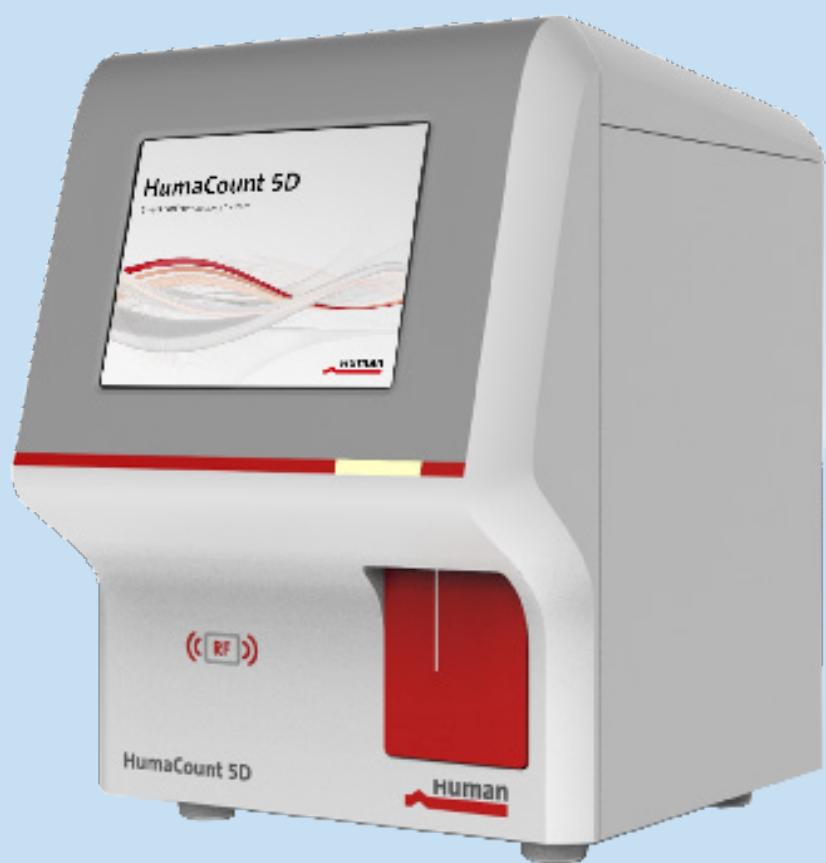


HumaCount 5D

| User Manual



CE

Cat No. 16450/1

Human

Diagnostics Worldwide

REVISION LIST OF THE MANUAL

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08/2019-10	Update of screenshots, new software version A13.2
09/2020-10	Update new instrument housing, small corrections
10/2021-03	Adjustment of Hazard- and Precautionary Statements

SYSTEM VERSION

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SERVICE AND SUPPORT

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1 SAFETY INSTRUCTIONS

1.1 Introduction

This manual is considered part of the instrument and must be available to the operator and the maintenance personnel. For accurate installation, use and maintenance, please read the following instructions carefully.

In order to avoid damage to the instrument or personal injury, carefully read the "GENERAL SAFETY WARNINGS", describing the appropriate operating procedures. Please contact your HUMAN authorised local Technical Service in the event of instrument failure or other difficulties with the instrument.

1.2 User Warranty

HUMAN warrants that instruments sold by one of its authorised representatives shall be free of any defect in material or workmanship, provided that this warranty shall apply only to defects which become apparent within one year from the date of delivery of the new instrument to the purchaser.

The HUMAN representative shall replace or repair any defective item within this warranty period at no charge, except for transportation expenses to the point of repair.

This warranty excludes the HUMAN representative from liability to replace any item considered as expendable in the course of normal usage, e.g.: lamps, valves, syringes, glassware, fuses, tubing etc.

The HUMAN representative shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer's instructions, altered in any way not specified by HUMAN, not regularly maintained, used with equipment not approved by HUMAN or used for purposes for which it was not designed.

1.3 Intended Use of the Instrument

The instrument must be used for its intended purpose (see paragraph 2). It must be operated in perfect technical conditions, by qualified personnel, in such working conditions and maintained as described in this manual, in the GENERAL SAFETY WARNINGS. This manual contains instructions for qualified professional operators.



1.4 General Safety Warnings

Use only chemical reagents and accessories specified and supplied by HUMAN and/or mentioned in this manual. Place the product so that it has proper ventilation.

The instrument should be installed on a flat, stationary working surface, that is free of vibrations.

Do not operate in area with excessive dust.

Operate at temperature and at a humidity level in accordance with the specifications listed in this manual, chapter 2.2.

Do not operate this instrument with covers and panels removed.

Use only the power cord specified for this product, with the grounding conductor of the power cord connected to earth ground.

Use only the fuse type and rating specified by the manufacturer for this instrument.

The use of fuses with improper ratings may pose electrical and fire hazards.

To avoid fire or shock hazard, observe all ratings and markings on the instrument.

Do not power the instrument in environments that are potentially explosive or at risk of fire.

Prior to cleaning and/or performing maintenance on the instrument, switch off the instrument and remove the power cord.

Only cleaning materials described in this manual may be used, as other materials may damage parts. It is recommended to always wear protective clothing and eye protection while using this instrument.

All warning symbols that appear in this manual must be carefully observed.

1.5 Disposal Management Concept

The applicable local regulations governing disposal must be observed. It is the user's responsibility to arrange for proper disposal of the individual components. All parts which may contain potentially infectious materials must be disinfected by suitable, validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal must be carefully observed. The instruments and electronic accessories (without batteries, power packs etc.) must be disposed of according to the applicable local regulations for the disposal of electronic components.

Batteries, power packs and similar power sources must be removed from electric/electronic parts and disposed of in accordance with applicable local regulations.

1.6 Biohazard Warning

Analytical instruments for in vitro diagnostic application involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious.

The "BIOHAZARD" warning label must be affixed to the instrument prior to first use with biological material!



FIGURE 1
Biological Hazard Symbol

1.7 Instrument Disinfection

Before performing any servicing on the instrument it is very important to thoroughly disinfect all possibly contaminated parts. Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. Decontamination must be performed by authorised well-trained personnel, and in observance of all necessary safety precautions.

1.8 Who Should Read This Manual of HumaCount 5D

This manual contains information written for clinical laboratory professionals to:

- Learn about the hardware and software of the analyzer.
- Customize system settings.
- Perform daily operations.
- Perform system maintenance and troubleshooting.

1.9 Special Symbols used in this Manual and on the Analyzer

When you see...	Then...
	Follow the instruction in the manual related to the symbol to avoid potential biocontamination.
	Follow the instruction in the manual related to the symbol to avoid personnel injury.
	Follow the instruction in the manual related to the symbol to avoid analyzer damage and failure, or unreliable analysis results.
! Note	Follow the instruction in the manual related to the symbol. The symbol highlight the important information in operating procedures that calls for special attention.
	Puncture Warning: The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.
	Laser Warning: This sign serves as a reminder of laser radiation.
When you see...	It means...
	Caution
	Biohazard
	Exercise caution to prevent puncture
	Laser radiation warning: It is Class 3R laser product with 5.0 mW maximum power output at 635 nm. Do not stare into the laser beam or view directly with optical instruments.
	Instruction for Moving
	Network interface

When you see...	It means...
	Protective grounding
	Alternating current (AC)
	For in vitro diagnosis only
	Lot No.
	Expiry date
	Serial No.
	European CE declaration of conformity
	Date of manufacture
	Manufacturer
	Storage temperature
	Humidity level for storage
	Atmospheric pressure level for storage
	Consult the operator's manual
	Avoid sunlight
	Keep dry
	No rolling
	No stacking
	Let this side face upward



Fragile, handle with care



Recyclable materials



The analyzer, after being scrapped, should not be disposed with other household garbage, instead, it should be collected and recycled following the disposal instructions for scrapped electronic and electrical equipment.

2 SYSTEM DESCRIPTION

2.1 Installation

The analyzer should only be installed by Human or its authorized agents. You need to provide the appropriate environment and space. When the analyzer needs to be relocated, please contact Human or your local agents. When you receive the analyzer, please notify Human or your local agent immediately.

2.2 Installation Requirements



WARNING

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



CAUTION

- Using a patch board may introduce electrical interference and generate incorrect analysis results. Please place the analyzer near the electrical outlet to avoid using the patch board.
- Please use the original electrical wires shipped with the analyzer. Using other electrical wires may damage the analyzer or generate incorrect analysis results.

Installation requirements for the analyzer are as follows.

Installation Environment	Requirements
Site	<ul style="list-style-type: none">- Level ground and stable workbench with load capacity ≥ 50 kg.- Free of dust, mechanical vibration, heat and wind sources, contamination, heavy-noise source or electrical interference.- Avoid direct sunlight and keep good ventilation.- It's recommended to evaluate the electromagnetic environment of the laboratory before operating the analyzer.- Keep the analyzer away from sources of strong electromagnetic interference, otherwise, its proper functioning may be affected.

TABLE 1

Space (In addition to the space required for the analyzer itself, set aside:)	<ul style="list-style-type: none"> - At least 50 cm from each side, which is the preferred access to perform service procedures. - At least 20 cm from the back for cabling and ventilation. - Enough room on and below the countertop to accommodate for the diluent and waste containers. - Place the analyzer near the electrical outlet and avoid being blocked by any objects, so that you can disconnect the power plug easily as required.
Temperature	15°C~30°C
Relative humidity	20%~85%
Operating atmospheric pressure	70kPa~106kPa
Ventilation	Keep air exchange to ensure good air circulation. The wind should not blow directly at the analyzer.
Power Requirements	AC110V~240V, Input Power ≤200VA, 50/60HZ.
Electromagnetic Wave	Keep the analyzer away from electric-brush motors, flashing fluorescent and electric-contact equipment which is switched on/off frequently.
Waste Disposal	Dispose of the waste as per the requirements of the local environment protection authorities.

2.3 Unpacking

Please unpack the analyzer by taking the following steps:

1. Open the outer packing box; take out the accessory pack; take out the analyzer together with the protective and cushioning materials.
2. Remove the foam and the protective PE bag.
3. Open the right door (open the linear-shaped cam lock on the right door with a slotted screwdriver).
4. Remove the binder clips, which are used for fixating two conveyor belts. To avoid the possible collision resulting from the slippage caused by shaking and slanting during transportation, the central position of those two belts is fixated with binder clips before they are shipped from the factory. The binder clips must be removed during unpacking.
5. Remove the binder clips, which are used for fixating sampling assembly. To avoid damage during the transportation, the sampling assembly of the analyzer is fixated with clamps. Do remove the clamps before using the analyzer.

2.4 Introduction

The HumaCount 5D is a quantitative, automated hematology analyzer and 5-part differential counter used in clinical laboratories. This section describes in details the intended use, measurement parameters, structure, user interface and compatible reagents of the analyzer.

2.5 Who Should Read This Manual

It is intended for blood cell counting, 5-part classification of white blood cell and hemoglobin concentration measurement in clinical examinations.

The analyzer is intended for screening in the clinical examination. When making clinical judgment based on the analysis results, the doctors should also take into consideration the clinical examination results or other test results.

2.6 Structure of the Analyzer



WARNING

- Please check the firmness of all the doors, covers and boards before running the analyzer.
- The analyzer is heavy, so moving by one person alone may cause injury. It is advisable for two people to move it together when the transportation is necessary, and make sure you follow the instructions and use the proper tools.
- Connect only to a properly grounded outlet.
- To avoid electrical shocks, disconnect the power supply before opening the cover.
- To prevent fire, use the fuses with specified model number and working current. The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it. This sign warns of laser radiation. Do not look directly at the laser beams or see through the optical instrument.



- The sampling probe is sharp and may contain biohazardous materials. Special care should be taken when working with it.
- This sign warns of laser radiation. Do not look directly at the laser beams or see through the optical instrument.



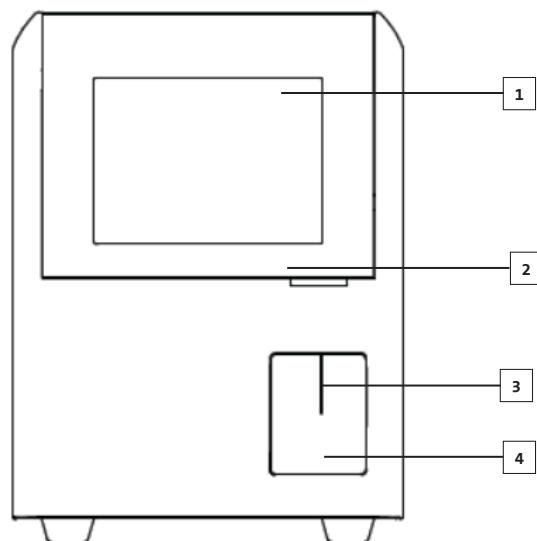
2.6.1 MAIN UNIT

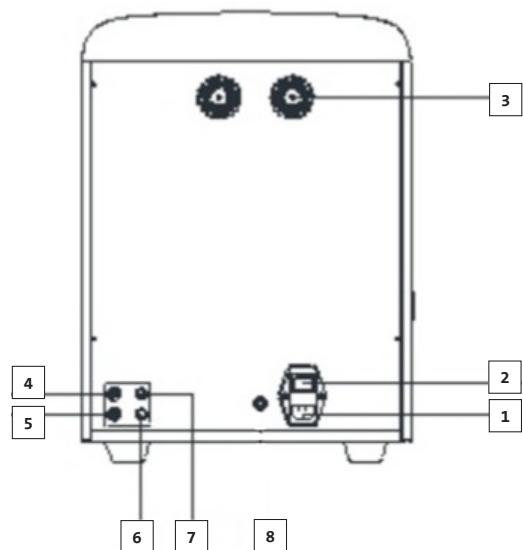
The Hematology Analyzer consists of the main unit (analyzer) and accessories. The main unit is for analysis and data processing.

FIGURE 2

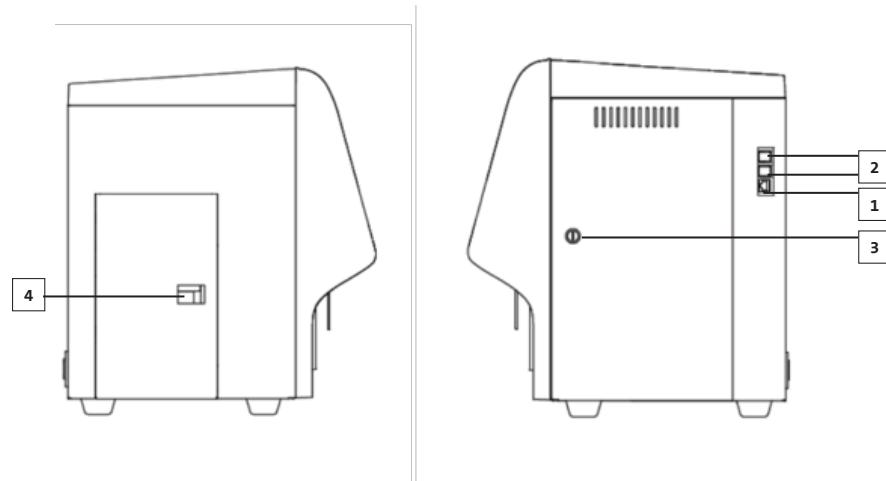
Front of the analyzer

- 1 Touch screen
- 2 Power/Status indicator
- 3 Sample probe
- 4 Aspirate key



**FIGURE 3**

Back of the analyzer

**FIGURE 4**

Side views of the analyzer

2.6.2 TOUCH SCREEN

The touch screen is located on the front side of the analyzer for performing interface operations and displaying the information.

2.6.3 ASPIRATE KEY

The aspirate key is located in the middle of the front side (behind the sample probe). With this switch, one starts the sample analysis, adds diluents, or cancels sleep.

2.6.4 POWER/STATUS INDICATOR

The status indicator is located in the middle section of the analyzer (front side). It shows the status of the analyzer including the following status, ready, running, error, sleep and on/off, etc.

The indicators change with the status of the main unit. Details are shown in Table 2.

TABLE 2
Main Unit Status Indicators

Instrument Status	Indicator Status	Remarks
Shutdown	Off	The main unit has been shut down.
Stopped running with error conditions	Red light on	Stopped running with the occurrence of errors
Running with error conditions	Red light flickering	Running with the occurrence of errors
Time sequence deactivated	Yellow light on	Initialization or sleep status irrelevant to running
Running	Green light flickering	Execution of the sequence actions is in process.
Ready	Green light on	Execution of the sequence actions is allowed.

While the analyzer is running, if the status indicator turns dim or off, please contact Human or Human's agent for maintenance.

2.6.5 POWER SWITCH



CAUTION

- To avoid damage, do not power on/off the analyzer repetitively within a short time.
- A power switch is located in the bottom back of the analyzer. It turns on or shuts down the analyzer. Please use shut down button of the software to turn off the analyzer.

2.6.6 USB INTERFACE

The USB interface is located on the right side of the main unit. There are 4 interfaces in total for external equipment (printer, barcode reader, mouse or keyboard, usb flash disk) connection or data transmission.

2.6.7 NETWORK INTERFACE

The network interface is located on the right side of the main unit. There is 1 network interface in total for connecting with the Ethernet.

2.6.8 EXTERNAL EQUIPMENT (OPTIONAL)

The analyzer can be connected with the following external equipment:

- **Keyboard**

The keyboard is connected with the USB interface on the right side of the analyzer for controlling the analyzer.

- **Mouse**

The mouse is connected with the USB interface on the right side of the analyzer for operations on the analyzer.

- **Printer**

The printer is connected with the USB interface on the right side of the analyzer for printing reports and other information displayed on the screen.

- **Barcode Reader**

The barcode reader is connected with the USB interface on the right side of the analyzer for entering barcode information in an easy and fast way.

- **USB flash disk**

The USB flash disk is connected with the USB interface on the right side of the analyzer for exporting sample data.

2.7 Accessories

2.7.1 SCOPE OF SUPPLY

HumaCount 5D Hematology analyzer	1	16450
User Manual	1	16450/1
Quick Guide HumaCount 5D	1	16450/5-1
Quick Guide Capillary Blood Mode	1	16450/5-2
Reagent Operation Guide	1	16450/5-3
Peripheral grounding cable	1	
Diluent Adapter tube	1	
Waste Float Adapter tube	1	
Waste Container	1	
Power Cable	1	
Data Cable	1	

2.7.2 OPTIONAL ACCESSORIES

2D Barcode Scanner	16430/11
Laser Printer	18993L

3 ROUTINE UTILIZATION AND MEASUREMENT

3.1 Working Principle

3.1.1 INTRODUCTION

The measurement methods used in this analyzer are: the electrical Impedance method for determining the RBC and PLT related parameters; the colorimetric method for determining the HGB; laser-based flow cytometry for determining the WBC related parameters. During each analysis cycle, the sample is aspirated, diluted and mixed before the determination for each parameter is performed.

3.1.2 ASPIRATION

The analyzer supports Whole Blood mode (including **Venous Whole Blood** and **Capillary Tube Auto-Dispense**) and Predilute mode. In Whole Blood mode, the analyzer will aspirate quantitative whole blood sample. In Predilute mode, the analyzer will aspirate the prediluted sample (with the dilution ratio of 1:25) which is a mixture of 20 μ l of whole blood/capillary blood sample and 480 μ l of diluent the diluted sample thus prepared is then delivered to the analyzer for sampling and aspiration.

In Capillary Tube Auto-Dispense mode, the analyzer will first dispense 480 μ l of diluent into a bullet tube. Afterwards an EDTA coated capillary filled with 20 μ l capillary blood is placed into the bullet tube and mixed carefully until the suspension is homogenous (dilution ration 1:25). The diluted capillary blood sample is then delivered to the analyzer for aspiration.

3.1.3 DILUTION

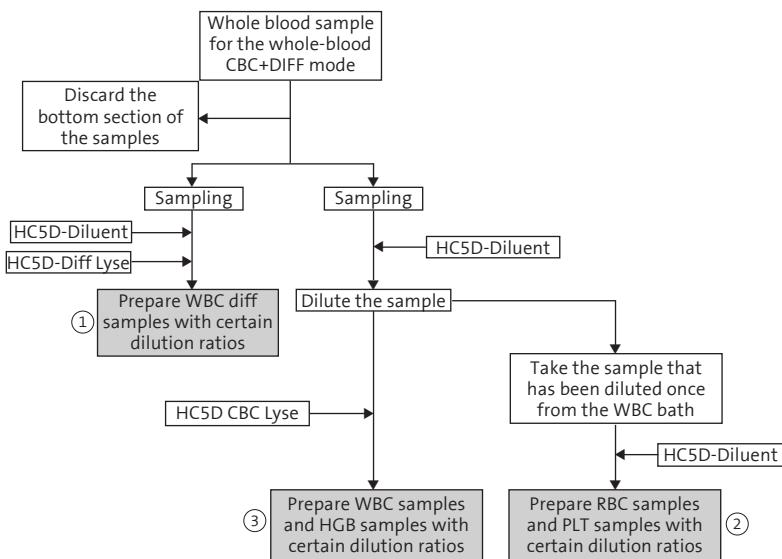
After being aspirated into the analyzer, the sample is divided into two parts. After the reaction with reagents in parallel dilution procedures, each part forms the sample for red blood cell/platelet, white blood cell count/hemoglobin measurement and white blood cell differential measurement. To meet different needs, the analyzer offers two working modes (Whole Blood and Predilute), and two measurement modes (CBC and CBC+DIFF). Taking CBC+DIFF mode as an example, this section introduces the dilution procedures of the test sample in Whole Blood mode and Predilute mode separately. (The dilution procedure in CBC mode is not introduced here since it's the same as that in CBC+DIFF mode.)

! Note: CBC mode, namely complete blood cell count, is intended for counting only, not for white blood cell classification. CBC+DIFF mode is intended for both counting and white blood cell classification.

3.1.3.1 Dilution Procedure in Whole-blood CBC+DIFF Mode

Dilution Procedures in Whole-Blood CBC+DIFF Mode are shown in Figure 5.

FIGURE 5
Dilution Procedure in
Whole-blood CBC+DIFF Mode

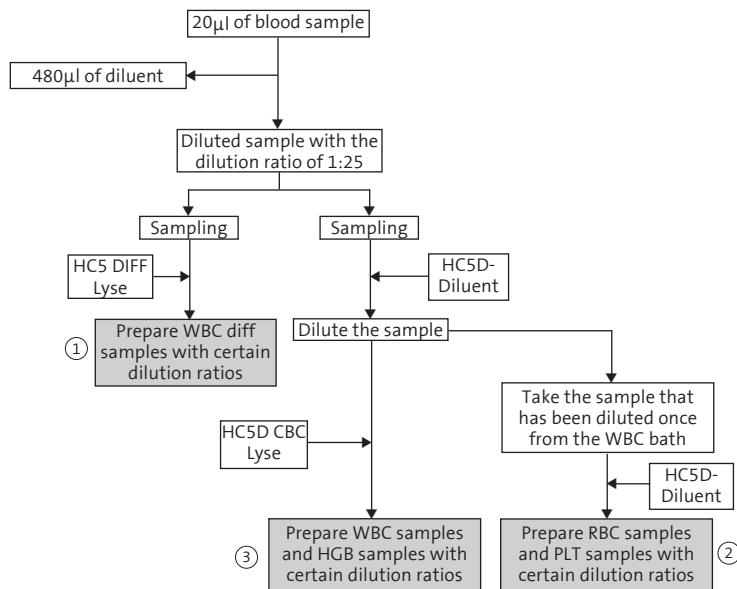


The figure shows the steps of:

1. Dilution procedure for white blood cell diff; namely DIFF.
2. Dilution procedure for red blood cell and platelet.
3. The dilution procedure for white blood cell count/hemoglobin; namely CBC.

3.1.4 DILUTION PROCEDURE IN PREDILUTE CBC+DIFF MODE

In CBC+DIFF mode, the dilution procedure for the prediluted sample is shown in Figure 6. The analyzer dispenses 480 µl HC5D-Diluent via the sample probe to an Eppendorf cuvette. Please put the 20 µl of blood into the dispensed Eppendorf cuvette and mix the sample carefully until you get a completely homogeneous sample.

**FIGURE 6**

Dilution Procedure in Predilute CBC+DIFF Mode

The figure shows the steps of:

1. The dilution procedure for white blood cell diff; namely DIFF.
2. The dilution procedure for red blood cell and platelet.
3. The dilution procedure for white blood cell count/hemoglobin; namely CBC.

3.1.5 FLUSHING

After each analysis cycle, each component of the analyzer is flushed.

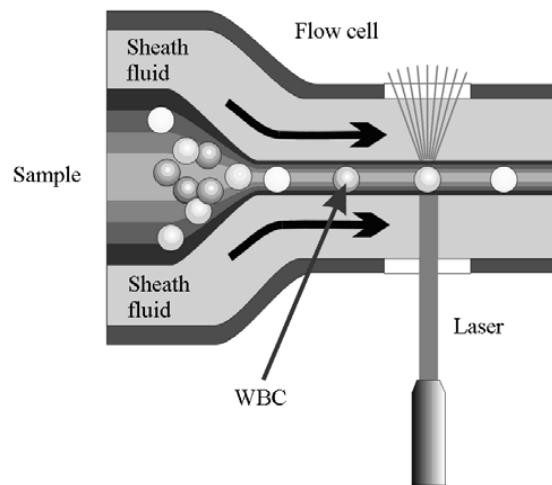
3.1.6 WBC MEASUREMENT

The analyzer obtains the white blood cell 5-part classification results and white blood cell count/basophils count using a semiconductor-laser-based flow cytometry and eventually calculates the parameters relevant to white blood cells.

3.1.6.1 Working Principle of Laser-based Flow Cytometry

The principle of laser-based flow cytometry is illustrated by Figure 7.

FIGURE 7
WBC Measurement



After a predetermined volume of blood is aspirated and diluted by a certain amount of reagent, it is injected into the flow chamber. Surrounded with sheath fluid (diluent), the blood cells pass through the centre of the flow chamber in a single column at a faster speed. When the blood cells suspended in the diluent pass through the flow chamber, they are exposed to a laser beam.

The intensity of scattered light reflects the blood cell size and intracellular density. The low-angle scattered light reflects cell size, while the high-angle scattered light reflects intracellular density (nucleus size and density). The optical detector receives this scattered light and converts it into electrical pulses. Pulse data thus collected can be used to draw four 2-dimensional distributions (scattergrams) as shown in Figure 8.

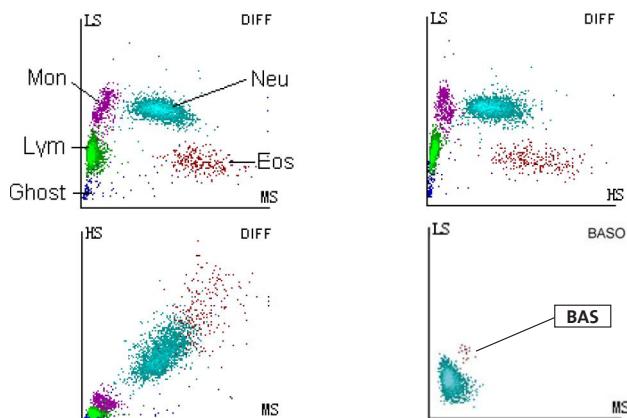


FIGURE 8
DIFF channel scattergram

The above figure shows the detection of white blood cells (WBCs) using dual channel scattergrams. Three-angle laser scatter technology and flow cytometry is used for counting and classification of various kinds of WBCs in different channels. The abbreviation for the low angle scatter channel is LS. MS means Medium angle scatter channel and HS stands for High angle scatter channel. By analysing the DIFF channel scattergram, the analyzer presents the LYM%, MON%, EOS% and NEU%. The independent WBC/BAS channel is using a specific kind of hemolytic agent that can extract the Basophil cell specificity, so as to reserve the complete information of Basophils.

After the lyse process, monocytes will be larger in size compared to lymphocytes. Therefore the monocyte population will be found above the lymphocyte population when looking at the LS axis. Eosinophils and neutrophils are more complex than lymphocytes, therefore these populations will give an increased signal in the high angle scatter and appear on the right side of the HS-axis. Atypical lymphocytes (ALY) are bigger than lymphocytes but smaller than monocytes. Therefore this population can be found between LYM and MON. The size of large immature cells (LIC) is much bigger compared to NEU, so this population gives a much stronger LS signal and can be clearly discriminated from the other cell populations.

3.1.6.2 Derivation of WBC-Related Parameters

Based on the DIFF scattergram and the analysis for the Lym zone, Neu zone, Mon zone, Eos zone, Aly zone and Lic zone the analyzer can get the percentage of lymphocytes (LYM%), the percentage of neutrophils (NEU%), the percentage of monocytes (MON%) the percentage of eosinophils (EOS%), as well as Atypical Lymphocytes (ALY%) and Large Immature Cells (LIC%) and then get the number of basophils (BAS#), the number of lymphocytes (LYM#), the number of neutrophils (NEU#), the number of monocytes (Mon#) the number of eosinophils (EOS#), the number of atypical lymphocytes (ALY#) and the number of large immature cells (LIC#) based on the calculation with the white blood cell count obtained with the working principle of laser-based flow cytometry. The unit of the number of cells is $10^9/l$.

- White Blood Cell count
WBC count is the number of leukocytes measured directly by counting the leucocytes passing through the flow chamber

- Number of Basophils (Bas#)
Bas# is the number of Basophils measured directly by counting the basophils passing through the flow chamber

- Percentage of Basophils (BAS%)

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

- Percentage of Lymphocytes (Lym%)

$$\text{Lym\%} = \frac{\text{Particles in Lym region of DIFF channel}}{\text{Sum of all particles in DIFF channel except those-Ghost region}} \times 100\%$$

- Percentage of Neutrophils (Neu%)

$$\text{Neu\%} = \frac{\text{Particles in Neu region of DIFF channel}}{\text{Sum of all particles in DIFF channel except those Ghost region}} \times 100\%$$

- Percentage of Monocytes (Mon%)

$$\text{Mon\%} = \frac{\text{Particles in Mon region of DIFF channel}}{\text{Sum of all particles in DIFF channel except those Ghost region}} \times 100\%$$

- Percentage of Eosinophils (EOS%)

$$\text{Eos\%} = \frac{\text{Particles in Eos region of DIFF channel}}{\text{Sum of all particles in DIFF channel except those Ghost region}} \times 100\%$$

- Percentage of Atypical Lymphocyte

$$\text{ALY\%} = \frac{\text{The number of granules which fall on ALY field (in DIFF channel)}}{\text{The total number of all granules except Ghost (in DIFF channel)}} \times 100\%$$

Note: ALY field locate in upper corner to LYM field

- Percentage of Large Immature Cells

$$\text{LIC\%} = \frac{\text{The number of granules which fall on ALY field (in DIFF channel)}}{\text{The total number of all granules except Ghost (in DIFF channel)}} \times 100\%$$

Note: LIC field located just above the horizontal line of NEU field and this horizontal line was drawn according to the granule shape of rear LS Axis.

- Number of lymphocytes (Lym#)
Lym#= WBC x Lym%
- Number of Neutrophils (Neu#)
Neu#= WBC x Neu%
- Number of Monocytes (Mon#)
Mon# = WBC x Mon%
- Number of Eosinophils (EOS#)
Eos# = WBC x Eos%
- Number of Atypical Lymphocytes
ALY# = WBC x ALY%
- Number of Large Immature Cells
LIC# = WBC x LIC%

3.1.7 HGB MEASUREMENT

HGB is determined by the colorimetric method.

3.1.7.1 Colorimetric Method

The WBC/HGB diluent is delivered to the HGB bath where it is mixed with a certain amount of lyse, which converts hemoglobin to a hemoglobin complex that is measurable at 525 nm. An LED is mounted on one side of the bath and emits a beam of monochromatic light with a central wavelength of 525 nm. The light passes through the sample and is then measured by an optical sensor mounted on the opposite side. The signal is then amplified and the voltage is measured and compared with the blank reference reading (readings taken when there is only diluent in the bath).

3.1.8 HGB

The HGB is calculated using the following equation and expressed in g/l.

$$\text{HGB (g/l)} = \text{Constant} \times \ln \left(\frac{\text{Blank Photocurrent}}{\text{Sample Photocurrent}} \right)$$

3.1.9 RBC/PLT Measurement

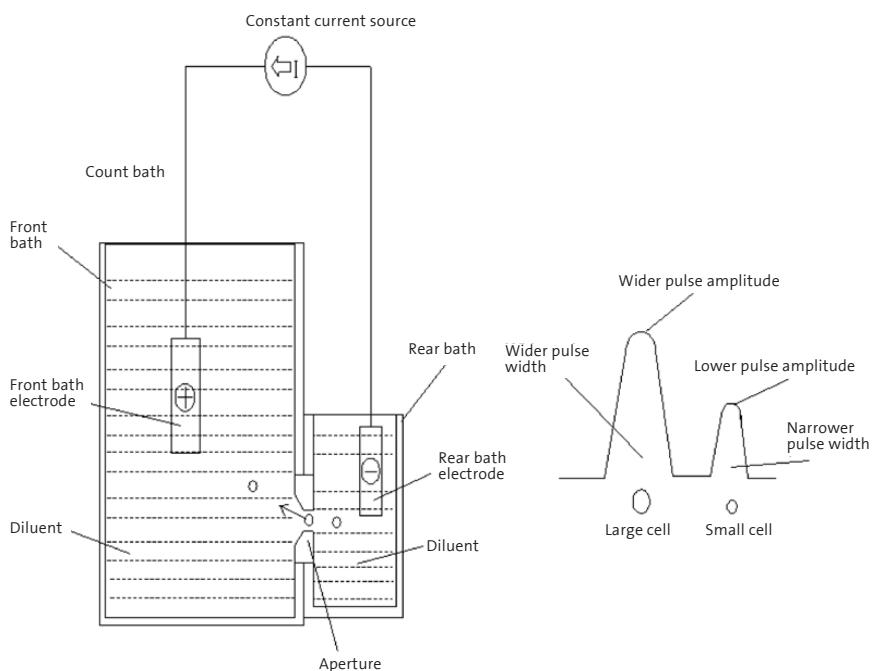
The analyzer detects the red blood cell count and platelet count and their volume distribution by impedance method and determines the results of related parameters.

3.1.9.1 Electrical Impedance Method

RBCs/PLTs are counted and sized by the Electrical Impedance method. This method is based on the measurement of changes in electrical resistance produced by a particle, which in this case is a blood cell, suspended in a conductive diluent as it passes through an aperture of known dimensions.

An electrode is submerged in the liquid on both sides of the aperture to create an electrical pathway. As each particle passes through the aperture, a transitory change in the resistance between the electrodes is produced. This change produces a measurable electrical pulse. The number of pulses thus generated is equal to the number of particles that passed through the aperture.

FIGURE 9
Electrical Impedance method



Each pulse is amplified and compared to the internal reference voltage channel, which only accepts the pulses of a certain amplitude. If the pulse generated is above the RBC/PLT lower threshold value, it is counted as a RBC/PLT. The analyzer presents the RBC/PLT histogram, where the x-coordinate represents the cell volume (fl) and the y-coordinate represents the number of the cells.

3.1.9.2 RBC

- **Red Blood Cell count**

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

- **Mean Corpuscular Volume (MCV)**

Based on the RBC histogram, this analyzer calculates the MCV and expresses the result in fl.

- **Hematocrit (HCT), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC)**

This analyzer calculates the HCT (%), MCH (pg) and MCHC (g/l) as follows, where the RBC is expressed in $10^{12}/l$, MCV in fl and HGB in g/l.

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

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

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

- **Red Blood Cell Distribution Width - Coefficient of Variation (RDW-CV)**

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

- **Red Blood Cell Distribution Width - Standard Deviation (RDW-SD)**

RDW-SD (RBC Distribution Width – Standard Deviation, fl) is obtained by calculating the standard deviation of the red blood cell size distribution.

3.1.9.3 PLT

- **Platelet count**

PLT is measured directly by counting the platelets passing through the aperture.

- **Mean Platelet Volume (MPV, fl)**

Based on the PLT histogram, this analyzer calculates the MPV.

- **Platelet Distribution Width (PDW) or PDWcv**

The PDW is the distribution width of the platelets. It is determined at the 20% level of peak height of the histogram

- **Plateletcrit (PCT)**

This analyzer calculates the PCT as follows and expresses it in %, where the PLT is expressed in $10^9/l$ and the MPV in fl.

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

3.1.10 MEASUREMENT PARAMETERS

The analyzer performs sample analysis for different parameters according to different measurement modes (CBC or CBC+DIFF).

- In CBC+DIFF mode, the analyzer provides quantitative analysis results for 29 parameters (including 23 hematology parameters and 6 research parameters), 3 histograms, and 4 DIFF scattergrams (including one BASO scattergram and three DIFF scattergrams).
- In CBC mode, the analyzer provides quantitative analysis results for 13 hematology parameters, 3 histograms, and one BASO scattergram.

Refer to the table below for the detailed parameters of HumaCount 5D.

TABLE 3

Type	Parameter Name	Abbreviation	CBC	CBC+DIFF
WBC (15 items)	White Blood Cell count	WBC	*	*
	Percentage of Neutrophils	Neu%	/	*
	Percentage of Lymphocytes	Lym%	/	*
	Percentage of Monocytes	Mon%	/	*
	Percentage of Eosinophils	Eos%	/	*
	Percentage of Basophils	Bas%	/	*
	Number of Neutrophils	Neu#	/	*
	Number of Lymphocytes	Lym#	/	*
	Number of Monocytes	Mon#	/	*
	Number of Eosinophils	Eos#	/	*
	Number of Basophils	Bas#	/	*
	Percentage of Abnormal Lymphocytes	ALY% (RUO)	/	*
	Percentage of Large Immature Cells	LIC% (RUO)	/	*
	Number of Abnormal Lymphocytes	ALY# (RUO)	/	*
	Number of Large Immature Cells	LIC# (RUO)	/	*
RBC (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	*	*

PLT	Platelet count	PLT	*	*
(4 or 6 items)	Mean Platelet Volume	MPV	*	*
	Platelet Distribution Width	PDW	*	*
	Plateletcrit	PCT	*	*
	Platelet-large cell ratio	P-LCR	*	*
	Platelet-large cell count	P-LCC	*	*
Histogram	White Blood Cell Histogram	WBC Histogram	*	*
(3 items)	Red Blood Cell Histogram	RBC Histogram	*	*
	Platelet Histogram	PLT Histogram	*	*
Scattergram	Differential Scattergram	DIFF Scattergram	/	*
	Basophils Scattergram	BASO Scattergram	*	*

- ! - “**” means the parameter is provided in the mode. “/” means the parameter is not provided.
- ALY%, LIC%, ALY#, P-LCC, P-CCR and LIC# are parameters for research use only (RUO), not for diagnostic use.

3.1.11 USER INTERFACE OF HUMACOUNT 5D

After the startup procedure, you will enter the user interface (**Sample Analysis** as default screen). See Figure 10.



FIGURE 10

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

- **Menu navigation area**
On the top of the screen is the menu navigation area. Once a menu button is pressed, the system goes immediately to the corresponding screen.
- **Menu content display area**
It displays the selected screen and the corresponding function buttons.
- **Error message area**
Upon the occurrence of a system failure, the corresponding error message will appear in this area. When there is more than one failure, the error message for the latest failure will appear in this area. Click in this area, you can deal with the failures in the pop-up dialogue box of troubleshooting help. For more information, see chapter 11 *Troubleshooting*.
- **Status display area**
On the lower left of the screen is the status display area where the connection status between the analyzer and the LIS system and printer status are displayed from left to right. The icons change with the status of the main unit, as shown in Table 4.

TABLE 4
Status Icon Description

Status	Icon	Remarks
LIS/HIS status	Grey icon	 The computer is not connected to the LIS/HIS.
	Black icon	 The computer is connected to the LIS/HIS.
Print status	Grey icon	 The external printer is not connected to the analyzer.
	Colour icon	 The external printer is connected to the analyzer.

- **Information area of the next sample**
This area displays the information about the sample ID, sample position, blood mode (whole blood/prediluted blood) and measurement mode (CBC/CBC+DIFF) of the next sample.
- **Current user, date and time**

3.1.11.1 System Reagents

The following reagents are intended to be used with the analyzer for 5-part diff counting, daily cleaning and other operations.

- **HC5D-Diluent (Ref.: 16450/10)**

This product is intended for sample dilution and preparation of cell suspension before running the samples.

The diluent is a solution with certain ion strength and conductivity, which can dilute the blood and form the sheath flow, providing a stable environment for blood cell counting.

Ingredients:

Sodium Chloride, Sodium Sulfate, Buffering agent; Antifungal and antibacterial agents.

Storage and Stability:

HC5D Diluent will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer:

Applicable to the HumaCount 5D hematology analyzers.

How to Use:

Restore HC5D-Diluent to the use temperature, unpack the reagent, insert the corresponding catheter to the diluent barrel according to the colour correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the blank determination to make sure that the measured value is within the blank counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Specifications:

The product should be clear liquid without particles, sediment and flocs.

Background result: WBC \leq 0.2x10⁹/l

RBC \leq 0.2x10¹²/l

HGB \leq 1g/l

PLT \leq 10x10⁹/l

Precautions:

- Do not inhale. In case of inhaling, immediately go see a doctor. Avoid skin or eye contact. In case of skin contact, flush the affected area with plenty of water immediately. In case of eye contact, flush the affected area with plenty of water immediately and go see a doctor.
- Use HC5D-Diluent before the expiration date.
- If product is frozen (either partially or completely), thaw completely, warm to room temperature and mix thoroughly by gentle inversion. Verify background results before analysing patient samples.
- Dispose of reagents, waste and consumables according to government regulations.
- Test result may be unreliable if:
 - Reagent is expired or invalid
 - Reagent is polluted with dust from the air
 - Sample is not processed cleanly
 - Reagent is mixed or used with third party reagents.

- HC5D CBC Lyse (Ref.: 16450/20)

This product is intended for lysing the red blood cells and white blood cell classification.

The HC5D CBC Lyse is added to lyse the red blood cells (RBC) and react with the released hemoglobin (HGB) for the measurement of HGB, white blood cell count (WBC) and Basophils (BAS).

Ingredients:

Surface active agent; Buffering agent; Antifungal and antibacterial agents.

Storage and Stability:

The HC5D CBC Lyse will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer:

Applicable to the HumaCount 5D hematology analyzers.

How to Use:

Restore HC5D CBC Lyse to the use temperature, unpack the reagent, insert the corresponding catheter to the diluent barrel according to the colour correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the blank determination to make sure that the measured value is within the blank counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Specifications:

The product should be clear liquid without particles, precipitate or floccule.

Background result: WBC \leq 0.2x10⁹/l
 HGB \leq 1g/l

Precautions:

- Do not inhale. In case of inhaling, immediately go see a doctor. Avoid skin or eye contact. In case of skin contact, flush the affected area with plenty of water immediately. In case of eye contact, flush the affected area with plenty of water immediately and go see a doctor.
- Use HC5D CBC Lyse before the expiration date.
- If product is frozen (either partially or completely), thaw completely, warm to room temperature and mix thoroughly by gentle inversion. Verify background results before analysing patient samples.
- Dispose of reagents, waste and consumables according to government regulations.
- Test result may be unreliable if:
 - Reagent is expired or invalid
 - Reagent is polluted with dust from the air
 - Sample is not processed cleanly
 - Reagent is mixed or used with third party reagents.

- **HC5D Diff Lyse (Ref.: 16450/30)**

This product is intended for lysing the red blood cells, determining the hemoglobin, white blood cell classification and counting the total number of white blood cells.

The HC5D Diff Lyse is added to lyse the red blood cells (RBC) and maintain the morphology of cells for white blood cell (WBC) differential.

Ingredients:

Surface active agent; Buffering agent; Antifungal and antibacterial agents.

Storage and Stability:

The HC5D Diff Lyse will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer:

Applicable to the HumaCount 5D hematology analyzers.

How to Use:

Restore HC5D Diff Lyse to the use temperature, unpack the reagent, insert the corresponding catheter to the diluent barrel according to the colour correspondence between the reagent bottle cap and the analyzer bottle cap assembly joint, screw the bottle cap assembly, replace the reagent according to the operator's manual of the analyzer, and then conduct the blank determination to make sure that the measured value is within the blank counting range required in the operator's manual of the analyzer before sample testing. Refer to the operator's manual of the analyzer for further information.

Specifications:

The product should be clear liquid without particles, precipitate or floccule.

Background result: WBC \leq 0.2x10⁹/l

Precautions:

- Do not inhale. In case of inhaling, immediately go see a doctor. Avoid skin or eye contact. In case of skin contact, flush the affected area with plenty of water immediately. In case of eye contact, flush the affected area with plenty of water immediately and go see a doctor.
- Use HC5D Diff Lyse before the expiration date.
- If product is frozen (either partially or completely), thaw completely, warm to room temperature and mix thoroughly by gentle inversion. Verify background results before analysing patient samples.
- Dispose of reagents, waste and consumables according to government regulations.
- Test result may be unreliable if:
 - Reagent is expired or invalid
 - Reagent is polluted with dust from the air
 - Sample is not processed cleanly
 - Reagent is mixed or used with third party reagents.

- HC5D-Clean (Ref.: 16450/60)

This product is intended for cleaning the fluidic system of the analyzer and regular instrument cleaning.

The HC5D Clean is a strong alkaline solution that effectively cleans out protein stains and other particles affecting blood cell counting.

Ingredients:

Surface active agent, Sodium Hydroxide, Sodium Hypochlorite

Storage and Stability:

The HC5D Clean will be stable for 2 years when stored at 2°C to 30°C (35°F to 86°F).

If the operating environment is 15°C to 30°C (59°F to 86°F), discard opened container after 60 days.

Applicable Analyzer:

Applicable to the HumaCount 5D hematology analyzers.

How to Use:

The HC5D Clean (16450/60) is intended to be used for cleaning purposes and the daily shutdown of the HumaCount 5D.

Follow the instructions on the analyzer operating screen and present the cleanser to the sample probe when required. Then press the aspirate key to start cleanser maintenance.

After opening the HC5D Clean bottle, crystals may form on the bottle neck and later on could also be found in the cleaner solution. It is recommended to decant the HC5D Clean solution into a transparent smaller bottle or tube for each use. Potentially present particles will sediment at the bottom of bottles/tubes and are easily visible. Therefore, a possible aspiration of these particles by the HC5D needle can be prevented.

Specifications:

The product should be clear liquid without particles, sediment and flocs.

Background result: WBC \leq 0.2x10⁹/l
 RBC \leq 0.2x10¹²/l
 HGB \leq 1g/l
 PLT \leq 10x10⁹/l

Precautions:

- Do not inhale. In case of inhaling, immediately go see a doctor. Avoid skin or eye contact. In case of skin contact, flush the affected area with plenty of water immediately. In case of eye contact, flush the affected area with plenty of water immediately and go see a doctor.
- Use HC5D Clean before the expiration date.
- If product is frozen (either partially or completely), thaw completely, warm to room temperature and mix thoroughly by gentle inversion. Verify background results before analysing patient samples.
- Dispose of reagents, waste and consumables according to government regulations.
- Test result may be unreliable if:
 - Reagent is expired or invalid
 - Reagent is polluted with dust from the air
 - Sample is not processed cleanly
 - Reagent is mixed or used with third party reagents.

3.1.12 REAGENTS, CONTROLS AND CALIBRATORS

Because the analyzer, reagents, controls, and calibrators are components of the system, system performance depends on the combined integrity of all the components. You must only use the Human-specified reagents (see A.2 Reagents), which are formulated specifically for the fluidic system of your analyzer in order to achieve optimal system performance. Do not operate the analyzer using reagents from multiple suppliers. Under such circumstances, the analyzer may not achieve the performance specified in this manual and may generate unreliable results.

All references to “reagents” in this manual refer to the reagents specifically formulated for this analyzer. Each reagent package should be examined before use. Inspect the package for signs of leakage or moisture. If there is evidence of leakage or improper handling, do not use the reagent.



- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- Store and use the reagents by following the instructions for use of the reagents.
- When you have changed the diluent or lyses, run a background check to see if the results meet the requirement.
- Pay attention to the expiration dates and open-container stability of all the reagents. Be sure not to use expired reagents.

3.1.12.1 Controls and Calibrators

- HC5D-Control (Ref.: 16450/40)

The controls and calibrators are used for quality control and analyzer calibration. The controls are dedicated whole-blood products used to verify that the analyzer is functioning properly. They are available in low, normal, and high levels. Daily use of all levels verifies the normal operation of the analyzer and ensures the acquisition of reliable results.

- HC-Calibrator (Ref.: 17400/50)

The calibrators are dedicated whole-blood products used to calibrate the analyzer. Read and follow the instructions to use the controls and calibrators. The “calibrators” and “controls” mentioned in this manual refer to Human-specified calibrators and controls and need to be purchased from Human or its specified agent.

- **Potential Biohazardous Material**

For in vitro diagnostic use. Each human donor/unit used in the preparation of HUMAN's products has been tested, and yielded non-reactive / negative results, according to FDA guidelines as contained in 21 CFR 610.40(a)(b). Specifically, a sample from each donation used has been tested by FDA-licensed tests and found nonreactive / negative for:

1. Antibodies to human immunodeficiency virus (anti-HIV 1,2), hepatitis C virus (anti-HCV), and antibodies to Trypanosoma cruzi (T cruzi, the causative agent of Chagas disease), and nonreactive for hepatitis B surface antigen (HBsAg)
2. Nucleic acid tests (NAT) for HCV ribonucleic acid (RNA), HIV-1 RNA, HBV deoxyribonucleic acid (DNA) and West Nile virus (WNV) RNA
3. Serologic test for syphilis

Because no test method can offer complete assurance that infectious agents are absent, material should be handled as potentially infectious. When handling or disposing of vials follow precautions for patient specimens as specified in the OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

- **Performance characteristics**

Assigned values of control and calibrator are presented as a Mean and Range. The Mean is derived from replicate testing on instruments operated and maintained according to the manufacturer's instructions. The Range is an estimate of variation between laboratories and also takes into account inherent imprecision of the method and expected biological variability of the control material. Assay values on a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the old lot are acceptable. The laboratory's recovered mean should be within the assay range. For greater control sensitivity each laboratory should establish its own mean and acceptable range and periodically reevaluate the mean. The laboratory range may include values outside of the assay range. The user may establish assay values not listed on the Assay Sheet, if the control is suitable for the method.

3.1.12.2 Safety Notes

The safety notes apply to the following REF numbers.

- [REF] 16450/10 HC5D Diluent
- [REF] 16450/20 HC5D CBC Lyse
- [REF] 16450/30 HC5D Diff Lyse
- [REF] 16450/40 HC5D Control
- [REF] 16450/60 HC5D Clean

Hazard statements

The following hazard statements are valid for the respective REF numbers.

- [REF] 16450/20 HC5D CBC Lyse
H412 Harmful to aquatic life with long lasting effects.
- [REF] 16450/60 HC5D Clean
H314 Causes severe skin burns and eye damage.

Precautionary statements

The following precautionary statements apply to the following REF numbers

- [REF] 16450/10 HC5D Diluent
- [REF] 16450/30 HC5D Diff Lyse
- [REF] 16450/40 HC5D Control

P234 Keep only in original container.

P260 Do not breathe, dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P401 Store in accordance with local/regional/national/international regulations.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

The following precautionary statements apply to the following REF number

- [REF] 16450/20 HC5D CBC Lyse

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

The following precautionary statements apply to the following REF number.

[REF] 16450/60 HC5D Clean

P260 Do not breathe dusts or mists.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P264 Wash thoroughly after handling.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3.1.12.3 Dangerous components

The following information about dangerous components are valid for the following REF numbers.

[REF] 16450/10 HC5D Diluent

CAS: 10043-35-3 boric acid 0.1-< 2.5%

[REF] 16450/20 HC5D CBC Lyse

CAS: 1119-94-4 Dodecytrimethylammoniumbromid 2.5-<10%

[REF] 16450/60 HC5D Clean

CAS: 1310-73-2 sodium hydroxide 0.5-<2%

CAS: 7681-52-9 sodium hypochlorite, solution 0.1-<0.25%



CAUTION

Do not turn on the analyzer immediately after its shutdown. Wait at least 10 seconds before power-on to avoid damage to the machine.



- To ensure stable analyzer performance and accurate analysis results, be sure to perform the Shutdown procedure to shut down the analyzer after it has been running continuously for 24 hours.
- When the analyzer is running or performing other fluidics sequence, do not force shutdown the analyzer.
- If any error is detected during shutdown procedure, the analyzer will return to the status before the shutdown procedure is performed, and then activate the alarm. See chapter 11 *Troubleshooting* for details of removing the error.
- Be sure to shut down the analyzer in strict accordance with the instruction below.

Procedures for shutting down the analyzer are as follows:

1. Click the button on the menu screen.

The interface pops up a dialogue box as shown below.

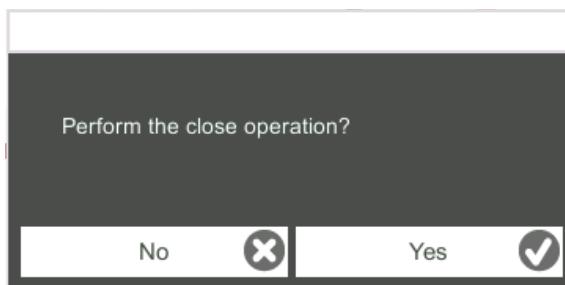


FIGURE 11

2. Click **Yes**.

The system starts to execute the shutdown sequence and a message box pops up showing the procedures for cleanser maintenance.

3. Follow the instructions and set the cleanser under the sample probe and press the aspirate key on the analyzer or click **Aspirate** to run the cleanser aspiration. Upon the completion of cleanser maintenance, you'll be prompted that the cleanser maintenance is completed.

Shutdown done. Please power off the analyzer!

4. Place the [O/I] switch at the back of the main unit in the [O] position.
5. After shutdown, empty the waste in the waste container, and dispose it.



WARNING

Be sure to dispose reagents, waste, samples, consumables, etc. according to local legislations and regulations.

3.1.13 SAMPLE COLLECTION AND HANDLING



All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them and the relevant areas in the laboratory.



WARNING

Do not touch the patients' blood sample directly.



Note:

- Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.
- Prepare the samples as per the procedures recommended by the reagent manufacturer.
- Be sure to use clean K2EDTA vacutainer blood collection tubes with anticoagulant, fused silica glass/plastic test tubes, centrifugal tubes and borosilicate glass capillary tubes.
- Be sure to use the Human-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
- For the whole blood samples to be used for WBC classification or PLT count, store them at room temperature and run them within 8 hours after collection.
- If you do not need the PLT, MCV and WBC differential results, you can store the samples in a refrigerator (2°C - 8°C) for 24 hours. You need to warm the keep samples at room temperature for at least 30 minutes before running them.
- Be sure to mix any sample that has been prepared for a while before running it.

3.1.13.1 Running the Venous Whole Blood Samples

The procedure for preparing venous whole blood sample is as follows:

1. Use clean K2 or K3 EDTA (1.5~2.2 mg/ml) vacutainer blood collection tubes with anticoagulant to collect venous blood samples.
2. Make sure the collected is not less than 80% of the draw volume of the tube.
Do not use short draws.
3. Mix the venous blood with the anticoagulant well in the tube immediately.



CAUTION

- For vacutainer blood collection tube (12x75, cap excluded), please make sure the volume of the whole blood sample is not less than 0.5 ml.
- Venous blood samples, collected in EDTA tubes in hematology should be used according to CLSI H18-A3, within 8 hours.

3.1.13.2 Capillary Whole Blood Samples

HumaCount 5D has a dedicated Capillary Tube Auto-Dispense sample mode. A detailed description on the how to use capillary blood samples is available on the Quick Guide REF 16450/5. Please follow the steps described below for capillary blood collection:

1. Dispense 480 µl of HC5D Diluent by the HC5D automatically into a bullet tube.
2. Perform blood collection by finger prick into a 20 µl HUMAN capillary tube (EDTA coded). After blood collection is completed, wipe away excess blood on the outer side of the capillary by a tissue free wet tissue. Avoid any contact of the tissue with the blood in the capillary tube.
3. Put the capillary into the bullet tube filled with Diluent, close the lid and invert the sample carefully, until the suspension is homogeneous.

The capillary blood suspended in the HC5D-Diluent can be used up to 4 hours after collection on HC5D. The HC5D diluent being dispensed in a clean unused bullet tube can be used for capillary tube suspension up to 8 hours. After that time, please use a new bullet tube filled with fresh HC5D-diluent.



CAUTION

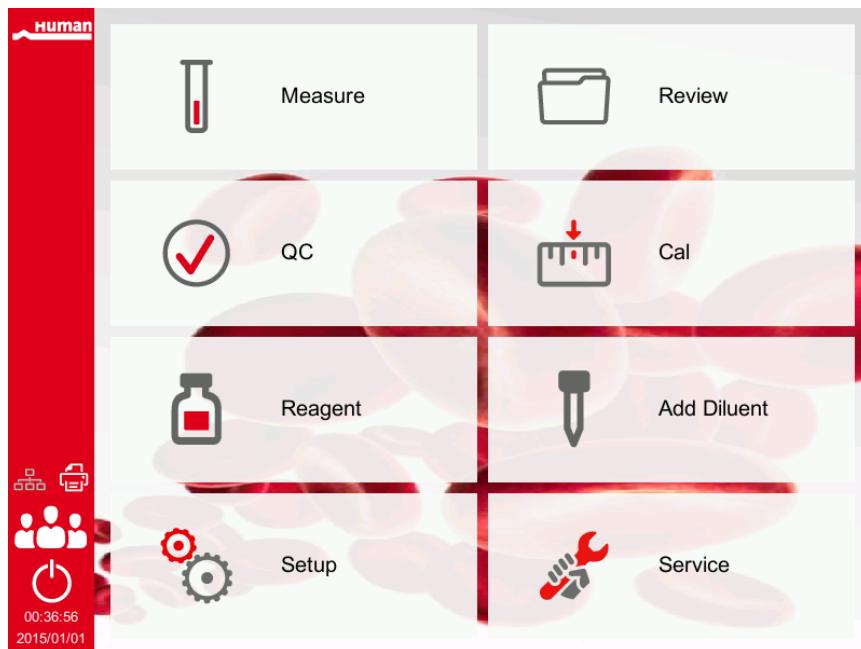
Never put pressure on the skintissue next to the capillary collection tissue to avoid dilution of blood by tissue liquids.

3.1.13.3 Prediluted Samples

The procedure for preparing prediluted sample is as follows:

1. Click the  button on the left side of the screen and enter the menu screen as shown in Figure 12.

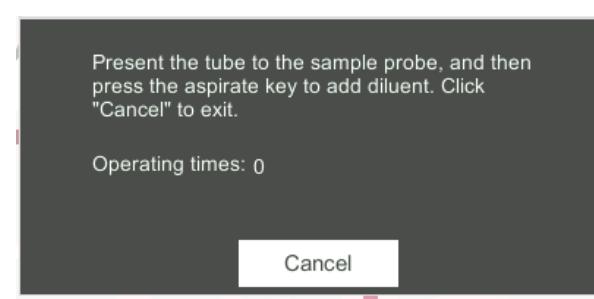
FIGURE 12
Menu Screen



2. Click the **Add Diluent** icon.

A prompt box will pop up on the screen as shown below.

FIGURE 13



3. Take a clean centrifugal tube, uncap it and present it to the sample probe in a manner as shown in the following picture in which the probe tip is vertically in contact with the bottom of the tube so as to avoid bubbles, liquid attached to the inner wall or spatter.
4. Press the aspirate key and add the HC5D diluent (480 µl at a time) automatically by the analyzer. After the diluent is added and you hear a beep, you can remove the centrifugal tube.
5. If more portions of diluent are needed, repeat steps 3~4.
6. Add 20 µl of blood to the diluent, close the tube cap and shake the tube to mix the sample.
7. After the prediluted sample is prepared, click **Cancel** to exit dispensing the diluent.
 - Ideally you use the HUMAN capillary (REF: 16070/30) and put it together with the blood inside the centrifuged tube. Close the tube and mix carefully until all blood is mashed out the capillary and dissolved homogeneously. Leave capillary inside.
 - You can also dispense 480 µl of diluent by pipette into the tube.
 - The prediluted sample prepared after single blood collection can be counted twice.
 - Be sure to keep dust from the prepared diluent.
 - Be sure to run the prediluted samples within 30 minutes after the mixing.
 - Be sure to mix any sample that has been prepared for a while before running it.
 - Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

- The centrifugal tube shall be placed vertically upward, not tilted or upside down. Otherwise, the inner wall of the tube would be stained with excessive sample, resulting in waste. Moreover, it may cause unevenly mixed sample and unreliable analysis results.

FIGURE 14



3.1.14 SAMPLE ANALYSIS

After the sample is prepared, you can perform the operations for sample analysis. For details, see chapter 4 *Sample Analysis*.

4 SAMPLE ANALYSIS

4.1 Introduction

Sample analysis is the most important function of the auto hematology analyzer. You can get the blood cell count, HGB concentration and the 5-part classification counting results of the white blood cells by performing the sample analysis. The summary of sample analysis procedures are as follows:

1. Entering the sample information.
2. Running the samples.
3. Processing the analysis results.

4.2 Interface Introduction

The Sample Analysis interface is the main interface of the analyzer (Figure 15). You can complete the operations such as entering the sample information, performing sample analysis, reviewing/printing analysis results in the Sample Analysis interface.

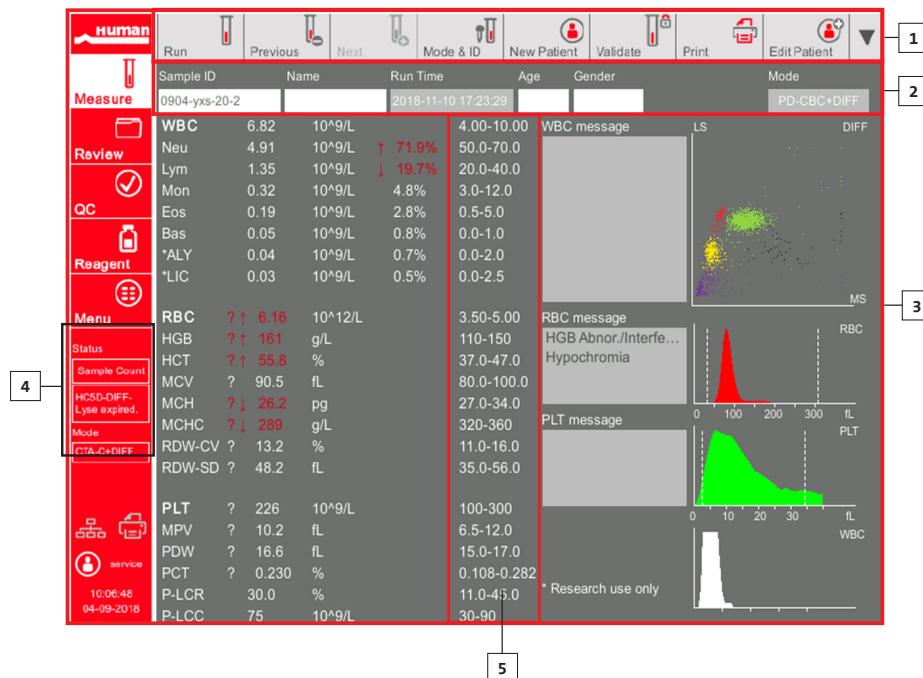


FIGURE 15
Sample analysis interface

- 1 Function buttons
- 2 Patient information area
- 3 Analysis results area
- 4 Information of the next sample
- 5 Reference values

Related descriptions:

- **Function buttons**

You can perform operations such as setting the mode for the samples, pre-entering information, reviewing previous/next records and printing. Click  and view all function buttons.

4.3 Functions of the Buttons.

- **Patient information area**

It displays the patient information corresponding to the current sample.

- **Analysis results area**

It displays the analysis results of the sample, including the parameter results, Flags, DIFF scattergrams, BASO scattergram and histograms (including WBC, RBC and PLT). The system displays the analysis results of the most recent run by default.

- **Parameter Results**

This list displays the analysis results of all the parameters of the samples.

You can compare the values in the Result column with the corresponding Ref. Range. If the values are within the reference range, it means that they are normal. If not, it indicates that the sample may be abnormal and the corresponding symbols will be displayed in the Flag column.

- **Reference Values**

This column displays the reference values for the selected sample. Reference Values are shown as absolute numbers for WBC, RBC, HGB, MCV, MCH, MCHC, RDW-SD, PLT, MPV, PDW and P-LCC. Reference Values are shown in % for NEU, LYM, MON, EOS, BAS, ALY, LIC, HCT, RDW-CV, PCT and P-LCR.

- **WBC Message**

Displays the alert message regarding the WBC.

- **RBC Message**

Displays the alert message regarding the RBC.

- **PLT Message**

Displays the alert message regarding the platelet.

- **DIFF**

WBC DIFF scattergram in the CBC+DIFF mode. Click the scattergram, three WBC DIFF scattergrams including LS-MS, LS-HS and HS-MS and one BASO scattergram will be displayed.

- **WBC**

WBC distribution histogram.

- **RBC**
RBC distribution histogram.
- **PLT**
Platelet distribution histogram.
- **Information of the next sample**
It displays the sample ID and analysis mode of the next sample.

4.4 Entering Sample Information

You can enter the worklist information of the samples to be tested before the analysis.

! You can also enter sample/patient information after the sample analysis is completed. For details, please refer to 8 *Result Review*. Detailed steps are shown below:

1. Click the **Edit Patient** button in the function button area. The interface as shown in Figure 16 will pop up on the screen.

Edit Patient		
First Name	Last Name	Sample ID
Patient Type	Sample Type	Department
Med Rec. No.	Area	Bed No.
Gender	Birthday	Age
Ref. Group	Sampling Time	Delivery Time
General	2015/01/01 00:16	2015/01/01 00:16
Submitter	Operator	Run Time
Mode	Approver	Report Time
Capillary Whole Blood		2015/01/01 00:32
Diagnosis		
Remarks		
Apply		Cancel
		OK

FIGURE 16
Pre-entering Patient Information

2. Enter patient information with reference to the parameter description in the following tables:

Parameter	It means	Operation
First Name	First name of patient.	Input in the textbox directly.
Last Name	Last name of patient.	Input in the textbox directly.
Patient Type	Type of patient. Values: - (Null) - Inpatient - Physical Examination - STAT - Outpatient	Select from the dropdown list.
Sample Type	Type of sample for microscopic examination. Values: - Venous blood - Capillary - Cord blood - Blood	Click the Sample Type dropdown list box and select the type of sample for microscopic examination.
Med Rec. No.	Medical record number of patient.	Input in the textbox directly.
Gender	Gender of patient. Values: - (Null) - Male - Female - Not defined	Select from the dropdown list.
Birthday	Birthday of a patient.	<p>Select from the date control.</p> <ul style="list-style-type: none"> - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd, you should input the data in the sequence of year, month, and date. - Click  or  to select the date or click the textbox to enter them directly. - Click  to clear the current data and re-enter the information.

Age	Age of a patient.	Select the unit of age from the dropdown list (Year, Month, Day or Hour) and enter the age of the patient in the textbox before the age unit.
Ref. Group	Reference group of the sample under analysis. The result is judged according to the reference range of the reference group and the result beyond the normal range will be flagged.	Select from the dropdown list.
Department	Department receiving the patient.	Select from the dropdown list.
Area	Ward area of patient.	Input in the textbox directly.
Bed No.	Bed No. of inpatient.	Select from the dropdown list or input directly. Note: The bed No. is required to be filled only for inpatients
Sampling Time	Date and time when the sample is collected.	Click the date control for the settings. <ul style="list-style-type: none"> - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd HH:mm, you should input the data in the sequence of year, month, date, hour, and minute. - Click  or  to select the date or click the textbox to enter them directly. - Click  to clear the current data and re-enter the information.
Submitter	Personnel submitting the sample.	Select from the dropdown list or input directly.

! Note: If the Birthday is set, the age will be displayed automatically.

! Note: If the Automatically match the customized reference group according to age and gender is set, gender and age of a patient will automatically match the reference group according to the corresponding relationship (No matter the reference group is selected or not). Refer to 5.4.3 Ref. Range for the setting of the reference group and range.

! Note: The system automatically displays the current time as sampling time. The sampling time can be no later than the current system time.

<p>! Note: The system automatically displays the current time as sample delivery time. The delivery time can be no later than the current system time and cannot be earlier than the sampling time.</p>	Delivery Time	Date and time when the sample is delivered.	Click the date control for the settings. <ul style="list-style-type: none"> - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd HH:mm, you should input the data in the sequence of year, month, date, hour, and minute. - Click  or  to select the date or click the textbox to enter them directly. - Click  to clear the current data and re-enter the information.
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Remarks	Clarifications or notes.	Input in the textbox directly.
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3. Click **Apply** or **OK** to save the configuration.

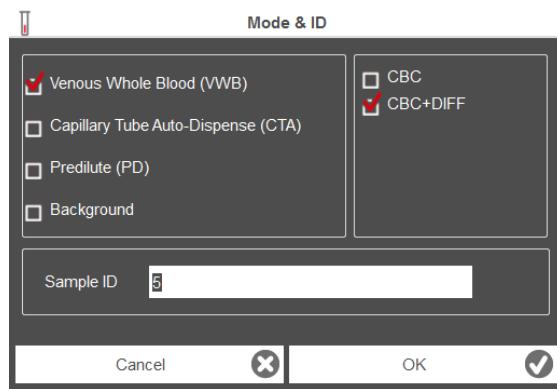
4.5 Running Samples



- The tube (or centrifugal tube) shall be placed vertically upward, not tilted or upside down. Otherwise, the inner wall of the tube may be stained with excessive sample, resulting in waste. Moreover, it may cause unevenly mixed sample and unreliable analysis results.
 - During aspiration, the tip of the probe should be kept at a certain distance from the bottom of the sample container, otherwise the accuracy of aspiration volume will be affected.
 - Keep the tip of the probe from contacting with the wall of the test tube to avoid blood splashing.
 - Proper reference range shall be selected on the Setup interface before analysis. Otherwise, the results may be flagged erroneously.
 - The default system setting for counting mode is Venous Whole Blood (VWB)-CBC+DIFF.
 - When the analyzer is running the samples, you can switch to Review interface to perform operations including browsing and exporting, etc., and you can also switch to other interfaces. But all the functions related to the fluidics sequence are not available. Take the following steps to perform sample analysis.
-
- Prepare samples as instructed by chapter 6.4 *Sample Collection and Handling*.
 - For details about the preparation of venous whole blood samples, see chapter 3.1.13.1 *Running the Venous Whole Blood Samples*.
 - For details about the preparation of capillary whole blood samples, see chapter 3.1.13.2 *Capillary Whole Blood Samples*.
 - For details about the preparation of prediluted samples, see chapter 3.1.13.3 *Prediluted Samples*.
4. Mix the capped tube of sample for a homogeneous specimen.
 5. When the green indicator light is steady-on, click **Mode & ID** in **Sample Analysis** interface.

A dialogue box will pop up as shown in Figure 17. The analyzer supports six counting modes: venous whole blood (VWB)-CBC+DIFF, venous whole blood (VWB)-CBC, Capillary Tube Auto-Dispense (CTA)-CBC+DIFF, Capillary Tube Auto-Dispense (CTA)-CBC, Predilute(PD)-CBC+DIFF, and Predilute(PD)-CBC.

FIGURE 17
Mode & ID Settings



6. Select the blood sample mode **Venous Whole Blood (VWB)**, **Capillary Tube Auto-Dispense (CTA)** or **Predilute (PD)** of the sample.
7. Select the measurement mode **CBC** or **CBC+DIFF** according to the actual test case, and enter the Sample ID.

Refer to Table 5 for the description of relevant parameters.

TABLE 5
Sample Analysis
Parameter Descriptions

Note: Letters, numbers and all characters that can be entered through the keyboard (including special characters) are allowed for the Sample ID. Chinese and other languages (such as Japanese, Korean, etc) are not supported.

! The length of the entries ranges from 1 to 25 and the entries shall not be empty.

! The last character of a sample ID must be numeric, but a string of "0" only is not an acceptable sample ID.

Parameter	It means	Operation
CBC	Complete Blood Count with no differential count for white blood cells. The counting results comprise 13 parameters, 3 histograms (including WBC, RBC and PLT), and one BASO scattergram.	Selected from the radio box.
CBC+DIFF	Complete Blood Count plus differential count for white blood cells. The counting results comprise 23 measurement parameters, 4 RUO parameters, one DIFF scattergram, one BASO scattergram, and three histograms (including WBC, RBC and PLT).	Selected from the radio box.
Sample ID	Identification number for the samples to be run.	Enter in the textbox directly.

8. Click **OK**.
9. Remove the tube cap carefully and place the sample under the probe so that the probe can aspirate the well-mixed sample.
10. Press the aspirate key on the analyzer to start running the sample. The sample will be automatically aspirated by the sample probe.

11. When you hear a beep, remove the sample tube. The analyzer will automatically run the sample and the analysis status icon and analyzer indicator is flickering in green. When the analysis is complete, the analyzer indicator returns to constantly-on green.
12. Repeat steps 1~9 to run the remaining samples.

4.5.1 SOFTWARE-SWITCH FROM CBC TO C+DIFF

In case HC5D should be used only in CBC-mode and you would not like to connect any HC5D-Diff-Lyse to save reagent costs. Please follow the instructions below.

1. Use an empty and clean HC5D-Diff-Lyse bottle, fill it with HC5D-Diluent and connect it with HC5D the same way as you use a HC5D-Diff-Lyse. In case HC5D is used again in C-Diff mode.
2. Connect a regular HC5D-Diff-Lyse before activating the software switch.

4.6 Dealing with the Analysis Results

4.6.1 AUTOMATIC SAVING OF ANALYSIS RESULTS

This analyzer automatically saves sample results. When the maximum number has been reached, the newest result will overwrite the oldest (up to 40.000 samples will be stored on hard drive of analyzer).

4.6.2 PARAMETER FLAGS

- If parameter is followed by a “↑” or “↓”, it means the analysis result has exceeded the upper or lower limit of the reference range but still within the display range.
- If the parameter is followed by a “?”, it means the analysis result is suspicious.
- If you see “***” instead of a result, it means the result is either invalid or beyond the display range. For the background test, the flags for parameters or abnormal blood cell differential and morphology are not available.

4.6.3 FLAGS OF ABNORMAL BLOOD CELL DIFFERENTIAL OR MORPHOLOGY

The analyzer will flag abnormal or suspicious WBC, RBC and PLT according to the scattergrams and histograms. The flag information is defined in the table below.

TABLE 6
Flags of abnormal blood cell differential or morphology

Flag Type		Flag information
WBC	Abnormal	Leucocytosis Leucopenia Neutrophilia Neutropenia Lymphocytosis Lymphopenia Moncytosis Eosinophilia Basophilia
	Suspicious	WBC abnormal Abnor. WBC scattergram Abnor. WBC histogram Left Shift? Immature Cell? RBC Lyse Resistant? Abn./Atypical Lym? Abnormal WBC Channel Abnormal DIFF Channel
RBC/HGB	Abnormal	Erythrocytosis Anisocytosis Macrocytosis Microcytosis Anemia Hypochromia
	Suspicious	Abnor. RBC Distr. Dimorphologic Iron Deficiency? HGB Abnor./Interfere? RBC Clump? Abnormal RBC Channel Abnormal HGB Channel
PLT	Abnormal	Thrombocytosis Thrombopenia
	Suspicious	Abnor. PLT Distr. PLT Clump?

The system shows flags for abnormal or suspicious items in different samples and measurement modes in accordance with the impact of the abnormal or suspicious WBC, RBC or PLT items on the results of the parameters. The correlation is shown in the following table:

Type	Flag	Whole Blood		Predilute (PD)	
		CBC	CBC + DIFF	CBC	CBC + DIFF
WBC	WBC abnormal?	✓	✓	✓	✓
	RBC Lyse Resistant?	✗	✓	✗	✓
	Abnor. WBC scattergram	✗	✓	✗	✓
	Abnor. WBC histogram	✓	✓	✓	✓
	Left Shift?	✗	✓	✗	✓
	Immature Cell?	✗	✓	✗	✓
	Abn./Atypical Lym?	✗	✓	✗	✓
	Leucocytosis	✓	✓	✓	✓
	Leucopenia	✓	✓	✓	✓
	Neutrophilia	✗	✓	✗	✓
	Neutropenia	✗	✓	✗	✓
	Lymphocytosis	✗	✓	✗	✓
	Lymphopenia	✗	✓	✗	✓
	Monocytosis	✗	✓	✗	✓
	Eosinophilia	✗	✓	✗	✓
	Basophilia	✗	✓	✗	✓
RBC/HGB	Abnormal WBC Channel	✗	✓	✗	✓
	Abnormal DIFF Channel	✗	✓	✗	✓
	Dimorphologic	✓	✓	✓	✓
	HGB Abnor./Interfere?	✓	✓	✓	✓
	Anisocytosis	✓	✓	✓	✓
	Microcytosis	✓	✓	✓	✓
	Macrocytosis	✓	✓	✓	✓
	Erythrocytosis	✓	✓	✓	✓
	Anemia	✓	✓	✓	✓
	Hypochromia	✓	✓	✓	✓
	Abnor. RBC Distr.	✓	✓	✓	✓
	Iron Deficiency?	✓	✓	✓	✓
	RBC Clump?	✓	✓	✓	✓
	Abnormal RBC Channel	✓	✓	✓	✓
PLT	Abnormal HGB Channel	✓	✓	✓	✓
	PLT Clump?	✓	✓	✓	✓
	Thrombocytosis	✓	✓	✓	✓
	Thrombopenia	✓	✓	✓	✓
	Abnor. PLT Distr.	✓	✓	✓	✓

TABLE 7

Flags for abnormal or suspicious items in different samples and measurement modes

- “✓” indicates that flags will be displayed in the mode.”✗” indicates that flags will not be displayed in the mode.
- When the PLT value is less than $100 \times 10^9/l$, a manual count by the microscope is recommended.

4.7 Functions of the Buttons

4.7.1 PREVIOUS/NEXT

Click **Previous**, and the screen will display the sample analysis results prior to the current one.

Click **Next**, and the screen will display the sample analysis results after the current one.

4.7.2 MODE & ID

Click **Mode&ID** to set the sample mode and measurement mode during the sample analysis. See chapter 4.5 *Running Samples*.

4.7.3 PRINT

You can click **Print** to print the report of the sample result.

4.7.4 PATIENT INFORMATION

You can browse and edit the patient information of the selected sample in the **Sample Analysis** interface. The operation procedures are as shown below:

- Click **Edit Patient** to enter the patient information setting interface as shown in Figure 18.

The screenshot shows the 'Edit Patient' dialog box. It has two columns of input fields. The left column includes fields for First Name, Patient Type (dropdown), Med Rec. No., Gender (dropdown), Ref. Group (dropdown), Submitter (dropdown), Mode (dropdown), and a 'Venous Whole Blood' button. The right column includes fields for Last Name, Sample Type (dropdown), Area (dropdown), Birthday (date input), Age (dropdown), Sampling Time (date/time dropdown), Delivery Time (date/time dropdown), Operator (dropdown), Run Time (date/time dropdown), Approver (dropdown), Report Time (date/time dropdown), and a 'Diagnosis' text area. Below these fields is a 'Remarks' text area. At the bottom are three buttons: 'Apply' (with a red square icon), 'Cancel' (with a red X icon), and 'OK' (with a green checkmark icon).

FIGURE 18
Patient Information

- Enter patient information with reference to the parameter description in Table 8.

Parameter	Meaning	Operation
Sample ID	Number of the selected sample.	It will be displayed automatically, and you can modify it manually.
First Name	First name of patient.	Input in the textbox directly.
Last Name	Last name of patient.	Input in the textbox directly.
Patient Type	Type of patient. Values:	Select from the dropdown list. - Inpatient - Physical Examination - STAT - Outpatient
Sample Type	Type of selected sample.	Select from the dropdown list. - Venous blood - Capillary - Cord blood - Blood
Med Rec. No.	Med Rec. No. of patient.	Input in the textbox directly.

TABLE 8
Parameter Description
of Patient Information

Gender	Gender of patient. Values: - (Null) - Male - Female - Not defined	Select from the dropdown list.
Birthday	Birthday of a patient.	Select from the date control. - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd, you should input the data in the sequence of year, month, and date. - Click or to select a date and time or enter the information in the textbox directly. - Click to clear the current data and re-enter the information.
Age	Age of a patient.	Select the unit of age from the dropdown list (Year, Month, Day or Hour) and enter the age of the patient in the textbox before the age unit.
Ref. Group	Reference group of the sample under analysis. The result is judged according to the reference range of the reference group and the result beyond the normal range will be flagged.	Select from the dropdown list. Note: - If the Automatically match the customized reference group according to age and gender is set, gender and age of a patient will automatically match the reference group according to the corresponding relationship (No matter the reference group is selected or not). - Refer to chapter 7.3.4.11 Ref. Range for the setting of the reference group and range.
Department	Department receiving the patient.	Select from the dropdown list.
Area	Ward area of patient.	Input in the textbox directly.
Bed No.	Bed No. of inpatient.	Select from the dropdown list or input directly. Note: The bed No. is required to be filled only for inpatients.

Sampling Time	Date and time when the sample is collected.	<p>Click the date control for the settings.</p> <ul style="list-style-type: none"> - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd HH:mm, you should input the data in the sequence of year, month, date, hour, and minute. - Click or to select a date and time or enter the information in the textbox directly. - Click to clear the current data and re-enter the information. <p>Note:</p> <p>The sampling time can be no later than the current system time.</p>
Submitter	Personnel submitting the sample.	Select from the dropdown list or input directly.
Mode & ID	Counting mode of the selected sample. The format is blood sample mode-measurement mode.	You do not need to enter it and it will be displayed automatically.
Delivery Time	Date and time when the sample is delivered.	<p>Click the date control for the settings.</p> <ul style="list-style-type: none"> - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd HH:mm, you should input the data in the sequence of year, month, date, hour, and minute. - Click or to select a date and time or enter the information in the textbox directly. - Click to clear the current data and re-enter the information. <p>Note:</p> <p>The delivery time can be no later than the current system time and cannot be earlier than the sampling time.</p>
Operator	Personnel running the sample.	You do not need to enter it and it will be displayed automatically.

Run Time	Time when the sample is run.	You do not need to enter it and it will be displayed automatically.
Approver	Personnel validating the sample.	This parameter will be automatically displayed after the sample is validated.
Report Time	The date and time when the report is printed for the first time.	This parameter will be automatically displayed after the report is printed.
Diagnosis	Suspected diagnosis information.	Input in the textbox directly.
Remarks	Clarifications or notes.	Input in the textbox directly.

3. Click **Apply** or **OK** to save the settings.

4.7.5 CUSTOMIZED PARAMETERS

You can browse and edit the customized parameters results of the selected sample in the **Sample Analysis** interface. The procedures are shown as below:

1. Click **Custom Para.** to enter the customized parameters setting interface as shown in Figure 19.

FIGURE 19
Customized Parameters

Para.	Flag	Value	Unit	Range
Blood Type				
RH Blood Group				
ESR				
C-reactive Protein				
Reticulocyte				

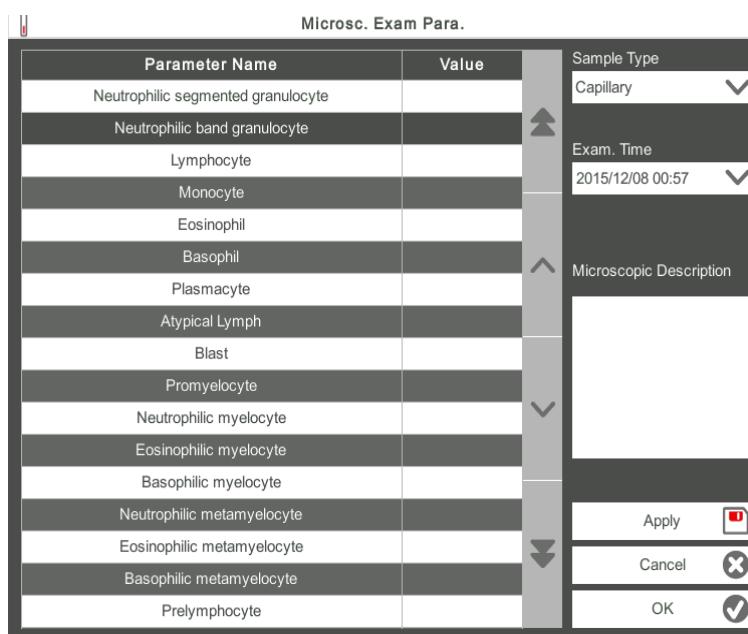
2. Click the cell corresponding to its **Value** column of the parameter, and enter the value. If the unit and reference range of parameters have been set in the **Setup > Parameter > Custom Para.** interface, the corresponding unit and range (lower limit~upper limit) will be displayed in this tab. When both the value and range of parameters are numbers, and the number is out of the reference range, the relevant mark \uparrow or \downarrow will be displayed in the **Flag** column. Please refer to chapter 4.7.5 *Customized Parameters* for customized parameters settings.

4.7.6 MICROSCOPIC EXAM. PARAMETERS

You can perform the microscopic exam. settings as per the following steps.

Click **Microscopic Exam. Para.**

The microscopic examination parameters interface as shown in Figure 20 will pop up on the screen:

**FIGURE 20**

Adding a New Microscopic Exam. Parameter

Refer to Table 9 for parameter description and operation methods regarding the microscopic examination.

Parameter	It means	Operation
Sample Type	Type of sample for microscopic examination. - Venous blood - Capillary - Cord blood - Blood	Click the Sample Type dropdown list box and select the type of sample for microscopic examination.
Exam. Time	Time of microscopic examination.	Click the Exam. Time combo box and select the time and date for the microscopic examination.
Microscopic Description	Description of cells morphology.	Enter the morphology information for WBC, RBC and PLT respectively into the multi-line textbox.

TABLE 9

Microscopic Exam. Parameters

4.7.7 COMMUNICATION

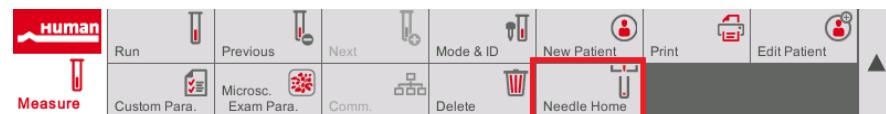
You can transmit the current sample data (except the background sample) to the LIS/HIS system in the **Sample Analysis** interface.

1. Click  to unfold all function buttons.
2. Click **Comm.**

4.7.8 NEEDLE HOME

Clicking on **needle home** retracts the needle of the device when the device is not in use. This procedure can reduce the possible risk of injury.

FIGURE 21



5 RESULT REVIEW

5.1 Introduction

Upon the completion of each sample analysis, the analyzer will automatically save the sample information, result data, flag messages, histograms and scattergrams to the Review Database. In the **Review** Interface, you can browse the saved sample information, result data, flag messages, histograms and scattergrams, and can search, compare or export the saved sample information.

5.2 Interface Introduction

You can browse, search, compare, print, and export the existing results in the **Review** interface. Click **Review** to enter the sample review interface.

See Figure 22.

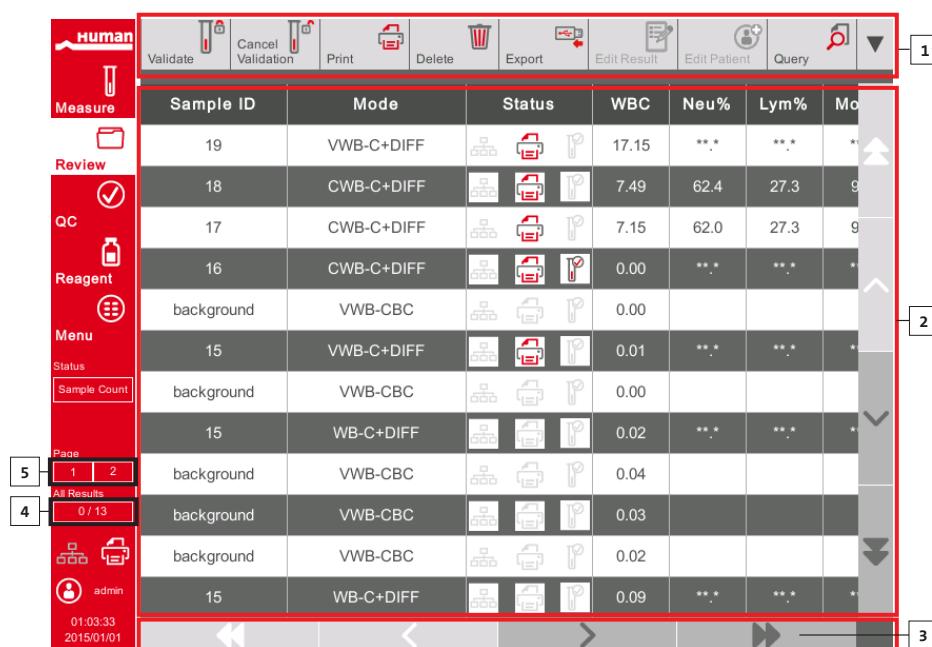


FIGURE 22

Review

1 Function buttons

2 Result list

3 Direction button

4 Current page/Total pages

5 Sequence Number/ Total number of results

Interface Description:

- Result list: You can browse detailed sample records.
- Function buttons: You can perform the operations such as comparing or searching the sample results, deleting and viewing the Run Charts, exporting and printing reports.

- Direction button: If you click different direction buttons, the list will move toward the corresponding directions.
 - From left to right, it indicates in sequence: The first column, moving to the left page, moving to the right page, and the last column.
 - From top to bottom, it indicates in sequence: The first page, the previous page, the next page, and the last page.

5.3 Sample List

The review interface shows a list of the analyzed samples, which contains the sample number, status, mode and results of various parameters and other information.

Click a sample or multiple samples in the list area, then you perform operations such as exporting in batch for the selected samples. To cancel the selection, click the selected samples again.

5.4 Functions of the Buttons

5.4.1 PRINT

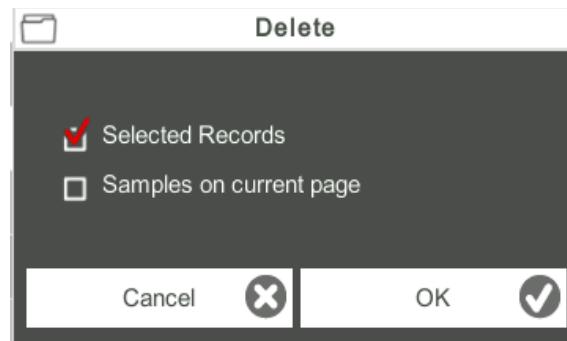
Click **Print** to print the result report of the selected sample.

5.4.2 DELETE

- Validated samples are not allowed to be deleted.
 - The common user has no access to delete the sample records.
1. Select one or several sample records to be deleted.
 2. Click **Delete**.

A prompt box will pop up on the screen as shown below.

FIGURE 23
Delete Sample Records



3. Select one or several sample records to be deleted according to the actual situation.
 - Selected Records: The sample results shown on the highlighted page.
 - Samples on current page: Results of all the samples shown on the current page.
4. Click **OK** to delete the selected record(s).

5.4.3 EXPORT

The operator can export the sample data to the USB flash disk for backup. There are two ways of exporting the sample data: Exporting selected records and exporting records of specified dates.

- Export Selected Records
 - Insert a USB flash disk in the USB interface on the analyzer.
 - Select records to be backed up, and click **Export**.

As shown in the following figure, the export range of the system is **Selected Records** by default.

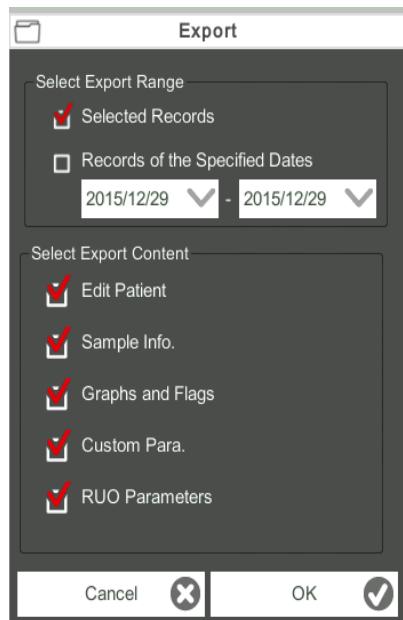
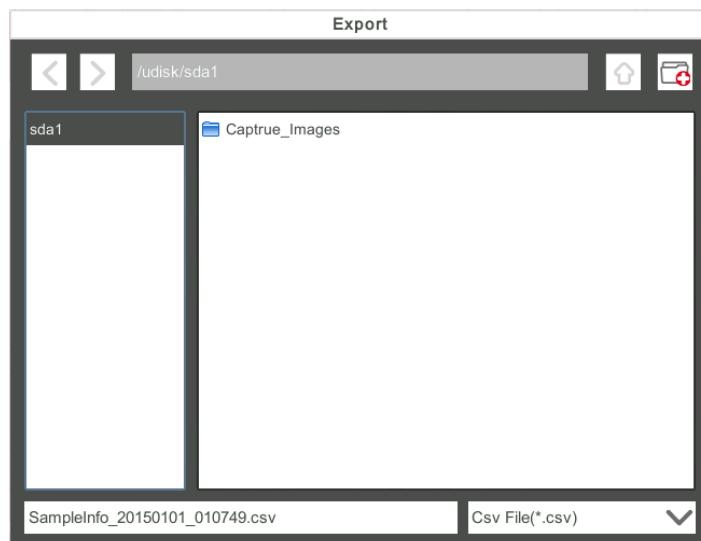


FIGURE 24
Export Selected Records

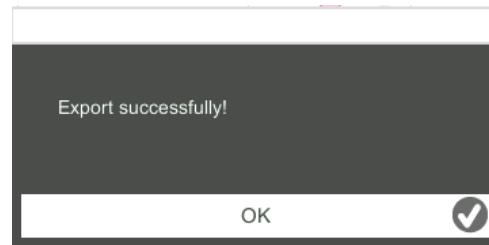
- Select the content to be exported according to the actual demand. Content available for export includes: **Patient Info., Sample Info., Graphs and Flags, Custom Para., RUO Parameters**.
- Click **OK**.

- Select the data export path in the popup dialogue box, enter the backup file name, and click **Save**.
- The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo_yyyyMMdd_hhmmss.csv**. Among which, **yyyyMMdd_hhmmss** means data export year, month, date, hour, minute, and second.

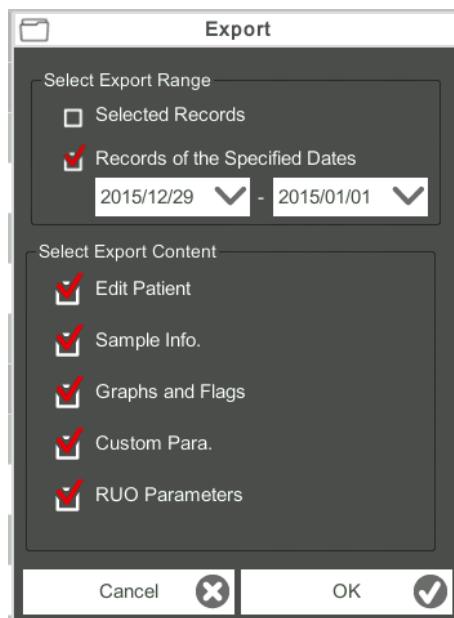
FIGURE 25

- Click **Save**.

The system pops up a dialogue box as shown below to indicate that the data export is successful.

FIGURE 26

- Export Records of the Specified Dates
 - Insert a USB flash disk in the USB interface on the analyzer.
 - Click **Export**.
 - Select **Records of the Specified Dates** and set the run date range of sample in the two date textboxes. See Figure 27.

**FIGURE 27**

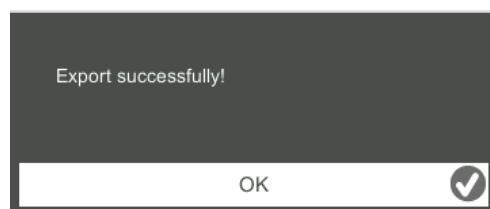
Export Records of the Specified Dates

- Select the content to be exported according to the actual demand. Content available for export includes: **Patient Info.**, **Sample Info.**, **Graphs and Flags**, **Custom Para.**, **RUO Parameters**.

- Click **OK**.
- Select the data export path in the popup dialogue box, enter the backup file name, and click **Save**.

The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo_yyyyMMdd_hhmmss.csv**. Among which, yyyyMMdd_hhmmss means data export year, month, date, hour, minute, and second.

- Click **Export**.
- The system pops up a dialogue box as shown below to indicate that the data export is successful.

**FIGURE 28**

5.4.4 PATIENT INFO.

You can browse and edit sample/patient information after the sample analysis is completed. Detailed steps are shown below:

1. Click **Patient Info**

The interface as shown in Figure 29 will pop up on the screen.

FIGURE 29
Patient Info

Edit Patient		
First Name	Last Name	Sample ID
		7
Patient Type	Sample Type	Department
Med Rec. No.	Area	Bed No.
Gender	Birthday	Age
	/ /	
Ref. Group	Sampling Time	Delivery Time
General	2015/01/01 00:54	2015/01/01 00:54
Submitter	Operator	Run Time
	admin	2015/01/01 00:54
Mode	Approver	Report Time
Venous Whole Blood		2015/01/01 00:55
Diagnosis		
Remarks		
Apply		Cancel
		OK

2. Enter patient information with reference to the parameter description in Table 10.

TABLE 10
Parameter Description

Parameter	It means	Operation
Sample ID	Number of the selected sample.	It will be displayed automatically, and you can modify it manually.
First Name	First name of patient.	Input in the textbox directly.
Last Name	Last name of patient.	Input in the textbox directly.
Patient Type	Type of patient. Values: - Inpatient - Physical Examination - STAT - Outpatient	Select from the dropdown list.

Sample Type	Type of selected sample.	Select from the dropdown list. <ul style="list-style-type: none"> - Venous blood - Capillary - Cord blood - Blood
Med Rec. No.	Med Rec. No. of patient.	Input in the textbox directly.
Gender	Gender of patient. Values:	Select from the dropdown list. <ul style="list-style-type: none"> - (Null) - Male - Female - Not defined
Birthday	Birthday of a patient.	Select from the date control. <ul style="list-style-type: none"> - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd, you should input the data in the sequence of year, month, and date. - Click or to select a date and time or enter the information in the textbox directly. - Click to clear the current data and re-enter the information.
Age	Age of a patient.	Select the unit of age from the dropdown list (Year, Month, Day or Hour) and enter the age of the patient in the textbox before the age unit.
Ref. Group	Reference group of the sample under analysis. <p>The result is judged according to the reference range of the reference group and the result beyond the normal range will be flagged.</p>	Select from the dropdown list. Note: <ul style="list-style-type: none"> - If the Automatically match the customized reference group according to age and gender is set, gender and age of a patient will automatically match the reference group according to the corresponding relationship (No matter the reference group is selected or not). - Refer to chapter 7.3.4.11 <i>Ref. Range</i> for the setting of the reference group and range.

Department	Department receiving the patient.	Select from the dropdown list.
Area Bed No.	Ward area of patient. Bed No. of inpatient.	Input in the textbox directly. Input in the textbox directly.
		! Note: The bed No. is required to be filled only for inpatients.
Sampling Time	Date and time when the sample is collected.	<p>Click the date control for the settings.</p> <ul style="list-style-type: none"> - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd, you should input the data in the sequence of year, month, and date. - Click or to select a date and time or enter the information in the textbox directly. - Click to clear the current data and re-enter the information.
		! Note: The sampling time can be no later than the current system time.
Submitter	Personnel submitting the sample.	Select from the dropdown list or input directly.
Mode & ID	Counting mode of the selected sample. The format is blood sample mode-measurement mode.	You do not need to enter it and it will be displayed automatically.

Delivery Time	Date and time when the sample is delivered.	<p>Click the date control for the settings.</p> <ul style="list-style-type: none"> - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd, you should input the data in the sequence of year, month, and date. - Click or to select a date and time or enter the information in the textbox directly. - Click to clear the current data and re-enter the information. <p>Note: The delivery time can be no later than the current system time and cannot be earlier than the sampling time.</p>
Operator	Personnel running the sample.	You do not need to enter it and it will be displayed automatically.
Run Time	Time when the sample is run.	You do not need to enter it and it will be displayed automatically.
Approver	Personnel validating the sample.	This parameter will be automatically displayed after the sample is validated.
Report Time	The date and time when the report is printed for the first time.	This parameter will be automatically displayed after the report is printed.
Diagnosis	Suspected diagnosis information.	Input in the textbox directly.
Remarks	Clarifications or notes.	Input in the textbox directly.

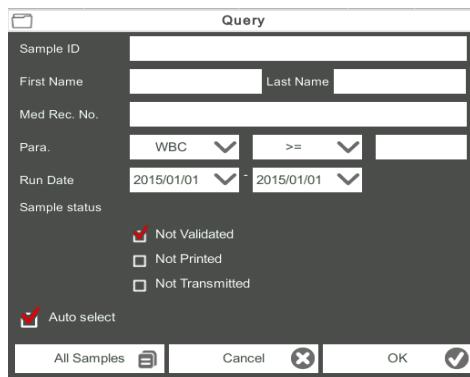
Click **Apply** or **OK** to save the configuration.

5.4.5 QUERY

You can view the test results of a patient within a certain test date range by entering the query conditions. The procedures are shown as below:

1. Click the **Query** button to enter the multi-conditional query dialogue box as shown below.

FIGURE 30
Query Conditions



2. Determine the query conditions as needed.

For the specific parameter description, see Table 11.

TABLE 11
Parameter Description of Query
Conditions

Parameter	It means	Operation Description
Sample ID	Sample ID to be queried.	Input in the textbox directly.
Name	Name of patient.	Input in the textbox directly.
Med Rec. No.	Med Rec. No. of patient.	Input in the textbox directly.
Para.	Parameter and its range to be queried.	Select a parameter from the first dropdown list, and a comparison symbol (\geq , $>$, \leq , $<$, $=$) from the second dropdown list, then input a value in the textbox. For example, if you select WBC and $>$, then input 3 in the textbox. The sample results which WBC value is greater than $3.0 \times 10^{12}/l$ will be queried and displayed.
Run Date	Test date range of sample.	Select the starting and ending dates of the sample test in the two data controls successively.
Sample status	Status of validation, printing or communication of the sample. - Not Validated - Not Printed - Not Transmitted	Please choose according to the actual situation. The default value is Not Validated .



- Auto select checked by default indicates that the query result is being selected (with a blue background colour). If it's unchecked, the query result will remain on a white background colour.
- Click **All Samples** to close the current window, display all the samples again and restore all the filter conditions to the default values.

3. Click **Query**.

The system will display all the query results which meet the conditions.

5.4.6 RESULTS

In the Review interface, you can click **Results** to browse the selected sample results, parameter results and flag messages. The procedures are shown as below:

1. Select a result to review in results interface.
2. Click to unfold all function buttons.
3. Click **Results** to enter the results interface of the selected sample. In the **Results** interface, you can view sample information such as parameter results, graph results and flag messages. In addition, you can also print the analysis report.

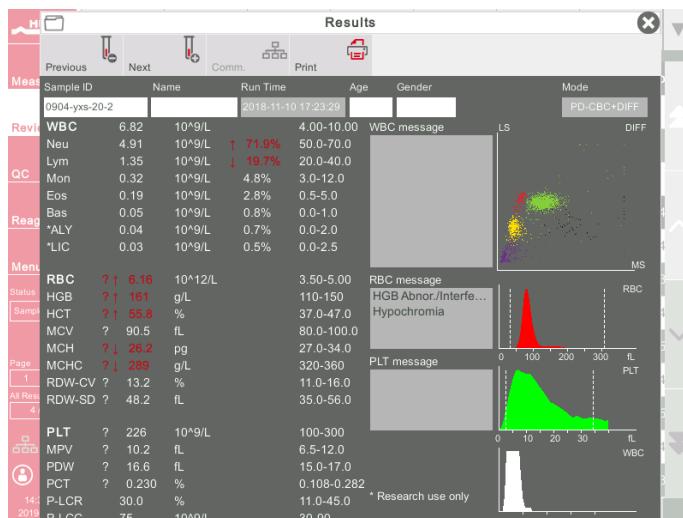


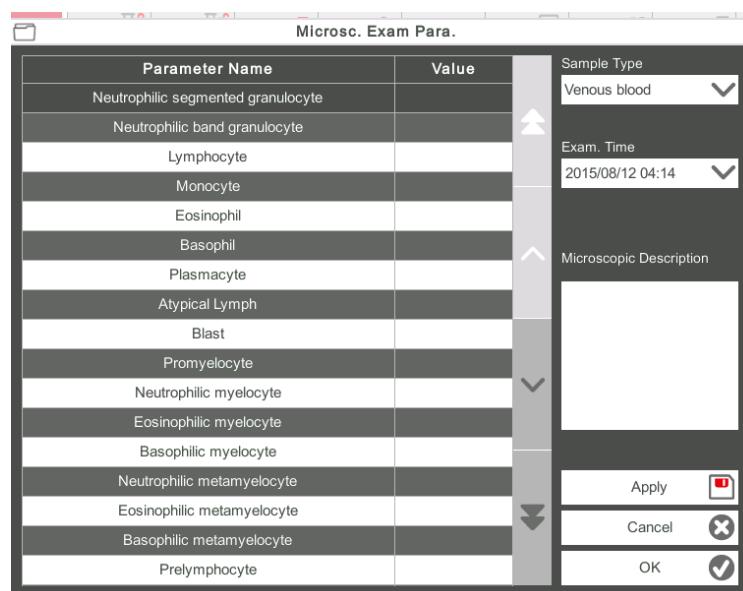
FIGURE 31

5.4.7 MICROSCOPIC EXAM. PARAMETERS

You can perform the microscopic examination settings as per the following steps.

1. Click **Microscopic Exam. Para**. The microscopic examination parameters interface as shown in Figure 32 will pop up on the screen.

FIGURE 32
Adding a New Microscopic
Exam. Parameter



2. Set the microscopic examination parameters by referring to Table 12.

Parameter	It means	Operation
Sample Type	Type of sample for microscopic examination. - Venous blood - Capillary - Cord blood - Blood	Click the Sample Type dropdown list box and select the type of sample for microscopic examination.
Exam. Time	Time of microscopic examination.	Click the date control for the settings. - The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd , you should input the data in the sequence of year, month, and date. - Click or to select a date and time or enter the information in the textbox directly. - Click to clear the current data and re-enter the information.
Microscopic Description	Description of cells morphology.	Enter the morphology information for cells into the multi-line text-box.

TABLE 12

Microscopic Exam. Parameters

5.4.8 CUSTOMIZED PARAMETERS

You can browse and edit the customized parameters results of the selected sample in the Review interface. The procedures are shown as below:

1. Select one sample.
2. Click  to unfold all function buttons.
3. Click **Custom Para.** to enter the customized parameters setting interface as shown in Figure 33.

FIGURE 33



The screenshot shows a dialog box titled "Custom Para." with a table of customized parameters. The table has columns: Para., Flag, Value, Unit, and Range. The rows contain the following data:

Para.	Flag	Value	Unit	Range
Blood Type				
RH Blood Group				
ESR				
C-reactive Protein				
Reticulocyte				

At the bottom of the dialog box are three buttons: "Apply" (with a red square icon), "Close" (with a red X icon), and "OK" (with a green checkmark icon).

4. Click the cell corresponding to its **Value** column of the parameter, and enter the value. If the unit and reference range of parameters have been set in the **Setup > Parameter > Custom Para.** interface, the corresponding unit and range (lower limit~upper limit) will be displayed in this tab. When both the value and range of parameters are numbers, and the number is out of the reference range, the relevant mark \uparrow or \downarrow will be displayed in the **Flag** column. Please refer to chapter 4.7.5 *Customized Parameters* for customized parameters settings.

5.4.9 RUN CHART

Operators can check and review run charts of sample parameter results in the database. There are three view modes: Selected samples, samples on current page and samples on specified run dates.

- View the run chart of the selected sample (default)
 - Check no fewer than three sample records.
 - Click  to unfold all function buttons.
 - Click **Run Chart**.

The system pops up a dialogue box as shown below.

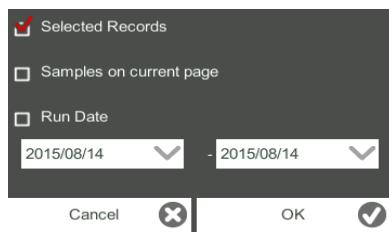


FIGURE 34

Viewing the Run Chart
of the Selected Sample

- Click **OK**.

The screen will show the parameter result run chart of the selected sample.

See Figure 35.

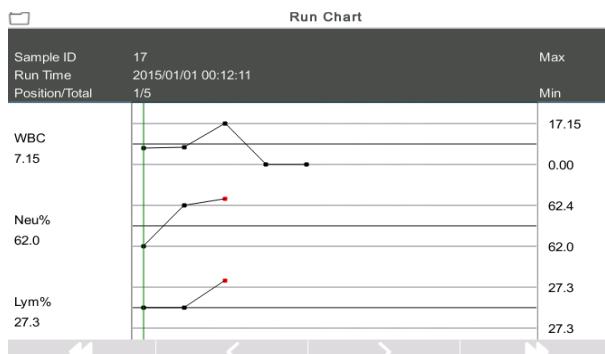


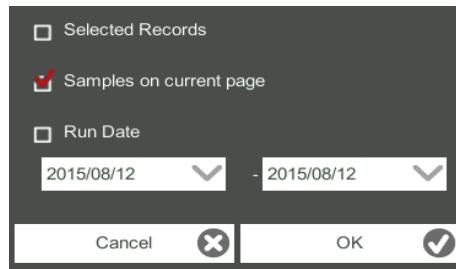
FIGURE 35

Run Chart

- View the run chart of samples on current page
 - Click  on the current page to unfold all function buttons.
 - Click the **Run Chart** button and select Samples on current page in the pop-up dialogue box. See Figure 36.

FIGURE 36

Viewing the Run Chart of Samples on the Current Page



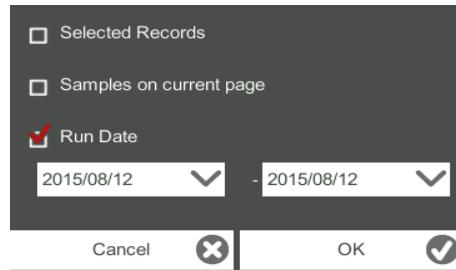
- Click **OK**.

The screen will show the parameter result run chart of the selected sample.

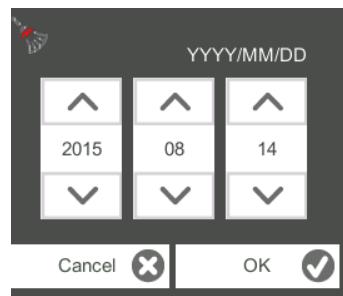
- View the run chart of samples on specified run dates
 - Click to unfold all function buttons.
 - Click the **Run Chart** button, and select Run Date in the pop-up dialogue box. See Figure 37.

FIGURE 37

Viewing the Run Chart of Samples on Specified Run Dates



- Click the date edit box, set a date range in the pop-up dialogue box, then click **OK**.

FIGURE 38

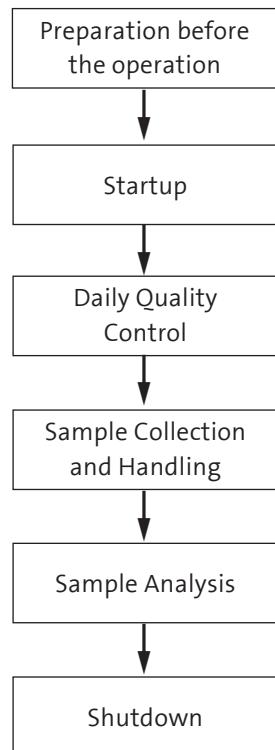
The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sequence of year, month, and date.

Click or to select a date and time or enter the information in the textbox directly.

Click **Cancel** to keep the selected run date.

- Click **OK**. The screen will show the parameter result run chart of the selected sample.

6 DAILY OPERATIONS



6.1 Pre-operation Preparation

Perform the following checks before turning on the analyzer.

- **Waste container**

Check and make sure the waste container is empty.

- **Fluidic tubing and power connections**

Check and make sure the reagents and waste tubing are properly connected and not bent.

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

- **Printer (Optional)**

Check and make sure enough paper is installed.

Check and make sure the power cord of the printer is properly plugged into power outlet, and the printer is properly connected to the peripheral computer.

- **Network Cable (Optional)**

Check and make sure the network cable is properly connected to the analyzer.

6.2 Startup

This section introduces the operations related to the startup of the analyzer.

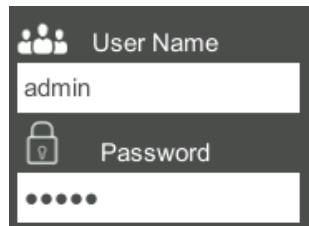
Note:

- ! - If you failed to start the analyzer continuously, please contact Human customer service department or your local agent immediately.
- After startup, please make sure the data/time displayed on the screen is correct.

1. Place the power switch at the back of the analyzer in the [I] position. The power indicator light will be on.
2. Check the indicator light on the analyzer.
If the indicator light is on, it indicates the analyzer has been started up. The analyzer will perform self-test and initialization in sequence. The whole process will last for 4 to 10 minutes. (Time needed for initializing the fluidic systems depends on how the analyzer was previously shut down.)
3. Enter the correct user name and password in the **Login** message box. See Figure 39.

FIGURE 39

Login



The initial user name and password of administrator are **admin**, which was set by service engineer.

1 to 12 digits of numeric characters can be entered for the user name and the password. No Chinese characters are allowed.

4. Click **OK** to enter the user interface.

The system will display the **Sample Analysis** screen by default and display the test result of the background when the analyzer is started.

**Note:**

- The background test is designed for detecting particle interference and electrical interference. For the background reference range of each parameter, please see A.4.2 *Normal Background*.
- The sample ID for the background test is **background**.
- If the background results exceed the Ref. Range for the first time during fluidics initialization, the analyzer will run the background test one more time.
- Running a test when there is a Background abnormal, you would obtain an unreliable testing result.
- If any error is detected during initialization (e.g. the background results exceed the **Ref. Range**), the analyzer will activate the alarm. For details, see chapter 11 *Troubleshooting*.
- To lock or switch a user, click on the menu screen and click **Yes** on the pop-up dialogue box. The system will return to the login dialogue box. Enter the user name and password, click , then you can log in again or log in the software interface with another user identity.

6.3 Daily Quality Control

To ensure reliable analysis results, conduct daily QC analysis on the analyzer before running samples. For details, see chapter 7.1 *Quality Control*.

6.4 Sample Collection and Handling

6.4.1 SAMPLE ANALYSIS

After the sample is prepared, you can perform the operations for sample analysis. For details, see chapter 4 *Sample Analysis*.

6.4.2 INTERFERING SUBSTANCES

The following substances can interfere with parameter measurement and alternate measurement procedures may be required.

TABLE 13

Parameter	Interference
WBC	> 5 NRBCs/100 WBCs, PLT clumps/ large PLTs
RBC	WBC Count > $75.0 \times 10^3/\mu\text{l}$
MCV	WBC Count > $75.0 \times 10^3/\mu\text{l}$
PLT	PLT clumps/ large PLTs
Hemoglobin	WBC count > $75.0 \times 10^3/\text{ul}$, Lipids > 280 g/dl
Differential	> NRBCs/ 100 WBCs, PLT clumps/ large PLTs

7 ADVANCED OPERATION

7.1 Quality Control

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

Analysis of the results with statistical methods allows the inference that sample results are reliable. HUMAN recommends running the QC program on a daily basis with low, normal and high level controls. A new lot of controls should be analyzed in parallel with the current lot prior to their Exp. dates. This may be accomplished by running the new lot of controls twice a day for five days using any empty QC file.

- You should only use the HUMAN-specified controls and reagents. Store and use the controls and reagents by following the instructions for use of the controls and reagents.
- Controls beyond their Exp. date shall not be used. Controls (similar to standard blood samples) must be well mixed before use.
- General users only have the access for browsing and executing the QC analysis.

7.1.1 L-J QC OVERVIEW

You can set the QC information by setting the QC file before performing the QC analysis. Each QC file can be assigned with one Lot number for high, normal and low level controls. Each QC file can store up to 500 QC results. When there are more than 500 QC results, the new QC results will overwrite the oldest results in sequence. In the L-J quality control, quality control can be applied to 23 parameters. All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them and the relevant areas in the laboratory.

7.1.2 QC SETTINGS

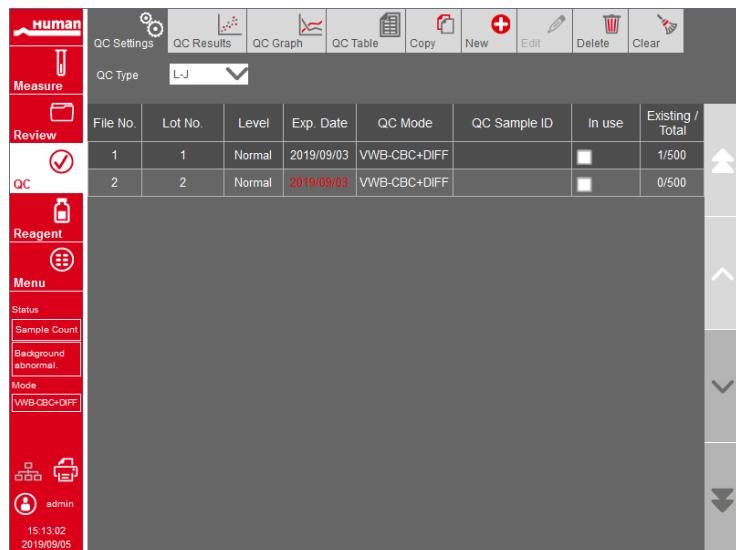
Before running a new batch of controls, you need to assign a QC file to each batch of controls. You can complete the QC settings by setting QC information in the QC files. Only users with administrator-level access can edit the L-J settings.

7.1.2.1 Entering QC Information

The administrator can set the QC files by operations such as Copy, New, and Edit. Detailed steps are shown below:

1. Click **QC** to access the **QC** interface.
2. Click **QC Settings** to enter the **QC Settings** interface. See Figure 40.

FIGURE 40
L-J Quality Control



3. Click the **New** button, or select a QC file (**Existing/Total** is **0/500**) without QC counting results and click the **Edit** button. The interface as shown in Figure 41 will pop up on the screen.

Entering QC Information (Target values), see Figure 41.

You can type in the target values according to the target value sheet of the control material. Alternatively you can read the 2D barcode on the assay value sheet (optional 2D barcode reader (Ref.: 16430/11)) and automatically upload all target values into the analyzer. Another option is to upload the target values by a USB flash drive.

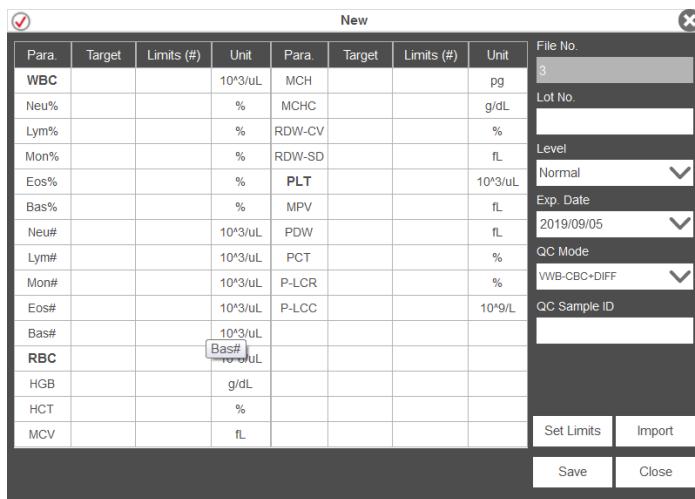


FIGURE 41
Entering QC Information
(Target values)

You can also select the QC file of which data has been set and then click **Copy**, and edit the content based on the original data. Set related information of the controls with reference to Table 14.

Parameter	Parameter Description	Operation Description
File No.	QC file No.. The system provides 60 QC files in total for users to set the parameters.	Read only.
Lot No.	Lot number of controls.	Enter into the textbox directly.
Level	Level of the controls, including 3 levels, i.e. High, Normal and Low.	Select from the dropdown list.
Exp. Date	Exp. date of the controls.	The default Exp. Date is the current system date and needs to be changed to the actual Exp. date of the controls.
QC Mode	QC mode of the controls, including Whole Blood-DIFF and Predilute-DIFF.	Select from the dropdown list.

TABLE 14
File Information

QC Sample ID	Number of the QC sample	Enter into the textbox directly.
	<ul style="list-style-type: none"> - Users need to set the number of the controls here if he/she is used to performing the analysis with the controls placed among the daily samples. See chapter 7.1.3.1 <i>Completing QC Analysis in the Sample Analysis Interface</i>. - If the user performs the analysis in the QC Analysis interface, the ID cannot be entered. 	<p>Note:</p> <p>! Letters, numbers and all characters that can be entered through the keyboard (including special characters) are allowed for the Sample ID. Chinese and other languages (such as Japanese, Korean, etc) are not supported.</p> <ul style="list-style-type: none"> - The length of the entries ranges from 1 to 25 and the entries shall not be empty. - The last character of a sample ID must be numeric, but a string of "0" only is not an acceptable sample ID.
Target	Target of the QC parameter.	Enter the targets in the cell corresponding to the expected QC parameter according to the control target list with the corresponding lot No.
Limits (#)	Limits (#) of the QC parameter.	Enter the limits in the cell corresponding to the expected QC parameter according to the control target list with the corresponding lot No.

Note:

! You can click **Set Limits** to set the display form of the limits or the calculation method of the limits among the preset values.

- By SD: the limits displays in form of absolute value. Click 2SD or 3SD to select either double or triple standard deviation to be the limits.
- By CV: the limits displays in form of percentage. Click 2CV or 3CV to select either double or triple coefficient of variation to be the limits.

In use	Set if you want to specify the QC sample ID in the selected file so that you can run the QC sample in the interface other than the QC interface.	It's unchecked by default. Set the parameter according to the actual situation.
Existing/ Total	The existing data and total QC results in the current QC file. Up to 500 QC results can be saved for each QC file.	Read only.

4. According to the target list of the corresponding lot No., enter the target value and limits into the textboxes of the parameters to be included in the QC run.
5. Click the **Save** button to save all the settings of the QC.

7.1.2.2 Deleting QC File

If you want to delete QC files which will not be used any more, please take the following steps:

1. Click **QC** to access the **QC** interface.
2. Click **QC Settings** to enter the **QC Settings** interface.
3. Select the QC file to be deleted, and click **Delete**.

The interface pops up a dialogue box as shown below.

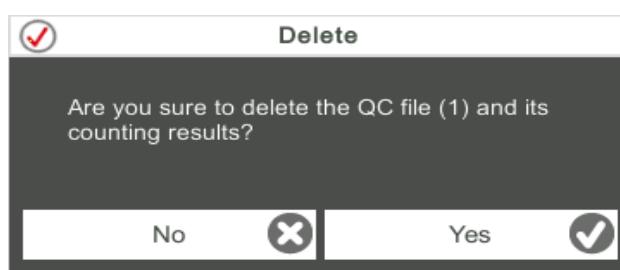


FIGURE 42

4. Click **Yes**.

All selected QC files together with their QC results will be completely deleted.

7.1.3 QUALITY CONTROL ANALYSIS

After completing the QC settings, you can choose one of the following two modes according to the selected QC mode to run the quality control samples.

- Completing QC analysis in the **QC Analysis** interface
- Completing QC analysis in the **Sample Analysis** interface



CAUTION

- Running quality controls in presence of errors may lead to incorrect analysis results. If you see the error alarms when running the quality controls, please stop and resume the analysis until the errors are removed.
- Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.
- Sample clump may lead to incorrect analysis results. Check if clump exists before running the controls; if it does, handle it as per the related laboratory procedures.



Note:

- You should only use the Human-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents. Using other controls may lead to incorrect QC results.
- Before being used for analysis mix gently the controls that have been settled for a while according to the instruction of controls.
- Be sure to use the Human-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
- If the blood-sample mode is **Predilute**, then a reminder of predilute counting will pop up if the user presses the aspirate key to perform the counting. To close the prompt, please refer to *Auxiliary Settings*.

7.1.3.1 Completing QC Analysis in the QC Analysis Interface



All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them and the relevant areas in the laboratory.

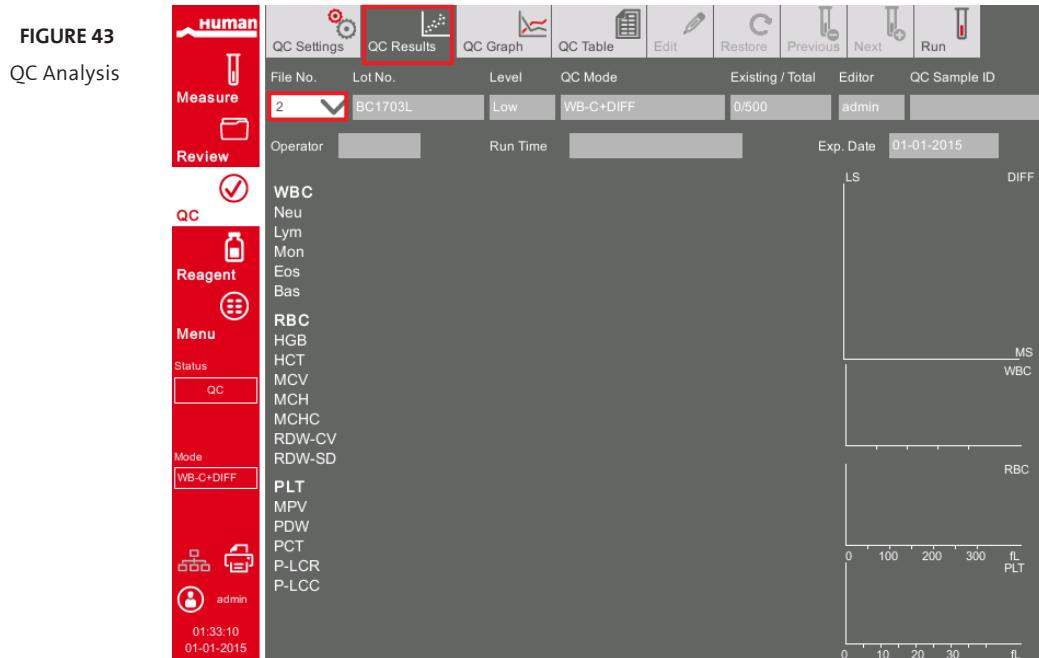
**WARNING**

- The sample probe (needle) is sharp and potentially biohazardous. Exercise caution to avoid contact with the probe when working around it.
- The sample may spill from the unclosed collection tubes and cause biohazard. Exercise caution to the unclosed collection tubes.
- Collection tubes broken may cause personal injury and/or biohazard. Be sure to place the collection tubes in the right adapter before running, otherwise, the collection tubes may be broken and cause biohazard.
- Keep your clothes, hairs and hands away from the moving parts to avoid injury.
- Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.

After completing the QC settings, users can perform the **QC analysis** in the QC Analysis interface.

Detailed steps are shown below:

1. Click **QC** to access the QC interface.
2. Click **QC Analysis** and enter the QC analysis interface as shown in Figure 43.



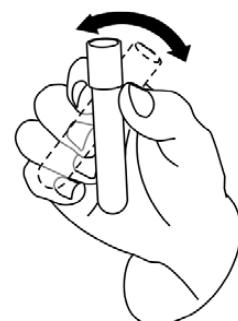
3. Select the QC file No. to be run. The screen will display the corresponding information and QC parameters.
4. Be sure that the level of the control to be run is the same with the current QC file, and the control to be run is not expired.
5. Prepare the controls according to control instructions. If the QC mode is Pre-dilute-DIFF, Predilute the controls with reference to chapter 6.4 *Sample Collection and Handling* and get diluted QC samples.

Note:

- Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

6. Mix the prepared control as shown below to mix it well.

FIGURE 44
Mixing the Controls



7. In the ready for counting state (namely, the indicator light of the main unit is green), place the controls under the sample probe where the probe can aspirate the well-mixed controls.
8. Press the aspirate key and start running the controls.
9. Upon the completion of the aspiration, you'll hear a beep and you can remove the controls. When the running of QC analysis is complete, the QC results will be displayed in the current screen (as shown in Figure 45) and saved in the QC file automatically.



FIGURE 45
Analysis Results

10. Perform the above procedures to continue running the controls if necessary.



Note:

- If the QC file is outdated, its valid period will be displayed in red.
- “↑” or “↓” alarm symbol will be displayed next to the results with deviations exceeding the set limits.

7.1.3.2 Completing QC Analysis in the Sample Analysis Interface

CAUTION



- Running quality controls in presence of errors may lead to incorrect analysis results. If you see the error alarms when running the quality controls, please stop and resume the analysis until the errors are removed.
- Do not re-use such disposable products as collection tubes, test tubes, capillary tubes, etc.
- Sample clump may lead to incorrect analysis results. Check if clump exists before running the controls; if it does, handle it as per the related laboratory procedures.



Note:

- You should only use the HUMAN-specified controls and reagents. Store and use the controls and reagents as instructed by instructions for use of the controls and reagents. Using other controls may lead to incorrect QC results.
- Before being used for analysis shake well the controls that have been settled for a while.
- Be sure to use the HUMAN-specified disposable products including vacutainer blood collection tube, vacutainer blood collection tubes with anticoagulant and capillary tubes etc.
- If the blood-sample mode is **Predilute**, then a reminder of predilute counting will pop up if the user presses the aspirate key to perform the counting. To close the prompt, please refer to *Auxiliary Settings*.

After completing the QC settings, you can place the controls among the daily samples and perform analysis together in the **Sample Analysis** interface. After the analysis is completed, the system will store the results to the QC file with the corresponding ID.

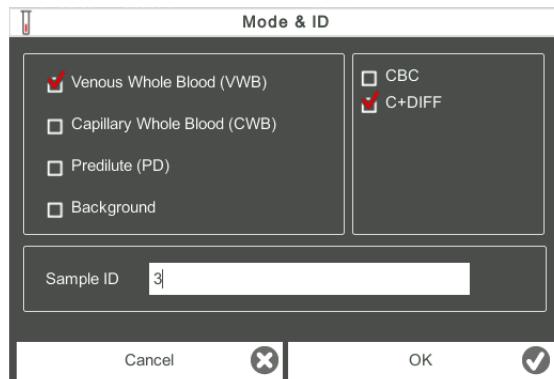
Specific steps for performing QC analysis in the Sample Analysis interface are as follows:

1. Prepare the controls according to the set control mode and control instructions.
2. In pre-dilution mode: Predilute the controls with reference to chapter 3.1.13 *Sample Collection and Handling* and get diluted QC samples if the QC mode is **Predilute**.

3. Enter the set QC Sample ID in the **Sample ID** edit box (other options can be ignored). Refer to chapter 7.1.2.1 *Entering QC Information* for the setting of the QC Sample ID.
4. Well mix the prepared controls.
5. In the ready for counting state of the analyzer (namely, the indicator light of the main unit is green), place the controls under the sample probe where the probe can aspirate the well-mixed controls.
6. Press the aspirate key and start running the controls.
7. Upon the completion of the aspiration, you'll hear a beep and you can remove the controls. When the running of the controls is complete, the QC results will be saved in the QC file automatically.
8. Perform the above procedures to continue running the controls if necessary.
 - If the QC file is outdated, its valid period will be displayed in red.
 - “ \uparrow ” or “ \downarrow ” alarm symbol will be displayed next to the results with deviations exceeding the set limits.

**Note:**

- It is not recommended to exceed the limits higher than shown on the target value sheet of the control.
- Be sure to evaluate predilute stability based on your laboratory's sample population and sample collection techniques or methods.

**FIGURE 46**

7.1.4 QC RESULT REVIEW

After running controls, you can review the QC results in the following two forms:

- QC Graph
- QC Table

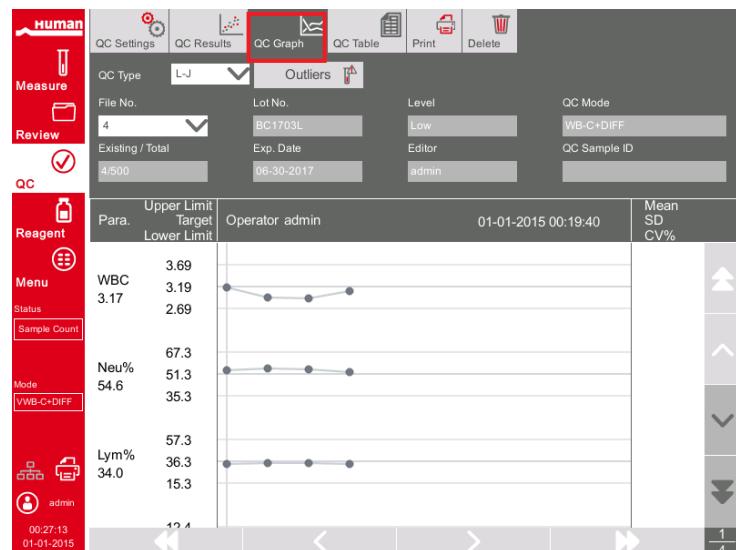
7.1.4.1 Levy-Jennings Diagram



You can review the result of L-J QC graph as per the following steps.

1. Click **QC** to access the QC interface.
2. Click **QC Graph** to enter the interface as shown in Figure 47.

FIGURE 47
Graph Interface



3. Select the QC file No. you want to review. The screen will display the corresponding information and the graph. See Figure 48.

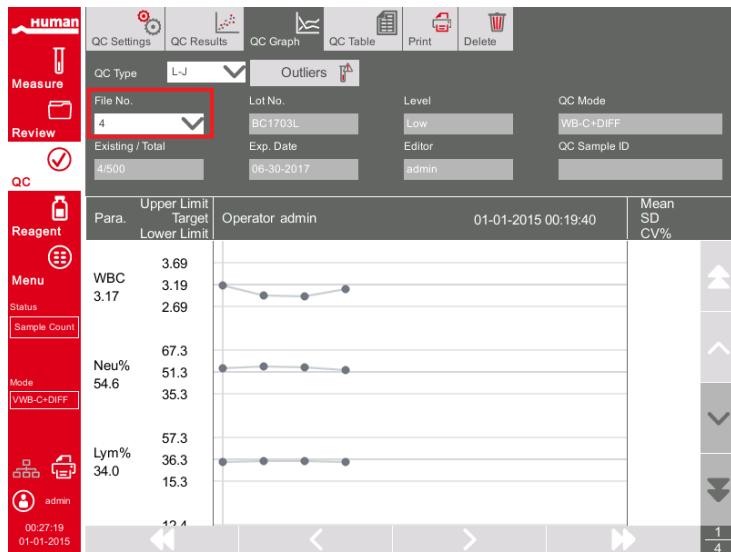


FIGURE 48
QC Graph

- Click the buttons at the right side of the QC graph, then you can browse QC graphs of different parameters; click the buttons at the bottom of the QC graph, then you can browse all QC results.

Introduction to the Levy-Jennings Interface

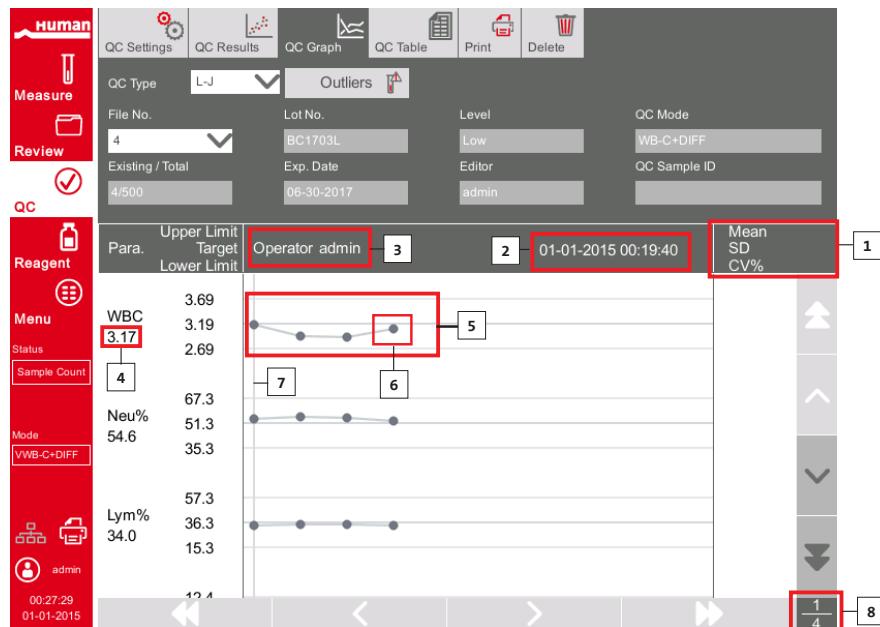


FIGURE 49

Interface Description:

1. The Mean, SD and CV% of all the QC results of each parameter in the current graph.
2. The saving date and time of the QC points located on the grey line.
3. The operator who run the QC analysis and obtained the QC points located on the grey line.
4. The QC results of the parameters that correspond to the QC points located on the grey line.
5. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest. The QC points are connected by a line to illustrate the distribution trend.
6. The QC point corresponds to each QC result. Only the selected QC point displays its value under the parameter. The black QC point indicates the value is within the limit; the red QC point indicates the value is out of the limit.
7. When you clicking a QC point in the graph, the QC points of other parameters saved together with this one will be marked by a grey line.
8. The relative position of the QC point located on the grey line and the total QC points saved currently.

Note:

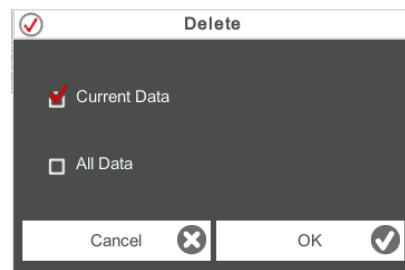
- The outliers are excluded from the calculation of Mean, SD and CV%.
- See below how to define a value as outlier.

Delete

The administrator can delete the QC results by the following steps:

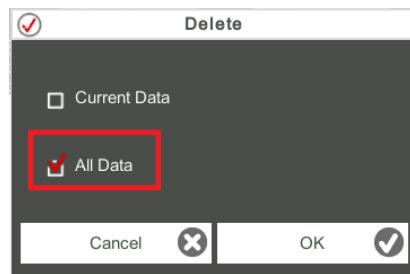
- Delete a single QC result
 - Move the grey line to the desired QC result, and click **Delete**.
 - Select **Current Data** in the pop-up dialogue box as shown in Figure 50.

FIGURE 50
Deleting Current QC Data
(QC Graph)



- Click **OK**.

- Deleting all the QC results in the current QC file. Click **Delete**, select **All Data** in the pop-up dialogue box, then click **OK**. See Figure 51.

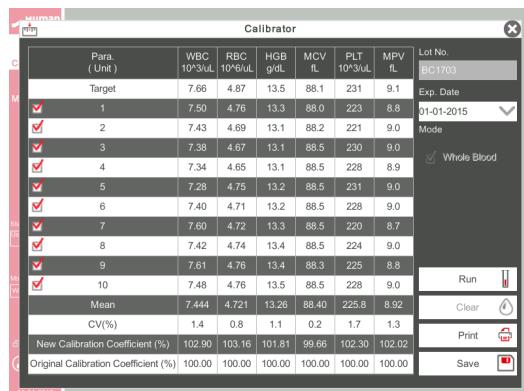
**FIGURE 51**

Deleting all QC Data (QC Graph)

Entering the Reasons for the Outliers

Do as follows to enter the reasons for the outliers:

1. Move the grey line to the desired QC point, and then click **Outliers**. The pop-up window displays the QC results, reference values and target value range of all parameters corresponding to the grey line as shown in Figure 52. The QC results exceeding the limit will be displayed in red.

**FIGURE 52**

Deleting all QC Data (QC Graph)

2. You can select the reason from the given ones or manually enter the reasons (up to 200 characters) into the textbox after selecting **Others**.
3. Click **OK** to save the reasons for the outliers and exit.



Note:

If you enter the reason for the group of QC points whose results are actually within the limits, then their corresponding QC data both in the QC Graph and QC Table will be displayed in red. And the data will return in black if you cancel the reason and then save the changes.

Print

You can have the QC data of the current page or all QC data in the QC file printed by clicking the **Print** button.

7.1.4.2 Table

All the samples, controls, calibrators, reagents, wastes and areas in contact with them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them and the relevant areas in the laboratory.

1. Click **QC** to access the QC interface.
2. Click **QC Table** to access the interface as shown in Figure 53.

FIGURE 53

3. Select the QC file No. you want to review. The screen will display the corresponding information and the table.
4. Click the buttons at the bottom of the table to browse the QC data of desired parameters; click the buttons on the right of the table to browse the QC results.

Editing

Choose a row in the QC table and click **Edit**, then you can edit the selected QC data. The edited data will be marked with an **E**. See Figure 54.

	Date	Time	WBC
Target	/	/	3.19
Limits (#)	/	/	0.50
4	01-01-2015	00:24:56	3.10
3	01-01-2015	00:23:01	2.93
2	01-01-2015	00:21:25	2.94
1	01-01-2015	00:19:40	E ↑ 4.17

FIGURE 54
Editing QC Results

Restoring

Click **Restore** to cancel the editing of the QC results. After the data is restored, the **E** mark will disappear.

Delete

With the administrator-level access, users can delete the selected QC data, QC data on the current page and all QC data.

- Delete a selected QC result
 - Click the column containing the desired QC result, and then click **Delete**.
 - Select **Current Data** in the pop-up dialogue box as shown in Figure 55.

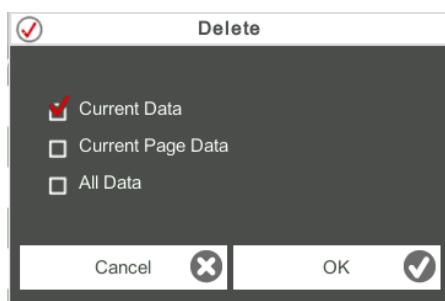
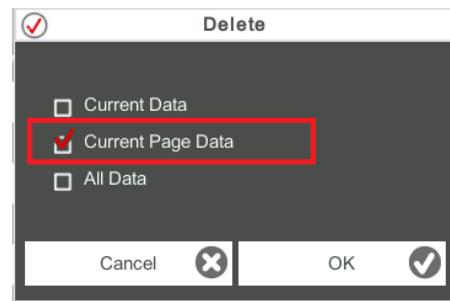


FIGURE 55
Deleting Current QC Data
(QC Graph)

- Click **OK**.

- Delete QC data on the current page
 - Click **Delete** on the page which contains the QC results expected to be deleted.
 - Select **Current Page Data** in the pop-up dialogue box as shown in Figure 56.

FIGURE 56



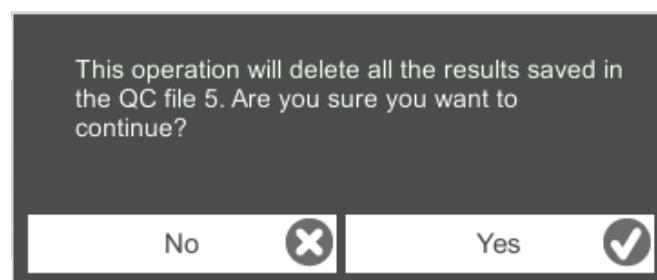
- Click **OK**.
- Delete all QC results

- Note:**
- ! Please be careful to perform this operation as it will delete all QC data of the selected QC file and cannot be reverted.

- Click **Delete**.
- Select **All Data** in the pop-up dialogue box.
- Click **OK**.

The interface pops up a dialogue box as shown below.

FIGURE 57



- Click **Yes** to delete all the QC results in the current QC file.

Print

You can print all the QC data or the data within the specified date range of the selected QC file.

Detailed steps are shown below:

1. Select a QC file No. to be printed.
2. Click **Print**.

The interface pops up a dialogue box as shown below.

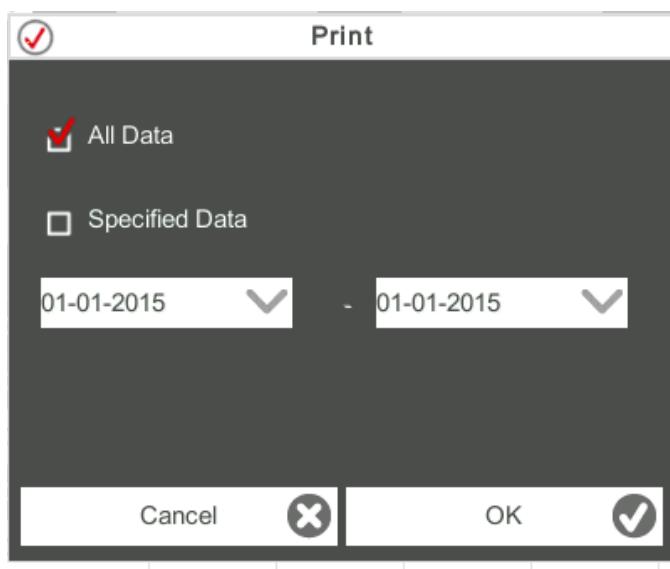


FIGURE 58

Printing all QC Data (QC Graph)

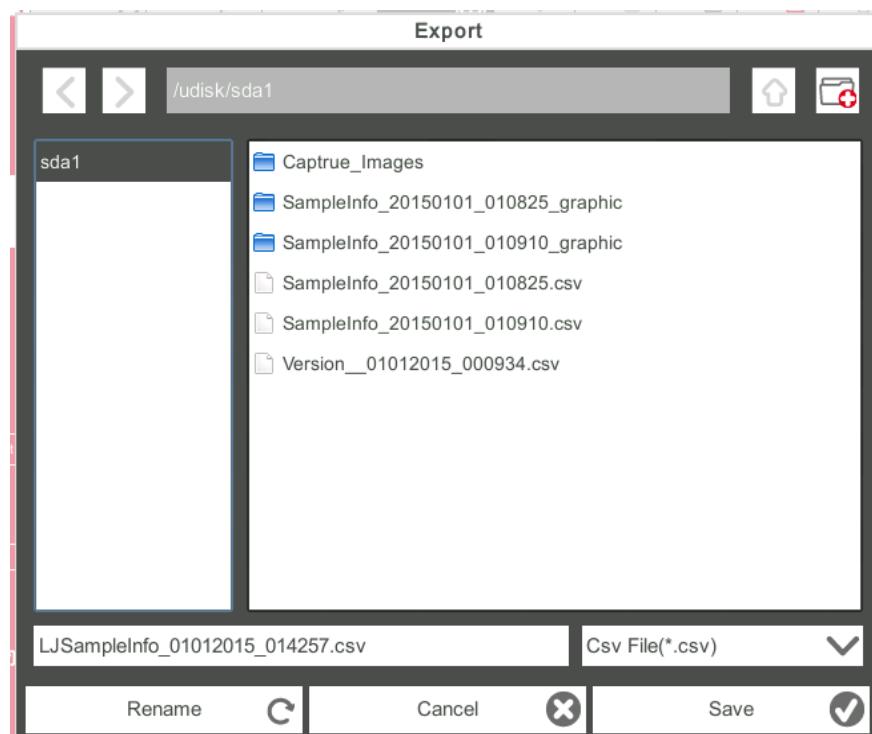
3. Select the QC data to be printed: all data or specified data.
 - When **All Date** is selected, all the QC data of the table will be printed.
 - When **Specified Data** is selected, and the date range is set in the date controls, the QC data within the specified date range will be printed.
4. Click **OK** to print the data.

Export

If you wish to export the information and the result of the current QC file, do as follows:

1. Insert a USB flash disk in the USB interface on the analyzer.
2. Click **Export**.
3. A dialogue box will pop up as shown below:

FIGURE 59
Exporting all QC Data
(QC Graph)



4. Select an export path for the data and enter the file name. The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo_yyyyMMdd_hhmmss.csv**. Among which, **yyyyMMdd_hhmmss** means data export year, month, date, hour, minute, and second.

5. Click **Save**. When the export is finished, a message box as shown below will pop up.

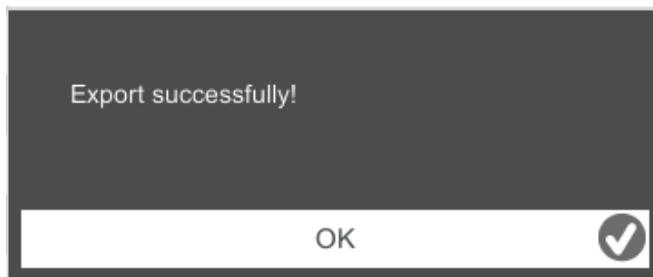


FIGURE 60

6. Click **OK** to close the message box.

7.2 X-B Quality Control

7.2.1 QC Principle

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

This is a QC method without controls, and reflects only an indicator for a correct analyzer performance. HUMAN highly recommends to use control materials. Both methods reflect the analysis performance of the analyzer from different perspective. Thus, one method should not be replaced with the other. It is recommended the X-B analysis be activated when the sample volume of your laboratory is greater than 100 samples per day.

Effective use of X-B requires randomization of samples and a normal cross section of patients to prevent skewing of indices. A reference range is established by the given reference values as well as lower and upper limits for the purpose of observing the variation of QC results within the reference range. The analyzer performs X-B QC for three parameters, MCV, MCH, and MCHC.

Twenty to two hundred samples can be grouped together for X-B numerical analysis. The samples are derived from the results of normal analyzer counting, with no distinction of whole-blood or predilute mode. The analyzer can save maximum 500 X-B QC results. When the saved QC results have reached the maximum number, the newest result will overwrite the oldest.

7.2.2 QC SETTINGS

Note:

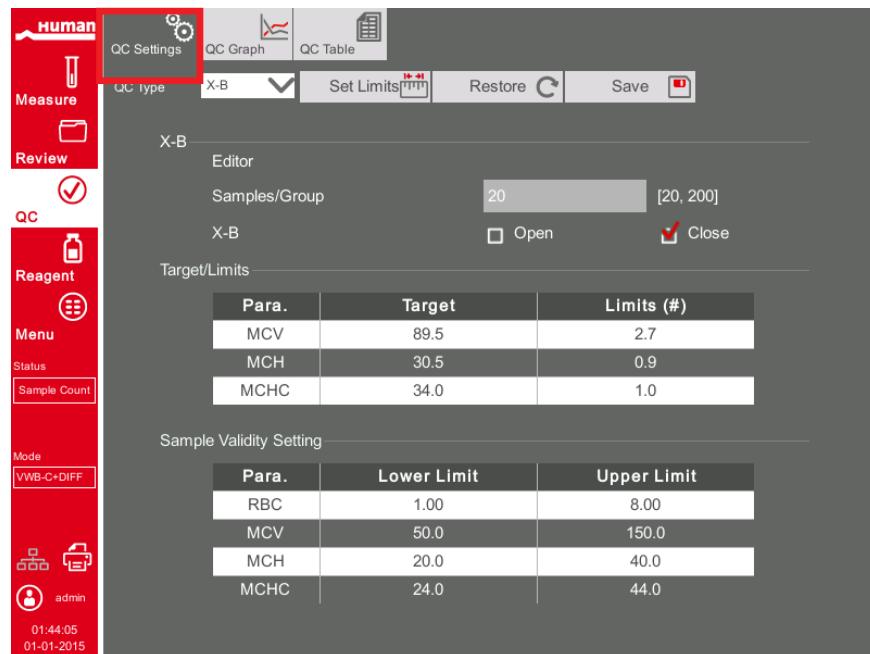
- Only users with administrator-level access can edit the X-B settings.
- Perform the QC Settings before running the controls. You can complete the QC settings by entering the QC information.

7.2.2.1 Entering QC Information

You can complete the X-B QC settings as per the following steps:

1. Click **QC** to access the **QC** interface.
2. Select **X-B** from the dropdown list of the **QC Type**.
3. Click **QC Settings**. You'll enter the **QC Settings** interface as shown in Figure 61.

FIGURE 61



4. In the **Samples/Group** edit box, enter the amount of samples to be included in calculating for an X-B QC point. The range is between 20 and 200 and the recommended value is 20.

**Note:**

Once the **Samples/Group** is changed, the number of valid sample results will be recalculated. For example, if 20 valid samples are needed for the X-B QC calculation, when you change the value of **Samples/Group** after 10 group of valid sample results have been acquired, these 10 group of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.

5. Click the **Open** button of **X-B** to open the X-B quality control. The samples results will be included to calculate the X-B.
6. Enter the targets and limits for the QC parameters.

**Note:**

- All the targets and limits for the QC parameters must be entered.
- When first use, the default setting will provide the Initial values for the targets and limits of the three QC parameters.
- If the QC data have existed in the QC file, you are not allowed to edit the target and limits.
- You can set the display form of the limits or the calculation method of the limits among the preset values see chapter 7.2.2.2

7. Set the valid upper and lower limits for the QC parameter in **Sample Validity Setting** field. Setting sample validity is to set the valid range of four QC parameters, RBC, MCV, MCH and MCHC. To be incorporated into X-B QC calculation, the sample results should satisfy the validity ranges of all these four parameters.

**Note:**

Once the **Samples/Group** is changed, the number of valid sample results will be recalculated. For example, if 20 valid samples are needed for the X-B QC calculation, when you change the value of **Samples/Group** after 10 group of valid sample results have been acquired, these 10 group of results will be discarded, and only valid sample results generated afterwards will be used in the QC calculation.

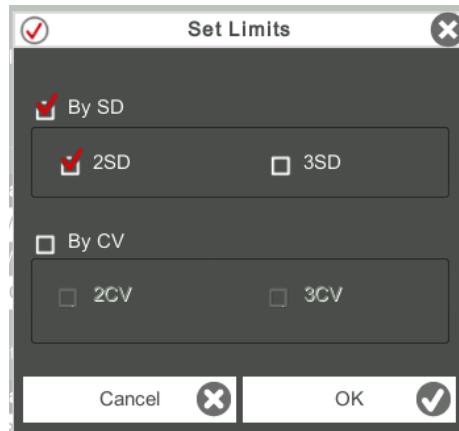
8. Click the **Save** button to save all the settings of the QC. If the entered value exceeds the acceptable range or the upper limit is lower than the lower limit, a reminder message will pop up and you will be prompted to re-enter the correct data and save the entry again.

7.2.2.2 Setting Limits

You can take the following steps to adjust the display format of the limits and the calculation method of the preset limits.

1. Click **Set Limits**. The interface pops up a dialogue box as shown below.

FIGURE 62



2. Select **By SD** or **By CV** according to the actual needs.
 - If **By SD** is selected, the limits will be displayed in form of absolute value. Click **2SD** or **3SD** to select either double or triple standard deviation to be the limits.
 - If **By CV** is selected, the limits will be displayed in form of percentage. Click **2CV** or **3CV** to select either double or triple coefficient of variation to be the limits.
3. Click **OK** to save all the settings for the limits.

7.2.2.3 Restoring Defaults

In QC setting, click **Restores Defaults** button to restore the parameter reference values, limits and sample validity to the default settings.



Note:

- If QC data are existing in the QC file, you are not allowed to restore the parameters.
- Clicking Restores Defaults can only store the default settings of **Target**, **Limits** and **Sample Validity Setting**, while **Samples/Group**, X-B QC switch and limit settings cannot be restored.

7.2.3 QUALITY CONTROL ANALYSIS

After the QC settings, the analyzer will automatically start the X-B QC analysis. After every 20~200 results (determined by the setting) are obtained, the system will perform the X-B calculation once automatically. You can review the result in X-B graph or X-B table. In X-B QC, sample results conforming to any of the following conditions will be considered as invalid and cannot be used in the QC calculation.

- Sample results exceeding the linearity range
- Background results
- Sample results not conforming to the **Sample Validity Setting**
- QC data for other QC programs (such as L-J QC)
- Calibration data
- Results generated while there are errors which could affect the accuracy of the results (insufficient aspiration volume or clogging for example).

7.2.4 QC RESULT REVIEW

After running controls, you can review the QC results in the following two forms:

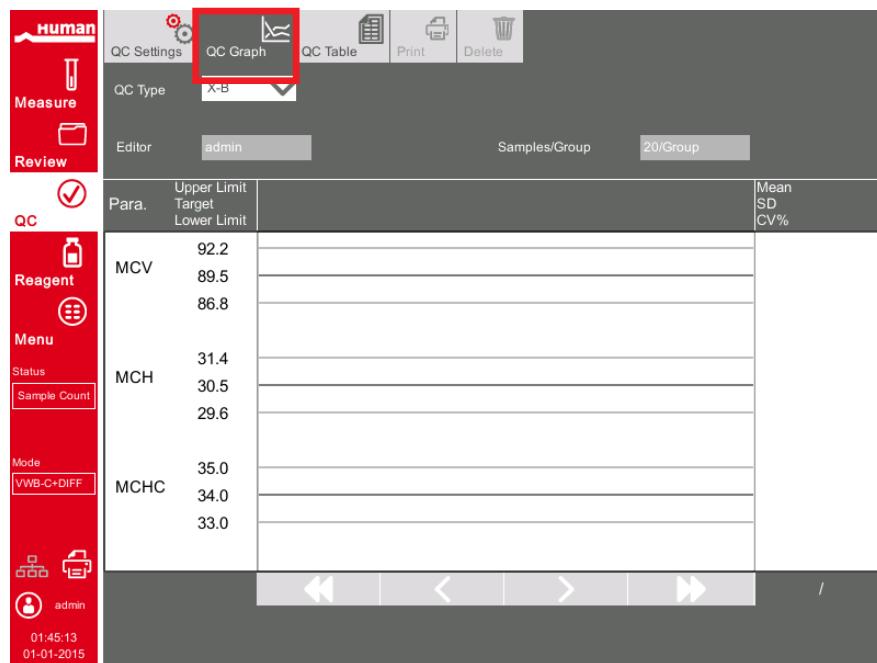
- QC Graph
- QC Table

7.2.4.1 Graph

Access the **X-B QC** Graph interface by taking the following steps:

1. Click **QC** to access the **QC** interface.
2. Select **X-B** from the dropdown list of the **QC Type**.
3. Click **Graph**. The X-B QC Graph interface will be displayed, see Figure 63.

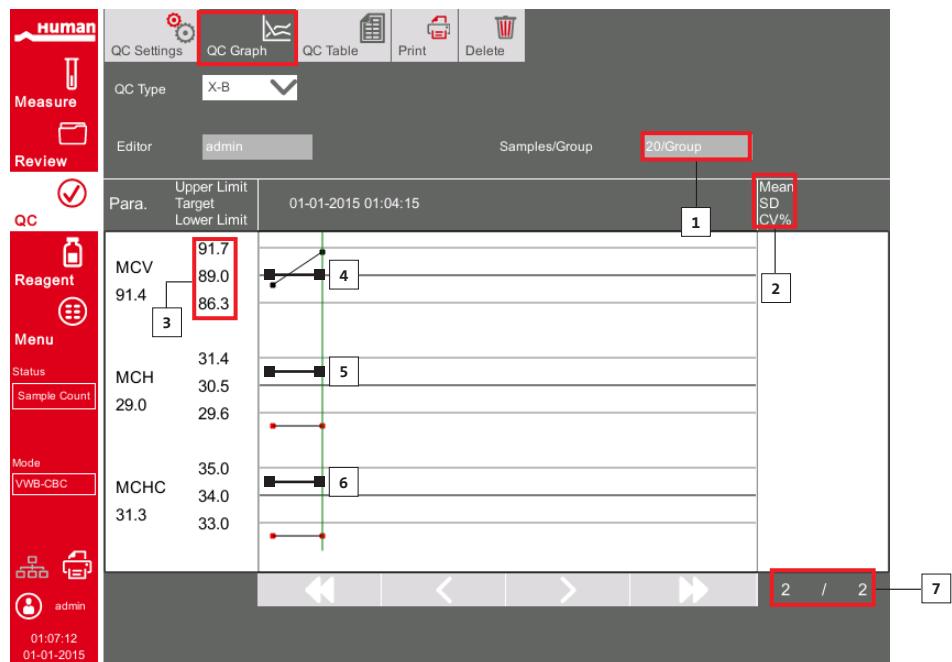
FIGURE 63
QC Graph



4. You can also drag the scroll bar down to the graph horizontally to browse all the QC results.

Introduction to the Graph Interface

FIGURE 64



1. The amount of samples included in calculating for each QC point.
2. The Mean, SD and CV% of all the QC results of each parameter in the current graph.
3. The QC results of the parameters that correspond to the QC points located on the green line.
4. The QC points in each graph are displayed from left to right according to the sequence from the earliest to the latest. The QC points are connected by a line to illustrate the distribution trend.
5. The QC point corresponds to each QC result. Only the selected QC point displays its value under the parameter. The black QC point indicates the value is within the limit; the red QC point indicates the value is out of the limit.
6. When you clicking a QC point in the graph, the QC points of other parameters saved together with this one will be marked by a green line.
7. The relative position of the QC point located on the green line and the total QC points saved currently.

Delete

The administrator can delete the QC results by the following steps:

- Delete a single QC result
 - Move the green line to the desired QC result, and click **Delete**.
 - Select **Current Data** in the pop-up dialogue box as shown in Figure 65.

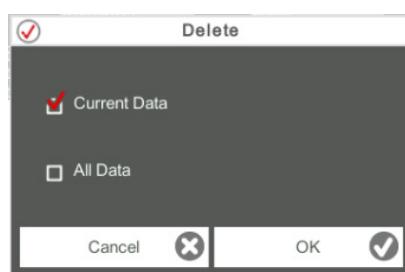


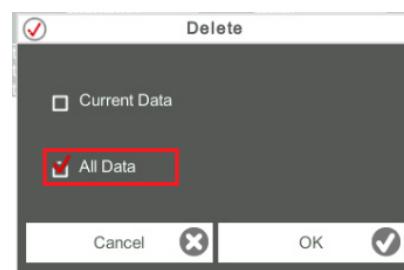
FIGURE 65

Deleting Current QC Data
(QC Graph)

- Click **OK**.

- Deleting all the QC results in the current QC file. Click **Delete**, select **All Data** in the pop-up dialogue box, then click **OK**. See Figure 66.

FIGURE 66
Deleting all QC Data
(QC Graph)



Print

Click the **Print** button to print the QC graph.

7.2.4.2 Table

Access the X-B QC Table interface by taking the following steps:

1. Click **QC** to access the QC interface.
2. Select **X-B** from the dropdown list of the **QC Type**.
3. Click **QC Table**. The X-B QC table interface will be displayed. See Figure 67.

FIGURE 67
QC Table

	Date	Time	MCV	MCH	MCHC
Target	/	/	89.0	30.5	34.0
Limits (#)	/	/	2.7	0.9	1.0
1	01-01-2015	00:41:33	88.0	28.5	31.0
2	01-01-2015	01:04:15	91.4	29.0	31.3

Introduction to the QC Table Interface

			1	2
			Samples/Group	20 Group
	Date	Time	MCV	MCH
Target	/	/	89.0	30.5
Limits (#)	/	/	2.7	0.9
1	01-01-2015	00:41:33	88.0	28.5
2	01-01-2015	01:04:15	91.4	31.0
			31.3	

FIGURE 68

1. The amount of samples included in calculating for each QC point.
2. QC parameters (displayed in the same order as the **QC Graph** screen).
3. The No. of the QC result saved in the QC file (arranged from left to right in the order that from the earliest to the latest).
4. QC Result. The value of the QC result is the X-B result of each group of samples.
5. QC flag: A \uparrow or a \downarrow next to the values are used to prompt the results that are out of the limits.

Delete

With the administrator-level access, users can delete the selected QC data, QC data on the current page and all QC data.

- Delete a selected QC result
 - Click the column containing the desired QC result, and then click **Delete**.
 - Select Current Data in the pop-up dialogue box as shown in Figure 69.

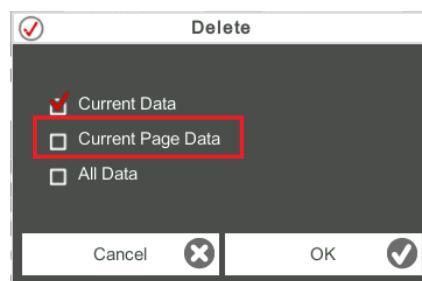


FIGURE 69

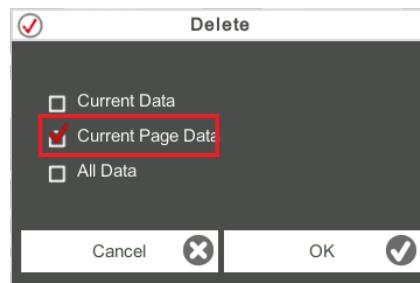
Deleting Current QC Data
(QC Graph)

- Click **OK**.

- Delete QC data on the current page.
 - Click **Delete** on the page which contains the QC results expected to be deleted.
 - Select **Current Page Data** in the pop-up dialogue box as shown in Figure 70.

FIGURE 70

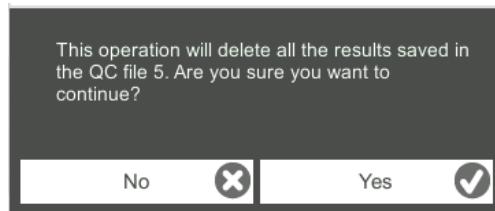
Deleting all QC Data (QC Graph)



- Click **OK**.
- Delete all QC results.

**Note:**

- Please be careful to perform this operation as it will delete all QC data of the selected QC file and cannot be reverted.
- Click **Delete**.
- Select **All Data** in the pop-up dialogue box.
- Click **OK**. The interface pops up a dialogue box as shown below.
- Click **Yes** to delete all the QC results in the current QC file.

FIGURE 71**Print**

You can print all the QC data or the data within the specified date range of the selected QC file. Detailed steps are shown below:

1. Select a QC file No. to be printed.
2. Click **Print**.

The interface pops up a dialogue box as shown below.

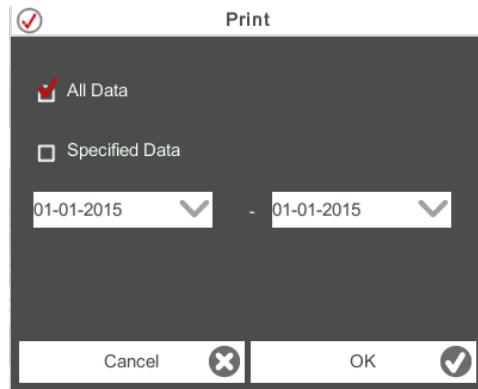


FIGURE 72

3. Select the QC data to be printed: all data or specified data.
 - When **All Date** is selected, all the QC data of the table will be printed.
 - When **Specified Data** is selected, and the date range is set in the date controls, the QC data
 - Within the specified date range will be printed.
4. Click **OK** to print the data.

Export

If you wish to export the information and the result of the current QC file, do as follows:

1. Insert a USB flash disk in the USB interface on the analyzer.
2. Click **Export**.
3. A dialogue box will pop up as shown below.

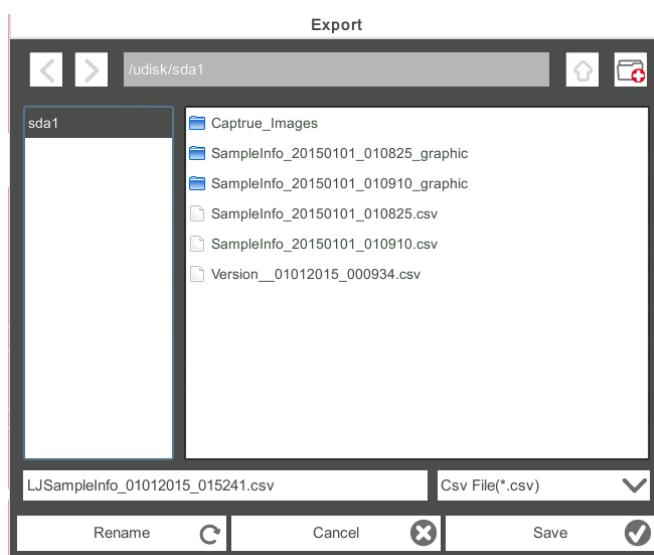
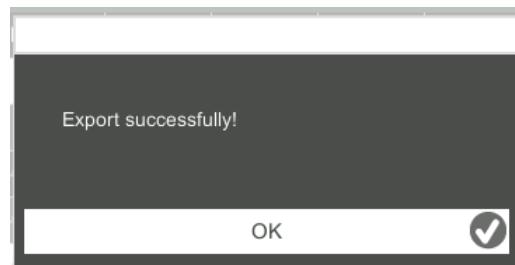


FIGURE 73

4. Select an export path for the data and enter the file name. The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) and named in the format of **SampleInfo_yyyyMMdd_hhmmss.csv**. Among which, yyyyMMdd_hhmmss means data export year, month, date, hour, minute, and second.
5. Click **Save**. When the export is finished, a message box as shown below will pop up.

FIGURE 74
Export successfully



6. Click **OK** to close the message box.

7.3 Setup

7.3.1 INTRODUCTION

This chapter introduces the daily operations from the startup to the shutdown of the analyzer.

A flow chart indicating the common daily operation process is presented in chapter 6 *daily operations*.

The analyzer has been initialized before delivery. The interfaces upon the initial startup of the analyzer are system settings by default. Some parameters of the analyzer can be reset to meet various demands in practical applications. The analyzer divides the operators into two access levels, common user and administrator. Note that an administrator can access all the functions accessible to a common user. This chapter introduces how to customize your analyzer as an administrator.

7.3.2 INTERFACE INTRODUCTION

After logging in the system (see chapter 6.2 *Startup*), click **Setup** to access the **Setup** interface. Figure 75 will pop up.

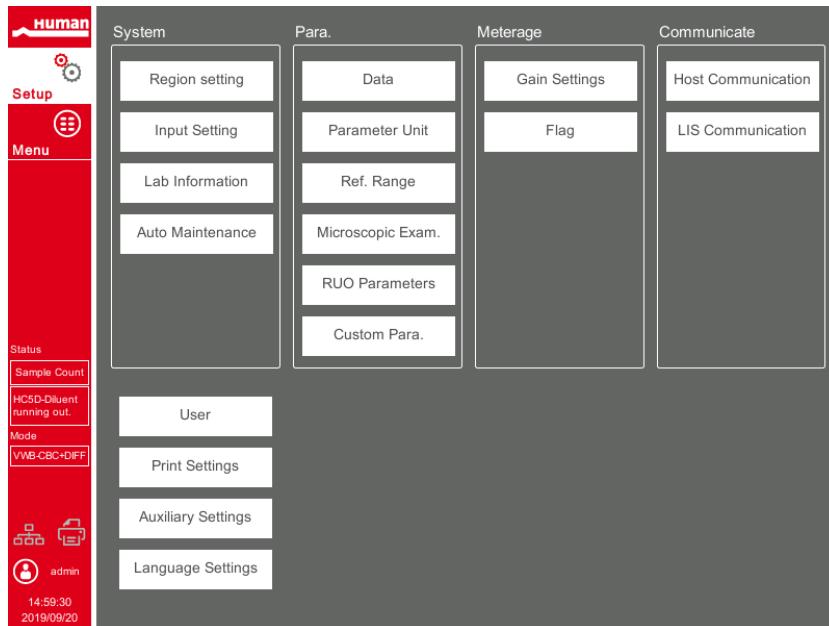


FIGURE 75

Setup

The administrator is allowed to set the following functions in the Setup interface:

- System settings
- Parameter settings
- Meterage settings
- LIS communication
- User management
- Print settings
- Auxiliary settings
- Language Settings

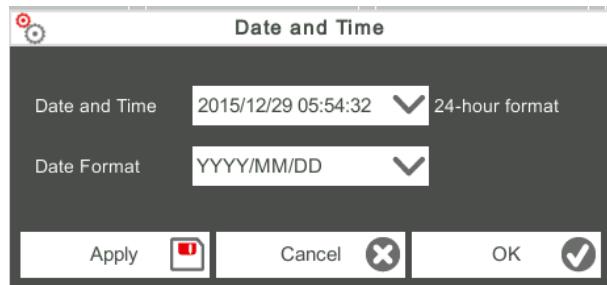
7.3.3 SYSTEM SETTINGS

7.3.3.1 Date and Time

You can set the current date and time, as well as the date display format in the analyzer system. Specific steps are shown below:

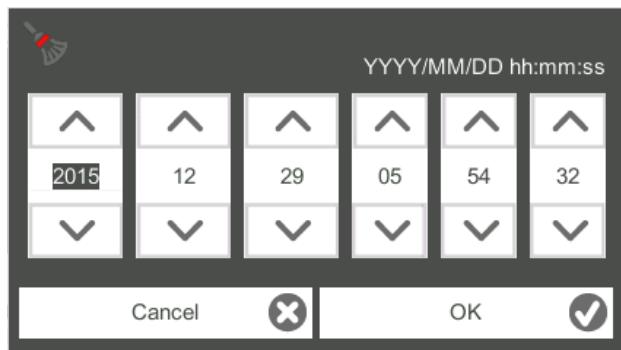
1. Click **Date and Time** in the **System** area. The date and time format setting interface pops up.

FIGURE 76



2. Click the **Date and Time** dropdown list and set the current date and time of the system in the popup dialogue box.

FIGURE 77



Related descriptions:

- The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is yyyy/MM/dd HH:mm:ss, you should input the data in the sequence of year, month, date, hour, minute, and second.
- Click **▲** or **▼** to select a date and time or enter the information in the textbox directly.
- Click **Cancel** to close the window and keep the current date and time settings.

3. Click **OK** to save and close the message box.
4. Select the format setting from the dropdown list of the **Date Format**. See Figure 78.

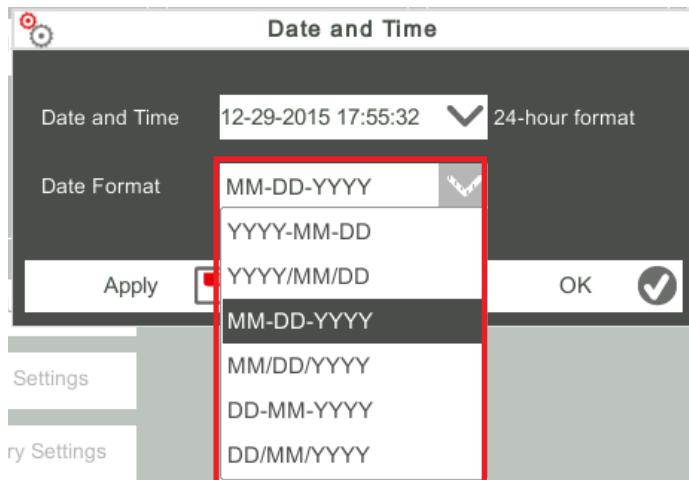


FIGURE 78

5. Click **Apply**. The system message will pop up, indicating the successful setting. See Figure 79.

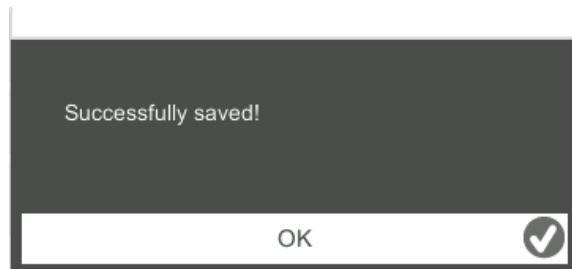


FIGURE 79

Successful Setting
of the Date Format

The date and time at the bottom right corner will be displayed in the newly set format as shown in

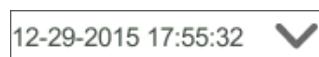


FIGURE 80

Click **OK** to close the message box.
Click **OK** to exit.

7.3.3.2 Input Settings

Click **Input Setting** in the **System** area, and then you can set the soft keyboard for screen input.

FIGURE 81



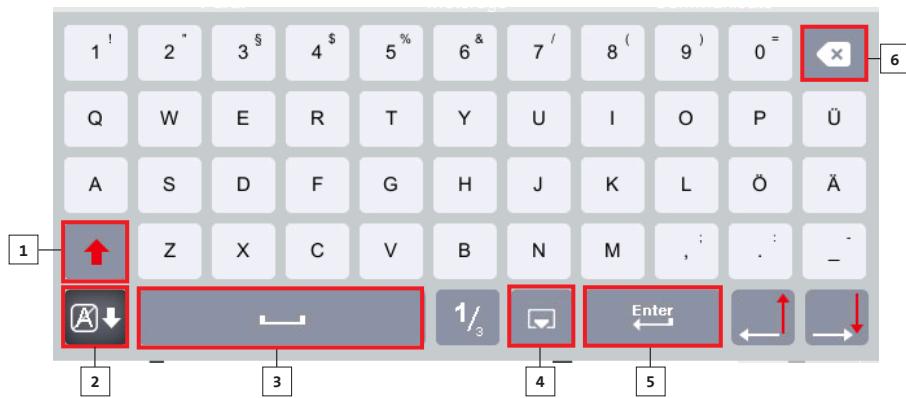
As shown in Figure 81, You can set to turn the soft keyboard on or off.

- Soft Keyboard
 - On (default)

You can enter content using the soft keyboard popped up on the screen. Functions and applications for the keys are shown in Figure 82.

FIGURE 82

- 1 Toggling between upper and lower case
- 2 Toggling between number and symbol input
- 3 Hiding the soft keyboard
- 4 Hiding the soft keyboard
- 5 Line feed/Enter key
- 6 Delete key



- Off

You need to use an externally connected USB keyboard for entering content.

7.3.3.3 Lab Information

Click **Lab Information** in the **System** selection, then you can set the lab information. See Figure 83.

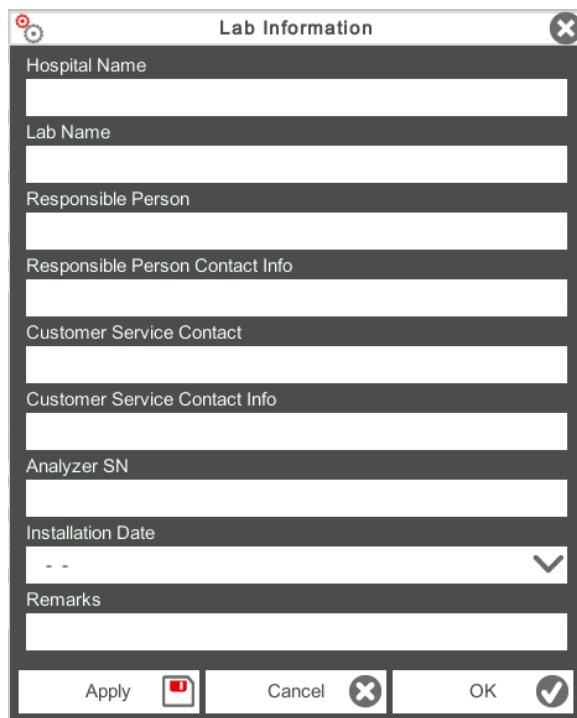


FIGURE 83
Setting Lab Information



Note:

Only the administrator has the access for setting the lab information. General users are only allowed to browse such information. Refer to the table below for the detailed instructions of parameter setting

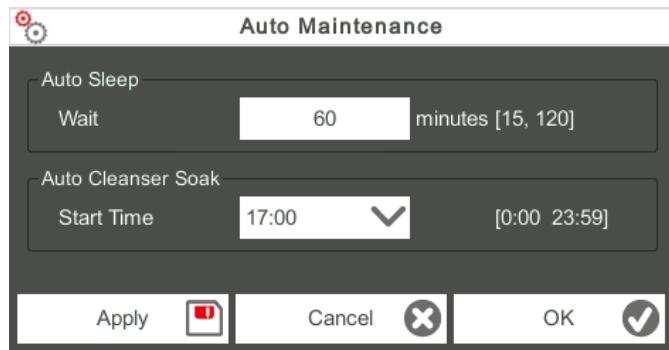
Parameter	Setting Description
Hospital Name	Enter the name of the hospital where the lab is located.
Lab Name	Enter the lab name.
Responsible Person	Enter the responsible person of the lab.
Contact Information	Enter the contact information (telephone number or E-Mail) of the lab.
Contact in Service Department	Enter the name of the contact person in Service Department.
Contact Information of Service Department	Enter the contact information of the contact person in the Service Department.
Analyzer SN	Display the serial number of the analyzer. Read only.
Installation Date	Display the installation date of the analyzer. Read only.
Remarks	Enter the remarks regarding the lab.

TABLE 15
Setting Lab Information

7.3.3.4 Auto Maintenance

Click **Auto Maintenance** in the **System** selection to access the **Auto Maintenance** setting interface. The system auto sleep waiting time and cleanser maintenance time can be set in the **Auto Maintenance** interface.

FIGURE 84
Auto Maintenance



Auto Sleep

In the **Wait** textbox, the administrators can set the waiting time for entering the sleep state after the main unit is halted. The range is between 15 and 120 minutes and the default value is 60 minutes.

Auto Cleanser Soak

The administrator is allowed to set the start time of the cleanser soak in the **Start Time** textbox. The acceptable value ranges from 0:00 to 23:59 and the default value is **17:00**.

7.3.4 PARAMETER SETTINGS

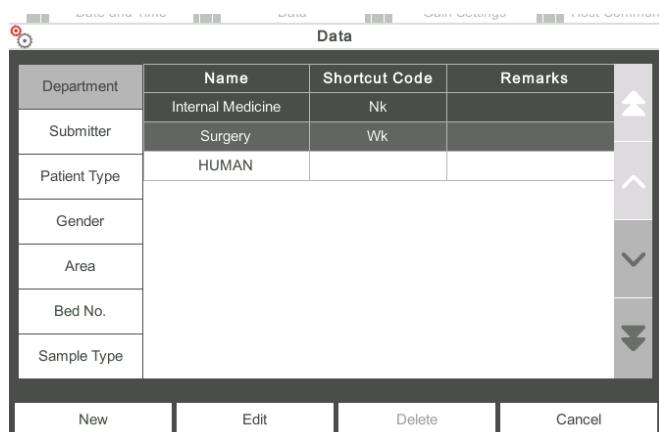
7.3.4.1 Data Dictionary

You can set shortcut codes for the relevant items of the patient information. If a shortcut code is set, the shortcut code corresponding to the above mentioned item can be entered directly when the information is input or numbered, then the complete information can be displayed without entering (or selecting) complete information. It is a shortcut operation.

Different items can share one shortcut code.

7.3.4.2 Accessing the interface

Click **Data** in the **Para.** selection to access the data dictionary setting interface. See Figure 85. You can set the shortcut code for the relevant items of the patient information in this interface.



	Name	Shortcut Code	Remarks
Department	Internal Medicine	Nk	
Submitter	Surgery	Wk	
Patient Type	HUMAN		
Gender			
Area			
Bed No.			
Sample Type			

New Edit Delete Cancel

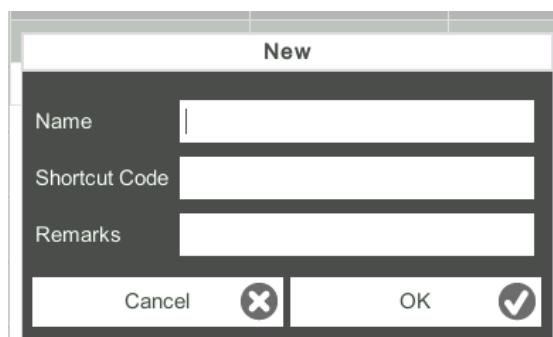
FIGURE 85
Shortcut Code

You can set the shortcut code for the following items: **Department, Submitter, Patient Type, Gender, Area, Bed No. and Sample Type.**

7.3.4.3 Adding a New Item

This section takes the adding of a new department as an example to introduce the method for adding a new item and its shortcut code. The method for adding other new items is similar and is not introduced in details herein. Steps for adding a new department are shown as follows:

1. Click **New** in the **Department** interface. A dialogue box will pop up as shown in Figure 86.



New

Name	<input type="text"/>
Shortcut Code	<input type="text"/>
Remarks	<input type="text"/>

Cancel OK

FIGURE 86
Adding a New Item

2. Enter a new department name, shortcut code and remarks.
 - Newly added department name must be entered and it can not be the same as existing ones.
 - The shortcut code is not necessary to be entered, but once set, every code must be unique.
3. Click **OK** to save the information about the new department. Information about the newly added department will be displayed in the department interface. See Figure 87.

FIGURE 87
Information of the
Newly Added Department

Department	Name	Shortcut Code	Remarks
Submitter	Internal Medicine	Nk	
Patient Type	Surgery	Wk	
Gender	HUMAN		
Area	Ophthalmology	OP	
Bed No.			
Sample Type			

New Edit Delete Cancel

7.3.4.4 Editing Items/Shortcut Code

This section takes the editing of a department as an example to introduce the method for editing items and its shortcut code. The method for editing other new items is similar and is not introduced in details herein.

Steps for editing a department are shown as follows:

1. Select the department to be modified in the Department interface (for example the Internal Medicine), then click **Edit**. A dialogue box will pop up as shown in Figure 88.

FIGURE 88
Editing Item/Shortcut Code

Edit	
Name	Ophthalmology
Shortcut Code	OP
Remarks	
Cancel	OK

2. Modify the **Name, Shortcut Code and Remarks** in each textbox according to the actual demand.
 - Newly added department name must be entered and it can not be the same as existing ones.
 - The shortcut code is not necessary to be entered, but once set, every code must be unique.
3. Click **OK** to save the information.

7.3.4.5 Deleting a Shortcut Code

This section takes the deleting of a department as an example to introduce the method for deleting items and its shortcut code. The method for deleting other new items is similar and is not introduced in details herein.

Steps for deleting a department are shown as follows:

1. Select the department to be deleted in the **Department** interface, and then click **Delete**. The interface pops up a dialogue box as shown below:

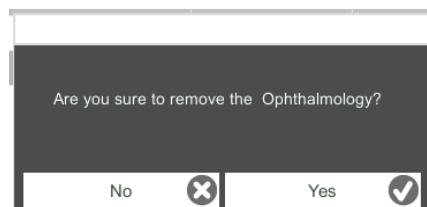


FIGURE 89
Deleting a Department

2. Click **Yes** to delete the department.

7.3.4.6 Parameter Unit

Some of the parameters of the analyzer can use different units which can be chosen as per user demand.

7.3.4.7 Accessing the Interface

Click **Parameter Unit** in the **Para.** selection to access the **Parameter Unit** setting interface. See Figure 90.

FIGURE 90
Shortcut Code



7.3.4.8 Selecting Unit System

Click the **Select unit system** dropdown list and select a unit system for the parameters among the 7 unit systems (**Custom, China, International, Britain, Canada, USA and Netherlands**). The default unit system is **USA**.

- When selecting different unit standards, the corresponding unit list and unit option will be displayed differently.
- If another option is selected except the **Custom**, then the unit of each parameter can only be browsed.

7.3.4.9 Customizing Parameter Unit

1. Select **Custom** from the dropdown list of **Select unit system**.

FIGURE 91



2. Click the parameter, of which the unit is to be set, from the parameter list (such as WBC).
3. Select a new parameter unit from the **Unit Options** list.

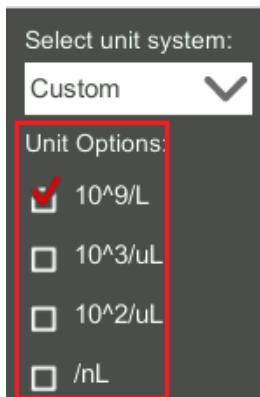


FIGURE 92

4. Click **Apply** or **OK** to save the configuration.
 - For parameters in the same group, if the unit of any parameter changes, the units of the other parameters change accordingly. (In the list, parameters will be sorted by group; the first parameter will be displayed in black and the other parameters in the same group will be displayed in grey.)
 - If the parameters units change, the display format of the list data will change accordingly.

7.3.4.10 Retrieving Defaults

When setting the **Custom** unit system, if you click **Default**, the unit of the parameters can be restored to the initial default values.

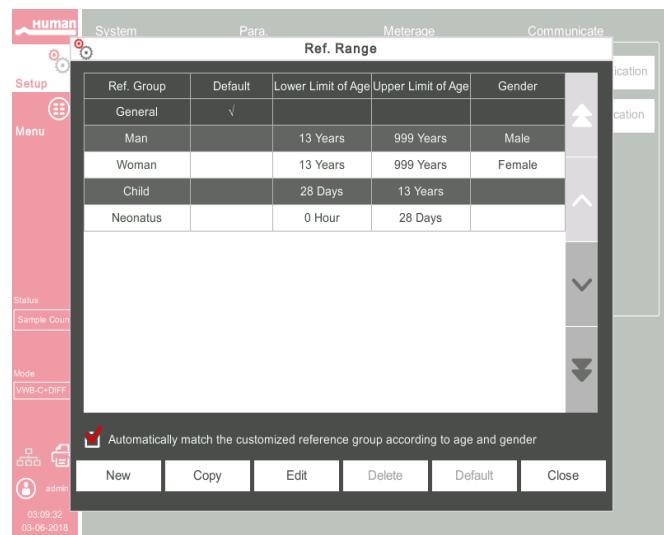
7.3.4.11 Ref. Range

The reference range based on various normal groups can be set for the analyzer in the actual practice. If the analysis result of a sample is beyond the reference range, it will be regarded as clinically abnormal. The **Ref. Range** interface is where you view and set the high and low limits for your patients. The analyzer flags any parameter value above (\uparrow) or below (\downarrow) these limits. This analyzer divides the patients into 5 demographic groups: General, Man, Woman, Child and Neonate. You can also customize other groups. The built in limits are for reference only. To avoid misleading parameter flags, be sure to set the patient limits according to the characteristics of local population.

7.3.4.12 Accessing the Interface

Click **Ref. Group** in the **Para.** selection to access the reference group settings interface. See Figure 93.

FIGURE 93
Ref. Range



7.3.4.13 Copying a Ref. Group

Select a reference group and click **Copy**, and a new reference group with everything the same except the name of the reference group will be added to the system and a screen as shown in Figure 94 will pop up.

FIGURE 94
Copying a Ref. Group

Para.	Lower Limit	Upper Limit	Unit	Para.	Lower Limit	Upper Limit	Unit	Ref. Group
WBC	4.00	10.00	10^3/uL	RBC	3.50	5.50	10^6/uL	
Neu%	50.0	70.0	%	HGB	11.0	16.0	g/dL	
Lym%	20.0	40.0	%	HCT	37.0	54.0	%	
Mon%	3.0	12.0	%	MCV	80.0	100.0	fL	
Eos%	0.5	5.0	%	MCH	27.0	34.0	pg	
Bas%	0.0	1.0	%	MCHC	32.0	36.0	g/dL	
Neu#	2.00	7.00	10^3/uL	RDW-CV	11.0	16.0	%	
Lym#	0.80	4.00	10^3/uL	RDW-SD	35.0	56.0	fL	
Mon#	0.12	1.20	10^3/uL	PLT	100	300	10^3/uL	
Eos#	0.02	0.50	10^3/uL	MPV	6.5	12.0	fL	
Bas#	0.00	0.10	10^3/uL	PDW	9.0	17.0	fL	
ALY#	0.00	0.20	10^3/uL	PCT	0.108	0.282	%	
ALY%	0.0	2.0	%	P-LCR	11.0	45.0	%	
LIC#	0.00	0.20	10^3/uL	P-LCC	30	90	10^9/L	
LIC%	0.0	2.5	%					

You can edit the new reference group. Save and close the screen, and then the copied reference group will be shown in the reference group list.

Ref. Range				
Ref. Group	Default	Lower Limit of Age	Upper Limit of Age	Gender
General	✓			
Man		13 Years	999 Years	Male
Woman		13 Years	999 Years	Female
Child		28 Days	13 Years	
Neonatus		0 Hour	28 Days	
newgroup		0 Year	12 Years	Male

FIGURE 95
Copying a Ref. Group

! **Note:** The reference group name entered is not allowed to be empty nor the same as the existing ones.

7.3.4.14 Adding a New Ref. Group

If the built-in reference groups cannot meet the actual demand, you can add new ones and manually enter the information such as reference ranges for each parameter, names and genders. The procedures are shown as below:

1. Click **New**, and a screen for adding a new reference group will pop up. See Figure 96

Para.	Lower Limit	Upper Limit	Unit	Para.	Lower Limit	Upper Limit	Unit	Ref. Group
WBC			10^3/uL	RBC			10^6/uL	newgroup
Neu%			%	HGB			g/dL	
Lym%			%	HCT			%	
Mon%			%	MCV			fL	
Eos%			%	MCH			pg	
Bas%			%	MCHC			g/dL	
Neu#		10^3/uL		RDW-CV			%	
Lym#		10^3/uL		RDW-SD			fL	
Mon#		10^3/uL		PLT		10^3/uL		
Eos#		10^3/uL		MPV			fL	
Bas#		10^3/uL		PDW			fL	
ALY#		10^3/uL		PCT			%	
ALY%			%	P-LCR			%	
LIC#		10^3/uL		P-LCC		10^9/L		
LIC%			%					

FIGURE 96
Adding a New Ref. Group

2. Complete the entries for each parameter with reference to the parameter description in Table 16.

TABLE 16
Description of Ref. Group
parameters

Parameter	Meanings	Operation
Ref. Group	Name of the new reference group.	Click the edit box and enter the information using the soft keyboard. English characters and numbers are allowed to be entered, while special characters are not.
Lower Limit of Age	Lower limit of age of the reference group.	<p>Note:</p> <ul style="list-style-type: none"> The reference group name entered is not allowed to be empty nor the same as the existing ones.
Upper Limit of Age	Upper limit of age of the reference group.	<p>Note:</p> <ul style="list-style-type: none"> The Lower Limit of Age must be smaller than the Upper Limit of Age.
Gender	Gender of the reference group.	<p>Note:</p> <ul style="list-style-type: none"> The Lower Limit of Age must be smaller than the Upper Limit of Age.
Lower Limit (of parameter)	Lower limit of parameters of the reference group. If the test result is lower than this value, it would be regarded as clinically abnormal.	Select Man , Woman , Not defined from the dropdown list. The default setting is empty.
		Click the Lower Limit cell which corresponds to the parameter and enter a new value.
		<p>Note:</p> <ul style="list-style-type: none"> The Lower Limit must be smaller than the Upper Limit.

Upper Limit (of parameter)	Upper limit of parameters of the reference group. If the test result is higher than this value, it would be regarded as clinically abnormal.	Click the Lower Limit cell which corresponds to the parameter and enter a new value.
		Note: ! The Lower Limit must be smaller than the Upper Limit.

3. Click **Save** to save the settings.
4. Click **Close** to exit the interface.

7.3.4.15 Editing a Ref. Group

You can modify the reference range of the parameters according to actual needs and set suitable reference intervals (age range, gender, etc.). The procedures are shown as below:

1. Select the reference group to be set, and click **Edit** to enter the interface as shown in Figure 97.

New							
Para.	Lower Limit	Upper Limit	Unit	Para.	Lower Limit	Upper Limit	Unit
WBC	4.00	10.00	10 ³ /uL	RBC	3.50	5.50	10 ⁶ /uL
Neu%	50.0	70.0	%	HGB	1.1	1.6	g/dL
Lym%	20.0	40.0	%	HCT	37.0	54.0	%
Mon%	3.0	12.0	%	MCV	80.0	100.0	fL
Eos%	0.5	5.0	%	MCH	27.0	34.0	pg
Bas%	0.0	1.0	%	MCHC	3.2	3.6	g/dL
Neu#	2.00	7.00	10 ³ /uL	RDW-CV	11.0	16.0	%
Lym#	0.80	4.00	10 ³ /uL	RDW-SD	35.0	56.0	fL
Mon#	0.12	1.20	10 ³ /uL	PLT	100	300	10 ³ /uL
Eos#	0.02	0.50	10 ³ /uL	MPV	6.5	12.0	fL
Bas#	0.00	0.10	10 ³ /uL	PDW	15.0	17.0	fL
ALY#	0.00	0.20	10 ³ /uL	PCT	0.108	0.282	%
ALY%	0.0	2.0	%	P-LCR	0.5	0.7	%
LIC#	0.00	0.20	10 ³ /uL	P-LCC	3	5	10 ⁹ /L
LIC%	0.0	2.5	%				

Ref. Group
 newgroup
 Lower Limit of Age
 0 Year ✓
 Upper Limit of Age
 12 Year ✓
 Gender
 Male ✓

Save
 Close

FIGURE 97
Adding a New Ref. Group

2. Refer to Table 16 for the description of the parameters to finish the editing.

! **Note:**

- For the built-in reference group, you can modify the upper limit and lower limit of the parameters, but not its name, the upper limit and lower limit of age as well as gender.
- Click **Set as default** to restore the setting of the selected reference group to the default value.
- Non-built-in reference group (which is added by user) cannot restore defaults.

3. Click **Save** to save the modification.
4. Click **Close** to exit.

7.3.4.16 Deleting a Ref. Group

Click **Delete**, and select **Yes** in the pop-up dialogue box to delete the selected customized reference group.

Built-in reference group can not be deleted.

7.3.4.17 Setting Default Ref. Group

When you pre-enter patient information in the **Sample Analysis** interface, the **Ref. Group** displayed by default is the default reference group. The default setting is **General**. You can change it as required. Select a reference group and click **Set as default** to set the selected reference group as the default reference group. As shown in Figure 98, the reference group with a check mark in its **Default** column is a default reference group.

FIGURE 98
Setting Default Ref. Group

Ref. Range				
Ref. Group	Default	Lower Limit of Age	Upper Limit of Age	Gender
General				
Man		13 Years	999 Years	Male
Woman		13 Years	999 Years	Female
Child		28 Days	13 Years	
Neonatus		0 Hour	28 Days	
newgroup	✓	0 Year	12 Years	Male

Automatically match the customized reference group according to age and gender

New Copy Edit Delete Default Close

7.3.4.18 Automatically Match the Customized Reference Group According to Age and Gender

If **Automatically match the customized reference group according to age and gender** is checked, the customized reference group will be automatically assigned patients by the system according to their age and gender when the patient information is entered. If it fails to find a matching customized reference group for a patient, the patient will be assigned to the built-in reference group. When the system automatically matches the reference group according to age and gender, the rules listed in Table 17 shall be followed.

Automatically match the customized reference group according to age and gender	Customized Ref. Match the reference group Group	
Unchecked	N/A	Built-in reference group
Checked	None	Built-in reference group
Checked	Created	Preferentially match the customized reference group


Note:

When the customized ref. groups are used to match the reference group, the matching will be performed from top down according to the customized ref. groups displayed in the screen.

TABLE 17

Rules for Matching the Reference Group

7.3.4.19 Microscopic Exam. Settings

You can perform the microscopic exam. settings, including adding, editing, deleting and adjusting the list order as per the actual demand.


Note:

The operations of adding, editing, deleting and adjusting the list order do not affect the sample record in which the microscopic examination results have been entered and saved. Such operations are only valid for the record in which the microscopic examination results have not been saved, and the samples analyzed after the setting operations.

7.3.4.20 Accessing the Interface

Click **Microscopic Exam.** in the **Para.** selection to access the microscopic examination setting interface. See Figure 99.

FIGURE 99
Microscopic Exam. Settings

No.	Parameter Name	Code System
1	Neutrophilic segmented granulocyte	
2	Neutrophilic band granulocyte	
3	Lymphocyte	
4	Monocyte	
5	Eosinophil	
6	Basophil	
7	Plasmacyte	
8	Atypical Lymph	
9	Blast	

New Edit Delete Cancel

7.3.4.21 Adding a New Microscopic Exam. Parameter

Do as follows to add a new microscopic examination parameter.

1. Click **New** in the **Microscopic Exam. Settings** interface. A dialogue box will pop up as shown in Figure 100.

FIGURE 100
Adding a New Microscopic
Exam. Parameter

New

Parameter Name	<input type="text"/>
Code System	<input type="text"/>
Cancel	OK

Note: coding system is the code ID in LIS transmission. You may not input the value if it is not needed.

2. Input the parameter name and its coding system in the corresponding text boxes.
 - The **Parameter Name** can not be empty and up to 32 characters can be entered.
 - The **Code System** is the code ID of the parameter. It is used for LIS transmission only when the parameter is transmitted to the LIS. You may not input the value if it is not needed. Up to 20 characters can be entered.
3. Click **OK**. The name of the new parameter will be displayed in the microscopic exam. parameter list.

7.3.4.22

Editing a Microscopic Exam. Parameter

Select a parameter name from the list and click **Edit** to modify it. See Figure 101.

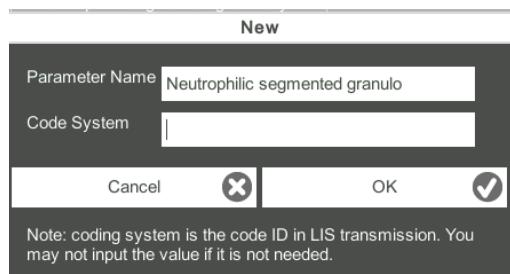


FIGURE 101

Editing a Microscopic Exam. Parameter

7.3.4.23 Deleting a Microscopic Exam. Parameter

Select a parameter name from the list, click the **Delete** button and then click **Yes** in the pop-up dialogue box to delete this parameter.

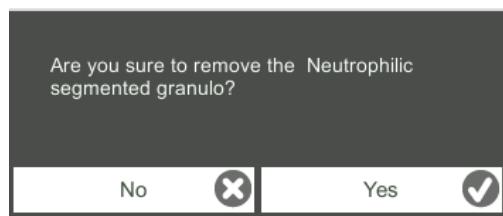


FIGURE 102

Deleting a Microscopic Exam. Parameter

7.3.4.24 Research Use Only (RUO) Parameters

Click **RUO Parameters** in the **Setup > Parameter** interface to enter the **RUO Parameters** setting interface. See Figure 103.

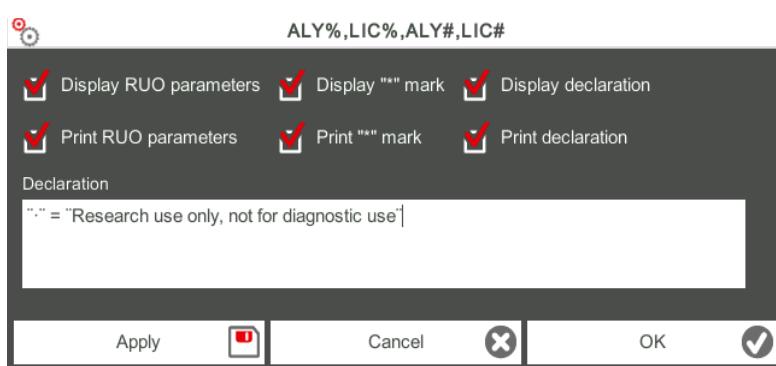


FIGURE 103

Setting RUO Parameters


Note:

- **Display RUO Parameters**

It's checked by default, which means the information regarding the RUO parameters will be displayed in the counting results. If it's unchecked, the RUO parameters, the "*" mark and the declaration will not be displayed in the counting results.

- **Display “*” mark**

It's checked by default, which means the “*” mark will be displayed in the counting results; if it's unchecked, the “*” mark and the declaration will not be displayed.

- **Display declaration**

It's checked by default, which means the declaration will be displayed in the counting results; if it's unchecked, the declaration will not be displayed.

- **Print RUO parameters**

It's checked by default, which means the RUO parameters will be printed in the report. If it's unchecked, the RUO parameters, the “*” mark and the declaration will not be printed in the report.

- **Print “*” mark**

It's checked by default, which means the “*” mark will be printed in the report. If it's unchecked, the “*” mark and the declaration will not be printed in the report.

- **Print declaration**

It's checked by default, which means the declaration will be printed in the report. If it's unchecked, the declaration will not be printed in the report.

- **Editing Declaration**

The default declaration is: “*” means “research use only, not for diagnostic use”. You can modify the declaration in the textbox as per the actual demand. Up to 50 characters can be entered, including all characters, numbers, letters and other special characters (except “/” and “\”) on the keyboard.


Note:

Any change made to the display settings or printing of the RUO parameters, the “*” mark and the declaration will be applied to all the RUO parameters (before and after the change).

7.3.4.25 Customized Parameters

Except for this analyzer's analysis parameters, parameters collected from other testing instruments or via manual testing by the user are customized parameters. You can set customized parameters so they can be printed together with this analyzer's analysis parameter details on the Hematology Analysis Report.

This analyzer's default customized parameters include: **Blood Type, RH Blood Group, ESR, C-reactive Protein** and **Reticulocyte**. You can set the unit and reference range of default customized parameters as well as add and set customized parameters.

7.3.4.26 Accessing the Interface

Click **Custom Para.** in the **Para.** selection. The customized parameters setting interface as shown in Figure 104 will pop up on the screen.

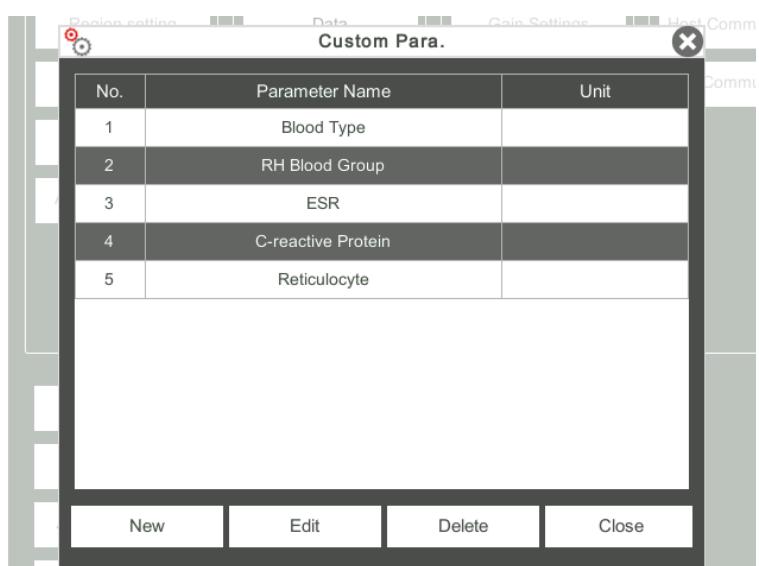


FIGURE 104

Customized Parameter Settings

7.3.4.27 Adding a Customized Parameter

1. Click **New**. The interface as shown in Figure 105 will pop up on the screen.

FIGURE 105

Adding a Customized Parameter

New

Ref. Group	Lower Limit	Upper Limit	Parameter Name
General			
Man			Unit
Woman			
Child			
Neonatus			
newgroup			

Apply

Cancel

OK

2. Click the textboxes of **Parameter Name** and **Unit** respectively, and enter the name and unit of the customized parameter.
3. Click corresponding cells of the **Upper Limit** and **Lower Limit** of the reference group, and input values. You can also customize the reference group according to the actual situation. For details, see chapter 7.3.4.11 *Ref. Range*.
4. Click **OK**. The added parameter will be displayed in the customized parameter list.

7.3.4.28 Editing a Customized Parameter

You can set the unit and reference range of customized parameters. Detailed steps are shown below:

1. Select the customized parameter to be edited, and click **Edit**. The interface as shown in Figure 106 will pop up on the screen.

FIGURE 106

Editing a Customized Parameter

Edit

Ref. Group	Lower Limit	Upper Limit	Parameter Name
General			Reticulocyte
Man			Unit
Woman			
Child			
Neonatus			
newgroup			

Apply

Cancel

OK

2. Click the textboxes of **Parameter Name** and **Unit** respectively, and modify the name and unit of the customized parameter.
3. Click corresponding cells of the **Upper Limit** and **Lower Limit** of the reference group, and modify the values. You can also customize the reference group according to the actual situation. For details, see chapter 7.3.4.11 *Ref. Range*.
4. Click **Save**.

7.3.4.29 Deleting a Customized Parameter

Select a customized parameter, and click on **Delete**. Then, the parameter and its corresponding reference group will be deleted.

7.3.5 USER MANAGEMENT

After logging in the system, the administrator has the access to set the account information of general users and other administrators; common users can only browse the user list and change their own passwords.

7.3.5.1 Accessing the Interface

Click **User** in the **Setup** interface to access the user management interface as shown in Figure 107.

The screenshot shows a user management interface with a table header:

User Name	Name	User Group	Default User	Remarks
admin	admin	Administrator		

Below the table are several buttons:

- New
- Edit
- Delete
- Default
- Reset Password
- Change Password
- Close

FIGURE 107
User management

7.3.5.2 Creating a User

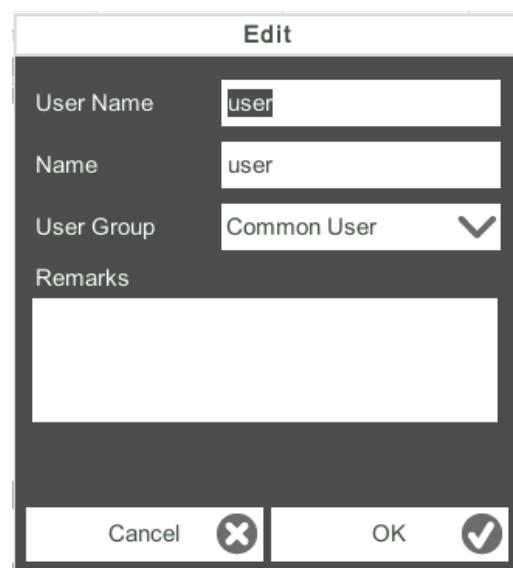
Click **New** to set the account information of a new user in the popup interface, including username, first and last name, password, user group and remarks, etc. See Figure 108.

FIGURE 108**Note:**

User Group includes Common User and **Administrator**. Users are assigned different access levels according to the user group they belong to. Click **OK** after the setting is complete. The information of the new user will be shown in the user list.

7.3.5.3 Editing a User

Select the user to be edited and click **Edit** to modify the name and user group.

FIGURE 109

7.3.5.4 Deleting a User

Select the user to be deleted and click **Delete**, and then select **OK** in the pop-up dialogue box to delete the user.



Note:

The administrator cannot delete his/her own information.

7.3.5.5 Setting the Default User

Select a user and click **Set as default user** to set this user as the default user. After the setting is completed, the following message box will pop up.

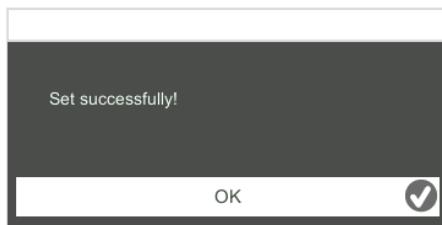


FIGURE 110

After it is set successfully, the default user name will be displayed in the login box next time and you only needs to enter the corresponding password. See Figure 111.

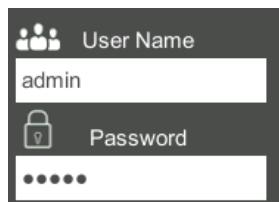


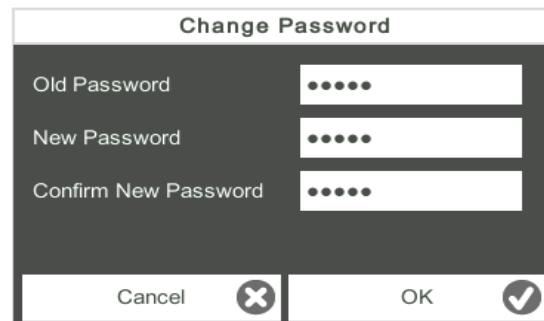
FIGURE 111

Login after Setting the Default Use

7.3.5.6 Changing Password

Click **Change Password**, enter the old password and new password of the user and confirm the new password in the pop-up dialogue box, then click **OK**.

FIGURE 112
Changing Password

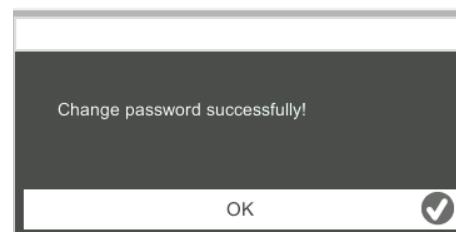


- Note:**
! You can only change his/her own password and cannot change the password of other users.

7.3.5.7 Resetting Password

If the user forgets the password or the password is required to be reset due to other reasons, please click **Reset Password** to reset the password of the selected user to the initial password. The reset password is the same as the user name. Figure 113 shows that the password is successfully reset.

FIGURE 113
Resetting Password



- Note:**
! The administrator is allowed to reset the password of all administrators and general users; general users do not have the access to reset the password.

7.3.6 PRINT SETTINGS

Click **Print Settings** in the **Setup** interface for relevant print settings, including the default printer, template, report, copies and margins, etc.

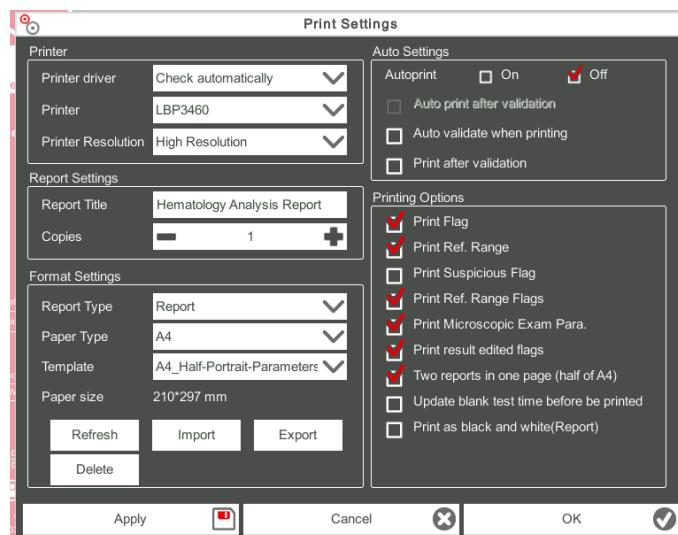


FIGURE 114

Printer Settings

You can set the printer and driver of the system in the **Printer** selection. See Figure 115.

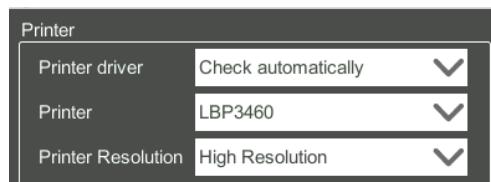


FIGURE 115

Printer Settings

- **Printer Driver**

The system automatically detects the printer driver by default.

- **Printer**

Select a printer to be used from the dropdown list. If the dropdown list is blank, it indicates that no printer has been installed for the operating system. In this case, install a printer, and then perform the relevant settings and printing operations.

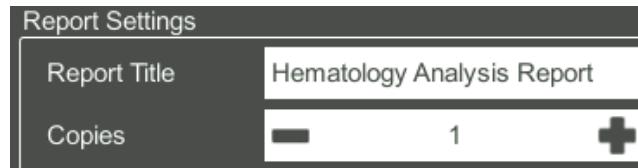
- **Printer Resolution**

Select a proper resolution from the dropdown list. The higher the resolution of the printer, the better the print quality.

Report Settings

You can set relevant parameters of the report in the **Report Settings** combo box. See Figure 116

FIGURE 116
Report Print Setting



- **Report Title**

Enter the title of the report in the **Report Title** textbox. The default setting is **Hematology Analysis Report**.

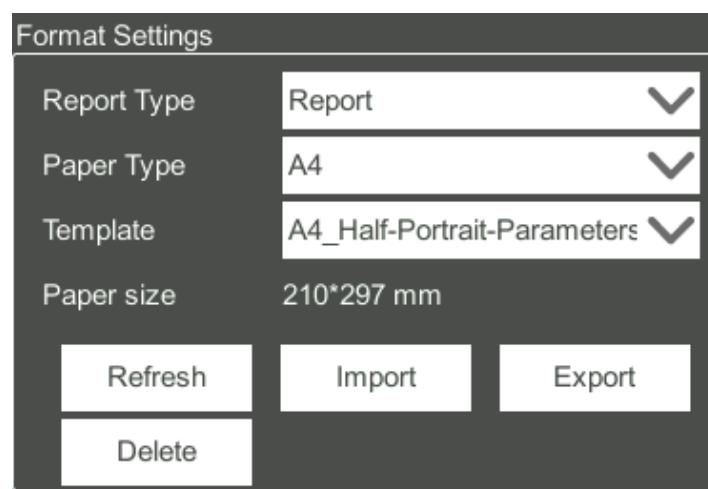
- **Copies**

You can enter the number of copies to be printed for a report in the **Copies** textbox according to the actual demand. Click **+** to increase the number of copies and click **—** to decrease the number of copies or enter the number of copies in the edit box directly. Range of the copies is between 1 and 100 and the default value is 1.

Format Settings

Report type and template of prints can be set in the **Format Settings** combo box. See Figure 117.

FIGURE 117
Format Settings



- **Selecting Report Type**

Select the format type to be set from the dropdown list of the **Report Type**. The default setting is Report.

- **Selecting Paper Type**

Select the paper type (size) from the dropdown list of the **Paper Type**, such as **A4**. After the selection is completed, the corresponding paper size will be shown at the bottom of the list, such as **210*148 mm**.

- **Selecting Template**

Select the template to be set from the dropdown list of the **Template**.

- **Refresh**

Click **Refresh** to refresh the format list after the customization by the administrator. Importing/Exporting template

You can export the existing template to a USB flash disk, and edit the template. After editing, import the template to the system to complete the customization of the template.



Note:

Before importing/exporting template, insert a USB flash disk in the USB interface on the analyzer.

- **Exporting template**

Select the template to be exported from the dropdown list of **Template** and click **Export**. Select the export path in the popup dialogue box, and click **Save**.

- **Importing template**

Click **Import** and select the required template in the pop-up dialogue box, then click **Open**.

- **Deleting template**

Select the template to be deleted from the dropdown list of the **Template**.



Note:

Only customized templates can be deleted, the built-in templates can not be deleted.

Auto Settings

- **Autoprint**

The default setting is **Off**, which means the report should be printed manually after the results are obtained.

If it is set to **On**, the system will automatically print the report of the sample as per the current report template once the counting results are obtained.

- If Print after validation is checked, the autoprint function becomes invalid.
- Auto print is not applicable for the background results.

- **Auto print after validation**

It's unchecked by default, which means the system can print the report automatically without validation. If it's checked, the report will be printed automatically after it's been validated instead of being printed right after the results are obtained each time.

The parameter is valid only when the **Autoprint** is set to **On**.

- **Auto validate when printing**

It's unchecked by default, which means the report will not be automatically validated by the system at the time of printing.

If it's checked, the report will be automatically validated and printed by the system at the time of printing.

- **Print after validation**

It's unchecked by default, which means the report can be printed without validation. If it's checked, the report can be printed only after validation and autoprint is unexecutable.

Printing Options

- **Print Flag**

It's checked by default, which means the flag information will be printed in the report. If it's not checked, it will not be printed.

- **Print Ref. Range**

It's checked by default, which means the reference range of the parameter will be shown in the printed report; If it's unchecked, the results alone, rather than reference range, will be shown in the printed report and the reference range will not.

- Print Suspicious Flag

It's unchecked by default, which means the suspicious flag “?” will not be shown in the printed report; if it's checked, such flag can be shown.

- Print Ref. Range Flags

It's checked by default, which means the printed report can show the ref. range flag (\uparrow or \downarrow); If it's unchecked, such a flag will not be shown.

- Print Microscopic Exam. Para.

It's checked by default, which means the result of **Microscopic Exam. Parameters** will be printed in the report. If it's not checked, it will not be printed.

- Print result edited flags

It's unchecked by default, which means the mark for the edited results will not be shown in the printed report. If checked, the mark (**M** or **m**) for the edited results will be shown in the printed report if the parameters have been modified.

- Two reports in one page (half of A4)

It's unchecked by default. If this is checked, the default template size in Format Settings is half an A4 page (e.g., A4_Half-Portrait-Parameters), so two reports can be printed in one piece of A4 paper.

When **Auto Increment** is selected as the Sample ID entry method, you can add a prefix to a certain batch or samples for identification. Enter the prefix length ranging from 0 to 24 (e.g. 2) of the sample ID in the **Prefix Length** textbox. The prefix length will be applied to all sample IDs after the setting is saved.

Startup sample ID and mode

Set the sample ID and measurement mode for the next sample after startup.

- Next sample ID and mode after startup

The sample ID and mode set by the user will be used by the system after the next startup when the specified sample ID is entered into the textbox and the measurement mode (CBC or CBC+DIFF) is selected from the dropdown list. If the **Effective tomorrow** is checked, the modification of the next sample ID and mode after startup will become effective on the next day.

- Continue using the sample ID and mode before the last shutdown

If checked, the system will by default add 1 to the last sample ID analyzed before shutdown as the next sample ID after startup.

Predilute

Set if you wish to see a pop-up dialogue box when you perform the Predilute counting.

- Ask for confirmation (default setting): In the **Predilute** mode, when you press the aspirate key to start the analysis, a dialogue box will pop up to remind you that the ongoing analysis is for **Predilute** counting.
- Do not ask for confirmation: The dialogue box for confirming the **Predilute** counting will not pop up.

Other

- **Show Result Edited Flags**

It's unchecked by default, which means the edited results are marked with an **M** at the end, while the corresponding results with manual modifications are marked with an **m** at the end. **M** or **m** is displayed between the result data and the parameter unit by default.

If unchecked, the edited result will not be marked with an **M** or **m**.

- **Automatically generate the delivery date**

It is checked by default, which means you do not need to manually enter the Delivery Time when you modify patient information after running a sample. The operating date will be displayed in the date textbox.



Note:

When **Autoprint** is **On**, a page remains to be printed with one report.

- **Update blank test time before be printed**

It's unchecked by default, which means the blank test time will not be processed by the system.

If it's checked, the **Delivery Time** will be automatically updated as the **Run Time** by the system at the time of printing.

- **Print as black and white**

It's unchecked by default, which means the report will be printed according to the default settings of the printer.

If it's checked, the report will be printed as black and white.

7.3.7 AUXILIARY SETTINGS

Click **Auxiliary Settings** in the **Setup** interface to access the **Auxiliary Settings interface**. See Figure 118.

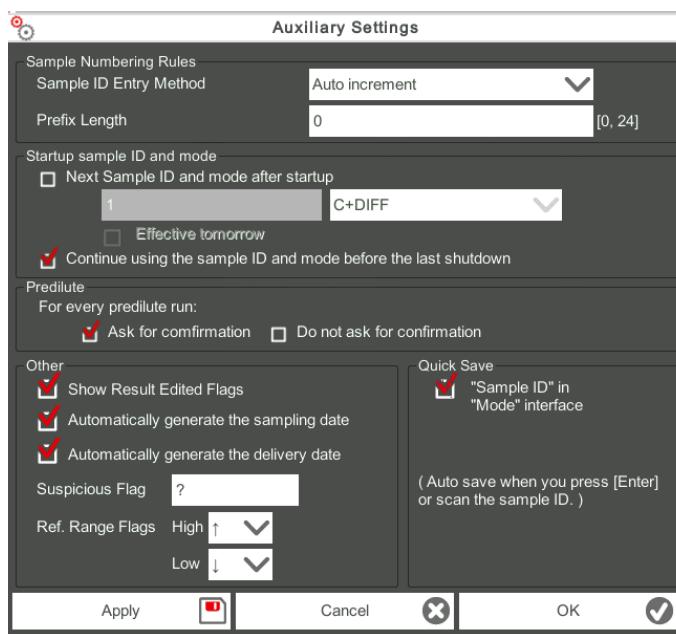


FIGURE 118
Auxiliary Settings

The administrator is allowed to set the following functions in the **Auxiliary Settings** interface:

- Sample Numbering Rules
- Startup sample ID and mode
- Predilute
- Other

Sample Numbering Rules

Set the sample ID entry rules.

- Sample ID Entry Method

Click the dropdown list of the **Sample ID Entry Method** and select the entry method of the sample ID from the following options.

- Auto increment (default setting)
- Manual entry

- **Prefix Length**

When **Auto Increment** is selected as the Sample ID entry method, you can add a prefix to a certain batch of samples for identification. Enter the prefix length ranging from 0 to 24 (e.g. 2) of the sample ID in the **Prefix Length** textbox. The prefix length will applied to all sample IDs after the setting is saved.

Startup sample ID and mode

Set the sample ID and measurement mode for the next sample after startup.

- **Next Sample ID and mode after startup**

The sample ID and mode set by the user will be used by the system after the next startup when the specified sample ID is entered into the textbox and the measurement mode (CBC or CBC+DIFF) is selected from the dropdown list.

! **Note:**

When Autoprint is On, a page remains to be printed with one report. If the Effective tomorrow is checked, the modification of the next sample ID and mode after startup will become effective on the next day.

- Continue using the sample ID and mode before the last shutdown. If checked, the system will by default add 1 to the last sample ID analyzed before shutdown as the next sample ID after startup.

Predilute

Set if you wish to see a pop-up dialogue box when you perform the Predilute counting.

- Ask for confirmation (default setting): In the **Predilute** mode, when you press the aspirate key to start the analysis, a dialogue box will pop up to remind you that the ongoing analysis is for **Predilute** counting.
- Do not ask for confirmation: The dialogue box for confirming the Predilute counting will not pop up.

Other

- **Show Result Edited Flags**

It's unchecked by default, which means the edited results are marked with an **M** at the end, while the corresponding results with manual modifications are marked with an **m** at the end. **M** or **m** is displayed between the result data and the parameter unit by default. If unchecked, the edited result will not be marked with an **M** or **m**.

- **Automatically generate the delivery date**

It is checked by default, which means you don't need to manually enter the **Delivery Time** when you modify patient information after running a sample. The operating date will be displayed in the date textbox. If unchecked, the **Delivery Time** shall be manually entered when patient information is modified in **Sample Analysis** interface.

- Automatically generate the sampling date

It is checked by default, which means you don't need to manually enter the **Sampling Time** when you modify patient information after running a sample. The operating date will be displayed in the date textbox. If unchecked, the **Sampling Time** shall be manually entered when patient information is modified in **Sample Analysis** interface.

- **Suspicious Flag**

A single character (an English letter only) can be re-entered in the textbox as a suspicious flag. The default value is ?.

- **Ref. Range Flags**

You can select the **Ref. Range Flags** from the dropdown list. The default high flag is ↑ (or H) and the default low flag is ↓ (or L).

7.3.8 LANGUAGE SETTINGS

Click **Language Settings** in the **Setup** interface to access the **Language Settings interface**. See Figure 119.

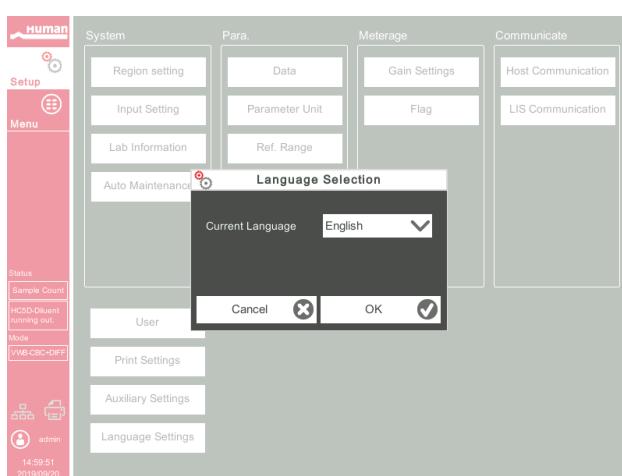
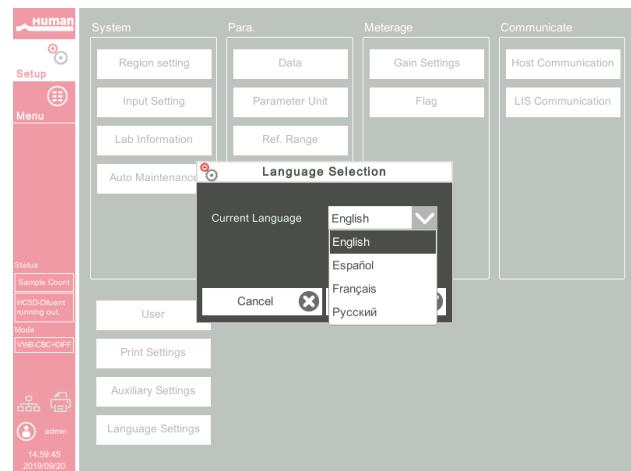


FIGURE 119

By activation of the drop-down menu, the administrator can select a language (English, Spanish, French, Russian) as shown by Figure 120 .

FIGURE 120



After having selected a new language the analyzer needs to be restarted to apply the changes.

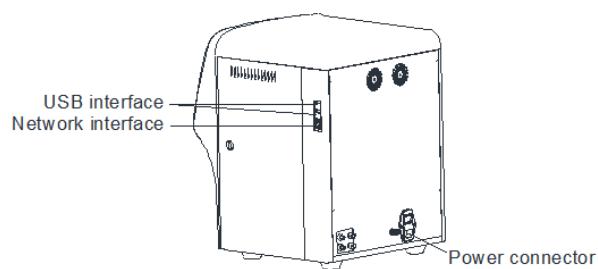
7.3.9 CONNECTING THE ANALYZER SYSTEM

7.3.9.1 Electrical Connections

Please refer to Figure 121 for the electrical connections of the analyzer.

FIGURE 121

Connecting the electrical devices



7.3.9.2 Reagent Connections



WARNING

- Be sure to dispose reagents, waste, samples, consumables, etc. according to local legislations and regulations.
- Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.



CAUTION

- Please make sure the length of the diluent pipe and the waste pipe should be no longer than 1500 mm; the length of the lyse pipe and the cleanser pipe should be no longer than 850 mm.
- Tighten the panel connector of the fluidic line so that the overall fluidic line is closed to prevent leakage and seepage caused by siphonage, etc. Refer to Figure 122 for the connection of the reagents placed outside the analyzer.

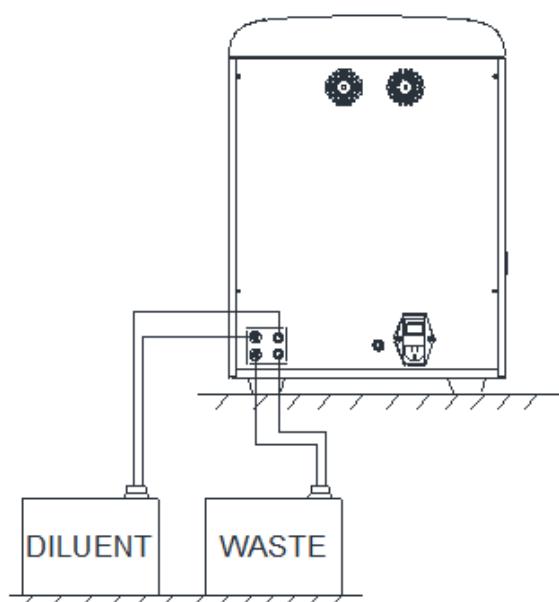


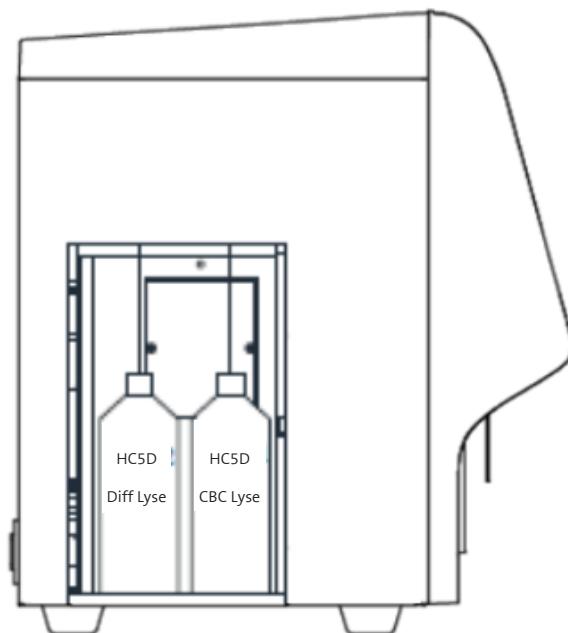
FIGURE 122

Connecting reagents placed outside the analyzer

Refer to Figure 123 for the connection of the reagent placed inside the analyzer HumaCount 5D.

FIGURE 123

Connecting reagents placed inside the analyzer HumaCount 5D (left door opened)



7.3.9.3 Installing the Diluent Float Sensor and Replacing the Reagents

Please install the diluent float sensor and replace the diluent as per the approaches stated in this section.

7.3.9.4 Installing the Diluent Float Sensor

Install the diluent float sensor according to the following steps.

1. Press down and remove the round cardboard with dotted cutting line on the top side of the diluent box so as to reveal a round hole.
2. Pull out the cover of the container so that the cardboard around the round hole can seize the neck under the vial cap to prevent invagination.
3. Turn and open the cap (keep the cap) and prevent any foreign objects from getting into the container.
4. Install the diluent float sensor assembly in the accessory pack as shown in Figure 124. The float sensor shall be kept as vertical as possible during installation and the self-contained cap of the sensor shall be tightened.

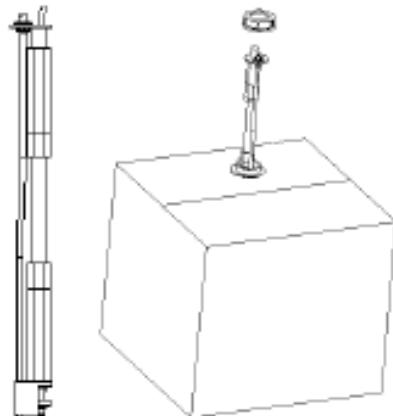


FIGURE 124
Installing the Diluent Float Sensor

7.3.9.5 Replacing Reagents

Steps for the replacing the diluent are the same as that for installing the sensor. Please keep the empty diluent container and the cap for future use.

7.3.9.6 Installing the Waste Float Sensor

The float sensors used in the analyzer are only applicable to HUMAN-supplied waste containers or the containers with the same specification and model (such as the vacant diluent container).

1. Take a proper waste container (it can be a vacant diluent container, the opening of which is required to be pulled out of the hole of the box to expose the opening) and open the vial cap.
2. Install the waste float sensor assembly in the accessory pack as shown in Figure 125. The float sensor shall be kept as vertical as possible during installation and the self-contained cap of the sensor shall be tightened at the same time to prevent the spilling of the waste.

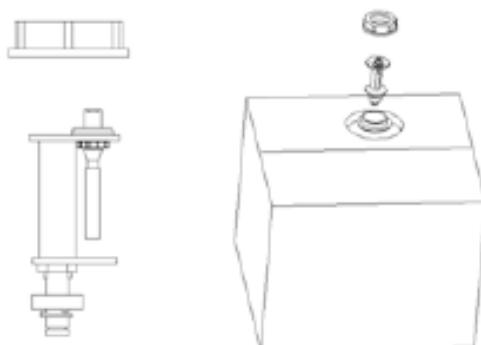


FIGURE 125
Installing the Waste Float Sensor

The waste container can be replaced according to the steps mentioned above. The replaced waste shall be properly disposed to avoid contamination.

**WARNING**

- Be sure to dispose reagents, waste, samples, consumables, etc. according to local legislations and regulations.

7.3.9.7 Connecting the LIS

If the analyzer needs to be connected to laboratory information system (hereinafter referred to as LIS), you can complete the connection by following the steps in this section.

7.3.9.8 Installing LIS Workstation

1. Install LIS workstation and set instrument type and model.
2. Enter LIS workstation network setup interface after installation and set monitoring IP address and port number.

Please contact the Human customer engineer to get **Description of LIS Communication Protocol for Human Hematology Analyzers** to complete the support of the LIS workstation to the LIS communication protocol.

7.3.9.9 Host Communication Settings

1. Use a network cable to connect the analyzer to LIS local area network.
2. Please log on the hematology analyzer software as administrator; if the analyzer is turned on, skip this step. For details, see 6.2 *Startup*. The whole process lasts for 4 to 12 minutes. Please be patient.

3. In the **Setup** interface, click **Host Communication** in the **Communication** selection to access the Laboratory Information System (LIS) communication setting interface. See Figure 126.

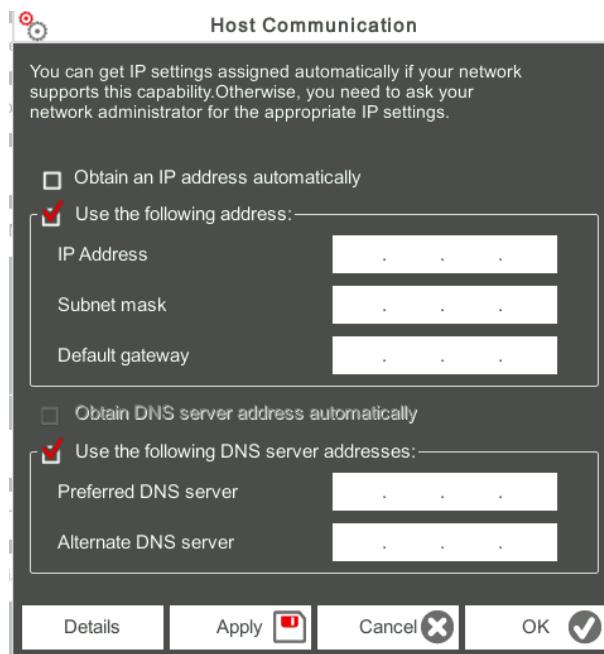


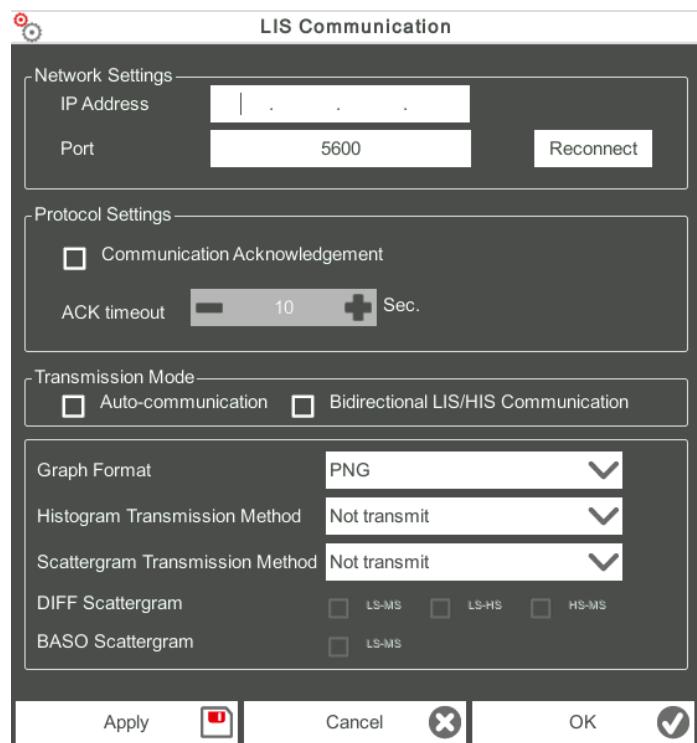
FIGURE 126
Host Network Settings

4. Set the IP address and other network information of the analyzer according to the actual situation.
 - If the network is accessed through a router on the site, please select **Obtain an IP address automatically** and Obtain DNS server address automatically.
 - If the network is accessed through a network switch, or the analyzer is directly connected to the LIS on the site, please select **Use the following address**, so as to manually set the IP address and subnet mask of the analyzer. The IP addresses of the analyzer and LIS must be in the same network segment. Furthermore, their subnet masks shall be the same, while other parameters can maintain null. Click **OK** to save the settings and close the dialogue box.

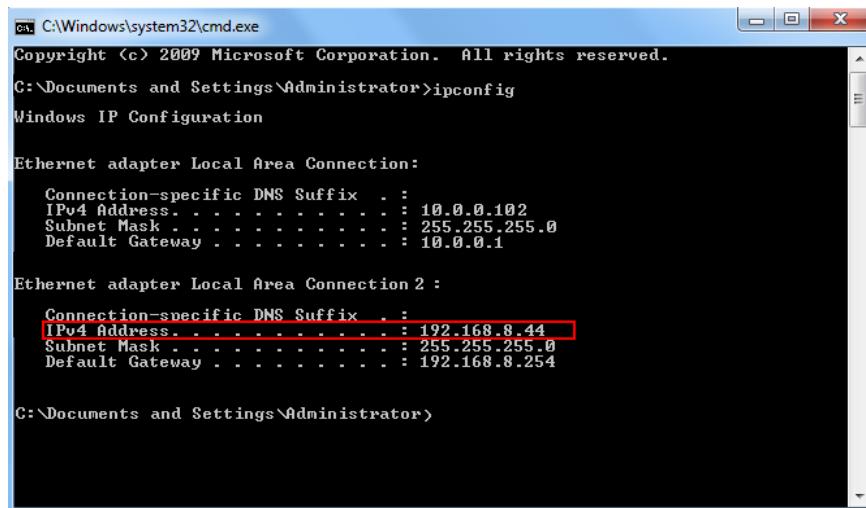
7.3.9.10 Connecting Analyzer with LIS

1. Please log on the hematology analyzer software as administrator; if the analyzer is turned on, skip this step. For details, see 6.2 *Startup*. The whole process lasts for 4 to 12 minutes. Please be patient.
2. In the **Setup** interface, click **LIS Communication** in the **Communication** selection to access the Laboratory Information System (LIS) communication setting interface. See Figure 127.

FIGURE 127
Communication Settings



3. Input the IP address and port of LIS workstation in **Network Settings** area. Find the IP address and port of LIS in the network setup interface in the LIS workstation; if IP address can't be found, try the method below:
 - Enter the operating system of LIS workstation.
 - Press combination key [Windows+R] to open the **Run** window.
 - Input **cmd**, and then click **OK**.
 - Input the **ipconfig** command into the cmd.exe window popped out. The interface shows similar content as follows:



```
cmd C:\Windows\system32\cmd.exe
Copyright <c> 2009 Microsoft Corporation. All rights reserved.

C:\Documents and Settings\Administrator>ipconfig

Windows IP Configuration

Ethernet adapter Local Area Connection:
  Connection-specific DNS Suffix . :
  IPv4 Address . . . . . : 10.0.0.102
  Subnet Mask . . . . . : 255.255.255.0
  Default Gateway . . . . . : 10.0.0.1

Ethernet adapter Local Area Connection 2 :
  Connection-specific DNS Suffix . :
    IPv4 Address . . . . . : 192.168.8.44
    Subnet Mask . . . . . : 255.255.255.0
    Default Gateway . . . . . : 192.168.8.254

C:\Documents and Settings\Administrator>
```

FIGURE 128

The IPv4 address in the red box is the IP address of LIS workstation.

- The IP address **192.168.8.44** of the LIS workstation shown as above is used as an example, real IP should be in the same network segment with LIS server.
- 4. Click **OK** to save the settings.
- 5. Check if the connection is successful.

The LIS icon in the upper right side on the analyzer screen turns from grey to black , which indicates auto hematology analyzer software is connected to LIS successfully. If the icon stays grey, the connection fails. Please check if the IP address and port of LIS is correct and reconnect as the steps above; if the problem still exists, please contact the hospital network administrator or HUMAN customer service engineer to handle it.

7.4 Ranges of parameters.

7.4.1 REFERENCE/NORMAL RANGES

TABLE 18
Reference values
implemented
in software of
HumaCount 5D

Parameter	Unit	Patient Type									
		General		Man		Women		Child		Newborn	
WBC	$10^9/l$	4	10	4	10	4	10	4	12	4	20
Neu%	%	50	70	50	70	50	70	50	70	40	80
Lym%	%	20	40	20	40	20	40	20	60	10	60
Mon%	%	3	12	3	12	3	12	3	12	3	13
Eos%	%	0,5	5	0,5	5	0,5	5	0,5	5	0,5	5
Bas%	%	0	1	0	1	0	1	0	1	0	1
Neu#	$10^9/l$	2	7	2	7	2	7	2	8	1,6	16
Lym#	$10^9/l$	0,8	4	0,8	4	0,8	4	0,8	7	0,4	12
Mon#	$10^9/l$	0,12	1,2	0,12	1,2	0,12	1,2	0,12	1,2	0,12	2,5
Eos#	$10^9/l$	0,02	0,5	0,02	0,5	0,02	0,5	0,02	0,8	0,02	0,8
Bas#	$10^9/l$	0	0,1	0	0,1	0	0,1	0	0,1	0	0,2
ALY#	$10^9/l$	0	0,2	0	0,2	0	0,2	0	0,2	0	0,2
ALY%	%	0	2	0	2	0	2	0	2	0	2
LIC#	$10^9/l$	0	0,2	0	0,2	0	0,2	0	0,2	0	0,2
LIC%	%	0	2,5	0	2,5	0	2,5	0	2,5	0	2,5
RBC	$10^{12}/l$	3,5	5,5	4	5,5	3,5	5	3,5	5,2	3,5	7
HGB	g/l	11	16	120	160	110	150	120	160	170	200
HCT	%	37	54	40	54	37	47	35	49	38	68
MCV	fL	80	100	80	100	80	100	80	100	95	125
MCH	pg	27	34	27	34	27	34	27	34	30	42
MCHC	g/l	320	360	320	360	320	360	310	370	300	340
RDW-CV	%	11	16	11	16	11	16	11	16	11	16
RDW-SD	fL	35	56	35	56	35	56	35	56	35	56
PLT	$10^9/l$	100	300	100	300	100	300	100	300	100	300
MPV	fL	6,5	12	6,5	12	6,5	12	6,5	12	NA	NA
PDW	fL	9	17	9	17	9	17	9	17	9	17
PCT	ml/l	0,108	0,282	1,08	2,82	1,08	2,82	1,08	2,82	NA	NA
P-LCR	%	11	45	11	45	11	45	11	45	NA	NA
P-LCC	$10^9/l$	30	90	30	90	30	90	30	90	NA	NA

7.4.2 ANALYTICAL MEASUREMENT RANGES

Range	Display Range		Linearity Range		
Parameter	Low	High	Low	High	Unit
WBC	0	999	0	300	$10^9/l$
NEU#	0	999	0	300	$10^9/l$
LYM#	0	999	0	300	$10^9/l$
MON#	0	999	0	300	$10^9/l$
EOS#	0	999	0	300	$10^9/l$
BAS#	0	999	0	300	$10^9/l$
ALY#	0	999	0	300	$10^9/l$
LIC#	0	999	0	300	$10^9/l$
NEU%	0	99.9	NA	NA	%
LYM%	0	99.9	NA	NA	%
MON%	0	99.9	NA	NA	%
EOS%	0	99.9	NA	NA	%
BAS%	0	99.9	NA	NA	%
ALY%	0	99.9	NA	NA	%
LIC%	0	99.9	NA	NA	%
RBC	0	18	0	8.5	$10^{12}/l$
HGB	0	300	0	250	g/l
MCHC	0	9999	NA	NA	g/l
MCH	0	999	NA	NA	pg
HCT	0	80	0	67	%
MCV	0	250	NA	NA	fL
RDW-SD	0	999	NA	NA	fL
RDW-CV	0	99.9	NA	NA	%
PLT	0	5000	0	3000	$10^9/l$
MPV	0	99.9	NA	NA	fL
PDW	0	999	NA	NA	NA
PCT	0	0.999	NA	NA	%
P-LCR	0	99.9	NA	NA	$10^9/l$
P-LCC	0	5000	NA	NA	%

TABLE 19

Display ranges and Linearity ranges of all parameters of Hu-
maCount 5D.

8 CALIBRATION

8.1 Introduction

Calibration is a procedure to standardize the analyzer by determining its deviation, if any, from calibration references and to apply any necessary correction factors. To get accurate blood analysis results, perform calibration of the analyzer following the procedures given in this chapter when it's needed.

**Note:**

- Calibration procedures can only be performed by users with the administrator-level access. The login users with the access level of general users can not perform the calibration procedures but only browse the calibration coefficients.
- You should only use the Human-specified calibrators and reagents. Store and use the calibrator and reagents following the instructions for use of the calibrations and reagents.
- The analyzer identifies a sample as a calibration sample only if the analysis is started from the Cal interface.
- The calculation of repeatability is included in the calibration procedure.

8.2 When to Calibrate

This analyzer is calibrated at the factory just before shipment. It is electronically stable and does not require frequent recalibration if you operate and maintain it as instructed by this manual. You need to recalibrate this analyzer if:

- It is the first time this analyzer has been used (usually done by a Human-authorized representative when installing the analyzer).
- An analytical component has been changed.
- The quality control results indicate that there may be a problem.
- The operating environment (such as the temperature) has changed significantly.

**Note:**

- All of the measured parameters must be calibrated before readings of this analyzer can be used as valid analysis results.
- For laboratories conducting routine tests, the calibration should be applied at least once every six months.

8.3 How to Calibrate

There are three calibration programs available on this analyzer: manual calibration, auto calibration using calibrators and auto calibration using fresh blood samples. All or part of the parameters of WBC, RBC, HGB, MCV and PLT can be calibrated by the calibration procedure.

1. Check and make sure enough reagents have been prepared for the calibration. You need to start over the calibration if the reagents run out during the process.
2. Do the background check. If the analyzer alarms are activated for abnormal background results, see 11 *Troubleshooting* for solutions. Run the median controls in whole blood-CBC+DIFF mode consecutively for 11 times, take and view repeatability of the counting results from the 2nd run through the 11th run in the Review interface and make sure they are within the range specified in A.4.4 Repeatability.
3. Run the corresponding diluent for 3 times immediately after running the high-level controls for 3 times and calculate the carryover by the following formulae:

$$\text{Carryover (\%)} = \frac{\text{First low-value sample result} - \text{Third low-level sample result}}{\text{Third high-value sample result} - \text{Third low-level sample result}} \times 100\%$$

The calculated carryovers shall meet the requirements in A.4.5 Carryover.

4. It is recommended that you create a log table for your analyzer. The suggested items that you may want to include in the log table are: calibration date, supplier of calibrator, lot number, expected results and limits, and result of background check.

8.3.1 MANUAL CALIBRATION

Complete the manual calibration as per the following procedure:

1. Click **Cal** in the menu page to access the calibration interface.
2. Click **Manual** to access the manual calibration interface. See Figure 129.

Manual		
Whole Blood		Predilute
Para.		Cal. Coefficient (%)
WBC	100.00	05-19-2017
RBC	100.00	05-19-2017
HGB	100.00	05-19-2017
MCV	100.00	05-19-2017
PLT	100.00	05-19-2017
MPV	100.00	
Save		Print
		Exit

FIGURE 129
Manual Calibration

The calibration coefficients of whole blood mode and predilute mode are displayed on the manual interface.



Note:

- The login users with the access level of general users can not perform the calibration procedures but only browse the calibration coefficients on the current screen. To perform the calibration, please log out and then log in as users with administrator-level access.

3. Check the calibration coefficient and calculate the new coefficient using the following equation.

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

For example, the WBC reference value of a calibrator is 8.3, and the current calibration coefficient of the whole blood mode is 99.00%. Run the calibrator in whole blood mode for 11 consecutive times and calculate the WBC results of the 2nd to 11th runs (n=10): The obtained CV is 1.1% and the Mean is 8.22, which meet the requirements. The new calibration coefficient is obtained:

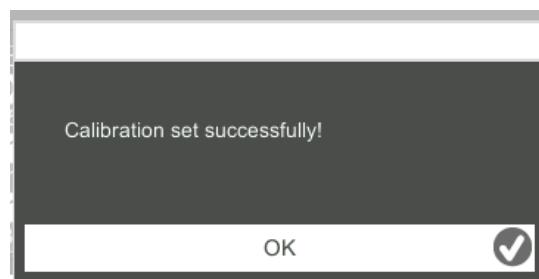
$$\text{New calibration factor} = \frac{99.00\% \times 8.3}{8.22} = 99.96\%$$

The calculated calibration coefficients shall be between 75%~125%. In case of an invalid calibration coefficient, try to find out the reason (e.g. calibration material not thoroughly mixed, incorrect operation, etc.). Then recalibrate the analyzer and recalculate the calibration coefficients.

4. Enter the new calibration coefficients into the factor cell of the parameter that requires calibration. The entered calibration coefficients shall be between 75.0%~125.0% (calculation results rounded to two decimal places).
 5. Click **Save**.
- If the new calibration coefficient is valid and different from the original value, the following dialogue box will pop up.

FIGURE 130

Calibration set successfully

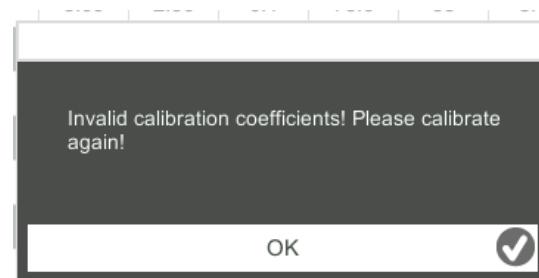


On the screen, the calibration coefficient is refreshed to be the new one and the calibration date is refreshed to be the current system date.

- If the new calibration coefficients are invalid, the message box will pop up. Click **OK** to close the message box and enter a valid factor.

FIGURE 131

Invalid Coefficients



6. (Optional) Click Print to print the current calibration coefficient.
7. Click Exit to close the Manual interface.

8.3.2 AUTO CALIBRATION USING CALIBRATORS

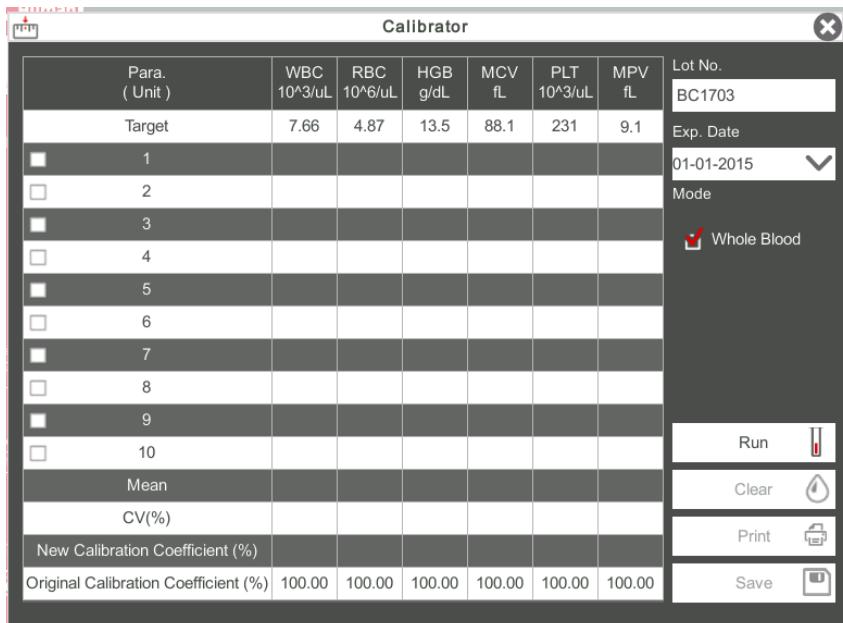


Note:

- Only Human-specified calibrators shall be used. Human will not be responsible for any erroneous result caused by using other calibrators.
- See the instructions for use of the calibrators for the lot No., Exp. Date and the target. Complete the calibration with calibrators as per the following procedure:

1. Click **Cal** in the menu page to access the calibration interface.
2. Click **Calibrator**.

The **Calibrator** interface pops up as shown in Figure 132.

**FIGURE 132**

Auto Calibration Using
Calibrators

3. Enter the lot No. of the calibrator into the Lot No. box.
4. Click the **Exp. Date** box, and then edit the **Exp. Date**.



Note:

- The Exp. Date can be no earlier than the current system date.
- The entered Exp. Date should be either the Exp. Date printed on the labeling or the open-container expiration date, whichever is earlier. The open-container expiration date is calculated as follows: The date on which the container is opened + the open-container stability in days.

5. Input the target values of the parameters in the corresponding cell of the Target.
6. Prepare the calibrators following their instructions for use and place the calibrators under the sampling probe.
7. Press the aspirate key to start the calibration counting. After every calibration run, the progress bar will close automatically and the analyzer will have different responses according to different analysis results.
- If the results are valid and within the linearity range, they will be displayed directly.

- If the calibration counting data of any parameter in the current counting is out of the display range or linearity range of the parameter, a message box will pop up on the screen prompting that the calibration data is invalid. Click **OK** to close the message box and delete the data from the table without saving.
- If any of the parameter's value in the calibration counting differs from the Target value by more than 50%, the system will prompt you with a message box asking if the calibration counting results should be kept. To keep the results, click **Yes**; to remove the results, click **No**.



Note:

- After the valid calibration result is obtained, the parameters with corresponding checkboxes ticked off will be involved in the calculation of the calibration coefficients by default.
 - If you switch to other interfaces before the new calibration coefficients are obtained, the system will discard the current calibration data and keep the original calibration coefficients.
8. To get 10 valid counting results, repeat steps 6~7 ten times. The analyzer will, by default, calculate the Mean, CV% and the new calibration coefficients based on all the ticked-off calibration data according to the formulae.
 9. You can select a few groups of data for the calculation of the calibration coefficients which can be obtained unless at least 5 groups of ticked-off data are included. Each time when you tick off or uncheck the checkboxes, the calibration coefficients will be refreshed and displayed in time. When the amount of the valid calibration data in the list reaches 10, a message box of Calibrator calibration done! will pop up. Click **OK** to close the message box.

**Note:**

The out-of-range CV% does not influence the display of the calibration coefficients.

10. Click **Save**.

- If the calculated calibration coefficients of all parameter are within the range of 75%~125% and the CV% of all parameter are also within the repeatability, then a dialogue box prompting the successful calibration setting will pop up. Click **OK** to close the message box.
- If the obtained calibration coefficient of any parameter is not within the range of 75%~125% or the CV% of any calibrated parameter does not meet the repeatability, the calibration coefficient will not be saved and a dialogue box indicating invalid new calibration coefficient will pop up. Click **Yes** to close the dialogue box and repeat the calibration operations.

11. (Optional) Click **Print** to print the calibration results.

8.3.3 AUTO CALIBRATION USING FRESH BLOOD SAMPLES

Complete the calibration using fresh blood samples as per the following procedure:

1. Click **Cal** in the menu page to access the calibration interface.
2. Click **Fresh Blood**.

The fresh blood sample calibration interface pop up, as shown in Figure 133.

Para. (Unit)	WBC 10 ³ /uL	RBC 10 ⁶ /uL	HGB g/dL	MCV fL	PLT 10 ³ /uL	MPV fL
Target						
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Mean						
CV(%)						
Calibration Coefficient 1 (%)						

FIGURE 133

Auto Calibration Using Calibrators

3. Prepare 3 to 5 normal fresh blood samples as instructed by 6.4 *Sample Collection and Handling*.
4. Run each of the prepared samples on the reference instrument three times at least. Average the results for your reference values.

! **Note:**
The reference instrument must be a properly running standard analyzer so as to ensure the accuracy of the reference values.

5. Enter the reference values for the parameters to be calibrated in the corresponding **Target** textbox.
6. Place the blood sample under the sampling probe, press the aspirate key on the analyzer to run the samples. The system will calculate the values for WBC, RBC, HGB, MCV and PLT of the sample. If used in VWB mode, use 20 µl of calibrator material. If used in Pre-diluted mode, first dispense diluent by the analyzer into a bullet tube, than add 20 µl of calibrator material into the bullet tube -prefilled with diluent.
7. Repeat step 6 for 10 times and calculate the counting results for sample No. 1 in the 10 runs. The system will calculate the Mean, CV and Calibration coefficient for each parameter of the sample. If the obtained calibration coefficient for any sample is not within the valid range or CV% or any calibrated parameters does not meet the repeatability, a dialogue box indicating invalid new calibration coefficient will pop up when you are selecting other blood samples. Click **Yes** to clear the calibration data of the sample. Redo the calibration or redo after running another sample meeting all criteria.
8. Refer to steps 6~7 and perform the counting operations for the remaining four blood samples. The system will calculate the Mean, CV and Calibration Coefficient for each parameter of the remaining 4 blood samples.
9. Click **Calculate**. The system will calculate the average of the calibration coefficients, namely, the mean calibration coefficient (%), as the new calibration coefficient based on the five blood samples. You can also check at least three accurate calibration coefficients and the system will re-calculate the mean calibration coefficient (%).

**Note:**

The mean calibration coefficient is invalid if its absolute value of deviation from the original calibration coefficient is greater than or equal to 5%.

10. Click **Save.**

- If the mean calibration coefficient is within the valid range (the absolute value of deviation from the original calibration coefficient is less than 5%), you'll be prompted that the mean calibration coefficient is saved successfully.
- If the mean calibration coefficient is not within the valid range (the absolute value of deviation from the original calibration coefficient is greater than or equal to 5%), you'll be prompted that the mean calibration coefficient is invalid.

CV% out of standard will not affect the display of calibration coefficient.

11. (Optional) Click **Print to print the calibration results.**

8.4 Verifying Calibration Coefficients

It is recommended that you take the following steps to verify the calibration coefficients:

1. Run the calibrator at least three times and check whether the means of the obtained results are within the expected ranges.
2. Run the low-, normal- and high-level controls each for three times at least, and check whether the means of the obtained results are within the expected ranges.
3. Run at least three fresh blood samples with known reference values, each for six times at least, and check whether the means of the obtained results are within the expected ranges.

9 REAGENT MANAGEMENT

Once the new reagent is connected to the analyzer, you can set the reagent configurations, including validity period, residue volume and reagent barcode on the Reagent Management interface. Upon the completion of reagent configuration, you can perform the procedures for reagent replacement.

**Note:**

- Reagents can be irritating to the eyes, skin, and mucosa. Wear proper personal protective equipment (e.g. gloves, lab uniforms, etc.) and follow laboratory safety procedures when handling them in the laboratory.
- If the reagent accidentally comes in contact with your skin, wash it off immediately with plenty of water and see a doctor if necessary. Do the same if you accidentally get any of the reagent in your eyes.

9.1 Accessing the Interface

Click Reagent Management in the menu navigation area, to access the reagent management setting interface. See Figure 134.

Reagent Management											
Measure		Setup Reagent									
Review		Replace									
QC		Replace All									
Current Model: Closed System Agent (Code): 1501											
Reagent Name											
HC5D-Diluent	Exp. Date	Open-container Date	Period After Opening	Open-container Exp. Date	Residue Volume						
HC5D-CBC-Lyse	05-18-2019	05-19-2017	2 Year	05-18-2019	17.444 L						
HC5D-DIFF-Lyse	05-18-2019	05-19-2017	2 Year	05-18-2019	193.6 ml						
HC5D-DIL-Lyse	05-18-2019	05-19-2017	2 Year	05-18-2019	477 ml						

FIGURE 134

TABLE 20
Parameter Description for
Reagent Management

Parameter	NOTE
Current Model	Current model of the analyzer. - Open system - Closed system Reagent setting procedures for different analyzer models vary, please refer to chapter 9.2 <i>Setting Reagent Information</i> .
Reagent Name	Name of the reagent.
Exp. Date	Exp. Date of the unopened reagent will be shown upon the completion of the reagent settings. Any reagent, regardless of its container being opened or not, should not be used beyond this date.
Open-container Date	The date on which the reagent container is opened. The default open-container date is the date on which the reagent settings are completed.
Period after opening (PAO)	The validity period (days) after the reagent container is opened. It will be shown upon the completion of the reagent settings.
Open-container Exp. Date	Expiration date of the opened reagent, and it will be shown upon the completion of the reagent settings.
Residue Volume	The current residue volume of the reagent, and it will be shown in ml upon the completion of the reagent settings. The unit is ml.

9.2 Setting Reagent Information

Once the new reagent is connected to the analyzer, you should set the reagent configurations, including validity period, residue volume and reagent barcode on the Reagent Management interface. Upon the completion of reagent configuration, you can perform the procedures for reagent replacement.

Reagent setting procedures for different analyzer models vary. The reagent setting procedures will be presented on the following pages.

9.2.1 SYSTEM REAGENT

For setting procedures for the HC5D system reagent please follow below instructions:

1. Select the reagent to be set, and then click **Setup**. A dialogue box as shown in Figure 135 pops up.

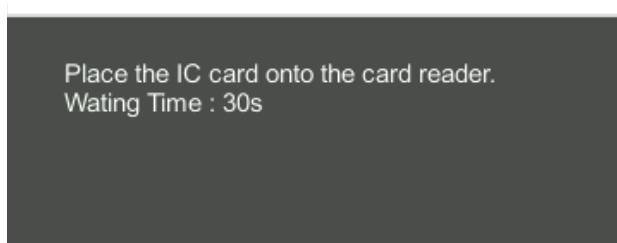


FIGURE 135
RF Card Verification

2. Put the RF card attached to reagent packing on the RF card reader in front of the analyzer. The beeping of the card reader and a pop-up dialogue box as shown in Figure 136 indicate the successful reagent settings.

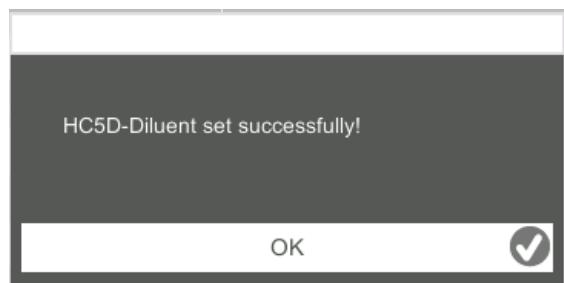


FIGURE 136
Successful Reagent Settings



Note:

- The RF card is intended for single use only.
- If RF card verification fails, please follow the system prompts and use a valid RF card for re-reading.

3. Click **OK**.
4. Click **Close** to exit.



Note:

- Once the reagent settings are successfully completed, the system prompt at the top right corner of the screen will show that the reagent has not been replaced. To remove this error, click the error message and then click **Remove Error** in the pop-up dialogue box. The analyzer will complete the replacement of the reagent and remove the error.

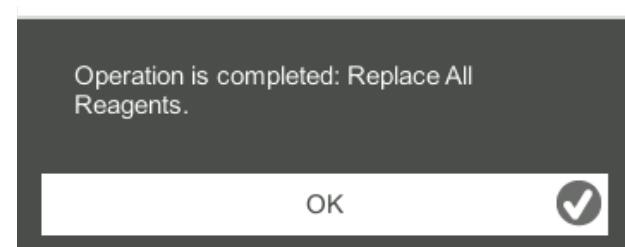
9.3 Replacing Reagents

After completing the reagent settings, you should perform the reagent replacement operations. You can select to replace one type of reagent at a time or all reagents. The method is applied as follows:

- Select a type of reagent to be replaced, and click Replace; or click Replace All to replace all the reagents.

After the replacement is completed, a message box as shown below will pop up on the screen.

FIGURE 137



- Click **OK** to close the message box.



Note:

When you have changed the reagents, run a background check to see if the results meet the requirement. If RF card verification fails, please follow the system prompts and use a valid RF card for re-reading.

10 SERVICE

10.1 Introduction



This analyzer provides multiple maintenance functions for this purpose. This chapter introduces how to use the provided functions to maintain and troubleshoot your analyzer. Preventive and corrective maintenance procedures are required to keep the analyzer in a good operating condition. All the analyzer components and surfaces are potentially infectious, take proper protective measures for operation or maintenance.



CAUTION

- Performing unauthorized maintenance procedures can damage your analyzer. Do not perform any maintenance procedures that are not described in this chapter.
- In case of problems not specified in this manual, contact Human customer service department or your local agent for assistance.
- Only Human-supplied parts can be used for maintenance. For any question, contact Human customer service department or your local agent.
- Exercise caution to avoid contact with the sharp sample probe when performing maintenance.



WARNING

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



Note:

- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- When you have changed the diluents, cleansers or lyses, run a background check to see if the results meet the requirement.

You should replace the reagents when:

- The system indicates that the reagent is used up
- The suspicious flag indicates that the reagent in the pipeline is contaminated
- The reagent is contaminated or expired
- WBC or RBC bubbles are identified.

You can replace any of the following reagents:

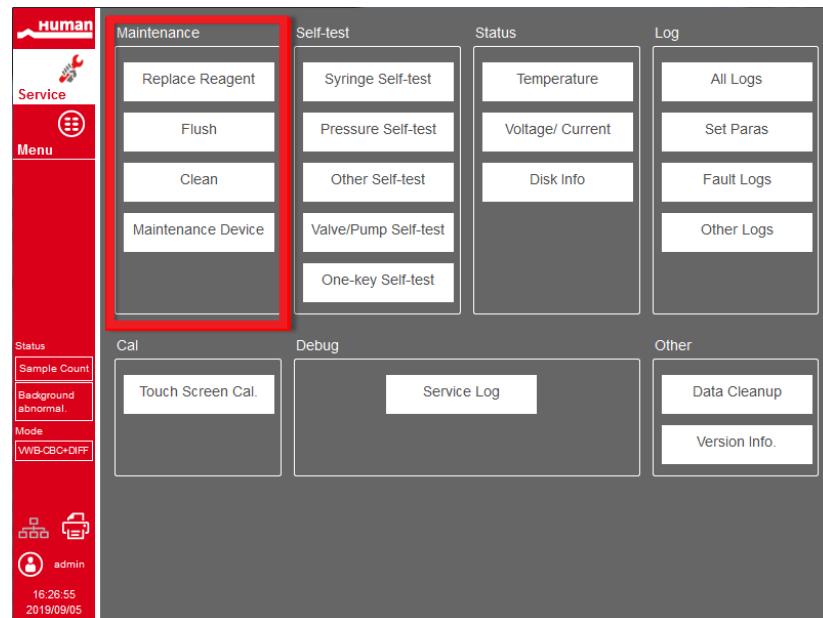
- HC5D-Diluent
- HC5D CBC Lyse
- HC5D Diff Lyse

Do as follows to replace the reagents:

1. Refer to Figure 122 in 7.3.9.1 *Electrical Connections* for reagent connections.
2. Click the **Service** icon in the menu page to access the **Service** interface as shown in Figure 138.

FIGURE 138

Service



3. Click **Replace Reagent** in the **Maintenance** selection.
 - The interface as shown in Figure 139 will pop up on the screen.

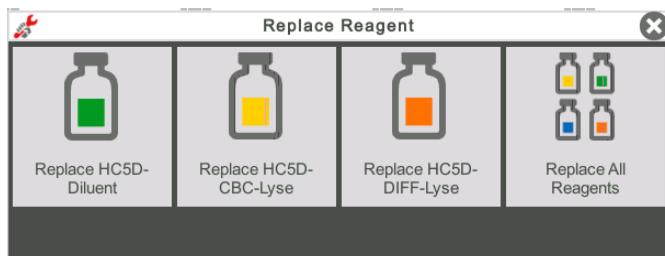


FIGURE 139
Reagent Replacement

4. Click the name of the reagent that needs to be replaced, such as **Replace All Reagents**. After the replacement is completed, the following message box will pop up.

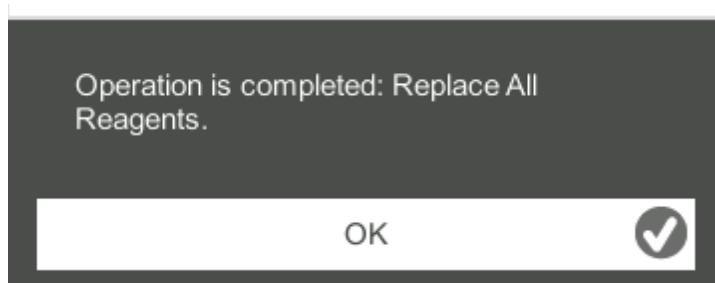


FIGURE 140

5. Click **OK** to close the message box.
6. Perform the above procedures to replace other reagents if necessary.



Note:

- After long-distance transportation, the reagent must be allowed to settle for more than one day before use.
- When you have changed the diluents, cleansers or lyses, run a background check to see if the results meet the requirement.

10.1.1 CLEANING

Clean corresponding parts according to the actual situation:

- WBC bath

You should clean the WBC bath when:

- The background of the scattergram has abnormal excessive cells
- the background of WBC- and/or HGB-specific parameters exceeds the reference range
- RBC bath

When the background of RBC- and (or) PLT-specific parameters exceeds the reference range, you should clean the RBC bath.

- Flow chamber

When the background of the scattergram has abnormal excessive cells, or bad differential of WBC, you should clean the flow chamber.

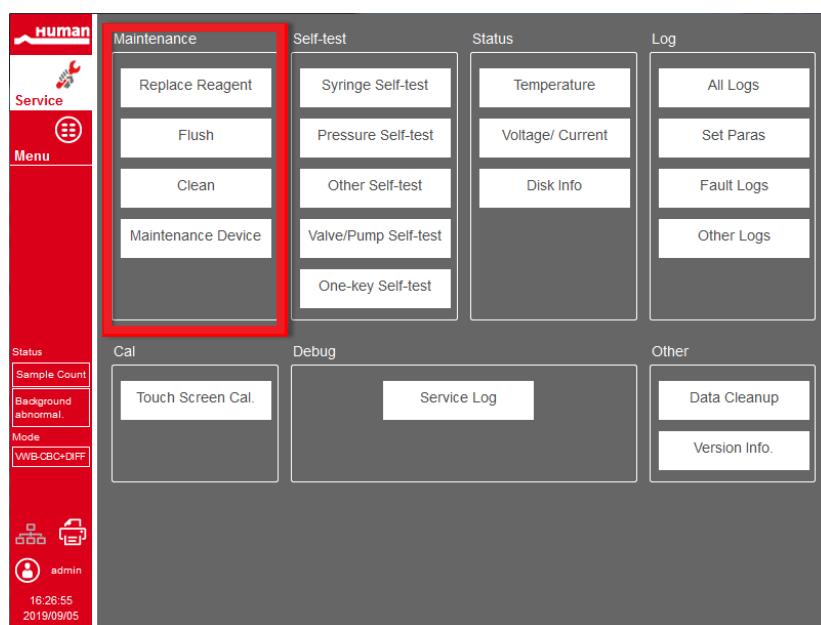
- Sample probe

When the sample probe is dirty, you should clean the sample probe.

The cleaning procedures are as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.

FIGURE 141
Service



2. Click **Clean** in the **Maintenance** selection, an interface as shown in Figure 141 will pop up on the screen.

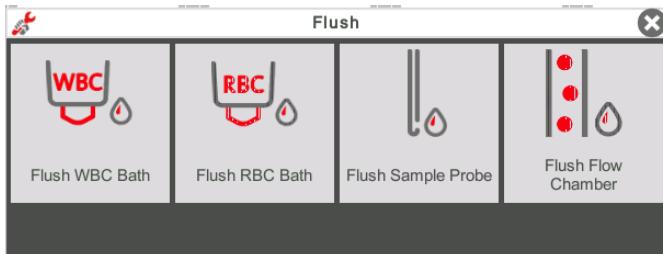


FIGURE 142

Cleaning

3. Click the icon of the part that needs to be cleaned, such as **Clean Sample Probe**. When the system cleaning is complete, the message box will pop up to show that the cleaning is done.

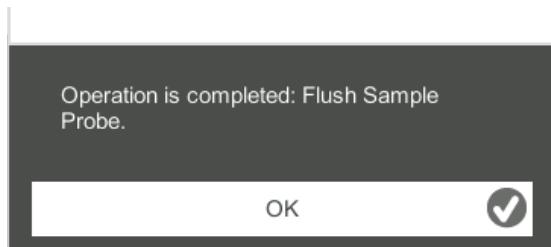


FIGURE 143

4. Click **OK** to close the message box.
5. Perform the above procedures to clean other components if necessary.

10.1.2 MAINTENANCE

Maintenance of the analyzer includes: unclogging, cleanser soak, cleanser soak for WBC channel and cleanser soak for RBC channel.

10.1.2.1 Unclogging

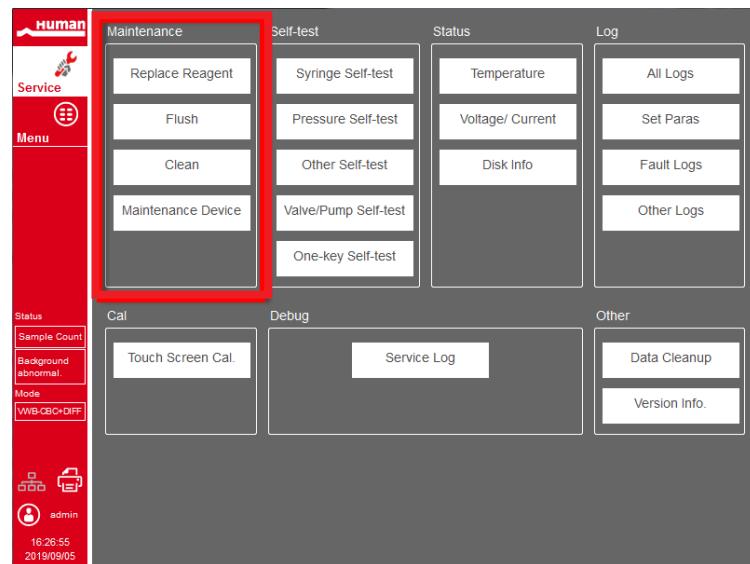
If clogging is found, or it is suspected that the counting results are not accurate due to aperture clogging, you can perform the unclogging operations.

The unclogging procedures are shown as follows:

1. Click the **Service** icon in the menu page to access the Service interface.

FIGURE 144

Service



2. Click **Maintain** in the **Maintenance** selection.

- The interface as shown in Figure 145 will pop up on the screen.

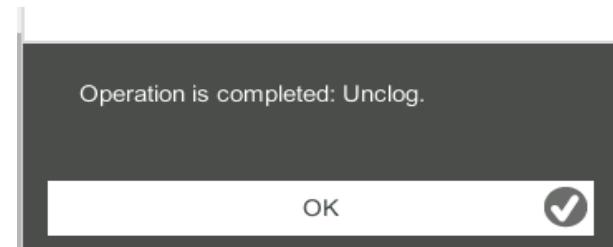
FIGURE 145

Maintenance



3. Click the **Unclog** icon.

The system will start unclogging, and a message box will pop up. After the unclogging is completed, a message box will pop up to show that the unclogging is done.

FIGURE 146

4. Click **OK** to close the message box.
5. Perform the above procedures to continue unclogging if necessary.

10.1.2.2 Cleanser Soak

The cleanser soak should be performed under the following circumstances:

- When the problems including the background results exceed the Ref. Range, bad differential of scattergram and clogging still exist after other maintenance procedures have been adopted.
- Analyzer has been running for more than 24 hours. The cleanser soak procedures are shown as follows.

1. Click the **Service** icon in the menu page to access the **Service** interface.

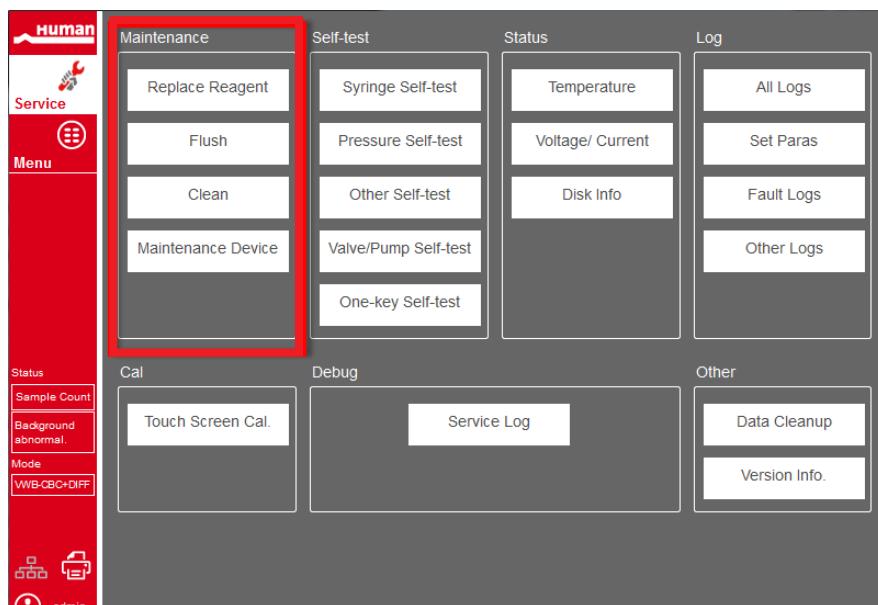


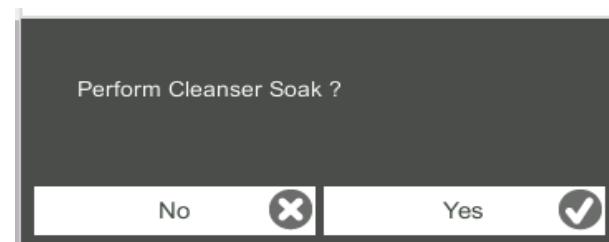
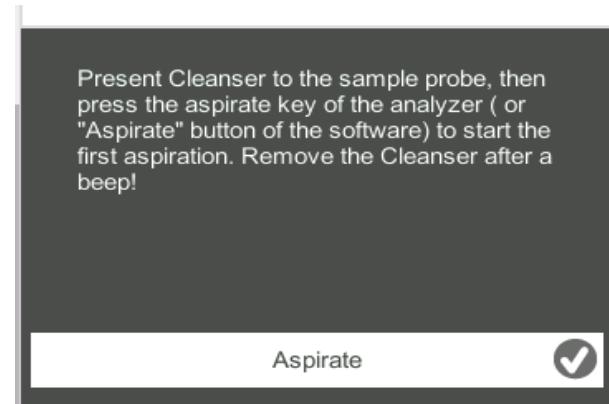
FIGURE 147

Service

2. Click **Maintain** in the **Maintenance** selection.
The interface as shown in the following picture will pop up on the screen.

FIGURE 148

3. Click the icon of **Cleanser Soak**.
4. A dialogue box as shown below will pop up.

FIGURE 149
Cleanser Soak**FIGURE 150**
Cleanser Soak

5. Present the cleanser to the sample probe as per the prompt, and press the aspirate key or click the **Aspirate** button. **Cleanser soaking...** and the soaking time will appear as shown below. See Figure 151.



FIGURE 151
Cleanser Maintenance Done

6. Click **Close**.
7. Perform the above procedures to perform the cleanser soak again if necessary.

10.1.2.3 Cleanser Soak for WBC Channel

Probe cleanser soaking for WBC channel can be used to remove the errors for aperture clogging or abnormal scattergram. Please refer to chapter 10.1.2.2 *Cleanser Soak* for performing the operations for cleanser soaking for WBC channel.

10.1.2.4 Cleanser Soak for RBC Channel

In case the RBC distribution histogram is abnormal or the clogging is believed to exist in the flow chamber, cleanser soak for RBC channel feature can be used as a means for troubleshooting.

Please refer to chapter 10.1.2.2 *Cleanser Soak* for performing the operations for cleanser soaking for WBC channel.

10.2 Comprehensive Device Maintenance

The comprehensive device maintenance feature includes fluidics initialization, comprehensive device cleaning, emptying fluidics and preparing to ship.

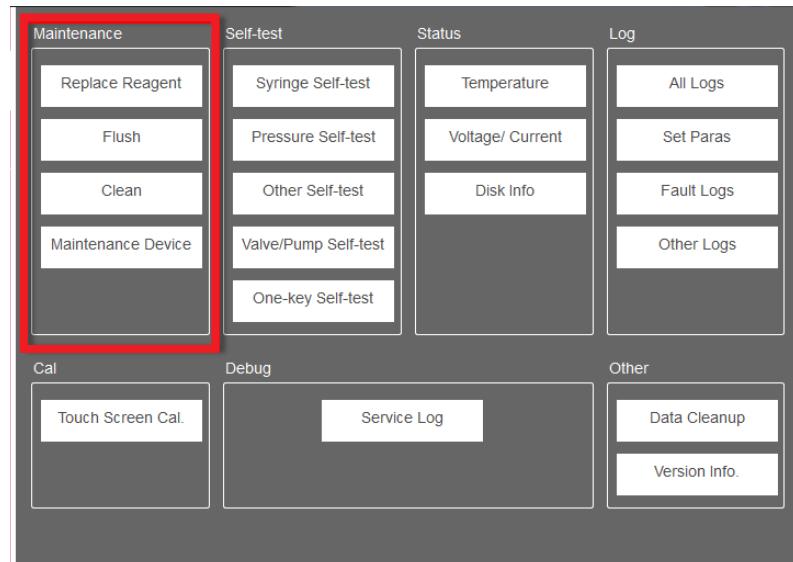
10.2.1 FLUIDICS INITIALIZATION

After maintaining the fluidic system or replacing a main part of the analyzer, you should perform this procedure to initialize the fluidic system.

Do as follows to perform the fluidics initialization:

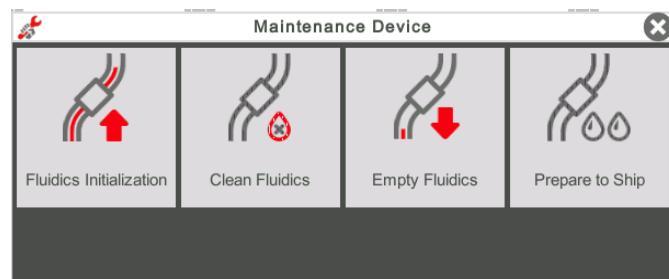
1. Click the **Service** icon in the menu page to access the **Service** interface.

FIGURE 152
Service



2. Click **Comprehensive Device** in the **Maintenance** selection.
 - The interface as shown below will pop up on the screen.

FIGURE 153



3. Click the icon of **Fluidics Initialization**.

The analyzer starts to perform the fluidics initialization procedure. After the initialization is complete, a message box will pop up.

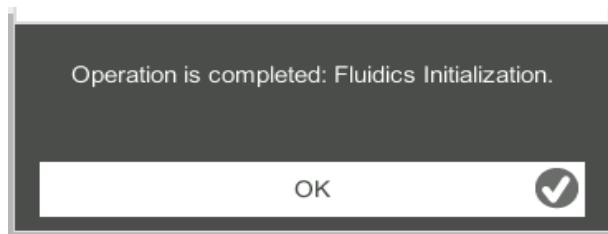


FIGURE 154

4. Click **OK**.

10.2.1.1 Clean Fluidics

If the background results of parameters are out of the background range, the comprehensive device cleaning should be cleansed.

Procedures for comprehensive device cleaning are shown as below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.

The interface as shown below will pop up on the screen.

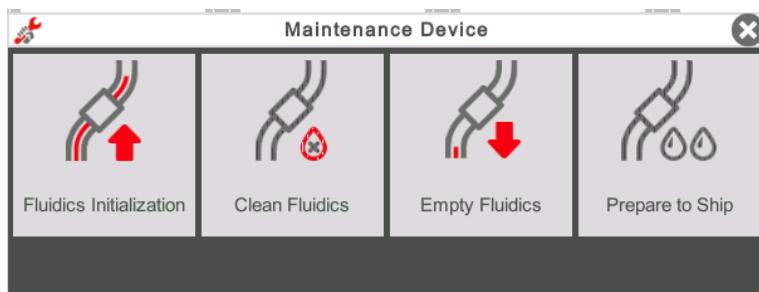


FIGURE 155

3. Click **Comprehensive Device** in the **Maintenance** selection.

The analyzer starts to perform the fluidics cleaning procedure. After the cleaning is completed, the following message box will pop up.

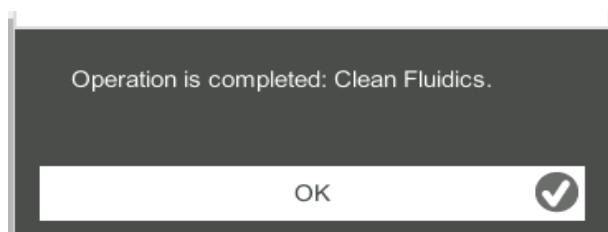


FIGURE 156

4. Click **OK**.

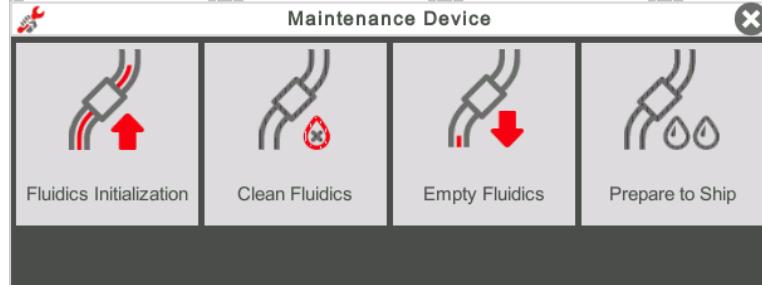
10.2.1.2 Empty Fluidics

This function enables the device to empty fluidics to prevent crystallization and maintain device performance when the device has not been used for more than one week. Procedures for emptying fluidics are shown as below:

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.

- The interface as shown below will pop up on the screen.

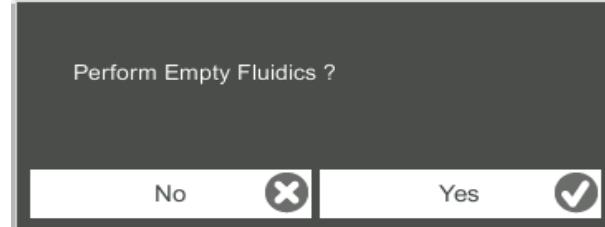
FIGURE 157



3. Click the icon of **Empty Fluidics**.

- A dialogue box will pop up as shown below.

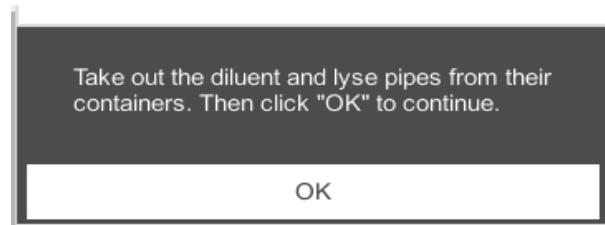
FIGURE 158



4. Click **Yes**.

- A dialogue box will pop up as shown below.

FIGURE 159



5. Remove all reagent pickup tube assemblies according to the prompt, and then click **OK** to start emptying the fluidic system. After the emptying is complete, a message box will pop up.

6. Place the [O/I] switch at the left side of the main unit in the [O] position.
7. After shutdown, empty the waste in the waste container, and dispose it.

**WARNING**

- Be sure to dispose reagents, waste, samples, consumables, etc. according to local legislations and regulations.

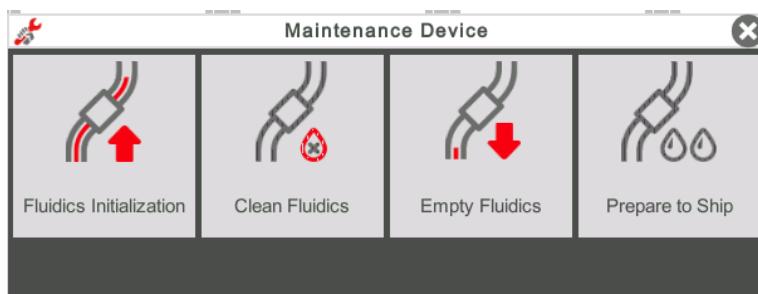
10.2.1.3 Prepare to Ship

If the analyzer is not to be used for over two weeks or needs be transported over a long distance (transporting time > 2h), you should perform this procedure.

Do as follows to perform the prepare-to-ship procedure:

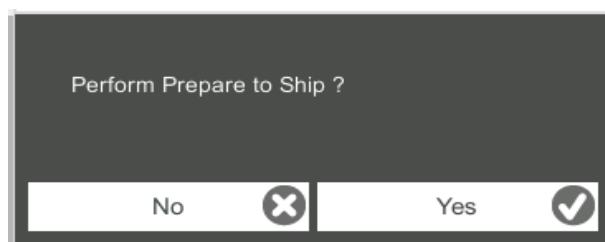
1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Comprehensive Device** in the **Maintenance** selection.

The interface as shown below will pop up on the screen.

**FIGURE 160**

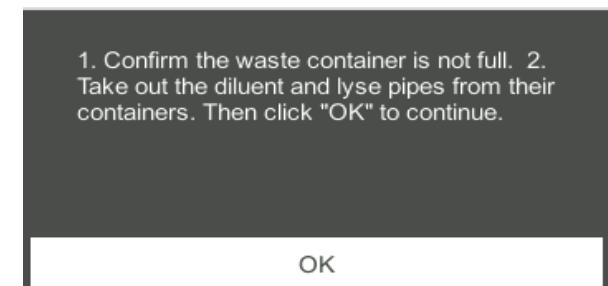
3. Click the icon of **Prepare to Ship**.

A dialogue box will pop up as shown below.

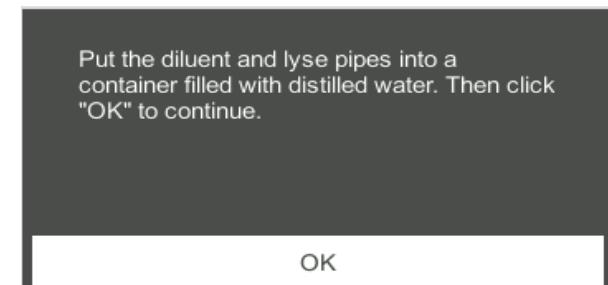
**FIGURE 161**

4. Click **Yes**.

The interface pops up a dialogue box as shown below.

FIGURE 162

5. Remove all reagent pickup tube assemblies according to the prompt, and then click **OK** to start emptying the fluidic system. After the emptying is complete, a message box will pop up.

FIGURE 163

6. Place all reagent pickup tube assemblies into the distilled water, and then click **OK** to start priming.

**Note:**

- Be sure to use distilled water in order to ensure the normal use of the device in the future. In addition, the beaker holding the distilled water needs to be cleaned thoroughly.
- The diluent pipe and lyse pipes should be stored separately in two beakers. System performs the filling operation. After the filling is completed, the following dialogue box will pop up.

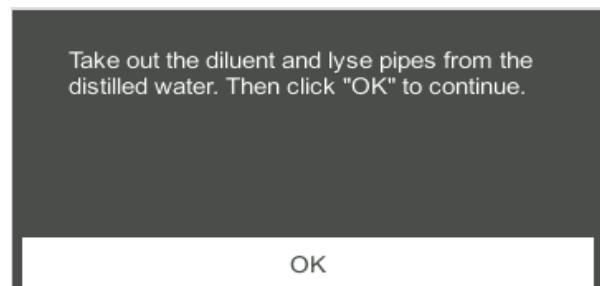


FIGURE 164

7. Take out the diluent and lyse pipes from the distilled water as per the prompt, then click OK.

A dialogue box will pop up to prompt you to power off the device.

**Note:**

Prepare to ship done. Please power off the analyzer!

1. Place the [O/I] switch at the left side of the main unit in the [O] position.
2. After shutdown, empty the waste in the waste container, and dispose it.

**WARNING**

- Be sure to dispose reagents, waste, samples, consumables, etc. according to local legislations and regulations.

10.2.2 AUTO CLEAN

There will be a certain amount of contamination accumulated after running a certain amount of samples without shutting down the analyzer. When the sample count amounts to over 100, the analyzer will perform the cleaning procedure automatically once, and a prompt will be displayed on the screen. In addition, the analyzer will perform the auto clean procedures if there has been no fluidics sequential operation for more than one hour.

10.2.3 AUTO PROMPT FOR CLEANSER SOAK

If the analyzer has been running for more than 24 hours but hasn't performed cleanser maintenance when the auto maintenance time is reached, the system will prompt to perform cleanser soak immediately, so as to prevent the accumulation of contamination.

- Click **Yes**, then you can perform the cleanser maintenance as per the prompt and the description in 10.1.2.2 *Cleanser Soak*.
- Click **No**, then the system will remind you every 10 minutes until you perform the maintenance.



Note:

- At the **Self-test** or **Status** interface, the analyzer does not ask for confirmation to perform the cleanser soak.
- If the analyzer is running or has problems when the conditions of auto prompt for cleanser soak is satisfied, the analyzer will prompt again after the current operation is completed or the problems are resolved.
- After cleanser soak is completed, the accumulative count values will be cleared automatically.
- Cleanser soak is an important step in comprehensive device maintenance. It is recommended not to stop soaking halfway.

10.2.4 AUTO SLEEP

When the fluidics system stops working for 60 minutes (default setting), the analyzer will enter the sleeping status automatically. You can change the waiting time for auto sleeping as needed, see 7.3.3.4 *Auto Maintenance*. When the analyzer is in the sleep mode, a prompt will be displayed on the screen. Touch the screen or press the aspirate key on the analyzer to wake it up.

- If it is the time to auto sleep but the analyzer is error status, then only after the error is removed will auto sleep start accordingly.
- Different maintenances will be performed by the analyzer automatically when exiting the sleep mode, and the exiting time depends on how long the analyzer was in the sleep mode.
- If errors occur when you are trying to cancel the auto sleep of the analyzer, please refer to chapter 11 *Troubleshooting* for solving the problems.

10.3 Self-test

This feature is to test if some important components of the device can function properly or not, including syringe and sampling assembly self-test, pressure and vacuum self-test, valve self-test and other self-test.



Note:

If the testing result is abnormal, you should try again for several times; if the abnormalities persist, please contact Human customer service department or your local agent.

10.3.1 SYRINGE AND SAMPLING MECHANISM

You can test the performance of all syringes and sampling mechanisms.

The self-inspection procedures are shown as below:

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Syringe Self-test** in the **Self-test** selection.

The interface as shown in Figure 165 will pop up on the screen.

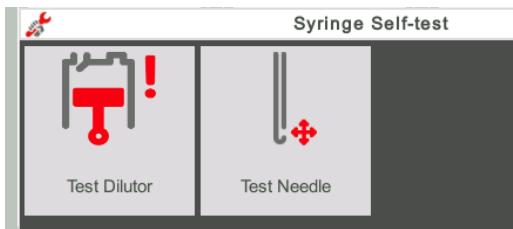


FIGURE 165
Syringe

3. Click the part that needs to be tested, e.g. Sample Syringe, and wait for the self-inspection results. After the self-test is completed, a dialogue box will pop up to show the self-test results.

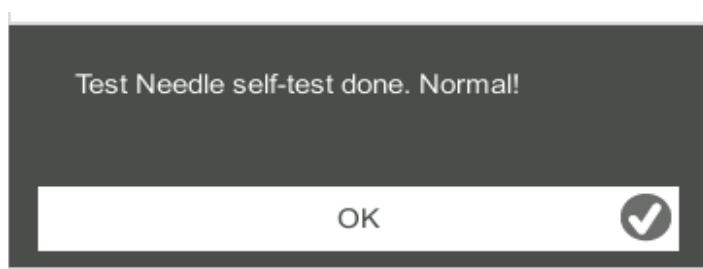


FIGURE 166
Syringe Self-test Results

4. Click **OK** to close the message box.

10.3.2 PRESSURE AND VACUUM

This feature is to test the pressure and vacuum inside the device.

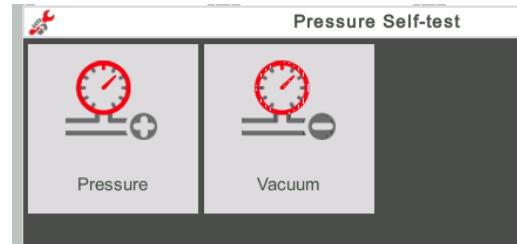
Procedures for pressure (or vacuum) self-inspection are shown as below:

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Pressure Self-test** in the **Self-test** selection.

The interface as shown in Figure 167 will pop up on the screen.

FIGURE 167

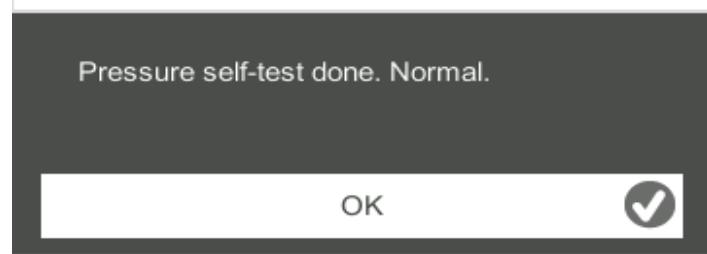
Pressure and Vacuum Self-inspection



3. Click **Pressure** (or **Vacuum**).

The system will perform the corresponding self-test operations. After the self-test is completed, a dialogue box will pop up to show the self-test results.

FIGURE 168



4. Click **OK** to close the message box.

10.3.3 VALVE & PUMP

When controlling the switches of different valves (pumps), you can judge if the valves (pumps) are operating properly by the sound of opening, closing or manually touching the corresponding valves (pumps).

The procedures for valve self-inspection are shown as follows:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Valve/Pump Self-test** in the **Self-test** selection.

The interface as shown in Figure 169 will pop up on the screen.

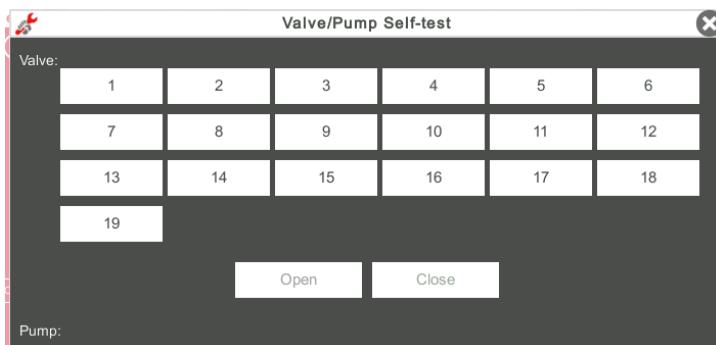


FIGURE 169

Valve Self-test

3. Click the desired valve number (e.g. 1), then confirm whether it works properly by the sound of its opening and closing.

10.3.4 OTHERS

You can perform the self-test for RBC aperture voltage.

RBC aperture voltage

The self-test procedure of RBC aperture voltage is shown as below:

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Other Self-test** in the **Self-test** selection.

The interface as shown in Figure 170 will pop up on the screen.

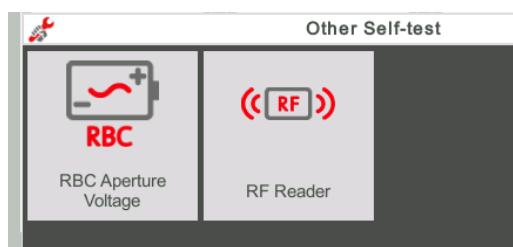
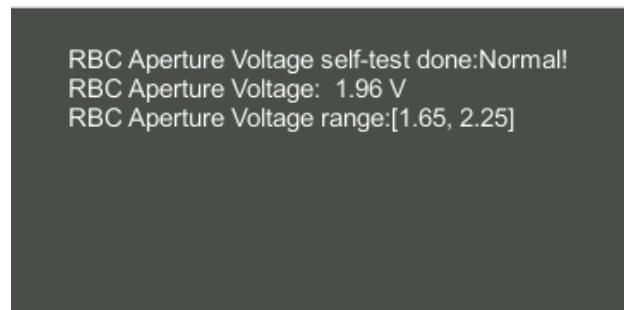


FIGURE 170

Pressure and Vacuum
Self-inspection

3. Click **RBC Aperture Voltage** to start self-test. The system will perform the corresponding self-test operations. After the self-inspection is completed, a dialogue box will pop up to show the self-inspection results.

FIGURE 171
RBC Aperture Voltage Self-test
Results



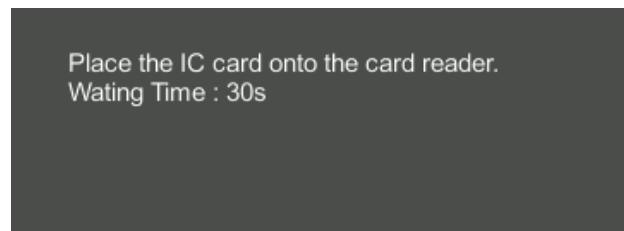
RF Card Reader

You can carry out a self-test on its built-in RF card reader. The operation procedures are as shown below.

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Other Self-test** in the **Self-test** selection.
3. Click the icon of **RF Reader** to start self-test.

A dialogue box will pop up as shown below.

FIGURE 172
Syringe Self-test Results



10.3.5 ONE-KEY SELF-TEST

Clicking on **One-key self-test** will run an automatic process which is testing the temperature, Pressure, Voltage/Current, Syringe/Sampling Assembly and Communication at the same time. After completion, a summary of all test results will be shown.

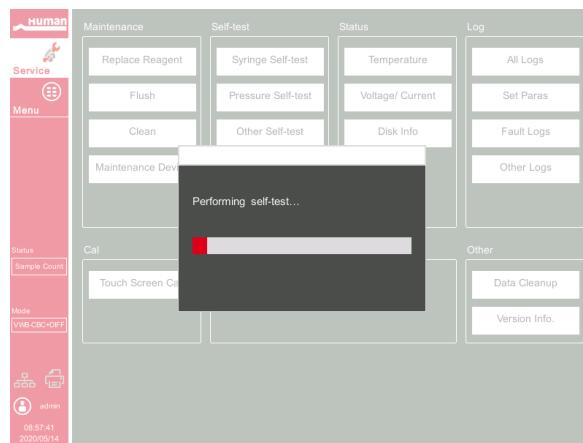


FIGURE 173

Temperature			Pressure		
Item	Result	Range	Item	Result	
Ambient Temperature	21.18 °C	5.0 ~ 40.0 °C			
Optical System Temperature	33.87 °C	30 ~ 40 °C	Pressure	PASS	
Preheating bath temperature	49.43 °C	48.5 ~ 51.5 °C	Vacuum	PASS	

Voltage/Current			Syringe/Sampling Assembly		
Item	Result	Range	Item	Result	
Constant Current Source Voltage	58.02 V	50.0 ~ 75.0 V	test Needle	PASS	
HBG Background Voltage	4.53 V	4.2 ~ 4.8 V	test Dilutor	PASS	
Laser Diode Current	15.08 mA	/			
A-12V	-12.29 V	-15.0 ~ -10.0 V			
P12V	11.98 V	10.0 ~ 15.0 V			
P24V	24.18 V	20.0 ~ 28.0 V			
A+12V	12.03 V	10.0 ~ 15.0 V			
RBC Aperture Voltage	2 V	1.65 ~ 2.25 V			

Comm.		
Item	Result	
Main Control Board FPGA	PASS	
Driver Board MCU	PASS	
RF Reader	PASS	

FIGURE 174

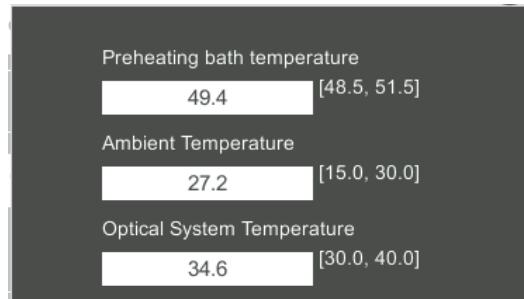
10.4 System Status

You can view the current status information of the analyzer in the **Status** selection, including temperature, voltage and current, and version information.

10.4.1 TEMPERATURE

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Temperature** in the **Status** selection.
 - The interface as shown in Figure 175 will pop up on the screen.

FIGURE 175
View Temperature Status

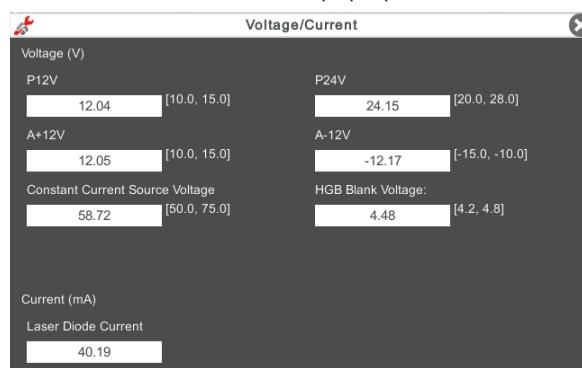


User can view the current temperature information of the analyzer, including the temperature of preheating bath temperature, ambient temperature and the temperature of the optical system. If the results of the temperature testing exceed the normal range, they will be highlighted by the red background.

10.4.2 VOLTAGE AND CURRENT

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Voltage/Current** in the **Status** selection.
 - The interface as shown below will pop up on the screen.

FIGURE 176
Voltage and Current



You can view the voltage and current information of the analyzer. The voltage or current value that exceeds the normal range will be displayed in a red background.

10.4.3 DISK INFORMATION

You can view the disk information of the analyzer, including disk name, capacity and used space. Specific steps are shown below.

1. Click the **Service** icon in the menu page to access the Service interface.
2. Click **Disk Info** in the **Status** selection.

The disk information interface displays. See Figure 177.

Item	Capacity	Used space
Flash	501.5M	0%
SD card	7.3G	10%

FIGURE 177
Disk Information

10.5 Log

In the Log interface, you can view the records of **Set Paras**, **Other Logs**, **Fault Logs** and **All Logs**.

- If a new record is added when the log is full, the newest record will overwrite the oldest one automatically.
- The administrator can view both his/her own operation logs and the general users' operation logs, while the general users can only review their own operation logs.
- The log can keep records of up to 5 years.

10.5.1 ALL LOGS

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **All Logs** in the **Log** selection.

You can view all logs (visible to the users of the current access level).

FIGURE 178
All Logs

The screenshot shows a software interface titled "All Logs". At the top, there are two date pickers: "01-01-2015" and "07-01-2015". Below the title is a table with ten rows of log entries. The columns are labeled "No.", "Time", "Summary Information", "Details", and "Operator". The log entries are as follows:

No.	Time	Summary Information	Details	Operator
1	01-01-2015 00:06:08	Run	Background Count mode countin...	Administrator a...
2	01-01-2015 00:00:44	Startup	Startup	Administrator a...
3	01-01-2015 00:00:36	Login	admin(admin) Login	Administrator a...
4	01-01-2015 00:10:34	Normal Shutdown	Normal Shutdown	Administrator a...
5	01-01-2015 00:06:28	Run	Background Count mode countin...	Administrator a...
6	01-01-2015 00:00:43	Startup	Startup	Administrator a...
7	01-01-2015 00:00:35	Login	admin(admin) Login	Administrator a...
8	01-01-2015 00:44:22	Normal Shutdown	Normal Shutdown	Administrator a...
9	01-01-2015 00:32:12	QC file added	L-J QC , 3File added	Administrator a...
10	01-01-2015 00:27:17	QC file added	L-J QC , 2File added	Administrator a...

At the bottom of the interface, there is a message box containing the following information:

```

Date and Time:01-01-2015 00:06:08
Operator:Administrator admin (admin)
Summary Information:Run
Details:Background Count mode counting run successfully

```

3. Select the dates in the two date textboxes, and then you can view the all logs within the date range, including operation time, log information and the operator.

10.5.2 PARAMETER REVISION LOGS

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Set Paras** in the Log selection.

You can view the parameter revision logs (which can be viewed by the user with the current level of access) within a specified date range.

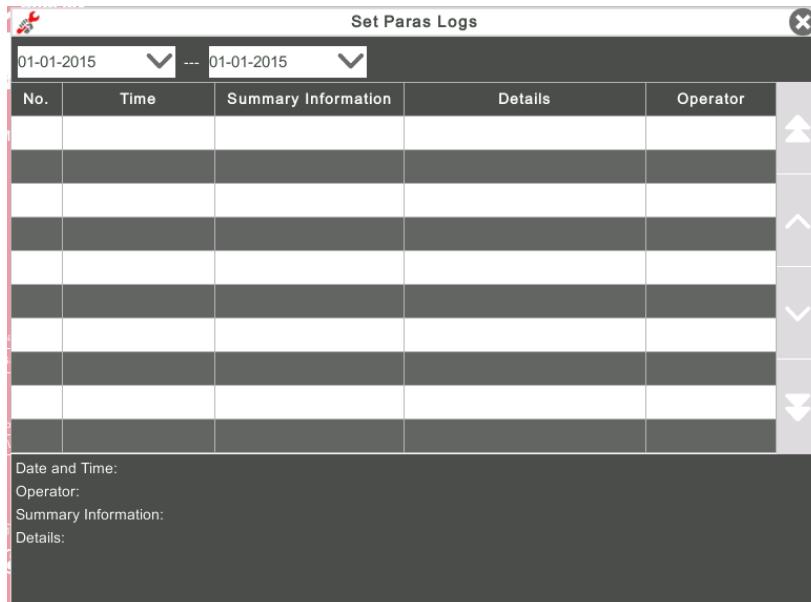


FIGURE 179

Parameter Revision Logs

3. Select the dates in the two date textboxes, and then you can view the parameter revision logs within the date range, including the revision date and time, revision summary and the operator.

10.5.3 FAULT LOGS

1. Click the **Service** icon in the menu page to access the **Service** interface.
 2. Click **Fault Logs** in the **Log** selection.

You can view all logs (visible to the users of the current access level).

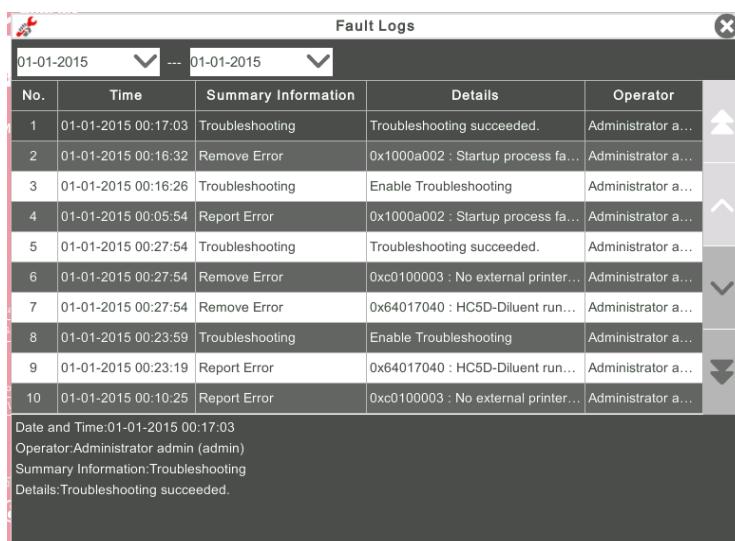


FIGURE 180

Fault Logs

3. Select the dates in the two date textboxes, and then you can view the fault logs within the date range, including date and time when the faults occur, fault description and the operator.

10.5.4 OTHER LOGS

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Other Logs** in the **Log** selection.

You can view other logs besides parameter revision logs and fault logs.

FIGURE 181
Other Logs

No.	Time	Summary Information	Details	Operator
1	01-01-2015 00:06:08	Run	Background Count mode countin...	Administrator a...
2	01-01-2015 00:00:44	Startup	Startup	Administrator a...
3	01-01-2015 00:00:36	Login	admin(admin) Login	Administrator a...
4	01-01-2015 00:10:34	Normal Shutdown	Normal Shutdown	Administrator a...
5	01-01-2015 00:06:28	Run	Background Count mode countin...	Administrator a...
6	01-01-2015 00:00:43	Startup	Startup	Administrator a...
7	01-01-2015 00:00:35	Login	admin(admin) Login	Administrator a...
8	01-01-2015 00:44:22	Normal Shutdown	Normal Shutdown	Administrator a...
9	01-01-2015 00:32:12	QC file added	L-J QC , 3File added	Administrator a...
10	01-01-2015 00:27:17	QC file added	L-J QC , 2File added	Administrator a...

Date and Time:01-01-2015 00:06:08
Operator:Administrator admin (admin)
Summary Information:Run
Details:Background Count mode counting run successfully

3. Select the dates in the two date textboxes to view the logs within the date range, including operation date and time, operation records and the operator.

10.6 Data Cleanup

You can clean up the data stored in the analyzer. Specific steps are shown below.

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Data Cleanup** in the **Other** selection.

The data cleanup interface displays. See Figure 182.

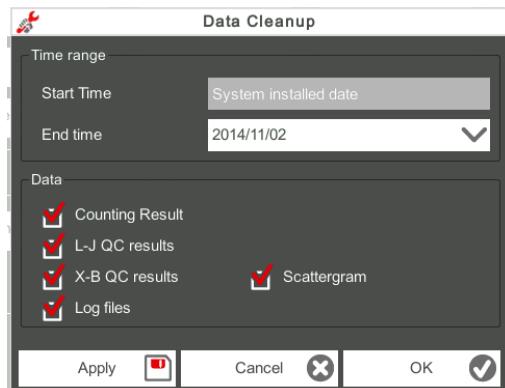


FIGURE 182
Data Cleanup

- Click the **End time** combo box, set the date range of the data to be cleaned up in the pop-up dialogue box.

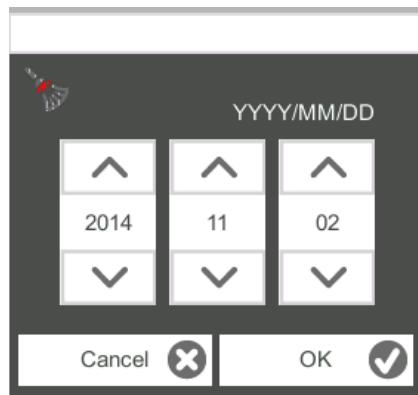


FIGURE 183

- The input sequence of the controls is the same with the date format on the top right corner of the dialogue box. For example, if the data format is **yyyy/MM/dd**, you should input the data in the sequence of year, month, and day.
 - Click **▲** or **▼** to select a date.
 - Click **Cancel** to cancel the process. The data will not be cleaned up.
 - For example, If the End time is set to **2016/03/31**, the data generated from system installation
 - Date to 31 March 2016 will be cleared.
- Click **OK** to save the settings and close the dialogue box.
 - Select the data to be cleaned up.

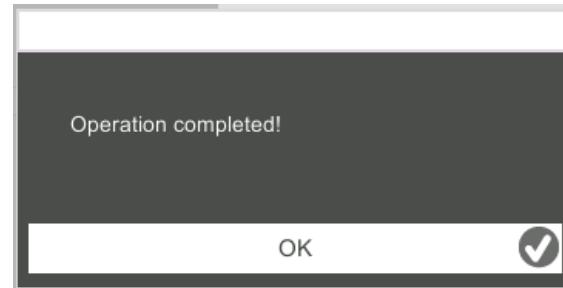
You can clean up the following data:

- Counting results
- L-J QC results
- X-B QC results
- Log files
- Scattergram

Click **Apply** or **OK**.

The interface pops up a dialogue box as shown below, indicating the cleanup is completed.

FIGURE 184



10.7 Version Information

You can view the current version information of all parts of the analyzer, and export the version information to a USB flash disk. Detailed steps are shown below:

1. Click the **Service** icon in the menu page to access the **Service** interface.
2. Click **Version Info** in the Other selection.

Version information interface will pop up on the screen. See Figure 185.

FIGURE 185
Version Information

Version	
Software Full Version	Software Release Version
0.5.20.15100	5
Technical File Version	Machine Type
A9	N1104
Application Software	Algorithm
0.9.0.475	1.5.5.20170418
Boot Software	ML0
0.11.9.13558	0.11.9.13558
MCU	FPGA
1.3.0.3741	0.1.0.1243
Fluidics Sequence	Operating System
0.1.9.16	3.2.0.14472
LIBS	RF Reader MCU
0.1.0.4794	1.1.0.2865
Export	

3. Insert a USB flash disk in the USB interface on the analyzer.
4. Click **Export**, and select the export path in the dialogue box, and then enter the file name. The file will be exported to the root directory of the USB flash disk (**/udisk/sda1**) by default as shown below.

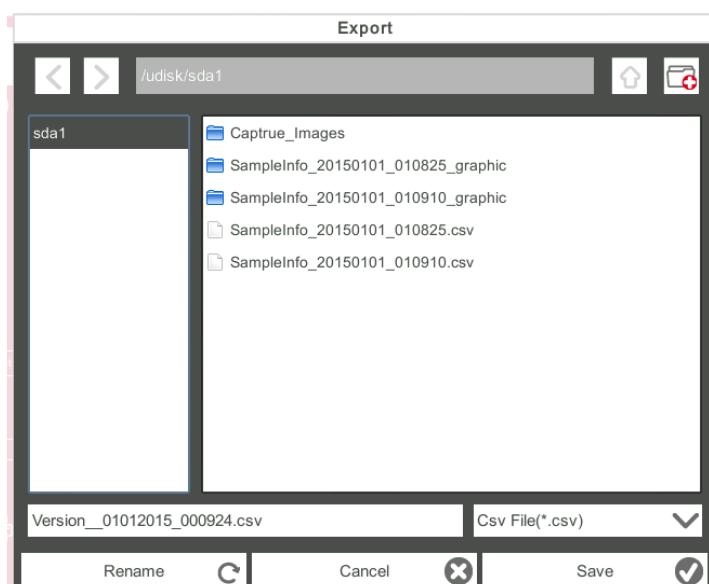


FIGURE 186

5. Click **Save** to start exporting.
 - After Export is completed, the message box as shown below will pop up.

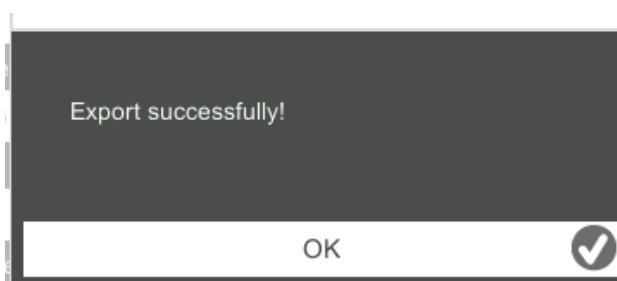


FIGURE 187

6. Click **OK** to exit.

10.8 Touch Screen Calibration

When the touch screen has offset, it needs to be recalibrated. Detailed steps are shown below:

1. Click the **Service** icon in the menu page to access the **Service** interface.

2. Click **Touch Screen Cal.** in the **Cal** selection.

3. Click the calibration point “+” on the screen in order.

When the calibration point disappears and the system return to the service screen, it indicates the completion of the calibration.

10.9 Exporting Host Information File

In the use of the analyzer, when errors occur and can not be removed, it's recommended that you export the host information to a USB flash disk and send the file to Human customer service engineer. Specific steps are shown below.

1. Insert a USB flash disk into the USB interface on the analyzer.

2. Click the **Service** icon in the menu page to access the **Service** interface.

3. Click **Download** in the **Debug** selection.

The **host_download.tar** file is exported to the root directory of the USB flash disk.

4. Send the **host_download.tar** file to Human customer service engineer for handling.

11 TROUBLESHOOTING

11.1 Introduction

This chapter contains information that is helpful in locating and resolving problems that may occur during the operation of your analyzer.

This chapter is not a complete service manual and is limited to problems that are readily diagnosed and/or corrected by the user of the analyzer. If the recommended solution fails to solve the problem, contact Human customer service department or your local agent.

11.2 Dealing with Error Messages

In the use of the analyzer, when the software detects abnormalities, an error message will be displayed on the upper right of the screen as shown in Figure 188 and the main unit will sound an alarm.

Background abnormal.

FIGURE 188
Error Messages

You can refer to the following steps to deal with the error messages.

1. Click the error message area.
2. Touch the screen to disable the beep.
3. Click **Remove Error**. Normally, the system will automatically remove the errors. For errors which cannot be removed automatically, you can take appropriate actions by following the error help information or 11.3 *Error Message Reference*.

TABLE 21
Error Message Reference

11.3 Error Message Reference

Possible errors and the corresponding help information are shown in Table 21.

Problem Name	Troubleshooting Information
-12V power is not working properly.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Optical assembly cover is open.	1. Close the optical assembly cover. 2. Click the Remove Error button to remove this error. 3. If the error still exists, contact our customer service department.
The CC source voltage is abnormal.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Abnormal laser current.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Startup failure.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Startup initialization is not executed.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
The right-side door is open.	1. Close the right side door. 2. Click the Remove Error button to remove this error. 3. If the error still exists, contact our customer service department.
+12V power is not working properly.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
HC5D-Diluent expiration.	1. Check if the HC5D-Diluent expires. If so, replace it with a new container of HC5D-Diluent. 2. Click the Remove Error button, the Reagent Management screen will be displayed. 3. Set the reagent information by referring to chapter 9 <i>Reagent Management</i> . 4. If the error still exists, contact our customer service department.

HC5D CBC Lyse expiration	1. Check if the HC5D CBC Lyse expires. If so, replace it with a new container of HC5D CBC Lyse. 2. Click the Remove Error button, the Reagent Management screen will be displayed. 3. Set the reagent information by referring to chapter 9 <i>Reagent Management</i> . 4. If the error still exists, contact our customer service department.
HC5D Diff Lyse expiration	1. Check if the HC5D Diff Lyse expires. If so, replace it with a new container of HC5D Diff Lyse. 2. Click the Remove Error button, the Reagent Management screen will be displayed. 3. Set the reagent information by referring to chapter 9 <i>Reagent Management</i> . 4. If the error still exists, contact our customer service department.
Preheating bath temperature out of working range.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal HGB background voltage.	Please contact our customer service department.
Abnormal RBC aperture voltage.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal background.	1. Check whether the diluent is contaminated. 2. If not, click the Remove Error button to remove the error. 3. If the error still exists, contact our customer service department.
Failed to read sample syringe parameter.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to configure sample syringe parameter.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Sample syringe timeout	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Sample syringe is busy.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Vertical motor instruction parameter error.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.

Failed to read vertical motor parameter.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Vertical motor timeout	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read the remaining steps of vertical motor.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
The vertical motor is busy.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read preheating bath temperature.	1. Make sure the temperature sensor is correctly installed. 2. Click the Remove Error button to remove the error. 3. If the error still exists, contact our customer service department.
Failed to read optical system temperature.	1. Make sure the temperature sensor is correctly installed. 2. Click the Remove Error button to remove the error. 3. If the error still exists, contact our customer service department.
Failed to read ambient temperature.	1. Make sure the temperature sensor is correctly installed. 2. Click the Remove Error button to remove the error. 3. If the error still exists, contact our customer service department.
Waste is full.	1. Empty the waste container or install a new waste container. 2. Click the Remove Error button to remove the error. 3. If the error still exists, contact our customer service department.
The setting temperature of optical system out of range.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Optical system temperature out of working range.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Flow cell clog.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Failed to read horizontal motor parameter.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.

Failed to configure Horizontal motor parameter.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Horizontal motor timeout	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
The optocoupler of the horizontal motor is not working properly.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
The horizontal motor is busy.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
No HC5D-Diluent	1. Check whether the HC5D-Diluent container is empty. If so, install a new container of HC5D-Diluent. 2. Click the Remove Error button to remove the error. 3. If the error still exists, contact our customer service department.
HC5D CBC Lyse running out or air bubbles in inlet tubing.	1. Check whether the HC5D CBC Lyse is running out or there are air bubbles in the inlet tubing of HC5D CBC Lyse. If it is running out, install a new container of HC5D CBC Lyse; If there is still plenty of HC5D CBC Lyse or there are bubbles, perform step 2. 2. Click the Remove Error button to remove the error. 3. If the error still exists, contact our customer service department.
HC5D Diff Lyse running out or air bubbles in inlet tubing.	1. Check whether the HC5D Diff Lyse is running out or there are air bubbles in the inlet tubing of HC5D Diff Lyse. If it is running out, install a new container of HC5D Diff Lyse; If there is still plenty of HC5D Diff Lyse or there are bubbles, perform step 2. 2. Click the Remove Error button to remove the error. 3. If the error still exists, contact our customer service department.
HC5D-Diluent not replaced.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
HC5D CBC Lyse not replaced.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
HC5D Diff Lyse not replaced.	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.

DIFF probe clogging	1. Click the Remove Error button to remove this error. 2. If the error still exists, contact our customer service department.
Abnormal 12V driving power supply.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Abnormal 24V driving power supply.	1. Please power off the analyzer directly and restart later. 2. If the error still exists, contact our customer service department.
Insufficient HC5D-Diluent.	1. Check whether the HC5D-Diluent container is empty. If so, install a new container of HC5D-Diluent. 2. Click the Remove Error button, the Reagent Management screen will be displayed. 3. Set the reagent information by referring to chapter 9 <i>Reagent Management</i> . 4. If the error still exists, contact our customer service department.
Insufficient HC5D CBC Lyse.	1. Check whether the HC5D CBC Lyse container is empty. If so, install a new container of HC5D CBC Lyse. 2. Click the Remove Error button, the Reagent Management screen will be displayed. 3. Set the reagent information by referring to chapter 9 <i>Reagent Management</i> . 4. If the error still exists, contact our customer service department.
Insufficient HC5D Diff Lyse.	1. Check whether the HC5D Diff Lyse container is empty. If so, install a new container of HC5D Diff Lyse. 2. Click the Remove Error button, the Reagent Management screen will be displayed. 3. Set the reagent information by referring to chapter 9 <i>Reagent Management</i> . 4. If the error still exists, contact our customer service department.

Appendix A Specifications

A.1 Classification

According to the CE classification, the Auto Hematology Analyzer belongs to in vitro diagnostic medical devices, rather than those covered by Annex II and devices for performance evaluation.

A.2 Reagents

Reagent Type	Reagent Name
Diluent	HC5D-Diluent
Lyse	HC5D Diff Lyse
	HC5D CBC Lyse
Medical cleanser	Cleanser

TABLE 22

A.3 Parameters

Parameter	Abbreviation	Default Unit
White Blood Cell count	WBC	$10^9/l$
Number of Neutrophils	Neu#	$10^9/l$
Number of lymphocytes	Lym#	$10^9/l$
Number of Monocytes	Mon#	$10^9/l$
Number of Eosinophils	Eos#	$10^9/l$
Number of Basophils	Bas#	$10^9/l$
Number of Abnormal Lymphocytes	ALY# (RUO)	$10^9/l$
Number of Large Immature Cells	LIC# (RUO)	$10^9/l$
Percentage of Neutrophils	Neu%	%
Percentage of Lymphocytes	Lym%	%
Percentage of Monocytes	Mon%	%
Percentage of Eosinophils	Eos%	%
Percentage of Basophils	Bas%	%
Percentage of Abnormal Lymphocytes	ALY% (RUO)	%
Percentage of Large Immature Cells	LIC% (RUO)	%
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 Blood Cell Distribution Width - Standard Deviation (RDW-SD)	RDW-SD	fL

TABLE 23

Red Blood Cell Distribution Width - Coefficient of Variation (RDW-CV)	RDW-CV	%
Platelet count	PLT	$10^9/l$
Mean Platelet Volume	MPV	fL
Platelet Distribution Width	PDW	None
Plateletcrit	PCT	%
Platelet-large cell count	P-LCC	$10^9/l$
Platelet-large cell ratio	P-LCR	%
White Blood Cell Histogram	WBC Histogram	None
Red Blood Cell Histogram	RBC Histogram	None
Platelet Histogram	PLT Histogram	None
Basophils Scattergram	BASO Scattergram	None
DIFF Scattergram	DIFF Scattergram	None

A.4 Performance Specifications

A.4.1 Display Range

TABLE 24

Parameter	Display Range
WBC	0-999 $10^9/l$
Neu#	0-999 $10^9/l$
Lym#	0-999 $10^9/l$
Mon#	0-999 $10^9/l$
Eos#	0-999 $10^9/l$
Bas#	0-999 $10^9/l$
ALY# (RUO)	0-999 $10^9/l$
LIC# (RUO)	0-999 $10^9/l$
Neu%	0-99.9 %
Lym%	0-99.9 %
Mon%	0-99.9 %
Eos%	0-99.9 %
Bas%	0-99.9 %
ALY% (RUO)	0-99.9 %
LIC% (RUO)	0-99.9 %
RBC	0-18 $10^{12}/l$
HGB	0-300 g/l
HCT	0-80 %
MCV	0-250 fL
MCH	0-999.9 pg
MCHC	0-9999 g/l
RDW-SD	0-999.9 fL
RDW-CV	0-99.9 %
PLT	0-5000 $10^9/l$
MPV	0-99.9 fL
PDW	0-999.9 %

PCT	0-0.999 %
P-LCC	0-5000 $10^9/l$
P-LCR	0-99.9 %

A.4.2 Normal Background

TABLE 25

Parameter	Normal Background
WBC	$\leq 0.2 \times 10^9/l$
RBC	$\leq 0.02 \times 10^{12}/l$
HGB	$\leq 1 g/l$
PLT	$\leq 10 \times 10^9/l$
HCT	$\leq 0.5\%$

A.4.3 Linearity Range

TABLE 26

Parameter	Linearity range	Deviation range (Whole blood mode)
WBC	(0.00~100.00) $\times 10^9/l$	$\pm 0.30 \times 10^9/l$ or $\pm 5\%$
	(100.01~300.00) $\times 10^9/l$	$\pm 10\%$
RBC	(0.00~8.50) $\times 10^{12}/l$	$\pm 0.05 \times 10^{12}/l$ or $\pm 5\%$
HGB	(0~250) g/l	$\pm 2 g/l$ or $\pm 2\%$
PLT	(0~1000) $\times 10^9/l$ (RBC ≤ 7.0)	$\pm 10 \times 10^9/l$ or $\pm 8\%$
	1001~3000 $\times 10^9/l$ (RBC ≤ 7.0)	$\pm 12\%$
HCT	0~67%	$\pm 2\%$ (HCT value) or $\pm 3\%$ (deviation percent)

A.4.4 Analytical Range

TABLE 27

Parameter	Analytical Range
WBC	(0.2-300) $\times 10^9/l$
RBC	(0.02-8.50) $\times 10^{12}/l$
HGB	(1-250) g/l
PLT	(10-3000) $\times 10^9/l$
HCT	0.5%-67%

A.4.5 Repeatability

These repeatability requirements apply only to the situation in which a qualified sample has been run for 11 times and the results of the 2nd to 11th runs are used to calculate the repeatabilities.

TABLE 28

Parameter	Condition	Whole Blood Repeatability (CV%/ absolute deviation d*)
WBC	(4.0~15.0) $\times 10^9/l$	$\leq 2.0\%$

Neu%	50.0%~60.0%	± 4.0 (absolute deviation)
Lym%	25.0%~35.0%	± 3.0 (absolute deviation)
Mon%	5.0%~10.0%	± 2.0 (absolute deviation)
Eos%	2.0%~5.0%	± 1.5 (absolute deviation)
Bas%	0.5%~1.5%	± 0.8 (absolute deviation)
RBC	$(3.50\sim 6.00) \times 10^{12}/l$	$\leq 1.5\%$
HGB	$(110\sim 180) g/l$	$\leq 1.5\%$
PLT	$(150\sim 500) \times 10^9/l$	$\leq 4.0\%$
MCV	$(70\sim 120) fl$	$\leq 1.0\%$
MPV	-	≤ 4.0

A.4.6 Carryover

TABLE 29

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

A.5 Input/output Device



WARNING

Accessory equipment connected to the analogue and digital interfaces must comply with the relevant Safety and EMC standards (e.g., IEC 60950 Safety of Information Technology Equipment Standard and CISPR 22 EMC of Information Technology Equipment Standard (CLASS B)). Anyone who connects additional equipment to the signal input or output ports and configures an IVD system is responsible for ensuring that the system works properly and complies with the safety and EMC requirements. If you have any problem, consult the technical services department of your local agent.

- Analyzer
- Touch screen: 10.4 inches embedded touch screen with a resolution of 800×600
- One LAN interface
- USB interfaces
- Power
- Voltage: A.C 110V~240V
- Input power: $\leq 200VA$
- Frequency: 50/60 Hz
- Keyboard (Optional, USB)

- Mouse (Optional, USB)
- External barcode reader (optional, USB)
- Printer (optional, USB)
- USB flash disk (optional, USB)

Test Item	Test Standard	Test Requirement
Conducted Disturbance	EN 61326-1:2013 EN 61326-2-6:2013	1Mode-Class B
Radiated Disturbance	EN 61326-1:2013 EN 61326-2-6:2013	1Mode-Class B
Harmonic Current	EN 61326-1:2013 EN 61326-2-6:2013	Class A
Voltage Fluctuation and Flicker	EN 61326-1:2013 EN 61326-2-6:2013	/
ESD Immunity	EN 61326-1:2013 EN 61326-2-6:2013	air discharge: ±2, ±4, ±8kV contact discharge: ±2, ±4kV
Radiated Electromagnetic Field Immunity	EN 61326-1:2013 EN 61326-2-6:2013	80MHz-1GHz,1.4GHz-2GHz 3V/m 80%AM(1kHz); 2GHz-2.7GHz 1V/m 80%AM(1kHz)
EFT Immunity	EN 61326-1:2013 EN 61326-2-6:2013	1kV 5/50 ns Tr/Th 5kHz repetition frequency
Surge Immunity	EN 61326-1:2013 EN 61326-2-6:2013	1.2/50(8/20)µs Tr/Th 1kV L-N 2kV L-PE,N-PE
Conducted Immunity	EN 61326-1:2013 EN 61326-2-6:2013	0.15MHZ~80MHZ 3V(r.m.s) (unmodulated)
Voltage Dips and Interruptions Immunity	EN 61326-1:2013 EN 61326-2-6:2013	Voltage dips: 0%UT, 1cycle 40%UT, 5cycle 70%UT, 25cycle Voltage interruption: <5%UT, 250cycle

TABLE 30

A.6 EMC Description

This equipment complies with the emission and immunity requirements of the IEC 61326-1:2012, EN 61326-1:2013, IEC 61326-6-2-6:2012 and EN 61326-2-6:2013. 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.

The test items, standards and requirements on electromagnetic compatibility for the environment are shown in the table below.

A.7 Environment Conditions



Note:

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

TABLE 31

Environment Conditions	Operating Environment	Storage Environment	Running Environment
Ambient temperature	15°C~30°C	-10°C~40°C	5°C~40°C
Relative humidity	20%~85%	10%~90%	10%~90%
Atmospheric pressure	70kPa~106kPa	50kPa~106kPa	70kPa~106kPa

A.8 Dimensions and Weight

FIGURE 189

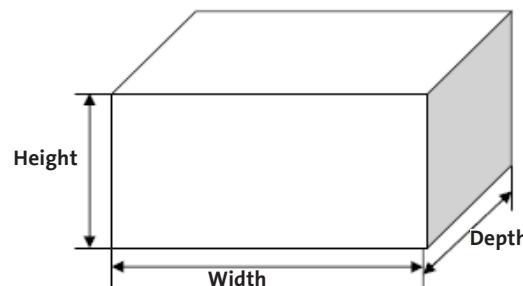


TABLE 32

Analyzer	Dimensions and Weight
Width (mm)	364
Height	498
Depth (mm)	431
Weight (kg)	28

12 APPENDIX

Appendix B Terms and Abbreviations

CTA Capillary Tube Auto-Dispense

PD Predilute

VWB Venous Whole Blood

12.1 Human Software update and settings

Information about the latest Software and settings are accessible via

<https://www.human.de/sw-hc5D>

or by scanning the QR Code with a mobile device which supports QR Codes. You also find this barcode as a label on the device.



If the information is not accessible via the internet, they can be obtained free of charge from your local distributor. In case you do not have the latest software or settings installed, please contact your local distributor.

HUMAN

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