WOODLEY
EQUIPMENT COMPANY LTD.

InSight V3® PLUS

Veterinary Haematology Analyser

Operator's Manual

NOTE

1) Please read this manual carefully before operating the analyser.
2) Inspect the electrical requirements of the analyser before powering on and properly connect the grounding wire.
3) Turn off the power to the analyser and disconnect the power cord if the analyser is idle for a long time.
4) Do not run the analyser if it’s in an abnormal or damaged condition.
5) There is potential biohazard of the reagents and samples; the operator should follow the correct biosafety practices. Dispose of waste reagent and sample in accordance with local, national regulations.

Contents

Copyright and Declaration

Declaration:

All contents in this manual were strictly compiled according to related laws and regulations as well as the specific condition of the InSight V3® Plus Veterinary Haematology Analyser, covering all the updated information before printing. Woodley Equipment Company Ltd is fully responsible for the revision and explanation of the manual and reserves the right to update the relevant contents without separate notification. All images are for illustrative purposes only.

All instructions must be followed strictly during operation. In no event is Woodley Equipment Company Ltd responsible for failures, errors and other liabilities resulting from user's non-compliance with the procedures and precautions outlined herein.

Limited Responsibility for Quality Warranty:

The manual for the InSight V3 Plus Veterinary Haematology Analyser defines the rights and obligations between the manufacturer and the customer about the responsibility for quality warranty and after-sales service, also the related agreements on commencement and termination.

Woodley Equipment Company warrants the InSight V3 Plus supplied by Woodley Equipment Company and its authorised agents to be free from defects in workmanship and materials during normal use by the original purchaser.
Woodley Equipment Company assumes no liability in the following situations:

1) Failure due to abuse of the instrument or neglecting the maintenance.
2) Use of reagents and accessories other than those manufactured or recommended by Woodley Equipment Company.
3) Failure due to operation which is not under the instructions described in the manual.
4) Replacement of accessories which are not specified by Woodley Equipment Company. Maintenance or repair of the analyser by a service agent who is not approved or authorised by Woodley Equipment Company.
5) Components have been dismounted, stretched or readjusted.

CAUTION:

THE ANALYSER IS FOR VETERINARY USE ONLY.

Technical service and troubleshooting are provided by the Service Department and Technical Support Department of Woodley Equipment Company.

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Guidance

General information for the operation of the analyser is contained in this manual which covers the best guidance for a new operator to understand the characteristics of the analyser and its operation methods, as well as for daily enquiry. Please read the InSight V3 Plus Operator's Manual thoroughly before using the analyser.

This manual uses the following warning conventions:

WARNING: Denotes a hazard which, if not avoided, could result in moderate to serious injury.

CAUTION: Denotes potential hazards that could result in a minor injury, also used for conditions or activities which could interfere with proper function of the analyser.

NOTE: Denotes special operator/service information or standard practices.

Please read this manual before operating the analyser.

Chapter 1 System Description

1.1 Overview

The InSight V3 Plus is a multi-parameter automated Veterinary Haematology analyser, designed for in vitro diagnostic use in clinical laboratories to analyse blood cells.

1.1.1 Function

The InSight V3 Plus uses Coulter electrical impedance and colourimetry methods to test the WBC, RBC, PLT, MCV and HGB parameters, three WBC differentials with eosinophil estimation and provides histogram information.

1.1.2 Intended Use

The InSight V3 Plus is a quantitative, automated haematology analyser and 3-part differential counter for animal blood samples.

1.1.3 Front Panel

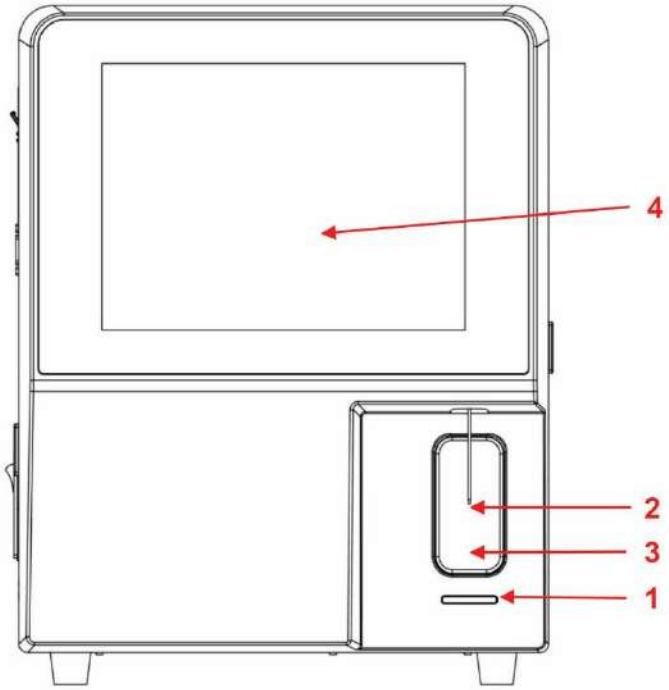


Figure 1-1

1. Status Indicators

Standby Indicator: Indicator light turns orange; the analyser is in sleep mode.

Ready to Test Indicator: Indicator light turns green; the analyser is ready to run a sample.

Alarm Indicator: Indicator light turns red; the analyser has an error.

2. Aspiration Probe

Aspirate samples.

3. RUN Key

Press the RUN key to start up the aspiration probe and then analyse the specimen when the Main Menu and Quality Control screens are displayed. On other screens, the RUN key is invalid.

4. Display

10.4-inch colour LCD. The screen is divided into 7 areas as shown in Figure 1-2.

Figure 1-2

(1) Function Buttons Area

Display function buttons. There are three sets of function buttons. The first set. See Figure 1-3.

Figure 1-3

Test: Display the main interface and run a test

Data: Enter data storage interface and query sample results

QC: Enter the QC interface to run quality control

Cal: Enter the calibration interface to run calibration

Setup: Enter the setup interface to set system parameters

The second set. See Figure 1-4:

Figure 1-4

Next sample: New sample details

Mode switch: Switch the test mode to whole blood mode or diluent mode

Audit: Audit the sample

Diluent: Dispense 0.8ml from sample probe into a plain tube for

background test or to dilute blood sample

The third set. See Figure 1-5:

Select or to enter the third set menu. See Figure 1-5:

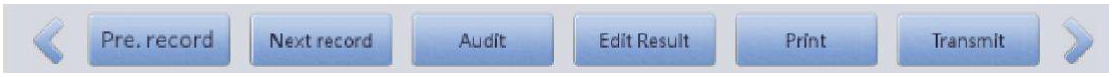


Figure 1-5

Pre. record: To see the previous record

Next record: To see the next record. If the current record is the last one, the button will be grey

Audit: Audit the sample

Edit Result: Modify sample results

Print: Print the sample results

Transmit: Transmit sample data to LIS

(2) Fault Prompt

System fault errors and information.

(3) Analysis Mode

Select and indicate the system running state: whole blood sampling mode or pre-dilute mode.

(4) Patient Information

Display the information of patient sample.

(5) Parameter Information Display

Display each parameter results.

(6) Graphic Display

Display the histograms of WBC, RBC and PLT.

(7) Status Area

Display the current time, date, operator, next sample number and printer status.

1.1.4 Side & Rear Panels

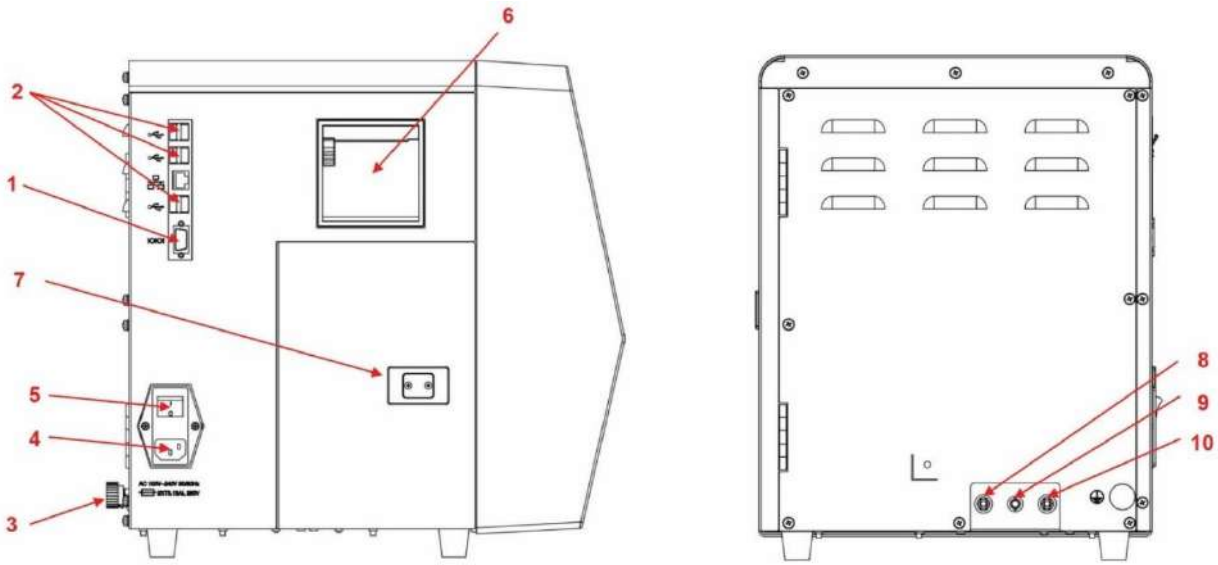


Figure 1-7

1. COM

Connect to the standard RS-232 network.

2. USB Port

Connect to USB equipment.

3. Grounding Terminal

Used to ground the analyser.

4. Power Input

Connect the main power cord to the analyser.

5. Power Switch

Turn the power supply on or off.

6. Thermal Printer

Print the test result.

7. LYSE

Lyse port connects to the lyse inlet tube.

8. SENSOR

Connect to the waste sensor.

9. WASTE

Waste port connects to the waste outlet tube.

10. DILUENT

Diluent port connects to the diluent inlet tube.

1.2 Parameters

The analyser automatically analyses the sample data and displays the histogram of WBC (3 part differential count), RBC and PLT.

Table 1-1

Abbreviation	Full Name	Unit
WBC	White Blood Cell Count	10^9cells/L
LYM%	Lymphocyte Percent	%
MID%	Monocyte Percent	%
GRAN%	Granulocyte Percent	%
LYM#	Lymphocyte Count	10^9cells/L
MID#	Monocyte Count	10^9cells/L
GRAN#	Granulocyte Count	10^9cells/L
RBC	Red Blood Cell Count	10^{12}cells/L
HGB	Haemoglobin Concentration	g/L（or g/dL）
HCT	Haematocrit (relative volume of erythrocytes)	%
MCV	Mean Corpuscular Volume	fL
MCH	Mean Corpuscular Haemoglobin	pg
MCHC	Mean Corpuscular Haemoglobin Concentration	g/L（or g/dL）
RDW_CV	Red Blood Cell Distribution Width repeat precision	%
RDW_SD	Red Blood Cell Distribution Width STDEV	fL
PLT	Platelet Count	10^9cells/L
MPV	Mean Platelet Volume	fL
PDW	Platelet Distribution Width	fL
PCT	Plateletcrit	%
P_LCR	Large Platelet Ratio	%
P_LCC	Large Platelet	10^9cells/L

1.3 Structure

The analyser consists of a flow system, electrical system and display.

1.3.1 Flow System

The flow system is composed of solenoid valves, a vacuum pump and a plastic tube.

Solenoid Valve – These two-way or three-way solenoid valves control the flow of reagent.

Vacuum Pump – Pump the waste out of the analyser and produce negative pressure.

Plastic Tube – Reagent and waste flow in the plastic tube.

Vacuum Chamber – Generate negative pressure and play the role of temporary waste reservoir. It can also generate positive pressure when flushing.

1.3.2 Electrical System

1.3.2.1 A/D and Central Control Board

The central control board is the control centre of the analyser. It controls the following parts:

- The opening and closure of all valves, reagent aspiration, rinse and waste discharge
- Run force pump and vacuum pump to mix reagent
- Eliminate clogs, aspirate and discharge reagents
- Control step motors to aspirate sample and reagent
- Control the A/D conversion of WBC, RBC/PLT and HGB
- Check all the optical and electrical switch movements

1.3.2.2 WBC/RBC/PLT Metering Assembly

WBC Metering Assembly is composed of a signal collection board, electrodes, micro-aperture sensor and flow system.

- Signals Collection Board – Provides electrodes constant current, amplifies and deals with the collected pulse signal for mainboard.
- Electrodes – There are two electrodes in the sample cup, one inner electrode located in the front chamber and one outer electrode located in the back chamber. Both electrodes are submerged in the conductive liquid, creating an electrical pathway through the micro-aperture.

- Micro-aperture Sensor – Micro-aperture sensor is mounted on the front of the sample cup. The diameter of WBC and RBC/PLT metering assembly is 100μm and 68μm respectively.
- Flow System – The flow system uses negative pressure to aspirate diluent and sample from each container into the metering tube and discharge waste at the end of the processing. There is a lyse adding and mixing unit in front of the sample cup. The control board controls the step motor. When testing the WBC, the lyse will be added into the sample cup and then the vacuum pump will generate compressed gas to mix the samples.

1.3.3 Display

InSight V3 Plus uses a 10.4-inch colour LCD which displays 21 parameters (with 3 histograms).

1.4 Accessories

Please see InSight V3 Plus packing list.

1.5 Sample Volume

Whole Blood Mode: Whole Blood (Venous Blood) 8.5μl
Pre-Dilute Mode: Diluted Blood 20μl

1.6 Reagent Volume for Single Sample

Diluent: 25mL
Lyse: 0.4mL

NOTE: Reagent consumption varies according to the software version.

1.7 Test Speed

InSight V3 Plus is able to process 55 samples per hour.

1.8 Storage

InSight V3 Plus can store 100,000 results.

1.9 Background

WBC≤0.2×10^9/L；RBC≤0.02×10^{12}/L；HGB≤1g/L；PLT≤10×10^9/L.

1.10 Carryover

WBC≤0.5%；RBC≤0.5%；HGB≤0.6%；PLT≤1.0%.

1.11 Repeatability

The precision of the analyser is shown in Table 1-3.

Table 1-3

Parameter	Acceptable Limits （CV/%）	Precision Range
WBC	≤3.5%	4.0×10^9/L ~ 15.0×10^9/L
RBC	≤1.5%	3.00×1012/L ~6.00×1012/L
HGB	≤1.5%	100 g/L ~180g/L
HCT	≤2.0%	35%~50%
MCV	≤1.0%	76fL ~110fL
PLT	≤4.0%	100×109/L ~500×109/L

1.12 Linearity

The linearity of the analyser is shown in Table 1-4.

Table 1-4

Parameter	Linearity Range	Acceptable Limits
WBC	0×10^9/L~10.0×10^9/L	≤±0.3×10^9/L
	10.1×10^9/L ~99.9×10^9/L	≤±5%
RBC	0×10^{12}/L ~1.00×10^{12}/L	≤±0.05×10^{12}/ L
	1.01×10^{12}/L ~9.99×10^{12}/L	≤±5%
HGB	0 g/L ~70 g/L	≤±2g/L
	71 g/L ~300 g/L	≤±2%
PLT	0×10^9/L ~100×10^9/L	≤±10×10^9/L
	101×10^9/L ~999×10^9/L	≤±10%
MCV	25 – 120	≤±1%

1.13 Transport and Storage Specifications

a) Temperature: -10℃~55℃
b) Relative Humidity: ≤95%RH
c) Barometric: 50kPa~106kPa

1.14 Environment Requirement

a) Temperature: 10~35°C
b) Relative Humidity: ≤90%RH
c) Barometric: 60kPa~106kPa

1.15 Electrical Requirement

Power Supply: AC 100V～240V
Frequency: 50/60Hz
Power: 130VA-180VA
Fuse: 250V/3.15A

1.16 Reagent

The reagent is formulated specifically for the InSight V3 Plus flow systems in order to provide optimal system performance. Use of reagents other than those specified in this manual is not recommended as analyser performance can be affected. Each InSight V3 Plus is checked using the specified reagents and all performance claims were generated using these reagents.

Reagents must be stored at room temperature to ensure optimal performance. All reagents should be protected from direct sunlight, extreme heat, and freezing during storage. Temperatures below 0°C may cause reagent layering and abnormal results.

The reagent inlet tubes have a cap attached that minimises evaporation and contamination during use. However, reagent quality may deteriorate with time. Therefore, use all reagents within the dating period.

1.16.1 Diluent

Diluent is a buffer solution. The InSight V3 Plus Diluent:
a) Dilutes WBC, RBC, PLT and HGB
b) Maintains cell volume during the test process
c) Offers an appropriate background value
d) Cleans WBC and RBC micro-aperture and tubes

1.16.2 Lyse

The InSight V3 Lyse Reagent:
a) Lyses RBC with minimum ground substance complex.
b) Lyses the membrane of the WBC to diffuse the cytoplasm, leaving the remaining WBC nuclei.
c) Transforms the haemoglobin to the haemo-compound which is suitable for measurement by a spectrophotometer at a wavelength of 540nm.

1.16.3 Probe Detergent

Probe detergent contains effective oxide to clean the analyser apertures, probes and tubing.

1.16.4 Note of Reagent Use

1) Use InSight V3 Plus reagents only.
2) Please operate as advised by Woodley Equipment Company.
3) Avoid contact with skin and eyes. If contact occurs, rinse with water and seek medical advice immediately.
4) Avoid inhaling reagent gas.

1.16.5 Reagent Storage

1) Please store at room temperature.
2) Seal the cap of the container to avoid evaporation and contamination.
3) Avoid freezing.
4) Reagent should be used within 90 days after opening. If not, dispose as waste.
5) Please refer to the package or label for the model, lot number and date of manufacture.

Chapter 2 Principles of Operation

The principles of operation of InSight V3 Plus Veterinary Haematology Analyser will be discussed in this chapter. The two independent measurement methods used in the analyser are:

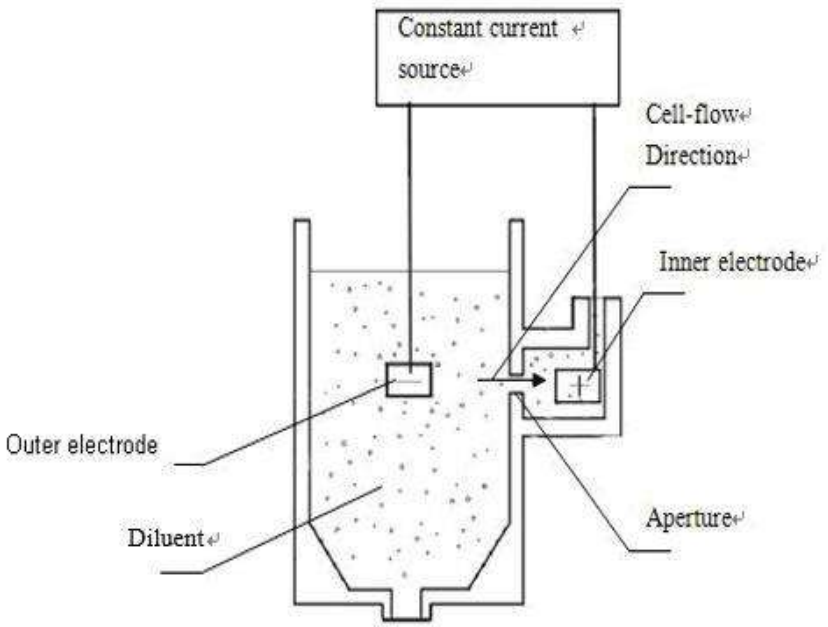
1) The electrical impedance method for determining the quantity and volume of blood cell.
2) The colourimetric method for determining the content of haemoglobin.

2.1 Test Principles

The test is split into blood cell counting, volume measurement and HGB measurement.

2.1.1 Electrical Impedance Principle for Blood Cells

The analyser uses the traditional electrical impedance method for the blood cells sizing and counting. As shown in Figure 2-1, 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 generated is equal to the number of particles that passed through the aperture.



The analyser automatically divides the cells into RBC, WBC, PLT and other groups in accordance with pre-set volume classification procedure.

WBC	35—450	fL
RBC	30—110	fL
PLT	2—30	fL

According to the volume, WBCs handled by lyse can be subdivided into three categories: Lymphocyte (LYM), Monocyte (MID) and Granulocyte (GRAN).

LYM	35—98	fL
MID	99—135	fL
GRAN	136—350	fL

2.1.2 Colourimetry Principle for HGB Metering

The analyser adds lyse into the blood sample, the lyse will break down the membrane of RBC and convert haemoglobin to a haemoglobin complex. This compound is measurable at 540nm. The absorbency of the blank material (diluent) is compared with the absorbency of the sample. The analyser will calculate the haemoglobin concentration.

2.2 Calculation of Parameters

Parameters are expressed in three ways:

- Parameters generated by the analyser directly: WBC, RBC, PLT, HGB, MCV
- Parameters generated by histograms: LYM%, MID%, GRAN%, HCT, RDW_CV, RDW_SD, MPV, PDW, P_LCR, P_LCC
- Parameters derived from certain formulas: LYM#, MID#, GRAN#, MCH, MCHC, PCT

The formulas are as follows:

- HCT（%）= RBC×MCV/10
- MCH（pg）= HGB/RBC
- MCHC（g/L）= 100×HGB/HCT
- PCT（%）=PLT×MPV/10000
- LYM（%）= 100×AL /（AL+AM+AG）
- MID （%）= 100×AM /（AL+AM+AG）
- GRAN（%）= 100×AG/（AL+AM+AG）

WBC histogram is shown in Figure 2-2.

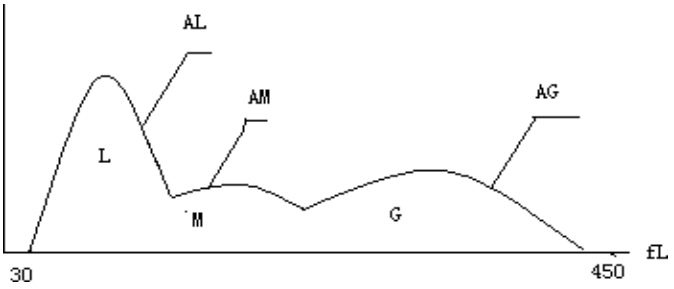


Figure 2-2

AL: Quantity of cells in area of LYM

AM: Quantity of cells in area of MID

AG: Quantity of cells in area of GRAN

The calculation formulas for the absolute value of lymphocyte (LYM#), monocyte (MID#) and granulocyte (GRAN#) are as follows:

- Lymphocyte（10^9L）LYM# = LYM%×WBC/100
- Monocyte（10^9L）MID# = MID%× WBC/100
- Granulocyte（10^9L）GRAN# = GRAN%×WBC /100
- RBC Distribution Width Coefficient of Variation（RDW_CV）is derived from the RBC histogram. It shows the volume distribution coefficient of variation of RBC with the unit of %.
- RBC Distribution Width Standard Deviation (RDW_SD) is derived from RBC histogram. It shows the volume distribution standard deviation of RBC with the unit of fL
- Platelet Distribution Width (PDW) is derived from PLT histogram. It shows the volume distribution of PLT.
- Mean Platelet Volume (MPV) is derived from PLT distribution histogram.

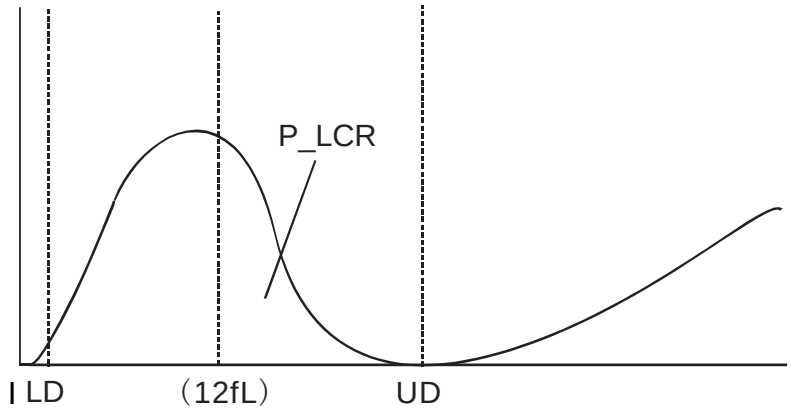


Figure 2-3 PLT Histogram

- P_LCR indicates the ratio of large platelet (≥12 fL). It is derived from PLT histogram. See Figure 2-3. LD, UD is the differentiating line of 2~6 fL and 12~30 fL. These two lines are decided by the analyser automatically. P_LCR is the ratio of particles between 12 fL line and UD to particles between LD and UD.
- P_LCC: Large platelet，it is the particles ≥12 fL

Chapter 3 Installation and Specimen Analysis

Initial installation of the analyser must be performed by Woodley Equipment Company authorised personnel to ensure that all system components are functioning correctly and to verify system performance. Installation procedures must be repeated if the analyser is moved from the original installation site.

NOTE: Installation of the analyser by an unauthorised or untrained person could result in damage to the analyser which will void the warranty. Never attempt to install and operate the analyser without Woodley Equipment Company authorised personnel.

3.1 Unpacking and Inspection

Carefully remove the analyser and accessories from the packaging. Keep the packaging for further transport or storage. Check the following:

a) Quantity of accessories according to the packing list.
b) Leakage.
c) Mechanical damage.
d) Power lead, inserts and accessories.

Contact your Distributor if outside the UK and Woodley Equipment Company if in the UK should any problems occur.

3.2 Installation Requirements

Please refer to Section 11.2 of Chapter 11.

WARNING: Not for home use.
WARNING: Not for therapy.

CAUTION: Keep away from direct sunlight.
CAUTION: Avoid extreme temperatures.
CAUTION: Keep away from centrifuges or X-ray equipment.
CAUTION: Do not use mobile phones, wireless phones or equipment with strong radiation which may interfere with the normal operation of the analyser.

3.3 Power Supply Inspection

Be sure that the system is located at the desired site before attempting any connections. See Table 3-1 for details.

Table 3-1

Optimal Voltage	Voltage Range	Frequency
AC220V	AC（100—240）V	50/60Hz

WARNING: A grounded power outlet is required to connect directly with the grounding terminal on the rear panel. Be sure to guarantee the security of the work site.

CAUTION: A fluctuated voltage would impair performance and reliability of the analyser.

CAUTION: Frequent power failure will decrease the performance and reliability of the analyser. Proper action such as the installation of UPS (not provided by Woodley Equipment Company) should be taken before operation.

3.4 Tubing Installation

There are two tube-connectors on the rear of the analyser: DILUENT and WASTE. The LYSE tube connector is built into the analyser in the door on the left side of the analyser.

3.4.1 LYSE Tubing Installation

Connect the LYSE container to the LYSE tubing. Twist the cap until secure. Place the container inside the door on the left side of the analyser.

3.4.2 DILUENT Tubing Installation

Remove the diluent tube with the blue connector from the accessory kit and attach it to the DILUENT connector on the back of the analyser. Place the other end into the diluent container. Twist the cap until secure. Place the container on the same level as the analyser.

3.4.3 WASTE Tubing Installation

Remove the waste tube with the black connector from the accessory kit and attach it to the WASTE connector on the back of the analyser. Connect the BNC plug with the socket marked “SENSOR” on the rear panel. Twist the tube’s cap clockwise onto the waste container until secure. Place the container on a flat surface at least 50cm lower than the analyser.

CAUTION: Keep the tube in good condition after installation, do not twist or fold the tubing.
CAUTION: All the tubes should be installed manually. Do NOT use a tool to attach tubes.
CAUTION: If any damage or leakage occurs in the reagent container or the reagents have exceeded the expiry date, contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.
WARNING: The waste must be disposed of according to local legislations and regulations.

3.5 Printer Installation (Optional)

The analyser has a built-in thermal printer. If an external printer is needed:

a) Find a suitable location adjacent to the analyser (at least 30cm away from the analyser).
b) Assemble the printer as directed in the printer manual.
c) The printer should connect to a USB port on the left side of the analyser.
d) Ensure that the printer power switch is OFF; plug one end of the power cord into the power socket.
e) Install printing paper as directed in the manual.

3.6 Keyboard and Mouse Installation (Optional)

Remove the keyboard and mouse from the shipping carton and insert the plugs of the keyboard and mouse into the USB port on the left side of the analyser.

It is recommended to place the keyboard directly beneath the display.

3.7 Power Connection

Make sure the power switch is OFF (O) and the grounding terminal on the back of the analyser is well grounded. Then, connect the analyser to the main power with the power cable.

3.8 Startup

Turn on the power switch on the left panel. The indicator is orange and the analyser program starts and enters a self-checking interface. When the analyser self-checks, it fills with diluent and lyse and cleans the fluid system.

Login interface pops up after initialising. The default username is “admin” and the password is “admin”. See Figure 3-1.

Figure 3-1

Select on the input field and the virtual keyboard appears. See Figure 3-2.

Figure 3-2

After inputting the username and password, the analyser enters the test interface. See Figure 3-3.

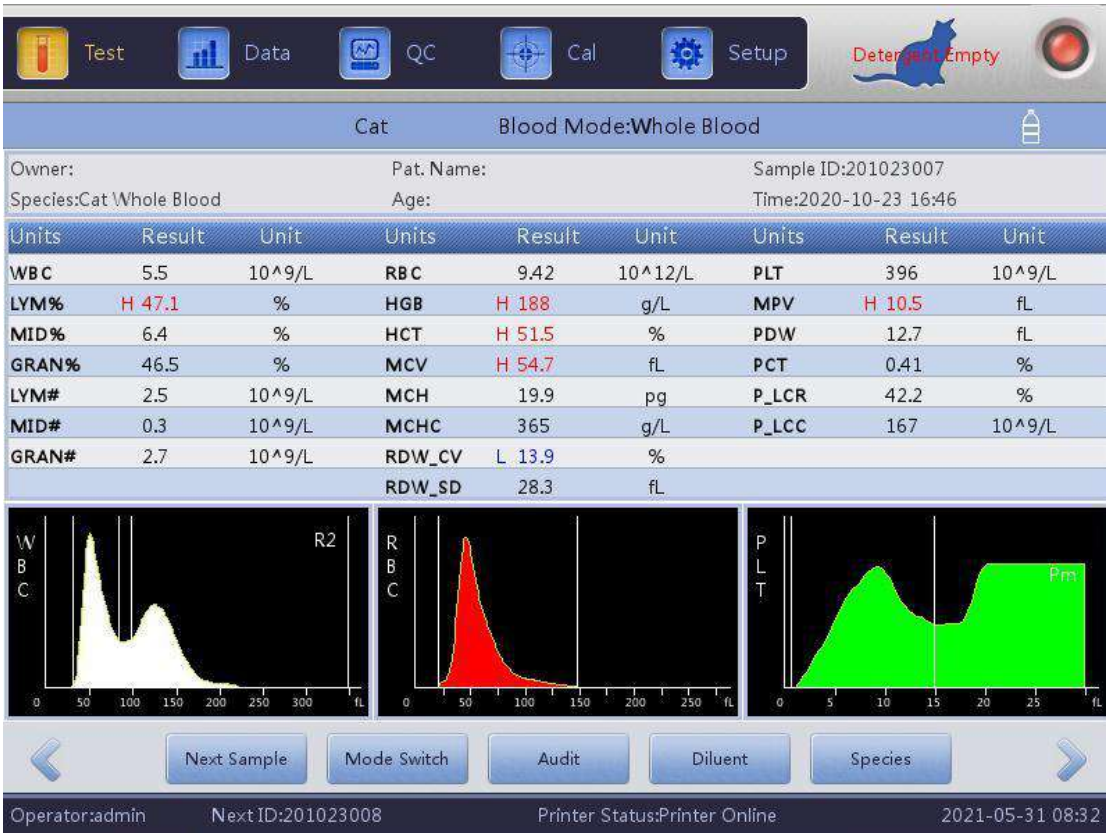


Figure 3-3

3.9 Background Test

A background test should be performed after startup and before blood sample test, operate as follows:

a) Select “mode switch” and select “diluent”.

b) Put a plain empty tube under the aspiration probe. On the main menu, select “Drain” to dispense 0.8ml of diluent into the tube.

c) On the main menu, select “next sample” and then modify ID to 0, select “OK” to save it.

d) Put the tube containing diluent beneath the aspiration probe which should touch the bottom of the tube.

e) Press the “RUN” key on the front panel, move the tube away after the beep sounds. Then, the analyser starts to count and measure automatically.

f) The counting time of RBC and WBC will be displayed at the lower right corner of the screen during counting.

g) The acceptable range of background test is listed in Table 3-2.

Table 3-2

Parameter	Acceptable Range
WBC	≤0.2x10^9/L
RBC	≤0.02x10^{12}/L
HGB	≤1g/L
PLT	≤10x10^9/L

If the background result is out of the acceptable range, repeat the above procedures until reaching the acceptable results.

Ensure the mode is switched back to “whole blood” before running patient tests.

NOTE: The ID number of the background test is set to 0 by the software so the result is not memorised by the analyser.
NOTE: The ID number of the blood sample test cannot be set to 0.

3.10 Quality Control

Quality control should be performed before daily test or on the initial installation. Refer to Chapter 5.

3.11 Calibration

Woodley Equipment Company calibrates the analyser before shipment. On the initial installation, if the background results and quality control are normal, recalibration is not necessary. If not and there are shifts or trends in some parameters, recalibrate the analyser referring to Chapter 6.

3.12 Collection of Blood Sample

CAUTION: Consider all clinical specimens, controls and calibrators etc. that contain blood or serum as potentially infectious. Wear a lab coat, gloves, safety glasses and follow required laboratory or clinical procedures when handling these materials.
NOTE: Blood collection and disposal should be performed according to the local and national environmental regulations or laboratory’s requirements.
NOTE: Be sure the blood collection tubes are clean and contamination-free. All specimens must be properly collected in tubes containing the EDTA (EDTA-K2)

anticoagulant used by the laboratory.

NOTE: Do not shake the sample tube.

NOTE: Venous blood can only be stored for 4 hours at room temperature. Woodley Equipment Company recommends the blood sample be kept at a temperature between 2-8°C for longer storage.

3.12.1 Whole Blood Collection

Collect a whole blood sample through venipuncture and store in a clean sample tube with EDTA-K2. Gently invert the tube 5~10 times to mix the sample.

3.12.2 Peripheral Blood Collection (Pre-diluent)

Capillary blood is usually collected from the marginal ear vein. The volume of the sample tube is 20µl.

3.13 Mode Switch

Select “Mode Switch” on the main interface and choose the mode you need in the dialog box. See Figure 3-4.

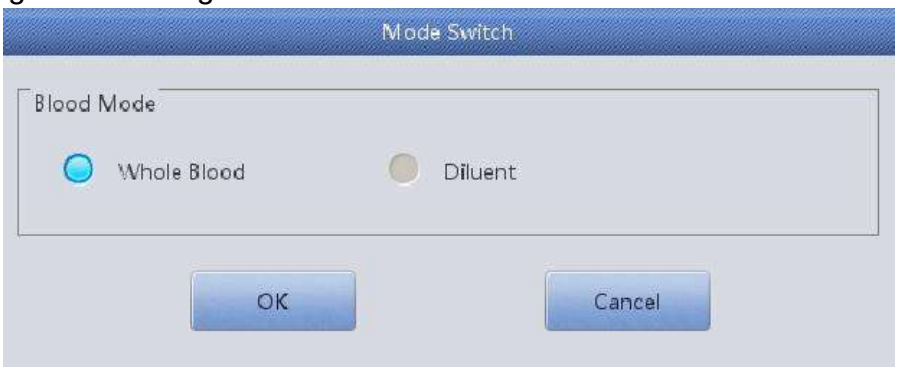


Figure 3-4

Select the mode and select “OK”, the blood test mode changes.

3.14 Sample Counting and Analysis

Sample counting and analysis is processed as following procedures.

3.14.1 Information Input

In the blood cell analysis interface, select “Next sample” to input detailed

sample information before sample analysis. See Figure 3-5.

Figure 3-5

Select the corresponding input box to open the virtual keyboard. If necessary, the user can connect to external PS2 or USB interface keyboard to help enter the information.

Owner Name: Input alphanumeric characters.

Pet Name: Input alphanumeric characters.

Sex: Select male or female. If not selected, default as blank**.**

Age: Input Year, Month and Day.

Tel.: Input owner's telephone number.

Vet: Requesting vet.

Sample No.: Input alphanumeric characters.

ID: The ID number is in range from 00000000-99999999. If no ID input, the ID of current sample will be automatically generated by the analyser.

NOTE: The ID number is set to 0 only under background test. The blood sample ID CAN NOT be 0.

3.14.2 Counting and Analysis

1) On the main screen, select “Animal” to enter the screen as Figure 3-6 shows:

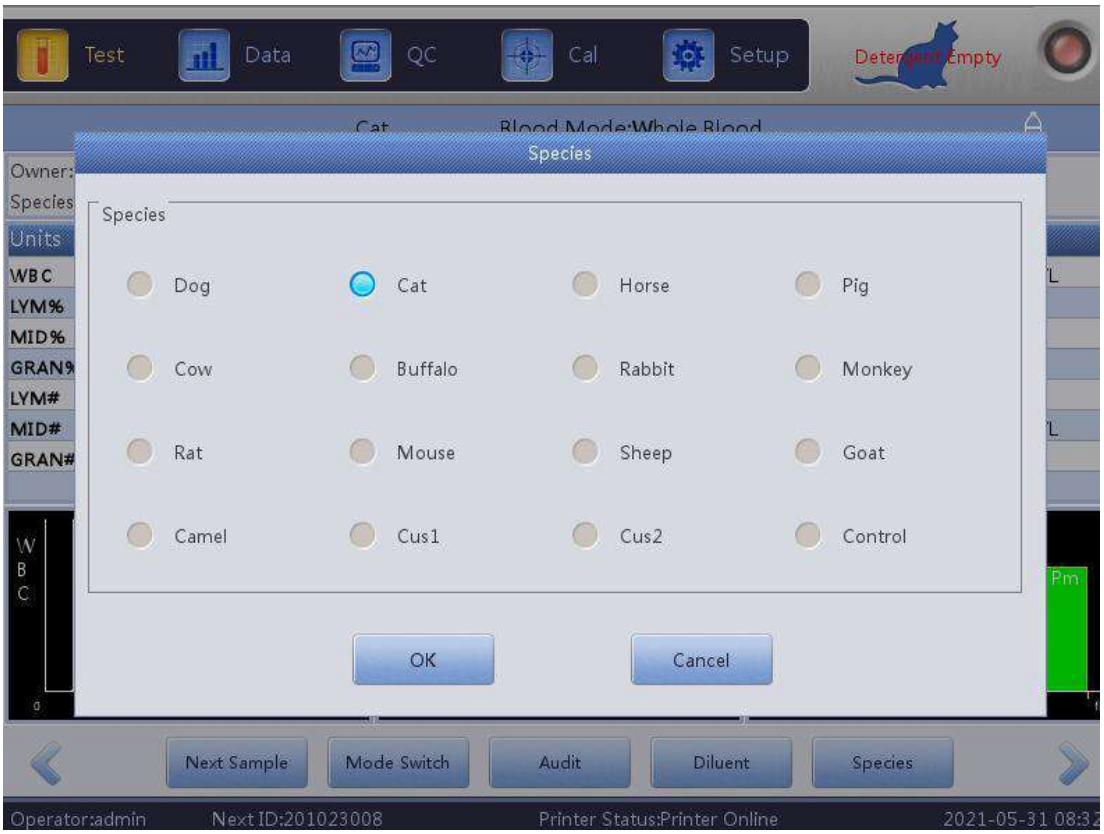


Figure 3-6

2) Select the species type needed and select “OK” to save.
3) There are 2 types of testing modes:

- **Pre-diluent Blood Mode – Ensure Pre-Diluent Mode is Selected**
  a) Place an empty sample tube under the aspiration probe. On the main menu, select “Diluent”; the diluent will be dispensed into the tube.
  b) Remove the tube, add 20ul of the blood sample to the tube with diluent and gently invert the tube to mix the sample.
  c) Place the well-mixed sample under the aspiration probe; make sure the probe is in the sample.
  d) Press the “RUN” key on the front panel and remove the sample after hearing a beep sound.
  e) The results will be available after the analysis is performed. Results are automatically calculated based on the dilution factor.

- **Whole Blood Mode – Ensure Whole Blood Mode is Selected**
  a) Gently invert the blood tube to mix the blood sample, then present the

sample tube beneath the probe. Make sure the probe touches the tube bottom slightly.

b) Press the “RUN” key and remove the sample after hearing a beep sound.
c) The results will be available after the analysis is performed.

The test results and histograms of WBC, RBC and PLT will be displayed on the main menu screen after counting and analysis (see Figure 3-1).
If “Auto Print” is ON (set in “System Settings” interface), the test results will be printed out automatically.
If the analyser detects a clot or air bubble during the counting and analysis cycles, the analyser will alarm and display a message at the top left corner of the screen ‘Test results are invalid’. Refer to Chapter 10 for troubleshooting.

3.14.3 Special Function

There are two types of flags: parameter flag and histogram flag.

3.14.3.1 Parameter Flag

1. “H” or “L” present on the left side of the parameter means the result is out of the species reference range.
2. “***” means the result is invalid or out of the readable range.

3.14.3.2 Histogram Flag

If the WBC Histogram is abnormal, R1, R2, R3, R4 or RM will be displayed on the right side of the histogram.
R1 indicates there is an abnormality in the left side of the LY wave peak, which was probably caused by incomplete haemolysis of RBC, platelet clump, giant platelet, plasmodium, nucleated RBC, abnormal lymphocyte, proteinic and fat granule, or electrical noise.
R2 indicates there is abnormality in the area between the LY wave peak and MO wave, which was probably caused by pathologic lymphocyte, plasmocyte, atypia lymphocyte, an increase in original cell or eosinophil, basophilia.
R3 indicates there is abnormality in the area between the MO wave and GR wave peak which was probably caused by immature granulocyte, abnormal cell subpopulation or eosinophilia.
R4 indicates there is abnormality in the right side of the GR wave peak which was probably caused by an absolute increase in granulocyte.
RM indicates there are two or more preceding flags.

When the PLT histogram has abnormalities, PM alarm will be shown in the right side.

PM indicates there is a discrepancy between PLT and RBC measurements which are probably caused by the presence of giant platelets, platelet clumps, small RBC, cell debris or fibrin.

It is recommended a blood film is reviewed if a histogram flag is present.

3.15 Result Analysis

InSight V3 Plus provides various convenient result analysis functions.

- Select the histogram display to modify the test results. Refer to Section 3.17 in this chapter for details.
- Select "Transmit" to transmit the data to the network.
- Select "Print" to print a data report of the current blood sample on the built-in thermal printer.
- "H" or "L" present on the left side of the parameter means the result is out of the reference range. "L" means the result is lower than the range while "H" means the result is higher than the upper limit of the reference range.
- If a clot or air bubble is detected, the system will alarm "WBC clog" or "RBC clog", and at the same time display "C" before test result.

NOTE: If the parameter value is "***", it means invalid data.
NOTE: If there is PLT Histogram Alarm, the PDW probably is "***".
NOTE: WBC differentiation may be incorrect if WBC is lower than 0.5 $x10^9$ /L. Microscope examination is recommended.

3.16 Report Output

After blood sample analysis is complete, if Auto Print is ON, the test report will be printed automatically on the built-in thermal printer. If the Auto Trans is ON, test results will be transmitted to the LIMS automatically.

The printer, transmit and test reports are set up in Settings. Refer to Chapter 4 for details.
Select "Transmit" to transmit data of the current sample to the LIMS.
Select "Print" to print the test report of current sample by the printer.

3.17 Result Modification

If the auto-classification of WBC, RBC and PLT does not meet clinical or laboratory requirements on special samples, manual classification is feasible.

CAUTION: Unnecessary or incorrect manual classification will cause unreliable test results. It is recommended to conduct a microscopic exam before manual classification.

The procedures are as follows:

a) On the main menu, select the graphics field with different parameters. The corresponding interface displays, see Figure 3-7. The RBC histogram is selected.

Figure 3-7

b) Once the diagram parameter needed to be modified is selected, select “Classify” to select the desired classification. The classified line will change from white to red.

c) Select “Left Shift” or “Right Shift” to move the classified line and the value of the classified line will be indicated on the lower right of the screen.

d) Select “Return” after modification, the dialog box as shown in Figure 3-8 will display. Select “Cancel” to cancel the modification or select “OK” to save the modified results.

Figure 3-8

3.18 Shutdown

Shutdown procedure is performed after daily operation (depending on use) and before turning the analyser off at the power supply. Daily maintenance will avoid protein aggregation during non-working hours and keep the system clean.
Shutdown procedure is as follows:

a) On the main menu, select “Exit”, shutdown information will appear (see Figure 3-9).

Figure 3-9

b) If turning off the instrument, select “OK”. After finishing the maintenance, cleaning and shutdown procedures, “Thank you, now turn off the power” will appear to instruct the operator to turn off the power switch on the left panel.
c) Dispose of the waste.
d) Select “Cancel” if the operator does not want to turn off the analyser.

NOTE: Incorrect operations during the shutdown procedure will decrease reliability and performance of the analyser. Any problems

derived from incorrect operation will void the warranty.

CAUTION: May lead to data loss if the analyser is turned off using incorrect procedures.

3.19 Data Query

After each test, the results are automatically saved in the database that can store at least 100,000 results including 24 parameters (with 3 histograms). The operator can review all of the results and histograms stored in the database.

3.19.1 Data Query

Select “Data” to enter the query interface. See Figure 3-10.

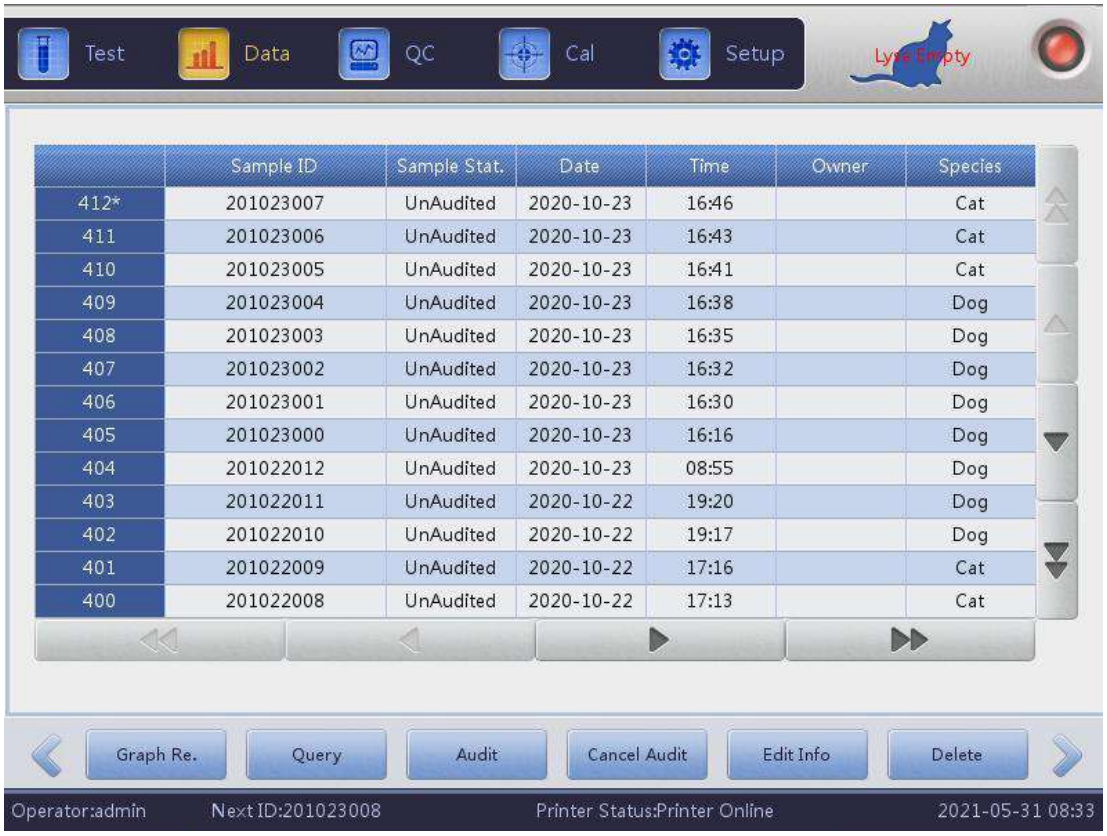


Figure 3-10

Select “Query” to pop up the following dialog box. See Figure3-11.

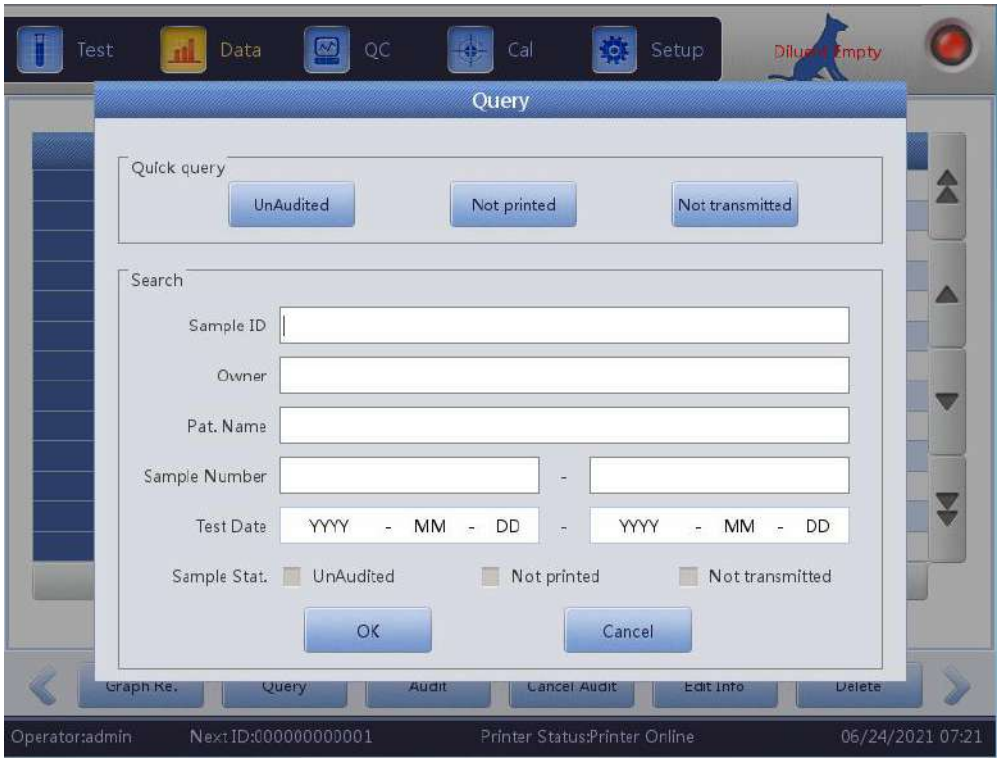


Figure 3-11

Data Query:

- Quick Search

  Unaudited: display last unaudited sample

  Unprinted: display last unprinted sample

  Not transmitted: display current result not transmitted

- Advanced Search

  Advanced search can filter specified results by specified “ID”, “Name”, “Case ID”, “Sample number” or “Test date”.

3.19.2 Data Selection

There will be a “*” in front of the selected sample ID. As shown in Figure 3-10, it shows records of sample 000000000005. Select “Graph Review” to see detailed data and graphs. See Figure 3-12.

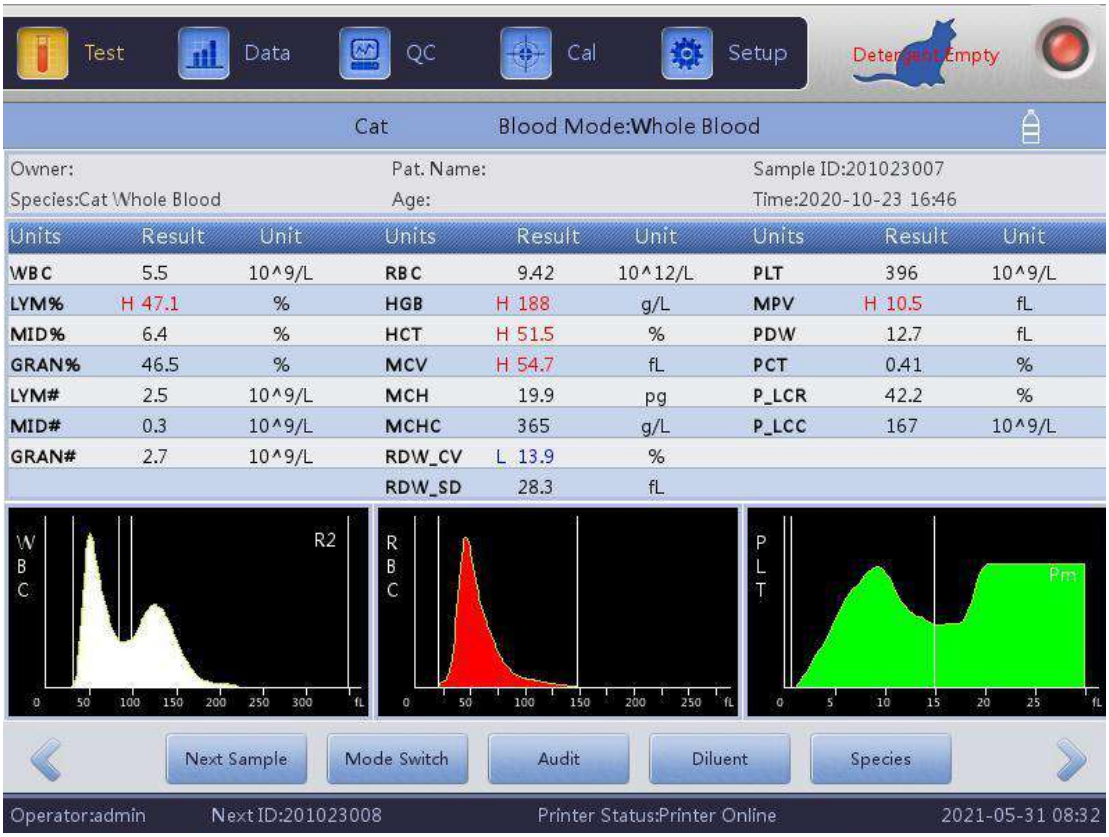


Figure 3-12

3.19.3 Data Deletion

As the stored memory gets full, old data may need to be deleted. The operator can choose to “Delete All” or selected data to delete. Select “Delete” to delete chosen data.

NOTE: Be aware that once the data is deleted, it can NOT be recovered. Please operate with caution.

3.19.4 Edit Information

Choose “Sample ID” and select “Edit Info” to pop up dialog box, see Figure 3-13. Edit the information in the dialog box. Select “OK” to save the edit or select “Cancel” to discard changes.

An audited sample cannot be edited. If it needs to be edited, please cancel the audit first.

Figure 3-13

3.20 Special Function

3.20.1 Export

Select “Export” to pop up the following dialog box, see Figure 3-14:
Select “Chosen record” and “All records” in “Range” and select relevant items in “Content”.
Please insert the USB before exporting. Select “OK” to start exporting. The exported data is in Excel format. Select “Cancel” to cancel export.

Figure 3-14

3.20.2 CV Value and Trend graph

To check the CV value, select “CV” in the data tab and test the same blood sample 11 times. Remove the first test result, choose the remaining results and select “CV” to see the CV value. See Figure 3-15.
Select “Trend graph” to see the trend graph of parameter. See Figure 3-16.

Figure 3-15

Figure 3-16

Chapter 4 System Setting

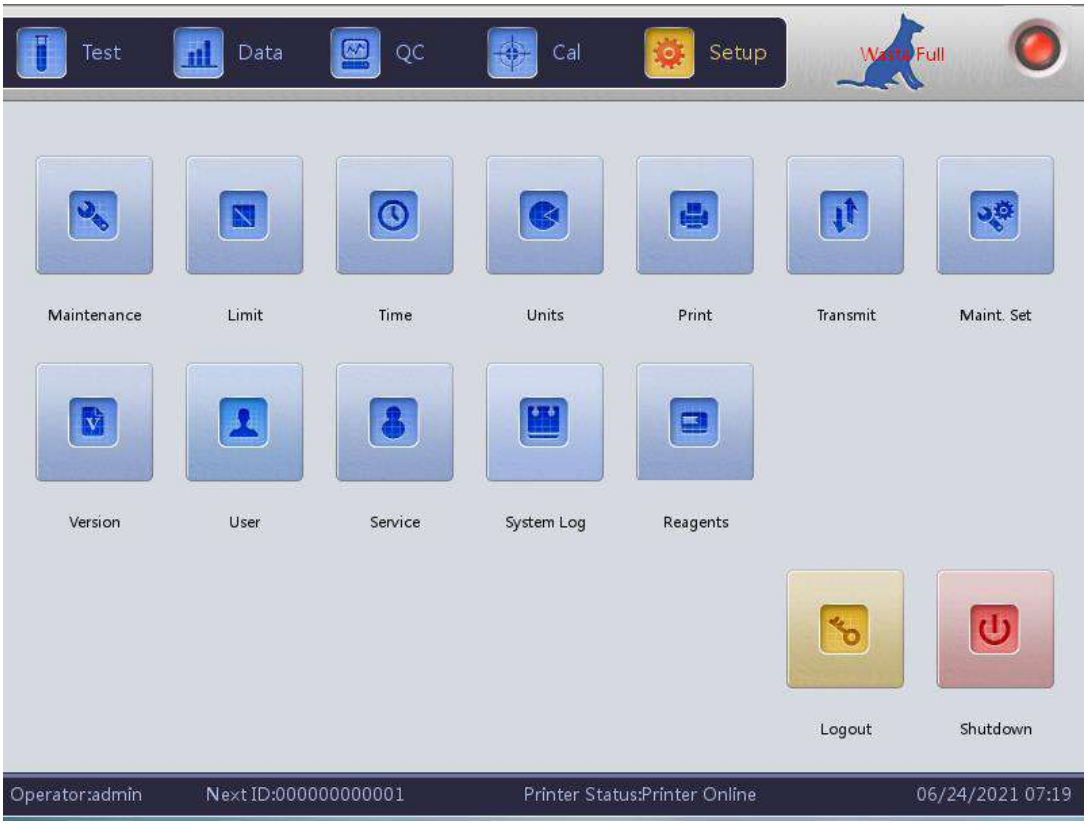
Appropriate settings of the InSight V3 Plus will be set before shipment. Settings can be amended by the user.

4.1 Settings

Select “Setup” to enter the settings interface, see Figure 4-1.

Figure 4-1

4.2 System Maintenance



Select “Maintenance” to enter maintenance interface, see Figure 4-2.

Figure 4-2

Change Lyse: Select “Change Lyse” to prime lyse automatically after replacement.

Change Diluent: Select “Change Diluent” to prime diluent automatically after replacement.

Clean Rear Chamber: Select “Clean Rear Chamber” to prime diluent in the rear chamber for cleaning.

Zap Aperture: Select this option to remove clogging.

Flush Aperture: Select this option to remove clogging.

Rinsing Cups： Select this option for daily maintenance or if getting high background results.

Prime: Select this button to prime all reagents.

Draining Cups: Select this button to drain the counting baths.

Prepare Shipping: Perform this function before shipping the analyser or if the analyser is not going to be used for more than 5 days.

4.3 Limit

Select “Limit” to view or edit the species reference ranges. See Chapter 7 for details.

4.4 Time

Select “Time” to set the correct date and time.
There are three formats of date, which are YYYY-MM-DD, MM-DD-YYYY and DD-MM-YYYY. Y indicates Year, M indicates Month and D indicates Day. See Figure 4-3.
The date display format changes according to date format. Select “OK” to save modified settings.

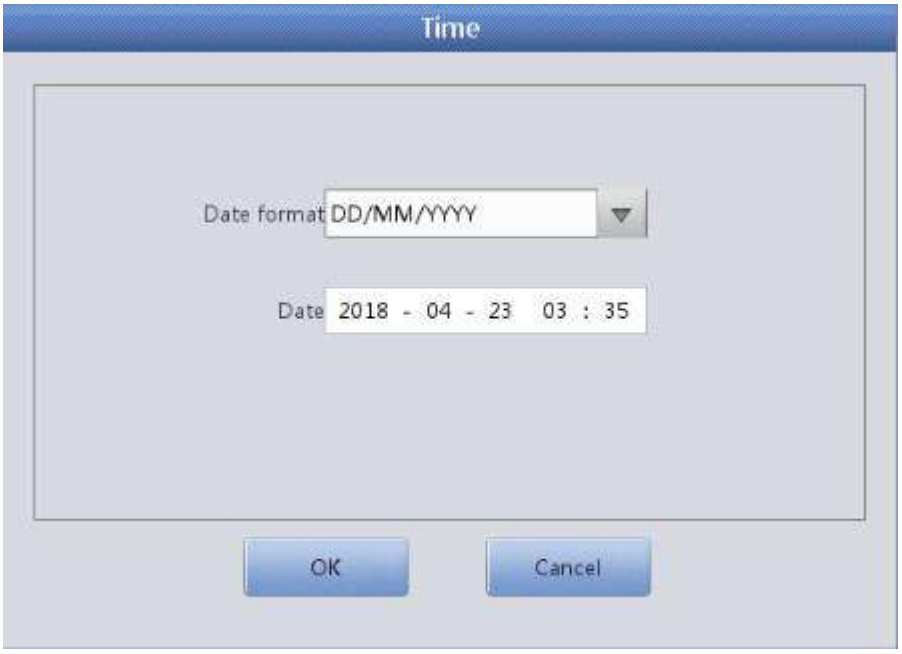


Figure 4-3

4.5 Parameter

Choose unit of WBC, RBC, PLT and MCHC. Select “OK” to save modified settings. See Figure 4-4.

Figure 4-4

4.6 Print

See Figure 4-5:

Printer Type: Select printer type.

Print Format: Print portrait or landscape and with or without histograms and reference ranges.

Auto Print: Switch auto print on or off.

Print Title: Input laboratory name, lab name displays in printed report title.

Select “OK” to save the modified settings.

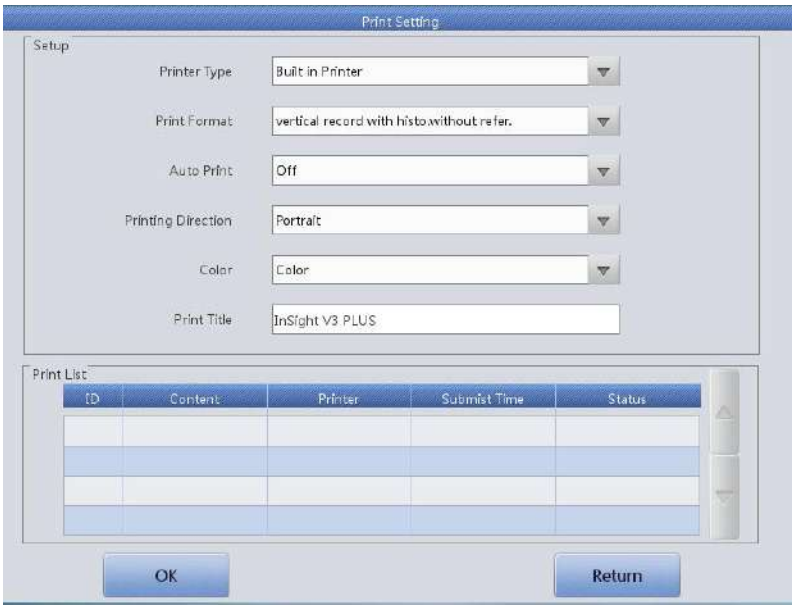


Figure 4-5

4.7 Transmit

Select “Transmit” to enter the interface as shown in Figure 4-6.
There are two transmission modes: internet transmission and serial transmission. The user can make the choice in the transmission selection bar.

If internet transmission is chosen, please set the local IP, server IP, local mask, local gateway and port number as connecting with LIS system. The native mask and the local gateway can be selected by default, the others shall be reset. After finishing the setting, select “save” and then “unconnected”. If the button displays “connected”, it is connected successfully. If serial transmission is chosen, please set the baud rate, stop bit, data bit and parity bit. The port number can be selected by default. Select “Save” after setting.

Choose on/off auto transmit as connecting with LIS system.

Auto Transmit: Transmit the result automatically through communication port after sample testing.

Figure 4-6

4.8 Maintenance

Select “Maintenance” to enter the interface. See Figure 4-7.

Figure 4-7

Auto Blank: Select to select “On” or “Off” and then select “OK” to save settings. If turned “On”, a blank test will automatically start when the analyser is switched on. The analyser does not perform a background automatically if it is “Off”.

Auto Clean: Select to select how often an auto clean is carried out (options are after 50 times, 75 times, 100 times, 125 times and 150 times) according to the customer’s requirements. Auto clean is performed after 50 samples, if 50 times is selected.

Dilute Mode Reminders: Dialog box pops up for each test if “On” is selected and the analyser has been left in Dilute mode.

Auto Sleep: The analyser automatically goes into sleep mode after the set time. The maximum sleep time is 4 hours.

Soak and Exit: Cleaner Soak is performed when shutting down if “On” is selected. The analyser prompts to put the detergent under the aspiration probe. Shut down the analyser after soaking. Woodley Equipment Company recommends this is switched “On” to maintain the analyser.

Auto Soak: Select to choose how often the analyser performs a cleaner soak. The analyser reminds users to put detergent under the sample probe as part of the analyser maintenance.

4.9 Version

Select “Version” to show the analyser’s software versions. See Figure 4-8.
The current version information displays here.
Select “Return” to return to the setup interface.

Figure 4-8

4.10 User

Select “User” to enter the user interface. See Figure 4-9

Figure 4-9

Select “Delete” to delete selected user.

Select “Add” to add a new user and edit the new username, password and group. “Group” is divided into “Ordinary user” and “Administrator” which are given different permissions. The administrator's permissions are higher than the ordinary user’s. The administrator can operate all the functions while the general user cannot delete data, use the export function or calibrate the analyser. See Figure 4-10.

Figure 4-10

4.11 Service

Select “Service” to pop up the following dialog. Only Woodley Equipment Company service engineers can perform this function in maintenance. See figure 4-11.

Figure 4-11

4.12 Reagents

To replace the reagent bottles, select “Reagents” to activate the RF Card from the new reagents. Select the diluent box and “Replace”. Select “Setup”.

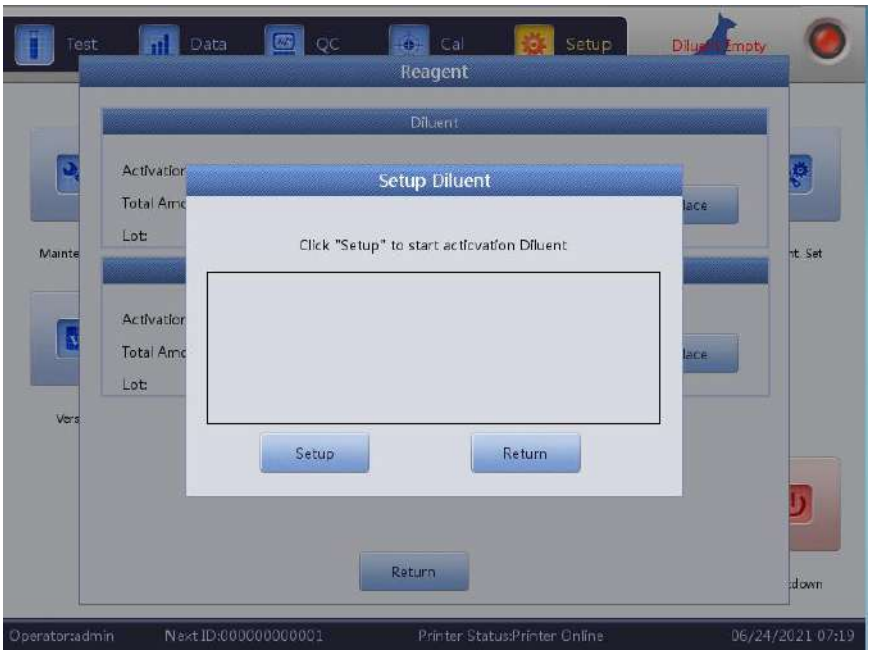


Figure 4-12

Hold the diluent RF Card to the RF Card reader on the front of the analyser.

Figure 4-13

Repeat this process for lyse. After activating the RF cards, go to “Maintenance” and “Prime” to prime the new reagent bottles.

Chapter 5 Quality Control

In order to maintain the analyser's precision and eliminate system errors, it's important to perform quality control. Perform quality control procedures using control material recommended by Woodley Equipment Company.

Quality control tests should be performed:

- After daily start-up procedures are completed
- When the reagent lot number has changed
- After calibration
- After maintenance or component replacement
- In accordance with the laboratory or clinical QC protocol
- In suspicion of parameter value

To ensure accuracy of the results, controls must be handled as follows:

- Make sure the controls are stored between 2-8°C.
- Gently mix the controls according to the manufacturer's recommendations.
- Never use controls which are opened for longer than the period recommended by the manufacturer.
- Never subject controls to extreme heat or shaking.

CAUTION: Consider all clinical samples, controls and calibrators etc. that contain blood or serum as potentially infectious. Wear a lab coat, gloves, safety glasses and follow required laboratory or clinical procedures when handling these materials.

5.1 Quality Control Options

L-J QC

L-J QC (Levey-Jennings graph) is a simple and visual QC method which the operator can draw the QC value directly on the graph after finding out the Mean, SD and CV. The Mean, SD and CV are derived from the following formulas:

$$\overline{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

$$SD = \sqrt{\frac{\sum (X_i - Mean)^2}{n-1}}$$

$$CV\% = \frac{SD}{Mean} \times 100$$

5.2 QC Mode Select

Select the button “QC” on the top of the main interface and select the QC mode. See Figure 5-1. Select the mode in the drop-down box of QC mode and the corresponding interface pops up.

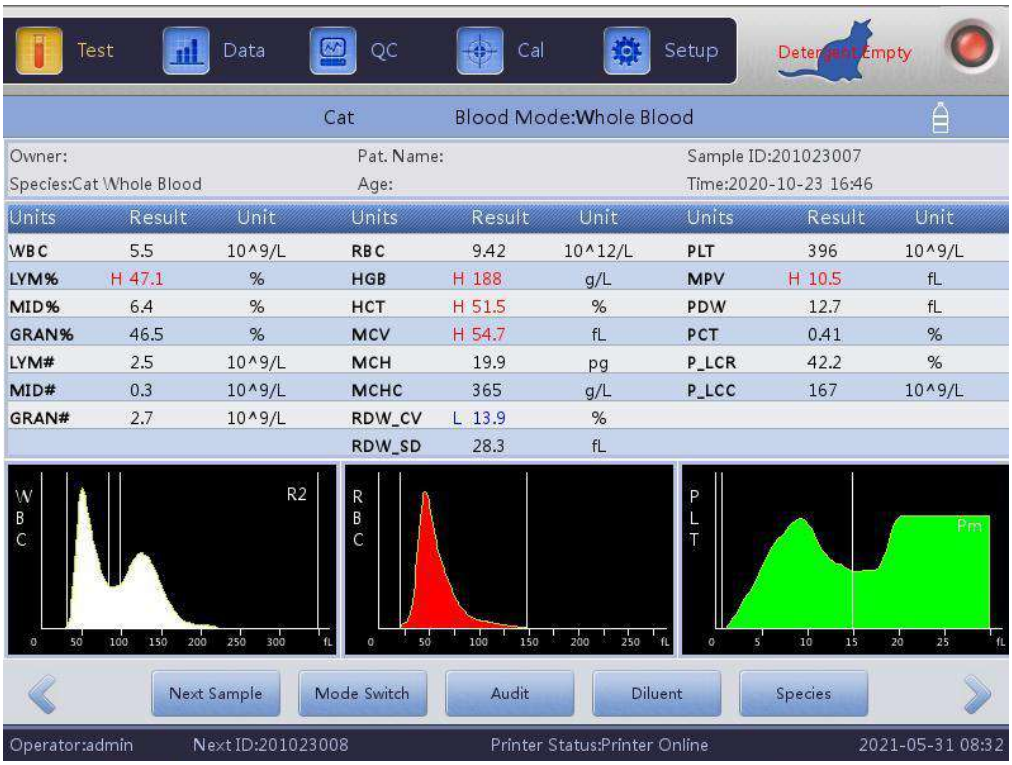


Figure 5-1

5.3 L-J QC

5.3.1 L-J QC Setting

Select “setup” to enter new QC values, see Figure 5-2.

Figure 5-2

There are 14 different QC groups set. Users can set several groups if needed.
Select “New” to set up a new lot of QC and edit information. See Figure 5-3.
A new lot of QC saves 100 test data.

Edit Information: User can edit the Lot, QC material type, QC case ID, level, SD, expiry date, reference and limit of an existing QC entered.

Limit Setup: To set up standard deviation as an absolute value or percentage. Woodley Equipment Company release SD as an absolute value.
Select “Return” after editing. Select “OK” in popup dialog box and the setting is saved.
Choose one group and select “Test” to test in QC interface. Select “Delete” to delete the selected group, select “Empty” to delete all groups.
Format of Expiry Date: year/month/day.

Figure 5-3

See Figure 5-4.

Choose the reason for it being out of control or input other reasons manually. Select “OK” to save your settings.

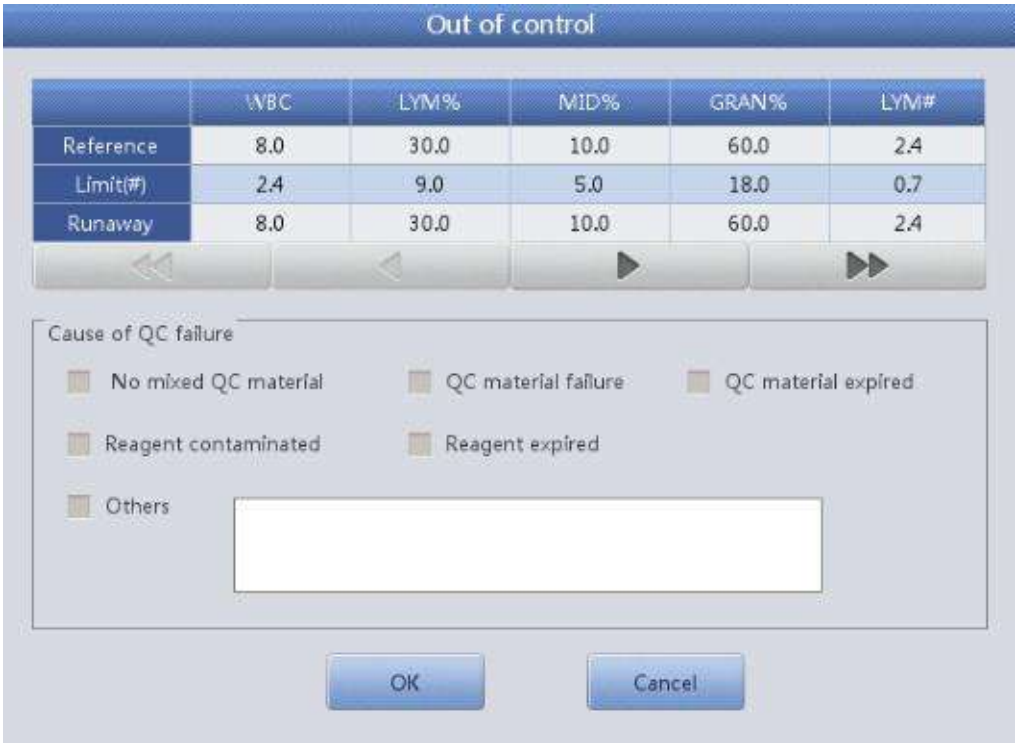


Figure 5-4

QC Graph Instruction

1. A graph with times of QC count on the horizontal axis and results of QC count on the vertical axis.
2. Every parameter graph displays 20 dots, other dots will be on the next page.
3. The top line of each parameter indicates the upper limit of the reference range.
4. The lower line of each parameter indicates the lower limit of the reference range.
5. The 3 values on the left side of the parameter graph mean:
    - Upper Limit of QC reference range
    - Middle Line is the target value of QC
    - Lower Limit of QC reference range

If the control falls within the range, the analyser is working to specification. If the QC is out of range, contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

5.3.2 L-J QC List

Select “QC list” to see the test sample data. See Figure 5-5.

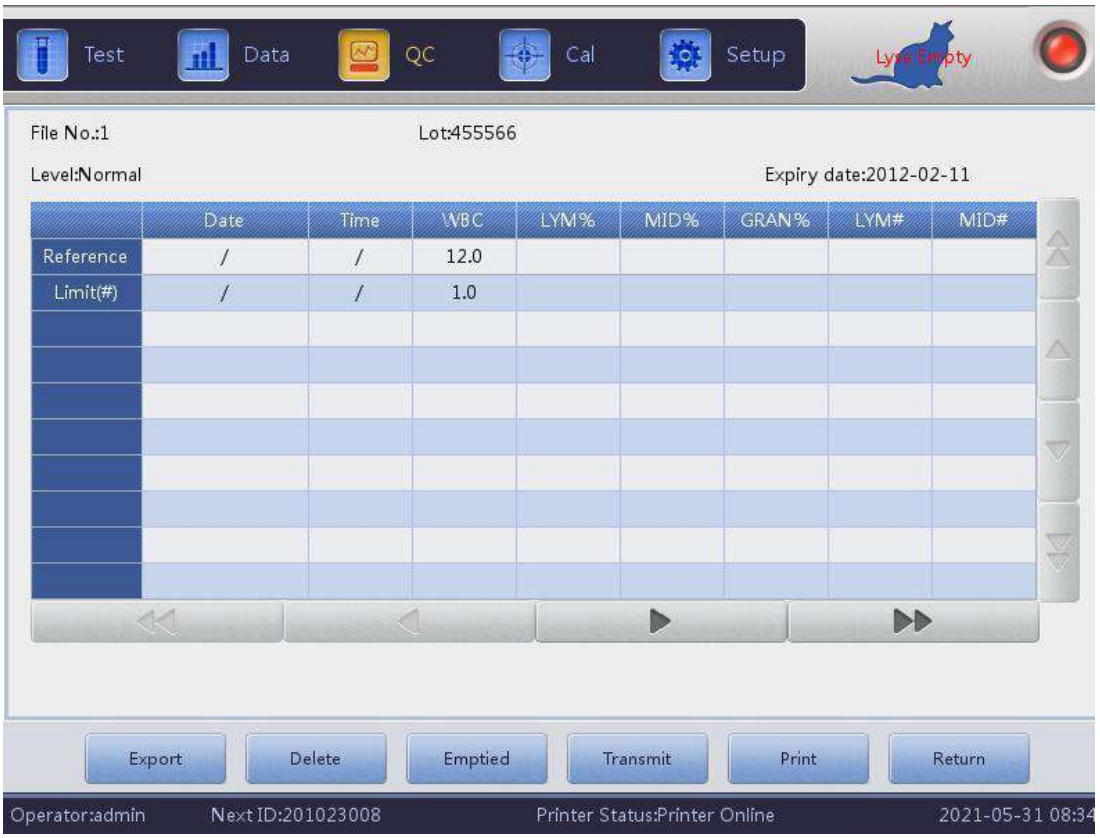


Figure 5-5

100 pieces of data can be viewed in the QC list. Select  ,

 ,  ,  ,  ,  ,  and  to review test results.

Select “Delete” to delete the selected test results.

The reference and limit shown in this interface are the values inputted in QC editing.

The QC list saves every QC test results.

Chapter 6 Calibration

Calibration is a procedure to standardise the analyser by determining its deviation, if any, from calibration references and to apply any necessary correction factors. The analyser is set up and calibrated before delivery. When the analyser is used for the first time, the results may be out of range and calibration may be necessary.

The analyser provides three calibration modes which are “Standard”, “Blood” and “Manual”.

CAUTION: Only calibrators recommended by Woodley Equipment Company can be used to calibrate the analyser.
CAUTION: Follow the instructions to store and use the calibrator.
CAUTION: Check the container is not broken or cracked before using the calibrator.
CAUTION: Make sure the calibrators are brought to room temperature and gently mixed before use.
CAUTION: Make sure the calibrators are in date.
CAUTION: Make sure the analyser is maintained and meets the requirements before calibration.
CAUTION: Do not test clinical samples until calibration has been completed accurately.

6.1 Calibration Frequency

To ensure precision and obtain reliable test results, the parameters (WBC, RBC, PLT, HGB and MCV) must be calibrated in the following situations.

1. Working environment changes greatly.
2. Any major component that affects the measurement is replaced.
3. Analyser out of use for a long period of time.
4. Requirement of the laboratory or the clinic.

5. The reagent has been replaced.
6. The analyser shows deviation when running quality control.

WARNING: Consider all specimens, control materials and calibrators that contain blood or serum as being potentially infectious. Wear a lab coat, gloves, safety glasses and follow required laboratory or clinical procedures when handling these materials.

6.2 Preparation

Before calibration, inspect the analyser so the following requirements are met.

1. Ensure the reagents are within the shelf life, uncontaminated and sufficient volume.
2. Run a blank test and make sure the results are in accordance with Table 6-1.

Table 6-1

Parameter	Range
WBC	≤0.20×10^ 9/L
RBC	≤0.02×10^ 12/L
HGB	≤1g /L
PLT	≤10.0×10^ 9/L

3. Ensure there are no errors.
4. Verify the accuracy of precision. Run continuous counting with mid-value control material or blood 11 times. Take the results from the second to eleventh tests and check the CV in the data interface. Make sure the CVs are in accordance with Table 6-2.
5. Ensure maintenance is up to date.

Table 6-2

Parameter	Range	CV
WBC	≤3.5%	4.0×10^9/L ~ 15.0×10^9/L
RBC	≤1.5%	3.00×10^{12}/L ~6.00×10^{12}/L
HGB/	≤1.5%	100 g/L ~180g/L
HCT	≤2.0%	35%~50%
MCV	≤1.0%	76fL ~110fL
PLT	≤4.0%	100×10^9/L ~500×10^9/L

6.3 Calibration Modes

6.3.1 Manual Calibration

Select “Manual” on the “Cal” interface. See Figure 6-1.

The Principles of New Calibration Value

- Mean value=(value1+value2+value3+value4)/4
- New calibration value= (old calibration value x target value) / mean
- If the new calibration value is <70%, consider it equal to 70%, if the new calibration value is >130%, consider it equal to 130%

Figure 6-1

Select “Save” to save the new calibration value in database.

Select “Print” to print the calibration value.

Select “Export” to export the data sheet.

NOTE: The analyser can calibrate individual or all parameters of WBC, RBC HGB, MCV, MPV, RDW_CV, RDW_SD, PLT and PDW.

NOTE: Remember to select “Save” to save the calibration value before exiting the Cal interface.

Validation of Calibration Coefficient

After calibration, Woodley Equipment Company recommends following the steps below to validate the calibration coefficients.

1. Test the calibrators at least three times and check whether the results are within range.
2. Test levels “High”, “Normal” and “Low”. Each one should be tested at least three times. Check whether the results are within the allowed range.
3. Analyse three normal fresh blood samples, three times for each.

NOTE: The calibration coefficient is allowed in the range of 70%~130%. If the test values exceed the limit, the critical value in the limit range should be selected as the new coefficient for calibration. Then, the operator should find the reasons and calibrate again.

6.3.2 Standard Calibration

Select “Standard” in “Cal” interface as Figure 6-2.

Figure 6-2

Calibrate according to the following procedures:

1. Input the lot number according to the calibrator used.
2. Input the reference according to the data sheet, the reference values of parameters which do not need to be calibrated should be left blank.
3. Select “Test” to start calibration. The analyser can automatically calculate the mean value of 10 tests at most. Woodley Equipment Company recommend testing at least 5 times.
4. The new calibration coefficient is automatically calculated according to the reference value of the calibrators and mean.
5. Select “Save” to save the new calibration coefficient. Select “Print” to print the new calibration coefficient.
6. Select “Export” to export the backup calibration coefficient data.

Validation of Calibration Coefficient

After calibration, Woodley Equipment Company recommends following the steps below to validate the calibration coefficients.

1. Test the calibrators at least three times and check whether the results are within range.
2. Test levels “High”, “Normal” and “Low”. Each level should be tested

at least three times. Check whether the results are within range.

3. Analyse three normal fresh blood samples, at least three times for each. Check whether the results are within range.

Input reference in standard mode. Put the prepared calibrator under the aspiration probe and press the button on the front housing. The counting starts and displays test results in a box. The first calibration test result displays in value 1 and so on. The analyser recalculates the new calibration value based on the reference and the measured mean after each analysis.

The Principles of New Calibration Value

$$\text{Mean}=\frac{\sum_{i=1}^{n} X_i}{n}$$

New calibration value = (old calibration value x target value) / mean.

If the new calibration value is <70%, consider it equal to 70%. If the new calibration value is >130%, consider it equal to 130%.

6.3.3 Blood Calibration

Select “Blood” on the “Cal” interface. See Figure 6-3.

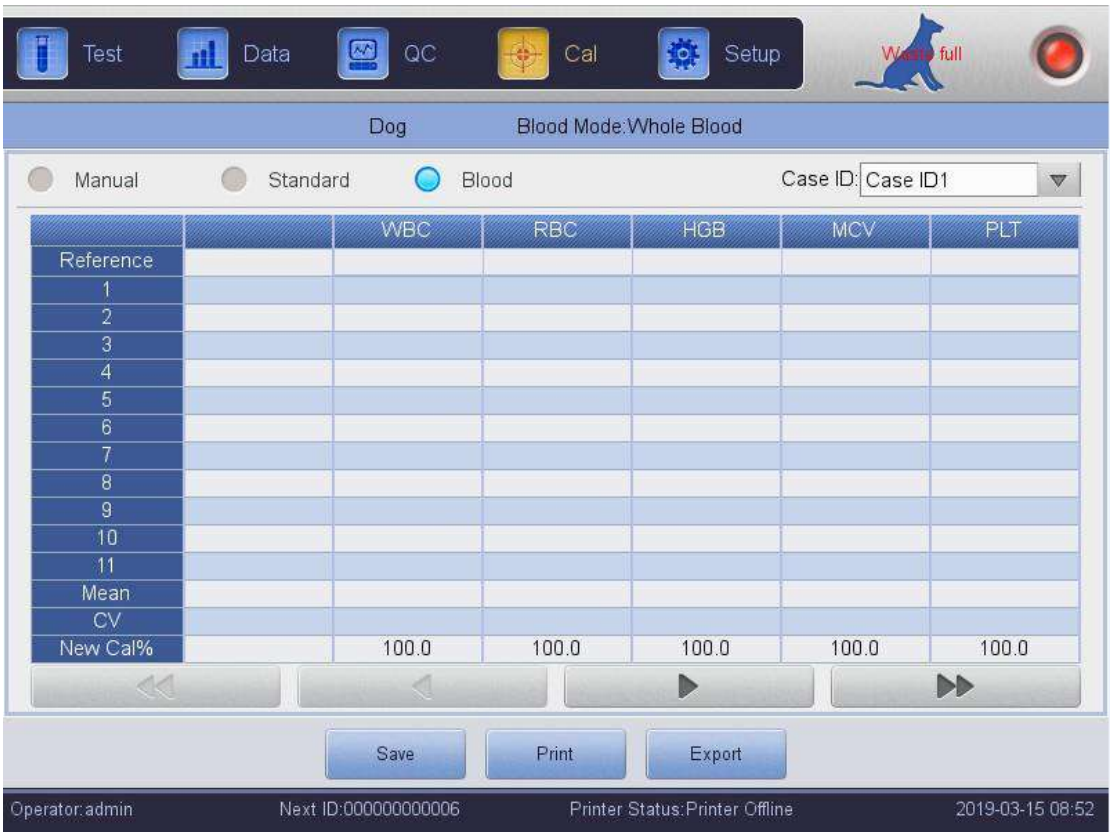


Figure 6-3

Calibrate the analyser as follows.

- Prepare 5 normal whole blood samples and test each of the prepared samples by another QC'd analyser at least 5 times to get the mean and input the mean value into the reference value frame.
- Select SN1 sample and press the count button to make 5-10 times of counting and get the mean value. Select SN 2 sample and make 5-10 times of counting and get the mean value. Repeat for each of the five samples.
- The system adds the measured values and calculates the average of parameters. The system automatically calculates the new calibration coefficient via reference, mean value and calibration coefficient.
- Select "Save" to save the new calibration coefficient, select "Print" to print it.
- Select "Export" to export the backup calibration coefficient data.

New calibration value = (old calibration value x target value) / mean
If the new calibration value is <70%, consider it equal to 70%. If the new calibration value is >130%, consider it equals to 130%

NOTE: Remember to select "Save" to save counting results before exiting.

Chapter 7 Reference Ranges

To monitor abnormal blood sample results, it is essential for the operator to set up normal ranges according to laboratory or clinical requirements. Information or indication is given if the test values exceed the range. The ranges are discussed in this chapter, any results exceeding the range will be marked H (High) or L (Low). H means the results are higher than the upper limits, while L means the results are lower than the lower limits.

CAUTION: A change in reference range may cause changes in identification of abnormal results. Please confirm the necessity for changing.

7.1 Limit Review

On the Reference Range screen, the operator may input their own normal ranges or use the default ranges. Default ranges are species specific. Figure 7-1 shows an example of dog reference ranges.

Param.	Lower	Upper	Param.	Lower	Upper
WBC	6.0	17.0	MCV	62.0	72.0
LYM%	12.0	30.0	MCH	20.0	25.0
MID%	2.0	9.0	MCHC	300	380
GRAN%	60.0	83.0	RDW_CV	11.0	15.5
LYM#	0.8	5.1	RDW_SD		
MID#	0.0	1.8	PLT	117	460
GRAN#	4.0	12.6	MPV	7.0	12.0
RBC	5.50	8.50	PDW		
HGB	110	190	PCT		
HCT	39.0	56.0	P_LCR		
			P_LCC		

Figure 7-1

Select “Animal” and select other animal. See Figure 7-2.

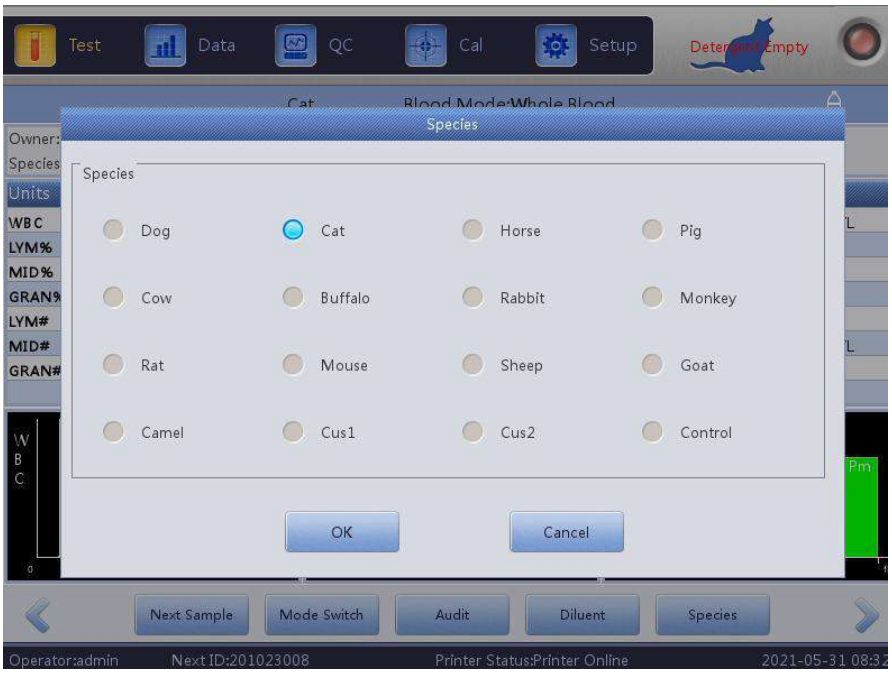


Figure 7-2

Selecting “Default” will restore the system to its factory settings. For example, selecting “Default” in the main group interface will restore the ranges of the main groups to factory settings.

7.2 Range Modification

Follow the procedure below to modify the parameter limit:

1. On the main menu screen, select “Setup”, then select “Ranges” to enter the reference range setting screen.
2. Select “Animal”, the screen displays the lower and upper ranges of the current species selected.
3. Select “Save” and the dialog box below pops up. Select “Cancel” to discard changes, the interface goes back to reference ranges without modification. Select “OK” to save the modification.

Figure 7-4

7.3 Print

Select “Save” to save the edited species range.
Select “Export” to output the current species range.
Select “Print” to print the current species range.
Select “Return” to return to the settings interface.

Chapter 8 Maintenance

Routine care and regular maintenance are essential to maintain accuracy and precision, to minimise system problems, as well as to prolong the life span of the analyser. Procedures and instructions for preventative maintenance are discussed in this chapter. More information is available from Woodley Equipment Company.
Preventative maintenance should be performed daily and weekly.

WARNING: Analyser failure may occur if regular maintenance guidelines are not followed.
WARNING: Wear personal protection before performing instrument maintenance. Wear a lab coat, gloves, safety glasses and follow required laboratory or clinical procedures.

8.1 Daily Maintenance

InSight V3 Plus has a daily auto-maintenance program. The operator can select the auto-clean time to maintain the system. The auto-clean can be programmed to run after a certain number of test cycles. See page 43 for further details.

Figure 8-1

8.2 Weekly Maintenance

8.2.1 Surface Maintenance

Clean stains on the surface of the analyser, especially any spilt blood on the aspiration probe and surrounding area, to remove the protein build up or debris and reduce the possibility of a blockage. Wipe the outside of the probe and surrounding area with a cloth soaked in detergent before cleaning other parts.

CAUTION: Never use corrosive acids, alkali or volatile organic solvent (such as acetone, aether and chloroforms) to wipe the outside of the analyser.

8.3 System Maintenance

Select “Setup” and then “Maintenance” to enter the maintenance interface. See Figure 8-2.

Figure 8-2

InSight V3 Plus offers ten maintenance functions as follows:

- Zap Aperture
- Flush Aperture
- Clean Cups
- Rinsing Cups
- Change Lyse
- Change Diluent
- Clean Rear Chamber
- Prime
- Prepare Shipping
- Draining Cups

8.3.1 Zap Aperture

Zap Aperture may prevent and remove aperture clogs. The procedure is as follows:

1. Select “Zap Aperture” on the maintenance screen.
2. The analyser starts to perform the function and all buttons will turn grey.
3. The operation is complete and will return to the maintenance screen.

8.3.2 Flush Aperture

Flush Aperture may prevent and remove aperture clogs associating with Zap Aperture. The procedure is as follows:

1. Select “Flush Aperture” on the maintenance screen.
2. The analyser starts to perform the function and all buttons will turn grey.
3. The operation is complete and will return to the maintenance screen.

8.3.3 Draining Cups

This operation will drain diluent out of WBC and RBC cups.

8.3.4 Clean Cups

This operation may rinse the cups to prevent blockage. The procedure is as follows:

1. Select “Rinse Cups” on the maintenance screen.
2. The analyser starts to perform the function and all buttons will turn grey.
3. The operation is complete and will return to the maintenance screen.

8.3.5 Rinsing Cups

CAUTION: The operator should wear a lab coat, gloves and follow required laboratory or clinical procedures when performing maintenance.

This operation may prevent blockage. Rinsing Cups is to rinse the WBC and RBC cups and related tubing with probe detergent. If the analyser is left switched on, perform Rinsing Cups every three days. If the analyser is powered off daily, perform Rinsing Cups every week.

The procedure is as follows:

1. Place the probe detergent under the aspiration probe. Select “Rinsing Cups” on the Maintenance interface.
2. Select “Yes” in the dialog box. Take the detergent away after the sample probe has retracted. About 10 seconds later, the probe will return to its initial position. When the analyser pops up a dialog box, place the probe detergent under the sample probe and select “Yes”. The progress bar will display. Rinsing Cups takes approximately 6 minutes.
3. The operation is complete and will return to the Maintenance interface.

8.3.6 Change Lyse

CAUTION: Treat all clinical specimens, controls and calibrators etc. which contain blood or serum as potentially infectious. Wear a lab coat, gloves, safety glasses and follow required laboratory procedures when handling these materials.

NOTE: After shipping, allow Lyse to sit at room temperature for 24 hours.
NOTE: After replacement of diluent or lyse, perform a background test to make sure the background values are in the acceptable range.

The procedure is as follows:

1. Replace Lyse bottle.
2. Select “Change Lyse” on the maintenance screen.
3. The analyser starts to prime the new Lyse reagent.
4. The operation is complete and will return to the maintenance screen.

8.3.7 Change Diluent

CAUTION: Treat all clinical specimens, controls and calibrators etc. which contain blood or serum as potentially infectious. Wear a lab coat, gloves, safety glasses and follow required laboratory procedures when handling these materials.

NOTE: After shipping, allow the Diluent to sit at room temperature for 24 hours.
NOTE: After replacement of diluent or lyse, perform a background test to make sure the background values are in the acceptable range.

The procedure is as follows:

1. Replace Diluent bottle.
2. Select “Change Diluent” on the maintenance screen.
3. The analyser starts to prime the new Diluent reagent.
4. The operation is complete and will return to the maintenance screen.

8.3.8 Clean Rear Chamber

CAUTION: Consider all clinical specimens, controls and calibrators etc. which contain blood or serum as potentially infectious. Wear a lab coat, gloves, safety

glasses and follow required laboratory procedures when handling these materials.

NOTE: After replacing the diluent or lyse, perform a background test to make sure the background values are in the acceptable range.

This operation cleans the analyser fluidics. The procedure is as follows:

1. Select “Clean Rear Chamber” on the maintenance screen.
2. The analyser starts to perform the function and all buttons will turn grey.
3. The operation is complete and will return to the maintenance screen.

8.3.9 Prime

CAUTION: Consider all specimens, controls and calibrators etc. which contain blood or serum as potentially infectious. Wear a lab coat, gloves, safety glasses and follow required laboratory procedures when handling these materials.
The procedures as follows:

1. Select “Prime” on the maintenance screen.
2. The analyser starts to perform the function and all buttons will turn grey.
3. The operation is complete and will return to the maintenance interface.

8.3.10 Prepare Shipping

Perform this function before shipping or if the analyser is to be left out of use for more than 14 days. Refer to Section 8.5 for details. The procedure is as follows:

1. Select “Prepare Shipping” on the maintenance screen.
2. The analyser starts to perform the function and all buttons will turn grey.
3. The operation is complete and will return to the maintenance screen.
4. The analyser can be switched off and packed for shipping or storage.

8.4 Maintenance before Shipping

If the analyser is left unused for 14 days or before preparing the analyser for shipping, maintain the analyser as follows:

a) Take out the diluent inlet tube connected to the diluent port.

b) Take out the lyse inlet tube connected to the lyse port.

c) Keep the remaining reagents in their containers and store them according to the instructions. The operator should store the reagents correctly to avoid reagent deteriorating.

d) Keep the diluent and lyse inlet tubes hanging in the air.

e) On the main menu screen, select “Drain” several times until the top right corner of the screen presents “No Diluent, No Lyse”. Select “Drain” once again.

f) Insert diluent and lyse tubes into distilled water.

g) On the main menu screen, select “Setup”, then select “Maint”, and then select “Prepare Shipping”. See Figure 8-3.

Figure 8-3

h) After completion, take out the diluent and lyse tubes from distilled water and select “Prepare Shipping” again to drain the reagent in the tubes.

i) On the main menu screen, “Thank you, now turn off power” will appear to instruct the operator to turn off the power switch on the rear panel.

j) Pull out the outlet tubes from the rear panel, clean them with distilled water and put it in a plastic bag when dry.

k) Cover the connectors of DILUENT and WASTE on the rear panel with caps which were taken out at initial installation.

l) Disconnect the power cord of the analyser. Place the analyser and components into the shipping carton.

Chapter 9 Service

This chapter introduces the Service function with which the operator may check the system status, valve and motor status. More information is available from Woodley Equipment Company.

CAUTION: Incorrect maintenance may lead to analyser functions being impaired. Please maintain the analyser according to this manual.
NOTE: If there are any problems which cannot be solved using the manual, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

9.1 System Check

Select “Setup” on the main menu screen, select “Service”. Input “2006” in the pop-up dialog box to enter the System Check screen.

9.1.1 System Status Check

The System Status Check screen presents the current status information such as temperature, vacuum etc. See Figure 9-1.

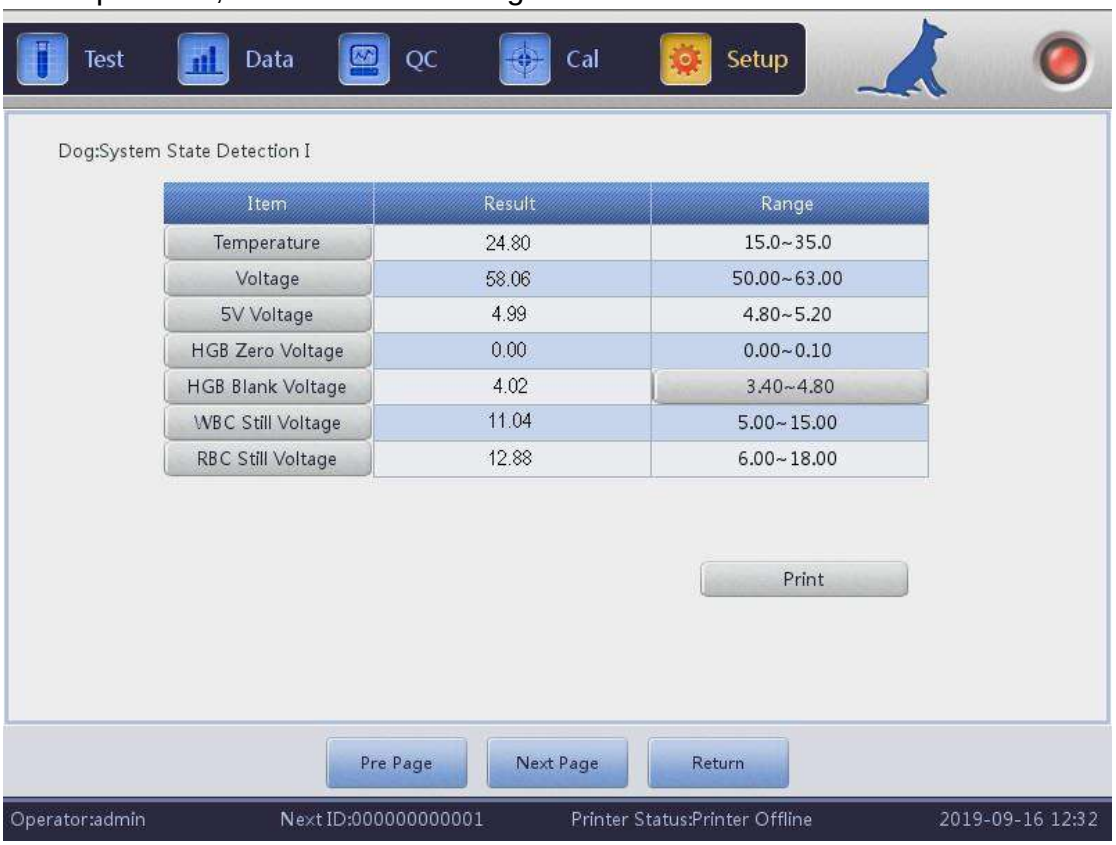


Figure 9-1

NOTE: On the System Status Check screen, the operator may view the value of temperature, vacuum, etc. but cannot modify these values.
Select “Return” to return to the main menu.

9.1.2 Valve Check

On the Valve Check screen (see Figure 9-2), the operator can check whether the valves are in normal condition.

Figure 9-2

On the Valve Check screen, select the valve number. The corresponding results will be displayed. Select "Return" to return to the main interface of the system.

9.1.3 Motor Check

On the Motor Check interface, the operator can check if the motors are in normal condition. On the screen, select the motor icon, the corresponding result will be displayed. See Figure 9-3.

Figure 9-3

Select "Return" to return to the main interface of the system.

9.2 System Log

Select “Setup” on the main menu screen, select “System log”. Enter the System Log screen as shown in Figure 9-4.

Figure 9-4

9.2.1 Date Query

On the system log query interface, select the start and end date and press Enter on the keyboard. Select the shortcut key on the left interface to make a shortcut query according to the log type. See Figure 9-4.

After the system log query, the analyser can perform the following operations:

1. Select “Export” to output the system log. See Figure 9-5.
2. Select “Return” to exit the current interface.

Figure 9-5

Chapter 10 Troubleshooting

This Chapter gives instructions for identifying, troubleshooting and solving problems with the analyser. If errors are not solved according to guidance or more information is needed, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

10.1 Troubleshooting Guidance

The Troubleshooting Guidance is designed to assist the operator in identifying and resolving analyser problems. Instructions are also given for obtaining technical assistance from Woodley Equipment Company. The first step in the process is to understand normal analyser operation and preventative maintenance. Good experience of the analyser is essential for identifying and resolving operational problems.

10.2 Obtaining Technical Assistance

Technical Assistance can be obtained by contacting your Distributor if outside the UK and Woodley Equipment Company if in the UK. When assistance is needed, please be prepared to provide the following information:

1. The analyser model
2. Serial number and version number
3. Description of the problem
4. The lot numbers of the reagents (lyse and diluent)

The operator can identify the cause of the problem according to the warning information and operate according to the Troubleshooting Guide.

10.3 Troubleshooting

Problems and corrective actions are listed as follows. If the problems cannot be corrected or technical assistance is needed, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

10.3.1 Faults Related to Reagents

Fault	Probable Cause	Corrective Action
Lyse Empty	1. Lyse has run out or lyse inlet tube is blocked. 2. Lyse inlet tube has bubbles.	1. Check if the lyse has run out. 2. Perform Setup → Maintenance →Change Lyse. 3. Perform “Prime”. 4. If fault still occurs, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.
Diluent Empty	1. Diluent has run out. 2. Diluent inlet tube has bubbles.	1. Check if the diluent has run out. 2. Perform Setup →Maintenance →Change Diluent. 3. Perform “Prime”. 4. If fault still occurs, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.
Waste Full	Waste container is full or waste sensor has a fault.	1. Check if the waste is full. 2. Check if the sensor is connected to the waste container correctly. 3. If fault still occurs, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

10.3.2 Faults Related to Vacuum

Fault	Probable Cause	Corrective Action
Low Vacuum	The vacuum doesn’t reach the standard value.	1. Select “Service”, input password “2006” to enter System Check screen. Ensure the vacuum items are in normal condition. 2. Please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

10.3.3 Faults Related to 5V Voltage

Fault	Probable Cause	Corrective Action
5V Voltage Problem	Power supply module abnormal.	1. Select “Service”, input password “2006” to enter System Check screen. Ensure the 5V Voltage is in normal condition. 2. Please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

10.3.4 Faults Related to Test Value

Fault	Probable Cause	Corrective Action
High Background Value	1. Diluent is contaminated or past expiry date. 2. Analyser maintenance not performed. 3. Blockage in system.	1. Check if the diluent is out of date or contaminated. 2. Enter maintenance screen and perform “Prime”. 3. If fault occurs, perform “Rinsing Cups” on the maintenance screen using probe detergent. Run a background test again to check if the fault has been corrected. 4. If fault still occurs, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.
HGB Inaccuracy	1. HGB background voltage is out 2. Sample cup is contaminated.	1. Select “Service”, input password “2006” to enter System Check screen, check the HGB_BACK and HGB_ZERO. 2. If the HGB_BACK and HGB_ZERO are out of range, contact your Distributor if outside the UK and Woodley Equipment Company if in the UK to modify the values. 3. Perform “Prime” and then run a background test to check if the HGB_BACK is within range.

WBC Clog or RBC Clog	Aperture clogged; WBC counting time incorrect; solenoid valve problem	1. Perform Zap Aperture and Flush Aperture in Maintenance and then run a background test. 2. If fault occurs, perform Rinsing Cups in Maintenance. Aspirate the probe detergent and rinse aperture. 3. If fault still occurs, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

10.3.5 Faults Related to Hardware

Fault	Probable Cause	Corrective Action
Motor sounds abnormal	1. Motor connecting wire loose 2. Travel switch problem 3. Motor problem 4. Motor drive circuit problem	1. Select “Service”, input password “2006” to enter System Check screen. Ensure the motor items are in normal condition. 2. Please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.
Test time is too long	1. Aperture clogged 2. Valve isn’t moving	1. If the fault occurs after eliminating the aperture clog, select “Service”. Input password “2006” to enter System Check screen, ensure the Valves are in normal condition. 2. If fault still occurs, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

10.3.6 Faults Related to Temperature

Fault	Probable Cause	Corrective Action
Temperature abnormal	Temperature abnormal or temperature sensor problem.	1. Select “Service”, input password “2006” to enter System Check screen. Check the temperature in System Status Check. 2. If the temperature is out of the range of 15-30°C, please move the analyser to an area within the temperature range. 3. If fault still occurs, please contact your Distributor if outside the UK and Woodley Equipment Company if in the UK.

Chapter 11 Precautions, Limitations and Hazards

Improper operation of the analyser may affect analyser performance and may cause damage. Improper operation may also cause risk to the operator.

11.1 Limitations

a) The instrument is designed for veterinary use only.
b) Any operation, shipment, installation or maintenance of the analyser must strictly follow the contents outlined in this manual. If any problems occur from improper use, the warranty will be void.
c) Woodley Equipment Company has designed the instrument components for optimal performance. Substitution of reagents, controls, calibrators and components not recommended by Woodley Equipment Company may adversely affect the performance of the analyser or cause incidents and void the warranty.
d) Any repairs must be permitted and any component replacement must be specified by Woodley Equipment Company. If any problems occur from unauthorised repairs or accessories, the warranty will be void.
e) Follow the recommended maintenance schedules and procedures as outlined in Chapter 8. Non-compliance may shorten the life span, affect the test results or cause incidents, thus voiding the warranty.

11.2 Location Limitations

a) Woodley Equipment Company authorised personnel must perform the initial installation.
b) Place the analyser on a stable, level surface:
- Away from direct sunlight.
- Away from the path of a cooled or heated air outlet with temperature extremes.
- Away from drying ovens, centrifuges, x-ray equipment, copiers or ultrasonic cleaner.

c) Place the reagent containers on the same level or below the analyser.
d) Adequate space should be provided around the analyser. 40cm of space from the surrounding objects is needed for proper ventilation and $2m^2$ of space is needed for the analyser and the reagents. Please do not place the instrument in a location where it is difficult to operate and disconnect the device. Adequate space should be provided around the analyser to

perform necessary maintenance procedures.

e) Before operating the analyser for the initial measurement, verify that each reagent tubing is connected to the appropriate inlet and reagent container. Make sure the waste tubing is not twisted and connected to the appropriate outlet and routed to a suitable waste container or drain.
f) Do not disconnect any electrical connection while the power is ON. Verify the analyser is well connected to prevent electrical interference and ensure safety.

11.3 Safety and Infection Control

a) Follow required laboratory procedures during daily operation or maintenance. Wear gloves, lab clothing and safety glasses to avoid direct contact with the samples.
b) Consider all clinical specimens, controls and calibrators etc. which contain blood or serum as potentially infectious. Wear standard laboratory clothing, gloves, safety glasses and follow required laboratory procedures when handling these materials. Do not smoke, eat or drink near the analyser. Do not suck or blow the reagent tubing.
c) Blood samples and waste are potentially of biological and chemical hazard, the operator should handle samples and waste with extreme care during the disposal process and follow local government guidelines when cleaning and handling.
d) Follow the instructions in this manual and on the product labels for storage of reagents, calibrators and controls. The reagent should be stored away from extreme temperatures.

CAUTION: Reagents will freeze and cannot be used when they are stored in temperatures below 0°C.

CAUTION: Keep the reagents away from direct sunlight to avoid evaporation and contamination. Seal the cap of the container.

Appendix A: Analyser Specifications

Dimensions and Weight

Dimensions:
380(L)×305mm(W)×395mm(H)
Weight: 18Kg

Environmental Requirements

Temperature: 15-35°C
Relative Humidity: ≤90%RH
Barometric: 60kPa~106kPa

Transport and Storage Specifications

Temperature: -10℃~55℃
Relative Humidity: ≤95%RH
Barometric: 50kPa~106kPa

Power Specifications

Power Supply: AC 100V～240V
Frequency: 50/60Hz
Power: 130VA-180 VA
Fuse: 250V/3.15A

Appearance Specifications

Display: 10.4-inch colour LCD
Language: English
Parameters: 21 parameters and 3 histograms
Indicator: Status Indicators/Work Mode Indicators
System Alert: Alert message/Alert beep
Ports: Power Receptacle
Printer Ports
RS-232 Port
USB Ports

Printer Specifications

Printer Width: 48mm
Paper Width: 57.5mm
Paper Roll Diameter: 50mm
Print Speed: 12.5 mm/S

Sample Volume

Whole Blood Mode: Whole Blood (8.5μl)
Pre-diluent Peripheral Blood Mode: Peripheral Blood (20μl)

Reagent Volume for Single Sample

Diluent: 29mL

Lyse: 0.7mL

Background

WBC≤0.2×10^9/L；RBC≤0.02×10^{12}/L；HGB≤1g/L；PLT≤10×10^9/L

Carryover

WBC≤0.5%；RBC≤0.5%；HGB≤0.6%；PLT≤1.0%

Accuracy

Table A-1 Accuracy Specifications

Parameter	Acceptable Limits（%）
WBC	≤±8.0%
RBC	≤±4.0%
HGB	≤±4.0%
MCV	≤±3.0%
HCT	≤±5.0%
PLT	≤±10.0%

Precision

Table A-2 Precision Specifications

Parameter	Acceptable Limits (CV/%）	Precision Range
WBC	≤3.5%	4.0×10^9/L ~ 15.0×10^9/L
RBC	≤1.5%	3.00×10^{12}/L ~6.00×10^{12}/L
HGB	≤1.5%	100 g/L ~180g/L
HCT	≤2.0%	35%~50%
MCV	≤1.0%	76fL ~110fL
PLT	≤4.0%	100×10^9/L ~500×10^9/L

Linearity

Table A-3 Linearity Specifications

Parameter	Linearity Range	Acceptable Limits
WBC	0×10^9/L~10.0×10^9/L	≤±0.3×10^9/L
	10.1×10^9/L ~99.9×10^9/L	≤±5%
RBC	0×10^{12}/L ~1.00×10^{12}/L	≤±0.05×10^{12}/ L
	1.01×10^{12}/L ~9.99×10^{12}/L	≤±5%
HGB	0 g/L ~70 g/L	≤±2g/L
	71 g/L ~300 g/L	≤±2%
PLT	0×10^9/L ~100×10^9/L	≤±10×10^9/L
	101×10^9/L ~999×10^9/L	≤±10%
MCV	25 – 120 fL	≤±1%

Appendix B: Analyser Icons and Symbols

Caution

Caution, risk of electric shock

Biohazard

Equipotential Bonding

Protective Grounding

Protect from heat and radioactive sources

Consult Instruction for Use

Serial Number

Manufacturer

Appendix C: Communication

The system transfers sample data and analyser information to an external computer through RS-232 COM. This operation can be done automatically after analysis or manually when the instrument is in idle mode. This appendix explains the settings of communication parameters and data communication formatter for easy operation.

Before communication, please ensure the analyser is connected to an external computer through appropriate COM.

Communication can be done in hexadecimal format or ASCII format.

1 Hexadecimal Format Communication

1.1 Data Link MAC Sublayer Parameters Convention

Baud Rate: 115200
Parity Digit: None
Data Bit: 8 bits
Stop Bit: 1 bit

1.2 Data Link Layer Frame Format

1.2.1 Frame Format

STX	LENGTH	Message	ETX	LRC

1.2.2 Meaning of Each Field or Control Field

Name	Meaning	Value
STX	Start of Text	0x02
ETX	End of Text	0x03
Message	Sending Message	Determine by Message content.
LENGTH	Length (2 bytes)	Determine by Message length
LRC	Checksum	Determine by the content among STX and ETX, exclude STX.

1.2.3 Convention

Comply with Big-Endian format, high byte is prior when transferring.

1.3 Message Field Structure

1.3.1 Message Structure

TYPE	DATA

Field Definition:

	Field	Length
1	TYPE	1
2	DATA	xx

TYPE Value:

Type	Value
TRANS_CONDITION	0x42

1.3.2 DATA Field Definition

DATA Type（1 Byte）	DATA Content（depends on specific DATA type）

TYPE Value of DATA Field:

DATA Type	Value	Definition	Receive	Transmit
CON_TRANS	0x01	Request online status	Yes	
TRANS_CON	0x02	Transmit online status		Yes

DATA Field Content:

If TYPE value of DATA field is TRANS_CON and the opposite party can receive 0x01 message, the analyser is connected.

2 ASCII Format Communication

2.1 Message Transfer Format

Message transfer formats are <SB> ddddd <EB><CR>.

<SB> means the start of message and its corresponding ASCII sign is <VT>, namely 0x0B;
<EB> means the end of message and its corresponding ASCII sigh is <FS>, namely 0x1C;
<CR> means the confirmation of termination and the field mark of different message, namely 0x0D;
ddddd is the actual transfer content. It includes several fields, each field will end with <CR>, namely 0x0D.

2.2 Message Grammar

|	Field mark
^	Component mark
&	Child component mark
~	Repeat mark
\	Escape character

2.3 Data Type

CX	extended composite id which checks digit
CE	code element
CM	composite
CQ	composite quantity with units
DR	datetime range
DT	data
DLN	driver’s license number
EI	entity identifier
HD	hierarchic designator
FN	family name
FT	formatter text
IS	coded value for user-defined Tables
ID	coded values for HL7 Tables
JCC	job code
NM	numeric
PT	processing type
PL	person location
ST	string
SI	sequence ID
TS	time stamp
TQ	timing quantity

TX text data
XAD extended address
XCN extended composite ID number and name
XON extended composite name and ID number for organizations
XPN extended person name
XTN extended telecommunications number
VID version identifier

2.4 Message Type

The structure of a message is as follows：

```
MSH                                  //Message Header
{
    [PID]                            //Patient Data
    {
        OBR                          // Medical Advice
        [OBX]                        //Inspection Result
    }
}
```

Definition of MSH (Message Header):

Number	Field	Type	Length	Remark
1	Field mark	ST	1	
2	Encoding chars	ST	4	
3	Sending Application	EI	180	
4	Sending Facility	EI	180	
5	Receiving Application	EI	180	
6	Receiving Facility	EI	180	
7	DateTime Message	TS	26	
8	Security	ST	40	
9	MessageType	CM	7	
10	Message Control ID	ST	20	
11	Processing ID	PT	3	
12	VersionID	VID	60	
13				Keep

14				Keep
15				Keep
16				Keep
17				Keep
18	Encoder	ST		Encoding (with UNICODE)

Example:
MSH|^~\&|CompanyName|InstrName|LIS|PC|20100930100436||ORU^R01|
CompanyName-BLD |P|2.3.1|||||UNICODE

Definition of PID(Patient Data) Field:

Number	Field	Type	Length	Remark
1	Set ID PID	SI	4	Confirm different fields, generally set 1
2	Patient ID	EI	20	
3	Patient Identifier List	CX	20	
4	Alternate Patient ID	CX	20	
5	PatientName	XPN	48	
6	Mother Maiden Name	XPN	48	Set null
7	Date/Time of Birth	TS	26	
8	Sex	IS	1	M or F
9	Patient Alias	XPN	48	Keep
10	Race	CE	80	Keep
11	Patient Address	XAD	106	Keep
12	County Code	IS	4	Keep
13	Phone Number	XTN	40	Keep
13	Phone Number Bus	XTN	40	Keep
14	Primary Language	CE	60	Keep
15	Marital Status	CE	80	Keep
16	Religion	CE	80	Keep
…	Do not need to fill			

Example: PID|1|1010051|A1123145|15|Jame||19811011|M

OBR Field:

Number	Field	Type	Length	Remark
1	Set ID OBR	SI	4	Confirm different fields, generally set 1 or null
2	Placer Order Number	EI	22	
3	Assigned Patient Location	EI	22	
4	Universal Service ID	CE	200	
5	Priority	ID	2	Set null
6	Requested DateTime	TS	26	
7	ObservationDatetime	TS	26	
8	Observation DateTime end	TS	26	Set null
9	Collection Volume	CQ	20	Set null
10	Collector Identifier	XCN	60	Set null
11	SPE ActionCode	ID	1	Set null
12	Danger Code	CE	60	
13	Relevant Clinical Info	ST	300	Clinical information, diagnosis or remark etc.
14	SPE Received DateTime	TS	26	
15	SPE Source	CM	300	Blood, urine or others
16	Ordering Provider	XCN	120	
17	OrderCallback Phone Number	XTN	40	Set null
18	Placer Field1	ST	60	Inspection applicant
19	Placer Field2	ST	60	Set null
20	Filler Field1	ST	60	Set null

Example: PID|1|1010051|A1123145|15|Jame||19811011|M

…	Do not need to fill			Set null

Example:

OBR|1|1010051|000001|CompanyName^InstrName||20101010093020|20101

OBX:

Number	Field	Type	Length	Remark
1	Set ID OBX	SI	4	Confirm different fields, generally use 1 or null
2	Value Type	ID	3	NM indicates number type, ST indicates value type
3	Observation Identifier	CE	590	Observation Identifier or item ID
4	Observation SubID	ST	20	
5	Observation value	ST	65535	Test result
6	Units	CE	90	
7	References Range	ST	90	
8	Abnormal Flags	ID	5	Value mark: L H N
9	Probability	ID	5	Set null
10	Nature of Abnormal Test	ID	2	Set null
11	Observe Status	ID	1	Observe results and take F as final result
12	Date Last Observe	TS	26	Set null
13	User Defined Access Checks	ST	20	Original result, such as absorbance
14	DateTime	TS	28	Use for biochemical result
15	Producer ID			
16	Responsible Observer			
17	Observation	CE	60	Use for biochemical analyser

	Method			

A complete ASCII data example:

<SB>

MSH|^~\&|[CompanyName]|[InstrName]|LIS|PC|[ResultTime]||ORU^R01|[InstrType]|P|2.3.1|||||UNICODE<CR>

PID|[PatType]|[PatID]|[PatBarCode]|[PatBedCode]|[PatName]||[PatBirth]|[PatSex]<CR>

OBR|[SampleType]|[REQID]|[SampleID]|[CompanyName]^[InstrName]||[SampleTime]|[StartTime]||||||[Symptom]||[SampleType]|[SendDOCName]||[Sen dDP]<CR>

OBX|[ResultType]|[ValueType]|[ItemID]|[ItemName]|[TestResult]|[Unit]|[ConsultValue]|[Flag]||F||||[DocDP]|[DOCName]|<CR>

OBX|1|NM|[ItemID]^LeftLine||[TestResult]||||||F||||[DocDP]|[DOCName]|<CR>

OBX|1|NM|[ItemID]^RightLine||[TestResult]||||||F||||[DOCDP]|[DOCName]|<CR>

OBX|1|ED|[ItemID]||[InstrID]^Histogram^32Byte^HEX^[TestResult]||||||F|||[DOCDP]|[DOCName]|<CR>

<EB>

<CR>

3 Communication Operations

If hexadecimal is chosen as the transmission mode, the system will send data in hexadecimal format. Likewise, if ASCII is chosen, the system will send data in ASCII format.

If automatic transmission is on, after finishing each analysis, the system will transmit data through COM automatically. If not needed, please choose “off” in the settings interface. Users can press “Transmit” on the main menu screen to transmit data.

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