

URIT



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US -1680

AI-Libre Urinalysis System

OPERATION MANUAL

NOTE:

- Carefully read this manual before operating the analyzer in first time.
- Inspect the electrical requirements of the analyzer before power on, and properly connect the grounding wire.
- Turn off the power and pull out the power plug if the analyzer is idle for a long time.
- Do not run the analyzer if it's in an abnormal or damaged condition.
- There is potential biohazard of the reagents and samples; operator should follow proper biosafety practices. Dispose of waste reagent and sample in accordance with local, national regulations.

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Copyright and Declaration

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Declaration:

All contents in this manual were strictly compiled according to related laws and regulations in China, as well as the specific condition of US-1680 AI-Libre Urinalysis System, covering all the updated information before printing. URIT Medical Electronic Co., Ltd. is fully responsible for the revision and explanation of the manual, and reserves the right to renovate the relevant contents without separate notification. Some of the demonstration pictures are for reference and subject to real object if any differences.

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All instructions must be followed strictly in operation. In no event should URIT Medical Electronic Co., Ltd. be responsible for failures, errors and other liabilities resulting from user's noncompliance with the procedures and precautions outlined herein.

Limited Responsibility for Quality Warranty:

The manual for US-1680 AI-Libre Urinalysis System, defines the rights and obligations between the URIT and the customers about the responsibility for quality warranty and after-sale service, also the related agreements on commencement and termination.

URIT warrants the US-1680 sold by the URIT and its authorized agents to be free from defects in workmanship and materials during normal use by the original purchaser. This warranty shall continue for a period of one year since the date of installation. The analyzer life is ten years.

URIT assumes no liability in the following situations even during the period of warranty:

- ◆ Failure due to abuse the analyzer or neglect the maintenance.
- ◆ Use reagents and accessories other than manufactured or recommended by URIT.
- ◆ Failure due to operation not under the instructions described in the manual.
- ◆ Replace accessories not specified by URIT, or after maintenance or

repair by a service agent not approved or authorized by URIT.

CAUTION:

THE ANALYZER IS FOR PROFESSIONAL AND PRESCRIPTION USE ONLY.



URIT Medical Electronic Co., Ltd.

Address: No. D-07 Information Industry District, High-Tech Zone, Guilin,
Guangxi 541004, P. R. China

Tel: +86(773)2288586

Fax: +86(773)2288560

Web: www.urit.com

Email: service@uritest.com

Supplied by URIT Medical Electronic Co., Ltd.



Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

How to use this manual

This user manual contains general information on the use of the instrument. This is the best guide for new users to use the instruments. Before using it for the first time, users are advised to read this manual from beginning to end. If you read this manual, you will learn about the features and operation of the instrument. In your daily use, you can use the content to quickly find the information you need.

Symbol	Meaning
 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 analyzer.
Note	Denotes special operator/service information or standard practices.
	Denotes potential bio-hazard.

All the illustrations provided in this manual are only for example purposes and should not be used for other purposes. The graphics, settings, or data in the illustration may not be exactly consistent with what you actually see on the instruments of US-1680.

Target users: the equipment apply to the medical institutions and laboratory professionals. The operator must be able to read and understand the contents and requirements of the product operation manual. The equipment must be used in accordance with the the operation manual.

Intended operating site: medical institutes and laboratories.

Statement:

- The equipment meets the emission and anti-disturbance requirements specified in IEC 61326-1 and IEC 61326-2-6.
- This instrument 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.
- It is recommended to evaluate the electromagnetic environment before the equipment is used.

- Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.
-
-



Caution

- All personnel who use, move, and maintain the instrument should read this manual.
 - Please strictly follow the instructions in the manual.
 - In the dry environment, especially in the dry environment where there are artificial materials (artificial fabrics, carpets, etc.), the use of this instrument may cause damaging electrostatic discharge, leading to wrong conclusions.
 - Do not use it near strong radiation sources, as this may interfere with normal operation of the device.
-

NOTE

- It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.
 - It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.
-

Chapter 1 Introduction

1.1 Overview

US-1680 AI-Libre Urinalysis System (hereinafter referred to as Urinalysis System) is in vitro diagnosis instrument with high automation for trained medical professionals. Routine urine analysis for urine samples, quantitative and qualitative analysis for Urine Sediment can be completed with one sampling.

1.1.1 Structure and Composition

It consists of automatic feeding mechanism, automatic selection mechanism, test strip transmission detector, waste collection mechanism, fluid system, microscopic imaging system, identification software, analysis software, control system, and input and output parts.

1.1.2 Intended Use

The analysis system applies to the quantitative and qualitative analysis for sediments in human urine. Also, it can be used together with the urine analysis test strips for semi-quantitative or qualitative detection of biochemical components in urine samples.

The items that can be tested include:

No.	Sediment items	Full name	Sub No.	Sediment subclass	Full name
1	RBC	Red blood cell	1	/	/
2	DRBC	Dysmorphic RBC	2	G1	G1 cells
			3	Coin	Coin cells
			4	Ghost	Ghost cells

3	WBC	White blood cell	5	/	/
4	WBCC	White blood cell clumps	6	/	/
5	SQEP	Squamous epithelia cells	7	/	/
6	NSQEP	Non-squamous epithelial cells	8	/	/
7	HYA	Hyaline cast	9	/	/
8	PAT	Pathological cast	10	GRAN	Granular cast
			11	WAXY	Waxy cast
			12	CELL	Cellular cast
9	CAOX	Calcium oxalate crystals	13	CaOxm	Calcium oxalate monohydrate crystals
			14	CaOxd	Calcium oxalate dihydrate crystals
10	URIC	URIC acid crystals	15	/	/
11	STRUVITE	/	16	/	/
12	AMOR	Amorphous crystals	17	/	/
13	OTCRY	Other Crystals	18	CaPh	Calcium Phosphate Crystal
14	BACT	Bacteria	19	Cocci	/
			20	Scoccus	Streptococcus
			21	Bacilli	/
15	YST	Yeast	22	/	/
16	MUCS	Mucus	23	/	/
17	SPRM	Sperm	24	/	/
18	OTHER	Other	25	/	/

In addition, the items that can be measured include:

- Ascorbic Acid
- Nitrite
- Microalbumin
- Leucocytes
- Creatinine
- Ketone
- Urobilinogen
- Bilirubin
- Glucose
- Protein
- Specific Gravity
- pH
- Blood
- Calcium
- Microalbumin-to-Creatinine Ratio (ACR)
- Protein-to-Creatinine Ratio (PCR)

The analysis system can also test physical items:

- Specific Gravity
- Color
- Turbidity
- Osmotic pressure
- Conductivity

It can also be used to test cerebrospinal fluids, pleuroperitoneal fluids and gynecological secretions. The test results are as follow:

Cerebrospinal fluids	RBC, WBC
Pleuroperitoneal fluids	RBC, WBC
Gynecological secretions	RBC, WBC, EP, BACT

1.1.3 Main Technical Parameters

Index	Functional Performances
Chemistry test items	Ascorbic Acid, Nitrite, Microalbumin, Leucocytes, Creatinine, Ketone, Urobilinogen, Bilirubin, Glucose, Protein, Specific Gravity, pH, Blood, Calcium. Microalbumin-to-Creatinine Ratio (ACR), Protein-to-Creatinine Ratio (PCR).
Urine Sediment test items	RBC, DRBC(G1, Coin, Ghost), WBC, WBCC, SQEP, NSQEP, HYA, PAT(GRAN, WAXY, CELL), CAOX(CaOxm, CaOxd), URIC, STRUVITE, AMORF, OTCRY(CaPh), BACT(Cocci, Scoccus, Bacilli), YST, MUCS, SPRM, OTHER.
Physical measurement items	Specific gravity, Color, Turbidity, Osmotic pressure, Conductivity.
Body fluids test items	cerebrospinal fluids: RBC, WBC. pleuroperitoneal fluids: RBC, WBC. gynecological secretions: RBC, WBC, EP, BACT.
RBC morphology test items	MCV, MCV-CV, R-RATE and RBC volume distribution histogram can be measured and displayed.
Urine Sediment measurement principles	Principle of automatic recognition of digital imaging. Flow and deep learning AI recognition technology.
Urine Chemistry measurement principles	CIS image scanning analysis technology
Refractometer measurement principle	Specific gravity : refractometer method Turbidity: scattering method + transmission method Color: RGB three primary color method
Wavelength of chemistry testing	720nm、620nm、570nm、550nm、470nm
Testing speed	Urine chemistry test mode: 300 samples/ hour Urine sediment test mode: 120 samples/ hour

	United test mode: 120 samples/ hour
Required sample volume	Urinalysis test mode: 1.5mL Urine Sediment test mode: 2mL United test mode: 2mL
Puncture sampling	Puncture the test tube sealed with film
Storage capacity	At least 400,000 results (including urine sediment images and urinalysis strips images)
Applicable test strips	URIT 11FA、 URIT 12FA、 URIT 14FA
Data interfaces	Mouse interface, keyboard interface, USB interface, serial port, network interface, video output port, audio output port.
Operating environment	Indoor Temperature: 5°C~40°C Relative humidity: ≤85% Power supply: AC100V-240V, 50/60Hz

1.1.4 Principle

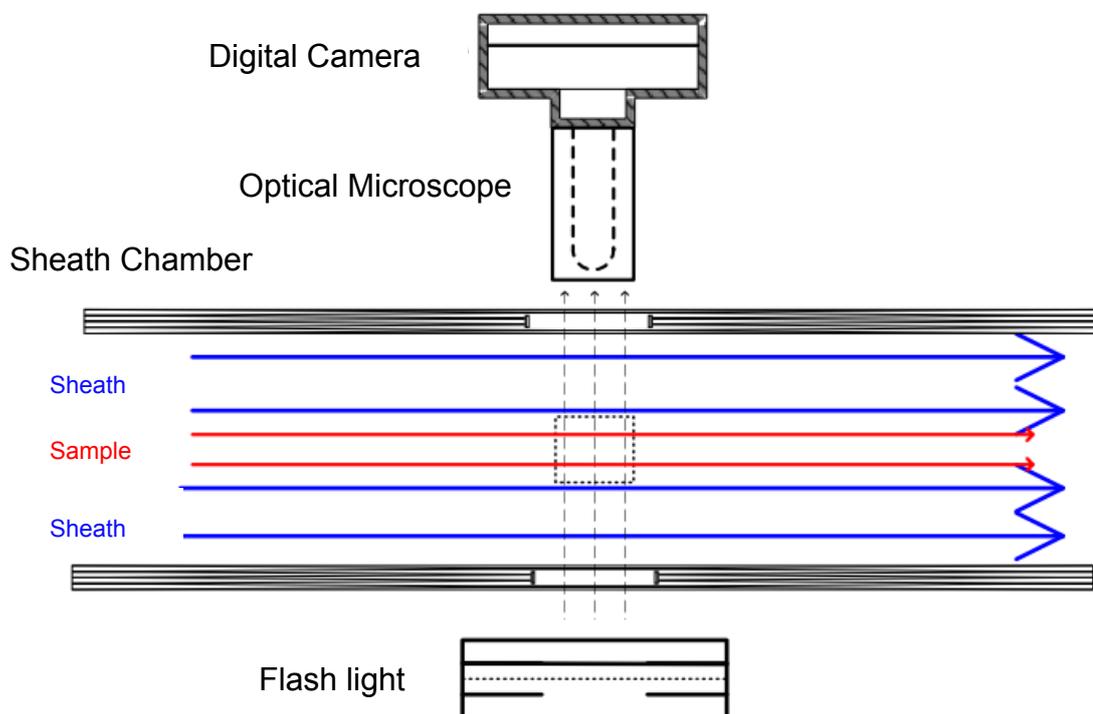
1) Urine Sediment measurement principle

Adopt the principle of automatic recognition of digital imaging and flow and deep learning AI recognition technology. Using planar flow technology, fluid system actuates sheath and sample under test to form sheath--sample--sheath laminar flow in sheath flow chamber, and restrains the thickness of sample laminar flow to make sediments in sample solution flow in single-layer status. Stable tiled single-layer laminar flow is an important guarantee of clear image.

Optical system and digital camera constitutes digital imaging system. It shoots sample's sediments in shooting area of sheath flow regulator rapidly and clearly.

Advanced deep learning AI recognition system can identify and classify sediments. Its highly optimized recognition algorithm guarantees accuracy of classification. Meanwhile, system can save original drawing and the

recognized sediment images for results audit and recalls.



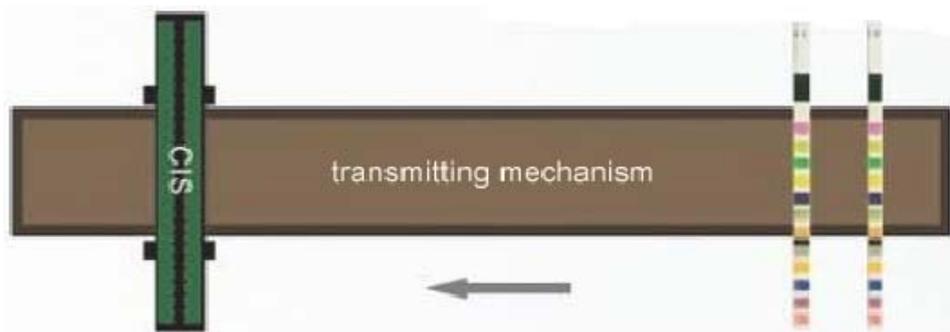
2) Urinalysis Measurement Principle

Urinalysis measurement principle is CIS image scanning analysis technology.

Placing tube racks loaded with samples on the rack puller and clicking the Start button, the instrument will automatically perform a series of operations, such as transmitting samples, selecting strips, reading barcode, aspirating samples, dropping samples, measuring samples and printing test results, until all tube racks are done. During the measurement, the reacted pads on strips (calibration pad is not involved in reaction, just for reference) will change colors as a result of chemical reaction within 60 seconds. The instrument scan each strip pad and semi-quantitative results can be obtained by image analysis technology and photoelectric colorimetry.

Urinalysis measurement system adopts CIS image sensor, which is composed of a row of photoelectric sensor array, LED light source array and columnar lens array. During measurement, the test strip passes through the

sensor detection area at a uniform speed, and the LED light source array can obtain specific monochromatic light by switching light sources with different wavelength and then irradiate it on the test strip. The absorbent and reflective light amounts vary with the color of reagent pads. If the color is darker, more light is absorbed, and less light is reflected, vice versa. i.e., the degree of color development is proportional to the concentration of analytes in urine.



The reflected light of test strip enters photoelectric sensor array and the optical signals are transformed into electrical signals. The intensity of the current is related to the intensity of light reflection. Then the current signals are transformed through I/V converter and processed by CPU. By scanning the test strip comprehensively, the reaction image of the test strip is obtained, the image analysis and reflectance calculation are carried out, and the detection results were obtained. The reflectance is calculated using the following formula:

$$R\% = \frac{T_m \cdot C_s}{T_s \cdot C_m} \times 100\%$$

R: Reflectance

T_m: Reflective light amount at the reactive pad with the measurement wavelength.

T_s: Reflective light amount at the reactive pad with the reference wavelength.

C_m: Reflective light amount at the calibration pad with the measurement wavelength.

C_s: Reflective light amount at the calibration pad with the reference wavelength.

3) Specific gravity measurement principle

Specific gravity test method adopts refractometer, using the correlation between light refractive index and total solids in the solution to determine. Refractometer method is available at the temperature range of 15 °C ~ 38 °C. It can be calibrated by the temperature compensation device before use; can be calibrated by known standard high specific gravity concentration solution and standard low specific gravity deionized water. It's easy to standardization and the required sample volume is small, which especially suitable for patients with oliguria and pediatric patients. Refractometer method is recommended as reference method by Clinical Laboratory Standard Institution, CLSI and Chinese Committee for Clinical Laboratory Standards, CCCLS.

Specific gravity measurement principle is based on the principle of different concentrations of urine sample which have different refractive indexes to measure, that is uses the same wavelength of monochromatic parallel light comes into the triple prism which contains urine sample, and then according to position of refracted ray in photoelectric technology detector(displacement sensor)to determine the specific gravity value. Specific gravity measurement principle functional block diagram is shown in Figure 1-1 below.

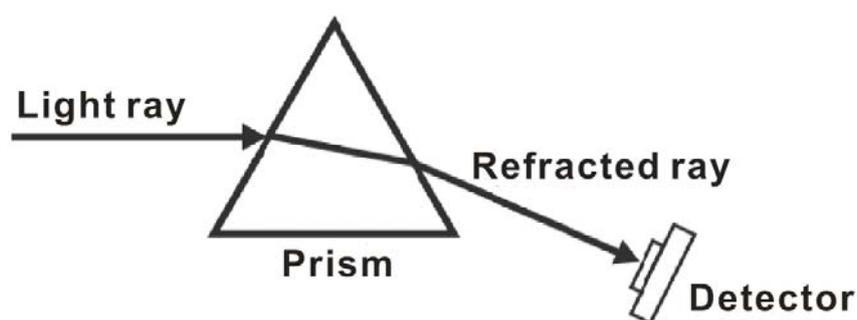


Figure 1-1 Specific Gravity Measurement Principle

Specific gravity results are calculated by the following formulas:

$$SG_x = (SG_H - SG_L) \cdot (K_x - K_L) / (K_H - K_L) + SG_L \text{ (Formula1)}$$

Formula 1 can change to: $\frac{SG_x - SG_L}{SG_H - SG_L} = \frac{K_x - K_L}{K_H - K_L}$ (relationship between

them is linear)

SG_H : The specific gravity of high concentration solution

SG_L : The specific gravity of low concentration solution

SG_x : The specific gravity of sample solution

K_H : High concentration solution position coefficient

K_L : Low concentration solution position coefficient

K_x : Sample solution position coefficient

Position coefficient: It is calculated by the data output by detector, and has a linear relationship with the refractive index.

Refractive index change depends on the temperature of the sample solution, and the specific gravity value is using the following formula to correct.

$$SG_t = SG_x + (T_{SAM} - T_{STD}) C_t \text{ (Formula 2)}$$

SG_t : The specific gravity of high concentration solution

SG_x : The specific gravity of low concentration solution

T_{SAM} : The temperature of sample solution

T_{STD} : The temperature of low concentration solution

C_t : Temperature coefficient (SG 0.001/3° C)(temperature coefficient)

If the urine sample contains large amounts of glucose or protein, the specific gravity will be affected. According to WS/T 229-2002 "Physical, chemical and microscopic examination of urine" 5.4.1 requirements: 1 g/L protein will increase urine specific gravity 0.0003, 1 g/L glucose will increase urine specific gravity 0.0004. So the specific gravity results will be corrected through the glucose and protein level which was measured by the test strip.

$$SG = SG_t - C_{GLU} - C_{PRO} \text{ (Formula 3)}$$

SG: Specific gravity value which after the temperature compensation

SG_t : Specific gravity value which gets from formula 2

C_{GLU} : Glucose correction value

C_{PRO} : Protein correction value

4) Turbidity measurement principle

It adopts scattered light- transmission light comparison measurement method. This method can simultaneously measure the intensity of the scattered light and the transmitted light. Based on Lambert beer law and scattering law, the turbidity was measured according to the ratio of these two intensities. It can not only eliminate the influence of light source aging on the measurement accuracy, but also correct the interference caused by chromaticity or light-absorbing material, and reduce the shift. Besides, it gives full play to the advantages of scattering method and transmission method, and can provide a measurement method suitable for solutions with low turbidity to high turbidity, effectively improving the adaptability and accuracy of measurement.

Light emitted from turbidity module goes through the sample. The intensity of scattered light is detected in the direction of 90° with the incident light, and the intensity of transmitted light is detected in the direction of 180° with the incident light. According to the intensity ratio of scattered light and transmitted light, the turbidity value is calculated. Turbidity measurement principle diagram is shown in Figure 1-2 below.

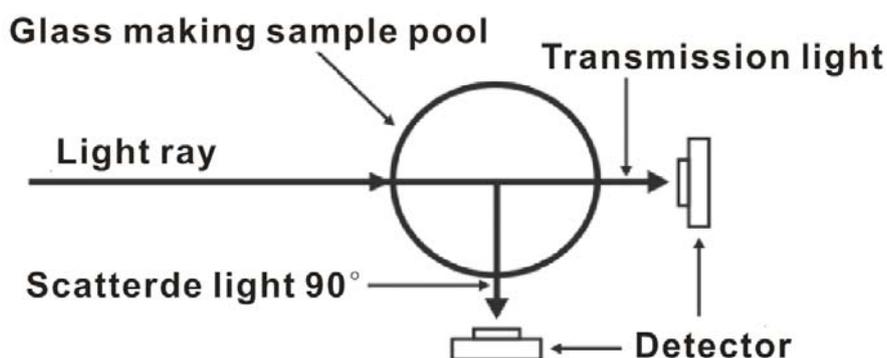


Figure 1-2 Turbidity Measurement Principle

Turbidity result is calculated by the following formula:

$$T = (S_s / T_s - S_w / T_w) / K$$

T : Turbidity level

S_s : Sample scattered light level

Ts : Sample transmission light level

Sw : Flushing fluid scattered light level

Tw : Flushing fluid transmission light level

K : Coefficient factor

5) Color measurement principle

It adopts RGB three-primary colors method. Primary colors are the "basic color" which cannot be gotten by other colors mixed. Mix the primary colors in different proportion will get other new colors. Three primary colors of light are RGB (Red, Green, and Blue). Equivalent red light +green light=yellow light, green light +blue light = cyan light. Equivalent red light +blue light = magenta lights, equivalent red +green+ blue=white, and if the intensity of these three light is zero, it is black (dark).

When the white light through colored solution, the non-solution colors light will be absorbed, so the color of the light through the solution can be expressed as the color of the solution, and then the solution color can be detected by the professional color recognition sensor (filter) which in the back-end of the solution. Color measurement principle diagram is shown in Figure 1-3 below.

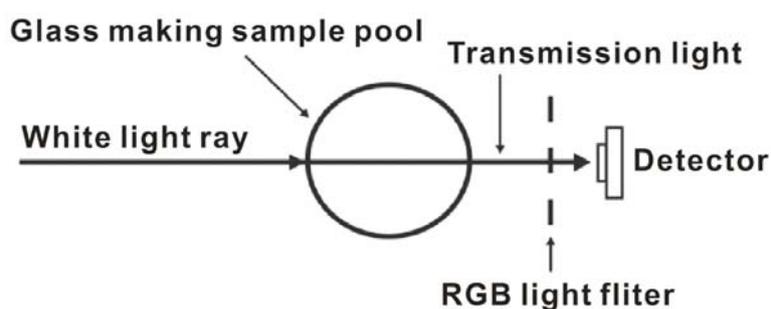


Figure1-3 Principle of Color Detection

6) Conductivity measurement principle

It adopts impedance method. According to Ohm's law, it stimulates the urine in conductivity cell with voltage. The corresponding impedance value is got by ACD sampling and statistic conversion of data. Then calculate the

conductivity value based on the relationship amount conductivity, impedance value and conductivity cell constant.

Schematic diagram of conductivity cell is shown as Figure 1-4.

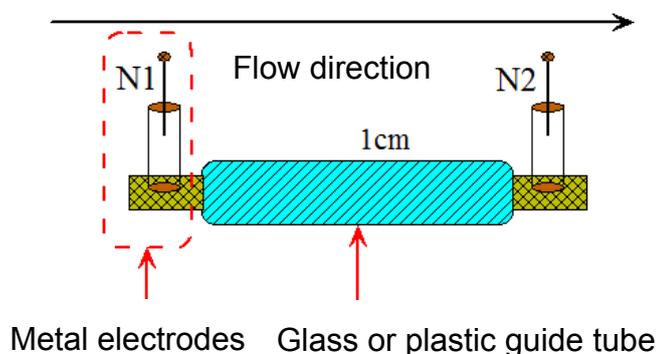


Figure 1-4 Conductivity cell

N1 and N2 are electrodes of conductivity cell, by which the current I through urine can be measured.

Conductivity result is calculated by the following formula:

$$\kappa = k \times G = k \times \frac{1}{R} = k \times \frac{1}{(U_o / I) - R_f}$$

$$U_o = ADC \times \frac{V_A}{4096}$$

$$I = \frac{U_o - U_i}{R_f}$$

k : Conductivity cell constant

R_f : Feedback resistance

ADC: Sampling value

V_A : Reference voltage

U_i : Input voltage

7) Osmotic pressure measurement principle

Osmotic pressure indicates the number of particle (osmotic particles) in the solution, which has no concern with the type, size and its charge. It mainly depends on the content of electrolyte in urine. The main substance which affects osmotic pressure is crystalline solute, especially ionized particle. Substances which cannot be ionized and macromolecular

substances (except glucose) have little effects on it, so it's negligible. Therefore, there is a good linear relation between osmotic pressure and conductivity, and the corresponding osmotic pressure can be worked out based on the measured glucose concentration. Osmotic pressure result is calculated by the following formula:

$$OSM = a \times \kappa + b \times C_{GLU}$$

a: Coefficient of association between conductivity and osmotic pressure

b: Correction coefficient of glucose content

C_{GLU} : Glucose concentration

1.1.5 Main Performance Indexes

1.1.5.1 Blank Test

Testing normal saline and deionized water, the results of each sediment should be less than 1/ μ L.

1.1.5.2 Detection Line

For RBC and WBC, detection limit should be 5/ μ L.

1.1.5.3 Repeatability

- Repeatability of chemistry measurement

Coefficient of variation (CV) of analyzer reflectance test results $\leq 0.8\%$.

- Repeatability of Urine Sediment measurement

CV of test results should meet requirements in Table 1-1.

Table 1-1 CV

Sediment	CV	
	Concentration	Requirement
	600/ μ L	$\leq 5\%$

- Repeatability of Specific gravity measurement(Optional)

For the adopted urine specific gravity control solution, CV should be $\leq 0.5\%$.

1.1.5.4 Accuracy

- Chemistry Measurement

Detect the accuracy of the test strip with the adapted urine analyzer. The difference between the test result and the reference value of the corresponding reference solution does not exceed one order of magnitude, and there shall be no reverse difference. There is no negative result for the positive reference solution and no positive result for the negative reference solution.

- Urine Sediment Measurement

Accuracy should meet requirements in Table 1-2.

Table 1-2 Accuracy

Sediment	Accuracy	
	Concentration	Allowable deviation
RBC	200/ μL	$\pm 15\%$
	600/ μL	$\pm 5\%$

- Specific gravity measurement(Optional)

In the linearity range of 1.000~1.055, the allowable deviation should be no more than ± 0.002 .

1.1.5.5 Carryover

Measure the positive samples in urinalysis test items with the highest concentration, and then measure negative samples. The negative sample cannot be positive (except for specific gravity and PH). Carryover of Urine Sediment measurement should be $\leq 0.05\%$.

Chapter 2 Precautions, Limitation and Hazards

Improper operation will not accomplish optimal performance, even cause damage to the operator or others. To avoid the damage and get a successful measurement, a criterion should be designed to perfect the service conditions.

2.1 Limitations

- 1) US-1680 is designed for in vitro diagnostic use.
- 2) Any operation, shipment, installation or maintenance must strictly follow the contents outlined in this manual, or if any problems derived from that, URIT will not offer free warranty.
- 3) All reagents assigned or recommended by URIT have been inspected strictly for optimal performance. Substitution for reagents, controls and calibrators and components recommended by other companies may adversely affect the performance of the instrument or cause incidents, thus lose the free warranty.
- 4) Any repairing must be permitted and any accessory replacement must be specified by URIT, if any problems derived from that, URIT will not offer free warranty.
- 5) Follow the recommended maintenance schedules and procedures. Any incompliance will shorten the life span and affect the test results, or cause incidents, thus lose the free warranty.

2.2 Installation Limitation

- 1) A URIT authorized Engineer must perform the initial installation.
 - Away from direct sunlight,
 - Away from path of a cooled or heated air outlet with temperature extremes

- Away from drying ovens, centrifuges, x-ray equipment, copiers or ultrasonic cleaner.

- 2) Adequate space should be provided around the instruments. Keep at least 40cm away from the surrounding objects for proper ventilation. 3 square meters workbench is needed to place instruments and reagents.
- 3) Before operating the instruments for the initial measurement, verify that power cord and network cable is connected properly, reagent connection is correct and reliable. Make sure the outlet tubing is not twisted and the waste tubing is connected to the appropriate outlet and routed to a suitable waste container.
- 4) Don't pull and plug any connectors when instruments are in power-on state.

Note

- Anyone without authorization of URIT should NOT remove the screws on the cover, or the customer must take all the responsibility.
-

2.3 Personnel Protection and Infection Control

a) Follow required laboratory or clinical procedures during daily operation or maintenance. Wear gloves, lab clothing and safety glasses to avoid direct contact with the samples.

b) Consider all the clinical specimens, controls and calibrators etc, that contain human blood or serum as being potentially infectious, wear standard laboratory clothing, gloves and safety glasses and follow required laboratory or clinical procedures when handling these materials. Do not smoke, eat or drink at working area. Do not suck or blow the tubing.

c) Since the blood samples and waste have potential source of biological and chemical hazard, the operator should handle with extreme care during the

disposal process and follow regulations of the local government when cleaning, handling, discharging.

d) Follow the manual to keep reagents from deterioration, misapplication or eating by mistake. The reagent should be away from temperature extremes.

e) During sample testing and routine maintenance, the user should pay attention to the label of "Prick" on the sampling mechanism. Please avoid damage by moving sample probe when you place the sample.

f) The instrument is equipped with a bar code scanner with laser warning label. Avoid look directly at the laser.

Note

- Reagent will freeze when it is below 0°C, for which the reagent cannot be used.
 - Keep the reagents away from direct sunlight to avoid evaporation and contamination. Seal the cap of the container. Minimize the diameter of the hole to avoid evaporation and contamination.
-

Chapter 3 Installation

Initial installation of instruments must be performed by a URIT authorized engineer or representative to ensure that all system components are functioning correct and to verify system performance. Installation procedures must be repeated if the instruments are moved from the original installation site.



- Installation of the analyzer by unauthorized or untrained personnel by URIT could result in damage to the analyzer which is exclusive of the warranty. Never attempt to install and operate the analyzer without a URIT authorized representative.
-

3.1 Unpacking and Inspection

Carefully remove the instruments and accessories from shipping cartons, keep the kit for further transport or storage. Check the following:

- Quantity of accessories according to the packing list;
- Leakage or soakage;
- Mechanical damage;
- Bare lead, inserts and accessories.

Do contact URIT after-sale department if any problem occurs.

3.2 Installation Requirements

Please refer to *Section 2.2*.

WARNING

- Not for home use.
 - Not for therapy.
-

CAUTION

- Keep the analyzers away from direct sunlight.
 - Avoid temperature extreme.
 - Keep away from centrifuge, X-ray equipment, or copier, which will interfere with the normal operation of the analyzer.
 - The side lock door cannot be opened during the test.
 - Do not place it at the place where switch is hard to cut off.
-

3.3 Power Supply Inspection

Be sure that the power supply meets requirements before installation
See Table 3-1 for details.

Table 3-1 Power Supply Requirements

Optimum voltage	Voltage Range	Frequency
AC 220V	AC 100V-240V	50/60Hz

Note

- The grounding post on the rear panel of the instrument must be directly connected to the grounding system of the user through the grounding wire. The user is obliged to ensure the reliability of the power supply protection ground of the instrument.
 - Frequent fluctuations of voltage will lead to a decrease in the performance and reliability of the instrument. Users should solve this problem before using the instruments, such as installing the ac voltage stabilizer (provided by the user).
 - Frequent interruptions in power can result in severe degradation of instrument performance and reliability. Users should resolve this issue before using the instruments, such as installing an uninterruptible power supply (UPS).
-

3.4 Tubing Installation

There are three tube-connectors on the rear panel of instrument: SHEATH, WASTE and SENSOR. Each of which is wrapped with a cap by URIT to avoid contamination before shipment. Uncover and set the caps aside carefully for further use on initial installation.

3.4.1 SHEATH Tubing Connection

Remove the sheath tube with yellow connector from the reagent package and connect it to the interface labeled "SHEATH" on the rear panel of the instrument. Connect the other end of the tube to the sheath tank and tighten the bottle cover.

3.4.2 WASTE Tubing Installation

Remove the waste tube with black faucet from reagent package and connect it to the interface labeled "WASTE" on the rear panel of the instrument, connect 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 the level at least 50cm lower than the analyzer.

Note

- Keep all tubes in the natural state after installation. Do not forcibly twist.
 - Do not use any tools but with hands to install the line joints.
 - If found any abnormal occurrences, such as reagent bottles broken, weeping or beyond warranty period, please stop use it and contact the URIT after-sale department for changing.
-



- To prevent waste liquid damage to the environment, it is forbidden to pour it directly into the sewer. The waste liquid should be treated with biological or chemical processing before discharging into sewer. It is an obligation for hospitals and labs to abide by the relevant regulations of local government.
-

3.5 Installation of IPU, Display, Keyboard and Mouse

Carefully take out the host, monitor, keyboard, mouse, etc. from the packing box, install the keyboard and mouse respectively on the port corresponding to the host, and connect the monitor with the VGA port using the

VGA line.

It is recommended to place the keyboard beneath the display.

3.6 Power Connection

Make sure the power switch is OFF (O) and the grounding terminal on the rear panel is well grounded firstly, and then connect the analyzer to the main power with the power cable.

Chapter 4 Part Name and Function Introduction

4.1 Instrument Instruction

4.1.1 Instrument Composition

The structure of the instrument is shown in Figure 4-1.

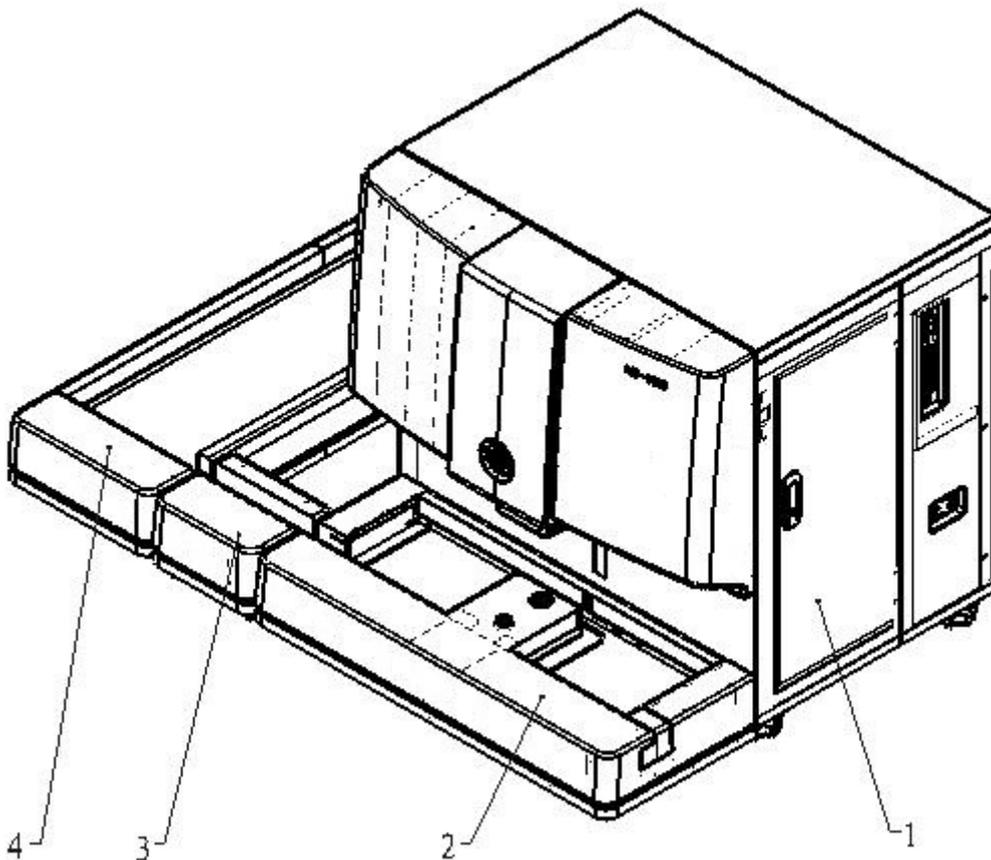


Figure 4-1 Instrument composition

1) The main unit of the instrument

The main unit of the instrument is used to test samples, with selection mechanism, detection mechanism and fluid system mechanism inside.

2) Sample Loader

The sample loader is used to push the test tube rack for testing, scan the test tube rack number and detect the presence or absence of the test tube. The sample loader is equipped with an emergency test function. It can be used independently but not with sample extension racks, and can be placed up to 6 rows of test tube racks. Also, it can scan the barcode of test tube.

3) Cross Structure

For facilitate removing waste strip box, the transition rack is added for the convenience of pushing the tube racks to the extension rack.

4) Expansion Rack

It's used to store the tested tube racks temporarily.

4.1.2 Front Panel

The front panel structure of the instrument is shown in Figure 4-2.

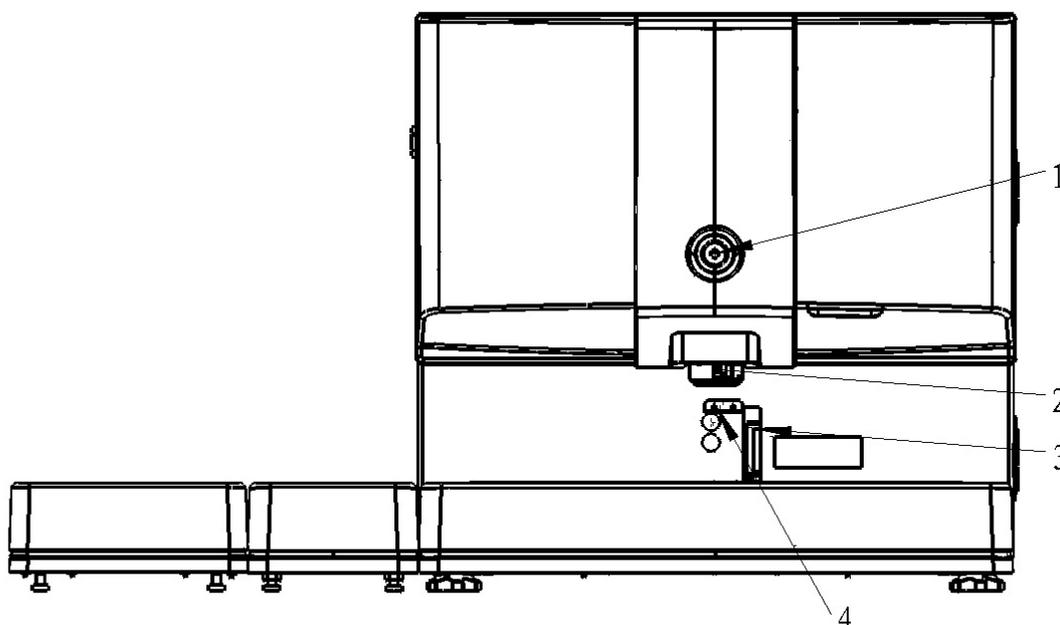


Figure 4-2 Instrument front panel

1) Indicator Light

The indicator light is used to display the working status of the instrument. The status is described in Table 4-1.

Table 4-1 Description table of the indicator light status

Indicator light status	Description of instrument status
Red, always bright	Error or warning arise and haven't been solved.
Green, always bright	Standby or idle
Green, flashing	Working (busy)
Blue, flashing	Initializing(from standby to turn on / when it is reset).
Blue, breathing	Sleeping or node.

- 2) Sample probe outlet
The probe extends to sample from it.
- 3) Barcode scanning position
It's used to scan the sample information of the tube.
- 4) Baffle of puncture sampling
It prevents the test tube being taken when puncture sampling.

4.1.3 Rear Panel

The rear panel structure of the instrument is shown in Figure 4-3.

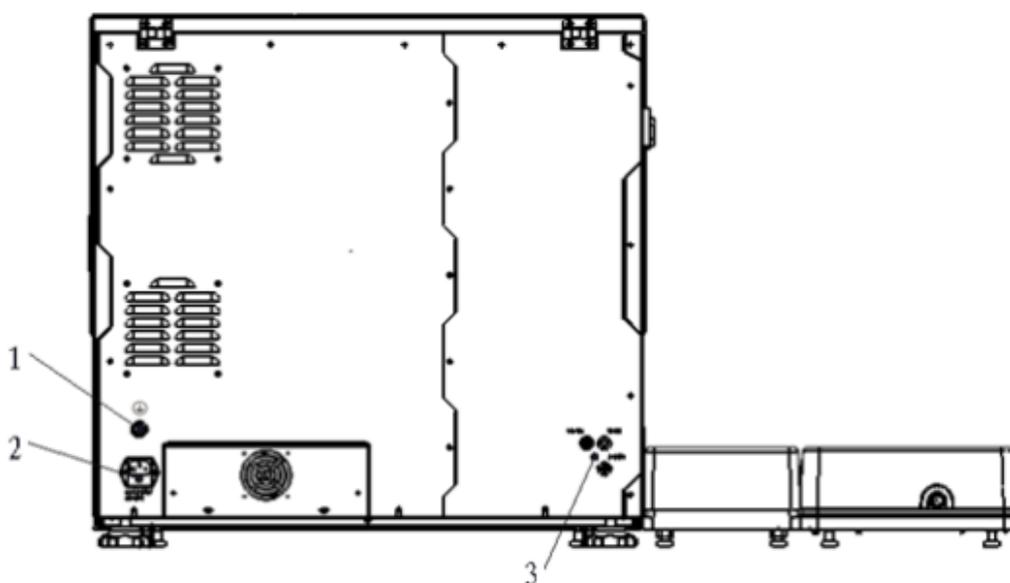


Figure 4-3 Instrument rear panel

- 1) Protective conductor terminal
It's used to connect the instrument and hospital ground system.
- 2) Power interface
Three-core power socket, can be connected to three-core power cord.
- 3) Fluid system interface
It is used to connect external reagents and remove waste liquid. For details, please refer to Figure 4-4 below.

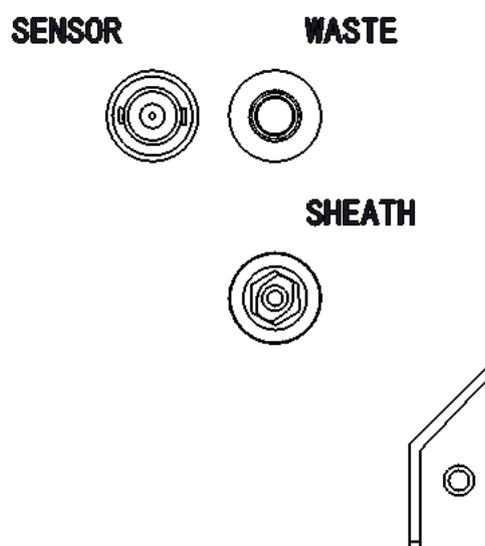


Figure 4-4 Fluid system interface

SHEATH

The sheath interface is connected with the sheath fluid.

SENSOR

The waste liquid sensor interface is connected with the waste liquid sensor to detect whether the waste liquid in the waste liquid bottle is full.

WASTE

The waste liquid interface connects the waste liquid pipeline and discharge the waste liquid.

4.1.4 Side Panel

The instrument side panel structure is shown in Figure 4-5.

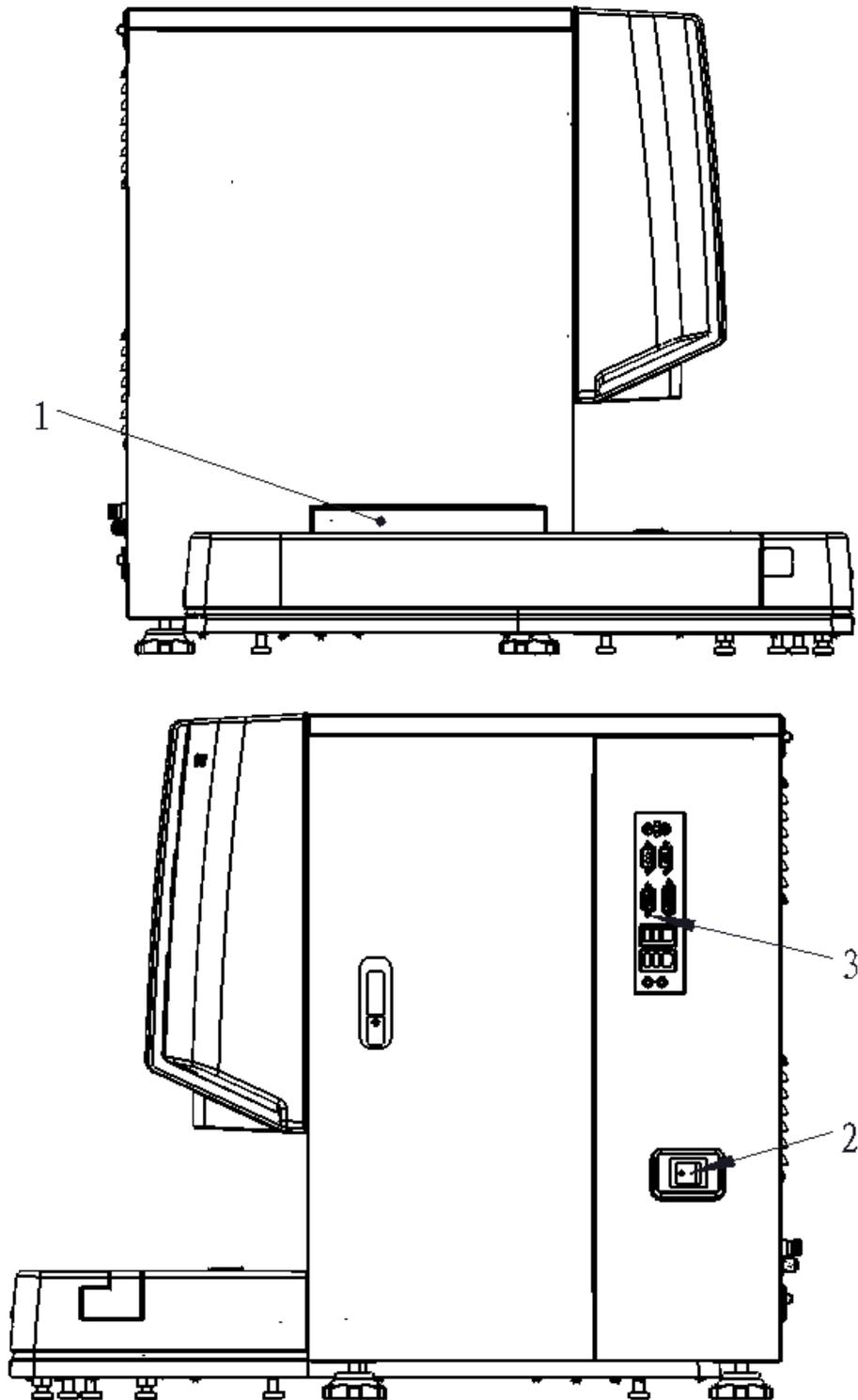


Figure 4-5 Instrument side panel

1) Waste strips box

Store waste test strips.

2) Power switch

Main Power switch

3) Input/output interface

The specific definition of input/output interface is shown in Figure 4-6 below.

(1)Voice output

(2)Voice input

(3)Network interface

(4)USB

(5)DVI interface

(6)VGA video interface

(7)Serial port COM 1

(8)Serial port COM 2

(9)Mouse interface

(10)Keyboard interface

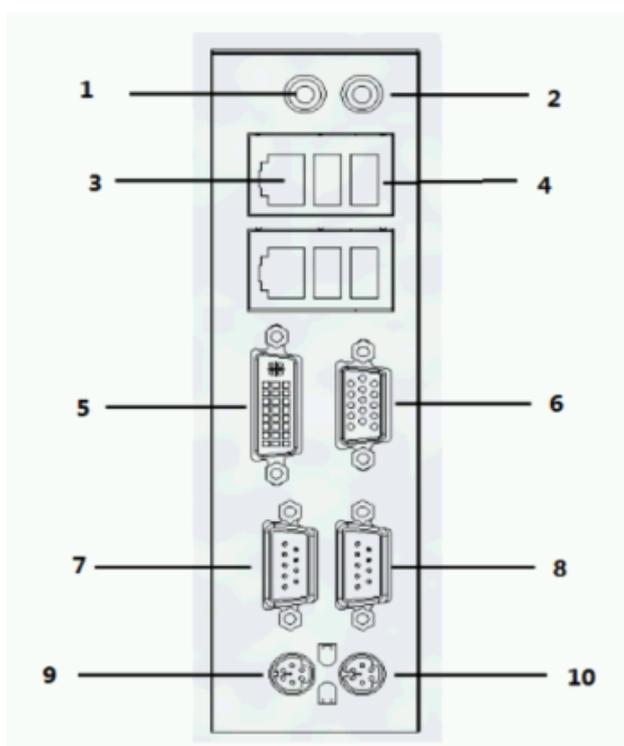


Figure 4-6 Input/output interface

4.1.5 Top Panel

The structure of top panel is shown in Figure 4-7.

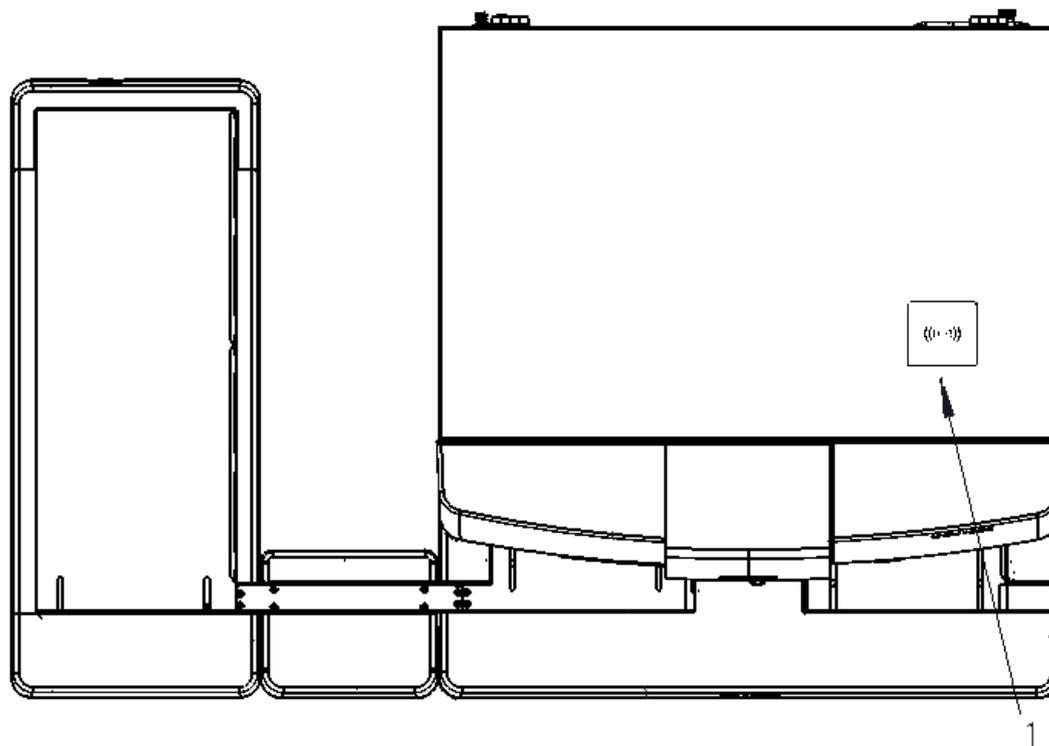


Figure 4-7 Top Panel

1) Activation Area

For reading sheath activation card.

4.1.6 Sample loader

This section mainly introduces the standard sample loader module of this instrument, the optional extension rack and cross structure, and the sample rack module does not need to be installed by users. Sample loader module can be connected to expansion rack with cross structure.

Sample loader module and optional expansion rack are shown in Figure 4-8.

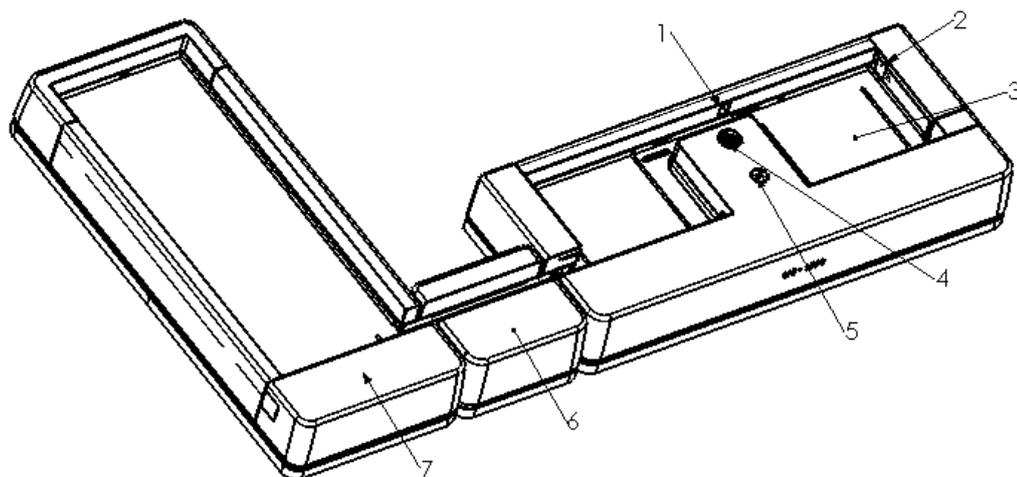


Figure 4-8 Sample loader module and optional expanding rack

- 1) Photoelectric sensor detection
For detecting the presence and absence of the tubes in corresponding position.
- 2) Test tube rack No. detection
For scanning test tube rack No..
- 3) Inlet of test tube rack and storage area for racks that need to be tested.
Area for test tube racks inlet and for the storage of racks that need to be tested. It can place 6 rows of test tubes at most.
- 4) Hole for emergency tube
For placing emergency test tube.
- 5) Emergency button
For controlling emergency test.
- 6) Cross structure
It's used to transit the tested tube racks from sample loader to storage rack.
It's used for the convenience of removing waste strip box.
- 7) Storage area for tested tube racks
For storage of tested tube rack, up to 20 rows of test tube rack can be stored.

4.2 Main structure and Composition of the Instrument

The analysis system consists of automatic feeding mechanism, automatic selection mechanism, test strip transmitting detection mechanism, waste collection mechanism, fluid system, photomicrographic system, recognition software, analysis software, control system and output/input parts.

4.2.1 Automatic Feeding Mechanism

It consists of test tube rack induction device, rack No. scanning device and test tube detection device.

4.2.2 Automatic Selection Mechanism

It consists of roller, strip rotor, strip recognition sensor and rotary encoder.

4.2.3 Test Strip Transmitting Detection Mechanism

It consists of recognition mechanism, round belt conveyor and imaging sensor detection mechanism.

4.2.4 Waste Collection Mechanism

It consists of waste box and identifiers, using for the collection of waste strips.

4.2.5 Fluid System

It consists of solenoid valve, plunger pump, force pump, vacuum pump and plastic tubes.

Solenoid valve: contact two-way/ three-way solenoid valve control fluid circulation.

Plunger pump: for pushing sample and sheath to sheath regulator, and pushing samples to SG module.

Force pump: for pumping sheath to liquid tank from reagent container.

Vacuum pump: for pumping waste liquid produced in the process of measurement to waste container.

Plastic tubes: carrier of reagents and waste liquid.

4.2.6 Photomicrographic System

It consists of xenon flash lamp, light control mechanism, sheath regulator control mechanism, objective lens, lens cone, camera and focus platform. It's mainly for displaying, enlarging, shooting and recording samples under test in sheath regulator.

4.2.7 Recognition Software

It's used to process, recognize and classify the shot images.

4.2.8 Analysis System

It's used for the optical detection and image analysis of strips.

4.2.9 Control System

Control system is mainly divided into information processor, fluid controller and switching power supply device.

◆ Information processor

It consists of a set of multi-core processor, taking charge of image processing operation, to ensure rapid and batch image processing.

◆ Fluid control system

It controls automatic sampling, taking charge of the switches of valves and pumps, to ensure that samples in chambers form stable sheath flow, which facilitates to image collection.

4.2.10 Input and Output

It includes interfaces of display, mouse, keyboard, printer, reagents and waste liquid containers.

4.3 Test Tube Rack

Test tube racks are dedicated. 10 standard hard tubes can be placed in each rack.

4.4 Required Reagent Volume

Sheath: about 20mL;

Detergent: about 5mL;

The required reagent is various according to the different version.

4.5 Testing Speed

Chemistry test mode is 300 samples at most per hour. Urine Sediment test mode is 120 samples per hour. United test mode is 120 samples per hour.

4.6 Storage Capacity

400, 000 test results at most (including urine sediment images and urinalysis strip images).

4.7 Normal Operation Environment

- 1) Temperature: 5°C~40°C
- 2) Relative Humidity: ≤85%RH
- 3) Atmospheric pressure: 86kPa~106kPa

4.8 Electrical Requirement

- 1) Power supply: AC 100V-240V 50/60Hz

- 2) Fuse: T3.15AL 250V
- 3) Power: 180VA-280VA

4.9 Reagent

The reagent is formulated specifically for the US-1680 in order to provide optimal system performance. Use of reagents other than those specified in this manual is not recommended as instrument performance can be affected. Each US-1680 is checked at the factory using the specified reagents and all performance claims were generated using these reagents. Thus, non-URIT reagents will lead to defects in the performance of the analyzer and serious mistakes, even accidents.

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, which changes the tonicity and conductivity of the reagents.

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

4.9.1 SHEATH

The sheath is mainly used for daily cleaning of the fluid system, the sheath flow regulator and sample probe, also it wraps sample to form sheath flow.

4.9.2 Control and Calibrator

Control and calibrator are for quality control and calibration. Control material is a kind of industrial reagent products, which is used to test whether the counting is normal or not. Calibrator is also a kind of industrial reagent products for calibration. Operation and storage methods please refer to the instruction of control and calibrator.

4.9.3 Reagent Specification

Name	Model/Specification
Urine test strip	URIT 11FA/URIT 12FA/URIT 14FA
Detergent	URIT D16
Sheath for Urine Analysis	URIT S11
Focusing Fluid for Urine Sediment Analyzer	URIT FC 23
Control Material for Urine Sediment Analyzer	*URIT QC 22
Calibrator for Urine Sediment Analyzer	URIT CA 21
UQ Urine QC solution	*UQ-14
Control material for urine analysis	**URIT YQ 3 ^{STC}
Calibration solution for urine analysis	**URIT YC 2 ST

*Please use the reagent, of which the specification is 8 mL.

**Use it when the analyzer is equipped with SG.

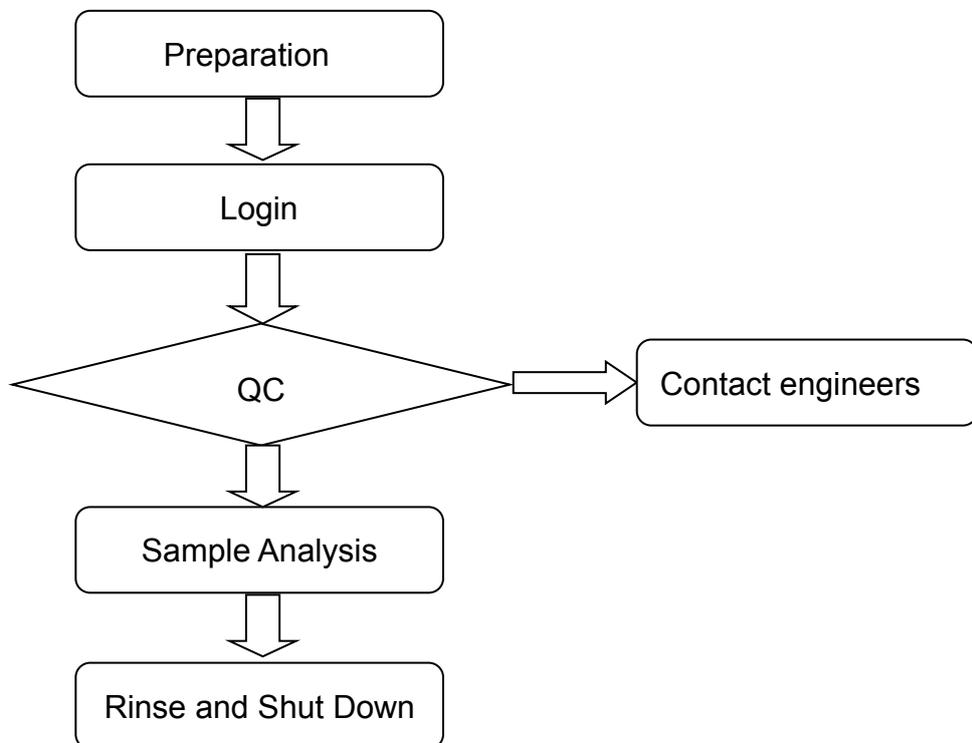
The "control material" and "calibrator" mentioned in this manual refer to the special control material and calibrator assigned by URIT. Users can purchase from URIT or agents designated by URIT.

Chapter 5 Daily Operation

5.1 Overview

This chapter presents the whole daily operation process from startup to shut down and emphasizes on sample analysis.

The procedure of daily operation is as follows:



5.2 Preparation

Before startup, the operator must check the analyzer according to the following requirements to make the analyzer ready.

Note

- Wear protective gloves to prevent infection.
 - Dispose of used gloves in accordance with local regulations.
 - To prevent bacteria infection, avoid urine samples contact body or being spilled on operators.
 - Avoid instrument being exposed in moist and hyperthermal environment for a long time. It should be installed in air-conditioned room where temperature and humidity meet technical requirements. In order to ensure the accuracy of test results, please keep the temperature and humidity of strips are in accordance with requirement.
 - Accuracy of test results cannot be ensured if the instrument site of instrument doesn't meet requirement.
-

5.2.1 Precautions

- If abnormal conditions are found, please turn off the power immediately to avoid damage to the instrument and short circuit.
- If the instrument malfunctions, please contact URIT. Do not attempt to repair the instrument by yourself. Any repair may damage the instruments.
- Do not place the bottle containing liquid on the instruments to avoid overturning, causing liquid to penetrate into the instrument.
- After completing the one-day measurement, daily routine maintenance must be performed to keep the instrument in the best condition.

5.2.2 Analysis System

- Check wastes
 1. Used strips

Pull out the waste strip box and check if there are used strips in it. If there

are, discard them.

2. Waste container

Waste container must be checked before startup, to make sure it's empty or has enough capacity.

● Consumable items

1. Sheath

Make sure there is enough sheath. If not, please replenish it.

2. Test strips

Prepare the test strips for measurement. Check if the strips type in selection mechanism is accordance with the required. If not, please empty selection mechanism and load with corresponding type. Fasten the cap and load strips in correct types.

Up to 500 strips can be loaded into selection mechanism. Please load moderate strips according to actual condition.

Note

- DO NOT touch the reagent pads on the strips.
- Load the strips in correct direction.
- Tighten the cap of strip canister to prevent strip from moisture.
- Please do not put too many test strips at one time. Too many test strips will affect the measurement speed of the instrument. It is best to place 100 test strips at a time.
- After completing the one-day measurement, put the remaining test strips in the test strip delivery slot back into the test strip canister and tighten the test strip cap to prevent from getting wet.

3. Desiccant

Take out the desiccants from the strip canister and put them into the desiccant boxes in the Strip Feeder. See Figure 5-1. Close the cover of the Strip Feeder and lock it.

Note

- The desiccant in the desiccant box should be replaced once a day.
 - When the ambient humidity is greater than 80%, the paper strip should be placed each time to check whether the desiccant in the desiccant box is invalid, if the desiccant has lost the effect please replace it in time.
-

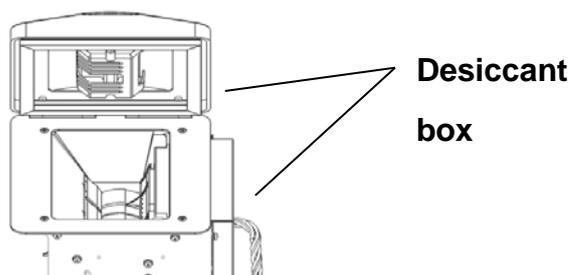


Figure 5-1

- Check tubes and power supply
Check whether the reagent tube and waste tube are connected firmly and without bending.
Check whether the power plug is well inserted into the power socket.
- Check printer
Check whether the printer is installed well, power supply and cable are connected well, and whether the printing paper is enough.
- Check Keyboard, Mouse and Display
Check whether the cable of keyboard, mouse and display is well connected with analyzer.

5.2.3 Samples

- A urine sample can be mixed well before measurement, but can't be centrifuged.
- Fresh urine sample should be collected as soon as possible with a clean and dry vessel. Placing the urine sample under room temperature should not exceed one hour, otherwise, keep it in the refrigerator with temperature

between 2°C~8°C and analyze it within two hours.

- DO NOT add any preservative, disinfectant or detergent to the samples.
- The urine sample should avoid exposing to direct sunlight.
- Injecting and taking Vitamin C may lead to the test results of NIT, BIL, GLU and BLD lower than the actual values or even false negative.
- DO NOT measure hematuria as residue in it may cause incorrect test results. The color tone of visually judged hematuria may not consist with the result with the instrument.
- Urine after a drug is taken may cause incorrect test results.
- Fill sample tubes with at least 2 ml urine sample. Correct test results may not be obtained if the volume of sample is insufficient.
- Place the sample tubes in a sample rack which is allowed to place ten tubes at most.
- If the barcode is to be scanned by the scanner built in the instrument, the bar code should be pasted 5mm below the tube mouth, (as shown in Figure 5-2), and the bar code should face to the instrument after it is pasted.
- Fill the sample into test tube sealed with film. The instrument has function of puncturing, so it can sample without taking off the cap.

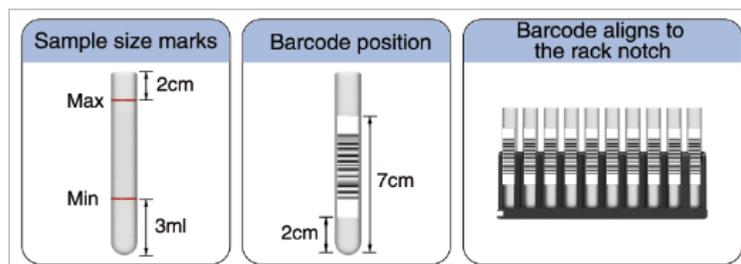


Figure 5-2

Note

- Insert the sample tubes straight in the bottom rubber cushions correctly. Otherwise, mechanical malfunction may be incurred.
- The bar-code label should be placed in correct position and face to bar

code reader.

- Place test tube rack

Place the tube racks to the platform on the right of feeding mechanism. The notch of rack should be clipped into the board on the right of feeding mechanism. The order of placement is from outside of sampling mechanism to inside, as shown in Figure 5-3. Up to 6 test tube racks can be placed.

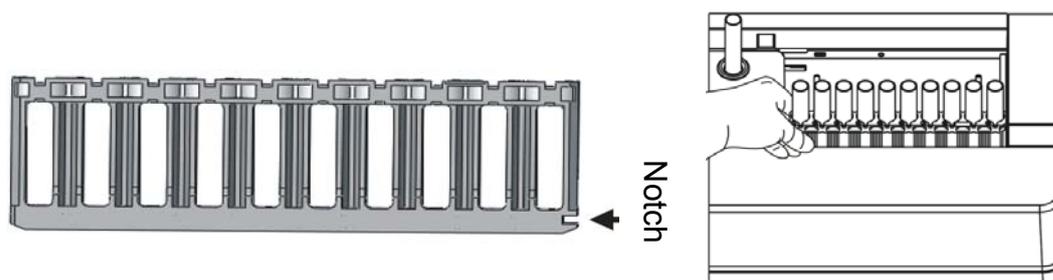


Figure 5-3

Note

- Please place the test tube rack correctly, otherwise the test tube rack may dump or sample probe may bump, which will damage the instrument.
 - If the urine sample overflows, wipe it clean before measurement, otherwise the urine may crystallize and affect the movement of the test tube rack.
-

5.3 Login

Power on

The interface of log in IPU is shown in Figure 5-4. Enter user name and password. For details please refer to *Section 6.2*.

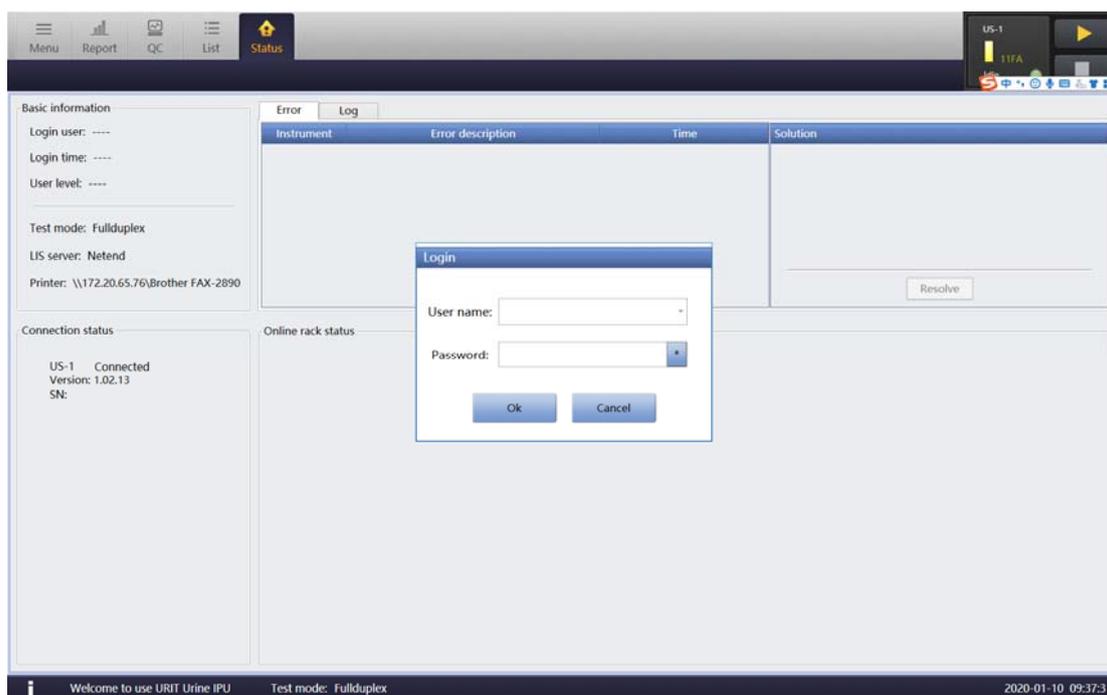


Figure 5-4 Log in

5.4 QC

To ensure reliable results, quality control analysis must be done every day before sample measurement. Details please refer to Chapter 7.

5.5 Menu

Overview: all operation interfaces of IPU can be entered from the menu interface, including report, QC, status, IPU setup, instrument setup and system setup. The interface is shown in Figure 5-5.

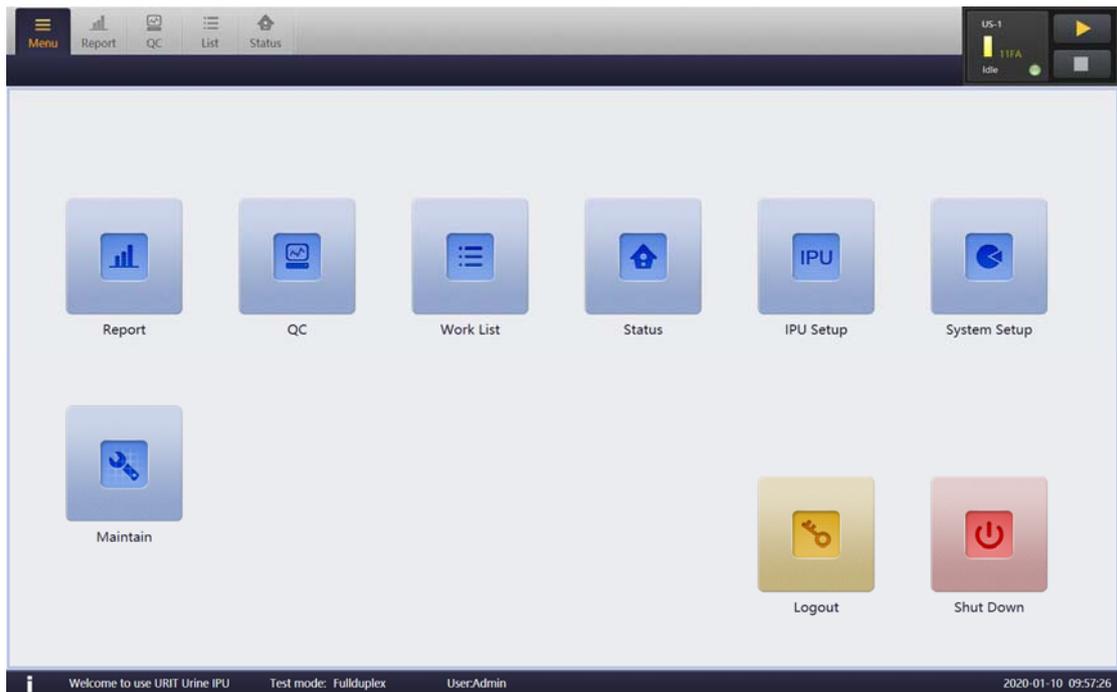


Figure 5-5 Menu

- 1) Report: Click " "to enter the report interface.
- 2) QC: Click " " to enter the QC interface.
- 3) List: Click " "to enter the list interface.
- 4) State: Click " "to enter the status interface.
- 5) IPU setup: Click " " to pop up the window of IPU setting. Refer to "*Chapter 6 IPU setting*" for detailed operation.



- 6) System setup: Click "System Setup" to pop up the system setting window, including online setting and test mode setting. The interface is shown in Figure 5-6.

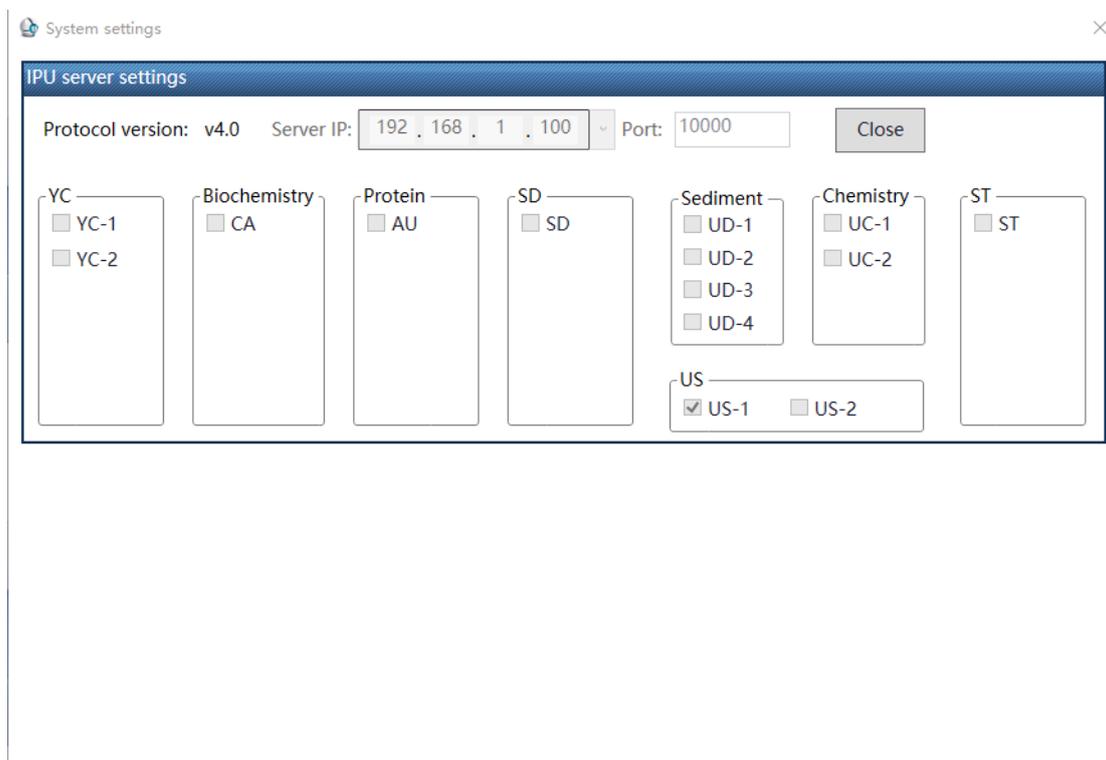


Figure 5-6 System setting interface

- ◆ Instrument configuration: check the instrument to connect the system. The US series can only be checked separately. The other four models can be configured in any combination.
- ◆ IPU server settings: by default, the system starts up the server. Close the server before you change the IP and port of the server.

5.6 Sample Test

5.6.1 Test Items

The instrument measures urinalysis and Urine Sediment.

The test items are controlled by setting QC, list, LIS duplex and default

rules. The priority is QC>List>LIS duplex>default rules.

5.6.2 List



Click "List" in toolbar, as shown in Figure 5-7.

Function: Preset the work of test tube. (when the sample No. and rack No. of test tube are coincident with the information in List, the test is done according to the list.)

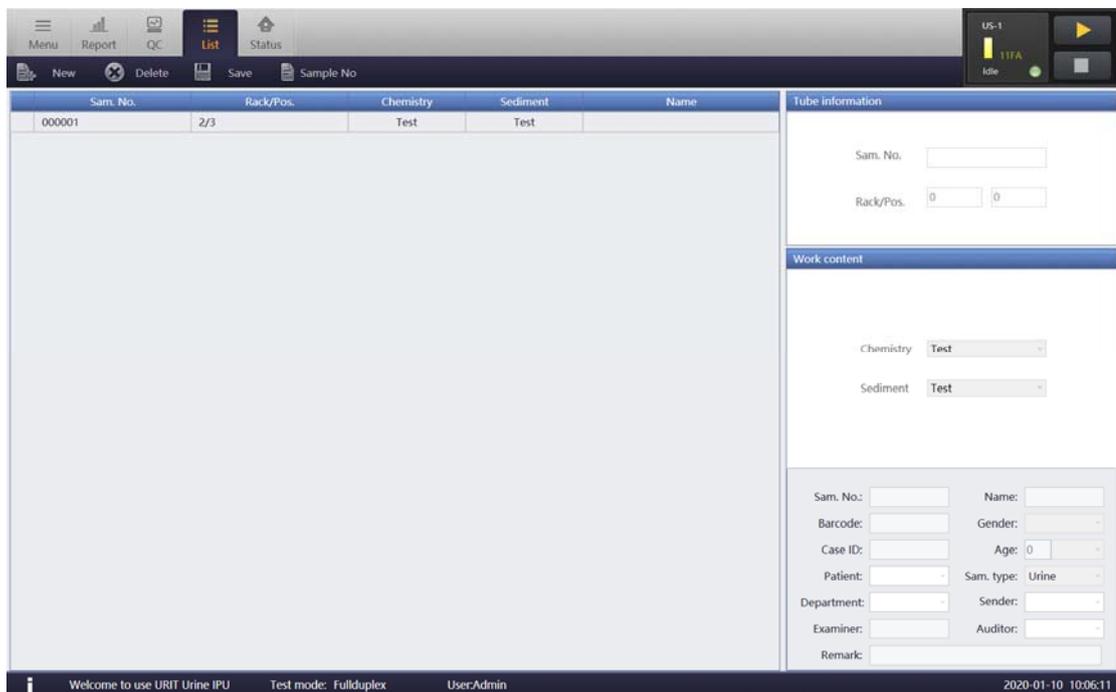
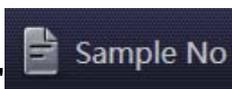


Figure 5-7 List

- 1)  "New": Create a new list.
- 2)  "Delete": Delete the selected items in the list.
- 3)  "Save": Save the selected items in the list.
- 4)  "Sample No": You can modify the next emergency and next sample in the resulting dialog box, as shown in Figure 5-8.

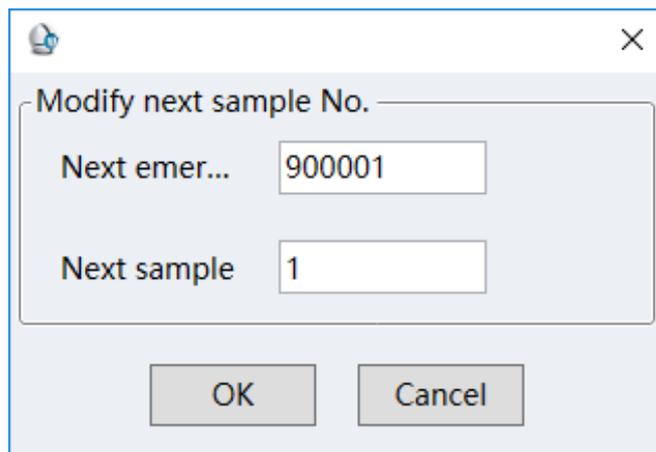


Figure 5-8 Next sample

List of worksheet: all lists are shown in the left area of list interface.

Information of test tube: Input the information of test tube that needs to set work content, as shown in Figure 5-9.

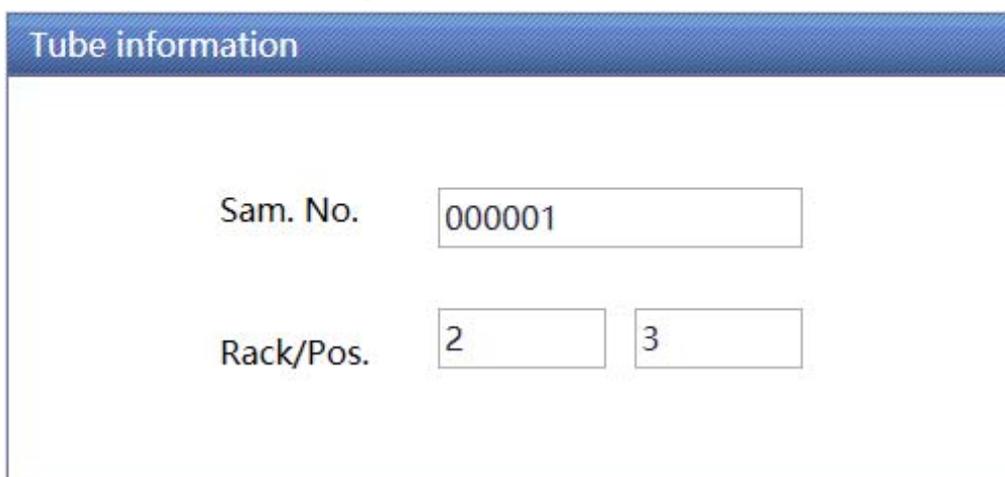


Figure 5-9 Test Tube Information

Work content: Preset test content and patient information, as shown in Figure 5-10.

Work content

Chemistry

Sediment

Sam. No.: Name:

Barcode: Gender:

Case ID: Age:

Patient: Sam. type:

Department: Sender:

Examiner: Auditor:

Remark:

Figure 5-10 List

5.6.3 Daily Test Interface



The daily test interface is in the main interface of IPU. Click "Report" in the toolbar, as shown in the Figure 5-11.



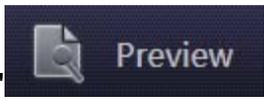
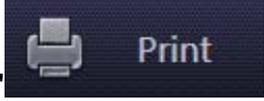
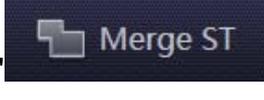
Figure 5-11 Report Interface

5.6.4 Operating Buttons

Overview: They are mainly used for daily operation.



Figure 5-12 Operating Buttons

- 5) : Delete the selected items in the sample list.
- 6) : Preview the selected sample results.
- 7) : Print the selected sample results.
- 8) : Send the selected samples to LIS.
- 9) : Save the results that are audited manually.
- 10) : Merge emergency test results.

5.6.5 Query and Status

- ◆ Today: you can quickly check today's samples by clicking the

"" in the lower left corner. The result of the query is displayed in the list on the left, and the date is displayed in the status box. As shown in Figure 5-13.

000182	9000398036	58/01			Finish
000183	9000427163	58/02			Finish
000184	9000412950	58/03			Finish
000185	9000409479	58/04			Finish
000186	9000421270	58/05			Finish
000187	9000350261	58/06			Finish
000188	9000398255	58/07			Finish
000189	9000433579	58/08			Finish
000190	9000421180	58/09			Finish
000191	9000421292	58/10			Finish

2019-06-24  Query Info. Total: 195 Selected: 1

Figure 5-13 Today's Query

- ◆ Query: Query conditions box pops-up by clicking on "" in the lower left corner. Set query condition and click "OK", then the results that meet requirements display in the left side list. If the query conditions box is empty, conditions is not added there, the condition is 'and'. As shown in Figure 5-14.

Date:	<input type="text" value="2019-04-03"/> 	~	<input type="text" value="2020-01-10"/> 
Sam. No.:	<input type="text" value="0"/>	~	<input type="text" value="999999"/>
Name:	<input type="text"/>	Status:	<input type="text" value=""/>
Barcode:	<input type="text"/>	Examiner:	<input type="text"/>
<input type="button" value="Query"/>		<input type="button" value="Cancel"/>	

Figure 5-14 Senior Query

Note: When the state box in the lower left corner is displayed as  "Today" , the list shows all the samples of the day. When it is displayed as  "Query" , the list shows the samples that are searched according to conditions of senior query as shown in Figure 5-15.

000273	9000321231	68/03	✓	✓	Finish
000274	9000295631	68/04	✓	✓	Finish
000275	9000295626	68/05	✓	✓	Finish
000276	9000295601	68/06	✓	✓	Finish
000277	9000331366	68/07	✓	✓	Finish
000278	9000276210	68/08	✓	✗	Finish

Date: ~

Sam. No.: ~

Name: Status:

Barcode: Examiner:

Total: 552 Selected: 1

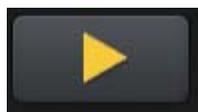
Figure 5-15 Query status list

- ◆ The status includes: Error, Test, Skip, Testing, Finish, Checked, Printed
- ◆ Error: The test is abnormal.
- ◆ Test: Next sample to be tested.
- ◆ Skip: New sample, not to test.
- ◆ Testing: The sample is being tested, and results have not come out yet.
- ◆ Finish: The test has been completed and the result has been given.
- ◆ Checked: Tested and audited samples.
- ◆ Printed: The report has been printed.

5.6.6 Sample Test

Ordinary Batch Test:

Step 1: Place the test tube rack to under test area correctly and click



on the "



" interface.

Step 2: Instrument enters into detection status .When the test tube rack is detected, the instrument will move test tube rack and measure automatically.

Step 3: In measure process, sample status is Test ->Testing ->Finish. "Finish" means the measurement is finished and the urine sediment results have been got.

Step 4: You can check results, input patients' information and print report when instrument is measuring.

Note

- ◆ Do not move or take out the test tubes in under test area of feeding mechanism when the test tubes are being measured.
-

Emergency Test

Step 1: Put the emergency sample tube into the emergency position and press "ST" button. System will automatically sample the emergency tube before the next one is sampled. After the completion of emergency sample measurement, the system will automatically return to the normal measurement.

Step 2: After identification, the output results will be displayed in the main interface as well. Unlike the normal sample measurement, the sample number

of the emergency sample starts with 9 and the tube rack/position has the word "Emergency".

5.6.7 Chemistry Results

The urinalysis items, results and reference range are shown in Figure 5-16.

Item	Result	Reference
VC	+3	-
NIT	-	-
MA	<=10mg/L	<=10
WBC	-	-
CR	>=26.4mmol/L	4.4~17.6
KET	-	-
URO	Normal	Normal
BIL	-	-
GLU	-	-
PRO	-	-
SG	1.005	1.010~1.030
PH	5.0	5.0~7.5
BLD	-	-
CA	<=1.0mmol/L	2.5~7.5
MA/CR	<0.01mg/mmol	Normal
COLOR	Yellow	Yellow

Figure 5-16 Urinalysis Results

5.6.8 Scan Imagery of Chemistry Strips

Double click chemistry items and the scan imagery of this strip pops up, as shown in Figure 5-17.

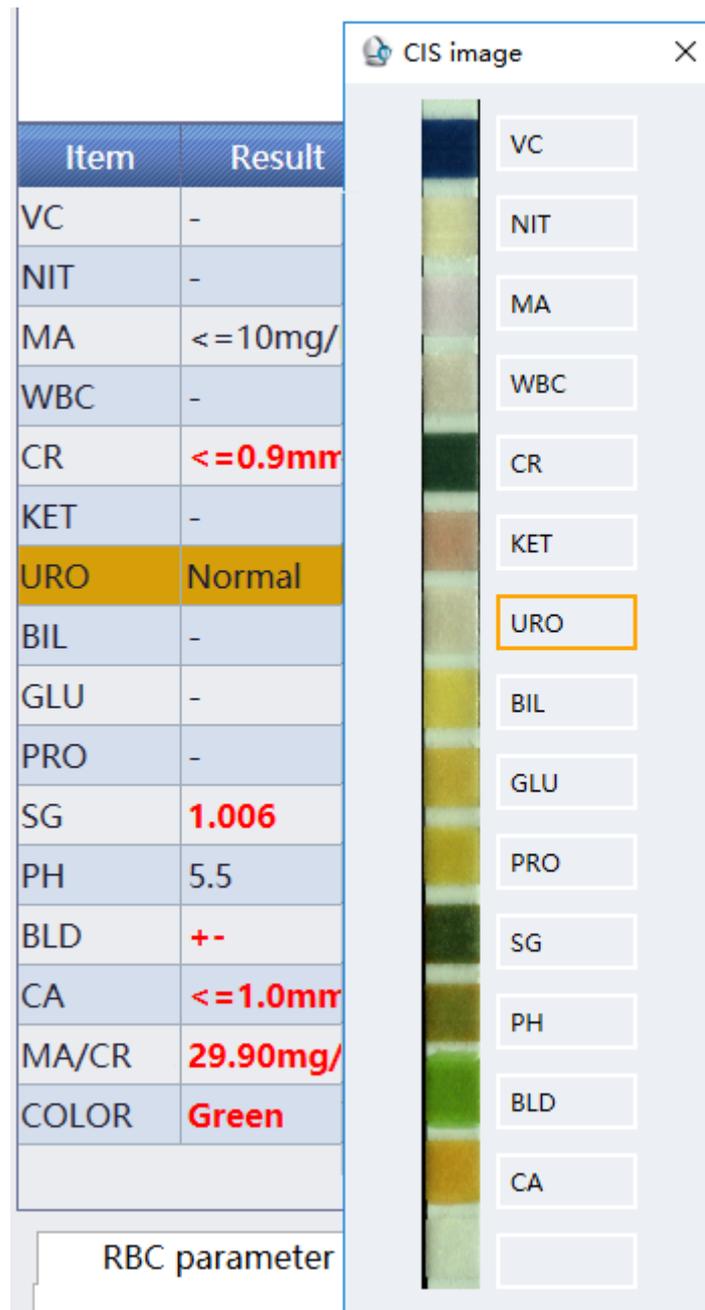


Figure 5-17 Scan imagery of strip

5.6.9 Urine Sediment Results

It displays urine sediment items, results and reference range, as shown in Figure 5-18.

Item	Result	Reference	Unit
RBC	15.7	0-10	/uL
RBCA	0.0	0-10	/uL
WBC	24.5	0-15	/uL
WBCC	0.0	0-5	/uL
HYA	5.2	0-1	/uL
PAT	3.9	0-0	/uL
SQEP	25.6	0-15	/uL
NSE	0.0	0-15	/uL
CAOX	0.0	0-15	/uL
URIC	0.0	0-15	/uL
STRUVITE	0.0	0-15	/uL
AMORF	+-	-	
UNCX	-	-	
YST	0.0	0-15	/uL
BACT	0.0	0-15	/uL
MUCS	+-	-	
OTHER	25.9	0-50	/uL

Figure 5-18 Urine Sediment Results

5.6.10 Artificial Classification

- ◆ Purpose: For manual audit and verify test results. With audit program, you can audit and verify the results of Urine Sediment measurement .
- ◆ Interface: As shown in Figure 5-19, the "RBC" in the middle of the title in the upper right corner of the Figure is a small image indicating the type of item currently displayed. "639.9/uL" indicates the result of current item, the left and right arrows are used to switch items. Manual classification process: checking in small image area, if there are any non-conformance particles, you can make them into correct items with

"Classification" button, until all particles in the item are correct.



Figure 5-19 Artificial Classification

◆ **Classification:**

Classify to "CAST" : Double left-click on the item to select the item to be audited. The cell diagram is shown in the right area. Left-click on the "CAST", which will turn into blue unit bar with an arrow when selected. Right-click it to classify it into. In the process of classification, the results of each item will be calculated and updated automatically. (Figure 5-20)

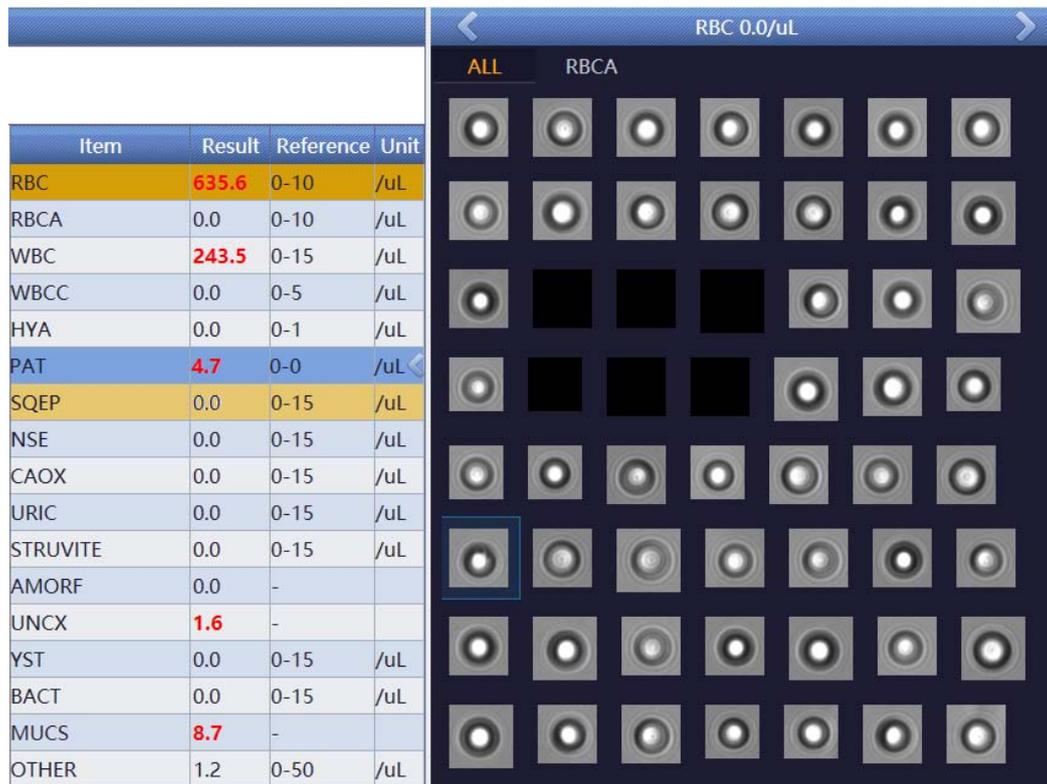


Figure 5-20 Classify to "Impurities"

- ◆ Undo: A small image of the cells being classified will turn black background, and a right mouse click will undo the classification of the cells.
- ◆ Toggle items: You can use the button above the picture to toggle the item. Or you can double-click the microscopy items on the right to view the item.

5.6.11 RBC Phase

Purpose--It is mainly used to provide size distribution, mean volume, abnormal ratio, distribution width CV and other data of RBC. Doctors can judge the source of the red blood cells with these data and cells shape. As shown in Figure 5-21.

$$\text{Abnormal Scale(\%)} = (\text{Abnormal RBC Quantity} / \text{RBC Total Quantity})\%$$

Average Diameter(um): $\bar{x} = \frac{\sum_{i=1}^n x_i}{n}$

Distribution Width CV (%) = $\frac{\sqrt{\frac{\sum (x_i - \bar{x})^2}{n-1}}}{\bar{x}} \times 100\%$

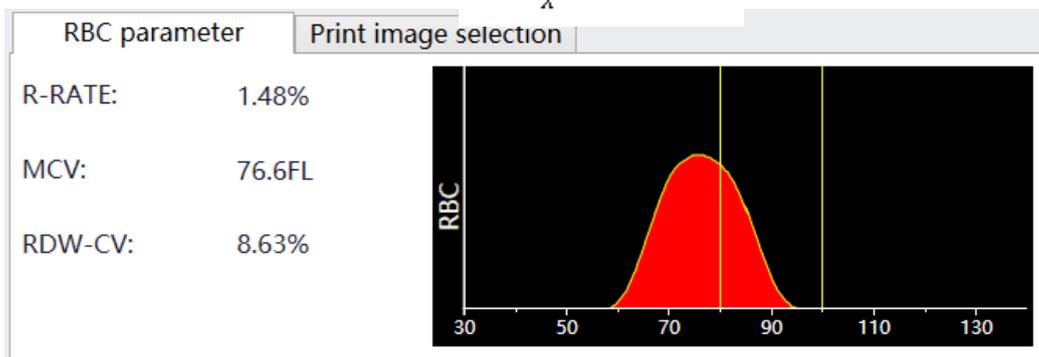


Figure 5-21 RBC Phase

5.6.12 Patient Information Input

Click "**Info.**" in the left lower bottom, and the patient information input box appears, as shown in Figure 5-22.

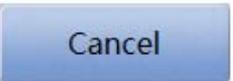
Sam. No.:	<input type="text" value="000181"/>	Name:	<input type="text"/>
Barcode:	<input type="text"/>	Gender:	<input type="text" value="v"/>
Case ID:	<input type="text"/>	Age:	<input type="text" value="0"/> <input type="text" value="v"/>
Patient:	<input type="text" value="v"/>	Sam. type:	<input type="text" value="Urine"/> <input type="text" value="v"/>
Department:	<input type="text" value="v"/>	Sender:	<input type="text" value="v"/>
Examiner:	<input type="text" value="Admin"/>	Auditor:	<input type="text" value="v"/>
Test time:	<input type="text" value="2019-06-24 10:41:52"/>		
Remark:	<input type="text"/>		

Figure 5-22 Patient Information Input

◆ Common Operation

- 1) Switch to the next input box-- press keyboard TAB key or click with mouse.

- 2) After information input, click "  Save " to save patient information. Sometimes the operator forgets to save, when he checks other sample information, the dialog as shown in Figure 7-19 will pop

up to prompt whether to save the operation. Click "  " to save, click "  " to cancel the operation.

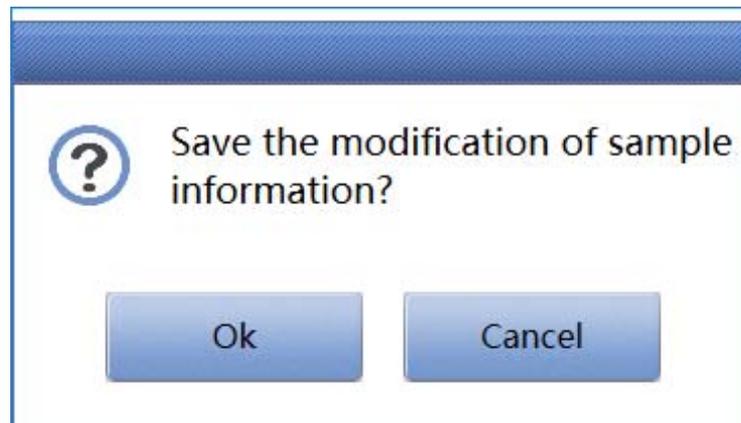


Figure 5-23 Save

- 3) Sample No.: System generates Sample No. automatically. You can change it but it's unnecessary by default.
- 4) Case ID: Input patient's case ID here.
- 5) Bar Code-- Generally the bar code does not need to be input, the analyzer can automatically access it.
- 6) Name-- Input patient's name in "Name" box.
- 7) Gender-- Select patient sex in the "Sex" drop-down list box. The default gender is not to fill.
- 8) Age-- Select input mode in the "Age" drop-down list, and input patient age before the unit.

- 9) Bed No. -- Input patient bed number in "Bed No." box.
- 10) Patient: select patient type in the "Patient type" drop-down list or enter patient type directly in the list box.
- 11) Clinician: Select the sender in the "Sender" drop-down list or enter the clinician name directly in the list.
- 12) Department: In the "Department" drop-down list, select the inspection department or enter the inspection department name directly in the list.
- 13) Examiner and auditor: the logged user who tests is the examiner, and who audits is the auditor.
- 14) Test time: system generates it, without modification function.
- 15) Remark: Enter sample note information here.

Chapter 6 IPU Settings

6.1 General

IPU Software Version:V4.00.

Overview: General settings include time format, font and log settings. The interface is shown in Figure 6-1.

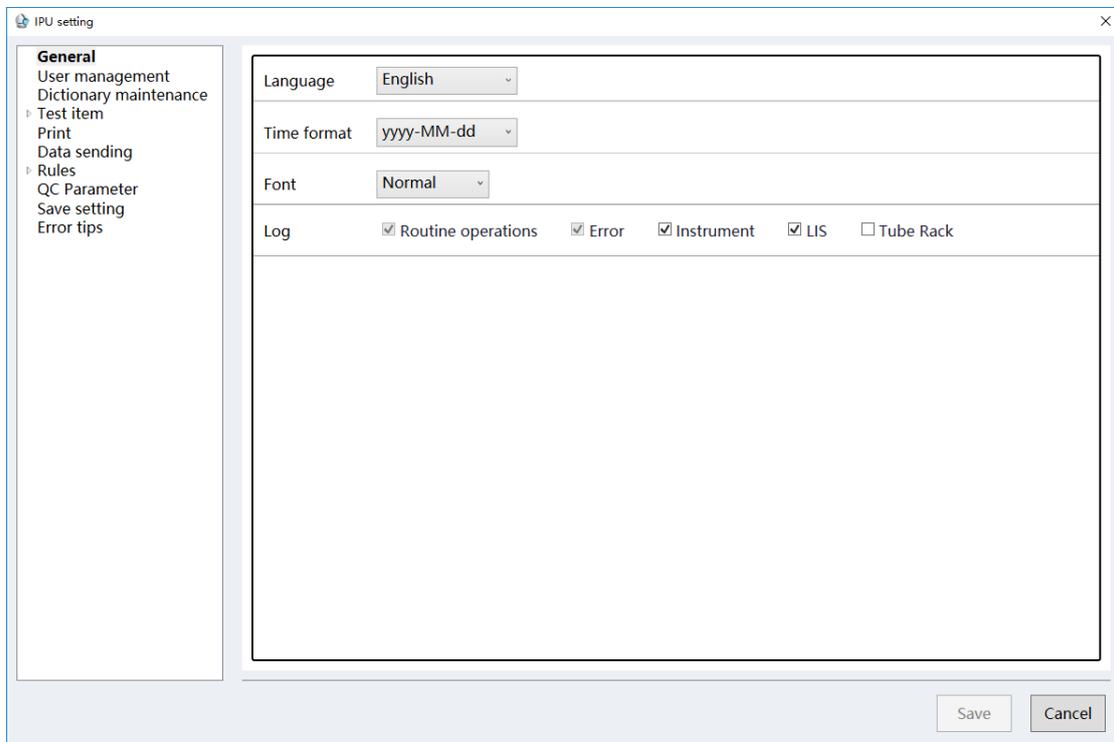
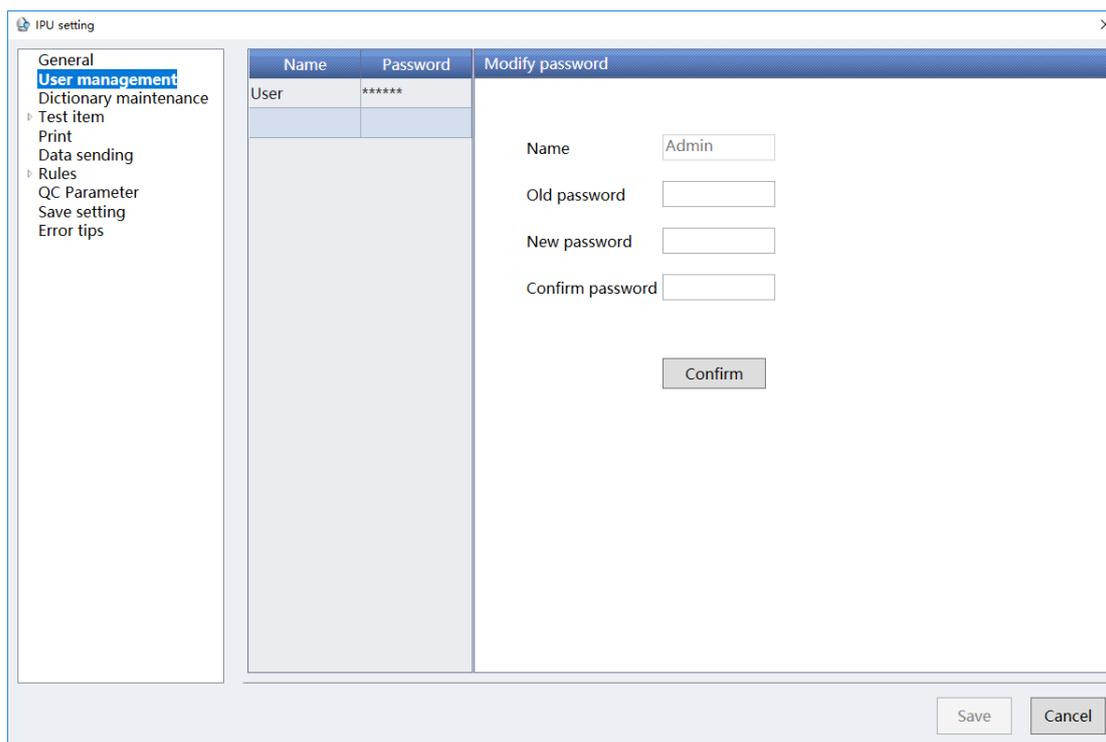


Figure 6-1 General Settings

6.2 User Management

Overview: User management mainly manages user information, including adding users, modifying user names and passwords, as shown in Figure 6-2.

**Figure 6-2 Users Management**

- 1) Add user: the user can only be added as admin user logs in. Fill in the user and password directly in the blank line of the user list. After successful filling, press the Enter key. The "Save" button will be lit up. Click the "Save" button to complete the adding user operation.
- 2) Modify the user name: the user can only be modified as admin user logs in. Modify the user name directly in the user list, press the Enter key when the fill is complete, and the "Save" button will be lit up and click "Save" to complete the operation.
- 3) Modify password: In Admin user login mode, you can modify all user passwords and Admin user passwords in the user list. The user password in the list can be directly modified. The old password can be modified after modifying the admin password. Ordinary users can only change their password in login mode, and the old password needs to be confirmed when changing.

6.3 Dictionary Maintenance

Overview: It is for setting the department, doctor name and patient. Operator can select the items needed by the drop-down list after setup or input the swift code then press Enter for display, which can improve the efficiency of information input. As shown in Figure 6-3.

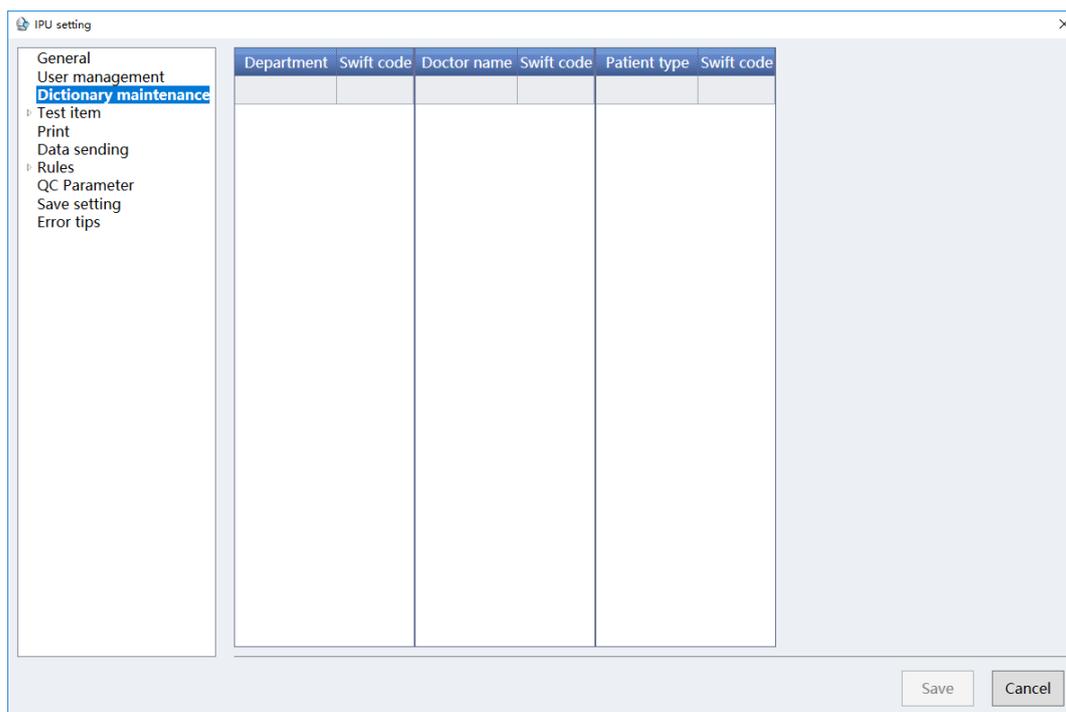


Figure 6-3 Dictionary Maintenance

Operator can modify and edit the information directly in the list, add the content in the last line, or empty line for delete. Click "Save" to take effect.

6.4 Test Items

Overview: Set the unit, display name, reference value, etc of Urine Sediment and chemistry items.

6.4.1 Chemistry Items Setting

The chemistry item settings include display, item, Lis ID, name, unit, reference, strip type. It's used to set result interface display and system online matching, etc., as shown in Figure 6-4.



Figure 6-4 Chemistry

- 1) Display: Checking indicates that the item is displayed in the result table. If it is not checked, it will not be displayed.
- 2) Item: In online mode, the item name is used to match the chemistry result item. It can be edited.
- 3) Lis ID: In the connection LIS server mode, this item is used to match the result item with LIS. It can be edited.
- 4) Name: It is used to display the result name of the interface. It can be edited.
- 5) Unit: select the unit of displayed items, including PLUS, SI, ENG and CONV, and the "reference" will be automatically updated to the corresponding set value when the unit is modified.
- 6) Reference: It represents the reference value when the unit is used.
- 7) Gate criteria rules: When the status of new sample is **【Gating】**, measuring Urine Sediment or not depends on the test results of Urinalysis.(if the test results are greater than gate rules, the Urine Sediment will be measured; otherwise don't measure.

- 8) Move up: Set the order of the results in the interface. Select the row and click the move up button to move the row up.
- 9) Move down: set the order of the results in the interface. Select the row and click the move up button to move the row down.
- 10) Save: After modifying the contents of the form, the "Save" button will be lit up. Click the "Save" button to save the modified data.
- 11) Cancel: Abandon the modification or exit the settings interface.

Strip types: 11FA, 12FA and 14FA represent the strip types used in the measurement. This option must be corresponding to the strip used in the actual measurement, otherwise the test results will be affected.

6.4.2 Settings of Urine Sediment Items

Settings of Urine sediment items include display, item, Lis ID, name, unit, "-", "+-", "+1" and "+2", which are used to display settings of the result interface and online matching of the system, etc. The interface is shown in Figure 6-5.

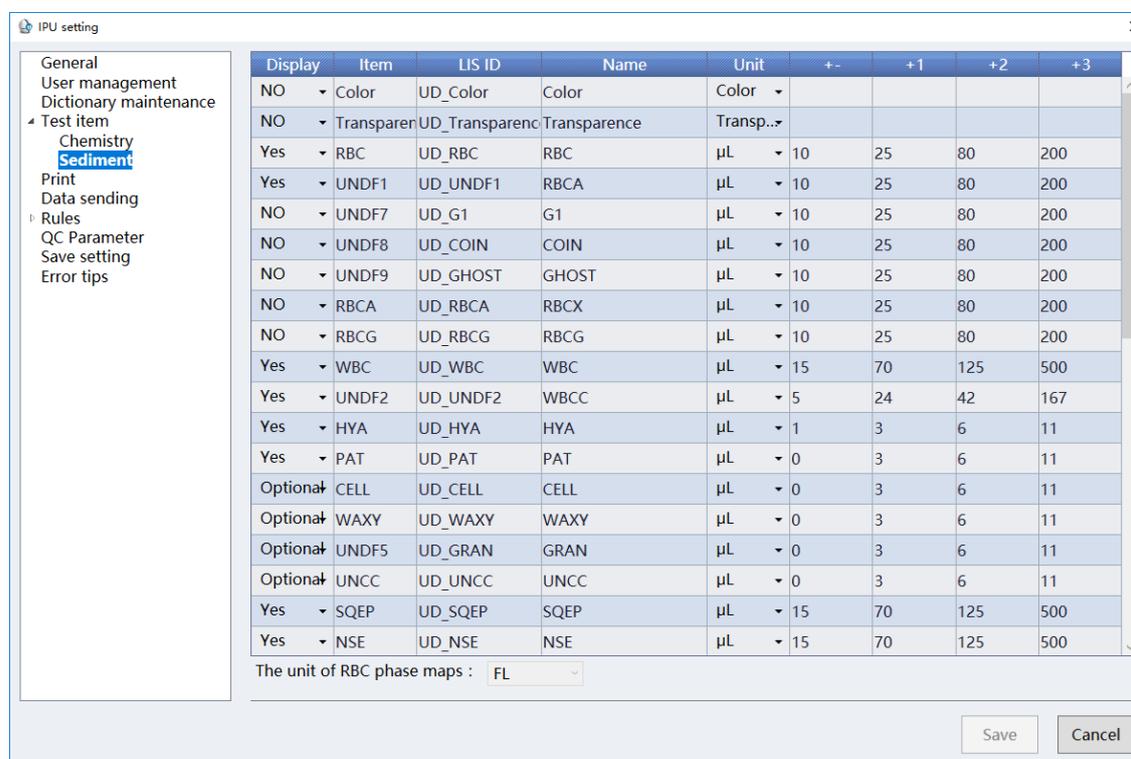


Figure 6-5 Settings of Urine Sediment Items Settings

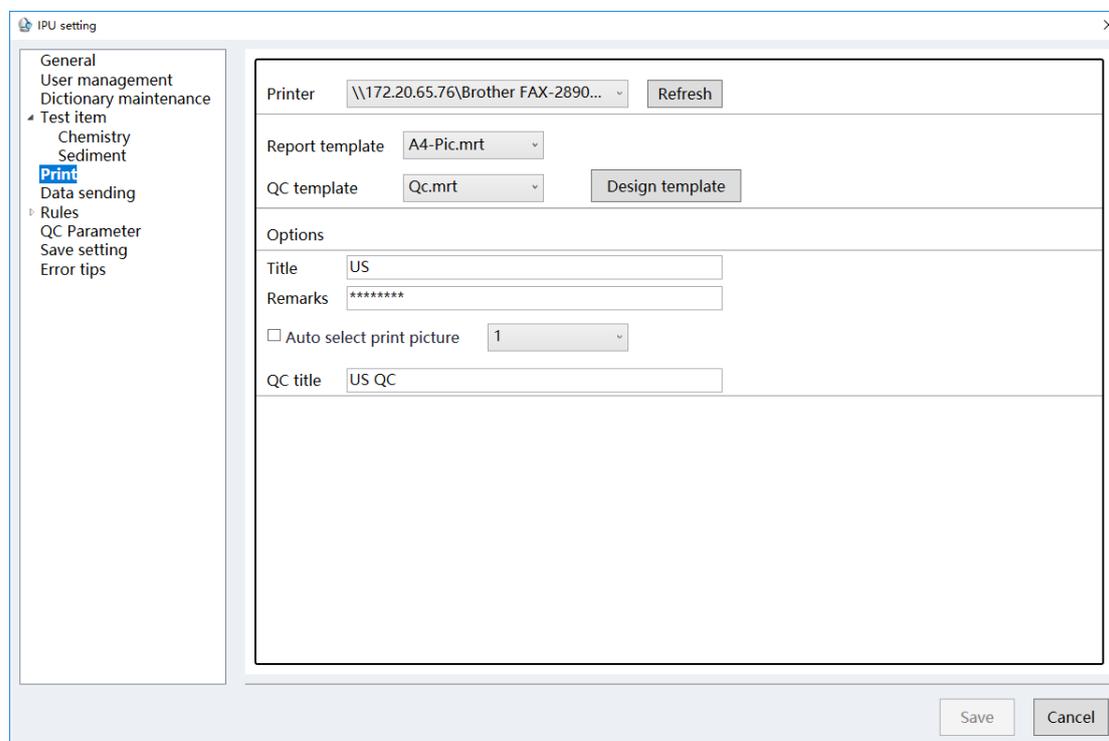
- 1) Display: Click the down-drop list to select display modes.
- 2) Item: English name of the item. It cannot be edited.
- 3) Lis ID: In the connection LIS server mode, this item is used to match the result item with LIS. It can be edited.
- 4) Name: It is used to display the result name of the interface. It can be edited.
- 5) Unit: Select the unit of the item, including uL, LPF, HPF, HalfRation, Color, and Transparence. After the unit is modified, "-", "+-", "+1", "+2" will be automatically updated to the corresponding settings value.

Note

- Unit conversion: $1/\mu\text{L} \approx 0.18 \text{ HPF}$, $1/\mu\text{L} \approx 2.90 \text{ LPF}$
- 6) "-", "+-", "+1", "+2" indicate the semi-quantitative threshold, which is divided into four files, namely: "-", "+-", "+1", "+2" ". Fill the result threshold in each file. If the result of the test is less than this value, and "HalfRation" is selected to be the unit, it will display the semi-quantitative result of the file. (For example, according to the settings in the figure, if the RBC result of the test is 80, it displays as "+1").
 - 7) Move up: It is used to set the order in which the results are displayed on the screen, select the row and click the move up button to move the row up.
 - 8) Move down: It is to set the order in which the results are displayed on the screen, select the row and click the move up button to move the row down.
 - 9) Save: After modifying the contents of the form, the "Save" button will be lit up. Click the "Save" button to save the modified data.
 - 10) Cancel: Abandon the modification or exit the Setting interface.

6.5 Print

Overview: for selecting printers and printing templates, the interface is shown as Figure 6-6.



The screenshot shows the 'IPU setting' window with the 'Print' section selected in the left-hand navigation pane. The main area contains the following settings:

- Printer:** A drop-down menu showing '\\172.20.65.76\Brother FAX-2890...' and a 'Refresh' button.
- Report template:** A drop-down menu showing 'A4-Pic.mrt'.
- QC template:** A drop-down menu showing 'Qc.mrt' and a 'Design template' button.
- Options:**
 - Title:** A text field containing 'US'.
 - Remarks:** A text field containing '*****'.
 - Auto select print picture:** A checkbox with a value of '1' in a small drop-down menu.
 - QC title:** A text field containing 'US QC'.

At the bottom right of the window are 'Save' and 'Cancel' buttons.

Figure 6-6 Print

- 1) **Printer:** click the drop-down list to select the printer, (click the "Refresh" button to refresh the printer).
- 2) **Report Template:** Settings of print template
- 3) **Options:** Report title, QC title, remarks and whether to select print picture automatically.
- 4) **Save:** Save your settings.
- 5) **Cancel:** Cancel modification or exit.

6.6 Data Sending

This setting is mainly used for LIS communication, as shown in Figure 6-7.

Test mode: including full duplex and half duplex. Full duplex indicates that testing information is obtained from LIS server. Half-duplex indicates that

information is not obtained from LIS, only sending results.

LIS connection settings: fill in LIS server IP and port; you can check the function of "Send to LIS automatically".

Sending rules: sending data to LIS.

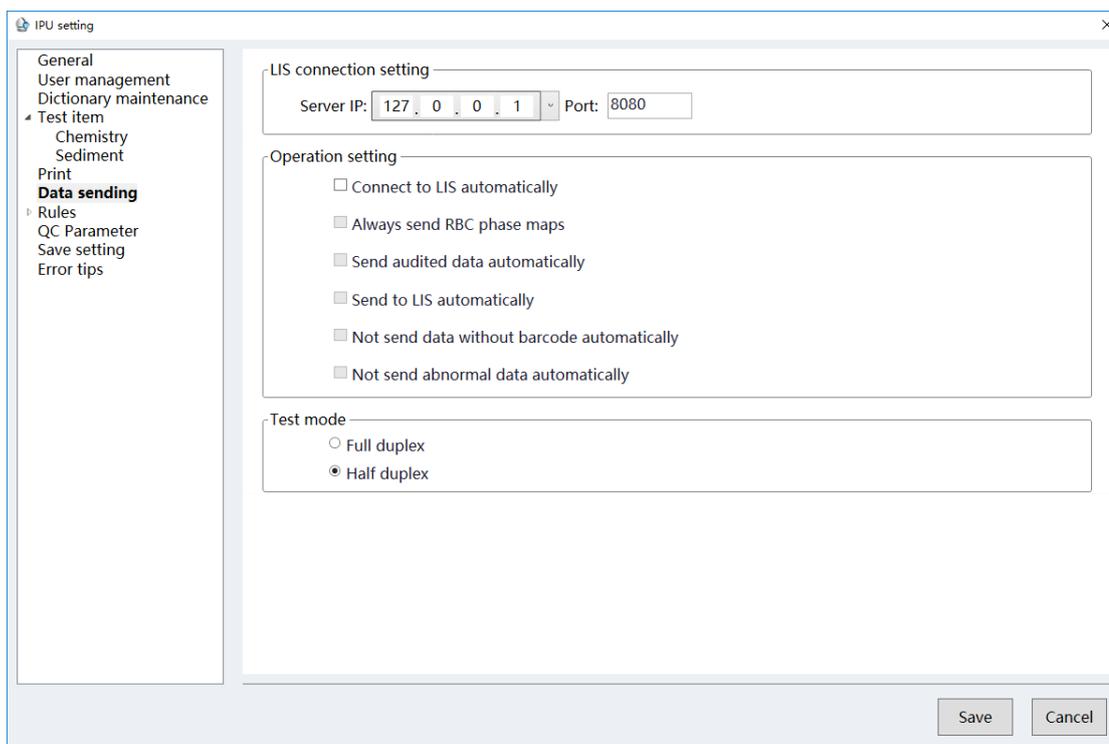


Figure 6-7 Data Sending

6.7 Rules

6.7.1 Test Rules

Overview: for test rule in use, the interface is shown in Figure 6-8:

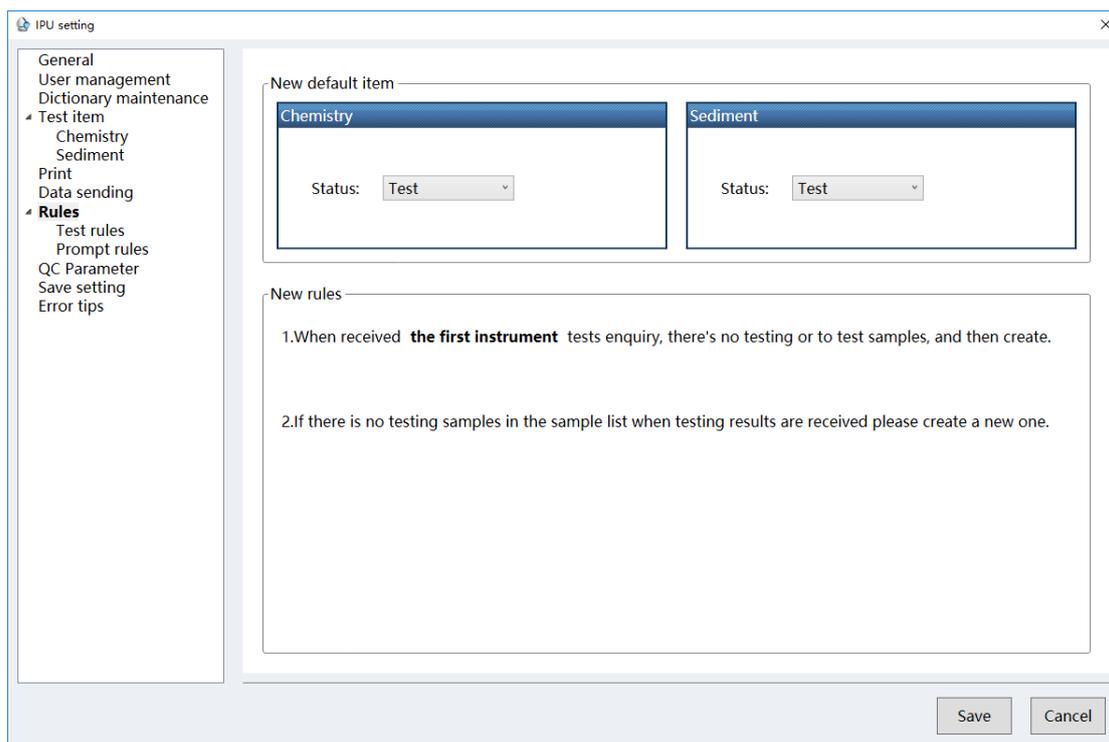


Figure 6-8 Test Rules

New default item: for setting the default test mode for new samples.

- 1) Chemistry mode: Chemistry: Test; Urine sediment: skip.
- 2) Urine sediment mode: Chemistry: Skip; Urine sediment: Test.
- 3) United test mode: Chemistry: Test; Urine test: Test.

New rules: Indicates when the instrument will automatically create a new sample.

- 1) Rule 1: New sample records will be created when the rightmost device connected to the test tube is found.
- 2) Rule 2: When instrument sends results to the IPU, and there is no corresponding state (by option), a new sample will be created.

6.7.2 Prompt Rules

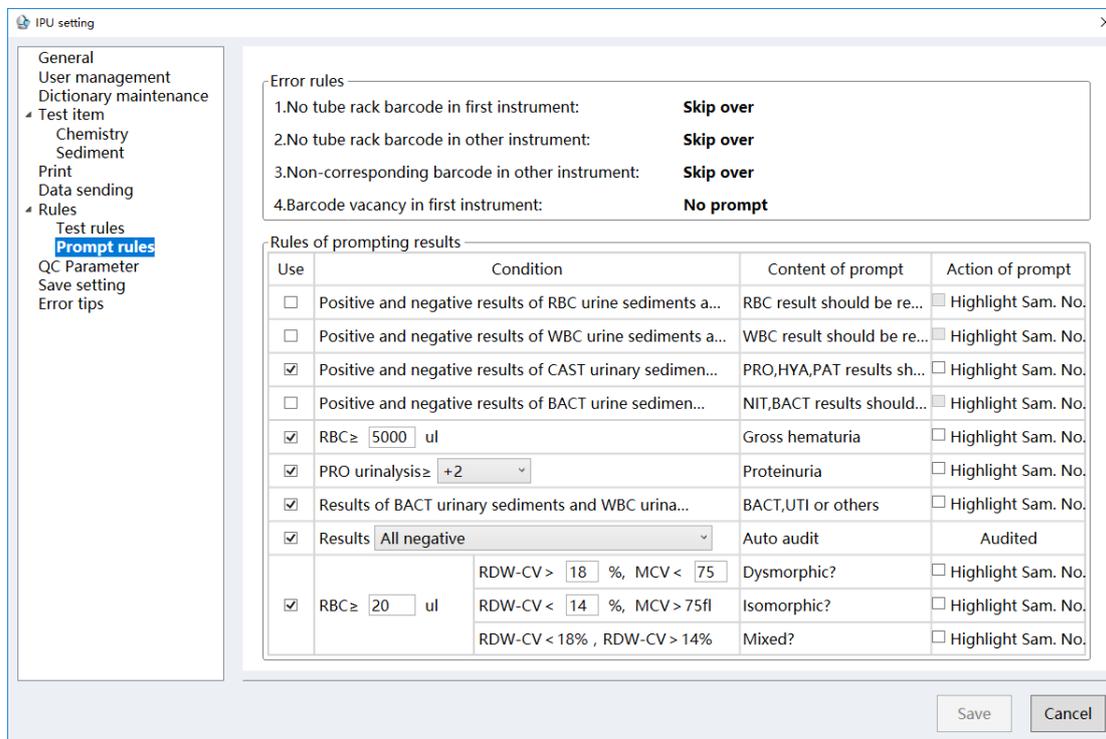


Figure 6-9 Prompt Rules

Error rules: a treating method when there is a problem with a test tube rack or position scanned by multiple instruments.

- 1) Rule 1: Treating method when the rightmost instrument has not found the rack code.
- 2) Rule 2: Treating method of other instruments have not found the rack code.
- 3) Rule 3: The code read by other instruments is different with order.
- 4) Rule 4: The rightmost instrument finds that there is a gap in the test tube.

Rules of prompting results: it is used to set what kinds of result will be highlighted in the report interface, and see what the sample specific prompt information is.

6.8 Save Setting

Overview: it is used to set the cleanup log and image data files, as shown in Figure 6-10:

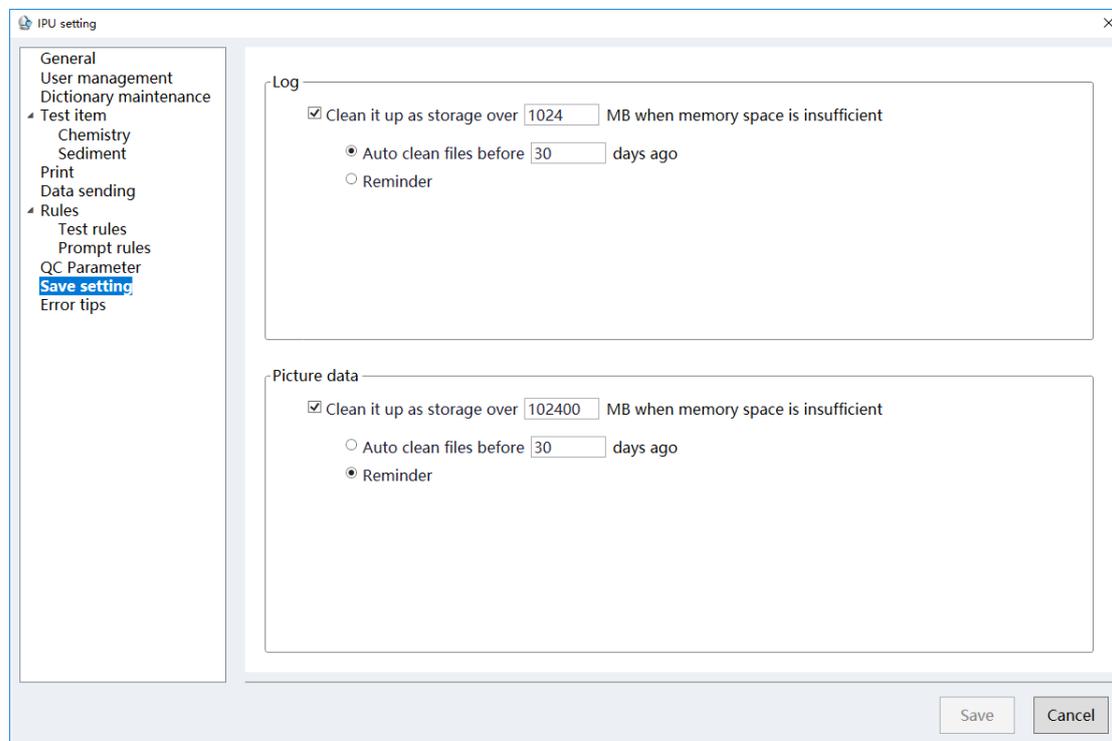


Figure 6-10 Save settings

- 1) Log: When the file memory is larger than the set value, you can choose to automatically clean or remind you to clean up.
- 2) Picture data: It is similar to the log, when the file memory is larger than a certain value, you can choose to clean it automatically or remind you to clean it.

6.9 Error Tips

It is mainly for voice broadcast settings. See Figure 6-11:

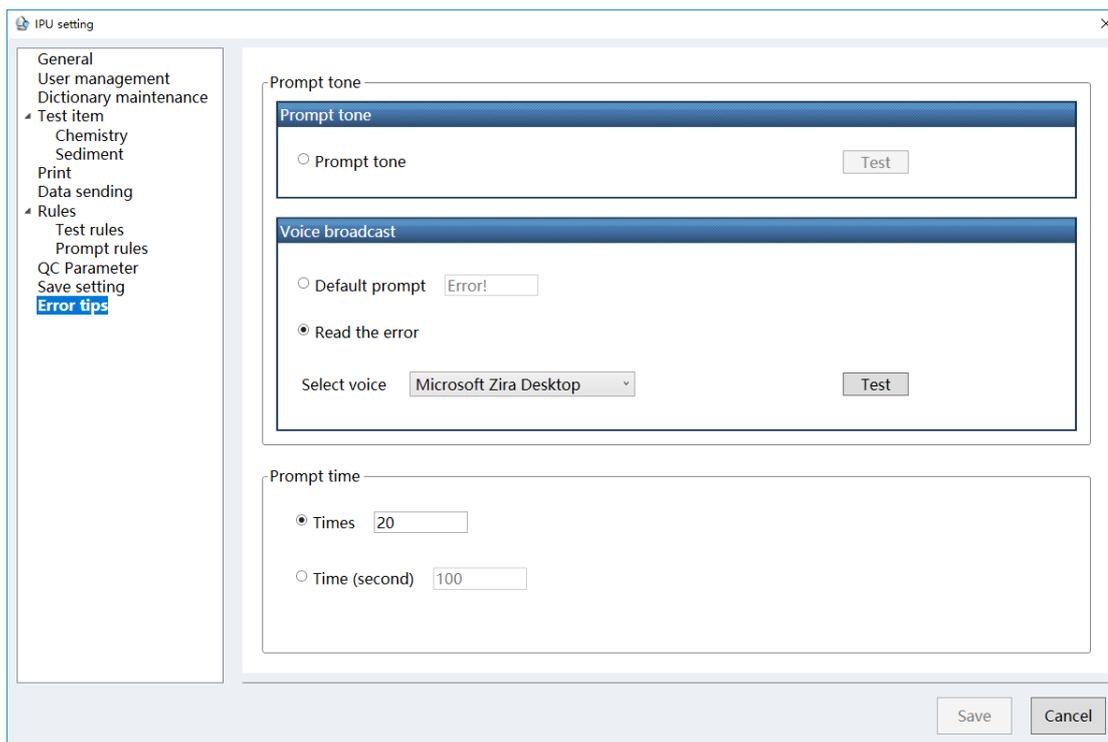


Figure 6-11 Error prompt

- 1) Prompt Tone: turn the prompt tone on or off.
- 2) Voice broadcast: select broadcast content, including default prompt content and broadcast specific error.
- 3) Prompt time: you can select the number of broadcasting and time.

Chapter 7 Quality Control

7.1 Overview

To understand the status of the instrument and obtain reliable results, it is recommended to run quality control before measurement everyday. If the result is within the control, the analyzer is normal. If the result is out of control, you can find the reason from the microscope focus (see Chapter 8), the status of the control materials, and so on. After the adjustment, run quality control again. If the results are within control, you can measure samples.

7.2 QC Interface

As shown in Figure 7-1.

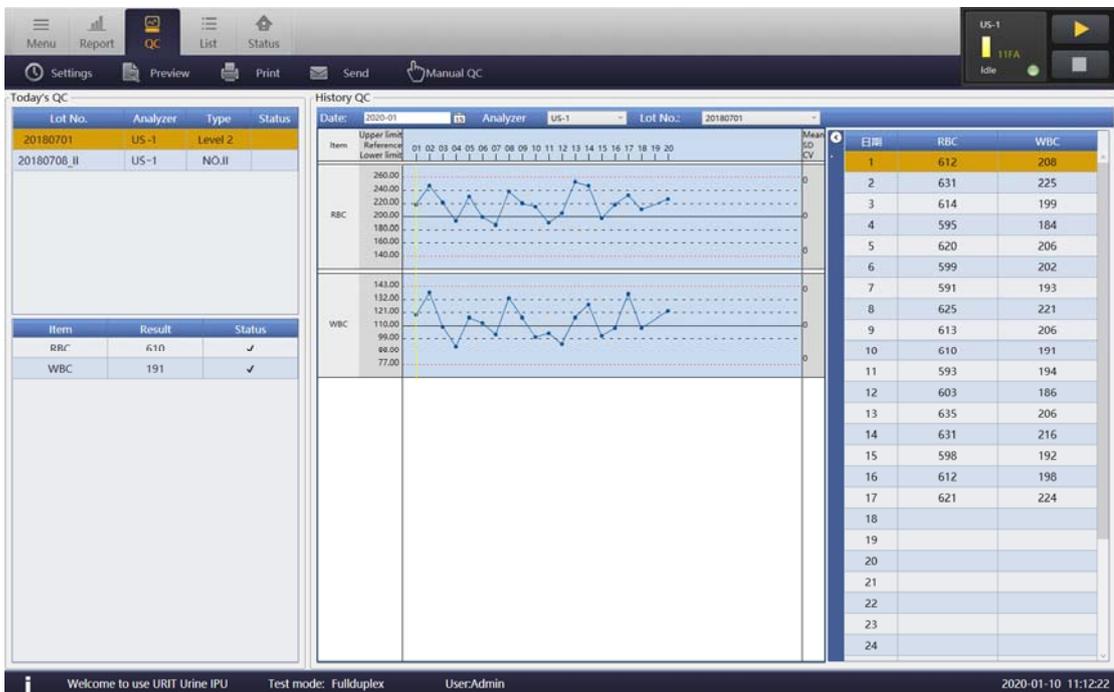


Figure 7-1 QC Interface

- ◆ Today's QC: It is located on the left side of the QC interface and is divided into two lists. The upper list is used to check whether the

quality control has passed today, including the Lot No., analyzer, remarks, status (Pending, testing, success, fail); The lower list shows the specific item results and status of the QC selected in the above list (↑: exceeds the upper limit; ↓: below the lower limit; √: the result is in the upper and lower limits).

- ◆ Historical QC: It is located in the middle and right side of the QC interface and is divided into three areas. Query area: You can query by selecting the month, analyzer, and lot No.. QC chart area: Display the data in the query as LJ QC chart. Result display area: Display the data results of the query by date in the list.

7.3 QC Settings

Lot No.	Model	Validity	QC type
20180701	US-1	2018-07-29	Level 2
20180621	US-1	2018-06-29	Level 0
20180708_II	US-1	2018-07-30	NO.II

Item	Lower limit	Upper limit
RBC	511	691
WBC	136	252

Figure 7-2 Quality control parameter

As shown in Figure 7-2, the quality control parameter interface is divided into two parts. The upper part is used to fill in the quality control Lot No., model, validity, remarks. The table in the lower part is used to represent the reference value, upper and lower limit of each quality control item selected in the above

table.

Operation:

- ◆ Add: Switch the line or click the save button after filling in the corresponding information in the blank line.
- ◆ Delete: Delete all the contents of the line, or click on the delete menu.
- ◆ Correct: Change the content of the selected line, switch the line or click the save button.

7.4 Calculation Method

The calculation method of the quality control test results is shown in Table 7-1.:

Table 7-1 Calculation method

Average (\bar{x})	$\bar{x} = \frac{\sum_{i=1}^n x_i}{n}$
Standard deviation(SD)	$SD = \sqrt{\frac{\sum (x_i - \bar{x})^2}{n-1}}$
Coefficient of variation(CV)	$CV = \frac{SD}{\bar{x}} \times 100\%$

7.5 QC Test

1. Manual QC: Click the Manual QC button on the quality control interface, the manual quality control dialog box will pop up, as shown in Figure 7-3. Click "OK" and test the control materials on corresponding instrument by QC button. (You can follow the prompts in the dialog box).

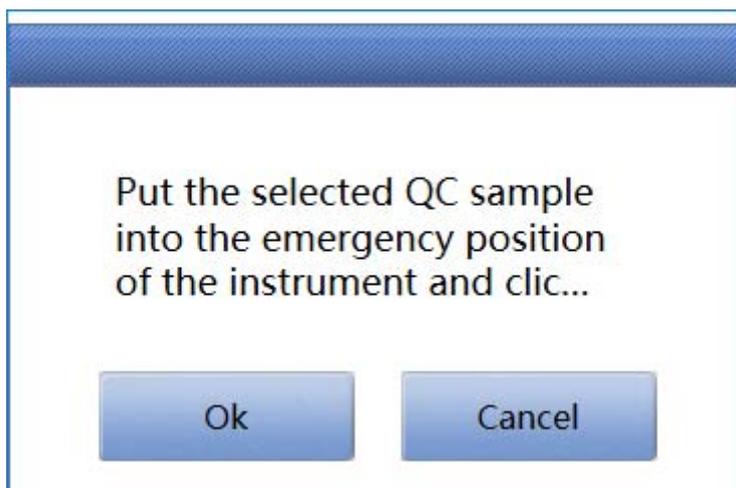


Figure 7-3 Quality control test inquiry

2. Automatic quality control test:

In QC parameter interface, scan the barcode on the QC tube with scanner, the Lot No., applicable instrument, validity and QC type are inputted automatically.

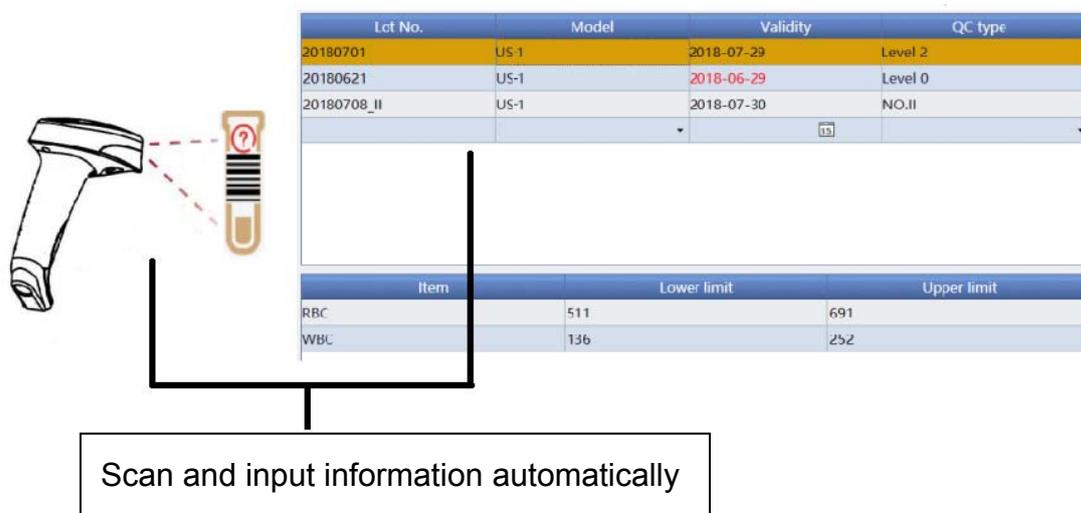


Figure 7-4 Input the QC information automatically

Click Test button, put the inputted QC material into tube rack, and place the rack to the right of the platform. The built-in scanner scans the QC barcode in turn, and match them with the inputted QC information. After the corresponding test, it is marked as "Success" or "Failed" automatically, and the curve graph is generated.



Figure 7-5 Auto test and display result

7.6 QC Print

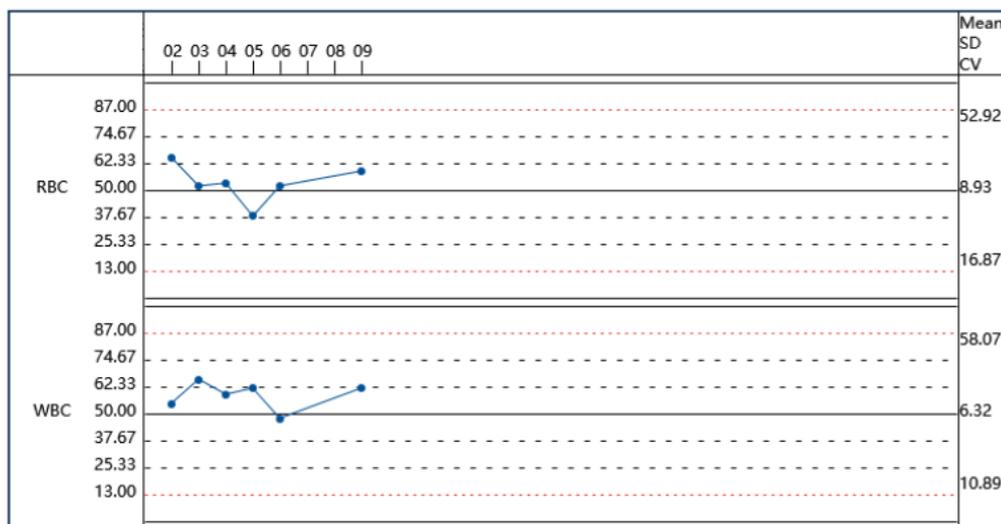
Print the quality control test results. Figure 7-6 and Figure 7-7 below are the printed quality control report.

US QC															
Month Year: 2020-01				Name: US-1				Lot No.: 20180708_II							
Day	PH	NIT	GLU	SG	BLD	PRO	BIL	URO	KET	LEU	CR	CA	MA	VC	状态
1															
2	5.5	-	-	1.005	-	-	-	Normal	-	-	<=0.9	<=1.0	<=10	-	✓
3	5.5	-	-	1.005	-	-	-	Normal	-	-	<=0.9	<=1.0	<=10	-	✓
4	5.0	-	-	1.005	-	-	-	Normal	-	-	<=0.9	<=1.0	<=10	-	✓
5	5.0	-	-	1.005	-	-	-	Normal	-	-	<=0.9	<=1.0	<=10	-	✓
6	5.5	-	-	1.005	-	-	-	Normal	-	-	<=0.9	<=1.0	<=10	-	✓
7															
8															
9	5.0	-	-	1.010	-	-	-	Normal	-	-	<=0.9	<=1.0	<=10	-	✓
10															
11															
12															
13															
14															
15															
16															
17															
18															
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21															
22															
23															
24															
25															
26															
27															
28															
29															
30															

Figure 7-6 Chemistry QC Report

US QC

Month Year: 2020-01 Name: US-1 Lot No.: 6319000107UQ211



Day	RBC	WBC	状态
1			
2	64.7	54.4	✓
3	51.7	65.4	✓
4	53.0	58.5	✓
5	37.9	61.3	✓
6	51.7	47.5	✓
7			
8			
9	58.5	61.3	✓
10			

Figure 7-7 Urine Sediment QC Report

Chapter 8 Maintenance

Periodical maintenance is very important to keep these precise instruments work properly. If there's something wrong with the instruments, they should be maintained by professionals or sent to maintenance departments authorized by URIT.

Precautions for Maintenance

1. Carefully read through the Operation Manual, as well as the reagent and strip Instruction before maintenance.
2. Keep the instruments clean to guarantee the good performance.
3. Empty the fluid system and cover the instruments with cloth if it is disused for a long time, and perform Quality Control analysis when resuming the instrument.
4. DO NOT dismantle the instrument at will.

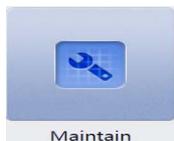


Biohazard

- Wear protective gloves to prevent bacterial infection.
- Dispose of waste liquid, used consumables, gauze, cotton swabs and gloves according to local regulations.

All maintenance is performed in the built-in software. Maintenance includes replacement of sheath and detergent, settings of maintenance plan, query of maintenance records and so on.

8.1 Basic Operation



Click "Maintain" in IPU software menu, the dialog box is shown as Figure 8-1.

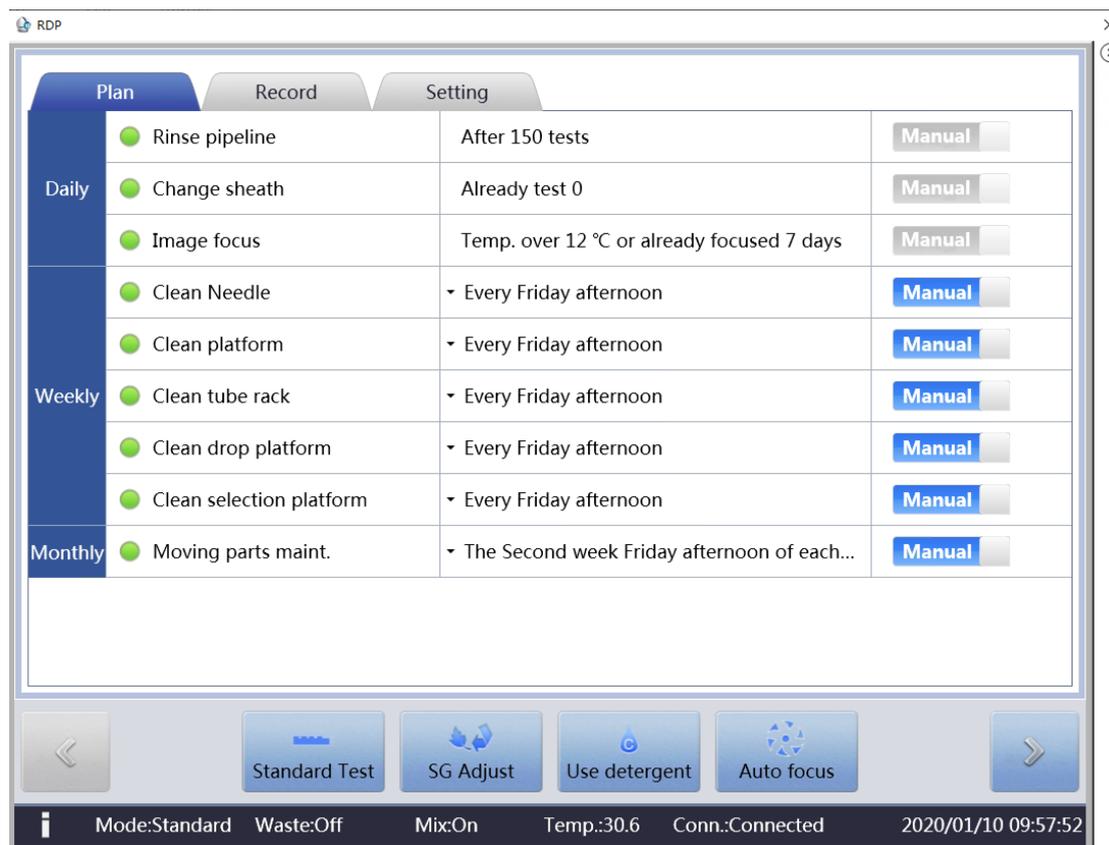
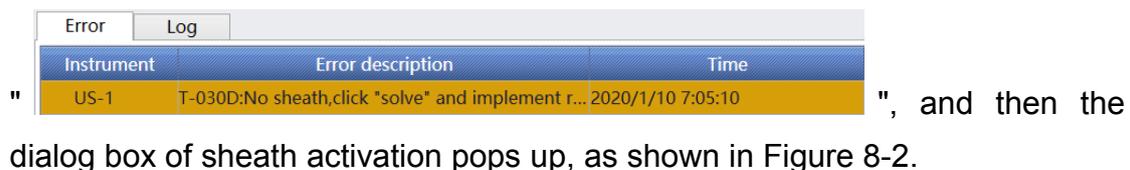


Figure 8-1 Maintenance

8.1.1 Change Sheath

Click "Resolve", when the system prompts



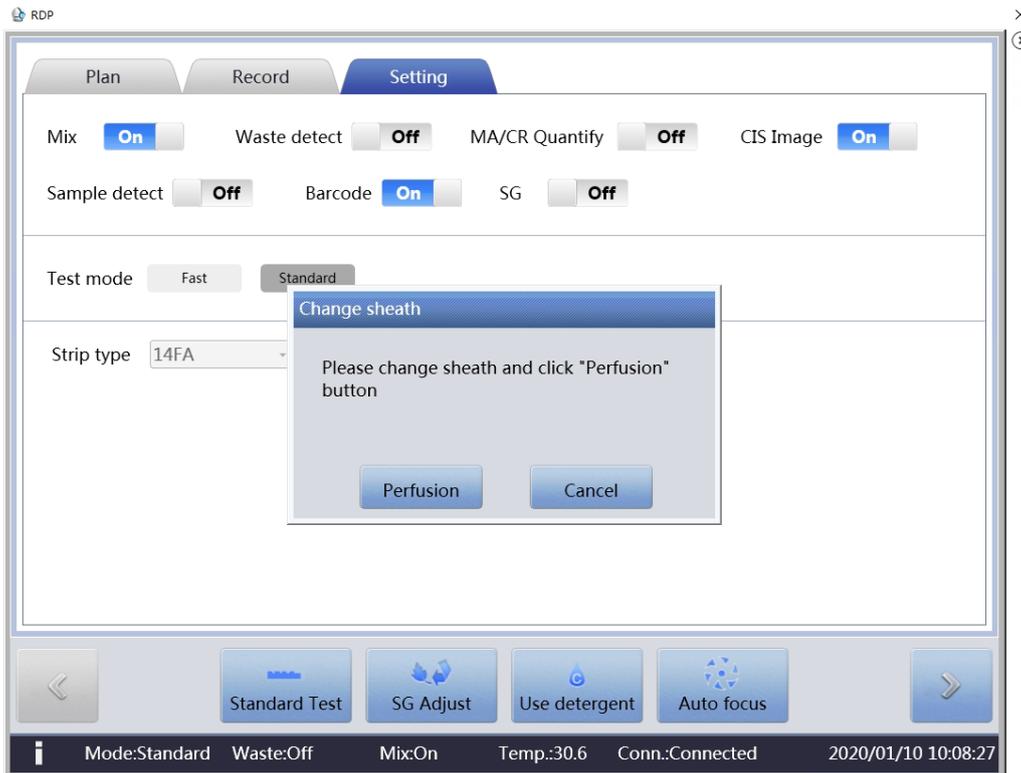


Figure 8-2 Change Sheath

Click "" to prime sheath, as shown in 8-3.

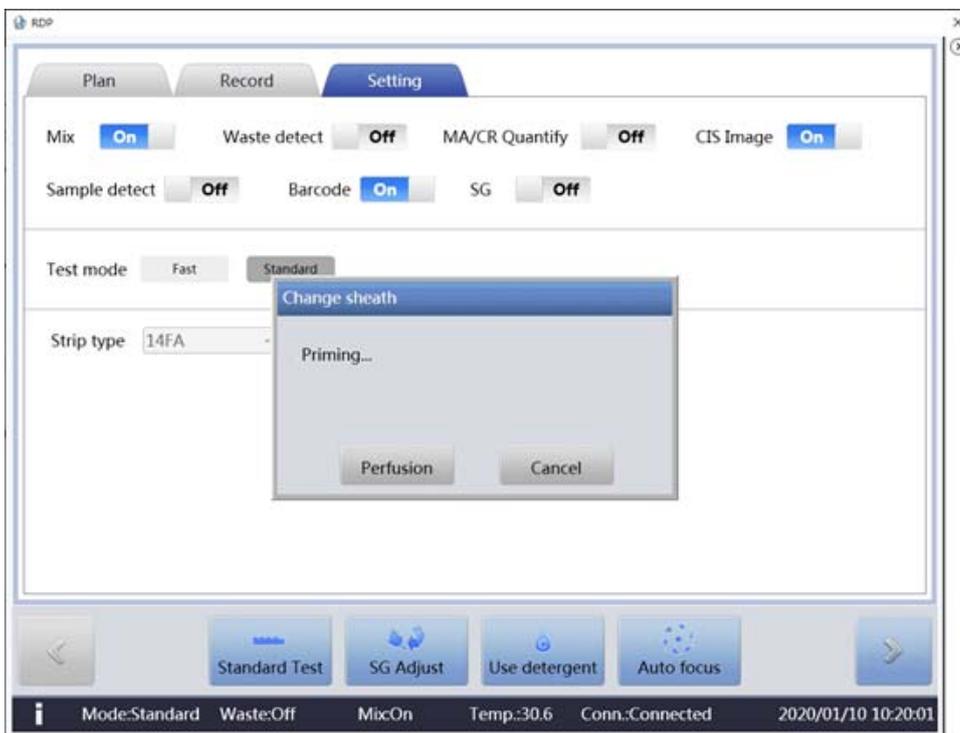


Figure 8-3 Change Sheath

Replacement is completed, see Figure 8-4.

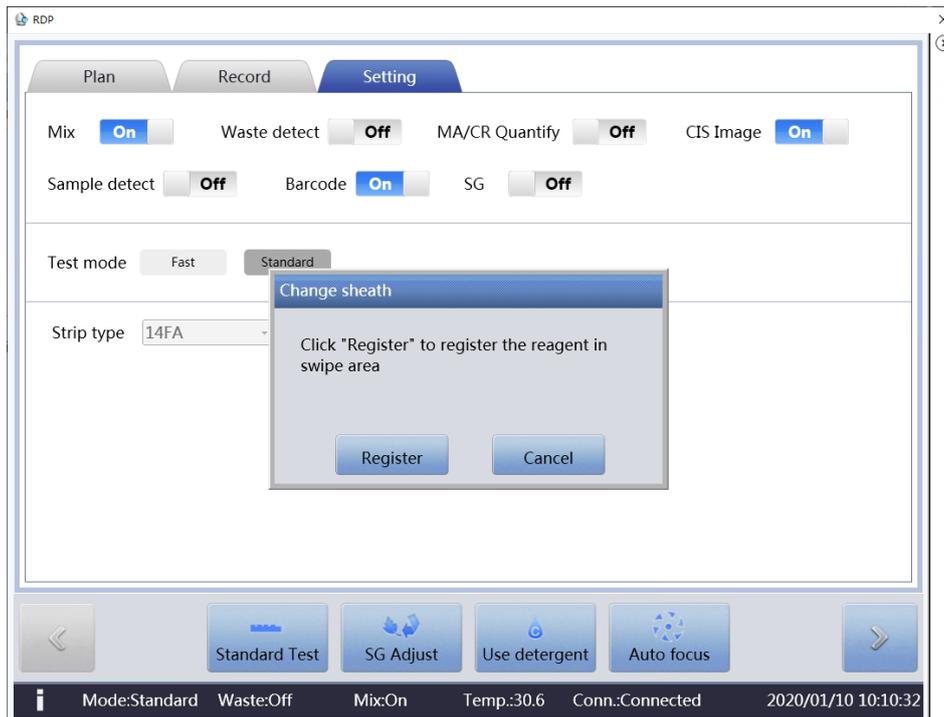


Figure 8-4 Change Sheath

Now click "", and activate the card in activation area, as shown in Figure 8-5.

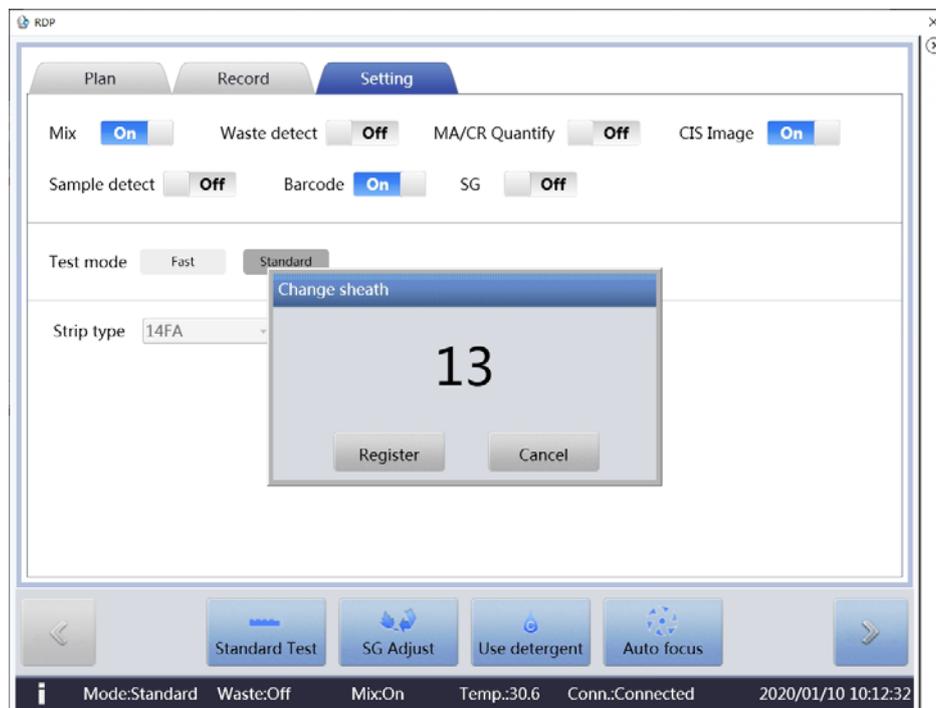


Figure 8-5 Change Sheath

A prompt box will pop up after successful activation, as shown in Figure 8-6.

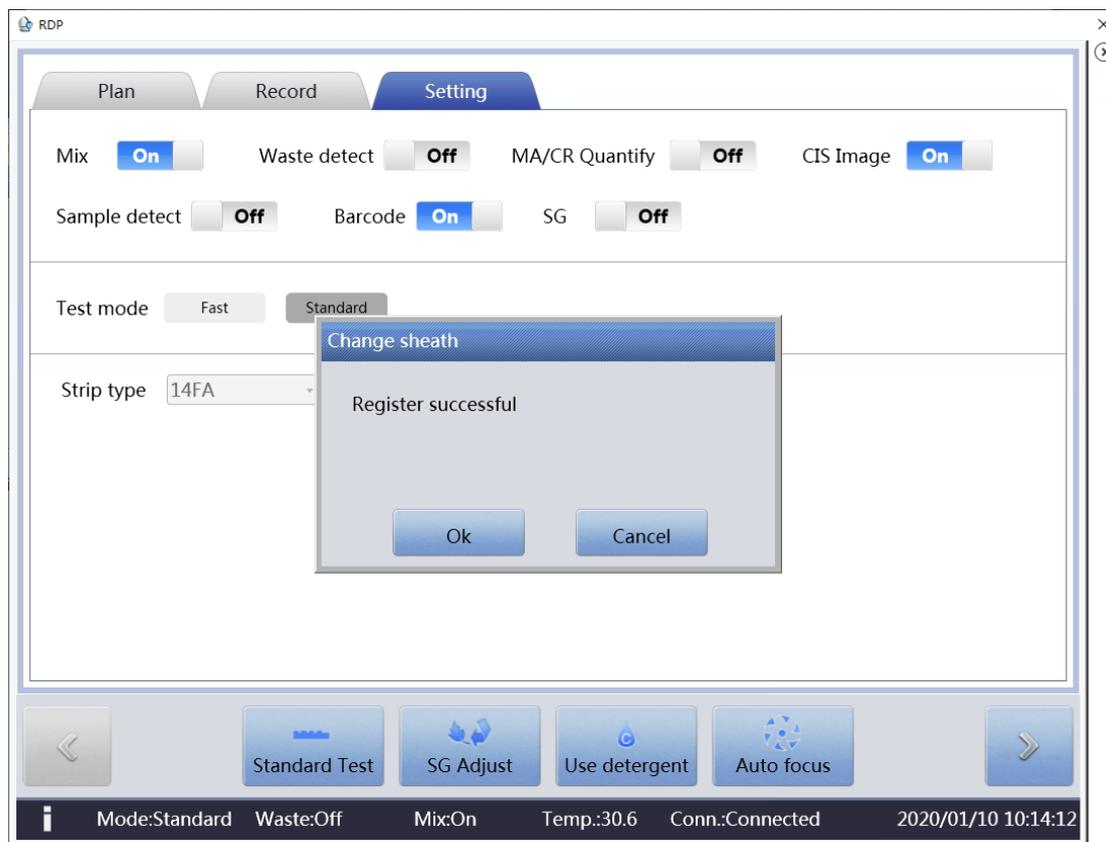
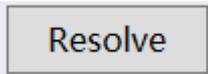


Figure 8-6 Change Sheath

8.1.2 Use Detergent

Click "  ", when the system prompts

Instrument	Error description	Time
US-1	T-D025:Please pour the detergent into the first...	2020/1/10 7:40:49

" , and then the dialog box of using detergent pops up, as shown in Figure 8-7.

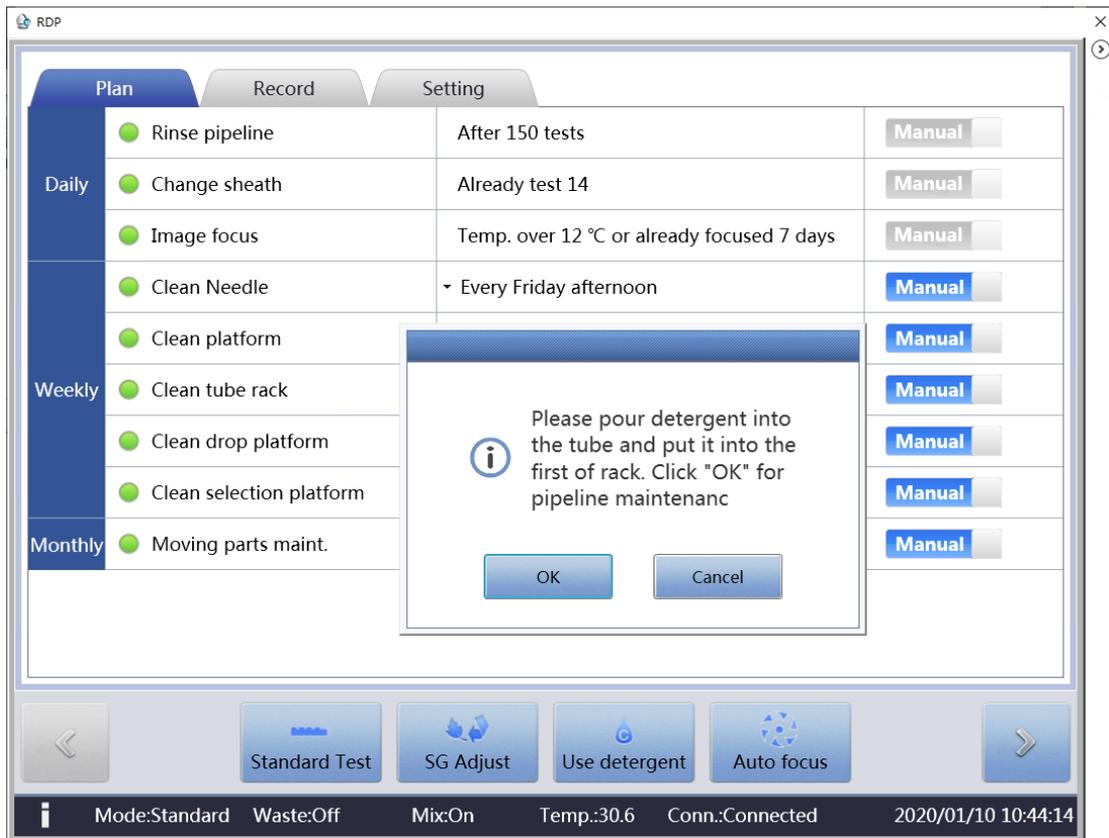


Figure 8-7 Use Detergent

Now add 5ML detergent into test tube and place it to the first position of test tube rack. Put the rack to the right of sample loader and click

"  "to start the procedure of using detergent, as shown in Figure 8-8.

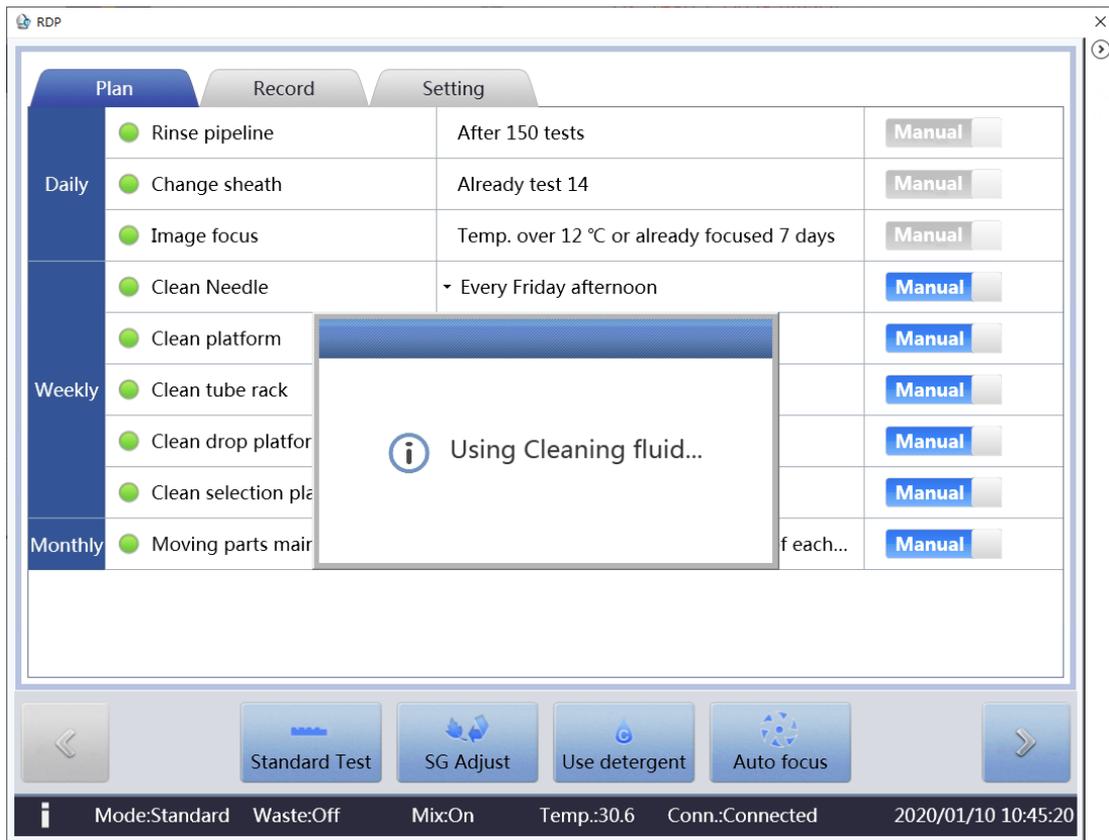


Figure 8-8 Use Detergent

8.1.3 Flush

Click , and a dialog box pops up, as shown in Figure 8-9.

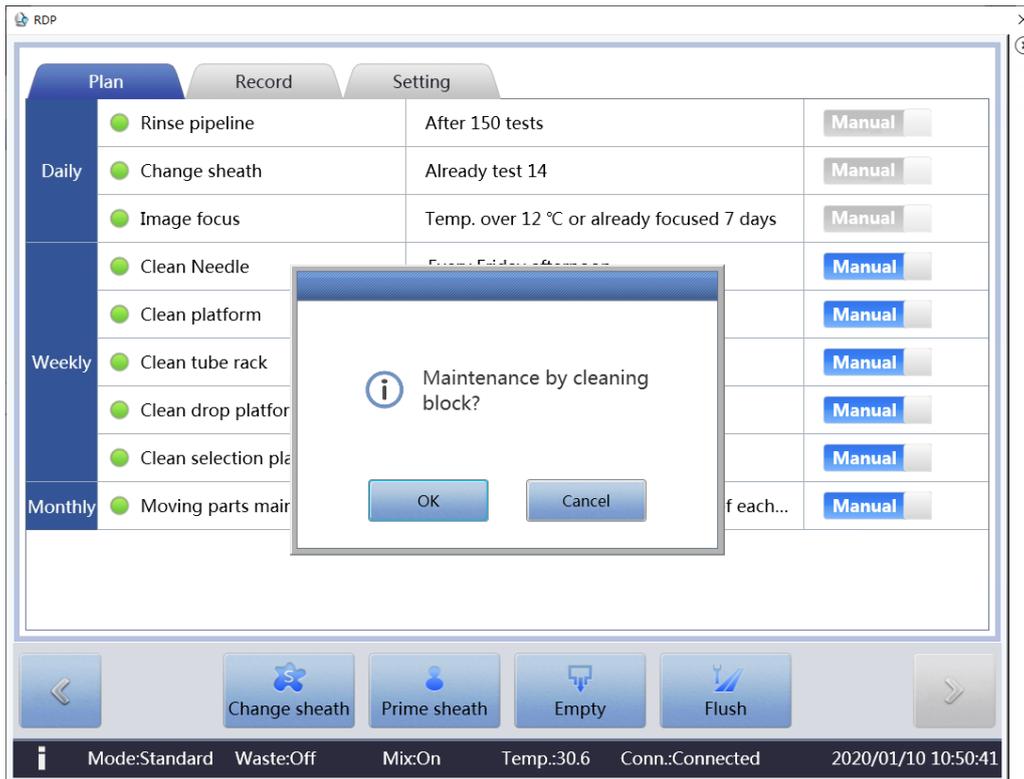


Figure 8-9 Flush

Click "OK" to start flush, as shown in Figure 8-10.

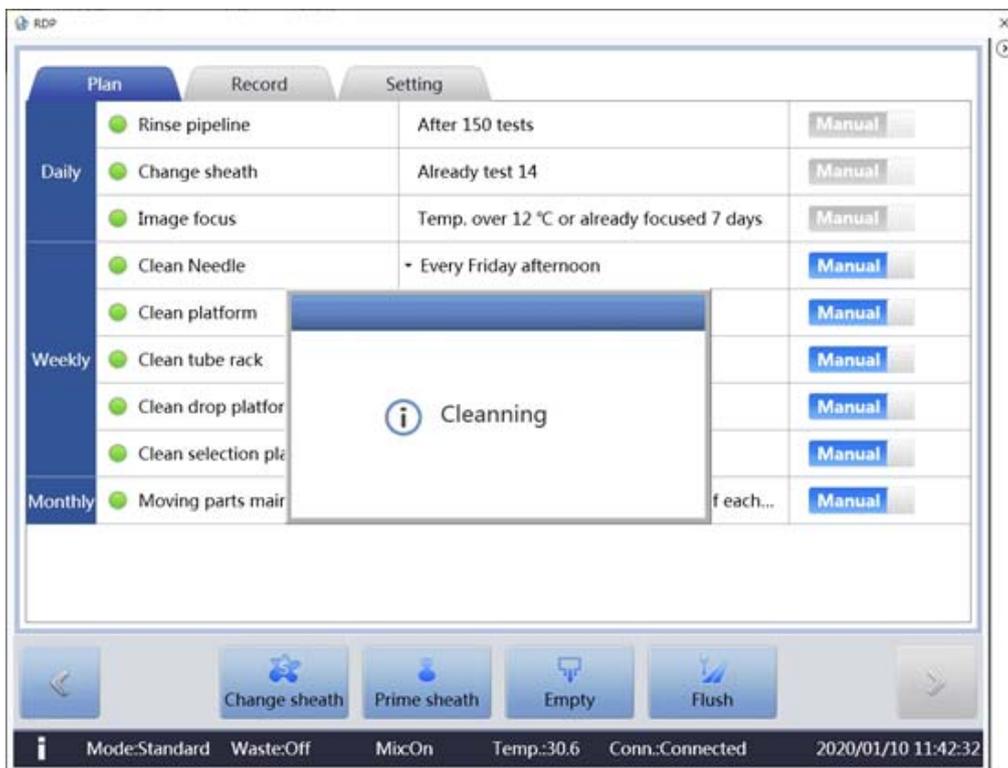
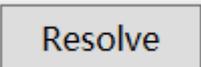


Figure 8-10 Flush

8.1.4 Auto Focus

When microscope is out of focus or instrument prompts for auto focus, the system prompts

Error		Log
Instrument	Error description	Time
US-1	T-D023:It has been 7 days since last focus,Pleas...	2020/1/10 7:54:40

Click "  ",and the prompt is shown as Figure 8-11:

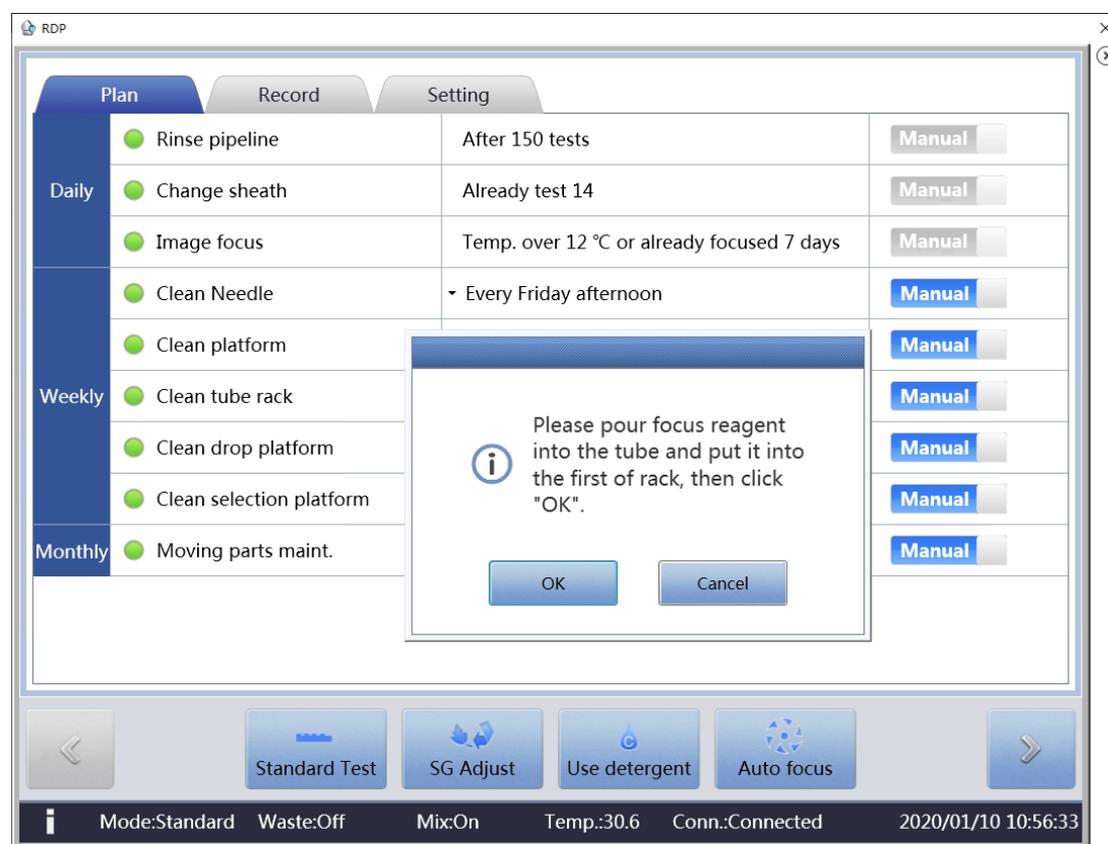


Figure 8-11 Auto Focus

Add focus solution into test tube and put it to emergency position. Click

"  " to start auto focus procedure, as shown in Figure 8-12.

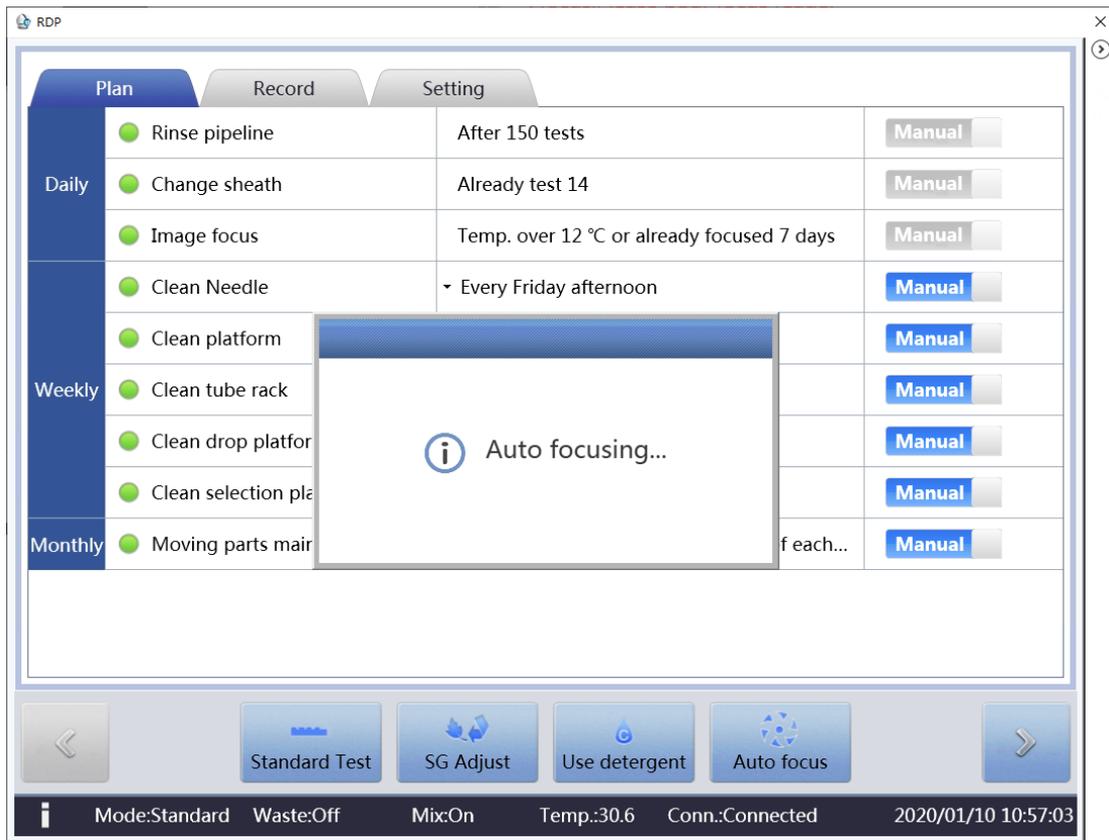


Figure 8-12 Auto Focus

After it's completed, it prompts "Focus success", as shown in Figure 8-13, or "Focus failed. Please manually debug first.", as shown in Figure 8-14.

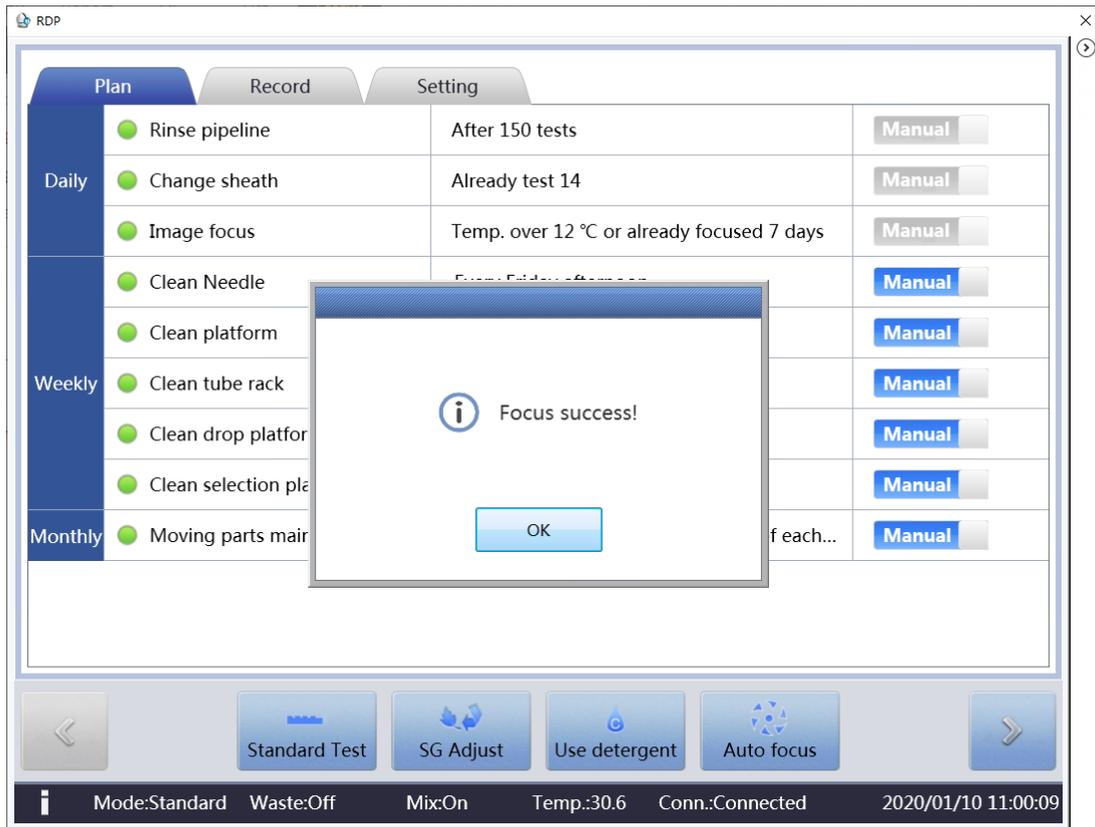


Figure 8-13 Focus Successfully

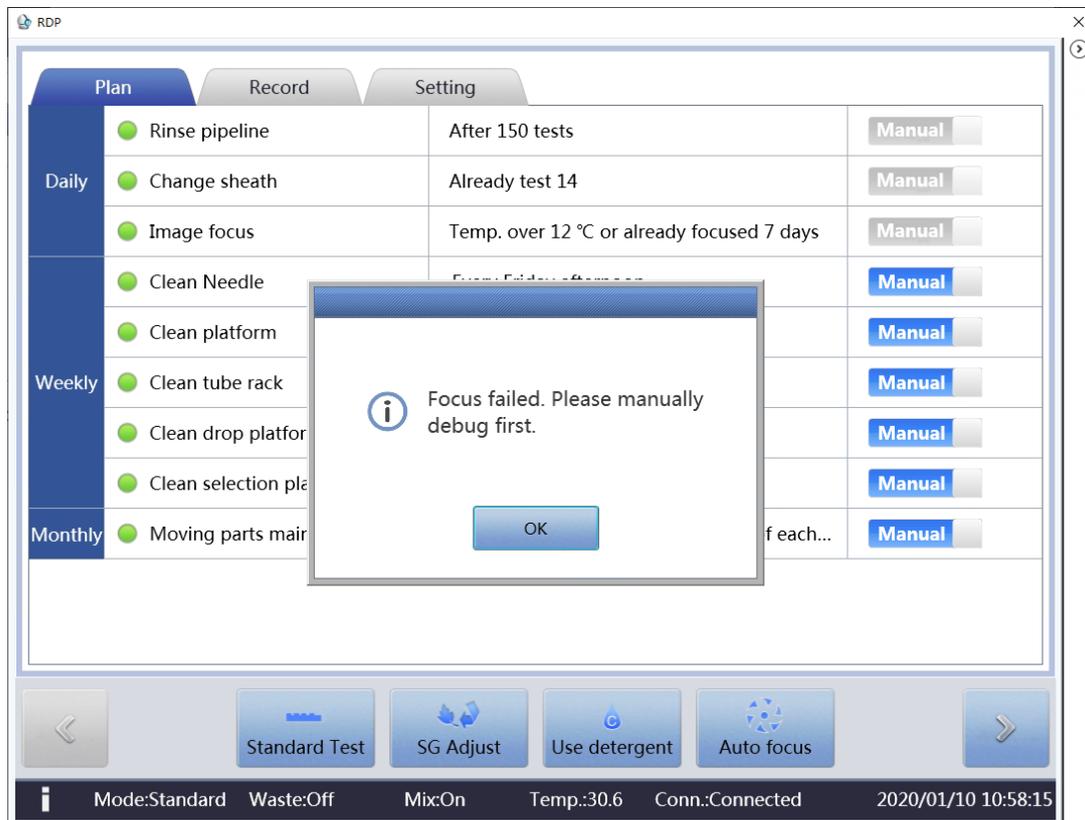


Figure 8-14 Focus Failed

If "Focus success" appears, the auto focus is completed, and you can do next operations. If " Focus failed. Please manually debug first" appears, please perform auto focus continuously. Please contact after-sale engineer if it fails 5 times.

8.1.5 Empty



Click "  ", and the dialog box below pops up, as shown in Figure 8-15.

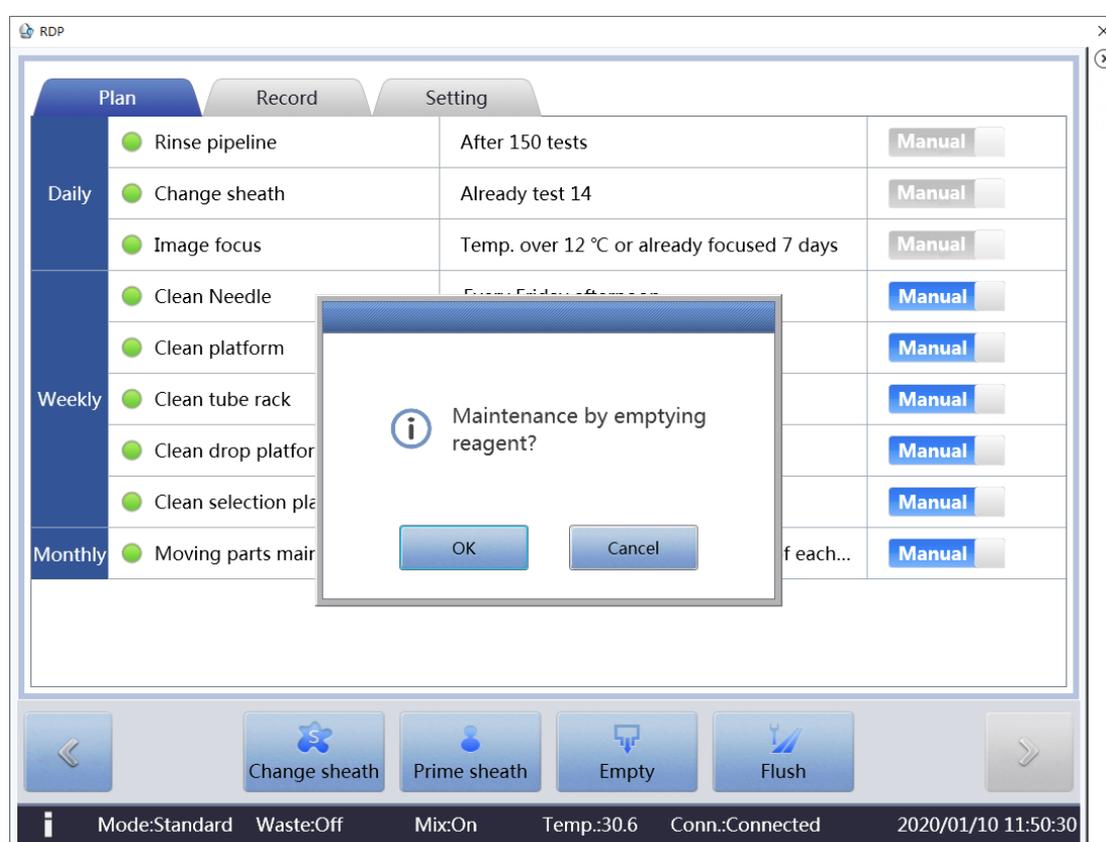
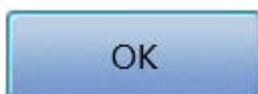
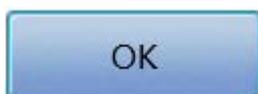


Figure 8-15 Empty Fluid System



Click "  "to start the procedure of empty fluid system,as shown in Figure 8-16.

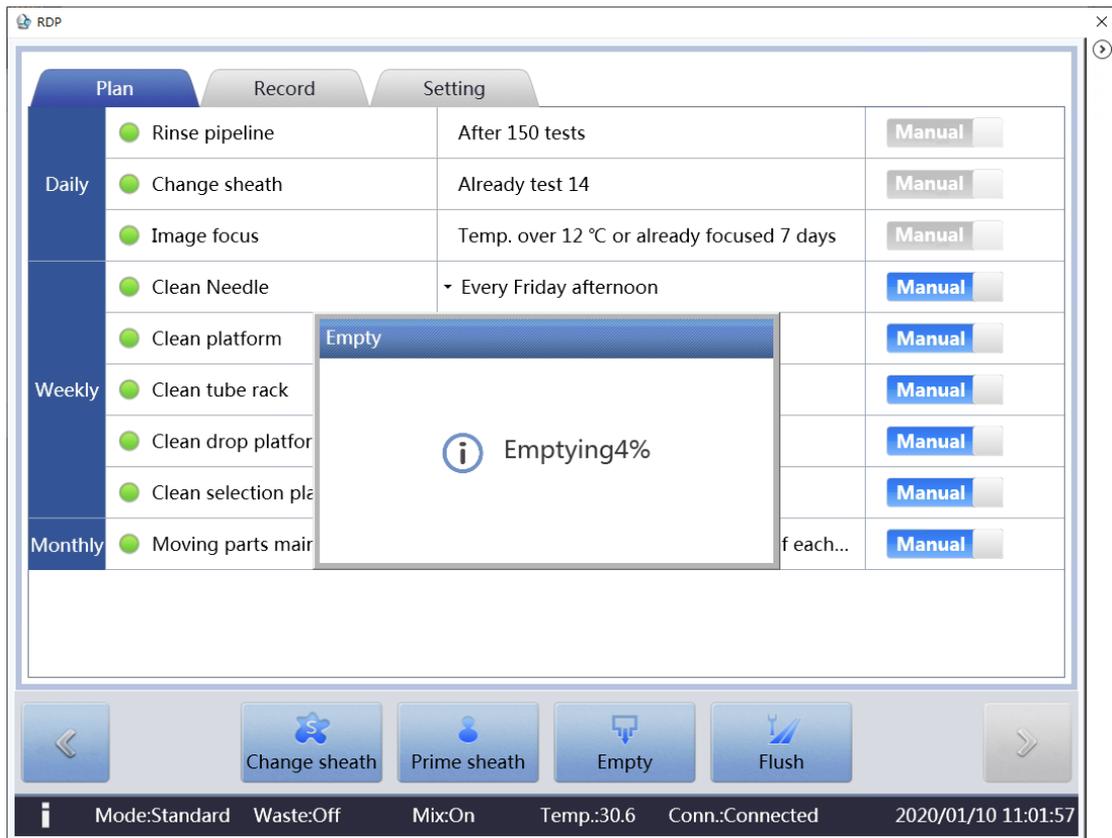


Figure 8-16 Empty Fluid System

8.1.6 Prime Sheath

Click "Resolve" to start the program of priming sheath, when system

prompts "Error Log", as shown in Figure 8-17.

Instrument	Error description	Time
US-1	T-D052:Please perfusion sheath	2020/1/10 7:54:40

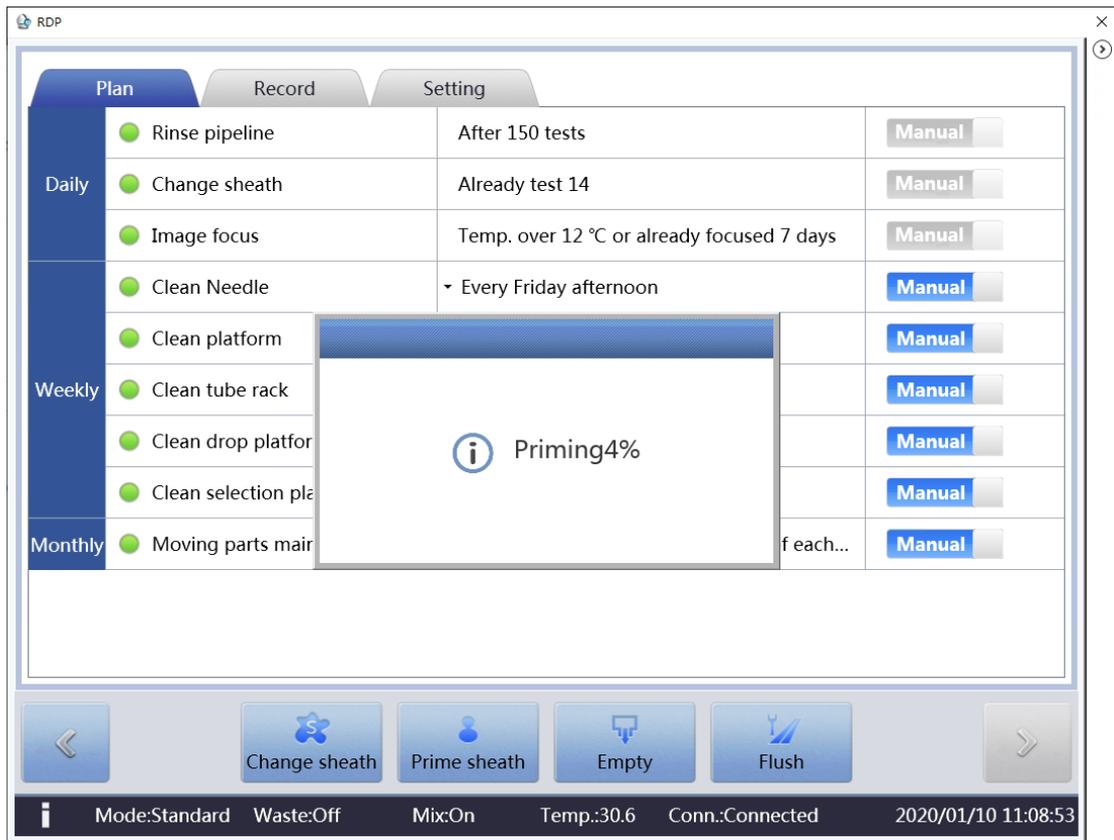


Figure 8-17 Prime Sheath

8.2 Maintenance Plan

The maintenance plan is divided into three parts: daily, weekly, and monthly, as shown in Figure 8-18.

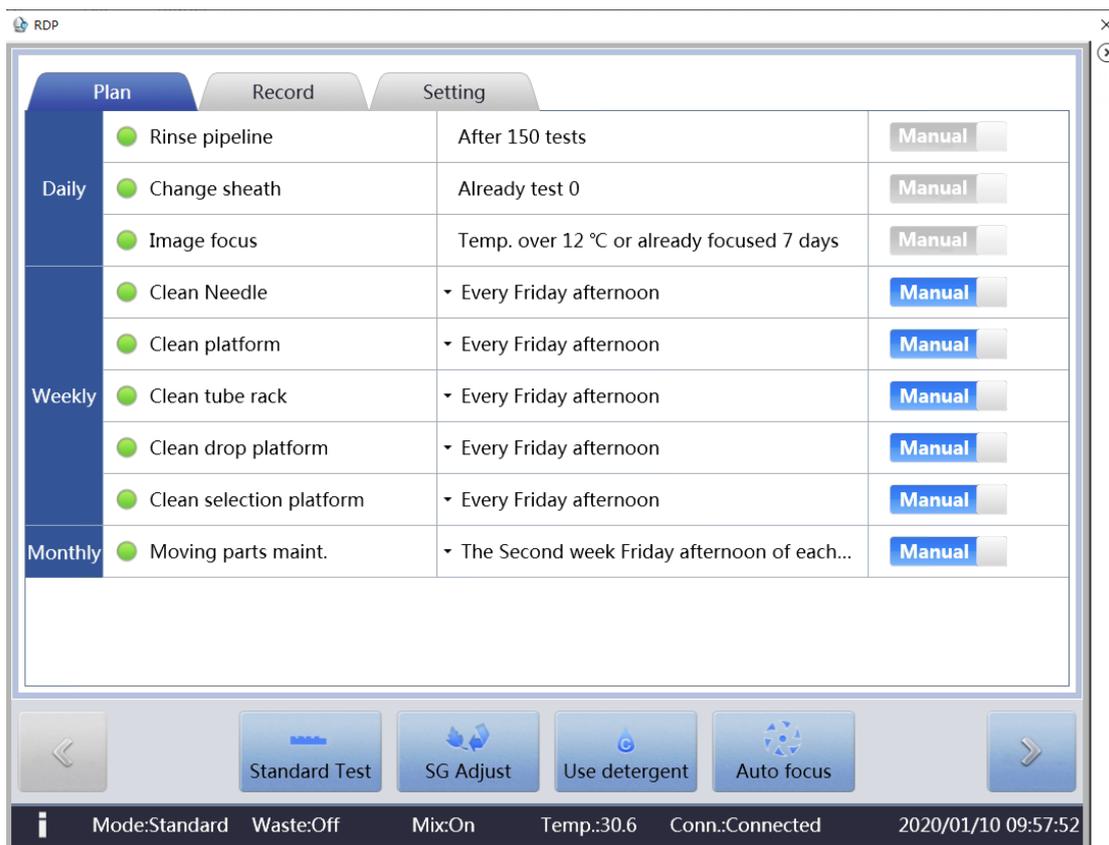


Figure 8-18 Maintenance Plan

1. Daily

1) Rinse pipeline: After testing 150 samples, when the instrument is idle, it will prompt for cleaning regulator and tubes. This function cannot be turned off.

2) "Changing sheath" : it shows how many samples have been tested after sheath replacement. This function cannot be turned off.

3) "Image Focus": The condition of image focus is 7 days or the temperature change is greater than 12 °C . When conditions are met, the system prompts the operator to focus manually. To ensure the normal operation of the instrument, it is recommended that the operator manually focus the image after the instrument is prompted. This function cannot be turned off.

4) "Clean needle": Clean sample probe every week. This function can be turned off.

5) "Clean platform": Clean sample loader and inductor every week. This function can be turned off.

6) "Clean tube rack": Once a week. This function can be turned off.

7) "Clean drop platform": Once a week. This function can be turned off.

8) "Clean selection platform": Once a week. This function can be turned off.

9) "Moving parts maint.": Once a week. This function can be turned off.



Biohazard

- Wear protective gloves to prevent bacterial infection.

Note

- Discard the used strips and gloves according to local regulations.

Required Items : Alcohol, cotton fabric, protective gloves.

Step 1: discard the used strips

- 1) Make sure the instrument is at standby or shutdown status.
- 2) Open the waste box, and discard the used reagent strips.

Step 2: Disinfect the waste box

- 1) Clean the waste box with alcohol, and then wash it with water.
- 2) Dry the waste box with cotton fabric.

Step 3: Install the waste box

Install the waste box back.

10) "Discard the waste liquid": Discard the waste liquid everyday.

Required Items: Alcohol, Protective gloves.



Biohazard

- Wear protective gloves to prevent bacterial infection.

Note

- Discard the used reagent strips and gloves according to local regulations.

Step 1: Discard waste liquid

- 1) Make sure the instrument is at standby or shutdown status.
- 2) Remove the cap from the waste bottle.
- 3) Discard the waste liquid.

Step 2: Clean the waste container

Clean the waste container with alcohol, and wash it with water.

Step 3: Cap the waste container

Put the cap back on the waste container and tighten it.

2. Weekly

1) Clean platform, which can be done by operator manually. Instrument will prompt at relevant time if this function is enabled. To ensure the normal operation, it's recommended to clean them manually if it prompts for cleaning.

Required items: alcohol, gauze or cotton swab, cloth or paper towels, protective gloves.



Biohazard

- Wear protective gloves to prevent bacterial infection.

Note

- Discard used cleaning items according to local regulations.

Step 1: Turn off the power

Make sure the instrument is standby, and then exit the system and power off.

Step 2: Empty test tube racks on the platform.

Empty test tube racks on the feeding sample mechanism.

Step 3: Clean surface of the platform.

Use gauze or cotton swab with alcohol to clean sampling feeding

mechanism. Clear up the urine scale and dirt on the platform.

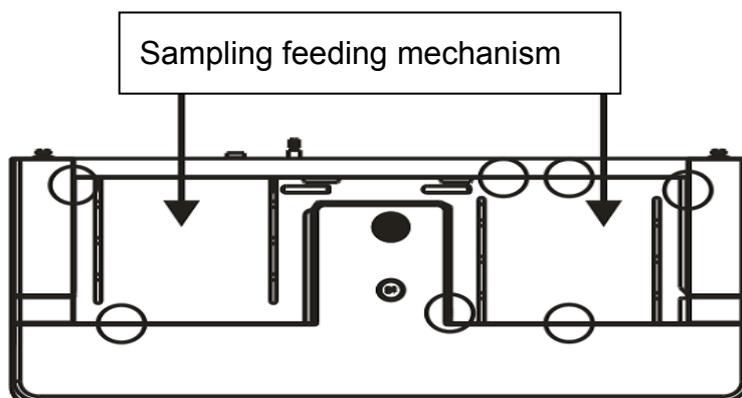


Figure 8-19

Step 4: Clean induction optocoupler

Use gauze or cotton swab with alcohol to clean induction optocoupler of sample feeding mechanism (See Figure 8-19, the circled position is induction optocoupler). Clear up the urine scale and dirt on the surface of induction optocoupler.

2) The purpose of cleaning the test tube rack is to ensure the bar code of the test tube holder is clear and increase the recognition rate. Please clean it on every Monday morning. To ensure the normal operation, it's recommended to clean it manually if it prompts for cleaning.

3) The residue urine on the dripping platform could affect strips movement. Please clean the platform every week.

Required items: alcohol, gauze or cotton swab, cloth or paper towels, protective gloves.



Biohazard

- Wear protective gloves to prevent bacterial infection.

Note

- Discard used cleaning items according to local regulations.

Step 1: Turn off the power supply

Make sure the instrument is standby, and then exit the system and power off.

Step 2: Open the side cover

Open the side cover with the key(as shown in Figure 8-20).

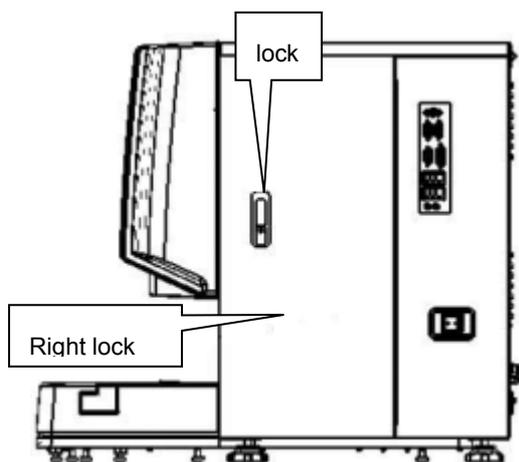


Figure 8-20

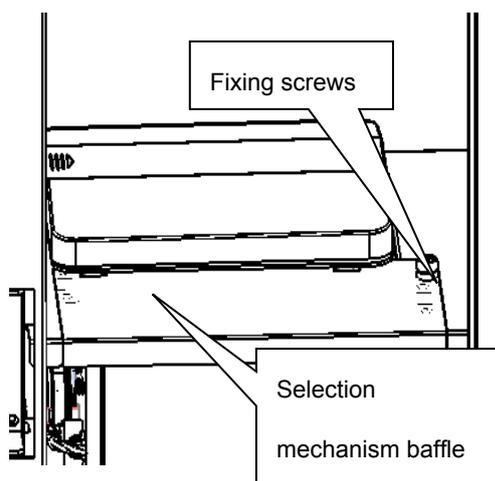


Figure 8-21

Step 3: Remove the selection mechanism baffle

1. Remove the fixing screws of the selection mechanism baffle and take out the baffle (as shown in Figure 8-21).
2. Reverse the selection mechanism to the right (as shown in Figure 8-22).

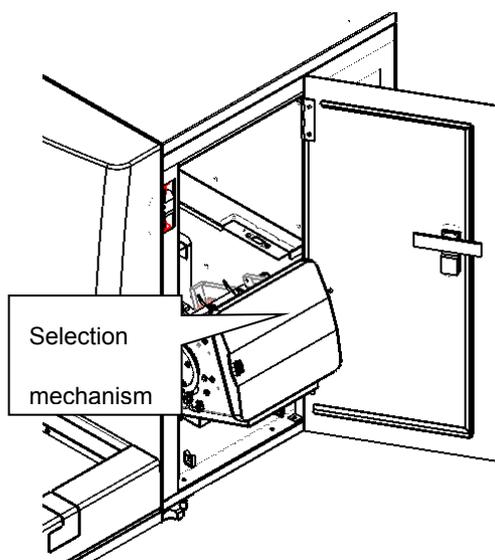


Figure 8-22

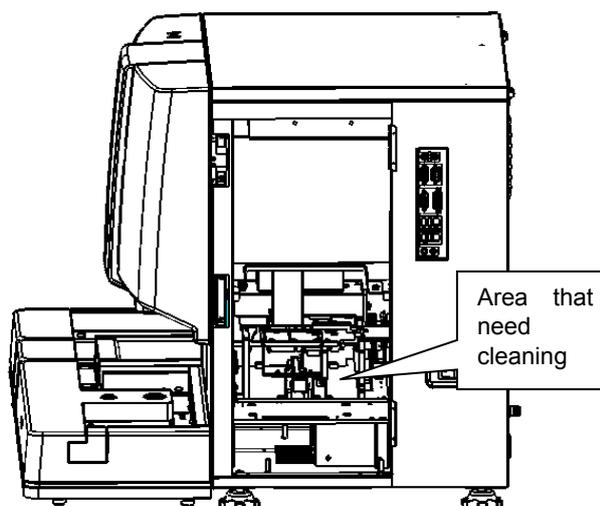


Figure 8-23

Step 4: Clean the dropping platform

Use soft fabric with alcohol to clean the urine scale on dropping platform.(Figure 8-23)

Note

- Do not scratch the dropping platform when cleaning, otherwise it may affect the movement of the strip.

Step 5: Install the selection mechanism and the baffle

1. Put the selection mechanism back in place.
2. Install the baffle and fasten the fixing screws.

Step 6: Install the side cover

1. Install the side cover.
2. Close the side cover switch and lock the side cover.

4) Dust on selection mechanism could affect the normal falling of test strips. Please clean it every week.

Items required: Big-size air pump, tissue paper.

Step 1: Turn off the power supply

Make sure the instrument is standby, and then exit the system and power off.

Step 2: Remove test strips

- 1) Open the sealed cap up(Figure 8-24).
- 2) Remove test strips from test strip feeder (Figure 8-25).
- 3) Wrap them with tissue paper to prevent dust contamination.

Note

- Do not touch the reagent pads of strip for it may cause incorrect test results.

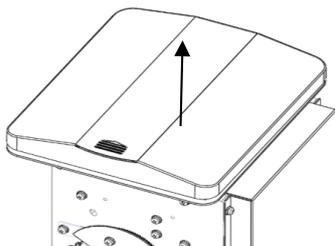


Figure 8-24

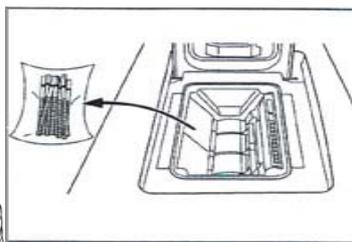


Figure 8-25

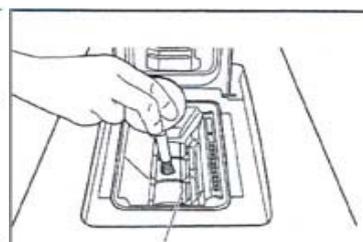


Figure 8-26

Step 3: Clean the test strip feeder

- 1) Using the air pump to clean the test strip feeder.(Figure 8-26).
- 2) Place the test strips back in the test strip feeder.
- 3) Replace the feeder cover and lock it.

Step 4: Open side cover

Open the side cover with the key (as shown in Figure 8-20).

Step 5: Remove the selection mechanism baffle (Figure 8-21).

- 1) Remove four screws in the corner of plate.
- 2) Remove the baffle.

Step 6: Clean the feeding components

- 1) Reverse the test strip feeder to the right (Figure 8-22).
- 2) Clean the pathway areas with the pump (Figure 8-27).

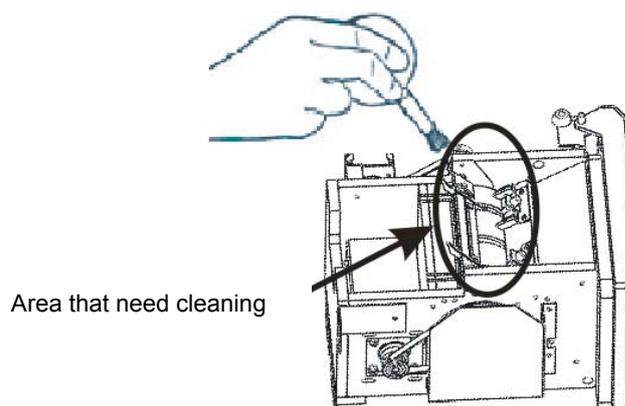


Figure 8-27

Step 7: Install the selection mechanism and baffle

- 1) Install the selection mechanism
- 2) Install the baffle, and tighten the screws.

Step 8: Install the side cover

- 1) Install the side cover.
- 2) Close the side cover and lock it.

3. Monthly

Maintain moving components on the first week of the month manually. To ensure the normal operation, it's recommended to maintain moving components manually if it prompts for maintenance.

8.3 Record

The maintenance record interface is shown in Figure 8-28. The system displays daily, weekly, and monthly maintenance items. The green dot on the date represents maintenance has been done on that day. The operator can query the maintenance record through the operation area on the right side of the interface.

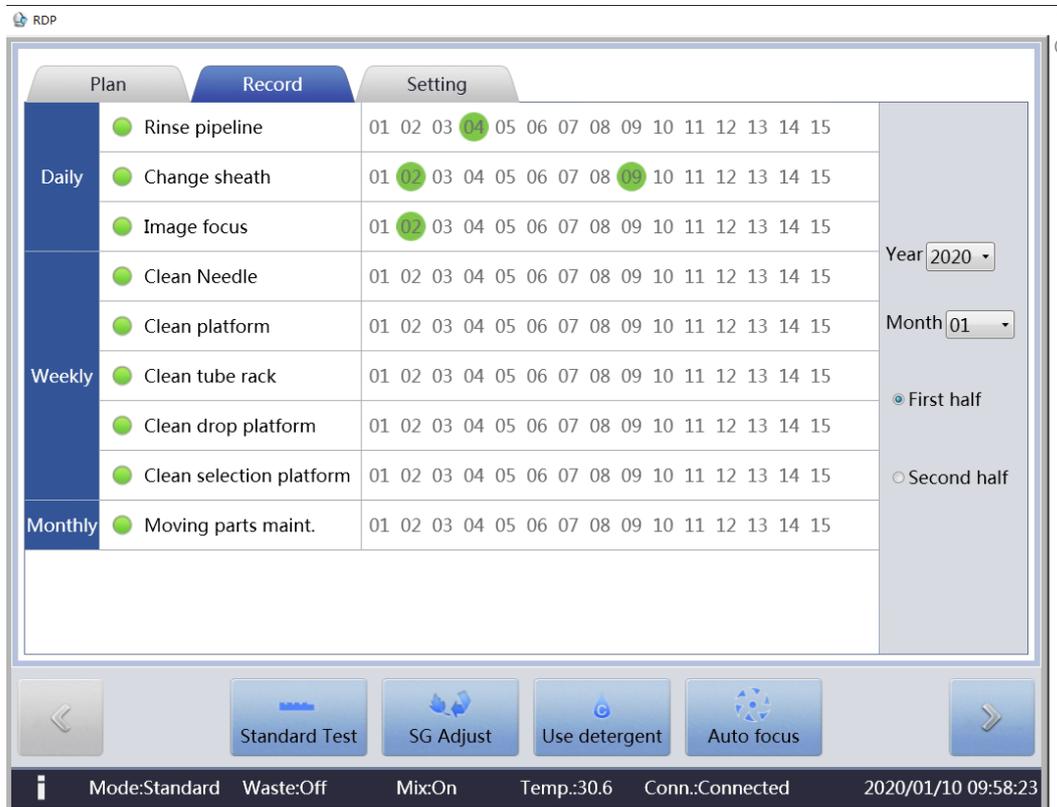


Figure 8-28 Maintenance Record

8.4 Settings

The interface includes the settings for Mix, Waste, Sample detect, Bar code, SG module and Strip type, as shown in Figure 8-29.

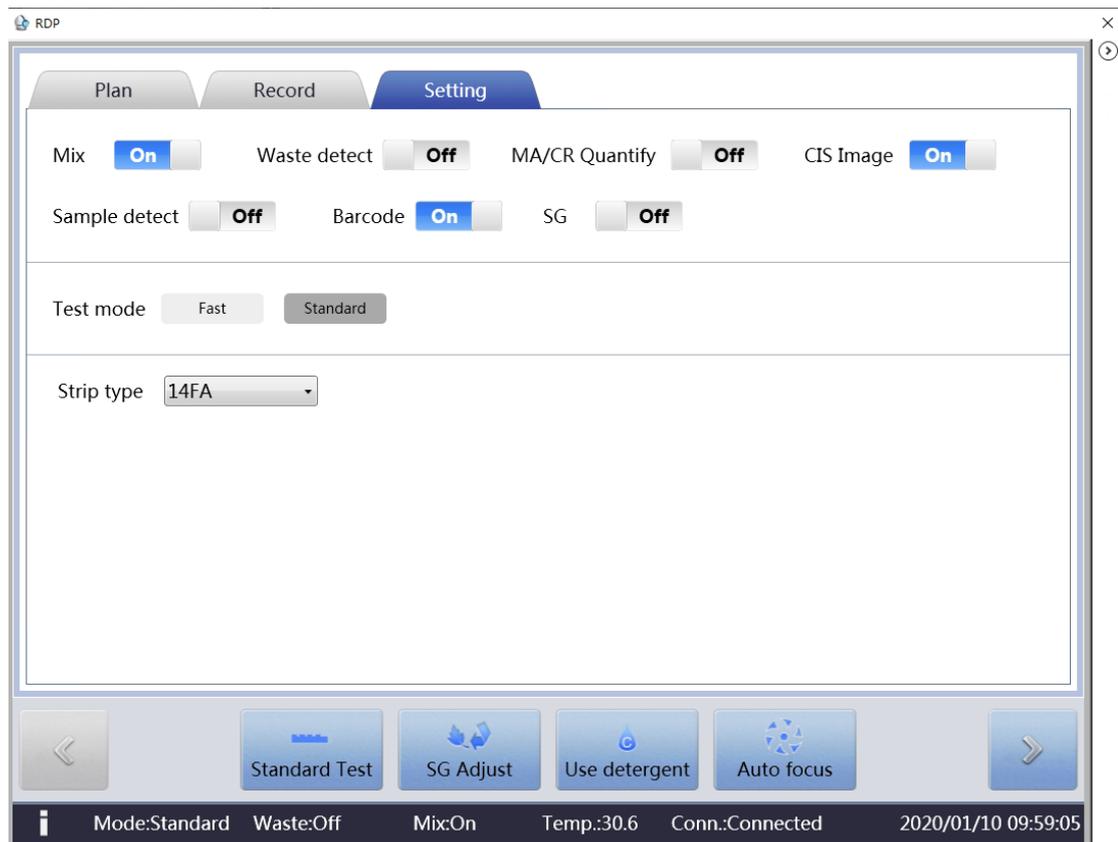


Figure 8-29 Maintenance Settings

8.5 Maintenance for Long-term Disuse



Biohazard

- Wear protective gloves to prevent bacterial infection.

Note

- Discard used cleaning items, waste liquid, replaced components and gloves according to local regulations.

Required Items: distilled water, cotton swabs, alcohol, cleaning brush, paper towels, protective gloves.

Step 1: Clean the selection mechanism, the dropping detection platform, and the test tube rack feeding mechanism.

Refer to *Section 8.2*.

Step 2: Discard used test strips

Discard the used test strips in the waste box.

Step 3: Drain Fluid System

- 1) Make sure the instrument is in standby status.
- 2) Pull out the sheath inlet tube from bottle.
- 3) Click [Empty] in maintenance interface. Rinse the fluid system with distilled water (insert the sheath inlet tube into distilled water), and click [Prime sheath]. Then click [Empty] again.
- 4) When the instrument is in standby, exit the system and turn off the power.

Step 4: Seal up the sheath

Cover the cap of sheath bottle and store it to properly.(Check whether it's expired before reuse. Please discard the expired sheath.)

Step 5: Discard waste liquid

Discard waste liquid from the waste bottle.

Step 6: Keep the power cord well

Pull the power cord from the socket.

8.6 Scraped Instrument

Don't discard the instrument at will after its service life. Please contact manufacturer for recycle.

Chapter 9 Transportation and Storage

9.1 Transportation

The instruments are precision measuring instruments. The necessary protective measures should be taken in the course of transportation. Keep away from toxicant, nocuous and corrosive material.

Transport condition: $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$, $\text{RH} \leq 95\%$.

Atmospheric Pressure: $86\text{kPa} \sim 106\text{kPa}$.

9.2 Storage

Wrapped instruments should be stored in a breezy room with temperature of $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$, relative humidity $\leq 95\%$, and keep away from toxicant, nocuous and corrosive material.

Atmospheric Pressure: $86\text{kPa} \sim 106\text{kPa}$.

Chapter 10 Troubleshooting

This Chapter gives instructions for identifying, troubleshooting, and correction of analyzer problems. If malfunction is not solved according to guidance or more information is needed, please contact URIT after-sale department.

10.1 Troubleshooting Guidance

The Troubleshooting Guidance is designed to assist the operator in identifying and resolving instrument problems. Instructions are also given for obtaining technical assistance immediately from URIT after-sale department. The first step in the process is to understand normal operation and preventive maintenance.

Be sure to read through this Operating Manual and be familiar with the operation flow and maintenance.

Experience helps for identifying and resolving operational problems. Logical troubleshooting may be divided into three steps:

1. Problem Identification
2. Fault Classification
3. Trouble Removal

Step 1: Problem Identification means not only identifying what is wrong but also what is right.

Step 2: Problems are generally divided into three categories:

1. Hardware component related
2. Software computer programs related
3. Sample analysis related

Hardware and software problems can only be corrected by a URIT

authorized engineer. The operator can correct sample measurement problems with assistance from URIT engineers.

Step 3: URIT engineers will take corrective measures to remove troubles, or user can get it done with the help from engineers authorized by URIT.

10.2 Obtaining Technical Assistance

Technical Assistance is obtained by calling the URIT after-sale department. When assistance is needed, please provide the following information for Customer Support Specialists:

1. The instrument model
2. Serial number and version number
3. Description of the problem and surroundings, including status and operation
4. The lot numbers of the reagents.
5. Data and report of the problem

Common problems and disposals are given in this Chapter. The operator can identify the cause and deal with problems according to the warning information and Troubleshooting Guidance.

10.3 Troubleshooting

Common faults and corrective actions are listed as follows. If the problems cannot be corrected, or technical assistance is needed, please contact with URIT after-sale department.

10.3.1 Startup Error

Probable Cause:

- ① Power receptacle damaged;
- ② The fuse in the rear panel melted.

Corrective Action:

- ① Replace the analyzer power receptacle.
- ② Replace the fuse on the rear panel.

10.3.2 Not display

Probable Cause:

The signal cable of display is loose.

Corrective Action:

Reconnect the signal cable of display well and fasten the screws.

10.3.3 Mouse Error

Probable Cause:

- ① The cable of mouse was loose;
- ② The mouse was broken.

Corrective Action:

- ① Reconnect the cable well.
- ② Replace the mouse.

10.3.4 Keyboard

Probable Cause:

- ① The keyboard cable was loose;
- ② The keyboard was broken.

Corrective Action:

- ① Reconnect the keyboard cable well.
- ② Replace the keyboard.

10.3.5 Printer Error

Probable Cause:

- ① The printer cable was loose;
- ② Connection errors between the cable and power receptacle;
- ③ The power of printer is turn off.

Corrective Action:

- ① Reconnect the cable of printer well;
- ② Reconnect the cable with the power receptacle well;
- ③ Turn on the power of printer.

10.3.6 A warning message appears on the screen: Change sheath, and activate.

Probable Cause:

The sheath is used up.

Corrective Action:

- ① Change sheath
- ② In the menu of instrument operation on the screen, click the key of "Change sheath", and activate with the matching activation card.

10.3.7 Waste full

Probable Cause:

- ① Waste is full;
- ② Waste sensor cable was loose.

Corrective Action:

- ① Empty the waster container;

- ② Reconnect the waste sensor cable well.

10.4 Fault Code Table

Fault Code	Inspection information	Type	Solution
T-0101	Drum reset error	Error	<ol style="list-style-type: none"> 1. Please check whether there is jammed test strips in space block. If yes, take it out. 2. Click Solve and system resets. 3. If the fault is still unsolved, contact our after-sales service engineer.
T-0102	Transfer paper reset error	Error	<ol style="list-style-type: none"> 1. Please check whether there is jammed test strips. If yes, take it out. 2. Click Solve and system resets. 3. If the fault is still unsolved, contact our after-sales service engineer.
T-0103	Stuck paper error	Error	<ol style="list-style-type: none"> 1. Please turn off the analyzer and take out the foreign matters in the roller. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0104	No paper error, please put in the test paper and click the "solve"	Error	Add test strips into selection mechanism and click Continue.

T-0131	A1 communicate error	Error	<ol style="list-style-type: none"> 1. Restart the analyzer. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0201	Stir bar reset error	Error	<ol style="list-style-type: none"> 1. Restart the analyzer. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0202	Drop position test paper reverse	Error	<ol style="list-style-type: none"> 1. Check that the test strips are placed correctly. Restart the analyzer. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0203	Drop position no paper error	Error	<ol style="list-style-type: none"> 1. Please turn off the analyzer. Then restart it after cleaning the dripping platform. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0205	Check position no paper	Error	<ol style="list-style-type: none"> 1. Please check whether there is foreign matters on the belt. If yes, take it out. 2. Click Solve and system resets. 3. If the fault is still unsolved, contact our after-sales service engineer.

T-0208	Wast paper full	Error	Clear up the waste strips and click Continue.
T-020a	Adjust CIS error	Error	Calibrate CIS again.
T-020b	No CIS paper	Error	Debug fault information
T-020c	CIS save file error	Error	Debug fault information
T-020d	CIS calibration file is failed to open	Error	Debug fault information
T-020e	CIS open file error	Error	1. Restart the analyzer. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-020f	CIS no light	Error	1. Restart the analyzer. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0210	CIS adjust light failed	Error	Debug fault information
T-0211	Adjust move paper failed	Error	Debug fault information
T-0214	White block calibration failed	Error	Debug fault information
T-0215	Black block calibration failed	Error	Debug fault information
T-0231	A2 communication error	Error	1. Restart the analyzer. If the fault is still unsolved, contact our after-sales service engineer.

T-0301	X motor error	Error	<ol style="list-style-type: none"> 1. Click "Solve", and reset motor. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0303	Y motor error	Error	<ol style="list-style-type: none"> 1. Click "Solve", and reset motor. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0308	Waste full	Error	<ol style="list-style-type: none"> 1. Check that the waste liquid sensor wire is connected properly. If the waste container hasn't been used, please disable the function of waste detection. Then click Solve. 2. Check the waste container, If it's full, please empty it and click Solve. 3. If the fault is still unsolved, contact our after-sales service
T-0309	Liquid sensor error	Error	<ol style="list-style-type: none"> 1. Click "Solve", and reset motor. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-030a	Sample empty	Error	<ol style="list-style-type: none"> 1. If the sample in the tube is insufficient, it's normal. 2. If the sample is enough but it can not be detected, please contact our after-sale service engineer.

T-030b	SG model Communication error	Error	<ol style="list-style-type: none"> 1. Restart the analyzer. 2. If the fault is still unsolved, please turn off SG module in 【Maint.】-【Setting】 interface or contact our after-sales service engineer.
T-030c	Active reagent card,click "solve" and implement reagent registration process	Error	<ol style="list-style-type: none"> 1. Replace reagents. 2. Click Solve and active the card according to the prompt. 3. If the fault is still unsolved, contact our after-sales service engineer.
T-030d	No sheath,click "solve" and implement reagent registration process	Error	<ol style="list-style-type: none"> 1. Replace reagents. 2. Click Solve and active the card according to the prompt. 3. If the fault is still unsolved, contact our after-sales service engineer.
T-030e	No card Reader	Error	<ol style="list-style-type: none"> 1. Click Solve and system resets. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-030f	No card or read error	Error	<ol style="list-style-type: none"> 1. Click Solve and system resets. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0310	Card data error	Error	<ol style="list-style-type: none"> 1. Click Solve and system resets. 2. If the fault is still unsolved, contact our after-sales service engineer.

T-0312	Rinse tank plug	Error	<ol style="list-style-type: none"> 1. Check whether the tube is bent or blocked. 2. Clear up the water on the well. 3. Click Solve and system resets. 4. If the fault is still unsolved, contact our after-sales service engineer.
T-0313	Pump 25ML error	Error	<ol style="list-style-type: none"> 1. Click Solve and system resets. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0314	Pump 500UL error	Error	<ol style="list-style-type: none"> 1. Click Solve and system resets. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0315	Pump 250UL error	Error	<ol style="list-style-type: none"> 1. Click Solve and system resets. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0320	Upgrade error	Error	<ol style="list-style-type: none"> 1. Click Solve and system resets. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0331	A3 communication error	Error	<ol style="list-style-type: none"> 1. Click Solve and system resets. 2. If the fault is still unsolved, contact our after-sales service engineer.

T-0341	SG adjust color light failed	Error	<ol style="list-style-type: none"> 1. Restart the analyzer. 2. If the fault is still unsolved, please turn off SG nodule in 【Maint.】 - 【Setting】 interface or contact our after-sales service engineer.
T-0342	SG adjust color data error	Error	Debug information
T-0343	SG adjust light failed	Error	Debug information
T-0344	SG adjust read data error	Error	Debug information
T-0345	SG adjust result failed	Error	Debug information
T-0346	SG adjust turbidity light failed	Error	Debug information
T-0347	SG adjust turbidity data error	Error	Debug information
T-0348	SG adjust turbidity result failed	Error	Debug information
T-034D	Color test failed	Error	<ol style="list-style-type: none"> 1. Restart the analyzer. 2. If the fault is still unsolved, please turn off SG nodule in 【Maint.】 - 【Setting】 interface or contact our after-sales service engineer.

T-034E	SG test failed	Error	<ol style="list-style-type: none"> 1. Restart the analyzer. 2. If the fault is still unsolved, please turn off SG nodule in 【Maint.】 - 【Setting】 interface or contact our after-sales service engineer.
T-034F	Turbidity test failed	Error	<ol style="list-style-type: none"> 1. Restart the analyzer. 2. If the fault is still unsolved, please turn off SG nodule in 【Maint.】 - 【Setting】 interface or contact our after-sales service engineer.
T-0501	M1 right motor reset error	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0502	M2 Left motor reset error	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0503	M3 inside motor reset error	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.

T-0504	M4 right motor reset error	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0505	M4 left motor reset error	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved,
T-0506	Left rack full	Error	Move away the test tube racks on the left side of sample loader and click Solve.
T-0509	Connect barcode timeout	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-050a	CIS rack No. scanning module connection timeout	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-050b	401 optocoupler fault in right inner part of injection mechanism	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.

T-050c	401 optocoupler fault in the right outside of A5	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-050d	401 optocoupler fault in the left inner of A5	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-050e	401 optocoupler fault in the left outside of the A5	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-050f	In tube 401Opt error	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0511	M6 motor reset error	Error	<ol style="list-style-type: none"> 1. Click Solve and the analyzer resets automatically. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-0531	A5 communication error	Error	<ol style="list-style-type: none"> 1. Restart the analyzer 2. If the fault is still unsolved, contact our after-sales service engineer.

T-0601	A6 communicate error	Error	<ol style="list-style-type: none"> 1. Restart the analyzer; 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D004	Open communication port failed!	Error	<ol style="list-style-type: none"> 1. Restart the analyzer; 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D020	Server not responding Make sure server is on	Error	<ol style="list-style-type: none"> 1. Check that the IPU network connection is proper. 2. If the network setting is proper but the fault is still unsolved, contact our after-sales service engineer.
T-D023	It has been {0} days since last focus, Please put focus reagent into the emergency position. Click "solve" for auto focus	Error	Click Solve and the analyzer focus automatically.
T-D024	Temperature variation is out of range, Please put focus reagent into the emergency position. Click "solve" for auto focus	Error	Click Solve and the analyzer focus automatically.
T-D025	Please put the detergent into the emergency position. Click "solve" for	Error	Put the detergent to emergency position. Click Solve, and the tube maintenance is performed.

T-D026	Cannot found acquisition card! Power off and restart!	Error	<ol style="list-style-type: none"> 1. Power off and reboot. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D027	Acquisition card error! Power off and restart!	Error	<ol style="list-style-type: none"> 1. Power off and reboot. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D028	Open acquisition card failed! Power off and restart!	Error	<ol style="list-style-type: none"> 1. Power off and restart. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D035	High light. Set auto brightness.	Error	<ol style="list-style-type: none"> 1. Click Solve to enable auto brightness. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D036	Low light. Set auto brightness.	Error	<ol style="list-style-type: none"> 1. Click Solve to enable auto brightness. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D044	PCIE DMA error, power off and restart.	Error	<ol style="list-style-type: none"> 1. Power off and restart. 2. If the fault is still unsolved, contact our after-sales service engineer.

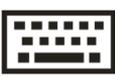
T-D045	Too many impurities, power off and restart.	Error	<ol style="list-style-type: none"> 1. Power off and restart. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D046	Camera init error, please check whether the camera connection is normal, power off and restart the system.	Error	<ol style="list-style-type: none"> 1. Power off and restart. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D047	Acquisition card initialization failed! Power off and restart!	Error	<ol style="list-style-type: none"> 1. Power off and restart. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D048	Flashlight works abnormally, please auto brightness and restart.	Error	<ol style="list-style-type: none"> 1. Power off and restart. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D050	Set auto brightness	Error	Click Solve to enable auto brightness.
T-D051	A6 communicate error	Error	<ol style="list-style-type: none"> 1. Power off and restart. 2. If the fault is still unsolved, contact our after-sales service engineer.
T-D052	Please perfusion sheath	Error	Click "Solve" to prime sheath.

T-D053	HID device connect failed	Error	Check whether the USB cable between A2 and industrial control is normal.
T-D061	Clean Needle	Warning	<ol style="list-style-type: none"> 1. Clean the sample probe with cloth. 2. Click Solve to eliminate the prompt.
T-D062	Clean sample loader and sensor	Warning	<ol style="list-style-type: none"> 1. Clean the sample loader and sensor with cloth. 2. Click Solve to eliminate the prompt.
T-D063	Clean sample rack	Warning	<ol style="list-style-type: none"> 1. Clean the tube rack with cloth. 2. Click Solve to eliminate the prompt.
T-D064	Maintain moving parts	Warning	<ol style="list-style-type: none"> 1. Check whether the moving components are normal, such as lever and belt. 2. Click Solve to eliminate the prompt.
T-D066	Clean selection platform	Warning	<ol style="list-style-type: none"> 1. Clean selection mechanism with cloth. 2. Click Solve to eliminate the prompt.
T-D067	Clean drop platform	Warning	<ol style="list-style-type: none"> 1. Clean dripping platform with cloth. 2. Click Solve to eliminate the prompt.

T-I001	Open server failed	Error	Check that server IP settings are correct in setting interface.
T-I002	Connect LIS failed	Error	<ol style="list-style-type: none"> 1. Check the network. 2. Confirm LIS IP and port. Check that the LIS server settings are correct. 3. LIS server is turned on.
T-I003	Instrument not connected.	Error	<ol style="list-style-type: none"> 1. Check the sub instrument network. 2. Check IP address and port. 3. Please confirm that the sub instrument communicates normally.
T-I004	Sub instrument error.	Error	Please solve the problem on the corresponding sub instrument.
T-I005	Log module loading exception.	Error	Please restart software or contact after-sale service engineer.
T-I006	In bridge timeout.	Error	<ol style="list-style-type: none"> 1. Check whether the test tube rack is blocked or has been taken away. 2. Confirm that the corresponding test tubes are on the sub instrument and click Solve.

T-I007	Unable to keep starting state	Error	Click Solve to stop and eliminate error.
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Appendix A: Instrument Icon and Symbols Specification

	Shock hazard		Caution		Biohazard
	Power on		Power off		Functional grounding
	In Vitro Diagnostic medical device		Manufacturer		Serial number
	Temperature limit		Electronic products recycling logo		Protect from heat and radiation
	Upward		Fragile		Protect from water
	Stacking level limit		No turning over		Consult instructions for use
	Serial port		Ethernet interface		USB interface
	Mouse interface		Keyboard interface		Watch your finger and hand
	Protect from heat		Environment-friendly use period: 10 years		Date of manufacture
	Validity		Fuse		Alternating current

Appendix B: Instrument Specification

Dimensions and Weight

Dimension(HxWxD):

618mmx630mmx680mm

Instrument weight: 82.5kg

Total weight: 150kg

Transport and Storage Specifications

Temperature: -20°C~55°C

Relative Humidity: ≤95%

Barometric: 86kPa~106kPa

Applicable people

The product is suitable for all people.

Environmental Requirements

Temperature: 5°C~40°C

Relative Humidity: ≤85%

Barometric: 86kPa~106kPa

Power Specifications

Power Supply: AC 100V-240V
50/60Hz

Fuse: T3.15A L250V

Power: 180VA-280VA

Contraindication

None

Appendix C: List of Replaceable Components

No.	Name	Remarks
1	Power Supply	
2	Fuse	
3	Fixed size lens cone	
4	Camera	
5	Flashlight	
6	40X objective lens	
7	Image capture card	
8	Three-way Solenoid Valve	
9	Two-way Solenoid Valve	
10	Plunger pump	Including motor
11	Plane sheath	
12	Vacuum pump	
13	Liquid pump	
14	Air pump	
15	Plastic tube	
16	Silicone tube	
17	Selection mechanism	
18	Sampling mechanism	Including motor
19	Feeding mechanism	Including motor
20	Sample Probe	
21	Probe wiper	
22	Main control panel	
23	Sample control panel	
24	Power switch board	
25	Temperature capture board	
26	Industrial control computer	
27	LCD	
28	Mouse	
29	Keyboard	
30	Monitor	
31	Touch screen	
32	SG module	
33	Detector	

NOTE:

- Please use specified parts for maintenance and replacement, which is performed by the personnel authorized by URIT.
 - We do not undertake any responsibility for all the consequences caused by using or replacing any devices not recognized by URIT.
 - The list above is for reference only. URIT reserves the right of final explanation for the replaceable components.
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Appendix D: List of Attachments

SN.	Item	Quantity	Remark
	Wooden Case		
1	Urinalysis System	1	US-1680
2	Cautions for startup	1	In Accessory Bag
3	Waste Container(20L)	1	
4	Urine Sediment atlas	1	
5	Bung spanner	1	In Accessory Bag
6	Concise Guide to Use	1	
7	Power cord	1	In Accessory Bag
8	3 meters ground wire	1	In Accessory Bag
9	Product certification	1	
10	Operation Manual	1	
11	Sheath external tubing	1	In Accessory Bag
12	Waste Liquid external tubing	1	In Accessory Bag
13	Large pump	1	In Accessory Bag
14	Fuse	2	In Accessory Bag
15	Verification test strip	2	In Accessory Bag
16	Steel needle for unblocking	1	In Accessory Bag
17	Soft needle for unchoking	1	In Accessory Bag
18	Brush for maintenance	1	In Accessory Bag
19	Grease for maintenance	1	In Accessory Bag
20	Side door switch key	1	In Accessory Bag
21	Urine Analyzer Test Tube Rack	10	In Accessory Bag
22	10ml Centrifuge tube with screw top	100	In Accessory Bag
23	Small test tube holder	100	In Accessory Bag
24	Plastic Tube ABH02017(1/4X3/8INCH)	1	In Accessory Bag

Appendix D: List of Attachments

	Carton		
1	IPU Host	1	
2	Monitor	1	
3	Keyboard & Mouse(<input type="checkbox"/> Wired keyboard and mouse <input type="checkbox"/> Wireless keyboard and mouse&USB Extended line)	1	
4	100M switches	1	
5	1.5 Meters Network Cable	1	
6	3 Meters Network Cable	2	
7	Mouse Pad	1	
8	Barcode scanning gun	1	
9	Socket(2500W-10A)	1	
10	DVI-D Display data line 2meters	1	In Accessory Bag

Appendix E: Turbidity/color Recognition Cross - reference

Table

Serial number	English name
1	Clear
2	Micro turbid
3	Turbid
4	Very turbid
5	Red
6	Yellow
7	Brown
8	Green
9	Colorless
10	Other

Appendix F: Item Name Comparison Table

SN	Abbreviation	Full name
1	VC	Vitamin C
2	WBC	White blood cells
3	KET	ketone
4	NIT	Nitrite
5	URO	Urobilinogen
6	BIL	Bilirubin
7	PRO	Protein
8	GLU	Glucose
9	SG	Urine specific gravity
10	BLD	Occult blood
11	pH	pH
12	CR	Creatinine
13	Ca	Urinary calcium
14	MA	Microalbumin
15	ACR(also called MA/CR)	The ratio of microalbumin to creatinine
16	Color	Color
17	Turbidity	Turbidity
18	Temperature	Temperature

Appendix G: Unit Results Comparison Table

Measure items	Semi-quantitative symbol and related concentration value						
VC	Semi-quantitative symbol	-	±	+1	+2	+3	
	international unit(mmol/L)	0	0.6	1.4	2.8	5.6	
	traditional unit (mg/dL)	0	10	25	50	100	
	English unit	Negative	Trace	Small	Middle	Large	
WBC	semi-quantitative symbol	-	±	+1	+2	+3	
	international unit(CELL/μL)	0	15	70	125	500	
	traditional unit (leu/μL)	0	15	70	125	500	
	English unit	Negative	Trace	Small	Middle	Large	
KET	semi-quantitative symbol	-	±	+1	+2	+3	
	international unit(mmol/L)	0	0.5	1.5	4.0	≥8.0	
	traditional unit (mg/dL)	0	5	15	40	≥80	
	English unit	Negative	Trace	Small	Middle	Large	
NIT	semi-quantitative symbol	-	+				
	international unit	Neg	Pos				
	traditional unit	Neg	Pos				
	English unit	Negative	Positive				
URO	semi-quantitative symbol	Normal		+1	+2	+3	
	international unit(μmol/L)	Normal		33	66	≥131	
	traditional unit (mg/dL)	Normal		2.0	4.0	≥8.0	
	English unit	Normal		Small	Middle	Large	
BIL	semi-quantitative symbol	-		+1	+2	+3	

Appendix G: Unit Results Comparison Table

	international unit($\mu\text{mol/L}$)	0		8.6	33	100				
	traditional unit (mg/dL)	0		0.5	2.0	6.0				
	English unit	Negative		Small	Middle	Large				
PRO	semi-quantitative symbol	-	\pm	+1	+2	+3				
	international unit(g/L)	0	0.15	0.3	1.0	≥ 3.0				
	traditional unit (mg/dL)	0	15	30	100	≥ 300				
	English unit	Negative	Trace	Small	Middle	Large				
GLU	semi-quantitative symbol	-	\pm	+1	+2	+3	+4			
	international unit(mmol/L)	0	2.8	5.5	14	28	≥ 55			
	traditional unit (mg/dL)	0	50	100	250	500	≥ 1000			
	English unit	Negative	Trace	Small	Middle	Large	Large			
SG	semi-quantitative symbol									
	international unit	1.005	1.010	1.015	1.020	1.025	1.030			
	traditional unit									
	English unit									
BLD	semi-quantitative symbol	-	\pm	+1	+2	+3				
	international unit(CELL/ μL)	0	10	25	80	200				
	traditional unit (mg/dL)	0	0.03	0.075	0.24	0.6				
	English unit	Negative	Trace	Small	Middle	Large				
pH	semi-quantitative symbol									
	international unit	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
	traditional unit									
	English unit									
CR	international unit(mmol/L)	≤ 0.9	4.4	8.8	17.6	≥ 26.4				
	traditional unit	≤ 10	50	100	200	≥ 300				

Appendix G: Unit Results Comparison Table

	(mg/dL)						
Ca	international unit(mmol/L)	≤1.0	2.5	5.0	7.5	≥10	
	traditional unit (mg/dL)	≤4.0	10	20	30	≥40	
MA	international unit(mg/L)	≤10	30	80	≥150		
	traditional unit (mg/dL)	≤1	3	8	≥15		
ACR (MA/CR)	international unit(mg/mmol)	<3.4		3.4-33.9	>33.9		
	traditional unit (mg/g)	<30		30-300	>300		

Appendix H: Toxic and Hazardous Substances or Elements

Parts		Toxic and Hazardous Substances or Elements					
		Plumbum (Pb)	Mercury (Hg)	Cadmium (Cd)	Chromium VI(Cr(VI))	Polybromi nated Biphenyls (PBB)	Polybrominated Diphenyl Ethers(PBDE)
Host	Shell	○	○	○	○	○	○
	Printed circuit board Assembly	○	○	○	○	○	○
	Sheet metal Parts	○	○	○	○	○	○
	Plastic Parts	○	○	○	○	○	○
	Machining parts	○	○	○	○	○	○
	Hardware	○	○	○	○	○	○
	Flow System Parts	○	○	○	○	○	○
	Cable	○	○	○	○	○	○
Accessories		○	○	○	○	○	○
Packaging Materials		○	○	○	○	○	○
<p>The table is compiled in accordance with SJ/T 11364.</p> <p>○: The content of toxic or hazardous substance in the homogeneous materials of the parts above is in the acceptable range of GB/T 26572.</p> <p>×: The content of toxic or hazardous substance is exceed the acceptable range of GB/T 26572 in at least one kind of homogeneous material of the parts above.</p> <p>(The circuit board used lead solder in machining process and some parts of the board contain plumb; And some sheet metal parts use chromium VI for surface)</p> <p>Memo: Printed circuit board Assembly is consist of printed circuit board, capacitance, connector and other parts. Lithium cell is detachable and recyclable part.</p>							

Appendix I: HL7 Protocol for URIT Urine Sediment Analyzer

I.1 Communication Protocol

I.1.1 Communication Mode

The HL7 protocol of URIT Urine Sediment Analyzer is created according to the HL7 v2.3.1 standards.

<SB>information<EB><CR>

SB Start Block Character 1 byte ASCII<VT> 0x0B

EB End Block Character 1byte ASCII<FS> 0x1C

CR Carriage Return 1byte ASCII <CR> 0x0D

I.1.2 Response

HL7 regulates that data receiving party must return a confirmation message to data provider for any news. It is suggested all the analyzers use 0x06 and don't pass back data so as to improve the compatibility.

I.2 Information Grammar

I.2.1 Delimiter

- | Fields Delimiter
- ^ Component Delimiter
- & Subcomponent Delimiter
- ~ Repeat Delimiter
- \ Escape Character

I.2.2 Identifier Meaning

Identifier	Hexadecimal Code	ASCII Code	Meaning
<SB>	0x0Bh	<VT>	Data Head

<EB>	0x1Ch	<FS>	Data Tail
<CR>	0x0Dh	<CR>	New line

I.2.3 Message Type

The communication between analyzer and lis adopts QRU. That is Unsolicited Observation Reporting.

The news regulation: instrument actively transmits the data to the lis.

ORU includes the following contents:

- Patient Data: Name, sex and sample No. etc.
- Doctor's advice: Sample type, sender, inspection doctor, clinical diagnosis and remark etc.
- Result: Parameter test results and related multimedia data, such as diagram etc.

I.2.4 Message structure

I.2.4.1 Overall structure

```

MSH                               Message head
{
  [PID]                             Patient data
  {
    OBR                               Observation report
    [OBX]                             Test result
  }
}

```

I.2.4.2 Urine Sediment Analyzer Structure

<SB>

```

MSH|^~\&|[CompanyName]||[InstrName]||LIS|PC|[ResultTime]||ORU^R01|[Instr
Type]||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]|||[SendDP]<CR>

OBX|1|[ValueType]||[ItemID]||[ItemName]||[TestResult]||[Unit]||[ConsultValue]||[Flag]|||F||[OD]||[ItemResultTime]||[DocDP]||[DOCName]||[Method]<CR>

OBX|1|ED|[ItemID]||[ItemName]||[InstrID]^|Image^[FormartName]^Base64^Qk02XgEAAA...|||||F|||[ItemResultTime]||[DocDP]||[DOCName]

<EB><CR>

{Repeat OBX, send several parameters test results of a sample once},
Please pay more attention to the OBX format of image data. For JPEG format data, use base64 for code conversion.

1.2.4.3 Message Head Meaning

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

Identifier	Meaning	Format
[CompanyName]	Company Name	ASCII Character String
[InstrName]	Instrument Name	ASCII Character String
[ResultTime]	Result Sent Time	yyyyMMddhhmmss
[InstrType]	Instrument Type	ASCII Character String

For example:

MSH|^~\&|URIT|UT-1200|LIS|PC|20101010093505||ORU^R01|URIT-USA|P|2.3.1|||||UNICODE

1.2.4.4 Patient Data Meaning:

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

Identifier	Meaning	Format
[PatID]	Patient ID.(Optional)	ASCII Character String
[PatType]	Patient Type	1 byte ASCII Character String 1 Normal 2 Emergency
[PatName]	Patient Name (Optional)	Unicode Character String
[PatBarCode]	Barcode (Optional)	ASCII Character String
[PatBedCode]	Bed code(Optional)	ASCII Character String
[PatBirth]	Patient Birth(Optional)	yyyyMMdd
[PatSex]	Patient Sex(Optional)	1byte ASCII Character String M mail F female

For Example: PID|1|1010051|A1123145|15|Zhangsan||19811011|M

1.2.4.5 Doctor Advice Meaning

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

Identifier	Meaning	Format
[SampleType]	Sample Type(Optional)	1 byte ASCII Character String 1 Normal 2 Control 3 Calibration
[REQID]	Request ID(Optional)	ASCII Character String
[SampleID]	Sample ID	ASCII Character String
[CompanyName]	Company Name	ASCII Character String

[InstrName]	Instrument Name	ASCII Character String
[SampleTime]	Send Time(Optional)	yyyyMMddhhmmss
[StartTime]	Start Test Time(Optional)	yyyyMMddhhmmss
[Symptom]	Symptom(Optional)	Unicode Character String
[SampleType]	Sample Type(Optional)	1 byte ASCII Character String 1 Normal 2 Control 3 Calibration
[SendDOCName]	Send Doctor(Optional)	Unicode Character String
[SendDP]	Send department ID(Optional)	ASCII Character String

For Example:

OBR|1|101009001|000001|URIT^UT-1200||20101010093000|20101010093500|||||Blood Urine||URI|Lisi||011

1.2.4.6 OBX File of Common Item Meaning

OBX|1|[ValueType]||[ItemID]||[ItemName]||[TestResult]||[Unit]||[ConsultValue]||[Flag]|||F||[OD]||[ItemResultTime]||[DocDP]||[DOCName]||[Method]<CR>

Identifier	Meaning	Format
[ValueType]	Value Type	NM is number, ST indicates text ED means others.
[ItemID]	Item ID	ASCII Character String
[ItemName]	Item Name(Optional)	Unicode Character String
[TestResult]	Test Result	SCII Character String
[Unit]	Unit	ASCII Character String
[ConsultValue]	Reference	SCII Character String
[Flag]	Abnormal Result Flay	1byte H is high N is normal L is low

[OD]	Original Result(Optional)	ASCII Character String
[ItemResultTime]	Item Result Send Time(Optional)	yyyyMMddhhmmss
[DocDP]	Inspection Doctor Department ID(Optional)	
[DOCName]	Doctor's Name(Optional)	
[Method]	Test Method(Optional)	ASCII Character String

For Example

OBX|1|NM|001^WBC|WBC|0.4|ul|0.0-1.0|N|||F|||20101010094505|011|Wangwu|

1.2.4.7 OBX Image Field Meaning

OBX|1|ED|[ItemID]|[ItemName]|[InstrID]^Image^[FormartName]^Base64^Qk02XgEAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA...|||F||| [ItemResultTime]|[DocDP]|[DOCName]|

Identifier	Meaning	Format
[ItemID]	Item ID	ASCII Character String
[ItemName]	Item Name(Optional)	Unicode Character String
[InstrID]	Remark ID	ASCII Character String
[FormartName]	Image Type	ASCII Character String
[ItemResultTime]	(Optional)	yyyyMMddhhmmss
[DocDP]	Item Result Send Time(Optional)	
[DOCName]	Doctor's Name(Optional)	

For Example:

OBX|1|ED|IMG1|3|UT1200^Image^JPEG^Base64^Qk02XgEAAAAAAAAA

AAAAAAAAAAAAAAAAAAAAAAAAAAAAA|||||F|||20101010093515|011|Wangwu|

I.3 Integrated Example

I.3.1 Example

<SB>

```
MSH|^~\&|URIT|UT-1200|LIS|PC|20101010093505||ORU^R01|URIT-USA|
P|2.3.1|||||UNICODE
PID|2|1010051|A1123145|15|Zhangsan||19811011|M<CR>
OBR|1|101009001|000001|URIT^UT-1200||20101010093000|2010101009350
0|||||Blood Urine||URI|Lisi||011<CR>
OBX|1|NM|001^WBC|WBC|0.4|u|0.0-1.0|N|||F|||20101010094505|011|Wangw
u|<CR>
OBX|1|NM|002^RBC|RBC|0.2|u|0.0-1.0|N|||F|||20101010094505|011|Wangwu
|<CR>
OBX|1|ED|IMG1|Image1|UT1200^Image^JPEG^Base64^Qk02XgEAAAAAAAA
AAAAAAAAAAAAAAAAAAAAAAAAAAAAA|||||F|||20101010093515|011|Wangwu|<
CR>
<EB>
```

<CR>

I.3.2 Nature Language

【Data Head】

transmission time: At 9:03:05 on Oct. 10th, 2010

Format: ORU R01

Data Type: Biochemical Data

Version: HL7.2.3.1

Code: UNICODE

【Patient】

Patient ID: 1010051

Barcode: A1123145

Bed No.:15

Name: Zhang San

Date of Birth: Oct.11th, 1981

Gender: Male

【Doctor Advice】

Request No.: 101009001

Sample No.: 000001

Inspection Instrument: UD-1320

Send Time: At 9:30am on Oct.10th, 2010

Inspection Time: At 9:35am on Oct.10th, 2010

Symptom: Blood Urine

Doctor: Li Si

Department: 011

【Result】

WBC: 0.4 μ L

Reference Value: 0.0-1.0

Report Time: At 9:45:05am on Oct. 10th, 2010

Doctor ID.: 011

Name: Wang Wu

RBC: 0.2 μ L

Reference Value: 0.0-1.0

Report Time: At 9:45:05am on Oct. 10th, 2010

Doctor No.: 011

Name: Wang Wu

【Result Image】

Name: Image1

Format: JPEG, the format is converted into

Qk02XgEAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA

Report Time: At 9:35:15(am) on Oct.10th, 2010

Doctor ID: 011

Name: Wang W