Automated Nucleic Acid Purification and Real Time PCR System

Instruction for Use

REF FQD-A1600(EA4), FQD-A1600 (EA5), FQD-A1600 (EA6)

IVD

Hangzhou Bioer Technology Co., Ltd.

Attention:

- It is recommended that users read the instructions carefully before using the Automated Nucleic Acid Purification and Real Time PCR System. Please pay special attention to the warnings and precautions stated in this instruction manual.
- Please store the IFU in a safe place where it is readily available for reference when needed.

Thank you for your purchase of this product.

Before initial use of this instrument, please read this manual thoroughly ！

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Important Notes

01 Customs and Usages

Declaration:	Note that this item contains particularly important information, please read it carefully. Failure to follow these instructions may cause damage to the instrument or cause it to malfunction.

Warning!	A warning message means that you must be especially careful when performing a given step or method. If the equipment is not used in the manner prescribed by the manufacturer, the protections provided by the equipment may be compromised.

02 Safety

The following basic safety measures must be observed at all stages of operation, maintenance, and repair of the instrument. Failure to comply with these measures or the warnings and precautions indicated in this manual may impact the basic protection provided by the instrument. Meanwhile, such non-compliance can undermine the safety standards of the design and fabrication of the instrument as well as its intended use.

Hangzhou Bioer Technology Co., Ltd. shall not be liable for any consequences caused by users' failure to comply with the following requirements.

Notice:	This instrument is Class I Equipment in line with GB4793.1 Standard, and its protection grade is IP20. This instrument is for indoor use only.

Notice:	The instrument is an *in vitro* diagnostic (IVD) medical device in accordance with YY0648 standards.

A) Grounding

To avoid electric shock, the input power line of this instrument must be reliably grounded. The instrument uses a grounded 16A three-prong plug, which has a third (grounding) prong and can only be used with a grounded electrical outlet. This is a type of safety device. If the plug cannot be inserted into the outlet, please ask an electrician to

install the correct type of outlet so that the safety protection function of the grounded plug is not lost.

B) Keep away from live circuits

The operator must not disassemble the protective parts or covers of the instrument, replace components, or adjust the machine without authorization. If necessary, this must be completed by certified professional service personnel. It is strictly prohibited to replace the components of the device while it is connected to a power supply.

C) Power supply

Before turning on the AC power supply, make sure that the power supply meets the requirements for the instrument (220V to 50Hz) and that the electrical outlet is rated to carry a load not less than the maximum load of the instrument (2800VA).

D) Power cord

Normally, the power cord that was supplied with the instrument should be used. If the power cord is damaged, it must be replaced and not repaired. Replace the power cord with another of the same type and specifications. When using the instrument, do not allow anything to put pressure on the power cord, and keep the cord out of the path of foot traffic. If the power cord will come into contact with a hot surface during use, it is necessary to add protection to prevent the insulating layer of the power cord from being damaged.

E) Power cord plug

Make sure you hold the plug correctly when plugging in or unplugging the power cord. When inserting the plug, make sure that it is completely and firmly inserted into the outlet. Do not pull or yank on the power cord when unplugging the machine.

F) Pay attention to the placement of the instrument

When moving the instrument, raise the foot, push the instrument to the appropriate position, then lower the foot and adjust the level.

The instrument should not be placed in a position that makes it difficult to disconnect the power supply.

The instrument should be placed in a location with low humidity, little dust and far away from water sources (such as pools, water pipes, etc.). The room should be well-ventilated and free from corrosive gases or strong magnetic field interference. Do not place the instrument in damp or dusty areas. The table on which the instrument is placed should be level and stable.

The openings on the instrument are for ventilation and air circulation. Do not block or cover these vents in order to avoid overheating of the body. When a single instrument is in use, there should be a distance of no less than 30cm between the ventilation opening and the nearest object. When multiple instruments are used at the same time, there should be a distance of no less than 50cm between each instrument.

High ambient temperature may affect the test performance of the instrument or cause faults. Do not use the instrument in areas with exposure to direct sunlight or a strong light source to avoid affecting the fluorescence detection of the instrument. Keep away from heaters, furnaces and all other heat sources.

The power supply should be turned off when not in use. If the instrument is not going to be used for an extended period, disconnect the power supply, unplug the power cord, and cover the instrument with a soft cloth or plastic film to prevent dust and foreign matter from getting into the instrument.

Warning: Do not put the device on a flammable surface!

G) Precautions

- Avoid allowing liquid to drip onto the instrument during testing. Consumables, reagents and other waste used in tests must be disposed of in accordance with relevant requirements and must not be discarded or dumped at will.
- If a test includes hazardous substances, the operator must complete related training before use.
- Hazardous substances should be properly handled and stored in strict accordance with the instructions for use.
- The tester must be trained and qualified to operate this instrument.

- Ensure that the protective cover, Pipet Tips and PCR tubes are placed in the correct positions. If not, the test will fail and the instrument may be damaged.
- Only protective covers, 9-tube strips, 9-tube strip racks and PCR tubes provided by Bioer Technology can be used. The protective cover, 9-tube strips and PCR tubes cannot be reused.
- Do not remove the nucleic acid purification drawer, sample rack or consumables drawer while the instrument is running. Failure to comply will result in suspension of the test and possible damage to the instrument.
- During the lysis and elution of the nucleic acid purification module and at the end of the test, the heating block will become very hot. Do not touch the heating block.
- While operating the PCR module and just after the test, the hot cover will become very hot. Do not touch the hot cover.
- Do not load any other software programs onto the computer that is used with the instrument. Other programs may cause the system to run slower.
- Do not open the doors of the nucleic acid purification and PCR areas of the instrument while the UV lamp is running to prevent UV damage.

Notice: Under the following circumstances, the power supply should be disconnected immediately, the power plug of the instrument should be removed from the electrical outlet. The supplier or qualified maintenance personnel should be contacted in the event of:

- Liquid spilling into the instrument.
- The instrument becoming drenched or taking on water.
- The instrument not working normally, or if there is any abnormal sound or smell.
- The instrument housing being damaged.
- A significant change in the function of the instrument.

Notice: When handling potentially infectious substances (such as human samples or reagents), protective gloves or other protective measures are required if there is a chance that these substances might meet skin.

H) Relocation

If the instrument needs to be relocated, it should be thoroughly cleaned and disinfected with ultraviolet light before transportation.

I) Equipment Safety

The instrument was designed, produced, and tested in accordance with EN 61010-1 (IEC 61010-1) “Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements”. It has left the factory in a perfectly safe condition.

The instrument meets the requirements of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

03. Instrument labels

A) **Warning** Sign

- Warning identification

Caution - Danger		Where this label appears on the instrument, the operator should avoid improper use and be cautious of hazards.
Caution - Hot Surface		Where this label appears on the instrument, high temperatures are generated during use. Be careful of scalding.
Biohazard		Where this label appears on the instrument, the use of reagent poses a biohazard. Be sure to use protection.
Warning - Laser		Where this label appears on the instrument, laser radiation occurs during use. Be sure to use protection.
Watch Your Hands		Where this label appears on the instrument, there are moving parts during use. Be careful of pinching injuries.
Beware of Ultraviolet Rays		Where this label appears on the instrument, there are ultraviolet rays during use. Be sure to use protection.

- Warning mark

Warning!	Where a "HOT SURFACE!" label appears on the instrument, the operator must NOT touch the metal part (module) near the label with any part of the body during operation of the instrument or for a period after the program has stopped running to avoid scalding!

Warning!	The operator may meet or be exposed to residues of infectious substances or substances that are harmful to organisms while using the instrument. The operator should understand the hazards associated with the instrument and strictly comply with the relevant national regulations for PCR laboratories. Operators must be trained and qualified.

B) Other Symbols on the packaging

Date of manufacture		Indicates the date when the medical device was manufactured.
RoHS		Restriction on the use of certain hazardous materials (restriction of hazardous substances)
Consult instructions for use		Indicates the need for the user to consult the instructions for use.
Serial number		Indicates the manufacturer's derail number so that a specific medical device can be identified.
Catalogue number		Indicates the manufacturer's catalogue number so that the medical device can be identified.
In vitro diagnostic medical device		Indicates a medical device that is intended to be used as an *in vitro diagnostic medical device*.
CE mark		Indicates the medical device meets the CE related Directives.
Manufacturer		Indicates the medical device manufacturer.
Authorised representative in the European Community		Indicates the authorized representative in the European Community.
Up		Indicates that the correct position of the transport package is vertical upward.
Fragile		The transport packages contain fragile goods, so they should be handled with care.

Keep dry		The package should be rain-proof.
The limit of stacking layer		Maximum stacking layer of the same package is 1.
Temperature limit		Indicates that the temperature limit of transportation package should be -20 ℃ to 55 ℃.
Relative humidity limit		The relative humidity should be controlled below 93%.
Atmospheric Pressure Limitation		Indicates that atmospheric pressure must be within the range of 75kpa ~ 106kpa.

04. Maintenance of Instrument

If the surface of the instrument becomes soiled, it can be cleaned with a soft cloth and cleaning paste.

Do not use heat transfer oil medium in the instrument module openings.

Warning!	Disconnect the power supply before cleaning the instrument. Do not us a corrosive cleaning agent to clean the surface of the instrument. The instrument modules contain precision optical devices. Avoid allowing dust, foreign matter, and residual liquid to get into the instrument.

05. Disposal

 Potentially infectious material and all parts that may meet potentially infectious material must be disposed in accordance with the relevant legal provisions.

All parts which have been replaced must be disposed in accordance with the relevant legal provisions.

 Disposal of the instrument must be carried out in accordance with the relevant legal provisions.

Disposal of the packaging material must be carried out in accordance with the relevant legal provisions.

06. After-Sales Service

Please refer to the warranty leaflet for information regarding the content and scope of the warranty.

Notice:

- After unpacking the instrument, the contents of the packing box should be immediately checked and verified against the packing list. If any item is found to be damaged or missing, please contact the supplier immediately.
- After checking and accepting the package contents, please fill in the relevant content on the product acceptance form and send (or fax) a return copy of the form to the shipping unit for filing and maintenance.
- Before using the product, please submit the product registration form to Hangzhou Bioer Technology Co., Ltd. to register your product.
- After unpacking the device, keep the packing box and packing materials in a safe place for easy maintenance.
- The instrument must be disinfected before being sent to the maintenance department.
- After the instrument is delivered to the maintenance department and unpacked, maintenance personnel must immediately disinfect the instrument.
- Hangzhou Bioer Technology Co., Ltd. shall not bear any responsibility for the instrument sustaining damage due to poor packaging while in transit to the maintenance department.

Contents

Chapter 1 General Description

This chapter mainly describes the use, characteristics, specifications, performance parameters and software functions of the Automated Nucleic Acid Purification and Real Time PCR System.

1.1 Application

Based on the principle of fluorescence quantitative polymerase chain reaction and used in conjunction with complementary detection reagents, the product is used clinically to extract and purify human samples such as whole blood, serum, plasma, urine, and swabs and conduct qualitative and quantitative detection of analytes in the DNA/RNA of extracted nucleic acid samples, including pathogens and human gene items.it can be used in the field of clinical labs and hospitals and so on.

1.2 Intended Use

The Automated Nucleic Acid Purification and Real Time PCR System is an automated instrument used for extraction and purification of pathogen nucleic acid in various human clinical samples such as whole blood, serum, plasma, urine, nasopharyngeal and oropharyngeal and qualitative and quantitative detection of the analytes in the DNA/RNA of the samples using the polymerase chain reaction process. The instrument is for in vitro diagnostic only.

1.3 Applied Reagents

The product is a standalone instrument and can be applied to various polymerase chain reaction (PCR) detection kits. Just like the MagaBio plus Virus DNA/RNA Purification Kit II and Influenza A Virus / Influenza B Virus Nucleic Acid Detection Kit (Fluorescence RT-PCR) form Hangzhou Bioer Technology Co., Ltd.

1.4 Features

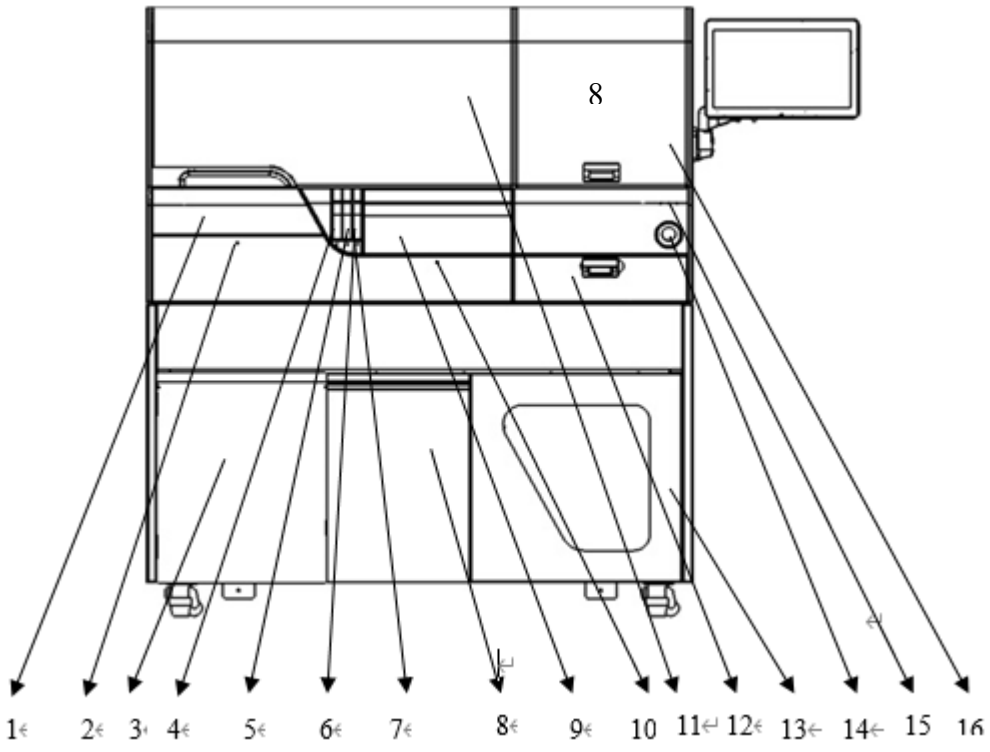
- Fully integrated: including the whole automated process of sample pre-treatment, nucleic acid extraction and fluorescence quantitative PCR.

- Absolute efficiency: Drive laboratory efficiency in a number of ways, the first round results will be completed within 1 hour and the next round results will be issued every 30 minutes.
- Anti-Pollution: fully enclosed design, unique sample processing unit, minimizes contamination.
- Unmatched flexibility: touch-controlled interface, full automatic result analysis, easy to operate.

1.5 Product Structure and Composition

This product is mainly composed of nucleic acid purification parts, sample tube capping/decapping parts, host machine arm parts, centrifugal transmission parts, rapid PCR parts, vacuum filtration parts, power supply parts and software (V1).

The main view of the instrument is as follows:



1. Nucleic acid purification drawer: Pull out to replace nucleic acid purification consumables.

2. Nucleic acid purification drawer status indicator: Indicates whether the nucleic acid purification drawer can be pulled out. Red light indicates that the drawer cannot be pulled out; Green indicates that the drawer can be pulled out; No light indicates that the drawer is not completely closed.

3: Door to temporary storage for consumables: Consumables to be used during testing can be stored here temporarily.

4. Sample storage rack: Templates for nucleic acid extraction can be stored here temporarily.

5: Sample rack 1: Place sample tubes here.

6: Sample rack 2: Place sample tubes here.

7: Sample rack status indicator: Indicates the status of the sample cache rack, sample rack 1 and sample rack 2, respectively. Red light indicates that the sample rack cannot be pulled out; Green light indicates that the sample rack can be pulled out; No light indicates that the drawer is not completely closed and the instrument cannot operate.

8: Waste tip compartment door: Open to dispose of waste tips.

9: Consumables rack drawer: Can hold 1 ml Pipet Tips, 50 ul Pipet Tips, PCR tubes and reagent.

10: Consumables rack status indicator: Indicates whether the consumables rack drawer can be pulled out. Red light indicates that the drawer cannot be pulled out; Green indicates that the drawer can be pulled out; No light indicates that the drawer is not completely closed.

11: Nucleic acid purification area tilt-up door: This door can be opened for instrument maintenance and to clean the counter. DO NOT open this door while the instrument is running!

12: Waste PCR tube compartment door: Open to remove waste PCR tubes.

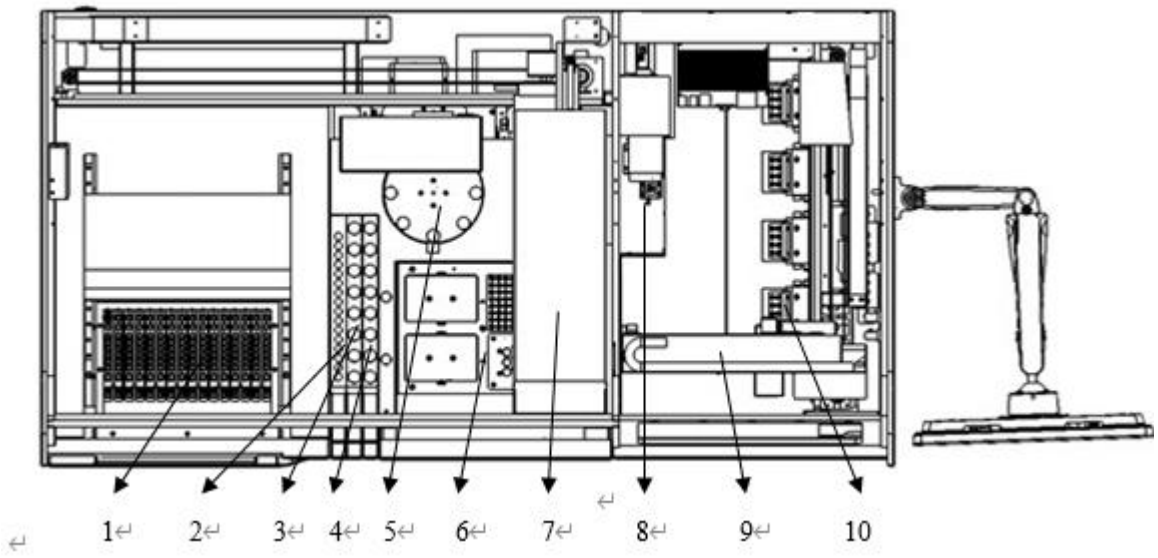
13: Vacuum assembly door: Open to replace the filter.

14: Power button: This button controls power to the entire machine.

15: Device status indicator: Displays the operating status of the device, including normal, warning, and error statuses.

16: The nucleic acid purification area door can be opened for instrument maintenance and to clean the counter. DO NOT open this door while the instrument is running!

The instrument layout is as follows (hidden under tilt-up door):



1. Nucleic acid purification module: Performs all nucleic acid purification functions.

2. Sample storage rack: Templates for nucleic acid extraction can be stored here temporarily.

3: Sample rack 1: Place sample tubes here.

4: Sample rack 2: Place sample tubes here.

5: Sample tube decapping module: Opens and closes caps of 10 ml sample tubes. This is where samples are vacuum extracted.

6: Consumables rack module: Can hold 1 ml Pipet Tips, 50 ul Pipet Tips, PCR tubes and reagent.

7: Main robotic arm module: Performs pipetting and transfer of 10 ml sample tubes and PCR tubes.

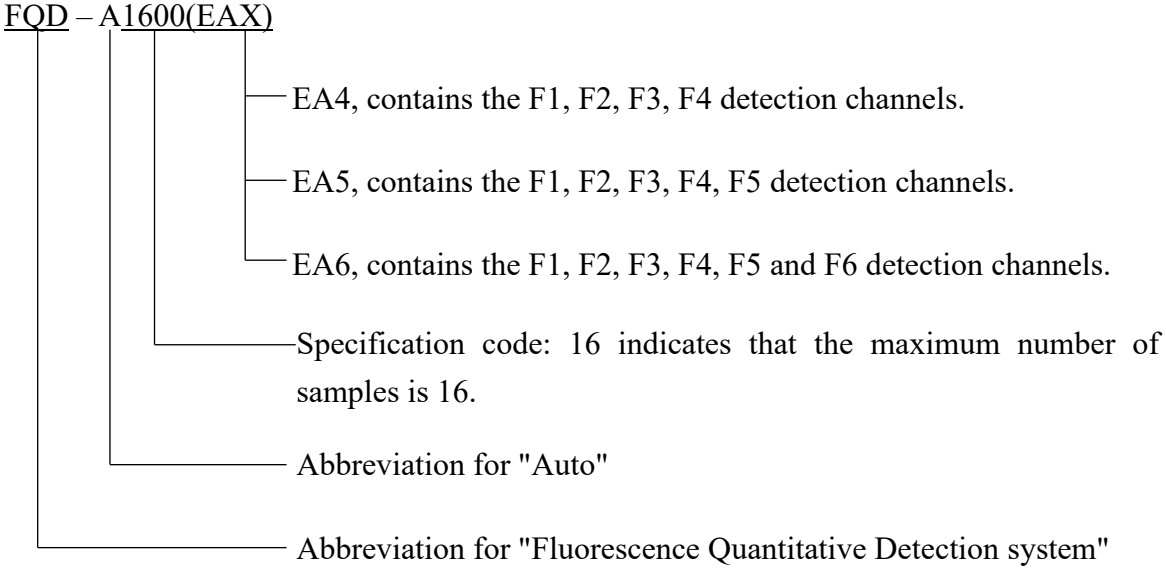
8: Centrifugal transfer module: Opens and closes PCR tube caps, constructs PCR systems, performs centrifugation, and transfers PCR tubes from the nucleic acid purification zone to the PCR zone.

9: PCR mechanical arm module: Transfers PCR tubes.

10: Rapid PCR module: Performs PCR reaction functions.

1.6 Specifications and Model Description

Model:



1.7 Performance Parameters

Type	FQD-A1600(EA4), FQD-A1600 (EA5), FQD-A1600 (EA6)
Sample throughput	16 (applies to sample storage tubes, vacuum blood collection tubes, 1.5 ml and 2 ml centrifuge tubes, measuring cups, etc.)
Pipetting performance	Under 5 μl: Accuracy ≤±5%, repeatability ≤5%
	5 μl to 10 μl: Accuracy ≤±5%, repeatability ≤3%
	10μl to 50 μl: Accuracy ≤±3%, repeatability ≤1.5%
	Over 50 μl: Accuracy ≤±2%, repeatability ≤1%
Nucleic acid purification processing	20-1000 μl

volume						
Magnetic bead recovery efficiency	≥98%					
Purification pore variance	CV<3%					
PCR reaction system	5-30μl					
Detection channel	F1	F2	F3	F4	F5	F6
Applicable dyes	FAM, SYBR Green I	VIC, HEX, TET, JOE,	ROX, TEXAS -RED	Cy5 Quasar -670	Cy5.5 Quasar -705	Cy3 TAMRA
Module working temperature range	4 - 99.9 ℃ (minimum setting scale: 0.1 ℃)					
Average heating rate	From 50℃ to 90℃, should not be less than 8℃/s					
Average cooling rate	From 90℃ to 50℃, should not be less than 5℃/s					
Module temperature control accuracy	Should not be greater than 0.1℃					
Temperature uniformity	Temperature difference is within 0.4℃					
Fluorescence intensity detection repeatability	CV≤1%					
Input power	220V - 50Hz 2800VA					
Overall dimensions	1850mm×730mm×1530mm (length, width, height)					

1.8 Production Date and Service Life

Date of production: See label for details.

Product service life: 5 years

The service life of this product is determined based on the accelerated life test method. During use, users must maintain and repair the product in accordance with the requirements in the product manual. After maintenance, service or repair, products that are confirmed to maintain basic safety and effectiveness can be used normally.

1.9 Function Overview of Supporting Software

a) Experiment settings: Set sample information, select an experiment template, and manage reagents.

b) Running experiment: Monitor purification and PCR data for running experiments.

c) Reagent management: Manage Pipet Tips, nucleic acid purification, PCR tubes, and PCR reagents.

d) Template management: Create a new template or import an existing template.

e) Experimental analysis: Analyze test data.

f) Process experimental results: Process experimental results and generate reports.

g) System parameter maintenance: Maintain system parameters, including calibration and other operations.

Notice:	The above software functions are for reference only, and no further notice will be given regarding changes in software functions.

1.10 Product Software Version

Software release version for this product: V1

Chapter 2 Instrument Installation

This chapter mainly introduces the installation requirements, transportation and storage conditions, and preparations to be made before starting the Automated Nucleic Acid Purification and Real Time PCR System.

2.1 Installation Requirements

2.1.1 Space Requirements

Make sure there is enough open space around the instrument to perform repairs and maintenance. Take into account the dissipation of heat from the instrument, the installation of the host machine must meet the following requirements:

Maintain ≥ 50 cm of open space between the right panel of the host machine and the wall;

Maintain ≥ 30 cm of open space between the rear panel of the host machine and the wall;

2.1.2 Power Supply Requirements

Power supply: 220V - 50Hz 2800VA

Notice:	Before using the instrument, please confirm that the working conditions meet the above requirements. Ensure that the power supply is plugged into a 3-prong outlet with a reliable ground. Please use the power cord that was provided with the instrument. The use of other power cords may damage the analyzer or cause incorrect analysis results.

2.1.3 Environment Requirements

Ambient temperature: 10 °C to 30 °C

Ambient humidity: ≤ 80%

Working atmosphere pressure range: 75 kPa - 106 kPa

Notice:	The environment must be free of dust, mechanical vibration, pollution, sources of loud noise and power interference to the greatest extent possible. Do not place the device near a strong electromagnetic interference source.

Otherwise, the normal operation of the device may be affected.

Avoid direct sunlight and keep away from heat sources and wind sources.

Choose a well-ventilated location.

Do not place the host machine on an inclined surface.

2.2 Instrument Transportation and Storage Conditions

Ambient temperature: -20 ℃ - 55 ℃

Relative humidity: ≤ 93%

Atmospheric pressure: 75kpa - 106kpa.

2.3 Preparation before the Instrument is Switched on

Power Cord Connection: the power cord attached to the instrument should be used. When connected, the instrument power switch should be in the closed state; After connecting, check whether the power cord and the instrument socket are too loose, if too loose, it should be replaced.

Caution: The attached power cord is reliable but may cause the connection to be too loose after several unplugging. In this case, the power cord should be replaced.

The power cord should be replaced with the same specification.

Chapter 3 Instrument Operation

3.1 Prepare the Experiment

3.1.1 Check Before Starting the Machine

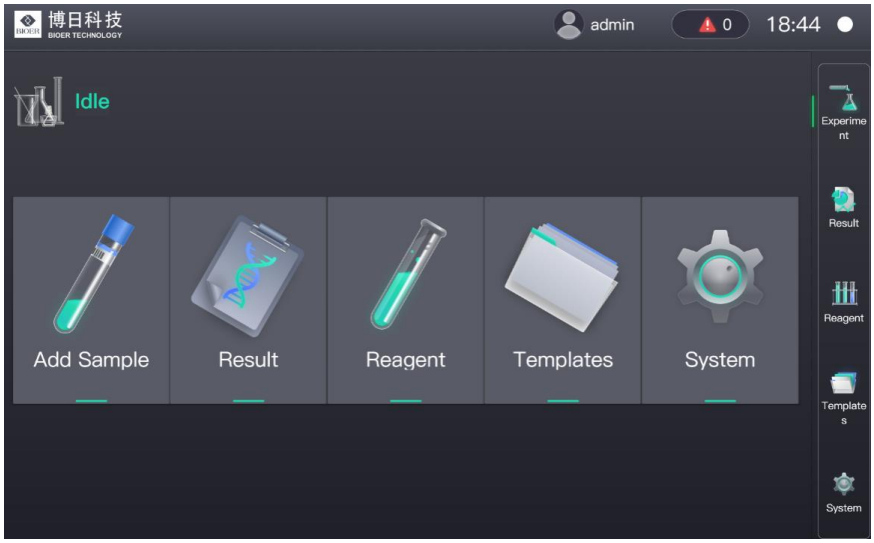
Before plugging in and turning on the detection system, confirm the following:

- Confirm that the power supply meets the voltage requirements for the system.
- Confirm that the power cord plug has been correctly and reliably inserted into the electrical outlet.
- Confirm that the surrounding working environment and the place where the instrument is located meet the requirements.
- Make sure the Pipet Tip and PCR tube waste containers have been emptied before starting the machine.

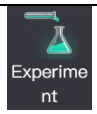
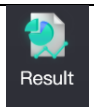
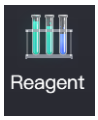
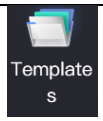
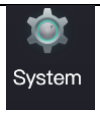
3.1.2 Startup and User Login

a) Press the power switch on the rear panel of the instrument to turn the instrument on. At this time, the instrument will start up automatically. If the power button of the instrument is already switched to the "on" position, press the power button on the front panel of the instrument to turn it on.

b) Double-click the "bioerPCR" shortcut on the desktop to display the interface shown below. Click the user icon in the upper right and enter your account name and password to log in to the system.

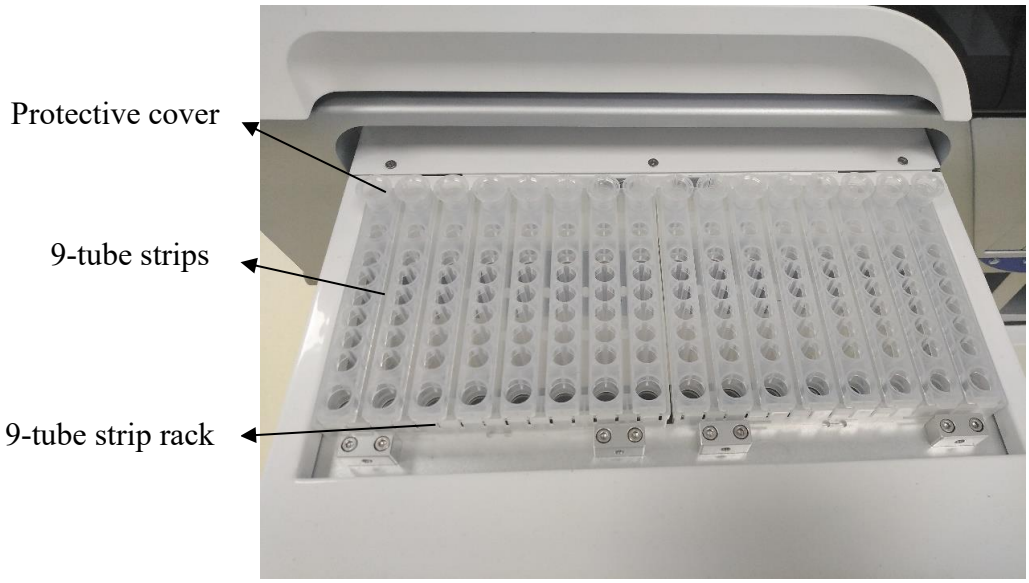


c) Descriptions of the function of each component on the login page:

Icon	Function
	On the Experiment main interface, you can start a test, pause the test, stop the test, and view the test progress.
	Set the test sample placement, sample details, test items, etc.
	View current test results, test results history, and test samples.
	Set the positions of the lysis and elution zones of the template. Set the position and number of Pipet Tips in the Pipet Tip rack. Set the position and number of PCR tubes in the PCR tube rack. Set the reagent to be used.
	Set the template to be used in the experiment.
	Set the instrument for maintenance, upgrade information, calibrate the layout, change the language, etc.

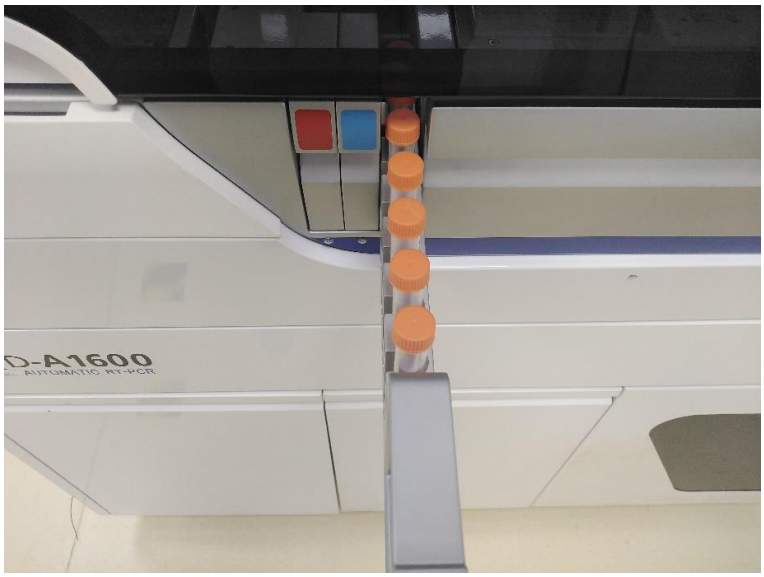
3.1.3 Add Consumables

a) Add nucleic acid purification consumables: Pull out the nucleic acid purification drawer and insert the prepacked reagent and protective cover after removing the film. Then, press down on the 9-tube strip rack, clamp into place, and close the drawer.



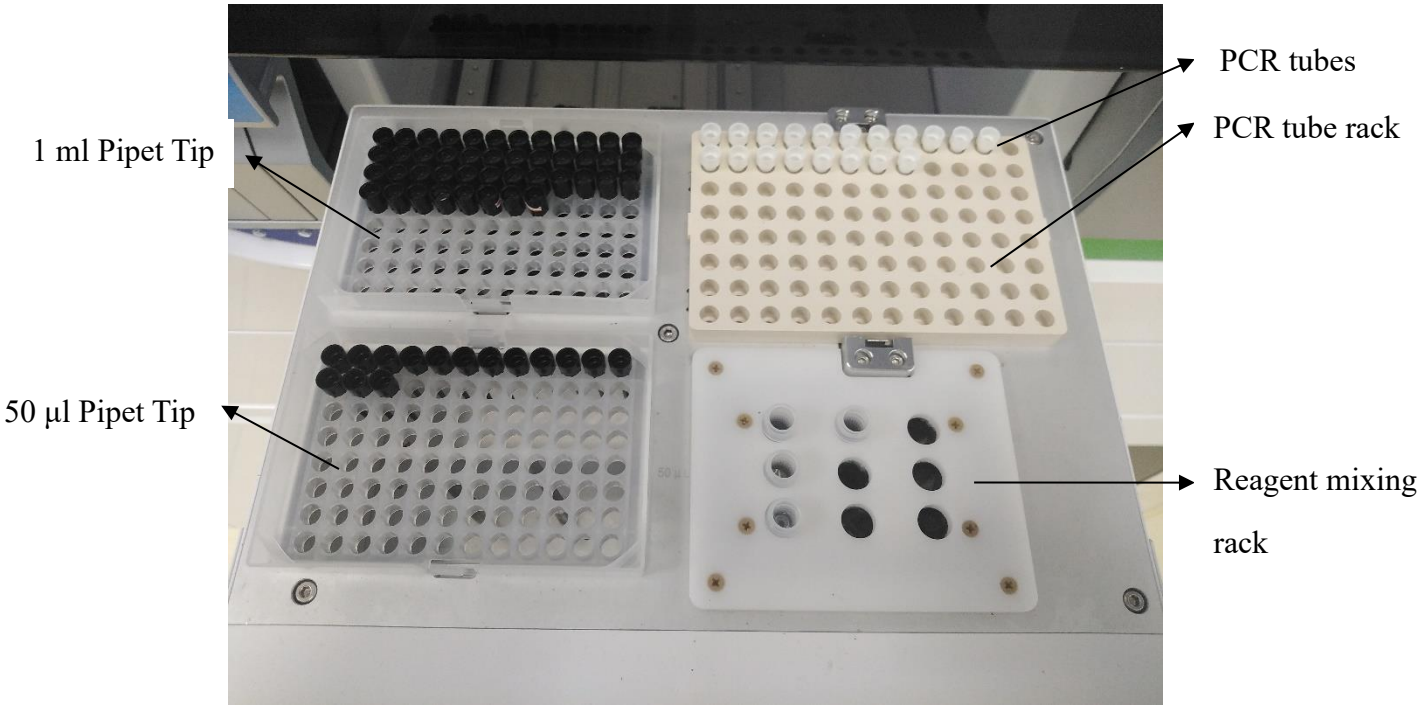
Notice: Please confirm that the cover is in place before each experiment to avoid contamination.

b. Add Samples: Pull out the sample rack and insert a sample tube, then close the drawer.



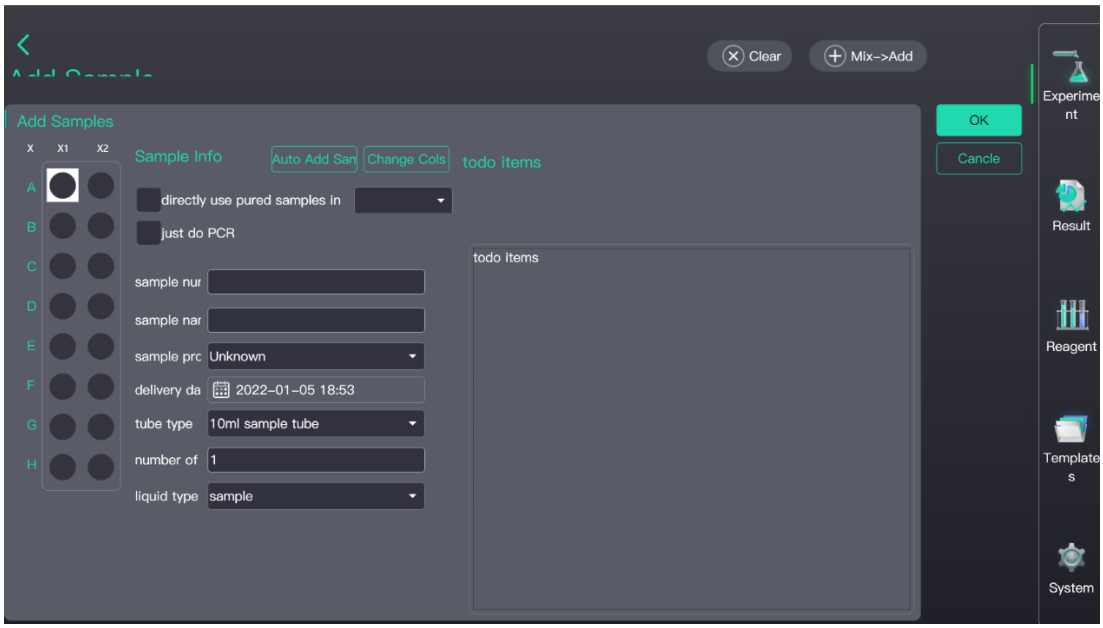
Note: Any sticky material in the sample will cause the suction head to be blocked and the sample will not be added.

c. Add Pipet Tip, PCR tubes and reagent: Pull out the consumables rack and insert 1 ml Pipet Tip, 50 µl Pipet Tip, PCR tubes, and reagent, then close the drawer.



3.2 Set Up the Experimental Process

3.2.1 Add Samples



a) Add Samples: Select a hole to edit the sample for this hole position (sample number, sample name, sample class, sample date, etc.), then click X to select all, or click X1 or X2 to select all in a row.

b) Auto Add Samples: Sample numbers are arranged in a given order.

c) Change Cols: Change the sample display information.

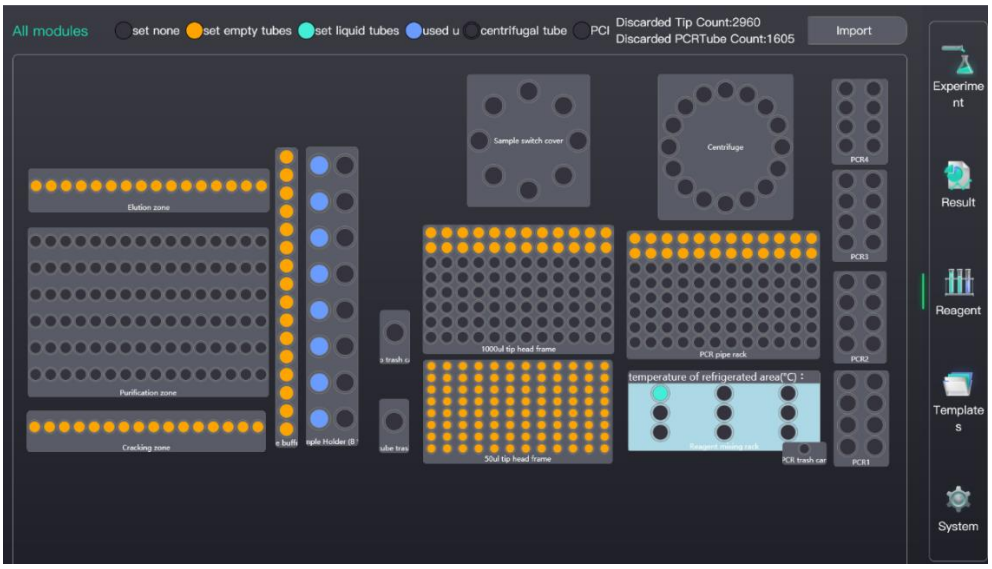
d) To-Do Items: Pre-edited experiment template.

e) Directly use purified samples in: Select "Directly use purified samples in" and then use the drop-down menu to directly use the purification products from the elution area or sample buffer rack to perform PCR (i.e., to perform a process other than purification);

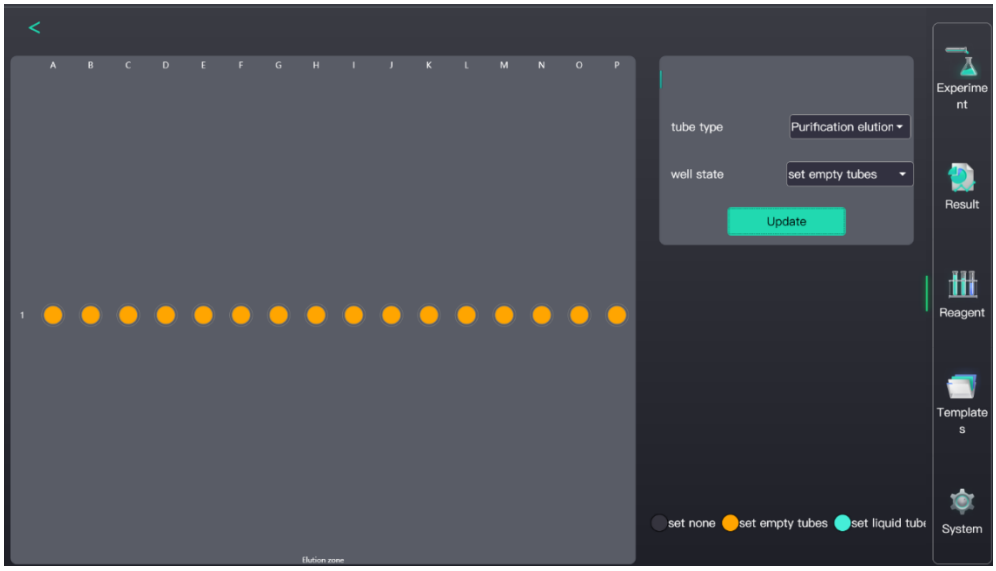
f) Just do PCR: Manually configure the reaction system within the PCR tube, then the PCR tube is placed in the corresponding hole in the PCR tube rack, and the instrument automatically centrifuges for detection.

After setup is complete, select the new sample and the corresponding project to be done, then click "Confirm";

3.2.2 Add Reagent



a) Elution zone: During operation, set the hole to orange (empty tube). If "Directly use purified samples in Elution zone" is run as mentioned above, set the hole position status to “Set liquid tubes” and click "Update" to apply;



b) Pipet Tip: Set the hole position where the Pipet Tip is placed as “Set empty tubes”, and click "Update”.

c) PCR tube rack: Select the corresponding number of hole positions based on the number of samples, click this area to set the selected hole position status to "Set empty tubes";If running "Direct PCR", set the hole position status to "Set liquid tubes" and click

"Update";

d) Reagent mixing rack: For each hole, you can set the name of the reagent (from the template), expiration date, test tube model and other information, then select a hole position to place an empty tube for mixing reagent components and update its status to "Set empty tubes".

3.2.3 Run the Experiment

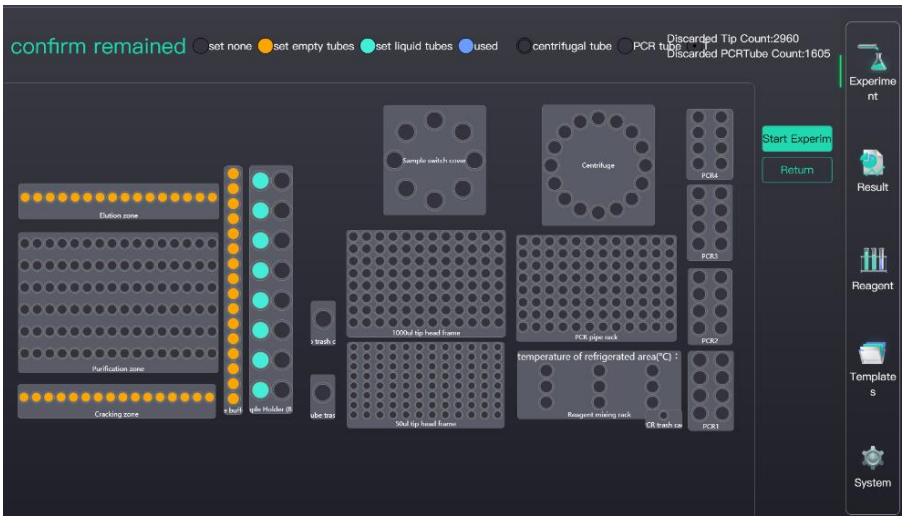


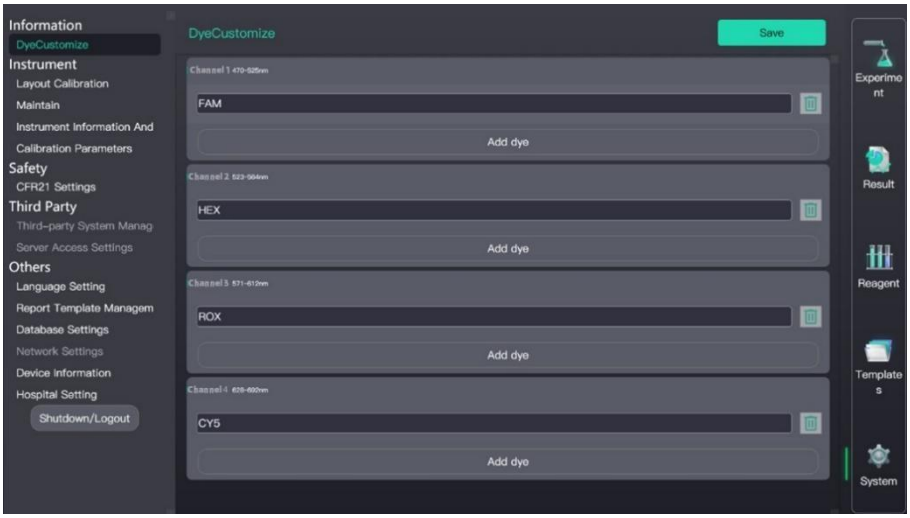
Figure 14

After completing the setup above to add samples and reagents, click "Start Experiment" Figure 14 to enter the experiment operation interface. Click each PCR module to see the remaining operation time, real-time fluorescence curve and temperature operation curve of the instrument.

3.3 Powering Off

3.3.1 Exit Software

Click System - Shutdown/Logout.



3.3.2 Turn Off the Instrument

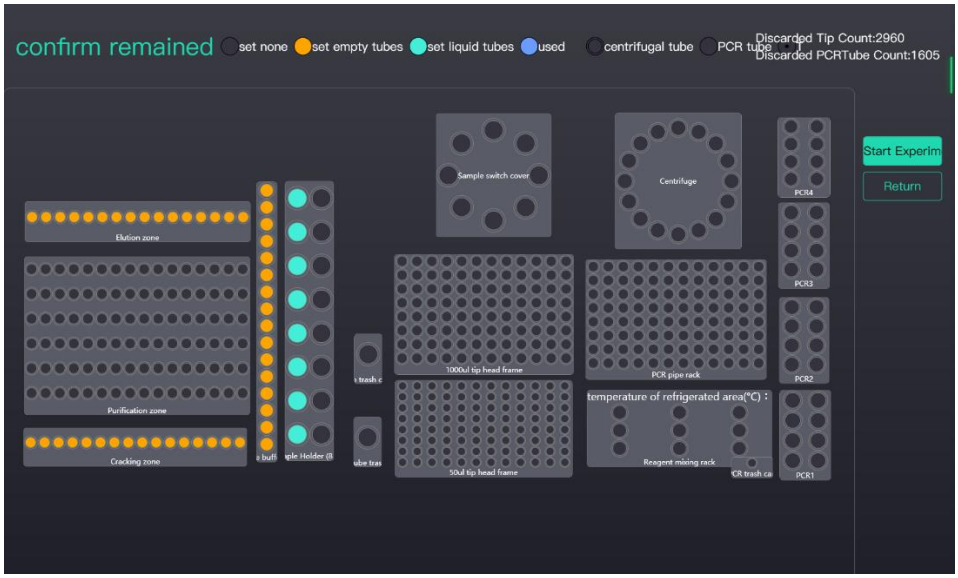
Select Power - Off on the display screen or press and hold the power button for more than 3 seconds to turn off the instrument, then press the power button on the rear panel of the instrument to cut off the power supply.

Notice:	Do not turn off the power directly by pressing the power button on the rear panel of the instrument. This may cause the instrument computer to malfunction.

Chapter 4 Reagent Management

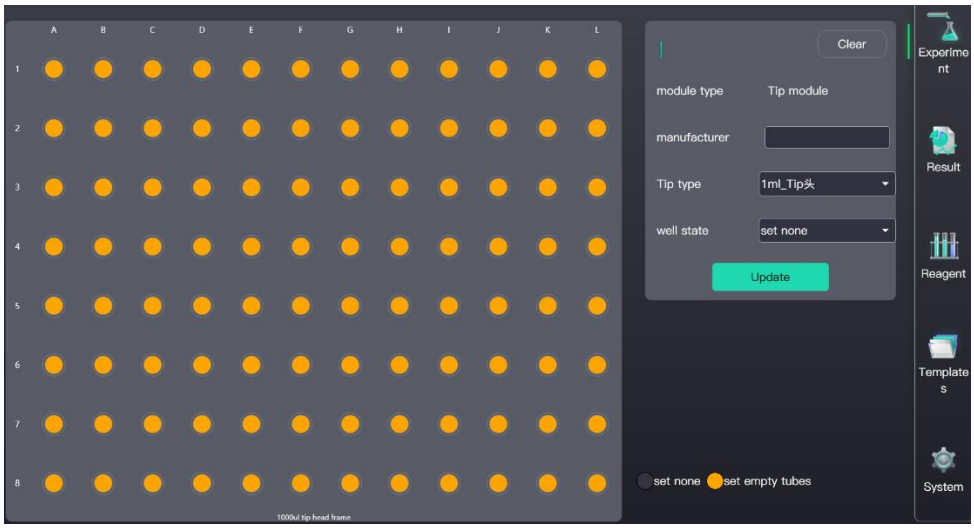
This section describes how to manage consumables. This section includes Pipet Tip management, nucleic acid purification management, PCR tube management and PCR reagent management.

Click Reagent, and the reagent interface will display the status of the current consumables.



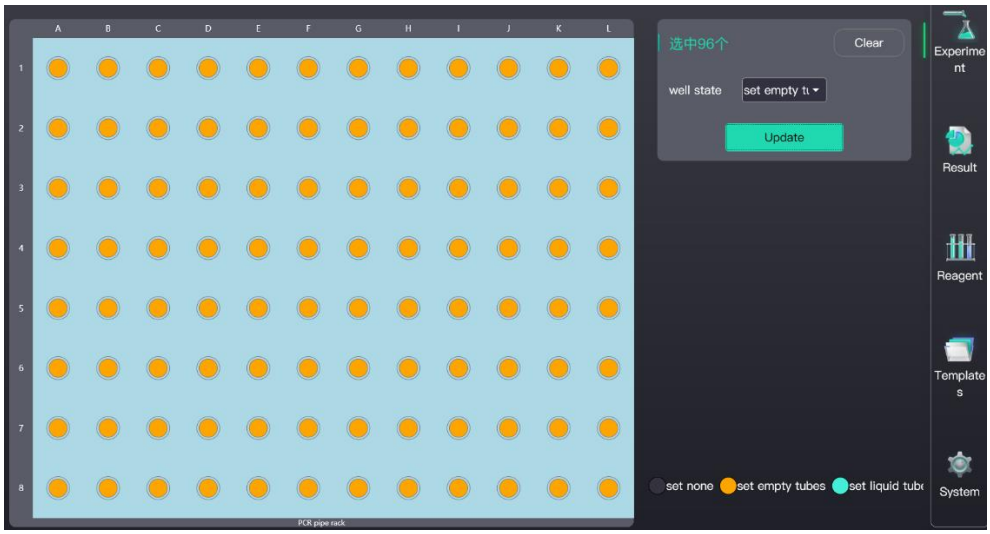
4.1 Pipet Tip Management

Select the hole position that was set to hold Pipet Tips, then select Set empty tubes and click Update. If the hole position is marked yellow, it means that it contains a Pipet Tip, as shown in the figure below:



4.2 PCR Tube Management

Select the hole position where a PCR tube has been placed, then select “Set empty tubes” and click “Update”. If the hole position is marked yellow, it means that it contains a PCR tube. As shown in the figure below, there are three PCR tube statuses: “Set none” indicates no PCR tube; “Set empty tubes” indicates that there is an empty PCR tube; “Set liquid tubes” indicates that there is a PCR tube containing configured reagent.



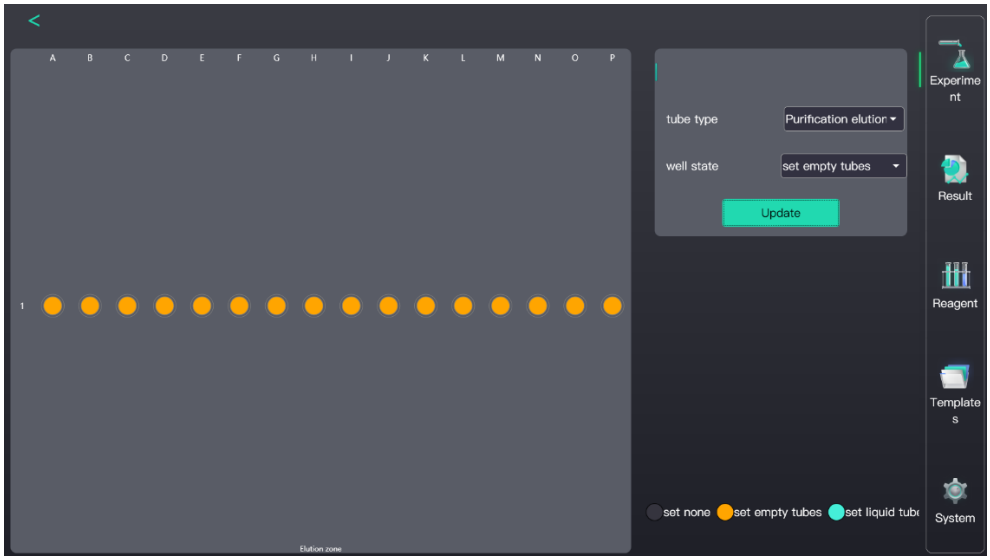
4.3 Nucleic Acid Purification Management

The nucleic acid purification zone, the lysis zone and the elution zone need to be set.

a. Click on the lysis zone, select the hole position where a nucleic acid purification test tube has been placed, then select the tube and click “Update”. If the hole position is

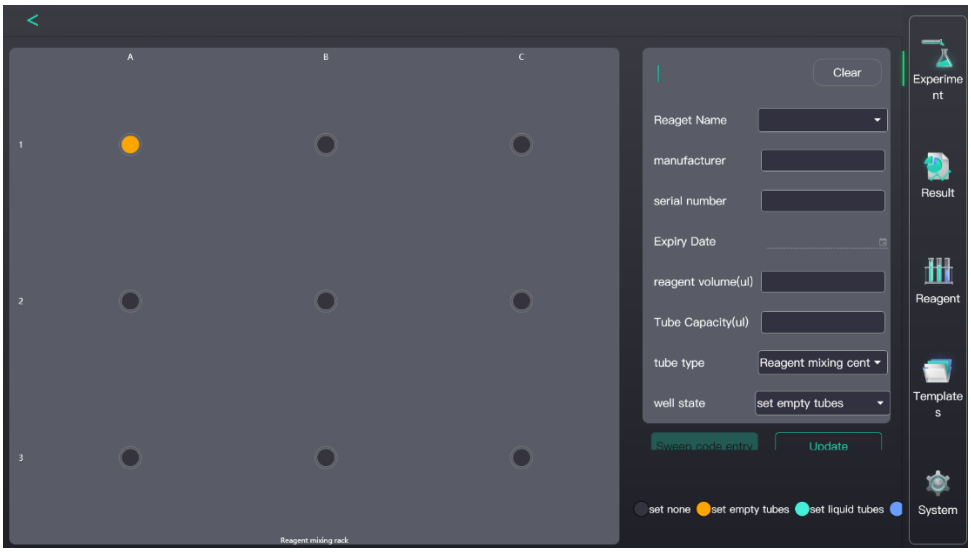
marked yellow, it means that it is for lysis.

b. Click on the elution zone, select the hole position where a nucleic acid purification test tube has been placed, then select the tube and click “Update”. If the hole position is marked yellow, it means that it is for elution. As shown in the figure below, there are three test tube statuses in the elution zone: “Set none” indicates no test tube, “Set empty tubes” indicates that there is an empty test tube, and “Set liquid tubes” indicates that there is an extracted template in the test tube in the elution zone and no extraction is required. Select “Purification elution” for the test tube type.



4.4 PCR Reagent Management

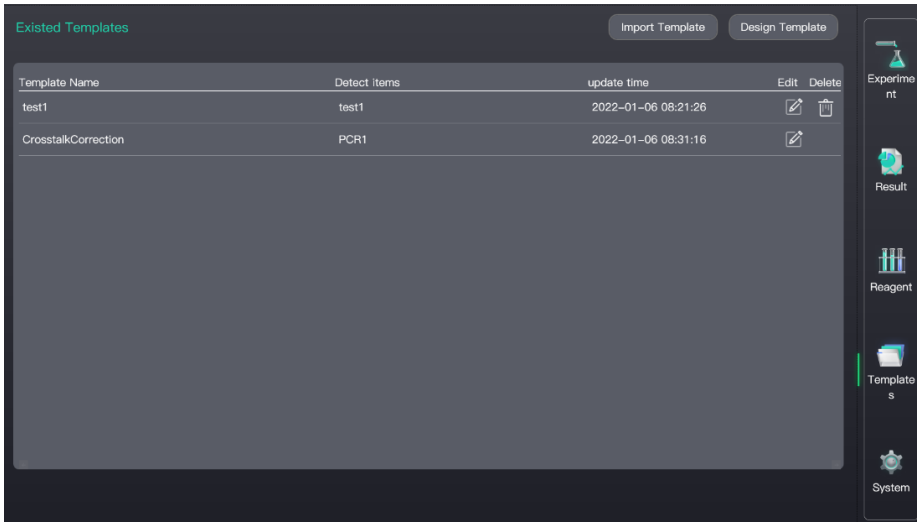
The placement position and tube type for the reagent are already set in the template, so only the position of the mixing hole needs to be set. If there is only one reagent, there is no need to set a mixing hole.


A
B
C
1
2
3
Reagent mixing rack
Clear
Reaget Name
manufacturer
serial number
Expiry Date
reagent volume(ul)
Tube Capacity(ul)
tube type
Reagent mixing cent
well state
set empty tubes
Update
set none
set empty tubes
set liquid tubes
Experiment
Result
Reagent
Templates
System

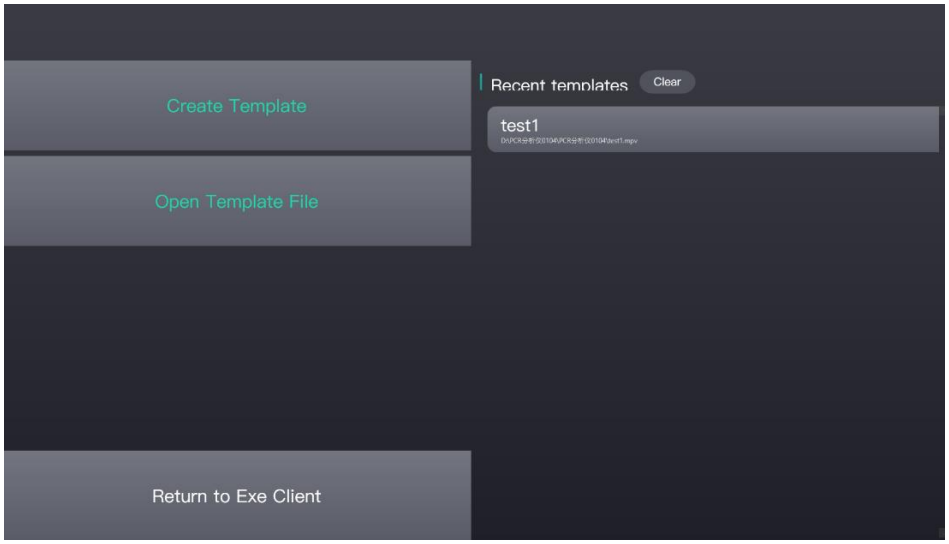
Chapter 5 Template Management

This section explains how to manage templates, including creating modules, importing existing templates, configuring PCR information, and editing pre-sample processing programs.

Click “Templates” to enter the module management interface, where the existing template is displayed. The operator can edit and delete the existing template. “Import Template”: Existing templates can be imported, and new templates can be created for experiment template designs.

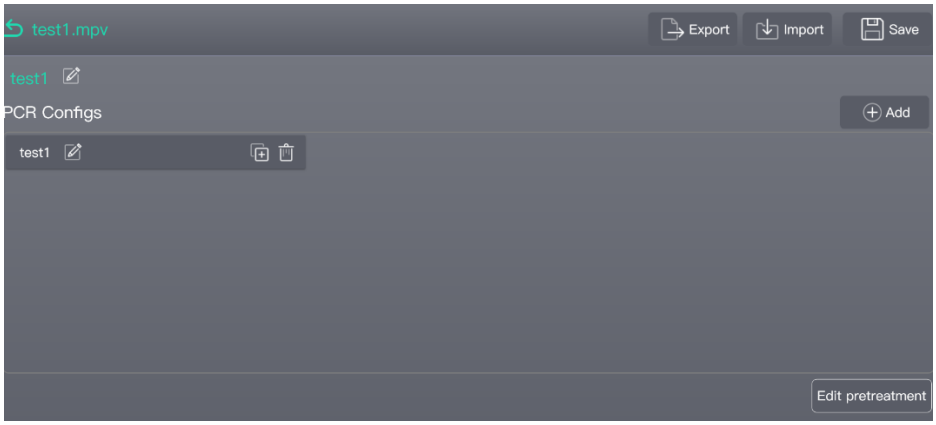


Click “Design Template” to enter the experiment template design interface. Template designs can be created or edited based on existing templates.



5.1 Create a Template

Click “Create Template” to create a blank template. The template design interface is shown below.



a. Unnamed template: Name the template.

b. Unnamed PCR configuration: Name the PCR items.

c. Add: PCR items can be added.

d. Click Edit preprocessing configuration to edit the preprocessor.

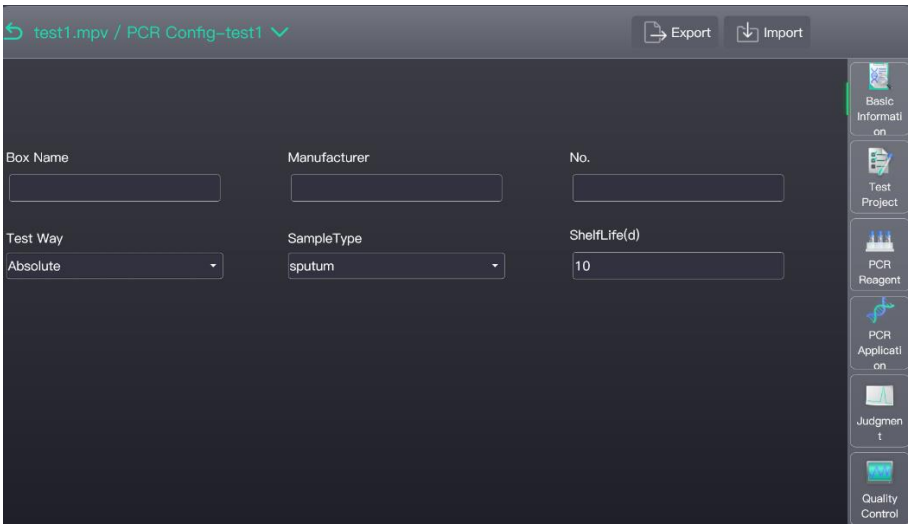
5.1.1 PCR Configuration

Double click “PCR Config” to enter the PCR configuration interface, which consists of 5 parts:

Basic information	PCR reagent basic information, test method and sample type
Test items	Test item settings
PCR reagent	Reagent components and dosage settings for each Test
PCR program	PCR reaction procedure
Interpretation	Analysis conditions, criteria for positive and negative determinations
Quality control	Quality control settings

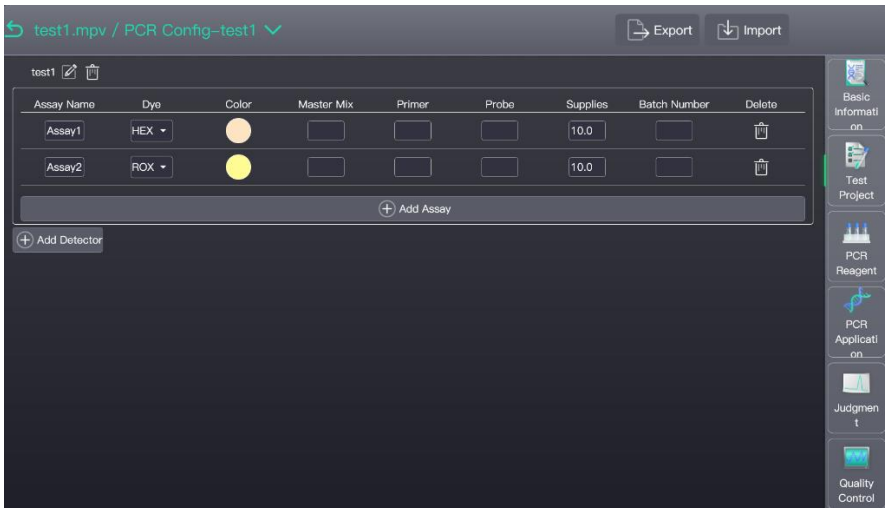
5.1.1.1 Basic information

The operator can add the kit name, manufacturer, number and shelf life information, and select the test method. The test methods are divided into quantitative, relative quantitative, SNP and high-resolution dissolution curves.



5.1.1.2 Assays

The operator can add assays and report information related to fluorescence and reagents included in each assay.

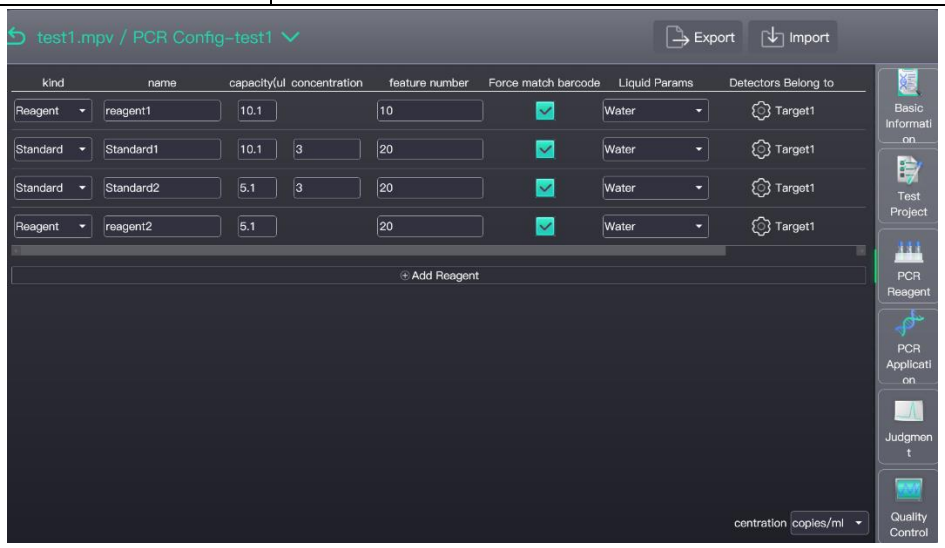


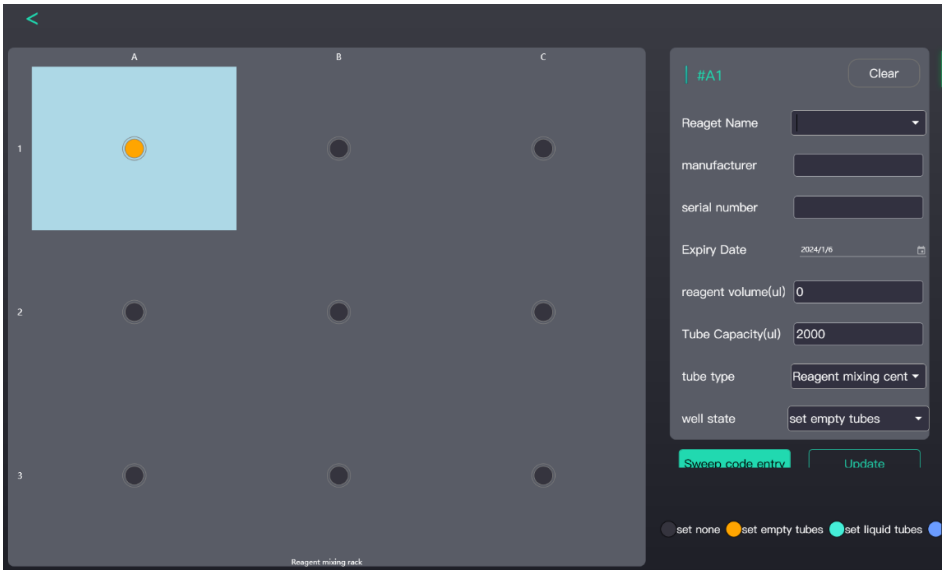
5.1.1.3 PCR reagent

Information related to reagents and parameters for adding samples can be added.

Kind	Reagent properties include the reaction solutions, enzymes, standard products, and negative/positive controls
Name	Name of each reagent component
Capacity (μl)	Dosage per test
Liquid Params	Reagent liquid type (generally low viscosity liquid selective reagent, high selective enzyme)

Detectors Belong To	Test items for each type of reagent
GE parameters	Set up the reagent container and the location of the reagent within the reagent zone





Note: GE setting instructions: For the test tube type, fixed suction means that the suction position is at the bottom of the tube. Generally, reagents with less liquid are used.

4.1.1.4 The PCR program

Set up the PCR reaction program.

a. Add RunSt: The operator can create a new constant temperature section, circulation section or melting section.

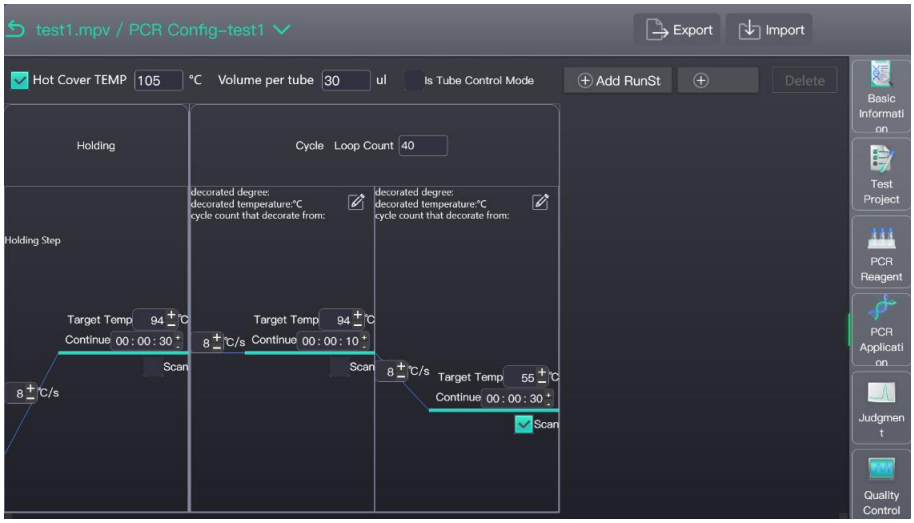
b. Add section: The operator can create a new section before or after the currently

selected section.

c. Delete: The operator can delete the currently selected section or operation section.

d. Set the experimental data for the constant temperature section, circulation section and melting section.

e. Set the hot cover temperature and volume of liquid to be added.



5.1.1.5 Judgement

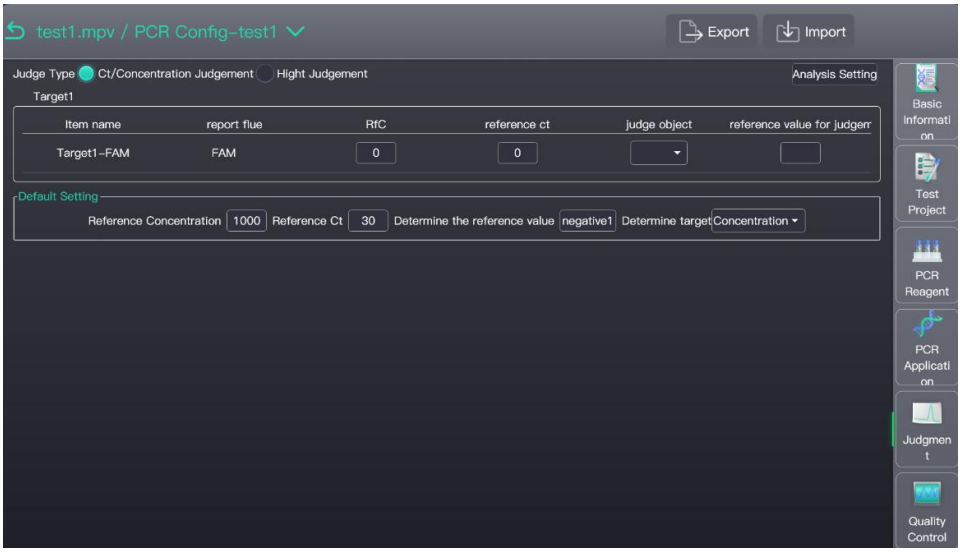
Set the Judgement Type for the PCR reaction results.

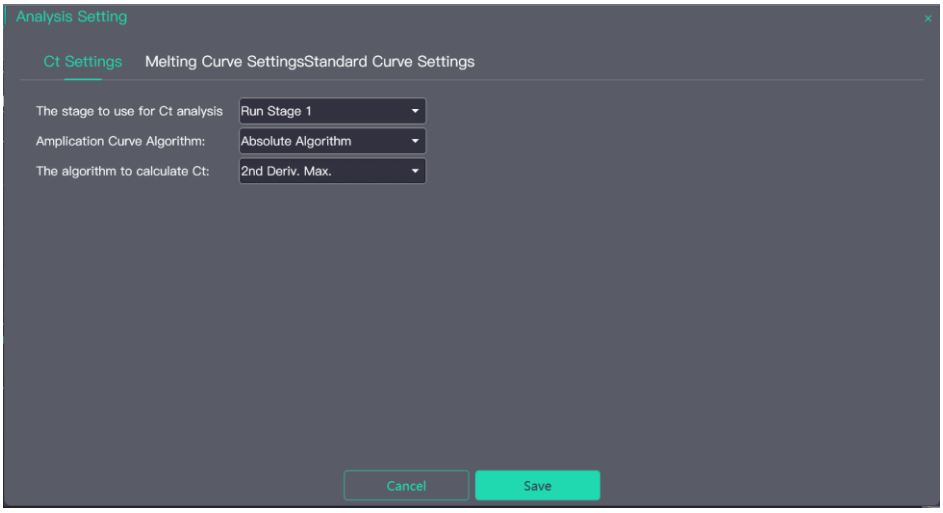
CT/Concentration Judgement: Set the parameters for PCR yin-yang judgement conditions and analysis.

a. If there are multiple items and the different channels of each item have different judgement conditions, each item can be set separately. If all items and channel judgement conditions are consistent, the default setting can be used.

b. Analysis Settings: Relative fluorescence and baseline thresholds are recommended.

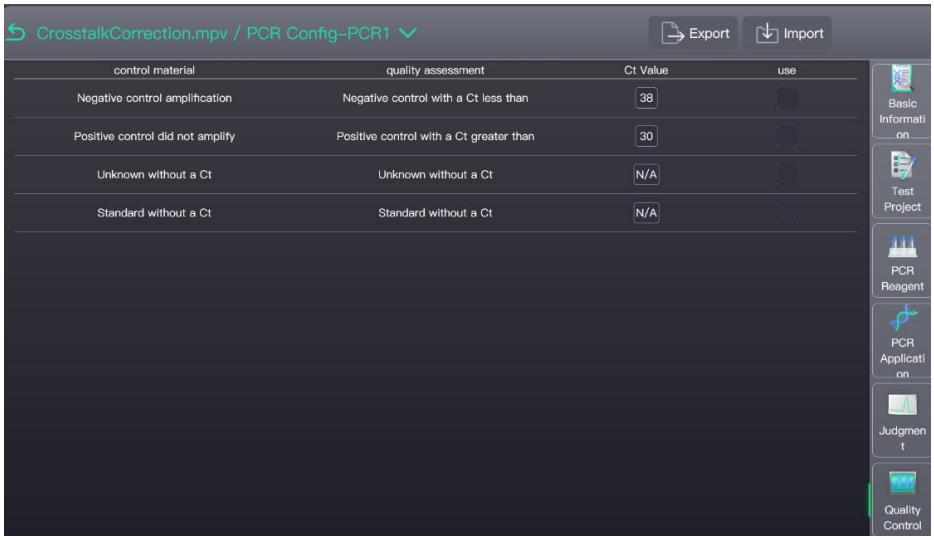
Advanced judgement is drawing different conclusions based on different results of the project. If you need this function, please contact us.





5.1.1.6 Quality control

Quality control information settings



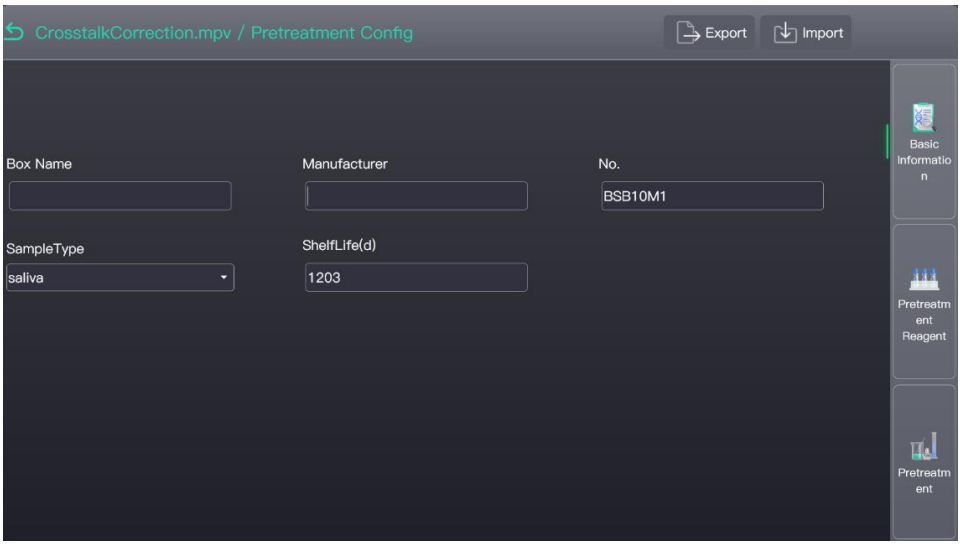
5.1.2 Pretreatment Configuration

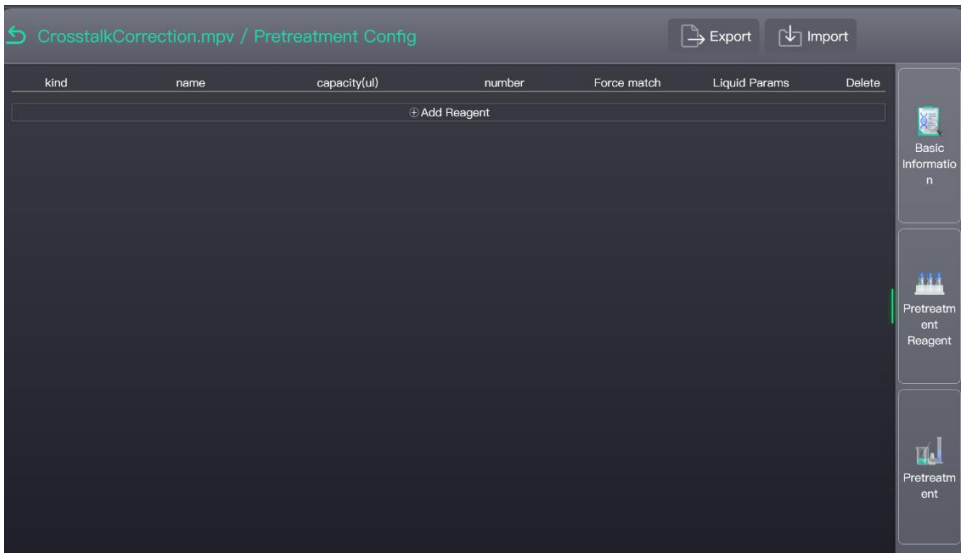
Click “Edit Pretreatment Configuration” to enter the preprocessing configuration page, which consists of 3 parts.

Basic Information	Basic information about nucleic acid purification reagents
Pretreatment Reagent	Pretreatment reagent information, reserved/temporarily unavailable
Pretreatment	Edit the pretreatment test process

5.1.2.1 Basic Information

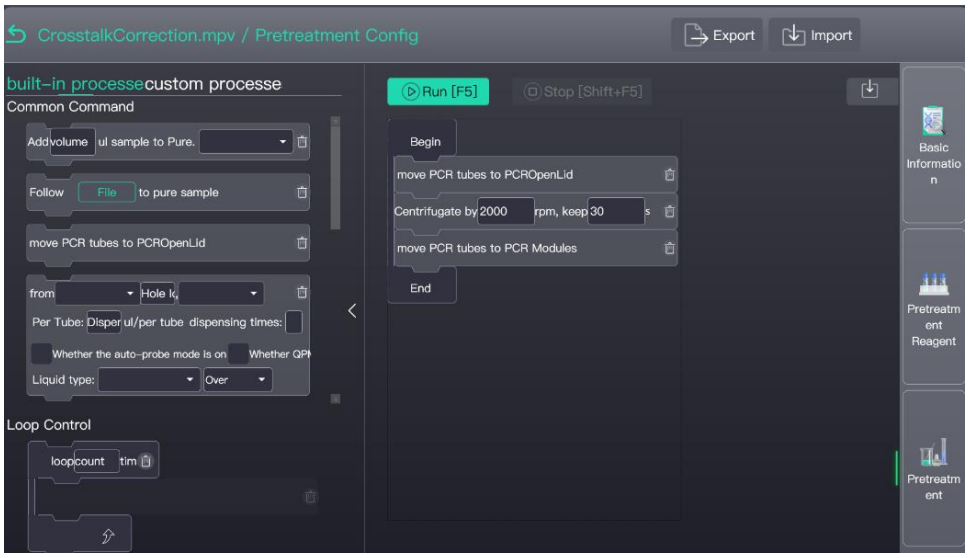
The operator can add information about the kit name, manufacturer, number and shelf life. The test methods are divided into quantitative, relative quantitative, SNP and high-resolution dissolution curves.





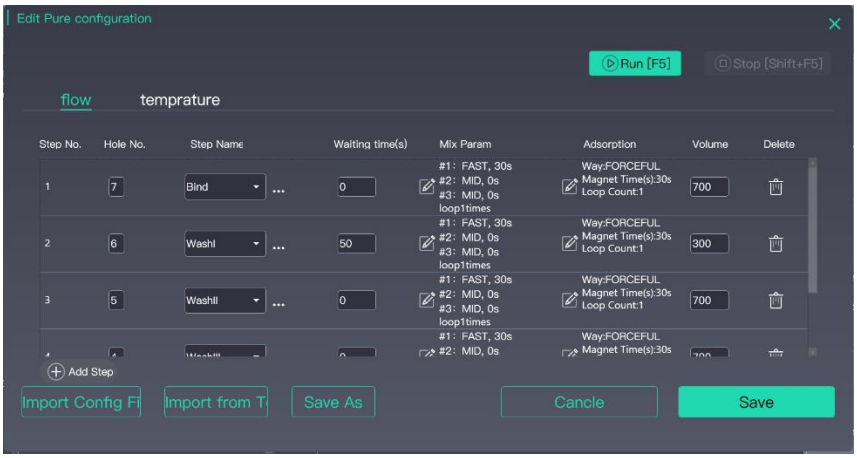
5.1.2.2 Pretreatment

According to the active decomposition of pretreatment, the main steps are divided into the following points: Adding sample, transferring the PCR tube, configuring the PCR mix reagent, purification, adding the PCR mix reagent, adding a template and centrifugation. The built-in subroutine of the instrument includes a standard sequence of the above actions so the sequence of pre-processing actions can be designed quickly. Drag the built-in subroutines in the "Common Commands" module on the left to the right one by one to edit the sequence based on the experimental process.



a. Add sample: Add the sample to the lysis zone of the nucleic acid purification module, then set the sample processing capacity and sample suction type (sample is selected by default);

b. Purification file settings: Click "File" to set the purification steps, set the nucleic acid purification steps, reagent hole position, wait time, mixing parameters, adsorption parameters and volume. You can import gps32 files or import purification settings from MPV files;



c. Move the PCR tube to capper/decapper: The device will clip an empty PCR tube into the centrifuge module based on the sample and item settings.

d. PCR mix reagent configuration: Mainly sets the mixing speed and number of times to mix the PCR reagent. It is recommended to set the mixing speed between 1000 and 2000, because too fast a speed will produce bubbles.

e. Separate the reagent mixture: Add mix to the PCR tube and set the liquid separation type and position. The default fixed position of the liquid separation position does not need to be changed.

f. Add a template: Select the amount of liquid added to the template, liquid type and liquid separation position. The liquid separation position is fixed by default, and the liquid absorption does not need to be changed.

If there are multiple PCR and multiple actions are required, the amounts for different PCR templates can be set separately.

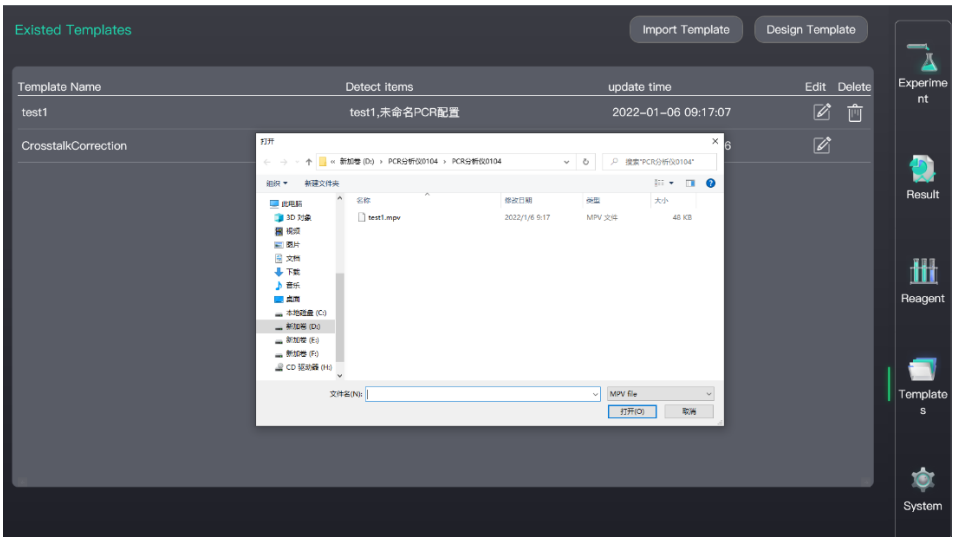
g. Centrifugation: Set the centrifugation time and speed (maximum speed: 2000rpm).

h. Move the PCR tube to the PCR module: Transfer the PCR tube from the centrifugal transfer module to the PCR module.

When all settings are complete, select Save to complete the new module.

5.2 Import Template

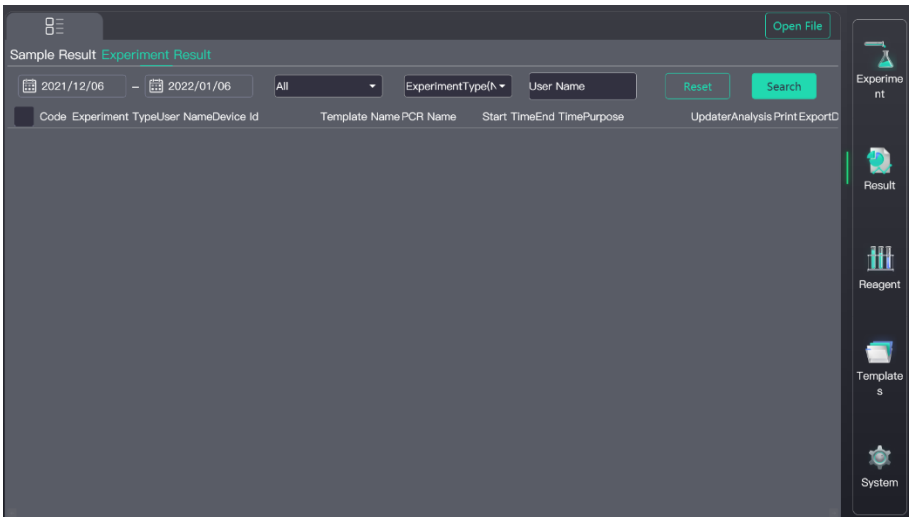
Click “Import Template”, find the location where the existing template is stored, select the template, and click “Open” to import the new template.



Chapter 6 Analysis of Results

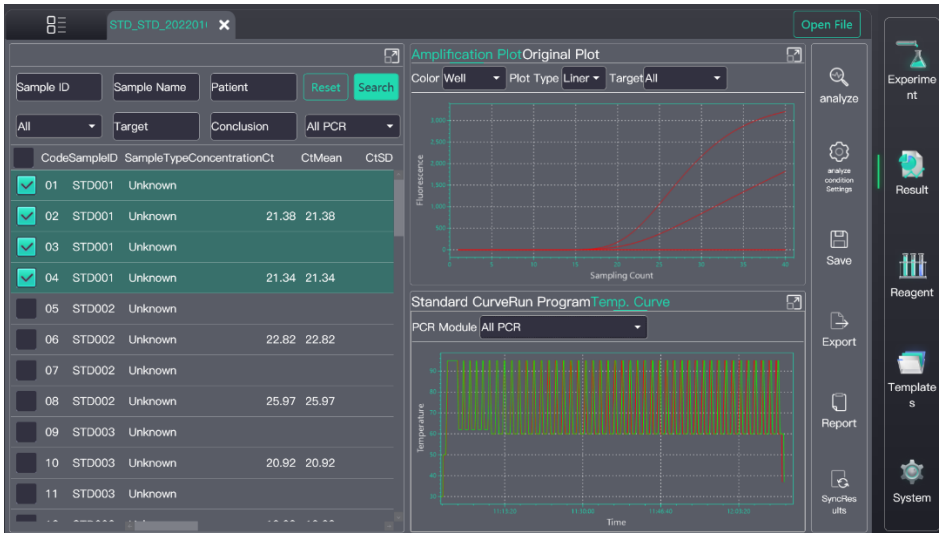
This section describes how to view the experimental analysis results after running an experiment and how to adjust parameters to re-analyze, save, export, report and synchronize the results.

There are two ways to view the results: as sample results and as experimental results. After the experiment, the results will be saved in the list at the bottom of the interface. Users can view the sample results directly, or select a test file and click Test analysis to view the test results, or click Open file to select a file to open directly.



6.1 View Results

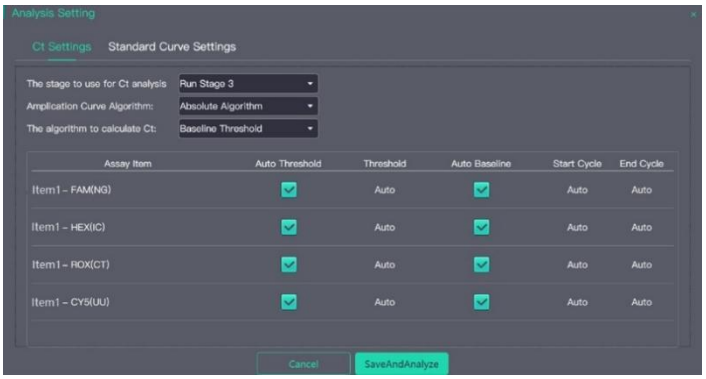
The results interface is divided into three parts. On the left is the list of sample results, which can be queried or viewed directly in the drop-down list. On the top right is the fluorescence curve of the test, which is divided into amplification curve and original curve, and on the bottom right is the standard curve, running program and temperature curve.



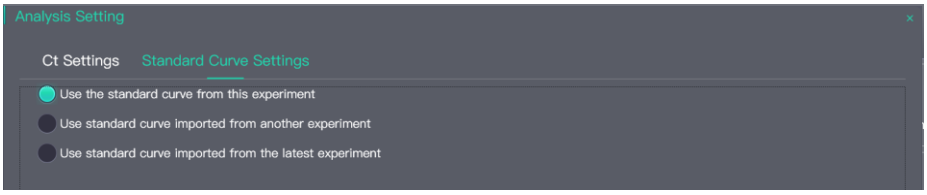
6.2 Analysis Condition Settings

The results can be re-analyzed by changing the analysis conditions.

a. Ct Settings: The control program segment, amplification curve algorithm and CT analysis algorithm can be selected for analysis.



b. Standard Curve Settings: The operator can choose to use the standard items set for the test, externally imported standard items or the latest standard items.

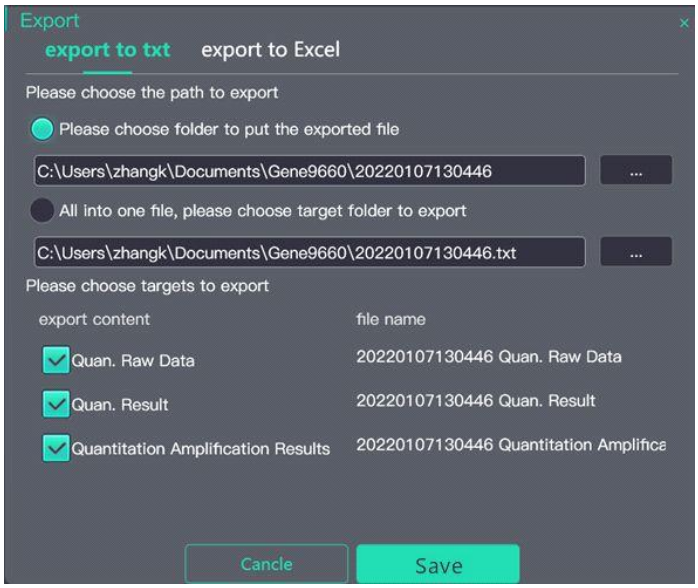


6.3 Save

Save the results of the reanalysis.

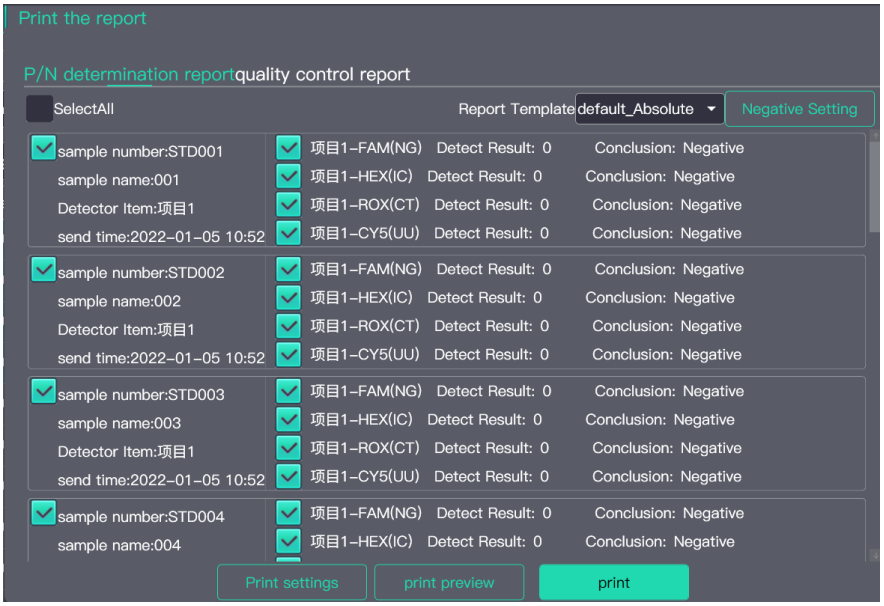
6.4 Export

Operators can export results in two formats: txt and Excel.



6.5 Print

Select the sample to print and the print template, which can be imported from system settings.

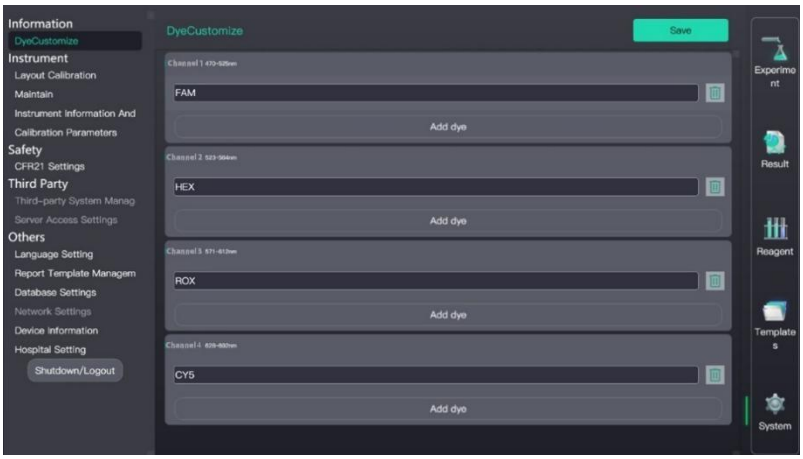


6.6 Sync to Database

Reanalysis will affect the conclusion determination, which can be synchronized to the database update.

Chapter 7 System Settings

The system settings are divided into five parts: Information, Instrument, Safety, Third Party and Others.



7.1 Information

Dye Customization:

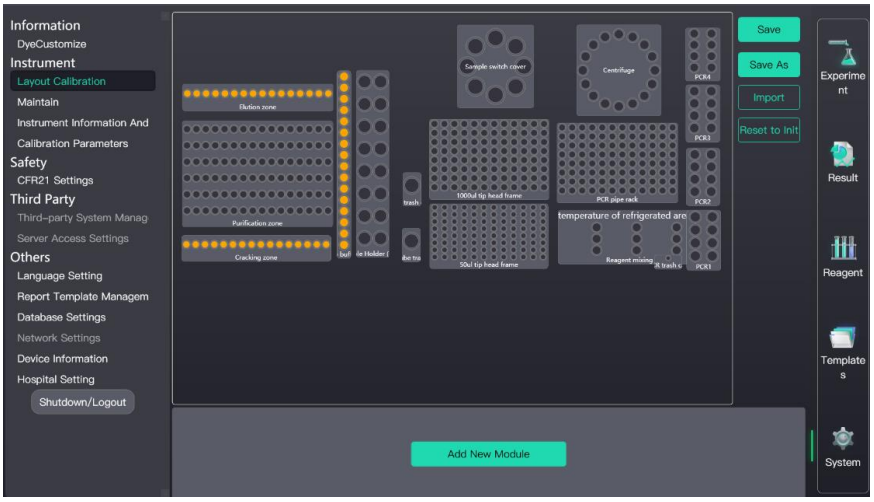
The Dye Customization tool is used to set up existing dyes and new dyes. The default dyes are FAM, HEX, ROX and CY5. You can add dyes according to the wavelength range.

Note: Please measure crosstalk parameters after adding or modifying dyes.

7.2 Instrument

7.2.1 Layout Calibration:

Adjust the panel layout. The panel layout is set by the manufacturer. Please contact the manufacturer for adjustment.

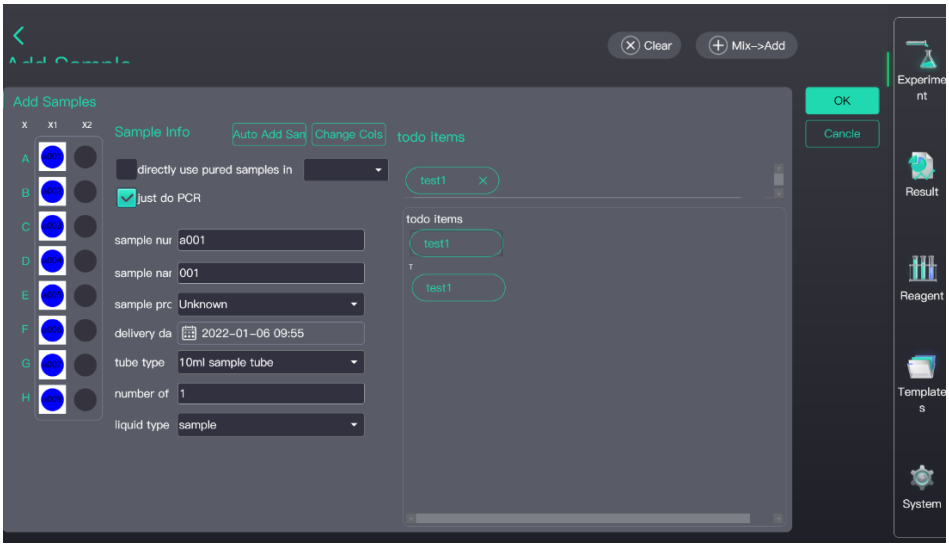


7.2.1 Maintenance

Crosstalk Correction Calibration Parameters: Used to measure crosstalk correction parameters. Users can add and modify the channels and dyes to be tested as required. Load the corresponding reaction tube and run the test. After the test is completed, the system automatically saves the crosstalk correction parameters and can also import them from an icp file.

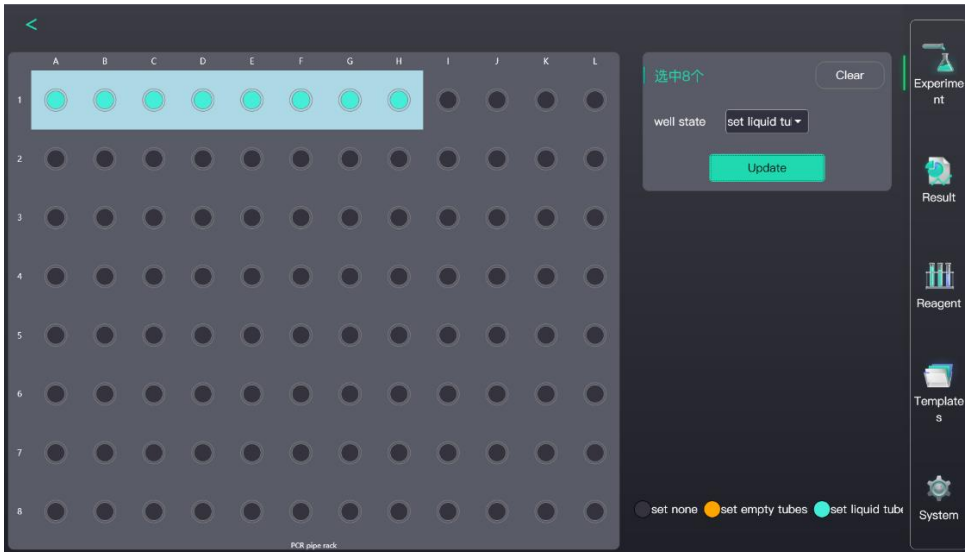
The specific operation process is as follows:

a. Click “Crosstalk Correction Parameter Measurement” to enter the following interface, then set the dye for crosstalk parameter measurement, select “Crosstalk Project”, and click “Confirm”;



b. The reagent configuration page will be displayed.

Put the PCR tube with the corresponding dyes on the PCR tube rack, click the PCR tube rack, set the corresponding hole of the PCR tube to the “Set liquid tubes” status, and click Update;



c. Click "Start" and the experimental equipment will automatically complete the dye correction parameter measurement.

7.2.3 Instrument Disinfection

Run the UV lamp controls and choose the disinfection time and whether to shut down after disinfection.

7.2.4 Machine Reset

Recover the PCR tubes in the centrifuge and PCR modules. The whole process takes about 5-6 minutes.

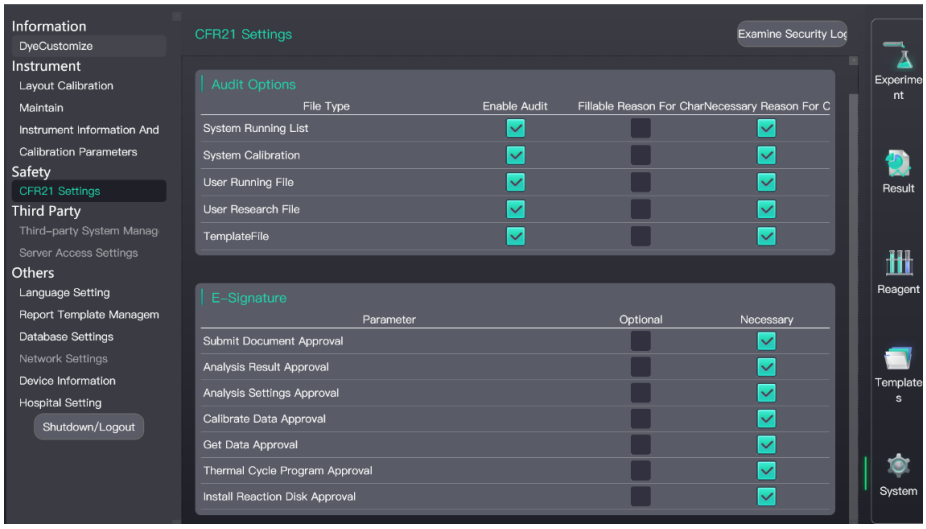
7.2.5 Test Tube Recovery

Recover the sample tube if an unknown failure occurs. Click once and rotate the rotary table of the decapping module with the sample tube by 45 degrees to manually recover the test tube.

7.3 Security Settings

7.3.1 CFR21 Settings

Auto logout after no activity means that if there is no activity for the set amount of time, the system will automatically display a login pop-up box to log in. If the time is set to 0, you will need to log in once at startup and will not need to log in again. If CFR21 is enabled, the cause will be recorded when performing list operations. Changes are recorded without starting the program but the reason is not required.



7.4 Third-Party Information

7.4.1 Third-Party System Management:

Only for querying related information

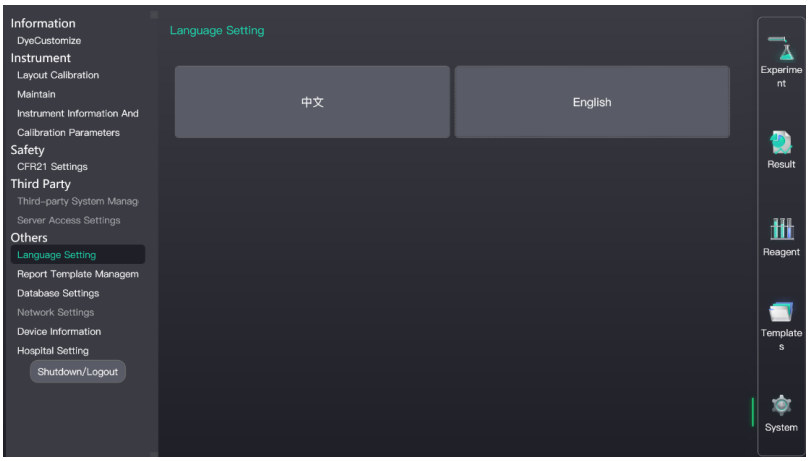
7.4.2 Server Access Settings

Only for querying related information

7.5 Other

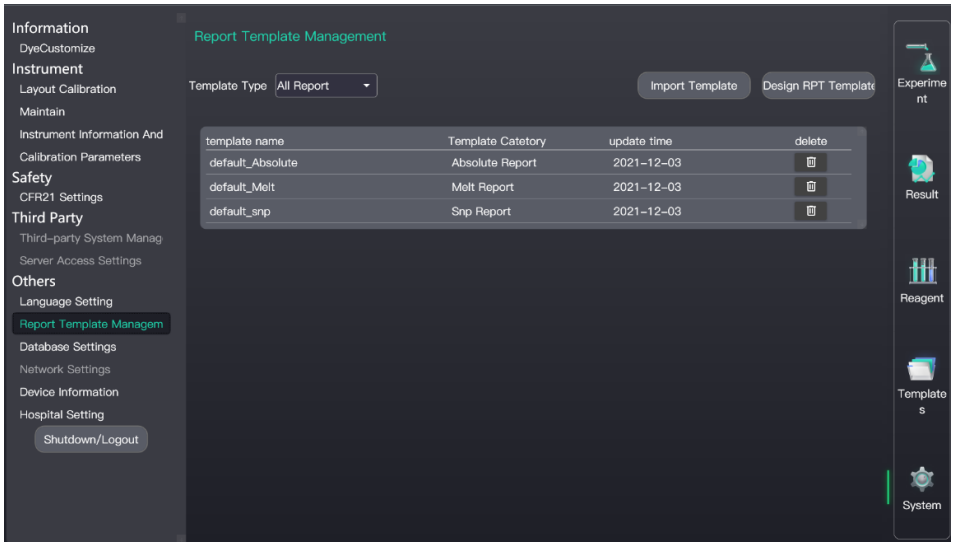
7.5.1 Language Settings

Available in Chinese or English.



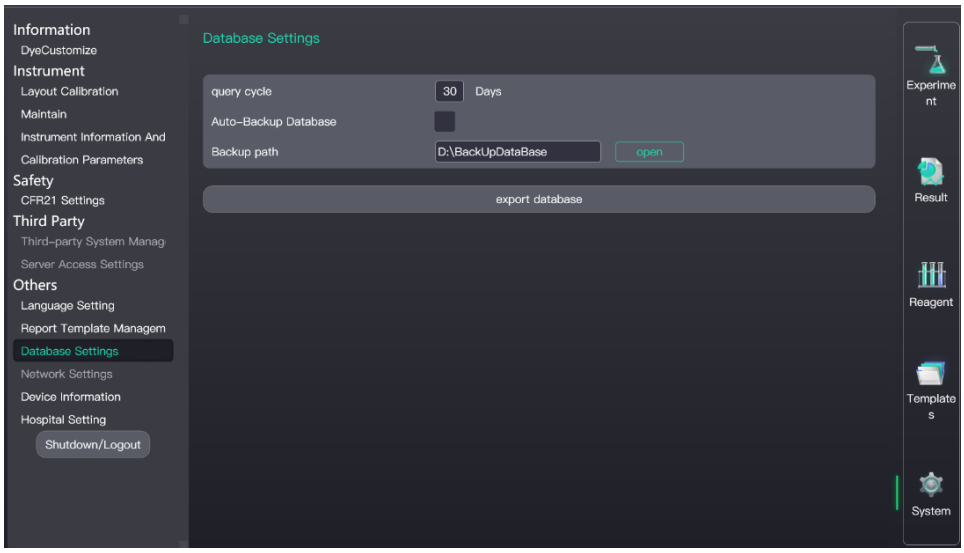
7.5.2 Report Template Management

Operators can import PRT templates or edit templates with the RPT template tool.



7.5.3 Database Settings

Set the database query period, automatic backup, and backup path.



7.5.4 Network Settings

7.5.5 Equipment Information

Query equipment model and serial number

7.5.6 Hospital Settings

Set hospital name

Shutdown/Logout: Click the “Shutdown/Logoff” button to exit the software.

Chapter 8 Maintenance

8.1 Cleaning Maintenance

8.1.1 Daily Cleaning

To ensure the normal operation, detection and use of the instrument, it is recommended to clean the instrument regularly.

- Clean the inner surface of the instrument: Wipe the magnetic rod, the inner counter top and the instrument cover with a cloth soaked in 70% ethanol after each use.
- Clean the refrigerated reagent zone: Since reagents are stored at 2-8℃ in the refrigerated reagent zone, condensed water will be generated on the surface and the reagent position. Clean with dry cloth or paper towel after each use.
- Clean the PCR module holes: Use dust-free cleaning cotton swabs, and dip in a small amount of 70% medical anhydrous ethanol or distilled water when necessary.

8.1.2 Abnormal Maintenance

- If the protective cover is not in place, the magnetic bar will complete its operation in an unprotected state. If this happens, the magnetic bar assembly needs to be cleaned. Wear gloves or use other protective measures. Clean the magnetic bar with a soft cloth dipped in 70% ethanol.
- If the reagent in the instrument spills, wear gloves or use other protective measures and wipe off any apparent spills with a cloth. Dry materials should be wiped with a wet paper towel.
- If the holes in the PCR module are contaminated, the fluorescence signal will be abnormal, and the baseline will be too high, or the signal will be too weak. Dip a duster clean cotton swab into 70% medical anhydrous ethanol and wipe it.

Warning!	1. When cleaning the instrument, the power must be disconnected. 2. Do not us a corrosive cleaning agent to clean the surface of the instrument. If in doubt, contact the manufacturer or an agent.

8.2 Troubleshooting

Serial number	Fault phenomenon	Cause analysis	Treatment method
1	The power switch behind the instrument has been set to on, but the instrument is not responding.	The RUN SWITCH on front of the instrument was not pressed	Press the RUN SWITCH
2	Insufficient liquid volume	There is not enough liquid in the test tube	Add reagent
		Test tube volume setting error	Set the correct reagent container
3	Pipette initialization failed	Hardware not working	Contact the supplier or manufacturer
4	Z-axis drive movement error	Hardware not working	Contact the supplier or manufacturer
5	Bubbles detected during suction	Bubbles are detected	Centrifuge the tube before suction to avoid air bubbles
6	Suction empty detected during suction	The test tube is empty or empty when aspirating	Add reagent
7	Blockage detected during suction	The liquid viscosity is too high and the Pipet Tip is blocked	Dispose of the liquid and remove foreign matter
8	Clamping claw colliding with the sample tube and PCR tube	The sample tube does not meet the instrument requirements	Use the recommended sample tube
		The instrument position changed	Contact the supplier or manufacturer
10	No test results for the sample	The sample is too thick and has clogged the suction nozzle, or a swab has clogged the nozzle and the sample cannot be extracted	Remove any viscous floating matter from the sample before the experiment
11	Sample tube cap cannot be opened	The sample tube does not meet the instrument requirements	Use the recommended sample tube
		The instrument capper/decapper module is faulty	Contact the supplier or manufacturer
12	The instrument does not start the experiment or stops midway through the experiment	The nucleic acid purification drawer, sample rack or consumables drawer are not completely closed	The nucleic acid purification drawer, sample rack and consumables drawer are not completely closed, and the status indicator is green

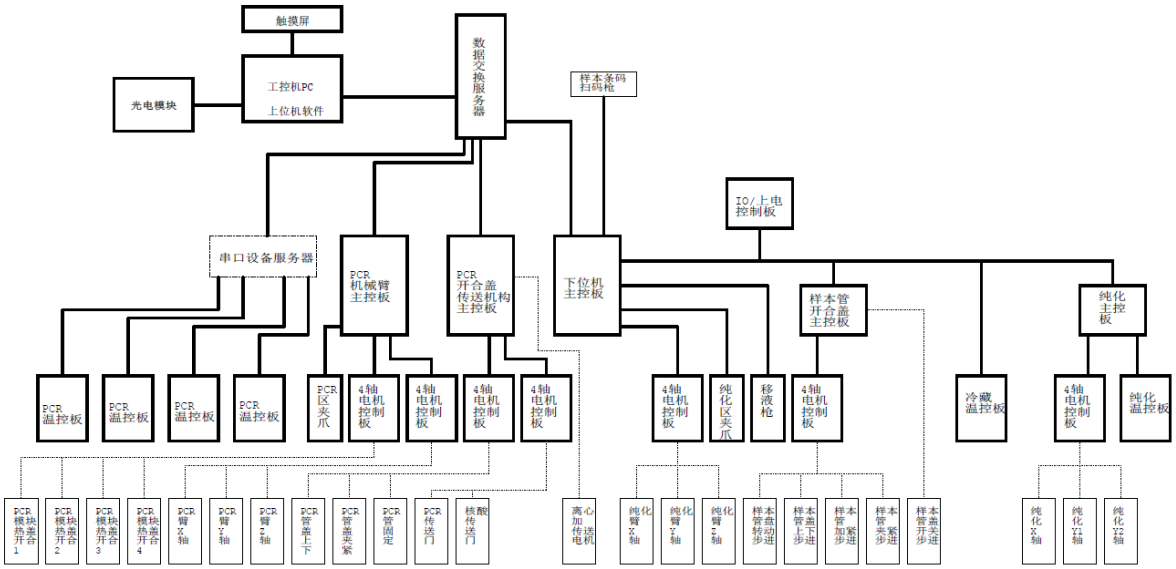
13	The temperature rise and fall speed of the module is obviously slower or the temperature control is inaccurate	The vent is blocked	Remove obstructions from vents
		Loose connecting wire	Contact the supplier or manufacturer
		The thermoelectric cooler is damaged	
		The fan is damaged or does not work	
		The temperature sensor is damaged	
14	Modules do not heat or cool	Internal failure of the instrument	Contact the supplier or manufacturer
		The thermoelectric cooler is damaged	
		Hot cover heating process	Wait for the hot cover temperature to reach the target value. When the module stops running, the temperature is automatically controlled at 30℃
15	Abnormal temperature or fluorescence curve: straight line,	The running program is infected with a virus and the computer CPU is seriously occupied.	Reinstall the application software after running antivirus.
16	The hot cover does not heat up	The thermal fuse is damaged	Contact the supplier or manufacturer
		Loose connector	
		The heating element in the hot cover is damaged	
		The temperature sensor in the hot cover is damaged	
17	The difference in the fluorescence value of each hole increases without a test tuber the background is very large	The test tube hole or hot cover is contaminated. The baseline background parameter is being misused	Decontamination. Each instrument must correspond to the baseline file one for one. After long-term use, if the optical elements are offset, contact the manufacturer to recalibrate the background.
18	Inter channel signal crosstalk	There is crosstalk between dye signals in each channel.	This can be measured through the "crosstalk coefficient measurement" function in the software, and the calibration parameters can be saved for correction.

19	Abnormal fluorescence detection value	Photoelectric system damage	Contact the supplier or manufacturer

Notice: During the warranty period, it is strictly prohibited for users to open the instrument casing for self inspection. In case of any fault in table above that requires opening the instrument casing for inspection, contact the supplier or manufacturer right away.

It is strictly prohibited for users to inspect or replace parts without permission. Only the manufacturer or an agent can inspect or provide parts.

Appendix: Auto Gene 1600 Series Wiring Diagram



Appendix: Product EMC Statement

Group I Class A Equipment

The invention is used in a dry environment, particularly in a dry environment with artificial materials (artificial fabrics, carpets, etc.)

When the device is installed, it may cause damaged electrostatic discharge, which may lead to mistaken identification.

Do not use the device near sources of strong radiation (such as unshielded radio frequency sources). Otherwise, normal operation of the device may be affected.

Electromagnetic compatibility should meet the requirements of GB/T 18268.1-2010 and GB/T 18268.26-2010.

1. Immunity requirements:

Table 1 Immunity Requirements of the Device

Port	**Test items**	**EMC Basis Standards**	**Test value**	**Performance criterion**
Casing	Electrostatic discharge (ESD)	GB/T 17626.2	Air discharge: 2kV, 4kV, 8kV; Contact discharge: 2kV, 4kV	B
	Radiated electromagnetic field	GB/T 17626.3	3V/m, 80MHz - 2.0GHz, 80%AM	A
	Rated power frequency magnetic field [a]	GB/T 17626.8	3A/m, 50Hz	A
AC power supply	Voltage sag [d]	GB/T 17626.11	1 cycle 0%;	B
			5 cycles 40%	C
			25 cycles 70%	C
	Voltage interruption [d]	GB/T 17626.11	5%, duration: 250 cycles	C
	Pulse group	GB/T 17626.4	1kV (5/50ns.5kHz)	B
	Surge	GB/T 17626.5	Line to ground: 2KV / line to ground: 1kV	B
	RF conduction	GB/T 17626.6	3V, 150kHz - 80MHz, 80%AM	A
DC	Pulse group	GB/T 17626.4	1kV (5/50ns.5kHz)	Not

power supply [C]				applicable
	Surge	GB/T 17626.5	Line to ground: 2KV / line to ground: 1kV	Not applicable
	RF conduction	GB/T 17626.6	3V, 150kHz - 80MHz, 80%AM	Not applicable
I/O signal [b]	Pulse group	GB/T 17626.4	0.5kV (5/50ns.5kHz)	Not applicable
	Surge	GB/T 17626.5	None	Not applicable
	RF conduction	GB/T 17626.6	3V, 150kHz - 80MHz, 80%AM	Not applicable
I / O signal connected to main power supply	Pulse group	GB/T 17626.4	1kV (5/50ns.5kHz)	Not applicable
	Surge	GB/T 17626.5	None	Not applicable
	RF conduction	GB/T 17626.6	3V, 150kHz - 80MHz, 80%AM	Not applicable
a The test is only applicable to equipment potentially sensitive to magnetism. The interference value displayed by CRT is allowed to be greater than 1A / m. b Only for cables longer than 3m. c Not applicable to input ports intended to be connected to batteries or rechargeable batteries (to be removed or disconnected from the device when recharging). Equipment with a DC power input port (using AC-DC power adapter) should be tested at the AC input port of AC-DC power adapter specified by the manufacturer. If not specified, a typical AC-DC power adapter should be used. This test is applicable to DC power input ports that are expected to be permanently connected to long-distance lines. d "5 / 6 cycles" refers to "5 cycles for 50Hz test" and "6 cycles for 60Hz test".				

2. Emission requirements:

Table 2 Emission Requirements for the Device

Emission test	Compliance
RF emission GB 4824	Group 1
RF emission GB 4824	Class A

The equipment is designed and tested in accordance with Class A equipment in GB4824. In a home environment, this equipment may cause radio interference, so protective measures need to be taken.

It is recommended to evaluate the electromagnetic environment before using the

equipment.

Appendix: Accessories List

Number	Name	Model and specification	Unit	Quantity
1	Power cord	250V 16A	Piece	1

Hangzhou Bioer Technology Co., Ltd.

Hangzhou Bioer Technology Co., Ltd.

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MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany