run a background test to see if the results meet the requirement.
- Once the reagent volume is recharged to the analyzer successfully, this reagent card can be used only in the current analyzer.

You should replace reagents when:

- the reagent ran out and a new container of reagent is installed.
- the reagent in the tubing is contaminated.
- there are bubbles in the tubing.

You can replace the following reagents in the fluidics:

- Diluent
- Lyse
- Whole container/bottle of reagent

9.2.7 Gain Setup (for Administrators Only)

Tap **"Setup" > "Gain Setup"** in the menu to enter the following screen. Gain setup function allows you to adjust the digital potentiometers. The operation shall not be performed frequently.

9.2.7.1 Setup

	Gain Factor (%)	Adjustment Rate(%)
WBC Width	99.20	100.0%
RBC Width	98.20	100.0%

	Set Value	Adjustment Rate(%)	Blank Volt.(V)
MCP	156	100.0	/
WCP	101	100.0	/
HGB B.V.	22	/	4.12

Auto Cal HGB B.V.

Administrator : Admin 07-11-2019 16:00

9.2.7.2 HGB Gain

Tap the **"Auto Cal HGB B.V."** button to set the HGB background voltage to 4.2 V.

9.3 Saving the Settings

To save the modified settings, you may switch to another screen, the following dialog box will display.

Prompt

Save?

Tap **"Yes"** to save the settings and switch to the corresponding screen. Tap **"No"** to switch to the corresponding screen without saving the settings.

10 Servicing 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.



BIOLOGICAL RISKS

- All the analyzer components and surfaces are potentially infectious, so take proper protective measures for operation and maintenance.
 - Before maintaining, transporting or servicing the instrument, clean and sterilize the instrument cover as well as the parts and components with biological risks (such as the sample probe). Remind the persons who handle the instrument of the related risks.
 - Discard the system according to government regulations.
-



WARNING

- Do not use any decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in it. If there is any doubt about the compatibility of the decontamination or cleaning agents with parts of the equipment or with material contained in it, please contact our customer service department or the local distributor.
 - If you accidentally spill hazardous material on the instrument, clean and sterilize the instrument with specified disinfectant. Wear proper personal protective equipment (such as lab coat, gloves, and goggles) and follow safe laboratory procedures when performing clean and sterilization procedures.
 - If any of the pipes or fluidic components are worn out, stop using the analyzer and contact Mindray customer service department immediately for inspection or replacement.
 - Check the equipment state after repair. Make sure the equipment is safe before offering it to users.
-



CAUTION

- Improper service may damage the system. Make sure you service the instrument strictly as instructed by this manual.
 - For problems not mentioned in this manual, contact Mindray customer service department for Mindray's service advice.
 - Only parts supplied by Mindray can be used for maintenance. For any questions, contact Mindray customer service department.
 - Exercise caution to avoid contact with the sharp sample probe when performing maintenance.
 - Only use the accessories and consumables manufactured or recommended by Mindray to achieve the promised system performance and safety. For more information, contact Mindray Customer Service Department or your local distributor. Contact the manufacturer or authorized distributors in time if any damaged part is found.
-

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

Maintenance options of the analyzer includes: maintenance, cleaning and fluidics maintenance.

10.2.1 Maintenance

You should maintain the following parts or components when:

Programs	Timing	Purpose
Overall Soak	- Background results are outside the specified range, QC results are abnormal, or other maintenance operations fail to solve the clog error - The analyzer is started up after shutdown due to abnormal power break-off	Clean the fluidics
Clear Aperture	The instrument is clogged	Unclog the instrument
Drain Liquid	Before moving the analyzer	Empty the entire instrument to avoid leakage during moving
WBC bath flushing and zapping	When the clogging error of baths is frequently reported	Clear the WBC bath clogging
RBC bath flushing and zapping		Clear the RBC bath clogging

Tap "**Service**" > "**Maintenance**", and select the "**Maintenance**" tab to enter the following screen.



10.2.1.1 Clear Aperture

Unclogging includes zapping and flushing the aperture. When a clog error is reported, you should unclog the aperture.

The unclogging procedures are:

1. Tap the **"Clear Aperture"** button to start unclogging.
2. When the progress ends, a message will display indicating **"Maintaining finished!"**.
3. Do the above procedures to continue unclogging aperture if necessary. If the error persists, perform probe cleanser maintenance of the related channels.

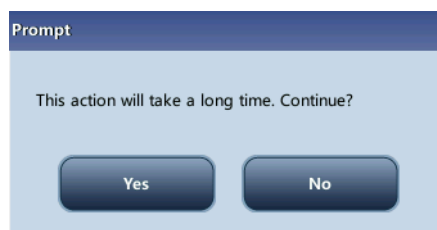
10.2.1.2 Overall Soak

You should perform the overall soak procedure with the probe cleanser when:

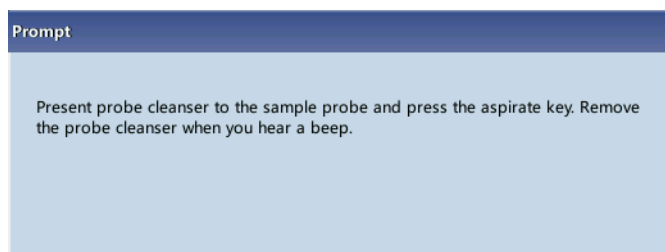
- Background results are outside the specified range, QC results are abnormal, or other maintenance operations fail to solve the clog error.
- the analyzer shuts down due to abnormal power break-off; probe cleanser maintenance must be performed after it is started up again.

The overall soak maintenance procedures with the probe cleanser are as below:

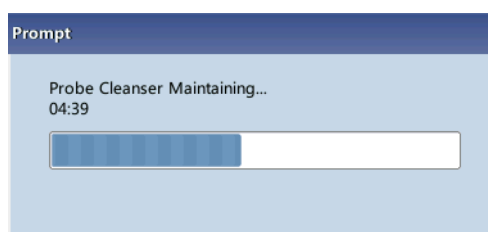
1. Tap the **"Overall Soak"** button. The following dialog box will display.



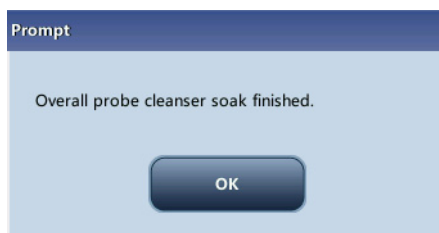
2. Tap **"Yes"**. The analyzer starts to prepare for the maintenance.
3. When the preparation is done, the following dialog box will display.



4. After aspirating probe cleanser, the analyzer performs probe cleanser soak automatically, and a progress bar will display indicating the progress.



5. When the progress ends, the following dialog box will display, click **"OK"** to close the dialog box.



10.2.2 Cleaning

You should clean the following components when:

- WBC and (or) HGB background results exceed their limits, perform WBC bath cleaning. If WBC bath cleaning does not solve the problem, perform WBC probe cleanser maintenance.
- RBC and (or) PLT background results exceed their limits, perform RBC bath cleaning. If RBC bath cleaning does not solve the problem, perform RBC probe cleanser maintenance.
- Sample probe gets dirty, perform sample probe cleaning.

Tap **"Service"** > **"Maintenance"**, and select the **"Cleaning"** tab to enter the following screen.



You may perform cleaning operation to the following components:

- **Fluidics**
- **Sample Probe**
- **WBC Bath**
- **RBC Bath**

The cleaning procedures are:

1. Tap the button of the component you want to clean. The message **"Cleaning in process. Please wait..."** will display.
2. When the progress ends, a message will display indicating **"Cleaning finished!"**.
3. Clean other components as per the above procedures if needed.

10.2.3 Fluidics

Tap "**Service**" > "**Maintenance**", and select the "**Fluidics**" tab to enter the following screen.

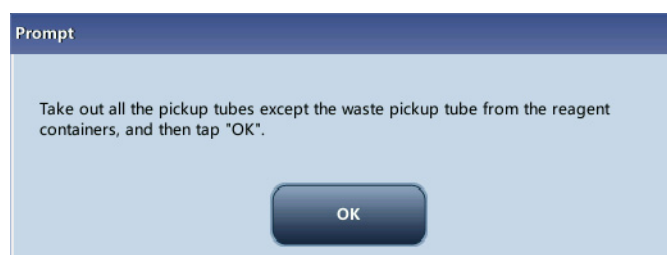


10.2.3.1 Packing up

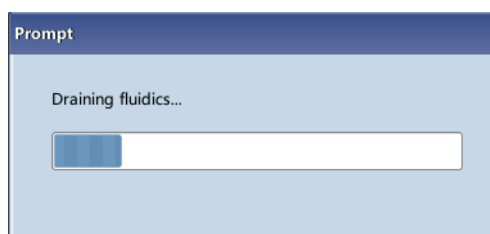
If the analyzer is not to be used for over 2 weeks, you should perform this procedure.

Do as follows to pack up:

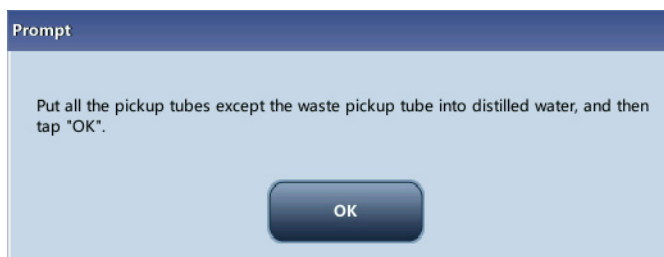
1. Tap "**Pack-up**". The dialog box "**Start pack-up?**" will pop up.
2. Tap "**Yes**" to perform the pack-up procedure. The following dialog box will be displayed.



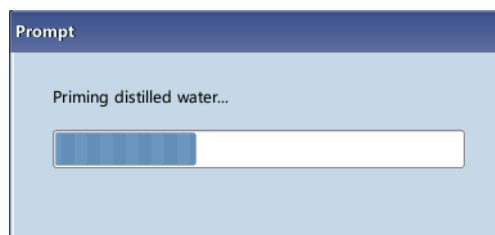
3. Remove all reagent pickup tube assemblies according to the prompt, and then tap the "**OK**" button to start emptying the fluidic system.



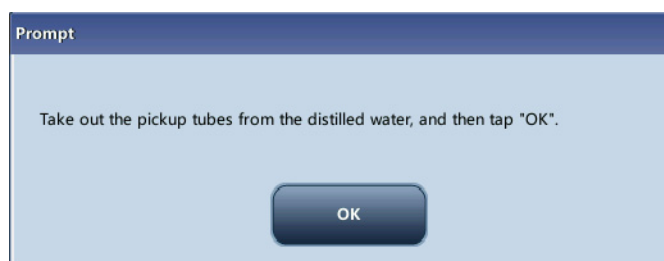
4. After the emptying is completed, a message box will pop up.



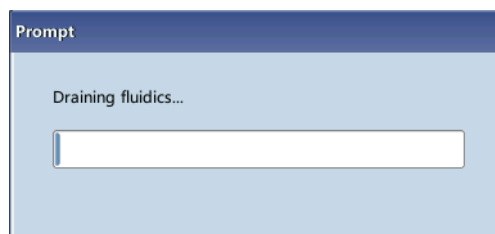
5. Place all reagent pickup tube assemblies into the distilled water, and then tap "**OK**" to start priming.



6. After the priming is done, a message box will display.



7. Take out the tubes as instructed and then tap "**OK**" to drain the fluidics again.



8. After the emptying is completed, a message box will display.



9. Turn off the power switch according to the prompt displayed on the screen.

NOTE

- **This software can still be used after the pack-up.**

10.2.3.2 Resetting the Fluidics

When major components of the analyzer have been replaced, or the fluidic system has been serviced, you must reset the fluidics. Do as follows:

1. Tap the **"Reset"** button, a dialog box will pop up asking you to confirm the operation.
2. Tap **"OK"** to start initialization, the message **"Resetting fluidics. Please wait..."** will be displayed.
3. When the progress ends, a dialog box will display indicating **"Resetting fluidics finished!"**.
4. Do the above procedures to continue resetting fluidics if necessary.

10.2.4 Cover Cleaning



BIOLOGICAL RISKS

- **Mindray does not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.**
-
-



WARNING

- **Do not use any decontamination or cleaning agents which could cause a hazard as a result of a reaction with parts of the equipment or with material contained in it. If there is any doubt about the compatibility of the decontamination or cleaning agents with parts of the equipment or with material contained in it, please contact our customer service department or the local distributor.**
 - **If you accidentally spill hazardous material on the instrument, clean and sterilize the instrument with specified disinfectant. Wear proper personal protective equipment (such as lab coat, gloves, and goggles) and follow safe laboratory procedures when performing clean procedures.**
-
-



CAUTION

- **The user shall perform regular cleaning to the cover of the system. Use the specified materials to clean the equipment only. For any damage to the instrument or other accidents caused by using materials other than specified, Mindray will not provide any warranty.**
 - **Mindray does not claim the validity of the listed chemicals in infection control. For effective control of infection, please consult the Infection Prevention Department of the hospital or the epidemic professionals.**
 - **The cleaning may damage the system to some extent. It is recommended to perform the cleaning only when necessary according to your laboratory protocol.**
-
-

Recommended cleaning materials: water, 70% ethanol; 70% isopropyl alcohol; Cidex 2% Glutaral + Activator.

Prohibited cleaning materials: 3% hydrogen peroxide; Aerodesin 2000, Cidex OPA.

10.3 Self-Test

Select "**Service**" > "**Self-Test**" from the pull-down menu to enter the following screen and perform system and valve self-tests.

The screenshot shows the 'Self-Test' screen with a top navigation bar containing icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. Below the navigation bar, there are two tabs: 'System Self-Test' and 'Valve Self-Test'. The 'Valve Self-Test' tab is active. The main area contains a table with two columns: 'Test Items' and 'Status'.

Test Items	Status
Syringe module	
Probe rotary movement	
Probe vertical movement	
Aperture voltage RBC	
Aperture voltage WBC	

At the bottom right, the status bar shows 'Administrator : Admin' and the date/time '07-11-2019 16:03'.

10.4 Sample Probe Debug

Select "**Service**" > "**Sample Probe Debug**" from the pull-down menu to enter the following screen, where you may initialize the sample probe position and fix the probe height.

The screenshot shows the 'Sample Probe Debug' screen with a top navigation bar containing icons for Menu, Sample Analysis, Table Review, QC, Reagent Setup, Diluent, and Print. The main area is divided into four sections:

- Probe position initialize:** Contains a button labeled 'Initial position'.
- Sample probe horizontal position:** Contains three buttons labeled 'RBC Bath', 'WBC Bath', and 'Aspiration pos.'.
- Fix sample probe height:** Contains a button labeled 'Height-fixed pos.'.
- Vertical aspiration position:** Contains three buttons labeled 'Up', 'Down position', and 'Middle position'.

At the bottom right, the status bar shows 'Administrator : Admin' and the date/time '07-11-2019 16:03'.

10.5 Gain Calibration

Select "**Service**" > "**Gain Calibration**" from the pull-down menu to enter the following screen and calibrate the gains.

Mode WB

	Select	WCP	MCP	WBC Width	RBC Width	HGB B.V.
Target						4.10
1						
2						
3						
4						
5						
6						
Result						

Export

Administrator : Admin 07-11-2019 16:03

10.6 Temperature Calibration

Tap "**Service**" > "**Temperature Calibration**" from the pull-down menu to enter the following screen and calibrate the temperature for diluent and preheat bath.

Diluent temperature Preheat bath temperature

Total difference 0.0 New difference

Machine measurement value 29.8 (°C) Meter measurement value (°C) [10.0, 50.0]

Calculate new diff. Save

Administrator : Admin 07-11-2019 16:04

10.7 Touch Screen Calibration

Tap "**Service**" > "**Calibrate Touchscreen**" in the menu to enter the following screen.



10.8 Advanced Toolbox

Select "**Service**" > "**Advanced Toolbox**" from the pull-down menu to enter the following screen, where you can switch the languages and perform one-key export.



10.9 Log

Tap **"Service"** > **"Log"** in the menu to enter the following screen.



	Date/Time	Operator	Summary	Times	Detail
1	07-11-2019 15:58	Admin (Admi...	Modify reference gro...	1	Modify reference group setting to: Re...
2	07-11-2019 15:55	Admin (Admi...	Modify reference gro...	1	Modify reference group setting to: Re...
3	07-11-2019 15:49	Admin (Admi...	Add Species	1	Add Species: 45 (Dog)
4	07-11-2019 15:48	Admin (Admi...	Delete Species	1	Delete Species: 金毛
5	07-11-2019 15:16	Admin (Admi...	Modify auto mainten...	1	Modify auto maintenance setting to: ...
6	07-11-2019 15:15	Admin (Admi...	Modify auto mainten...	1	Modify auto maintenance setting to: ...
7	07-11-2019 14:59	Admin (Admi...	Login	1	Admin(Administrator) logged in
8	07-11-2019 14:25	Admin (Admi...	注销	1	Admin (Administrator) 注销

Date/time: 07-11-2019 15:58
 Operator: Admin (Administrator)
 Summary: Modify reference group setting
 Details: Modify reference group setting to: Ref. group: -> Custom Group 3

Detail Export

Administrator : Admin 07-11-2019 16:05

You may view the error info., parameter modification info. and records of daily operation in the log.

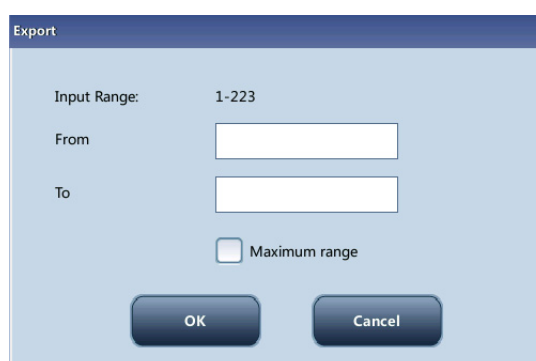
The **"Log"** screen records all activities of the analyzer. It contributes significantly to searching for operation history and troubleshooting the analyzer.

NOTE

- The oldest record will be overwritten automatically when number of log records reaches the utmost.
- Records of two years can be stored at most.

10.9.1 Exporting Logs

1. Click **"Export"**, the following dialog box will display.



Export

Input Range: 1-223

From

To

☐ Maximum range

OK Cancel

2. Select the range of the logs that you want to export.
3. Tap **"OK"** to close the dialog box and export the logs.

10.10 Checking the Analyzer Status

NOTE

- If the status is outside normal range, it will be highlighted with red background.

10.10.1 Counter

Tap "**Status**" > "**Counter**" in the menu to enter the following screen.



You can check detailed statistics on the screen, for example, running times of the analyzer and the valid sample runs.

10.10.1.1 Viewing Details

You may tap the "**Detail...**" button to view the details of sample runs, QC runs, calibration runs and so on.

10.10.1.2 Print

Tap the "**Print**" icon to print all information on the screen.

10.10.2 Temperature and Pressure

Tap "**Status**" > "**Temp & Pressure**" in the menu to enter the following screen. You may check, export or print the temperature and pressure values of different components of the analyzer.

Menu

Sample Analysis

Table Review

QC

Reagent Setup

Diluent

Print

	Temperature (°C)	Range
Diluent Temperature	29.8	[5.0, 45.0]
Reagent preheating temperature	42.7	[40.6, 70.0]

	Pressure (KPa)	Range
Vacuum	-28.5	[-29.9, -25.9]

Administrator : Admin

07-11-2019 16:07

10.10.3 Voltage

Tap "**Status**" > "**Voltage**" in the menu to enter the following screen. You may view the current voltage of the analyzer.

Menu

Sample Analysis

Table Review

QC

Reagent Setup

Diluent

Print

	Volt. (V)	Range
Power +12V	13.0	[11.0, 14.0]
Power +24V	28.4	[20.0, 30.0]
Analog +12V	12.1	[11.0, 13.0]
Analog -12V	-11.9	[-14.0, -9.0]
Digital +56V	56.8	[47.0, 63.0]
HGB Blank Voltage	4.12	[3.85, 4.85]

Administrator : Admin

07-11-2019 16:07

10.10.4 Sensor

Tap **"Status"** > **"Sensor"** in the menu to enter the following screen. You may view the current sensor information of the analyzer.

Component		Status
Float Sensor	Waste	Off
Reagent photocoupler	Diluent	Off
	Lyse	Off
Syringe Photocoupler	Sample Syringe	Block
Aspiration Module Photocoupler	Vertical Photocoupler	Unblock
	Inboard Photocoupler	Block
	Outboard Photocoupler	Unblock
Other	Aspirate Key	On

Administrator : Admin 07-11-2019 16:07

10.10.5 Version Information

Tap **"Status"** > **"Version Info"** in the menu to enter the following screen. You may view the current version information of the analyzer.

Version Info	
Application	01.00.00.2823
Release	01

Detail

Administrator : Admin 07-11-2019 16:07

NOTE

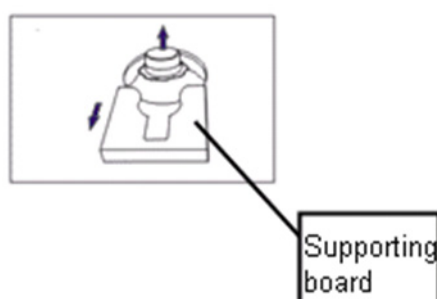
- The version information displayed in the above figure is only for demonstration. Take the queried version information of the analyzer as standard.

10.11 Replacing Waste Container

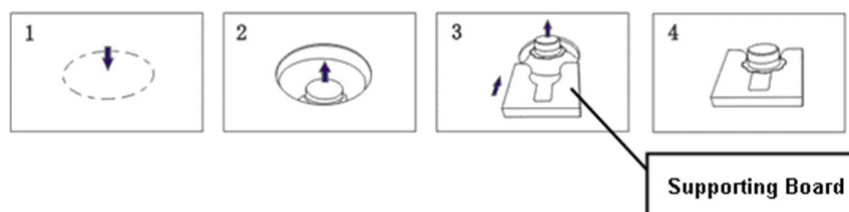
WARNING

- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
- Remove the waste container cap and replace the waste container only when the power indicator is not flickering, in order not to make the waste overflow from the container.
- When you are using a waste container to dispose waste, make sure the pickup tube is smooth, not bend, and is above the cap assembly of the waste container.
- If the waste is discharged directly, make sure the waste pump is at a lower position than the waste outlet on the analyzer.

1. Get an empty waste container, remove the cap and place it next to the one to be replaced.
2. Remove the supporting board under the cap of the old container.



3. Turn the cap counterclockwise and remove the cap assembly from the old container with caution.
4. Insert the old cap assembly into the new container as vertically as possible, and secure the cap by turning it clockwise.
5. Install the supporting board under the new container's cap as shown below.



6. Cap the old container with the cap of the new one, and then dispose of the waste properly.

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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.

BIOLOGICAL RISKS

- **Samples, controls, calibrators and waste are potentially infectious. Wear proper personal protective instrument (such as gloves, lab coat, and goggles) and follow safe laboratory procedures when handling them and the contacted areas 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.**

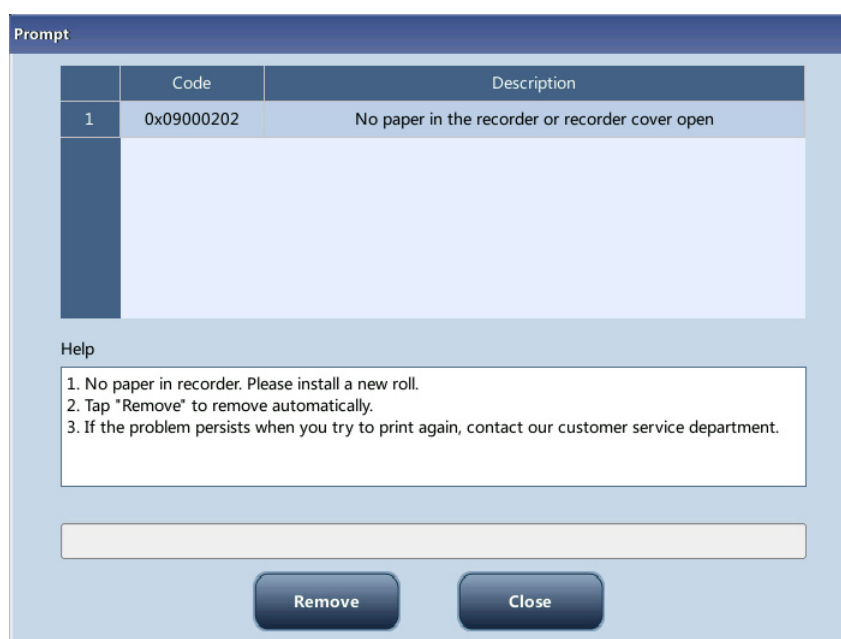
11.2 Error Messages and Solutions

During the operation, if error(s) is detected, the analyzer will beep and display the corresponding error message in the error information area at the bottom right of the screen. Meanwhile, the indicator will turn red.

According to the severity of the errors, the colors of error messages are red, orange, and blue.

- **Red:** fatal error. When this kind of error occurs, the analyzer will stop running immediately, and any further operation is prohibited.
- **Orange:** error that stops operation. When this kind of error occurs, the analyzer will stop running immediately.
- **Blue:** error that restricts certain operations. When this kind of error occurs, the analyzer can still continue with the current operation, but any other operations related to the error will be restricted.

The following figure is the error information dialog box.



The screenshot shows an error information dialog box with a blue header bar labeled 'Prompt'. Below the header is a table with two columns: 'Code' and 'Description'. The table contains one row with the code '0x09000202' and the description 'No paper in the recorder or recorder cover open'. Below the table is a 'Help' section with a list of three steps: 1. No paper in recorder. Please install a new roll. 2. Tap "Remove" to remove automatically. 3. If the problem persists when you try to print again, contact our customer service department. At the bottom of the dialog box are two buttons: 'Remove' and 'Close'.

	Code	Description
1	0x09000202	No paper in the recorder or recorder cover open

Help

1. No paper in recorder. Please install a new roll.
2. Tap "Remove" to remove automatically.
3. If the problem persists when you try to print again, contact our customer service department.

Remove Close

The name and troubleshooting method of the errors are displayed. Names of the errors are displayed by the order of their occurrence.

You may tap to select the error, and view its troubleshooting information in the **"Help"** box. The troubleshooting information of the first error is displayed by default. Follow the instruction in the **"Help"** box to remove error(s) one by one.

The following functions are provided:

11.2.1 Clearing the Errors

Tap the **"Remove"** button to clear all the errors that can be removed automatically. For the errors that cannot be removed automatically, follow the troubleshooting method to solve them.

11.2.2 Closing the Fault Prompt Dialog Box

Tap **"Close"** to close the dialog box, but the errors will still be displayed in the error information area on the screen. Tap the error information area again, the dialog box will be displayed.

The possible error(s) and the corresponding troubleshooting information are listed below:

Error Message	Actions
Main control board error	1. Power off the analyzer directly and contact our customer service department.
System clock error	1. Power off the analyzer directly and contact our customer service department.
IP address collision	1. Please modify the IP address in the interface of communication settings
Diluent ran out	1. Tap the "Remove" button, a reagent replacement dialog box pops up. 2. Change the reagent container. Tap the reagent card to the RFID area, the analyzer will replace the reagent automatically after successfully reading this card. 3. If the error persists after replacing the reagent, contact our customer service department.
Lyse ran out	1. Tap the "Remove" button, a reagent replacement dialog box pops up. 2. Change the reagent container. Tap the reagent card to the RFID area, the analyzer will replace the reagent automatically after successfully reading this card. 3. If the error persists after replacing the reagent, contact our customer service department.
Diluent expired	1. Tap the "Remove" button, a reagent replacement dialog box pops up. 2. Change the reagent container. Tap the reagent card to the RFID area, the analyzer will replace the reagent automatically after successfully reading this card. 3. If the error persists after replacing the reagent, contact our customer service department.
Lyse expired	1. Tap the "Remove" button, a reagent replacement dialog box pops up. 2. Change the reagent container. Tap the reagent card to the RFID area, the analyzer will replace the reagent automatically after successfully reading this card. 3. If the error persists after replacing the reagent, contact our customer service department.
Waste container full	1. Empty the waste container or replace it with a new one. 2. Tap "Remove" button to remove automatically. 3. If the problem persists, contact our customer service department.
Diluent ran out	1. Tap the "Remove" button, a reagent replacement dialog box pops up. 2. Change the reagent container. Tap the reagent card to the RFID area, the analyzer will replace the reagent automatically after successfully reading this card. 3. If the error persists after replacing the reagent, contact our customer service department.
Lyse ran out	1. Tap the "Remove" button, a reagent replacement dialog box pops up. 2. Change the reagent container. Tap the reagent card to the RFID area, the analyzer will replace the reagent automatically after successfully reading this card. 3. If the error persists after replacing the reagent, contact our customer service department.

Power error	1. Power off the analyzer directly and contact our customer service department.
Preheat bath temperature sensor error	1. Power off the analyzer directly and contact our customer service department.
Diluent temperature sensor error	1. Power off the analyzer directly and contact our customer service department.
RFID comm. abnormal	1. Tap "Remove" button to remove this error. 2. If the error persists, contact our customer service department.
RFID read&write abn.	1. Tap "Remove" button to remove this error. 2. If the error persists, contact our customer service department.
Background abnormal	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
HGB blank voltage abnormal	1. Check if there is diluent reagent in the container. If not, replace the container with a new one. 2. Tap "Remove" to remove automatically. 3. If the problem persists, contact our customer service department.
Vacuum pressure abnormal	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
Diluent temperature goes beyond higher limit	1. Diluent temperature must be within [5°C, 45°C].
Diluent temperature goes beyond lower limit	1. Diluent temperature must be within [5°C, 45°C].
Preheat bath temperature is too high	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
Preheat bath temperature is too low	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
Clogging(WBC)	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
Clogging(RBC)	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
Aperture voltage abnormal(WBC)	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
Aperture voltage abnormal(RBC)	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
WBC channel signal interference	1. Remove interference source. 2. Tap "Remove" button to remove the error.
RBC channel signal interference	1. Remove interference source. 2. Tap "Remove" button to remove the error.
Syringe module error	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
Aspiration module lift mechanism error	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
Aspiration module rotary mechanism error	1. Tap "Remove" button to remove automatically. 2. If the problem persists, contact our customer service department.
No paper or paper jam	1. Please check whether there is no paper or paper jam. 2. Tap "Remove" to remove automatically. 3. If the problem persists when you try to print again, contact our customer service department.

Other printer error	1. Tap "Remove" to remove automatically. 2. If the problem persists when you try to print again, contact our customer service department.
Printer not connected	1. Check whether the printer is connected to the instrument properly. 2. Tap "Remove" button to remove the automatically. 3. If the problem persists when you try to print again, contact our customer service department.
Recorder error	1. Tap "Remove" to remove automatically. 2. If the problem persists when you try to print again, contact our customer service department.
No paper in the recorder or recorder cover open	1. No paper in recorder. Please install a new roll. 2. Tap "Remove" to remove automatically. 3. If the problem persists when you try to print again, contact our customer service department.
Communication disconnected	1. Communication disconnected. Please check the network connection. 2. Tap "Remove" to remove automatically. 3. If the problem persists when you try to communicate again, contact our customer service department.
Communication error	1. Tap "Remove" to remove automatically. 2. If the problem persists when you try to communicate again, contact our customer service department.

A Specifications

A.1 Reagents

The analyzer supports the following reagents, controls and calibrators.

NOTE

- For any questions about the configuration of reagents, controls and calibrators configuration, please consult your sales representative.

Reagent name	Model
V-3D Diluent	V-3D
V-3CFL Lyse	V-3CFL
Probe Cleanser	/
Hematology Control	B30
Calibrator	S30
Hematology Control	BC-3D
Hematology Calibrator	SC-CAL PLUS

A.2 Parameters

The analyzer provides 4-part leukocyte differential count and reports 23 parameters for dog samples. See Table A-1 for details.

The analyzer provides 4-part leukocyte differential count and reports 21 parameters for cat samples. See Table A-1 for details.

The analyzer provides 3-part leukocyte differential count and reports 21 parameters for horse, rat, mouse, rabbit, monkey, pig, cow, sheep, llama, and camel samples. See Table A-2 for details.

The analyzer provides 3-part leukocyte differential count and reports 15 parameters for goat samples. See Table A-2 for details.

Table A-1 Report parameters of blood sample test (applied to cat and dog samples)

Group	Parameter name	Abbreviation
WBC group (9)	White Blood Cell count	WBC
	Neutrophils number	Neu#
	Lymphocytes number	Lym#
	Monocytes number	Mon#
	Eosinophils number	Eos#
	Neutrophils percentage	Neu%
	Lymphocytes percentage	Lym%
	Monocytes percentage	Mon%
	Eosinophils percentage	Eos%

RBC group (8)	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
PLT group (6)	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*

*Note: P-LCR and P-LCC are available only in reports for dog samples.

Table A-2 Report parameters of blood sample test (applied to horse, rat, mouse, rabbit, monkey, pig, cow, sheep, llama, camel, and goat samples)

Group	Parameter name	Abbreviation
WBC group (7)	White Blood Cell count	WBC
	Lymphocytes number	Lym#
	Monocytes number	Mon#
	Granulocyte number	Gran#
	Lymphocytes percentage	Lym%
	Monocytes percentage	Mon%
	Granulocyte percentage	Gran%
RBC group (8)	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

PLT group (6)*	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

* Note: The parameters in the PLT group are not available in the goat samples.

A.3 Sampling Features

A.3.1 Sample Volumes Required for Each Analysis

Whole blood mode	≤ 9 μL
Predilute mode	≤ 20 μL

A.3.2 Throughput

Mode	Applied to	Throughput
4-part leukocyte differential	Cat and dog	No less than 30 samples/hour
3-part leukocyte differential	Horse, rat, mouse, rabbit, monkey, pig, llama, and camel	No less than 50 samples/hour
	Cow	No less than 30 samples/hour
	Sheep and goat	No less than 25 samples/hour

A.4 Performance Specifications

A.4.1 Display Ranges for Major Parameters

Parameter	Display
WBC	$0.00 \times 10^9/\text{L} \sim 999.99 \times 10^9/\text{L}$
RBC	$0.00 \times 10^{12}/\text{L} \sim 99.99 \times 10^{12}/\text{L}$
HGB	0.0 g/L ~ 350.0 g/L
PLT	$0 \times 10^9/\text{L} \sim 9999 \times 10^9/\text{L}$
MCV	0.0 fL ~ 350.0 fL

A.4.2 Blank Count Parameter Specifications

Parameter	Requirement
WBC	$\leq 0.30 \times 10^9 / \text{L}$
RBC	$\leq 0.03 \times 10^{12} / \text{L}$
HGB	$\leq 1 \text{ g} / \text{L}$

Parameter	Requirement
HCT	$\leq 0.5\%$
PLT	$\leq 10 \times 10^9/\text{L}$

A.4.3 Linearity Range

Parameters	Linearity range	Deviation range (whole blood/ Predilute)	Measurement linearity tolerance
WBC	$(0.40 \sim 99.9) \times 10^9/\text{L}$	$0.4 \sim 6.6 \times 10^9/\text{L}$	$\pm 0.4 \times 10^9/\text{L}$
		$6.7 \sim 99.9 \times 10^9/\text{L}$	$\pm 6\%$
RBC	$(0.20 \sim 16.99) \times 10^{12}/\text{L}$	$0.20 \sim 0.60 \times 10^{12}/\text{L}$	$\pm 0.06 \times 10^{12}/\text{L}$
		$0.61 \sim 16.99 \times 10^{12}/\text{L}$	$\pm 6\%$
HGB	$(3 \sim 250) \text{ g/L}$	$3 \sim 99 \text{ g/L}$	$\pm 3 \text{ g/L}$
		$100 \sim 250 \text{ g/L}$	$\pm 3\%$
PLT	$(10 \sim 2999) \times 10^9/\text{L}$	$15 \sim 149 \times 10^9/\text{L}$	$\pm 15 \times 10^9/\text{L}$
		$150 \sim 2999 \times 10^9/\text{L}$	$\pm 15\%$

Note: The linearity range does not apply to the goat, sheep, camel, and llama samples.

A.4.4 Repeatability

Table A-3 Repeatability range of analyzer

Parameters	Condition	Whole blood mode (CV)	Predilute mode (CV)
WBC	$(7.50 - 15.0) \times 10^9/\text{L}$	$\leq 3.0\%$	$\leq 4.0\%$
RBC	$(3.50 - 6.00) \times 10^{12}/\text{L}$	$\leq 2.0\%$	$\leq 3.0\%$
HGB	$(120 - 180) \text{ g/L}$	$\leq 2.0\%$	$\leq 3.0\%$
MCV	$(40.0 - 110) \text{ fL}$	$\leq 1.0\%$	$\leq 1.5\%$
PLT	$(200 - 500) \times 10^9/\text{L}$, $(\text{MCV} > 60 \text{ fL})$	$\leq 6.0\%$	$\leq 8.0\%$

Note 1: The repeatability range does not apply to the goat samples.

Note 2: The repeatability range in the predilute mode only applies to the rat and mouse samples.

A.4.5 Carryover

Parameter	Carryover
WBC	$\leq 0.5\%$
RBC	$\leq 0.5\%$
HGB	$\leq 0.6\%$
PLT	$\leq 1.0\%$

A.5 Input/Output Devices

NOTE

- Be sure to use the specified devices only.
- Protect the external equipments from water.
- External equipment connected to the analyzer and digital interfaces must be authorized and complied with relevant safety and EMC standards (e.g. IEC 60950 Safety of Information Technology Equipment Standard (Class B)). Any persons who connects additional equipment to the signal input or output ports and configures an IVD system, is responsible for ensuring that the system works normally and complies within the safety and EMC requirements. If you have any questions, consult the technical service department of your local representative.

A.5.1 Touch Screen

8.4 inch TFT color touch screen, supporting 24 bit color at highest, with display resolution of 800×600.

A.5.2 Indicator

The indicator indicates analyzer the status of the analyzer, including on/off, running or sleeping.

A.5.3 Keyboard (Optional)

101-Key alpha-numeric USB keyboard

A.5.4 Mouse (Optional)

USB mouse.

A.5.5 Barcode Scanner (Optional)

External USB barcode scanner.

A.5.6 Printer (Optional)

USB printer is supported.

A.5.7 Recorder

A thermal recorder is included.

A.5.8 Buzzer

The buzzer sounds when there is an error. Tap the touch screen or when the error is removed, the buzz alarm will be silent automatically.

A.5.9 USB Wireless Network Card (Optional)

Wireless network card with chip RTL8192CU.

A.6 Interfaces

- One network interface, built-in network card, network access and TCP/IP compatible.
- Four USB ports (specification: DC 5V, 500mA, USB 2.0).

A.7 Power Supply

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

A.8 Fuse

WARNING

- Only install fuses of specified specification on the system.

Fuse: 250V T3.15AH

A.9 EMC Description

- This IVD medical equipment complies with the emission and immunity requirements described in IEC 61326-1:2012 / EN 61326-1:2013 and IEC 61326-2-6:2012 / EN 61326-2-6:2013.
- The intended use environments of this IVD medical equipment includes typical healthcare environments (hospitals, clinics, doctor's offices), this equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- It is recommended to estimate the electromagnetic environment before using the equipment.
- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

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.

Radio Regulatory Compliance

RF parameters

Radio devices	RFID
Operating frequency	13.56MHz
Modulation mode	ASK
RF output power/Transmitter H-field	≤60 dBuA/m@10m



The radio device used in this product as well as our product is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

A.10 Sound Pressure

Maximal sound pressure: 80 dB

A.11 Normal Operation Environment

Ambient temperature: 15°C~30°C

Operating humidity: 20%~85%

Atmospheric pressure: 70.0kPa~106.0kPa

A.12 Storage and Transportation Environment

Ambient temperature: -10°C~40°C

Relative humidity: 10%~90%

Atmospheric pressure: 50.0kPa~106.0kPa

A.13 Running Environment

Ambient temperature: 10°C~40°C

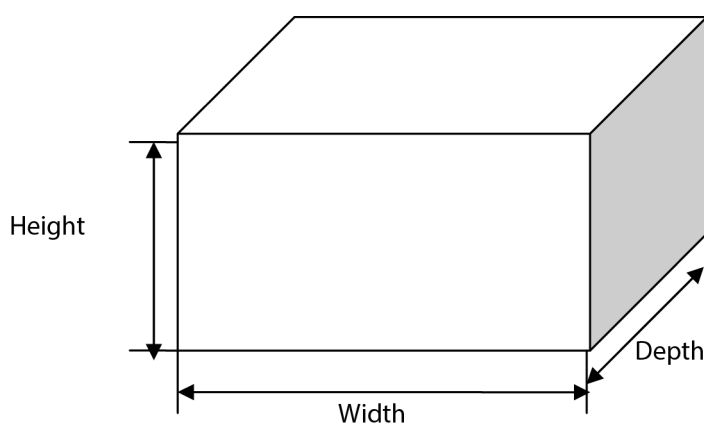
Relative humidity: 10%~90%

Atmospheric pressure: 70.0kPa~106.0kPa

NOTE

- Be sure to use and store the analyzer in the specified environment.

A.14 Dimensions and Weight



	Analyzer
Width (mm)	≤305
Height (mm)	≤ 400 (foot pad included)
Depth (mm)	≤410
Weight (Kg)	≤20

A.15 Safety Classification

Level of transient overvoltage: Category II.

Rated pollution degree: 2.

A.16 Contraindication

None

A.17 Packing List

Your product accessories may vary based on your actual product configuration. For any questions about the configured/optional accessories, consult your sales representative.

	Material Name	Quantity	Unit
1	Main unit (BC-30 Vet)	1	EA
2	Original record of factory calibration factors	1	EA
3	Power cord	1	EA
4	BC-30 Vet Operator's Manual	1	EA
5	BC-30 Vet Operation Instructions and Precautions	1	EA
6	Analyzer FQC verification record	1	EA
7	Safety verification record	1	EA
8	Lyse container cap assembly	1	EA
9	Waste container cap assembly	1	EA
10	Diluent container cap assembly	1	EA
11	20L Reagent soft bottle	1	EA
12	Printer paper	1	EA
13	Hand-held barcode scanner	1	EA

B

Communication

The LIS/HIS function of BC-30 Vet enables the communication between the analyzer and the PC in laboratory through Ethernet, including sending analysis results to and receiving worklist from PC.

The LIS/HIS communication protocol involved in communication of BC-30 Vet are 15ID and HL7. For details about the connection control, and the introduction, message definition and examples, please contact Mindray Customer Service Department or your local distributor.

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 - HGB Measurement 3-5
 - RBC/PLT Measurement 3-6
- Using the QC Programs 7-1
 - QC 7-1

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D Declaration of Conformity

Declaration of Conformity V 2.0

Declaration of Conformity

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: **Auto Hematology Analyzer**

Model: **BC-30 Vet**

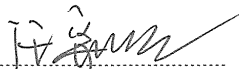
We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2014/53/EU concerning radio equipment. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:

☒ EN 61010-1:2010	☒ EN 61326-1: 2013
☒ EN 50364: 2018	☒ ETSI EN 301 489-1 V2.2.3
☒ ETSI EN 301 489-3 V2.1.1	☒ ETSI EN 300 330 V2.1.1

Start of CE-Marking: 2019-8-19

Place, Date of Issue: Shenzhen, 2020-2-20

Signature: 

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

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E

Maintenance Log

NOTE

- The log table is intended for one month's use. Make enough copies for future use.
- Refer to Chapter 10 Servicing Your Analyzer for recommended maintenance protocols.

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Maintenance log to BC-30 Vet

Manual cleaning:

Day	Instrument cover	Day	Instrument cover
1		17	
2		18	
3		19	
4		20	
5		21	
6		22	
7		23	
8		24	
9		25	
10		26	
11		27	
12		28	
13		29	
14		30	
15		31	
16			

