BC-760[B]/BC-760[R]/BC-780[R]

AUTO HEMATOLOGY ANALYZER

OPERATOR'S MANUAL

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

NOTE

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

WARNING

- This instrument is intended to be used by clinical laboratory professionals trained by Mindray or Mindray-authorized distributors.
- Be sure to use the instrument under specified environment in this manual. If not, the instrument may not work properly, the measurement may be unreliable, thus causing damage to the instrument and harm to the body.

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

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

Customer Service Department

| Manufacturer: | Shenzhen Mindray Bio-Medical Electronics Co., Ltd. | | |
|--------------------|---|--|--|
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| Tel: | 0049-40-2513175 | | |
| Fax: | 0049-40-255726 | | |

Safety Information

Labels and Symbols on the System 1.1

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

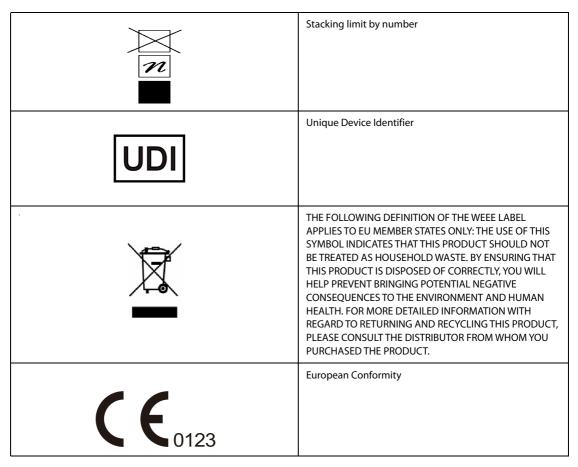


A CAUTION

During the daily use of the analyzer, especially the cleaning process, the operator shall ensure the intactness of the labels.

| When you see | It means |
|--------------|--|
| <u></u> | Caution Note: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
| | Biological risks |
| | Warning, laser beam |
| | PROTECTIVE CONDUCTOR TERMINAL |
| | Off (Power) |
| | On (Power) |
| • | USB connection |
| 盎 | Computer Network |
| \sim | Alternating current |

| | Serial number |
|--|--|
| SN | |
| IVD | In vitro diagnostic medical device |
| ~~ <u></u> | Date of manufacture |
| | Temperature limit |
| <u>%</u> | Humidity limitation |
| | Atmospheric pressure limitation |
| 严禁在仪器 指示灯闪烁 状态下进行更换废 液桶操作! Do not replace the waste container when the power indicator is flickering! | Biological risks (on the tube of the waste container cap assembly) Do not replace the waste container when the power indicator is flickering! |
| | Fragile, handle with care |
| <u>†</u> | This way up |
| | Keep dry |
| | Do not roll |



The general meaning assigned to geometric shapes, safety colors and contrast colors for safety signs are as follows:

| Geometric shape | Meaning | Safety color | Contrast color | Graphical symbol color |
|-----------------|---------|--------------|----------------|------------------------|
| | Warning | Yellow | Black | Black |
| | | | | |
| | Warning | Yellow | Black | Black |
| | | | | |

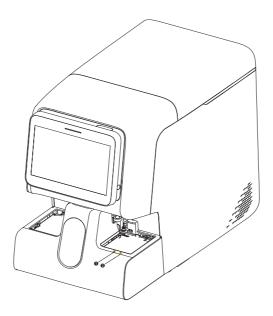


Figure 1-1 Warning labels on the front of main unit



①Warning

Biohazard



- 2 Precautions
- 1. Test tubes must come into the rack smoothly. If not, shape the tube by replacing the labels.
- 2. Make sure cap the tubes securely.
- 3. Make sure the left tray is not full and the detection photocoupler is not blocked, and then start analysis.

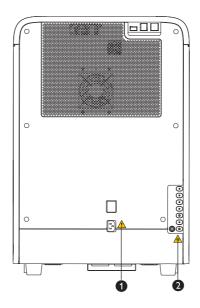


Figure 1-2 Warning labels on the back of main unit



1 Warning

- 1. Connect only to a properly earth grounded outlet.
- 2. To avoid electric shock, disconnect power cord prior to maintenance or servicing the analyzer.



② Warning BIOHAZARD

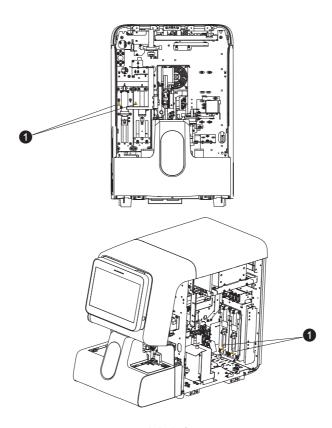


Figure 1-3 Warning labels for moving parts 1



1Warning

To avoid personal injury, do not put your hand under the syringe or inside the slot!

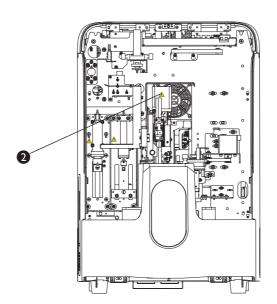


Figure 1-4 Warning labels for moving parts 2



2 Warning

To avoid personal injury, do not put your hand under the pipette assembly or inside the moving track!

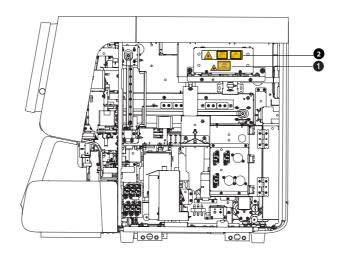


Figure 1-5 Optical assembly laser warning labels 1



1 Warning

CIASS 3B LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED AVOID EXPOSURE TO THE BEAM



2 Warning

LASER RADIATION

AVOID EXPOSURE TO BEAM

CLASS 3B LASER PRODUCT

MAXIMUM OUTPUT: 15mW

WAVELENGTH: 635nm

STANDARD NAME: IEC 60825-1:2014

PUBLICATION DATE: 2014.05

1.2 Safety-related Symbols and Messages

You will find the following symbols in this manual:



BIOLOGICAL RISK

Alert you to a potentially biohazardous condition.



WARNING

Alert you to an operating condition that can cause death, serious personnel injury or property damage.



CAUTION

Alert you to an operating condition that can cause minor personnel injury, system failure/ damage, and property damage.

NOTE

Alert you to information that requires your attention.

1.2.1 **General Safety Messages**



BIOLOGICAL RISK

- All the samples, controls, calibrators, wastes and areas contacted them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, goggles, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
- Discard the system according to government regulations.



⚠ WARNING

- The fuse used in the instrument is not a replaceable one. If there is any problem with the fuse, contact Mindray Customer Service Department or your local distributor your local distributor.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.



CAUTION

- Be sure to operate the instrument under the situation specified in this manual. If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.
- Be sure to use the specified external devices only, and keep them away from water.
- External devices 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 instrument Standard and CISPR 22 EMC of Information Technology instrument Standard (Class B)). Any persons who connects additional instrument 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.

- Make sure all the safety measurements are adopted. It is prohibited to disable any safety device or
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- Be sure to use the instrument under specified environment in this manual. If not, the instrument may not work properly, the measurement may be unreliable, thus causing damage to the instrument and harm to the body.
- This instrument is intended to be used by clinical laboratory professionals trained by Mindray or Mindray-authorized distributors.
- When power cut occurs suddenly, turn off the instrument immediately.
- Dilution is required when the analyte content in the sample exceeds the upper limit of the linear range.
- The instrument must be within the calibration validity period; otherwise, the measurement results may be inaccurate.

1.2.2 Analyzer Transportation and Installation-related Safety Messages

🔔 WARNING

- Before turning on the instrument, make sure the input voltage meets the requirements.
- When installing the instrument, ensure that the power switch is in close proximity to the instrument and within your easy access.

CAUTION

- Unpacking, installation or transportation by personnel not authorized or trained by Mindray may cause personal injury or damage your instrument. Do not unpack, transport or install your instrument without the presence of Mindray-authorized personnel.
- The installation, authorization, upgrade and modification of the system software must be performed by personnel authorized by Mindray. Make sure to install only Mindray-authorized software.
- 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 power cord provided by the manufacturer. Using the power cord other than provided by the manufacturer may lead to system damage or unqualified smear output.
- When connecting the reagents, make sure the color of the reagent container cap assembly is the same as that of the reagent inlet to which it is connected.
- Check if the reagent tubes are properly connected before using the system. Otherise, the results may be inaccurate.

1.2.3 Reagent, Control, and Calibrator-Related Safety Messages



CAUTION

- The reagents are irritating to eyes, skin and airway. Wear proper personal protective equipment (e.g. gloves, lab coat, goggles, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory. If reagents accidentally spill on your skin or in your eyes, rinse the area with ample amount of clean water, and seek medical attention immediately.
- Use the reagents, controls and calibrators specified by the manufacturer only. Using other reagents, controls and calibrators, may lead to system damage and inaccurate measurement, control and calibration results.
- Pay attention to the expiration dates and open-container stability days of all the reagents. Be sure not to use expired reagents. Otherwise, the results may be inaccurate.

To ensure measurement accuracy, do not mix the new container of reagent with the residue in the replaced container to ensure accurate measurement, and prevent reagents from pollution following safe laboratory procedures.

1.2.4 **Maintenance-related Safety Messages**



BIOLOGICAL RISK

- 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.
- 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.
- If the waste is discharged using waste container, make sure the pickup tube of the waste container cap assembly is above, and the tube is smooth and not bent. If the waste is discharged directly, make sure the waste pump is at a lower position than the waste outlet on the instrument.
- After replacing the reagent container/bag, check the tubing connected to the cap assembly and make sure it is not bent over.



CAUTION

- Before cleaning the floating blood barrier and the blood barrier bracket, make sure the analyzer is shut down.
- Improper maintenance may damage the analyzer. Operators must follow the instruction of this Operator's Manual to perform maintenance operations. For problems not mentioned in this manual, contact Mindray customer service department for Mindray service advice.
- Only parts supplied by Mindray can be used for maintenance. For any question, contact Mindray customer service department.
- If you accidentally spill hazardous material (for example, reagents or samples) on the instrument, clean the instrument with specified disinfectant. 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.
- The user shall perform regular cleaning and sterilization to the cover of the instrument. Use the specified materials to sterilize the instrument only. For any damage to the instrument or other accidents caused by using materials other than specified, Mindray will not provide any warranty.
- The cleaning and sterilization may damage the instrument to some extent. It is recommended to perform sterilization only when necessary according to your laboratory protocol. Remember to clean the instrument before sterilizing.
- Do not use any decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the instrument or with material contained in it.
- 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.
- 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.
- When the power indicator is flickering, it indicates that the sampling probe is lowering down. Be sure your hand is away from the sampling probe during the process, otherwise, your hand may be hurt.

1.2.5 **Laser Warning**

Class 1 laser product

CAUTION

- Class 3B laser radiation when open and interlocks defeated.
- Avoid exposure to the beam
- Optical density: OD4+
- Radiation exposure level: 56.77mW/cm²
- Maximum output: 15mW
- Wavelength: 635nm
- Standard name: IEC 60825-1:2014
- Publication date: 2014.05
- Use goggles when necessary



WARNING

This product is a CLASS 1 embedded laser product. When opened or when the interlock defeated, there are Class 3B laser radiation. Users must not open, disassemble or damage the interlock device; otherwise may be exposed to laser exposure. For any further information or questions, please contact Mindray's Customer Service Department.

NOTE

The service and maintenance of the laser product must be handled by professionals. Return the product to Mindray Customer Service for service and maintenance.

1.2.6 **Network Security**

NOTE

- The instrument software uses closed-loop operating system, meaning that the applications of the instrument works in exclusive mode and are free from other application's disturbance. Users can only operate the software interface but cannot directly access the operating system or install software. Therefore, the system is far less vulnerable to viruses, spyware, or malware attacks.
- When the instrument connects to an external computer, install anti-virus software on the computer and scan for viruses and update patches periodically. Do not use it for unintended purposes.
- Data transmission must be performed in a closed-loop network or virtual network. The network must be isolated.
- Users have the responsibility to protect the network authentication information, such as password and user information, from being obtained by unauthorized personnel.

The analyzer software is developed based in the following Ready-for-Use software.

| Name | Model | Version | Title | Manufacturer |
|------------------|---------|---------|---------------------------------|-----------------------------------|
| Operating system | OS Core | 4.14.98 | Linux embedded operating system | Linux Kernel Organization, Inc |

Safety Information

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2 Using this Manual

2.1 Overview

This chapter explains how to use your Operator's Manual of BC-760[B]/BC-760[R]/BC-780[R] Auto Hematology Analyzer (hereby referred to as "the analyzer"). The manual is shipped with your product and describes the purpose, functions, and operations of the product. Read this manual carefully before operating your analyzer and operate your analyzer strictly as instructed in this manual.

NOTE

 This manual describes the use, functions and operation methods of the product based on the most complete configuration; and some of the content may not be applicable to your product. Contact Mindray if you have any questions.

2.2 Who Should Read This Manual

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

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

2.3 How to Find Information

This operator's manual comprises 13 chapters and 7 appendices. Refer to the table below to find the information you need.

| If you want to | See |
|---|---|
| learn about the safety messages of the analyzer | 1Safety Information |
| learn about the intended use and parameters of the analyzer | 3Understanding Your System |
| learn about the analyzer's system composition and software structure | 3Understanding Your System |
| learn about how the analyzer works | 4Understanding the System Principles |
| learn about the installation requirements of the analyzer | 5Installing and Connecting the System |
| learn about how to define/adjust system settings | 6Customizing the Analyzer Software |
| learn about how to collect, prepare and analyze the samples | 70perating Your Analyzer |
| learn about how to use the analyzer to perform daily operating tasks | 70perating Your Analyzer |
| learn about how to review the saved analysis results | 8Reviewing Sample Results |
| learn about basic requirements of quality control and quality control methods of the analyzer | 9Using the QC Program |
| learn about basic requirements of calibration and calibration methods of the analyzer | 10Calibrating Your Analyzer |
| learn about how to use the quality control programs of the analyzer | 11Printing |
| learn about how to maintain/test the analyzer | 12Service |
| learn about the troubleshooting methods of the analyzer | 13Troubleshooting |

| If you want to | See |
|--|----------------|
| learn about the technical specifications of the analyzer | BSpecification |

2.4 Conventions Used in This Manual

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

| | Format | Meaning |
|---|--------|---|
| | [xx] | All capital letters enclosed in [] indicate a key name (either on the pop-up keyboard or the external keyboard), such as [ENTER]. |
| Ī | "xx" | Letters included in " " indicate text you can find on the screen of the analyzer. |

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

3.1 Intended Use

The Auto Hematology Analyzer is a quantitative, automated hematology analyzer for In Vitro Diagnostic Use in clinical laboratories. It provides Complete Blood Count, Leukocyte Differential, Hemoglobin Concentration Measurement, Reticulocyte Measurement, Nucleated Red Blood Cell Measurement and Erythrocyte Sedimentation Rate Measurement for blood samples, and provides WBC and RBC counts, and WBC Differential Measurement for body fluid samples.

Erythrocyte Sedimentation Rate (ESR) is a non-specific marker used for auxiliary diagnosis of certain pathological conditions, mainly including inflammation, injury, rheumatism, etc.

| Model | Configuration Differences | | |
|-----------|---------------------------|-----|-----------------------|
| Wodel | RET | ESR | Data storage capacity |
| BC-760[B] | | • | 130,000 |
| BC-760[R] | • | • | 130,000 |
| BC-780[R] | • | • | 150,000 |

NOTE

- The subtypes of body fluid supported by the analyzer include cerebrospinal fluid, pleural fluid, ascitic fluid, and synovial fluid. You may not get accurate results if you analyze body fluid samples other than specified above.
- The analyzer 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.

3.2 Test Parameters

The analyzer is used for quantitative determination of the following report parameters and Research Use Only (RUO) parameters of blood sample tests and body fluid sample tests, and provides histograms and scattergrams.

3.2.1 Blood Sample Test Parameters, Histograms, and Scattergrams

Table 3-1 Blood sample test report parameters

| Group | Name | Abbreviation | Applicable Model |
|---------------------------------|--|--------------|------------------|
| WBC group | White blood cell count | WBC | General |
| | Basophil count | Bas# | General |
| | Basophil percentage | Bas% | General |
| | Neutrophil count | Neu# | General |
| | Neutrophil percentage | Neu% | General |
| | Eosinophil count | Eos# | General |
| | Eosinophil percentage | Eos% | General |
| | Lymphocyte count | Lym# | General |
| | Lymphocyte percentage | Lym% | General |
| | Monocyte count | Mon# | General |
| | Monocyte percentage | Mon% | General |
| | Immature granulocyte count | IMG# | General |
| Immature granulocyte percentage | | IMG% | General |
| RET group | *Reticulocyte percentage | RET% | BC-760[R] |
| | *Reticulocyte count | RET# | BC-780[R] |
| | *Reticulocyte hemoglobin expression | RHE | |
| | *Immature reticulocyte fraction | IRF | |
| | *Low fluorescent ratio | LFR | |
| | *Middle fluorescent ratio | MFR | |
| 1 | *High fluorescent ratio | HFR | |
| RBC group | Red blood cell count | RBC | General |
| | Hemoglobin concentration | HGB | General |
| | Mean corpuscular volume | MCV | General |
| | Mean corpuscular hemoglobin | MCH | General |
| | Mean corpuscular hemoglobin concentration | MCHC | General |
| | Red blood cell distribution width coefficient of variation | RDW-CV | General |
| | Red blood cell distribution width standard deviation | RDW-SD | General |
| | Hematocrit | НСТ | General |
| | Nucleated red blood cell count | NRBC# | General |
| | Nucleated red blood cell percentage | NRBC% | General |

| Group | Name | Abbreviation | Applicable Model |
|----------------|--------------------------------|--------------|--|
| Platelet group | Platelet count | PLT | General |
| | Mean platelet volume | MPV | General |
| | Platelet distribution width | PDW | General |
| | Plateletcrit | PCT | General |
| | Platelet-large cell ratio | P-LCR | General |
| | Platelet-large cell count | P-LCC | General |
| | *Immature platelet fraction | IPF | BC-760[R] BC-780[R]this parameter is optional, for more information, consult Mindray Customer Service DepartmentFor BC-760[B], this parameter is optional, for more information, consult Mindray Customer Service Department |
| | Platelet count- impedance | PLT-I | General (find the parameter result on the "Other Para." - "Analysis Para." |
| | *Platelet count hybrid | PLT-H | BC-760[R] BC-780[R] (find the parameter result on the "Other Para." - "Analysis Para.")For BC-760[B], this parameter is optional. For more information, consult Mindray Customer Service Department |
| | *Optical platelet count | PLT-O | BC-760[R] BC-780[R] (find the parameter result on the "Other Para." - "Analysis Para.") |
| ESR | Erythrocyte sedimentation rate | ESR | General |

• The parameters marked with * are parameters for specified models.

Table 3-2 Blood sample test RUO parameters

| Name | Abbreviation | Applicable Model |
|----------------------------------|--------------|------------------|
| High fluorescent cell count | HFC# | General |
| High fluorescent cell percentage | HFC% | General |
| White blood cell count -DIFF | WBC-D | General |
| Total nucleated cell count-DIFF | TNC-D | General |
| Immature eosinophil percentage | IME% | General |

| Name | Abbreviation | Applicable Model |
|---|--------------|------------------------|
| Immature eosinophil count | IME# | General |
| Neutrophil-to-lymphocyte ratio | NLR | General |
| Infected red blood cell count | InR# | General |
| Infected red blood cell permillage | InR‰ | General |
| NEU# Minus IMG# | Neu#& | General |
| NEU% Minus IMG% | Neu%& | General |
| LYM# Minus HFC# | Lym#& | General |
| LYM% Minus HFC% | Lym%& | General |
| Microcyte count | Micro# | General |
| Microcyte percentage | Micro% | General |
| Macrocyte count | Macro# | General |
| Macrocyte percentage | Macro% | General |
| *Optical red blood cell count | RBC-O | BC-760[R] BC-780[R] |
| *Optical white blood cell count | WBC-O | |
| *RBC fragment count | FRC# | |
| *RBC fragment percentage | FRC% | |
| *Reticulocyte production index | RPI | |
| *Mean reticulocyte volume | MRV | |
| *RET scattergram, mean reticulocyte distribution-forward scatter intensity | RET-Y | |
| *RET scattergram, mean reticulocyte distribution-side fluorescent intensity | RET-X | |
| *RET scattergram, mean immature reticulocyte fraction distribution-forward scatter intensity | IRF-Y | |
| *RET scattergram, mean immature reticulocyte fraction distribution-side fluorescent intensity | IRF-X | |
| *RET scattergram, mean red blood cell distribution-forward scatter intensity | RET-RBC-Y | |
| *RET scattergram, mean red blood cell distribution-side fluorescent intensity | RET-RBC-X | |
| High fluorescent immature platelet fraction | H-IPF | General |
| Immature platelet count | IPF# | General |
| Platelet-to-lymphocyte ratio | PLR | General |
| Platelet distribution width standard deviation | PDW-SD | General |
| Dimorphic population, smaller distribution RBC count | SRBC | General |
| Dimorphic population, larger distribution RBC count | LRBC | General |
| Dimorphic population, smaller distribution mean corpuscular volume | SMCV | General |
| Dimorphic population, larger distribution mean corpuscular volume | LMCV | General |

| Name | Abbreviation | Applicable Model | |
|---|--------------|---|--|
| DIFF scattergram, mean neutrophil distribution-side scatter intensity | Neu-X | General | |
| DIFF scattergram, mean neutrophil distribution-side fluorescent light intensity | Neu-Y | General | |
| DIFF scattergram, mean neutrophil distribution-forward scatter intensity | Neu-Z | General | |
| DIFF scattergram, mean lymophocyte distribution-side scatter intensity | Lym-X | General | |
| DIFF scattergram, mean lymophocyte distribution-side fluorescent intensity | Lym-Y | General | |
| DIFF scattergram, mean lymophocyte distribution-forward scatter intensity | Lym-Z | General | |
| DIFF scattergram, mean monocyte distribution-side scatter intensity | Mon-X | General | |
| DIFF scattergram, mean monocyte distribution-side fluorescent light intensity | Mon-Y | General | |
| DIFF scattergram, mean monocyte distribution-forward scatter intensity | Mon-Z | General | |
| DIFF scattergram, neutrophil side scatter distribution width | Neu-XW | General | |
| DIFF scattergram, neutrophil side fluorescent light distribution width | Neu-YW | General | |
| DIFF scattergram, neutrophil forward scatter distribution width | Neu-ZW | General | |
| DIFF scattergram, lymophocyte side scatter distribution width | Lym-XW | General | |
| DIFF scattergram, lymophocyte side fluorescent light distribution width | Lym-YW | General | |
| DIFF scattergram, lymophocyte forward scatter distribution width | Lym-ZW | General | |
| DIFF scattergram, monocyte side scatter distribution width | Mon-XW | General | |
| DIFF scattergram, monocyte side fluorescent light distribution width | Mon-YW | General | |
| DIFF scattergram, monocyte forward scatter distribution width | Mon-ZW | General | |
| *Immature platelet fraction- DIFF | IPF-D | These parameters are | |
| *Reticulocyte percentage- DIFF | RET%-D | available on BC-760[R]/BC-780[R] (when the user- | |
| *Reticulocyte count- DIFF | RET#-D | defined test panel includes DIFF tests, but not Ret | |
| *Immature reticulocyte fraction- DIFF | IRF-D | tests.) | |
| *Low fluorescent ratio- DIFF | LFR-D | For BC-760[B], this parameter is optional. For | |
| *Middle fluorescent ratio- DIFF | MFR-D | more information, consult Mindray Customer Service | |
| *High fluorescent ratio- DIFF | HFR-D | Department | |
| Corrected erythrocyte sedimentation rate | ESR-Corr. | General | |
| Surface area | SA | General | |
| Amplitude | AMP | General | |

| Name | Abbreviation | Applicable Model |
|-----------------------|--------------|------------------|
| Aggregation index | AI | General |
| Minimum | MIN | General |
| Aggregation half time | T1/2 | General |

- RUO parameters are for research purpose only. They cannot be used for diagnosis purpose.
- The parameters marked with * are parameters for specified models.
- To print the RUO parameter results, tap "Setup"-" System Setup"-" Print Setup"-" Printing Content ", and check "Print RUO Parameters".

Table 3-3 Blood sample test histograms

| Name | Abbreviation | Applicable Model |
|---------------------------------|-------------------|--|
| Red blood cell histogram | RBC histogram | General |
| Platelet histogram | PLT histogram | General |
| * Platelet hybrid histogram | PLT-H histogram | BC-760[R] BC-780[R]For BC-760[B], this histogram is optional. For more information, consult Mindray Customer Service Department. |
| White blood cell –FSC histogram | WBC-FSC histogram | General |

NOTE

• The parameters marked with * are parameters for specified models.

Table 3-4 Blood sample test scattergrams

| Name | Abbreviation | 3D Scattergra m | Applicable Model |
|---------------------------------------|-------------------------|-----------------------|---|
| Differential(FS/FL) scattergram | DIFF(FS/FL) scattergram | Available | General |
| Differential(FS/SS) scattergram | DIFF(FS/SS) scattergram | | General |
| Differential(FL/SS) scattergram | DIFF(FL/SS) scattergram | | General |
| *Reticulocyte scattergram | RET scattergram | Available | BC-760[R] |
| *Optical platelet scattergram | PLT-O scattergram | Unavailable | BC-780[R] |
| *Reticulocyte - extension scattergram | RET-EXT scattergram | Unavailable | |
| *Platelet hybrid scattergram | PLT-H scattergram | Available | BC-760[R] BC-780[R] For BC-760[B],, this scattergram is optional. For more information, consult Mindray Customer Service Department. |

The parameters marked with * are parameters for specified models.

3.2.2 Body Fluid Sample Test Parameters, Histograms, and Scattergrams

Table 3-5 Body fluid sample test report parameters

| Group | Name | Abbreviation | Applicable Model |
|-----------|--|--------------|---------------------|
| WBC group | White blood cell count-body fluid | WBC-BF | General |
| | Total nucleated cell counts-body fluid | TC-BF# | General |
| | Mononuclear cell count | MN# | General |
| | Mononuclear cell percentage | MN% | General |
| | Polymorphonuclear cell count | PMN# | General |
| | Polymorphonuclear cell percentage | PMN% | General |
| RBC group | Red blood cell count-body fluid | RBC-BF | General |

Table 3-6 Body fluid sample test RUO parameters

| Name | Abbreviation | Applicable Model |
|--|--------------|------------------|
| Eosinophil count- body fluid | Eos-BF# | General |
| Eosinophil percentage- body fluid | Eos-BF% | General |
| Neutrophil count- body fluid | Neu-BF# | General |
| Neutrophil percentage- body fluid | Neu-BF% | General |
| Lymphocyte count- body fluid | Lym-BF# | General |
| Lymphocyte percentage- body fluid | Lym-BF% | General |
| Monocyte count- body fluid | Mon-BF# | General |
| Monocyte percentage- body fluid | Mon-BF% | General |
| High fluorescent cell count - body fluid | HFC-BF# | General |
| High fluorescent cell percentage- body fluid | HFC-BF% | General |
| Red blood cell count-body fluid | RBC-BF(R) | General |

NOTE

- RUO parameters are for research purpose only. They cannot be used for diagnosis purpose.
- To print the RUO parameter results, tap "Setup"-" System Setup"-" Print Setup"-" Printing Content ", and check "Print RUO Parameters".

Table 3-7 Body fluid sample test histograms

| Name | Abbreviation | Applicable Model |
|--------------------------------|-------------------|------------------|
| Red blood cell histogram | RBC histogram | General |
| White blood cell–FSC histogram | WBC-FSC histogram | General |

Body fluid sample test scattergrams

| Name | Abbreviation | 3D Scattergram | Applicable Model |
|------------------------------------|----------------------|----------------|---------------------|
| Differential scattergram | DIFF scattergram | Available | General |
| Differential-extension scattergram | DIFF-EXT scattergram | Unavailable | General |

3.3 Device Description

3.3.1 Structure and Components

BC-760[B]/BC-760[R]/BC-780[R]Auto Hematology Analyzer consists of the sample processing unit, data management unit, result output unit, and the accessories.

3.3.2 Modules and Components



CAUTION

- Do not use anything sharp on the touch screen or strike on it.
- Clean the touch screen with a clean and soft cloth, as well as clean water, rather than chemical solution, acid or alkali solution.

3.3.2.1 Front of the analyzer

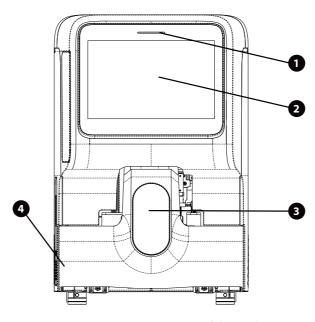


Figure 3-1 Front of the analyzer

① Status indicator

②Touch screen

3 Sample compartment

4 Autoloader

| 1 | Status Indicator | The indicator locates on the top of the | Ready: indicator stays in green |
|---|--------------------|--|---|
| | | touch screen; and it tells you about the status of the instrument including ready, running, error, standby and on/off, etc. | Running: indicator flickers in green |
| | | | Sampling probe piercing: indicator flickers fast |
| | | | Error: indicator stays in red |
| | | | Sleep: indicator stays in orange |
| | | | Off: indicator off |
| 2 | Touch screen | The touch screen locates on the front of the main unit, which can be used to operate the instrument and display information. | / |
| 3 | Sample compartment | Tap closed-tube sampling mode on touch screen, and the analyzer opens the sample compartment automatically. Place applicable adapters in the compartment and sample tubes to perform analysis tests. | / |
| 4 | Autoloader | The autoloader is in the front of the analyzer. You can use it to load tubes automatically. | / |

3.3.2.2 Back of the analyzer

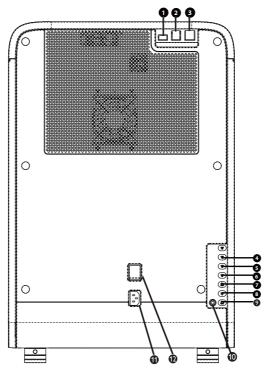


Figure 3-2 Back of the analyzer

- ① USB port (protocol 3.0)
- ③ Network interface
- $\ensuremath{\mbox{5}}\mbox{LD}$ Lyse inlet

- ② USB port (protocol 2.0)
- 4 DR Diluent inlet (applicable to the BC-760[R]/BC-780[R] model)
- 6 LH Lyse inlet

- **7**ESR Solution Reagent inlet
- 9 Waste sensor
- 11) Power inlet

- **®DS** Diluent inlet
- 10 Waste outlet
- 12 Power switch

3.3.2.3 Right side view of the analyzer

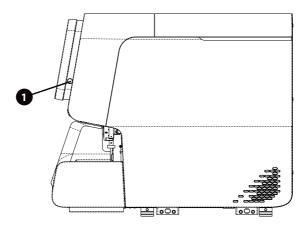


Figure 3-3 Right side view of the analyzer

1 Standby

3.3.2.4 Left side view of the analyzer

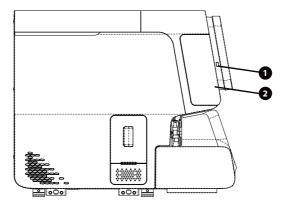


Figure 3-4 Left side of the analyzer

①USB port (protocol 2.0)

②Dye replacing compartment

3.3.3 Accessories

The analyzer is provided with the following configured or optional accessories.

Table 3-8 List of Accessories

| | Configured | Optional |
|-------------------------------|------------|----------|
| Handheld Barcode Scanner | | ✓ |
| HP LaserJet Printer | ✓ | |
| Tube Rack Assembly (CAL 8000) | ✓ | |

| | Configured | Optional |
|------------------------------------|------------|----------|
| Capillary blood tube rack assembly | | ✓ |

- For any questions about the configured/optional accessories, consult your sales representative.
- The accessories actually attached to the product depend on your product configuration.

\wedge

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 system or lead to unreliable analysis results.

3.4 Supported Tubes, Tube Racks and Adapters

3.4.1 Supported Tubes

NOTE

 For the use of the tubes not mentioned hereof, please contact our customer service department or the local distributor.

3.4.1.1 Specifications of tubes and recommended sample volume in AL-WB mode

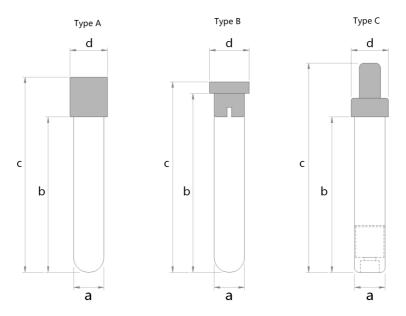


Figure 3-5 Specifications of tubes supported in AL-WB mode

| Tube Diameter (a) | 11 mm≤a≤15mm |
|-------------------------------|--------------|
| Length Excluding Tube Cap (b) | b≥58mm |
| Length Including Tube Cap (c) | 60 mm≤c≤91mm |

| Tube Cap Diameter (d) | (a+1mm)≤d≤18mm |
|-----------------------|----------------|
| | |

Table 3-9 Recommended sample volume in AL-WB mode

| Tube Diameter | Recommended Blood Sample Volume |
|--|---------------------------------|
| 11 mm≤a≤13mm | ≥0.9 mL |
| 13 mm <a≤15mm< th=""><th>≥ 2.0 mL</th></a≤15mm<> | ≥ 2.0 mL |

Table 3-10 Tube types supported in different sampling mode

| Sampling mode | Supported tube type |
|---------------|---------------------|
| CT-WB | Type A and Type B |
| AL-WB | Type A, B and C |

• In CT-WB mode, do not use Sarstedt Monovette tubes for analysis.

3.4.1.2 Specifications of tubes and recommended sample volume supported in AL-Micro WB mode

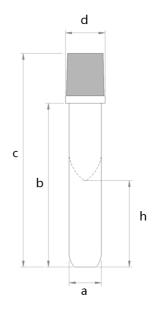


Figure 3-6 Specifications of tubes supported in AL-Micro WB mode

| Tube Diameter (a) | 11.6mm≤a≤12.6mm |
|---|-----------------|
| Length Under Tube Cap or Bulge (b) | b≥58mm |
| Length Including Tube Cap (c) | 60 mm≤c≤85mm |
| Diameter of Tube Cap or Bulge (d) | (a+1mm)≤d≤18mm |
| Spacing Between Cavity Bottom and Tube Bottom (h) | 20mm≤h≤36.5mm |

Mindray has performed tests on following tubes:

| Manufacturer | Recommended sample volume |
|----------------------------------|---------------------------|
| Kangjian KJ001-1 | ≥ 80µL |
| Xinle D type K ₂ EDTA | ≥ 80µL |

NOTE

 The cap of the long micro WB tubes supported in AL-Micro WB mode must be pierceable and supports the pressure balancing function.

3.4.1.3 Specifications of tubes and recommended sample volume supported in CT-BF mode:

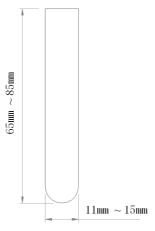


Figure 3-7 Specifications of cap-free tubes supported in CT-BF mode

Table 3-11 Recommended sample volumes supported in CT-BF mode

| Tube Diameter | Recommended Sample Volume |
|---------------|---------------------------|
| 11 mm~13mm | ≥1.0 mL |
| 13 mm~15mm | ≥ 2.0 mL |

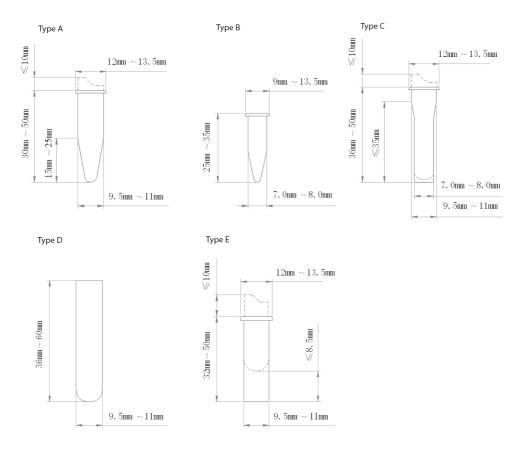


Figure 3-8 Specification of tubes supported in CT-Micro WB mode (type A - E)

Table 3-12 Recommended sample volume for tubes in CT-Micro WB mode (type A - E)

| Туре | Recommended sample volume |
|------|---------------------------|
| Α | ≥120µL |
| В | ≥110µL |
| С | ≥150µL |
| D | ≥200µL |
| E | ≥200µL |

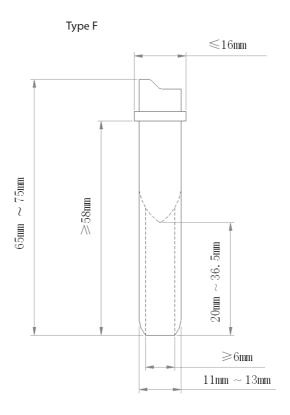


Figure 3-9 Specification of tubes supported in CT-BF mode (type F)

Mindray has performed tests on following type F tubes:

Table 3-13 Recommended sample volume for long tubes in CT-Micro WB mode (type F)

| Туре | Manufacture | Model | Recommended Blood Sample Volume |
|------|------------------------|--------------------|---------------------------------------|
| F | BD (the United States) | Microtainer MAP | ≥200μL |
| | Guangzhou Yangpu | IMPROMINI MAP only | ≥200μL |
| | Zhejiang Gongdong | GD005EK2S | ≥150μL |
| | Jiangsu Kangjian | KJ001-1 | ≥170μL |

3.4.1.4 Specifications of tubes and recommended sample volume supported in CT-Micro WB mode

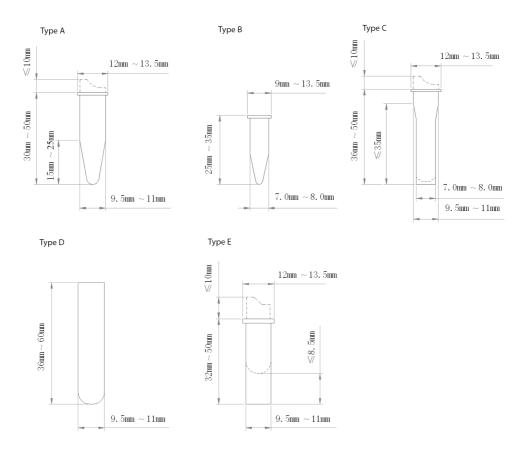


Figure 3-10 Specifications of short tubes supported in CT-Micro WB mode (type A - E)

Table 3-14 Recommended sample volume for short tubes in CT-Micro WB mode (type A - E)

| Туре | Recommended Blood Sample Volume | |
|------|---------------------------------|--|
| Α | 70μL | |
| В | 60μL | |
| С | 100μL | |
| D | 120μL | |
| Е | 100μL | |

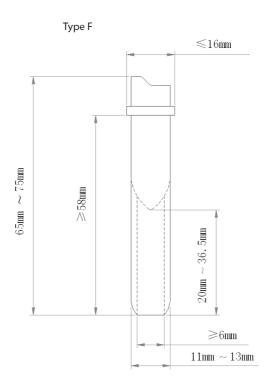


Figure 3-11 Specifications of long tubes supported in CT-Micro WB mode (type F)

Mindray has performed tests on following type F tubes:

Table 3-15 Recommended blood sample volume for long micro tube in CT-Micro WB mode (type F)

| Туре | Manufacture | Model | Recommended Blood Sample Volume |
|------|------------------------|--------------------|---------------------------------------|
| F | BD (the United States) | Microtainer MAP | 120µL |
| | Guangzhou Yangpu | IMPROMINI MAP only | 100μL |
| | Zhejiang Gongdong | GD005EK2S | 80μL |
| | Jiangsu Kangjian | KJ001-1 | 80μL |

3.4.1.5 Specifications of tubes and recommended sample volume supported in CT-PD mode:

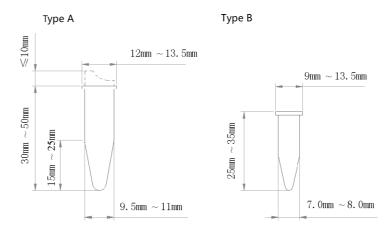


Figure 3-12 Specification of tubes supported in CT-PD mode

Recommended blood sample volume for short tube: at least 20µL.

3.4.2 Supported Tube Racks

NOTE

Please use the tube racks specified by the manufacturer only.

The specifications of the tube racks supported by the analyzer are shown in the figure below:

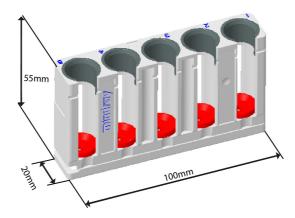


Figure 3-13 Tube rack for regular tubes in AL-WB mode (5 positions)

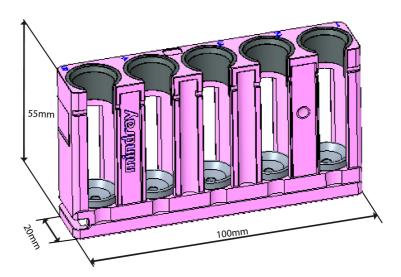


Figure 3-14 Tube rack for AL-Micro WB mode (5 positions)

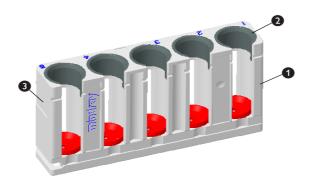
In the auto-loading mode, the downward depth of the sampling probe may vary for the different samples in the tubes with different specifications. During installation, Mindray Service Engineer will set the downward depth of sampling probe for the tube racks with different number according to the tube types in your laboratory. Users may recognize the purposes of different tube racks based on their characteristics and number.



CAUTION

 The tube racks for different modes cannot be misused, otherwise, the sampling probe may fail to aspirate the sample due to insufficient downward depth, be damaged or touch the tube bottom and damage the tube due to excessive downward depth.

• To change the tube rack number, please contact Mindray Customer Service Department.



| 1 | Tube racks |
|---|------------------------|
| 2 | Tube position adapters |
| 3 | Tube rack numbers |

Table 3-16 Types of tube rack

| | Supported tube types | Tube rack characteristics | Other Information |
|-------------------------------------|---|--|--|
| Tube rack 1 for AL-WB mode | For Type A and B, refer to Figure 3-5Specifications of tubes supported in AL- WB mode | White tube racks; gray inserts | Specification of tube rack depends on the analyzer model. |
| Tube rack 2 for AL-WB mode | Refer to Figure 3- 5Specifications of tubes supported in AL-WB mode. | White tube racks; colored inserts ((customization supported) | Confirm that the supported tubes include BD Microtainer MAP Microtube and Sarstedt Monovette tube. In case of analysis with BD Microtainer MAP Microtube and Sarstedt Monovette, it is forbidden to use the different tube racks at the same time. |
| Tube racks for AL- Micro WB mode | Refer to Figure 3- 6Specifications of tubes supported in AL-Micro WB mode | The tube racks are pink The inserts are white | Specification of tube rack depends on the analyzer model. |

3.4.3 Supported Adapters

The analyzer may use the adapters for the tube positions of Micro-WB/prediluted samples and the adapters for the tube positions of calibrators.

3.4.3.1 Adapters for the tube positions of Micro-WB/prediluted samples

When analyzing samples under CT-Micro WB/Predilute mode, the adapters are placed in the tube positions of CT-Micro WB/prediluted samples in the sample compartment to match with the tubes of different specifications.

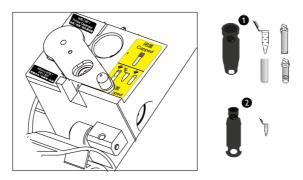


Figure 3-15 Adapters for sample compartment

| 1 | The adapters with the larger-diameter end upward |
|---|---|
| 2 | The adapters with the smaller-diameter end upward |

NOTE

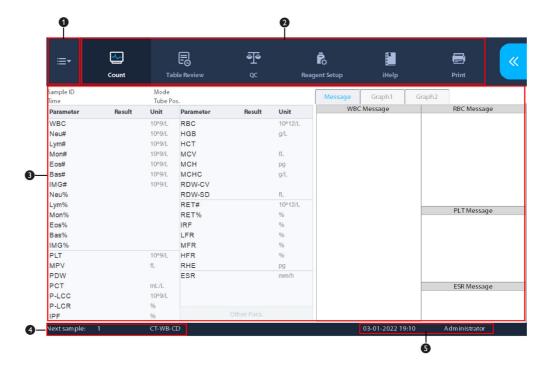
 If the sample to be analyzed is micro whole blood or prediluted sample, be sure to uncap the tube before analysis.

Table 3-17 Tube position and adapters of sample compartment

| Tube Position | Adapter | Supported Mode | Applicable Tubes |
|--|--|-------------------|--|
| WB/BF/Probe Cleanser Tube Position | / | CT-WB | Tube type A and tube type B (capped tube), as shown in Figure 3-5Specifications of tubes supported in AL-WB mode |
| | | CT-BF | As shown in Figure 3-7Specifications of cap-free tubes supported in CT-BF mode. |
| Micro-WB/PD/BF Tube Position | / | CT-Micro WB | Tube type F, as shown in Figure 3-7Specifications of cap-free tubes supported in CT-BF mode. |
| | | CT-BF | |
| | | CT-Micro WB | Tube types A, C, D and E, as shown in Figure 3- 10Specifications of short tubes supported in CT- Micro WB mode (type A - E) . |
| | | CT-PD | Tube type A, as shown in Figure 3-12Specification of tubes supported in CT-PD mode. |
| | (the adapter with the larger- diameter end upward) | CT-BF | Tube types A, C, D and E, as shown in Figure 3-10Specifications of short tubes supported in CT-Micro WB mode (type A - E) . |

| Tube Position | Adapter | Supported Mode | Applicable Tubes |
|---------------|--|-------------------|--|
| | | CT-Micro WB | Tube type B, as shown in Figure 3-10Specifications of |
| | | CT-PD | short tubes supported in CT-Micro WB mode (type A - E). |
| | | CT-BF | |
| | (the adapter with the smaller- diameterend upward) | | |

3.5 Overview of Software Interfaces



■ ① Menu 🚞 🔻

Tap the button at the top left of the software screen to display the system menu.

The following table lists the menu functions of the software system:

| No. | Level 1 | Level 2 | Level 3 |
|-----|--------------|---------|---------|
| 1 | Count | 1 | / |
| 2 | Table Review | 1 | 1 |
| 3 | QC | r-1 GC | Setup |
| | | | Count |
| | | X-B QC | Setup |
| | | | Graph |

| No. | Level 1 | Level 2 | Level 3 |
|-----|-------------|---|---------------------------------------|
| 4 | Calibration | Manual | / |
| | | ESR(Administrator) | / |
| | | Calibrator(Administrator) | / |
| | | Fresh Blood(Administrator) | / |
| | | Calibration History(Administrator) | / |
| 5 | Status | Statistics | / |
| | | Temp.&Pressure(Administrator) | / |
| | | Floater Status (Administrator) | / |
| | | Sensor(Administrator) | / |
| | | Voltage & Current(Administrator) | / |
| | | Version Info. | / |
| 6 | Setup | System Setup | Print Setup |
| | | | Communication(Administrator) |
| | | | Barcode(Administrator) |
| | | | Date/Time Setup |
| | | | Lab Info. Setup |
| | | | Flag Alarm Sensitivity(Administrator) |
| | | | Flag Rules Setup(Administrator) |
| | | | Tube Rack Type Setup |
| | | | Ext. PLT Tests(Administrator) |
| | | User Management | / |
| | | Auxiliary Setup | / |
| | | Para. Setup | Parameter Unit Setup |
| | | | Ref. Range Setup |
| | | | Microsco. Para. Setup(Administrator) |
| | | Maintenance(Administrator) | / |
| | | Reagent Setup | / |
| | | Auto-loading(Administrator) | / |
| | | Gain Setup(Administrator) | / |
| | | Re-exam Rules Setup(Administrator) | / |
| | | Auto Startup/Shutdown(Administrator) | / |
| 7 | Service | Debug & Self-Test | Self-Test |
| | | Precise Fault Diagnosis (Administrator) | / |
| | | iHelp | / |
| | | Maintenance | / |
| | | Screen Cal. | / |
| | | Log | / |
| 8 | Logout | / | / |

| No. | Level 1 | Level 2 | Level 3 |
|-----|----------|---------|---------|
| 9 | Shutdown | 1 | 1 |

NOTE

- When a function is followed by "administrators", it means the function is only available to operators at administrator's level.
- ② Utility Button area

| Name | Icon | Functions |
|---------------|------------------|---|
| Count | Count | Tap to enter the "Count" screen. |
| Table Review | Table Review | Tap to enter the " Table Review " screen. |
| QC | ⊕ [∳ ∝ | Tap to enter to enter the "QC" screen. When the "QC" button lighted in orange, it means the analyzer is out of quality control |
| Reagent Setup | Reagent Setup | Tap to enter the "Reagent Setup" screen, check or set the remaining volumes and expiration date, and replace the reagent; When the "Reagent Setup" button lights in orange, it means some reagent is expired or not sufficient |
| iHelp | iHelp | Tap to enter the " iHelp " screen. |
| Print | Print | When the analyzer is on the "Count" screen, tap the "Print" button to print the analysis results, histograms and scattergrams of the current sample in accordance with operator-customized print template When the analyzer is on the "Table Review" screen, tap the "Print" button to print the analysis results for all or selected samples in the table print or graph print form When the analyzer is on the "Graph" screen, tap the "Print" button to print the analysis results, histograms and scattergrams of the current sample in accordance with operator-customized print template When the analyzer is on the "QC Table" screen, tap the "Print" button to print all QC results included in the selected QC file When the analyzer is on the "QC Graph" screen, tap the "Print" button to print the QC graphs included in the selected QC file When the analyzer is on the "Manual" screen, tap "Print" to print the manual calibration factors |

■ ① Operation area

Displays contents of the screens.

For example, on the "Count" screen, the area displays function buttons related to sample analysis as well as the sample analysis results.

2 Auxiliary information area

This area displays auxiliary information of the current screen;

For example, on the "Count" screen, the area displays the ID and analysis mode of the next sample; on the "Table Review" or "Graph" screen, the area displays position of the current sample and total number of samples

■ ③ Other information

It displays the current system time;

When error occurs, the area displays the error message;

If you log in as an administrator, the area displays "Administrator".

3.6 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, controls, and calibrators 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, controls, and calibrators from multiple suppliers. In such case, the analyzer may not meet the performance specified in this manual and may provide unreliable results.

All the reagents, controls, and calibrators mentioned in this manual refer to the reagents, controls, and calibrators specifically formulated for this analyzer. You must buy those reagents, controls, and calibrators from Mindray or Mindray-authorized distributors. When you need to buy reagents and consumables, please call Mindray Customer Service Department.

3.6.1 Reagent

All reagents used by this analyzer are specifically matched with Mindray equipment. Use for any other purpose is prohibited.

Correctly use ans store reagents according to their Instructions for Use.

NOTE

- For the reagent model, intended use, test principle, main components, storage conditions, expiration date, applicable models, and other information, please refer to the reagent IFU.
- For any questions related to reagents, controls, and calibrators, please consult your sales representatives.

Table 3-18 Reagents

| Applicable Channel | BC-760[B] | BC-760[R]/BC-780[R] |
|--------------------|----------------------|----------------------|
| HGB Channel | LH Lyse | LH Lyse |
| DIFF Channel | LD Lyse | LD Lyse |
| | FD Dye | FD Dye |
| RET Channel | / | *DR Diluent |
| | / | *FR Dye |
| / | DS Diluent | DS Diluent |
| | Probe Cleanser | Probe Cleanser |
| ESR channel | ESR Solution Reagent | ESR Solution Reagent |

3.6.2 Controls and Calibrators

The controls and calibrators are used to verify accurate operation and calibration of the analyzer.

The controls are suspension of simulated human blood, specifically manufactured to monitor and evaluate the analysis precision of the analyzer. The controls are prepared with three levels, namely low, normal and high. Daily use of all levels verifies the operation of the analyzer and ensures reliable results are obtained. The calibrators are commercially prepared whole-blood products used to calibrate some parameters (WBC, RBC, HGB, MCV and PLT etc.) of analyzer to build the metrological traceability of analysis results. For the use and storage of controls and calibrators, please refer to the Instruction for Use of each product.

All references related to controls 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.

The following models of controls are used with the analyzer:

Table 3-19 Controls for complete blood count tests

| Name | Model | Level | Applicable Model | *QC Parameters |
|--------------------|--------|----------------------|-----------------------------------|---|
| Hematology Control | BR60 | High, Low, Normal | BC-760[B]/BC- 760[R]/BC-780[R] | All blood sample test report parameters except ESR |
| Hematology Control | BC-6D | High, Low, Normal | BC-760[B]/BC- 760[R]/BC-780[R] | All blood sample test report parameters except RET series |
| Hematology Control | BC-RET | High, Low, Normal | BC-760[R]/BC- 780[R] | RET group report parameters |

Table 3-20 Controls for body fluid tests

| Name | Model | Level | Applicable Model | QC Parameters |
|--------------------|-------|----------------------|-----------------------------------|--|
| Hematology Control | BC-BF | High, Normal, Low | BC-760[B]/BC-760[R]/ BC-780[R] | Body fluid sample test report parameters |

Table 3-21 Controls for ESR tests

| Name | Model | Level | Applicable Model | QC Parameters |
|--------------------|-------|----------------|-----------------------------------|---------------|
| Hematology Control | BC-6D | Normal, Low | BC-760[B]/BC-760[R]/BC- 780[R] | ESR |

The following models of calibrators are used with the analyzer:

Table 3-22 Calibrator for complete blood count tests

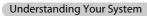
| Name | Model | Applicable Model |
|-----------------------|-------------|-------------------------------|
| Hematology Calibrator | SC-CAL PLUS | BC-760[B]/BC-760[R]/BC-780[R] |

NOTE

 For the specific test parameters and reference values of parameters, see the reference value sheets of controls and calibrators.

Figure 3-16 Calibrator for ESR tests

| Name | Model | Applicable Model |
|-----------------------|-------------|-------------------------------|
| Hematology Calibrator | SC-CAL PLUS | BC-760[B]/BC-760[R]/BC-780[R] |



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4 Understanding the System Principles

4.1 Overview

The principles used by the analyzer are:

- Sheath flow impedance method, laser scatter and SF Cube cell analysis technology (3D analysis using information from scatter of laser light at two angles and fluorescence signals) for cell differentiation and counting;
- Colorimetric method for HGB measurement.

Based on the above data, the analyzer calculates other parameters.

4.2 WBC Measurement

4.2.1 SF CUBE Cell Analysis Technology

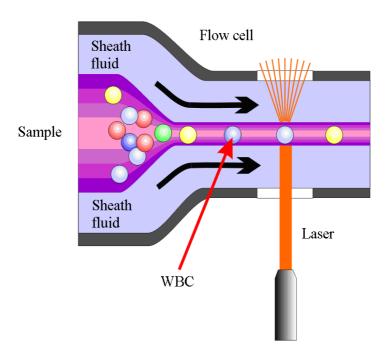


Figure 4-1 Laser flow cytometry

In normal peripheral blood, white blood cells can be classified into five categories: lymphocytes, monocytes, neutrophils, eosinophils and basophils. Analyzing all types of white blood cells will provide a great deal of useful information for the clinical diagnosis of diseases. Under the influence of certain diseases, the peripheral blood may contain various abnormal cells apart from the five subpopulations of normal cells, such as

atypical lymphocytes, immature cells, etc. Most of these abnormal cells are different kinds of immature cells in the cell generation process. But what they have in common is they contain a great deal of nucleic acid (DNA and RNA), the content of which decreases as the cell gets maturer. Therefore, normal cells and immature cells can be differentiated by detecting the content of nucleic acid in the cells.

Body fluid refers to the fluid in side body cavities except blood vessels. There are many sub-types of body fluid, among which the most commonly seen sub-types are cerebrospinal fluid, pleural fluid, ascitic fluid, and synovial fluid. Both cerebrospinal fluid and serous cavity fluid are colorless and transparent in normal case, but in abnormal cases, there could be increase of cells (including leukocytes and erythrocytes). Leukocytes in body fluid can be categorized into mononuclear cells (MN) and polymorphonuclear cells (PMN). The analysis of the cells in body fluid can provide useful information for clinical diagnosis.

The analyzer adopts the SF Cube cell analysis technology to recognize and detect the immature cells in blood accurately besides doing WBC 5-part differentiation, as well as identify the nucleated cells in body fluid.

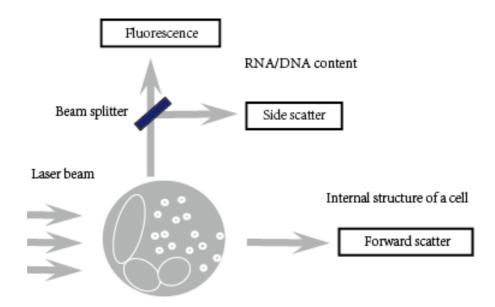


Figure 4-2 SF cube technology

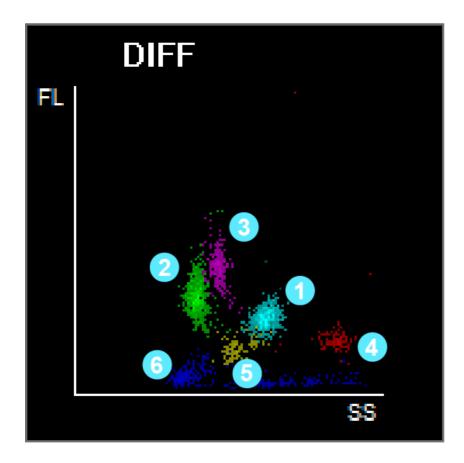
The analyzer adopts the fluorescent staining technology in its DIFF channels. The RBCs are lysed and the WBC subpopulations are made different in size and complexity by the lyse; the nucleic acid substances in WBCs are marked by the new asymmetric cyanine fluorescent substance. Due to the different content of nucleic acid in different WBC subpopulations, maturity stages or abnormal development status, the volume of fluorescent dye staining the nucleic acid substances can be different; the low-angle light scatter reflects the cell size, the high-angle light scatter reflects the intracellular granularity, and the intensity of fluorescent signal reflects the degree that the cell is stained. By sensing the difference in signal in three dimensions of the cells processed with lyse, the DIFF channel differentiates the subpopulations of WBCs (lymphocytes, monocytes, neutrophil and eosinophils), as well as identifies and flags abnormal cells like immature granulocytes, abnormal lymphocytes and blast cells.

The lymphocytes are smaller in size with the nucleus taking most part of them. Lymphocytes have a high nucleus-to-cytoplasm ratio, but their nucleic acid content is low, therefore they are at a lower position in the direction of fluorescence and side scatter. The monocytes are larger in size, with high nucleus-to-cytoplasm ratio and high nucleic acid content, and less complex in structure, therefore they are at a higher position in the direction of fluorescence, and have stronger side scatter. The neutrophils and basophils are larger in size, and have medium nucleus-to-cytoplasm ratio and low nucleic acid content, therefore they are at a lower position in the direction of fluorescence, but they have stronger side scatter. The characteristics of the eosinophils are similar to those of the neutrophils, but they contain a lot of alkaline grains, so they have very strong side scatter. The blast cells, atypical lymphocytes and immature granulocytes have high nucleic acid content, so they are at a higher position in the direction of fluorescence on the scattergram.

In body fluid samples, the mononuclear cells (MN) are less complex in intracellular granularity, so the side scatter is weaker, while polymorphonuclear cells are more complex in intracellular granularity, so the side scatter is stronger.

4.2.2 Derivation of WBC-Related Parameters

DIFF Scattergram



- 1. Neu region
- 2. Lym region
- 3. Mon region
- 4. Eos region
- 5. Baso region
- 6. Ghost region

| Parameters | Name | Formula/Test Methods | Unit |
|------------|------------------------|--|--------------------|
| WBC | White blood cell count | WBC=Sum of all particles in the WBC region in the DIFF channel | 10 ⁹ /L |
| Bas# | Basophil count | Bas# = WBC x Bas% | 10 ⁹ /L |
| Bas% | Basophil percentage | $Bas\% = \frac{\text{Particles in the Bas reagion in the DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost reagion}} \times 100\%$ | % |
| Neu# | Neutrophil count | Neu# = WBC x Neu% | 10 ⁹ /L |
| Neu% | Neutrophil percentage | Neu% = $\frac{\text{Particles in the Neu reagion in the DIFF channel}}{\text{Sum of all particles in DIFF channel except those in Ghost reagion}} \times 100\%$ | % |
| Eos# | Eosinophil count | Eos# = WBC x Eos% | 10 ⁹ /L |
| Eos% | Eosinophil percentage | $Eos\% = \frac{Particles in the Eos reagion in the DIFF channel}{Sum of all particles in DIFF channel except those in Ghost reagion} \times 100\%$ | % |
| Lym# | Lymphocyte count | Lym# = WBC x Lym% | 10 ⁹ /L |
| Lym% | Lymphocyte percentage | $Lym\% = \frac{Particles \ in \ the \ Lym \ reagion \ in \ the \ DIFF \ channel}{Sum \ of \ all \ particles \ in \ DIFF \ channel \ except \ those \ in \ Ghost \ reagion} \times 100\%$ | % |
| Mon# | Monocyte count | Mon# = WBC x Mon% | 10 ⁹ /L |

| Parameters | Name | Formula/Test Methods | Unit |
|------------|---------------------------------|--|--------------------|
| Mon% | Monocyte percentage | $Mon\% = \frac{Particles \ in \ the \ Mon \ reagion \ in \ the \ DIFF \ channel}{Sum \ of \ all \ particles \ in \ DIFF \ channel \ except \ those \ in \ Ghost \ reagion} \times 100\%$ | % |
| IMG# | Immature granulocyte count | IMG# = WBC x IMG% | 10 ⁹ /L |
| IMG% | Immature granulocyte percentage | IMG%= Particles in the IMG reagion in the DIFF channel Sum of all particles in DIFF channel except those in Ghost reagion ×100% | % |

4.3 Hemoglobin Concentration Measurement

4.3.1 A Test Model Using the Colorimetric Method

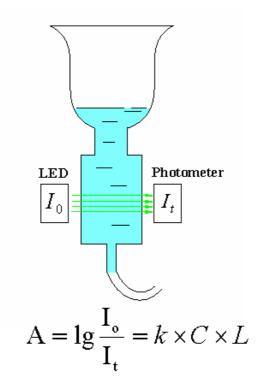


Figure 4-3 Colorimetric method

According to the Lambert-Beer Principle, when a beam of monochromatic light passes through a well-proportioned non-scattering light-absorbing solution, the absorbance A is proportional to the product of the thickness L and the concentration C. The sample in the HGB channel acts as the light absorbing substance after being treated by reagent, therefore the HGB concentration can be measured by measuring the absorbance.

4.3.2 Derivation of HGB

Hemoglobin Concentration (HGB) is calculated using the following equation and expressed in g/L.

| Param eters | Name | Formula/Test Methods | Unit |
|----------------|-----------------------------|--|------|
| HGB | Hemoglobin Concentration | $HGB = Constant \times Ln \left(\frac{Blank Photocurrent}{Sample Photocurrent} \right)$ | g/L |

4.4 RBC/PLT Measurement

4.4.1 Sheath Flow Impedance Method

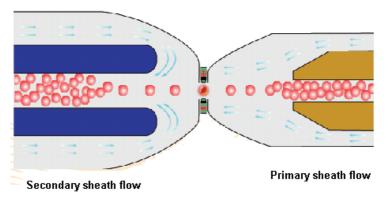


Figure 4-4 Sheath flow impedance method

RBCs/PLTs are counted by the sheath flow impedance method. A sensor is designed to enable the RBCs and PLTs to pass through the aperture one by one in a queue under the "focusing" effect of fluid, during which process pulses will be generated according to the Coulter Principle. The backend processor amplifies the pulses and compares them with the voltage thresholds of the RBC/PLT channel, and then the number of pulses in the RBC/PLT channel is calculated. That is to say, the pulses collected are sorted per the voltage thresholds of different channels, the number of pulses falling in the range of the RBC/PLT channel is the number of RBC/PLT. The number of cells in each channel defines the volume distribution of cells. The analyzer presents the RBC/PLT histogram, whose x-coordinate represents the cell volume (fL) and y-coordinate represents the number of the cells.

Compared with the common impedance method, the sheath flow impedance method is featured by higher efficiency, better signal quality, more accurate analysis results and lower consumption of reagents.

4.4.2 Measurement Principle of Platelets in DIFF Channel (PLT-H)

Traditional impedance method counts platelets by sorting and detecting the pulses fall in the PLT channel per cell size. However, as microcytes and fragments are similar in size with platelets with relatively large size, when there are microcytes/fragments present, the impedance method may deliver not so accurate PLT results. To solve the problem, the analyzer lyses the erythrocytes in the DIFF channel, so the count of platelets in relatively large sizes in DIFF channel will not be affected by erythrocytes. By combining the large-size platelet count result in DIFF channel and the small-size platelet count result in the impedance channel, the analyzer provides more accurate PLT results.

4.4.3 SF CUBE Cell Analysis Technology

The RET channel also adopts the SF CUBE Cell Analysis Technology. The general measurement principle in RET channel is similar to that of DIFF channel, only that in the RET channel, the RBCs are not lysed, but are spherized by RET diluent. Then the nucleic acid of the spherized RBCs and the PLTs are stained by fluorescent dyes.

NOTE

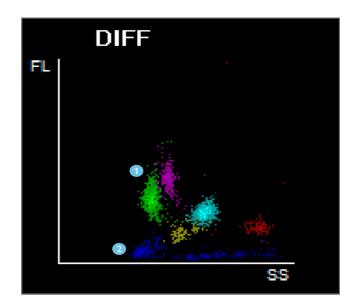
• RET channel is available only on BC-760[R]/BC-780[R] model.

4.4.4 RBC-Related Parameters

| Parameters | Name | Formula/Test Methods | Unit |
|--------------------|---|---|--------------------|
| RBC | Red blood cell count | Red blood cell (RBCs) number is measured directly by counting the red blood cells passing through the aperture. | |
| MCV | Mean corpuscular volume | Calculated based on the red blood cell histogram | fL |
| НСТ | Hematocrit | $HCT = \frac{RBC \times MCV}{10}$ | % |
| MCH | Mean corpuscular hemoglobin | $MCH = \frac{HGB}{RBC}$ | pg |
| МСНС | Mean corpuscular hemoglobin concentration | memoglobin $MCHC = \frac{HGB}{HCT} \times 100$ | |
| RDW-CV | Red blood cells distribution width coefficient of variation | RBC Histogram | % |
| RDW-SD | Red blood cells distribution width standard deviation | Derived based on the standard deviation of red blood cell volume distribution | fL |
| NRBC% ¹ | Nucleated red blood cell percentage | Calculated based on the information derived from LYM region ① and Ghost region ② of DIFF scattergram | /100WBC |
| NRBC# | Nucleated red blood cell count | NRBC#=WBC x NRBC% | 10 ⁹ /L |

Note:

1. LYM region ① and Ghost region ② of DIFF scattergram are as follow:

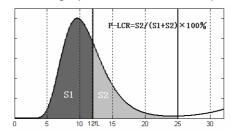


4.4.5 PLT-Related Parameters

| Paramete rs | Name | Formula/Test Methods | Unit |
|--------------------|------------------------------|--|--------------------|
| PLT | Platelet count | Method 1: The analyzer provides the number of platelet directly by counting the platelets passing through the aperture. Method 2: Based on the analysis result of large platelet in DIFF channel, correct the analysis result of platelet in impedance channel | 10 ⁹ /L |
| MPV | Mean platelet volume | Mean platelet volume (MPV) is calculated based on the PLT histogram. | fL |
| PDW | Platelet distribution width | Platelet distribution width is derived from the platelet histogram, and is reported as 10 geometric standard deviation (10 GSD) | / |
| PCT | Plateletcrit | $PCT = \frac{PLT \times MPV}{10000}$ | % |
| P-LCR ¹ | Platelet-large cell ratio | P-LCR is derived from the platelet histogram, it represents the ratio of the number of platelets with a size over 12 fL to the total platelets number | % |
| P-LCC | Platelet-large cell count | P-LCC = PLT x P-LCR | 10 ⁹ /L |
| IPF ² | Immature platelet fraction* | For BC-760[R]/BC-780[R], , the parameter is derived based on PLT-O scattergram: $IPF = \frac{Immature\ platelet\ number\ in\ the\ optical\ channel}{Sum\ of\ all\ platelet\ particles\ in\ the\ optical\ channel} \times 100\%$ For BC-760[B], this is an optional parameter and is derived based on PLT-H scattergram. $IPF = \frac{Immature\ platelet\ number\ in\ the\ DIFF\ channel}{VIPF} \times 100\%$ | |
| PLT-I | Platelet count- Impedance | PLT-H result Platelet number (PLT) is measured directly by counting the platelets passing through the aperture. | |
| PLT-H | Platelet count hybrid | PLT results derived from impedance channel, which are corrected by the DIFF channel large size platelet results. | 10 ⁹ /L |
| PLT-O | Optical platelet count | PLT results derived from the RET channel | 10 ⁹ /L |

Note:

1. Platelet-Large Cell Ratio (P-LCR) is derived from the platelet histogram; it represents the ratio of the number of platelets with a size over 12fL to the total platelets number. The ratio is represented in %. In the following figure, S2 represents the number of larger platelet cells, and S1+S2 represents the total PLT count.



- 2. IPF parameters are applicable to the BC-760[R]/BC-780[R]model only. For BC-760[B], this is an optional parameter. For more information, contact Mindray Customer Service Department.
- 3. PLT-O is applicable to BC-760[R]/BC-780[R]model only.
- 4. PLT-H is applicable to BC-760[R]/BC-780[R]model only. For BC-760[B], this is an optional parameter. For more information, contact Mindray Customer Service Department.

4.4.6 Reticulocyte Parameters*

| Paramete rs | Name | Formula/Test Methods | Unit |
|----------------|--|---|---------------------|
| *RET% | Reticulocyte percentage | $RET\% = \frac{\text{Number of cells in the reticulocyte region}}{\text{Number of cells in mature RBC region} + \text{Number of cells in RET region}} \times 100\%$ | % |
| *RET% | Reticulocyte count | RET# = RBC x RET% | 10 ¹² /L |
| *HFR | High fluorescent ratio | $HFR = \frac{\text{Number of cells in HFR region}}{\text{Number of cells in RET region}} \times 100\%$ | % |
| *MFR | Middle fluorescent ratio | $MFR = \frac{Number of cells in MFR region}{Number of cells in RET region} \times 100\%$ | % |
| *LFR | Low fluorescent ratio | $LFR = \frac{Number\ of\ cells\ in\ LFR\ region}{Number\ of\ cells\ in\ RET\ region} \times 100\%$ Note: Sum of all particles in the reticulocyte region = Sum of all particles in the LFR region + Sum of all particles in the HFR region + Sum of all particles in the HFR region | % |
| *IRF | Immature reticulocyte fraction | IRF = MFR + HFR | % |
| RHE | Reticulocyte hemoglobin expression | Calculated based on the light scatter information of RET | pg |

^{*}Note: The reticulocyte parameters are only available on the BC-760[R]/BC-780[R] model.

4.5 Erythrocyte Sedimentation Rate Measurement

The analyzer uses the photometric method to measure the aggregation of erythrocytes within a specified time period and calculates the sedimentation rate. RBCs separated in the whole blood sample first aggregate and form Rouleaux formation; then the aggregation falls. The sedimentation rate depends on the degree of aggregation. As the measuring beam is subject to the RBC aggregation state, specifically manifested in that its light transmittance increases with the aggregation degree. As a result, the aggregation degree of RBCs can be obtained by measuring the change in the light transmittance of whole blood samples over time, and then the erythrocyte sedimentation rate is calculated.

4.6 Body Fluid Parameters

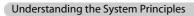
Body fluid refers to the fluid in side body cavities except blood vessels. There are many sub-types of body fluid, among which the most commonly seen sub-types are cerebrospinal fluid, pleural fluid, ascitic fluid, and synovial fluid. Both cerebrospinal fluid and serous cavity fluid are colorless and transparent in normal case, but in abnormal cases, there could be increase of cells (including leukocytes and erythrocytes). Leukocytes in body fluid can be categorized into mononuclear cells (MN) and polymorphonuclear cells (PMN). The analysis of the cells in body fluid can provide useful information for clinical diagnosis.

| Paramete rs | Name | Formula/Test Methods | Unit |
|----------------|-----------------------------------|--|--------------------|
| WBC-BF | White blood cell count-body fluid | WBC-BF = Sum of all particles in the DIFF channel except those in Ghost region and HFR | 10 ⁹ /L |

| Paramete rs | Name | Formula/Test Methods | Unit |
|----------------|--|--|---------------------|
| TC-BF# | Total nucleated cell counts-body fluid | TC-BF# = Count of all particles in the DIFF channel except those in Ghost region | 10 ⁹ /L |
| MN% | Mononuclear cell percentage | $MN\% = \frac{\text{Paticles in MN reagion of DIFF channel}}{\text{WBC} - \text{BF}} \times 100\%$ | % |
| PMN% | Polymorphonucle ar cell percentage | $PMN\% = \frac{Paticles in PMN reagion of DIFF channel}{WBC - BF} \times 100\%$ | % |
| MN# | Mononuclear cell number | MN#=WBC-BF ×MN% | 10 ⁹ /L |
| PMN# | Polymorphonucle ar cell number | PMN#=WBC-BF×PMN% | 10 ⁹ /L |
| RBC-BF | Red Blood Cell count-body fluid | Red blood cells in body fluid (RBC-BF) are measured directly by counting the red blood cells passing through the aperture. | 10 ¹² /L |

4.7 Wash

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



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Installing and Connecting the System

5.1 **Notes for Analyzer Installation**

CAUTION

- The installation, authorization, upgrade and modification of the system software must be performed by personnel authorized by Mindray. Make sure to install only Mindray-authorized software.
- Unpacking, installation or transportation by personnel not authorized or trained by Mindray may cause personal injury or damage your instrument. Do not unpack, transport or install your instrument without the presence of Mindray-authorized personnel.

NOTE

- The safety of any system incorporating the equipment is the responsibility of the assembler of the
- The equipment 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.
- After you open the package, check the integrity of the product according to the packing list. If you find any part missing, contact Mindray Customer Service Department or your local distributor immediately.

5.1.1 **Space Requirements**

For the dimensions and weight of the analyzer, please refer to **B.16Dimensions and Weight**.

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

- Proper height to place the analyzer;
- At least 500 mm on each side of the analyzer, which is the preferred access to perform service procedures;
- At least 600 mm above the analyzer;
- At least 250 mm behind the analyzer;
- The diluent container must be placed within 1.0 meter's reach under the main unit, the lyse container must be placed on a plane of the same level with the main unit.
- Desktop or platform must be capable to bear about the weight of 180kg.

5.1.2 **Power Requirements**

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 system or lead to unreliable analysis results.

| | Voltage | Frequency | Input power |
|-------------------------|-------------------|---------------------|-------------|
| Main Unit (Analyzer) | 100-240 V~ (±10%) | 50 Hz/60 Hz (±1 Hz) | 600VA |

5.1.3 **Environment Requirements**

| | Normal Operation Environment | Storage and Transportation Environment | Operation Environment |
|----------------------|----------------------------------|---|-----------------------|
| Ambient temperature | 10~35℃ | -10~40℃ | 5~40℃ |
| Relative Humidity | 30%~85% | 10%~90% | 10%~90% |
| Atmospheric pressure | 70.0kPa~106.0kPa ^{Note} | 50.0kPa~106.0kPa | 70.0kPa~106.0kPa |

Note:

- The altitude requirement for normal operation is -400 m to +3000 m
- Install the instrument at a position not exposed to splashing water.
- The environment should be as free as possible from dust, mechanical vibrations, loud noises and electrical interference;
- It is advisable to evaluate the electromagnetic environment prior to operation of this analyzer.
- Do not use this instrument in close proximity to sources of strong electromagnetic radiation;
- Do not place the analyzer near brush-type motors, flickering fluorescent lights, and electrical contacts that regularly open and close;
- Do not place the analyzer in direct sunlight or in front of a source of heat or drafts;
- Do not use the instrument in a working environment with conductive or combustible gases.
- The environment shall be well ventilated;
- Do not place the analyzer on a slope;
- Connect only to a properly earth grounded outlet;
- Only use this analyzer indoors.

5.1.4 **Fuse Requirement**



WARNING

The fuse used in the instrument is not a replaceable one. If there is any problem with the fuse, contact Mindray Customer Service Department or your local distributor.

5.1.5 Moving and Installing 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.

A CAUTION

- When installing or using the analyzer, make sure at least the two inside supporters of the autoloader are on the supporting table of the analyzer.
- After the autoloader is installed, do not lay too much pressure to it or transport the analyzer by holding the autoloader.

5.1.5.1 **Analyzer transportation**

Insert the handle bars horizontally into the four handling holes at the bottom plate of the main unit to the limit positions respectively, as shown in the figure below.



Figure 5-1 Inserting the handle bar

Rotate the handles to the vertical position, as shown in the following figure. Pull the handles out to see whether they are firm. If yes, the main unit can be conveyed..



Figure 5-2 Handling position of the handle bar

NOTE

- The main unit must be carried by two persons with the handles to avoid tilting and other accidents. Sufficient space must be reserved for the main unit to ensure that the two inside supporters of the autoloader can be placed onto the deck panel of the main unit.
- Avoid colliding with the main unit, especially the inlets on the rear panel of the main unit.

5.2 Connecting the Analyzer System

5.2.1 Connecting the Reagents

NOTE

• When connecting the reagents, make sure the color of the reagent container cap assembly is the same as that of the reagent inlet to which it is connected.

Connecting the reagent containers to the analyzer as shown in the following figure

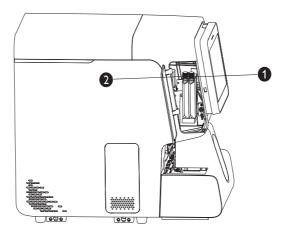


Figure 5-3 Reagent connection - connecting fluorescent dyes

| Interface No. | Туре | Description |
|------------------|--------|--|
| 1 | FR Dye | Applicable to BC-760[R]/BC-780[R]model |
| 2 | FD Dye | / |

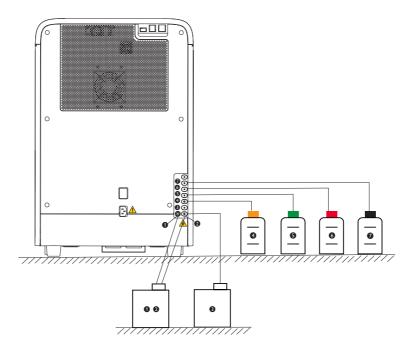
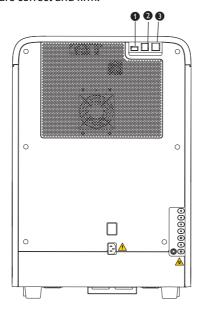


Figure 5-4 Connecting reagents - lyse, diluent, and waste

| Interface No. | Type of Connected Reagent | Description |
|------------------|---------------------------|--|
| 12 | Waste container | Interface ② is used to connect the waste container, and interface ① connects to the waste floater sensor to detect whether the waste container is full |
| 3 | DS Diluent | / |
| 4 | ESR Solution Reagent | / |
| 5 | LH Lyse | / |
| 6 | LD Lyse | / |
| 7 | DR Diluent | Applicable to BC-760[R]/BC-780[R] model |

5.2.2 **Connecting the Peripherals**

Make sure that the connections are correct and firm.



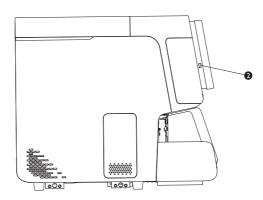


Figure 5-5 Connecting the peripherals

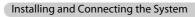
| Interface No. | Interface | Connection |
|------------------|-------------------------|---|
| 1 | USB port (protocol 3.0) | Connect to optional devices such as the printer and scanner through the USB |
| 2 | USB port (protocol 2.0) | ports as needed |
| 3 | Network interface | Connect to the network port on the PC |

(L) CAUTION

- Be sure to use the specified external devices only, and keep them away from water.
- External devices 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 instrument Standard and CISPR 22 EMC of Information Technology instrument Standard (Class B)). Any persons who connects additional instrument 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.

NOTE

- The user should ensure the data safety of the USB devices connecting to the analyzer.
- When the instrument connects to an external computer, install anti-virus software on the computer andscan for viruses and update patches periodically. Do not use it for unintended purposes.



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6.1 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.

For the security of the settings and data, two access levels are provided to the operator of the analyzer: "General User" and "Administrator". The administrator access level provides the operator with access to more functions or settings, some of which can be configured to be accessible to operators.

The following tables list the users' access by the access levels.

| | | | Administrator's level | Operator's level |
|-----------------|------------------------|--|-----------------------|------------------|
| System Setup | Print Setup | | √ | Partly |
| | Communication | | √ | |
| | Barcode | | √ | |
| | Date/Time Se | tup | √ | √ |
| | Lab Info. Setu | р | √ | √ |
| | Flag Alarm Se | nsitivity | √ | |
| | Flag Rules Set | up | √ | |
| | Tube Rack Typ | oe Setup | Review only | Review only |
| | Ext. PLT Tests | | √ | |
| User | New | | √ | |
| Management | Modify Password | | √ | |
| | Delete | | √ | √ |
| Auxiliary Setup | Get Sample Information | | √ | √ |
| | Other Settings | Predilute mode prompt | √ | √ |
| | | Pop-up keyboard | √ | √ |
| | | Enable fluorescent reagent detect sensor | √ | √ |
| | | Monitor reagent expiration date | √ | |
| | | Flags | √ | |
| | | Alarm Volume | √ | |
| | | Enable auto exit STAT | √ | √ |
| | | Auto replace reagent after setup | √ | √ |
| | | De-identify health information | √ | |
| | | Auto log-out | √ | |

| | | Administrator's level | Operator's level |
|---------------------------|-----------------------|-----------------------|------------------|
| Para. Setup | Parameter Unit Setup | √ | Review only |
| | Ref. Range Setup | √ | Review only |
| | Microsco. Para. Setup | √ | |
| Maintenance | / | √ | |
| Reagent Setup | / | √ | √ |
| Auto-loading | / | √ | |
| Gain Setup | / | √ | |
| Re-exam Rules Setup | / | V | |
| Auto Startup/ Shutdown | / | √ | |

6.2 Saving Settings after Changes

After you have changed or modified analyzer settings, follow below steps to save the changes.

- 1. Tap "Menu" > "Setup" and select the setting item you want to change.
- 2. Make necessary changes on the setting screen.
- 3. Tap another button on the software screen.
- $\sqrt{}$ A dialog box displays asking if you want to save the change.
- 4. Tap "**Yes**".
- $\sqrt{}$ The new setting is saved.

6.3 Analyzer Settings

6.3.1 System Setup ("Menu" > "Setup" > "System Setup")

6.3.1.1 Print Setup ("Menu" > "Setup" > "System Setup" > "Print Setup")

For the description about print setup, refer to 11Printing.

6.3.1.2 Communication ("Menu" > "Setup" > "System Setup" > "Communication") (Administrators)

Administrators can configure the following communication settings.

- Protocol Setup
- Transmission Mode

Before you set up the communication settings, make sure that:

- you have logged in as an administrator;
- the network wire is firmly connected to the analyzer.

Protocol Setup

- 1. Tap "Menu" > "Setup" > "System Setup" > "Communication" to enter the "Communication" screen.
- 2. Set up the communication protocol in accordance with the real needs in your laboratory.

See below for setting descriptions

| IP Address | Enter the correct IP address | For correct network settings, consult Mindray Customer Service Department or your network administrator. |
|---------------------------------|---|--|
| Subnet Mask | Enter the correct subnet mask | |
| Default Gateway | Enter the correct gateway | |
| ACK Synchronous Transmission | Check "ACK Synchronous Transmission" to enable the ACK synchronous transmission function. | When "ACK Synchronous Transmission" is enabled, enter the ACK overtime in the "ACK Overtime" field (10 seconds by default) |

Transmission Mode

- 1. Tap "Menu" > "Setup" > "System Setup" > "Communication" to enter the "Communication" screen.
- 2. Set up the transmission mode in accordance with the real needs in your laboratory.

See below for setting descriptions

| Transmission Mode | When you select LIS as a data channel, check to enable one or more transmission functions: Auto Retransmit Auto Communicate Transmit as Print Bitmap Data Communicate L-J QC results as sample results | Only when "ACK Synchronous Transmission" is enabled, can you enable the "Auto Retransmit" function. |
|---|--|---|
| Data channel | Data channel: • LIS • labXpert | Operators with user level or administrator level accounts cannot change the setting |
| Scattergram transmitted as/ Histogram transmitted as | When you select LIS as a data channel, you can select the following options from the pull-down list: Not to be transmitted Bitmap Data | |

6.3.1.3 Setting up the Barcode Type (Menu" > "Setup" > "System Setup" > "Barcode" (Administrators)

Administrators may set up barcode system as needed.

The following barcode types are supported:

- CODE128
- CODE39
- ITF
- CODE93
- CODABAR
- UPC/EAN/JAN

For the length limits and check bit of different code types, see **B.18Barcode Specifications**.

- 1. Tap "Menu" > "Setup" > "System Setup" > "Barcode" to enter the "Barcode" screen.
- 2. Tap the desired code type to go to the corresponding setup screen.
- 3. Check the "Apply" box to apply the code type.
- 4. Select the number of digits used on site in the "**Digits**" area.
- 5. (Optional) If you are using CODE39, ITF, and CODABAR with check bit, check the "**Check Bit**" box.

NOTE

- When you are using ITF, CODE39, and CODABAR with check bit, actual checked barcode digits length should be the length of barcode information plus 1 check bit.
- If you are using 9 digits barcode, and check the "Check Bit" box, you should select "10" for barcode length.
- 6. (Optional) Set other code types if needed.

NOTE

- For code types supporting check bit, use check bit in barcode labels if possible to reduce the rate of misreading.
- The code types and length limits set on the analyzer shall be those used in your laboratory.
- Do not select the code types that are not used, which may increase the rate of misreading.
- Do not use barcodes longer than 20 digits. Barcodes longer than 20 digits will not be read correctly.

6.3.1.4 Date/Time ("Menu" > "Setup" > "System Setup" > "Date/Time")

You can set up date and time on the "Date/Time Setup" screen.

- 1. Tap "Menu" > "Setup" > "System Setup" > "Date/Time Setup" to enter the "Date/Time Setup" screen.
- 2. Set up the date and time.

See below for setting descriptions:

| Date | Enter the current date | / |
|-------------|--|--|
| Time | Enter the current time | The analyzer uses the 24-hour clock system |
| Date Format | Select a date format from the pull-down list | / |

6.3.1.5 Lab Info. Setup ("Menu" > "Setup" > "System Setup" > "Lab Info. Setup")

Users may enter necessary laboratory information on the "Lab Info. Setup" screen.

- Tap "Menu" > "Setup" > "System Setup" > "Lab Info. Setup" to enter the "Lab Info. Setup" screen.
- 2. Enter laboratory information as needed.

6.3.1.6 Flag Alarm Sensitivity ("Menu" > "Setup" > "System Setup " > "Flag Alarm Sensitivity") (administrators)

The analyzer provides the following flags for abnormal blood cell morphology.

| Flag Message | Indication | Conditions |
|--------------------------|---|---|
| Blasts? | Possible presence of blast cells | Presence of excessive dots in blast sensitive region of the scattergram |
| Immature Gran? | Possible presence of immature granulocytes | Presence of excessive dots in immature granulocyte sensitive region of the scattergram |
| RBC Lyse Resistance? | Possible presence of RBC lyse resistance | Presence of abnormally distributed dots in the WBC sensitive region of the DIFF scattergram |
| Abn Lymph/blast? | Possible presence of abnormal lymphocytes or blasts | Presence of excessive dots in abnormal lymphocyte/blast sensitive region of the scattergram |
| Turbidity/HGB Interfere? | HGB results may be abnormal or interference may exist | Calculate and compare special parameters |
| Fragments? | Possible presence of RBC fragments | Presence of abnormally distributed dots in sensitive region of the RET channel |

| Flag Message | Indication | Conditions |
|--------------------|---|---|
| Infected RBC? | Possible presence of infected RBC | Presence of excessive dots in infected RBC sensitive region of the scattergram |
| Left Shift? | Possibility of left shift | Presence of excessive dots in left shift sensitive region of the scattergram |
| Atypical Lymph? | Possible presence of atypical lymphocytes | Presence of excessive dots in atypical lymphocyte sensitive region of the scattergram |
| RBC Agglutination? | RBC results possibly inaccurate | Calculate and compare special parameters |
| Iron Deficiency? | May indicate iron deficiency anemia | Calculate and compare special parameters |
| PLT Clump? | Possibility of PLT clump | Calculate and compare special parameters |
| Lipid Particles? | Possible presence of lipid particles | Presence of excessive dots in lipid particle sensitive region of the scattergram |
| WBC Fragments? | Possible presence of WBC fragments. | Presence of abnormally distributed dots in WBC fragment sensitive region |

During sample analysis, the analyzer evaluates and scores the possibility of the presence of all types of abnormal blood cell morphology. When the score for a certain type of abnormal blood cell morphology exceeds the set threshold, the analyzer reports the flag accordingly.

Administrators may tap "**Setup**" > "**System Setup**" > "**Flag Alarm Sensitivity**" to set up the flag alarm threshold values. The higher the threshold value, the lower the alarm sensitivity of the flag.

Follow below instructions:

- Tap "Menu" > "Setup" > "System Setup" > "Flag Alarm Sensitivity" to enter the "Flag Alarm Sensitivity" screen.
- 2. Define the flag alarm threshold values in the "Value (0-100)" edit boxes as needed.

NOTE

- The allowed range for all flag alarm threshold values is [0, 100].
- The flag alarm items vary with the models with different configurations. Please be subject to the interface of your analyzer.
- The default flag alarm threshold for "Infected RBC?" is 100; and the default thresholds for all other flags are all 40.

6.3.1.7 Flag Rules Setup ("Menu" > "Setup" > "System Setup" > "Flag Rules Setup") (administrators)

The analyzer provides the following flag messages:

| Flag Message | Indication | Conditions |
|----------------|----------------|---------------------------------|
| Leukocytopenia | WBC count low | WBC < 2.50×10 ⁹ /L |
| Leucocytosis | WBC count high | WBC > 18.00×10 ⁹ /L |
| Neutropenia | Neu# low | Neu# < 1.00×10 ⁹ /L |
| Neutrophilia | Neu# high | Neu# > 11.00×10 ⁹ /L |
| Lymphopenia | Lym# low | Lym# < 0.80×10 ⁹ /L |
| Lymphocytosis | Lym# high | Lym# > 4.00×10 ⁹ /L |
| Monocytosis | Mon# high | Mon# > 1.50×10 ⁹ /L |

| Flag Message | Indication | Conditions |
|------------------|----------------------|---|
| Eosinophilia | Eos# high | Eos# > 0.70×10 ⁹ /L |
| Basophilia | Bas# high | Bas# > 0.20×10 ⁹ /L |
| NRBC Present | NRBC detected | NRBC% > 1.00% and NRBC# > 0.010×10 ⁹ /L |
| Anisocytosis | Anisocytosis | RDW-CV > 22.0% or RDW-SD > 64.0fL |
| Hypochromia | Hypochromia | Hypochromia<290g/L |
| Microcytosis | MCV low | MCV < 70.0fL |
| Macrocytosis | MCV high | MCV > 110.0fL |
| Erythrocytosis | RBC high | RBC > 6.50×10 ¹² /L |
| Anemia | Anemia | HGB < 90g/L |
| *Reticulocytosis | RET high | RET% > 5% or RET#>0.20×10 ¹² /L |
| Thrombocytopenia | PLT low | PLT<60×10 ⁹ /L |
| Thrombocytosis | PLT high | PLT>600×10 ⁹ /L |
| Pancytopenia | WBC, RBC and PLT low | WBC < 4.00×10^9 /L and RBC < 3.50×10^{12} /L and PLT < 100×10^9 /L |

• The item with * only applies to the BC-760[R]/BC-780[R] model.

Administrators may tap "Menu" > "Setup" > "System Setup" > "Flag Rules Setup" to set the flag rules for classified alarms.

Follow below instructions:

- Tap "Menu" > "Setup" > "System Setup" > "Flag Rules Setup" to enter the "Flag Rules Setup" screen.
- 2. Editing a rule:
 - a Tap in the flag rule list to select the rule to be defined and edit the rule setup below.
 - b Tap another button, and save the setting as prompted.

Other operations:

| Resume | To restore an edited rule to factory default, tap the "Resume" button. |
|-------------------|--|
| All to Default | To restore all the edited rules to factory default, tap the "All to Default" button. |
| Import | Insert the USB device for saving the flag rules in the analyzer, and tap "Import" to import flag rules from the USB device. |
| Export | Insert the USB device for saving the flag rules in the analyzer, and tap "Export" to export the set flag rule to the USB device. |

6.3.1.8 Tube Rack Type Setup (Menu > Setup > System Setup > Tube Rack Type Setup)

Tap "Menu"> "Setup"> "System Setup"> "Tube Rack Type Setup" to check the information of tube rack and tubes.

6.3.1.9 Ext. Tests ("Menu" > "Setup"> "System Setup"> "Ext. PLT Tests") (administrators)

The series of analyzers provide the "Ext. PLT Tests" function for the PLT test.

After the "Ext. PLT Tests" function is enabled, the analyzer automatically predicts the PLT results during the sample test, and automatically starts the sample rerunning analysis mode of low value when the PLT value is

lower than the set threshold. The whole process is completed at one time, not requiring re-aspirating of the sample or additional consumption of lyse and dye.

| PLT 5X re-exam | During sample test procedure, the analyzer predicts PLT results. When the predicted result is lower than the set threshold, the analyzer automatically lengthens the test |
|----------------|---|
| | duration in the PLT-O channel to 5 times that of a normal test to obtain 5 times particles in the normal test mode. |

Follow below instructions:

1. Tap "Menu" > "Setup" > "System Setup" > "Ext. PLT Tests" to enter the "Ext. PLT Tests" screen.

Check "Rerun low PLT samples"" and set the threshold as needed.

NOTE

- The Ext. PLT Tests mode only applies to the BC-760[R]BC-780[R] model.
- The Ext. Tests mode do not apply to prediluted and body fluid samples.
- The default value of low PLT sample is $50 \times 10^9 / L$.

6.3.2 User Management ("Menu > "Setup" > "User Management")

The "User Management" screen displays all the user accounts registered on the analyzer.

6.3.2.1 Adding new account (administrators)

Administrators can create new users on the "User Management" screen.

- 1. Tap "Menu"-"Setup"-"User Management" to enter "User Management" screen.
- 2. Tap "New" to go to the "Add User" screen.
- 3. Select "Access Level":
- General User
- Administrator
- 4. Enter the "User ID", "Name", and "Password" in turn.
- 5. Tap "**OK**" to save the settings.
- $\sqrt{}$ The new user account is activated.

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 can be null and up to 20 characters can be entered.

6.3.2.2 Changing password

- Users at either administrator's or operator's level can only change the passwords for the users currently logged in.
- 1. Tap "Menu"-"Setup"-"User Management" to enter "User Management" screen.
- 2. Select the current user, and tap "Modify Password".
- 3. In the "Modify Password" dialog box, enter "Old Password", and then enter the new password in the "New Password" and "Confirm Password" edit boxes.
- 4. Tap "**OK**" to save the new password.
- $\sqrt{}$ The new password is activated.

6.3.2.3 Deleting account (administrators)

An administrator can delete any users registered under his/her own account.

NOTE

You cannot delete a built-in user!

- 1. Tap "Menu"-"Setup"-"User Management" to enter "User Management" screen.
- 2. Select a user and tap "Delete" to delete it.
- √ A confirmation box displays.
- 3. Tap "**Yes**".
- $\sqrt{}$ The selected user is deleted.

6.3.3 Auxiliary Setup ("Menu" > "Setup" > "Auxiliary Setup")

Tap "Menu"-"Setup"-"Auxiliary Setup" to enter "Auxiliary Setup" screen. You can set up the following contents:

- **■** Get Sample Information
- Other Settings

6.3.3.1 Getting sample information

Setting of the next sample

Tap "Menu" > "Setup" > "Auxiliary Setup" > "Get Sample Information" to enter the "Get Sample Information" screen. You can set the following options:

- Entry of next sample ID
 - **♦** Auto increase
 - **♦** Manual Entry

When "Auto increase" is selected for "Entry of next sample ID":

- $\sqrt{}$ When you are running samples under the auto-loading analysis cycle and manually enter the first Sample ID, the Sample IDs for the following samples automatically increase.
- $\sqrt{}$ When you are running samples under closed-tube analysis, you only need to enter an ID for the first sample, and the subsequent sample IDs will automatically increase by 1 based on the previous one.

When "Manual Entry" is selected for "Entry of next sample ID":

- √ When you are running samples under closed-tube analysis, you need to enter each sample ID manually.
- Prefix Length

When "Auto increase" is selected for "Entry of next sample ID", this edit box will be activated.

Enter a number (n) into the edit box of "**Prefix Length**". The first n characters in the sample ID will not be auto increased.

NOTE

Prefix Length cannot exceed 20 digits.

Setting of the first sample after startup

Set the test panel for the first sample after startup in accordance with the real needs in your laboratory.

Follow below instructions:

- Tap "Menu" > "Setup" > "Auxiliary Setup" > "Get Sample Information" to enter the "Get Sample Information" screen.
- 2. In the "Setting of the first sample after startup" area, set the test panel for the first sample after startup.
- Define the mode for the first sample after startup:

- 1. In the "First sample after startup" pull-down list, select "Custom".
- 2. In the "Mode" pull-down list, select the desired mode.
- 3. In the "Sample ID" edit box, enter the ID (1 by default) of the first sample after startup.
- $\sqrt{}$ After each startup, the first sample is analyzed according to the set sample ID and mode by default.
- Test the sample according to the mode of the last sample before shutdown:
- In the "First sample after startup" pull-down list, select "Run the suspended sample after restart".
- $\sqrt{}$ The sample ID of the first sample after each startup increases by 1 on the basis of the ID of the last sample before shutdown; the sample is tested according to the mode of the last sample before shutdown.

Getting sample information

The setup is applicable to the analyzer with built-in rotary scanner.

This function is for "Auto-Scan rack No." setup under autoloading mode. Select "Auto-Scan rack No.", and the analyzer starts to scan rack No. automatically.

Follow below instructions:

- 1. Tap "Menu" > "Setup" > "Auxiliary Setup" > "Get Sample Information" to enter the "Get Sample Information" screen.
- 2. Tap "Auto-Scan rack No." in the "Get Sample Information" area.

6.3.3.2 Other Settings

On the "Other Settings" screen, you can set the following functions:

- Predilute mode prompt
- Pop-up keyboard
- Enable fluorescent reagent detect sensor
- Monitor reagent expiration date
- Flags (administrators)
- Alarm Volume (administrators)
- Auto exit STAT
- Auto replace reagent after setup
- De-identify health information
- Auto log-out
- 1. Tap "Menu" > "Setup" > "Auxiliary Setup" > "Other Settings" to enter the "Other Settings" screen.
- 2. Define the settings as needed.

See the table below for setting descriptions:

| Predilute mode prompt | When "Predilute mode prompt" is checked, in predilute mode, when you start analysis, a dialog box will pop up to remind you that the current analysis mode is predilute. Uncheck "Predilute mode prompt" to disable the function. | / |
|-----------------------|---|---|
| Pop-up keyboard | Check "Pop-up keyboard" to enable the pop-up keyboard. Tap on the edit area on each screen, the pop-up keyboard will display for you to input information. When you are using an external keyboard, you can uncheck "Pop-up keyboard" to disable the function. | |

| Enable fluorescent reagent detect sensor | When "Enable fluorescent reagent detect sensor" is checked, if the fluorescent reagents are not sufficient, the analyzer will send an alarm. | 1 |
|--|--|---|
| Monitor reagent expiration date | Check "Monitor reagent expiration date" to enable the function. When the function is enabled, the analyzer gives warning when a reagent gets expired. | / |
| Flags | Select from the pull down list to define the suspect, high and low flags (default: "R" for | Suspect: R, r |
| | suspect, "H" for high and "L" for low). | High: H, h, ↑ |
| | | Low: L, I, ↓ |
| Alarm Volume | Select the alarm volume you want | Low Medium High Max |
| Auto exit STAT | When "Auto exit STAT" is selected, if you do not place STAT samples in the sample compartment during the pre-defined time range, the analyzer automatically exits STAT. When "Auto exit STAT" is not selected, manually select "Exit STAT" to exit STAT. | The default waiting time is 2 minutes. The setup range is [2-5] minutes. |
| Auto replace reagent after setup | When "Auto replace reagent after setup" is checked, after you replace the reagent with a new one and enter the barcode information of the new reagent on the "Reagent Setup" screen, the analyzer automatically replaces the reagent in the reagent container. If this option is not checked, you need to manually tap the "Replace" button to replace the reagent in the reagent container after replacing the old reagent and entering the new barcode information. | The default waiting time is 30 seconds. The setup range is [0-100] seconds. |
| De-identify health information | After "De-identify health information" is checked, when you print, export sample information or view it on "Table Review" screen, identifiers (like name, gender, age and date of birth) will be shown as "****". | / |
| Auto log-out | When "Auto log-out" is selected, the current account will automatically log out if the user has not performed any operation for the defined period of time. | The default log-out time is 60 minutes. The setup range is [1-120] minutes. |

6.3.4 Para. Setup ("Menu" > "Setup" > "Para. Setup") (Administrators)

6.3.4.1 Parameter Unit Setup (Administrators)

Administrators may set up unit systems and parameter units.

- Tap "Menu" > "Setup" > "Para. Setup" > "Parameter Unit Setup" to enter the "Parameter Unit Setup" screen.
- 2. (Optional) When necessary, select the unit system from the "**Unit System:**" pull-down list.
- 3. Tap the "**Unit**" column of the parameter for which you want to change the unit.

The available units for the parameter displays on the right side of the screen.

- 4. Check the desired unit for the parameter in the "Unit option:" area.
- $\sqrt{}$ The parameter unit refreshes.

- Users at operator's level can only review the unit system and the parameter units.
- Tap "Default" to restore the default units for all parameters.

6.3.4.2 Ref. Range Setup (Administrators)

The "Ref. Range Setup" screen provides 5 factory reference groups for your selection. In addition, you can set up to 10 custom reference groups. Users at administrator's level may select and customize reference ranges and reference groups.

- 1. Tap "Menu"-"Setup"-"Ref. Range Setup" to enter "Ref. Range Setup" screen.
- 2. Add a new reference group, edit or delete reference groups, or set default groups as needed.

Follow below instructions:

| New | Tap "New" to add a new reference group. On the new reference group setup screen, set up the name, lower and upper limits of ages, as well as the gender information for the new "Reference group". When necessary, tap and edit the "Upper" and "Lower" limits for the parameters. | |
|---|--|---|
| Edit | Tap to select the reference group to edit, and tap " Edit ". | For the 5 factory reference groups, you can only edit the "Upper" and "Lower" limits of the parameters. For the custom reference groups, you can edit the group name, lower and upper limits of age, gender information, and "Upper" and "Lower" of the parameters. |
| Delete | Tap to select the custom reference group to delete, and tap " Delete ". | You cannot delete factory reference groups. |
| Set to Default | Tap and select a reference group, and tap "Set to Default" to set the selected reference group as default reference group. | / |
| Match customized ref. group first | Check to enable "Match customized ref. group first". | When "Match customized ref. group first", the analyzer first finds the matching reference group based on the sample age/gender conditions. When the "Match customized ref. group first" is not enabled, the analyzer first finds the matching group in the factory reference groups based on the age/gender. |

6.3.4.3 Microsco. Para. Setup (Administrators)

In the default mode, the "Microsco. Para. Setup" screen displays 22 microscopic parameters of hematology analysis.

Administrators may add new parameters, edit or delete existing microscopic parameters on the "Microscopic Para. Setup" screen.

- Tap "Menu" > "Setup" > "Para. Setup" > "Microsco. Para. Setup" to enter the "Microsco. Para. Setup" screen.
- 2. Add new microscopic parameters, or edit or delete existing microscopic parameters as needed.

Follow below instructions:

| Add a new microscopic | Tap "New" to add a row in the microscopic parameter name area. Enter the new |
|-----------------------|--|
| parameter | parameter name in the "Microscopic Parameter Name" column. |

| Edit the microscopic parameters | Tap a parameter name in the table to edit the name. |
|-----------------------------------|--|
| Delete the microscopic parameters | Select a row in the table, and tap the " Delete " button to delete the parameter. |

The analyzer can save at most 40 microscopic parameters.

6.3.5 Maintenance ("Menu" > "Setup"> "Maintenance") (Administrators)

6.3.5.1 Standby

When the time for which the analyzer is free from fluidic operations reaches that you have set on the "Maintenance" screen of the analyzer, the analyzer automatically enters the standby status.

On the "Maintenance" setup screen, administrators may set the wait time before the analyzer enters the "Standby" status, when the fluidic system stops working.

- 1. Tap "Menu"-"Setup"-"Maintenance" to enter "Maintenance" screen.
- 2. Set up the wait time before the analyzer entering the standby status.

NOTE

 The allowed range is 30 to 60 minutes. Make sure you enter the valid time and in the required format.

6.3.5.2 Probe cleanser maintenance

Administrators may set up the start time for daily Probe Cleanser maintenance on the "**Maintenance**" setup screen.

- 1. Tap "Menu"-"Setup"-"Maintenance" to enter "Maintenance" screen.
- 2. Set the start time and reminding interval for daily Probe Cleanser maintenance as needed.

| Item | Description | Remark |
|--------------|--|---|
| Start at | When conditions for daily probe cleanser maintenance are met, the analyzer prompts you to maintain the Probe Cleanser at the set time. | The allowed range of time is 00: 00 to 23: 59. The start time for Probe Cleanser maintenance should be earlier than that for auto shut-down, see 6.3.10Setting Auto Startup/Shutdown Time ("Menu" > "Setup" > "Auto Startup/Shutdown") (Administrators). |
| Remind every | If you disable the daily probe cleanser, the analyzer prompts you to maintain the Probe Cleanser when the remind time is out of the set value. | The allowed range of time is 5 to 60min. |

 $\sqrt{}$ Set the start time of Probe Cleanser maintenance. The system will perform Probe Cleanser maintenance for the relevant parts at the specified time according to the operating condition of the analyzer.

- When the analyzer prompts you to maintain the Probe Cleanser, you can tap "Cancel" to ignore the
 prompt and up to three times is allowed to ignore. You must perform the maintenance when the
 prompt appears for the forth time.
- For conditions of daily probe cleanser maintenance, see 12.4.1Daily Probe Cleanser Maintenance.

6.3.6 Reagent Setup ("Menu" > "Setup" > "Reagent Setup")

For the reagent replacing steps, refer to 12.3.2Replace the Reagents.

6.3.7 Setting up Functions for the Auto-Loading of Samples (Menu > "Setup" > "Auto-loading") (administrators)

Administrators may set up the following functions regarding the autoloading of samples in accordance with the real needs in your laboratory.

- How to proceed when blood/analysis mode inquiry failed
- When there is tube vacancy, sample ID
- Display summary after autoloading finishes
- Auto load tube racks
- 1. Tap "Menu"-"Setup"-"Auto-loading" to enter "Auto-loading" screen.
- 2. Set up how to proceed when blood/analysis mode inquiry failed, to set up the next sample IDs when there is tube vacancy and whether to display summary after auto-loading finishes.

See below for setting descriptions

| When Blood/ Analysis Mode Inquiry Failed | When "Use the mode of the previous sample" is enabled, the analyzer will use the analysis mode of last samples; Set up how to proceed when blood/analysis mode inquiry from LIS fails. If you have selected "Skip after", set up the wait time (n) in seconds (default setting is 10 seconds, and n cannot be longer than 15 seconds); If you have selected "Use specified mode", select a mode from the pull-down list |
|--|--|
| When there is tube vacancy, sample ID | Tap the radio button to select the rule of sample ID increment when there is tube vacancy in the tube rack: increases does not increase |
| Display summary after autoloading finishes | When you have checked " Display summary after autoloading finished ", the screen displays the auto-loading summary, including finished blood samples, rack vacancies, ID reading errors, etc. |
| Auto load tube racks | When "Automatically load the tube racks on the autoloader" is selected, also set the waiting time (1-30 seconds) before analyzer auto loading tube racks. When you place tube racks on the right tray of the autoloader, the analyzer will automatically load tube racks for sample analysis after the pre-defined waiting time. When "Automatically load the tube racks on the autoloader" is not selected, select "Start Count" to start sample analysis. |

6.3.8 Gain Setup ("Menu" > "Setup" > "Gain Setup") (Administrators)

When the analyzer reports the HGB blank voltage abnormal error, and you cannot remove the error by pressing the "Remove Error" button, adjust the HGB gains to correct the HGB blank voltage.

- 1. Tap Menu > "Setup" > "Gain Setup" > "WB" to enter the "Gain Setup" screen of whole blood.
- 2. Adjust the HGB default gain in the "**HGB**" "**Set**" text box, until the HGB blank voltage is in the range of [4.30, 4.50].

NOTE

- When you modify the HGB default gain, the HGB blank voltage will change accordingly.
- 3. If necessary, repeat above procedure to adjust the HGB voltages for other modes.

6.3.9 Setting Re-exam Rules ("Menu" > "Setup" > "Re-exam Rules Setup") (Administrators)

Administrators may enable and set up re-exam rules on the "Re-exam Rules Setup" screen of the analyzer.

Re-exam means to reexamine the analyzed samples whose results match certain conditions. The way to re-exam is determined by the laboratory procedure, which may include re-analyze on the analyzer, smear review, etc.

You can set re-exam rules for autoloading analysis on the analyzer. When the re-exam rules are enabled, the analyzer will check the auto-loading sample results and information based on the applied rules. If a sample triggers a re-exam rule, the analyzer will automatically transports the sample back for re-exam.

NOTE

- The re-exam rules only apply to auto-loading analyses.
- If the analyzer is connected to Mindray's labXpert software, set the re-exam rules on the labXpert.
 For more information about the labXpert software, consult your sales representative.

Follow the following instructions to set re-exam rules for autoloading analysis on the analyzer:

- Tap "Menu" > "Setup" > "Re-exam Rules Setup" to enter the "Re-exam Rules Setup" screen.
- 2. Set the re-exam rules as required.
- Tap another button on the software screen to save the settings.

| Settings | Description | Remark |
|--|--|---------------------------------------|
| Enable re-exam rules | When "Re-exam Rules Setup" is checked/unchecked, this function is enabled/disabled. | / |
| Re-exam when WBC count is low | When "Re-exam when WBC count is low" is checked, re-exam rules will be triggered and a related message will be prompted if measured WBC count is below the set values. | Set range: (0~4) x 10 ⁹ /L |
| Re-exam when PLT count is low | When "Re-exam when PLT count is low" is checked, re-exam rules will be triggered and a related message will be prompted if measured PLT count is below the set values. | Set range: (0~4) x 10 ⁹ /L |
| Re-exam when abnormal RBC/PLT result is reported | When Re-exam when abnormal RBC/PLT result is reported" is checked, the analyzer will give a re-exam prompt if PLT is below 30 when the following flags occur: PLT Clump? PLT Scattergram Abn. Microcytosis | / |

- $\sqrt{}$ After the re-exam rules are enabled, the analyzer checks the auto-loading sample results and information based on the applied rules.
- When the sample result triggers the re-exam rules, the "Need Re-exam" message is displayed on the graph review screen of the sample. In the meanwhile, the analyzer automatically transports the sample back for re-exam.

Sample ID 2

Time 07-28-2020 16:07 Need Re-exam

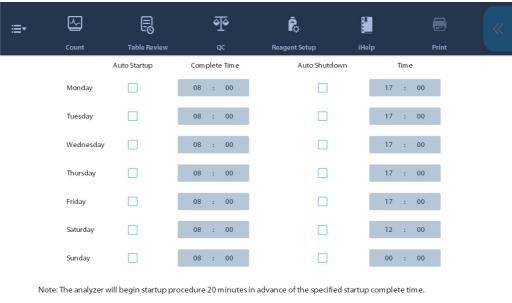
Mode AL-WB-CD Tube Pos. 1-1

6.3.10 Setting Auto Startup/Shutdown Time ("Menu" > "Setup" > "Auto Startup/ Shutdown") (Administrators)

Administrators may set up the auto startup and shutdown time for the analyzer on the "**Auto Startup/Shutdown**" screen.

When you have set the auto startup/shutdown time, the analyzer automatically starts and shutdown at the set time.

- 1. Tap "Menu" > "Setup" > "Auto Startup/Shutdown" to enter the "Auto Startup/Shutdown" screen.
- 2. Check require dates.



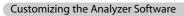
- Define the auto startup complete time in the auto startup "Complete Time" field.
- For example, if you set the "Complete Time" for auto startup to 8:00 on Monday, the analyzer automatically starts the startup procedure at 7:40, and completes the procedure at 8:00.
- Define the auto shutdown time in the auto shutdown "Time" field.

CAUTION

For example, if you set the "Time" for auto shutdown to 17:00 on Monday, the analyzer automatically starts the shutdown procedure at 17:00.

NOTE

To use the auto startup function, do not power off the analyzer.



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7.1 Overview

This chapter provides step-by-step procedures for operating your analyzer on a daily basis.

7.1.1 Operating Your Analyzer

A flow chart indicating the common daily operating process is presented below.



7.1.2 Introduction to the Screen

7.1.2.1 Introduction to the Count Screen

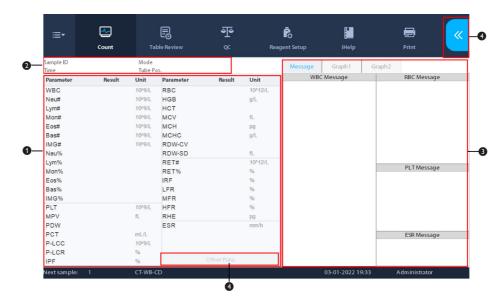


Figure 7-1 Count screen

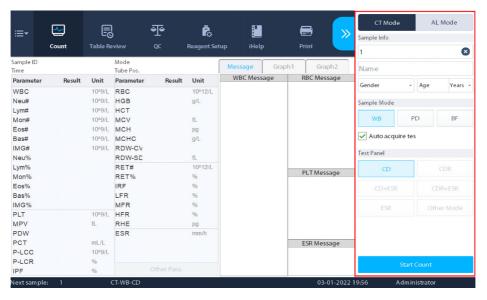


Figure 7-2 Count screen - pop-up window

| 1 | Report parameter result area | The area displays the sample report parameter results. |
|---|------------------------------|--|
| 2 | Sample information area | The area displays sample information |
| 3 | Flags and graphs area | Tap the "Message" tab to review the abnormal blood cell differential or morphology flags for current sample |
| | | Tap "Graph1" and "Graph2" to view the scattergrams and histograms for current samples (Graph 2 only applies to blood sample analysis and the BC- 760[R]/BC-780[R] model) |

| 4 | Button area | Tap the button to display the pop-up window and set the sample information, sample mode and test panel as needed. |
|---|-------------|--|
| | | • When using the auto-loading analysis mode, tap "Start Count" to start analysis. |
| | | When auto-loading analysis is started, the "Start Count" button turns to "Stop Count". Tap "Stop Count" to stop auto-loading analysis. |
| | | • During auto-loading analysis, tap "STAT" to insert STAT samples. |
| | | When sample analysis is completed, tap the "Other Para." button to review the RUO parameters results of current sample, or review or edit microscopic parameter results. |

7.1.2.2 Introduction to the test panel screen

"**Test Panel**" area in the dialog box shows some common analysis modes. Tap "**Other Mode**" button to select more desired modes.

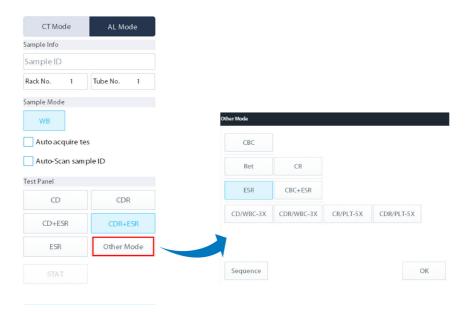
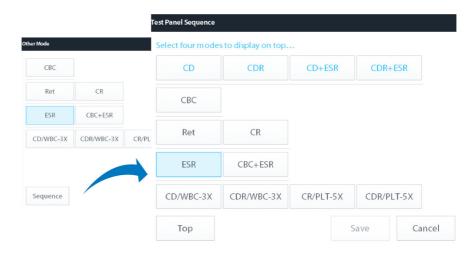


Figure 7-3 Other mode dialog box

Adjusting the sequences of analysis modes

The analyzer supports function of sequencing analysis modes. You can adjust the sequences of analysis modes in the "Other Mode" dialog box as needed.

- 1. In the "Other Mode" dialog box, tap "Sequence" button.
- $\sqrt{}$ The "**Test Panel Sequence**" dialog box pops up.



2. Set the sequences of modes.

| Function | Description | Remark |
|----------|---|---|
| Тор | Tap " Top " to top up the selected mode. | A minimum of four modes can be topped up. |
| Save | Tap " Save " to save current settings. | / |
| Cancel | Tap "Cancel" to return to previous page. | / |

7.2 Preparations before Operation

Perform the following checks before turning on the analyzer.

Checking the waste container

Provide a waste container, check and make sure the waste container is not full before startup.

To replace the waste container, refer to $\sqrt{The analyzer automatically completes the operation.}$

Checking the reagents

Check whether any reagent has expired and frozen. The reagent needs to be kept still for 24 hours after long-distance transportation.

Check whether there are enough reagents for the test of the day. If the reagents run out during analysis, the analyzer will pause working automatically and prompt the operator to replace the reagents. Follow the instruction to replace the reagents. Otherwise you cannot continue the analysis.

For the safety precautions of reagents, refer to **1.2.3Reagent**, **Control**, **and Calibrator-Related Safety Messages**; for the use of reagents, controls, and calibrators, refer to the corresponding IFU; for how to connect and replace reagents, refer to **5.2.1Connecting the Reagents**, **12.3.2Replace the Reagents**.

Checking for fluidic tubes and powers

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

Check and make sure the power cord of the analyzer is properly plugged into the power outlet. For the power requirements, refer to *5.1.2Power Requirements*.

Checking the printer

Check and make sure the printer is properly installed, and there is enough paper. Check whether the printer power cord is inserted into the power socket and whether the printer cable is connected properly.

Checking the keyboard, mouse, and external computer

Check whether the network wire of the external computer is properly connected to the main unit.

7.3 Start up and Login

7.3.1 Start up the Analyzer

Start up the analyzer in accordance with the actual conditions:

| Analyzer status | Operation |
|-------------------------------------|--|
| When the power switch is turned off | Turn on the power switch on the back of analyzer. The power switch lights in green. |
| When the power switch is turned on | Press the [Standby] key on the side of analyzer. |

The system automatically performs the background test and initializes the system. When the self-test and startup initialization procedures complete, the analyzer software displays the main screen.



M WARNING

Before turning on the instrument, make sure the input voltage meets the requirements.



CAUTION

Please check the firmness of all the doors and covers before running the system, and make sure they will not open or get loose during analysis. Exercise caution when open/close, install/uninstall the doors and covers to avoid dropping to the ground.

NOTE

- Time needed for initializing the fluidic systems depends on how the analyzer was previously shut down. Generally the startup process takes about 10 minutes.
- Users with different accounts have different access to software functions.
- If a fault occurs during initialization (for example, the background check result exceeds the acceptable range of background/blank count results), the analyzer will send an alarm. For the troubleshooting method, refer to 13Troubleshooting.
- Background test refers to test on particle and electrical interference.
- If the first background test result obtained during the fluidic initialization exceeds the background range, the analyzer will automatically perform background check again.
- The sample ID of the background test is "0".
- The analyzer does not flag background test result with H/L or suspect flag.
- For the background range of each parameter, refer to Appendix B.6.1Background/Blank Count Requirements.

The status indicator of the analyzer works as follows:

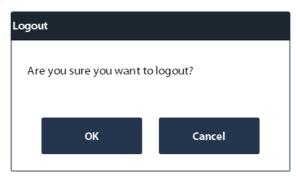
| Status indicator status | Meaning |
|-------------------------|-------------------------|
| Stay in green | Ready |
| Flicker in green | Running |
| Flicker fast | Sampling probe piercing |
| In red | Error |
| In orange | Standby |
| Off | Analyzer shutdown |

7.3.2 Switching Login Account

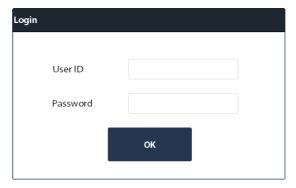
If logged in as an administrator's account, the lower right corner of the screen displays "Administrator".

If necessary, perform the following steps to switch the login account. To set an account or change the password, refer to **6.3.2User Management ("Menu > "Setup" > "User Management")**.

- 1. Tap "Menu" > "Logout" in turn.
- √ A dialog box displays



- 2. Tap "**OK**".
- $\sqrt{}$ The login dialog box displays



3. Enter the new "User ID" and "Password", and tap "OK" to log in.

7.4 Daily QC

Before running any samples, run the controls to ensure reliable results of the analyzer. Please see **9Using the QC Program** for details.

7.5 Preparing Samples

7.5.1 Preparing Whole Blood Samples (For WB Mode)

To attain accurate analysis results, make sure the venous blood sample volume meets the following requirements:

Table 7-1 Whole Blood Sample Volume

| Sampling and sample modes | Tube Position | Cap open? |
|---------------------------|----------------------------|-----------|
| CT-WB | Regular tube/Micro-WB tube | Either |
| AL-WB | Tube rack | No |

1. Use evacuated blood collection tubes to collect venous blood samples, or centrifugal tubes to collect peripheral blood samples.

- Use tubes matching adapter. For details, see 3.4Supported Tubes, Tube Racks and Adapters. For details about other supported tubes that are not specified here, consult your local sales representative or Mindray Customer Service Department.
- 2. Well mix the blood sample and EDTA K₃/EDTA K₃ anticoagulant in the test tube rapidly.

A CAUTION

- Be sure to use the Mindray-specified disposable products like blood collection tubes. Do not reuse disposal products, otherwise the result may be inaccurate.
- Samples may volatize if the sample tube cap is opened for too long time, which will result in incorrect analysis results.
- To attain accurate analysis results, make sure the sample volume meets requirements. Otherwise, the results may be inaccurate.
- The samples stored under refrigeration condition (2°C to 8°C) must be kept at room temperature for at least 15 minutes before analysis.
- Be sure to mix any sample that has been prepared for a while before running it. Otherwise, the result
 may be inaccurate.
- For the samples to be tested for ESR, run them within 24 hours after collection if they are stored under refrigeration condition (2°Cto 8°C).
- For the whole blood samples to be tested for WBC differential or MPV analysis, run them within 8 hours after collection if stored at room temperature.
- The samples not to be tested for WBC differential, MCV or PLT counts can be stored in a refrigerator at the temperature of 2°Cto 8°Cfor 24 hours after collection.

NOTE

- Capillary samples cannot be tested for ESR.
- Gently squeeze when collecting capillary blood. Pressing hard will make body fluid mix into the blood, thus reducing the reliability of the measurement results.
- Before making analysis, wait for at least 5 minutes after capillary sample. You are advised to complete the test within 1 hour

7.5.2 Preparing Predilute Samples (For PD Mode)

Prepare the prediluted samples in the ratio of 20:100 (venous blood/capillary blood:diluent).

To attain accurate analysis results, make sure the predilute sample volume meets the following requirements:

Table 7-2 Preparing predilute samples (for PD mode)

| Sampling and sample modes | Tube Position | Cap open? |
|---------------------------|---------------------------------|-----------|
| CT-PD | Micro-WB/PD/BF Tube Position | Yes |

1. Use a centrifugal tube to collect venous blood or capillary blood.

- Gently squeeze when collecting capillary blood. Pressing hard will make body fluid mix into the blood, thus reducing the reliability of the measurement results.
- 2. On the "Count" screen, tap subtron.
- $\sqrt{}$ A pop-up window appears.
- 3. Switch to "CT Mode" screen and select "PD".

- $\sqrt{}$ The analyzer switches to the predilute mode.
- $\sqrt{}$ When the analyzer in on the predilute mode, the software status bar lights in orange.
- 4. Tap "**Diluent**" in the pop-up window.
- Make sure the tube position switch is at the regular tubes position side and proper adapter is installed.
 Then uncap the centrifugal tube filled with prediluted samples and place it at Micro-WB tube position.
- 6. Tap "**OK**" button
- √ The analyzer starts to dispense diluent.

- You can tap "OK" button for multiple times to dispense the diluent. The number shown on the
 "Cancel" button represents how many times you have dispensed diluent. indicates that you
 have dispensed diluent twice.
- The analyzer dispenses 100μL of diluent at a time.
- 7. After completing dispensing diluent, tap "Cancel" button.

CAUTION

- After mixing the capillary sample with the diluent, be sure to wait at least for 3 minutes, and mix the sample again before running the sample. Otherwise, the results may be inaccurate.
- Fully mix the blood sample with the diluent for reaction. Run the prediluted samples within 30 minutes after the dilution; otherwise the measurement results may be inaccurate.
- Be sure to mix any sample that has been prepared for a while before running it. Otherwise, the result
 may be inaccurate.
- Samples may volatize if the sample tube cap is opened for too long time, which will result in incorrect analysis results.
- If there is much prediluted sample adhering to the tube cap or the tube wall, the analyzer may not be able to aspirate sufficient volume of the sample.
- When preparing prediluted samples, slightly tap the bottom of the EP tubes with a finger. There should be no less than 100µL of prediluted sample settled at the tube bottom.

NOTE

- You can also dispense diluent by piptette into the tube.
- Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

7.5.3 Preparing Body Fluid Samples (For BF Mode)

The subtypes of body fluid supported by the current analyzer include cerebrospinal fluid, pleural fluid, ascitic fluid, and synovial fluid.

To attain accurate analysis results, make sure the sample volume meets the following requirements:

Table 7-3 Body fluid sample volume

| Sampling and sample modes | Tube Position | Cap open? |
|---------------------------|---|-----------|
| CT-BF | WB/BF/Probe Cleanser or Micro-WB/PD/BF Tube Position | Yes |

Use evacuated blood collection tubes, centrifugal tubes to collect body fluid samples.

CAUTION

- To ensure sample stability, process serous cavity fluid (pleural fluid and ascitic fluid) samples and synovial fluid samples with EDTA anticoagulant. It is not recommended to process cerebrospinal fluid samples with anticoagulant.
- To attain accurate analysis results, make sure the sample volume meets requirements. Otherwise, the results may be inaccurate.
- The samples stored under refrigeration condition (2°C-8°C) must be kept at room temperature for at least 15 minutes before analysis. Otherwise, the results may be inaccurate.
- To attain accurate analysis results, make sure the sample volume meets requirements. Otherwise, the results may be inaccurate.
- Samples may volatize if the vial is opened for too long time, which result in incorrect analysis results.
- Misleading results may occur if the body fluid sample has floccules, clots. cryoglobulin, leukocyte clumps, bacteria, or high protein. Follow your laboratory protocol to deal with such samples.
- 2. Mix the sample according to your laboratory's protocol.

NOTE

Slightly mix the body fluid samples.

7.5.4 Placing Barcode Labels

To ensure good readability of the barcode, you must place the label right on the region. To ensure good readability of the barcode, you must place the label right on the region as shown in *Figure 7-4Where to place the barcode label*, and place the label correctly as shown in *Figure 7-5How to place the barcode label*.

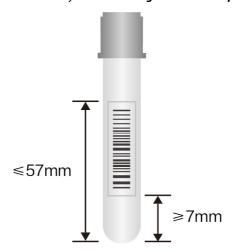


Figure 7-4 Where to place the barcode label

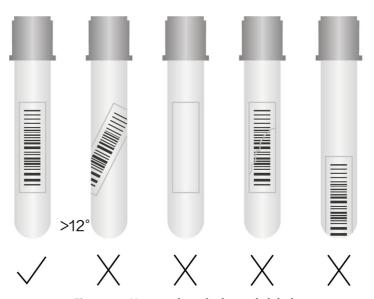


Figure 7-5 How to place the barcode label

7.6 Running Samples under Closed-tube Mode

7.6.1 Setting up Analysis Orders

You can set analysis order information on the main unit of Auto Hematology Analyzer.

- 1. Tap on the "Count" screen.
- $\sqrt{}$ The pop-up window appears.
- 2. Tap "CT Mode" button.
- $\sqrt{}$ The sample compartment reaches out.

- When the sample compartment is reaching out, do not block it.
- 3. Select the desired sampling mode and sample mode.
 - ◆ WB
 - ◆ PD
 - ◆ BF

• If the main unit is connected to LIS or labXpert, you can check "Auto acquire test mode". The system will automatically read the sample mode information set at the LIS or labXpert end.



4. In the "Sample ID" column, manually enter the Sample ID, or use an eternal barcode scanner to scan the barcode label on the tube to enter Sample ID into the "Sample ID" field.

- If you have set "Entry of next sample ID" to "Auto Increase", you only need to enter the sample ID for the first sample. The subsequent sample IDs will automatically increase by 1 based on the previous one.
- If you have set "Entry of next sample ID" to "Manual entry", you need to enter the sample ID for each sample.
- For more information about the sample ID entry method, refer to 6.3.3.1 Getting sample information.
- 20 characters are allowed for sample ID maximally (including prefix); the ID must end with a number, and must not be consisted of "0" only.
- 5. Select the desired test panel according to your model.

| Test Panel | Meaning | Description |
|------------|-----------------------|---|
| СВС | CBC | Complete blood count |
| CD | CBC+DIFF | Complete blood count + WBC differentiation tests |
| Ret | Ret | Complete blood count |
| CR | CBC+Ret | Complete blood count + Reticulocyte-related tests |
| CDR | CBC+DIFF+Ret | Complete blood count + WBC differentiation tests + Reticulocyte-related tests |
| ESR | ESR | Erythrocyte Sedimentation Rate |
| CD/WBC-3X | CBC+DIFF, WBC 3X mode | Complete blood count + WBC differentiation tests, using the extended sampling method (WBC 3X) |

| Test Panel | Meaning | Description |
|------------|---------------------------|--|
| CDR/WBC-3X | CBC+DIFF+Ret, WBC 3X mode | Complete blood count + WBC differentiation tests + Reticulocyte-related tests, using the extended sampling method (WBC 3X) |
| CR/PLT-5X | CBC+ Ret, PLT 5X mode | Complete blood count + Reticulocyte-related tests, using the extended sampling method (PLT 5X) |
| CDR/PLT-5X | CBC+DIFF+Ret, PLT 5X mode | Complete blood count + WBC differentiation tests + Reticulocyte-related tests, using the extended sampling method (PLT 5X) |

- In the "Test Panel" area of the pop-up window, only the most commonly used analysis modes are displayed. You can tap "Other Mode" to select other desired analysis modes.
- The Ret test panel only applies to the BC-760[R]/BC-780[R] model.
- Peripheral blood samples cannot be used for ESR test panel.
- The test panels vary with the models with different configurations. For details, refer to the configuration interface of your model.
- For the description of the test panels supported by the analyzer, refer to B.5.1Sample modes, test panel, and applicable model.

7.6.2 Performing Sample Analysis

7.6.2.1 Analyzing samples in whole blood mode

Check the following before analysis:

- Sample(s) prepared in accordance with the laboratory protocol (refer to **7.5.1Preparing Whole Blood Samples (For WB Mode)** and **7.5.4Placing Barcode Labels**).
- Analysis orders are set (refer to **7.6.1Setting up Analysis Orders**).
- The entered sample ID, sampling mode, sample mode, and the test panel are strictly in accordance with the sample to be run.
- The analyzer is ready to run samples (i.e. the analyzer indicator stays in green). Sample compartment is open.
- The bottom area of the "Count" screen displays the "Mode" as "CT-WB".

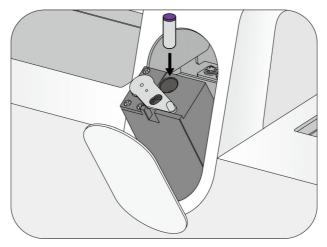
NOTE

• If you start sample analysis immediately after selecting work mode, then the default reference range is "General". After the analysis finishes, the analyzer will flag results per the reference range "General". To change the category of a reference group, follow the instructions in 6.3.4.2Ref. Range Setup (Administrators).

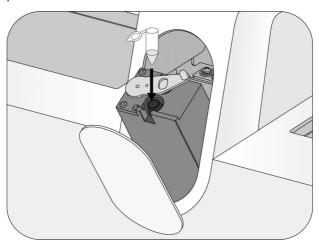
Follow below instructions:

- Mix the sample.
- If you are running a venous blood sample collected in an evacuated blood collection tube, shake the tube as instructed by the picture below to mix the sample thoroughly.
- If you are running a capillary blood sample collected in a centrifugal tube, cap the tube and shake the capped tube to mix it thoroughly.
- 2. Place the sample tube into the appropriate tube position in the sample compartment.

■ If you are running a sample collected in an evacuated collection tube, make sure the tube position switch is at the Micro WB tube position side. Then place the evacuated collection tubes into the regular position of sample compartment..



■ If you are running capillary whole blood sample collected in centrifuge tubes, make sure the tube position switch is at the regular tube side and proper adapter is installed, then uncap the centrifuge tube and place it at Micro-WB tube position.



NOTE

- When the sample compartment is reaching out, do not block it.
- 3. Press the "Start Count" key on screen to start sample analysis.
- $\sqrt{}$ The sample compartment closes, and the sampling probe automatically aspirates sample.
- 4. After the analyzer finishes aspirating sample, the sample compartment opens. You can remove the sample safely.
- $\sqrt{}$ The analyzer automatically analyzes the sample, the analyzer indicator is flickering in green.
- $\sqrt{}$ When the analysis completes, the analyzer indicator returns to "Ready" status (stay in green).
- $\sqrt{}$ The screen displays the current sample results, histograms, scattergrams and flags (if there is).

- 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 13Troubleshooting for solutions.
- When 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. See
 13Troubleshooting for solutions.

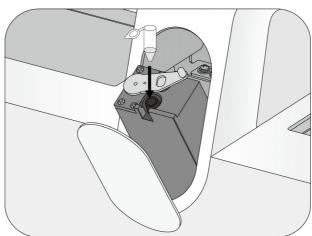
7.6.2.2 Analyzing samples in predilute mode

Check the following before analysis:

- Sample(s) prepared in accordance with the laboratory protocol (refer to 7.5.2Preparing Predilute Samples (For PD Mode) and 7.5.4Placing Barcode Labels)
- Analysis orders are set (refer to 7.6.1Setting up Analysis Orders).
- The entered sample ID, sampling mode, sample mode, and the test panel are strictly in accordance with the sample to be run.
- The analyzer is ready to run samples (i.e. the analyzer indicator stays in green). Sample compartment is open.
- The bottom area of the "Count" screen displays the "Mode" as "CT-PD". The bottom area of the "Count" screen lights in orange.

NOTE

- If you start sample analysis immediately after selecting work mode, then the default reference range is "General". After the analysis finishes, the analyzer will flag results per the reference range "General". To change the category of a reference group, follow the instructions in 6.3.4.2Ref. Range Setup (Administrators).
- 1. Shake the capped tube of the predilute sample to mix it thoroughly.
- 2. Make sure the tube position switch is at the regular tube side and proper adapter is installed, then uncap the centrifuge tube filled with prediluted samples and place it at Micro-WB tube position.



NOTE

- When the sample compartment is reaching out, do not block it.
- 3. Press the "Start Count" key on screen.
- $\sqrt{}$ If "**Predilute mode prompt**" is enabled, a dialog box will pop up to remind you that the current analysis mode is PD.

- For more information about the enabling or disabling predilute mode prompt, see 6.3.3.20ther Settings.
- 4. Press the "Start Count" key on screen to start sample analysis.
- $\sqrt{}$ The sample compartment closes, and the sampling probe automatically aspirates sample.
- 5. After the analyzer finishes aspirating sample, the sample compartment opens. You can remove the sample safely.
- $\sqrt{}$ The analyzer automatically analyzes the sample, the analyzer indicator is flickering in green.
- $\sqrt{}$ When the analysis completes, the analyzer indicator returns to "Ready" status (stay in green).

 $\sqrt{}$ The screen displays the current sample results, histograms, scattergrams and flags (if there is).

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 13Troubleshooting for solutions.
- When 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. See
 13Troubleshooting for solutions.

7.6.2.3 Analyzing samples in body fluid mode

Check the following before analysis:

- Sample(s) prepared in accordance with the laboratory protocol (refer to 7.5.3Preparing Body Fluid Samples (For BF Mode) and 7.5.4Placing Barcode Labels).
- Analysis orders are set (refer to **7.6.1Setting up Analysis Orders**).
- The entered sample ID, sampling mode, sample mode, and the test panel are strictly in accordance with the sample to be run.
- The analyzer is ready to run samples (i.e. the analyzer indicator stays in green). Sample compartment is open.
- The bottom area of the "Count" screen displays the "Mode" as "OV-BF-CD".

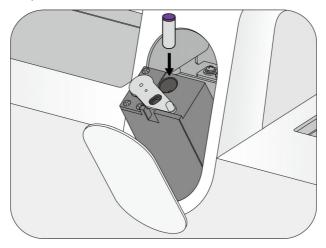
NOTE

- If you start sample analysis immediately after selecting work mode, then the default reference range
 is "General". After the analysis finishes, the analyzer will flag results per the reference range
 "General". To change the category of a reference group, follow the instructions in 6.3.4.2Ref. Range
 Setup (Administrators).
- Mix the sample.
- If you are running a sample collected in an evacuated blood collection tube, shake the tube as instructed by the picture below to mix the sample thoroughly.
- If you are running a sample collected in a centrifugal tube, cap the tube and shake the capped tube to mix it thoroughly.

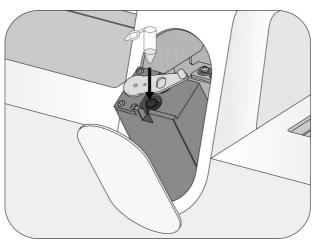
A CAUTION

- To attain accurate analysis results, make sure the sample volume meets requirements. Otherwise, the results may be inaccurate.
- Misleading results may occur if the body fluid sample has floccules, clots. cryoglobulin, leukocyte clumps, bacteria, or high protein. Follow your laboratory protocol to deal with such samples.
- 2. Place the sample tube into the appropriate tube position in the sample compartment.

■ If you are running a sample collected in an evacuated collection tube, make sure the tube position switch is at the Micro WB tube position side. Then place the evacuated collection tubes into the regular tube position of sample compartment.



■ If you are running body fluid sample collected in centrifuge tubes, make sure the tube position switch is at the regular tube side and proper adapter is installed, then uncap the centrifuge tube and place it at Micro-WB tube position.



- 3. Press the "Start Count" key on screen to start sample analysis.
- $\sqrt{}$ The sample compartment closes, and the sampling probe automatically aspirates sample.
- 4. After the analyzer finishes aspirating sample, the sample compartment opens. You can remove the sample safely.
- $\sqrt{}$ The analyzer automatically analyzes the sample, the analyzer indicator is flickering in green.
- $\sqrt{}$ When the analysis completes, the analyzer indicator returns to "Ready" status (stay in green).
- $\sqrt{}$ The screen displays the current sample results, histograms, scattergrams and flags (if there is).

- 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 13Troubleshooting for solutions.
- When 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. See
 13Troubleshooting for solutions.

7.7 Running Samples

7.7.1 Setting up Analysis Orders

You can set analysis order information on the main unit of Auto Hematology Analyzer.

- 1. Tap " « "on the "Count" screen.
- $\sqrt{}$ The pop-up window appears.
- Select "AL Mode".



3. Enter the sample ID, rack No., and tube No. as needed.

- If built-in barcode scanner is configured on your analyzer, the analyzer will scan the sample ID
 automatically after you check "Auto-Scan sample ID". Make sure that the barcode labels are intact
 and readable.
- If you uncheck "Auto-Scan Sample ID", manually enter the first Sample ID, and the following sample IDs will automatically increase. For more details, refer to 6.3.3.1 Getting sample information.
- Totally 20 characters are allowed for sample ID maximally (including prefix); the ID must end with a number, and must not be consisted of "0" only.
- 4. Select the desired test panel according to your model.

| Test panel | Meaning | Description |
|------------|--------------|---|
| СВС | CBC | Complete blood count |
| CD | CBC+DIFF | Complete blood count + WBC differentiation tests |
| Ret | Ret | Reticulocyte-related tests |
| CR | CBC+Ret | Complete blood count + Reticulocyte-related tests |
| CDR | CBC+DIFF+Ret | Complete blood count + WBC differentiation tests + Reticulocyte-related tests |
| ESR | ESR | Erythrocyte sedimentation rate test |

| Test panel | Meaning | Description |
|------------|--------------------------|--|
| CR/PLT-5X | CBC+ Ret, PLT-5X mode | Complete blood count + Reticulocyte-related tests, using the extended sampling method (PLT-5X) |
| CDR/PLT-5X | CBC+DIFF+Ret/PLT-5X mode | Complete blood count + WBC differentiation tests + Reticulocyte-related tests, using the extended sampling method (PLT-5X) |
| CD/WBC-3X | CBC+DIFF, WBC-3X mode | Complete blood count + WBC differentiation tests, using the extended sampling method (WBC-3X) |
| CDR/WBC-3X | CBC+DIFF+Ret?WBC-3X mode | Complete blood count + WBC differentiation tests + Reticulocyte-related tests, using the extended sampling method (WBC-3X) |

- Only some commonly used analysis modes are displayed on the "Test Panel" area of pop-up window. You can tap "Other Mode" button to select other desired analysis modes.
- The Ret test penal only applies to the BC-760[R]/BC-780[R] model.
- Capillary samples cannot be tested for ESR.
- The test panels vary with the models with different configurations. For details, refer to the configuration interface of your model.
- For the description of the test panels supported by the analyzer, refer to B.5.1Sample modes, test panel, and applicable model.

7.7.2 **Performing Sample Analysis**



A CAUTION

Do not run prediluted samples in autoloading mode. Otherwise the results may be inaccurate.

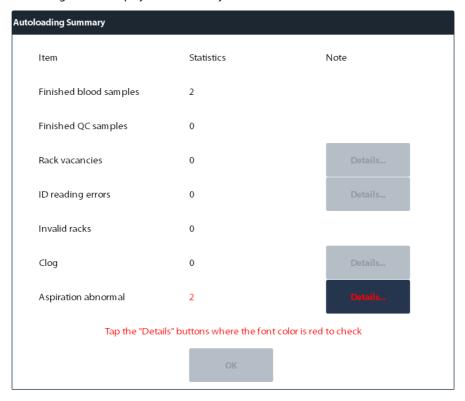
Check the following before analysis:

- Sample(s) prepared in accordance with the laboratory protocol (refer to 7.5.1Preparing Whole Blood Samples (For WB Mode) and 7.5.4Placing Barcode Labels).
- Analysis orders are set (refer to 7.7.1Setting up Analysis Orders).
- Make sure the entered sample ID, rack No., tube No. and the analysis mode are strictly in accordance with the sample to be run.
- The analyzer is ready to run samples (i.e. the analyzer indicator stays in green).
- The "Next Sample" area of the "Count" screen displays the "Mode" as "AL-WB".
- When you have selected "Auto-Scan Sample ID" as the sample ID entry method, make sure the barcode labels are clear, complete and are properly pasted on the sample tubes.
- Place the racks with tubes on the right tray of the autoloader, with the side opening facing the analyzer.
- (Optional) Tap "Start Count" on the "Count" screen. 2.

- When "Auto load tube racks" is enabled, the analyzer automatically loads the tube racks on the right tray of the autoloader for sample analysis. For the instruction of enabling "Auto load tube racks", refer to 6.3.7Setting up Functions for the Auto-Loading of Samples (Menu > "Setup" > "Auto-loading") (administrators).
- Repeated piercing of the vacuum blood collection tube can damage the rubber cap. The resulting debris can cause inaccurate analysis results. The recommended number of piercing actions per vacuum tube is not more than 3.
- If abnormal power interruption occurs after analysis is started, you should remove the racks manually and open the front cover to see if there are dropped tubes to be removed.

- $\sqrt{}$ The analyzer automatically analyzes the sample. During this process, the analyzer indicator is flickering in green.
- $\sqrt{}$ Save results from each sample analysis to "Table Review".
- 3. (Optional) Review the autoloading summary.

If you have enabled "Display summary after autoloading finished" on the "Auto-loading" setup screen, a statistical result dialog box will display when the analyses are finished.



(Optional) If the results of certain items on the statistical result dialog box are not 0, tap the "Details..." button to check the sample ID, analysis time and sample position of the corresponding samples.



- b Tap "OK" to close the dialog box.
- 4. When the autoloading analyses are finished, all the tube racks are moved to the left tray of the autoloader automatically, and then you can remove the racks of tubes safely.

NOTE

When you have selected "Auto-Scan Sample ID" as the sample ID entry method, but the sample ID scanned is invalid, then "Inv. test time _ tube position" will be the sample ID.

- If "Auto-Scan sample ID" is selected and the tube No. scanned is invalid, then "??" will be the tube No.. For the information of enabling or disabling "Auto-Scan sample ID", refer to 6.3.3.1 Getting sample information.
- For the information of enabling or disabling "Display summary after autoloading finished", refer to 6.3.7Setting up Functions for the Auto-Loading of Samples (Menu > "Setup" > "Auto-loading") (administrators).

7.7.3 Stop Count

If you need to stop auto-loading analysis during the analysis process, follow below instructions.

During the analysis process, tap the "Stop Count" button on the pop-up window.

- $\sqrt{}$ The analyzer will stop running after the current sample is analyzer,
- $\sqrt{}$ The rack of the sample will move to the left tray of the autoloader.

7.8 STAT

Use this function to insert STAT samples during the auto-loading analysis process.

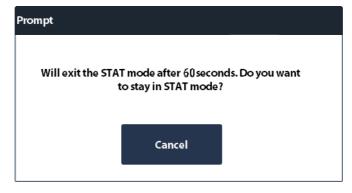
- 1. On the "**Count**" screen, tap

 and then tap the "**STAT**" button on the pop-up window.
- $\sqrt{}$ After the current sample has been analyzed, the analyzer will stop the autoloading operation and switch from AL Mode to CT Mode.
- $\sqrt{}$ The pop-up window is switched to "**CT Mode**" page.
- √ The sample compartment reaches out.
- 2. Enter the sample information and select the desired sample mode and analysis mode.
- 3. Place STAT samples in the sample compartment.
- 4. Select "Start Count" to start STAT samples analysis.
- 5. When STAT samples analysis completes, the sample compartment reaches out. Take out STAT samples.
- 6. (Optional) Repeat steps 2 to 5 to complete all STAT samples analysis.
- 7. Exit STAT using either of the following methods.
- Exit STAT manually.

Select "Exit STAT".

■ Exit STAT automatically.

- For the instruction of enabling "Auto exit STAT" function, refer to 6.3.3Auxiliary Setup ("Menu" > "Setup" > "Auxiliary Setup").
 - When you do not place STAT samples in the sample compartment during the pre-defined time range, a prompt as shown in the figure below is displayed.



- b (Optional) To continue STAT samples analysis, select "Cancel".
- c The analyzer automatically exits STAT when count-down ends.

The analyzer switches back to "AL Mode", then you can proceed with analysis under auto-loading mode.

NOTE

- For the information of setting analysis order under closed-tube sampling mode, refer to 7.6.1Setting up Analysis Orders.
- When the sample mode or sampling mode changes, the analyzer will switch the mode automatically and a pop-up message will be displayed.

7.9 **Entering/Exiting Standby Status**

When the analyzer is free from fluidic operations or when it reaches the set standby time, the analyzer automatically enters the standby status.

When the user starts sample tests, or performs any operation that initiates fluidic system actions or moving parts actions, the analyzer automatically exits standby.

NOTE

Refer to 6.3.5Maintenance ("Menu" > "Setup"> "Maintenance") (Administrators) for how to edit waiting time before entering the standby mode.

7.10 Shutting down the Analyzer

CAUTION

- Be sure to shut down the analyzer strictly as instructed. Otherwise, the tubes may be polluted, leading to wrong results.
- Do not start up the analyzer immediately after shutdown. Wait at least 10 seconds.

7.10.1 Shutting down the analyzer

Follow below instructions to perform the shutdown procedure.

- Tap "Menu"->"Shutdown" on the "Count" screen.
- 2. Tap "OK" to perform the shutdown procedure. The dialog box disappears automatically.
- (Optional) When a dialog box pops up, asking you to perform Probe Cleanser maintenance, present Probe Cleanser to the sampling probe as instructed, and start Probe Cleanser maintenance.

NOTE

- For how to perform Probe Cleanser maintenance, see 12.4Probe Cleanser Maintenance.
- Prompt "The analyzer will power off" displays on the screen.

NOTE

- When the screen goes black, the analyzer exits normal working conditions and just certain modules continue working.
- (Optional) Turn off the power switch on the back of the analyzer.
- Empty the waste in the waste container, and then dispose of the waste properly.

7.11 **Viewing Guidance Videos in iHelp**

Video Guidance is available in iHelp on analyzer. You can view guidance videos and know how to operate your analyzer.

Follow below instructions to view guidance videos.

- 1. Tap "Menu" > "Service" > "iHelp" on the "Count" screen or tap "iHelp" utility button.
- 2. Tap video thumbnails to play videos.

NOTE

• If you have any questions about guidance videos, contact out customer service department.

8 Reviewing Sample Results

8.1 Introduction

After every analysis cycle, the analyzer automatically saves the analysis results into the sample database.

Up to 130,000 analysis results can be stored in the BC-760[B]/BC-760[R] analyzers. Up to 150,000 analysis results can be stored in the BC-780[R] analyzers. When the maximum number has been reached, the newest result will overwrite the oldest.

You can review all the analysis results, scattergrams and histograms.

8.2 Reviewing Sample Results

NOTE

 The screenshots in this Operator's Manual are only for reference. The actual screens are subject to the configuration of your analyzer.

8.2.1 Entering the "Table Review" Screen

Select "Menu" > "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.

The sample results are sequentially displayed from left to right on the "**Table Review**" screen, the latest on the utmost right of the table, including the sample information, parameter results, and patient information.

8.2.2 Operations on the "Table Review" Screen

8.2.2.1 Browsing sample record

Tap (), (), and () to turn to the left/right column (page).

Tap (), (), and () to turn to the previous/next row (page).



Figure 8-1 Table review - parameter results



Figure 8-2 Table review - patient information

Tap to switch to the second tool bar.



Figure 8-4 tool bar - 2

The position of the current sample result and the total sample results are shown in the form of "**Position/Total**" at the bottom left the screen.

NOTE

 When the WBC result is lower than WBC DIFF threshold (0.1×10⁹ by default), the analyzer does not display the specific result. To review the result, contact our Customer Service Department.

8.2.2.2 Selecting/deselecting records

- Tap the record that you want to select to select it.
- Tap a selected record to deselect it.
- Tap the records that you want to select one by one to select multiple records.
- $\sqrt{}$ The selected sample records are highlighted.

8.2.3 Searching for Sample Records

You can search sample records that match defined conditions.

- Select "Menu" > "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. Tap "Search" on the tool bar.

 $\sqrt{}$ The following dialog box displays.

| Search | | | | | |
|-----------------|----------------|------------------|------|--------------|------------|
| Not Validate | d Today | Not Printed Toda | ау | Not Transmit | ited Today |
| Sample ID | | | | | |
| Patient ID | | | | | |
| First Nam e | | Last Nan | n e | | |
| Date | 08 - 21 - | 2021 - | 08 - | 21 - 2021 | |
| Sample No. | | - | | | |
| Sample State | Not validated | Not pri | nted | Not trans | smitted |
| ✓ Auto select s | earched record | | ОК | | Cancel |

3. Define the searching conditions.

See below for setting descriptions.

Search today's samples by sample status:

| Not Validated Today | Tap "Not Validated Today", "Not Printed Today", or "Not Transmitted Today" to search for the samples on the current day that are not | |
|-----------------------|--|--|
| Not Printed Today | validated, printed or transmitted. | |
| Not Transmitted Today | | |

Search for sample records that match defined conditions.

You can define one or more searching conditions.

When you have defined more than one searching condition, the analyzer will search for the sample records that match all defined conditions.

| Sample ID | Enter "Sample ID" as a search condition, the analyzer searches for and displays all sample records whose sample ID includes the entered sample ID. | For example, if you enter "1235" into the " Sample ID " field, the analyzer will searches for all sample records whose sample ID includes "1235". |
|--------------|--|--|
| Patient ID | Enter "Patient ID" as a search condition, the analyzer searches for and displays all sample records whose patient ID includes the entered sample ID. | For example, if you enter "1235" into the " Patient ID " field, the analyzer will search for all sample records whose patient ID includes "1235". |
| Name | Enter patient name as a search condition. The analyzer will search for all sample records whose patient name matches the defined name. | / |
| Date | Define the test time period in the " Date " fields as a search condition. The analyzer searches for all sample records tested between the defined time period of " Date ". | The " Date " range is set to the current date by default. |
| Sample No. | Enter "Sample No." as a search condition, the analyzer searches for and displays all sample records whose sample ID includes the entered sample ID. | / |
| Sample State | Check "Not validated", "Not printed", or "Not transmitted", and the analyzer searches from all sample records that match the checked state. | You can check for more than one sample state, and the analyzer searches from all sample records that match the checked states. |

| "Auto select searched | When "Auto select searched record" is checked, the analyzer highlights and | / |
|--------------------------|--|---|
| record" check box | displays all searched results. | |

- 4. Tap "**OK**".
- $\sqrt{}$ All searched results display on the screen.
- 5. (Optional) Tap "Cancel" to return to the "Table Review" screen.

8.2.4 Graph Review

Follow below instructions:

- 1. Select "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. Select one or more sample records of which you want to review the graph data.
 - $\sqrt{\text{The selected sample record is highlighted.}}$
- 3. Tap "Graph" to go to the "Graph" screen.

See below for relevant operations on the "Graph" screen:

8.2.4.1 Previous/Next

Tap "Previous" or "Next" to browse the previous or next samples.

8.2.4.2 Table Review

Tap "Table Review" to enter the "Table Review" screen.

8.2.4.3 Other Parameters

The "Other Para." screen displays the RUO parameter results, reference results, and microscopic parameter results.

- Select "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- Select one or more sample records of which you want to review the RUO parameter results, reference results, and microscopic parameter results.

 $\sqrt{\text{The selected sample record is highlighted.}}$

Tap "Graph" to go to the "Graph" screen.

Tap "Other Para." to go to the "Other Para." screen.

Research Use Only (RUO) Parameters

Tap the "RUO Para." tab to review the RUO parameter results.

NOTE

- RUO parameters and scattergrams are for research purpose only. They cannot be used for diagnosis purpose.
- When the user selects to use the PLT-5X test mode, or the PLT-5X test mode is automatically triggered in accordance with the re-exam settings for low PLT/WBC samples, besides the normal PLT-O result, the system will give another PLT-O result in a pair of parenthesis, and that one has one more decimal place than that of the normal one.

Reference Results

When the system decides a parameter result is not reliable (for example, the DIFF parameter results of certain abnormal samples), the Sample Report screen will not display the results in values, but as "****". The estimated results will be provided on the "**Reference results**" screen. Decide if the reference results can be used for report based on a comprehensive consideration regarding information, like historical results, microscopic exam results or re-exam results.

Tap the "Reference results" tab to check the analysis parameter results of the corresponding samples.

Microscopic Parameters

Before you can review microscopic parameter results, make sure you have set the microscopic parameters on the "Setup" > "Para. Setup" > "Microsco. Para. Setup" screen.

NOTE

- For the method of defining "Microscopic Para.", refer to section 6.3.4.3Microsco. Para. Setup (Administrators).
- 1. Tap the "Microscopic Para." tab to review the "Microscopic Para." results or tap the "Result" cell for a certain parameter to enter the microscopic parameter result.
- (Optional) Enter the blood group information and ESR result of the sample in the "Blood Group" and "ESR" edit boxes.
- 3. (Optional) If necessary, tap the "**Print**" button on the "**Microscopic Para.**" screen to print the microscopic parameter results.

NOTE

- For the method of defining "Microscopic Para.", refer to section 6.3.4.3Microsco. Para. Setup (Administrators).
- You cannot edit the microscopic parameter results of a validated sample. For the method of validating samples, refer to section 8.2.9Validating/Cancelling Validation (Administrators).

8.2.4.4 Editing Results (Administrators)

Administrators may edit analysis results.

- Select "Menu" > "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. Tap to select the sample record of which you want to edit the analysis results.
 - $\sqrt{}$ The selected sample record is highlighted.

Tap "Graph" to go to the "Graph" screen.

- 3. Tap "Edit Result".
- $\sqrt{}$ The "Edit Result" dialog box is displayed.
- 4. Tap the "Results" edit box of the parameter you want to edit and modify the parameter result.
- 5. Tap "OK" to close the dialog box.
- $\sqrt{}$ The analyzer saves the new parameter results.
- $\sqrt{}$ "E" is marked behind the parameter result data directly modified manually. If modifying a parameter result directly and manually leads to the modification of its related parameter result, "e" is marked behind its result data.

NOTE

 You cannot edit the sample results of the samples that have been validated and samples for background tests. For the method of validating samples, refer to section 8.2.9Validating/Cancelling Validation (Administrators).

Follow below instructions to restore the edited results to its original analysis results:

- 1. Select "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. Tap to select the sample record of which you want to restore the original analysis results.
- $\sqrt{}$ The selected sample record is highlighted.
- 3. Tap "Graph" to go to the "Graph" screen.
- 4. Tap "Edit Result".

- $\sqrt{}$ The "**Edit Result**" dialog box is displayed.
- 5. Tap "Restore".
- $\sqrt{}$ The edited results will be changed back into the initial values.
- $\sqrt{}$ The "E" and "e" flags disappear.

NOTE

 The analyzer only saves the original measurement results of the latest 2000 samples with results modified.

8.2.4.5 Reviwing Special Information

Follow below instructions:

- Select "Menu"- "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. Tap to select the samples of which you want to review the special information.
- $\sqrt{}$ The selected sample record is highlighted.
- 3. Tap "Graph" to go to the "Graph" screen.
- 4. Tap "Special Info.".
- $\sqrt{}$ The screen displays the instrument-related information when analyzing the current sample.
- 5. (Optional) Tap the "Error Information" pull-down list to review the error logs (if there are) when analyzing the current sample.

8.2.4.6 Reviewing Traceability Information

The "Traceability" screen displays the information of the reagents and controls when analyzing the current sample.

Follow below instructions:

- Select "Menu" > "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. Tap to select the samples of which you want to review the traceability information.
- $\sqrt{}$ The selected sample record is highlighted.
- 3. Tap "Graph" to go to the "Graph" screen.
- Tap "Traceability".
- $\sqrt{}$ The "Traceability" screen displays the information of the reagents and controls when analyzing the current sample.

8.2.5 Communication

Before transmitting the sample records, make sure the network connection is good.

8.2.5.1 Transmitting selected records

- 1. Select samples to be transmitted on the "Table Review" screen.
- 2. Tap "Comm.", the "Comm." dialog box displays.
- 3. Select the "Selected records" button.
- 4. Tap "**OK**" to close the dialog box and start transmitting data.

8.2.5.2 Transmitting all records

- Tap "Comm.", the "Comm." dialog box displays.
- 2. Select the "All records" button.

Tap "OK" to close the dialog box and start transmitting data.

8.2.6 **Exporting Sample Results**

Users of administrator level can export the sample records, graphic data, flags, and other parameters of the selected sample records to a USB flash drive.

Before exporting sample records, make sure that you have inserted a safe USB flash drive into the USB port on the analyzer.



CAUTION

- The USB port of the analyzer is only used to connect to a designated peripheral device. For details about supported devices and models, refer to B.7Requirements for Input/Output Devices.
- The user should ensure the data safety of the USB devices connecting to the analyzer.

8.2.6.1 **Exporting some or all sample records**

Follow below instructions to export selected or all sample records:

- Select "Menu" > "Table Review" or tap the "Table Review" utility button to enter the "Table Review"
- 2. Tap to select one or more samples records that you want to export; to export all the sample records, go to the next step.
- 3. Tap "Export".
- $\sqrt{}$ The "Export" dialog box displays.
- 4. To export some sample records, tap "Selected records" in the "Export Range" area; to export all the sample records, tap "All records" in the "Export Range" area.
- 5. (Optional) To export "Flags", check "Flags".
- 6. Tap "**OK**".
- The analyzer exports the corresponding sample records to the USB device.

8.2.7 **Calculating CV Values**

Follow the instructions below to calculate the CV values of sample results.

- Select "Menu"- "Table Review" or tap the "Table Review" utility button to enter the "Table Review"
- 2. Tap to select multiple sample records for which you want to calculate the CV values.
- 3. Tap "**CV**".
- The screen displays the Mean value, SD value and the CV value for each parameter.

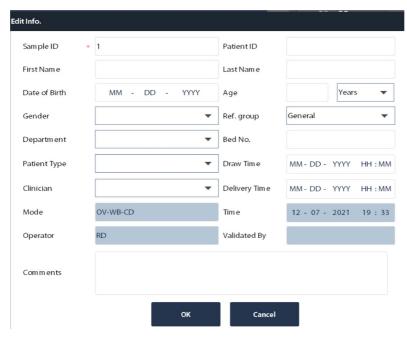
NOTE

To calculate CV values, select at least 3 samples.

8.2.8 **Editing Information**

- Select "Menu" > "Table Review" or tap the "Table Review" utility button to enter the "Table Review"
- 2. Tap to select the sample records of which you want to edit the sample information.
- The selected sample record is highlighted.
- Edit the sample information. 3.
 - Tap "Edit Info.".

 $\sqrt{}$ The following dialog box displays.



- b Enter necessary information as needed.
- 4. Tap "**OK**" to save the entered information.

NOTE

• For the setup of reference groups, refer to section 6.3.4.2Ref. Range Setup (Administrators).

8.2.9 Validating/Cancelling Validation (Administrators)

Users of administrator level can validate/cancel validate sample records.

- Select "Menu" > "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. Tap to select the sample you want to validate or cancel validation.
- $\sqrt{}$ The selected sample record(s) is/are highlighted.
- 3. Tap "Validate" or "Cancel Validate".
- √ For the validated sample records, the "Validated By" cell displays the role of the validator.
- $\sqrt{}$ The "Validated By" cell for the unvalidated sample records will be empty.

NOTE

You cannot validate background test results or invalid sample records.

8.2.10 Deleting Sample Records

Administrators can delete sample records on the "Table Review" screen.

8.2.10.1 Deleting some or all sample records

Follow instructions below to delete some or all sample records:

- 1. Select "Menu- "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. To delete some sample records, tap to select one or more samples to delete; to delete all the sample records, go to the next step.
- $\sqrt{}$ The selected record(s) is/are highlighted.

- 3. Tap "Delete".
- The "Delete" dialog box displays.
- To delete some selected sample records, tap to select "Selected records". To delete all the sample records, tap to select "All records".
- Tap "**OK**". 5.
- The system deletes the corresponding records.

8.3 **Flags of Analysis Results**

The analyzer provides two types of flags for analysis results:

- Parameter flags;
- Flags of Abnormal Blood Cell Differential or Morphology

8.3.1 **Parameter Flags**

The analyzer provides the following parameter flags.

| Flag | Message | Meaning |
|--|-----------------------------|---|
| "H" (default) and "L" or "h" and "l" or "^" and "\sqrt{"}" | High and low result flags | The analysis result exceeds the upper or lower limit of the reference range, but still within the display range |
| "R" (default) or "r" | Suspect flags | The analysis result is suspicious |
| "&" | Algorithm-rectified flag | The analysis result is rectified by the algorithm of the analyzer |
| @ | Out of linearity range flag | The analysis result is out of the linearity range |
| "++++" | Out of display range flag | The analysis result is out of the display range |
| 11.4.4.4.4.11 | Screened results | When the system decides a parameter result is not reliable (for example, the DIFF parameter results of certain abnormal samples), the Sample Report screen will not display the results in values, but as "****". |

NOTE

- The results of background check will not be flagged for abnormal parameters, abnormal blood cell differential or morphology.
- For the linearity range of each parameter, refer to B.6.2Linearity Ranges.

8.3.2 Flags of Abnormal Blood Cell Differential or Morphology Results



CAUTION

Abnormal cells may not necessarily trigger the flags during the analysis process, it is recommended that reexamination is conducted per the operation instruction of your laboratory.

The analyzer reports the flags for the following abnormal blood cell differential or morphology.

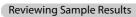
| Flag Message | Indication | Criteria |
|----------------------|--------------------------|--|
| Abn. WBC scattergram | WBC scattergram abnormal | The DIFF channel scattergram is abnormal |
| Neutropenia | Neu# low | Neu# < 1.00×10 ⁹ /L |

| Flag Message | Indication | Criteria |
|--------------------------|---|---|
| Neutrophilia | Neu# high | Neu# > 11.00×10 ⁹ /L |
| Lymphopenia | Lym# low | Lym# < 0.80×10 ⁹ /L |
| Lymphocytosis | Lym# high | Lym# > 4.00×10 ⁹ /L |
| Monocytosis | Mon# high | Mon# > 1.50×10 ⁹ /L |
| Eosinophilia | Eos# high | Eos# > 0.70×10 ⁹ /L |
| Basophilia | Bas# high | Bas# > 0.20×10 ⁹ /L |
| Leukocytopenia | WBC count low | WBC < 2.50×10 ⁹ /L |
| Leucocytosis | WBC count high | WBC > 18.00×10 ⁹ /L |
| NRBC? | Possible presence of nucleated red blood cells | Presence of excessive dots in NRBC sensitive region of the scattergram |
| Blasts? | Possible presence of blast cells | Presence of excessive dots in blast sensitive region of the scattergram |
| Abn Lymph/blast? | Possible presence of abnormal lymphocytes or blasts | Presence of excessive dots in abnormal lymphocyte/blast sensitive region of the scattergram |
| Immature Gran? | Possible presence of immature granulocytes | Presence of excessive dots in immature granulocyte sensitive region of the scattergram |
| Left Shift? | Possibility of left shift | Presence of excessive dots in left shift sensitive region of the scattergram |
| Atypical Lymph? | Possible presence of atypical lymphocytes | Presence of excessive dots in atypical lymphocyte sensitive region of the scattergram |
| RBC Histogram Abn. | Abnormal distribution of RBC histogram | Abnormal distribution of RBC histogram |
| *RET Scattergram Abn. | The distribution of RET scattergram is abnormal | The distribution of RET scattergram is abnormal |
| Dimorphic Population | Dimorphic population distribution | Presence of two or more peaks on the RBC histogram |
| Anisocytosis | Anisocytosis | RDW-CV> 22 or RDW-SD> 64fL |
| Microcytosis | MCV low | MCV < 70fL |
| Macrocytosis | MCV high | MCV > 110fL |
| Hypochromia | Hypochromia | MCHC<290 |
| Anemia | Anemia | HGB< 90g/L |
| Erythrocytosis | RBC high | $RBC > 6.5 \times 10^{12}/L$ |
| RBC Agglutination? | RBC results possibly inaccurate | Calculate and compare special parameters |
| Turbidity/HGB Interfere? | Abnormal HGB or there may be interference | Calculate and compare special parameters |
| Iron Deficiency? | May indicate iron deficiency anemia | Calculate and compare special parameters |
| Fragments? | Possible presence of RBC fragments | Presence of abnormally distributed dots in sensitive region of the RET channel |
| *PLT Scattergram Abn. | PLT Scattergram Abn. | PLT Scattergram Abn. |
| PLT Histogram Abn. | PLT Histogram Abn. | PLT Histogram Abn. |
| Thrombocytopenia | PLT low | PLT<60×10 ⁹ /L |
| Thrombocytosis | PLT high | PLT>600×10 ⁹ /L |

| Flag Message | Indication | Criteria |
|-----------------------|--|--|
| PLT Clump? | Possibility of PLT clump | Calculate and compare special parameters |
| Pancytopenia | WBC, RBC and PLT low | WBC< 4.0 and RBC< 3.5 and PLT< 100 |
| Lipid Particles? | Possible presence of lipid particles | Presence of excessive dots in lipid particle sensitive region of the scattergram |
| Infected RBC? | Possible presence of infected RBC | Presence of excessive dots in infected RBC sensitive region of the scattergram |
| *WBC Fragments? | Possible presence of WBC fragments. | Presence of abnormally distributed dots in WBC fragment sensitive region |
| Aspiration Abnormal | The sample probe is clogged or the sample volume is insufficient | Insufficient sample aspiration due to clogging of the sample probe, or insufficient sample volume |
| *Reticulocytosis | RET high | RET% $>$ 5% or RET# $>0.20\times10^{12}$ /L or presence of abnormally distributed dots in sensitive region of the DIFF RET channel |
| ^PLT-H Histogram Abn. | The PLT-H histogram is abnormal. | The PLT-H histogram is abnormal. |
| ESR analysis error | The ESR channel may be abnormal and the ESR measurement may be inaccurate. | Analyze and monitor the measurements of the ESR channel. |

NOTE

- Items marked with * apply only to the BC-760[R]/BC-780[R] models.
- $^{\bullet}$ $\;$ ltems marked with \land is optional on models configured with PLT-H parameter.



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Using the QC Program

9.1 **Overview**

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.

A new lot of controls should be analyzed in parallel with the current lot prior to their expiration dates.

In order to ensure the reliability of sample analysis results, it is recommended that operators use low-level, normal-level, and high-level hematology controls. When the control of a new lot needs to be used, use the control of the new lot and the existing control in parallel for five days. Run QC twice a day. The results shall be within the reference range specified for the control.

This analyzer provides the L-J QC (including blood, BF, and protein QC) and X-B QC programs.



A CAUTION

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

NOTE

For the description of reagents and controls, refer to sections 3.6.1Reagent and 3.6.2Controls and Calibrators.

9.2 L-J QC

L-J QC is named after S. Levey and E.R. Jennings, who in 1950 introduced statistical control into the clinical laboratories. Laboratories may set up allowable deviations (by standard deviations (SD) or coefficient of variation (CV%)) from the targets for the control based on their real scenario.

QC points are then plotted so the operators may easily see how far the actual QC results are from their targets. The x-aixs indicates the QC date and time; and the Y-aixs indicates the targets as well as the defined limits. Draw a straight line respectively at the reference value position and the upper and lower deviation limit position of control parameter along the X-axis direction on the QC graph. Lines run across the graph at the target as well as at the upper and lower limits to either side of the target value for the control. The QC points' distance from the target value is measured in SD or CV%.

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

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

Setting up L-J QC Files (Administrators) 9.2.1

9.2.1.1 Introduction to the L-J QC file setup

Lot No.

Mode

You can set up L-J QC files on the QC file setup screens, as shown in *Figure 9-1L-J QC File Setup Screen*.

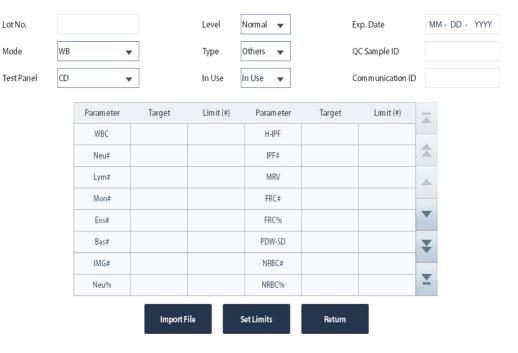


Figure 9-1 L-J QC File Setup Screen

Table 9-1 L-J QC File

| Items | Description | Note |
|-----------|--|--|
| Lot No. | Find the Lot No. of controls on the vial labels of the controls | Up to 16 digits can be entered for the lot No. You can enter characters, numbers, letters and special characters. Chinese characters are not supported. The lot No. is required. Enter the lot No. of the controls by one of the following ways: Manual entry, or using an external barcode scanner. |
| Level | Levels of controls "High", "Normal", "Low" | / |
| Exp. Date | Expiration dates of the controls | The expiration date shall not be earlier than the current system date. |
| Mode | The loading and sample modes in QC tests: "AL-WB" "CT-WB" "CT-BF" | |

| Test Panel | The analysis modes supported in QC tests: CD, *CDR, *Ret, ESR, or CD+ESR | When you are using BR60 controls, select the CD test panel or *CDR test panel; When you are using BC-6D controls, select the CD test panel; When you are using the BC-RET controls, select the *RET test panel; When you are using the BC-BF controls, select the CD test panel; When you are using the BC-BF controls, select the CD test panel; Note: The item with * only applies to the BC-760[R] and BC-780[R]model. |
|-------------------|---|--|
| Туре | The controls are classified into two types: "Others" or "Mindray" | / |
| In Use | QC files in use or not: In Use Not in Use | If the "In Use" option is selected in the "In Use" pull down list of QC file, the QC results will be stored in the file. |
| QC Sample ID | If you are used to analyze control together with 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. | You can enter letters, digits and all other characters on the keyboard (including special characters) for QC sample ID. Chinese and other languages are not supported (e.g. Japanese, Korean, etc.) If you are using external barcode scanner to scan sample IDs, make sure the QC sample IDs set on the QC file screen are the same as that of the Lot No. labels on the control vials. If you are manually entering sample IDs, make sure the QC sample IDs set on the QC file screen are the same as the sample IDs you entered on the "Mode" screen. |
| Communicat ion ID | If you are using 2-way LIS, LIS identifies QC results by the communication ID set here. | / |
| Target | The target values for the QC parameters Find the targets in the target sheet of the controls | / |
| Limit | The allowed deviation limit for each QC parameter Find the limits information in the target sheet of the controls | The limits are represented by SD or by CV. Tap "Set Limits" and select to represent the deviations "By SD" or "By CV". |

9.2.1.2 Setting up new L-J QC file

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

- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup"in turn, to enter the L-J QC file setup screen.
- 2. Tap "New" to enter the new L-JQC file screen.
- 3. Enter the necessary QC file information.

You shall enter the required "File Info." and "Target/Limit" using one of the following ways:

- Reading the information provided by the manufacturer
 - a Insert the USB device saving the QC files to the USB port on the analyzer.
 - b On the new QC file screen, tap "Import File" and follow the software instruction to import the QC file.
- Manually enter the necessary QC file information.

NOTE

- For the introduction of the L-JQC file setup, refer to *Table 9-1L-J QC File*.
- The user should ensure the data safety of the USB devices connecting to the analyzer.
- 4. Define "QC Sample ID" and "Communication ID".
- 5. (Optional) If necessary, set the QC file to "In Use" in the "In Use" pull-down list.

NOTE

- You can check or uncheck to "In Use" option on the QC file table screen to activate or deactivate the QC files.
- For files having the same "QC Sample ID" and presentation mode, only one of them can be "In Use".
- For files having the same QC type and level, only one of them can be "In Use".
- 6. Saving the QC file.
 - a Tap "Return" or other buttons on the screen.
- √ A confirm dialog box displays.
 - b Tap "Yes" to save the new QC file.

9.2.1.3 Editing L-J QC files

You can only edit empty L-JQC files.

NOTE

- You cannot edit the QC files that already have QC data.
- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup"in turn, to enter the L-JQC file setup screen.
- 2. Tap to select the QC file to edit.
- $\sqrt{}$ The "*" mark displays next to the "**File No.**" of the selected QC file.
- 3. Tap "Edit" to enter the L-JQC file editing screen.
- 4. Edit the QC file as necessary.

NOTE

- For the introduction of the L-JQC file setup, refer to *Table 9-1L-J QC File*.
- 5. (Optional) If necessary, set the QC file to "In Use" in the "In Use" pull-down list.

NOTE

- You can check or uncheck to "In Use" option on the QC file table screen to activate or deactivate the QC files.
- For files having the same "QC Sample ID" and presentation mode, only one of them can be "In Use".
- For files having the same QC type and level, only one of them can be "In Use".
- 6. Saving the QC file.
 - a Tap "Return" or other buttons on the screen.
- √ A confirm dialog box displays.
 - b Tap "Yes" to save the new QC file.

9.2.2 Running L-J QC Tests

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

- Run controls under the "QC" screen.
- Put controls together with normal samples, and run the controls on the "**Count**" screen

9.2.2.1 Running controls on the QC count screen

Check the following before running QC analysis:

Make sure you have set up a suitable and correct QC file for the control to be run, and the QC file is "In Use". (Refer to 9.2.1Setting up L-J QC Files (Administrators).)

- Make sure you have prepared the controls in accordance with your laboratory protocols, and the requirements in the Instruction for Use of the controls.
- Make sure the analysis system is without error.

AL-WB

Follow below instructions:

- 1. Select "Menu" > "QC" > "L-J QC" > "Count" or directly tap "QC" to enter the QC count screen.
- Select "File No." of the desired QC file corresponding to the control to be run from the "File No." pull-down list.
- 3. Make sure the QC file information displayed on the screen is correct. Make sure the level of the control to be run is the same with the current QC file, and the control is not expired.

NOTE

The expiration date of expired controls is displayed in red.

- 4. Prepare the control as instructed by instructions for use of the controls, and paste barcode labels to the control vials (for details about pasting barcodes, see *7.5.4Placing Barcode Labels*).
- To run QC counts:
 - a Place the prepared controls into the tube rack.
 - b Place racks loading controls on the right tray of the autoloader, with the back of "MINDRAY" mark on the carrier facing the analyzer.
 - c Tap "Count" to start running.
- $\sqrt{}$ The analyzer automatically analyzes the sample.
 - d When running finishes, you may remove the racks from the left of the autoloader.
- $\sqrt{}$ When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

NOTE

- Up to 372 QC results can be saved in each QC file.
- 6. Perform the above procedures to continue running QC analysis if necessary.

CT-WB/CT-BF

Follow below instructions:

- 1. Select "Menu" > "QC" > "L-J QC" > "Count" or directly tap "QC" to enter the QC count screen.
- 2. Select "File No." of the desired QC file corresponding to the control to be run from the "File No." pull-down list.
- 3. Make sure the QC file information displayed on the screen is correct. Make sure the level of the control to be run is the same with the current QC file, and the control is not expired.

NOTE

• The expiration date of expired controls is displayed in red.

- Prepare the control as instructed by instructions for use of the controls, and paste barcode labels to the control vials (for details about pasting barcodes, see 7.5.4Placing Barcode Labels).
- 5. To run QC counts:
 - a Place racks loading controls into the appropriate tube position in the sample compartment. Make sure the tube position switch is at micro-WB tube side, then place the controls tube into the regular tubes of compartment.
 - b Tap "Count" to start running.
- $\sqrt{}$ The sample compartment closes, and the sampling probe automatically aspirates control.
 - c After the analyzer finishes aspirating sample, the sample compartment opens. You can remove the control safely.

- $\sqrt{}$ The analyzer automatically analyzes the control. During this process, the analyzer indicator is flickering in green.
- $\sqrt{}$ When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

NOTE

- Up to 372 QC results can be saved in each QC file.
- 6. Do the above procedures to continue running QC analysis if necessary.

9.2.2.2 Putting controls together with normal samples, and run the controls on the "Count" 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 on the "Count" screen.

Check the following before analysis:

- Make sure you have set up a suitable and correct QC file for the control to be run, and the QC file is "In Use". (Refer to 9.2.1Setting up L-J QC Files (Administrators).)
- Make sure you have prepared the controls in accordance with your laboratory protocols, and the requirements in the Instruction for Use of the controls.
- The analyzer is ready to run samples (i.e. the analyzer indicator stays in green).
- Make sure the analysis system is without error.

Note when you set sample ID for the control:

- If you are using external barcode scanner to scan sample IDs, make sure the QC sample IDs set on the QC file screen are the same as that of the Lot No. labels on the control vials.
- If you are manually entering sample IDs, make sure the QC sample IDs set on the QC file screen are the same as the sample IDs you entered on the "**Mode**" screen.

Follow below instructions:

- 1. On the "Count" screen, tap the "Mode" button.
- $\sqrt{}$ The "**Mode**" dialog box displays.
- 2. Select the desired mode.

NOTE

- Make sure the set mode is the same with that you set in the QC file for the control.
- In the "Sample ID" column, manually enter the Sample ID, or use an eternal barcode scanner to scan the barcode label on the tube to enter Sample ID into the "Sample ID" field.

NOTE

- Make sure the Sample ID you entered is the same with the QC sample ID you set in the QC file for the control.
- 4. Run the samples in accordance with the normal sample analysis procedure.
- $\sqrt{}$ After the analysis, the QC results will be automatically saved to the corresponding QC file.

NOTE

- For the normal sample analysis procedures, refer to 7.6Running Samples under Closed-tube Mode.
- When the sample mode or sampling mode changes, the analyzer will switch the mode automatically and a message will be displayed.
- Up to 372 QC results can be saved in each QC file.

9.2.3 Reviewing L-J QC Results

After QC analysis, you can review the QC results in the "QC Table" review or "QC Graph" review.

9.2.3.1 QC Graph Review

Reviewing QC Graph

- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup" in turn, to enter the L-JQC file setup screen.
- 2. Select the desired QC file to review.
- $\sqrt{}$ The "*" mark displays next to the "**File No.**" of the selected QC file.
- 3. Tap "QC Graph" to enter the QC graph review screen of the selected QC file.

Introduction to the L-J Blood QC Graph Screen

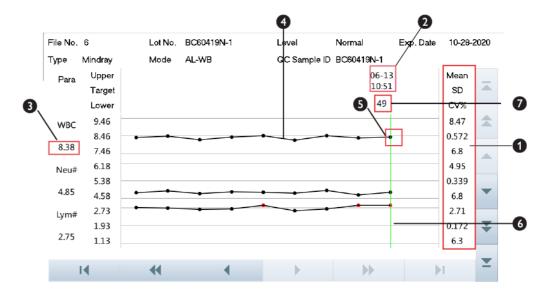


Figure 9-2 L-J Blood QC Graph

- $1\\ -- The Mean, SD and CV\% of all the QC results of each parameter in the current graph.$
- 2— The saving date and time of the QC point on the green line.
- 3— The QC result of the QC point on the green line.
- 4—The line connecting all QC points of the same parameter to show the trend. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest.
- 5— Currently selected QC point. The analysis result of the selected QC point is displayed under the parameter. A black QC point indicates the value is within the limit; a red QC point indicates the value is out of the limit.
- 6— The green vertical line is used to identify a selected QC point and all parameter values of the QC point.
- 7— The sequence number of the QC point on the green line among all the QC points in the current QC file.

Introduction to the L-J BF QC Graph Screen

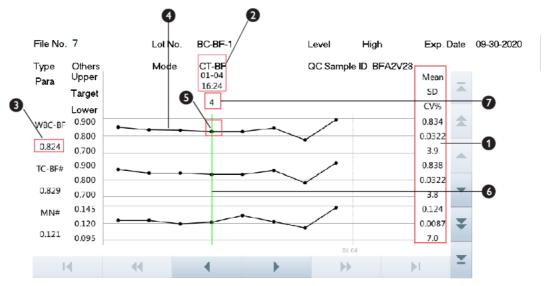


Figure 9-3 L-J BF QC Graph

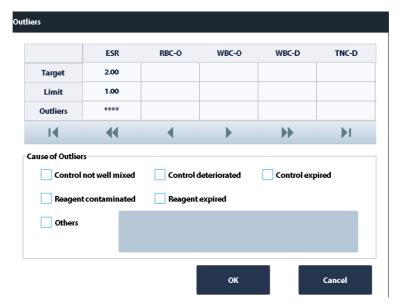
- 1—The Mean, SD and CV% of all the QC results of each parameter in the current graph.
- 2— The saving date and time of the QC point on the green line.
- 3— The QC result of the QC point on the green line.
- 4—The line connecting all QC points of the same parameter to show the trend. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest.
- 5— Currently selected QC point. The analysis result of the selected QC point is displayed under the parameter. A black QC point indicates the value is within the limit; a red QC point indicates the value is out of the limit.
- 6— The green vertical line is used to identify a selected QC point and all parameter values of the QC point.
- 7— The sequence number of the QC point on the green line among all the QC points in the current QC file.

Entering the Causes of Outliers (Administrators)

A red QC point indicates the value is out of the limit.

If necessary, follow below instruction to enter the reasons for the outliers.

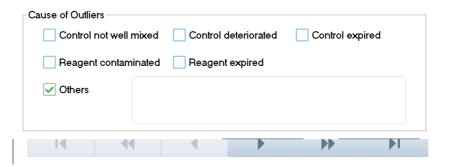
- 1. Tap "Menu"> "QC" > "L-J QC" > "Setup" and tap the "Routine Blood Test QC" tab to enter the L-J blood and BF QC file setting screen.
- 2. Select the desired QC file to review.
- $\sqrt{}$ The "*" mark displays next to the "File No." of the selected QC file.
- 3. Tap "QC Graph" to enter the QC graph screen of the selected QC file.
- 4. Moving the green line to the desired QC point, and tap the "Outliers" button.
- $\sqrt{}$ A dialog box displays the QC results, targets and limits of all the parameters.



5. Enter the reasons for outliers.

Check the suitable causes for outliers;

or check "Others" and enter the causes of outliers in the edit box.



NOTE

- You may enter up to 200 characters to the "Others" edit box.
- 6. Tap "OK" to save the reasons and exit the dialog box.

9.2.3.2 QC Table Review

Reviewing QC Table

- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup"in turn, to enter the L-J QC file setup screen.
- 2. Select the desired QC file to review.
- $\sqrt{}$ The "*" mark displays next to the "**File No.**" of the selected QC file.
- 3. Tap "QC Table" to enter the QC Table screen of the specified QC file.

Introduction to the L-J Blood QC Table Screen



Figure 9-4 L-J Blood QC Table

- 1— The sequence number of the QC results saved in the QC file (earliest to the latest from top to down)
- 2— QC result
- 3— QC parameters (displayed in the same order as those on the QC graph screen)

Introduction to the L-J BF QC Table Screen

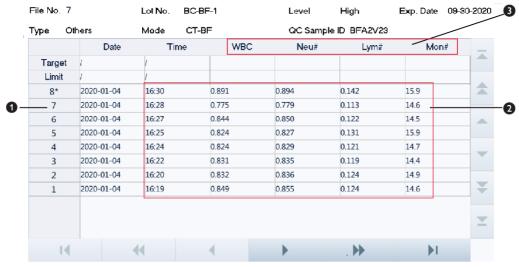


Figure 9-5 L-J BF QC Table

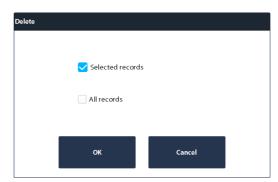
- 1—The sequence number of the QC results saved in the QC file (earliest to the latest from top to down)
- 2— QC result
- 3— QC parameters (displayed in the same order as those on the QC graph screen)

Deleting QC Records (Administrators)

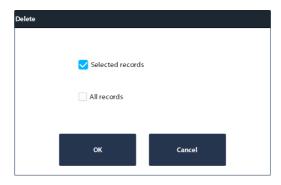
Administrators may deleted selected or all QC record in the QC file.

- Deleting selected QC record(s)
- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup"in turn, to enter the L-J QC file setup screen.
- 2. Select the desired QC file.
- $\sqrt{}$ The "*" mark displays next to the "**File No.**" of the selected QC file.

- 3. Tap the "QC Table" button to enter the QC table screen of the corresponding QC file.
- 4. Select the QC record(s) you want to delete.
- $\sqrt{}$ The selected QC records are highlighted.
- 5. Tap "Delete".
- $\sqrt{}$ The following dialog box displays.



- 6. Tap to select "Selected records" and then tap "OK" to delete selected records.
- Delete all QC records
- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup"in turn, to enter the L-JQC file setup screen.
- 2. Tap the "QC Table" button to enter the QC table screen of the corresponding QC file.
- 3. Tap "Delete".
- $\sqrt{}$ The following dialog box displays.



4. Tap to select "All records" and then tap "OK" to delete all records.

Communication

You can transmit QC data to the external data management software or LIS/HIS.

Before transmitting QC data, make sure the network is properly connected.

- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup"in turn, to enter the L-J QC file setup screen.
- 2. Select the desired QC file.
- $\sqrt{}$ The "*" mark displays next to the "**File No.**" of the selected QC file.
- 3. Tap the "QC Table" button to enter the QC table screen of the corresponding QC file.
- 4. Tap "Comm.".
- $\sqrt{}$ Communication starts. All QC data of the selected QC files will be transmitted by default.

NOTE

- The QC data saved in the process of transmission will not be transmitted.
- 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.

Exporting data (administrators)

Administrators may export selected or all QC records to an external USB device.

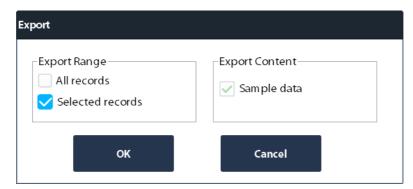
Before exporting data, make sure the USB device is firmly connected to the USB port on the side of the analyzer.

NOTE

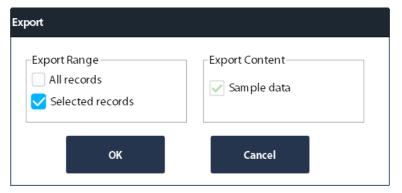
- The user should ensure the data safety of the USB devices connecting to the analyzer.
- Export selected records

Follow below instructions:

- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup"in turn, to enter the L-J QC file setup screen.
- 2. Select the desired QC file.
- $\sqrt{}$ The "*" mark displays next to the "**File No.**" of the selected QC file.
- 3. Tap the "QC Table" button to enter the QC table screen of the corresponding QC file.
- 4. Select the QC record(s) you want to export.
- √ The selected QC records are highlighted.
- 5. Tap "Export".
- $\sqrt{}$ The following dialog box displays.



- 6. Tap to select "**Selected records**" and then tap "**OK**" to export the selected records.
- Exporting all QC records
- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup"in turn, to enter the L-J QC file setup screen.
- 2. Tap the "QC Table" button to enter the QC table screen of the corresponding QC file.
- 3. Tap "Export".
- $\sqrt{}$ The following dialog box displays.



4. Tap to select "All records" and then tap "OK" to export all records from the QC Table.

9.2.3.3 Editing QC results (administrators)

When necessary, administrators can edit the QC results on the QC count screen.

Follow below instructions:

- 1. Select "Menu" > "QC" > "L-J QC" > "Count" or directly tap "QC" to enter the L-J QC count screen.
- 2. In the "File No." pull-down list, select the QC file "File No.".
- 3. (Optional) If necessary, tap "Previous" or "Next" to switch QC samples.
- 4. Tap "Edit Result" to enter the "Edit Result" screen.
- 5. Modify the results of the parameters as needed.
- 6. Tap "**OK**" to return to the QC count screen.
- $\sqrt{}$ The modified results are saved on the count screen.
- $\sqrt{}$ "E" is marked behind the parameter result data directly modified manually. If modifying a parameter result directly and manually leads to the modification of its related parameter result, "e" is marked behind its result data.
- 7. (Optional) If necessary, tap "Restore".
- $\sqrt{}$ The edited results will be changed back into the initial values.

9.2.4 Viewing Results of Single QC Count

If necessary, you can view the test results, RUO parameter results, histogram, scattergram, and other information of a QC analysis on the QC count screen.

Follow below instructions:

- 1. Select "Menu" > "QC" > "L-J QC" > "Count" or directly tap "QC" to enter the L-J QC count screen.
- 2. In the "File No." pull-down list, select the QC file "File No.".
- 3. (Optional) If necessary, tap "Previous" or "Previous" to switch QC samples.
- $\sqrt{}$ The screen displays the test results, scattergrams and histograms of corresponding QC samples.
- 4. Tap button, and then tap "RUO Para." to go to the "RUO Para." screen.
- √ The screen displays the QC "RUO Para." results.

9.3 X-B QC

The X-B analysis is a weighted moving average analysis that uses values obtained from patient samples. It uses the 3 red cell indices, MCV, MCH and MCHC to indicate the hematology instrument performance.

It is recommended the X-B QC be activated when the sample volume of your laboratory is greater than 100 samples per day. Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices. It observes the trend of QC results in the reference range formed by the specified target and limits.

The analyzer implements X-B QC on the three parameters: MCV, MCH and MCHC, each group of samples for X-B QC analysis consists of 20-200 sample results obtained from normal analysis of both WB and PD modes. The analyzer can save up to 3,000 X-B QC results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest result.

9.3.1 Validity Determination for X-B QC Samples

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

- Sample results exceeding the linearity range;
- Background results;
- Sample results not conforming to the "Sample Validity Setup";
- L-J QC results
- Calibration data.

9.3.2 Setting up X-B QC Rules

Administrators may set up X-B QC rules on the XB QC setup screen.

- 1. Tap "Menu" > "QC" > "X-B QC" > "Setup" in turn to enter the X-B QC file setup screen.
- 2. Set up X-B QC rules as needed.

See below for setting descriptions.

Table 9-2 X-B QC count setup items

| X-B QC On/Off | Select " On " or " Off " to enable or disable the X-B QC. | When you select " Off ", the analyzer does not run X-B QC program. |
|--------------------------|--|---|
| Samples/Batch | The amount of samples to be included in calculating for an X-B QC point. | Setup range: 20 to 200; For example, when "Samples/Batch" is set to 20, and there are 20 valid samples, the analyzer starts to run X-B QC. |
| Target/Limits Setup | Enter the target/limit for each parameter | Do not leave any of the targets and limits for the QC parameters blank. The units of target/limits of all parameters are the same as those on the "Parameter Unit Setup" screen of the hematology analyzer. |
| Sample Validity Setup | In the "Sample Validity Setup" of the X-B QC setup screen, set the upper and lower limits of the 4 parameters in the sample validity setup area. | "Sample Validity Setup" is to set up the ranges of valid RBC, MCV, MCH and MCHC results. Only when the results of all these four parameters are within the specified ranges, the sample results can be used for X-B QC calculation. In the sample validity setup, the upper limit shall be no smaller than the lower limit. Otherwise, there will be a message asking you to revise. The valid ranges of the RBC parameters are their linearity ranges; the valid ranges of other parameters are their display ranges. All the entries shall be numbers with only one decimal point. The length of the number entered cannot be longer than the length of the text box. The units of lower and upper limits of all parameters are the same as those on the "Parameter Unit Setup" screen. |
| Restore Defaults | Tap " Restore Defaults " to restore the targets and limits to the default values. | / |
| Set Limits | Tap " Set Limits " and select "By SD (#)" or "By CV (%)" | When "By SD(#)" is selected, the limits are displayed in the format of SD value; When "By CV(%)" is selected, the limits are displayed in the format of CV percent. |



BIOLOGICAL RISK

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

After editing X-B setup, the system will start X-B QC automatically.

After every 20 to 200 valid sample results (determined by the "**Samples/Batch**" setup, the system will perform the X-B calculation once automatically. You can review the result in X-B QC graph or X-B QC table.

9.3.3 Reviewing X-B QC Results

After QC analysis, you can review the QC results in the "QC Table" review or "QC Graph" review.

9.3.3.1 QC Graph Review

Tap "Menu" > "QC" > "X-B QC" > "Graph" in turn to enter the X-B QC Graph screen.

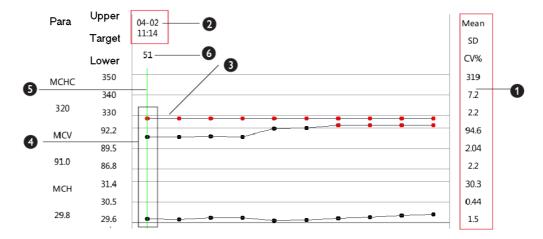


Figure 9-6 X-B QC Graph Screen

- 1—The Mean, SD and CV% of all the QC results of each parameter in the current graph.
- 2— The saving date and time of the QC points on the green line.
- 3—The line connecting all QC points of the same parameter to show the trend. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest.
- 4— Currently selected QC point. The analysis result of the selected QC point is displayed under the parameter. A black QC point indicates the value is within the limit; a red QC point indicates the value is out of the limit.
- 5—The green vertical line is used to identify the QC points of the same analysis, all of which are displayed on the line when you select one of them.
- 6—The relative position of the QC point where the green vertical line is located in all QC points of the current QC file.

9.3.3.2 QC Table Review

- 1. Tap "Menu" > "QC" > "X-B QC" > "Graph" in turn to enter the X-B QC Graph screen.
- 2. Tap "QC Table" to go to the "QC Table" screen.

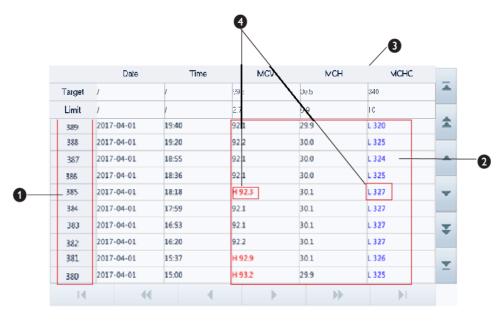


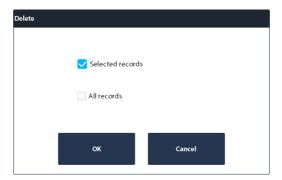
Figure 9-7 X-B QC table screen

- 1— The sequence number of the QC results saved in the QC file (the earliest to the latest from top to down)
- 2— QC result
- 3— QC parameters (displayed in the same order as the Graph screen)
- 4— QC flags: The flag "H" or "L" (or other flags configured) will mark the results that are out of the limits

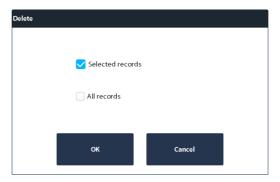
Deleting QC Records (Administrators)

Administrators may delete selected or all QC record in the QC file.

- Deleting selected QC record(s)
- 1. Tap "Menu" > "QC" > "X-B QC" > "Graph" in turn to enter the X-B QC Graph screen.
- 2. Tap "QC Table" to go to the "QC Table" screen.
- 3. Select the QC record(s) you want to delete.
- √ The selected QC records are highlighted.
- 4. Tap "Delete".
- $\sqrt{}$ The following dialog box displays.



- 5. Tap to select "Selected records" and then tap "OK" to delete selected records.
- Deleting all QC records
- 1. Tap "Menu" > "QC" > "X-B QC" > "Graph" in turn to enter the X-B QC Graph screen.
- 2. Tap "QC Table" to go to the "QC Table" screen.
- 3. Tap "Delete".
- $\sqrt{}$ The following dialog box displays.



4. Tap to select "All records" and then tap "OK" to delete selected records.

Exporting data (administrators)

Administrators may export selected or all QC records to an external USB device.

Before exporting data, make sure the USB device is firmly connected to the USB port on the side of the analyzer.

CAUTION

- The user should ensure the data safety of the USB devices connecting to the analyzer.
- Exporting selected records

Follow below instructions:

- Tap "Menu" > "QC" > "X-B QC" > "Graph" in turn to enter the X-B QC Graph screen. 1.
- 2. Tap "QC Table" to go to the "QC Table" screen.
- Select the QC record(s) you want to export.
- The selected QC records are highlighted. $\sqrt{}$
- 4. Tap "Export".
- The "Export" dialog box displays. $\sqrt{}$
- 5. Tap to select "Selected records" and then tap "OK" to export the selected records.
- Exporting all QC records
- Tap "Menu" > "QC" > "X-B QC" > "Graph" in turn to enter the X-B QC Graph screen. 1.
- 2. Tap "QC Table" to go to the "QC Table" screen.
- Tap "Export". 3.
- The "Export" dialog box displays. $\sqrt{}$
- Tap to select "All records" and then tap "OK" to export all records.

9.4 When QC Results are Out of Range

If a QC result falls outside the control range, the "QC" button on the software screen lights in orange.

Troubleshooting

When a QC result falls outside the control range, follow below steps to solve the problem.

- Analyze the cause of outliers, take corrective measures, and verify effectiveness of the corrective measures.
- If the corrective measures fail, report it according to the laboratory protocol.
- Contact Mindray Customer Service Department.

Analyzing the Causes

Retest the samples with outliers. If the retest result still contains outliers and the trend is the same as that of the previous result with outliers, find out the cause of outliers by sequence referring to *Figure 9-8Analyze the Cause of QC Outliers*.

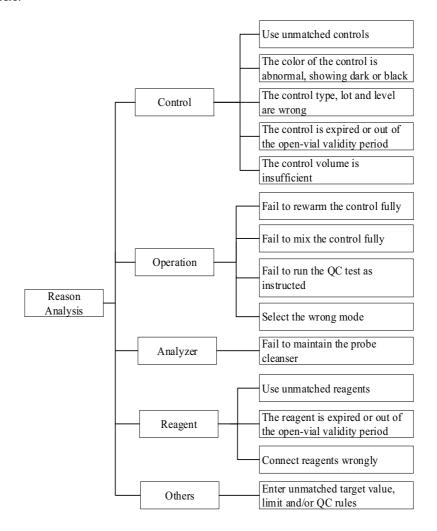


Figure 9-8 Analyze the Cause of QC Outliers

Taking Corrective Measures

Analyze the possible causes of QC outliers and make corrections in time according to *Figure 9-8Analyze the Cause of QC Outliers*.

Verifying Effectiveness of Corrective Measures

After taking corrective measures, retest the QC samples and verify whether the QC results are within the range.

If the cause of outliers is still not determined after all factors are analyzed, replace the controls with new one for verification, or directly contact Mindray Customer Service Department

10 Calibrating Your Analyzer

10.1 Overview

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 four calibration programs available on this analyzer: auto calibration, manual calibration, ESR manual calibration, auto calibration using calibration using fresh blood samples and protein gain calibration

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

10.2 When to Calibrate

Your analyzer has been 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. It is recommended that you run the calibration program every half year. You only need to recalibrate this analyzer if:

- you are going to use this analyzer for the first time (usually done by a Mindray-authorized representative when installing the analyzer).
- a major analytical component (including sampling probe, syringe, etc.) 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.

CAUTION

 The instrument must be within the calibration validity period; otherwise, the measurement results may be inaccurate.

10.3 Checking before Calibration

Before calibration, follow the CLSI standards or your laboratory protocol to do tests, and make sure the analyzer's background (blank count) results, repeatability results and carryover results are all within the specified ranges.

If any of the above items is not in the range, check if the analyzer is in error. Remove the errors (if there are) and check again. If the problem persists, contact Mindray Customer Service Department.

NOTE

 For information of blank count, repeatability, and carryover of the analyzer, refer to Appendix B.6Performance Specifications.

10.4 Running the Calibration Programs

The analyzer supports the following calibration programs:

- Manual
- ESR(administrators)
- Calibrator(administrators)
- Fresh Blood(administrators)

10.4.1 Notes before Calibration

Before calibration, check and make sure the analyzer works properly and enough reagents have been prepared for the calibration. You need to start over the calibration if the reagents run out during the process.

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.

10.4.2 Manual Calibration

NOTE

 If you log in at the operator access level, you can only review calibration factors on the manual calibration screen. You cannot edit the calibration factors.

10.4.2.1 Sample requirements for manual calibration

You can use Mindray-specified calibrators or value-assigned fresh blood samples to perform manual calibration.

If you are using value-assigned fresh blood samples, make sure the samples meet the following requirements:

- has normal erythrocyte, leukocyte, and platelet morphology
- the test results are within corresponding ranges
- has sufficient sample volume for the whole calibration procedure

10.4.2.2 Performing manual calibration

Do as follows to calibrate the analyzer.

- Select a calibrator or a value-assigned fresh blood sample which meets the sample requirements for manual calibration, and run the sample consecutively for n times (not less 3 times), in whole blood or predilute mode.
- 2. Calculate the CV values and the Mean values for the n tests.

NOTE

- You may review the CV and Mean values through the "Table Review" screen. See 8.2.7Calculating CV
 Values for more details.
- 3. Check if the CV values are in the acceptable ranges.

NOTE

- When the CV value for any parameter exceeds the acceptable range, check if the analyzer is in error.
 If there are errors, remove the errors and test again. If the problem cannot be solved, contact
 Mindray Customer Service Department.
- 4. Tap "Menu" > "Calibration" > "Manual" in turn to enter the "Manual" screen.
- 5. Calculate the new calibration factors for the parameters according to the following equation. The calculated factors should show 2 decimal places.

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

For example: Suppose the WBC reference value of a calibrator is 8.40, and the current calibration factor of the whole blood mode is 98.90%.

Run the sample under whole blood mode for 10 consecutive times (n=10) and take the WBC results of the 10 runs to calculate: 8.10, 8.00, 8.10, 8.30, 8.30, 8.20, 8.00, 8.10, 8.30. The obtained CV is 1.5% and Mean is 8.16, which meet the requirements.

Therefore:

New Calibration Factor =
$$\frac{98.90\% \times 8.40}{8.16} = 101.81\%$$

6. The calculated calibration factors shall be between 75.00% - 125.00%.

If not, the calibration factor is invalid. 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.

- 7. Enter the new calibration factors into the factor cell of the parameter that require calibration.
- $\sqrt{}$ The "Date" cells automatically display the date when the new calibration factors are entered.

If the entered calibration factors are invalid, the factors will be highlighted in red.

NOTE

- The calibration factor entered must be in the range of 75.00% to 125.00%, and only two decimal places can be reserved.
- 8. Save calibration factors.
 - a Tap another button on the software screen.
- $\sqrt{}$ The following dialog box displays.
 - b Tap "Yes" to save new calibration factors.
- 9. If the entered calibration factors are invalid, a dialog box will display prompting "Invalid entry" when you are switching to another screen.



- a If you want to re-do the calibration, tap "No", and perform the calibration procedures again.
- b Tap "**Yes**" to close the dialog box and switch to another screen without saving the changes; the original calibration factors and dates will remain unchanged.

10.4.3 Calibrating with ESR (administrators)

The ESR calibrators are used to calibrate the analyzer deviation so as to align the measurement results and the target value.

NOTE

 Perform ESR calibrators function under the guidance of engineers from Mindray Customer Service Department.

10.4.4 Calibrating with Calibrators (administrators)

10.4.4.1 Sample requirements for calibrators

You must use Mindray-specified calibrators for calibration.

10.4.4.2 Performing calibration with calibrators

NOTE

• The calibration with calibrators can only be performed in AL-WB mode.

- 1. Make sure you have prepared the calibrators in accordance with your laboratory protocols, and the requirements in the use instruction of the calibrators.
- 2. Tap "Menu" > "Calibration" > "Calibrator" in turn to enter the "Calibrator" screen.
- 3. Set up calibrator information.

Enter the "Lot No.", "Exp. Date" and the target for each parameter.

See below for setting descriptions.

| Lot No. | Find the lot No. on the label on the vial of the calibrator, or on the target sheet of the corresponding calibrator. |
|-------------------|--|
| Exp. Date | The entered expiration date should be either the expiration date printed on the labeling or the open-vial expiration date, whichever is earlier. The open-vial expiration date is calculated as follows: the date that container is opened + the open-vial stability days. |
| Parameter Targets | Find the parameter targets on the target sheet of the corresponding calibrator. |

- 4. Place racks loading calibrators on the right tray of the autoloader, with the back of "MINDRAY" mark on the carrier facing the analyzer.
- 5. Perform the calibrator calibration.
 - a Tap "Start Count" on the calibrator calibration screen.
- $\sqrt{}$ The analyzer starts the calibration.

NOTE

• To obtain valid calibration factors, we need 3 to 10 valid calibration results.

- b When the first calibration finished, removed the tube rack with the calibrator from the unloading tray, and place it on the loading tray again.
- c Press the "Start Count" key on the calibrator calibration screen to start the second analysis.
- d Repeat steps a to c for the remaining tests.
- The analyzer automatically calculates the calibration factors for the parameters.
- (Optional) You may select to use which calibration results to calculate the calibration factors.

Check the "Select" cells of the calibration results that are to be involved in the calculation of calibration factors. Select at least 3 groups of calibration results.

The calibration results are invalid under the following circumstances.

- if there is a parameter whose calibration data is out of its linearity range but still within the display range;
- 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;

When there are invalid calibration results, a dialog box displays. Tap "OK" to close the message box, and the data will be deleted from the table without saving automatically.

- 7. Save calibration factors.
 - a Tap another button on the software screen.
- $\sqrt{}$ The analyzer gives different suggestions depending on the calculated calibration factors.

b Read the software messages, and save the new calibration factors or exit the screen directly as prompted.

10.4.5 Calibrating with Fresh Blood Samples (administrators)

10.4.5.1 Requirements for fresh blood samples used for calibration

If you are using value-assigned fresh blood samples, make sure the samples meet the following requirements:

- has normal erythrocyte, leukocyte, and platelet morphology
- the test results are within corresponding ranges
- has sufficient sample volume for the whole calibration procedure

10.4.5.2 Calibrating with fresh blood samples

NOTE

The calibration with fresh blood samples can only be performed under AL-WB mode.

Do as follows to calibrate the analyzer with fresh blood:

- Follow the instruction in 7.5.1Preparing Whole Blood Samples (For WB Mode) to prepare sufficient fresh blood samples.
- 2. Tap "Menu" > "Calibration" > "Fresh Blood" in turn to enter the "Fresh Blood" screen.
- 3. Select a sample ID from the "Current Sample ID:" pull-down list.
- 4. Enter the targets corresponding to the parameters for calibration into the "Target" text boxes.
- 5. Place the prepared whole blood sample in a tube, and place the racks with tubes on the right tray of the autoloader, with the back of "MINDRAY" mark on the carrier facing the analyzer.
- 6. Perform the fresh blood sample calibration.

NOTE

To obtain valid calibration factors, we need 3 to 10 valid calibration results.

- a Tap "Start Count" on the fresh blood sample calibration screen.
- √ The analyzer starts the calibration.
 - b When the first calibration finished, removed the tube rack with the calibrator from the unloading tray, and place it on the loading tray again.
 - c Press the "Start Count" key on the fresh blood sample calibrator screen to start the second analysis.
 - d Repeat steps a to c for the remaining tests.
- $\sqrt{}$ The analyzer automatically calculates the calibration factors for the parameters.
- 7. (Optional) You may select to use which calibration results to calculate the calibration factors.

Check the "**Select**" cells of the calibration results that are to be involved in the calculation of calibration factors. Select at least 3 groups of calibration results.

 $\sqrt{}$ The analyzer automatically calculates the calibration factors for the parameters.

The calibration results are invalid under the following circumstances.

- if there is a parameter whose calibration data is out of its linearity range but still within the display range;
- 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.

When there are invalid calibration results, a dialog box displays. Tap "OK" to close the message box, and the data will be deleted from the table without saving automatically.

Under the following circumstances, the calculated calibration factors are invalid:

When the calculated calibration factor for a blood sample is not within the valid range (75% to 125%).

■ The CV% value of any calibration parameter exceeds the precision index of the analyzer.

When there are invalid calibration factors, a dialog box displays. Tap "OK" to close the message box, and the data will be deleted from the table without saving automatically.

- 8. Repeat steps 3 to 7 to complete the analysis of other blood samples.
- 9. Calculate the mean calibration factor.

You must have at least 3 groups of valid calibration factors to calculate the mean calibration factors.

- a Tap "Calculate" button to enter the screen for calculating the mean calibration factor of fresh blood samples.
- b Tap to select at least 3 groups of calibration factors that are to be involved in the calculation of a mean calibration factor.
- $\sqrt{}$ The analyzer automatically calculates the mean calibration factor.

Under the following circumstances, the calculated mean calibration factors are invalid.

- when the deviation of absolute value between the calibration factors included in calculating the mean and the original calibration factors reaches or exceeds 5%;
- when the calculated calibration factor is not within the specified range (75%-125%).
- 10. Save calibration factors.
 - a Tap another button on the software screen.
- $\sqrt{}$ The analyzer gives different suggestions depending on the calculated calibration factors.
- Read the software messages, and save the new calibration factors or exit the screen directly as prompted.
- $\sqrt{}$ Read the software messages, and save the new calibration factors or exit the screen directly as prompted.

10.4.6 Verifying Calibration Factors

Verify the calibration factors after calibration.

Verify the calibration factors using any of the following methods:

- Run the calibration at least 3 times, and check if the results are within the allowed range.
- Run the controls of high, normal, and low levees at least 3 times, and check if the results are within the allowed range.
- Run at least 3 fresh blood samples from normal patients, each sample for at least 3 times, and check if the results are within the allowed range.

10.5 Calibration History ("Menu" > "Calibrate" > "Calibration History")

Only administrators can view the calibration history.

Tap "Menu" > "Calibration" > "Calibration History" in turn to enter the "Calibration History" screen.

The relevant items are described below:

| Details | Select a calibration record and tap " Details " to view the detailed calibration information. | |
|---------|--|--|
| Go to | Tap "Go to" to view the calibration history of the specified time period. | |
| Export | Tap "Export" to export the specified or all calibration records to a USB device. | |

NOTE

The user should ensure the data safety of the USB devices connecting to the analyzer.

11 Printing

You can set up the print templates for sample results report, graphs, QC results, QC graphs, manual calibration factors etc., and print them using the print templates.

11.1 Setting up Print Template

You can set up print settings on the "Print Setup" screen.

11.1.1 Operation Procedure

- 1. Tap "Menu" > "Setup" > "System Setup" > "Print Setup" to enter the "Print Setup" screen.
- 2. Tap the "Print Setup", "Printing Content", and "Auto print after sample analysis" tabs as needed to perform print settings as needed.

See below for setting descriptions

| Print device | Select a print device on the network from the pull-down list: | For questions about the print device and print drive settings, contact the customer service personnel of your print device supplier. (administrators) |
|--|---|---|
| Printer driver | Select a proper print drive from the pull-down list: | |
| Paper | Select the desired paper type from the pull-down list: The analyzer supports two paper types: • A4 • A5 | |
| Blood Sample Report Title/ Body Fluid Sample Report Title | Select "Blood Sample Report Title" or "Body Fluid Sample Report Title" from the pull-down list. Enter the desired title in the edit box. √ The report titles set up here will display on the printed analysis reports. | |
| Blood Sample Report Template/ Body Fluid Sample Report Template | Select "Blood Sample Report Template" or "Body Fluid Sample Report Template" from the pull-down list. Select the desired template format from the pull-down list: One page with histogram One page without histogram | When "One page with histogram" is selected, the print results include the parameter results and graphs. When "One page without histogram" is selected, the print results include only the parameter results. |
| Para. Language | Select a parameter language from the pull-down list: Chinese Chinese/English | When "Chinese" is selected, the printed report displays the Chinese parameter names. When "Chinese/English" is selected, the printed report displays Chinese and English parameter names in a pair. |
| Copies | Enter the number of report copies to be printed when you tap " Print ". The default value is 1 copy, and the setting range is [1 to 20]. | |

| Printing Content | Check the options you want to display on the printed report: Print flags of edited result Print high/low result flags Print suspect flags Print result edit flag Print out of linearity range flag Print flags Print reference range Monochrome Print Print RUO Parameters | For the description of setting up high/low results as well as suspect fresults lags, refer to section 6.3.3.20ther Settings. For the description of setting up reference ranges, refer to section 6.3.4.2Ref. Range Setup (Administrators). |
|--|---|--|
| Auto print after sample analysis | Check to enable one or more desired auto print settings: Auto print after analysis Auto print after validating Auto print after QC count | When "Auto print after analysis" is selected, the analyzer automatically print the sample results after each analysis. When "Auto print after validating" is selected, the analyzer automatically print the validated sample results. When "Auto print after QC count" is selected, the analyzer automatically print the results of QC count results after each QC count ends. |

11.2 Printing Sample Result Report

NOTE

• The analyzer prints at most 700 records at one time.

Before printing a sample test report, confirm the following items:

- The printer has been set up and connected correctly.
- There are enough paper in the printer.

11.2.1 Printing Current Sample Result Report

When a cycle of sample analysis finishes, tap the "Print" button on the "Count" screen.

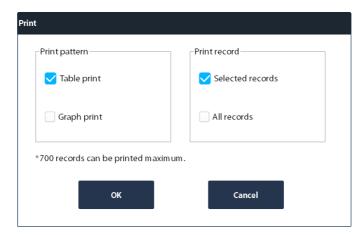
 $\sqrt{}$ The analyzer automatically prints the results of the current sample according to the print setup.

11.2.2 Printing from the Table Review Screen

Follow below instructions:

- 1. Select "Menu- "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- (Optional) Tap to select one or more sample records to be printed on the test result report. If you are going to print all sample records, skip this step.
- 3. Tap "Print" in the utility button area.

√ A dialog box for printing displays.



4. Set up the print methods.

See below for setting descriptions.

| Print pattern | Table print | Select " Table print ", only to print sample results, but not to print graphs (histograms and scattergrams). | |
|---------------|------------------|---|--|
| | Graph print | Select " Graph print ", print sample results as well as the graphs (histograms and scattergrams). | |
| Print record | Selected records | Check "Selected records" to print the selected sample records. | |
| | All records | Check "All records" to print all the sample records. | |

- 5. Tap "**OK**".
- $\sqrt{}$ The analyzer prints the sample result reports of the selected samples.

11.2.3 Printing from the Graph Review Screen

Follow below instructions:

- 1. Select "Menu-"Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- 2. Select one or more sample records of which you want to review the graph data.
- $\sqrt{}$ The selected sample record is highlighted.
- 3. Tap "Graph" to go to the "Graph" screen.
- 4. Tap "**Print**" in the utility button area.
- $\sqrt{}$ The analyzer automatically prints the results of the current sample according to the print setup.

11.2.4 Printing RUO Parameter Results

Follow below instructions:

- 1. Tap "Menu"-"Setup"-"System Setup"-"Print Setup".
- 2. Tap "Printing Content" and check "Print RUO Parameters".

NOTE

- If you select to print "RUO parameters", the statement will be printed by default. The statement cannot be edited.
- 3. Tap another button on the screen to save the settings and exit the "Printing Content" setup screen.
- $\sqrt{}$ The report will display the RUO parameter results .

11.2.5 Printing Microscopic Parameter Results

Follow below instructions:

- Select "Menu"- "Table Review" or tap the "Table Review" utility button to enter the "Table Review" screen.
- Select one or more sample records of which you want to review the microscopic parameters.
- $\sqrt{}$ The selected sample record is highlighted.
- 3. Tap "Graph" to go to the "Graph" screen.
- 4. Tap "Other Para." > "Microscopic Para." to enter the "Microscopic Para." screen.
- 5. Tap the "Print" button to print the microscopic parameter results.

11.3 Printing QC Result Report

Before printing a QC test result report, confirm the following items:

- The printer has been set up and connected correctly.
- There is enough paper in the printer.
- To print the L-J QC results, confirm that there are results in the L-J QC file.
- To print the X-B QC results, confirm that X-B QC is enabled and there are valid X-B results.

11.3.1 Printing L-J QC Result from the L-J QC Table Screen

Follow below instructions:

- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup" to enter the L-J QC file setup screen.
- 2. Select the desired QC file.
- 3. Tap "QC Table" to enter the QC Table screen of the specified QC file.
- 4. Tap "Print" in the utility button area.
- $\sqrt{}$ The analyzer prints all the QC test results under the specified QC file.

NOTE

 When the QC test results are printed from the QC table screen, the printed report does not include QC graph.

11.3.2 Printing L-J QC Graph from the L-J QC Graph Screen

Follow below instructions:

- 1. Tap "Menu"-"QC"-"L-J QC"-"Setup" in turn to enter the L-J QC file setup screen.
- 2. Select the desired QC file.
- 3. Tap "QC Graph" to enter the QC graph review screen of the selected QC file.
- 4. Tap "Print" in the utility button area.
- $\sqrt{}$ The analyzer prints the QC graph in the specified QC file.

11.3.3 Printing X-B QC Graph from the X-B QC Graph Screen

- Tap "Menu" > "QC" > "X-B QC Graph" > "Graph" in turn to enter the X-B QC Graph screen.
- 2. Tap "Print" in the utility button area.
- √ The analyzer prints the X-B QC graph.

11.3.4 Print X-B QC Parameter Result from the X-B QC Table Screen

Follow below instructions:

- 1. Tap "Menu" > "QC" > "X-B QC Graph" > "Graph" in turn to enter the X-B QC Graph screen.
- 2. Tap "QC Table" to go to the "QC Table" screen.
- 3. Tap "Print" in the utility button area.
- √ The analyzer prints the X-B QC parameter result report.

11.4 Printing Manual Calibration Factors

Before printing manual calibration factors, confirm the following items:

- The printer has been set up and connected correctly.
- There is enough paper in the printer.

- 1. Tap "Menu" > "Calibration" > "Manual" in turn to enter the "Manual" screen.
- 2. Tap "**Print**" in the utility button area.
- $\sqrt{}$ The analyzer prints the manual calibration factors.

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12 Service

12.1 Overview

Preventive and corrective maintenance procedures are required to keep the analyzer in good operating conditions. This analyzer provides multiple maintenance functions for this purpose.

This chapter introduces how to use the provided functions to maintain and troubleshoot your analyzer.

12.2 When and Why to Perform the Maintenance

12.2.1 Maintenance of Parts and Components

Table 12-1 Maintenance of parts and components

| Item/Software access | | | Purpose |
|--|-----------------------|--|---|
| Self-Test (Service-Debug & Self-Test-Self- Test) | Valve | Perform the self-test under the instruction of Mindray's service people | / |
| | Fluidics Debug | Perform the self-test under the instruction of Mindray's service people | / |
| Probe Cleanser Maint. (Service- Maintenance- Probe Cleanser | Flow Cell | when there are a great amount of bad blood sample differential cases when there are flow cell errors reported | Clean the flow cell |
| Maint.) | Apertures | when clogging error is frequently reported | Clean the RBC channel |
| Auto-cleaning the Parts and Components (Service- Maintenance- Cleaning) | Clean fluidics | When the background background results are unqualified | Fluidics cleaning |
| Fluidics(Service- Maintenance- Fluidics) | Probe Cleanser Maint. | When the background results are unqualified or repeatability results continuously do not meet requirements | Thoroughly clean the fluidics, parts and components |
| | Pack-up | When the analyzer will not be used for a long time (over 10 days) | Remove the residue reagents in the pipelines |
| Sensor Maint.(Service- | Unclog Aperture | when clogging error is frequently reported | clean the aperture |
| Maintenance- Sensor Maint.) | Clean Flow Cell | when there are a great amount of bad blood sample differential cases when there are flow cell errors reported | Clean the flow cell |

| Item/Software access | | | Purpose |
|---|-------------|---|------------------------|
| Screen Cal.(Service- Screen Cal.) | Screen Cal. | when the touch screen response to touching is not sensitive or accurate | Calibrate touch screen |

Table 12-2 Replacing and priming with reagents

| Item/Software access | | Timing | Purpose of maintenance |
|--------------------------|----------------------|--|--|
| Replace Reagent | DS Diluent | when the reagent runs out or insufficient | Replace the residue reagent in the pipelines |
| (Service > Maintenance > | Replace HGB lyse | | |
| Reagent) | Replace DIFF lyse | | |
| | *Replace RET diluent | | |
| | Replace DIFF dye | | |
| | *Replace RET dye | | |
| | ESR Solution Reagent | | |
| Prime Reagent | DS Diluent | when reagents are contaminated or expire. | Replace the residue reagents in the fluidic system |
| (Service > Maintenance > | Prime HGB lyse | | |
| Reagent) | Prime DIFF lyse | | |
| | *Prime RET diluent | | |
| | Prime DIFF dye | | |
| | *Prime RET dye | | |
| | ESR Solution Reagent | | |

• The item with * only applies to the BC-760[R]/BC-780[R] model.

12.2.2 Manual Cleaning

Table 12-3 Manual cleaning

| Program | Timing | Purpose |
|---|--------------------------------------|--|
| Clean the probe wipe, floating blood barrier and the blood barrier bracket | Every month | Remove the blood sample and other residues in the probe wipe |
| Cover cleaning | As needed | Remove contaminators on the cover |
| Clean the filtering net | As needed/Recommend monthly cleaning | Clean the dust on the surface of air inlet filtering net |

12.2.3 **Replacing the Parts and Components**

Table 12-4 Replacing parts and components

| Program | Timing | |
|------------------------|---|--|
| Replace Sampling probe | The sampling probe is damaged | Contact service engineer to replace the component. |
| Replace the filters | The analyzer reports a pressure fault, and the automatic drainage device fails to work normally | Contact service engineer to replace the component. |

Table 12-5 Replacing wearing parts

| Program | Timing | |
|---|---------------------------------|--|
| Replace the sampling probe and probe wipe | 120,000 times of work | When the sampling probe, the probe wipe filter or the HGB waste filter are near their service life, the software |
| Replace the probe wipe filter | 3 years or 60,000 times of work | will give alarm. Contact service engineer to replace the component. |
| Replace the HGB waste filter | 60,000 times of work | |
| Replace the DIFF waste filter | 60,000 times of work | |
| Replace the RET waste filter | 60,000 times of work | |

MARNING

To avoid analyzer damage or personal injury, only Mindray-supplied parts can be used for maintenance.

12.3 **Reagent Management**

12.3.1 Viewing Reagent Information ("Menu" > "Setup" > "Reagent Setup")

On the "Reagent Setup" screen, you may review the expiration dates, use before dates, open dates, valid days and remaining volumes.

Tap "Menu" > "Setup" > "Reagent Setup" to go to the Reagent Setup" screen.

You may review the expiration dates, use before dates, open dates, valid days and remaining volumes of the analyzing reagents on the "Reagent Setup" screen.

12.3.2 Replace the Reagents

Replace the reagent when the reagent runs out, is insufficient or expired.

The whole reagent replacing procedure includes 3 steps:

- Install a new reagent;
- 2. Enter the new reagent information into the analyzer;
- 3. Replace the old reagent in the fluidic system.

12.3.2.1 Install a new reagent

Replacing the DS Diluent Container

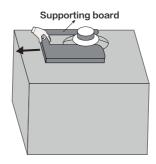


BIOLOGICAL RISK

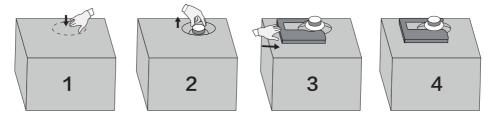
After replacing the reagent container/bag, check the tubing connected to the cap assembly and make sure it is not bent over.

NOTE

- Keep the diluent container from severe shock or crashing against other object. Otherwise, the alarming would be unreliable.
- Remove the cap of a new DS diluent container, and place the container next to the one to be replaced.
- Remove the supporting board under the cap of the old container. 2.



- 3. Turn the cap of the old container counterclockwise, and then take out the cap assembly with caution.
- Insert the pickup tube of the cap assembly into the new reagent container, and then turn the cap clockwise until it is secured.
- Install the supporting board under the new container's cap as shown below.



Replacing the Fluorescent Reagent Bag



BIOLOGICAL RISK

After replacing the reagent container/bag, check the tubing connected to the cap assembly and make sure it is not bent over.

Before replacing the fluorescent reagent, confirm that the reagent name on the reagent bag label is consistent with that on the connecting cable label of the cap assembly.

- Open the fluorescent dye compartment.
- Get a new bag of fluorescent dye, open the cap and the aluminum film sealing the bag.

WARNING

While installing or replacing the fluorescent dye bag, hold the upper corners of the bag or the part under the bag mouth (where the interior tube is located), in order not to extrude the reagent out.

- 3. Take out the bag to be replaced along the direction of the supporting rack.
- 4. Turn the cap of the old reagent container counterclockwise, and then take out the cap assembly with caution.

- If the pickup tube of the cap assembly is stuck when it is taken out of the fluorescent reagent bag, slightly adjust the position of the pickup tube and then take it out without pulling by force.
- 5. Insert the pickup tube of the cap assembly vertically into the new container, and then turn the cap clockwise until it is secured.

NOTE

- During replacement, make sure that the pickup tube of the cap assembly does not reach the bottom
 of the reagent bag, otherwise the reagent cannot be aspirated normally.
- 6. Put the sealed new bag back on the support rack, making sure the bag is securely accommodated.
- 7. Cap the old bag using the cap of the new bag and dispose of the old bag properly.

Replacing Other Reagent Containers (Except DS Diluent and Fluorescent Reagent)

- 1. Remove the cap of a new reagent container, and place the container next to the one to be replaced.
- 2. Turn the cap of the old container counterclockwise, and then take out the cap assembly with caution.
- 3. Insert the pickup tube of the cap assembly into the new container, and then turn the cap clockwise until it is secured.
- 4. Cap the old container with the cap of the new container and dispose of the container properly.

12.3.2.2 Entering reagent information

Follow below instructions:

1. Enter the "Reagent Setup" dialog box.

You can enter the "Reagent Setup" dialog box in either of the following ways:

- Tap "Menu" > "Setup" > "Reagent Setup" or the "Reagent Setup" button directly to enter the "Reagent Setup" screen, and then tap "Setup".
- Tap the reagent error alarm on the right lower corner on the screen to enter the "Remove Error" screen, and then tap "Remove Error".
 - √The "**Reagent Setup**" dialog box pops up, and the top part displays the information of the reagent to be replaced.
- 2. Enter the reagent information in one of the following ways:

| If | Then |
|--|---|
| Barcode entry is selected | Tap "Enter Reagent Information" edit box and use a pop-up keyboard to enter the reagent barcode; or scan the reagent barcode labels with an external barcode scanner. |
| Information entry through RFID is selected | Swipe the reagent on RFID region of " Reagent Setup " screen. |

NOTE

- If you want to change the way of entering reagent information, please contact Mindray Customer Service Department.
- Only when replacing the dye or ESR cleanser, reagent information can be entered through RFID.

 $\sqrt{}$ If the barcode is valid, the reagent information will be refreshed.

- If the barcode is entered/scanned in the "Barcode Entry" edit box of the "Reagent Setup" dialog box, and the reagent corresponding to the barcode is not in the reagent list displayed at the top of the dialog box, the software will prompt an alarm. Check and make sure that you have selected the correct reagent for replacement.
- If necessary, you can manually modify the reagent validity period and reagent volume information, and the software will automatically save and refresh the information.
- 3. (Optional) If more than one reagent needs to be replaced, repeat step 3 to complete the setup of all reagents.
- 4. Replace the old reagent in the pipelines.
- If "Auto replace reagent after setup" is checked on the "Setup" > "Auxiliary Setup" > "Other Settings" screen, the analyzer will automatically start the program to replace the old reagent in the pipelines at defined time.

As shown in the figure below, when "**Auto replace reagent after setup**" is enabled, the count-down timer displays on the "**Replace**" button after the reagent setup is completed. After the countdown ends, the analyzer automatically starts the program to replace the old reagent in the fluidic system.

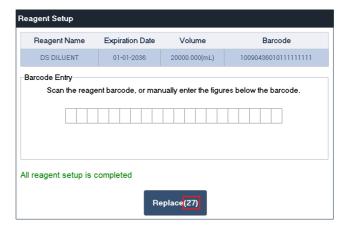


Figure 12-1 Countdown - replacing reagents through barcode entry

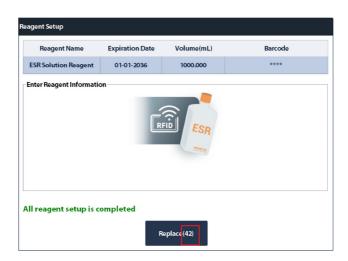


Figure 12-2 Countdown - replacing reagents through RFID

■ If "Auto replace reagent after setup" is unchecked on the "Setup" > "Auxiliary Setup" > "Other Settings" screen, and you tap "Replace", the analyzer will start the program to replace the old reagent in the pipelines.

 For the instruction to enable "Auto replace reagent after setup", refer to section 6.3.3.20ther Settings.

√ The analyzer automatically eliminates the fault, loads new reagent information, and replaces the reagent in the remove the error. When you are replacing expired reagents, the analyzer will also perform the reagent priming process.

12.3.2.3 Replacing the reagent in the fluidic system and priming reagent

Under the following circumstances, you can replace the old reagent or prime reagent in the pipelines on the reagent maintenance screen.

| Program | Timing | Purpose |
|---------------------|---|--|
| Reagent Replacement | when the reagent runs out, is insufficient or expired | Replace the residue reagent in the pipelines |
| Reagent Priming | when reagents are contaminated or expire, or all reagents in the machine need to be replaced under special circumstances | Replace the residue reagent in the pipelines |

Follow below instructions:

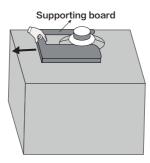
- 1. Tap "Menu" > "Service" > "Maintenance" > "Reagent" in turn to enter the reagent maintenance screen.
- 2. Tap the reagent for replacing or priming in the pipelines.
- $\sqrt{}$ The analyzer automatically completes the operation.

12.3.3 Replacing the Waste Container



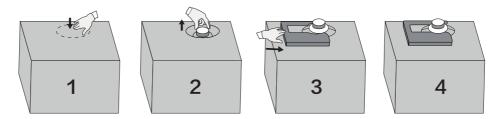
BIOLOGICAL RISK

- 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.
- If the waste is discharged using waste container, make sure the pickup tube of the waste container cap assembly is above, and the tube is smooth and not bent.
- 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.

12.4 Probe Cleanser Maintenance

12.4.1 Daily Probe Cleanser Maintenance

When the Probe Cleanser maintenance conditions are met, the prompt for Probe Cleanser maintenance pops up:

NOTE

- For more details, see 6.3.5.2Probe cleanser maintenance.
- For information on Probe Cleanser maintenance, contact Mindray Customer Service Department.

You can perform Probe Cleanser maintenance when the "Time for maintenance. Perform Probe Cleanser maintenance now?" dialog box displays or complete maintenance directly on the "Fluidics" screen.

Follow procedures below:

- Start the Probe Cleanser maintenance.
- When the "Time for maintenance. Perform Probe Cleanser maintenance now?" dialog box displays, tap "Yes".
- Tap "Menu"-"Service"-"Maintenance"-"Fluidics" in turn to enter the reagent maintenance screen, and tap "Probe Cleanser Maint." button.
- $\sqrt{}$ The analyzer prepares for Probe Cleanser maintenance. After the preparation for Probe Cleanser maintenance completes, a dialog box displays.
- $\sqrt{}$ The sample compartment opens.
- 2. Pick up a tube as instructed, and slowly pour at least 4mL Probe Cleanser into the tube. Place the tube with the Probe Cleanser uncapped into the regular tubes in the compartment.
- 3. Start the Probe Cleanser maintenance procedure.
- √ The analyzer aspirates Probe Cleanser.
- 4. Remove the tube with Probe Cleanser when the sample compartment opens.
- $\sqrt{}$ The analyzer automatically completes Probe Cleanser maintenance.

12.4.2 Probe Cleanser Maintenance to Parts and Components

You may perform Probe Cleanser maintenance to parts and components when necessary.

- Tap "Menu"-"Service"-"Maintenance"-"Probe Cleanser Maint." in turn to enter the "Probe Cleanser Maint." screen.
- 2. Tap the buttons of the parts and components that need Probe Cleanser maintenance.
- $\sqrt{}$ The analyzer prepares for Probe Cleanser maintenance. After the preparation for Probe Cleanser maintenance completes, a dialog box displays.
- $\sqrt{}$ The sample compartment opens.

- Pick up a clean anticoagulant collection tubes as instructed, and slowly pour at least 4ml Probe Cleanser into the tube. Place the tube with the Probe Cleanser uncapped into the regular tubes in the compartment.
- Start the Probe Cleanser maintenance procedure.
- $\sqrt{}$ The analyzer aspirates Probe Cleanser.
- Remove the tube with Probe Cleanser when the sample compartment opens. 5.
- The analyzer automatically completes Probe Cleanser maintenance.

12.5 **Auto-cleaning the Parts and Components**

You should clean the following parts or components when:

Follow below instructions:

- Tap "Menu"-"Service"-"Maintenance"-"Cleaning" to enter the cleaning screen.
- 2. Tap the corresponding cleaning program.
- The analyzer automatically completes the operation.

12.6 **Manual Cleaning of Parts and Components**

You should clean the following parts or components when:

| Program | Timing | Purpose | Tools needed |
|---|---|--|--|
| Clean the probe wipe, floating blood barrier and the blood barrier bracket | Every month | Remove the blood sample and other residues in the probe wipe | Alcohol, Probe Cleanser, clean water, and sterilized cotton swab |
| Cover cleaning | As needed | Remove contaminators on the cover | Disinfectant (see 12.6.2Cleaning the Analyzer Front Cover for types of disinfectant) |
| Clean the filtering net | As needed/ Recommend monthly cleaning | Clean the dust on the surface of air inlet filtering net | Clean water |

12.6.1 Cleaning the Probe Wipe, Floating Blood Barrier and the Blood Barrier Bracket



BIOLOGICAL RISK

The probe wipe, floating blood barrier and blood barrier bracket are potentially infectious as there may be residue blood sample or reagent on them. Wear proper personal protective equipment (e.g. gloves, lab coat, glasses, etc.) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.



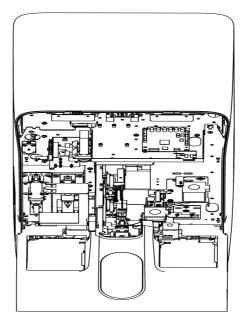
WARNING

Before cleaning the probe wipe, blood barrier, and blood barrier bracket, make sure the analyzer is shut down and the power supply is turned off.

Follow the following instructions:

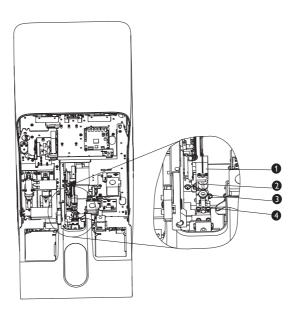
Opening the front cover of the analyzer

Hold the protruding parts at the bottom of the front cover with both hands and open the front cover upward.



Cleaning the probe wipe, floating blood barrier and the blood barrier bracket

Push the sampling probe assembly forward slightly to reserve sufficient operation and maintenance space.
 See the arrow direction shown in the figure below.



1 Sampling probe assembly

②Probe wipe

③ Floating blood barrier

- 4 Blood barrier bracket
- 2. Use a sterilized cotton swab dipped with Probe Cleanser to wipe the surface of the probe wipe. Then, use a sterilized cotton swab dipped with clean water to wipe the surface until no blood residue or other residues are visible.

CAUTION

- After dipping a cotton swab in the Probe Cleanser or clean water, ensure that the cotton swab has no droplet. Otherwise, the droplet may drop into the autoloader, damaging components.
- Use a sterilized cotton swab dipped with alcohol to wipe the surface of the blood barrier and blood barrier bracket until no blood residue or other residues are visible.

A CAUTION

After dipping a cotton swab in the alcohol or clean water, ensure that the cotton swab has no droplet. Otherwise, the droplet may drop into the autoloader, damaging components.

Closing the Front Cover of the Analyzer

Gently lower the cover and close it.



CAUTION

Closing the front cover gently to prevent the vibration from damaging internal parts of the analyzer.

12.6.2 **Cleaning the Analyzer Front Cover**



BIOLOGICAL RISK

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.

CAUTION

- The user shall perform regular cleaning and sterilization to the cover of the instrument. Use the specified materials to sterilize the instrument only. For any damage to the instrument or other accidents caused by using materials other than specified, Mindray will not provide any warranty.
- The cleaning and sterilization may damage the instrument to some extent. It is recommended to perform sterilization only when necessary according to your laboratory protocol. Remember to clean the instrument before sterilizing.
- Do not use any decontamination or cleaning agents which could cause a HAZARD as a result of a reaction with parts of the instrument or with material contained in it.
- If you accidentally spill hazardous material (for example, reagents or samples) on the instrument, clean the instrument with specified disinfectant. 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.

Perform regular cleaning on the covers of the analyzer.

Recommended disinfectant: water, 75% ethanol.

Prohibited disinfectant: 3% hydrogen peroxide.

12.6.3 Cleaning the Filter

1. Open the filtermesh compartment on the left side of the analyzer.



2. Pull out the air inlet filter.



3. Wash the filter with clean water, and use a piece of clean and dry cloth to wipe up the water in the filter.



4. Install the filter to its original position, and then close the filtermesh compartment.

12.7 Preparing to Ship

If the analyzer is not to be used for a long time (over 10 days), you should perform this procedure.

- 1. Tap "Menu"-"Service"-"Maintenance"-"Fluidics" to enter the "Fluidics" screen.
- 2. Tap "Prepare to Ship", and follow the software instruction to complete the pack-up procedure.

12.8 Screen Calibration

If the touch screen does not correctly respond to the positions you touched, perform the procedure to calibrate the touch screen.



CAUTION

Do not use anything sharp on the touch screen or strike on it.

NOTE

Do not click with the mouse to calibrate the touch screen.

Follow below instructions:

- 1. Tap "Menu"-"Service"-"Screen Cal." to enter the "Screen Cal." screen.
- 2. Tap "Screen Cal." in the middle of the screen.
- 3. Tap the black plus sign at the upper left corner of the screen as instructed by the screen display to start the calibration.
- $\sqrt{}$ After the calibration is completed, the software displays "Calibration succeeded." on the screen.

12.9 Viewing and Exporting Logs

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

The analyzer can save logs of the recent two years. If number of logs exceeds the upper limit, the latest log will overwrite the oldest one. You can browse and print logs, but cannot delete them.

Administrators and common users have different authorities:

Table 12-6 Log Types

| | Administrator's level | Operator's level |
|----------------------|---|---|
| All Logs | Review all types of logs | View the logs for analyzer startup and shutdown, user logging in and logging out at the operator's level. |
| General Logs | View all operation-related logs at both administrator's and operator's levels. | View the logs for analyzer startup and shutdown, user logging in and logging out at the operator's level. |
| Setup Adjustment | View all setting adjustment logs at both administrator's and operator's levels. | Cannot review |
| Error Information | Review error information and troubleshooting information of the analyzer. | Cannot review |

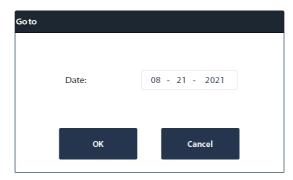
12.9.1 Viewing Logs

- 1. Tap "Menu"-"Service"-"Log" in turn to enter the "Log" screen.
- 2. Tap a type of logs to be viewed.



- 3. (Optional) Review the logs at specified date range.
 - a Tap "Go to".

A confirm dialog box displays.



- b In the "Date" edit box, specify the date on which the logs need to be viewed.
- Tap "**OK**".
- The screen displays the logs at the specified date.

12.9.2 **Exporting Logs**

You may export the logs in specified time range to the USB device.

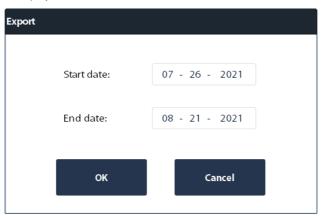
Before exporting sample records, make sure that you have inserted a safe USB flash drive into the USB port on the analyzer.



A CAUTION

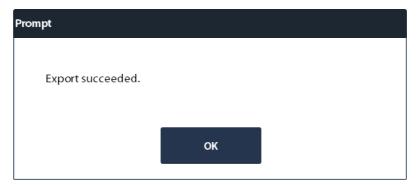
The user should ensure the data safety of the USB devices connecting to the analyzer.

- Tap"Menu"-"Service"-"Log" in turn to enter the "Log" screen. 1.
- Tap "Export". 2.
- A confirm dialog box displays.



- 3. In the "Start date:" and "End date:" edit boxes, specify the time range in which logs need to be exported.
- 4. Tap "**OK**".
- The analyzer automatically exports the logs in specified time range to the USB device.

 $\sqrt{}$ After export ends, the screen displays the "**Export succeeded.**" dialog box.



12.10 Upgrading Analyzer

A CAUTION

- Once upgraded, the analyzer cannot be restored to the last version.
- Analyzer upgrade may only be performed under the instruction from a Mindray-authorized service personnel. Do not perform the procedure by yourself.

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13 Troubleshooting

13.1 Overview

This chapter contains information that is helpful in locating and correcting problems that may occur during operation of your analyzer.

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.

13.2 Checking Analyzer Status

You can check analyzer information from the "**Status**" menu, including statistics, temperature and pressure, floater status, sensor status, voltage and current, as well as version information. Checking the status information on the "**Status**" screen is significant for you to locate and remove errors of the analyzer.

Follow the path below to review analyzer status:

| Item/Software access | Status | Path | Access Level Requirement |
|----------------------|---|----------------------------|-----------------------------|
| Statistics | Valid Runs | Menu-Status-Statistics | All |
| | Runs since latest initialization | | |
| | Sample Runs | | |
| | QC Runs | | |
| | Calibration Runs | | |
| | Valid Sample Runs | | |
| | Valid Runs After Latest Startup | | |
| | Runs after Probe Cleanser Maintain | | |
| | Clogs in Impedance Channel | | |
| | Background Runs | | |
| | Wearing Parts | | |
| Temp.&Pressure | Displays the current temperature and pressure as well as the acceptable range for various items. Out-of-range values are highlighted in red background. | Menu-Status-Temp.&Pressure | Administrator's level |
| Floater Status | Displays the full or empty status of the bathes and waste cistern. | Menu-Status-Floater Status | Administrator's level |
| Sensor | Displays the status of the sensors of the fluorescent dye detection, and the sensors on the drive board and the main control board. | Menu-Status-Sensor | Administrator's level |

| Item/Software access | Status | Path | Access Level Requirement |
|----------------------|---|----------------------------------|-----------------------------|
| Voltage & Current | Displays the voltage and current information Out-of-range values are highlighted in red background. | Menu-Status-Voltage & Current | Administrator's level |
| Version Info. | Review the analyzer software version information | Menu-Status-Version Info. | All |

13.3 Error Messages and Solutions

During the operation, if error(s) is detected, "Error Information" dialog box will pop up and the analyzer will beep.

The background colors of error messages turn red, orange, blue, and green according to error severity.

- 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.
- Green: prompting error when this kind of error occurs, the analyzer can still continue with the current operation, and other operations are not restricted.

The name and troubleshooting method of the errors are displayed in the "Error Information" dialog box. 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 "Error Description". The troubleshooting information of the first error is displayed by default. Follow the instructions in the dialog box to remove error(s).

The following functions are provided:

■ Remove error

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

■ To mute the alarm sound

Tap the touch screen to eliminate the alarm sound of the main unit.

■ Close the "Error Information" dialog box

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

| Error ID | Error Message | Description | Solution |
|----------|------------------------------------|------------------------------------|---|
| 0x10103 | Waste Container Full | Waste Container Full | 1.Replace the waste container with an empty one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10000 | No DS Diluent. Replace the reagent | No DS Diluent. Replace the reagent | Replace the DS Diluent. Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|---|---|--|
| 0x10001 | No LD Lyse. Replace the reagent | No LD Lyse. Replace the reagent | 1.Replace the LD Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10003 | No LH Lyse. Replace the reagent | No LH Lyse. Replace the reagent | 1.Replace the LH Lyse with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10002 | No DR Diluent. Replace the reagent | No DR Diluent. Replace the reagent | 1.Replace the DR Diluent with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10009 | No ESR Solution Reagent. Replace the reagent | No ESR Solution Reagent. Replace the reagent | 1. Replace the ESR Solution Reagent; 2. Tap the "Remove Error" button to remove this error; 3. If the error still exists, contact our customer service department. |
| 0x10005 | No FD Dye. Replace the reagent | No FD Dye. Replace the reagent | 1.Replace the FD Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10006 | No FR Dye. Replace the reagent | No FR Dye. Replace the reagent | 1.Replace the FR Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10200 | DS Diluent expires. Replace the reagent | DS Diluent expires. Replace the reagent | 1. Replace the DS Diluent. 2. Click the "Remove Error" button to remove this error. 3. If the error persists, contact our Customer Service Department. |
| 0x10201 | LD Lyse expires. Replace the reagent | LD Lyse expires. Replace the reagent | 1.Replace the LD Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10202 | LH Lyse expires. Replace the reagent | LH Lyse expires. Replace the reagent | 1.Replace the LH Lyse with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10203 | DR Diluent expires. Replace the reagent | DR Diluent expires. Replace the reagent | 1.Replace the DR Diluent with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|---|---|---|
| 0x10209 | ESR Solution Reagent expires. Replace the reagent | ESR Solution Reagent expires. Replace the reagent | 1. Replace the ESR Solution Reagent; 2. Tap the "Remove Error" button to remove this error; 3. If the error still exists, contact our customer service department. |
| 0x10204 | FD Dye expires. Replace the reagent | FD Dye expires. Replace the reagent | 1.Replace the FD Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10205 | FR Dye expires. Replace the reagent | FR Dye expires. Replace the reagent | 1.Replace the FR Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10400 | DS Diluent low volume. Replace the reagent | DS Diluent low volume. Replace the reagent | Replace the DS Diluent. Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x10401 | LD Lyse low volume. Replace the reagent | LD Lyse low volume. Replace the reagent | 1.Replace the LD Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10402 | LH Lyse low volume. Replace the reagent | LH Lyse low volume. Replace the reagent | 1.Replace the LH Lyse with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10403 | DR Diluent low volume. Replace the reagent | DR Diluent low volume. Replace the reagent | 1.Replace the DR Diluent with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10409 | ESR reagent low volume. Replace the reagent | ESR reagent low volume. Replace the reagent | Replace the ESR Solution Reagent; Z.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10404 | FD Dye low volume. Replace the reagent | FD Dye low volume. Replace the reagent | 1.Replace the FD Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10405 | FR Dye low volume. Replace the reagent | FR Dye low volume. Replace the reagent | 1.Replace the FR Dye with a new one; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|---------------------------------------|---|---|
| 0x40003 | Import "Key." file | Import "Key." file | Tap Menu - "Service" - "Advanced Toolbox" - "Debug Setup" - "Import Password", otherwise, reagents cannot be replaced when built-in authorization run out. |
| 0x10100 | DIL preheating bath sensor abnormal | DIL preheating bath sensor abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, tap "Precise Fault Diagnosis" to enter the "Precise Fault Diagnosis" screen to locate the error. 3. If no error is found, re-start the analyzer; otherwise, contact our Customer Service department. |
| 0x10102 | Waste cistern floater status abnormal | WC2 waste cistern floater status abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x10101 | Cistern floater status abnormal | SCI cistern floater status abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, tap "Precise Fault Diagnosis" to enter the "Precise Fault Diagnosis" screen to locate the error. 3. If no error is found, re-start the analyzer; otherwise, contact our Customer Service department. |
| 0x30105 | FS baseline abnormal | FS baseline abnormal | 1.Tap the "Remove Error" button to remove the error; 2.Switch off and then switch on the instrument power; 3.If the error still exists after the restart, contact our customer service department. |
| 0x30106 | FS baseline abnormal | SS baseline abnormal | 1.Tap the "Remove Error" button to remove the error; 2.Switch off and then switch on the instrument power; 3.If the error still exists after the restart, contact our customer service department. |
| 0x30107 | FS baseline abnormal | FL baseline abnormal | 1.Tap the "Remove Error" button to remove the error; 2.Switch off and then switch on the instrument power; 3.If the error still exists after the restart, contact our customer service department. |
| 0x30200 | HGB baseline abnormal | HGB baseline abnormal | 1.Tap the "Remove Error" button to remove the error; 2.Switch off and then switch on the instrument power; 3.If the error still exists after the restart, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|---|---|
| 0x30401 | ESR signal abnormal | ESR signal abnormal | 1. Tap the "Remove Error" button to remove the error; 2. Switch off and then switch on the instrument power; 3. If the error still exists after the restart, contact our customer service department. |
| 0x00300 | DIL syringe action abnormal | Invalid command to DIL syringe | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00301 | DIL syringe action abnormal | Conflicting DIL syringe actions | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00303 | DIL syringe action abnormal | Error occurs when DIL syringe leaves sensor area | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00302 | DIL syringe action abnormal | Error occurs when DIL syringe returns to home position | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00305 | DIL syringe action abnormal | DIL syringe aspiration/ dispensation action failure 1 | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00304 | DIL syringe action abnormal | DIL syringe aspiration/ dispensation action failure 2 | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00307 | DIL syringe action abnormal | DIL syringe aspiration/ dispensation action not allowed 1 | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00306 | DIL syringe action abnormal | DIL syringe aspiration/ dispensation action not allowed 2 | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00308 | DIL syringe action abnormal | DIL syringe aspirated volume too high | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00310 | DIL syringe action abnormal | DIL syringe action time out | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00309 | DIL syringe action abnormal | DIL syringe dispensed volume too high | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------------|--|---|
| 0x00200 | SP syringe action abnormal | Invalid command to SP syringe | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00201 | SP syringe action abnormal | Conflicting SP syringe actions | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00203 | SP syringe action abnormal | Error occurs when SP syringe leaves sensor area | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00202 | SP syringe action abnormal | Error occurs when SP syringe returns to home position | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00205 | SP syringe action abnormal | SP syringe aspiration/ dispensation action failure 1 | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00204 | SP syringe action abnormal | SP syringe aspiration/ dispensation action failure 2 | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00206 | SP syringe action abnormal | SP syringe aspiration/ dispensation action not allowed 1 | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00207 | SP syringe action abnormal | SP syringe aspiration/ dispensation action not allowed 2 | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00208 | SP syringe action abnormal | SP syringe aspirated volume too high | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00210 | SP syringe action abnormal | SP syringe action time out | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x00209 | SP syringe action abnormal | SP syringe dispensed volume too high | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07000 | Sampling assembly action abnormal | Invalid command to sample probe | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------------|---|---|
| 0x07100 | Sampling assembly action abnormal | Sampling assembly failed to return to home position in vertical direction | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07101 | Sampling assembly action abnormal | Sampling assembly failed to leave home position in vertical direction | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07200 | Sampling assembly action abnormal | Sampling assembly failed to return to home position in horizontal direction | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07201 | Sampling assembly action abnormal | Sampling assembly failed to leave home position in horizontal direction | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07202 | Sampling assembly action abnormal | Sampling assembly confirmation sensors in horizontal direction abnormally blocked | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07203 | Sampling assembly action abnormal | Sampling assembly notch count jumps in horizontal direction abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07102 | Sampling assembly action abnormal | Sample probe pierce action loses steps | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07103 | Sampling assembly action abnormal | Sample probe lifting action loses steps | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07001 | Sampling assembly action abnormal | Conflicting command to sampling assembly | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07204 | Sampling assembly action abnormal | Sampling assembly actions in horizontal direction time out | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07104 | Sampling assembly action abnormal | Sampling assembly actions in vertical direction time out | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x07105 | Sampling assembly action abnormal | Vertical home position sensors are not blocked before sampling assembly actions in horizontal direction | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|--------------------------------|---|--|
| 0x01000 | Mixing gripper action error | Mixing gripper action error | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01001 | Mixing gripper action error | Mixing gripper action error | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x04100 | Loading mechanism action error | Loading mechanism fails to leave sensor area in initialization | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04101 | Loading mechanism action error | Loading mechanism fails to return to sensor area in initiation | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04102 | Loading mechanism action error | Fails to load tube racks | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04103 | Loading mechanism action error | Loading mechanism home position sensor status abnormal | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04104 | Loading mechanism action error | Loading mechanism end position sensor status abnormal | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04105 | Loading mechanism action error | Sensor mistakenly triggered during loading mechanism returning to home position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|--|--|---|
| 0x04106 | Loading mechanism action error | Loading end position sensor is mistakenly triggered | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04107 | Auto loading sensor abnormal | Auto loading sensor abnormal | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04200 | Loading mechanism action error | Unloading mechanism fails to leave sensor area in initialization | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04201 | Loading mechanism action error | Unloading mechanism fails to return to sensor area in initiation | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04202 | Remove all the tube racks on the unload tray | Unloading tray is full | 1.Remove all the tube racks on the unload tray, and the instrument will automatically remove the error; 2.If the error still exists, contact our customer service department. |
| 0x04203 | Loading mechanism action error | Sensor mistakenly triggered during unloading mechanism returning to home position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04204 | Loading mechanism action error | Unloading mechanism protruding failed | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04300 | Loading mechanism action error | Feeding mechanism fails to leave sensor area in initialization | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04301 | Loading mechanism action error | Feeding mechanism fails to return to sensor area in initiation | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04302 | Loading mechanism action error | Sensor failed during feeding mechanism returning to right position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|---|--|---|
| 0x04303 | Loading mechanism action error | Feeding mechanism failed to leave home position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04304 | Loading mechanism action error | Sensor mistakenly triggered during feeding mechanism returning to home position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04305 | Loading mechanism action error | Sensor mistakenly triggered during feeding mechanism returning to right position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04306 | Loading mechanism action error | Feeding mechanism loses step at the left side | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04307 | Loading mechanism action error | Feeding mechanism loses step at the right side | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04308 | Loading mechanism action error | Left sensor abnormal during feeding mechanism initialization | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04309 | Loading mechanism action error | Sensor failed during feeding mechanism reaching left position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04310 | Loading mechanism action error | Sensor mistakenly triggered during feeding mechanism reaching left position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04002 | Loading mechanism action error | Manually move of tube rack | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04311 | Adjacent tubes with the same barcode in the tube rack | Adjacent tubes with the same barcode in the tube rack | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|--|--|---|
| 0x04312 | Loading mechanism action error | Feeding mechanism loses step when returning | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x02000 | Scanning mechanism error | Scanning mechanism error | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x02002 | Rotary scanning mechanism action error | Tube clamping mechanism stretch failed | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x02003 | Rotary scanning mechanism action error | Tube clamping mechanism retraction failed | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x02004 | Rotary scanning mechanism action error | Tube fixing mechanism failed to leave home position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x02005 | Rotary scanning mechanism action error | Tube fixing mechanism failed to return to home position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x02006 | Rotary scanning mechanism action error | Sensor mistakenly triggered during tube fixing mechanism returning to home position | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x02001 | Scanner communication abnormal | Scanner communication abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x02007 | Rotary scanning mechanism action error | Tube fixing mechanism slide rail is stuck | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04500 | Sample compartment action abnormal | Sample compartment failed to leave home position | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x04501 | Sample compartment action abnormal | Sample compartment failed to return to home position | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|------------------------------------|--|--|
| 0x04502 | Sample compartment action abnormal | Sample compartment failed to open | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x04503 | Sample compartment action abnormal | Sensor mistakenly triggered during sample compartment returning to home position | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x04504 | Sample compartment action abnormal | Sample compartment home position sensor status abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x01100 | Mixing gripper action error | Sensor mistakenly triggered during tube gripper returning to home position in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01101 | Mixing gripper action error | Tube gripper failed to leave home position in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01102 | Mixing gripper action error | Tube gripper failed to return to home position in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01104 | Mixing gripper action error | Tube gripper Y direction home position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|---|--|
| 0x01300 | Mixing gripper action error | Tube gripper Y direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01305 | Mixing gripper action error | Tube gripper Y direction end position sensor mistakenly triggered | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01302 | Mixing gripper action error | Mixing gripper failed to stretch to front position in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01109 | Mixing gripper action error | Mixing gripper failed to retract to rear position in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01200 | Mixing gripper action error | Mixing gripper failed to stretch to midposition in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|---|--|
| 0x01201 | Mixing gripper action error | Sensor mistakenly triggered during mixing gripper stretching to midposition in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01202 | Mixing gripper action error | Mixing gripper failed to retract to midposition in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01203 | Mixing gripper action error | Sensor mistakenly triggered during mixing gripper retracting to midposition in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01204 | Mixing gripper action error | Mixing gripper Y direction midposition sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01205 | Mixing gripper action error | Mixing gripper Y direction midposition sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|--|--|
| 0x01103 | Mixing gripper action error | Tube gripper Y direction home position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01105 | Mixing gripper action error | Mixing gripper failed to return to home position in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01106 | Mixing gripper action error | Tube gripper Y direction home position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01107 | Mixing gripper action error | Mixing gripper Y direction home position sensor mistakenly triggered | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01303 | Mixing gripper action error | Mixing gripper failed to reach end position in Y direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|---|--|
| 0x01304 | Mixing gripper action error | Tube gripper Y direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01301 | Mixing gripper action error | Tube gripper Y direction end position sensor mistakenly triggered | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01306 | Mixing gripper action error | Tube gripper Y direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01307 | Mixing gripper action error | Tube gripper Y direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01108 | Mixing gripper action error | Tube gripper Y direction home position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|--|--|
| 0x01406 | Mixing gripper action error | Sensor mistakenly triggered during tube gripper returning to home position in Z direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01402 | Mixing gripper action error | Tube gripper failed to leave home position in Z direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01403 | Mixing gripper action error | Tube gripper failed to return to home position in Z direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01411 | Mixing gripper action error | Tube gripper Z direction home position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01500 | Mixing gripper action error | Tube gripper Z direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|--|--|
| 0x01510 | Mixing gripper action error | Tube gripper Z direction end position sensor mistakenly triggered | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01502 | Mixing gripper action error | Tube gripper failed to lift up in Z direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01405 | Mixing gripper action error | Tube gripper failed to lower down in Z direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01401 | Mixing gripper action error | Sensor mistakenly triggered during tube gripper returning to home position in Z direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01511 | Mixing gripper action error | Tube gripper Z direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|--|--|
| 0x01504 | Mixing gripper action error | Tube gripper Z direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01412 | Mixing gripper action error | Tube gripper Z direction home position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01512 | Mixing gripper action error | Tube gripper Z direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01404 | Mixing gripper action error | Tube gripper Z direction home position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01409 | Mixing gripper action error | Mixing gripper failed to descend in Z direction at capillary blood position (micro-WB position) | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|---|--|
| 0x01410 | Mixing gripper action error | Mixing gripper Z direction home position sensor at micro-WB position mistakenly triggered | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01407 | Mixing gripper action error | Tube gripper Z direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01508 | Mixing gripper action error | Sensor mistakenly triggered at end position in Z direction of the micro-WB position of the mixing gripper | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01509 | Mixing gripper action error | Mixing gripper failed to ascend in Z direction at micro-WB position | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01408 | Mixing gripper action error | Tube gripper Z direction home position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|-----------------------------|--|--|
| 0x01600 | Mixing gripper action error | Sensor mistakenly triggered during tube gripper returning to home position in R direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01601 | Mixing gripper action error | Tube gripper failed to leave home position in R direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01602 | Mixing gripper action error | Tube gripper failed to return to home position in R direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01603 | Mixing gripper action error | Tube gripper R direction end position sensor status abnormal | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x01604 | Mixing gripper action error | Tube gripper Z direction end position sensor status abnormal during mixing | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |

| Error ID | Error Message | Description | Solution |
|----------|--------------------------------|--|--|
| 0x01605 | Mixing gripper action error | Tube gripper failed to move to home position in R direction | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x04600 | Micro-WB mixer action abnormal | Sensor mistakenly triggered during micro-WB mixer returning to home position | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x04601 | Micro-WB mixer action abnormal | Micro-WB mixer failed to leave home position | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x04602 | Micro-WB mixer action abnormal | Micro-WB mixer failed to return to home position | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x04603 | Micro-WB mixer action abnormal | Micro-WB mixer sensor status abnormal | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x04604 | Micro-WB mixer action abnormal | Micro-WB mixer sensor jump | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x04605 | Micro-WB mixer action abnormal | Sensor mistakenly triggered during micro-WB mixer returning to home position | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x04606 | Micro-WB mixer action abnormal | Micro-WB mixer failed to leave home position | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x04607 | Micro-WB mixer action abnormal | Micro-WB mixer failed to return to home position | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x04400 | Counter error | Counter sensor status error | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04003 | Counter error | Wrong counter count jump times | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|---|---|--|
| 0x04004 | Counter error | Manually move of tube rack | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x04000 | Autoloading status error | Autoloading status error | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x04505 | Sample compartment status error | Sample compartment status error | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x01002 | Mix assembly status error | Mix assembly status error | 1. Open the front cover and check whether there are test tubes in the mixing gripper and micro-WB mixer. If yes, remove the test tubes. 2. Remove all tube racks from the loading platform. 3. Click the "Remove Error" button to remove this error. 4. If the error persists, contact our Customer Service Department. |
| 0x07002 | Motor debug error | Motor debug error | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x04001 | Clear all the tube racks on the feeding channel | There are tube racks on the feeding channel | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x10308 | Auto pressure building out of time | Auto pressure building out of time | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x99800 | Startup initiation not performed | Startup initiation not performed | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x04005 | Autoloader board communication out of time | Autoloader board communication out of time | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|---|---|---|
| 0x20012 | Drive board communication out of time | Drive board communication out of time | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x10107 | SCI priming out of time | SCI priming out of time | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x99805 | Background abnormal | Background abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x10306 | Fluidic system status abnormal | Sampling probe clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x10307 | Fluidic system status abnormal | Flow cell clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x99801 | Exiting standby status failed | Exiting standby status failed | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x99802 | Exiting standby status failed | Exiting standby status failed | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x99803 | Auto startup failed | Auto startup failed | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x10111 | SCI priming failed | SCI syringe is busy | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x20008 | Closed-reagent RFID board communication timeout | Closed-reagent RFID board communication timeout | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x01003 | Mix motor board communication timeout | Mix motor board communication timeout | 1.Remove all the tube racks on the load tray; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x30109 | Optical signal board communication timeout | Optical signal board communication timeout | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|--|--|---|
| 0x30400 | ESR board communication timeout | ESR board communication timeout | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x20011 | Power supply board communication timeout | Power supply board communication timeout | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x10300 | 50kPa pressure out of range | 50kPa pressure out of range | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, tap "Precise Fault Diagnosis" to enter the "Precise Fault Diagnosis" screen to locate the error. 3. If no error is found, re-start the analyzer; otherwise, contact our Customer Service department. |
| 0x10304 | -40kPa pressure out of range | -40kPa pressure out of range | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, tap "Precise Fault Diagnosis" to enter the "Precise Fault Diagnosis" screen to locate the error. 3. If no error is found, re-start the analyzer; otherwise, contact our Customer Service department. |
| 0x10302 | 40 kPa pressure out of range | 40 kPa pressure out of range | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, tap "Precise Fault Diagnosis" to enter the "Precise Fault Diagnosis" screen to locate the error. 3. If no error is found, re-start the analyzer; otherwise, contact our Customer Service department. |
| 0x10104 | Waste channel abnormal | Waste channel abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x10301 | Pressure cell pressure release abnormal | Pressure cell pressure release abnormal | 1.Tap the "Remove Error" button to remove this error; 2.If the error still exists, contact our customer service department. |
| 0x10303 | SCI bath pressure release abnormal | SCI bath pressure release abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x10305 | WC2 bath pressure release abnormal | WC2 bath pressure release abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x30000 | Reaction bath temperature high | Reaction bath temperature high | 1.Click"Remove Error"button and recheck the temperature; 2.If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|--|---|--|
| 0x30001 | Preheating bath temperature control abnormal | Preheating bath temperature out of the upper limit for counting | 1.Tap the "Remove Error" button to remove this error; 2.If the error still exists, contact our customer service department. |
| 0x30005 | Ambient temperature is high | Ambient temperature is high | 1. Make sure the ambient temperature is within acceptable range. 2. Tap the "Remove Error "button to re-test the temperature. 3. If the error still exists, contact our customer service department. |
| 0x30002 | Temperature inside analyzer out of range | Temperature inside analyzer out of range | 1. Make sure the analyzer is placed in a place with good ventilation, heat dispersion and with no direct sunlight. 2. Tap the "Remove Error" button to re-test the temperature. 3. If the error still exists, contact our customer service department. |
| 0x30404 | ESR assembly temperature too high | ESR assembly temperature too high | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x30003 | Reaction bath temperature low | Reaction bath temperature low | 1.Click"Remove Error"button and recheck the temperature; 2.If the error still exists, contact our customer service department. |
| 0x30004 | Preheating bath temperature control abnormal | Preheating bath temperature out of the lower limit for counting | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x30006 | Ambient temperature low | Ambient temperature low | 1. Make sure the ambient temperature is within acceptable range. 2. Tap the "Remove Error "button to re-test the temperature. 3. If the error still exists, contact our customer service department. |
| 0x30403 | ESR assembly temp. too low | ESR assembly temp. too low | 1.Tap the "Remove Error" button to remove this error; 2.If the error still exists, contact our customer service department. |
| 0x30007 | Ambient temperature is high | Ambient temperature is high | 1. Make sure the ambient temperature is within acceptable range. 2. Tap the "Remove Error "button to re-test the temperature. 3. If the error still exists, contact our customer service department. |
| 0x30008 | Ambient temperature low | Ambient temperature low | 1. Make sure the ambient temperature is within acceptable range. 2. Tap the "Remove Error "button to re-test the temperature. 3. If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution |
|----------|---|---|---|
| 0x30009 | Reaction bath temperature control assembly is damaged | Reaction bath temperature control assembly is damaged | 1.Click"Remove Error"button and recheck the temperature; 2.If the error still exists, contact our customer service department. |
| 0x30010 | Preheating bath temperature control abnormal | Preheating bath does not achieve target temperature after startup procedure | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x30100 | Optical system working voltage abnormal | PMT voltage abnormal | 1.Tap the "Remove Error" button to remove the error; 2.Switch off and then switch on the instrument power; 3.If the error still exists after the restart, contact our customer service department. |
| 0x30201 | HGB blank voltage abnormal | HGB blank voltage abnormal | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, tap "Precise Fault Diagnosis" to enter the "Precise Fault Diagnosis" screen to locate the error. 3. If no error is found, re-start the analyzer; otherwise, contact our Customer Service department. |
| 0x30402 | ESR background intensity abnormal | ESR background intensity abnormal | 1.Click"Remove Error"button and recheck the temperature; 2.If the error still exists, contact our customer service department. |
| 0x30103 | Flow cell contaminated | DIFF channel FS blank voltage abnormal | 1.On the instrument main unit software, tap Menu - "Service" - "Maintenance" - "Fluidics" to enter the "Fluidics" maintenance screen, and perform the daily probe cleanser maintenance procedure; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x30104 | Flow cell contaminated | RET channel FS blank voltage abnormal | 1.On the instrument main unit software, tap Menu - "Service" - "Maintenance" - "Fluidics" to enter the "Fluidics" maintenance screen, and perform the daily probe cleanser maintenance procedure; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x20203 | Fan in the analyzer faulty | Radiator fan in the analyzer is blocked | 1.Check if the fan located on the back of the analyzer main unit is stuck by any foreign objects; 2.Tap the "Remove Error" button to remove the error; 3.If the error still exists after restarting the instrument, contact our customer service department. |

| Error ID | Error Message | Description | Solution | |
|----------|--------------------------------------|--------------------------------------|--|--|
| 0x99804 | Front cover is open | Front cover is open | 1.Tap the "Remove Error" button to remove this error; 2.If the error still exists, contact our custome service department. | |
| 0x30108 | Optical system shielding box is open | Optical system shielding box is open | 1.Close the Optical system shielding box; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. | |
| 0x40001 | System time error | System time error | 1.On the instrument main unit screen, tap Menu"- "Setup" - "Date/Time Setup" to enter the "Date/Time Setup" screen and set up the correct system time; 2.Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. | |
| 0x30300 | Clog | Aperture voltage abnormal | 1. Aperture voltage abnormal. 2. Tap the "Remove Error" button to remove this error. 3. If the error still exists, contact our customer service department. | |
| 0x30301 | Clog | Aperture voltage abnormal | 1. Aperture voltage abnormal. 2. Tap the "Remove Error" button to remove this error. 3. If the error still exists, contact our customer service department. | |
| 0x30302 | Clog | RBC sample preparation abnormal | 1. RBC sample preparation abnormal. 2. Tap the "Remove Error" button to remove this error. 3. If the error still exists, contact our customer service department. | |
| 0x30303 | Clog | RBC sample preparation abnormal | 1. RBC sample preparation abnormal. 2. Tap the "Remove Error" button to remove this error. 3. If the error still exists, contact our customer service department. | |
| 0x20200 | Power fan error | Power fan blocked | Check whether the power fan is stuck. If the error persists, contact our Customer Service Department. | |
| 0x20201 | Board fan faulty | Board radiator fan is blocked | 1.Check if the fan located on the back of the analyzer main unit is stuck by any foreign objects; 2.Tap the "Remove Error" button to remove the error; 3.If the error still exists after restarting the instrument, contact our customer service department. | |

| Error ID | Error Message | Description | Solution |
|----------|---------------------------------------|--|--|
| 0x20202 | Board fan faulty | Board radiator fan is blocked | 1.Check if the fan located on the back of the analyzer main unit is stuck by any foreign objects; 2.Tap the "Remove Error" button to remove the error; 3.If the error still exists after restarting the instrument, contact our customer service department. |
| 0x20002 | Air pressure detection board error | Air pressure detection board communication error | 1. Tap the "Remove Error" button to remove the error; 2. Switch off and then switch on the instrument power; 3. If the error still exists after the restart, contact our customer service department. |
| 0x20003 | Air pressure detection board error | Air pressure detection board calibration parameter error | 1. Tap the "Remove Error" button to remove the error; 2. Switch off and then switch on the instrument power; 3. If the error still exists after the restart, contact our customer service department. |
| 0x03001 | Tube in wrong tube rack | Tube in wrong tube rack | Click the "Remove Error" button to remove this error. Place the tube in the correct type of tube rack. If the error persists, contact our Customer Service Department. |
| 0x03000 | Sample type detection sensor abnormal | Sample type detection sensor abnormal | Click the "Remove Error" button to remove this error. If the error persists, contact our Customer Service Department. |
| 0x30202 | Waste channel abnormal | HGB waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x30203 | Waste channel abnormal | HGB waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x30204 | Waste channel abnormal | HGB waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x30600 | Waste channel abnormal | DIFF waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |
| 0x30601 | Waste channel abnormal | DIFF waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. |

| Error ID | Error Message | Description | Solution | |
|----------|-------------------------------------|--|--|--|
| 0x30602 | Waste channel abnormal | DIFF waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x30603 | Waste channel abnormal | RET waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x30604 | Waste channel abnormal | RET waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x30605 | Waste channel abnormal | RET waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x10108 | Waste channel abnormal | Probe wipe waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x10109 | Waste channel abnormal | Probe wipe waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x10110 | Waste channel abnormal | Probe wipe waste channel clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x30304 | Waste channel abnormal | Cleaning channel of RBC sample preparation clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x30305 | Waste channel abnormal | Cleaning channel of RBC sample preparation clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x30306 | Waste channel abnormal | Cleaning channel of RBC sample preparation clogged | 1. Tap the "Remove Error" button to remove this error; 2. If the error still exists, contact our customer service department. | |
| 0x07005 | Probe wipe filter near service life | Probe wipe filter near service life | 1. The probe wipe filter will reach the end of their service life after 1500 more tests. Customer Service to replace the component; 2. Tap the "Remove Error" button to remove this error; 3. If the error still exists, contact our customer service department. | |

| Error ID | Error Message | Description | Solution |
|----------|--|--|--|
| 0x07006 | Probe wipe filter reached service life | Probe wipe filter reached service life | 1. The probe wipe filter have reached the end of their service life. Customer Service to replace the component; 2. Tap the "Remove Error" button to remove this error; 3. If the error still exists, contact our customer service department. |
| 0x99806 | Maintenance failed | Maintenance failed | 1.Tap the "Remove Error" button to remove this error; 2.If the error still exists, contact our customer service department. |
| 0x07003 | Sample probe near service life | Sample probe near service life | 1.The sample probe will reach the end of its service life after 3000 more tests. Contact Mindray's Customer Service to replace the component; 2. Tap the "Remove Error" button to remove this error; 3.If the error still exists, contact our customer service department. |
| 0x07004 | Sample probe reached service life | Sample probe reached service life | 1. The sample probe has reached the end of its service life. Contact Mindray's Customer Service to replace the component; 2. Tap the "Remove Error" button to remove this error; 3. If the error still exists, contact our customer service department. |
| 0x30405 | ESR assembly version not match | ESR assembly version not match | Please contact Mindray Customer Service Department. |
| 0x99807 | Maintenance failed | Cleaning failed | 1.Tap the "Remove Error" button to remove this error; 2.If the error still exists, contact our customer service department. |
| 0x10309 | Probe cleanser aspirated volume not enough | Probe cleanser aspirated volume not enough | The Probe Cleanser volume is not enough for maintenance, which may cause frequent auto-cleaning when the instrument is in measurement. For the next time maintenance, make sure the Probe Cleanser volume is no less than 4mL. |

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B Specification

B.1 Classification

According to the CE classification, the device belongs to Class B in vitro diagnostic medical device according to rule 6, annex VIII of REGULATION (EU) 2017/746.

B.2 Reagent

The analyzer can be used with the following reagents, controls, and calibrators.

NOTE

• For any questions related to reagents, controls, and calibrators, please consult your local distributor.

Table B-1 Reagents

| Applicable Channel | BC-760[B] | BC-760[R]/BC-780[R] | |
|--------------------|----------------------|----------------------|--|
| HGB channel | LH Lyse | LH Lyse | |
| DIFF channel | LD Lyse | LD Lyse | |
| | FD Dye | FD Dye | |
| RET channel | / | DR Diluent | |
| | / | FR Dye | |
| / | DS Diluent | DS Diluent | |
| | Probe Cleanser | Probe Cleanser | |
| ESR channel | ESR Solution Reagent | ESR Solution Reagent | |

Table B-2 Controls/calibrators for complete blood tests

| Name | Model | Applicable Model | |
|-----------------------|-------------|-------------------------------|--|
| Hematology control | BR60 | BC-760[B]/BC-760[R]/BC-780[R] | |
| Hematology control | BC-6D | BC-760[B]/BC-760[R]/BC-780[R] | |
| Hematology control | BC-RET | BC-760[R]/BC-780[R] | |
| Hematology calibrator | SC-CAL PLUS | BC-760[B]/BC-760[R]/BC-780[R] | |
| Hematology calibrator | SC-CAL RET | BC-760[R]/BC-780[R] | |

Table B-3 Controls for body fluid tests

| Name | Model | Applicable Model | |
|--------------------|-------|-------------------------------|--|
| Hematology control | BC-BF | BC-760[B]/BC-760[R]/BC-780[R] | |

Table B-4 Controls/calibrators for ESR tests

| Name | Model | Applicable Model | |
|-----------------------|-------------|-------------------------------|--|
| Hematology control | BC-6D | BC-760[B]/BC-760[R]/BC-780[R] | |
| Hematology calibrator | SC-CAL PLUS | BC-760[B]/BC-760[R]/BC-780[R] | |

Table B-5 Part number for reagent controls/calibrators

| Name | Model | Part Number | |
|--------------------|-------|--|--|
| LH Lyse | M-6 | 105-012291-00 (4L*1) | |
| | | 105-012292-00 (1L*4) | |
| LD Lyse | M-6 | 105-012287-00 (4L*1) | |
| | | 105-012288-00 (1L*4) | |
| FD Dye | M-6 | 105-012297-00 (48mL*1) | |
| | | 105-012298-00 (12mL*4) | |
| *DR Diluent | M-6 | 105-012285-00 (4L*1) | |
| | | 105-012286-00 (1L*4) | |
| *FR Dye | M-6 | 105-012295-00 (48mL*1) | |
| | | 105-012296-00 (12mL*4) | |
| DS Diluent | / | 105-012283-00 (20L) | |
| | | 105-012284-00 (10L) | |
| Probe Cleanser | / | 105-002225-00 (50 mL*1) | |
| | | 105-009432-00 (25mL*6) | |
| Hematology control | BC-6D | 105-002421-00 (High/4.5mL*6) | |
| | | 105-002422-00 (Normal/4.5mL*6) | |
| | | 105-002423-00 (Low/4.5mL*6) | |
| | | 105-002424-00 (High/Normal/Low)*2/4.5mL*6) | |
| | | 105-003219-00 (High/Normal/Low)*1/4.5mL*3) | |
| Hematology control | BR60 | 105-009074-00 (4ml*6/H/M/L) | |
| | | 105-009073-00 (4ml*3/H/M/L) | |
| | | 105-009072-00 (4ml*6/L) | |
| | | 105-009068-00 (4ml*6/M) | |
| | | 105-009064-00 (4ml*6/H) | |

| Name | Model | Part Number |
|--------------------------------------|---------|--|
| *Hematology control | BC-RET | 105-002429-00 (High 4.5mL*6) |
| | | 105-002430-00 (Normal 4.5mL*6) |
| | | 105-002431-00 (Low 4.5mL*6) |
| | | 105-002432-00 ((High/Normal/Low)*2/ 4.5mL*6) |
| | | 105-003221-00 ((High/Normal/Low)*1/4.5mL*3) |
| | | 105-004088-00 (High/4.5mL*1) |
| | | 105-004089-00 (Normal/4.5mL*1) |
| | | 105-004090-00 (Low/4.5mL*1) |
| C-reaction protein control | / | 105-018801-00 (I/II level/1.5ml*2) |
| | | 105-018803-00 (I/II level/1.5ml*6) |
| ⁺ Serum amyloid A control | / | 105-021028-00 (Level I/II 1.5ml*2) |
| | | 105-021029-00 (Level I/II 1.5ml*6) |
| *Hematology control | I BC-BF | 105-018564-00 (H/N/L level/3ml*6) |
| | | 105-018567-00 ((N level/3ml*6) |
| | | 105-018572-00 (H/N/L level/3ml*3) |
| | | 105-018573-00 (N level/3ml*1) |
| | | 105-018582-00 (L level/3ml*6) |
| | | 105-018586-00 (H level/3ml*1) |
| | | 105-018587-00 (L level/3ml*1) |
| | | 105-018588-00 (H level/3ml*6) |
| Hematology calibrator | SC-CAL | 105-003223-00 (3mL*2) |
| | PLUS | 105-004091-00 (3mL*1) |
| ESR Solution Reagent | ESR | 105-026688-00 (1L*1) |
| | | 105-026689-00 (1L*4) |

NOTE

• The items with * only apply to the BC-760[R]/BC-780[R] model.

B.3 Models

NOTE

- For details of tube specifications, refer to 3.4 Supported Tubes, Tube Racks and Adapters.
- For the details of tube information not specified in the manual, contact Mindray Customer Service Department or the local distributor.

B.4 Parameters

Table B-6 Blood sample test report parameters

| Group | Parameter name | Abbreviation | Applicable Model |
|------------|--|--------------|---------------------|
| WBC series | White blood cell count | WBC | General |
| | Basophil count | Bas# | General |
| | Basophil percentage | Bas% | General |
| | Neutrophil count | Neu# | General |
| | Neutrophil percentage | Neu% | General |
| | Eosinophil count | Eos# | General |
| | Eosinophil percentage | Eos% | General |
| | Lymphocyte count | Lym# | General |
| | Lymphocyte percentage | Lym% | General |
| | Monocyte count | Mon# | General |
| | Monocyte percentage | Mon% | General |
| | Immature granulocyte count | IMG# | General |
| | Immature granulocyte percentage | IMG% | General |
| RET group | Reticulocyte percentage | RET% | BC-760[R]/BC-780[R] |
| | Reticulocyte count | RET% | |
| | Reticulocyte hemoglobin expression | RHE | |
| | Immature reticulocyte fraction | IRF | |
| | Low fluorescent ratio | LFR | |
| | Middle fluorescent ratio | MFR | |
| | High fluorescent ratio | HFR | |
| RBC group | Red blood cell count | RBC | General |
| | Hemoglobin concentration | HGB | General |
| | Mean corpuscular volume | MCV | General |
| | Mean corpuscular hemoglobin | МСН | General |
| | Mean corpuscular hemoglobin concentration | МСНС | General |
| | Red blood cell distribution width coefficient of variation | RDW-CV | General |
| | Red blood cell distribution width standard deviation | RDW-SD | General |
| | Hematocrit | НСТ | General |
| | Nucleated red blood cell count | NRBC# | General |
| | Nucleated red blood cell percentage | NRBC% | General |

| Group | Parameter name | Abbreviation | Applicable Model |
|----------------|--------------------------------|--------------|--|
| Platelet group | Platelet count | PLT | General |
| | Mean platelet volume | MPV | General |
| | Platelet distribution width | PDW | General |
| | Plateletcrit | PCT | General |
| | Platelet-large cell ratio | P-LCR | General |
| | Platelet-large cell count | P-LCC | General |
| | Immature platelet fraction | IPF | BC-760[R]/BC-780[R] For BC-760[B], this parameter is optional. For more information, consult Mindray Customer Service Department |
| | Platelet count- impedance | PLT-I | General (find the parameter result on the "Other Para."- "Analysis Para.") |
| | Platelet count hybrid | PLT-H | BC-760[R]/BC-780[R] For BC-760[B], this parameter is optional. For more information, consult Mindray Customer Service Department |
| | Optical platelet count | PLT-O | BC-760[R]/BC-780[R] |
| ESR | Erythrocyte Sedimentation Rate | ESR | General |

Table B-7 Body fluid sample test report parameters

| Group | Parameter name | Abbreviation | Applicable Model |
|-----------|---------------------------------------|--------------|------------------|
| WBC group | White blood cell count-body fluid | WBC-BF | General |
| | Total nucleated cell count-body fluid | TC-BF# | General |
| | Mononuclear cell count | MN# | General |
| | Mononuclear cell percentage | MN% | General |
| | Polymorphonuclear cell count | PMN# | General |
| | Polymorphonuclear cell percentage | PMN% | General |
| RBC group | Red blood cell count-body fluid | RBC-BF | General |

B.5 Sampling Features

B.5.1 Sample modes, test panel, and applicable model

Table B-8 List of sample modes, test panel, and applicable models

| Sample Mode | | Test Panel | Applicable Model |
|---------------------------|------------|--|------------------------|
| Whole blood sample CT-WB | | CBC,CD,Ret,CR,CDR; ESR,CBC+ESR,CD+ESR,CDR+ESR | BC-760[R] BC-780[R] |
| | | CBC,CD; ESR,CBC+ESR,CD+ESR | BC-760[B] |
| | CT-Low WBC | CD/WBC-3X | BC-760[B] |
| | | CD/WBC-3X, CDR/WBC-3X | BC-760[R] BC-780[R] |
| | CT-Low PLT | CR/PLT-5X,CDR/PLT-5X | BC-760[R] BC-780[R] |
| CT-PD | | CBC,CD,Ret,CR,CDR | BC-760[R] BC-780[R] |
| | | CBC,CD | BC-760[B] |
| CT-BF | | CD | General |
| Whole blood samples AL-WB | | CBC,CD,Ret,CR,CDR; ESR,CBC+ESR,CD+ESR,CDR+ESR | BC-760[R] BC-780[R] |
| | | CBC,CD; ESR,CBC+ESR,CD+ESR | BC-760[B] |

B.5.2 Sample Volumes Required for Each Analysis

| Sample Mode | Test Panel | Sample Volume (μl) Required for Each Analysis | Applicable Model |
|----------------|----------------------|--|-------------------------------|
| Whole | CBC, CD | 25±2 | BC-760[B]/BC-760[R]/BC-780[R] |
| blood | Ret, CR, CDR | 33 | BC-760[R]/BC-780[R] |
| | ESR | 140 | BC-760[B]/BC-760[R]/BC-780[R] |
| | CBC+ESR, CD+ESR | 160 | BC-760[B]/BC-760[R]/BC-780[R] |
| | CDR+ESR | 160 | BC-760[R]/BC-780[R] |
| Low WBC | CD/WBC-3X | 37 | BC-760[B]/BC-760[R]/BC-780[R] |
| | CDR/WBC-3X | 42 | BC-760[R]/BC-780[R] |
| Low PLT | CR/PLT-5X,CDR/PLT-5X | 33 | BC-760[R]/BC-780[R] |
| Predilute | CBC,CD | 20 | BC-760[B]/BC-760[R]/BC-780[R] |
| | Ret, CR, CDR | 20 | BC-760[R]/BC-780[R] |
| Body fluid | CD | 85 | BC-760[B]/BC-760[R]/BC-780[R] |

B.5.3 Throughput

Table B-9 Throughput

| Sample Mode | Test Panel | Throughput (test/hour) | Applicable Model |
|-------------|----------------------|------------------------|-------------------------------|
| Whole blood | CBC, CD | At least 80 | BC-760[B]/BC-760[R]/BC-780[R] |
| | ESR | At least 50 | BC-760[B]/BC-760[R]/BC-780[R] |
| | Ret, CR, CDR | At least 45 | BC-760[R]/BC-780[R] |
| | CBC+ESR, CD+ESR | At least 40 | BC-760[B]/BC-760[R]/BC-780[R] |
| | CDR+ESR | At least 30 | BC-760[R]/BC-780[R] |
| Low WBC | CD/WBC-3X | At least 60 | BC-760[B]/BC-760[R]/BC-780[R] |
| | CDR/WBC-3X | At least 40 | BC-760[R]/BC-780[R] |
| Low PLT | CR/PLT-5X,CDR/PLT-5X | At least 35 | BC-760[R]/BC-780[R] |
| Predilute | CBC,CD | At least 50 | BC-760[B]/BC-760[R]/BC-780[R] |
| | Ret,CR,CDR | At least 33 | BC-760[R]/BC-780[R] |
| Body fluid | CD | At least 50 | BC-760[B]/BC-760[R]/BC-780[R] |

B.6 Performance Specifications

B.6.1 Background/Blank Count Requirements

Table B-10 Background/blank count requirements for blood samples

| Parameters | Acceptable Range |
|------------|--------------------------------|
| WBC | ≤ 0.10 × 10 ⁹ / L |
| RBC | $\leq 0.02 \times 10^{12} / L$ |
| RBC-O | $\leq 0.02 \times 10^{12} / L$ |
| HGB | ≤1 g/L |
| PLT | ≤ 3 ×10 ⁹ / L |

Table B-11 Background/blank count requirements for body fluid samples

| Parameters | Acceptable Range |
|---------------|---------------------------------|
| WBC-BF/TC-BF# | ≤ 0.001 × 10 ⁹ / L |
| RBC-BF | $\leq 0.003 \times 10^{12} / L$ |

B.6.2 Linearity Ranges

Table B-12 Linearity requirements for blood samples

| Paramet ers | Linearity Range | Acceptable Deviation Range (WB) | Acceptable Deviation Range (PD) | Correlation Coefficient |
|----------------|--------------------------------------|--|--|----------------------------|
| WBC | (0 ~ 100.00)×10 ⁹ /L | ±0.20×10 ⁹ /L±2% | ±0.50×10 ⁹ /L±5% | ≥ 0.990 |
| | (100.01 ~ 350.00)×10 ⁹ /L | ±6% | ±6% | ≥ 0.990 |
| | (350.01 ~ 500.00)×10 ⁹ /L | ±11% | ±11% | ≥ 0.990 |
| RBC | (0 ~ 8.60)×10 ¹² /L | ±0.03×10 ¹² /L±2% | ±0.05×10 ¹² /L ±5% | ≥ 0.990 |
| HGB | (0 ~ 260) g/L | ±2g/L±2% | ±2g/L or ±3% | ≥ 0.990 |
| НСТ | (0.0 ~ 75.0)% | ±1.0% (HCT) or ±2% (percentage error) | ±2.0% (HCT) or ±4% (percentage error) | / |
| PLT | (0 ~ 1000)×10 ⁹ /L | ±10×10 ⁹ /L±5% | ±10×10 ⁹ /L±10% | ≥ 0.990 |
| | (1001 ~ 5000)×10 ⁹ /L | ±6% | ±10% | ≥ 0.990 |
| RET% | (0.00 ~ 30.00)% | ±0.30% (RET% value) or ±20% (percentage error) | / | / |
| RET% | (0.0000~0.8000)×10 ¹² /L | ±0.0150×10 ¹² /L±20% | / | / |

Table B-13 Linearity requirements for body fluid samples

| Parameters | Linearity Range | Deviation range |
|---------------|-----------------------------------|-----------------------------------|
| WBC-BF/TC-BF# | (0~0.050)×10 ⁹ /L | ±0.010×10 ⁹ /L |
| | (0.051~1.000)×10 ⁹ /L | ±20% |
| | (1.001~10.000)×10 ⁹ /L | ±20% |
| RBC-BF | (0.000~0.100)×10 ¹² /L | ±0.010×10 ¹² /L or ±5% |
| | (0.101~5.000)×10 ¹² /L | ±0.030×10 ¹² /L or ±2% |

B.6.3 Accuracy

B.6.3.1 Blood parameter accuracy

Table B-14 Accuracy requirements

| Parameters Measurement Range | | Acceptable Relative Deviation Range/% |
|------------------------------|---|---------------------------------------|
| WBC | 3.50×10 ⁹ /L~9.50×10 ⁹ /L | Within ±10.0 |
| RBC | 3.80×10 ¹² /L~5.80×10 ¹² /L | Within ±6.0 |
| HGB | 115g/L~175g/L | Within ±6.0 |
| PLT | 125×10 ⁹ /L~350×10 ⁹ /L | Within ±20.0 |
| HCT/MCV | 35%~50% (HCT) or 82.0f~100.0fL (MCV) | Within ±9.0 (HCT) or ±7.0 (MCV) |

B.6.4 Repeatability

Table B-15 Repeatability requirements for blood samples

| Parameters | Range | Whole Blood (CV/Absolute Deviation d*/SD) | Predilute (CV/Absolute Deviation d*) |
|------------|---|---|---|
| WBC | (3.50 ~ 4.50)×10 ⁹ /L | ≤ 3.0% | ≤ 4.0% |
| | ≥4.51×10 ⁹ /L | ≤ 2.5% | ≤ 3.5% |
| RBC | ≥3.50×10 ¹² /L | ≤ 1.5% | ≤ 2.0% |
| HGB | (110 ~ 180)g/L | ≤ 1.0% | ≤ 2.0% |
| MCV | (80.0 ~ 100.0) fL | ≤ 1.0% | ≤ 3.0% |
| НСТ | (30.0 ~ 50.0)% | ≤ 1.5% | ≤ 3.0% |
| MCH | / | ≤ 1.5% | / |
| MCHC | / | ≤ 1.5% | / |
| RDW-SD | / | ≤ 2.0% | / |
| RDW-CV | / | ≤ 2.0% | 1 |
| PLT | ≥100×10 ⁹ /L | ≤ 4.0% | ≤ 8.0% |
| | | ≤ 2.5% Applicable to the CDR/PLT-5X and CR/PLT-5X test panels | / |
| | (20~100)×10 ⁹ /L | ≤ 5.0% Applicable to the CDR/PLT-5X and CR/PLT-5X test panels | / |
| | ≤20×10 ⁹ /L | ≤ 1.5(SD) Applicable to the CDR/PLT-5X and CR/PLT-5X test panels | / |
| PDW | PLT≥100×10 ⁹ /L | ≤ 10.0% | / |
| MPV | PLT≥100×10 ⁹ /L | ≤ 3.0% | / |
| P-LCR | PLT≥100×10 ⁹ /L | ≤ 15.0% | / |
| P-LCC | PLT≥100×10 ⁹ /L | ≤ 15.0% | / |
| PCT | PLT≥100×10 ⁹ /L | ≤ 5.0% | / |
| Neu% | Neu%≥30.0% WBC≥ 4.00×10 ⁹ /L | ≤6.0% | ≤12.0% |
| Lym% | Lym %≥15.0% WBC≥ 4.00×10 ⁹ /L | ≤6.0% | ≤12.0% |
| Mon% | Mon %≥5.0% WBC≥ 4.00×10 ⁹ /L | ≤16.0% | ≤32.0% |
| Eos% | WBC≥ 4.00×10 ⁹ /L | ≤20.0% or ±1.5%(d) | ≤40.0% or ±3.0%(d) |
| Bas% | WBC≥ 4.00×10 ⁹ /L | ≤30.0% or ±1.0%(d) | ≤60.0% or ±2.0%(d) |
| Neu# | ≥1.20×10 ⁹ /L | ≤6.0% | ≤12.0% |
| Lym# | ≥0.60×10 ⁹ /L | ≤6.0% | ≤12.0% |
| Mon# | ≥0.20×10 ⁹ /L | ≤16.0% | ≤32.0% |
| Eos# | WBC≥ 4.00×10 ⁹ /L | ≤20.0% or ±0.12×10 ⁹ /L(d) | ≤40.0% or ±0.24×10 ⁹ /L(d) |
| Bas# | WBC≥4.00×10 ⁹ /L | ≤30.0% or ±0.06×10 ⁹ /L(d) | ≤60.0% or ±0.12×10 ⁹ /L(d) |

| Parameters | Range | Whole Blood (CV/Absolute Deviation d*/SD) | Predilute (CV/Absolute Deviation d*) |
|------------|---|--|---|
| IMG% | WBC≥4.00×10 ⁹ /L IMG%≥2.0% | ≤25.0% or ±1.5%(d) | / |
| IMG# | ≥0.10×10 ⁹ /L | ≤25.0% or ±0.12×10 ⁹ /L(d) | / |
| RET% | RBC≥ 3.00×10 ¹² /L RET%: 1.00% ~ 4.00% | ≤ 15% | ≤ 30% |
| RET% | RBC≥ 3.00×10 ¹² /L RET%: 1.00% ~ 4.00% | ≤ 15% | ≤ 30% |
| RHE | RET#≥ 0.0200×10 ¹² /L | ≤ 5% | / |
| LFR | RBC≥ 3.00×10 ¹² /L RET%: 1.00% ~ 4.00% LFR≥20% | ≤ 30% | / |
| MFR | RBC≥ 3.00×10 ¹² /L RET%: 1.00% ~ 4.00% MFR≥20% | ≤ 50% | / |
| HFR | RBC≥ 3.00×10 ¹² /L RET%: 1.00% ~ 4.00% | ≤ 100% or ±2.0%(d) | / |
| IRF | RBC≥ 3.00×10 ¹² /L RET%: 1.00% ~ 4.00% IRF≥20% | ≤ 30% | / |
| IPF | PLT ≥ 50×10 ⁹ /L IPF≥3.0% | ≤ 25% | / |
| ESR | 0 ~ 20mm/h | ≤1.8(SD) | / |
| | > 20mm/h | ≤ 9% | / |

Note:

- 1. *Absolute deviation d = MAX|Measured value measured mean|
- 2. **Range = Maximum measurement value Minimum measurement value

Table B-16 Repeatability Requirements for Body Fluid Samples

| Parameters | Measurement Range | CV or Range |
|---------------|-----------------------------------|------------------------|
| WBC-BF/TC-BF# | (0.015-0.100)×10 ⁹ /L | ≤30% |
| RBC-BF | (0.003-0.050)×10 ¹² /L | ≤40% or range ≤7000/µL |

B.6.5 Carryover

Table B-17 Carryover requirements for blood samples

| Parameters | Carryover |
|------------|-----------|
| WBC | ≤1.0% |
| RBC | ≤1.0% |
| HGB | ≤1.0% |
| нст | ≤1.0% |
| PLT | ≤1.0% |

| Parameters | Carryover |
|------------|-----------|
| ESR | ≤1.0% |

Table B-18 Carryover requirements for body fluid samples

| Parameters | Carryover |
|-----------------|-------------------------------------|
| WBC-BF / TC-BF# | ≤0.3% or ≤0.001×10 ⁹ /L |
| RBC-BF | ≤0.3% or ≤0.003×10 ¹² /L |

B.6.6 Correlation

Correlation with reference instrument must meet the requirements of *Table B-19 Correlation requirements for blood sample test*.

Table B-19 Correlation requirements for blood sample test

| Parameters | Correlation with Reference Instrument |
|------------|---------------------------------------|
| WBC | ≥ 0.99 |
| Neu% | ≥ 0.90 |
| Lym% | ≥ 0.90 |
| Mon% | ≥ 0.80 |
| Eos% | ≥ 0.90 |
| Bas% | ≥ 0.60 |
| RBC | ≥ 0.99 |
| HGB | ≥ 0.98 |
| MCV | ≥ 0.98 |
| нст | ≥ 0.95 |
| RDW-CV | ≥ 0.85 |
| RDW-SD | ≥ 0.85 |
| PLT | ≥ 0.95 |
| MPV | ≥0.80 |
| RET% | ≥ 0.90 |
| RET# | ≥ 0.90 |
| RHE | ≥ 0.90 |
| IPF | ≥ 0.80 |
| IMG% | ≥ 0.80 |
| NRBC% | ≥ 0.80 |
| ESR | ≥0.90 |

B.7 Requirements for Input/Output Devices

The analyzer can be connected to a USB flash drive, keyboard, mouse, and barcode scanner as required.



WARNING

- Be sure to use the specified devices only.
- 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 and CISPR 22 EMC 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.

B.7.1 Keyboard

USB port (supporting the protocol of USB2.0 and above) keyboard.

B.7.2 Mouse

USB port (supporting the protocol of USB2.0 and above) mouse.

B.7.3 External barcode scanner

USB port (supporting the protocol of USB2.0 and above) hand-held barcode scanner.

B.7.4 Printer

USB port (supporting the protocol of USB2.0 and above) printer.

B.7.5 USB Drive

Supporting the protocol of USB2.0 and above.

B.7.6 Electronic Interface Specifications

NOTE

 Connection of the electronic interface to an IT network that includes other equipment could result in previously unidentified risks to patients, users or third parties; the responsible organization should identify, analyse, evaluate and control these risks.

| | Specifications | |
|--|---|---|
| Communication format (protocol) and relevant standards | USB ports | Type A interface, complied with USB 2.0/3.0 standard. |
| and relevant standards | Network ports | TCP/IP protocol bottom layer. DICOM/HL7 protocol application layer. RJ45 interface, supporting wired network 10 M/100 M/ 1000 M, and complied with technical standard IEEE802.3. NTP/SNTP Calibration protocol of TCP/IP. |
| Time setting | The time on the analyzer should be set to the correct local time. | |

B.8 Interfaces

NOTE

- The USB interfaces on the back of the analyzer shall only be used to connect the peripheral devices specified in this manual. See Appendix B.7 Requirements for Input/Output Devices for details about supported devices and models.
- One network port (compatible with 10/100/1000M Ethernet and complying with the 802.3u/802.3ab standard)
- Four USB ports including three supporting USB2.0 and one supporting USB3.0 (specification: DC 5V; 500 mA)

B.9 Power supply

| | Voltage | Input power | Frequency |
|-----------|-------------------|-------------|---------------------|
| Main unit | 100V-240V~ (±10%) | 600 VA | 50 Hz/60 Hz (±1 Hz) |

B.10 Fuse



WARNING

• The fuse used in the instrument is not a replaceable one. If there is any problem with the fuse, contact Mindray Customer Service Department or your local distributor.

B.11 Electromagnetic compatibility (EMC)

The IVD device complies with the EMC standard IEC 61326-1 and IEC 61326-2-6.

For EMISSIONS and IMMUNITY specific requirements, see *Table B-20 GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS* and *Table B-21 GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY*.



WARNING

- The IVD MEDICAL EQUIPMENT complies with the emission and immunity requirements described in this part of IEC 61326.
- This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
- This equipment is designed for use in a PROFISSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is
 likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that
 performance is affected by electromagnetic interference, correct operation may be restored by
 increasing the distance between the equipment and the source of the interference.
- The electromagnetic environment should be evaluated prior to operation of the device.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with 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 equipment can be maintained in order that the
 device will perform as intended.

The calculation formula to determine the separation distance between an IVD MEDICAL EQUIPMENT and a mobile phone is given by $d = 6/E \cdot \sqrt{P}$, where d is the minimum separation distance in meters, P is the maximum power in watts, and E is the immunity test level in V/m.

Table B-20 GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC EMISSIONS

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

| EMISSIONS TEST | COMPLIANCE |
|--|------------|
| RF emissions CISPR 11 | Group 1 |
| RF emissions CISPR 11 | Class A |
| Harmonic Emissions IEC 61000-3-2 | N/A |
| Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3 | |

Table B-21 GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

The system is intended for use in the electromagnetic environment specified below. The customer or the user of system should assure that it is used in such an environment.

| IMMUNITY TEST | BASIC STANDARD | TEST VALUE | PERFORMANCE CRETERION |
|---|-------------------|---|--------------------------|
| Electrostatic Discharge (ESD) | IEC 61000-4-2 | ± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air | B B |
| Electromagnetic field | IEC 61000-4-3 | 3 V/m (80 MHz to 6 GHz) | А |
| Electrical fast Transient / burst | IEC 61000-4-4 | AC Power: ± 1 kV I/O single/Control ^a : ± 0.5 kV | В |
| Surge | IEC 61000-4-5 | line-to-line: ± 0.5kV,1kV, ± 2kV line-to-ground: ± 0.5kV,1 kV | B B |
| Conducted RF | IEC 61000-4-6 | 3 V (150 kHz to 80 MHz) | A |
| Voltage dips, Short interruptions and voltage variation on power supply input voltage | IEC 61000-4-11 | 0 % during 0,5 cycles 0 % during 1 cycle 70 % during 25/30 cycles ^b 0 % during 250/300 cycles | B B C |
| Power frequency magnetic field | IEC 61000-4-8 | 3 A/m (50 Hz, 60 Hz) | А |

GUIDANCE AND MINDRAY DECLARATION—ELECTROMAGNETIC IMMUNITY

NOTE:

^a Only in case of line >3m

 $^{\rm b}$ "25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test".

Performance criterion:

A: The equipment shall continue to operate as intended during and after the test.

B: The equipment shall continue to operate as intended after the test.

C: LOSS OF FUNCTION is allowed, provided the function is self-recoverable or can be restored by the operation of the controls.

B.12 Noise Level

Maximal sound pressure: 80 dBA

NOTE

Be sure to use and store the analyzer under the specified environment conditions.

B.13 Normal Operating Environment

- Normal operating temperature range: 10°C to 35°C
- Normal operating humidity range: 30% to 85%
- Normal operating atmospheric pressure range: 70.0 kPa to 106.0 kPa

B.14 Storage Environment

- Ambient temperature range: -10°C to 40°C
- Relative humidity range:10% to 90%
- Atmospheric pressure range: 50.0 kPa to 106.0 kPa

B.15 Operating Environment

- Ambient temperature range: 5°C to 40°C
- Relative humidity range: 10% to 90%
- Atmospheric pressure range: 70.0 kPa to 106.0 kPa

B.16 Dimensions and Weight

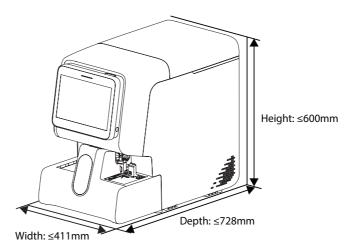


Figure B-1 Main unit dimensions

| Main Unit Dimensions and Weight | Value |
|---------------------------------|--------|
| Width (autoloader included) | ≤411mm |
| Height (autoloader included) | ≤600mm |
| Depth (autoloader included) | ≤728mm |
| Weight (autoloader included) | ≤73kg |

B.17 Contraindication

None

B.18 Barcode Specifications

The analyzer can read barcodes that are stuck to the test tubes. The sample ID read from the barcode will be stored and used as the only identification of the sample.

The barcodes used shall meet the specifications stated in this section.

1. Supported barcode types

All code types and check digit supported by the analyzer are listed as follows.

Table B-22 Supported barcode types

| Code Type | Check Digit | Number of Digits |
|-------------|--|---|
| CODE128 | Self-checking (check digit is always included) | No more than 20 digits (sample ID) |
| CODE93 | Self-checking (check digit is always included) | No more than 20 digits (sample ID) |
| UPC/EAN/JAN | Self-checking (check digit is always included) | Fixed length: 8 or 13 digits |
| ITF | Not use check digit | No more than 20 digits (sample ID) |
| | Use check digit | No more than 19 digits (sample ID)+1 digit (check digit) = no more than 20 digits |
| CODE39 | Not use check digit | No more than 20 digits (sample ID) |
| | Use check digit | No more than 19 digits (sample ID)+1 digit (check digit) = no more than 20 digits |
| CODABAR | Not use check digit | No more than 20 digits (sample ID) |
| | Use check digit | No more than 19 digits (sample ID)+1 digit (check digit) = no more than 20 digits |

NOTE

Use check digit whenever possible, so as to reduce the possibility of misreading.

2. Barcode label dimensions

Barcode height: A≥10mm

Label width: B≤50mm

Clear area width: C≥5mm

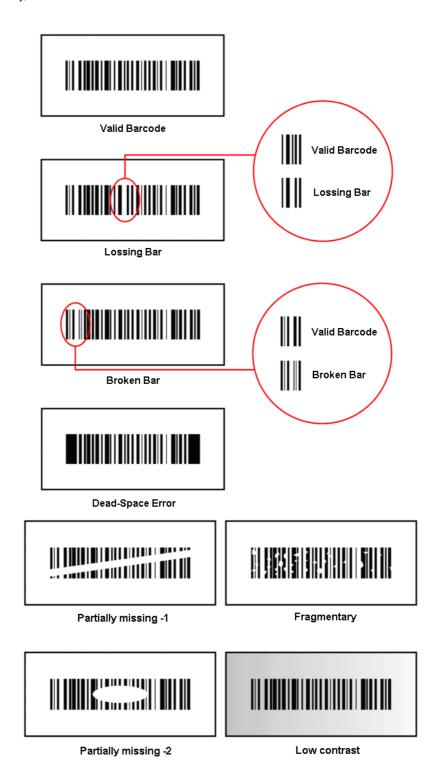
Width of the narrowest bar: above 0.152 mm



Code quality: According to ANSI MH10.8M standard, the code quality shall be Level C or above.

3. Samples of valid and invalid barcode labels:

Use of invalid barcode labels shown in the following figures will increase the possibility of misreading. To ensure good readability, use valid labels.



B - 17

4. Where to place the barcode label

You must place the label on the region as shown in *Figure B-2 Where to place the barcode label* in accordance with instructions as shown in *Figure B-3 How to place the barcode label*.

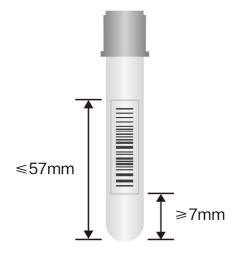


Figure B-2 Where to place the barcode label

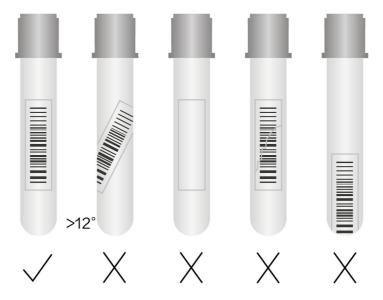


Figure B-3 How to place the barcode label

5. How to select the barcode label

It is recommended to use the matte label paper instead of the glossy label paper to print labels.

B.19 Safety Classification

Level of transient overvoltage: Category II.

Rated pollution degree: 2.

B.20 Limitations

B.20.1 For Blood Routine Tests

Table B-23 Blood Routine Tests

| Parameters | Interfering substances | | |
|--|--|--|--|
| WBC | Where the following is present, the WBC may be reported falsely low: WBC agglutination Where the following is present, the WBC may be reported falsely high: Cryoglobulin Fibrin Lyse resistant RBC Giant platelet Platelet clumps Where the following is present, the RBC may be reported falsely low: | | |
| RBC | Where the following is present, the RBC may be reported falsely low: RBC cold agglutination Microcytosis RBC fragment Where the following is present, the RBC may be reported falsely high: Giant platelet | | |
| HGB | Where the following is present, the HGB result may be reported falsely low: Lyse resistant RBC RBC cold agglutination Where the following is present, the HGB result may be reported falsely high: Leukocytosis (> 100000/μL) Hyperlipidemia | | |
| MCV | Where the following is present, the MCV result may be reported falsely low: Giant platelet Where the following is present, the MCV result may be reported falsely high: RBC fragments Microcytosis RBC agglutination Spherocyte | | |
| PLT | Where the following is present, the PLT count may be reported falsely low: Platelet clump Giant platelet Where the following is present, the PLT count may be reported falsely high: Microcytosis RBC fragments WBC fragment Cryoglobulin | | |
| RET# (only available on BC-760 [R] and BC-780 [R]) | Where the following is present, the RET count may be reported falsely high: Howell-Jolly body Giant Platelet RBC agglutination Malaria | | |
| NRBC# | Where the following is present, the NRBC count may be reported falsely high: Lyse resistant RBC Malaria | | |

B.20.2 ESR Tests

Erythrocyte sedimentation rate (ESR) is not only a non-specific inflammation index, but also one of indicators of erythrocyte aggregation. The analyzer measures the erythrocyte sedimentation rate by detecting the signals from erythrocyte aggregation process. However, the analyzer has limitations when analyzing the following samples:

- 1. Samples from patients with plasma cell diseases (e.g., multiple myeloma). In these samples, the erythrocytes may have already accumulated to rouleaux formation; therefore the analyzer may not be able to detect the process of erythrocyte aggregation, and may produce wrong results. The analyzer will give an alarm and may shield the results. To ensure accurate ESR results of these samples, it is recommended to use the traditional Westphal method to measure such samples.
- 2. Samples in which red blood cell agglutination has occurred (e.g., patient's blood containing cold agglutinin, and red blood cells aggregates in vitro cold environment). For such samples, the analyzer may not be able to detect the process of erythrocyte aggregation, and may produce wrong results. The analyzer will give an alarm and may shield the results. To ensure accurate ESR results of these samples, it is recommended to use the traditional Westphal method to measure such samples.
- 3. Other samples that may have rouleaux formation, blood coagulation, and abnormal erythrocyte morphology. The analyzer may give wrong results. Doctors should report based on the comprehensive judgment taking in consideration of analyzer-provided flags and prompts, as well as other clinical information of the patients.

C Accessories and Packing List

C.1 Accessories of the Analyzer

| Name | Part Number |
|------------------------------------|---------------|
| Handheld Barcode Scanner | 023-000866-00 |
| HP LaserJet Printer | 023-001523-00 |
| Tube Rack Assembly (CAL 8000) | 115-070616-00 |
| Capillary blood tube rack assembly | 115-072433-00 |

NOTE

• The accessories actually attached to the product depend on your product configuration. For details about the configured/optional accessories, consult your sales representative.

C.2 Optional Accessories of the Analyzer

- Handheld barcode scanner
- Lyse cap assembly (black, die sinking connector)
- Waste container cap assembly
- Capillary blood tube rack assembly
- Tube rack assembly

C.3 Packing List

- Main power cords
- Network cable
- Display
- Handheld barcode scanner (optional)
- Computer
- Diluent container supporting board
- Lyse cap assembly (green, die sinking connector)
- Lyse cap assembly (red, die sinking connector)
- Lyse cap assembly (black, die sinking connector) (optional)
- Lyse cap assembly (purple, die sinking connector)
- DS diluent cap assembly
- Waste container cap assembly (Optional)
- Operator's Manual
- Main Unit (Analyzer)
- Autoloader that may accommodate 6 rows of 5-position tube racks
- Capillary blood tube rack (optional)
- Tube rack assembly (optional)
- Handle bar
- Laboratory Data Management Software

Accessories and Packing List

D Communication

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

In the LIS/HIS communication process of the analyzer involves the HL7 communication protocol. For details about the connection control, and the introduction, message definition and examples, please contact Mindray Customer Service Department or your local distributor.

Communication

Radio Regulatory Compliance

RF Parameters

| Radio Devices | RF ID |
|-------------------------------------|----------------|
| 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.

Declaration of Conformity V 2.0



Declaration of Conformity

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Mindray Building, Keji 12th Road South, High-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-760[B], BC-760[R], BC-780[R], BC-700[B] \

BC-700[R] BC-720[R]

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 61326-1: 2020 | É EN 50364: 2018 |
|---------------------------|----------------------------|
| ☑ ETSI EN 301 489-1 2.2.3 | ☑ ETSI EN 301 489-3 V2.1.1 |
| ☑ ETSI EN 300 330 ¥2.1.1 | |

Start of CE-Marking:

2022-4-19

Place, Date of Issue:

Shenzhen, 2022-12-20

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company:

Deputy Director, Technical Regulation Department

References

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References

G Maintenance Logs

NOTE

- You are advised to prepare a maintenance checklist suitable for the operating environment of the analyzer.
- For more information about the maintenance procedure, refer to 12Service.

Maintenance Logs

Routine maintenance items

| Date | Probe Cleanser Maintenance | Cleaning the Analyzer Front Cover | Probe wipe cleaning | Date | Probe Cleanser Maintenance | Cleaning the Analyzer Front Cover | Probe wipe cleaning |
|------|-------------------------------|---|---------------------|------|-------------------------------|--------------------------------------|---------------------|
| 1 | | | | 21 | | | |
| 2 | | | | 18 | | | |
| 3 | | | | 19 | | | |
| 4 | | | | 20 | | | |
| 5 | | | | 12 | | | |
| 9 | | | | 22 | | | |
| 7 | | | | 23 | | | |
| 8 | | | | 24 | | | |
| 9 | | | | 25 | | | |
| 10 | | | | 26 | | | |
| 11 | | | | 27 | | | |
| 12 | | | | 28 | | | |
| 13 | | | | 29 | | | |
| 14 | | | | 30 | | | |
| 15 | | | | 31 | | | |
| 16 | | | | | | | |

Maintenance items when necessary

| Maintenance Items | Signature, MM/DD/ YYYY | Signature, MM/DD/ YYYY |
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Replacing reagents and parts

| Maintenance Items | Signature, MM/DD/ YYYY | Signature, MM/DD/ YYYY |
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