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ZYBIO is responsible for the effects on safety, reliability and performance of this product, only if:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by ZYBIO authorized personnel.
- The electrical installation of the relevant room complies with the applicable national and local requirements.
- The product is used in accordance with the instructions for use.

⚠ WARNING

It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine break down or injury of human health.
Be sure to operate the analyzer under the situation specified in this manual; otherwise, the analyzer will not work normally and the analysis results will be unreliable, which would damage the analyzer components and cause personal injury.

NOTE

This equipment must be operated by skilled/trained clinical professionals.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

ZYBIO's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by ZYBIO or repairs by people other than ZYBIO authorized personnel.

This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Customer Service Department

Manufacturer:	ZYBIO INC.
Address:	Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082.
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Contents

1. Using This Manual

1.1. Overview

This chapter describes how to use the service manual. In this manual, the repair methods of EXC200 is described in detail. Before servicing EXC200, please carefully read and understand the content in order to properly carry out maintenance procedures and ensure the safety of service personnel.

This manual must be used in conjunction with the EXC200 Operator's manual. It does not contain information and procedures already covered in the Operator's manual of EXC200.

Notes

Be sure to operate and service the analyzer strictly as instructed in this manual and the operator's manual.

1.2. Who should read this manual

This manual is intended to be read by service professionals who:

- Have comprehensive knowledge of circuitry and fluidics;
- Have comprehensive knowledge of reagents;
- Have comprehensive knowledge of quality control;
- Have comprehensive knowledge of troubleshooting;
- Are familiar with the operations of the system;
- Are able to use basic mechanical tools and understand the terminology;
- Are skilled users of the digital voltmeter and oscillograph;
- Are able to analyze the circuit diagrams and fluidic charts.

1.3. Conventions used in this manual

This manual uses certain typographical conventions to clarify meaning in the text:

Format	Meaning
[××]	all capital letters enclosed in [ ] indicate a key name (either on the pop-up keyboard or the external keyboard)
"××"	letters included in " " indicate text you can find on the screen of EXC200
××	Italic letters indicate titles of the chapters that are referred to

All illustrations in this manual are provided as examples only. They may not necessarily reflect your analyzer setup or data displayed.

1.4. Safety information

You will find the following symbols in this manual.

Symbols	Meaning
	Read the statement below the symbol. The statement is alerting you to a potentially biohazardous condition.
WARNING	Read the statement below the symbol. The statement is alerting you to an operating hazard that can cause personnel injury.
⚠CAUTION	Read the statement below the symbol. The statement is alerting you to a possibility of analyzer damage or unreliable analysis results.
NOTE	Read the statement below the symbol. The statement is alerting you to information that requires your attention.

- All the samples, controls, calibrators, reagents, wastes and areas contacted by them are potentially biohazardous. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
- If the main unit of the instrument leaks, the leaked liquid is potentially biohazardous.

⚠WARNING

- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or injury of human health.
- Never use combustible gas (e.g. anesthetic) or combustible liquid (e.g. ethanol) around the analyzer. Otherwise, the risk of explosion may exist.
- Contacting exposed electronic components while the equipment is attached to power can cause personal injury from electric shock or damage to electronic components. Power down before removing covers to access electronic components.
- Connect the analyzer to a socket having sole fuse and protective switch. Do not use the same fuse and protective switch with other equipment (e.g. life supporting equipment). Otherwise, the equipment failure, over current or impulse

current that occurs at the startup moment may lead to tripping.

- To prevent personal injury during the maintenance, keep your clothes, hairs and hands from the moving parts, such as the sample probe.
- Possible mechanical movement of the warned position may lead to personal injury during normal operation, removal, maintenance and verification.
- Be sure to dispose of reagents, waste, samples, consumables, etc. according to government regulations.
- The reagents are irritating to eyes, skin and diaphragm. Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling them in the laboratory.
- If the reagents accidentally spill on your skin, wash them off with plenty of water and if necessary, go see a doctor; if the reagents accidentally spill into your eyes, wash them off with plenty of water and immediately go see a doctor.

⚠CAUTION

- Improper maintenance may damage the analyzer. Maintain the analyzer strictly as instructed by the service manual and inspect the analyzer carefully after the maintenance.
- For problems not mentioned in the service manual, contact ZYBIO customer service department for maintenance advice.
- To prevent personal injury or damage to equipment components, remove metal jewelry before maintaining or servicing electronic components of the equipment.
- Electrostatic discharge may damage electronic components. If there is a possibility of ESD damage with a procedure, then do that procedure at an ESD workstation, or wear an antistatic wrist strap.

Notes

- The operator is required to follow the instructions below this symbol.
- The instructions will emphasize important information or information that requires particular attention of the operator.

1.5. When you see...

Symbols used in this service manual:

Symbol	Meaning
	The operator is required to follow the instructions below this symbol. Failure to do so may place the operator at a potential risk of biohazard.
WARNING	The operator is required to follow the instructions below this symbol. Failure to do so may cause personal injury.
CAUTION	The operator is required to follow the instructions below this symbol. Failure to do so may cause malfunction or damage of the product or affect the test results.
NOTE	The operator is required to follow the instructions below this symbol. The instructions will emphasize important information or information that requires particular attention of the operator.

The analyzer system may contain the following symbols:

⚠CAUTION

Ensure the labels are in good condition and not damaged while servicing the analyzer.

When you see…	It means…
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS. Note: It is recommended that the reader refers to the accompanying documents for important safety information.
	BIOLOGICAL RISK
	WARNING, LASER BEAM
	PROTECTIVE EARTH (GROUND)
	USB port

	Network interface
	ALTERNATING CURRENT
	FOR IN VITRO DIAGNOSTIC USE
	Batch code
	USE BY (YYYY-MM-DD)
	Serial number
	DATE OF MANUFACTURE
	Pricking danger
	Manufacturer
	TEMPERATURE LIMITATION
	CONSULT INSTRUCTIONS FOR USE
	The device fully complies with requirements of EU IVD Directive 98/79/EC
	This electronic product contains certain toxic substances, and has an Environmental Protection Use Period (EPUP) of 20 years. It can be used safely during the EPUP, but shall be recycled after the EPUP.

2. Safety Information

2.1. Overview

This chapter introduces the significance of the safety symbols, the labels related to the product, and silkscreen printing used in the Operation Manual, as well as the potential safety hazards and precautions when using the instrument.

Note: the following symbols are for reference only. For details, please refer to the Operation Manual.

2.2. Symbols used in the operation manual

Symbol	Meaning
 Warning	Prompt the operator to follow the instructions below the symbol. Failure to do so may result in personal injury.
 Caution	Prompt the operator to follow the instructions below the symbol, otherwise it may cause product failure, damage or affect the test results.
 Attention	Prompt the operator to follow the instructions below the symbol and emphasize important information or contents requiring special attention of the operator in the operation steps.
 Biological hazard	Prompt the operator to follow the instructions below the symbol, otherwise there is a risk of potential biological infectivity.

2.3. Silkscreen printing and labeling related to products

Various warning labels and silkscreen printing are used on the instrument to identify the characteristics of the instrument and remind operators to pay attention. Other marks related to the use of the instrument are also explained below. Please check the warning labels frequently to keep them clean and complete. If the label can’t be read normally due to blurring or falling off, please contact our customer service department for replacement.

Note: The following signs or symbols are for reference only, and the specific pictures are subject to the actual objects.

Symbol	Meaning
	Please refer to the specific files delivered with the instrument.
	Moving parts prompt label
	**Electric shock** When the power is on, unauthorized maintenance personnel must not open the analyzer panel. Splashing liquid shall be avoided on the table. If liquid flows into the analyzer, please immediately turn off the analyzer and contact Zybio in time.
	**Biohazard** The background color of this symbol is yellow, and the symbol and outline are black. 1) All test samples, calibrators, quality control, etc. Shall be considered infectious and gloves shall be worn when contacting; 2) All waste liquid should be considered infectious and gloves should be worn when contacting. Parts in contact with the test sample, such as suction nozzle and measuring cuvette, shall be considered infectious, and gloves shall be worn during contact; 3) All wastes are considered infectious and should be treated as medical wastes according to current regulations; 4) When the instrument reaches its service life, it should be treated according to the requirements of the local environmental protection department, and should not be treated and discarded as ordinary wastes.
	**High temperature** It may cause injury to human body.
	**Corrosion** Cleaning fluid is chemically corrosive, and protective gloves should be worn during operation.
	Alternating current symbol
	This electronic information product contains some toxic and harmful substances. The environmental protection service period is 20 years, within which it can be used safely. After the environmental protection service period, it should be put into the recycling system.
	Only for in vitro diagnostic use

Symbol	Meaning
	Serial number
	Date of production
	Manufacturer
	Please refer to the Operation Manual
	On (power)
	Off (power)
DW1	Deionized water inlet
DW2	Deionized water outlet
HW	Concentrated waste liquid outlet
LW	Dilute waste liquid outlet
CW	Concentrated cleaning fluid inlet
DW-D	Pure water float sensor
CW-D	Float sensor for concentrated detergent
W-D	Waste liquid float sensor

2.4. Matters needing attention

2.4.1 Scope of application

Caution

1) EXC2X series automatic chemistry analyzer is mainly used in medical institutions for quantitative examination of human serum, plasma, urine and other samples.
2) When making clinical judgment according to the test results, please consider the clinical examination results or other test results.

2.4.2 Operator

Caution

EXC2X series automatic chemistry analyzer is only applicable to personnel trained by Zybio or its agents.

2.4.3 Application environment

Attention

1) Please install correctly according to the installation environment specified in this Operation Manual. Installing or using not under the specified conditions may lead to unreliable results and may damage the instrument.
2) If you need to change the working environment of the analyzer, please contact Zybio or the agent in your region.

2.4.4 Data backup

Attention

The system itself carries out backup processing on the data and stores the data in the industrial control board. If the industrial control board data is deleted or damaged due to some reasons, the data will be lost. Please back up the analysis data and analysis parameters to other mobile storage devices on a regular basis.

2.4.5 Analysis parameters

Attention

Incorrect analysis parameters will lead to incorrect test results, please consult Zybio or reagent supplier.

Attention

Carefully check the reagent and sample, which cannot contain insoluble floaters, such as cellulose, fibrin, etc. Otherwise, the reagent-sample probe will be blocked.

2.4.6 Electromagnetic interference

Attention

1) The analyzer is vulnerable to electromagnetic interference during operation, which may affect the test results and lead to misoperation. Please do not use electric drills, mobile phones, interphones and other devices that generate electromagnetic waves during operation.
2) During the operation of the analyzer, electromagnetic waves will be radiated to the outside. Do not install or use electromagnetic sensitive equipment near the analyzer.

2.4.7 Imperfect grounding

Attention

1) The power supply must be grounded correctly, otherwise there is danger of electric shock.
2) The grounding impedance must be less than 10mΩ. Poor grounding may lead to unstable test results and leakage of electricity from the casing, thus posing a risk of electric shock.

2.4.8 Label falling off

Attention

When the label of the instrument is fuzzy or falls off, please contact Zybio for replacement.

2.4.9 Leakage

Attention

1) Before testing, carefully check the manually tighted joints of each pipe to see if there is liquid leakage, which will lead to inaccurate suction and discharge capacity.
2) Do not place reagents or samples on the analyzer table to avoid liquid splashing and leakage.

2.4.10 Ultraviolet transparent plastic cuvette


Attention

Ultraviolet transparent plastic cuvette (referred to as colorimetric cup or plastic cuvette) used by EXC2X series automatic chemistry analyzer. Please use cuvette specified by Zybio, otherwise the expected use effect may not be obtained.

2.4.11 Water quality


Attention

The water quality shall meet the requirements of ISO3696 Class II, otherwise it will easily lead to valve and pump damage and not thorough cleaning.

2.4.12 System applicable

1) Please use the system according to the instructions in the Operation Manual. Incorrect use may lead to incorrect measurement results, and may even lead to system damage or personal injury.
2) Before using the system for the first time, calibration should be carried out before quality control to confirm that the system works normally.
3) When using the system on a daily basis, it is recommended to carry out quality control to ensure the reliability of the results.


Warning

4) Before analysis, please cover the reaction tray and reagent-sample tray.
5) Do not uncover the reaction tray during the analysis.
6) During the analysis, please ensure that there are no obstacles in the movement track of the probe and stirring rod.
7) When the reaction tray and reagent-sample tray rotate, do not touch them to prevent scratches.
8) Do not install any software or hardware other than those specified by Zybio on this system, or it may hinder the normal operation of this system. Please do not run other software during the operation of this system.
9) Do not use this system for other purposes. Incorrect use may cause the instrument to be infected with virus. Computer viruses may spread through USB, programs, networks, etc.

2.4.13 System maintenance

1) Please follow the instructions in this Operation Manual for system maintenance. Incorrect maintenance may lead to incorrect analysis results and even system damage or personal injury.
2) After replacing the main components, such as light source lamp, reagent-sample probe and syringe piston assembly, please carry out calibration analysis.


Warning

3) If you stop using the instrument due to malfunction or other reasons and needs repair or disposal, please contact Zybio or local agent in time. At the same time:
   - Please take other measures, such as replacing the unfinished tests with other instruments or methods, so as not to cause delay in the results.
   - Please take out the reagent on the instrument and store it separately according to the instructions for using the reagent in the kit. Put the reagent back in the refrigerator for cold storage to prevent it from deteriorating.

2.4.14 Sample

1) Please use a completely separated serum sample and a urine sample without suspended substances. If the serum sample contains fibrin or the urine sample contains suspended substances, the reagent-sample probe may be blocked, thus affecting the accuracy of the analysis results.
2) Drugs, anticoagulants, preservatives, etc. Present in the sample may interfere with some analysis results.


Warning

3) Lipemia, jaundice, hemolysis, etc. in the sample may affect the analysis results, and it is recommended to make blank analysis of the sample.
4) Please store the sample correctly. Incorrect sample storage conditions may change the composition content of samples, thus affecting the accuracy of analysis results.
5) Do not leave the sample tube open for a long time to prevent the sample from volatilizing, otherwise the accuracy of analysis results may be affected.
6) There is a requirement on sample volume in the analysis of this system. When sampling, please take appropriate sample volume according to the relevant instructions in this Operation Manual.

2.4.15 Reagent, calibrator and control


Warning

1) When using this system for analysis, please use appropriate reagents, calibrator and QC.
2) Please select suitable reagents according to this system. If you are not sure whether the reagent is available, please consult the manufacturer, agent of the reagent or manufacturer, agent of Zybio.
3) For the use and storage of reagents, calibrator and QC, please refer to the instructions of reagent manufacturers or distributors.
4) If reagents, calibrator and QC are not stored properly, even within the validity period, correct test results may not be obtained.
5) Please calibrate after replacing the reagent. Without calibration and quality control, correct analysis results may not be obtained.
6) Cross contamination of reagents may affect analysis results during analysis. For information on reagent cross-contamination, please consult the relevant reagent manufacturer or distributor.

2.4.16 Instrument discard


Warning

Some substances of waste analyzers are controlled by pollution regulations. Please follow the local waste disposal standard to dispose of the waste analyzer.

2.4.17 Picture

All the pictures in this Operation Manual are for illustration or example only and shall not be used for other purposes.

2.5. Installer


Warning

The installation of the instrument can only be carried out by Zybio's technicians or technicians authorized by Zybio.

EXC2X series automatic chemistry analyzer can only be installed by Zybio or its authorized agent, and users need to provide corresponding environment and space. When the analyzer needs to be relocated, please contact Zybio or the local agent.

When you receive the analyzer, please inform Zybio and the local agent immediately.

2.6. Damage examination

All analyzers have passed the strict inspection of Zybio before packaging and transportation. When you receive the analyzer, please check carefully before unpacking and pay attention to the following damages:

1) The outer package is inverted or deformed;
2) The outer package has obvious traces of being wetted by water;
3) The outer package has obvious marks of impact;
4) There are signs that the outer packing has been opened.

Once the above damages are found, please inform Zybio or its authorized local agent immediately. If the outer package is in good condition, please open the packing case and check it after unpacking in the presence of the designated staff of Zybio:

1) Check whether all components are complete according to the packing list in the packing box;
2) Carefully check the appearance of all devices for cracks, bumps or deformation.

After unpacking, please carefully inspect the appearance of the instrument and check the packing list. If there is any handling damage or the configuration is found to be incomplete, please immediately declare it to Zybio or its authorized local agent.

2.7. Installation requirements

2.7.1. Site

- For indoor installation only;
- The installation table should be flat (inclination is less than 1/200);
- The mounting table can bear at least about 80kg of weight;
- Good ventilation;
- The environment should be as dust-free as possible;
- Avoid direct sunlight;
- Avoid heat sources and wind sources;
- No corrosive and flammable gases;
- No vibration on the table surface;
- No loud noise source and power interference;
- Keep away from brush-type engines and electrical contact equipment that are frequently switched on and off;
- Keep away from devices that emit electromagnetic waves, such as cell phones, radio transceivers, etc.

2.7.2. Power

- 100~240 V~, 50/60 Hz, properly grounded with grounding resistance of less than 10 mΩ
- Input power: ≥500 VA

Warning

Please ground the power socket correctly. Incorrect grounding may cause electric shock and system damage. Please confirm that the power outlet output voltage fits the system requirements.

2.7.3. Humidity and temperature

- Ambient temperature: 10℃-30℃
- Ambient humidity: 30%~85%, no frost

Caution

The system must be operated within the specified ambient temperature and humidity range, otherwise the test results may be unreliable. If the ambient temperature and humidity exceed the specified range, use air conditioning equipment.

2.7.4. Atmospheric pressure

- Atmospheric pressure: 70.0 kPa~106.0 kPa

2.7.5. Space

Please install the instrument according to the space requirements shown in the figure below.

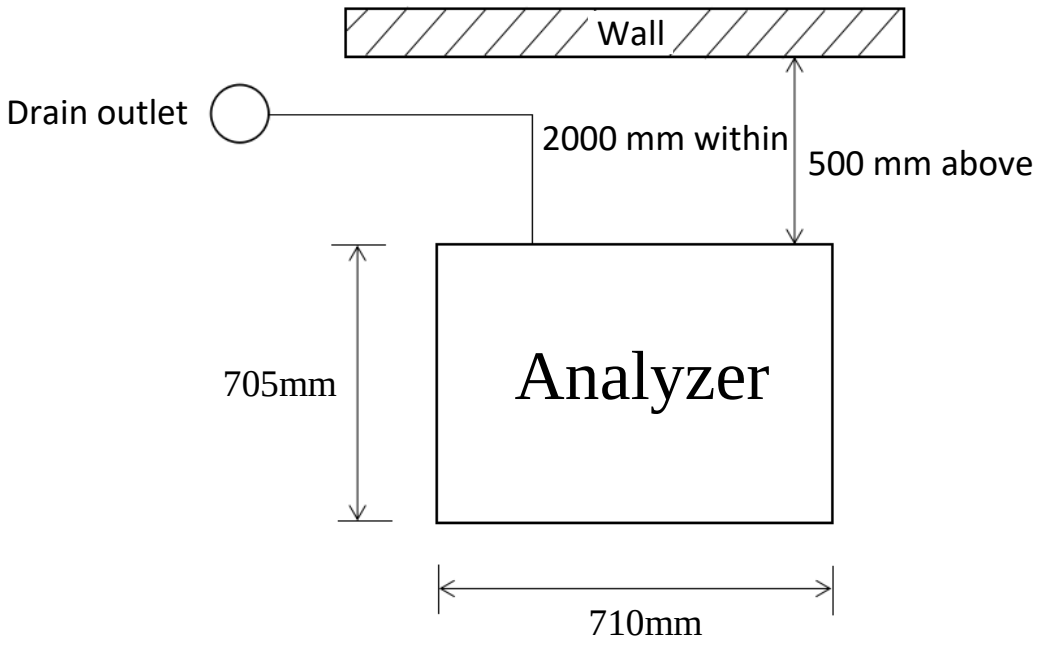

Figure 2-1 Installation Space Requirements

2.7.6. Water supply and drainage requirements

- The water quality of the water supply must meet the requirements of ISO3696 Class II;

Caution

The water quality must meet the water supply requirements. Otherwise, the water purity may affect the test results.

- Water supply volume: not less than 5L/h;
- The distance between the water supply device and the water inlet of the chemistry analyzer shall not exceed 10 meters;
- Waste container connection: the waste container shall be placed at the same level as the instrument or lower than the level of the instrument, and it must be ensured that its mouth is lower than the waste container outlet on the rear plate of the machine;
- Sewer connection: the height of waste liquid outlet from the ground shall not be higher than 12cm;
- The length of waste liquid pipe shall not be longer than 2m.

Biological hazard

Biological pollution
Please wear gloves, work clothes to prevent infection and protective glasses as needed when operating.

After installing the instrument, please connect the fluidic component correctly according to the following figure:

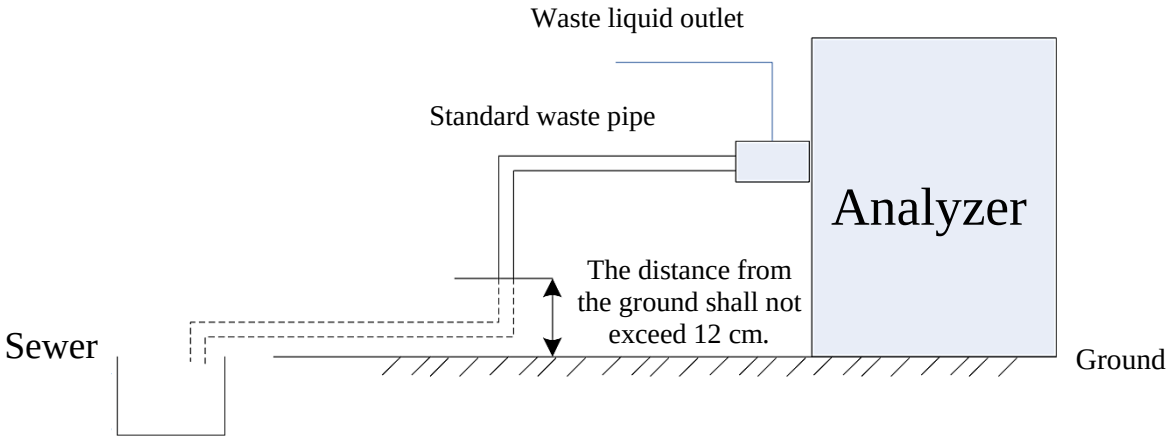

Figure 2-2 Requirements for Fluidic Component Connection

Please treat the discharged waste liquid according to the local discharge standard.

Attention

When connecting the drain pipes, be careful not to fold or flatten them.

Biological hazard

Biological pollution
Waste liquid is mainly consists of blood. Please treat the waste liquid discharged by the instrument according to the local discharge standard.

2.8. Product composition

The automatic chemistry analyzer consists of a reagent-sample processing unit, a mixing unit, a reaction unit, a photoelectric detection unit, a control and data processing unit and software.

2.8.1. Reagent-sample processing unit

The reagent-sample processing unit mainly completes the whole operation process of loading reagent and sample, including adding the first reagent, adding the sample, adding the second reagent, etc.

2.8.2. Mixing unit

The mixing unit mainly completes the mixing operation of reagents and samples.

2.8.3. Reaction unit

The reaction unit mainly completes the reaction of reagent and sample, incubation and automatic cleaning of the reaction cuvette.

2.8.4. Photoelectric detection unit

The photoelectric detection unit is mainly used to collect photoelectric signals and other functions.

2.8.5. Control and data processing unit

The control and data processing unit mainly consists of touch screen, built-in main control board and industrial control board. It can be operated on the touch screen interface to control the operation of the instrument. The main control board and the industrial control board can process the photoelectric signal value and convert it into various results required for detection.

2.8.6. Software

The name of the software is automatic chemistry analyzer software, with functions of sample, result, reagent, status, calibration, quality control, setting and maintenance. Users can operate the software for sample application, results query, reagent management, online status checking, calibration application, quality control application, instrument settings, and various maintenance operations.

2.8.7. Accessories and consumables

Accessories and consumables refer to the components necessary for sample testing of the instrument, which shall be checked frequently to ensure sufficient quantity, supplemented and replaced when necessary.

2.9. Instrument structure

2.9.1. Front view of instrument

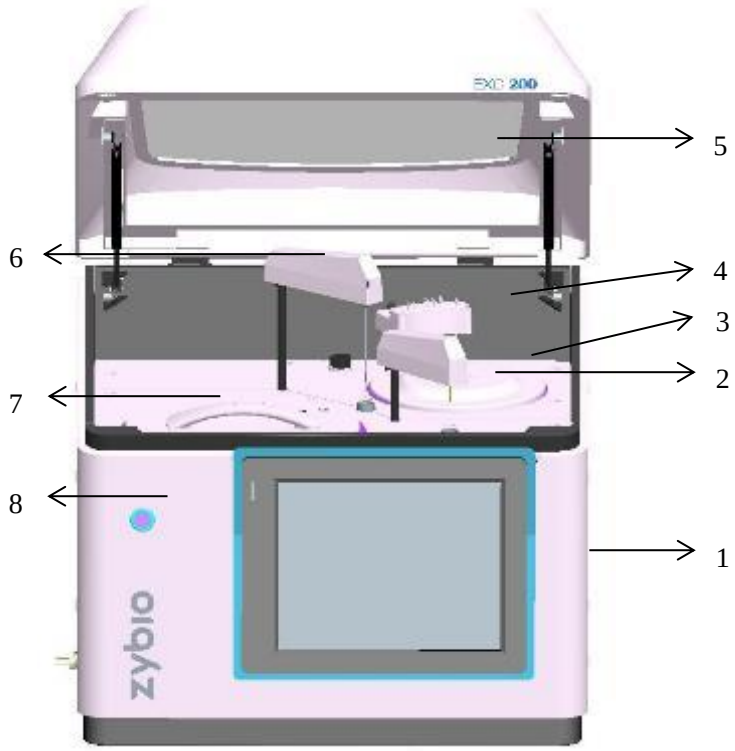

Figure 2-3 Front Structure

1-Touch Screen; 2-Stirring Rod; 3-Reaction Tray

4-Automatic Cleaning Mechanism; 5-Top Cover; 6-Reagent - Sample Probe

7-Reagent - Sample Tray; 8-Analysis Switch

2.9.2. Rear view of instrument

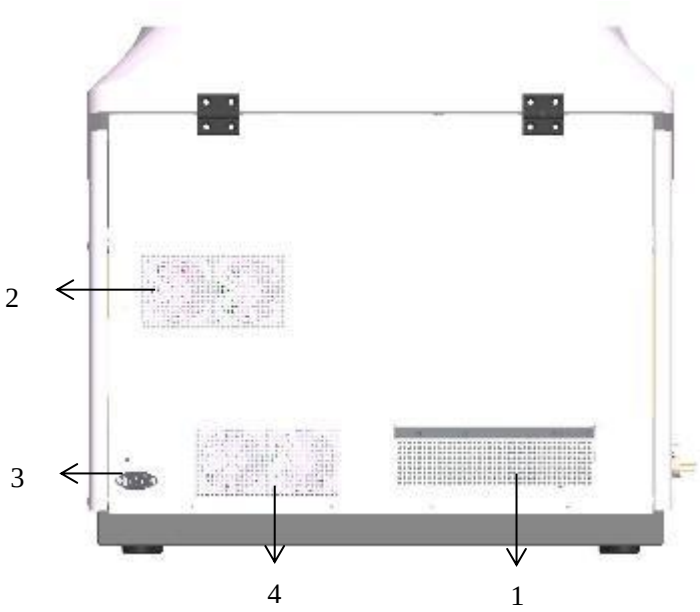

Figure 2-4 Rear Structure

1-Air Inlet; 2-Fan; 3-Power Socket; 4-Fan

2.9.3. Side view of instrument

- Left side

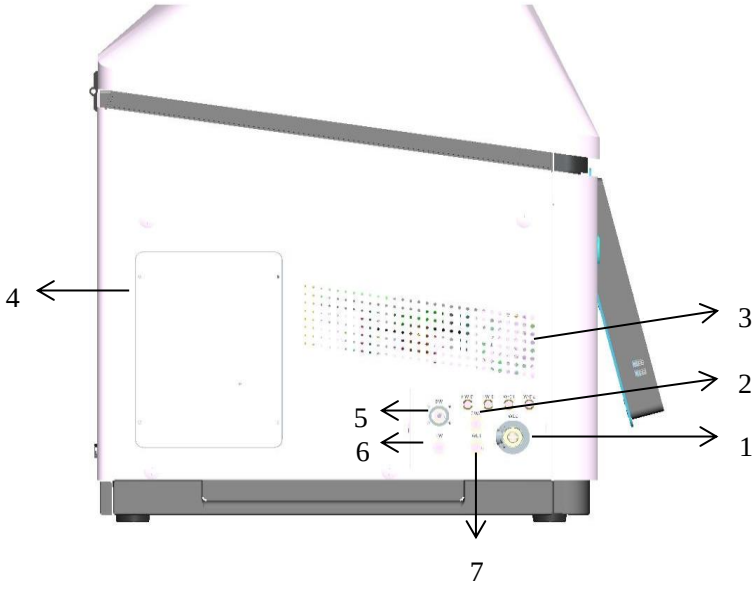

Figure 2-5 Left Side Structure

1-Waste Liquid Pipe Interface 2; 2-Purified after Interface 2; 3-Air Inlet

4-Maintenance Window; 5-Purified Water Interface 1;

6-Acid-Base Detergent Interface 7-Waste Liquid Pipe Interface 1

- Right side

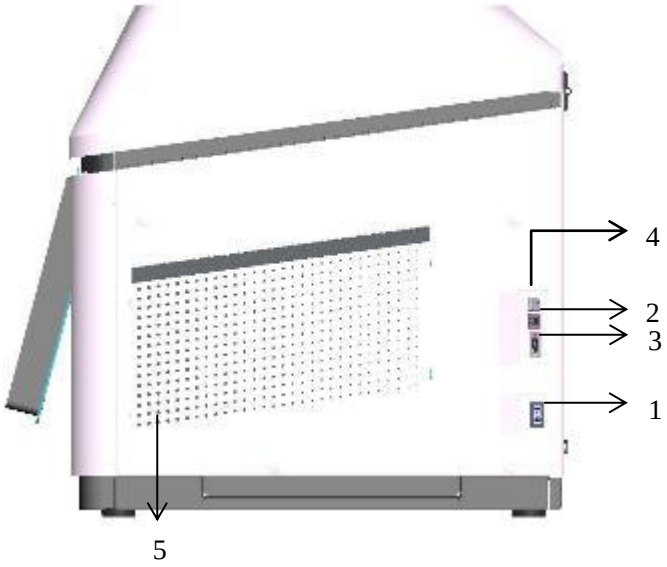

Figure 2-6 Right Side Structure

1-Main Power Switch; 2-Serial Port Interface; 3-Network Port Interface

4-USB Interface; 5-Air Inlet

The functions of each communication interface are as follows:

Network port: Use a network cable to connect the router for LIS data transmission.

Serial port: Can connect to printer or perform serial communication.

USB interface: Can be connected to a USB printer, or for U disk to insert data to copy.

2.9.4. Reagent-sample processing unit

The reagent-sample processing unit is used for loading reagents and samples, sending each reagent and sample to a corresponding reagent absorption position and a sample absorption position respectively for absorption, then injecting into a reaction cuvette for reaction, and measuring the absorbance of the reaction liquid by the photoelectric detection unit. The reagent sample processing unit is mainly composed of the following components:

- Reagent-sample tray assembly
- Reagent-sample bar code scanning assembly
- Reagent-sample probe assembly
- Sample tube
- Reagent bottle

2.9.4.1. Reagent-sample tray assembly

The reagent-sample tray assembly includes a reagent-sample tray (including a reagent-sample tray cover) and a reagent refrigeration system.

The reagent-sample tray is designed with a disc structure and is located on the left side of

the analyzer table, which is used for loading sample tubes and reagent bottle. Each sample tube and reagent bottle is rotated to the corresponding sample suction position and reagent suction position respectively, waiting for the reagent-sample probe to suck.

The reagent refrigeration system is used to ensure that the reagents in the reagent bottle are always kept in a low temperature environment to keep the properties of the reagents stable and reduce volatilization. The reagent-sample tray has a 24-hour uninterrupted cooling function, which can ensure that the reagents in the reagent bottle are always stored in a low-temperature environment, ensure stable properties of the reagents, and reduce volatilization.

The following is the picture of reagent-sample tray:

Figure 2-7 Reagent-sample Tray

The reagent-sample tray is divided into inner, middle and outer circles, with a total of 80 reagent/sample positions. Among them:

- The inner circle contains 19 R1/R2 reagent positions +1 acid-base cleaning site
- The middle circle contains 19 R1/R2 reagent positions +1 acid-base cleaning site
- The outer circle is 40 sample positions

2.9.4.2. Installation of reagent-sample tray

1) Hold the handle in the middle of the reagent-sample tray by hand, and vertically lower the alignment hole under the handle to the pin position of the base.
2) Press the 2 panel fasteners on the reagent-sample tray.

2.9.4.3. Disassembly of reagent-sample tray

1) Pull out the 2 panel fasteners on the reagent-sample tray.
2) Lift the handle of the reagent-sample tray up vertically and take it out.

Warning

Before loading or removing the reagent-sample tray, it must be confirmed that all moving parts of the analyzer have stopped, such as reagent-sample probe, stirring rod, cleaning mechanism, reaction tray and reagent-sample tray.

Biological hazard

Biological pollution
Please wear gloves, work clothes to prevent infection and protective glasses as needed when operating.

2.9.4.4. Reagent-sample probe assembly

The reagent-sample probe assembly consists of a probe, a probe rocker arm, a drive shaft, a probe syringe, a cleaning basin and related fluidic components. It is mainly used to suck a specified amount of sample or reagent from a sample tube or reagent bottle and inject it into a reaction cuvette to participate in the reaction.

2.9.4.5. Reagent-sample probe

The reagent-sample probe integrates the functions of the sample probe, the first reagent probe and the second reagent probe, and the amount of sample or reagent to be sucked depends on the type of assay.

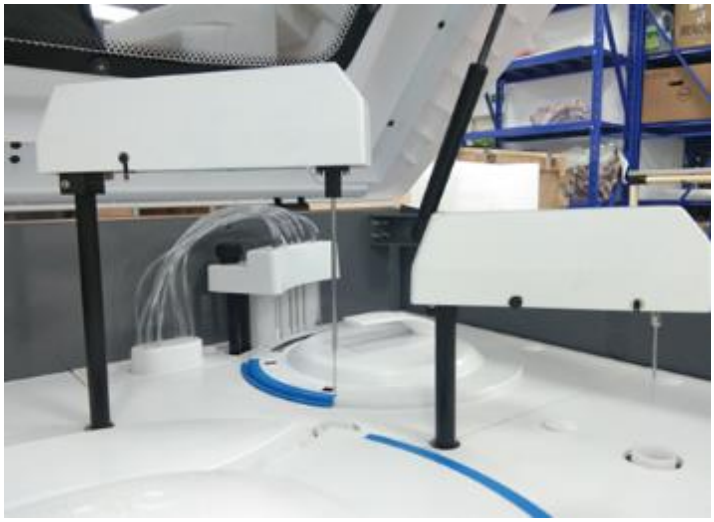

Figure 2-8 Reagent-sample Probe

1) Function

   Absorb a specified amount of sample from the sample tube or R1/R2 reagent from the reagent bottle and place it in a cuvette (colorimetric cuvette).

2) Specifications

   Samples: 2 ~ 50 μL, increasing by 0.5 μL each time;

   Reagent: 10 ~ 400 μL, increasing by 0.5 μL each time.

3) Action

   Move down and up at the following positions.

- Sample suction:

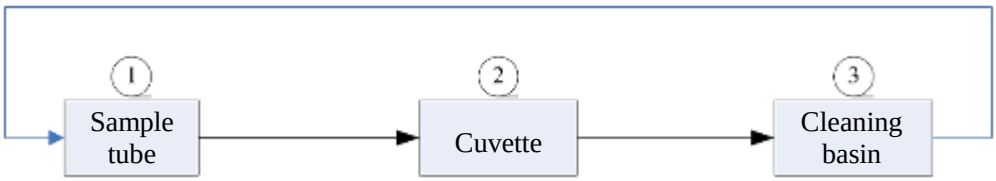

Figure 2-9 Sampling Position

- Suction reagent:

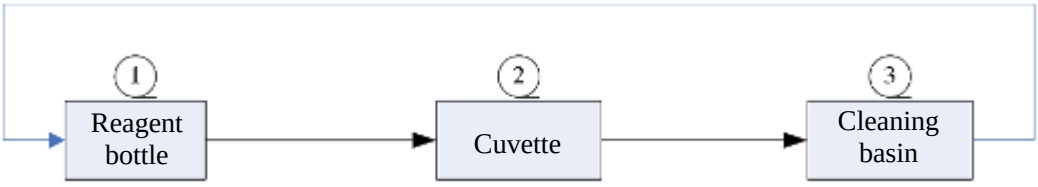

Figure 2-10 Reagent Aspiration Position

4) Fluidic component diagram

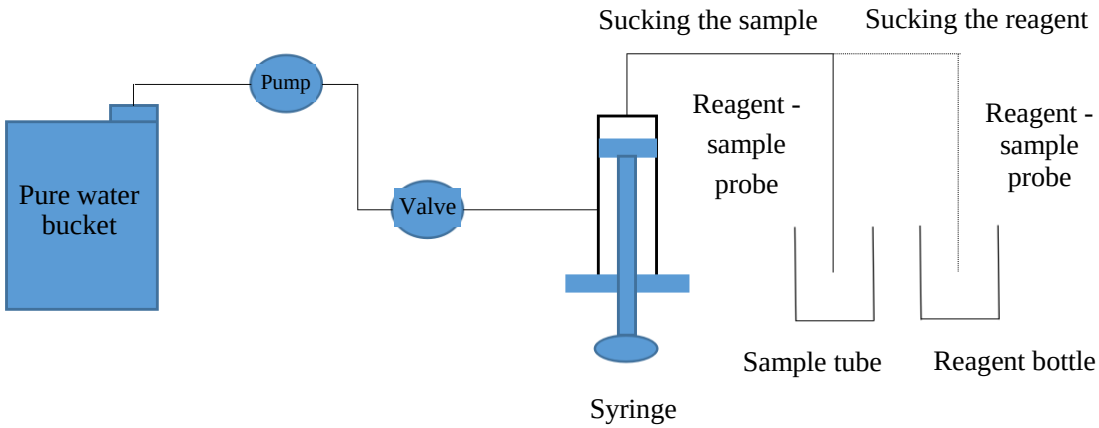

Figure 2-11 Fluidic Component Diagram

In addition to the basic sample /reagent suction functions, the reagent-sample probe also has the following functions:

- Vertical collision avoidance: it can detect obstacles in the vertical direction. In case of collision, the automatic protection system will be activated to prevent the reagent-sample probe from being damaged.
- Liquid level detection and tracking with quantity: the liquid level in the sample tube can be automatically detected and the depth falling below the liquid level can be determined according to the amount of liquid absorbed.

Warning

When the system is running, do not place your hands, other parts of your body or any obstacles on the swing path of the reagent-sample probe rocker arm, otherwise personal injury or system damage may occur.

2.9.4.6. Cleaning of reagent-sample probe

Clean the interior and outer wall of the reagent-sample probe in the cleaning basin, and the reagent-sample probe syringe can be seen by opening the maintenance window at the left rear of the analyzer.

2.9.4.7. Reagent cooling system

A cooling plate is installed at the bottom of the reagent sample cabin, which can absorb the heat inside the reagent sample cabin and radiate the heat to the outside through the air duct to achieve the cooling effect. There is a temperature sensor at the cooling plate, which will monitor the temperature of the cooling plate in real time. When the temperature drops to (2 ± 0.1) °C, the control system will appropriately reduce the current flowing through the cooling plate according to the control algorithm, thereby reducing the power of the cooling plate. When the temperature rises, the control system will increase the current flowing through the cooling fins, thereby increasing the power of the cooling plate and stabilizing the temperature of the cooling plate at (2 ± 0.1) °C. At the same time, insulation foam is adhered around and at the bottom of the reagent sample pot for thermal insulation. As a result, the temperature around the reagent sample tray can be maintained at 2-10 °C, which ensures that the detection reagents are always stored in a low temperature environment, so that the environmental temperature will not affects the reagent performance if the test time is long.

2.9.4.8. Sample tube

The sample tube is used for holding samples. The sample tray supports the following sample tube types.

- Micro measuring cuvette: φ 14*25 mm, φ 12*37 mm
- Original blood collection tube/plastic test tube: φ 12*68.5 mm, φ 12*99 mm, φ 12.7*75 mm, φ 12.7*100 mm, φ 13*75 mm, φ 13*95 mm, φ 13 * 100 mm;

Different specifications of sample tubes require different minimum sample volume. The minimum sample volume of each sample tube must be guaranteed, otherwise sample suction errors may result. If the sample volume is less than the dead volume, transfer the sample to a smaller sample tube before testing. The minimum sample volume of the sample tube is the sum of the minimum sample volume required for the test and the dead volume of the sample tube.

2.9.4.9. Reagent bottle

Reagent bottle is used to contain reagents and is divided into 35mL and 20mL specifications.

2.9.5. Reaction unit

The reaction unit mainly consists of a reaction system and an automatic cleaning system.

2.9.5.1. Reaction system

It comprises reaction tray, cuvette and heater, wherein the reaction tray is used for placing the cuvette, and plastic cuvette is used as the cuvette, which is used as a reaction container and used for colorimetric measurement.

The heater is used to provide a constant temperature environment for the reaction. The driving part turns the cuvette to the corresponding reagent adding position, sample adding position, stirring position and cleaning position respectively.

1 Reaction tray

In the analysis process of the reaction tray, place the designated cuvette at the reagent adding position, sample adding position, stirring position or cleaning position.

The reaction tray is a single circle and can accommodate 63 plastic cuvettes.

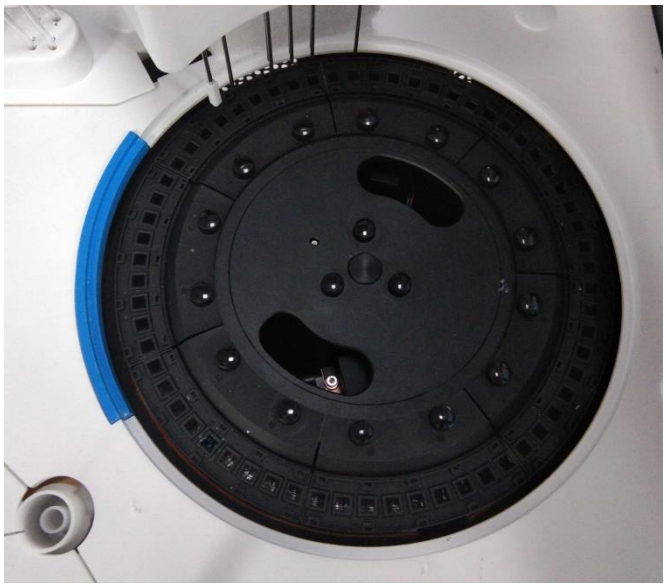

Figure 2-12 Reaction Tray

1) Function

   Load cuvette, allowing a sample and a reagent to react in a constant temperature bath at 37℃, and directly conduct colorimetric measurement through the plastic cuvette.

2) Specifications

   Number of cuvette: 63

   Material of cuvette: Ultraviolet transparent plastic cuvette

3) Action

   Rotate anti-clockwisely

2 Cuvette

The material is plastic, and the optical diameter of each reaction cuvette is 5 mm±0.03 mm.

After each test, the system automatically 6-steps cleans and dries the cuvette for the next test.

3 Temperature control tank

There is a heater in the temperature control tank. The heater will heat the temperature control tank before the test. There is also a temperature sensor. When the temperature is too high, the heater will automatically stop heating. When the temperature is too low, the heater will automatically continue to heat. In order to ensure that the entire temperature

control tank maintains a constant temperature of 37 °C, it provides a constant temperature platform for the reaction, effectively simulates the temperature of the human body, and ensures the accuracy of the test results.

1) Function

   Keep the reaction temperature at 37°C

2) Specifications

   Setting temperature: 37°C

   Temperature accuracy: 37°C±0.2°C

   Temperature fluctuation: ±0.1°C

2.9.5.2. Automatic cleaning system

The system supports 6-step automatic cleaning. After the test is finished, the cuvette is automatically cleaned through 6-step cleaning.
The automatic cleaning system consists of a cleaning probe, a lifting motor and related fluidic components. The lifting motor controls the cleaning probe to move up and down in each cleaning stage to complete the cleaning of the reaction cuvette.

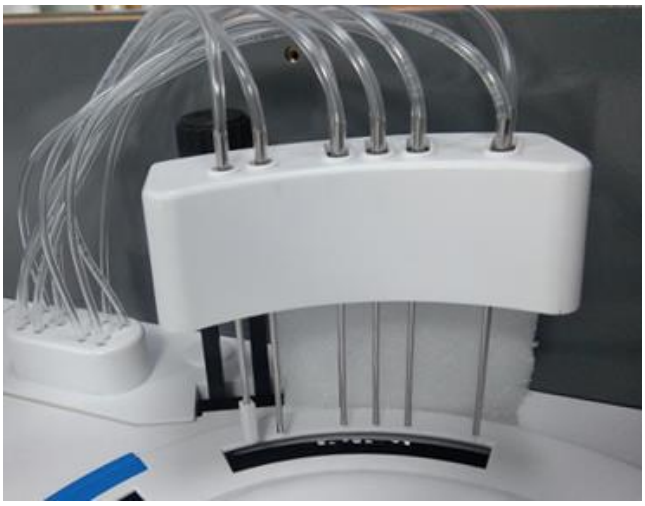

Figure 2-13 Cleaning System

1) Function

   Clean the plastic cuvette after the test, suck out the reaction solution, inject purified water and concentrated detergent, and drain it.

2) Specifications

   There are six cleaning heads in total, of which:

   - Section 1 sucks the reaction liquid and injects purified water mixed with concentrated cleaning liquid;
   - Sections 2 to 4 suck the purified water injected in the previous section and inject purified water again;
   - Sections 5 and 6 suck out the remaining water droplets in the plastic cuvette.

3) Action

   Move up and down in cuvette to complete the action of sucking the reaction liquid and fill concentrated cleaning liquid and purified water.

2.9.5.3. Mixing unit

It is mainly composed of a stirring rod and a stirring rod cleaning basin. The stirring rod is driven by the motor to stir the mixed reaction liquid in the reaction cuvette to ensure a complete reaction. The stirring rod cleaning basin provides stirring after the reaction. The function of the rod cleaning avoids carrying pollution in the reaction or affects the accuracy of the measurement results.

1) Function

   Mix the reagent and sample in the plastic cuvette (colorimetric cuvette).

2) Action

   Move down, rotate and move up at the undermentioned positions.

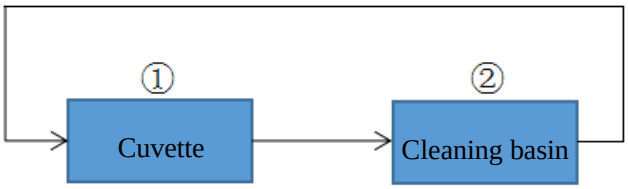

Figure 2-14 Mixing Position

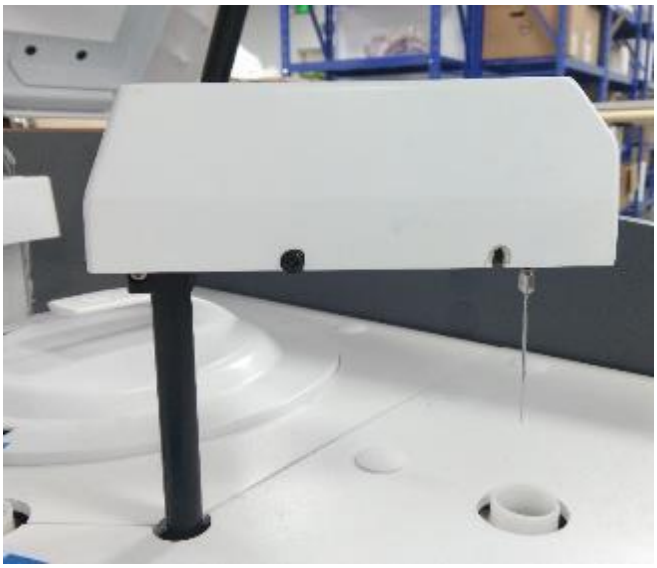

Figure 2-15 Stirring Rod

2.9.5.4. Photoelectric detection unit

The photoelectric detection unit is used for measuring the absorbance of the reaction liquid in the cuvette and consists of an optical system and a signal detection system. Its main function is to detect the change of light intensity of light-transmitting reactant, convert the optical change signal caused by chemical reaction into electrical signal by photoelectric conversion method, and reflect the change of light intensity by detecting the change of electrical signal.

The optical system consists of a light source, an optical diameter colorimetric system and a light splitting component, and is used for providing monochromatic light with sufficient intensity and a stable and reliable colorimetric optical path structure.

The signal detection system includes photoelectric conversion part and AD acquisition and

processing part. Its main function is to convert the light intensity signal of monochromatic light absorbed by the reactant and focused on the photoelectric conversion device into an electrical signal. The electrical signal is amplified and then collected by A/D to output photoelectric data reflecting the light intensity, which is then transmitted to the corresponding control unit for absorbance calculation.

1) Function

The absorbance of the reaction solution in the plastic cuvette was measured during the rotation of the reaction tray.

2) Specifications

Wavelength: 340 nm ~ 800 nm, optional wavelength

Simultaneous determination of wavelengths: simultaneous determination of one or more wavelengths

Wavelength accuracy: ±2 nm

Half wave width: 8±2 nm

Inspector: photoelectric diode

Light source: tungsten halogen lamp, 12 V 20 W, 2000 h

3) Schematic diagram

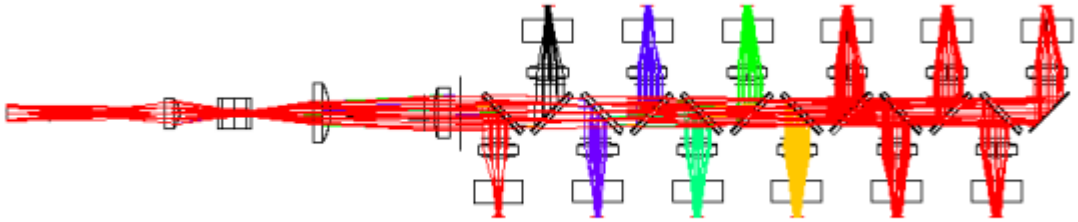

Figure 2-16 Optical Path Diagram

2.10. Software interface

■ Interface

The operation interface of EXC2X series automatic chemistry analyzer includes toolbar, status bar and function display area, as shown in the following figure:

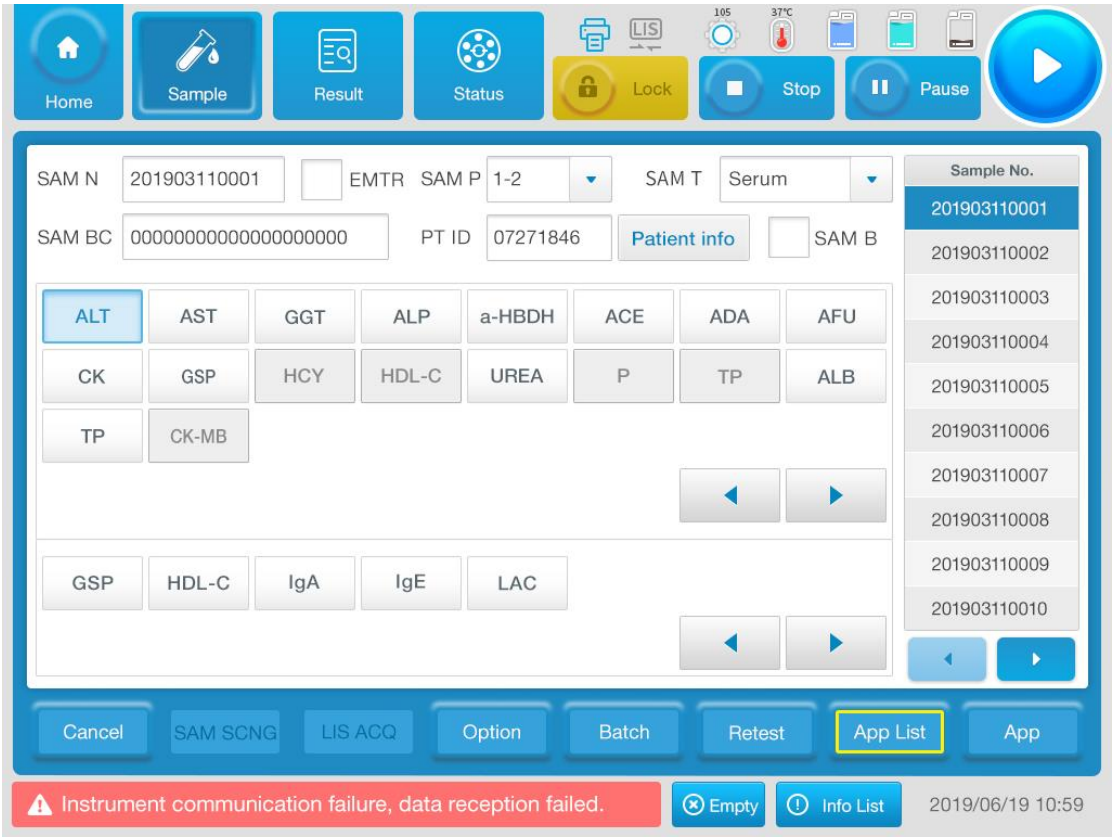

Figure 2-17 Software Operation Interface

■ Status bar

Includes status display area and alarm information display area.

(1) Status display area

It displays system status, test period, reaction tray temperature, cleaning container status, pure container status, waste container status and system time.

1) System status: When the analyzer is in the test state, the gear in the upper right corner rotates, and the number on the gear indicates the total number of running cycles of the reaction tray in the most recent test (or ongoing test);

2) Reaction tray temperature: Indicates the actual temperature of the reaction tray;

3) Printer connection status: highlighted as connected printer and gray as unconnected printer;

4) LIS connection status: highlighted as connected LIS system, and grayed out as unconnected LIS system;

5) Cleaning container, pure water container and waste liquid container: display the state of water container;

6) System date and time: date and time are displayed in the lower right corner;

7) User: the logged-in user name is displayed above the system date.

(2) Alarm information display area

When the system has error information, error information or alarm information will be displayed in the error information column. Click "**Clea**r" in the function button area to clear the current error message or alarm message, and directly click "**Info List**" to enter the alarm information details page.

- Toolbar

Includes various function buttons and shortcut buttons.

(1) Function button

Used to open various function pages of the system, mainly including the following buttons:

1) Sample: Carry out patient sample test (including batch application) and support functions such as patient information input, sample location setting and sample position release.
2) Calibration: You can set calibrator information, apply for calibration test and reagent blank test, and review calibration results and reagent blank results.
3) Quality control: You can set up QC information, apply for quality control tests, review quality control results and other operations.
4) Status: Displays information about the sample tray, reagent tray, and reaction tray. In sample tray interface, you can view the sample information, release the sample position, view the reaction curve, etc. In reagent tray interface, you can set the reagent position, check the reagent information, detect the reagent volume, etc. In reaction tray interface, you can check the state of the reaction tray, the test information, the reaction curve, etc.

   Note: structurally, the sample tray and the reagent tray are combined into a reagent-sample tray, which is separated in software for easy operation. The sample tray on the software interface corresponds to 40 sample positions on the outer circle of the instrument reagent-sample tray; the reagent tray corresponds to 40 reagent positions in the middle circle and the inner circle. If there is something similar below, it will not be explained again.
5) Reagent: It can be used to query reagent information, scan reagent, detect remaining volume, load and unload reagent, etc.
6) Results: Patient sample results can be reviewed, reaction curves can be viewed, and patient information can be viewed and edited.
7) Settings: Including test setting, system setting, user setting and assay setting.
8) Maintenance: Including routine maintenance consisting of periodic maintenance, fault handling, data backup, temperature curve, fluidic component status and unit status and engineering maintenance consisting of maintenance and commissioning.

(2) Shortcut button

1) Start: Start all tests that have been applied for.
2) Pause: Pause the sample adding action.

3) Stop: Stop adding R1 reagent.

4) Lock: Lock the interface, and clicking other function keys is invalid.

5) Home page: Return to the home page interface with one key.

This figure shows the current alarm information before and after viewing.

This figure is to enter the fault processing and view the fault information

- Function display area

  The function interface displays after clicking the function button.

3. Analysis Principle and Calculation Method

This chapter briefly introduces the measuring principle of the instrument, including:

- Analytical method
- Calibration type and measurement principle
- Prozone inspection

3.1. Analytical method

Using the absorption law of solution to light or the transmission law of suspension to light, the absorbance of each photometric point in the reaction process is monitored, and the concentration or activity of the measured substance is calculated according to the change of absorbance before and after the reaction or the change rate of absorbance in the reaction process, combined with corresponding calibration parameters or calculation factors.

3.2. Analysis method and reactivity calculation

In EXC2X series automatic chemistry analyzer, the calculation formula of absorbance is as follows:

Absorbance of solution =Lg (Ad water-ad dark)/(Ad dissolved-ad dark)

Among them:

1) “Lg" means carrying out common logarithmic operation with 10 as the base;
2) "AD" means the value of transmitted light intensity after photoelectric conversion and digital-to-analog conversion;
3) "AD dark" means the AD value when the bulb is not turned on, "AD water" means the AD value of purified water in the cuvette, "AD dissolved" means the AD value when the solution to be tested in the cuvette;
4) The absorbance data on the reaction curve of EXC2X series automatic chemistry analyzer is a value that is magnified 20,000 times of the absorbance value.

According to the characteristics of reaction speed in the reaction process, EXC2X series automatic chemistry analyzers classify all reactions into three categories: endpoint method, two-point method and kinetic method, which are described respectively below.

- Analysis methods: endpoint method, two-point method and kinetic method.
- Reaction time N P: a period of time from the start of a test to the end of reaction monitoring. For a single reagent item, the reaction time refers to the time after adding S while for dual reagent assay, it refers to the time after R2 is added. Such interval includes two input boxes, which respectively input the start time and end time of the reaction monitoring, and are respectively replaced by using N and P.

- Blank time [L] [M]: the time before a test starts a reaction. For a single reagent assay, blank time refers to the duration between adding R1 and adding sample S while for dual reagent item, it refers to the duration between adding sample S and R2. The interval also includes two input boxes, which input start time and end time of blank monitoring respectively, and are respectively replaced by using L and M.
- For a dual-wavelength assay, A is the difference between the absorbance of dominant wavelength and that of the secondary wavelength; For a single wavelength assay, A is the absorbance of the dominant wavelength.

3.2.1. End-point method

After a certain period of time, the reaction reaches the equilibrium point, at which time the absorbance no longer changes, and the increase (or decrease) amplitude of absorbance caused by the reaction is proportional to the concentration of the measured substance. Also known as the "Balance" method.

3.2.1.1. Single reagent endpoint method

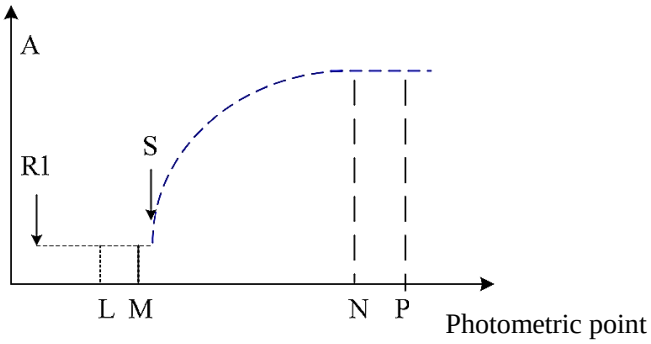

Figure 5-1 Reaction Curve of Single Reagent Endpoint Method

Reaction time [N] [P], 10≤N≤P≤51, where N+4 ≥ P;

Blank time [L] [M], 0≤L≤M≤8, where L+4 ≥ M.

- Calculation of absorbance Ai participating in the calculation of reactivity in the reaction time interval.

  1) If N=P, input [P] [P] and use only one point, then $A_i = A_N$.

  2) If P=N+1, input [N] [N+1], and use two points for $A_i = \frac{A_N + A_{N+1}}{2}$.

  3) If P=N+2, i.e. Input [N] [N+2] and use 3 points, then A_i is the absorbance values after the maximum and minimum values are removed.

  4) If P=N+3, i.e. Input [N] [N+3], and use 4 points,then A_i is the average of the remaining 2 absorbance values after removing the maximum and minimum absorbance values.

  5) If P=N+4, i.e. Input [N] [N+4], and use 5 points,then A_i is the average of the remaining 3 absorbance values after removing the maximum and minimum

absorbance values.

- Absorbance participating in the calculation of reactivity in the blank time interval A_b: the calculation method is the same as that of absorbance participating in the calculation of reactivity A_i in the reaction time interval.

- Calculation of reactivity: $R = A_i - KA_b$.

- Where $k = \frac{V_{R1}}{V_{R1} + V_S}$ is the single reagent volume correction factor, V_{R1} , V_s represents the first reagent and sample volume respectively. The second item kA_b in the above R formula represents the reagent blank correction value, and reagent blank can be deducted in real time, but sample blank cannot be deducted. If sample blank correction is required, a sample blank test must be applied separately. The calculation method of sample blank reactivity R_{Sb} is the same as that of R above, that is $R_{sb} = A_i - kA_b$, so the reactivity after sample blank correction is $R' = R - R_{Sb}$.

3.2.1.2. Dual reagent endpoint method

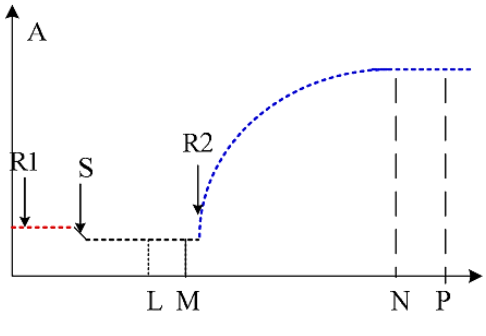

Figure 5-2 Reaction Curve of Dual Reagent Endpoint Method

Reaction time N P, 22≤N≤P≤51, where N+4 ≥ P;

Blank time L M, 10≤L≤M≤21, where L+4 ≥ M.

- Calculation of absorbance *Ai* participating in the calculation of reactivity in the reaction time interval: same as single reagent endpoint method.
- Calculation of absorbance A_b participating in the calculation of reactivity in blank time interval: same as single reagent endpoint method.
- Calculation of reactivity R: $R = A_i - k' A_b$.

1) The second term $k' A_b$ in the formula represents the correction value of the mixed blank of the first reagent and the sample, and $k' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$ is a dual

reagent volume correction factor.

2) The mixed blank of the first reagent and the sample blank can be deducted in real time, but R2 (second reagent) blank cannot be deducted. If R2 correction is required, a reagent blank test must be applied separately. The calculation method of blank reactivity R2 is the same as that of r above, that is R_{R2}, which means $R_{R2} = A_i - k' A_b$, so the reactivity after sample blank correction $R' = R - R_{R2}$.

3.2.2. Two-point method

The two-point method is also called the first-order kinetic method, the two-point rate method and the fixed-time method. It means that the reaction rate is proportional to the one-power of the substrate concentration within the specified reaction time, i.e. V=K[S]. Due to the constant consumption of substrate, the whole reaction speed is continuously decreasing, which shows that the increasing (or decreasing) speed of absorbance is smaller and smaller. The increase (or decrease) (△A/min) of absorbance of the reaction solution within the specified reaction time is proportional to the concentration of the measured substance.

According to whether the sample blank needs to be deducted, the two-point method is divided into single interval two-point method and dual interval two-point method. The dual interval two-point method can deduct the sample blank in real time, that is, the absorbance change rate between two points in the sample blank period is used as the sample blank deduction.

The two-point method can be used to check substrate depletion. If substrate depletion occurs, the corresponding mark will be given on the result.

3.2.2.1. Single reagent two-point method

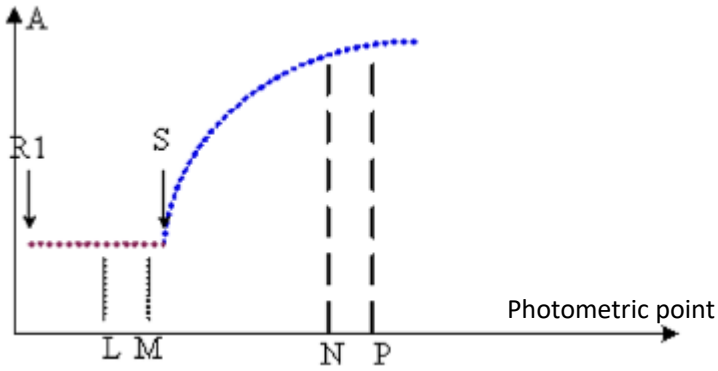

Figure 5-3 Reaction Curve of Single Reagent Two-Point Method

Reaction time N P, 10 ≤ N < P ≤ 51;

Blank time L M, 0≤L<M≤8, L and M are blank by default without performing blank correction.

- Reactivity R calculation: $R = \frac{A_P - A_N}{t_P - t_N}$ (R needs to be converted into R per minute);

- Blank reactivity R_b : the algorithm is the same as the above reactivity R , $R_b = \frac{A_M - A_L}{t_M - t_L}$ (R_b needs to be converted into R_b per minute);
- If blank time is set, blank correction must be carried out. After blank correction, the reactivity $R' = R - KR_b$, where K is the single reagent volume correction factor, $K = \frac{V_{R1}}{V_{R1} + V_S}$.

3.2.2.2. Dual reagent two-point method

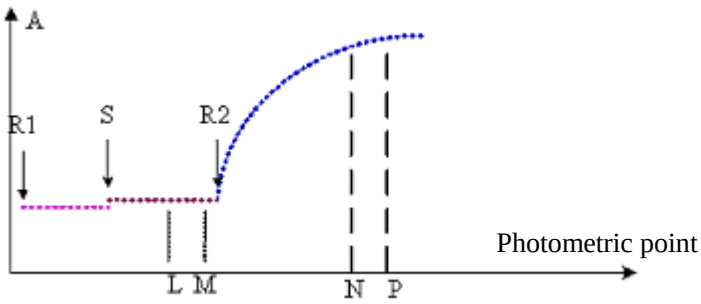

Figure 5-4 Reaction Curve of Dual Reagent Two-Point Method

Reaction time N P, 22 ≤ N < P ≤ 51;

Blank time L M, 10≤L<M≤21, L and M are blank by default without performing blank correction.

- Reactivity R : the algorithm is the same as the single reagent two-point method.
- Reactivity R_b : the algorithm is the same as the single reagent two-point method.
- If blank time is set, blank correction must be carried out. The reactivity after blank correction is $R' = R - K'R_b$ where K' is the dual reagent volume correction factor, $K' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$. By setting the blank time, the instrument can only automatically deduct the mixed blank of the first reagent and the sample, but cannot deduct the blank of the second reagent. If the blank of the second reagent needs to be deducted, the reagent blank test shall be applied separately. The reactivity algorithm of the second reagent blank R_{R2} is the same as the above-mentioned reactivity R, and the reactivity corrected by the blank of the second reagent $R'' = R - R_{R2}$.

3.2.3. Kinetic method

1) Also called zero-order rate method, rate method and continuous monitoring method, it refers to that the reaction speed is proportional to the zero square of the substrate concentration, i.e. Independent of the substrate concentration. Therefore, during the whole reaction process, the reactant can generate a certain product at a uniform speed, resulting in the absorbance of the measured solution uniformly decreasing or increasing at a certain wavelength. The decreasing or increasing speed (△A/min) is proportional to the activity or concentration of the measured substance (catalyst). It is mainly used for the determination of enzyme activity.
2) In practical application, as the concentration of substrate cannot be infinite, the reaction will no longer be zero-order after the substrate is consumed to a certain extent as the reaction progresses. Therefore, the zero-order rate method is aimed at a specific time period, and the zero-order reaction time period must be selected for monitoring to ensure the accuracy of the results.
3) According to whether the sample blank needs to be deducted, the kinetic method is divided into single interval two-point method and dual interval two-point method. The dual interval two-point method can deduct the sample blank in real time, that is, the absorbance change rate in the sample blank period is used as the sample blank deduction.
4) Kinetic method can be used to check substrate depletion. If substrate depletion occurs, corresponding prompt marks will be given on the results.
5) The dynamic method can be used to check the linearity limit. If the situation of exceeding the linearity limit occurs, the corresponding prompt mark will be given on the result.

Calculation of reactivity

In the zero-order kinetic reaction interval, the least square method is used to calculate the reactivity, and the least square method calculation formula is as follows:

$$R = \frac{\sum_{i=N}^{P}(t_i - \bar{t}) \cdot (A_i - \overline{A})}{\sum_{i=N}^{P}(t_i - \bar{t})^2}$$

Where N is the starting point of the zero-order kinetic reaction interval and P is the end point of the zero-order kinetic reaction interval, A_i is the absorbance at point i, $\overline{A}$ is the average absorbance from point n to point P, T_i is the time at point i, and $\bar{t}$ is the average time from point L to point M.

3.2.3.1. Single reagent kinetic method

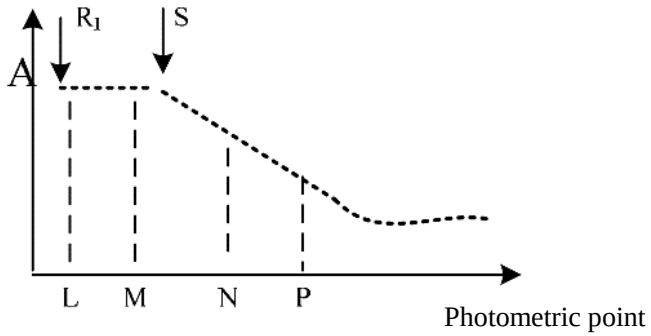

Figure 5-5 Reaction Curve of Single Reagent Rate Method

The reaction time N P, same as that of the single reagent two-point method, but N+2≤P, i.e. At least 3 photometric points are required;

The blank time L M, same as the single reagent two-point method, but L+2≤M, i.e. there must be at least 3 photometric points; the default values of L and M are blank, and no blank correction is performed.

- Reactivity R : $R = \Delta A_{NP}$, Δ means the change rate of absorbance per minute between photometric points (N, P) obtained by least square method.
- Blank reactivity R_b : the algorithm is the same as the above reactivity R , $R = \Delta A_{LM}$.
- If blank time is set, blank correction must be carried out. After blank correction, the reactivity $R' = R - KR_b$, where K is the single reagent volume correction factor, $K = \frac{V_{R1}}{V_{R1} + V_S}$.

3.2.3.2. Dual reagent kinetic method

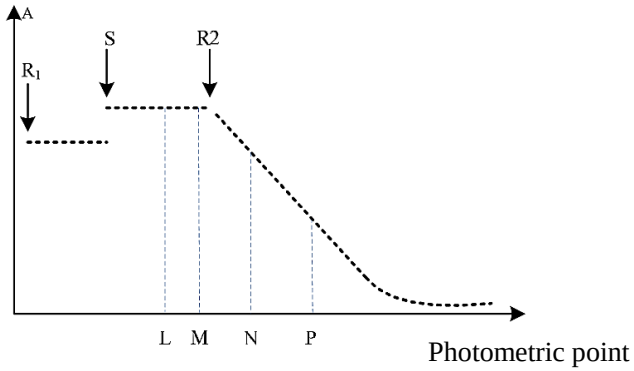

Figure 5-6 Reaction Curve of Dual Reagent Rate Method

The reaction time N P is the same as that of the dual reagent two-point method, but N+2≤P, i.e. there must be at least 3 photometric points;

The blank time L M is the same as the dual reagent two-point method, but L+2≤M, i.e. There must be at least 3 photometric points; L=0, M=0 by default without performing blank correction.

- Reactivity R : $R = \Delta A_{NP}$, Δ means the change rate of absorbance per minute between photometric points (N, P) obtained by least square method.
- Reactivity R_b : the algorithm is the same as the single reagent kinetic method.
- If blank time is set, blank correction must be carried out. The reactivity after blank correction is $R' = R - K' \times R_b$ where K' is the dual reagent volume correction factor, $K' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$. By setting the blank time, the instrument can only automatically deduct the mixed blank of the first reagent and the sample, but cannot deduct the blank of the second reagent. If the blank of the second reagent needs to be deducted, a reagent blank test shall be applied separately. The reactivity algorithm of the blank of the second reagent R_{R2} is the same as the above-mentioned reactivity R and the reactivity corrected by the blank of the second reagent is $R'' = R - R_{R2}$.

4. Maintenance and Service

This chapter introduces the maintenance methods of the instrument, including common maintenance instructions and regular maintenance. The purpose, use timing, required supplies, instrument status, precautions and operation steps of each maintenance item are introduced in detail.

4.1. Overview

In order to ensure the system reliability and good working condition and service life, please operate and regularly maintain the system in strict accordance with this Operation Manual.

4.1.1. Maintenance tools

- A set of hex wrench
- Cross screwdriver (large, medium and small)
- Stainless steel wire (inner diameter 0.3 mm and 0.5 mm, respectively)
- Plastic syringe (approx. 10 ml, without probe)
- Clean gauze
- Clean cotton swabs
- Brush (for cleaning the barrel)
- Non-ionic surfactant detergent
- Anhydrous ethanol
- 84 disinfectant
- Medical latex gloves

4.2. Regular maintenance items

Regular maintenance items are defined according to the conditions of various parts of the instrument and actual use. Trained personnel are required to strictly implement the items according to the specified cycle to ensure the performance of the instrument and reduce unnecessary service calls. Before performing maintenance, please make sure to read the maintenance procedures in this section thoroughly.

The system provides the customization function. You can customize the required maintenance items through the customization function except the system-defined maintenance items that are not allowed to be edited. After the maintenance operation is completed, the maintenance log can be filled in according to the maintenance situation to record the abnormalities and other necessary information during maintenance.

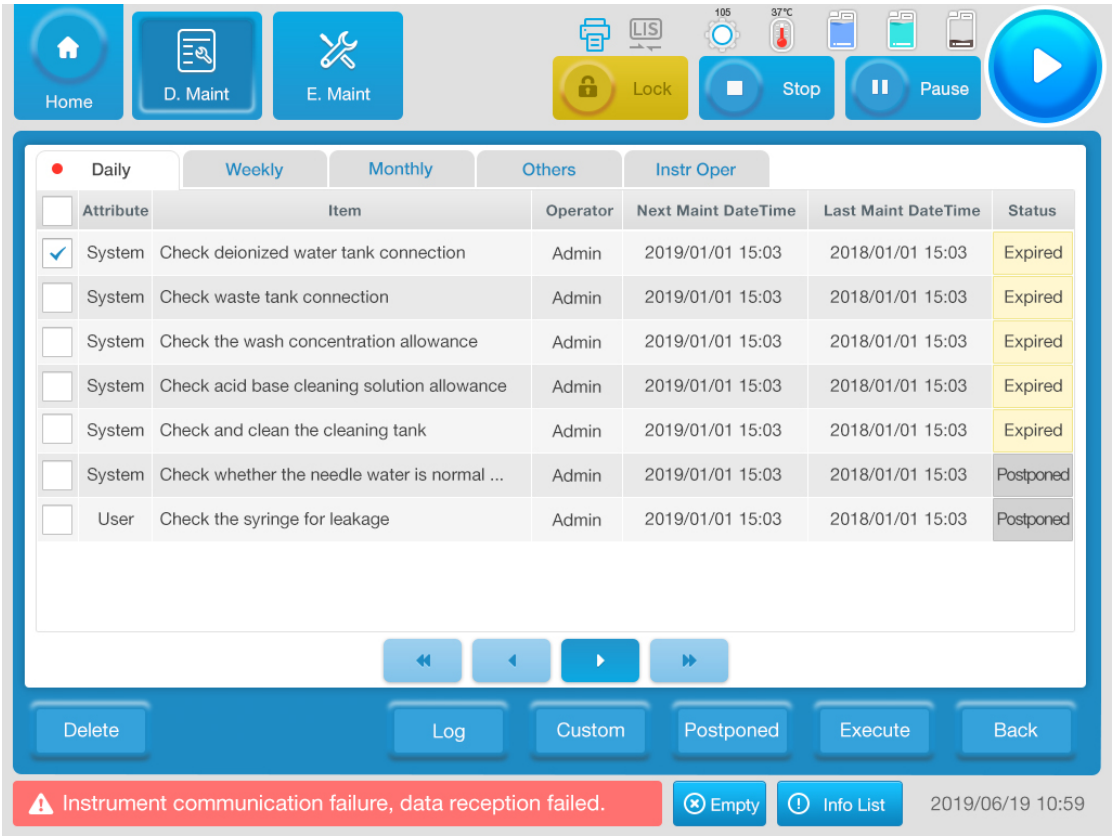

Figure 4-1 Periodic Maintenance

4.2.1. Maintenance cycle

The periodic maintenance list is divided into the following maintenance periodic units:

- Daily-1 day
- Weekly-7 days
- Monthly-30 days
- Other-irregular
- Order operation

The system starts with the current maintenance time of each maintenance item and counts down the maintenance items.

4.2.2. Maintenance content

Maintenance cycle	Maintenance items (Arranged in order)	
Daily	1	Check deionized water connection
	2	Check waste connection
	3	Check the remaining amount of concentrated detergent
	4	Check the reagent-sample probe syringe for leaks
	5	Check the balance of acid-base detergent
	6	Check whether the probe outlet water is normal (Verify whether the probe inner wall is blocked)
	7	Check and clean the cleaning basin
Weekly	1	Clean the reagent-sample tray
	2	Clean the reagent sample barcode scanning window
	3	Clean the analyzer panel
	4	Check and clean the automatic cleaning mechanism and stirring rod (Outer wall)
	5	Check and clean reagent -sample probe (Outer wall)
	6	Intensified cleaning
	7	Reaction cuvette (Dirty) detection-cuvette pollution (Including light source lamp detection)
	8	Reaction cuvette (Residual) detection-scraping of cuvette inner wall
Monthly	1	Clean ball spline
	2	Clean the cleaning basin for reagent -sample probe and stirring rod
Other	1	Fluidic component emptying

4.2.3. Maintenance interface

- Attribute

Displays the definition properties of the maintenance item. There are two values, "system"

and "user". The system indicates that the maintenance item has been set when the instrument leaves the factory, and the user is the maintenance item which the user adds through the "customization" function.

- Assay

Displays all system pre-defined assays and user-defined maintenance assays for the current maintenance cycle.

- Operator

Displays the operator for the current execution of the corresponding maintenance item, i.e. the user ID of the current software login.

- Time to be maintained

Displays the time this item needs maintenance next time.

- Maintained time

Displays the last maintenance time of the item.

- State

Displays whether the current item has expired or been postponed and the date to be maintained.

- Log

Record exceptions and other necessary information generated during maintenance.

- Customization

Customization function is used to customize the required maintenance items according to the reagent usage of the instrument. The system also allows adding and deleting custom maintenance items.

- Delete

If a maintenance item is not needed, the system allows it to be deleted. Please note that only custom maintenance items are allowed to be deleted, and system pre-defined maintenance items are not allowed to be deleted.

- Delay

The maintenance of the item is delayed by one cycle.

- Execution

After selecting one or more maintenance items, click this button to start the inspection of maintenance items.

4.2.4. Daily maintenance

The daily maintenance items shall be carried out before the test starts every day, and the reagent -sample probe, cleaning basin, syringe, deionized water connection, waste liquid connection and the remaining amount of concentrated cleaning liquid shall be checked.

4.2.4.1. Connection of deionized water check

Abnormal connection of the deionized water will result in the insufficient water supply or water leakage, which may cause the machine works improperly.

- Purpose

Check the connection of deionized water to ensure normal water supply.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

- Operating steps

1) Check whether the switch of the water purification system or other water storage module is on;
2) Check and confirm that the liquid guide pipe is dredged and free from bending, twisting and leakage of liquid;
3) Select **Maintenance-Periodic maintenance-Daily Maintenance**;
4) Click the check box corresponding to checking deionized water connection;
5) Click **Execute** to perform maintenance;
6) Click **Log** to record the exceptions or other information to be filed during maintenance;
7) Click **Save** to save the log.

4.2.4.2. Waste connection check

Improper connection of waste lines, or full high-concentration waste liquid barrel without emptying in time, will cause waste liquid overflow, environmental pollution, cross-contamination and even damage to instruments. Therefore, it is necessary to check the waste liquid connection of the instrument frequently.

- Purpose

Check whether the waste liquid pipeline connection and high-concentration waste liquid container are empty to avoid overflow of waste liquid.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Check whether the waste liquid discharge system is normal, keep the waste liquid pipeline free from bending, discharge smoothly, and discharge high-concentration waste liquid properly (waste liquid shall be discharged as per local regulations);

2) Empty the waste liquid in the high-concentration waste liquid barrel;

3) Select **Maintenance-Periodic maintenance-Daily Maintenance**;

4) Click the check box corresponding to the connection of waste liquid.

5) Click **Execute** to perform maintenance;

6) Click **Log** to record the exceptions or other information to be filed during maintenance;

7) Click **Save** to save the log.

4.2.4.3. Enhanced detergent volume check

Inadequate balance of enhanced detergent will cause the instrument to fail continuous testing. It is recommended to check the balance of concentrated detergent or intensified detergent before starting the test every day. If it is insufficient, please add it in time.

- Purpose

Check the remaining amount of the enhanced detergent to avoid the test being unable to continue due to insufficient remaining amount.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Open the reagent-sample tray and observe whether the intensified detergent is sufficient. If it is insufficient, add it in time.

2) Select **Maintenance-Periodic maintenance-Daily Maintenance**;

3) Click the check box corresponding to checking the balance of acid-base detergent;

4) Click **Execute** to perform maintenance;

5) Click **Log** to record the exceptions or other information to be filed during maintenance;

6) Click **Save** to save the log.

4.2.4.4. Probe syringe check

Reagent-sample probe syringe is a device for precisely distributing samples and reagents. If the syringe leaks, the dispensing amount will be inaccurate and even damage the syringe. Before starting the analysis every day, be sure to check whether the reagent -sample probe syringe leaks.

- Purpose

Check the reagent-sample probe syringe for leakage and internal air bubbles.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Maintenance supplies

Clean gauze.

■ Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Open the analyzer maintenance window to see the reagent -sample probe syringe.
2) Select **Maintenance-Periodic Maintenance-Daily Maintenance**;
3) Click the check box corresponding to checking whether the reagent-sample probe syringe leaks;
4) Observe whether the syringe leaks liquid, wipe the joints between the syringe and the manually tighted joints with clean gauze, and check whether the gauze is wet to judge whether the liquid leaks:
   - If not, proceed to the next step.
   - If there is leakage, tighten the hand-tight joint.
   - Check again. If there is any leakage, please tighten the hand tight joint to confirm whether its gasket is in good condition.
5) Check whether there are air bubbles inside the syringe. If there are air bubbles, please perform the maintenance operation of "remove air bubbles from the syringe".
6) Close the analyzer maintenance window;
7) Click **Execute** to perform maintenance;
8) Click **Log** to record the exceptions or other information to be filed during maintenance;
9) Click **Save** to save the log.

4.2.4.5. Acid and alkali detergent volume check

Insufficient balance of acid-base detergent will cause the instrument to be unable to continuously test. It is recommended to check the balance of acid-base detergent before starting the test every day. If it is insufficient, please add it in time.

■ Purpose

Check the remaining content of acid-base detergent to avoid that the test cannot be preceded due to insufficient of it.

■ Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

■ Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Select **Maintenance-Periodic maintenance-Daily Maintenance**;
2) Select the check box corresponding to checking the balance of acid-base detergent, click Execute, and then click Continue to execute the rotation of reagent-sample probe

and drop to the acid-base cleaning position, record the drop in the liquid level of the current cleaning position, and then mechanically reset.

3) Click **Execute** to perform maintenance;

4) Click **Log** to record the exceptions or other information to be filed during maintenance;

5) Click **Save** to save the log.

4.2.4.6. Probe water discharging check

If there are foreign matters or abnormalities in the reagent-sample probe, the test may be affected, leading to inaccurate results. Therefore, please check whether the water outgoing state of the probe is normal before testing every day.

- Purpose

Check whether the water outgoing state of reagent-sample probe is normal.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Open the upper cover of the analyzer;

2) Select **Maintenance-Periodic maintenance-Daily Maintenance**;

3) Select the check box corresponding to check whether the probe outlet water is normal;

4) Click **Execute**, and then click **Continue** to clean the inner wall of reagent-sample probe.

5) Observe the water outgoing condition when cleaning the inner wall of reagent-sample probe (as shown in the following figure). If the cleaning water is sprayed or not vertically discharged from the probe tip, the probe may be blocked. Firstly, carry out "intensified cleaning" maintenance operation; if it is still abnormal, it is necessary to carry out the maintenance operation of "replacing reagent-sample probe" or contact the service engineer.

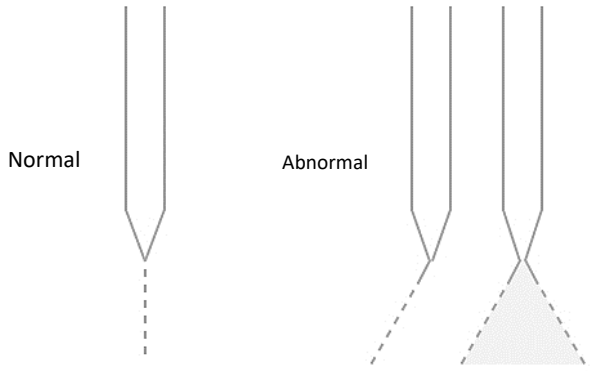

Figure 4-2 Water Outgoing From Probe Inner Wall Cleaning

6) Click **Log** to record the exceptions or other information to be filed during maintenance;

7) Click **Save** to save the log.

4.2.4.7. Cleaning basin check and cleaning

Foreign matters or abnormalities in the cleaning basin may affect the test and lead to inaccurate results. Therefore, please check whether the outlet state of the outlet tank is normal before testing every day.

- Purpose

Check whether the outgoing state of the outlet tank is normal.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, please ensure that the instrument is powered off or idle.

Operating steps

1) Open the upper cover of the analyzer;

2) Select **Maintenance-Periodic maintenance-Daily Maintenance**;

3) Check and clean the check box corresponding to the cleaning basin.

4) Click **Execute**, and then click **Continue** to clean the outer wall of reagent-sample probe. Refer to the following figure to observe the water output of the cleaning basin.

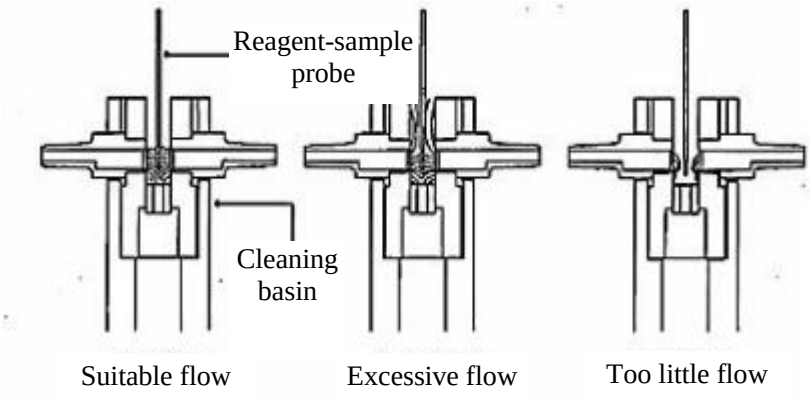

Figure 4-3 Water Outgoing From Probe Outer Wall Cleaning

5) If the flow rate is too small, click **Exit** and clean the cleaning basin before performing the operation of the maintenance item;

6) Click **Log** to record the exceptions or other information to be filed during maintenance;

7) Click **Save** to save the log.

4.2.5. Weekly maintenance

Mainly for cleaning reagent-sample tray, cleaning sample/reagent bar code scanning

window, cleaning analyzer panel, cleaning stirring rod/reagent-sample probe, intensified cleaning (cleaning reagent-sample probe inner wall and reaction cuvette), reaction cuvette detection and light source lamp detection.

4.2.5.1. Reagent-sample tray cleaning

When the reagent is accidentally spilled in the reagent-sample tray, or dust is accumulated on the inner wall through visual inspection, it should be cleaned in time to reduce the risk of cross contamination.

- Purpose

Clean the reagent-sample tray assembly, keep the working environment and table clean and tidy, so as to reduce the risk of cross contamination.

- Maintenance timing

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Clean gauze, deionized water, alcohol, cotton swab.

- Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Biological risk

Biological pollution

The table surface should be considered infectious and protective gloves should be worn during operation.

Operating steps

1) Please confirm that the instrument is in shutdown or idle state;
2) Uncover the reagent-sample tray, remove the reagent-sample tray and place it in a safe and reliable place;
3) Wipe the inner tray with gauze dipped in a small amount of deionized water or alcohol. When necessary, a small amount of neutral detergent can be dipped into gauze to wipe it.
4) Put the reagent-sample tray back into the bin and cover the tray.
5) Select **Maintenance- Daily Maintenance- Weekly Maintenance** to check the corresponding options of cleaning reagent-sample tray.
6) Click **Execute** to perform maintenance;
7) Click **Log** to record the exceptions or other information to be filed during maintenance;
8) Click **Save** to save the current log content.

4.2.5.2. sample/reagent barcode scan screen cleaning

When dust or stains are accumulated in the barcode scanner through visual inspection, it should be cleaned in time to reduce the risk of cross contamination.

- Maintenance timing

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Clean gauze, deionized water, cotton swab.

- Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Biological risk

Biological pollution

The table surface should be considered infectious and protective gloves should be worn during operation.

Operating steps

1) Please confirm that the instrument is in shutdown or idle state;
2) Uncover the reagent-sample tray, remove the reagent-sample tray and place it in a safe and reliable place;
3) Wipe the barcode scanning window with gauze dipped in a small amount of deionized water or alcohol;
4) Put the reagent-sample tray back into the bin and cover it
5) Select **Maintenance-Daily Maintenance-Weekly Maintenance** to check the clean sample/reagent barcode scanning window.
6) Click **Execute** to perform maintenance;
7) Click **Log** to record the exceptions or other information to be filed during maintenance;
8) Click **Save** to save the current log content.

4.2.5.3. Analyzer table cleaning

Reagents, reaction solutions and serum are easy to drip on the analyzer table, which should be removed in time. In order to ensure a clean working environment and reduce biological risks, exposed parts such as analyzer table and tray cover should be cleaned in time.

- Purpose

Clean the analyzer table and tray cover and keep the working environment and table clean and tidy, so as to reduce the risk of cross contamination.

- Maintenance timing

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Clean gauze, deionized water, cotton swab.

- Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.


Biological risk

Biological pollution

The table surface should be considered infectious and protective gloves should be worn during operation.

Operating steps

1) Please confirm that the instrument is in shutdown or idle state before opening the upper cover of the analyzer.
2) Wipe the analyzer table and tray cover with gauze dipped in a small amount of alcohol.
3) Cover the upper cover of the analyzer;
4) Select **Maintenance-Daily Maintenance-Weekly Maintenance**, and check the relevant options of cleaning analyzer panel;
5) Click **Execute** to perform maintenance;
6) Click **Log** to record the exceptions or other information to be filed during maintenance;
7) Click **Save** to save the current log content.

4.2.5.4. Reagent - sample probe/stirring rod (outer wall) check and cleaning

If the reagent-sample probe and stirring rod are dirty, cross-contamination between samples or reagents may occur and correct analysis results cannot be obtained. To prevent cross contamination, clean reagent-sample probes and stirring rods weekly.

- Purpose

Keep the outer wall of the reagent-sample probe free of contaminants to reduce cross contamination between samples or reagents.

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Clean gauze, deionized water, cotton swab.

- Instrument status

Before performing maintenance, please ensure that the instrument is in shutdown or idle state.


Biological risk

Biological pollution

The table surface should be considered infectious and protective gloves should be worn during operation.

Operating steps

1) Click **Maintenance-Daily Maintenance-Weekly Maintenance** to check and clean the corresponding options of reagent-sample probe/stirring rod (outer wall).
2) Click **Execute-Continue** to perform reagent-sample probe reset operation, click

Continue to reset the stirring rod, and then descend to the cleaning basin to clean the outer wall. Reset the stirring rod vertically after 5 seconds. Click **Continue** to reset the reagent-sample probe, click **Continue** to lower the cleaning basin to be cleaned for outer wall cleaning after reset, and then reset vertically after 5S.

Operating steps for cleaning the outer wall of reagent-sample probe

Step	Process prompt
1	Click **Continue** and the reagent-sample probe will be in the state to be maintained
2	Please use clean gauze to dip in alcohol and wipe the outer wall of reagent-sample probe until it is clean and smooth
	After cleaning, click **Continue** to proceed to the next step. Please stay away from the movement area of reagent-sample probe
3	This maintenance has been completed
	Click **Continue** to exit the maintenance status

1) After cleaning, click exit.

4.2.5.5. Intensified cleaning

Use acid-base detergent to clean reagent-sample probe.

- Purpose

Keep the outer wall of the reagent-sample probe free of contaminants to reduce cross contamination between samples or reagents.

It is recommended to perform this maintenance operation weekly.

- Instrument status

Before performing maintenance, please ensure that the instrument is in shutdown or idle state.

Operating steps of intensified cleaning

Step	Process prompt
1	Preparation: place a bottle of acid-base cleaning agent (cleaning dose > 50 ml) at the acid-base cleaning position
	Check the option to directly perform dirty cuvette detection after intensified cleaning
	Click **Continue**, the system will start to perform intensified cleaning
2	Please wait while the system performs reaction cuvette testing
	After completion, the next step will be automatically entered
3	This maintenance has been completed
	Click **Continue** to exit the maintenance status

4.2.5.6. Dirty cuvette detection

Judging whether the reaction cuvette is dirty or not and whether the light source lamp is too

weak by testing the water blank of each reaction cuvette.

Dirty reaction cuvette detection operation steps

Step	Process prompt
1	First, make sure that the startup time is more than 30 min so that the light source is stable. Otherwise, please exit the detection process
	Select whether to proceed with "residual cuvette detection"
	Click **Continue** to start the reaction cuvette (dirty) test
2	Please wait while the system detects the reaction cuvette (dirty)
	After completion, the next step will be automatically entered
3	This maintenance has been completed
	Click **Continue** to exit the maintenance status

4.2.5.7. Cuvette residual detection

On the premise of completing the dirty cuvette test, whether the reaction cuvette is a residual cuvette is judged by testing the water blank dynamic AD fluctuation of each channel wavelength of each reaction cuvette.

Operating steps for residual cuvettes in reaction cuvettes

Step	Process prompt
1	First, make sure that the startup time is more than 30 min so that the light source is stable. Otherwise, please exit the detection process
	Place a box of deionized water (＞20 mL) at reagent # 1
	Click **Continu**e to start the reaction cuvette test
2	Please wait while the system performs reaction cuvette testing
	After completion, the next step will be automatically entered
3	This maintenance has been completed
	Click **Continue** to exit the maintenance status

4.3. Monthly maintenance

- Maintenance item

  Clean ball spline and reagent-sample probe and stirring rod cleaning basin

- Operational flow

  1) Manual maintenance items

  Clean the ball spline (to be done with the analysis part switch off)

  2) Semi-automatic maintenance item

  Clean the cleaning basin for reagent-sample probe and stirring rod

  Purpose: to prevent dust from depositing in the cleaning basin and blocking the

cleaning basin after a long time.

Operating steps for cleaning the cleaning basin

Step	Process prompt
1	Click **Continue** to clean the cleaning basin for reagent-sample probe and stirring rod according to the following prompts
2	Manually remove the reagent-sample probe and the rocker arm of the stirring rod from the cleaning basin
	Use the label to dip NaClO and wipe each cleaning basin
	After cleaning is completed, Click **Continue** to proceed to the next step. Please keep away from the moving area of reagent-sample probe and stirring rod pair
3	This maintenance has been completed
	Click **Continue** to exit the maintenance status

4.4. Irregular maintenance items

4.4.1. Cleaning basin cleaning

Biological risk

Biological pollution

All stains should be considered infectious and protective gloves should be worn during operation.

1) Turn off the switch of the analysis unit;
2) Dip a cotton swab into the detergent, gently wipe the inner and outer walls of the cleaning basin of the reagent-sample probe and stirring rod until there is no obvious stain, and then dry with clean gauze.

4.4.2. Cuvette cleaning

1) Turn off the switch of the analysis unit;
2) Remove the cleaning head and remove the reaction tray cover.
3) Loosen the reaction tray fixing screw;
4) Hold the two sides of the reaction tray with both hands respectively, and evenly exert upward force to remove the reaction tray;
5) Dip clean gauze or cotton swab into the supernatant lotion, clean all parts of the inner wall of the reaction tank until there is no obvious stain, and then dry with clean gauze.
6) Install the reaction tray and fix the fastening screws.
7) Cover the reaction tray cover, and then install the cleaning head.

Biological risk

Biological pollution

All stains should be considered infectious and protective gloves should be worn during operation.

4.4.3. Drive rod wipe

1) Turn off the switch of the analysis unit;
2) Move the stirring rod so that its driving rod rotates to an angle suitable for wiping;
3) Wipe the drive rod up and down lightly with clean gauze until there are no obvious dust or stains, then apply lubricating oil, and pull the drive rod up and down to evenly distribute the lubricating oil on the drive rod;
4) Wipe the driving rod of the reagent-sample probe by same method ;
5) Move the reagent-sample probe and stirring rod above the corresponding cleaning basin.

4.4.4. Inspection of pure water bucket

On the left side of the analyzer, a pure water bucket will be placed.

Check the pure water bucket: check whether the bottom of the pure water bucket is clean. If it has become dirty, clean the pure water bucket thoroughly before use.

4.4.5. Probe tube/suction nozzle of cuvette cleaning

When the probe tube of the cuvette cleaning mechanism is not clean, there will be adhesion of reaction liquid, moisture and the like, which should be checked in time after daily shutdown. In case of the above situation, please refer to the following steps for cleaning:

1) Dip a clean cotton swab with absolute ethyl alcohol and gently wipe the drainage probe tube and probe tip until there is no obvious adherent.
2) Dip a clean cotton swab with absolute ethyl alcohol, and gently wipe the suction probe tube and probe tip until there is no obvious adherent.
3) Clean cotton swabs with purified water and gently wipe the four sides and upper and lower parts of the suction nozzle until there is no obvious adherent.
4) Dip a clean cotton swab with absolute ethyl alcohol and gently wipe the four sides and upper and lower parts of the suction nozzle until there is no obvious adherent.

Attention

When cleaning, attention should be paid to the possibility that cotton fibers on cotton swabs may be clamped between the drainage probe tube and the suction probe tube, and the cotton fibers should be removed in time if necessary.

Biological pollution

All parts shall be considered infectious and protective gloves shall be worn during operation.

Biological risk

4.4.6. Waste container cleaning

This step can be omitted if the waste liquid is directly discharged into the sewer; otherwise, it will be carried out according to the following step:

1) Unscrew the waste liquid container cover and take out the waste liquid sensor and waste liquid pipe;
2) Take out the waste liquid container, wash it thoroughly with a brush and then put it in.

Biological risk

Biological pollution

All waste liquid shall be considered infectious and protective gloves shall be worn during operation.

4.4.7. Probe dredge

When the probe is blocked, it needs to be dredged immediately.

1) Turn off the analysis unit;
2) Turn the reagent-sample probe to the appropriate position and open the upper cover of the reagent-sample probe rocker arm;
3) Pull off the connection line with the liquid level detection plate;
4) Loosen the teflon tube connecting the reagent-sample probe;
5) Loosen the compression spring piece;
6) Take out reagent-sample probe upwards;
7) Use stainless steel wire with an inner diameter of 0.3 mm to dredge the reagent-sample probe upwards from the probe tip, and dredge repeatedly back and forth for many times;
8) Connect a disposable syringe with a reagent-sample probe through a matching hose, draw water into the probe tube through the syringe, and make sure that water is ejected from the probe tip in a straight line, which indicates that the probe tube has been dredged.
9) Install the reagent-sample probe and close the cover of the rocker arm in the reverse sequence of the above operation.
10) Move the reagent-sample probe above the cleaning basin.

Biological risk

Biological pollution

Reagent-sample probes should be considered infectious and protective gloves should be worn during operation.

4.4.8. Probe replacement

When the probe is broken, bent or cannot be dredged after being blocked, it needs to be replaced immediately. Refer to "Sample Probe Dredge" in the previous section for the operation process.

1) Turn off the analysis unit;
2) Move the reagent-sample probe to a suitable position, open the upper cover of the reagent-sample probe rocker arm, loosen the teflon tube, and pull off the lead of the liquid level detection sensor;
3) Loosen the compression spring piece and take out the reagent-sample probe;
4) Install the new probe on the rocker arm, press on the spring leaf, connect the teflon tube, insert the lead of the liquid level detection sensor, and close the upper cover of the rocker arm.
5) Move the reagent-sample probe above the cleaning basin.

Biological risk

Biological pollution

Reagent-sample probe should be considered infectious and protective gloves should be worn during operation.

4.4.9. Stirring rod replacement

When the stirring rod is broken, bent or frequently hung, it needs to be replaced immediately.

1) Turn off the analysis unit;
2) Move the stirring rod to a suitable position;
3) Loosen the two top screws fixed on the rotating shaft of the stirring motor;
4) Take off the stirring rod;
5) Install the new stirring rod upward into the rotating shaft of the motor until it touches.
6) Fix the stirring rod on the rotating shaft of the stirring motor by using two jacking screws;

Biological risk

Biological pollution

Mixing rod shall be considered infectious and protective gloves shall be worn during operation.

4.4.10. Bulbs replacement

When the bulb is used for more than half a year, or when the analyzer prompts that the bulb needs to be replaced, it needs to be replaced immediately.

Note: before replacing the light bulb, make sure that the power supply of the analysis

department is turned off; otherwise the light beam emitted by the light bulb will cause damage to eyes.


Caution

Screw falls off

When loosening or fixing the bulb screws, be careful not to fall off the screws.

1) Turn off the switch of the analysis unit and carry out the following steps after half an hour.
2) Take off the automatic cleaning head, and then remove the reaction tray cover;
3) After removing the reaction tray, loosen the fixing screws on the bulb base with M3 hexagonal screwdriver.
4) After the light source lamp is removed, loosen the power cord of the light source lamp on the binding post;
5) Take out the old bulb;
6) Install the new bulb, screw in the fixing screw, and plug in the power cord of the new bulb;
7) Install the reaction tray and screw on the fixing screw;
8) Close the cover of the reaction tray and install the cleaning head.

4.4.11. Syringe replacement

1) Open the maintenance window on the left rear of the analyzer to see the reagent-sample probe syringe;
2) Firstly, loosen up the fixing screws at the piston end of the syringe, and then loosen up the two fixing screws of the tee joint;
3) Take out the syringe and tee joint, pinch the metal part on the upper part of the syringe, rotate counterclockwise to separate the syringe from the tee joint, and take off the syringe;
4) Push the metal thread on the upper part of the new syringe into the thread opening of the tee joint and rotate clockwise to fix it.


Caution

Sealing washer

There is a sealing gasket in the threaded opening of the tee joint, be careful not to lose it when disassembling.

5) Place the syringe in the installation position, and sleeve the piston end of the syringe into the drive screw; screw on the tee joint and the fixing screw of the syringe piston end.

4.4.12. Peristaltic pump head replacement

1) Turn off the switch of the analysis unit and open the maintenance window at the

left rear of the analyzer to see the peristaltic pump;

2) Pull out the peristaltic pump head which is connected with rubber tube from the pipe. Then press the snap on both ends of peristaltic pump head and pull out the pump head. Replace a new pump head;

3) Replace the new peristaltic pump head， connect the pipeline and install the maintenance window.

5. Hardware Replacement

5.1. Reaction disk

Reaction disk assembly:

The reaction disk assembly holds the reaction cuvettes and drives the reaction disk to rotate. It makes every reaction cuvette locate at the specified position to help the sample probes dispense sample, reagent probes dispense the reagent, the mixer mix, and the optical system do the optical acquisition.

Composition and structure

Reaction disk and temperature control assembly position figure:

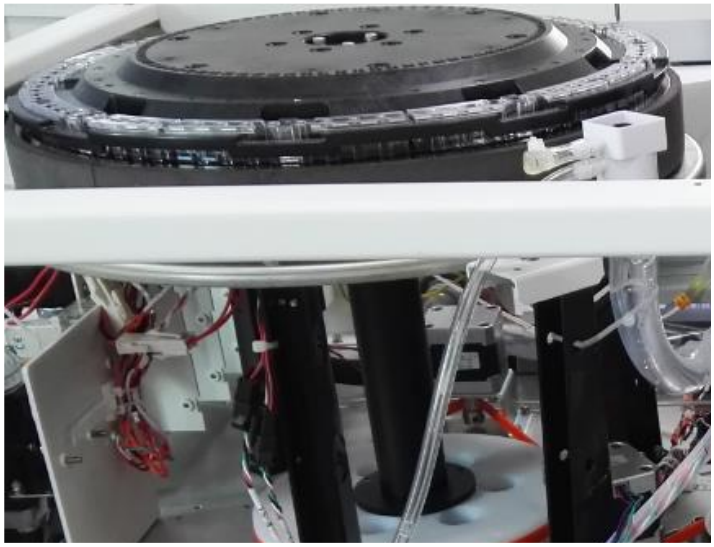

Figure 5-1 Reaction disk and temperature control assembly figure

Composition

Reaction disk and temperature control unit consists of reaction disk assembly, reaction disk driving assembly, coder sensor assembly, and temperature control assembly.

Reaction disk assembly:

The reaction disk assembly is used for fixing the reaction cuvettes, providing the reagent and sample with reaction sites, and helping the optical system for absorbance.

Reaction disk driving assembly:

The reaction disk driving assembly is used for driving the reaction disk assembly rotating in accordance with the timing. It helps the reaction cuvettes, reagent probes, eight wash sections, mixers, and auto-wash system work properly. It consists of stepper motor, pinion, gear, shaft, bush, shaft fixed pedestal, backplane, bracket.

Coder sensor assembly:

The coder sensor assembly is used for confirming the initial position and recording the gear numbers that the reaction disk has rotated. It consists of bracket and two photoelectric sensors.

Temperature control assembly:

The temperature control assembly is used for keeping the reaction cuvette constant temperature. **Reaction disk temperature control assembly structure figure:**

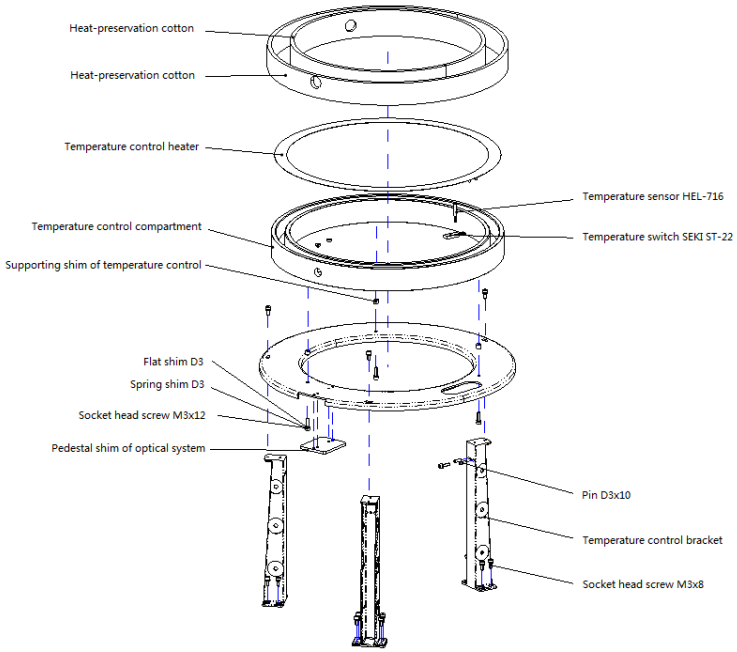

Figure 5-2 Reaction disk assembly

5.2. Installing reaction disk assembly

Reaction disk assembly figure:

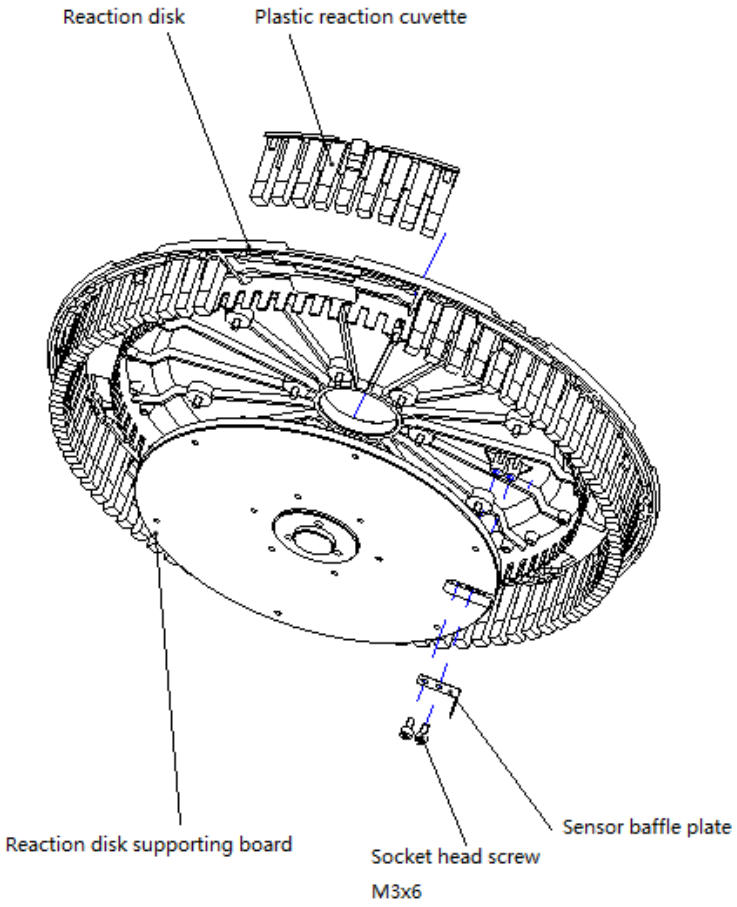

Figure 5-3 Reaction disk assembly

Reaction disk assembly consists of 63 plastic reaction cuvettes, plastic disk, reaction disk supporting board, sensor baffle plate. Press the reaction cuvettes into the reaction disk.

5.3. Installing reaction disk driving assembly

Reaction disk driving assembly installation figure:

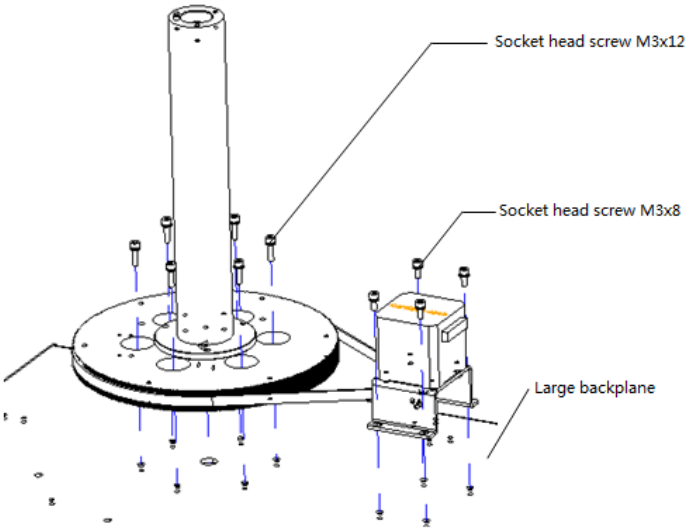

Figure 5-4 Reaction disk driving assembly

The reaction driving assembly is tightened to the backplane by six screws M3x12. And the motor bracket is tightened to the backplane by four screws M3x8. Locate the raised part under the pedestal to the corresponding installation hole of the large backplane, and then tighten the screws.

Pinion installation figure:

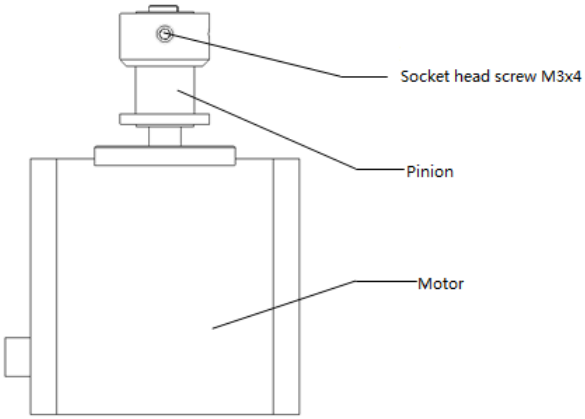

Figure 5-5 Pinion

The distance between the bottom of the pinion and the top of the motor is 3mm. Align the M3x4 lock screw to the rotating shaft facet and tighten the screw.

5.4. Installing coder sensor assembly

Code sensor assembly installation figure:

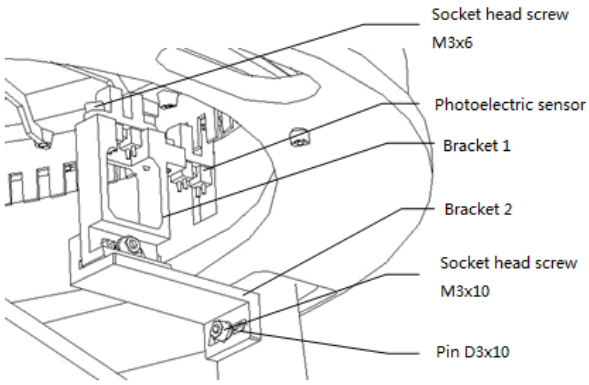

Figure 5-6 Coder sensor assembly

There are long slot holes on bracket 1 and 2 and located by two pins. When the reaction disk gear and sensor baffle plate are intervened by photoelectric sensor, or adjusting the corresponding positions of the reaction disk and wash system, loosen the screws to move the brackets. Tighten the screws until they are not intervened.

5.5. Installing temperature control assembly

Temperature control assembly installation figure:

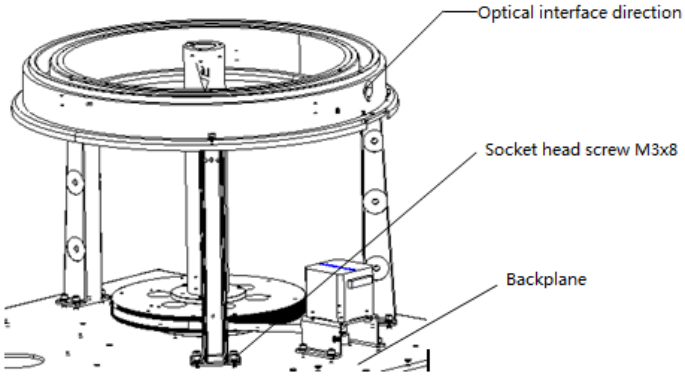

Figure 5-7 Temperature control assembly

Align the reaction disk to the shaft with one heart by calibration tool. Tighten the twelve socket head screws M3x8 and notice the optical interface direction. Remove the connections before dismantling.

5.6. Reagent/Sample disk unit

The reagent/sample disk assembly holds the reagent/sample cuvettes and drives the reagent/sample disk to rotate to the specified position. It helps the reagent probes aspirate reagent/sample and dispense sample to reaction cuvettes. And the reaction disk has the function of refrigeration to ensure the stability of the reagents and reducing volatilization, it also can input the reagent information automatically. Three loops, 40 reagent/sample positions. It rotates clockwise/counterclockwise.

Reagent/sample disk assembly:

The reagent/sample disk assembly holds the reagent cuvettes and is driven by the driving assembly to rotate. It provides sample probe with reagent/sample and consists of handle, reagent cuvette base, reagent disk bracket, center canister, and center canister cover.

Reagent/sample disk driving assembly:

The reagent/sample disk driving assembly drives the reagent disk to rotate and locate accurately. It consists of rotating shaft assembly, motor assembly, and sensor assembly.

Reagent refrigeration assembly:

The reagent refrigeration assembly refrigerates and keeps constant temperature for the reagent disk. It consists of refrigeration pot, heat-preservation cotton, peltier assembly, tube radiator and tube bracket.

Reagent/sample disk unit structure figure:

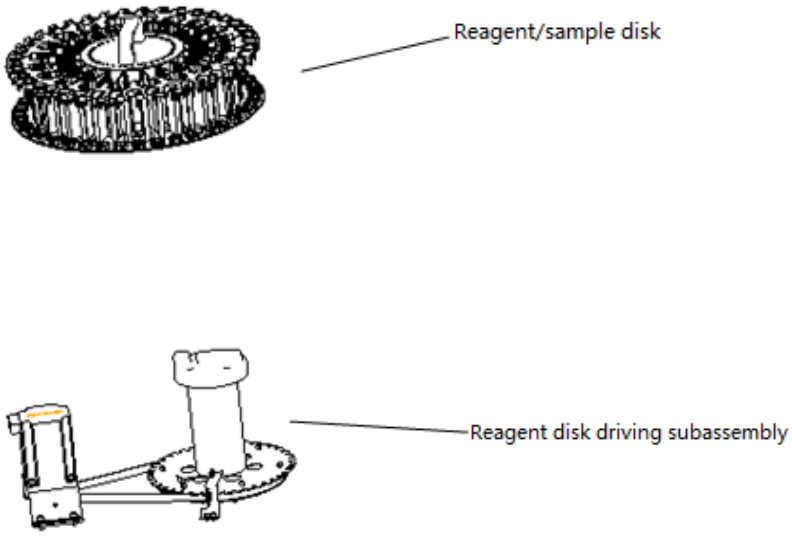

Figure 5-8 Reagent disk structure figure

5.7. Installing reagent/sample disk assembly

The reagent/sample disk assembly consists of handle, reagent cuvette base, reagent cuvette, reagent disk bracket, center canister cover, center canister, and screws.

Reagent/sample disk assembly figure:

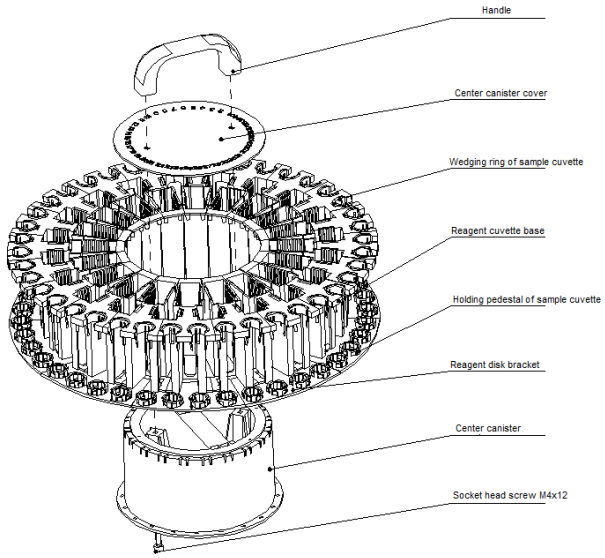

Figure 5-9 Reagent disk assembly

Steps of installing reagent disk:

1 Place the reagent cuvette base into the center canister of reagent disk. Insert the two position columns at the top of reagent cuvette base into two position holes at the top of center canister, and insert the position column at the bottom of reagent cuvette base into the position hole at the bottom of center canister.

2 Place the reagent disk bracket into the slot of reagent disk bracket.

3 Place the center canister cover to the top of the reagent cuvettes to make in four position columns below the center canister cover at the right position.

4 Tighten reagent disk-handle to the reagent bracket with two socket head screws M4x12.

5.8. Installing reagent disk driving assembly

The reagent disk driving assembly consists of shaft assembly, motor assembly. They use synchronous belt and two-grade deceleration.

Reagent disk driving assembly figure:

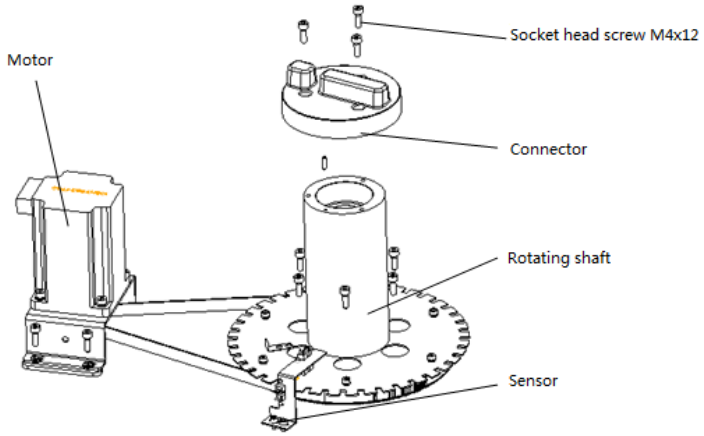

Figure 5-10 Reagent disk driving assembly figure

Install the rotating shaft assembly to the large backplane position hole, tighten it with six socket head screws M3x12. Install the motor assembly to the position hole, strain the synchronous belt, tighten it with four socket head screws M3x8.
Tighten the sensor assembly with the socket head screws M3x6 according to the positions of sensor baffle plate and coder adjustment sensor assembly.
Install the connector after installing the reagent refrigeration pot with three socket head screws M4x20. Align the connector to the position pin when installing.

5.9. Sample probe unit

The sample probe unit consists of sample probe assembly, sample probe driving assembly, sample probe rocker assembly, mixer assembly, mixer driving assembly, mixer rocker assembly.
The sample probe unit is used for dispensing sample, dispensing reagent, and mixing reaction liquid.

Sample probe unit figure:

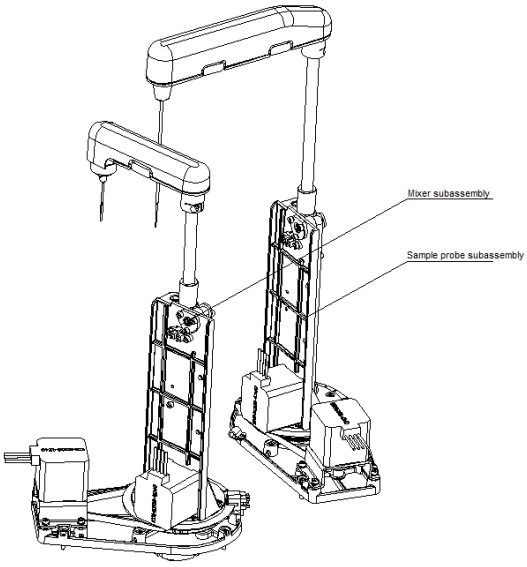

Figure 5-11 Sample probe unit

5.10. Installing sample probe assembly

Sample probe assembly includes sample probe. Sample probe is used for dispensing sample and reagent to reaction cuvettes. Driving assembly drives the circulation motion of the sample probe on the reagent/sample disk (electrolyte), reaction disk, and wash pool.
The sample probe has the functions of detecting liquid level, preventing from being collided in vertical motion and rotary motion.

Sample probe assembly figure:

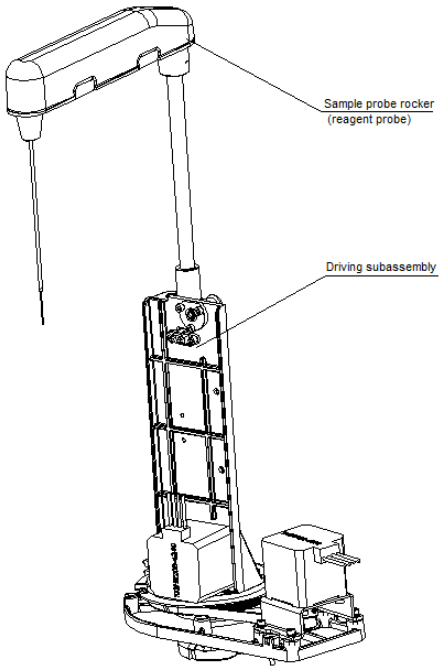

Figure 5-12 Sample probe and reagent probe assembly

5.11. Installing sample probe driving assembly

The sample probe driving assembly can drive the rocker assembly to do the speedy vertical motion and rotary motion respectively.

The sample probe driving assembly consists of pedestal assembly, linear motion assembly, and rotary motion.

The pedestal assembly consists of chassis and bracket and is used for supporting and fixing the motors and moving system.

The linear motion assembly consists of stepper motor, belt pulley, belt pulley axle, synchronous belt, guide shaft, driving block, axletree, briquetting, sensor baffle plate, and photoelectric sensor.

The rotary motion assembly consists of stepper motor, belt pulley, belt pulley axle, synchronous belt, axle, axletree, rotating rocker, position coder, and photoelectric sensor.

The position coder of every driving assembly is different because the trajectory of every probe is different and the components are the same except the coder.

The sample probe driving assembly figure:

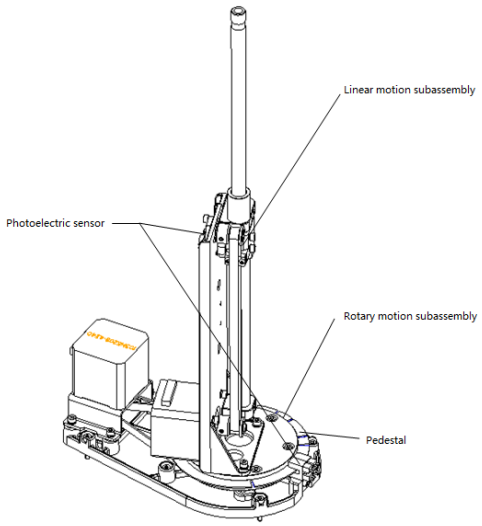

Figure 5-13 Sample probe driving assembly

Install the driving assembly to the large backplane with six socket head screws M3x16 and unplug the motor connection and sensor connection before removing it.

5.12. Installing sample probe rocker assembly

Sample probe rocker assembly consists of upper cover, lower cover, sample probe assembly, sliding cover, liquid level detection board, supporting pedestal of liquid level detection board, platen, and fixed axis.

1 The rocker assembly is connected by fixed axis and driving assembly and tightened by a socket head screw M3x8. Loosen the screw to remove rocker assembly or adjust the rocker position. Notice that protect the connection when removing and protect the probe

when adjusting.

2 Extrude two sides of lower cover to separate from the pothook and then open the upper cover. Fix the fixed axis and lower cover with two socket head screws M3X8 and gasket. There is a long slot on the lower cover. Loosen the screws to move about 1.5mm to adjust the position of the lower cover.

3 Sample probe (reagent probe) is limited by the sliding cover in the copper hole. Loose two cross head screws M2.5x4 and undrawn the sliding cover to take out the sample probe (reagent probe). Check the vertical motion of the probe and anti-collision function when installing.

Sample probe rocker assembly figure:

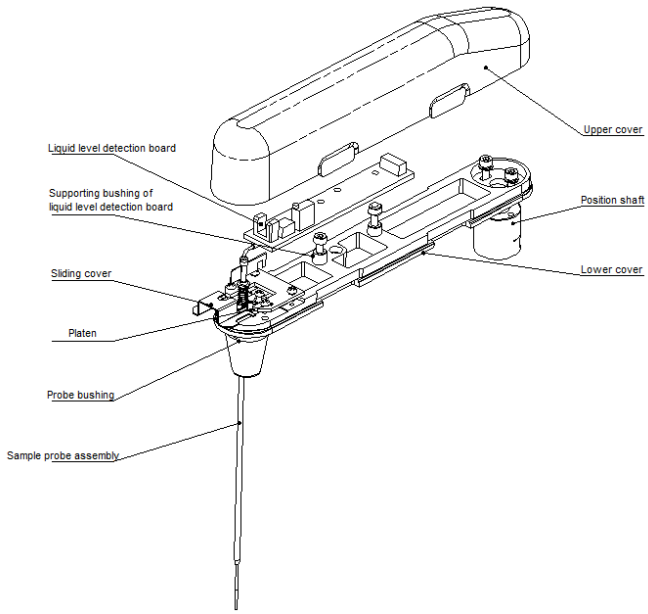

Figure 5-14 Sample probe rocker assembly

5.13. Installing mixer assembly

Mixer assembly consists of driving assembly and mixer rocker assembly. The driving assembly is used for driving the rocker assembly to do vertical motion and horizontal rotary motion. The rocker assembly is installed with two motors and mixer to mix the sample and reagent.

Mixer assembly figure:

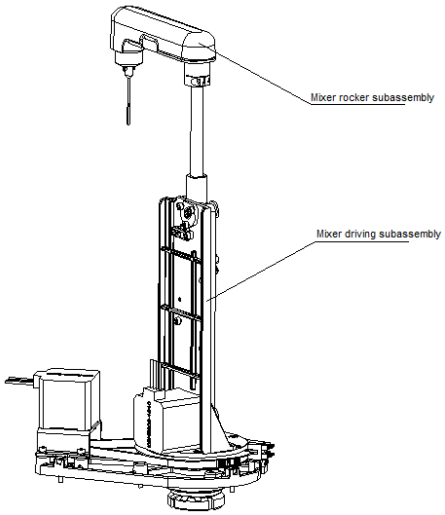

Figure 5-15 Mixer assembly

5.14. Installing mixer driving assembly

The mixer driving assembly drives the mixer roc k, axletree, briquetting, sensor baffle plate, photoelectric sensor, and linear motion stop block.

The rotary motion assembly consists of stepper motor, belt pulley, belt pulley axle, synchronous belt, axle, axletree, rotating rocker, position coder, and photoelectric sensor.

Mixer driving assembly figure:

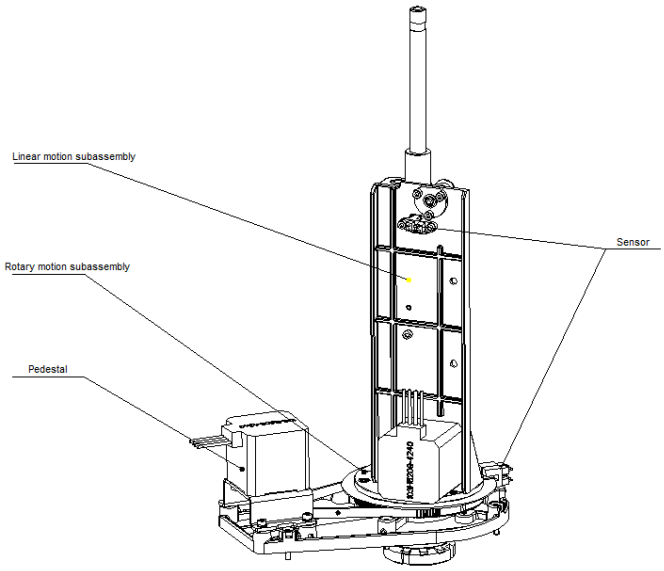

Figure 5-16 Mixer driving assembly

Install the driving assembly to the large backplane with six socket head screws M3x16 and unplug the motor connection and sensor connection before removing it. Mind the whole direction of the driving assembly.

5.15. Installing mixer rocker driving assembly

Mixer rocker assembly consists of upper cover, lower cover, motor, mixer, and fixed axis.
1 The rocker assembly is connected by fixed axis and driving assembly and tightened by a socket head screw M3x8. Loosen the screw to remove rocker assembly or adjust the rocker position. Notice to protect the connection when removing and protect the probe when adjusting.
2 Extrude two sides of lower cover to separate from the pothook and then open the upper cover. Fix the fixed axis and lower cover with two socket head screws M3X8 and gasket. There is a long slot on the lower cover. Loosen the screws to move about 1.5mm to adjust the position of the lower cover.

3 The mixer motor is tightened by three socket head screws M3x6 and gasket. There is a long slot on the motor connection board to adjust the motor position according to the requirements.

4 The mixer and motor axis are connected and tightened by two socket head screws M3x4. The two sides should be symmetrical and tightened gradually. The mixer should be clenched upwards to the panel of the motor axis in order to prevent the mixer too long.

Mixer rocker assembly figure:

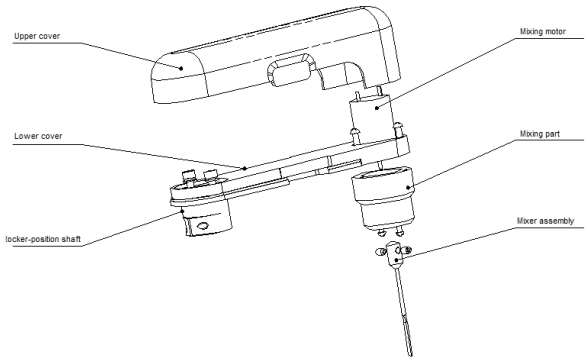

Figure 5-17 Mixer rocker assembly

6. Troubleshooting

The analyzer software provides 7 solutions to different levels of alarms. When an alarm occurs, it identifies the alarm level and handles it with one of the 7 solutions and then reminds you of the alarm with bright red bar displayed at the bottom of the screen. By clicking the read bar, you can see the error message, probable causes and corrective actions.

6.1. Testing forbidden

Any testing is forbidden; only diagnosis and maintenance are allowed.

6.2. Testing stopped

All current tests are terminated; the system enters standby mode, waiting for operation.

6.3. New tests stopped

All unstarted tests are terminated, while the tests with sample and reagent dispensed are continued.

6.4. Certain samples stopped

Analysis of certain samples is terminated with others continued.

6.5. Certain reagents stopped

Tests of certain reagents are terminated with others continued.

6.6. Warning

The system takes no action but displaying an alarm message.

6.7. Prompt

The system takes no action but displaying a prompt message.
This chapter presents all alarm messages that may occur when the system is running and recommended corrective actions. When an alarm occurs, find it through the following table and handle it with its corresponding corrective actions. If the alarm remains, please contact local agency.