The sample probe automatically aspirates the control.

6. When you hear the beep, remove the control.

   When analysis finishes, the QC results will be displayed in the current screen and be saved in the QC file automatically.

   NOTE:

   Up to 372 QC results can be saved in each QC file.

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

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".
- 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. In the "Count" screen, tap "Next Sample".
2. In the "Next Sample" screen, manually enter or use a barcode scanner to scan the barcode label on the tube to enter the sample ID and sample information into the "**Sample Info.**" 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.

3. Select the desired test panel.

   NOTE:

   Make sure the set test panel is the same with that you set in the QC file for the control.

4. Run the samples in accordance with the normal sample analysis procedure.

   After the analysis, the QC results will be automatically saved to the corresponding QC file.

   NOTE:

   - For instructions about sample analysis, see "7.6 Sample Analysis"
   - Up to 372 QC results can be saved in each QC file.

9.2.3 Reviewing QC Results

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

QC graph review

Reviewing QC Graph:

1. Tap "**Menu** > **QC** > **Setup**" to enter the QC file setup screen.
2. Select the desired QC file to review.

   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.

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 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.	The QC result of the QC point on the green line.
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)

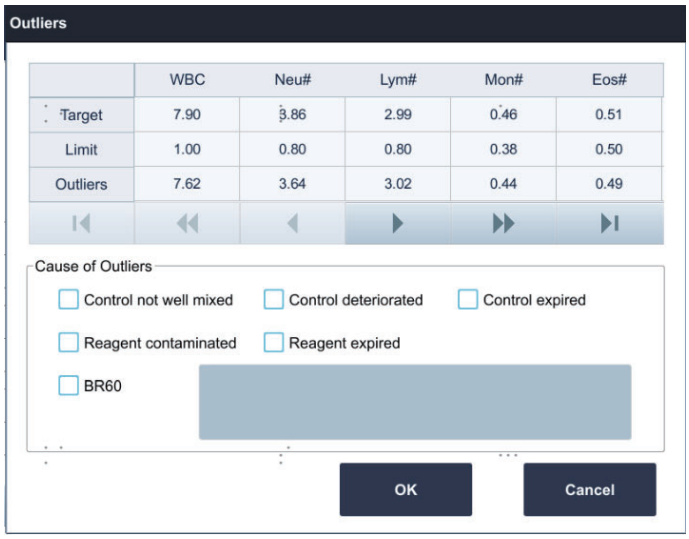
The QC point is out of value when its value is out of the limit. A red QC point indicates the value is out of the limit.

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

1. Tap "**Menu** > **QC** > **Setup**" to enter the QC setup screen.
2. Select the desired QC file to review.

   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.

   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 "**BR60**" and enter the causes of outliers in the edit box.

   NOTE:

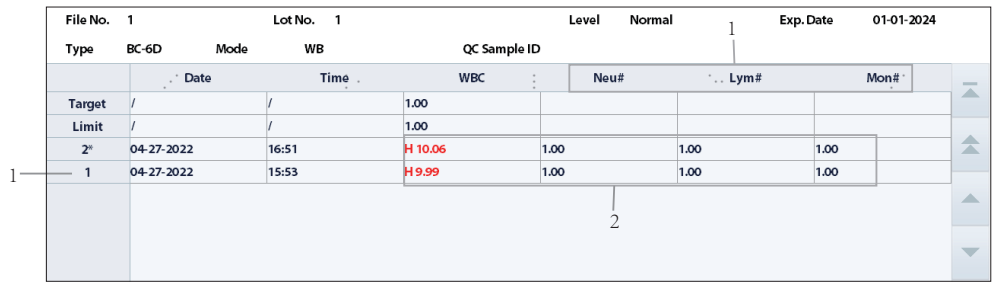
   You may enter up to 200 characters in "**BR60**" edit box.
6. Tap "OK" to save the reasons and exit the dialog box.

QC table review

Reviewing QC table:

1. Tap "**Menu** > **QC** > **Setup**" to enter the QC file setup screen.
2. Select the desired QC file to review.

   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.



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.

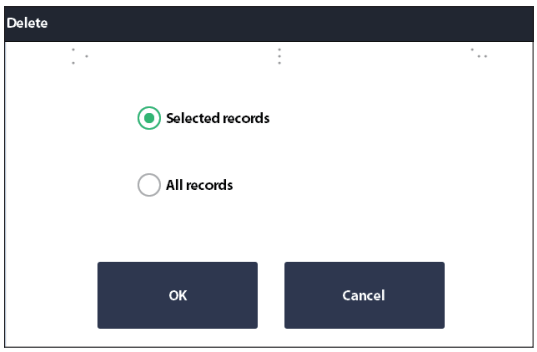
Delete selected QC record(s):

1. Tap "**Menu** > **QC** > **Setup**" to enter the QC file setup screen.
2. Select the desired QC file.

   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.

   The selected QC records are highlighted.
5. Tap "**Delete**".

   The following dialog box displays.

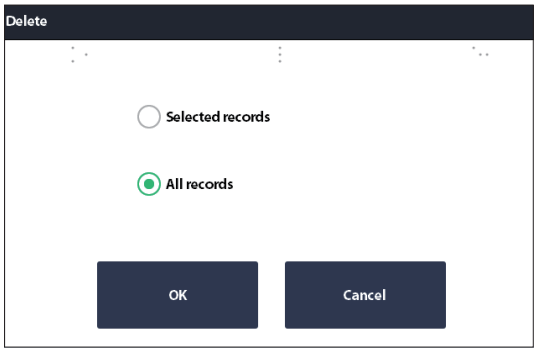


6. Tap to select "**Selected records**" and then tap "**OK**" to delete selected records.

Delete all QC records:

1. Tap "**Menu** > **QC** > **Setup**".
2. Tap the "**QC Table**" button to enter the QC table screen of the corresponding QC file.
3. Tap "**Delete**".

   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** > **Setup**" to enter the QC file setup screen.
2. Select the desired QC file.

   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.**".

   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 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:

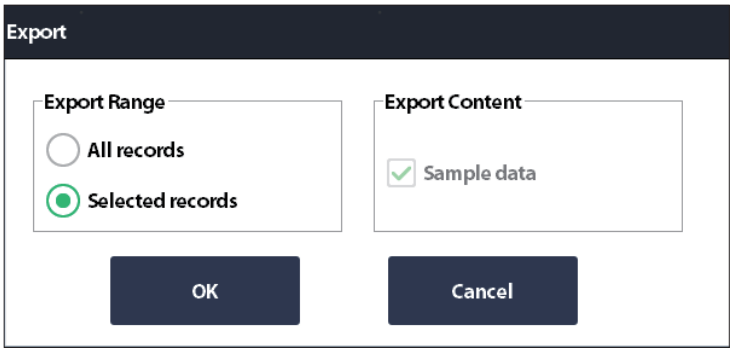
1. Tap "**Menu** > **QC** > **Setup**" to enter the QC file setup screen.
2. Select the desired QC file.

   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**".

   The following dialog box displays.

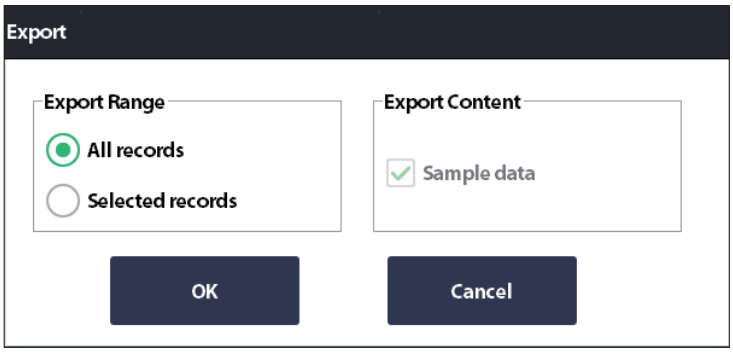


6. Tap to select "**Selected records**" and then tap "**OK**" to export the selected records.

Export all QC records:

1. Tap "**Menu** > **QC** > **Setup**" to enter the QC file setup screen.
2. Tap the "**QC Table**" button to enter the QC table screen of the corresponding QC file.
3. Tap "**Export**".

   The following dialog box displays.



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

9.3 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.

9.3.1 Troubleshooting

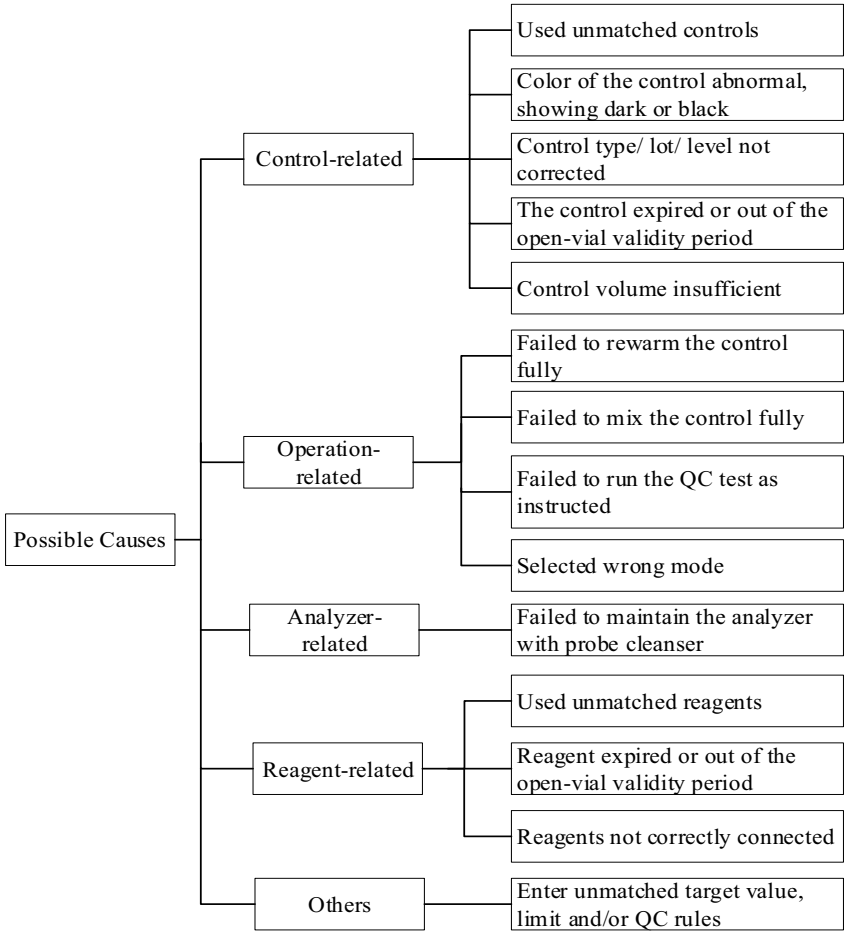
When a QC result falls outside the control range, follow below steps to solve the problem.

- 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 Customer Service Department.

9.3.2 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, see “Figure 9-5 Analyze the cause of QC outliers” to find out the cause of outliers.

Figure 9-5 Analyze the cause of QC outliers



9.3.3 Taking Corrective Measures

Analyze the possible causes of QC outliers and make corrections in time, see “Figure 9-5 Analyze the cause of QC outliers”.

9.3.4 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 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 two calibration programs available on this analyzer: manual calibration, calibration using calibrators. All the parameters or part of the parameters of WBC, RBC, HGB, MCV, 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. You only need to recalibrate this analyzer if:

- you are going to use this analyzer for the first time.
- a major analytical component (including sample 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

All of the measured parameters must be calibrated before readings of this analyzer can be used as valid analysis results.

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 Customer Service Department.

NOTE:

For information of blank count, repeatability, and carryover of the analyzer, see “B.4 Performance Specifications”.

10.4 Running the Calibration Programs

The analyzer supports the following calibration programs:

- **Manual**
- **Calibrator** (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.

NOTE:

Be sure to mix any calibrators that have been prepared for a while before running it.

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.

Performing manual calibration

Do as follows to calibrate the analyzer.

1. Select a calibrator which meets the sample requirements for manual calibration, and run the sample consecutively for n times (not less 3 times) in whole blood 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 “8.2.7 Calculating CV Values”.
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 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.

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

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

Run the sample under whole blood mode and take the WBC results of the 10 runs to calculate: 8.10, 8.00, 8.10, 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:

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

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.

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% - 125.00%, and only two decimal places can be reserved.

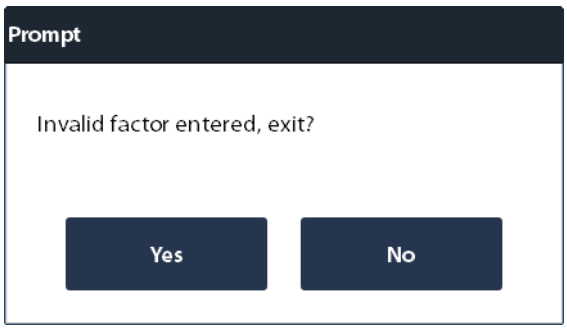
8. Save calibration factors.

a. Tap another button on the software screen.

A dialog box displays to remind you to save calibration factors.

b. Tap "**Yes**" to save new calibration factors.

9. If the entered calibration factors are invalid, a dialog box will display 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 Calibrators (administrators)

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, glasses) and follow safe laboratory procedures when handling them and the contacted areas in the laboratory.

Sample requirements for calibrators

You must use Mindray Animal Medical-specified calibrators for calibration.

NOTE:

For the description of calibrators, see "3.5.2 Controls and Calibrators".

Performing calibration with calibrators

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

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

   See below for setting descriptions.

Item	Description
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.
Target	Find the parameter targets on the target sheet of the corresponding calibrator.

4. Place the prepared calibrator in a tube, and place the tube under the sample probe.
5. Perform the calibrator calibration.
   a. Press the [Aspirate] key on the analyzer to start calibration.
      The analyzer starts the calibration procedure.

   NOTE:

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

   b. When the first calibration is finished, put the tube with the calibrator under the sample probe again.
   c. Press the [Aspirate] key on the analyzer to start the second sample analysis.
   d. Repeat steps a. to c. for analyzing remaining samples
      The analyzer automatically calculates the calibration factors for the parameters.

6. (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 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.

   The analyzer gives different suggestions depending on the calculated calibration factors.

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

10.4.4 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 levels 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

Only administrators can view the calibration history.

Tap "**Menu** > **Calibration** > **Calibration History**" to enter the "**Calibration History**" screen.

The relevant items are described below:

Item	Description
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

For information about print setup, see “6.3.1 System Setup”.

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 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.

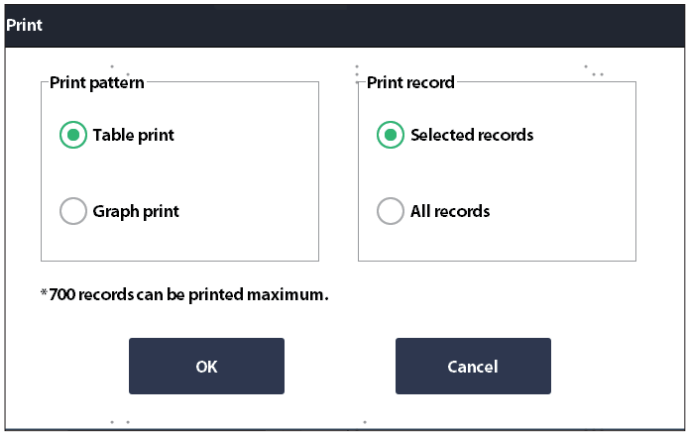
The analyzer automatically prints the results of the current sample according to the print setup.

11.2.2 Printing from the Table Review Screen

Follow below instructions:

1. Tap “**Menu** > **Table Review**” or tap “**Table Review**” button to enter the “**Table Review**” screen.
2. (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.

Item		Description
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**".

   The analyzer prints the sample result reports of the selected samples.

11.2.3 Printing from the Graph Review Screen

Follow below instructions:

1. Tap "**Menu** > **Table Review**" or tap "**Table Review**" button directly to enter the "**Table Review**" screen.
2. Select one or more sample records of which you want to review the graph data.

   The selected sample record is highlighted.
3. Tap "**Graph**" to enter the "**Graph**" screen.
4. Tap "**Print**" in the utility button area.

   The analyzer automatically prints the results of the current sample according to the print setup.

11.2.4 Printing Microscopic Parameter Results

Follow below instructions:

1. Tap "**Menu** > **Table Review**" or tap "**Table Review**" button to enter the "**Table Review**" screen.
2. Select one or more sample records of which you want to review the microscopic parameters.

   The selected sample record is highlighted.
3. Tap "**Graph**" to enter the "**Graph**" screen.
4. Tap "**Other Para.** > **Microscopic Para.**" to enter the "**Microscopic Para.**" screen.

   Tap "**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 QC results, confirm that there are results in the QC file.

11.3.1 Printing QC Results in Specified QC Files

Follow below instructions:

1. Tap "**Menu** > **QC** > **Setup**" to enter the QC file setup screen.
2. Select the desired QC file.
3. Tap "**QC Table**" to enter the QC table screen of the selected QC file.
4. Tap "**Print**" in the utility button area.

   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 QC Graphs in Specified QC Graph

Follow below instructions:

1. Tap "**Menu** > **QC** > **Setup**" in turn to enter the 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.

   The analyzer prints the QC graph in the specified QC file.

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.

Follow below instructions:

1. Tap "**Menu** > **Calibration** > **Manual**" in turn to enter the "**Manual**" screen.
2. Tap "**Print**" in the utility button area.

   The analyzer prints the manual calibration factors.

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.

⚠ CAUTION

- **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 Customer Service Department for service advice.**
- **Only parts supplied by Mindary Animal Medical can be used for maintenance. For any question, contact Customer Service Department.**

NOTE:

Contact the Mindary Animal Medical or authorized distributors in time if any damaged part is found.

12.2 When and Why to Perform the Maintenance

12.2.1 Maintenance of Parts and Components

Table 12-1 Replacing and priming with reagent

Item/Software access		Timing	Purpose of maintenance
Replace Reagent (**Service** > **Maintenance** > **Reagent**)	**DS Diluent**	when the reagent runs out or insufficient	Replace the residue reagent in the pipelines
	Replace HGB lyse		
	Replace DIFF lyse		
	Replace RET diluent		
	Replace DIFF dye		
	Replace RET dye		
	SR Solution Reagent		

Table 12-1 Replacing and priming with reagent

Prime Reagent (**Service** > **Maintenance** > **Reagent**)	**DS Diluent**	when reagents are contaminated or expired	Replace the residue reagent in the pipelines
	Prime HGB lyse		
	Prime DIFF lyse		
	Prime RET diluent		
	Prime DIFF dye		
	Prime RET dye		
	SR Solution Reagent		

12.2.2

12.2.3 Replacing the Parts and Components

⚠ CAUTION

Only parts supplied by Mindary Animal Medical can be used for maintenance. For any question, contact Customer Service Department.

12.3 Reagent Management

⚠ CAUTION

In case of power failure or upgrade, take out the latex reagent stored in the latex reagent compartment in time and store it in a refrigeration environment of 2°C to 8°C.

12.3.1 Viewing Reagent Information

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 enter 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 Replacing the Reagents

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

The whole reagent replacing procedure includes the following steps:

1. Read reagent information by swiping RFID card.
2. Install new reagent.
3. Tap "**Replace**" button.

BIOLOGICAL RISK

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

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.

Read reagent information by swiping RFID card

Follow below instructions:

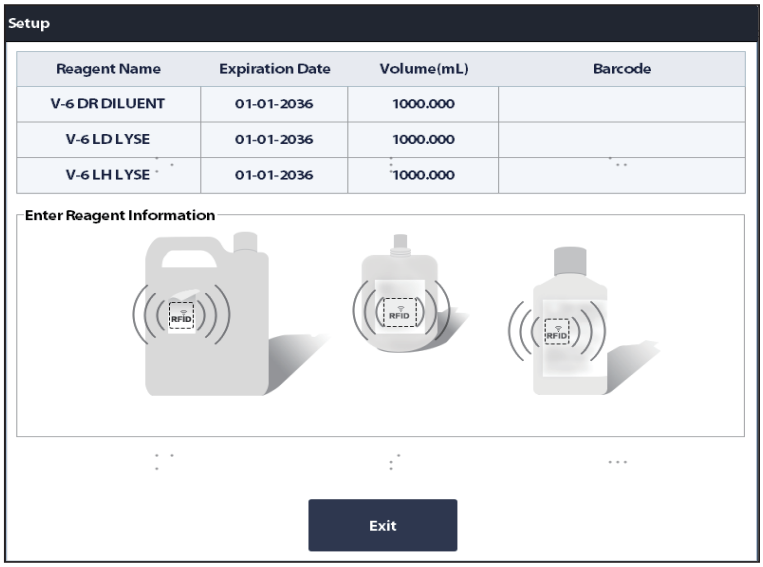
1. Enter the "**Setup**" dialog box.

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

   – When reagent-related errors occur, alarm messages occur in the lower right corner of the screen. The "**Error Information**" dialog box prompts and tap "**Remove Error**".

   – Tap the "**Reagent Setup**" button or tap "**Menu** > **Setup** > **Reagent Setup**" to enter the "**Reagent Setup**" screen. Select the reagent that needs to be replaced (multiple reagents can be selected concurrently), and then tap "**Setup**".

   The "**Setup**" dialog box pops up, and the top part displays the information of the reagent to be replaced



2. Read reagent information by swiping RFID card.

   – DS diluent: tear the RFID card from DS diluent and close the RFID card to the swiping card area.

   – FD dye and FR dye: close the label on the reagent bag to the swiping card area directly.

   – LD, LH, DR and SR reagent: close the RFID card on label of the reagent bottle to the swiping card area.

Identification rules:

– A beep sound occurs if the reagent information is successfully identified.
– Three beep sounds occur if there is a mismatch between the RFID card and the reagent.

NOTE:

- The current system date is set as the open date of the reagent if the reagent information is successfully identified for the first time.
- A RFID card can only be used for once.
- When you are entering an expired reagent, the analyzer will prompt you to check whether the reagent is expired.
- When multiple reagents need to be replaced, swipe RFID cards for these reagent and perform the next steps.

Install new reagent

NOTE:

When installing new reagents, make sure the color of reagent cap assembly is the same as the color in the rectangle box in reagent label.

Replace dye

Follow below instructions:

1. Open the dye compartment door.
2. Get a new dye bag, open the cap and the aluminum film sealing the bag.
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.

   NOTE:

   If the pickup tube of the cap assembly is stuck when it is taken out of the dye 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

Follow below instructions:

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.

Tap “Replace” button

After swiping RFID card and installing new reagents, tap “**Replace**” button in the “**Setup**” dialog box. The analyzer will automatically prime reagent and replace the old reagent.

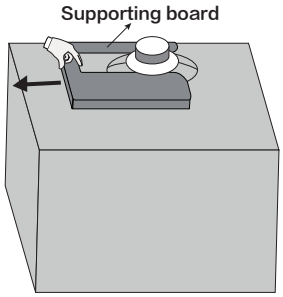
12.3.3 Replacing the Waste Container

BIOLOGICAL RISK

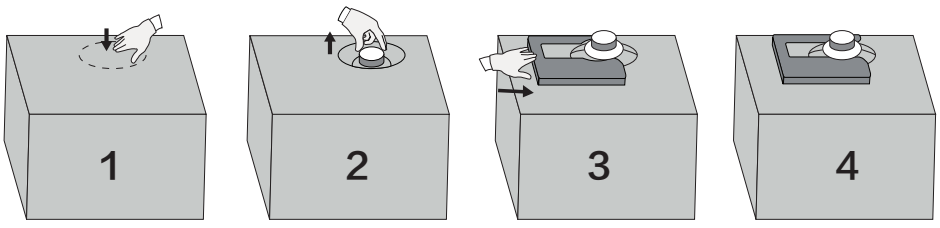
- **Remove the waste container cap and replace the waste container only when the power indicator is not flickering, in order not to make the waste overflow from the container.**
- **If the waste is discharged using waste container, make sure the pickup tube of the waste container cap assembly is above, and the tube is smooth and not bent.**

Follow below instructions:

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

After you set the probe cleanser maintenance time in "**Setup** > **Maintenance**", the analyzer prompts you to maintain the probe cleanser at the set time every day.

Follow below instructions:

1. When the "**Time for maintenance. Perform Probe Cleanser maintenance now?**" dialog box displays, tap "**Yes**".
   - The analyzer prepares for Probe Cleanser maintenance. After the preparation for Probe Cleanser maintenance completes, a dialog box displays.
   - The sample probe lowers to the aspiration position.
2. Present the uncapped Probe Cleanser under the sample probe as instructed on the screen.
3. Press the [Aspirate] key to start probe cleanser maintenance.

   The analyzer aspirates Probe Cleanser.
4. Remove the Probe Cleanser.

   The analyzer automatically completes Probe Cleanser maintenance.

You can also complete daily probe cleanser maintenance on the "**Fluidics**" screen.

Follow below instructions:

1. Tap "**Menu** > **Service** > **Maintenance** > **Fluidics**" in turn to enter the "**Fluidics**" screen.
2. Tap "**Probe Cleanser Maint.**".
   - The analyzer prepares for Probe Cleanser maintenance. After the preparation for Probe Cleanser maintenance completes, a dialog box displays.
   - The sample probe lowers to the aspiration position.
3. Present the uncapped probe cleanser under the sample probe as instructed on the screen.
4. Press the [Aspirate] key to start probe cleanser maintenance.

   The analyzer aspirates Probe Cleanser.
5. Remove the Probe Cleanser.

   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

.

Follow below instructions:

1. 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.
   - The analyzer prepares for probe cleanser maintenance. After the preparation for probe cleanser maintenance completes, a dialog box displays.
   - The sample probe lowers to the aspiration position.
3. Present the uncapped probe cleanser under the sample probe as instructed on the screen.

4. Press the [Aspirate] key to start probe cleanser maintenance.

   The analyzer aspirates probe cleanser.

5. Remove the probe cleanser.

   The analyzer automatically completes probe cleanser maintenance.

12.5 Auto-cleaning of the Parts and Components

You should clean the following parts or components when:

Follow below instructions:

1. Tap "**Menu** > **Service** > **Maintenance** > **Cleaning**" to enter the "**Cleaning**" screen.
2. Tap the corresponding cleaning program.

   The analyzer automatically completes the operation.

12.5.1 Cleaning the Probe Wipe and Blood Barrier Bracket

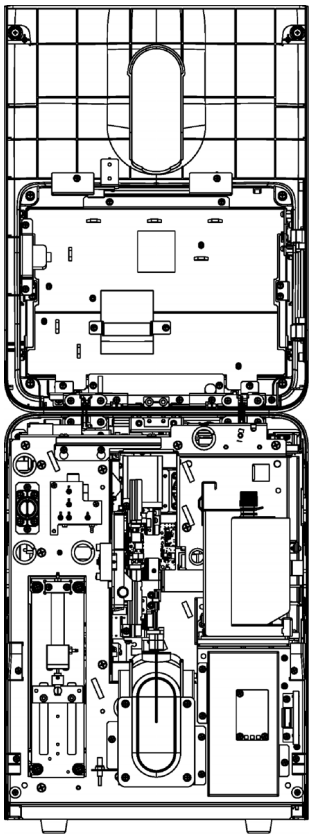
⚠ CAUTION

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

Follow the following instructions:

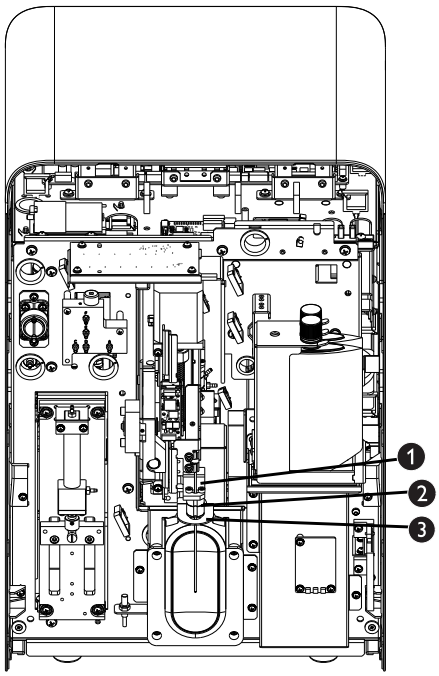
1. Open the front cover of the analyzer

   Hold the bottom of the front cover with both hands and open the front cover upward until it stands on the top cover.



2. Clean the probe wipe and blood barrier bracket

a. Push the sample probe assembly forward slightly to reserve sufficient operation and maintenance space.



Item	Name
1.	sample probe assembly
2.	Probe wipe
3.	Blood barrier bracket

b. 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.

c. Use a sterilized cotton swab dipped with alcohol to wipe the surface of the blood barrier bracket until no blood residue or other residues are visible.

3. Close 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.

12.5.2 Cleaning the Analyzer Front Cover

BIOLOGICAL RISK

Mindary Animal Medical 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, Mindary Animal Medical 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 Preparing to Pack-up

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

Follow below instructions:

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

12.7 Screen Calibration

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

NOTE:

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

Follow below instructions:

1. Tap "**Menu** > **Service** > **Screen Cal.**" to enter the touch screen calibration 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.

   After the calibration is completed, the software displays "**Calibration succeeded.**" on the screen.

12.8 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 12-2 Log Types

Item	Administrator's level	Common user's level
All Logs	View 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

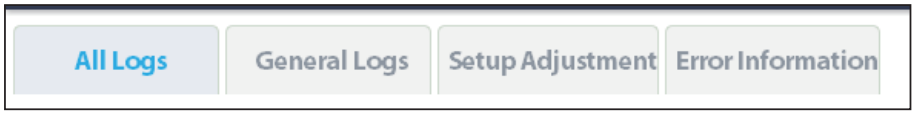
Table 12-2 Log Types

Item	Administrator's level	Common user's level
Error Information	View error information and troubleshooting information of the analyzer.	Cannot review

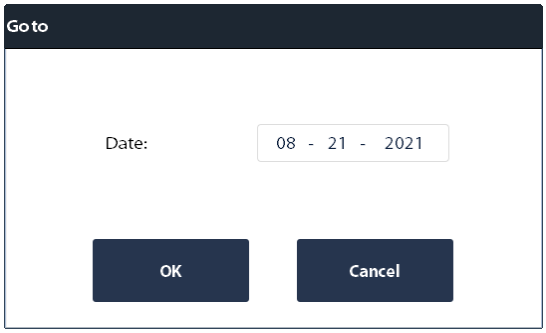
12.8.1 Viewing Logs

Follow below instructions:

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.
   c. Tap "**OK**".
      The screen displays the logs at the specified date.

12.8.2 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.

NOTE:

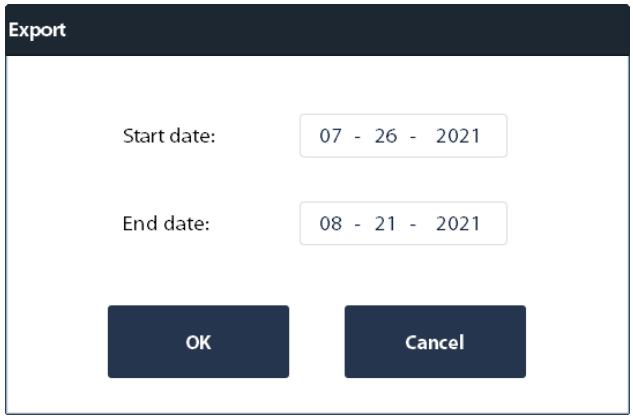
The user should ensure the data safety of the USB devices connecting to the analyzer.

Follow below instructions:

1. Tap "**Menu** > **Service** > **Log**" in turn to enter the "**Log**" screen.

2. Tap "**Export**".

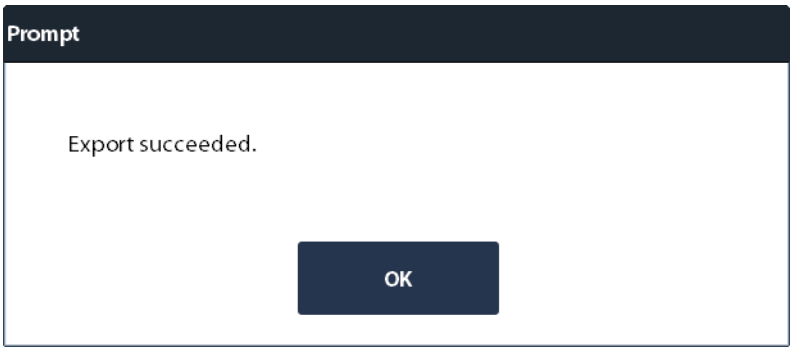
   A confirm dialog box displays.



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.

   After export ends, the screen displays the "**Export succeeded.**" dialog box.



NOTE:

Analyzer upgrade may only be performed under the instruction from a Mindary Animal Medical-authorized service personnel. Do not perform the procedure by yourself.

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		

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 fluorescent reagent detect sensor and motherboard sensor.	**Menu** > **Status** > **Sensor**	Administrator's level
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	Follow below instructions: **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	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10001	No LD Lyse. Replace the reagent	No LD Lyse. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error" button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10003	No LH Lyse. Replace the reagent	No LH Lyse. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.

Error ID	Error Message	Description	Solution
0x10002	No DR Diluent. Replace the reagent	No DR Diluent. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10005	No FD Dye. Replace the reagent	No FD Dye. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10006	No FR Dye. Replace the reagent	No FR Dye. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10200	DS Diluent expires. Replace the reagent	DS Diluent expires. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.

Error ID	Error Message	Description	Solution
0x10201	LD Lyse expires. Replace the reagent	LD Lyse expires. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10202	LH Lyse expires. Replace the reagent	LH Lyse expires. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10203	DR Diluent expires. Replace the reagent	DR Diluent expires. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10204	FD Dye expires. Replace the reagent	FD Dye expires. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.

Error ID	Error Message	Description	Solution
0x10205	FR Dye expires. Replace the reagent	FR Dye expires. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10400	DS Diluent low volume. Replace the reagent	DS Diluent low volume. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10401	LD Lyse low volume. Replace the reagent	LD Lyse low volume. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10402	LH Lyse low volume. Replace the reagent	LH Lyse low volume. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.

Error ID	Error Message	Description	Solution
0x10403	DR Diluent low volume. Replace the reagent	DR Diluent low volume. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10404	FD Dye low volume. Replace the reagent	FD Dye low volume. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x10405	FR Dye low volume. Replace the reagent	FR Dye low volume. Replace the reagent	Follow below instructions: **1.** Touch “Remove Error” button and register new reagent information into the reagent setup dialog box displayed. **2.** Touch “Replace” to prime reagent after replacing the reagent container. **3.** If error persists, contact Technical Support Services.
0x40003	Import "Key." file	Import "Key." file	Follow below instructions: **1.** 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	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x10102	Waste cistern floater status abnormal	WC2 waste cistern floater status abnormal	Follow below instructions: **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
0x10101	Cistern floater status abnormal	SCI cistern floater status abnormal	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x30105	FS baseline abnormal	FS baseline abnormal	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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
0x00301	DIL syringe action abnormal	Conflicting DIL syringe actions	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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
0x00310	DIL syringe action abnormal	DIL syringe action time out	Follow below instructions: **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	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x00200	SP syringe action abnormal	Invalid command to SP syringe	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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
0x00206	SP syringe action abnormal	SP syringe aspiration/ dispensation action not allowed 1	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x10308	Auto pressure building out of time	Auto pressure building out of time	Follow below instructions: **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	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x20012	Drive board communication out of time	Drive board communication out of time	Follow below instructions: **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
0x10107	SCI priming out of time	SCI priming out of time	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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
0x20008	Closed-reagent RFID board communication timeout	Closed-reagent RFID board communication timeout	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x30109	Optical signal board communication timeout	Optical signal board communication timeout	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x10304	-40kPa pressure out of range	-40kPa pressure out of range	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x10302	40 kPa pressure out of range	40 kPa pressure out of range	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x10104	Waste channel abnormal	Waste channel abnormal	Follow below instructions: **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	Follow below instructions: **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
0x10303	SCI bath pressure release abnormal	SCI bath pressure release abnormal	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **1.** Click “Remove Error”button and recheck the temperature? **2.** If the error still exists, contact our customer service department.
0x30001	Preheating bath temperature control abnormal	Preheating bath temperature out of the upper limit for counting	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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.
0x30003	Reaction bath temperature low	Reaction bath temperature low	Follow below instructions: **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
0x30004	Preheating bath temperature control abnormal	Preheating bath temperature out of the lower limit for counting	Follow below instructions: **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	Follow below instructions: **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.
0x30007	Ambient temperature is high	Ambient temperature is high	Follow below instructions: **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	Follow below instructions: **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.
0x30009	Reaction bath temperature control assembly is damaged	Reaction bath temperature control assembly is damaged	Follow below instructions: **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	**3.** Follow below instructions: **4.** Tap the “Remove Error” button to remove this error; **5.** If the error still exists, contact our customer service department.

Error ID	Error Message	Description	Solution
0x30100	Optical system working voltage abnormal	PMT voltage abnormal	Follow below instructions: **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	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x30103	Flow cell contaminated	DIFF channel FS blank voltage abnormal	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x30108	Optical system shielding box is open	Optical system shielding box is open	Follow below instructions: **1.** Close the Optical system shielding box;\r\n2.Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x40001	System time error	System time error	Follow below instructions: **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; \r\n3.If the error still exists, contact our customer service department.
0x30300	Clog	Aperture voltage abnormal	Follow below instructions: **1.** Aperture voltage abnormal. **2.** Tap the “Remove Error” button to remove this error. \r\n3. If the error still exists, contact our customer service department.
0x30301	Clog	Aperture voltage abnormal	Follow below instructions: **1.** Aperture voltage abnormal. \r\n2. Tap the “Remove Error” button to remove this error. **2.** If the error still exists, contact our customer service department.
0x30302	Clog	RBC sample preparation abnormal	Follow below instructions: **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.

Error ID	Error Message	Description	Solution
0x30303	Clog	RBC sample preparation abnormal	Follow below instructions: **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	Follow below instructions: **1.** Check whether the power fan is stuck. **2.** If the error persists, contact our Customer Service Department.
0x20201	Board fan faulty	Board radiator fan is blocked	Follow below instructions: **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.
0x20202	Board fan faulty	Board radiator fan is blocked	Follow below instructions: **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	Follow below instructions: **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
0x20003	Air pressure detection board error	Air pressure detection board calibration parameter error	Follow below instructions: **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.
0x30202	Waste channel abnormal	HGB waste channel clogged	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.
0x30602	Waste channel abnormal	DIFF waste channel clogged	Follow below instructions: **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
0x30603	Waste channel abnormal	RET waste channel clogged	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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	Follow below instructions: **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
0x30306	Waste channel abnormal	Cleaning channel of RBC sample preparation clogged	Follow below instructions: **1.** Tap the “Remove Error” button to remove this error; **2.** If the error still exists, contact our customer service department.

A Index

T

W

B Specification

B.1 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	Model	Name
Diluent	V-6	V-6 DS DILUENT
DIFF channel	V-6	V-6 LD LYSE
	V-6	V-6 FD DYE
RET channel	V-6	V-6 FR DYE
	V-6	V-6 DR DILUENT
HGB channel	V-6	V-6 LH LYSE
Solution	V-6	V-6 Solution Reagent
Probe cleanser	V-P	V-P Probe Cleanser

Table B-2 Controls / Calibrators

Name	Model
Controls	BR60
	BC-6D
	BC-RET
Calibrators	SC-CAL PLUS

B.2 Parameter Description

Table B-3 Blood sample test report parameters

Group	Name	Abbreviation
WBC group (11 items)	White blood cell count	WBC
	Neutrophil count	Neu#
	Lymphocyte count	Lym#
	Monocyte count	Mon#
	Eosinophil count	Eos#
	Basophil count	Bas#
	Neutrophil percentage	Neu%
	Lymphocyte percentage	Lym%
	Monocyte percentage	Mon%
	Eosinophil percentage	Eos%
	Basophil percentage	Bas%
RBC group (8 items)	Red blood cell count	RBC
	Hemoglobin concentration	HGB
	Mean corpuscular volume	MCV
	Mean corpuscular hemoglobin	MCH
	Mean corpuscular hemoglobin concentration	MCHC
	Red blood cell distribution width coefficient of variation	RDW-CV
	Red blood cell distribution width standard deviation	RDW-SD
	Hematocrit	HCT
Platelet group (7 items)	Platelet count	PLT
	Mean platelet volume	MPV
	Platelet distribution width	PDW
	Plateletcrit	PCT
	Platelet-large cell ratio	P-LCR
	Platelet-large cell count	P-LCC
	Immature platelet fraction	IPF
RET group (7 items)	Reticulocyte count	RET#
	Reticulocyte percentage	RET%
	Reticulocyte hemoglobin expression	RHE
	Immature reticulocyte fraction	IRF
	Low fluorescent ratio	LFR
	Middle fluorescent ratio	MFR
	High fluorescent ratio	HFR

B.3 Sampling Features

B.3.1 Sample Mode and Test Panel

Table B-4 Sample mode, test panel

Sample Modes	Test Panel
Whole blood mode	CD
	CDR

B.3.2 Sample Volumes Required for Each Analysis

Table B-5 Sample Volumes Required for Each Analysis

Sample Mode	Test Panel	Sample Volume Required for Each Analysis (µl)
Whole blood	CD	≤ 28
	CDR	≤ 34

B.3.3 Throughput

Table B-6 Throughput

Sample Mode	Test Panel	Throughput (test/hour)
Whole blood	CD	60
	CDR	40

B.4 Performance Specifications

B.4.1 Background/Blank Count Requirements

Table B-7 Background/blank count requirements for blood samples

Parameters	Acceptable Range
WBC	≤ 0.10×10^{9}/L
RBC	≤ 0.02×10^{12}/L
HGB	≤ 1 g/L
PLT	≤ 5×10^{9}/L

B.4.2 Repeatability

Table B-8 Repeatability requirements for blood samples

Parameter	Range	Whole Blood (CV/Absolute Deviation d*/SD)
WBC	(3.50 ~ 4.50)×10^9/L	≤ 3.0%
	≥4.50×10^9/L	≤ 2.5%
RBC	≥3.50×10^{12}/L	≤ 1.5%
HGB	(110 ~ 180) g/L	≤ 1.0%
MCV	(80.0 ~ 100.0) fL	≤ 1.0%
PLT	≥100×10^9/L	≤ 4.0%

B.4.3 Carryover

Table B-9 Carryover requirements for blood samples

Parameters	Carryover
WBC	≤1.0%
RBC	≤1.0%
HGB	≤1.0%
HCT	≤1.0%
PLT	≤1.0%

B.5 Input/Output Devices.

B.5.1 Keyboard

USB port (supporting the protocol of USB2.0 and above) keyboard.

B.5.2 Mouse

USB port (supporting the protocol of USB2.0 and above) mouse.

B.5.3 External Barcode Scanner

USB port (supporting the protocol of USB2.0 and above) hand-held barcode scanner.

B.5.4 Printer

USB port (supporting the protocol of USB2.0 and above) printer.

B.5.5 USB Drive

Supporting the protocol of USB2.0 and above.

B.6 Interfaces

NOTE:

The USB interfaces on the back of the analyzer shall only be used to connect the peripheral devices specified in this manual. For details about supported devices and models, see “B.5 Input/Output Devices.”.

- 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.7 Power Supply

	Voltage	Input power	Frequency
Main unit	100V-240V~ (±10%)	300 VA	50 Hz/60 Hz (±1 Hz)

B.8 Fuse

⚠ WARNING

The fuse of the analyzer is not replaceable. In case of any questions, contact Customer Service Department or your local distributor.

B.9 Temperature Protection Switch

Rated voltage: 9V

Rated current: 25A

NOTE:

If the temperature protection switch is damaged, please contact Customer Service Department or the local distributor. Operators can not replace or repair the temperature protection switch by themselves.

B.10 EMC Description

Statement and warning:

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

NOTE:

- It is the manufacturer's responsibility for providing equipment electromagnetic compatibility information of the equipment to the customer or user.
- It is the user's responsibility for ensuring that a compatible electromagnetic environment for the equipment can be maintained so that the equipment will operate normally.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is
- connected.
- Consult the dealer or an experienced radio/TV technician for help.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

This device complies with Industry Canada’s licence-exempt RSSs. Operation is subject to the following two conditions:

- This device may not cause interference; and
- This device must accept any interference, including interference that may cause undesired operation of the device.

The distance between user and products should be no less than 20cm
Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

- l'appareil ne doit pas produire de brouillage, et

- l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si lebrouillage est susceptible d'en compromettre le fonctionnement.

La distance entre l'utilisateur et de produits ne devrait pas être inférieure à 20cm

Industry Canada ICES-003 Compliance:CAN ICES-3(B)/NMB-3(B)

B.11 Noise Level

Maximal noise level: 80 dBA

NOTE:

Be sure to use and store the analyzer under the specified environment conditions.

B.12 Normal Operating Environment

- Normal operating temperature range: 10°C to 30°C
- Normal operating humidity range: 30% to 85%
- Normal operating atmospheric pressure range: 70.0 kPa to 106.0 kPa

B.13 Storage Environment

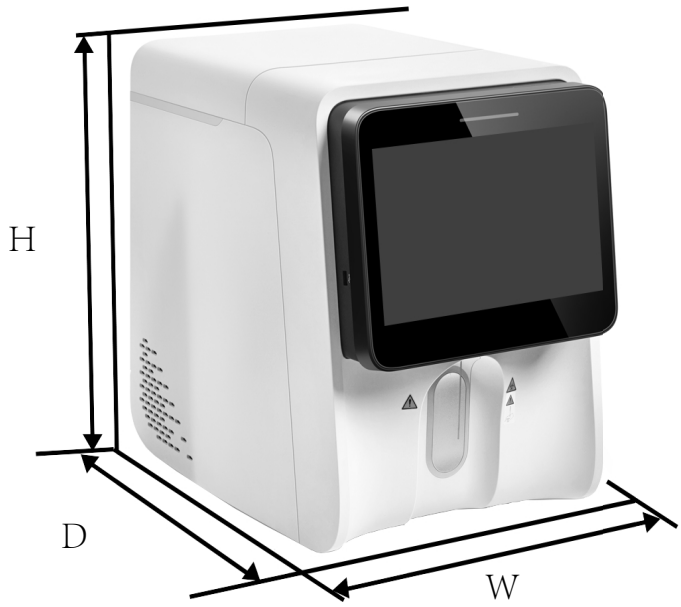
- Ambient temperature range: -10°C to 40°C
- Relative humidity range:10% to 90%
- Atmospheric pressure range: 50.0 kPa to 106.0 kPa

B.14 Operating Environment

- Ambient temperature range: 10°C to 40°C
- Relative humidity range:10% to 90%
- Atmospheric pressure range: 70.0 kPa to 106.0 kPa

B.15 Dimensions and Weight

Figure B-1 Main Unit Dimensions



Main Unit Dimensions and Weight	Value
Width (W)	≤325 mm
Height (H)	≤450 mm
Depth (D)	≤500 mm
Weight	≤35 kg

B.16 Contraindication

None

B.17 Safety Classification

Level of transient overvoltage: Category II.

Rated pollution degree: 2.

C Accessories and Packing List

C.1 Accessories of the Analyzer

- Reagent cap assembly
- Waste tube assembly
- Main power cords

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

- Computer
- Display

C.3 Packing List

- Main power cords
- Network cable
- Display (optional)
- Computer (optional)
- Lyse cap assembly (green, die sinking connector)
- Lyse cap assembly (red, die sinking connector)
- Lyse cap assembly (black, die sinking connector)
- Cap assembly (orange, die sinking connector)
- DS diluent cap assembly
- Waste container cap assembly
- Reagent bag (Optional)
- 20L reagent soft bottle
- Operator’s Manual
- Main Unit (Analyzer)
- Quick Reference Guide

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 Customer Service Department or your local distributor.

E Declaration of Conformity

DoC – V1.0

DECLARATION OF CONFORMITY

CE

Manufacturer: Shenzhen Mindray Animal Medical Technology Co., Ltd.

Address: *Room 702, Tower 4, YESUN Intelligent Community III, No.1301-88 Guanguang Road, Xinlan Community, Guanlan Street, Longhua District, Shenzhen 518110, P. R. China*

declares under our sole responsibility that the mentioned product below:

Device: *Auto Hematology Analyzer*

Model: *BC-60R Vet*

is in conformity with the essential requirements of the Community harmonization legislation listed below:

Directive 2014/53/EU – Radio Equipment

Standards Applied:

EN 61010-1: 2010+A1:2019	EN 61326-1: 2013
EN 50364: 2018	ETSI EN 301 489-1 V2.2.3
ETSI EN 301 489-3 V2.1.1	ETSI EN 300 330 V2.1.1

Place, Date of Issue: **Shenzhen, 2022-06-06**

Signature: 2022.6.6.

Name of Authorized Signatory: **Mr. Zhang Liguo**

Position Held in Company: **R&D Platform Management Dept. Manager**

F References

1. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline; Second Edition. CLSI document EP7-A2. Clinical and Laboratory Standards Institute; 2005.
2. Levey S, Jennings ER. The use of control charts in the clinical laboratory. Am J Clin Pathol. 1950;20” 1059-1066
3. Westgard, J.O., P.L. Barry, and M.R. Hunt (1981). “A Multi-rule Shewhart Chart for Quality Control in Clinical Chemistry,”Clinical Chemistry, vol. 27, pp. 493-501.
4. Westgard, J.O., P.L. Barry (1986). “Cost-Effective Quality Control: Managing the Quality and Productivity of Analytical Processes”AACC Press.
5. Bull BS. A statistical approach to quality control. Quality Control in Hematology, Symposium of the International Committee for Standardization in Haematology. Lewis SM and Coster JF, eds,Academic Press, London, England, 1975.
6. International Committee for Standardization in Haematology. Lewis SM and Coster JF, eds, Academic Press, London, England, 1975.
7. Bull BS. A study of various estimations for the derivation of quality control procedures from patient erythrocyte indexes [J]. Am J Clin Pathol 1974.61(4):473-481
8. M.W. Rampling, G. Martin. A comparison of the Myrenne erythrocyte aggregometer with older techniques for estimating erythrocyte aggregation, Biorheology 9 (1989), 41–46.
9. M. Plebani, S. De Toni, M.C. Sanzari , et al., The TEST 1 automated system – A new method for measuring the erythrocyte sedimentation rate, Am J Clin Pathol 110 (1998), 334–340.
10. Bull BS. A study of various estimations for the derivation of quality control procedures from patient erythrocyte indexes [J]. Am J Clin Pathol 1974.61(4):473-481

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, see “12 Service”.

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

Maintenance Items When Necessary

Maintenance Items	Signature, MM/ DD/YYYY	Signature, MM/ DD/YYYY

Replacing Reagents and Parts

Maintenance Items	Signature, MM/ DD/YYYY	Signature, MM/ DD/YYYY