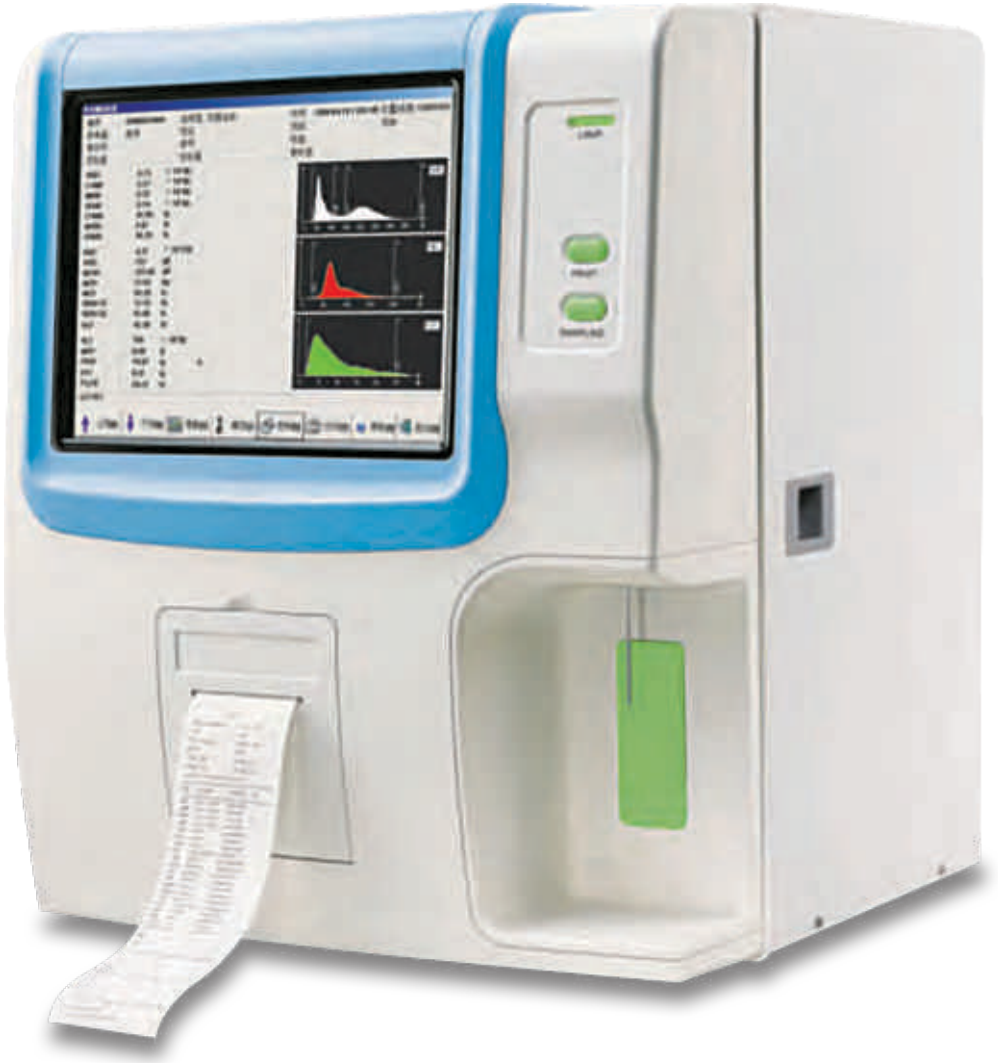
BeneSphera™ Brand

3-PART DIFFERENTIAL

Hematology Analyzer H32

User Manual



BeneSphera™ | Part of AVANTOR™ PERFORMANCE MATERIALS

BeneSphera™ Brand
3-Part Differential Hematology Analyzer H32
User Manual

Rev: 2.0

How to Use This Manual

For the best results, you should familiarize yourself with this analyzer and its performance before conducting clinical tests. This manual provides guidelines for using the BeneSphera™ Brand 3-Part Differential Hematology Analyzer, including instructions on installation, daily tests, daily maintenance and Quality Control (QC).

The functionality of instruments with different software versions or configurations may be different than what is described in this manual. In addition, the content of this user manual may differ from the actual instrument because of upgrades. If you have any questions, please contact the distributor. We recommend retaining all packaging materials in the event that the unit needs to be stored, transported or returned to the distributor for maintenance.

Declaration and Notice of Liability Limitation

Avantor Performance Materials, Inc. ("Avantor") warrants the proper functioning of this unit for a period of one (1) year from the date of sale, and will repair or replace this unit (at Avantor's option) if the unit fails to function properly due to defects in parts or workmanship. Avantor assumes no liability of any type or kind, including for bodily injury (including death),or for property damage, or for the accuracy of the results obtained using this product. Avantor's responsibility is limited to repair or replacement of this product in the event of product failure to the extent due to a defect in parts or workmanship.

AVANTOR DOES NOT PROVIDE ANY OTHER WARRANTIES WITH RESPECT TO THIS PRODUCT, INCLUDING THE WARRANTIES OF FITNESS FOR ANY PARTICULAR PURPOSE OR USE, OR MERCHANTABILITY.

Further, while Avantor has undertaken reasonable efforts to ensure the accuracy of the information in this manual, Avantor provides no warranty that all of the information in this manual is accurate or up to date. The figures in the manual are only for demonstration, and may be different from the actual display.

Warnings and Directions

All warnings and directions must be followed strictly to minimize the risk of injury, and to ensure the normal performance of the instrument and the accuracy of test results

	**WARNING:** Flags a procedure that, if not followed properly, can prove to be extremely hazardous to either the operator or the environment or both.
	**CAUTION:** Emphasizes operating procedures that must be followed to avoid possible damage to or destruction of the instrument, or loss of important data.
	**BIOLOGICAL RISKS:** Consider all specimens, reagents, calibrators, controls and other components that contain human blood or serum as potentially infectious! Use established, good laboratory working practices when handling specimens.
	**ELECTRICAL RISKS:** Avoid contact with interior electrical circuits. Contact with interior electrical circuits presents a risk of electrical shock.

IMPORTANT NOTES:

- Emphasizes operating procedures that must be followed to avoid erroneous results.
- Emphasizes the important information especially helpful to the operator before, during or after a specific operational function.

WARNINGS AND PRECAUTIONS

The instrument must be connected to a power outlet of correct voltage. Power-off this instrument whenever it is being serviced or if it will not be used for an extended period of time.

Proper maintenance is essential. If the instrument is not maintained properly or repaired as needed, it may cause abnormal or inaccurate results and the instrument itself may sustain damage.

This instrument must be operated under the stated conditions. If not, abnormal or inaccurate results may occur and the instrument itself may sustain damage.

This instrument is an automated hematology analyzer and is intended only for *in vitro* diagnostic use in clinical laboratories. The warnings below are required to be strictly followed.

If you experience smoke, a peculiar smell or sound while using this device, the power supply must be immediately switched off and the distributor or seller immediately advised. If the instrument continues to be used under these circumstances, serious injury could result (including death and property damage) as a result of fire or other instrument malfunction.

Keep blood samples, reagents and metal pieces, such as tools, away from the interior of the instrument to avoid causing a short circuits or other electrical malfunction. If any blood samples, reagents or metal pieces come into contact with the interior of the instrument, immediately switch

off the power supply and disconnect and the plug from the power socket.

Avoid contact with interior electrical circuits. Contact with interior electrical circuits presents a risk of electrical shock and death.

Use of protective clothing and gloves is strongly recommended when operating or maintaining this instrument. After completion of work, wash hands with soap, water and appropriate disinfectants.

All specimens, reagents, calibrators, controls and other components that contain or come into contact with human blood or serum are potentially infectious. Wear protective clothing and gloves, and follow all bio-safety practices. Should blood or serum come into contact with an open wound, mucous membrane or eyes, immediately rinse the area well and seek immediate medical advice.

Use of Reagents

Avoid direct contact with reagents. Reagents can cause irritation of the eyes, skin and mucous membranes. Should you come in contact with reagents, immediately rinse the area with plenty of water and seek immediate medical advice.

Do not swallow the reagents. If swallowed, follow the instructions on the Material Safety Data Sheet (MSDS) and contact your local poison control center.

Disposal procedures for residual reagents, detergents and other waste must meet the requirements of all applicable local regulations. The appropriate biological precautions should be taken.

Voltage, Connection and Grounding of Power Supply

The instrument must be connected to a power outlet of correct voltage and must be properly grounded.

The power switch and input voltage supply connection should always be accessible.

Risk of Electrical Shock and Death: Avoid damaging the power cable. Do not place any appliances on the same circuit. Do not pull the power cable. When the peripherals are connected, the power supply must first be powered off, or a short circuit or open circuit might be caused.

Risk of Electrical Shock and Death: Do not open the side or rear covers or upper panel while the instrument is running.

Graphics and Symbols

	Temperature Limitation
	Fragile: Handle with Care
	Upwards This symbol indicates that the transport package shall be kept in a vertical, upright position
	Keep Dry
	Limit the Number of Stacking Tiers This symbol indicates the maximum number of packages that should be stacked. The number three indicates that only three packages should be stacked.
SN	Serial Number
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
EC REP	Authorized Representative in the European Community

CONTENTS

1. Instrument Introduction

1.1 Product Introduction

This analyzer uses the impedance principle (colorimetric for hemoglobin measurement) to categorize and count blood cells in blood. All test parameters are shown in Table 1-1.

Table 1-1

System Parameters	Abbreviation	Unit (Default)
White Blood Cell count	WBC	10^9/L
Lymphocyte count	LYM#	10^9/L
MID Cell count	MID#	10^9/L
Granulocyte count	GRA#	10^9/L
Lymphocyte percentage	LYM%	%
MID Cell percentage	MID%	%
Granulocyte percentage	GRA%	%
Red Blood Cell count	RBC	10^{12}/L
Hemoglobin concentration	HGB	g/L
Hematocrit	HCT	%
Mean corpuscular volume	MCV	fL
Mean corpuscular hemoglobin	MCH	pg
Mean corpuscular hemoglobin concentration	MCHC	g/L
Red Cell Distribution Width SD	RDW-SD	fL
Red Cell Distribution Width CV	RDW-CV	%
Platelet count	PLT	10^9/L
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	%
Plateletcrit	PCT	%
Platelet–large cell ratio	P-LCR	%
White Blood Cell histogram	WBC Histogram	
Red Blood Cell histogram	RBC Histogram	
Platelet histogram	PLT Histogram	

1.2 Product Technical Parameters

Test principle	:	WBC/RBC/PLT: Impedance method; HGB: colorimetric
Aspiration volume	:	9.8μL (Whole Blood), 9.8μL (Anticoagulant Peripheral Blood), 20μL (Pre-diluted Peripheral Blood)
Test rate	:	About 1 min/ea.
Working environment	:	15°C～35°C, relative humidity 10%～90%
Storage environment	:	0°C～40°C, relative humidity ⩽ 80%
Power supply	:	a.c.110V～220V, 50/60Hz
Input power	:	96VA

1.3 Instrument Design and Structure

The analyzer is composed of counting chambers, flow tubing system, computer control system and software.

1.3.1 Front View

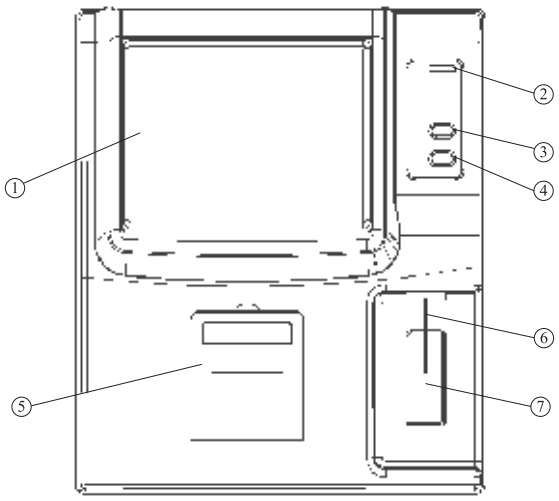


Fig. 1-1 Front view

1. Display screen: displays the software interface.
2. Indicator light: yellow at startup, turns red when starting sample test and turns green when sample test is finished.
3. Feed key: built-in printer releases the paper outward.
4. Test key: the instrument will aspirate sample when this key is pressed in analysis mode.
5. Printer cover: paper installation position for built-in printer.
6. Sampling needle: use sampling needle to aspirate blood sample.
7. Aspiration key: the instrument will aspirate sample when this key is pressed in analysis mode. This has the same function as the Test key.

1.3.2 Rear View

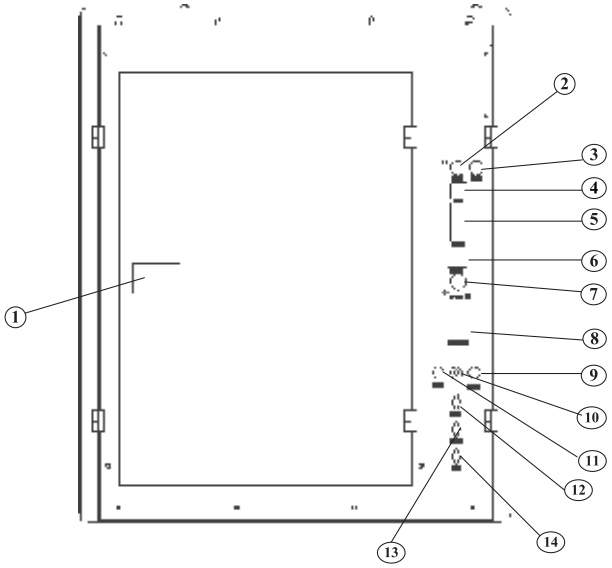


Fig. 1-2 Rear view

1. Rear cover lock switch: unlock this switch to open the rear cover to replace reagent.
2. Keyboard interface: PS/2 keyboard interface
3. Mouse interface: PS/2 mouse interface
4. USB port
5. RS-232 serial port: to connect with data receiving devices
6. Network interface
7. Power interface: to connect with external power supply
8. Power switch: switch instrument power
9. Diluent sensor
10. Grounding hole: used for instrument grounding
11. Cleanser sensor
12. Cleanser port
13. Diluent port
14. Waste port

2. Installation

2.1 Unpacking the Instrument

1. Unpack the instrument from its packing and remove the material used for transportation. Please keep the original packing carton and packing material, in case you need to repack the instrument in the future.

2. Remove the instrument from plastic package.

3. In accordance with the packing list, make sure the packing carton includes:

- BeneSphera™ Brand 3-Part Differential Hematology Analyzer
- User manual
- Packing list
- Agent warranty certificate
- Power adapter
- Product COA

NOTE: please remember to review the packing list that came with this product. In case of a discrepancy, please contact the distributor.

2.2 Installation Environment

In order to ensure proper instrument functionality, please consider the following working conditions for the BeneSphera™ Brand 3-Part Differential Hematology Analyzer:

- Avoid direct sunlight
- Avoid a dusty environment
- Avoid electromagnetic radiations and fields
- Ensure sufficient working space around the instrument

NOTE: for the best performance, this product should be operated in an environment with a temperature between 15°C and 35°C and relative humidity of 10% to 90%.

CAUTION: FAILURE TO OBSERVE THE ABOVE WORKING CONDITIONS AND ENVIRONMENTAL FACTORS CAN RESULT IN INSTRUMENT MALFUNCTION AND INACCURATE RESULTS.

2.3 Power Requirement

- a.c.110V～220V
- 50/60Hz
- l96VA

WARNINGS:

(1) AC power must be properly grounded.

(2) AC power must be stable; avoid using other instruments that consume large amounts of power on the same power group.

(3) If there is smoke, smell or noise coming from the instrument, immediately shut off the power, disconnect the power cable and contact your distributor.

(4) When (un)plugging the power connector, hold the connector by the plug itself, instead of by the power cord.

FAILURE TO FOLLOW THE ABOVE REQUIREMENTS AND INSTRUCTIONS CREATES A RISK OF ELECTRICAL SHOCK, INJURY AND DEATH.

2.4 Reagents

The instrument uses lyse, cleanser and diluent for measurement and maintenance. Failure to use the reagents shipped with the instrument or reagents recommended by the distributor can affect the accuracy of test results and can void the manufacturer's warranty.

2.4.1 Connection of Lyse

1. From the reagent packing carton, take out lyse and cleanser bottles respectively, open the door at the rear panel of the instrument and place the lyse bottle in the lyse compartment.

2. Open the bottle lid and insert the lyse reagent adapter into the lyse bottle and tighten the bottle cap.

2.4.2 Connection of Cleanser

1. Take out the cleanser reagent adapter from the accessories bag.
2. Connect the cleanser reagent adapter tube to the "Cleanser" connector on rear panel of instrument.
3. Insert the other end of the reagent adapter into cleanser bottle, and tighten the bottle cap.

2.4.3 Connection of Diluent

1. Take out the diluent reagent adapter from the accessories bag.
2. Connect the diluent reagent adapter end to the "Diluent" connector on rear panel of instrument.
3. Insert the other end of catheter into diluent bottle and tighten the bottle cap.

2.4.4 Connection of Waste

1. Take out the waste tubing from accessories bag.
2. Connect the waste tubing end to the "Waste" connector on the rear panel of instrument.
3. Rotate the bottle cap clockwise on the waste tubing to tighten it on the waste bottle.

CAUTION:

(1) The reagent tubings must not be twisted, folded or blocked.

(2) Please do not use expired reagents.

(3) Use only the reagents provided with the instrument or recommended by Avantor or a licensed distributor.

BIOLOGICAL RISKS:

(1) The waste must be treated in accordance with country and local regulations.

(2) Wear rubber gloves and appropriate protective clothing during waste disposal.

2.5 Connection of Keyboard, Mouse

1. Carefully take out the keyboard and mouse from the packing carton.
2. Carefully insert keyboard cable plug into the socket marked "Keyboard" on the instrument's rear panel.
3. Carefully insert the mouse cable plug into socket marked "Mouse" on instrument rear panel.

2.6 Connection of External Printer

1. Make sure both the printer and instrument have been shut down.
2. Insert one end of USB cable into printer USB interface socket.
3. Insert the other end of USB cable into instrument USB interface.
4. Connect printer to AC power supply with the power connector supplied with printer.

3. Sample Test

3.1 Preparation Before Startup

Before startup, the operator must complete the following steps to make sure the system is ready:

1. Check if the diluent, lyse and cleanser levels are sufficient for testing. Check if the waste bottle is empty, the reagent tubing system is connected and clear and all the connections are tight.
2. Check whether there is sufficient paper in the built-in or external printer.

3.2 Startup

Switch on the instrument. The system will start to initialize and check mechanical parts, prime reagents and run blank tests, as shown in figures below:

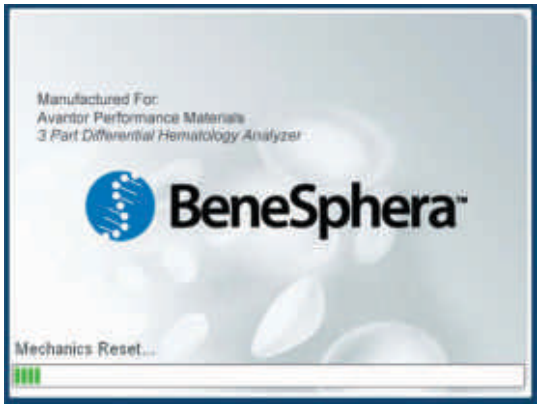


Fig. 3-1 Startup program

After startup, the sample test screen is shown:

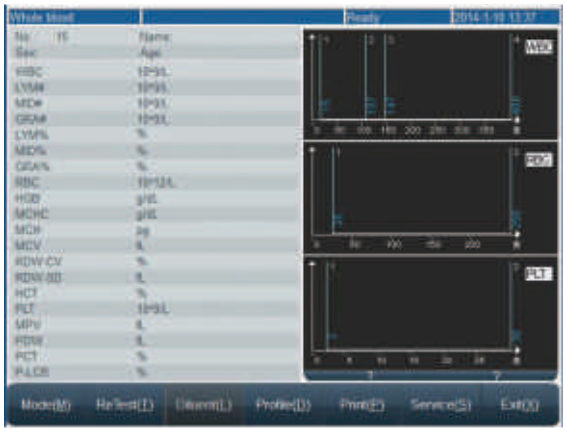


Fig. 3-2 Sample test screen

The blank test only shows test results for WBC, RBC, HGB, HCT and PLT. The operator can run a blank test at any time. In sample test menu, click the "Profile" button. After the "Data Edit" menu appears, change the sample no. to 999, then click the "Yes" button and return to sample test menu. Press the "Aspiration Key" to start the blank test. During the test, the indicator light will turn red, and the status column on top of screen will display the test status.

Blank test acceptable ranges are as follows:

Parameter	Reference Range
WBC (White Blood Cell)	$\leqslant 0.2 \times 10^9$/ L
RBC (Red Blood Cell)	$\leqslant 0.02 \times 10^{12}$/ L
HGB (Hemoglobin)	$\leqslant$1 g / L
HCT (Hematocrit)	$\leqslant$ 0.5 %
PLT (Plateletes)	$\leqslant 10 \times 10^9$ / L

If the blank test results exceed this range, the operator should repeat the above test steps until test results are acceptable. If the test results still do not meet the specifications after five test runs, please check the reagent open dates and replace the reagents if needed (suggested reagent open time is no great than 4 months). If the reagents dates are within this time period, and test results are still out of range, then use the "Back Flush" function in "Service" module to clean the counting chambers and to eliminate any blockages. If test results are still not within range, do not use the instrument and contact the distributor for service.

After completing the blank tests, you can fill in another sample no. manually in the "Data Edit" menu and begin to run blood samples.

3.3 Blood Sample Collection

Blood sample collection can be divided in venous blood or peripheral blood collection.

BIOLOGICAL RISK:

Avoid any contact with samples containing blood cells. Wear gloves and appropriate protective clothing while running blood samples.

3.3.1 Venous Blood Collection

Venous blood can be collected by using either vacuum tubes or through atmospheric pressure. Blood collection tubes should contain an anticoagulant (usually EDTA.K2.2H2O in a concentration of 1.5-2.2mg/ml).

3.3.2 Peripheral Blood Collection

Blood Sampling Position:

For adults, use the inner side of the tips of the middle finger or ring finger; for children 6 months or older, the middle finger is preferred; for infants younger than 6 months, blood is usually sampled from the thumb or outer side of foot heel.

Blood Sampling Method:

Blood sampling should be carried out in accordance with the peripheral blood collection standards of the laboratory. The typical collection method is the "finger prick." The common blood tube contains 20μL of constant volume. It is recommended that you collect at least 30μL of blood to facilitate retesting.

If blood flow stagnates during blood collection, press slightly press around piercing hole, without applying to much pressure. Avoid mixing the tissue fluid with the blood sample. Doing so will influence the accuracy of the results.

3.3.3 Blood Sample Mixing

Before testing, blood samples must be properly mixed. The recommended method is to gently invert the vial until the blood cells are completely and uniformly mixed. Avoid vigorous shaking.

The blood sample to be tested must be at room temperature. It is recommended that the testing should be performed within 4 hours of collection. Prolonged storage or inferior mixing will influence accuracy of the test results.

3.4 Blood Sample Analysis

Prior to the blood sample analysis, you should measure the quality control (QC) samples on the instrument. See Chapter 4, “Quality Control”, for detailed operation instructions.

	**CAUTION:** **This instrument is designed to analyze blood samples; aspiration of other substances into the sample needle, may lead to inaccurate results and to instrument malfunction.**

3.4.1 Sample Data Edit

The “Sample data entry” module enables you to modify the Sample No. or input sample data before testing. Modifications can be made after testing is done in the "History Data" module. See Chapter 6, “History Data”, for detailed operation instructions. Click the "Profile" button. The “Data Edit” menu will pop up as follows:

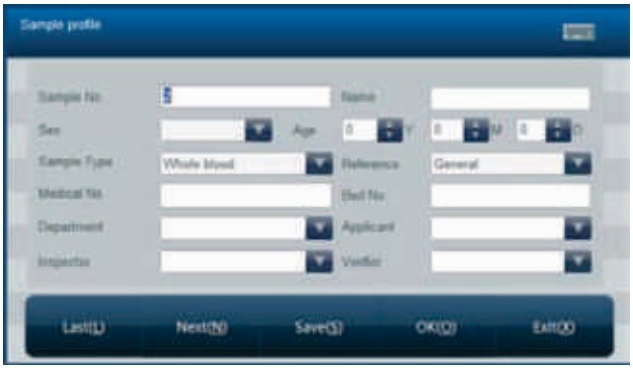


Fig. 3-3 Sample data entry

- Sample No.: to modify the sample no., please input the maximum 11-digit number in the sample no. box (for example: use format of "year + month + day + 3-digit sequence number"). If this sample No. exists in the database, you will be asked to use a different sample no. *Otherwise, the system will overwrite the existing test results*. The system will start with sample number 001 every new day.
- Name: maximum 20 letters.
- Sex: male or female may be selected; if the sex is not selected, the system will leave that field blank.
- Age: for "Year", "Month", and "Day", input only one number for each category. If multiple numbers are input, then the year may overwrite the month and day, or the month

may overwrite the day. Age range is 1-150, month range is 1-30, and day range is 1-90.

- Sample type: select anti-coagulating whole blood, anti-coagulating peripheral blood or pre-diluted peripheral blood.
- Reference: select general, male adult or adult female, 16-18 years, 6-15 years, 3-5 years, 3 months-2 years, 8 days-2 months, the 1st week or enter a user-defined value. The default is general.
- Medical No.: patient medical record no. if applicable.
- Bed No.: bed number of the patient if applicable.
- Department, Applicant, Inspector and Verifier: directly input or select from dropdown box. Please see Chapter 7, "System Settings", for more detailed information. Click " " to open soft keyboard, as shown below:

Fig. 3-4 Systemsoft keyboard

When using the soft keyboard, click the curser in the input box to begin inputting data. "Caps" is used to toggle between uppercase and lowercase letters. Click "Close" to close soft keyboard. Click the "OK" button to update or save the sample data. Click the "Cancel" button to return to sample test screen. The soft keyboard function is available to use in other input fields.

3.4.2 Blood Sample Counting

To select the blood type, click the "Mode" button or go to the "Sample Data Edit" menu and select the blood type from the box. Three kinds of blood types are available for selection: whole blood, anticoagulant peripheral blood, or pre-diluted peripheral blood.

If pre-diluted peripheral blood mode is selected, first add 20μl peripheral blood into a diluting cup, and then click the "Diluent" button. A message box will appear as follows:

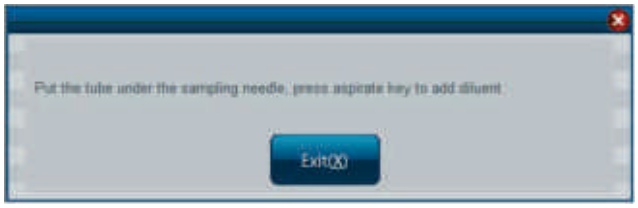


Fig. 3-5 Add diluent

Press the aspiration key. This will add 700μl diluent to the diluting cup to complete the dilution out of the instrument. After this, the analyzer will aspirate the 300μl diluent sample for counting.

The sample test sequence is as follows:

1. Place the sample tube or cup under the sampling needle, be sure no fingers or body parts in the way, and then press the aspiration key. A needle will extend and the instrument will aspirate the blood sample. Wait until the sampling needle retracts back into the instrument before removing the sample tube or cup.
2. The instrument will start to analyze the sample. A message box with the status will appear, indicating the sample is "Being tested…" After the test, all relevant parameters, test results and histograms will be shown as follows:

Fig. 3-6 Blood sample counting screen

If the "Print instantly" setting has been selected, the instrument will automatically print the analysis result after the test ends.

If the counting and analysis operation environment is below 15°C or above 35°C, the result of the blood sample will be unreliable and the "Temperature Low" or "Temperature High" alarm will appear in message field of screen.

If a block hole (aperture clog) or bubbles appears during counting and analysis, the "Block hole" or "Bubble" alarm will appear in message field of screen.

If the remaining volume of reagents is not enough to compete the analysis, the message field will indicate "Reagent volume not enough." The message also will indicate which reagent is low, such as diluent, cleanser or lyse.

If the test result exceeds the system output range, the individual parameter result will be shown as "---" If this occurs, check validity of test sample.

BIOLOGICAL RISK:

Avoid any contact with samples containing blood cells. Wear gloves and appropriate protective clothing while running blood samples.

WARNING:

Pay attention during aspiration as the movement of the sampling needle may cause body injury.

3.4.3 Parameter Prompt Message

H+: indicates that parameter test result is higher than maximum of predetermined pathogenic value.

L-: indicates that parameter test result is lower than minimum of predetermined pathogenic value.

H: indicates that parameter test result is less than or equal to maximum pathogenic value, greater than maximum of normal value.

L: indicates that parameter test result is greater than or equal to minimum of pathogenic value, less than minimum of normal value.

3.4.4 Histogram Prompt Message

LF1: the region on the left side of lymphocyte peak is abnormal, possibly because of: platelet agglutination, giant platelets, plasmodium, nucleated red blood cells, non-lysed red blood cells, abnormal lymphocytes, cryoglobulin.

LF2: the lymphocyte peak and intermediate cell region are abnormal, possibly because of: heteromorphic lymphocyte, plasma cell, atypical cell, initial cell, eosinophils and basophils population.

LF3: the region between intermediate cell area and neutrophil peak is abnormal, possibly because of: immature granulocyte, abnormal cell and eosinophils.

LF4: the region on the right side of neutrophil is abnormal, possibly because of: granulocytosis.

PF2: the region on the right side of platelet is abnormal, indicating probable existence of: large platelet, platelet aggregate, small red blood cell, cell fragment and fibrous protein.

PF1: the region on the left side of platelet is abnormal, indicating probable existence of: small platelet cell fragment, red blood cell inclusion body and electronic noise interference.

3.4.5 Print

Before running the sample test, please set up the printer and print format using the system settings module. See Chapter 7, “System Setting”, for more detailed instructions. Click "Print" to print this test result.

4. Quality Control

Quality Control reflects the accuracy and repeatability of the system. The instrument Quality Control program provides a reliable and efficient way to check for and prevent possible system errors. If there is a system error, the results of sample analysis will be unreliable. To maintain accurate analysis results, you should regularly, advisable on a daily base, measure Quality Control samples on the instrument in order to identify and eliminate errors with the instrument measurement system.

The BeneSphera™ Brand 3-Part Differential Hematology Analyzer provides three QC methods, L-J QC, X-B QC and X-R QC.

4.1 L-J QC

In main screen, click the "QC" button. You will be able to choose among 20 QC files of "L-J QC". The system can control 20 parameters at a time. L-J QC uses QC samples for QC analysis.

4.1.1 L-J QC Setting

Fig. 4-1 L-J QC setting

Save : select the QC file; enter the lot No., expiry date, parameter target values and limits, then click the "save" button to save QC data of current QC file. If there is data in this QC file, then update the information.

Rules : select QC rules for each of the QC files. Users can select one or more rules or unselect a rule. The system will check the rules during measurements and alarms during QC test according to the rules set.

The QC Rules box is shown below:

Fig. 4-2 L-J QC criteria

Items : user may select/unselect parameters for QC measurement.

Delete : delete the QC data within the QC file currently selected.

Send : use the instrument's RS-232 serial port to transfer the QC data from the QC file currently selected to the designated receiver. Prior to transfer, please use the RS-232 serial port cable to connect BeneSphera™ Brand 3-Part Differential Hematology Analyzer to equipment ready to receive data, then set up the receiver software parameters. To set the transfer terminal parameters, please refer to Chapter 7, "System Setting", for more details.

Exit : return to main screen.

4.1.2 L-J QC Run

After you have set the QC parameters for the QC file selected, you may begin QC parameter setting analysis of this QC file. From the main screen, select the QC file and enter the QC Run screen as shown below:

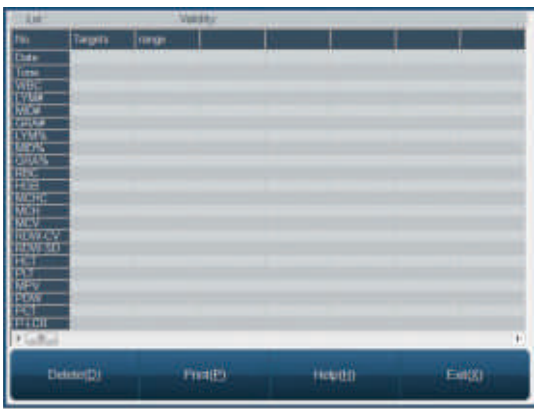


Fig. 4-3 L-J QC runs

1. With the QC sample ready, press the Aspiration key to start the test.
2. After the test, the QC run result will be shown in the column that corresponds to the current QC number. If a fault alarm occurs during this test, the test results may be inaccurate. You can click the "Delete" button to delete this test result. Troubleshoot or eliminate the related fault before next run. If you selected the out-of-control rule during QC set-up, the system will provide a prompt if the sample does not conform to the QC rules during the analysis. You can then delete the current QC run and begin the test again.
3. You can save a maximum of 500 QC results to each QC file. Press "Exit" button to return to main screen.

4.1.3 L-J QC List

The instrument can look up QC run data in the list. From the main screen, select the QC file, and then enter the QC list, as shown below:

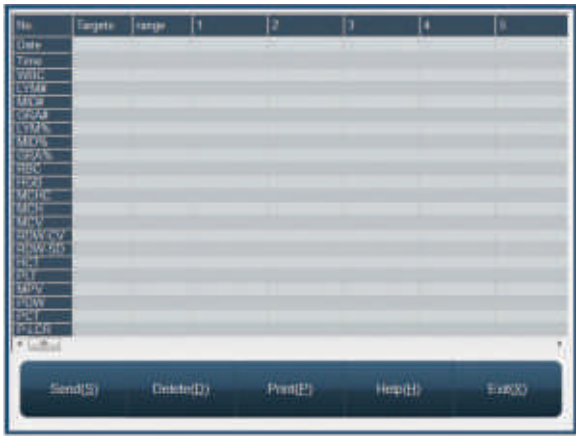


Fig. 4-4 L-J QC list

The instrument will display the 20-parameters QC result. If some parameters are not controlled, the corresponding row will be blank.

The send function can transfer part or all of the L-J QC data to an external receiver. Use the mouse or touch pen to select a list column, and select one group of QC data. Using keyboard Ctrl key or Shift key, multiple columns can be selected. To send all data, click the "Send" button. The open transfer dialog box will appear as follows:

Select the data to be submitted, and then click "Send".

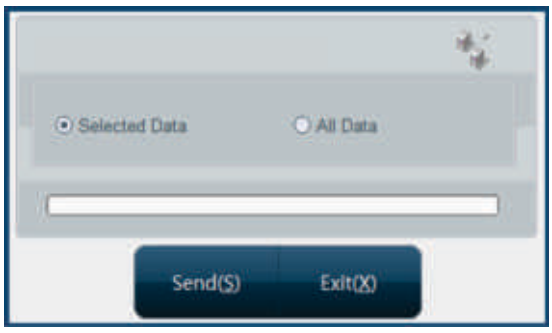


Fig. 4-5 L-J data transfer

Click the "Delete" button. A confirmation dialog box appears. After confirmation you can delete parts of or all of the QC data. Use the same method to select the data that was used during data transfer.

4.1.4 L-J QC Chart

The QC chart displays the QC data distribution in graphs, to facilitate understanding of the instrument deviation trend. From the main screen, select the QC file, then open the QC chart screen, as follows:

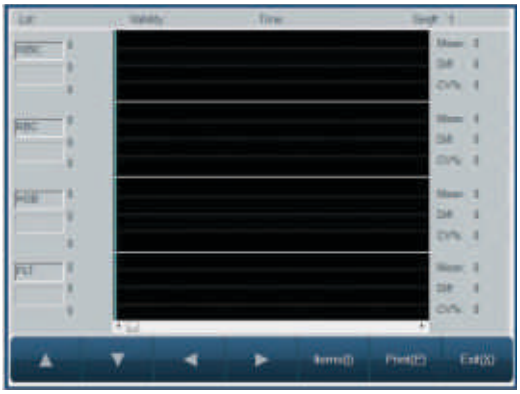


Fig. 4-6 L-J QC chart

Lot No. : Lot Number of QC sample corresponding to QC file.

Expiry : Validity period of QC sample.

Time : Test time of datum corresponding to QC point.

Seq# : Sequence number of current QC point in all QC data points.

Each screen displays a four-parameter QC chart, Mean (average), Diff (standard deviation), and CV (variation coefficient) of each parameter.

The three values on the left of QC chart are, from top to bottom: QC sample target value + deviation, QC sample target value, QC sample target value - deviation.

Press " ↓ ", " ↑ " keys on keyboard or frame to switch between items.

Press "Items" button to individual parameters select.

Press "←", "→" keys on keyboard or frame, to show the QC data of different sequence Numbers.

Press "Print" button to print out one current group of QC data, as shown on the screen.

4.2 X-B QC

X-B QC does not use QC samples, but is used to measure the instrument's quality performance based on specific parameters. X-B QC data is calculated from random samples, not classified according to disease type. The given value and upper and lower limits comprise a reference range, observe trends of each lot of X-B values in a specified reference range. The instrument makes X-B QC of all 20 parameters, quantity of samples for X-B numeric analysis in each lot is within 20-200, the default is 20.

4.2.1 X-B QC Setting

Fig. 4-7 X-BQC setting

If X-B analysis is "On", the samples that are tested are also used in the X-B QC analysis data.

X-B QC target value and limits are manually calculated and filled out by the user. The parameter target value is the average of statistic calculation result of sample data after test of the same patient base. It is recommended that you use at least 1000 samples. The sample source must be random. Dependent on the patient base, data reference values of different regions will be different. Limit ranges are recommended to be 5%-10% of the target value.

Save : save QC setting data.

Items : user can select QC for all parameters, or select QC for some parameters.

Delete : delete X-B QC setting data.

Send : use the instrument's RS-232 serial port to transfer X-B QC setting data to designated receiver. Before sending, please use the RS-232 serial port cable to connect BeneSphera™ Brand 3-Part Differential Hematology Analyzer instrument to the receiving equipment to receive data, start up and set up receiver software parameters. Please refer to Chapter 7, "System Settings", for information on setting the parameters for the instrument transfer terminal.

Help : display system help.

Exit : return to main screen.

4.2.2 X-B QC List

The instrument can save up to 2000 pieces of X-B QC data. Open X-B QC list, as shown below:

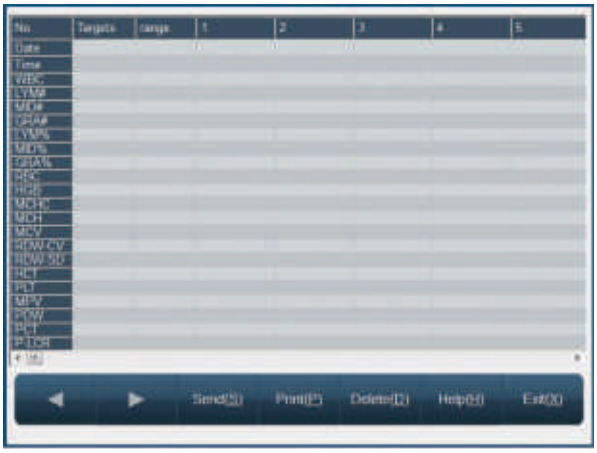


Fig. 4-8 X-BQC list

The instrument displays 20-parameters of the QC

results. If some parameters are not controlled, the corresponding column will be blank.

The system can show up to 200 QC data columns at a time from the X-B QC list. If there are more than 200 columns of data, users can view the additional columns by using "and".

The Send function can transfer some or all X-B QC data to external equipment. The method is the same as data transfer in Chapter 4.1.3, "L-J QC List".

In list frame, click the "Delete" button. The delete confirmation dialog box pops up. After confirmation, some or all QC data will be deleted.

4.2.3 X-B QC Chart

The system provides a graph to look up X-B QC analysis data, as shown below:

Fig. 4-9 X-B QC chart

Current/Total : to display current QC data point location and X-B QC analysis total.

Time : test time of data corresponding to QC point.

Each screen displays four-parameter QC chart. Three values on the left of QC chart are, from top to bottom: target value + deviation, target value, target value - deviation.

Press " ↓ ", " ↑ " keys on keyboard or frame to switch between parameters.

Press "←", "→" keys on keyboard or frame to display QC data of various data points.

Press "Print" button to print out one current group of QC data.

4.3 X-R QC

X-R QC, or mean - range QC, is common quality control method in industry. It is an efficient way to determine and forecast abnormal fluctuations of quality and it complements L-J QC. X-R uses QC sample for QC analysis.

X-R QC primarily uses the control chart to reflect QC data stabilities; its QC chart is a combined chart.

4.3.1 X-R QC Setting

Before running X-R QC, users must set the necessary QC parameters. The setting screen is as follows:

Fig. 4-10 X-R QC setting

Lot No. : lot number of QC product.

Expiry : validity period of QC product.

Group No. : 2-60, default is 20.

Number of samples in each group : 2-10, default is 5.

Save : select QC file, input lot No., validity period, and parameter target value and limits. Click the "Save" button to save QC data of current QC file. If this QC file has data, then update the data.

Delete : delete QC data of currently selected QC file.

Send : use instrument RS-232 serial port to transfer QC data of currently selected QC file to designated receiver. Before sending, please

connect BeneSphera™ Brand 3-Part Differential Hematology Analyzer to equipment to receive data with RS-232 serial port cable, start up and set up receiver software parameters. Please refer to Chapter 7, "System Settings", for information on setting the parameters for the instrument transfer terminal.

Help : to display system help.

Exit : return to main screen.

4.3.2 X-R QC Run

After setting the QC parameters of the QC file selected, you can begin analysis of the QC file. From the main screen, select the QC file; go to the QC run screen, as shown below:

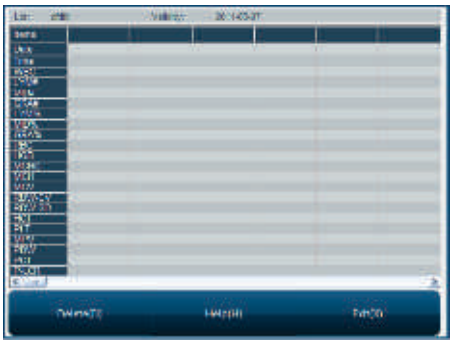


Fig. 4-11 X-R QC runs

1. With the QC sample ready and press the Aspiration key to start test, taking care to keep fingers and other body parts away from the moving needle.
2. After the test, the QC results will be shown in the column corresponding to the QC number. If there is fault alarm during the test, the test result may be inaccurate. Before performing the next text, you can select the test result then click the "Delete" shortcut key to delete this test result and eliminate the related fault.
3. You can save up to (group numbers preset in QC setting × number of samples in each group) QC results in each QC file. Press the "Exit" button to return to main screen.

4.3.3 X-R QC List

The instrument can look up X-R QC data by listing.

From the main screen, select QC file, and go to the QC list, as follows:

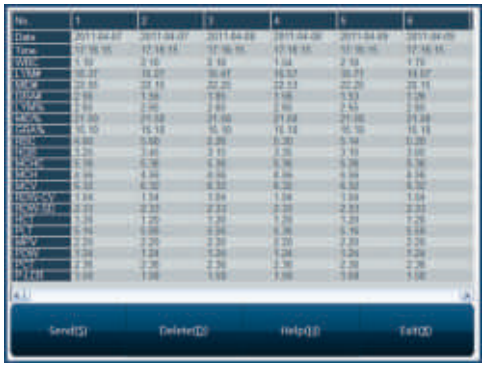


Fig. 4-12 X-RQC list

The instrument will display 20-parameter QC result.

Click "Send" button, to transfer some or all of the QC results to an external receiver. The operation method is the same as data transfer in Chapter 4.1.3, "L-J QC List".

Click the "Delete" button. The deletion confirmation dialog box appears. After confirmation, some or all QC data will be deleted.

4.3.4 X-R QC Chart

X-R QC chart can visually reflect the instrument's stability. When the instrument is controlled, data points in chart will be randomly distributed on both sides of centerline, and there will be just a few points near to the upper/lower control limits. The graphic screen is as follows:

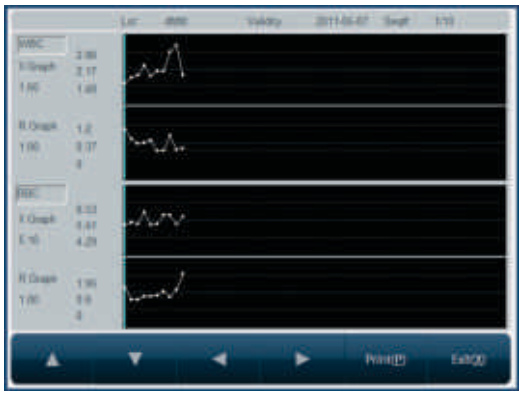


Fig. 4-13 X-R QC chart

Lot No. : lot number of QC object

Expiry : validity period of QC object

Seq#. : sequence number of current QC point

Each screen displays two-parameter QC data distributions. The QC chart of each parameter is composed of an X Graph and an R Graph, reflecting QC data mean and range fluctuation respectively. Three values on the left of X chart are, from top to bottom: $\overline{\overline{X}} + A_2\overline{R}$, $\overline{\overline{X}}$, $\overline{\overline{X}} - A_2\overline{R}$, respectively. Three values on the left of R chart are, from top to bottom: $D_4\overline{R}$, $\overline{R}$, $D_3\overline{R}$, respectively. Where, $\overline{\overline{X}} = \sum_{i=1}^{k} \overline{X_i} / K$; $\overline{X_i}$ is mean value of group I; $\overline{R} = \sum_{i=1}^{k} R_i / K$; R_i is the difference between maximum and minimum of group i; K is subgroup quantity; A_2, D_4, D_3 are coefficients determined by number of samples in each group.

Press "↓", "↑" keys on keyboard or frame to switch between parameters.

Press "←", "→" keys on keyboard or frame to display QC data of various data points.

Press "Print" button to print out the current group of QC data.

5. Calibration

Before delivery, all instruments are tested according to strict testing and calibration protocols. After transportation or usage, test results may drift due to different reasons. In order to ensure instrument test accuracy and stable and reliable test results, the instrument must be calibrated in the following situations:

1. First installation for use and reinstallation at another location.
2. Instrument has been repaired.
3. Deviations in QC results.

5.1 Preparation Before Calibration

Commercial controls, calibrators or a reference hematology instrument can be used to calibrate this instrument. All mathematic calculations related with calibration can be done by the instrument automatically, and the calibration coefficient is automatically saved.

The BeneSphera™ Brand 3-Part Differential Hematology Analyzer Instrument has three sets of calibration coefficients: anti-coagulating whole blood; anti-coagulating peripheral blood and pre-diluted peripheral blood.

Anti-coagulating whole blood, peripheral blood and pre-diluted peripheral blood are calibrated separately.

Prior to instrument calibration, you must check the performance of the instrument:

1. Check reagent status and be sure that instrument is in normal status.
2. Run blank tests to ensure that the blank test meets the specification.
3. In the counting screen, use a median blood sample to check the reproducibility and make sure that instrument reproduces according to the specifications.

5.2 Manual Calibration

In the "Main Menu" screen, select "Calibration" and then "Manual Calibration". The system goes to the manual calibration screen as shown below:

Fig. 5-1 Manual calibration

The manual calibration procedure is as follows:

1. Obtain reference values from the calibrator, control or human blood samples measured on a reference hematology instrument.
2. In "Sample Test" menu, use the calibration sample to test several times (at least three).
3. Record the tested data and compare with the reference values.
4. Calculate new calibration coefficient as per formula below:

$$\text{new\_calibration\_coefficient} = \frac{\text{current\_calibration\_coefficient x sample\_reference\_value}}{\text{mean\_of\_test\_values}}$$

5. From the "Manual Calibration" screen, input the new calibration coefficient for each parameter that needs calibration. Input the calibration date manually.
6. Click the "Save" button to save current calibration result. When the "Exit" button is used, the system will not save the newly calculated coefficients and will return directly to the main menu screen.

NOTE: If parameters other than those listed above have to be calibrated, the user should log in the Engineer Mode. A password is required to use this mode. See "Chapter 7.2.1, User Settings".

5.3 Auto-Calibration

When automatic calibration is selected, the instrument automatically calculates new calibration coefficients, after the calibration samples are measured. From the "Main Menu"

screen, select “Calibration” and then “Auto-Calibration”. The system goes to the auto-calibration screen as shown below in Figure 5-2:

Fig. 5-2 Auto-calibration

To begin, set up the calibration sample. Click the "Setting (T)" button to open the auto-calibration setting menu, see Figure 5-3.

Fig. 5-3 Auto-calibration setting

Lot No. : lot number or ID of calibration sample. When you input a number and save it, you can select from dropdown list on next logon.

Expiry : validity period of calibration sample. When the validity period is earlier than current system date, the instrument will provide an alarm alerting you to use another calibration sample to calibrate.

Sample Type : blood type of calibration sample.

Targets : reference value of each parameter of calibration sample.

Items : parameters to calibrate.

The "Delete" button is used to delete the current calibration sample settings. Click "OK" or "Save" to save current lot number data and exit. Click "Exit" button to return directly to the “Auto-Calibration” running screen.

After setup you will return to the “Auto-Calibration” screen as shown in Fig.5-2.

The process to start the auto-calibration is as follows:

1. Prepare the calibration sample and press Aspiration key to start the test.
2. After testing, the calibration result will be shown in the column that corresponds to the current test number.
3. Repeat test at least three times (the instrument allows a maximum of 20 runs).
4. The statistic results and new calibration coefficients will automatically be shown in the table below the parameter results.
5. Unsatisfactory or incomplete test data rows can be deleted at any time.

6. Results

After testing each sample, the system automatically saves the tested data. The BeneSphera™ Brand 3-Part Differential Hematology Analyzer instrument can store sample data for a maximum of 50,000 samples. The user can check, print, delete or modify stored data and histograms of all samples.

From the "Main Menu" screen, click the "RESULTS" button. The "History Data List" menu opens, as shown below:

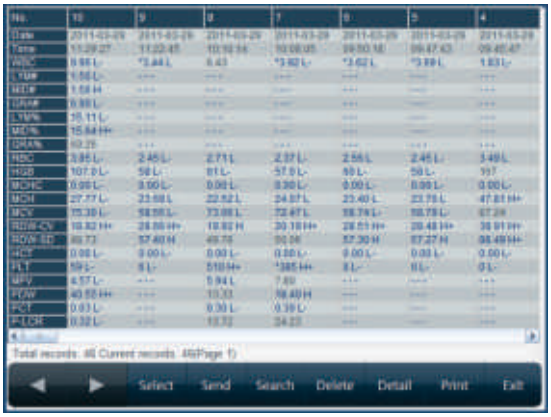


Fig. 6-1 History record list

"H", "L" or "H+", "L-" after parameter indicates that test result exceeds the upper or the lower limit of system setting parameter pathogenic value or normal value.

Parameters results with "- - -", indicates that result is beyond the test ranges, that a fault occurred during test or that the parameter is not measured at all.

If the history record number is higher than 500, you can click "<<-" and "->>" buttons to switch between data samples.

Select : Click the "Select" button to open the select dialog box:

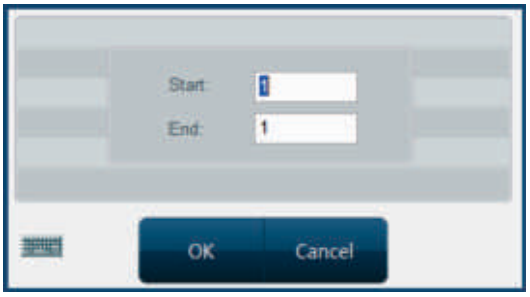


Fig. 6-2 Select dialog box

Input the record sequence numbers to choose the start and end number to select. Then click "OK" to select. If the same value is entered in the start and end box, the record shown corresponds to the number selected. By clicking the "Cancel" button, the system will not select or search any record.

Send : provides a data transfer function that sends selected data. Samples can be selected by using the select function or by using the mouse or touch pen, to select a single column. By using the keyboard Ctrl key or Shift key, you can select multiple columns. If no specific data is selected, all data can be sent. Click the "Send" button to open the transfer dialog box shown below. Select data to send and then click "Send (S)".

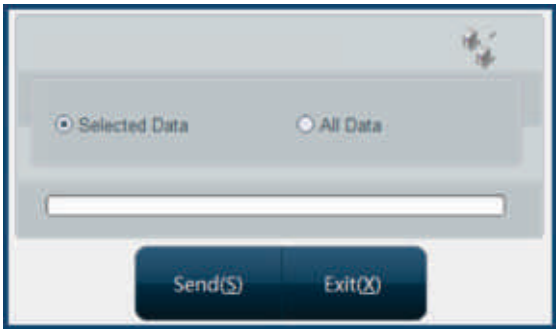


Fig. 6-3 Data transfer

Search

The search function allows a user to search a specific record according to specified search conditions. Click the "Search" button and the search dialog box opens:

Fig. 6-4 Search condition

Sample no. is the only identification of a historical data record. If you input a specific sample no., other search conditions are disabled. The user can use one or multiple conditions to search a data record. After entering search conditions, click "OK". If there is a matching data record, it will be shown in the history record list. If there is no match, the system will display a message indicating that there is no match.

Delete

The delete function can be used to delete selected data or all historical data. Samples can be selected by using the select function or by using the mouse or touch pen, to select a single column. By using the keyboard Ctrl key or Shift key, you can select multiple columns. If no specific data is selected, all data can be deleted.

Print

The print function prints the historical data selected, according to system setting print mode. See print setting explanation in Chapter 7, "System Settings".

Detail

The detail function is used to check detail data message of a certain sample. Select one record in the data history list and click the "Detail" button. The system will go to the "Sample Detail Message Review" menu as follows:

Fig. 6-5 Sample history data

This menu displays the sample data and message, parameter values and histograms. Click "Last (L)" or "Next (N)" buttons to change between samples.

In rare occasions WBC thresholds 2 and 3 may be placed incorrectly around the MID-Cell area, due to blood abnormalities. To adjust the WBC histogram thresholds 2 and 3, select the "misplaced" threshold (the color changes to dark blue) and use the left/right cursor keys on the keyboard to move them. After press the Adjust (J) button and select one of the options, as shown in Fig.6.

Fig.6-6 Threshold Adjustment

In the sample history data menu, click the "Print (P)" button to print out the sample listed. See "Chapter 7, System Settings", for information on adjusting the print settings.

7. System Settings

The "System Settings" menu is used to set up different system settings. From the main menu screen, click "Setting" to go to the "System Settings" menu:

Fig. 7-1 System settings

7.1 General Settings

Serial Number : instrument serial number, used to identify the instrument.

Time : input or use adjust bar on the right to modify the time settings. Always Save (S) after any change.

Language : used to switch between different system languages. If you wish to use a different language after next startup, please select the appropriate language and click save after any changes have been made.

Print settings

1. Printer: Select "Internal Printer" to use the internal thermal printer to print samples or system parameters. Select "External Printer" to use an external printer from the list. You also can select "Print Instantly".
   If "Print Instantly" is checked, test results automatically will be printed once the sample test ends.
2. Print items: click the "Set" button to open the print item setting menu where you can select the parameters that need to be printed. The system provides 3 templates for the user. To change printer settings for a particular printer, view Printer Properties.
3. Printout: The internal printer has two formats for printing with histogram or without histogram.
4. Hospital: The name entered here will be printed in every report title.

Special

1. Startup Blank Test: if checked, an automatic blank test will be performed after startup.
2. Clean Freq (times): input the test sample quantity, after which the instrument will perform an automatic cleaning. If it is set zero, the instrument will not execute an automatic cleaning.
3. Test Default Mode: default mode selected after startup.
4. Pre-diluted test mode inform: if this box is selected, the instrument will trigger an alarm before every pre-diluted peripheral blood test.
5. Transmit instantly: after the sample test, the result will be transferred to the computer by RS-232 serial port synchronously.
6. Standby time (min): if the instrument is idle for xx minutes, the instrument goes to standby.
7. Reagent Alarm: if Software is checked, the software will calculate the amount of reagents used. If Hardware is checked, the instrument checks the liquid levels using the individual reagent adapters.

7.2 Other Settings

By clicking the "Other" button, the next menu is shown:

Fig. 7-2 Other settings

7.2.1 User Settings

The system has different levels of users: common user, system administrator, and advanced user. The default setting is the common user, in which you will not have the ability to change certain settings. To enable these settings, please click the "Log on" button to open the logon dialog box:

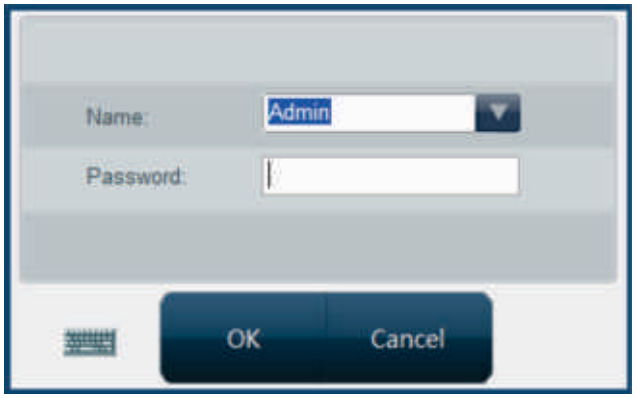


Fig. 7-3 Logon dialog box

Select "Admin", "Engineer", or "Factory". Enter the appropriate password and then click the "OK" button.

The "Admin" password is 1008. The “Engineering” and “Factory” passwords are available upon request from your distributor. If you're the system administrator, all functions in “Other Settings” screen are enabled (the buttons will be highlighted).

If you click the "Log off" button, the user identity will be changed to common user.

Fig. 7-4 Other settings

7.2.2 Normal Limits

Click "Normal Limits" button to open the “Limits Settings” menu:

Fig. 7-5 Normal limits value settings

General reference ranges for each parameter have been set prior to the delivery of the instrument. To modify any parameter reference ranges, you can select blood type and different population categories. Enter the lower and upper limits for single parameters. Click the "Save" button.

7.2.3 Pathologic Limits

When parameter values exceed the normal value ranges, this does not indicate that the patient results are abnormal. If it falls within the pathologic limits, this conclusion has to be made per case. Click "Pathologic Limits" button to open the settings menu:

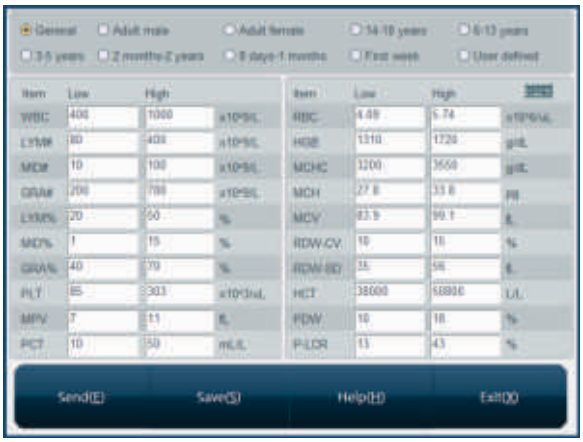


Fig. 7-6 Panic limits

General reference ranges for each parameter have been set prior to the delivery of the instrument. To modify any parameter reference ranges, you can select blood type and different population categories. Enter the lower and upper limits for single parameters. Click the "Save" button.

7.2.4 Units

To change any parameter units, click the "Units" button to view the units setting menu:

Fig. 7-7 Units settings

You can set parameters for 10 units. Note that WBC, LYM#, MID#, GRA# use the same unit. Select the desirable unit and click "OK" to save and exit. Click "Cancel" when no units have to be changed.

7.2.5 Communication

The communication setting is used to set up each parameter value for the serial port transfer interface. To check or modify these settings, click the "Communication" button to open the communication setting menu:

Instrument default values are: Baud rate: 115200; Data bits: 8; Parity: None; Stop bit: 1.

To modify any setting, click the dropdown box, select "Other Preset Values," and click the "OK" button.

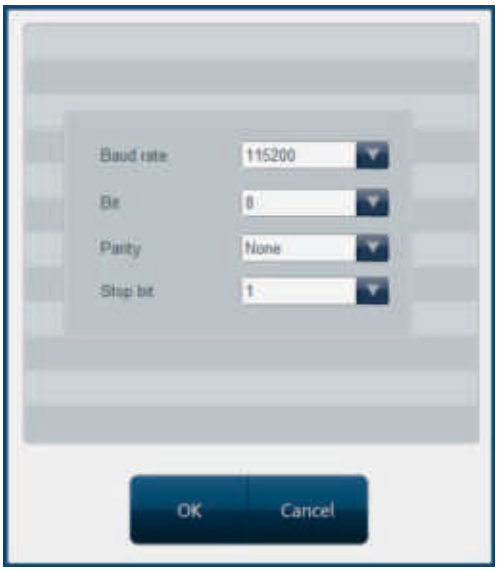


Fig. 7-8 Communication setting

7.2.6 Department Information

Department information is used to set up department information. Department information can speed up the patient results approval process. Click the "Dept. Info" button to open the department message menu:

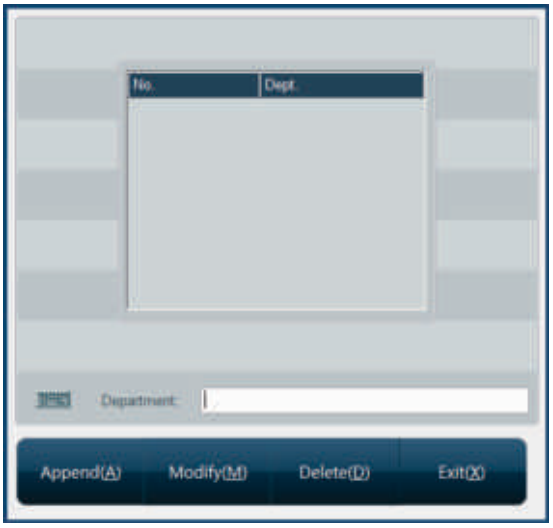


Fig. 7-9 Department information setting

1. Append (A): input a department name in the “Department” field and click the "Append" button. The inserted department name will be saved under a number.

2. Modify (M): select the row you want to modify, input new department name, then click the "Modify" button to update the info. If the input is blank, it will not update.
3. Delete: select one or several rows of data, then click the "Delete" button, confirm, and delete selected department name.
4. Exit: return to other setting frame.

7.2.7 Doctor Information

Doctor information is used to set up individual doctor data, which will be shown in the sample data entry. Click the "Doctor Info" button to open doctor information menu:

Fig. 7-10 Doctor setting

1. Append: enter the doctor's name in the name box and select department using the dropdown list (Set up department in department info field (see 7.2.6)). Then, check if the Doctor is Applicant, Inspector or Verifier.
2. Modify: select a data row you want to modify, input the doctor's new information and click "Modify" to update the doctor's information. If the input is blank, it will not update.
3. Delete: select one or several rows of data and click the "Delete" button. Confirm and the selected doctor will be deleted.
4. Exit: return to “Other Settings” menu.

8. System Information

System information provides relevant information about the system. Click the "System Info" button to go to the "System Info" menu:

Fig. 8-1 System Info

8.1 System Status

On "System Info" menu screen, click the "System Status" button to go to the "System Status" menu:

Fig. 8-2 System Info

The system monitors two test parameters now. If test values are out of the reference range, related troubleshooting is necessary.

8.2 System Log

The system log records main events and logs technical problems of the instrument during usage.

In the system info menu screen, click "Log" to go to system log messages:

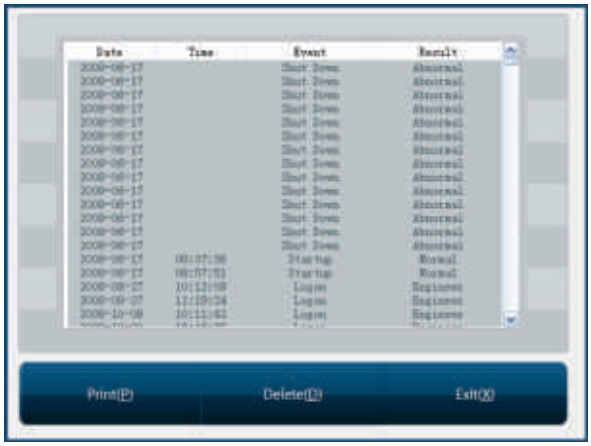


Fig. 8-3 System log

8.3 Statistic Information

Statistic information includes instrument run time and the number of samples tested. In the "System Info" screen, click "Statistic" to go to the "Statistic Information Menu":

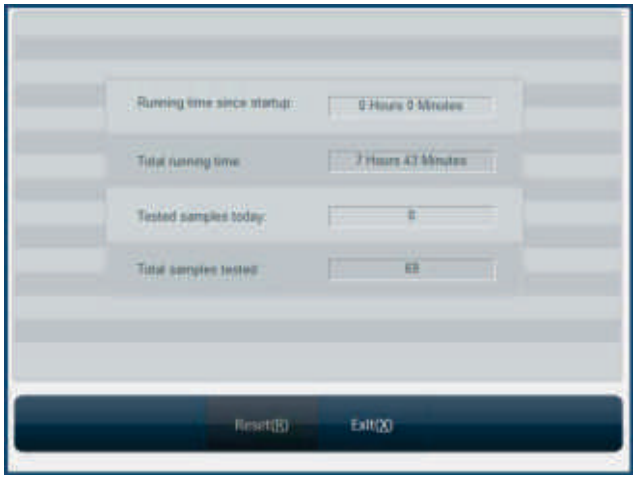


Fig. 8-4 Statistic information

9. Shutdown

After usage, you must run the shutdown program before turning off the instrument's power. During shutdown, the instrument will perform routine maintenance and rinse test tubing. From the main menu screen, click the "Shut down" button in the left bottom corner.

Fig. 9-1 Main menu screen

The system will ask for a confirmation:

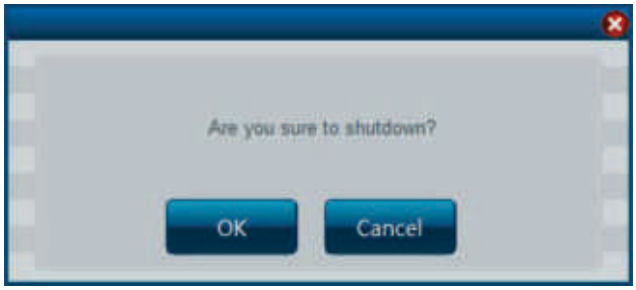


Fig. 9-2 Shut down confirmation

Click "OK" and the system will run the shutdown program. When finished, the instrument screen will display "Please power off." The instrument power now can be switched off.

	**CAUTION**: Avoid powering off without running the shutdown function.

10. Service

This instrument is a precise auto hematology analyzer. To ensure that the instrument continues to work effectively, it is essential that the periodic maintenance described below is performed. **Failure to perform the required maintenance can result in instrument failure and inaccurate results.**

	**CAUTION**: Please perform the maintenance operation according to user's manual and service manual; otherwise, damage to the instrument may occur.

	**BIOLOGICAL RISKS:** Consider all Specimens, Reagents, Calibrators, Controls, etc… that contain human blood or serum as potentially infectious! Use established, good laboratory working practices when handling specimens.

10.1 Routine Maintenance

10.1.1 Startup and Shutdown Process

At startup, the instrument will run mechanical checks and an automatic blank test (if selected in the "Settings" menu).

While running the shutdown operation, the daily shutdown maintenance is automatically performed. After powering off the instrument, just clean workbench and instrument surfaces.

10.1.2 Automatic Rinse

If the number of samples has reached the number preset by the user in the settings menu (clean frequency), the instrument will run the automatic rinse program. Rinsing can also be performed from the "Maintenance" menu.

10.1.3 Clean Instrument Surface

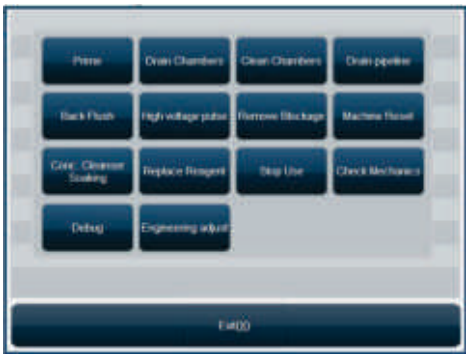
Keep instrument working environment clean.

Instrument surface can be cleaned with neutral detergent and wet cloth.

	**CAUTION**: Do not use any solvents, fatty or corrosive substances to clean the instrument covers.

10.2 Maintenance/Service Program

In the main menu screen, click the "Service" button to open the "Service" menu:



10.2.1 Prime

The system will prime the fluidic system automatically during sample test. If you have performed the drain operation or you replaced the reagent, you have to perform priming.

1. All reagents: diluent, lyse and cleanser will be primed into the fluidic system.
2. Diluent: diluent will be primed into the fluidic system.
3. Lyse solution: lyse solution will be primed into the fluidic system.
4. Cleanser: cleanser will be primed into the fluidic system.

10.2.2 Drain Chambers

Function to drain and empty the liquid from both the WBC and RBC chambers.

10.2.3 Clean Chambers

If the chamber has been contaminated or polluted or the blank test returns unacceptable results, use this function.

10.2.4 Drain Pipeline

Function to drain all fluids from the fluidic system and reagent lines.

10.2.5 Back Flush

Function to back flush the aperture holes, to remove any blockages or dirt from the aperture opening.

10.2.6 High Voltage Pulse

This burn function is to clean the aperture opening, by putting a high voltage over it.

	**ELECTRICAL RISKS:** RISK OF ELECTRICAL SHOCK AND DEATH. KEEP FINGERS AND OTHER BODY PARTS, AND ANY CONDUCTIVE MATERIALS, AWAY FROM THE APERTURE WHEN USING THIS FUNCTION.

10.2.7 Remove Blockage

Extended procedure to eliminate any blockage from the aperture opening.

10.2.8 Machine Reset

Function to home-position all motors from the instrument.

10.2.9 Concentrated Cleanser Soaking

Concentrated cleanser is an alkalescent wash solution. It is used for cleaning the fluidic system and counting chambers. When you select "concentrated cleanser soaking" in the "Service" menu, the system alarms alerts you to add cleanser manually into the chambers. You must perform this operation every three days or when high backgrounds occur.

10.2.10 Replace Reagent

The system will monitor the usage of reagents during usage of the instrument. When you are replacing the reagent, input the correct volume of the reagent. The system will record this volume and monitors the usage of reagents. When the remaining volume is not enough, that the system will provide a notification.

10.2.11 Stop Use

If the instrument will not be used for more than two weeks or it needs to be prepared for shipping, please perform the next steps:

1. In the "Service" menu, select "Stop Use" and complete all operations according to the instructions given by system. When the screen indicates that the instrument is ready to shut down, power off the instrument.
2. Close the remaining diluent, cleanser and lyse bottles and store as per reagent instructions.
3. When the instrument is prepared for shipping: clean the reagents adapters and place them in the accessory bag; place instrument in the plastic bag and place it in the packing carton box; include mouse and keyboard.

10.2.12 Check Mechanics

From the "Service" menu, click "Check Mechanics" button to open mechanical test menu:

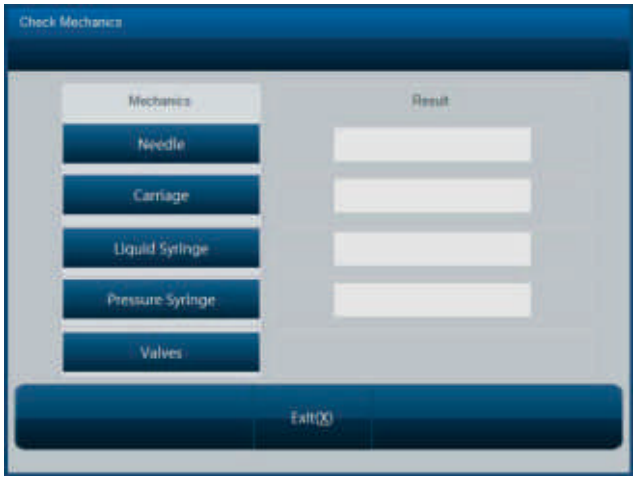


Fig. 10-2 Mechanical test

	**WARNING**: KEEP FINGERS AND OTHER BODY PARTS AWAY FROM ANY MOVING PARTS.

Click "Needle", "Carriage", "Liquid Syringe" or "Pressure Syringe" to test working condition of these components. The test results will be shown in the corresponding box on the right.

While the component is moving, carefully watch whether the component movement is smooth and uniform. If there is still an abnormality after repeated test, please contact your distributor or vendor.

Click the "Valves" button to open individual solenoid valve test screen:

Fig. 10-3 Solenoid valve test

The instrument has a total of 11 solenoid valves. You can test individual valves, or click the "All Valves" button to test them. Click the "Exit" button to return mechanical check screen. The function of each solenoid valve is as follows:

Valve 1 : Controls the dispensing of LYSE.

Valve 2 : Releases pressure from the pressure syringe; aspirate air (venting).

Valve 3 : Add CLEANSER to WBC counting bath.

Valve 4 : Drains waste from the waste chamber of pressure syringe to the waste bottle.

Valve 5 : It is activated when the WBC/RBC counting bath is counting and controls the negative pressure.

Valve 6 : Adds DILUENT into WBC counting bath.

Valve 7 : Drains the waste from the wash block when washing the sampling needle.

Valve 8 : Adds DILUENT into sampling needle wash block.

Valve 9 : Controls the dispensing of DILUENT.

Valve 10 : Drains WBC counting bath.

Valve 11 : Drains RBC counting bath.

10.2.13 Debug

The "Debug" menu is used to debug, test and check the hardware settings of the instrument. It is only accessible if you are logged in as an "Engineer" user.

10.2.14 Engineering Adjust

The "Engineering Adjust" menu contains important hardware system parameters. It is only accessible if you are logged in as an "Engineer" user. Changing these settings can have direct impact on test results, or functionality of the system.

	**CAUTION**: Engineers not trained by Avantor Performance Materials or authorized third parties are not advised to change settings in the"Debug" and "Engineering Adjust" menus. Improper settings can result in inaccurate test results.

11. Troubleshooting

This chapter describes common faults of instrument and their solutions. If these tips do not help eliminate the issues, or more detailed instructions are required, please contact the Avantor Performance Materials customer service department.

	**BIOLOGICAL RISKS:** Consider all specimens, reagents, calibrators, controls, etc. that containhuman blood or serum as potentially infectious! Use established, good laboratory working practices when handling specimens.
	**WARNING**: KEEP FINGERS AND OTHER BODY PARTS AWAY FROM ANY MOVING PARTS.
	**ELECTRICAL RISKS:** RISK OF ELECTRICAL SHOCK. KEEP FINGERS AND OTHER BODY PARTS, AND ANY CONDUCTIVE MATERIALS , AWAY FROM ANY ELECTRONIC PARTS DURING TROUBLESHOOTING.

Problem	Possible Solutions
1. Instrument cannot start	Check the power supply of instrument. Check if the power cord has been properly connected. Check the voltage from power supply. Turn off the instrument, restore power and turn on the instrument again.
2. No Diluent	Change diluent; perform the operation of Prime->Diluent in "Maintenance" menu.
3. No Cleanser	Change cleanser; perform the operation of Prime->Cleanser in the "Maintenance" menu.
4. No Lyse	Change lyse; perform the operation of Prime->Lyse in the "Maintenance" menu.
5. Waste bottle full	Empty the waste bottle
6. Temperature abnormal	Click "System Info" -> "System status" at main menu of software, check the environment temperature, if it is not in the range of 15C ~35C, adjust the environment temperature to this range
7. Blank value remains high	Check if the reagent has run out. Check if the reagent is contaminated and replace accordingly. Perform the operation of "Back Flush" at the maintenance menu. If this does not solve the problem, perform the "Concentrated cleanser soaking" procedure and repeat the Blank tests.
8. Blockage in Aperture	Perform the operation of "Remove Blockage" in the maintenance menu. If needed perform the operation of "Concentrated cleanser soaking". If this does not solve the problem, perform the operation "Burn" from the maintenance menu.
9. Air bubbles	Perform the operation of "Cleaning" in the maintenance menu. Check if the solenoids are working well. Check if the reagent tubings are well connected and check for any leakages inside the instrument.
10. Printer does not print	Check if there is paper in the printer. Check if the printer and instrument are well connected. Check the printer settings in the "Settings" menu.
11. Abnormal noise in the instrument	Open the two side doors of the instrument, check if an unexpected object is blocking the movement parts. If yes, remove that object. Check if the piston of the pressure syringe is out of the pump body. If so, restore the piston towards the pump body and push it back to the original position. If the problem persists, arrange for a service visit

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Paris, KY 9001:2008
Mexico City, Mexico 9001:2008
Deventer, the Netherlands 9001:2008, 14001:2004 & 13485:2003
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Avantor Performance Materials manufactures and markets high-performance chemistries and materials around the world under several respected brand names, including the J.T.Baker®, Macron Fine Chemicals™, Rankem™, BeneSphera™ and POCH™ brands.

Avantor products are used in a wide range of industries. Our biomedical and life science solutions are used in pharmaceutical production, laboratory research for academic, industry and quality control, and in medical lab testing. Our electronics materials products are used in the manufacturing of semiconductors.

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